Pro Series RapidHeat™ Sterilizers

High-Velocity Hot Air™ ("HVHA") Sterilizer Models: RapidHeat™ RH-Pro9/RH-Pro11

OPERATION MANUAL

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CONGRATULATIONS on selecting an RH-Pro Series High-Velocity Hot Air Sterilizer. The RH-Pro Series of sterilizers 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-Pro Series 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-Pro Series retains the same pre-set sterilization cycles for unwrapped (6 minutes), wrapped (12 minutes), and dental handpieces (8 minutes) at 375°F 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.

The RH-Pro Series also has the ability to operate at three additional temperatures (280°F, 300°F, and 320°F) for those items that may be incompatible with 375°F exposures. These cycles will require operator validation to their effectiveness to meet the required 12 Log_{10} reductions of *Bacillus atrophaeus* spores, dependent on instrument number, weight, and configuration. Provided with the RH-Pro11 are validation protocols and an ancillary thermo-sensor to ensure required biological spore inactivation efficacies.

The RH-Pro Series also has included a cycle for N95 respirator decontamination that can

be used for the duration of the present 2020-2021 FDA Emergency Use Authorization guidelines issued November 2020. The use of the RH-N95 "dry heat" technology meets the requirements for Covid-19 virus inactivation while assuring respirator performance and physical integrity characteristics are retained.

Please read this manual carefully, paying particular attention to the requirements for instrument preparation, packaging, and loading of the RH- Pro Series of Sterilizers. 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.

1. 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 parts and labor warranty.

2. SAFETY INFORMATION

The RapidHeat™ Pro Series Sterilizers are designed for easy operation and maintenance. For safe and reliable operation, please read and understand the installation and operating instructions contained in this Operation Manual. All personnel charged with the operation of the RH-Pro9/Pro11 should be aware of this Operation Manual and follow its contents.

2.1 RH-Pro Series Use 

Never use the RH-Pro9/Pro11 for sterilizing liquids, chemicals or radioactive materials. All cycles use high temperatures to decontaminate/sterilize their intended-use instruments or articles and heat-resistant gloves should be worn during loading and unloading of trays and instruments.

2.1.1 The High-Temperature cycle, 375°F (191°C), is designated for the sterilization of medical devices that are not heat-sensitive and that can withstand sterilization at temperatures of 350°F (177°C) wrapped or pouched and 375°F (191°C) unwrapped.

2.1.2 The three Low-Temperature cycles (280°F, 300°F, and 320°F) are used for the sterilization of those instruments and articles that are incompatible with the high sterilization temperature of 375°F (191°C). These cycles require operator efficacy validation for the type of instrument or article requiring sterilization to assure a 12 Log_{10} reduction of *Bacillus atrophaeus* spores can be achieved by the completion of each of the prescribed time-temperature cycles. It is also the responsibility of the operator to assure that the time-temperature for the selected cycle is thermally compatible with the instrument or article requiring sterilization. Efficacy validation protocols and a thermosensor are provided with the RH-Pro9/Pro11 to assist the operator in assuring the required microbial efficacy conditions are met.

2.1.3 The N95 Respirator Decontamination cycle is to be used to decontaminate N95 masks only for the duration of the present 2020-2021 FDA Emergency Use Authorization guidelines issued November 2020. The use of the RH-N95 "dry heat" technology meets the requirements for Covid-19 virus inactivation while assuring respirator performance and physical integrity characteristics are retained.

2.2 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

2.3 Important Safeguards

When using your RapidHeat™ Pro9/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 the unit has been dropped or damaged until a qualified service technician has examined the unit.
- 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 re-assembly 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 (~41kg) and is best lifted by two individuals.

2.4 General 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.
- 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 allowed to thoroughly dry before being placed in the sterilizer. Absolutely no combustible liquids in any quantity are to be placed into the sterilizer.

2.5 General Recommendations

Read the entire instruction manual before installation or operation of the RapidHeat™ Pro9/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.

3. ACCESSORIES AND CONSUMABLES

DESCRIPTION	PART NUMBER
RH-Pro11 Instrument Tray	PR0057
RH-Pro9 Instrument Tray	PR0514
Heat Protective Gloves	400672

3.1. Consumables (Contact CPAC Equipment for More Information)

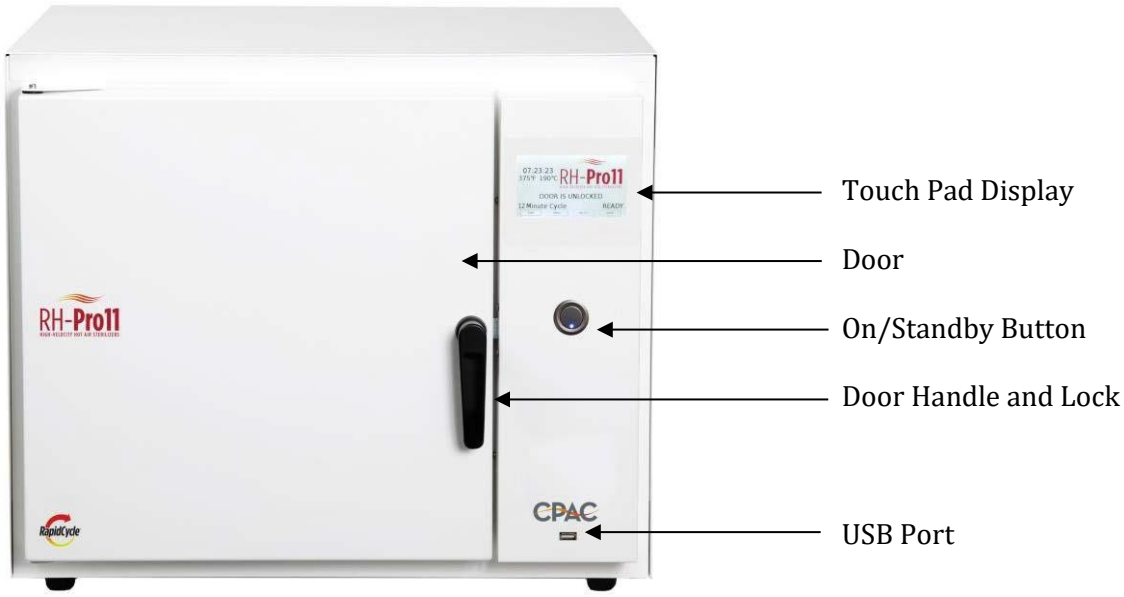
DESCRIPTION
RapidHeat Peel Pouches
RapidHeat Sterilization Wrap
Chemical Indicators
Biological Spore Test Indicators
Biological Spore Test Monitoring System
Handpiece Synthetic Lubricant
Handpiece Cleaner

3.2. Included with the Sterilizer

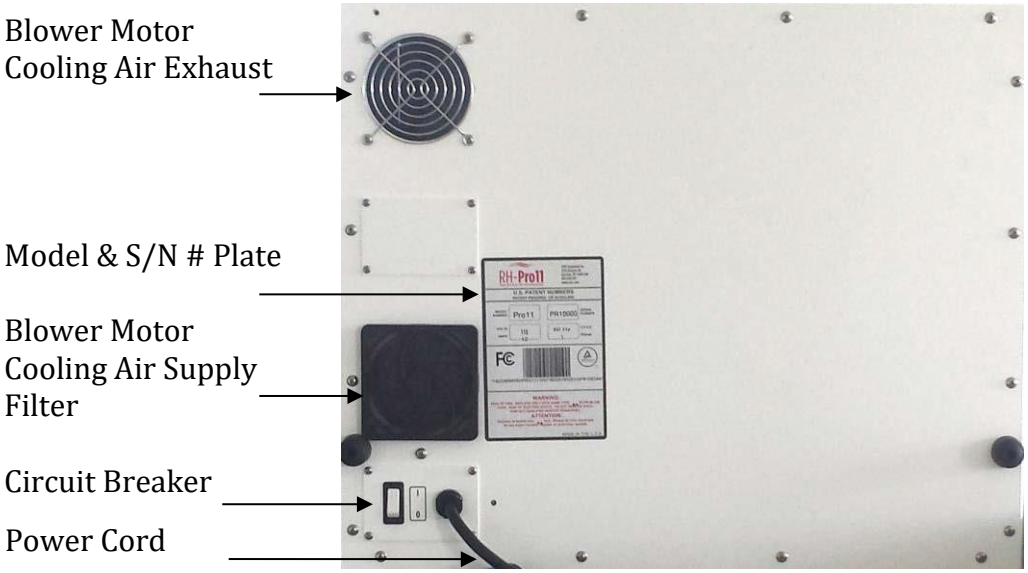
DESCRIPTION
Power Cord
Four (4) Trays- Pro11/ Three (3) Trays – Pro9
Heat Protective Gloves (One Pair)
User Manual
CIR Thermo-sensor
Operator Quick Start Guide

4. COMPONENTS AND CONTROL FUNCTIONS

FRONT ELEVATION



REAR ELEVATION



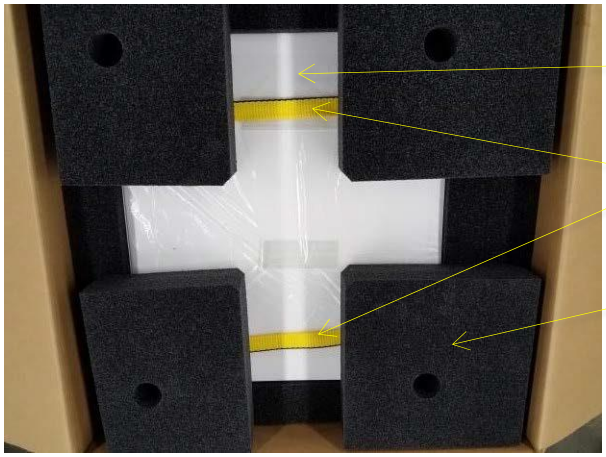
FRONT ELEVATION – OPEN DOOR WITH INSTRUMENT TRAYS

5. INSTALLATION

Unpacking the Sterilizer

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

The RH-Pro11 and RH-Pro9 weighs approximately 90 pounds (~41kg) and 70 pounds (~32kg), respectively, and with their dimensions, makes either unit difficult to lift by one person. To remove from the shipping carton, it is best to remove the top packing cushion and use the two nylon lifting slings (see picture below) encompassing the sterilizer to make lifting the unit easier. It is recommended that two individuals 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.*



5.0 Location

5.0.1 The RH-Pro9/Pro11 is designed for operation indoors in a protected, relatively dust-free ambient temperature environment at a relative humidity of < 80% up to 88°F (31°C).

5.0.2 Surface Support – Level and of sufficient construction for weight of loaded sterilizer (approximately 100 pounds) and ancillary equipment.

5.1 Sterilizer Dimensions and Required Clearances

5.2.1 Outer dimension RH-Pro11: 22.5" (572mm)W x 25" (625mm)D x 19.5" (492mm)H.
Outer dimension RH-Pro9: 19.63" (499mm)W x 20" (508mm)D x 13.75" (349mm)H.

5.2.2 Back of Unit to Back Wall: 4" (102mm)

5.2.3 Front Support Surface to Front Sterilizer: 1" (25mm)

5.2.4 Right Side of Unit to Side Wall: 4" (102mm) – *See Note below*

5.2.5 Left Side of the Unit to Side Wall: No clearance

5.2.6 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. See APPENDIX II: RH-Pro9 and RH-Pro11 Cabinet Installation.

The cooling air supply filter (pictured on page 10) requires occasional rinsing to remove accumulated dust. Installation should include consideration of access to that filter.

5.3 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.	

5.4 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. Materials Compatibility, Preparation, Loading, and Processing

6.0.1 Instrument and Materials Compatibility

Operation at 375°F - For a high-velocity hot air (HVHA™) sterilizer operating at 375°F (191°C), 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.

Operation at Low-Temperatures- Selection of operational temperature can be based on an instrument manufacturer's maximum temperature recommendation. Devices that have been traditionally made of or contain a temperature resistant plastic compatible only with autoclave temperatures, such as Polypropylene (PP), should be compatible with 280°F and 300°F operational temperatures.

Operation for N95 Mask Decontamination- The operational temperature setting for the N95 Decontamination cycle is set for 180°F and for most N95 masks should be thermally compatible with the materials used for mask construction, most specifically the polyester filtration materials, elastic bands, nose cushioning, and adhesives.

WARNING – INSTRUMENT PROTECTION

Before sterilizing instruments in the RH-Pro9/RH-Pro11, check with the instrument manufacturer to ensure material compatibility with the process temperature selected. Always use instrument pouches and wrap compatible with that temperature.

6.0.2 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 interfere with 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 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.

6.0.3 Loading Instrument Trays 

Heated air flow is an extremely important component of heat conduction and instrument sterilization. Placement of pouched instruments and unwrapped instruments should be in a loading configuration that does not impinge on airflow to an instrument or to pouched instruments.

- Pouches or sterile wrap must be compatible with the higher temperatures used in the RH-Pro9/RH-Pro11 (up to 380°F; 193°C) 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-Pro9/RH-Pro11 that have been designed to provide required hot airflow from all directions to unwrapped and wrapped/pouched instruments.
- Wrapped 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.

6.1 Operation of the RH-Pro9/RH-Pro11 

6.1.1 Before Running Your First Sterilization Cycle

- Before starting the sterilizer, 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 cooling air supply on back panel (maintained distance from wall) and clean exterior air exhaust filter if required.
- Check seal around door to ensure it is clean and free of obstructions.
- Close sterilizer door and turn handle counterclockwise into fully closed position.

- Perform “Start-of-Day” Sterilizer Preheating Procedures” (See Section 6.1.2).
- Check to ensure “Time and Day” are accurate and re-set if necessary (See Section 6.6.1). This is to ensure cycle documentation is properly time-stamped when stored for later retrieval. Press any active MENU button which leads to the "Select Item" screen. "Set Time and Date" is the first listing. Select and follow screen instructions.

IMPORTANT NOTE

BEFORE RUNNING FIRST STERILIZATION CYCLE OF THE DAY CHECK TO ENSURE THAT THE “TIME AND DAY” SETTINGS ARE ACCURATE TO ENSURE THAT STORED CYCLE DOCUMENTATION IS PROPERLY TIME-STAMPED.

6.1.2 “Start-of-Day” Sterilizer Preheating Procedures

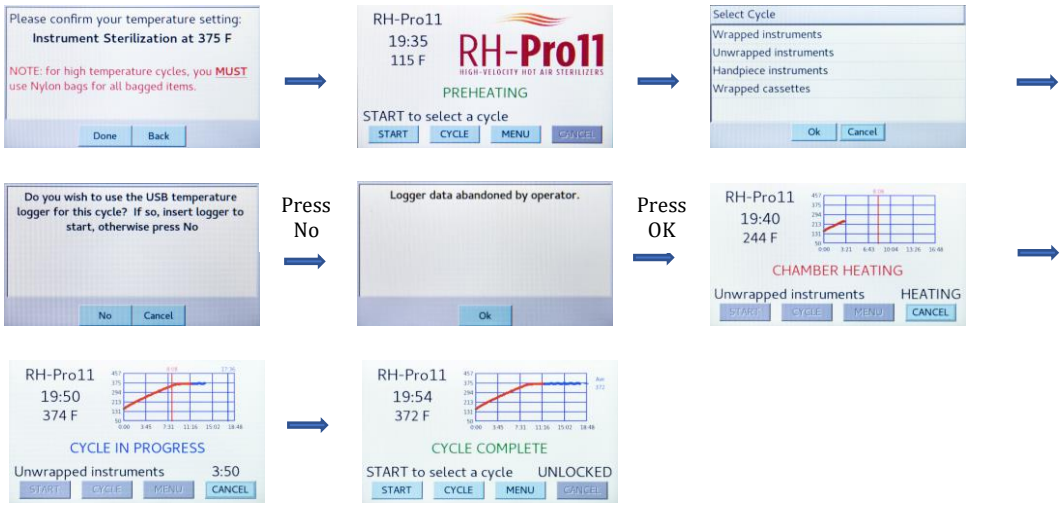
At the start of the day the RH-Pro9/RH-Pro11 will require time to pre-heat the internal metal and insular components that serve as a heat sink to the heated air of the system. “Start-of-Day” sterilizer heating process includes the heating of the chamber to cycle temperature and holding that temperature for 10 minutes.

Close the door, ensuring the handle is in the fully closed (vertical) position.
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:

Select the Operating Temperature Cycle desired for the first sterilization cycle of the day. Pressing the desired cycle will lead to the following sequence for the “Cold Start” or “Start-of-Day” sterilizer chamber heating process:

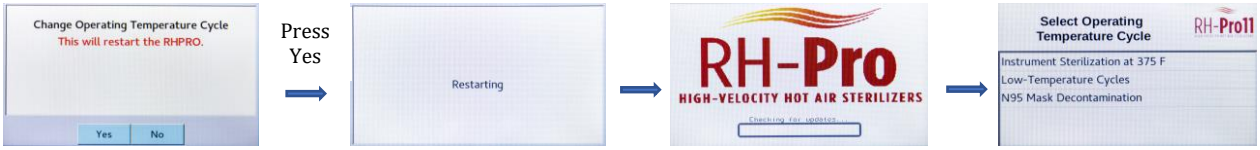
Press Done	Press Start	Select Cycle and Press OK



The RH-Pro9/RH-Pro11 is now ready for instrument sterilization. The complete process takes approximately 22-24 minutes from a cold start depending on cycle temperature selected.

6.1.3 Selection of Desired Temperature Cycles

The RH-Pro9/RH-Pro11 offer three Operating Temperature Cycles: High-Temperature (375°F), Low-Temperature (280°F, 300°F, and 320°F), and N95 Mask Decontamination (176°F). Another Operating Temperature Cycle can be selected by pressing any active "CYCLE" button. "CYCLE" will reboot the sterilizer to the main "Select Operating Temperature Cycle" screen as sequenced:

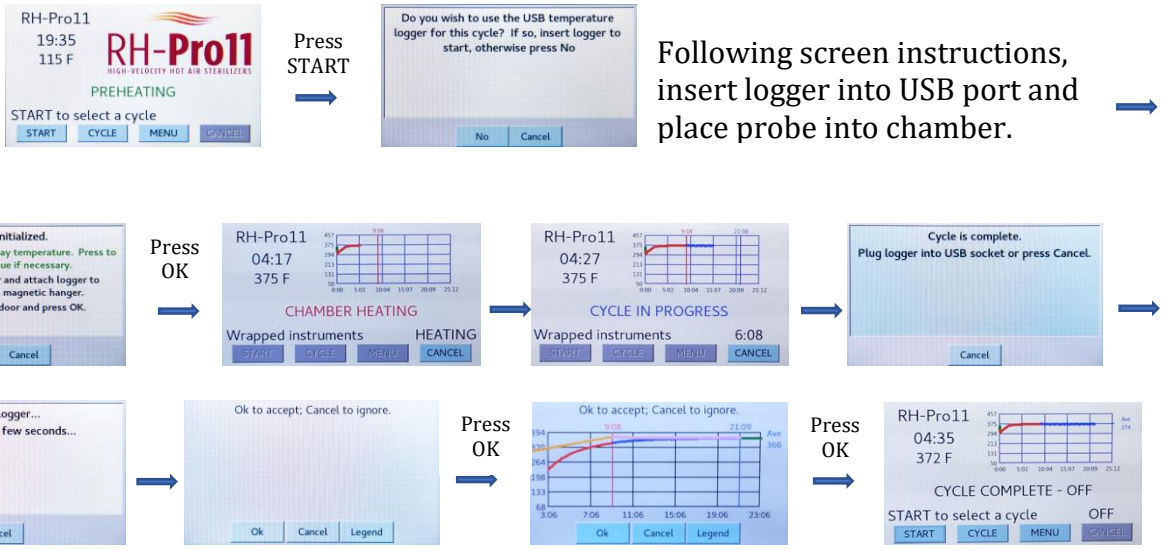


It is important to note when selecting a lower operating temperature than the previous cycle utilized that the residual chamber temperature may still be over the operating temperature limit for the lower temperature cycle. If this occurs, the following screen appears:

To remedy this condition, open the chamber door to expedite chamber cooling.

6.1.4 Use of the Time-Temperature Logger

The CIR™ Thermo-sensor may be used for Low-Temperature cycle validation documentation or for routine use as a replacement of a chemical indicator/integrator to corroborate the proper time-temperature conditions at the site of an instrument. Initiation of the CIR logger function begins with pressing the "START" button on "PREHEATING", "READY", or "CYCLE COMPLETE" screen. Resulting screen sequence is as follows:



Cycle data from both the CIR Thermo-sensor and the sterilizer's internal thermocouple recorded into the sterilizer's computer for later downloading onto a flash drive (see Section 6.64).

It should be noted that insertion of an incompatible time-temperature logger in the USB port will result in the following error message screen:

IMPORTANT NOTE

NEVER PLACE THE LOGGER INTO THE STERILIZER CHAMBER. ONLY THE THERMOCOUPLE PROBE AND ITS ASSOCIATED LOGGER CONNECTION WIRE ARE COMPATIBLE FOR THESE INSTRUMENT AND MASK PROCESSING TEMPERATURES.

High-Temperature Cycle Operation

6.3. High-Temperature Cycle Operation

6.3.1 High-Velocity Hot Air Sterilization Principles

- The RH-Pro9/RH-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-Pro9/RH-Pro11sterilizer, 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 four 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 380°F (193°C) can be sterilized in the RH-Pro9/RH-Pro11 sterilizer.

6.3.2. Pre-set Sterilization Cycles

The RH-Pro9/RH-Pro11sterilizer is equipped with four 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 Logs for:

- Unwrapped Instruments
- Unwrapped Handpieces
- Wrapped Instruments
- Wrapped Cassettes

Note: The conditions presented below for Unwrapped Solid Instruments, Unwrapped Handpieces, Wrapped Instruments (including Handpieces), and Wrapped Cassettes 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

6.3.3.1. Unwrapped Instrument Sterilization 

- To sterilize unwrapped instruments, place them into the instrument tray under the loading and capacity limitations and restrictions noted below for the “Unwrapped Instruments” Cycle. Instruments sterilized in the “Unwrapped Instruments” Cycle may reach 375°F (191°C) 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. Close the door ensuring the handle is in the fully closed (vertical) position.
- Touch “Start” on keypad, select “Unwrapped Instruments.” Door will lock and sterilization cycle will initiate once the chamber has reached 375°F (191°C).
- At the end of the cycle, a beep will sound and “CYCLE COMPLETE” 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 10-15 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 closed position to retain temperature in the sterilizer chamber.

Unwrapped Instruments
• Instrument Weight Limitation Per Tray: 800 g or 1.75 lbs.; Limit 3 Trays
• Single Instrument Weight Should Not Exceed 220 g or 0.5 lbs.
• Instruments Cannot Overlap, 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

6.3.3.2 Unwrapped Handpiece Sterilization

To sterilize unwrapped handpieces, place them into the instrument tray under the loading and capacity limitations and restrictions noted below for the "Unwrapped Handpieces" Cycle. Instruments in the "Unwrapped Handpieces" Cycle may reach 375°F (191°C) 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. Close the door ensuring the handle is in the fully closed (vertical) position.
- Touch "Start" on keypad, select "Unwrapped Handpieces". Door will lock and sterilization cycle will initiate once the chamber has reached 375°F (191°C).
- At the end of the cycle, a beep will sound and "CYCLE COMPLETE" 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 10-15 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 closed position to retain temperature in the sterilizer chamber.

Unwrapped Handpieces
• Handpiece Weight Limitation Per Tray: 800 g or 1.75 lbs.; Limit 3 Trays
• Single Instrument Weight Should Not Exceed 220 g or 0.5 lbs.
• Handpieces Cannot Overlap, be Layered, Piled, or Stacked
• Handpieces Must Lay Directly on Tray Bottom

6.3.3.3. Wrapped Instrument Sterilization

- To sterilize pouched handpieces or pouched instruments, place them into the instrument tray under the loading and capacity limitations and restrictions noted below for the "Wrapped Instruments" Cycle.
- Instruments in the "Wrapped Instruments" Cycle will not exceed 375°F (191°C) by the completion of the cycle. In most instances the temperature threshold of the instruments will not exceed 350°F (177°C).
- Place the tray into sterilizer by sliding the tray all the way to the rear of the heating chamber. Close the door ensuring the handle is in the fully closed (vertical) position.
- Touch "Start" on keypad, select "Wrapped Instruments". Door will lock and sterilization cycle will initiate once the chamber has reached 375°F (191°C).
- At the end of the cycle, a beep will sound and "CYCLE COMPLETE" 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 10-15 minutes.
- Shut sterilizer door and turn handle to the vertical closed position to retain temperature in the sterilizer chamber.

Wrapped (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 (limit 5 Pouches/Tray)
• Single Instrument Weight Should Not Exceed 140 g or 0.30 lbs.; Limit 4 Trays; Limit 800 g (1.75 lbs.) per Tray
• Pouched Instruments Cannot Overlap, be Layered, Piled, or Stacked

• Pouched Instruments Must Lay Directly on Tray Bottom

Wrapped (Pouched) Handpieces Laying Horizontal in Tray
• Handpiece Weight Limitation Per Tray: 800 g or 1.43 lbs.; Limit 4 Trays: Limit 160 g (0.35) per Pouch
• Single Instrument Weight Should Not Exceed 140 g or 0.30 lbs.; Limit 4 Trays; Limit 800 g (1.75 lbs.) per Tray
• Pouched Handpieces Cannot Overlap, be Layered, Piled, or Stacked
• Pouched Handpieces Must Lay Directly on Tray Bottom

6.3.3.4. Wrapped Cassette Sterilization Instructions

This cycle is required for instruments housed in metal cassettes or organizers and pertains to both pouched and sterile wrapped cassettes (packs). Plastic cassettes are incompatible with the HVHA sterilization process. Cassette sizes compatible with RH-Pro trays are those designated quarter- (~2½-3.0"x 8"x 1¼"), half- (~5½"x 8"x 1¼"), and full- (~8"x 11"x 1¼") size and include both single- and double-tiered configurations.

It is important to note that both pouches and sterile wrap must be compatible with the HVHA sterilization process. **ONLY USE CPAC NYLON POUCHES, PAPER WRAP, AND DRY HEAT STERILIZATION TAPE THAT HAVE BEEN RECOMMENDED BY CPAC EQUIPMENT, INC. TO AVOID POTENTIAL MELTING OR OFF-GASSING OF NON- COMPATIBLE MATERIALS.**

- To sterilize wrapped cassettes (packs), place them into the instrument tray under the loading and capacity limitations and restrictions noted below for the "Wrapped Cassettes" Cycle. It should be noted that due to the extra mass of the cassettes and air entrapment within their pouches that additional time is necessary to bring the instruments to their "spore inactivation temperature." This time may vary but is minimally set at 28 minutes. Once this temperature or time has been achieved, the sterilization cycle of 12 minutes is initiated.
- Instruments in the "Wrapped Cassettes" Cycle will not exceed 375°F (191°C) by the completion of the cycle. In most instances the temperature threshold will not exceed 350°F (177°C).
- Place the tray into sterilizer by sliding the tray all the way to the rear of the heating chamber. Close the door ensuring the handle is in the fully closed (vertical) position.
- Touch "Start" on keypad, select "Wrapped Cassettes". Door will lock and sterilization cycle will initiate once the chamber has reached 375°F (191°C).
- At the end of the cycle, a beep will sound and "CYCLE COMPLETE" 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 10-15 minutes.

- Shut sterilizer door and turn handle to the vertical closed position to retain temperature in the sterilizer chamber.

Pouched/Wrapped Cassettes
☐ Instrument: Cassette Weight Limitation* Per Tray: 1.4Kg or 3.0 lbs.; (e.g., One 8”x 11”x 1¼” Cassette** per Tray; Two 5½”x 8”x 1¼” Cassettes** per Tray; Four 2½-3.0”x 8”x 1¼” Cassettes** per Tray); Limit 4 Trays.
☐ Single Instrument Weight Should Not Exceed 140 g or 0.3 lbs.
☐ Pouched/Wrapped Instruments Cannot Overlap or Be Layered, Piled, or Stacked; Cassettes Must be Placed at Least ½” Apart
☐ Pouched Instruments Must Lay Directly on Tray Bottom

* Weight Limitation Does Not Include Tray Weight

** Cassette(s) at Manufacturer’s Recommended Instrument Placement and Capacity

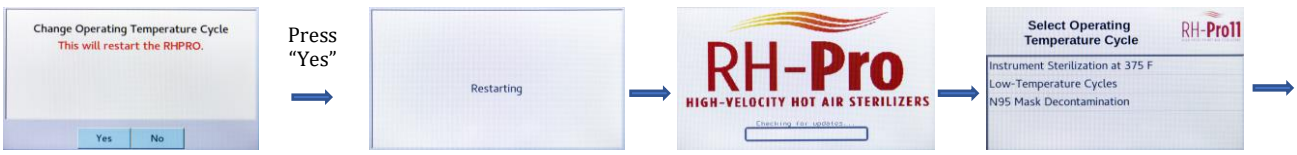
6.3.4 High-Temperature Cycle (375°F) - Detailed Cycle Operation

IMPORTANT NOTE

PREHEAT STERILIZER CHAMBER BEFORE RUNNING FIRST STERILIZATION CYCLE OF THE DAY. ALSO CHECK TO VERIFY THE “TIME AND DAY” SETTINGS ARE ACCURATE TO ENSURE STORED CYCLE DOCUMENTATION IS PROPERLY TIME-STAMPED.

Once the sterilizer has been preheated to its operation temperature (See Section 6.1.2), the RH-Pro9/RH-Pro11 is now ready for instrument sterilization at 375°F and instrument trays may now be loaded into the chamber. **Ensure all pouches used are heat-resistant nylon pouches.** Close and lock door. **Ensure “Time and Date” setting is correct.** If not, press “Menu” button and select “Time and Date”. See Section 6.6.1. Note: Cycle button will revert temperature setting back to main cycle selection screen if desiring a Low-Temperature cycle or the N95 mask decontamination setting. If no immediate use of the sterilizer is planned, it is best to keep the door closed and in locked position to minimize temperature loss to the sterilization chamber. The blower and heater will shut down upon completion of each cycle.

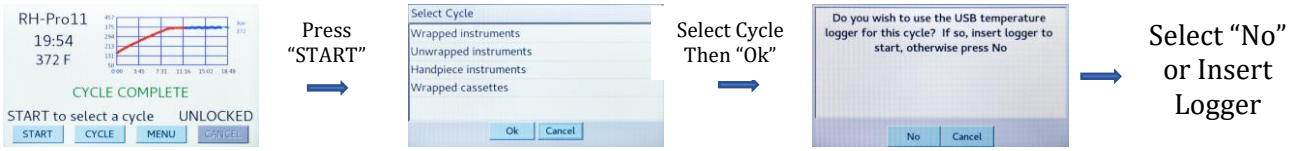
- Sequence for Starting Sterilization Cycle After Reboot:



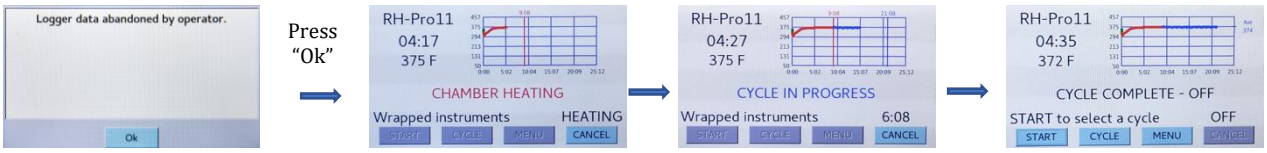
Press “Done”

Select “No” or Insert Logger

■ Sequence for Starting Sterilization Cycle from either the "CYCLE COMPLETE", "PREHEATING" OR "READY" screens:

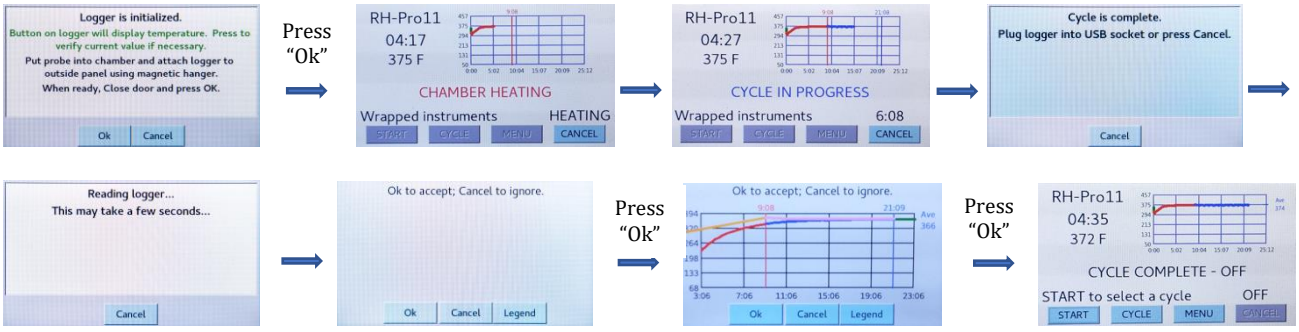


(1) No Use of Logger - Select "No":



OR

(2) Use of Logger - Insert Logger:



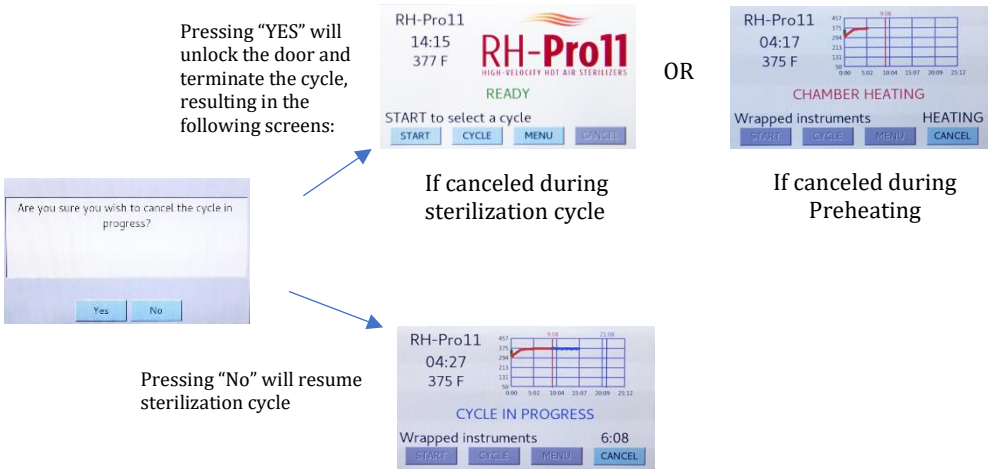
The countdown timer is initiated at the start of the sterilization cycle with "Unwrapped instruments", "Wrapped instruments", "Handpiece instruments", "Wrapped cassettes" (cycles of 6, 12, 8, and 12 minutes, respectively once chamber temperature has reached 375°F). At the end of the sterilization cycle, the screen displays "CYCLE COMPLETE -OFF" with audible notification and the door is unlocked to be opened manually for instrument tray removal. The heater and blower are also turned off, allowing the chamber to slowly cool if the door remains closed.

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 (191°C) 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 (191°C). Readings slightly lower that 375°F (191°C) 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.

6.3.5 Premature Canceling of a Cycle

When a sterilization 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:



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

6.3.6 Turning Off the RH-Pro11/RH-Pro9 Sterilizer

At the completion of sterilization activities, the sterilizer may be shut down by pressing the On/Standby button and holding it for approximately 7-8 seconds until the screen goes dark and the blue LED in the On/Standby button is illuminated.

Low-Temperature Cycle Operation

It is the operator's responsibility to validate all Low-Temperature Cycles to Verify that the Time-Temperature Parameters Result in a Full 12 - Log_{10} Spore Kill. See Appendix III for Validation Details and Protocols.

6.4 Low-Temperature Cycle Operation 

6.4.1 High-Velocity Hot Air Sterilization Principles

- The RH-Pro9/RH-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-Pro9/RH-Pro11sterilizer, 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 cycle lengths owing to the time necessary for instrument preheating and the different times necessary to inactivate 12 Log_{10} spores at each offered temperature.
- Operator validation of the Low-Temperature settings is required to assure that for the operator's specific conditions the requirement to inactivate 12 Log_{10} spores is met (protocols are provided by CPAC Equipment to assist the operator in validation compliance).
- 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 temperatures of 280°F through 320°F can be sterilized in the RH-Pro9/RH-Pro11 sterilizer.

6.4.2 Pre-set Sterilization Cycles

The RH-Pro9/RH-Pro11sterilizer 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 Logs for:

- 280°F
- 300°F
- 320°F

Note: The conditions presented below for the three Low-Temperature settings 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 and to validate that these conditions meet the 12 Log_{10} spore inactivation requirement. 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.

6.4.3. Wrapped Instrument Sterilization 

- To sterilize pouched handpieces or pouched instruments, place them into the instrument tray under the loading and capacity limitations and restrictions noted below for “Wrapped Instruments” and Wrapped Handpieces.”
- Instruments in the Low-Temperature cycle will not exceed the designated Low-Temperature settings by more than 2-3 degrees during the cycle.
- Place the tray into sterilizer by sliding the tray all the way to the rear of the heating chamber. Close the door ensuring the handle is in the fully closed (vertical) position.
- At the end of the cycle, a beep will sound and “CYCLE COMPLETE” 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 10-15 minutes.
- Shut sterilizer door and turn handle to the vertical closed position to retain temperature in the sterilizer chamber.

Wrapped (Pouched) Instruments Laying Horizontal in Tray
• Instrument Weight Limitation Per Tray: 300 g or 0.67 lbs.; Limit 4 Trays/Pro11and Limit 3 Trays/Pro9: Limit 60 g (0.15) per Pouch (limit 5 Pouches/Tray) Single Instrument Weight Should Not Exceed 60 g or 0.15lbs.
• Pouched Instruments Cannot Overlap, be Layered, Piled, or Stacked
• Pouched Instruments Must Lay Directly on Tray Bottom

Wrapped (Pouched) Handpieces Laying Horizontal in Tray
• Handpiece Weight Limitation Per Tray 300 g or 0.67 lbs.; Limit 4 Trays/Pro11and Limit 3 Trays/Pro9: Limit 60 g (0.15) per Pouch (limit 5 Pouches/Tray) Single Instrument Weight Should Not Exceed 60 g or 0.15lbs.
• Pouched Handpieces Cannot Overlap, be Layered, Piled, or Stacked
• Pouched Handpieces Must Lay Directly on Tray Bottom

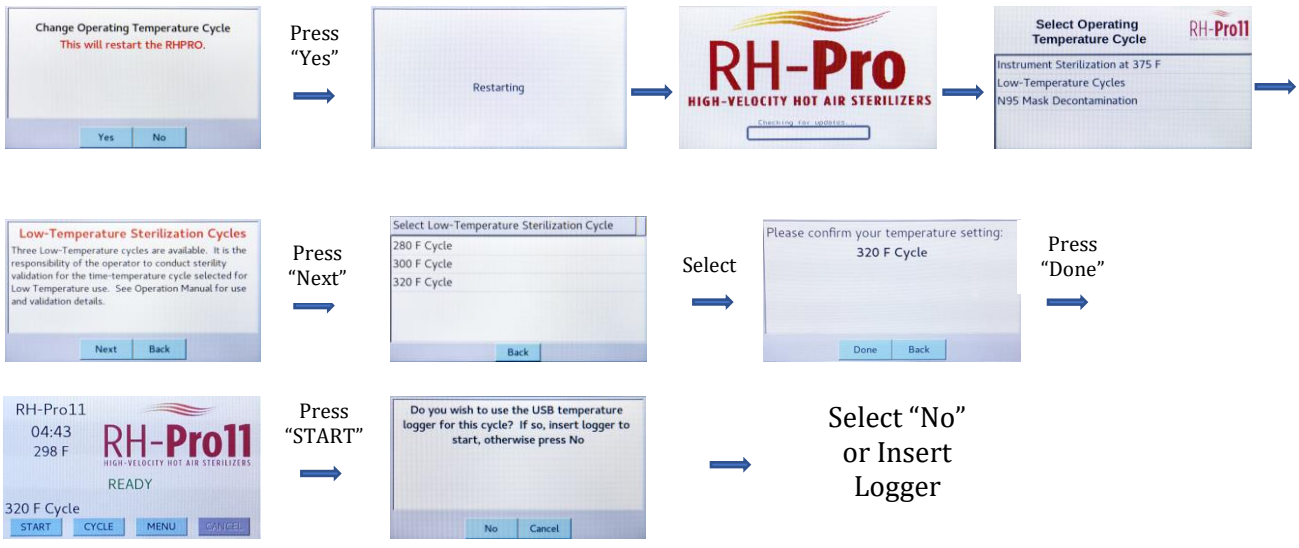
6.4.4 Low-Temperature Cycle - Detailed Cycle Operation

IMPORTANT NOTE

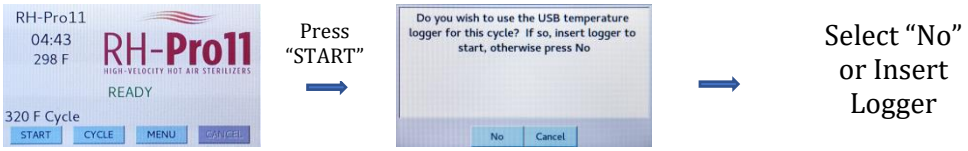
PREHEAT STERILIZER CHAMBER BEFORE RUNNING FIRST STERILIZATION CYCLE OF THE DAY. ALSO CHECK TO VERIFY THAT THE "TIME AND DAY" SETTINGS ARE ACCURATE TO ENSURE THAT STORED CYCLE DOCUMENTATION IS PROPERLY TIME-STAMPED.

Once the sterilizer has been preheated to its operation temperature (See Section 6.1.2), the RH-Pro9/RH-Pro11 is now ready for instrument sterilization and instrument trays may now be loaded into the chamber. **Autoclavable pouches may be used for all Low-Temperature settings, but pre-test them to ensure temperature compatibility. Any chemical indicators printed on these pouches are not appropriate for these three settings and should be disregarded. Use the CIR Thermo-sensor as a substitute for chemical indicators/integrators.** Close and lock door. **Ensure that "Time and Date" setting is correct.** If not, press "Menu" button and select "Time and Date". See Section 6.6.1. Note: Cycle button will revert temperature setting back to main cycle selection screen if desiring another Low-Temperature cycle, the 375°F cycle, or the N95 mask decontamination setting (Section 6.1.3). If no immediate use of the sterilizer is planned, it is best to keep the door closed and in locked position to minimize temperature loss to the sterilization chamber. The blower and heater will shut down upon completion of each cycle.

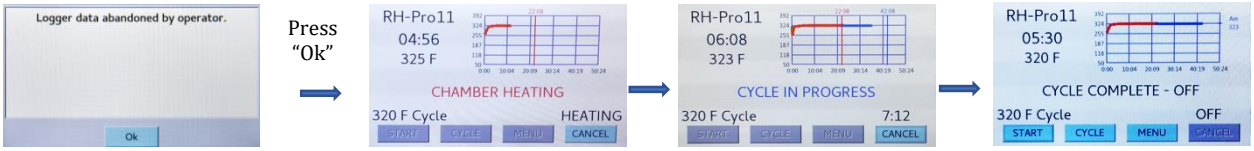
■ Sequence for Starting Sterilization Cycle After Reboot:



- Sequence for Starting Sterilization Cycle from either the “CYCLE COMPLETE”, “PREHEATING” OR “READY” screens:

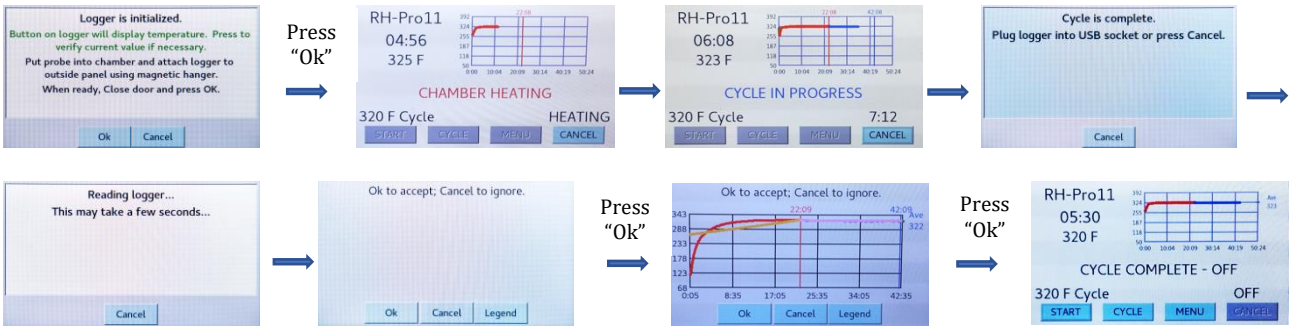


No Use of Logger - Select “No”:



OR

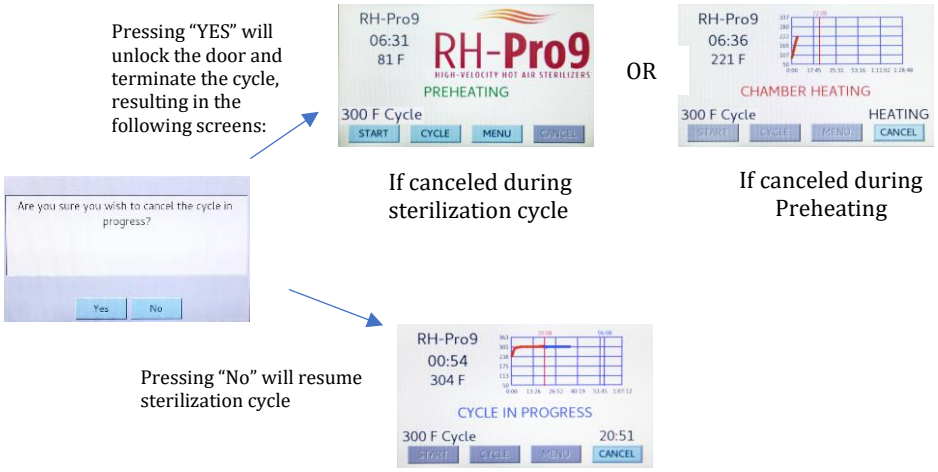
Use of Logger - Insert Logger:



The countdown timer is initiated at the start of the sterilization cycle once chamber temperature has reached temperature. At the end of the sterilization cycle, the screen displays “CYCLE COMPLETE -OFF” with audible notification and the door is unlocked to be opened manually for instrument tray removal. The heater and blower are also turned off, allowing the chamber to slowly cool if the door remains closed.

6.4.5 Premature Canceling of a Cycle

When a sterilization 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:



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

6.4.6 Turning Off the RH-Pro11/RH-Pro9 Sterilizer

At the completion of sterilization activities, the sterilizer may be shut down by pressing the On/Standby button and holding it for about 7-8 seconds until the screen goes dark and the blue LED in the On/Standby button is illuminated.

N95 Respirator Decontamination Operation

6.5 N95 Respirator Decontamination Operation.

The RH-N95 is for the decontamination of N95 masks **ONLY** that are not heat-sensitive and that can withstand decontamination at temperatures of 167°F (75°C). **Never use the RH-N95 for processing liquids, chemicals or radioactive materials.**

IMPORTANT NOTICE–PLEASE READ CAREFULLY AND COMPLETELY

IMPORTANT

The RH-Pro11/RH-Pro9 is intended for the bioburden reduction of compatible N95 respirators as provided under applicable FDA guidelines. As of June 30, 2021, Emergency Use Authorization (EUA) previously granted by FDA has been rescinded. The N95 Cycle available on RH-Pro11/RH-Pro9 Sterilizers therefore cannot be used for N95 Respirator decontamination or for bioburden reduction until that time FDA issues another EUA deemed necessary to meet N95 Respirator need requirements. Please note that CPAC Equipment, Inc. bears no responsibility for the operator's or the owner 's actions regarding N95 cycle use during periods of FDA non-authorization. Any use of the RH-Pro9 or RH-Pro11 sterilizer's N95 cycle for decontamination of N95 masks sterilizer becomes the responsibility of the operator and the owner of that equipment.

The RH-Pro11/RH-Pro9 employs High-Velocity Hot Air (HVHA) to decontaminate N95 masks, using fluidized hot, dry air to transfer dry heat energy to N95 masks by a combination of convection and conductive processes. Conventional practices necessary for steam sterilization do not apply to HVHA technology and in many instances are contrary to HVHA protocols provided in this user manual.

The N95 edition of RH-Pro series of this technology has been designed to address the critical shortage of N95 masks in healthcare during the Covid-19 pandemic. This unit has one dedicated "N95 Mask" cycle that incorporates the time and temperature parameters that provide the conditions necessary (1) to destroy coronavirus and Mycobacterium and (2) to maintain the performance of the mask for breathability and microbial filtration.

There are many manufacturers and variations of N95 masks. Initial testing on material compatibility has been performed on only a limited number of N95 masks to date. All masks use polyester and polypropylene nonwoven fabrics as filtration material which are compatible with our dry heat process. Other materials may not be compatible and should be checked before and after mask reprocessing. Such incompatibilities may be found in the elastic bands, foam nose fittings, and adhesives. Although internal testing by CPAC Equipment has indicated a mask can be

re-processed at least 10 times, the number or recycles can also be limited to use and wear conditions. Before using a reprocessed mask, check elasticity, adhesive connections, form fit to nose and face to ensure proper and secure fit.

Please read this manual carefully, paying particular attention to the requirements for loading capacities, load configurations, and other restrictions of the RH-Pro11/RH-Pro9. Failure to follow the operating instructions in this manual may result in damage to the unit, user injury, or reduction in microbial killing efficacy. Following these instructions will result in a worry-free decontamination process.

6.5.1. Cautions

- During operation, the exterior surface of the RH-N95 remains comfortable to the touch; however, the tray will be hot. Use only the provided heat-resistant gloves for removing the tray. **The RH-Pro11/RH-Pro9 is designed for use only with N95 respirators**. There are many different brands and mask types that are designated N95. CPAC is doing its best to test compatibilities of these masks, but unfortunately not all have received performance testing. Contact the manufacturer of any mask that has not been tested (updated list on CPAC.com). Many plastics (e.g., nylon, polyester), and silicone rubber products can be used in this moderate temperature environment, but extreme care should be used in decontaminating N95 masks until compatibility has been confirmed by the manufacturer.

6.5.2. Temperature Safety Features

- The temperature in the RH-Pro11/RH-Pro9 sterilizer is controlled by computer logic, which is programmed to maintain uniform temperature throughout the processing chamber. The temperature control maintains a uniform exhaust temperature of 180°F (82°C) as indicated on the keypad display with a variability of +/- 1°F. The actual temperature as indicated on the CIR Thermo-sensor (logger) probe placed on the tray at site of mask placement will read 176°F (80°C). The logger serves to replace the use of a chemical indicator by directly recording time and temperature at site of decontamination.
- The door cannot be opened during a processing cycle without the operator pressing “Cancel” on the keypad. Any interruption in processing cycle will result in a cycle interruption error and notification which will be documented in memory.

6.5.3 General Guidelines for N95 Mask Loading

- The RH-Pro9/RH-Pro11 sterilizer utilizes dry, rapidly flowing air to decontaminate respirators. This process is both a heat conduction and heat convection process and requires that all respirators be directly subjected to the hot, high velocity moving air. In the RH-Pro9/RH-Pro11 sterilizer, airflow moves constantly across the tray from the left to right of the sterilizer chamber.
- Airflow can be restricted by the misplacement of N95 respirators, which may interfere with the performance of the unit.
- For high-velocity hot air (HVHA™) RH-Pro11/RH-Pro9 operating at 176°F, most of the N95 mask/respirator filtration materials are thermally tolerant at this operating temperature along with elastic, adhesive and nose foam materials.
- Use trays provided with the RH-Pro11/RH-Pro9 that have been designed to provide required hot airflow from all directions to N95 masks/ respirators.
- Masks should be placed individually into Ziploc™ sandwich bags.
- Bagged masks/respirators are to be placed flat on the tray.
- Masks must fit within the tray.
- Trays must be fully inserted into the treatment chamber to assure full airflow to the masks.

6.5.4 Pre-set N95 Cycle

The RH-Pro11/RH-Pro9 is equipped with a pre-programmed decontamination cycle, representing the time and temperature required to achieve a 6-Log reduction of coronavirus and Mycobacteria according to peer-reviewed studies. This cycle is set with a 4-minute warm-up period followed by a 30-minute decontamination cycle at 176˚F (75˚C) (temperature at site of masks as measured by the CIR thermal sensor logger). Chamber temperature will display a temperature of 180 +/- 1˚F on the touch pad which is being measured by a thermocouple located at the chamber's exhaust port.

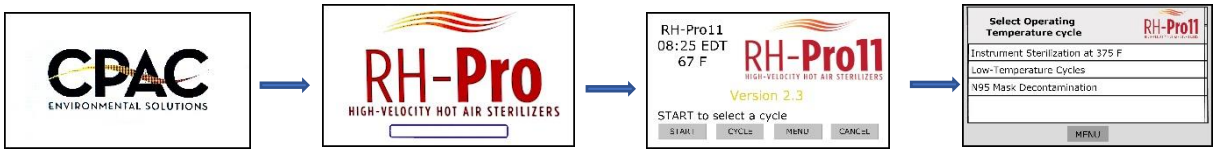
6.5.5 N95 Cycle - Capacity Restrictions, Limitations, Loading

The N95 cycle has been designed to operate at 180°F (82°C) with a decontamination cycle time of 30 minutes plus 4-minute warm-up (total of 34 minutes per processing). Up to four trays can be processed per cycle under the following configuration (2 x 3) as shown in a 6 mask per tray configuration:

6.5.6 Operation of the N95 Respirator Decontamination Cycle

The On/Standby button will show an illuminated blue LED when electric power is present and the RH-N95 is in its "standby" mode. With the door open or closed, press the On/Standby button to activate the unit. The blue LED in the On/Standby button will go dark after being pressed.

Allowing about 12-15 seconds after pressing the On/Standby button will result in the following screen sequence which initiates "Start-of-Day" Preheating:



IMPORTANT NOTE

PREHEAT STERILIZER CHAMBER BEFORE RUNNING FIRST STERILIZATION CYCLE OF THE DAY. ALSO CHECK TO ENSURE THAT THE "TIME AND DAY" SETTINGS ARE ACCURATE TO ENSURE THAT STORED CYCLE DOCUMENTATION IS PROPERLY TIME-STAMPED.

6.5.7 "Start-of-Day" Preheating

At the start of the day the RH-Pro11/RH-Pro9 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. The "Start-of-Day" pre-heating process includes the heating of the chamber to 180°F when "N95 Mask Decontamination" is

selected. Note that if any other higher temperature cycles have previously been run, the chamber will be, in all likelihood, above the high-temperature threshold for mask decontamination and the following screen will appear:

To remedy this condition, open the chamber door to expedite chamber cooling to a temperature below 180°F.

Follow the protocols outlined in Section 6.1.2 for "Start-of-the-Day" preheating procedures. This process includes the preheating of the trays that will subsequently hold the N95 masks requiring decontamination. Place empty trays into chamber; Close and turn handle counterclockwise to full vertical position; and press "START"

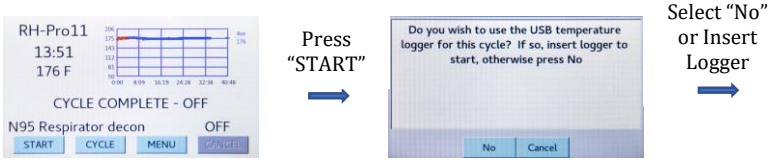
Once the sterilizer has been preheated to its operation temperature, the RH-Pro9/RH-Pro11 is now ready for N95 mask sterilization and masks may now be placed onto the preheated trays for processing. Close and lock door. **Ensure that "Time and Date" setting is correct.** If not, press "Menu" button and select "Time and Date". See Section 6.6.1.

If no immediate use of the sterilizer is planned, it is best to keep the door closed and in locked position to minimize temperature loss to the sterilization chamber. The blower and heater will shut down upon completion of each cycle.

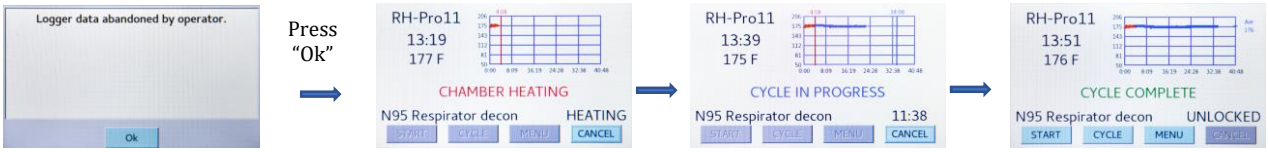
6.5.7 N95 Respirator Decontamination Sequences

- Sequence for Starting Sterilization Cycle After Reboot:

- Sequence for Starting Sterilization Cycle from either the "CYCLE COMPLETE", "PREHEATING" OR "READY" screens:

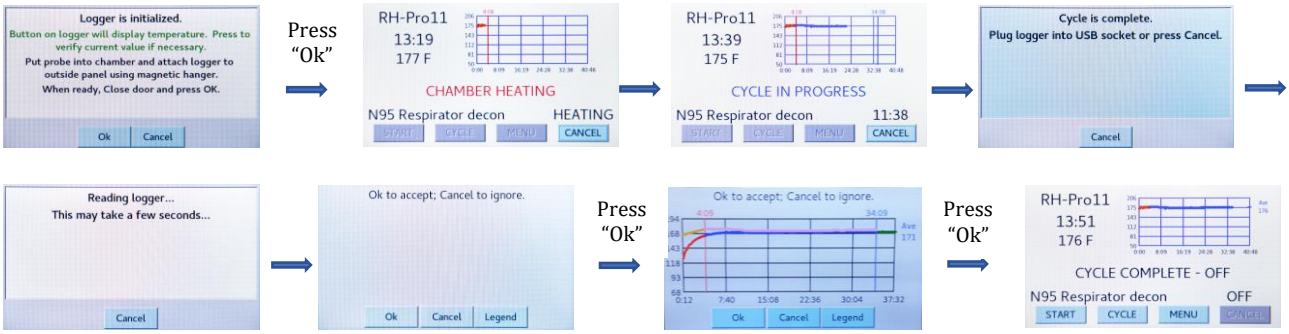


No Use of Logger - Select "No":



OR

Use of Logger - Insert Logger:

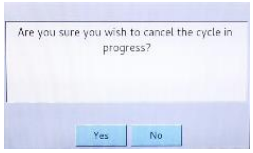


Upon completion of the cycle or for later retrieval of the time-temperature cycle log for both the internal thermocouple and the CIR Thermo-sensor, refer to Section 6.6.4 for detailed instructions.

6.5.8 Premature Canceling of a Cycle

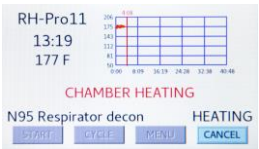
When a sterilization cycle is in process, the door is in a "Locked" position and cannot be opened unless "CANCEL" is pressed. Pressing "CANCEL" results in the following screen sequence:

Pressing "YES" will unlock the door and terminate the cycle, resulting in the following screens:



If canceled during sterilization cycle

OR



If canceled during Preheating

Pressing “No” will resume sterilization cycle

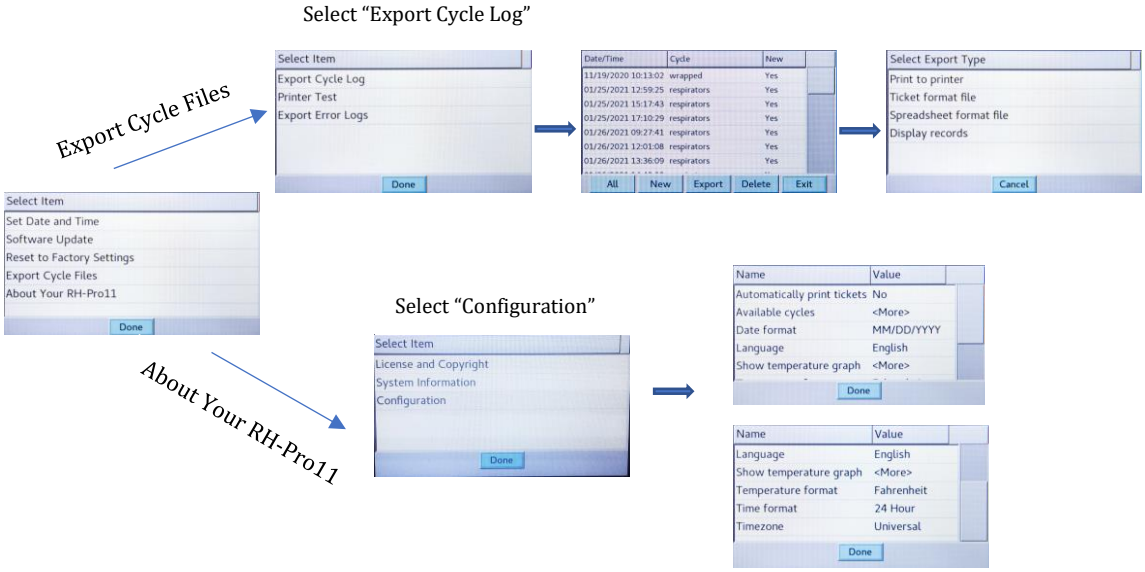
The interruption of the sterilization cycle is noted in memory. A new sterilization cycle can be initiated by pressing “START” on the “READY” display.

6.5.9 Turning Off the RH-Pro11/RH-Pro9 Sterilizer

At the completion of sterilization activities, the sterilizer may be shut down by pressing the On/Standby button and holding it for about 7-8 seconds until the screen goes dark and the blue LED in the On/Standby button is illuminated.

6.6 Menu Set-Up

To set “Date and Time”, “Update Software”, “Reset to Factory Settings” Export Cycle Files, or reconfigure several internal settings, press “MENU” from active “READY” or “PREHEATING screens to display “SELECT ITEM, then press desired category. For viewing all “CONFIGURATION” files, a scrolling menu is displayed. The scroll bar on far right of screen will allow advancement through the entirety of the screen as depicted:



Five “MENU” screens and eight Configuration screen formats/ operational

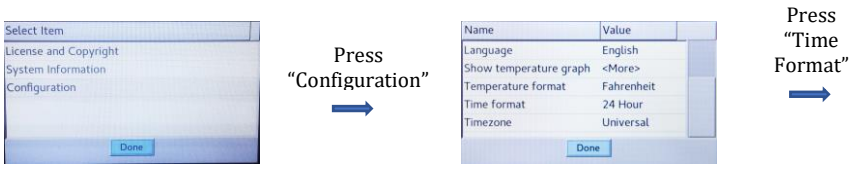
parameters are presented of which the operator may make changes. Note that none of these operator configurations will affect treatment times and temperatures required of the decontamination process. Press the desired category and follow instructions on the screen for attribute selection. If no more changes are to be made, press “DONE” to return to “READY” or main screen.

6.6.1 Setting Time and Date

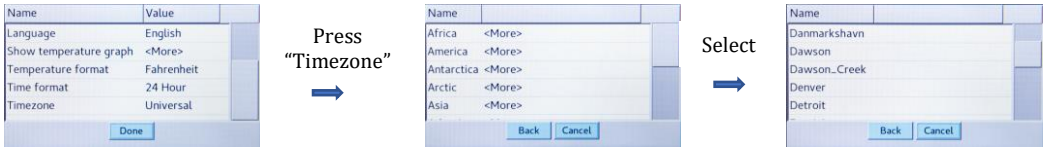
The RH-Pro11/RH-Pro9 has as an option in the selection of a time zone. However, it is important to set the time zone before you set the time as setting the time zone may alter the time previously selected (i.e., if the device were displaying Pacific time of 05:00 pm, setting the time zone to Eastern time would change the displayed time to 08:00 pm). If you set the time prior to setting the time zone, you may likely need to re-set the time.

From the Main Screen touch “Menu” then select and touch “Set Time and Date” to display a screen that allows a date and time to be set. Depending on the “Time Format” selected (within “Menu” under “Configuration above), time can be expressed as 24-hour clock or as AM/PM. Once a date and time has been selected, touch “OK“ to set.

Or a 24-Hour Clock:



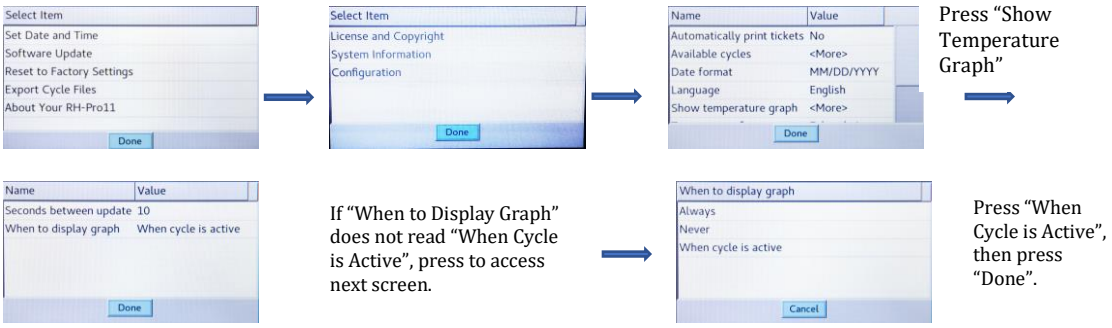
A time zone may be selected, but as an optional feature. From the Main Screen touch “Menu” then select and press “Configuration” and touch “Time Zone”, selecting and touching the appropriate area of the world to locate the nearest city within your designated time zone. The feature does not allow an automatic time-change during Standard time to Daylight time and reverse. Once selected touch “Back” or “Done” on each successive screen to return to the Main Menu.



6.6.2. Placing Time-Temperature Graph on Display Screen During Cycle

The RH-Pro11/RH-Pro9 features an optional display graphic depicting the time-temperature of the treatment chamber during the decontamination cycle to aid as an assurance that the unit is operating at specification and to provide a visual aid as to the progress of the process. This graph depicts the progress in red during 8-minute "Chamber Heating" and in blue during a 6-minute "Cycle in Progress" (Unwrapped Cycle) as depicted below:

This option if not already pre-set may be accessed by pressing "MENU" from "READY" or "PREHEAT" screens to display "SELECT ITEM, then press "About Your RH-Pro11" to access the "CONFIGURATION" screen as shown:

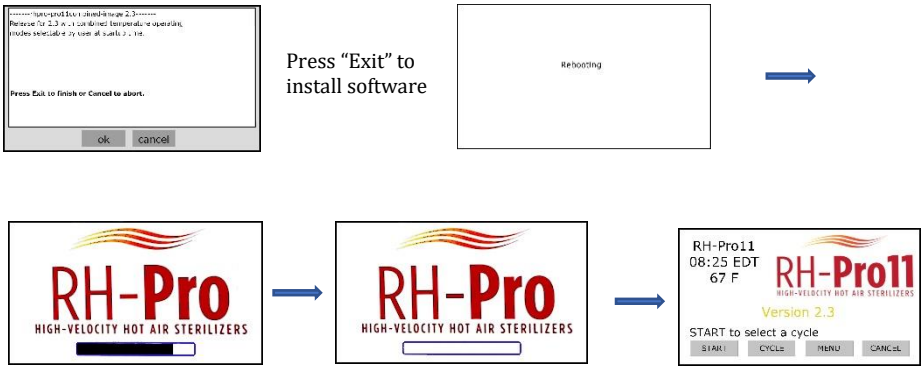


Screens then will be displayed in reverse order by pressing "DONE" until return to "READY" or "PREHEAT" screens. Upon reaching "Chamber Heating" in next decontamination process, the time-temperature graph will appear through the duration of the treatment process.

6.6.3. Software Transfer Via USB Port

Software is occasionally updated by CPAC Equipment, Inc. (CEI) via email containing a downloadable file labeled "Update.zip" to a USB flash drive via your computer. This file is a compressed "zip" file which can be downloaded to via either MAC or Windows systems. Do not "unzip". If the flash drive has been used previously for updates, remove any previous file before uploading new file. The RH-Pro11/RH-Pro9 will not recognize differences between the old and new update files. Follow instructions contained in the email. Once the "Update.zip" file is loaded onto the flash drive from your computer. The flash drive may be inserted into the RH-Pro11/RH-Pro9 USB port at any time other than during the running of a sterilization cycle. Once inserted the screen will display "Flash Drive Ready". Press "MENU" from "READY" or "PREHEAT" screens to display "SELECT ITEM" screen as sequenced below:

Press "SOFTWARE UPDATE" and the following typical automatic sequence is initiated:

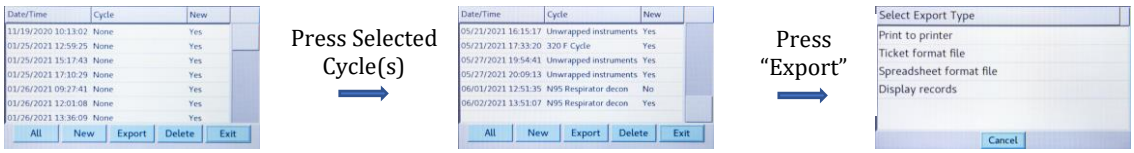


6.6.4. Downloading Cycle Data to Flash Drive

The RH-Pro11 internally stores time-temperature data from the internal thermal sensor. This data can be retrieved by loading onto a flash drive for off-site electronic storage or for hard copy documentation. Two standard formats are available for downloading these records: "Ticket Format File" and "Spreadsheet Format File." Of these two, the Ticket Format File" provides the most easily read format. See below for an example. The "Spreadsheet Format File" will print as an Excel spreadsheet. "Display Records" allows the graphical representation of individual cycle data on the RH-Pro11/RH-Pro9 screen. (See below).

Stored data is loaded to a flash drive via the following screen sequence:

Press "Export Cycle Logs" to select which cycles to be saved to the flash drive as sequenced:



Pressing "Display records" will graphically display selected sterilization cycle for both the internal sterilizer thermocouple and CIR Thermo-sensor. This display cannot be transferred to the flash drive at this time.

Pressing the selected format (e.g., Ticket format file") will automatically transfer cycle data to the inserted flash drive as partially shown below.

****

Operator_____

Start Date - 06/04/2021
Start Time - 02:26:06
Cycle Name - 300f/150c
Temp Setting - 304 F
Time Setting - 36 min.
Warmup delay - 22 min.
Cycle Number - 220
Serial Number - 10253
RhPro Version - 2.3.beta5
Logger Model - EL-USB-TC-LCD
Logger S/N - 210800868

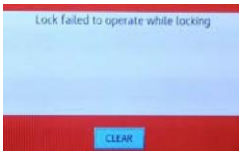
Cycle Phase	Time	Temp(F)	Log
Warm-up start	02:26	170	104
Warm-up end	02:48	306	300
1 min.	02:49	304	300
2 min.	02:50	303	300
3 min.	02:51	303	300
4 min.	02:52	302	299
5 min.	02:53	302	299
6 min.	02:54	302	299
7 min.	02:55	302	299
8 min.	02:56	302	299
9 min.	02:57	302	299
10 min.	02:58	303	299
.			
.			
32 min.	03:20	302	299
33 min.	03:21	302	299
34 min.	03:22	302	299
35 min.	03:23	302	299
36 min.	03:24	302	299

Warm-up time = 22.1 min.
Exposure time = 36.0 min.
Total Cycle time = 58.2 min.

Cycle status = Success
****

6.6.5 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:

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

7. CYCLE VALIDATION GUIDELINES – BIOLOGICAL INDICATORS

The American Dental Association, United States Air Force, The Joint Commission, and the Centers for Disease Control and Prevention 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-Pro9/RH-Pro11.

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-Pro9/RH-Pro11. Spore test strips as well as test services are widely available. CPAC Equipment, Inc. recommends using the following:

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

7.1 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 Log (operator collects and maintains). 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 full trays) consisting of instruments normally sterilized during the day.
2. Conduct 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 12-minute cycles, load the instruments into thermally-compatible self-sealing pouches or other CPAC pouches recommended for dry heat and insert the CIR-Thermo-sensor probe 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 via Step 3, place the instrument tray into the sterilizer.
8. Start the sterilization cycle.
9. 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 Log. 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 10.
    (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 Log.
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 Log. 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 Log.
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 Log. Correct those conditions and repeat the test (Steps 3 through 10).

7.2 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, Inc. 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 Log 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 (189°C) and 380°F (193°C) 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. MAINTENANCE

- The RH-Pro9/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 longlife, heavy-duty parts that require no maintenance. See Section 6.6.5 "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, DATA STORAGE AND RETRIEVAL

RH-Pro9/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.

Data Storage

RH-Pro9/RH-Pro11 Sterilizer is capable of downloading cycle data to a Point–Of - Sale (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 RH-Pro9/RH-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 RH-Pro9/RH-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-Pro9/RH-Pro11 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.

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-Pro9/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 6.6.1 "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.

Printer

If direct printing is desired, the RH-Pro9/RH-Pro11 has 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-Pro9/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

10. INDEPENDENT TIME-TEMPERATURE LOGGER

To monitor conditions at the site of heat treatment, chemical indicators (CIs) are typically used to determine if the conditions have been met to inactivate microorganisms. For the dry heat process these conditions are time and temperature. No chemical indicator has been developed for this cycle. A better and more direct approach has been taken using an independent temperature sensor (CIR) that replaces the use of a chemical indicator. The CIR™ Thermo-sensor will document and record the time and temperature every 10 seconds (printout records every minute) at the location of mask placement. Data gleaned from this logger is stored on the logger during the decontamination cycle and downloaded into the sterilizer's data log upon completion of the cycle for future retrieval.

It has been demonstrated by CPAC Equipment that this approach to replacing CIs with a CIR does provide the time and temperature parametric data far superior to that of a CI. The thermocouple probe is attached by tape to the probe as shown in Figure I. The handpiece-probe combination is subsequently placed into a sterilization pouch and the flap is closed and sealed over the thermocouple wire. The pouch is then placed onto either the top or bottom tray of the sterilizer leading the thermocouple wire out the chamber to be connected the CIR™ Thermo-sensor (Figure II). Once the remainder of the challenge load has been placed into the chamber, the door is closed sealing the thermocouple wire between the door and the sterilization chamber gasket. (See Figure III below.) The CIR™ Thermo-sensor is then inserted into the USB port on the bottom right front of the sterilizer. The CIR™ Thermo-sensor is initiated during starting sequence of the Low-Temperature cycle with data recorded and stored for viewing and downloading from the sterilizer's computer. The temperature sensor probe is accurate to a maximum ± ½ degree F to our laboratory's LabJack time-temperature recording equipment as shown below.

Comparison of LabJack Research Thermocouple with CIR™ Thermo-sensor

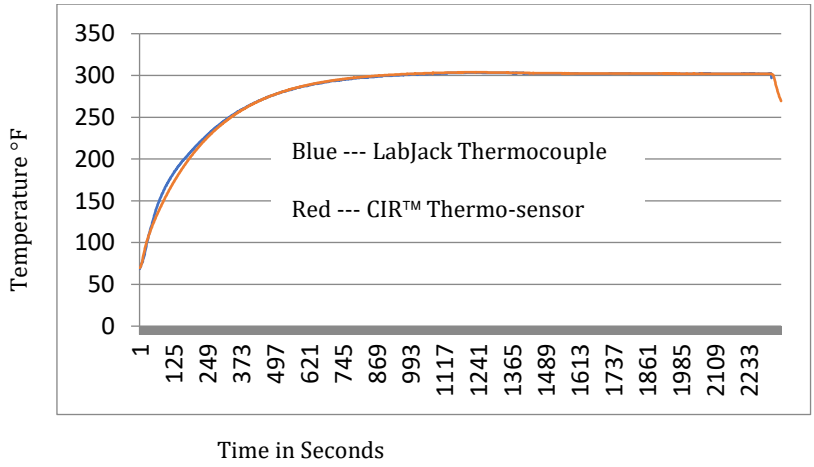


Figure I

Figure II

Figure III

BATTERY INFORMATION

Replacement

It is recommended that the battery be replaced annually, or prior to logging critical data. Only use 3.6V ½AA lithium metal batteries. (Recommended: Tekcell SB-AA02 14250 1/2 lithium batteries; https://www.amazon.com/gp/product/B016LBSHLU?pldnSite=1

The data logger does not lose its stored readings when the battery is discharged or replaced; however, the data logging process will stop and will not resume until the battery is replaced and the logger restarted. Please note that leaving the data logger plugged into the USB port for extended periods will cause some of the battery capacity to be lost.

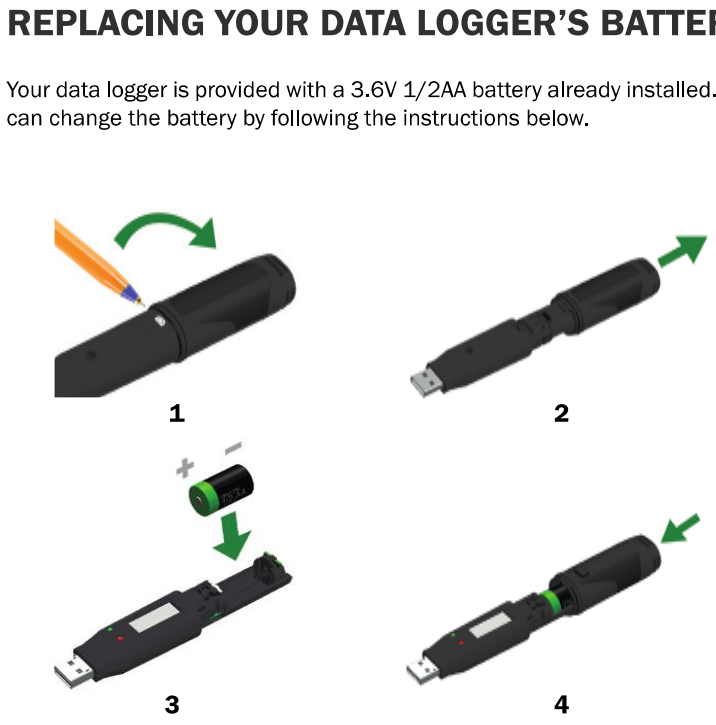
Passivation

If left unused for extended periods of time lithium metal batteries naturally form a non-conductive internal layer preventing them from self-discharge and effectively increasing their shelf life. When first installed in the data logger, this may cause a momentary drop in the battery voltage (the Transient Minimum Voltage) as the internal layer is broken down, resulting in the data logger resetting. Inserting the batteries in the data logger and leaving it connected to the RH-N95 for about 30 seconds remove this layer. After this, remove and re-install the batteries to reset the data logger. Overall battery life will not be affected.

WARNING

Handle lithium metal batteries carefully, observe warnings on battery casing. Dispose of in accordance with local regulations.

CIR Battery Replacement



11. 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/ERR	-Clear Error -Latch handle fully vertical
Chamber Overheating <390ºF	-Main PCB or Thermocouple Malfunction	WARN/ERR	-Attempt to Clear -Contact Authorized Service Technician
Chamber Temp not reaching 375ºF	-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 -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 selected cycle -Pouches Interfering with Chamber Fan -Pouches Not Removed Immediately After Cycle Complete	IND/WARN IND/WARN IND/WARN	-Use SteriDent Brand Nylon Pouches -Re-align Pouches to Prevent Fan Interference -Promptly Remove Pouches After Cycle Completion
Failing Spore Test	-Improper Instrument Spacing -Torn or Open Biological Indicator Envelope	IND/WARN IND/WARN	-Space Cassettes or Pouches 1” Apart -Do Not Overlap Pouches -See Sec 7.3 -Check Biological Indicator Envelopes for Proper Seals, Cuts, or Tears - See Sec 7.3

12. RH-Pro9/RH-PRO11 SPECIFICATIONS

RH-Pro9 SPECIFICATIONS	
Electrical Rating	
RH-Pro9 115 VAC	120 VAC +/- 10%, 60Hz, 12 Amps 1400 Watts warm-up, 300 Watts operating Transient Over-Voltage Category II Applies
RH-Pro9 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)	68.2 pounds (31 kg)
Width (OD)	19.63" (499mm)
Depth (OD)	20.00" (508mm)
Height (OD)	13.75" (349mm)
Chamber Dimension	9.5" (241mm) W x 15.6" (396mm) D x 7.85 (199mm) H
Chamber Capacity	1163 cubic inches (5 gal/19 liters)
Instrument Tray (ID)	7.3" (76mm) W x 12" (305mm) D x 0.85" (22mm) H
Instrument/Material Compatibility	Check Web Site for List of Compatible Materials and Instruments for RH-Pro9 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
Wrapped Cassettes	24 Minute Warm-up, 12 Minute Cycle; 36 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	
MARKINGS	UL, CE, US FC
510(k)	K872643A; K881371
PATENTS PENDING	US 62/632,906

RH-Pro11 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/38liters)
Instrument Tray (ID)	9” (229mm) W x 15” (381mm) D x 1.0” (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
Wrapped Cassettes	28 Minute Warm-up, 12 Minute Cycle; 40 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	
MARKINGS	UL, CE, US FC
510(k)	K872643A; K881371
PATENTS PENDING	

13. 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 timelier 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/ RH-Pro9 Sterilizer (Upon Completion Place This Form in Biological Test Data Log)

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 selected temperature
- ☐ 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 are 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-Pro9/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 Log
- ☐ Verified that all CIR Thermo-sensor readings were satisfactory and the results entered into the Biological Test Data Log
- ☐ 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 Log
- ☐ 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 Log

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

RH-Pro9/RH-PRO11 CABINET INSTALLATION

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. RH-Pro9 and RH-Pro11 sterilizers have 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 RH-Pro9's/RH-Pro11's internal blower motor and helps cool the control panel circuit boards. The other significant item on the RH-Pro9/RH-Pro11 rear panel is a switch which controls main power and provides an overcurrent protection circuit breaker for the RHPro9/RH-Pro11.

The main considerations for installation of the RH-Pro9/RH-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 RH-Pro9/ RH-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 RH-Pro9/RH-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

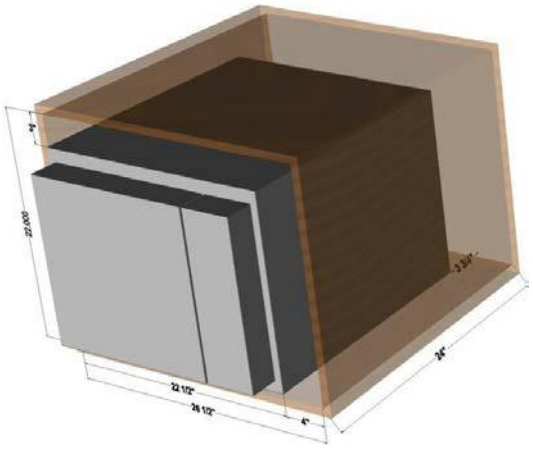


Fig. 1, Alcove installation with no pullout shelf:

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

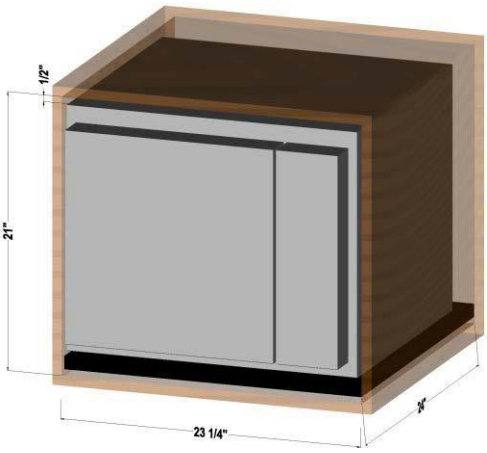


Fig. 2A, Pullout enclosure

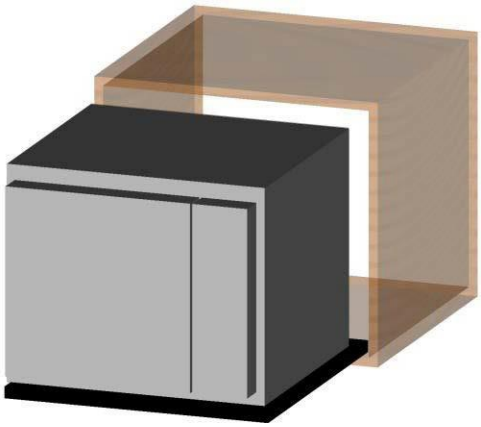


Fig. 2B, Pullout fully Extended

APPENDIX III
LOW-TEMPERATURE CYCLE VALIDATION PROTOCOLS

It has been recognized that many medical and dental instruments that require sterilization are composed of materials that are incompatible with the conventional high temperatures (340-375°F) employed by dry heat technologies. It is also recognized that certain instruments are difficult or feasibly impossible to sterilize because of their mechanical or electrical construction and/or incompatibilities with other thermal and chemical sterilization technologies. Furthermore, lower dry heat sterilization temperatures may offer a solution to these incompatibilities if times required for instrument sterilization could be reduced to make these lower time- temperature parameters logistically implementable. The Low-Temperature Cycles pre-set in the RH-Pro9/RH-Pro11. Studies performed by CPAC Equipment have demonstrated that dry heat temperatures ranging from 280-320°F provide logistically acceptable time parameters to achieve FDA-required level of bacterial spore kill.
As such, three pre-set, low-temperature cycles have been incorporated into the RH-Pro9/RH-Pro11 sterilizers to meet the low-temperature sterilization needs of the medical and dental practitioner.

Using the "Instruction-for-Use" parameters found in the Operation Manual as a basis for standard load characteristics of weight and time of processing, the practitioner can apply each temperature setting to specific temperature compatibility requirements necessitated for an instrument's particular composition. As each low-temperature application is different due to these compositional requirements, the low-temperature settings provided by CPAC cannot be FDA-validated. FDA recognizes that these situations exist and has made allowance for the operator/practitioner to internally validate the biological kill efficacy of these low-temperature settings as applied to the practitioner's needs.

Two measurements are required by the practitioner: (1) The accurate measurement of time and temperature and (2) the measurement of biological kill efficacy. CPAC Equipment provides through its HVHA sterilization system and through the use of its CIR™ Thermo-sensor, the ability to accurately measure and monitor an instrument's temperature over the pre-set cycle times during the validation process. CPAC Equipment also provides the data by which to compare the practitioner's generated data to determine if the time-temperature profiles generated are adequate to kill 6 Log_{10} of bacterial spores over a Half-Cycle of heat exposure. If these conditions are met, commercial bacterial spore strips containing 6 Log_{10} of bacterial spores can be used to determine the biological kill success of the process. Provided in this document are those protocols that allow the practitioner to validate the use of these low-temperature settings.

These cycle temperatures, times, and conditions (as outlined in the Operations Manual) are pre-set. It is the operator's responsibility to validate that his/her specific situation (the instruments' weight, composition and number) is in accordance with the conditions prescribed in the Operator's Manual for the Low-Temperature Cycle selected. Validation requires that the operator's specific situation meets the FDA's sterilization requirements. This requires measurement of time, temperature at the site or the instrument, and documentation that 6 Log_{10} spore kill can be attained in a Half- Cycle. Using the information provided in Table I and the validation protocols provided to enable a smooth and easy validation process.

TABLE I

Temp. Setting RH-Pro9	Warm-Up Cycle (Minutes)	D-Value (Time in Minutes	Time to 6 Log_{10} ½-Cycle*	Time to 12 Log_{10} (Full Sterilization Cycle)	Total Processing Cycle (Time Required for Warm-Up and 12-Log Kill)
320	16	1.5	10	20	36 Min.
300	20	4.0	18	36	56 Min. (1Hr.)
280	22	10.0	52	104	126 Min. (2.1 Hr.)

Temp. Setting RH-Pro11	Warm-Up Cycle (Minutes)	D-Value (Time in Minutes	Time to 6 Log_{10} ½-Cycle*	Time to 12 Log_{10} (Full Sterilization Cycle)	Total Processing Cycle (Time Required for Warm-Up and 12-Log Kill)
320	22	1.5	10	20	42 Min.
300	22	4.0	18	36	58 Min. (1Hr.)
280	22	10.0	52	104	126 Min. (2 Hr.)

*As Correlated with 6 Log Biological Spore Kill

Cycle Validation

The three Low-Temperature cycles provided with the RH-Pro9 and RH-Pro11 have been selected based on the various heat resistances of plastics, adhesives, lubricants, and O-rings found in common dental and medical articles. CPAC Equipment has provided the time-temperature relationship necessary to reduce a *Bacillus atrophaeus* spore population by 12 Log_{10} to meet FDA standards. However, the successful use of these Low-Temperature cycles is dependent on a number of different factors that are unique to the operator's needs. These factors include weight of the instrument, composition of the instrument, and the number of instruments to be processed per tray and per total load. These Low-Temperature cycles under specific conditions require validation by the operator as sanctioned by the FDA to assure a 12 Log_{10} reduction is achieved.

Low-Temperature cycle validation protocols are provided in the Operation Manual to assist the operator in demonstrating the FDA 12 Log_{10} reduction requirement is met. CPAC Equipment also includes a CIR™ Thermo-sensor to be used to document instrument or article time-temperature profiles, which can be used to determine if adequate instrument temperature and time at that selected temperature have been achieved to obtain the required spore inactivation. This time-temperature data is coupled with *Bacillus atrophaeus* spore testing at half-cycle conditions to document that 6 Log_{10} spores (the number of spores on a Biological Indicator test strip) are inactivated.

Step 1: Validation testing begins with the selection of the appropriate temperature cycle. Consideration of the temperature is of primary importance, but processing time may also be a factor for deliberation. It is recommended that a discarded instrument or article that is similar or identical to that item requiring sterilization be used in a trial run to determine thermal compatibility with the temperature selected. For handpieces, organic-based lubricants and their propellants are not compatible with 375°F. If it is not desirable to use a synthetic, high-temperature lubricant, 300°F may be compatible with that lubricant. Pre-testing of a small amount of lubricant applied to a discarded stainless steel instrument should be performed to visually determine if any discoloration results after five to seven processing cycles.

Step 2: Following the validation protocols provided, particular attention should be paid to the weight and number of instruments per tray and per load. Overloading a pouch, tray, or chamber will influence the time

requires to heat those items being treated. All loading instructions should be followed since adequate airflow is required between pouches and over and under the trays to ensure good heat conduction. It is equally important that the validation procedures are performed on an instrument load that presents the same challenges as will be seen during typical use. This includes type of instruments, number of instruments per pouch, maximum weight of instrument(s) to be tested, number of instruments per tray, and number of instruments per total load. A construction description of such a "Challenge" load should be recorded, and that load should never be exceeded in actual use.

Step 3: Additionally, a selected "Challenge" instrument should be designated as the attachment point for the CIR™ Thermo-sensor. If loads are to be comprised of handpieces, select that handpiece that weighs the most. If the loads will be a variety of similar instruments, select the instrument that weights the most. Instrument weight or mass has a direct relationship to how fast the instrument heats to temperature; the higher the mass, the longer it takes for the instrument to heat to temperature. Ensure that the maximum singe-instrument weight allowed (see instructions-for-use in Operations Manual) is not exceeded. The thermocouple probe is attached by tape to the probe as shown in Figure II. The handpiece-probe combination is subsequently placed into a sterilization pouch and the flap is closed and sealed over the thermocouple wire (Figure III). The pouch is then placed onto either the top or bottom tray of the sterilizer leading the thermocouple wire out the chamber to be connected the CIR™ Thermo-sensor. Once the remainder of the challenge load has been placed into the chamber, the door is closed sealing the thermocouple wire between the door and the sterilization chamber gasket. (See Figure IV.) The CIR™ Thermo-sensor is then inserted into the USB port on the bottom right front of the sterilizer. The CIR™ Thernmo-sensor is initiated during starting sequence of the Low-Temperature cycle with data recorded and stored for viewing and downloading from the sterilizer's computer. The temperature sensor probe is accurate to a maximum ± ½ degree F to our laboratory's LabJack time-temperature recording equipment as demonstrated in Figure I.

Figure I

Comparison of LabJack Research Thermocouple with CIR™ Thermo-sensor

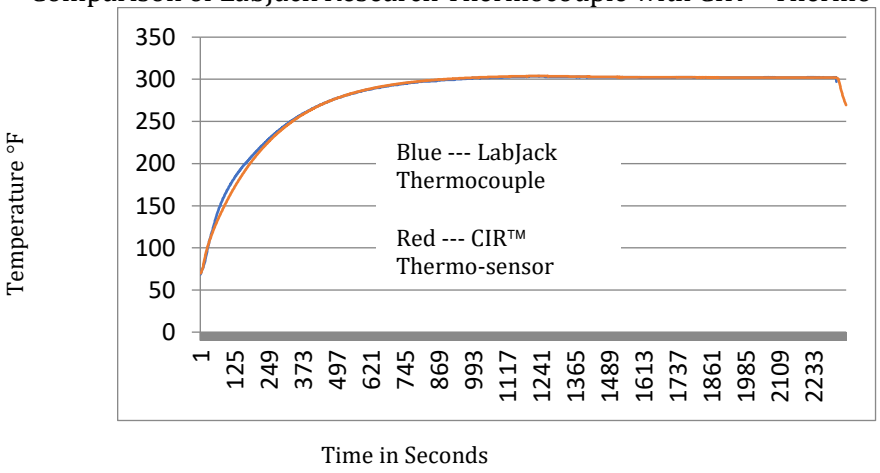
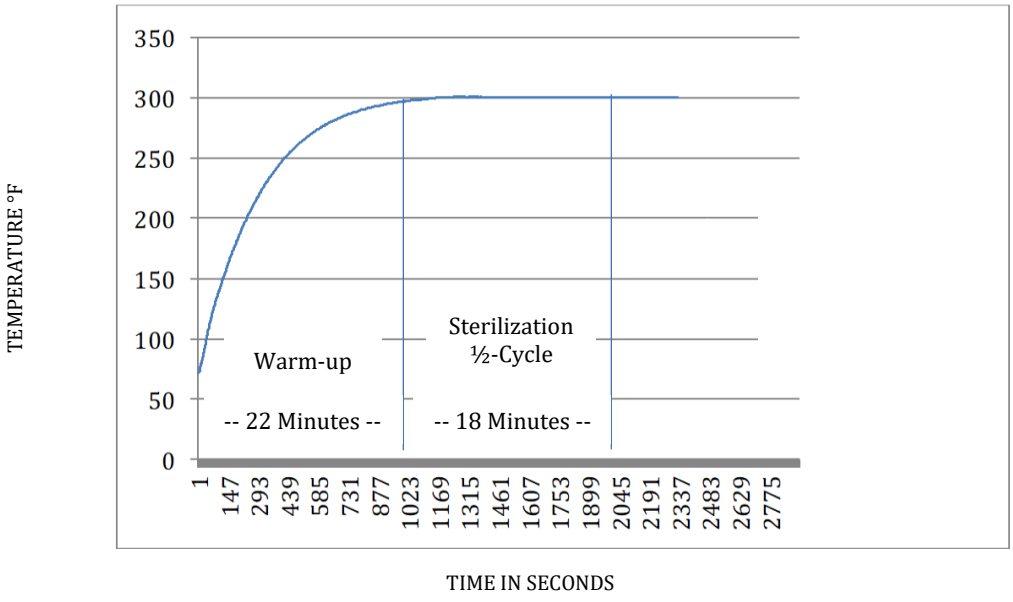


Figure II **Figure III** **Figure IV**

Step 4: The first step in instrument sterilization validation requires the parametric documentation that time-temperature parameters are met in accordance with those conditions established in Table I. Specifically, the time-temperature profile collected from the validation trails should provide similar "Warm-up" times before the sterilization temperature is reached. The goal of these trials is to ensure that the sterilization temperature is held for a time adequate to meet a 12 Log_{10} spore reduction during by the end of the sterilization cycle. As shown in Figure V for a 300°F Cycle, the "Warm-up" phase is defined as the initial portion of the time-temperature profile before the sterilization temperature plateau is reached and held. The three Low-Temperature settings are pre-set to an established process time that is the sum of "Warm-up" minutes and time required at temperature for instrument sterilization. The CIR™ Thermo-sensor generates the identical graphical representation as in Figure V and from that graph the length of the "Warm-up" phase and the length of the time at sterilization temperature can be calculated. For a 300°F Cycle using the RH-Pro11, the "Warm-up" phase is 22 minutes, and the sterilization cycle is 18 minutes for a Half-Cycle. Comparison of these values to those in Table I will provide an excellent indication of whether sterilization conditions were met.

Figure V
Graphical Representation of Warm-up and
Half-Cycle Sterilization Phases of Instrument Heating at 300°F



Step 5: Satisfying parametric conditions is the first step of two in the validation of the sterilization process. The ultimate goal is to verify a 6 Log reduction (Half-Cycle) in *Bacillus atrophaeus* spores. Commercially prepared biological indicators containing 6 Logs of *Bacillus atrophaeus* spores are used to conduct spore kill trials at a half-sterilization cycle (e.g., for 300°F a full sterilization cycle is 36 minutes which includes the additional 6 Logs Sterility Assurance Level; a half-sterilization cycle is 18 minutes; Table I). Spore strips contained in their carrier envelopes are attached to the instrument-probe complex for final time-temperature and spore viability trials. Data from these combination trials will provide the time-temperature data in direct conjunction with spore kill data to support successful validation. Spore analysis can be easily performed on-site with commercially available spore testing kits and block incubators. (See Figure VI.)

Figure VI
Spore Testing Kit and Block Incubator

Use of the RH-Pro11 and RH-Pro9 for N95 Respirator Decontamination

The use of HVHA technology was investigated for use to decontaminate N95 respirators and masks for re-use during their severe shortage caused by the Covid-19 pandemic. Published peer-reviewed reports have demonstrated that dry heat processing is the preferred method to assure that both viral inactivation and N95 respirator performance efficacies are maintained for numerous re-use cycles. CPAC Equipment has re-purposed their RH-Pro11 and RH-Pro9 sterilizers for N95 mask reprocessing through the development of a dedicated decontamination cycle based on a documented time-temperature parameter of 176°F for 30 minutes that has been shown to inactivate coronavirus without interfering with mask filtration and breathability performance for up to 20 re-uses. RH-Pro11 and RH-Pro9 units can process up to 96 and 24 pouched masks per hour, respectively, for their re-use by the respirator's original owner. The N95 Decontamination System meets the FDA criteria for emergency use authorization during this ongoing Covid-19 crisis.