



Instruction Manual for the Revolutionary Science **SANICLAVE FRONT-LOADING SERIES**

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NOTE: Read this manual before use! This manual contains important information, safeguards and operating instructions for the operation of the REVOLUTIONARY SCIENCE model Saniclave by Alternative Pioneering Research & Development, Inc. (APR&D, Inc.)

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INTRODUCTION

Dear Valued Customer,

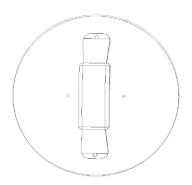
Thank you for purchasing the Revolutionary Science Saniclave. We are confident that the Saniclave will provide years of reliable service. The high quality of construction and durable parts deliver a performance equivalent to much costlier equipment.

You are invited to visit our web site at www.revsci.com. Please know that we welcome any feedback that might help us enhance and improve future RevSci products.

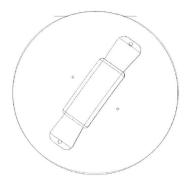
Sincerely yours,

REVOLUTIONARY SCIENCE

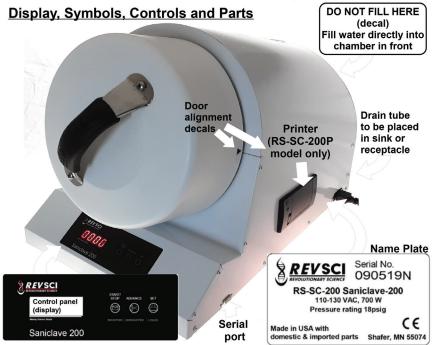




Open Door Door handle vertical



Close Door Rotate handle clockwise until it stops





INSTALLATION INSTRUCTIONS

Remove Saniclave from packaging and place it on a dry level surface. Plug it into an accessible 120 VAC power receptacle. For optional printer setup, see pg. 6. The Saniclave is now ready for use. See operating instructions on pg. 7.

Upon receiving the Saniclave, it is important that you follow these simple steps:

- 1. Examine carton and contents for possible damage to the product caused during shipping. If damage is present contact the carrier at once. Failure to do so immediately may release the carrier from any liability of damage.
- 2. Fill out the checklist (see pg. 14). If the shipment is incomplete, please contact us at support@revsci.com or (800) 775-7942 x 2.
- 3. Carefully read this instruction manual before operating the Saniclave.
- 4. 4. Visit the product registration webpage provided on pg. 12 by scanning the QR code or entering the URL manually and complete the registration online.

INTENDED USE

The Revolutionary Science Saniclave is designed to be used in medical and dental clinics, hospitals and other facilities where reusable sterile equipment is used. It is intended to sterilize wrapped and unwrapped heat and moisture stable solid instruments, mated surfaces, knurled and hinged devices (excluding lumened devices and dental hand pieces) that are compatible with saturated steam sterilization at 121 degrees C° for 30 minutes.

SAFEGUARDS & CAUTIONS

WARNING! Do not use this autoclave in an explosive or oxygen rich atmosphere. Failure to do so may result in serious injury or death.

CAUTION: Chamber contains hot water and steam during and after operation. Hot water may drip from cover during removal and can cause scalding.

Occasionally parts such as the door seal, control panel decal, and ZPD should be replaced after heavy usage: These easily replaceable parts are available through Revolutionary Science. No tools are required.



LIMITATIONS OF USE

Revolutionary Science is not responsible for misuse of the Saniclave.

- 1.The load should be considered non-sterile unless the display reads 'CC' after the cycle.
- 2. NEVER attempt to dismantle or modify the Saniclave.
- 3. NEVER leave an operating Saniclave unattended.
- 4. NEVER block the drain (located on the inside of the chamber below heating element).
- 5. NEVER block the steam trap (located on the inside of the chamber, near the top, directly above drain).
- 6. NEVER operate the Saniclave with a damaged cord or plug or after the unit malfunctions or has been damaged in any manner.
- 7. NEVER use accessory attachments not recommended by Revolutionary Science. Their use may cause fire, electrical shock or injury.
- 8. NEVER use the Saniclave or any purpose other than the intended use.
- 9. ALWAYS close the door properly before operating.
- 10. NEVER attempt to force the door open or release pressure while sterilizer is in operation.
- 11. ALWAYS use distilled water. The sensor detects ion content in the water If distilled water is too pure, the autoclave may not detect the presence its presence. Salt may be added to the water to increase detectability. Class III distilled water is recommended.
- 12. NEVER reuse water left in the exhaust tank. Re-used water may contain endotoxins. Drain water tank and refill chamber with clean, distilled water before each cycle.
- 13. NEVER attempt to modify the plug to fit an outlet other than the required 3-slot, grounded outlet. The enclosed 3 prong plug is equipped with a grounded type 3 conductor wire to further ensure the safe operation of the Saniclave.
- 14. NEVER immerse the autoclave, cord, or plug in water or operate on wet surfaces.
- 15. NEVER fill the exhaust tank with water (See pg. 3 for location of exhaust tank and cap). The Saniclave must be filled by pouring water directly into the chamber.
- 16. ALWAYS load the Saniclave with instruments compatible with steam sterilization at 121 degrees C° for at least 30 minutes. Always contact the instrument's manufacturer if you are unsure that this sterilization technique is suitable for instruments being sterilized.
- 17. ALWAYS inspect the silicone seal before each use for dirt, grime or cracks
- 18. NEVER clean the Saniclave with organic solvents like thinner or benzene as it will damage the surfaces.
- 19. ALWAYS test regularly with Geobacillus stearothermophilus. See pg. 17 for sterilization monitoring and control for more information.
- 20. This sterilizer has not been validated for double pouching.



OPERATING THE SANICLAVE

PREPARATION FOR STERILIZATION (DEFAULT MODE)

Important:The load should be considered non-sterile unless the display reads 'CC' after the cycle.

- 1.Preclean instruments according to their manufacturer's recommendations. WARNING! Failure to properly clean instruments before autoclaving, may result in unsterile equipment. Using unsterile equipment may result in serious injury or death.
- 2.It is recommended that all instruments be dismantled, if possible. CAUTION: Stacking instruments improperly may result in nonsterile equipment.
- 3. Use a sterilization indicator strip with each set of instruments being autoclaved.
- 4. The recommended load is 4.5 lb (not including the tray). Never exceed the maximum load. Exceeding maximum load may result in nonsterile equipment.
- 5.Run a biological indicator spore test (Geobacillus stearothermophilus) at least weekly to confirm proper sterilization. For additional information on purchasing biological indicators, see pg. 17.

PRINTER INSTALLATION AND OPERATION

Saniclave: The recommended printer model is the Zebra 2844 with a serial cable connection. Printer paper must accommodate printout width of 4 inches. Follow printer manufacturer's recommendations for regular repair, cartridge replacement and service. The printer must be powered and connected to the Saniclave via a serial cable prior to use.

Saniclave 200P: The printer is affixed on the right side of the autoclave. The Saniclave 200P printer requires 2" wide thermal paper.

Sufficient paper must be installed in the printer. At the end of the cycle (whether it is a complete cycle or a failure), the SET button, found on the

control panel may be pressed to obtain the printout. If the Saniclave is reset or powered down, the printout data cannot be recovered.

Printouts should be made in accordance to your facility's standard operating procedures. A successful printout should look similar to the following sample printout:

Saniclave cycle data Date & time cycle started: 1431 Y2011, 15:51:19 Cycle parameters set 15psi 121.00 temp 30 min sterilization 30 min dry mode Cycle number: 3 Autoclave ID: 050211A Modes: parameter recorded at the Time Temp(C)
Preheat: 16:33 121.1 end phase Pai Preheat: 16:33 Sterilize: 30:00 123.0 Total Time: 76:33 Exposure temperatur Min: Status: Successful Cycle Complete



OPERATING INSTRUCTIONS

- 1. Place the Saniclave on a dry, level surface and rest the drain tube in a sink, bucket, or other receptacle. Alternatively, the drain tube may be pinched shut and the water drained every few cycles (see pg. 10).
- 2. Remove the chamber door by rotating door counterclockwise.
- 3. Fill the chamber with approximately 500mL of distilled water (until the heating element is fully submerged and the metal portion of the temperature sensor is in contact with the water). ALWAYS use distilled water. The sensor detects ion content in the water. If distilled water is too pure, the autoclave may not detect the water. Salt may be added to the water to increase detection. Class III distilled water is recommended.
- 4. Place the tray support in the bottom of the chamber, put the tray on the support, and load the instruments to be sterilized (wrapped or unwrapped) on top of the tray.
- 5. Inspect the door to assure that the seal is clean and not damaged. Be sure that the inner portion of the door is also clean and clear, ensuring a secure fit.
- 6. If the seal has been removed re-install seal in the door by evenly tucking seal under all lugs. Seal may be cleaned with warm, soapy water (discard seal when it becomes noticeably cracked or worn).
- 7. Place the door on the chamber, aligning the marking on the door with the 'OPEN' marking on the autoclave. To close, rotate the door clockwise, ensuring that the marking on the door is aligned with the 'CLOSE' marking on the autoclave. Never attempt to rotate the door past this CLOSE marking! Improper closing of the door can cause pressure leaks or damage to the autoclave.
- 8. Insert the plug of the cord into the wall outlet. NEVER modify the plug to make it fit, as the plug will only fit in one way. The autoclave must be grounded when in use.
- 9. The 4-digit LED indicator will turn on and show '0000.'
- 10. Press 'START/STOP' to begin the sterilization process for wrapped items. If using unwrapped items press the 'ADVANCE' button instead.

NOTE: To abort the cycle at any time, press 'START/STOP' again. Display will then read 'Err 1' and chamber will instantly depressurize. Allow a few minutes for the chamber to depressurize before opening the door.

11. The display will briefly read 'C1' or 'C2' for wrapped and unwrapped cycles respectively, then change to 'Ph' for the preheat mode which takes around 25 minutes to complete.

NOTE: Monitor the display for any errors. If an error warning is displayed, the cycle will be aborted (see troubleshooting section on pg. 10).

- 12. When the preheat mode is finished the display will automatically begin to count down during the 30-minute sterilization cycle. For your convenience, the display will show the temperature reading. To view the pressure or cycle time left, 12. see pg. 8. 13. After the sterilization cycle the display will read 'drn' and the unit will automatically depressurize and begin draining. Due to door locking safety feature
- of the seal, opening the door is not possible until the chamber is completely depressurized. You may hear sound of the chamber depressurizing, which is normal.



17. When the chamber has completed draining the autoclave will make an audible beep. and the screen will read 'turn door' or 'CC' after wrapped or unwrapped sterilization cycles respectively. If you autoclaved a wrapped load, rotate the door counterclockwise, remove the door from the chamber, and tuck the bottom lip of the door under the retainer clip so that the door gently rests against the autoclave providing a small air gap for the drying cycle. Then press the ADVANCE button to begin the drying mode. During this mode, the heater warms the chamber for 30 minutes and moist air vents out of the door gap. When drying is completed, the screen will read 'CC'. To avoid condensation let your items cool for an additional 30 minutes before removing. If you autoclaved an unwrapped load, rotate the door counterclockwise, remove the door from the chamber, and recover your items. Use caution as internal chamber contents may be hot to the touch.

18. If the Saniclave is connected to a printer, a cycle report will print when SET button is pressed, showing the date/time, preset and achieved parameters.

A RECOMMENDED LOAD CONFIGURATION

Load must not exceed 4.5 lbs. Stand packs upright if possible.

CYCLE PHASES

Fill Display reads "Fill" if the 'START/STOP' button is pressed and the chamber has not yet been filled with sufficient water.

Preheat Mode.

Display will read 'Ph' for Preheat. This mode usually lasts about 30 minutes, depending on the load size.

Sterilization Mode

Display will show temperature in Celsius:

- Press ADVANCE to view the pressure reading
- in psi
- Press SET to view the cycle time remaining.

Dry Mode

When the sterilization cycle is successfully completed, the display will read 'drn,' for drain mode. As the water drains, the chamber completely depressurizes and shortly thereafter (if selected), the Dry Mode may be initiated. During dry mode, the display will alternate between 'dry' and the 30-minute timer.

CC Mode

After a successful completion of the entire cycle, the display will read 'CC' for Cycle Complete. Remove the door and remove the instruments. Instruments may be warm to the touch.

Print Date/time, preset and achieved parameters are printed.



SETTING YOUR SANICLAVE

The sterilization cycle parameters are as follows: 30 minutes, 121 °C, 15 psi. These parameters cannot be adjusted.

For wrapped loads, the user must use wraps or pouches that are cleared by the FDA for human use. Unwrapped loads must be used immediately upon sterilization.

Setting the Time and Date – To set the time and date, press and hold the 'SET' button. The 'ADVANCE' button may be used to move from the time, date, and year. The 'START/STOP' and 'SET' buttons adjust the settings up and down. Disconnecting the power between uses may interrupt the clock's timing and it may need to be reset. If set correctly, the time and date will be printed on the printout.

Print – After a cycle is complete, when the display reads 'CC,' press the SET button once. The Saniclave does not record cycle data other than the printouts.

See pg. 6 for more printer information.



TROUBLESHOOTING

Please visit the Revolutionary Science troubleshooting webpage by scanning the QR code or entering it in manually to view instructional videos covering potential Saniclave issues and their solutions.



https://www.revsci.com/pages/troubleshooting.

TROUBLESHOOTING CONTINUED...



Error Conditions and Display Readings

Note: If a failure occurs, the load must be considered non-sterile. The sterilizer and load should then be investigated. Contact Revolutionary Science if problem persists.

- 1. Manual Cycle Abort: If 'START' is pressed, display will read 'Err 1' for cycle abort. User may abort the cycle anytime during preheat, sterilize, or dry phases. If the cycle is aborted, the contents of the load shall be considered non-sterile. Press SET to acknowledge the error.
- 2. Preheat Too Long (Door Ajar): If door is not closed properly and the cycle is initiated, the cycle will fail when the autoclave cannot pressurize. The display will read 'Err 2.' Press SET to acknowledge the error then take off the door. Remove the door seal and inspect the door seal for cracks; replace with a new seal if necessary. Reinstall the seal into door and properly close the door by lining up the marking on the door with the marking on the autoclave body and twist the door clockwise to close. Restart the cycle.
- 3. Over Temperature Alarm: If the internal temperature exceeds a maximum of 124 °C the display will read 'Err 3.' Allow the unit to fully drain the chamber into the exhaust tank or sink. Press SET to acknowledge the error. Open the door when the chamber has cooled and remove the load from chamber. Refill the chamber with distilled water and reinsert the load, then close the door and restart the cycle. If an over temperature condition occurs again, contact Revolutionary Science to investigate the problem further and discontinue use until problem is resolved.
- 4. Under Temperature Alarm: If the temperature or pressure of the chamber falls below 121 °C during the sterilization cycle, the digital display will read 'Err 4.' Press SET to acknowledge the error. After the chamber has cooled open the door, remove the load from the chamber, refill the chamber with distilled water, reinsert the load, close the door, and restart the cycle. If an under-temperature condition occurs again please contact Revolutionary Science to investigate further and discontinue use until the problem is resolved.
- 5. Low Water: The display will read 'Err 5' if there is an insufficient amount of water in the chamber. Press SET to acknowledge the error, fill the chamber up to the temperature sensing probe, and restart the cycle.
- 6. Exhaust tank full: After a few cycles, the Saniclave display will flash 'drn tank full.' If the end of the drain tube is already resting in a sink or bucket and water is drained after each cycle then press any button to clear the warning. However, if the drain tube has been blocked by pinching, plugging, etc. because a sink or bucket was not readily available for drainage during sterilization then the exhaust tank has accumulated water during cycles. At this point, the exhaust tank must be emptied by unblocking the drain tube and allowing water to drain from the exhaust tank into a sink or other receptacle. If the exhaust tank is not drained water may overflow during the draining phase.



TROUBLESHOOTING CONTINUED

7. Door is difficult to open or close:

There may be a few reasons why the door is difficult to open or close.

- 1) Ensure that the door seal is tucked under all lugs in the door (see pg. 19).
- 2) The seal offset spring (bent steel piece on the door) must rest against the outside diameter of the seal and should not overlap the seal.
- 3) The chamber may have not yet depressurized. Wait up to five minutes after the display reads 'CC,' 'turn door' or an error mode to attempt to open the door.
- 4) If the door feels loose, but it is still hanging up, the edge of the door may be caught on the edge of the chamber. Try wiggling the door loose.
- 5) If the door is difficult to rotate, the door seal may need lubrication. To do this, remove and dry the seal completely. Lightly dust the seal with talcum powder (or talc-based baby powder) and spread evenly around the entire seal approximately once every 50 to 100 cycles or as needed. Caution: Never use oil or petroleum jelly for lubrication.

8. Display reads '8888'

This means that your real time clock has reset. The time and date settings will reset if the Saniclave is left unplugged longer than three days. See pg. 9 for setting the date and time. Unplug and replug the power cord. The display should now read '0000' and you can commence with sterilization. The real time clock does not need to be set properly in order to operate the Saniclave.

Printouts

If the printer is connected and SET is pressed following the displayed error, a printout will provide a brief description of the failure. The printout will not display any sterilization time if the failure occurred during the sterilization mode.

Additional errors

Power Outage: If a power outage occurs the display will revert to standby mode and read '0000.' It will not display 'CC' until the Saniclave is restarted and a successful cycle has occurred. This will happen even if the outage took place after a successful completion of a cycle and the unit was left unattended. If this happens refill with water and restart the sterilization cycle.

Water Leakage: Water may leak from the unit if the drain tube is not placed in a sink or water receptacle. To troubleshoot first check the drain tube. If leaking comes from another source, unplug the machine and contact Revolutionary Science.

If any of the above occurs, turn off the Saniclave and investigate. If the problem persists, contact Revolutionary Science.



WARRANTY REGISTRATION

Please visit the registration webpage by scanning the QR code or entering it in manually to register your Revolutionary Science Saniclave.



https://www.revsci.com/pages/product-registration-and-feedback

WARRANTY

Your Revolutionary Science Saniclave is warrantied to be free from defects of material and workmanship under normal use for a period of two years from date of purchase. If your Saniclave proves to be defective within this warranty period, APR&D, Inc. will repair or replace your unit at our option. This warranty will be void if malfunction is caused by accident, misuse, negligence, tampering, abuse, and/or damage in transit. This warranty excludes any relief for incidental or consequential damages.



SPECIFICATIONS

Power requirements: 120 VAC, 700 watts, grounded outlet

Net weight: 20 lb.

Dimensions: 16 in. tall x 13.5 in. wide x 21 in. deep

Internal chamber dimensions: 9 in. diameter x 10.5 in. long

Pressure: 15-18 psi

Normal operating temperature: 121-124°C

Temperature lower tolerance: 121°C

Temperature upper tolerance: 124°C

Preheat time: Automatic

Sterilization time: 30 minutes

Dry time: 30 minutes

Capacity: 10 Liters

PRODUCT SAFETY AND COMPLIANCE STANDARDS:

FDA Listing: RS-SC-200 is a 510k cleared product for medical use. K112811

FDA Registered: Revolutionary Science is an FDA Registered Company

CE / IEC Safety:

RS-SC-200 tested to and found to be compliant with IEC 61010A and associated safety standards.

ISO 9001: Revolutionary Science is an ISO Registered Company

IQ/OQ/PQ:

Revolutionary Science provides a range of compliance statements and IQ/OQ/PQ documents that will enable customers to successfully validate their products in accordance with regulations and standards. Contact Revolutionary Science for IQ/OQ/PQ documentation.

CONTACT US

REVOLUTIONARY SCIENCE 17319 Lake Blvd. Shafer, MN 55074 USA

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E-mail: support@revsci.com Web site: www.revsci.com



CHECKLIST

(See pg. 3 for visu	al identification of checklist parts)
Part:	Model number:
Autoclave	
Door seal	200-A00003
Tray	100-A00104
Tray support	100-A00105
Manual	310-A00001
Power cord	400-P00004
Notes & Service R	Record
,	re reference and to expedite answers to your questions, please owing information:
Date Purchased: _	
Serial Number:	
ruichaseu i ioin. ₋	
Your Notes:	
Revolutionary Scie	ence recommends the weekly use of G. Bacillus

Stearothermophilus biological indicator ampules. Place indicator in center of full load and test weekly.

The use of FDA cleared class 5 integrators should be used with each load. Follow the manufacturer's recommendations for class 5 integrator use.



CARE, STORAGE AND MAINTENANCE INSTRUCTIONS

Daily	Inspect and clean door seal with mild soap or detergent. Rinse with distilled water, wipe with damp lint-free cloth. Inspect for cracks. Reinstall in door. Clean Chamber with mild soap or detergent. Inspect chamber for calcium or other deposits. Wipe with damp, lint-free cloth. If needed, repeat cleaning procedure. Do not use harsh chemicals in autoclave. Unplug unit at the end of each day.
Weekly	Clean tray with warm water and a mild soap or detergent. Inspect for residues or deposits. Repeat cleaning if necessary. Rinse in warm, distilled water and wipe with a clean, lint-free cloth.
As Needed	Replace door seal if torn or cracked. If a printer is installed, replace paper as needed and according to printer manufacturer's instructions.

For regular Sterilizer Monitoring Guidelines, see pg. 17

When storing the Saniclave:

- 1. Unplug the Saniclave.
- 2. Drain all water from the chamber and exhaust water tank.

In the rare situation where water remains in the chamber after use (such as after a power failure). Drain the chamber by tipping the Saniclave unit forward, emptying the chamber into a vessel or sink.

Caution: Water from the chamber may be warm or hot!

3. When your Saniclave is cool, wipe both the exterior and the interior of the autoclave with a clean, dry paper towel or terry cloth. If needed, clean plastic parts with warm water or isopropyl alcohol. To remove calcium buildup, pour a small amount of CLR® or Alfa Clean® into chamber and clean thoroughly with a dry terry cloth.

All repairs must be performed by a trained professional. Contact

Revolutionary Science for more information. (See the contact section on pg. 13)



SANICLAVE CYCLE DOCUMENTATION TABLE

Signature						
Display reading at cycle end	22					
Cycle	\leftarrow					
Results according to class 5 Integrator	Parameters were met					
Set cycle parameters (default): 121C for 30 minutes	121C for 30 minutes					
Date						
Time cycle started	10:45:00 AM					
Serial #	102281A					

It is recommended to keep records of each sterilization cycle. This table may be copied.



STERILIZATION MONITORING GUIDELINES

Note

Revolutionary Science provides the following information only for reference. The user must contact state and local government for proper regulations regarding sterilizer use and sterilization monitoring. Additionally, the Centers for Disease Control and Prevention (CDC), American Dental Association (ADA) and the Organization for Safety and Asepsis Procedures (OSAP) may be contacted for further information regarding infection control.

Physical Monitors

Sterilizer malfunctions may be detected by pressure and temperature measurement devices. The sterilizer's programming aborts the cycle and displays a message on the display screen if physical conditions exceed the proper limits.

Note

Only FDA cleared chemical indicators and biological indicators designed for steam sterilization are to be used. Additionally, such indicators must be compatible with the cycle parameters of the Saniclave. When monitoring the cycle with such indicators, load the chamber according to your facility's standard operating procedures.

Chemical Indicators

The purpose of chemical indicators (CI) is to determine whether the sterilization cycle parameters are sufficient to accomplish an effective sterilization. CIs are not intended to be used to validate the sterility of the load. However, if the CI shows failure, the load must be considered non-sterile and the load configuration and sterilizer shall be investigated, due to the fact that proper cycle parameters may have not been correctly achieved. Note: Wrapping, packing and loading improperly may result in failures. In addition, the failure may be a result of sterilizer malfunction. Check load configuration and verify that it is in accordance with the manufacturer's instructions. Also, check the CI's instructions for proper use, storage and disposal. Only CI's that are cleared by the FDA and labeled for use with the same cycle parameters (of exposure time and temperature) of the Saniclave shall be used to monitor sterility conditions of loads processed in Saniclave.



Biological Indicators

Microbial devices such as biological indicators (BI) are designed to accompany a load to be sterilized. When a BI shows failure, the load must not be considered sterile. Note: Wrapping, packing and loading improperly may result in failures. In addition, the failure may be a result of sterilizer malfunction. Check the load configuration and verify that it is in accordance with the manufacturer's instructions. Also, check the BI's instructions for proper use, storage and disposal. Only BI's that are cleared by the FDA and labeled for use with the same physical parameters (of exposure time and temperature) of the Saniclave shall be used to monitor sterility of loads processed in Saniclave.

Class 5 Integrators

A Class 5 integrator are a type of chemical indicator. It does not contain microbial organisms. A Class 5 Integrator monitors the time, temperature and pressure. These single use devices are calibrated to confirm that parameters have been met. Only use FDA cleared integrators that are validated for 121C for 30 minutes. Follow manufacturer's recommendations."

Use an FDA approved biological indicator (BI) weekly to confirm sterility and STEAMPlus Class 5 integrators with each load. Follow the BI manufacturer's instructions. Revolutionary Science recommends the use of biological indicators and class 5 integrators (not supplied by Revolutionary Science).



Door Seal

Proper placement of the door seal. The door seal should be tucked under the lugs.





Rear of Saniclave

Allow to the Saniclave to drain during each run by placing the drain tube in a receptacle or empty the exhaust tank via drain tube every few cycles.





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