



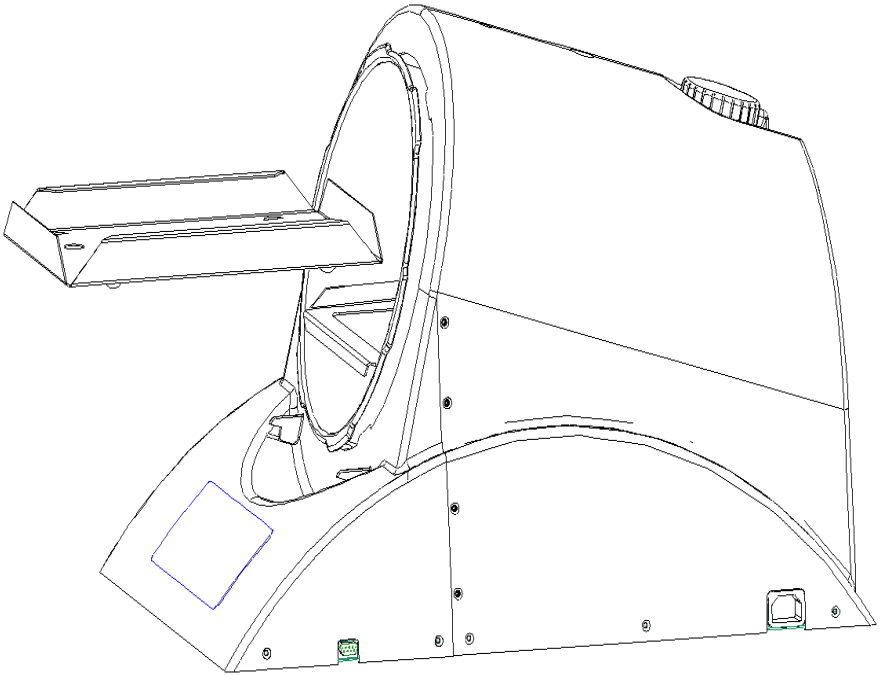
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REVOLUTIONARY SCIENCE

The Saniclave 200

Instruction Manual

RS-SC-200



SC-200 tray and support rack in correct

Instruction Manual for the Revolutionary Science RS-SC-200 Saniclave



REVOLUTIONARY SCIENCE

Making Science Simple

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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 200 by Alternative Pioneering Research & Development, Inc. (APR&D, Inc.)

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REVOLUTIONARY SCIENCE

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Introduction

Dear Valued Customer,

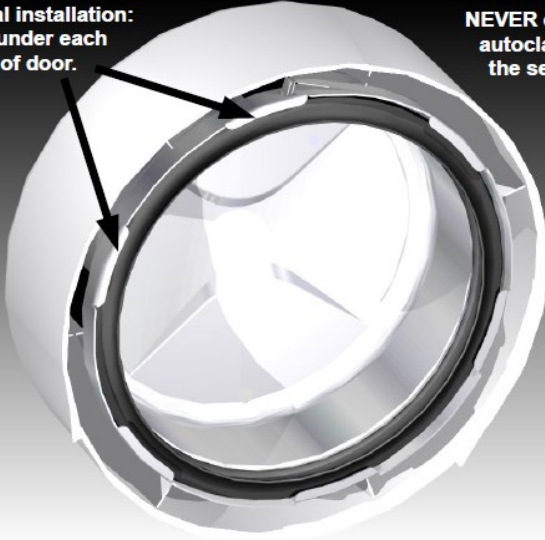
Thank you for purchasing the Revolutionary Science Saniclave 200. We are confident that the Saniclave 200 will provide years of reliable service. The high quality of construction and durable parts deliver a performance equivalent to much costlier equipment.

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,

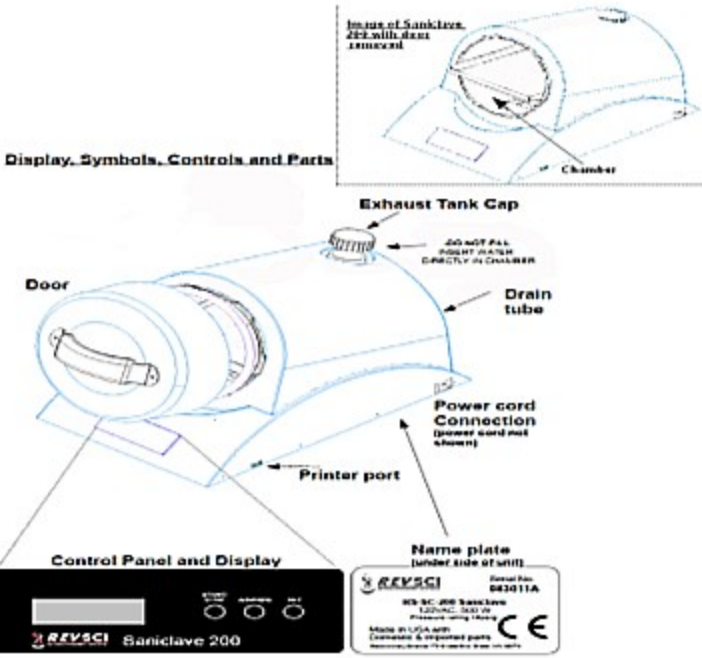
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Proper seal installation:
Tuck seal under each
flange lug of door.



NEVER operate the
autoclave without
the seal properly
installed.

Display, Symbols, Control and Parts



Installation Instructions

Remove Saniclave 200 from packaging and place it on a dry level surface. Plug it into an accessible 120 VAC power receptacle. For optional printer setup, see page 6. The Saniclave 200 is now ready for use. See operating instructions on page 7.

Upon receiving the Saniclave 200, 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 carrier at once. Failure to do so immediately may release the carrier from any liability of damage.
2. Fill out the checklist (see instruction manual). If the shipment is incomplete, please contact us at support@revsci.com or 651-257-0633.
3. Carefully read this instruction manual before operating the Saniclave 200.
4. Fill out warranty registration card and mail it to

Revolutionary Science
17319 Lake Blvd.
Shafer, MN 55074.

Intended Use

The Revolutionary Science Saniclave 200 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 Celsius 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 should be replaced with heavy usage: The door seal, Control panel decal and ZPD. These easily replaceable parts are available through Revolutionary Science and covered under warranty. No tools are required.

Limitations of Use

Revolutionary Science is not responsible for misuse of the Saniclave 200

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 200.
3. NEVER leave operating Saniclave 200 unattended.
4. NEVER block drain (located on the inside of the chamber below heating element).
5. NEVER block steam trap (located on the inside of the chamber, near the top, directly above drain).
6. NEVER operate the Saniclave 200 with a damaged cord or plug or after the appliance 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 200 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 200.
14. NEVER immerse the autoclave, cord, or plug in water or operate on wet surfaces.
15. NEVER fill the exhaust tank with water (See page 3 for location of exhaust tank and cap). The Saniclave 200 must be filled by pouring water directly into the chamber.
16. ALWAYS load the Saniclave 200 with instruments compatible with steam sterilization at 121 degrees Celsius 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 200 with organic solvents like thinner or benzene. It will damage the surfaces.
19. ALWAYS test regularly with *Geobacillus stearothermophilus*. See page 14 for sterilization monitoring and control for more information.
20. This sterilizer has not been validated for double pouching.



Operating the Saniclave 200

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.
2. Follow instrument manufacturer's instructions for correct cleaning and lubricating procedures.

WARNING! Failure to properly clean instruments before autoclaving, may result in unsterile equipment. Using unsterile equipment may result in serious injury or death.

3. It is recommended that all instruments be dismantled, if possible.

CAUTION: Stacking instruments improperly may result in nonsterile equipment.

4. Use a sterilization indicator strip with each set of instruments being autoclaved.
5. The recommended load is 4.5 lbs (not including the rack). **Never exceed the maximum load. Exceeding maximum load may result in nonsterile equipment.**
6. Run a biological indicator spore test (*Geobacillus stearothermophilus*) at least weekly to confirm proper sterilization. For additional information on purchasing biological indicators, see page 12.

Printer installation and operation

Saniclave 200: 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 200 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 200 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: 14JLY2011, 16:51:19
Cycle parameters set: 15Psi
                    121.9C temp
                    30 min sterilization
                    30 min dry mode
Cycle number:      3
Autoclave ID:     050211A
Modes: parameter recorded at the end phase
Time  Temp(C)  Psi
Preheat: 16:33  121.1  15
Sterilize: 30:00  123.0  17
Dry:      30:00  100.0  0
Total Time: 76:33
Exposure temperature
Min: 121.0
Max: 123.0
Status: Successful. Cycle Complete
Operator signature

```


Operating Instructions

1. Place Saniclave 200 on a dry, level surface.
2. Remove chamber door by rotating door counter clockwise.
3. Fill 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 presence of water. Salt may be added to the water to increase detectability. Class III distilled water is recommended.
4. Place rack in the bottom of the chamber and place instruments to be sterilized (wrapped or unwrapped) on top of rack.
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 silicone seal has been removed re-install silicone seal in the door by evenly tucking seal under all lugs. Seal may be cleaned with warm, soapy water (replace seal when it becomes noticeably cracked or worn).
7. **Closing the door:** 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. Press the door in snugly and gently turn the door handle clockwise. The door marking should be aligned with the marking on the autoclave.
9. 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. **Autoclave must be grounded when in use.**
10. **Standby Mode:** The 4-digit LED indicator will turn on and appear as “0000.”
11. Press ‘START/STOP’ to begin the default 30 minute sterilization cycle.
12. **Preheat Mode:** Display will change to ‘Ph’ for the preheat mode (about 25 minutes).
13. Observe the display. If an error warning is displayed, the cycle will be aborted (see troubleshooting section on page 10).
14. **Sterilization Mode:** After the preheat mode, the display will automatically begin to count down from 30 minutes. For your convenience, the display will show the temperature reading. To view the pressure or cycle time left, see page 8
15. 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.
16. **Drain Mode:** At this point, the display will read “dry” and the unit will automatically depressurize.
Due to door locking safety feature of the silicone seal, the opening of the door is not possible until the chamber is completely depressurized.

- 17. **Dry Mode:** After the chamber drains, the autoclave will sound an audible alarm that reads “turn door.” Rotate door counter clockwise until it is in the open position. Tuck the door under the retainer clips below the door opening. Then press the ADVANCE button and the alarm will cease. During this mode, the heater warms the chamber for 30 minutes. Moist air vents out of the door gap.
- 18. **Cycle Complete:** “CC” will display if the cycle was successful.
- 19. **Print Mode:** If the Saniclave 200 is connected to a printer, a cycle report will print when SET button is pressed, showing the date/time, preset and achieved parameters.

Caution: internal chamber contents may be hot to the touch.

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' button is pressed and the chamber has not yet been filled with sufficient water.
Preheat Mode.	Display will read 'Ph' for Preheat. This mode will usually last for about 30 minutes, depending on the load size.
Sterilization Mode	Display will show temperature in Celsius: <ul style="list-style-type: none">• Press ADVANCE to view the pressure reading in PSig.• Press SET to view the cycle time remaining.
Dry Mode	When the sterilization cycle is successfully completed, the display will read 'dry,' for drain mode. As the water drains, the chamber completely depressurizes and shortly thereafter (if selected), the Dry Mode begins. Display will alternate between “dry” and the 30 minute timer. When the display reads “turn door,” the door must be opened by rotating the door counter clockwise to the open position until the Dry Mode is complete.
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 200.

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

Load Settings

Load type	Instructions
Wrapped Loads	Press the WRAPPED button. The display should change from 0000 to 'C1' and the preheat mode will immediately follow. After the sterilization mode is complete, the display will read 'turn door.' At this time, remove the door and insert the bottom edge under the retainer clips. Press ADVANCE to begin the dry mode. When the dry mode ends, the unit will read 'CC' <i>This setting employs the dry mode .</i>
Unwrapped Loads	Press the UNWRAPPED button. The display should change from 0000 to 'C2' and the preheat mode should commence. When the sterilization cycle ends, the unit will read 'CC' <i>This setting does not employ the dry mode.</i>

Note: 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.

Set Time and Date – To set the time and date, press and hold the 'SET' button. The 'ADVANCE' button may be used to advance from the time, date and year. The 'START' and 'SET' buttons can be used to adjust the settings up and down. Disconnecting the power between uses may interrupt the clock's timing. Date and time 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 display reads 'CC,' press the SET button once. Other than the printouts, the Saniclave 200 does not record cycle data.

See page 6 for more printer information.

Troubleshooting

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 modes. If 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. Display will read '**Err 2.**' Press SET to acknowledge the error. Take off the door. Remove door gasket. Inspect the door gasket for cracks. Replace with a new gasket if necessary. Reinstall gasket into door. Properly close door by lining up markings on door and on body and twisting the door closed. Restart the cycle.
3. **Over Temperature Alarm:** If temperature exceeds the maximum of 124°C the display will read '**Err 3.**' Allow unit to drain the reservoir fully into the exhaust tank or sink. Press SET to acknowledge the error. Open door when chamber has cooled. Remove load from chamber. Refill reservoir. Reinsert load. Close the door. Restart cycle. If an over temperature condition occurs again, contact Revolutionary Science to investigate the problem further. Discontinue use until problem is resolved.
4. **Under Temperature Alarm:** If the temperature or pressure of the chamber falls below sterilization temperature of 121°C during the sterilization cycle, the digital display will read '**Err 4.**' Press SET to acknowledge the error. Open door when chamber has cooled. Remove load from chamber. Refill reservoir. Reinsert load. Close the door. Restart cycle. If an under temperature condition occurs again, contact Revolutionary Science to investigate further. Discontinue use until 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 reservoir up to the temperature sensing probe. Restart cycle.
6. **Exhaust tank full:** After every five cycles, the Saniclave display will flash '**drn tank full.**' At this point, the exhaust tank must be emptied if the end of the drain tube is not already resting in a sink or bucket. Revolutionary Science recommends that the drain tube be left in the sink or other reservoir for regular drainage. The drain tank warning can be bypassed by pressing any button. If exhaust tank is not drained after every sixth cycle, water may overflow.
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 picture on page 19)
 - 2) The gasket offset spring must rest against the outside diameter of the seal and should not overlap the seal.
 - 3) Check to make sure door markings line up properly. Misaligned door markings will inhibit the door functionally
 - 4) The chamber may have not yet depressurized. Wait up to five minutes and then attempt to open the door.
 - 5) the door stop may be caught on the door clip near the bottom of the door. This can be dislodged by pushing up on the bottom of the plastic door housing.
 - 6) The door seal may need lubricant. To do this, remove and dry the seal completely. lightly dust the seal with talcum powder and spread evenly around the entire seal (or talc based baby powder) approximately once every 50 to 100 cycles or as needed. *Caution: Too much lubrication may compromise the seal.*
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 page 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.



Warranty Registration

Please fill out this page, or a copy of it, and send it to the address below to validate your warranty. Warranty Registration Card for the REVOLUTIONARY SCIENCE Saniclave 200. (Please Print)

Date Purchased _____ Serial Number _____

Purchased From _____

(Please check one) _____ Company _____ School _____ Individual _____

Name of Department or Institution: _____

Address:

Intended use:

Where did you hear of our product?

Comments:

Warranty

Your REVOLUTIONARY SCIENCE Saniclave 200 is warranted 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 200 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 listed 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 Information

Revolutionary Science

17319 Lake Blvd

Shafer, Minnesota 55074, USA

Customer Service: 1(800) 775-7942

Technical Assistance: (651) 674-3112

Fax: (775) 218-7015

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



Checklist

(See page 3 for visual identification of checklist parts)

<u>Part:</u>	<u>Model number:</u>
_ Autoclave	200-A00001
_ Door	100-A00002
_ Silicone seal	200-A00003
_ Rack	100-A00004
_ Manual	310-A00001

Notes & Service Record

For your own future reference and to expedite answers to your questions, please complete the following information:

Date Purchased: _____

Serial Number: _____

Model Number: _____

Purchased From: _____

Your Notes:

Revolutionary Science 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	<p>Inspect and clean door gasket with mild soap or detergent. Rinse with distilled water, wipe with damp lint-free cloth. Inspect for cracks. Reinstall in door.</p> <p>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.</p>
Weekly	<p>Clean rack and coils with warm water and a mild soap or detergent. Inspect rack and holder for residues or deposits. Repeat cleaning if necessary. Rinse in warm, distilled water and wipe with a clean, lint-free cloth.</p>
As Needed	<p>Replace door gasket if torn or cracked. If a printer is installed, replace paper and ink cartridges as needed and according to printer manufacturer's instructions.</p>

For regular Sterilizer Monitoring Guidelines, see page 16

When storing the Saniclave 200:

1. Disconnect Saniclave 200 from mains.
2. Drain all water from the chamber and exhaust water tank. To drain the water exhaust tank (located in the rear, right side of the unit to the open position).

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 200 unit forward, emptying the chamber into a shallow vessel or sink.

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

3. When your Saniclave 200 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 page 12)

Saniclave 200 Cycle Documentation Table

Serial #	Time cycle started	Date	Set cycle parameters (default): I21C for 30 minutes	Results according to class 5 Integrator	Cycle #	Display reading at cycle end	Signature
102281A	10:45:00 AM	11/21/12	I21C for 30 minutes	Parameters were met	1	CC	_____ _____
			I21C for 30 minutes				_____ _____
			I21C for 30 minutes				_____ _____
			I21C for 30 minutes				_____ _____
			I21C for 30 minutes				_____ _____
			I21C for 30 minutes				_____ _____
			I21C for 30 minutes				_____ _____

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. In addition, 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 200. 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. CI's 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 200 shall be used to monitor sterility conditions of loads processed in Saniclave 200.

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 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 200 shall be used to monitor sterility of loads processed in Saniclave 200.

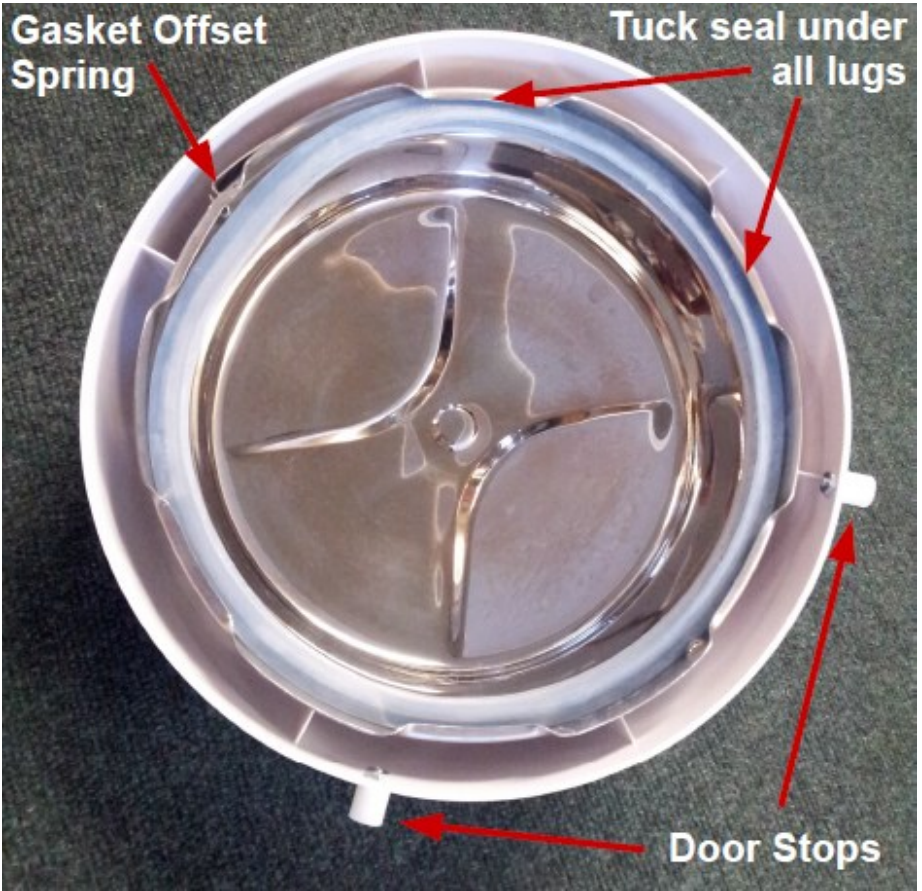
Class 5 Integrators

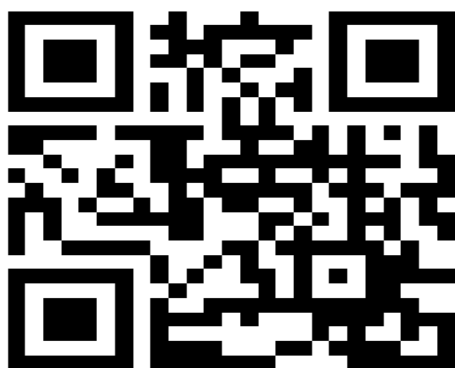
A Class 5 integrator are a type of chemical indicator. It does not contain microbial organisms. A Class 5 Integrator monitors the time, temperature and pressure. These single use devices are calibrated to confirm that parameters have been met. Only use FDA cleared integrators that are validated for 121C 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 manufactured by SPS Medical.

SPSmedical Supply Corp. 6789 W Henrietta Road Rush, NY 14543 USA
(800) 722-1529 www.spsmedical.com

Proper placement of the door seal.





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