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The Saniclave

Instruction Manual

Revolutionary Science
Shafer, MN
USA

'Based on user feedback, we have supplied your Saniclave with two new design updates.

- 1. New, high capacity basket. This new basket (not yet shown in the video or our website) has an increase of 1.75" in height and 0.4" in diameter over the original basket design. The 34% increase in capacity allows for larger loads and instruments.*
- 2. Larger, blue LED display. The LED display has been updated to a larger, LED display. This allows for improved readability over the original, small, red display.'*



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 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 manufactured by SPS Medical.

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

Instruction Manual for the Revolutionary Science Saniclave Model RS-SC-102 and RS-SC-50



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 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. 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



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

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

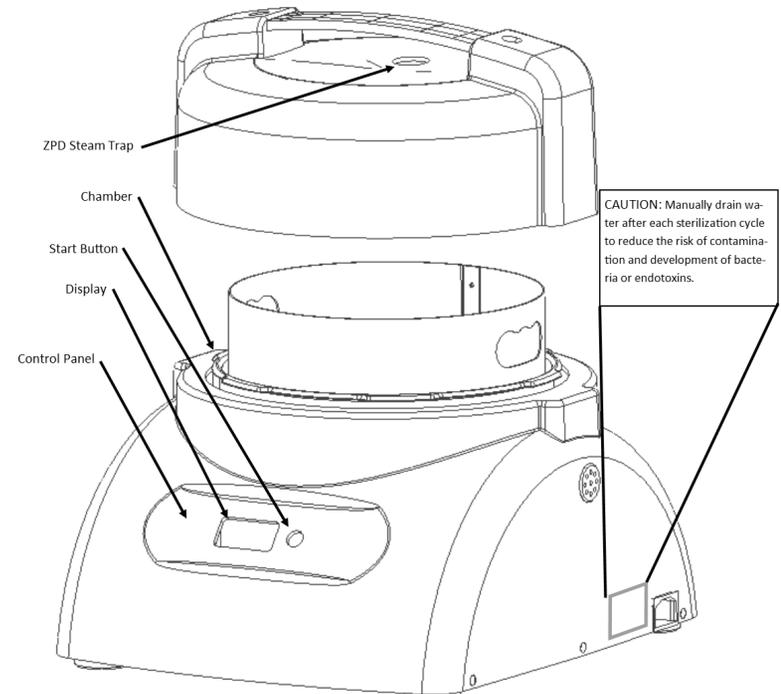
Saniclave Cycle Documentation Table

Signature						
Display reading at cycle end	CC					
Cycle #	1					
Results according to class 5 Integrator	Parameters were met					
Set cycle parameters (default): 121C for 30 minutes	121C for 30 minutes					
Date	11/21/12					
Time cycle started	10:45:00 AM					
Serial #	102281A					

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



Display, Symbols, Control and Parts



Installation Instructions

Remove Saniclave from packaging and place it on a dry level surface. Plug it into an accessible 120 VAC power receptacle. The Saniclave is now ready for use. See operating instructions on page 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 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.
4. Fill out warranty registration card and mail it to

Revolutionary Science
 17319 Lake Blvd.
 Shafer, MN 55074.

Saniclave 102 —Indications For Use (applies to the Saniclave 102):

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 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. Unwrapped instruments that were sterilized should be used immediately after sterilization is completed (immediate use sterilization). The chamber must be manually drained and wiped dry after each cycle.

Outside dimensions: 14.5" (L), 13.5" (W), 12.5" (H)

Internal chamber dimensions (including door): 9" diameter x 8.25" deep

Chamber volume: 8 liters

Cycle Parameters

	Recommended Use	Maximum Load	Sterilization Temperature	Sterilization Time	Dry Time
Unwrapped	Instruments intended to be used immediately upon sterilization	4.5 lbs	121 °C	30	0

Saniclave 50 —Indications For Use (applies to the Saniclave 50):

The Saniclave 50 is intended for laboratory and veterinary purposes. It is not FDA listed and not designed to be used in the following human use applications: dental, body art, surgical and nail/salon. The Saniclave 102 is suited for human use applications.

Care, Storage and Maintenance Instructions

Daily	Inspect and clean door gasket with mild soap or detergent. Rinse with distilled water, wipe with damp lint-free cloth. Inspect for cracks. Re-install 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.
Weekly	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.
As Needed	Replace door gasket if torn or cracked.

For regular Sterilizer Monitoring Guidelines, see page 16

When storing the Saniclave:

1. Disconnect Saniclave from mains.
2. Drain all water from the chamber.

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 page 12)



Checklist

(See page 3 for visual identification of checklist parts)

Part: Model number:

- _ 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.



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.

Limitations of Use:

Revolutionary Science is not responsible for misuse of the Saniclave

1. **Important:** 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 operating Saniclave unattended.
4. NEVER block steam trap (ZPD) valve (located in the top of the chamber, near the back).
5. NEVER operate the Saniclave with a damaged cord or plug or after the appliance malfunctions or has been damaged in any manner.
6. NEVER use accessory attachments not recommended by Revolutionary Science. Their use may cause fire, electrical shock or injury.
7. NEVER use the Saniclave or any purpose other than the intended use.
8. ALWAYS close the door properly before operating.
9. NEVER attempt to force the door open or release pressure while sterilizer is in operation.
10. ALWAYS turn off the unit by unplugging the Saniclave from the power outlet.
11. ALWAYS use distilled water. The sensor detects ion content in the water. If distilled water is too pure, the autoclave may not detect 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 chamber. Manually drain water after each sterilization cycle to reduce the risk of contamination and development of bacteria or endotoxins. Fresh water should be used at every sterilization 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. ALWAYS load the Saniclave with instruments compatible with unwrapped steam sterilization at 121 degrees Celsius at 30 minutes. Always contact the instrument's manufacturer if you are unsure that this sterilization technique is suitable for instruments being sterilized.
16. ALWAYS inspect the silicone seal before each use for dirt, grime or cracks.
17. NEVER clean the Saniclave with harsh solvents. It may damage surfaces.
18. 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 textiles, liquid loads, wrapped, lumened devices and dental hand pieces.
21. The temperature and pressure are monitored and the temperature is visible on the digital display for one sterilization cycle only and print out option is not available. See page 8 for pressure extrapolation.
22. Printer option is not available for the Saniclave sterilizer. The user should manually maintain the sterilization cycle records and specifications separately in a log book. See page 13 for more information.
23. User is responsible for ensuring there is no moisture present after each sterilization cycle.
24. Since there is no printer option, record keeping must be maintained in a log book

Operating the Saniclave

Preparation for Sterilization (Default mode)

1. **Warm up cycle:** Run a warm up cycle each day prior to use. Cycle may be aborted during the sterilization mode to conserve on time. Remove door and commence with sterilization needs.
2. Preclean instruments according to their manufacturer's recommendations.
3. 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.

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

CAUTION: Stacking instruments improperly may result in unsterile equipment!

5. Use a sterilization indicator strip with each set of instruments being sterilized.
6. The recommended load is 4.5 lbs (not including the rack). **Never exceed the maximum load. Exceeding maximum load may result in unsterile equipment.**
7. 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.

Specifications

Power requirements:	120 VAC, 1250 watts, grounded outlet
Net weight:	20 lb.
Dimensions:	14.5 in. length x 13.5 in. width x 12.5 in. Height
Internal chamber dimensions:	9 in. diameter x 8.25 in. tall
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
Capacity:	8 Liters

Product Safety and Compliance Standards:

FDA Listing:	RS-SC-102 is a 510k listed product for medical use. K122978
FDA Registered:	Revolutionary Science is an FDA Registered Company
CE / IEC Safety:	RS-SC-102 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



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. (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 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 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.



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

Operating Instructions

1. Place Saniclave on a dry, level surface.
2. Remove chamber door by rotating door counter clockwise.
3. Fill chamber with approximately 1 liter of distilled water, until the metal portion of the probe 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 (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. Place the door on the chamber, ensuring that the arrow on the door is aligned with the "open" arrow on the autoclave.
8. Press the door in snugly and gently turn the door handle clockwise until it can no longer turn. The door arrow should be aligned with the "close" arrow 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 3-digit LED indicator will turn on and appear as "-00."
11. Press 'START' to begin the 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 cycle time left, press 'START.' This will not abort the cycle. It will change the reading on the display to cycle time.
15. To abort the cycle at any time unplug power cord. Display will then go blank and chamber will instantly begin to slowly depressurize. Allow a few minutes for the chamber to fully depressurize before restarting the autoclave.
16. **Cycle Complete:** "-CC" will display if the cycle was successful.

Caution: The chamber and contents may be hot to the touch.

Recommended Load Configuration

Load must not exceed 4.5 lbs.

Cycle Phases

Standby Mode	Display reads “-00”
Preheat Mode	Display will read 'Ph' for Preheat. This mode will usually last for about 20 to 25 minutes, depending on the load size.
Sterilization Mode	Display will show temperature in Celsius: •Press START to view the cycle time remaining.
Cycle Complete 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.

Note: The sterilization cycle parameters are as follows: 30 minutes, 121C. The cycle is initiated by pressing the START button. The sterilization cycle parameters cannot be adjusted.

Troubleshooting

Error Conditions and Display Readings

Note: **If an error occurs a warning will show on the display and alarm will sound. 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 the power cord is unplugged, display will go blank to signal a power disruption or an aborted cycle. User may abort the cycle anytime, during, pre heat or sterilize. If power cord is plugged back in, the display will read '-00' for 'standby mode.' The contents of the load shall be considered non-sterile.

2. Error: 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 'Lo' Press 'START' 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 arrows on door and on body and twisting the door closed. Restart the cycle.

3. Error: Over Temperature Alarm:

If temperature exceeds the maximum of 124°C the display will read 'Oht.' Press 'START' 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. Error: 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 'Lo' Press START 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 the problem further. Discontinue use until problem is resolved.

5. Error: Low Water:

The display will read 'Lo' if there is an insufficient amount of water in the chamber. Press START to acknowledge the error. Fill chamber. Restart cycle.

6. Error no power:

The door must be closed properly or there will be no power. Verify the door tab is engaged with the corresponding slot in the back of the unit.

Additional errors

Power Outage.

If a power outage occurs the display will revert to standby mode and read '-00.' It will not display “CC” until the Saniclave is restarted and a successful cycle is passed. This would happen even if the outage took place after a successful completion of a cycle and the unit was left unattended. If this occurs refill with water and restart sterilization cycle. Alarm will not sound for a power outage failure or manual abort.

No power.

Make sure the safety switch is being actuated. There is a slot at the back of the in the enclosure . The tab on the door, must be inside that slot to actuate the safety switch.

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

Pressure readings may be extrapolated by viewing the temperature reading on the display and referring to the chart below.

Gauge pressure (in. Hg Vac)	Absolute pressure (psia)	Temperature (oC)
15	29.7	121
16	30.7	122.06
17	31.7	123.11
18	32.7	124.11