

	Standard Operating Procedure Operation and Cleaning of the Autoclaves in the QC Laboratory	SOP Number D-824	Revision 8
		Effective Date 10/26/23	Page Page 1 of 7
Written by/ Date  10/19/23	Reviewed by/ Date SAS 10/19/23	Approved by/ Date  10/19/23	
Title: Quality Control Director	Title: Analytical Development Scientist	Title: Quality Assurance Director	

1.0 Purpose

The purpose of this procedure is to define the process for the cleaning and operation of the autoclaves located in the QC Laboratory.

2.0 Scope

The procedure covers the weekly and monthly cleaning and quarterly testing of the autoclaves when in use. Specific procedures are also given for sterilizing wrapped and unwrapped utensils, glassware, plastics, and liquids.

3.0 Responsibility

- 3.1 It is the responsibility of QC Laboratory personnel to follow this procedure.
- 3.2 It is the responsibility of QC Laboratory Management to implement this procedure and to ensure that the procedure is being followed.
- 3.3 It is the responsibility of QC Laboratory Management or designee to keep this procedure aligned with current practices.

4.0 Definitions

- 4.1 QC – Quality Control
- 4.2 PQV – Process Quality Verification

5.0 References

- 5.1 Tuttnauer EZ10 Operation and Maintenance Manual

- 5.2 Tuttnauer 3850EA Operation and Maintenance Manual
- 5.3 C-502, SOP, Record Storage, Retention, and Destruction
- 5.4 C-501, SOP, Document Control Procedure
- 5.5 A-106, SOP, Documentation Guidelines for cGMP Records
- 5.6 D-824-F1, Form, Autoclave Usage Log
- 5.7 D-824-F2, Form, Autoclave Cleaning Log
- 5.8 D-824-F3, Quarterly Testing Log for Autoclave

6.0 Procedure

6.1 Weekly Cleaning

6.1.1 Each week of operation, the below defined tasks must be performed. Document on Form D-824-F2 Autoclave Cleaning Log.

6.1.1.1 Cleaning the chamber and trays

6.1.1.1.1 Drain the water from the reservoir using the drain tube located on the front of the unit.

6.1.1.1.2 Wash the inside of the chamber and trays with mild soap or Speed-Clean and Millipore water.

6.1.1.1.3 Refill the reservoir with Millipore water.

Note: Do not use abrasive or bleaching agents in the chamber, such as scouring powder, steel wool, bleach, or wire brushes.

6.2 Monthly Cleaning

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6.2.1 Each month of operation, the below defined tasks must be performed. Document on Form D-824-F2 Autoclave Cleaning Log.

6.2.1.1 Cleaning the chamber and plumbing

6.2.1.1.1 With a cooled chamber, drain the reservoir and fill it with clean Millipore water.

6.2.1.1.2 Add one packet of Chamber Brite autoclave cleaner directly to the bottom of the chamber.

6.2.1.1.3 Run one “Wrapped” cycle with dry time set at zero.

6.2.1.1.4 Drain the reservoir and refill it with Millipore water.

6.2.1.1.5 Rinse by running one “Unwrapped” cycle.

6.2.1.1.6 After the cycle has completed, drain and refill the reservoir with Millipore water.

6.2.1.1.7 Allow the sterilizer to cool.

6.2.1.1.8 Remove the trays and tray rack and wipe off with a damp cloth.

6.2.1.1.9 Wipe out the inside of the chamber, using care not to damage the heating element, steam temperature probe, or level sensor probe.

6.2.1.1.10 Reinstall the tray rack.

6.3 Quarterly testing for *Bacillus stearothermophilus* ATCC 7953 to ensure steam production

6.3.1 Each quarter of operation, the below test is required to be performed. Document

on Form D-824-F3 Quarterly Testing Log for Autoclave.

- 6.3.1.1 Place a test strip in autoclave (10^{-6} spore population) in a small sterile tube with cap. Fill with TSB broth, making sure to completely submerge the strip.
- 6.3.1.2 Press the program “3” button.
- 6.3.1.3 Press the “Start” button.
 - 6.3.1.3.1 Conditions: 250°F (121°C), 16psi, sterilize 25min; dry 25min, slow vent.
- 6.3.1.4 Allow all liquids to cool for one hour before handling.
- 6.3.1.5 Prepare a second sterile tube with a test strip and TSB broth, but do not autoclave. Place both tubes in a heating block set at 55°C for 5 days.
- 6.3.1.6 Analyze the autoclaved test strip for the presence of *Bacillus stearothermophilus*. The test strip that was not autoclaved should display luxuriant growth; if there is no growth, assess whether there was a problem during sample preparation or incubation and repeat testing.

6.4 Sterilizing unwrapped instruments (Program 1)

- 6.4.1 When appropriate, attach a piece of autoclave tape to each instrument.
- 6.4.2 Place the instruments or tubing loose on the tray.
- 6.4.3 Press the “Unwrapped” button.
- 6.4.4 Press the “Start” button.

6.4.4.1 Conditions: 270°F (132°C), 28psi, sterilize 3min; dry 0min.

6.5 Sterilizing wrapped instruments and porous loads (Program 2)

6.5.1 Place the instruments or tubing in an appropriate sized autoclave pouch with an indicator and seal.

6.5.2 Place the pouched or loosely wrapped instruments on the tray.

6.5.3 Press the “Wrapped” button.

6.5.4 Press the “Start” button.

6.5.4.1 Conditions: 270°F (132°C), 28psi, sterilize 7min; dry 30min.

6.6 Sterilizing glassware (Program 3)

6.6.1 Wrap the instruments in aluminum foil, cover the openings of the glassware/plasticware with aluminum foil, cover capped bottles with aluminum foil and make sure the cap is loosened ½ turn.

6.6.2 Attach a 1 to 2 inch strip of autoclave tape to each piece on the aluminum foil.

6.6.3 Place the packs, glassware and/or plasticware loosely spread out on the tray.

6.6.4 Press the “Glassware” button.

6.6.5 Press the “Start” button.

6.6.5.1 Conditions: 250°F (121°C), 16psi, sterilize 30min; dry 0min.

6.6.6 Allow all glassware to cool for fifteen minutes before handling.

6.7 Sterilizing liquids

6.7.1 Cover all openings on glassware containing liquids with aluminum foil, cover

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capped bottles with aluminum foil and make sure the cap is loosened ½ turn.

6.7.2 Place containers with liquids loosely on tray. Do not exceed 2.0 liter of total liquid volume to be sterilized in the small autoclave, and 4.0 liter of total liquid volume to be sterilized in the large autoclave. Place autoclave tape on outside of container.

6.7.3 Press the program “3” button.

6.7.4 Press the “Start” button.

6.7.4.1 Conditions: 250°F (121°C), 16psi, sterilize 25min; dry 25min, slow vent. (PSI and Time may vary according to liquid being processed, see manufacturer instructions)

6.7.5 Allow liquids to cool for one hour before handling. Check to see that autoclave tape indicates sterilization.

6.8 Logging use and cleaning of the Tuttnauer Autoclaves

6.8.1 Prior to running the autoclave, complete the log book entries on Form D-824-F1 Autoclave Usage Log for description of process, program, temperature, pressure, time, analyst and date.

6.8.2 At the completion of the autoclave cycle, review the tape and check that during the sterilization phase the temperature did not exceed +/- 4°C from target and the pressure did not exceed +/- 2psi the operation temperature and pressure. Log information on Form D-842-F1 Autoclave Usage Log.

6.8.2.1 Alternatively, if no print-out is available from the autoclave, ensuring the autoclave tape indicates sterilization was completed is also acceptable.

6.9 Refer to manufacturer’s operation and maintenance manual for complete instructions on

programming, cleaning and operating the autoclave.

- 6.10 Documentation will be maintained following SOP C-502 Record Storage, Retention, and Destruction and C-501 Document Control Procedure.
- 6.11 A PQV check must be performed for each completed logbook page as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	01/17/13	New	-	-
2	04/03/13	Changed SOP log. Added section 5.9. Changed monthly testing to quarterly testing in section 5.3	13-238	B. Johns
3	12/02/14	Updated format. Added Form D-824-F2. Updated Form D-824-F1. Updated responsibilities.	14-0969	B. Johns
4	04/04/17	Biennial review: Changed conditions in steps 6.3.3.1 and 6.7.4.1	16-1101	N. Zhang
5	04/18/18	Updated for new autoclave model and changed title to reflect. Clarified quarterly testing for <i>Bacillus stearothermophilus</i> ATCC 7953.	18-0128	E. Johnson
6	06/01/21	Updated SOP to include both models of Autoclave	CC-21-0225	G. Shaw
7	02/02/23	Updated SOP to ensure time is included as well as PSI, Added that PSI and time can be changed according to manufacturer instructions on liquid being autoclaved.	CC-23-0060	G. Shaw
8	10/02/23	Added Form D-824-F3 for clarity on quarterly testing. Other minor edits. Made SOP more general. Added documentation requirements. Updated logo.	CC-23-0514	J. Sassman



Autoclave Usage Log

Form: D-824-F1

CCR No. CC-23-0514

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Logbook Number: _____

Logbook Page: _____

Autoclave Equipment Number:			
Autoclave Run Number:			
Program:		Temperature:	
Time:		PSI (if required):	
Autoclaved Date / Tech:		Cycle:	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Items Autoclaved:

Item Name	Lot Number	Expiration Date	Qty	Size	Notebook #/Page#

Comments:

Performed By/Date: _____

Reviewed By/Date: _____

