



BODYBIO

SOP# 02-005.5	Standard Operating Procedure	Written/Revised By:  12/20/21
Effective Date: JAN 06 2022	Interim Cleaning/Sanitizing Verification Check for Water Based Applications	Approved By:  12/20/21
Supersedes: 04/28/20		Page 1 of 5

1. Purpose

- 1.1. To implement a quick check to increase confidence over cleaning and sanitizing processes at BodyBio facilities.

2. Scope

- 2.1. This procedure applies to all cleaning and sanitizing of manufacturing and packaging equipment used in water-based activities occurring at BodyBio facilities: 45 Reese Rd and 25 Driskill St.

3. Responsibility and Frequency

- 3.1. The Equipment Cleaner or designee will perform and record the cleaning and sanitizing in accordance with the current cleaning and sanitizing procedures.
- 3.2. Quality Control will perform, and record cleaning and sanitizing verification checks as outlined in this procedure.


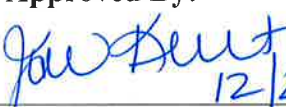
4. References

- 4.1. 21 CFR 110
- 4.2. 21 CFR 111
- 4.3. A guide to ATP Hygiene monitoring

5. Procedure

- 5.1. The equipment shall be cleaned in accordance with current cleaning procedures. The production verification check will be completed during the final RO water rinse.

BODYBIO

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Supersedes: 04/28/20		Page 2 of 5

5.2. After the completion of the required final RO water rinse, continue rinsing and collect a sample of the water in a clean sampling container. The container must be rinsed with RO water and completely drained prior to collecting the sample.

5.2.1. Samples for tanks must be collected from the bottom drain valve.

5.2.2. The collection point for other equipment will vary, but all samples collected must be representative of all product contact surfaces.

5.3. After the sample is collected, it must be immediately checked for conductivity using a calibrated Conductivity Meter (See SOP 04-012). Record this value on the cleaning record form.

5.3.1. After sanitizing, the value is recorded in an equipment logbook.

5.4. Rinse the meter reservoir several times with RO water and then take a reading. Record this reading on the cleaning record form.

5.5. Compare the Rinse water reading to the RO water reading.

5.5.1. If they are both below 1.3 μ S, no further rinsing is required.



5.5.2. If the Rinse reading is higher than 1.3 μ S, continue rinsing until the reading is below 1.3 μ S.

5.6. Production will inform QC when the equipment is dry and ready for testing.

5.7. QC will take swab samples at random spots on the cleaned equipment using the Hygiena ATP Ultra Snap Surface swabs. (SOP 04-050)

5.8. Each piece of equipment has different locations identified as critical points. These critical points are programmed in the Hygiena EnSURE Monitoring System.

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Supersedes: 04/28/20		Page 3 of 5

5.9. Data collected from all equipment swabs will be tracked and trended for a minimum of a year in order to determine accurate limits for BodyBio Equipment. Until then, the Hygiena general guideline limits will be used and are as follows:

5.9.1. Pass: < 20 RLU

5.9.1.1. The control point has been properly cleaned. Proceed to sanitizing.

5.9.2. Caution: 21-59 RLU

5.9.2.1. The control point may not have been adequately cleaned. Choose to proceed with sanitizing and monitoring this location for future problems, or re-clean and re-test.

5.9.3. Fail: >60 RLU

5.9.3.1. The control point was not cleaned properly and must be re-cleaned until a Pass result is achieved. Locations with consistent Failing results will be cause for a change in the cleaning process for that piece of equipment.

5.10. Once QC signs off on the cleaning, the equipment will be sanitized.

5.11. Rinse the sanitizer off with RO water and collect a sample of the water in a clean sampling container. The container must be rinsed with RO water and completely drained prior to collecting the sample.

5.12. Repeat steps 5.3 to 5.5, including the subparts.

5.13. When the readings are the same, collect two rinse samples for QC and label it with the date, piece of equipment and lot number of the product being prepared, if applicable.

BODYBIO

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Supersedes: 04/28/20		Page 4 of 5

5.14. QC will test the Rinse water for Total Plate Count and Coliforms (SOP 04-014), which will be recorded in the micro book.

5.15. QC will also test the Rinse water for conductivity (SOP 04-012) and sanitizer residue and record it in the micro book.

BODYBIO

SOP# 02-005.5	Standard Operating Procedure	Written/Revised By: <i>JSN 12/20/21</i>
Effective Date:	Interim Cleaning/Sanitizing Verification Check for Water Based Applications	Approved By: <i>Jonathan</i> 12/20/21
Supersedes: 04/28/20		Page 5 of 5

Revision History

Date	Revision	Comments
08/26/10	0	New
08/17/16	1	Removed Iodine LaMotte testing strips. Added Minncare Residual Testing strips and Model 4P. Deleted level of detection.
08/21/19	2	Updated format. Updated titles. Added procedure for Hygiena ATP swab check, along with pass/fail test limits.
09/05/19	3	Added record of conductivity after sanitizing in the equipment book. Added two QC rinse samples.
04/28/20	4	Removed names of conductivity meters and added calibrated conductivity meter.
JAN 06 2022	5	Added the addresses of both BodyBio facilities.