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|  | Standard Operating Procedure | | SOP Number B-608 | Revision 4 |
| | Induction Sealer | | Effective Date 05/23/22 | Page Page 1 of 3 |
| Written by/ Date K. Bunnell 04/19/22 | | Reviewed by/ Date Daniel M. Williams 05/10/22 | | Approved by/ Date S. A. Miller 05/02/22 |
| Title: Quality Systems Manager | | Title: Maintenance Manager | | Title: QA Manager |

1.0 Purpose

The purpose of this procedure is to define the process for the setup, operation, and cleaning of the cap induction sealer.

2.0 Scope

This procedure applies to the cap induction sealer in operation at Ion Labs, Inc.

3.0 Responsibility

3.1 It is the responsibility of Production (Packaging) Personnel to follow this procedure.

3.2 It is the responsibility of the Department Supervisor/Manager to implement this procedure and to ensure that the procedure is being followed.

4.0 Definitions

4.1 **IPA** – 70% Isopropyl Alcohol

4.2 **Induction Seal** – The process in which the foil lined cap is adhered to the bottle

5.0 References

5.1 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

6.0 Procedure

6.1 Setup and Operation

- 6.1.1 Using empty bottles and caps from the components that will be used in the packaging run, adjust the head of the induction unit approximately $\frac{3}{4}$ " above the capped bottle.
- 6.1.2 Adjust by using the hand crank on the back of the unit.
- 6.1.3 Adjust the feed conveyor.
- 6.1.4 Press the start button on the unit's control panel.
- 6.1.5 Adjust the power level to start the sealing setup, setting between 75 and 95 depending on the speed of the conveyor and the cap size.
- 6.1.6 Allow ten empty capped bottles under the sealing head on the conveyor.
- 6.1.7 Allow approximately one minute for the bottles to cool down after they have been under the sealing head.
- 6.1.8 Check the bottles and caps to ensure that a complete seal around the entire cap has been achieved.

Note: Do not reach under the unit's power sealing head while the unit is on.

6.1.8.1 Adjust the conveyor and/or heat setting if any bottles are not properly sealed during setup.

6.1.8.2 Continue adjustments until a safe and complete seal is noticed in the all sample test bottles by increasing and decreasing the power level.

6.2 Cleaning

- 6.2.1 Refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to follow the cleaning procedure applicable to this type of equipment.

7.0 Revision History

| Revision | Date | Description of Changes | CCR # | By |
|----------|----------|---|------------|-------------|
| 0 | 08/17/10 | New | - | - |
| 1 | 04/29/13 | Updated SOP format | 13-280 | B. Mosall |
| 2 | 06/18/15 | Biennial review. Updated SOP format. | 15-0529 | E. Cummings |
| 3 | 01/14/19 | Scheduled review: Removed obsolete definition. Added reference to SOP B-111. Revised section 6.2. | 19-0042 | K. Burris |
| 4 | 04/18/22 | Scheduled review: Updated log. Revised cleaning section. | CC-22-0190 | K. Burris |