

	Standard Operating Procedure DPP 260H Blister Pack Machine		SOP Number B-614	Revision 4
			Effective Date 07/25/23	Page Page 1 of 4
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1.0 Purpose

The purpose of this procedure is to define the process for the operation of the blister pack machines Model DPP 260H and Model DPP-260K

2.0 Scope

This procedure applies to the blister pack machine in use at Ion Labs, Inc.

Responsibility

- 3.1 It is the responsibility of Production (Packaging) personnel to follow this procedure.
- 3.2 It is the responsibility of Production Management to implement this procedure and to ensure that the procedure is being followed.

4.0 Definitions

- 4.1 **BPR** – Batch Production Record

5.0 References

- 5.1 B-103, SOP, Small Parts Cleaning and General Sanitation
- 5.2 B-111, SOP, Cleaning of Manufacturing/Production Areas and Equipment

6.0 Procedure

- 6.1 Operation

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- 6.1.1 Plug in the air hose.
- 6.1.2 Turn on the power at disconnect.
- 6.1.3 Turn on two switches on chiller.
- 6.1.4 Touch the PLC screen to activate.
- 6.1.5 Touch the Login button on the screen.
- 6.1.6 Touch the Temp menu.
- 6.1.7 Turn on the temp settings by touching each one and let it warm up until the temperature hits the set temperature, approximately 20 minutes.
 - 6.1.7.1 While the machine is warming up, check all hardware and handles for positioning and that they are secured.
- 6.1.8 Touch the Operation menu.
- 6.1.9 Check the waste recovery and remove excess waste.
- 6.1.10 Check the operation of each station by pressing the white run button for ten cycles, then press the black stop button.
- 6.1.11 Check the blister packs for uniformity, cuts, and alignment.
- 6.1.12 Fill the hopper with the product.
- 6.1.13 Close the safety door and brush hood.
- 6.1.14 Adjust the brushes on the brush hood with the speed knobs and turn on the vibration with the red switch.
- 6.1.15 Start the machine with the white button and stop the machine when the tablets are under the inspection station with the black button.

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6.1.16 Click OK twice. Start the machine for operation with the white button.

6.1.17 Watch the machine run for proper operation and alignment.

6.1.18 When the batch and/or shift are complete, hit the stop button.

6.1.19 Turn off all four stations in the temp menu.

6.1.20 Turn off all functions in the operation menu.

6.1.21 Turn off the chiller.

6.1.22 Disconnect air from the wall.

6.1.23 Turn off the electrical disconnect on the wall.

6.2 Cleaning

6.2.1 Turn off the machine and disconnect the power supply.

6.2.2 Remove all product and paperwork from the previous batch.

6.2.3 Refer to SOP B-103 Small Parts Cleaning and General Sanitation to follow appropriate cleaning steps for small parts.

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

6.2.5 Document cleaning as outlined in SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	02/24/14	New procedure	14-0173	S. Grimes
1	04/10/17	Scheduled review: added packaging responsibility. Added cleaning steps. Removed functions not being used.	16-0773	K. Burris
2	10/19/20	Scheduled review: changed cleaning section. Removed unnecessary steps.	CC-20-0726	K. Burris
3	10/17/22	Scheduled review: updated to include all Blister Pack Machine Models. Changed logo.	CC-22-0216	M. Busse
4	06/23/23	Changed SOP number from B-801 to B-614. Updated SOP logo.	CC-23-0323	K. Burris