

	Standard Operating Procedure Rx-4 Automatic Tablet/Capsule Counter	SOP Number B-602	Revision 0
		Effective Date 09/10/21	Page Page 1 of 4
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1.0 Purpose

This procedure defines the operation, cleaning, and troubleshooting of the Rx-4 Automatic Tablet and Capsule Counter in use at Ion Labs, Inc.

2.0 Scope

This procedure only applies to the Rx-4 Automatic Tablet and Capsule Counter used during packaging operations at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of Production and QC personnel to follow this procedure. Production and QC personnel are responsible for performing bottle count verifications during the packaging process.
- 3.2 It is the responsibility of Production personnel to adequately clean the Rx-4 tablet/capsule counter as a part of normal room cleaning procedure.
- 3.3 It is the responsibility of QC personnel to ensure that the Rx-4 tablet/capsule counter has been cleaned and properly documented as a part of normal room cleaning procedure.
- 3.4 It is the responsibility of the department supervisor/manager to implement this procedure and to ensure that the procedure is followed.

4.0 Definitions

- 4.1 QC – Quality Control

5.0 References

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

6.0 Procedure

6.1 Operation

6.1.1 Turn machine on.

6.1.2 Be certain that the collection trays are properly inserted.

6.1.3 Pour pills onto turntable disc. Eliminate stacked pills.

6.1.4 Adjust the separator tab.

6.1.4.1 Pointed end UP for capsules.

6.1.4.2 Pointed end approximately the height of the pill for flat and small sizes.

6.1.5 Select Mode using the Key Pad.

6.1.5.1 Single Mode (SGL) – used for counting a desired quantity of pills that will dispense into the top collection tray. When the top tray is removed, excess pills will drop into the bottom tray. Do not use the vial drawer in Single Mode.

6.1.5.2 Multiple Mode (MULTI) – used when performing multiple counts of the same quantity of the same pill. When the desired quantity is dispensed, press START and the Rx-4 will count the same quantity again. This can be done as many times as needed. To clear the turntable after the last count, leave the top drawer out and press CLEAR / INVENTORY / START.

6.1.5.3 Inventory Mode (INV) – used to count an entire quantity of pills. If the count surpasses 999, the display will roll over to 000, 001, 002, etc.

6.1.6 Press START. The auto-gate will automatically open to adjust for pill size and shape.

6.2 Using the Vial Drawer

6.2.1 The vial drawer enables rapid, direct filling of vials.

6.2.2 Remove both collection drawers and insert the vial drawer into the upper drawer slot.

- 6.2.3 Insert the vial onto the dispensing tube. The vial retaining tab will hold the vial firmly in place. For large vials, inset all the way onto the dispensing tube. For small vials, insert into the open front of the dispensing tube.
- 6.2.4 Use the vial drawer only in multi or inventory count modes. Do not use the funnel drawer in single mode.
- 6.2.5 If the vial drawer was used in single count mode, press STOP before removing the drawer. To clear the turntable disc, replace the top drawer and press CLEAR / INVENTORY / START.

6.3 Cleaning

- 6.3.1 Remove all product and paperwork from the previous batch.
- 6.3.2 Refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to follow the cleaning procedure applicable to this type of equipment.
- 6.3.3 Document cleaning in the cleaning logbook.
- 6.3.4 Contact a QC inspector to verify equipment cleanliness and to check the cleaning logbook.
- 6.3.5 Specific cleaning activities for this piece of equipment are as follows:
 - 6.3.5.1 Turn off the power to the counter.
 - 6.3.5.2 Tilt back the auto-gate assembly.
 - 6.3.5.3 Remove any powder build-up from the bottom of the gate.
 - 6.3.5.4 Remove and clean the sensor cover.
 - 6.3.5.5 Remove and clean the sorting wheel.
 - 6.3.5.6 Remove and clean the turntable disc.
 - 6.3.5.7 The discs and plastic parts may be cleaned with a lint-free damp cloth. Always clean both the top and bottom of the removed parts. Drawers should be cleaned often to avoid contamination. Before replacing, ensure that all parts are dry.

6.4 Troubleshooting

6.4.1 If the pills are dispensed but the unit does not count, does not count properly, counts by itself, the sensor signal lamp stays on, or the automatic gate will not open:

6.4.1.1 Turn off the power.

6.4.1.2 Locate the sensor area in the front-left corner of the top of the unit. The sensor is located in the square hole ringed by black plastic. The sensor consists of two sets of glass eyes affixed under the black plastic in the front and rear of the hole.

6.4.1.3 Using an alcohol-dampened cloth or wipe (do not use a cotton ball or swab), gently scrub both sets of glass eyes in a horizontal manner. Scrubbing in a vertical motion can misalign the sensor eyes.

6.4.1.4 Visually inspect the sensor hole to ensure that there are no other hard-to-see items such as a fiber or hair obstructing the area between the sets of glass eyes.

6.4.1.5 Reassemble the unit and resume counting.

6.4.2 If there is no power to the unit:

6.4.2.1 Check the power cord to ensure that it is firmly inserted into a working, grounded AC outlet.

6.4.2.2 Check the fuse in the rear of the unit. Replace with 1 amp fuse only.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/01/21	New procedure.	N/A	K. Burris