

	Standard Operating Procedure Manual Metal Detector		SOP Number B-630	Revision 5
			Effective Date 03/03/22	Page Page 1 of 3
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Title: Maintenance Manager	Title: Production Director		Title: Quality Systems Manager	

1.0 Purpose

The purpose of this procedure is to define the process for the Setup, Operation, Cleaning, and Calibration of the Manual Metal Detectors (to include Pipeline).

2.0 Scope

This procedure applies to the Manual Metal Detectors in operation at Ion Labs, Inc.

3.0 Responsibility

- 3.1 It is the responsibility of all personnel operating the manual metal detector 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 QC – Quality Control

5.0 References

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

6.0 Procedure

- 6.1 Setup, Operation, and Calibration Verification
- 6.1.1 Calibration verification will be performed prior to each use using a calibration sample kit. Annual calibration will be performed with a QC-Controlled Calibration sample kit. The sample kit will consist of the following test pieces for tablets, capsules, powders:
- 6.1.1.1 1.50mm Ferrous Red
- 6.1.1.2 2.00mm Ferrous Red

- 6.1.1.3 2.00 Aluminum Yellow
- 6.1.1.4 3.00mm Aluminum Yellow
- 6.1.1.5 2.00mm SS316 Blue (Stainless Steel)
- 6.1.1.6 3.00mm SS316 Blue (Stainless Steel)
- 6.1.2 Calibration verification will be performed prior to each use using a calibration sample kit. Annual calibration will be performed with a QC-Controlled Calibration sample kit. The sample kit will consist of the following test pieces for liquids (Pipeline):
 - 6.1.2.1 1.00mm Ferrous Red
 - 6.1.2.2 1.50mm Ferrous Red
 - 6.1.2.3 1.50mm Non-Ferrous Yellow
 - 6.1.2.4 2.00mm Non-Ferrous Yellow
 - 6.1.2.5 2.00mm SS316 Blue (Stainless Steel)
 - 6.1.2.6 2.50mm SS316 Blue (Stainless Steel)
- Note:** Refer to the machine manual for setup and operation instructions.
- 6.1.3 Turn the power on.
- 6.1.4 This machine is pre-setup for sensitivity and does not require adjustments. If adjustments are needed, contact Maintenance department.
- 6.1.5 The machine will go through a system startup that will take a minute.
- 6.1.6 Pass the calibration sample kit through the center of the machine. The samples contain different metals and should activate the machine to alert that metal is present. The sample should be automatically discarded into the reject container below the machine. If this process does not happen, contact the department supervisor and refer to the troubleshooting section of the machine manual.
- 6.1.7 When the calibration samples have successfully passed, the machine is ready for operation.

Note: Document calibration sample results in batch record as required at start-up or additional customer requirements.

- 6.1.8 Production will perform hourly metal checks after startup and record the checks in the batch record.
- 6.1.9 QC will perform metal checks as deemed necessary per a risk assessment.
- 6.1.10 During operation, if metal is detected, the product will be discarded into the reject container. The rejected product is to be accounted for in the waste section of the batch production record and disposed of. Immediately contact Quality Control department for investigation.
- 6.1.11 Annual external metal detector validation will be performed annually by Loma Systems, Inc.

6.2 Cleaning

- 6.2.1 Remove all materials and paperwork from the previous batch.
- 6.2.2 Refer to SOP B-111 Cleaning of Manufacturing/Production Areas and Equipment to follow the cleaning process applicable to equipment type.
- 6.2.3 Document the cleaning in the cleaning log book.
- 6.2.4 Contact a QC inspector to verify equipment cleanliness and to initial/date the cleaning log book.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
1	07/25/13	New	13-621	B. Mosall
2	09/04/15	Biennial Review: updated SOP format. Added note in Section 6.1.5.	15-0731	P. Zittere
3	06/21/16	Add calibration information	16-0624	D. Popp
4	10/07/19	Scheduled review: Removed obsolete definitions. Added reference to SOP B-111. Added required sample pieces.	19-0654	K. Burris
5	12//06/21	Add sizes for calibration sample kits for liquids (Pipeline Metal Detector) .	CC-21-0452	J. Mireles