



AuBurn Pharmacy

Pharmacy Automation Policy and Procedures

Automation: Parata Max[®] and Parata Mini[®]

Includes software versions 3.6.3 — 4.0.0

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Introduction

This document details the processes + uses to ensure the safety and quality of all prescriptions dispensed with Parata automation devices.

Some of the data about Parata automation has been provided by Parata Systems; however AuBurn Pharmacy has supplemented the information provided with pharmacy-specific practices designed to meet state and local requirements.

Installation requirements for automation

Requirements for locating, testing and installing automation

After the Parata Max/Mini is installed and after each incidence of repair, parts replacement, or other system modifications, AuBurn staff with the assistance of Parata Technical support will perform a Parata Max/Mini Canister Drop Test to ensure accurate dispensing of medications.

Documentation requirements

Cleaning/Maintenance Log
Malfunction Log Report
Ongoing Training Log

Access to Max/Mini unit

Parata Max/Mini can be customized to track and require operator sign-in for all functions or for specific functions. There are five security function levels ranging from All (high security - operators sign in to perform virtually every transaction) to Configuration (low security - operators are only required to sign in to perform configuration tasks).

It is important to determine which functions you want to track and restrict to specific technicians and then to set up your Parata automation accordingly.

For example, selecting a security function level that governs only one section of the unit (Pharmacy Side, Inventory Side or Locking Cells) will require technicians to log in only when performing tasks in that section. Areas not covered by the selected function do not require anyone to log in to perform any tasks.

If you are dispensing controlled substances from the Max/Mini and want to monitor and limit all activity related to those substances, it would be appropriate to select one of the following levels:

- **Inventory Side:** Appropriate if the controlled substances are in non-locking and/or locking cells
- **Locking Cells:** Appropriate if controlled substances are only in locking cells

- **All:** To require sign-in for every activity on the unit.

Following is a description of the five security function levels. Additional information is available in the Operator Auditing section of the Operator's Guide for your Parata automation.

- **All:** All functions on both sides of the unit require operator sign-in.
- **Inventory Side:** Replenishment and cell functions require operator sign-in on the Inventory Side of the unit.
- **Prescription Side:** Retrieval functions require operator sign-in on the Prescription Side of the unit.
- **Locking Cells:** Retrieval, replenishment and maintenance functions related to locking cells require operator sign-in on the appropriate side of the unit.
- **Configuration:** Only system configuration functions require operator sign-in. All operators have authority to perform retrieval, replenishment, return-to-stock, cell calibration and management and other daily tasks on locking and non-locking cells.

A single security function group is assigned to the Max or Mini unit itself. The security function groups act as "overrides" to the individual operator levels by enforcing auditing based on the unit's side or cell type. The default value is **Configuration**, which sets the minimal level of auditing and security on the machine. The function group **All** sets the maximum level of auditing and security on the machine.

All Pharmacists and Technicians will have the same access level to the Parata Max/Mini.

Individual access

The Auditing feature provides five levels of operator access. Each operator level "inherits" the access rights of the level below it and gains additional rights.

The following are the levels of operator access in the Parata application. Determine which levels apply and assign an access level to each technician who uses the Parata automation. Each operator must have a unique operator name and PIN.

Privilege

Description

Technician 1 — Retrieval-only operators

They can:

- Pick up and clear scripts dispensed from both locking and non-locking cells.
- Perform routine script queue-management operations, including advancing and deleting scripts.
- On the Prescription side General tab, access all functions, including reports.
- On the Inventory side, access reports only. Other access is restricted to "read-only".

Technician 2 — Non-locking-cell replenishment

Acquires all Technician1-level access privileges. In addition, they can:

- Perform manual fill operations on non-locking cells. Drugs housed in locking cells or in cells containing controlled substances cannot be selected.
- Edit Drug, Cell and Other parameters on the Parameters window.
- Edit inventory for non-locking cells.
- Delete cells, both locking and non-locking.
- Run the New Drug Wizard.
- Run the New Cell, Replenish and Return-to-Stock wizards for non-locking cells.

Technician 3 — Locking-cell replenishment operators

Acquires all Technician 2-level access privileges. In addition, they can:

- Perform manual fill operations on **both** locking and non-locking cells.
- Edit inventory for **both** locking and non-locking cells.
- Run the New Cell, Replenish and Return-to-Stock wizards for locking **and** non-locking cells.

Technician 4 — Controlled substances operators

Acquires all Technician 3-level access privileges. In addition, they can:

- Perform all operations on cells housing controlled substances (that is, drugs classified CI-CV).

Pharmacist — *There must be a Pharmacist-level operator assigned. This level operator is responsible for adding and managing other system operators.*

Acquires all Technician 4-level access privileges.

They also can:

- Run the Operator Setup Wizard and configure the auditing feature.
- Print operator ID bar codes and delete operator accounts.
- Enable/disable the Replenish Approval feature.
- Approve replenishment operations (if the Replenish Approval feature is enabled).

For a list of all the Max/Mini roles defined at AuBurn Pharmacy, including the privileges enabled for each role and the employees assigned to each role, see Appendix A, "Max/Mini roles and users."

All Pharmacists and Technicians will have the same access level to the Parata Max/Mini.

User and role setup

The PIC at each AuBurn Pharmacy location chooses the person(s) to fulfill each role.

Auditing processes

The Parata Max/Mini records the login ID and name of the logged-in user when a canister is refilled. This information is available in the Refill History report.

Staff education and training

Initial training

Following initial installation of Parata Max/Mini, a Parata-certified trainer provides initial training for pharmacy staff. Classes include demonstrations by the trainer along with opportunities for participants to get hands-on practice and receive feedback.

All Pharmacists and Technicians will be trained on the Parata Max/Mini.

Staff training is documented and signed by the staff as well as the pharmacy staff trainer to show date of training completion.

Training provided by Parata Systems for the Max and Mini dispensing units is as follows:

- **Basic Operator class:** Covers basic system operation, replenishment of consumables and optimizing the Parata Max/Mini workflow.
Who should attend: Staff members whose primary interaction with the Max/Mini will be filling prescriptions during day-to-day operations.
- **Specialist class:** Covers advanced Parata Max/Mini procedures, basic troubleshooting, and reporting functions. (Pre-requisite: Max/Mini Basic Operator)
Who should attend: Staff members who will be responsible for keeping the Max/Mini running.
- **Pharmacist-Level Operator class:** Covers operator accounts, replenish approvals
Who should attend: Staff members (usually pharmacists and/or pharmacy managers) who are responsible for administrative tasks associated with the Max/Mini.

On-going training

Parata provides blank Skills Verification Sheets that you can use as a template for documenting ongoing training.

On-going training for AuBurn Pharmacy employees can be done by current staff that has received Parata Max/Mini training from a Parata certified trainer or from the Parata Training Manual.

All Staff can receive additional training by reviewing the Parata Max/Mini administrator training manual.

Maintenance, service and repair protocols

Max/Mini maintenance procedures

At regular intervals as specified by your service agreement, ParataSM service personnel will perform Preventive Maintenance service on your Max/Mini unit.

Reference the Operator's Guide for your Parata automation. Maintenance requirements and procedures are described and a sample log form is included. It is recommended that you keep a copy of your service contract with the outlined procedures as well as any maintenance records.

In addition to the scheduled Preventive Maintenance performed by Parata service, pharmacy personnel are responsible for performing the tasks described in the Parata Max/Mini Maintenance Guide and Parata Max/Mini Canister Cleaning Guide. These tasks include routine cleaning of unit components, reloading labels, and rebooting the associated workstation(s). All cleaning is to be done with lint free clothes. (AuBurn Pharmacy uses Parata recommended-PEC PAD by Photosol, Inc. When required Isopropyl Alcohol is also used).

Downtime procedures

When there is a power failure to the Parata Max or Mini, the internal UPS provides power long enough for the unit to complete the current dispense process and safely shut down.

Data backup and disaster recovery procedures

The Parata Max/Mini backup system is designed to be used for disaster recovery. The databases in the system are backed up daily at a time determined by the pharmacy workflow. Backups are generally stored on a thumb drive residing on PC2 within the unit; they can also be stored on a hard drive on the pharmacy network.

Inventory Control

Our pharmacy software maintains our perpetual inventory count of all medication in stock. The Parata medication cassettes for class CIII-CV medications are verified at the time of replenishment in the cell. We also conduct a controlled substance verification every 6 months and verify the count in our pharmacy software.

Troubleshooting

Max/Mini

The “Troubleshooting” chapter of the Max Operator Guide contains instructions for clearing cap, vial and printer label jams as well as reseating loose drop-off shelves and resolving counting cell issues. The “Troubleshooting” chapter of the Mini Operator Guide contains instructions for using the troubleshooting wizard and resolving counting cell issues.

For assistance with other issues, phone support is available from the Parata Technical Assistance Center (PTAC). Depending on the nature of the issue, PTAC may dispatch a Parata service technician, in accordance with the terms of your service agreement.

Reports and data

Max and Mini Reports

Reports are available for both the Inventory and Prescription side (some are only available on the Inventory side).

Information security/confidentiality

This section describes whether and how PHI is accessible from the Max/Mini.

The patient name is the only personal information used by the Parata Max/Mini. The name is displayed in the status queues on the Prescription side of the unit and contained in reports generated by system operators. The patient name is stored in encrypted fields in the system databases.

Other than viewing the status queues, system operators can only access patient names by creating specific reports. These reports can be exported to Excel or PDF files and printed. Pharmacy policy governs how these reports are utilized.

Medication security

System security

The pharmacy is responsible for creating policies and procedures that govern physical access to the Max/Mini (which contains medications stored in cells) and to packaged medications that are produced by the Max/Mini unit.

*The Parata Max/Mini machines are placed inside the confines of the pharmacy area. There is NO patient access to the machine at all.

*The Parata Max/Mini machines are only to be operated while a licensed pharmacist is present.

*The Parata Max/Mini machines contain no CII controlled substances (drugs of concern) in their inventory.

Medication inventory management

Discuss your pharmacy's procedures for stocking and restocking.

- Pharmacists and Technicians will refill the medications in the machines using the Lot number and NDC verification processes.
- Once the medication is loaded a label will be printed to mark the canister.
- Medications expiration dates are entered as a year from the date they are instilled in the machine or by the expiration on the bottle if it is less than a year.
- If returning a medication to stock, the Pharmacist and Technicians will scan the barcode and do a visual verification of the medication.

Stocking/Replenishment

- The Pharmacists and Technicians can replenish medications into the Parata Max/Min.

Dispensing controlled substances via Max/Mini automation

AuBurn Pharmacy does not dispense CII controlled substances via Parata Max/Mini.

Safety and security measures for dispensing controlled substances with Parata automation

Parata Max and Mini dispensing units have hardware and software features that contribute to securing/monitoring controlled substances: locking cells (hardware), security function levels (software) and the Replenish Approval feature (software).

A locking cell contains a solenoid that is activated —unlocked— through the software as part of the replenish and return-to-stock processes. Combining this feature with a security function level that monitors all locking cell activities increases security and provides an audit trail.

AuBurn Pharmacy does NOT place NIOSH listed hazardous medications in their automation.

Quality assurance/quality improvement

*A monthly report is ran out of the Parata software to identify drugs that are expiring. Then those medications need to be pulled and destroyed in accordance to the pharmacy's expired drugs policy.

Appendix

Appendix A: Max/Mini roles and users

Max/Mini role	Privileges enabled for this role	Employees assigned to this role
Technician1	<p>Retrieval-only operators. They can:</p> <ul style="list-style-type: none"> • Pick up and clear scripts dispensed from both locking and non-locking cells. • Perform routine script queue-management operations, including advancing and deleting scripts. • On the Prescription side General tab, access all functions, including reports. • On the Inventory side, access reports only. Other access is restricted to "read-only" . 	All Trained Pharmacy Staff
Technican2	<p>Non-locking-cell replenishment operators. Acquires all Technician 1-level access privileges. In addition, they can:</p> <ul style="list-style-type: none"> • Perform manual fill operations on non-locking cells. Drugs housed in locking cells or in cells containing controlled substances cannot be selected. • Edit Drug, Cell and Other parameters on the Parameters window. • Edit inventory for non-locking cells. • Delete cells, both locking and non-locking. • Run the New Drug Wizard. • Run the New Cell, Replenish and Return-to-Stock wizards for non-locking cells. 	All Trained Pharmacy Staff

Max/Mini role	Privileges enabled for this role	Employees assigned to this role
Technican3	<p>Locking-cell replenishment operators. Acquires all Technician 2-level access privileges. In addition, they can:</p> <ul style="list-style-type: none"> • Perform manual fill operations on both locking and non-locking cells. • Edit inventory for both locking and non-locking cells. • Run the New Cell, Replenish and Return-to-Stock wizards for locking and non-locking cells. 	All Trained Pharmacy Staff
Technican4	<p>Controlled substances operators. Acquires all Technician 3-level access privileges. In addition, they can:</p> <ul style="list-style-type: none"> • Perform all operations on cells housing controlled substances (that is, drugs classified CI-CV). 	CII Controlled Substances are NOT kept in the Parata
Pharmacist	<p>There must be a Pharmacist-level operator assigned. This level operator is responsible for adding and managing other system operators. Acquires all Technician 4-level access privileges. They also can:</p> <ul style="list-style-type: none"> • Perform all operations on cells housing controlled substances (that is, drugs classified CI-CV). 	Pharmacists Only

