GeneXpert® Infinity

Reference Guide

Refer to the **GeneXpert® Infinity System** Operator manual for a complete list of operating procedures.

IVD In Vitro Diagnostic Medical Device

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A better way.

Good Laboratory Practice

Real Time Polymerase Chain Reaction (RT-PCR) is a standard laboratory testing method that is used to select a specific sequence of DNA or RNA. This segment is amplified exponentially which creates billions of detectable copies. This technique has become an important tool in clinical laboratories for the detection of infectious pathogens at extremely low levels. This highly sensitive technique makes RT-PCR highly susceptible to cross-contamination, particularly from sample to sample transfer, if proper clean molecular technique is not used. Implementation of safeguards and strict adherence to robust protocols is often sufficient to ensure that cross-contamination in the molecular laboratory is a rare event.

Follow general CMS guidance for good laboratory practice

CMS.gov Centers for Medicare & Medicaid Services

Preventing Cross Contamination

Use of Personal Protective Equipment (PPE)

Gloves: Change gloves after touching a sample. The outside of the sample harbors much of the sample DNA/RNA that transfers to the surface of gloves.

Lab coats: Wear a lab coat while processing samples. Wearing lab coats will prevent the transfer of sample DNA/RNA to other areas of the room.

Eye/face protection: Wear surgical masks, face shields, or other physical barriers, like a splash shield for procedures with a high likelihood of generating droplets or aerosols.

Cleaning

Bleach: Use a final concentration of 1:10 dilution of 5% household chlorine bleach (used within 1 day of preparation). Final active chlorine concentration should be 0.5%.

70% ethanol: Use only 70% ethanol or denatured ethanol (70% ethanol containing 5% methanol and 5% isopropanol).

- Disposable lint-free wipes
- Disposable paper towels

Reagent Storage

Store reagents according to their expected storage conditions in the Information for Use. In addition, cartridges should be kept in their original boxes with the lid shut.

Sample Setup

Dirty area (work area): Area where samples and controls are processed.

Clean area (loading area): Area where the prepared cartridge is loaded onto the instrument.

Cartridge Disposal

Used cartridges may contain potentially infectious materials, as well as highly amplified PCR target(s). **Do not open or attempt to alter any part of the cartridge for disposal**.

Each state has different regulations for classifying regulated medical waste (RMW). The first step to safe biohazard waste disposal is to check with your state's Department of Health to learn the specific regulations you'll need to follow.

Maintenance

Instrument maintenance is required to be performed according to the user guide or operator manual. Some of the maintenance is described in this reference guide, however not all requirements are covered.

Infinity System Overview

1. **Monitor with Touchscreen**
   Scans the ID and/or barcode for the patient, specimen sample, and the cartridge into the system.

2. **Kiosk Barcode Scanner**
   Scans the ID and/or barcode for the patient, specimen sample, and the cartridge into the system.

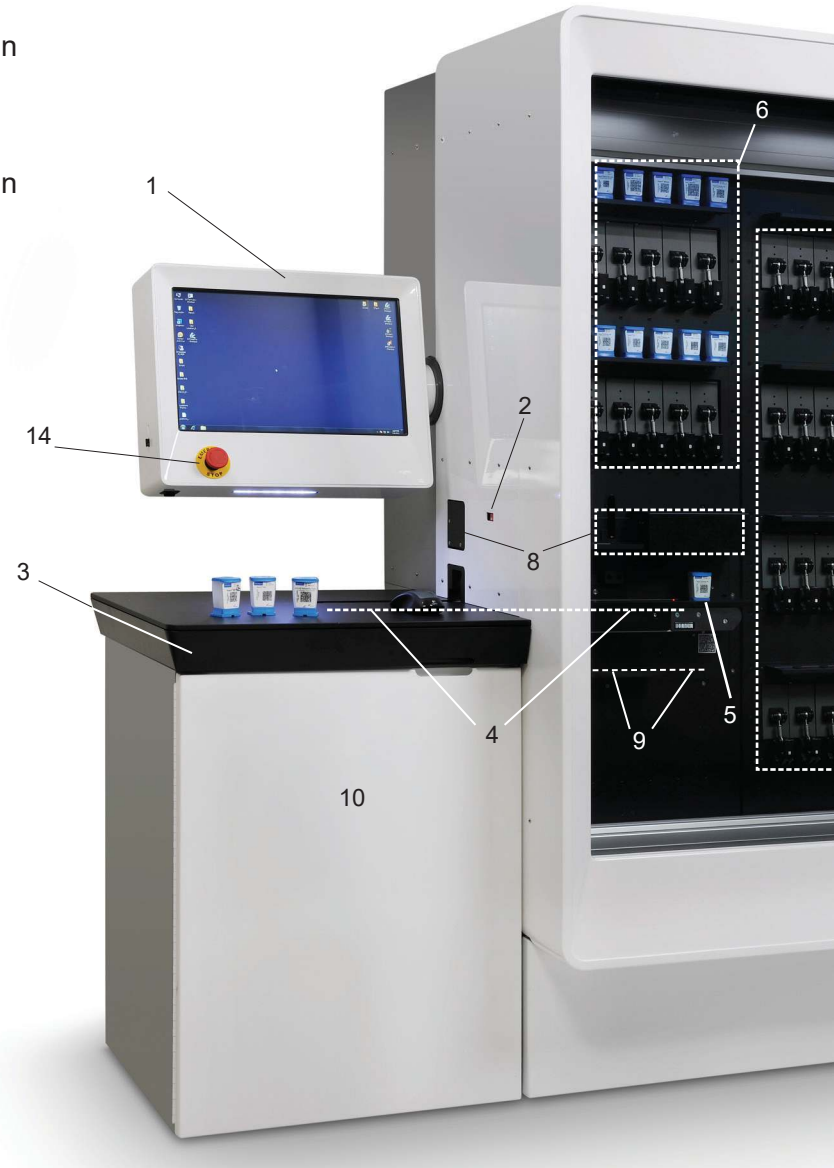
3. **Keyboard and Mouse** (not shown, located in kiosk drawer)
   Used for data entry and to make selections in the software.

4. **Conveyor**
   Moves sample-prepared cartridges into the GeneXpert® Infinity System.

5. **Lobby**
   Transition location between the Conveyor and the Gantry.

6. **Accumulator**
   This is a waiting area in which:
   - A cartridge waits to be loaded into an available module.
   - A cartridge to be retained is placed after the test is completed (e.g., Re-test).
   - A cartridge is temporarily held when it cannot be processed and when there is no room in the Shuttle (See Shuttle below).

7. **GeneXpert® Modules Area**
   - A cartridge is inserted into a module where the sample is processed.
   - Each panel contains an 8-module array, labeled A1-A8, B2-B8, etc.



8. **Shuttle**
   - The area where the operator can access a used or rejected cartridge.
   - Has a sensor that detects cartridge presence.
   - Capacity is 4 cartridges.
   - Processing STAT samples
   - Removal of cartridge from the accumulator

9. **Waste Disposal Shelf**
   The area where a cartridge is moved after test completion. When this shelf is full, used cartridges are pushed into the Waste Container.

10. **Waste Container** (not shown)
    A cartridge is dropped into this area when the Waste Disposal Shelf is full. The waste container door is locked when the system is ON.

11. **Robotic Gantry System**
    - Automatically picks up sample-prepared cartridges from the lobby and places the cartridges into the GeneXpert modules or to accumulator shelves for processing.
    - After test completion, the robotic arm moves tested cartridges from the GeneXpert module to be off-loaded to the shuttle, waste container or the accumulator.

12. **Gripper**
    Grips, holds and releases the cartridge. It is located on the Gantry.

13. **Gantry Barcode Scanner**
    Scans the cartridge barcode when the cartridge is inside the GeneXpert Infinity System.

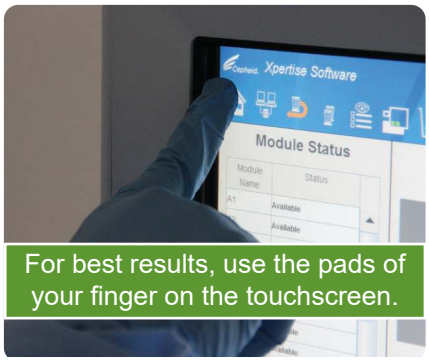
14. **Emergency STOP Button**
    When a hardware emergency stop button is pressed, the transport system is stopped immediately.

15. **Power Switch**

Desktop & Xpertise™

To Exit to Desktop: Windows Key+M

Touchscreen Tip:



Desktop Icons

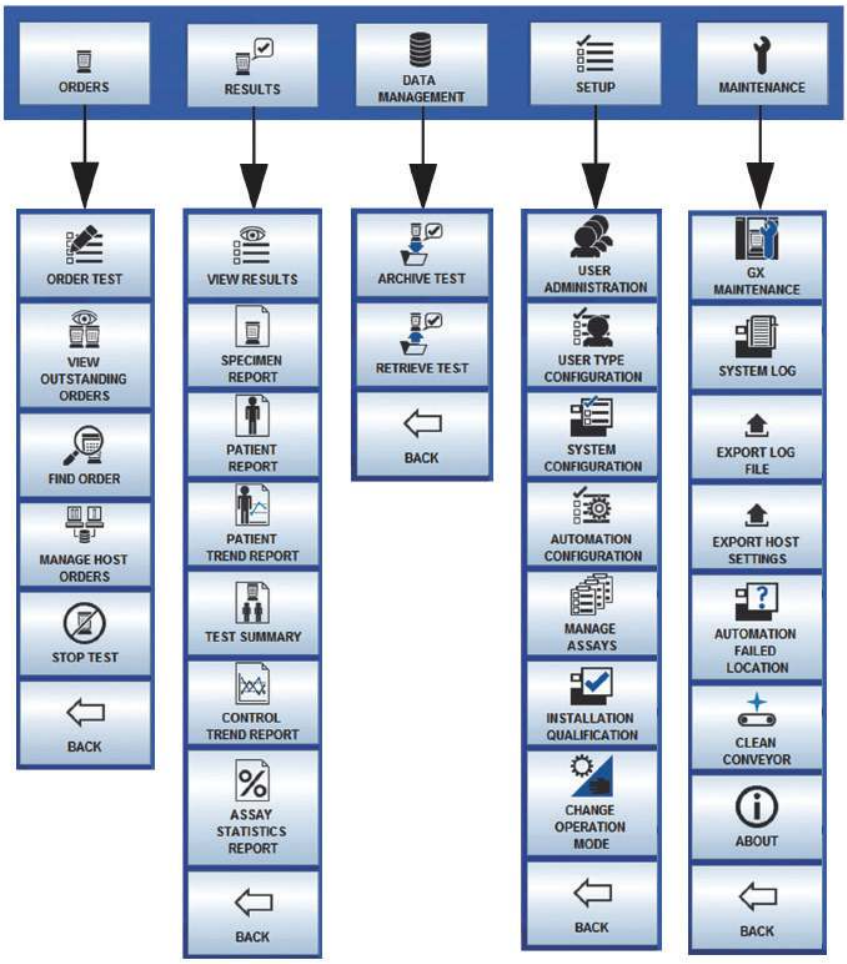
ICON	FUNCTION	ICON	FUNCTION	ICON	FUNCTION
Xpertise Software	Shortcut to Xpertise software	Cepheid Remot...	Shortcut to Cepheid Remote Support	EloSetup.exe - Shortcut	Shortcut to Touchscreen Calibration Software
GeneXpert Folder	Shortcut to GeneXpert folder	Remote DB Backup	Shortcut to GeneXpert Support Database backup	GX_Infinity Operator ..	Shortcut to Infinity Operator Manual
Shutdown Infinity ...	Shortcut to Shutdown Infinity	Adobe Reader X	Shortcut to Adobe Reader Software		

Xpertise Icons

STATUS BAR		DASHBOARD PANEL			
	Login		Home screen		View Another Test
	Logout		Host		Utilization
	Change pasword		Load or Retrieve Cartridges		Waste container
	Exit software		View outstanding orders		Database alert
					Pause

Xpertise Icons Continued

MENU PANEL MAP



OTHER COMMONLY USED ICONS

Shuttle is open

Glass door is unlatched

Silence Alarm button

Manual mode operation

Message Log

Error

Shutting Down the System

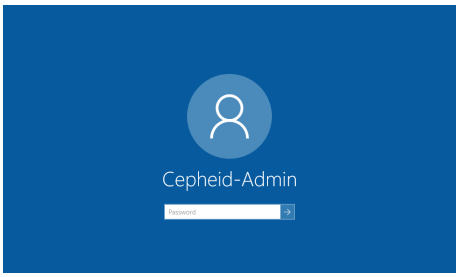
Important: Make sure no tests are running on the system.
Do not shut down from the Windows Power menu.

1. Select **Exit**. 
2. Select **OK** to confirm exiting the software.
3. Perform database management activities, if needed.
4. Wait for the software to completely exit.
5. Double-click the **System Shutdown** shortcut on the desktop.
6. Select **OK** to confirm system shutdown.
7. Wait a minimum of 2 minutes before powering off the system.
8. Turn the power switch to the OFF position (O).
9. Wait a minimum of 2 minutes before restarting the system.

Starting the System

1. Turn the power switch to the ON position (|).
2. Wait 2 minutes for the system to boot.
3. Close the shuttle door.
4. Enter your Windows password: cphd
5. Double click the **Xpertise** shortcut on the desktop.
6. Log in with your user name and password.
7. Perform database management activities, if needed.

The Infinity is now ready.



Ordering Test in Automation Mode

1. Follow the IFU to prepare the cartridge.
   Note: Refer to Xpert Cartridge Labeling Guide for proper patient label placement.
2. Select **Orders**

   or select **Manage Host Orders.**

3. Select **Order Test**.

4. Scan or type the Patient ID, if necessary, and select **Continue**.
5. Select priority – normal (unchecked) or **STAT** (checked)
6. Scan or type the Sample ID.
7. Enter notes.

   Note: You cannot enter notes if auto submit is enabled.

8. Select **Submit**.
9. If required, enter your password.
10. Load (or place) the cartridge in the loading zone on the conveyor, outside the yellow and black lines.

    Make sure to place the cartridge on the conveyor with the cartridge bar code label facing you.

Checking a Test in Progress

- View Another Test

- Home screen showing the tests since software launch

Viewing Results/Printing Reports

1. Select **Results.**

2. Select **Report** or **View Another Test.**

3. Select **Preview PDF**

Importing Assay Definitions

To import new assay definitions:

1. Select Setup.

2. Select Manage Assays.

3. Select the **IMPORT** button

4. Under the Look in: Navigate to the DVD or file location for the folder containing the ADF files.
5. Under the DVD directory, select the Infinity Systems folder.
6. Select the assay definition (.gxa/.nxa) file then select the **OPEN** button. The new assay name and version number will appear in the assay list in the Manage Assays workspace.
7. Remove the CD from the DVD drive.

Archiving and Purging the Tests

1. Select Data Management

2. Select Archive Test

3. Select the check box that is adjacent to each test you want to archive. The buttons at the bottom of the Archive Test workspace give you the option to:
   - **SELECT ALL** – Selects all of the tests in the table.
   - **SELECT HIGHLIGHTED** – Selects the tests you highlighted.
4. Select the **OK** button.
   - Place a check mark in the box next to Purge Selected Tests from List After Archiving
5. Select the **PROCEED** button.
6. Use the **Save In**: drop-down to locate and select the folder in which you want to store the archive file, retype a name for the archive file, if necessary, and then select the **SAVE** button.
7. Select the **OK** button to confirm that the tests have been archived.
8. Select the **OK** button to confirm that you want to purge the tests.
9. Select the **OK** button to close the confirmation workspace.

Replacing Waste Container Bag

1. On the dashboard, select the **Waste Container** icon.

2. Select the **UNLATCH DOOR** button.

3. Open the access door. Grab the handle of the waste container and remove it from the container housing until it is resting on the floor.
4. Remove the waste container bag from the waste container and dispose of the bag of used cartridges.
5. Place a new bag into the waste container. Push the bottom of the bag to the bottom of the waste container. Fold the top of the waste container bag over each of the four corners of the container.
6. Place the waste container back into its housing with the **FRONT** label facing forward.
7. Slide the waste container all the way back against the back wall so that the container breaks the optical beam.
8. Close the waste access door. The Waste Container workspace empty confirmation screen is displayed. Select the **YES** button.
9. Confirm that the waste container workspace shows the **Disposed Cartridge** count in the container reset to zero.

Retrieving Cartridges (from Accumulator)

Note: These steps apply only to Automation Mode.

1. Select View Outstanding Orders. Cancel order if indicated.

2. Select **the Cartridge I/O icon**

3. In the Accumulator tab, check the box(es) adjacent to the cartridge(s) you want to remove

4. Select **Move to Shuttle or Fill Shuttle**.

5. Select **Open Shuttle**.

6. The shuttle door opens slightly.
7. Pull the shuttle door open and remove the cartridge(s).
8. Close the shuttle door and select **OK**.

Pausing the System

You can safely open the glass doors to adjust or remove a cartridge or to clean a spill inside the cabinet.

> **Caution:** Pausing the system for a long time can cause tests to expire. Plan to resume from a "pause" within a short time.

To pause the system:

1. Select **Pause**.

2. Select **Confirm Pause**.
3. Open the glass door.
4. Adjust or remove the cartridge.
5. If you remove a cartridge, select **Remove Cartridge**.

6. Scan the cartridge barcode.
7. Close the glass doors.
8. Select **Resume**.

Emergency Stop

Push the Emergency Stop button at anytime to prevent user injury or instrument damage.

> **Caution:** Stopping the system for a long time can cause tests to expire.

To stop all automation:

1. Press the **Emergency Stop** button.
2. Select **Unlatch Glass Doors**.

3. Open the glass doors.
4. Remove all cartridges from the conveyor.

> **Note:** Retain these cartridges to be reordered and run upon Resume.

5. If any cartridges fell, remove them and clean up any spills.
6. Twist the emergency stop button clockwise until it resets.
7. Select **Resume**.

8. Close the glass doors.
9. Select **Latch Glass Doors**.

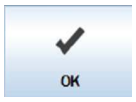
Automation to Manual Mode

1. Select **Setup**.

2. Select **Change Operation Mode.**

3. Select **Edit**.

4. Select **Manual Mode**.
5. Select **Save** and then **OK**.



6. Open the glass doors.
7. Remove all cartridges from the accumulator, shuttle, conveyor, and unused modules.
8. Select **Cartridges removed**.

9. Select **OK**.

10. Select **Close** and confirm that the Manual mode icon is present on the dashboard.

Manual Mode Workflow

1. Follow the IFU to prepare the cartridge.
2. Select **Orders**.

3. Select **Order Test**.

4. Scan the Patient ID (optional) and Sample ID. Press **Continue**.

5. Scan the cartridge bar code
6. Select **Submit**.

7. If required, enter your password.
8. Select **Continue** and follow screen prompts.

9. Put the cartridge into the module with the flashing green light.
10. Close the module door, using the hinge on the door.
11. Select order next test or end order test.
12. When the test finishes, open the module door using the hinge on the door and leave it open.
13. Remove processed cartridges. Do not dispose of cartridges in the Infinity waste container

Manual to Automation Mode

Make sure no tests are running on the system.

1. Remove all cartridges from the conveyor, accumulator shelves, shuttle, and modules before changing to automation mode.
2. Select **Setup.**

3. **Select Change Operation Mode.**

4. Select **Edit**.

5. Select **Automation Mode**.
6. Select **Save** and then **OK**.

7. Select **OK** and restart the system immediately or select **CONTINUE** to save the new operation mode and restart the Xpertise software

Excluding (disabling) Modules

1. Select **Maintenance**.

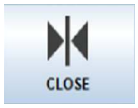
2. Select **GX Maintenance**.

3. Select **Exclude Modules From Test**.

4. Select **Edit**.

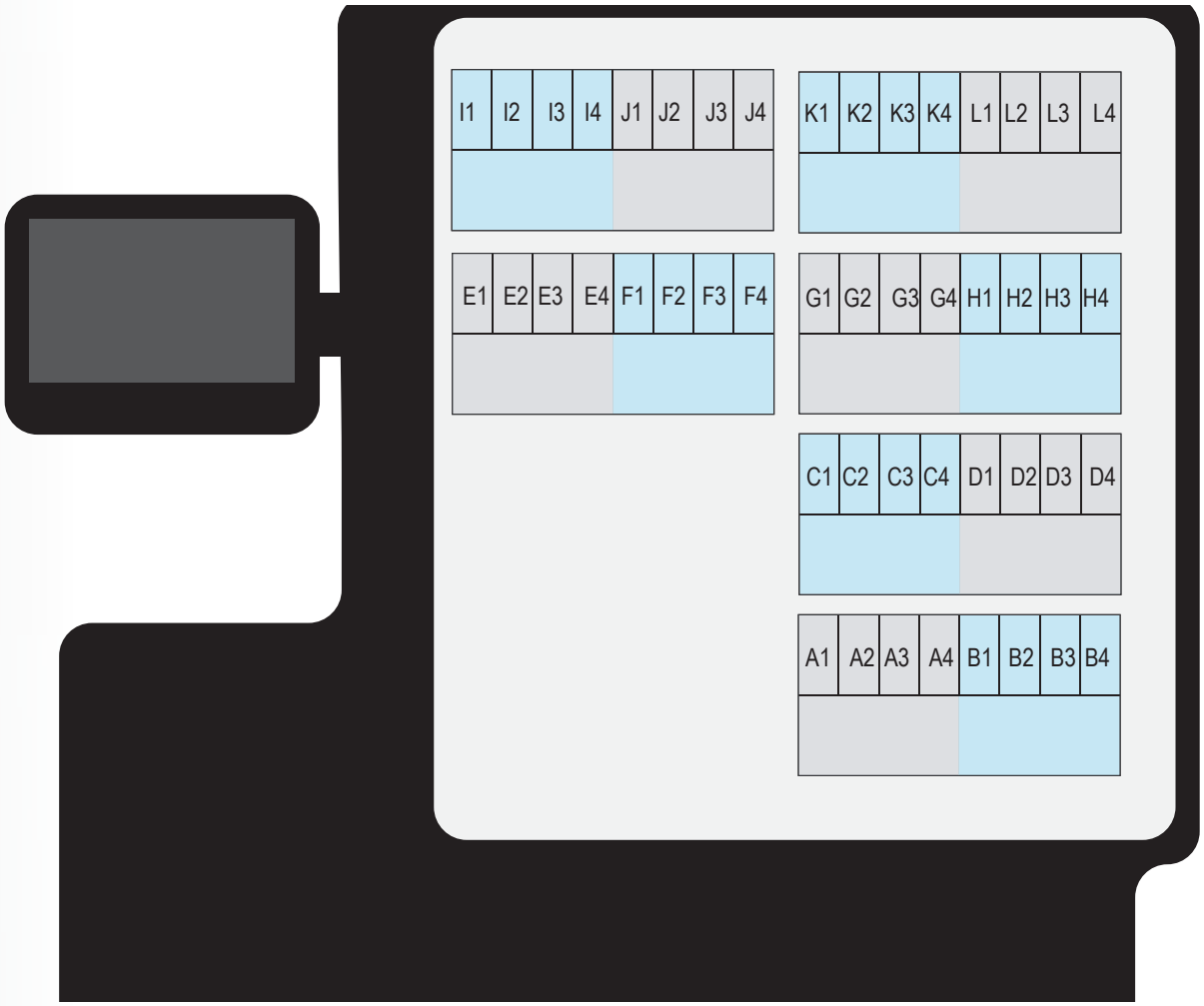
5. Select the check box(es) next to the modules you want to exclude.
6. Select **Save**.

7. Select **Close**.

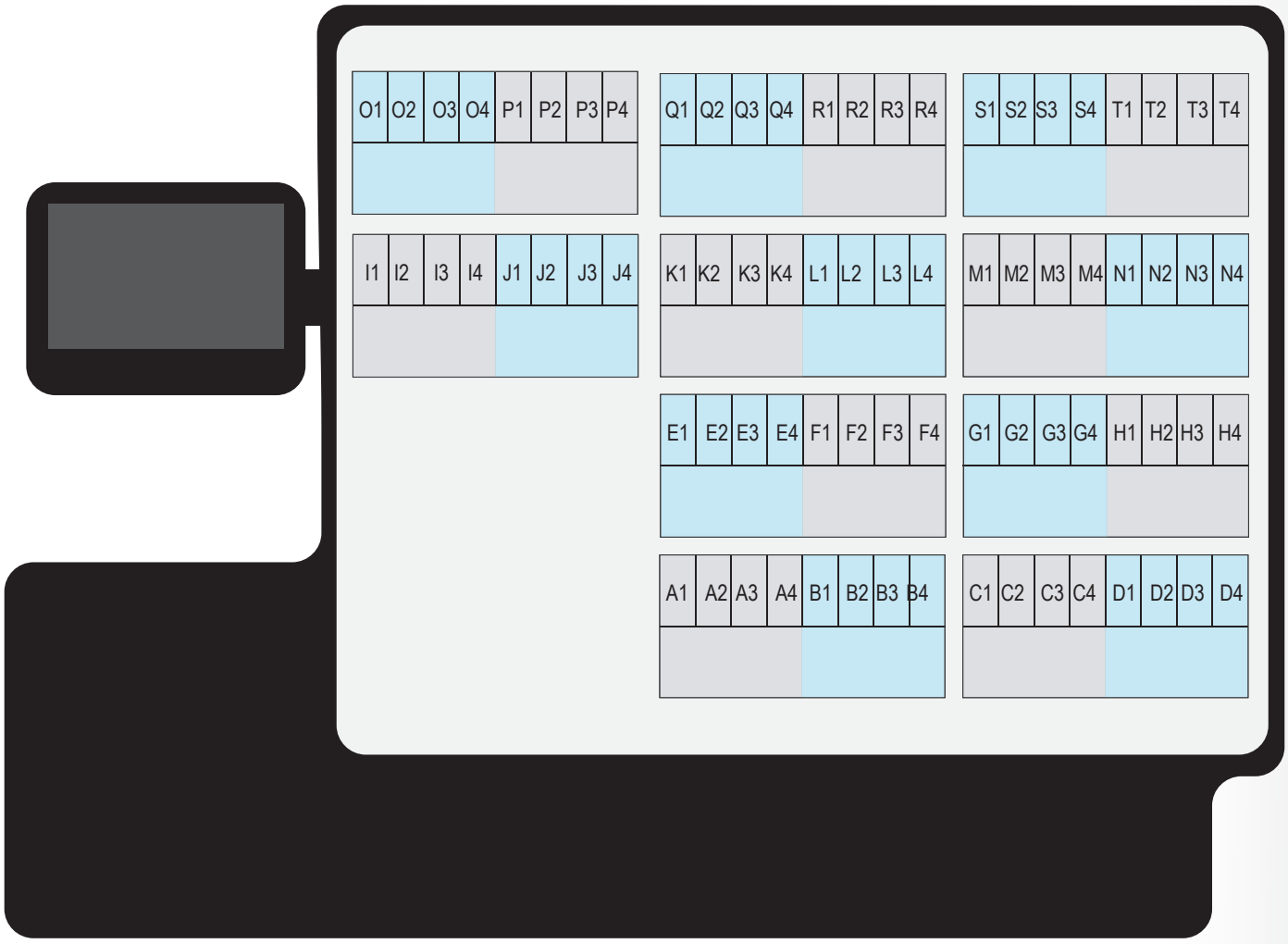


Notes:

Module locations - Infinity 48s



Module Locations - Infinity 80



Notes:

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301-0707, Rev. H April 2024