Element Biosciences

AVITI Dx™ System

User Guide

FOR USE WITH

AVITI Dx System
AVITI Dx Operating Software v4.0

ELEMENT BIOSCIENCES

The AVITI Dx System product family delivers precise, high-quality raw DNA sequencing data from a variety of biological samples. The product is intended solely as a data generation tool and does not provide diagnostic interpretations or direct clinical recommendations.

Document # MA-00088 Rev. C
November 2026

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CHAPTER 1

System Overview

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Introduction

The AVITI Dx System is a multidimensional genomics instrument that integrates state-of-the-art sequencing in a benchtop platform.

The AVITI Dx System offers flexibility through multiple sequencing kit configurations that support an extensive range of applications. The dual flow cell design enables parallel runs or staggered runs with independent run setup options. AVITI Dx Operating Software (AVITI Dx OS) provides an abundance of additional features to promote adaptive run setup and streamline analysis.

This guide provides an overview of system components, analysis options, maintenance instructions, configuration settings, and safety information for the AVITI Dx System.

Site Prep and Safety

Before installation of an AVITI Dx System, ensure your site meets the requirements in the *AVITI Dx System Site Prep Guide (MA-00089)*. Before operating or maintaining the instrument, review the safety and regulatory information in *Safety and Compliance* on page 59.

The instrument does not contain any user-serviceable parts. Exterior shells enclose the instrument to protect the operator from laser light exposure and mechanical parts. Software and interlocks prevent exposure to hazards, and using the AVITI Dx System in an unspecified manner can compromise these protections.

Warranties and Services

The purchase of an AVITI Dx System includes a standard one-year warranty. Element offers supplemental procedures, preventative maintenance service, and annual service plans. For more information, visit elementbiosciences.com/instrument-service-coverage.

System Compatibility

For sequencing runs, the AVITI Dx System is compatible with an array of library types, including third-party libraries. For more information about library compatibility, see *Product Compatibility* on the Element website.

To avoid mixing and matching components from different kit configurations and versions, AVITI Dx OS validates the compatibility of the cartridge and flow cell provided in each sequencing kit.

Additional Documentation

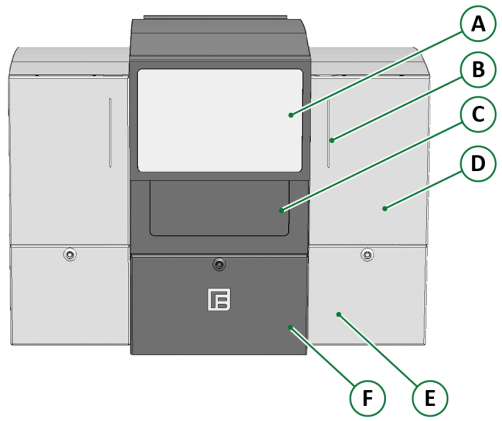
For run preparation and setup instructions for a specific workflow, see the following guide:

- *Cloudbreak Freestyle Dx™ Sequencing User Guide (MA-00087)*

AVITI Dx System Components

The instrument is divided into two sides, side A on the left and side B on the right when facing the instrument. Each side operates independently so you can engage one side while the other is in use. Side A and B each include a dedicated pump bay and reagent bay enclosed with bay doors.

Between sides A and B is the glove-compatible touchscreen monitor that displays the AVITI Dx OS interface. Below the monitor is the nest bay and the waste bay. Lighting illuminates the interior of each bay. During a run, AVITI Dx OS locks all doors except the pump bay doors to protect against laser light exposure, mechanical moving parts, and other hazards.



- **A** Touchscreen monitor
- **B** Lightbars
- **C** Nest bay with automated nest door
- **D** Pump bays hold fluidic pumps
- **E** Reagent bays hold reagents for each run
- **F** Waste bay holds waste bottles

CAUTION
Do not place items on top of the instrument or on open doors. The doors can support the weight of run and wash components, but applying extra weight or bumping into an open door can damage the instrument.

Status Lights

The AVITI Dx System includes two types of status lights: an interior nest light in front of each nest and an exterior lightbar on each side. The nest light colors indicate flow cell status. The lightbar colors indicate the current process and overall system status. Unless the system is initializing, each lightbar is side-specific.

Nest Light Colors

Color	Status
Blue	The flow cell is present and ready to be unloaded.
Green	The flow cell is properly loaded and ready for priming, sequencing, or washing.
Red	The flow cell is improperly loaded: the lid is open or the nest is empty.
None	The flow cell is present but is not ready to be unloaded.

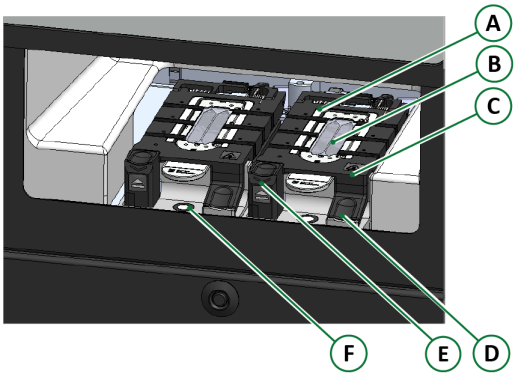
Lightbar Colors

Color	Status
White fade	The system is initializing.
Solid white	The system is initialized and idle.
Solid blue	Run or wash setup is in progress.
Blue fade	The system is priming, sequencing, or washing.
Solid orange	The system experienced a warning. The color changes after the run finishes.
Solid red	The system experienced an error or run failure. The color immediately changes when an error occurs.

Nest Bay

The nest bay includes two nests, one for each side, and each nest holds one flow cell. A hinged flow cell lid secures the flow cell in place. A button on each nest unlatches and opens the hinged lid to a 40° angle. To ensure proper alignment, three silver pins on the loading area fit into three corresponding holes on the flow cell cartridge.

An automated nest door on the middle shell encloses the nest bay. During a run, a camera and four tube lenses above the nest image the flow cell in four channels.

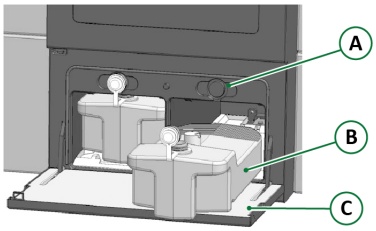


A Wall around the loading area
B Flow cell loaded on the nest
C Lid secured over a loaded flow cell
D Tab to close the lid
E Button to open the lid
F Nest status light

Waste Bay

The waste bay holds two waste bottles, one for each side. Two threaded cap holders above the waste bay secure the tethered transport cap to keep the caps clear of the door.

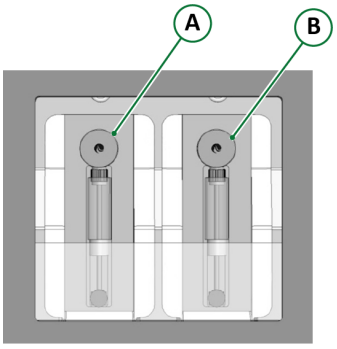
A sealed tray built into the bottom of the waste bay collects spills and leaks and directs liquid to the front of the instrument. During run or wash setup, sensors confirm the waste bottle is present and empty and allows the run or wash to proceed. Another sensor detects spills.



A Cap holder
B Waste bottle
C Open waste bay door

Pump Bays

Each pump bay contains two pumps that control the flow of liquid. The left pump pulls fluid through the left lane of the flow cell and the right pump pulls fluid through the right lane. Keep the pump bay doors closed during normal operation and maintenance.

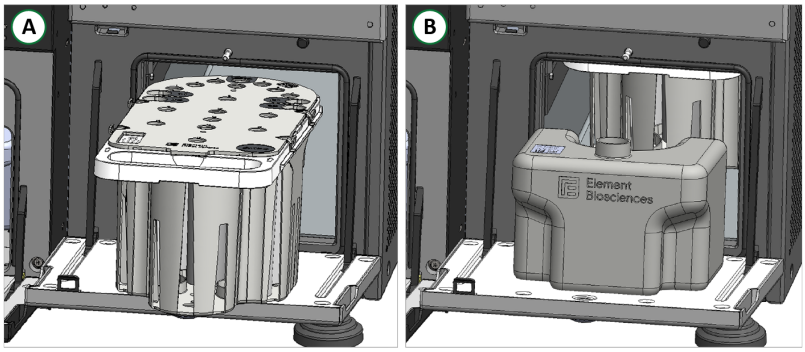


A Pump controlling the left lane of a flow cell
B Pump controlling the right lane of a flow cell

Reagent Bays

Each reagent bay holds a buffer bottle and cartridge basket that contains a cartridge or a wash tray, depending on whether the system is sequencing or washing. Keep the reagent bay doors closed to maintain the refrigeration, which chills reagents.

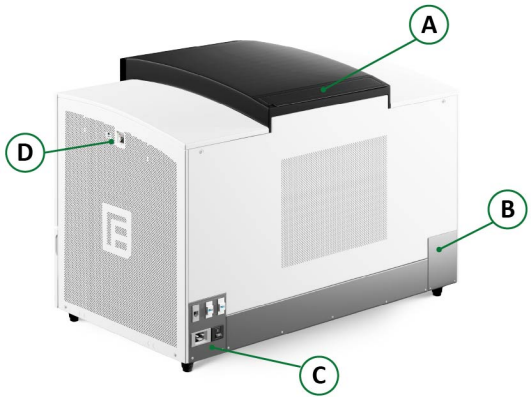
When priming starts, sippers descend into the bay, pierce the foil seals covering the cartridge wells, and aspirate reagents from the bottom of each well. The sippers continue to aspirate reagents throughout the run. Functioning similarly for a wash, the sippers aspirate wash solution instead of reagents.



A Loading a basket and cartridge
B Loading a buffer bottle

Back Panel

The back panel includes the air filter tray and input and output (IO) panel. A compliance label displays regulatory symbols for regulatory compliance, the instrument serial number, and electrical specifications. The right side of the instrument includes the IVD and RUO mode selector switch. For more information on labeling, compliance, declarations, and certifications, see *Safety and Compliance* on page 59.



A Air filter tray
B Compliance label
C IO panel
D IVD/RUO mode selector

Air Filter Tray

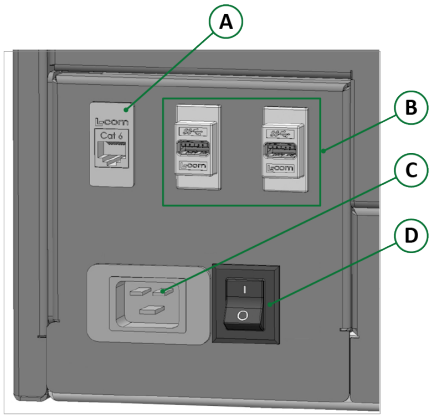
Air enters the instrument through a disposable air filter rated MERV 8. This type of filter keeps dust out of the instrument but does not filter smoke or particles < 3 microns. Keep aerosol and particulate sources away from the instrument to extend filter life.

The filter is positioned in a vertical tray that lifts from the top of the instrument to facilitate easy replacement. See *Replace the Air Filter* on page 34.

Input/Output Panel

Instrument connections and the power switch are located on the input/output panel on the back of the instrument. The panel includes a Category 6 (Cat6) Ethernet port and a power connection. Use only the power cord that Element provides.

The input/output panel includes two USB 3.0 ports for a mouse, keyboard, or USB drive for file transfer.

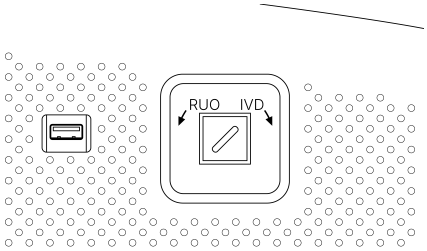


A Cat6 Ethernet port
B USB 3.0 ports
C Power entry module
D Power switch in the on position

A third USB 3.0 port is located on the instrument side panel on side B. USB drives used for file transfer must be formatted as FAT32 or exFAT.

IVD and RUO Mode Selector

The instrument operates in either IVD mode or RUO mode. Switching modes requires a software selection, a physical mode switch, and a system restart.

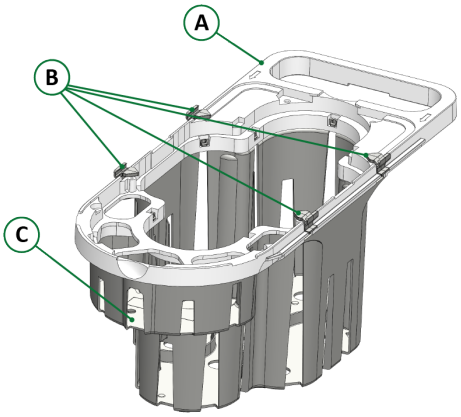


Reusable Accessories

Reusable accessories include two cartridge baskets, four wash trays, and two waste bottles. Although reusable for many runs, each accessory requires care, inspection, and periodic replacement.

Cartridge Basket

The cartridge basket holds and protects the cartridge during a run. The back of the basket extends into a handle with arrows to indicate the loading direction. Clips along the top of the basket secure the basket to the cartridge. A window at the front of the basket enables library inspection. The basket design accommodates the shape of the buffer bottle, which is loaded into the reagent bay behind the basket.



A Handle at the back
B Latches along the top
C Window at the front

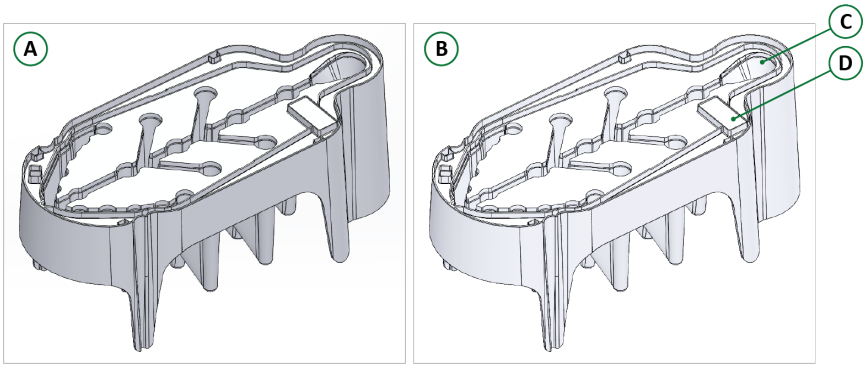
Wash Trays

The AVITI Dx System includes two types of wash trays, each dedicated to different wash solutions:

- AVITI Dx Wash Tray 1, Gray, for use with Wash 1 Solution.
- AVITI Dx Wash Tray 2, White, for use with Wash 2 Solution and nuclease-free water.

For more information, see *Perform a Maintenance Wash* on page 29.

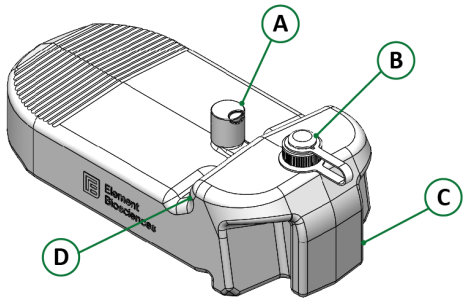
The back of a wash tray forms a handle and a fill area for adding wash solution. Interior fill lines indicate approximate volumes. An overflow wall contains any wash solution that exceeds the 800 ml maximum fill volume. Each tray includes a waterproof barcode label for validation purposes.



A Gray wash tray
B White wash tray
C Handle with fill area
D Barcode label

Waste Bottle

A waste bottle collects spent reagents and library throughout the run. The maximum capacity of 3.2 L per bottle is sufficient to contain all waste from one run. The tethered transport cap seals the bottle during transport. The vent cap improves flow when emptying waste. Ridges on the back of the bottle and a handle at the front facilitate handling.



- **A** Vent cap
- **B** Transport cap
- **C** Handle
- **D** Thumb indentations

Sequencing Kits

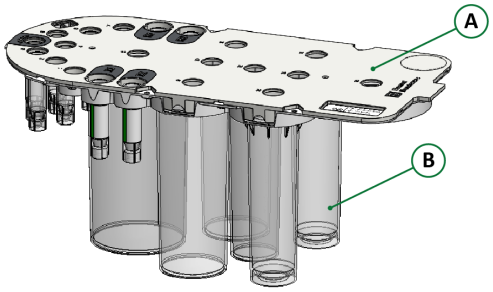
A sequencing kit provides a flow cell, a reagent cartridge, loading buffer, and wash buffer required for one run. The cartridge for each kit supports a specific number of cycles and output levels. Components include a barcode label for tracking and validation. For a complete list of kits, see the *Cloudbreak Freestyle Dx Sequencing User Guide (MA-00087)*.

To ensure the compatibility of run components, see the *Product Compatibility* page on the Element website.

Sequencing Reagent Cartridge

The reagent cartridge is a collection of reagents and buffers in foil-sealed wells that are packaged in an easy-to-load container. The cartridge lid secures the wells and labels the reagent positions. Each well is transparent to allow visual inspection after thawing. A barcode label enables tracking and validation.

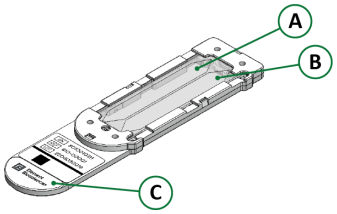
The Library well is reserved for the diluted library. For kits that are compatible with the Individually Addressable Lanes add-on, the AUX well is reserved for a second library. For more information, see *Individually Addressable Lanes* on page 19.



A Cartridge lid
B Transparent well

Sequencing Flow Cell

The flow cell is a two-lane glass substrate encased in a plastic cartridge. The cartridge includes a gripper for safe handling. Proprietary surface chemistry coats the flow cell and enables polony generation. Library and reagents enter the flow cell through inlet ports and exit as waste through outlet ports.



A Lane 1
B Lane 2
C Gripper

Loading and Wash Buffers

A sequencing kit includes loading and wash buffers that are packaged separately.

Buffer	Packaging	Description
Library Loading Buffer	Tube	Reagent for diluting the libraries to the target loading concentration
AVITI Universal Wash Buffer (UWB)	Buffer bottle	Reagent that flushes reagents from the flow cell during a run
Instrument Wash	Cartridge	Wash solution for the automatic post-run wash

Wash Buffers

Sequencing kits include a wash buffer that is packaged separately and labeled with a barcode for tracking and validation purposes.

Buffer	Packaging	Description
AVITI Universal Wash Buffer (UWB)	Buffer bottle	Reagent that flushes reagents from the flow cell during a run
Instrument Wash	Cartridge	Wash solution for the automatic post-run wash

CHAPTER 2

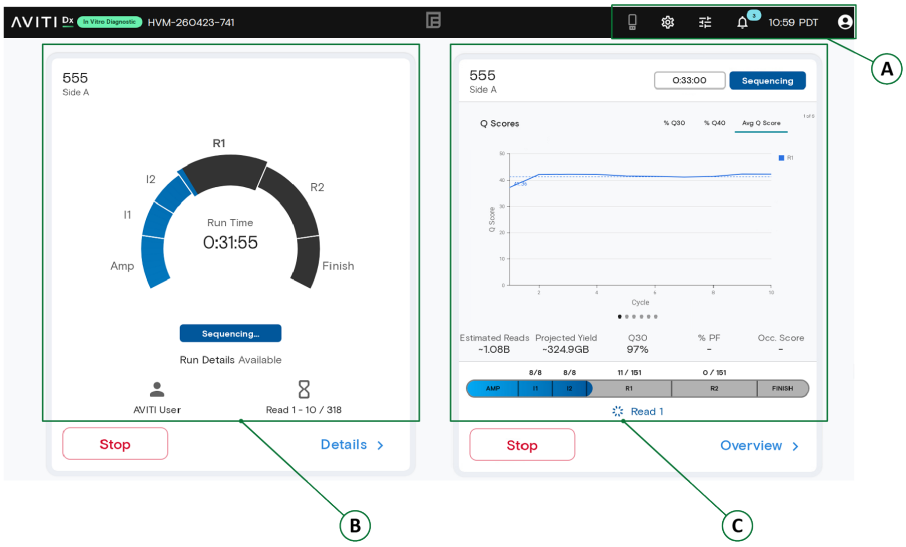
Software and Analysis

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AVITI Dx Operating Software

AVITI Dx OS controls instrument operations during sequencing, analysis, and instrument washes. The Home screen functions as a system dashboard, displaying the status of each side with features to start runs and washes and monitor runs.

AVITI Dx OS operates in one of two modes: In Vitro Diagnostic (IVD) mode or Research Use Only (RUO) mode. The interface styling identifies which mode is active. In IVD mode, the top left banner displays AVITI Dx with a green background shading the phrase In Vitro Diagnostic, and the interface displays in light mode with a white background. In RUO mode, the top left banner displays a blue background shading the phrase Research Use Only, and the interface displays in dark mode with a black background.



A Taskbar
B Overview view
C Details view

Home Screen Views

The Home screen includes buttons that display the following views:

- **Overview**—Displays general system status and previous run times for each side, or displays active run or wash information.
- **Details**—Displays metrics for the last completed run or a currently active run. When a run starts, AVITI Dx OS automatically switches to this view for the active run. When no run or wash is active, this view is available for the last completed run.

Taskbar Icons

A taskbar at the top of the Home screen provides the following icons. The Settings and Notifications icons each open a unique screen. USB Drive and User icons each access additional features and functions.

Icon	Name	Function
	USB Drive	View a list of USB drives that are connected to the instrument and safely disconnect a USB device.
	Settings	View system information and configuration settings. See *Settings* on page 18.
	Notifications	Review notifications and perform the indicated action. See *Notifications* on page 19.
	User	Open the User menu. Alternatively, this icon displays initials.

Settings

AVITI Dx OS includes configurable and read-only settings that control the instrument profile and system connections. AVITI Dx OS divides the settings among the following tabs:

- **About**—Displays software and instrument information:
  - » AVITI Dx OS version and the last license acceptance date
  - » AVITI Dx System name, instrument type, serial number, available local storage, compute ID, and software UDI

  NOTE
  Compute ID is a unique code for the integrated circuit that identifies the instrument computer.
- **General**—Controls the system name and displays on-screen keyboard, and elevation settings. Also, exports log files from offline systems.
- **Network**—Controls network and internet connections for the system. Includes a connectivity indicator.
- **Storage**—Lists storage connections with connectivity indicators and settings for adding and managing storage connections.
- **Service**—Resets the air filter time, and shows the last maintenance wash and power cycle.
- **Add-Ons**—Displays the add-ons that are enabled on the system and any applicable expiration dates.
- **Manage Users**—Available only to administrators, this tab provides user management for offline systems with local authentication.

Network Status

The Network tab displays the following icons, which indicate the status of the network connection. An additional indicator appears on the tab to show internet connectivity.

Icon	Network Status
	Connected
	Local internet only
	Disconnected

Storage Status

The Storage tab displays the following icons, which indicate the status of the storage connections. An additional indicator appears on the tab to show storage connectivity.

Icon	Storage Status
	At least one storage connection
	No storage connection

Add-Ons

The Add-Ons tab lists each add-on available on the instrument.

High Output Kits

The High Output Kits add-on enables sequencing with high-output kits.

Individually Addressable Lanes

The Individually Addressable Lanes add-on enables loading one library pool in each lane of a flow cell for sequencing runs. The second library is loaded into the AUX well of the sequencing cartridge.

The add-on is only compatible with sequencing kits that meet the following requirements:

- Cloudbreak Freestyle Dx™ chemistry
- 2 x 75 or 2 x 150 cycle kits
- A high- or low-output configuration

Notifications

Notifications display system messages across three tabs: General, Side A, and Side B. Expand a notification to see the message, date, and time.

Notification	Icon	Description	Action
Success		A run or wash completed successfully.	Acknowledge successful completion.
Information		The software is ready to be updated to a new version.	Acknowledge the update.
Warning		The system requires your attention, but you can continue operation.	Acknowledge the warning and resolve it by the indicated date.
Error		The system has malfunctioned and requires action to proceed.	Follow the onscreen prompt.

Unread Notifications

Notifications include badges that indicate the number of unread messages. Checkboxes mark notifications as read or unread. Marking a notification as read can reset the status lights on that side of the instrument.

Filtering and Sorting

Notifications include filters with sorting from newest to oldest or oldest to newest.

Filter	Description
All	View all messages on the selected tab.

Filter	Description
Read	View only read messages on the selected tab.
Unread	View only unread messages on the selected tab.

Run Start Options

AVITI Dx OS includes the following options for starting a run:

- **Single start**—Set up and start a run on one side of the instrument.
- **Dual start**—Concurrently set up and start runs of the same run type on both sides of the instrument.
- **Flexible start**—Set up and start a run or recovery wash on a side of the instrument while a run is active on the other side.

AVITI Dx OS allows sequencing with different kits on each side of the instrument. Because both sides share a camera, the setup of one run can increase the duration of the other run.

Flexible Start

Flexible start safely pauses the active run and initiates a run or recovery wash on the other side of the instrument. When setting up the second run, AVITI Dx OS finds a safe pause point before proceeding. While the run is paused, set up and start a run or recovery wash on the other side. The runs on both sides proceed asynchronously. For a flexible start recovery wash, the run on the other side proceeds concurrently.

AVITI Dx OS indicates the typical wait time for the current run step. Pausing the first run typically takes several minutes but can take as long as ~2 hours depending on the run step. AVITI Dx OS also includes options to cancel flexible start and resume the active run.

Run setup steps differ based on the type of kit you are using. For run setup instructions, see *Additional Documentation* on page 6.

Wash Setup Screens

Initiating a wash opens a series of wash setup screens that guide you through setting up a maintenance, standby, service, or recovery wash. Wash setup functions similar to run setup, but closing the door validates the wash tray presence.

Run Setup Screens

AVITI Dx OS guides you through a series of run setup screens. Each screen provides a set of steps and indicates run setup progress. AVITI Dx OS unlocks the reagent and waste bay doors at the appropriate steps and prompts the loading of consumables. Closing a door validates the presence of each consumable and scans the consumable barcode.

After the step to empty waste and reload the waste bottle, priming starts automatically. Priming prepares reagents for delivery and pumps air and reagents through a used flow cell and the fluidic tubes, preventing contamination between runs.

Run setup steps differ based on the type of kit you are using. For run setup instructions, see *Additional Documentation* on page 6.

Signing In and Out

Signing in to AVITI Dx OS requires the email address and password for individual account(s). The first time you sign in to AVITI Dx OS after instrument installation or an update, you must accept the license agreement. A Logout option on the User menu signs you out.

Switching Between In Vitro Diagnostic (IVD) and Research Use Only (RUO) Mode

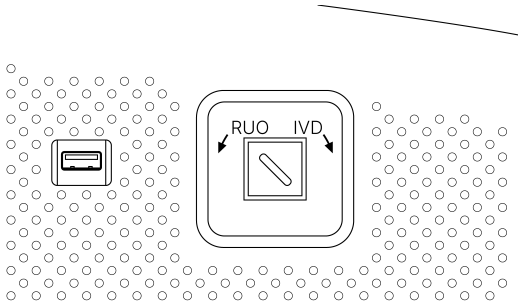
The instrument operates in either IVD mode or RUO mode. Switching modes requires a software selection, a physical mode switch, and a system restart.

NOTE
Switching modes requires a full system shutdown and restart.

WARNING
Perform this procedure only when the instrument is idle and no sequencing runs are active. Failure to do so may result in loss of run data.

Switching from IVD to RUO Mode

1. Verify the instrument is idle and no sequencing runs are active.
2. Turn the Mode Selector on the right side of the instrument to the **RUO** position.

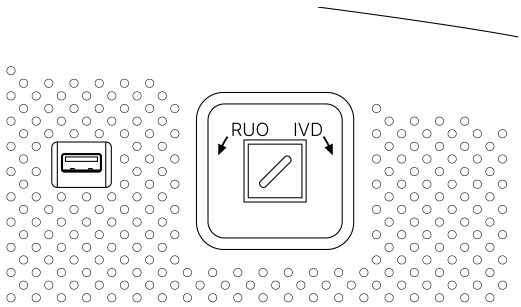


3. Open the **User** menu on the instrument touchscreen.
4. Select the box *The selector is switched to the RUO position*.
5. Select **Shut Down**.
6. Wait until the display shows **No Signal**.
7. Power off the instrument using the rear power switch.
8. Wait *10 seconds*.
9. Turn on the instrument.

After startup, the system operates in RUO mode.

Switching from RUO to IVD Mode

1. Verify the instrument is idle and no sequencing runs are active.
2. Turn the Mode Selector on the right side of the instrument to the **IVD** position.



3. Open the **User** menu on the instrument touchscreen.
4. Select the box *The selector is switched to the IVD position*.
5. Select **Shut Down**.
6. Wait until the display shows **No Signal**.
7. Power off the instrument using the rear power switch.
8. Wait *10 seconds*.
9. Turn on the instrument.

After startup, the system operates in IVD mode.

Run Manifest

AVITI Dx OS uses a run manifest as an input file that stores run information, including demultiplexing settings, settings for FASTQ files, and a list of samples with any corresponding index sequences. After a sequencing run, AVITI Dx OS provides the run manifest as an output file to support run analysis and Bases2FastqDx.

The run manifest uses a comma-separated values (CSV) file format and can be created using a template on the Resources page of the Element Biosciences website. For more information, see the *Run Manifest Documentation* in the *Online Help*.

Sequencing Run Manifest

For sequencing runs, the run manifest includes demultiplexing settings, settings for FASTQ files, and a list of samples with any corresponding index sequences. After a sequencing run, you can use the run manifest that AVITI Dx OS provides to support secondary analysis and Bases2FastqDx. Demultiplexing indexed libraries requires preparing a run manifest.

When a sequencing run does not include a run manifest, AVITI Dx OS generates a default run manifest that assigns all reads to one sample during FASTQ file generation.

Demultiplexing indexed libraries is ***not possible*** with a default run manifest. To use a default run manifest with Bases2FastqDx, you must edit the file and create a corrected run manifest that includes sample and index information.

Run Manifest for Sequencing with Individually Addressable Lanes

If you are using the Individually Addressable Lanes add-on, the Lane column in your run manifest must correctly associate samples with both library pools.

- Lane 1 refers to the library pool loaded into the Library well of the sequencing cartridge.
- Lane 2 refers to the library pool loaded into the AUX well of the sequencing cartridge.

For an example run manifest for the Individually Addressable Lanes add-on, see *Sample Specification Examples* in the *Online Help*.

Analysis Overview

AVITI Dx OS calls bases, assigns quality scores (Q scores), and generates run metrics. The software extracts and corrects intensities from images to call a base, then assigns a Q score to the base.

Run Monitoring

During a run, the Details view displays initial estimates for primary-analysis-generated run metrics that monitor overall run health and progress. As the run progresses, metrics appear and regularly update. Sequencing runs that use the Individually Addressable Lanes add-on display metrics and charts for each library pool. The metrics are included in the run output and remain onscreen until you set up a new run.

The metrics and charts for a run depend on your workflow. Additional metrics appear in the charts, which you can cycle through. For more information on the types of metrics and charts that can appear during a run, see *Sequencing Metrics and Charts* in the *Online Help*.

NOTE
To obtain final metrics for a sequencing run, execute the Bases2FastqDx Software after the run completes. For more information, see the *Bases2FastqDx Documentation* in the *Online Help*.



A Example chart
B Carousel for available charts
C Example metrics
D Run progress information

Thumbnail Image

The thumbnail image displays a snapshot of the polonies on a tile from the first cycle in the run. The image is from the first cycle of the run. If you are performing a sequencing run with the Individually Addressable Lanes add-on and two library pools, AVITI Dx OS displays an image for each pool.

The thumbnail image can serve as a quality check for your run. The image indicates sample density and loading concentration on the flow cell. You can use the image as a quality check to identify overloaded or underloaded flow cells.

Run Output and Data Transfer

Run output is stored in a run folder. The run folder contains specific files depending on the run type. A storage connection transfers the run folder from the instrument to your local storage location. For more information, see *Storage Connections* on page 36.

Sequencing Run Output

The run folder for a sequencing run contains bases files with genomic data and other run data. Bases files are the primary output of a sequencing run. An AvitiRunStats.json file serves as the source file for run metrics. You can set up the integration of metrics into another system, such as a LIMS interface. For more information on output files, see *Sequencing Run Output Files* in the *Online Help*.

After a sequencing run, use Bases2FastqDx to perform demultiplexing and convert the bases files into FASTQ files for secondary analysis with the third-party software of your choice. For more information, see the *Bases2FastqDx Documentation* in the *Online Help*.

Local Disk Storage

Because the system software transfers runs to off-instrument storage locations, local disk storage is intended only for temporary storage. Accordingly, the instrument hard drive has sufficient space to store at least two runs and start an additional two runs. When you initiate run setup, AVITI Dx OS checks whether the system has sufficient space to support the run. If AVITI Dx OS indicates that the system does not have sufficient space, contact Element Technical Support.

CHAPTER 3

Maintenance

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Maintenance Schedule

A maintenance wash is recommended weekly and required every 30 days. AVITI Dx OS provides a warning 2 days before a maintenance wash is due.

Procedure	Frequency	Purpose
Maintenance wash	Every 7 days	Cleans the outside of the sippers and prevents microbial growth and particulate debris from accumulating in the fluidic system.

Element recommends the following maintenance schedule for optimal performance.

Procedure	Frequency	Purpose
Power cycle	Every 7 days	Reinitializes the system and resets the instrument computer, which helps maintain instrument performance.
Standby wash	Preparing for an idle period of ≥ 7 days	Prepares one or both sides for an idle period of ≥ 7 days.
Recovery wash	When advised by Element Technical Support after an unexpected run termination	Restores system fluidics to the same state as an automated post-run wash.
Air filter replacement	Every 6–12 months	Ensures proper cooling and continuous operation. The optimum frequency depends on lab cleanliness.
Exterior cleaning	As needed	Wipe the exterior with a damp microfiber cloth and Simple Green. Avoid harsh chemicals and abrasives.

To perform a wash after an incomplete run, see *Perform Recovery Wash* on page 53.

For a list of maintenance consumables, see the *AVITI Dx System Site Prep Guide (MA-00089)*.

Wash Tray Maintenance

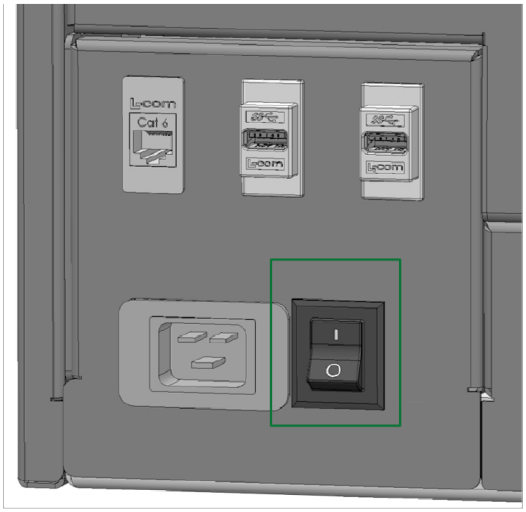
Keep the wash trays in good condition to maximize time between replacements and prevent cross-contamination.

- After each use, discard residual wash solution, rinse the wash tray with nuclease-free water, and air-dry upside down.
- Store clean and dry wash trays upside down. Stack up to two wash trays.

Power Cycle the System

A power cycle resets the instrument computer, safely shutting down and restarting the system to maintain performance or recover from a problem. Turning off the system without a proper power cycle is reserved for emergencies.

1. Select the user menu, and then select **Shut Down**.
2. When prompted, select **Shut Down** again to shut down the instrument computer.
3. Wait for the screen to go blank and a No Signal message to appear.
4. On the IO panel on the back of the instrument, press the power toggle switch to turn off the instrument.



5. Wait ***10 seconds*** to make sure the system fully shuts down.
6. On the IO panel, press the power toggle switch to turn on the instrument.

   —The system initializes and displays the Home screen.—
7. If a USB drive is connected to the instrument, reconnect it:

   a. In the taskbar, select **USB Drive**, and then select **Eject**.
   b. Detach the USB drive from the instrument.
   c. Reconnect the USB drive to the instrument.

   —Reconnecting the USB drive allows AVITI Dx OS to detect it after a power cycle.—

Perform a Maintenance Wash

The maintenance wash is a two-part wash that takes a total of ~1.5 hours. Wash 1 cleans the system, removing residual library and carryover. Wash 2 rinses the system, removing residual Wash 1 solution and preparing for the next run. Each wash requires specific volumes of freshly prepared wash solutions.

Prepare Wash Solutions

1. Gather the following materials:
   - » 2 L bottles (2)
   - » 4.00–4.99% sodium hypochlorite
   - » Gray wash tray
   - » Nuclease-free water
   - » Pipette controller
   - » Serological pipettes (2)
   - » Tween 20
   - » Used flow cell
   - » White wash tray

   —A used flow cell might already be present on the instrument.—
2. Add 1.5 L nuclease-free water to a new 2 L bottle.
3. Attach a new serological pipette to a pipette controller.
4. Add 37.5 ml 4.00–4.99% sodium hypochlorite to the bottle to prepare 1.54 L ~0.12% sodium hypochlorite.
5. Label the bottle **Wash 1 Solution**.
6. Cap the bottle and invert several times to mix.
7. Set aside Wash 1 Solution at room temperature. Use within the day or discard.
8. Add 1.5 L nuclease-free water to a new 2 L bottle.
9. Attach a new serological pipette to the pipette controller.
10. Add 4.5 ml Tween 20 to the bottle to prepare 1.5 L 0.3% Tween 20.
11. Label the bottle **Wash 2 Solution**.
12. Cap the bottle and invert several times to mix.
13. Set aside Wash 2 Solution at room temperature.

Initiate a Maintenance Wash

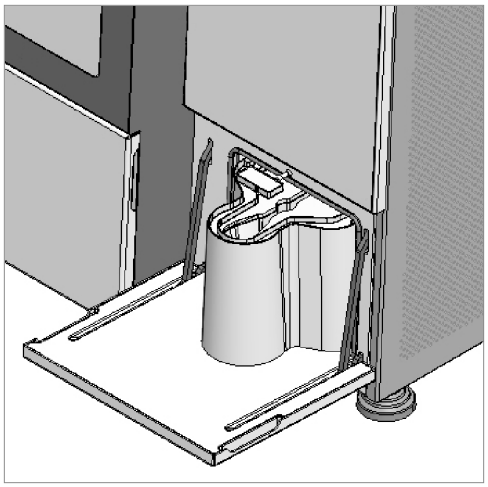
1. On the Home screen, select **New Run**.
2. If AVITI Dx OS prompts that the flow cell is missing, load a ***used*** flow cell:
   a. Select **Open Nest**.
   b. Place the used flow cell onto the nest and close the lid.
   c. Select **Close Nest**.
3. Select which side to wash:
   - » **Side A**—Set up a maintenance wash on side A.
   - » **Both**—Set up maintenance washes on sides A and B.

» **Side B**—Set up a maintenance wash on side B.

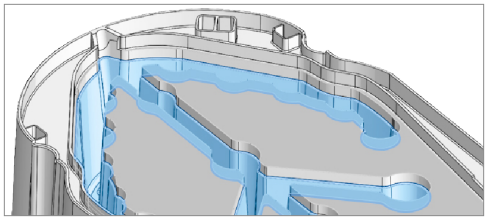
4. Select **Wash**, and then select **Maintenance**.
5. Select **Next** to proceed to the Load Wash 1 screen.

Load Wash 1 Solution

1. Open the reagent bay door.
2. Remove any materials from the reagent bay and set aside.
3. Place a clean, uncovered gray wash tray onto the open door.
4. Slide ~2/3 of the wash tray into the reagent bay, so the barcode edge is about flush with the entrance.



5. Add 590 ml freshly prepared Wash 1 Solution to the fill area, filling the wash tray to slightly above the lower fill line.



6. Slide the wash tray all the way into the reagent bay until it stops and close the reagent bay door.
7. Select **Next** to proceed to the Empty Waste screen.

Empty Waste and Run Wash 1

1. Open the waste bay door.
2. Unscrew the transport cap from the cap holder above the waste bay.
3. Remove the waste bottle from the waste bay and close the transport cap.

CAUTION
Waste bottle contents are considered hazardous. Dispose of waste according to local, state, and regional laws and regulations.

4. [Optional] Insert a funnel into a waste receptacle. Make sure the funnel is secure.
5. Open the transport cap and the vent cap.
6. Support the waste bottle with both hands and empty the waste:

a. Position the bottle over the funnel or waste receptacle.
   - If you inserted a funnel, align the handle to the inner edge of the funnel.
   - If you did not insert a funnel, center the handle over the waste receptacle.

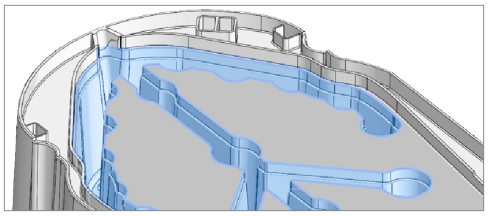
b. Tip the bottle forward and drain. Invert the bottle and shake to expel all droplets.

c. If necessary, wipe liquid off the bottle.

7. Close the vent cap and return the empty waste bottle to the waste bay.
8. Screw the transport cap onto the cap holder and close the waste bay door.
9. Select **Next** to open the Run Wash 1 screen and automatically start the wash, which takes ~34 minutes.
10. During the wash, process the materials removed from the reagent bay:
    - » If you removed a used buffer bottle and cartridge basket, follow the discard instructions in the user guide for the kit.
    - » If you removed a wash tray, follow the guidelines in *Wash Tray Maintenance* on page 27.
11. When the wash is complete, select **Next** to proceed to the Load Wash 2 screen.

Load Wash 2 Solution

1. Open the reagent bay door.
2. Remove the gray wash tray from the reagent bay and set aside.
   —Residual liquid in the wash tray is normal.—
3. Place a clean, uncovered white wash tray onto the open door.
4. Slide ~2/3 of the wash tray into the reagent bay, so the barcode edge is about flush with the entrance.
5. Add 660 ml freshly prepared Wash 2 Solution to the fill area, filling the wash tray to slightly above the upper fill line.



6. Slide the wash tray all the way into the reagent bay until it stops and close the reagent bay door.
7. [Optional] Store leftover Wash 2 Solution at 2°C to 8°C for ≤ 2 weeks.

Run Wash 2

1. Select **Next** to open the Run Wash 2 screen and automatically start the wash, which takes ~52 minutes.
2. When the wash is complete, select **Done** to return to the Home screen.
3. Leave all materials in the instrument.
4. Process the gray wash tray from the first wash per *Wash Tray Maintenance* on page 27.

Perform a Standby Wash

A standby wash takes ~52 minutes and flushes nuclease-free water through the fluidic system, removing any residual Tween 20. When complete, the washed side is idle. Performing a maintenance wash on the idle side ends the idle period and enables sequencing.

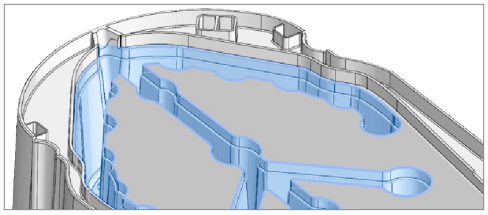
Initiate a Standby Wash

1. Gather the following materials:
   - » Nuclease-free water
   - » Used flow cell
   - » White wash tray

   —A used flow cell might already be present on the instrument.—
2. On the Home screen, select **New Run**.
3. If AVITI Dx OS prompts that the flow cell is missing, load a ***used*** flow cell:
   a. Select **Open Nest**.
   b. Place the used flow cell onto the nest and close the lid.
   c. Select **Close Nest**.
4. Select which side to wash:
   - » **Side A**—Set up a standby wash on side A.
   - » **Both**—Set up standby washes on sides A and B.
   - » **Side B**—Set up a standby wash on side B.
5. Select **Wash**, and then select **Standby**.
6. Select **Next** to proceed to the Load Water screen.

Load Nuclease-Free Water

1. Open the reagent bay door.
2. Remove any materials from the reagent bay and set aside.
3. Place a clean, uncovered white wash tray onto the open door.
4. Slide ~2/3 of the wash tray into the reagent bay, so the barcode edge is about flush with the entrance.
5. Add 660 ml nuclease-free water to the fill area, filling the wash tray to slightly above the upper fill line.



6. Slide the wash tray all the way into the reagent bay until it stops.
7. Close the reagent bay door.
8. Select **Next** to proceed to the Empty Waste screen.

Empty Waste and Run the Standby Wash

1. Open the waste bay door.
2. Unscrew the transport cap from the cap holder above the waste bay.
3. Remove the waste bottle from the waste bay and close the transport cap.

   CAUTION
   Waste bottle contents are considered hazardous. Dispose of waste according to local, state, and regional laws and regulations.

4. [Optional] Insert a funnel into a waste receptacle. Make sure the funnel is secure.
5. Open the transport cap and the vent cap.
6. Support the waste bottle with both hands and empty the waste:

   a. Position the bottle over the funnel or waste receptacle.
      - If you inserted a funnel, align the handle to the inner edge of the funnel.
      - If you did not insert a funnel, center the handle over the waste receptacle.

   b. Tip the bottle forward and drain. Invert the bottle and shake to expel all droplets.

   c. If necessary, wipe liquid off the bottle.

7. Close the vent cap and return the empty waste bottle to the waste bay.
8. Screw the transport cap onto the cap holder and close the waste bay door.
9. Select **Next** to open the Run Water screen and automatically start the wash.
10. When the wash is complete, select **Next** to proceed to the Remove Tray screen.

Unload the Wash Tray

1. When prompted, open the reagent bay door and remove the wash tray.

   —Residual liquid in the wash tray is normal.—
2. Close the reagent bay door.
3. Select **Done** to proceed to the Home screen.
4. Leave the flow cell in the nest.
5. Process the materials removed from the reagent bay:

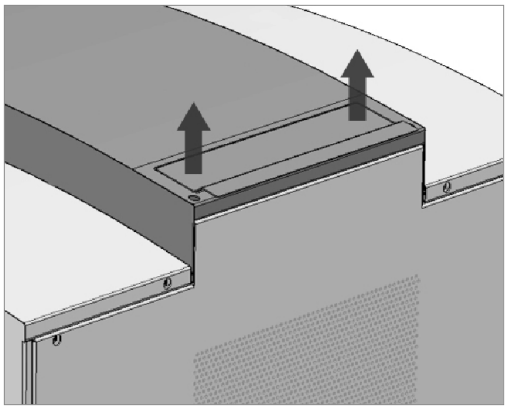
   » If you removed a used buffer bottle and cartridge basket, follow the discard instructions in the user guide for the kit.

   » If you removed a wash tray, follow the guidelines in *Wash Tray Maintenance* on page 27.

Replace the Air Filter

To ensure proper cooling and continuous operation of the system, replace your air filter every 12 months. If your site is located at a high elevation, replace your air filter every 6 months. For more information, see the *AVITI Dx System Site Prep Guide (MA-00089)*.

1. If the instrument is performing a run or washing, wait for the run or wash to complete.
2. Select the user menu, and then select **Shut Down**.
3. When prompted, select **Shut Down** again to shut down the instrument computer.
4. Wait for the screen to go blank and a No Signal message to appear.
5. On the IO panel on the back of the instrument, press the power toggle switch to turn off the instrument.
6. Using the flange toward the back of the instrument, lift the air filter tray out of the top.



7. Remove the air filter from the tray and discard.

   —The filter might be loose in the tray, which is normal.—
8. Place the tray on a table or benchtop.
9. With the small arrow on the side of the filter pointing up, place the new air filter into the tray.
10. Lower the tray into the instrument. Use the pins to align the tray to the rails and guide entry.
11. On the IO panel, press the power toggle switch to turn on the instrument.

    —The system initializes and displays the Home screen.—
12. Reset the air filter timer. See *Reset the Air Filter Time* on page 38.

CHAPTER 4

System Configuration

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System Connections

The AVITI Dx System uses a combination of network, internet, and storage connections to operate. Each system requires at least one storage connection.

Mode	Network Connection	Internet Connection	Storage Connection
Online	Internet	DHCP or static	Local
	Local	DHCP or static	Local
Offline	Local	None	Local

Storage Connections

A storage connection establishes an off-instrument location for run output files. Each run delivers bases files and other run output files to the default storage location unless you specify a different location during run setup.

AVITI Dx OS supports local storage connections:

- A local storage connection transfers files to a storage location on a local network or USB drive.

Storage Connection Requirements

Adding a storage connection requires permissions, network information, and account information that your IT administrator can provide.

For comprehensive storage requirements, see the *AVITI Dx System Site Prep Guide (MA-00089)*.

Supported Storage Connections

For local storage, AVITI Dx OS supports Server Message Block (SMB) and USB.

The storage location for a cloud storage connection is a bucket. A connected bucket is available to all systems. Local storage is exclusive to the system.

Local Storage

Local Storage Connection	Description
SMB	• Connects the system to the server running SMB via a path to a folder. • Uses the SMB protocol based on service user authentication to transfer data. • Enables import of a run manifest from an SMB storage location during run setup. • Supports automatic export of log files from offline systems. • Supports Kerberos or NTLMv2 authentication.
USB	• Transfers data and log files to a USB drive connected to the instrument. • Supports automatic and manual export of log files from offline systems. • Supports USB-A 3.0 or newer versions and FAT32 or exFAT formats. • Must store ≥ 1.6 TB of data, which is sufficient for at least two full runs.

Configure General Settings

General settings include the instrument name setting, the on-screen keyboard setting, the AVITI Dx OS interface language setting, file output settings for instrument priming and wash runs, air filter time resetting, and read-only settings that control the instrument profile. For offline systems, general settings also include features to export log files. For instructions, see *Exporting Log Files* on page 45.

Name the Instrument

1. On the taskbar, select **Settings**.
2. Select the **General** tab, and then select **Edit**.
3. Enter a preferred name consisting of 1–20 alphanumeric characters, hyphens (-), and underscores (_) to identify the instrument.

   —The default name is the serial number, field-programmable gate array (FPGA) ID, or Unnamed Instrument.—
4. Select **Save** to apply the name.

Configure On-Screen Keyboard

1. On the taskbar, select **Settings**.
2. Select the **General** tab.
3. Select the **Show on-screen keyboard** toggle to enable or disable the on-screen keyboard for text-entry fields.

Configure Language

1. On the taskbar, select **Settings**.
2. Select the **General** tab.
3. Select the down arrow next to the current language in the **Language** drop-down box.
4. Select a preferred language from the list.

   —A confirmation window displays.—
5. Select **Proceed** to apply the language change.

Configure File Output Settings

1. On the taskbar, select **Settings**.
2. Select the **General** tab.
3. Select the **Save prime output to storage** toggle to enable or disable the output files for instrument priming.
4. Select the **Save wash run output to storage** toggle to enable or disable the output files for a wash run.

   —When you enable the setting, AVITI Dx OS requires you to configure a storage connection before you start a wash.—

Review Read-Only Settings

1. On the taskbar, select **Settings**.
2. Select the **General** tab.
3. Review the following read-only settings. To change a setting, contact Element Technical Support.

Setting	Default	Description
High Elevation	Disabled	Calibrates the system to operate at a high elevation
Offline Mode	Disabled	Prevents an internet connection

Reset the Air Filter Time

1. On the taskbar, select **Settings**.
2. Select the **Service** tab.
3. From the Reset Air Filter Time setting, select **Reset**.
4. When prompted, select **Reset** again to confirm that you have replaced your air filter. The timer is reset.

Connect to the Network

Network settings connect the system to your network via a Dynamic Host Configuration Protocol (DHCP) or a static IP address. When the system is connected to an Ethernet port, AVITI Dx OS automatically connects to a DHCP server and autopopulates the network settings. Alternatively, you can assign a static IP address and manually configure the network settings.

Select a DHCP Server

1. On the taskbar, select **Settings**.
2. Select the **Network** tab.
3. In the drop-down menu, select **Automatic (DHCP)**.

   —AVITI Dx OS assigns a dynamic IP address and all other network settings.—

Assign a Static IP Address

1. On the taskbar, select **Settings**.
2. Select the **Network** tab.
3. In the drop-down menu, select **Manual**.

   —AVITI Dx OS assigns a unique and permanent IP address.—
4. Select **Edit**, and then configure the following network settings.

Setting	Example	Description
IP Address	11.2.34.178	The destination IP address
Gateway	11.2.34.177	The IP address of the gateway computer that manages network communications
Subnet Mask	11.2.34.176	The subnet mask that separates the IP address into host and network addresses
Name Server IP(s)	ngs-1.yourlab.com	The names of up to four Domain Name System (DNS) servers that provide IP addresses

   —Two additional network settings, Host name and Mandatory Access Control (MAC) address, are read-only.—
5. Select **Save** to apply the settings and connect to the network.

Add Storage Connections

The Storage tab lists storage connections for the system, including available storage for each local storage connection. An Element representative adds the first storage connection at installation. After installation, you can add additional storage connections.

AVITI Dx OS only lets you add local storage connections.

Add an SMB Storage Connection

1. On the taskbar, select **Settings**.
2. Select the **Storage** tab.
3. Select **Add Storage**, and then select **Local File Server (SMB)** as the storage provider.
4. In the Name field, enter a preferred name for the storage connection.
5. Complete the following fields to configure an SMB network storage location for the SMB storage connection.

Field	Instruction
Host	Enter the host network IP address or fully qualified domain name (FQDN). The Kerberos authentication protocol requires an FQDN. • Example IP address: 1.222.333.44 • Example FQDN: datapc.elembio.com
Port	Enter a port number for the file transfer service or leave blank to accept the default of port 445.
Workgroup/Domain	Enter the name of the workgroup or domain that the user belongs to. The Kerberos authentication protocol requires you to enter the Kerberos realm name. • Example workgroup/domain for Kerberos: elembio.com
Share	Enter the name of the share that makes the directory accessible to SMB.
Path	Enter the path to an ***existing*** folder where you want to output data.
User	Enter the user name for the service user.
Password	Enter the password for the service user.

—All fields except Port and Path are required. Certain server configurations require a work group or domain.—

6. In the Temporary Prefix drop-down menu, select **Disabled** or **Enabled**.

   —The Temporary Prefix setting appends two underscores to the name of a file (e.g., __ExampleFileName.zip) while in transfer to the SMB location. The prefix disappears when the file transfer finishes.—

7. In the Session Security drop-down menu, select a setting for the level of encryption:
   - **High (Recommended)**—AVITI Dx OS requests an encrypted connection with the SMB server. This option is the default setting.
   - **Medium**—The SMB server determines use of an encrypted connection. The server determines if a connection is encrypted or signed.
   - **Low**—AVITI Dx OS disables extended SMB security negotiation (SPNEGO) for wider compatibility with SMB servers. The SMB server determines if a connection is encrypted or signed.
8. In the File Checksums drop-down menu, select **Disabled** or **Enabled**.

   —The File Checksums setting computes the MD5 checksum for each transferred file and lists them in the RunUploaded.json file. You can use this information to verify the integrity of files.—

9. If prompted, select **Confirm** to set the Session Security selection.
10. Select **Save** to add the storage connection.

Add a USB Storage Connection

For a USB storage connection, the instrument supports USB-A 3.0 or newer versions and the FAT32 or exFAT formats. The USB drive must have > 1.6 TB of available storage space, and the USB name can only use alphanumeric characters, hyphens, and underscores.

1. Connect a USB drive to a USB port on the side or back of the instrument.
2. On the taskbar, select **Settings**.
3. Select the **Storage** tab.
4. Select **Add Storage**, and then select **USB Drive** as the storage provider.
5. In the USB Drive drop-down menu, select the USB drive connected to the instrument.
6. In the Name field, enter a preferred name for the storage connection.
7. Select **Save** to add the storage connection.

   —AVITI Dx OS makes sure the USB drive is connected to the instrument and has write permission and sufficient storage.—

Disconnect the USB for a Storage Connection

1. Select **More** for the USB storage connection, and then select **Eject**.
2. Detach the USB drive from the instrument.
3. To reuse the USB after disconnecting, reconnect the device to a USB port.

   —The USB name must remain the same for AVITI Dx OS to identify the storage connection.—

Manage Storage Connections

Storage settings manage storage connections and include setting the default storage connection. Unless you reset the default storage connection, the default storage connection is the first local network location.

You can verify any storage connection, and connections can be edited and deleted in AVITI Dx OS.

Verify a Storage Connection

1. On the taskbar, select **Settings**.
2. Select the **Storage** tab.
3. For the applicable storage connection, select **More**, and then select **Verify Storage**.
4. Wait ~20 seconds for a success message to appear, indicating a valid storage connection.

   —AVITI Dx OS indicates that the connection is connected, unverified, or partially verified with a blocked network.—
5. If AVITI Dx OS cannot verify the storage connection, troubleshoot:

   a. Make sure the storage connection is correctly set up.
      - For an SMB storage connection, check the permissions associated with the users.
      - For a USB storage connection, make sure the USB is not ejected, and check that the USB name and type are correct. For USB requirements, see *Local Storage* on page 36.

   b. If the storage connection is correctly set up, contact Element Technical Support.

Set the Default Storage Connection

1. On the taskbar, select **Settings**.
2. Select the **Storage** tab.
3. For the applicable storage connection, select **More**, and then select **Set as Default**.
4. When prompted, select **Set Default**.

Edit a Local Storage Connection

1. On the taskbar, select **Settings**.
2. Select the **Storage** tab.
3. For the local storage connection you want to edit, select **More**, and then select **Edit**.

   —Editing a busy storage connection can affect where run output is stored.—
4. On the Edit Storage Connection screen, edit any of the following fields.

Field	Instruction
Name	Enter a preferred name for the storage connection.
Workgroup/Domain	Enter the name of the workgroup or domain that the user belongs to. The Kerberos authentication protocol requires you to enter the Kerberos realm name. • Example workgroup/domain for Kerberos: elembio.com
User	Enter the user name for the service user.
Password	Enter the password for the service user.
Session Security	Select **High (Recommended)**, **Medium**, or **Low**.

—The Host, Share, Port, Path, Temporary Prefix, and File Checksums fields are read-only. If you must edit these fields, create another storage connection.—

5. Select **Save** to apply the edits and update the storage connection.

Delete a Local Storage Connection

1. On the taskbar, select **Settings**.
2. Select the **Storage** tab.
3. For the local storage connection you want to delete, select **More**, and then select **Delete**.
4. When prompted, select **Delete**.

   —AVITI Dx OS does not allow you to delete a busy storage connection.—

Update the Software

For software updates contact ElemBio Support at support@elembio.com.

Manage an Offline System

For AVITI Dx System in offline mode, AVITI Dx OS lets you export log files, password-protect the system, and perform manual software updates. To install add-ons, an offline system requires a specific procedure that uses a USB drive with an add-on key downloaded from ElemBio Cloud. These procedures and features are unique to offline mode and help manage the system while offline.

Exporting Log Files

An offline AVITI Dx System supports manual export of log files to a USB drive, as needed, to provide troubleshooting resources to Element Technical Support. AVITI Dx OS lets you perform a **Run Log Export**, a **Limited Log Export**, or a **Full Offline Log Export**:

- **Run Log Export**—Export the complete set of logs for a selected run. Use when Element Technical Support requests logs for a specific run.
- **Limited Log Export**—Export a small, encrypted file of summary data for a selected run. This file does not include system, event, or control logs. Use only when directed by Element Technical Support; do not use for general troubleshooting.
- **Full Offline Log Export**—Export system, event, control, and run logs for a selected date range. Use to support in-depth system and run troubleshooting.

When exporting log files to a USB drive, a solid-state drive (SSD) offers significant time savings compared to a flash drive.

Manually Export Run Log Files

1. Connect a USB drive to a USB port on the side or back of the instrument.
2. On the taskbar, select **Settings**.
3. Select the **General** tab.
4. In the drop-down menu for manual exports, select **Run Log Export**.
5. In the USB Drive drop-down menu, select the USB drive connected to the instrument.
6. In the Export Run drop-down menu, select the run for which you want log files.
   - Only runs from the last 14 days are available.
   - If you select an active run, only certain files might be available.
   - If you attempt to export log files soon after an active run starts, you might receive an error message. Wait until the run progresses further and attempt the export again.
7. Select **Export**.

   —AVITI Dx OS exports the log files to the USB drive.—
8. On the taskbar, select **USB Drive**, and then select **Eject** to disconnect the USB drive.
9. Detach the USB drive from the instrument.
10. Upload the log files to the location that Element Technical Support provides.

Manually Export Limited Log Files

1. Connect a USB drive to a USB port on the side or back of the instrument.
2. On the taskbar, select **Settings**.
3. Select the **General** tab.
4. In the drop-down menu for manual exports, select **Limited Log Export**.
5. In the USB Drive drop-down menu, select the USB drive connected to the instrument.

6. In the Export Run drop-down menu, select the run for which you want log files.
   - » Only runs from the last 14 days are available.
   - » If you select an active run, only certain files might be available.
   - » If you attempt to export log files soon after an active run starts, you might receive an error message. Wait until the run progresses further and attempt the export again.
7. Select **Export**.

   —AVITI Dx OS exports the log files to the USB drive.—
8. On the taskbar, select **USB Drive**, and then select **Eject** to disconnect the USB drive.
9. Detach the USB drive from the instrument.
10. Upload the log files to the location that Element Technical Support provides.

Manually Export Full Offline Log Files

1. Connect a USB drive to a USB port on the side or back of the instrument.
2. On the taskbar, select **Settings**.
3. Select the **General** tab.
4. In the drop-down menu for manual exports, select **Full Offline Log Export**.
5. In the USB Drive drop-down menu, select the USB drive connected to the instrument.
6. Enter an Export Range using the Start Date, End Date, and time fields.

   —The Export Range cannot exceed 14 days.—
7. [Optional] Select the **All Day** toggle to remove time fields and export all log files for the dates in the Export Range.
8. Select **Export**.

   —AVITI Dx OS exports the log files to the USB drive.—
9. On the taskbar, select **USB Drive**, and then select **Eject** to disconnect the USB drive.
10. Detach the USB drive from the instrument.
11. Upload the log files to the location that Element Technical Support provides.

Manage Users

Use the Settings menu to manage user accounts and account settings. System Administrators can export audit logs and change, reset, and deactivate user accounts.

Add a User

1. On the taskbar, select **Settings**.
2. Select the **Manage Users** tab.
3. Select **Add User**.
4. The New User screen appears.
5. Fill in the required fields.
6. In the Password field, enter a new password.

   —The password must be 8 to 64 characters and can include letters, numbers, and special characters. Spaces are not allowed.—
7. In the Confirm Password field, reenter the new password.
8. Select **Save**.

Set a Password

1. On the taskbar, select **Settings**.
2. Select the **Manage Users** tab.
3. Locate the user account in the Users list.
4. Select the More Options icon (**...**), then select **Edit**.
5. In the Password field, enter a new password.

   —The password must be 8 to 64 characters and can include letters, numbers, and special characters. Spaces are not allowed.—
6. In the Confirm Password field, reenter the new password.
7. Select **Save**.
8. When prompted, select **Yes, Set Password**.

Change the Password

1. On the taskbar, select **Settings**.
2. Select **Manage Users**.
3. Locate the user account in the Users list.
4. Select the More Options icon (**...**), then select **Edit**.
5. In the Current Password field, enter the current password.
6. In the Password field, enter a new password.

   —The password must be 8 to 64 characters and can include letters, numbers, and special characters. Spaces are not allowed.—
7. In the Confirm Password field, reenter the new password.
8. Select **Save** to apply the new password.

Reset a Lost Password

If you forget your password, ask an administrator to set a new password for your account. Administrators refer to *Set a Password* on page 47 for the steps.

If an administrator forgets their password

If the system has multiple administrators: Ask an alternate administrator to set a new password for the account. The alternate administrator can refer to *Set a Password* on page 47 for the steps.

If the system has only one administrator: Contact Element Technical Support to schedule a Field Service Engineer (FSE) visit. The FSE must visit the instrument to reset the password.

NOTE
If you select **Reset Password?** on the login screen, the system displays a message that recommends asking an administrator to set a temporary password and, if that is not possible, contacting Element Technical Support.

Deactivate a User

1. On the taskbar, select **Settings**.
2. Select the **Manage Users** tab.
3. Locate the user account in the Users list.
4. Select the More Options icon (**...**), then select **Deactivate**.

5. Select **Deactivate** to confirm.

Export Audit Log

1. On the taskbar, select **Settings**.
2. Select the **Manage Users** tab.
3. Select the **Export Audit Log**.
4. In the USB Drive drop-down menu, select the connected USB drive.
5. Select **Export**.

   —AVITI Dx OS exports the audit log to the USB drive as a PDF file.—

   NOTE
   Exporting the audit log PDF generates a matching .sha256 file on the USB drive. Use the checksum in this file to verify the integrity of the exported PDF.

CHAPTER 5

Troubleshooting

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General Troubleshooting

Error messages communicate hardware or software problems and describe both the problem and solution. A power cycle typically resolves a problem. For instructions, see *Power Cycle the System* on page 28. If a problem persists, contact Element Technical Support.

Problem	Solution
The monitor does not display AVITI Dx OS.	Power cycle the system.
Initialization sequence does not complete, and the loading screen persists.	
Software, keyboard, or mouse stop operating.	
The reagent or waste bay contains liquid.	See *Clean Spills and Leaks* on page 57.
Liquid is spilling from the front or bottom of the instrument.	
The nest is wet.	
AVITI Dx OS detects a full waste bottle but the bottle is empty.	Reload the waste bottle and make sure the waste bay is unobstructed.
Reagent bay contains condensation.	Dry the inside of the reagent bay with a clean, dry microfiber cloth. Avoid sensors and cables.
The door to the reagent, nest, or waste bay is locked, or you need to open a door to retrieve or swap consumables outside of a run.	RUO mode only. On the taskbar, select **Settings**, and then select the **Services** tab. In the **Troubleshooting Tools** section, select **Open Controls** next to **Instrument Door Controls**. On the Instrument Door Controls screen, select the button for the door you want to open or unlock, follow the on-screen instructions, and then select **Finish**.
Instrument does not accept a USB device.	Confirm that the USB device meets the following requirements: • Contains > 1.6 TB available space • USB is USB-A 3.0 or a newer version • Formatted as FAT32 or exFAT format • Name is alphanumeric characters, hyphens, and underscores only
AVITI Dx OS does not proceed with run setup despite sufficient on-instrument storage.	Set up a storage connection. A storage connection is required for a run. On-instrument storage is reserved as a backup in case of network disruption.
A run continues after you stop it.	Wait for the run to stop. AVITI Dx OS waits for a safe point to stop the run, which can take several minutes to ~2 hours depending on the run stage.
Network connection is lost in the middle of a run.	Wait for the AVITI Dx System to reconnect to the network. Sequencing chemistry is not impacted by network disruptions. After the system reconnects, data transfer resumes. The system has enough local disk storage for two sequencing runs.
Connection to storage location is lost and the instrument cannot reconnect.	Confirm with your IT department that all necessary ports and URLs in the *AVITI Dx System Site Prep Guide (MA-00089)* are allowlisted.

Problem	Solution
Run folder is missing data.	Make sure the user interface indicates that the system is uploading and wait for the upload to complete. • A slow connection delays data transfer. • Data transfer failure prompts a notification.

Cancel Runs

AVITI Dx OS displays the following buttons for canceling runs and washes:

- **Discard**—Cancels run. The button appears when you can discard setup without compromising consumables.
- **Stop**—Appears on the Home screen and cancels an active run. The button is always enabled so you can free the instrument when run parameters are incorrect, data quality is poor, or a hardware problem occurs.

Discard Run Setup

1. On any run setup screen before priming, select **Discard**.
2. When prompted to confirm the discard, select an option:
   - » **Unlock Door A** or **Unlock Door B**—Discard the run and save the cartridge. Proceed to step 3.
   - » **Discard Setup**—Discard the run, delete the run, and return to the Home screen without saving the cartridge. No further action is required.
3. Open the reagent bay door and remove the cartridge.
4. Place the cartridge on ice or refrigerate at 2°C to 8°C.
5. Place a clean, uncovered white wash tray onto the open reagent bay door.
6. Slide ~2/3 of the wash tray into the reagent bay, so the barcode edge is about flush with the entrance.
7. Add 660 ml nuclease-free water to the fill area, filling the wash tray to slightly above the upper fill line.
8. Slide the wash tray all the way into the reagent bay until it stops.
9. Close the reagent bay door.
10. Set up a new run and use the cartridge within ***4 hours***.

Discard Wash Setup

1. On any wash setup screen, select **Discard**.
2. When prompted to confirm the discard, select **Discard Setup**.

Stop an Active Run

Stopping an active run is a two-part process: stop the run and then perform a ~60-minute recovery wash to remove residual library from the fluidic system.

CAUTION
Stopping a run is ***final***. You cannot resume a stopped run or reuse any of the consumables.

1. On the applicable side of the Home or Run Details screen, select **Stop**.
2. When prompted, select **Yes, Stop Run**. Wait for the current step to complete and the run to terminate.
3. Proceed to *Perform Recovery Wash* on page 53 and complete the recovery wash.

Perform Recovery Wash

After a run has been stopped or after any run does not complete, perform a ~60-minute recovery wash to remove residual library from the fluidic system.

Prepare Wash 2 Solution

1. Gather the following materials:
   - » 2 L bottle
   - » Nuclease-free water
   - » Pipette controller
   - » Serological pipette
   - » Tween 20
   - » Used flow cell
   - » White wash tray

   —A used flow cell might already be present on the instrument.—
2. Add 1.5 L nuclease-free water to a new 2 L bottle.
3. Attach a new serological pipette to a pipette controller.
4. Add 4.5 ml Tween 20 to the bottle to prepare 1.5 L 0.3% Tween 20.
5. Label the bottle **Wash 2 Solution**.
6. Cap the bottle and invert several times to mix.
7. Set aside Wash 2 Solution at room temperature.

Initiate a Recovery Wash

1. On the Home screen, select **New Run**.
2. If AVITI Dx OS prompts that the flow cell is missing, load a ***used*** flow cell:
   a. Select **Open Nest**.
   b. Place the used flow cell onto the nest and close the lid.
   c. Select **Close Nest**.
3. Select which side to wash:
   - » **Side A**—Set up a recovery wash on side A.
   - » **Both**—Set up recovery washes on sides A and B.
   - » **Side B**—Set up a recovery wash on side B.
4. Select **Wash**, and then select **Recovery**.
5. Select **Next** to proceed to the Load Wash 2 screen.

Load Wash 2 Solution

1. Open the reagent bay door.
2. Remove the buffer bottle and cartridge basket from the reagent bay. Set aside both materials.
3. Place a clean, uncovered white wash tray onto the open door.

4. Slide ~2/3 of the wash tray into the reagent bay, so the barcode edge is about flush with the entrance.
5. Add 660 ml freshly prepared Wash 2 Solution to the fill area, filling the wash tray to slightly above the upper fill line.
6. Slide the wash tray all the way into the reagent bay until it stops.
7. Close the reagent bay door, and select **Next** to proceed to the Empty Waste screen.
8. [Optional] Store leftover Wash 2 Solution at 2°C to 8°C for ≤ 2 weeks.

Empty Waste and Run Wash 2

1. Open the waste bay door.
2. Unscrew the transport cap from the cap holder above the waste bay.
3. Remove the waste bottle from the waste bay and close the transport cap.

   CAUTION
   Waste bottle contents are considered hazardous. Dispose of waste according to local, state, and regional laws and regulations.
4. [Optional] Insert a funnel into a waste receptacle. Make sure the funnel is secure.
5. Open the transport cap and the vent cap.
6. Support the waste bottle with both hands and empty the waste:
   a. Position the bottle over the funnel or waste receptacle.
      - If you inserted a funnel, align the handle to the inner edge of the funnel.
      - If you did not insert a funnel, center the handle over the waste receptacle.
   b. Tip the bottle forward and drain. Invert the bottle and shake to expel all droplets.
   c. If necessary, wipe liquid off the bottle.
7. Close the vent cap and return the empty waste bottle to the waste bay.
8. Screw the transport cap onto the cap holder and close the waste bay door.
9. Select **Next** to open the Run Wash 2 screen and automatically start the wash.
10. When the wash is complete, select **Next** to proceed to the Home screen.
11. Discard the sequencing cartridge and buffer bottle and wash the basket. See the discard instructions in the user guide for your sequencing kit.

Perform Service Wash

Perform a service wash only when directed by Element Technical Support to troubleshoot a suspected fluidic obstruction. After the service wash is complete, Element Technical Support reviews the wash logs to determine whether the obstruction has been resolved..

Prepare Wash 2 Solution

1. Gather the following materials:
   - » 2 L bottle
   - » Nuclease-free water
   - » Pipette controller
   - » Serological pipette
   - » Tween 20
   - » Used flow cell
   - » White wash tray

   —A used flow cell might already be present on the instrument.—
2. Add 1.5 L nuclease-free water to a new 2 L bottle.
3. Attach a new serological pipette to a pipette controller.
4. Add 4.5 ml Tween 20 to the bottle to prepare 1.5 L 0.3% Tween 20.
5. Label the bottle **Wash 2 Solution**.
6. Cap the bottle and invert several times to mix.
7. Set aside Wash 2 Solution at room temperature.

Initiate a Service Wash

1. On the Home screen, select **New Run**.
2. If AVITI Dx OS prompts that the flow cell is missing, load a ***used*** flow cell:
   a. Select **Open Nest**.
   b. Place the used flow cell onto the nest and close the lid.
   c. Select **Close Nest**.
3. Select which side to wash:
   - » **Side A**—Set up a service wash on side A.
   - » **Both**—Set up recovery washes on sides A and B.
   - » **Side B**—Set up a recovery wash on side B.
4. Select **Wash**, and then select **Service**.
5. Select **Next** to proceed to the Load Wash 2 screen.

Load Wash 2 Solution

1. Open the reagent bay door.
2. Remove the buffer bottle and cartridge basket from the reagent bay. Set aside both materials.
3. Place a clean, uncovered white wash tray onto the open door.

4. Slide ~2/3 of the wash tray into the reagent bay, so the barcode edge is about flush with the entrance.
5. Add 660 ml freshly prepared Wash 2 Solution to the fill area, filling the wash tray to slightly above the upper fill line.
6. Slide the wash tray all the way into the reagent bay until it stops.
7. Close the reagent bay door, and select **Next** to proceed to the Empty Waste screen.
8. [Optional] Store leftover Wash 2 Solution at 2°C to 8°C for ≤ 2 weeks.

Empty Waste and Run Wash 2

1. Open the waste bay door.
2. Unscrew the transport cap from the cap holder above the waste bay.
3. Remove the waste bottle from the waste bay and close the transport cap.

   CAUTION
   Waste bottle contents are considered hazardous. Dispose of waste according to local, state, and regional laws and regulations.

4. [Optional] Insert a funnel into a waste receptacle. Make sure the funnel is secure.
5. Open the transport cap and the vent cap.
6. Support the waste bottle with both hands and empty the waste:
   a. Position the bottle over the funnel or waste receptacle.
      - If you inserted a funnel, align the handle to the inner edge of the funnel.
      - If you did not insert a funnel, center the handle over the waste receptacle.
   b. Tip the bottle forward and drain. Invert the bottle and shake to expel all droplets.
   c. If necessary, wipe liquid off the bottle.
7. Close the vent cap and return the empty waste bottle to the waste bay.
8. Screw the transport cap onto the cap holder and close the waste bay door.
9. Select **Next** to open the Run Wash 2 screen and automatically start the wash.
10. When the wash is complete, select **Next** to proceed to the Home screen.
11. Discard the sequencing cartridge and buffer bottle and wash the basket. See the discard instructions in the user guide for your sequencing kit.

Clean Spills and Leaks

Clean the nest, waste bay, or reagent bay to recover from a leak or spill observed when setting up a run or wash. A leak or spill that occurs in the waste bay during a run causes an error and requires cleaning and contacting Element Technical Support.

If the bottom of the instrument is leaking or liquid is spilling from the front of the instrument: shut down and unplug the instrument if doing so is safe and contact Element Technical Support.

Clean the Nest

1. Dampen a microfiber cloth with isopropyl alcohol.
2. Wipe the nest with the damp microfiber cloth and allow to dry.
3. If necessary, use a polyurethane foam-tip swab to clean additional areas around the nest.
4. Resume run or wash setup.

Clean the Reagent Bay

1. Keep the reagent bay door open.
2. Remove any materials from the reagent bay and set aside.
3. Wipe the interior of the reagent bay with a damp microfiber cloth, cleaning to the back of the bay while avoiding sensors and cables.
4. Inspect the exterior of the instrument for any visible fluid. If necessary, wipe with a damp microfiber cloth.
5. Resume run or wash setup.

Clean the Waste Bay

1. Keep the waste bay door open. If the leak occurs during a run, open the door:
    a. Wait for any runs or washes on the unaffected side to finish.
    b. On the taskbar, select **Notifications**.
    c. On the applicable error, select **Unlock Waste Module Door**.
    d. Open the waste bay door.
2. Unscrew the transport cap from the cap holder on the affected side.
3. Remove the waste bottle from the waste bay and close the transport cap.

    CAUTION
    Waste droplets might be on the exterior of the waste bottle.
4. Inspect the waste bottle for cracks, holes, and other defects.
5. [Optional] Insert a funnel into a waste receptacle. Make sure the funnel is secure.
6. Open the transport cap and the vent cap.
7. Support the waste bottle with both hands and empty the waste:
    a. Position the bottle over the funnel or waste receptacle.
        - If you inserted a funnel, align the handle to the inner edge of the funnel.
        - If you did not insert a funnel, center the handle over the waste receptacle.
    b. Tip the bottle forward and drain. Invert the bottle and shake to expel all droplets.

c. If necessary, wipe liquid off the bottle.

8. Close the vent cap, leave the transport cap open, and set aside the waste bottle.
9. Wipe the interior of the waste bay with a damp microfiber cloth.
10. Inspect the exterior of the instrument for any visible fluid. If necessary, wipe with a damp microfiber cloth.
11. Return the waste bottle to the waste bay.
    - » If the bottle is defective and you have a spare, load the spare.
    - » If the bottle is defective and you do not have a spare, load the defective bottle. Do not use the affected side until the defective waste bottle is replaced.

    —A run or wash on either side requires the presence of both bottles.—
12. Screw the transport cap onto the cap holder and close the waste bay door.
13. Resume run or wash setup. If necessary, set up a new run with new consumables and clean accessories.

CHAPTER 6

Safety and Compliance

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General Safety

Review this chapter before operating or maintaining the AVITI Dx System to ensure safe, correct usage. The procedures described in this guide are tested and optimized, so any deviation can compromise results, cause personal injury, or damage the instrument. All personnel operating the instrument must be trained in correct operation and safety.

The *AVITI Dx System Site Prep Guide (MA-00089)* provides delivery information and installation requirements, including instrument specifications, power specifications, and environmental conditions. A field service engineer (FSE) installs the AVITI Dx System.

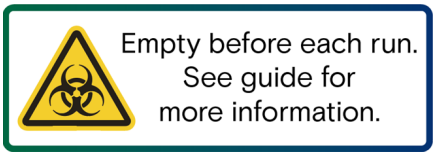
WARNING
Do not attempt to move the instrument, which can result in injury. Only trained Element personnel are qualified to safely move the instrument.

WARNING
Do not position the instrument in a way that restricts access to the rear power switch. The rear-mounted power switch, located next to the power cord inlet, serves as the disconnecting device for this instrument. Install the instrument with the clearance specified in the *AVITI Dx System Site Prep Guide (MA-00089)* so the switch remains visible and operable at all times.

Safety Labels

The following table lists the safety labels affixed to the instrument. The labels identify potential hazards associated with installation, service, and operation. Follow the procedures in this guide as described to avoid interactions that expose you to these hazards.

WARNING
This product can expose you to chemicals including formaldehyde, which is known to the State of California to cause cancer, and methanol, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Potential Hazard	Label	Description
Class 4 Laser		The instrument is a Class 1 laser product that contains a Class 4 laser. See *Laser Safety* on page 61.
Heat hazard		The nest has a hot surface and exposure can cause burns.
Biological risks		Indicates biohazard risk from spent reagents and library collected in the waste bottles. Use appropriate biohazard precautions when emptying waste bottles before each run.

Laser Safety

The AVITI Dx System is certified as a Class 1 laser product per the US Federal Product Performance Standard for Laser Products requirements described in 21 CFR Subchapter J. The exception to these requirements is the deviations described in FDA Laser Notice #56. The product is classified per IEC/EN 60825-1:2014.

WARNING
Adjusting or performing procedures other than those described in this guide or other Element guides can result in hazardous radiation exposure.

Class 4 Laser

The instrument is a Class 1 laser product that contains a Class 4 laser. The Class 4 laser produces Class 4 levels of visible laser radiation, which can be hazardous to eyes and skin. Protective shells and safety interlocks prevent exposure or access to laser radiation levels that exceed Class 1 during operation, maintenance, or normal service.

The following figure depicts the label that identifies noninterlocked portions of the shells that prevent access to laser radiation. Additionally, the nest bay and both reagent bays contain barcode scanners that emit Class 1 levels of laser radiation.

Label identifying noninterlocked locations:



Operating Conditions

Do not operate an AVITI Dx System with bypassed interlocks, damaged shells, or any portion of the shells removed. These conditions make Class 4 levels of laser radiation possible and risk exposure to direct or reflected laser light.

Only Element service personnel, Element-authorized agents, or Element-trained personnel can perform services that require internal interlock bypass or removal of portions of the shells. If you are present during service, take the proper safety precautions to mitigate the risk of direct and reflected laser light.

Product Compliance

The AVITI Dx System meets the EU requirements for safety and electromagnetic compatibility (EMC). The system has been tested to and complies with the standards in the following sections.

EU Safety and EMC Standards

The AVITI Dx System has been tested to and complies with the following safety standards:

- Low Voltage Directive 2014/35/EU
  - » EN 61010-1, general safety requirements for electrical equipment for measurement, control and laboratory use
  - » EN 61010-2-010, particular requirements for laboratory equipment for the heating of materials
  - » EN 61010-2-081, particular requirements for automatic and semiautomatic laboratory equipment for analysis and other purposes
  - » EN 60825-1, safety of laser products

The system has been tested to and complies with the following EMC standards:

- EMC Directive 2014/30/EU, EMC requirements
  - » EN 61326-1 and 61326-2, general EMC requirements for electrical equipment for measurement, control and laboratory use

The system also complies with the Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU) as amended by the Directive (EU) 2015/863. The directives restrict the use of certain hazardous substances in electrical and electronic equipment.

Regulatory Markings

The following markings indicate that the instrument complies with conformity requirements, including EMC and safety requirements, for the EU and the US.

Symbol	Description
CE	European Conformity (CE) Marking
	WEEE Marking for EU
EC REP	QbD RepS BV, Groenenborgerlaan 16, 2610 Wilrijk, Belgium, SRN: BE-AR-000000040

APPENDIX A

RUO Workflow and Operating Procedures

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RUO Workflow and Operating Procedures

This appendix contains procedures and information specific to operating the AVITI Dx System in RUO mode. RUO mode enables additional cloud-connected and online workflows not supported in IVD mode, including ElemBio Catalyst™ cloud storage connections and installation of add-ons for offline systems.

Refer to this appendix for RUO-specific configuration and operational procedures.

ElemBio Cloud

ElemBio Cloud is a central online platform that provides real-time remote run monitoring, data analysis, and account management for Element instruments, including AVITI Dx Systems. Any system in online mode automatically connects to the platform. ElemBio Cloud allows you to connect to cloud service providers for data storage and initiate data analysis automation through flows.

You can access ElemBio Cloud on a computer or mobile device to support your organization from anywhere. For more information, see the *ElemBio Cloud Documentation* in the *Online Help*.

ElemBio Cloud Metadata

By default, AVITI Dx OS sends the following metadata to a secure and customer-specific ElemBio Cloud database:

- Run description.
- Sample names from the run manifest, if applicable.

Metadata populate the run monitoring pages in ElemBio Cloud, which is separate from the telemetry database. Therefore, telemetry does not collect metadata. If you prefer to keep metadata on the instrument, contact Element Technical Support and request Restrict Metadata mode. When the mode is enabled, a lock appears on the run description in ElemBio Cloud and sample names are masked as numbers. The numbering reflects the order of samples in the run manifest.

ElemBio Catalyst

ElemBio Catalyst is a native cloud storage and analysis subscription service within ElemBio Cloud. ElemBio Catalyst allows Element to host and manage cloud storage connections on your behalf. Your data is stored in Amazon Simple Storage Service (Amazon S3) storage buckets that are completely dedicated to you.

To use ElemBio Catalyst, purchase an ElemBio Catalyst subscription or subscribe to a 45-day free trial. If your ElemBio Catalyst storage connection is disabled, an **Expired** badge is displayed for 14 days and the run storage connection cannot be used to upload runs. After 14 days, the ElemBio Catalyst storage connection is no longer visible in AVITI Dx OS. To resubscribe to ElemBio Catalyst, contact Element Technical Support at support@elembio.com. For more information, see the *ElemBio Catalyst documentation* in *Online Help*.

Install Add-Ons on an Offline System

Add-ons on offline AVITI Dx Systems require an installation procedure using a USB with a key downloaded from ElemBio Cloud. The add-on key file must be located at the root level of the USB. For instructions to download the add-on key, see *Add-Ons* in the *Online Help*.

1. Use a USB port on the side or back of the instrument to connect the USB drive with the add-on key file downloaded from ElemBio Cloud.
2. On the taskbar, select **Settings**.
3. Select the **Add-Ons** tab.
4. In the drop-down menu, select the USB Drive.
5. Select **Upload**.

   —AVITI Dx OS uploads the key file, which installs the add-ons. The Add-Ons tab displays the add-ons and expiration dates.—

Supported Storage Connections (RUO Mode)

The storage location for a cloud storage connection is a bucket. A connected bucket is available to all systems. Local storage is exclusive to the system.

Cloud Storage (RUO Mode)

Cloud Storage Connection	Description
ElemBio Catalyst	• Subscription-based service. • Connects the system to an Amazon Simple Storage Service (Amazon S3) bucket that Element creates and operates on your behalf. For more information, see *ElemBio Catalyst* on page 65. • Transfers data using AWS Identity and Access Management (IAM).
AWS	• Connects the system to an Amazon S3 bucket. • Transfers data using secret key authentication through IAM.
DNAnexus	• Connects the system to a DNAnexus project. • Transfers data using an API key for authentication.
GCS	• Connects the system to a Cloud Storage bucket. • Transfers data using secret key authentication through a keyed-hash message authentication code (HMAC).

Manage Storage Connections

Storage settings manage storage connections and include setting the default storage connection. Unless you reset the default storage connection, the default storage connection is the first cloud location added to the instrument. If a cloud location does not exist, the default storage connection is the first local network location.

You can verify any storage connection, but only local storage connections can be edited and deleted in AVITI Dx OS. If you must edit a cloud storage connection, access ElemBio Cloud. For more information, see *Storage Connections* in the *Online Help*.

For ElemBio Catalyst, storage connections that have been expired less than 14 days appear as expired in the storage connections list and cannot be selected in the run setup. Storage connections that have been expired more than 14 days do not appear in the storage connections list.

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Document History

Revision	Description of Change
July 2026 Document # MA-00088 Rev. A	• Initial release.
October 2026 Document # MA-00088 Rev. B	• Added RUO and IVD mode selector description to the AVITI Dx System Components chapter. • Added description of IVD and RUO mode visual indicators (banner text, color shading, and light/dark interface styling) to the AVITI Dx Operating Software overview. • Added Service tab to the AVITI Dx OS Settings description list. • Added graphics depicting the RUO and IVD mode selector location on the right side of the instrument to the Switching Between In Vitro Diagnostic (IVD) and Research Use Only (RUO) Mode section. • Added instructions to configure the AVITI Dx OS interface language to the Configure General Settings chapter. • Updated Exporting Log Files instructions to include Run Log Export and updated descriptions of each export option. • Added warning to the General Safety chapter to not position the instrument in a way that restricts access to the rear power switch. • Added Biological Risk label and description to the Safety Labels chapter. • For RUO mode only, added troubleshooting procedure for opening or unlocking the reagent, nest, or waste bay door, including for consumable retrieval or swap outside of a run.
November 2026 Document # MA-00088 Rev. C	• Removed descriptions of software update capabilities from the Settings chapter, and removed the Perform a Manual Update section. The AVITI Dx System is an offline system and does not receive software updates through the instrument software. • Removed the telemetry reference and the air filter time reset reference from the General settings description. Air filter time reset is described under Service settings. • Removed the notification icon table from the Unread Notifications section. • Updated the Signing In and Out section to describe signing in with individual user accounts. • Added instructions for adding a user to the Manage Users section.

Technical Support

Visit the User Documentation page on the Element Biosciences website for additional guides and the most recent version of this guide. For technical assistance, contact Element Technical Support.

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ELEMENT BIOSCIENCES
The AVITI Dx System product family delivers precise, high-quality raw DNA sequencing data from a variety of biological samples. The product is intended solely as a data generation tool and does not provide diagnostic interpretations or direct clinical recommendations.