Stratys[™] System User Guide

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Revision History

Revision	Notes
A	Initial release.

Stratys[™] System User-Supplied Materials

ltem		Supplier	Part Number
Kimtech Science™ Kimwipes™ Delica or equivalent	ate Task Wipes	KIMTECH	34120
Lens Tissues or equivalent		Thorlabs	MC-50E
Ethanol, 200 Proof, Molecular Biology Or Isopropanol (IPA), ≥ 99.5%, Molecul Or Methanol, 99.% for Spectroscopy		Sigma-Alrich Fisher Scientific Fisher Scientific	E7023 327270010 167835000
Recommended 10 µl Pipette Tips			
Brand name	Part Number	Performance	
Olympus Barrier	26-400	Preferred	
Microlit Sterile Filter	R-10-FS	Preferred	
ART10 Barrier	2139-05PK	Preferred	
USA Scientific TipOne RTP	1181-3810	Preferred	
Corning DeckWorks	CLS4135-960EA	Acceptable	
Greiner Sapphire	771352	Acceptable	
VWR Universal Filter Tip	732-3631	Acceptable	

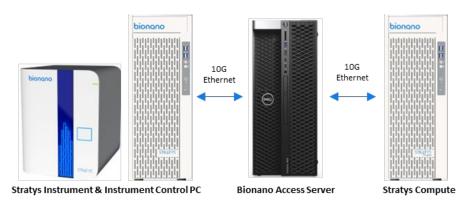
NOTE: For hydration, please use Ultra Pure Water (PN 20355) from the Bionano Prep DLS-G2 Labeling Kit (PN 80046).

Overview

Introduction

CAUTION: Prior to operating the Stratys[™] Instrument, please review the *Stratys System Safety Guide* (CG-00023) for all safety and compliance information.

The Stratys System (Stratys Instrument with Instrument Controller, Bionano Access[™] Server and Stratys Compute Server) provides rapid, high-throughput optical genome mapping for sensitive and accurate detection of genome-wide structural variation and an integrated software solution for the visualization, interpretation, and reporting of results with VIA software.



Features

- Intuitive loading workflow: The adaptive loading feature in the Instrument Control Software (ICS) ensures that the optimal conditions for DNA molecule loading are maintained throughout the scanning process. The initial hands-on-time is approximately five minutes per sample.
- Convenient and easy setup: Bionano Access allows users to set up chip runs, track and review run metrics, perform downstream analysis, and export and share data.
- Real-time analysis: Bionano Access enables users to view real-time data and performance metrics from any internet browser with connection to the Access Server as the run progresses.
- Bionano Assure: Optional instrument health monitoring service that continuously inspects data quality and instrument performance. Additionally, this provides a streamlined diagnostic workflow for customers to interact with Bionano Support.

Workflow



To perform a run on the Stratys, use the workflow example (Figure 1) as a guide:

- 1. Perform DNA isolation and labeling of samples.
- 2. Set up a Chip Run and specify run parameters in Bionano Access.

- 3. Turn the Stratys instrument and the Instrument Controller on and sign into the ICS.
- 4. Load the sample(s) on a Stratys Chip.
- 5. Insert the Stratys Chip(s) into the instrument.
- 6. Setup a run.
- 7. Track run performance and analyze data in Bionano Access.
- 8. Remove the chip(s) from the instrument.

Prepare Sample

For details on DNA isolation and labeling of samples, visit Bionano Support.

Getting Started

Start the Stratys Instrument

- 1. Locate the power switch on the back of the instrument in the bottom left. Toggle the power switch to turn the instrument on.
- 2. Turn on the Stratys Instrument Controller with the power button located at the front. The software is in "kiosk" mode and will boot directly to the ICS. Kiosk mode allows the users to interact with ICS only, while keeping the Instrument Controller in a secure environment.

NOTE: The Instrument Controller may take several minutes to boot up.

Front Panel Light

IMPORTANT: Before running the instrument, ensure the front panel light is blue, as seen in Figure 2 If the front panel light is red, do not proceed and contact <u>Bionano Support</u> for assistance. For additional information, please refer to the Stratys System Safety Guide (CG-00023).



Figure 2. When the front panel light is illuminated red (right panel of figure), the instrument is not safe to run. Turn the instrument off and contact Bionano Support.

Instrument Status Light

The instrument status light on the front panel indicates the following described in **Table 1**.

Color	Description
Light off	The instrument is powered off.
Flashing yellow	The instrument is initializing.
Green	The instrument is ready to use.
Flashing green	The instrument is running.
Blue	The system interlocks are not engaged.
Red	The instrument encountered an error. NOTE : This does not present a safety issue to the user.

Table 1. Instrument status light indications

Sign in to the Stratys[™] ICS

1. When the software is launched, the Stratys instrument will initialize. This can be visualized by clicking on the

Instrument Status icon. A description of all icons is in Appendix C.

- 2. Click **Login** at the top right of the screen. Enter the username and password. This is the same information that has been set up on Bionano Access. See the "Configure Analysis Settings in Bionano Access" section for instructions.
- 3. Click Logon.

ICS Home Screen

The **Home** screen will show options to load or remove chips. It will also show any chips that are currently running. See the "Perform Run" section for details.

Configure Analysis Settings in Bionano Access

The ICS and Bionano Access interact to allow users to track run progress and view results in real time. Prior to performing the run on the Stratys instrument, a chip run must be set up in Bionano Access. For details on how to do this, as well as all Bionano Access analysis and visualization features, see the *Bionano Access Software User Guide* (CG-30142).

Prepare Chip

Load Sample on Stratys[™] Chip

Equilibrate the labeled samples and Stratys Chip (sealed in pouch) to room temperature for <u>at least 30 minutes</u> prior to use. See **Figure 3**.



Figure 3: Stratys Chip in pouch

IMPORTANT: Do not open the pouch containing the Stratys Chip when the chip is cold. Wait until the pouch is at room temperature before removing the chip. Opening a chip while it is cold may damage the chip and cause performance degradation.

Important tips for loading chips:

- Proceed through the following steps carefully, without interruption, and ensure there is no airflow around the chip, to minimize sample evaporation.
- If loading multiple chips, load one at a time.
- Use gloves (powder-free) when loading chips.

IMPORTANT: Note the 16-digit serial number of the chip so the chip can be associated with the correct Chip Run in the "Perform Run" section below.

- 1. Open the pouch containing the Stratys Chip and remove the chip from the pouch. Handle the chip by the sides and do not touch the bottom of the chip. Check the underside of the chip for cracks, dust, or debris. If there is dust or debris, gently wipe the underside of the chip with lens paper. Avoid touching the underside of the chip with anything other than lens paper. If there are cracks, contact Bionano Support.
- 2. Place the chip onto lint-free paper and a clean and level lab bench (see Figure 4).



Figure 4. Stratys[™] Chip with opened lid, showing the inlet and outlet ports.

3. With a 10 µl pipette, set to 8 µl, press the plunger down and hold at the first stop.

NOTE: Read the following instructions carefully. Correct pipetting technique is important for successful sample loading. Whether aspirating or dispensing, always stop at the first plunger stop when pressing down. Pushing past the first stop will introduce bubbles or air gaps. Always use a fresh pipette tip for each new draw.

NOTE: Please refer to the User Supplied Materials for preferred pipette tips.

4. Lower the pipette tip into the sample, positioning the tip near the middle of the sample, and slowly aspirate 8 μl of the sample.

NOTE: To avoid any air gaps, visually inspect at eye level that the pipette tip is fully immersed in the sample prior to aspirating sample.

NOTE: Pipette tips that are long and skinny may require more time for the liquid to fill completely. We recommend leaving the tip in the liquid for at least 7 seconds after the plunger has been fully released, to allow the tip to fill completely, prior to removing the tip from the liquid.

NOTE: If there are visible air gaps or bubbles in the tip, or if any droplets are stuck to the side of the tip, return the sample to the tube, and try again with a fresh pipette tip.

5. Insert the pipette tip into the inlet well, perpendicular to the chip, until the pipette tip touches the bottom, and you feel a hard stop, as shown in **Figure 5**.

NOTE: The tip must make contact with the hard stop at the bottom, but do not apply excessive pressure or the flowcell could break.

NOTE: For some pipette tips that are long and skinny, the tip may not sit stably on the hard stop without bending or wobbling. Use a gloved finger to stabilize the tip at a vertical orientation.

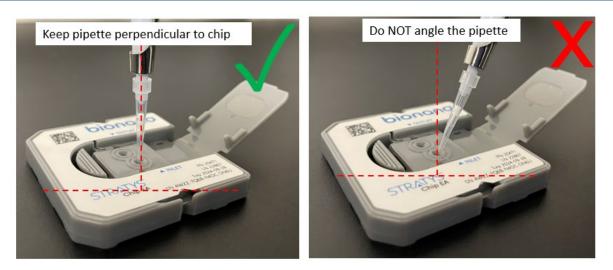


Figure 5. Correct positioning of pipette in the inlet well.

6. Slowly dispense the sample by depressing the pipette plunger steadily down to the first stop. **DO NOT** depress the pipet plunger past the first stop, and DO NOT release the plunger yet. Ensure that the pipette tip remains inserted all the way in, perpendicular to the chip, and touching the hard stop, during the entire time that sample is being dispensed.

NOTE: If sample is viscous, dispense steadily over 10 seconds.

7. After dispensing, keep the plunger pressed down to the first stop, hold for 5 seconds in the well, then gently remove by pulling the pipette up perpendicularly while holding the chip down with the other hand. Keep the plunger pressed down to the first stop until the pipette is completely removed from the well.

NOTE: Releasing the plunger before the tip is fully removed from the well can cause sample to be inadvertently drawn out of the chip.

- 8. Wait 30 seconds before proceeding to the next step.
- With a 10 μl pipette, set to 10 μl, press the plunger down and hold at the first stop. Lower the pipette tip into the sample. Follow the same techniques as in Steps 4-7 to aspirate 10 μL of sample and load the outlet well.
- 10. Add 2 µL of nuclease-free water into the inlet well, using the same techniques as in Steps 4-7.

NOTE: For hydration, please use Ultra Pure Water (PN 20355) from the Bionano Prep DLS-G2 Labeling Kit (PN 80046).

- 11. Add 2 µL of nuclease-free water into the outlet well, using the same techniques as in Steps 4-7.
- 12. Close the lid by pressing the tip of the lid into the latch until it clicks, as shown in **Figure 6** and **Figure 7**. DO NOT press in the center of the lid as it can cause the flowcell to break.

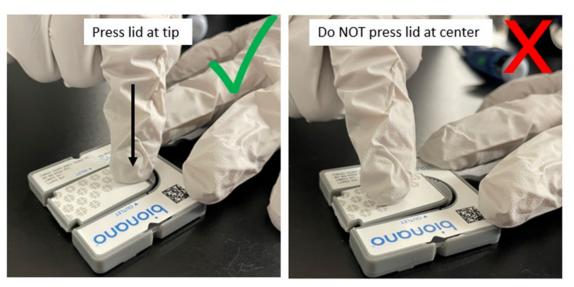


Figure 6. Latch closing



Figure 7. Press to engage latch (as pictured by the blue dot)

Perform Run

Load Stratys Chip into Stratys Instrument

- 1. Click **Login** in the top right corner of the screen. Employ the same username and password used for Bionano Access.
- 2. From the Home screen, seen in Figure 8, click Load and Remove Chips or Load and Remove Priority Chips.

TRATYS	(= 1 = 2 2 =	HRUP 😂 🤇
me		🚊 Bionano User Logout
Inactive	Imaging	
	Loading DNA	
Controls		
Load and Remove Chips		
Load and Remove Priority Chips		
Stop all Runs		
		bionano
		olonano

Figure 8. Click Load and Remove Chips or Load and Remove Priority Chips in the bottom left of the screen.

- If no chips are in the instrument, the user can insert up to 12 chips and/or 3 priority chips.
- Priority chips will be prioritized during data acquisition and will go to the front of the queue for data analysis after the chip is fully imaged.
- If there are inactive chips, the user can load chips to replace those inactive chips in the system.
- 3. Select the number of chips to be loaded into the instrument (see Figure 9). Click Start.

Configure Chip O	perations
AVAILABLE CHIP LOCATIONS: NUMBER OF CHIPS TO INSERT: EMPTY POSITIONS TO BE FILLED:	12 2 2 2
	Start Cancel

Figure 9. Select the number of chips to be inserted and press Start.

- The chip tray door will open, and the chip tray will present itself for loading; if an inactive chip was selected for removal, this chip will be present on the tray to be removed.
- 4. Check the underside of the chip for cracks, dust, or debris. If there is dust or debris, gently wipe the underside of the chip with lens paper. Avoid touching the underside of the chip with anything other than lens paper. Set the first chip on the tray, with the orientation as shown in **Figure 10** below. The chip will be guided into place magnetically.



Figure 10. Correct chip orientation

- 5. Once the chip is loaded onto the tray, click **OK**. The chip tray will retract into the instrument.
 - The instrument will read the barcode to identify the chip. If the instrument is unable to identify the chip barcode, see the "Troubleshooting" section.
 - If the user selects more than one chip, the tray will present itself again a few seconds later so the user can place the next chip. This process will continue until all the chips have been inserted.

Configure Run

- 1. The newly inserted chips will be shown by serial number in the center of the screen. **NOTE**: The user can configure runs for chips that are inserted while additional chips are being inserted. There is no need to wait until all chips have been inserted.
- At the Chip Name field, select the chip setup to associate with the chip from the drop-down list. If a serial number was already entered in Bionano Access when setting up the chip, the Chip Name will already be selected. See the Bionano Access User Guide (CG-30142) for details on how to create a Chip Run.
 - [Optional] Click + to create a new chip setup. This will bring up Bionano Access within the ICS. See the *Bionano Access Software User Guide* (CG-30142) for instructions on setting up a chip.
 - [Optional] Click the **Refresh** icon to update the list.
- 3. Review the runtime and throughput target parameters for each of the chips, as shown in **Figure 11.** These values will default to the ones that were entered into Bionano Access during setup. The user may change the runtime or throughput as desired. **NOTE:** If the chip has been run previously, the runtime limit and throughput target may be modified. See **Appendix B** for details.

	ZGFXNNG	BN63CNN6U
PART INFO:	20471	
CHIP NAME:	Chip B	- + \$
RUNTIME LIMIT:	120.0 hr	0
THROUGHPUT TARGET:	1,500 Gbp	0
MOLECULE SET:	Sample: Reference: Enzyme: Backbone: Projected Total:	Sample B hg38.DLE1.(kb.0labels_masked_YPARs.cmap DLE-1-Green 01 Backbone Blue 01 1,500 Gbp

Figure 11. The configure run screen allows the user to select the Chip Name that was previously set up in Bionano Access.

- 4. Click Start Run.
- 5. Repeat **Steps 1-4** to configure all chips.
- 6. During scanning (see **Figure 12**), the user can view the **Run** metrics on the **Home** Screen. Run metrics are also available to view in Bionano Access.

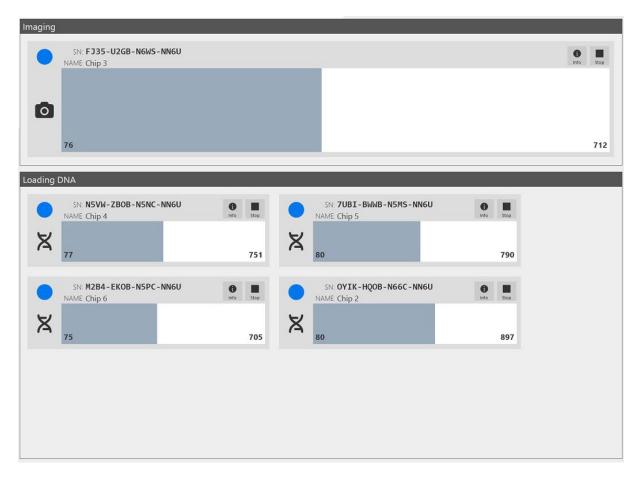


Figure 12. During the run, the software shows the state of each chip as well as the progress towards completing data collection. The blue dot next to the chip indicates the Stratys Core Chip. The mint dot next to the chip represents the Stratys Plus Chip. A yellow border around the blue or mint circle indicates a priority run.

7. Clicking on one of the chips expands the details of the run metrics for that chip.

Chip States

Depending on the situation, the chips may be in various states. **Table 2** lists descriptions for user reference.

Table 2	Chin state	e descriptions
	Omp statt	

Chip State	Description	lcon
Loading	DNA is being loaded into nanochannels in preparation for scanning.	X
Scanning	The chip is being imaged.	0
Cleaning	Post-scanning cleaning is taking place.	* +
Complete	Chip has achieved its throughput target or runtime limit as defined in the Run Configuration.	\bigcirc
Evaporated	The instrument is unable to load DNA in the chip due to loss of contact.	\$\$\$
Error	An error has occurred that has prevented the instrument from collecting data.	
Cancelled	The chip was cancelled by the user and will stop when possible.	×
Transferring	The chip is being transferred to or from the imaging stage.	ţ
Aligning	The chip is being aligned on the imaging stage	ש ע' א ג
Waiting	The chip is waiting for instrument resources to become available to load or scan.	0

Stopping a Run

1. To stop the chip run before it reaches the limits that were set at the beginning of the run, press the **Stop** icon next to the chip to be stopped (see **Figure 13**). Otherwise, the run will continue until the throughput or time limit is met.

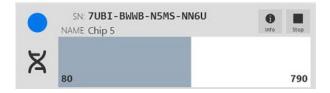


Figure 13. To stop the chip before it has collected all its data, press the Stop icon associated with that chip.

- 2. Users will be asked to confirm that the chip run will stop.
- 3. To stop all chips, press **Stop all Runs** at the bottom left of the screen.
- 4. Users will be asked to confirm that all chip runs will stop.

Remove Chip(s)

Users can remove Stratys Chips from the Stratys instrument when that chip has successfully completed its run or when the run is stopped (see **Figure 14**).

1. From the **Home** screen, click **Eject** next to the chip to be removed. The chip will be ejected from the instrument.

	SN: OYIK-HQOB-N66C-NN6U		
0	NAME Chip 2	Start	Eject
0			1540
	SN: N5VW-ZBOB-N5NC-NN6U		
	NAME Chip 4	Start	Eject
\heartsuit			1500

Figure 14. To eject the chip, press the Eject button next to the corresponding chip.

- 2. Remove the chip from the tray.
- 3. Click **OK** after the chip has been removed from the tray.
- 4. Repeat Steps 1-3 for all chips that are to be removed.
- 5. Alternatively, chips can be removed through the **Load and Remove Chip** workflow, as described above in the "Load Stratys Chip" section.

Analyze Data

Data Transfer for Analysis

After the instrument scans the chip for 2 to 3 minutes, users can monitor the run progress and view quality metrics in real time on Bionano Access. Following the completion of a run, users can launch a variety of downstream data analysis pipelines. For more details on Bionano Access analysis and visualization features, see the *Bionano Access Software User Guide* (CG-30142) and the *Variant Interpretation Applications (VIA) User Guide* (CG-00043).

Bionano Assure

Bionano Assure is a remote service provided by Bionano that enables the ICS to transmit instrument health metrics, run diagnostics, and configuration information to enable Bionano to proactively provide support to customers. Bionano Assure enables users to install software updates for Stratys ICS, allowing for quick and easy updates. Bionano Assure also manages Windows updates, checking to ensure the system is always running with the latest validated updates.

To enable the instrument health monitoring feature of Bionano Assure:

- 1. Log into ICS as a user with Project Lead permissions (granted in Bionano Access).
- 2. Click on the Bionano Assure icon.
- 3. Check the box next to Enable Health Monitoring, as shown in Figure 15.

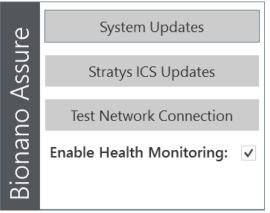


Figure 15. Health Monitoring

4. The Terms of Service for instrument health monitoring will appear. Review them and click **OK** to agree. You can find the terms in the ICS Help screen if you need to reference them later.

Updating Software

Software on the instrument controller must be updated via the Bionano Assure icon at the top right of the ICS,



seen in **Figure 16**. When a software update or system update is available, the Bionano Assure icon will turn orange. To perform the updates:

- 1. Click on the **Bionano Assure** icon.
- 2. Select Stratys ICS Updates or System Updates, as needed.

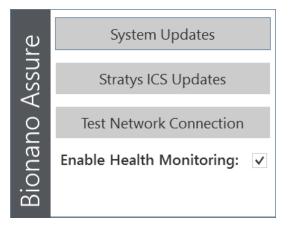


Figure 16. System Updates screen

- 3. Select the update(s) that you wish to install. Click **Install**.
- 4. The system will alert the user that a restart is needed to complete the installation. Select **Yes** to proceed. See *Data Security Guidelines* (CG-30292).

Enabling Remote Access

To enable remote support by Bionano personnel, click the Remote Support icon located at the top right of the ICS, and check the Remote Support box. Once enabled the Remote Support icon will be green, as detailed in **Appendix C**. To disable the remote support, uncheck the remote support box. When disabled the icon will be blue, as detailed in **Appendix C**.

For details regarding the networking requirements to enable remote support, please refer to *Stratys*® *Site Preparation Guide* (CG-00056). For details regarding the security of our remote support tool, please refer to *Data Security Guidelines* (CG-30292).

Logging off and System Administration

To either restart the Instrument Controller or to turn off the Instrument Controller, click the applicable icon at the top right of the screen. Users with System Administrator credentials will also see an icon that will allow them access to the **System Settings** menu as well as the **Windows** login.

Maintenance

Replace Air Filter

There is an air filter at the back of the Stratys instrument. This air filter should be replaced <u>every three months</u> by the user. Air filters are included in the accessory kit that comes with the Stratys instrument. Additional air filters will be provided during the annual preventative maintenance of the Stratys instrument. To replace the air filter:

- 1. Turn off the Stratys instrument using the switch at the back.
- 2. On the back of the instrument, pull up on the tab at the top of the air filter cover, as shown in **Figure 17**, and allow the cover to pivot open.



Figure 17. Air filter cover with the release tab circled in red.

- 3. Pull up on the air filter to remove it completely from the instrument (see Figure 18).
- 4. Insert a new air filter. Make sure the **Air Flow** arrow symbols are facing towards the instrument (air flows into instrument).
- 5. Pivot the air filter cover back into place until the latch snaps closed.



Figure 18. Air filter cover opened with air filter exposed.

Appendix A

Troubleshooting

Issue	Possible Causes	Solution
Unable to log into ICS	Incorrect password was entered.	 Check that log on to Bionano Access is available. Refer to <i>Bionano Access Software User Guide</i> (CG- 30142) if password is forgotten.
	The Bionano Access™ server is not active.	 Check whether the Access service status is active. If the user can browse Bionano Access, the service is active.
		2. Reboot the Stratys Instrument Controller.
Data service is unable to connect to Bionano Access.		 Check if the Access webserver is active. Confirm that the cable connection between the
		 instrument controller and Access is secure. If the issue is not resolved, contact Bionano Support at <u>support@bionano.com</u>.
Instrument does not initialize (Figure 16).	There is likely a hardware issue.	 Make sure to close ICS first. Turn off the Instrument Controller using the power icon in ICS. Turn off the instrument using the switch at the back and wait for at least 15 seconds before switching
		 back on. Wait approximately 30 seconds. Restart ICS (or turn on the Instrument Controller) and wait for system to re-initialize.
		 If this does not resolve the issue, contact Bionano Support.
Instrument reports Invalid	Barcode on the chip is damaged.	1. Remove the chip from the instrument.
Chip or Barcode Error	Barcode reader on the	 Ensure there is no physical damage to the chip that may prevent it from fitting well into the instrument.
	instrument failed or is	 Ensure that the barcode on the label is not damaged or smeared.
	misaligned.	4. Try loading the chip again.
		5. Contact Bionano Support if the chip is unable to run.
Cannot start run, sample contact failed	The instrument was unable to establish electrical contact.	 Eject the chip and reinsert it into the instrument. If the same error message occurs, there may be a
		fault with the chip, or there may have been a problem with sample loading.
		3. Use the remaining labeled sample and pipette into a new chip.
		4. Contact Bionano Support if the problem persists.

Issue	Possible Causes	Solutio	n
Bionano Access dashboard is not updating in real time as the run proceeds.	Connection has been lost between Bionano Access and the Stratys Instrument Controller.	1. 2.	Confirm that the cable linking both components is plugged in at both ends. Refresh Bionano Access webpage (allow some time for the run data to populate in Access). NOTE : When loss of connection occurs, the instrument keeps running and data is stored locally on the Instrument Controller. Transfer will restart when the connection restored.
Map rate is zero	Reference not provided. Wrong reference provided. Wrong labeling enzyme selected.	1. 2.	Do not stop the run! Wait for the run to complete and for the sample's corresponding Molecules Job to populate in the designated project in Bionano Access Make sure the correct reference is loaded in Bionano Access. If it is not, refer to the "Edit Job" section in th <i>Bionano Access Software User Guide</i> (CG-30142) to add or change the reference.
	Instrument Status:		
	Instrument ready		
	Device Details:		
	System Status:	Initialized	
	Focuser:	Initialized	
	Focus Motor:	Initialized	
	Focus Sensor:	Initialized	
	Sample Stage:	Initialized	
	X Axis:	Initialized	
	Y Axis:	Initialized	
	Illumination:	Initialized	
	Green Laser:	Initialized	
	Cyan Laser:	Initialized	
	DNA Loader 1:	Initialized	
	DNA Loader 2:	Initialized	
	Barcode Reader:	Initialized	
	Carousel:	Initialized	
	Chip Transfer:	Initialized	
	Chip Shuttle:	Initialized	
	Camera Status:		
	Camera Ready		

Figure 19. Image of initialization status of each instrument component.

Export Tier 1 Run Diagnostics

If there is an issue with a chip run that needs to be addressed by Bionano Support for troubleshooting, a small diagnostic package known as Tier 1 Run Diagnostics can be generated. If connected to the Bionano Assure service, these diagnostic files can be transmitted directly to Bionano Support through the ICS. At the top right of the ICS, click on the **Run Info** icon (see **Appendix C**).

1. A list of recent chip runs will be displayed. Locate the desired chip by serial number and click on the down arrow to the left of the serial number (**Figure 20**).

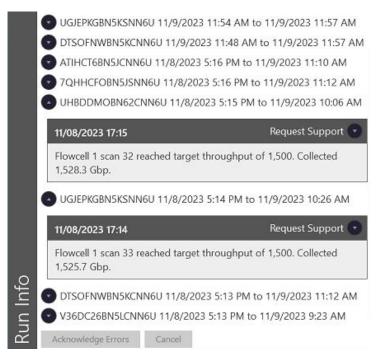
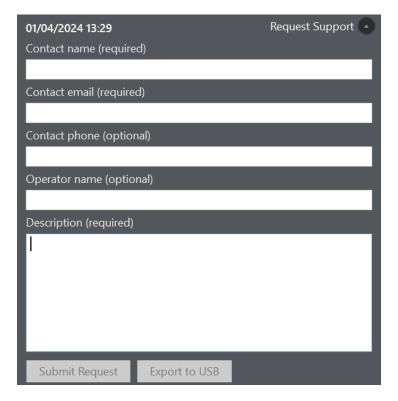
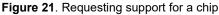


Figure 20. Recent chip Runs.

2. Click on the down arrow to the right of **Request Support** for the desired chip.





 In the dropdown, enter the applicable information (see Figure 21). The Contact Name, Contact Email, and Description fields are required for submission. The Operator Name will be automatically populated with the User ID of the person who started the run. Click Submit Request to transmit the Tier 1 Run Diagnostics directly to Bionano Support.

NOTE: If the submission begins but does not complete due to a network connection problem, it will automatically be re-submitted when connection is restored.

NOTE: For users who have not opted into Bionano Assure or do not have network access to enable connection to Bionano Assure, the diagnostic package must be saved and emailed to Bionano support. Follow **Steps 1-3** above, then follow the instructions below:

- i. Insert one USB flash drive into the Instrument Controller and wait thirty seconds for device recognition.
- ii. In the dropdown that appears, fill in the applicable information and click **Export to USB**.
- iii. ICS will generate a Stratys Archive (.str) file and will save it to the root of the USB drive; when export is complete, a green checkmark appears.
- iv. Remove the USB drive and insert it into another computer; email the .str file to Bionano Support (support@bionano.com). The file size is intended to be small enough to email as an attachment using most standard email service providers.

Export Tier 2 Run Diagnostics

If the Tier 1 diagnostic package is insufficient to address the issue, Bionano will need to collect additional data from the chip run. For users connected to Bionano Assure, this will occur without any intervention from the user.

Users not connected to Bionano Assure will be instructed by Bionano Support to assist in providing the additional information. The user will be provided a Diagnostic Request File (.drf) from Bionano Support. Save the .drf file on a USB drive. The USB drive may only have one .drf file. Attach the USB drive to the Instrument Controller. Only one USB drive may be attached to the Instrument Controller at any time.

- 1. At the top right of the ICS, click on the **Run Info** icon and select **Open Diagnostic Request** to import a .drf file.
- 2. Once the file is imported, ICS will generate another .str file and will save it to the USB drive. When the export is complete, remove the USB drive from the ICS Controller and transfer the .str file to Bionano Support. NOTE: The Tier 2 .str file may be much larger than the Tier 1 .str file. Instead of sending by email, Bionano Support will provide you with a file sharing link.

Export Data Configuration

In some cases, users may be asked by Bionano Support to upload or export certain instrument configuration data, such as log and calibration data, for additional troubleshooting.

1. From the **Home** Screen, click the **Help** icon at the top-right corner of the screen. A dialog box appears, as in **Figure 22**.

STRATYS			
ICS - 0.0.1.0 Copyright © 2023 Bionano Stratys PN: 60534	BIOS - LENOVO - 1042 N2OET55W (1.42) Lenovo - 1042 Config - Stratys Camera - Mock Camera		
Export Configuratio	n Resubmit Data to Access	EULA Health Monitoring ToS	
Contact name (required	Contact name (required) Contact phone (optional)		
Contact email (required)		Description (required)	
Compress and Upload Configuration			
	Cancel		
Export Configuration to USB			

Figure 22. Upload configuration, as seen on a system connected to Bionano Assure.

- 2. <u>For users connected to Bionano Assure</u>, click **Export Configuration**. Fill out the required information and click **Compress and Upload Configuration**.
- 3. For users NOT connected to Bionano Assure, click Export Configuration.
 - a. Insert a USB drive into the Instrument Controller
 - b. Click Export Configuration to USB.

NOTE: The file will be saved directly to the root drive of the USB drive. Only one USB drive may be inserted into the Instrument Controller at a time.

c. When ICS has finished saving the file, navigate to the location of the .zip file on a separate PC, and send it to Bionano Support.

Appendix B

Rerunning a Chip

The Stratys ICS allows for user flexibility in collecting data to accommodate various workflow situations and scenarios. Each Stratys Chip has an associated maximum accumulated <u>throughput</u> and maximum accumulated <u>runtime</u>. The chip can be re-run as many times as desired to collect the amount of data needed, until either the throughput limit or the runtime limit is reached.

To rerun a chip, insert the chip into the instrument following the instructions in the "Perform Run" section above. Once the chip is inserted, the instrument will read the barcode and automatically associate the chip with the previous chip run(s). The runtime and throughput target may be automatically modified by the ICS so they do not exceed the allowable values for the chip.

Appendix C

ICS Icons

A variety of icons are located at the top right of the Stratys ICS.

Stratys Instrument Status

The Instrument Status icons indicate the status of the Stratys instrument (Table 3)

lcon	Color	Description
-	Blue	The instrument is working normally.
	Flashing Green	The instrument is initializing.
	Red	The instrument encountered an error. Contact Bionano Support for assistance.
	Flashing Light Blue	The instrument door is open.
	Flashing Amber	The instrument is not receiving power or is not turned on.
	Purple	The instrument hardware is not correctly configured. Contact Bionano Support for assistance.
19	Flashing Dark Orange	There is an interlock fault. Contact Bionano Support before attempting to start the run.

Table 3. Instrument Status Icons.

Run Info

The Run Info icons indicate the status of recent runs (Table 4).

Table 4. Run Info.

lcon	Color	Description
	Blue	There are no run errors, or any previous run errors have been acknowledged.
	Red	There is a run error that has not yet been acknowledged.

Bionano Access[™] Connection Status

The **Bionano Access Connection** icon indicates the status of the network connection between the Stratys Instrument Controller and the Bionano Access server (see **Table 5**).

The Stratys Instrument must be connected to the Bionano Access server before it can begin a run. If the connection fails while a run is in progress, the ICS will temporarily store the run data on the Instrument Controller. When the connection is re-established, the run data will be transferred to Bionano Access.

Table 5.	Bionano	Access	Connection	Status.
----------	---------	--------	------------	---------

lcon	Color	Description
문	Blue	The ICS is connected to Bionano Access.
문	Amber	The ICS is unable to connect to Bionano Access.

Bionano Assure Status

The **Bionano Assure Status** icons indicate the status of the Bionano Assure connection and whether there are any available software updates (see **Table 6**).

Table 6. Bionano Assure Status.

lcon	Color	Description
	Green	Bionano Assure is connected and health monitoring is enabled.
⊟	Blue	Bionano Assure is connected and health monitoring is disabled.

Icon	Color	Description
$\overline{\mathbf{x}}$	Red	There is a connection error between ICS and Bionano Assure.
	Amber	Update(s) are available for either ICS or Windows
$\overline{\mathbf{x}}$	Blue	Disabled / Establishing Connection

Remote Support

The Remote Support icons indicate whether the system is connected to remote support (Table 7).

Table 7. Remote Support

lcon	Color	Description
₽	Green	Remote support is enabled.
₽	Blue	Remote support is disabled.

Appendix D

Upload Run to Access

The **Resubmit Run to Access** option from the **Help** screen allows users to resubmit a dataset for reanalysis. This may be used if an error in the initial analysis of the Run data has occurred. **NOTE:** If ICS and Access disconnect during a Run, the Run will continue. Access will automatically resume collecting data once the connection is reestablished. In this case, there is no need to resubmit the data. The status of the data transfer to Access can be monitored using the **Data Service Status** icon.

- 1. Click on **Help** in the upper right corner of the screen.
- 2. Select Resubmit Data to Access.
- 3. Select Upload Run to Access (Figure 23).

Upload Run to Access		
	•	
Submit		
Cancel		

Figure 23. Upload Run to Access.

- 4. Select the Run to resubmit from the dropdown list.
- 5. Click Submit.
- 6. The existing Chip Run will be deleted from the Access database, and a new Chip Run will be created in Access. **NOTE:** The Chip Run ID will remain the same.

Appendix E

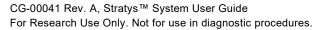
Instrument Disposal

This label indicates that the instrument meets the 2012/19/EU Directive on waste electrical and electronic equipment (WEEE).

Email support@bionano.com for instrument disposal in the EU.

WEEE Label





Additional Resources

The following documentation is available for download from the **Bionano Support** website.

Resource	Description
Stratys System Safety Guide (CG-00023)	Provides information about instrument safety considerations.
Stratys Site Preparation Guide (CG-00056)	Provides specifications for laboratory space, electrical requirements, and environmental considerations.
Bionano Access Software User Guide (CG-30142)	Provides instructions to set up and monitor chip runs, as well as an overview on data analysis and visualization.
Data Security Guidelines (CG-30292)	Provides information about how Bionano data is handled.

Technical Assistance

For technical assistance, contact Bionano Technical Support.

You can retrieve documentation on Bionano products, SDS's, certificates of analysis, frequently asked questions, and other related documents from the Support website or by request through e-mail and telephone.

ТҮРЕ	CONTACT
Email	support@bionano.com
Phone	Hours of Operation: Monday through Friday, 9:00 a.m. to 5:00 p.m., PST US: +1 (858) 888-7663 Monday through Friday, 9:00 a.m. to 5:00 p.m., CET UK: +44 115 654 8660 France: +33 5 37 10 00 77 Belgium: +32 10 39 71 00
Website	www.bionano.com/support
Address	Bionano, Inc. 9540 Towne Centre Drive, Suite 100 San Diego, CA 92121

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