



Data Security Guidelines

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Revision History

REVISION	NOTES
A	Initial release of document.
B	Added Saphyr Assure information and updated Instrument Controller information
C	Additional security features added from Access 1.7 release.
D	Revised for Access 1.8 release
E	Revised for introduction of the Stratys System
F	Added section for Resource Strategy Added content for VIA

Introduction

The purpose of this document is to describe the security profile of the Bionano solution. Information Security groups receiving our systems need to understand what security controls are provided and what work is needed to ensure secure operation. This document seeks to provide a full end to end picture from instrument, through reporting including our full gamut of systems and software tools.

Data Privacy Statement

Bionano is committed to protecting the security of personal and protected data. We take reasonable physical, electronic, and administrative safeguards to help protect personal information from unauthorized or inappropriate access. We do not sell or share personal or protected data with third parties without explicit permission. Bionano Compute On Demand does not retain any protected data on the hosted systems beyond the life of the job as indicated in its terms of use. Bionano Assure does not collect any protected data; it only collects system health and diagnostic data.

Solution Landscape

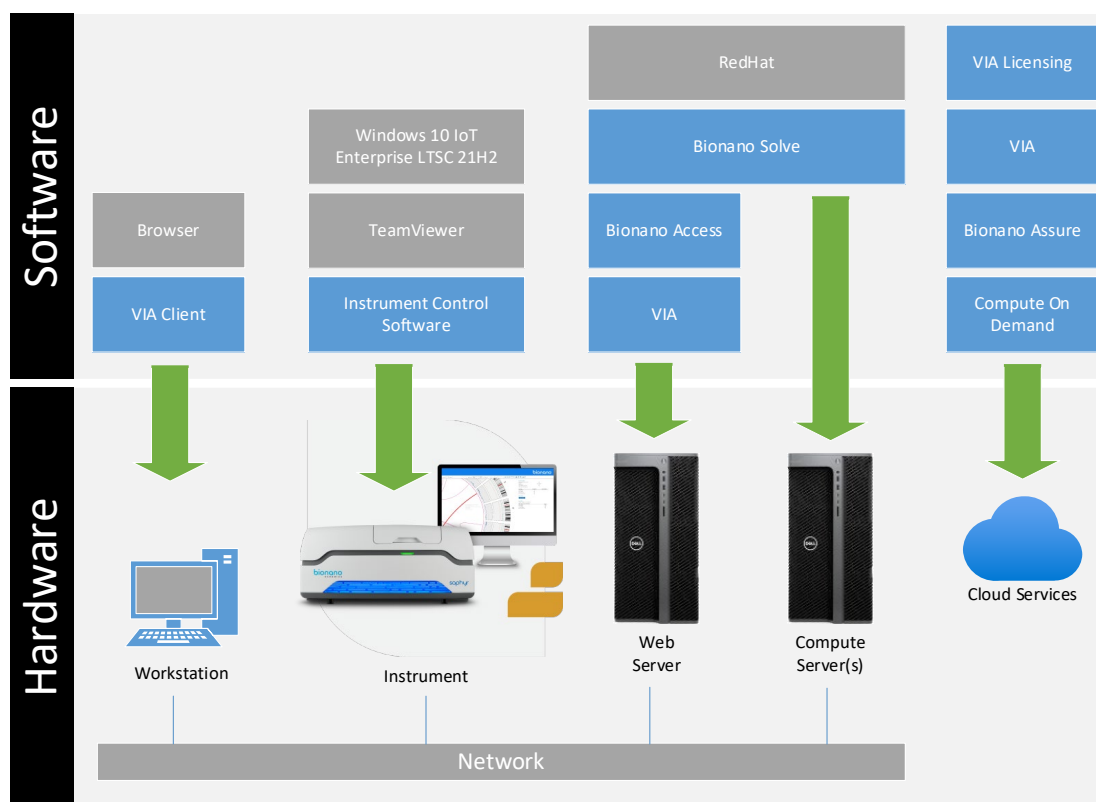


Figure 1. Solution Landscape

The high-level landscape of the Bionano ecosystem is depicted in figure 1. The top section of the diagram shows the major software components, and the bottom section shows the hardware elements. The exact components will vary for each customer depending on their configuration. The following sections provide a description of each component.

Software Components

Bionano Assure

Bionano Assure is an optional remote service provided by Bionano that enables the Instrument Control Software (ICS) to transmit system health metrics, run diagnostics and configuration information to enable Bionano to proactively provide support to customers. Bionano Assure analyzes run metrics and alerts the support team to potential issues so that they can reach out to the customer to address issues before data quality and run performance are impacted. Bionano Assure enables users to install software updates for Saphyr® ICS or Stratys™ ICS, allowing for quick and easy updates. Bionano Assure also manages Microsoft Windows updates, checking to ensure the system is always running with the latest validated updates.

Compute On Demand

Compute On Demand is a hosted solution designed to provide compute resources to perform Bionano Solve operations for customers who have no local compute resources or temporarily require additional compute resources. Bionano Compute On Demand works in conjunction with Bionano Access™. This service is optional and is pay per use.

Bionano Solve

Bionano Solve is a bioinformatics software engine used for analyzing Optical Genome Mapping (OGM) data. It serves as the core variant-calling engine that processes genome imaging data generated by the Bionano instruments to identify and characterize structural variations across the genome. These variations include insertions, deletions, duplications, inversions, translocations, and copy number changes.

Bionano Access

Bionano Access is the software platform for managing, visualizing, and reviewing optical genome mapping (OGM) data and analysis results. It provides a user-friendly interface that enables users to monitor workflows, explore structural variants and copy number changes, review quality metrics, and interpret genomic findings generated by Bionano Solve.

Instrument Control Software

Bionano Instrument Control Software (ICS) is the software platform used to operate and manage Bionano optical genome mapping instruments. It controls instrument workflows, coordinates data acquisition, monitors performance, and manages the collection of high-resolution genome imaging data from labeled DNA molecules.

The software provides users with an interface for configuring runs, tracking instrument status, monitoring quality metrics, and ensuring efficient execution of optical genome mapping experiments.

VIA

Bionano VIA is an integrated software platform for genomic data analysis, interpretation, and reporting. It enables users to analyze and interpret data from optical genome mapping (OGM), as well as other genomic technologies such as array and NGS, by combining automated variant calling, annotation, visualization, and AI-assisted interpretation workflows within a unified environment. VIA does communicate with a hosted licensing server.

Hardware Components

Workstation

Bionano does not provide workstations. End users will use their existing workstations to interact with OGM data. A browser such as Google Chrome or Microsoft Edge is necessary to interact with Bionano Access. To interact with a VIA Server the user must install the VIA Client.

Instrument Controller

There is a computer attached to the instrument. This system is running Windows in kiosk mode and should be considered physically part of the instrument. It cannot be used as a regular workstation.

Web Server

Bionano Access and VIA are both web applications. Bionano Access Servers sold with our instruments are used to host Bionano Access and VIA. While a site may have multiple instruments and or compute servers, only one production Bionano Access Server is required per site. Some customers may have a secondary Bionano Access Server for redundancy and validation. VIA and Bionano Access can also be installed on other systems that meet the minimum system requirements. We do not support the use of virtual machines for the web server.

Compute Servers

The compute servers are a high-performance compute platform designed to support Optical Genome Mapping (OGM) workflows using the Bionano Solve bioinformatics software. Newer generation compute servers are powered by advanced NVIDIA RTX GPUs, it delivers rapid bioinformatics processing, structural variant analysis, and data management capabilities, enabling laboratories to efficiently scale genomic analysis while reducing computational costs. Generally a customer will have one compute per instrument, but that may vary depending on their application and throughput needs.

Information Classification

To understand potential security risks, we classify the data involved. Personally identifiable data is non-health information that can be traced to an individual. When personal data becomes tied to health information, it becomes protected health information, as defined by HIPAA. Bionano does not ask for, transmit, or store protected health information. Specifically, Bionano stores and transmits only de-identified genomic data. Below (**Table 1**) we have identified the types of data in the Bionano Compute On Demand and Bionano Assure that fall into these categories. Bionano provides security features to protect all the following data.

Table 1. Information Categories

Service	Category	Data	Description
Compute On Demand	Personal	User Account	User account information, including email addresses, is used to track token and job ownership. Contact information is used to convey job and system status messages.
Compute On Demand	Personal	Jobs Metrics	General metrics regarding jobs such as the user, organization, job status, operation type, run time, and cost are tracked. This information is necessary to provide an accurate accounting of tokens spent, system health, and troubleshooting.
Bionano Assure	Performance	Chip Metrics	General information about chip usage (i.e., throughput, data quality) is tracked to continuously improve instrument, chip performance, and provide enhanced support.
Bionano Assure	Performance	System Alerts	Error conditions and alerts are tracked to monitor the health of the environment and to provide enhanced support.
Compute On Demand	Other	Genomic Data	De-identified genomic data is stored temporarily on the Bionano Compute On Demand service during the analysis. After the operation has been completed and downloaded the input files are deleted. All data transfers are encrypted.
Access	Personal	User Account	User accounts are needed for login. User accounts include name and email address. Shared accounts are not permitted.
Access	Other	Genomic Data	The access server is used to manage OGM workflows and to visualize data. Mapping and sample data are deidentified.
VIA	Personal	User Account	User accounts are needed for login. User accounts include name and email address. Shared accounts are not permitted.
VIA	Other	Genomic Data	VIA facilitates the classification of Array, NGS, and OGM data. Curation of variant data is compiled into reports. All sample and variant data are de-identified.
ICS	Other	Genomic Data	Molecule data is collected in image form then converted to BNX files which are then transferred to the Bionano Access Server.

Data Flow

Bionano Access and the ICS system exchange data to facilitate the collection of molecule data from the instrument. Bionano Access and Bionano solve exchange data to facilitate the execution of mapping and analysis jobs on the compute server. Bionano Access passes copy number and variant data to VIA for classification and reporting.

The following table lists the exchange of data between software systems.

Source System	Target System	Data
Bionano Access	ICS	User Authentication
Bionano Access	ICS	Chip Setup
ICS	Bionano Access	Chip Run Status
ICS	Bionano Access	Molecule Data
Bionano Access	Bionano Solve	Analysis Jobs
Bionano Solve	Bionano Access	Analysis Job Results
Bionano Access	VIA	Copy Number Probes
Bionano Access	VIA	OGM Variants

System Design

Several features have been built into Bionano products to ensure the protection of user data. This section will describe the security features. **NOTE:** While some of these features are automatic and do not require user action (i.e., data encryption), many features (i.e., HTTPS SSL certificate) do need active management by qualified personnel at the customer site.

Security Feature	Products
Encrypted Data Transfer All data transfers are encrypted. This includes all local communication between systems as well as communication to hosted Compute On Demand and Bionano Assure services. File uploads to the Compute On Demand	All products

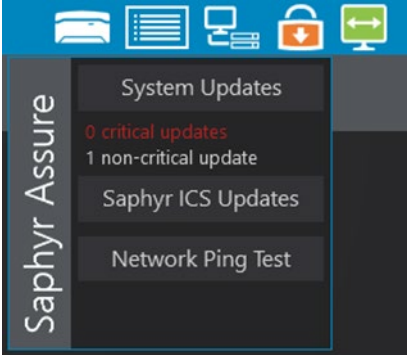
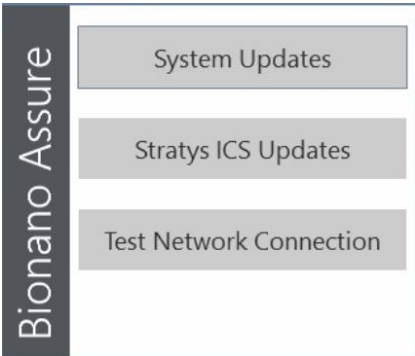
service do utilize HTTP, but those transfers are encrypted via the Java library used.	
No Customer Access These are systems that are accessible to Bionano employees only.	Compute On Demand Bionano Assure
Pass Through Authentication Users log into ICS using Bionano Access user accounts. The ICS system uses the Bionano Access authentication service.	Bionano Access ICS
Password Protection User passwords stored in the system are hashed and stored in a database.	All products
Password Expiration Administrators can set how often passwords should expire. They can also set how long previous passwords should be retained.	Bionano Access
Password Complexity Administrators can also control password complexity. They can set the minimum length, inclusion of numbers, special characters, and case changes in a valid password.	Bionano Access
Detect CAPS Lock The login page will display a message if CAPS lock is on.	Bionano Access
First Login On first login the user will be prompted to change their password.	Bionano Access
Forgot Password Workflow From the login page users can indicate they have forgotten their password. The system will allow the user to reset their password from a link sent by email. The link is valid for a limited period.	Bionano Access
Password Change From the account profile screen, users can change their password at any time. Each password provided will be retained in their password history for the configured password expiration period.	Bionano Access VIA
Login Attempts: Administrators can control how many login attempts are permitted before a user account is locked. Administrators can unlock accounts.	Bionano Access

Session Controls Users are not permitted to share accounts. When the system detects a new login on a user account any previous sessions are invalidated.	Bionano Access
Session Inactivity Sessions will be deactivated after a set period of inactivity on the website. Bionano Access can detect activity on a given page, so activity is not measured solely by page loads.	Bionano Access
Logging All system activity is logged. The log files are rolled on a periodic basis. The log files can be archived or configured to remain for longer periods of time. The logs are in JSON format so they can be parsed easily.	All products
User Roles Permissions are controlled by the assignment of a role to a user account. There are four roles in the system: Administrator, Project Lead, User, and Read-Only. User accounts can only be assigned a single role. These roles are described in detail in the <i>Bionano Access User Guide</i> .	Bionano Access
System Privileges Permissions are controlled by the assignment of privileges to a given user account. For more details on the privileges available refer to the <i>VIA User Guide</i> .	VIA
Account Deactivation Only accounts that have no data associated with them can be deleted. User accounts that have performed any operations cannot be deleted; they can only be deactivated. This ensures that all records of system activity are retained properly. Only administrators can delete or deactivate accounts. Users cannot log into accounts that have been deactivated.	Bionano Access
Project Based Data Access All data in Bionano Access is tied to projects. Project Leads can create projects and control who can access them.	Bionano Access
Job Ownership Protection Several forms of identification are tracked with each Bionano Compute On Demand job to determine ownership. Only the instance of Bionano Access that submitted the job can download the results.	Bionano Access Compute on Demand

Code Obfuscation Bionano Access JavaScript source code has been obfuscated and is not legible to prevent malicious modification of the source code.	Bionano Access Compute On Demand
Binaries The software is compiled to a binary executable.	ICS VIA
Token Balance Protection All voucher usage and token balances are managed by the Bionano Compute On Demand solution and do not reside on Bionano Access.	Compute On Demand Bionano Access
Debugging Prevention Bionano Access JavaScript source code is self-defending and cannot be debugged.	Bionano Access Compute On Demand
Login Banner Administrators can use the Bionano Access Login Banner feature to post corporate policies on the login screen related to the use of Bionano Access.	Bionano Access
Input Validation Data files are validated to ensure required fields are not empty, and data is of the correct data type and within valid ranges.	All products
HTTPS Support All HTTP traffic is secure over TLS 1.2. Customers must provide SSL certificates valid for their environment for local Bionano Access and VIA instances.	All products
Firewall All Bionano-provided computers have their firewalls enabled and are set to only allow native traffic.	All products
Diagnostic Data Scrubbing When instrument diagnostic data is generated, all identifiers are automatically scrubbed to remove any personal or protected data. The sanitized data set can then be shared with Bionano Support to diagnose instrument issues. All automated system health monitoring datasets that are transmitted to Bionano Assure are also scrubbed to remove any personal or protected data.	ICS Bionano Assure

Enterprise Data Centers Bionano only contracts with certified enterprise level data centers for our hosted services. They support the following standards: ISO/IEC 27001, GDPR, FedRamp, HITRUST, HIPAA, and many others. Although subject to change, currently, those data centers are associated with Amazon Web Services (AWS) and Microsoft Azure. Datacenters used for Bionano Compute On Demand are localized in the United States and Europe (currently, Ireland, Netherlands, and Germany) and a customer may choose to point their Bionano Access to any of the supported localized datacenters. Bionano Assure data is hosted in a datacenter in the United States.	Compute On Demand Bionano Assure
Remote Support Tools Bionano utilizes TeamViewer to provide remote support to the Saphyr Instrument Controller or Stratys Instrument Controller, and the Bionano Access Server. Bionano has enabled multi-factor authentication for its users in addition to a separate machine level password. The Instrument Controller and Bionano Access Server are locked to Bionano's TeamViewer account and cannot be accessed by any other users. Remote sessions will only be initiated with the express permission of a customer representative. The user is free to enable / disable TeamViewer access when not in use if required by their IT policy. This is easily done by clicking on the Remote Support Icon in the ICS to enable / disable remote access. TeamViewer is compliant with many security standards such as ISO/IEC 27001, ISO/IEC 9001:2015, GDPR, HITRUST, HIPAA, and others. See https://www.teamviewer.com/en-us/trust-center/compliance/ for further details. Remote support may be left enabled to allow for unattended access or, at the user's discretion, can be turned on and off as needed via the ICS interface or Bionano Access user interface to provide attended access.	ICS
Instrument Controller Operating System The Instrument Controller has been designed to limit and reduce the attack surface by disabling unnecessary operating system services, blocking user access to the operating system, blocking all applications not provided by Bionano and disabling all incoming network traffic. The Instrument Controller is preconfigured with the Saphyr or Stratys Instrument Control Software (ICS) which runs on an embedded version of the Windows 10 operating system (Saphyr: Windows 10 IoT Enterprise LTSC 2019, Stratys: Windows 10 IoT Enterprise LTSC 2021) that has been configured to run in Kiosk mode. Kiosk mode allows the user to interact solely with the ICS application and does not present access to the operating system to the user. Saphyr Systems shipped prior to the release of ICS 5.1 do not have kiosk mode enabled and are running Windows 10 IoT Enterprise LTSC 2016. Saphyr P/N 60325 and	ICS

60396 are compatible with kiosk mode and may be upgraded by contacting Bionano support.	
Saphyr Instrument Controller Operating System Access By default, access to the operating system on the Instrument Controller is limited. All functions that the instrument requires of the user or user's IT administrator can be accomplished within the ICS user interface. As there is no requirement for operating system access for instrument setup or operation, the default policy is to not supply operating system credentials to end users. Exceptions to this policy can be requested from Bionano Support. • NOTE: The Instrument Controller is not a general-purpose PC, and the user should not modify any operating system parameters or settings, change any existing operating system user accounts or passwords, install any 3rd Party software, or modify the computer hardware without prior approval from the Bionano support team. Bionano is unable to guarantee the performance or accuracy of the Saphyr or Stratys system if any unapproved modifications are made. • NOTE: The user should not attempt to join the instrument controller to a domain as this will interfere with the group policy configuration that the instrument control software requires to run reliably and can also cause a failure of the kiosk mode feature.	ICS
Stratys Instrument Controller Operating System Access Access to the operating system on the Stratys Instrument Controller is not available. All functions that the instrument requires of the user or user's IT administrator can be accomplished within the ICS user interface. • NOTE: The Instrument Controller is not a general-purpose PC. The user should not modify any operating system parameters or settings, change any existing operating system user accounts or passwords, install any 3rd Party software, or modify the computer hardware without prior approval from the Bionano support team. Bionano cannot guarantee the performance or accuracy of the Stratys system if unapproved modifications are made. • NOTE: Do not attempt to join the instrument controller to a domain. Joining a domain will interfere with the critical operating system configuration required to successfully run the instrument. Joining a Domain will interfere with the operation of kiosk mode and can also change windows update settings that will have been specifically configured to prevent unintended computer restarts while the instrument is processing samples resulting in termination of data collection. Additionally, domains can force policy changes that could allow untested drivers to be installed on the machine that could	ICS

cause the instrument to perform unexpectedly. Great care has been taken in the design of the Instrument Controller to tailor the Group Policy, Firewalls, and kiosk environments to work in a reliable, consistent, secure, and validated manner.	
Windows Updates Bionano is committed to providing tested and validated security updates in a timely manner. The Instrument Controller does not permit automatic Windows updates as they often cause a system restart which would interrupt instrument operations. The ICS had been designed to manage the detection, validation, and installation of Windows updates to ensure that the system is kept up to date with the latest security updates while ensuring compatibility with our systems. The ICS checks (daily) for available windows updates from Microsoft's servers. When an update is detected, it is sent to the Bionano Assure service to check whether it has been tested and validated to function properly with the Instrument Controller. When an update has been tested and released, the user will be notified of pending updates to install. When the instrument is idle and not processing a chip, the user can click the update icon and install pending updates (Figure 2 or Figure 3).  Figure 2. Saphyr System Updates  Figure 3. Stratys System Updates	ICS

Windows Defender The Instrument Controller includes the Windows Defender antivirus and malware detection program and is configured to protect the system without adversely affecting the performance of the ICS. Security Intelligence Updates for Windows Defender are downloaded and installed via the Windows Update mechanism described in the preceding section. The use of other products can interfere with the operation and performance of the ICS application and is not recommended.	ICS
Download Warnings Administrators can add custom system messages to warn users regarding proper data handling that must be acknowledged each time they attempt to download data.	Bionano Access
Proxy Support The Bionano Access Server can be configured to support proxy use when connecting to Bionano Compute On Demand services. The ICS Controller can be configured to use proxy settings for connection to Bionano Assure and Teamviewer Remote Support.	Bionano Access ICS

AUTOMATED HEALTH MONITORING BENEFITS

Bionano Assure is designed to maximize the performance and availability of the Saphyr and Stratys instruments. By continually monitoring run performance, Bionano Assure can detect future performance issues before they impact customer workflow and data quality. If any potential issues are identified, the Bionano support team will proactively contact the customer and determine a time to service the instrument before system performance is compromised. Depending on the nature of the issue, support personnel can connect to the system remotely (if enabled) and perform real-time repairs eliminating downtime.

DATA COLLECTION

Bionano Assure is designed to collect only information related to instrument and chip performance that is useful in determining current instrument health and predicting future servicing needs. The service has been carefully designed to ensure that no protected Personal Information is collected. This information detailed below is also collected when a user initiated diagnostic request is generated (**Table 2**).

Table 2. Types of information collected.

Information Type	Description of Collected Data
Instrument configuration	ICS version number, Instrument serial number, part number, hardware configuration (component serial numbers, firmware versions), calibration information

Run setup	Sample unique ID (random, machine generated unique identifier), Enzymes, Fluorescent Label, Genome Type (human, or non-human)
Chip	Chip serial number, barcode, chip registration data
Run performance	Operation start / end time DNA Loading recipe and electrophoresis trace data Chip cleaning metrics Hardware performance metrics (i.e., focus, uniformity, lasers, stages) DNA quantity and distribution statistics Mapping metrics (Map Rate, NLV/PLV rate, BPP ...)

Bionano Assure does **not** collect protected Personal Information and does **not** collect any optical genome map data or any other identifying information (**Table 3**).

Table 3. Types of information not collected.

Information Type	Description of Uncollected Data
Sample	Sample Name, Sample Description, User ID
Genome Reference	Reference Name, Reference File Name
Project	Project Name
Run	Operator ID
Chip Setup	Chip Name
Molecule	Individual DNA molecule data (BNX)

All communication with the Bionano Assure service is performed over an encrypted https connection using Transport Layer Security (TLS) V1.2. All data stored in the Bionano Assure service is encrypted using 256-bit AES encryption using the Microsoft Azure infrastructure. Access to health monitoring and diagnostic data is secured via multi-factor authentication (MFA).

Molecule Detection

The Instrument Controller (**Figure 4**) is connected to the Saphyr or Stratys Instrument via USB3. The Instrument Controller will take the captured images and convert them to BNX files. BNX is a proprietary Bionano data format that describes the molecules detected and the label locations on them. Refer to Bionano.com for current specifications on all our proprietary data formats. The Instrument controller will also generate molecule metrics (i.e., the count of molecules detected, label density, etc.).

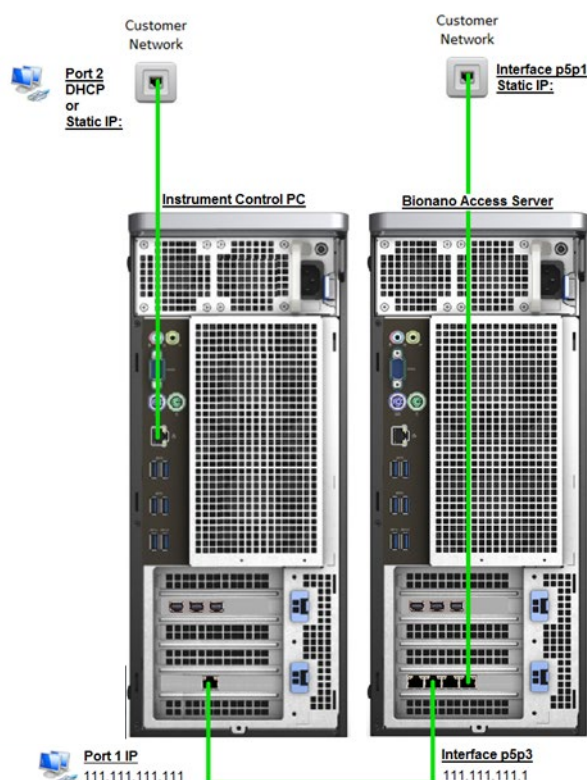


Figure 1. Instrument Controller

There are two ways the instrument controller can be connected to the Bionano Access Server. Typically, the Instrument Controller and Bionano Access Server are tethered with a network cable. This allows chip runs to be processed even if the customer's network is down. The Bionano Access Server is accessible to the Instrument Controller with the IP address of 111.111.111.1. To tether the Bionano Access Server it must sit in proximity to the Instrument Controller in the lab. When it is not possible to place the Bionano Access Server in the lab it can be reached over the customer's network. The customer must assign a static IP address to the Bionano Access Server. 1GB bandwidth on the network is sufficient for transferring molecule data to the Bionano Access Server.

Saphyr System

In the Saphyr system, chip run data is grouped into cohorts. There are eight cohorts per scan per flowcell. For each cohort, the Instrument Controller will send a BNX file with molecule metrics to the Bionano Access server over HTTPS (port 3005). The Bionano Access Server will then generate mapping metrics such as the map rate. The Instrument Controller will pull mapping metrics for each cohort over HTTPS (port 3005). Both ICS and Bionano Access will dashboard the molecule and mapping metrics so the operator can monitor the chip run at the instrument or from their workstation. When the chip run is completed the individual cohort BNX files for a flowcell (assuming users are not multiplexing) are merged and the resulting BNX file is inserted into the selected Bionano Access project as a new Molecules Object.

Stratys System

In the Stratys system, the mapping metrics are generated on the Instrument Controller. The ICS will send the molecule metrics and the mapping metrics to Bionano Access, which will then display them on the dashboard. When the chip run is completed, the ICS will send the final BNX file as well as the data that is included in the MQR to the Access Server to be placed in the selected project as a new Molecules Object.

Local Saphyr Compute Cluster

The Bionano Compute cluster will consist of at least one Saphyr Compute system. Each Saphyr Compute server consists of four individual servers inside a single 2U rack mount chassis. Detailed information about the server configuration is provided in the *Saphyr® Networking and Setup Guide* (CG-30251). To launch jobs and transfer files the Bionano Access Server will communicate with the Saphyr1a over SSH. The Bionano Access Server will not communicate with any other nodes in the compute cluster. The Saphyr1a node must be assigned a static IP and be accessible to the Bionano Access Server. The Compute systems are rack mount so they are often in data center that can be distant from the lab. 1GB band with is sufficient, but 10GB is recommended if possible. The size and complexity of the files transferred has continued to grow over time. When a node finishes a compute job it will do two things. First, it will curl an HTTPS post (port 3005) to the Bionano Access Server to semaphore that the job has been completed. Second, it will output a file with the completion status. Every 5 minutes the Bionano Access Server will SSH to the Saphyr1A node and check for completion marker files for each active job. After the Bionano Access Server receives a semaphore or finds a completion marker file it will download the result files from the Saphyr1A node via SSH. Once the results have been downloaded the Bionano Access Server will email the user who launched the job to let them know the results are available. By default, the Bionano Access Server will relay emails through Amazon SES services. Bionano Access Server can be configured to use local SMTP email services within the customers infrastructure instead if desired. Contact Bionano Support to learn how to change SMTP settings. A cron job on Saphyr1a will delete job files that are older than 2 weeks automatically.

Stratys Compute

Stratys Instrument users may have a Stratys Compute that is collocated with their instrument. The Stratys Compute is connected directly to the Bionano Access Server using a network cable and does not need a direct connection to the user's network. Detailed information about the server configuration is provided in the *Stratys Site Preparation Guide* (CG-00056). Prior to beginning each assembly job on the Stratys Compute, the amount of available disk space is determined. If not enough disk space is available, the software will delete the oldest compute job(s) until enough space is available.

2

Bionano Compute On Demand

The flow of data for a Bionano Compute On Demand job is like how they are processed locally. Data is just being routed to the hosted Bionano Compute On Demand service instead of the local compute cluster. All communication to and from the Bionano Compute On Demand service is encrypted. To use the Bionano Compute On Demand service the organization's Bionano Access Server must have Internet access. The Bionano Access Server can be configured to work with a proxy that does not require authentication credentials if necessary. Bionano Compute On Demand can be configured to use only regional datacenters to process the data to ensure the data does not leave those regional boundaries. Contact Bionano Support for more information about the regional datacenters.

Before launching each job, the Bionano Compute On Demand service is contacted to provide a token estimate. When the job is launched the tokens needed are reserved. Then the input files are uploaded serially. Once all the files have been uploaded the analysis will start. Each analysis job runs on its own independent compute environment. When the job is finished it can be downloaded back to the local Bionano Access Server. The Bionano Compute On Demand service tracks what instance of Bionano Access launched the job and will only allow that instance to retrieve the results. Once the results have been successfully downloaded the input and result files on the Bionano Compute On Demand service are deleted. If the job does not successfully complete any input and result files will still be deleted automatically after 30 days. End users only ever interact with their local Bionano Access Server to use the Bionano Compute On Demand service. They do not ever directly access the Bionano Compute On Demand service. After completion, the Bionano Compute On Demand services will reconcile the cost of the job and refund any unused tokens that were not consumed. The user will receive a refund email in this case from the Bionano Compute On Demand service.

Communication Channels

Below (**Table 4**) is an inventory of the communication protocols used between systems.

Table 4. Communication Protocols

Originating From	Target	Protocol
Bionano Access Server	Saphyr1a Compute Node or Stratys Compute	SSH (port 22)
Bionano Access Server	Amazon SES Email service	SMTP (port 587)
Saphyr or Stratys Instrument Controller Customer Workstations Compute Servers	Bionano Access Server	HTTPS (port 3005 or 3006)
Saphyr or Stratys Instrument Controller	Bionano Assure Service	HTTPS (port 443)
Bionano Access Server	Compute On Demand	HTTPS (ports 443 and 3000) HTTP (port 3001)
TeamViewer	Bionano Access Server, Saphyr or Stratys Instrument Controller Workstation	TCP port 5938
VIA Client	VIA Server	HTTPS (Port 8443)

Resource Strategy

As noted in the previous section outlining Communication Channels, the Bionano instrument solution is dependent on other resources such as network, database, file system, and queuing systems. Some general strategies have been incorporated into the software product to ensure it is resilient and robust.

- **Error Handling:** Potential errors are handled and logged gracefully. Issues are reported to the user with meaningful error messages.
- **Global Error Handling:** Handling is in place to catch uncaught exceptions to provide proper detail for troubleshooting and resolution.
- **Timeouts:** Timeouts have been set for all communication between systems to prevent stalls when there are communication failures.
- **Retry:** If another system may temporarily not be available, the system should queue the request and retry it later. The system should have a limited number of retry attempts to prevent infinite loops. The retry attempts will implement a backoff delay on each attempt up to the maximum attempts permitted.
- **Semaphore Backup:** If a semaphore signal from another system could be missed, have a backup process that will poll for the results to be sure they are captured.
- **Logs:** Logging levels can be tuned up or down. Product will ship with logging levels such that all warnings and errors are reported. The output logs can be archived and mined to determine any trends or potential issues.
- **Startup Checks:** On startup, the systems will verify connectivity to dependent systems, check dependency versions, and verify proper system configuration settings. The system will fail to start if the environment is not configured properly.
- **Email Notifications:** The system will send email notifications to users to let them know when there are issues or conditions that require their attention.
- **Rate Limit:** Bionano Access includes a library to rate limit requests to prevent denial of service attacks.
- **Ban IP:** Bionano Access includes a feature to blacklist IP addresses if they make too many unauthenticated http requests.

Required Customer Controls

While Bionano products have been designed to provide data security, protection of data also depends on security policies in use by the customer's organization. The following security controls should be considered.

- **Information Security Policy:** the organization should have formal security policies established.
- **Access Authorization:** If formal approval or authorization is needed for a Bionano Access user account, a procedure is needed to document the authorization for each account created. Bionano Access does not have the means to track this approval process.
- **Remote Support:** Bionano support may require remote access to the system to troubleshoot issues. Understand the organization's guidelines for external access and work within those regulations. Establish connectivity for support personnel in advance to avoid operational interruptions.

- **Disaster Recovery:** Establish procedures for backup, data retention, emergency operation, and recovery for the environment that is compliant with the organization's regulations. These policies will vary within each organization depending on the criticality of the Bionano system and the tolerance for data loss.
- **Record Retention:** Bionano Access does not have a mechanism to expire, retire, or delete expired data. We do track the date each object was created. If there are specific policies about record retention procedures will be required to manually delete them.
- **De-identification:** Various data elements within the system require a name. These include projects, samples, experiments, and objects. The organization should have a procedure for de-identification or pseudonymization of these data elements to prevent the identification of protected data.
- **Shared Accounts:** Shared accounts are not allowed and Bionano Access features prevent their use. Under no circumstances should accounts or account credentials be shared.
- **Unattended Access:** The system will deactivate accounts after a period of inactivity. If leaving a workstation log out before walking away.
- **Clear Desk Policy:** Most organizations have a clear desk policy that prohibits leaving any personal or protected data out on the desk or workstation where it is plainly visible. It is a good practice to prevent the loss of protected data or give an easy mechanism to defeat the system's de-identification.
- **System Updates:** Each Bionano software release includes important security patches in addition to new and improved functionality. It is important to upgrade as soon as possible the latest version when it is released.
- **Patching:** Customer must consider how often they want to patch their Centos operating system. At a minimum we recommend patching the system when installing updated versions of Bionano software. Some sites with tightened security patch more frequently. Bionano Access includes a [security page](#) that indicates the current patching status at Bionano and if there are any known patching issues. Users can also sign up for security patching notifications from this page.
- **User Audits:** An audit of user accounts should be conducted on a regular basis. Accounts that are no longer necessary should be deactivated.
- **Default User Account:** The default user account provided with the initial Bionano Access installation should be deactivated once true administrator accounts have been created and tested.
- **Banners:** Banners can be added to login and download screens to warn users regarding appropriate use and related policies.

Risk Management

Bionano has activities that are conducted as part of each software release. This section outlines some of the activities being conducted to harden Bionano security offerings.

- **Ticketing System:** A ticketing system is used in-house to track all defects and feature requests. The ticketing system ensures that all changes are visible to the Bionano Software Quality Assurance (SQA) team. The ticketing system also enforces and documents the workflow necessary to validate every system change completed.
- **System Validation:** All features of Bionano systems are tested for each release. Regression testing ensures that existing security features are not compromised due to code changes. Test cases are

generated for each user story. A Validation Plan is generated for each release to document what was tested.

- **Threat Mitigation:** Testing is conducted with security in mind. Defects, usability issues, and security concerns are logged as tickets for development to address.
- **Change Control:** All Bionano systems are under source control. Code check-ins reference the ticket driving the change and tickets are given the commit numbers so they can be cross-referenced.
- **Security Patches:** Bionano reviews all libraries, packages in use, and determines which need to be updated. Tools such as retire.js for Nodejs or Safety for Python are used to automate this review where possible. Libraries are then updated in our code base and tested during development to ensure stability.
- **Security Scans:** Tools such as Qualys are used to perform security scans on our configured systems for each release cycle. Security issues identified are ticketed for resolution. We also support customers who choose to perform their own security scans.

Common Security Considerations

This section describes some typical security concerns encountered during installation.

- **Anti-Virus Software / Hard Disk Encryption:** It is common for customers to have rules that dictate corporate standardized anti-virus and/or hard disk encryption software be installed on all workstations including the Instrument Controller. The Instrument Controller should be considered part of the instrument and not a general-purpose workstation. It is secured with kiosk mode to prevent any interaction with the system other than through the Instrument Control Software. The Instrument Controller is already equipped with anti-virus software which updates automatically and has been tested with our solution. Thousands of individual files can be created during a typical chip run and adding anti-virus software is certain to have a significant performance impact, which may lead to a loss of sample or data.
- **Internet Access:** Some sites prefer to limit Internet access where possible. Internet access is required to use the Bionano Compute On Demand and/or Bionano Assure services. Internet access is also required for Bionano to provide remote support. Internet access is also required to perform some system updates. Internet access can be limited, but these service offerings would be impacted.
- **VLANS:** We support a configuration for the local Compute cluster where all the nodes except the submission node are in a VLAN. This can be helpful where the customer has limited static IP addresses.
- **Customer Clusters:** This document only pertains to the use of Bionano validated systems. It does not extend to customer resources used to provide compute resources. Contact Bionano Support for concerns regarding using customer compute resources.
- **Web Server in the Data Center:** Some customers require all web servers to be secured in the data center and do not allow their placement in the lab. The Bionano Access Server can support this configuration, but network outages could interrupt the operation of the Saphyr or Stratys. When placing the Bionano Access Server in a data center, we recommend a 10 GB ethernet connection if possible.

Bionano Compute On Demand and Bionano Assure Terms and Conditions

These terms of use are in addition to any applicable end user license agreement for the Bionano Compute On Demand and Bionano Assure software between you or your organization and Bionano Genomics, Inc. ("Bionano"). By connecting to and using the Bionano Compute On Demand and the Bionano Assure software, you agree to be bound to these terms of use.

1. You may only use the Bionano Compute On Demand software to process data that is owned or licensed and lawfully obtained by you in connection with Bionano hardware and software that is owned or licensed and lawfully obtained by you. You may only use the Bionano Assure software in connection with Bionano hardware and software that is owned or licensed and lawfully obtained by you.
2. You must comply with the current Bionano technical documentation applicable to the data you send to be processed by the Bionano Compute On Demand software. Noncompliance with the technical documentation may result in failure of operations that would not be reimbursable by Bionano.
3. Genomic data (i.e. BNX files) will be transferred from your local server to a hosted Bionano Compute On Demand resource for the purpose of computing in the cloud. These resources exist in either or both AWS and Microsoft Azure datacenters and not on Bionano-owned infrastructure. The data is encrypted during transit to those datacenters. Refer to Bionano Genomics Data Security Guidelines (document number 30292) available at www.bionano.com for details of the data that is transmitted. For clarity, the Bionano Assure software does not require the transfer of genomic data (i.e. BNX files) from your local server to any hosted or other resource.
4. For the Bionano Compute-On-Demand service, upon successful completion of data processing, the data are returned to your Bionano Access™ server and are deleted from the Bionano Compute-On-Demand servers.
5. When an operation fails in a Bionano Compute On Demand server, data are retained temporarily within the Bionano Compute On Demand servers. You may authorize Bionano Support to view this data for the sole purpose of troubleshooting the failure. Whether or not you contact Bionano, this temporary data will be deleted pursuant to Bionano procedures in effect at that time.
6. Tokens provided by Bionano are required to run operations in the Bionano Compute On Demand servers. You will act lawfully, ethically and in accordance with Bionano procedures in effect at that time in procuring and using the tokens. You agree that you will not attempt to misuse or otherwise attempt to subvert the use of the tokens.
7. You agree to the sharing of system data from your optical genome mapping system with Bionano as described in the Bionano Genomics Data Security Guidelines (document number 30292). For clarity, the Bionano Assure software does not transfer genomic data (i.e. BNX files) from your system to Bionano resources, hosted or otherwise.
8. You agree that system health metrics will be transferred from your optical genome mapping system to a Bionano Assure server that is hosted in a Microsoft Azure datacenter (or other datacenter as determined by Bionano in its sole discretion). The data will be encrypted during transit to this datacenter. Refer to Bionano Genomics Data Security Guidelines (document number 30292) for details of the data that is transmitted.
9. By enabling Bionano Compute On Demand and the Bionano Assure software, you authorize Bionano to collect summary metrics for the purposes of billing, support, and improvement of Bionano products. These metrics include information on the status of your optical genome mapping system and are not shared with third parties. Bionano does not accept and does not collect any protected health information nor will Bionano collect your actual run data or pipeline results. You can select Bionano Assure Only without Compute On Demand. If you select this option, that will enable the collection of the same

summary metrics, but will not allow your genomic data (i.e. BNX file) to be sent to a Bionano Compute On Demand server.

10. You agree to receive emails from Bionano pertaining to the Bionano Compute On Demand system maintenance and upgrade events. Bionano will not share your email with any third parties. These emails will be sent to either or both of the email addresses registered in your Bionano Access™ server and associated with your account within Bionano's systems.
11. You agree not to use the Bionano Compute on Demand or the Bionano Assure software for any purpose related to monitoring availability, performance or functionality, benchmarking or for any competitive purpose.
12. You will be responsible for verifying system compatibility and requirements prior to the installation, update or download of any software.
13. Bionano, at its sole discretion and without prior notice, may terminate your access to the Bionano Compute On Demand and Bionano Assure software if you are not in compliance with the terms of use the applicable end user license agreement or behave in an illegal or unethical way.

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.

TYPE	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
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