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GOLD STANDARD DIAGNOSTICS
Storm 3.2 User's Manual for the Bolt

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Effective Date: 2023-12-18

GOLD STANDARD DIAGNOSTICS

Storm 3.2 User's Manual for the Bolt®
(REF 00500, REF 00500 CL)

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1 Introduction

The purpose of this manual is to identify the system components and provide instructions for use of the Storm Software Suite with a Bolt instrument (EIA) REF 00500, and Bolt (CLIA) REF 00500 CL, (the "system"). This manual provides basic safety information, instructions for use and maintenance, as well as general troubleshooting guidance. It is recommended that this manual be kept near the instrument and accessible to the user at all times.

NOTE: All references to CLIA (Chemiluminescent Immunoassay), luminescence, or RLU (Relative Light Units) measurement are only available for use with Bolt instruments equipped with the chemiluminescence option.

1.1 Intended Use

The system is designed to automate the processing of enzyme immunoassay (EIA) REF 00500 and Enzyme Immunoassay (EIA) / Chemiluminescent Immunoassay (CLIA) REF 00500 CL tests on Gold Standard Diagnostics (GSD) EIA/CLIA instruments. The system is only intended to be used by properly trained personnel.

The intended use of the system is as a discrete photometric chemistry analyzer intended to duplicate manual analytical procedures by performing various steps such as pipetting, heating, and measuring color intensity automatically. The system is also intended to perform as an 'accessory' to be used with another device (i.e.: assay test kit) to enable that device to be used in accordance with its intended purpose.

NOTE: Different instrument models contain slightly different components which do not affect the testing capabilities of the instrument, but may be different in appearance from the images shown in this manual. Follow the instructions applicable for the model being used, as explained in documentation provided, as prompted by the instrument software, and as instructed by instrument Distributor.

1.2 Certifications and Registrations

For up-to-date registration and licensing information, please refer to the official online registration databases, such as

- FDA's Establishment Registration & Device Listing database

- EUDAMED - European Database on Medical Devices

- Health Canada's Medical Devices Active Licence Listing (MDALL) database

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2 Safety Information

The following safety instructions are to be observed at all times during the operation of the system. It is strongly recommended that all first time personnel read this manual prior to working with the system and receive training from GSD or a GSD distributor.

The Bolt is designed and manufactured in accordance with the safety requirements for electronic and medical systems listed in the certifications section above to ensure that they function safely, both electrically and mechanically, under normal use conditions. The instrument is supplied in a condition that allows for safe and reliable operation.

2.1 General Safety

The system must only be operated in accordance with the stated intended use. It is recommended that the instrument is used only with the spare parts and accessories suggested or provided by GSD. The use and maintenance activities defined in this manual are intended to ensure the safety of the operator and the proper functionality of the system. All instrument surfaces must be dry while operating the system. GSD recommends that all operators be trained in good laboratory practices and observe general laboratory safety guidelines.

NOTE: Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

2.2 Electrical Safety

The system must be operated using a power source with an operating voltage compatible with the requirements stated on the device label. The Bolt instrument is to be used only with the provided 3-prong grounding type plug to connect the instrument to the main power supply. It is important to ensure the power switch is in the Off position prior to connecting the instrument to the main power supply. The attached computer is to be used only with its supplied power cord.

The use of a multi plug is not allowed and it is recommended that the instrument be run from a dedicated socket or a backup power supply. Use only extension cables with a protective conductor and grounded contact. The Bolt instrument uses two fuses, one AC fuse (part number 5015) and one DC fuse (part number 5383). Fuses that are non-functioning must be replaced using fuses which match the values (nominal voltage, nominal current, and type) specified for the instrument. A spare AC fuse is included with the instrument.

If at any time the instrument becomes unsafe to use, immediately switch it off and disconnect it from the main power supply.

2.3 Mechanical Safety

Installation and service of the system must be completed by a trained technician to ensure a minimized exposure of the operator to mechanical risks. Improper use or handling of the system may cause serious damage to the instrument or result in injury to the user. Avoid touching the probe and other moving parts while the system is in operation. Protective covers should not be removed while the instrument is on due to potential contact with moving parts. Exercise extreme caution when working on or near the peristaltic pump when the cover is not in place (applicable models only). Openings on the instrument provided for ventilation are not meant as access points.

If the cover must be opened during operation, verify that the movement of the probe has stopped before reaching inside the instrument. This should be done cautiously and only when absolutely necessary.

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2.4 Biological Safety

Any parts of the system (including any attached computers/keyboards) that have come into contact with samples/test reagents are to be treated as being potentially infectious. Some of the general purpose reagents have the potential to cause irritation of the skin and mucous membranes. It is recommended that the operator use appropriate personal protective equipment (PPE) such as gloves, lab coat, and eye protection while using the system. For devices used in conjunction with the system, it is the responsibility of the user to observe the instructions and warnings provided by the manufacturer for proper use of reagents.

2.5 Safety Labels

The Bolt instrument is labeled with universal general warning labels to identify risks which may be encountered by the operator.

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3 System Instrument

The Bolt is a fully automated microtiter plate processor that is able to completely perform sample processing steps, including dilutions, dispenses, incubations, shaking, and wash processes. The Bolt also provides photometric and luminescent measurement and evaluation. The Bolt is controlled by a Windows PC software program (Storm Instrument Manager) that is specifically designed for the system.

3.1 Instrument Overview

The Bolt instrument is a robotic platform that performs programmed EIA and CLIA tests. It is attached to a computer that enables automated running of assay steps, worklist generation, data management, and data analysis.

The instrument components are as follows:

1   Instrument Cover

2   Reagent Rack

3   Sample Rack

4   Microtiter Plate Carrier

5   Probe Assembly

3.2 Instrument Details

It is recommended that the area for use and storage of the Bolt instrument be a dedicated space which is able to accommodate the following specifications. For optimum instrument performance, the room temperature should be controlled at temperatures between 20°C and 24°C (68°F to 75.2°F), the relative humidity should be between 20% and 90% (non-condensing), and the environment should be relatively dust-free and free of excessive vibration.

3.2.1 Instrument Power Specifications

Voltage: 100 – 265 V
Frequency: 50 – 60 Hz
Power Consumption: 12W without incubator, 120W max

It is recommended that the instrument be operated off of a dedicated power source. Ideally the Bolt should be placed near an outlet and connected to a surge protector or an uninterruptable power supply (UPS).

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Instrument Dimensions and Weight
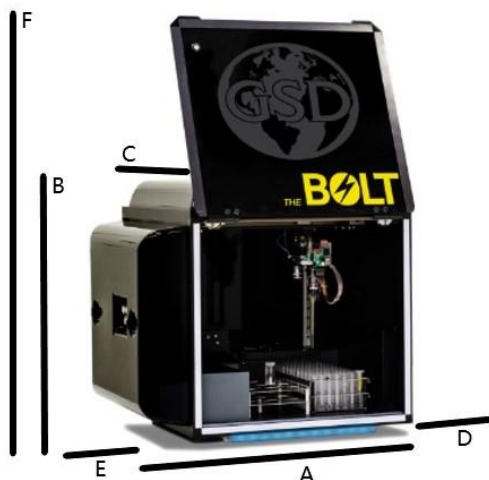
Dimensions:

A/Width of instrument alone: 64.8 cm (25.5 in)

B/Height of instrument alone: 54.6 cm (21.5 in)

C/Depth of instrument alone: 61 cm (24 in)

D/Width of suspended computer: 33 cm (13 in)

E/Width of attached Wash/Waste: 15.3 cm (6 in)

F/Height with door open: 86.4 cm (34 in)

Weight: 50 kg (110 lbs.)

The total bench space recommended to accommodate the Bolt and related equipment is 113 cm (44.5 in.) wide x 86.4 cm (34 in.) high x 61 cm (24 in.) deep. The laboratory bench must be sturdy enough to support the full weight of the Bolt as well as additional equipment. Expect the total weight of the Bolt and accessory equipment to be approximately 50 kg (110 lbs.).

3.3 Instrument Components

NOTE: Certain instrument models may not contain all of the components listed below.

3.3.1 Sample Racks

The removable stainless-steel rack is available in various interchangeable sizes to accommodate 12, 13 or 16mm diameter sample tubes (up to 100mm in height). The 12mm and 13mm racks can accommodate up to 96 patient samples, while the 16mm rack can hold up to 72 patient samples. Sample tube positions are numbered beginning in the back left corner of the rack and proceeding left to right across each row, from back to front.

Custom racks are also available. Contact a GSD Technical Service representative or your local GSD Distributor for details.

3.3.2 Reagent Rack

The Reagent Rack contains nine reagent positions and accepts 22mm-35mm diameter bottles (Reagent Adapters are required).

Custom Reagent Racks and/or Adapters are also available. Contact a GSD Technical Service representative or your local GSD Distributor for details.

3.3.3 Microtiter Plate Carrier

The microtiter plate carrier contains one reaction microtiter plate position (left plate position) and one pre-dilution plate position (right plate position).

3.3.4 Probe Assembly

The Bolt utilizes a single probe, dual needle system; no disposable tips are used. This system is capable of precise pickups and dispenses for volumes between 1 µl and 300 µl. The high-precision micro-syringe aspirates 1 µl with less

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than 3% CV across an entire reaction plate. Liquid detection is performed via conductivity, with a minimum detection volume of 50 µl.

3.3.5 Incubator

The integrated Incubator on the Bolt uses forced convection heating which is capable of a maximum temperature of 45°C. The Bolt can aspirate and/or dispense fluid to the Wells in the MTP while the incubator is on or off.

3.3.5.1 Incubator Specifications

Temperature Range: Room Temperature to 45°C
Temperature Variance: ± 1°C Well to Well over the MTP
Heating Time: 9 min (Room Temperature to 37°C in an MTP Well with 150 µL of fluid)
Cooling Time: 19 min (37°C to Room Temperature in an MTP Well with 150 µL of fluid)
Voltage: 24 V

3.3.6 Reader

The Bolt's on-board reader is an ultra-compact, fully integrated LED spectrophotometer which contains the standard wavelengths of 405nm, 450nm, 490nm, 550nm and 630nm. Custom wavelengths are also available.

For Bolt instruments equipped with the chemiluminescence option, the on-board reader also contains a Photon Multiplier Tube (PMT) for the detection of chemiluminescent assays. Bolt instruments with these readers can support both traditional EIA assays as well as CLIA assays.

3.3.6.1 Reader Specifications - Spectrophotometer

Photometric range: 0 to 3.0 OD
Spectral range: 400 nm to 700 nm
Read time: approx. 2min/plate
Precision: 0 to 2.000 OD: +-0.003 OD or CV < 1%, 2.001 OD to 3.000 OD: CV < 1.5%
Resolution: 0.001 OD
Linearity: < 1% 0 to 2.000 OD (typical), < 2% 2.001 OD to 3.000 OD

3.3.6.2 Reader Specifications - Chemiluminesence

Detection Type: Glow
Spectral Range: 300nm-500nm
Dark Count: 50 counts per second (standard)
Measuring time: 100ms (adjustable 100-1000ms)
Dynamic range: 6 decades (orders of magnitude)

3.3.7 Shaker

The integrated linear shaker features a no-spill design which closely replicates manual shaking. The Bolt can dispense and/or incubate while the shaker is in motion.

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3.3.7.1 Shaker Specifications

Amplitude:	0.6 mm
Adjustable speed:	up to 900 RPM
Capacity:	2 MTP (1 reaction, 1 predilution)
Voltage:	5 V DC

3.3.8 Computer

The included computer is attached to the instrument via a USB connection. The computer also contains Ethernet, RS232, and additional USB ports. Computer specifications are listed below:

3.3.8.1 Instrument Computer Specifications

The instrument computer (in a single or multiple instrument environment) must meet the following <u>minimum</u> specifications:

Processor:	Intel Core i3 12100T 4 Core 2.2 GHz
Memory (RAM):	4 GB
Hard Disk:	120 GB
Ports:	USB 2.0 or greater (RS232, Ethernet ports optional)
Graphics:	Intel(R) UHD Graphics 600, 1.00 GB RAM, 1366x768 resolution
Operating System:	Windows 10 Pro 21H1 19043
.NET Framework:	.NET 4.8

3.3.8.2 Server Computer Specifications

If running in a multiple instrument environment with a separate server computer, the server computer (with the Storm Server and **Storm System Configuration Tool**) must meet the following <u>minimum</u> specifications, depending on the number of instruments connected to the server:

# of Instruments	Processor	Memory (RAM)	Memory (Hard Disk)	Ports	Graphics	Operating System	.NET Framework
1	Intel Core i3 12100T 4 Core 2.2GHz	4.00 GB	120GB	USB 2.0 or greater, Ethernet, RS232 (optional)	Intel(R) UHD Graphics 600, 1.00 GB RAM, 1366x768 resolution	Win 10 Pro 21H1 19043	.NET 4.8
5	Intel Core i7 1180G7 4 Core 2.2GHz	8.00 GB	240GB				
10	Intel Core i9 11900F 8 Core 2.5GHz	16.00 GB	500GB				

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4 System Software

The pre-installed Storm Software Suite runs on the Windows based computer included with the instrument. It provides the ability to create and run Worklists, analyze results from Worklist runs, generate reports of Worklist run results, and integrates with any LIS that supports the NCCLS LIS1-A and LIS2-A specifications.

The Storm Software Suite is highly configurable and includes support for audible alerts for various events that occur during the use of the instrument. Computer speakers should be enabled at all times and additional speakers are recommended.

The Storm Software Suite is required in order to operate the instrument and is comprised of three components: the **Storm Server**, the **Storm System Configuration Tool**, and the **Storm Instrument Manager**.

The Storm Server is a process that responds to requests from one or more Storm Instrument Manager instances to provide management of data generated from Worklist runs. The Storm Server also stores system configuration information shared by all Storm Instrument Manager instances connected to the server.

The Storm System Configuration Tool is used to configure settings for the system – that is, the Storm System Configuration Tool is used to configure settings that are common to all Storm Instrument Manager instances connected to the Storm Server. The Storm System Configuration Tool must always be installed on the same computer on which the Storm Server is running.

The Storm Instrument Manager allows the user to select, configure, and run ELISA and CLIA assays for a given set of Samples on the instrument. These configurations are saved and run as Worklists. The Storm Instrument Manager also allows the user to evaluate the results of Worklist runs, as well as perform instrument maintenance.

All software components are pre-installed on the computer included with the instrument.

NOTE: Gold Standard Diagnostics periodically provides software updates to distributors and customers. This User's Manual describes the functionality of the Storm 3.2 software with the Bolt instrument. Contact the local instrument distributor with any further questions about software versions or software update instructions. Be sure to refer to the User's Manual appropriate to the software version in use.

4.1 System Configuration Options

There are two ways in which the system can be configured. The two configurations are described in detail in the following sections.

4.1.1 Single Instrument Configuration

For labs with a single instrument, or a small number of instruments which will not be run together as a system, the Single Instrument Configuration can be used. In this configuration, all three components of the Storm Software Suite are installed and run on a single instrument computer, as shown in the following diagram:

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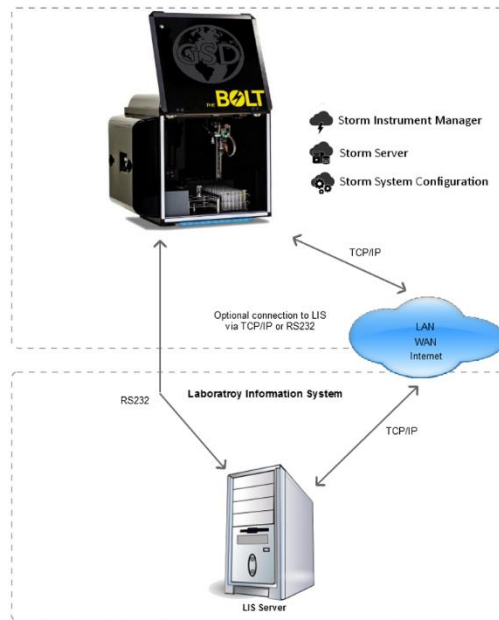
The system is configured in this way by default at the time of purchase and no additional software installation or configuration is necessary to run in this format.

NOTE: This configuration is limited by the amount of computing power and storage space on the instrument computer.

4.1.2 Multiple Instrument/Central Server Configuration

For labs with multiple instruments, it is recommended that the Storm Server be installed and run on a central computer that is connected via a TCP/IP network to each instrument computer running the Storm Instrument Manager. This configuration is shown in the following diagram:
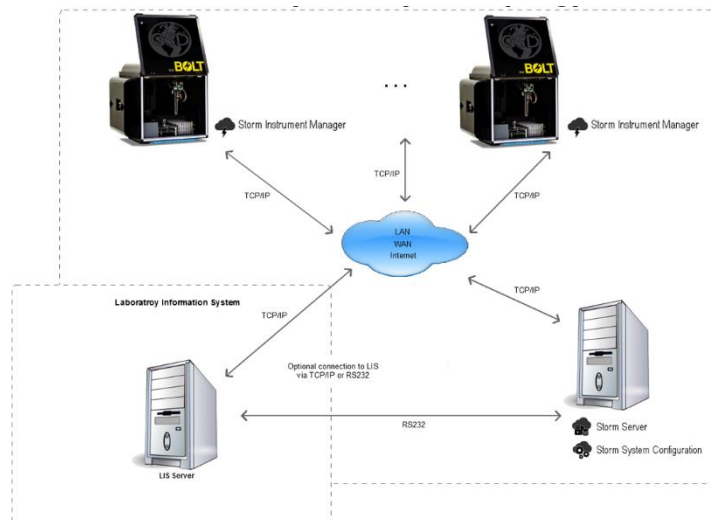
The central, shared Storm Server allows for a common configuration of all Storm Instrument Managers and a single connection to the LIS.

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If using the Central Server Configuration, contact the local instrument distributor for additional instructions regarding software installation on the central server computer and proper configuration of all software components.

4.2 Storm Server

The Storm Server is a Windows Service that runs in the background of the computer on which it is installed. The Storm Server service starts automatically when the Windows operating system on the computer boots up. The Storm Server service stores configuration data for the system and processes requests from Storm Instrument Manager instance(s) to store and retrieve data generated from Worklist runs performed on the associated instrument(s).

4.3 Storm System Configuration Tool

The Storm System Configuration Tool is used to specify configuration settings for the Storm system. These settings are stored by the Storm Server and used by all Storm Instrument Manager instances connected to the server. The Storm System Configuration Tool must be installed on the same computer on which the Storm Server service is running.

4.3.1 Launching the Storm System Configuration Tool

To launch the Storm System Configuration Tool, double click/tap the associated icon on the desktop.

NOTE: All connected Instrument Manager instances must be closed (as prompted) before opening the Storm System Configuration Tool.

Choose **Yes** if asked to allow the program to make changes to the computer. The Storm System Configuration Tool will prompt the user to choose a Storm System User Account to log in. Only users with Administrator or Tech Service accounts are allowed to access the Storm System Configuration Tool. Select the desired user account (only Administrator or Tech Service user accounts appear in list), enter the password on the login screen as prompted, and click/tap the "Log on" button:
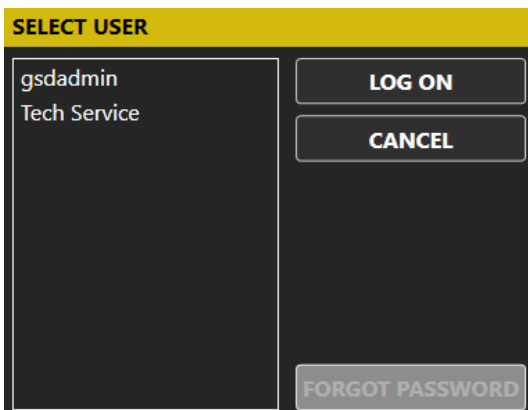
NOTE: If an Administrator user forgets his/her password, a new password may be set using the Forgot Password button and following the subsequent instructions which appear on the screen.

If the user has entered a valid password for the selected Administrator or Tech Service user account, the Storm System Configuration Tool will then open, as shown in the screen shot below:

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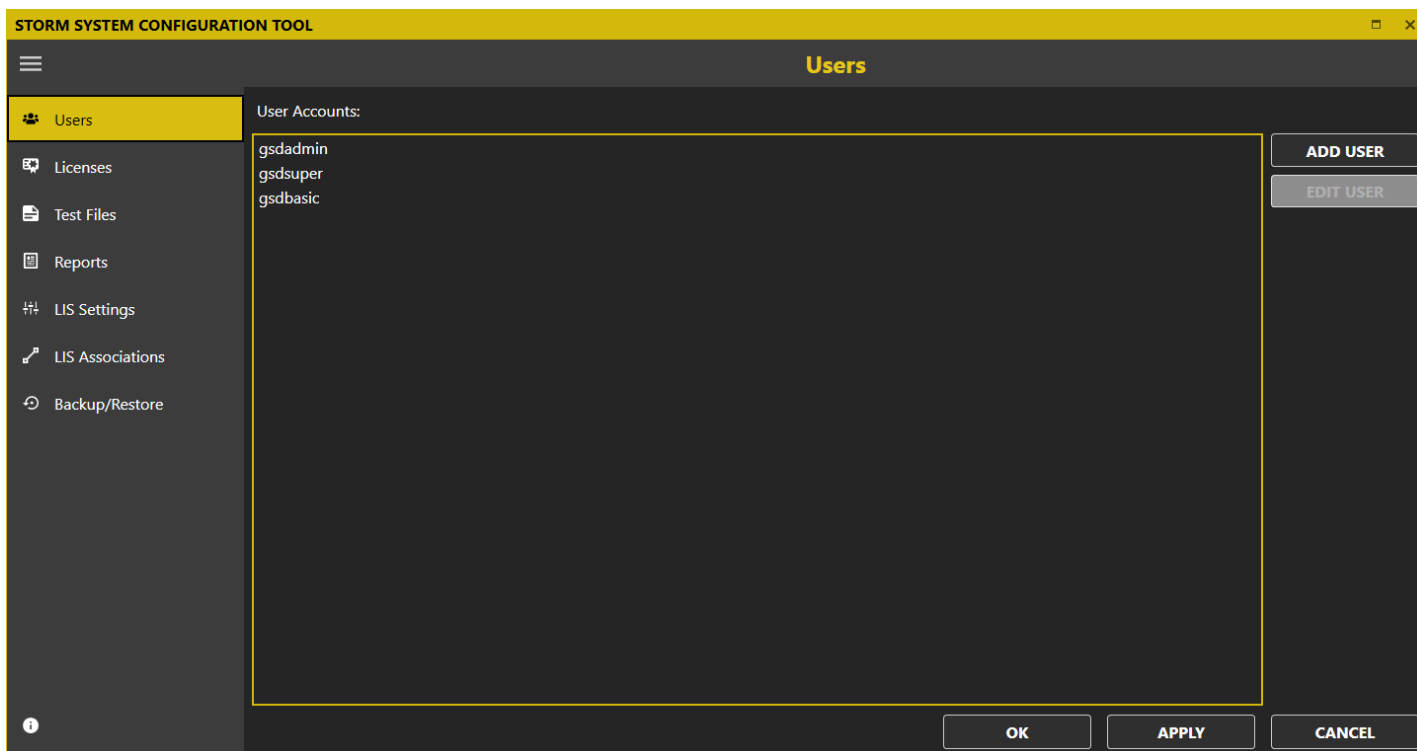
4.3.2 The Storm System Configuration Tool Interface

The Storm System Configuration Tool presents different categories of system settings in an expandable/collapsible menu on the left-hand side of the window. The user can select the category of settings to modify by clicking/tapping on the items in this menu. When an item is selected, the related settings will appear in the pane on the right.

In general, the user can click/tap the **Apply** button anytime to indicate that any changed settings should be saved and used. The Storm System Configuration Tool will save the settings and remain open for the user to continue. The user can click/tap the **OK** button to save any changed settings and dismiss the Storm System Configuration Tool. If the user clicks/taps the **Cancel** button, any unsaved settings changes will be discarded and the Storm System Configuration Tool will be dismissed.

*NOTE: Some settings changes made in the Storm System Configuration Tool may require the Storm Server to be restarted. The Storm System Configuration Tool will notify the user as needed when the **Apply** or **OK** buttons are clicked/tapped and proceed to restart the Storm Server.*

The different setting categories that can be configured with the Storm System Configuration Tool are described below.

4.3.2.1 Users

Use this tab to add and edit Storm System user accounts. These user accounts are used to log in to the Storm System Configuration Tool and to the Storm Instrument Manager instance(s) connected to the corresponding Storm Server in which these settings are stored.

4.3.2.1.1. *Add a User*

Click/tap **Add User**. Enter a username and password, email address (optional for run notifications), and cell phone number (optional for run notifications). Activate the user by selecting the **Active User** option. Select Basic User, Super

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User, or Administrator for the **Account Type**. See USER ACCOUNT TYPES for details about the different capabilities of each user account type. Click/tap **OK** to save changes.

4.3.2.1.2. *Edit a User*

Select desired user from the list and click/tap **Edit User**. Edit user information and settings as desired, then click/tap **OK**.

4.3.2.1.3. *Deactivate a User*

User accounts cannot be deleted, but they can be deactivated by deselecting the **Active User** option in the **Edit User** window. Deactivated users will not be listed on logon screens for the Storm software applications.

4.3.2.1.4. *User Account Types*

There are several types of user accounts:

- **Basic User** accounts are intended for the normal users of the Storm Instrument Manager and its associated instrument. This type of user can perform instrument maintenance and create Worklists and run them on the instrument.
- **Super User** accounts are intended for users who will review worklists and send results to the LIS. This type of user can perform all tasks of Basic Users, and can also review Worklist Reports and send results to the LIS.
- **Administrator** accounts are intended for users with extra privileges. Users with Administrator accounts can perform all tasks of Basic and Super user accounts, as well as other tasks: Only Administrator users can log in to and change settings in the Storm System Configuration Tool. Also, only Administrator users can access the Settings screen in the Storm Instrument Manager. Certain tools (ie: Wash Pump Calibration) are also reserved for Administrator users. At least one Administrator account must always be active.
- **GSD Tech Service** is an account only for use by GSD personnel.

4.3.2.2 Licenses

Use this tab to add, remove, or renew Test File licenses (if applicable).

NOTE: Test File Licenses are only required by certain customers. Contact GSD or your local Distributor for additional information if a license is required. If no license is required, no action is needed on this tab.

4.3.2.3 Test Files

The Test Files shown on this tab will be available to run in Worklists by the Storm Instrument Manager instance(s) connected to the Storm Server in which these settings are stored. Test Files define all of the reagents, layout, action steps, and calculations for a given assay kit. Test Files can be added to and removed from the Storm System, and organized into folders (nodes).

4.3.2.3.1. *Add/Rename Nodes*

To add a grouping or node of tests, click/tap the **Add Node** button. Enter the desired node name as prompted and click **OK**. Multiple nodes can be added to organize/group tests. Rename a node by selecting and click/tapping the **Rename Node** button.

4.3.2.3.2. *Add Test Files*

To add Test Files to the Storm system, first, make sure the Test Files which will be added to the Storm system are available in a folder that is accessible by the computer running the Storm Server and Storm Configuration Tool. The suggested file location is:

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```
C:\Users\Public\Documents\Storm\Tests
```

To add Test Files to the main Root folder or to a previously defined node, select the desired location, and click/tap the **Add Tests** button. The **Storm System Configuration Tool** will open a **File Open** window. In the **File Open** window, select the desired test file type:
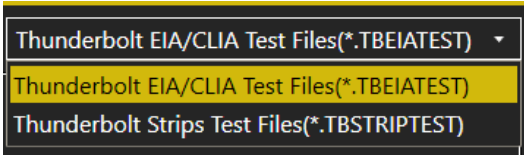
Using the navigation panel of the **File Open** window on the left, navigate to the folder location containing the Test File(s) to add. The **Refresh** button can be used to refresh the selected file location.

Select the Test File(s) to add by tapping/clicking on the Test File(s) listed in the panel on the right. Multiple files can be selected using the CTRL or SHIFT keys:
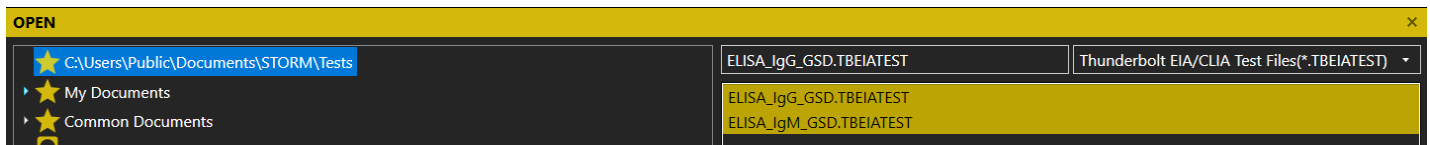
After selecting desired file(s), click/tap the **Open** button. Once added, nodes and tests will appear on the Tests screen:
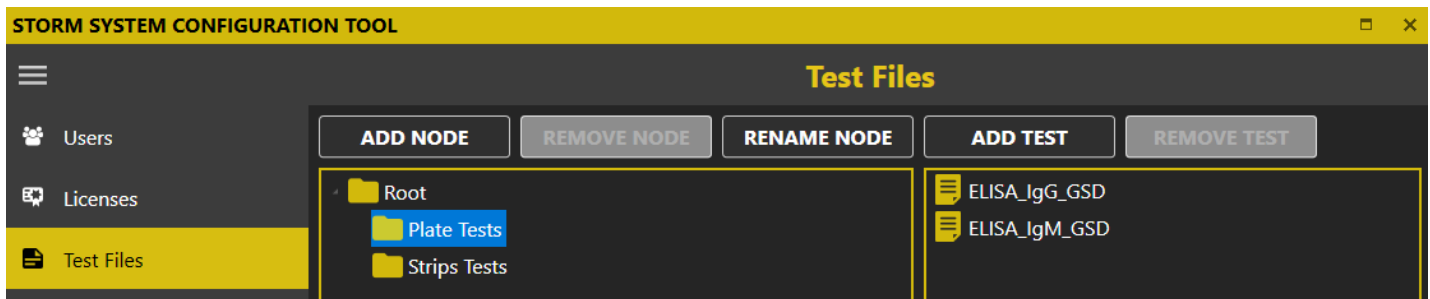
NOTE: Loading a Test File into the Storm system copies the test protocol into the Storm system database. The Test File stored in the folder on the computer hard disk is no longer referenced and can be removed.

4.3.2.3.3. *Remove/Reorganize Nodes and Tests*
To remove nodes or tests from the Storm system database, highlight the test(s) or node to be removed and click/tap the **Remove Test** or **Remove Node** button, as appropriate.

NOTE: All tests within a node must be removed before that node can be removed. To move a node or test(s), simply drag and drop to the desired location within the node or test window shown above.

4.3.2.4 Reports
The Reports screen allows the user to customize the Worklist reports and Test reports by specifying alternate report templates and laboratory information. To specify custom report templates and/or laboratory information, first make sure the report template files and laboratory logo files to be used are available in a folder that is accessible by the computer running the Storm Server and Storm Configuration Tool.

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Use the **…** buttons to select custom report template(s) and/or logo and use the red **X** buttons to restore default settings. Default report templates and the GSD logo will be used on Worklist Reports if no changes are made.

4.3.2.4.1. *Customizing Worklist Reports*

Select a custom report template, if required (most users use default template). Select to order strips test reports by test, if desired (strips test reports will be ordered by Sample ID by default). Enter the name and address of the lab as it will appear on worklist and search reports generated by the connected Storm Instrument Manager(s). Upload a logo if desired:

Worklist Report

Report Template:	C:\Program Files\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMWORKLISTREPORT	…	X
	☐ Order strip test reports by test		
Laboratory Name:	Laboratory Name	LAB LOGO HERE	IMPORT
Laboratory Address:	123 ABC Street City, State Zip Code		EXPORT
Laboratory Logo:	lab logo.PNG	…	X

Laboratory name, address, and logo can be exported to an .xml file and later imported, if the same information should be used in multiple instrument systems, using the Import and Export buttons.

4.3.2.4.2. *Customizing Test Reports*

Select different custom report templates for each test, if required. Default EIA and STRIPS report templates remain selected by most users:

Test Reports

TEST NAME	REPORT TEMPLATE		
ELISA Strip 1	iles\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMSTRIPTESTREPORT	…	X
ELISA Strip 2	iles\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMSTRIPTESTREPORT	…	X
ELISA_IgG_GSD	n Files\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMEIATESTREPORT	…	X
ELISA_IgM_GSD	n Files\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMEIATESTREPORT	…	X

Contact the local instrument distributor if additional information about custom report options is required.

4.3.2.5 LIS Settings

The LIS Settings screen enables the user to configure the Storm system to communicate with a Laboratory Information System (LIS).

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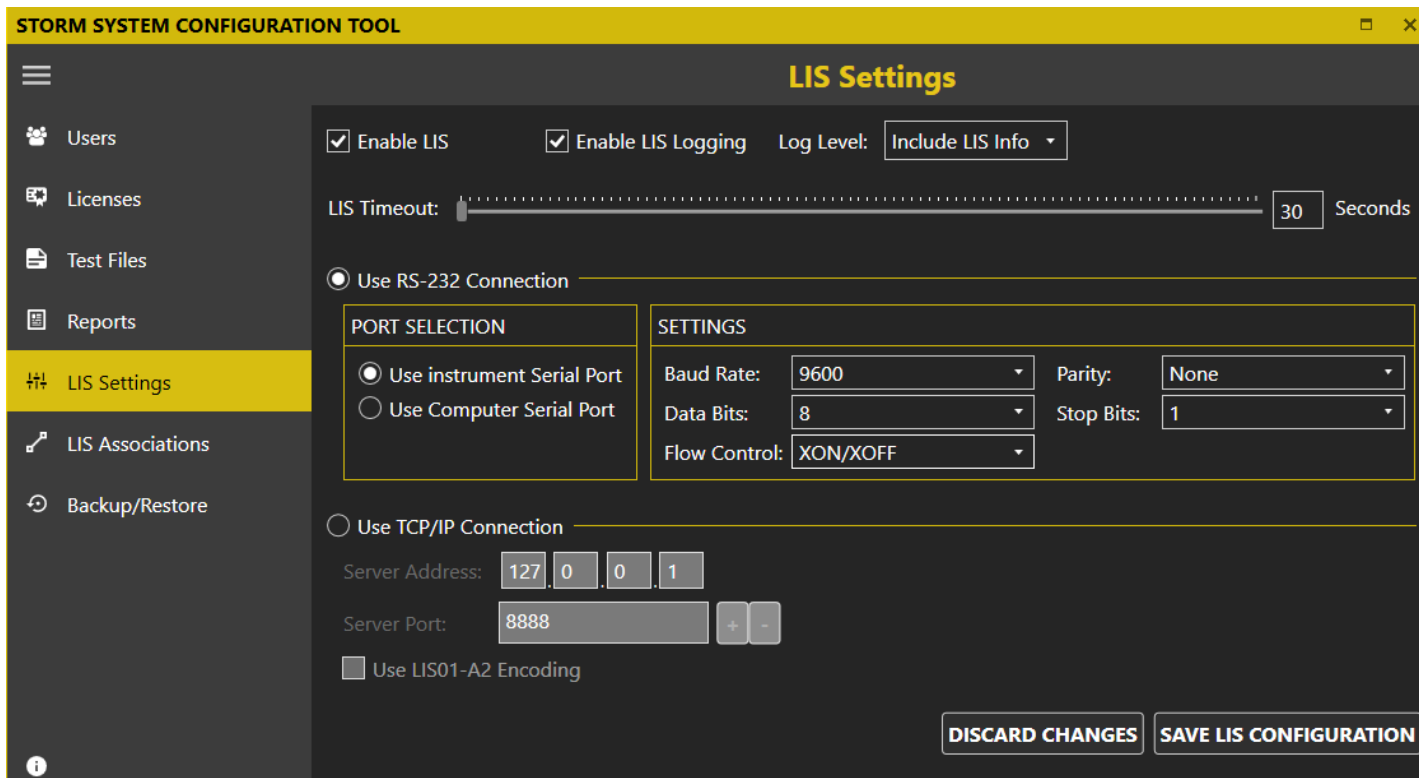
If the Storm system is required to communicate with an LIS, then the **Enable LIS** checkbox should be checked. It is highly recommended that the **Enable LIS Logging** checkbox is also checked so that Storm will generate LIS log data that can be reviewed in case there are communication issues. The LIS log data can be generated with several different levels of detail. Set the **LIS Log Level** as appropriate.

The **LIS Timeout** setting indicates how long the Storm system will wait for a response from the LIS system. The default timeout period is 30 seconds. Some LIS systems may require longer timeout periods. Set the timeout period as appropriate for the Laboratory LIS.

The Storm system can connect to an LIS using two protocols: RS-232 or TCP/IP. Select which LIS connection type will be used (RS-232 or TCP/IP) and set port/server settings as appropriate. Be sure that all settings match those of the LIS system being connected.

Click/tap the **Save LIS Configuration** button to save changes or the **Discard Changes** button to discard any changes made since the last save and revert the settings. This screen must be completed before LIS communication can be attempted from within the **Storm Instrument Manager**.

4.3.2.6 LIS Associations

A Laboratory LIS will have a unique name or code to represent different Tests/Assays. Recall from section **4.3.2.3 TEST FILES**, the Storm system uses Test Files to define the Test/Assay protocols it can execute. Each Test File loaded into the Storm system is identified by the Test File name. In order for the Storm system to exchange information with the Laboratory LIS for a given Test/Assay, the LIS Test name/code must be associated with the corresponding Storm system Test File name. The **LIS Associations** screen provides a list of Test File names for all Test Files loaded into the Storm

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system. The user must provide the corresponding LIS Test/Assay code name used for each Test/Assay. The user must be sure to enter LIS Test/Assay names or codes exactly according to the Laboratory LIS naming convention.

Test Name	LIS Name
ELISA Strip 1	ST1
ELISA Strip 2	ST2
ELISAIgG_GSD	IGG
ELISAIgM_GSD	IGM

NOTE: The Storm system will not be able to send or receive information for a Test/Assay if the LIS Association for the Test/Assay is not defined properly.

Once all the LIS Test/Assay names have been entered for each Test File, click/tap **Save LIS Associations** to save changes or **Discard Changes** to remove changes.

4.3.2.7 Backup/Restore

The **Backup/Restore** screen is used to create backups of the Storm database and/or restore previously saved backups of the Storm database. The different backup/restore features are available as separate tabs at the top of the screen.

4.3.2.7.1. *Backup*

The **Backup** tab allows the user to create a backup of the Storm database. The user must specify a valid file pathname to which the database will be saved. The **…** button is used to display the **File Save** window. In the **File Save** window, the folder pane on the left hand side can be used to navigate to a folder location. The filename field at the top of the File Save window is used to specify a name for the backup file. The backup is saved as a TAR file. Clicking/Tapping the **OK** button on the **File Save** window will dismiss the window and enter the specified file path name in the **Backup File Name** field.

The **Auto-purge backed up images** check box should be checked if Well images associated with ARRAY assays should be deleted after they have been backed up. This is often helpful to free up disk space on the Storm server computer.

*NOTE: The **Auto-purge backed up images** setting only applies to Storm systems running ARRAY assays on a Hailstorm instrument. This setting has no effect on Storm systems which only include ThunderBolt and/or Bolt instruments.*

When a valid path to a backup filename has been specified, the **Backup** button will be enabled. The user can click/tap the **Backup** button to create a backup of the Storm server database at the file location specified.

4.3.2.7.2. *Restore*

The **Restore** tab allows the user to restore a previously saved backup of the Storm database. The restore function supports backup files saved in the ZIP or TAR format.

NOTE: The ZIP format was used with previous versions of the Storm software prior to Storm 3.0. The ZIP format is supported to provide backward compatibility for Storm databases saved with previous versions of Storm.

The **…** button is used to display the **File Open** window. In the **File Open** window, the folder pane on the left-hand side can be used to navigate to the folder location containing the file to restore. The file pane on the right-hand side will display ZIP or TAR files in the selected folder. The user should select the desired backup file to be restored and click/tap

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the **Open** button. The **File Open** window will be dismissed and the selected file pathname will be entered in the **Restore File Path** field.

When a valid file pathname is entered in the **Restore File Path** field, the **Restore** button will be enabled. The user can click/tap the **Restore** button to restore the specified database backup file.

NOTE: Restoring a previously saved database backup file will overwrite the current database. Any information in the current database that has not been backed up will be lost. It is highly recommended to make a backup of the current database before performing a restore.

4.3.2.7.3. *Scheduled Backup*

The **Scheduled Backup** screen can be used to configure Storm to automatically create backups of the Storm database at prescribed times/intervals to a prescribed folder location.

To enable automatic scheduled backups, the user can check the **Run scheduled backup at** checkbox and specify a time of day at which the backup will be created. The user can also specify how frequently the scheduled backup is to be performed. There are three basic frequency selections: Daily, Weekly, or Monthly. Each of the frequency selections allows further customization. For example, the **Daily** setting allows the user to also specify if the backup should be run every N days (where N is a positive number between 1 and 31), or if the daily backup should be run every weekday. The **Weekly** and **Monthly** frequency settings allow similar customization.

The **Backup Path** field specifies the folder to which the automatic scheduled back up will be saved. The default value for this field is the path:

`C:\Users\Public\Documents\Storm\DatabaseBackups`

The user can click the **…** button to open the **Folder Select** window to navigate file system and select a different folder. Storm will automatically save a backup of the database to this folder according the scheduled back up settings. Storm will save each of the backup files with a unique name which follows the format:

"`ScheduledBackupStorm_YYYY_MM_DD_H_M.tar`"

Where YYYY_MM_DD_H_M specifies the year, month, day, hour, and minute at which the backup is being created. The .tar extension specifies the file is saved in the TAR format.

A maximum of three backups will be saved to the folder specified. When Storm attempts to save more than three backups to this folder, Storm will delete the oldest backup file and save the new backup file. This is done to ensure that the hard disk space is not filled up by users who forget to manage their backup files.

4.3.2.7.4. *Purge*

The **Purge** screen is used to purge MicroArray Well images from the Storm server hard disk.

NOTE: The Purge functionality only applies to Storm systems running MicroArray assays on a Hailstorm instrument. This setting has no effect on Storm systems which only include ThunderBolt and/or Bolt instruments.

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4.4 Storm Instrument Manager

The Storm Instrument Manager enables the user to execute Worklists on a Bolt instrument and/or review and evaluate the results of Worklists that have been executed. A Worklist contains a list of Samples and the corresponding Test(s) to be run on those Samples. The available Tests are defined by the Test Files that are installed on the Storm system.

The Storm Instrument Manager can be run in two modes:

"Full Functionality Mode": This mode enables the running of Worklists and the review and evaluation of Worklist results. In this mode, a Bolt instrument must be connected via a USB connection to the computer on which the Storm Instrument Manager is installed. The instrument is powered on when the Storm Instrument Manager is started.

"Evaluation Only Mode": This mode allows for evaluation of Worklist results only. In this mode, an instrument is not required to be connected to the computer on which the Storm Instrument Manager is installed. If an instrument is connected, the instrument will not be powered on when the software is started and the software will not interact with the instrument. This mode is a subset of the Full Functionality Mode -- the Storm Instrument Manager in Evaluation Only Mode provides access to functionality related to reviewing and evaluating results only. This mode is most useful in laborites with multiple instruments connected to a central server as described in **4.1.2 MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION**. The Storm Instrument Manager can be run in Evaluation Only Mode on the server computer to allow the review and evaluation of Worklist data from all instruments connected to the central server.

NOTE: The Evaluation Only Mode is a subset of the Full Functionality Mode. That is, all functionality provided in the Evaluation Only Mode is also available in the Full Functionality Mode. Therefore, only the Full Functionality Mode will be described further in this document.

4.4.1 Launching the Storm Instrument Manager

To launch the Storm Instrument Manager, verify that the computer on which the Storm Instrument Manager is installed is connected to the Bolt instrument via a USB connection. Power on the computer and allow the Windows operating system to boot up.

NOTE: By default, Bolt instrument computers are setup with a Windows user account which has a username of "GSD" and no password. When the computer is powered on, the Windows operating system will boot up and the "GSD" user account will login automatically. Some Laboratory IT policies require the computer to have a Windows user account that requires the user to login with a password. If the Laboratory IT has configured the instrument computer to have a Windows user account that requires a password, you will have to login with the appropriate password when Windows boots up. Contact the Laboratory IT if needed. This Windows user account and password is separate from the Storm user account and password which will be described in more detail below.

If the Storm Instrument Manager was installed with the option to "Launch at Startup", then the Storm Instrument Manager will startup when the Windows operating system boots up. Otherwise, the Storm Instrument Manager will have to be launched by double clicking/tapping the Storm Instrument Manager icon on the desktop.

By default, the Storm Instrument Manager is configured to run in the Single Instrument Configuration (see **4.1.1 SINGLE INSTRUMENT CONFIGURATION** for details). In this configuration the Storm Instrument Manager will communicate with the Storm Server service running on the instrument computer to obtain Storm user account information and prompt the user to login to the Storm system. When the Multiple Instrument with Central Server Configuration is used (see **4.1.2 MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION** for details), the Storm Instrument Manager will communicate

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with the Storm Server service running on the server computer. If this is the first time the Storm Instrument Manager is being launched, or if there is a network communication issue, the Storm Instrument Manager may prompt for the IP address of the server computer on which the Storm Server service is running. Contact the Laboratory IT for assistance setting the Storm Server IP address if needed.

Once the Storm Instrument Manager is able to communicate with the Storm Server service and obtain Storm user account information, the Storm Instrument Manager log on screen will appear to allow the user to log on to the Storm system:
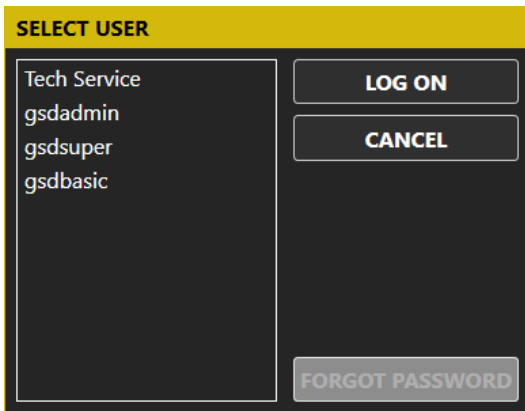
The Storm Instrument Manager log on screen lists all active user accounts defined in the Storm system database. See **4.3.2.1 USERS** for information on how to define user accounts using the Storm System Configuration Tool.

NOTE: The Tech Service user account is a special account which is present on all Storm systems. This account is to be used by certified GSD Technical Service representatives when performing service on the instrument, or when troubleshooting issues. This account is to be used by GSD Technical Service representatives only.

To log on to the Storm Instrument Manager, the user selects the appropriate user account name and taps/clicks the **Log On** button. The Storm Instrument Manager will prompt the user for the user account password.

*NOTE: If a user with a Basic User or Super User account forgets his/her password, a user with an Administrator account can reset the password using the Storm System Configuration Tool. If a user with an Administrator account forgets his/her password, a new password may be set using the **Forgot Password** button and following the subsequent instructions.*

Once the user specifies the correct password for the selected user account, the instrument will initialize and move to the starting, or 'home', position. This homing process requires approximately 30 seconds. The instrument must always be allowed to complete this homing procedure uninterrupted before being used.
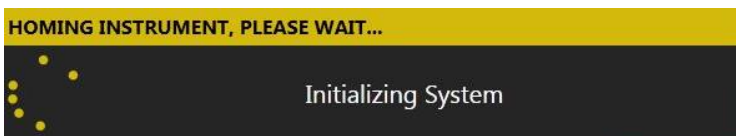
After the homing procedure completes, the Storm Instrument Manager will open.

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NOTE: When the Storm Instrument Manager opens, the user is prompted to perform daily startup maintenance (as well as weekly maintenance, if due and set to be prompted at System Startup). The user must respond to each maintenance prompt before continuing.

4.4.2 The Storm Instrument Manager Interface

The Storm Instrument Manager main window is shown below:
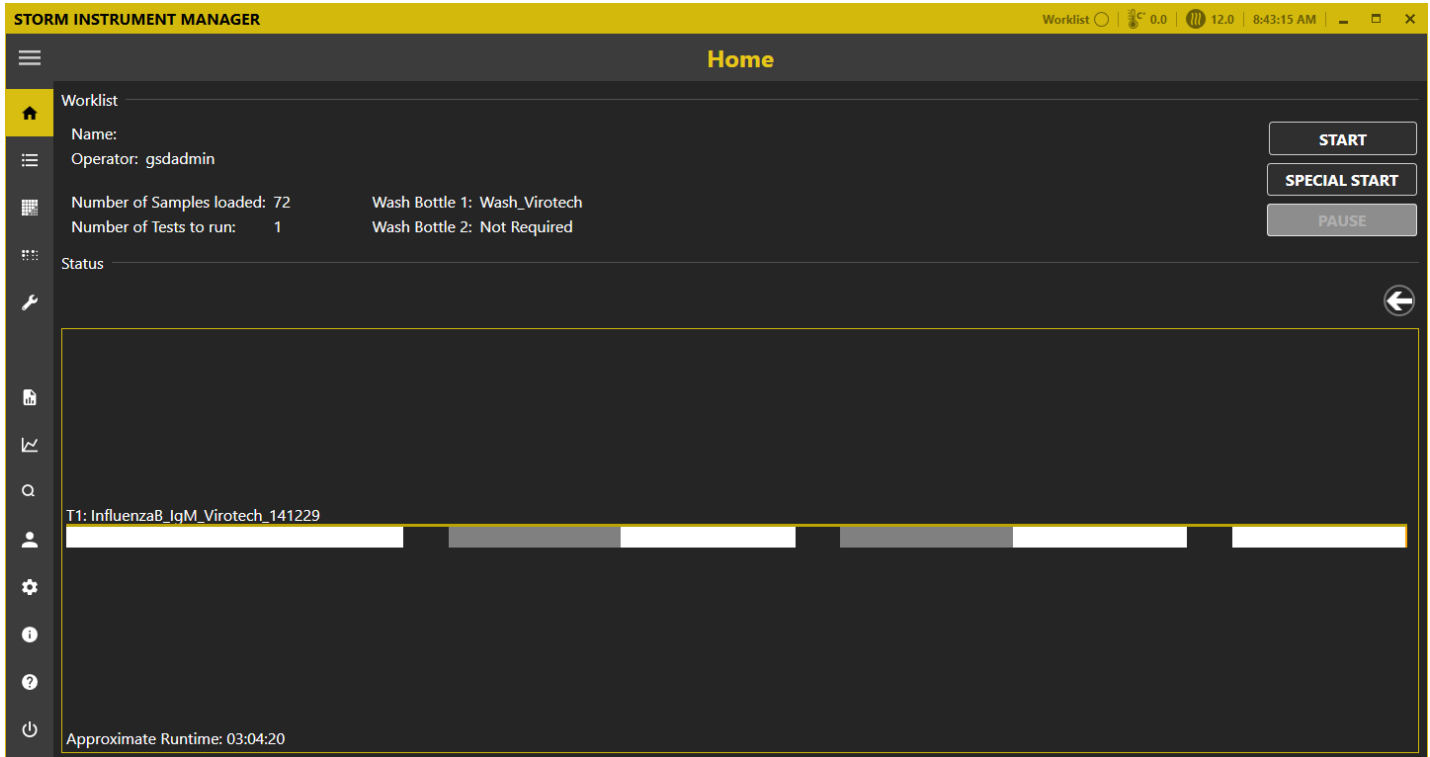
The interface for the Storm Instrument Manager is designed with a title bar, an expandable/collapsible side menu containing items for the different categories of functionality, and a window pane which displays controls and information based on the selected item in the side menu.

The Storm Instrument Manager title bar contains indicators pertaining to the general status of the instrument, as well as some controls to manipulate the Storm Instrument Manager window. The different status indicators and controls in the title bar are described in the table below.

Status Indicator / Control	Description
Worklist State Icon	Indicates if a worklist is being created (open circle), running (arrow), paused (double lines), stopped (solid square), or completed (checkmark).
	NOTE: The exterior status indicator light also shows worklist status (on applicable models only). • *Blue: Instrument is idle; ready to load and run worklist.* • *Green: Instrument is running a worklist.* • *Red: Instrument has an error, alarm, or message stopping the worklist.*
Temperature Displays	The thermometer icon displays the internal temperature of the instrument. If/when the incubator is turned on during the running of a worklist, temperatures of the left/ right MTP position(s) is/are also displayed.

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Status Indicator / Control	Description
Current Computer Time	Displays the current time as set on the attached computer.
Minimize/Maximize/Restore Down	Used to minimize/maximize/restore down the **Storm Instrument Manager** main window.
Close (X icon)	Used to close the Storm Instrument Manager window and exit the software without shutting down the instrument/computer. (Daily shutdown maintenance will be prompted).

The different functional categories of the Storm Instrument Manager available in the expandable side menu are described below.

4.4.2.1 Home

The **Home** screen displays the overall status including details about the currently loaded Worklist, a timing diagram of the Worklist run, and the internal live camera feed of the instrument. This screen is used to start, monitor, pause, and/or stop a Worklist run.

4.4.2.1.1. *Worklist Summary and Actions*

The Worklist Summary section of the **Home** screen displays information for the currently loaded Worklist. The name of the Worklist is displayed, the currently logged on user (or operator of the instrument) is displayed, as well as a summary of the Worklist including the number of Samples loaded in the Worklist, the number of Tests included in the Worklist, and the Wash Bottles used by the Worklist.

The buttons in the Worklist Summary section can be used to start, stop, and pause a Worklist run for the currently loaded Worklist.

Start/Stop: The **Start** button will start the Worklist run in full. While a Worklist run is in progress, the **Start** button label will transition to **Stop** and can be used to stop the Worklist run.

Special Start: The **Special Start** button will start the Worklist in a special or custom manner. For example, the Worklist can be started from a specific step. If the currently loaded Worklist has already been run, the **Special Start** functionality will also allow the user to specify that the Microtiter Plates should be reread.

Pause: The **Pause** button can be used to temporarily suspend a Worklist run. The user can click the **Pause** button to suspend a Worklist run that is in progress to check things such as Reagent Bottles, then continue with the Worklist run from the point at which it was suspended.

4.4.2.1.2. *Status*

The **Status** section of the **Home** screen displays the current status of the instrument. If a Worklist run is in progress, the first line of the **Status** section shows the current action being executed. The full Status log showing all actions executed as part of the Worklist run can be seen by clicking the arrow button on the right side of the screen.

Timing Diagram: The timing diagram displays the anticipated run time for the currently loaded Worklist. Each Test File in the Worklist is listed with colored bars representing the different actions of the test.

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The length of the colored bars correpsonds to the amount of time estimated to complete the action. The user can hover the mouse pointer over each colored bar to display additional information about each action. If the Worklist run has not been started, the estimated time to run the Worklist is displayed in the bottom left corner. This estimated run time is based on the actions defined in the Tests, as well as the number of Samples added to the Worklist. If the Workist run is in process, the start time is displayed in the bottom left corner, the estimated finish time is displayed in the bottom right corner, and the current position in the Worklist run with the estimated time remaining is displayed with a vertical red line.

4.4.2.2 Worklist

The **Worklist** screen is used to load or create a Worklist to be run on the instrument. A Worklist is a list of Samples, along with the Tests that are assigned to those Samples, that are scheduled to be processed as part of a Worklist run. The information displayed on the **Worklist** screen is considered the currently loaded and active Worklist.

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4.4.2.2.1. *Name*

The **Name** field on the **Worklist** screen allows the user to enter a name for the Worklist. If no name is entered, the Worklist will be automatically named with a date and time stamp when the Worklist run is started.

4.4.2.2.2. *Worklist Grid*

The Worklist grid shows the work items in the Worklist. The work items consist of a Sample ID, the Rack Position of the Sample tube in the Samples Rack, and a list of Tests to be run on the Samples. Samples and Tests are added to the Worklist grid using the ADD SAMPLES and ADD TEST features, respectively.

Test Properties: The user can click/tap on the test name of each Test in the Worklist grid to open the **Test Properties** window. The **Test Properties** window allows the user to specify the lot number, expiration date, and appropriate runtime variables (including calibrator values and control ranges) as obtained from the test assay kit (box labels, insert, and vials), as appropriate.

*NOTE: Test Properties may also be added via barcode scanning using the **Scan Barcode** option in the **Test Properties** window if the test is configured for barcode scanning of test properties in its Test File definition.*

4.4.2.2.3. *New*

The **New** button allows the user to clear the current Worklist and create a new Worklist. When clicked, the **Name** field is cleared, Samples and/or Tests are cleared form the Worklist grid, and any other settings related to the current Worklist are cleared. The user is provided a new, empty Worklist to which he/she can add Samples and Tests and configure for a Worklist run.

4.4.2.2.4. *Load*

The **Load** button allows the user to load a previously saved Worklist. By default, Worklist files of the type *.TBSTORMWORKLIST can be loaded. If Import Plugins are installed, the Open File dialog will also support opening files of other formats to load a Worklist. See **4.4.2.10.11 PLUGINS** for more details.

When a previously saved Worklist is loaded, it is the user's responsibility to ensure all Samples, Controls, Calibrators, and Reagents are physically located on the instrument according to the loaded Worklist configuration.

4.4.2.2.5. *Save*

The **Save** button allows the user to save the current Worklist configuration to a file. The file format is a proprietary format with a *.TBSTORMWORKLIST file extension.

Saving a Worklist to a file can be helpful if a common Worklist configuration is used repeatedly. For example, if the same set of Tests need to be run on different sets of Samples, a Worklist can be configured with the Tests loaded and no Samples added, and then saved. Later, this saved Worklist can be loaded, Samples added and assigned to the Tests.

*NOTE: When a Worklist run is started, the Worklist file is automatically saved to the **Worklists** folder as described in 4.4.3.10 WORKLISTS. This saved Worklist file can be used to quickly reload the Worklist in case or errors encountered during the Worklist run. Subsequently, when the Worklist run is completed, the Worklist results are saved to the Storm system database and the Worklist file is automatically saved to the **Worklist** folder again, overwriting the previously saved Worklist file.*

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4.4.2.2.6. *Add Samples*

The **Add Samples** button allows the user to add Samples to the Worklist as they are loaded into the Sample Racks on the instrument.

NOTE: Eppendorf or other conical-shaped tubes are not recommended for use in the instrument. The needles on the instrument probe can be pinched by the conical shape when the probe descends into the tube. This can interfere with the aspiration and/or dispense of fluid from the needles. In addition, when the probe ascends out of the tube, the pinched needles may apply enough force to the sides of the tube to pick up the tube, which often results in spills. Only standard-diameter sample tubes (12mm, 13mm, 16mm) are recommended for use on the instrument.

The user can click/tap the **Add Samples** button to open the **Add Samples** window. The **Add Samples** button will appear as a dropdown button with two items: **Add Samples to Worklist** and **Preload Sample Rack**. The **Add Samples to Worklist** item will open the **Add Samples** window and allow the user to add Samples to the Sample Racks on the instrument and to the Worklist. There are several different methods for adding Samples to the instrument and Worklist. These different methods are described in more detail below. The **Preload Sample Rack** item will open the **Preload Sample Rack** window and allow the user to load Samples to a Sample Rack not on the instrument. These Samples are not added to the current Worklist, but can be added to the instrument and the Worklist later using the **Preloaded Sample Rack** option from the **Add Samples** window. The **Preloaded Sample Rack** option is described in more detail below.

When the **Add Samples** window is opened, it will appear in the foreground with the **Racks** screen in the background to allow for monitoring of Sample tube placement as Samples are loaded.
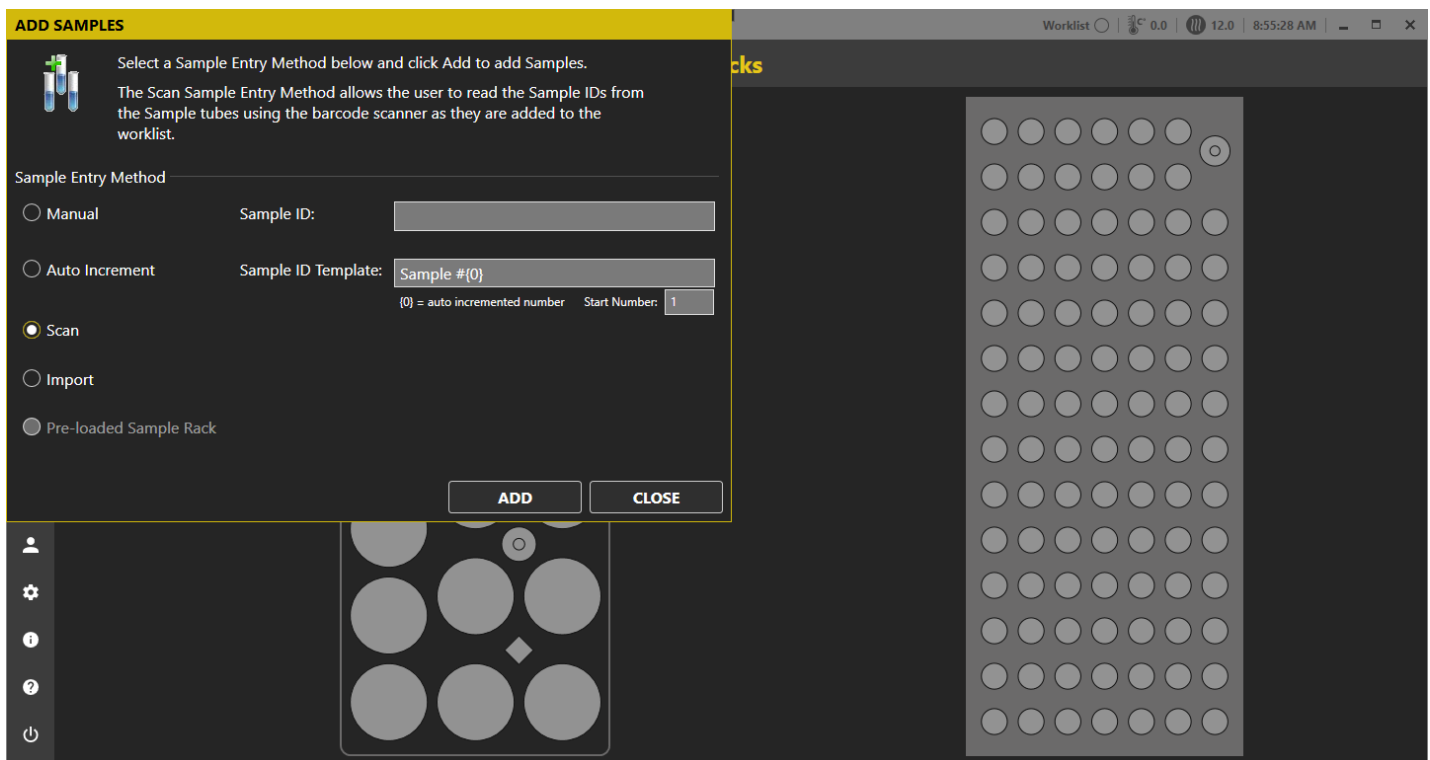
Sample Entry Methods: The **Add Samples** window provides several methods for loading Samples into the Sample Racks on the instrument and adding them to the Worklist. The user can select the desire Sample Entry Method and click/tap

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the **Add** button to add the Samples by following the detailed on-screen instructions. The different Sample Entry Methods are described below.

- **Manual:** The **Manual** Sample entry method can be used for non-barcoded Sample tubes which have unique or custom IDs associated with them.

  When adding Samples using this Sample entry method, select the **Manual** Sample entry method and type the sample ID into designated field. Next, click/tap the **Add** button. Place the Sample tube in the rack as prompted. The Sample will be added to the Worklist with the ID that was manually entered. Repeat for all manually labeled samples.

- **Auto Increment:** The **Auto Increment** Sample entry method can be used for non-barcoded Sample tubes which have no defined ID associated with them. Storm will automatically assign an ID to the Sample based on the specified Sample ID template. The Sample ID template can contain any sequence of characters, however it must contain the character sequence '{0}'. This character sequence will be replaced with the auto-incremented number. For example, if the Sample ID template is set to 'Sample #{0}' and the start number is set to 1, then the Sample IDs assigned to the Sample tubes as they are added will be 'Sample #1', 'Sample #2', 'Sample #3', etc…

  When adding Samples using this Sample entry method, select the **Auto Increment** Sample entry method and change the **Sample ID Template** and **Start Number** as desired. Next, click/tap the **Add** button. Place Sample tubes in the Sample Rack, one by one, as prompted. Samples will automatically be numbered consecutively, according to the auto-increment Sample ID template.

- **Scan:** The **Scan** Sample entry method can be used for Sample tubes which are labeled with a barcode that contains the Sample ID.

  When adding Samples using this Sample entry method, select the **Scan** Sample entry method and click the **Add** button. Scan the barcoded Sample tube using a handheld scanner attached to the instrument by USB. The Sample ID will be added to the Worklist and the user will be instructed to place the Sample tube in the Sample Rack. Repeat for all barcoded Sample tubes.

- **Import:** The **Import** Sample entry method can be used to import Sample IDs into the Worklist from an Excel spreadsheet. Select the desired XLS or XLSX file as prompted. When this Sample entry method is used, it is the user's responsibility to ensure the Sample tubes have been physically placed in the Sample Racks according to the layout specified in the import file.

  NOTE: This option requires the user to fill in an Excel document template (Inquire with local distributor for guidelines of proper template format) with all sample IDs and rack position locations prior to adding samples to the Worklist.

- **Preloaded Sample Rack:** Use to add preloaded racks (prepared as described in Worklist Preparation). Click/tap the **Add** button. Select the desired rack from the **Preloaded Sample Racks** list and click/tap **Add**. Scan the rack as prompted and place it into the indicated position inside the instrument (scanned barcode must match the selected rack in order to add the rack to the Worklist). Repeat to add additional preloaded sample racks to the

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Worklist.

When all Samples have been added, click/tap the **Done** button to exit the **Add Samples** window. The Storm Instrument Manager main window display will return to the **Worklist** screen, where all added Sample IDs will be listed in the Worklist grid.

NOTE: Sample IDs cannot be edited after placement. To edit a Sample ID, remove the Sample from the Worklist and add it again with a new ID. Duplicate Sample IDs are not permitted; user will be prompted to change the Sample ID during sample addition if a sample with a duplicate ID is added.

4.4.2.2.7. *Multiply Samples*

In some situations, it may be desirable to load a single Sample tube in the Sample Racks, but process the Sample multiple times during the Worklist Run. This can be done using the **Multiply Samples** button. After Samples have been added to the Worklist, the user can select one or more Sample IDs in the Worklist grid and click the **Multiply Samples** button. The user can specify how many multiples of each selected Sample should be added to the Worklist. The selected Sample ID(s) is/are duplicated in the Worklist, but refer to the same Sample tube in the Sample Racks.

4.4.2.2.8. *Remove Samples*

The **Remove Samples** button can be used to remove Samples from the Worklist. The user can select Sample IDs from the Samples grid and then click/tap the **Remove Samples** button. The selected Samples will be removed from the Worklist. Once the Sample ID is removed from the Worklist, the user may remove the corresponding Sample tube from the Sample Racks. If the Sample tube is left on the Sample Racks during the Worklist run, the Sample tube will simply be ignored – that is, the Sample tube will not be processed during the Worklist run.

4.4.2.2.9. *Add Test*

The **Add Test** button allows the user to add a Test to the Worklist. Once the Test is added, the user can assign the Test to be performed on Samples when the Worklist is run.

The **Add Test** button is a drop-down button. When clicked/tapped it presents a list of Tests that are loaded into the Storm system (see **4.3.2.3 TEST FILES**). Initially, when there are no Tests added to the Worklist, the **Add Test** dropdown will display all Tests loaded into the Storm system. The user can select the desired test from the list and it will be added to the Worklist. The added Test appears as a column in the Worklist grid with a checkbox in each cell corresponding to a Sample ID. To assign the Test to be performed on the Sample, the user simply checks the appropriate checkbox. The user can right click or double tap the Test name to toggle assignment of the Test to all Sample IDs.

The user can add multiple Tests to the Worklist by clicking/tapping the **Add Test** button again, after a Test has been added to the Worklist. The **Add Test** dropdown will only display Tests that are compatible with Tests that have already been added to the Worklist. Compatibility is based on various factors, including incubation temperature, timing scheme, wash bottle usage, number of reagents, and plate frame type.

*NOTE: Tests with different timing schemes can be run together the **Allow Tests with different timing schemes to be run together** option is enabled as described in 4.4.2.10.3 WORKLIST. However, all other Test compatibility criteria will still apply.*

As multiple Tests are added to the Worklist, the Test names will appear listed from left to right across the top of the Worklist grid. The order of the Tests can be changed by dragging and dropping.

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4.4.2.2.10. *Remove Test*

The **Remove Test** button allows the user to remove a Test from the Worklist. The **Remove Test** button is a dropdown button that displays a list of all Tests added to the Worklist. To remove a Test from the Worklist, the user simply has to select the Test name from the **Remove Test** dropdown list.

4.4.2.2.11. *Query LIS*

The **Query LIS** button allows the user to query the LIS for which Tests are to be run on the Sample IDs added to the Worklist. The **Query LIS** button is enabled if the Storm system has been configured for use with an LIS. See **4.3.2.5 LIS SETTINGS** and **4.3.2.6 LIS ASSOCIATIONS** for details on configuring the Storm system for use with an LIS. If the Storm system is not configured for use with an LIS, then the **Query LIS** button will be disabled.

To query the LIS, the user should add Samples to the Worklist, then click/tap the **Query LIS** button. The Storm system will communicate with the LIS and request which Tests have been ordered for the Samples in the Worklist. If the Tests indicated in the LIS Order records have been loaded in the Storm system, they will be automatically added to the Worklist and the Test will be assigned to be performed on the Sample. See **6.3 LIS QUERY AND TRANSMISSION EXAMPLES** for more details on how Storm queries the LIS.

*NOTE: Adding Tests to a Worklist using the Query LIS functionality is subject to the same compatibility criteria mentioned in **4.4.2.2.9 WORKLIST>ADD TEST**. At the conclusion of the LIS query, Storm will display a warning message for any Tests that could not be added to the Worklist due to compatibility issues.*

4.4.2.2.12. *Smart Fill Tests*

The **Smart Fill Tests** button allows the user to quickly assign Tests to be performed on Samples in the Worklist. The Smart Fill functionality will assign all available Samples to the first Test and then assign all remaining Samples to the second Test automatically according to available space on the Microtiter Plates.

4.4.2.3 Racks

The **Racks** screen displays the current layout and status of the Sample Racks and Reagent Racks. The user can refer to this screen to verify placement of Samples, Reagents, Controls, and Calibrators on the instrument when configuring a Worklist.

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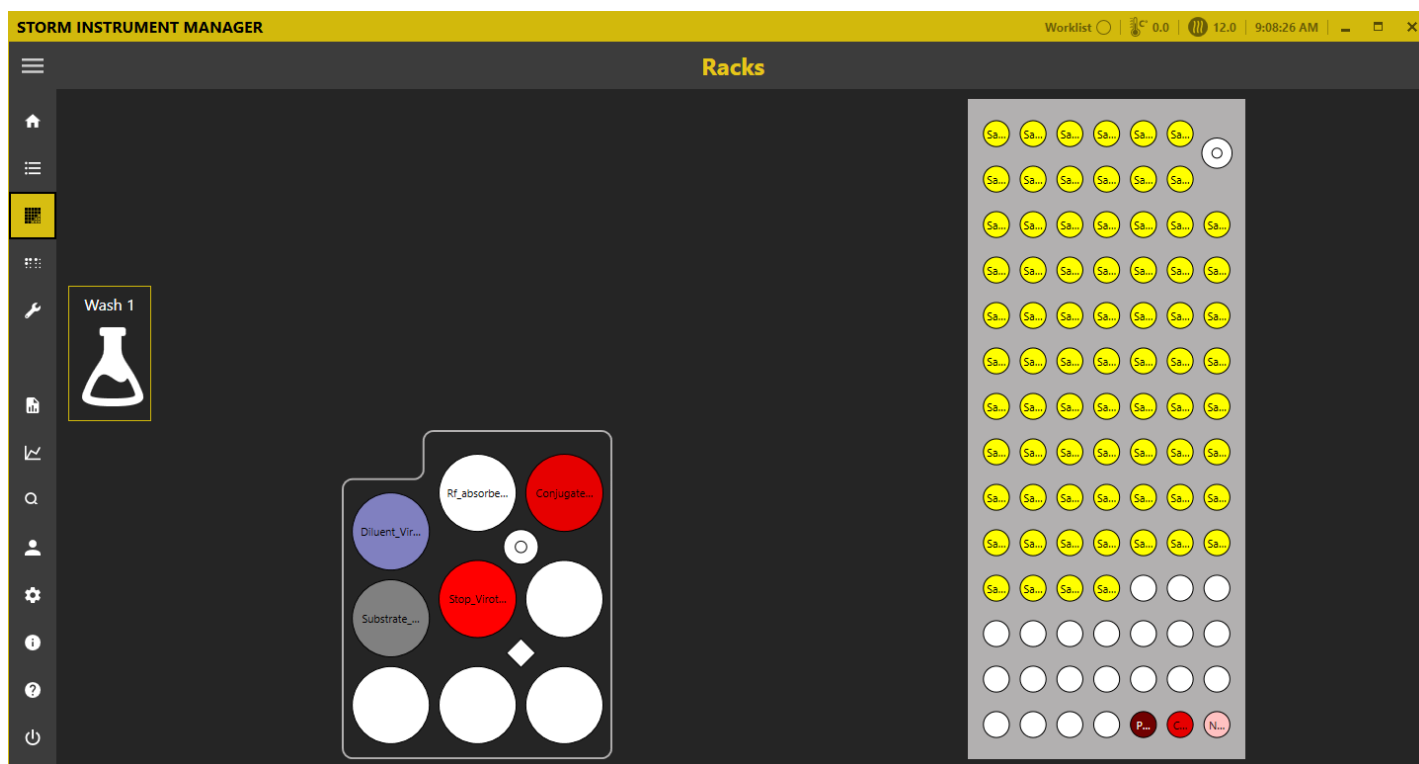
Additional information about an item in a Rack position can be seen by hovering the mouse cursor over the desired location.

The Sample Racks on the Racks screen display the position of the Samples added to the Worklist. See **4.4.2.2.6 WORKLIST>ADD SAMPLES** for details on adding Samples to a Worklist. Samples positions are labeled with their Sample ID and colors are used to indicate the status of the Sample position: Yellow indicates the presence of a Sample tube; White indicates an empty position; Grey indicates an occupied position that is unused by the Worklist. Controls and Calibrators that are placed in the Sample racks are colored according to the definition of the item in the Test File.

Calibrator and control locations are automatically assigned to the first available rack position, beginning with the front right corner of the Sample Racks and proceeding to the back of the rack, then continuing right to left across the rack(s). The user should be sure to place prepared calibrator and/or control vials into the indicated locations in the Sample Rack(s).

*NOTE: When a Worklist run is started, the **Reagent Loading Wizard** will also guide the user through the process of adding reagents and calibrators/controls (if the **Reagent Loading Wizard** is enabled in the Worklist section of the Storm Instrument Manager Settings).*

The Reagent Racks on the **Racks** screen display the position of the Reagents according to the Tests that have been added to the Worklist. Reagent locations are automatically assigned according to the instrument model being used. The Reagent positions are labeled and colored according to the Reagent definition in the corresponding Test File. When loading Reagents in the instrument Reagent Rack, the user should be sure to follow the layout indicated on the screen and use appropriately sized Bottle Adapters.

If desired, the user can right click/tap on any Reagent Bottle on the Reagent Rack to set a custom dead volume for that bottle or to split the bottle into two positions.

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NOTE: Depending on the Test and the number of Samples being run, a Reagent Bottle may be split automatically. In this case, two identical reagent positions will be indicated on the Racks screen.

4.4.2.4 Microtiter Plates

The **Microtiter Plates** screen is used to indicate the number of Wells, Strips, and Plates required for the Worklist run. All Well locations on the Microtiter Plate (MTP) positions and the Predilution Plate positions that are required to perform the Tests assigned to the Samples in the Worklist are displayed.
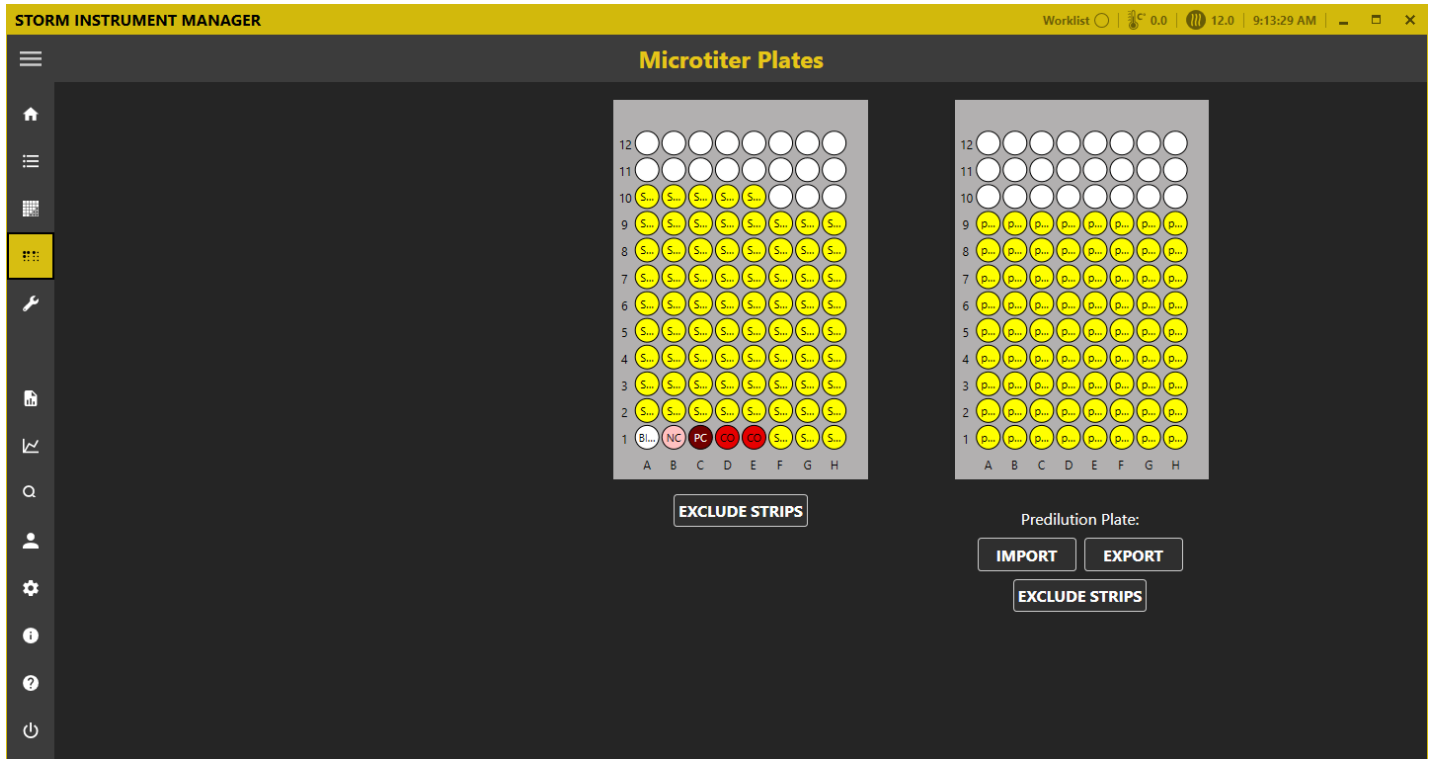
Additional information about each Well can be seen by hovering the mouse cursor over the Well. The **Microtiter Plates** screen should be used to visually confirm that all desired Test Wells and Samples appear on the MTP layout in the correct plate locations.

NOTE: Control wells may be positioned before and/or following Sample wells, depending on the Test(s) being run.

The layout displayed on the **Microtiter Plates** screen can be used to ensure the required number of Wells for the Test(s) to be run are secured into place in the appropriate plate frame(s), and that the plate frame(s) are placed in the proper locations in the MTP Carrier.

4.4.2.4.1. *Exclude Strips*

The **Exclude Strips** buttons allow the user to specify that Samples should be processed in plate positions starting in locations other than the default A1 position. This can be set during Worklist preparation, after Samples and Tests have been added to the worklist.

4.4.2.4.2. *Predilution Plate Import/Export*

These options allow Predilution Plates to be shared between Tests. Typically, a user will create and run a Worklist containing a Test with a protocol which only dispenses to a Predilution Plate. After this Worklist run has completed, the

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user can click/tap the **Export** button to save the Predilution Plate definition file for later use. Next, the user creates a new Worklist with a Test that uses the Predilution Plate. When configuring this Worklist, the user clicks/taps the **Import** button to open the previously saved Predilution Plate definition file and load the Predilution Plate into the current Worklist. The user is responsible for ensuring the proper Predilution Plate is physically loaded onto the MTP Carrier in the Predilution Plate position.

NOTE: When a Predilution Plate is imported, any previously added Samples are removed from the Worklist and replaced by the Samples defined in the imported Predilution Plate. Therefore, when using a Predilution Plate it is best to add the Predilution Plate to the Worklist first, then add any other Samples to the Worklist afterwards.

Contact a GSD representative or your local Distributor for additional information, if needed.

4.4.2.5 Tools

The **Tools** screen displays the instrument functions that may be utilized outside of a normal Worklist run. These functions are available for use any time that a Worklist is not running and are organized into the sub-categories **General**, **Plate Reading**, **Alignment**, and **Calibration**.
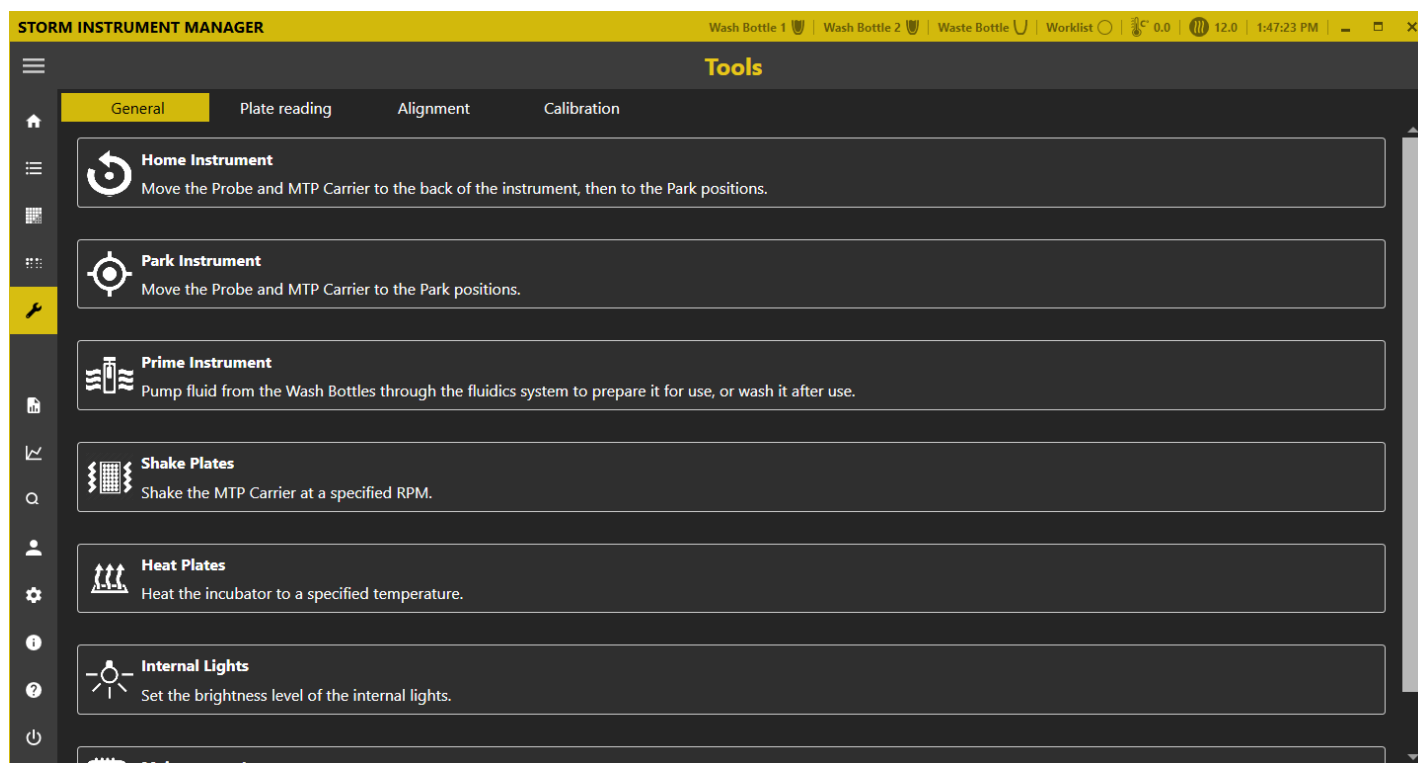
4.4.2.5.1. *General*

The **General** category provides access to general instrument functionality.

Home Instrument: Use this button to 'home' the instrument, just as is done automatically at startup. The probe and MTP carrier will move to the back of the instrument and then to their 'parked' positions.

Park Instrument: Use this button to reset the instrument back to its starting, or 'parked' position (with the probe assembly above the wash cup).

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Prime Instrument: In the pop up window, select desired Wash Bottle(s) and number of priming cycles and click/tap the **Start** button. If both Wash Bottles are selected, the set number of priming cycles will be performed with Wash Bottle 1 and then immediately subsequently performed with Wash Bottle 2. Liquid from the wash bottle(s) will be pulled through the instrument fluidics system as the progress bar tracks priming cycle progress. Priming can be interrupted using the **Stop** button.

Shake Plates: Use this button to manually shake one, two, or three plates on the Microtiter Plate Carrier. Select preferred speed using the +/- buttons. Use the Start and Stop buttons or set timer if desired.

Heat Plates: Use this button to manually incubate one or two microtiter plates in incubator locations on the Microtiter Plate Carrier. Select preferred temperature using the +/- buttons. Use the **Start** and **Stop** buttons to turn incubator on and off.

Internal Lights: Use the slider bar to adjust default light intensity of the interior LED lights.

Maintenance Logs: Click/tap the **Maintenance Logs** button to view dates/times of all recent maintenance events (priming, probe and reader auto alignment, reader calibration, wash pump calibration). Select a month to add notes to that month's maintenance log or to display a maintenance report with all maintenance actions for that entire month (included any added notes), which can be saved/exported and/or printed.

NOTE: Any days/weeks which the instrument was not used/maintenance was not performed are marked with "/" on the maintenance action log.

4.4.2.5.2. *Plate Reading*

Any 96 well plate can be read with the instrument reader (RLU reading capability is only available on instruments with the chemiluminescence option).

Read Plate ODs: Click/Tap this button to read the OD values for specified Wells on the Microtiter Plates using the spectrophotometer in the instrument reader. In the **Manual Read Plate** window, select the desired Wells to be read using the mouse cursor to select the Microtiter Plate Well positions. The CTRL and SHIFT buttons can also be used to highlight specific Wells on either/both the left and right plate(s). A comment can be added to the **Comment** field – this comment will be included if the manual reads are saved to a file. The **Measurement** and **Referenced Measurement** wavelength values should be set according the read being done.The **Start** button is used to start the read operation. Measurement values will appear on the screen as the plate(s) is/are read. After the operation completes, the values can be printed using the **Print** button, or saved to a file using the **Export to TSV** button. The **Close** button will dismiss the **Manual Read Plate** window.

Read Plate RLUs: Click/Tap this button to read the RLU values for specified Wells on the Microtiter Plates using the photonmultiplier tube in the instrument reader. In the **Manual Read Plate** window, select the desired Wells to be read using the mouse cursor to select the Microtiter Plate Well positions. The CTRL and SHIFT buttons can also be used to highlight specific Wells on either/both the left and right plate(s). A comment can be added to the **Comment** field – this comment will be included if the manual reads are saved to a file. The **Integration Time** value should be set according the read being done.The **Start** button is used to start the read operation. Measurement values will appear on the screen as the plate(s) is/are read. After the read completes, the values can be printed using the **Print** button, or saved to a file using the **Export to TSV** button. The **Close** button will dismiss the **Manual Read Plate** window.

NOTE: Manual plate readings are NOT saved automatically by the software.

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4.4.2.5.3. *Alignment*

The **Alignment** screen provides tools to the user to align different components of the instrument. The instrument componenets are aligned regularly as part of the daily, weekly, and monthly maintenance procedures. The user should perform alignment as part of routine instrument maintenance as prompted by the Storm Instrument Manager. The alignment tools on this screen can be used to align the instrument components outside of the maintenance procedures, as needed. Each alignment tool provides detailed step by step instructions which should be followed very carefully.

NOTE: Always be sure to perform instrument alignment after any of the following: the instrument has been moved, probe-related maintenance has been performed, or if different-sized racks have been placed on the instrument since the previous alignment.

If an alignment procedure is cancelled and only partially completed, the user should be sure to fully complete the alignment procedure prior to the next instrument use.

NOTE: The alignment procedures always start from default positions. They do not start from the last aligned position. This is to ensure alignment is as accurate as possible by avoiding alignment 'creep' across multiple alignments.

Manually Align Probe: Manual alignment of the instrument probe is available for legacy reasons with Bolt instruments. The user can click/tap the **Manually Align Probe** button to launch the **Manual Probe Alignment** wizard. The user should carefully follow the instructions for each step in the alignment process provided by the wizard.

NOTE: Manual alignemnt is subject to variations depeding on the user performing the alignment. It is highly recommended that auto-alignment is used instead to ensure the alignment is accurate and consistent.

Auto Align Probe: The user can click/tap the **Auto Align Probe** button to launch the **Auto Probe Alignment** wizard. The user will be required to perform some initial steps such as inserting auto-alignment plates, then the instrument will auto-align itself. The user should carefully follow the instructions for each step in the alignment process provided by the wizard.

Auto Align Reader: The reader auto alignment process is performed to ensure that the reader is properly aligned for reading MTPs. The user can click/tap the **Auto Align Reader** button to launch the **Auto Reader Alignment** wizard. The user will be required to perform some initial steps such as moving the reader into a valid start position, then the instrument will auto-align itself. The user should carefully follow the instructions for each step in the alignment process provided by the wizard.

Verify Alignments: The **Verify Alignments** tool is used to verify the positions of the current alignment. The user can click/tap the **Verify Alignments** button to launch the **Verify Alignment** wizard. The wizard will walk the user through each alignment position to show the user the current alignment offsets. No alignment adjustments can be made when verifying alignment positions.

4.4.2.5.4. *Calibration*

The **Calibration** screen provides tools to calibrate the different components of the instrument that require adjustment and correlation to a standard reference. Calibration procedures are typically performed by GSD Technical Service representatives or by trained and certified Distributor representatives. The calibration tools are made available on this screen in case a user needs to perform calibration themselves. The user should only perform calibration procedures under the guidance of a GSD Technical Service representative or a trained and certified Distributor representative.

Calibrate Spectrophotometer: Photometric reader calibration is performed during maintenance visits or service calls, as applicable (e.g.: if reader is replaced). Calibration should only be performed by a trained service technician using a calibrated plate. Contact the local instrument distributor for additional information.

Calibrate Luminometer: If the instrument is equipped with the chemiluminescence reader option, this portion of the reader can also be calibrated, using a standard Harta Calibration Plate. Calibration should only be performed by a trained service technician using a calibrated plate. Contact the local instrument distributor for additional information.

Calibrate Wash Pump: The **Calibrate Wash Pump** option is used by service technicians to verify that the wash pump is functioning properly. To use, verify that wash buffer is loaded in the Wash 1 position and that a cuvette is in place in front of or next to the wash cup (as applicable for the instrument model being used), then click/tap the Calibrate Wash Pump button. Follow instructions as prompted to calibrate the wash pump.

4.4.2.6 Evaluation

The **Evaluation** screen is used to review Worklist run results. Worklist run results from all instruments connected to the same Storm Server can be reviewed from any of the instrument computers running the Storm Instrument Manager in Full Functionality mode, or from the server computer running the Storm Instrument Manager in Evaluation Only mode. Users can view, export, and print Worklist reports, mark a Worklist run as reviewed, review Worklist run errors, change Test Properties and drop replicas, and send results to the LIS on this screen.

4.4.2.6.1. *Select a Worklist*

Select a Worklist to review by selecting a Worklist name from the Worklists dropdown menu on the top left. The list of Worklists is obtained from the Storm Server. Therefore, if multiple instruments are connected to a central server as described in 4.1.2 MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION, any Worklist from any of the instruments can be reviewed. Worklists are listed in order of date with the most recent at the top of the list. The first Worklist in the list

is selected by default when the Evaluation screen is initially opened. When a Worklist name is selected from the dropdown list, the Worklist Report for the selected Worklist is shown on the right.

NOTE: When reviewing Worklists from a Storm Instrument Manager connected to an instrument, if the instrument is currently running a Worklist and at least one Test in the Worklist has been completed, that in-progress Worklist will be selected automatically on the Evaluation screen and results for any completed Test(s) from that Worklist can be viewed. As additional tests from the Worklist finish, a **Refresh Report** *button will be available. Click/tap this button to refresh the Worklist report shown to include newly available results from the Worklist run in progress.*

4.4.2.6.2. *Worklist Report*

The **Evaluation** screen displays the Worklist Report for the selected Worklist to allow the user to view the Test results from the Worklist run. The Worklist Report contains a header section with provides general information about the Worklist run. The Worklist Report also contains sub-sections for each Test performed as part of the Worklist run.

The format of the Worklist Report and the Test Report sub-sections can be modified by using report templates. See **4.3.2.4 REPORTS** for information about how to specify the use of custom report templates.

NOTE: If you are interested in having custom report templates created, please contact GSD Technical Service or your Distributor.

The Worklist Report view contains a toolbar across the top with a set of controls which allow the user to navigate, search, print, and save the Worklist Report. The user can print the Worklist Report using the **Print** toolbar button. The user can also save the Worklist Report to a PDF file using the **Save to PDF** toolbar button.

4.4.2.6.3. *Worklist Reviewed*

The **Worklist Reviewed** checkbox is used as a flag to indicate if the Worklist has been reviewed or not. The **Worklist Reviewed** checkbox is enabled only if the logged-on user reviewing the Worklist has a User Account Type of Super User or higher. See **4.3.2.1.4 USERS>USER ACCOUNT TYPES** for details about the capabilities of the different User Account Types.

After a user with account type of Super User or higher has reviewed the Worklist Report and determined the results are acceptable, they should check the **Worklist Reviewed** checkbox. The **Evaluation** screen will refresh to display the Worklist Report with the **Worklist Reviewer** field filled in with the reviewer's username. Checking the **Worklist Reviewed** checkbox will also allow other actions to be completed, such as **Send to LIS**, which require the Worklist results to be reviewed and approved before they can be performed.

4.4.2.6.4. *Worklist Errors*

The user can click/tap the **Worklist Errors** button to view/export any errors or anomalies from the Worklist run. This button will be disabled if the Worklist run did not contain any errors or anomalies. Worklist run errors and anomalies are also displayed on the Worklist report.

Worklist errors and anomalies included events such as failed clog checks, insufficient Sample or Reagent volume detected, etc… Failed validations rules associated with specific Tests in the Worklist run are not considered Worklist errors or anomalies. Failed validation rules are reported in the Test specific section of the Worklist Report.

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4.4.2.6.5. *Add/Edit Comments*

The user can click/tap the **Add/Edit Comments** button to add or edit comments on the Worklist Report. The **Add/Edit Comments** window provides a list of sections from the Worklist Report consisting of the Worklist Comments section and then a Test Comments section for each Test in the Worklist. The user can select a comments section and add a new comment or edit an existing comment for that section. The user can click the **Apply** button to apply the comments added or modified and continue to add or edit. The user can click the **OK** button to apply the comments added or modified and exit the **Add/Edit Comments** window. The user can click the **Cancel** button to discard and changes that have not yet been applied and exit the **Add/Edit Comments** window.

When the **Add/Edit Comments** window is dismissed, the Worklist Report will refresh and the added or modified comments will appear on the Worklist Report. The Test comments appear at the end of each Test section in the Worklist Report. The Worklist comments appear at the end of the Worklist Report. Each comment is stamped with the name of the user that entered the comment and the date/time the comment was added.

4.4.2.6.6. *Export Worklist*

The **Export Worklist** button allows the user to export the Worklist Report currently selected. The Worklist Report can be exported to Microsoft Excel format or to Tab Separated Value (TSV) format.

4.4.2.6.7. *Send to LIS*

The **Send to LIS** button is used to send the Worklist results to an LIS. The **Send to LIS** button is enabled only if the logged-on user has a User Account Type of Super User or higher and LIS communication has been enabled for the Storm system. See **4.3.2.1.4 USERS>USER ACCOUNT TYPES** for details about the capabilities of the different User Account Types. See **4.3.2.5 LIS SETTINGS** and **4.3.2.6 LIS ASSOCIATIONS** for details about enabling LIS communications.

The user can click/tap the **Send to LIS** button to open the **Send Results to LIS** window. The **Send to LIS** button includes a sub-label which indicates the date when the Worklist results were last sent to the LIS. If the Worklist results have never been sent to the LIS, the sub-label will display the text 'Worklist has not been sent'.

If the Worklist has not yet been marked as reviewed when the user clicks/taps the **Send to LIS** button, a warning message will be displayed informing the user that the Worklist must be marked as reviewed before the results can be sent to the LIS. See **4.4.2.6.3 EVALUATION>WORKLIST REVIEWED** for details.

The **Send Results to LIS** window displays a table of Sample results for the Tests performed on the Samples in the Worklist. The table also includes a column indicating if the Test has an LIS Test Name associated with it. Results for a Test cannot be sent to the LIS if the Test does not have an LIS Test Name associated with it. See **4.3.2.6 LIS ASSOCIATIONS** for details about associating LIS Test Names with Tests in the Storm system.

If the Test validation for the Sample result was successful, the Sample result is automatically selected (a checkmark is present in the first column) to be sent to the LIS. Otherwise, the Sample result is not selected. The user can select or unselect Sample results to be sent to the LIS by checking or unchecking the checkbox in the first column of the Send Results to LIS table.

The user can click the **Send** button to send the selected results to the LIS. The user can click the **Cancel** button to dismiss the **Send Results to LIS** window and not any results to the LIS.

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4.4.2.6.8. *Drop Replicas*

The **Drop Replicas** button allows the user to drop replicated Controls or Calibrators from Test result calcuations in the Worklist Report. The **Drop Replicas** button is only available if the logged-on user has a User Account Type of Administrator or higher. See **4.3.2.1.4 USERS>USER ACCOUNT TYPES** for details about the capabilities of the different User Account Types.

The user can click/tap the **Drop Replicas** button to open the **Drop Replicas Test Selector** window. This window presents a list of Tests included in the Worklist run. The user can select the Test for which they wish to drop replicate Controls or Calibrators. When the user selects a Test in the list, the **Drop Replicas** button in this window will enable if the Test contains replicates and the Test protocol allows replicates to be dropped. Otherwise, the **Drop Replicas** button in this window will be disabled.

The user can click/tap the **Drop Replicas** button in the **Drop Replicas Test Selector** window to open the **Drop Control or Standard Replicas** window. This window provides a list of Controls and Standards (also known as Calibrators) that can be dropped from the Test result calcuations. The user can select one or more items to be dropped and click/tap the **OK** button. The Worklist Report in the Evaluation screen will refresh to display the Test results with the selected Controls and/or Calibrators ommited from the calculations.

4.4.2.6.9. *Change Test Properties*

The **Change Test Properties** button allows the user to change properties of the Tests included in the Worklist. Test properties include expiration date, lot Number, and runtime variables. The **Change Test Properties** button is only available if the logged-on user has a User Account Type of Administrator or higher. See **4.3.2.1.4 USERS>USER ACCOUNT TYPES** for details about the capabilities of the different User Account Types.

If Worklist contains Test(s) with test property information that was not correctly entered at the start of the Worklist run (lot number, expiration date, or runtime variables), the user can click/tap the **Change Test Properties** button to modify test properties as needed. The **Select Test** window will appear to allow the user to select the Test from the Worklist for which the Test Properties should be changed. The user can select the desired Test and click/tap the **Change Test Properties** button in this window. This will open the **Test Properties** window for the selected Test and allow the user to modify the Test properties as desired.

After the Test Properties and the Select Test windows have been dismissed, the Worklist Report in the **Evaluation** screen will refresh to display with the modified test properties information. If runtime variable information was changed, any Test result values that depend on the runtime variables is recalculated and displayed on the Worklist Repot.

4.4.2.7 Analysis

The **Analysis** screen is used to provide additional information regarding Worklist and Test performance. This information can be helpful in analyzing the instrument performance.

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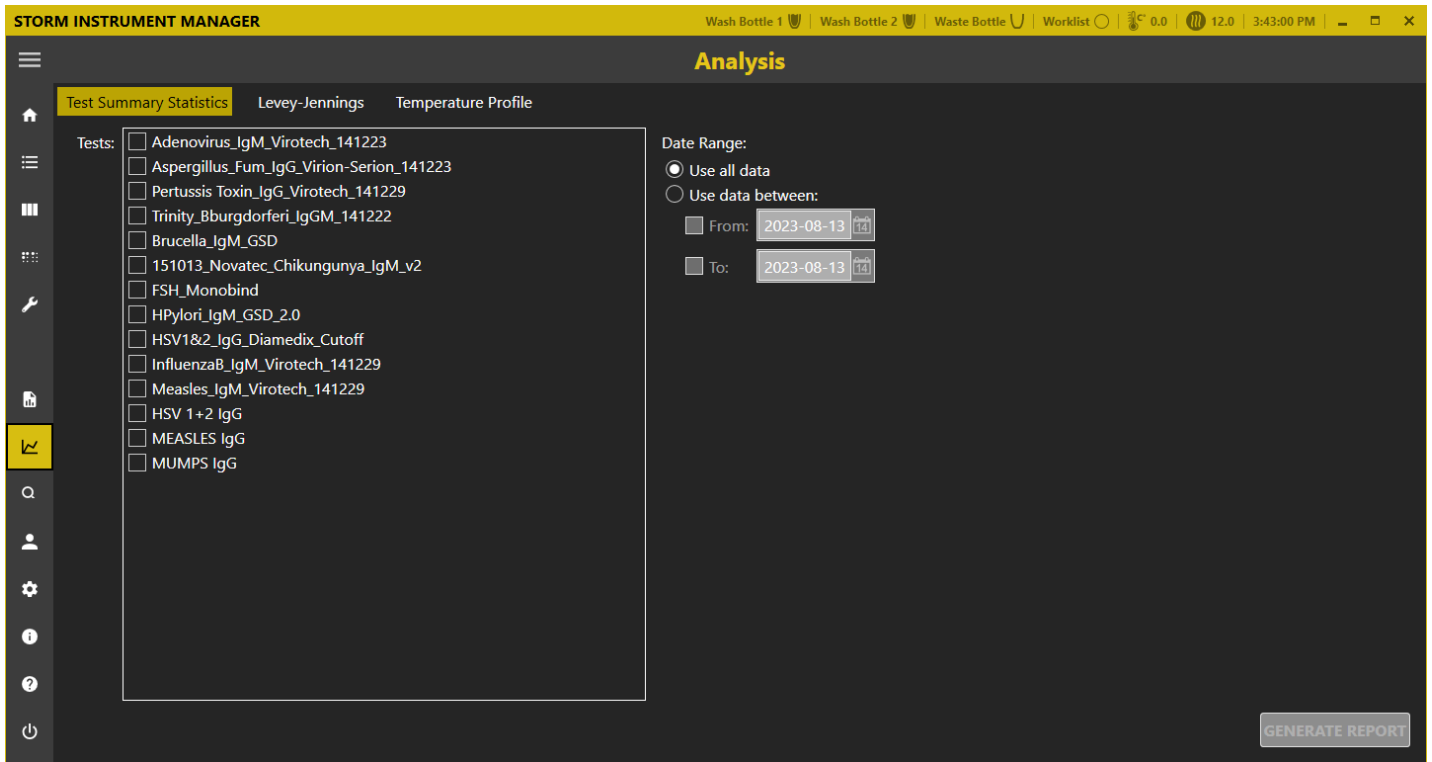
4.4.2.7.1. *Test Summary Statistics*

The **Test Summary Statistics** screen allows the user to generate a report showing basic statistics regarding the Tests loaded into the Storm system. These statistics include how many times the Test has been run, how many Samples have been run on the Test, and how many MTP Wells have been used to run the Test. These statistics can be provided for all dates in the Storm system database, or for a specific date range.

Once the user has selected the Tests they are interested in, as well as a date range, the click/tap the **Generate Report** button to display results. A Test Summary Statistics Report will be generated, containing information about the number of runs, samples, and wells of each selected test, along with lot number data.

This report can be printed or saved to a PDF file as desired.

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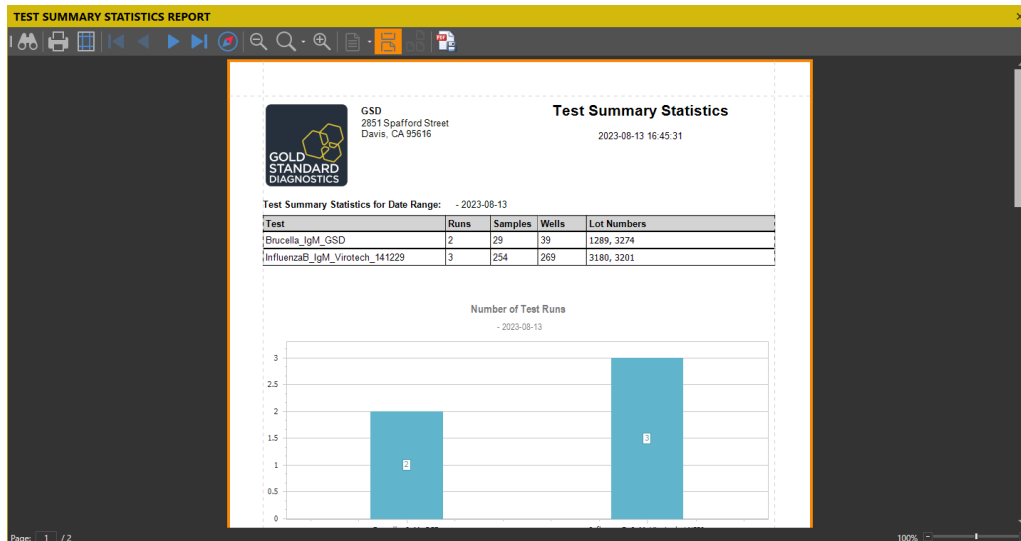
4.4.2.7.2. *Levey Jennings*

The **Levey-Jennings** screen allows the user to select a Test and configure parameters for a Levey-Jennings analysis. A Levey-Jennings analysis provides a method to easily monitor and interpret the performance of the Controls and Standards for a Test over time.

The user selects a Test from the **Tests** dropdown on which they desire a Levey-Jennings analysis to be performed. The **Tests** dropdown is populated with all Tests loaded into the current Storm system. When a Test is selected, the **Standards/Controls** table will be populated with the Standards and Controls defined in the Test. The user can specify which Standards and Controls they want included in the analysis, as well as report parameters for each Standard and Control. For each Standard and Control selected, a Levey-Jennings analysis will be done on both the OD and Concentration values for that Standard or Control.

The report parameters that can be configured include such things as whether a graph will be displayed for the Standard or Control, how many Standard Deviation lines will be shown on the graph, and if Min/Max values should be included. The user can click the **…** button to configure these parameters.

After the user has specified the Standards and Controls parameters, the Lot Number, and Data Range that should be included in the report, they can click/tap the **Generate Report** button. A report with the Levey-Jennings analysis of the specified controls will be generated.

This report can be printed or saved to a PDF file as desired.

4.4.2.7.3. *Temperature Profile*

The **Temperature Profile** screen allows the user to analyze the temperature data for a Worklist run.

The user can select a Worklist from the **Worklists** dropdown and specify the temperature data they are interested in. The user can select to view the data for the internal instrument temperature, external instrument temperature, as well as the incubator temperature as measured by the instrument during the Worklist run. To view the report, the user clicks/taps the **Generate Report** button.

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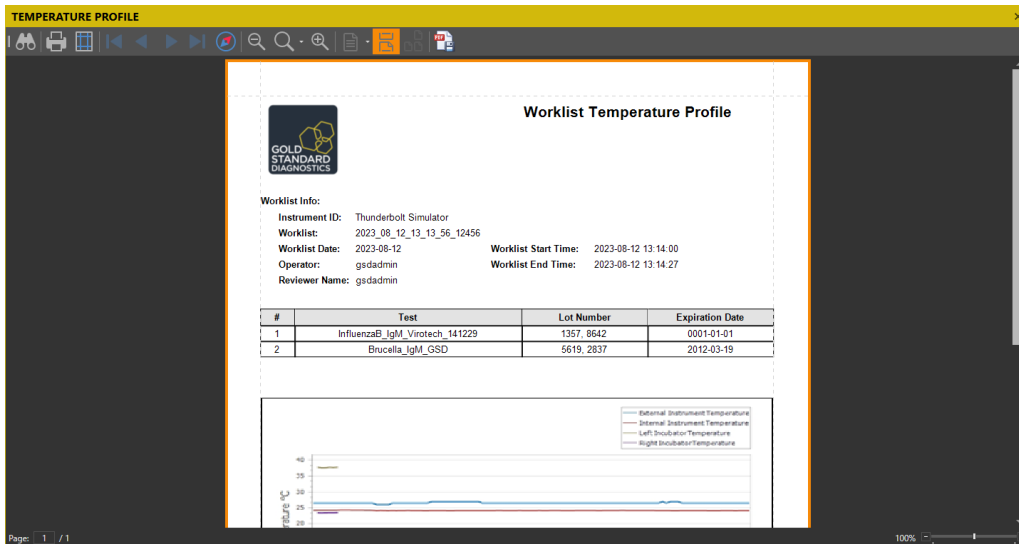
This report can be printed or save to a PDF file as desired.

4.4.2.8 Search

The **Search** screen allows the user to search for results from any Worklist run in the Storm system database.

The user can specify any combination of search criteria using the **Search Fields**. Once the desired search criteria has been set, the user clicks/taps the **Search** button to execute the search. The **Search Results** table is populated with the items found. The user can double click/tap on a search item in the **Search Results** table to view the corresponding Worklist Report in the **Evaluation** screen. The user can click/tap the **Search Result** button to export the search results to an Excel or Tab Separated Value (TSV) file.

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4.4.2.9 User

The **User** button will display the **Current User** window.
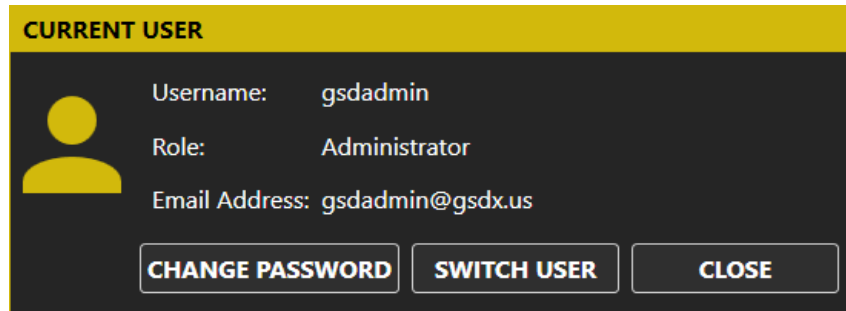
The **Current User** window displays information for the currently logged-on user. The user can change their password using the **Change Password** button.

The **Current User** window also allows a different user to log on without the need to exit and restart the **Storm Instrument Manager**. The user who wishes to log on can click the **Switch User** button and will be prompted with the **Select User** logon window. They can then select the desired user account and log on with the appropriate password to take control of the Storm Instrument Manager session. All access privileges of the Storm Instrument Manager session will be updated based on the User Account Type used to log on. See **4.3.2.1.4 USERS>USER ACCOUNT TYPES** for details about the capabilities of the different User Account Types.

4.4.2.10 Settings

The **Settings** button opens the **Settings** window which allows the user to configure settings specific to the Storm Instrument Manager running on the instrument computer (as opposed to **4.3 STORM SYSTEM CONFIGURATION TOOL** which allows the user to configure settings for the overall Storm system). The **Settings** button is only available if the logged-on user has a User Account Type of Administrator or higher. See **4.3.2.1.4 USERS>USER ACCOUNT TYPES** for details about the capabilities of the different User Account Types.

The **Settings** window provides a list of settings categories on the left-hand side. The user can click/tap the different categories to display the settings controls in view on the right-hand side of the window.

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Once the user has configured the settings in the different categores as desired, they can click/tap the **OK** button to save the settings changes, or they can click/tap the **Cancel** button to discard the settings changes.

NOTE: The Storm Instrument Manager may need to be restarted before some settings changes will take effect. The Storm Instrument Manager will notify the user of the need for a restart when appropriate.

4.4.2.10.1. *Instrument*

The **Instrument** settings view displays information about the instrument connected to the Storm Instrument Manager and allows the user to configure some aspects of the instrument.

Instrument Information: This section of the **Instrument** settings view includes general information about the instrument.

Serial Number: This field displays the Serial Number of the connected instrument. This value cannot be changed by the user. This value is a unique identifier assigned incrementally or sequentially to the instrument by GSD, to uniquely identify it.

Instrument ID: This field displays the ID given to the instrument. The user can configure this to be any alpha-numeric value they desire to meet the needs of the laboratory. The instrument ID is used to identify the instrument on Worklist Reports.

Runtime since last reset: The **Runtime since last reset** field shows the Days, Hours, Minutes the instrument has been running since this value was last reset. This can be used when troubleshooting instrument issues to help determine how much the instrument has been run over a given time interval. The user can click/tap the **Reset** button to set this value back to zero.

Total Runtime: The **Total Runtime** field displays the total amount of time in Days, Hours, Minutes that the instrument has been run. This value does not reset. It gives and overall indication of how much the instrument has been run over the lifetime of the instrument.

Spectrophotometer: This section of the **Instrument** settings view includes information about the spectrophotometer in the instrument reader.

Wavelength Set ID: This field displays the ID setting on the reader which determines the light wavelengths it supports.

Available Wavelengths: This field displays the available wavelengths of the spectrophotometer based on the **Wavelength Set ID**. The wavelength values are displayed in nanometers.

Reader is using a formula to correct readings: This field indicates that the reader has been calibrated and a calibration formula is being used to adjust the readings accordingly.

Barcode Scanner: This section of the **Instrument** settings view includes information about the barcode scanner on the instrument.

Turn of integrated scanner/use attached handheld scanner: This setting is only used for ThunderBolt instruments with classic Intelligent Sample Racks. The user can click/tap the checkbox to enable or disable the use of the built-in barcode scanner on the front of the instrument. If the checkbox is unchecked, the built-in barcode scanner will be used to scan barcodes. If the checkbox is checked, the built-in barcode scanner will not be used. Instead, the user can plug in a handheld barcode scanner to the back of the instrument using one of the USB ports and scan barcodes with the handheld scanner.

4.4.2.10.2. *Samples*

The **Samples** settings view is used to configure how events regarding the processing of Samples are handled during Worklist runs.

Aspiration Failure: This section of the **Samples** settings view includes information and settings related to the handling of aspiration failure events during a Worklist run.

Action when insufficient Reagent volume detected: This setting allows the user to specify how the Storm Instrument Manager should proceed during a Worklist run when there is not enough Reagent fluid to process the current (and subsequent) Samples. There are two options available:

- **Automatically continue Worklist and skip all subsequent Samples that use Reagent**
  This option will cause the Storm Instrument Manager to continue with a Worklist run when insufficient Reagent volume is detected to process a Sample, however, the current Sample and all subsequent Samples that require the depleted Reagent will not be processed. This event will be noted in the Worklist Status Log and the Error and Anomalies section of the Worklist Report and the skipped Samples will not have a result reported for them.

- **Ask the Operator**
  This option will cause the Storm Instrument Manger to display a **Bottle is Empty** warning message and prompt the user for information on how to proceed when insufficient Reagent volume is detected to process a Sample.

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Action when insufficient Sample volume detected: This setting allows the user to specify how the Storm Instrument Manager should proceed during a Worklist run when there is not enough Sample fluid to process the current Sample. There are two options available:

- **Automatically continue with next Sample**
  This option will cause the Storm Instrument Manager to continue with a Worklist run when insufficient Sample volume is detected to process a Sample. The current Sample will not be processed. This event will be noted in the Worklist Status Log and the Error and Anomalies section of the Worklist Report and the skipped Sample will not have a result reported for it.

- **Ask the Operator**
  This option will cause the Storm Instrument Manger to display a **Bottle is Empty** warning message and prompt the user for information on how to proceed when insufficient Sample volume is detected to process a Sample.

*NOTE: The prompt that is displayed during a Worklist run when the **Ask the Operator** option is selected for insufficient Reagent or Sample volume provides the user with information about the Reagent bottle or Sample tube that has low volume. The options for proceeding can consist of **Retry, Skip, Manual Pipette**, and **Abort Worklist**. The actual options for proceeding depend on how the Reagent or Sample is to be aspirated and dispensed according to the Test protocol defined in the Test File. In some circumstances, it may not be possible to skip or manually pipette the Reagent or Sample fluid. In those situations, the **Skip** and/or **Manual Pipette** options will not be presented.*
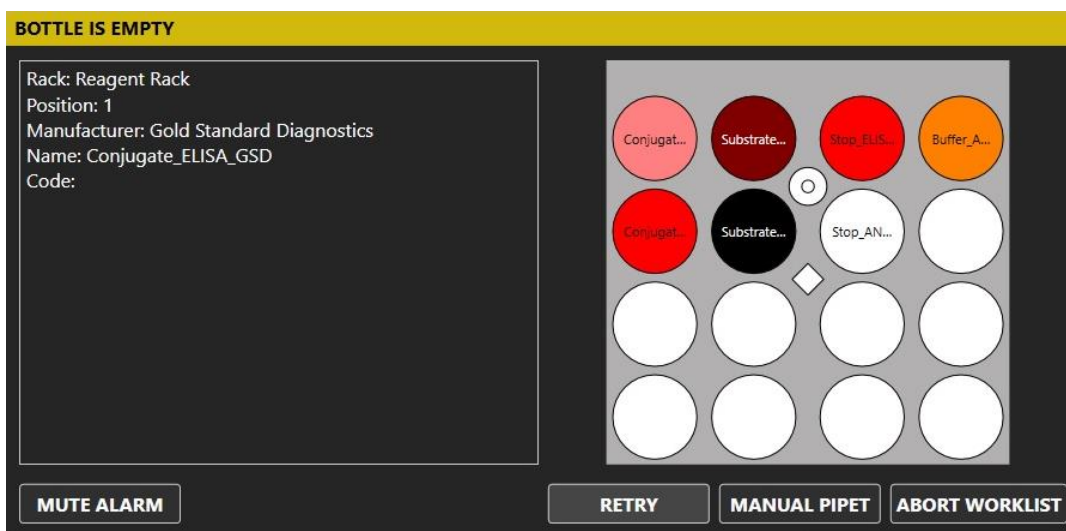
Number of retries when bubble destroyed: Insufficient volume detection can sometimes be caused by bubbles in the Reagent bottle or Sample tube. If the probe needle are lowered into a bubble (or pocket of air) in the bottle or tube, this may cause the Storm Instrument Manager to determine there is no fluid present. If the bubble is destroyed, the volume detection may succeed. This option specifies how many times the Storm Instrument Manager should lower the probe needles into the bottle before determining there is insufficient volume. Multiple attempts may destroy the bubble and allow the final attempt to successfully detect the fluid.

Incubation: This section of the **Samples** settings view includes information and settings related to the handling incubation issues detected during a Worklist run.

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Warn if incubator temperature is out of range: This setting allows the user to indicate if the Storm Instrument Manager should issue a warning if the incubation temperature is detected to be out of range with respect to the programmed temperature in the Test File. The user can specify the acceptable temperature range in the **Range** field. These warnings appear in the Worklist Status Log and the Errors and Anomalies section of the Worklist Report.

4.4.2.10.3. *Worklist*

The **Worklist** settings view is used to configure how Worklist runs are executed by the Storm Instrument Manager.

Worklist Startup: This section of the **Worklist** settings view includes information and settings related to the startup of a Worklist run.

Enable Worklist Loading Wizard at Start of Worklist: This setting allows the user to specify if the **Worklist Loading Wizard** should be used when a Worklist run is started. The **Worklist Loading Wizard** is an aide to the user to make sure the proper Reagents, Controls, and Calibrators are loaded on the Worklist before the Worklist run is started. If this option is enabled, the Worklist Loading Wizard will be launched when the user clicks the **Start** button on the **Home** screen to start a Worklist run. The **Worklist Loading Wizard** will walk the user through each Reagent, Calibrator, and Control to ensure it is loaded in the correct location on the instrument. If this option is not enabled, the **Worklist Loading Wizard** will not appear at the start of a Worklist run. The user must ensure that all Reagents, Calibrators, and Controls are properly loaded on the instrument before a Worklist run with no assistance from the Storm Instrument Manager.

Scan for barcodes of Calibrators/Controls and Reagent bottles: This setting allows the user to specify if the **Storm Instrument Manager** should scan for barcodes on Reagent, Calibrator, and Control bottles. The **Worklist Loading Wizard** must be enabled for this setting to take effect.

NOTE: The Test File which defines the test protocol in which the Reagent, Calibrator, or Control is used must specify that barcodes are used for these bottles and define the format for the barcoded information. Contact a GSD Technical Service representative or your Distributor for information on how to create or modify Test Files which support barcodes on Reagent, Calibrator, and Control bottles.

Enable Reagent Volume Check at Start of Worklist: This setting allows the user to specify if the Storm Instrument Manager should perform volume checks at the start of a Worklist run. If this option is enabled, the Storm Instrument Manager will descend the probe into each Reagent and Control bottle before the Worklist run is started to determine the fluid height and calculate the volume in the bottle. If there is not enough volume in the bottle to complete the Worklist run, the Storm Instrument Manager will display an error message. If this option is not enabled, then no volume check will be done at the start of a Worklist run.

NOTE: The Storm Instrument Manager must know the bottle dimensions to calculate the volume in the bottle. This is accomplished by defining a Bottle Adapter or a Custom Rack Position for the bottle. The use of a Bottle Adapter or Custom Rack Position must be specified for the bottle in the Test File. Contact a GSD Technical Service representative or your Distributor for information on how to create or modify Test Files which specify Bottle Adapters or Custom Rack Positions for bottles.

Optimization Options: This section of the **Worklist** settings view includes information and settings related to the optimizing a Worklist run.

Allow Tests with different timing schemes to be run together: This setting allows the user to specify if Tests with different timing schemes should be allowed to run together in the same Worklist run. When this option is not enabled, only Tests with the same timing schemes can be added to a Worklist and executed during the Worklist run. If this option is enabled, then Tests with different timing schemes can be added to a Worklist and execute during the Worklist run.

When adding Tests with different timing schemes to a Worklist, the user can specify whether the shorter or longer Tests should be added first.

- **Prefer Shortest Tests First**
  This option specifies that shorter Tests should be performed before longer Tests during the Worklist run.

- **Prefer Longest Tests First**
  This option specifies that longer Tests should be performed before shorter Tests during the Worklist run.

*NOTE: The **Allow Tests with different timing schemes to be run together** option is often, incorrectly referred to as the "Interleaving" option. This is incorrect because the Storm Instrument Manger will *always* attempt to interleave Test actions from different Tests in the Worklist during a Worklist run regardless of the setting of this option.*

*If the **Allow Tests with different timing schemes to be run together** option is not enabled, the Tests in the Worklist will have the same timing schemes and the Storm Instrument Manager will be able to interleave the actions from both Tests in a less strict manner without incurring too much timing drift in the processing of the Wells on the Microtiter Plates.*

*However, if the **Allow Tests with different timing schemes to be run together** option is enabled, the Tests in the Worklist may have different timing schemes and the Storm Instrument Manager must follow strict interleaving rules for the Test actions to ensure no significant timing drift is incurred in the processing of the Wells on the Microtiter Plates. This can result in the Test actions not being interleaved and the Tests being run sequentially during the Worklist run. This can significantly increase the overall Worklist run time.*

4.4.2.10.4. *Strips*
The **Strips** settings view is used to configure how events regarding the processing of monotest format Test (or "Strips") are handled during Worklist runs.

Foil Puncture: This section of the **Strips** settings view includes information and settings related to puncturing the foil of a monotest format Strip during a Worklist run.

Number of puncture retries: This setting allows the user to specify how many times the Storm Instrument Manager will attempt to puncture the foil of a monotest format Strip with the probe before an error message is displayed.

Auto Skip Strips: This section of the **Strips** settings view includes information and settings related to the processing of monotest format Strips if an error is encountered.

Auto Skip Strips After Timeout: This setting allows the user to specify if a monotest format Strip should be skipped after a specified timeout when an error is encountered. If this option is enabled and an error is encountered processing a monotest format Strip, the Strip will be skipped after the timeout period has passed. The event will be entered in the Status Log and appear in the Error and Anomalies section of the Worklist Report. If this option is not enabled, the

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monotest format Strip will not be skipped if an error is encountered. The error message will be displayed and the user must dismiss it for the Worklist run to continue.

Auto Skip Timeout: This option allows the user to specify the timeout period for auto skipping Strips if an error is encountered.

4.4.2.10.5. *Racks*

The **Racks** settings view is used to configure the Reagent and Sample Racks used on the instrument.
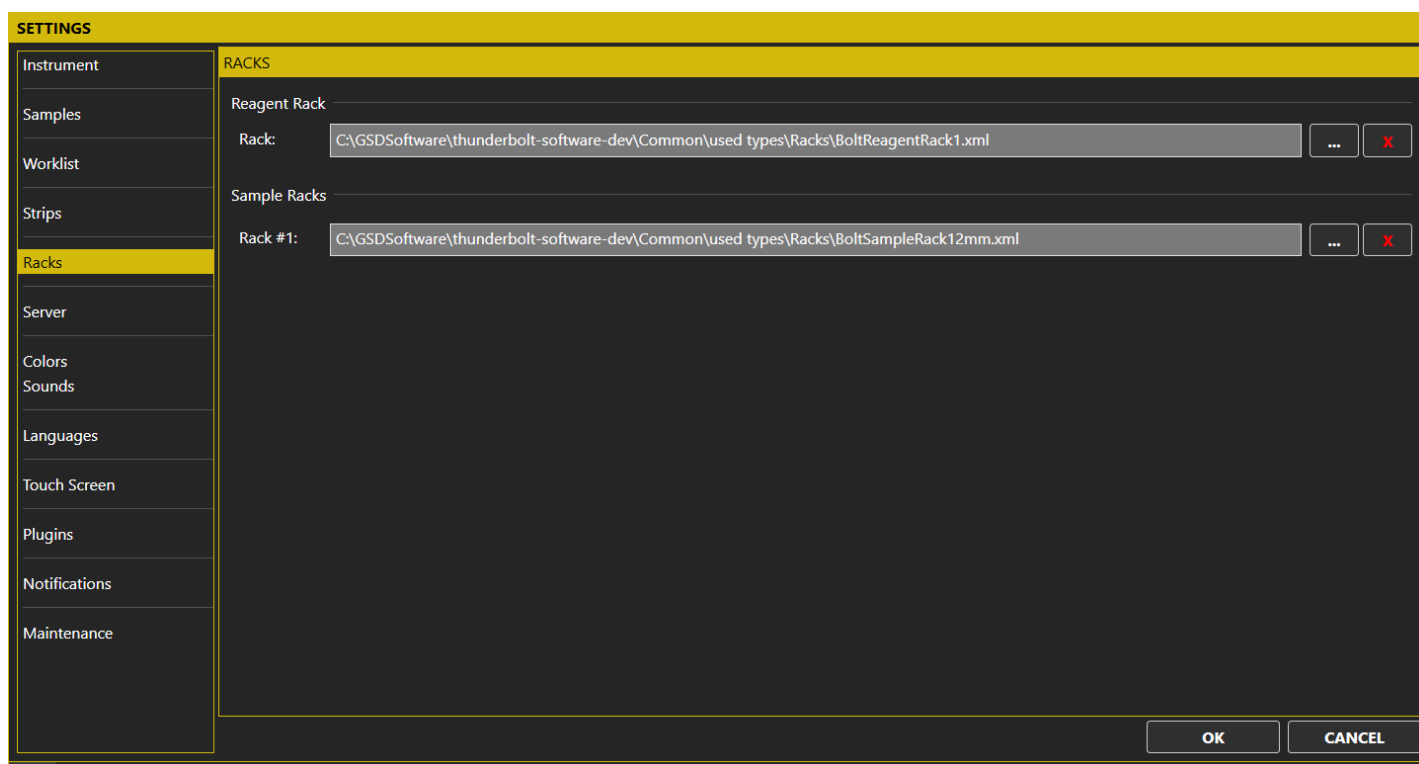
Reagent Rack: This section of the **Racks** settings view includes information and settings related to the Reagent Rack.

Rack: This setting specifies the Rack Definition file for the Reagent Rack. The Rack Definition file defines the physical rack dimensions and layout to the Storm Instrument Manager software. By default, this value is set to the Rack Definition file for the Reagent Rack the instrument was built with. If a custom Reagent Rack is used on the instrument, this setting should specify the Rack Definition file that corresponds to the custom Reagent Rack. The user can click/tap the **…** button to select a different Rack Definition file, or click/tap the **X** button to reset the Rack Definition file to its default value.

Sample Racks: This section of the **Racks** settings view includes information and settings related to the Sample Racks.

Rack #1: This setting specifies the Rack Definition file for the Sample Rack. The Rack Definition file defines the physical rack dimensions and layout to the Storm Instrument Manager software. By default, this value is set to the Rack Definition file for the default Bolt Sample Rack. The user can click/tap the **…** button to select a different Rack Definition file, or click/tap the **X** button to reset the Rack Definition file to its default value.

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4.4.2.10.6. *Server*

The **Server** settings view is used to configure how the Storm Instrument Manager should communicate with the Storm Server.

Server Location: This section of the **Server** settings view includes information and settings related to how where the Storm Sever is located and how the Storm Instrument Manager can connect to it.

Local Computer: This option indicates that the Storm Server is running on the same local computer that the Storm Instrument Manager is running on. This option is used when the Storm system is configured in a Single Instrument Configuration as described in **4.1.1 SINGLE INSTRUMENT CONFIGURATION**. If this option is selected, the Storm Instrument Manager will attempt to connect to the Storm Server running on the local computer.

Remote Computer: This option indicates that the Storm Server is running on a separate remote computer. This option is used when the Storm system is configured in a Multiple Instrument configuration as described in **4.1.2 MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION**. This Storm Server computer must be connected to the instrument computer via a TCP/IP network connection. The **IP Address** field indicates the IP address of the computer on which the Storm Server is running. If this option is selected, the Storm Instrument Manager will attempt to connect to the Storm Server running on the remote computer located at the IP address specified. Consult with your laboratory IT representative for information regarding IP addresses.

Evaluation: This section of the **Server** settings view includes information and settings related to information the Storm Server will provide for the evaluation of Worklists.

Maximum number of Worklists in Evaluation Tab: The **Worklists** dropdown on the Storm Instrument Manager **Evaluation** screen provides a list of Worklists the user can select to evaluate (see **4.4.2.6.1 SELECT A WORKLIST** for details). The Storm Server provides this list with Worklist names starting from the newest to oldest. This option specifies how many Worklists the Storm Server will provide to the Storm Instrument Manager for evaluation.

4.4.2.10.7. *Colors*

The **Colors** settings view is used to configure the display colors the Storm Instrument Manager.

Theme: This option sets the basic background, or theme, color for the Storm Instrument Manager. The two choices are *Base Dark* and *Base Light*. Setting this option will change the background color for the Storm Instrument Manager.

Accent: This option sets the accent color (border color, highlight color, etc.) for the Storm Instrument Manager. A preset list of twenty three colors can be selected.

4.4.2.10.8. *Sounds*

The **Sounds** settings view is used to configure the sounds the Storm Instrument Manager uses for different event notifications.

Enable sound at end of run: This option allows the user to specify if the Storm Instrument Manager should play a sound at the end of a Worklist run. If it is enabled, a sound will be played at the end of a Worklist run. If disabled, no sound will be played.

Customize sounds: This section of the **Sounds** settings view allows the user to customize the sounds used for different event notifications. The first five event sound notifications **End of Run**, **Drop between needles**, **Reagent/Sample tube empty**, and **Incubation Time Exceeded** are set to default sound files. The user can click the **…** button for any of the event

sound notification settings to display a File Open and select a .wav file to be used for the event sound notification. The user can click the X button to set the event sound notification value back to the default setting.

4.4.2.10.9. *Languages*

The **Languages** settings view is used to specify the language/locale in which the Storm Instrument Manager should be displayed.

Select the desired display language: This setting allows the user to select a language/locale in which the Storm Instrument Manager should be displayed. When the *Automatic Language Selection* item is selected, the Storm Instrument Manager will be displayed in the same language/locale as the Windows operating system. When any other language/locale is selected from the list, the Storm Instrument Manager will be displayed in this language/locale regardless of the Windows operating system language/locale setting.

NOTE: By default, the list of available languages/locales includes only two choices: Automatic Language Selection and English. A Storm Language Pack must be installed for more choices to be available. If a Storm Language Pack is not installed, the Storm Instrument Manager will always be displayed using its native U.S. English language/locale. In addition, if the Automatic Language Selection setting is selected and the Windows operating system is using a language/locale that is not supported by the Storm Language Pack, then the Storm Instrument Manager will revert to its native U.S. English language/locale. Contact a GSD Technical Service representative or your Distributor for more information regarding Storm Language Packs.

4.4.2.10.10. *Touch Screen*

The **Touch Screen** settings view is used to specify how the Storm Instrument Manager should provide touch screen interaction.

NOTE: The Storm Instrument Manager supports all basic touch screen interaction by default. When the Storm Instrument Manager is run on a netbook computer with a touchscreen, the user can use all basic touch screen input methods and gestures when interacting with the software.

Enable On Screen Keyboard: This option specifies if the on-screen keyboard should be enabled for entering input with a touch screen device. If enabled, an on-screen keyboard will appear when the user clicks/taps in any field that accepts text input. The use can enter the text input using the on-screen keyboard. If not enabled, the on-screen keyboard will not appear when the user clicks/taps in a field that accepts text input. The user will have to use the netbook computer keyboard to enter text.

4.4.2.10.11. *Plugins*

The **Plugins** settings view is used to provide information and allow the user to configure settings for plugins used by the Storm Instrument Manager. A plugin is an optional software component that provides additional functionality to the Storm Instrument Manager. Plugins are implemented as shared libraries which are dynamically loaded at run time. To install a plugin, the shared library file (*.dll) simply must be copied into the *Plugins* folder of the Storm installation directory.

Plugins come in two types: *Import Plugins* and *Export Plugins*. *Import Plugins* are always enabled and provide support for additional file formats when loading a Worklist. See **4.4.2.2.4 WORKLIST>LOAD** for more details. *Export Plugins* can be enabled or disabled on the Plugins settings screen. When enabled, they save the Worklist run data to a custom format when the Worklist run is complete.

Auto Export Plugins: This list box provides a list of available export plugins. The export plugin can be enabled by clicking the checkbox next to the plugin so it contains a check mark. Enabled export plugins will be executed when a Worklist run completes. If the Export Plugin includes configurable settings, a button with a gear icon will appear to the right of the plugin. The user can click/tap the button to open a window to configure settings specific to that plugin.

4.4.2.10.12. *Notifications*

The **Notifications** settings view is used to configure SMS and/or Email notification messages to be sent to users of the Storm system for events that occur on the instrument connected to the Storm Instrument Manager.

NOTE: In order for a Storm system user to receive SMS and/or Email notification messages, the user account must include a mobile phone number and/or email address. If the user account was defined without a mobile phone number, then the user will not be able to receive SMS notification messages. If the user account was defined without an email address, then the user will not be able to receive Email notification messages. See 4.3.2.1 USERS for more details.

NOTE: The Storm system must be connected to the internet in order to use SMS and/or Email notifications. See your laboratory IT for information about whether your Storm system has internet access.

Worklist Operator Notifications: This section of the **Notifications** settings view includes information and settings related to notification messages sent to the user currently logged-on to the Storm Instrument Manager operating the instrument and performing Worklist runs.

Send SMS Text Notification: This option allows the user to specify if SMS notifications should be sent to the currently logged-on user who is operating the instrument and performing Worklist runs. If this option is enabled, the user will receive SMS notifications for events that occur on the instrument. The alarms and events that the user will receive notifications for are: Worklist End, Bottle Refill, Wash Bottle Empty, Waste Bottle Full, Clogged Probe, Fluid Detection Error, and other Miscellaneous Worklist Errors.

Send Email Notification: This option allows the user to specify if Email notifications should be sent to the currently logged-on user who is operating the instrument and performing Worklist runs. If this option is enabled, the user will receive email notifications for events that occur on the instrument. The alarms and events for which the user will receive notifications are: Worklist End, Bottle Refill, Wash Bottle Empty, Waste Bottle Full, Clogged Probe, Fluid Detection Error, and other Miscellaneous Worklist Errors.

Additional User Notifications: This section of the **Notifications** settings view includes information and settings related to notification messages sent to Storm system users other than the user currently logged-on to the Storm Instrument Manager operating the instrument and performing Worklist runs. These settings can be useful if the user logged-on to the Storm Instrument Manager operating the instrument needs backup to handle alarms or notifications.

Additional User Table: This table provides a list of Storm system users not currently logged-on to the Storm Instrument Manager. The table displays the user name, the user mobile phone number (if defined in the user account), and the user email address (if defined in the user account).

NOTE: The mobile phone number and email address are partially obscured with asterisk characters (*) to protect the privacy of the user.

The user can select users from the list in the table and configure the alarms and/or events the user should receive notifications before in the **Alarms/Events for selected User** settings below.

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Alarms/Events for selected User: These options allow the user to specify which alarms and/or events the user selected in the **Additional User Table** should receive notifications for. The user can specify whether the selected user should receive SMS and/or Email notifications for the following alarms and events: Worklist End, Bottle Refill, Wash Bottle Empty, Waste Bottle Full, Clogged Probe, Fluid Detection Error, and other Miscellaneous Worklist Errors.

4.4.2.10.13. *Maintenance*

The **Maintenance** settings view is used to configure aspects of the maintenance procedures for the instrument.

Weekly Maintenance: This section of the **Maintenance** settings view includes information and settings related to the execution of the Weekly Maintenance procedures.

Perform Weekly Maintenance on: These settings allow the user to specify the day of the week and time of the day the Weekly Maintenance procedures should be performed. The user can use the **Day** dropdown to select the desired day of the week and the **Time** dropdown to select the time of the day.

Perform Weekly Maintenance at: This setting allows the user to specify if the Weekly Maintenance procedures should be run at system startup (when the instrument is powered on) or at system shutdown (when the instrument is powered off).

4.4.2.11 Information

The **Information** button opens the **About** window which displays version and copyright information for the Storm Instrument Manager.

4.4.2.12 Help

The **Help** button opens a copy of this User's Manual on the instrument computer.

4.4.2.13 Power

The **Power** button is used to exit the Storm Instrument Manager software and power off the instrument/computer. Daily shutdown maintenance procedures will be prompted.

4.4.3 Storm Software Folders

The Storm system software (Storm Server, Storm System Configuration Tool, Storm Instrument Manager) stores data and information files in the Windows file system at the location:

```
C:\Users\Public\Documents\Storm
```

The data and information files are stored in sub-folders based on the type of data and information they contain. Examples of the type of data and information include database backups, Worklist files, error logs, and more.

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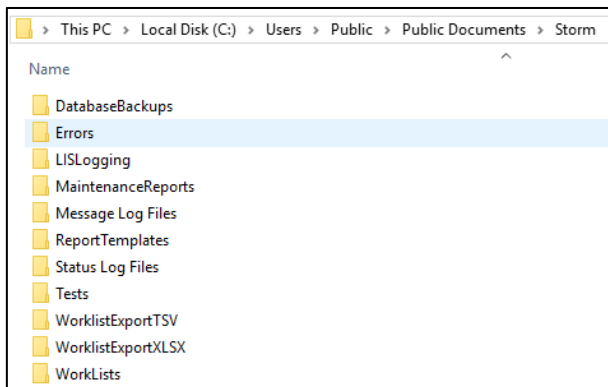
If the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION, all these files will be located in sub-folders under the C:\Users\Public\Documents\Storm folder on the instrument computer.

If the Storm system is being run in the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION, some of these files will be located on the instrument computer, and some will be located on the server computer. The computer on which the files and sub-folders are stored depends on which Storm system component they are associated with. Files associated with the Storm Instrument Manager will be located in sub-folders under the C:\Users\Public\Documents\Storm folder on the instrument computer. Files associated with the Storm Server or the Storm System Configuration Tool will be located in sub-folders under the C:\Users\Public\Documents\Storm folder on the server computer.

The following sub-sections describe each of the folder locations and the files they contain.

4.4.3.1 DatabaseBackups

This is the recommended/default location for any database backups created via the Storm System Configuration Tool.

If the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the instrument computer.

If the Storm system is being run in the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the server computer.

NOTE: This folder is only the recommended/default location for database backup files. When a backup of the database is performed, the user has the ability to specify any folder to which the backup should be saved. See 4.3.2.7.1 BACKUP and 4.3.2.7.3 SCHEDULED BACKUP for details.

4.4.3.2 Errors

Errors that are encountered during use of the Storm system are named by the date and time at which they occur and stored in the Errors subfolder as text files:

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If the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the instrument computer and will contain error files generated by all software components (Storm Server, Storm Configuration Tool, Storm Instrument Manager).

If the Storm system is being run in the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on both the instrument computer and the server computer. The folder on the instrument computer will contain error files generated by the Storm Instrument Manager. The folder on the server computer will contain error files generated by the Storm Server and the Storm System Configuration Tool.

4.4.3.3 LISLogging

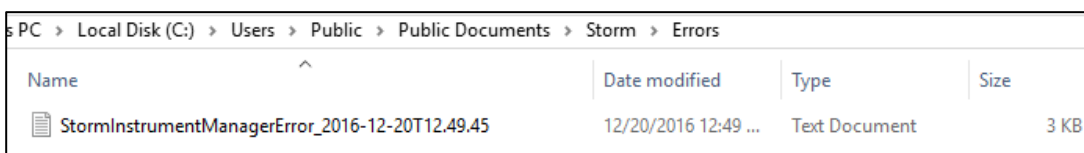If LIS logging is enabled as described in 4.3.2.5 LIS SETTINGS, LIS log files will be stored in this folder.

If the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the instrument computer.

If the Storm system is being run in the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the server computer.

4.4.3.4 Maintenance Reports

Records of users' performance of all prompted maintenance actions are stored (one file per month) in the Maintenance Reports subfolder in portable document format (PDF), as shown in the image below:

Storm Software-Recorded Maintenance Action Log

Instrument Serial Number: 12456   **Month:** October   **Year:** 2018

Daily Startup	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Do 10 primes with wash buffer	/	/	/	/	/	/	/	/	/	/	/			/	/		/	/	/	/	/	/	/	/	/	/	/	/	/	/	/

Daily Shutdown	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Do 50 primes with DI water	/	/	/	/	/	/	/	/	/	/	/		/	/		/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Shut down instrument and computer	/	/	/	/	/	/	/	/	/	/	/	gs	/	/	gs	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Empty waste bottle	/	/	/	/	/	/	/	/	/	/	/	gs	/	/	gs	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/

Weekly	Week 1 Date/Initials:	Week 2 Date/Initials	Week 3 Date/Initials:	Week 4 Date/Initials:	Week 5 Date/Initials:
Remove sample racks, inspect for damage and clean with alcohol	/		2018-10-15/ngsdadmin	/	/
Clean outside of probe with alcohol wipe	/		2018-10-15/ngsdadmin	/	/
Do 20 primes with 1% Liquinox and 50 primes with DI water	/			/	/
Clean wash bottles	/		2018-10-15/ngsdadmin	/	/

Monthly Maintenance	Date/Initials
Perform Instrument Alignment	/
Perform Reader Alignment	/

The **Maintenance Reports** folder is always located under the C:\Users\Public\Documents\Storm folder on the instrument computer, regardless of whether the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION or the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION.

4.4.3.5 Message Log Files

When an error message, warning message, or software prompt appears to the user during their use of the system, the prompt and the user response are recorded in a log file in this folder (one log file for each day).

The **Message Log Files** folder is always located under the C:\Users\Public\Documents\Storm folder on the instrument computer, regardless of whether the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION or the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION.

4.4.3.6 Report Templates

Any custom Worklist Report Templates or Test Report Templates should be stored in the Report Templates subfolder.

If the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the instrument computer.

If the Storm system is being run in the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the server computer.

4.4.3.7 Status Log Files

The Status Log files record all actions and events from a Worklist run, including any anomalies encountered (such as bubble retries). These Status Log files are automatically saved as text files, named with the Worklist name and status (completed, stopped, etc.), and organized into folders for each month, in the Status Log Files subfolder:

The **Status Log Files** folder is always located under the C:\Users\Public\Documents\Storm folder on the instrument computer, regardless of whether the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION or the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION.

4.4.3.8 Tests

Test files can be stored in the Tests subfolder.

If the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the instrument computer.

If the Storm system is being run in the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION, this folder is located under the C:\Users\Public\Documents\Storm folder on the server computer.

NOTE: Test files must be added to the Storm system using the Tests screen in the Storm System Configuration Tool before they will be available in the Storm Instrument Manager. See 4.3.2.3.2 ADD TEST FILES for details. When a test file is added to the Storm Server using the Storm System Configuration Tool, a copy of the test file is stored in the Storm Server

Database. Changes to the original test file saved in the Tests subfolder will not be recognized by the Storm system until the test file is re-added to the Storm System using the Storm System Configuration Tool.

4.4.3.9 Worklist Export TSV/XLSX

Worklist reports exported from the Evaluation screen of the Storm Instrument Manager as tab separated value (.tsv) files and excel (.xlsx) files are stored by default in the **Worklist Export TSV** and **Worklist Export XLSX** subfolders, respectively.

These folders are always located under the C:\Users\Public\Documents\Storm folder on the instrument computer, regardless of whether the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION or the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION.

4.4.3.10 Worklists

Worklists are automatically saved, named with the worklist name, and organized into folders for each month, in the Worklists subfolder. These can be opened from within the Storm Instrument Manager using the **Load** button on the **Worklist** screen. See **4.4.2.2.4 LOAD** for details.

This folder is always located under the C:\Users\Public\Documents\Storm folder on the instrument computer, regardless of whether the Storm system is being run in the SINGLE INSTRUMENT CONFIGURATION or the MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION.

4.5 Other Software Applications

Other related software applications for protocol design and service purposes, such as the Storm Test Designer and the Instrument Testing Tool, are available from Gold Standard Diagnostics. These are provided to, and should only be used by, trained service technicians. Please contact a GSD Technical Service representative, or a representative from your Distributor for details.

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5 Maintenance

Maintenance procedures should be followed to ensure proper instrument functionality. Maintenance actions are automatically recorded by the software and monthly Maintenance Reports are accessible as described in 4.4.2.5.1 TOOLS>GENERAL>MAINTENANCE LOGS. The information below describes the routine maintenance steps for the system.

5.1 Daily Maintenance

Daily maintenance includes startup and shutdown tasks. Startup tasks are prompted and should be performed when the Storm Instrument Manager is opened, prior to the first Worklist run of the day. Shutdown tasks are prompted and should be performed following the last Worklist run of the day, when the Storm Instrument Manager is closed and the instrument is powered off.

5.1.1 Startup Maintenance Tasks

The Startup Maintenance consists of the following tasks:

1. Daily Startup Prime
    The user should ensure the Wash Bottle(s) is/are properly connected to the instrument and contain the appropriate wash buffer. The user should also ensure that all wash buffers are within their expiration date prior to each use. Typically, Phosphate Buffered Saline (PBS) is used as the wash buffer, but this may vary depending on the assays being run in the laboratory. The user should also ensure that an empty Waste Bottle is properly connected to the instrument. The Daily Startup Prime consists of 20 priming cycles per Wash Bottle to ensure the fluidics lines are properly primed prior to the first Worklist run of the day.

NOTE: If the instrument is idle for four or more hours after the Daily Startup Prime is performed, it is recommended that the user prime the instrument again prior to a Worklist run. The user can prime the instrument as described in 4.4.2.5.1 TOOLS>GENERAL>PRIME INSTRUMENT. This will help ensure that any potential build-up is cleared from the fluidics lines.

5.1.2 Shutdown Maintenance Tasks

The Shutdown Maintenance consist of the following tasks:

1. Daily Shutdown Prime
    The user should ensure the Wash Bottle(s) is/are properly connected to the instrument and contain deionized (DI) water. The user should also ensure that a Waste Bottle is properly connected to the instrument. The Daily Shutdown Prime consists of 50 priming cycles per Wash Bottle to ensure all traces of wash buffer are cleared from the fluidics lines. This will help ensure that no build-up occurs in the fluidics lines while the instrument sits idle after shutdown.

2. Empty the Waste Bottle
    The user should empty the Waste bottle by disposing of the contents according to the appropriate laboratory guidelines.

3. Unload the instrument and close the cover
    The user should remove any remaining Reagent bottles and Sample tubes from inside the instrument. Reagent bottles and Sample tubes should be stored in the laboratory according to the appropriate laboratory guidelines. The user should ensure all instrument surfaces are clean and dry. Finally, the user should close the instrument cover.

5.2 Weekly Maintenance

Weekly maintenance includes tasks that are prompted and should be performed every seven days. It is recommended that the same day of the week be used for consistency. The user can specify which day of the week these tasks should be performed as described in 4.4.2.10.13 SETTINGS>MAINTENANCE. Weekly maintenance consists of the following tasks:

1. Sample Rack and Reagent Rack inspection and cleaning
   The user should remove the Sample Racks and Reagent Racks and inspect each one for cleanliness and damage. The user should use an alcohol wipe to gently clean all Sample Racks and Reagent Racks.

2. Rack Deck inspection and cleaning
   With all Sample Racks and Reagent Racks removed, the user should inspect the Rack deck for cleanliness and damage. The user should use an alcohol wipe to gently clean the Rack deck surface.

3. Probe cleaning
   The user should inspect the outside of the Probe for cleanliness and damage. The user should clean the outside of the Probe (including both the center probe shaft and the probe needles) by wiping it down gently with an alcohol wipe.

4. Decontamination Priming
   The user should decontaminate the instrument tubing by priming the instrument for 20 cycles with a Liquinox solution. The Liquinox solution is prepared by making a 1:100 dilution of the Liquinox Concentrate supplied with the instrument and DI water. The user should then flush the instrument tubing by priming the instrument for 50 cycles with DI water.

5. Clean the Wash/Waste Bottles
   The user should clean the Wash Bottles by rinsing them with DI Water. The user should clean the Waste Bottle by rinsing it with wash buffer. The user should also ensure that the wash buffer is within its expiration date prior to each use. Typically, Phosphate Buffered Saline (PBS) is used as the wash buffer, but this may vary depending on the assays being run in the laboratory. The user should then rinse the Waste Bottle with DI water.

NOTE: Care should be taken to ensure that no excess liquid comes into contact with the instrument surfaces while cleaning. Cleaning should only be performed with the recommended substances and liquids.

5.3 Monthly Maintenance

Monthly maintenance includes tasks that are prompted and should be performed once a month. The Monthly maintenance consists of the following tasks:

1. Probe Alignment
   The user will be prompted to align the instrument Probe. The user should carefully follow the instructions for each step in the alignment process provided by the Probe Alignment Wizard.

2. Reader Alignment
   The user will be prompted to align the instrument Reader. The user should carefully follow the instructions for

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each step in the alignment process provided by the Reader Alignment Wizard.

3. Replace Outer Waste Tubing
   If instrument contains a peristaltic waste pump (older models only), monthly waste pump tubing replacement is also required. Contact local instrument distributor for detailed instructions.

   NOTE: Changing the tubing of the waste pump is only applicable only for older instrument models with a peristaltic waste pump. Newer instruments models which contain a membrane/diaphragm waste pump do not require the waste pump tubing to be replaced as part of the monthly maintenance.

5.4 Periodic Maintenance

Approximately once a year (time will vary depending on instrument usage) a Preventative Maintenance procedure should be performed on the instrument by a trained Technical Service representative. Contact a GSD Technical Service representative or your Distributor for more information.

5.5 Storage, Transportation, and Disposal

Storage, transportation, and disposal of the instrument must be completed by a trained Technical Service representative. A complete reinstallation must be performed following any move or storage of the instrument.

The recommended storage and transportation conditions for the instrument should be similar to the use conditions. If the instrument is moved from its installed location or removed from service for an extended period of time, it is recommended that the maintenance tasks described in **5.2 WEEKLY MAINTENANCE** be performed, followed by dry priming cycles to remove liquids from the system. The instrument should also be returned to the original packaging.

Environmental conditions for extended storage periods should be as follows:

Temperature:	10°C – 60°C (50°F – 140°F)
Relative Humidity:	20 – 90% non-condensing

After shipping, it is recommended that the instrument be stored at room temperature for at least 24 hours before powering on the instrument.

It is recommended that any trained Technical Service representative disposing of an instrument consult applicable local regulations prior to disposal.

6 Laboratory Information System Integration

The LIS implementation provided by Storm completely conforms to the NCCLS LIS2-A2 and NCCLS LIS01-A2 (formerly known as ASTM E1394-91 and ASTM E1381-91) specifications. The instrument can communicate successfully with LIS systems that also conform to these specifications. Some LIS companies will need to create special drivers before they will be able to be integrated with the instrument.

In addition to the TCP/IP implementation of NCCLS LIS01-A2, the software also supports a "clean" TCP/IP transmission. In this mode the software will send the unmodified NCCLS LIS2-A2 frames including the <CR> at the end of the frame. No checksum or control characters are added.

All LIS Settings are found within the **LIS Settings** and **LIS Associations** screens of the Storm Configuration Tool as described in **4.3.2.5 LIS SETTINGS** and **4.3.2.6 LIS ASSOCIATIONS**, respectively. When creating Worklists, the LIS can be queried from the **Worklist** screen of the Storm Instrument Manager as described in **4.4.2.2.11 WORKLIST>QUERY LIS**. After a Worklist run is complete, Worklist results can be sent to the LIS from the **Evaluation** screen of the Storm Instrument Manager as described in **4.4.2.6.7 EVALUATION>SEND TO LIS**.

6.1 LIS Configuration

To configure a Storm system to communicate with an LIS, follow these steps:

1. Verify that the Storm system is correctly installed and setup in the desired configuration as described in **4.1.1 SINGLE INSTRUMENT CONFIGURATION** and **4.1.2 MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION**.

2. Verify that all physical cords and cables of the Storm system and the LIS system are securely connected. If the Storm system is connecting to the LIS using a TCP/IP connection, then an Ethernet cord must be connected to the system. If the Storm system is connecting to the LIS using an RS-232 connection, then a RS-232 serial cord must be connected to the system.

3. Verify that Test Files for all Tests supported by the LIS have been added to the Storm system using the Storm System Configuration Tool as described in **4.3.2.3.2 TEST FILES>ADD TEST FILES**.

4. Specify how the Storm system will communicate with the LIS using the Storm System Configuration Tool as described in **4.3.2.5 LIS SETTINGS**. These settings must be configured properly before any communication with LIS is attempted. Consult with your Laboratory IT representative and/or LIS representative to determine the proper communication settings for the LIS used in your laboratory.

5. Assign LIS Test IDs to Storm Test Files using the Storm System Configuration Tool as described in **4.3.2.6 LIS ASSOCIATIONS**. Be careful to enter all LIS Test IDs exactly as they are used in the LIS system.

   NOTE: An LIS Test ID is seldom the full name of the test, but often a shorter, abbreviated name. The LIS Test ID could also be a number or code, depending on the laboratory policy. Consult with your Laboratory IT representative and/or LIS representative to determine the proper LIS Test IDs for the LIS used in your laboratory.

6. Test the connectivity between the Storm system and the LIS.

   a. Launch the Storm Instrument Manager connected to an instrument in the Storm system.

b. Log on using a User Account of the type Super User or Administrator.

c. Create a new Worklist and add Samples using any of the methods described in **4.4.2.2.6 WORKLIST>ADD SAMPLES**. Be sure to verify in the LIS that the Samples that were added actually have pending orders for Tests.

d. Query the LIS by clicking the **Query LIS** button on the **Worklist** screen as described in **4.4.2.2.11 WORKLIST>QUERY LIS**. If connectivity is working properly, Tests will be added to the Worklist and assigned to the Samples based on the Order records sent by the LIS.

    *NOTE: Adding Tests to a Worklist using the Query LIS functionality is subject to the same compatibility criteria mentioned in **4.4.2.2.9 WORKLIST>ADD TEST**. At the conclusion of the LIS query, Storm will display a warning message for any Tests that could not be added to the Worklist due to compatibility issues.*

e. Run the Worklist by clicking/tapping the **Special Start** button on the **Home** screen to start the Worklist run as described in **4.4.2.1.1 HOME>WORKLIST SUMMARY AND ACTIONS**. Be sure to specify that the Worklist run starts from the Read step to avoid running the full Worklist which could take hours depending on the Tests in the Worklist. Performing just the Read step should only take a few minutes.

    NOTE: If reading is not performed, there will be no results to be transmitted to the LIS.

f. After the Worklist run is complete, navigate to the **Evaluation** screen and view the Worklist Report. Mark the Worklist as reviewed as described in **4.4.2.6.3 EVALUATION>WORKLIST REVIEWED**.

g. On the **Evaluation** screen, click/tap the **Send to LIS** button to send results to the LIS as described in **4.4.2.6.7 EVALUATION>SEND TO LIS**. In the Send to LIS window, select which results to send and click/tap **Send**. If connectivity is working properly, results will be transmitted and appear in the LIS.

6.1.1 RS-232 Pin Layout

If connecting to an LIS using an RS-232 connection, it may be necessary to know the pin layout of the physical connection. The pin layout is specified below:

RS-232 DB-9 Male Pinout

PIN 1: Data Carrier Detect
PIN 2: Receive Data
PIN 3: Transmit Data
PIN 4: Data Terminal Ready
PIN 5: Signal Ground
PIN 6: Data Set Ready
PIN 7: Request to Send
PIN 8: Clear to Send
PIN 9: Ring Indicator
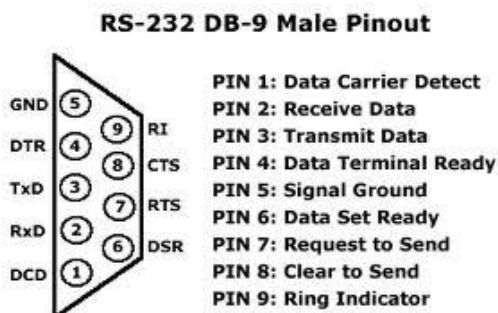
6.2 LIS Records

As stated previously, the LIS implementation provided by Storm completely conforms to the NCCLS LIS2-A2 and NCCLS LIS01-A2 (formerly known as ASTM E1394-91 and ASTM E1381-91) specifications. The NCCLS LIS2-A2 specification defines the conventions for the exchange of clinical results and patient data between laboratory instruments and an LIS.

This section provides summary information about the records used to exchange information. For full details, refer to the NCCLS LIS2-A2 specification.

6.2.1 Header Record

All communications begin with the Header Record. By default, the "|" character is used to delineate fields in the record.

Example:

```
H|\^&|||STORM^3.2.3.0|||||||||LIS2-A2|20101022162157
```

The Header Record starts with H in the first field.

The second field in the Header Record is the "Delimeter Defintion" field. This field defines the delimeters to be used throughout the subsequent records of the message. The The first character in the second field is the "Repeat Delimeter". The second character in this field is the "Component Delimeter". The third character in the second field is the "Escape Delimeter".

The third and fourth fields in the Header Record are unused by Storm and can be ignored. They are blank in the example above.

The fifth field in the Header Record is the "Sender Name or ID" field. The purpose of this field is to identify the sender of the information. Using Repeat Delimiters and/or Component Delimiters, this field may reflect different attributes to identify the sender. Storm uses the Component Delimiter to divide this field into three components to identify itself as the sender. The first component is the name of the system, in this case "Storm". The second component is the version of the Storm software.

The next six fields are unused by Storm and left blank.

The twelfth field in the Header Record is the "Version Number" field. This is set to "LIS2-A2" to indicate the version of the protocol being used to send the information.

The last field of the Header Record is the "Date and Time" field. This field contains the date and time that the Header Record was sent. The format is YYYYMMDDHHMMSS.

6.2.2 Request Information Record (aka Query Record)

The Storm system will query the LIS using Request Information Records, which are also referred to as Query Records.

Example:

```
Q|1|^S001^||ALL||||||||O
```

The Query Record starts with Q in the first field. The second field is a sequence number.

The third field in the Query Record is the "Starting Range ID" field. Positions within the field are indicated by the ^ delimiters. The first position in this field denotes the "Laboratory Assigned Patient ID", which is unknown by the Storm system at the time a query and, therefore, left blank. The second position in this field denotes the "Specimen ID" which is filled with the Sample ID from the Worklist.

The fourth field is the "End Range ID" field and is left blank indicating the query is for only the Sample ID specified, not a range of Sample IDs.

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The fifth field is the "Universal Test ID" field and is set to 'ALL' to indicate all ordered tests for the Sample ID are being requested.

Several other fields are left blank. There are eight field separators (|). These fields are typically not used by Storm. See the NCCLS LIS2-A2 specification for information regarding these fields.

The final field is the Request Information Status Code field. It is set to 'O' to indicate Test Orders are being requested.

6.2.3 Patient Information Record

The LIS system will respond to the software using Patient Information Records.

Example:

P|1|1234|5678|*****

The Patient Record starts with a P in the first field. The second field is a sequence number.

The third field in the Patient Record is the "Physician Assigned Patient ID" field. This field is ignored by the Storm system for GDPR/HIPPA reasons.

The fourth field in the Patient Record is the "Laboratory Assigned Patient ID" field. This field is read by the Storm system and stored in the Storm database along with the Sample ID.

The ***** in the Patient Record example above represents other fields of the Patient Record which the LIS may provide, but the Storm system does not use. Storm will ignore these fields.

6.2.4 Test Order Record

The LIS system will give specific Patient/Test information using "Test Order Records".

Example:

O|1|S001||^^^CMVG|R

The Order Record starts with an O in the first field. The second field is a sequence number.

The third field in the Order Record is the "Specimen ID" field. Storm uses this field to identify the Sample ID in the Worklist which this Order record is associated with. In this example, the Sample ID is "S001".

The fourth field in the Order Record is unused by Storm. This field is left blank in the example above.

The fifth field in the Order Record is the "Universal Test ID" field. This field is used to identify the Test being ordered for the Sample ID. This field is divided into four components. Storm does not use the first three components of this field and they are left blank in the example above. The fourth component in this field, the "Manufacturer defined test code" component, identifies the Test ID as defined by the LIS. In the example above, the Test ID is "CMVG". The values provided by the LIS in this field component must be associated with Storm Test Files loaded in the Storm system as described in **4.3.2.6 LIS ASSOCIATIONS**.

6.2.5 Result Record

The Storm system will send Sample results from Worklist runs back to the LIS using "Result Records".

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Examples:

`R|1|^^^CMVG|1.33|ng/ml|||||F`

`R|1|^^^HSVG^ST1|4.89|ng/ml|||||F`

`R|1|^^^HSVG^ST2|3.52|ng/ml|||||F`

`R|1|^^^HPLG|1.75^high|ng/ml|||||F`

The Result Record starts with an R in the first field. The second field is a sequence number.

NOTE: Result Records are nested within Patient Records and Order Records to identify which Patient and Sample the Result Record is associated with. See 6.3 LIS QUERY AND TRANSMISSION EXAMPLES below.

The third field in the Result Record is the "Universal Test ID" field. This field is used to identify the Test for which Results are being provided. This field is divided into four components. Storm does not use the first three components of this field and they are left blank in the example above. The fourth component in this field, the "Manufacturer defined test code" component, identifies the Test ID as defined by the LIS. In the examples above, the Test ID is "CMVG". The values provided by the LIS in this field component must be associated with Storm Test Files loaded in the Storm system as described in **4.3.2.6 LIS ASSOCIATIONS**.

According to the LIS2-A2 specification, the "Universal Test ID" field can be divided into further components to provide additional information to indicate the relationship of the result to the test, battery, or batteries ordered. If a test contains multiple results or subtests (e.g. panel based tests), the subtest name is added after the test ID separated by a component delimiter. In the second and third examples above, the Test ID is given as "HSVG" and an additional result is indicated by the component of "ST1" or "ST2".

The fourth field in the Result Record is the "Data or Measurement Value" field. This field can contain numeric, text, or coded values recorded in ASCII notation. If the result has a message associated with it (e.g. "Low", "Medium", "High"), the message is stored after the numerical result, separated by a component delimiter.

The fifth field in the Result Record is the "Units" field. The abbreviation of units for numerical results is provided in this field. Units can be reported in upper or lower case.

The next three fields in the Result Record are used for Reference Ranges and Abnormal result information. These fields are typically not used, but may be if the test protocol defines this information. Refer to the NCCLS LIS2-A2 specification for details on these fields.

The final field in the Result Record is the "Result Status" field. This field contains a one letter code indicating the status of the result information. The possible values for this field are:

Result Status Code	Description
C	Correction of previously transmitted result
P	Preliminary results
F	Final results
X	Order cannot be done
I	In instrument, results pending
S	Partial results
M	This result is an MIC level

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R	This result was previously transmitted
N	This result record contains necessary information to run a new order

NOTE: If a Sample is skipped during a Worklist run, a Result Record is still transmitted for that Sample, but the "Result Status" field is then set to "X" (order cannot be done). If the result is ok this field is set to "F" (final results).

6.2.6 Message Terminator Record

This is the last record in the message. This record indicates the end of a message containing information encoded as Query Records, Patient Records, and/or Result Records.

Example:

L|1|N

The Message Terminator Record starts with an L in the first field. The second field is a sequence number. For the Message Terminator Record the sequence number should always be 1.

The final field in the Message Terminator Record is the "Termination Code" This field provides an explanation for the end of the message. The possible values are:

Termination Code	Description
N	Normal termination
T	Sender aborted
R	Receiver requested abort
E	Unknown system error
Q	Error in last request for information
I	No information available from last query
F	Last request for information processed

6.3 LIS Query and Transmission Examples

The following sections provide examples of messages sent between a Storm system and an LIS for common communication scenarios.

6.3.1 Example 1: Query of Tests ordered for Sample IDs

Storm → LIS
H|\^&|||Storm^3.2.3.0|||||||P|LIS2–A2|20101022162157

    Q|1|^S001^||ALL|||||||||O

    Q|2|^S002^||ALL|||||||||O

    Q|3|^S004^||ALL|||||||||O

L|1|N

6.3.2 Example 2: Response of Tests ordered for Sample IDs

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LIS → Storm

```
H|\^&||||LIS||||||||P|LIS2-A2|20101022162157

    P|1|1211|2322|*****

        O|1|S001||^^^CMVG|R

    P|2|3433|4544|*****

        O|1|S002||^^^CMVG|R

        O|2|S002||^^^HPLG|R

    P|3|5655|6766|*****

        O|1|S004||^^^HSVG|R

L|1|N
```

*NOTE: The "*****" in the Patient Records above indicate fields fo the Patient Record that the LIS may provide but the Storm system does not use. Storm will ignore these fields.*

6.3.3 Example 3: Transmission of results

Storm → LIS

```
H|\^&|||Storm^3.2.3.0|||||||||P|LIS2-A2|20101022162157

    P|1||2322

        O|1|S001||^^^CMVG|R

            R|1|^^^CMVG|1.33|ng/ml|||||F

    P|2||4544

        O|1|S002|^^^CMVG|R

            R|1|^^^G|2.45|ng/ml|||||F

        O|2|S002|^^^HPLG|R

            R|1|^^^HPLG|1.24^low|ng/ml|||||F

    P|3||6766

        O|1|S004|HSVG|R

            R|1|^^^HSVG^ST1|4.89|ng/ml|||||F

            R|2|^^^HSVG^ST2|3.52|ng/ml|||||F

    L|1|N
```

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7 Running a Worklist

To run a Worklist on the instrument, follow the steps below.

1. Verify that the Storm system is correctly installed and setup in the desired configuration as described in **4.1.1 SINGLE INSTRUMENT CONFIGURATION** and **4.1.2 MULTIPLE INSTRUMENT/CENTRAL SERVER CONFIGURATION**.

2. Verify that all physical cords and cables of the Storm system are securely connected. If an LIS is used, make sure all physical cords and cables related to the LIS are securely connected.

3. Verify that Test Files for all Tests to be run have been added to the Storm system using the Storm System Configuration Tool as described in **4.3.2.3.2 TEST FILES>ADD TEST FILES**. If an LIS is used, make sure the Test Files have associations to the LIS Test IDs as described in **4.3.2.6 LIS ASSOCIATIONS**.

4. Launch the Storm Instrument Manager connected to one of the instruments in the Storm system and allow the instrument to initialize and home. Be sure to perform any maintenance tasks as prompted.

5. Navigate to the **Worklist** screen and add Samples to the Worklist using any of the Sample addition methods described in **4.4.2.2.6 WORKLIST>ADD SAMPLES**.

6. Add Tests to the Worklist and assign them to the Samples.

   a. If not using an LIS, add Tests to the Worklist and assign them to Samples manually as described in **4.4.2.2.9 WORKLIST>ADD TEST**.

   b. If using an LIS, add Tests to the Worklist and assign them to Samples by clicking the Query LIS button as described in **4.4.2.2.11 WORKLIST>QUERY LIS**.

7. Prepare all materials for the Tests to be performed as part of the Worklist run. It is essential that all package insert instructions for reagent handling and storage are carefully followed for all assay kits run on the instrument. Reagent and sample preparation must be performed according to instructions from technical service, specific to each kit. Prior to the use of reagents, calibrators, controls, or samples, also visually verify that there are no bubbles in the bottles or vials. Air bubbles must be removed (a clean transfer pipette or toothpick can be used) before placing vials on the instrument.

8. Navigate to the **Racks** screen and verify the layout of the Samples and Reagents. Place the Reagent and Control bottles on the instrument as indicated on the **Racks** screen.

9. Navigate to the **Microtiter Plates** screen and verify the layout of the MTP plates.

1. Navigate to the **Home** screen and start the Worklist run by clicking/tapping the **Start** button. If the Worklist Loading Wizard is enabled as described in **4.4.2.10.3 SETTINGS>WORKLIST**, then follow the prompts of the Worklist Loading Wizard to ensure the Worklist if properly setup before the run starts.

   If any of the Tests to be performed during the Worklist run are Strips Tests (mono-test format assays, i.e. GSD

EZStrips), the Storm System will prompt the user with the Strips Loading Wizard to scan and load the stips into the MTP Carrier. The Strip Loading Wizard may be skipped using the Skip Wizard button.

10. Allow the Worklist run to complete. Worklist actions can be monitored throughout the run in the **Status** section of the **Home** screen. The **Status** section provides a text description of the current Worklist action, a timing diagram to visually indicate the progress of the run, and a live camera feed showing the instrument in action.

    NOTE: It is important to keep the cover closed for the entire duration of the Worklist run, especially when running Workists which include Chemiluminesence tests. The luminescence reader is very sensitive to stray light.

    *NOTE: If necessary, use the **Pause** button to temporarily pause a Worklist run, or the **Stop** button to completely abort a Worklist run (instrument movement will stop and door will unlock).*

11. At the completion of a Worklist run the Storm Instrument Manager will notify the user with a prompt that the run has completed. The user can click/tap the **OK** to dismiss the prompt and stop the audio alarm (if end of run sound is enabled). The user can also navigate to the **Evaluation** screen to review the Worklist run results. If using and LIS, the results can also be sent to the LIS from the Evaluation screen by clicking/tapping the **Send to LIS** button.

12. The user should remove all Test kit components (Microtiter Plates, Reagents, Controls) and Samples from the instrument. Ensure that all instrument surfaces are clean and dry, and close the cover.

13. The user can evaluate results by navigating the **Evaluation** screen to review and/or send the results to an LIS.

8 Troubleshooting Guide

Issue	Details	User Action
Storm Instrument Manager software will not start up	Is "No Connection to Server" message displayed?	Check that instrument computer is connected to server computer and both are on. Check that power switch on the instrument is turned on and power cord is plugged into instrument and outlet. Check that USB cable from instrument to computer is secure at both ends. Try rebooting. If problem persists, contact technical service.
Run will not start	Does instrument display an MTP loading warning message?	Check that MTP (s) and predilution plate is/are correctly loaded and seated securely.
		Check that sufficient strips/wells are placed.
		Check positions of probe during probe alignment. If misaligned, realign probe and restart.
	Does instrument display a clog error?	Prime 10x, lift probe briefly (1-2sec) to check for steady dispense flow. If dispensing appears correct, restart run. If not, carefully use stylet to clean probe.
		Check if blue liquid detection light is functioning properly by placing a small tube of liquid beneath the needles. Blue light should go on when in liquid and turn off when out of liquid. If light is not responding correctly, check for secure connections at the white connector above the probe and at flat cable connection points near the probe. If problem still persists, contact technical service.
		Check aspiration and dispense during priming. Replace waste tubing if needed (as indicated for monthly maintenance- older models only).
	Is the blue light constantly on?	Remove probe, clean with alcohol, dry it off from top to bottom, allow to sit for several hours. Carefully replace and check all tubing and electrical connections to the probe.
Sample(s) not pipetted during run	Are the samples also missing from the Microtiter Plates screen?	If missing samples are not selected on the Worklist screen, select them and rerun. If missing samples do not appear on the Worklist or Racks screens, re-add them to Worklist and reselect them.
Run stops in the middle of a Worklist	Is there an IO or read/write error message displayed?	Power off computer and instrument, unplug/replug power and USB connections, and restart. Load Worklist and special start from aborted position. If problem persists, contact technical service.
	Is the machine jammed during the read step?	Turn off machine, carefully remove plate and move reader back, load Worklist, place plate back in, special start Worklist from the read step.
	Is the probe assembly jammed?	Make sure there are no obstructions to probe movement. Make sure probe tubing is zip-tied to flat cable and not being caught anywhere.

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Issue	Details	User Action
	Is there a drop between needles error?	Pause the Worklist, wipe off any visible drops or clots, clean with an alcohol wipe. Resume Worklist. When Worklist finishes, carefully clean the probe with the stylet and perform Liquinox decontamination.
Failed Run	Were cold reagents or wash used?	Make sure to allow all reagents to come to room temperature before start of Worklist and rerun.
	Were reagents from different lot numbers used on the same run?	Rerun with reagents all coming from the same kit lot.
	Was there a pause during the run due to insufficient reagent volume?	Be sure reagent loading wizard is enabled. Use appropriate volumes and split bottles if necessary. Rerun Worklist.
	Did user forget to prime instrument before the start of the Worklist?	Prime instrument 10 cycles per line used with wash buffer and rerun Worklist.
	Are controls significantly out of range?	Check that correct ranges are entered for the kit lot being run. If using site-specific ranges, ensure that these are entered. Use Change Test Properties button on Evaluation screen and view updated report.
	Are controls just barely out of range?	Special start Worklist to reread MTPs, and generate another report. If controls still fail, contact technical service.
		If controls and calibrators were not vortexed or mixed before run, gently mix them and rerun Worklist.
	Do points on curve appear out of order on report? Do high and low controls appear switched?	Check if physical positioning of calibrators and controls in sample rack matches Racks screen. If not, contact technical service to produce a manual report.
	If test is in duplicate: Do calibrator/control replicates show large differences?	Contact technical service to produce a manual report, omitting the outlier control/calibrator replicate(s) or use the Drop Replicas option on the Evaluation screen.
	Does it appear that only a single calibrator or control is missing?	Check for sufficient volume and bubbles in reagents/calibrators/controls. Rerun with sufficient volume, bubbles removed. *NOTE: Even if no bubbles are observed at the end of the run, a bubble could have caused the problem and later popped.*
	Do all OD values on report appear elevated?	Check position of red light during reader auto alignment. If misaligned, realign reader and reread plate.

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Issue	Details	User Action
		Check if kit has been open too long or if it is expired; check physical reagent positions to see if any are switched. If yes, rerun with new, correctly placed reagents.
		Check aspiration and dispense during priming. Replace waste tubing if applicable (as indicated for monthly maintenance- older models only).
	Do all OD values on report appear low?	Check if kit has been open too long or if it is expired; check physical reagent positions to see if any are switched. Rerun with new, correctly placed reagents.
	Is recorded room temperature on report outside acceptable range?	Rerun Worklist once laboratory temperature is within an acceptable range according to kit package insert.
	Do several calibrators/controls appear to be off?	Check for bubbles in reagents/calibrators/controls. If bubbles are observed, remove them and rerun.
		Check for bubbles in supply line and microsyringe. Prime instrument until bubbles disappear and rerun. If bubbles continue, check tubing for any visible leaks. Contact technical service if problem persists.
		Check pinch valves to ensure that tubing is fully inserted.
Flooded Run	Is the flooding inside the wells (wells overflowing)?	Check aspiration and dispense during priming. Replace waste tubing if applicable (as indicated for monthly maintenance-older models only).
	Is the flooding outside the wells on the MTP carrier?	Check positions of probe during probe alignment. If misaligned, realign probe and rerun Worklist.
		Perform a manual shake to check if shaker homes properly at the end of the shake. Repeat manual shake several times to confirm.
		Check if there is a visible clog on the probe. Even if no visible clog is seen, carefully remove probe and use stylet to clean both probe needles.
		Check that MTPs are correctly loaded and seated securely.
		Check that the correct number of wells are loaded in the MTP using the Microtiter Plates screen.
Need to reprint or find past data	Does user know in which Worklist the desired data was run?	Select Worklist on Evaluation screen and print or export Worklist reports as desired. If data is from very old Worklist, it may be necessary to first adjust Evaluation setting on Server screen of **Storm Instrument Manager** Settings.

Issue	Details	User Action
Dripping Probe Needles	Is the dripping coming from the dispense needle?	While priming the instrument, follow tubing at the top of the probe and check for any droplets. Remove the left side panel, prime again, and check for any droplets in visible tubing. Check pinch valves to ensure that tubing is fully inserted.
	Is the dripping coming from the aspiration needle?	Check aspiration and dispense during priming. Also remove left side panel and check for any droplets on the tubing. Replace waste tubing if applicable (as indicated for monthly maintenance- older models only).
	Is the dripping/fluid observed after the needles have been sitting for several hours?	Droplets and small amounts of fluid after sitting overnight or following homing are normal. Prime instrument for several cycles and proceed as usual.
Strips do not fit securely in MTP frame	Are different strip types being placed into the same plate frame?	Contact technical service
Common reagents are not being shared between tests	Has the user checked that the reagents to be shared are exactly the same?	Contact technical service
Cannot enter new lot-specific information	Is the information necessary for calculations or validation rules?	Contact technical service
LIS connectivity problems	Are all LIS and LIS Association settings correct in Storm Configuration Tool?	Contact IT.
Resistance (red) or Liquid detection (blue) lights do not illuminate properly.	Is instrument malfunctioning?	Remove probe and clean and dry thoroughly. Check that probe wires are connected to PCB and that flex cable connections are secure. Replace Z axis flex cable, if available and training has been provided. If problem persists, contact technical service.
X,Y, or Z-axis movements are not smooth	Is instrument malfunctioning?	Contact technical service

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9 Symbols Glossary

Symbol	Title	Explanation	Reference	Reference number
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
EC REP	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	ISO 15223-1	5.1.2
REF	Catalogue number	Indicates the manufacturer's catalogue number so that a specific medical device can be identified	ISO 15223-1	5.1.6
SN	Serial number	Indicates the manufacturer's serial number so that the medical device can be identified	ISO 15223-1	5.1.7
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1	5.1.8
IVD	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device	ISO 15223-1	5.5.1
CE	CE marking of conformity	Indicates CE marking of conformity	Regulation (EU) 2017/746, Annex V	-
	Symbol for marking of EEE (electrical and electronic equipment)	Indicates separate collection for EEE	Directive 2012/19/EU, Annex IX	-

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10 Device Manufacturer

	Company Name:	Gold Standard Diagnostics Corp.
	Company Address:	2795 2nd St Ste 300 Davis, CA 95618
	Country:	United States
	Phone:	530-759-8000
	Fax:	530-759-8012
	Website:	www.gsdx.us
	Bolt:®	Catalog # 00500; 00500-CL

11 Revision History

Revision	Date	Change
A	2023-12-18	New document for Storm 3.2