

GOLD STANDARDSM D I A G N O S T I C S

Storm User's Manual for the Bolt[®]



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1. Introduction

The purpose of this manual is to identify the instrument components and provide instructions for use of the Bolt Instrument. 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 Bolt is designed to automate the processing of enzyme immunoassay (EIA) and Chemiluminescent Immunoassay (CLIA) tests. The system is only intended to be used by properly trained personnel.

The intended use for the Bolt 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 Bolt is also intended to perform as an 'accessory' to be used with a device to enable that device to be used in accordance with its intended purpose.

1.2. Certifications

The Bolt is registered and certified as having met the following regulatory requirements: 13485:2003
EN ISO 13485:2012

Directive EN 98/79/EC

EN 61010-1:2010

EN 61010-2-081:2002 + A1:2003

CMDR SOR/98-282

21 CFR

2. Safety Information

The following safety instructions are to be observed at all times during the operation of the Bolt. It is strongly recommended that all first time personnel read this manual prior to working with the instrument and receive training from Gold Standard Diagnostics (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 the instrument functions safely, both electrically and mechanically under normal use conditions. The Bolt is supplied in a condition that allows for safe and reliable operation.

2.1. General Safety

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

2.2. Electrical Safety

The Bolt must be operated using a power source with an operating voltage compatible with the requirements stated on the device label. The Bolt 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 Bolt to the main power supply.

The use of a multi plug is not allowed and it is recommended that the instrument be run from a dedicated socket connected to an uninterruptible power supply or surge protector. Use only extension cables with a protective conductor and grounded contact. The Bolt 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 Bolt is completed by a trained technician to ensure a minimized exposure of the operator to mechanical risks. Improper handling of the Bolt 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. Openings provided for ventilation are not meant as access points into the system.

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.

2.4. Biological Safety

Any parts of the Bolt 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 instrument. For devices used in conjunction with the Bolt, 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 is labeled with universal general warning labels to identify risks which may be encountered by the operator.

3. System Description

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 that is specifically designed for the system.

Note: Due to the modular nature of the Bolt, some features/components may not be available on all instrument models.

3.1. System

The Bolt system consists of a robotic platform that performs programmed EIA and CLIA tests and a Laptop PC with software that enables automated running of assay steps, worklist generation, data management, and data reduction.

The system components are as follows:

- 1 System Cover
- 2 Reagent Rack
- 3 Sample Rack
- 4 Microtiter Plate Carrier
- 5 Probe Assembly



3.2. System Details

It is recommended that the area for use and storage of the Bolt be a space dedicated to the instrument 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.

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).

Instrument Dimensions and Weight

Width: 48.3 cm (19 in)

Depth: 53.3 cm (21 in)

Height: 55.8 cm (22 in)

Weight: 27 kg (60 lb.)

The total bench space recommended to accommodate the Bolt and related equipment is 127 cm (50 in.) wide x 88.9 cm (35 in.) high x 60cm (23.6 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. Component Details

Note: Certain instrument models may not contain all of these components.

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. Custom racks are also available. 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.

Reagent Rack

The reagent rack contains 9 reagent positions and accepts 22 to 35mm diameter bottles (reagent adapters are required). Custom reagent adapters are also available.

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).

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 1ul and 300ul. The high-precision micro-syringe aspirates 1ul with less than 3% CV across a 96-well plate (as part of 1:100 dilution). Liquid detection is performed via conductivity, with a minimum detection volume of 50ul.

Incubator

The incubator heats to a maximum of 45°C.

Reader

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

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

Instruments equipped with the chemiluminescence option also contain a chemiluminescence reader and can handle both EIA and CLIA assays.

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)

Shaker

The integrated linear shaker features a no-spill design. The Bolt can incubate while the shaker is in motion.

Amplitude: 0.6 mm

Adjustable speed: up to 900 RPMs

Capacity: 2 MTP (1 reaction, 1 predilution)

Voltage: 5 V DC

Computer

The 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:

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

Processor: Intel Celeron 1.6 GHz

Memory (RAM): 4 GB (32-bit) or 8 GB (64-bit)

Memory (Hard Disk): 120 GB

Ports: USB 2.0 (RS232, Ethernet ports optional)

Display: DirectX 11 graphics device with WDDM 1.2 driver, 1366x768 resolution

Operating System: Windows 8 (Windows 10 recommended)

.NET Framework: .NET 4.5

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 specifications, depending on the number of instruments connected to the server:

# of Instruments	Processor	Memory (RAM)	Memory (Hard Disk)	Ports	Display	Operating System	.NET Framework
1	Intel Celeron 1.6 GHz	4.00 GB	120GB	USB 2.0 (RS232, Ethernet ports optional)	DirectX 11 graphics device with WDDM 1.2 driver, 1366x768 resolution	Win 8 (Win 10 recommended)	.NET 4.5
5	Intel i3 2.0 GHz	8.00 GB	240GB				
10	Intel i5 2.5 GHz	8.00 GB	500GB				

Software

The pre-installed Storm System Software 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 results, and integrates with any LIS that supports the NCCLS LIS1-A and LIS2-A specifications.

The Storm System Software 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 System Software is described in detail in the following sections of this manual.

4. Storm System Software

The Storm System Software 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 Storm System; 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.

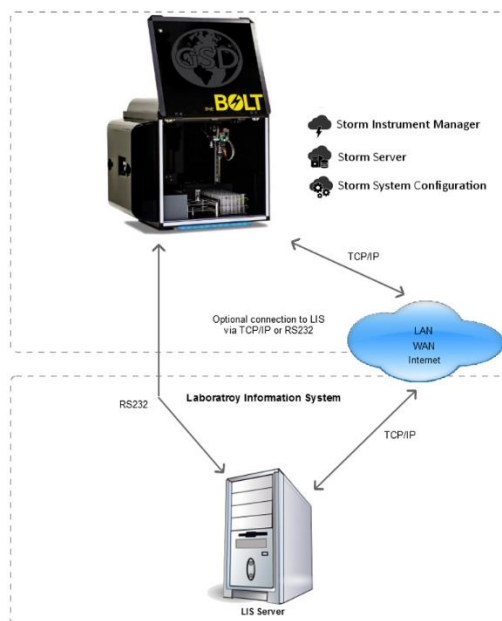
All software components are pre-installed on the computer included with the instrument. Note: Gold Standard Diagnostics periodically provides software updates to distributors and customers. This manual describes the current version of software. Contact the local instrument distributor with any further questions about software versions or software update instructions.

4.1. Storm System Configuration Options

There are two ways in which the Storm System Software can be configured:

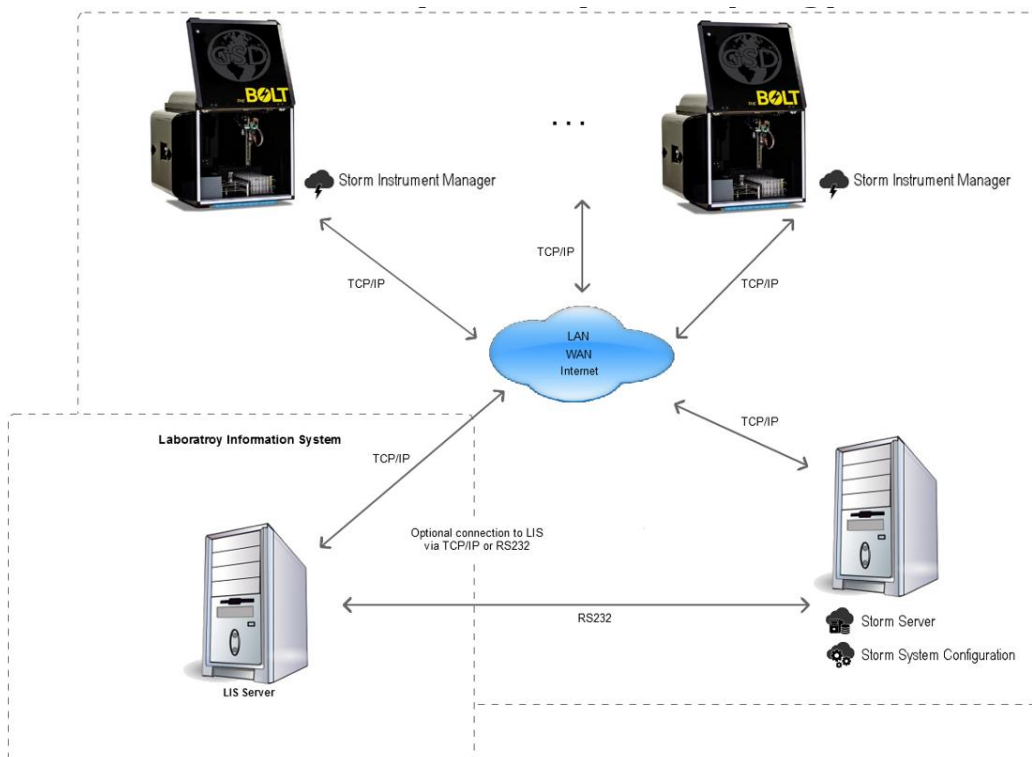
1. Single Instrument Configuration (default):

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 System Software are installed and run on a single instrument computer, as shown in the following diagram:



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.

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 and Storm Configuration Tool Components

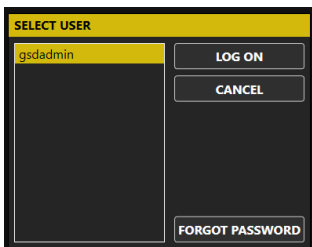
The Storm Server is a Windows Service that runs in the background of the computer on which it is installed. The Storm Server service stores configuration data for the Storm System and processes requests from Storm Instrument Manager instance(s) to store and retrieve data generated from Worklist runs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

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. The Storm System Configuration Tool can be utilized as follows:

Storm System Configuration Tool Access

To launch the Storm System Configuration Tool, double click/tap the associated icon on the desktop. 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 to the Storm System. Only users with Administrator accounts are allowed to configure the Storm System. Select

desired user account (only users with Administrator accounts appear in list), enter the password on the login screen as prompted, and click/tap OK:



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.

The Storm System Configuration Tool will then open:



Storm System Configuration Tool Settings

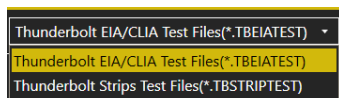
The settings selected in the Storm Configuration Tool, as described below, apply to all Storm Instrument Manager instances that are connected to the Storm Server in which these settings are stored. The following tabs are available in the Storm Configuration Tool software:

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.
 - a. To add a user: Click/tap Add User. Enter User Name and Password, and Email Address (optional) as indicated. Activate the user by selecting the Active User option. Allow administrator rights for the user (if desired) by selecting the Administrator option. Otherwise, select the Operator option. Click/tap OK to save changes.
 - b. To 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.
 - i. User accounts cannot be deleted, but can be deactivated by deselecting the Active User option in the Edit User window. Deactivated users will not be listed on login screens for the Storm software applications.
 - c. User Account Types: There are two types of user accounts: Operator accounts and Administrator accounts.
 - i. Operator accounts are intended for the normal users of the Storm Instrument Manager and its associated instrument(s). They can perform instrument maintenance and create Worklists and run them on the instrument(s).
 - ii. Administrator accounts are intended for users with extra privileges. Users with Administrator accounts can perform all tasks that users with Operator accounts can perform, as well as other tasks which users with normal Operator accounts cannot perform. Only Administrator users can log in to/change settings in the Storm System Configuration Tool and access the Settings screen in the Storm Instrument Manager. Other tasks reserved for Administrator users include: marking worklists as reviewed, modifying worklist reports, and sending results to the LIS. At least one Administrator account must always be active.
2. **Tests:** The selected test files 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

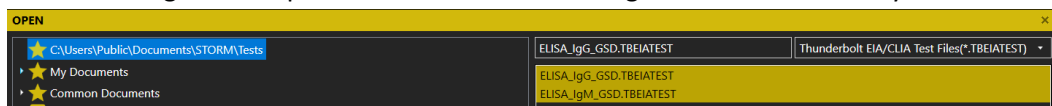
of the reagents, layout, action steps, and calculations for a given assay kit. Test files can be added to and removed from the Storm System, and organized into folders (nodes).

- a. To add Nodes: To add a grouping or node of tests, click the Add Node button. Enter the desired node name as prompted and click OK. Multiple nodes can be added to organize/group tests.
- b. To add Tests: To add test(s) to the Storm system, first, copy/paste any test files which will be added into a folder that is accessible by the computer running the Storm Server and Storm Configuration Tool. The suggested/default file location is C:\Users\Public\Documents\Storm\Tests.

To add tests to the main Root folder or to a previously defined node, select the desired location, and click/tap the Add Tests button. Select test file type:



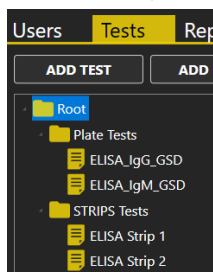
Then select desired test file(s) using the navigation panel on the left and highlighting the files on the right. Multiple files can be selected using the CTRL or SHIFT keys:



After selecting desired file(s), click/tap the Open button.

The Refresh button can be used to refresh the selected file location and the Cancel button can be used to cancel test addition.

Once added, nodes and tests will appear on the Tests tab:



- c. To Remove Nodes/Tests: To remove nodes or tests, highlight the test(s) or node(s) to be removed and click the Remove Test or Remove Node button, as appropriate.
3. **Reports:** Customize worklist report and test report information on this tab, as desired. First, copy/paste any custom templates/logos into a folder that is accessible by the computer running the Server and Configuration Tool. Use the "..." buttons to select custom template(s)/logo and use the red X buttons to restore default settings. Default report templates and GSD logo will be used on worklist reports if no changes are made.
 - a. To Customize Worklist Report: 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:

Users Tests **Reports** LIS LIS Mappings Backup/Restore Archive/Purge

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

Laboratory Address: 123 ABC Street
City, State
Zip Code

Laboratory Logo: lab logo.PNG ... X

LAB
LOGO
HERE

IMPORT

EXPORT

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.

- b. **To Customize 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	Files\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMSTRIPTESTREPORT ... X
ELISA Strip 2	Files\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMSTRIPTESTREPORT ... X
ELISA_IgG_GSD	n Files\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMEIAESTESTREPORT ... X
ELISA_IgM_GSD	n Files\Gold Standard Diagnostics\Storm Suite\DefaultReports\Default.STORMEIAESTESTREPORT ... X

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

4. **LIS:** Check to enable Laboratory Information System (LIS) communication, if system is connected to an LIS. Check to enable LIS logging, if desired, and select desired log level. Select which LIS connection type will be used (RS-232 or TCP/IP) and set port/server settings as applicable:

Users Tests Reports **LIS** LIS Mappings Backup/Restore Archive/Purge

☒ Enable LIS ☐ Enable LIS Logging Log Level: Include LIS Info

☐ Use RS-232 Connection

PORT SELECTION

☒ Use Instrument Serial Port

☐ Use Computer Serial Port

SETTINGS

Baud Rate: 9600 Parity: None

Data Bits: 8 Stop Bits: 1

☒ Use TCP/IP Connection

Server Address: 127 0 0 1

Server Port: 8888 + -

☐ Use LIS01-A2 Encoding

DISCARD CHANGES SAVE LIS CONFIGURATION

Be sure that all settings match those of the LIS system being connected. Click/tap Save LIS Configuration to save changes or Discard Changes to remove changes. This tab must be completed before LIS communication can be attempted from within the Storm Instrument Manager.

5. **LIS Mappings:** Map each test name to the LIS Name and click/tap Save LIS Mappings to save changes or Discard Changes to remove changes.

Users Tests Reports LIS LIS Mappings Backup/Restore Archive/Purge	
Test Name	LIS Name
ELISA Strip 1	ST1
ELISA Strip 2	ST2
ELISA_IgG_GSD	IGG
ELISA_IgM_GSD	IGM

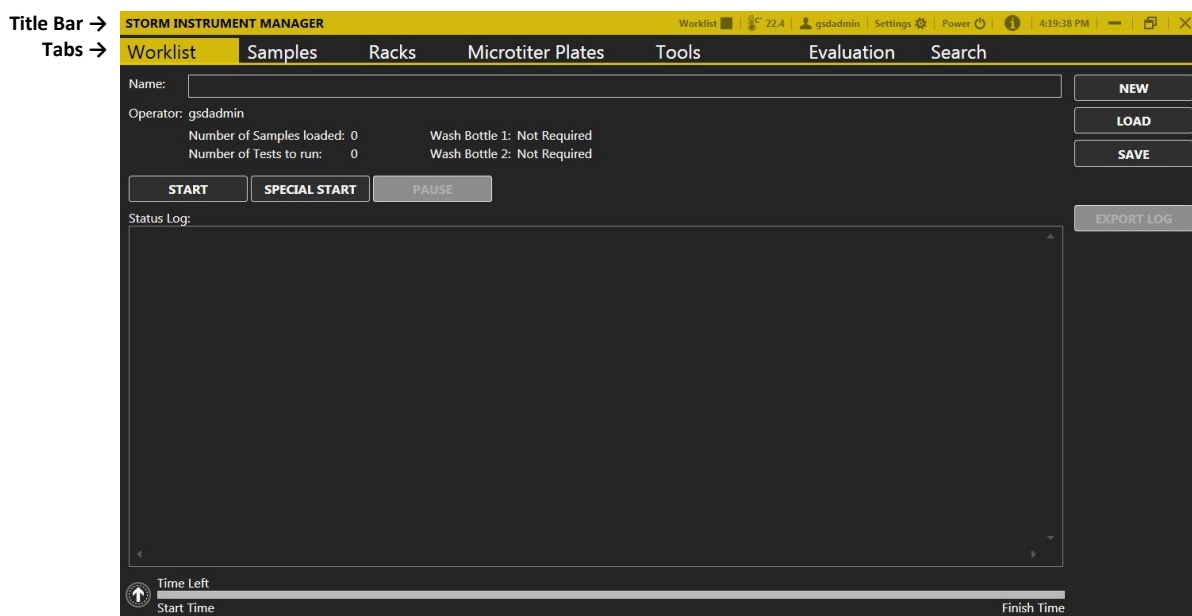
An LIS name is seldom the real test name, but often a shorter one. It could also be a number or code, depending on the laboratory policy. Be sure to enter LIS Names (often referred to as test codes) exactly according to the laboratory's LIS configuration.

6. **Backup/Restore:** Select the Backup or Restore button to backup or restore server database (with all worklist report information/results) as desired or as required by the laboratory.
7. **Archive/Purge:** Archive, unarchive, and purge data as required by computer storage capacity or laboratory regulations.
 - a. To Archive/Unarchive: Select desired date from before which to archive worklist data from the database. If desired, select date after which to unarchive previously archived data. Only worklists which are not archived are available for viewing on the Evaluation and Search tabs of the connected Storm Instrument Manager(s).
 - b. To Purge: Select desired date from before which to purge worklist data from the database. Once worklist data has been purged, it cannot be recovered.

Close the Configuration window using the X in the top right corner. If necessary, the Storm Server will automatically be restarted to apply the changes specified in the Storm Configuration Tool settings.

4.3. Storm Instrument Manager

The Storm Instrument Manager enables the running of test files that are installed on the Storm system. The instrument must be attached to a computer on which the Storm Instrument Manager is installed in order to be operational. The interface for the Storm Instrument Manager is designed with a title bar and tabs:



Storm Instrument Manager Modes

The Storm Instrument Manager can be run in two modes:

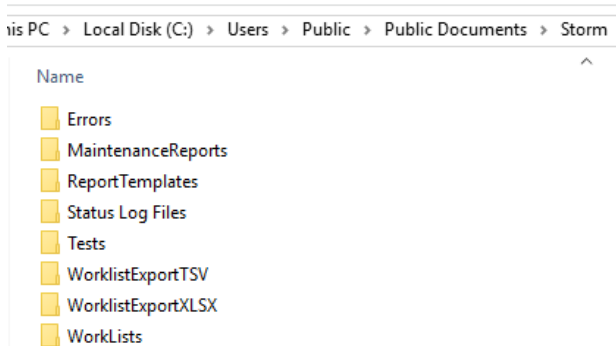
1. **Full Functionality Mode:** This mode enables the running of Worklists and evaluation of test results. In this mode, the instrument is powered on when the software is started (all tabs shown above are available).

2. **Evaluation Only Mode:** This mode allows for data evaluation without Worklist running functionality. The instrument is not powered on when the software is run in this mode (Only Evaluation and Search tabs are available).

Note: If using the Multiple Instrument/Central Server Configuration, contact the instrument distributor for additional instructions for installation of the Storm Instrument Manager on the central server computer to be used in Evaluation Only mode.

Storm Document Folder

All relevant data related to the Storm Instrument Manager is located in the Storm documents folder:
C:\Users\Public\Documents\Storm



These folders and files can be accessed at any time, including when software applications are in use.

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

PC > Local Disk (C:) > Users > Public > Public Documents > Storm > Errors

Name	Date modified	Type	Size
StormInstrumentManagerError_2016-12-20T12.49.45	12/20/2016 12:49 ...	Text Document	3 KB

2. **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 here:

Storm Software-Recorded Maintenance Action Log

Instrument Serial Number: 12456

Month: December

Year: 2016

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										
Empty waste bottle																					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											12/19/2016 gsdadmin																				
Clean outside of probe with alcohol wipe											12/19/2016 gsdadmin																				
Perform Instrument Alignment																															
Perform Reader Alignment																															
Do 20 primes with 1% Liqueonox and 50 primes with DI water																															
Clean wash bottles											12/19/2016 gsdadmin																				
Monthly Maintenance	Date/Initials:																														

3. **Report Templates:** Any custom worklist or test report templates (if applicable) should be stored in the Report Templates subfolder.
4. **Status Log Files:** The status (worklist action) logs from each worklist 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:

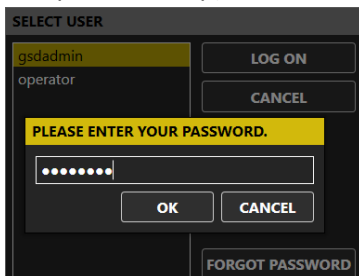
is PC > Local Disk (C:) > Users > Public > Public Documents > Storm > Status Log Files > 2016_12

Name	Date modified	Type	Size
2016_12_20_12_49_33_Completed	12/20/2016 12:49 ...	Text Document	5 KB
new run_2016_12_20_12_59_15_Stopped	12/20/2016 12:59 ...	Text Document	1 KB

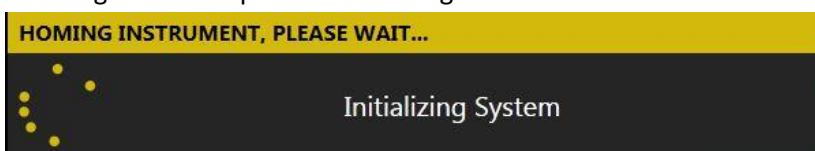
5. **Tests:** Test files should be stored in the Tests subfolder. Note: Test files must be added using the Tests tab in the Storm Configuration Tool before they will be available in the Storm Instrument Manager, even if they are stored in the Tests subfolder. When a test file is added to the Storm Server 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.
6. **Worklist Export TSV/XLSX:** Worklist reports exported from the Evaluation tab 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.
7. **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 tab.

Storm Instrument Manager Initialization

1. Verify that computer with installed Storm Instrument Manager is attached to the instrument, system is connected to a computer with Storm Server and Storm Configuration Tool, power is connected to instrument and to computer(s), and instrument power button is in the on position. Turn on attached computer and double click/tap the Storm Instrument Manager (Full Functionality Mode) icon (if Storm Instrument Manager does not initialize automatically at computer startup) to initialize the system. Login screen will appear:



2. Select a user (only active users are displayed for selection), click/tap Log On, enter password, and click/tap OK.
Note: If a user with an Operator account forgets his/her password, a user with an Administrator account can reset the password using the Storm System Configuration Tool. If an Administrator user forgets his/her password, a new password may be set using the Forgot Password button and following the subsequent instructions.
3. After login is complete, the instrument requires approximately 30 seconds to automatically move to its starting, or “home” position. The instrument must always be allowed to complete this “homings” uninterrupted before being used:



After homing, the Storm Instrument Manager opens.

Note: Whenever the Storm Instrument Manager opens, user is prompted to perform daily startup maintenance, as well as weekly maintenance (if due). User must address each maintenance prompt before continuing.

Storm Instrument Manager Title Bar

The following are displayed/accessible in the Storm Instrument Manager Title Bar:

1. **Worklist State Icon:** Indicates whether instrument is currently running a worklist or if the instrument is idle/stopped.
2. **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.
3. **Current User:** Displays the user ID of the logged in user. Logged in user can be changed by selecting this icon and selecting Switch User. Password of the current user can also be changed by selecting the Change Password option here and entering old and new passwords as indicated.
4. **Settings:** Used to select various software options, described in detail below.
5. **Power:** Used to close the software and shut down the instrument/computer. (Daily shutdown maintenance will be prompted).
6. **Application Version Information:** Displays the version of the software/license information.
7. **User's Manual:** Displays a PDF of the instrument User's manual.
8. **Current Computer Time:** Displays the current time as set by the attached computer.
9. **Minimize/Maximize:** Used to minimize/maximize the Storm Instrument Manager main window.
10. **Close:** Used to close the software without shutting down the instrument/computer. (Daily shutdown maintenance will be prompted).

*Note: Label/information about each icon is shown when hovering over each one.

Storm Instrument Manager Settings

Clicking/tapping the Settings icon on the Title Bar brings up the Settings window, used to adjust various settings for running the Storm Instrument Manager (these settings can only be adjusted by users with Administrator accounts):

1. **Instrument Information:** Displays instrument and reader details, including serial number and runtime.
2. **Samples:** Aspiration Failure options allow user to decide what actions will be taken by the instrument when insufficient sample volume is detected. User can choose to automatically continue with the next sample or ask the operator for every low-volume sample.
Incubation setting allows implementation of an optional warning if the incubator is out of range of the programmed temperature during a Worklist run (if incubator is used in the Worklist).
3. **Worklist:** Allows user to select whether or not tests with different timing schemes should be allowed to run together. If tests with different timing schemes are allowed, user must select whether the shortest or longest tests should be run first in the Worklist.
4. **Strips:** For monotest/strips assays, user can select the number of foil puncture retries, as well as whether to automatically continue with the next sample or ask the operator for each strip when the foil cannot be punctured. User can also choose to auto-skip strips after timeout/set number of seconds.

5. **Racks:** Allows the user to enable the Reagent Loading Wizard, (a window which prompts the user to check the volume of each reagent before starting a Worklist- it is recommended to always enable this wizard), enable bottle volume check at the start of the Worklist, and set reagent rack's and sample rack's size/definition. Use the "x" to set default settings, or the "..." to select a different rack definition.
 6. **Server:** Allows the user to set the server location as the local computer or a remote computer and set IP Address. User also selects the number of days, from the current date, to include in the Worklist history display on the Evaluation tab (This does not delete Worklists from the database).
 7. **Colors:** User can select desired color theme and accent color for the user interface.
 8. **Sounds:** Allows user to decide which alarms/sounds are enabled and to select which sounds are used. Additional custom alarm sounds (as .WAV files) may be added to the computer for selection here. Use the "x" to set default settings, or the "..." to select different sounds.
 9. **Languages:** User can select the display language for the Storm Instrument Manager here. A language pack (provided separately from the software) is needed in order to select languages other than English.
 10. **Touch Screen:** Allows the user to turn on/off the on screen keyboard for use with touch screens.
 11. **Plugins:** Auto Export Plugins for specific instrument users/distributors are available for selection here. Output path can also be selected. These are only applicable for specific applications.
- Click/tap OK to save Settings changes or Cancel to discard.

Note: The Storm Instrument Manager must be restarted before some Settings selection changes are applied. The Storm Instrument Manager indicates when an applicable setting is changed that requires a software restart before taking effect.

4.4. Other Software Applications

Other related software applications are available from Gold Standard Diagnostics for protocol design and service purposes. These are provided to and can only be used by trained service technicians.

5. Running a Worklist

To run a Worklist on the instrument, initialize the Storm Instrument Manager in Full Functionality Mode as described above and follow the steps below.

5.1. Worklist Preparation

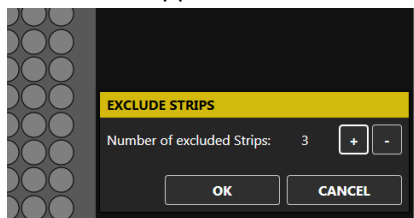
Standard Worklist Preparation:

1. **Perform Maintenance:** Prior to each instrument use, verify that the maintenance log is up to date. Perform daily startup maintenance as described in the Maintenance section of this manual (as prompted by the Storm Instrument Manager each time instrument is turned on/software is opened) if Worklist is the first run of the day/shift. If the instrument has been moved or probe-related maintenance has been performed, since the previous alignment, also perform instrument alignment prior to use.
If prompted by the software, perform weekly maintenance.
2. **Check Settings:** Be sure to adjust/view the Storm Instrument Manager Settings (described in previous section) as necessary prior to running the instrument.
3. **Prepare Kit:** 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

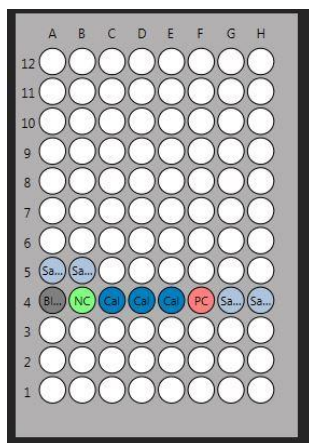
be performed according to instructions from technical service, specific to each kit. Prior to the use of reagents, calibrators, controls, or samples, also visually verify that there are no bubbles in the bottles or vials. Air bubbles must be removed (a clean transfer pipette or toothpick can be used) before placing vials on the instrument.

Additional Preparation Selections (Optional):

1. **Exclude Strips:** If test(s) to run should start from a position other than the default A1 on the MTP reaction or predilution plate, navigate to the Microtiter Plates tab and click/tap the Exclude Strips button below the desired plate(s). Use the + and – buttons to select the number of strips that should be skipped:



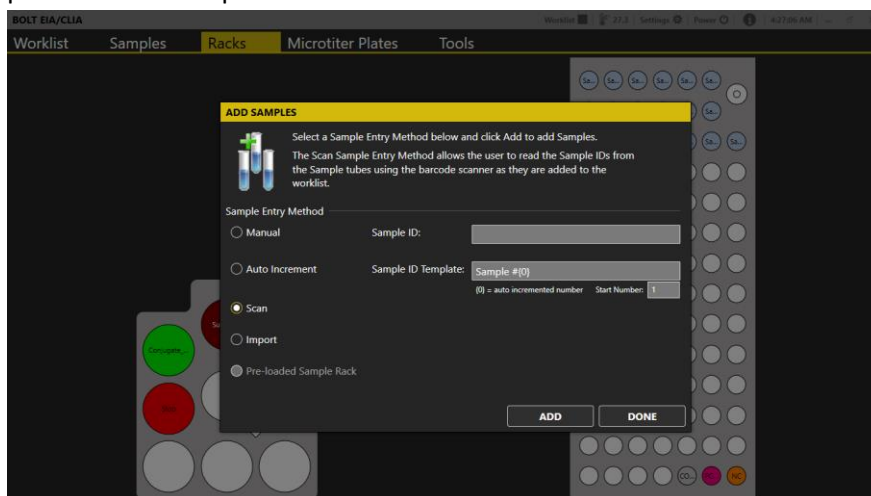
For example, if the first 3 columns of the plate should not be used, 3 strips should be excluded; reaction wells will be placed beginning in column 4 (after completing the necessary steps to run a Worklist on the other tabs as described in the following sections):



2. **Preload Sample Racks:** Prior to or during a worklist run, the user can preload racks with sample tubes (outside the instrument) to be used in future worklists. To preload racks:
 - a. On the Samples tab, click/tap Add Samples; select Preload Sample Rack.
 - b. In the Add Samples window that appears, specify the Sample Rack ID, Rack Description, and Tubes per Sample, then click/tap Add. Note: Rack ID must be in the format XXX-XXXX. The first digits indicate the rack size (101 for a 12mm rack, 102 for a 16mm rack, or 104 for a 13mm rack). The 4 digits after the dash are used to differentiate the racks (the unique number can range from 0000 to 9999).
 - c. Add samples to the rack using one or more of the Sample Entry Methods described in the following section. Click/tap Done when complete.
 - d. Repeat these steps for each preloaded rack. Racks are stored until removed.
 - e. To remove a rack from the stored list: Click/tap Add Samples, select Preload Sample Rack. Click the Remove Preloaded Racks button. Select the rack(s) to remove from the list (selection is highlighted) and click/tap Remove.

Navigate to the Samples Tab. This tab is used to select samples and tests for the Worklist. The following steps are taken to complete this tab:

1. **Add tests:** Select the desired test(s) from the Add Test drop down list. Test names will appear listed from left to right on the screen as they are added to the Worklist.
 - a. **Test Properties:** Click/tap on each test name to open the Test Properties window. Enter the lot number, expiration date, and appropriate runtime variables (including calibrator values and control ranges) as obtained from the assay kit (box labels, insert, and vials), as appropriate.
 - b. **Multiple Tests:** Multiple tests can be added if settings are compatible; only compatible tests will be available in the Add Tests drop down menu once the first test file has been chosen. 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 if user has enabled that option in the Storm Instrument Manager Settings.
 - c. **Test Files:** New test files can be added to the Add Test drop down menu by selecting the test files from the Tests tab of the Configuration Tool.
 - d. **Remove Test:** Any added test can be removed from the Worklist by selecting it in the Remove Test drop down list.
2. **Add samples:** Click/tap the Add Samples button. The Add Samples window will appear in the foreground, and the Racks view will appear in the background to allow for monitoring of sample placement as samples are loaded:



Use the radio buttons to select the Sample Entry Method. Follow the detailed on-screen instructions for placement of samples using each method.

Important Notes:

Tube Placement: Samples must be placed in the designated blinking positions in the sample rack. While placing samples, verify that samples are recognized by the software (spaces with loaded samples display yellow or blue; unoccupied spaces will remain white or grey). Samples are placed beginning in the back left corner of the rack, and moving from left to right across each row, filling the rack from back to front.

Note: Eppendorf or other conical-shaped tubes are not recommended for use in the instrument; only standard-diameter sample tubes are recommended for holding samples.

Sample IDs: 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; a suffix will be added to the sample ID if a sample with a duplicate ID is added.

Sample Entry Methods:

- a. **Manual:** Use for non-barcoded samples with custom IDs. Type the sample ID into designated field and click/tap Add (or press Enter on the netbook keyboard). Place the sample in the rack as prompted and repeat for all manually-labeled samples.
- b. **Auto Increment:** Use for Auto-numbered samples. Change the Sample ID Template and Start Number if desired and click/tap Add. Place samples in the sample rack, one by one as prompted. Samples will automatically be numbered consecutively, beginning with Sample #1 and continuing with Sample #2, #3, #4 etc. (according to ID Template and Start Number).
- c. **Scan:** Use for barcoded samples. Click/tap Add. Scan the barcoded sample tube using an attached handheld scanner. Place the sample in the rack as prompted and repeat for all barcoded samples.
- d. **Import:** Use to import sample lists from an Excel spreadsheet. Select the desired XLS or XLSX file as prompted.

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 positions locations prior to adding samples to the worklist.
- e. **Preloaded Sample Rack:** Use to add preloaded racks (prepared as described in Worklist Preparation). Click/tap Add. Select the desired rack from the Preloaded Sample Racks list and click/tap Add. Scan the rack as prompted (using an attached handheld scanner and place it inside the instrument (Scanned barcode must match the selected rack in order to add the rack to the Worklist).

When all samples have been added, click/tap Done to exit the Add Samples window. Display will return to the Samples tab, where all added samples are listed.

3. **Additional Sample Tab Options (optional):** Click/tap the sample ID to select sample(s) (selection is highlighted). Use the CTRL and SHIFT keys to highlight multiple samples.
 - a. **Remove Samples:** Click/tap this button to remove highlighted sample(s).
 - b. **Multiply Samples:** Click/tap this button to change the replicate of highlighted sample(s). Use the + and – buttons to adjust the indicated sample multiplication (Sample will be pipetted multiple times from the same sample tube.)
 - c. **Drag and Drop:** Samples will be pipetted in the order listed on the Samples tab. Drag and drop samples to adjust processing order as desired. (If using a touchscreen, touch and hold the Sample ID, then tap the Move button which appears and specify new sample position in the Move Sample window.)
4. **Query LIS (optional):** If LIS-prompted sample selection is desired and LIS connectivity has been correctly configured, click/tap the Query LIS button at this time. LIS will select appropriate samples for the chosen test(s) in the Worklist.
5. **Select Samples:** If LIS-prompted sample selection is not used, click/tap on the box(es) next to the samples to select them for test(s). Check marks appear to indicate selection.

- Multiple samples can be selected for a test simultaneously by highlighting multiple samples, then clicking/tapping a box next to a sample to select all highlighted samples for a test.
- To select all samples for a test, right click/tap on the desired test name at the top of the column. All samples in the test column will be selected.
- If the same test file is run twice in the same Worklist, Use the Smart Fill Tests button to fill all available sample positions on the first test file and select remaining samples to run in the second test file automatically.

Following is an example of a Samples tab that has been properly prepared for a Worklist run:

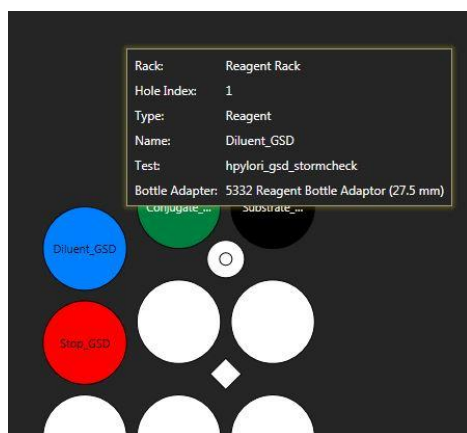
#	SAMPLE ID	Rack Position	Worklist 2 IgG Test	Worklist 2 IgM Test		Add Test ▾
1	#1	1:1	<input checked="" type="checkbox"/>	<input type="checkbox"/>		Remove Test ▾
2	#2	1:2	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
3	#3	1:3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
4	#4	1:4	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
5	#5	1:5	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
6	#6	1:6	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
7	#7	1:7	<input type="checkbox"/>	<input checked="" type="checkbox"/>		

Note: Rack Position is indicated for each sample (rack#1: tube position #).

5.2. Racks Tab

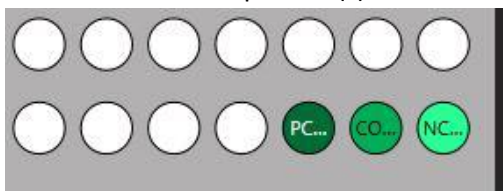
This tab displays the reagent rack and sample racks and is used to load reagents, calibrators, and controls, and to verify sample placement. Additional information about each position can be seen by hovering over the desired location. The following steps are taken to complete this tab:

Reagents: Load reagents into the instrument reagent rack using appropriately sized reagent adapters and following the colors/descriptions indicated on the screen:



- Use appropriate reagent adapters. Be sure the notched edge of each reagent adapter is facing forward.
 - If desired, right click/tap on any reagent bottle to set a custom dead volume for that bottle or to split the bottle into two positions.
 - Reagent locations are automatically assigned, starting in the back of the reagent rack and proceeding to the front.

2. **Calibrators and Controls:** Place prepared calibrator and/or control vials into the indicated locations in the sample rack(s):



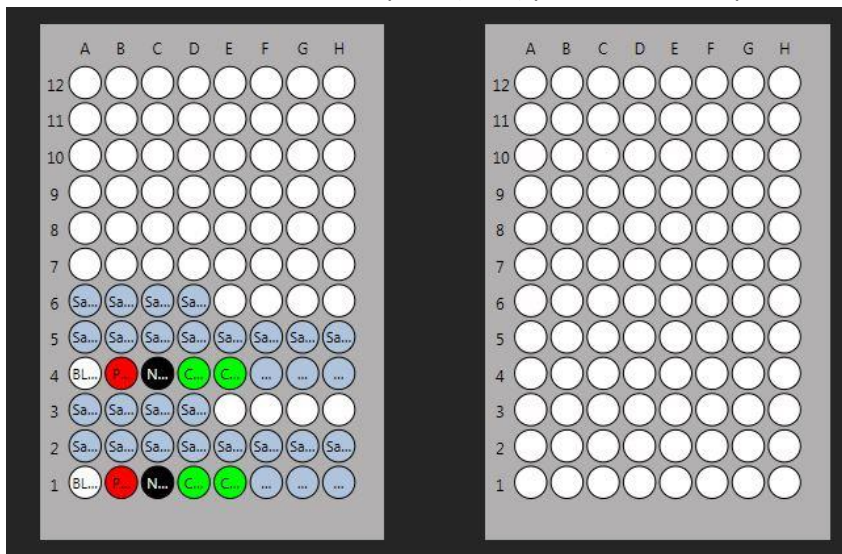
- a. Calibrator and control locations are automatically assigned to the first available rack position, beginning with the front right corner and proceeding to the left, then continuing front to back across the rack in rows (filling rows from right to left).

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

3. **Samples:** Verify the placement of all loaded samples.
4. **Check:** Check for/remove any bubbles from reagent/calibrator/control/sample bottles/tubes.

5.3. Microtiter Plates Tab

This tab is used to determine the number of wells/strips/plates required for the run by displaying all well locations on the microtiter plate (MTP) position and the predilution plate position:



Additional information about each well is displayed on the screen when hovering over the well. The following steps are taken to complete this tab:

1. **Verification:** Visually verify that all desired test wells and samples appear on the MTP layout in the correct plate locations.
2. **Wells:** Obtain the required number of wells for the test(s) as indicated by the MTP image and secure them into appropriate plate frame(s).
3. **Plate Frames:** Place the plate frame(s) with the appropriate wells onto the MTP carrier.
4. **Additional Microtiter Plates Tab Options (optional):**
 - a. **Exclude Strips:** This option, which allows tests to start in plate positions other than the default A1 position, can only be used if set during Worklist preparation, as described in previous section.

- b. **Predilution Plate Import/Export:** These options, which allow predilution plates to be shared between tests, can only be used in combination with predilution sharing test files. Contact the local distributor for additional information, if needed.
 - i. After using a Worklist to create a predilution plate, click/tap the Export button to save the predilution plate for later use.
 - ii. To use a previously created and exported predilution plate, click/tap the Import button and select the desired plate.
 - iii. Note: If importing a predilution plate, all samples will be removed from the sample list and replaced by the samples present in the imported plate.
- c. **Strips Loading Wizard:** For monotest/strips assays, the Strips Loading Wizard is enabled. Click/tap this button to be guided through scanning/placement of each required strip.

5.4. Worklist Tab

This tab displays the Worklist action log and the estimated run time. This tab is used to start, load, save, monitor, pause, stop, and finish a Worklist. The following steps are taken to complete this tab:

1. **Name:** Enter the name of the Worklist in this field. If no name is entered, Worklist will be automatically named with a date and time stamp.
2. **Operator:** Verify that the correct user is logged in.
3. **Verification:** Verify that the number of samples loaded and number of tests to run is correct.
4. **Wash Bottles:** Place appropriate wash bottles in the indicated locations. Note: Wash Bottle 1 is located in first wash position (closest to the front of the instrument); Wash Bottle 2 is located in the second wash position (behind Wash Bottle 1).
5. **Timing:** If desired, click/tap the arrow button at the bottom left of the tab to view estimated timing of the Worklist actions:



Hovering over the colored bars displays additional information about each action.

6. **Start:** Press the Start button to start the Worklist.
 - a. The Special Start button can be used to start the Worklist from a stopped/aborted position, from a specific step of the selected test(s), or to reread the plate(s) (plates can only be reread if Worklist has already been run).
7. **Check:** Check required reagent and calibrator/control volumes as prompted by the Reagent Loading Wizard (if wizard is enabled). If multiple bottles of a single reagent are required to accommodate the indicated volume, use the Split Bottle option within the wizard window to load additional bottle(s). A split bottle can also be removed, if desired, using the Remove Split Bottle button.
8. **Run:** Close the lid as prompted and wait for tests to run. Worklist actions can be monitored throughout the run using the Status Log, the live camera feed, and the timing bar at the bottom of the screen.
 - a. It is important to keep cover closed for the entire duration of the Worklist, especially when using the chemiluminescence option.
 - b. If necessary, use the Pause button to temporarily pause a Worklist or the Stop button to completely abort a Worklist (instrument movement will stop and door will unlock).

5.5. Worklist Completion

Standard Worklist Completion:

1. **Finish:** After the Worklist is completed, click/tap OK to stop the alarm (if end of run sound is enabled).
2. **Remove Kit Components/Samples:** Remove microtiter plate(s), reagents, controls, and samples from inside the instrument.
 - a. Ensure that all instrument surfaces are clean and dry, and close the cover.
3. **Evaluate Results:** Instrument user or other designated laboratory employee can review/display/export/send Worklist and/or sample results on the Evaluation tab as described in a following section of this manual.

Note: If multiple tests are included in the Worklist, results for each test will become available for viewing on the Evaluation tab as each one finishes (even if remaining test(s) in the Worklist is/are not yet completed). User can view results for completed test(s) while Worklist is still in progress.
4. **Perform Maintenance:** After each instrument use, verify that the maintenance log is up to date. If run is the last of the day/shift, click/tap the Power icon and perform daily shutdown maintenance as prompted (described in the maintenance section of this manual).

Additional Completion Selections (optional):

1. **Export Log:** Use this button, if desired, to export the Worklist action log to another file location (it is automatically saved in the Status Log Files folder by default).
2. **New:** Click/tap New to clear samples and tests from the completed Worklist and allow the setup of a subsequent new Worklist.
3. **Load:** Click/tap Load to open and run/rerun a previously saved Worklist. All tests, information, and samples are loaded when a previously run/saved Worklist file is loaded; it is the user's responsibility to ensure that all items are properly placed inside the instrument when running a loaded Worklist. Test/sample selections cannot be edited within a loaded Worklist.
4. **Save:** Click/tap Save to save the current Worklist with a new file name or to overwrite a previously saved Worklist file.

6. Evaluation and Search Tabs

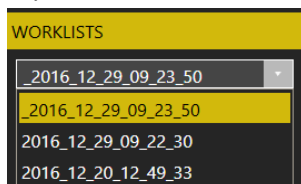
After a Worklist is completed, various options are available for evaluation and review of results in the Storm Instrument Manager Evaluation and Search tabs. These tabs can be accessed at any time from within the Storm Instrument Manager in both the Full Functionality Mode (instrument computer) as well as in the Evaluation Only mode (on instrument computer or another/server computer). If desired, the person reviewing all Worklist results can be different from the person operating the instrument(s) and results from all instruments connected to the same Storm Server can be reviewed on one central computer.

6.1. Evaluation Tab

This tab is used to review Worklist results. Users can view, export, and print Worklist reports, mark a Worklist as reviewed, review Worklist errors, change test properties and drop replicas, and send results to the LIS on this tab.

Worklist Review:

1. **Select a Worklist:** Select a Worklist to view (by Worklist name) from the dropdown menu on the top left:



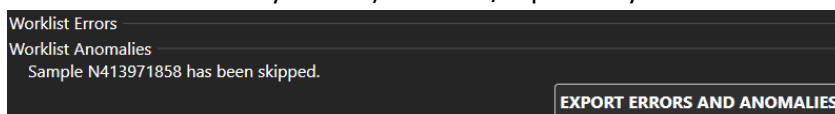
Worklists are listed in order of date with the most recent at the top of the list and most recent Worklist selected by default. Once selected, the Worklist report from the selected Worklist is shown on the right.

Note: If 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 tab, 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 at the bottom of the screen:



Click/tap this button to refresh the Worklist report shown to include newly available results.

2. **View Worklist Errors:** Click/tap the Worklist Errors button (button will be greyed out if Worklist does not contain any errors) to view/export any errors or anomalies from the Worklist:

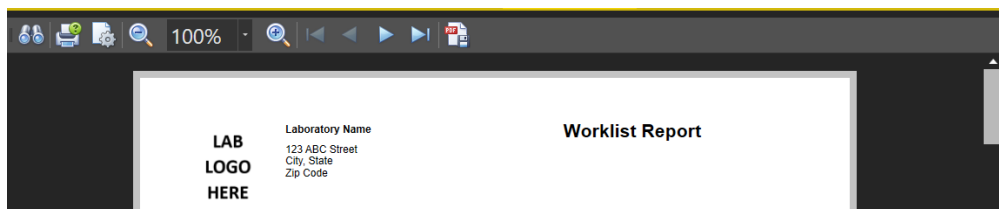


Worklist errors are also included on the Worklist report.

3. **Modify Worklist if needed:** Use the Drop Replicas and Change Test Properties Buttons to make any necessary changes to the selected Worklist.

Note: The modification option buttons below are only available for Administrator users.

- a. **Drop Replicas:** If Worklist contains tests with multiple control or calibrator replicates, and user desires to omit an out-of-range replicate from the calculations, click/tap the Drop Replicas button, select desired test, select desired well(s) to omit from calculations, and click/tap OK. Evaluation tab will refresh to display the Worklist report with the selected well(s) omitted from the calculations. Note: This option can only be used if test file permits replicate dropping.
 - b. **Change Test Properties:** If Worklist contains test(s) with test property information that was not correctly entered at the start of the Worklist (lot number, expiration date, or runtime variables), click/tap this button to modify test properties as needed. Evaluation tab will refresh to display the Worklist report with modified test properties information.
 - c. **Result Options:** This button is only intended to be used by GSD technical service.
4. **Mark Worklist as reviewed:** After making any changes to the Worklist, check the Worklist Reviewed box. Evaluation tab will refresh to display the Worklist report with reviewer noted.
 5. **Print/Export Worklist:** Print the Worklist report directly (if computer is connected to a printer) or export to a PDF using the respective icons at the top of the screen:



If desired, use the Export Worklist button to display the Worklist report in a separate window or export the Worklist results to Excel or TSV files. Use radio buttons and dropdown menu in the pop up window to make desired selection.

6. **Send to LIS:** Click/tap the Send to LIS button to send Worklist results to the LIS (if LIS connectivity has been correctly configured). In the pop up window, select which results to send and click/tap send. The Send to LIS button indicates if the “Worklist has not been sent” or the date on which the Worklist results were sent to the LIS, if they have already been sent.

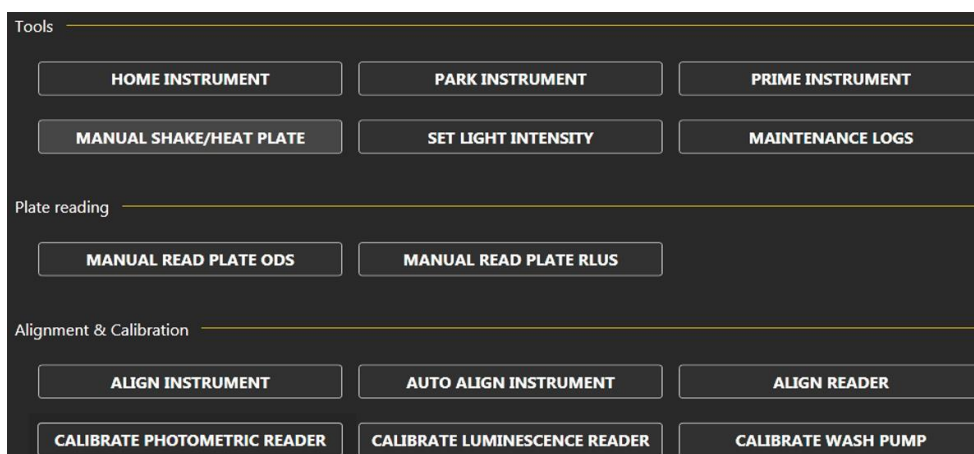
6.2. Search Tab

This tab is used to search for and create reports for previously run Worklists.

1. **Search:** Enter all desired search criteria (multiple criteria are allowed) using the checkboxes, text fields, and dropdown menus/date selection tools; then click/tap the Search button.
 - a. Searches can be made based on Sample ID, User, Worklist, Test, and date range. Archived Worklists can be included in search results if desired.
 - b. The results will be displayed under the Search Results section.
 - c. Double click/tap any row to directly view the selected Worklist on the Evaluation tab.
2. **Search Result:** Click/tap the Search Result button to display the search results in a separate window (to print or to save a PDF) or to export the search results to Excel or TSV files. Use radio buttons and dropdown menu in the pop up window to make desired selection.

7. Tools Tab

The Tools tab 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:



7.1. Tools

1. **Home Instrument:** Use this button to “home” the instrument, just as is done automatically at Storm Instrument Manager startup.

2. **Park Instrument:** Use this button to reset the instrument back to its starting, or “parked” position. Probe descends to empty the reservoir cup and then ascends to its parked position (with the probe assembly above the reservoir cup).
3. **Prime Instrument:** In the pop up window, select desired wash bottle(s) and number of priming cycles and click/tap Start. If both washes 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. Priming can be interrupted using the Stop button.
4. **Manual Shake/Heat Plate:** Use this button to manually shake and /or incubate a plate. Select preferred speed and/or temperature as desired. Use the Start and Stop buttons or set timer if desired.
5. **Set Light Intensity:** Use the slider bar to adjust default light intensity of the interior LED lights.
6. **Maintenance Logs:** Click/tap to view dates/times of all recent maintenance actions (priming, instrument and reader alignment, reader calibration, wash pump calibration). Select a month to display a maintenance report with all maintenance actions for that entire month.

7.2. 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). In the pop up window, select desired wells to be read using cursor to highlight. CTRL and SHIFT buttons can also be used to highlight specific wells.

Set the applicable options for the read type:

1. **Manual Read Plate ODs:** Set measurement wavelength and reference wavelength (optional).
2. **Manual Read Plate RLUs:** Set integration time.

Label the read data using the comment field (optional). Click/tap start. Measurements will appear on the screen as the plate is read. When read is complete, export readings using the Export to TSV button or print using the Print button. Note: Manual readings are NOT saved automatically by the software.

7.3. Alignment and Calibration

These instructions are intended to provide an overview of these functions; detailed step by step instructions are included in pop up windows within the Storm Instrument Manager when each function is performed.

Align Instrument/Auto Align Instrument

The instrument alignment/auto alignment processes are performed to align the probe with the reagent and sample rack and the microtiter plates. Either equivalent process may be used, according to laboratory preference.

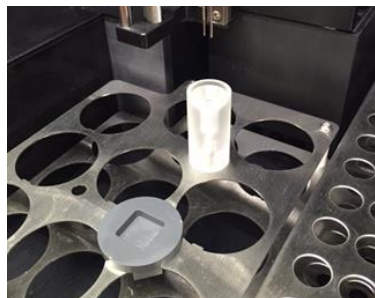
General Information

1. Perform and record instrument alignment or auto alignment as part of routine instrument maintenance, when prompted by the Storm Instrument Manager.
2. If an alignment/auto alignment is partially completed and then cancelled, fully complete the procedure prior to the next instrument use.
3. Move the probe throughout the alignment procedures using the buttons on the screen or the alternative keyboard keys:
 - a. The left and right arrow keys are used to move the probe to the left and right (X-axis).

- b. The up and down arrow keys are used to move the probe toward the front and back of the instrument (Y-axis).
 - c. The Page Up and Page Down keys move the probe up and down (Z-axis).
4. Carefully align the probe assembly in the X and Y positions as indicated. The Z-axis position does not need to be manually aligned; it is aligned automatically by the instrument during the instrument alignment/auto-alignment processes.
5. Be sure to wait for the probe assembly to reach each position before clicking/tapping Next Step.
6. It is normal to hear motor humming sounds during the alignment/auto-alignment processes.

Auto Align Instrument Instructions:

1. Preparation:
 - a. Place one auto alignment plate in each of the two MTP positions (reaction/left plate and predilution plate) on the MTP carrier. Be sure that plates are seated securely.
 - b. Remove the cuvette from the instrument reagent rack (Be sure to remove all reagents and adapters from the reagent rack as well) and place the auto-alignment plug in the square hole with the circular part flush against the rack top:

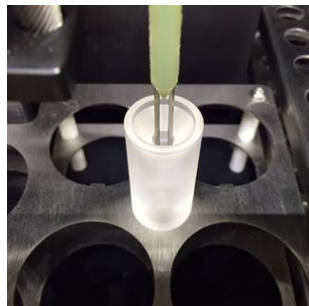


- c. Click/tap the Auto Align Instrument button. A pop up window will appear and provide instructions.
2. Alignment:
 - a. Verify proper plate and plug positioning when prompted and allow the instrument to complete the alignment automatically (This step takes approximately 2 - 3minutes). DO NOT touch the instrument during this time.
3. Completion:
 - a. Click/tap Finish when prompted to complete and save the auto alignment and exit the Auto Align Instrument window (instrument will return to its home position). Remove the auto alignment plates and plug.

Align Instrument Instructions:

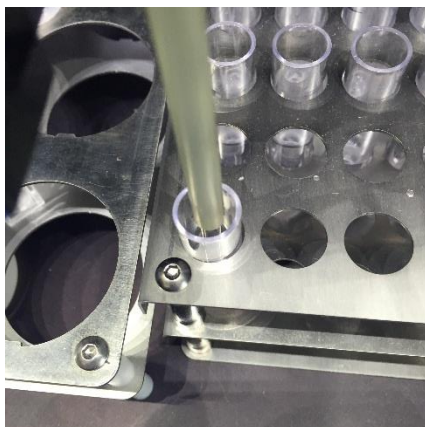
1. Preparation:
 - a. Place an empty sample tube in the front left position of the sample rack.
 - b. Place one alignment plate or empty MTP in each of the two MTP positions (reaction/left plate and predilution plate) on the MTP carrier. Be sure that plates are seated securely.
 - c. Click/tap the Align Instrument button. A pop up window will appear and provide instructions for each alignment step.
2. Alignment:
 - a. Use the buttons or keys to position the probe needles over the center of each location as prompted, clicking/tapping Next Step after aligning each position. Some example alignment positions are shown below:

Wash cup alignment: Align the probe to the middle of the wash cup, then move it down to verify that the probe can reach the bottom of the wash well without resistance:

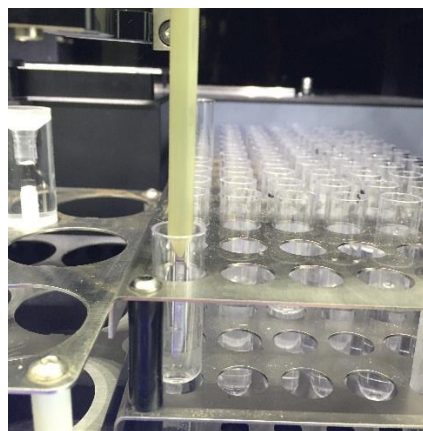


After the aligning the wash cup and clicking/tapping Next Step, the instrument will automatically calibrate the Z-axis position of the probe to the bottom of the wash cup. (the spindle will move up and down and the red light will turn on and off).

Sample tube alignment: Align the center of the probe needles to the center of the sample tube (X and Y axes):



(Top View)



(Front View)

It is not necessary to move the probe needles to the bottom of the tubes, only far enough to clearly see the needle position in the tubes.

MTP well alignment: Align the center of the probe needles to the center of each indicated reaction plate or predilution plate well:



It is not necessary to move the probe needles to the bottom of the wells, only far enough to clearly see the needle position in the wells.

3. Completion:

- a. Click/tap Finish when prompted to complete and save the alignment and exit the Align Instrument window (instrument will return to its home position).

Align Reader

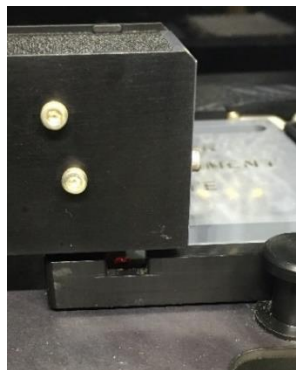
The reader alignment process is performed to ensure that the reader is in the correct position for reading the MTP.

General Information

1. Perform and record reader alignment as part of routine instrument maintenance, when prompted by the Storm Instrument Manager.
2. If a reader alignment is partially completed and then cancelled, fully complete the procedure prior to the next instrument use.
3. Click/tap Next after each step.
4. Place the reader alignment plate in the reaction/left MTP position with the lettering on the plate facing forward and the plate notch located in the front left corner when aligning the reader.
5. Move the reader /MTP carrier using the buttons on the screen or the alternative keyboard keys as listed below:
 - a. Use the left and right arrow keys to move the MTP carrier to the left and right.
 - b. Use the up and down arrow keys to move LED guide light toward the front and back of the instrument.

Align Reader Instructions

1. Preparation:
 - a. Remove all microtiter plates and alignment plates from the MTP carrier.
 - b. Click/tap the Align Reader button. A pop up window will appear and provide instructions for each alignment step.
2. Alignment:
 - a. Place the reader alignment plate in the reaction/left MTP position, as prompted.
 - b. Verify that the reader LED guide light is in the center of the front left hole of the reader alignment plate, as prompted. Adjust positioning as necessary.



- c. Close the cover of the instrument when prompted.
3. Completion:
 - a. Wait for the instrument to complete the LED calibration and reader alignment (This step takes approximately 10 minutes).
 - b. Click/tap Finish when prompted to complete and save the alignment and exit the Align Reader window (instrument will return to its home position).

Calibrate Photometric Reader

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 Luminescence Reader

If the instrument is equipped with the chemiluminescence reader option, this portion of the reader can also be calibrated. 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 on the reagent rack, then click/tap the Calibrate Wash Pump button. Follow instructions as prompted to calibrate the wash pump.

8. Maintenance

Maintenance procedures, as prompted by the software, should be followed to ensure proper instrument functionality. It is suggested that maintenance activities be recorded using the provided maintenance log. (Maintenance actions are also automatically recorded by the software and monthly reports accessible from the Tools tab and in the Maintenance Reports subfolder of the instrument's Storm Documents folder.) The information below describes the routine maintenance steps for the instrument system.

8.1. Daily Maintenance

Daily maintenance includes startup and shutdown steps. Startup steps are prompted/performed prior to the first run of the day/each time the Storm Instrument Manager software is opened, and shutdown steps are prompted/performed following the last run of the day/each time the Storm Instrument Manager software is closed/instrument is powered off. It is recommended that the startup and shutdown steps be performed any time the instrument is idle for four or more hours to prevent build-up in the fluidics lines.

Startup

1. Ensure wash bottle(s) are properly connected to the instrument.
2. Prime the instrument using the wash buffer(s) that will be used for testing a minimum of 10 priming cycles per line.
 - a. Ensure that all wash buffers are within their expiration date prior to each use.

Shutdown

1. Use the Power button within the Instrument Manager software to shut down the instrument and attached computer.
2. Empty waste bottle.
3. Prime the instrument using DI water a minimum of 50 priming cycles per line.
4. Remove any remaining reagents and samples from inside the instrument and close the lid.
 - a. Ensure all instrument surfaces are clean and dry.

8.2. Weekly Maintenance

Weekly maintenance includes cleaning and alignment steps that are prompted/performed every seven days. It is recommended that the same day of the week be used for consistency. 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 reagents. Weekly Maintenance steps should be performed as follows:

1. Remove sample rack and inspect for cleanliness and damage.
 - a. Use alcohol wipe to gently clean sample rack.
2. Clean the reagent rack and sample tray deck with an alcohol wipe.
3. Clean the outside of both probe needles by wiping them down gently with an alcohol wipe.
4. Perform instrument and reader alignments as described in further detail in the Alignment and Calibration section of this manual.
5. Decontaminate the instrument tubing by priming the instrument 20 priming cycles per line with Liquinox solution.
 - a. The Liquinox solution is prepared by making a 1:100 dilution of the Liquinox Concentrate supplied with the instrument, using DI water.
 - b. Rinse the tubing by priming the instrument 50 priming cycles per line with DI Water.
6. It is recommended that any wash bottles used be cleaned weekly to avoid contamination.

8.3. Periodic Maintenance

Approximately every year (time will vary depending on instrument usage) a professional maintenance procedure should be performed by a trained service engineer. Service agreements are typically laboratory-dependent and established to meet the specific needs of each client. Contact the local instrument distributor for more information.

8.4. Storage, Transportation, and Disposal

Storage, transportation, and disposal of the instrument must be completed by a trained technician. 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 a minimum of a weekly maintenance (as described above) followed by dry priming cycles to remove liquids from the system, be performed and that the instrument 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 technician disposing of the instrument consult applicable local regulations prior to disposal.

9. Laboratory Information System Integration

The LIS implementation of the Storm software package 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 Communication and LIS Mappings tabs of the Storm Configuration Tool. LIS is queried from the Samples tab of the Storm Instrument Manager during Worklist setup and results are sent to the LIS from the Evaluation tab of the Storm Instrument Manager after run is complete.

9.1. LIS Records

Data is sent to the LIS according to the following:

Header Record: All communications begin with the header record. In the “Sender Name or ID” field, the name of the software and the version are displayed.

Example:

```
H|\^&|||Bolt EIA^0.42.0.73|||||P|LIS2-A2|20101022162157
```

Request Information Record Specifics: The software will query the LIS system using “Request Information Records”. The field used to transmit the Sample ID to the LIS is the “Starting Range ID Number” field. In this field the first component is used: “Patient ID”

Example:

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

In this example, the Sample ID is “S001”

Patient Information Record: The LIS system will respond to the software using “Patient Information Records”. In the “Laboratory Assigned Patient ID” field the Sample ID is stored.

Example:

```
P|1||S001||
```

In this example, the Sample ID is “S001”

Test Order Record: The LIS system will give specific Patient/Test information using “Test Order Records”. In the “Specimen ID” field the Sample ID is stored. From the “Universal Test ID” field the “Manufacturer defined test code” component is used to store the test information. This can be defined by the lab; a lookup table is used to match those codes to the real test names.

Example:

```
O|1|S004||^^^CMVlgG|R
```

In this example, the Sample ID is “S004”, the test name is “CMVlgG”.

Result Record: The instrument will send the results of patients back to the LIS using “Result Records”. In the “Data or Measurement Value” field, the numerical result of a patient is stored. If the test has a message (e.g. “Low”, “Medium”, “High”), the message is stored after the numerical result, separated by a component delimiter. In the “Units” field, the units of the numerical result are stored. From the “Universal Test ID” field, the “Manufacturer defined test code” component is used to store the test information. This can be defined by the lab; a lookup table is used to match those codes to the real test names. If a test contains multiple results (subtests) (e.g. panel based tests), the subtest name is added after the test ID separated by a component delimiter. If a sample is skipped, the result is still transmitted, 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).

Examples:

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

```
R|1|^^^CMVlgG|1.33^high|ng/ml||||F
```

```
R|1|^^^CMVlgG^Subtest1|1.33|ng/ml||||F
```

9.2. LIS Query and Transmission Examples

Example 1: Query of sample IDs

Instrument → LIS

H|\^&|||Bolt EIA^0.42.0.73|||||P|LIS2-A2|20101022162157
Q|1|S001^^|ALL
Q|2|S002^^|ALL
Q|3|S004^^|ALL
L|1|N

LIS → Instrument

H|\^&|||LIS|||||P|LIS2-A2|20101022162157
P|1|S001
O|1|S001|^^^CMVlgG|R
P|2|S002
O|1|S002|^^^CMVlgG|R
O|2|S002|^^^HPLlgG|R
P|3|S004
O|1|S004|^^^CMVlgG|R
O|2|S004|^^^HPLlgG|R
L|1|N

Example 2: Transmission of results

Instrument → LIS

H|\^&|||Bolt EIA^0.42.0.73|||||P|LIS2-A2|20101022162157
P|1|S001
O|1|S001|^^^CMVlgG|R
R|1|^^^CMVlgG|1.33|ng/ml|||F
L|1|N

Example 3: Transmission of multiple test results per patient

Instrument → LIS

H|\^&|||Bolt EIA^0.42.0.73|||||P|LIS2-A2|20101022162157
P|1|S001
O|1|S001|^^^CMVlgG|R
R|1|^^^CMVlgG|1.33|ng/ml|||F
O|2|S002|^^^HPLlgG|R
R|1|^^^HPLlgG|1.24|ng/ml|||F
L|1|N

Example 4: Transmission of multiple subtest results per patient

Instrument → LIS

H|\^&|||Bolt EIA^0.42.0.73|||||P|LIS2-A2|20101022162157
P|1|S001
O|1|S001|^^^CMVlgG|R
R|1|^^^CMVlgG^ST1|1.33|ng/ml|||F
R|2|^^^CMVlgG^ST2|1.24|ng/ml|||F
L|1|N

9.3. LIS Configuration

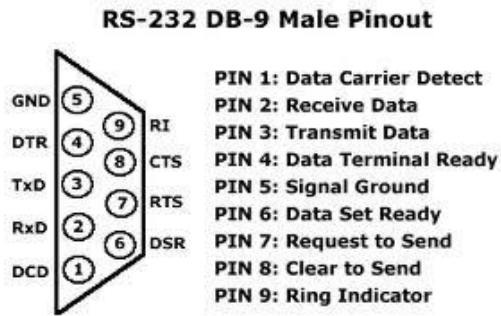
1. Verify that instrument is correctly installed and all power correctly connected to instrument and netbook.
 - a. Verify that tests have been added to the system using the Storm Configuration Tool.
2. Ensure that all relevant cords and cables for LIS system are connected to the instrument.
 - a. TCP/IP: Ethernet cord; RS232: serial cord
3. Select correct settings within the Storm Configuration Tool LIS Communication section. These must be entered before any communication with LIS is attempted. Select appropriate settings according to LIS being used:

The screenshot shows the 'LIS Communication' configuration window. At the top, there are checkboxes for 'Enable LIS' (checked) and 'Enable LIS Logging' (unchecked), along with a 'Log Level' dropdown set to 'Errors Only'. Below this, there are two radio buttons: 'Use RS-232 Connection' (unchecked) and 'Use TCP/IP Connection' (checked). The 'Use TCP/IP Connection' section contains a 'Server Address' field with the value '127.0.0.1' and a 'Server Port' field with the value '8888'. There are also '+' and '-' buttons next to the port field. A checkbox for 'Use LIS01-A2 Encoding' is checked. At the bottom right, there are two buttons: 'DISCARD CHANGES' and 'SAVE LIS CONFIGURATION'.

- a. In the **RS-232 Connection** section, set the baud rate, data bits, parity, and stop bits of the port.
 - b. In the **TCP/IP Connection** section, set the Server address and the Server port of the LIS TCP Server.
 - i. If the “Use LIS01-A2 Encoding” option is used, the software will use a “telnet”-like system (same data as through the RS-232 connection).
 - c. Save LIS Configuration.
4. Assign LIS test IDs to instrument test file names within the Storm Configuration Tool on the LIS Mappings tab. List all LIS names and corresponding test file names, being careful to copy codes exactly as they are used in the LIS system.
 - a. An LIS name is seldom the real test name, but often a shorter one. It could also be a number or code, depending on the laboratory policy.
 5. Set up a Worklist to test connectivity:
 - a. Open the Storm Instrument Manager software and log in as an administrator user.
 - b. Follow standard Worklist setup procedure:
 - i. Add tests, being sure to enter a valid expiration date for each.
 - ii. Add samples, verify on the Samples tab that they have been added to the samples list.
 1. Verify in the LIS system that the samples that were added actually have pending orders for the tests that were selected in the Worklist.
 - c. Test receiving capability: Click/tap Query LIS button.
 - i. If connectivity is working properly, checkmarks will appear in the appropriate boxes on the Samples tab.
 - d. Test Sending capability: Run the Worklist using the Special Start from Specific Position option on the Worklist tab and starting from the read step of the test.

- i. After read is complete, click/tap Send to LIS button on Evaluation tab.
 1. Select which results to send, as prompted and click/tap Send.
 2. If connectivity is working properly, results will be transmitted and appear in the LIS with the corresponding test code.
 3. Note: If reading is not performed, there will be no valid results or information that could be transferred to the LIS.

9.4. RS-232 Pin Layout



10. 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 and predilution plate is/are correctly loaded and seated securely.
		Check that sufficient strips/wells are placed.
		Check positions of probe during instrument alignment. If misaligned, realign instrument 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).
	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 tab?	If missing samples are not selected on the Samples tab, select them and rerun. If missing samples do not appear on the Samples or Racks tabs, 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 and replug power and USB connections, and restart. Load Worklist and special start from aborted position. If problem persists, contact technical service.

Issue	Details	User Action
Run stops in the middle of a Worklist (cont).	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.
	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 tab 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 tab. 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 Tab.

Issue	Details	User Action
Failed run (cont.)	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 alignment. If misaligned, realign reader and reread plate.
		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).
	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).
	Is the flooding outside the wells on the MTP carrier?	Check positions of probe during instrument alignment. If misaligned, realign instrument 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 Tab.
Need to reprint or find past data	Does user know in which Worklist the desired data was run?	Select Worklist on Evaluation tab 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 tab of Storm Instrument Manager Settings.
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).
	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 Mappings 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

11.Contact Information

11.1. Device Manufacturer



Company Name	Gold Standard Diagnostics Corp.
Company Address	2851 Spafford Street Davis, CA 95618
Country	United States
Phone	530-759-8000
Fax	530-759-8012
Website	www.gsdx.us
Bolt®	Catalog # 00500; 00500-CL

11.2. Authorized Representative

EC	REP
----	-----

Company Name	Emergo Europe
Company Address	Prinsessegracht 20 2514 AP, The Hague
Country	The Netherlands
Phone	+31 70.345.8570
Fax	+31 70.346.7299
Website	www.emergogroup.com