Storm 3.1 User's Manual

for the ThunderBolt®

(REF 00300, REF 00300 CL)

CE

IVD

Contents

1. Introduction

The purpose of this manual is to identify the system components and provide instructions for use of the Storm Software Suite with a ThunderBolt instrument (EIA) REF 00300, and ThunderBolt (CLIA) REF 00300 CL, (the "system"). This manual provides basic safety information, instructions for use and maintenance, as well as general troubleshooting guidance. It is recommended that this manual be kept near the instrument and accessible to the user at all times.

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

1.1. Intended Use

The system is designed to automate the processing of enzyme immunoassay (EIA) REF 00300 and Enzyme Immunoassay (EIA) / Chemiluminescent Immunoassay (CLIA) REF 00300 CL tests on Gold Standard Diagnostics (GSD) EIA/CLIA instruments. The system is only intended to be used by properly trained personnel.

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

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

1.2. Certifications and Registrations

Gold Standard Diagnostics is certified as being compliant with the following regulatory requirements:

ISO 13485:2016

CMDR SOR/980282

21 CFR

The ThunderBolt instrument is certified as being compliant with the following safety requirements for medical devices:

Directive EN 98/79/EC

EN 61010-1:2001

EN 61010-1:2001-02

US AND CA national deviations as shown in the test report 586125.01

The ThunderBolt instrument is registered with the FDA as a Class 1 Chemistry Analyzer for Clinical Use.

2. Safety Information

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

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

2.1.   General Safety

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

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

2.2.   Electrical Safety

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

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

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

2.3.   Mechanical Safety

Installation and service of the system must be completed by a trained technician to ensure a minimized exposure of the operator to mechanical risks. Improper use or handling of the system may cause serious damage to the instrument or result in injury to the user. Avoid touching the probe and other moving parts while the system is in operation. Protective covers should not be removed while the instrument is on due to potential contact with moving parts. Exercise extreme

caution when working on or near the peristaltic pump when the cover is not in place (applicable models only). Openings on the instrument provided for ventilation are not meant as access points.

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

2.4.   Biological Safety

Any parts of the system (including any attached computers/keyboards) that have come into contact with samples/test reagents are to be treated as being potentially infectious. Some of the general purpose reagents have the potential to cause irritation of the skin and mucous membranes. It is recommended that the operator use appropriate personal protective equipment (PPE) such as gloves, lab coat, and eye protection while using the system. For devices used in conjunction with the sytem, 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 ThunderBolt instrument is labeled with universal general warning labels to identify risks which may be encountered by the operator.

3. System Instrument

The ThunderBolt 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 ThunderBolt also provides photometric and luminescent measurement and evaluation. The ThunderBolt is controlled by a Windows PC software program (Storm Instrument Manager) that is specifically designed for the system.

3.1. Instrument Overview

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

The instrument components are as follows:

1. Instrument Cover
2. Computer
3. Barcode Scanner or Indicator Light and Camera
4. Sample Racks (Intelligent or Slide-in)
5. Reagent Rack(s)
6. Microtiter Plate Carrier
7. Probe (with mounted camera)

3.2. Instrument Details

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

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 ThunderBolt should be placed near an outlet and connected to a surge protector or an uninterruptable power supply (UPS).

Instrument Dimensions and Weight

Dimensions:
A/Width of instrument alone: 66.1 cm (26 in)
B/Height of instrument alone: 55.9 cm (22 in)
C/Depth of instrument alone: 57.2 cm (22.5 in)
D/Width of suspended computer: 33.1 cm (13 in)
E/Width of attached Wash/Waste: 15.3 cm (6 in)
F/Height with door open: 99.1 cm (39 in)
Weight: 50 kg (110 lbs.)

The total bench space recommended to accommodate the Bolt and related equipment is 114.3 cm (45 in.) wide x 99.1 cm (39 in.) high x 57.2cm (22.5 in.) deep. The laboratory bench must be sturdy enough to support the full weight of the ThunderBolt as well as additional equipment. Expect the total weight of the ThunderBolt and accessory equipment to be approximately 50 kg (110 lbs.).

3.3.   Instrument Components

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

Sample Racks

ThunderBolt instrument models contain one of two types of sample racks, as explained in detail below.

Intelligent Sample Racks

The Intelligent sample racks use automatic sample location management to track sample IDs, regardless of loaded sample positions. The three racks can accommodate up to 192 patient samples. The removable racks are interchangeable (though if racks are moved to different locations, probe alignment should be performed) and can accommodate 12, 13 or 16 x 75 mm tubes. Custom racks are also available. Rack positions are numbered as follows: Front right is rack 1, front left is rack 2, back left is rack 3. Sample tube positions are numbered in each rack beginning in the back left corner and proceeding down each column from top to bottom and continuing across the rack from left to right.

Slide-In Sample Racks

The Slide-In sample racks use a camera scanning system to detect sample tubes and track sample IDs. Each of the 12 racks can accommodate 16 samples (up to 192 patient samples total). The removable racks are interchangeable and can accommodate 12 to16 x 75-100 mm tubes. Rack positions are numbered from left to right and sample tube positions are numbered from back to front.

Reagent Rack

Depending on instrument model type, the reagent rack is either located on a sliding tray (with 16 reagent positions) or the slide-in reagent racks (with 14 total reagent positions) are located in the far right positions, for maximum accessibility. 22 to 35mm bottles are accepted and custom reagent adapters are also available.

Microtiter Plate Carrier

The microtiter plate carrier contains two reaction microtiter plate positions and one pre-dilution plate position.

Camera

The probe-mounted camera monitors internal operations in real-time and facilitates remote troubleshooting.

Probe Assembly

The ThunderBolt utilizes a single probe, dual needle system; no disposable tips are used. This system is capable of precise pickups and dispenses for volumes between 1 µl and 300 µl. The high-precision micro-syringe aspirates 1 µl with less than 3% CV across an entire reaction plate. Liquid detection is performed via conductivity, with a minimum detection volume of 50 µl.

Barcode Scanner (applicable only for models with intelligent sample racks)

The fully integrated barcode scanner supports the following barcode types: codabar, code39, interleaved 2 of 5, code 93, code 2 of 5, IATA code 2 of 5, matrix 2 of 5, code 11, code 128, telepen, UPC A, UPC E, EAN 13, EAN 8, MSI, Plessey, RSS-14, RSS-14 Limited, RSS-14 Expanded, China Post Code, and PDF417.

Barcode Camera (applicable only for models with slide-in sample racks)

The fully integrated camera is used in conjunction with the slide-in rack system to detect sample tube location and ID. The camera supports the following barcode types: codabar, code39, interleaved 2 of 5, code 93, code 128, UPC A, UPC E, EAN 13, EAN 8, QR code, Data Matrix.

Indicator Light (applicable only for models with slide-in sample racks)

Exterior status indicator light shows worklist status, with the different colors indicating the worklist state. A red light indicates that the worklist is stopped or not yet started and a green light indicates that the worklist is running.

Incubator

The forced convection incubator heats to a maximum of 45°C.

Reader

The ThunderBolt'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.

Reader Specifications

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

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

Chemiluminesence Reader Specifications

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)

Orbital Shaker

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

Shaker Specifications

Amplitude: 1 mm

Adjustable speed: up to 900 RPMs

Capacity: 3 MTP (2 reaction, 1 predilution)

Voltage: 24 V

Computer

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

Instrument Computer Specifications

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

Processor: Intel Celeron 1.1 GHz

Memory (RAM): 4 GB

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 4.6

Server Computer Specifications

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

# of Instruments	Processor	Memory (RAM)	Memory (Hard Disk)	Ports	Display	Operating System	.NET Framework
1	Intel Celeron 1.1 GHz	4.00 GB	120GB	USB 2.0, Ethernet (RS232 port optional)	DirectX 11 graphics device with WDDM 1.2 driver, 1366x768 resolution	Win 8 (recommend Win10)	.NET 4.6
5	Intel i3 2.0 GHz	8.00 GB	240GB				
10	Intel i5 2.5 GHz	8.00 GB	500GB				

4. System Software

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

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

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

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

The Storm System Configuration Tool is used to configure settings for the system; 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 most recently released version of software. Contact the local instrument distributor with any further questions about software versions or software update instructions; be sure to use the manual appropriate to the software version in use.

4.1. System Configuration Options

There are two ways in which the system 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 Software Suite are installed and run on a single instrument computer, as shown in the following diagram:
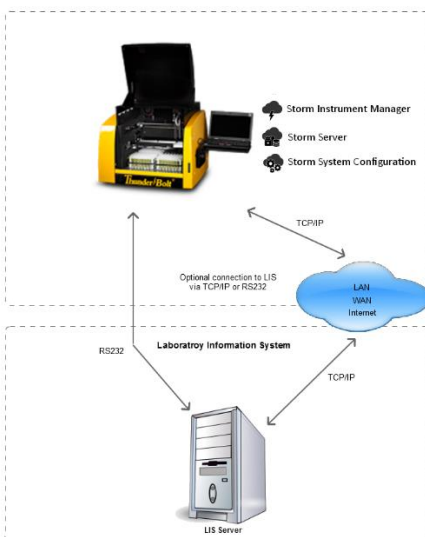
The system is configured in this way by default at the time of purchase and no additional software installation or configuration is necessary to run in this format.

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

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:
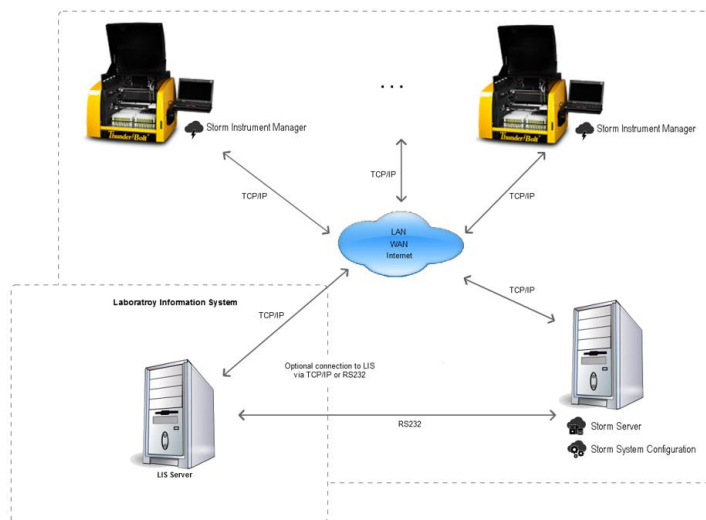
The central, shared Storm Server allows for a common configuration of all Storm Instrument Managers and a single connection to the LIS.

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 System 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 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).
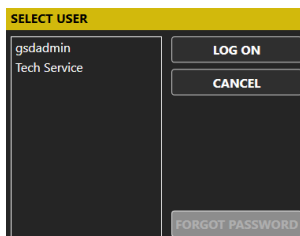
The Storm System Configuration Tool is used to specify configuration settings for the system. These settings are stored by the Storm Server and used by all Storm Instrument Manager instances connected to the server. The Storm System Configuration Tool must be installed on the same computer on which the 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.
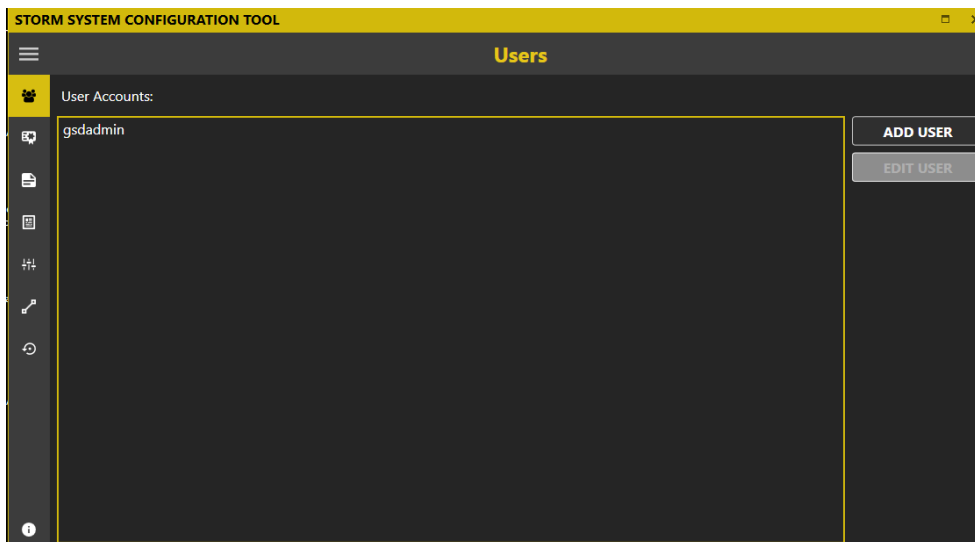
Note: All connected Instrument Manager instances must be closed (as prompted) before opening the Storm System Configuration Tool.

Choose 'Yes' if asked to allow the program to make changes to the computer. The Storm System Configuration Tool will prompt the user to choose a Storm System User Account to log in to the Storm System. Only users with Administrator or Tech Service accounts are allowed to configure the Storm System. Select the desired user account (only users with Administrator or Tech Service 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 screens (accessible via the icons on the left of the screen or the menu ☰)are available in the Storm Configuration Tool software:
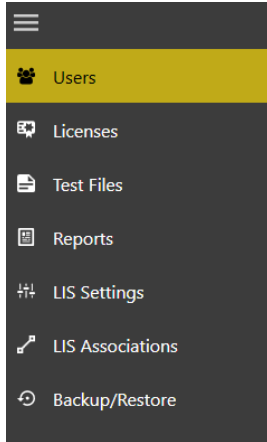

1. **Users**: Use this tab to add and edit Storm System user accounts. These user accounts are used to log in to the Storm System Configuration Tool and to the Storm Instrument Manager instance(s) connected to the corresponding Storm Server in which these settings are stored.

   a. To add a user: Click/tap 'Add User'. Enter User Name and Password, Email Address (optional for run notifications), cell phone number (optional for run notifications) as indicated. Activate the user by selecting the Active User option. Select Basic User, Super User, or Administrator rights for the user using the dropdown. 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 several types of user accounts:

      i. **Basic User** accounts are intended for the normal users of the Storm Instrument Manager and its associated instrument. This type of user can perform instrument maintenance and create Worklists and run them on the instrument.

      ii. **Super User** accounts are intended for users who will review worklists and send results to the LIS. This type of user can perform all tasks of Basic Users, and can also review worklist reports and send results to the LIS.

      iii. **Administrator** accounts are intended for users with extra privileges. Users with Administrator accounts can perform all tasks of Basic and Super user accounts, as well as other tasks: Only Administrator users can log in to and change settings in the Storm System Configuration Tool. Also, only Administrator users can access the Settings screen in the Storm Instrument Manager. Certain tools (ie: Wash Pump Calibration) are also reserved for Administrator users. At least one Administrator account must always be active.

iv. **GSD Tech Service** is an account only for use by GSD personnel.

2. **Licenses**: Use this tab to add, remove, or renew licenses (if applicable).

   Note: Licenses are only required by certain customers. Contact GSD or local instrument distributor for additional information if a license is required. If no license is required, no action is needed on this tab.

3. **Test Files**: 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. <u>To add/rename Nodes:</u> To add a grouping or node of tests, click/tap the 'Add Node' button. Enter the desired node name as prompted and click 'OK'. Multiple nodes can be added to organize/group tests. Rename a node by selecting and click/tapping the 'Rename Node' button.

   b. <u>To add Tests:</u> 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:
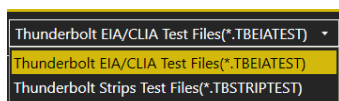
   Then select desired test file(s) using the navigation panel on the left and highlighting the files on the right. Multiple files can be selected using the CTRL or SHIFT keys:

   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 screen:
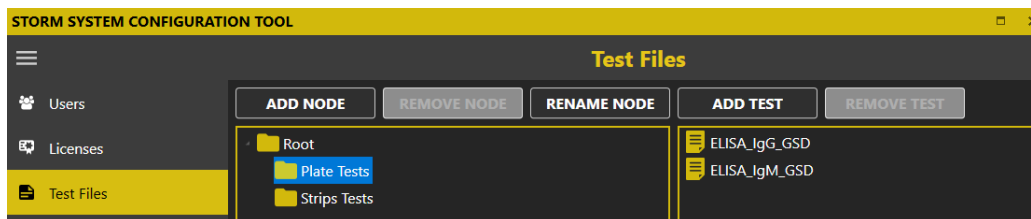
c. To Remove/Reorganize Nodes/Tests: To remove nodes or tests, highlight the test(s) or node to be removed and click/tap the 'Remove Test' or 'Remove Node' button, as appropriate.

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

4. **Reports**: Customize worklist report and test report information on this screen, 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:

   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:

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

5. **LIS Settings**: 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 LIS Timeout. Select which LIS connection type will be used (RS-232 or TCP/IP) and set port/server settings as applicable:

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 screen must be completed before LIS communication can be attempted from within the Storm Instrument Manager.

6. **LIS Associations**: Associate each Test File test name to the LIS test name and click/tap 'Save LIS Associations' to save changes or 'Discard Changes' to remove changes.

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

An LIS test 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 test names (often referred to as test codes) exactly according to the laboratory's LIS configuration.

7. **Backup/Restore**: Use this screen to select the backup and/or restore settings of the server database as desired or as required by the laboratory.
Backup can be used to perform a backup of the data saved in the data base from the selected date. Only the data from the data range selected will be saved.
Restore is used to bring back a server database from a previous backup into the software.
Scheduled backups (with all worklist report information/results) can be automatically performed at pre-selected times/intervals to a pre-selected location on this screen. Backups can also be made of all data or data from selected dates manually.
Purge the database of all images from between the date ranges, Not applicable for the ThunderBolt.

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 Worklists which contain one or more Tests defined by the 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, side screen icons, and side buttons icons(click/tap the ☰ icon to view/collapse the side screen/button names), as shown:
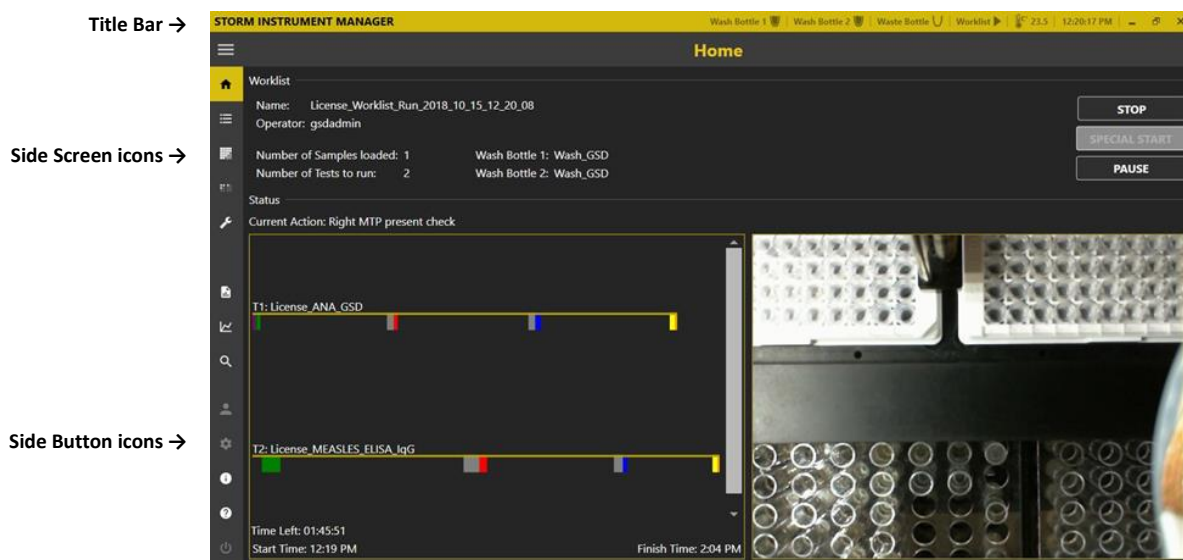
Storm Instrument Manager
The Storm Instrument Manager can be run in two modes:

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 screens/buttons 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, Analysis, and Search screens are available in this mode; some items are excluded from title bar and side buttons in this mode as well).

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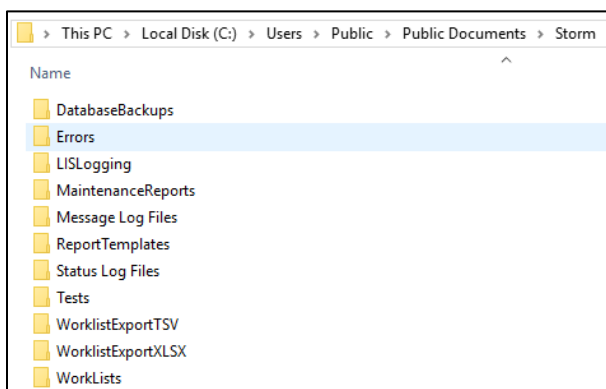
These folders and files can be accessed at any time, including when software applications are in use.

1. **DatabaseBackups:** This is the recommended/default location for any database backups created via the Storm System Configuration Tool.
2. **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:
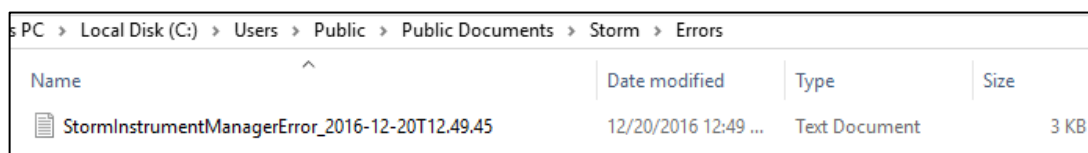
3. **LISLogging**: If LIS logging is enabled, LIS log files will be stored in this folder.
4. **Maintenance Reports**: Records of users' performance of all prompted maintenance actions are stored (one file per month) in the Maintenance Reports subfolder in portable document format (PDF), as shown in the image below:

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

6. **Report Templates**: Any custom worklist or test report templates (if applicable) should be stored in the Report Templates subfolder.

7. **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:

These logs include all of the actions of the instrument for each worklist run, including any anomalies encountered (such as bubble retries).

8. **Tests**: Test files can be stored in the Tests subfolder.

   Note: Test files must be added to the Storm system using the Tests screen in the Storm System Configuration Tool before they will be available in the Storm Instrument Manager, 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.

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

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

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:
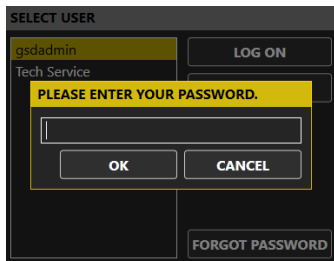
2. Select a user (only active users are displayed for selection), click/tap Log On, enter password, and click/tap 'OK'.

   Note: If a basic or super user 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 "homing" uninterrupted before being used:
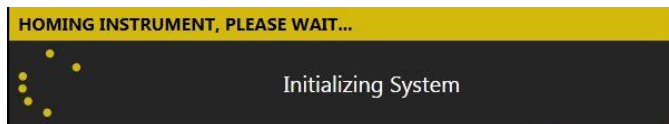
   After homing, the Storm Instrument Manager opens.

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

Storm Instrument Manager Title Bar
1. **Wash and Waste Bottle Status Icons**: Indicate which wash/waste sensors are enabled and the liquid level of wash and waste (empty or full).
2. **Worklist State Icon**: Indicates if a worklist is being created (open circle), running (arrow), paused (double lines), stopped (solid square), or completed (checkmark).

   Note: Exterior status indicator light also shows worklist status (on applicable models only).

   Blue: Instrument is idle; ready to load and run worklist
   Green: Instrument is running a worklist
   Red: Instrument has an error, alarm, or message stopping the worklist

3. **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.
4. **Current Computer Time**: Displays the current time as set by the attached computer.
5. **Minimize/Maximize/Restore Down**: Used to minimize/maximize/restore down the Storm Instrument Manager main window.
6. **Close (X icon)**: Used to close the software without shutting down the instrument/computer. (Daily shutdown maintenance will be prompted).

Storm Instrument Manager Side Buttons
1. **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.
2. **Settings**: Used to select various software options, described in detail below.
3. **About:** Displays the version of the software/license information.
4. **Help**: Displays a PDF of the system user's manual.
5. **Power**: Used to close the software and shut down the instrument/computer. (Daily shutdown maintenance will be prompted).

Storm Instrument Manager Settings
Clicking/tapping the Settings button brings up the Settings window, which is used to adjust various settings for running the Storm Instrument Manager (these settings can only be adjusted by users with Administrator or GSD Tech Service accounts):
1. **Instrument**: Displays instrument and reader details, including serial number and runtime. Integrated barcode scanner can also be enabled/turned off here (applicable only for models with intelligent sample racks).
2. **Wash/Waste Bottles**: Allows user to turn on/off liquid detection sensing of the wash/waste bottles. Bottle detection icons are displayed in the title bar. User can also choose whether or not Worklist will pause when the wash bottles are empty or the waste bottle is full.
3. **Samples**: Aspiration Failure options allow user to decide what actions will be taken by the instrument when insufficient reagent or sample volume is detected. User can choose to automatically continue worklist (and skip all samples that use the low-volume reagent/skip the low volume sample) or ask the operator for every low-volume reagent/sample.

    Example: If "Ask the Operator" is selected for insufficient sample volume and a low volume sample is encountered during a Worklist run, an alarm window will appear to allow the operator to decide on a case by case basis what to do when insufficient sample volume is detected during sample pickup (the image below is from an instrument with intelligent sample racks):
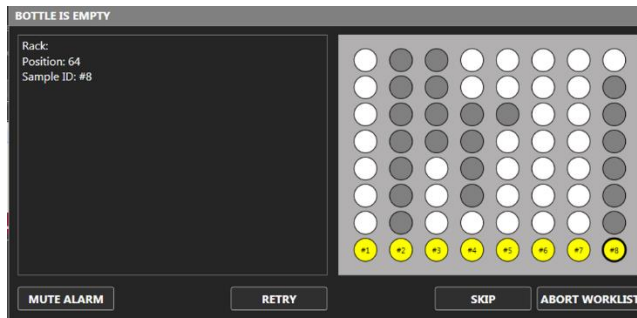
The window will indicate which sample tube requires attention, with the image matching the racks of the instrument model being used.

Note: For models with slide-in racks, the rack indicator light on the front of the sample rack that requires attention will also turn red.

The number of retries when a bubble is destroyed is also selected on the Samples screen of the Settings dialog. (If probe encounters a bubble in a reagent bottle or sample/control tube, it will wash the probe needles and then retry the liquid pickup as indicated per the number of retries selected here.) 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).

4. **Worklist:** Worklist Startup options allow the user to enable/disable the Reagent Loading Wizard (a window which prompts the user to check the volume of each reagent before starting a Worklist run - it is recommended to always enable this wizard) and bottle volume check at the start of a Worklist run. Optimization Options allow 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, the user must select whether the shortest or longest tests are preferred to be run first during the Worklist run.

5. **Strips:** For monotest/strips assays, the user can select the number of foil puncture retries, as well as whether or not to auto-skip strips after timeout/set number of seconds for timeout.

6. **Racks**: Allows the user to enable/disable intelligent rack and tube detection (for models with intelligent sample racks, depending on laboratory's preference), and set reagent rack's and intelligent racks' (applicable models and settings only) size/definition. Use the red 'x' to set default settings, or the '…' to select a different rack definition (if applicable).

Note: User will be prompted to realign the instrument probe if a new rack definition is selected.

7. **Server**: Allows the user to set the server location as the local computer or a remote computer and set IP Address. The user also selects the maximum number Worklists to include in the Worklist history display on the Evaluation screen (this does not delete Worklists from the database).

8. **Colors**: The user can select desired color theme and accent color for the user interface.

9. **Sounds**: Allows the 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 red 'x' to set default settings, or the '…' to select different sounds.

10. **Languages**: The 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.
11. **Touch Screen**: Allows the user to turn on/off the on screen keyboard for use with touch screens.
12. **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.
13. **Notifications:**
    User can decide if they receive SMS (text messages) or Email notification when alarms or events occur during a run while their operator profile is loaded.
    Additional user notification can select more users be notified when specific events occur when *anyone* is running a worklist.
14. **Maintenance:** Allows the user to decide which day and time weekly maintenance will be prompted by the software, as well as whether weekly maintenance should be prompted/performed at system startup or system shutdown.

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 should 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:** Perform all Daily and Weekly Maintenance tasks as prompted by the Storm Instrument Manager each time instrument is turned on/software is opened. Prior to the first use of the instrument during a shift/day, verify that the maintenance tasks are up to date by checking the Maintenance Log.

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

2. **Check Settings:** Be sure to adjust/view the Storm Instrument Manager Settings (described in previous section) as necessary prior to running a Worklist (Administrator privileges required).
3. **Prepare Materials:** 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 screen 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:
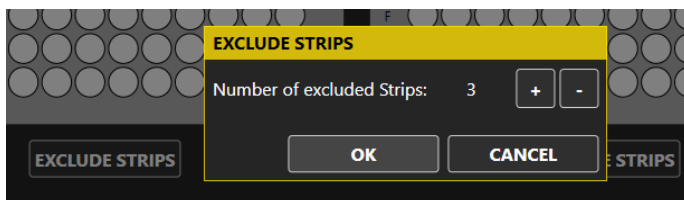
For example, if the first 3 columns of the plate should not be used, 3 strips should be excluded; reaction wells will be placed beginning in column 4 (after completing the necessary steps to run a Worklist on the other screens as described in the following sections):
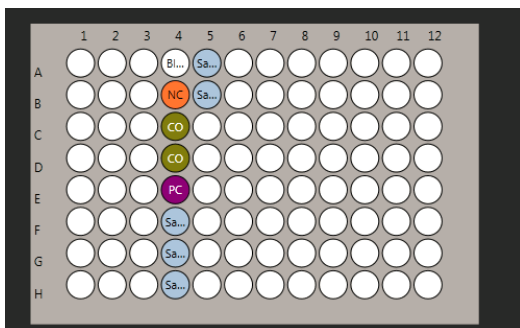
2. **Preload Sample Racks (applicable only for models with intelligent sample racks):** Prior to, or during, a Worklist run, the user can preload racks with sample tubes (outside the instrument) to be used in future Worklists. To preload racks:
    a. On the Worklist screen, click 'Add Samples' and select '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 X-XXXX. The first digit is the rack type (1 for a 12mm rack, 2 for a 16mm rack, or 4 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' after each sample entry method is complete, and then 'Close' when sample addition to the preloaded rack is 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/tap the 'Remove Preloaded Racks' button. Select the rack(s) to remove from the list (selection is highlighted) and click/tap 'Remove'.

Note: Preloading Sample Racks option is only available on models with intelligent sample racks when the intelligent rack detection is disabled.

5.2. Worklist Screen

The Worklist screen is used to select samples and tests for the Worklist. The following steps are taken to complete this screen:

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. **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, and can be re-ordered by dragging and dropping.
    a. **Test Properties**: Click/tap on each test name (once test is added) 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. Click/tap 'OK' to save changes.

Note: Test properties may also be added via barcode scanning using the 'Scan Barcode' option in the Test Properties window (if test is configured for barcode scanning of test properties).

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 screen of the Storm System Configuration Tool.
d. **Remove Test:** Any added test can be removed from the Worklist by selecting it in the Remove Test drop-down list.

3. **Add samples**: Click/tap the 'Add Samples' dropdown button, and select 'Add Samples to Worklist' item. 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.

Note: the Racks view in the background will appear differently depending on the model of the ThunderBolt instrument being used (Intelligent Sample Rack model versus Slide-in Rack model). These differences are shown below:

Models with Intelligent Sample Racks
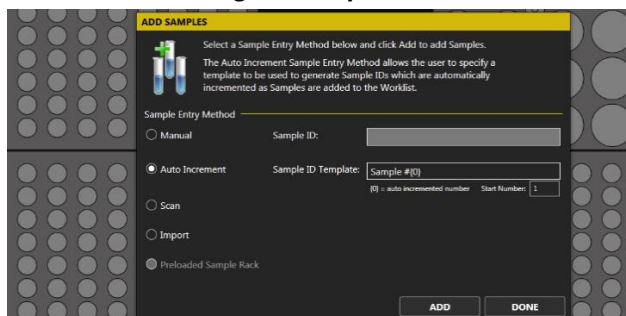
Models with Slide-In Sample Racks
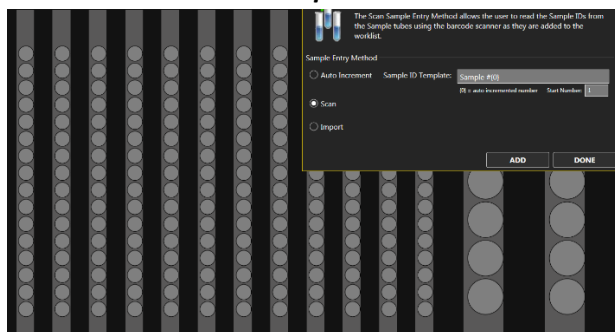
Sample Entry Methods

Use the radio buttons to select the Sample Entry Method. Follow the detailed on-screen instructions for placement of samples using each method, as applicable for instrument models with intelligent sample racks or slide-in sample racks.

a. **Manual (applicable only for models with intelligent sample racks):** 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.

Note: For models with slide-in sample racks the Manual sample entry method is only available as an option when the barcode scanning system detects one or more sample tubes as being present in the rack(s), but is unsuccessful in reading the sample barcode(s).

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.

   i. **For models with intelligent sample racks:** (barcode scanner light will turn on when selected). Click/tap 'Add'. Scan the barcoded sample tube approximately 4 inches (10 cm) in front of the built-in barcode scanner (or use a handheld scanner attached by USB if desired). When the sample is recognized, a beep will be heard, and the scanner light will turn off. Place the sample in the rack as prompted and repeat for all barcoded samples.

   Note: A tube must be placed in order for the scanner to reactivate to continue loading additional samples (if intelligent rack tube detection is enabled).

   ii. **For models with slide-in sample racks**: (camera scanner will turn on and move into position when selected). Click/tap 'Add'. Physically place all desired barcoded sample tubes into the slide-in racks with labels facing outward. As prompted, use the rack handle to carefully slide each rack into the indicated position on the slide-in rack deck (as indicated by the green LED). When all tubes of a rack are detected/read, the system will prompt for the next rack to be added, proceeding from left to right until all racks are in place. If any problems with tube/barcode recognition are encountered, the user will be alerted to retry or use another sample entry method.

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 position locations prior to adding samples to the Worklist.

e. **Preloaded Sample Rack (applicable only for models with intelligent sample racks):** 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 and place it into the indicated position inside the instrument (Scanned barcode must match the selected rack in order to add the rack to the Worklist). Repeat to add additional preloaded sample racks to the Worklist.

Note: This Sample Entry Method is only available for use when intelligent rack tube detection is disabled.

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

Important Notes for Models with Intelligent Sample Racks
Tube Detection: If intelligent rack tube detection is enabled, samples can be placed in any desired locations in the sample racks. If intelligent rack tube detection is not enabled, samples must be placed in the designated blinking positions.
Tube Placement: While placing samples, verify that samples are recognized (spaces with loaded samples display yellow or blue; unoccupied spaces remain white or grey). If sample tubes are removed prior to starting the Worklist run (and intelligent rack tube detection is enabled), they will be removed from the Worklist, and their identification will be lost. To be included in the Worklist run, they must be added again using one of the Sample Entry Methods described below.

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; user will be prompted to change the sample ID during sample addition if a sample with a duplicate ID is added.

Important Notes for Models with Slide-In Sample Racks
Tube Placement: Samples can be placed in any desired locations in the sample racks; empty spaces are permitted in any sample location(s). While placing samples, verify that sample tubes are pushed all the way down into the racks and that all barcode labels are facing outwards.

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.

Rack Placement: If a rack is slid into place too quickly, an error will be shown in the software and user will be prompted to try scan again.
Sample IDs: Duplicate sample IDs are not permitted; user will be prompted to change the sample ID during sample addition if a sample with a duplicate ID is added.

4. **Complete Additional Sample 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:** Use this dropdown to change the replicate of highlighted sample(s). Use the preset multiplication factors or enter a custom multiplication factor (use the + and – buttons in the Multiply Samples window) 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 Worklist screen. 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.) Multiple samples may be selected and moved as a group, if desired.
    d. **Set Runtime Dilution:** Set the runtime dilution for each sample/test (only applicable for tests which contain runtime dilution options).
5. **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.
6. **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.
    a. 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.
    b. 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.
    c. 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 Worklist screen that has been properly prepared for a Worklist run:

#	SAMPLE ID	Rack Position	ELISA_IgM_GSD	ELISA_IgG_GSD	
1	Sample #1	1:1	✔	☐	
2	Sample #2	1:2	✔	☐	
3	Sample #3	1:3	✔	☐	
4	Sample #4	1:4	☐	✔	
5	Sample #5	1:5	☐	✔	
6	Sample #6	1:6	✔	✔	
7	Sample #7	1:7	☐	☐	
8	Sample #8	1:8	☐	☐	
9	Sample #9	1:9	☐	☐	

Name: First Daily ELISA Worklist Lab XYZ

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

7. **Perform Additional Worklist Screen Actions (as needed):**
    a. Use the New button to discard all current worklist information (name, added tests and samples, sample selection) and begin entering information for a new worklist. This

button should always be used between runs (when instrument remains on after the first run of the day and user desires to run additional worklist(s)).

b. Use the Load button 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.

Note: The intelligent rack is disabled when a Worklist is loaded (even if it was previously enabled when original Worklist was run).

Note: Samples may be deselected or removed from a loaded worklist, if desired.

c. Use the Save button to save the current Worklist with a new file name or to overwrite a previously saved Worklist file.

5.3. Racks Screen

The Racks screen 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 screen:

1. **Load Reagents**: Load reagents into the instrument reagent rack using appropriately sized reagent adapters and following the colors/descriptions indicated on the screen, according to the instrument model in use:
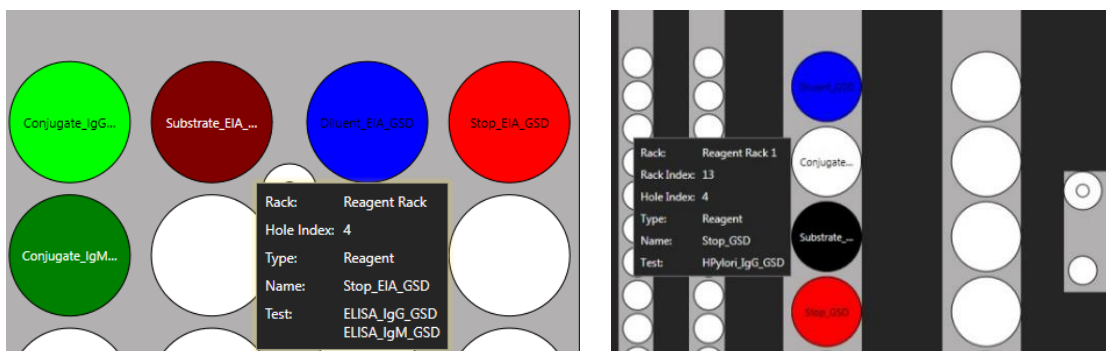
a. Use appropriate reagent adapters. Be sure the notched edge of each reagent adapter is facing forward.

b. 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.

Note: Depending on the test file and the number of samples being run, bottle may be split automatically. In this case, two identical reagent positions will be indicated on the Racks screen.

c. Reagent locations are automatically assigned according to the instrument model being used. For models with intelligent sample racks, reagent positions are assigned starting in the back left corner of the reagent rack and proceeding to the right across the rack, then

continuing back to front in rows. For models with slide-in sample racks, reagent positions are assigned starting in the back of the leftmost reagent rack and proceeding to the front of the rack, then continuing to the rightmost reagent rack (back to front).

2. **Load Calibrators and Controls**: Place prepared calibrator and/or control vials into the indicated locations in the sample rack(s), according to the instrument model in use:
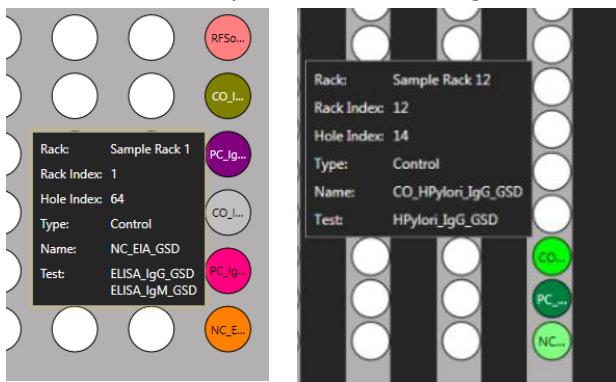
a. Calibrator and control locations are automatically assigned to the first available rack position, beginning with the front right corner and proceeding to the back of the rack, then continuing right to left across the rack (s).

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

3. **Samples**: Verify the placement of all loaded samples in the sample racks, according to the instrument model in use.

4. **Check**: Check for/remove any bubbles from reagent/calibrator/control/sample bottles/tubes.

5.4. Microtiter Plates Screen

The Microtiter Plates screen is used to determine the number of wells/strips/plates required for the run by displaying all well locations on the microtiter plate (MTP) positions and the predilution plate position:
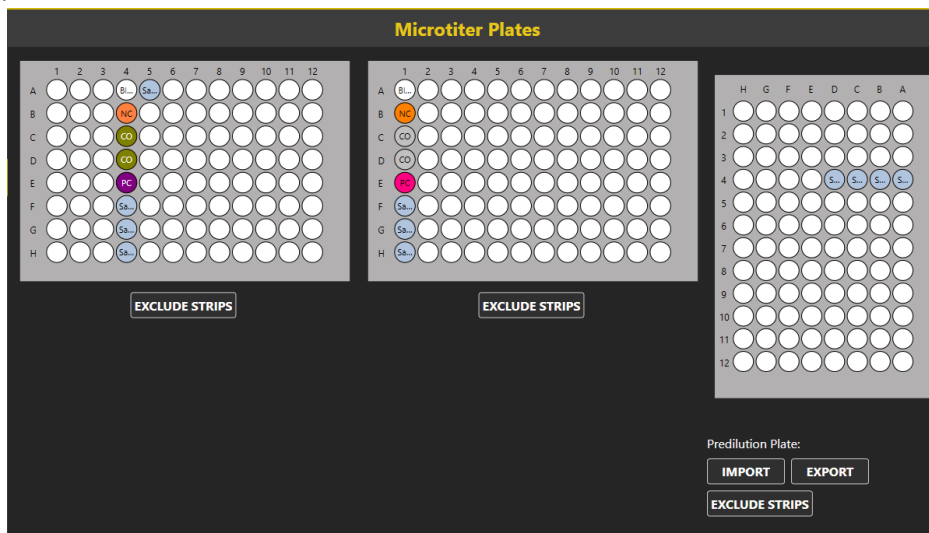
Additional information about each well is displayed on the screen when hovering over the well. The following steps are taken to complete this screen:

1. **Verify**: Visually confirm that all desired test wells and samples appear on the MTP layout in the correct plate locations.

   Note: Control wells may be positioned before and/or following sample wells, depending on the test file being run.

2. **Obtain 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. **Place Frames**: Place the plate frame(s) with the appropriate wells onto the MTP carrier.
4. **Additional Microtiter Plates Screen Options (optional)**:
   a. **Exclude Strips**: This option, which allows tests to start in plate positions other than the default A1 position, can be set during Worklist preparation (as described in previous section) or at this point, after tests and samples have been added to the worklist.
   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.

         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.

5.5.   Home Screen

The Home screen displays the system status including details about the currently loaded Worklist, a timing diagram of the Worklist run, and the internal live camera feed of the instrument. This screen is used to start, monitor, pause, and/or stop a Worklist run. The following steps should be performed on this screen before starting a Worklist run:

1. **Verify**: Verify that the Worklist name, the operator, the number of samples loaded, and number of tests to run is correct.
2. **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).

3. **Timing**: View the anticipated worklist timing in the Status section. Hover over each colored bar to display additional information about each action:
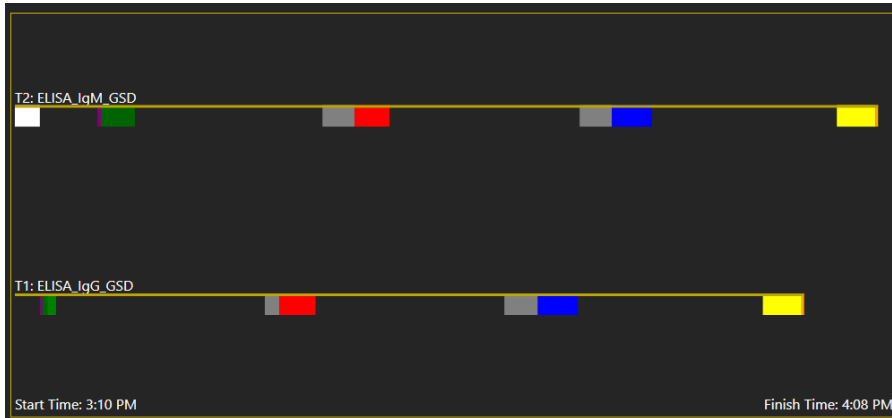
Start a Worklist Run

To start a Worklist run, the user clicks/taps the 'Start' button.

Note: the 'Special Start' button can be used to start the Worklist run from a stopped/aborted position (if a Worklist run was previously stopped/aborted), 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).

At the beginning of a Worklist run the Storm system will prompt the user as follows:

1. **MTP Check**: The Storm system will prompt the user to check that the MTPs are loaded properly. The user should check that the required MTPs are placed in the MTP carrier and seated correctly.
2. **Reagent Loading Wizard (optional)**: If the user has enabled the Reagent Loading Wizard, the Storm system will prompt the user to check that the required reagents are loaded and that the wash/reagent and calibrator/control volumes are correct. If multiple bottles of a single reagent are required to accommodate the indicated reagent volume, use the 'Split Bottle' option within the wizard window to load additional bottle(s), if not prompted automatically. A split bottle can also be removed, if desired, using the 'Remove Split Bottle' button.
3. **Strips Loading Wizard (optional)**: If the Worklist contains Strips Tests (mono-test format assays, i.e. GSD EZStrips), the Storm System will prompt the user to scan and load the stips into the MTP Carrier .
   a. Scan the barcode on the strip packaging and load the strip into the appropriate position on the instrument.
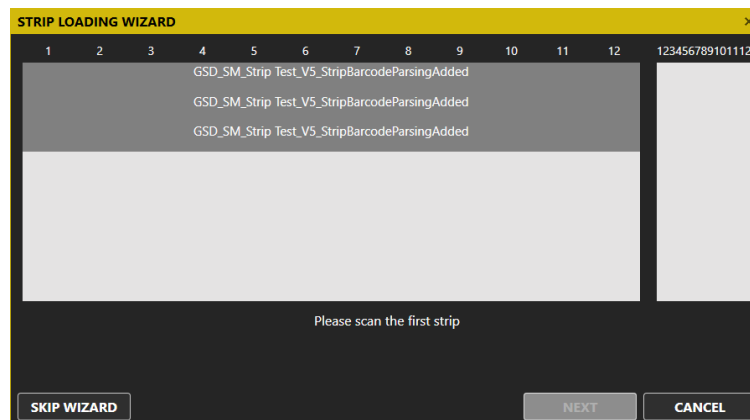
Note: The Strip Loading Wizard may be skipped using the Skip Wizard button.

4. **Cover Check**: If the cover to the instrument is open, the Storm sytem will prompt the user to close the cover in order to begin the Worklist run.

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

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

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

<u>Worklist Run Completion</u>
At the completion of a Worklist run the Storm Instrument Manager will notify the user with a prompt that the run has completed. The user can click/tap 'OK' to dismiss the prompt and stop the audio alarm (if end of run sound is enabled). The user should perform the following tasks after a Worklist run.

1. **Remove Kit Components/Samples**: Remove microtiter plate(s), reagents, controls, and samples from inside the instrument. Ensure that all instrument surfaces are clean and dry, and close the cover.
2. **Evaluate Results**: The lab technician, or other designated laboratory employee, can review/display/export/send Worklist and/or sample results on the Evaluation screen 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 screen as each test finishes (even if remaining test(s) in the Worklist is/are not yet completed). The user can view results for completed test(s) while Worklist is still in progress.

   Note: Sufficient user rights are required to review worklists and/or send results to the LIS.

3. **Perform Maintenance**: If the completed Worklist 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).

6. Evaluation, Analysis, and Search Screens

After a Worklist is completed, various options are available for evaluation and review of results in the Storm Instrument Manager Evaluation, Analysis, and Search screens. These screens 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 Screen

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

Worklist Review:

1. **Select a Worklist:** Select a Worklist to view (by Worklist name) from the dropdown menu on the top left:
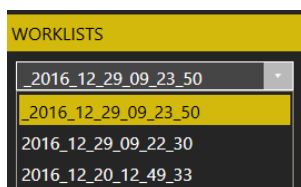
Worklists are listed in order of date with the most recent at the top of the list and most recent Worklist selected by default. Once selected, the Worklist report from the selected Worklist is shown on the right.

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 screen, and results for any completed test(s) from that Worklist can be viewed. As additional tests from the Worklist finish, a 'Refresh Report' button will be available. Click/tap this button to refresh the Worklist report shown to include newly available results.

2. **View Worklist Errors:** Click/tap the 'Worklist Errors' button (this button will be disabled if the Worklist run did not contain any errors) to view/export any errors or anomalies from the Worklist run. Worklist run errors are also included on the Worklist report.

3. **Modify Worklist if needed (requires Administrator rights):** Use the 'Drop Replicas', 'Result Options', and 'Change Test Properties' buttons to make any necessary changes to the selected Worklist.

    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'. The Evaluation screen will refresh to display the Worklist report with the selected well(s) ommited 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 run (lot number, expiration date, or runtime variables), click/tap the 'Change Test Properties' button to modify test properties as needed. The Evaluation screen will refresh to display the Worklist report with modified test properties information.

c. Result Options: This button is only intended to be used in very specific circumstances by an administrator to modify well results. Inquire with technical service for additional information.

4. **Mark Worklist as reviewed (requires at least Super user rights):** After reviewing the Worklist report and making any desired modifications to the Worklist, check the Worklist Reviewed box. The Evaluation screen 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:
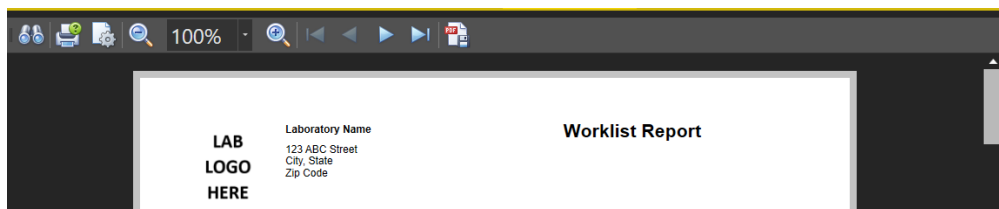
If desired, use the 'Export Worklist' button to display the Worklist report in a separate window or export the Worklist results to Excel or TSV files. Use radio buttons and dropdown menu in the pop up window to make desired selection.

6. **Send to LIS (requires at least Super user rights):** 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'.

Note: The pop up window will indicate if the worklist includes tests which do not have a properly configured LIS Association.

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. Analysis Screen

The Analysis screen is used to analyze test summary statistics, levey-jennings calculations, and temperature profiles.

1. **Test Summary Statistics:** Select tests to analyze as well as date range to include in analysis. Click/tap the 'Generate Report' button to display results. A Test Summary Statistics Report will be generated, containing information about the number of runs, samples, and wells of each

selected test, along with lot number data. An excerpt from such a report is shown here:

Test Summary Statistics for Date Range:	5/27/2016 - 5/27/2017			
Test	Runs	Samples	Wells	Lot Numbers
T3	13	200	2,642	0123456789, 987654321, 65748291
T4	15	250	3,767	0189, 0421, 6591
Influenza IgG	10	175	1,796	0189223, 4298651, 6592361

This report can be printed or exported as desired.

2. **Levey Jennings:** Select a test to analyze from the dropdown menu. Then select which controls to analyze, along with which tables and graphs should be displayed. Analysis can be restricted to certain lots or certain dates, as desired. Click/tap the 'Generate Report' button to display results. A report with the Levey-Jennings analysis of the specified controls will be generated. This report can be printed or exported as desired.

3. **Temperature Profile:** Select one Worklist from the dropdown menu for which to analyze temperature data. Select which temperature(s) to include in the analysis. Click/tap the 'Generate Report' button to display results. An excerpt from such a report is shown here:
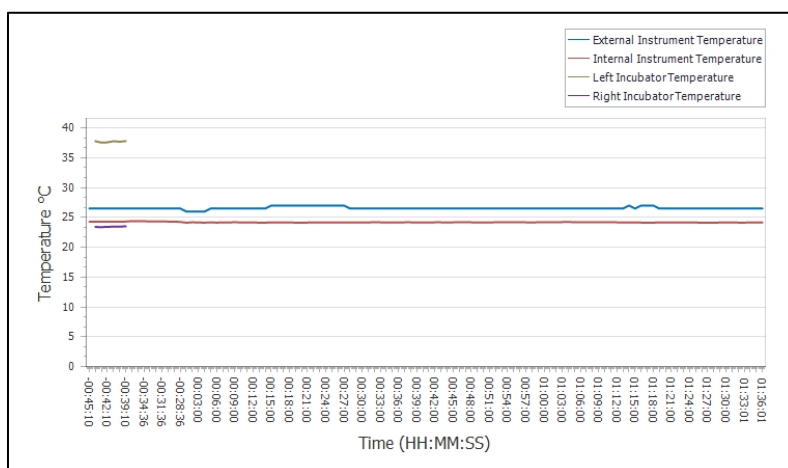
This report can be printed or exported as desired.

6.3.   Search Screen

The Search screen is used to search for and create search reports for previous Worklist runs.

1. **Search**: Enter all desired search criteria (multiple criteria are allowed) using the checkboxes, text fields, and dropdown menus/date selection tools in the Search Fields section; then click/tap the Search button.
    a.   Searches can be made based on Sample ID, User, Worklist, Test, Instrument, and date range.
    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 screen.
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 Screen

The Tools screen displays the instrument functions that may be utilized outside of a normal Worklist run. These functions are available for use any time that a Worklist is not running and are organized into sub-categories as shown below:

Tools

General   Plate reading   Alignment   Calibration
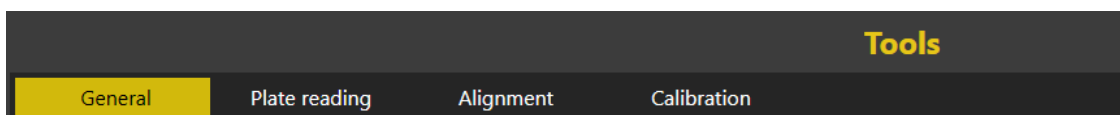
7.1.   General

1. **Home Instrument:** Use this button to "home" the instrument, just as is done automatically at Storm Instrument Manager startup. The probe and MTP carrier will move to the back of the instrument and then to their "Park" positions.
2. **Park Instrument:** Use this button to reset the instrument back to its starting, or "Park" position (with the probe assembly above the wash 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.

   Note: For models with intelligent sample racks: Make sure the Sample tray is pushed back before priming and do not move it during priming, as indicated by the software prompts.

   Liquid from the wash bottle(s) will be pulled through the instrument fluidics system as the progress bar tracks priming cycle progress. Priming can be interrupted using the Stop button.
4. **Shake Plates:** Use this button to manually shake a plate/plates. Select preferred speed using the +/- buttons. Use the Start and Stop buttons or set timer if desired.
5. **Heat Plates:** Use this button to manually incubate a plate/plates. Select preferred temperature using the +/- buttons. Use the Start and Stop buttons to turn incubator on and off.
6. **Internal Lights:** Use the slider bar to adjust default light intensity of the interior LED lights.
7. *Maintenance Logs:* Click/tap to view dates/times of all recent maintenance events (priming, probe and reader auto alignment, reader calibration, wash pump calibration). Select a month to add notes to that month's maintenance log or to display a maintenance report with all maintenance actions for that entire month (included any added notes), which can be saved/exported and/or printed.

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

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 manual read pop up windows, select

desired wells to be read using cursor to highlight. CTRL and SHIFT buttons can also be used to highlight specific wells on either/both the left and right plate(s).

Set the applicable options for the read type:

1. **Read Plate ODs:** Set measurement wavelength and reference wavelength (optional).
2. **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(s) is/are read. When read is complete, export readings using the Export to TSV button or print using the Print button.

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

7.3. Alignment

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.

Manually Align Probe/Auto Align Probe

The manual and auto probe alignment processes are performed to align the probe with the reagent and sample racks and microtiter plates. Either equivalent process may be used, according to laboratory preference, and if available on the instrument model being used.

General Information

1. Perform and record probe alignment or auto alignment as part of routine instrument maintenance, when prompted by the Storm Instrument Manager.
2. If a probe 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 probe 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 probe alignment/auto alignment processes.

Auto Align Probe Instructions:

1. Preparation:
    a. For rack alignment:

i. Models with Intelligent Sample Racks: 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:

Place empty sample racks in each of the three sample rack positions. There should be NO sample tubes in the sample racks.

ii. Models with Slide-In Sample Racks: Remove the racks from the positions indicated by the software. Place the three alignment adapters into the indicated rack positions, as prompted. Be sure that adapters are fully seated:

b. For plate alignment: Place one auto alignment plate in each of the three MTP positions on the MTP carrier. Be sure that plates are seated flat/securely.

c. Make sure all applicable racks are positioned inside the instrument (with any alignment components fully seated) and click/tap the Auto Align Probe button. A pop up window will appear and provide instructions for each auto alignment step.

2. Alignment:

a. Align the probe needles to the edge of the MTP carrier as prompted. The Y axis (front to back) position of the probe must be exactly above the rear carrier lip:
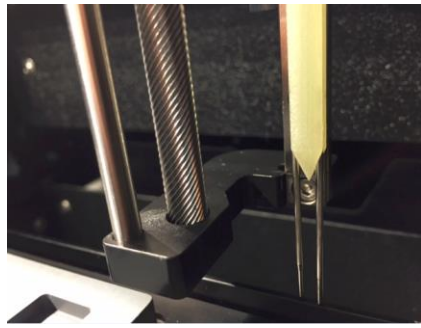
  b. Only the Y axis position is important at this step .

  c. The correct position has been obtained when the needles can be moved down until the red light turns on, while touching the lip of the carrier.

  d. After verifying that the auto alignment components have been properly placed inside the instrument and clicking/tapping Next Step, wait while the instrument proceeds automatically througout the remainder of the probe auto alignment process (This step takes approximately 10-15 minutes). DO NOT touch the instrument during this time.

3. Completion:

  a. Click/tap 'Finish' when prompted to complete and save the probe auto alignment and exit the Auto Align Probe window (instrument will return to its home position). Remove the auto alignment components, and replace the cuvette (if applicable for the instrument model being used).

Manually Align Probe Instructions (applicable only for models with intelligent sample racks):

1. Preparation:

  a. Place empty sample racks in each of the three sample rack positions.

   Note: If intelligent rack detection is disabled, verify that the proper sample rack sizes have been selected in the Storm Instrument Manager Settings before starting the Manually Align Probe process.

  b. Place one alignment plate or empty MTP in each of the three MTP positions on the MTP carrier. Be sure that plates are seated securely.

  c. Slide the tray in and click/tap the 'Manually Align Probe' 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).

MTP well alignment: Align the center of the probe needles to the center of each indicated reaction plate or predilution plate well:
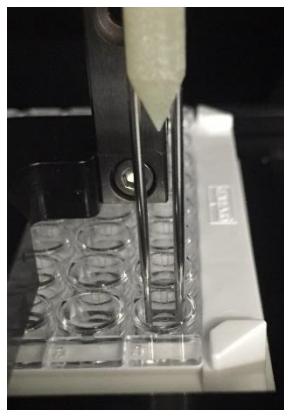
It is not necessary to move the probe needles to the bottom of the wells, only far enough to clearly see the needle position in the wells.

3. Completion:
   a. At the final alignment step, remove the alignment plates or empty MTPs as prompted (If these are not removed, the Z axis position cannot be properly set). Ensure that the probe is centered above the left MTP carrier position, as prompted. The correct placement of the probe is with the tip centered between four holes and roughly above the word "Hot" printed on the incubator surface:
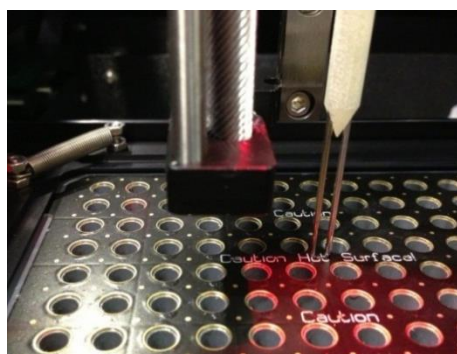
b. Click/tap Finish when prompted to complete and save the alignment and exit the Manually Align Probe window (instrument will return to its home position).

Auto Align Reader

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

General Information

1. Perform and record reader auto alignment as part of routine instrument maintenance, when prompted by the Storm Instrument Manager.
2. If a reader auto 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. Move the reader or 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 LED guide light to the left and right.
    b. Use the up and down arrow keys to move MTP carrier toward the front and back of the instrument.

Auto Align Reader Instructions

1. Preparation:
    a. Remove all microtiter plates and alignment plates from the MTP carrier.
    b. Click/tap the 'Auto Align Reader' button. A pop up window will appear and provide instructions for each alignment step.
2. Alignment:
    a. Verify that the reader LED guide light is in the center of the hole under the upper left A1 position when prompted. Adjust positioning as necessary.
    b. 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 Auto Align Reader window (instrument will return to its home position).

7.4.   Calibration

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

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

Calibrate Wash Pump

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

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 screen and in the Maintenance Reports subfolder of the instrument's Storm Documents folder.) The information below describes the routine maintenance steps for the 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. Ensure that all wash buffers are within their expiration date prior to each use.

Shutdown

1. Use the Power button within the Instrument Manger 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. Ensure all instrument surfaces are clean and dry.

8.2. Weekly Maintenance

Weekly maintenance includes cleaning 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 racks and inspect each one for cleanliness and damage. Use an alcohol wipe to gently clean all sample racks.
2. Clean the reagent rack(s) and the intelligent rack or slide-in rack deck with an alcohol wipe.
3. Clean the outside of both probe needles by wiping them down gently with an alcohol wipe.
4. 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.

5. It is recommended that any wash bottles used be cleaned weekly to avoid contamination.

8.3.   Monthly Maintenance

Monthly maintenance includes alignment of the instrument probe and reader, as well as changing the tubing of the waste pump.

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

1. Perform Probe Alignment (either Auto or Manual alignment) as described in detail in a previous section of this manual.
2. Perform Reader Auto Alignment as described in detail in a previous section of this manual.
3. If instrument contains a peristaltic waste pump (older models only), monthly waste pump tubing replacement is also required. Contact local instrument distributor for detailed instructions.

8.4.   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.

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

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

All LIS Settings are found within the LIS Communication and LIS Mappings screens of the Storm Configuration Tool. LIS is queried from the Samples screen of the Storm Instrument Manager during Worklist setup and results are sent to the LIS from the Evaluation screen of the Storm Instrument Manager after a Worklist 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, software version, and instrument serial number are displayed.

Example:
H|\^&|||STORM^2.0^172901-021|||||||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||^^^CMVG|R
In this example, the Sample ID is "S004", the test name is "CMVIgG".

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|^^^CMVG|1.33|ng/ml||||F
R|1|^^^CMVG|1.33^high|ng/ml||||F
R|1|^^^CMVG^Subtest1|1.33|ng/ml||||F

9.2.   LIS Query and Transmission Examples

Example 1: Query of sample IDs

Instrument → LIS

H|\^&|||Thunderbolt 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||^^^CMVIgG|R
P|2||S002
O|1|S002||^^^CMVIgG|R
O|2|S002||^^^HPLIgG|R
P|3||S004
O|1|S004||^^^CMVIgG|R
O|2|S004||^^^HPLIgG|R
L|1|N

Example 2: Transmission of results

Instrument → LIS

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

Example 3: Transmission of multiple test results per patient

Instrument → LIS

H|\^&|||Thunderbolt EIA^0.42.0.73|||||||P|LIS2-A2|20101022162157
P|1||S001
O|1|S001||^^^CMVIgG|R

R|1|^^^CMVIgG|1.33|ng/ml||||F
O|2|S002||^^^HPLIgG|R
R|1|^^^ HPLIgG|1.24|ng/ml||||F
L|1|N

Example 4: Transmission of multiple subtest results per patient

Instrument → LIS

H|\^&|||Thunderbolt EIA^0.42.0.73|||||||P|LIS2-A2|20101022162157
P|1||S001
O|1|S001||^^^CMVIgG|R
R|1|^^^CMVIgG^ST1|1.33|ng/ml||||F
R|2|^^^CMVIgG^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. Also 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. If the Storm system is connecting to the LIS using a TCP/IP connection, then an Ethernet cord must be connected to the system. If the Storm system is connecting to the LIS using an RS-232 connection, then a RS-232 serial cord must be connected to the system.
3. Select correct settings within the Storm Configuration Tool LIS Settings section. These must be entered before any communication with LIS is attempted. Select appropriate settings according to LIS being used:

  a. In the **RS-232 Connection** section, set the baud rate, data bits, parity, and stop bits of the port (select instrument or computer serial port). Select Flow Control setting.
  b. In the **TCP/IP Connection** section, set the Server address and the Server port of the LIS TCP Server. 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 Associations screen. List all LIS names and corresponding test file names, being careful to copy codes exactly as they are used in the LIS system.

   Note: 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.
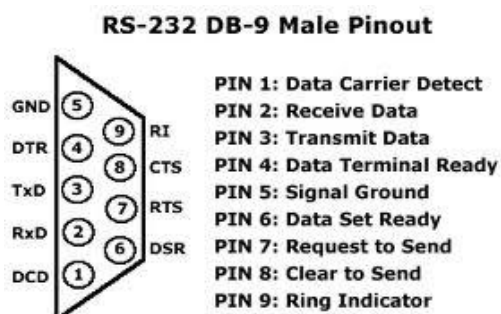
5. Set up a Worklist to test connectivity:
   a. Open the Storm Instrument Manager software and log in as a super user or administrator.
   b. Follow standard Worklist setup procedure:
      i. Add tests, being sure to enter a valid expiration date for each.
      ii. Add samples, verify on the Worklist screen that they have been added to the samples list.
   c. Verify in the LIS system that the samples that were added actually have pending orders for the tests that were selected in the Worklist.
   d. Test the Query LIS functionality. On the Worklist screen, test the receiving capability of Storm by clicking/tapping the 'Query LIS' button. If connectivity is working properly, checkmarks will appear in the appropriate check boxes next to the Samples on the Worklist screen.
   e. Test Send to LIS functionality.
      i. Run the Worklist using the Special Start from Specific Position option on the Home screen and start from the read step of the test.

         Note: If reading is not performed, there will be no valid results or information that could be transferred to the LIS.

      ii. After the read is complete, navigate to the Evaluation screen.
         1. Mark the Worklist as reviewed.
         2. Click/Tap the 'Send to LIS' button.
         3. In the Send to LIS dialog, select which results to send and click/tap 'Send'.

   If connectivity is working properly, results will be transmitted and appear in the LIS with the corresponding test code.

9.4.   RS-232 Pin Layout

RS-232 DB-9 Male Pinout

GND (5)
DTR (4)   (9) RI
          (8) CTS
TxD (3)
          (7) RTS
RxD (2)
          (6) DSR
DCD (1)

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

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 (s) and predilution plate is/are correctly loaded and seated securely.
		Check that sufficient strips/wells are placed.
		Check positions of probe during probe alignment. If misaligned, realign probe and restart.
	Does instrument display a clog error?	Prime 10x, lift probe briefly (1-2sec) to check for steady dispense flow. If dispensing appears correct, restart run. If not, carefully use stylet to clean probe.
		Check if blue liquid detection light is functioning properly by placing a small tube of liquid beneath the needles. Blue light should go on when in liquid and turn off when out of liquid. If light is not responding correctly, check for secure connections at the white connector above the probe and at flat cable connection points near the probe. If problem still persists, contact technical service.
		Check aspiration and dispense during priming. Replace waste tubing if needed (as indicated for monthly maintenance- older models only).
	Is the blue light constantly on?	Remove probe, clean with alcohol, dry it off from top to bottom, allow to sit for several hours. Carefully replace and check all tubing and electrical connections to the probe.
Sample(s) not pipetted during run	Are the samples also missing from the Microtiter Plates screen?	If missing samples are not selected on the Worklist screen, select them and rerun. If missing samples do not appear on the Worklist or Racks screens, re-add them to Worklist and reselect them.
Samples disappear from sample list (models with intelligent racks)	Are the samples flickering/beeping?	Check to make sure that samples are being placed all the way to the bottom of the intelligent racks. If the sample rack and sample tubes being used are not matching sizes, place samples in the appropriately sized rack.

Issue	Details	User Action
Run stops in the middle of a Worklist	Is there an IO or read/write error message displayed?	Power off computer and instrument, unplug/replug power and USB connections, and restart. Load Worklist and special start from aborted position. If problem persists, contact technical service.
	Is the machine jammed during the read step?	Turn off machine, carefully remove plate and move reader back, load Worklist, place plate back in, special start Worklist from the read step.
	Is the probe assembly jammed?	Make sure there are no obstructions to probe movement. Make sure probe tubing is zip-tied to flat cable and not being caught anywhere.
	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.
Waste Bottle alarms during run	Are there bubbles or liquid on the waste sensor needles or the white plastic waste connector?	Wipe connector and needles completely dry. If alarm persists, disable waste bottle alarm in Wash/Waste Bottles section of Storm Instrument Manager Settings.
	Is unused wash bottle being sensed as empty?	Disable Wash bottle 2 alarm in Wash/Waste Bottles section of Storm Instrument Manager Settings.
Failed Run	Were cold reagents or wash used?	Make sure to allow all reagents to come to room temperature before start of Worklist and rerun.
	Were reagents from different lot numbers used on the same run?	Rerun with reagents all coming from the same kit lot.
	Was there a pause during the run due to insufficient reagent volume?	Be sure reagent loading wizard is enabled. Use appropriate volumes and split bottles if necessary. Rerun Worklist.
	Did user forget to prime instrument before the start of the Worklist?	Prime instrument 10 cycles per line used with wash buffer and rerun Worklist.
	Are controls significantly out of range?	Check that correct ranges are entered for the kit lot being run. If using site-specific ranges, ensure that these are entered. Use Change Test Properties button on Evaluation screen and view updated report.
	Are controls just barely out of range?	Special start Worklist to reread MTPs, and generate another report. If controls still fail, contact technical service.
		If controls and calibrators were not vortexed or mixed before run, gently mix them and rerun Worklist.

Issue	Details	User Action
Failed run (cont.)	Do points on curve appear out of order on report? Do high and low controls appear switched?	Check if physical positioning of calibrators and controls in sample rack matches Racks screen. If not, contact technical service to produce a manual report.
	If test is in duplicate: Do calibrator/control replicates show large differences?	Contact technical service to produce a manual report, omitting the outlier control/calibrator replicate(s) or use the Drop Replicas option on the Evaluation screen.
	Does it appear that only a single calibrator or control is missing?	Check for sufficient volume and bubbles in reagents/calibrators/controls. Rerun with sufficient volume, bubbles removed. *Note: Even if no bubbles are observed at the end of the run, a bubble could have caused the problem and later popped.*
	Do all OD values on report appear elevated?	Check position of red light during reader auto alignment. If misaligned, realign reader and reread plate.
		Check if kit has been open too long or if it is expired; check physical reagent positions to see if any are switched. If yes, rerun with new, correctly placed reagents.
		Check aspiration and dispense during priming. Replace waste tubing if applicable (as indicated for monthly maintenance- older models only).
	Do all OD values on report appear low?	Check if kit has been open too long or if it is expired; check physical reagent positions to see if any are switched. Rerun with new, correctly placed reagents.
	Is recorded room temperature on report outside acceptable range?	Rerun Worklist once laboratory temperature is within an acceptable range according to kit package insert.
	Do several calibrators/controls appear to be off?	Check for bubbles in reagents/calibrators/controls. If bubbles are observed, remove them and rerun.
		Check for bubbles in supply line and microsyringe. Prime instrument until bubbles disappear and rerun. If bubbles continue, check tubing for any visible leaks. Contact technical service if problem persists.
		Check pinch valves to ensure that tubing is fully inserted.

Issue	Details	User Action
Flooded Run	Is the flooding inside the wells (wells overflowing)?	Check aspiration and dispense during priming. Replace waste tubing if applicable (as indicated for monthly maintenance-older models only).
	Is the flooding outside the wells on the MTP carrier?	Check positions of probe during probe alignment. If misaligned, realign probe and rerun Worklist.
		Perform a manual shake to check if shaker homes properly at the end of the shake. Repeat manual shake several times to confirm.
		Check if there is a visible clog on the probe. Even if no visible clog is seen, carefully remove probe and use stylet to clean both probe needles.
		Check that MTPs are correctly loaded and seated securely.
		Check that the correct number of wells are loaded in the MTP using the Microtiter Plates screen.
Need to reprint or find past data	Does user know in which Worklist the desired data was run?	Select Worklist on Evaluation screen and print or export Worklist reports as desired. If data is from very old Worklist, it may be necessary to first adjust Evaluation setting on Server screen of Storm Instrument Manager Settings.
Dripping Probe Needles	Is the dripping coming from the dispense needle?	While priming the instrument, follow tubing at the top of the probe and check for any droplets. Remove the left side panel, prime again, and check for any droplets in visible tubing. Check pinch valves to ensure that tubing is fully inserted.
	Is the dripping coming from the aspiration needle?	Check aspiration and dispense during priming. Also remove left side panel and check for any droplets on the tubing. Replace waste tubing if applicable (as indicated for monthly maintenance- older models only).
	Is the dripping/fluid observed after the needles have been sitting for several hours?	Droplets and small amounts of fluid after sitting overnight or following homing are normal. Prime instrument for several cycles and proceed as usual.
Strips do not fit securely in MTP frame	Are different strip types being placed into the same plate frame?	Contact technical service
Common reagents are not being shared between tests	Has the user checked that the reagents to be shared are exactly the same?	Contact technical service

Issue	Details	User Action
Cannot enter new lot-specific information	Is the information necessary for calculations or validation rules?	Contact technical service
Intelligent Rack is not working properly (models with intelligent racks)	Are racks correctly placed on the sliding tray?	Check for any liquid damage on bottom of rack. Be sure that any spills are cleaned immediately and the bottom of the rack is dry. Check the bottom of all sample racks to make sure no metallic objects are stuck on the magnets. Contact technical service if problem persists.
LIS connectivity problems	Are all LIS and LIS Association settings correct in Storm Configuration Tool?	Contact IT.
Resistance (red) or Liquid detection (blue) lights do not illuminate properly.	Is instrument malfunctioning?	Remove probe and clean and dry thoroughly. Check that probe wires are connected to PCB and that flex cable connections are secure. Replace Z axis flex cable, if available and training has been provided. If problem persists, contact technical service.
X,Y, or Z-axis movements are not smooth	Is instrument malfunctioning?	Contact technical service

11.Symbols Glossary

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

12. Contact Information

12.1. Device Manufacturer

	Company Name	Gold Standard Diagnostics Corp.
	Company Address	2795 2nd St Ste 300 Davis, CA 95618
	Country	United States
	Phone	530-759-8000
	Fax	530-759-8012
	Website	www.gsdx.us
	ThunderBolt®	Catalog # 00300; 00300-CL

13. Revision History

Revision	Date	Change
A	6/30/2022	New document for Storm 3.1
B	11/11/2022	Added statement about incident reporting (section 2.1); updated Symbols Glossary (section 11) and Revision History (section 12); corrected format for manufacturer street address (section 13.1).
C	03/16/2023	Removed Authorized Representative section; switched order of sections 12 and 13