GOLD STANDARD℠
DIAGNOSTICS

ThunderBolt® User's Manual

CE

IVD

Contents

1. Introduction

The purpose of this manual is to identify the instrument components and provide instructions for use of the ThunderBolt. 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.

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 ThunderBolt is designed to automate the processing of enzyme immunoassay (EIA) and Chemiluminescent Immunoassay (CLIA) tests. The system is only intended to be used by properly trained personnel.

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

1.2. Certifications

The ThunderBolt is registered and certified as having met the following regulatory requirements:

ISO 13845:2003
EN ISO 13485:2012
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

2. Safety Information

The following safety instructions are to be observed at all times during the operation of the ThunderBolt. It is strongly recommended that all first time personnel read this manual prior to working with the instrument.

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 the instrument functions safely, both electrically and mechanically under normal use conditions. The ThunderBolt is supplied in a condition that allows for safe and reliable operation.

2.1. General Safety

The ThunderBolt must only be operated in accordance with the stated intended use. It is recommended that the ThunderBolt is used only with the consumables and accessories suggested or provided by Gold Standard Diagnostics. The use and maintenance activities defined in this manual are intended to ensure the safety of the operator and the proper functionality of the instrument. All system surfaces must be dry while operating the ThunderBolt. Gold Standard Diagnostics

recommends that all operators be trained in good laboratory practices and observe general laboratory safety guidelines.

2.2. Electrical Safety

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

The use of a multi plug is not allowed and it is recommended that the instrument be run from a dedicated socket. Use only extension cables with a protective conductor and grounded contact. The ThunderBolt 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 ThunderBolt is completed by a trained technician to ensure a minimized exposure of the operator to mechanical risks. Improper handling of the ThunderBolt may cause serious damage to the instrument or result in injury to the user. Avoid touching the probe and other moving parts while the system is in operation. Protective covers should not be removed while the instrument is on due to potential contact with moving parts. Exercise extreme caution when working on or near the peristaltic pump when the cover is not in place. Openings provided for ventilation are not meant as access points into the system.

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

2.4. Biological Safety

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

3. System Description

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

3.1. System

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

The system components are as follows:

1 System Cover
2 Laptop PC (Netbook)
3 Barcode Scanner
4 Intelligent Rack
5 Reagent Rack
6 Microtiter Plate Carrier
7 Probe (with mounted camera)

3.2. System Details

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

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

Width: 64 cm (25.2 inches)
Depth: 57 cm (22.4 inches)
Height: 45 cm (17.7 inches)
Weight: 28 kg (61.7 pounds)

The total bench space recommended to accommodate the ThunderBolt and related equipment is 84.4 cm (33.2 in.) wide x 182.2 cm (71.7 in.) high x 72.2 cm (28.4 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. Component Details

3.3.1. 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 and can accommodate 12, 13 or 16 x 75 mm tubes. Custom racks are also available.

3.3.2. Reagent Rack

The reagent rack contains 16 reagent positions and accepts 22 to 35mm bottles. Custom reagent adapters are also available. The sample racks and reagent rack are located on a sliding tray for maximum accessibility.

3.3.3. Microtiter Plate Carrier

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

3.3.4. Camera

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

3.3.5. 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 1ul and 300ul. The high-precision micro-syringe aspirates 1ul with less than 3% CV across an entire reaction plate. Liquid detection is performed via conductivity, with a minimum detection volume of 50ul.

3.3.6. Barcode Scanner

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.

3.3.7. Incubator

The forced convection incubator heats up to a maximum of 46°C.

3.3.8. 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.

Photometric range: 0 to 3.0 OD
Spectral range: 400 nm to 700 nm
Read time: approx. 2 min/ 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.

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

3.3.9. 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 shake is in motion.

Amplitude: 1 mm
Adjustable speed: up to 900 RPMs
Capacity: 3 MTP (2 reaction, 1 pre-dilution).
Voltage: 24 V

3.3.10. Notebook PC

The included notebook PC is attached to the instrument via a USB connection. The PC also contains ethernet, RS232, and additional USB ports.

PC Minimum requirements are listed below:

Processor:	Intel Atom
Memory (RAM):	1GB
Memory (hard disk):	160GB
Ports:	USB, RS232
Integrated monitor:	800x600 display

3.3.11. Software

The pre-installed MS Windows Graphical User Interface operates using Windows 7 or Windows 8. The software integrates with most LIS systems and provides a fully bidirectional interface.

The ThunderBolt instrument and software comprise an audible system. This system is designed to produce sounds to alert users at various points during use. Computer speakers should be enabled at all times and additional speakers (provided) are recommended.

4. Maintenance

Maintenance procedures should be followed to ensure proper instrument functionality. It is suggested that maintenance activities be recorded using the provided maintenance log. The information below describes the periodic maintenance steps for the ThunderBolt system.

4.1. Daily Maintenance

Daily maintenance includes startup and shutdown steps. Startup steps are performed prior to the first run of the day and shutdown steps are performed following the last run of the day. 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.

4.1.1. Startup

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

4.1.2. Shutdown

1. Prime the instrument using DI Water. A minimum of 10 priming cycles per line is suggested.
2. Ensure all instrument surfaces are clean and dry.
3. Remove any remaining reagents and samples from the ThunderBolt and close the lid.
4. Shut down the instrument by shutting down the attached computer.
5. Empty waste bottle.

4.2. Weekly Maintenance

Weekly maintenance includes cleaning and alignment steps. Weekly maintenance steps are to be performed approximately 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.
2. Use isopropyl alcohol to gently clean racks.
3. Clean the intelligent rack deck with isopropyl alcohol.
4. Clean the outside of both probe needles by wiping them down gently with an alcohol wipe.
5. Gently clean the inside of both probe needles with the stylet provided with the instrument.
   a. Cleaning is performed by inserting and removing the stylet one time into each needle, wiping with alcohol in between.
   b. Care must be taken not to push the stylet past the needles into the tubing.
6. Perform instrument and reader alignments as described in further detail in the Alignment section of this manual.
7. Decontaminate the instrument tubing by priming the instrument 20 priming cycles per line with Liquinox solution.

Note: The Liquinox solution is prepared by making a 1:100 dilution of the Liquinox Concentrate supplied with the instrument, using DI water.

8. Rinse the tubing by priming the instrument 50 priming cycles per line with DI Water.
9. It is recommended that wash bottles be cleaned weekly to avoid contamination.

4.3. Monthly Maintenance

In addition to the weekly maintenance steps, monthly maintenance is performed to replace tubing and prevent issues with the instruments' ability to aspirate liquid. It is recommended that the outer waste pump tubing be replaced once per month at minimum (more frequently in high throughput laboratories).

Monthly Maintenance steps should be performed as follows:

1. Shut down the ThunderBolt prior to opening the waste pump cover. Motors can be damaged if instrument is not powered down prior to tubing replacement.
2. Remove waste pump tubing as follows:
   a. Pull the ends of the tubing off of the white barbed fittings.
   b. Hold the top retaining clip open to remove the tubing. Carefully remove the tubing from around the motor and the bottom clip.
3. Replace new waste pump tubing as follows:
   a. Connect both tubing ends to the barbed fittings.
   b. Insert tubing into the jaws of 1 retaining clip, leaving a small excess of tubing next to the connector.
   c. Push the tubing into place around the motor while simultaneously manually turning the motor to ensure that the tubing is as far into the pump as possible. Once the tubing is placed, there should be an equal amount of excess at both ends as shown below.
   d. Gently tug on both tubing loops to ensure that tubing is securely seated around the pump.

4. Close the waste pump cover prior to powering on the instrument.
5. Turn on the instrument and wait for it to home.
6. Prime the instrument for 1 cycle while visually monitoring the wash cup.
   a. Verify that the wash cup is not filling up with liquid, and that the liquid level in the wash cup is not fluctuating significantly.
   b. Prime for an additional 5 cycles while continuing to watch the levels in the wash cup.
   c. If the liquid level fluctuates significantly or the cup fills with liquid in steps a. or b., readjust tubing and monitor priming again. If problem persists, contact technical service.

4.4. Periodic Maintenance

Approximately every 6 months, a professional maintenance procedure should be performed by a trained service engineer. Service agreements are typically lab-dependent and established to meet the specific needs of each client.

4.5. Storage, Transportation, and Disposal

Storage, transportation, and disposal of the ThunderBolt 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

Disposal of the instrument must be performed by a trained technician. It is recommended that the technician disposing of the instrument consult applicable local regulations prior to disposal.

5. General Operation

Prior to each use, verify that the maintenance log is up to date and perform system start up as described in the maintenance section of this manual. If 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, perform instrument alignment prior to use.

NOTE: It is essential that all package insert instructions for reagent handling and storage are carefully followed for all kits run on the ThunderBolt. Reagent and sample preparation is performed according to instructions from technical service, specific to each test. Prior to the use of reagents, calibrators, controls, or samples, visually verify that there are no bubbles in the bottles or vials. Air bubbles can be removed using a clean transfer pipette or toothpick.

6. Operation of User Interface

The version of the instrument software can be found by selecting About in the Help drop down menu. The instrument Graphic User Interface (GUI) enables the running of test protocols that are installed on the ThunderBolt. Initial test files are pre-installed during the instrument installation process; additional files can also be added by a member of the technical services staff.

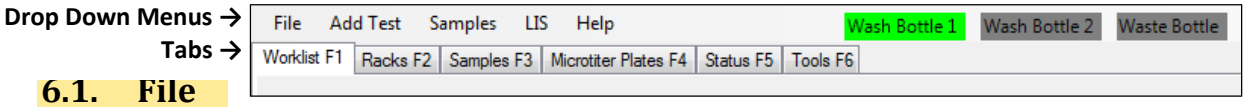
The instrument must be attached to a computer programmed with the instrument GUI in order to be operational. The ThunderBolt is powered on when the GUI is started; in most cases this occurs automatically when the computer is powered on. When the system is powered on, the instrument requires approximately 30 seconds to automatically move to its starting, or “home” position.

This section of the manual explains the use of the GUI for setting up and running tests. Each section with a function key reference in the title is representative of a tab in the GUI and includes instructions for the

functions performed while working within that tab. The function keys (F1 – F6 as seen in the photo below) can also be used for navigation of the tabs within the GUI. Additional function keys can be used as labeled within the Drop Down Menus (functions not shown: F8 displays the worklist report, F9 minimizes the GUI window, F12 selects Sample Scan).

The interface for the ThunderBolt GUI is designed with Drop Down Menus and Tabs, all of which are explained in further detail throughout this guide.

The following photo shows an enlarged version of the upper left portion of the system GUI to provide a reference for the location of Drop Down Menus and Tabs. The Drop Down Menus include; File, Add Test, Samples, LIS, and Help functions.



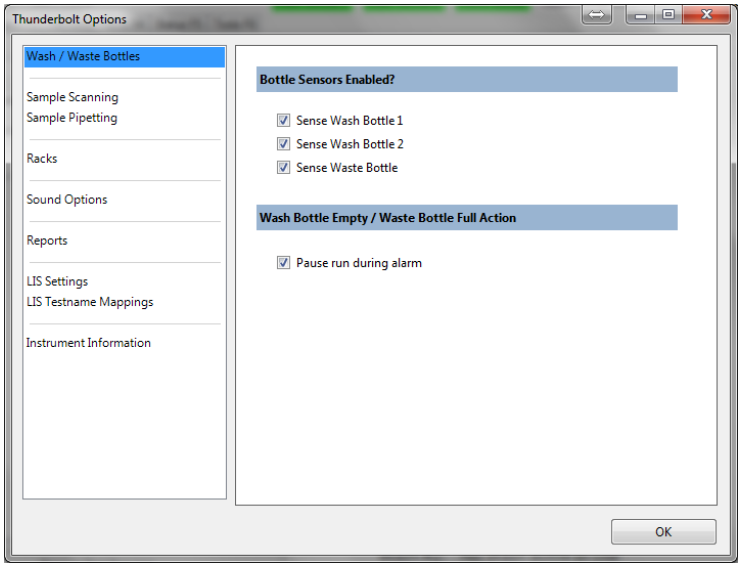
6.1. File Drop Down Menu

The following actions are available in the File Menu:

1. **New** – Enables setup of a new worklist.
2. **Open** – Use this option to open a previously saved worklist. All tests, information, samples, and results are loaded when a worklist file is opened.
3. **Save As** – Saves the current Worklist with a new file name. Each worklist run on the ThunderBolt is automatically saved in the Worklists folder within the Data folder and named by the date and time at which it was run.
4. **Save** – Saves current Worklist with no change to file name.
5. **Import Tests** –Imports new tests to the Add Tests drop down menu without exiting the program.
6. **Show Report**– Use this option to show the result report from a worklist.

6.1.1. Options

Located within the File drop down menu, the ThunderBolt Options window (shown below) is used to adjust various settings for running the instrument GUI. The use of each setting with its applicable options is described below.



1. **Wash/Waste Bottles:** Allows user to turn on/off liquid detection of the wash/waste bottles. Bottle detection icons are displayed at the top of the instrument GUI main screen and are grey when detection is turned off and red or green when detection is turned on. User can also choose whether or not worklist will pause when the wash bottle volumes are low or the waste bottle is full.
2. **Sample Scanning:** Allows the running of tests which require duplicate sample IDs and also enables the auto placement of samples.
3. **Sample Pipetting:** Allows user to decide what actions will be taken by the instrument when a sample or other fluid pickup fails due to insufficient volume. Fluid can be discarded, kept within the needle, or dispensed back. The operator also has the option of making this decision on a case by case basis.
4. **Racks:** Allows the user to enable the Reagent Loading Wizard, a window which prompts the user to check the volume of each reagent before starting a worklist. Intelligent rack tube detection is also enabled here, allowing sample racks to detect the location of sample tubes. Reagent rack hardware configuration is also set here. Users should not change rack configuration unless instructed to do so by a member of technical service.
5. **Sound Options:** Allows user to decide which alarms are enabled and to select which sounds are used. Additional custom alarm sounds (as WAV files) may be added to the Sounds folder within the Data folder for selection here.
6. **Reports:** Allows user to customize appearance of worklist reports, including the addition of a plate map to the top of the report.
7. **LIS Settings:** Allows user to access and set LIS connection options.
8. **LIS Testname Mappings:** Allows user to assign LIS test IDs to instrument test names. Test lists can be imported or exported to/ from MS excel spreadsheets.
9. **Instrument Information:** Displays reader and instrument details, including serial number and run time. The intensity of the interior LED lights can also be adjusted here.

6.2. Worklist Tab (F1)

This tab is used to select tests and enter test-specific details for the run. The following steps are taken to complete this tab:

1. Enter the technician name in the Operator window.
2. Add tests to the worklist by selecting the desired test from the Add Test drop down menu.
    a. Enter the lot number and expiration date as obtained from the kit for each test.
    b. Enter the appropriate runtime variables, including calibrator values and control ranges as appropriate for each test.
    c. Check all values against kit insert(s) and vials.
3. Add additional tests to the worklist by repeating these steps. Multiple tests can be run simultaneously if timing, temperature settings, and wash solution settings are compatible.
    a. The GUI will not allow tests to be added that do not meet this criteria; only compatible tests will be available in the Add Tests drop down menu.
        b. Tests requiring a predilution plate should be listed first in a worklist (if run with other tests not requiring a predilution).
4. New assays provided by technical services staff can be added to the Add Test drop down menu by importing. Insert a USB drive with the new test file into the netbook computer. On the

Worklist tab of the GUI, select the File Import option and drag the test file from the Source Test Files pane to the Installed Test Files pane.

a. Alternatively, new assays can also be copied and pasted directly into the Tests folder within the Data folder.

6.3. Racks Tab (F2)

This tab displays the reagent rack and sample racks and is used to load reagents, calibrators, controls, and samples. It is recommended to load samples while working in the racks tab in order to see the location and addition of each sample tube. The following steps are taken to complete this tab:

1. Load reagents into the ThunderBolt reagent rack using appropriately sized reagent adapters and following the colors/descriptions indicated on the Racks tab.
2. Place prepared calibrator and control vials into the indicated locations in the sample rack.
3. Samples are loaded by using the Samples drop down menu and selecting Scan F12. While placing samples, it is essential to verify on the Racks tab that samples are recognized (spaces with loaded samples display yellow; unloaded spaces will remain white or grey). When the intelligent rack is disabled or the Auto Place sample option is selected, the sample loading process described below will vary slightly. Technical service will advise laboratories that use these options.

   For Barcoded Samples: select the Use Barcode Scanner option.

   a. Scan the barcoded sample tube approximately 4 inches (10 cm) in front of the scanner window.
   b. When the sample is recognized, a beep will be heard, the sample ID will be displayed on the screen, and the scanner light will turn off.
   c. Place the sample in the rack. A tube must be placed in order for the scanner to reactivate and continue loading additional samples.

   Non-Barcoded Samples: select the Manual Entry option.

   a. Type the sample ID into the open window and press Enter on the netbook keyboard (Sample ID will be highlighted in blue). Once Enter is pressed, that sample ID cannot be edited. To edit a sample name, remove sample from rack, rename, press Enter, and replace.
   b. Place the sample in the rack.
   c. Repeat for all non-barcoded samples.

   Auto-numbered Samples: select the Use Auto Increment Sample ID option.

   a. Place samples in rack, one by one.
   b. Samples will be automatically numbered starting with Sample#1.
4. When all samples have been added, click Finish.
5. If scanned sample tubes are removed prior to starting the worklist, their identification will be lost and they must be re-scanned.

6.4. Samples Tab (F3)

This tab displays a detailed list of all samples in the worklist, including the rack position of each sample. This tab is used to assign samples to tests, to adjust sample replicate number, and to select sample pipetting order. The following steps are taken to complete this tab:

1. Right click on the box(es) next to each sample to select them for test(s). Be sure that green check marks appear to indicate selection.
2. To select all samples for a test, right click on the test number at the top of the sample list.

3. Additional options: Left click to select samples (selected samples highlight in blue). Use the CTRL and SHIFT keys to highlight multiple samples.
    a. Use Check Cells, Uncheck Cells, and Remove Selected Samples options as needed.
    b. Use Multiply Selected Samples to increase sample replicates.
    c. Samples will be pipetted in the order listed on the Samples tab. This order can be adjusted by moving samples within the list. Select desired sample, then right click at the new position and select the desired option.
2. If the same testfile is run twice in the same worklist, use the Smart Fill tests button to add all samples to the tests.

6.5. Microtiter Plates Tab (F4)

This tab is used to determine the number of wells/strips required for the run by displaying all well locations on the two microtiter plates and the predilution plate. Additional information about each well is displayed on the right side of the screen when the mouse cursor is placed over the well. This tab is also used to verify that all samples have been properly selected for the run. The following steps are taken to complete this tab:

1. Visually verify that all desired tests and samples appear on the MTP layout in the correct plate locations.
2. 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 the plate frame(s) with the appropriate wells onto the MTP carrier.

6.6. Status Tab (F5)

This tab displays the internal live camera feed, the worklist log file, and the estimated run time. This tab is used to start, monitor, pause, stop, or finish a worklist. The following steps are taken to complete this tab:

1. Click Start Worklist
    a. Use the Start Worklist drop down menu to start a worklist from a position other than the beginning.
    b. Check required reagent volumes as prompted by the Reagent Loading Wizard (if wizard is enabled).
2. Close the lid and wait for tests to run. Worklist actions can be monitored using the log file and the live camera feed. The bar at the bottom of the screen estimates necessary run time.
    a. It is important to keep cover closed for the entire duration of the test when using the chemiluminescence option.
3. If necessary, use the Pause Worklist option to temporarily pause a run or the Stop Worklist option to completely abort a run.
4. After the worklist is completed, click OK to stop the alarm (if end of run sound is enabled).
5. Select File and Show Report.
    a. Choose File and Print to print directly.
    b. Choose File and Export Document to save the report file to another location or in another format.
6. To start another worklist, click File and New and repeat the procedure described above.

6.7. Tools Tab (F6)

This tab displays tools, plate reading, and alignment and calibration features. This tab is used to perform functions outside of a normal test run. These features are available for use any time that a worklist is not running. Use of the tools and plate reading options are described here; the alignment and calibration options are described in the following section.

6.7.1. Tools

Available tools include Prime Instrument, Manual Shake/Heat Plate, and Home Instrument.

- **Prime Instrument**

In the pop up window, select desired wash and number of priming cycles. Priming can be interrupted using the Stop button. Do not move sliding reagent tray while priming is in progress.

- **Home Instrument**

Use this button to reset the ThunderBolt back to its starting, or "home" position.

- **Manual Shake/Heat Plate**

Use this button to manually shake and /or incubate a plate. Select preferred speed and temperature. Use the Start and Stop buttons or set timer if desired.

6.7.2. Plate Reading

Any 96 well plate can be read with the ThunderBolt reader, using either OD or RLU options. In pop up window, select plate columns to be read; columns 1-12 correspond to MTP position 1 and columns 13-24 correspond to MTP position 2. Set measurement wavelength and reference wavelength for OD, or Integration time for RLU. After clicking start, measurements will appear on the screen as the plate is read. OD or RLU readings can then be exported using the Export to CSV option.

6.8. Data

Data for each run on the ThunderBolt is automatically saved in the ThunderBolt GUI Data Folder in the Worklist Reports subfolder. Worklist reports include two files for each run: a text file with the worklist action log, and a PDF copy of the worklist report. These files are named by the date and time at which they were run on the instrument and can be retrieved at any time.

7. Alignment and Calibration

Instructions for carrying out the alignment and calibration procedures are outlined below. These instructions are intended to provide additional information as necessary to perform each step instructed by the instrument GUI. All alignment and calibration procedures are performed from the Tools tab in the ThunderBolt GUI.

7.1. Instrument Alignment

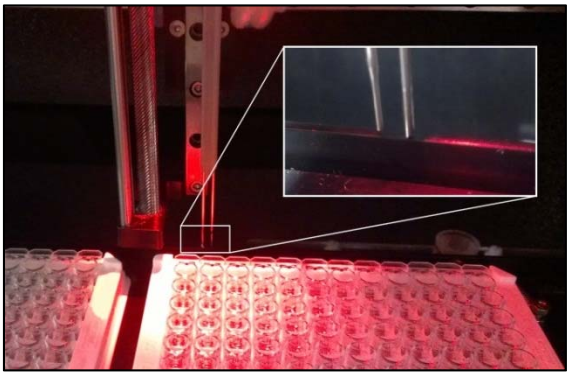
The instrument alignment process is performed to align the X and Y-axis positions of the probe with the sample racks and microtiter plates. The Z-axis position, which moves the probe up and down, is not manually aligned by the user during this procedure; it is aligned automatically by the instrument during the last step of the instrument alignment process.

7.1.1. General Information

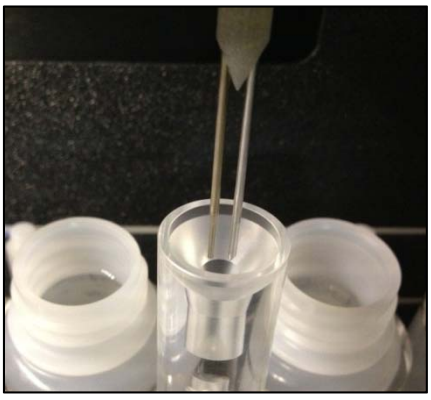
1. If an alignment is cancelled, it is recommended that the alignment procedure be fully completed prior to the next instrument use.
2. It is required that three sample tubes and three microtiter plates (MTP) be placed on the instrument as follows prior to starting the alignment process:
   a. One sample tube is placed in the top left position of each sample rack.
   b. One MTP is placed in each of the three MTP positions on the MTP carrier. Be sure that plates are seated securely before performing the alignment procedure.
3. The left and right arrow keys are used to move the probe to the left and right (X-axis).
4. The up and down arrow keys are used to move the probe toward the front and back of the instrument (Y-axis).
5. The Page Up and Page Down keys move the probe up and down with respect to the plate or tube.

7.1.2. Instructions

1. In the Tools tab of the GUI click on the Align Instrument button. A pop up window will appear and provide instructions for each alignment step.
2. To align the probe at each position, use the arrow keys to center the probe tip over each location as instructed by the instrument GUI.
3. The first alignment position will align the probe to the edge of the MTP carrier. Proper alignment is shown below.

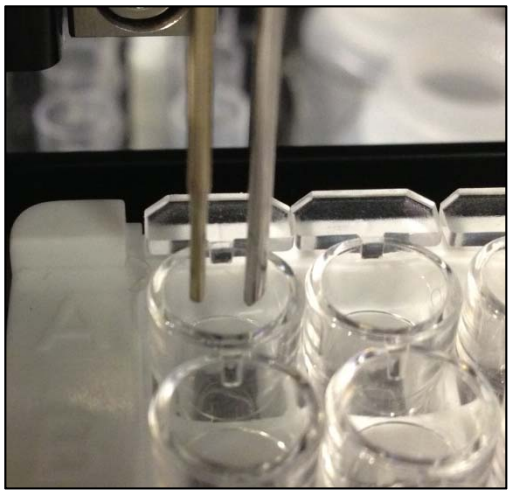


4. The second alignment position will align the probe to the middle of the wash cup. After aligning the probe to the center of the wash well, use the Page Up and Page Down keys to verify that the probe can go to the bottom of the wash well with as little resistance as possible. Proper alignment is shown below:



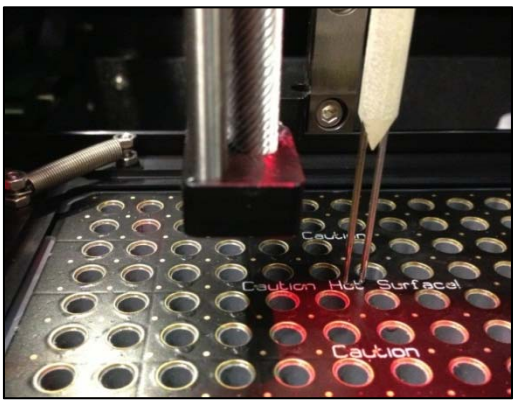
5. The following steps align the probe with the racks and MTP's by aligning to sample tubes and sample wells. Examples of proper alignment are shown below.

Sample Tube Alignment



Sample Well Alignment

6. Three alignment positions will align the probe with the sample racks.
7. The next series of alignment positions will align the probe with the microtiter plates.
   a. The probe is aligned with each plate at the A1 and H12 position when prompted by the GUI.
   b. The order for MTP alignments is left plate, right plate, and then the pre-dilution plate. All three plates are aligned twice in this sequence- once in the back MTP carrier position and once in the front MTP carrier position.
   c. Following the completion of the last alignment, prior to continuing, the left microtiter plate must be removed when prompted by the GUI. If the microtiter plate is not removed, the Z-max position will not be correctly set.
8. Once the left MTP is removed, use the arrow keys to position the probe over the center of the exposed incubator's surface area. The correct placement of the probe is shown below with the tip centered between four holes and roughly above the word "Hot" printed on the incubator surface.
9. When the Finish button is clicked, the instrument GUI will automatically align the Z-axis by moving the probe down to touch the incubator surface and establish the Z-max position. The red light will illuminate when the probe touches the surface. The probe will pause for approximately 15 seconds. Shown below is the correct placement of the probe during the Z-axis positioning.



10. After establishing the Z-axis position at the MTP carrier, the probe will move to check the alignment position of the wash cup. The probe alignment procedure is now complete and all of the alignment information is saved.
11. It is recommended that the probe alignment be performed and recorded as a part of the weekly instrument maintenance.

7.2. Reader Alignment

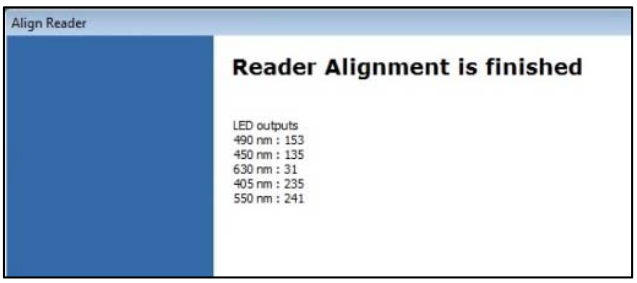
This process is performed to ensure that the reader is in the correct position for performing an auto-alignment.

7.2.1. General Information

1. Remove all microtiter plates from the MTP carrier prior to starting the reader alignment procedure.
2. Use the left and right arrow keys to move the LED guide light to the left and right.
3. Use the up and down arrow keys to move MTP carrier toward the front and back of the instrument.

7.2.2. Instructions

1. In the Tools tab of the GUI click on the Align Reader button. A window will appear and provide instructions for each alignment step.
2. Click on the Next button to proceed with the alignment procedure.
3. Verify that the reader LED guide light is in the center of the hole under the upper left A1 position. Adjust LED guide light positioning as necessary using the arrow keys.
4. Close the cover of the instrument and click on the Next button. The system will perform an LED calibration and then an auto alignment procedure. This step will take approximately 8 minutes.
5. When the auto alignment is finished, the reader alignment process is complete and the following information will appear on the screen. **NOTE:** Each wavelength value is expected to be between 5 and 245; if values outside of this range are observed, notify a service technician.



6. Once the alignment is complete, the software will prompt the user to click on the Finish button. The reader alignment procedure is now complete and all of the alignment information is saved.

7.3. Reader Calibration

Reader calibration is performed at the time of installation, during scheduled preventative maintenance visits, as well as during service calls. Additional reader calibrations and verifications can be performed using a calibrated reader test plate. Calibration procedures are performed from the Tools tab.

7.3.1. Instructions

1. In the Tools tab of the GUI click on the Calibrate Reader button. A window will appear and provide instructions for each alignment step.
2. Click on the Next button to proceed with the calibration procedure.
3. The software will prompt for a password to perform the reader calibration.
   a. The password is a number that is twice the number of the current day. For example, if the current date is January 13, the password is 13 × 2 which is 26. Enter the password value and click on the OK button.
4. A window will open in which the absorbance OD standards for each position and wavelength can be entered manually.
   a. The information required to complete this step is located on the absorbance test plate calibration certificate. **NOTE:** Test plate calibration certificates are unique to each plate and must be within the calibration due date.
   b. After entering all the appropriate information, click on the Start Calibration button.
5. The instrument GUI will prompt the user to place the calibration plate in the left microtiter plate holder and close the door. Once the plate is placed and the door is closed, clicking on the OK button will begin the reader calibration process.
   a. The calibration is complete when the progress bar is filled.
   b. If any OD values are out of range, a text box displaying each wavelength that has an OD out of range will be shown. If an OD is out of range, contact technical service.
6. When the process is complete and if all OD values are within range, the Calibrate Reader window can be closed.

7.4. Wash Pump Calibration

The Wash Pump Calibration option is used primarily 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 click the Calibrate Wash Pump button.

8. Laboratory Information System Integration

All LIS Settings are found within the Options section of the File drop down menu, in the LIS Settings and LIS Testname Mappings selections. When utilizing the LIS interface options, the LIS drop down menu is used to query or send results to the LIS.

The LIS implementation of the ThunderBolt completely conforms to the NCCLS LIS2-A2 and NCCLS LIS01-A2 (formerly known as ASTM E1394-91 and ASTM E1381-91) specifications.

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.

8.1. Header Record Specifics

All communications begin with the header record.
In the "Sender Name or ID" field, the name of the software and the version are displayed.
Example:

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

8.2. 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"

8.3. Patient Information Record Specifics

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"

8.4. Test Order Record Specifics

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||^^^CMVIgG|R
```

In this example, the Sample ID is "S004", the test name is "CMVIgG".

8.5. Result Record Specifics

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|^^^CMVIgG|1.33|ng/ml||||F
R|1|^^^CMVIgG|1.33^high|ng/ml||||F
R|1|^^^CMVIgG^Subtest1|1.33|ng/ml||||F
```

8.6. LIS Configuration

To configure the LIS, in the instrument GUI software, click on “File”, “Options” and select “LIS Settings”.
In the **RS-232** Settings section, baud rate can be set, as wells as the data bits, parity, and stop bits of the connection.
In the **TCP/IP Settings section,** the Server address and the Server port of the LIS TCP Server can be selected.
The “Use Frame Pooling” option allows the system to put more than one ASTM message (for example a Header Record) into a TCP Packet. This can speed the transfer.
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).
In the **Map Test Names** section, the available tests can be given an LIS name.
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.

8.7. 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

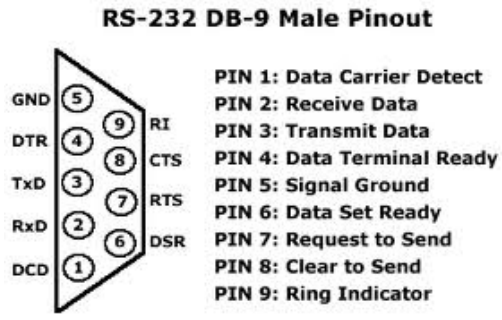
H|\^&|||Thunderbolt EIA^0.42.0.73|||||||P|LIS2-A2|20101022162157
P|1||S001
O|1|S001||^^^CMVIgG|R
R|1|^^^CMVIgG|1.33|ng/ml||||F
O|2|S002||^^^HPLIgG|R
R|1|^^^ HPLIgG|1.24|ng/ml||||F
L|1|N

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

RS-232 DB-9 Pin Layout



9. Troubleshooting Guide

Issue	Details	User Action
Instrument software will not start up	Is "No Instrument Found" error displayed?	Check that power switch on the back of the instrument is turned on. Check that power cord is plugged into the instrument and the 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 plate error?	Check that MTP plate(s) and predilution plate is/are correctly loaded and seated securely.
		Check that sufficient wells are placed.
		Check positions of probe during instrument alignment. If misaligned, realign instrument and restart.
	Does instrument display a clog error?	Prime 10x, lift probe briefly (1-2sec) to check for steady dispense flow. If dispensing appears correct, restart run. If not, use stylet to clean probe.
Run will not start (cont.)		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 if waste pump tubing has been replaced within the past month. Check aspiration and dispense during priming. Refer to User manual monthly maintenance section and replace waste tubing if needed.
	Is the blue light constantly on?	Disconnect probe, dry it off from top to bottom. Carefully replace and check all tubing and electrical connections to the probe.
	Is there a cuvette calibration error?	Check for cracks and liquid or buildup in cuvette. Check for any liquid on the probe. Check aspiration and dispense during priming. Check for proper liquid detection (blue light).
Sample(s) not pipetted during run	Are the samples also missing from the microtiter plate tab?	If missing samples are not selected on the sample tab, select them and rerun. If missing samples do not appear on the sample tab, they were likely moved after being scanned; rescan and reselect them.

Issue	Details	User Action
Samples disappear from sample list	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.
Run stops in the middle of a worklist	Is there an IO or read/write error message displayed?	Power off computer and instrument, unplug and replug power connections and USB connection, and restart. Reopen worklist and rerun from aborted position.
		Contact technical service
	Is the machine jammed during the read step?	Turn off machine, carefully remove plate and move reader back, reopen worklist, place plate back in, 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
Run stops in the middle of a worklist (cont.)	Is there a drop between needles error?	Pause the worklist and wipe off any visible drops. If a clot is visible on the needle, clean with an alcohol wipe. Resume worklist. When worklist finishes, clean the probe with the stylet and perform Liquinox decontamination. See Weekly Maintenance section of the User Manual.
Waste Bottle Alarm 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 using the File dropdown menu, Options, Wash/Waste Bottles selection.
	Is unused wash bottle being sensed as empty?	Disable Wash bottle 2 alarm using the File dropdown menu, Options, Wash/Waste Bottles selection
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?	If there was a pause due to insufficient reagent volume, be sure reagent loading wizard is enabled in Options of File dropdown menu. Use appropriate volumes and split bottles if necessary. Rerun.
	Did user forget to prime instrument before the start of the worklist?	Prime instrument 10 cycles with wash buffer and rerun.

Issue	Details	User Action
	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. After adjusting runtime variables, show report again.
	Are controls just barely out of range?	Start worklist again from read step to reread, 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.
	Do points on curve appear out of order on report? Do high and low controls appear switched?	Check if physical positioning of calibrators and controls in sample rack matches Racks tab. If not, contact technical service to produce a manual report.
	If test is in duplicate: Do calibrator/control replicates show large differences?	Contact technical service to produce a manual report.
Failed Run (cont.)	If test is in singles: 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.
	Do all OD values on report appear elevated?	Check position of red light during reader alignment. If misaligned, realign 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 if waste pump tubing has been replaced within the past month. Check aspiration and dispense during priming. Replace waste tubing if needed. Refer to User manual monthly maintenance section.
	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 above 25°C?	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 observed, remove them and rerun.

Issue	Details	User Action
		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.
		Check pinch valves to ensure that tubing is fully inserted.
Flooded Run	Is the flooding inside the wells (wells overflowing)?	Check if waste pump tubing has been replaced within the past month. Check aspiration and dispense during priming. Refer to User manual monthly maintenance section and replace waste tubing if needed.
		Check positions of probe during instrument alignment. If misaligned, realign instrument and rerun.
		Perform a manual shake to check if shaker homes properly at the end of the shake. Repeat manual shake several times to confirm.
Flooded Run (cont.)		Check if there is a visible clog on the probe. Even if no visible clog is seen, use stylet to clean both probe needles. Refer to the Weekly Maintenance section of the User Manual.
	Is the flooding outside the wells on the MTP carrier?	Check that MTPs are correctly loaded and seated securely.
		Check that the correct number of wells are loaded in the MTP using the Microtiterplates Tab.
Need to reprint or find past data	Does user know which date the desired data was run?	Retrieve data from the Worklist or Worklist Report folders within the Data folder. Refer to the Data section of the User Manual.
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 if waste pump tubing has been replaced within the past month. Check aspiration and dispense during priming. Also remove left side panel and check for any droplets on the tubing. Refer to User manual monthly maintenance section and replace waste tubing if needed.
Dripping Probe Needles/Small amount of fluid in wash cup	Is the dripping/fluid observed after the needles have been sitting for several hours?	Droplets and small amounts of fluid after sitting overnight following a DI flush are normal. Prime instrument and proceed as normal.

Issue	Details	User Action
Strips do not fit securely in MTP frame	Are different strip types being placed into the same plate frame?	Contact technical service
Common reagents are not being shared between tests	Has the user checked that the reagents to be shared are exactly the same?	Contact technical service
Cannot enter new lot-specific information	Is the information necessary for calculations or validation rules?	Contact technical service
Intelligent Rack is not working properly	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.
LIS connectivity problems	Are all settings and names correctly entered?	Contact technical service
Resistance or Liquid detection lights do not illuminate properly.	Is instrument malfunctioning as a result?	Check that probe wires are connected to PCB and that flat cable connections are secure. If problem persists, contact technical service.
X,Y, or Z-axis movements are not smooth	Is instrument malfunctioning or making strange noises?	Contact technical service

10. Contact Information

10.1. Device Manufacturer

Company Name	Gold Standard Diagnostics
Company Address	2851 Spafford Street Davis, CA 95618
Country	United States
Phone	530-759-8000
Fax	530-759-8012
Website	www.gsdx.us

10.2. Authorized Representative

Company Name	Emergo Europe

Company Address	Molenstraat 15 2513 BH, The Hague
Country	The Netherlands
Phone	+31 70.345.8570
Fax	+31 70.346.7299
Website	**www.emergogroup.com**