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Applied Biosystems[™] 3500/3500xL Genetic Analyzer for Protein Quality Analysis with GlycanAssure[™] Data Acquisition Software v2.0 USER GUIDE

Publication Number 100036372 Revision C







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Products:

3500 Genetic Analyzer for Protein Quality Analysis, with software 3500xL Genetic Analyzer for Protein Quality Analysis, with software

Manufacturer:



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Products:

GlycanAssure[™] Data Acquisition Software

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Revision history: Pub. No. 100036372

Revision	Date	Description
С	26 February 2018	Revision for v2.0 software. Add SAE functionality.
В	18 February 2016	Add information on selecting wells, preparing plates and plate assembly, estimated time for spatial calibration, updated information in library overview and create library items. Add protein quality analysis skus for polymer and buffers.
А	Early Access Sites Only: September 2015	New document for new product.

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Contents

CHAPTER 1 System and instrument description	10
System overview	. 10
Instrument hardware description	11
Overview	
Instrument interior components	. 12
Instrument front panel indicators	. 12
Instrument and computer requirements	13
Windows [™] software requirements	13
Antivirus software requirements	. 13
Other software	13
Instrument firmware	. 13
Theory of operation	13
Preparing samples	
Preparing the instrument	
During a run	
Results	
Instrument consumables handling usage limits and expiration	
Buffers	
Polymer	
Conditioning reagent	
Capillary arrays	
Important notice regarding use of consumables that exceed supported limits	
Parts of the GlycanAssure $^{^{ imes}}$ Data Acquisition Software	18
CHAPTER 2 Start the system	21
Workflow: start the system	. 21
Start the computer and instrument	. 22
Start the GlycanAssure [™] Data Acquisition Software	. 23
Check system status in the Dashboard	. 23
Check maintenance notifications	
Check consumables status	. 24
How the polymer sample and injection counters calculate usage	. 25
Check for leaks and spills	. 25
Check buffer fill levels	. 26

	Replenish consumables Ensure proper installation of CBC septa	
	Set preferences (optional)	
	Preferences overview	
	System preferences	
	User preferences	
	osci preferences	
	CHAPTER 3 Create and run experiments	28
	Run Setup workflow	28
	Create a plate	31
	Create an instrument method	. 33
	Create an experiment and start a run	34
	Open a previously run experiment	. 35
	Prepare and load sample plates	
	Capillary-to-plate mapping	
	Prepare sample plates	36
	Prepare the plate assembly	37
	Load the plate in the instrument	38
	Monitor a run from the Dashboard	38
	Export results	38
	CHAPTER 4 Run calibrations and install checks	
•		39
•	Run a spatial calibration	39
		39 39 39
•	Run a spatial calibration	39 39 39 39
	Run a spatial calibration	39 39 39 39 39
	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time	39 39 39 39 39
•	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles	39 39 39 39 39 40 41
	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results	39 39 39 39 39 40 41 41
	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history	39 39 39 39 39 40 41 41 42
	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration	39 39 39 39 39 40 41 41 42 42
•	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration Spectral calibration overview	39 39 39 39 39 40 41 41 42 42 42
	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration Spectral calibration overview When to perform a spectral calibration	39 39 39 39 39 40 41 42 42 42
•	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration Spectral calibration overview When to perform a spectral calibration Estimated run time	39 39 39 39 40 41 41 42 42 42 42
•	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration Spectral calibration overview When to perform a spectral calibration Estimated run time Prepare for spectral calibration	39 39 39 39 39 40 41 42 42 42 42 42
•	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration Spectral calibration overview When to perform a spectral calibration Estimated run time Prepare for spectral calibration Perform a spectral calibration	39 39 39 39 39 40 41 42 42 42 42 42 42 42
•	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration Spectral calibration overview When to perform a spectral calibration Estimated run time Prepare for spectral calibration Spectral Quality Values and Condition Numbers	39 39 39 39 40 41 42 42 42 42 42 42 42 42
•	Run a spatial calibration Spatial calibration overview When to perform a spatial calibration Estimated run time Perform a spatial calibration Evaluate the spatial calibration profile Example spatial profiles Export spatial calibration results Print, save, or view history Run a spectral calibration Spectral calibration overview When to perform a spectral calibration Estimated run time Prepare for spectral calibration Perform a spectral calibration	39 39 39 39 39 40 41 42 42 42 42 42 42 42 45 46

Example spectral calibration data	49
Print, save, or view history	49
Run an install check	49
When to perform an install check	49
Estimated run time	49
Prepare for the install check	
Perform the install check	51
What you see during an install check	52
Pass/fail criteria for the install check	
Evaluate install standard data	
Example install standard results	
Print, save, or view history	54
CHAPTER 5 Manage library resources	55
Overview of libraries	55
Overview of libraries	
	56
Create library items	56 56
Create library items	56 56 56
Create library items	56 56 56 57
Create library items Import, export, edit, delete, or sign a library entry Plates library File Name Conventions library	56 56 56 57 57
Create library items Import, export, edit, delete, or sign a library entry Plates library File Name Conventions library File name convention overview	56 56 57 57 57
Create library items Import, export, edit, delete, or sign a library entry Plates library File Name Conventions library File name convention overview File name convention settings	56 56 57 57 57 58
Create library items Import, export, edit, delete, or sign a library entry Plates library File Name Conventions library File name convention overview File name convention settings Results Group library	56 56 57 57 57 58 58
Create library items Import, export, edit, delete, or sign a library entry Plates library File Name Conventions library File name convention overview File name convention settings Results Group library Results Group overview	56 56 57 57 57 58 58 58
Create library items Import, export, edit, delete, or sign a library entry Plates library File Name Conventions library File name convention overview File name convention settings Results Group library Results Group overview Results group settings	56 56 57 57 57 58 58 58 59
Create library items Import, export, edit, delete, or sign a library entry Plates library File Name Conventions library File name convention overview File name convention settings Results Group library Results Group overview Results group settings Instrument method library	56 56 57 57 57 58 58 58 59

	ons	
	overview of SAE functions	
Users overview	of SAE functions	6
Security		6
Log in		6
View and cl	change the user profile	6
	sion	
Change you	ur password when it expires	6
Audit		6
View, gene	erate, and print object audit logs	6
View, gene	erate, and print event audit logs	6
Electronic signa	ature	6
_	s for multiple e-signatures	
E-sign an i	instrument method	6
View, gene	erate, export, and print e-signature logs	6
CHAPTER 7	Maintain the Instrument	7
Maintenance sc	chedule	7
Review ma	aintenance reminders	7
Daily instru	ument maintenance tasks	7
	strument maintenance tasks	
Monthly ins	strument maintenance tasks	7
Annual pla	anned maintenance tasks	7
As-Needed	d instrument maintenance tasks	7
Use the mainter	nance calendar	7
Create mai	intenance calendar entries	7
	tenance notifications	7
	e Notifications Log	7
View maint	ument	7
View maint Review the		
View maint Review the Clean the instru		7
View maint Review the Clean the instru Install buffers.		
View maint Review the Clean the instru Install buffers . Install the a	anode buffer container (ABC)	7
View maint Review the Clean the instru Install buffers . Install the a	anode buffer container (ABC)	
View maint Review the Clean the instru Install buffers . Install the a Replenish, chan	anode buffer container (ABC)	
View maint Review the Clean the instru Install buffers . Install the a Install the a Replenish, chan Precaution	anode buffer container (ABC)	
View maint Review the Clean the instru Install buffers . Install the a Install the a Replenish, chan Precaution Replenish p	anode buffer container (ABC) cathode buffer container (CBC) nge, or store polymer ns for use polymer or change polymer type	
View maint Review the Clean the instru Install buffers . Install the a Install the a Replenish, chan Precaution Replenish p	anode buffer container (ABC) cathode buffer container (CBC) nge, or store polymer ns for use polymer or change polymer type ially used polymer	
View maint Review the Clean the instru Install buffers . Install the a Install the a Replenish, chan Precaution Replenish p Store partia	anode buffer container (ABC) cathode buffer container (CBC) nge, or store polymer ns for use polymer or change polymer type ially used polymer iry array with fresh polymer	
View maint Review the Clean the instru Install buffers . Install the a Install the a Replenish, chan Precaution Replenish p Store partia Fill capillar Change and store	anode buffer container (ABC) cathode buffer container (CBC) nge, or store polymer ns for use polymer or change polymer type ially used polymer	

Maintain the pump	81
Avoiding damage to the pump assembly	81
Remove bubbles from the polymer pump	
Wash the pump chamber and channels	
Flush the water trap (pump trap) Glycan DC	
Shutdown move and reactivate the instrument	
Shutdown the instrument	
Move and level the instrument	
Reactivate the instrument	
Maintain the computer Back up the datastore during software uninstall	
Archive, purge, and restore data	
Monitor disk space	
Manage software licenses	
Create an email address for license activation and renewal	
Obtain and activate a software license	
View instrument sensor details	
APPENDIX A Troubleshooting	90
Restart the instrument and the computer	91
Instrument components	
Instrument troubleshooting	
RFID troubleshooting	
•	
Error messages	
Dashboard troubleshooting	
Software troubleshooting	
Run, re-run, or re-inject troubleshooting	
Data/electropherogram troubleshooting	
Spatial calibration troubleshooting	
Spectral calibration troubleshooting	
Install standard troubleshooting	110
Audit troubleshooting	111
Electronic signature troubleshooting	111
Troubleshooting procedures	111
•	
View the log files	111
View the log files	111 112
View the log files	111 112 112

APPENDIX B	Instrument specifications	. 114
Environmental red	icationsquirementsunication connections	115
APPENDIX C	Part numbers	. 117
Instrument consu	mablesagents	117
APPENDIX D	Radio Frequency Identification (RFID) technology .	. 119
Locations of RFID Function Specifications	read/write units	120 120 121
APPENDIX E	Safety	. 123
Conformity sy Safety alerts on the Location of sa Instrument safety General Physical injunction Electrical Cleaning and Laser Safety and electro Safety (compostery) EMC Environments Chemical safety . Biological hazard	nstrument ymbols nis instrument afety labels on this instrument ry decontamination magnetic compatibility (EMC) standards liance) al design	124 125 126 126 126 127 127 127 128 128 128
Documentatio	on and support	. 131
Customer and tec	tshnical support	131

	40	٠,	,
Inday	11.	£.	
ndex	1.	J١	



System and instrument description

System overview	10
Instrument hardware description	11
Instrument and computer requirements	13
Theory of operation	13
Instrument consumables handling usage limits and expiration	15
Parts of the GlycanAssure [™] Data Acquisition Software	18

System overview

The GlycanAssure[™] System is an integrated glycan analysis platform with three components:

- 1. **GlycanAssure**[™] **Kits**—Provide reagents for sample preparation (to release, purify, and label glycans) and for capillary electrophoresis.
- Applied Biosystems[™] 3500/3500xL Genetic Analyzer for Protein Quality Analysis (POP-7[™] polymer, 50-cm capillary array) (described in Pub. No. 100036372)—Runs GlycanAssure[™] Data Acquisition Software to collect data for samples prepared with the GlycanAssure[™] Kits.
- 3. **GlycanAssure**™ **Data Analysis Software** (described in Pub. No. 100036373)— Processes and analyzes glycan data and includes data trending and profile matching features.

Instrument hardware description

Overview

The Applied Biosystems[™] 3500/3500xL Genetic Analyzer for Protein Quality Analysis with GlycanAssure[™] Data Acquisition Software is a fluorescence-based glycan analysis instrument using capillary electrophoresis technology with 8 or 24 capillaries.

The 8-capillary model and the 24-capillary model are shipped with the following components:

- 8-capillary or 24-capillary array and POP[™] polymer
- Reagents and consumables for your application and for system qualification
- Computer workstation and monitor



IMPORTANT! The protection provided by the equipment may be impaired if the instrument is operated outside the environment and use specifications, the user provides inadequate maintenance, or the equipment is used in a manner not specified by the manufacturer (Thermo Fisher Scientific).

IMPORTANT! Observe current good laboratory practices when using this instrument.

Instrument interior components

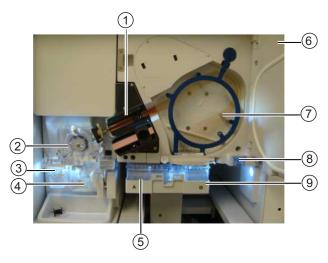


Figure 1 Instrument interior

- 1 Detection cell heater block
- 2 Polymer delivery pump (PDP)
- 3 Anode buffer container (ABC)
- 4 Polymer or conditioning pouch
- (5) Cathode buffer container (CBC)
- 6 Oven door
- 7 Capillary array
- (8) Oven condensation reservoir
- 9 Autosampler

Instrument front panel indicators

Indicator	Status
All lights off	Instrument off
Green light	Idle
Green light (blinking)	Run is in progress
	Note: You can only abort an injection when the green light is flashing, not when it is solid green.
Amber light (blinking)	Power-up self-test is in progress
	Instrument has paused. If the door is open, close it. If the amber light is still blinking, restart the software, then repeat the run.
Amber light	Standby
Red light	Self-test failed or instrument failure. Restart the instrument and computer (see "Restart the instrument and the computer" on page 90).

Instrument and computer requirements

IMPORTANT! Do not modify the instrument hardware or software without notifying Thermo Fisher Scientific. Any modifications must be made by Thermo Fisher Scientific under change control.

For minimum computer requirements, see "Instrument specifications" on page 114.

Windows[™] software requirements

The computer provided with the instrument contains validated software and settings.

Do not update the Windows[™] operating system or firewall settings.

Antivirus software requirements

The computer provided with the instrument does not include antivirus software because customer preferences and network requirements vary.

We recommend Norton Antivirus, which has been tested and approved for use with the Applied BiosystemsTM 3500/3500xL Genetic Analyzer with GlycanAssureTM Data Acquisition Software.

Other software



CAUTION! Do not install additional software on the computer other than antivirus software. Changes to the configured software could void the instrument warranty and cause the instrument software to be non-operational.

IMPORTANT! Do not rename the computer after the GlycanAssure[™] Data Acquisition Software is installed. The instrument computer has been assigned a unique name. Changing the name may cause the GlycanAssure[™] Data Acquisition Software to malfunction.

Instrument firmware

Instrument firmware is to be updated only by a Thermo Fisher Scientific representative.

Theory of operation

Preparing samples

When samples are prepared for glycan analysis on the 3500/3500xL instrument, a fluorescent dye is attached to the glycan molecules.

Preparing the instrument

Two calibrations and an installation check are required to prepare the instrument for sample runs:

- Spatial calibration Determines the position of the image from each capillary on the CCD array.
- Spectral calibration Generates a matrix for each capillary that compensates for dye overlap and is used to convert the 20-color data into 4-, 5-, or 6-dye data.
- Installation check Ensures the instrument meets specifications

During a run

During a run, the instrument:

- Prepares the capillaries by pumping fresh polymer solution under high pressure from the polymer delivery pump to the waste position in the cathode buffer container (CBC).
- Electrokinetically injects the sample into the capillaries by briefly applying a low voltage.
- Washes the capillary tips in the rinse position of the CBC, then returns the capillary to the buffer position of the CBC.
- Ramps the voltage up to a constant level.

A high electric field is created between the ground end of the anode buffer container (ABC) and the negative voltage applied to the load header of the capillary array. This field pulls the negatively charged molecules through the separation polymer. The smaller molecules migrate faster than the larger molecules and reach the detector first.

To ensure optimal separation and maintain denaturation of the molecules, the capillaries are thermally controlled in the oven and in the detection cell. The oven has a Peltier heat unit and fan-circulated air.

In the detection cell, the dyes attached to molecules are excited by a narrow beam of laser light. The laser light is directed into the plane of the capillaries from both the bottom and top. A small amount of laser light is absorbed by the dyes and emitted as longer wavelength light in all directions.

- Captures the fluorescent light on the instrument optics while blocking the laser light. The light passes through a transmission grating, which spreads the light out. The light is imaged onto a cooled CCD array. For each capillary, 20 zones on the CCD are collected to provide 20-color data for each capillary.
- Converts the 20-color data into multi-dye data for the entire run.

Results

The software generates an electropherogram (intensity plot) for the glycan dye based on the migration time of glycan molecules over the run.

Instrument consumables handling usage limits and expiration

IMPORTANT! Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, etc).

Containers and pouches are ready-to-use. Labels include a radio frequency identification (RFID) tag that the instrument uses to track usage and expiration date.

Buffers

Cat. no.	Description	Storage conditions	
A31278	Anode Buffer Container (ABC) for Protein Quality Analysis, 1X running buffer, 4 containers	Store at 2–8°C. The 1X running buffer has been qualified to ship at ambient conditions. For a description of the	
A31279	Cathode Buffer Container (CBC) for Protein Quality Analysis, 1X running buffer, 4 containers	ambient conditions. For a description of the qualification, visit http://find.thermofisher.com/ambientbuffers/email?CID=fl-we18868.	

Instrument	On-instrument supported limits Lower of:	Guidelines
8-capillary	14 days, 240 injections, or expiry date	The buffer has been verified for use for
24-capillary	14 days, 100 injections, or expiry date	up to 14 days on the instrument. The software displays a warning message when a usage limit is met and allows you to continue running. Before doing so, see "Important notice regarding use of consumables that exceed supported limits" on page 17.

Polymer

Cat. no.	Description	Storage conditions
A30936	POP-7 [™] Polymer for Protein Quality Analysis (384)	Store at 2–8°C.
A31122	POP-7 [™] Polymer for Protein Quality Analysis (960)	

IMPORTANT! The on-instrument supported limit for POP- $7^{\text{\tiny IM}}$ polymer is 14 days only when the instrument operating temperature is 15 to \leq 25°C. When the instrument operating temperature is > 25°C, the supported limit is 7 days.

Pouch size	Instrument	On-instrument supported limits ^[1] Lower of:	Guidelines
384 samples	8-capillary	14 days, 384 samples, 60 injections, or expiry date	The polymer has been verified for use for up to 14 days on the instrument.
	24-capillary	14 days, 384 samples, 20 injections, or expiry date	The software displays a warning message when a usage limit is met and allows you to continue running. Before doing so, see
960 samples	8-capillary	14 days, 960 samples, 120 injections, or expiry date	"Important notice regarding use of consumables that exceed supported
	24-capillary	14 days, 960 samples, 50 injections, or expiry date	limits" on page 17.

^[1] The pouch has adequate polymer to support the stated number of samples or injections, plus additional volume to accommodate installation and wizard operations. Multiple pouch installations and/or excessive use of wizards reduce the number of remaining samples and injections. For example, if you run the **total bubble remove** option in the Remove Bubbles wizard more than four times, the number of remaining samples and injections is reduced.

Conditioning reagent

Cat. no.	Description	Storage
4393718	Conditioning reagent, 1 pouch	2°C to 8°C
		After removing from storage, use the pouch within 24 hours.

On-instrument supported limits	Guidelines
Once installed on the instrument, the pouch is good for a one-time use.	Refer to the expiration date on the label. See "Important notice regarding use of consumables that exceed supported limits" on page 17.

Capillary arrays



WARNING! SHARP The load-end of the capillary array has small, blunt ends that can lead to piercing injury.

Cat no.	Description	Storage conditions
4404685	8-Capillary, 50 cm	Room temperature
4404689	24-Capillary, 50 cm	

On-instrument limits	Recommendation
160 injections or expiration date listed on packaging and RFID label	Capillary arrays have been verified for use for 160 injections.
	Store capillary arrays with the loading-end of the capillary array in distilled water to prevent the polymer from drying in the capillaries.

Important notice regarding use of consumables that exceed supported limits

BEFORE DISMISSING THE WARNING THAT THE CONSUMABLES HAVE REACHED SUPPORTED LIMITS AND CONTINUING WITH OPERATION OF THE INSTRUMENT, PLEASE READ AND UNDERSTAND THE FOLLOWING IMPORTANT NOTICE AND INFORMATION:

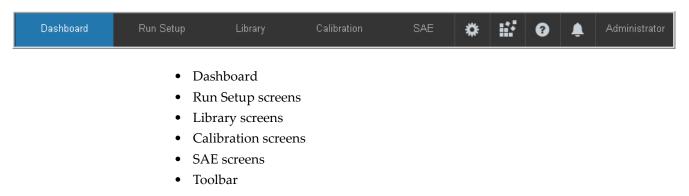
Life Technologies does not recommend the use of consumables that exceed supported limits. The recommended limits are designed to promote the production of high quality data and minimize instrument downtime. Reagent and consumable lifetime minimum performance are based on testing and studies that use reagents and consumables that have not exceeded supported limits.

The use of consumables beyond the supported limits may impact data quality or cause damage to the instrument or capillary array. The cost of repairing such damage is *NOT* covered by any Life Technologies product warranty or service plan. Customer use of expired consumables is at customer's own risk and without recourse to Life Technologies. For example, product warranties do not apply to defects resulting from or repairs required due to misuse, neglect, or accident including, without limitation, operation outside of the environmental or use specifications or not in conformance with Life Technologies instructions for the instrument system, software, or accessories.

Please see your specific service contract or limited product warranty for exact language regarding coverage and ask your Life Technologies representative if you have further questions.

Parts of the Glycan Assure $^{^{\mathrm{TM}}}$ Data Acquisition Software

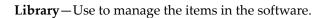
Click the tabs and icons at the top of the screen to access the parts of the software.

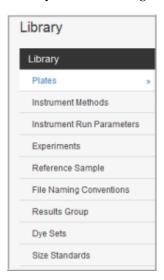


Φ **Experiment Status** Run Progress... Experiment Name: ---Experiments Status: Idle Estimated completion time hh:mm:ss 0/0 Monitor Run Not Started Last Experiment 02 Aug 2015 10:3:14 Experiments Last Week Experiments Experiment 5 Experiment 4 08 Sep 2015 | 11:51:29 04 Sep 2015 | 03:29:45 Last Month Instrument Genetic Analyser idle Spatial Spectral Instrument Door 53.50 °C 23.50 °C Oven Status ON Oven 55.4 Oven Door Open 3500xL Pre-heat Consumables Anode Buffer Cathode Buffer Capillary Array Polymer Pouch 4 days left 23 Samples 4 days left 150 Injections left

Dashboard—Displays status for experiments, instrument, and consumables.

Run Setup—Use to create plates and experiments, run experiments, view run progress, and view and export results. See "Run Setup workflow" on page 28 for more information.





Calibration – Use for spatial and spectral calibration, and for install standard checks.



Logs—Use to manage audit and e-signature logs.



Toolbar—Use to access Preferences, Maintenance wizards, help, Maintenance Notifications, and User Profile.





Start the system

	Workflow: start the system	21
	Start the computer and instrument	22
	Start the GlycanAssure™ Data Acquisition Software	23
	Check system status in the Dashboard	23
	Set preferences (optional)	27
Workflow: start t	he system	
	Power on the computer (do not log in), then power on the instrument	
	▼	_
	When the green front panel indicator stops blinking, log in to Windows [™] operating system, then start the software (see "Start the GlycanAssure [™] Data Acquisition Software" on page 23)	
	▼	٦
	"Check maintenance notifications" on page 23	
	▼	_
	"Check consumables status" on page 24	
	▼	_
	"Replenish consumables" on page 26	
	▼	7
	"Set preferences (optional)" on page 27	

Start the computer and instrument

IMPORTANT! The order in which you turn on the computer and instrument is critical for proper communication between the instrument and the computer. Follow the sequence of steps given in this section (power on computer but do not log in, power on instrument, log in to Windows operating system).

- Power on the computer and monitor, but do not log in to the Windows[™] operating system.
- 2. Verify that the instrument is connected to the appropriate power supply.



CAUTION! Do not unpack or plug in any components until a service representative has configured the system for the proper operating voltage.

IMPORTANT! Do not rename the computer after the GlycanAssure[™] Data Acquisition Software is installed. The instrument computer has been assigned a unique name. Changing the name may cause the software to malfunction.

- **3.** Inspect the instrument interior. Ensure that:
 - a. The oven door is closed.
 - **b.** No objects are left inside the instrument.

IMPORTANT! Misplaced objects left inside the instrument can cause damage.

- Close the instrument door.
- **5.** Power on the instrument:



Power button Tray button

Light button

a. Press the power on/off button on the front of the instrument and wait for the green status light to turn on.

Note: If the door is open during power on, the yellow light will continue to flash until you close the door. See indicator descriptions in "Instrument front panel indicators" on page 12.

- **b.** If desired, press the Light button to turn on the interior light.
- **c.** Check the instrument status. Ensure the green status light is on and not flashing before proceeding. See indicator descriptions in "Instrument front panel indicators" on page 12.
- **6.** Log on to the Windows[™] operating system.

Start the GlycanAssure[™] Data Acquisition Software

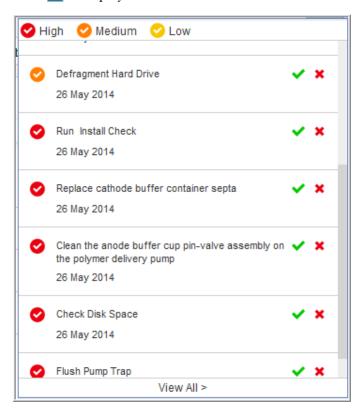
- 1. After you log on to the Windows[™] operating system, wait ~1 to 2 minutes.
- 2. Select Start ▶ Programs ▶ Applied Biosystems ▶ GlycanAssure Software ▶ Data Acquisition v2.
- **3.** Log in to the GlycanAssure[™] Data Acquisition Software.

Check system status in the Dashboard

Check maintenance notifications and consumables status in the **Dashboard**.

Check maintenance notifications The **Maintenance Notifications** list displays reminders for the tasks listed in the maintenance calendar (see "Create maintenance calendar entries" on page 75). You can set the time to trigger maintenance notifications in **Preferences**.

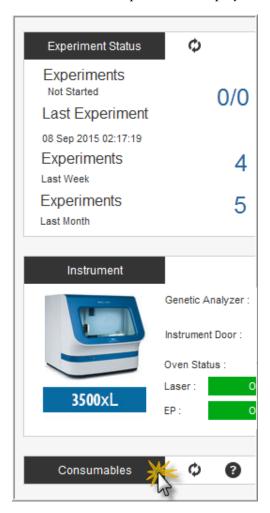
1. Click 1 to display the list of notifications.



- 2. Perform any scheduled tasks, then click of to mark it as complete, (or click to mark it as dismissed if you do not perform the task). Actions are recorded in the **Notifications Log** (for more information, see "Review the Notifications Log" on page 76.
- **3.** Perform any daily, monthly, or quarterly tasks that are not listed in the Maintenance Notifications list (see "Maintenance schedule" on page 71).

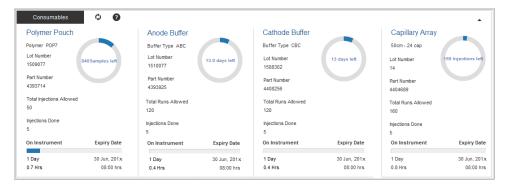
Check consumables status

1. If the Consumables pane is not displayed, click **Consumables**.



2. Click to update consumable status.

The **Consumables** pane displays expiration dates and lot numbers (determined from the RFID tags on the consumable containers).



Note: The **Expiration Date** for consumables is displayed in red if the consumable is within the following days of expiration: Pouch 7 days, Buffers 7 days, Capillary array 1 day.

The status circle is displayed in red when <10% of the allowed use of the consumable remains.

3. Check the consumables gauges for the number of injections, samples, or days remaining for a consumable.

IMPORTANT! We recommend that you add a maintenance notification for polymer and buffer replacement. Set the notification to display two days before the polymer should be replaced.

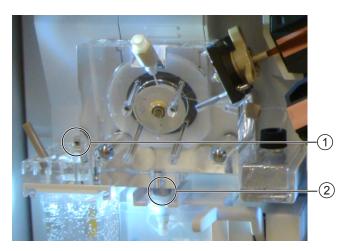
How the polymer sample and injection counters calculate usage

The Polymer Sample Counter decrements only for wells that contain sample, but the Polymer Injection Counter decrements for each injection, regardless of whether all wells contain sample. The sample limit and the corresponding injection limit may not coincide. The first limit that is reached depends on whether you perform partial or full injections.

Example: Instrument configuration: 24-capillary, 960 sample polymer pouch			
Partial injection example (not all wells contain sample)	1 injection with 24 samples + 49 injections with 1 sample = 73 samples, 50 injections	The 50 injection count limit is reached before the 960 sample count limit.	
Full injection example (all wells contain sample)	40 injections with 24 samples = 960 samples, 40 injections	The 960 sample count limit is reached before the 50 injection count limit.	

Check for leaks and spills

- 1. Inspect the instrument interior.
- 2. Wipe any spills.
- 3. Check for leaks around the Buffer-Pin Valve, check valve, and array locking lever.



- 1 Buffer-pin valve
- (2) CV (check valve) fitting
- **4.** Remove dried residue and ensure that the array locking lever is pushed securely in place.

Check buffer fill levels

Check the fill levels on buffers. Verify that the buffer level is at the top of the fill line and check that the seal is intact. The meniscus must line up at or above the fill line. Ensure that the septa on the CBC are properly seated.

IMPORTANT! Replace the buffer if the buffer level is too low.

Replenish consumables

If any consumables are expired or if buffer fill level is too low, replenish the consumables as described in:

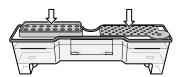
• "Replenish polymer or change polymer type" on page 79

IMPORTANT! Wear gloves while handling polymer, the capillary array, septa, ABC, or CBC.

- "Install the anode buffer container (ABC)" on page 77
- "Install the cathode buffer container (CBC)" on page 77
- "Fill capillary array with fresh polymer" on page 79
- "Install or change the capillary array" on page 80

Ensure proper installation of CBC septa

When you install the CBC buffer septa, press firmly to seat the septa.



IMPORTANT! Look at the CBC from the side and ensure there is no gap between the container and the lip of the septum.

Set preferences (optional)

Preferences overview

To access the **Preferences** dialog box, click in the toolbar. You have the option to set any or all preferences.

System preferences

These preferences apply to all users. Click **Apply** to save the preference.

System preference	Sets
Date Format	Date and time format for the software.
Instrument Settings	 Instrument name (appears in the Dashboard, reports, file name conventions, instrument sensor details, view sequencing results.)
	Note: If you have multiple instruments, you can assign each instrument a unique instrument name.
	Suppress the messages that are displayed when at the start of a run that indicate the number of days left before a consumable expires or should be replaced.
	 Number of runs to preserve in the Run Log (accessed by selecting SAE ➤ Logs).
Scheduler Preference	Time for maintenance notifications to be displayed in the Dashboard.
Spectral Calibration	Number of allowed borrowing events for spectral calibration.
Glycan settings	 Default home page (page displayed when you start the software) Consumables on Dashboard: Collapsed or expanded

User preferences

In the **Preferences** dialog box, click a user preference, select a setting, then click **Apply** to save the preference.

User preference	Sets
Library Filtering	Default filter for items displayed in selection boxes. Use an asterisk (*) wildcard character to indicate that text may precede or follow the text you specify. Excluded text is not casesensitive.
	Example: To exclude only items named "ABC", enter ABC . To exclude items named "ABCDE", enter ABC* . To exclude items named "123ABC", enter *ABC .
Plate setup	Default settings for sample names and types, polymer and capillary length .
Run Setup	 Default storage location for data files in file name conventions and results groups. Note: You can override this setting in file name conventions and results groups. Pause After Last Injection — When enabled, allows reinjection of the last injection by pausing after the last injection is complete (before completing the run).
Warning Dialogs	Suppress warning messages for deleting an injection or exporting a library item.

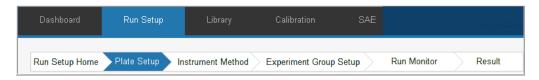


Create and run experiments

Run Setup workflow	28
Create a plate	31
Create an instrument method	33
Create an experiment and start a run	34
Open a previously run experiment	35
Prepare and load sample plates	35
Monitor a run from the Dashboard	38
Export results	38

Run Setup workflow

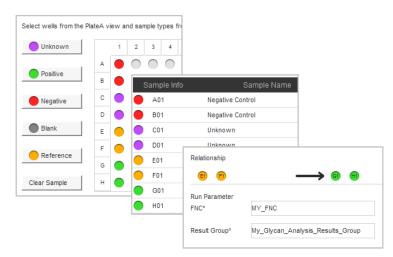
Click **Run Setup**, then click each tab to advance through the workflow.



1 Plate Setup includes three screens, click **Next** and **Back** at the bottom of the screen to advance through the screens.

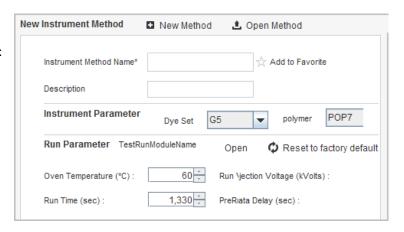


- Define Plate (specify sample types, replicates, and reference samples), click Next
- Add Sample Name (specify sample names and plate name), click Next
- 3. **Preview** (specify file name convention and results group), click **Save**, then click **Save**.



2 Instrument Method:

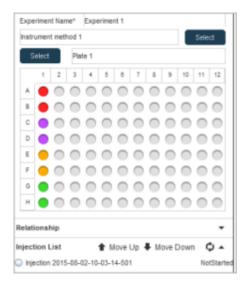
- Specify instrument method, click Save (saves an experiment), then click Start Experiment
- (If needed) Create a new instrument method



•

3 Experiment Group Setup

 Manage the injections list, then click Start Run



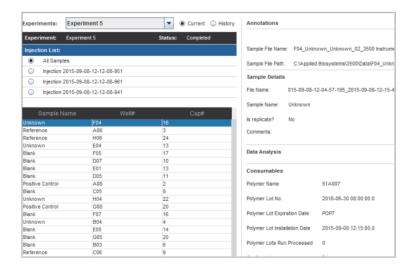
4 Run Monitor

- Add duplicate injections, adjust injection list
- Terminate or delete injections
- Pause, resume, or terminate a run
- View raw data



5 Result

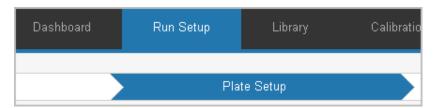
- View sample details when a run is complete
- Print and export results



Create a plate

In the **Dashboard**:

1. Click **Run Setup**, then click **Plate Setup**.



2. Define the plate:

a. Assign sample types to wells: Select wells, then click a sample type button at the left of the plate.

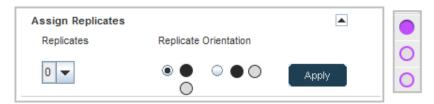


You can select wells by:

- Clicking individual wells, Ctrl-clicking non-contiguous wells, or Shift-clicking contiguous wells
- Clicking a column header to select a column of cells

b. Assign replicates: Click **v** to expand the **Replicates** pane, select wells, select **Replicate Orientation**, then click **Apply**.

Replicates are displayed in the same color as the first sample, but with gray interior.

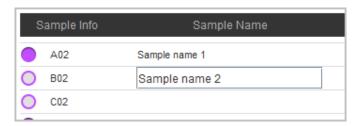


c. Assign reference samples: Click ▼ to expand the **Relationship** pane, click **Add Row**, select reference sample wells, then click •. Select the sample wells to associate with the reference wells, then click •.



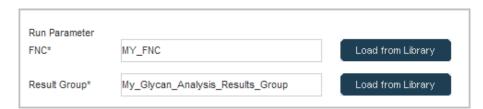
- d. Click Next.
- **3.** Add sample names and name the plate:
 - **a.** Add sample names to wells: Select the **Sample Name** field for a well, then type a name.

You can also right-click to copy and paste user names, or type a name with a numeric suffix, select a range of wells, right-click, then select **Fill Series**.



- **b.** Type a plate name, then click **Next**.
- **4.** Preview the plate, select File Name Convention and Results Group, and save the plate:
 - a. Review the plate setup. If necessary, click **Back** to make changes.

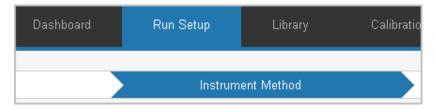
b. Click **Load from Library** to select **File Name Convention** and **Result Group** or use the defaults.



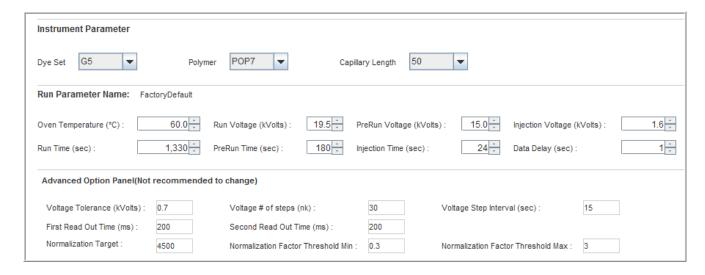
c. Click Save.

Create an instrument method

1. Click Run Setup, then click Instrument Method.



- 2. Specify the settings shown in the figure below.
- 3. Click Save.



Create an experiment and start a run

An experiment is a plate and an instrument method.

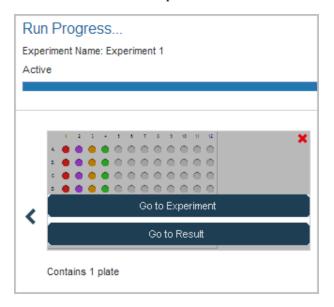
- 1. Create a plate (see "Create a plate" on page 31) and an instrument method (see "Create an instrument method" on page 33).
- 2. Click Run Setup, then click Experiment Group Setup.



- 3. Click New Experiment.
- **4.** Enter **Experiment Name** and other descriptive information as needed.
- **5.** Select an instrument method and a plate from the drop-down lists, then click **Save All**.
- **6.** If needed, modify the injection list by moving or deleting injections.
- **7.** Load the plate in the instrument.
- 8. Click Start Run.

Open a previously run experiment

1. In the **Dashboard**, click a plate.



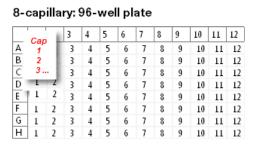
2. Click Go to Experiment or Go to Result.

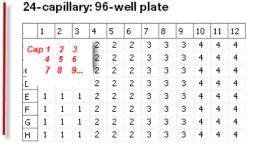
Prepare and load sample plates

IMPORTANT! Do not use warped or damaged plates.

Capillary-to-plate mapping

The capillary-to-plate mapping for the default injection order is shown below. If you change the injection order in the injection list, mapping differs from the examples shown below.



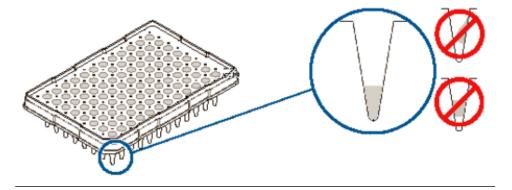


Chapter 3 Create and run experiments Prepare and load sample plates

Prepare sample plates

- 1. Pipet samples into the plate.
- **2.** Briefly centrifuge the plate.
- **3.** Verify that each sample is positioned correctly in the bottom of its well.

IMPORTANT! If the contents of any well contain bubbles or are not located at the bottom of the well, briefly centrifuge the plate, remove the plate from the centrifuge, and verify that each sample is positioned correctly in the bottom of its well.



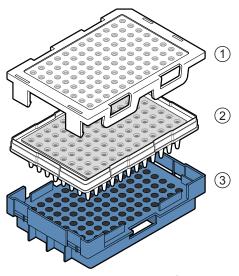
4. Store the plate on ice and protected from light until you prepare the plate assembly and load the plate in the instrument.

Prepare the plate assembly

Prepare the plate assembly on a clean, level surface. Wear gloves when handling septa. Do not heat plates that are sealed with septa.

96-well plate assembly

IMPORTANT! Use the correct plate base for standard plates. Using the wrong plate base may affect performance.



- 1 Plate retainer
- 2 Plate with septa strip
- (3) Plate base
- 1. Align the holes in the septa strip with the wells of the plate (general purpose supply), then firmly press down on the plate until the septa clicks in to position.
- **2.** Place the plate into the plate base.
- **3.** Snap the plate retainer (cover) onto the plate, septa, and plate base.
- **4.** Verify that the holes of the plate retainer and the septa strip are aligned. If holes are not aligned, take it apart, then re-assemble.

IMPORTANT! The array tips will be damaged if the plate retainer and septa strip holes do not align correctly.

5. If the contents of any well contain bubbles or are not located at the bottom of the well, briefly centrifuge the plate, remove the plate from the centrifuge, and verify that each sample is positioned correctly in the bottom of its well.

Load the plate in the instrument

- 1. Click the Tray button on the front panel to move the autosampler to the front position, then open the instrument door.
- 2. Place the plate in the autosampler with the labels facing you (or the instrument door) and the notched corner of the plate in the notched corner of the autosampler.
- **3.** Close the instrument door to initialize the instrument.

Monitor a run from the Dashboard

In the Dashboard, view the run progress. For more details, click Monitor Run.



Export results

- 1. Select Run Setup ▶ Results.
- **2.** Select the experiment of interest.
- 3. Select the samples of interest.
- 4. Click Export.



Run calibrations and install checks

Run a spatial calibration	39
Run a spectral calibration	42
Run an install check	49

Run a spatial calibration

Spatial calibration overview

The software uses images collected during the spatial calibration to establish a relationship between the signal emitted by each capillary and the position where that signal falls on, and is detected by, the CCD camera.

When to perform a spatial calibration

Perform a spatial calibration after you:

- Remove or replace the capillary array.
- Replace the capillary when it expires.

Note: When the instrument reads the information from a newly installed capillary array, you are required to run a spatial calibration and a spectral calibration before you can run plates.

- Open the detector door or move the detection cell.
- Move the instrument.

Estimated run time

< 5 minutes

Perform a spatial calibration

IMPORTANT! Do not open the instrument door during a spatial calibration run. Doing so will stop the run and require you to restart the GlycanAssure $^{\text{\tiny{IM}}}$ Data Acquisition Software.

- 1. Preheat the oven if you will be selecting the **Fill** option for the calibration (fill the array with polymer).
- 2. Select Calibration ▶ Spatial.

Note: The screen does not display results unless you have previously performed a spatial calibration.

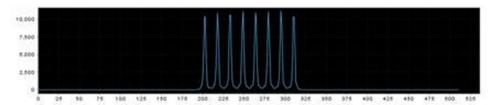
- **3.** Select **No Fill**, or select **Fill** to fill the array with polymer before starting the calibration.
- 4. Select Perform QC Checks.

5. Click Start Calibration.

During the calibration, the software performs quality checks and calculates the following values:

Attribute	Calculation	Threshold
Average peak height	(sum of all peak heights) divided by (number of peaks)	8-cap: 6400 RFU24-cap: 3000 RFU
Individual peak height	Peak height	1000 RFU
Uniformity (peak height similarity)	(standard deviation) divided by (average peak height)	0.2
Capillary spacing	max. spacing - min. spacing	2 pixels

The display updates as the run progresses.



A Spatial QC Check error message is displayed if:

- The average peak height or individual peak height is below the threshold
- Uniformity or capillary spacing exceeds the threshold

Evaluate the spatial calibration profile

When the run is complete:

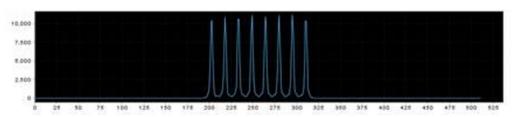
- 1. Evaluate the spatial calibration profile to ensure that you see:
 - One sharp peak for each capillary. Small shoulders are acceptable.
 - An even peak profile (all peaks about the same height).
- **2.** If the results meet the criteria above, click **Accept Results**.

If the results do not meet the criteria above, the **Accept** button is dimmed. Go to "Spatial calibration troubleshooting" on page 106.

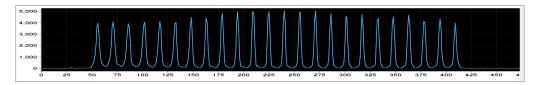
IMPORTANT! Do not log off or close the software before clicking Accept Results. Spatial calibration results are not saved until you click Accept Results.

Example spatial profiles

8-capillary spatial



24-capillary spatial



Export spatial calibration results

1. Click Export Result.



- 2. Enter an export file name.
- **3.** Select the export file type, then click **Save**.

The export file contains the following results:

- Capillary Number
- **Position** (pixels)
- Spacing
- Intensity

Print, save, or view history

То	Do this
Print	Click Print
Save	Click Report
View history	Click the History tab

Run a spectral calibration

Spectral calibration overview

A spectral calibration creates a de-convolution matrix that compensates for dye overlap (reduces raw data from the instrument) in the dye data stored in each sample file.

When to perform a spectral calibration

Perform a spectral calibration when you:

- Use a dye set that you have not previously calibrated
- Replace the capillary array for maintenance purposes
- Replace the capillary when it expires (the expiration date is indicated on the packaging and the RFID tag)

Note: When the instrument reads the information from a newly installed capillary array, you are required to run a spatial calibration and a spectral calibration before you can run plates.

• See a decrease in spectral separation (pull-up/pull-down in peaks) in the raw or analyzed data

Estimated run time

 \leq 40 minutes

Prepare for spectral calibration

Before you begin

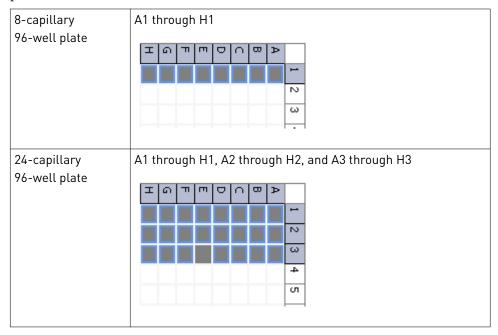
If you have not already done so, perform a spatial calibration (see "Perform a spatial calibration" on page 39).

Prepare the instrument

- 1. In the Dashboard, ensure that consumables are not expired and adequate injections remain for consumables.
- 2. Check that buffer levels are at the fill lines.
- **3.** Set the oven temperature, then click **Start Pre-heat**. We recommend that you pre-heat the oven for at least 30 minutes before you start a run if the instrument is cold.
- **4.** Check the pump assembly for bubbles and run the Remove Bubble wizard if needed.

Prepare the standard and plate

- 1. Prepare the standard as described in the product information sheet.
- **2.** Load the standards in any injection position in the plate. The example below shows injection position 1, but you can specify the starting well for an injection position.



- **3.** Briefly centrifuge the plate containing the standards.
- 4. Verify that each standard is positioned correctly in the bottom of its well.

IMPORTANT! If the contents of any well contain bubbles or are not located at the bottom of the well, briefly centrifuge the plate, remove the plate from the centrifuge, and verify that each standard is positioned correctly in the bottom of its well.

- **5.** Store the plate on ice until you prepare the plate assembly and load the plate in the instrument.
- **6.** Prepare the plate assembly.

Load the plate in the instrument

- 1. Click the Tray button on the front panel to move the autosampler to the front position, then open the instrument door.
- 2. Place the plate in the autosampler with the labels facing you (or the instrument door) and the notched corner of the plate in the notched corner of the autosampler.
- **3.** Close the instrument door to initialize the instrument.

Perform a spectral calibration

IMPORTANT! Do not change e-signature settings during a spectral calibration.

1. Select Calibration > Spectral.

Note: The screen does not display results until you perform a spectral calibration. To view previous calibration data, click **History View**.

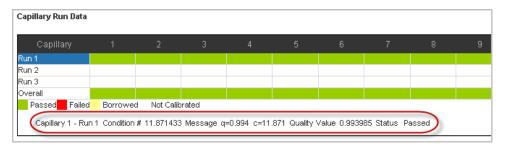
- 2. Select the plate position for the plate loaded in the instrument.
- **3.** Specify the starting well for the injection position in which you loaded the standard in the plate.
- 4. (*Optional*) Select **Allow Borrowing**. Selecting this option instructs the software to automatically replace information from failed capillaries with information from an adjacent passing capillary with the highest Quality value. For more information, see "What you see during a spectral calibration" on page 47.
- 5. Click Start Run. The following occurs:
 - If you used the default setting "Perform run 2 and 3 if run 1 fails", the
 instrument sets up three injections (see "What you see during a spectral
 calibration" on page 47 for information on the number of injections
 performed).
 - The Capillary Run Data display updates after each injection is complete.
 - The status bar updates during Run 1.

IMPORTANT! The status bar does not update during Run 2 or Run 3.

Passing and failing capillaries are shown in green and red respectively.
 Borrowed capillaries are shown in yellow with an arrow indicating the adjacent capillary from which results were borrowed.

To display the result for each capillary (spectral data, **Quality Value**, and **Condition Number**) below the run results table, click a capillary in the table.

Note: The results displayed when you click a borrowed capillary are the passing results borrowed from the adjacent capillary. To determine the reason that a capillary fails, view the spectral calibration report.



For all spectral calibration injections (even capillaries that are green in the **Overall** row), evaluate the data as described in "Evaluate the spectral calibration data" on page 46.

Spectral Quality Values and Condition Numbers

Spectral Quality Value

A spectral Quality Value reflects the confidence that the individual dye emission signals can be separated from the overall measured fluorescence signal. It is a measure of the consistency between the final matrix and the data from which it was computed. A Quality Value of 1.0 indicates high consistency, providing an ideal matrix with no detected pull-up/pull-down peaks.

In rare cases, a high Quality Value can be computed for a poor matrix. This can happen if the matrix standard contains artifacts, leading to the creation of one or more extra peaks. The extra peak(s) causes the true dye peak to be missed by the algorithm, and can lead to a higher Quality Value than would be computed with the correct peak. Therefore, it is important to visually inspect the spectral calibration profile for each capillary.

Condition Number

A Condition Number indicates the amount of overlap between the dye peaks in the fluorescence emission spectra of the dyes in the dye set.

If there is no overlap in a dye set, the Condition Number is 1.0 (ideal conditions), the lowest possible value. The condition number increases with increasing peak overlap.

The ranges that the software uses to determine if a capillary passes or fails are:

Dye Set	Quality Value Minimum	Condition Number Maximum
G5	0.95	13.5

Evaluate the spectral calibration data

IMPORTANT! Do not accept a spectral calibration until you examine the data for all capillaries.

When a spectral calibration completes successfully, the **Overall** row displays green, red, or yellow results.

For each capillary:

- 1. Click a capillary to display the spectral and raw data for a capillary.
- 2. Check that the data meet the following criteria:

Attribute	Acceptance Criteria	Example
Order of the peaks in the spectral profile (intensity vs pixel) from left to right	4-dye: blue-green-yellow-red	Elus Green Yellow Red
	5-dye: blue-green-yellow-red-orange	Blue Green Yellow Red Orange
Order of the peaks in the raw data profile from left to right	 4-dye: red-yellow-green-blue 5-dye: orange-red-yellow-green-blue 	Orange Red Yellow Green Blue
Peak morphology in the spectral profile (intensity vs pixel)	 No gross overlaps, dips, or other irregularities Peaks separate and distinct Peak apexes are separate and distinct (the tails will overlap) 	

- **3.** As needed, click-drag to zoom on the spectral profile traces to determine if the data meet the criteria.
- **4.** If the data for all capillaries meet the criteria above, click **Accept Results**.
- **5**. If any capillary data does not meeting the criteria above, click **Reject Results**, then go to "Spectral calibration troubleshooting" on page 107.

What you see during a spectral calibration

A spectral calibration can run up to three injections. The number of injections performed depends on:

- The number of capillaries that pass or fail during an injection
- Whether you select the Allow Borrowing option

Note: The first time you perform a spectral calibration (for each dye set) after installing a new capillary array, you may notice pull-down peaks (or mirror image peaks). While the run is in progress, these pull-down peaks will eventually correct themselves. Once the run completes the electropherogram, the pull-down peaks disappear.

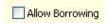
Capillary information sharing

A spectral calibration can share capillary information:

- **Between injections** If a capillary in an injection does not meet the spectral Quality Value and Condition Number limits shown on page 105, the software automatically uses the information from that capillary in a different injection.
- Within an injection If a capillary in an injection does not meet the spectral
 Quality Value and Condition Number limits shown on page 105 and the Allow
 Borrowing option is selected, the software can also use the information from a
 capillary to the left or the right of that capillary, if the values are higher than those
 for that capillary in a different injection.

Spectral calibration with Borrowing disabled

When Borrowing is *disabled*, all capillaries must pass (meet the spectral Quality Value and Condition Number limits) for the calibration to pass.



Injection 1	The software evaluates the Quality Value and Condition Number of all capillaries.
	• If all capillaries pass, the calibration is complete, and injections 2 and 3 are not performed.
	If any capillaries fail, injection 2 is performed.
Injection 2	The software evaluates the Quality Value for each capillary across injections 1 and 2 and uses the information from the capillary with the highest Quality Value.
	• If all capillaries now pass, the calibration is complete and injection 3 is not performed.
	If the same capillary fails in both injection 1 and 2, injection 3 is performed.
Injection 3	The software evaluates the Quality Value for each capillary across injections 1, 2, and 3 and the information from the capillary with the highest Quality Value.
	If all capillaries now pass, the calibration passes.
	If the same capillary fails in injection 1, 2, or 3, the calibration fails.

Spectral calibration with Borrowing enabled

When Borrowing is *enabled*, all capillaries have to pass (meet the spectral Quality Value and Condition Number limits) within the borrowing limits:

✓ Allow Borrowing

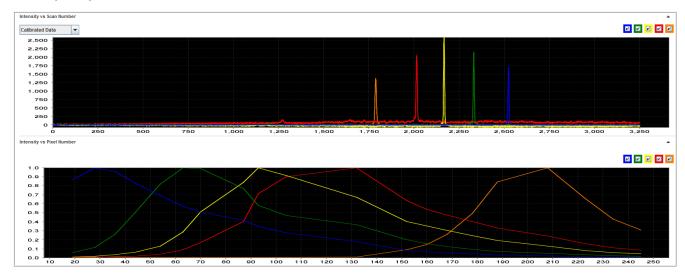
- 8-capillary instruments One adjacent-capillary borrowing event allowed
- 24-capillary instruments Up to three adjacent-capillary borrowing events allowed (the number of allowed borrowing events can be decreased in Preferences).

The software identifies a borrowed capillary with an arrow pointing from the capillary from which the data is borrowed.



Injection 1	The software evaluates the Quality Value and Condition Number of all capillaries.
	• If all capillaries pass, the calibration is complete, and injections 2 and 3 are not performed.
	If any capillaries fail, the software borrows from an adjacent capillary.
	 If, after borrowing, >1 or > 3 capillaries fail, injection 2 is performed.
Injection 2	The software evaluates the quality values between adjacent capillaries in injection 2 and for each capillary across injections 1 and 2 and uses the information with the highest Quality Value for each capillary.
	• If all capillaries pass, the calibration is complete and injection 3 is not performed.
	• If, after borrowing, >1 or > 3 capillaries from injection 1 or 2 do not pass, injection 3 is performed.
Injection 3	 The software evaluates the quality values between adjacent capillaries in injection 3 and for each capillary across injections 1, 2, and 3, then uses the information with the highest Quality Value for each capillary.
	If all capillaries now pass, the calibration passes.
	• If after borrowing, >1 or > 3 capillaries from injection 1, 2, or 3 do not pass, the calibration fails.

Example spectral calibration data



Print, save, or view history

То	Do this
Print	Click Print
Save	Click Report
View history	Click the History tab

Run an install check

When to perform an install check

When your instrument is installed, the service engineer runs an install check.

We recommend that you run an install check monthly to verify that the instrument conforms to precision, sizing range, and peak height specifications.

Estimated run time

40 minutes

Prepare for the install check

Before you begin install check

If you have not already done so, perform a spectral calibration (see "Perform a spectral calibration" on page 44).

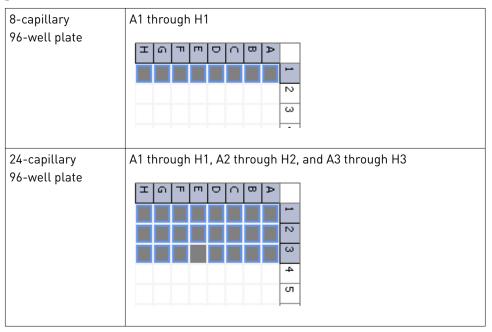
Prepare the instrument

- 1. In the Dashboard, ensure that consumables are not expired and adequate injections remain for consumables.
- 2. Check that buffer levels are at the fill lines.

- 3. Set the oven temperature, then click **Start Pre-heat**. We recommend that you pre-heat the oven for at least 30 minutes before you start a run if the instrument is cold.
- **4.** Check the pump assembly for bubbles and run the Remove Bubble wizard if needed.

Prepare the standard and plate

- 1. Prepare the standard as described in the product information sheet.
- **2.** Load the standards in any injection position in the plate. The example below shows injection position 1, but you can specify the starting well for an injection position.



- **3.** Briefly centrifuge the plate containing the standards.
- 4. Verify that each standard is positioned correctly in the bottom of its well.

IMPORTANT! If the contents of any well contain bubbles or are not located at the bottom of the well, briefly centrifuge the plate, remove the plate from the centrifuge, and verify that each standard is positioned correctly in the bottom of its well.

- **5**. Store the plate on ice until you prepare the plate assembly and load the plate in the instrument.
- **6.** Prepare the plate assembly.

Load the plate in the instrument

- 1. Click the Tray button on the front panel to move the autosampler to the front position, then open the instrument door.
- **2.** Place the plate in the autosampler with the labels facing you (or the instrument door) and the notched corner of the plate in the notched corner of the autosampler.
- 3. Close the instrument door to initialize the instrument.

Perform the install check

- 1. Select Calibration > GlycanAssure Install Standard.
- **2.** Select the plate position in the instrument.
- **3.** Specify the starting well for the injection position in which you loaded the standard in the plate.

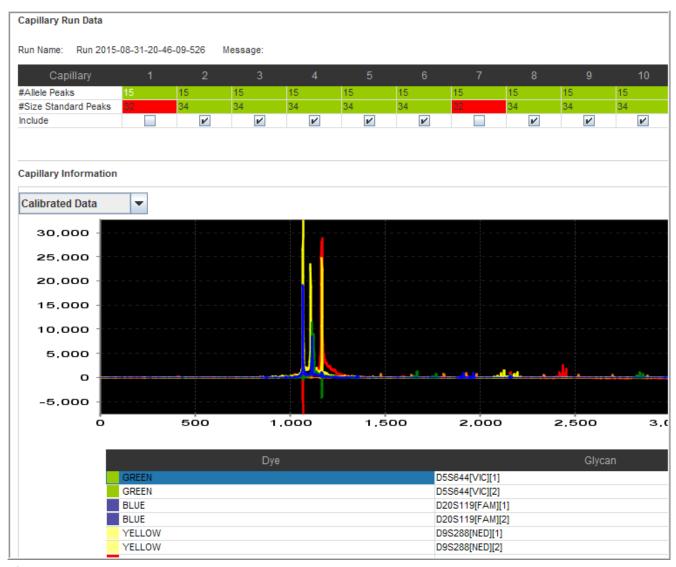
Note: If you navigate away from the **Install Check** screen after you start the install check, the starting well may be reset to A01. This is a display issue only; the starting well you specify is used for the install check.

4. Click Start Run.

What you see during an install check

The instrument performs one run and indicates the number of observed allele and size standard peaks.

The **Capillary Run Data** display updates after the run is complete. The number of observed size standard and allele peaks is shown. Results for each allele are shown at the bottom of the screen in the **Run Information** table.



- 1 Number of peaks per capillary
- 2 Plot and allele size/height for selected capillary
- 3 Allele results for all capillaries

Pass/fail criteria for the install check

The software evaluates peaks in the data for each capillary. To be identified as a possible allele, peaks must be within the following ranges (nominal allele size, or reference bin size, is hard-coded):

For all peaks that are within the nominal size range, the software calculates the **Average Peak Height** and the **Sizing Precision**. Peaks that meet the thresholds below pass.

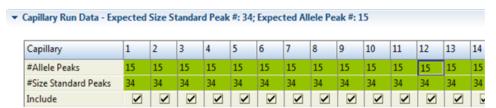
Fragment Analysis

All markers between ± 0.4 bp or ± 0.5 bp of nominal size for the allele

Result	Description	Threshold	
Min Peak Height	Minimum of peak heights for observed allele peaks of the included capillaries.	>175 RFU	
Sizing Precision	Standard deviation of the observed alleles allele fragment sizes		
Pass/Fail	Alleles with a sizing precision and minimum peak height that do not meet thresholds fail.		
	Review the data for failed alleles as described below.		
For information of	For information only		
Nominal Size	Expected allele fragment peak size (bp).		
Mean	Average fragment size for the observed allele peaks.		
Peak Height % > Min	Percentage of observed allele peaks with a peak height above the minimum threshold.		
Sizing Accuracy	Difference between the expected allele size and the mean allele size.		

Evaluate install standard data

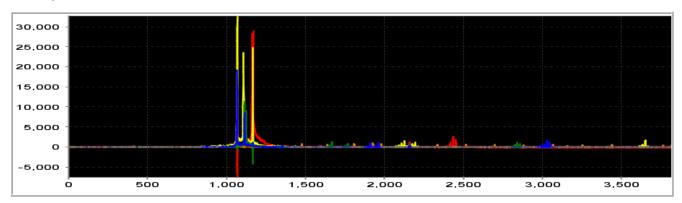
1. Examine the number of size standard and allele peaks found for each capillary.



2. If all capillaries pass, click **Accept Results**.

If any capillaries fail, the **Accept Results** button is dimmed. Evaluate the raw data for failed capillaries. You can deselect 1 failed capillary for 8-capillary instruments or 2 failed capillaries for 24-capillary instruments to recalculate results and then click **Accept**.

Example install standard results



Print, save, or view history

То	Do this
Print	Click Print
Save	Click Report
View history	Click the History tab



Manage library resources

Overview of libraries	55
Create library items	56
Import, export, edit, delete, or sign a library entry	56
Plates library	56
File Name Conventions library	57
Results Group library	58
Instrument method library	59

Overview of libraries

The **Library** contains Items that you select when you set up a run:

- **Plates** Contains plates that have been created in the software.
- **Instrument methods** Contains factory-provided instrument method templates that you use to create new methods. The run module settings used in earlier versions of data collection software are built in to instrument methods.

Note: Instrument methods differ from instrument protocols used in the

- **Instrument run parameters** Not used.
- **Experiments** Contains experiments created in the Run Setup workflow.
- **Reference Sample** Contains reference samples you have added to plates.
- **Filename Conventions** Contains factory-provided file name conventions that you cannot modify. You can also create new file name conventions.
- **Results Groups** Contains factory-provided results groups that you cannot modify. You can also create new results groups.
- **Dye Sets** Contains factory-provided dye sets used in instrument methods. You cannot create new dye sets in the library.
- **Size Standards** Contains factory-provided size standards used in instrument methods.

Create library items

Library item	To create
Plates	See "Create a plate" on page 31 "Create a plate" on page 31.
Instrument methods	See "Create an instrument method" on page 33.
Instrument run parameters	Not used.
Experiments	See "Create an experiment and start a run" on page 34.
Reference Sample	Add a reference sample to a plate (see "Create a plate" on page 31).
Filename Conventions	Click the Library tab, select the library, then Click Create .
Results Groups	Click the Library tab, select the library, then Click Create .
Dye Sets	You cannot create new dye sets.
Size Standards	You cannot create new size standards.

Import, export, edit, delete, or sign a library entry

Click the Library tab to access a library, select the library, then:

- Import Click Import, then select the .xml file to import. If any items in the import file exist in the library, the software displays a message and gives you the option to replace or skip the item.
- Export Select one or more entries, then click Export, then specify a location for the export file. To select multiple entries, Shift-click to select contiguous entries, Ctrl-click to select non-contiguous entries.

IMPORTANT! You must save a plate before you export it.

- Edit Select an entry, then click ✓ Edit, then modify as needed.
- Delete Select an entry, then click Delete.
 Deleting a library entry does not affect existing items that contain the entry.
- **Sign** Select an entry, then click **✓ Sign**, then enter your user name and password to apply an e-signature.

Plates library

The **Plates** library contains all plates that have been saved in the software (plates that have been run and plates that have not yet been run).

File Name Conventions library

File name convention overview

A File Name Convention (FNC) specifies the naming convention for sample data files.

It is an optional component in a plate.

If you do not specify a file name convention, data files are named in this format:

<sample name>_<well>

Note: The file location specified in a file name convention is used only if a results group is not specified for a well.

When you set up a plate for a run, you can optionally add file name conventions to the plate. If you add this item from the library, a *copy* of the item is added to the plate, and can be modified independently from the original item stored in the library.

File name convention settings

Setting	Description	
Name	Name of the file name convention. Names must be unique.	
Preview of name	Interactively displays the attributes you select.	
Available attributes	 Time of Run (run start time) Injection Number Plate Name Polymer Type Run name Sample Type Sample Name Unique Time Stamp Integer - (numeric string in milliseconds that does not correspond to the current time) User Name (available only when security is enabled in the SAE module) Well Position Custom Text fields (≤3) Capillary Number IMPORTANT! The maximum allowed length of a file name, including the path, is 240 characters. The software warns you if your selections will possibly exceed the maximum, but allows you to save the file name convention. However, you will see a pre-check validation error when you 	
Delimiters	start a run if the file name will exceed 240 characters. Symbols you can include in the file name: Dash (-), Dot (.), Underscore (_), Plus (+), Dollar (\$), Equals (=).	

Setting	Description
Custom text	Text to display for the custom text attribute fields.
File location	The file location in the file name convention is used only if no results group is specified for a well.
	The Results Group file location overrides the File Name Convention file location.

Results Group library

Results Group overview

A Results Group is used to name, sort, and customize the folders in which sample data files are stored. It is an optional component in a plate.

Note: The file location specified in a results group overrides the file location in the file name convention specified for a well.

When you set up a plate for a run, you can optionally add results groups to wells in the plate. If you add this item from the library, a *copy* of the item is added to the plate, and can be modified independently from the original item stored in the library.

Results group settings

Setting	Descr	iption
Name	Name of the results group. Names must be unique.	
	The Results Group Name is a required attribute from the Selected Attribute lis	
Preview of name	Interactively displays the attributes you select.	
Available attributes	Results Group Name (required)	Plate Name (required)
	Injection Number	Prefix
	Instrument Method (instrument protocol)	Start Instrument Run Date/time Stamp
		Suffix
Delimiters	Symbols you can include in the results group name: Dash (-), Dot (.), Underscore (_), Plus (+), Dollar (\$), Equals (=).	
Prefix/suffix text	Text to display for the prefix or suffix text attribute fields.	
Select re-injection folder option	This function is not supported in this release of software.	

Setting	Description	
Select folder option	Location: • Default file location (specified in Preferences ➤ User ➤ Run Setup) • Custom location	
	 Sub-folder options: Include an instrument run name folder (run name can be user-defined in the Load Plates for Run screen) Include a results group name folder Include an injection folder 	

Instrument method library

Instrument method overview

An instrument protocol contains the parameters that control the instrument during data acquisition.

Instrument method settings

Setting	Description	
Instrument Method Name	Name of the method. Names must be unique.	
Description	Optional text entry.	
Capillary Length, Polymer, Dye set	Capillary length, polymer type, and dye set with which the protocol will be used	
Oven temperature (°C)	Temperature setting for main oven throughout run.	
Run voltage (kVolts)	Final sample electrophoresis separation run voltage.	
Prerun voltage (kVolts)	Prerun voltage setting before sample injection.	
Injection voltage (kVolts)	Injection voltage setting for sample injection.	
Run time (sec)	Length of time data is collected after voltage is ramped up to the run voltage and the run starts.	
PreRun time (sec)	Prerun voltage time.	
Injection time (sec)	Sample injection time.	
Data delay (sec) Time from the start of separation to the start of sample data collection.		
Advanced options - Do not change unless advised otherwise by support personnel		
Voltage tolerance (kVolts)	Maximum allowed voltage variation.	
Voltage # of Steps (nk)	Number of voltage ramp steps to reach Run Voltage.	
Voltage step interval (sec)	Dwell time at each voltage ramp step.	

Setting	Description
First read out time (ms)	The interval of time for a data point to be produced. First Read Out time should be equal to Second Read Out time.
Second read out time (ms)	The interval of time for a data point to be produced. Second Read Out time should be equal to First Read Out time.
Normalization Target	The expected average RFU for the subset of peaks in the GS600 LIZ [™] v2 size standard used for normalization.
	The default value for each run module has been experimentally determined based on the average peak height of selected peaks in the GS600 size standard with a specific injection time.
	IMPORTANT! If you change the injection time in an instrument protocol, adjust the Normalization Target proportionately. For example, for an instrument protocol with an injection time of 10 seconds and a Normalization Target of 2000: if you change the injection time to 15 seconds (50% increase), change the Normalization Target to 3000 (50% increase).
Normalization Factor Thresholds	The passing range for Normalization Factor (default range is 0.3 to 3.0).
Tilleshotus	IMPORTANT! Increasing the factor threshold above 3.0 may cause amplification of noise.
	If the calculated Normalization Factor is outside the Normalization Factor range, the software multiplies the peak heights of the sample by the low or high Normalization Factor threshold setting (for example, if the Normalization Factor range is 0.3 to 3.0 and the calculated Normalization Factor is 5, the software applies a Normalization Factor of 3.0).



Use security, audit, and e-signature (SAE) functions

Administrators overview of SAE functions	61
Users overview of SAE functions	62
Security	63
Audit	66
Electronic signature	69

The SAE functions are available if your system includes the GlycanAssure™ Security, Audit, and E-signature (SAE) Administrator Console (SAE Admin Console).

Administrators overview of SAE functions

The SAE Admin Console provides the following SAE functions for administrators.

Note: This section provides a brief overview of the functions that the SAE IT Administrator or SAE System Administrator can perform in the SAE Admin Console. For more information, see the *GlycanAssure™ Security, Audit, and E-signature (SAE) Administrator Console v1.0 Help* (Pub. No. MAN0016774) and *GlycanAssure™ Security, Audit, and E-signature (SAE) Administrator Console v1.0 User Guide* (Pub. No. MAN0016773).

Function	Description	Administrator permissions in the SAE Admin Console
Security	Controls user access to the GlycanAssure [™] Data Acquisition Software and GlycanAssure [™] Data Analysis Software.	Create additional user accounts for the Data Acquisition Software and Data Analysis Software.
	A default System Administrator user account is provided at installation.	 Set security policies: Password expiration, allowed login attempts, session lockout (the software remains idle for a specified period).
		 Set password policies: Password length, required characters, and use of previous passwords



Function	Description	Administrator permissions in the SAE Admin Console
Audit	Automatically tracks the following: Data Acquisition Software—Tracks changes made to objects and actions performed by users. Data Analysis Software—Tracks changes made to objects and actions performed by users. SAE Admin Console—Tracks changes made to the SAE settings.	View and generate audit logs. The logs contain detailed information about the audited events.
Electronic signature (e-signature)	Controls user requirements to e-sign (provide a user name and password) the following objects: • Data Acquisition Software—Instrument methods • Data Analysis Software—Projects and project reports	 Grant e-signature authority to user accounts. Enable e-signatures for the following objects: Instrument methods, projects, and/or project reports, and configure the number of e-signatures required. Create e-signature reasons. View, generate, and export e-signature logs. The logs contain detailed information about the e-signature events.

Users overview of SAE functions

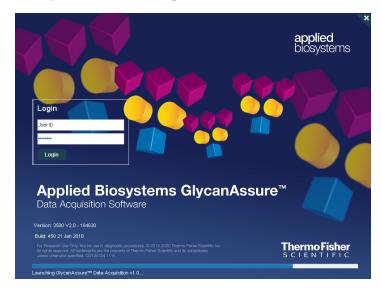
The SAE Admin Console controls the following SAE functions for users in the GlycanAssure $^{\text{\tiny TM}}$ Data Acquisition Software.

Function	Description	User permissions in the Data Acquisition Software
Security	Controls user access to the GlycanAssure [™] Data Acquisition Software.	 Log in to and out of the software. View the user profile. Lock a session. Change expired passwords. See "Security" on page 63.
Audit	Automatically tracks changes made to objects and actions performed by users.	View and export audit logs. The logs contain detailed information about the audited events. See "Audit" on page 66.
Electronic signature (e-signature)	Controls user requirements to e-sign (provide a user name and password) instrument methods. Once an instrument method has been completely e-signed, it cannot be modified or deleted.	 E-sign instrument methods. View and export e-signature logs. The logs contain detailed information about the e-signature events. See "Electronic signature" on page 69.

Security

Log in

Enter your user name and password to access the software.

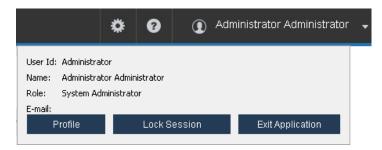


Your access to functions in the software is based on the permissions associated with your user account. Functions for which you do not have permissions are dimmed.

If your system is configured for password expiration, you will be periodically prompted to change your password. If your system is configured to monitor failed log in attempts, you will be locked out of the software if you incorrectly enter your user name or password more than a specified number of times.

Exit

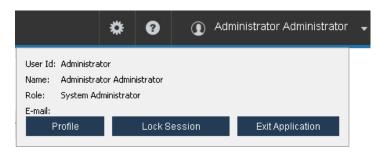
1. Click the name of the logged in user in the far right of the menu bar.



2. Click Exit Application.

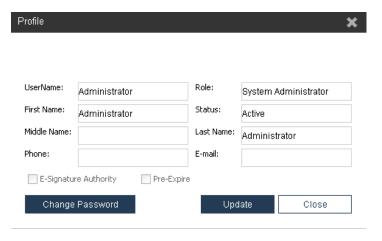
View and change the user profile

1. Click the name of the logged in user in the far right of the menu bar.



- 2. Click Profile.
- **3.** Change the profile as needed, click **Update**, then close the **Profile** dialog box.

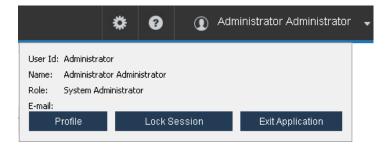
Note: You cannot change the **User Name**, **Role**, **Status**, **E-Signature Authority**, or **Pre-Expire**.



Lock a session

If you need to leave the software running while you are away, you can lock a session. The software continues to run the session, but other users will not be able to access the session.

1. Click the name of the logged in user in the far right of the menu bar.

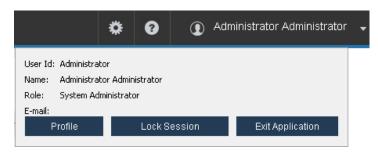


2. Click **Lock Session**, then click **Yes** to confirm.

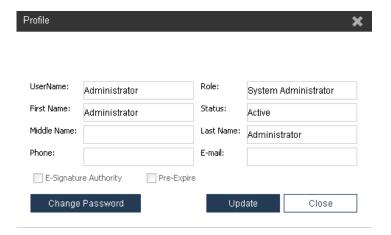
Change your password when it expires

When your password is about to expire, a message is displayed when you log in.

1. Click the name of the logged in user in the far right of the menu bar.



- 2. Click Profile.
- **3.** Change your password:
 - a. Click Change Password.



- **b.** Enter the old password.
- **c.** Enter a new password, confirm the new password, then click **OK**.

Audit

View, generate, and print object audit logs

- 1. In the SAE tab, click Audit Log, then click the Objects tab.
- **2.** Click **Refresh** to synchronize the SAE Admin Console with the Data Acquisition Software.
- 3. (Optional) Click **Filters**, select or enter the filter criteria as needed, then click **Apply Filter** to display the filtered list.

To filter by the	Do this	
Date range	In the From and To fields, click the 🛗 (calendar) , then select a date	
Record name	In the Record field, enter a record name. Partial entry is sufficient (for example, if you enter IgG , all record names that include IgG are displayed).	
User name	In the Username field, enter a user name. Partial entry is sufficient (for example, if you enter Smith , all user names that contain Smith are displayed).	
Object type	Select an object Type :	
	Instrument Method	
	Schedule	
	Plate	
	Experiment	
	File Name Convention	
	Result Group	
Actions performed	Select an Action :	
	Note: The list of actions varies, depending on the object type that you selected.	
	• Create	
	Update	
	• Delete	

Note: To remove the filters, click **Reset Filter**.

4. Generate or print the log:

If you want to	Then
Generate summary information	Click Summary Report to generate and open a .pdf file.
Generate detailed information	Select the objects of interest in the list, then click Detailed Report to generate and open a .pdf file.
Print the log	Click Print .

View, generate, and print event audit logs

- 1. In the SAE tab, click Audit Log, then click the Events tab.
- **2.** Click **Refresh** to synchronize the SAE Admin Console with the Data Acquisition Software.
- 3. (*Optional*) Click **Y Filters**, select or enter the filter criteria as needed, then click **Apply Filter** to display the filtered list.

To filter by the	Do this	
Date range	In the From and To fields, click the 🛗 (calendar), then select a date	
Record name	In the Record field, enter a record name. Partial entry is sufficient (for example, if you enter admin , all record names that include admin are displayed).	
User name	In the Username field, enter a user name. Partial entry is sufficient (for example, if you enter Smith , all user names that contain Smith are displayed).	
Event type	Select an Event Type: Schedule Instrument Method Reference Sample System System System Preference Consumables Injection User Preference Plate User File Name Convention Experiment Data Archive	
	 Calibration Result Group 	
	 Manual Command Data Purge 	



To filter by the	Do this
Actions performed	Select an Action:
	Note: The list of actions varies, depending on the event type that you selected.
	• Login
	• Logout
	Run Completed
	• Fill Array
	Polymer Flush
	Recalculate Install Standard Calibration
	Run Paused
	Data Restore
	Command Sent
	Prime Pump
	• Purge
	License Set
	User Authentication
	Validate Polymer
	• Insert
	• Import
	Restore
	Array Info
	Injection Duplicated
	Run Started
	Update
	Injection Deleted
	Session Timed Out
	Verify Pouch
	Pouch Info
	Archive
	• Delete
	• Export
	• Run Resumed
	Run Terminated The second se
	Remove Bubbles
	Wash

Note: To remove the filters, click **Reset Filter**.

4. Generate or print the log:

If you want to	Then
Generate summary information	Click Summary Report to generate and open a .pdf file.
Print the log	Click Print .

Electronic signature

Guidelines for multiple e-signatures

If an object requires two or more e-signatures:

- The signers are not required to sign at the same time.
- When the first signer signs, the icon next to the **e-sign** button changes to **\$\overline{\mathbb{S}}\$**, and the **Signed Status** in the **Manage** tab is set to **Partially Signed**.
- When all required signers sign, the icon next to the **e-sign** button changes to **\$\mathscr{\mathscr{\mathscr{\mathscr{\mathcal{e}}}}{2}}\$**, and the **Signed Status** in the **Manage** tab is set to **Signed**.

E-sign an instrument method

If your system is configured for electronic signature, you can optionally e-sign the instrument methods.

- 1. In the **Library** tab, click the **Instrument Methods** tab.
- 2. Click e-sign.
- **3.** Select a reason for the e-signature, enter your user name and password, then click **Apply**.

The icon next to the **e-sign** button changes to **\$\instrument\$**, and the **Signed Status** in the **Instrument Methods** tab is set to **Signed**.

Note: If two or more e-signatures are required, see "Guidelines for multiple e-signatures" on page 69.

View, generate, export, and print e-signature logs

E-signature logs contain e-signature records from the GlycanAssure $^{^{\text{TM}}}$ Data Acquisition Software and GlycanAssure $^{^{\text{TM}}}$ Data Analysis Software.

The log information is automatically recorded by the software and cannot be modified.

- 1. In the SAE tab, click E-signature Log.
- 2. Click **Refresh** to synchronize the SAE Admin Console with the Data Acquisition Software.

3. (*Optional*) Click **Tilters**, select or enter the filter criteria as needed, then click **Apply Filter** to display the filtered list.

To filter by the	Do this
Date range	In the From and To fields, click the 🛗 (calendar) , then select a date
Reason for the e-signature	In the Reason field, enter a reason. Partial entry is sufficient (for example, if you enter review , all reasons that include review are displayed).
User name	In the Username field, enter a user name. Partial entry is sufficient (for example, if you enter Smith , all user names that contain Smith are displayed).
Object type	Select an Object Type :
	Instrument Method
Object name	In the Object Name field, enter an object name. Partial entry is sufficient (for example, if you enter Demo , all object names that contain Demo are displayed).

Note: To remove the filters, click Reset Filter.

4. Generate, export, or print the log:

Option	Description
Generate summary information	Click Summary Report to generate and open a .pdf file.
Export the log	Click Export to export a .csv, .pdf, or .xls file to a location of your choosing.
Print the log	Click Print .



Maintain the Instrument

Maintenance schedule	71
Use the maintenance calendar	75
Clean the instrument	76
Install buffers	76
Replenish, change, or store polymer	78
Change and store a capillary array	80
Maintain the pump	81
Shutdown move and reactivate the instrument	83
Maintain the computer	85
Manage software licenses	87
View instrument sensor details	89

Maintenance schedule

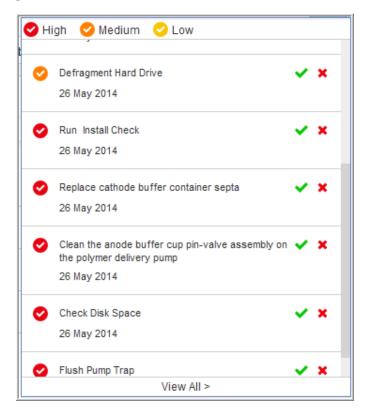


WARNING! This section lists the common tasks required to maintain your Applied Biosystems[™] 3500/3500xL Genetic Analyzer in good working condition. Wear appropriate protection, including gloves, laboratory goggles, and coat whenever you work with the fluids used on this instrument, or parts that may come into contact with these fluids.

IMPORTANT! Use only the cleaning agents listed in this guide. Use of cleaning agents other than those listed in this guide may damage the instrument.

Review maintenance reminders

1. Click to view the maintenance notifications in the **Dashboard** daily, then perform the scheduled tasks.



2. When you complete a task, click w to mark it as complete, click to mark it as dismissed.

Completed and dismissed tasks are:

- Recorded in the **Notification Log**. See "Review the Notifications Log" on page 76.
- Removed from the **Maintenance Notifications** list, and they do not appear again unless they are repeating tasks. Dismissed tasks can be logged in the Notifications Log.

Note: It is the end users' responsibility to comply with maintenance notifications displayed in the software by completing the maintenance tasks at the recommended frequencies as shown in "Maintenance schedule" on page 71.

Daily instrument maintenance tasks

Clean the assemblies, anode buffer container, and cathode buffer container, and ensure that the outside of the assemblies is dry.

IMPORTANT! Use only the cleaning agents listed in this guide. Use of cleaning agents not listed in this manual can impair instrument function.

Task	Frequency	For information, see
Click Refresh , then check consumables on the Dashboard - Refer to the gauges on the Dashboard to see the status for anode buffer container, cathode buffer container, and polymer.	Before each run	"Check system status in the Dashboard" on page 23
Visually inspect the level of fluid inside the anode buffer container and the cathode buffer container. The fluid must line up with the fill line.		"Install the anode buffer container (ABC)" on page 77
Ensure that the CBC septa are properly seated on the		"Install the cathode buffer container (CBC)" on page 77
container.		"Ensure proper installation of CBC septa" on page 26
Ensure that the plate assemblies are properly assembled.		_
Align the holes in the plate retainer with the holes in the septa to avoid damaging capillary tips.		
Ensure that the plate assemblies and the cathode buffer container are positioned on the plate deck properly. They should sit securely on the deck.		"Load the plate in the instrument" on page 38
Ensure the array locking lever on the capillary array is secured.		Figure 2
Check for bubbles in the pump block and channels.	Daily or before	"Remove bubbles from the polymer
Use the Remove Bubble wizard to remove bubbles.	each run	pump" on page 81
Check the loading-end header to ensure that the capillary tips are not crushed or damaged.		"Install or change the capillary array" on page 80
Ensure that the pump block is in pushed back position.	Daily	Figure 2
Clean the instrument surfaces of dried residue, spilled buffer, or dirt.		"Clean the instrument" on page 76
Check for leaks and dried residue around the buffer-pin valve, check valve, and array locking lever.		Figure 3
If leaks persist, contact Thermo Fisher Scientific.		

Weekly instrument maintenance tasks

Task	Frequency	For information, see
Check the storage conditions of the used arrays to ensure the array tip is covered in the reservoir.	Weekly	"Store a capillary array" on page 80
Run the Wash Pump and Channels wizard.		"Wash the pump chamber and channels" on page 81
Use a lab wipe to clean the anode buffer container valve pin assembly on the polymer delivery pump.		Figure 2
Restart the computer and instrument.		"Restart the instrument and the computer" on page 90

Monthly instrument maintenance tasks

Task	Frequency	For information, see
Run install check.	Monthly or as	"Run an install check" on page 49
Flush the pump trap.	needed	"Flush the water trap (pump trap) Glycan DC" on page 82
Empty the oven condensation reservoir.		Figure 2
Replace cathode buffer container septa.		"Install the cathode buffer container (CBC)" on page 77
Clean the autosampler.		"Clean the instrument" on page 76
Clean the drip tray.		
Check disk space.		"Monitor disk space" on page 86
View, generate, and print audit logs.		"Audit" on page 66
Defragment the hard drive.	Monthly, or before fragmentation reaches 10%	"Defragment the computer hard drive" on page 87

Annual planned maintenance tasks

Call your Thermo Fisher Scientific representative to schedule annual planned maintenance.

As-Needed instrument maintenance tasks

Task	Frequency	For information, see
Change the tray.	As needed	"Clean the instrument" on page 76
Remove dried polymer from the capillary tips with a lint-free tissue moistened with deionized water.		
Archive and purge library objects.		Chapter 5, "Manage library
Dashboard ➤ Manage ➤ Archive or Dashboard ➤ Manage ➤ Purge.		resources"

Use the maintenance calendar

The Maintenance calendar is a monthly or daily view of the routine maintenance tasks scheduled for your instrument. When a task is due to be performed, it is listed when you click in the **Dashboard**.

To access the maintenance calendar, click the Maintenance tab, then click Schedule.

A set of recommended tasks are scheduled in the calendar, flagged with FR (Factory Repeating) in the monthly view and F (Factory) in the daily view. User-specified repeating tasks are flagged with R (Repeating) in the monthly view.

Weekly factory repeating tasks in calendar	Mothnly factory repeating tasks in calendar
 Clean the anode buffer cup pin-valve assembly on the polymer delivery pump Restart instrument and computer 	 Replace cathode buffer container septa Clean drip tray Clean autosampler Check disk space Defragment hard drive Run install check Flush pump trap

You can change the priority of factory tasks, but you cannot remove them from the calendar or alter the frequency at which the notifications for the tasks are displayed.

Additionally, we suggest that you add to the maintenance calendar:

- The regular maintenance tasks.
- A maintenance task to replace a consumable based on its installation date (for example, create a task to replace the polymer for two days before the polymer will expire).

Create maintenance calendar entries

- 1. Click , then click **Schedule**.
- Click Add, then follow the prompts.The Month and Day tabs allow you to view your schedule in different formats.

Chapter 7 Maintain the Instrument Clean the instrument

View maintenance notifications

- 1. Click <u>...</u>
- **2.** Review the notifications for maintenance tasks listed in the maintenance calendar.
- **3.** Click or at to mark the task as

Review the Notifications Log

The Notifications Log is a history of the action taken on maintenance notifications in the **Dashboard** (see "View maintenance notifications" on page 76).

- 1. Click , then click **Notifications**.
- **2.** View the **Notification Log Report** and print as needed.

Clean the instrument

IMPORTANT! Wear appropriate protection, including gloves, laboratory goggles, and coat whenever you work with the fluids used on this instrument, or parts that may come into contact with these fluids.

IMPORTANT! Use only the cleaning agents listed in this guide. Use of cleaning agents other than those listed in this guide may damage the instrument.

- 1. Ensure the oven is closed.
- **2.** Press the Tray button on the front of the instrument to move the autosampler to the forward position.
- 3. Wipe off any liquid on or around the autosampler using a lint-free tissue.
- 4. Clean off any polymer build-up crystals on the instrument, including the capillary tips, with deionized water and lint-free tissue.
- **5.** Clean the array plug with deionized water and lint-free tissue.
- **6.** Clean out the drip trays with deionized water, or ethanol, and lint-free tissue. Note: The drip tray can be removed.

Install buffers

IMPORTANT! Wear appropriate protection, including gloves, laboratory goggles, and coat whenever you work with the fluids used on this instrument, or parts that may come into contact with these fluids.

Install the anode buffer container (ABC)

- 1. Check the expiration date on the label to ensure it is not expired and will not expire during use.
- **2.** Allow the refrigerated ABC to equilibrate to room temperature prior to first use. Do not remove the seal until you have completed step 5.
- **3.** Verify that the seal is intact. Do not use if buffer level is too low or seal has been compromised. A fill tolerance of ±1 mm is acceptable.
- **4.** Invert the ABC, then tilt it slightly to move most of the buffer to the larger side of the container. The smaller side of the container should contain <1 mL of the buffer.
- **5.** Verify that the buffer is at the fill line.
- 6. Peel off the seal at the top of the ABC.
- 7. With the RFID label toward instrument, place the ABC into the anode-end of the instrument, below the pump. Position the anode in the large chamber of the ABC, then push the ABC up and back to install.

IMPORTANT! The RFID label must be facing the instrument (away from you) to ensure that the RFID information is read accurately by the instrument.

- 8. Close the instrument door to re-initialize.
- In the Dashboard, click Refresh, then check the Quick View section for updated status.

Install the cathode buffer container (CBC)

- 1. Check the expiration date on the label to ensure it is not expired and will not expire during use.
- 2. Allow refrigerated CBC to equilibrate to ambient temperature.
- **3.** Wipe away condensation on the CBC exterior with a lint-free tissue. Condensation can cause arcing and termination of the run.
- **4.** Check that seal is intact. Do not use if buffer level is too low or seal has been compromised. A fill tolerance of ± 0.5 mm is acceptable.



- (1) Fill line
- **5.** Tilt the CBC back and forth gently and carefully to ensure that the buffer is evenly distributed across the top of the baffles. If you do not tilt the CBC back and forth, the buffer sticks to the baffles because of surface tension.
- **6.** Verify that the buffer is at or above the fill line.
- 7. When ready to install CBC, place the container on a flat surface (such as a lab bench) and peel off the seal.

- **8.** Wipe off any buffer on top of the CBC with a lint-free tissue. Ensure that the top of the container is dry. Moisture can cause arcing and termination of a run.
- **9.** Place the appropriate septum on each side of the CBC:
 - Align the buffer septum (the part that is symmetrical) over the 24 holes of the CBC.
 - **b.** Push the septum lightly into the holes to start and then push firmly to seat it.
 - **c.** Align the capillary washing septum over the other chamber of the CBC.
 - **d.** Push the septum lightly into the holes to start and then push firmly to seat it.

IMPORTANT! Look at the CBC from the side and ensure there is no gap between the container and the lip of the septum.

IMPORTANT! Ensure that the washing septum is securely seated to prevent displacement of the septum during operation.

- **10.** Click the Tray button on the front panel to move the autosampler to the front position.
- 11. With the tab facing you and the RFID tag to the right, install the CBC on the autosampler. When properly installed, the CBC tabs will click as you snap them into place on the autosampler.
- **12.** Click the Tray button to retract the autosampler, then close the instrument door to initialize.
- 13. In the **Dashboard**, click **Refresh**, then check the **Quick View** section for updated status.

Replenish, change, or store polymer

IMPORTANT! Note the following:

- Wear appropriate protection, including gloves, laboratory goggles, and coat
 whenever you work with the fluids used on this instrument, or parts that may
 come into contact with these fluids.
- To minimize background fluorescence, use clean, powder-free, silicone-free latex gloves whenever you handle the pump assembly or any item in the polymer path.

Precautions for use

- Do not reuse a polymer pouch that has been installed on another type of instrument. For example, if you remove a partially used polymer pouch from an 8-capillary instrument, do not reuse that polymer on a 24-capillary instrument.
- If you remove a polymer pouch for storage (2–8°C), place a pouch cap (Cat. No. 4412619) onto the pouch, then place an empty pouch (or conditioning reagent) on the connector to prevent desiccation of any residual polymer on the connector. Follow the instructions in the wizard to ensure proper operation of the pouch and the instrument.

Replenish polymer or change polymer type

1. Check the expiration date on the label to ensure that the polymer is not expired and will not expire during intended use.

IMPORTANT! Do not use if the product is expired, if the pouch or label is damaged, or if the top seal is missing or damaged.

- **2.** Allow the refrigerated polymer to equilibrate to ambient temperature (15–30°C) before use.
- 3. Click , then click **Replenish Polymer** (requires 10 to 20 minutes) or **Change Polymer Type** (requires 60 to 70 minutes).
- **4.** Follow the prompts in the Wizard window.
- **5.** When instructed to install the polymer, peel off the seal at the top of the pouch fitment.

Note: You may notice a tiny droplet of polymer inside the fitment (residual from the pouch filling process). This is **not** expected to cause any performance issues.

6. With the RFID label facing the instrument, slide the pouch fitment onto the slot of the lever assembly. Push the lever up to snap the pouch into the connector end of the instrument pump.

Note: The RFID label must face the instrument (away from you) to ensure that the RFID information is read accurately by the instrument.

7. In the **Dashboard**, expand the Consumables pane, click , then check for the updated polymer status.

Store partially used polymer

If you remove a polymer pouch for storage $(2-8^{\circ}C)$, place a pouch cap onto the pouch, then place an empty pouch (or conditioning reagent) on the connector to prevent desiccation of any residual polymer on the connector. Follow the instructions in the wizard to ensure proper operation of the pouch and the instrument.

Fill capillary array with fresh polymer

- 1. Click , then click Fill Array with Polymer.
- 2. Follow the prompts in the Fill Array wizard window.
- **3.** Click **Refresh** in the Dashboard to update the screen.
- **4.** In the **Dashboard**, expand the Consumables pane, click , then check for the updated polymer status.

Change and store a capillary array



WARNING! SHARP The load-end of the capillary array has small, blunt ends that can lead to piercing injury.

IMPORTANT! Wear appropriate protection, including gloves, laboratory goggles, and coat whenever you work with the fluids used on this instrument, or parts that may come into contact with these fluids.

Install or change the capillary array

IMPORTANT! Before installing a capillary array, examine the loading-end header to ensure that the capillary tips are not crushed or damaged.

Note: The Install Capillary Array wizard takes 15 to 45 minutes to complete.

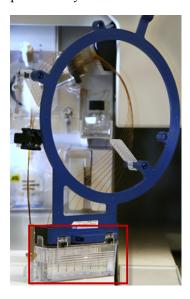
- 1. Click , then click **Install Capillary Array**.
- 2. Follow the prompts in the Install Capillary Array wizard window.
- 3. In the **Dashboard**, expand the Consumables pane, click Φ, then check for the updated polymer status.

Store a capillary array



WARNING! SHARP The load-end of the capillary array has small, blunt ends that can lead to piercing injury.

If you remove a capillary array for storage, insert the loading-end of the capillary array in distilled water to prevent the polymer from drying in the capillaries. Check periodically and add distilled water as needed.



Maintain the pump

IMPORTANT! Wear appropriate protection, including gloves, laboratory goggles, and coat whenever you work with the fluids used on this instrument, or parts that may come into contact with these fluids.

IMPORTANT! To minimize background fluorescence, use clean, powder-free, silicone-free latex gloves whenever you handle the pump assembly or any item in the polymer path.

Avoiding damage to the pump assembly

The polymer delivery pump can be irreversibly damaged if:

- Polymer dries in the polymer channels of the pump assembly, which can scratch the channels in the pump, and can cause blockage.
- The pump assembly is exposed to organic solvent, which can cause cracking and clouding of the acrylic pump material.
- The pump assembly is exposed to temperatures greater than 40°C, which can damage the pump components.
- There is arcing in the pump assembly, which can damage the acrylic pump material.

Remove bubbles from the polymer pump

Remove bubbles from the polymer pump fluid path before each run.

Note: The Bubble Remove wizard takes 5 to 15 minutes to complete.

- 1. Click , then click **Remove Bubbles**.
- 2. Follow the prompts in the Bubble Remove wizard window.
- **3.** In the **Dashboard**, expand the Consumables pane, click , then check for the updated polymer status.

Wash the pump chamber and channels

In the following situations, use the Polymer Delivery Pump Cleaning Kit (Cat. No. 4414007) in addition to the **Wash Pump wizard** to thoroughly clean the polymer delivery pump:

- Polymer has dried in the channels of the lower polymer block.
 Mechanical malfunctions may cause dried polymer to appear in the polymer delivery pump. Washing with the Wash Pump Chamber and Channels wizard or this kit may not remove dried polymer—the lower polymer block may need to be replaced by Thermo Fisher Scientific.
- A contaminant in the polymer delivery pump is suspected of causing problems.
 The check valve fitting might be clogged or contaminated.

The Wash Pump and Channels wizard takes >40 minutes to complete.

- 1. Click , then click Wash Pump and Channels.
- 2. Follow the prompts in the Wash wizard window.

Flush the water trap (pump trap) Glycan DC

Flush the water trap monthly to prolong the life of the pump and to remove diluted polymer from the pump.

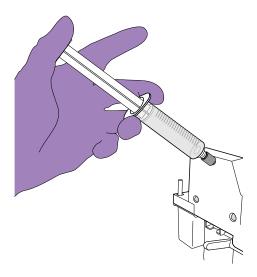
Flush with distilled or deionized water and ensure that the water flows into the overflow container. Dispose of the excess water (inside the overflow container).

Note: Leave the trap filled with either distilled or deionized water.

1. Fill the supplied 20-mL, all-plastic Luer lock syringe with distilled or deionized water. Expel any bubbles from the syringe.

IMPORTANT! The 20-mL, all-plastic Luer lock syringe is supplied in the Polymer Delivery Pump Cleaning Kit (Cat. No. 4414007). Do not use a syringe smaller than 20 mL. Doing so may generate excessive pressure within the trap.

2. Attach the syringe to the forward-facing Luer fitting at the top of the pump block. Hold the fitting with one hand while threading the syringe onto the fitting with the other hand.



- **3.** Open the Luer fitting by grasping the body of the fitting and turning it to loosen.
- Grasp the attached syringe and turn counterclockwise approximately one-half turn.
- **5.** Slowly depress the plunger.

IMPORTANT! DO NOT USE EXCESSIVE FORCE when you push the syringe plunger as this may damage the trap seals. Take approximately 30 seconds to flush 5 mL of either distilled or deionized water through the trap.

Note: Because the water trap volume is approximately 325 μ L, a relatively small volume of water is adequate for complete flushing. However, a larger volume improves flushing as long as force and flow rate are kept within the limits given above.

- **6.** Remove the syringe from the Luer fitting. Hold the fitting with one hand while turning the syringe counterclockwise with the other hand.
- 7. Close the Luer fitting by lightly turning clockwise until the fitting seals against the block.

Shutdown move and reactivate the instrument

Shutdown the instrument

A conditioning reagent pouch is required for this procedure.

Use the **Instrument Shutdown wizard** for short- and long-term shutdown.

Note: The Instrument Shutdown wizard takes 60 minutes to complete.

- 1. Click , then click **Shutdown the Instrument**.
- **2.** Follow the prompts in the Instrument Shutdown wizard window. Perform the appropriate shutdown procedure based on the information in the following table:

IMPORTANT! Place a conditioning reagent pouch onto the instrument before performing instrument shutdown.

If the instrument will be unattended for	Perform this shutdown procedure	
< 1 week	No action is required.	
1 to 2 weeks	Keep the load-end of the capillary array in 1X buffer to prevent the polymer from drying in the capillaries. If fluid level is low, add DI water to buffer solution. Install the new CBC when ready to resume runs.	
> 2 weeks	 Run the Install Capillary wizard and store the capillary array. Clean any spills or residual polymer. Run the Shutdown the Instrument wizard. Unplug the instrument. 	

Move and level the instrument

IMPORTANT! If you relocate the instrument, we recommend that you have an IQ OQ performed. Contact Thermo Fisher Scientific to schedule the IQ OQ service.



WARNING! PHYSICAL INJURY HAZARD. Do not attempt to lift the instrument or any other heavy objects unless you have received related training. Incorrect lifting can cause painful and sometimes permanent back injury. Use proper lifting techniques when lifting or moving the instrument. Two or three people are required to lift the instrument, depending upon instrument weight.

- 1. Remove the following components from the instrument:
 - Any plate assemblies from the autosampler.
 - CBC from the autosampler.
 - Capillary array: Run the shutdown wizard (see "Shutdown the instrument" on page 83).
 - Anode buffer reservoir.
- **2.** Switch off the circuit breaker on the back of the instrument.
- **3.** Disconnect the power cord and the Ethernet cable.

IMPORTANT! While moving the instrument, avoid any shock or vibration.

- **4.** Move the instrument.
- **5.** Turn the instrument legs to level the instrument.

To move the instrument corner	Turn the leg
up	right (clockwise)
down	left (counterclockwise)

6. Have an IQ OQ performed before using the instrument.

IMPORTANT! After performing a conditioning wash, ensure that the buffer level inside the ABC is at or above fill line before proceeding to the next step.

Reactivate the instrument

Note: The **Instrument Reactivate wizard** takes ~45 minutes to complete.

- 1. Click , then click **Reactivate the Instrument**.
- **2.** Follow the prompts in the **Instrument Reactivation** wizard window.

Maintain the computer

This section lists the common tasks required to maintain the computer for your 3500/3500xL instrument in good working condition.

Note: In the event of a power disruption, restart the computer ("Restart the instrument and the computer" on page 90).

Back up the datastore during software uninstall

IMPORTANT! Do not uninstall the software unless instructed to do so by Thermo Fisher Scientific.

When you uninstall the software, you are prompted to back up the datastore (the directory that contains all library items you created, such as plates and protocols).

Select a location other than the install directory for the datastore backup.

IMPORTANT! Do not back up the datastore to the installation directory. The installation directory is deleted during the uninstall.

Archive, purge, and restore data

IMPORTANT! The customer is responsible for validation of archive, restore, and purge functions.

- Archive—Makes a copy of the data in an external file that you can save in another location.
- Purge Allows you to delete (purge) user-created items stored in the library.
 Factory-provided items are not purged. You have an option to archive the items, also.
- **Restore**—Restores archived data back to the system.

IMPORTANT! These functions affect items stored in the library (datastore). These functions do not affect sample data files.

Frequency

We recommend that you purge the library objects once every three months.

Archive library items

- 1. Click **#**, then select **DataStore** ▶ **Archive**.
- **2.** Specify a date range, then click **OK**.
- **3.** Specify a location and file name for the archive (.dsz) file, then click **Save**.

IMPORTANT! Do not specify <install directory>>:\Applied Biosystems\3500\datastore as the archive location. If you do so, your archive can be deleted if you uninstall the software.

If you specify a location to which you do not have permission to save, a warning message is displayed and gives you the option to save in another location. A message is displayed when the archive is complete.

Chapter 7 Maintain the Instrument Maintain the computer

Archive data files

 Use the Windows[™] backup function (Start ➤ Control Panel ➤ Backup and Restore) to archive the data files.

Note: If you export audit records for samples that are not in their original location (samples have been deleted or moved), an error message is displayed. Return sample data files to their original location, then export again.

2. Copy the archive to a network or external drive.

Restore library entries

This function restores items archived from the library. To restore audit records, see "Archive, purge, and restore data" on page 85.

- 1. Click **■**, then select **DataStore ▶ Restore**.
- **2.** Select the archive (.dsz) file to restore, then click **Open**. If the archive file contains items that exist in the system, a message is displayed.
- Select an option to continue.A message is displayed when the restore is complete.

Purge library items

This function purges (deletes) items stored in the library.

- 1. Click **□**, then select **DataStore** ▶ **Purge**.
- **2.** Specify the date category and range, then click **OK**.
- Click Yes in the Purge warning message.A message is displayed when all records are deleted.

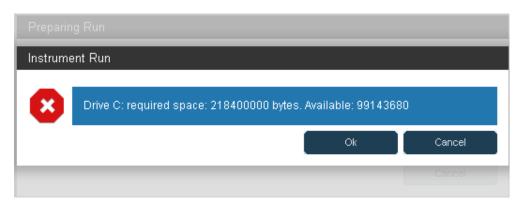
Monitor disk space

Ensure that you have sufficient drive space by regularly:

- Archiving data
- Deleting unneeded files
- Emptying the trash
- Defragmenting the drives

Automatic disk space check before a run

Before a run, the software checks free disk space and displays a message when the hard disk is 70–75% full. At 78% full, the software will not start a run.



Manually check hard disk space

- 1. Go to My Computer, right-click the drive, then select **Properties** General.
- **2.** If there is insufficient space on the hard disk:
 - Archive the sample files.
 - Delete the sample file data from the drive D and empty the contents of the Recycle Bin.

Defragment the computer hard drive

This option can be set as a reminder in the scheduler. The fragmentation of files decreases the performance of both the Data Collection software and the computer operating system. Programs take a longer time to access files by performing multiple search operations of the fragments.

Go to **Start** > **Programs** > **Accessories** > **System Tools** > **Disk Defragmenter** and follow the prompts.

Note: You can click Analyze to see if you should defragment or not.

Manage software licenses

The GlycanAssure[™] Data Acquisition Software requires a license to run.

IMPORTANT! If you replace or add a network card in the computer running the software or relocate the software to a new computer, contact Thermo Fisher Scientific to update your license for the new network card or computer.

Create an email address for license activation and renewal

You must use the same email address to activate and renew software licenses.

Create an email address that is routinely monitored by your team (rather than a single individual). Use this email address to activate and renew software licenses.

Obtain and activate a software license

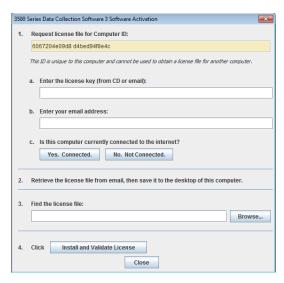
The GlycanAssure $^{\text{TM}}$ Data Acquisition Software **Software Activation** dialog box is displayed when you start the software if no license is installed and activated on your computer.

This task is typically performed by the Thermo Fisher Scientific service representative during installation of the instrument.

1. Ensure that all network cards in the computer are enabled.

IMPORTANT! You can run the GlycanAssure[™] Data Acquisition Software using only the network cards that were enabled when you activate the software license. For example, if you activate the software when your wireless network card is disabled, you will not be able to run the software when the wireless network card is enabled.

2. Display the Software Activation dialog box by starting the GlycanAssure[™] Data Acquisition Software.



- **3.** Obtain the license key. The license key is provided on the GlycanAssure[™] Data Acquisition Software CD case, or in an email from Thermo Fisher Scientific.
- **4.** Request the software license file by performing steps 1a, 1b, and 1c as listed on the activation screen.

IMPORTANT! Keep a record of the email address used to activate the software license. You must use the same email address to renew the software license when it expires.

- **5.** Obtain the software license file from your email.
- **6.** Make a copy of the software license file and keep in a safe location.
- **7.** Copy the software license file to the desktop of the GlycanAssure[™] Data Acquisition Software computer.
- **8.** If the Software Activation dialog box has closed, start the software again.

- 9. Click **Browse**, then navigate to the software license file saved on your computer.
- **10.** Click **Install** and **Validate License**. A message is displayed when the license is installed and validated.
- 11. Click Close.

View instrument sensor details

In the Dashboard, click Instrument Sensor.

Status for laser, current and voltages, and oven are displayed.



Troubleshooting

Restart the instrument and the computer
Instrument components
Instrument troubleshooting
RFID troubleshooting
Error messages
Dashboard troubleshooting
Software troubleshooting
Run, re-run, or re-inject troubleshooting
Data/electropherogram troubleshooting
Spatial calibration troubleshooting
Spectral calibration troubleshooting
Install standard troubleshooting
Audit troubleshooting
Electronic signature troubleshooting
Troubleshooting procedures

Restart the instrument and the computer

When to use this procedure:

- If communication errors are displayed
- If the front panel indicator is blinking red
- At the end of spatial calibration, if Accept/Reject buttons are dimmed
- If maintenance wizards are taking longer than expected
- If software operations are taking longer than expected

When you are instructed to restart the instrument and the computer:

- **1.** Exit the GlycanAssure[™] Data Acquisition Software.
- **2.** Power off the computer.
- **3.** Make sure the instrument door is closed, then power off the instrument.
- **4.** When the computer is completely powered off, wait 60 seconds, then power on the computer. Wait until the Windows[™] login screen is displayed. Do not log in.

- **5.** Power on the instrument and wait until the green status light on the front panel is on and not flashing before proceeding.
- **6.** Log in to Windows[™] operating system.
- **7.** Start the GlycanAssure $^{\text{TM}}$ Data Acquisition Software.

Instrument components

Figure 2, Figure 3, and Figure 4 are provided below for reference in this section.

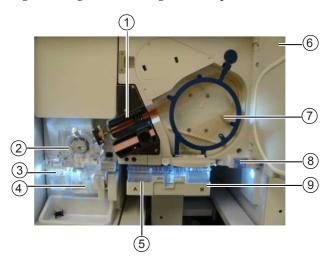


Figure 2 Instrument interior

- 1 Detection cell heater block
- 2 Polymer delivery pump (PDP)
- 3 Anode buffer container (ABC)
- 4 Polymer or conditioning pouch
- (5) Cathode buffer container (CBC)
- 6 Oven door
- 7 Capillary array
- 8 Oven condensation reservoir
- Autosampler

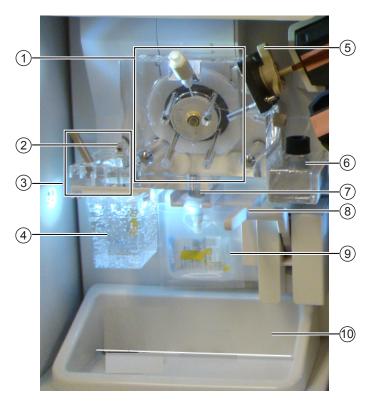


Figure 3 Polymer delivery pump (PDP)

- 1 Upper polymer block
- 2 Buffer-pin valve
- 3 Lower polymer block
- 4 Anode buffer container (ABC)
- (5) Array locking lever
- 6 Water trap waste container
- 7 Check valve fitting
- 8 Polymer pouch lever
- Polymer pouch
- 10 Drip tray



Figure 4 Detection cell

Instrument troubleshooting

Symptom	Possible cause	Action
Power failure to instrument and computer	Power failure.	Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).
Front panel indicator: Amber light	Run paused	Resume run.
(blinking)	Door open	Close the instrument door.
CBC septum is lifted off the container	Septum was not seated properly when installed.	See "Ensure proper installation of CBC septa" on page 26.
Autosampler does not move the plate to a higher position	Array electrodes are bent. The plate is not aligned correctly resulting in the array tips missing center of septa. The plate retainer may not be snapped onto the plate base.	Ensure that the plate retainer, plate (or tube strip), and plate base are assembled correctly. Listen for a snap when the plate retainer and the plate base are clipped together. IMPORTANT! If array tips are bent, replace the array.

Symptom	Possible cause	Action
Autosampler does not move the plate to a higher position	The plate base is not sitting properly on the autosampler.	The plate base should sit flat on the autosampler. When placing the plate on the autosampler, ensure that the pins in the autosampler are properly aligned with the holes at the bottom of the plate base, and that the left and right sides are latched.
	The plate retainer is lifted off the plate base by array.	Securely clip the plate retainer and plate base together.
	The septum is lifted off the CBC.	Ensure that the septum is completely inserted into position. Listen for the light clicking sound that occurs when the septum is pressed down firmly into position.
Polymer delivery pump (PDP) is extremely noisy and vibrating while running any wizard	The array locking lever is not in the correct position. IMPORTANT! If the lever is not in the correct position, you will receive "Leak error" message.	Lock the lever in the correct position. If this is not possible contact Thermo Fisher Scientific.
	Polymer delivery pump block is not pushed back into position after capillary array change	Gently push the buffer-pin valve lever (yoke). If the lever does not move up and down freely, restart the instrument and the computer. (see "Restart the instrument and the computer" on page 90).
		After the instrument has restarted, check the lever movement. If the lever does not move up and down freely, contact Thermo Fisher Scientific.
		If the lever moves up and down freely, push the upper polymer block all the way back against the wall.

Symptom	Possible cause	Action
Polymer delivery pump (PDP) is extremely noisy and vibrating while running any wizard	Figure 5 Buffer-pin valve lever (yoke) 1 Yoke 2 Buffer-pin valve	
Polymer is not pumping properly - wizard fails - filling array	Check Valve is clogged Crystals present in polymer delivery pump path	Run the Wash Pump and Channels wizard. See "Flush the water trap (pump trap) Glycan DC" on page 82 and "Wash the pump chamber and channels" on page 81. If the problem persists, contact Thermo Fisher Scientific.
	2 Figure 6 Pump chamber and valve fitt 1 Debris in chamber 2 Check valve fitting	ring

Symptom	Possible cause	Action
Buffer-pin valve does not move	Polymer crystallizations have formed around the buffer-pin valve	If you see any crystals, leaks, and dried residue around the buffer-pin valve, clean the valve and the array locking lever immediately.
		Add DI water to the buffer solution to dissolve crystals.
		Note: Use the lint-free swabs, included in the Polymer Delivery Pump Cleaning Kit [Cat. No. 4414007].
		If leaks persist, contact Thermo Fisher Scientific.
		Perform maintenance tasks routinely as described in "Maintenance schedule" on page 71. If leaks persist, contact Thermo Fisher Scientific.
	The vent hole behind the buffer-pin valve is clogged	Clean the vent hole behind the buffer- pin valve with DI water.
	The PDP block is not in the correct position	See "Polymer delivery pump (PDP) is extremely noisy and vibrating while running any wizard" . If the problem persists, contact Thermo Fisher Scientific.
Polymer crystals on the buffer-pin valve	Buffer valve leakage	Clean the buffer-pin valve. Perform maintenance tasks routinely as described in "Maintenance schedule" on page 71.
Fluid does not move through the polymer delivery pump and into the ABC from polymer or conditioning pouch	Blockage in fluid path or problem with polymer delivery pump	Contact Thermo Fisher Scientific.
Poor signal and resolution after replenishing polymer	The Check Valve is clogged (see "Instrument troubleshooting" on page 93.	Wash the channels using the Polymer Delivery Pump Cleaning Kit (Cat. No. 4414007). If the problem persists, contact Thermo Fisher Scientific.
Any of the following visual or audible conditions:	The buffer level is below the fill line.	Verify that buffer level is at or above the fill line.
Unstable current	The buffer spilled on top of the CBC.	IMPORTANT! Ensure that the
 Arc-detect errors A crackling noise at the beginning of electrophoresis 	The buffer spilled on top of the Autosampler.	environment (humidity) is non- condensing.
A blue lightning symbol below	Condensation on the CBC.	
the oven	Condensation around the septa.	

Symptom	Possible cause	Action
An error message regarding electrical current	Condensation on the lower part of the oven door, near the array header.	Wipe away spills, moisture, and condensation with a lint-free lab
Electric discharge	Condensation inside the oven.	cloth. If the problem persists, contact Thermo Fisher Scientific.
	There is not enough fluid in larger chamber of ABC, or the anode buffer has spilled into smaller overflow chamber.	Pipette the buffer from the smaller overflow chamber to the larger chamber. Ensure that the buffer is filled to within ±1 mm of the fill line.
		When installing new ABC, tilt the container to move buffer to the larger side of the container as described in "Install the anode buffer container (ABC)" on page 77.
When you remove the heat seal from a new pouch, some residual seal remains on top of the pouch.	The top seal of the pouch has become delaminated and left the polyethylene behind on the pouch cap.	Use a pipette tip to remove the entire seal from the pouch cap before installing on the instrument.

RFID troubleshooting

Symptom	Possible cause	Action
Unable to read RFID information. "Failure to Read from RFID tag"	Consumable package is improperly installed or label is defective. Polymer/Conditioning reagent pouch	Ensure that the RFID label is not visibly damaged and consumable package is properly installed.
	is not positioned properly.	Ensure that label is close, and parallel, to the instrument.
		Reposition or re-install pouch, then click Refresh on the Dashboard.
		Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).
		Install a new consumable (if available).
		If problem persists, contact Thermo Fisher Scientific.
	Malfunctioning RFID label or reader.	Place a used CBC, ABC, pouch, or array on the instrument:
		If the instrument can read the RFID label, install a new CBC, ABC, pouch, or array.
		If the instrument cannot read the RFID label, contact Thermo Fisher Scientific.

Error messages

Symptom	Possible cause	Action
"An error has been detected from the instrument."	Instrument monitor circuit failure	Restart the instrument and the computer. (see "Restart the instrument and the computer" on page 90"Restart the instrument and the computer" on page 90).
"Unable to transmit measurement data. Internal data buffer overflow."	Communications error.	Restart the instrument and the computer. (see "Restart the instrument and the computer" on page 90).
Electric discharge message during	The ABC buffer may be low.	Replace the ABC.
runs.		Ensure that the ABC is being replaced per calendar notifications.
"Leak error" message.	The array locking lever is not in the correct position.	Secure the array locking lever (see "Instrument troubleshooting" on page 93).
arrays are filled with fresh polymer or	Debris is clogging the check valve (CV) fitting (see "Instrument troubleshooting" on page 93).	While wearing gloves, use a lint-free cloth and water to wipe the CV Fitting.
		Note: To prevent crystals from forming around the check valve, always install the Conditioning Reagent Pouch after removing a used or a partially used polymer pouch.
		Completely remove the top seal of the Polymer pouch or Conditioning Reagent Pouch before use.
		If the problem persists, contact Thermo Fisher Scientific.

Symptom	Possible cause	Action
"Leak error" occurs when capillary arrays are filled with fresh polymer or when replenishing polymer, causing the wizard to fail to complete.	The Yoke is not seated properly on the buffer-pin valve.	Make sure the buffer-pin valve lever (yoke) is seated properly on the buffer-pin valve (see "Instrument troubleshooting" on page 93).
		If the lever does not move up and down freely, close the door. Restart the instrument and the computer. (see "Restart the instrument and the computer" on page 90).
		After the instrument has restarted, check the lever movement.
		If the lever does not move up and down freely, contact Thermo Fisher Scientific.
		If the lever moves up and down freely, push the upper polymer block all the way back against the wall.
"Leak detected during polymer delivery"	Bubbles in the polymer system.	Run the Remove Bubbles wizard to clear bubbles.
 "Leak detected during bubble compression" 	Leak in the polymer system.	Check for evidence of leaks.
The run aborts.		If a polymer leak occurred, conduct a water wash and wash the pump trap using the Polymer Delivery Pump Cleaning Kit (Cat. No. 4414007) supplied with the instrument.
	Buffer valve leakage.	Check the buffer-pin valve and see if it closes correctly.
		Clean the buffer-pin valve.
		Ensure that the maintenance schedule is followed per GlycanAssure [™] Data Acquisition Software notifications.
	Filling the array during install array.	Run Fill the Array with fresh Polymer wizard, or run Change Polymer Type wizard.
"Bubble" error	Bubbles present	Run the Remove Bubbles wizard .
"Java update scheduler" error message	The Java updater is unable to complete the update.	Close the Java update scheduler.
		Note: The Java update scheduler does not affect the performance of the GlycanAssure [™] Data Acquisition Software or the quality and accuracy of the data collected.

Symptom	Possible cause	Action
"Invalid Contents" message In Assign Plate Contents screen when you use Ctrl+D	The first row you have selected to fill from is empty.	 Enter sample name or select an assay in the first row in you have selected to fill from. Use the table view to add the assay to the samples.
"Injection failed" message after some of the injections complete.	Capillary RFID cannot be read.	Check the connection between the instrument and computer. Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).
"Instrument is not connected" message after you start GlycanAssure™ Data Acquisition Software.	Bad connection between the computer and instrument.	Check the connection between the instrument and computer and restart both the instrument and computer (see "Restart the instrument and the
"Internal buffer data overflow" message.		computer" on page 90].

Dashboard troubleshooting

Symptom	Possible Cause	Action
When you click on the Dashboard , and consumables information is listed as " Unknown ."	Bad connection between the computer and instrument.	Check the connection between the instrument and computer.
Consumables status in the Dashboard is not updated.	Dashboard does not update automatically.	Click .
After installing new CBC or ABC, the consumables status in the Dashboard is not updated automatically.	Dashboard does not update automatically.	Click after changing or installing consumables.
Expiration dates are displayed in red.	The consumable is within the following days of expiration: Pouch 7 days, Buffers 7 days, Capillary array 1 day	No action.
Dashboard indicates a consumable is expired, but expiry date on consumable indicates it is not expired.	RFID issue.	Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).
		Contact Thermo Fisher Scientific

Software troubleshooting

Symptom	Possible cause	Action
When you start the GlycanAssure [™] Data Acquisition Software, " Windows cannot find 3500.exe " message is displayed.	The Norton Antivirus Sonar Protection feature is enabled on the instrument computer.	 Disable the optional Sonar feature in Norton Antivirus software (contact your IT department for assistance). Contact Thermo Fisher
		Scientific.
Print dialog box is not displayed when you select or click Print.	Dialog boxes are sometimes displayed behind the main screen	Minimize the main screen.
The Load plate for run message does not display correctly.	The window is not refreshing properly.	Click OK to dismiss the message and continue.
Save option is not available (only Save As) when you edit a plate template from the library.	You must select a plate template from the main workflow to edit it.	Go to Define Plate Properties screen > Open Plate > Edit Existing Template.
Software is not behaving as expected.	You open the instrument door after you start a run	Do not open the instrument door during a run.

Symptom	Possible cause	Action
Software is not behaving as expected.	You restarted the instrument only, not the computer.	Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).
		Note: Restart the instrument and the computer as part of weekly maintenance.
Software operations are taking longer than expected.	Communication problem between the computer and instrument.	Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).

Run, re-run, or re-inject troubleshooting

Symptom	Possible cause	Action
Run stops unexpectedly or will not start	Plate or sample information contains invisible, non-ASCII characters.	IMPORTANT! If you copy/paste sample or plate information into the Assign Plate Contents screen or into a plate import file, copy from a plain text editor such as Notepad. Do not copy from a word processing program such as Microsoft Word®, which may include invisible, non-ASCII characters. Non-ASCII characters in plate or sample information may cause a run to stop or may prevent a run from starting.
If you re-run a plate that specifies a re-injection, and the re-injection specifies a protocol other than the protocol used for the original injection, the new protocol for the re-injection is not used	New protocols are not retained for reinjections.	Before re-running a plate, examine the protocols specified for re-injections and change as needed.

Data/electropherogram troubleshooting

Symptom	Possible cause	Action
Signal too high.	Sample concentration is too high.	Dilute the sample.
		Decrease the injection time.
No signal.	Blocked capillary.	Run the Fill Array with Polymer wizard.
		Install a new capillary array.
	Bent capillary array tips or cracked or broken capillary array.	Visually inspect the capillary array, including the detector window area for signs of breakage. Replace the capillary array.
	Failed reaction	Repeat reaction.
	Not enough sample: Pipetting error.	Prepare new sample.
	No dye-labeled glycans are present.	No action.
Low signal.	Sample has high salt concentration.	Dilute or desalt samples.
	Insufficient mixing.	Vortex the sample thoroughly, and then centrifuge the tube to condense the sample to the bottom of the tube.
	Sample volume is <10 μL.	Check that sample volume is at least 10 µL.
	Autosampler out of calibration.	Contact Thermo Fisher Scientific.
Elevated baseline.	Possible contaminant in the polymer path.	Run the Wash Pump and Channels wizard.
	Poor spectral calibration.	Perform new spectral calibration.
Loss of resolution.	Too much sample injected.	Dilute the sample and re-inject.
	Poor quality water.	Use distilled or deionized water.
	Degraded polymer.	Replace polymer.
	Capillary array used for more than 160 injections.	Replace the capillary array. Run the Install Capillary Array wizard.
	Sample has high salt concentration.	Dilute or desalt samples.
Poor resolution in some capillaries.	Insufficient filling of capillary array.	Tighten the connectors and array locking lever. Run the Fill Array with Polymer wizard and look for polymer leakage. Check for broken capillaries, run the Install Capillary Array wizard if needed.
		Re-inject the same samples.

Symptom	Possible cause	Action
Poor resolution in some capillaries.	Poor quality samples.	Check the sample preparation.
	Leak in system.	Tighten the connectors and array locking lever.
No current.	Not enough buffer in ABC.	Ensure that the buffer is filled up to the fill line. See "Check buffer fill levels" on page 26.
	Bubble(s) present in the lower polymer block and/or the array and/or channels.	Pause the run and inspect for bubbles in the tubing connectors. Run the Remove Bubbles wizard .
Elevated current.	Degraded polymer.	Run the Replenish Polymer wizard .
	Arcing in the lower polymer block.	Inspect the lower polymer block for discoloration or damage. Contact Thermo Fisher Scientific.
Fluctuating current.	Bubble in polymer block.	Pause run and inspect for bubbles hidden in the tubing connectors. Run the Remove Bubbles wizard .
	Slow leak	Check polymer blocks for leaks. Tighten the connectors and array locking lever.
	Not enough buffer in ABC.	Ensure that the buffer is filled up to the fill line. See "Check buffer fill levels" on page 26.
	Arcing	Check for moisture in and around the septa, the CBC, the oven, and the autosampler. Wipe condensation.
Poor performance of capillary array used for fewer than 100 runs.	Poor quality samples, possible cleanup problems.	Desalt samples.
	Leak in system.	Tighten the connectors and array locking lever.
Migration time becomes progressively slower.	Leak in system.	Tighten the connectors and array locking lever.
	Improper filling of the system with polymer.	Polymer delivery pump may need to be serviced. If the issue persists, contact Thermo Fisher Scientific.
Migration time becomes progressively faster.	Buffer valve leakage.	Ensure the buffer-pin valve is closed correctly.
Extra peaks in the electropherogram.	Data off scale.	Dilute the sample and re-inject the sample.
Electrophoresis current is unstable.	Bubbles in the polymer system.	Run the Remove Bubbles wizard .

Symptom	Possible cause	Action
Electrophoresis failure.	Buffer below fill line.	Ensure that the buffer is filled up to the fill line. "Check buffer fill levels" on page 26 .
	There is not enough fluid in larger chamber of ABC, or the anode buffer has spilled into smaller overflow chamber.	Pipette the buffer from the smaller overflow chamber to the larger chamber. Ensure that the buffer is filled to within ±1 mm of the fill line.
		When installing new ABC, tilt the container to move buffer to the larger side of the container as described "Install the anode buffer container (ABC)" on page 77.
Extra peaks in the electropherogram.	Data off scale.	Dilute the sample and re-inject the sample.

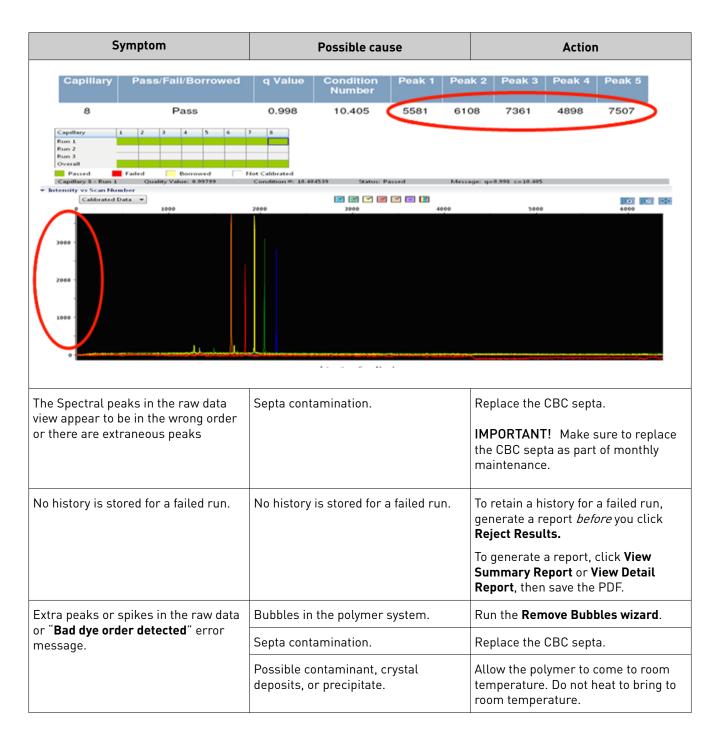
Spatial calibration troubleshooting

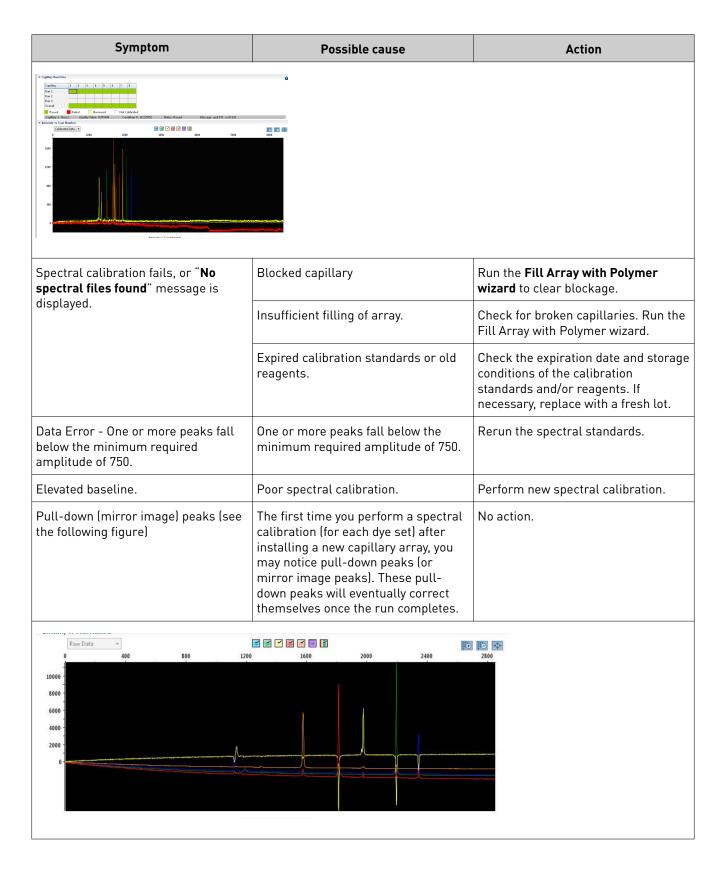
Symptom	Possible cause	Action
"Start" Spatial Calibration button is disabled.	Communication failure between the Data Collection Software and instrument	Check the connection between the instrument and computer.
		Restart instrument and computer (see "Restart the instrument and the computer" on page 90).
Unusual peaks or a flat line for the spatial calibration.	Improper installation of the array window in the detection cell (see Figure 4).	Run the Install a Capillary Array wizard to uninstall, then re-install the array. If the calibration fails again: Fill the capillaries with polymer. Repeat the spatial calibration.
	Broken capillary resulting in a bad array fill.	Check for a broken capillary, particularly in the detection cell area. If necessary, replace the capillary array using the Install Capillary Array wizard.
Persistently bad spatial calibration results.	Bad capillary array.	Replace the capillary array using the Install Capillary Array wizard, then repeat the calibration.
		If the problem persists, contact Thermo Fisher Scientific.
"Spatial Calibration Error" message.	Conditioning reagent is installed. The instrument cannot perform Spatial Calibration with Array fill.	Replace the conditioning reagent with polymer.

Symptom	Possible cause	Action
Spatial calibration takes >5 minutes to complete, and green light goes from blinking to solid	Communication problem between the computer and instrument.	Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).
	Oven is on.	Do not preheat the oven before running the spatial calibration.
Accept/Reject buttons are dimmed.	Communication problem between the computer and instrument.	Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).

Spectral calibration troubleshooting

Symptom	Possible cause	Action
No signal	Bubbles in sample wells	Centrifuge samples to remove bubbles.
	Capillaries are not aspirating sample	Check that sample volume is at least 10 µL.
		If sample volume is adequate, contact Thermo Fisher Scientific.
	The capillary tips may be hitting the bottom of the wells. Autosampler not correctly aligned.	Contact Thermo Fisher Scientific.
Peak heights in the Spectral report are different from the values seen when viewing the spectral data in the electropherogram display.	The raw data electropherogram display in the software does not have the Run Scale Divisor applied to the data. The final peak height values displayed in the Spectral report have the Run Scale Divisor applied.	No action.





Install standard troubleshooting

Symptom	Possible cause	Action
Report contains blank pages or incomplete information.	All dyes are not selected before you generate the report.	Select all dyes, then generate the report.
No signal	Incorrect preparation of sample	Replace samples with fresh samples prepared with fresh Hi-Di [™] Formamide.
	Bubbles in sample wells	Centrifuge samples to remove bubbles.
	The capillary tips may not be touching the samples.	Check the volume of your samples. If no results, call your Thermo Fisher Scientific representative.
	The capillary tips may be hitting the bottom of the wells. Autosampler not correctly aligned.	Call your Thermo Fisher Scientific. representative.
Install check fails.	Blocked capillary	Refill capillary array. You may have to install a fresh array or consider that capillary non-usable for purposes of planning your runs.
	Insufficient filling of array.	Check for broken capillaries and refill the capillary array.
	Expired matrix standards or old reagents.	Check the expiration date and storage conditions of the matrix standards and/or reagents. If necessary, replace with a fresh lot.
	Bubbles in the polymer system.	Select the Bubble Remove wizard to clear the bubbles.
	Possible contaminant or crystal deposits in the polymer.	Properly bring the polymer to room temperature; do not heat.
The starting well value you set reset to A01 after you start the install check.	If you navigate away from the Install Check screen after you start the install check, the starting well may be reset to A01. This is a display issue only; the starting well you specify is used for the install check.	No action.

Audit troubleshooting

Symptom	Possible Cause	Action
"Export did not complete successfully"	You exported records for samples that are not in their original location (samples have been deleted or moved).	Return sample data files to their original location, then export again.
Audit report does not print after you change font settings.	Font settings are not activated until you close the report.	Close the report, reopen it, then print.

Electronic signature troubleshooting

Symptom	Possible Cause	Action
The dye set calibrated is not listed in a spectral calibration e-signature record.	The e-signature function creates a record when a spectral calibration is performed, but does not record the dye set calibrated.	To include the dye set calibrated in the e-signature record, enter the dye set in the Comments field.
Electronic signature prompt is displayed when you edit sample comments.	Electronic signature prompt is displayed for sample comments, regardless of the electronic signature setting.	No action.

Troubleshooting procedures

View the log filesUse a text editor (such as Wordpad) to view the GlycanAssure[™] Data Acquisition Software-generated log files:

Log file	Description	Location
3500UsageStatistics.txt	Provides a summary of the number of plates run and number of run types	<pre><<install drive="">>:\Applied Biosystems\3500\LogFiles You can also view this log from the Maintenance workflow under Planned Maintenance > Usage Statistics.</install></pre>
3500ConsumableUpdates.txt	Provides a summary of consumables installation information and dates	< <install drive="">>:\Applied Biosystems\3500\LogFiles</install>

View instrument sensor details

Click **View Instrument Sensor Details** in the Dashboard to display instrument information.

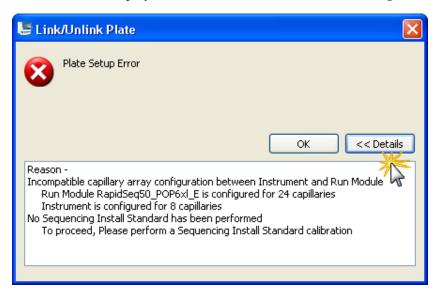


Figure 7 Instrument sensor details Run status of the instrument is displayed while a run is in progress.

Review error message details

 $Error\ messages\ in\ the\ Glycan Assure^{^{\text{\tiny TM}}}\ Data\ Acquisition\ Software\ include\ a\ Details\ button.$

Click **Details** to display more information about an error message.



Reset the instrument

Resetting powers off, then powers on, the instrument. Reset the instrument when:

- There is a fatal error as indicated by the red status light
- The instrument does not respond to the Data Collection software
- 1. Shut down the computer.
- 2. Close the instrument doors.
- 3. Reset the instrument with the Reset button, as shown.

Note: The Reset button is accessible through a small hole to the left of the Tray button.





Instrument specifications

Instrument specifications

Table 1 Applied Biosystems $^{™}$ 3500/3500xL Genetic Analyzer physical dimensions, weight, and power consumption

Parameter	Instrument footprint	Recommended clearance
Depth	61 cm (24 in.)	25.4 cm (10 in.) ^[1]
Width	61 cm (24 in.) (closed door) 122 cm (48 in.) (open door)	158 cm (62 in.) ^[2]
Height	72 cm (28.3 in.)	31 cm (12 in.)
Weight	≈82 kg (180 lbs)	

^[1] At the rear of the instrument to ensure adequate airflow and cooling

Table 2 Computer dimensions and weight

Parameter	Computer	Monitor	Keyboard
Depth	41.7 cm (16.42 in.)	19.3 cm (7.6 in.)	44.7 cm (17.5 in.)
Width	17.5 cm (6.89 in.)	44.7 cm (17.5 in.)	15.25 cm (6 in.)
Height	37.4 cm (14.7 in.)	36.6 cm (14.4 in.)	5 cm (2 in.)
Weight	9.6. kg (21 lbs)	6.9 kg (15.2 lbs)	0.09 kg (0.2 lbs)

Table 3 Applied Biosystems[™] 3500/3500xL Genetic Analyzer operating specifications

Component	Specification	
Laser	Long-life, single-line 505 nm, solid-state laser excitation source	
	Laser Output power 20mW	
	Beam divergence 1.4 mrad	
LED	Emitting color Natural White	
	Luminous Intensity 250 Cd	
Electrophoresis Voltage	Up to 20 kV	
Oven Temperature	Active temperature control from 18°C to 70°C	

^[2] For the instrument, computer, and computer monitor.

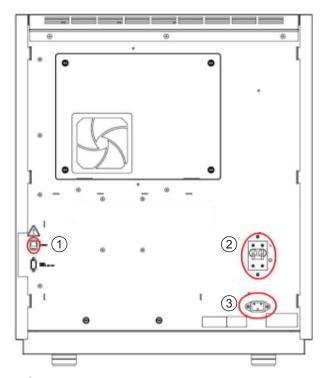
Component	Specification
Minimum Computer Requirements	 Hardware: OptiPlex[™] XE, E8400, 3 GHZ Processor or OptiPlex[™] XE2, with Intel[™] Core I7-47705, 3.1 GHz Processor Operating system: Windows[™] 7 SP1 32-bit Installed RAM: 16 GB Hard drive: 500 GB SATA 3.0 Gb/s and 8 MB Data Burst Cache

Environmental requirements

Table 4 Environmental requirements

Condition	Requirement	
Installation site	Indoor use only	
Altitude	Safety tested up to 2,000 m (6,562 ft)	
Electrical ratings	 Power cord with ground pin required Instrument—AC 100–240 V ±10%, 50/60 Hz, 3.1 A, power rated 320 VA Maximum current—15 A Maximum power dissipation—417 VA, 371 W (approximately, not including computer and monitor) Computer—AC 100–240 V ±10%, 50/60 Hz, 2.1 A, power rated 125 VA Monitor—AC 100–240 V ±10%, 50/60 Hz, 1.5 A, power 	
Mains AC line voltage tolerances	rated 65 VA Up to ±10 percent of nominal voltage	
Transient category	Installation categories II	
Pollution degree	2	
Operating conditions	15 to 30°C (59 to 86°F) (Room temperature should not fluctuate ±2°C during an instrument run) 20–80% relative humidity, noncondensing	
Transport and storage conditions	-30 to +60°C (-22 to +140°F) Minimum 20% relative humidity, maximum 85% (non-condensing)	

Power and communication connections



- 1 Ethernet port for computer instrument connection
- 2 Circuit breaker
- $\ensuremath{\mathfrak{G}}$ Connector for instrument power cable



Part numbers

Plates bases retainers and septa

 Table 5
 Plates and caps

Part Description	General purpose supply, obtain from any laboratory supplier
96-well	General purpose supply, obtain from any laboratory supplier: 96-well PCR microtiter plate, standard or optical-grade polypropylene, 0.1 mL or 0.2 mL, half- or semi-skirted design, with or without barcode.
	Note: We recommend MicroAmp [™] Optical 96-Well Reaction Plates (Cat. No. 4306737).

Table 6 Bases, retainers, and septa

Part Description	Part Number
Retainer and base (Standard), 96-well RUO	4410228
Septa, 96-well RUO	4412614

Instrument consumables

Name	Part Number
Anode Buffer Container (ABC) for PQA (Protein Quality Analysis)	A31278
Capillary array, 8-Capillary, 50 cm	4404685
Capillary array, 24-Capillary, 50 cm	4404689
Cathode Buffer Container (CBC) for PQA (Protein Quality Analysis)	A31279
Conditioning reagent	4393718
POP-7 [™] Polymer for Protein Quality Analysis (960)	A31122
POP-7 [™] Polymer for Protein Quality Analysis (384)	A30936

Appendix C Part numbers Glycan analysis reagents

Glycan analysis reagents

Catalog number
4345833
4376911
4408399
4311320 (25 mL) 4440753 (4 x 5 mL)



Radio Frequency Identification (RFID) technology

The instrument uses four identical wireless radio frequency identification (RFID) read/write units to monitor instrument consumables.

Precautions for use



WARNING! Radio frequency identification (RFID) could possibly disrupt the operation of patient-worn and/or implanted active medical devices. To minimize such effects, do not come within 8 inches (20 cm) of this instrument if you have a patient-worn and/or implanted active medical device.



WARNING! Radio frequency identification (RFID) signals from external devices could possibly disrupt the operation of the 3500 RFID read/write units. RFID signals from the 3500 RFID read/write units could possibly disrupt the operation of external RFID devices. To minimize such effects, do not bring external RFID devices within 10 cm of this instrument during instrument operation.

Locations of RFID read/write units

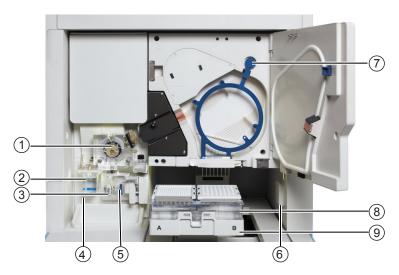


Figure 8 RFID read/write unit locations within instrument interior (shown with door open)

- 1 Polymer delivery pump (PDP)
- 2 Anode buffer container (ABC)
- 3 Polymer or conditioning pouch
- 4 ABC RFID read/write unit (behind reservoir)
- ⑤ Pouch read/write unit (behind pouch)
- (6) CBC RFID read/write unit
- 7 Capillary array read/write unit
- (8) Cathode buffer container (CBC)
- 9 Autosampler

Function

The RFID read/write units:

- 1. Read up to 256 bytes from the RFID consumables tags.
- 2. Write up to 256 bytes to the RFID consumables tags.
- 3. Re-read the written data on the tags to confirm that it is accurate, using a checksum to verify data integrity.

The RFID read/write units perform the functions listed above at the start of each $GlycanAssure^{TM}$ Data Acquisition Software run.



Specifications

Table 7 RFID read/write unit specifications

Component	Specification
RFID read/write unit	 Ultra-Compact Proximal-Type RFID Reader / Writer Model ASI4000-98-BS1 Manufactured by ART Technology Co., Ltd.
RF frequency	13.56 MHz
RF output power	60 mW
RFID tags	Texas Instruments RI-I03-112A-03 tags, tested by the manufacturer to reliably read and write 100,000 times with zero data loss and retain written data for more than 10 years
Effective range between RFID tag and internal RFID read/write units	 ABC tag: 3 cm CBC tag: 4 cm Capillary tag: 3 cm Polymer tag: 3 cm
Typical use range between RFID tag and internal RFID read/write units	0.5 cm
Minimum separation distance of the instrument from external RFID read/write units	10 cm
Minimum separation distance of the instrument from other wireless technologies	3 feet
Wireless security	 RFID tag read/write/re-read with checksum Password access for use of software Base-64 encoding of data between the instrument and the computer

RFID troubleshooting

Symptom	Possible cause	Action
Unable to read RFID information. "Failure to Read from RFID tag"	Consumable package is improperly installed or label is defective. Polymer/Conditioning reagent pouch is not positioned properly.	Ensure that the RFID label is not visibly damaged and consumable package is properly installed. Ensure that label is close, and
	is not positioned property.	parallel, to the instrument.
		Reposition or re-install pouch, then click Refresh on the Dashboard.
		Restart the instrument and the computer (see "Restart the instrument and the computer" on page 90).
		Install a new consumable (if available).
		If problem persists, contact Thermo Fisher Scientific.
	Malfunctioning RFID label or reader.	Place a used CBC, ABC, pouch, or array on the instrument:
		If the instrument can read the RFID label, install a new CBC, ABC, pouch, or array.
		If the instrument cannot read the RFID label, contact Thermo Fisher Scientific.

Safety





WARNING! GENERAL SAFETY. Using this product in a manner not specified in the user documentation may result in personal injury or damage to the instrument or device. Ensure that anyone using this product has received instructions in general safety practices for laboratories and the safety information provided in this document.

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, etc). To obtain SDSs, see the "Documentation and Support" section in this document.

Symbols on this instrument

Symbols may be found on the instrument to warn against potential hazards or convey important safety information. In this document, the hazard symbol is used along with one of the following user attention words:

- CAUTION! Indicates a potentially hazardous situation that, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.
- **WARNING!** Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.
- **DANGER!** Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury.

Symbol	English	Français
<u> </u>	Caution, risk of danger	Attention, risque de danger
∠ • \	Consult the manual for further safety information.	Consulter le manuel pour d'autres renseignements de sécurité.

Symbol	English	Français
(Protective conductor terminal (main ground)	Borne de conducteur de protection (mise à la terre principale)
	Do not dispose of this product in unsorted municipal waste CAUTION! To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.	Ne pas éliminer ce produit avec les déchets usuels non soumis au tri sélectif. MISE EN GARDE! Pour minimiser les conséquences négatives sur l'environnement à la suite de l'élimination de déchets électroniques, ne pas éliminer ce déchet électronique avec les déchets usuels non soumis au tri sélectif. Se conformer aux ordonnances locales sur les déchets municipaux pour les dispositions d'élimination et communiquer avec le service à la clientèle pour des renseignements sur les options d'élimination responsable.

Conformity symbols

Conformity mark	Description	
c UL us	Indicates conformity with safety requirements for Canada and U.S.A.	
C€	Indicates conformity with European Union requirements.	
	Indicates conformity with Australian standards for electromagnetic compatibility.	

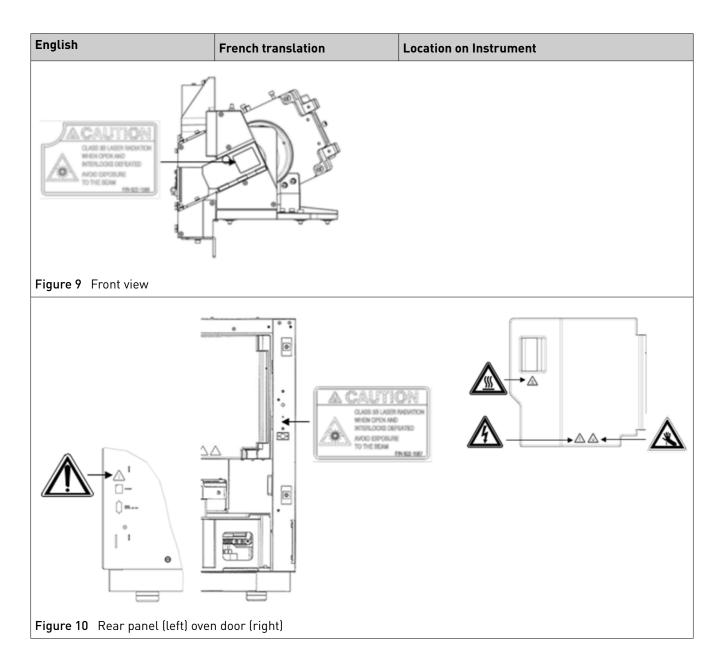
Safety alerts on this instrument

Additional text may be used with one of the symbols described above when more specific information is needed to avoid exposure to a hazard. See the following table for safety alerts found on the instrument.

English		Français	
	CAUTION! Hazardous chemicals. Read the Safety Data Sheets (SDSs) before handling.	MISE EN GARDE! Produits chimiques dangereux. Lire les fiches signalétiques (FS) avant de manipuler les produits.	
<u>^</u>	CAUTION! Hazardous waste. Refer to SDS(s) and local regulations for handling and disposal.	MISE EN GARDE! Déchets dangereux. Lire les fiches signalétiques (FS) et la réglementation locale associées à la manipulation et à l'élimination des déchets.	

Location of safety labels on this instrument

English	French translation	Location on Instrument
(III) visible and/or invisible laser radiation present when open and interlegies defeated	ATTENTION! Rayonnement laser visible ou invisible de classe 3B (III) présent en position ouverte et avec les dispositifs de sécurité non enclenchés. Éviter toute exposition au faisceau.	Detection cell cover



Instrument safety

General



CAUTION! Do not remove instrument protective covers. If you remove the protective instrument panels or disable interlock devices, you may be exposed to serious hazards including, but not limited to, severe electrical shock, laser exposure, crushing, or chemical exposure.

Physical injury



CAUTION! Moving Parts. Moving parts can crush, pinch and cut. Keep hands clear of moving parts while operating the instrument. Disconnect power before servicing.

Electrical



WARNING! Ensure appropriate electrical supply. For safe operation of the instrument:

- Plug the system into a properly grounded receptacle with adequate current capacity.
- Ensure the electrical supply is of suitable voltage.
- Never operate the instrument with the ground disconnected. Grounding continuity is required for safe operation of the instrument.



WARNING! Power Supply Line Cords. Use properly configured and approved line cords for the power supply in your facility.



WARNING! Disconnecting Power. To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.

Cleaning and decontamination



CAUTION! Cleaning and Decontamination. Use only the cleaning and decontamination methods specified in the manufacturer's user documentation. It is the responsibility of the operator (or other responsible person) to ensure the following requirements are met:

- No decontamination or cleaning agents are used that could cause a HAZARD as a result of a reaction with parts of the equipment or with material contained in the equipment.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) prior to having the instrument serviced at your facility or sending the instrument for repair, maintenance, trade-in, disposal, or termination of a loan (decontamination forms may be requested from customer service).
- Before using any cleaning or decontamination methods (except those recommended by the manufacturer), users should confirm with the manufacturer that the proposed method will not damage the equipment.

Laser

Safety and electromagnetic compatibility (EMC) standards

The instrument design and manufacture complies with the standards and requirements for safety and electromagnetic compatibility as noted in the following table:

Safety (compliance)

Reference	Description	
EU Directive 2006/95/EC	European Union "Low Voltage Directive"	
IEC 61010-1	Safety requirements for electrical equipment for measurement,	
EN 61010-1	control, and laboratory use – Part 1: General requirements	
UL 61010-1		
CSA C22.2 No. 61010-1		
IEC 61010-2-010	Safety requirements for electrical equipment for measurement,	
EN 61010-2-010	control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials	
IEC 61010-2-081	Safety requirements for electrical equipment for measurement,	
EN 61010-2-081	control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
IEC 60825-1:2007	Safety of laser products – Part 1: Equipment classification and	
EN 60825-1:2007	requirements	

EMC

Reference	Description
Directive 2004/108/EC	European Union "EMC Directive"
EN 61326-1	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
EN 61326-2-6-20061	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment
FCC Part 15 (47 CFR)	U.S. Standard "Industrial, Scientific, and Medical Equipment"
AS/NZS 2064	Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment
ICES-001, Issue 3	Industrial, Scientific and Medical (ISM) Radio Frequency Generators

Environmental design

Reference	Description
Directive 2012/19/EU	European Union "WEEE Directive" – Waste electrical and electronic equipment
Directive 2011/65/EU	European Union "RoHS Directive" – Restriction of hazardous substances in electrical and electronic equipment

Chemical safety



WARNING! GENERAL CHEMICAL HANDLING. To minimize hazards, ensure laboratory personnel read and practice the general safety guidelines for chemical usage, storage, and waste provided below. Consult the relevant SDS for specific precautions and instructions:

- Read and understand the Safety Data Sheets (SDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. To obtain SDSs, see the "Documentation and Support" section in this document.
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing).
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with adequate ventilation (for example, fume hood).
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended in the SDS.
- · Handle chemical wastes in a fume hood.
- Ensure use of primary and secondary waste containers. (A primary waste container holds the immediate waste. A secondary container contains spills or leaks from the primary container. Both containers must be compatible with the waste material and meet federal, state, and local requirements for container storage.)
- After emptying a waste container, seal it with the cap provided.
- Characterize (by analysis if necessary) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure that the waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.
- IMPORTANT! Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

Biological hazard safety



WARNING! BIOHAZARD. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Conduct all work in properly equipped facilities with the appropriate safety equipment (for example, physical containment devices). Safety equipment can also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Individuals should be trained according to applicable regulatory and company/ institution requirements before working with potentially biohazardous materials. Follow all applicable local, state/provincial, and/or national regulations. The following references provide general guidelines when handling biological samples in laboratory environment.

- U.S. Department of Health and Human Services, *Biosafety in Microbiological* and *Biomedical Laboratories (BMBL)*, 5th Edition, HHS Publication No. (CDC) 21-1112, Revised December 2009; found at:
 - www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf
- World Health Organization, *Laboratory Biosafety Manual*, 3rd Edition, WHO/CDS/CSR/LYO/2004.11; found at:
 - www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

Documentation and support

Related documents

The following related documents are available:

Document	Publication Number
GlycanAssure [™] Data Acquisition Software v2.0 Help	MAN0014719
3500/3500xL Genetic Analyzer with GlycanAssure [™] Data Acquisition Software v2.0 User Guide	100036372
GlycanAssure [™] Data Analysis Software v2.0 Help	MAN0014720
GlycanAssure [™] Data Analysis Software v2.0 User Guide	100036373
GlycanAssure [™] Security, Audit, and E-signature (SAE) Administrator Console v1.0 Help	MAN0016774
GlycanAssure [™] Security, Audit, and E-signature (SAE) Administrator Console v1.0 User Guide	MAN0016773
GlycanAssure [™] System Quick Reference	100038224

Note: For additional documentation, see "Customer and technical support" on page 131.

Customer and technical support

Visit **thermofisher.com/support** for the latest in services and support, including:

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 - User guides, manuals, and protocols
 - Certificates of Analysis
 - Safety Data Sheets (SDSs; also known as MSDSs)

Note: For SDSs for reagents and chemicals from other manufacturers, contact the manufacturer.

Limited product warranty

Life Technologies Corporation and/or its affiliate(s) warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale found on Life Technologies' website at www.thermofisher.com/us/en/home/global/terms-and-conditions.html. If you have any questions, please contact Life Technologies at www.thermofisher.com/support.

Index

3500/3500xL Genetic Analyzer 10 384-well, capillary map 35 96-well capillary map 35 plate assembly 37 plate base 37	check stored 80 fill with polymer 79 install 80 maintenance 80 part numbers and limits 17 storage conditions 80 store 80
A	capillary-to-plate map, diagram 35 cathode buffer
ABC. See anode buffer	install 77
	location 12
amber indicator light 12 anode buffer	on-instrument limits 15
install 77	part numbers and limits 15
location 12	CBC. See cathode buffer
on-instrument limits 15	computer
part numbers and limits 15	archive, purge, and restore data 85
antivirus software 13	check hard drive space 87
archive	disk space, check ¹ 86
data files 86	do not rename 13
library items 85	maintain 85
as-needed instrument maintenance 75	name requirement 13, 22
audit, troubleshooting 111	restart 90
audit, administrators, overview 61	start up 22
audit, users, overview 62	condition number 45
	conditioning reagent 16
B	connections
В	communication 116
biohazard safety 130	power 116
borrowing	consumables
defined 47	anode buffer 77
disabled 47	capillary array 80
enabled 48	cathode buffer 77
buffer. See anode buffer, cathode buffer	polymer 79
	status in Dashboard 24
C	suppress pre-expiration warning messages 27
calendar create entries 75	D
maintenance 75	daily instrument maintenance 73
review notifications 72	Dashboard
calendar notifications, Dashboard 23, 72	consumables status 23
calendar reminders, log 76	troubleshoot 102
capillary array	Data Acquisition Software 10
change 80	Data Analysis Software 10
	data files. <i>See</i> sample data files

data troubleshooting 104	with file name convention 57
datastore, backup during install or uninstall 85	without file name convention 57
date format, setting 27	file name maximum length 57
detection cell location 91	Fill Array with Polymer maintenance wizard 79
disk space, computer 86	firmware 13
documentation, related 131	fragment install check
,	results, example 54
_	troubleshoot 110
E	front panel indicators 12
e-sig, troubleshoot 111	
e-signature, library items 56	
e-signature logs, view, generate, export, print 69	G
electronic signature, administrators	GlycanAssure Kits 10
overview 61	green indicator light 12
troubleshoot 111	guidelines, electronic signature 69
	guidelines, electronic signature 07
electronic signature, users guidelines 69	
	Н
overview 62	
signing 69	hard drive
electropherogram troubleshooting 104	check space 87
environmental requirements 115	defragment 87
error messages	
display detail 112	1
instrument 99	
RFID 98, 122	import, library items 56
spatial calibration 106	Index Term 28
spectral calibration 107	injection
event audit logs, view, generate, print 67	folder 58
exit 63	pause after last 27
experiment	Install Capillary Array maintenance wizard 80
create 34	install check
open previously run 35	evaluate data 53
export	plate, prepare 43, 50
library items 56	run 51
plate 56	installation standard 118
spatial calibration 41	instrument
	clean 76
F	components 12
Г	during a run 14
Failure to Read from RFID tag 98, 122	interior components 91
file location	load plate 38, 43, 51
default 27	maintenance, weekly 74
in file name convention 57	move and level 84
with file name convention 57	prepare 42, 49
with results group 58	reactivate 84
without file name convention 57	reset 113
without results group 58	restart 90
file name conventions	routine cleaning 76
create 57	shutdown 83
defined 57	start up 22
file location 57	startup after storage 84
in plate 57	theory of operation 13
settings 57	troubleshoot 93, 99, 102
file name format	instrument maintenance. See maintenance

instrument method, signing 69	computer 85
instrument method settings 33	computer archive, purge, and restore data 85
instrument protocol	library 85
defined 59	pump 81
settings 59	pump, wash 81
instrument run, pause after last injection 27	weekly 74
instrument run name, folder name 58	maintenance calendar
instrument sensor details 89, 112	create entries 75
Instrument Shutdown maintenance wizard 83	recommended entries 75
	view 75
V	maintenance notifications
K	complete a task 72
kits. See GlycanAssure Kits	dismiss a task 72
	trigger time, setting 27
L	maintenance wizards
	fill array with polymer 79
laser specifications 114	install capillary array 80
leaks and spills 25	instrument reactivate 84
library	instrument shutdown 83
archive 85	remove bubbles 81
create items 56	replenish polymer 79
delete 56	wash pump and channels 81
e-signature 56	maintenance, computer
edit 56	data files, archive 86
export 56	defragment 87
file name conventions 57	disk space, monitor 86
filtering 27	library items, archive, purge, and restore 85
import 56	uninstall software 85
instrument protocol 59	maintenance, consumables
maintenance 85	anode buffer, change 77
overview 55	capillary array, change 80
plates 56	capillary array, check stored 80
purge 85	cathode buffer, change 77 polymer, fill array 79
purge entries 86 restore entries 86	polymer, replenish 79
results group 58	polymer, store partially used pouch 79
license. See software license	maintenance, instrument
license, software	annual planned 74
activate 88	as-needed 75
email for activation 87	daily 73
obtain 88	monthly 74
requirements 87	move and level the instrument 84
limited product warranty 132	pump, flush water trap 82
load plate 38, 43, 51	pump, remove bubbles 81
log files	pump, wash chamber and channels 81
search and use 111	reactivate 84
view 111	routine cleaning 76
log out. See exit	schedule 71
login, software 63	shutdown 83
	matrix standard 118
м	monitor run 38
М	monthly instrument maintenance 74
maintenance	move the instrument 84
capillary array 80	

log for calendar reminders 76 maintenance notifications in Dashboard 23, 72 O Object audit logs, view, generate, print 66 oven temperature in instrument protocol 59 pre-heat 42, 49 P part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 polymer 117 polymer 117 polymer 117 polymer 117 palate 1912 96-well assembly 37 assembly 37 assembly 37 assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 plandling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 requirements; problem of the damage of the proposition of label 79 trap, IIIIs 82 traubleshoot 93 wash chamber and channels 81 water trap, flush 82 purge library 85 library entries 86 library items 85 Recivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group, folder 58 RFID error message 98, 122 overview 119 required position for label 79	N	maintenance 81
notifications log for calendar reminders 76 maintenance notifications in Dashboard 23, 72 O Object audit logs, view, generate, print 66 object audit logs, view, generate, print 60 object audit logs, view, generate, print 66 object audit logs, view, generate, print 66 object audit logs, view, generate, print 60 object audit logs, view, generate, print 66 object audit logs, view, generate, print 8 toubleshoot 93 wash chamber and channels 81 water trap, flush 82 troubleshoot 93 wash chamber and channels 81 water trap, flush 82 troubleshoot 93 wash chamber and channels 81 water trap, flush 82 troubleshoot 92 library tems 85 library tems 85 library tems 85 library tems 85 library tems 84 leading value, spectral calibration 45 paulity value, spectral calibration 45 paulity value, spectral calibration 45 li	notification log, review 76	*
troubleshoot 93 wash chamber and channels 81 water trap, flush 82 purge bipect audit logs, view, generate, print 66 oven temperature in instrument protocol 59 pre-heat 42, 49 P part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 ass	notifications	
maintenance notifications in Dashboard 23, 72 O object audit logs, view, generate, print 66 oven temperature in instrument protocol 59 pre-heat 42, 49 P part numbers buffer 117 capillary array 117 conditioning reagent 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 poolymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 store 79 store 79 store 79 requirements 114	log for calendar reminders 76	
object audit logs, view, generate, print 66 oven temperature in instrument protocol 59 pre-heat 42, 49 P part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 plates 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 required position for label 79		
purge biject audit logs, view, generate, print 66 oven temperature in instrument protocol 59 pre-heat 42, 49 P part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 requirements, environmental 115 results group defined 58 settings 58 results group, folder 58 RFID error message 98, 122 overview 119 required position for label 79	,	
belief audit logs, view, generate, print 66 oven temperature in instrument protocol 59 pre-heat 42, 49 P part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planed maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loraging 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 revert service meets 114	•	-
pre-heat 42, 49 Q and Condition 45 quality value, spectral calibration 45 P Q and Condition 45 quality value, spectral calibration 45 R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library items 85 R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85	U	
pre-heat 42, 49 Q and Condition 45 quality value, spectral calibration 45 buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storie 70 storie	object audit logs, view, generate, print 66	•
pre-heat 42, 49 Q and Condition 45 quality value, spectral calibration 45 R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 R	oven temperature	
P Q and Condition 45 quality value, spectral calibration 45 part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 plates 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 requirements 114	in instrument protocol 59	norary tents 65
Part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 storing partially used pouch 79 storing partially used pouch 79 Q and Condition 45 quality value, spectral calibration 45 R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	pre-heat 42, 49	
part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate library 56 plate loading 78 location 12 part numbers fill capillary array 79 shoring partially used pouch 79 storing partially used pouch 79 storing partially used pouch 79 storing partially used pouch 79 TR R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		Q
part numbers buffer 117 capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate library 56 plate loading 78 location 12 part numbers fill capillary array 79 shoring partially used pouch 79 storing partially used pouch 79 storing partially used pouch 79 storing partially used pouch 79 TR R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	P	O and Condition 45
buffer 117 capillary array 117 conditioning reagent 117 plates 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storie 79 storie 79 storie partially used pouch 79 R re-injection file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results ransfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		
capillary array 117 conditioning reagent 117 plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 reconstructions file location 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	•	1,
conditioning reagent 117 plates 117 plates 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 platet-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 rever requirements, 114		_
plates 117 polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plateton 78 plate library 56 plate loading 38, 43, 51 plate type, default 27 plateton 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 requirements 114 rection 58 troubleshooting 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 rest button on front panel 113 restore library entries 86 library items 85 results results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		R
polymer 117 password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 repower requirements 114 me totation 103 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFIID error message 98, 122 overview 119 required position for label 79		re-injection
password, change your own 65 pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 Reactivate the Instrument maintenance wizard 84 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		file location 58
pause after last injection 27 planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 redinctator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 red indicator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 redinctator light 12 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		troubleshooting 103
planned maintenance schedule 74 plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 related documentation 131 Remove Bubbles maintenance wizard 81 Replace with index term 39 Replenish Polymer maintenance wizard 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results group, folder 58 RFID error message 98, 122 overview 119 required position for label 79		Reactivate the Instrument maintenance wizard 84
plate 96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 requirements 114	-	
96-well assembly 37 assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		
assembly 37 base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 requirements, environmental 115 reset button on front panel 113 resetore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	-	
base, standard 37 create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storie 79 storie 79 storing partially used pouch 79 reports, default settings 27 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	· · · · · · · · · · · · · · · · · · ·	•
create 31 load in instrument 38, 43, 51 sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 requirements, environmental 115 reset button on front panel 113 restore library entries 86 library items 85 results results group defined 58 settings 58 results group defined 58 settings 58 results group defined 58 settings 58 results group defined 58 settings 27 requirements, environmental 115 reset button on front panel 113 restore library items 85 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	•	-
sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 reset button on front panel 113 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		-
sample plate, prepare 35 plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 restore library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results group, folder 58 RFID error message 98, 122 overview 119 required position for label 79	load in instrument 38, 43, 51	
plate library 56 plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 power requirements 114 library entries 86 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		-
plate loading 38, 43, 51 plate type, default 27 plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 power requirements 114 library items 85 results transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	plate library 56	
results plate-to-capillary map, diagram 35 polymer fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 requirements 114 results results results results results results group defined 58 settings 58 results group defined 58 settings 58 results group defined 58 settings 58 results group recutions for use 79 replenish 79 storing partially used pouch 79 requirements 114	plate loading 38, 43, 51	•
polymer view 35 fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 power requirements 114 transfer 38 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	plate type, default 27	the contract of the contract o
fill capillary array 79 handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 requirements 114 view 35 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	plate-to-capillary map, diagram 35	
handling 78 location 12 part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 results group defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79	polymer	
location 12 part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 power requirements 114 defined 58 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		
part numbers and handling 16 precautions for use 79 replenish 79 storing partially used pouch 79 power requirements 114 settings 58 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		
part numbers and handling 16 precautions for use 79 replenish 79 store 79 storing partially used pouch 79 requirements 114 results groups, folder 58 RFID error message 98, 122 overview 119 required position for label 79		
replenish 79 store 79 storing partially used pouch 79 requirements 114 source requirements 114		
store 79 overview 119 storing partially used pouch 79 requirements 114 required position for label 79		· .
store 79 storing partially used pouch 79 storing partially used pouch 79 requirements 114 requirements 114		error message 98, 122
power requirements 114		overview 119
power requirements 114 troubleshoot 08 122		required position for label 79
1100001850000 30, 122	-	troubleshoot 98, 122
· [UII]	pre-heat oven 42, 49	run
S HOHHOL 30	preferences	monitor 38
system 27 troubleshooting 103 table settings 27	·	
numn	_	
avoid damage 81	pump avoid damage 81	
bubbles, remove 81 run voltage 59	· ·	run voltage 59
flush water trap 82		

S	zoom 46
safety, biohazard 130	start the system 21
safety labels 125	status, consumables in Dashboard 23
sample data file storage	support, customer and technical 131
injection folder 58	symbols, safety 123
instrument run name folder 58	system overview 10
results group name folder 58	system specifications 114
~ -	system start up 21
sample data files, archive 86	
sample plate. See plate	-
scheduled maintenance notifications 71	Т
tasks 71	tables, settings, default 27
	terms and conditions 132
security, administrators, overview 61	theory of operation 13
security, users	troubleshoot
log in 63	Dashboard 102
overview 62	data 104
password change 65	e-sig 111
shutdown instrument 83	electronic signature 111
signing, electronic signature 69	electropherogram 104
size standard 118	error messages 112
software, start 23	fragment install check 110
software license	instrument 93, 99, 102
See also license, software	log files, search and use 111
activate 88	pump 93
obtain 88	RFID 98, 122
See also license, software	spatial calibration 106
spatial calibration	spectral calibration 107
estimated run time 39	view instrument sensor details 112
export 41	troubleshooting
perform 39	audit 111
purpose 39	view instrument sensor details 89
troubleshoot 106	
when to perform 39	
specifications 114	U
spectral calibration	uninstall the software 85
borrowing disabled 47	user profile 64
borrowing enabled 48	user-defined fields, including in file name 57
capillary sharing 47	user defined nervey merdaning in me name of
condition number 45	
estimated run time 42	W
evaluate data 46	warning messages, suppressing 27
examples 49	warranty 132
instrument, prepare 42	Wash Pump and Channels maintenance wizard 81
perform 44	weekly instrument maintenance 74
plate, prepare 43, 50	workflow diagram 21
pull-down peaks 47	worknow diagram 21
quality value 45	
troubleshoot 107	Z
what occurs 47	zoom, spectral calibration 46
when to perform 42	zoom, spectral campianon 40
•	

