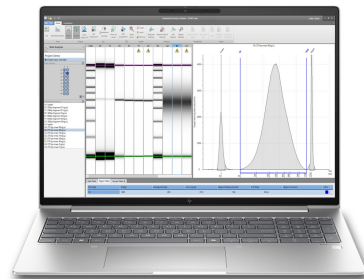




Agilent 4200 TapeStationDx System

User Guide



Notices

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Agilent Technologies
Hewlett-Packard-Strasse 8
76337 Waldbronn, Germany

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Intended Use / Indications for Use

Note

In this user guide, the term “TapeStationDx system” refers to the TapeStationDx instrument hardware and software.

Intended Use

The TapeStationDx system is an automated *in vitro* diagnostic electrophoresis system intended for *in vitro* examination of nucleic acids derived from human specimens. It is intended to be used by trained laboratory professionals for downstream *in vitro* diagnostic procedures.

Indications for Use

The TapeStationDx system is indicated for use in a clinical laboratory environment when measuring fluorescence signals of DNA and RNA samples derived from human origin used such as part of a quality control procedure.

Limitations for Use

The TapeStationDx system, which comprises the TapeStationDx instrument and the corresponding TapeStationDx software, is a CE IVD device intended for downstream diagnostic applications. ScreenTape devices (RUO) and reagents mentioned are for Research Use Only. They are not intended for diagnostic procedures. The TapeStationDx system can be used for Research Use Only (RUO) workflows. User-defined protocols created using the TapeStationDx software are for Research Use Only (RUO) workflows, not for use in diagnostic procedures.

Intended User

The TapeStationDx system is intended for use by trained laboratory professionals working in a clinical laboratory environment.

Test Principle

The Agilent TapeStationDx system is an automated electrophoresis system that offers qualitative and quantitative analysis of nucleic acids for downstream *in vitro* diagnostic procedures. Typical samples include DNA or RNA purified from human cells.

With the help of application specific ScreenTape devices (RUO) and reagents (RUO), nucleic acids are electrophoretically separated and detected by fluorescence. The TapeStationDx Analysis software displays the results in a variety of formats including electropherogram view, gel image and table format. See [TapeStationDx Analysis Software](#) on page 52 and [Data Analysis](#) on page 117.

The hardware components make up the instrument. See [Instrument Components](#) on page 20 for an overview of these components.

The instrument is controlled by the TapeStationDx Controller software component of the system, which is operated through the bundled laptop. See [Getting Started](#) on page 83 and [Operating the 4200 TapeStationDx System](#) on page 102 for instructions on setting up and operating the TapeStationDx system. See [Software Overview](#) on page 26 for a description of individual software screens, detailing the purpose of each feature on the screen.

The reagents and plastic consumables used with TapeStationDx are Research Use Only (RUO). See [ScreenTape Assay \(RUO\) Overview](#) on page 79 for further details on the ScreenTape Assay (RUO) portfolio available for TapeStationDx system and respective Quick Guide references. The TapeStationDx instrument has been verified to achieve the analytical performance requirements in accordance with the intended use of the TapeStationDx system.

Software Security

The TapeStationDx system is designed for operation in environments where access and storage are managed by authorized personnel who are responsible for maintaining the integrity of the electronic records stored within the system.

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In This Book

This manual covers the following:

- 4200 TapeStationDx Hardware K2991B
- TapeStationDx Software K2964-64030

For *in Vitro* Diagnostic Use

Before You Begin

Symbol Table

Table 1: Symbols

	The apparatus is marked with this symbol when the user should refer to the instruction manual in order to protect risk of harm to the operator and to protect the apparatus against damage.
	The apparatus is marked with this symbol when the user should refer to the instruction manual in order to protect risk of harm to the operator and to protect the apparatus against damage.
	Indicates a protected ground terminal.
	Confirms that a manufactured product complies with all applicable European Community directives. The European Declaration of Conformity is available at: http://regulations.corporate.agilent.com/DoC/search.htm
	Legal manufacturer.
	Manufacturing date.
	Power symbol indicates On/Off. The apparatus is not completely disconnected from the mains supply when the power switch is in the Off position.
	Pacemaker. Magnets could affect the functioning of pacemakers and implanted heart defibrillators. A pacemaker could switch into test mode and cause illness. A heart defibrillator may stop working. If you wear these devices keep at least 55 mm distance to magnets. Warn others who wear these devices from getting too close to magnets.

Before You Begin

Symbol Table



Magnetic field.

Magnets produce a far-reaching, strong magnetic field. They could damage TVs and laptops, computer hard drives, credit and ATM cards, data storage media, mechanical watches, hearing aids and speakers. Keep magnets at least 25 mm away from devices and objects that could be damaged by strong magnetic fields.



Indicates a pinching or crushing hazard.



Indicates a piercing or cutting hazard.



In Vitro Diagnostic Medical Device.



Importer.



Authorized representative in the European Community.



UK Responsible Person.



Authorized representative in Switzerland.



Consult Instructions for Use.



UK Conformity Assessed.



Unique Device Identifier.



Temperature Limitation (Storage condition).

Legal and Regulatory

Sound Emission

Manufacturer's Declaration

This statement is provided to comply with the requirements of the German Sound Emission Directive of 18 January 1991.

This product has a sound pressure emission (at the operator position) < 70 dB.

- Sound Pressure $L_p < 70$ dB (A)
- At Operator Position
- Normal Operation
- According to ISO 7779:1988/EN 27779/1991 (Type Test)

Waste Electrical and Electronic Equipment (WEEE) Directive

This product complies with the European WEEE Directive marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste.



NOTE

Do not dispose of in domestic household waste
To return unwanted products, contact your local Agilent office, or see <https://www.agilent.com> for more information.

Instrument Specifications

Table 2: Technical specifications of the instrument

Type	Specification
Weight	24.8 kg (54.7 lbs)
Dimensions (wxdxh)	435 x 510 x 445 mm (17.1 x 20.0 x 17.5 inches)
Line voltage	100 – 240 VAC $\pm$ 10 %
Line frequency	50 or 60 Hz $\pm$ 5 %
Power consumption	50 VA / 50 W
Interface	USB (Instrument: USB-B; PC: USB-A)
Ambient operating temperature	10 – 40 °C (50 – 104 °F)
Operating humidity	15 – 80 %, non-condensing
Storage temperature	-40 to 70 °C (-40 to 158 °F)
Operating altitude	Up to 3000 m (9842 ft)
Safety standards	IEC, EN, CSA, UL, Overvoltage category II, Pollution degree 2 For indoor use only.
ISM Classification	ISM Group 1 Class A According to CISPR 11
Sound pressure	<70 dB (A) According to ISO 7779:1988/EN 27779/1991

Materials Provided

Table 3: Materials provided together with the 4200 TapeStationDx instrument

p/n	Description
5067-5601	TapeStation Test Tape
5188-8047	USB cable A to B, 2 m
G2991-40007	ScreenTape Rack
G2992-40042	TapeStation Tube Strip Holder, tray for 16 Tubes
G2992-40046	TapeStation Tip Waste Bucket
5067-5783	Needle Change Cartridge
5067-5598	Loading Tips
5067-8502	96-well sample plates
5067-5154	96-well plate foil seal
401428	Optical Tube Strips, 8x strip
401425	Optical Caps, 8x strip

Cleaning Supplies

Use the cleaning materials listed below to manually clean the instrument. See [Cleaning the System Components](#) on page 159 for instructions.

Table 4: Cleaning materials for the instrument

Description	Purpose
Ethanol, 70%	Surface-cleaning of the instrument exterior and instrument deck
Isopropanol	Surface-cleaning of the instrument exterior and instrument deck
Interface cone Swab-cotton	Cleaning the narrow corners
Dry, lint-free, scratch-free, laboratory wipes	Surface-cleaning of the working area

Product Inspection

Upon receipt of a new Agilent 4200 TapeStationDx system, carefully inspect the product box for any visible signs of damage. If damage to the product box is detected, contact Agilent Worldwide Technical Support at <https://www.agilent.com/en/contact-us/page>.

Please ensure the box remains sealed for certified Agilent representatives.

Safety Precautions

The 4200 TapeStationDx system is designed for safe operation when it is used in the intended manner. Using the system for purposes other than those intended may impair those safety protections.

Safety Messages

WARNING

A WARNING

alerts you to situations that could cause physical injury or death.

- Do not proceed beyond a warning until you have fully understood and met the indicated conditions.

CAUTION

A CAUTION

alerts you to situations that could cause loss of data, or damage of equipment.

- Do not proceed beyond a caution until you have fully understood and met the indicated conditions.

The following general safety precautions must be observed during all phases of operation, service, and repair of this instrument. Failure to comply with these precautions or with specific warnings elsewhere in this manual violates safety standards of design, manufacture, and intended use of the instrument. Agilent Technologies assumes no liability for the customer's failure to comply with these requirements.

Electrical

Standard electrical safety precautions should be applied, including the following:

WARNING

Per North American and IEC requirements, install the instrument in a location where branch circuit protection is available in the power network.

WARNING

Install the instrument with the Agilent supplied power cord that is compatible with the electrical outlets in the operational region. Do not substitute with a power cord from another source.

WARNING

Ensure the proper usage of the equipment.

The protection provided by the equipment may be impaired.

- The operator of this instrument is advised to use the equipment in a manner as specified in this manual.
-

WARNING

Wrong voltage range, frequency or cabling

Personal injury or damage to the instrument

- Verify that the voltage range and frequency of your power distribution matches to the power specification of the individual instrument.
 - Never use cables other than the ones supplied by Agilent Technologies to ensure proper functionality and compliance with safety or EMC regulations.
 - Make all connections to the unit before applying power.
-

WARNING

Missing electrical ground

Electrical shock

- If your product is provided with a grounding type power plug, the instrument chassis and cover must be connected to an electrical ground to minimize shock hazard.
 - The ground pin must be firmly connected to an electrical ground (safety ground) terminal at the power outlet. Any interruption of the protective (grounding) conductor or disconnection of the protective earth terminal will cause a potential shock hazard that could result in personal injury.
-

WARNING

Instrument covers removed

Electrical shock

- Do not remove the instrument cover.
 - Only Agilent authorized personnel are allowed to remove instrument covers. Always disconnect the power cables and any external circuits before removing the instrument cover.
-

WARNING

Damage to the instrument

Personal injury (for example electrical shock, intoxication)

- Instruments that appear damaged or defective should be made inoperative and secured against unintended operation until they can be repaired by qualified service personnel.
-

WARNING

Do not touch any switches or outlets with wet hands.

WARNING

Unplug the instrument before cleaning any of the internal components.

CAUTION

Connect the power cord to a wall output that provides 100–240 VAC, 50/60 Hz.

CAUTION

Before disconnecting the power cord, turn off the instrument at the power button on the front.

Environmental Requirements**CAUTION**

Operating temperature

Keep the ambient temperature between 10 °C and 40 °C (50 – 104 °F).

CAUTION

Operating humidity

Keep the humidity levels between 15 % and 80 % non-condensing.

CAUTION

Altitude

Maximum altitude for instrument operation is 3000 m (9842 feet).

CAUTION

Condensation within the module

Condensation can damage the system electronics.

- Do not store, ship or use your module under conditions where temperature fluctuations could cause condensation within the module.
- If your module was shipped in cold weather, leave it in its box and allow it to warm slowly to room temperature to avoid condensation.

Installation Requirements**WARNING**

Install the instrument with the Agilent supplied power cord. Do not substitute with a power cord from another source.

WARNING

Install the instrument away from any flammable sources.

WARNING

Heavy weight

The instrument is heavy.

- Avoid back strain or injury by following all precautions for lifting heavy objects.
- Ensure that the load is as close to your body as possible.
- Ensure that you can cope with the weight of your load.

WARNING

Heart pacemakers

Magnets could affect the functioning of pacemakers and implanted heart defibrillators.

A pacemaker could switch into test mode and cause illness.

A heart defibrillator may stop working.

- Bearers of heart pacemakers or implanted defibrillators must stay off at least 55 mm from the magnets.

CAUTION

A new TapeStationDx system must be installed by an Agilent engineer or an Agilent authorized service provider.

It is within the customers' responsibility to ensure the bench area is free of contamination before the Agilent engineer or Agilent authorized service provider installs the instrument.

CAUTION

Retain the transport foams that secure the gantry and the camera transport lock which secures the camera during shipment. Anytime the instrument is moved, secure the moving parts with the parts supplied.

CAUTION

The instrument is for indoor use only.

CAUTION

Do not place the instrument in proximity to other lab equipment that is sensitive to vibrations or that generates vibrations during use. Proximity to lab equipment that generates vibrations can impact performance.

CAUTION

Maintain the following minimum distances for cleared space around the instrument:

- **Instrument sides:** 7.5 cm (3 inches) on each side to allow for proper ventilation from the side vents.
- **Back of the instrument:** 7.5 cm (3 inches) at the back to allow for proper ventilation from the back vent.
- **Top of the instrument:** 25 cm (10 inches) above to allow for opening the lid.

A laptop is supplied with the 4200 TapeStationDx instrument. Account for respective electrical outlets. Two plug sockets must be available near the allocated bench space for the instrument itself and a laptop.

CAUTION

Install the instrument in a location where the power cord can be easily reached for quick disconnection of the power supply.

Usage Requirements**CAUTION**

To maintain continuous workflow efficiency, ensure that enough sample is available in case sample re-testing is required.

CAUTION

To ensure proper function and maintain compliance with validated performance, only use Agilent-supplied unmodified consumables as specified in the [Materials Provided](#) on page 12.

CAUTION

Ensure that the appropriate ScreenTape device (RUO) is used for the intended analysis in terms of sizing and quantification range, as specified in the respective Quick Guide. Use of incompatible or mismatching ScreenTape devices (RUO) may result in inaccurate results or sample loss.

CAUTION

The ScreenTape database is stored exclusively on the associated laptop. To avoid sample loss, each ScreenTape device (RUO) must be used solely with the originally assigned laptop the ScreenTape device (RUO) was first used with.

2 Hardware Overview

Instrument Components

Front Side of the Instrument

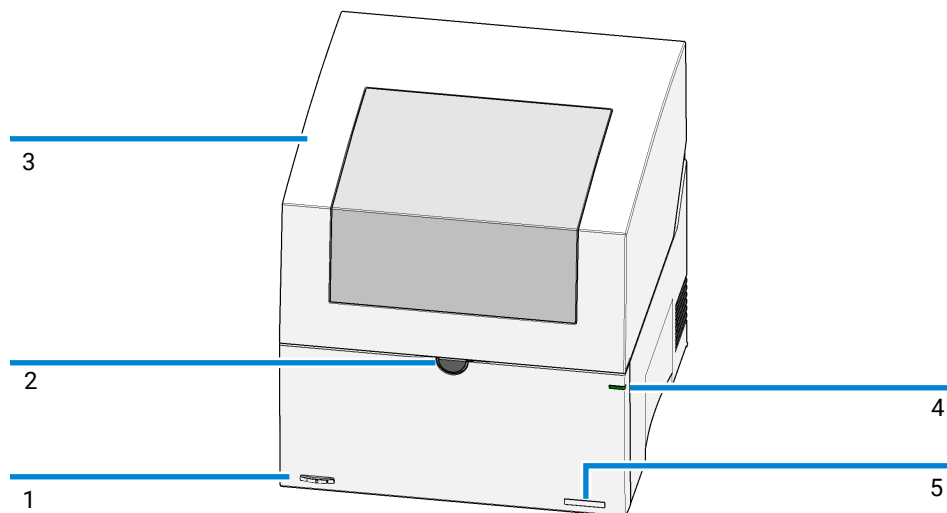


Figure 1: 4200 TapeStationDx instrument front view, lid closed

1	Power button
2	Lid release button
3	Lid
4	Status LED
5	Serial number

Lid Operation

WARNING

Heart pacemakers

Magnets could affect the functioning of pacemakers and implanted heart defibrillators.

A pacemaker could switch into test mode and cause illness.

A heart defibrillator may stop working.

- Bearers of heart pacemakers or implanted defibrillators must stay off at least 55 mm from the magnets.

CAUTION

Magnetic fields

Magnets produce a far-reaching, strong magnetic field.

You can damage for example televisions, laptops, computer harddisks, credit cards, magnetic cards may be damaged as well.

- Keep magnets at least 25 mm away from devices and objects that could be damaged by strong magnetic fields.

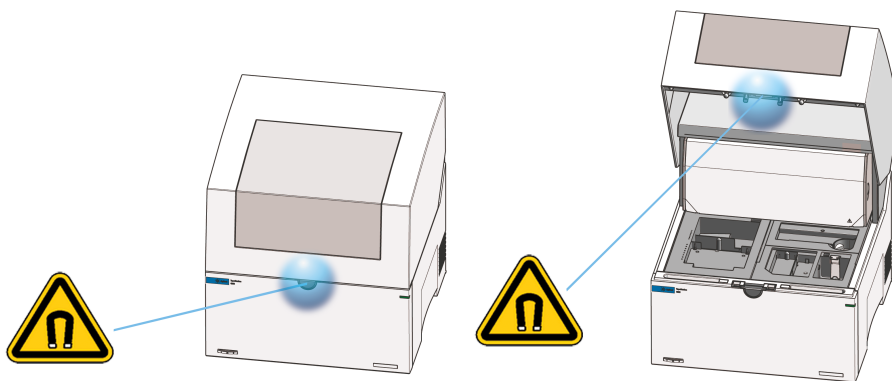


Figure 2: Position of magnet

To open the lid of the 4200 TapeStationDx instrument, press the lid release button. The lid will then swing open, providing access to the working area. For optimal operation, use both hands to guide the lid when opening and closing. Ensure the lid is closed whenever the 4200 TapeStationDx instrument is initialized, or the TapeStationDx Controller software is started. Close the lid by gently lowering it until it latches securely.

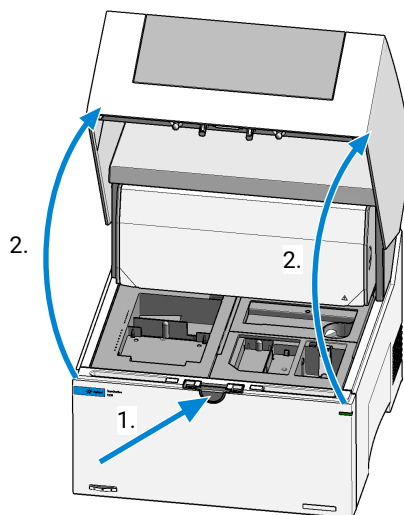


Figure 3: Lid operation

Overview of the Instrument Workspace

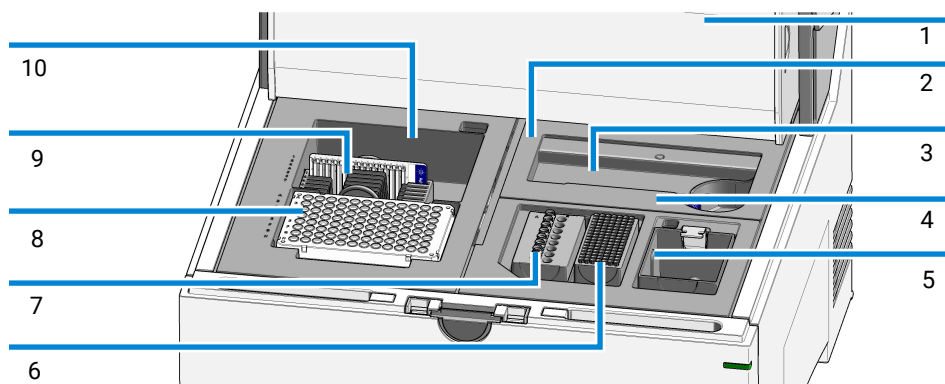


Figure 4: Overview of the instrument workspace

1	Gantry cover
2	Upper nest cover
3	Lower nest cover
4	ScreenTape nest

5	Tip waste
6	Tip rack
7	Tube strip holder
8	96-well sample plate
9	ScreenTape rack
10	ScreenTape waste location

Side of the Instrument

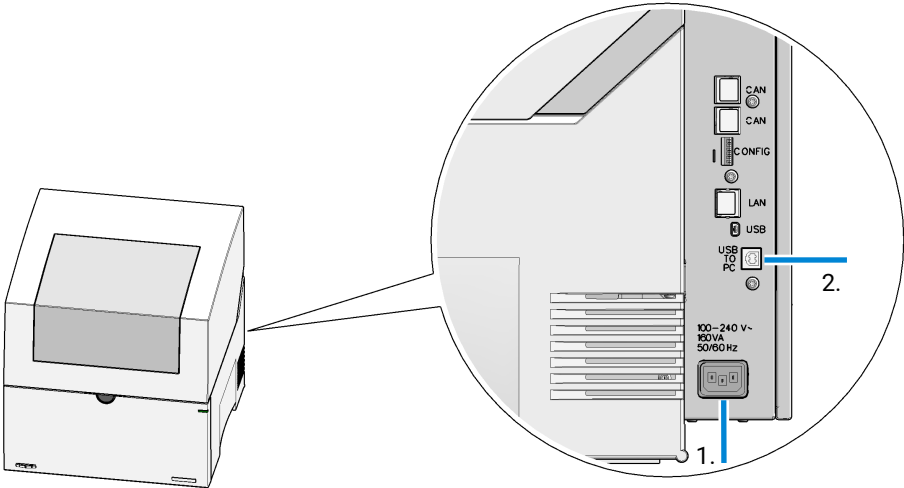


Figure 5: Electrical connections on the right side of the instrument

1	Power line in
2	USB-B to PC

The remaining connectors are blocked by plugs and reserved for factory use.

Instrument Status Indicator Lights

Status Indicators (LED)

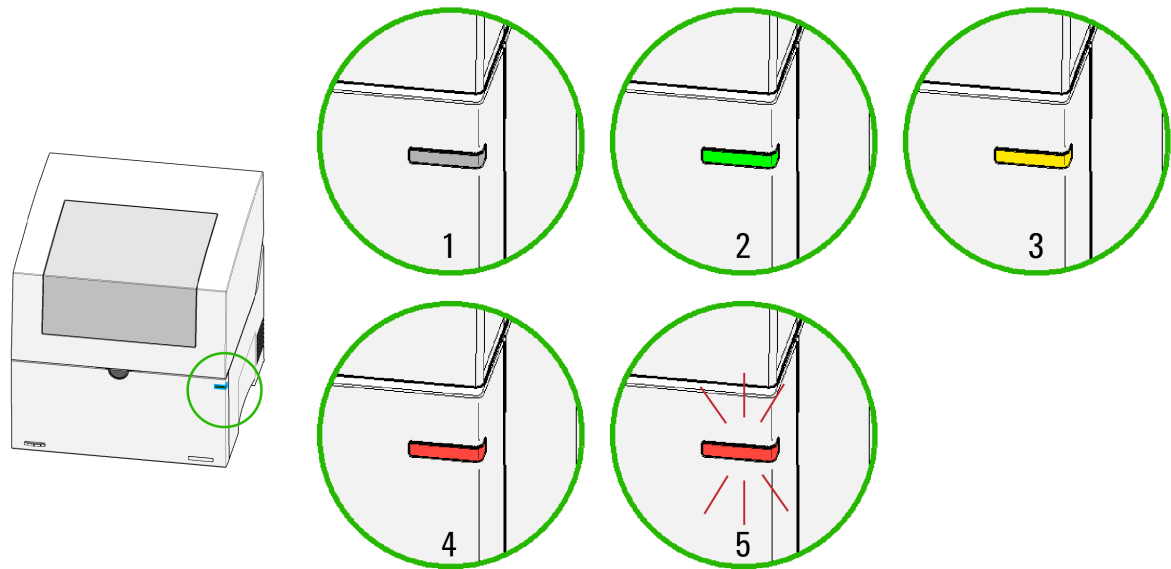


Figure 6: LED Status indicators for the 4200 TapeStationDx instrument

1	off	Idle
2	green	Run mode
3	yellow	Not-ready, waiting for a specific pre-run condition to be reached or completed
4	red	Error mode (restart required)
5	red blinking	Error mode (restart required) or ongoing firmware update

Status Indicators (Lid button)

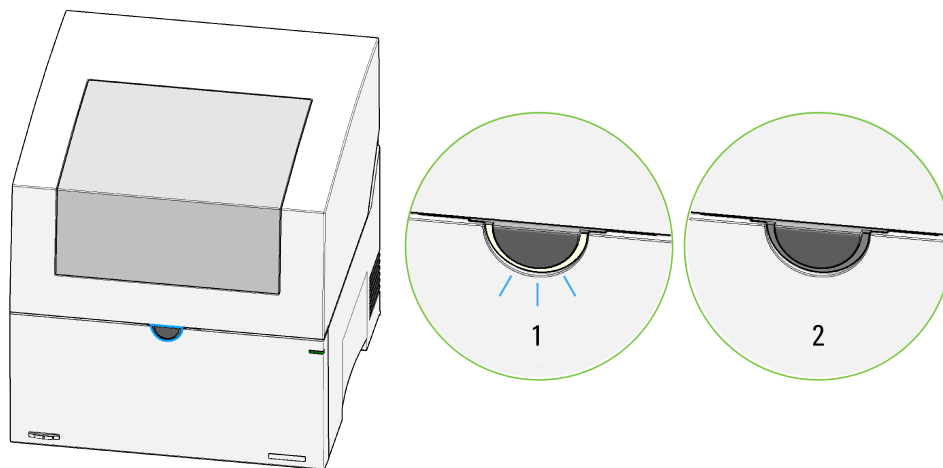


Figure 7: Lid status indicators for the 4200 TapeStationDx instrument. 1. On; 2. Off

Normal status is off. Blinking indicates an input request from the TapeStationDx Controller software to confirm a run stop request.

3 Software Overview

The TapeStationDx software supports the use of TapeStationDx instrument in regulated laboratory environments by providing a feature set including user authentication, user roles, electronic signatures, report locking, and audit trails.

The TapeStationDx software comes with three software components: the TapeStationDx Administration software, the TapeStationDx Controller software and the TapeStationDx Analysis software. See [Table 5 Overview of the TapeStationDx software components and functions](#) on page 26 for an overview of the functions from each software component.

Table 5: Overview of the TapeStationDx software components and functions

Icon	Name	Function
	TapeStationDx Administration software	• Setting authentication method • User management • Setting up and editing of projects • Creation of customized roles • Assigning roles to users • Defining data paths for projects • Creation of reports on projects, roles, users, and system wide activities • General security settings for the software
	TapeStationDx Controller software	• Controlling the instrument during runs • Sample selection and description • Capture of notes and lot information • Run of analytical assays based on barcodes • Hardware diagnostics and functional verification context • Maintenance counter • Needle and electrode cartridge change
	TapeStationDx Analysis software	• Data analysis and reporting • Review data as electropherogram and gel image • Peak and region integration and annotation • Size, quantity, molarity, and purity determination • Calculation of RIN®, DIN, %cfDNA or ribosomal ratios • Report templates • Sample comparison across multiple files from the same assay

All TapeStationDx software components are restricted to authenticated users. Users must be logged in with valid credentials to access and operate the software. For additional information on authentication, see [Authentication and System Administrator Setup](#) on page 83.

NOTE

This chapter includes multiple tables listing buttons and their corresponding functions within the TapeStationDx software. Please be aware that in non-English User Guides, the button names shown in bold within these tables may differ from the actual English terms displayed in the software interface.

TapeStationDx Administration Software



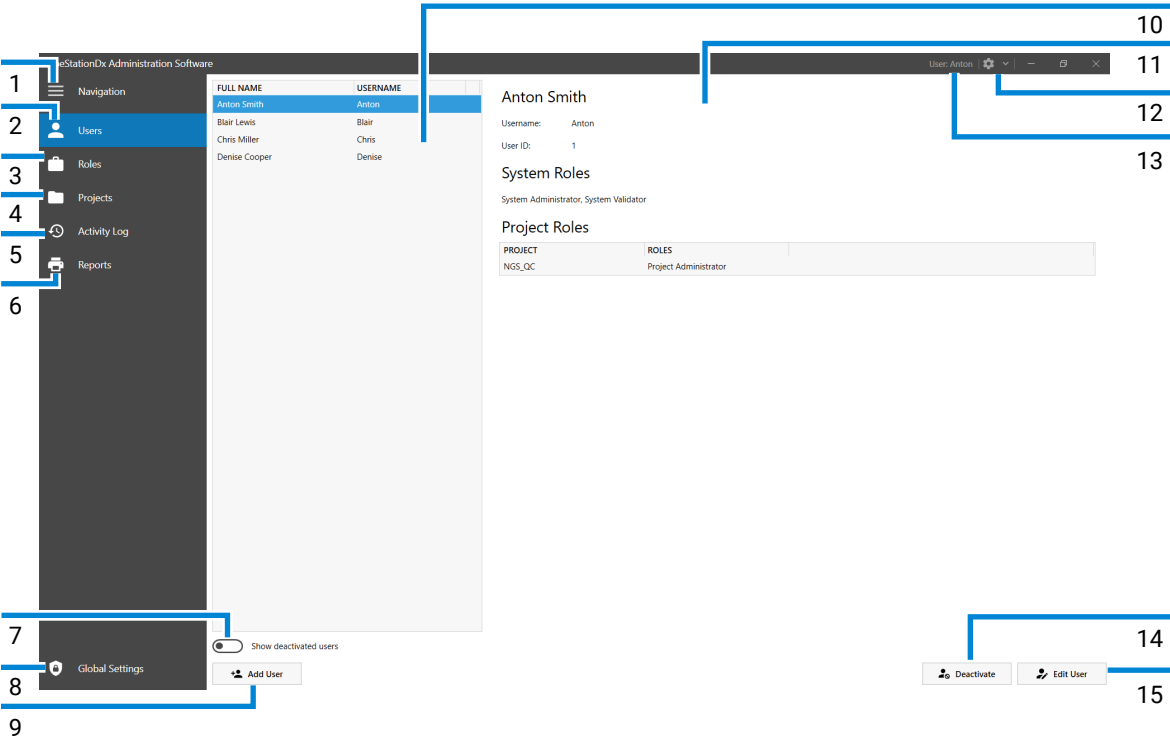
The TapeStationDx Administration software provides key features that apply to all TapeStationDx software components, such as user access levels, project workflows, and system configuration settings. It is designed to support clients in meeting compliance requirements, including those outlined in FDA 21 CFR Part 11 and EU GMP Annex 11; however, the TapeStationDx software itself is not a certified compliant system.

Users Screen

The **Users** dialog is destined to management of user accounts and their associated roles.

NOTE

If user permissions are modified, all TapeStationDx software applications need to be restarted for changes to take effect.



No.	Name	Description
1	Navigation	Shows/Hides the navigation side bar.
2	Users	Displays the Users dialog.
3	Roles	Displays the Roles dialog.
4	Projects	Displays the Projects dialog.
5	Activity Log	Displays the Activity Log dialog.
6	Reports	Displays the Reports dialog.
7	Show deactivated users	Shows/Hides deactivated users.

No.	Name	Description
8	Global Settings	Displays the Global Settings dialog.
9	Add User	Opens the Add User window.
10	Users list	Lists the users by their full name and username.
11	User details	Displays the details of the user selected in the users list, including respective system and project roles.
12	Cogwheel	Informs about TapeStationDx software version and regulatory labels.
13	Logged in User	Displays the logged in user and opens the user dropdown menu.
14	Deactivate	Deactivates the user selected in the users list. When Show deactivated users is selected, this button's name changes to Reactivate .
15	Edit User	Opens the Edit User window.

Add User Window

Add User

Search Users:

Full name

starts with

Enter search term here

Search

Type at least 3 characters and hit enter or click the search button

FULL NAME

USERNAME

Full Name *

Username *

System Roles

☐ Agilent Service Role

☐ Project Creator

☐ System Administrator

Project Roles

Analyst (0)

Project Administrator (0)

Reviewer (0)

Technician (0)

☐ NGS_QC

Cancel

Add

No.	Name	Description
1	Search Users	Selects filters to search users. Users can be searched by full name or username.
2	Search field	Field to enter search term (e.g., username or full name, depending on the selected filter).
3	Search	Searches for users according to the text entered in the search field.
4	Full Name	Field to enter the full name of the user.

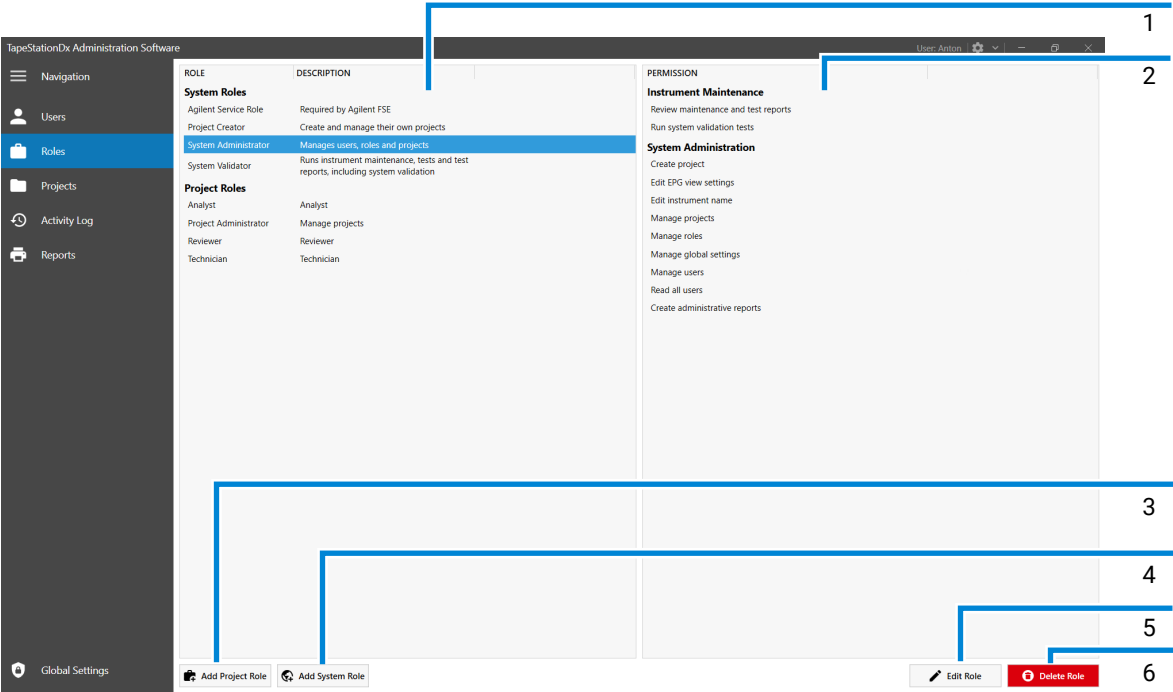
No.	Name	Description
5	Username	Field to enter the username. This must match the username from the authentication mode.
6	System Roles	Displays System Roles and allows you to assign these to the user.
7	Project Roles	Displays project roles in tabs. Selecting each tab allows you to assign specific projects to each role.
8	Projects	Displays projects. To specify what project you want to assign the project role to, select checkbox in front of the project's name.
9	Cancel	Discards the current configuration and exits the user creation process.
10	Add	Saves the configuration and adds the new user to the system.

NOTE

When searching for existing users, the respective full name or username must match those associated with the authentication mode selected (Windows local users or Windows Active Directory users).

Roles Screen

The **Roles** dialog shows all roles and associated permissions that can be assigned to a user. Customized roles can be created to meet specific organizational needs.



No.	Name	Description
1	Roles panel	Lists all roles for System Roles and Project Roles categories.
2	Permissions panel	Lists all permissions associated with the role selected in the roles panel.
3	Add Project Role	Opens a window that enables you to add a customized Project Role.
4	Add System Role	Opens a window that enables you to add a customized System Role.
5	Edit Role	Opens a window that enables you to edit the role selected in the roles panel.
6	Delete Role	Deletes the role selected in the roles panel.

Add Project Role Window

Add Project Role

Name *

Description

Permissions

Data Access

☐ Unlock file

☐ Lock file

☐ Review audit trail

General Analysis

☐ Save file

☐ Edit sample name in analysis software

☐ Load file

☐ Modify ladder

☐ Revert all file changes

☐ Edit marker alignment

☐ Revoke e-signature

☐ Edit study and comments in analysis software

☐ Import file

Cancel

Add

No.	Name	Description
1	Name	Enables manual assignment of a name to the new project role.
2	Description	Enables entry of a summary outlining the purpose of the role.
3	Data Access	Provides data access permissions to the role through checkbox selection.
4	General Analysis	Provides general analysis permissions to the role through checkbox selection.
5	Cancel	Cancels the current project role configuration.
6	Add	Saves the configuration and adds the new project role to the system.

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Add System Role Window

The Add System Role window closely resembles the Add Project Role window, with the key difference being the available permissions. In this window, users can assign permissions specifically related to instrument maintenance and system administration.

Add System Role

Name *

Description

Permissions

Instrument Maintenance

- ☐ Maintenance functionality
- ☐ Review maintenance and test reports
- ☐ Run system validation tests

System Administration

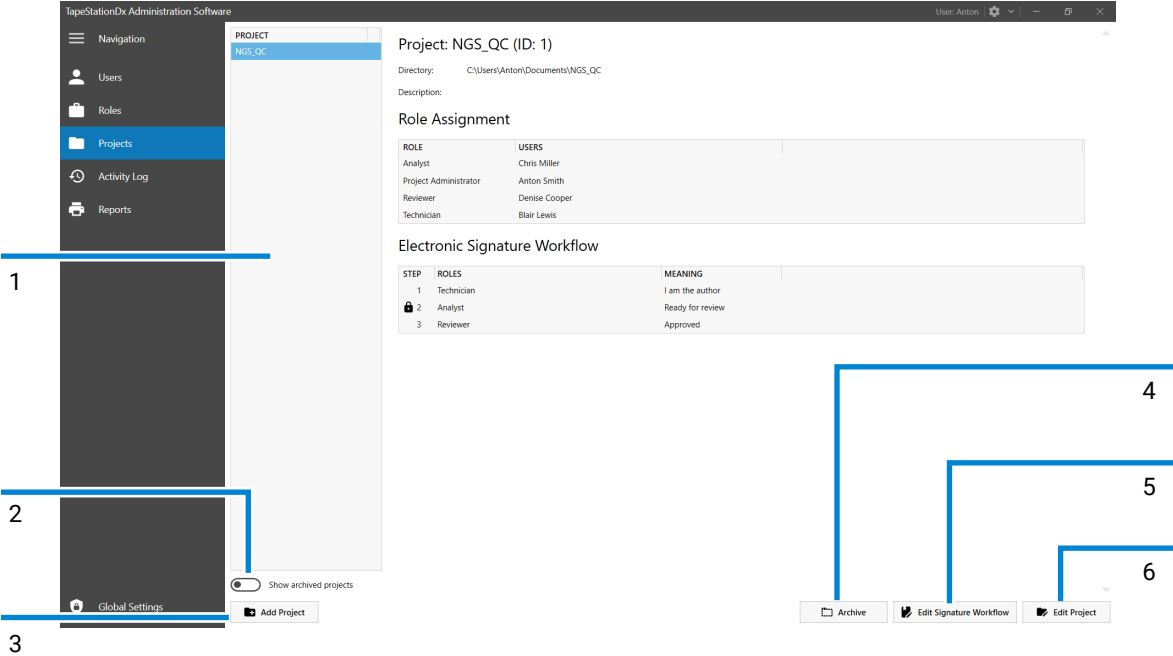
- ☐ Create administrative reports
- ☐ Create project
- ☐ Edit EPG view settings
- ☐ Edit instrument name
- ☐ Manage global settings
- ☐ Manage projects
- ☐ Manage roles
- ☐ Manage users
- ☐ Read all users

Cancel Add

Projects Screen

The **Projects** dialog is used to:

- Configure settings for analytical run data associated with a project.
- Assign required roles and users involved in the project.
- Define the electronic signature workflow for each project.



No.	Name	Description
1	Project list	Lists all active projects. When a project is selected, its configuration (output directory, description, roles and users, and Electronic Signature Workflow) is displayed to the right.
2	Show archived projects	When switched on, archived projects will be displayed.
3	Add Project	Opens the Add Project window, which enables adding and configuring a new project.
4	Archive	Archives the project selected in the projects list.
5	Edit Signature Workflow	Opens a window to edit signature workflow.
6	Edit Project	Opens the Edit Project window – functionally like the Add Project window – which enables reconfiguration of the project selected from the project list.

NOTE

If projects are reconfigured or archived/de-archived, the Controller and Analysis applications need to be restarted for changes to take effect.

Add Project Window

Add Project

Name *

Description

Output Directory *

Select output directory for this project

Project Roles

Analyst (0)

Project Administrator (1)

Reviewer (0)

Technician (0)

Anton Smith

Blair Lewis

Chris Miller

Denise Cooper

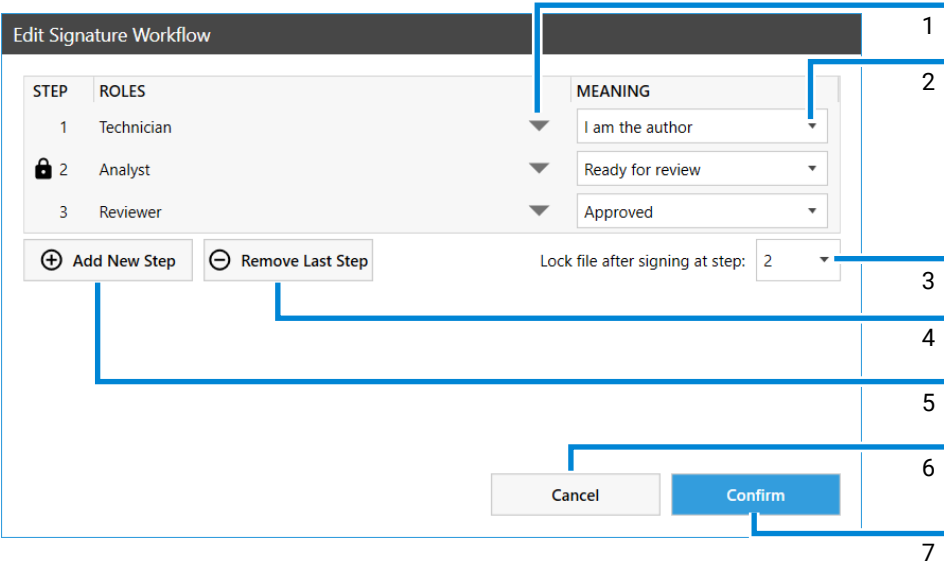
Project Administrator

Cancel

Add

No.	Name	Description
1	Name	Enables entry of a name to the new project.
2	Description	Enables entry of a summary outlining the purpose of the project.
3	Output Directory	Selects the output directory for all data files derived from this project.
4	Project Roles	Displays all existing project roles in tabs. Selecting each tab allows assignment of specific users to each role.
5	Users	Displays active users. To select role to a user, select checkbox in front of the desired user's full name.

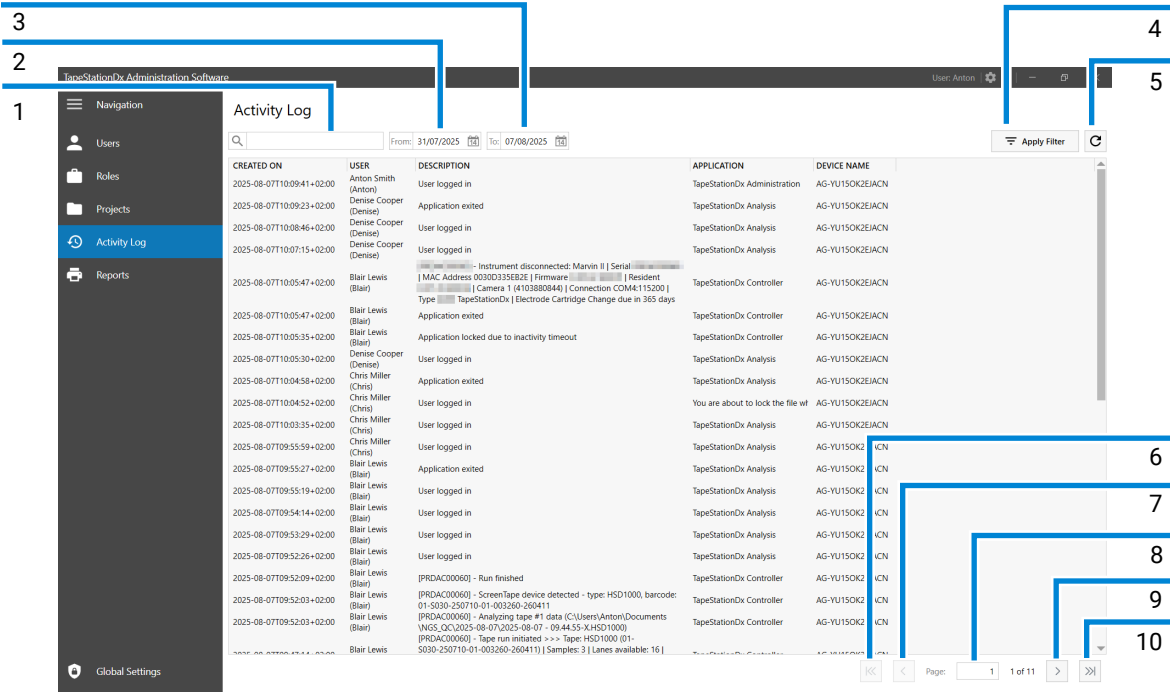
Edit Signature Workflow Window



No.	Name	Description
1	Role selector	Expands project roles and makes them available for selection.
2	Meaning selector	Displays Meanings for selection.
3	Lock file	Selects which signature step will lock the data file. It can be set to none.
4	Remove Last Step	Removes the last step from the workflow.
5	Add New Step	Adds new step to the workflow.
6	Cancel	Discards the current configuration.
7	Confirm	Applies the signature workflow to the project.

Activity Log Screen

The **Activity Log** dialog maintains detailed logs of actions and changes performed throughout all TapeStationDx software components, supporting traceability and accountability. The log can be searched for text strings and filtered for the date.



No.	Name	Description
1	Search field	Filters the activity log entries by typing in key words.
2	Date start	Sets a start date manually or via the calendar symbol.
3	Date end	Sets an end date manually or via the calendar symbol.
4	Apply Filter	Applies the configured filter.
5	Refresh	Restores activity log to display all activities.
6		Displays the first page of the activity log.
7		Displays the previous page of the activity log.
8	Page number	Entry of the page number.

No.	Name	Description
9	>	Displays the next page of the activity log.
10	>>	Displays the last page of the activity log.

Reports Screen

The **Reports** dialog allows users to generate comprehensive administrative reports on the following items: projects (including/excluding archived projects); users (including/excluding deactivated users or users from previous authentication modes); roles; and/or activity logs (filtered or unfiltered for date range). Reports can be previewed, saved as PDF, or directly printed.

1

Navigation

2

Users

3

Projects

4

Activity Log

5

Reports

6

7

11

Global Settings

Administrative Report

Project reports for output:
☒ Projects report
☐ Include archived projects
☐ Users report
☐ Include deactivated users
☐ Include users from previous authentication modes
☐ Roles report
☐ Activity Log Report (for following date range) From: 22/07/2025 To: 29/07/2025

8

Preview Summary

9

10

12

Print

TapeStationDx Software Report

Agilent

Date Generated: 2025-07-29T13:52:19+02:00

Generated By: "Anton Smith" <Anton: 1>

Operation Mode: IVD

TapeStationDx System GUID: 43740eb7-39fa-4107-965f-1ce63d8137a7

Device Name: AG-YU15OKZEJACN

Projects - Tuesday, 29 July 2025 13:52

Project	Path	Description
NGS_QC	C:\Users\Anton\Documents\NGS_QC	(no description)

Project Roles:

Role Name	Users assigned to role
Project Administrator	Anton Smith (Anton)
Technician	Blair Lewis (Blair)

No.	Name	Description
1	Projects report	Shows configurations of active projects.
2	Include archived projects	Shows configurations of archived projects.
3	Users report	Shows information on active users (e.g., username, full name, roles).

No.	Name	Description
4	Include deactivated users	Shows information on deactivated users.
5	Include users from previous authentication modes	Shows information on users from previous authentication modes.
6	Roles report	Shows all roles, as well as their respective permissions.
7	Activity Log Report	Shows activities performed by users.
8	Date start	Sets a start date manually or via the calendar symbol.
9	Date end	Sets an end date manually or via the calendar symbol.
10	Preview Summary	Displays the administrative report based on the selected settings.
11	Export PDF	Opens pop-up to set output path and export PDF.
12	Print	Prints report.

Global Settings Screen

The **Global Settings** dialog includes:

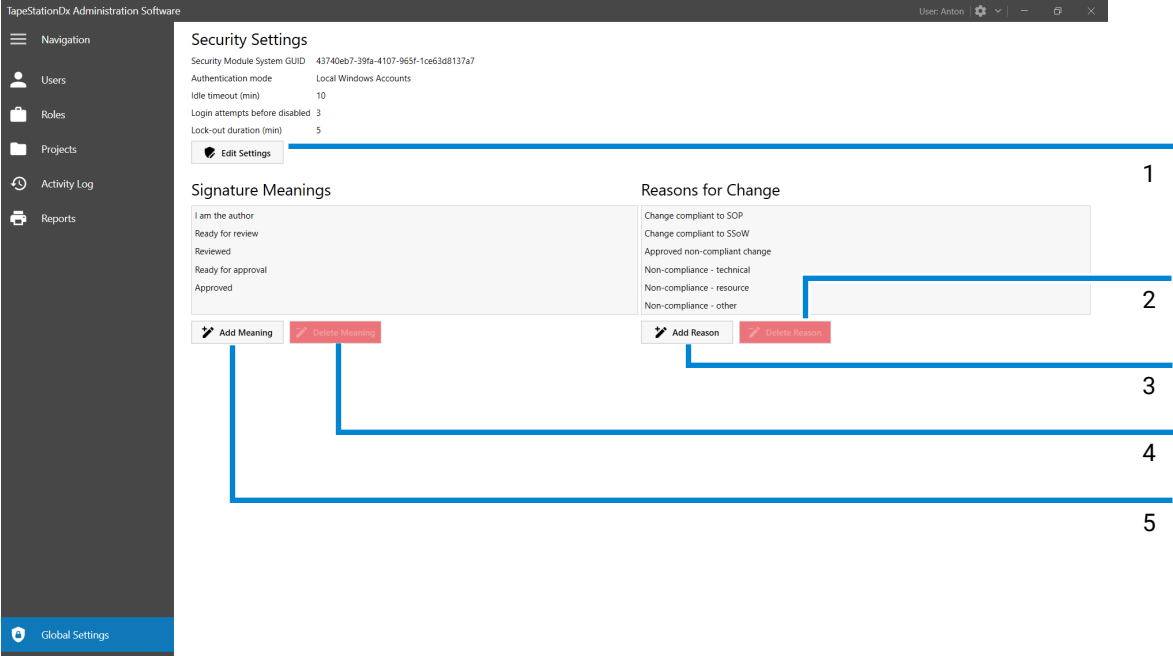
- Security Settings
Defines authentication mode, idle timeout duration, allowed failed login attempts, and lockout time. These settings apply to the entire TapeStationDx software and can be altered via **Edit Settings**.
- Signature Meanings and Reasons for Change
Used when applying electronic signatures. The software provides predefined entries, with the option to add custom text. Both are displayed in the audit trail to support traceability of data modifications.

NOTE

Ensure all other users are logged off before editing Global Settings.

NOTE

If Security Settings are modified, all TapeStationDx software applications need to be restarted for the changes to take effect.



No.	Name	Description
1	Edit Settings	Opens the Security Settings window.
2	Delete Reason	Deletes the selected Reason.
3	Add Reason	Opens a new window that enables adding a customized Reason.
4	Delete Meaning	Deletes the selected Meaning.
5	Add Meaning	Opens a new window that enables adding a customized Meaning.

Security Settings Window

Settings

Idle timeout (min)

10

+

−

** set as 0 to disable timeout*

Login attempts before lock-out

3

+

−

Lock-out duration (min)

5

+

−

Authentication mode

Change authentication mode

Cancel

Edit

No.	Name	Description
1	Idle timeout (min)	Configures the system's idle timeout period in minutes. The value can be adjusted manually or incremented/ decremented using the +/- buttons. Setting the value to zero disables the idle timeout function.
2	Login attempts before lock-out	Defines the maximum number of consecutive failed login attempts allowed before the user account is locked. The value can be adjusted manually or incremented/ decremented using the +/- buttons.
3	Lock-out duration (min)	Specifies the duration (in minutes) for which a user account remains locked after exceeding the allowed number of failed login attempts. The value can be adjusted manually or incremented/decremented using the +/- buttons.
4	Change authentication mode	Initiates the process to modify the current authentication mode.
5	Cancel	Discards any changes and closes the Security Settings window.
6	Edit	Saves all changes and exits the Security Settings window.

TapeStationDx Controller Software



The TapeStationDx Controller software is designed to operate and monitor the instrument during analytical runs, instrument diagnostic tests, and maintenance procedures. It establishes an automatic connection to the instrument via USB and manages the robotics and vision systems.

NOTE

The TapeStationDx Controller software supports a single TapeStationDx instrument connected to the laptop.

NOTE

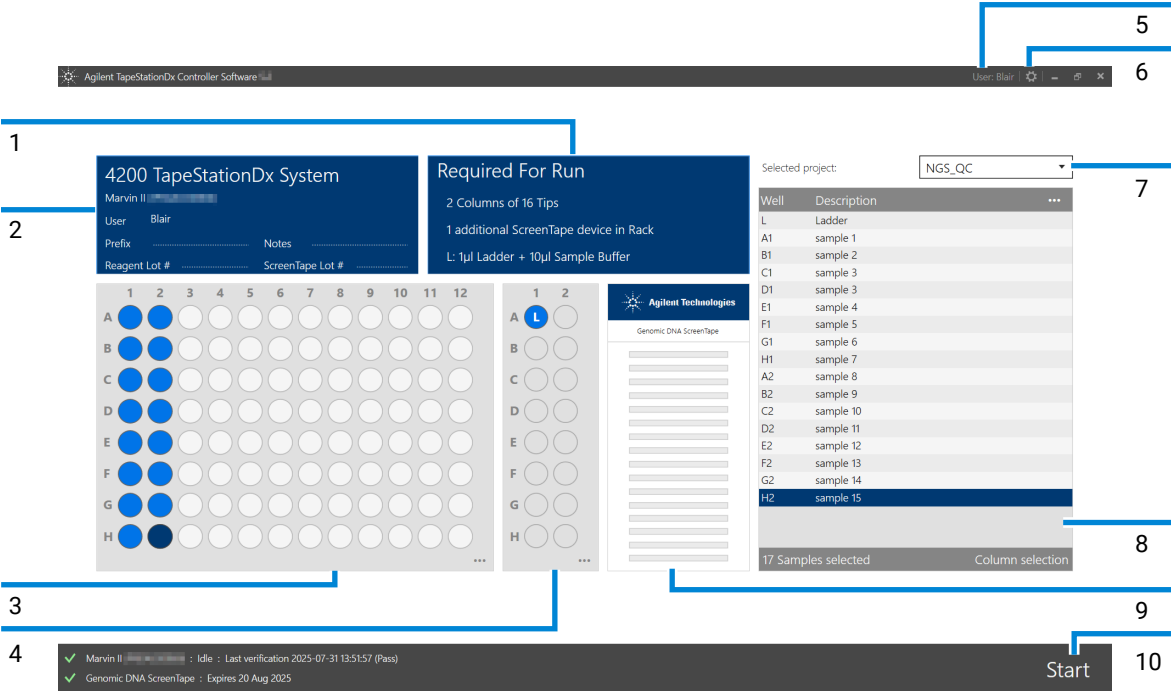
To keep software and firmware up to date, visit <https://www.agilent.com> regularly and review the respective release note of any successor revision.

Main Screen

The header displays the software application name and revision number, as well as the username of the logged-in user.

The main panel is used to set up the run, including sample layout.

The footer displays status messages (i.e., the instrument's serial number, verification status, and the ScreenTape device (RUO) status) and alerts marked with an exclamation mark (i.e., reasons why a run cannot start, upcoming maintenance, or errors that need attention).



No.	Name	Description
1	Required for Run	Displays the consumables required for the run once the sample locations are selected: • Number of tips – The required number of tips is provided in full columns of 16 tips for any run using 96-well plates. For runs using tube strips, the exact number of tips required is specified. • Number of ScreenTape devices (RUO) – The number of ScreenTape devices (RUO) required in the ScreenTape rack. This number does not include the ScreenTape device (RUO) already inserted in the nest. • Ladder and sample buffer volumes for ladder mix preparation.

No.	Name	Description
2	TapeStationDx system information field	Displays the instrument's name and serial number, as well as the logged-in user. Allows the user to insert an output prefix for data file, run notes, as well as reagent and ScreenTape lot numbers.
3	96-well plate	Sample locations on a 96-well plate.
4	Tube strips	Tube strips for ladder (A1) and sample locations.
5	User	Displays logged-in user. Opens the user dropdown menu.
6	Cogwheel	Opens the settings dropdown menu.
7	Project selector	Selects a project.
8	Sample descriptions	Table where a description for each sample location can be entered.
9	ScreenTape image	Displays the assay type corresponding to the ScreenTape device (RUO) inserted in the ScreenTape nest. For partially used ScreenTape devices (RUO), previously used lanes are shown in dark gray, while unused lanes appear in light gray.
10	Start	Initiates the run process.

The ladder must always be loaded in position A1 of the tube strip. While some ScreenTape assays (RUO) support the use of an electronic ladder, the use of a run ladder is strongly recommended for optimal performance.

To select an electronic ladder, right-click on the ladder position (L) or access the option through the sample function menu (...).

Refer to the relevant ScreenTape Assay (RUO) Quick Guides for additional information on ladder requirements and usage.

Samples can then be selected by clicking and dragging across either the tube strip or the 96-well sample plate locations. Once samples are selected, the sample descriptions table displays corresponding rows for each sample location and description entries are enabled.

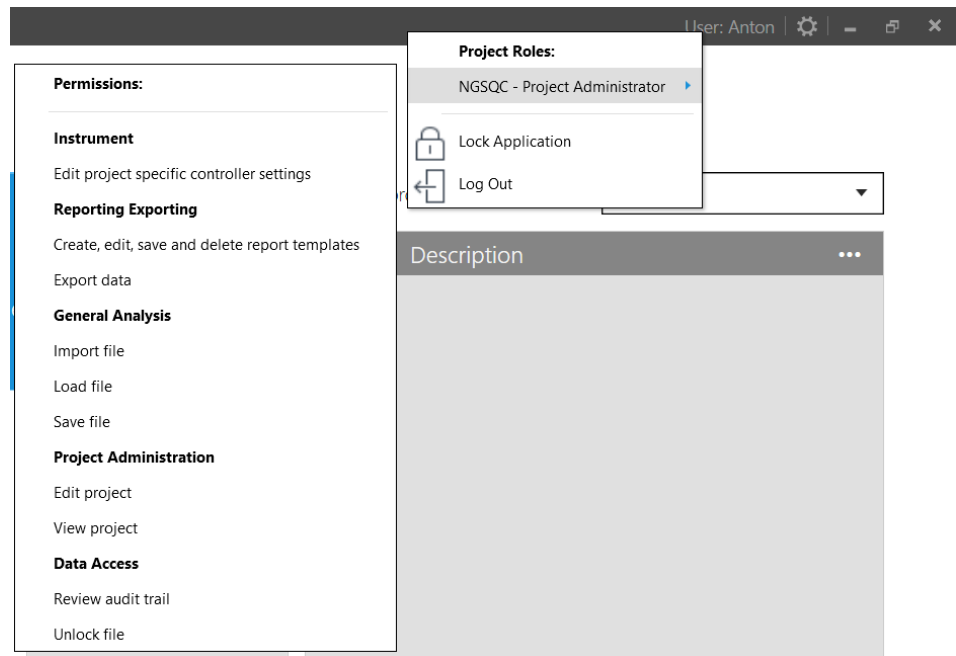
For detailed instructions on starting an analytical run, refer to [Performing a Run](#) on page 103.

User Dropdown Menu

Clicking on **User: [logged-in username]** in the Controller software's header opens the user dropdown menu.

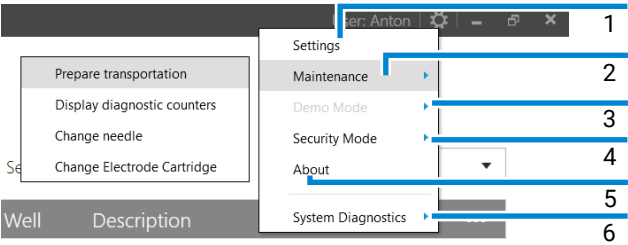
This menu displays the project roles associated with the current logged-in user and lists the respective permissions. It also allows the current user to lock the currently active software application and log out.

Similarly, the user dropdown menu can also be accessed from the header of the Administration and Analysis software.



Settings Dropdown Menu

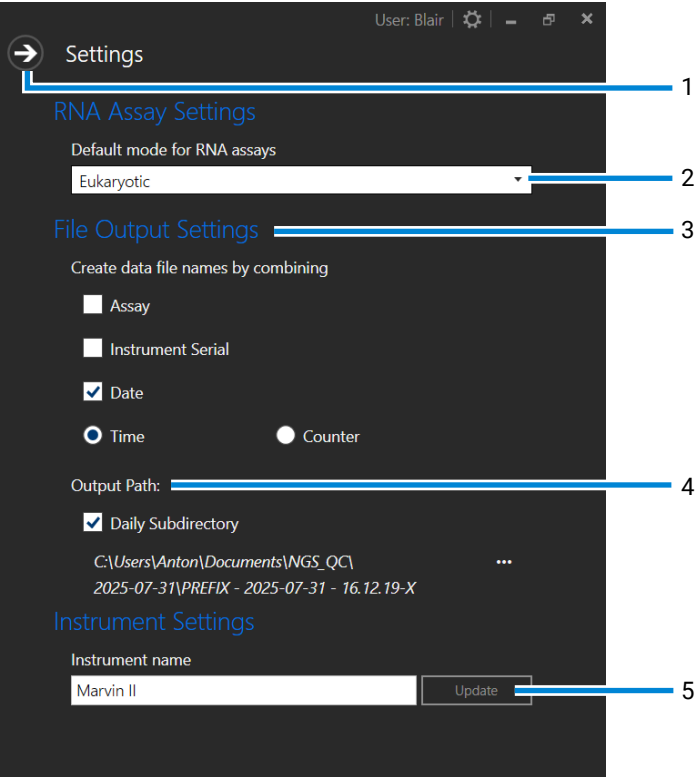
Clicking on the cogwheel of the TapeStationDx Controller software opens the settings dropdown menu.



No.	Name	Description
1	Settings	Opens the Settings dialog
2	Maintenance	Opens maintenance procedure options: • Prepare transportation (see Preparing the Instrument for Transportation on page 170); • Display diagnostic counters; • Change needle (see Exchange the Piercing Needle on page 145); • Change Electrode Cartridge (see Exchanging the Electrode Cartridge on page 151)
3	Demo Mode	Triggers a demo run featuring virtual ScreenTape assay (RUO) simulation.
4	Security Mode	Launches the TapeStationDx Administration software.
5	About	Informs about TapeStationDx software version and regulatory labels.
6	System Diagnostics	Opens the System Diagnostics interface.

Settings Dialog

The Settings dialog can be accessed through the settings dropdown menu. Here the user can edit settings associated with RNA assay, file output, and instrument name.



No.	Name	Description
1	Dialog close button	Closes the Settings dialog.
2	RNA assay mode	Preselects the analysis mode for RNA ScreenTape assays (RUO) (default setting Eukaryotic). The selected value can also be changed after the run, in the TapeStationDx Analysis software.
3	File name configuration	Customizes the data file name. Assay name, instrument serial number, and date can be selected. The file will have either time or a number from a continuous counter for identification.

No.	Name	Description
4	Output Path	Displays the output path. This section cannot be changed as the output directory for data files is configured within the project's settings.
5	Instrument name	The instrument's name can be modified. It will be subsequently displayed in the information field and status line of the main Controller software user interface.

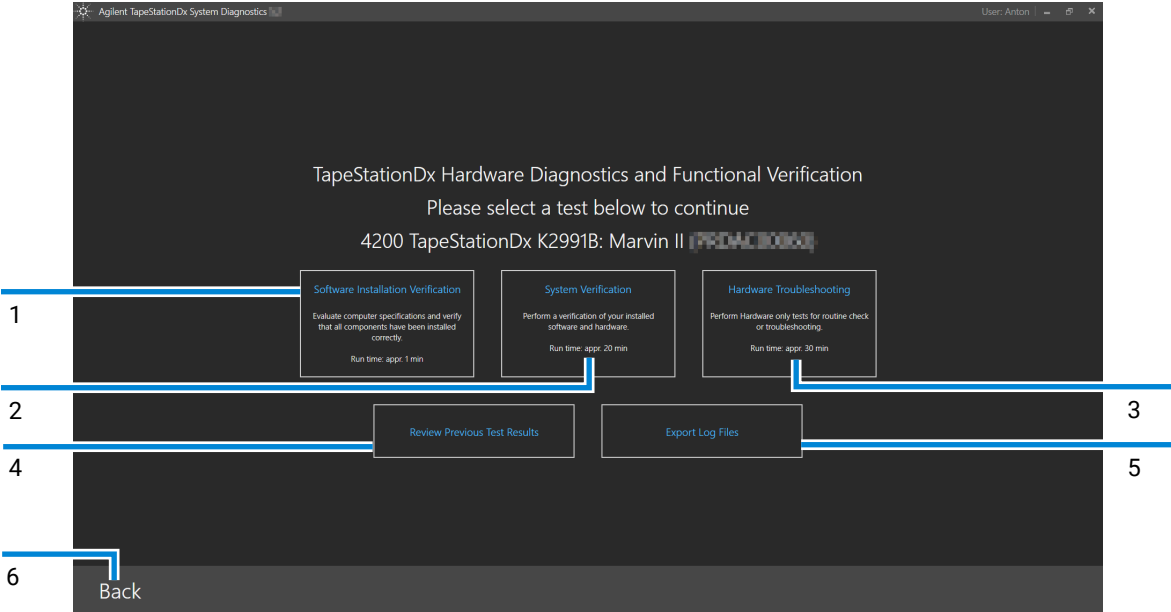
System Diagnostics Screen

The Agilent TapeStationDx System Diagnostics is an interface accessible through the TapeStationDx Controller software's settings dropdown menu. It displays the Hardware Diagnostics and Functional Verification context which provides advanced diagnostic test suites for routine TapeStationDx system functionality checks and troubleshooting, such as

- Software Installation Verification,
- System Verification, and
- Hardware Troubleshooting.

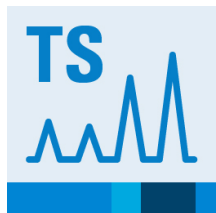
Some tests require using a dedicated TapeStation Test Tape device (see [TapeStation Test Tape](#) on page 128).

The results from instrument diagnostics are saved to **C:\Users\[Windows User Account]\Documents\Agilent\TapeStation Data\Diagnostic Files**.



No.	Name	Description
1	Software Installation Verification	Opens a test suite that evaluates the computer specifications and verifies if all components are correctly installed.
2	System Verification	Opens a test suite that is used to check the performance of electrical and optical components of the instrument.
3	Hardware Troubleshooting	Opens an extended version of the System Verification test suite.
4	Review Previous Test Results	Opens a window where previous test suite results can be previewed, printed, or exported into .pdf format.
5	Export Log Files	Exports a zipped folder containing log files, which can be used for remote support purposes (see View Reports for Instrument Diagnostic Tests on page 141 and Collecting Troubleshooting Information on page 190).
6	Back	Closes the System Diagnostics screen.

TapeStationDx Analysis Software



The TapeStationDx Analysis software offers a simple and intuitive interface for data analysis and reporting. Results can be viewed as electropherograms, gel-like images, or in tabular format for easy sample comparison. Based on the selected assay type, the software automatically calculates key metrics such as size, quantity, molarity, RIN®, DIN, %cfDNA, or ribosomal ratios. Reports can be generated and saved as PDF files. Access to these features is restricted to users with the appropriate roles and permissions. Additional functionality includes support for electronic signatures, data file locking, and comprehensive audit trails to ensure data integrity and traceability.

Electronic signatures:

- Electronic signatures can be required when approving changes, finalizing reports, locking the data file, or exporting data.
- During the signing process, users select a Meaning and Reason for Change, which are stored alongside the record.
- All applied signatures are recorded in the audit trail and are visible in the final report.

Audit trail functionality:

- A secure, tamper-resistant audit trail within the TapeStationDx Analysis software.
- The audit trail records all change events applied to a data file.
- Each entry includes the timestamp, user ID, action taken, and any associated Reason for Change.
- Audit trail data can be viewed within the software, printed, or exported for regulatory review if needed.

Data integrity and result management:

- An approval status for each sample must be set.
- Once an analysis is finalized and signed, the file may be locked from further modification, depending on user role and system settings.
- Exported reports include signature details and audit trail summaries, supporting full traceability.
- The system prevents unauthorized data overwriting, ensuring that previous results remain accessible and verifiable.
- Access to exporting audit trail reports or analysis results reports is role dependent. Users without export privileges cannot save data externally.

Data acquisition:

The software processes instrument data through a series of analysis steps to generate results. The image is then converted into a one-dimensional electropherogram. Peaks are detected via cross-correlation with a normal distribution. Then these peaks are matched to a known ladder to determine molecular weights and calculate the final analytical results.

Electropherogram:

The electropherogram (EPG) is a graphical representation of the sample analysis:

- The x-axis displays the fragment size in base pairs (bp) or nucleotides (nt).

- The y-axis shows the fluorescence signal intensity in fluorescence units.

The TapeStationDx Analysis software automatically detects and labels peaks. Each peak is marked with its corresponding size, and the upper and lower markers, where applicable, are clearly indicated in the EPG. The software also calculates:

- Total sample concentration, listed in the Sample Table.
- Concentration and molarity for each peak, listed in the Peak Table.
- Concentration and molarity for each region, listed in the Region Table.

Whenever samples are smeared rather than well-defined peaks (e.g., DNA libraries), the **Region** view is better suited for the analysis. A region is a user-defined area in the EPG used for quantification and calculation of average sizing.

Depending on the ScreenTape assay (RUO), the software automatically calculates the RNA Integrity Number equivalent (RIN®), labels large and small ribosomal subunits, calculates the DNA Integrity number (DIN), or calculates the percentage of cell-free DNA (%cfDNA).

Calibration:

Calibration uses known standards (markers or ladder, depending on the assay) to generate a curve for calibrating sample peaks.

Each assay has specific calibration parameters:

Molecular weight: Based on ladder, using fitting types like piecewise interpolation, genomic DNA sizing, or log-linear piecewise. Molecular weight calibration can be viewed in **File > Run Properties** and included in the report template for further export.

Concentration: Uses linear regression from either upper or lower markers, measured in ng/μl or pg/μl. Concentration calibration can be included in the report template for further export.

3 Software Overview

TapeStationDx Analysis Software

Home Screen

The screenshot displays the TapeStationDx Analysis Software interface. The top navigation bar includes 'File', 'Home', and 'Comparison' tabs. The 'Home' tab is active, showing a 'Data Analysis' panel on the left with a 'Project Demo' section. The main area features a gel electrophoresis image and a corresponding size distribution graph. The bottom of the screen shows a 'Peak Table' and a 'Sample Table'.

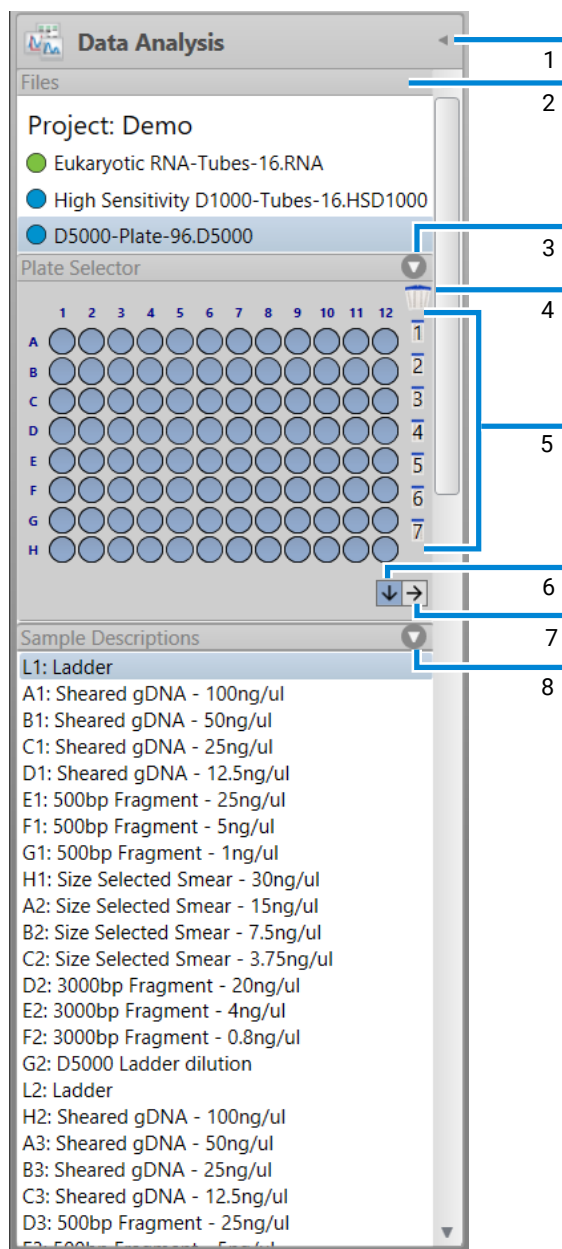
Numbered callouts indicate the following components:

- 1: File menu
- 2: Open file icon
- 3: Save icon
- 4: Quick access toolbar
- 5: Home tab
- 6: Comparison tab
- 7: Groups ribbon
- 8: Data Analysis panel
- 9: User profile dropdown
- 10: Logout icon
- 11: Lock status icon
- 12: Peak Table and Sample Table

No.	Name	Description
1	File	Displays the File screen.
2	Open	Opens a file.
3	Save	Automatically saves file. Only possible if data file has been edited.
4	Quick access toolbar	Shows the quick access toolbar below the Groups ribbon.
5	Home	Displays the Home screen.
6	Comparison	Displays the Comparison screen.
7	Groups ribbon	Set of buttons organized into groups that allow the user to perform changes in the data file.

No.	Name	Description
8	Data Analysis navigator	This navigator is divided into Files , Plate Selector , and Sample Descriptions . It enables the user to view different data files, or different sample locations and sample descriptions within the same data file.
9	Gel image	Gel representation of the run results.
10	Electropherogram	Graphical representation of the sample analysis.
11	Hide/Show	Hides/shows the Groups ribbon.
12	Tables	Tables context, where the user can display, consult, and edit the Peak Table , Region Table , and/or Sample Table .

Data Analysis Navigator



Software Overview

TapeStationDx Analysis Software

No.	Name	Description
1	Data Analysis navigator	Shows/hides the Data Analysis navigator.
2	Files	Lists imported data files. These data files are grouped by project. Selecting a data file from this list will update fields to that run. The user can access file management tools (e.g., save and close options) by right-clicking on the data file.
3	Plate Selector	Displays sample locations from tube strips or 96-well plate.
4	All ScreenTape devices	Displays sample locations from all ScreenTape devices (RUO).
5	Individual ScreenTape devices	Displays sample locations from individual ScreenTape devices (RUO).
6	Column order	Orders samples according to columns. Order will be updated in Sample Descriptions as well as in the gel image.
7	Row order	Orders samples according to rows. Order will be updated in Sample Descriptions as well as in the gel image.
8	Sample Descriptions	Displays Sample Descriptions . Sample descriptions can either be entered in the TapeStationDx Controller software when setting up the run or in the TapeStationDx Analysis software in the sample table.

Groups Ribbon

The **Home** screen from the TapeStationDx Analysis software contains multiple functions included into different groups. The tables below explain what each button does in each group.

Table 6: View group

Icon	Name	Description
	Gel	Expands gel image and shows sample table.
	Electropherogram	Shows peak data in the electropherogram for the selected sample, displays peak table, and activates peak analysis. Enables peak editing mode. When selected, it becomes possible to manually edit peaks via right-click on the electropherogram (EPG).
	Region	Shows region data in the electropherogram for the selected sample, displays region table, and activates region analysis. Enables region editing mode. When selected, it becomes possible to manually edit regions via right-click on the EPG.

Table 7: Display group

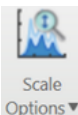
Icon	Name	Description
	Aligned	Aligns or unaligns the markers.
	Scale to MW Range	Scales each lane to the molecular weight range of the sample, ignoring residual content of the well. When this function is switched off, the residual content is included. Genomic DNA assays only.
	Scale Options	There are three scale options: - Global Scaling - same scaling for all samples to the tallest peak - Scale to Sample - scale each sample to its tallest peak - Scale to Highest - scale each sample to its tallest peak (including markers)

Table 8: Gel group

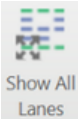
Icon	Name	Description
	Gel Snapshot	Takes a snapshot of the gel image. There are two ways of taking a gel snapshot: • Gel Snapshot to Clipboard - takes a snapshot of the gel and copies it to the clipboard • Gel Snapshot to Disk - takes a snapshot of the gel and saves it to disk. A window will open for selection of the location on the hard drive
	Contrast	Allows contrast management of gel image by: • Clicking on the circle - this resets contrast of the gel image • Dragging the rectangle left or right - this changes the contrast of the gel image
	Show All Lanes	When selected, this shrinks all gel lanes to fit into the gel view.

Table 9: EPG group

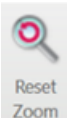
Icon	Name	Description
	EPG Snapshot	Takes a snapshot of the selected electropherogram (EPG). There are two ways of taking an EPG snapshot: • Gel Snapshot to Clipboard - takes a snapshot of the gel and copies it to the clipboard. • Gel Snapshot to Disk - takes a snapshot of the gel and saves it to disk. A window will open for selection of the location on the hard drive.
	Reset Zoom	Resets zoom to default EPG view.

Table 10: Ladder group

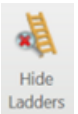
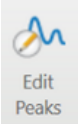
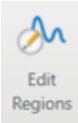
Icon	Name	Description
	Insert	Inserts an assay-specific electronic ladder. If a run ladder is assigned, it will be replaced.
	Insert all	Inserts an assay-specific electronic ladder to all ScreenTape devices (RUO). If run ladders are assigned, these will be replaced.
	Restore	Removes the inserted electronic ladder/s and restores the run ladder/s.
	Assign	Assigns the selected sample lane as ladder.
	Remove	Removes the currently assigned ladder.
	Hide ladders	Changes whether off plate ladders are visible.

Table 11: Analysis group

Icon	Name	Description
	Detection Settings	Displays the Peak Detection Settings dialog, which allows editing of peak detection parameters.
	Restore Default Settings	Reverts the file to its original default peak or region analysis settings. All user-defined peak or region changes will be lost.
	Edit Peaks	Allows the user to manually add a peak via double click on EPG or lane in the gel view (Electropherogram view only).
	Edit Regions	Allows the user to manually add a region via double click on EPG or lane in the gel view (Region view only).

Software Overview

TapeStationDx Analysis Software

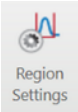
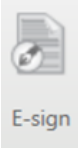
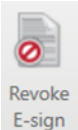
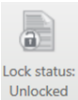
Icon	Name	Description
	Region Settings	Displays the Regions section within the Assay Options dialog, which allows editing of region settings.
	RNA Type	Selects the analysis mode for RNA analysis. Available for: • Eukaryotic (18S and 28S) • Prokaryotic (16S and 23S) RNA assays only.

Table 12: Traceability group

Icon	Name	Description
	Review Audit Events	Reviews the current file's unreviewed audit trail events. Audit events cannot be reviewed by the user who generated them.
	View Audit Trail	Displays the current audit trail events as a table in a new window.

Table 13: E-sign group

Icon	Name	Description
	E-sign	Displays the E-sign Results window, allowing the current file to be electronically signed.
	Revoke E-sign	Displays the Revoke E-Signature window, enabling revocation of the most recent electronic signature on the current file. This action results in a step back in the signature workflow and requires an electronic signature.
	Lock status	Changes the lock state of the current file to Locked or Unlocked. All file changes must first be saved. Changing the lock status requires an electronic signature.

Tables

The **Home** screen can display three tables: **Peak Table**, **Region Table**, and **Sample Table**.

Right-clicking on a row from the **Peak Table** or **Region Table** enables copying of the table or deletion of the selected peak or region. Deleting a peak or region in the respective table will also delete it on the EPG.

For each table, the user can add extra columns by right-clicking on a column > selecting **Show Column Chooser** > clicking and dragging the desired column to the table columns.

Peak Table

The **Peak Table** contains relevant information on peaks integrated by the software or the user on the current file.

Table 14: Available columns in the Peak Table

Name	Description
Size	Peak size correspondent to the peak bar on the EPG. Units can be given in base pairs (bp), nucleotides (nt).
Concentration	Concentration of nucleic acid in peak. Units are given in ng/μL or pg/μL, depending on the assay.
Peak Molarity	Molarity of nucleic acid in peak. Units are given in nmol/L or pmol/L, depending on the assay.
% Integrated Area	The area of the integrated peak as a percentage of the total integrated area in the EPG.
From	Lower limit of the peak. Units can be given in base pairs (bp) or nucleotides (nt).
To	Upper limit of the peak. Units can be given in base pairs (bp) or nucleotides (nt).
Peak Comment	Editable field destined for comments.
Observations	System-generated messages about peak (e.g., "Lower Marker"; "Upper Marker"; "18S", "28S", etc.)

Region Table

The **Region Table** contains relevant information on regions integrated by the software or the user on the current file.

Table 15: Available columns in the Region Table

Name	Description
From	Lower limit of the peak. Units can be given in base pairs (bp) or nucleotides (nt).
To	Upper limit of the peak. Units can be given in base pairs (bp) or nucleotides (nt).
Average Size	Average size of region. Units can be given in base pairs (bp), nucleotides (nt).
Concentration	Concentration of nucleic acid in the region. Units are given in ng/μL or pg/μL, depending on the assay.
Region Molarity	Molarity of nucleic acid in the region. Units are given in nmol/L or pmol/L, depending on the assay.
% of Total	The area of the integrated region as a percentage of the total area in the EPG.
Region Comment	Editable field destined for comments.
Color	Color used to represent the region in the EPG.

Sample Table

The **Sample Table** contains details of all samples in the current data file. The  or  icon in the **Sample Table** tab header indicates that one or several samples contain an error; the color of the icon indicates the severity of the error.

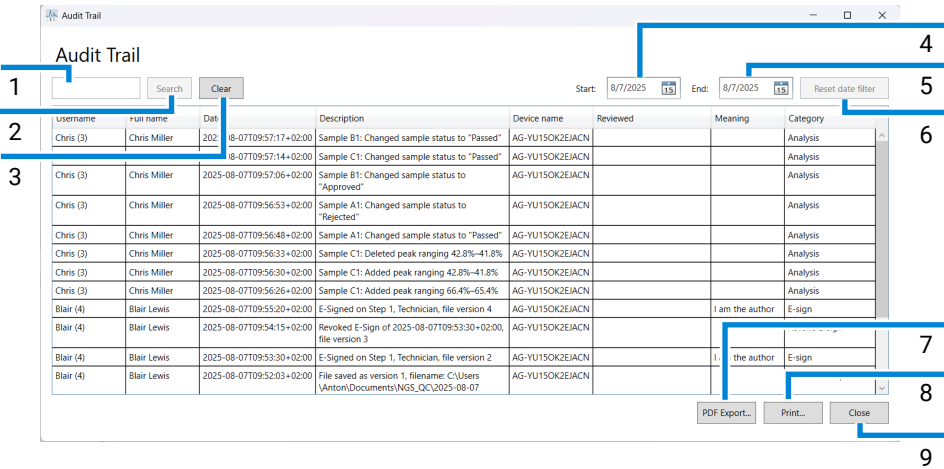
Table 16: Available columns in the Sample Table

Name	Description
Approval State	The sample approval status can be selected from the following options: In Progress, Passed, Under Review, Approved, Rejected, or None.
Well	Sample location.
Concentration	The total concentration of the integrated peaks/regions on the EPG (excluding markers).
Sample Description	Editable field destined for comments. Changes will be updated in the Sample Descriptions field of the Data Analysis navigator.
Alert	Indicator (exclamation mark) if something is wrong with the sample results.
Observations	System-generated messages about the sample. If an alert is present, it often describes the reason for the alert.

Name	Description
DIN	DNA Integrity Number (DIN) is a quality score given on a scale of 1 to 10, used to determine the fragmentation of a gDNA samples. A high DIN value indicates highly intact gDNA.
RIN ^e	RNA Integrity Number equivalent (RIN ^e) is a quality score given on a scale of 1 to 10, where 10 represents excellent RNA quality.
28S/18S (Area)	Peak area ratio of 28S and 18S ribosomal RNA fragments (Eukaryotic RNA type).
23S/16S (Area)	Peak area ratio of 23S and 16S ribosomal RNA fragments (Prokaryotic RNA type).
DV ₂₀₀ (%)	Percentage of RNA fragments larger than 200 nucleotides with respect to all RNA fragments. This is a quality score for highly degraded RNA samples (e.g., FFPE samples).
%cfDNA	The percentage of mono-, di-, and trinucleosomal cell-free DNA (cfDNA) based on the signal intensity within the fragment size range of 50 to 700 nucleotides, relative to the total sample. Reported values range from 0 % (no DNA fragments within the 50–700 bp range) to 100 % (no material/DNA fragments above 700 bp).

Audit Trail Window

An Audit Trail records all the change events applied to a data file.



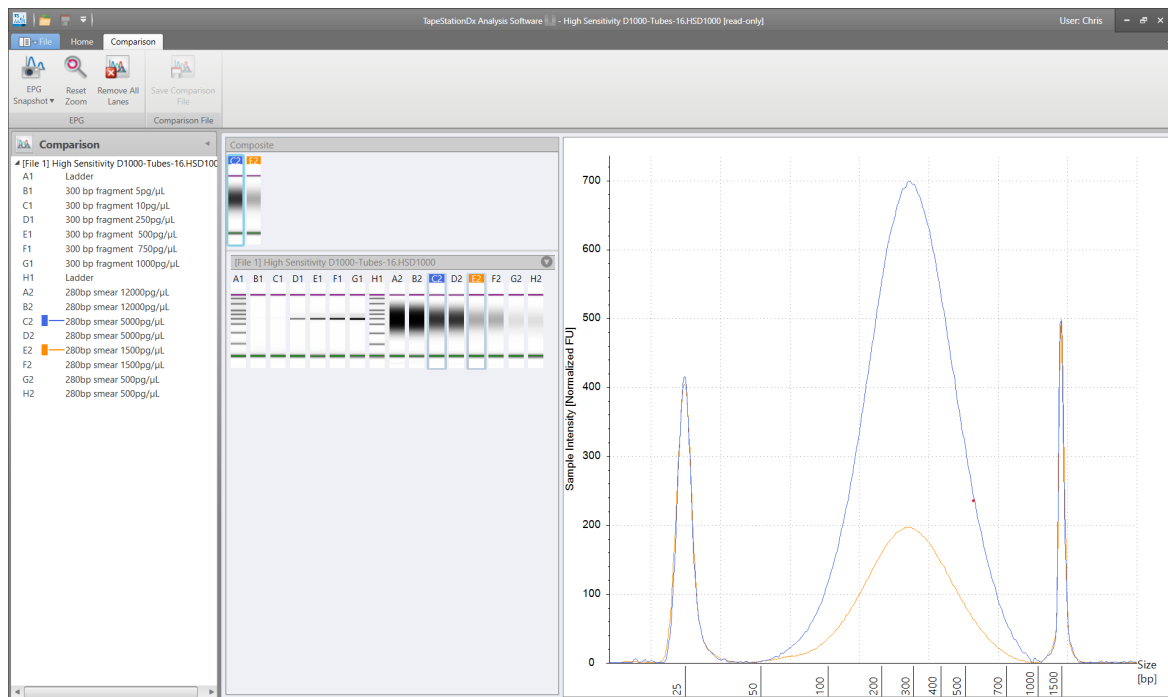
No.	Name	Description
1	Search field	Field to enter search term.
2	Search	Filters out audit trail for the search term and date filter applied.
3	Clear	Shows unfiltered audit trail results.
4	Start	Selects start date.
5	End	Selects end date.
6	Reset date filter	Resets date filter to default (current day).
7	PDF Export...	Opens the Windows File Explorer to export audit trail as a PDF.
8	Print...	Prints audit trail results.
9	Close	Closes the audit trail window.

Comparison Screen

The **Comparison** screen is used to compare multiple sample profiles from either one or different data files into one comparison file. Comparing sample profiles from distinct data files is only possible for data files from the same project and assay type.

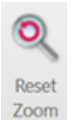
The **Comparison** tab is only visible when data files are loaded to the **Home** tab.

The audit trail of a composite file will subsequently contain the history of both files and continue with recording from the moment it was created.



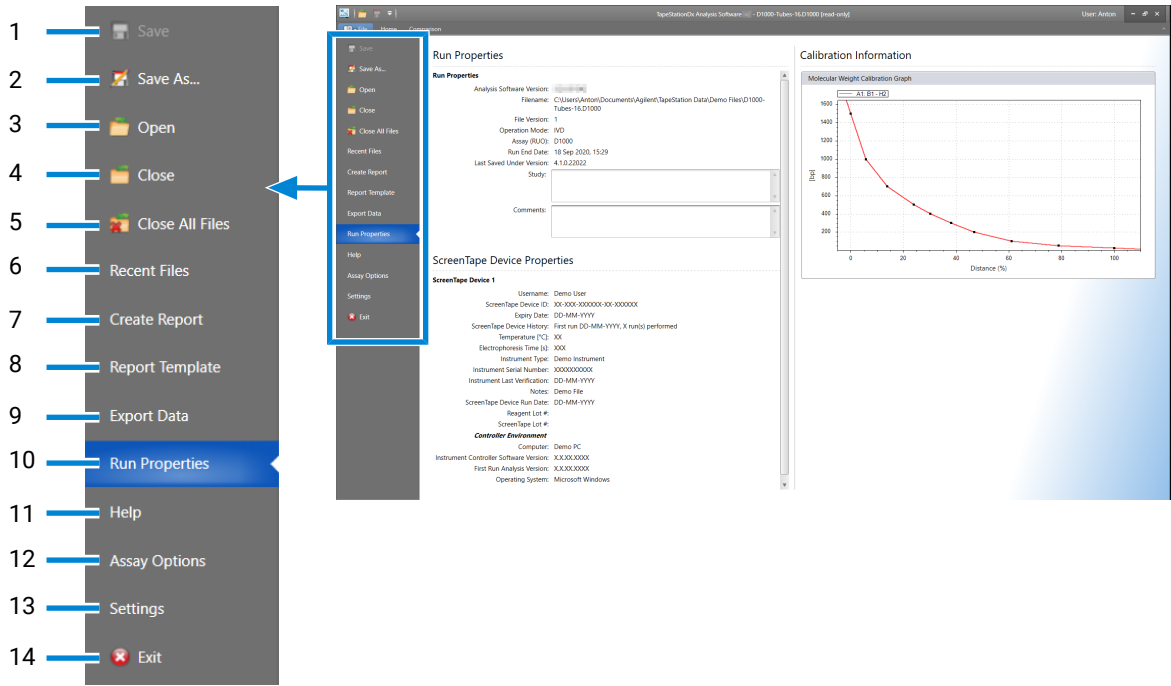
Groups Ribbon

Table 17: EPG and Comparison File groups

Icon	Name	Description
	EPG Snapshot	Takes a snapshot of the selected electropherogram (EPG). There are two ways of taking an EPG snapshot: • EPG Snapshot to Clipboard - takes a snapshot of the EPG and copies it to the clipboard. • EPG Snapshot to Disk - takes a snapshot of the EPG and saves it to disk. A window will open to select the location on the disk.
	Reset Zoom	Resets zoom to default EPG view.
	Remove All Lanes	Removes all lanes from the comparison file to start a new comparison.
	Save Comparison File	Allows to save the comparison to a file and choose its output location.

File Screen

The **File** screen provides access to core file management among other general functions within the TapeStationDx Analysis software.

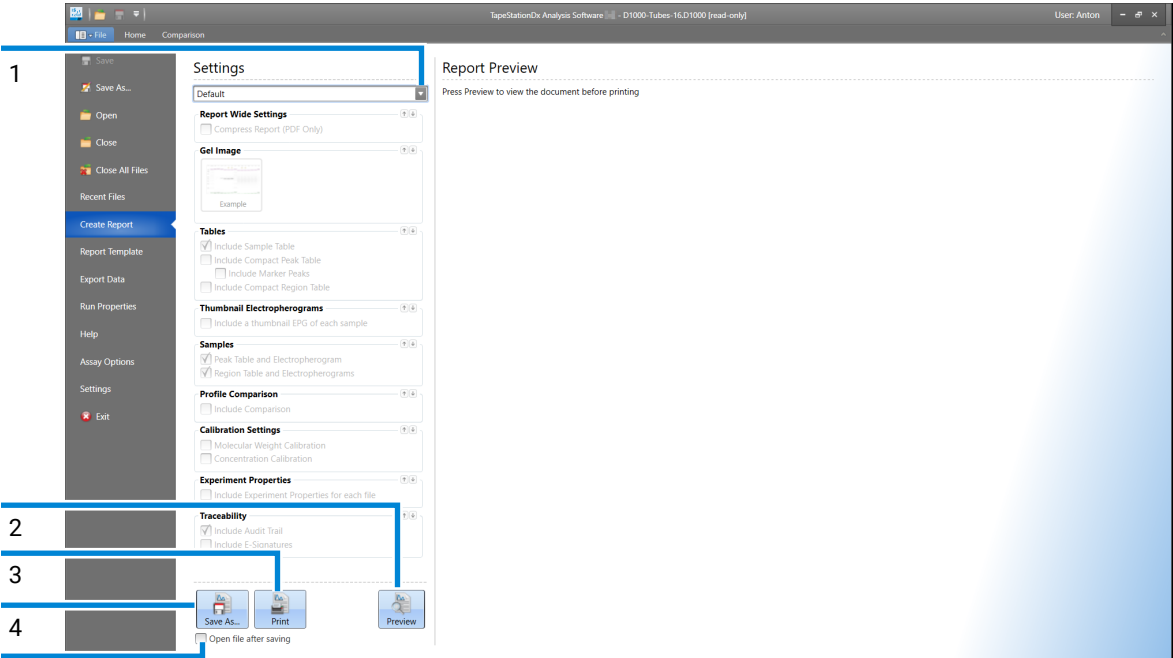


No.	Name	Description
1	Save	Saves the currently active file.
2	Save As...	Enables saving the active file under a new name or prefix.
3	Open	Loads a file into the TapeStationDx Analysis software.
4	Close	Closes the active file. If any changes have been made, a confirmation dialog appears prompting the user to save before closing.
5	Close All Files	Closes all files. If any changes have been made, a confirmation dialog appears prompting the user to save before closing.
6	Recent Files	Displays a list of recently opened files and accessed directories. Clicking on a recent file opens it in the Home tab. Clicking on a recent directory opens the Windows File Explorer, allowing a data file from that folder to be selected and loaded to the Home screen.
7	Create Report	Generates a report by selecting a report template and choosing to save, print, or preview the output.

No.	Name	Description
8	Report Template	Opens the interface for creating, editing, or deleting report templates.
9	Export Data	Enables export of data using distinct export types.
10	Run Properties	Displays properties for the run, ScreenTape devices (RUO), Controller environment, and calibration data. Supports entry of study notes and comments.
11	Help	Provides access to support resources and built-in utilities. Displays software version and related information.
12	Assay Options	Opens the Assay Options window, where region and assay-specific parameters can be configured.
13	Settings	Opens configuration options for customizing the electropherogram display, including trace color and background appearance. Changes apply globally across the software application.
14	Exit	Closes the TapeStationDx Analysis software application. If any changes have been made, a confirmation dialog appears prompting the user to save before exiting.

Create Report Screen

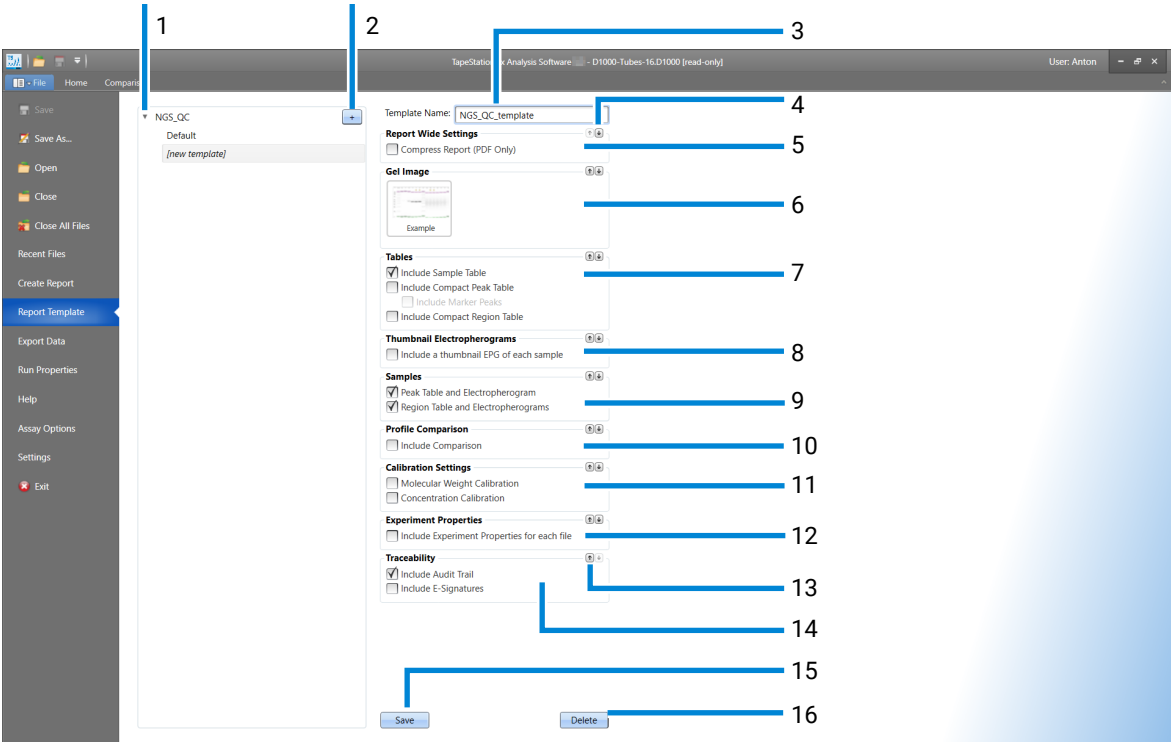
The **Create Report** dialog allows users to create reports using predefined templates. Users can select a template, save, print, and preview the report.



No.	Name	Description
1	Template selection	Selects the desired report template that will be used to create the report.
2	Preview	Displays the report on the Report Preview section on the right.
3	Print	Prints the report.
4	Save As...	Saves the report.
5	Open file after saving	When selected, this will automatically open the report in the default application.

Report Template Screen

The **Report Template** dialog allows users to manage and customize report templates for projects. Users can add new templates, configure various sections, and save or delete templates.

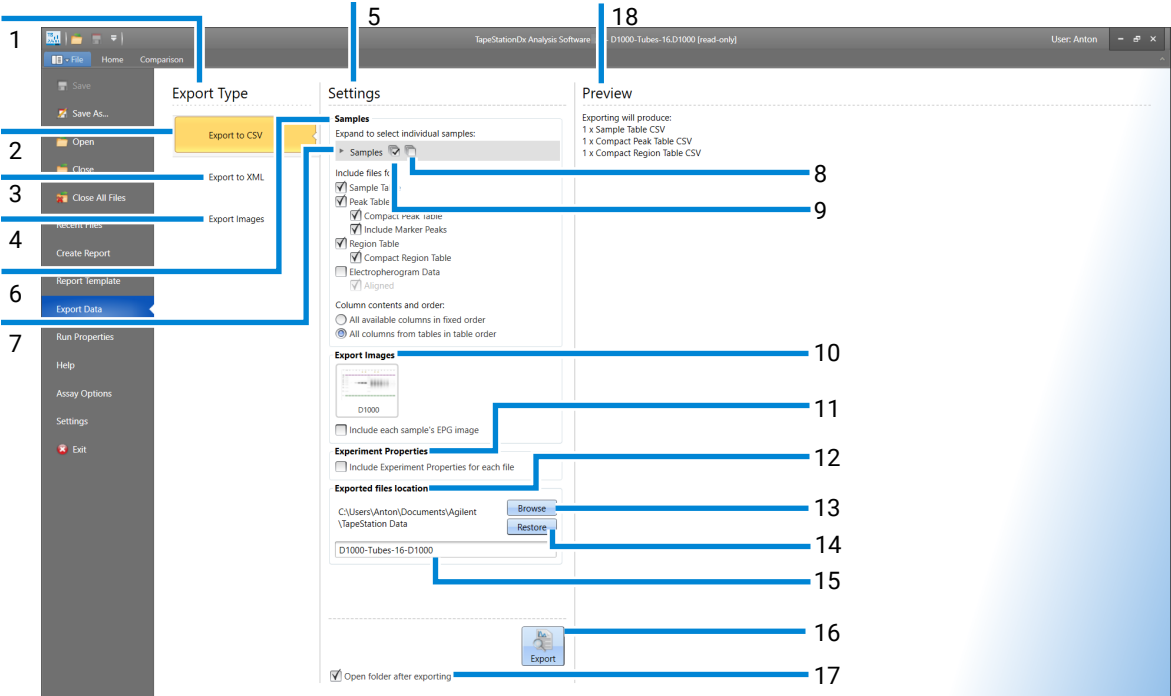


No.	Name	Description
1	Expand button	Shows/hides available report templates for a project.
2	Add button	Adds a new report template.
3	Template Name	Allows the user to enter the report template name.
4	Step down button	Changes the order of the field to one step below.
5	Report Wide Settings	Enables saving the report template in a compressed PDF file format.
6	Gel Image	Defines the Gel Image section in the report template.

No.	Name	Description
7	Tables	Defines the Tables section in the report template. Select/deselect each checkbox: • Include Sample Table • Include Compact Peak Table • Include Marker Peaks • Include Compact Region Table
8	Thumbnail Electropherograms	Enables inclusion of a thumbnail EPG of each sample by selecting the checkbox.
9	Samples	Enables inclusion of information about the samples by selecting the checkboxes: • Peak Table and Electropherogram • Region Table and Electropherogram
10	Profile Comparison	Enables inclusion of a comparison electropherogram (EPG) in the report, if one is associated with the active data file. Activate by selecting the corresponding checkbox.
11	Calibration Settings	Enables display of calibration settings in the report template by selecting the check boxes: • Molecular Weight Calibration. • Concentration Calibration.
12	Experiment Properties	Enables inclusion of experiment properties in the report. Activate by selecting the corresponding checkbox. This includes the properties listed in Run Properties tab.
13	Step up button	Changes the order of the field to one step up.
14	Traceability	Enables inclusion of audit trail and e-signatures. Activate by selecting the corresponding checkbox.
15	Save	Saves report template. Once saved, the new report template name will be displayed under the respective project, and it will be available for use in Create Report dialog.
16	Delete	Deletes the report template.

Export Data Screen

The **Export Data** screen is organized into three sections: **Export Type**, **Settings**, and **Preview**. It allows users to export sample data in various formats, configure export parameters, and preview the data before exporting.

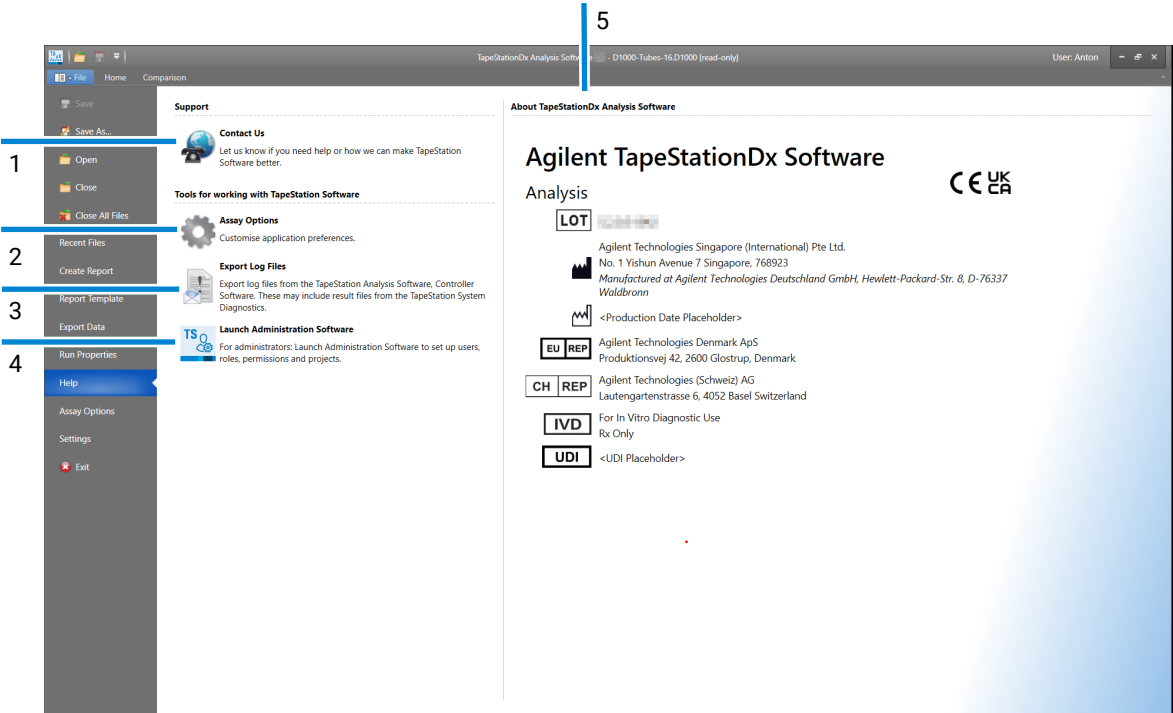


No.	Name	Description
1	Export Type	Displays export types.
2	Export to CSV	Enables export of sample data to files in .csv (comma-separated values) format.
3	Export to XML	Enables export of sample data to a file in .xml (extensible markup language) format.
4	Export Images	Enables export of individual EPG images in .png format for the selected samples.
5	Settings	Displays configurable export parameters. Available options vary depending on the selected export type.
6	Samples	Includes sample-specific export settings.
7	Expand/Collapse samples	Toggles the visibility of sample descriptions and selection.

No.	Name	Description
8		Deselects all samples for export.
9		Selects all samples for export.
10	Export Images	Enables inclusion of each sample's EPG image.
11	Experiment Properties	Enables inclusion of experiment-level metadata in the export.
12	Exported files location	Defines the output directory and file naming convention for exported data.
13	Browse	Opens a directory selection dialog to specify or create the export destination folder.
14	Restore	Resets the export path to the default location.
15	File name field	Allows manual entry or modification of the export file name.
16	Export	Executes the export process based on the current configuration.
17	Open folder after exporting	When enabled, automatically opens the export destination folder upon export completion.
18	Preview	Displays a summary of the data and files that will be included in the export, based on current settings.

Help Screen

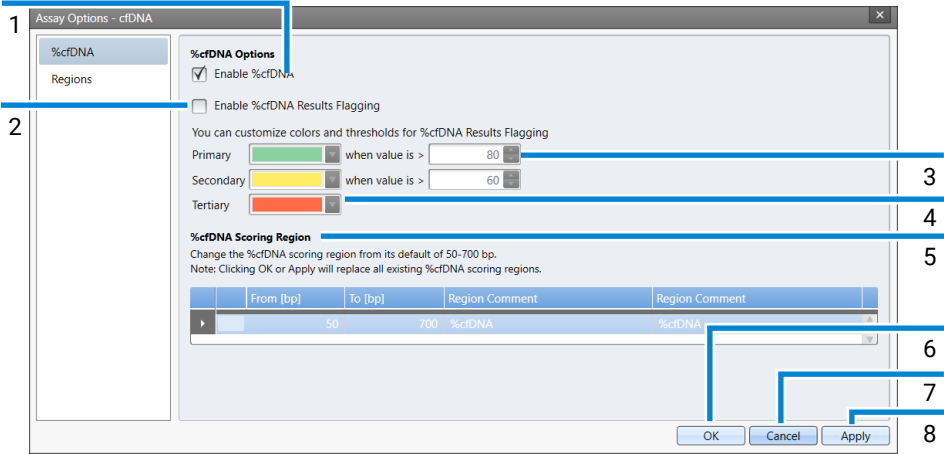
The **Help** tab provides various options to access support contact and collect troubleshooting information.



No.	Name	Description
1	Contact Us	Opens Agilent's Contact Us web page.
2	Assay Options	Opens the Assay Options window.
3	Export Log Files	Enables export of log files for further troubleshooting by Agilent remote support. Exported as a zipped folder.
4	Lauch Administration Software	Launches the TapeStationDx Administration software.
5	About TapeStationDx Analysis Software	Informs about TapeStationDx software version and regulatory labels.

Assay Options Window – Quality Metrics

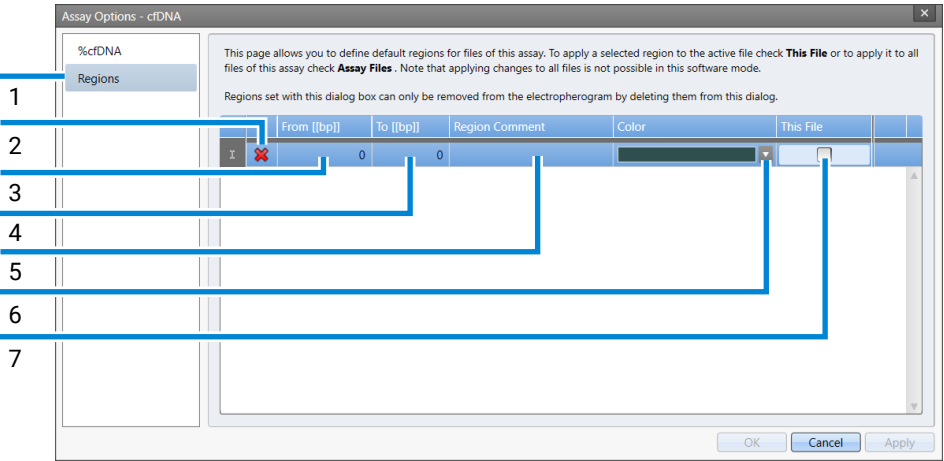
The **Assay Options** allow the user to configure quality metrics for the assay in the active file. The options include changing default quality score values and enabling flagging results.



No.	Name	Description
1	Enable %cfDNA	Enables assay-specific quality score. (%cfDNA for cfDNA assay; DIN for genomic DNA assays; RIN® for RNA assays)
2	Enable %cfDNA Results Flagging	Displays assay-specific quality score flags for each sample.
3	Value	Enables entry of a new value or adjustment of the current value by clicking the arrow buttons.
4	Flag color menu	Opens the color menu to change color of flag.
5	%cfDNA Scoring Region	Enables modification of the default region used for obtaining %cfDNA score (cfDNA assay specific).
6	OK	Applies changes and closes Assay Options window.
7	Cancel	Cancels changes.
8	Apply	Applies changes.

Assay Options Window – Regions

The **Regions** tab in the Assay Options window allows the user to apply regions for all samples of the active file. To add a new row that will define a region, click [Click here to add a new row](#).



No.	Name	Description
1	Regions	Displays assay region options.
2		Deletes row.
3	From [[bp]]	Enables setting the lower limit of the region.
4	To [[bp]]	Enables setting the upper limit of the region.
5	Region Comment	Enables entry of a comment.
6	Color	Enables selection of a color for the region.
7	This File	Applies the region to all samples in the active file.

When a region is defined using the Assay Options window, it must also be removed through that same interface. Deleting the region by right-clicking on the region in the electropherogram and selecting **Delete Region** is not supported in this context.

4 ScreenTape Assay (RUO) Overview



Figure 8: ScreenTape devices (RUO) for DNA and RNA assays

For the Agilent 4200 TapeStationDx system, a diverse portfolio of ScreenTape assays (RUO) is available. Details are shown in [Table 18 ScreenTape Assay \(RUO\) portfolio](#) on page 80. The credit card-sized, disposable ScreenTape

device (RUO) carries multiple separation lanes for analyzing DNA and RNA samples. Each ScreenTape device (RUO) has 16 lanes so that each sample is analyzed in an individual lane, eliminating contamination and carryover.

Storage conditions and other specifications, such as sensitivity, accuracy and quantitative range for ScreenTape assays (RUO) and the corresponding reagents can be found in the respective Quick Guide.

NOTE

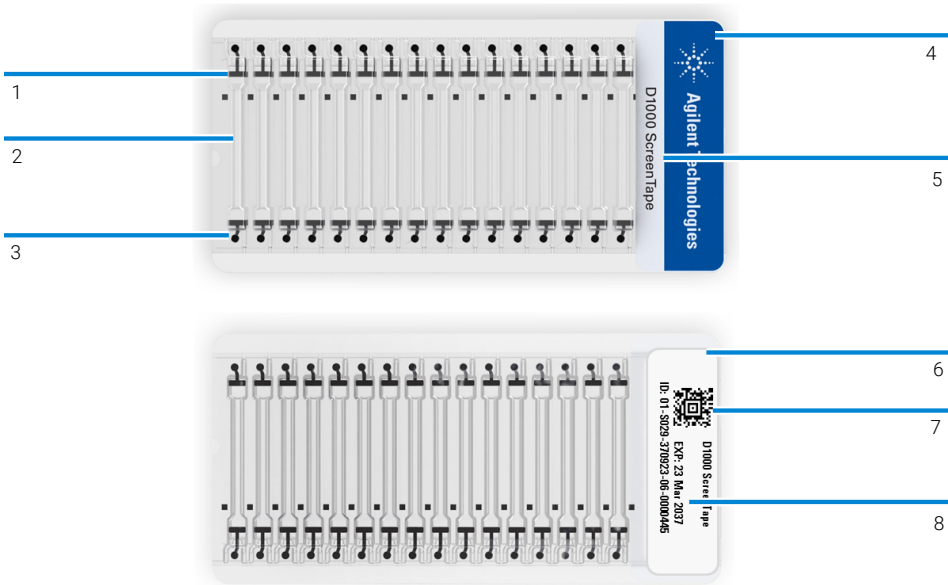
Expired ScreenTape devices (RUO) will block run initiation.

ScreenTape devices (RUO) expire on the labeled date or 14 days after the initial barcode scan, whichever occurs first.

Table 18: ScreenTape Assay (RUO) portfolio

ScreenTape Assay (RUO)	Temperature Range	Quick Guide (p/n)
D1000 ScreenTape	12 – 37 °C (54 – 99 °F)	G2991-90031
High Sensitivity D1000 ScreenTape	17 – 37 °C (63 – 99 °F)	G2991-90131
Genomic DNA ScreenTape	15 – 30 °C (59 – 86 °F)	G2991-90041
High Sensitivity Genomic DNA ScreenTape	16 – 37 °C (59 – 99 °F)	G2991-90140
RNA ScreenTape	14 – 30 °C (57 – 86 °F)	G2991-90021
High Sensitivity RNA ScreenTape	14 – 30 °C (57 – 86 °F)	G2991-90121
D5000 ScreenTape	15 – 30 °C (59 – 86 °F)	G2991-90051
High Sensitivity D5000 ScreenTape	15 – 30 °C (59 – 86 °F)	G2991-90151
Cell-free DNA ScreenTape	16 – 30 °C (61 – 86 °F)	G2991-90060

ScreenTape Architecture



No.	Name	Description
1	Buffer chamber	The buffer chamber is located at the top of each channel and contains optimized buffers for the effective separation of nucleic acid fragments.
2	Gel chamber	The gel contained within the ScreenTape device (RUO) has been developed specifically to resolve nucleic acids.
3	Electrodes	The integrated electrodes apply a current across the ScreenTape device (RUO) and eliminate the need for any additional electrophoresis equipment.
4	Front	Front part of the ScreenTape device (RUO).
5	ScreenTape name	ScreenTape assay (RUO) name.
6	Back	Back part of the ScreenTape device (RUO).

ScreenTape Assay (RUO) Overview
ScreenTape Architecture

No.	Name	Description
7	Barcode	The unique barcode allows tracking of lane usage within each ScreenTape device (RUO) and provides traceability of results. Information is stored locally on the bundled laptop.
8	ScreenTape details	The information is unique to each ScreenTape device (RUO). This includes: ScreenTape assay type (RUO), product expiry date and a unique serial number.

5

Getting Started

Authentication and System Administrator Setup

The first step when setting up the TapeStationDx software is to configure the authentication mode during the creation of the first user account via the TapeStationDx Administration software. This user will be assigned the role of System Administrator.

- 1 Launch the TapeStationDx Administration software.
When opened for the first time, a setup window will appear automatically, prompting the user to create a System Administrator account.
- 2 Select the authentication method.
Choose one of the following authentication modes:
 - Local Windows accounts
 - Active Directory accounts

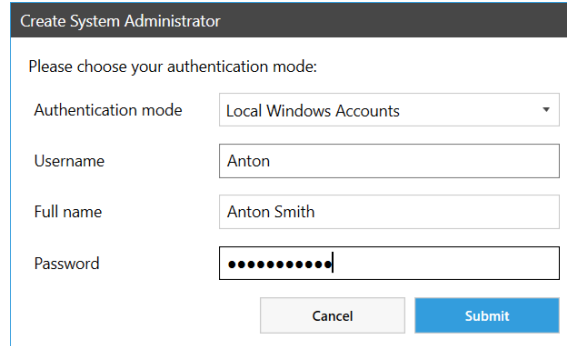
NOTE

Only one authentication mode is possible. A combination of two authentication modes is not supported.

- 3 Enter user details.
Fill in the required fields based on the selected authentication method:
 - Username – according to the authentication mode
 - Full Name – e.g., first and last name
 - Password – as required by the authentication mode

- 4 Click **Submit**.

The System Administrator account will be created and the authentication mode locked in. The authentication mode selected herein will be applied to all subsequent users.



Create System Administrator

Please choose your authentication mode:

Authentication mode: Local Windows Accounts

Username: Anton

Full name: Anton Smith

Password:

Cancel Submit

NOTE

The chosen authentication mode is hard to reverse. This selection should be made carefully before proceeding. Refer to [How to Change the Authentication Mode](#) on page 204.

CAUTION**Loss of data**

TapeStationDx software uses existing Windows credentials — either from a local Windows account or an Active Directory account. If the Windows password is changed, the updated password will automatically apply to the TapeStationDx software as well. Passwords cannot be changed or recovered by Agilent.

- Do not remove all System Administrators from the laptop or from the Windows Active Directory.

NOTE

A Windows administrator account is required to create users locally on the laptop or on the Windows Active Directory.

Creating Users and Roles

Users are individuals with valid login credentials, based on either Windows local accounts or Active Directory, depending on the selected authentication mode. Upon initial use, several functions within the TapeStationDx Controller and Analysis software are access-restricted. Access to these functions is managed through role-based permissions.

The TapeStationDx software defines two types of roles:

- System Roles ([Table 19 Permissions for different System Roles](#) on page 85): assign permissions that apply across the entire system.
- Project Roles ([Table 20 Permissions for different Project Roles](#) on page 86): assign permissions that are specific to projects.

A user may be assigned one or more roles, depending on their responsibilities and required access level.

NOTE

Permissions assigned to default roles can be customized. However, throughout this guide, references to default role names assume their standard permission settings as outlined in [Table 19 Permissions for different System Roles](#) on page 85 and [Table 20 Permissions for different Project Roles](#) on page 86.

Table 19: Permissions for different System Roles

		System Administrator	Project Creator	System Validator	Agilent Service Role
System Administration	Create administrative reports	x			
	Create project	x	x		
	Edit EPG view settings	x			
	Edit instrument name	x			
	Manage projects	x			
	Manage roles	x			
	Manage global settings	x			
	Manage users	x			
	Read all users	x	x		

		System Administrator	Project Creator	System Validator	Agilent Service Role
Instrument Maintenance	Maintenance functionality			x	x
	Review maintenance and test reports	x		x	x
	Run system verification tests	x		x	x

Table 20: Permissions for different Project Roles

		Technician	Analyst	Project Administrator	Reviewer
Instrument	Start a run	x			
	Abort or stop a run	x			
	Edit reagent lot	x			
	Edit sample descriptions	x			
	Edit run notes	x			
	Edit project specific controller settings	x		x	
	Edit filename prefix	x			
	Edit file output settings	x			
	Edit ScreenTape lot	x			
Project Administration	Edit project			x	
	View project	x		x	x
Data access	Unlock file			x	
	Lock file		x		x
	Review audit trail			x	x
General analysis	Revoke E-sign	x	x		x
	Edit sample name in analysis software	x			
	Import file			x	
	Load file	x	x	x	x
	Modify ladder		x		
	Edit marker alignment		x		
	Revert all file changes		x		
	Edit study and comments in analysis software		x		

	Technician	Analyst	Project Administrator	Reviewer
Edit RIN® options		x		
Edit DIN options		x		
Edit %cfDNA options		x		
Create, update, and delete peaks		x		
Select wells for analysis		x		x
Change display and gel settings		x		x
Change sample approval status		x		x
Change RNA type		x		
Add, delete, edit region		x		
Save file	x	x	x	x
Reporting / Exporting	Create, edit, save and delete report templates		x	
	Snapshot EPG			x
	Snapshot gel			x
	Create report			x
	Export data		x	
	Create report			x
	Export data		x	

NOTE

Ensure no other user is logged in while creating or modifying users or roles.

Add a User

- 1 Log in to the TapeStationDx Administration software.
To manage users, a System Administrator must log in to the TapeStationDx Administration software.
- 2 In the left sidebar, select **Users**.
This will display the **Users** dialog.
- 3 In the **Users** dialog, select **Add User**.

- 4 Search for the user by full name or username.

NOTE:

If the authentication mode is set to local Windows accounts, ensure the local Windows account is created on the PC. The username will appear in the software.

If the authentication mode is set to Windows Active Directory accounts, the username or full name must match the credentials in Active Directory.

- 5 Fill the mandatory fields, marked with an asterisk (*):

- Full Name
- Username

What is filled herein will be used across the TapeStationDx software and included in exported audit trails.

- 6 Optional:

- Assign System Roles to the new user.
- Assign Project Roles to the new user. If no project has been created yet, users can be assigned to project roles during project setup.

- 7 Click **Add** to complete the process.

The new user will be listed in the **Users** dialog. Selecting a user will display their username, full name, and assigned roles.

In the **Users** dialog, a leading exclamation mark with a user will appear when

- A user is locked out for too many failed logon attempts.
- The user is not yet assigned to a project.

System Administrators can add, deactivate, unlock, and edit users.

Full Name and role assignments of a user can be changed by a System Administrator at any time via **Edit User** in the **Users** dialog.

To deactivate a user, a System Administrator must select the user listed in the Users dialog and click **Deactivate** to proceed with the process. There is no need to remove the local Windows or Active Directory account to remove a user within the TapeStationDx software. The **Show Deactivated Users** function displays a dialog for reviewing deactivated users and reactivating them.

Creating a Project

All analytical runs must occur within a project. A project consists of a container that holds the requirements, information, and settings needed to carry out a workflow using the TapeStationDx system.

System Administrators can add, edit, or archive projects.

Add a Project

- 1 Log in to the TapeStationDx Administration software.

To create a project, a System Administrator or Project Creator must log in to the TapeStationDx Administration software.

- 2 In the left sidebar, select **Projects**.

This will display the **Projects** dialog

- 3 In the **Projects** dialog, select **Add Project**.

- 4 Fill the mandatory fields, marked with an asterisk (*):

- Name

This will be the project's identifier in the TapeStationDx Controller and Analysis software. Short identifiers are recommended.

- Output Directory

Choose a dedicated local data folder, accessible by the TapeStationDx software, wherein all measurements done under this project will be stored.

- 5 Optional:

- Enter the project's description.
- Assign existing users to project roles.

- 6 Click **Add** to complete the process.

The new project will be listed in the **Projects** dialog. Selecting the existing project will display the project's properties, including output directory, description, assigned roles and respective users, as well as Electronic Signature Workflow.

Both System Administrator and Project Administrator can manage existing projects and related settings.

CAUTION**Data Integrity**

The TapeStationDx software does not provide a content management system. Unauthorized modifications could lead to loss of data.

- It is the user's organization's responsibility to set up and control a compliant data management system.

NOTE

Ensure other users log off while setting up or modifying a project.

NOTE

When the TapeStationDx software is uninstalled, databases with existing users, roles and projects are not deleted. A transfer of this data from/to other TapeStationDx software installations is not possible. A reinstallation on the same laptop re-establishes the previous setup.

Configuring an Electronic Signature Workflow

An electronic signature is a digital version of handwritten signature used to authenticate or approve contents, actions, and other activities in the software. Adding an Electronic Signature Workflow to a project enables a predefined sequence of steps that users must follow when working with a data file in the TapeStationDx Analysis software. This workflow is optional and can be configured in the TapeStationDx Administration software.

- 1 Log in to the TapeStationDx Administration software.

To create a Signature Workflow, a System Administrator or Project Administrator must log in to the TapeStationDx Administration software.

- 2 In the left side bar, select **Projects**.

- 3 In the **Projects** dialog, select the desired project and click **Edit Signature Workflow**.

A new window will appear, prompting the user to create a signature workflow. This window contains a table that will list each signature with a corresponding step, role, and Meaning.

- 4 Click **Add New Step**.

Select the role that requires an electronic signature and choose the Meaning of the signature. The Meaning of the signature is recorded to the audit trail when the respective user executes the required step in the TapeStationDx Analysis software. It can be set to a certain predefined text or to 'Any'. To customize texts under the 'Any' list (see [Global Settings Screen](#) on page 41). Repeat this step to add multiple signature steps to the workflow.

5 Optional: Select a particular step to lock data file.

Select step number in **Lock File after signing at step**. This will automatically lock the data once the selected signature step takes place in the TapeStationDx Analysis software, preventing anyone from further editing the file.

6 Click **Confirm** to complete the process.

The table will now be visible under E-Signature Workflow when selecting the project in the Projects dialog.

An example workflow with four users is demonstrated in [Workflow Example](#) on page 122.

Archiving / De-Archiving a Project

Archiving and de-archiving projects are also done via the TapeStationDx Administration software.

To archive a project:

- 1 Go to **Projects** and select the project to be archived.
- 2 Click the **Archive** button.

To de-archive a project:

- 1 Go to **Projects** and click on **Show archived projects**.
- 2 Select the archived project and click the **De-archive** button.
- 3 Finally, click on **Show archived projects** again to return to the active **Projects** dialog.

Connecting the Instrument

WARNING

Inaccessible power plug.

In case of emergency it must be possible to disconnect the instrument from the power line at any time.

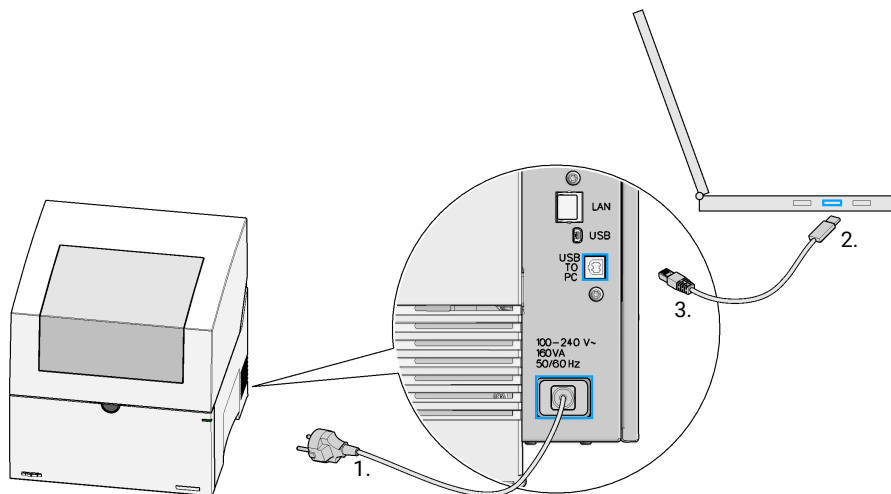
- Make sure the power connector of the instrument can be easily reached and unplugged.
 - Provide sufficient space behind the power socket of the instrument to unplug the cable.
-

Getting Started

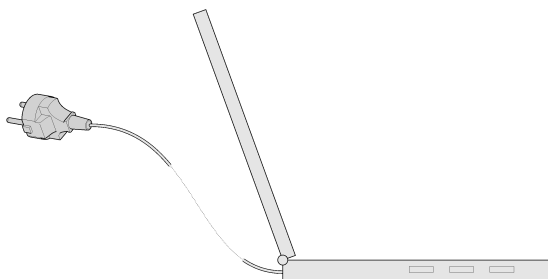
Connecting the Instrument

1 Connect the instrument in the following order:

1. Power plug to power socket,
2. USB-A to laptop,
3. USB-B to TapeStationDx instrument.



2 Connect laptop to power according to its accompanying documentation.



NOTE

Refer to [Performing a Run](#) on page 103 for the required order when turning the instrument on.

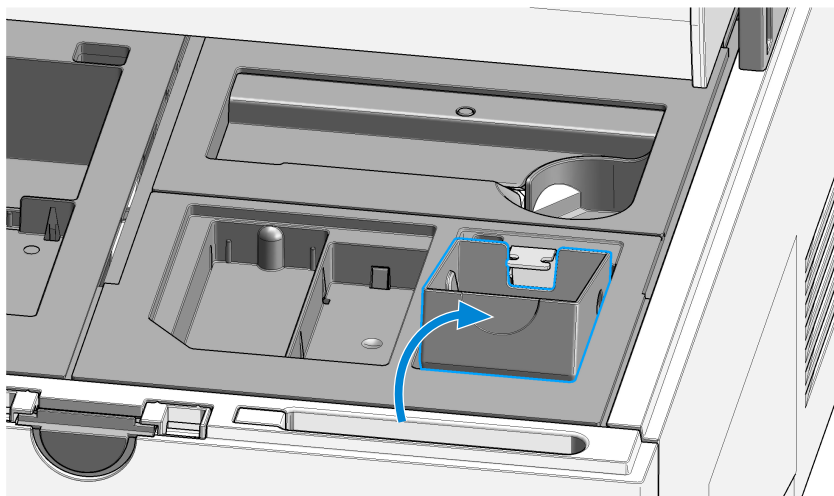
Preparing the Working Area

The steps below outline how to prepare the instrument working area with material provided. A shipment list of this material can be found in **Materials Provided** on page 12.

- 1 Install the tip waste bucket.

NOTE

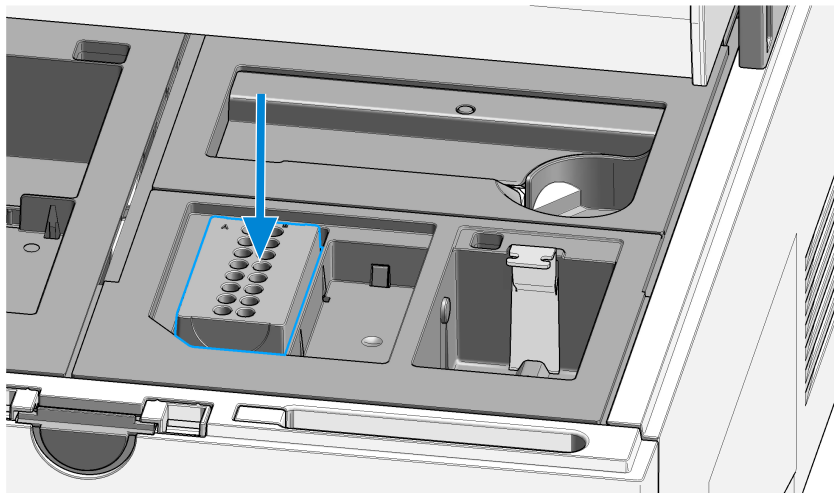
The sample tube holder and ScreenTape rack have recesses for orientation and only fit in one way. The tip rack is symmetrical and can be placed either way.



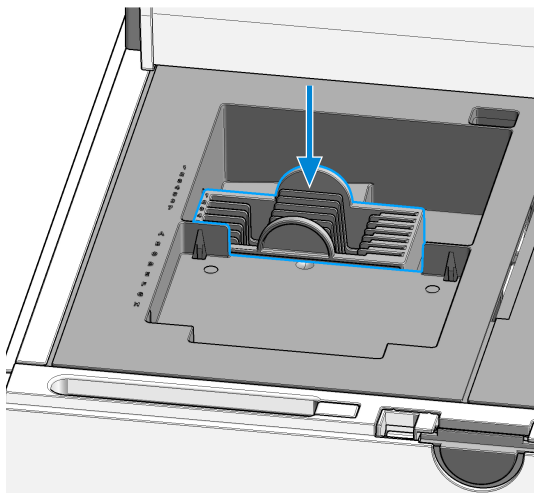
Getting Started

Preparing the Working Area

- 2 Install the sample tube strip holder.



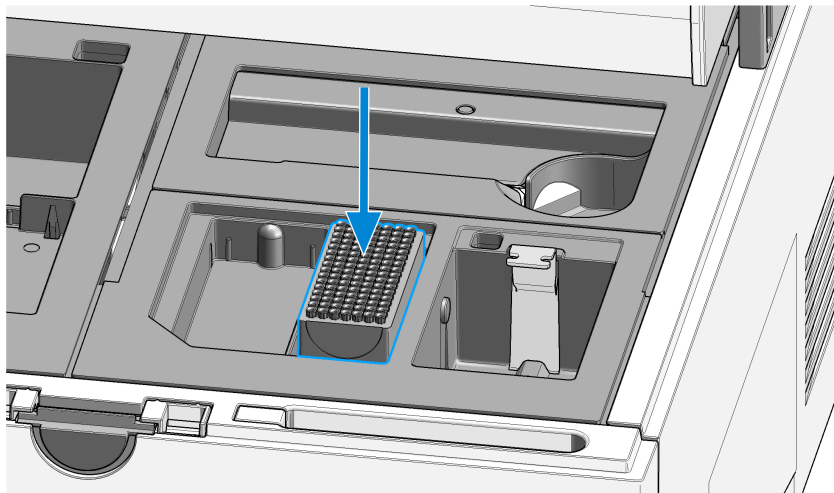
- 3 Install the ScreenTape rack.



Getting Started

Preparing the Working Area

- 4 Install the tip rack and remove the lid. Ensure sufficient tips are present.



- 5 Keep the working area clean and tidy. Refer to [Cleaning the System Components](#) on page 159 for cleaning recommendations.

CAUTION

Failures and errors during the run

Any spare material left in the instrument will cause failures and errors during the run. The instrument might get damaged by this.

- Ensure the working area is cleared before starting the run.

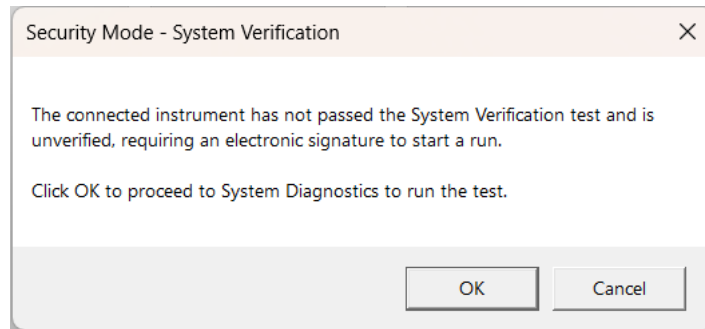
Instrument Verification

Before starting the first run in the TapeStationDx Controller software, the System Verification test suite must be successfully executed. The TapeStationDx Controller software will display a “No verification” message next to the instrument’s serial number, and request for System Verification.

- 1 Log in to the TapeStationDx Controller software.

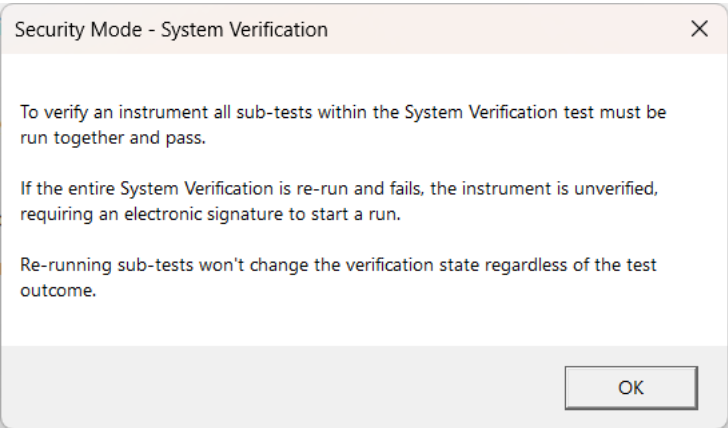
The System Verification test suite can be executed by a System Administrator, a System Validator, or an Agilent Service Role.

A message will automatically appear, prompting the user to proceed to System Diagnostics.



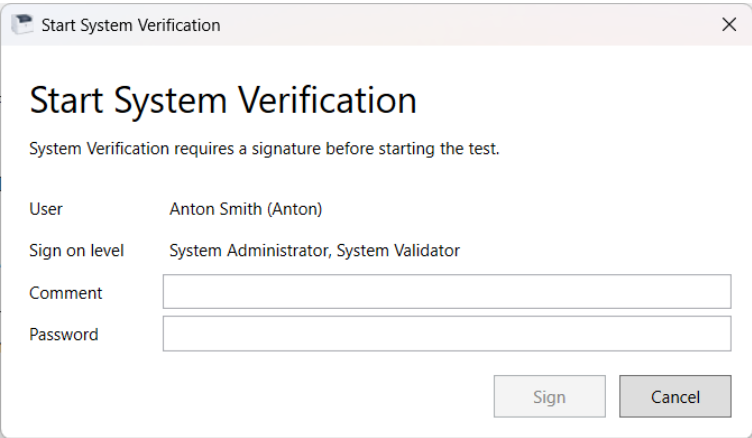
- 2 Click OK to acknowledge verification criteria.

When the System Verification test suite window from System Diagnostics opens automatically, all required tests will be pre-selected. Simultaneously, a dialog box will appear, outlining the verification requirements and conditions. The user must click **OK** to acknowledge and thereby consent before proceeding.



- 3 Click **Start** and provide electronic signature to begin System Verification.

After clicking **Start**, a prompt will appear requesting an electronic signature. To proceed, enter password and click **Sign** to authorize the initiation of the System Verification.



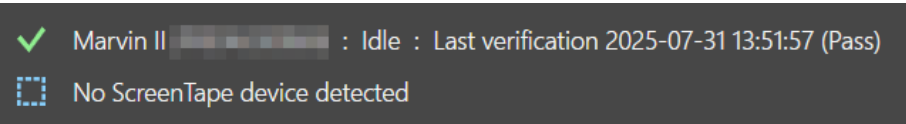
NOTE

To proceed with a System Verification, ensure that all other TapeStationDx software applications are closed.

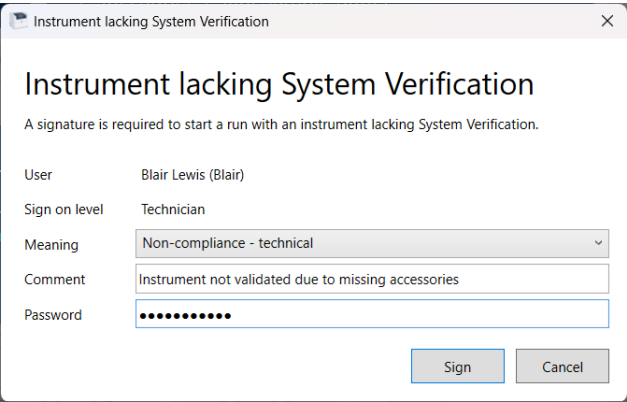
- 4 Follow the on-screen instructions during System Verification.

As the System Verification progresses, the software will guide the user through, prompting for any required actions or confirmations. Monitor the process and respond as instructed to ensure successful completion of all tests.

Importantly, all tests must pass to proceed with the first analytical run. The date of the last successful Verification will be displayed next to the instrument’s serial number.



It is not recommended to perform a run on non-verified instruments. If triggered, a dialog box will appear, requiring an electronic signature and Meaning for approval, which will be visible in the audit trail.



Later, the user may need or choose to run specific tests within the System Verification suite. Failing a subset of tests does not invalidate the instrument. For more details on how the results of different test suites affect the instrument’s status, please refer to [Table 21 Test results affecting instrument verification](#) on page 100.

Table 21: Test results affecting instrument verification

Test suite	Result affects Status	Availability
Software Installation Verification	No	User and Agilent Personnel
System Verification (all default tests selected)	Pass: verifies; Fail: invalidates	User and Agilent Personnel

Test suite	Result affects Status	Availability
System Verification (tests partially selected)	No	User and Agilent Personnel
Hardware Troubleshooting	No	User and Agilent Personnel
Qualification Tests (all default tests selected)	Pass: verifies; Fail: invalidates	Agilent Personnel only
Qualification Tests (tests partially selected)	Any Fail: invalidates	Agilent Personnel only
Field Service Engineer Tests	No	Agilent Personnel only



6

Operating the 4200 TapeStationDx System

Sample Preparation

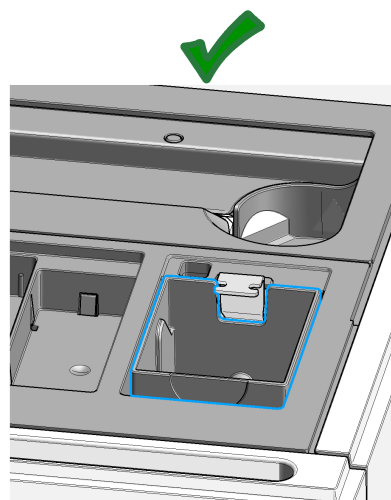
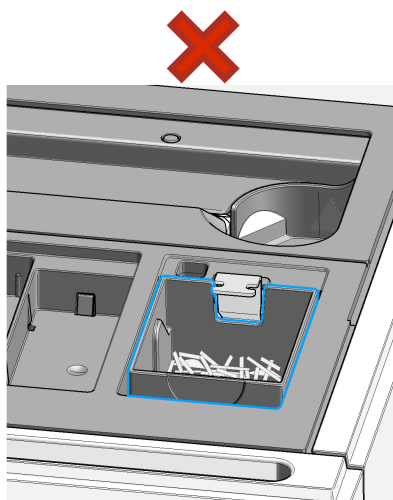
Prepare the samples according to the assay-specific Quick Guide see ScreenTape Assay (RUO) Overview. The Quick Guides for the ScreenTape devices (RUO) provide analytical and physical specifications such as sizing range, resolution, sensitivity, maximum sample buffer strength, quantitative range, analysis time, and the assay operating procedure.

Performing a Run

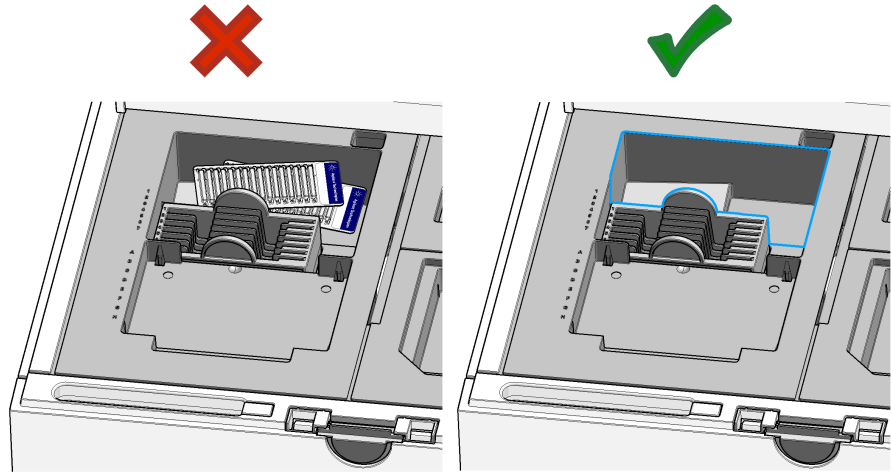
The TapeStationDx Controller software controls the instrument during the analytical run. It runs the desired assay based on the inserted ScreenTape barcode.

Prepare the Instrument for a Run

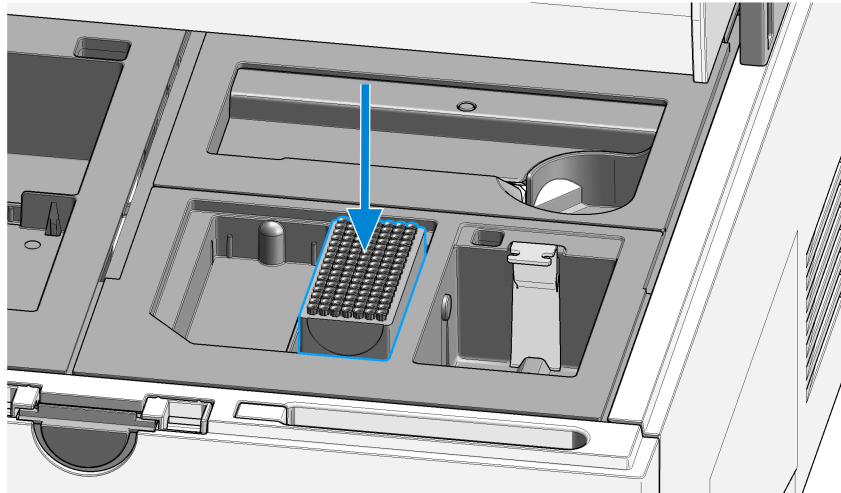
- 1 Power on the laptop, wait until it is booted.
- 2 Turn on the instrument by pressing the power button on the front of the instrument.
- 3 Allow the instrument to initialize.
- 4 Log in to the TapeStationDx Controller software.
- 5 Ensure that the connected instrument is verified.
- 6 Open the lid by pressing the lid release button.
- 7 Empty the tip waste.



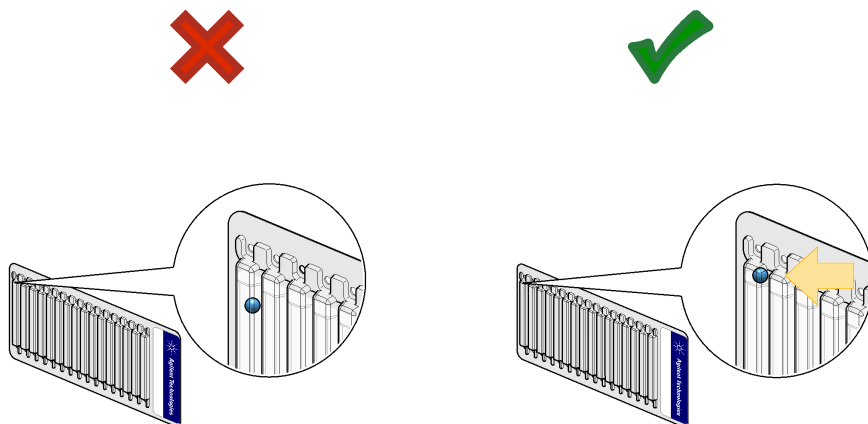
- 8 Discard the used up ScreenTape devices (RUO) present in the waste location.



- 9 Install the tip rack and remove the lid. Ensure sufficient tips are present.

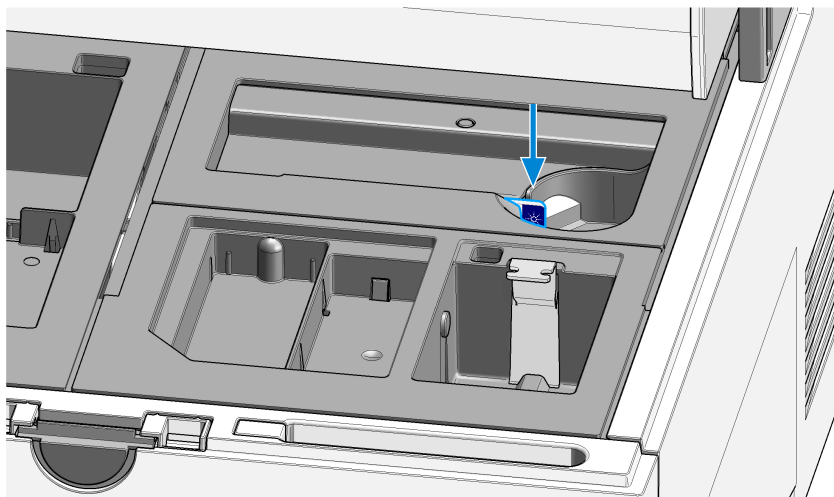


- 10 Flick the ScreenTape device (RUO). Trapped air bubbles will move up in the buffer chamber.

**NOTE**

The presence of small bubbles within the buffer chamber of the ScreenTape devices (RUO) is normal and acceptable. These bubbles often occur at the gel/buffer interface and need to be displaced prior to running. Failure to remove bubbles from the gel/buffer interface is detrimental to the performance of the ScreenTape assay (RUO).

- 11 Place the first ScreenTape device (RUO) into the ScreenTape nest. Make sure it is horizontal within the nest, fully inserted and that the label faces toward the front.



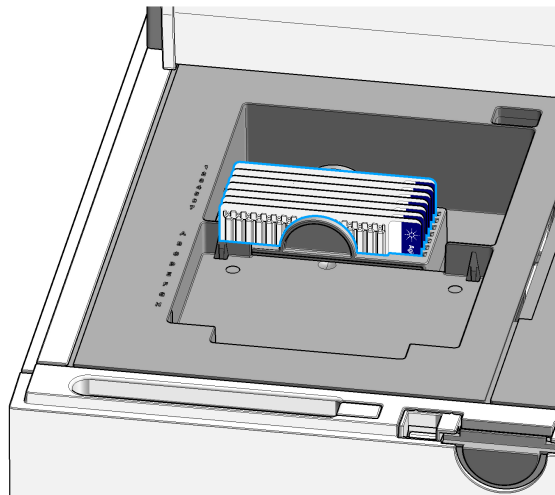
The TapeStationDx Controller software automatically detects the assay based on the ScreenTape barcode. Once recognized, the software interface will update to display the corresponding ScreenTape assay (RUO).

NOTE

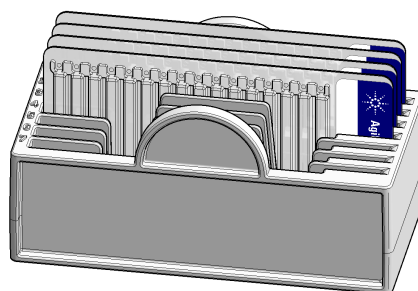
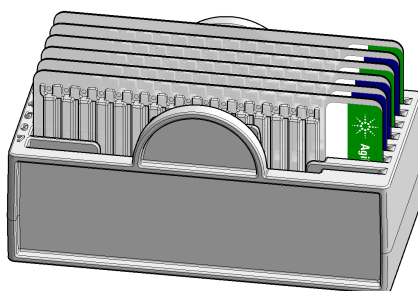
Expired ScreenTape devices (RUO) will block run initiation.

ScreenTape devices (RUO) expire on the labeled date or 14 days after the initial barcode scan, whichever occurs first.

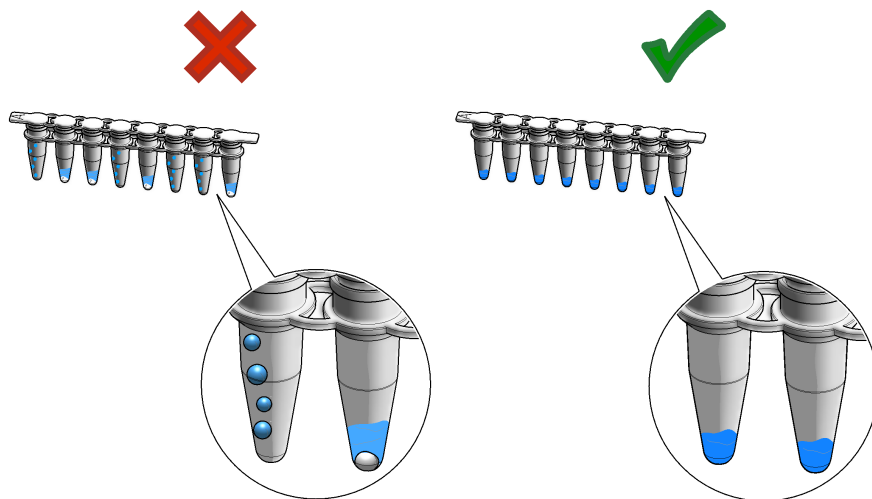
- 12 If additional ScreenTape devices (RUO) are required for the run, insert flicked unused ScreenTape devices (RUO) into the rack.



Ensure the additional ScreenTape devices (RUO) are from identical assays and not expired.



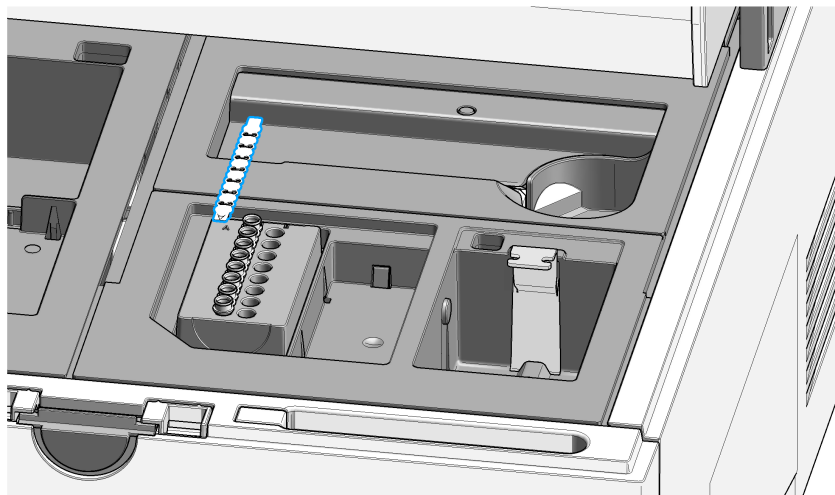
13 Centrifuge samples to remove spills and air bubbles.

**CAUTION**

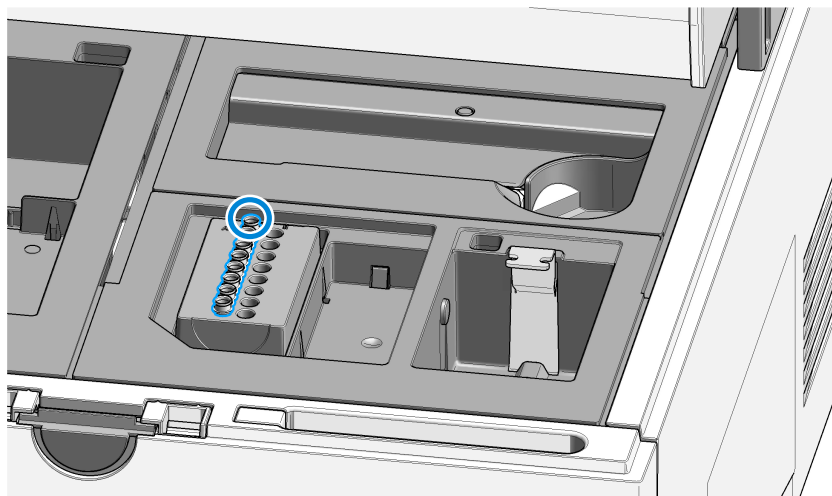
Blockage of the robotic system

- Remove the lid from the sample tube strips to prevent blockage of the robotics system during pipetting steps.

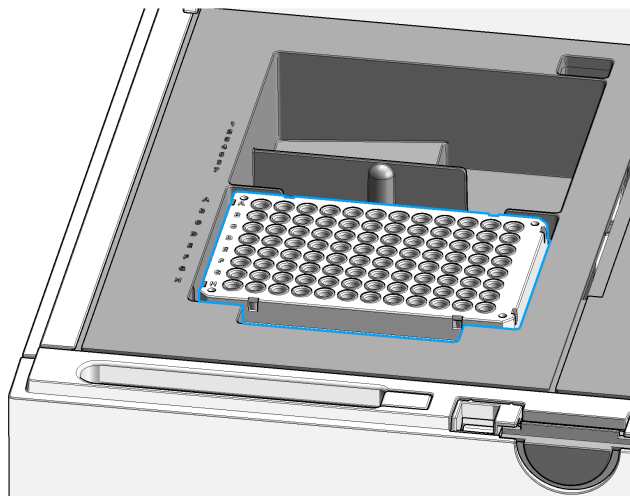
14 Insert sample tube strips. Remove the tube lids carefully ensuring not to create bubbles in the samples.



Ladder is exclusively provided from location A1 on the sample tube strip holder. For further details on handling the ladder within assays see the ScreenTape specific Quick Guides.



- 15 Alternatively, samples can be run from a sealed 96-well sample plate by inserting a sealed 96-well sample plate in correct orientation (The letters A to H are embossed for reference on the left-hand side of the recess for the 96-well sample plate). Vortex and centrifuge 96-well sample plates before insertion.

**NOTE**

Use 96-well plate foil seals to protect samples from evaporation during analysis. Use only Agilent approved 96-well plate foil seals and plates to avoid damaging the instrument or data loss.

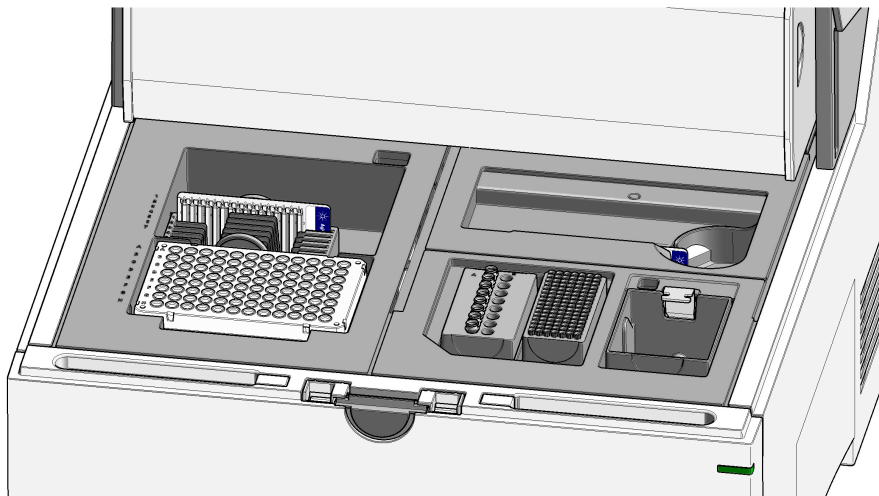
CAUTION

Failures and errors during the run

Any spare material left in the instrument will cause failures and errors during the run. The instrument might get damaged by this.

— Ensure the working area is cleared before starting the run.

16 Ensure the working area is clean and tidy.

**NOTE**

Keep in mind the robotics movements during analysis. Let material snap in place where appropriate. Do not leave lids, pipettes or packaging material in the working area.

17 Close the lid.

Execute an Analytical Run

1 Log in to the TapeStationDx Controller software.

To start a run, a Technician must log in to the TapeStationDx Controller software.

2 Ensure that the connected instrument is verified.

3 Select a project.

The data will be saved in the output directory defined for the selected project.

- 4 Select sample locations by clicking and dragging across either the tube strip or 96-well plate locations.

The 96-well plate and tube strip options (...) allow to select/clear all positions and to choose between a run or electronic ladder.

- 5 Optional:

- Enter sample descriptions in the sample table.
- Add notes, reagent and ScreenTape lot information and filename prefix in the information field.

- 6 Note required consumables:

- Ensure that sufficient ladder is present.
- Ensure that sufficient tips are present.
- Ensure that one ScreenTape device (RUO) is inserted in the ScreenTape nest.
- If applicable, ensure that enough ScreenTape devices (RUO) are present in the ScreenTape rack.

- 7 Click **Start** to initiate the analytical run.

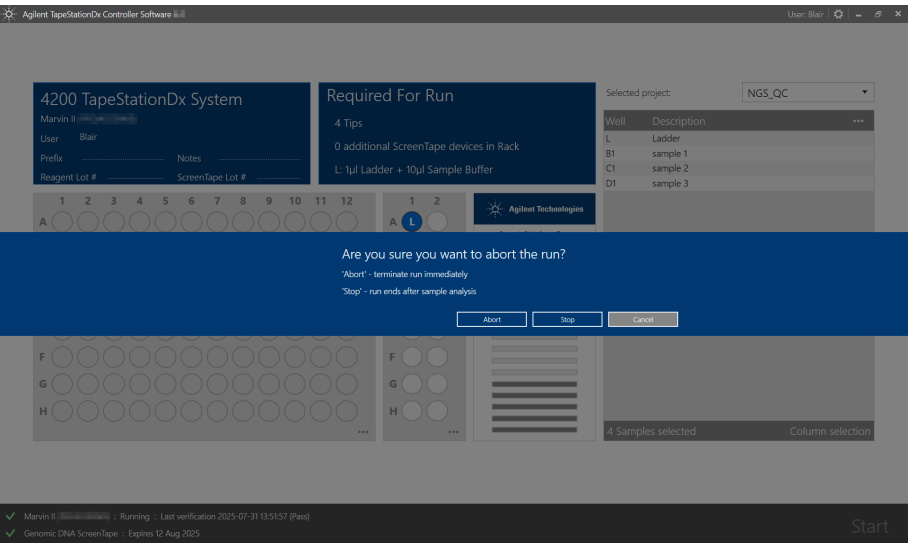
- 8 Confirm tip waste is empty. Confirm the tube strip lids are removed. Proceed.

Once the run is initiated, there is an initialization phase wherein the software checks for:

- the presence of consumables.
- properly inserted nest covers and correct movement of the lower nest cover.

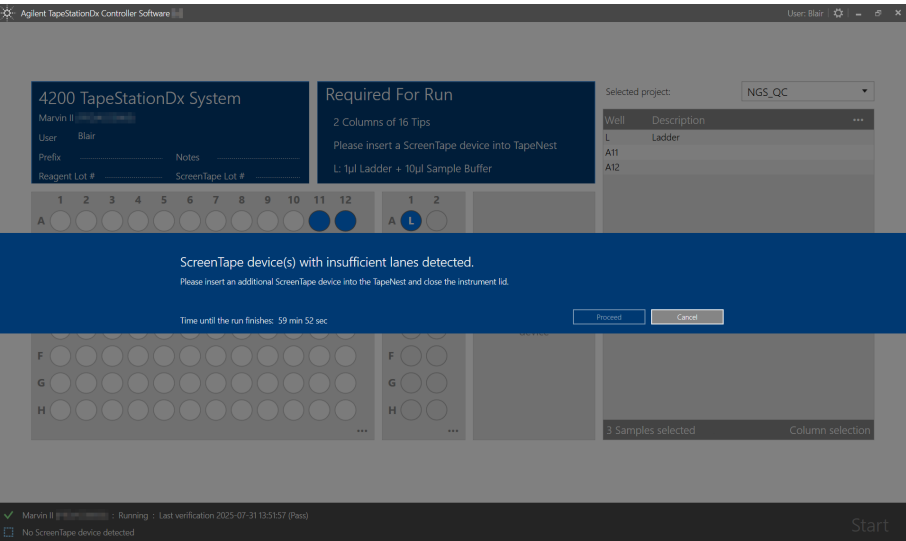
After initialization, sample analysis takes place. The remaining run time is displayed.

Clicking **Abort**: the analysis aborts either immediately or stops after the current ScreenTape device (RUO) is processed. The lid button will blink while this dialog is displayed:



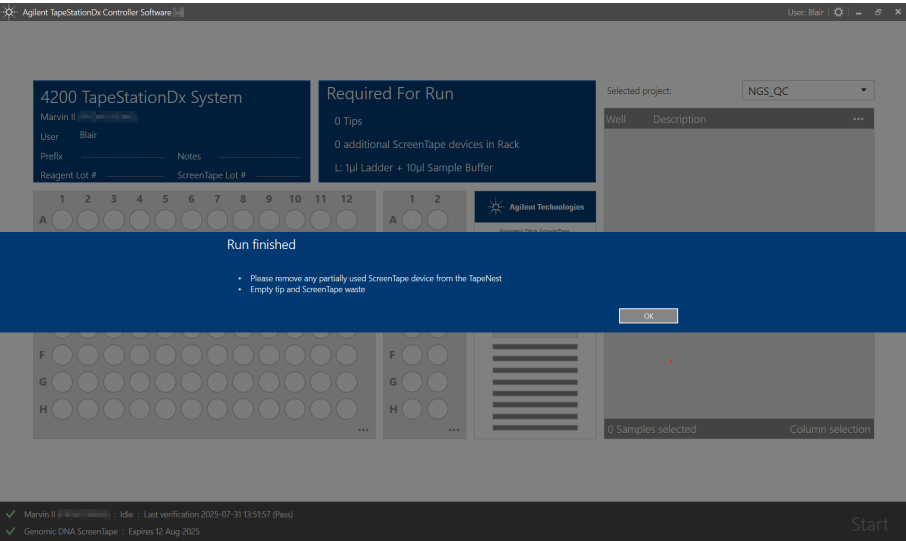
In case the button to open the lid of the instrument is pressed during the run, the same dialog will be prompted.

In case there are insufficient available lanes on a ScreenTape device (RUO) during a run, add another ScreenTape device (RUO) with unused lanes within given time to finalize the analysis.



Once the entire analysis is complete, the instrument is reset and the lid unlocked.

After acquisition of data from a first ScreenTape device (RUO) or when all samples are run, the TapeStationDx Analysis Software starts automatically and asks the user to log in. The TapeStationDx Controller software is kept active; therefore, its graphical interface may remain in the background. Please notice any remaining dialogue.



When the run is complete, all data acquired is displayed in the TapeStationDx Analysis software.

NOTE

For analysis runs using more than one ScreenTape device (RUO), the TapeStationDx Analysis software starts in read-only mode once data from the first device is available. It continues adding data from the second device to the same file. When all devices have finished running, the file is finalized.

Post run steps

After the analysis end, follow the post run steps listed below.

- 1 Gather any partially used ScreenTape device (RUO) from the nest and store it according to the Quick Guide instructions.
- 2 Empty the tip waste.
- 3 Remove the sample tube strip.
- 4 Cover the tip rack with lid until next use.
- 5 Close the lid.
- 6 Switch off the instrument.

Data Analysis

Once the analytical run is completed, the TapeStationDx Controller software automatically saves the data file and opens it in the TapeStationDx Analysis software for further processing. The Analyst is the role with most permissions to operate in the TapeStationDx Analysis software, followed by the Reviewer.

Peaks are automatically assigned by the software. The Analyst can modify the data file, for example by adding, deleting, or editing peaks and regions.

Add Peak

- 1 In the View field, select **Electropherogram**.
- 2 In the gel image, click to select the desired sample.
- 3 There are two ways to add a peak:
 - In the electropherogram, right-click on the peak and choose **Add Peak**.
 - Click **Edit Peaks**, then double click on the peak on the electropherogram.
- 4 Adjust the peak bar so that it aligns with the highest point of the selected peak. The newly added peak will automatically appear in the **Peak Table**, with relevant populated metrics.

Delete Peak

- 1 In the View field, select **Electropherogram**.
- 2 In the gel image, click to select the desired sample.
- 3 In the electropherogram of the selected sample, right-click on the peak bar and choose **Delete Peak**. The deleted peak will disappear from the **Peak Table**.

Add Region

- 1 In the View field, select **Region**.

- 2 In the gel image, click to select the desired sample.
- 3 There are two ways to add a region:
 - In the electropherogram, right-click on the fragment smear and choose **Add Region**.
 - Click **Edit Regions**, then double click on the fragment smear on the electropherogram.
- 4 Adjust the region boundaries to fully integrate the fragment smear. The newly added region will automatically appear in the **Region Table**, with relevant populated metrics.

Delete Region

- 1 In the View field, select **Region**.
- 2 In the gel image, click to select the desired sample.
- 3 In the electropherogram of the selected sample, right-click on the region bar and choose **Delete Region**. The deleted peak will disappear from the **Region Table**.

Peaks and regions can also be added or deleted directly in the gel image, in the same way as described for the electropherogram

Set Approval Status

Setting an approval status is a must and can be done for each sample:

- 1 Select **Sample Table**.
- 2 Select one of the predefined options for "Approval State" column in the **Sample Table**.

Else, the same approval state can be set, simultaneously, for all samples via right-click on the field.

If a signature workflow was implemented when creating the project, the user must sign the data file by clicking **E-sign**.

If the signature workflow for the project was not configured to lock the data file automatically at this step, the **Lock Status** will display 'Unlocked'. To manually lock the data file, click the **Lock Status** button. The status will then change to 'Locked'.

The data file can be saved by:

- Clicking on the disk symbol of the quick tool bar situated in the header.
- Pressing Ctrl+S on the keyboard
- Selecting the **File** tab and clicking **Save** or **Save As...**

Compare Samples From One or Multiple Data Files

The TapeStationDx Analysis software includes a comparison feature that enables the overlay of multiple sample electropherograms from the same assay and project. This function is optional and is not required for standard analysis or result interpretation.

1 Select the **Comparison** tab.

2 Choose samples in the **Comparison** navigator.

The electropherograms of the selected samples will be displayed in an overlaid format, allowing for direct visual comparison. Samples can be deselected and selected again.

3 To retain a copy of the overlaid comparison, select **Save Comparison File**.

The default output directory will be the one set up for the project.

Reporting

The TapeStationDx Analysis software comes with a default report template. The default report template is configured to include certain information about the data file (e.g., tables, electropherograms, gel image, and audit trail). To customize the content included in a report, a new report template must be created. Users with the Project Administrator role have permission to create, edit, save, and delete report templates.

Create a Report Template

- 1 In the TapeStationDx Analysis software, go to **File** tab and select **Report Template**.

This will display the existing projects in the TapeStationDx software.

- 2 Add a new report template to the desired project by clicking the **+** button next to the project name.

This will display a section where the user can customize what to include or exclude in the new report template.

- 3 Click **Save** to complete the process.

When exporting a report, the user will be able to select this report template, provided the data file was created within the same project where the customized template was originally saved.

Create a Report

- 1 In the TapeStationDx Analysis software, go to **File** tab and select **Create Report**.

Users with the Reviewer role have permission to create a report.

- 2 Choose the desired report template to create a report.
- 3 Optional: click **Preview** to view the document prior to saving or printing.

- 4 To save the report, click **Save As...** and browse the location where the report will be stored.
- 5 The report can also be directly printed by clicking **Print**.

Export Data

The TapeStationDx Analysis software provides flexible options for exporting analysis data in various formats:

Formats	Content
CSV	Sample table Compact peak table
XML	Run properties table
Images	Electropherogram images for each sample

To export these data formats, a user with Project Administrator permission must:

- 1 Navigate to the **File** tab and select **Export Data**.
- 2 Select the desired data types: CSV, XML, or Images.
- 3 Choose the desired export components.
The **Export Data** dialog allows users to edit inclusion/exclusion options on the fly.
- 4 Optionally, modify the output directory for the exported files.
- 5 Click **Export** to complete the process.
The software will automatically open the destination folder in File Explorer.

Workflow Example

The TapeStationDx workflow in a clinical environment is structured around clearly defined user roles to support data accuracy, traceability, and help healthcare organizations meet applicable regulatory requirements. To provide a clearer understanding of how these roles interact within the TapeStationDx software, the following example illustrates a typical workflow:

Consider the following four users, all of which have their own login credentials: Anton, Blair, Chris, and Denise.

	Anton  System Administrator System Validator Project Administrator	Blair  Technician	Chris  Analyst	Denise  Reviewer
TapeStationDx roles				
Main tasks	Set up authentication mode	Set up and start a run	Modify data file	Review results and audit trail
	Manage users, roles, and projects	E-sign and save data file	E-sign and save data file	E-sign
	Run instrument diagnostics			
	Create report template			

TapeStationDx Administration software TapeStationDx Controller software TapeStationDx Analysis software

Anton is the System Administrator who sets up the TapeStationDx authentication mode, adds users (e.g., Blair, Chris, and Denise), and adds the System Validator role to himself in the TapeStationDx software. As a System Validator, he can run instrument maintenance tests, review the results, and validate the instrument to ensure it meets operational requirements.

The System Administrator can add a project and assign users and corresponding roles to that project. In this example, Anton attributes the Technician role to Blair, the Analyst role to Chris, and the Reviewer role to Denise. When creating the project, the System Administrator is automatically assigned the role of Project Administrator.

Add Project

Name *

NGS_QC

Description

Output Directory *

C:\Users\Anton\Documents\NGS_QC

Project Roles

Analyst (1)

Project Administrator (1)

Reviewer (1)

Technician (1)

☐ Anton Smith

☐ Blair Lewis

☒ Chris Miller

☐ Denise Cooper

Project Administrator

Technician

Analyst

Reviewer

Cancel

Add

Additionally, Anton also configures the following electronic signature workflow:

Edit Signature Workflow

STEP	ROLES	MEANING
1	Technician	I am the author
2	Analyst	Ready for review
3	Reviewer	Approved

Add New Step

Remove Last Step

Lock file after signing at step: 2

Cancel

Confirm

Each signature is associated with a Meaning which will be recorded in the audit trail when the respective user executes the workflow step in the TapeStationDx Analysis software.

As a Project Administrator, Anton can manage report templates for the project, which can later be used for creating the report in the TapeStationDx Analysis software.

As a Technician, Blair sets up and starts the analytical run in the TapeStationDx Controller software. Once the run is completed, Blair signs off the data file via E-sign.

Afterwards, Chris can perform adjustments to the data file in the TapeStationDx Analysis software, such as add/remove peaks/regions and change the sample approval status. When saving the altered data file, an e-signature will be requested. Once signed, the data file will be automatically locked in accordance with the configured electronic signature workflow.

Reason For Changes

Username	Full name	Date	Description	Device name	Reviewed	Reason	Category
Chris (3)	Chris Miller	2025-08-07T10:01:24+02:00	Insert ladder lane	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T10:00:11+02:00	Sample A1: Added peak ranging 81.8%–81.0%	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T10:00:05+02:00	Sample A1: Changed sample status to "Passed"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:54+02:00	Sample C1: Changed sample status to "Under Review"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:52+02:00	Sample B1: Changed sample status to "Under Review"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:50+02:00	Sample A1: Changed sample status to "Under Review"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:48+02:00	Sample C1: Changed sample status to "Passed"	AG-YU15OK2EJACN			Analysis

User

Chris Miller (Chris)

Sign on level

Analyst

Meaning

Change compliant to SOP

Comment

Password

Sign

Cancel

Denise, the Reviewer, is responsible for final data verification and quality assessment. A Reviewer can access and unlock signed data files if further modification is required. In such cases, the Analyst may revoke the signature, apply necessary changes, and re-sign the file. The Reviewer generate a report with the final results. Then audit events can be exported via **View Audit Trail** and signed off via **Review Audit Events**.

Operating the 4200 TapeStationDx System
Workflow Example

Review Audit Events

Username	Full name	Date	Description	Device name	Reviewed	Reason	Category
Chris (3)	Chris Miller	2025-08-07T10:04:53+02:00	File lock by signature step 2	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T10:01:24+02:00	Insert ladder lane	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T10:00:11+02:00	Sample A1: Added peak ranging 81.8%–81.0%	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T10:00:05+02:00	Sample A1: Changed sample status to "Passed"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:54+02:00	Sample C1: Changed sample status to "Under Review"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:52+02:00	Sample B1: Changed sample status to "Under Review"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:50+02:00	Sample A1: Changed sample status to "Under Review"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:48+02:00	Sample C1: Changed sample status to "Passed"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:46+02:00	Sample B1: Changed sample status to "Passed"	AG-YU15OK2EJACN			Analysis
Chris (3)	Chris Miller	2025-08-07T09:59:39+02:00	Sample C1: Changed sample status to "Rejected"	AG-YU15OK2EJACN			Analysis

User

Denise Cooper (Denise)

Sign on level

Reviewer

Password

Sign

Cancel

Once the review is complete, the Reviewer signs off the data file via **E-sign** and generates the report using the report template.

E-Sign Results

Username	Full name	Date	Description	Device name	Reviewed	Reason	Category
Chris (3)	Chris Miller	2025-08-07T10:04:53+02:00	E-Signed on Step 2, Analyst, file version 6	AG-YU15OK2EJACN		Ready for review	E-sign
Blair (4)	Blair Lewis	2025-08-07T09:55:20+02:00	E-Signed on Step 1, Technician, file version 4	AG-YU15OK2EJACN		I am the author	E-sign
Blair (4)	Blair Lewis	2025-08-07T09:54:15+02:00	Revoked E-Sign of 2025-08-07T09:53:30+02:00, file version 3	AG-YU15OK2EJACN			Revoke E-sign
Blair (4)	Blair Lewis	2025-08-07T09:53:30+02:00	E-Signed on Step 1, Technician, file version 2	AG-YU15OK2EJACN		I am the author	E-sign

User

Denise Cooper (Denise)

Sign on level

Step 3, Reviewer

Meaning

Approved

Comment

Password

Sign

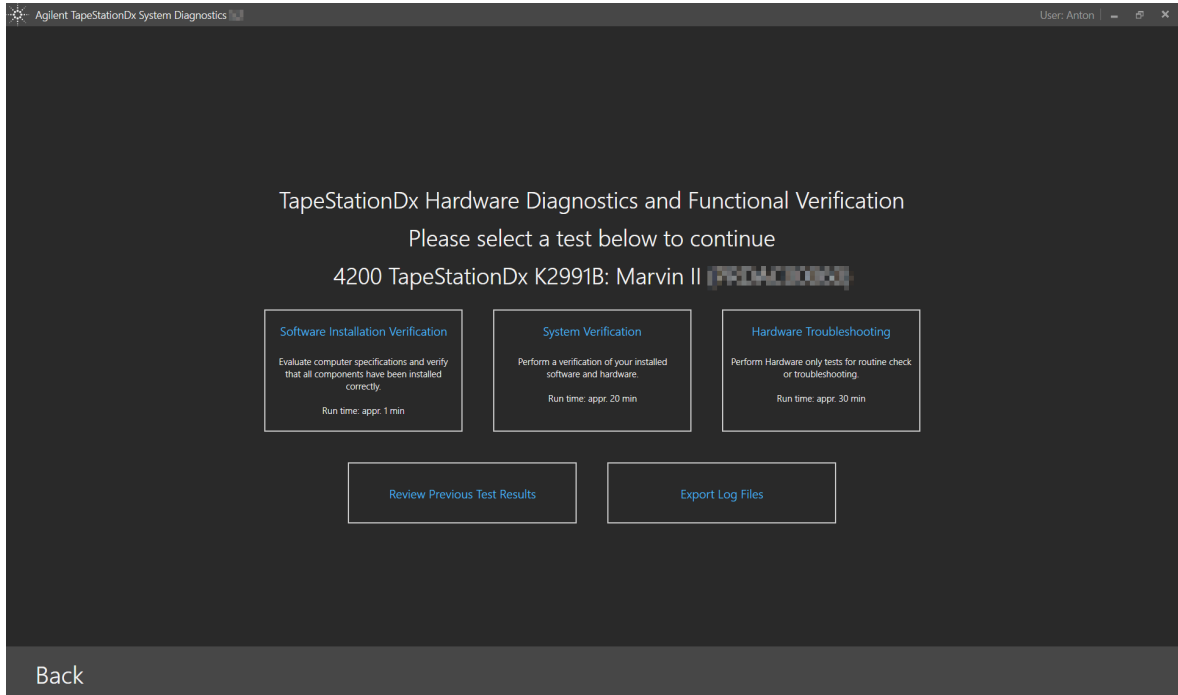
Cancel

The TapeStationDx Hardware Diagnostics and Functional Verification context (further referred to as System Diagnostics) is a specialized feature within the TapeStationDx Controller software. Its primary purpose is to ensure proper functioning of the TapeStationDx system. It provides features for maintenance, routine self-tests and service needs. This software includes diagnostic tests to verify proper performance of the mechanical, electrical, and optical components. It comes with tools supporting instrument maintenance.

System Diagnostics is designed for users and certified Agilent representatives.

System Diagnostics speeds up remote troubleshooting by providing detailed support information, such as log files for any instrument error that may arise. To ensure efficient troubleshooting and support, it is strongly recommended to include log files with every request to Agilent Support, as these contain essential information about the instrument's performance.

Export Log Files generates a package containing internal log files created by the TapeStationDx system (see [View Reports for Instrument Diagnostic Tests](#) on page 141 and [Collecting Troubleshooting Information](#) on page 190), and result files from recent instrument diagnostic tests. Log files do not contain sensitive patient data. This complete set is collected from various folder locations and provided as a ZIP file on the desktop to be sent out to Agilent technical support experts.

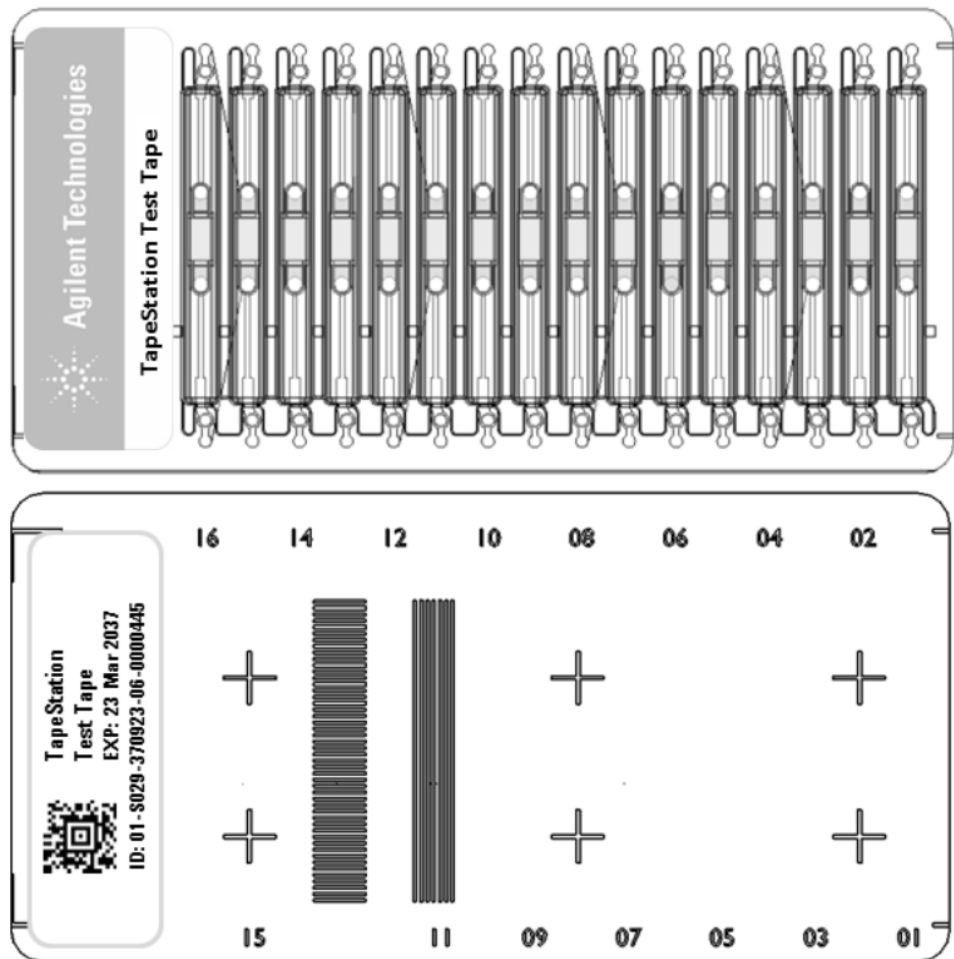


The System Verification and Hardware Troubleshooting comprises three test suites:

- Software Installation Verification
- System Verification
- Hardware Troubleshooting

TapeStation Test Tape

The Agilent TapeStation Test Tape (5067-5601) is a device designed to be used with the TapeStationDx system for hardware diagnostics. The TapeStation Test Tape can be used to check the performance of electrical and optical instrument components. It is part of the starter kit shipped with the TapeStationDx system.



Within the System Diagnostics, it can be used for routine confirmation of the system functionality in the System Verification (see [System Verification](#) on page 131).

CAUTION**Wrong insertion of TapeStation Test Tape**

The TapeStation Test Tape is a specialized test device that differs in physical properties from regular ScreenTape devices (RUO). Incorrectly inserting the TapeStation Test Tape can irreversibly damage it.

- Only insert the TapeStation Test Tape to the ScreenTape nest.
- Follow the instructions during the robotics test suite closely.

CAUTION**Influence of excessive force, heat, direct light and chemicals to TapeStation Test Tape**

The TapeStation Test Tape can be damaged by contact with heat, direct light, chemicals or by excessive force.

- Protect the TapeStation Test Tape from excessive force.
- Do not bend or flex the Test Tape and store away from heat, direct light and chemicals in the provided packaging when not in use.

NOTE

The TapeStation Test Tape is designed for instrument diagnostic purposes only, and as such will not apply any changes to the TapeStationDx instrument.

Each TapeStation Test Tape has an operation life of 2 years.

The TapeStation Test Tape is inserted into the TapeStationDx systems in the same way as a regular ScreenTape device (RUO). The label with the barcode faces towards the back of the instrument.

Upon insertion of the TapeStation Test Tape to a TapeStationDx instrument that is connected to the TapeStationDx Controller software, the start of the System Diagnostics context is triggered. A dialog will guide the user through this process.

Software Installation Verification

This evaluates computer specifications and verifies that all components have been installed correctly. Please refer to [Information on Failed Tests](#) on page 219.

Two procedures test the following items within 1 minute:

- Computer Specifications
- Software Environment

NOTE

In case all Software Installation Verification tests are passed, the laptop is fulfilling core requirements. The TapeStationDx instrument is distributed as bundle with laptops tested and fully supported by Agilent.

NOTE

In case no valid TapeStationDx system is connected, only those tests belonging to the Software Installation Verification can be run.

System Verification

The System Verification consists of tests to confirm functionality of various components of the system. See step by step instructions on this under [Executing System Verification Tests](#) on page 133. Test duration is approximately 20 minutes. Tests are organized in test groups for computer environment, robotics, electrophoresis, and vision system. The verification comes with predefined tests, see [System Diagnostics Test Details](#) on page 136. Deselection of individual tests is possible. After entering the System Verification, the selection can be modified. Some tests are interdependent and require execution of others as prerequisite. The System Verification runs automated and semi-automated tests which require user input during execution.

The System Verification requires the following material upon start:

- TapeStation Test Tape (5067-5601)
- Full rack of Loading Tips (5067-5598)
- TapeStation Tip Waste Bucket (G2992-40046)
- Empty 96-well plate (5042-8502)
- One regular ScreenTape device (RUO)

During the test on the 4200 TapeStationDx instrument, one ScreenTape device (RUO) of any assay type needs to be inserted temporarily into the ScreenTape rack to conduct a tape handling test. A used and/or expired ScreenTape device (RUO) can be utilized for this purpose.

It is required to ensure the ScreenTape nest covers, and the gantry cover are in place during execution of the System Verification.

Hardware Troubleshooting

The Hardware Troubleshooting tests for the 4200 TapeStationDx instrument consists of all tests present in the System Verification (see [System Verification](#) on page 131) plus additional tests. It creates comprehensive information for troubleshooting by service and support personnel. Test duration is approximately 30 minutes.

The optional liquid handling test within Hardware Troubleshooting requires the following additional material upon start:

A foil sealed 96-well sample plate (5042-8502) with:

- 5 μ L water in wells A1, H1, A12, H12
- 20 μ L water in wells D6, D7, E6, E7.

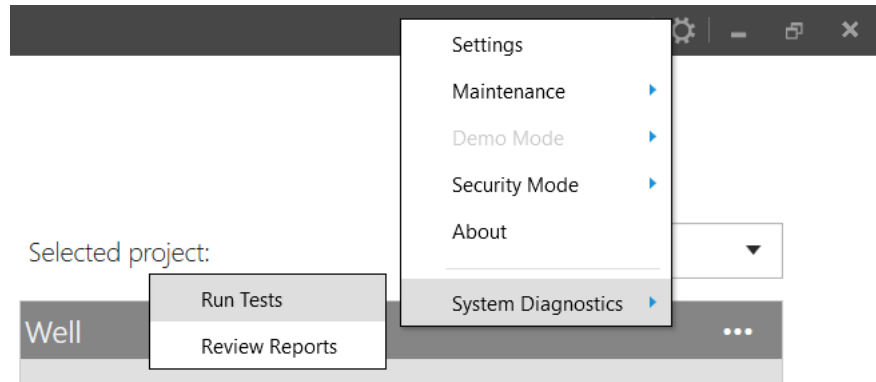
Two tube strips (401428) each with:

- 5 μ L water in wells A1, A2, H1, and H2.

Collect liquid at the bottom of the vial by centrifugation before starting the liquid handling check. Spilled liquid or trapped air bubbles affect the results.

Executing System Verification Tests

- 1 Turn on the laptop.
Let the operating system start entirely.
- 2 Power on the TapeStationDx instrument with the instrument lid closed.
Let it initialize entirely.
- 3 Log in to the TapeStationDx Controller software.
The System Diagnostics test suites can be executed by a System Administrator, a System Validator, or an Agilent Service Role.
- 4 Press the **cogwheel** in the header.
This opens the TapeStationDx Controller software settings.
- 5 Select **System Diagnostics** context and then **Run tests**.
The System Diagnostics interface will be opened.

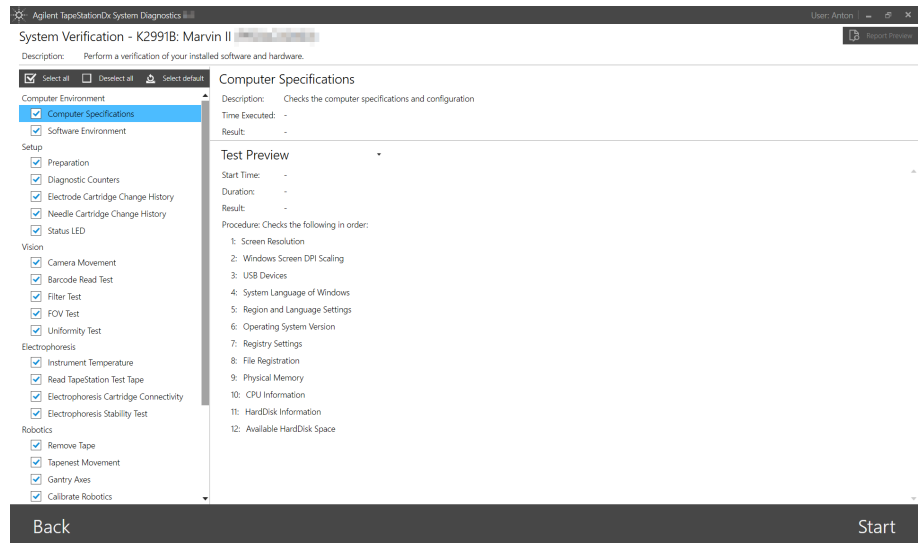


- 6 In the System Diagnostics interface, select one of the three test suites, for example the **System Verification** test suite.

Instrument Diagnostics

Executing System Verification Tests

The System Verification test suite window opens automatically, displaying all tests marked with a blue check to indicate their selection.



- 7 According to the user's needs, the user can either keep all tests selected or select specific tests by clicking **Deselect all** and checking individual tests.
NOTE: Some individual tests depend on others. When a test is selected, any dependent tests are also selected.

- 8 Click **Start** to initiate the System Verification.

A new window will open, requesting an electronic signature. To complete the process, click **Sign**.

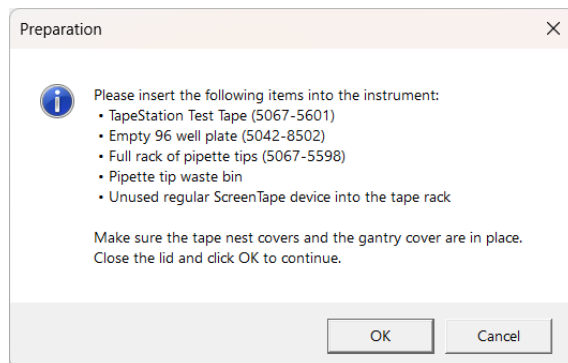
The **Start** button turns into an **Abort** button once the test suite is started.

- 9 Upon request, insert material required for the test execution.

For example, the following material is required for a System Verification:

- a TapeStation Test Tape to the ScreenTape nest,
- an empty 96-well plate,

- a full rack of pipette tips, and
- a regular ScreenTape device (RUO) to the ScreenTape rack.



- 10 Click **OK** to continue.
- 11 Upon request, monitor the status LED and lid indicator. Confirm status LED and lid indicator functionality by clicking respective buttons in pop-up windows.
- 12 Open the instrument lid and remove the TapeStation Test Tape from the ScreenTape nest upon request.
- 13 Click **OK** to continue.
- 14 Remove the regular ScreenTape device (RUO) at the end of the tests from the ScreenTape nest and click **OK**.
- 15 Click **Back** to exit the System Verification dialog or click **Report Preview**.

NOTE

Results can be reviewed and printed at a later point in time, see [View Reports for Instrument Diagnostic Tests](#) on page 141.

Any failed or aborted test remains selected even after the completion of the other tests. After all selected tests have been executed, Start reappears and allows the user to specifically execute these tests again. All repetitions of a test are recorded and are subsequently visible for review.

For information on failed tests, see [Information on Failed Tests](#) on page 219. Consult the section [Collecting Troubleshooting Information](#) on page 190 before contacting the Agilent technical support experts.

System Diagnostics Test Details

The following tables list each individual test details and whether these are present in the System Verification and Hardware Troubleshooting tests suites.

Table 22: Computer Environment

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Computer Specifications	Checks the computer specifications and configuration.	✓	✓
Software Environment	Checks the compatibility of TapeStationDx Controller Software with the computer.	✓	✓

Table 23: Setup

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Preparation	This step prepares the system for testing.	✓	✓
Diagnostic Counters	Reads diagnostic counters from instrument: needle pierce counter, total samples run and number of samples run with current electrode cartridge.	✓	✓
Status LED	Status LED test and lid button illumination. A user interaction is required.	✓	✓
Electrode Cartridge Change History	Records at which instrument total samples counter and which time a new cartridge was inserted.	✓	✓
Needle Cartridge Change History	Lists when a new needle cartridge was used to install a needle.	✓	✓

Table 24: Vision

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Camera Movement	Checks for camera movement to defined positions within the ScreenTape nest range.	✓	✓
Barcode Read Test	Checks barcode reading on the TapeStation Test Tape. Might also be executed with any ScreenTape device (RUO).	✓	✓
Filter Test	Checks that the built-in filters move to the correct positions. The check is done with expected ranges of intensities of the four combinations of filters and LEDs.	✓	✓
Camera Connection Test	Checks image transfer under conditions with increasing stringency.	✗	✓
FOV Test	Checks vision field of view (FOV) based on crosshairs on the TapeStation Test Tape.	✓	✓
Alignment Test	Checks vision alignment for optimal illumination in horizontal orientation based on the white reference surface of the TapeStation Test Tape.	✗	✓
Intensity Test	Checks vision intensity based on the white reference surface.	✗	✓
Uniformity Test	Checks the vision uniformity in the vertical orientation based on the reference surface of the TapeStation Test Tape.	✓	✓

Table 25: Electrophoresis

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Instrument Temperature	Checks values from instrument temperature. ScreenTape nest and main board temperatures are reported.	✓	✓
Read TapeStation Test Tape	Reads TapeStation Test Tape details from the barcode to record its use in a database.	✓	✓
Electrophoresis Cartridge Connectivity	Connects the electrodes to the TapeStation Test Tape, verifies electrical connectivity and records the disconnection distance.	✓	✓
Electrophoresis Voltage Supply Check	Checks the electrophoresis voltage. Sets a constant voltage. Uses resistors on the TapeStation Test Tape.	✓	✓
Electrophoresis Stability Test	Checks the electrophoresis stability. Sets a constant voltage with increasing load for the instrument. Uses resistors on the TapeStation Test Tape.	✗	✓
Electrophoresis Current Leakage	Checks the electrophoresis current leakage. Executed without TapeStation Test Tape. Measures leakage currents and crosstalk between lanes.	✗	✓

Table 26: Robotics

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Remove Tape	Requests to empty the ScreenTape nest for the next robotics tests. Removal of the TapeStation Test Tape is required, as this is too fragile for the next tests. This cannot be deselected.	✓	✓
Tapenest Movement	Checks the ScreenTape nest movement over the entire range.	✓	✓

Instrument Diagnostics

System Diagnostics Test Details

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Gantry Axes	Checks the movement of the gantry by driving the robotics to the four extreme positions.	✓	✓
Calibrate Robotics	Performs the robotics calibration procedure. This represents a series of steps in a run initiation during the pre-run checks. It is therefore of high informative value. A Pass is a prerequisite for a successful run.	✓	✓
Teach Pump-EL	Performs the teaching procedure at the tip waste location feature, 3-fold repetition of the individual task from calibration robotics.	✗	✓
Teach Pump-ML	Performs the teaching procedure at the tape waste location feature, 3-fold repetition of the individual task.	✗	✓
Teach Pump-ML-Z	Performs the teaching procedure with the pump at the 96-well plate, 3-fold repetition of the individual task from calibration robotics.	✗	✓
Teach Pump-Striptip	Performs the teaching procedures at the tip strip location, 3-fold repetition of the individual task from calibration robotics.	✗	✓
Teach Pump-Tapenest	Performs the teaching procedures at the tape nest to record its location, 3-fold repetition of the individual task from calibration robotics.	✗	✓
Teach Tapenest-Skew	Performs the teaching procedures at the tape nest to record its skew, 3-fold repetition of the individual task from calibration robotics.	✗	✓
Tip Detection And Handling	Checks the tip detection and its handling by removing three tips from a full rack of 112 pipette tips.	✓	✓

Instrument Diagnostics

System Diagnostics Test Details

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Needle To Pump	Checks the relationship between the piercing needle and the pump nozzle by the vision system. It yields crucial troubleshooting information for support.	✓	✓
Tape Handling	Checks tape handling. Transfers a device from the ScreenTape rack to the nest and reads a barcode. If a ScreenTape device (RUO) is present in the ScreenTape nest, this is first emptied. This allows both unload and load processes to be tested.	✓	✓

Table 27: Pipetting

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Liquid Handling Check	Checks liquid aspiration from the tube strips. Water must be deposited in tube strips at defined positions according to the on-screen instructions. This test must be ticked explicitly in the selection tree.	X	✓

Table 28: Cleanup

Test	Description	Test Suite	
		System Verification	Hardware Troubleshooting
Reset Instrument	Resets the instrument to its initialized state. Clears any instrument errors and drives the robotics to their home positions.	✓	✓
Recover Consumables	Requests recovery of consumables from the instrument.	✓	✓

View Reports for Instrument Diagnostic Tests

Reporting test results can be achieved by

- Printing the report after the end of test execution
or
- Saving the report as PDF, Excel, or Word file using either of the following methods
 - Pressing the **cogwheel** in the header of the TapeStationDx Controller software. Selecting **System Diagnostics** and then **Review Reports**.
 - Selecting **Review Previous Test Results** in the System Diagnostics interface.

For each method, a new context menu will open, allowing the user to select individual test results.

Click **Report Preview** to view the report.

To save the file, click the disk icon and choose the preferred output format.

The screenshot displays the 'Agilent TapeStationDx System Diagnostics' window. The left sidebar shows a list of tests, with 'System Verification' selected. The main area displays the details of the 'System Verification' test, including its description, date, duration, and result. A table lists various test categories and their results, all marked as 'Passed'. A 'Report Preview' button is visible in the top right corner.

Category	Test Name	Status
Computer Environment	Computer Specifications	Passed
Setup	Software Environment	Passed
	Preparation	Passed
	Diagnostic Counters	Passed
Vision	Electrode Cartridge Change History	Passed
	Needle Cartridge Change History	Passed
	Status LED	Passed
	Camera Movement	Passed
Electrophoresis	Barcode Read Test	Passed
	Filter Test	Passed
	FOV Test	Passed
	Uniformity Test	Passed
Robotics	Instrument Temperature	Passed
	Read TapeStation Test Tape	Passed
	Electrophoresis Cartridge Connectivity	Passed
	Electrophoresis Stability Test	Passed
Cleanup	Remove Tape	Passed
	TapeNet Movement	Passed
	Gantry Axes	Passed
	Tip Detection And Handling	Passed
Cleanup	Needle To Pump	Passed
	Reset Instrument	Passed
	Recover Consumables	Passed

System Verification
 Description: Perform a verification of your installed software and hardware.
 Date Run: Wednesday, September 17, 2025, 10:46:07 AM
 Duration: 6 Minutes
 Result: All 23 test runs passed

Computer Specifications
 Description: Checks the computer specifications and configuration
 Time Executed: 10:46 AM
 Result: All 1 test executions passed

Test Execution 1 of 1
 Start Time: 10:46 AM
 Duration: 1 Second
 Result: Passed
 Procedure: Checks the following in order:
 1: Screen Resolution
 2: Windows Screen DPI Scaling
 3: USB Devices
 4: System Language of Windows
 5: Region and Language Settings
 6: Operating System Version
 7: Registry Settings
 8: File Registration
 9: Physical Memory
 10: CPU Information
 11: HardDisk Information
 12: Available HardDisk Space

NOTE

From the TapeStationDx Analysis software log files in ZIP format can be exported to be sent to Agilent technical support experts. See [Collecting Troubleshooting Information](#) on page 190 for details. These log files will automatically contain the latest test results.

8 Performing Maintenance

The 4200 TapeStationDx instrument does not require manual calibration, however, it does require preventive maintenance, hence the TapeStationDx Controller software will actively flag the due date based on the instruments' throughput and time elapsed. A warning message appears after analysis of 50000 samples or after one year of operation.

The preventive maintenance consists of:

- needle replacement
- electrophoresis probe block replacement
- firmware and software update if applicable
- general cleaning of instrument
- execution of functional hardware test

For the 4200 TapeStationDx instrument most preventive maintenance tasks can be done by the user utilizing information provided in the user guide. For instructions, see [Exchanging the Electrode Cartridge](#) on page 151, [Exchange the Piercing Needle](#) on page 145, [Cleaning the System Components](#) on page 159 and [Electrode Cartridge](#) on page 148 for general information.

Optionally, Preventive Maintenance service is performed by an Agilent service engineer or Agilent authorized service provider. This service helps ensure the reliable operation of the system. Contact Agilent Worldwide Technical Support for further information.

A local certified Agilent representative will, in addition to the tasks listed above, do the following during a Preventive Maintenance service:

- inspect the internal of the instrument for wear
- lubricate rails
- general cleaning of instrument inside and outside
- apply dedicated sensor and positional recalibration steps
- review dedicated log information.

The Preventive Maintenance service executed by certified Agilent representatives does not include repair activities. For customers with high usage, the needle replacement procedure (see [Exchange the Piercing Needle](#) on page 145) might be required between yearly Preventive Maintenance services.

Needle Pierce Counter

Each time a ScreenTape lane is pierced for sample application during the analysis the needle pierce counter is increased. The TapeStationDx Controller software displays the number of pierces. The piercing needle should be exchanged after 3840 pierces to ensure optimal instrument performance. The TapeStationDx Controller software displays a warning message when this threshold value is reached. Starting an analysis is inhibited if 4480 pierces are reached. The command **Change Needle** (see [Exchange the Piercing Needle](#) on page 145) from the TapeStationDx Controller software leads to an exchange of the piercing needle and a reset of the needle pierce counter.

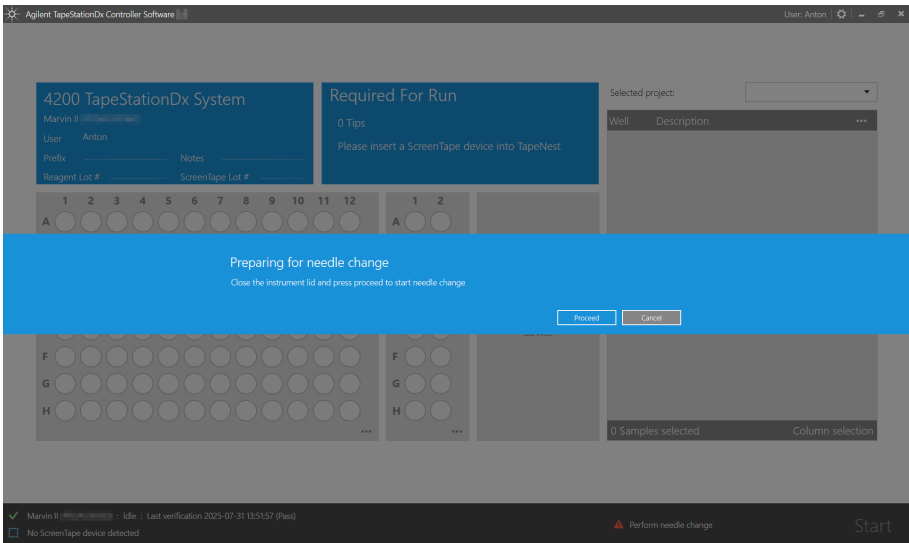
Samples Analyzed

Each time a ScreenTape lane is used for electrophoresis the maintenance counter is increased. The TapeStationDx Controller software shows the counter and a respective warning when a threshold value of 50000 samples or one year of usage is reached, whatever comes first. The electrodes in the ScreenTape nest contacting the electrodes on the ScreenTape devices (RUO) should be exchanged after a defined number of analyses to ensure optimal instrument performance. When the maintenance warning is displayed schedule a planned preventive maintenance or perform a self preventive maintenance.

Exchange the Piercing Needle

p/n	Description
5067-5783	Needle Change Cartridge

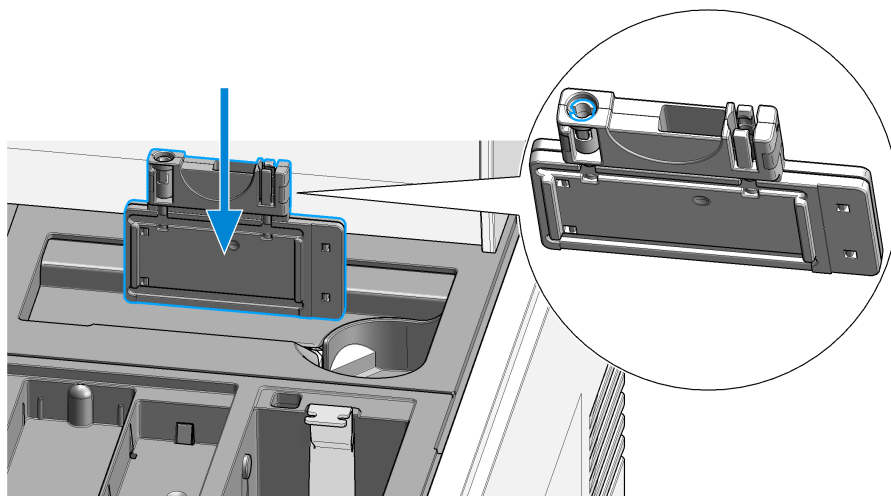
- 1 Prepare instrument by clicking the **cogwheel** > **Maintenance** > **Change needle** from the TapeStationDx Controller software.
- 2 The exchange process opens the ScreenTape nest to allow insertion of the Needle Change Cartridge. Close the lid. Click **Proceed**.



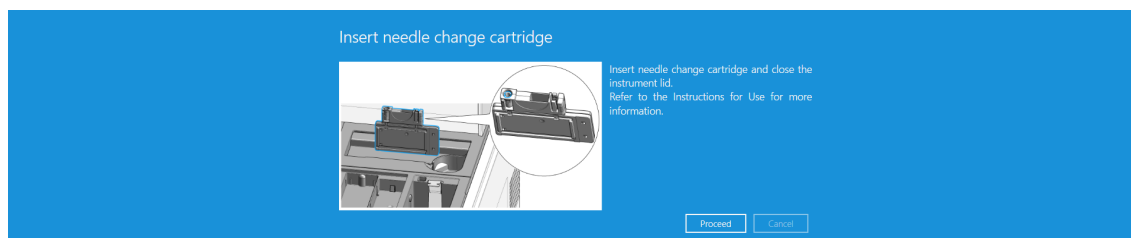
Performing Maintenance

Exchange the Piercing Needle

- 3 Insert an unused Needle Change Cartridge to the ScreenTape nest. Insert the cartridge with the bar code facing towards the back of the instrument. An unused new cartridge has a new piercing needle on the left side and an empty slot on the right. The open slot on the right-hand side has hooks.



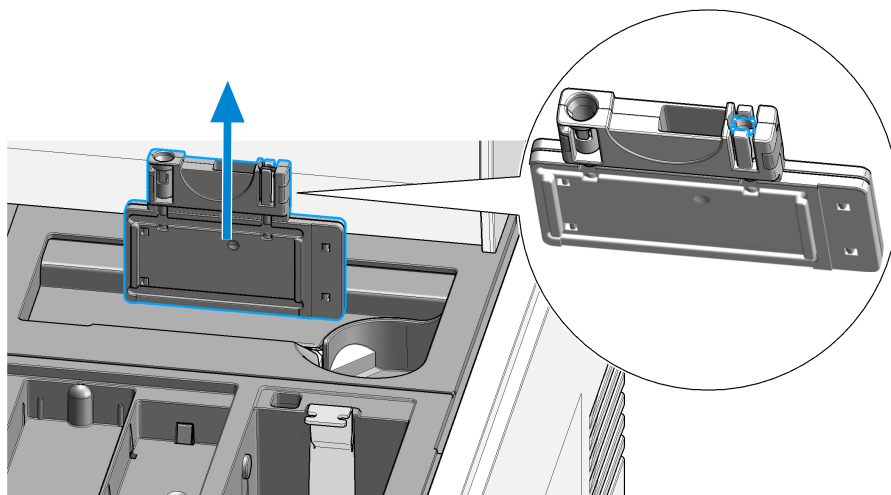
- 4 Click **Proceed** to continue.



Performing Maintenance

Exchange the Piercing Needle

- 5 After exchange: Remove Needle Change Cartridge from ScreenTape nest and discard. The used cartridge has an open slot on the left side and the old piercing needle in the slot on the right.



- 6 Close lid. Click **Removed**.
- 7 Wait approximately two minutes until the automated pierce needle calibration is complete. It is crucial not to turn off the instrument or terminate the software during the needle exchange; this could impact the performance of all future analysis.

Needle change complete
Needle changed and calibrated successfully

Ok

NOTE

In case the new pierce needle was transferred to the instrument but the automated calibration fails, the system shows dialogs which help to correct this. These dialogs cannot be turned off. In case the correction attempts are unsuccessful it is recommended to first execute the System Verification, collect troubleshooting information [Collecting Troubleshooting Information](#) on page 190 and to contact the local support.

Electrode Cartridge

The Electrode Cartridge in the TapeStationDx system is crucial for electrophoresis, featuring gold-coated pins for electrical contact with carbon electrodes on ScreenTape devices (RUO). During analytical runs, it applies separation voltage when the ScreenTape nest is closed.

Due to mechanical stress and contamination, the TapeStationDx Controller software prompts replacement after one year or 50000 samples.

Refer to the TapeStationDx Controller software for maintenance counters and diagnostic information. Proper positioning and careful handling of the Electrode Cartridge are essential to avoid damage. Follow the mounting instructions precisely to ensure correct insertion and function.

The figure below shows the Electrode Cartridge (5067-5786) for the 4200 TapeStationDx instrument. Positioning of the Electrode Cartridge inside the ScreenTape nest is crucial. Two components, the lever for latching and its pivot point, guide the Electrode Cartridge to its position. The correct position is reached when the lever is closed again. The lever for latching must point upward when the insertion begins and turns down while the Electrode Cartridge is lowered. The prerequisite to insert an Electrode Cartridge is that the ScreenTape nest is driven to a dedicated opening width. This is achieved when the TapeStationDx Controller software is used to assist the Electrode Cartridge Change process.

Performing Maintenance
Electrode Cartridge

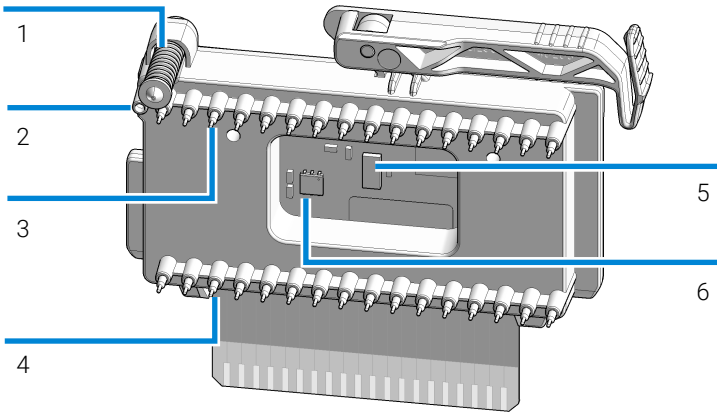


Figure 9: Electrode Cartridge front view for the 4200 TapeStationDx system and 4150 TapeStationDx system

1	Positioning spring
2	Empty position
3	Upper electrode contact pins
4	Lower electrode contact pins
5	Temperature sensor
6	Internal memory

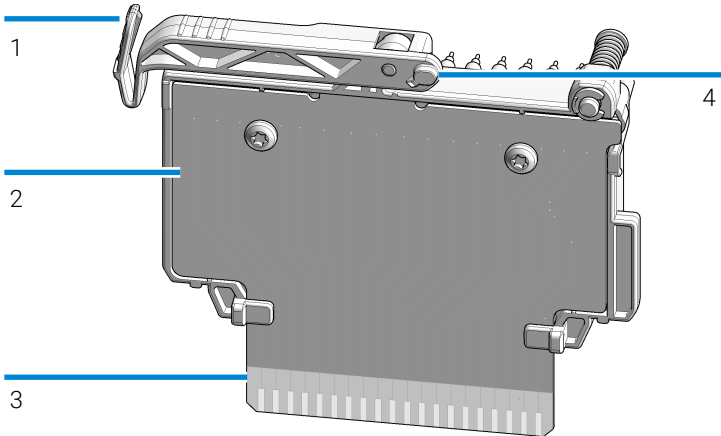


Figure 10: Electrode Cartridge rear view for the 4200 TapeStationDx system and 4150 TapeStationDx system

1	Lever for latching
2	Electronic board
3	Electric contact to instrument
4	Guiding pivot point

CAUTION

Wrong cartridge exchange

Instrument or cartridge damage.

- Use the software to prepare the Electrode Cartridge exchange procedure.
- Remove the Electrode Cartridge only when prompted by a software dialog.

Additional Functionality of the Electrode Cartridge

The Electrode Cartridge stores the following information in its internal memory:

- Electrode cartridge serial number
- Type of construction
- Date of first use
- Numerical sample counter

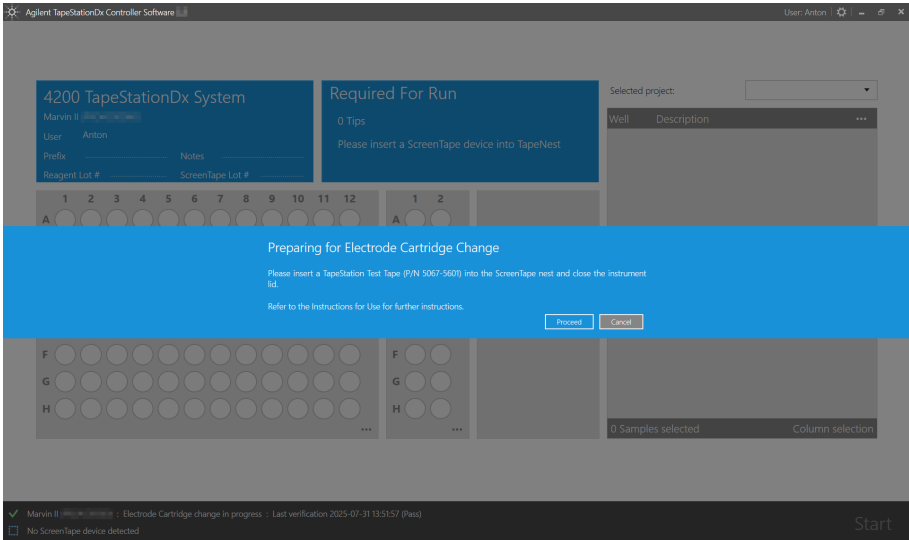
This information is accessed and displayed when diagnostic counters or results of the *Electrode Cartridge Change History Test* are displayed.

Exchanging the Electrode Cartridge

p/n	Description
5067-5782	Electrode Cartridge
5067-5601	TapeStation Test Tape

During a Preventive Maintenance service, the Electrode Cartridge is exchanged. For self-maintenance of the electrode cartridge proceed as follows:

- 1 Launch the TapeStationDx Controller software.
- 2 Prepare the instrument by selecting the **cogwheel > Maintenance > Change Electrode Cartridge**. Follow further onscreen instructions.

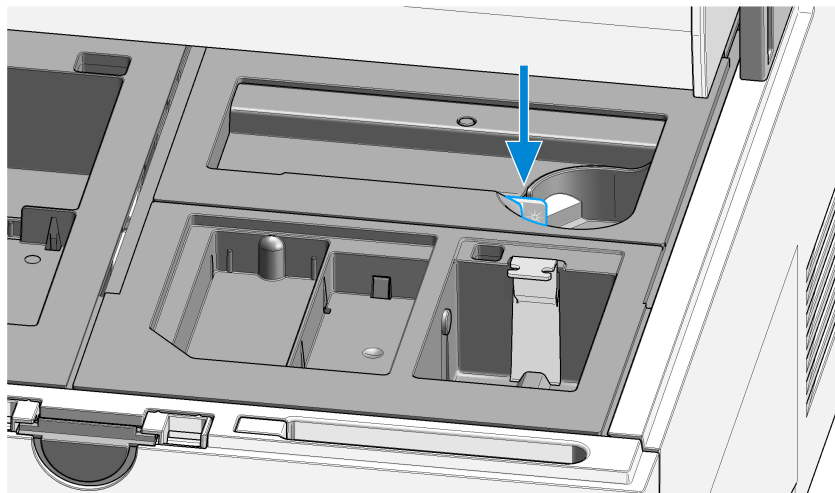


- 3 Open the lid by pressing the lid release button.

Performing Maintenance

Electrode Cartridge

- 4 Insert a TapeStation Test Tape into the ScreenTape nest.

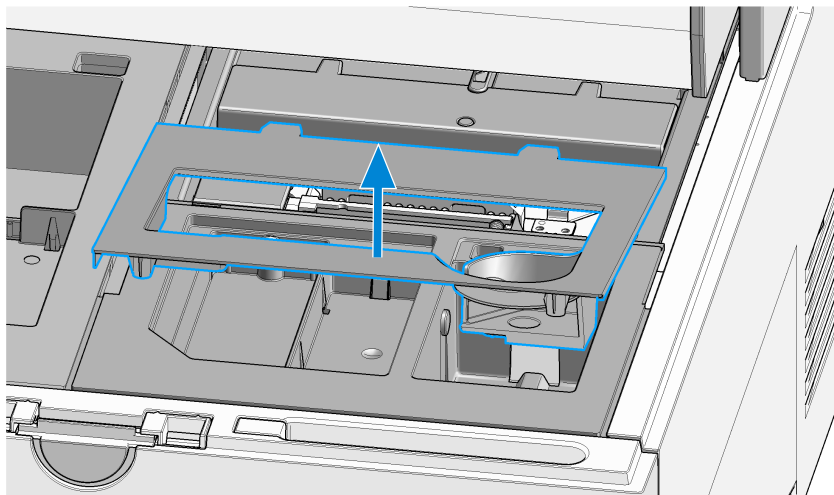


- 5 Close the lid.
- 6 Click **Proceed**.
- 7 The Electrode Cartridge is deactivated. The instrument remains inoperable until the following steps are performed successfully. Follow further onscreen instructions.
- 8 Open the lid by pressing the lid release button.
- 9 Remove the TapeStation Test Tape from the ScreenTape nest and store it properly.

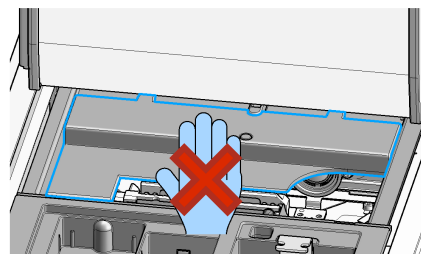
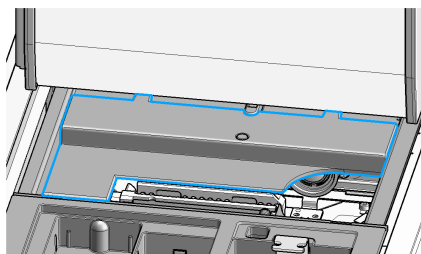
Performing Maintenance

Electrode Cartridge

- 10 Remove the upper nest cover as explained by the TapeStationDx Controller Software.



- 11 Do not alter the installed lower nest cover. Keep the lower nest cover in place.

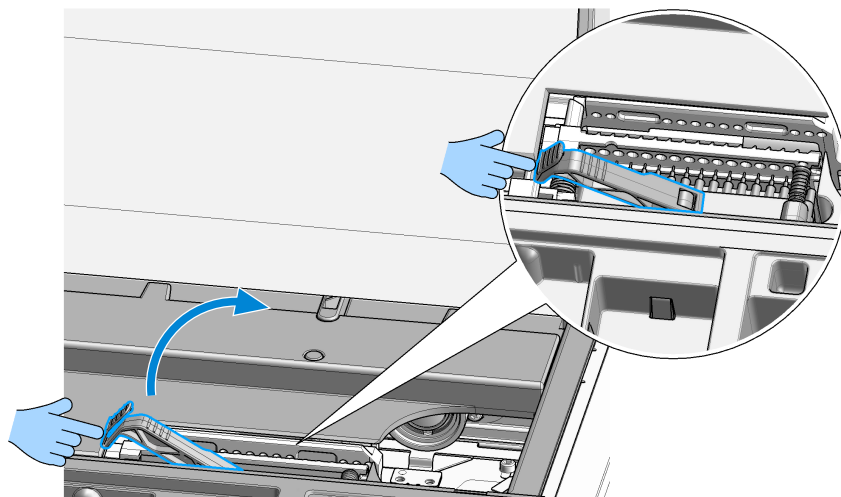


- 12 Click **Proceed**. Follow further onscreen instructions.

Performing Maintenance

Electrode Cartridge

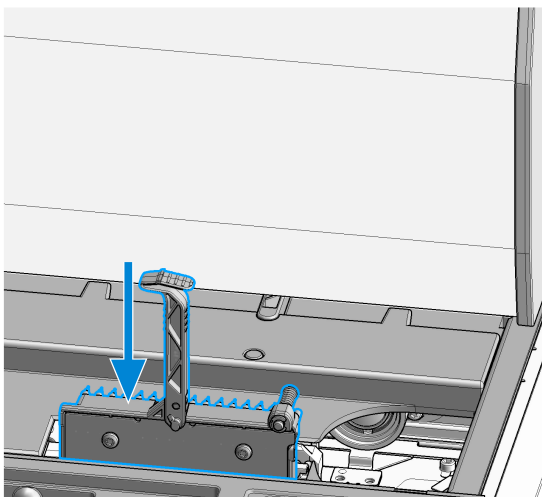
13 Release the cartridge lever with a push and bring it to the upright position.



14 Pull the Electrode Cartridge out in a straight upward movement.

15 Click **Proceed**. Follow further onscreen instructions.

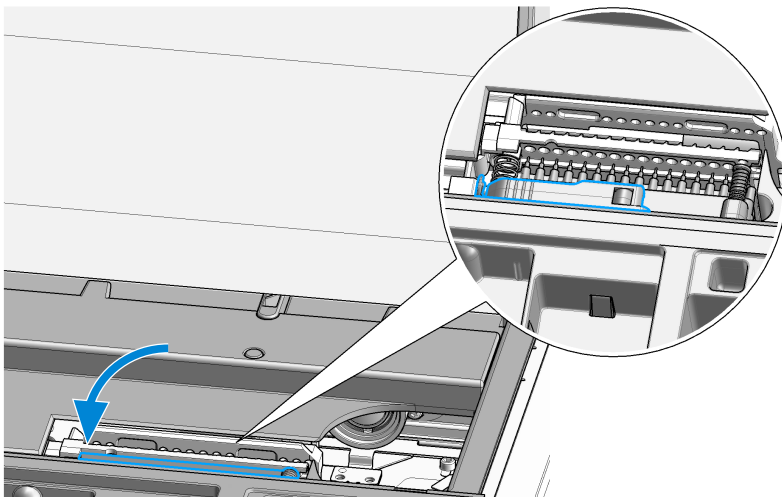
16 Insert the new Electrode Cartridge carefully. Push downwards until it reaches a resistance.



Performing Maintenance

Electrode Cartridge

- 17 Move the lever to the lock position.



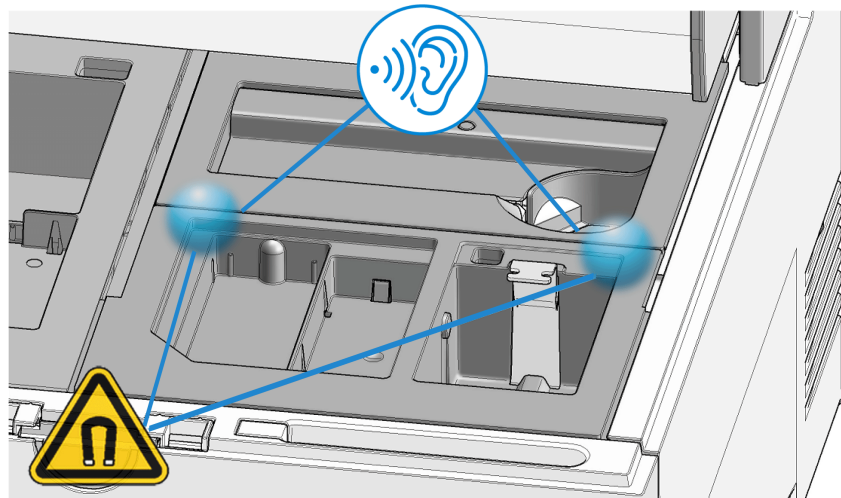
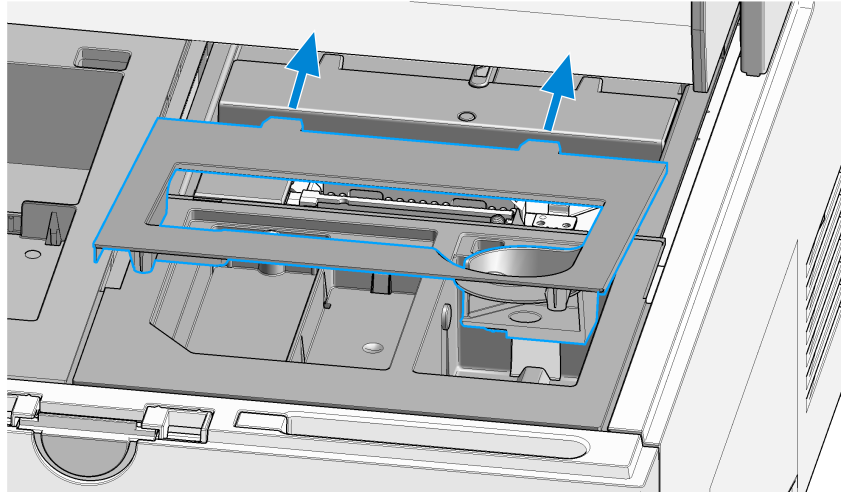
An internal locking bolt positions the Electrode Cartridge correctly.

- 18 Click **Proceed**. Electronic registration of the new cartridge is executed. Follow further onscreen instructions.

Performing Maintenance

Electrode Cartridge

- 19** Reinsert the upper nest cover: Guide the rear positioning extensions into the corresponding recesses under the gantry. Lower the cover until the magnets hold it in place.

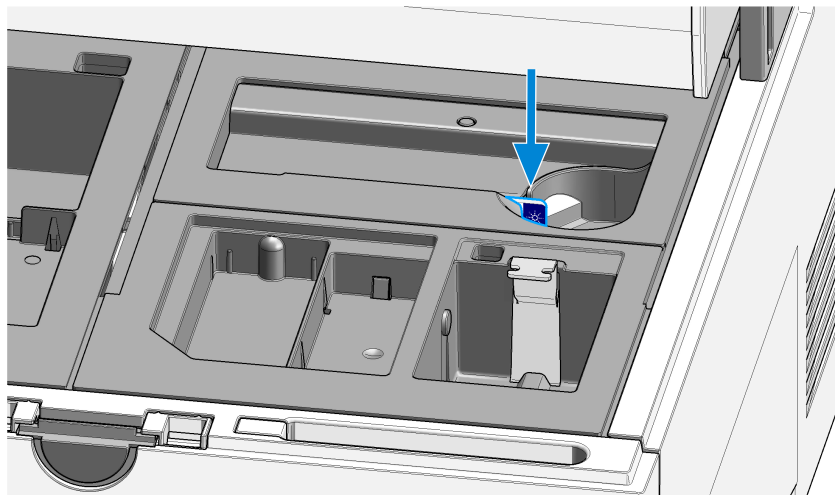


- 20** Click Proceed. Follow further onscreen instructions.

Performing Maintenance

Electrode Cartridge

- 21 Reinsert the TapeStation Test Tape into the ScreenTape nest to check functionality of the new electrode cartridge.



- 22 Close the lid.
- 23 Click **Proceed** to start a short verification.
- 24 Click **Proceed** to start System Verification tests. If the Electrode Cartridge Change was not successful, please refer to [Troubleshooting](#) on page 190.

Electrode Cartridge Change Results

The Electrode Cartridge Change was successful.

Proceed to execute System Diagnostic tests.

Proceed

- 25 Execute System Verification tests and review the results to verify instrument functionality, see [System Diagnostics Test Details](#) on page 136.

After an Electrode Cartridge Change a banner shows the results of the outcome. Users are subsequently guided to execute a System Validation test in any case. This additional system validation is not mandatory to continue working with the instrument but is recommended for good laboratory practice reasons.

The Electrode Cartridge Change is successful if the following criteria are fulfilled:

- The inserted Electrode Cartridge was successfully registered
- The date of first use is the current day
- The electrical functionality test with the TapeStation Test Tape passed

In case the electrical functionality test with the TapeStation Test Tape fails, the entire Electrode Cartridge Change is labelled as failed. The Electrophoresis Cartridge Connectivity test from the System Validation test will indicate lanes that caused the fail. The failure might be caused by a wrongly inserted or defective Electrode Cartridge, by a defective TapeStation Test Tape or by defective instrument electronics. The instrument will remain inoperable on the respective lanes. Please correct the cartridge installation or mount a different valid cartridge in case all lanes were operational before.

Please be aware of software notifications that are related to the Electrode Cartridge:

- **Used Electrode Cartridge Inserted** on page 201
- **Electrode Cartridge Change Failed** on page 200
- **Electrode Cartridge Not Detected** on page 202

Please collect and provide troubleshooting information **Collecting Troubleshooting Information** on page 190 and contact the Agilent support if you cannot correct the error yourself.

Cleaning the System Components

The surfaces of the TapeStationDx instrument, the waste bucket, tube strip holder, the lower nest cover and the upper nest cover can be cleaned regularly with the following reagents:

- Mild household detergents
- Mixture of 70% ethanol with 30% water
- Isopropanol
- RNaseZAP® (Ambion, Inc)

NOTE

Dislocation of lower and upper nest cover will create blockage errors during instrument operation. Please see [Assembling Lower Nest Cover](#) on page 160.

CAUTION

Heat deformation of plastic components

Deformed plastic components will create blockage errors during instrument operation.

- Do not expose plastic components to heat.
- Do not use a dishwasher.

Assembling Covers

Assembling Lower Nest Cover

Removing the lower nest cover is not required. If it has been removed inadvertently, please refer to the provided instructions for corrective measures.

CAUTION

Lower nest cover incorrectly mounted
Instrument malfunction and loss of material.

- Do not touch the lower nest cover.

CAUTION

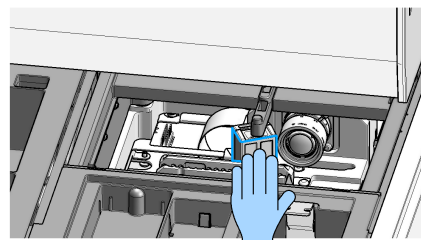
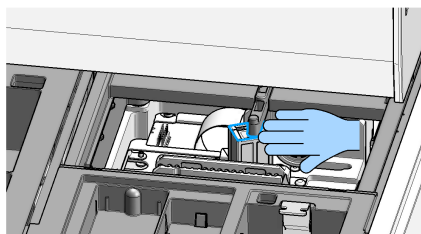
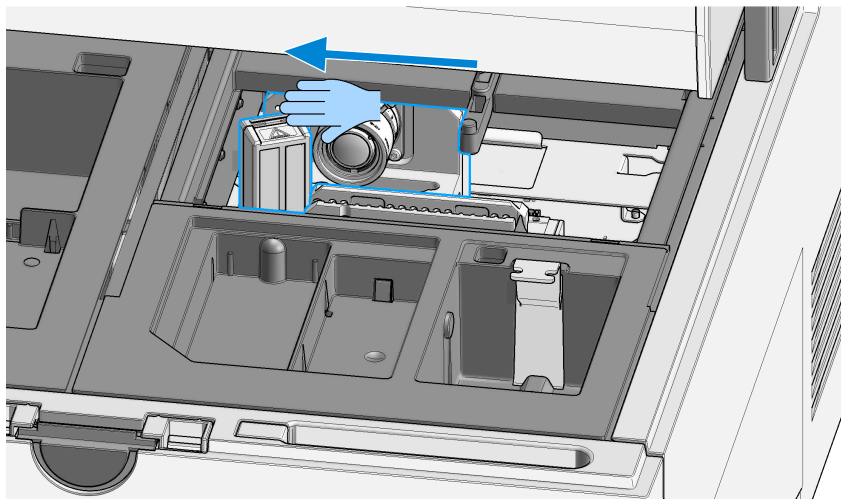
Unclean or dislocated LED module front
Analytical performance is impaired.

- Do not touch the LED module front.

Performing Maintenance

Assembling Covers

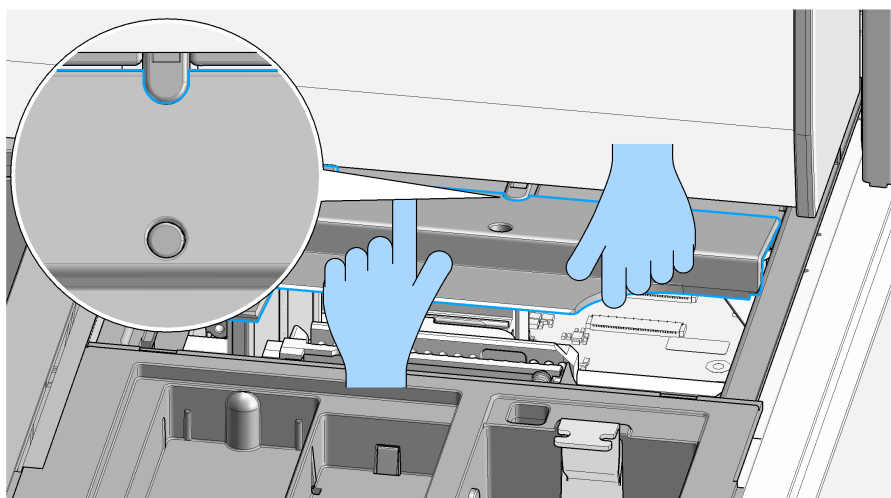
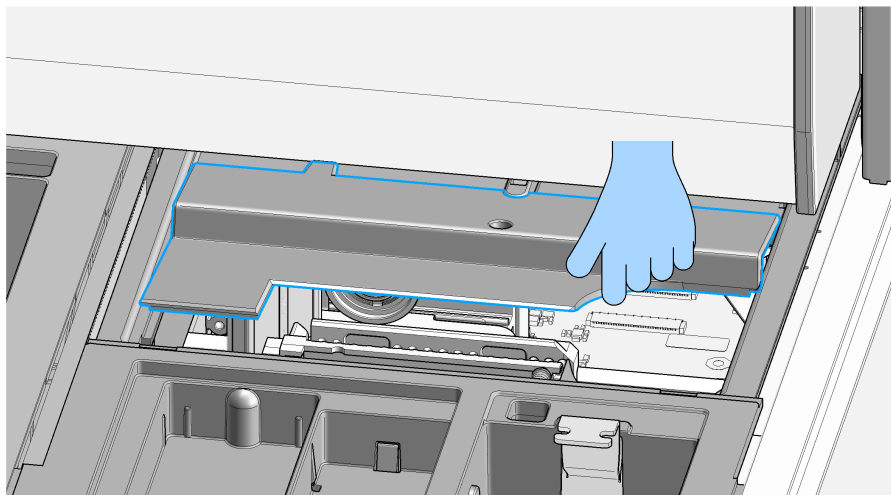
- 1 Carefully touch the LED module at its top and move the assembly to the left side.



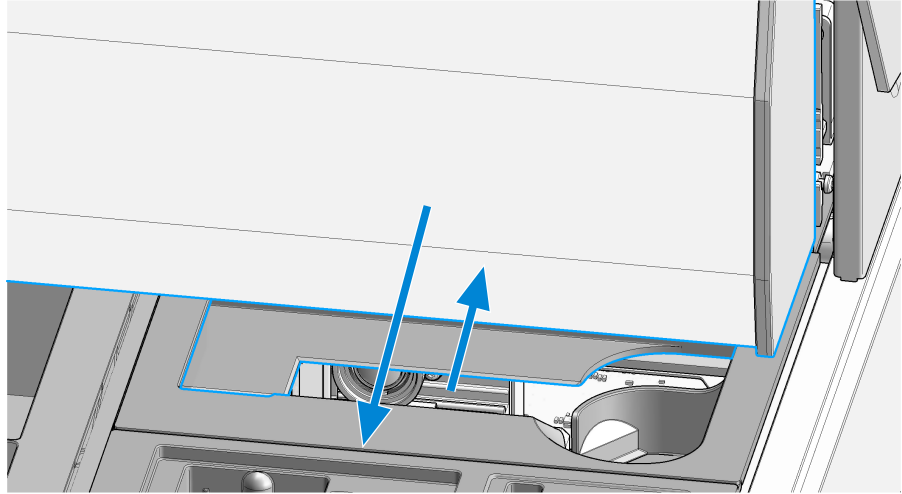
Performing Maintenance

Assembling Covers

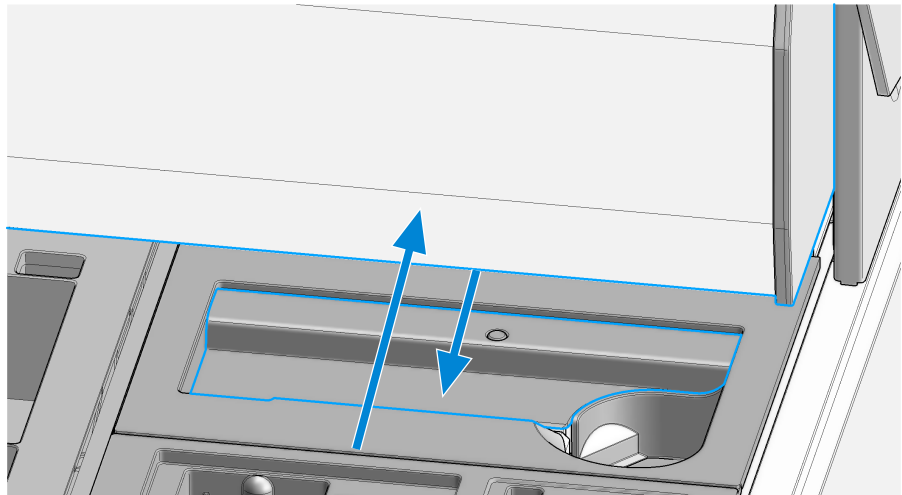
- 2 Mount the lower nest cover to the lever such that the half-round cutout meets its counterpart on the lever.



- 3 Reinsert the upper nest cover as explained in [Assembling Upper Nest Cover](#) on page 164: Guide the rear positioning extensions into the corresponding recesses under the gantry. Lower the cover until the magnets hold it in place.



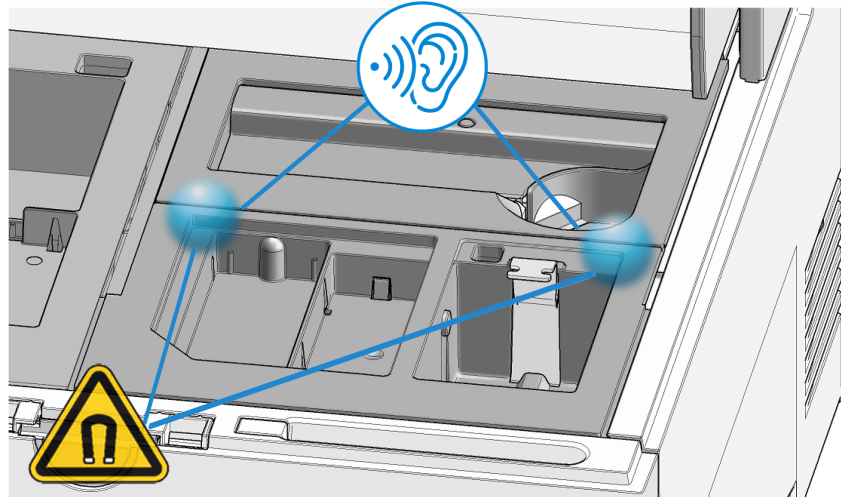
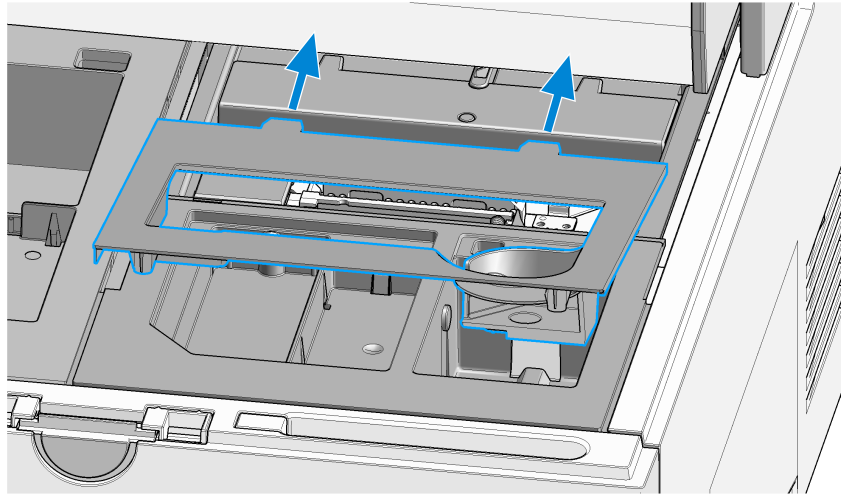
- 4 Move the gantry gently back again. The lower nest cover moves forward.



- ✓ The lower nest cover mounting is correct if it moves smoothly in opposite direction to the gantry cover.

Assembling Upper Nest Cover

- 1 Reinsert the upper nest cover: Guide the rear positioning extensions into the corresponding recesses under the gantry. Lower the cover until the magnets hold it in place.



Assembling Gantry Cover

Removing the Gantry cover is not required. If it has been removed inadvertently, please refer to the provided instructions for corrective measures.

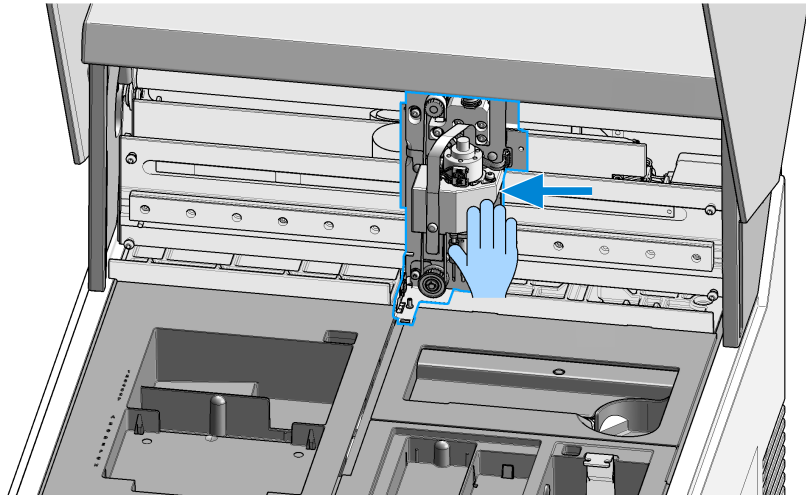
WARNING

Piercing needle located behind the gantry cover

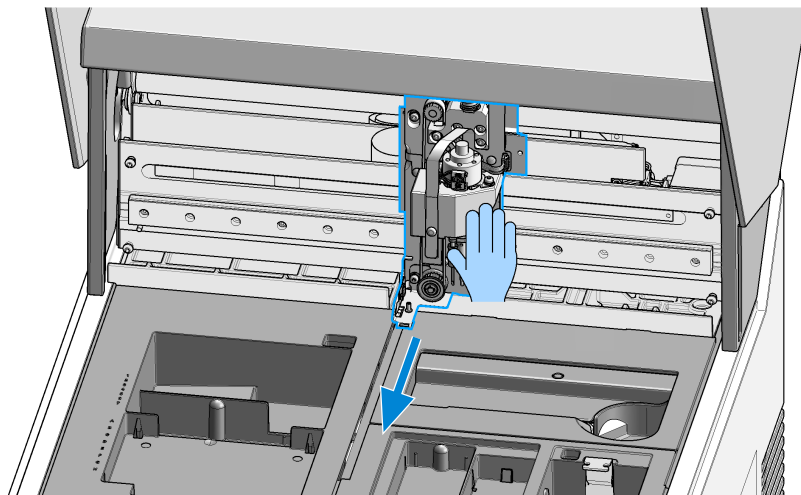
Careless operation may cause injury.

- Do not reach under the cover.
- Do not remove the cover.

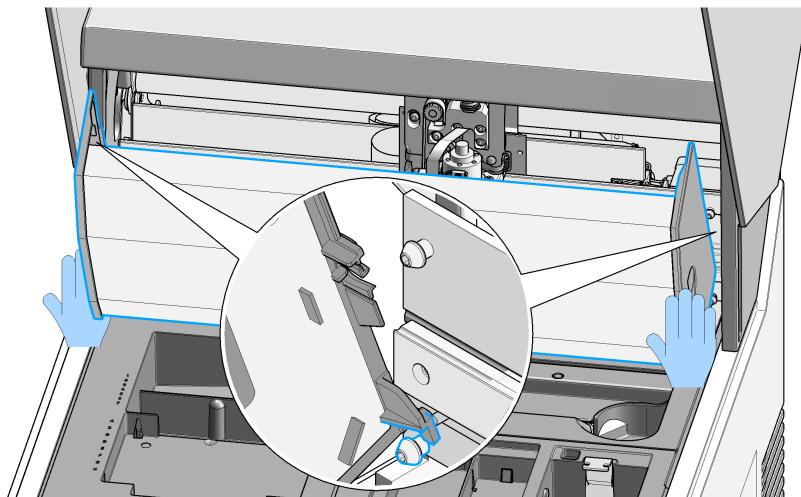
- 1 Move pump to middle position. Touch pump at metal body only.



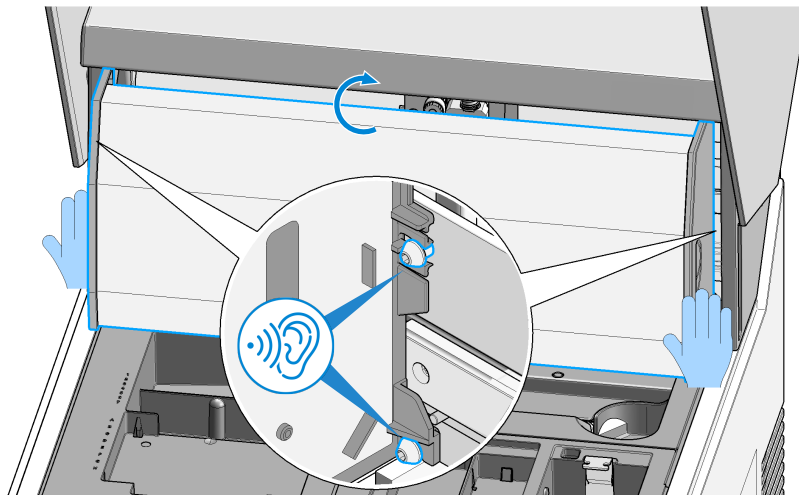
- 2 Pull the gantry carefully forward 5 cm.



- 3 Place lower slot opening of the gantry cover onto the lower peg with conical head (30°).



- 4 Rotate the gantry cover towards the gantry such that its snap fit rests over the upper peg with conical head.



- 5 Close the lid and let the instrument initialize. The gantry will drive to home position automatically.

CAUTION

Incorrect mounting might break the plastic guides of the gantry cover.



9 Instrument Movement

In case of questions, contact your Agilent representative before relocating the TapeStationDx system.

Transportation Lock

The execution of the command **Preparing Transportation** from the TapeStationDx Controller software assists the fixation of two moving mechanical parts of the 4200 TapeStationDx instrument. The robotics for liquid handling behind the gantry cover and the moving parts of the vision system are secured by foams and a Vision Lock Tape.

This procedure is required prior to any transportation of the instrument. The installation of the packaging material is assisted by illustrated software **Preparing the Instrument for Transportation** on page 170:

NOTE

If the unit needs to be transferred to another location, mount all packaging material before moving it. Follow the Unpacking instructions prior to next use **Unpacking the Instrument** on page 183.

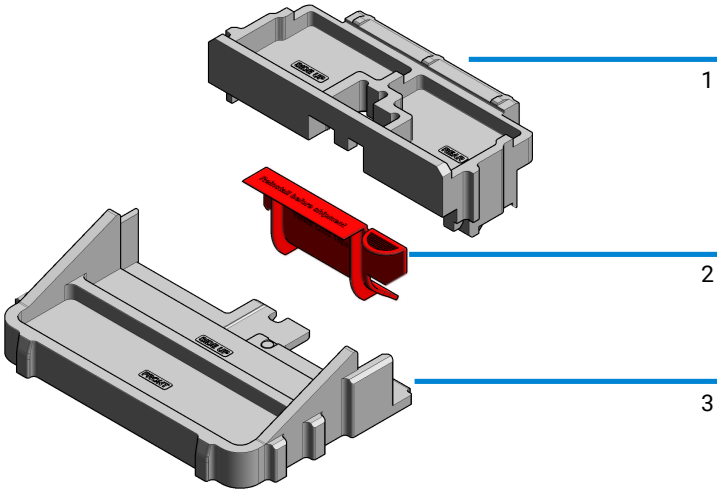
CAUTION

Incorrectly installed or missing packaging material
Incorrectly installed or missing packaging material can lead to instrument damage during transportation.

Preparing the Instrument for Transportation

To ensure safe relocation, the 4200 TapeStationDx instrument must be set to transport mode. This procedure, along with the subsequent movement, is facilitated through software dialogues.

- 1 Provide dedicated packaging material for later use. This material is used inside the instrument.

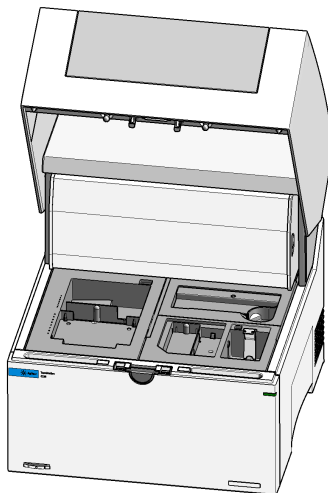


1	Pump Foam
2	Vision Lock Tape
3	Workspace Foam

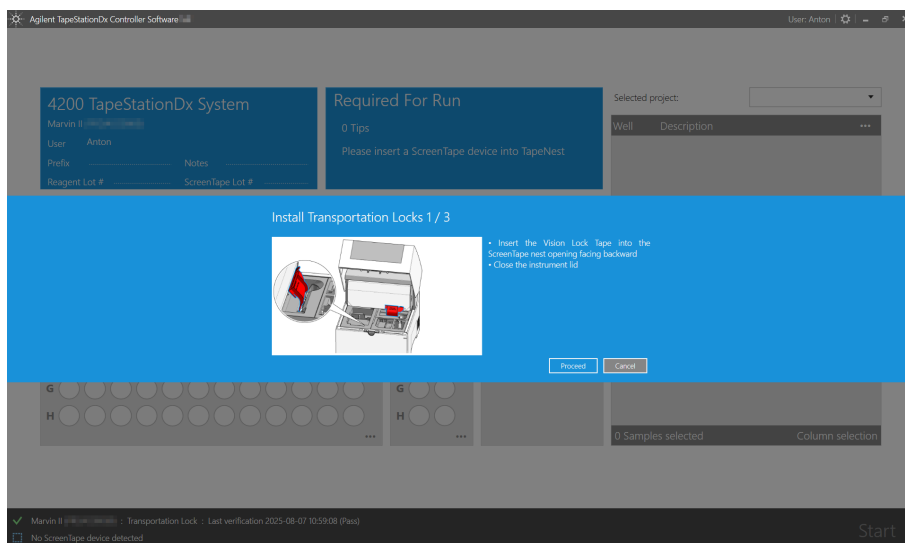
Instrument Movement

Transportation Lock

- 2 Remove all loose components such as tip waste, tip rack, tube strip holder, 96-well sample plate, and ScreenTape rack from the instrument.



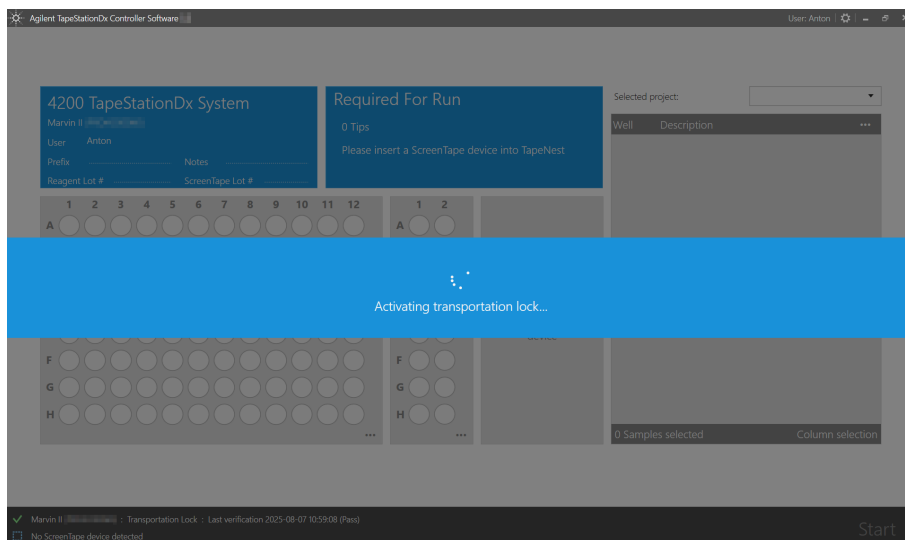
- 3 Close the lid.
- 4 Select **Prepare Transportation** from the TapeStationDx Controller software menu. The software guides you through steps for fixation of all robotic parts to a safe position.



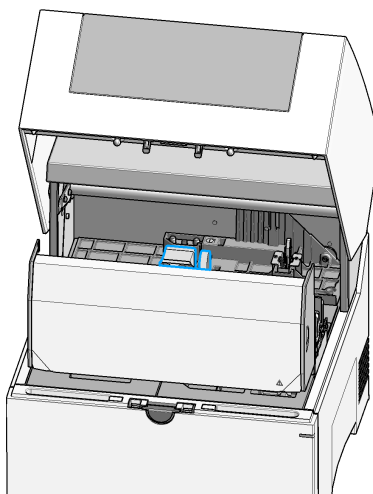
Instrument Movement

Transportation Lock

- 5 Open the lid by pressing the lid release button.
- 6 Insert the Vision lock tape into the ScreenTape nest in a curved and guided path. The handle and the upper surface of the vision lock tape are flush with the work surface.
- 7 Close the lid. Click **Proceed**.



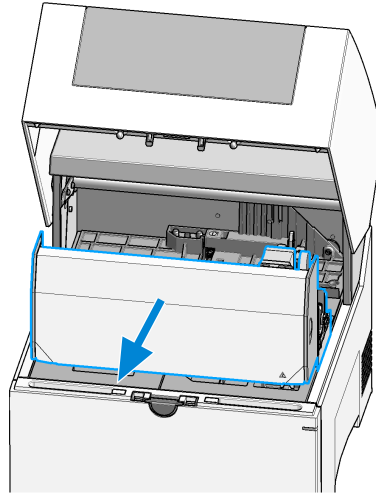
- 8 Open the lid.



Instrument Movement

Transportation Lock

- 9 Carefully pull the gantry towards the front of the instrument.



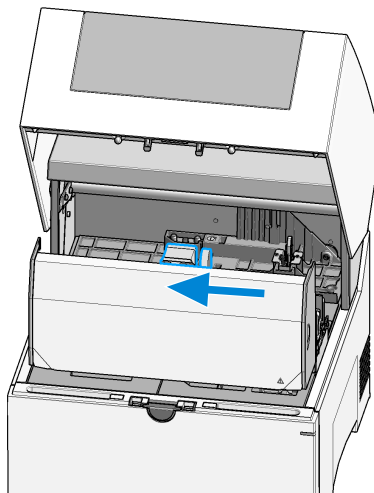
NOTE

The gantry is automatically moved to the front of the instrument. In case of defective instruments, this needs to be done carefully by hand. Take care not to pull off the gantry cover. If this happens by accident, refer to [Assembling Gantry Cover](#) on page 165 to remount the cover.

Instrument Movement

Transportation Lock

10 Move the pump to the middle of the axis.



NOTE

The pump is automatically moved to the front and middle of the axis. In case of defective instruments, this needs to be done carefully by hand.

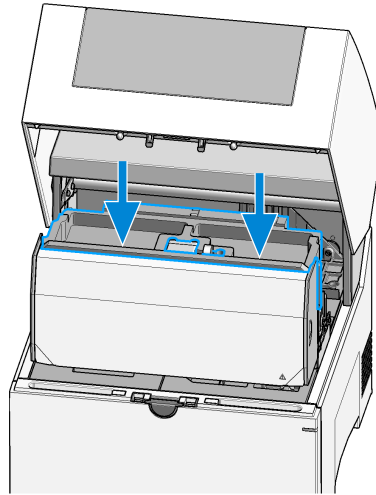
CAUTION

Damaged cables and pump

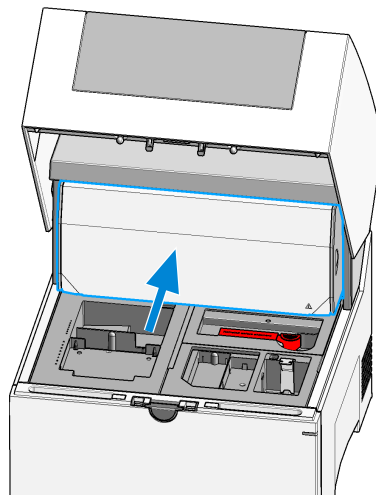
Fragile cables are near the pump foam. The pump is a movable part.

- Ensure not to damage the cables.
- Ensure not to push the pump downwards when inserting the pump foam.

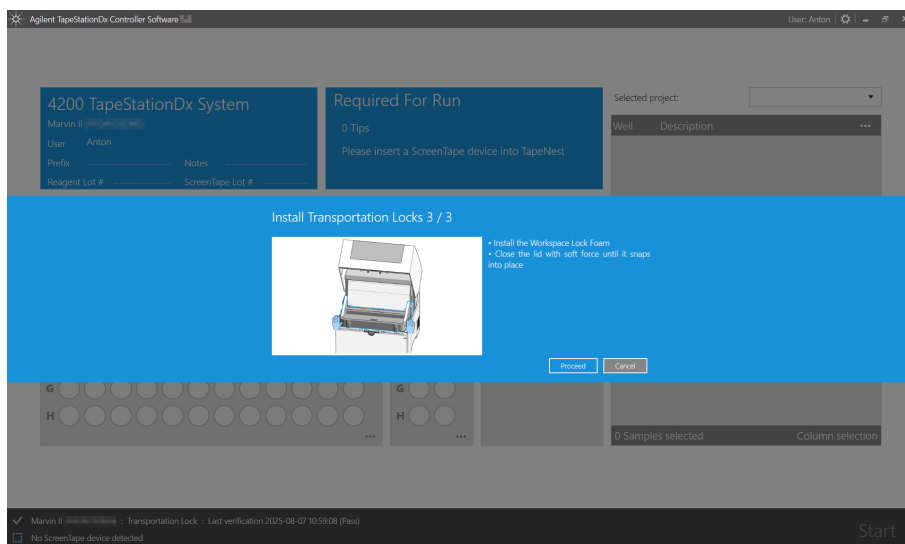
11 Install the pump foam carefully over the pump. Do not apply force: the pump foam with its recesses should fit easily in.



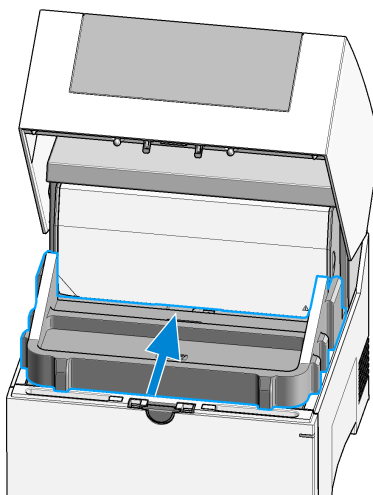
12 Push the gantry carefully towards the back of the instrument.



13 Click Proceed.



14 Insert the workspace foam. Do not apply force: slide the foam with its lower side flat under the gantry cover.

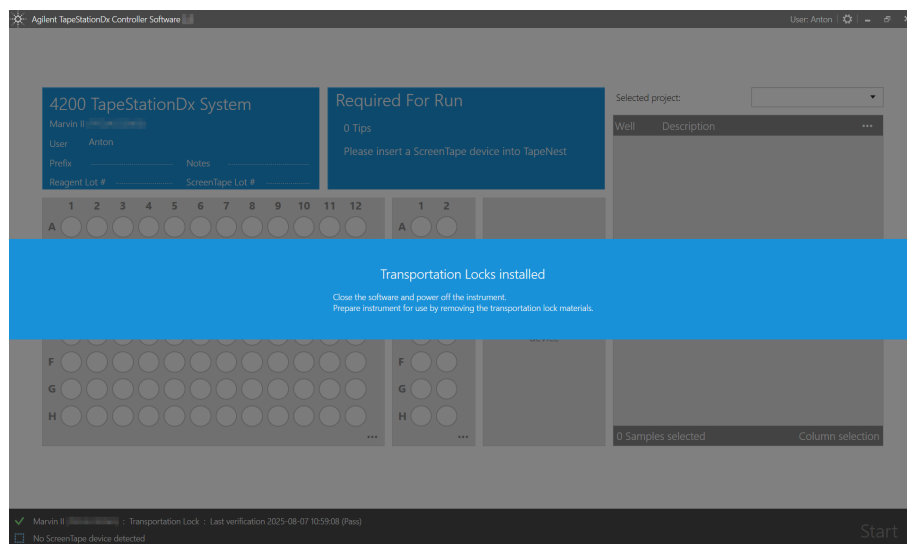


15 Close the lid.

Instrument Movement

Transportation Lock

16 Close the TapeStationDx Controller software.



17 Power down the instrument.

Packaging for Transportation

An instrument with activated transport lock and inserted fixation foam (see [Preparing the Instrument for Transportation](#) on page 170) is ready for boxing.

WARNING

Be careful when lifting the instrument.

- Because the instrument is heavy, lifting it will require the assistance of a second person to prevent injury.
-

CAUTION

Mechanical damage of the instrument

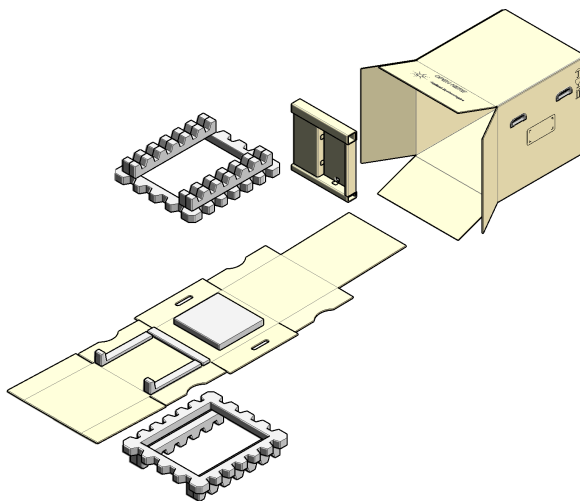
If the transport assembly is not prepared for transportation, the instrument could be damaged due to excessive shock of the shipping container during transport.

- Always prepare the unit for transportation before shipment, see [Preparing the Instrument for Transportation](#) on page 170.
 - Protect the instrument by transport protection material, see [Unpacking the Instrument](#) on page 183.
 - Store the transport protection material in a safe place to use for later transport of the instrument.
-

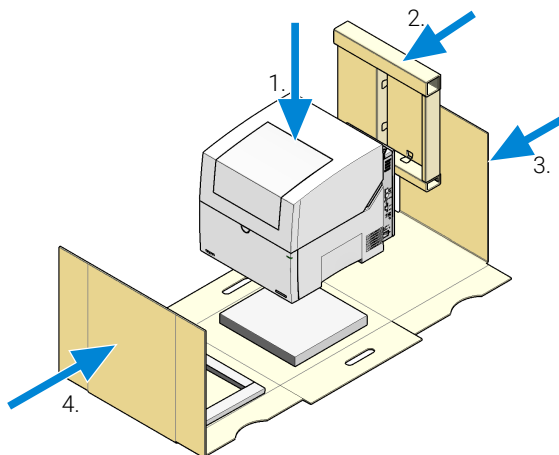
Instrument Movement

Packaging for Transportation

- 1 Provide dedicated packaging material for later use. This material will enclose the instrument later.



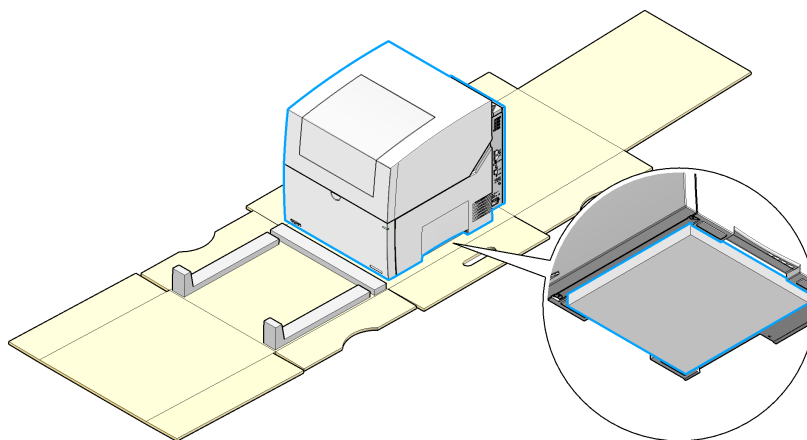
- 2 Place the inner cardboard box on the floor. Mind the orientation of the inner cardboard box and instrument.



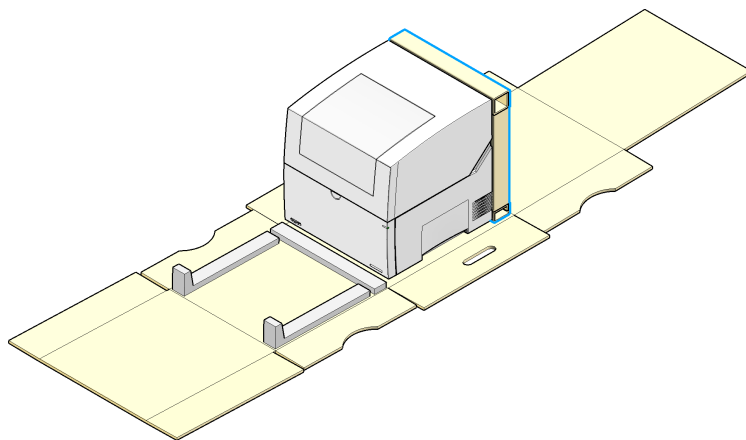
Instrument Movement

Packaging for Transportation

- 3 Lift instrument with two people onto inner cardboard. The foam fits in a recess of the bottom.



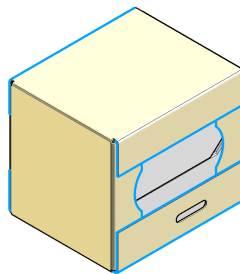
- 4 Mount the cardboard box to the back.



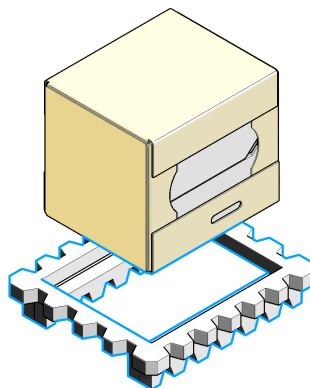
Instrument Movement

Packaging for Transportation

- 5 Close inner cardboard. First fold the rear part over the instrument. Next fold the front part over the instrument.



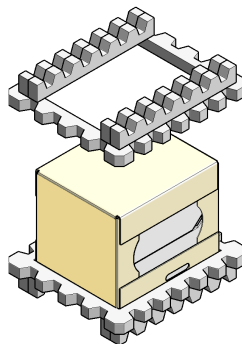
- 6 Place the instrument onto the bottom foam with two people.



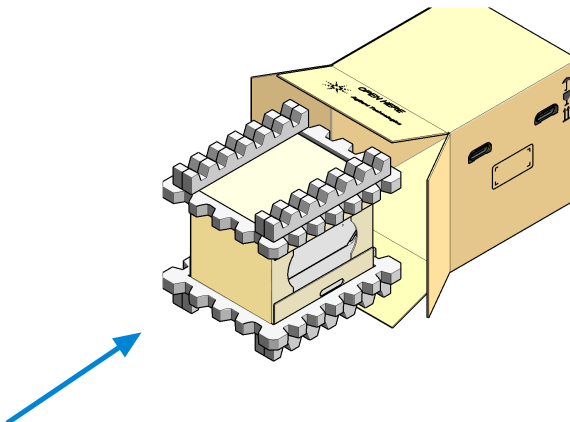
Instrument Movement

Packaging for Transportation

- 7 Add the top foam to the inner cardboard box.



- 8 Slide the instrument into the outer cardboard box.



Unpacking the Instrument

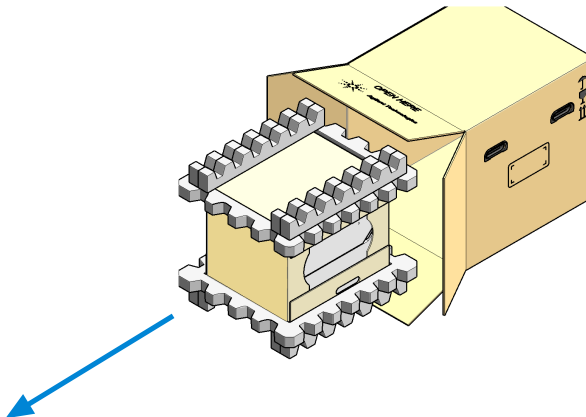
A certified Agilent representative must install a new TapeStationDx system and verify the instrument performance at the customer site.

For unpacking after relocation or repair follow the instructions listed below.

Do not remove the instrument from its original shipping box immediately. Upon delivery, store in a temperature stable, dry environment suitable for operation, see [Table 2 Technical specifications of the instrument](#) on page 11. If actual shipment conditions are unknown or were outside operating conditions, wait for at least 5 h before unpacking to allow the instrument to adjust to the ambient temperature and humidity of the operating environment.

Be aware of the Safety Precautions especially the [Environmental Requirements](#) on page 17 and the [Installation Requirements](#) on page 17.

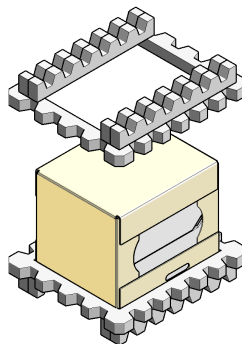
- 1 Place the instrument box on the floor and cut it open.
- 2 Pull the instrument out of the outer cardboard box.



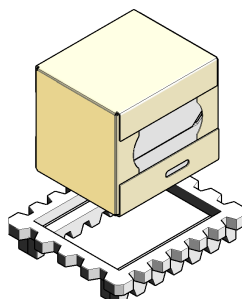
Instrument Movement

Unpacking the Instrument

- 3 Remove the top foam of the inner cardboard box.



- 4 Lift the instrument to remove the bottom foam packaging.



WARNING**Heart pacemakers**

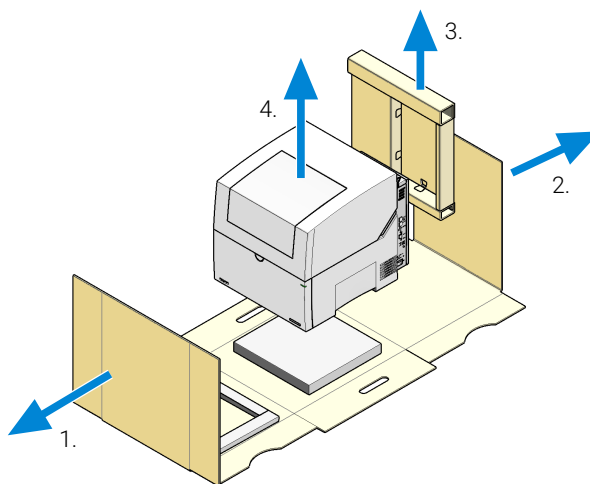
Magnets could affect the functioning of pacemakers and implanted heart defibrillators.

A pacemaker could switch into test mode and cause illness.

A heart defibrillator may stop working.

- Bearers of heart pacemakers or implanted defibrillators must stay off at least 55 mm from the magnets.

- 5 Open the inner cardboard box and move the instrument to its bench.

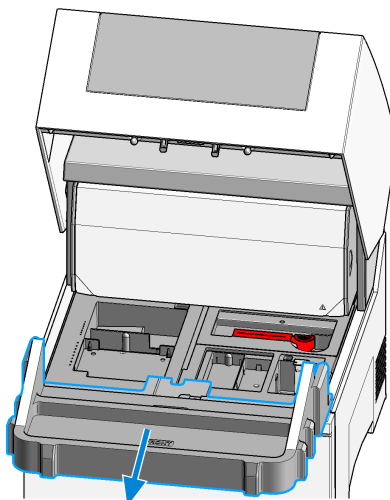


- 6 Open the lid by pressing the lid release button.

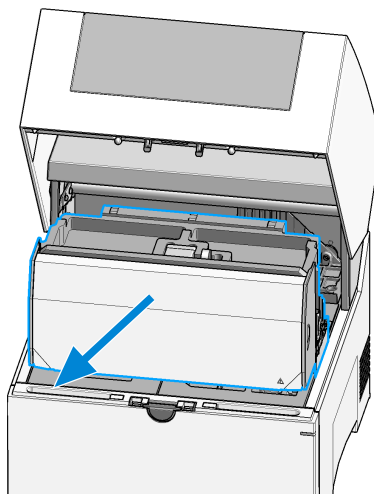
Instrument Movement

Unpacking the Instrument

- 7 Remove the workspace foam.



- 8 Carefully pull the gantry towards the front of the instrument.



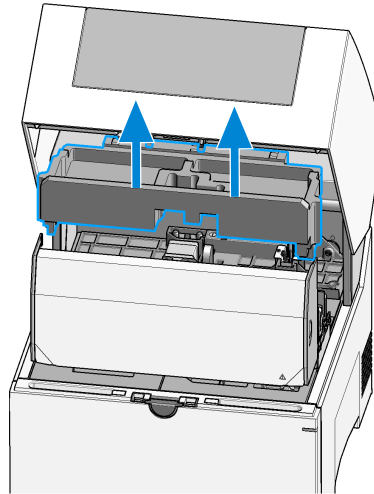
CAUTION

Damaged cables

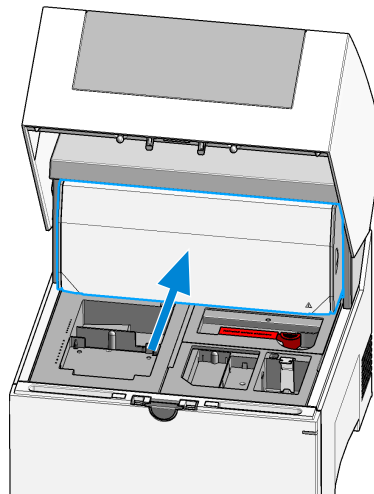
Instrument damage at pump cables.

— Handle the foam carefully without touching or damaging the cables.

9 Carefully lift the pump foam upwards.



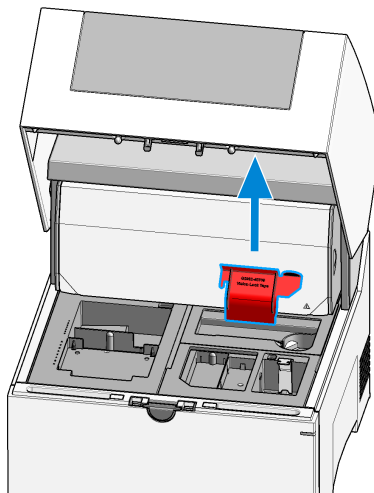
10 Push the gantry carefully towards the back of the instrument.



Instrument Movement

Unpacking the Instrument

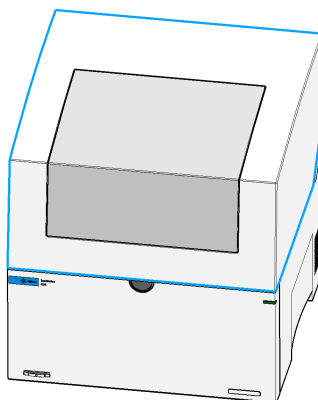
11 Remove the Vision lock tape.



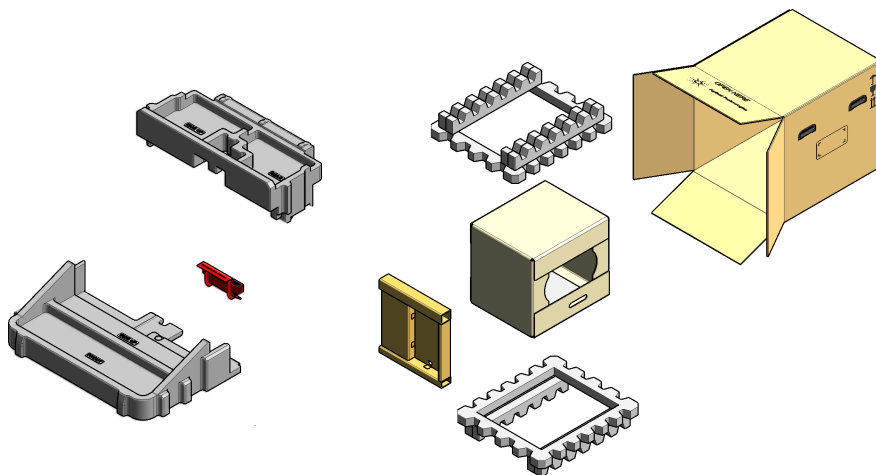
Instrument Movement

Unpacking the Instrument

12 Close the lid.



13 Keep all packaging material for later storage or shipment.



Collecting Troubleshooting Information

A feature within the TapeStationDx software is designed to assist in communication with Agilent technical support experts. For troubleshooting in a support case, the user might be asked to run the [System Verification](#) on page 131 and to provide the data created for review. There are two equivalent ways to collect this information conveniently:

- From the System Diagnostic Context of the TapeStationDx Controller software. See [Instrument Diagnostics](#) on page 126.
- From within the TapeStationDx Analysis software go to menu **File > Help > Export Log Files**.



Export Log Files

Export log files from the TapeStation Analysis Software, Controller Software. These may include result files from the TapeStation System Diagnostics.

The collected files contain internal log files generated by the TapeStationDx system, and result files from recent instrument diagnostic tests. This complete set is collected from various folder locations and provided as a ZIP file on the desktop to be sent out to Agilent technical support experts. Be aware that this package of log files does not include data files, experimental information or sample information. The exported information does not contain patient sensitive data. To properly describe an issue completely, the log files need to be collected, and additional information needs to be compiled.

NOTE

The log files must be created on the laptop connected to the TapeStationDx instrument with which the most recent or relevant tests have been performed.

Software Release Note

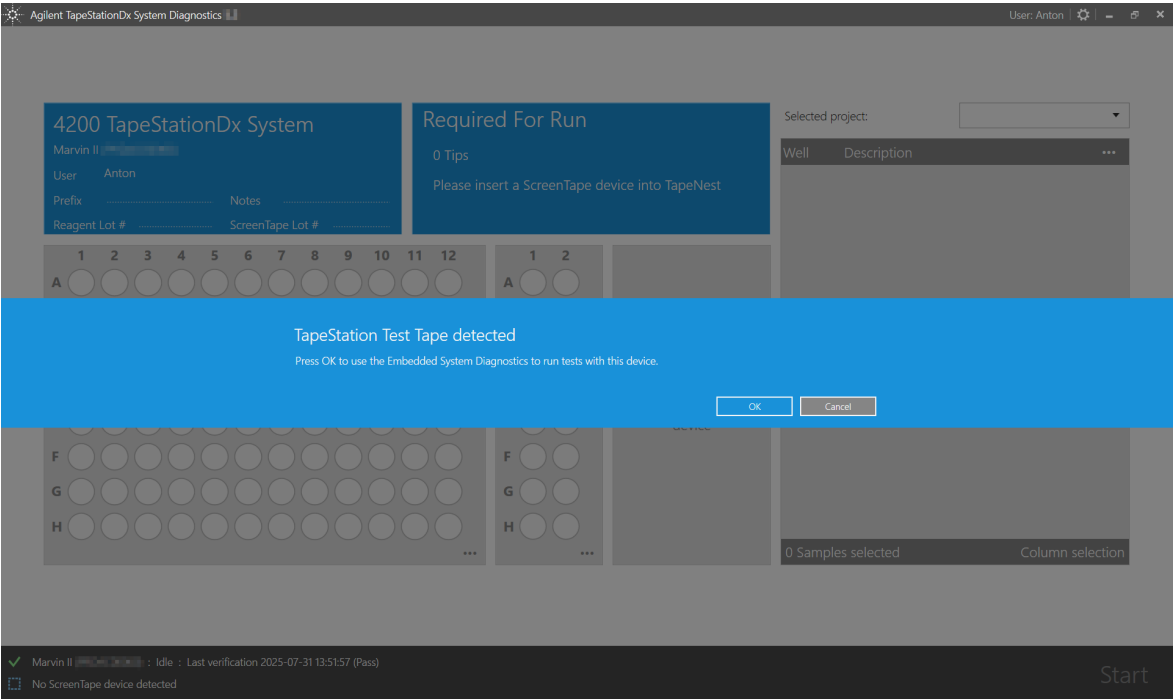
This document provides last-minute information and installation advice corresponding to the Agilent TapeStationDx software at the time of its release. To be up to date, visit <https://www.agilent.com> regularly and review the latest software release note revision.

The software release note contains information on new features and improvements of the respective software revision. This document contains valuable information on the minimum system requirements, such as PC hardware requirements, operating system requirements and system suitability. The software release note also provides software installation instructions. Additionally, it lists known limitations of the software to assist in bypassing any inconveniences.

Software Messages

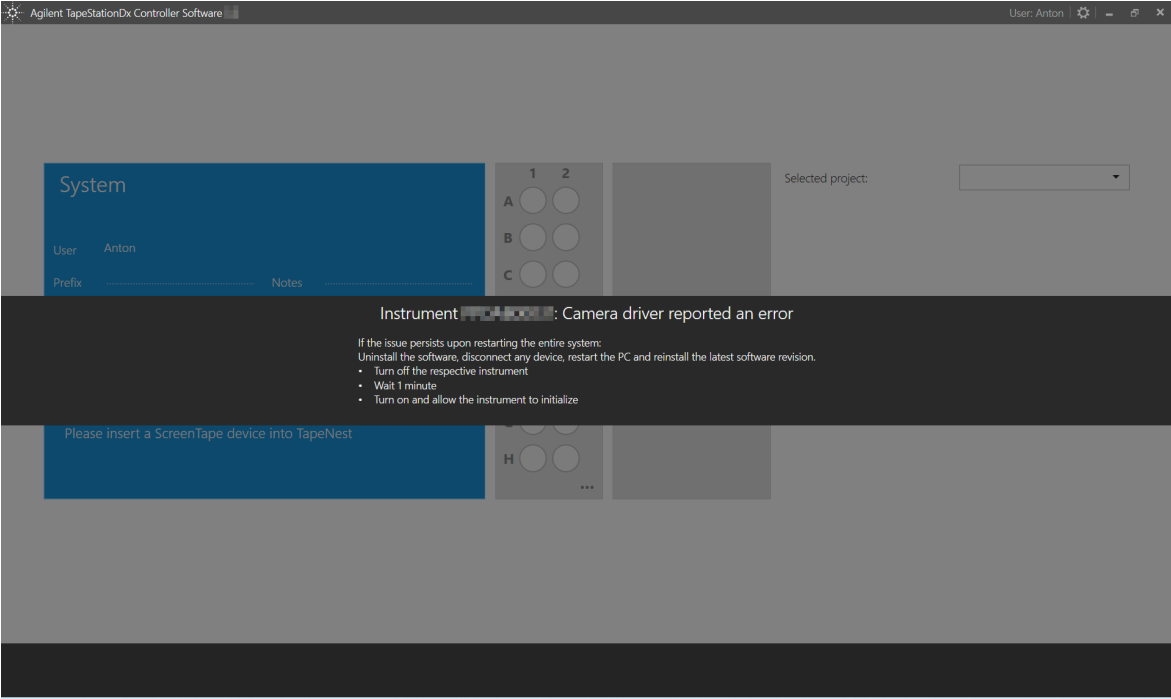
TapeStation Test Tape Detected

A TapeStation Test Tape (see [TapeStation Test Tape](#) on page 128) detected in the ScreenTape nest allows the user to start the System Diagnostics.



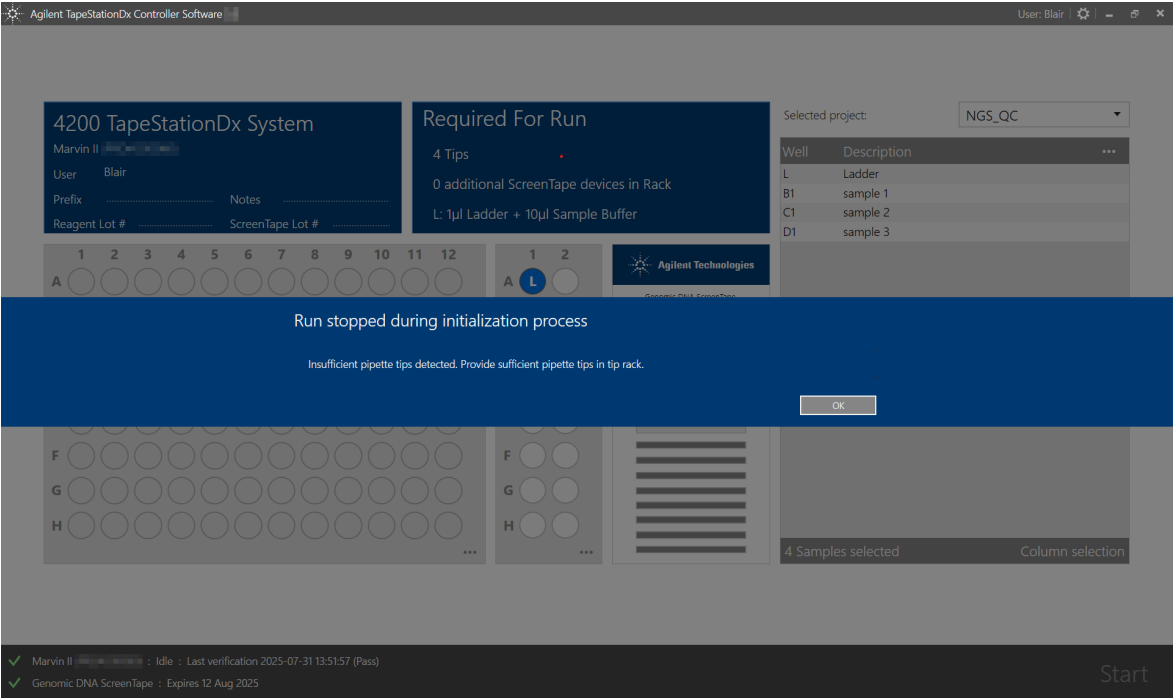
Camera Fault Detected

The TapeStationDx Controller software could not connect to the instrument’s camera. Check the USB connection to the instrument, power cycle the instrument and restart the software. In case of recurrence, reboot the laptop. See [Instrument Communication](#) on page 209 for details.



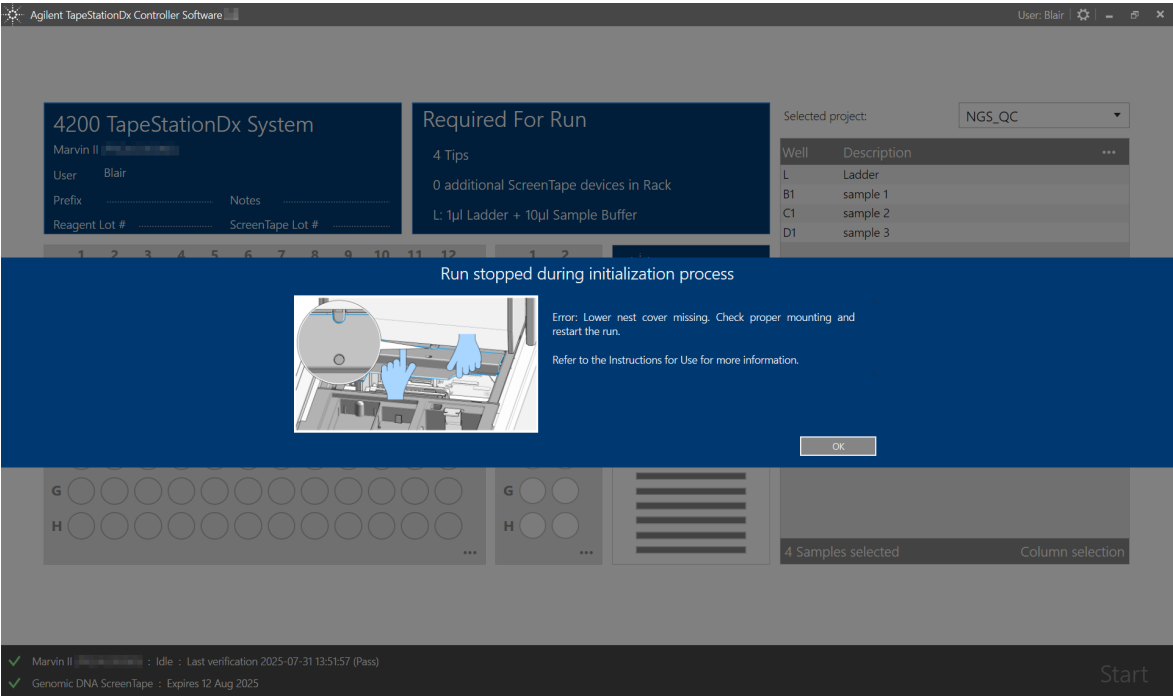
Run Stopped During the Initialization Process

The consumables required for a run were not detected. Provide sufficient ScreenTape devices (RUO) and loading tips in the tip rack. Remove tube strip caps, tip rack cover and empty the waste location.



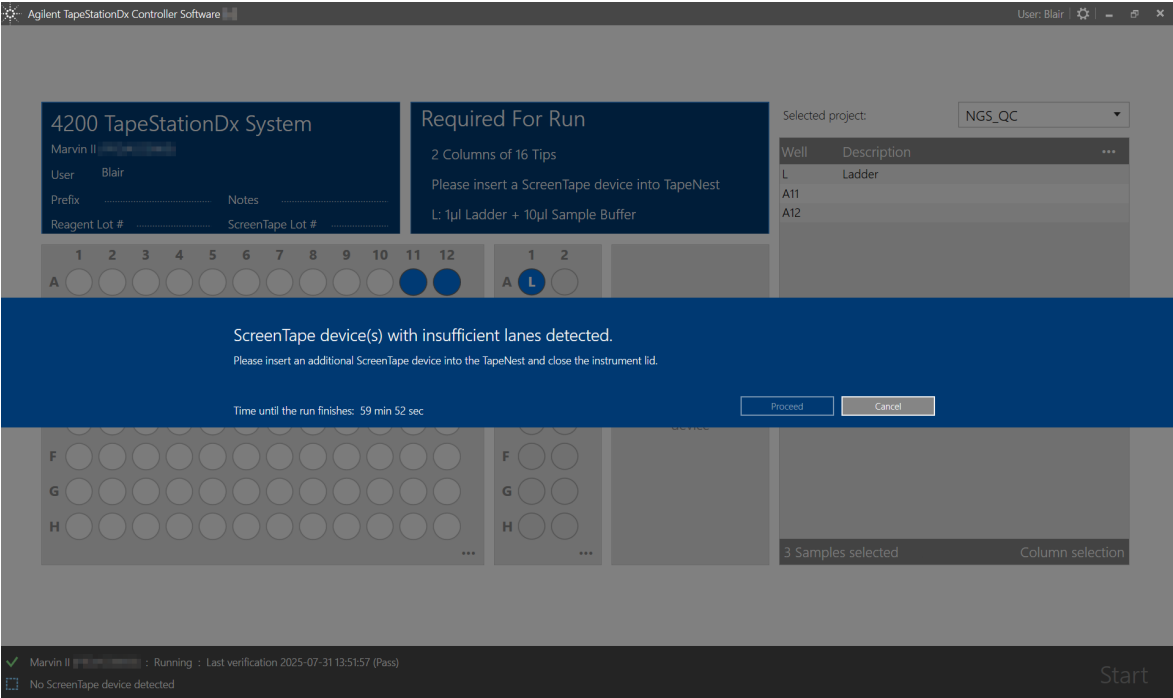
Block at Lower Nest Cover

The lower ScreenTape nest cover did not move and requires proper assembly. See [Assembling Lower Nest Cover](#) on page 160 for instructions.



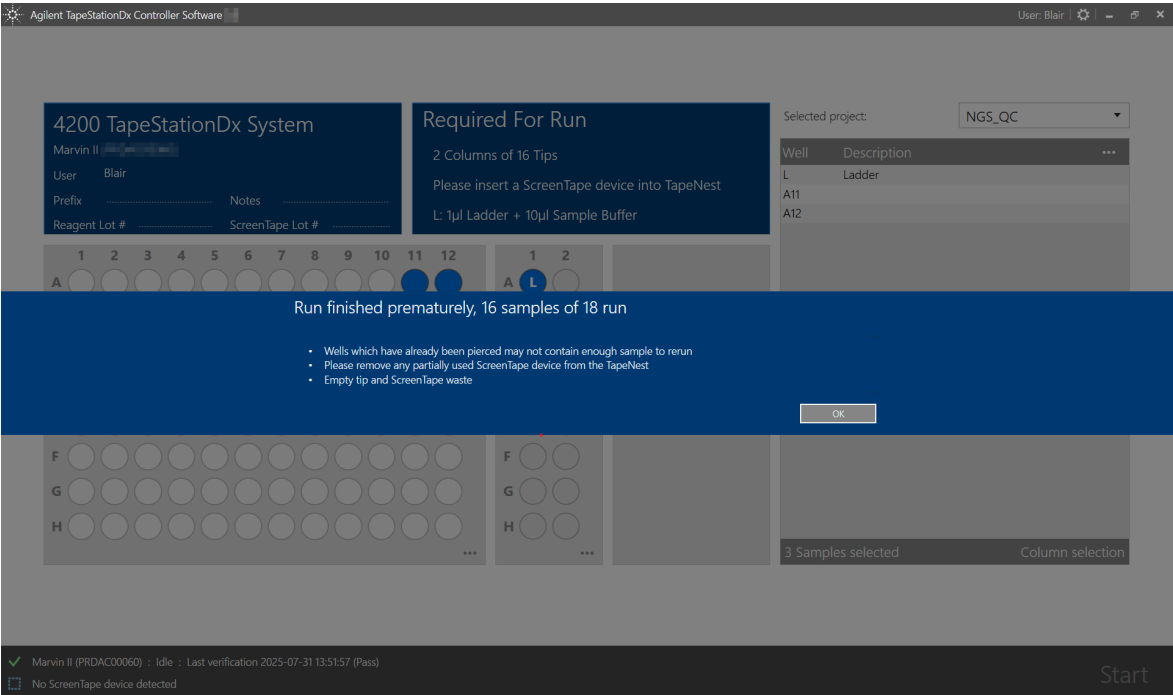
Insufficient Lanes Detected

Insufficient lanes on a ScreenTape device (RUO) were present. Add a second ScreenTape device (RUO) with sufficient unused lanes within the indicated time to finalize the analysis.



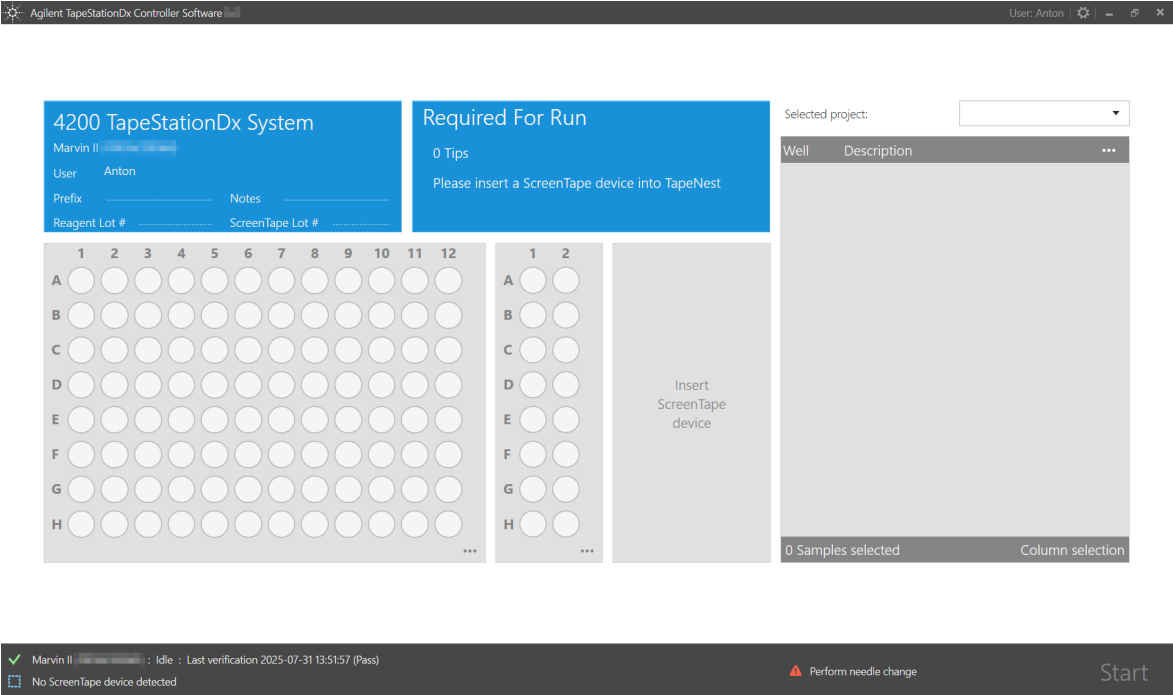
Premature End of Analysis

Insufficient number of correct ScreenTape devices (RUO) in the rack leads to a premature end of the analysis. Prepared samples that did not run due to an error may have aged, potentially rendering them unsuitable for analysis and requiring new preparation.



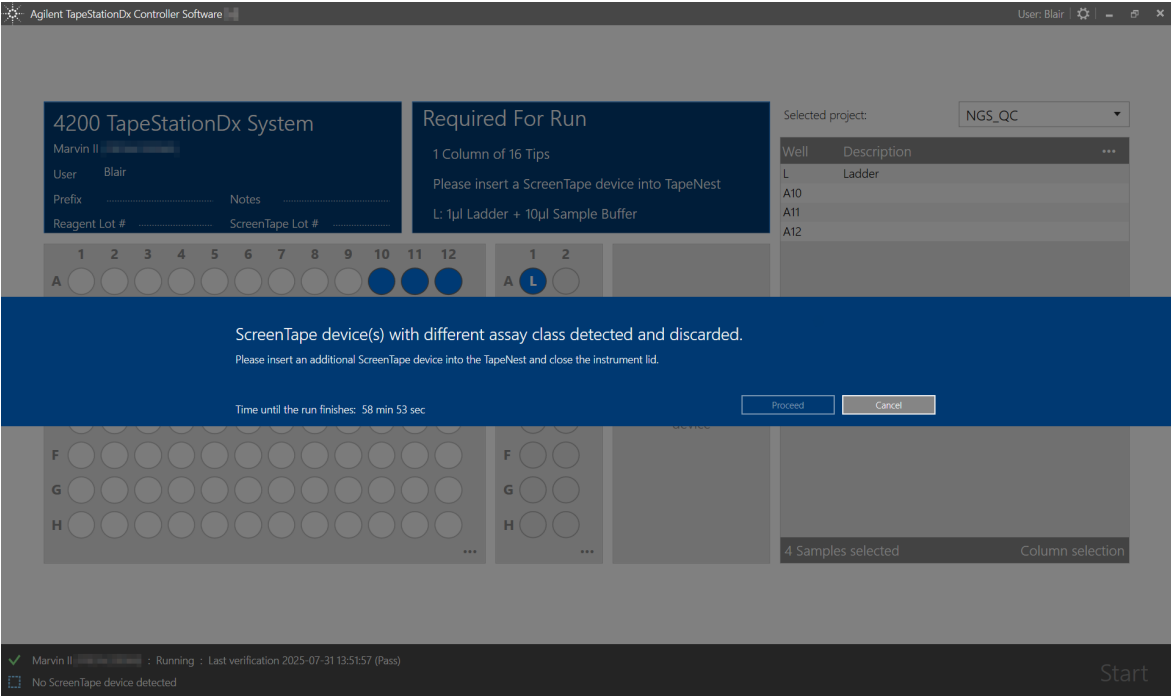
Perform Needle Change

Starting an analysis is inhibited if 4480 pierces are reached until a Needle Change is done. A warning message will be displayed after 3840 samples. This allows the user to prepare for corrective actions. See on page 144 and [Exchange the Piercing Needle](#) on page 145.



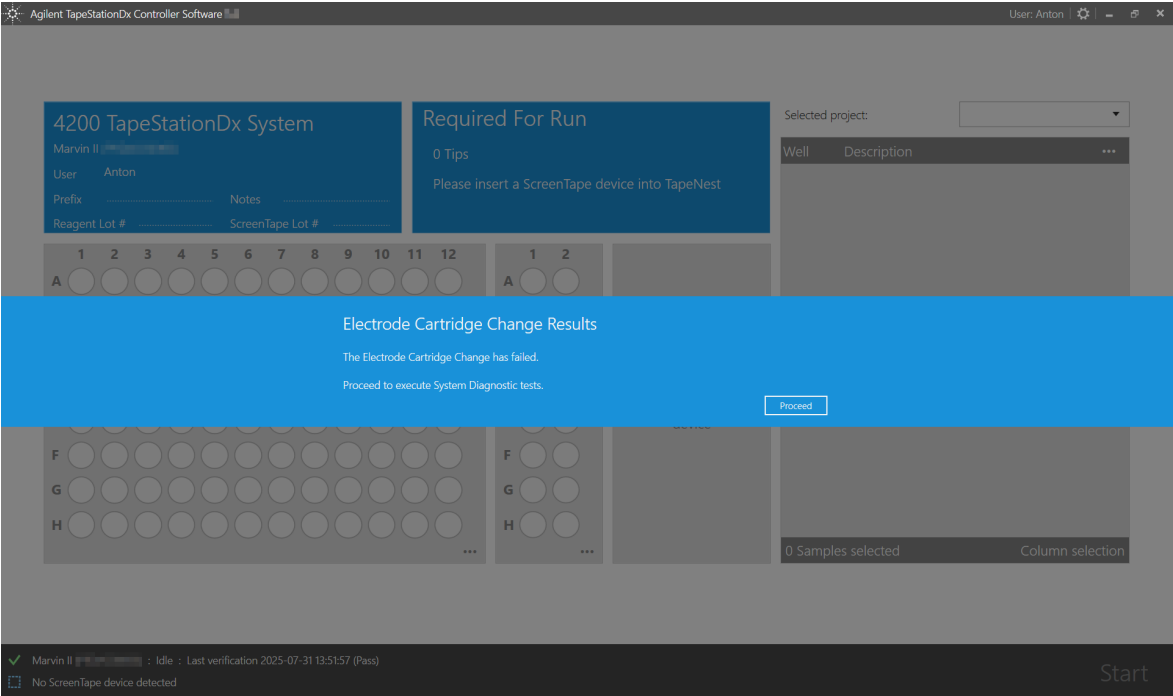
Different Assay Class Detected

ScreenTape devices (RUO) provided in the rack which do not match the assay are discarded during a run. Insertion of a correct ScreenTape device (RUO) into the ScreenTape nest is requested within 60 min at the end of analysis.



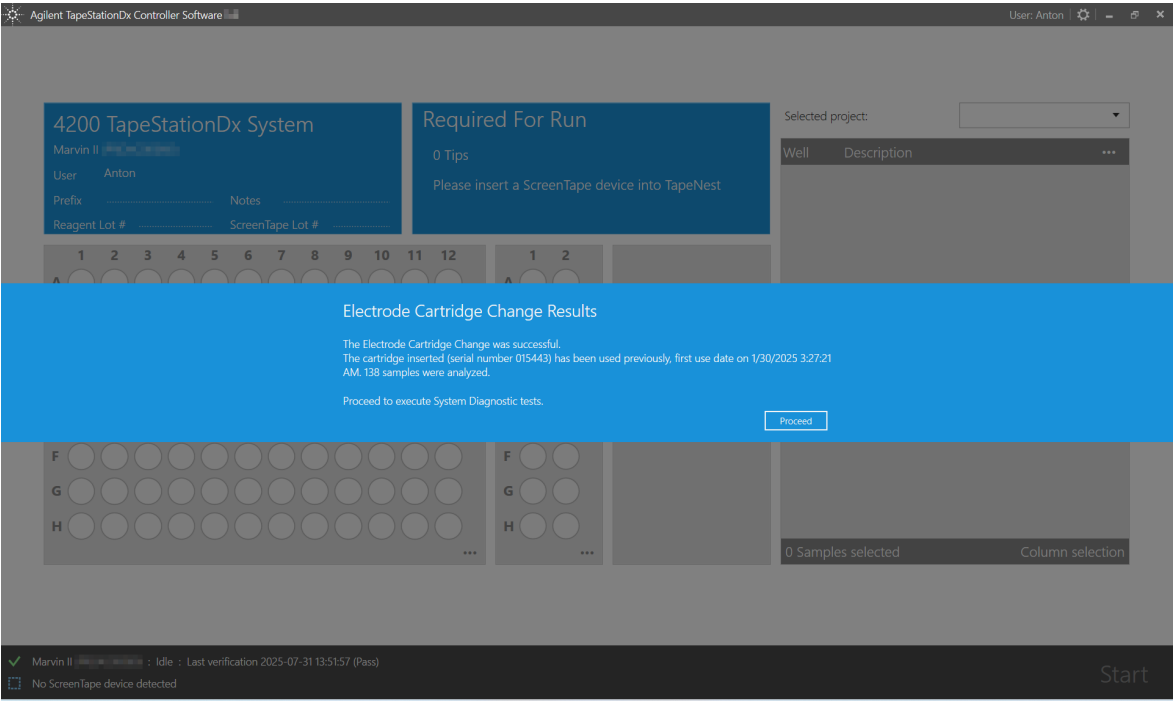
Electrode Cartridge Change Failed

If the electrode cartridge has failed, proceed to execute the System Diagnostic test. See [Executing System Verification Tests](#) on page 133. Repeat electrode cartridge exchange. If error persists, contact Agilent local support.



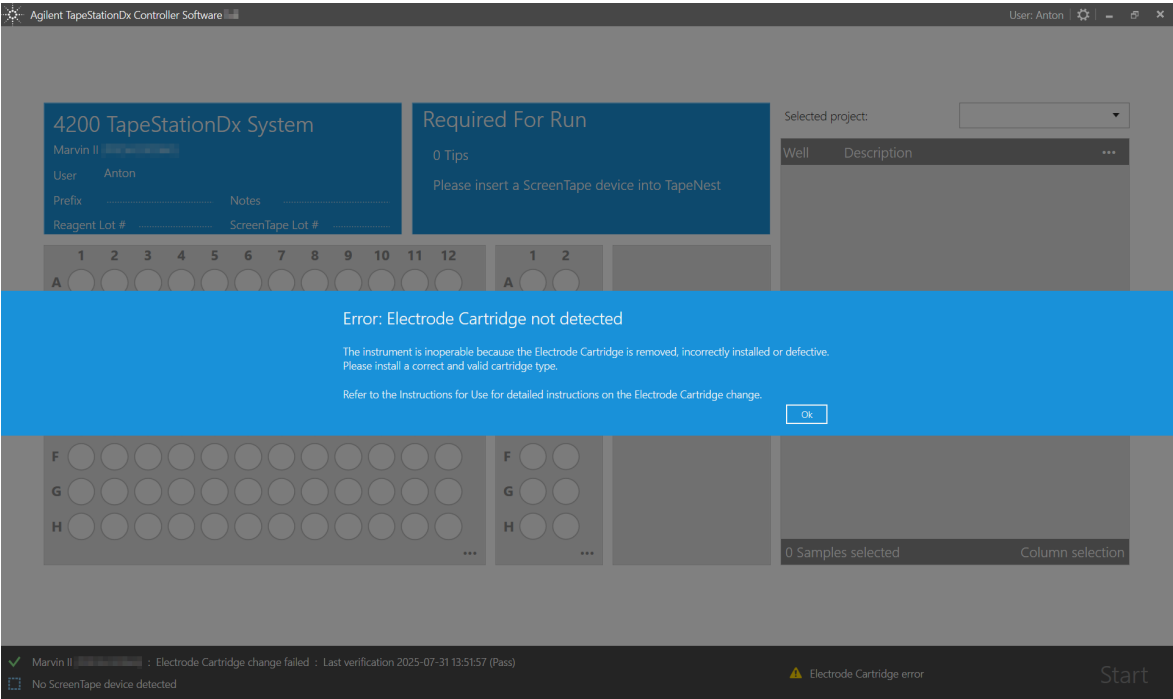
Used Electrode Cartridge Inserted

If a used cartridge is inserted, follow the instructions displayed on screen and proceed to execute System Diagnostic tests. See [Executing System Verification Tests](#) on page 133. Repeat exchange with a new electrode cartridge. If the error persists, contact local Agilent support.



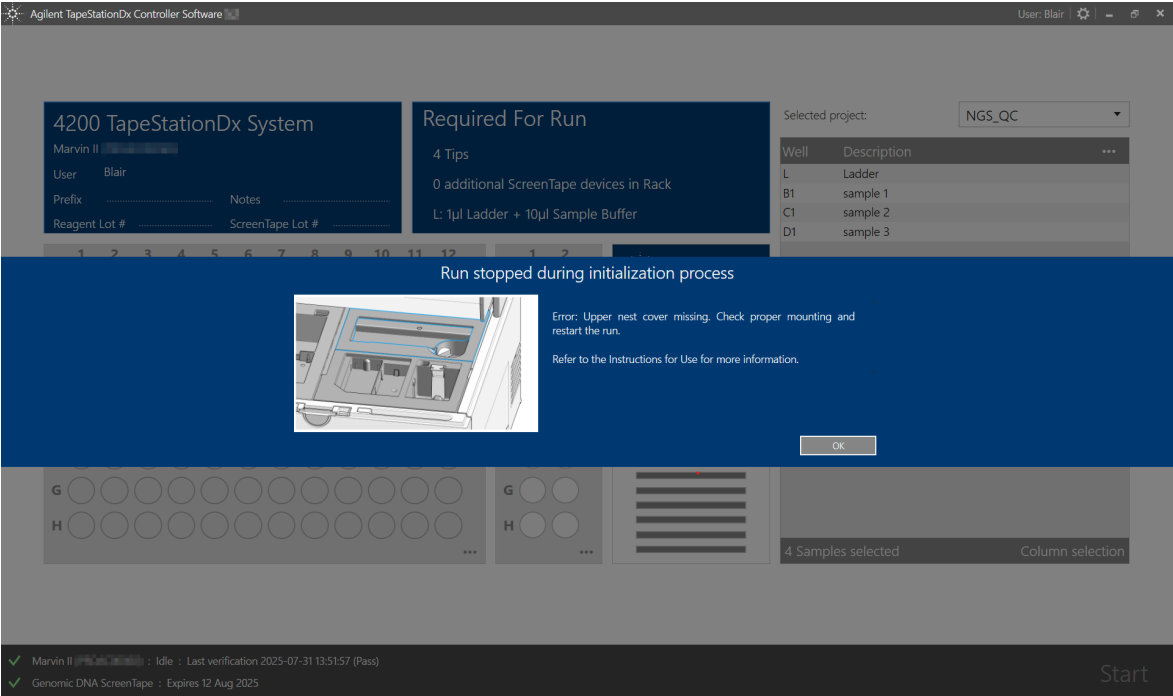
Electrode Cartridge Not Detected

The instrument is inoperable because the Electrode Cartridge is removed, incorrectly installed or defective. Click OK to start the installation process with a correct and valid cartridge. For further information, see [Electrode Cartridge](#) on page 148.



No Upper Nest Cover Detected

If the run stops during the initialization process because the upper nest cover is missing, check the proper mounting and restart the run. For more information see [Assembling Covers](#) on page 160.



Software and Data Troubleshooting

How to Change the Authentication Mode

Resetting the authentication mode equals changing the repository of users from Windows Active Directory to local Windows accounts, or vice versa. Resetting authentication mode is done under Global Settings within the TapeStationDx Administration software.

NOTE

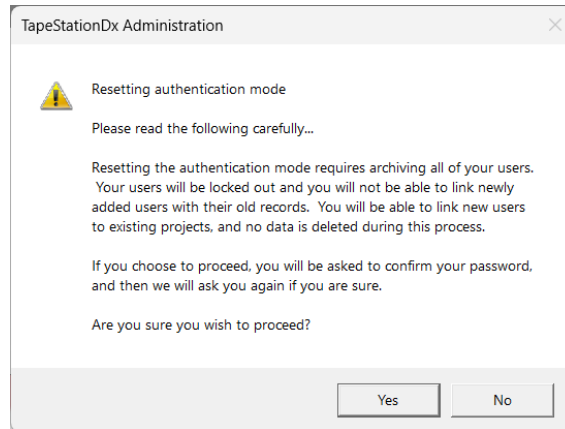
All previous users will be lost when changing the authentication mode.

When changing the authentication mode, previous users are automatically archived, which will lock out previous users. As a result, it will not be possible to link newly added users with their old data. For example, unlocking a data file or reverting an electronic signature becomes impossible. However, no data is deleted during this process. The user will be able to link new users to existing projects.

To change the authentication mode in the TapeStationDx Administration software, follow the steps below:

- 1 Log in to the TapeStationDx Administration software. A user with permission to manage global settings is required (e.g., a System Administrator).
- 2 Navigate to **Global Settings** and click **Edit Settings**. This opens the configuration window.
- 3 In the configuration window, select **Change Authentication Mode**.

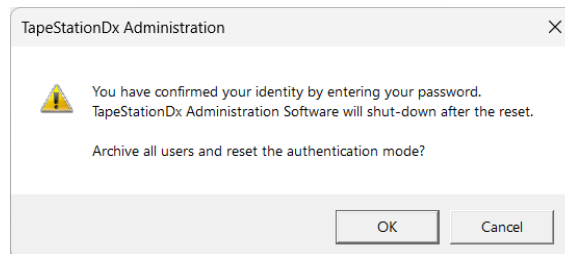
A confirmation dialog will appear with a disclaimer.



4 Click **Yes** to proceed.

5 Re-enter login credentials to confirm identity.

After successful authentication, a second confirmation window will appear.



6 Click **OK** to finalize the process. The TapeStationDx Administration software will automatically close.

How to Find the Role with Correct Permission

In case the default set of permissions lacks a permission to complete a task, please look up [Table 19 Permissions for different System Roles](#) on page 85 and [Table 20 Permissions for different Project Roles](#) on page 86 to identify the required permission.

Within the TapeStationDx software, project role permissions can be reviewed in:

- TapeStationDx Administration software under **Roles** tab.

- TapeStationDx Controller and Analysis software, from the respective user interface by clicking on the username in the header bar and selecting the relevant project.

To add the missing permission, a System Administrator can add the permission to an existing role via the **Roles** tab in the TapeStationDx Administration software.

Why Can't I Use Some of the Buttons?

Permission to use functions associated with buttons in software user interfaces are often bound to certain roles or permissions. Therefore, a button might appear grayed out and non-functional if the user currently logged in lacks the required permission. For any activity, Table [Table 19 Permissions for different System Roles](#) on page 85 and Table [Table 20 Permissions for different Project Roles](#) on page 86 indicate which default Role has which permission.

There might be other conditions underlying a disabled or greyed out button although permissions are present in principle. Be aware of software logic dependencies that may disable certain buttons until prerequisite steps are completed — for example, when a signature workflow is configured for the project.

Why is the Review Audit Events button disabled in the TapeStationDx Analysis software?

Users cannot review and sign their own modifications to the data file. In the TapeStationDx Analysis software, the button **Review Audit Events** will lead to a dialog that only has content if the respective modifications were not yet reviewed, and if the event originates from a user other than the currently logged-in user. Modifications which were already reviewed are visible in the **View Audit Trail** dialog with the timestamp and Meaning.

Can Data Files Be Reverted to an Earlier Version?

If changes have been made to a data file, the Analyst with the "Revert All File Changes" permission can reset the file to its original state, allowing the analysis to be restarted from the beginning. It is not possible to revert the file to a specific intermediate version.

Data file version changes are visible in the audit trail. The actual version is also visible under **File > Run Properties**.

How to Rescue Data From a Software Failure

If the TapeStationDx software becomes non-functional but data files and administrative reports related to projects and roles remain intact, the environment can be reestablished by uninstalling and reinstalling the software. In this case, projects, users, and roles will be automatically restored and available upon software reinstallation.

However, if a software failure not only hinders TapeStationDx software functionality but also leads to loss of data files and administrative reports related to projects and roles, reinstalling the software will not restore the environment. As a result, all projects, users and roles will need to be set up again. Data files will then need to be imported into newly created, projects. This correction leads to traces in the new audit trail of files and new system activity logs.

Is Archiving of Projects and Data Possible?

Archiving/de-archiving is done via the TapeStationDx Administration software under **Projects**. When a project is archived, it will no longer be selectable in the TapeStationDx Controller software. However, the data files previously recorded under the archived project remain in the data repository. All permissions associated with users assigned to the archived project are deactivated, including the ability to open these data files. As a result, the data becomes inaccessible to project members until the project is de-archived.

What Impact Do Runs With Non-Verified Systems Have on the Audit Trail?

If analytical runs are performed with a non-verified instrument, the top line of the audit trail will have a warning stating that the file was created using an instrument lacking a successful System Verification.

Audit Trail

Audit Trail

Warning: the file was created using an instrument lacking System Verification

Search

Clear

Start: 8/7/2025 15 End: 8/7/2025 15

Reset date filter

Username	Full name	Date	Description	Device name	Reviewed	Meaning	Category
Blair (6)	Blair Lewis	2025-08-07T14:32:56+02:00	File saved as version 1, filename: C:\Users\Anton\Documents\NGS_QC\2025-08-07\2025-08-07 - 14:26:34-X.HSD1000	AG-YU15OK2EJACN			Instrument Operation
Blair (6)	Blair Lewis	2025-08-07T14:32:56+02:00	Run finished on instrument TapeStationDx	AG-YU15OK2EJACN			Instrument Operation
Blair (6)	Blair Lewis	2025-08-07T14:28:13+02:00	Run started on instrument TapeStationDx using ScreenTape 01-S030-250710-01-003260 with 3 samples from Tube	AG-YU15OK2EJACN			Instrument Operation
Blair (6)	Blair Lewis	2025-08-07T14:26:34+02:00	Run initiated on instrument TapeStationDx for 2 samples from Tube. Last verification 2025-08-07 14:23:01 (Fail)	AG-YU15OK2EJACN			Instrument Operation
Blair (6)	Blair Lewis	2025-08-07T14:26:33+02:00	E-Signed "Instrument lacking System Verification" as Technician Comment: instrument not validated due to missing accessories Last verification 2025-08-07 14:23:01 (Fail)	AG-YU15OK2EJACN		Non-compliance - technical	Instrument Operation

PDF Export...

Print...

Close

Instrument Communication

Instrument and Laptop

This section gives an overview on best practices to help prevent communication issues between the laptop and the instrument.

Follow the guidelines outlined in [Table 29 Guidelines for preventing communication issues](#) on page 209 to ensure reliable communication between the control laptop and the TapeStationDx instrument.

Table 29: Guidelines for preventing communication issues

Category	Guidelines
Startup sequence	1. Power on the laptop and let it fully boot. 2. Power on the instrument with the lid closed. 3. Launch the TapeStationDx Controller software. See also Preparing the Working Area on page 95.
Data storage	Save data files to a local laptop folder. Network connection stability might be insufficient to store data during analytical runs. Transfer data files to network drives only after data acquisition is complete to avoid data loss and application crashes.
Regional settings	Set Windows operating system regional settings to English (United States). Confirm under customized format of numbers: • Decimal: . (dot) • Digit grouping: , (comma) • List separator: ; (comma) Different settings may cause failures.
Software restrictions	Avoid installing additional software applications. Avoid using USB devices unless these are HID-class USB devices.
User sessions	Always log off fully or reboot if multiple user accounts exist, as background processes from other users can cause communication issues.
Shutdown and maintenance	Power down the laptop and instrument when not in use. Check the latest software release note for issues. Keep Windows updated.

USB Connection

The TapeStationDx instrument connects to a bundled laptop via a specific USB cable (5188-8047 (USB cable A to B, 2 m)). Do not exchange this cable for a different one. Connection timeout due to different transfer rates can occur if using a different cable. For instructions on connecting the TapeStationDx instrument and laptop, please consult the section [Connecting the Instrument](#) on page 93 and additionally the latest release note.

- Do not install other USB devices.
Only HID (Human Interference Device)-class USB devices (e.g., keyboard, mouse, printer) are supported while the TapeStationDx instrument is running. Do not connect any other USB devices.
The imaging module in the TapeStationDx instrument is a high-resolution device that can use full USB bandwidth during imaging. Use of other USB devices at the same time can cause timing issues with the imaging module, which can lead to failed data acquisition or loss of camera connection.
The use of USB hubs, docking stations, or USB Type-C/micro-USB to USB-B converters is not supported and may result in instrument communication issues.
- Review the section [Windows Device Manager](#) on page 210 for further details on how to verify a proper USB connection.

NOTE

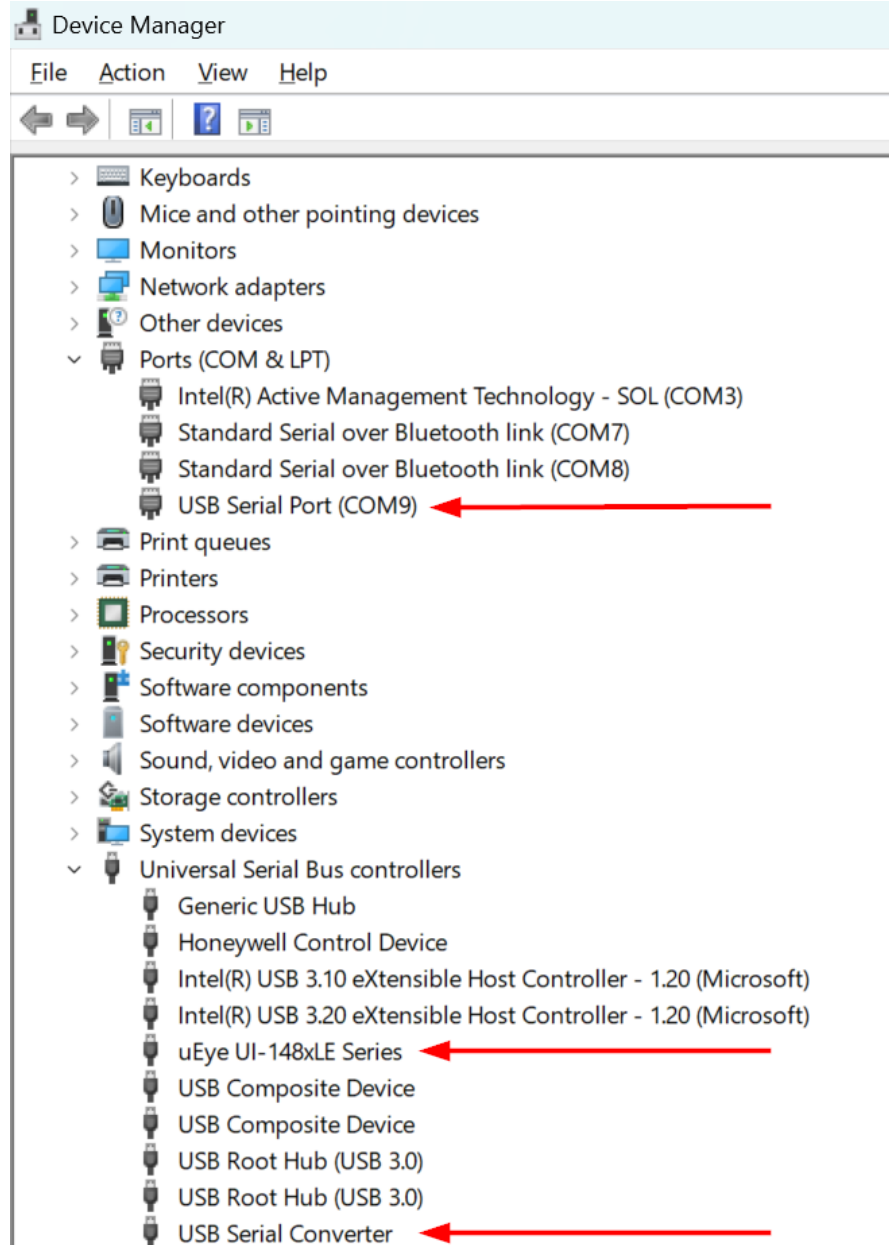
In case USB ports are swapped, give the operating system sufficient time to register this internally. Wait 1 minute after unplugging before plugging the USB connection into a different USB slot.

Windows Device Manager

Upon connecting the TapeStationDx instrument to the laptop, the device manager of the operating system will populate entries specific for the TapeStationDx instrument. Please refer to the figure below showing conditions for a correctly established instrument connection. In the following example, details may vary depending on the laptop model used.

The three relevant items associated with the connection of the TapeStationDx instrument are:

1. USB Serial Port (COM x)
2. uEye UI-148xLE Series
3. USB Serial Converter

**NOTE**

The COM port number (x) itself is variable. It is assigned by the operating system.

To access the device manager, go to Windows Start, type Device Manager, and click on the corresponding application.

In case one or more of the entries marked are missing or a problem is reported with one of them by the operating system, follow the steps provided in **Universal Corrective Actions** on page 212.

NOTE

Executing the System Diagnostics (see **Instrument Diagnostics** on page 126) to verify the laptop suitability and proper functions of the instrument assists the user to identify and correct connection issues of the system.

Universal Corrective Actions

This compilation of universal corrective actions will help to eliminate instrument communication issues.

NOTE

Executing the System Diagnostics (see **Instrument Diagnostics** on page 126) to verify the laptop suitability and proper functions of the instrument assists the user to identify and correct connection issues of the system.

NOTE

Ensure that the TapeStationDx instrument is NOT connected to the laptop during software installation or update. Else device drivers might be malfunctioning.

NOTE

Agilent does not support 3rd party PCs for the TapeStationDx system.

In case intermittent communication issues occur when connecting the instrument to the laptop, follow these steps:

- 1 Check if power and USB cables are plugged into the instrument.
- 2 If applicable, try a different USB port. Wait 1 minute between unplugging and re-plugging to another USB port. Check if the original issue persists.
- 3 Power cycle the instrument with closed lid. Check if the original issue persists.
- 4 Restart the laptop and the instrument. Check if the original issue persists.
- 5 Try a different USB port after the laptop is restarted and the instrument is initialized again. Check if the original issue persists.

- 6 Make sure all required Windows updates are present. See the latest software release note for reference.
- 7 Uninstall and reinstall the latest TapeStationDx software from the original media. Make sure all required Windows updates are installed.

In case the above steps did not resolve the original issue, the laptop might need to be re-imaged. This process is supported by the recovery media supplied with the system.

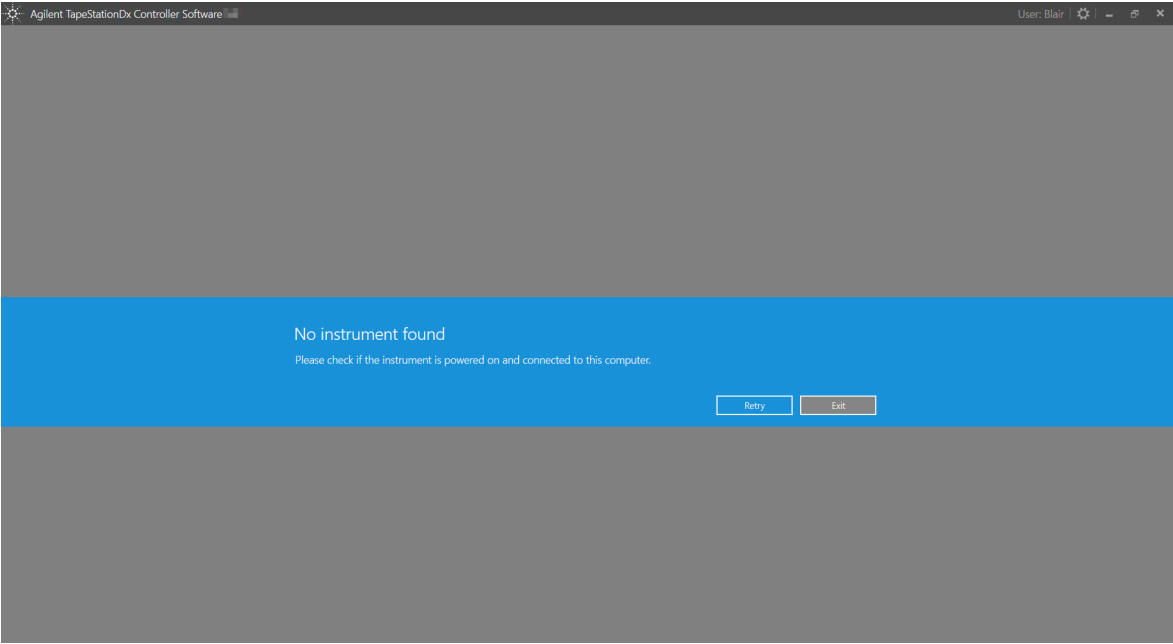
- 1 Carefully backup important data first.
- 2 Reimaging is done with the media provided in the shipment of the TapeStationDx system.
- 3 Set up the Windows operating system with regional settings English-US.
- 4 Apply Windows Updates through a connection to the internet. This process may take some time.

NOTE

Collect support information (see [Collecting Troubleshooting Information](#) on page 190) and contact local support.

Error Scenario: Instrument Not Connecting

In case an instrument is not connecting properly to the TapeStationDx Controller software, the user interface remains for 30 s with the animated message: Scanning for instrument. If no connection was established within this time frame, the following message appears: No instrument found. Check the instrument connection, power cycle the instrument and restart the software. If the error persists, restart the laptop.



NOTE

Ensure that the TapeStationDx instrument is NOT connected to the laptop during software installation or update. Else device drivers might be malfunctioning.

- 1 Follow the instructions provided by the software.
- 2 Execute the System Diagnostics ([Instrument Diagnostics](#) on page 126) to verify the laptop suitability and proper functions of the instrument.
- 3 Review failed tests and correct detected issues, if feasible.

Table 30: Further corrective actions

Possible reasons	Corrective actions
Instrument is turned off.	Connect power supply cable and turn the instrument on. Verify power cord is the one supplied with the instrument.
USB cable is unplugged or defective.	Connect the supported USB cable (5188-8047) properly or exchange it.

Possible reasons	Corrective actions
The laptop shows a malfunction in USB connection protocol. The operating system fails to enable USB or COM functionality.	Restart the laptop. See also Windows Device Manager on page 210.
The instrument is defective or not initializing correctly.	Turn on the instrument following all guidelines, see Connecting the Instrument on page 93 and Preparing the Working Area on page 95. If the error persists, execute the System Verification test suite. Collect support information (Collecting Troubleshooting Information on page 190) and contact local support
TapeStationDx Controller software is corrupt or inhibited by other conflicting software.	Restart the laptop to stop any interfering applications. If the issue continues, reinstall the TapeStationDx software and remove any additional software.
Drivers of other USB devices corrupted or inhibited TapeStationDx USB Device drivers.	Disconnect and uninstall foreign devices and software.
TapeStationDx USB Device drivers are not installed or malfunctioning.	Reinstall the TapeStationDx software. Make sure all required Windows updates are installed. See the latest software release note for reference.
Wrong Camera Driver Version Found.	The required camera driver is absent. Follow the instructions of the error message. Close the software, turn off any connected instrument, uninstall the TapeStationDx Software, restart the PC and finally reinstall the latest software revision to install the correct driver again.

NOTE

Refer to [Collecting Troubleshooting Information](#) on page 190 and contact local support.

Error Scenario: Unexpected Termination of the TapeStationDx Controller Software

The TapeStationDx Controller software may unexpectedly close when connected to an idle instrument or during an active run. Termination of the TapeStationDx Controller software might lead to error messages in the user interface containing

- Unexpected Error,
or
- Instrument Lost Connection.

If termination occurs during a run, a truncated data file may still contain results. Use File Explorer to navigate to the data folder and open the file by double-clicking it.

NOTE

In case a run with multiple tapes is terminated prematurely only that data is available that was recorded until the last completely processed ScreenTape device (RUO).

Table 31: Information for corrective actions

Possible reasons	Corrective actions
Instrument was turned off erroneously.	Verify that the instrument has no loose power connection. Put plugs in firmly. Avoid touching the cables while the instrument performs analytical runs. Avoid setups in which the power button can be touched accidentally. Check general power supply for instabilities or open fuses.
Instrument went into error mode (= resident).	Restart laptop and instrument. The instrument will initialize and try to clear the error.
USB cable is unplugged; physical connection is instable.	Verify that the USB connection has no loose cables. Put plugs in firmly. Exchange cable if appropriate. Avoid touching the cables during analytical runs.
Other USB devices or high USB traffic on the laptop, or busy network connections.	Disconnect and uninstall other USB devices. Avoid activities using the network during analytical runs.
Anti-virus scans dragging resources.	Avoid scheduled virus scans during analytical runs. If applicable, disconnect the PC from the Internet.
Communication issues with unknown root cause while using the laptop differently.	Avoid activities that include installing/uninstalling other applications, drivers, or use of the laptop which create extra USB/LAN data traffic.
Laptop is in power save mode for USB connections or the screen.	Do not activate additional power save settings or sleep modes for the laptop.
Error during startup of the TapeStationDx Analysis software after a run.	Ensure the TapeStationDx Analysis software has no open dialogue or is in error mode itself. Close the software entirely if in doubt; it will automatically reopen at the end of a run to display results.
Unforeseen activities or clicks in TapeStationDx Controller software.	Reduce activities such as changing preferred settings within the TapeStationDx Controller software to a minimum.

Error Scenario: ScreenTape Barcode Not Detected

In case the TapeStationDx Controller software graphical user interface doesn't display information of inserted tapes or even the assay:

- 1 Execute the System Diagnostics to verify the suitability of the laptop and the proper functions of the instrument.
- 2 Review failed tests and correct detected issues. Review the following information for further corrective actions.

Table 32: Information for corrective actions

Possible reasons	Corrective actions
ScreenTape device (RUO) inserted incorrectly	The barcode must be on the right-hand side and facing backwards. Push the ScreenTape device (RUO) down and ensure it is horizontally placed.
ScreenTape type (RUO) not supported	Do not use ScreenTape device (RUO) dedicated to other systems
Barcode is damaged, smeared or absent	Avoid mechanical stress on the ScreenTape barcode. Do not write on, dye, or remove and reattach the label.
Camera is not in default position after an instrument error	If an error occurred earlier, power cycle the instrument and restart the TapeStationDx Controller software. Keep the lid closed to allow full reinitialization.
The flashing green barcode illumination is absent	Power cycle the instrument and restart the TapeStationDx Controller software. Keep the lid closed to allow full reinitialization.
Data transfer issue of camera due to general communication issues	Follow the Universal Corrective Actions on page 212 for communication troubleshooting.

NOTE

Refer to [Collecting Troubleshooting Information](#) on page 190 and contact local support.

Error Scenario: Another Instance of the TapeStationDx Software Is Already Running

In case the TapeStationDx Controller software graphical user interface is unable to start while stating: Another instance of the TapeStationDx software is already running.

Table 33: Information for corrective actions

Possible reasons	Corrective actions
The controller application is running	Check open applications in the taskbar and avoid double-clicking repeatedly when starting.
Background process not yet turned off	Multiple processes require time for their proper termination. Allow 5-10 seconds after closing the application for this.
Background process not terminating despite wait time	Experts can end persistent processes via Task Manager, but a full laptop restart is recommended to terminate all processes.

Information on Failed Tests

Table 34: Troubleshooting for failed Computer Specifications checks

	Possible reasons	Corrective actions
Screen Resolution	Screen resolution is too low.	For information on the minimum resolution required, please refer to the appropriate software release note. To change screen resolution, right-click the desktop, select Display settings , then adjust the Display resolution dropdown.
Windows Screen DPI Scaling	DPI scaling is not set to 100%.	TapeStationDx works best with 100–200% DPI, ideally 125%. To adjust, right-click desktop > select Display settings > under Scale , select 125%.
Region and Language Settings	Regional settings are not set to English (US).	Go to Settings > Time & language > set Language & region settings to English (US).
Operating System Version	This operating system (OS) is not supported.	If the OS is unsupported, install a supported OS. For information on the supported OS for the installed software, please refer to the appropriate release note. Keep your OS updated regularly.
CPU Information	The PC does not meet the minimum requirements for the TapeStationDx software.	Ensure that the PC contains the minimum hardware requirements as per software release note.
Available Hard Disk Space	The largest amount of free space available on the TapeStationDx software installation drive (C:) is below our recommended free space limit of 20 GB.	Free up hard drive space: • Use disk analysis tools to find large files and folders • Uninstall unused programs and back up old data • Run Disk Cleanup to remove temporary files NOTE: Do not delete important system files, only personal files.

Table 35: Troubleshooting for failed Software Environment checks

	Possible reasons	Corrective actions
Incompatible Running Software	Incompatible software installed. Known conflict: Avast Antivirus 2015.	Avoid installing extra software on TapeStationDx bundled laptops.
Incompatible running software	An incompatible software or software process is currently running that prevents the TapeStationDx Controller software from running normally. Known co-execution conflicts: • Agilent LabAdvisor Software 2100 Expert Software	Close the conflicting software before continuing with performing the tests. To see which software is currently running, access the Windows Task Manager . Then select the incompatible application and click End Task .
.NET Framework	.NET version is older than required.	For information on the supported .NET version for the installed software, please refer to the appropriate release note. Check the installed .NET version on the laptop and if needed, download it directly from Microsoft.
TapeStationDx Software Installation	An issue with the TapeStationDx software installation was detected. The installation might not function properly.	Reinstall the TapeStationDx software. Consult the software release note for instructions on reinstalling the software.
Camera Driver Installation	The camera driver seems to be either of the wrong revision, missing or corrupted.	Reinstall the TapeStationDx software. Consult the software release note for instructions on reinstalling the software.

Table 36: Troubleshooting for failed Hardware Troubleshooting tests

	No.	Name	Description
Setup	Status LED	The user has accidentally selected the wrong button in the dialog box.	1. Repeat the test to rectify this. 2. If the test fails, contact Agilent support.
Vision	Barcode Read Test	The barcode of the TapeStation Test Tape or the Test Tape (TSTT) itself might be damaged and not readable. Failure of this test could also be caused by a communication conflict with other hardware or applications.	1. Repeat the test and try to insert the TSTT at a slightly different angle. 2. If the test still fails, repeat it with a different TSTT. NOTE: This test can be executed with any regular ScreenTape device (RUO). However, ensure that you do not use this regular ScreenTape device (RUO) for other diagnostic tests. 3. If the test still fails, ensure that no conflicting hardware is connected. Repeat the test and execute the software verification tests. 4. Restart the laptop and software then power cycle the instrument. Execute the System Verification tests again. 5. If the test fails, contact Agilent support.
	Filter Test	A ScreenTape device (RUO) has been inserted instead of a TSTT. A communication conflict with other hardware or applications.	1. Repeat the test using a TSTT. 2. If the test still fails, ensure that no conflicting hardware is connected. Repeat the test and execute the Software Verification tests. 3. Restart the laptop and software then power cycle the instrument. Execute the System Verification tests again. 4. If the test fails, contact Agilent support.
	FOV Test Intensity Test Uniformity Test	A ScreenTape device (RUO) was used. The TapeStation Test Tape (TSTT) used could be dirty or damaged.	1. Repeat the test using a TSTT. 2. If the test fails, try using a different TSTT. 3. If the test still fails, contact Agilent support.
Electrophoresis	Temperature Sensors	The temperature at the ScreenTape nest is too high.	1. Give the instrument time to cool down. 2. If the instrument cannot cool down, correct the ambient conditions, for example, move the instrument to another location. NOTE: If the unit has to be transferred to another location, engage the transportation lock before moving it. Release the lock before next use, see Transportation Lock on page 169 and Preparing the Instrument for Transportation on page 170. 3. If the test still fails, contact Agilent support.
	Read TapeStation Test Tape	A ScreenTape device (RUO) was used. The TapeStation Test Tape (TSTT) used could be dirty or damaged or expired	1. Repeat the test using a TSTT. 2. If the test fails, try using a different TSTT. 3. If the test still fails, contact Agilent support.

No.	Name	Description
Electrophoresis Cartridge Connectivity	The built-in resistors or the contact electrodes of the TapeStation Test Tape (TSTT) might be damaged.	1. Check whether a preventive maintenance of the instrument is overdue, especially if the same lane fails in the application. If necessary, schedule a preventive maintenance service. 2. If the test still fails, contact Agilent support.
Electrophoresis Voltage Supply Check Electrophoresis Stability Test	A ScreenTape device (RUO) was used. The built-in resistors or the contact electrodes of the TapeStation Test Tape (TSTT) might be damaged.	1. Repeat the test, using a TSTT. 2. If the test fails, try using a different TSTT. 3. If the test fails, check whether a preventive maintenance of the instrument is overdue, especially if the same lane fails in the application. If necessary, schedule a preventive maintenance service. 4. If the test still fails, contact Agilent support.
Electrophoresis Current Leakage	A TapeStation Test Tape (TSTT) or a ScreenTape device (RUO) was used.	1. Repeat the test, without any TSTT or ScreenTape device (RUO). 2. If the test fails, check whether a preventive maintenance of the instrument is overdue, especially if the same lane fails in the application. If necessary, schedule a preventive maintenance service. 3. If the test still fails, contact Agilent support.
Robotics	Gantry Axes	The cover for the pump and robotics unit is loose. 1. Visually check that the cover is properly mounted. 2. In the case of a loose or improperly mounted cover, contact Agilent support to schedule a visit by a service engineer to rectify this issue. NOTE: A piercing needle is located behind the gantry cover. Do not remove the cover or reach under it. 3. If the test fails for a different reason, contact Agilent support.
	Calibrate Robotics	The ScreenTape nest cover is not positioned correctly and gets stuck. 1. Visually check that the cover is properly mounted. 2. In the case of a loose or improperly mounted cover, contact Agilent support to schedule a visit by a service engineer to rectify this issue. NOTE: A piercing needle is located behind the gantry cover. Do not remove the cover or reach under it. 3. If the test fails for a different reason, contact Agilent support.
	Teach Pump-ML-Z	The requested 96-well sample plate was not inserted. 1. Insert a 96-well sample plate into the TapeStationDx instrument. 2. Repeat the test. 3. If the test still fails, contact Agilent support.

No.	Name	Description
Tip Detection And Handling	The tip rack is missing. There is an insufficient number of pipette tips in the tip rack (a full tip rack is required for this test). The tip rack is still covered by the lid.	1. Insert a full tip rack with 112 tips and remove its lid. 2. Repeat the test. 3. If the test fails for a different reason, contact Agilent support.
Needle To Pump	The piercing needle in the instrument was removed unintentionally, which is indicated by a "Perform needle change" message in the TapeStationDx Controller interface. An incomplete needle exchange. A failure indicates a bad piercing performance and, subsequently, the application might suffer.	1. Restart the laptop connected to the TapeStationDx instrument. 2. Power cycle the instrument. Make sure the lid is closed. 3. Restart the TapeStationDx Controller software. 4. Perform a needle exchange with a new and different needle cartridge. See Exchange the Piercing Needle for details. 5. Repeat the System Verification tests to verify that the piercing needle is now correctly positioned. 6. If other errors occur, or if the needle exchange fails repeatedly, contact Agilent support.
Tape Handling	It could fail if the requested ScreenTape device (RUO) in any position of the tape rack is missing, or if the barcode of the ScreenTape device (RUO) is not readable.	1. Insert a new regular ScreenTape device (RUO) into the tape rack and repeat the test. 2. If the test fails, use a different ScreenTape device (RUO). 3. If the test still fails, contact Agilent support.

Revision History

Table 37: Revision History

Revision	Date	Changes
A.00	January 2026	Initial release

Manufacturer and Service Informations

Legal Manufacturer



Agilent Technologies Singapore (International) Pte Ltd.
No. 1 Yishrun Avenue 7, Singapore 768923
Hardware Manufactured at:
Agilent Technologies LDA Malaysia Sdn. Bhd.
Bayan Lepas, Free Industrial Zone 11900, Penang, Malaysia
Software Manufactured at:
Agilent Technologies Deutschland GmbH
Hewlett-Packard-Str. 8
76337 Waldbronn, Germany

Authorized Representative for the European Union



Agilent Technologies Denmark ApS
Produktionsvej 42
2600 Glostrup, Denmark

Authorized Representative for the United Kingdom



Agilent Technologies LDA UK Limited
5500 Lakeside, Cheadle Royal Business Park
Cheadle, Cheshire, SK8 3GR, UK

Authorized Representative for Switzerland



Agilent Technologies (Schweiz) AG
Lautengartenstrasse 6
4052 Basel, Switzerland

European Union and Switzerland Importer



Agilent Technologies Deutschland GmbH
Hewlett-Packard-Str. 8
76337 Waldbronn, Germany



Agilent Technologies (Schweiz) AG
Lautengartenstrasse 6
4052 Basel, Switzerland

Agilent Worldwide Technical Support

Telephone support for US and Canada
Call 800-227-9770

For all other regions

Agilent's worldwide Sales and Support Center contact details for your location can be obtained at www.agilent.com/en/contact-us/page.

When contacting Agilent Worldwide Technical Support with a support issue, please be prepared to provide the following information:

- Instrument serial number
- Description of the issue
- Log files (see **Collecting Troubleshooting Information** on page 190)
- TapeStationDx run files

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority, or appropriate regulatory body, in the country or region in which the user and/or the patient is established.

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