QuantStudio[™] 6 Pro Real-Time PCR System and QuantStudio[™] 7 Pro Real-Time PCR System

USER GUIDE

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Revision	Date	Description
М	12 November	v1.8.1 or later
	2024	• The instructions to create a background plate were updated. The volume for a 96-well background plate was updated. Instructions were added to create a 384-well background plate ("Create a background plate (optional)" on page 104).
		• The environmental requirements were updated. The temperature was updated to indicate that rapid or extreme fluctuations in temperature should be avoided ("Environmental requirements" on page 222).
L	7 May 2024	v1.8.1 or later
		• Instructions were added to copy and delete sample setup files ("Manage sample setup files" on page 83).
		 The functions that can be controlled on the instrument were updated to include exporting files, overwriting files, and keeping multiple copies of files ("Functions that are controlled on the QuantStudio[™] 7 Pro Real- Time PCR Instrument" on page 148).
		 The information about default permissions after upgrading an application profile was corrected. The roles do not receive the permission for the new functions. Only the Administrator role receives the permissions for the new functions ("SAE Administrator Console roles" on page 151).
		 The default roles and permissions for data management on the instrument were updated ("Default permissions for the QuantStudio[™] 7 Pro Real-Time PCR Instrument" on page 152).
		The following sections were updated to include the new functions that are controlled:
		 "Transfer a data file immediately after a run" on page 86
		 "Transfer data files at a later time" on page 87
		 "Delete data files from the instrument" on page 89
		– "Copy plate files" on page 81
		 "Delete plate files" on page 82
		 "Perform calibrations" on page 97
		- "Perform calibrations" on page 108
		 "Perform a custom dye calibration" on page 126
		Calibrate for a custom melt curve run" on page 128
		 "Export a calibration report" on page 95
		- "Transfer calibration results" on page 101
		 "Transfer calibration data files" on page 101
		 "View the license agreement" on page 189
		 "Perform a hardware test" on page 198
		 "Perform a peripheral test" on page 199
		- "Export the instrument log" on page 204
		- "Back up the instrument" on page 206
		 The permission required to change the data management settings was updated ("Manage the settings for data export and data import" on page 214).
		 The instructions to update the software were updated to indicate that you might need to check for updates over one minute to two minutes if the software update is on a USB drive ("Update the software" on page 205).
		• The option to set the file name convention of the data file as a system setting was added ("Manage the file name convention of the data file" on page 211).
		 The instructions to connect the instrument to a network were updated ("Connect the computer to the instrument directly or to a LAN" on page 223).

Revision	Date	Description
K.0	23 February 2024	v1.8 or later
		• The feature to manage settings for data export and data import was added ("Manage the settings for data export and data import" on page 214).
		• The option to keep both data files or overwrite a data file was added when a data file is being transferred more than one time ("Transfer a data file immediately after a run" on page 86 and "Transfer data files at a later time" on page 87).
		• The information about backing up the instrument and restoring a backup of the instrument was corrected ("Back up the instrument" on page 206 and "Restore a backup of the instrument" on page 207).
		 The information roles and permissions was updated. When an application profile is upgraded, the default permissions of any new functions in the new application profile are not applied. All of the roles receive the permission for the new functions ("SAE Administrator Console roles" on page 151).
		• The functions that are controlled in the instrument and in the software were updated ("Functions that are controlled on the QuantStudio [™] 7 Pro Real-Time PCR Instrument" on page 148 and "Functions that are controlled in the QuantStudio [™] Design and Analysis Software 2" on page 149).
		 The default permissions for the instrument and the software were updated ("Default permissions for the QuantStudio[™] 7 Pro Real-Time PCR Instrument" on page 152 and "Default permissions for the QuantStudio[™] Design and Analysis Software 2" on page 154).
		 The information about the order of installing the application profiles was updated. The application profile for QuantStudio™ Design and Analysis Software v2.8 or later does not require that the application profile for the QuantStudio™ 7 Pro Real-Time PCR Instrument is installed ("Application profiles" on page 159).
		 The option to transfer a debug EDS file from calibration was added (applies to v1.5 and later, "Transfer calibration data files" on page 101).
		 The instructions to view calibration images were updated to include dye selection ("View the calibration images" on page 99).
J.0	27 October 2023	v1.5.0 or later
		The disclaimer of license statement for software was removed.
		 Recommendations were added for a password policy for SAE user accounts ("Recommendations for passwords" on page 17).
		 The definitions of Thermo Fisher[™] Connect Platform were updated ("Thermo Fisher[™] Connect Platform definitions" on page 29).
		 Information was added about installation tasks for a computer ("Installation and instrument verification" on page 45).
		• The information about the ramp rate was corrected. The maximum ramp rate depends on the block type ("Configure ramp rates" on page 66).
		 Additional information was provided for each SAE Administrator Console component ("Overview of the SAE Administrator Console components" on page 147).
		• The SAE functions were updated ("SAE Administrator Console functions" on page 148).
		Information was added to indicate that the template files and data files are checksum protected.
		 The information about application profiles for the SAE Administrator Console was updated ("Application profiles" on page 159).
		 The instructions to enable the SAE functions were updated in order to provide more information ("Enable the SAE functions" on page 159).
		 Additional information was provided if a connection cannot be made between the application and the SAE Administrator Console server ("SAE error messages and actions" on page 176).
		The default SAE user account permissions were added.
		 The following instructions were added: _ Enter an audit reason in the QuantStudio[™] Design and Analysis Software 2
		– Enter an e-signature in the QuantStudio [™] Design and Analysis Software 2
		– View audit records for objects in the QuantStudio [™] Design and Analysis Software 2
		_ View e-signature records in the QuantStudio [™] Design and Analysis Software 2
		 Generate an e-signature report
		Instructions were added to connect the instrument to a network drive.

Revision	Date	Description
J.0	27 October 2023	• The information about monitoring instruments was updated ("Monitor instruments" on page 228).
ued)		• The processor requirements for the computer for the desktop software were updated.
		• The safety standards were updated ("Safety standards" on page 254).
H.0	28 July 2021	v1.5.0
		Updated the RNase P instrument verification after calibration to a recommendation only.
		 Added instructions to select the language, to enable or disable the reminder to insert a plate, and to import a TaqMan[™] Assay file.
		Updated the instructions to manage the naming convention for the data file.
		• Removed the connection option of the instrument when connecting to the Thermo Fisher [™] Connect Platform (connection options are mobile device and computer).
		Updated the Security, Auditing, and E-signature (SAE) Administrator Console to v2.1 or later.
G.0	17 February 2021	v1.4.0
		Updated centrifuges for the TaqMan™ Array Card.
F.0	6 November 2020	v1.4.0
		 Specified that the instrument and the desktop software must be connected to the same SAE server for an account password to be updated on both applications.
		• Provided the option of a static IP address or a dynamic IP address to connect to the SAE server.
		Corrected standards on 384-well RNase P plate (Figure 14 on page 112).
		 Added a TaqMan[™] Array Card block, including system template file names, calibration workflow, instructions to edit the plate file, and instructions to load and unload from the instrument (QuantStudio[™] 7 Pro System only).
		• Added instructions to review the calibration status in the QuantStudio™ Design and Analysis Software 2.
		Added a peripheral self-test and updated the previous self-verification test to a hardware test.
		• Added instructions to upload a certificate for a TaqMan [™] Array Plate with RFID.
		Added the option of a voice recording for Smart Help.
		Added remote support.
		Updated the RFID labels (Figure 27 on page 244 and Figure 28 on page 245).
E.0	27 April 2020	v1.3.0
		Added protein thermal shift experiments to the instrument functions.
		Added a 96-well 0.1-mL block.
		 Updated instructions to export data files when setting up a run and added instructions to import or delete export settings.
		Updated instructions to save an edited run method.
		Updated instructions to add or edit reagents and then to apply the reagents to the plate.
		Updated instructions to view the amplification plot after a run.
		Added instructions to view QC Check status after the run.
		Added information about a locked template file.
		Added functions for using the instrument with the SAE Administrator Console.

Revision	Date	Description
D.0	7 January 2020	v1.2.1
		Added information about position to set up facial authentication and to sign in with facial authentication.
		• Added instructions to test the connection to the Thermo Fisher™ Connect Platform and to view the privacy policy for the Thermo Fisher™ Connect Platform.
		Added instructions to repair the software after a software update.
		Changed port 7000 to 7443 for the instrument-to-computer connection.
		Corrected Ct to Cq in description of instrument verification.
C.0	3 December 2019	v1.2.0
		Added a 384-well plate block.
		Updated instructions to set up facial authentication.
		Added a new voice command for calibration.
		Added custom melt curve run calibration.
		Added Security, Auditing, and E-signature (SAE) v2.0 module.
		Added instructions to generate and reset an access key for external software to connect to the instrument.
		Added instructions to import an Assay Information File.
		 Corrected that a Thermo Fisher[™] Connect Platform profile is required for the instrument schedule and Smart Help.
		Added new radio compliance standards.
B.0	22 August 2019	v1.1.0
		Corrected the text on the buttons for the following items:
		 Add facial authentication to an existing instrument profile.
		 View the license agreement.
		 Reset the instrument (restore factory default).
		Added the following items: TET ^{IIII} dve as a custom dve
		Information about sleep mode
		_ information about sleep mode.
		The entire to configure the instrument so that sign in is required (quest access is not permitted)
		 The option to compare the instrument so that sign-in is required (guest access is not permitted).
		Information about the appellar volume for each user
		Information about the speaker volume for each user. Instructions to back up the instrument and to restore a backup of the instrument.
		 Instructions to back up the instrument and to restore a backup of the instrument. Information about multiple instruments and email notification in the comparison of a local instrument
		protile and a Thermo Fisher™ Connect Platform protile.
		Instructions to unlink a memor isner Connect Platform profile.
		Lighting guidelings for facial authorition
		Badio compliance standarde and PE transcolver epositientions
		- Corrected the following items:
		 Indicators for voice commands.
		 Voice commands are only available in select countries.
		Instructions to remove VeriFlex [™] Zones and the Auto Delta setting.
		 Excitation and emission wavelengths of the filters in the calibration instructions.

Revision	Date	Description
B.0 (contin-	22 August 2019	 Add a four-digit PIN when signing into the instrument for the first time using a Thermo Fisher™ Connect Platform profile.
ueu)		 Add a four-digit PIN when linking a local instrument profile to a Thermo Fisher[™] Connect Platform profile.
		_ Select a region for the Thermo Fisher™ Connect Platform.
		 A run cannot be started if a block has never been calibrated on the instrument.
		 The options after a calibration run is complete.
		 The example files for the desktop software are embedded in the software and do not need to be downloaded.
		Updated the following items:
		 Cq Export checkbox is selected as the default.
		 Instructions to sign in with facial authentication.
A.0	18 April 2019	New document (v1.0.1).

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Network and password security requirements

Network configuration and security

The network configuration and security settings of your laboratory or facility (such as firewalls, antivirus software, network passwords) are the sole responsibility of your facility administrator, IT, and security personnel. This product does not provide any network or security configuration files, utilities, or instructions.

If external or network drives are connected to the software, it is the responsibility of your IT personnel to ensure that such drives are configured and secured correctly to prevent data corruption or loss. It is the responsibility of your facility administrator, IT, and security personnel to prevent the use of any unsecured ports (such as USB, Ethernet) and ensure that the system security is maintained.

Password security

Thermo Fisher Scientific strongly recommends that you maintain unique passwords for all accounts in use on this product. All passwords should be reset upon first sign in to the product. Change passwords according to your organization's password policy.

It is the sole responsibility of your IT personnel to develop and enforce secure use of passwords.

Recommendations for passwords

Thermo Fisher Scientific recommends enabling a password policy for SAE user accounts with the following minimum number of characters:

- Administrative users: 12 characters
- Non-administrative users: 8 characters

The use of a password manager is recommended in order to help to create secure passwords.



Instrument hardware description

Overview of the instrument

The Applied Biosystems[™] QuantStudio[™] 6 Pro and 7 Pro Real-Time PCR Systems use fluorescentbased polymerase chain reaction (PCR) reagents to perform the following functions:

- Quantitative detection of target nucleic acid sequences (targets)
- Qualitative detection of targets (endpoint analysis)
- Qualitative analysis of the PCR product (post-PCR target nucleic acid sequences melt curve analysis)
- Protein thermal shift experiments



Each instrument is available with an interchangeable block. The following blocks are available:

- 96-well 0.2-mL block
- 96-well 0.1-mL block
- 384-well block
- TaqMan[™] Array Card block (QuantStudio[™] 7 Pro System only)

The instrument can be used directly from the touchscreen to create and start runs. To design runs or to analyze data, the instrument can be integrated with the desktop software or the Thermo Fisher[™] Connect Platform.

Each instrument has the following features:

- Sign-in with facial authentication
- An interchangeable block
- Microphone for voice commands
- · Speakers for feedback from voice commands and for instructional videos

- Smart Help to request technical support or instrument service directly from the instrument
- Barcode scanner for tracking plates or TaqMan[™] Array Cards

Features of each instrument

Feature	QuantStudio [™] 6 Pro System	QuantStudio [™] 7 Pro System
Filter set ^[1]	Coupled five-color filter set	Decoupled six-by-six color filter set
VeriFlex™ Zones ^[2]	Three VeriFlex™ Zones	Six VeriFlex™ Zones
TaqMan™ Array Card block	_	Available
Security, Auditing, and E-signature Administrator Console	_	Available ^[3]

^[1] See "System dyes" on page 19.

^[2] See "VeriFlex[™] Zones" on page 21.

^[3] See Chapter 9, "Use the instrument with the Security, Auditing, and E-signature (SAE) Administrator Console".

Instrument filters and supported dyes

System dyes

The QuantStudio[™] 6 Pro Real-Time PCR System has a coupled five-color filter set.

The QuantStudio[™] 7 Pro Real-Time PCR System has a decoupled six-by-six color filter set.

For more information about available spectral dye calibration kits, contact Support.

Peak	Color	Filter wavelength (nm) ^[1]		Sustan duas	Example sustam dues	
filter		Excitation	Emission	System dyes	Example custom dyes	
x1-m1	Blue	470 ± 15	520 ± 15	FAM™ dye, SYBR Green™ dye	SYT09	
x2-m2	Green	520 ± 10	558 ± 11	VIC™ dye	JOE [™] dye, HEX [™] dye, TET [™] dye ^[2]	
x3-m3	Yellow	550 ± 11	586 ± 10	NED™ dye, TAMRA™ dye, ABY™ dye	Cy [®] 3 dye	
x4-m4	Orange	580 ± 10	623 ± 14	ROX™ dye, JUN™ dye	Texas Red™ dye	
x5-m5	Red	640 ± 10	682 ± 14	MUSTANG PURPLE™ dye, Cy [®] 5	LIZ™ dye	
x6-m6	Deep-Red	662 ± 10	711 ± 12	None ^[3]	Cy [®] 5.5 dye	

^[1] The central wavelengths are the optimized wavelengths.

[2] The HEX[™] dye and TET[™] dye from Thermo Fisher Scientific fall within the emission wavelength range of the system, therefore they can be added and adapted for use on the instrument.

^[3] This filter set currently does not support any dyes supplied by Thermo Fisher Scientific.



- (2) x2-m2−VIC[™] dye
- ③ x3-m3-ABY[™] dye, NED[™] dye, Cy[®]3, TAMRA[™] dye

(4) x4-m4−JUN[™] dye, ROX[™] dye, Texas Red[™] dye
(5) x5-m5−Cy[®] 5, MUSTANG PURPLE[™] dye

Custom dyes

The instrument can run assays designed with custom dyes. Custom dyes include the following options:

- Dyes that are not supplied by Thermo Fisher Scientific.
- Dyes or formulations of dyes that are not system dyes for the instrument.

To use a custom dye on the instrument, review the following requirements.

- Calibrate the instrument for the custom dye (see "Calibrate custom dyes" on page 120).
- Ensure that the custom dye excites between 455–672 nm and emits between 505–723 nm.
- Select a custom dye that does not overlap with other dyes used in the run (see "System dyes" on page 19).
- The custom dye for use in calibration must be attached to the 5' end of a short DNA oligonucleotide consisting of the first two bases of the probe sequence without a quencher at the 3' end.

Overview of data collection

The instrument collects raw fluorescence data at different points during the PCR cycle, depending on the type of run performed.

When you create a plate file, you can customize the optical filter channels through which the instrument collects data. You can specify a filter channel set for all PCR thermal protocols and for melt curve stages.

Run type	Run type	Data collection point
Real-time	 Standard curve Relative standard curve Comparative C_t (ΔΔC_t) Melt curve 	During the thermal cycling protocol. Typical timing is to collect data at each cycle of a PCR stage or continuously during a melt stage.
Post-PCR (endpoint)	GenotypingPresence/absence	 After thermal cycling is completed. For Presence/Absence and Genotyping analysis, data collection before the PCR cycle is optional, but recommended. (Optional) During the thermal cycling protocol. Collecting data during the run can confirm genotyping results by viewing traces in allelic discrimination plots or viewing genotyping calls at earlier cycles.

VeriFlex[™] Zones

VeriFlex[™] Zones provide independent temperature zones that offer enhanced functionality and precise control over your real-time PCR runs.

The independent zones are ideal for real-time PCR optimization. They also provide the ability to perform multiple runs at the same time. Unlike standard gradients which give a sigmoidal temperature curve across the columns, blocks with VeriFlex[™] Zones help to deliver accurate temperatures across every zone.

The QuantStudio[™] 6 Pro System has three VeriFlex[™] Zones (Figure 1 on page 22). The QuantStudio[™] 7 Pro System has six VeriFlex[™] Zones (Figure 2 on page 22).

Note: VeriFlex[™] Zones are only applicable for the 96-well 0.2-mL block and the 96-well 0.1-mL block.



Figure 1 Three VeriFlex[™] Zones



Figure 2 Six VeriFlex[™] Zones

Note: Plate files are not compatible between the QuantStudio[™] 6 Pro System and the QuantStudio[™] 7 Pro System. For more information, see "Compatibility of plate files" on page 32.

AutoDelta settings

AutoDelta enables an incremental increase or decrease in the temperature or time in a PCR cycle.

To use AutoDelta, specify a difference in the time and the temperature. Specify the PCR cycle for this change to be applied.

Parts of the instrument





- 1 Cameras
- (2) Touchscreen
- ③ Microphones
- ④ USB port
- 5 Indicator light

- 6 Proximity sensor
- \bigcirc Access door for block change
- (8) Speakers
- (9) Drawer



Note: The instrument recognizes only one external storage device at a time for data transfer.

The USB ports at the rear of the instrument can be used for external devices, for example, a mouse or a keyboard.



Instrument status indicator

Indicator	Instrument status
Off	Powered off
	Sleep mode
Blue light changing brightness slowly	Powering on
Blue light changing brightness	Standby
Blue light moving inwards towards middle of instrument	Drawer opening
Blue light moving outwards towards side of instrument	Drawer closing
Blue light moving back and forth	Block is being changed
Blue light on	Instrument is ready to start a run or is performing a run
Amber blinking	Error

Hands-free features

Facial authentication

The instrument allows hands-free facial authentication to sign in a user. The instrument camera detects a face. The instrument will sign in the user after the face is matched to the photo associated with a profile.

Voice commands

The instrument recognizes a set of commands for hands-free operation. For list of supported voice commands, see "Use voice commands" on page 49.

Voice commands are only available when a user is signed in with a Thermo Fisher[™] Connect Platform account. Voice commands are not available with a local instrument profile.

Voice commands are only available in select countries.

Voice commands use Amazon[™] Alexa[™] for Business.



Indicators for the hands-free features

Indicators for facial authentication

Display	Status of facial authentication
The Sign In screen displays 🌋.	Facial authentication for the instrument is enabled.
The Sign In screen does not display 🔹.	Facial authentication for the instrument is disabled.All users must sign in with a PIN.
	Note: To enable facial authentication, see "Configure the instrument for the hands-free features" on page 211.

Indicators for voice commands

For the location of the proximity sensor, see Figure 3 on page 23.

Display	Status of voice commands
(Gray)	The voice command function is not available because the proximity sensor does not detect a person.
(€)(Gray)	 The voice command function is not available if any of these conditions is true: The voice command function for the instrument is disabled by an administrator. The user is signed in with a local profile. The microphone was disabled by the user and the proximity sensor does not detect a person. The icon will return to a red state when the proximity sensor detects a person.
(Amber)	The instrument is preparing to accept voice commands. Note: The amber display is an intermediate state and will only appear for several seconds.
(Blue)	 The voice command function is available if all of these conditions are true: The voice command function for the instrument is enabled by an administrator. The user is signed in with a Thermo Fisher[™] Connect Platform account. The proximity sensor detects a person.
(Red)	The microphone was disabled by the user (see "Enable or disable the microphone" on page 49).

To enable voice commands, see "Configure the instrument for the hands-free features" on page 211.

For more information about linking a local instrument profile to a Thermo Fisher[™] Connect Platform account, see "Link the instrument to your Thermo Fisher[™] Connect Platform account" on page 135 and "If you link when you are signed in to the instrument" on page 139.

Software description

Parts of the home screen



Table 1 Parts of the home screen

Element of the home screen	Function
Instrument name	Set by the administrator to identify the instrument.
Calendar	Schedule time for a run or see runs that are scheduled.
Microphone	Shows the status of the microphone (see "Indicators for voice commands" on page 26 and "Enable or disable the microphone" on page 49).
Help	Access the Help.
Eject	Open or close the drawer to insert or remove a plate or a TaqMan™ Array Card.



Table 1	Parts of the home screen	(continued)
Tuble I		loonunaca	,

Element of the home screen	Function		
Status dial	• When the instrument is not in use—Displays Set up run .		
	• When the instrument is in use—Displays the sample block temperature, the elapsed run time, and the run status.		
	• When the instrument is locked while in use—Displays Locked within the status dial.		
	When a run is complete – Displays Run complete.		
Block type	The block that is installed on the instrument.		
	If applicable, the following items are noted:		
	If there is no block and heated cover set installed.		
	If the block and heated cover are mismatched.		
Current user	Displays the current signed-in user.		
Guest is displayed if no user is signed in.			
Connectivity	Only the icons that apply to the connectivity status of the instrument at the time are displayed.		
	 		
	 		
	 □ −A USB drive is plugged into the instrument. 		
	 — The instrument is connected to a network drive. 		
	 — The instrument is connected to a Thermo Fisher[™] Connect Platform account. 		
Buttons to access	Access a plate file to edit it or start a run.		
plate files[1]	• Set up run-Open a system template or a saved plate file.		
	 Load plate file)—Open a system template or a saved plate file. 		
	 ^(Run last)—Open the last plate file that was used to start a run. The last plate file is specific to the profile. 		
Instrument settings	Edit the file name convention.		
	 View the run history, and transfer or delete data files. 		
	Select the language.		
	 Install, change, or remove the block and the heated cover. 		
	Configure the instrument settings.		
	Configure the maintenance and service settings.		
	View notifications.		
	Configure hands-free operation.		

 $^{[1]}\;$ Plate files are applicable to TaqMan $^{\scriptscriptstyle \rm M}$ Array Cards.

Thermo Fisher[™] Connect Platform definitions

The terms Connect, Cloud, Thermo Fisher Connect, Thermo Fisher Cloud, and Thermo Fisher Connect Platform are used interchangeably on the instrument touchscreen. The terms Thermo Fisher[™] Connect Platform and Connect are used in this document.

The following icons are used interchangeably on the instrument touchscreen:

- 🛆
- •

The riangle icon is used in this document.

Instrument, desktop software, and Thermo Fisher[™] Connect Platform features

The instrument and the software include the features described below.

Note: System templates cannot be edited. They can be edited, then saved as a separate plate file.

Feature	Instrument	Desktop	Thermo Fisher™ Connect Platform
Use as guest (no sign in)	~	~	—
Schedule a run	~	_	\checkmark
Open system templates	~	~	\checkmark
Open system templates, edit them, and save them as plate files	~	~	\checkmark
Open plate files created on the desktop software	~	~	\checkmark
Open plate files created on the Thermo Fisher™ Connect Platform	~	~	\checkmark
Open plate file created on the instrument	~	~	\checkmark
Send plate files to the instrument run queue	_	~	—
Access the plate file associated with last run on the instrument	~	_	_
Load plate in instrument	~	_	—
Start run	~	_	—
View real-time data during a run	~	_	\checkmark
View results after a run is complete	~	\checkmark	\checkmark
	(Limited)		
See instrument status (run in progress)	~	_	\checkmark
Send email notifications	~	_	_



(continued)

Feature	Instrument	Desktop	Thermo Fisher™ Connect Platform
Check calibration status	~	~	~
Analyze and export results	~	\checkmark	\checkmark
View analysis of results	_	\checkmark	\checkmark
Set calibration reminders	~	—	~
Review exported calibration or RNase P verification results	_	\checkmark	\checkmark
			(RNase P only)

Overview of file locations and files

Note: The term plate file is applicable to both plates and TaqMan[™] Array Cards.

File locations

File location	Description and function
Run queue	Plate files sent from the desktop software.
Public	Plate files saved by guest users are stored in this folder.Data files from runs started by guest users are stored in this folder.
Templates	 System templates are stored in this folder. System templates cannot be edited. They must be saved as a separate plate file and stored in a different folder. Data files cannot be saved in this folder.
Thermo Fisher™ Connect Platform	 Plate files can be retrieved from a Thermo Fisher[™] Connect Platform profile. Data files can be saved to a Thermo Fisher[™] Connect Platform profile. You must have a Thermo Fisher[™] Connect Platform profile.
Network drive	 Plate files can be retrieved from a network drive. Data files can be saved to a network drive. The instrument must be connected to a network or a computer.
USB drive	 Plate files can be retrieved from a USB drive. Data files can be saved to a USB drive. A USB drive must be inserted into the instrument.



(continued)

File location	Description and function
My instrument	• This location is only available to a user who is signed in. Guest users cannot access this location to retrieve plate files or save data files.
	 This location is specific to a user. Files are not accessible to any other users, except for administrators.
	Plate files can be retrieved from this location.
	Data files are always saved to this location.
Post-read	In endpoint PCR, the pre-read data is saved in this folder for post-read analysis.

Files

IMPORTANT! Plate files and data files are not included in a back-up of the instrument and are not restored when a backup of the instrument is restored.

Plate files and data files must be transferred separately. See Chapter 6, "View and manage files". System templates are included in the back-up and are restored when a backup of the instrument is restored.

Item	Description and function	Supported in
System	A non-editable template.	Instrument
template	• Accessed from 🖆 (Load plate file) and the Templates folder (only system	Desktop
	templates are stored in this folder).	• Thermo Fisher™
	Accessed from the Set up run button.	Connect
	 Is saved as a separate plate file if it is edited. 	Platform
	Contains the thermal protocol for the real-time PCR.	
	Does not contain the sample information.	
	Does not contain the target information.	
	 Sample information and target information must be added (saved as a separate plate file). The sample information and target information can be added on the desktop software or on the Thermo Fisher[™] Connect Platform after the run is complete. 	

All file types are applicable to both plates and TaqMan[™] Array Cards.



(continued)

Item	Description and function	Supported in
Plate File From	 A file that has been saved from a system template. Can be edited and saved. Can be edited and saved as a separate plate file. Contains the thermal protocol for the real-time PCR. Can contain the sample information. Can contain the target information. Sample information and target information must be added if not present. The sample information and target information can be added on the desktop software or on the Thermo Fisher[™] Connect Platform after the run is complete. 	 Instrument Desktop Thermo Fisher™ Connect Platform
Plate File From	 The plate file associated with the last run for the profile. Can be edited and saved. Can be edited and saved as a separate plate file. Contains the thermal protocol for the real-time PCR. Contains the sample information. The sample information can be edited on the desktop software or on the Thermo Fisher™ Connect Platform after the run is complete. Contains the target information. The target information can be edited on the desktop software or on the Thermo Fisher™ Connect Platform after the run is complete. Sample information and target information can be edited on the instrument. If the sample information and the target information for the last run were added on the desktop software or on the Thermo Fisher™ Connect Platform after the run was complete, they will not be included on the plate file that is on the instrument. 	Instrument
Data file	 Contains the real-time PCR data. Can be viewed on the instrument only immediately after the run is complete. Transfer to the Thermo Fisher™ Connect Platform or to the desktop software to view and analyze data. 	 Instrument Desktop Thermo Fisher™ Connect Platform

Compatibility of plate files

The plate files are specific to the instrument.

A plate file for a QuantStudio[™] 6 Pro System can only be opened on this instrument. It cannot be opened on a QuantStudio[™] 7 Pro System.

A plate file for a QuantStudio[™] 7 Pro System can only be opened on this instrument. It cannot be opened on a QuantStudio[™] 6 Pro System.



Components of the files

Component	Instrument	Desktop	Thermo Fisher™ Connect Platform
Properties	 Data file name Reagent information Name Type Lot number Barcode Catalog number Expiry date Plate barcode or TaqMan[™] Array Card barcode Location to send data after the run is complete 	 Experiment file name Plate barcode or Taq User name Instrument type Block type Analysis module Chemistry (reagent in Run mode Comments (<i>Thermo Fisher™ Con</i> 	Man [™] Array Card barcode formation) <i>nect Platform only</i>) Notifications
Method	 Thermal cycling conditions Temperature Time Cover temperature Reaction volume Data collection points Ramp rates VeriFlex[™] Zones Auto Delta settings 	Thermal cycling condition	S
Plate	Sample names Targets SNP assays	Define and assign sample tasks in the Plate setup s	s, targets or SNP assays, and creen.
Run	Monitor a run in progress View time remaining, temperature, method, and amplification plots Pause, resume, or stop a run	Monitor a run in progress View time remaining	Monitor a run in progress (link to Thermo Fisher [™] Connect Platform Instrument Details) View time remaining, temperature, method, and amplification plots
Results	Not applicable	Review plots	
Export	Export results	Export results	
	Data files are transferred to the desktop software or the Thermo Fisher™ Connect Platform for analysis		



Third-party software

Before installing third-party software on the computer running the desktop software, confirm that the third-party software will not do the following:

- Restrict Ethernet communication.
- Interfere with instrument or computer operation.

Network connection options

You can connect an instrument to a network or computer in the configurations listed below. For more information, see Appendix B, "Connect the instrument to a network".

Direct connection	Local area network (LAN) connection	Thermo Fisher™ Connect Platform connection
wired	wired or wireless	wired or wireless

Types of runs

Standard curve run

A standard curve run determines the absolute target quantity in samples.

- 1. The software measures amplification of the target in a standard dilution series and in test samples.
- 2. The software generates a standard curve using data from the standard dilution series.
- 3. The software uses the standard curve to interpolate the absolute quantity of target in the test samples.



Relative standard curve run

A relative standard curve runs determines the relative target quantity in samples.

1. The software measures amplification of the target of interest and of an endogenous control target in a standard dilution series, in a reference (calibrator) sample, and in test samples.

The endogenous control is a target that is expressed equally in all samples; examples of endogenous controls are β -actin, GAPDH, and 18S ribosomal RNA. The software can algorithmically incorporate multiple endogenous control targets in relative quantification calculations.

The reference sample is used as the basis for relative quantification results (or $1 \times$ sample). For example, in a study of drug effects on gene expression, an untreated control is an appropriate reference sample.

- 2. The software generates standard curves for the target of interest and the endogenous control using data from the corresponding standard dilution series.
- 3. The software uses the standard curves to interpolate the quantities of the target of interest and the endogenous control in each sample. The target quantity in each sample is then normalized to the sample's endogenous control quantity.
- 4. To determine the relative quantity of the target in test samples, the software divides the normalized target quantity in the sample by the normalized target quantity in the reference sample.

Comparative C_t ($\Delta\Delta C_t$) run

A comparative C_t ($\Delta\Delta C_t$) run determines the relative target quantity in samples.

1. The software measures amplification of the target of interest and of an endogenous control target in a reference (calibrator) sample and in test samples.

The endogenous control is a target that is expressed equally in all samples; examples of endogenous controls are β -actin, GAPDH, and 18S ribosomal RNA. The software can algorithmically incorporate multiple endogenous control targets in relative quantification calculations.

The reference sample is used as the basis for relative quantification results (or 1× sample). For example, in a study of drug effects on gene expression, an untreated control is an appropriate reference sample.

- 2. The measurements for the target of interest are normalized to the endogenous control.
- 3. To determine the relative quantity of the target in test samples, the software compares the normalized ΔC_q (ΔC_t or ΔC_{rt}) for the sample to the normalized ΔC_q (ΔC_t or ΔC_{rt}) for the reference sample.



Genotyping run

A genotyping runs detects the single nucleotide polymorphism (SNP) variants of a target nucleic acid sequence.

Genotyping runs use preformulated TaqMan[™] SNP Genotyping Assays that include the following components:

- Two sequence-specific primers for amplification of sequences containing the SNP of interest
- Two allele-specific TaqMan[™] probes for Allele 1 and Allele 2
- 1. The software normalizes the fluorescence of the reporter dyes to the fluorescence of the passive reference dye in each well.
- 2. The software plots the normalized reporter dye signal of each sample well on an Allelic Discrimination Plot, which contrasts the reporter dye intensities of the allele-specific probes.
- 3. The software algorithmically clusters the sample data, and assigns a genotype call to the samples of each cluster according to its position on the plot.

Presence/absence run

Use presence/absence runs to determine the presence or absence of a target nucleic acid sequence in a sample.

The software calls the target present or absent based on an algorithmically determined call threshold. (The call threshold is different from the C_t threshold; the C_t threshold is not used to make calls.)

Melt curve run

Melt curve runs determines the melting temperature (Tm) of the amplification products of a PCR that used intercalating dyes.

In the software, melt curve analysis is included in the default run method for any run type that uses intercalating dyes.

- 1. The software plots a melt curve based on the fluorescence of the dye with respect to change in temperature.
- 2. Using the melt curve, the software calculates the melting temperature (T_m) .
System template file names

The first part of the file name varies, based on the instrument (QuantStudio[™] 6 Pro System or QuantStudio[™] 7 Pro System).

The instrument will display the system templates applicable to the block that is installed.

System template file names for the 96-well 0.2-mL block

System template name	Run type
QS7Pro-96-Well-0-2ml_GT_Fast.edt	 Genotyping run 96-well, 0.2-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-2ml_GT_Std.edt	 Genotyping run 96-well, 0.2-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-2ml_Melt_Fast.edt	 Melt curve run (no PCR stage) 96-well, 0.2-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-2ml_Melt_Std.edt	 Melt curve run (no PCR stage) 96-well, 0.2-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-2ml_PA_Fast.edt	 Presence/absence run 96-well, 0.2-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-2ml_PA_Std.edt	 Presence/absence run 96-well, 0.2-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-2ml_PCR_Melt_Fast.edt	 Melt curve run (with PCR stage) 96-well, 0.2-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-2ml_PCR_Melt_Std.edt	 Melt curve run (with PCR stage) 96-well, 0.2-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-2ml_RQ_Fast.edt	 Comparative C_t run 96-well, 0.2-mL Standard plate Fast cycling mode



(continued)

System template name	Run type
QS7Pro-96-Well-0-2ml_RQ_Std.edt	 Comparative C_t run 96-well, 0.2-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-2ml_RSC_Fast.edt	 Relative standard curve run 96-well, 0.2-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-2ml_RSC_Std.edt	 Relative standard curve run 96-well, 0.2-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-2ml_SC_Fast.edt	 Standard curve run 96-well, 0.2-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-2ml_SC_Std.edt	 Standard curve run 96-well, 0.2-mL Standard plate Standard cycling mode

System template file names for the 96-well 0.1-mL block

System template name	Run type
QS7Pro-96-Well-0-1ml_GT_Fast.edt	Genotyping run96-well, 0.1-mL Standard plateFast cycling mode
QS7Pro-96-Well-0-1ml_GT_Std.edt	 Genotyping run 96-well, 0.1-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-1ml_Melt_Fast.edt	 Melt curve run (no PCR stage) 96-well, 0.1-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-1ml_Melt_Std.edt	 Melt curve run (no PCR stage) 96-well, 0.1-mL Standard plate Standard cycling mode

Ť

(continued)

System template name	Run type
QS7Pro-96-Well-0-1ml_PA_Fast.edt	 Presence/absence run 96-well, 0.1-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-1ml_PA_Std.edt	 Presence/absence run 96-well, 0.1-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-1ml_PCR_Melt_Fast.edt	 Melt curve run (with PCR stage) 96-well, 0.1-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-1ml_PCR_Melt_Std.edt	 Melt curve run (with PCR stage) 96-well, 0.1-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-1ml_RQ_Fast.edt	 Comparative C_t run 96-well, 0.1-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-1ml_RQ_Std.edt	 Comparative C_t run 96-well, 0.1-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-1ml_RSC_Fast.edt	 Relative standard curve run 96-well, 0.1-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-1ml_RSC_Std.edt	 Relative standard curve run 96-well, 0.1-mL Standard plate Standard cycling mode
QS7Pro-96-Well-0-1ml_SC_Fast.edt	 Standard curve run 96-well, 0.1-mL Standard plate Fast cycling mode
QS7Pro-96-Well-0-1ml_SC_Std.edt	 Standard curve run 96-well, 0.1-mL Standard plate Standard cycling mode



System template file names for the 384-well block

System template name	Run type
QS7Pro-384-Well-GT-Fast.edt	Genotyping run384-well plateFast cycling mode
QS7Pro-384-Well-GT-Std.edt	Genotyping run384-well plateStandard cycling mode
QS7Pro-384-Well-Melt-Fast.edt	Melt curve run (no PCR stage)384-well plateFast cycling mode
QS7Pro-384-Well-Melt-Std.edt	Melt curve run (no PCR stage)384-well plateStandard cycling mode
QS7Pro-384-Well-PA-Fast.edt	Presence/absence run384-well plateFast cycling mode
QS7Pro-384-Well-PA-Std.edt	Presence/absence run384-well plateStandard cycling mode
QS7Pro-384-Well-PCR-Melt-Fast.edt	 Melt curve run (with PCR stage) 384-well plate Fast cycling mode
QS7Pro-384-Well-PCR-Melt-Std.edt	 Melt curve run (with PCR stage) 384-well plate Standard cycling mode
QS7Pro-384-Well-RQ-Fast.edt	 Comparative C_t run 384-well plate Fast cycling mode
QS7Pro-384-Well-RQ-Std.edt	 Comparative C_t run 384-well plate Standard cycling mode

(continued)

System template name	Run type
QS7Pro-384-Well-RSC-Fast.edt	Relative standard curve run
	384-well plate
	Fast cycling mode
QS7Pro-384-Well-RSC-Std.edt	Relative standard curve run
	384-well plate
	Standard cycling mode
QS7Pro-384-Well-SC-Fast.edt	Standard curve run
	384-well plate
	Fast cycling mode
QS7Pro-384-Well-SC-Std.edt	Standard curve run
	384-well plate
	Standard cycling mode

System template file names for the TaqMan[™] Array Card block

System template name	Run type
QS7Pro-TAC-PA-Fast.edt	 Presence/absence run TaqMan[™] Array Card Fast cycling mode
QS7Pro-TAC-PA-Std.edt	 Presence/absence run TaqMan[™] Array Card Standard cycling mode
QS7Pro-TAC-RQ-Fast.edt	 Comparative C_t run TaqMan[™] Array Card Fast cycling mode
QS7Pro-TAC-RQ-Std.edt	 Comparative C_t run TaqMan[™] Array Card Standard cycling mode
QS7Pro-TAC-SC-Fast.edt	 Standard curve run TaqMan[™] Array Card Fast cycling mode

Note: The TaqMan[™] Array Card is only available for the QuantStudio[™] 7 Pro System.



(continued)

System template name	Run type
QS7Pro-TAC-SC-Std.edt	Standard curve run
	 TaqMan[™] Array Card
	Standard cycling mode
QS7Pro-TAC-RQ-Melt-Fast.edt	Comparative C _t run with melt curve
	 TaqMan[™] Array Card
	Fast cycling mode
QS7Pro-TAC-RQ-Melt-Std.edt	Comparative C _t run with melt curve
	 TaqMan[™] Array Card
	Standard cycling mode
QS7Pro-TAC-SC-Melt-Fast.edt	Standard curve run with melt curve
	 TaqMan[™] Array Card
	Fast cycling mode
QS7Pro-TAC-SC-Melt-Std.edt	Standard curve run with melt curve
	 TaqMan[™] Array Card
	Standard cycling mode

Workflow

Sign in to your instrument profile or your Thermo Fisher™ Connect Platform account

(PIN or facial authentication)

▼

Open a plate file

(System template or saved plate file)

▼

(Optional) Edit the plate file

▼

Load the plate into the instrument

▼

Start the run

▼

Unload the plate from the instrument

▼

(Optional) Transfer the data file

(A location to transfer the data file might have been selected before the run. The data file only needs to be transferred manually after the run in order to transfer to a new location.)



Get started

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Enable or disable the microphone	49
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Precautions for use

CAUTION! PHYSICAL INJURY HAZARD. Do not remove the instrument cover. There are no components inside the instrument that you can safely service yourself. If you suspect a problem, contact technical support.



CAUTION! FIRE HAZARD. For continued protection against the risk of fire, replace fuses only with listed and certified fuses of the same type and rating as those currently in the instrument.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the sample block temperature can reach 100°C. Allow it to cool to room temperature before handling.



CAUTION! Before using a cleaning or decontamination method other than those recommended by Thermo Fisher Scientific, confirm with Thermo Fisher Scientific that the proposed method will not damage the instrument.



CAUTION! Use flat caps for tubes. Rounded caps can damage the heated cover.

Installation and instrument verification

The instrument is installed by a representative from Thermo Fisher Scientific. The following tasks will be performed during the installation process:

- Unpack the instrument and the computer
- Install the instrument and the computer
- Install QuantStudio[™] Design and Analysis Software 2 on the computer
- Perform calibrations and RNase P verification

Note: The tasks for the computer are performed only when the computer is purchased from Thermo Fisher Scientific with the instrument.

There is a recommended order to create instrument profiles and link Thermo Fisher™ Connect Platform accounts to the instrument (see "Recommended order to set up profiles" on page 132).

Overview of guest access

The instrument can be used without signing in. The following limits are in place if you do not sign in to the instrument:

- All actions are recorded to the guest profile.
- You have access only to the public folder for selecting and storing experiments.
- You cannot transfer data files to the Thermo Fisher™ Connect Platform.
- Data files can only be transferred to a USB drive or a network drive.

The instrument can be configured so that guest access is not permitted (see "Require sign-in" on page 131).



Use the instrument as a guest

If the **Guest** button is not visible on the **Sign In** screen, guest access has been disabled. An administrator must enable guest access (see "Require sign-in" on page 131).



① Guest button In the **Sign-In** screen, tap **Guest**.

Power on the instrument

If left unattended, the instrument automatically enters sleep mode to conserve power. The default time that an instrument is inactive before going into sleep mode is 15 minutes.

- Tap anywhere on the touchscreen to determine if the instrument is in sleep mode. If the screen becomes active, the instrument is already powered on.
- 2. If the home screen does not display, power on the instrument by pressing the ON/OFF switch on the rear panel.



1 ON/OFF switch

Note: The length of time that the instrument is inactive before going into sleep mode can be customized (see "Enable and edit sleep mode" on page 185).

Sign in

Sign in with a PIN

Create an instrument profile before signing into the instrument (see "Create a new local instrument profile" on page 136 and "Link the instrument to your Thermo Fisher™ Connect Platform account" on page 135).

1. In the Sign In screen, tap the PIN field, then enter your PIN.

If your instrument profile is not the default that is displayed, tap \checkmark , then select your instrument profile.

2. Enter your PIN, then tap Enter.

You are signed in and the home screen is displayed.

See "Parts of the home screen" on page 27.

Sign in with facial authentication

For information on indicators for facial authentication, see "Indicators for facial authentication" on page 26.

For lighting guidelines, see "Light guidelines" on page 221.

Create an instrument profile before signing into the instrument (see "Create a new local instrument profile" on page 136 or "Link the instrument to your Thermo Fisher™ Connect Platform account" on page 135). The instrument profile must be set up with facial authentication (see "Add facial authentication to an existing instrument profile" on page 142).

The instrument must accept facial authentication (see "Configure the instrument for the hands-free features" on page 211).

The instrument must have the sign-in screen displayed. Sign out the current user to return to the sign-in screen (see "Sign out" on page 50).

1. Stand in front of the instrument.

Center yourself in front of the instrument. The ideal position is approximately 27 inches (69 cm) from the camera.

Note: You do not need to position yourself as closely to the instrument to sign in as when you took the photos to set up facial authentication.

- 2. Wait while the instrument searches for a match with the photos associated with profiles.
- **3.** *(Optional)* Reposition yourself if the instrument indicates that the face is out of position. Ensure that you are centered in front of the instrument. Move away from the instrument and towards the instrument to find the correct position.

The user is signed into the instrument and the home screen is displayed.

Enable or disable the microphone

The microphone can be disabled if the voice command function is available. A blue microphone icon indicates that the voice command function is available.

The microphone cannot be manually disabled if the voice command function is already not available. A gray microphone icon indicates that the voice command function is unavailable.

To enable or disable the voice command function for the instrument, see "Configure the instrument for the hands-free features" on page 211.

For a description of the indicators, see "Indicators for voice commands" on page 26.

Tap () (Microphone).

The microphone icon will change to red with a bar to indicate that it is disabled ().

If the proximity sensor does not detect a person, the microphone icon will change to gray with a bar (\mathscr{P}) . It will change back to red with a bar when the proximity sensor detects a person.

Use voice commands

The instrument must accept voice commands (see "Configure the instrument for the hands-free features" on page 211).

A Thermo Fisher[™] Connect Platform account must be used. For information about linking a local instrument profile to a Thermo Fisher[™] Connect Platform account, see "Link a local profile to a Thermo Fisher[™] Connect Platform account" on page 137.

Voice commands are not available when the instrument is used as a guest. Voice commands are not available with a local instrument profile.

The instrument must display a screen where a voice command is supported.

For information on indicators for voice commands, see "Indicators for voice commands" on page 26. Say "Alexa™, open pro instrument", wait for the instrument audio prompt, then issue the voice command.

Voice command	Instrument audio output	Instrument action
Home	_	The home screen is displayed.
Open door	_	Instrument drawer opens.
Shut door	_	Instrument drawer closes.
Begin Run	"Are you sure you want to start the run? Yes or no."	If yes, the instrument starts the run. If no, the Plate properties screen is displayed.
End run	"Are you sure you want to stop the run? Yes or no."	If yes, the instrument stops the run and displays the Plate properties screen. If no, the run continues.
Lock screen	_	The instrument locks the screen. The status dial displays Locked.

The instrument audio prompt depends on the voice command that was issued.

(continued)

Voice command	Instrument audio output	Instrument action
Change Block ^[1]	_	If the instrument has a block installed, the Change Block screen is displayed. If there is no block in the instrument, the Install Block screen is displayed.
Instrument scheduler ^[1]	_	The instrument schedule is displayed.
Help	_	The help topic associated with the current page on the screen is displayed.
Smart support ^[1]	_	The Smart Help screen is displayed.
Calibrations	_	The Calibration screen is displayed.

^[1] Unsaved changes are discarded after the instrument action is completed.

Sign out

- 1. In the home screen, tap (Profile).
- 2. Tap Sign out, then tap Yes to confirm.

You are signed out and the Sign In screen is displayed.



Create and run plates on the instrument

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Unload a plate or a TaqMan [™] Array Card from the instrument	56

Options to run a plate

Create and run a plate from a system template or a saved plate file

A system template is a plate file that is pre-loaded on the instrument and not editable. It can be edited and saved as a new custom plate file.

Plate files can be edited in the Thermo Fisher[™] Connect Platform or the desktop software.

The Run Queue folder contains plate files sent to the instrument from the desktop software.

The location to access the system template or the plate file is set up in the instrument settings. Depending on the settings, not all of the locations can be selected.

The location to export the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected.

For more information, see "Manage the settings for data export and data import" on page 214.

- 1. In the home screen, tap one of the following options:
 - 📸 (Load plate file)
 - Set up run
- 2. Tap the location of the system template or the plate file in the left column.
 - 💼 Run Queue
 - 💼 Public
 - My Instrument

Note: My instrument is not available if you are using the instrument as a guest. You must be signed in.



- 💼 Templates

Note: You must be signed in with a Thermo Fisher[™] Connect Platform account.

- 🖀 Network Drive
- 🗇 USB Drive
- **3.** Tap the template file name in the right column. The **Plate Properties** screen is displayed.
- 4. (Optional) In the Plate Properties screen, edit the Data file name.

The default file name is the template name appended with the date and time. To edit the default file name, see "Manage the file name convention of the data file" on page 211.

- (Optional) Use the barcode scanner.
 See "(Optional) Scan a barcode using a barcode scanner" on page 55.
- 6. Tap the location to send the data file.
 - Connect platform

Note: You must be signed in with a Thermo Fisher[™] Connect Platform account.

- 🗆 USB drive
- 😑 Network drive
- This instrument

Note: This option is not available if you are using the instrument as a guest. You must be signed in.

The connection status of each location is displayed.

If the connection between the instrument and the location that was selected to save the data file is interrupted, the instrument completes the run. The data file is saved on the instrument. The data file must be transferred to another location manually (see "Transfer data files at a later time" on page 87).

7. (Optional) Select the Export run results with checkbox.

For more information about this setting, see "Overview of customized data export" on page 54. To import a different export setting, see "Import an auto export setting" on page 60.

- 8. (Optional) Edit the run method (see page 61).
- 9. (Optional) Edit the plate (see page 69).
- **10.** Load a plate into the instrument (see page 55).
- **11.** Tap **Start run**, then confirm that a plate was loaded.

The confirmation page can be disabled (see "Enable or disable the reminder to insert a plate" on page 212).

The status dial is displayed. The status dial contains the following information:

- The block temperature
- The elapsed time of the run
- The status of the run



Figure 7 Home screen during a run

For options during a run, see Chapter 5, "Options for a run".

Repeat the last run

The last run is associated with the profile. It is not the last run for the instrument.

The location to export the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

- In the home screen, tap
 ^C (Run last).
 The Plate Properties screen is displayed.
- 2. (Optional) In the Plate Properties screen, edit the Data file name.

The default file name is the template name appended with the current date and time. To edit the default file name, see "Manage the file name convention of the data file" on page 211.

- (Optional) Use the barcode scanner.
 See "(Optional) Scan a barcode using a barcode scanner" on page 55.
- 4. Tap the location to send the data.
 - Connect platform

Note: You must be signed in with a Thermo Fisher™ Connect Platform account.

- 🗆 USB drive
- 😑 Network drive



• 📮 This instrument

Note: This option is not available if you are using the instrument as a guest. You must be signed in.

The connection status of each location is displayed.

If the connection between the instrument and the location that was selected to save the data file is interrupted, the instrument completes the run. The data file is saved on the instrument. The data file must be transferred to another location manually (see "Transfer data files at a later time" on page 87).

5. (Optional) Select the Export run results with checkbox.

For more information about this setting, see "Overview of customized data export" on page 54. To import a different export setting, see "Import an auto export setting" on page 60.

- 6. (Optional) Edit the run method (see page 61).
- 7. (Optional) Edit the plate (see page 69).
- 8. Load a plate into the instrument (see page 55).

9. Tap Start run, then confirm that a plate was loaded.

The confirmation page can be disabled (see "Enable or disable the reminder to insert a plate" on page 212).

The status dial is displayed. The status dial contains the following information:

- The block temperature
- The elapsed time of the run
- The status of the run

See Figure 7 on page 53.

For options during a run, see Chapter 5, "Options for a run".

Overview of customized data export

The instrument can perform the primary analysis and the secondary analysis of the data, then export the results.

The instrument has a default export setting.

The export settings can be customized. The instrument will perform the primary and secondary analysis according to the export setting file.

The export settings are customized in the QuantStudio[™] Design and Analysis Software 2, then transferred to the instrument. The export settings are in a JSON file format.

The export settings cannot be created or edited on the instrument.

(Optional) Scan a barcode using a barcode scanner

The instrument is compatible with an optional Handheld Barcode Scanner (Cat. No. 4488442, purchased separately). The barcode scanner reads Code 128 (alphanumeric), which supports 128 ASCII character barcodes.

For safety information, see "Laser safety" on page 252.

- 1. Tap the Barcode field.
- 2. Hold the scanner 20–30 cm away from a plate or container label and aim at the center of the barcode, then press the trigger.
- 3. Slowly move the scanning beam across the barcode until the scanner emits a high-pitched tone.

When the scanner scans a barcode, it automatically transmits the following information:

- Transmits the alphanumeric equivalent of the barcode to the Barcode field.
- Transmits other reagent information.

For more information about the hand-held barcode scanner, see the user documentation provided with the barcode scanner.

Load a plate into the instrument

IMPORTANT! The instrument should be used by trained operators who have been warned of the moving parts hazard.



CAUTION! Use flat caps for 0.2-mL tubes and 0.1-mL tubes. Rounded caps can damage the heated cover.

- 1. Tap (a) (Eject) to open the drawer.
- 2. Load the plate onto the block.
 - Well A1 of the plate is in the top-left corner of the block.
 - If the plate has a barcode, the barcode faces the front of the instrument.
- 3. Tap (a) (Eject) to close the drawer.

Load a TaqMan[™] Array Card into the instrument

IMPORTANT! The instrument should be used by trained operators who have been warned of the moving parts hazard.

- **1.** Tap **(Eject)** to open the drawer.
- 2. Load the plate onto the block.
 - Well A1 of the array card is in the top-left corner of the block.
 - If the array card has a barcode, the barcode faces the front of the instrument.

The block has guides for the position of the array card.



The circles indicate the guides for the position of the array card.

3. Tap (a) (Eject) to close the drawer.

Unload a plate or a TaqMan[™] Array Card from the instrument



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. Allow it to cool to room temperature before handling.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the TaqMan[™] Array Card temperature can reach 100°C. Allow it to cool to room temperature before handling.

3

The status dial displays **Run complete** when the run is finished. If the automatic sign-out feature is enabled and the set time has elapsed, the instrument will display the **Sign In** screen.

- **1.** Tap (**Eject**) to open the instrument drawer, then remove the plate.
- 2. Tap (a) (Eject) to close the instrument drawer.

For information on plate disposal, see "Chemical safety" on page 258 and "Biological hazard safety" on page 259.



Edit a plate before starting a run

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Options to edit the well details of a plate file	66

Overview of a template file with restricted editing

A template file can be set up with restricted editing in the QuantStudio[™] Design and Analysis Software 2. If a template file is set up with restricted editing, only certain parts of the template file can be edited. The parts of the template file that cannot be edited are defined by the user in QuantStudio[™] Design and Analysis Software 2.

A user cannot set up the restricted editing properties on the instrument.

If a template file has restricted editing, it is noted in the following locations:

- The top of the screen
- Under the Data file properties heading
- In the Data file name field



- (1) The top of the screen
- (2) Under the Data file properties heading
- ③ In the Data file name field



Options to edit the properties of a plate file

The following files can be edited:

 A system template (see "Create and run a plate from a system template or a saved plate file" on page 51)

A system template that is edited must be saved as a plate file. A system template cannot be overwritten.

- A saved plate file (see "Create and run a plate from a system template or a saved plate file" on page 51)
- The plate file associated with the last run (see "Repeat the last run" on page 53)

The following items can be edited in the **Properties** tab:

• Import the sample setup (see page 59)

Import a sample setup file

This feature allows you to import a sample setup file. A sample setup file shows the position of each sample on the plate. The sample setup file is a TXT file or a CSV file.

The location to access the sample setup file is set up in the instrument settings. Depending on the settings, not all of the locations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

To copy or delete a sample setup file, see "Manage sample setup files" on page 83.

- 1. In the Properties tab, tap Actions, then tap Import sample setup.
- 2. In the **Import Sample Setup** screen, tap the location of the file in the left pane, then tap the file or the folder in the right pane.

If a folder was selected, continue to navigate within the folder until the file is displayed in the right pane.



Import an auto export setting

The export settings can be customized. For more information about the export settings, see "Overview of customized data export" on page 54.

The export settings file is in a JSON file format.

The location to access the file is set up in the instrument settings. Depending on the settings, not all of the locations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

The export settings must be customized in the QuantStudio[™] Design and Analysis Software 2, then they are imported onto the instrument.

1. In the **Properties** tab, tap the **Export run results with** field. The **Auto Export Settings** screen is displayed.

- 2. Tap Import.
- **3.** Tap the location of the file in the left pane, then tap the file or the folder in the right pane. If a folder was selected, continue to navigate within the folder until the file is displayed in the right pane.

Delete an auto export setting

- In the Properties tab, tap the Export run results with field. The Auto Export Settings screen is displayed.
- 2. Tap Delete.

Options to edit the method of a plate file

The following files can be edited:

 A system template (see "Create and run a plate from a system template or a saved plate file" on page 51)

A system template that is edited must be saved as a plate file. A system template cannot be overwritten.

- A saved plate file (see "Create and run a plate from a system template or a saved plate file" on page 51)
- The plate file associated with the last run (see "Repeat the last run" on page 53)

The following items can be edited in the Methods tab:

- Time and temperature for each PCR step (see page 61)
- Cover temperature and volume (see page 61)
- Number of cycles (see page 61)
- Steps (see page 62)
- Stages (see page 62)
- Data collection points (see page 63)



- VeriFlex[™] Zones (see page 63)
- Auto Delta (see page 65)
- Ramp rates (see page 66)
- Pauses (see page 66)

Method elements

)
6	

- 1 Method tab
- 2 Heated cover temperature
- ③ Reaction volume
- (4) Stage of thermal protocol
- (5) Step within a stage

Edit the method

- 1. In the Method tab, tap Edit.
- 2. Tap a field, then enter the changes.
 - Cover temperature
 - Volume
 - Temperature for any steps
 - Time for any steps
 - Number of PCR cycles
- 3. Tap Save.
- 4. Enter a name for the plate file, then tap **Done**.

- 6 Number of cycles for the stage
- ⑦ Temperature for the step
- 8 Hold time for the step
- 9 Data collection point



- 5. In the **Save Template** screen, select a storage location for the plate file, then tap **Done**. A confirmation is displayed.
- 6. Tap Close.

Add or remove steps

Add a PCR step or remove a PCR step.

1. In the **Method** tab, tap **Edit > Advanced > Manage steps**.

Note: Use \langle or \rangle to navigate through the method if it is not all displayed.

- 2. Tap Add step, then tap + (Add) in the location of the step to be added.
- 3. Enter the temperature and time, then tap **Enter**.
- 4. Tap **Remove step**, then tap (**Remove**) in the appropriate step.
- 5. Tap Done.

The **Method** tab is displayed with the updated method.

Add or remove stages

Add a PCR stage or remove a PCR stage.

1. In the Method tab, tap Edit > Advanced > Manage stages.

Note: Use \langle or \rangle to navigate through the method if it is not all displayed.

- 2. Tap Add Stage, then tap + (Add) in the location of the stage to be added.
- 3. Tap the type of stage.
 - Hold
 - Pre-Read
 - Post-Read
 - Infinite
 - PCR
 - Melt Curve

The new stage is added. The time and temperature must be edited as part of the method (see "Edit the method" on page 61).

- 4. Tap Remove stage, then tap (Remove).
- 5. Tap Done.

Add or remove data collection locations

1. In the Method tab, tap Edit > Advanced > Data collection location.

```
Note: Use \langle or \rangle to navigate through the method if it is not all displayed.
```

2. Tap
(Data collection location) to designate a step as a data collection location or to remove data collection from the step.

The in (Data collection location) button functions as an on-off switch.



Data collection is off
 Data collection is on

3. Tap Done.

Set up or remove VeriFlex[™] Zones

VeriFlex™ Zones are only available for 96-well blocks.

- The QuantStudio[™] 6 Pro System has three VeriFlex[™] Zones.
- The QuantStudio[™] 7 Pro System has six VeriFlex[™] Zones.

Note: For more information about compatibility of plate files with VeriFlex[™] Zones between the two instruments, see "VeriFlex[™] Zones" on page 21.

1. In the Method tab, tap Edit > Advanced > VeriFlex[™] Zones / Auto Delta.

Note: Use \langle or \rangle to navigate through the method if it is not all displayed.

Note: The PCR stage provides the option of VeriFlex[™] Zones or the Auto Delta feature. Ensure that the **VeriFlex[™] Zones** option is selected.

	€	Edit Ve	eriFlex™	() () ()
1—		⇒ VeriFlex [™] zones Adjust temperature	Auto Delta setting e range for this st	js cep	
	Stage 2				
			7 8	9 10 11	12
	Zone 1			Zone 3	ě
	- A A A	Ste	ep 1		
	Remove			Cancel	Done

Figure 8 VeriFlex[™] Zones and Auto Delta settings

- (1) VeriFlex[™] Zones is selected
- 2. Tap the temperature field in the appropriate VeriFlex[™] Zone.
- 3. Enter a temperature, then tap Enter.

The temperatures in adjacent zones must have a difference of \leq 5°C.

4. Tap **Done**.

A stage with VeriFlex[™] Zones is denoted with a icon.

5. In the Method tab, tap **■** • Remove • Done to remove the VeriFlex[™] Zones.

Note: The VeriFlex[™] Zones setting is removed from the Method tab.



① Indicates that this is the **Method** tab where the VeriFlex[™] Zones settings can be removed

② Indicates that VeriFlex[™] Zones are assigned. Tap to remove the VeriFlex[™] Zones.



Set up or remove the Auto Delta feature

Note: The Auto Delta feature is only available in the PCR stage.

1. In the Method tab, tap Edit → Advanced → VeriFlex[™] Zones / Auto Delta.

Note: Use \langle or \rangle to navigate through the method if it is not all displayed.

- 2. Tap / (Edit) in one of the PCR stages.
- 3. Tap Auto Delta settings.

See Figure 8 on page 64.

- 4. Enter the starting cycle to apply Auto Delta settings.
- 5. Set the **Delta temperature** slider to the + position or the position, then enter the numerical value for the difference in the temperature.
- Set the **Delta time** slider to the + position or the position, then enter the numerical value for the difference in the time.
- 7. Tap **Done**.

A PCR step with an Auto Delta setting applied to it is denoted with an **M**.

8. In the **Method** tab, tap **Method • Premove • Done** to remove the Auto Delta setting.

Note: The Auto Delta setting is removed from the Method tab.



(1) Indicates that this is the **Method** tab where Auto Delta settings can be removed.

(2) Indicates that Auto Delta is assigned. Tap to remove the Auto Delta settings.



Configure ramp rates

The ramp rate is how quickly the temperature changes from one stage or step to another stage or step. The maximum ramp rate for the instrument depends on the block type.

1. In the Method tab, tap Edit > Advanced > Ramp rates.

Note: Use \langle or \rangle to navigate through the method if it is not all displayed.

- 2. Tap a ramp rate, then edit the value.
- 3. Tap Done.

Add or remove a pause

A pause allows you to open the drawer to add additional reagents to the plate.

1. In the **Method** tab, tap **Edit** > **Advanced** > **Add pause**.

Note: Use \langle or \rangle to navigate through the method if it is not all displayed.

- 2. Tap || (Pause).
- Enter a temperature and the cycle.
 A pause in the thermal cycling protocol is denoted with a
 The cycle of the pause and the temperature of the pause are also denoted.
- 4. Tap || (Pause) to remove the pause.
- 5. Tap Done.

Options to edit the well details of a plate file

The following files can be edited:

• A system template (see page 51)

A system template that is edited must be saved as a plate file. A system template cannot be overwritten.

- A saved plate file (see "Create and run a plate from a system template or a saved plate file" on page 51)
- The plate file associated with the last run (see "Repeat the last run" on page 53)

The following items can be edited in the **Plate** tab:

- Sample name and sample type (see "Assign or edit a well for a plate" on page 69 and "Assign or edit a well for a TaqMan™ Array Card" on page 70)
- Target name, reporter dye, and quencher dye (see page 70)
- Reagents (see "Add or edit the reagent details for a plate" on page 70 and "Add or edit the reagent details for a TaqMan[™] Array Card" on page 72)
- Passive reference dye (see page 72)
- Import an assay information file (AIF; see page 73)

A plate layout file for preplated assays will already be populated with the target name, reporter dye, and quencher dye.

Options to view a plate layout

The following views are available for a plate layout:

- Plate view
 - 🏢
 - Shows each well on the plate
 - Tap to provide information about the sample name, sample type, target name, reporter dye, or quencher dye
 - An individual well
 - Multiple wells (tap each individual well)
 - A row (tap the letter)
 - A column (tap the number)
 - Tap M (Select all) to select all of the wells in the plate
- Well table view
 - ≣
 - Shows the well ID, the sample, the target, the reporter, the quencher, the type, and the reagents

The plate view and the well table view can show the sample color or the target color with the **Color By** dropdown list.



- 1 Select all button
- 2 Plate view button
- ③ Well table view button
- (4) Color by dropdown list

View a 384-well plate

The **Plate** tab displays a 384-well plate if the 384-well block is installed. The plate can be edited in the 384-well view. You can zoom in to a 96-well section of the 384-well plate in order to edit the plate.

\odot	۵ 🕐
Color by: Samples V	Method Plate
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 A O	384 Well Navigation To edit, use 2 fingers to zoom from a 384 well plate to a 96 well. Make the edits you need to make.
L	Don't show again Guide me
	Cancel Start run

- 1. In the region of the 384-well plate that you want to zoom in on, pinch outwards with two fingers.
- 2. (Optional) To change the region that you are zoomed in on, use two fingers to drag the plate in the appropriate direction.

The 384-well plate can zoom in on any 96-well section. It is not limited to specific 96-well quadrants.

4

If you selected a full row or column in the 96-well view, only the set of wells that was visible in the 96-well view is selected. The full row or column of the 384-well plate is not selected.

3. To return to the full 384-well view from the 96-well section, pinch inwards with two fingers.

View a TaqMan[™] Array Card

The **Plate** tab displays a TaqMan[™] Array Card if the TaqMan[™] Array Card block is installed.

The samples and reagents are edited by port. The samples and reagents are not edited by well.

The targets are added by an assay information file. The targets cannot be edited on the instrument touchscreen.



Figure 9 Plate tab for a TaqMan[™] Array Card

1 Port

Assign or edit a well for a plate

A target or an assay must be defined (see "Add a target or an assay" on page 70).

A sample setup file can be imported instead of assigning or editing a well manually (see "Import a sample setup file" on page 59).

- 1. In the **Plate** tab, tap a well or multiple wells.
- 2. Tap the Sample Information pane, then tap Samples.

Note: If no wells are selected, the pane is labeled Legend.

- 3. Enter a sample name.
- 4. Select a sample type from the dropdown list.

- 5. Tap Target/SNP, then select Target or Assay from the dropdown list.
- 6. Tap a row in the table, then tap **Done**.

Add a target or an assay

- 1. In the Plate tab, tap a well or multiple wells.
- 2. Tap the Sample Information pane, then tap Target/SNP.
- 3. Tap a row in the table, then tap Add New.
- 4. Enter the target, then select the reporter dye and the quencher dye from the respective dropdown lists.
- 5. Tap Add Target, then tap Close.

Assign the target or the assay to a well (see "Assign or edit a well for a plate" on page 69).

Assign or edit a well for a TaqMan[™] Array Card

An assay information file must be imported to assign targets (see "Import an assay information file (AIF)" on page 73). Targets cannot be assigned on the instrument touchscreen.

A sample can only be edited by port. It cannot be edited by individual well.

A sample setup file can be imported instead of assigning or editing a well manually (see "Import a sample setup file" on page 59).

- 1. In the **Plate** tab, tap a port. See Figure 9 on page 69.
- 2. Tap the Legend pane, then tap Samples.
- 3. Enter a sample name.
- 4. Select a sample type from the dropdown list.
- 5. Tap Done.

Add or edit the reagent details for a plate

- 1. In the Plate tab, tap one of the following items.
 - A single well
 - Multiple wells
 - 🔳 (Select all)
- 2. Tap the Sample Information pane, then tap Reagents.

Note: If no wells are selected, the pane is labeled Legend.



- 3. Tap a row in the table, then enter the information.
 - Reagent name

• SKU (Part number)

Expiration date

- Reagent type
- Lot number
- 4. Tap Save reagent.
- 5. Tap Done.

Apply the reagents to a plate

Add the reagents before they are applied to a plate (see "Add or edit the reagent details for a plate" on page 70).

- 1. In the **Plate** tab, tap one of the following items.
 - A single well
 - Multiple wells
 - 🔳 (Select all)
- 2. Tap the Sample Information pane, then tap Reagents.

Note: If no wells are selected, the pane is labeled Legend.

- **3.** Tap a row in the table to apply it to the plate.
- 4. Tap Done.

Delete the reagent details

- 1. In the **Plate** tab, tap one of the following items.
 - A single well
 - Multiple wells
 - 🔳 (Select all)
- 2. Tap the Sample Information pane, then tap Reagents.

Note: If no wells are selected, the pane is labeled Legend.

3. (Optional) Tap Clear all.



- 4. Tap a row in the table, then delete the information in each field.
 - Reagent name
 - Reagent type
 - Lot number
- 5. Tap Save reagent.
- 6. Tap Done.

Add or edit the reagent details for a TaqMan[™] Array Card

- In the Plate tab, tap a port. See Figure 9 on page 69.
- 2. Tap the Legend pane, then tap Reagents.
- 3. Tap a row in the table.
- 4. Tap Add new, then enter the information.
 - Reagent name
 - Reagent type
 - Lot number
- 5. Tap **Save reagent**, then tap **Done**.

Apply the reagents to a TaqMan[™] Array Card

Add the reagents before they are applied to a plate (see "Add or edit the reagent details for a TaqMan™ Array Card" on page 72).

A reagent can only be applied by port. It cannot be applied by individual well.

1. In the **Plate** tab, tap a port.

See Figure 9 on page 69.

- 2. Tap the Legend pane, then tap Reagents.
- 3. Tap a row in the table to apply it to the port.
- 4. Tap Done.

Edit a passive reference dye

A passive reference dye normalizes the fluorescent reporter signal in real-time PCR.

- In the Plate tab, tap Actions ➤ Edit passive reference dye. The Passive Reference Dye screen is displayed.
- 2. Select the passive reference dye.

- SKU (Part number)
- Expiration date
- Quencher dye

- SKU (Part number)
- Expiration date


The passive reference dye is displayed under the plate diagram.

Import an assay information file (AIF)

The assay information file is provided in TXT format and/or XML and HTML format, depending on the product line and order date. The HTML format is a reference for users. The XML or the TXT format is imported.

The location to access the AIF is set up in the instrument settings. Depending on the settings, not all of the locations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

For a detailed description of the AIF, see Understanding Your Shipment (Pub. No. MAN0017153)

- 1. In the Plate tab, tap Actions > Import AIF file.
- 2. In the **Import AIF file** screen, tap the location of the file in the left pane, then tap the file or the folder in the right pane.

If a folder was selected, continue to navigate within the folder until the file is displayed in the right pane.

Import a TaqMan[™] Assay file

The TaqMan[™] Assay file can be imported to the instrument directly from the Thermo Fisher Scientific website. The instrument must be connected to the internet.

- 1. In the Plate tab, tap Actions ▶ Import TaqMan[™] Assay files.
- 2. On the Select A Product screen, select one of the following options.
 - Fixed TaqMan[™] Array Plates
 - Custom TaqMan[™] Array Plates
 - TaqMan[™] Assays
- 3. Enter the information.

Option	Information
Fixed TaqMan™ Array Plates	Part number
	Batch number
Custom TaqMan™ Array Plates	Sales order
	Lot number
TaqMan™ Assays	Sales order
	Rack ID

4. Tap Import.

The plate layout contains the targets and samples.



Options for a run

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Screens available during a run

From the home screen, you can swipe or tap the arrows to navigate to different screens. The following screens are available:

- A screen displaying the method (swipe left once or tap the right arrow (>) once)
- The real-time amplification plot (swipe left twice or tap the arrow right (>) twice)
- The time remaining in the run (swipe left three times or tap the right arrow (>) three times)





Figure 10 Home screen during a run

1	Arrow	
0	A	

(2) Actions menu

Edit a plate file during a run

The targets and samples can be added or edited after a run has started. The method cannot be edited after a run has started.

- 2. Tap Set up.
- 3. In the Plate tab, tap a well or multiple wells.

Note: Use the plate view to edit or assign a well (see "Options to view a plate layout" on page 67).

4. Tap the Sample Information pane, then tap Samples.

Note: If no wells are selected, the pane is labeled Legend.

- 5. Enter a sample name, then select a sample type from the dropdown list.
 - Unknown
 - Standard
 - No template control (NTC)
- 6. Tap Target/SNP, then select Target or Assay from the dropdown list.
- 7. Tap a row in the table, then tap **Close > Done**.

Pause an instrument run

Pause a run to add reagents to the plate or to edit the number of cycles.

- 2. Tap Pause run, then enter a pause temperature.
- 3. (Optional) Tap Edit to change the number of cycles.
- 4. (Optional) Tap (a) (Eject) to open the drawer, then tap (a) (Eject) to close the drawer.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. If you want to access the plate during a run pause, enter room temperature as the pause temperature and allow the plate to cool to room temperature before handling.

Stop an instrument run



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. If you want to access the plate during a run pause, enter room temperature as the pause temperature and allow the plate to cool to room temperature before handling.

- 2. Tap Stop run.
- 3. Unload the plate (see "Unload a plate or a TaqMan[™] Array Card from the instrument" on page 56).

View the method during a run

- <u<image>
- 1. In the home screen during a run, swipe left once or tap the right arrow (>) once.

2. Swipe right once or tap the left arrow (<) once to return to the home screen.

View real-time data and plots during a run

1. In the home screen during a run, swipe left twice or tap the right arrow (>) twice.



- 2. (Optional) Tap the dropdown list then select the view for the plot.
 - Linear
 - Log 10
- 3. (Optional) Tap Actions > Analyze amp plots.
- 4. (Optional) Tap Actions > View well details to see the amplification for a specific well.
- 5. Swipe right twice or tap the left arrow (**〈**) twice to return to the home screen.

Adjust the display of real-time plots during a run

- 1. In the real-time amplification plot, tap (**Zoom**) or pinch.
- 2. Tap the arrows to pan left or right, or swipe left or right within the amplification plot.

View the time remaining during a run

- 1. In the home screen during a run, swipe left three times or tap the right arrow (>) three times. The time remaining in the run is displayed.
- 2. Swipe right three times or tap the left arrow ($\boldsymbol{\zeta}$) three times to return to the home screen.

Lock the touchscreen during a run

After you have started a run, you can lock the touchscreen so that other users cannot interfere with instrument operation.

Note: You must be signed in.

- 1. In the home screen during a run, tap (a) (Profile).
- Tap Lock screen ➤ Lock. The status dial displays Locked.

The touchscreen automatically unlocks when the run is complete.

The touchscreen can be unlocked during the run (see "Unlock the touchscreen during a run" on page 79).

Unlock the touchscreen during a run

The touchscreen can be unlocked by the user who locked it or an administrator. The touchscreen automatically unlocks when the run is complete.

- 1. Tap anywhere on the touchscreen.
- 2. Tap the **PIN Code** field, then enter your PIN. The status dial is displayed without **Locked**.

Instrument Schedule

Overview of the instrument schedule

The instrument schedule allows a user to reserve the instrument at a particular date and time.

A Thermo Fisher[™] Connect Platform account is required.

The instrument is not locked to prevent any other users at the time.

Schedule a run

- **1.** In the home screen, tap (Calendar).
- 2. Select a view.
 - Day
 - Week
 - Month
- 3. Tap a time.

The day on the calendar can be selected in the month view. The day view and the week view show the schedule in 30-minute increments.

- 4. Edit the start date, end date, start time, and end time.
- 5. (Optional) Add notes.
- 6. Tap Save, then tap Done to exit the schedule.

Cancel a scheduled run

- 1. In the home screen, tap in (Calendar).
- 2. Select a view.
 - Day
 - Week
 - Month



3. Tap the reservation.

The Edit Reservation screen is displayed.

4. Tap Cancel Reservation, then tap Yes.



View and manage files

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Manage plate files

Copy plate files

This feature allows you to copy an existing plate file. The plate file is an EDT file.

The location to save the copied sample setup file is set up in the instrument settings. Depending on the settings, not all of the locations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If the plate file was previously copied and you are copying the same plate file, you must decide whether to keep both files or overwrite the original plate file. You can also cancel the copying of the plate file.

If security is enabled on the instrument, your SAE account must have the permission of **Export general** data in order to copy the plate file. Your SAE account must have the permission of Allow overwriting of files in order to overwrite a plate file if it was previously copied to the same location. Your SAE account must have the permission of Allow keep both files in order to keep both plate files if the plate file was previously copied to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow overwriting of files** if the plate file was previously copied to the same location and you would like to overwrite the file.

- 1. In the home screen, tap 🚔 Load plate file or Set up run.
- 2. Tap the appropriate folder.
 - Image: Text and the second se second sec
 - Public
 - Connect
 - B Network Drive
 - USB Drive
- 3. Tap Manage.
- Tap the file, then tap Copy files. Multiple files can be selected.

- 5. Select the destination folder.
 - 庙 Public

 - 😑 Network Drive
 - 🗆 USB Drive

6. Tap Paste.

If the plate file was previously transferred, the **File Overwrite** screen is displayed.

7. In the File Overwrite, select one of the following options.

Option	Description	
Keep both	The file that was previously transferred is kept. The file that is being copied is also saved. A suffix is added to the file name in order to keep both of the files.	
Overwrite	The file that is being copied overwrites the file that was previously saved.	
Cancel	Cancel the file transfer.	

The copied file is displayed in the destination folder.

Tap
• (Back) to return to the home screen.

Delete plate files

System templates cannot be deleted. A plate file that was saved from a system template can be deleted.

For descriptions of files, see "Files" on page 31.

If security is enabled on the instrument, your SAE account must have the permission of **Allow deletion** of files.

- 1. In the home screen, tap 📾 Load plate file or Set up run.
- 2. Tap the appropriate folder.
 - 💼 Run Queue
 - 💼 Public

 - 😑 Network Drive
 - 🕞 USB Drive
- 3. Tap Manage.
- 4. Tap the file, then tap **Delete files**. Multiple files can be selected.
- 5. Tap Yes to confirm.
- Tap 🕒 (Back) to return to the home screen.

Manage sample setup files

Copy a sample setup file

This feature allows you to copy an existing sample setup file. A sample setup file shows the position of each sample on the plate. The sample setup file is a TXT file or a CSV file.

The location to save the copied sample setup file is set up in the instrument settings. Depending on the settings, not all of the locations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

A sample setup file cannot be copied to a location if it has previously been copied to the same location. The option to keep both files is not available.

A sample setup file cannot be overwritten. The option to overwrite the file is not available.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to copy a sample setup file.

- 1. In the Properties tab, tap Actions > Import sample setup.
- 2. In the Import Sample Setup screen, tap Manage.
- 3. Tap the location of the file in the left pane, then tap the file or the folder in the right pane.
- 4. Tap Copy files.
- 5. Tap the location to save the file in the left pane, then click **Paste**.

Delete a sample setup file

If security is enabled on the instrument, your SAE account must have the permission of **Allow deletion** of **files** in order to delete a sample setup file.

- 1. In the **Properties** tab, tap **Actions > Import sample setup**.
- 2. In the Import Sample Setup screen, tap Manage.
- 3. Tap the location of the file in the left pane, then tap the file or the folder in the right pane.
- 4. Tap Delete files.

Manage data files

View QC Check status after a run

The status dial displays **Run complete** when a run is complete. After **Done** is tapped, the amplification plot can no longer be viewed on the instrument.

1. In the home screen after a run is complete, see the status of the QC Check.

The status of the QC Check is displayed under the status dial.





1 QC Check



Figure 12 Review required for QC Check

1 QC Check

2. See the QC data in the QuantStudio[™] Design and Analysis Software 2 or the QuantStudio[™] Design and Analysis v2.



View an amplification plot after a run

The status dial displays **Run complete** when a run is complete. The amplification plot can only be viewed immediately after a run. After **Done** is tapped, the amplification plot can no longer be viewed on the instrument.



If the automatic sign-out feature is enabled and the set time has elapsed, the instrument will display the **Sign In** screen. The amplification plot cannot be viewed on the instrument after the run.

1. In the home screen after a run is complete, tap **Details**.

The amplification plot is displayed. The display can be adjusted (see "Adjust the display of realtime plots during a run" on page 78).

- 2. (Optional) On the Details screen, tap the Plot Types dropdown list, then select a plot type.
 - Rn vs. Cycle
 - dRn vs. Cycle
- 3. (Optional) On the Details screen, tap the Y-Scales dropdown list, then select the view for the plot.
 - Linear
 - Log 10
- 4. (Optional) Tap Well details, then tap Samples or Targets.
- 5. Select an amplification plot preview, then tap View amp plot.
- 6. (Optional) Tap a specific well on the right side of the amplification plot to see the details for the single well.
- 7. Tap Close to return to the home screen.

Transfer a data file immediately after a run

This section describes the transfer of a data file immediately after a run. To transfer a data file or a set of data files at a later time, see "Transfer data files at a later time" on page 87.

In the home screen, the status dial displays **Run complete** when a run is complete. The home screen also displays the location that the data file was transferred to. The location for transfer was selected before the run was started (see "Create and run a plate from a system template or a saved plate file" on page 51 and "Repeat the last run" on page 53).

If the automatic sign-out feature is enabled and the set time has elapsed, the instrument displays the **Sign In** screen. Data files cannot be transferred from the home screen. They can be transferred at a later time (see "Transfer data files at a later time" on page 87).

Data files are transferred to the location that was selected before the run was started, even if the user was automatically signed out.

The location to transfer the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If the data file was transferred after the run was completed and you are manually transferring the same data file, you must decide whether to keep both files or overwrite the original data file. You can also cancel the manual data file transfer.

If security is enabled on the instrument, your SAE account must have the permission of **Manual export run data** in order to export the data file. Your SAE account must have the permission of **Allow overwriting of files** in order to overwrite a data file if it was automatically transferred to the same location at the end of the run. Your SAE account must have the permission of **Allow keep both files** in order to keep both data files if the data file was automatically transferred to the same location at the end of the run.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Manual export run data** and **Allow overwriting of files** if the data file was automatically transferred to the same location at the end of the run and you would like to overwrite the file.

In the home screen after a run is complete, tap Transfer file.
 If the data file was transferred automatically after the run, the File Overwrite screen is displayed.

Option	Description	
Keep both	The file that was transferred automatically at the end of the run is kept. The file that is manually transferred is also saved. A suffix is added to the file name in order to keep both of the data files.	
Overwrite	The file that is manually transferred is saved and overwrites the file that was transferred automatically at the end of the run.	
Cancel	Cancel the data file transfer.	

2. In the File Overwrite, select one of the following options:

- **3.** Select the destination for the data file.
 - 💼 Public
 - Connect

Note: You must be signed in with a Thermo Fisher[™] Connect Platform account.

- 🚍 Network Drive
- USB Drive
- B My Instrument

Note: This option is not available if you are using the instrument as a guest. You must be signed in.

4. Tap OK, then tap Transfer.

Transfer data files at a later time

This section describes the transfer of a data file or a set of data files at any time. To transfer a data file immediately after a run, see "Transfer a data file immediately after a run" on page 86.

- Guests can only transfer guest data files.
- A user that is signed in can transfer their own data files.
- Administrators can transfer all data files.

The location to transfer the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If the data file was previously transferred and you are transferring the same data file, you must decide whether to keep both files or overwrite the original data file. You can also cancel the manual data file transfer.

If security is enabled on the instrument, your SAE account must have the permission of **Manual export run data** in order to export the data file. Your SAE account must have the permission of **Allow overwriting of files** in order to overwrite a data file if it was previously transferred to the same location. Your SAE account must have the permission of **Allow keep both files** in order to keep both data files if the data file was previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Manual export run data** and **Allow overwriting of files** if the data file was previously transferred to the same location and you would like to overwrite the file.

The **Run History** screen is displayed. It contains a list of the runs performed on the instrument associated with the profile. Administrators can view all of the runs performed.

- 2. (Optional) Tap the table header to sort by that parameter.
 - Run name
 - Date
 - Transferred



- User (Administrator only)
- 3. Tap the data files to be transferred or tap **Select all**.

Multiple data files can be selected.

4. Tap Transfer.

If the data file was transferred automatically after the run or was previously transferred, the **File Overwrite** screen is displayed.

5. In the File Overwrite, select one of the following options.

Option	Description	
Keep both	The file that was previously transferred is kept. The file that is being manually transferred is also saved. A suffix is added to the file name in order to keep both of the files.	
Overwrite	e The file that is being manually transferred is saved and overwrites the file that was previously transferred.	
Cancel	Cancel the data file transfer.	

- 6. Tap the storage location.
- 7. Tap **Done**.

View the list of data files on the instrument

- Guests can only view the list of guest data files.
- A user that is signed in can view the list of their own data files.
- Administrators can view all data files.
- 2. Tap an individual run record, then tap **View**. The following details are displayed:
 - The file name
 - The run status
 - The user name

- The duration of the run
- The reaction volume
- The cover temperature
- The start time and the end time
- (Optional) Tap Transfer to transfer the data file.
 See "Transfer data files at a later time" on page 87.
- (Optional) Tap Delete to delete the data file from the instrument. See "Delete data files from the instrument" on page 89.
- 5. Tap Cancel to return to the Run History screen.

Delete data files from the instrument

- Guests cannot delete any data files.
- A user that is signed in can delete their own data files.
- Administrators can delete all the data files.

If security is enabled on the instrument, your SAE account must have the permission of **Allow deletion** of files.

1. In the home screen, tap (settings) > Run history.

The **Run History** screen is displayed. It contains a list of the runs performed on the instrument associated with the profile. Administrators can view all of the runs performed.

- 2. (Optional) Tap the table header to sort by that parameter.
 - Run name
 - Date
 - Transferred
 - User (Administrator only)
- Tap the data files to be deleted or tap Select all. Multiple data files can be selected.
- 4. Tap **Delete**, then tap **Yes** to confirm.



Calibrate and verify instrument performance

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Instrument and block calibration

The QuantStudio[™] 6 Pro System and the QuantStudio[™] 7 Pro System have interchangeable blocks. The calibration status applies to the combination of the instrument and the block.

If a block is moved to an instrument that it has not been calibrated on, that combination of block and instrument needs to be calibrated. This applies even if the block has previously been calibrated on a different instrument.

If a block is moved back to an instrument that is has previously been calibrated on, it does not need to be calibrated again. It needs to be calibrated again if the calibration is expired.

A run can still be started if a calibration of the block on the instrument is expired. A run cannot be started if a block has never been calibrated on the instrument.

Calibration and verification schedule

The instrument and block will be calibrated during the installation. To ensure optimal performance, perform calibrations at the recommended frequency.

Note: After instrument calibration, we recommend performing instrument verification using the provided RNase P plate.

IMPORTANT! Perform calibrations and instrument runs under the specified environmental conditions (see "Environmental requirements" on page 222). Exposure to extreme temperatures can adversely affect the instrument performance and shorten the life span of the instrument components.

To set calibration frequencies and reminders, see one of the following sections:

- View the calibration status on the instrument (see page 93)
- View calibration status and set reminders on the Thermo Fisher™ Connect Platform (see page 94)

Calibration	Recommended frequency	
ROI/Uniformity	Every two years (recommended).	
	 Always perform new Background and Dye calibrations after an ROI/Uniformity calibration. 	
	You will be prompted to run a Background calibration after the ROI/Uniformity calibration is complete.	
	The ROI/Uniformity calibration and the Background calibration must pass in order to accept the results. It is recommended to transfer the files if the calibration fails in order to troubleshoot.	
	Note: Performing an ROI/Uniformity calibration invalidates all other calibrations.	
Background	Every month (recommended).	
	 Background calibration can also be performed, as needed: 	
	 To check for contamination (depends on usage and laboratory conditions). 	
	 To obtain the most accurate data for the removal of background fluorescence. 	
	Note: Performing a Background calibration does <i>not</i> invalidate any other calibration.	
Dye	Every two years (recommended).	
	• During a Dye calibration, only the dyes on the given spectral calibration plate are calibrated.	
	Note: Performing a Dye calibration for a given dye plate does <i>not</i> invalidate any other calibration.	
Normalization	Every two years (recommended).	
(TaqMan™ Array Card block only)		

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(continued)

Calibration	Recommended frequency
RNase P instrument verification	 After installing or moving the instrument. (<i>Recommended</i>) After performing any of the calibrations. As needed to confirm instrument performance.

Note: To prepare custom dye plates and to perform custom calibrations, see "Calibrate custom dyes" on page 120.

Calibration descriptions

The combination of the instrument and the block is calibrated (see "Instrument and block calibration" on page 90).

Calibration description and purpose	Pass criteria
ROI/Uniformity	
 The software captures images for each optical filter. The software uses calibration data to map the increase in fluorescence to the plate wells during subsequent runs and to evaluate well-to-well consistency of the signals. 	The image for each filter distinguishes all wells of the plate. Each well in the image is distinct.
Background	
 The software captures background images for each optical filter in the absence of sample and reagent, and it checks that the fluorescence from each well is below a fluorescence threshold. 	The plate images for all filters are free of abnormal fluorescence.
 The software uses calibration data to remove background fluorescence during a run. 	
Note: You can also run this calibration to determine if contamination is related to the sample block or the plate.	
Dye	
 The software extracts a spectral profile for each dye standard, then produces a set of spectral profiles plotted as fluorescence vs filter. 	Dye spectra peak within the same filter as their group.
 The software uses calibration data to characterize and distinguish the individual contribution of each dye in the total fluorescence signals collected by the instrument. 	

(continued)

Calibration description and purpose	Pass criteria
Normalization (TaqMan™ Array Card block only)	
 The software extracts a spectral profile for each normalization standard. The software uses the normalization standards to obtain a correction factor for the specific dyes, for example, FAM[™] dye or VIC[™] dye. 	Normalization standards have sufficient signals to generate a correction factor.
 The correction factor is used to generate comparable component signal levels across instruments. 	

View the calibration status and set reminders

View the calibration status on the instrument

The Status and Reminders screen also allows you to perform the following functions:

- Transfer the calibration results (see page 101)
- Transfer the calibration data files (see page 101)
- View the calibration images (see page 99)
- 1. In the home screen, tap (a) (Settings) > Maintenance and service > Calibrations > Status and reminders.

The Status and Reminders screen is displayed. It includes the following information:

Type of calibration

Note:

- For dye calibration of a TaqMan[™] Array Card block, the type of calibration is listed as the dye that was calibrated, for example, **FAM**.
- Normalization calibration is required for a TaqMan[™] Array Card block. The type of calibration is listed as **FAM/ROX** or **VIC/ROX**.
- Status of the calibration
- Last calibration
- Date that the calibration expires
- If a reminder is set
- 2. Tap a calibration row, then tap View to view the history of that specific calibration type.
 - Date performed

- Whether the calibration is current
- Result of the calibration
 Operator
- 3. Tap Cancel to return to the Status and Reminders screen.







Set calibration frequency and reminders on the instrument

The Status and Reminders screen is displayed.

- 2. Tap a calibration row, then tap Edit.
- **3.** Tap the **Expiration Interval** field, then enter the number of days. The default is 730 days (2 years).
- 4. Tap the **Reminder** field, then enter the number of days The **Next Reminder** field is be populated.
- 5. Set the **On/Off** slider to the **On** position to enable a reminder about calibration.
- 6. Tap Save.

The calibration reminder can be set as a home screen notification (see "Enable and disable home screen notifications" on page 213).

View calibration status and set reminders on the Thermo Fisher[™] Connect Platform

Note: The calibration reminders feature requires a connection between the instrument and a computer network.

- 1. Sign in to the Thermo Fisher[™] Connect Platform on a browser.
- 2. Tap 📮 (Instrument) to open InstrumentConnect.
- 3. Select any of your registered instruments.
- 4. In the **Summary** tab:
 - Tap + Calibrations to view the status of each calibration type.
 - (Optional) Tap + Calibration Reminders to set the calibration reminder time table and enter the notification email address or addresses.

Note: More than one email address can receive the calibration reminders.

Note: The settings are automatically saved.

• (Optional) In the **Downloads** section, tap **Maintenance Summary.pdf** to download the calibration status report.

5. In the Calibrations History tab:

- View the history of each calibration type.
- (Optional) Tap ± to download the calibration history report.

7

Review calibration status

The calibration status can be reviewed in the QuantStudio[™] Design and Analysis Software 2. The instrument must be added to the **Manage Instruments** list.

1. In the home screen, click Manage Instruments.

To access instruments from a different screen, click 🔅 System > Instruments.

2. In the **Summary** tab for the instrument, the calibration status is displayed in the **Calibration Status** column.

Export a calibration report

The calibration report is exported as a TXT file.

The location to transfer the calibration report is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

A calibration report file cannot be overwritten.

If security is enabled on the instrument, your SAE account must have the permission of **Export** general data in order to export the calibration report. Your SAE account must have the permission of **Allow keep both files** in order to keep both calibration reports if the calibration report was previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow keep both files** if the calibration report was previously transferred to the same location and you would like to keep both of the files.

- 1. In the home screen, tap (a) (Settings) > Maintenance and service > Calibrations > Status and reminders.
- 2. Tap a row associated with a calibration, then tap Export.
- 3. Select a destination.

 - 😑 Network Drive
 - 🗆 USB Drive

The connectivity status of each location is displayed.

4. Tap Done.

Perform ROI/uniformity, background, and dye calibrations for plate blocks

To calibrate the TaqMan[™] Array Card block, see "Perform ROI/uniformity, background, dye, and normalization calibrations for the TaqMan[™] Array Card block" on page 105.



Calibration workflow

Perform an ROI/uniformity calibration

You are automatically prompted to perform background calibration.

▼

Perform a background calibration

Perform any time that ROI/uniformity calibrations are current.

▼

Perform system dye calibrations

Perform any time that ROI/uniformity and background calibrations are current.

▼

(Optional) Perform custom dye calibrations (see "Calibrate custom dyes" on page 120)

Perform any time that ROI/uniformity and background calibrations are current.

Prepare a calibration plate

Required materials to prepare calibration plates

Note: We recommend calibrating with all Spectral Dye Calibrations Plates available for your block configuration even if you are not using all the dyes in the plates. This is recommended for optimal system performance.

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Item	Source
Calibration plates	
ROI/Uniformity plate	See Appendix D, "Parts and materials".
Background calibration plate	See Appendix D, "Parts and materials".
Dye calibration plates See Appendix D, "Parts and material	
Equipment and consumables	
Centrifuge with plate adapter; buckets cleaned before use	MLS
Powder-free gloves	MLS
Safety glasses	MLS

Thaw, vortex, and centrifuge a calibration plate

IMPORTANT! Keep calibration plates protected from light until you perform the calibration. Do not remove the plate from its packaging until you are ready to use it. Prolonged exposure to light can diminish the fluorescence of the dyes in the wells of calibration plates.

1. Remove the calibration plate from the freezer, then thaw the plate in its packaging for 30 minutes.

IMPORTANT! Use each plate within 2 hours of thawing.

2. While wearing powder-free gloves, remove the calibration plate from its packaging. Do not remove the optical film.

Note: Do not discard the packaging for the calibration plate. Each calibration plate can be used up to three time if the following conditions are met:

- The plate is stored in its packing sleeve at -25°C to -15°C.
- The plate is used within 6 months after opening.
- The plate is used before the plate expiry date.
- 3. Vortex the plate for 5 seconds, then centrifuge at $750-1,000 \times g$ for 2 minutes.
- 4. Confirm that the liquid in each well is at the bottom of the well and free of bubbles. If it is not, centrifuge the plate again.



IMPORTANT! Keep the bottom of the plate clean. Fluids and other contaminants on the bottom of the plate can contaminate the sample block and cause an abnormally high background signal.

Perform calibrations

The location to transfer the calibration data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to export the calibration data file. Your SAE account must have the permission of **Allow overwriting of files** in order to overwrite a calibration data file if it was previously transferred to the same location. Your SAE account must have the permission of **Allow keep both files** in order to keep both calibration data file was previously transferred to the same location.

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Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow overwriting of files** if the calibration data file was previously transferred to the same location and you would like to overwrite the calibration data file.

- 2. In the Calibration screen, select a calibration type.

Calibration type	Тар
ROI/uniformity	ROI and uniformity
Background	Background
Dye	System dye

Note: You are prompted to perform a background calibration after a ROI/Uniformity calibration.

- 3. (System dye calibration only) Select the calibration plate.
- 4. Follow the instructions on the screen to start the calibration.
- 5. Load the plate into the instrument.



CAUTION! The instrument should be used by trained operators who have been warned of the moving parts hazard.

6. Tap Start.

When the ROI/Uniformity run is complete, you are prompted to perform a background calibration. When the Background calibration is complete, the **Calibration Status** screen is displayed. It indicates whether the calibration passed or failed.

7. (For calibrations that pass) Select an option.

Option	Description
Details	View the calibration images.
Transfer EDS	Transfer the calibration data file to the Thermo Fisher™ Connect Platform, a USB drive, or a network drive.
Reject results	The calibration file is deleted.
Accept results	The calibration file is saved.

If the results are accepted and the calibration file is saved, previous calibration files associated with the combination of the instrument and the block is no longer be used.



8. (For calibrations that fail) Select an option.

Option	Description
Details	View the calibration images.
Transfer EDS	Transfer the calibration data file to the Thermo Fisher [™] Connect Platform, a USB drive, or a network drive (recommended for troubleshooting).
Close	The calibration file is deleted.

See "Troubleshoot calibration failure" on page 103.

9. Unload the plate from the instrument.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. Allow it to cool to room temperature before handling.

Note: Use Smart Help if the instrument does not eject the plate (see "Request technical support with Smart Help" on page 197).

10. Return the plate to its original packaging.

Note: Do not discard the packaging for the calibration plate. Each calibration plate can be used up to three time if the following conditions are met:

- The plate is stored in its packing sleeve at -25° C to -15° C.
- The plate is used within 6 months after opening.
- The plate is used before the plate expiration date.

View the calibration images

The instrument performs the ROI, uniformity, and background calibrations in sequence. You can view the calibration images after the background calibration is complete.

1. In the home screen, tap ⊕ (Settings) ➤ Maintenance and service ➤ Calibrations ➤ Status and reminders.

The Status and Reminders screen is displayed.

- 2. Tap a calibration type in the table, then tap **View**.
- **3.** Tap a calibration date in the table, then tap **View**. The following details are displayed:



- Calibration name
- Result
- Date
- Whether this calibration is current
- 4. Tap Detail.

- The operator
- Reagent name, part number, lot number, and expiration date
- Comments.

Calibration	Example results indicating successful calibration
ROI	Green circles around all wells and bright well centers.
Note: Select the desired filter combination from the Filter Set dropdown list.	
Uniformity	Signals from each well following a uniform trend.
Background	Few, if any, signals with abnormally high fluorescence.
Dye	Signals from each well following a uniform trend, and each dye

- 5. *(Optional)* For Uniformity, Background, and Dye calibration images, tap on an individual well on the right side to see the results for a single well.
- 6. *(Optional)* For Dye calibration images for a plate, tap on the dye dropdown list to view the image for the dye.

Transfer calibration results

The location to transfer the file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

The calibration results cannot be overwritten.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to transfer the calibration results. Your SAE account must have the permission of **Allow keep both files** in order to keep both files if the file was previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow keep both files** if the calibration results were previously transferred to the same location and you would like to keep both of the files.

1. In the home screen, tap (a) (Settings) > Maintenance and service > Calibrations > Status and reminders.

The Status and Reminders screen is displayed.

- 2. Tap a calibration type in the table.
- 3. Tap Export.
- 4. Select the destination for the file.
 - Connect platform

Note: You must be signed in with a Thermo Fisher™ Connect Platform account.

- 😑 Network Drive
- 🕞 USB Drive

Transfer calibration data files

This section describes transferring calibration files if the calibration passed.

If the calibration fails, the calibration data file is not saved. The data file can only be transferred immediately after the calibration (see "Perform calibrations" on page 97).

The location to transfer the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If the calibration data file was previously transferred and you are transferring the same calibration data file, you must decide whether to keep both files or overwrite the original file. You can also cancel the file transfer.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to export the calibration data file. Your SAE account must have the permission of **Allow overwriting of files** in order to overwrite a calibration data file if it was previously transferred to the same location. Your SAE account must have the permission of **Allow keep both files** in order to keep both calibration data files if the calibration data file was previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow overwriting of files** if the calibration data file was previously transferred to the same location and you would like to overwrite the file.

1. In the home screen, tap (a) (Settings) > Maintenance and service > Calibrations > Status and reminders.

The Status and Reminders screen is displayed.

- 2. Tap a calibration type in the table, then tap **View**.
- 3. Tap a calibration date in the table, then tap **View**.
- 4. Tap one of the following options:
 - Transfer EDS
 - Transfer debug EDS

The option to transfer the debug EDS includes additional raw data from the calibration run. The file can be used for troubleshooting purposes.

If the calibration data file was previously transferred to the same location, the **File Overwrite** screen is displayed.

5. In the **File Overwrite**, select one of the following options.

Option	Description
Keep both	The file that was previously transferred is kept. The file that is being transferred is also saved. A suffix is added to the file name in order to keep both of the data files.
Overwrite	The file that is being transferred is saved and overwrites the file that was previously transferred.
Cancel	Cancel the data file transfer.

6. Select the destination for the data file.

Note: You must be signed in with a Thermo Fisher™ Connect Platform account.

- 😑 Network Drive
- 🕞 USB Drive
- 7. Tap Done.

Observation	Possible cause	Recommended action
Calibration failed The plate was improperly prepared.	The plate was improperly	Ensure the following:
	prepared.	 The correct plate was used for the calibration performed.
		The plate was properly thawed.
		The plate was properly centrifuged.
		The plate was properly sealed.
The	The plate is damaged or contaminated.	Check for damage, improper plate seal, or contamination.
		Order a replacement plate. Use Smart Help if the replacement plate fails (see "Request technical support with Smart Help" on page 197).
High fluorescence signal in individual wells	Signals that exceed the limit of normal fluorescence may indicate fluorescent contaminants on the plate or the sample block.	See "Identify contamination" on page 103.
Calibration failed but plate is undamaged	The incorrect plate was used for calibration performed.	Use the plate that matches the calibration performed.
	The plate was improperly prepared.	Repeat the calibration with the plate properly prepared.
		If the calibration fails again, order a replacement plate. Use Smart Help if the replacement plate fails (see "Request technical support with Smart Help" on page 197).

Identify contamination

Signals that exceed the limit of normal fluorescence may indicate fluorescent contaminants on the calibration plate or the sample block. Common contaminants include ink residue from permanent pens, powder from disposable gloves, and dust.

- 1. View the calibration data and note the wells that failed the calibration.
- 2. Remove the plate from the instrument, rotate the plate 180°, then perform the calibration again.

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3. Determine the location of the failed wells again as in step 1.

Position of failed wells	Action
Identical	The sample block is contaminated. Decontaminate the sample block (see page 181).
Reversed	The plate is contaminated. Discard the plate, then perform the calibration using a new calibration plate.

4. Use Smart Help if the calibration fails after you decontaminate the sample block and replace the plate (see "Request technical support with Smart Help" on page 197).

Create a background plate (optional)

Whenever possible, use a background plate listed in "Required materials to prepare calibration plates" on page 96. These plates contain a buffer that accurately simulates the reagents used for PCR, and, therefore, produces high-quality calibration data.

If a background plate is not available, you can create one as described below.

Required materials:

- MicroAmp[™] optical 96-well reaction plate or MicroAmp[™] optical 384-well reaction plate
- · Optical adhesive cover or optical flat caps
- Pipettor, 200-µL (with pipette tips)
- Powder-free gloves
- Safety glasses
- Deionized water

IMPORTANT! Wear powder-free gloves while creating the background plate.

- 1. Remove a reaction plate from its box and place it on a clean, dry surface.
- 2. Aliquot deionized water to each well of the reaction plate.
 - 10-20 µL for a 96-well plate
 - 5 µL for a 384-well plate
- 3. Seal the plate using an optical adhesive cover or optical flat caps.
- 4. Use the plate for background calibration.



Perform ROI/uniformity, background, dye, and normalization calibrations for the TaqMan[™] Array Card block

To calibrate the plate blocks, see "Perform ROI/uniformity, background, and dye calibrations for plate blocks" on page 95.

This section covers procedures specific to the TaqMan[™] Array Card block. See the following sections for additional information:

- Transfer calibration results (page 101)
- Transfer data files from calibrations (page 101)
- Troubleshoot calibration failure (page 103) To troubleshoot normalization calibration, see "Troubleshoot normalization calibration failure" on page 110.
- Identify contamination (page 103)

Calibration workflow

Perform an ROI/uniformity calibration

You are automatically prompted to perform background calibration.

▼

Perform a background calibration

Perform any time that ROI/uniformity calibrations are current.

▼

Perform system dye calibrations

Perform any time that ROI/uniformity and background calibrations are current.

▼

Perform normalization calibration

Perform after a dye calibration.

▼

(Optional) Perform custom dye calibrations (see "Calibrate custom dyes" on page 120)

Perform any time that ROI/uniformity and background calibrations are current.



Prepare a calibration TaqMan[™] Array Card

Required materials to prepare calibration TaqMan[™] Array Card

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Item	Source
Calibration kit	
ViiA [™] 7 Array Card Spectral Calibration Kit, includes the following components:	
 Empty TaqMan[™] Array Cards 	
 FAM[™] dye 	
 VIC[™] dye 	
 ROX[™] dye 	4432314
ROI dye mix	
Background buffer	
 FAM[™]/ROX[™] dye 	
 VIC[™]/ROX[™] dye 	
Equipment and consumables	
Centrifuge with custom buckets and card holders, one of the following:	
 Sorvall[™] centrifuge 	Contact your local sales
 Multifuge[™] centrifuge 	office
 Megafuge[™] centrifuge 	
TaqMan™ Array Card Sealer	Contact your local sales office
Blank balance TaqMan™ Array Cards	Contact your local sales office
Pipette, 200 μL with tips	MLS
Permanent marker or pen	MLS
Powder-free gloves	MLS
Safety glasses	MLS

Fill the calibration TaqMan[™] Array Cards

For detailed instructions to prepare a TaqMan[™] Array Card, see Appendix C, "Detailed procedures for preparation of a TaqMan[™] Array Card".

IMPORTANT! Wear powder-free gloves while creating the calibration array cards.

This procedure explains how to create *all* of the array cards required to calibrate the block, but not all of them are required for at each calibration. Before preparing array cards for calibration, determine which calibrations are required (see "Calibration and verification schedule" on page 91).

Note: For more information on the array card loading procedure, contact Technical Support.

- 1. Remove the tubes of calibration solutions from the freezer, allow them to thaw, then vortex the tubes to mix the contents well.
- 2. Remove the TaqMan[™] Array Cards from their box and place them on a clean, dry surface.
- 3. Mark the side of the empty array cards with the following items:
 - Background
 - FAM[™]
 - ROI
 - ROX[™]

- VIC[™]
- FAM[™]/ROX[™]
- VIC[™]/ROX[™]



1 Location to mark each TaqMan[™] Array Card

4. For each array card, pipet 100 μ L of the appropriate calibration solution into each of the eight reservoirs in the array card.

See "Load the PCR reaction mix" on page 233.

- 5. Centrifuge the array cards, then check each array card for the correct fill. See "Centrifuge the card" on page 233.
- 6. Seal the array cards.

See "Seal the card" on page 235.

IMPORTANT! If an array card is sealed improperly, it can leak and contaminate the sample block and/or it can cause the associated calibration or RNase P test to fail.

IMPORTANT! After the array cards are sealed, store them in a dark place. Do not expose the array cards to light until you are ready to use them. The dyes in the array cards are photosensitive. Prolonged exposure to light can diminish the fluorescence of the dye.





Perform calibrations

The location to transfer the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general** data in order to export the calibration data file. Your SAE account must have the permission of **Allow** overwriting of files in order to overwrite a calibration data file if it was previously transferred to the same location. Your SAE account must have the permission of **Allow keep both files** in order to keep both calibration data files if the data file was previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow overwriting of files** if the calibration data file was previously transferred to the same location and you would like to overwrite the calibration data file.

1. In the home screen tap ((Settings) → Maintenance and service → Calibrations. The Calibration screen is displayed.

Calibration type	Тар
ROI/uniformity	ROI and uniformity
Background	Background
Dye	System dye
Normalization	Instrument normalization

2. In the Calibration screen, select a calibration type.

Note: You will be prompted to perform a background calibration after a ROI/Uniformity calibration.

- 3. (System dye calibration only) Select the dye to calibrate.
 - FAM
 - VIC
 - ROX
- 4. (Normalization only) Select the reporter dye and passive reference to calibrate.
 - FAM/ROX
 - VIC/ROX
- 5. Follow the instructions on the screen to start the calibration.
- Load the TaqMan[™] Array Card into the instrument.
 See "Load a TaqMan[™] Array Card into the instrument" on page 56.



CAUTION! The instrument should be used by trained operators who have been warned of the moving parts hazard.
7. Tap Start.

When the ROI/Uniformity run is complete, you will be prompted to perform a background calibration.

When the Background calibration is complete, the **Calibration Status** will display. It will indicate whether the calibration passed or failed.

8. (For calibrations that pass) Select an option.

Option	Description
Details	View the calibration images.
Transfer EDS	Transfer the calibration file to the Thermo Fisher™ Connect Platform, a USB drive, or a network drive.
Reject results	The calibration file is deleted.
Accept results	The calibration file is saved.

If the results are accepted and the calibration file is saved, previous calibration files associated with the combination of the instrument and the block will no longer be used.

9. (For calibrations that fail) Select an option.

Option	Description
Details	View the calibration images.
Transfer EDS	Transfer the calibration file to the Thermo Fisher [™] Connect Platform, a USB drive, or a network drive (recommended for troubleshooting).
Close	The calibration file is deleted.

See "Troubleshoot calibration failure" on page 103.

10. Unload the TaqMan[™] Array Card from the instrument.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the TaqMan[™] Array Card temperature can reach 100°C. Allow it to cool to room temperature before handling.

Note: Use Smart Help if the instrument does not eject the array card (see "Request technical support with Smart Help" on page 197).

View the calibration images

The instrument performs the ROI, uniformity, and background calibrations in sequence. You can view the calibration images after the background calibration is complete.

1. In the home screen, tap (a) (Settings) > Maintenance and service > Calibrations > Status and reminders.

The Status and Reminders screen is displayed.

2. Tap a calibration type in the table, then tap **View**.





- 3. Tap a calibration date in the table, then tap **View**.
 - The following details are displayed:
 - Calibration name
 - Result
 - Date
 - Whether this calibration is current
- 4. Tap Detail.

- The operator
- Reagent name, part number, lot number, and expiration date
- Comments.
- 5. *(Optional)* For Uniformity, Background, and Dye calibration images, tap on an individual well on the right side to see the results for a single well.

Troubleshoot normalization calibration failure

Normalization calibration is only required for the TaqMan[™] Array Card. For all other calibration troubleshooting, see "Troubleshoot calibration failure" on page 103.

Observation	Possible cause	Recommended action	
Normalization calibration failed	Abnormally low spectra across all wells of the array card.		CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the TaqMan [™] Array Card temperature can reach 100°C. Allow it to cool to room temperature before handling.
		1. Co	onfirm that you loaded the correct array card into the instrument. not, perform the calibration again using the correct consumable.
		2. If y us	you are using the correct array card, perform the calibration again ing a different normalization consumable.
		3. If 1	he calibration fails again, contact Support.
	One or more wells produced spectra that deviate significantly from the rest of the array	1. Lo im	cate the wells with the abnormal signal (see "View the calibration ages" on page 109).
		2. Ro	otate the array card 180°, then perform the calibration again.
		3. De po	etermine the location of the contaminated wells again. If the stitions of the wells identified in the steps above are:
	•	Identical : The sample block is contaminated. Decontaminate the sample block.	
		•	Reversed : The normalization array card is contaminated. Discard the consumable, then perform the normalization calibration using a new normalization array card.
		4. If 1	he calibration fails again, contact Support.

Perform verification using RNase P plates

Verification should be performed under the following circumstances:

- After installation and before first use of the instrument and the block
- (Recommended) After performing instrument and block calibrations
- As needed to confirm instrument and block performance

The instrument and block require valid ROI/uniformity, background, and dye calibrations to perform verification.

Instrument verification description

Purpose	Description	Pass criteria
Confirms the performance of the instrument.	Quantifies the number of copies of the human RNase P gene in samples with known concentrations of the corresponding DNA template.	The instrument passes performance specifications if the following inequality is true and the instrument successfully distinguishes between unknown populations A and B with a statistical confidence level of 99.7%. $[(C_{qA}) - 3(\sigma_{CqA})] > [(C_{qB}) + 3(\sigma_{CqB})]$ where: • C_{qA} = Average C_q of unknown population A • σ_{CqA} = Standard deviation of unknown population A • C_{qB} = Average C_q of unknown population B • σ_{CqB} = Standard deviation of unknown population B

RNase P instrument verification plate

The RNase P plate contains the reagents necessary for the detection and quantitation of genomic copies of the human RNase P gene (a single-copy gene encoding the RNase moiety of the RNase P enzyme). Each well contains the following components:

- PCR Master Mix
- RNase P primers
- A FAM[™] dye-labeled probe
- A known concentration of human genomic DNA template



Figure 13 96-well RNase P plate

- (1) Unknown A (5,000)
- 2 NTC (no template control)
- ③ STD 1,250 copies
- (4) STD 2,500 copies

- (5) STD 5,000 copies
- 6 STD 10,000 copies
- (7) STD 20,000 copies
- (8) Unknown B (10,000)



Figure 14 384-well RNase P plate

- ① NTC (no template control)
- (2) STD 1,250 copies
- ③ STD 2,500 copies
- ④ STD 5,000 copies

- (5) STD 10,000 copies
- 6 STD 20,000 copies
- (7) Unknown A (5,000)
- (8) Unknown B (10,000)



Performance specifications pass criteria

After the run, the software calculates average copy number values and standard deviation values. The instrument passes performance specifications if the following inequality is true and the instrument successfully distinguishes between unknown populations A and B with a statistical confidence level of 99.7%.

 $[(C_{qA}) - 3(\sigma_{CqA})] > [(C_{qB}) + 3(\sigma_{CqB})]$

where:

- C_{qA} = Average C_q of unknown population A
- σ_{CqA} = Standard deviation of unknown population A
- C_{qB} = Average C_q of unknown population B
- σ_{CqB} = Standard deviation of unknown population B

The software automatically adjusts the threshold and omits a defined number of wells from the unknown populations to meet the performance specifications. To view any omitted wells, open the data file for the verification in the desktop software.

Prepare an RNase P plate

Materials required for RNase P plate preparation

- RNase P instrument verification plate
- Centrifuge with plate adapter; buckets cleaned before use
- Powder-free gloves
- Safety glasses

Thaw, vortex, and centrifuge an RNase P plate

IMPORTANT! Expose the RNase P plate to room temperature for no more than 45 minutes, inclusive of thawing and preparation time.

After thawing, the RNase P plate cannot be refrozen.

- 1. Remove the RNase P plate from the freezer, then thaw the plate in its packaging.
 - Thaw the plate for approximately 5 minutes.
 - Use the plate within 30 minutes of thawing.
- 2. Confirm that the bench, vortex, and centrifuge are clean. Before use, wipe the vortex and centrifuge using a lint-free tissue.
- 3. While wearing powder-free gloves, remove the plate from its packaging.
- 4. Vortex the plate for 5 seconds, then centrifuge at $750-1,000 \times g$ for 2 minutes.



5. Confirm that the liquid in each well is at the bottom of the well and free of bubbles. If it is not, centrifuge the plate again.



IMPORTANT! Keep the bottom of the plate clean. Fluids and other contaminants on the bottom of the plate can contaminate the sample block and cause an abnormally high background signal.

Perform RNase P verification

- 1. In the home screen, tap (settings) > Maintenance and service > RNase P verification.
- 2. Follow the instructions on the screen to start the verification.
- **3.** Load the plate into the instrument.



CAUTION! The instrument should be used by trained operators who have been warned of the moving parts hazard.

- 4. Tap Start.
- 5. When the run is complete and the screen displays **Complete**, tap **View results** to confirm the status of the run.

Verification status	Action
Passed	Instrument is ready for use.
Failed	See "Troubleshoot verification failure" on page 115.

6. In the **RNase P Verification Status** screen, tap one of the following options.

Option	Description
Accept results	Save the results to the instrument.
Reject results	Deletes the RNase P verification results.
Export results	Exports the results.

7. Unload the plate from the instrument.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. Allow it to cool to room temperature before handling.



Note: Use Smart Help if the instrument does not eject the plate (see "Request technical support with Smart Help" on page 197).

The status of the RNase P verification is displayed on the **Status and Reminders** screen (see "View the calibration status on the instrument" on page 93).

IMPORTANT! RNase P plates can only be used one time. Do not reuse the RNase P plate.

Troubleshoot verification failure

Observation	Possible cause	Recommended action
Verification failed	The plate was improperly	Ensure the following:
	prepared.	 The correct plate was used for the verification performed.
		The plate was properly thawed.
		The plate was properly centrifuged.
		The plate was properly sealed.
		Open the data file for verification in the desktop software or the Thermo Fisher [™] Connect Platform to view the flags and the troubleshooting details for the failed wells.
	The plate is damaged or	Check for damage, improper plate seal, or contamination.
	contaminated.	Order a replacement plate. Use Smart Help if the replacement plate fails (see "Request technical support with Smart Help" on page 197).
High fluorescence signal	The reaction volume is not correct.	Ensure that reaction volumes in the plate are correct and match the volume that is entered in the Method tab.
	Signals that exceed the limit of normal fluorescence can indicate fluorescent contaminants on the plate or on the sample block.	Examine the bottom of the reaction plate. If there is contamination, prepare a new plate and run the experiment again.
		Identify the location of contamination on the plate or sample block.
		 Obtain or prepare a background plate (see "Create a background plate (optional)" on page 104).
		 Follow the procedures to identify contamination (see "Identify contamination" on page 103).
Verification failed but plate is undamaged	The incorrect plate was used for verification.	Use the correct RNase P plate for verification.



Observation	Possible cause	Recommended action
Verification failed but plate is undamaged	Verification failed but plate is undamaged continued)	Repeat the verification with a new properly prepared plate. Note: Each RNase P plate can only be used once.
(continued)		Open the data file for verification in the desktop software or the Thermo Fisher [™] Connect Platform to view the flags and troubleshooting details for failed wells.
		If the verification fails again, order a replacement plate. Use Smart Help if the replacement plate fails (see "Request technical support with Smart Help" on page 197).

Perform verification using RNase P with a TaqMan[™] Array Card

Verification should be performed under the following circumstances:

- After installation and before first use of the instrument and the block
- (Recommended) After performing instrument and block calibrations
- As needed to confirm instrument and block performance

The instrument and block require valid ROI/uniformity, background, normalization, and dye calibrations to perform verification.

For a description of verification, see "Instrument verification description" on page 111.

For a description of the pass criteria, see "Performance specifications pass criteria" on page 113.

RNase P instrument verification TaqMan[™] Array Card

The ViiA[™] 7 Array Card RNaseP Verification Kit includes one empty array card and eight tubes of solution. Each tube contains reaction mix (PCR master mix, RNase P primers, and FAM[™]-MGB dye-labeled probe) and a known concentration of human genomic DNA template.

To perform an instrument verification run, each solution is loaded into the empty array card. When complete, the array card contains five replicate groups of standards (200, 400, 800, 1600, and 3200 copies), two of unknown populations (800 and 1600 copies), and one that serves as a no template control (NTC).

See Figure 15 on page 117.



Figure 15 RNase P standards layout

- 1 Port 1, No Template Control
- (2) Port 2, Unknown A (800 copies)
- (3) Port 3, Unknown B (1,600 copies)
- (4) Port 4, Standard 200 copies
- (5) Port 5, Standard 400 copies
- (6) Port 6, Standard 800 copies
- (7) Port 7, Standard 1,600 copies
- (8) Port 8, Standard 3,200 copies

Prepare an RNase P TaqMan[™] Array Card

Required materials to prepare an RNase P TaqMan[™] Array Card

Unless otherwise indicated, all materials are available through **thermofisher.com**. "MLS" indicates that the material is available from **fisherscientific.com** or another major laboratory supplier.

Item	Source	
Calibration kit		
 ViiA[™] 7 Array Card RNaseP Verification Kit, includes the following components: TaqMan[™] Array Card Eight (8) vials of RNase P detection reagents, one for each port in the TaqMan[™] Array Card. Each vial contains the following reagents: PCR master mix RNase P primers A FAM[™] dye-labeled probe A known concentration of human genomic DNA template 	4432265	

7



(continued)

Item	Source	
Equipment and consumables		
 Centrifuge with custom buckets and card holders, one of the following: Sorvall[™] centrifuge Multifuge[™] centrifuge Megafuge[™] centrifuge 	Contact your local sales office	
TaqMan™ Array Card Sealer	Contact your local sales office	
Blank balance TaqMan™ Array Cards	Contact your local sales office	
Pipette, 200 μL with tips	MLS	
Permanent marker or pen	MLS	
Powder-free gloves	MLS	
Safety glasses	MLS	

Prepare an RNase P TaqMan[™] Array Card

For detailed instructions to prepare a TaqMan[™] Array Card, see Appendix C, "Detailed procedures for preparation of a TaqMan[™] Array Card".

IMPORTANT! Wear powder-free gloves while preparing the array card.

1. Remove the ViiA[™] 7 Array Card RNaseP Verification Kit from the freezer, then allow it to warm to room temperature (for approximately 15 minutes).

IMPORTANT! You must fill and run the RNase P array card within 60 minutes of thawing the kit.

- 2. Remove an array card from its box and place it on a clean, dry surface.
- 3. Using a permanent marker, mark the side of the empty array card with RNase P.



(1) Location to mark each TaqMan[™] Array Card

- 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 9 (1)в С 2) D F (3) E G (4) (5) ĸ (6)L Μ 7) Ν C (8) P
- 4. Pipet 100 µL of each solution into the appropriate port of the array card.

Figure 16 RNase P standards layout

- 1 Port 1, No Template Control
- 2 Port 2, Unknown A (800 copies)
- ③ Port 3, Unknown B (1,600 copies)
- (4) Port 4, Standard 200 copies
- 5 Port 5, Standard 400 copies
- 6 Port 6, Standard 800 copies
- 7 Port 7, Standard 1,600 copies
- 8 Port 8, Standard 3,200 copies

See "Load the PCR reaction mix" on page 233.

- 5. Centrifuge the array card, then check the array card for the correct fill. See "Centrifuge the card" on page 233.
- 6. Seal the array card.

See "Seal the card" on page 235.

IMPORTANT! If an array card is sealed improperly, it can leak and contaminate the sample block and/or it can cause the associated calibration or RNase P test to fail.

7. Run the prepared array card as soon as possible after filling it.

Perform RNase P verification

- 1. In the home screen, tap (settings) > Maintenance and service > RNase P verification.
- 2. Follow the instructions on the screen to start the verification.



3. Load the TaqMan[™] Array Card into the instrument.



CAUTION! The instrument should be used by trained operators who have been warned of the moving parts hazard.

4. Tap Start.

5. When the run is complete and the screen displays **Complete**, tap **View results** to confirm the status of the run.

Verification status	Action
Passed	Instrument is ready for use.
Failed	See "Troubleshoot verification failure" on page 115.

6. In the **RNase P Verification Status** screen, tap one of the following options.

Option	Description
Accept results	Save the results to the instrument.
Reject results	Deletes the RNase P verification results.
Export results	Exports the results.

7. Unload the TaqMan[™] Array Card from the instrument.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the TaqMan[™] Array Card temperature can reach 100°C. Allow it to cool to room temperature before handling.

Note: Use Smart Help if the instrument does not eject the plate (see "Request technical support with Smart Help" on page 197).

The status of the RNase P verification is displayed on the **Status and Reminders** screen (see "View the calibration status on the instrument" on page 93).

IMPORTANT! An RNase P TaqMan[™] Array Card can only be used one time. Do not reuse the RNase P TaqMan[™] Array Card.

Calibrate custom dyes

Overview of custom dyes

The instrument can run assays designed with custom dyes. The following items are defined as custom dyes:

- Dyes that are not manufactured by Thermo Fisher Scientific.
- Dyes or formulations of dyes that are not system dyes for the instrument.



Custom dye calibration workflow

Determine the optimal dye concentration for each custom dye. Use this concentration to prepare all subsequent dye calibration plates.

Dilute the custom dye

Prepare a custom dye dilution plate (page 122)

▼

Run the dilution plate (page 123)

▼

Determine the optimal dye concentration (page 124)

▼

Calibrate the custom dye using the optimal concentration

Create a custom dye calibration plate (page 125)

▼

Add a custom dye to the instrument (page 125)

▼

Perform a custom dye calibration (page 126)

Use a dilution series to determine an optimal custom dye concentration

Custom dye dilution guidelines

Prepare a dilution series for each custom dye.

- Target several dye concentrations within a range of 100–2,000 nM.
- The custom dye for use in calibration must be attached to the 5' end of a short DNA oligonucleotide consisting of the first two bases of the probe sequence without a quencher at the 3' end.
- Choose a 2- or 3-fold difference in dilution points.
- Dispense 10–20 µL per well for 96-well plates.
- Dispense 5 µL per well for 384-well plates.
- Dilute the dye in buffer compatible with your Master Mix.
- (Intercalating dyes only) Add the appropriate amount of amplified PCR product to generate fluorescence.



Prepare a custom dye dilution plate

IMPORTANT! Wear powder-free gloves throughout the procedure.

- 1. Prepare a 2- or 3-fold dilution series of the custom dye.
- **2.** Dispense aliquots of each dilution into the center of a reaction plate, then seal the plate. A full plate is not needed.



- (1) 100 nM
- 2 200 nM
- ③ 400 nM
- (4) 800 nM
- (5) 1,600 nM



- 3. Vortex the plate for 5 seconds, then centrifuge at $750-1,000 \times g$ for 2 minutes.
- 4. Confirm that the liquid in each well is at the bottom of the well and free of bubbles. If it is not, centrifuge the plate again.



IMPORTANT! Keep the bottom of the plate clean. Fluids and other contaminants on the bottom of the plate can contaminate the sample block and cause an abnormally high background signal.

Run the dilution plate

IMPORTANT! Do not run the dilution plate as a calibration.

1. Load the plate into the instrument.



CAUTION! The instrument should be used by trained operators who have been warned of the moving parts hazard.

2. Set up a genotyping plate file on the instrument (see "Create and run a plate from a system template or a saved plate file" on page 51).

To use a system template for genotyping, see "System template file names" on page 37. Select a genotyping method that is compatible with the Master Mix.



- 3. In the **Method** tab, set the hold to 60°C for 2 minutes.
- 4. In the **Plate** tab, enter the dilution series information for the appropriate wells.
- 5. Tap Start run.
- 6. When the run is complete, transfer the data files for analysis (see "Transfer a data file immediately after a run" on page 86 or "Transfer data files at a later time" on page 87).
- 7. Unload the plate from the instrument.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. Allow it to cool to room temperature before handling.

Note: Use Smart Help if the instrument does not eject the plate (see "Request technical support with Smart Help" on page 197).

Determine the optimal dye concentration

Use the Thermo Fisher[™] Connect Platform or the desktop software to review the dye signal data and select the dilution to use for dye calibration.

1. In the Results tab, select Raw data plot.

This plot displays the raw fluorescence signal of each optical filter, for individual wells.

Note: The raw data plot cannot be viewed on the instrument touchscreen.

- 2. For each replicate population of dilutions, select the wells in the plate layout to view in the plot.
- **3.** Examine the raw data to identify the wells yielding signals according to the ranges shown in the following table.

Plate type	Acceptable signal range ^[1]
96-well	800,000 to 3,200,000
384-well	400,000 to 2,000,000

^[1] Signal range for the optical filter where the dye is brightest.

- 4. Examine the raw data to identify the wells yielding signals in the acceptable range for the optical filter where the dye is brightest.
- 5. *(Optional)* Export the raw data, then calculate the average fluorescence value for each concentration.
- 6. Select the lowest optimal dye concentration that falls within the acceptable signal range.



Calibrate the custom dye

Create a custom dye calibration plate

IMPORTANT! Wear powder-free gloves while creating the dye plate.

Create a full plate of the custom dye diluted to the optimal concentration:

- Dilute the custom dye to the optimal concentration in buffer.
 Prepare an adequate volume, using a volume range of 10–20 µL/well for a 96-well plate.
- 2. Pipet the appropriate volume of the diluted custom dye to the plate wells.
- 3. Seal the plate.
- 4. Vortex the plate for 5 seconds, then centrifuge at $750-1,000 \times g$ for 2 minutes.
- 5. Confirm that the liquid in each well is at the bottom of the well and free of bubbles. If it is not, centrifuge the plate again.



IMPORTANT! Keep the bottom of the plate clean. Fluids and other contaminants on the bottom of the plate can contaminate the sample block and cause an abnormally high background signal.

Add a custom dye to the instrument

- In the home screen, tap (a) (Settings) ➤ Maintenance and service ➤ Calibrations ➤ Custom dye. The Custom Dye screen is displayed.
- 2. Tap Add custom dye.
- 3. Tap the **Custom Dye Name** field, then enter a name.

IMPORTANT!

- Do not use a system dye name for a custom dye name.
- Dye names are spacing sensitive and cannot contain special characters.



4. Select the type of dye.

Option	Description	
Reporter	The dye works in conjunction with a quencher dye to report an increase of PCR product.	
Quencher	The dye suppresses the fluorescence of a reporter dye until amplification of PCR product.	
Both	The dye can be used as a reporter dye or a quencher dye.	

5. Tap Save.

IMPORTANT! The custom dye must also be added to the desktop software library before creating, running, or analyzing experiments that use custom dyes.

Perform a custom dye calibration

The location to transfer the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to export the calibration data file. Your SAE account must have the permission of **Allow overwriting of files** in order to overwrite a calibration data file if it was previously transferred to the same location. Your SAE account must have the permission of **Allow keep both files** in order to keep both calibration data file was previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow overwriting of files** if the calibration data file was previously transferred to the same location and you would like to overwrite the calibration data file.

- 2. Tap a custom dye.
- 3. Review the information, then tap Update.
- 4. Enter the calibration temperature.

Note: The default calibration temperature is set to 60°C.

- 5. (Optional) Tap Reagents, then enter the reagent information.
- 6. Load the plate into the instrument, then tap Start.



CAUTION! The instrument should be used by trained operators who have been warned of the moving parts hazard.

Calibration complete is displayed when the run is complete.



7. Tap View results > Details.

8. Review the plot.

Calibration results that pass show uniform signals with peaks that are aligned with the dye wavelength.

Dook filtor	Filter wavelength (nm) ^[1]		
i eak inter	Excitation	Emission	
x1-m1	470 ± 15	520 ± 15	
x2-m2	520 ± 10	558 ± 11	
x3-m3	550 ± 11	586 ± 10	
x4-m4	580 ± 10	623 ± 14	
x5-m5	640 ± 10	682 ± 14	
x6-m6	662 ± 10	711 ± 12	

^[1] The central wavelengths are the optimized wavelengths.



Figure 17 An example of a dye calibration plot The peaks for your dye may align with a different filter set.

9. Select an action depending on whether the custom dye calibration passed or failed.

Calibration status	Action
Passed	a. Tap Accept Results or Reject Results.
	Note: Accepting the results saves the calibration data to the instrument and overwrites existing data.
	b. (<i>Optional</i>) Tap Transfer to EDS to transfer the calibration data to a USB drive.
Failed	 Perform the calibration again using a new custom dye plate. Create the plate using the next dye concentration greater than the optimal dye concentration (see "Determine the optimal dye concentration" on page 124).
	 b. For more information about calibration failures, see "Troubleshoot calibration failure" on page 103.



10. Unload the plate from the instrument.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. Allow it to cool to room temperature before handling.

Note: Use Smart Help if the instrument does not eject the plate (see "Request technical support with Smart Help" on page 197).

Calibrate for a custom melt curve run

Use this calibration to prepare for high resolution melt analysis runs.

Note: A custom melt calibration calibrates a custom dye and a melt calibration at the same time.

The location to transfer the data file is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to export the calibration data file. Your SAE account must have the permission of **Allow overwriting of files** in order to overwrite a calibration data file if it was previously transferred to the same location. Your SAE account must have the permission of **Allow keep both files** in order to keep both calibration data file was previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow overwriting of files** if the calibration data file was previously transferred to the same location and you would like to overwrite the calibration data file.

- Ensure that all calibrations are current (see "View the calibration status on the instrument" on page 93).
- Add a custom dye (see "Add a custom dye to the instrument" on page 125).
- 1. In the home screen, tap (settings) > Maintenance and service > Calibrations > Custom melt.
- 2. Select the option for the kit that you are using.
 - PCR + Melt
 - Melt only

3. Select or add a dye, then select a filter set appropriate for your dye's wavelength (see filter-

wavelength table below).

Note: See your reagent kit documentation for dye name and wavelength information.

	Filter wavelength (nm) ^[1]		
Peak filter	Excitation	Emission	
x1-m1	470 ± 15	520 ± 15	
x2-m2	520 ± 10	558 ± 12	
x3-m3	550 ± 10	587 ± 10	
x4-m4	580 ± 10	623 ± 14	
x5-m5	640 ± 10	682 ± 14	
x6-m6	662 ± 10	711 ± 12	

^[1] The central wavelengths are the optimized wavelengths.

IMPORTANT! If the selected filter set does not match your reagent kit documentation, then the incorrect wavelength may be collected during a run.

- 4. (Optional) Tap **Reagents**, then enter the reagent information.
- 5. Load the plate into the instrument
- 6. Tap Start.
- 7. When the run is complete and the screen displays Calibration complete, tap View results ► Details.
- 8. Review the plot.

Passing calibration results show uniform signals with peaks that are aligned with the dye wavelength.



Figure 18 An example dye calibration plot

Note: The peaks for your dye may align with a different filter set.



9. Select an action depending on whether the custom dye calibration passed or failed.

Calibration status	Action
Passed	a. Tap Accept Results or Reject Results.
	Note: Accepting the results saves the calibration data to the instrument and overwrites existing data.
	b. (<i>Optional</i>) Tap Transfer EDS to transfer the calibration data to a USB drive.
Failed	 a. Perform the calibration again using a new custom dye plate. Create the plate using the next dye concentration greater than the optimal dye concentration (see "Determine the optimal dye concentration" on page 124).
	b. For more information, see "Troubleshoot calibration failure" on page 103.

10. Unload the plate from the instrument.

Note: You must also add the custom dye to the desktop software dye library before you create, run, or analyze experiments that use custom dyes.

Note: To perform a custom melt experiment, you can either create a Standard Curve or a Custom experiment with melt, then specify the data points per degree in the method.



Manage profiles

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Require sign-in

- 2. Set the slider.

Option	Description	
Off	The instrument will allow guest users to access public folders.	
On	The instrument will require a user to sign in.	

3. Tap Done.

Q

Recommended order to set up profiles

Task	Description	
	The first profile on the instrument becomes the instrument administrator.	
Create a profile for the instrument administrator.	The first profile is set up during the initial install with a representative from Thermo Fisher Scientific.	
	See "Create an administrator instrument profile during initial start-up" on page 141.	
	A Thermo Fisher [™] Connect Platform administrator is distinct from an instrument administrator.	
Select a Thermo Fisher™ Connect Platform administrator.	The first Thermo Fisher [™] Connect Platform account to be linked to the instrument is automatically assigned the role of a Thermo Fisher [™] Connect Platform administrator. It is recommended that the first Thermo Fisher [™] Connect Platform account to be linked is the one that should be a Thermo Fisher [™] Connect Platform administrator.	
	The roles can be updated at a later time on the Thermo Fisher™ Connect Platform.	
	Create a local instrument profile. Thermo Fisher™ Connect Platform-enabled features are not available.	
Each person creates a profile.	<i>(Optional)</i> Link a local instrument profile to a Thermo Fisher™ Connect Platform account.	
	Sign in with a Thermo Fisher™ Connect Platform account. Thermo Fisher™ Connect Platform-enabled features are available.	
Assign additional instrument administrators. Any of the profiles can be assigned the role of instrument administrator. The loc profile must be created first or the Thermo Fisher™ Connect Platform account r linked first.		

Overview of local instrument profiles and Thermo Fisher™ Connect Platform accounts

- Local instrument profile
 - Plate files and data files are stored on the instrument.
 - Plate files and data files can be transferred to the desktop software.
 - Voice commands are not available.
 - Email notifications are not available.
 - The instrument schedule is not available.

- Smart Help is not available.
- Separate profiles are required for each instrument if multiple instruments are used.
- Thermo Fisher™ Connect Platform account
 - Plate files and data files are stored on the instrument.
 - Plate files and data files can be transferred to the Thermo Fisher[™] Connect Platform or the desktop software.
 - Voice commands are available.
 - Email notifications are available.
 - The instrument schedule is available.
 - Smart Help is available.
 - The same profile can be used for multiple instruments.

Thermo Fisher[™] Connect Platform roles and functions

The first user who links their local instrument profile to their Thermo Fisher[™] Connect Platform account is assigned a Thermo Fisher[™] Connect Platform account with administrator role.

Instrument profile	Location	Functions allowed
Standard	Thermo Fisher™ Connect Platform	 Create, save, open, import, and run plate files Create and modify run settings View and export data files
Administrator	Thermo Fisher™ Connect Platform	 All the permissions of a local administrator profile, plus the following functions performed in the Thermo Fisher™ Connect Platform: See a list of all the Thermo Fisher™ Connect Platform profiles that are linked to the instrument Assign Thermo Fisher™ Connect Platform administrator roles to one or more users Remove a user from an instrument Disconnect the instrument from the Thermo Fisher™ Connect Platform Change the instrument name

Test the connection to the Thermo Fisher[™] Connect Platform

 In the home screen, tap

 (Settings) ➤ Maintenance and service ➤ Connect services. The Connect Services screen is displayed.

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\odot	Connect Services	٢	?	۲
	Real time monitoring of run, instrument events and critical device statistics on Connect Connect platform Disable Enable			
Priva			Done	

2. Tap Test connection.

If the connection can be established, **You are able to connect to the Connect platform** is displayed.



If the connection cannot be established, **Unable to connect** is displayed.



3. Tap Close.

Link the instrument to your Thermo Fisher[™] Connect Platform account

This section describes using your Thermo Fisher[™] Connect Platform account when you use the instrument for the first time.

The first time you use your Thermo Fisher[™] Connect Platform account on an instrument, you will be prompted to create a four-digit numerical PIN. This PIN is to use when signing in to the instrument with your Thermo Fisher[™] Connect Platform account. It will apply to all other instruments when you use your Thermo Fisher[™] Connect Platform account. This does not change the password when signing in to your Thermo Fisher[™] Connect Platform account on a browser.

After the PIN is set up on the instrument, it must be changed with your Thermo Fisher[™] Connect Platform account on a browser (see "Change the PIN for a Thermo Fisher[™] Connect Platform account" on page 143).

The first time the instrument is used with a Thermo Fisher[™] Connect Platform account, a region must be selected.

For a detailed description of the profile, see "If you link when you are not signed in to the instrument" on page 140.

- 1. In the Sign In screen, tap Get started > Connect.
- 2. (Optional) Select the appropriate region.

Option	Description	
China	For users in China	
U.S.	For users in any country other than China	

3. Tap a connection option.

Option	Action
Mobile devices	Note: Before selecting this option, install and sign in to the InstrumentConnect application on your mobile device.
	 On the instrument: a. Tap D Mobile devices. b. Hold the camera on your mobile device over the QR code that is displayed on the touchscreen. c. Tap Close.
PC	 A link code is displayed on the instrument. On a computer: a. Access the Thermo Fisher[™] Connect Platform. b. Click Add instrument. c. Select QuantStudio. d. Enter the link code.

4. *(Optional)* In the Enter PIN screen, tap the PIN (4 digits required) field, enter a four-digit numerical PIN, then tap Enter.

Tap the **Show PIN** checkbox to show or hide the PIN.

- 5. (Optional) Tap the Confirm PIN field, enter the four-digit numerical PIN again, then tap Enter.
- 6. Tap Done.

Create a new local instrument profile

A local instrument profile is not compatible with Thermo Fisher[™] Connect Platform-enabled features. A local instrument profile can be linked to Thermo Fisher[™] Connect Platform at a later time.

To link a local instrument profile to Thermo Fisher[™] Connect Platform at a later time, see "Link a local profile to a Thermo Fisher[™] Connect Platform account" on page 137.

For a description of linking a local instrument profile to the Thermo Fisher[™] Connect Platform, see "If you link when you are signed in to the instrument" on page 139.

- 1. In the Sign In screen, tap Get Started.
- 2. Tap Create Profile.
- 3. Tap the **User name** field, enter a user name, then tap **Enter**.
- 4. Tap the **PIN (4 digits required)** field, enter a four-digit numerical PIN, then tap **Enter**. Tap the **Show PIN** checkbox to show or hide the PIN.

- 5. Tap the Confirm PIN field, enter the four-digit numerical PIN again, then tap Enter.
- 6. Tap Create Profile.

Proceed immediately to set up facial authentication (see "Set up facial authentication at the initial creation of an instrument profile" on page 141) or tap **Skip** to set up facial authentication at a later time.

Link a local profile to a Thermo Fisher[™] Connect Platform account

This section describes linking a local instrument profile to a Thermo Fisher[™] Connect Platform account, if a local instrument profile was created first.

The first time you use your Thermo Fisher[™] Connect Platform account on an instrument, you will be prompted to create a four-digit numerical PIN. This PIN is to use when signing in to the instrument with your Thermo Fisher[™] Connect Platform account. It will apply to all other instruments when you use your Connect account. This does not change the password when signing in to your Thermo Fisher[™] Connect Platform account on a browser.

After the PIN is set up on the instrument, it must be changed with your Thermo Fisher[™] Connect Platform account on a browser (see "Change the PIN for a Thermo Fisher[™] Connect Platform account" on page 143).

The first time the instrument is used with a Thermo Fisher[™] Connect Platform account, a region must be selected.

For a detailed description of the profile, see "If you link when you are signed in to the instrument" on page 139.

(Optional) Test the connection (see "Test the connection to the Thermo Fisher™ Connect Platform" on page 133).

- 1. In the home screen, tap () (Profile). The **My Profile** screen is displayed.
- 2. Tap Edit > Link.

The Connect to Connect Platform screen is displayed.

3. (Optional) Select the appropriate region.

Option	Description
China	For users in China
U.S.	For users in any country other than China

4. Tap a connection option.

Option	Action
Mobile devices	Note: Before selecting this option, install and sign in to the InstrumentConnect application on your mobile device.
	 On the instrument: a. Tap [] Mobile devices. b. Hold the camera on your mobile device over the QR code that is displayed on the touchscreen.
	c. Tap Close .
□ PC	 A link code is displayed on the instrument. On a computer: a. Access the Thermo Fisher[™] Connect Platform. b. Click Add instrument.
	c. Select QuantStudio.d. Enter the link code.

5. *(Optional)* In the Enter PIN screen, tap the PIN (4 digits required) field, enter a four-digit numerical PIN, then tap Enter.

Tap the Show PIN checkbox to show or hide the PIN.

- 6. (Optional) Tap the Confirm PIN field, enter the four-digit numerical PIN again, then tap Enter.
- 7. Tap Done.

Unlink a Thermo Fisher[™] Connect Platform account

Unlinking a Thermo Fisher[™] Connect Platform account is done from the Thermo Fisher[™] Connect Platform on your computer.

For more information about unlinking a Thermo Fisher[™] Connect Platform account, see "If you link when you are signed in to the instrument" on page 139 and "If you link when you are not signed in to the instrument" on page 140.

- 1. Sign in to your account on the desktop Thermo Fisher™ Connect Platform.
- 2. In the left pane, click **(Instrument)**.
- 3. Select the instrument, then click **m** Disconnect.
- 4. Tap Confirm.

If you link when you are signed in to the instrument

In this scenario, your local instrument profile name is created manually on the instrument before you link. Your local instrument profile name differs from your Thermo Fisher[™] Connect Platform account name on the instrument.

Phase	Steps that occur
Before you link:	You enter your local instrument profile name in the Sign In screen.
	• Your local instrument profile (<i>UserABC</i>) is displayed in the home screen of the instrument.
	 All plates and results that you create are accessible only when you are signed in with your local instrument profile.
When you link:	 You link your local instrument profile (see "Link a local profile to a Thermo Fisher™ Connect Platform account" on page 137).
	• If this is the first time you link, a Thermo Fisher [™] Connect Platform instrument profile is created using the <i>FirstNameLastInitial</i> of the user name from your thermofisher.com account.
	Example: <i>User1@thermofisher.com</i> First name is <i>User</i> , Last name is <i>Gray</i> . The Thermo Fisher™ Connect Platform account username is <i>User</i> G.
	 Your local instrument profile (UserABC) is linked to your Thermo Fisher[™] Connect Platform account (User1@thermofisher.com).
	 Your Thermo Fisher[™] Connect Platform instrument profile (User G.) replaces your local instrument profile.
After you link:	 Your Thermo Fisher[™] Connect Platform instrument profile (User G.) and
	 Plate files and data files from your local instrument profile can be transferred to the Thermo Fisher™ Connect Platform.
	 New plate files and data files are saved under your Thermo Fisher[™] Connect Platform instrument profile.
	 Your Thermo Fisher[™] Connect Platform instrument profile name (User G. △) is available for selection in the Sign In screen.
If your	• Your local instrument profile (UserABC) is displayed in the home screen of the instrument.
Thermo Fisher™ Connect Platform account is unlinked:	 Plate files and data files that were saved under your Thermo Fisher[™] Connect Platform instrument profile are accessible under your local instrument profile.
	 Plate files and data files are saved under local instrument profile and can be copied to Thermo Fisher™ Connect Platform (see "Copy plate files" on page 81 and "Transfer data files at a later time" on page 87).
	• Your local instrument profile name (<i>UserABC</i>) is available for selection in the Sign In screen.

If you link when you are not signed in to the instrument

In this scenario, your local instrument profile name is created automatically at the time that you link. The same user name is used for your local instrument profile and your Thermo Fisher[™] Connect Platform account. Plates and results are accessible when you sign in with either profile.

If you link to the Thermo Fisher[™] Connect Platform when you are not signed in to the instrument:

Phase	Steps that occur
Before you link:	 In the Sign In screen, you tap Get Started > Connect.
When you link:	• You link your profile (see "Link the instrument to your Thermo Fisher™ Connect Platform account" on page 135).
	 If this is the first time you link, a Thermo Fisher[™] Connect Platform instrument and a local instrument profile (with standard role) are created with the same name using the <i>FirstNameLastInitial</i> of the user name from your thermofisher.com account.
	Example: <i>User1@thermofisher.com</i> First name is <i>User</i> , Last name is <i>Gray</i> . The Thermo Fisher™ Connect Platform account username is <i>User G</i> .
	 Your local instrument profile (User G.) is linked to your Thermo Fisher[™] Connect Platform account (User1@thermofisher.com).
	 Your Thermo Fisher[™] Connect Platform instrument profile (User G.) replaces your local instrument profile.
After you link:	• Your Thermo Fisher [™] Connect Platform instrument profile (<i>User G.</i>) and
	• Plate files and data files from your local instrument profile can be transferred to the Thermo Fisher™ Connect Platform.
	 New plate files and data files are saved under your Thermo Fisher[™] Connect Platform instrument profile.
	 Your Thermo Fisher[™] Connect Platform instrument profile name (User G. △) is available for selection in the Sign In screen.
If your Thermo	• Your local instrument profile (User G.) is displayed in the home screen of the instrument.
Fisher™ Connect Platform account is unlinked:	 Plate files and data files that were saved under your Thermo Fisher[™] Connect Platform instrument profile are accessible under your local instrument profile.
	 New plates and results are saved under local instrument profile and can be copied to the Thermo Fisher[™] Connect Platform.
	• Your local instrument profile name (User G.) is available for selection in the Sign In screen.

IMPORTANT! If you sign in with a local profile, without linking to the Thermo Fisher[™] Connect Platform, sign out, then link to the Thermo Fisher[™] Connect Platform (**Get Started > Connect**), you can potentially have two instrument profiles with different names. Plate files and data files from when you are signed in with one instrument profile are not accessible when you are signed in with the other instrument profile.

Manage individual instrument profiles

Create an administrator instrument profile during initial start-up

The first instrument profile that is created during installation is assigned the role of an instrument administrator. Administrators can grant administrative privileges to other users (see "Enable or disable administrator privileges" on page 144).

Note: An instrument administrator is separate from a Thermo Fisher[™] Connect Platform administrator (see "Recommended order to set up profiles" on page 132).

- 1. Tap Name, enter a user name, then tap Done.
- 2. Tap PIN, enter a four-digit numerical PIN, then tap Enter.

Note: Tap the PIN checkbox to switch the PIN display on or off.

- 3. Tap **Confirm PIN**, then enter the four-digit numerical PIN again.
- 4. Tap Create Profile.

Set up facial authentication at the initial creation of an instrument profile

When a profile is set up for facial authentication, the photographs should reflect how the user appears in the lab. For example, safety glasses should be worn to set up facial authentication if safety glasses will be worn when signing in.

- 1. On the Instrument Profile page, tap Set up now.
- 2. Prepare for the photographs, then tap **Next**.
- 3. Center your face within the green frame, then tap Start.

Note: You must position yourself close enough to the instrument so that the green frame shows only your face without any of the surrounding background. This position is closer to the instrument than when you sign in with facial authentication.

The instrument will take three separate photos after you tap **Capture**. The instrument will display a countdown before each individual photo is taken.

- 4. Tap one of the following options.
 - Done
 - Re-take
- 5. Tap **Done** after **Your instrument profile has been created** is displayed.

Add facial authentication to an existing instrument profile

When a profile is set up for facial authentication, the photographs should reflect how the user appears in the lab. For example, safety glasses should be worn to set up facial authentication if safety glasses will be worn when signing in.

1. Sign in.

See "Sign in with a PIN" on page 48.

2. In the home screen, tap (a) (Profile) > Facial profile > Set up now.

Note: The instrument must be configured for facial authentication (see "Configure the instrument for the hands-free features" on page 211). The **Facial profile** button will not display if the instrument is not configured for facial authentication.

- 3. Prepare for the photographs, then tap **Next**.
- 4. Center your face within the green frame, then tap Start.

Note: You must position yourself close enough to the instrument so that the green frame shows only your face without any of the surrounding background. This position is closer to the instrument than when you sign in with facial authentication.

The instrument will take three separate photos after you tap **Capture**. The instrument will display a countdown before each individual photo is taken.

- 5. Tap one of the following options.
 - Done
 - Re-take

Change the PIN for an instrument profile

This section describes changing a PIN for a local instrument profile. To change a PIN for a Thermo Fisher[™] Connect Platform account, see "Change the PIN for a Thermo Fisher[™] Connect Platform account" on page 143.

- 1. In the home screen, tap (Profile).
- 2. Tap Edit.
- 3. Tap the **Old PIN** field, enter the current four-digit numerical PIN, then tap **Enter**.
- 4. Tap the **PIN (4 digits required)** field, enter a new four-digit numerical PIN, then tap **Enter**. Tap the **Show PIN** checkbox to show or hide the PIN.
- 5. Tap the **Confirm PIN** field, enter the new four-digit numerical PIN again, then tap **Enter**.
- 6. Tap Done.

Change the PIN for a Thermo Fisher[™] Connect Platform account

This section describes changing a PIN for a Thermo Fisher[™] Connect Platform account. To change a PIN for a local instrument profile, see "Change the PIN for an instrument profile" on page 142.

- 1. Sign in to the Thermo Fisher[™] Connect Platform on a browser.
- 2. Click Update PIN number.
- 3. In the **Update PIN number** dialog box, enter a new PIN, then enter the new PIN a second time to confirm it.
- 4. Click Send.

The 4-digit PIN to sign in to instruments with your Thermo Fisher[™] Connect Platform account is updated. This change applies to all of the instruments that you access with your Thermo Fisher[™] Connect Platform account.

Manage all instrument profiles as an administrator

View all instrument profiles

- In the home screen, tap () (Profile). The My Profile screen is displayed.
- 2. Tap All accounts.

A list of all the profiles is displayed. The following information is included for each profile.

Name

 Location (local or Thermo Fisher[™] Connect Platform)

- Date and time created
- Role (standard or administrator)
- 3. (Optional) Tap a column in the table to sort by that parameter.
- 4. Tap Done.

Reset the PIN for a profile

- 1. In the home screen, tap (a) (Profile). The My Profile screen is displayed.
- 2. Tap All accounts. A list of all the profiles is displayed.
- **3.** Tap a profile. The **Manage Account** screen is displayed.

- 4. Tap Delete PIN, then tap Yes.
- 5. Tap Done to return to the My Profile screen.

The profile must have a new PIN added the next time it is accessed.

Add a profile

- 1. In the home screen, tap (a) (Profile). The My Profile screen is displayed.
- 2. Tap All accounts.
- 3. Tap Add profile.
- 4. Tap the User name field, enter a user name, then tap Enter.
- 5. Tap the **PIN (4 digits required)** field, enter a four-digit numerical PIN, then tap **Enter**. Tap the **Show PIN** checkbox to show or hide the PIN.
- 6. Tap the Confirm PIN field, enter the four-digit numerical PIN again, then tap Enter.
- 7. Tap Create profile.

The new profile is displayed on the My Profile screen. The new profile is assigned a standard role.

To enable administrator privileges, see "Enable or disable administrator privileges" on page 144.

Enable or disable administrator privileges

Administrator privileges can only be enabled or disabled on the instrument for local instrument profiles. Thermo Fisher[™] Connect Platform accounts can only have instrument administrator privileges enabled or disabled on the Thermo Fisher[™] Connect Platform.

- In the home screen, tap () (Profile). The My Profile screen is displayed.
- 2. Tap All accounts.
- **3.** Tap a profile. The **Manage Account** screen is displayed.
- 4. Set the Grant admin rights slider to No or Yes.
- 5. Tap Done.

The user role will be updated on the My Profile screen.


Delete a profile

- In the home screen, tap () (Profile). The My Profile screen is displayed.
- 2. Tap All accounts.
- **3.** Tap a profile. The **Manage Account** screen is displayed.
- 4. Tap Delete account.
- Tap Yes to confirm.
 The profile is deleted and it is not listed on the My Profile screen.



Use the instrument with the Security, Auditing, and E-signature (SAE) Administrator Console

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The SAE Administrator Console is compatible only with the QuantStudio[™] 7 Pro Real-Time PCR System.

SAE Administrator Console v2.1 or later is compatible.

SAE Administrator Console v2.1 or later converts the URL to **HTTPS** when accessing the SAE Administrator Console. For more information, see the *SAE Administrator Console v2.0 or later User Guide for PCR systems* (Pub. No. MAN0017468).

The Security, Auditing, and E-signature (SAE) v2.2 includes a language selection.

For more information about the SAE Administrator Console, see the SAE Administrator Console v2.0 or later User Guide for PCR systems (Pub. No. MAN0017468).

Overview of the SAE Administrator Console components

The SAE Administrator Console includes three components:

- SAE Administrator Console This component is a tool that is used by an SAE administrator to configure the settings. The SAE Administrator Console runs in a web browser, even though it is installed locally on your computer. Google Chrome[™] is the recommended web browser, but Internet Explorer[™], Mozilla[™] Firefox[™], or Microsoft Edge[™] can be used.
- SAE server (server)—This component is a service that runs in the background and stores the settings, user accounts, audit records, and e-signature records. By default, the SAE server is installed on the same computer as the SAE Administrator Console. The communication between the SAE Administrator Console and the SAE server (v2.1 and later) uses the encrypted HTTPS protocol. The SAE server is started automatically when the computer is started.
- SAE screens (client)—This component are the screens that are displayed in an application such as the QuantStudio[™] 7 Pro Real-Time PCR Instrument. The screens require user input to sign in, provide audit reasons, or provide an e-signature. More than one application can be connected to and controlled by the same instance of the SAE Administrator Console.

The SAE Administrator Console provides the following SAE functionality on the instrument:

- System security-Controls user sign in and access to functions.
- Auditing-Tracks changes and actions performed by users.
- **E-signature**—Allows users to provide an electronic signature (user name and password) when performing certain functions.

Overview of the instrument features when the SAE functions are enabled

The following instrument features are not available when the SAE functions are enabled:

- Facial authentication
- Voice commands
- Linking to the Thermo Fisher[™] Connect Platform, including using a Thermo Fisher[™] Connect Platform account to log in
- System templates

Only SAE-enabled plate files that were created in the QuantStudio[™] Design and Analysis Software 2 can be opened on the instrument.

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SAE Administrator Console functions

Functions that are controlled on the QuantStudio[™] 7 Pro Real-Time PCR Instrument

The following functions are controlled on the instrument, depending on the user role:

- Setup, including the following functions:
 - Create a new template or run
 - Edit the run method
 - Edit the analysis settings
 - Define, edit, or delete the targets or the assays
 - Assign the target or the assay
 - Define, edit, or delete the sample
 - Assign the samples
 - Define, edit, or delete the reagents
 - Assign the reagents
 - Add a new custom dye
 - Edit the passive reference
- Instrument runs, including the following functions:
 - Start an instrument run
 - Stop an instrument run
- Calibrations, including the following functions:
 - Perform a system dye calibration
 - Perform ROI and uniformity calibration
 - Perform background calibration
 - Perform custom dye calibration
 - Perform custom melt calibration
- Instrument validation (perform an RNase P run)
- Instrument configuration, including the following functions:
 - Perform a firmware update
 - Configure the network
 - Change the instrument name
 - Modify the date and time
 - Modify the sleep mode settings
 - Modify the disk management settings
 - Perform a backup and restore
 - Manage the data, including export locations and import locations
 - Export data files
 - Export general files, including files associated with instrument maintenance
 - Overwrite files that have been previously transferred

- Keep both files if a file has previously been transferred
- Delete data files from the instrument
- Security configuration, including the following functions:
 - Log into timed out user sessions
 - Perform e-signing

Functions that are controlled in the QuantStudio[™] Design and Analysis Software 2

The following functions are controlled in the software, depending on the user role:

- Instrument management, including the following functions:
 - Add an instrument
 - Delete an instrument
 - Export an instrument
- Template management, including the following functions:
 - Install a template
 - Remove a template
- Setup, including the following functions:
 - Create a plate
 - Edit the run method
 - Edit the analysis settings
 - Add, edit, or delete the targets or the assays
 - Assign the target or the assay
 - Add, edit, or delete the sample
 - Assign the samples
 - Add, edit, or delete the reagents
 - Assign the reagents
 - Add an analysis module
 - Edit the passive reference
- Security configuration, including the following functions:
 - Log into timed out user sessions
 - Perform e-signing
- Plugin management, including the following functions:
 - Install or upgrade a plugin
 - Delete a plugin
- User preferences (edit preferences)
- Edit the file save destination
 - Edit the export destination
 - Edit the RDML export destination
 - Edit the report destination
 - Edit the save as destination

Objects that can be audited

The plate is an audited object for the QuantStudio[™] 7 Pro Real-Time PCR Instrument and the QuantStudio[™] Design and Analysis Software 2.

The audit summary for objects is viewed in the QuantStudio[™] Design and Analysis Software 2.

Each time one of the following items is changed, it can be audited, depending on the audit function setup:

- Plate layout
- · Analysis settings
- Run method
- Samples
- Assays

The following reasons are available:

- Manually edited
- Entry error
- Well anomaly
- Calculation error
- Need to change threshold
- Need to reanalyze

Actions that are audited

The actions are audited and listed in the action records regardless of whether audits are enabled or disabled. The audited actions are viewed in the SAE Administrator Console. They are not viewed in the application.

Note: Enabling and disabling audits only applies to objects that are audited. See "Objects that can be audited" on page 150.

The following user actions are audited:

- Sign in success
- Sign out
- Sign in failure
- Enable the SAE functions
- Disable the SAE functions
- Add a new instrument
- Remove an instrument
- Add a new plugin
- Remove a plugin
- Install a template
- Remove a template

Actions that require an e-signature in the QuantStudio[™] 7 Pro Real-Time PCR Instrument

Certain actions performed on the instrument can be set up to require an e-signature. This depends on how the e-signature settings have been configured in the SAE Administrator Console.

The following actions can be set up to require an e-signature:

- Start a calibration run
- Start a run
- Accept calibration

Each action that requires an e-signature is associated with an e-signature meaning and the data that are signed.

E-signature meaning	Data signed
Reviewed and approved template	Plate setupRun method
Accept calibration results	Calibration record

Actions that require an e-signature in the QuantStudio $^{\scriptscriptstyle\rm M}$ Design and Analysis Software 2

Certain actions performed in the software can be set up to require an e-signature. This depends on how the e-signature settings have been configured in the SAE Administrator Console.

Printing a report can be set up to require an e-signature.

Each action that requires an e-signature is associated with an e-signature meaning and the data that are signed.

E-signature meaning	Data signed
Reviewed and approved template	Plate setupRun method
Reviewed and approved plate results	Analysis resultsAnalysis setting

SAE Administrator Console roles

Role name	Description			
Administrator Has all the available privileges.				
Scientist Has all the privileges, except for privileges related to instrument configuration and maintenance.				
Technician	nician Has access to the instrument to perform a run.			

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IMPORTANT! When an application profile is upgraded, the default permissions of any new functions in the new application profile are not applied. The roles do not receive the permission for the new functions. Only the Administrator role receives the permissions for the new functions.

Default permissions for the QuantStudio[™] 7 Pro Real-Time PCR Instrument

Function	Role					
Function	Administrator	Scientist	Technician			
Setup						
Create a new plate file	Yes	Yes	Yes			
Edit the run method	Yes	Yes	No			
Edit the analysis settings	Yes	Yes	Yes			
Define, edit, or delete the targets or the assays	Yes	Yes	Yes			
Assign a target or an assay	Yes	Yes	Yes			
Define, edit, or delete a sample	Yes	Yes	Yes			
Assign a sample	Yes	Yes	Yes			
A user has permission to assign a sample if they have permission to define, edit, or delete a sample. This applies even if the Assign Sample checkbox is not selected in the Security, Auditing, and E-signature (SAE) Administrator Console.						
Define, edit, or delete a reagent	Yes	Yes	Yes			
Assign a reagent	Yes	Yes	Yes			
Add a new custom dye	Yes	Yes	No			
Edit the passive reference	Yes	Yes	No			
Instrument run						
Start a run	Yes	Yes	Yes			
Stop a run	Yes	Yes	Yes			
Calibration	Calibration					
Perform a system dye calibration	Yes	Yes	No			
Perform an ROI and uniformity calibration	Yes	Yes	No			
Perform a background calibration	Yes	Yes	No			
Perform a custom dye calibration	Yes	Yes	No			
Perform a custom melt calibration	Yes	Yes	No			

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(continued)

Function	Role					
	Administrator	Scientist	Technician			
Instrument validation	Instrument validation					
Perform an RNase P run	Yes	Yes	No			
Instrument configuration						
Perform firmware update	Yes	No	No			
Configure the network	Yes	No	No			
Change the instrument name	Yes	No	No			
Modify the date and the time	Yes	No	No			
Modify the SAE settings	Yes	No	No			
Modify the sleep mode settings	Yes	No	No			
Modify the instrument access settings	Yes	No	No			
Modify the disk management settings	Yes	No	No			
Perform a backup and restore	Yes	No	No			
Change data management settings	Yes	Yes	No			
Data management						
Allow overwriting of files	Yes	Yes	Yes			
Allow deletion of files	Yes	Yes	Yes			
Allow keeping both files	Yes	Yes	Yes			
Manually export run data	Yes	Yes	Yes			
Export general data	Yes	Yes	Yes			
Security configuration						
Log into timed-out user sessions	Yes	Yes	No			
Perform e-signing	Yes	Yes	No			



Default permissions for the QuantStudio[™] Design and Analysis Software 2

Function	Role			
	Administrator	Scientist	Technician	
Instrument management				
Add instrument	Yes	Yes	No	
Delete instrument	Yes	Yes	No	
Export instrument	Yes	Yes	No	
Template management				
Install template	Yes	Yes	No	
Remove template	Yes	Yes	No	
Setup				
Create a plate file	Yes	Yes	Yes	
Edit run method	Yes	Yes	No	
Edit analysis settings	Yes	Yes	Yes	
Add, edit, or delete targets and assays	Yes	Yes	No	
Assign targets and assays	Yes	Yes	No	
Add, edit, or delete samples	Yes	Yes	Yes	
Assign samples	Yes	Yes	Yes	
A user has permission to assign a sample if they have permission to define, edit, or delete a sample. This applies even if the Assign Sample checkbox is not selected in the Security, Auditing, and E-signature (SAE) Administrator Console.				
Add, edit, or delete reagents	Yes	Yes	Yes	
Assign reagents	Yes	Yes	Yes	
Add, edit, or delete custom dyes	Yes	Yes	No	
Assign an analysis module	Yes	Yes	Yes	
Edit passive reference	Yes	Yes	No	
Security configuration				
Log into timed-out user sessions	Yes	Yes	No	
Perform e-signing	Yes	Yes	No	



(continued)

Function	Role				
	Administrator	Scientist	Technician		
Plugin management					
Install or upgrade a plugin	Yes	No	No		
Delete a plugin	Yes	No	No		
User preferences					
Edit preferences	Yes	No	No		
Edit file save destination					
Edit export destination	Yes	No	No		
Edit RDML export destination	Yes	No	No		
Edit report destination	Yes	No	No		
Edit save as destination	Yes	No	No		



Screens that are displayed on the QuantStudio[™] 7 Pro Real-Time PCR Instrument

Some of the screens described might not be displayed. They are dependent on how the SAE administrator has configured the system.

		Screen			Description
۲		Enter Audit Reason	٢	?	This screen is displayed if an object is set up to be audited.
					See "Objects that can be audited" on page 150.
	Reason	Manually edited	~		
	Comments				
		<u> </u>			
				Save	
\sim		Mineral and		0 0	
•		Sign Plate	(J)	(?) (▲)	This screen is displayed if an action requires an e-signature.
	Plate name	Plate_20180902_1422440			
	Purpose	Reviewed & approved plate setup	~		
	Data type	Plate setup			
	User name	Administrator			
	Password				
View rec	cords	Cancel		Sign plate	

If you do not have access to a function, you cannot select it.

For example, the buttons to start any of the calibrations are inactive if your role does not have permission to perform a calibration.

\odot	Calibi	ration	۲	?	۲
	Status & reminders				

Profiles on the QuantStudio[™] 7 Pro Real-Time PCR Instrument when the SAE functions are enabled

After the SAE functions are enabled on the QuantStudio[™] 7 Pro Real-Time PCR Instrument, the local instrument profiles and the Thermo Fisher[™] Connect Platform profiles are not available.

An account from the SAE Administrator Console must be used to sign in to the instrument when the SAE functions are enabled. A local instrument administrator can sign in to the instrument to perform limited administrator functions.

The local instrument profiles and the Thermo Fisher[™] Connect Platform profiles are available if the SAE functions are disabled.

System components with the SAE functions enabled

The following system components can be used with the SAE functions enabled:

- QuantStudio[™] 7 Pro Real-Time PCR Instrument
- QuantStudio[™] Design and Analysis Software 2
- Plate files for the QuantStudio[™] 7 Pro Real-Time PCR Instrument—SAE-enabled plate files are created in the QuantStudio[™] Design and Analysis Software 2 with SAE functions enabled.
 - If the SAE functions are enabled in the QuantStudio[™] Design and Analysis Software 2, you can only create plate files for the QuantStudio[™] 7 Pro Real-Time PCR Instrument.
 - If the SAE functions are enabled on the QuantStudio[™] 7 Pro Real-Time PCR Instrument, you cannot create or edit a plate file from the instrument touchscreen.
- QuantStudio[™] 7 Pro Real-Time PCR Instrument data file—SAE-enabled data files are created on the QuantStudio[™] 7 Pro Real-Time PCR Instrument with SAE functions enabled.

We recommend enabling the SAE functions for all system components (see "Enable the SAE functions" on page 159). If one or more of the components have a conflicting SAE status, some features might not be available (see "Compatibility between SAE-enabled and SAE-disabled components" on page 158).

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Note: Template and data files are checksum protected.

- Checksum protection helps to ensure that files produced by the instruments are not edited outside of the system.
- Files produced by the software applications are checksum protected by the software, regardless of whether the SAE functions are enabled.

Compatibility between SAE-enabled and SAE-disabled components

We recommend enabling the SAE functions for all system components (for more information, see "Enable the SAE functions" on page 159). If one or more of the components have a conflicting SAE status, some features might not be available. See the following table for more information.

Component	Functionality with an SAE-enabled plate or data file	Functionality with an SAE- disabled plate or data file
QuantStudio™ Design and Analysis Software 2 with SAE functions enabled	The file can be edited, depending on the SAE configuration.The audit trail is continued.	 The file is opened in read-only mode. The file cannot be edited or saved.
QuantStudio™ Design and Analysis Software 2 with SAE functions disabled	 SAE-disabled files allowed—The file is opened and can be edited. The file can be saved as an invalid SAE file only.^[1] QuantStudio™ 7 Pro Real-Time PCR Instrument forbidden—The file cannot be opened. 	The file can be opened, edited, and saved.
QuantStudio™ 7 Pro Real- Time PCR Instrument with SAE functions enabled	 The file can be opened from the run queue, a USB drive, or other sources.^[2] The file cannot be edited. The audit record is continued. 	The file cannot be opened.
QuantStudio™ 7 Pro Real- Time PCR Instrument with SAE functions disabled	 The plate file can be opened and edited. The file can be saved as an invalid SAE file only.^[1] The file can be used to start a run, but the data file will be an invalid SAE file.^[1] 	The file can be opened, edited, and saved.

^[1] Invalid SAE files contain incomplete audit records.

^[2] You cannot import plate files from the Thermo Fisher™ Connect Platform when the instrument has the SAE functions enabled.

Enable the SAE functions

Workflow

Enable SAE functions Install the application profiles See "Application profiles" on page 159. Enable the SAE functions on the QuantStudio™ 7 Pro Real-Time PCR Instrument (page 160) Connect the QuantStudio™ Design and Analysis Software 2 to the SAE Administrator Console (page 161) Enable the SAE functions in QuantStudio™ Design and Analysis Software 2 (page 161)

Application profiles

For detailed instructions to install application profiles, see SAE Administrator Console v2.0 or later User Guide for PCR systems (Pub. No. MAN0017468).

The application profiles must be installed before the application can be connected to the SAE Administrator Console.

The following application profiles are available:

Application (instrument or software)	Application profile ^[1]
QuantStudio™ 7 Pro Real-Time PCR Instrument	QuantStudio 7 Pro Instrument (<>).dat
QuantStudio [™] Design and Analysis Software 2	Design and Analysis Software (<>).dat

[1] <...> is the version of the application profile. For more information, see SAE Administrator Console v2.0 or later User Guide for PCR systems (Pub. No. MAN0017468).

The application profile for QuantStudio[™] Design and Analysis Software v2.8 or later does not require that the application profile for the QuantStudio[™] 7 Pro Real-Time PCR Instrument is installed.

For QuantStudio[™] Design and Analysis Software v2.7 and earlier, the application profile for the QuantStudio[™] 7 Pro Real-Time PCR Instrument must be installed before the application profile for the QuantStudio[™] Design and Analysis Software 2.

Enable the SAE functions on the QuantStudio[™] 7 Pro Real-Time PCR Instrument

This procedure requires a local administrator profile on the instrument and an SAE administrator user account in the SAE Administrator Console.

- 2. In the SAE Mode screen, set the SAE Mode slider to Enable.
- 3. Tap the Server IP field, then enter the IP address of the SAE server.

The server IP is the IP address of the computer on which the SAE Administrator Console is installed.

\odot	SAE Mode	Ð	?	۲
	Connection settings used for SAE mode			
	Server IP			
	Port			
	Use HTTPS			
			Next	

- Tap the **Port** field, then enter the port. The port that is entered is the firewall port.
- 5. Tap Next.
- 6. Enter the SAE administrator user name and password when prompted, then tap Enable.

The home screen is displayed. The SAE administrator is signed in.

Connect the QuantStudio[™] Design and Analysis Software 2 to the SAE Administrator Console

Close all plate files and data files before connecting to the SAE Administrator Console.

Note: Connect the software and instruments to the same instance of the SAE Administrator Console to help ensure that audit records are maintained across system components.

- 1. In the menu bar, click 🔅 System > SAE Connection Settings.
- 2. Enter the server and port number of the SAE Administrator Console.

If the SAE Administrator Console is installed on the same computer as the QuantStudio[™] Design and Analysis Software 2, enter *localhost*.

If the SAE Administrator Console is installed on a different computer from the QuantStudio[™] Design and Analysis Software 2, enter the IP address of the computer on which the SAE Administrator Console is installed.

Note: If using a dynamic IP address, enter the hostname instead of the IP address to prevent the loss of a connection.

The port number is the firewall port.

- 3. (Optional) Click Test Connection to confirm that the connection information is correct.
- 4. Click Save.

Enable the SAE functions in QuantStudio[™] Design and Analysis Software 2

This procedure requires an SAE administrator user account.

Complete the following tasks before you enable the SAE functions in the QuantStudio[™] Design and Analysis Software 2:

- Connect to the SAE Administrator Console (see "Connect the QuantStudio™ Design and Analysis Software 2 to the SAE Administrator Console" on page 161).
- Close all plate files and data files.
- 1. In the QuantStudio[™] Design and Analysis Software 2, select **♦ System > Enable Security**.
- 2. Enter your SAE administrator account user name and password, then click Sign In.

The SAE administrator account is automatically signed into the software after the SAE functions are enabled. The SAE user account name is displayed in the upper-right corner of the software menu bar.



Disable the SAE functions

Disable the SAE functions in the QuantStudio[™] Design and Analysis Software 2

This procedure requires an SAE administrator account.

Close all plate files and data files.

- 1. In QuantStudio[™] Design and Analysis Software 2, select **♦ System > Disable Security**.
- 2. Enter the password of the SAE administrator account, then click Sign In.

Disable the SAE functions on the QuantStudio[™] 7 Pro Real-Time PCR Instrument (administrator only)

This procedure requires a local administrator profile and an SAE administrator user account.

Sign in with a local administrator account (see "Sign in as a local administrator when SAE functions are enabled" on page 163).

- 2. In the SAE Mode screen, set the SAE Mode slider to the Disable position, then tap Done.

3. Enter the password for the SAE administrator account, then tap **Disable**. The user name for the SAE administrator account is filled out and cannot be edited.

Disable SAE	۲	?	۲
ccount is required to disable SAE mode.			
ne admin			
d			
		Disable	
	Disable SAE ccount is required to disable SAE mode. admin d Cancel	Disable SAE	Disable SAE

The Sign In screen is displayed.

Sign in as a local administrator when SAE functions are enabled

Sign in as a local administrator to access the instrument settings. Plate files are not accessible if you are signed in as a local administrator.

1. In the Sign In screen, tap Sign in under Local sign in.

	Sign In	
SAE sign in Login for SAE accounts,	Local sign in Instrument administrator accounts can access Instrument settings.	
Sign in	Sign in	(

(1) Sign in for administrator

The Local Administrator Sign In screen is displayed.

- 2. In the Local Administrator Sign In screen, select your local administrator profile.
- 3. Enter your PIN, then tap Enter.

The Settings screen is displayed.

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Sign in with SAE enabled

You must create a profile on the SAE Administrator Console before you sign in when SAE is enabled on the instrument.

1. In the Sign In screen, tap Sign in under SAE sign in.

		Sign In
	SAE sign in Login for SAE accounts.	Local sign in Instrument administrator accounts can access instrument settings.
1	Sign In	

(1) Sign in to an SAE account

The **SAE Sign In** screen is displayed.

\odot	SAE Sign In
	User name
	Password
	Cancel Sign In

2. In the SAE Sign In screen, enter your SAE user name and your SAE password, then tap Sign in.



The home screen is displayed.



Figure 20 Home screen

Sign out with SAE enabled

In the home screen, tap () (Profile).
 The My Profile screen is displayed. The SAE button is selected and the profile that is signed in is





- 1 SAE button is active
- 2 Profile that is signed in
- 2. Tap Sign out, then tap Yes to confirm.

You are signed out and the Sign in screen is displayed.



The SAE functions must be enabled on the instrument.

Sign in to the instrument with your SAE user account.

See "Sign in with SAE enabled" on page 164.

1. In the home screen, tap (Profile).

The **My Profile** screen is displayed. The **SAE** button is selected, and the profile that is signed in is listed.



Figure 22 My Profile screen

- 1 SAE button is active
- 2 Profile that is signed in
- 2. Tap Edit.

The Edit My Profile screen is displayed.

Edit My Pr	ofile	۲	⊘ ⊗
SAE A			
Instrument profile	information rator		
Old passw	vord		
New pass	word		
Show passw	ord		
		Cancel	Done

Figure 23 Edit My Profile screen

- 3. Tap the Old password field, enter the current SAE user account password, then tap Enter.
- 4. Tap the **New password** field, enter a new SAE user account password, then tap **Enter**. *(Optional)* Tap the **Show password** checkbox to show or hide the password.
- 5. Tap the **Confirm password** field, enter the new SAE user account password again, then tap **Enter**.
- 6. Tap Done.

Your SAE user account password is also be changed on the QuantStudio[™] Design and Analysis Software 2 if the instrument and the software are connected to the same instance of the SAE Administrator Console.



Enter audit reasons and e-signatures

Enter an audit reason on the QuantStudio™ 7 Pro Real-Time PCR Instrument

Depending on the way that the audit settings are configured, the **Enter Audit Reason** screen can be displayed when you make changes to the plate file.

If the audit function is disabled, this screen is not displayed.

If the audit mode is set to silent, this screen is not displayed.

۲		Enter Audit Reason		. ?
r				
		Management		
	Reason	Manually edited		
	Comments			
		<u> </u>		
Ļ				
			Cancel	Save
				C. AVO

- Select the reason from the **Reason** dropdown list. If the audit mode is set to optional, a reason does not need to be selected.
- 2. (Optional) Enter comments in the Comments field.
- 3. Tap Save.

The audit record cannot be viewed on the instrument.

The audit record is displayed in the QuantStudio[™] Design and Analysis Software 2 (see "View audit records for objects for the QuantStudio[™] Design and Analysis Software 2" on page 172).

Enter an audit reason in the QuantStudio™ Design and Analysis Software 2

Depending on the way that the audit settings are configured, the **Enter audit reason** dialog box can be displayed when you save a plate file that has been edited.

If the audit function is disabled, this screen is not displayed.

If the audit mode is set to silent, this screen is not displayed.

	Enter audit reason					
Reason	Select option	•				
	Use custom reason					
Comment						
	Cancel OK					

- (Optional) Select the Use custom reason checkbox, then enter a reason in the Reason field. The Reason dropdown list changes to a field when the Use custom reason checkbox is selected.
- Select the reason from the Reason dropdown list.
 If the audit mode is set to optional, a reason does not need to be selected.
- 3. (Optional) Enter comments in the Comments field.
- 4. Click OK.

The audit record is displayed in the **Data Audit** tab (see "View audit records for objects for the QuantStudio[™] Design and Analysis Software 2" on page 172).

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Enter an e-signature on the QuantStudio™ 7 Pro Real-Time PCR Instrument

The screen to sign depends on action that requires and e-signature and the item that is being signed (see "Actions that require an e-signature in the QuantStudio[™] 7 Pro Real-Time PCR Instrument" on page 151).

In the following figure, the plate setup is being signed.

•		Sign Plate		٩	?	۲
Plat	te name	Plate_20180902_142	2440			
Pur	pose	Reviewed & approve	d plate setup	•		
Dat	a type	Plate setup				
Use	er name	Administrator				
Pas	sword					
					Sign pla	te

- 1. Select the e-signature meaning from the **Purpose** dropdown list.
- 2. Enter your SAE user account name and password.

Note: The SAE user account must have permissions to perform e-signatures.

3. Tap **Sign <...>**, where <...> is the data signed.

In the example above, the plate is signed. The button is **Sign plate**.

The e-signature records for a plate setup are viewed on the instrument (see "View e-signature records for a plate file on the QuantStudio[™] 7 Pro Real-Time PCR Instrument" on page 172).

The e-signature records for a calibration are not viewed on the instrument. They are included in a calibration report when it is exported from the instrument. They are also included in the EDS file for the calibration and can be viewed if the EDS file is opened in QuantStudio[™] Design and Analysis Software 2.

Enter an e-signature in the QuantStudio[™] Design and Analysis Software 2

	Electronic Si	gnature	
Meaning	Select option		•
Username			
Password			Q
Preview		Cancel	Sign

- 1. In the Electronic Signature dialog box, select the meaning from the Meaning drop-down list.
- 2. Enter your SAE user account name and password.

Note: The SAE user account must have permissions to perform e-signatures.

3. Click Sign.

The e-signature record is displayed in the **E-signature** tab (see "View e-signature records in the QuantStudio[™] Design and Analysis Software 2" on page 173).

View the audit and e-signature records in the applications

Note: The audit and e-signature records can only be viewed in the real-time PCR applications. They are contained in the template file or the data file. They cannot be viewed in the SAE Administrator Console.

Audit records for actions

The audit records for actions are viewed on the SAE Administrator Console.

For a list of actions that are audited, see "Actions that are audited" on page 150.



View audit records for objects for the QuantStudio[™] Design and Analysis Software 2

The audit records for the object are viewed for each specific object. The plate is the audited object in the QuantStudio[™] Design and Analysis Software 2.

Note: The audit record for the object is not viewed on the instrument, even if the change was made on the instrument.

Open the plate file of interest in the software.

1. Navigate to the Data Audit tab.

The audit records are displayed in the Audit Summary pane.

- 2. (Optional) Sort by the following parameters:
 - Date
 - User ID
 - Reason

View e-signature records for a plate file on the QuantStudio[™] 7 Pro Real-Time PCR Instrument

- 1. In the home screen, tap one of the following options:
 - 🚵 (Load plate file)
 - Set up run
- 2. Tap the location of the system template or the plate file in the left column.
 - 🚡 Run Queue
 - 💼 Public
 - My Instrument
 - 🚍 Network Drive
 - 🗆 USB Drive
- **3.** Tap the template file name in the right column. The **Plate Properties** screen is displayed.
- 4. In the Plate Properties screen, tap Actions. The Actions screen is displayed.
- 5. Tap View signing records. The Signing records screen is displayed.

Signature date	Purpose	Signed by	Role	Status
2019/07/31 14:42:07	Reviewed & approved plate setup	Administrator	Administrator	Currer

6. Tap a row to view the details.

	Signing Records	٢	?	۲
Signature date Plate name Purpose Data type Signed by	2019/09/02 15:22:08 Plate_20180902_1422440 Reviewed & approved plate setup Plate setup Administrator			
Role	Administrator			

7. Tap Close to return to the Signing records screen.

View e-signature records in the QuantStudio[™] Design and Analysis Software 2

Open the plate file or data file of interest in the software. Navigate to the **e-Signature** tab. The e-signatures for the file are displayed.

(Optional) Generate an e-signature report (see "Generate an e-signature report" on page 174).

Generate an e-signature report

View the e-signature records for a plate file or a data file ("View e-signature records in the QuantStudio™ Design and Analysis Software 2" on page 173).

- 1. Click ··· Generate E-signature Report.
- (Optional) In the Export E-Sig Report dialog box, edit the file name.
 The default file name is Esig Report <...>, where <...> is the date and time stamp.
- 3. Click Browse, then navigate to the location to save the file.
- 4. Click Export.

The e-signature report is saved as a PDF.

Use the instrument when the SAE server is offline

If your SAE administrator has configured your instrument to allow use when the SAE server is offline (**Client offline login** System setting in the SAE module), you can use the instrument for the period of time specified by the SAE administrator for **Client offline login**.

Note: If you have not previously signed in to the instrument with your SAE account, you cannot sign in when the SAE server is offline.

All SAE records are retained if the instrument is disconnected from an SAE server. When the instrument is reconnected to the SAE server, SAE records are uploaded to the server.

The following functions are not available when the SAE server is offline:

- · Account lockout, password reminder, mandatory password change
- Disable SAE
- Change Password

E-signature requirements to start a run

Depending on the way your SAE administrator has configured your instrument, E-signatures may be required when you start a run. If starting a run is configured to require signatures, a message is displayed when you start a run.



Tap **Sign plate** to sign the plate and start the run.

Signing in after automatic screen locking

Depending on the way your SAE administrator has configured your instrument, the instrument touchscreen may automatically lock after a specified duration.

An Administrator role or a Scientist role can sign in after automatic screen locking.

SAE error messages and actions

Message	Possible cause	Action
Unable to connect to SAE server.	The SAE server connection settings are incorrect for the QuantStudio [™] 7 Pro Real-Time PCR Instrument.	 In the instrument Sign In screen, sign in with a local administrator account. View the settings (see "Enable the SAE functions on the QuantStudio[™] 7 Pro Real-Time PCR Instrument" on page 160). Check the SAE server IP address. This is the IP address of the computer that the SAE Administrator Console is installed on. Check the port that is required for your version of the SAE Administrator Console. Note: The time difference between the SAE Administrator
		Console and the instrument must be less than five minutes in order to establish a connection.
	The SAE server connection settings are incorrect for the QuantStudio™ Design and Analysis Software 2.	 Check the SAE server IP address. This is the IP address of the computer that the SAE Administrator Console is installed on. If the SAE Administrator Console and the QuantStudio[™] Design and Analysis Software 2 are installed on the same computer, use <i>localhost</i> as the IP address.
		 Check the port that is required for your version of the SAE Administrator Console.
		Note: If the SAE Administrator Console and the QuantStudio [™] Design and Analysis Software 2 are installed on different computers, the time difference between the computers must be less than five minutes in order to establish a connection.

Message	Possible cause	Action
Unable to connect to SAE server.	There is a problem with the computer on which the SAE Administrator Console is installed or a problem with the network.	Troubleshoot computer or network problems.
	The computer on which the SAE Administrator Console has a dynamic IP address that is disconnecting the server when the computer is restarted.	Set a static IP address on the computer.



Maintain the instrument

Install a block	178
Change the block	179
Remove the block	180
Decontaminate the sample block	181
Replace the instrument fuses	183
Power on or off, store, and move	185

IMPORTANT! This chapter contains user maintenance procedures for the instrument. Procedures other than those described in this document must be performed by a qualified Thermo Fisher Scientific service representative.

Install a block

This section describes installing a block when there is no block in the instrument. To change a block, see "Change the block" on page 179.

A block can be installed by any user. This function is not restricted to administrators.

Each combination of a block and an instrument has its own calibration status. To determine the calibration status of a block on an instrument, see "View the calibration status and set reminders" on page 93. To calibrate a block on a specific instrument, see Chapter 7, "Calibrate and verify instrument performance".

- 1. Tap (a) (Settings) > Change block.
- 2. Insert the block and heated cover into the instrument drawer.

The instructions are displayed on the screen.

3. Tap Install.

The instrument displays one of the following options, depending on the calibration status:

- Confirmation that the block was installed successfully and the expiration date of the current calibration.
- A warning that the block is not calibrated on the instrument.
- A warning that the calibration of the block on the instrument is expired.



Change the block

CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the sample block temperature can reach 100°C. Allow it to cool to room temperature before handling.

This section describes changing a block and heated cover when there is already a block installed. To install a block when one is not installed, see "Install a block" on page 178.

A block can be changed by any user. This function is not restricted to administrators.

Each combination of a block and an instrument has its own calibration status. To determine the calibration status of a block on an instrument, see "View the calibration status and set reminders" on page 93. To calibrate a block on a specific instrument, see Chapter 7, "Calibrate and verify instrument performance".

- 1. Tap (❀) (Settings) → Change block.
- In the Change Block screen, tap Change, then tap Ok.
 The instrument unlocks the block and the heated cover. This step takes approximately one minute.
 The drawer opens with the block and the heated cover.
- 3. Use the handles to remove the block and the heated cover.

The instructions are displayed on the screen.

The block and the heated cover are removed together.

IMPORTANT! Only touch the block and the heated cover at the handles.



1 Heated cover handle

2 Block handle

4. Insert the new block and the heated cover into the instrument drawer, then tap Install.

The **Install** button is inactive until the instrument detects a block and heated cover that are positioned correctly in the drawer.

The instrument displays one of the following options, depending on the calibration status:

- Confirmation that the block was installed successfully and the expiration date of the current calibration.
- A warning that the block is not calibrated on the instrument.
- A warning that the calibration of the block on the instrument is expired.



It is recommended to store the block and the heated cover in the provided protective box when they are not installed on an instrument.

Remove the block



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the sample block temperature can reach 100°C. Allow it to cool to room temperature before handling.

This section describes removing the block and heated cover without installing another block and heated cover into the instrument.

- 1. Tap (Settings) → Change block.
- 2. In the Change Block screen, tap Change.
- 3. Tap OK.

The instrument unlocks the block and the heated cover. This step takes approximately one minute. The drawer opens with the block and the heated cover.

4. Use the handles to remove the block and the heated cover.

The block and the heated cover are removed together.

IMPORTANT! Only touch the block and the heated cover at the handle.



- 1 Heated cover handle
- 2 Block handle
- 5. Tap (Eject) to close the instrument drawer.

It is recommended to store the block and the heated cover in the provided protective box when they are not installed on an instrument.


Decontaminate the sample block

Perform this procedure to eliminate fluorescent contaminants from the instrument sample block. Contamination is generally evident in failed background calibrations where one or more wells consistently exhibit abnormally high signals.



CAUTION! PHYSICAL INJURY HAZARD. Do not remove the instrument cover. There are no components inside the instrument that you can safely service yourself. If you suspect a problem, contact Support.



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the sample block temperature can reach 100°C. Allow it to cool to room temperature before handling.



CAUTION! Before using a cleaning or decontamination method other than those recommended by Thermo Fisher Scientific, confirm with Thermo Fisher Scientific that the proposed method will not damage the equipment.

Materials required

- Safety glasses
- Powder-free gloves
- Tissue, lint-free
- Cotton or nylon swabs and lint-free cloths
- Pipette (100-µL) with pipette tips
- Deionized water
- Ethanol, 95% solution
- Na-hypochlorite, (0.1% v/v) solution

Clean the sample block



CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the sample block temperature can reach 100°C. Allow it to cool to room temperature before handling.

IMPORTANT! Wear powder-free gloves when you perform this procedure.

IMPORTANT! Always use deionized water to rinse wells after cleaning with bleach or ethanol solution.

- 1. Identify the contaminated wells of the sample block (see "Identify contamination" on page 103).
- 2. Remove the sample block and heated cover (see "Remove the block" on page 180).
- 3. Place the sample block and heated cover on a clean surface.



4. Rinse the contaminated wells with deionized water (see "Detailed procedures for cleaning the sample block" on page 182).



- 5. Install the block and heated cover (see "Install a block" on page 178).
- 6. Perform a background calibration to confirm that you have eliminated the contamination (see "Perform calibrations" on page 97).
- If the contamination remains, clean the contaminated wells with a 95% ethanol solution. Repeat step 2 to step 6 with a 95% ethanol solution (see "Detailed procedures for cleaning the sample block" on page 182).

IMPORTANT! Always use deionized water to rinse wells after cleaning with bleach or ethanol solution.

8. If the contamination remains, clean the contaminated wells with a 10% bleach solution.

Repeat step 2 to step 6 with a 10% bleach solution (see "Detailed procedures for cleaning the sample block" on page 182).

IMPORTANT! Always use deionized water to rinse wells after cleaning with bleach or ethanol solution.

9. Use Smart Help if the contamination remains (see "Request technical support with Smart Help" on page 197).

Detailed procedures for cleaning the sample block

IMPORTANT! Use these cleaning procedures *only* in conjunction with the complete decontamination procedure (see "Clean the sample block" on page 181).

- Rinse the sample block with deionized water.
 - a. Pipet a small volume of deionized water into each contaminated well.
 - b. In each well, pipet the water up and down several times to rinse the well.
 - c. Pipet the water to a waste beaker.
 - d. Use a cotton swab to scrub inside of each contaminated well.
 - e. Use a lint-free cloth to absorb the excess deionized water.



- Clean the sample block with 95% ethanol.
 - a. Pipet a small volume of 95% ethanol solution into each contaminated well.
 - b. In each well, pipet the solution up and down several times to rinse the well.
 - c. Pipet the ethanol solution to a waste beaker.

IMPORTANT! Always use deionized water to rinse wells after cleaning with bleach or ethanol solution.

- Clean the sample block with 10% bleach.
 - a. Pipet a small volume of 10% bleach solution into each contaminated well.
 - b. In each well, pipet the solution up and down several times to rinse the well.
 - c. Pipet the bleach solution to a waste beaker.

IMPORTANT! Always use deionized water to rinse wells after cleaning with bleach or ethanol solution.

Replace the instrument fuses

CAUTION! FIRE HAZARD. For continued protection against the risk of fire, replace fuses only with listed and certified fuses of the same type and rating as those currently in the instrument.

Materials required

- Fuses (2) 10A, Time-Lag T, 250VAC, 5 × 20 mm
- Safety glasses
- Powder-free gloves
- Screwdriver, flathead

Replace the fuses

- **1.** Power off, then unplug the instrument.
- 2. Allow the instrument cool for 15 minutes.



3. Using a flathead screwdriver, unscrew and remove the fuse holder.



4. Remove each fuse from its fuse holder, then inspect it for damage. Carbon typically coats the inside of failed fuses.



5. Replace each failed fuse.

Note: The voltage and amperage ratings are on the fuse holder.

6. Align each new fuse in the fuse holder as shown in the figure below.



(1) Fuse alignment in the fuse holder

- 7. Install the fuse holder back into the instrument.
- Plug in, then power on the instrument.
 The installation is successful if the instrument powers on.



Note: Fuse failure can result from fluctuations in the supplied power to the system. To prevent further failures, consider installing an electrical protective device, such as a UPS or a surge protector. If issues with the fuse persist, use Smart Help (see "Request technical support with Smart Help" on page 197).

Power on or off, store, and move

Enable and edit sleep mode

Sleep mode allows the instrument to use less energy when not in use. The length of time that the instrument is inactive before going into sleep mode can be customized.

- 1. In the home screen, tap (settings) > Instrument settings > Sleep mode.
- 2. Set the slider.

Option	Description	
Off	The instrument will not go into sleep mode.	
On	The instrument will go into sleep mode after a period if inactivity.	

- 3. Tap the Idle time before sleep mode field, then enter a time.
- 4. Tap Done.



Power on the instrument

If left unattended, the instrument automatically enters sleep mode to conserve power. The default time that an instrument is inactive before going into sleep mode is 15 minutes.

- Tap anywhere on the touchscreen to determine if the instrument is in sleep mode. If the screen becomes active, the instrument is already powered on.
- 2. If the home screen does not display, power on the instrument by pressing the ON/OFF switch on the rear panel.



Figure 24 Location of the ON/OFF switch

1 ON/OFF switch

Note: The length of time that the instrument is inactive before going into sleep mode can be customized (see "Enable and edit sleep mode" on page 185).

Power off the instrument

- 1. Power off the instrument using the ON/OFF switch on the back of the instrument. For the location of the ON/OFF switch, see Figure 6 on page 47.
- 2. Power off the computer if there is a computer directly connected to the instrument.

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Prepare the instrument to store, move, or ship

Remove the block and heated cover to store, move, or ship the instrument.

It is recommended to store the block and heated cover in the provided protective box when they are not installed on an instrument.

Ship the instrument and the block and heated cover separately.

- 2. In the Ship Prep Mode screen, tap Next.
- 3. Follow the instructions on the touchscreen to remove the block and heated cover.

The instrument is now ready to store, move, or ship.

Move the instrument



CAUTION! PHYSICAL INJURY HAZARD. Do not attempt to lift the instrument or any other heavy objects unless you have received related training. Incorrect lifting can cause painful and sometimes permanent back injury. Use proper lifting techniques when lifting or moving the instrument. At least two people are required to lift it.

IMPORTANT! Moving your instrument can create subtle changes in the alignment of the instrument optics. Recalibrate the instrument if necessary.

- Ensure that the surface on which you place the instrument can support at least 35.85 kg (79 lbs.).
- Ensure that the path to transport the instrument is clear of obstructions.
- At least two people are needed to lift and carry the instrument.
- Keep your spine in a good neutral position.
- Bend at the knees and lift with your legs.
- Do not lift an object and twist your torso at the same time.
- Coordinate your intentions with your assistant before lifting and carrying.

IMPORTANT! After moving the instrument, perform an RNase P instrument verification run. If the run fails, perform ROI/ uniformity, background, and dye calibrations.



Configure the instrument settings

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View the instrument details

1. In the home screen, tap (a) (Settings) > About instrument.

The **About Instrument** screen displays the following information:

- Model name
- Wired IP address
- Wireless IP address
- Instrument serial number

- Block serial number
- Heated cover serial number
- Block type
- Software version

2. (Optional) Tap Details.

The following information is displayed:

Block type

Software version

User interface version

Instrument server version

Block firmware version

Heated cover firmware version

Firmware version

- Instrument model name
- Wired IP address

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- Wired MAC address
- Wireless IP address
- Wireless MAC address
- Instrument serial number
- Block serial number
- Heated cover serial number
- 3. Tap 💿 (Back) to return to the Settings screen.
- View the license agreement

The license agreement cannot be overwritten if it has already been saved to the location. The option to overwrite a file is not available for the license agreement.

If security is enabled on the instrument, your SAE account must have the permission of **Allow keep both files** in order to save the license agreement to a location where it has already been saved.

- 2. Tap EULA.

The end user license agreement (EULA) is displayed.

- 3. (Optional) Tap Export, select a destination for the file, then tap Done.
- 4. Tap Close.

View the privacy policy for the Thermo Fisher[™] Connect Platform







- 2. Tap **Privacy**. The privacy policy is displayed.
- 3. Tap Close.

Configure the instrument settings

Enable or disable demonstration mode

Note: The instrument restarts when demonstration mode is turned on or off.

When the instrument is in demonstration mode, the following features apply:

- The instrument simulates a run but does not start a run.
- The instrument drawer will not open.
- In the home screen, tap

 (Settings) ➤ Instrument settings ➤ Demo mode.

 Turn demo mode off is displayed if the instrument is in demo mode.
- In the Confirmation screen, tap Ok.
 You will be prompted to restart the instrument.

Demo mode is displayed on the instrument when it is in demonstration mode.

Edit the instrument name (administrator only)

- 1. In the home screen, tap (settings) Instrument settings Instrument name.
- 2. Tap the *Instrument name* field, then enter or edit the instrument name. The instrument name must be unique if it is connected to a network.
- 3. Tap Done.



Set the date and the time

The date and time can be set manually or automatically. The instrument must be connected to the internet to set the date and time automatically.

- 1. In the home screen, tap ((Settings) → Instrument settings → Date and time. The Date and Time screen is displayed.
- 2. Set the slider to Off or On to determine if the date and time are set automatically.
- 3. (Optional) Select the time zone from the dropdown list.
- 4. Select the date format and the time format from the dropdown lists.
- 5. Tap Done.

Configure the heated cover settings

The heated cover can be heated when the instrument is idle or it can be left without being heated when the instrument is idle. To save power, configure the settings so the heated cover is left without heating. It will take longer to bring the heated cover up to the correct temperature when the instrument is brought back into use.

- 2. Set the slider.

Option	Description	
On	he heated cover remains heated when the instrument is idle.	
Off	The heated cover is not heated when the instrument is idle.	

- 3. Tap the *Cover temperature* field to edit the heated cover temperature.
- 4. Tap Done.

Adjust the speaker volume

The selected speaker volume is saved for each user.

When a new Thermo Fisher[™] Connect Platform account is linked to the instrument, the default speaker volume is set to the maximum.

- Slide the control to the adjust the volume.
 The speakers are muted when the slider is at the far-left side of the bar.
- 3. Tap **Done**.



Configure the network

For detailed instructions, see Appendix B, "Connect the instrument to a network".

- 2. Tap Edit.

The fields for Wired and Wireless are now editable.

- 3. Enter the information that is needed for a wireless or wired connection.
 - Tap the *Network* field to enter network information for a wireless connection.
 - Tap the *IP address* field to enter the IP address for a wired connection.
- 4. (Optional) Tap **Proxy server** to connect the instrument to a proxy server (see "Connect a proxy server" on page 192).
- 5. Tap Done.

Connect a proxy server

A proxy server sits between the instrument and the main server. The proxy server intercepts requests to the main server and evaluates if it can complete the request. If it cannot fulfill the request, it will forward the request to the main server.

Consult your Network or IT specialist before linking the instrument to a proxy server.

- 2. Tap each field to enter the required information.
 - Proxy server
 - Proxy port
 - User name
 - Password
- 3. Tap Done.

The instrument is connected to the specified proxy server.



Connect to a network drive

When importing or exporting files from and to a network drive, you are prompted to specify the network drive location and information.

If the instrument is already connected to a network drive, the folder structure of the network drive is displayed.

The network drive can be identified by the IP address of the computer. It can be identified by the domain name system (DNS) name for v1.5.0 or later.

For v1.8.0 or later, the location of the network drive can be set in the data management settings. If the network drive is defined in the data management settings, it cannot be changed at the time that files are imported or exported. For more information, see "Manage the settings for data export and data import" on page 214.

Set up the network drive as a shared folder (see "Create a shared network folder" on page 194).

If the network drive is identified by the IP address of the computer, determine the IP address of the computer (see "Determine the IP address of the computer" on page 194).

If the network drive is identified by the DNS name, determine the DNS name (see "Determine the DNS name" on page 194).

- 1. In the Network Destination screen, tap Network drive.
- 2. Select the drive location.

The drive location is required. For IP address, the drive location is <IP address>/<folder name>. For DNS name, the drive location is <DNS>/<folder name>.

- 3. Enter the following information, then tap **Connect**.
 - Domain name
 - User name
 - Password

The domain name, username, and password can be required, depending on the network requirements.

The username and password are for the network. They are not the username and password for the instrument.

4. Tap a folder to import a file from or to export a file to.

If there are folders nested within the top-level folder, continue to tap the folders until the correct folder is displayed for import or export of a file.

5. Tap the appropriate button to import the file from the network drive or export the file to the network drive.

Create a shared network folder

Files can be transferred from the instrument to a folder on the network.

The folder on the network must be set up as a shared folder.

- 1. To designate a folder as shared, right-click on the folder, then click Properties.
- 2. In the Properties dialog box, click the Sharing tab.
- 3. Click Advanced Sharing.
- 4. In the Advanced Sharing dialog box, select the Share this folder checkbox, then click Permissions.
- 5. Ensure that Everyone is selected in the Group or user name field.
- 6. Ensure that the checkboxes for Allow are selected for the permissions. The permissions are Full Control, Change, and Read.
- 7. In the Permissions dialog box, click OK.
- 8. In the Advanced Sharing dialog box, click Apply > OK.
- 9. In the Properties dialog box, click Close.

Determine the IP address of the computer

- 1. In the Windows[™] search bar, enter *cmd* to open the **Command Prompt**.
- 2. In the Command Prompt, enter *ipconfig/all*, then press Enter.
- 3. Locate the IPv4 Address.

The IP address is listed on the IPv4 Address line.

Determine the DNS name

- 1. In the Windows[™] search bar, enter *cmd* to open the **Command Prompt**.
- 2. In the Command Prompt, enter *ipconfig/all*, then press Enter.
- 3. Locate the DNS names.

The text indicating the DNS names might be different, depending on the configuration. The text **DNS** is displayed and there might be more than one field for the DNS names. Contact your IT administrator for assistance to determine the correct DNS name.



Select the region for the Thermo Fisher[™] Connect Platform

Note: The instrument restarts when the region for the Thermo Fisher[™] Connect Platform is changed.

- In the home screen, tap (e) (Settings) ➤ Instrument settings ➤ Connect region. The Select Region window opens.
- 2. Select the region.

Option	Description	
China	For users in China	
U.S.	For users in any country other than China	

3. Tap Done.

Select a disk storage management mode

This setting determines how the instrument manages data files when the disk space is full.

- 1. In the home screen, tap (Settings) > Instrument settings > Disk storage management.
- 2. Select a mode for disk storage management.

Option	Description			
Automatic	The instrument automatically deletes data files until there is disk space is available to complete a run.			
	Note: The instrument deletes data files in chronological order, starting with the oldes. Only data files that have been transferred to another location are deleted.			
	IMPORTANT! The system does not notify a user when data files are deleted.			
Manual	The instrument will not delete data files when there is no disk space available to complete a run.			
	Note: The system notifies a user when data files must be deleted (see "Delete data files from the instrument" on page 89).			

3. Tap Done.



Enable and edit automatic sign-out

The automatic sign-out feature signs out a user after a period of inactivity.

A run in progress is not considered inactivity. The period of inactivity begins after the run is complete.

The period of inactivity before a user is signed out automatically can be customized.

- 1. In the home screen, tap (Settings) > Instrument settings > Auto sign-out.
- 2. Set the slider.

Option	Description			
Off	he instrument will not automatically sign out a user after a period of inactivity.			
On	The instrument will automatically sign out a user after a period of inactivity.			

- 3. Tap the Idle time before auto sign-out field, then enter a time.
- 4. Tap Done.

Set an access key for external software to connect to the instrument

- 1. In the home screen, tap (settings) > Instrument settings > Instrument access.
- 2. In the **Instrument Access** screen, set the **Enable access** slider to the **On** position. The instrument displays an access code.
- (Optional) Set the Visible to all users slider.
 The Visible to all users slider is only displayed if the Enable access slider is set to the On position.
- 4. Tap Close.
- 5. In the external software that is being used to connect to the instrument, enter the remote access key to add the instrument.

Reset the access key for external software to connect to the instrument

- 1. In the home screen, tap (settings) > Instrument settings > Instrument access.
- 2. Tap Generate code.

The instrument displays a new access code.

- 3. (Optional) Set the Visible to all users slider.
- 4. Tap Close.

In the external software that is being used to connect to the instrument, enter the new remote access key to add the instrument.



Configure maintenance and service settings

Request technical support with Smart Help

Request technical support with Smart Help for any technical problem with the instrument. A Thermo Fisher™ Connect Platform account is required.

Note: A recording to describe the technical problem is not stored on the instrument.

- 2. Tap Edit, then enter a description in the Description field.
- 3. Fill out the **Email** field and the **Phone** field.
- 4. Select a country from the dropdown list.
- 5. Select a preferred contact method from the dropdown list.
- (Optional) Select the Include instrument log file checkbox.
 The log file is not required but it is recommended for troubleshooting.
- 7. (Optional) Tap Attach run files, select run files, then tap Attach files.
- 8. (Optional) Tap () to record a description of the technical issue.
- 9. Tap Done.

A confirmation email is sent. It is sent even if email was not selected as the preferred contact method.

Request instrument service with Smart Help

Request instrument service with Smart Help for any instrument service request. A Thermo Fisher™ Connect Platform account is required.

Note: A recording to describe the technical problem is not stored on the instrument.

- In the home screen, tap (a) (Settings) ➤ Maintenance and service ➤ Smart Help. The Smart Help screen is displayed.
- 2. Tap Edit, then enter a description in the Description field.
- 3. Fill out the **Email** field and the **Phone** field.
- 4. Select a country from the dropdown list.
- 5. Select a preferred contact method from the dropdown list.



- (Optional) Select the Include instrument log file checkbox.
 The log file is not required but it is recommended for troubleshooting.
- 7. (Optional) Tap Attach run files, select run files, then tap Attach files.
- 8. (Optional) Tap () to record a description of the technical issue.
- 9. Tap Done.

A confirmation email is sent. It is sent even if email was not selected as the preferred contact method.

Perform and view self-verification tests

Perform a hardware test

There will be elevated noise levels while the fans are tested.

The location to export the results is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general** data in order to export the results. Your SAE account must have the permission of **Allow keep both** files in order to keep both results if the results were previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow keep both files** if the results were previously transferred to the same location and you would like to keep both of the files.

IMPORTANT! Ensure that there is no obstruction at the front of the instrument. The instrument drawer opens and closes as part of the test.

- 2. Tap Hardware test.
- 3. Tap Start test.

The test takes approximately 10 minutes.

The **Hardware Test** screen is displayed when the self-verification test is complete. The **Hardware Test** screen displays the functions that pass and fail.

- 4. (Optional) Tap Export to export the results.
- 5. Tap Close.

Use Smart Help if any hardware functions fail (see "Request technical support with Smart Help" on page 197).



View the last hardware test result

The self verification test checks the instrument hardware functions. You can view the results of the last self-verification test that was run.

- 2. Tap Hardware test.
- 3. Tap Last test.

The Self-Verification Test screen displays the functions that pass and fail.

Use Smart Help if any hardware functions fail (see "Request technical support with Smart Help" on page 197).

Perform a peripheral test

The peripheral test takes approximately 5 minutes. Tap \times (Close) on any screen to exit the peripheral test.

The peripheral test checks the following functions:

- Touchscreen accuracy
- Speaker
- Microphone
- Camera
- Proximity sensor

The location to export the results is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to export the results. Your SAE account must have the permission of **Allow keep both files** in order to keep both results if the results were previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow keep both files** if the results were previously transferred to the same location and you would like to keep both of the files.

- 2. Tap Peripheral test.

3. Tap Start.

The peripheral test begins with the touch accuracy test.



4. In the Touch Accuracy Test screen, tap the screen in several locations.



Green dots appear where you tap.

- 5. Tap Yes to proceed.
- 6. In the Speaker Test screen, tap (Play).



A soundtrack is played.

7. Tap Yes to proceed.



8. In the Microphone Test screen, tap () to record.

Ν	Aicrophone Tes	t		۲
Press the m Did you manage	icrophone buttor to record and pl	and record. ay the record	ing?	
			No	Yes

- 9. Tap Yes to proceed.
- **10.** In the **Camera Test** screen, tap **Yes** to confirm that the camera is on. A preview is displayed if the camera is on.
- 11. In the Camera Test screen, tap Yes to confirm that the camera detects a face.



12. In the **Camera Test** screen, tap **Capture** to capture an image, then tap **Yes** to confirm that an image was captured.

The image should appear clear and in focus.





13. In the Camera Test screen, tap Yes to confirm that the depth map is displayed on the screen.





14. In the **Proximity Test** screen, move forwards towards the instrument and backwards away from the instrument.



The distance on the instrument screen changes to show your distance from the instrument.

15. Tap Yes to complete the test.

The Peripheral Test screen is displayed. It shows a Pass or Fail result for each test.

\odot	Results		Ø	?	۲
	Screen Test Result	Passed 🔵			
	Speaker Test Result	Passed 🔍			
	Microphone Test Result	Passed 🔍			
	Camera Switch On Test Result	Passed 🔍			
	Camera Face Detection Test Result	Passed 🥥			
	Camera Image Capture Test Result	Passed 🔍			
	Camera Depth Data Test Result	Passed 🔍			
	Proximity Sensor Test Result	Passed 🧅			
Report				Finish	

16. (Optional) Tap Export to export the results.

View the instrument log

In the home screen, tap

 ● (Settings) → Maintenance and service → Instrument log.
 The Instrument Log screen lists the instrument event types with a time stamp.



- Run
- Change Block
- Error
- Power

- Calibration
- Self-Test
- Update
- User
- 2. (Optional) Tap any of the table headings to sort by that parameter.
- **3.** *(Optional)* Tap an instrument event type in the left pane to filter the list that is displayed by that event type.
- 4. Tap Cancel.

Export the instrument log

The location to transfer the instrument log is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to export the instrument log. Your SAE account must have the permission of **Allow keep both files** in order to keep both instrument logs if the instrument logs were previously transferred to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow keep both files** if the instrument logs were previously transferred to the same location and you would like to keep both of the instrument logs.

- 1. In the home screen, tap (Settings) > Maintenance and service > Instrument log.
- **2.** *(Optional)* Tap a type of instrument event to export the log for only that type of event. If an instrument event is not selected, the logs for all the instrument events will be exported.
- 3. Tap Export.
- 4. Select a destination to save the instrument log files.

 - 🚍 Network Drive
 - 🗆 USB Drive

Note: You must be signed in with a Thermo Fisher[™] Connect Platform account in order to export the instrument log to the Thermo Fisher[™] Connect Platform.

5. Tap Done.

View the instrument statistics

- Disk Space Remaining (MB)
- Block Cycle Count
- Block Degree Climbed
- LED Usage (hours)
- 2. Tap Cancel.

Enable or disable remote monitoring

The following items can be monitored remotely:

- The progress of a run
- Instrument events
- Instrument statistics
- 1. In the home screen, tap (a) (Settings) > Maintenance and service > Connect services.
- 2. Set the slider to the On or Off position.
- 3. Tap Done.

Update the software

Software updates are displayed on the **Notifications** button in the **Settings** screen when they are available.

Software updates can be installed from a USB drive.

If **No available update detected** is displayed but a USB drive contains a software update, tap **Check Updates** after one minute to two minutes. The **Check Updates** might need to be tapped multiple times over the course of one minute or two minutes for the available update to display.

1) (7) Notifications

(1) Notifications, including software updates

To enable notifications to be displayed on the home screen, see "Enable and disable home screen notifications" on page 213.

- 1. In the home screen, tap (Settings) ➤ Maintenance and service ➤ Software update. The Software Update screen is displayed. It indicates if a software update is available.
- 2. Tap Update now.

The **Software Update** screen displays **Update is complete** when the software update is complete. The instrument restarts.

The software can be repaired if the update failed (see "Repair the software" on page 206).

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- RNase P Status
- Block Serial Number
- Heated Cover Serial Number
- Block Type



Repair the software

If a software update failed, the software can be repaired.

The software version installed during a repair is the same version that was previously installed on the instrument, even if a newer version is available.

Instrument settings, calibrations, profiles, and data files are preserved during a repair.

If the software update failed, the Software Update screen displays Failed to upgrade.



In the Software Update screen, tap Repair.

Back up the instrument

The instrument can be backed up to a USB drive or to the Thermo Fisher™ Connect Platform.

A backup of the instrument can be performed only by an administrator.

A backup of the instrument includes can include instrument settings and run data. The instrument settings are included if the instrument is restored from a backup. The run data cannot be included if the instrument is restored from a backup.

The instrument settings include the following items:

- Settings
- Profiles
- Template files
- Calibrations

If security is enabled on the instrument, the security configuration is included in the backup. Local instrument administrator profiles are included in the backup. Any information that is stored on the SAE Administrator Console server is not included in the backup, including accounts that are created on the server.



The location to transfer the backup is set up in the instrument settings. Depending on the settings, not all of the destinations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

If security is enabled on the instrument, your SAE account must have the permission of **Export general data** in order to back up the instrument. Your SAE account must have the permission of **Allow keep both files** in order to keep both instrument backups if the instrument backup was previously saved to the same location.

Multiple permissions might be required to perform the action. For example, you must have both the permissions of **Export general data** and **Allow keep both files** if the instrument backup was previously transferred to the same location and you would like to keep both of the instrument backup.

- 2. Select a location to store the backup of the instrument.
 - 🗆 USB Drive

 - B Network drive

The data management settings might not allow you to select the location (see "Manage the settings for data export and data import" on page 214).

- **3.** *(Optional)* If you are backing up the instrument to a USB drive, insert a USB drive into the USB port on the front of the instrument.
- 4. Enter a backup file name.
- 5. Select the elements to back up.
 - Instrument settings
 - Run data
- 6. Tap Back up.

Instrument back up is complete is displayed on the **Back Up Instrument** screen when the back up is complete.

7. Tap Done.

Restore a backup of the instrument

The following items are restored:

- Settings
- Profiles
- Template files
- Calibrations



If security is enabled on the instrument, the security configuration is included. Local instrument administrator profiles are included. Any information that is stored on the SAE Administrator Console server is not included, including accounts that are created on the server.

Restoring a backup of the instrument can only be performed by an administrator.

- 2. Select a location to store the backup of the instrument.
 - USB Drive

 - 🚍 Network drive

The data management settings might not allow you to select the location (see "Manage the settings for data export and data import" on page 214).

- 3. Select the backup to restore.
- 4. Tap Restore.

Your instrument has been restored is displayed on the Restore a Backup screen.

5. Tap Done.

Upload a certificate for a TaqMan[™] Array Plate with RFID

The location to access the certificate is set up in the instrument settings. Depending on the settings, not all of the locations can be selected. For more information, see "Manage the settings for data export and data import" on page 214.

- 2. Tap Upload.
- 3. Tap the location of the certificate.

Note: You must be signed in with a Thermo Fisher[™] Connect Platform account.

- 🖙 USB



Overview of an instrument reset (restore factory default)

IMPORTANT! Back up the instrument before resetting the instrument (see "Back up the instrument" on page 206). Transfer plate files and data files (see Chapter 6, "View and manage files"). Plate files and data files are not included in a backup of the instrument.

Resetting the instrument deletes the following information:

Instrument profiles

- Custom dyes
- User-created plate files and data files
- Custom melt calibrations

The following information is retained if the instrument is reset:

- System templates
- The last known calibrations, including expired calibrations

Reset the instrument (restore factory default)

IMPORTANT! Back up the instrument before resetting the instrument (see "Back up the instrument" on page 206). Plate files and data files are not backed up. Transfer plate files and data files (see Chapter 6, "View and manage files").

For a description of the information that is deleted and the information that is retained during an instrument reset, see "Overview of an instrument reset (restore factory default)" on page 209.

- 1. In the home screen, tap (Settings) > Maintenance and service > Restore factory default.
- 2. Restart the instrument when prompted.

Request remote support

Remote support grants a Thermo Fisher Scientific support representative the ability to access the instrument remotely.

A Support representative can perform the following functions during a remote support session:

- Use a pointer that displays on the touchscreen
- Draw on the touchscreen
- Capture an image of the touchscreen
- Capture a recording of the touchscreen
- Control the instrument via the touchscreen
- Send keyboard inputs
- Annotate on the touchscreen
- · View instrument disk space and memory information

The instrument must be connected to the internet to use remote support.

Contact Support to receive a PIN prior to beginning a remote support session.



- 2. Tap Start remote session, then enter the PIN provided by Support.

1		Remote Support	۲	?
	Connected: 10/20/20 14:10:03			
	[14:09] Connecting			
	[14:09] Waiting for technician			
	[14:10] Connected			
	[14:10] Richard is ready to chat			
	[14:10] Display viewing started.			
2	Type here			
-	Disconnect	C	ose	Send

1 Remote Session

2 Text field

Remote Session is displayed at the top of the touchscreen when a successful connection is established. A chat is displayed on the touchscreen.

- 3. Tap the text field to type a message, then tap Send.
- 4. (Optional) Navigate to another screen on the instrument.
 Remote Session is displayed at the top of the touchscreen to indicate that the session is active.
- 5. Tap **Remote Session** to return to the remote support session. The **Remote Support** screen is displayed.
- 6. In the **Remote Support** screen, tap the active session listed in the table, then tap one of the following options.
 - **Disconnect** to end the remote support session.
 - View to return to the chat.

The remote session can also be disconnected from the chat screen. A Support representative can end the remote support session. **Remote Session** is not displayed on the touchscreen after a session has been disconnected.



Configure the instrument for the hands-free features

The administrator must be signed in with a Thermo Fisher[™] Connect Platform account in order to enable voice commands.

- 1. In the home screen, tap (settings) > Hands-free operation.
- 2. Set the sliders to the Off position or the On position.
 - Enable facial authentication
 - Enable voice command
- 3. Tap Done.

Manage the run history

- To view the run history, see "View the list of data files on the instrument" on page 88.
- To export the run history, see "Transfer data files at a later time" on page 87.
- To delete the run history, see "Delete data files from the instrument" on page 89.

Manage the file name convention of the data file

- 2. (Optional) Select the Use as system setting checkbox.
- 3. Tap Attributes.

The list of available attributes for the data file name is displayed.

- 4. Select any of the following attributes to add to the data file name format, then tap **Done**.
 - Plate file name (default)
 - Time stamp (default)
 - User name
 - Barcode
 - Custom text



5. Tap the lines beside an attribute, then drag the attribute above or below the other attributes in the table.

\odot	Data File Naming Conventio	n (Ð	?	۲	
	Move attributes to rearrange the file Plate file name_Time star	e format np				
	Attribute name					
						-(1)
						\cup
	Use as system setting					
Attrib	utes	Cancel		Done		

1 Location to tap and drag an attribute

The order of the attributes in the table is the order that they will appear in the data file name.

6. Tap Done.

Enable or disable the reminder to insert a plate

- In the home screen, tap

 (Settings) ➤ Run settings ➤ Insert plate reminder. The Insert Plate Reminder screen is displayed.
- 2. Set the slider to the **On** or the **Off** position.
- **3.** Тар **ОК**.

Select the language

- 2. Tap the language of interest.
- 3. Tap Done.



View the notifications

- 2. Tap Close.

Enable and disable home screen notifications

When home screen notifications are enabled, the number of notifications appears on the **Settings** button.

- 2. Set the slider to the **On** or the **Off** position.
- 3. Tap Close.

Set up email notifications

Email notifications are only available when a user is signed in with a Thermo Fisher[™] Connect Platform account. The emails notifications will be sent to the email address associated with the Thermo Fisher[™] Connect Platform account.

1. In the home screen, tap (settings) > Email notifications.

Note: If a user is not signed in with a Thermo Fisher[™] Connect Platform account, the **Email notifications** button will not be displayed.

- 2. Select the event type.
 - Run started
 - PCR cycling started
 - Run paused
 - Run stopped
 - Run is about to end
 - Run is complete
 - Instrument error

Note: Deselect all of the event types in order to not receive email notifications.

3. Tap Done.



Clear the notifications

- 2. Clear the notifications.

Option	Description
Clear a single notification	Tap a single notification in the table, then tap Clear .
Clear all the notifications	Tap Clear all .

3. Tap Close to return to the Settings screen.

Manage the settings for data export and data import

Overview of the settings for data export and data import

Data export and data import can be controlled.

The settings include allowing data import and data export to and from the following locations:

- A network drive
- A USB drive
- The Thermo Fisher[™] Connect Platform

The network drive can be system-defined or user-defined.

The network drive settings apply to all of the users when they are system-defined. Any changes to any of the settings are applied to all of the users.

If the network drive location is defined in the **Data Management** screen, the network location cannot be selected when performing an export from the instrument.

The USB drive and the Thermo Fisher[™] Connect Platform are user-defined. Each user can configure their own data export and data import settings.

The Thermo Fisher[™] Connect Platform cannot be selected if the profile has not been linked to the Thermo Fisher[™] Connect Platform from the instrument.

If security is enabled on the instrument, you must have the permission of **Change Data Management Settings**.

If security is not enabled on the instrument, only an Administrator can edit the settings.

Data import settings and data export settings are defined separately. For example, data import can be allowed from a USB drive but a USB drive cannot be used for data export.



Manage the settings for data export

If security is enabled on the instrument, you must have the permission of **Change Data Management Settings**.

If security is not enabled on the instrument, only an Administrator can edit the settings.

- 1. In the home screen, tap (a) (Settings) > Data management.
- 2. Ensure that **Export** is selected.

The **Export** button has a light background and white text when it is selected.

- 3. For each export setting, select the checkbox associated with the permission.
 - Allow USB
 - Allow Cloud
 - Allow Network

The **Allow Cloud** checkbox is inactive if the profile has not been linked to the Thermo Fisher[™] Connect Platform from the instrument.

The following export settings are included:

- Run auto export
- Run history and transfer at the end of the run
- Calibrations
- Instrument log
- Back up
- Self-verification report
- Run result automatic export
- 4. If the network is selected, tap 📝 (Edit).

If the network is not selected, the *C* (Edit) button is inactive.

- 5. In the Network Settings screen, set the slider to User-defined or System-defined.
- 6. Tap the network field to edit the location.
- 7. In the **Network Settings** screen, perform one of the following actions:
 - Select a previously defined storage location from the table, then tap **Done**.
 - Tap Network drive to define a new location.
- 8. If you are defining a new location, tap the **Drive location** field, then enter a drive location. The drive location is required.

For IP address, the drive location is <IP address>/<folder name>. For DNS name, the drive location is <DNS>/<folder name>.



- 9. Enter the following information, then tap Connect.
 - Domain name
 - User name
 - Password

The domain name, username, and password can be required, depending on the network requirements.

The username and password are for the network. They are not the username and password for the instrument.

- **10.** *(Optional)* If there are folders within the drive location that was selected, tap a folder that is listed in the table until the appropriate folder is selected.
- **11.** Tap **Done**.
- 12. In the Network Settings screen, tap Close.
- 13. In the Data Management screen, tap Done.

Manage the settings for data import

If security is enabled on the instrument, you must have the permission of **Change Data Management Settings**.

If security is not enabled on the instrument, only an Administrator can edit the settings.

- 1. In the home screen, tap (settings) > Data management.
- 2. Ensure that Import is selected.

The Import button has a light background and white text when it is selected.

- 3. For each import setting, select the checkbox associated with the permission.
 - Allow USB
 - Allow Cloud
 - Allow Network

The **Allow Cloud** checkbox is inactive if the profile has not been linked to the Thermo Fisher[™] Connect Platform from the instrument.

The following import settings are included:

- Import auto export settings
- Import plate, including importing an assay information file (AIF)
- Sample setup
- Restore a backup
- RFID certificate
- 4. If the network is selected, tap *S* (Edit).

If the network is not selected, the *S* (Edit) button is disabled.


- 5. In the Network Settings screen, set the slider to User-defined or System-defined.
- 6. Tap the network field to edit the location.
- 7. In the Network Settings screen, perform one of the following actions:
 - Select a previously defined storage location from the table, then tap **Done**.
 - Tap **Network drive** to define a new location.
- If you are defining a new location, tap the Drive location field, then enter a drive location. The drive location is required.

For IP address, the drive location is <IP address>/<folder name>. For DNS name, the drive location is <DNS>/<folder name>.

- 9. Enter the following information, then tap **Connect**.
 - Domain name
 - User name
 - Password

The domain name, username, and password can be required, depending on the network requirements.

The username and password are for the network. They are not the username and password for the instrument.

- **10.** *(Optional)* If there are folders within the drive location that was selected, tap a folder that is listed in the table until the appropriate folder is selected.
- **11.** Tap **Done**.
- 12. In the Network Settings screen, tap Close.
- 13. In the Data Management screen, tap Done.



Instrument specifications and layout

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Instrument dimensions

The instrument, including a block, has a total weight of 35.85 kg.



2 Width: 33.7 cm





1 Depth: 52.5 cm

Instrument and computer clearances

During instrument installation and maintenance, it is necessary to access the back of the instrument. If the back of the instrument faces a wall, ensure that there is sufficient clearance on the bench to rotate the instrument for access.

IMPORTANT! For safety, the power outlet for the instrument must be accessible.

Component	Тор	Front	Sides	Back
Instrument	30.5 cm (12 in.)	30.5 cm (12 in.)	_	15.25 cm (6 in.)
Computer ^[1]	_	15.25 cm (6 in.)	_	15.25 cm (6 in.)

^[1] Co-locating the computer with the instrument is optional.



Appendix A Instrument specifications and layout Instrument dimensions

Configured system dimensions

Allow space for the configured instrument.

It is not a requirement to locate the computer next to the instrument. The clearances for the instrument shown in the figures also apply to an instrument without a computer.



- (1) Top clearance for the instrument: 30.5 cm
- 2 Width of system: 185 cm



- 1) Back clearance for the computer: 15.25 cm
- (2) Back clearance for the instrument: 15.25 cm
- (3) Front clearance for the instrument: 30.5 cm
- (4) Front clearance for the computer: 15.25 cm

Light guidelines

Use the following guidelines to ensure that there is proper lighting for facial authentication.

- Avoid direct light above or behind the user.
- Place the instrument in a position that minimizes backlight.
- For optimal results, place the instrument between two ceiling lights.

Electrical requirements



CAUTION! Do not unpack or plug in any components until they are configured for the proper operating voltage by the service representative.



WARNING! For safety, the power outlet for the instrument must be accessible at all times. See "Instrument dimensions" on page 218 for information about the space needed between the wall and the instrument. In case of emergency, you must be able to immediately disconnect the main power supply to all the equipment. Allow adequate space between the wall and the equipment so that the power cords can be disconnected in case of emergency.

- Electric receptacle required: Grounding capability required
- Maximum power dissipation: ~417 VA, 371 W (not including computer and monitor)
- Mains AC line voltage tolerances must be up to ±10 percent of nominal voltage

Device	Rated voltage	Circuit required	Rated frequency	Rated power
Instrument	100–240 ±10% VAC ^[1]	10 A	50/60 Hz	960 W
Computer (desktop)	100 240 + 100/ 1/00	10.4	50/60 LI -	125 VA
Monitor	100-240 ± 10% VAC	IUA	50/60 HZ	65 VA
Computer (laptop)	100-240 ± 10% VAC	10 A	50/60 Hz	90 VA

^[1] If the supplied power fluctuates beyond the rated voltage, a power line regulator may be required. High or low voltages can adversely affect the electronic components of the instrument.



Environmental requirements

Condition	Acceptable range
Installation site	Indoor use only
Electromagnetic interference	Do not use this device in close proximity to sources of strong electromagnetic radiation (for example, unshielded intentional RF sources). Strong electromagnetic radiation may interfere with the proper operation of the device.
	This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference. You may need to take measures to mitigate the interference.
Altitude	Located between sea level and 2000 m (6500 ft.) above sea level
Humidity (instrument and computer)	Operation: 15%–80% (noncondensing)
Temperature (instrument	15°C to 30°C (60°F to 85°F)
and computer)	Note: For optimal performance, avoid rapid or extreme fluctuations in room temperature.
Transient category	Installation categories II
Overvoltage category	Installation categories II
Vibration	The instrument is not adjacent to strong vibration sources, such as a centrifuge, pump, or compressor. Excessive vibration will affect instrument performance.
Pollution degree	11
	Install the instrument in an environment that has nonconductive pollutants such as dust particles or wood chips. Typical environments with a Pollution Degree II rating are laboratories and sales and commercial areas.
Liquid waste collection	Dispose of the polymer, buffer, reagents and any liquid waste as hazardous waste in compliance with local and national regulations.
Other conditions	Ensure the room is away from any vents that could expel particulate material on the components.
	Avoid placing the instrument and computer adjacent to heaters, cooling ducts, or in direct sunlight.



Connect the instrument to a network

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Connect the computer to the instrument directly or to a LAN

This section describes direct wired connection of the computer provided by Thermo Fisher Scientific to the instrument or to a local area network (LAN).

Do not connect a customer-provided computer to the instrument.

- 1. Connect an Ethernet cable from the instrument or a LAN to the computer.
- 2. Power on the computer, then log in using a Windows[™] Administrator account.
- 3. Open the Control Panel, then open the Network and Sharing Center.
- 4. In the left pane of the Network and Sharing Center window, click Change Adapter Settings.
- 5. Right-click Broadband Connection, then select Properties.
- 6. In the Networking tab, select Internet Protocol Version 4 (TCP/IPv4).
- 7. Click Properties.
- 8. In the Internet Protocol Version 4 (TCP/IPv4) Properties dialog box, select one of the following options.
 - Obtain an IP address automatically
 - Use the following IP address
- 9. If Use the following IP address was selected, enter the IP address.
- 10. Close all dialog boxes by clicking **OK**, then re-start the computer.

Connect the instrument to a wired network

- 2. Tap Edit. The fields are now editable.
- **3.** Tap one of the active fields under the **Wired** option. The **Network Connection** screen is displayed.
- 4. Select a wired network connection.

Wired network connection	Action
DHCP	No further action is required.
Static IP	 a. In the IP Address field, enter the static IP address. b. If necessary, enter a subnet mask. c. If necessary, enter a static gateway address in the Default Gateway field.

5. Tap Done.

The **Network Configuration** screen is displayed. The *Status* and *IP Address* fields under the **Wired** option have the information from the selected wired network.

6. Tap Done.

This instrument is now connected to the selected wired network.

Connect the instrument to a wireless network

Depending on the configuration of the network, the password for the network needs to be entered.

- 2. Tap Edit.

The fields are now editable.

- 3. Tap one of the active fields under the Wireless option.
- 4. Select a wireless network to connect to the instrument.
- 5. (Optional) Tap **Refresh** to prompt the instrument to search for available wireless networks.
- Tap Done.
 The Network Configuration screen is displayed.

The **Status** field, the **Network** field, and the **IP Address** field under the **Wireless** option are populated with the information from the selected wireless network.

7. Tap **Done**.

This instrument is now connected to the selected wireless network.

Instrument and computer connections



Figure 25 Instrument back panel

- 1 USB ports
- 2 Wi-Fi dongle port
- ③ Ethernet port
- (4) RS-232 port (service use only)
- 5 ON/OFF switch
- 6 Power inlet receptacle



Figure 26 Instrument-to-computer connections (minitower configuration)

- (1) Detachable power supply cord compatible with local power supply receptacle.
- (2) Connection between the computer and the instrument.
- ③ Connection between the computer and the monitor, keyboard, and mouse.
- (4) Connection between the computer and the *(optional)* handheld barcode scanner.

Download and install the desktop software

Computer requirements for the desktop software

QuantStudio[™] Design and Analysis Software 2 can be installed on a customer-provided computer. The following list contains the minimum software requirements for a customer-provided computer.

- Operating system—Windows[™] 10 (64-bit) or Macintosh[™] OS 10.01
- Processor—Intel[™] Core[™] or compatible
- Memory-4 GB RAM
- Hard drive-10 GB
- Monitor-1280 × 1024 resolution

Download the desktop software

- 1. Go to thermofisher.com/qpcrsoftware.
- 2. Select the link for the QuantStudio[™] 6 Pro and 7 Pro Real-Time PCR Systems.
- Download QuantStudio[™] Design and Analysis Software 2. The example files are included in the software.

Install the desktop software

If you ordered a computer supplied by Thermo Fisher Scientific, the field service engineer will configure the computer and install QuantStudio[™] Design and Analysis Software 2 during system installation.

- 1. Use an administrator account to log in to the computer on which you are installing the desktop software.
- Unzip the downloaded software.
 The example files are included in the software.
- 3. Double-click setup.exe.
- 4. Follow the InstallShield Wizard prompts to install the software.
- 5. Accept the license agreement.
- 6. Select Typical as the setup preference, then click Next.
- 7. Click Finish.

Networking

IMPORTANT! This section provides general networking information. It *does not* provide adequate detail to integrate the instrument into all possible network architectures. Because a network may contain advanced features (such as a firewall or network domains), we recommend that you consult a network administrator before connecting the instrument to your laboratory network.

Supported options for instrument and computer connections

We support the following direct, networked (LAN–local area network), or Thermo Fisher™ Connect Platform configurations. Configurations other than those listed are not recommended. Select a configuration that meets the needs of your laboratory's instrument, software, and workflow requirements.

Note: For detailed information about networking your instrument, see the *QuantStudio*[™] 6 *Pro and* 7 *Pro Real-Time PCR Systems IT Checklist* (Pub. No. MAN0018160).

Thermo Fisher[™] Connect Platform connection

• Internet access and a computer with the Chrome™ web browser to access the Connect platform.



(continued)

Thermo Fisher™ Connect Platform connection

- Computer-to-Thermo Fisher™ Connect Platform connection (select an option):
 - Wired connection to the internet using an Ethernet cable -or-
 - Wireless connection to the internet
- Instrument-to-Thermo Fisher™ Connect Platform connection (select an option):
 - Wired connection to the network using an Ethernet cable -or-
 - Wireless connection to the network using the instrument Wi-Fi module

Local area network (LAN) connection

- A computer provided by Thermo Fisher Scientific with QuantStudio™ Design and Analysis Software 2.
- The computer and instrument must be on the same subnet mask.
- Computer-to-LAN connection (select an option):
 - Wired connection to the network using an Ethernet cable -or-
 - Wireless connection to the network
- Instrument-to-LAN connection (select an option):
 - Wired connection to the network using an Ethernet cable or–
 - Wireless connection to the network using the instrument Wi-Fi module

Direct connection

- A computer provided by Thermo Fisher Scientific with QuantStudio™ Design and Analysis Software 2.
- Computer-to-instrument connection: Direct, wired connection between the computer and the instrument using an Ethernet cable.

IMPORTANT! A direct instrument-to-computer connection *cannot* be combined with LAN or Thermo Fisher[™] Connect Platform configurations.



Monitor instruments

- The status of the instrument can be viewed in QuantStudio[™] Design and Analysis Software 2. If the instrument is running, the time remaining in the run is displayed.
- The calibration status and calibration details of the instrument can be viewed in QuantStudio[™] Design and Analysis Software 2.
- A template file can be sent from the QuantStudio[™] Design and Analysis Software 2 to the instrument run queue.

The functions are also available in QuantStudio[™] Design and Analysis v2 (Thermo Fisher[™] Connect Platform).



LAN

Networking guidelines and best practices

- Consult a network administrator before connecting the instrument to a network.
- To enable the full functionality of the software, the computer requires a network connection.
- Open the firewall port for the instruments to be discovered. See "Firewall ports that must be open" on page 229.
- Observe the restrictions to mDNS and Autodiscovery.

The instrument supports mDNS but only when the instrument and computer share a direct network connection and are within the same subnet. Network computers that are separated from the instrument by a router, hub, or another network device may not be able to access the instrument by its host name.

- Confirm the uniqueness of the instrument name.
 - The instrument name must be unique within the subnet. The desktop software can automatically discover instruments on the link-local network.
 - The instrument does not test the uniqueness of the instrument name within the subnet when it is set.

Firewall ports that must be open

Ports	Condition
80/443	Standard ports for instrument-to-Thermo Fisher™ Connect Platform and computer-to-Thermo Fisher™ Connect Platform connections
mDNS, 7443	Instrument-to-computer connection
mDNS, 5353	Instrument discovery

Ethernet port overview

The Ethernet port of the instrument supports:

- Static IP network service with subnet mask, primary and secondary data network service (DNS), and default gateway settings, or dynamic host configuration protocol (DHCP) network service.
- mDNS/DNS for local domains.

Note: Because mDNS is limited to direct network connections, an instrument configured for mDNS may not be visible to other nodes that are separated by a router, hub, or another network device.

 IPv4 link-local (IPV4LL) in the RFC (also known as Automatic Private IP Addressing [APIPA] or Internet Protocol Automatic Configuration [IPAC]).

Note: When an instrument is set for DHCP, APIPA is automatically enabled, and the instrument provides an IP address when no address is supplied by the DHCP server.



Third-party software

Before installing third-party software on the computer running the desktop software, confirm that the third-party software will not do the following:

- Restrict Ethernet communication.
- Interfere with instrument or computer operation.



Detailed procedures for preparation of a TaqMan[™] Array Card

Guidelines for preparation of a card

- Keep the card protected from light and stored as indicated until ready for use. Excessive exposure to light may affect the fluorescent probes of the dried-down assays in the card.
- Before removing the card from its packaging:
 - Prepare each sample-specific PCR reaction mix.
 - Allow the card to reach room temperature.
- Load each fill reservoir with 100 µL of sample-specific PCR reaction mix.
 - Each fill reservoir contains a single sample as determined by the card layout.
 - The 100-µL volume ensures adequate filling of each reaction well. Volumes smaller than 100 µL result in insufficiently filled cards.
- Do not allow the micropipette tip to contact the coated foil beneath the fill port.



- Load the card with PCR reaction mix *before* centrifuging the card.
 During centrifugation, the PCR reaction mix resuspends the dried-down assays in each well of the card.
 Adding sample after centrifuging disrupts the assay layout of the card.
- Run the card within the time allowed by the PCR master mix. See the user guide for the assay or the master mix.
- If the card is not run immediately, protect it from light and store at 2-8°C.

TaqMan[™] Array Card diagram

A TaqMan[™] Array Card includes 8 fill reservoirs and 384 reaction wells.



The fill reservoir includes a fill port and a vent port. Use the fill port to load PCR reaction mix into the card.





Load the PCR reaction mix

Before removing the card from its packaging:

- Prepare each sample-specific PCR reaction mix.
- Allow the card to reach room temperature.
- 1. Carefully remove the card from its packaging.
- 2. Place the card on the benchtop with its foil-side down.
- 3. Load 100 μL of the sample-specific PCR reaction mix into a micropipette.
- 4. Hold the micropipette in an angled position, then place the tip into a fill port of the card.
- 5. Slowly dispense the entire volume of reaction mix so that it sweeps in and around the fill reservoir toward the vent port.



Centrifuge the card

- 1. Load the cards into the centrifuge buckets.
 - a. Place the bucket on the benchtop with its label facing the front of the bench.
 - b. Insert the cards into the card holder, ensuring that:
 - The fill reservoirs extend upwards out of the card holder.
 - The reaction wells face the label-side of the card holder.
 - **c.** Insert blank balance cards into any empty positions of the card holder. All three positions in the card holder must be filled.

QuantStudio™ 6 Pro Real-Time PCR System and QuantStudio™ 7 Pro Real-Time PCR System User Guide



d. Place the loaded card holder into the bucket so that the card holder label faces the front of the bucket.



- 2. Configure the centrifuge using its front-panel controls.
 - a. Set the bucket type to 15679.
 - b. Set the following parameters according to the control panel type.

Parameter	EASYSet (touchpad-operated)	QUIKSet (knob-operated)
Increasing ramp rate	9	3
Decreasing ramp rate	9	_
Rotational speed	1,200 rpm (331 × <i>g</i>)	1,200 rpm
Centrifugation time ^[1]	1 minute	1 minute

^[1] You will centrifuge the cards twice, each time for 1 minute (see step 4).

IMPORTANT! A speed that is set too high can deform the card.

- 3. Load the buckets into the centrifuge.
 - a. Press a on the centrifuge control panel to open the centrifuge cover.
 - Place each loaded bucket onto an open rotor arm of the centrifuge.
 Ensure that each bucket can swing easily within its slotted position on the rotor arm.
 - c. If there are empty rotor arms, prepare buckets with blank balance cards as described in step 1. Place the balance buckets onto the rotor arms.

The rotor must be evenly loaded and opposing buckets must hold the same weight.

d. Close the centrifuge cover.



Centrifuge is properly loaded and balanced.



- 4. Run the centrifuge.
 - a. Press ▶.

The centrifuge will start, then automatically stop after 1 minute.

b. Repeat substep 4a so that the cards are centrifuged for a total of two, consecutive, 1-minute centrifugations.

IMPORTANT! Do not centrifuge the cards continuously for 2 minutes. The ramping up in speed during the *two, consecutive 1-minute* centrifugations is important for proper filling.

- 5. Remove the cards from the centrifuge.
 - a. Press 🔔.
 - b. Remove the buckets from the centrifuge, then remove the card holders from the buckets.
 - c. Remove each card from the card holder by lifting it gently by the card carrier sides.
- 6. Examine the cards for proper filling.

When properly filled, the remaining volumes of PCR reaction mix are consistent reservoir to reservoir.



Seal the card

The TaqMan[™] Array Card Sealer isolates the wells of an array card after it is loaded with PCR reaction mix and centrifuged. The sealer uses a precision stylus assembly (under the carriage) to seal the main fluid distribution channels of the array card.

Note: In some documents, the TaqMan™ Array Card Sealer is referred to as a Stylus Staker.

- 1. Position the TaqMan[™] Array Card Sealer and its carriage before inserting a card.
 - Place the sealer on a benchtop that is approximately waist-high so that the carriage can be easily maneuvered.
 - **b.** Position the sealer with the carriage starting position toward the front of the bench.

Ensure that the engraved arrows on the sealer point away from you.



- Carriage
- ② Carriage starting position
- ③ Carriage ending position



c. Ensure that the carriage for the sealer is at the starting position.

IMPORTANT! Do not insert a filled card into the sealer if the carriage is *not* in its starting position. The card will be irreparably damaged if the carriage is moved backwards across the card towards the starting position.

- 2. Insert a filled, centrifuged card into the sealer.
 - a. Hold the card with its foil-side up.
 - b. Orient the card over the sealer with the fill reservoirs of the card toward the ending position.
 - c. Align the rear pin grooves of the card to the alignment pins of the sealer.





- **d.** Gently place the card on top of the sealer.
- e. Gently push the card until it is seated securely in the sealer.

When properly seated, the foil surface of the card is level with the base of the sealer and the spring clips hold the card securely in place.



Slowly and steadily push the carriage across the sealer in the direction of the engraved arrows.
 Push the carriage across the entire length of the card until the carriage meets the mechanical stops at the ending position.



IMPORTANT!

- . Do not use excessive force or speed when pushing the carriage across the card.
- Do not move the carriage back across the card. Leave the carriage at the ending position while removing the card from the sealer.
- 4. Remove the sealed card from the sealer by grasping the sides of the card and lifting it off. Use the thumb slot in the middle of the sealer to access the card.
- 5. Examine the card for proper sealing.

Note: When properly sealed, the indentations from the sealer carriage align with the main channels of the card.

If the indentations do not align or if the foil is damaged, do not use the card.

6. Use scissors to trim the fill reservoir strip from the card. Use the edge of the card carrier as a guide.



IMPORTANT! Completely remove the fill reservoir strip. Any remaining plastic that extends beyond the card edge can prevent the card from seating properly on the sample block and can affect amplification.

Correct trim	Incorrect trim

The card is now ready to run on the instrument.

(Optional) Store the sealed card, protected from light, at 2–8°C. The length of time the card can be stored depends on the master mix. See the user guide for the assay or the master mix.





Parts and materials

Kits, consumables, accessories, and reagents

Unless otherwise indicated, all materials are available through thermofisher.com.

Store all calibration and RNase P plates at –20°C. All other items can be stored at 15–30°C. Use all materials by the expiration date on the packaging.

Catalog numbers that appear as links open the web pages for those products.

96-well 0.2 mL consumables

Consumable	Amount	Cat. No.
MicroAmp [™] Optical 8-Cap Strips	300 strips	4323032
MicroAmp [™] Optical 8-Tube Strip, 0.2 mL	125 strips	4316567
MicroAmp [™] Optical Tube without Cap, 0.2 mL	2,000 tubes	N8010933
MicroAmp [™] Optical 96-Well Reaction Plate with Barcode		4306737
		4326659
MicroAmp [™] EnduraPlate [™] Optical 96-Well Clear GPLE Reaction Plates with	20 plates	4483348
Barcode	500 plates	4483351
Instrument verification or calibration plate		Cat. No.
TagMan™ RNase P Instrument Verification Plate. 96-Well 0.2-mL		4432382

TaqMan [™] RNase P Instrument Verification Plate, 96-Well 0.2-mL	4432382
Region of Interest (ROI) and Background Plates, 96-Well 0.2-mL (2 plates)	4432364
QuantStudio [™] 3/5 10-Dye Spectral Calibration Kit, 96-Well 0.2-mL (contains all 3 spectral calibration plates listed below)	A26343
QuantStudio™ 3/5 Spectral Calibration Plate 1, 96-Well 0.2-mL (FAM™, VIC™, ROX™, SYBR™ dyes)	A26331
QuantStudio™ 3/5 Spectral Calibration Plate 2, 96-Well 0.2-mL (ABY™, JUN™, MUSTANG PURPLE™ dyes)	A26332
QuantStudio [™] 3/5 Spectral Calibration Plate 3, 96-Well 0.2-mL (TAMRA [™] , NED [™] , Cy [®] 5 dyes)	A26333

96-well 0.1 mL consumables

Consumable	Contents	Cat. no.
MicroAmp [™] Optical 8-Cap Strips	300 strips	4323032
MicroAmp [™] Fast 8-Tube Strip, 0.1 mL	125 strips	4358293
MicroAmp [™] Fast Reaction Tube with Cap, 0.1 mL	1000 tubes	4358297
MicroAmp [™] 96-Well Tray for VeriFlex [™] Block	10 trays	4379983
MicroAmp [™] Fast Optical 96-Well Reaction Plate, 0.1 mL	10 plates	4346907
MicroAmp [™] EnduraPlate [™] Optical 96-Well Fast Clear Reaction Plates with Barcode		4483485
		4483494

Calibration or instrument verification plate	Cat. no.
Region of Interest (ROI) and Background Plates, Fast 96-Well 0.1-mL (2 plates)	4432426
QuantStudio™ 3/5 10-Dye Spectral Calibration Kit, 96-well, 0.1-mL	A26342
QuantStudio [™] 3/5 Spectral Calibration Plate 1, (FAM [™] , VIC [™] , ROX [™] , and SYBR [™] dyes), 96-well, 0.1 mL	A26336
QuantStudio [™] 3/5 Spectral Calibration Plate 2 (ABY [™] , JUN [™] , MUSTANG PURPLE [™] dyes), 96-well (0.1-mL) plate	A26337
QuantStudio [™] 3/5 Spectral Calibration Plate 3 (TAMRA [™] , NED [™] and Cy [®] 5 dyes) 96-well (0.1-mL) plate	A26340
TaqMan™ RNase P Instrument Verification Plate, Fast 96-Well	4351979

384-well consumables

Consumable	Contents	Cat. no.
MicroAmp [™] Optical 384-Well Reaction Plate with Barcode		4309849
		4326270
		4343814
MicroAmp [™] EnduraPlate [™] Optical 384-Well Clear Reaction Plate with Barcode		4483285
		4483273

Calibration or instrument verification plate		
TaqMan™ RNase P Instrument Verification Plate, 384-well	4455280	
Region of Interest (ROI) and Background Plates, 384-well	4432320	
QuantStudio™ 5 10-Dye Spectral Calibration Kit, 384-well	A06041	
(contains the 2 spectral calibration plates listed below)	A20341	
QuantStudio [™] 5 Spectral Calibration Plate 1, (FAM [™] , VIC [™] , ROX [™] TAMRA [™] , and SYBR [™] dyes), 384-well	A26334	
QuantStudio [™] 5 Spectral Calibration Plate 2 (ABY [™] , JUN [™] , MUSTANG PURPLE [™] , NED [™] , and Cy [®] 5 dyes), 384-well	A26335	

TaqMan[™] Array Card consumables

Go to thermofisher.com/taqmanarrays to select assays and order TaqMan[™] Array Cards.

Item	Source
Calibration kit	
 ViiA[™] 7 Array Card Spectral Calibration Kit, includes the following components: Empty TaqMan[™] Array Cards FAM[™] dye VIC[™] dye ROX[™] dye ROI dye mix Background buffer FAM[™]/ROX[™] dye VIC[™]/ROX[™] dye 	4432314
Verification kit	
 ViiA[™] 7 Array Card RNaseP Verification Kit, includes the following components: TaqMan[™] Array Card Eight (8) vials of RNase P detection reagents, one for each port in the TaqMan[™] Array Card. Each vial contains the following reagents: PCR master mix RNase P primers A FAM[™] dye-labeled probe A known concentration of human genomic DNA template 	4432265

Accessories

Item	Amount	Cat. No.
MicroAmp [™] 96-Well Tray/Retainer Set	10 trays	4381850
MicroAmp™ Multi Removal Tool	1 tool	4313950
MicroAmp [™] Cap Installing Tool (handle style)	1 tool	4330015
MicroAmp [™] Optical Adhesive Film	25 films	4360954
	100 films	4311971
MicroAmp [™] Adhesive Film Applicator	5 applicators	4333183
RT-PCR Grade Water	10 × 1.5 mL tubes	AM9935
Handheld Barcode Scanner	1 scanner	4488442

The following accessories are required for TaqMan[™] Array Cards. Contact your local sales office for details.

- Centrifuge with custom buckets and card holders, one of the following:
 - Sorvall[™] centrifuge
 - Multifuge™ centrifuge
 - Megafuge[™] centrifuge
- TaqMan™ Array Card Sealer (referred to as the Stylus Staker in some documents)
- Blank balance TaqMan[™] Array Cards (included with the instrument block upgrade / installation kit)





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

- Before using an instrument or device, read and understand the safety information provided in the user documentation provided by the manufacturer of the instrument or device.
- Before handling chemicals, read and understand all applicable Safety Data Sheets (SDSs) and use appropriate personal protective equipment (gloves, gowns, eye protection, and so on). To obtain SDSs, visit thermofisher.com/support.

Symbols on this instrument

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

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

Standard safety symbols

	Symbol and description
	CAUTION! Risk of danger. Consult the manual for further safety information.
	CAUTION! Risk of electrical shock.
	CAUTION! Hot surface.
	CAUTION! Potential biohazard.
	CAUTION! Ultraviolet light.
	Symbole et description
	MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité.
	MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité. MISE EN GARDE ! Risque de choc électrique.
<u>^</u>	MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité. MISE EN GARDE ! Risque de choc électrique. MISE EN GARDE ! Surface chaude.
▲ ▲	MISE EN GARDE ! Risque de danger. Consulter le manuel pour d'autres renseignements de sécurité. MISE EN GARDE ! Risque de choc électrique. MISE EN GARDE ! Surface chaude. MISE EN GARDE ! Danger biologique potentiel.



Additional safety symbols

	Symbol and description	
A	CAUTION! Moving parts.	
	Symbole et description	
	MISE EN GARDE ! Parties mobiles.	

Location of safety labels

The instrument contains warnings at the locations shown in the figures below.



Figure 27 Labels on the back of the instrument (QuantStudio™ 6 Pro Real-Time PCR System)

- 1 Electrical rating label
- 2 RFID label
- ③ Safety label





1 Electrical rating label
2 RFID label
3 Safety label



1 Moving parts label



Figure 30 Labels on the top of the block

1 Hot surface label



Figure 31 Labels on the bottom of the block



Figure 32 Labels on drawer and the installed block

- 1 Hot surface label
- Moving parts label





1 Hot surface label



Figure 34 Labels on the bottom of the heated cover

Control and connection symbols

Symbols and descriptions	
	On (Power)
\bigcirc	Off (Power)

Conformity symbols

Conformity mark	Description	
c us	Indicates conformity with safety requirements for Canada and U.S.A.	
25	Indicates conformity with China RoHS requirements.	
CE	Indicates conformity with European Union requirements.	
ß	Indicates conformity with Australia/New Zealand standards for electromagnetic compatibility and radio frequency requirement.	

(co	ntin	ue	d)
· · ·			- /

Conformity mark	Description
X	INDICATES CONFORMITY WITH THE WEEE DIRECTIVE 2012/19/EU.
	CAUTION! To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.
F©	Indicates conformity with US radio frequency standard.

Safety information for instruments not manufactured by Thermo Fisher Scientific

Some of the accessories provided as part of the instrument system are not designed or built by Thermo Fisher Scientific. Consult the manufacturer's documentation for the information needed for the safe use of these products.

Instrument safety

General



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



CAUTION! Solvents and Pressurized fluids. Wear eye protection when working with any pressurized fluids. Use caution when working with any polymeric tubing that is under pressure:

- · Extinguish any nearby flames if you use flammable solvents.
- Do not use polymeric tubing that has been severely stressed or kinked.
- Do not use polymeric tubing with tetrahydrofuran or nitric and sulfuric acids.
- Be aware that methylene chloride and dimethyl sulfoxide cause polymeric tubing to swell and greatly reduce the rupture pressure of the tubing.
- Be aware that high solvent flow rates (~40mL/min) may cause a static charge to build up on the surface of the tubing and electrical sparks may result.

QuantStudio™ 6 Pro Real-Time PCR System and QuantStudio™ 7 Pro Real-Time PCR System User Guide

Physical injury



CAUTION! Moving and Lifting Injury. The instrument is to be moved and positioned only by the personnel or vendor specified in the applicable site preparation guide. Improper lifting can cause painful and permanent back injury.

Things to consider before lifting or moving the instrument or accessories:

- Depending on the weight, moving or lifting may require two or more persons.
- If you decide to lift or move the instrument after it has been installed, do not attempt to do so without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques.
- Ensure you have a secure, comfortable grip on the instrument or accessory.
- Make sure that the path from where the object is to where it is being moved is clear of obstructions.
- Do not lift an object and twist your torso at the same time. Keep your spine in a good neutral position while lifting with your legs.
- Participants should coordinate lift and move intentions with each other before lifting and carrying.
- For smaller packages, rather than lifting the object from the packing box, carefully tilt the box on its side and hold it stationary while someone else slides the contents out of the box.



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

Electrical safety



WARNING! Fuse Installation. Before installing the instrument, verify that the fuses are properly installed and the fuse voltage matches the supply voltage. Replace fuses only with the type and rating specified for the unit. Improper fuses can damage the instrument wiring system and cause a fire.



AVERTISSEMENT ! Installation des fusibles. Avant d'installer l'instrument, vérifier que les fusibles sont correctement insérés et que leur tension correspond à celle fournie par le circuit d'alimentation. Ne remplacer les fusibles que par des modèles du type et de la puissance spécifiés pour l'appareil. L'utilisation de fusibles inadaptés peut endommager le circuit électrique de l'instrument et provoquer un incendie.



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

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



AVERTISSEMENT ! Veiller à utiliser une alimentation électrique appropriée. Pour garantir le fonctionnement de l'instrument en toute sécurité :

- Brancher le système sur une prise électrique correctement mise à la terre et de puissance adéquate.
- · S'assurer que la tension électrique est convenable.
- Ne jamais utiliser l'instrument alors que le dispositif de mise à la terre est déconnecté. La continuité de la mise à la terre est impérative pour le fonctionnement de l'instrument en toute sécurité.



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



AVERTISSEMENT ! Cordons d'alimentation électrique. Utiliser des cordons d'alimentation adaptés et approuvés pour raccorder l'instrument au circuit électrique du site.



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



AVERTISSEMENT ! Déconnecter l'alimentation. Pour déconnecter entièrement l'alimentation, détacher ou débrancher le cordon d'alimentation. Placer l'instrument de manière à ce que le cordon d'alimentation soit accessible.

Laser safety

A



WARNING! LASER HAZARD. The QuantStudio[™] 6 Pro System and the QuantStudio[™] 7 Pro System are compatible with an optional Handheld Barcode Scanner. Lasers can burn the retina, causing permanent blind spots. To ensure safe laser operation:

- · Never look directly into the laser beam.
- · Do not remove safety labels, instrument protective panels, or defeat safety interlocks.
- The system must be installed and maintained by a Thermo Fisher Scientific Technical Representative.
- . Remove jewelry and other items that can reflect a laser beam into your eyes or those of others
- Wear proper eye protection and post a laser warning sign at the entrance to the laboratory if the laser protection is defeated for servicing
- DO NOT operate the laser when it cannot be cooled by its cooling fan; an overheated laser can cause severe burns on contact.

The following table lists laser safety symbols and alerts that may be present on the instrument.

A CAUTION! LASER HAZARD, Bar Code Scanner. The bar code scanner included with the instrument is a Class 2 laser. To avoid damage to eyes, do not stare directly into the beam or point into another person's eyes.

Alert

Alerte

MISE EN GARDE ! RISQUE LIÉ AU RAYONNEMENT LASER, Lecteur de code-barres. Le lecteur de code-barres inclut dans l'instrument est un appareil laser de classe 2. Pour éviter toute lésion oculaire, ne regardez pas directement le faisceau et ne le dirigez pas vers les yeux d'une autre personne.
Cleaning and decontamination



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

- No decontamination or cleaning agents are used that can react with parts of the equipment or with material that is contained in the equipment. Use of such agents could cause a HAZARD condition.
- The instrument is properly decontaminated a) if hazardous material is spilled onto or into the equipment, and/or b) before the instrument is serviced at your facility or is sent for repair, maintenance, trade-in, disposal, or termination of a loan. Request decontamination forms from customer service.
- Before using any cleaning or decontamination methods (except methods that are recommended by the manufacturer), confirm with the manufacturer that the proposed method will not damage the equipment.



MISE EN GARDE ! Nettoyage et décontamination. Utiliser uniquement les méthodes de nettoyage et de décontamination indiquées dans la documentation du fabricant destinée aux utilisateurs. L'opérateur (ou toute autre personne responsable) est tenu d'assurer le respect des exigences suivantes:

- Ne pas utiliser d'agents de nettoyage ou de décontamination susceptibles de réagir avec certaines parties de l'appareil ou avec les matières qu'il contient et de constituer, de ce fait, un DANGER.
- L'instrument doit être correctement décontaminé a) si des substances dangereuses sont renversées sur ou à l'intérieur de l'équipement, et/ou b) avant de le faire réviser sur site ou de l'envoyer à des fins de réparation, de maintenance, de revente, d'élimination ou à l'expiration d'une période de prêt (des informations sur les formes de décontamination peuvent être demandées auprès du Service clientèle).
- Avant d'utiliser une méthode de nettoyage ou de décontamination (autre que celles recommandées par le fabricant), les utilisateurs doivent vérifier auprès de celui-ci qu'elle ne risque pas d'endommager l'appareil.

Instrument component and accessory disposal

To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

Safety and electromagnetic compatibility (EMC) standards

The instrument design and manufacture complies with the following standards and requirements for safety and electromagnetic compatibility.



Safety standards

Reference	Description
EU Directive 2014/35/EU	European Union "Low Voltage Directive"
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and
EN 61010-1	laboratory use – Part 1: General requirements
UL 61010-1	
CAN/CSA C22.2 No. 61010-1	
IEC 61010-2-010	Safety requirements for electrical equipment for measurement, control and
EN 61010-2-010	laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-081	Safety requirements for electrical equipment for measurement, control and
EN 61010-2-081	laboratory use – Part 2-081: Particular requirements for automatic and semi- automatic laboratory equipment for analysis and other purposes

EMC standards

Reference	Description
EMC Directive 2014/30/EU	European Union "EMC Directive"
IEC 61326-1	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements
AS/NZS CISPR 11	Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment
ICES-003, Issue 6	Industrial, Scientific and Medical (ISM) Radio Frequency Generators
FCC Part 15 Subpart B (47 CFR)	U.S. Standard Radio Frequency Devices

Environmental design standards

Reference	Description
Directive 2012/19/EU	European Union "WEEE Directive"—Waste electrical and electronic equipment
Directive 2011/65/EU	European Union "RoHS Directive"—Restriction of hazardous substances in electrical and electronic equipment
SJ/T 11364-2014	"China RoHS" Standard—Marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products
	For instrument specific certificates, visit our customer resource page at www.thermofisher.com/us/en/home/technical-resources/rohs-certificates.html.

Reference	Description
Directive 2014/53/EU	European Union "RE Directive"—Radio equipment
	Hereby, Thermo Fisher Scientific declares that the radio equipment type: QuantStudio [™] 6 Pro Real-Time PCR System and QuantStudio [™] 7 Pro Real-Time PCR System are in compliance with Radio Equipment Directive 2014/53/EU. The full text of the EU declaration of conformity is available at thermofisher.com.
FCC Part 15	Contains FCC ID: 2ADEZMRM102A
	FCC Notice (for U.S. Customers):
	This device complies with Part 15 of the FCC Rules:
	Operation is subject to the following conditions:
	1. This device may not cause harmful interference, and
	2. This device must accept any interference received, Including interference that may cause undesired operation.
	Changes and modifications not expressly approved by Thermo Fisher Scientific can void your authority to operate this equipment under Federal Communications Commissions rules.
	Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the 47 CFR 2.1091 of the FCC radio frequency (RF) Exposure rules.

Radio compliance standards



(continued)

Reference	Description
ICES (Innovation, Science and Economic Development Canada)	This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:
	1. This device may not cause interference.
	2. This device must accept any interference, including interference that may cause undesired operation of the device.
	L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:
	1. L'appareil ne doit pas produire de brouillage;
	 L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.
	This product complies to ICES-3 (A)/NMB-3(A). This equipment complies with ISED (IC) radiation exposure limits set forth for an uncontrolled environment and meets the ESS-102 of the ISED (IC) radio frequency (RF) Exposure rules.
IMDA (Infocomm Media Development Authority) (Singapore)	Complies with IMDA standards DA107256
ANATEL (Agencia	Módulo Modelo: ID ISC.MRM102-A
Nacional de Telecomunicacoes)	
(Brazil)	06094-19-08681
	Este equipamento não tem direito à proteção contra interferência prejudicial e não pode causar interferência em sistemas devidamente autorizados.
KCC (Korea	이 기기는 업무용 환경에서 사용할 목적으로 적합성평가를 받은 기기로서
Communications Commission) (Korea)	가정용 환경에서 사용하는 경우 전파간섭의 우려가 있습니다 .
MIC (Ministry of Internal Affairs and Communications) (Japan)	This product includes approved RFID module with MIC approval number AC-19073.
NCC (National Communications Commission) (Taiwan)	低功率電波輻射性電機管理辦法
	第十二條經型式認證合格之低功率射頻電機,非經許可,公司、商號或使
	用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。
	第十四條低功率射頻電機之使用不得影響飛航安全及干擾合法通信; 經發
	現有干擾現象時,應立即停用,並改善至無干擾時方得繼續使用。
	前項合法通信,指依電信規定作業之無線電信。低功率射頻電機須忍受合法通信或工業、科 學及醫療用電波輻射性電機設備之干擾。

RFID readers		
Description	ID ISC.MRM102-A RFID module with asynchronous RS232 interface	
Frequency	13.56 MHz	
Modulation	ASK	
Transmit power	54.5 dBuV/m at 10m	
Antenna	3674.000.00 (ID ISC. ANT40/30 HF PCB Antenna)	
	Dimensions: 40 mm x 30 mm (1.57 inches x 1.18 inches)	
	Antenna: 50 Ohm	
Supply voltage	12 Vdc	

RF transceiver specifications

Chemical safety



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

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



AVERTISSEMENT ! PRÉCAUTIONS GÉNÉRALES EN CAS DE MANIPULATION DE PRODUITS

CHIMIQUES. Pour minimiser les risques, veiller à ce que le personnel du laboratoire lise attentivement et mette en œuvre les consignes de sécurité générales relatives à l'utilisation et au stockage des produits chimiques et à la gestion des déchets qui en découlent, décrites ci-dessous. Consulter également la FDS appropriée pour connaître les précautions et instructions particulières à respecter :

- Lire et comprendre les fiches de données de sécurité (FDS) fournies par le fabricant avant de stocker, de manipuler ou d'utiliser les matériaux dangereux ou les produits chimiques. Pour obtenir les FDS, se reporter à la section « Documentation et support » du présent document.
- Limiter les contacts avec les produits chimiques. Porter des équipements de protection appropriés lors de la manipulation des produits chimiques (par exemple : lunettes de sûreté, gants ou vêtements de protection).
- Limiter l'inhalation des produits chimiques. Ne pas laisser les récipients de produits chimiques ouverts. Ils ne doivent être utilisés qu'avec une ventilation adéquate (par exemple, sorbonne).
- Vérifier régulièrement l'absence de fuite ou d'écoulement des produits chimiques. En cas de fuite ou d'écoulement d'un produit, respecter les directives de nettoyage du fabricant recommandées dans la FDS.
- Manipuler les déchets chimiques dans une sorbonne.

- Veiller à utiliser des récipients à déchets primaire et secondaire. (Le récipient primaire contient les déchets immédiats, le récipient secondaire contient les fuites et les écoulements du récipient primaire. Les deux récipients doivent être compatibles avec les matériaux mis au rebut et conformes aux exigences locales, nationales et communautaires en matière de confinement des récipients.)
- · Une fois le récipient à déchets vidé, il doit être refermé hermétiquement avec le couvercle fourni.
- Caractériser (par une analyse si nécessaire) les déchets générés par les applications, les réactifs et les substrats particuliers utilisés dans le laboratoire.
- Vérifier que les déchets sont convenablement stockés, transférés, transportés et éliminés en respectant toutes les réglementations locales, nationales et/ou communautaires en vigueur.
- **IMPORTANT !** Les matériaux représentant un danger biologique ou radioactif exigent parfois une manipulation spéciale, et des limitations peuvent s'appliquer à leur élimination.



WARNING! HAZARDOUS WASTE (from instruments). Waste produced by the instrument is potentially hazardous. Follow the guidelines noted in the preceding General Chemical Handling warning.



WARNING! 4L Reagent and Waste Bottle Safety. Four-liter reagent and waste bottles can crack and leak. Each 4-liter bottle should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position.

Biological hazard safety

WARNING! Potential Biohazard. Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.



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

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020 cdc.gov/labs/bmbl
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)
 who.int/publications/i/item/9789240011311



Documentation and support

Related documentation

Document	Pub. No.	
QuantStudio™ 6 Pro Real-Time PCR System and QuantStudio™ 7 Pro Real-Time PCR System Hands-Free Features Quick Reference		
TaqMan™ Array Plates with RFID for use with QuantStudio™ 6 Pro and 7 Pro Real-Time PCR Systems Quick Reference Guide		
QuantStudio™ 6 Pro Real-Time PCR System and QuantStudio™ 7 Pro Real-Time PCR System Connectivity Quick Reference		
QuantStudio™ 6 Pro Real-Time PCR System and QuantStudio™ 7 Pro Real-Time PCR System Site Preparation Guide		
Desktop software		
QuantStudio™ Design and Analysis Software 2 User Guide		
QuantStudio™ Design and Analysis Software 2 Standard Curve Analysis Module User Guide		
QuantStudio™ Design and Analysis Software 2 Relative Quantification Analysis Module User Guide		
QuantStudio™ Design and Analysis Software 2 Presence Absence Analysis Module User Guide		
QuantStudio™ Design and Analysis Software 2 Genotyping Analysis Module User Guide		
QuantStudio™ Design and Analysis Software 2 High Resolution Melt Analysis Module User Guide		
Thermo Fisher™ Connect Platform		
QuantStudio™ Design and Analysis v2 User Guide	MAN0018202	
Security, Auditing, and E-signature (SAE) Administrator Console		
SAE Administrator Console v2.0 or later User Guide for PCR systems	MAN0017468	
About the Assay Information File		
Understanding Your Shipment		

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 - Certificates of Analysis
 - Safety Data Sheets (SDSs; also known as MSDSs)

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

Limited product warranty

Life Technologies Corporation and its affiliates warrant their products as set forth in the Life Technologies' General Terms and Conditions of Sale at www.thermofisher.com/us/en/home/global/terms-and-conditions.html. If you have questions, contact Life Technologies at www.thermofisher.com/support.

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QuantStudio™ 6 Pro Real-Time PCR System and QuantStudio™ 7 Pro Real-Time PCR System User Guide
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