

QuantStudio™ 5 Real-Time PCR Instrument (for Human Identification)

USER GUIDE

Installation, maintenance, and administration

for use with:

HID Real-Time PCR Analysis Software v1.3 and v1.4

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diagnostic procedures.

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B.0	9 November 2022	<ul style="list-style-type: none">• Updated to include HID Real-Time PCR Analysis Software v1.4.• Updated to include instrument firmware v1.5.1.• For the instrument-to-computer connection, added firewall port 7443 (for instruments with firmware v1.5.1).
A.0	15 June 2017	New document for Human Identification workflows using instrument firmware v1.3.1.

The information in this guide is subject to change without notice.

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Product information

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Instrument overview

The QuantStudio™ 5 Real-Time PCR Instrument uses fluorescence-based polymerase chain reaction (PCR) reagents to perform:

- Quantitative detection of target nucleic acid sequences (targets).
- Qualitative detection of targets (endpoint analysis, genotyping, and presence/absence).



The instrument is configured with a 96-well 0.2-mL fixed block (6 color de-coupled).

To run experiments using HID assays, the instrument must be integrated with the HID Real-Time PCR Analysis Software.

Installation, verification, and calibration

Your HID Support Representative will contact you to schedule the installation. During instrument installation, the service representative will perform the initial instrument verification using an RNase P plate and calibrate the instrument for the versions of ABY™ and JUN™ dye used by HID-validated workflows.

Instruments are factory calibrated, so ROI, uniformity, background, and system dye calibrations are not necessary at installation.

You do have the option to install the instrument yourself. Before first use of the instrument, complete the following tasks:

- Install the instrument (see page 14).
- Verify instrument performance (see page 55).
- Perform custom dye calibrations for ABY™ and JUN™ dyes (see page 51).

After installation, perform regular calibration and verification according to the “Calibration and verification schedule” on page 43.

Instrument filters and supported dyes

System dyes

The instrument uses a de-coupled six-color optical filter set that supports the dyes shown in the following table and figure. For more information about the spectral dye calibration kits available for the instrument, contact your HID Support Representative.

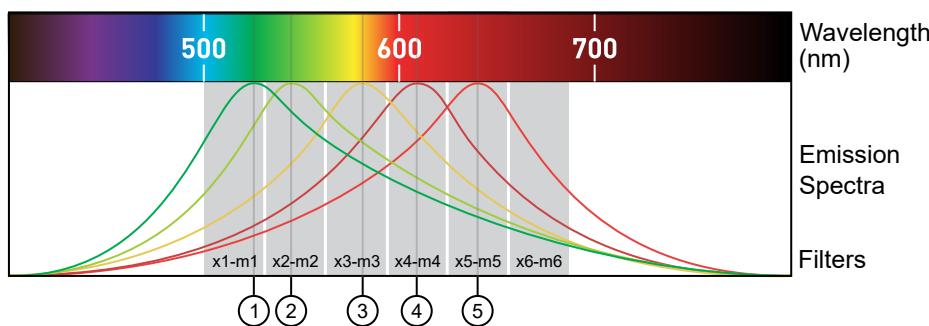
Peak filter	Color	Filter wavelength (nm) ^[1]		Factory-calibrated dyes	Example custom dyes
		Excitation	Emission		
x1-m1	Blue	470 ± 15 nm	520 ± 15 nm	FAM™ dye, SYBR™ Green dye	SYT09
x2-m2	Green	520 ± 10 nm	558 ± 12 nm	VIC™ dye	JOE™ dye, HEX™ dye, TET™ dye ^[2]
x3-m3	Yellow	550 ± 10 nm	587 ± 10 nm	NED™ dye, TAMRA™ dye, ABY™ dye ^[3]	Cy®3 dye
x4-m4	Orange	580 ± 10 nm	623 ± 14 nm	ROX™ dye, JUN™ dye ^[3]	Texas Red™ dye
x5-m5	Red	640 ± 10 nm	682 ± 14 nm	MUSTANG PURPLE™ dye, Cy™5	LIZ™ dye
x6-m6	Deep-Red	662 ± 10 nm	711 ± 12 nm	None ^[4]	Cy® 5.5 dye

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

^[2] The HEX™ and TET™ dyes 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] HID-validated workflows use versions of ABY™ and JUN™ dyes that are considered custom dyes.

^[4] This filter set currently does not support any dyes supplied by Thermo Fisher Scientific.



- ① x1-m1 — FAM™ dye, SYBR™ Green dye
- ② x2-m2 — VIC™ dye
- ③ x3-m3 — ABY™ dye, NED™ dye, Cy®3 dye, TAMRA™ dye
- ④ x4-m4 — JUN™ dye, ROX™ dye, Texas Red™ dye
- ⑤ x5-m5 — Cy™5 dye, MUSTANG PURPLE™ dye

Custom dyes

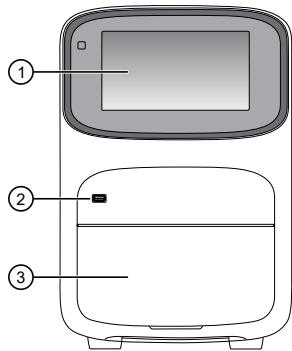
The instrument can run assays designed with custom dyes.

Custom dyes include:

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

Note: HID-validated workflows use versions of ABY™ and JUN™ dyes that are considered custom dyes for the instrument. To calibrate these ABY™ and JUN™ dyes, see page 51. To calibrate any other custom dye, contact your HID Support Representative.

Parts of the instrument

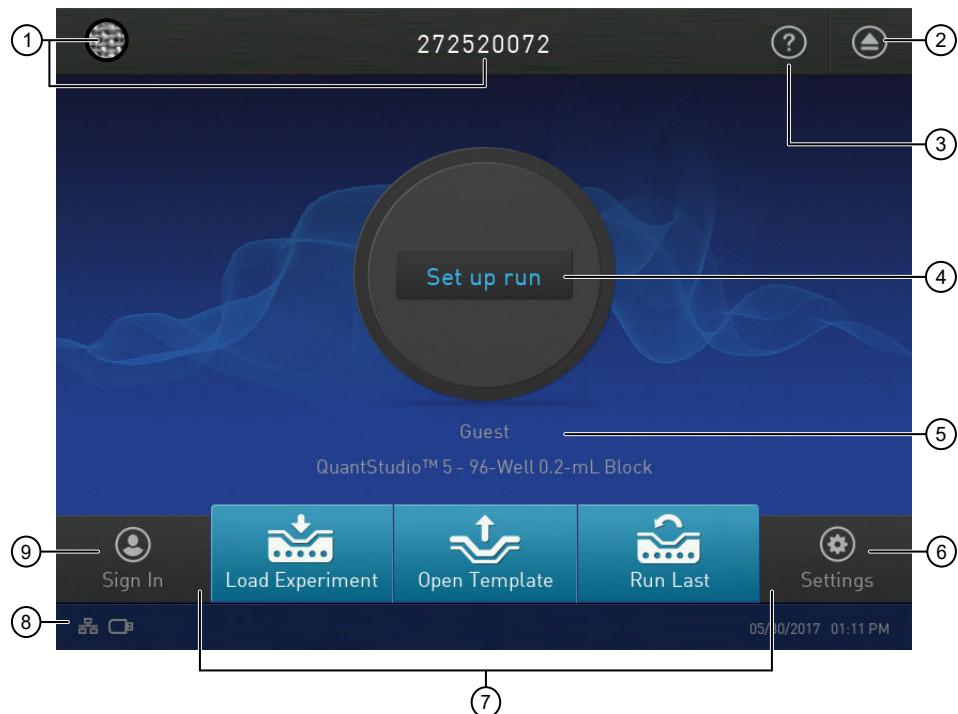


- ① **Touchscreen** – Controls the instrument.
- ② **USB port** – For connection to an external network drive or external data storage device.
- ③ **Instrument drawer** – Contains sample plate.

The instrument includes three additional USB ports on the back of the instrument.

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

Parts of the home screen



- ① Avatar and Instrument name
- ② Eject instrument drawer icon
- ③ Help system icon
- ④ Status dial
- ⑤ Instrument profile name; instrument block type
- ⑥ Settings button
- ⑦ Access templates buttons (not applicable for HID-validated workflows)
- ⑧ Connectivity icons
- ⑨ Sign In (or My Profile) button

Table 1 Parts of the home screen

Element of the home screen	Function
Avatar and Instrument name	Set by the administrator to uniquely identify the instrument.
Eject instrument drawer icon	Touch ② to open or close the instrument drawer.
Help icon	Touch ③ to launch the touchscreen Help system to access step-by-step instructions.
Status dial	<p>When the instrument is not in use – Displays Set up run.</p> <p>Note: Instrument runs must be set up and started from the desktop software.</p> <p>When the instrument is in use – Displays the sample block temperature, the elapsed run time, and the run status.</p> <p>Note: Swipe the dial to the left or touch ④ to access real-time views of the run.</p>
Instrument profile username and block type	<p>Displays the username of a signed-in user and the instrument block type.</p> <p>Note: If no user is signed in, the instrument defaults to the Guest profile.</p>

Table 1 Parts of the home screen (continued)

Element of the home screen	Function
Settings button	Touch  Settings to configure, calibrate, or learn about the instrument.
Connectivity icons	<ul style="list-style-type: none"> – The instrument is connected via a wired configuration. – A USB drive is plugged into the instrument.
Sign In button (My Profile button when a user is signed in)	<ul style="list-style-type: none">Touch  Sign In to sign into an instrument profile.Touch  My Profile to change instrument profile settings.

Comparison of features in desktop software and the instrument

To run experiments using HID assays, the instrument must be integrated with the HID Real-Time PCR Analysis Software.

Actions	Desktop software	Instrument
Enter or edit properties ^[1]		
Edit experiment name; enter user name	✓	—
Select instrument, experiment type, chemistry, run mode	✓	—
Edit method ^[1]		
Edit the thermal protocol, reaction volume, optical filter selection	✓	—
Set up plate and well details ^[1]		
Define samples	✓	—
Assign samples to wells	✓	—
Define targets	✓	—
Assign targets to wells	✓	—
Instrument run		
Start an instrument run ^[1]	✓	—
Monitor a run in progress	✓	✓
View time remaining	✓	✓
View real-time plots	—	✓
Run results		
Review run results (analyzed run data)	✓	—
Configure analysis settings	✓	—
Export		
Select export options for run data and run results (analyzed run data)	✓	—
Export run data	✓	✓
Export template settings	✓	—

^[1] Feature is available in the instrument touchscreen, but it is not validated for the HID assay workflow.



Install the instrument

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Workflow: Install the instrument

Perform all steps in “Before you begin installation” on page 14



“Unpack and install the instrument” on page 15



“Power on and follow the startup wizard” on page 15



“Perform instrument verification using RNase P plates” on page 55



“Calibrate dyes for HID-validated workflows” on page 51

Before you begin installation

A Thermo Fisher Scientific service representative will contact you to schedule an installation. However, you do have the option to install the instrument yourself.

Before starting the installation:

- Review the site requirements in the *QuantStudio™ 5 Real-Time PCR Instrument Site Preparation Guide (for Human Identification)* (Pub. No. MAN0016701).
- Review the HID-validated computer-to-instrument configuration (page 16).

Unpack and install the instrument

1. Prepare the installation site as described in the *QuantStudio™ 5 Real-Time PCR Instrument Site Preparation Guide (for Human Identification)* (Pub. No. MAN0016701).
2. Follow the pre-printed instructions on the instrument box to unpack the instrument, accessories, and reference documentation. Save the packing material for future use or recycle it.

The instrument box contains:

- Reference documentation: Welcome note, unpacking and set up instructions card, system documentation insert
- One instrument
- Accessories: power cable, Ethernet cable, USB drive, reaction tube retainer
- Shipping plate

Note: Save the shipping plate but do not use it to operate the instrument.

- Spectral calibration plates for HID-validated workflows.

Note: Store these plates at -20°C (-15°C to -25°C).

3. Place the instrument on the bench.
4. Plug the power cable into the power port on the back panel of the instrument, then plug the cable into an electrical receptacle.
5. Connect an Ethernet cable to the Ethernet port on the back panel of the instrument, then connect the cable to the computer.

Power on and follow the startup wizard

1. Power on the instrument.
2. Follow the startup wizard through the following tasks:
 - Select the language for the instrument.
 - Accept the license agreement.
 - Configure the instrument date and time.
 - Create an administrator instrument profile.

Note: You can perform any of the steps above at a later time if you do not have the information needed to complete the startup screens. See page 23.

IMPORTANT! Before using the instrument for the first time, we recommend that you perform instrument verification using RNase P plates (see “Perform instrument verification using RNase P plates” on page 55).

Instrument and computer connections

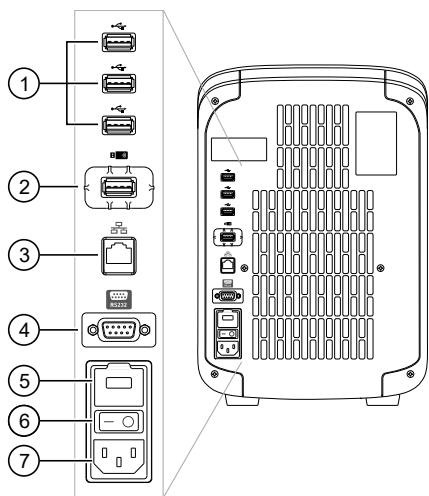


Figure 1 Instrument back panel

- | | |
|---|-----------------------------------|
| ① USB ports | ④ RS232 Port—For service use only |
| ② WiFi USB port—Not applicable | ⑤ Fuse Cover |
| ③ Ethernet Port—RJ45 port for 100/1,000 Mbps Ethernet communication with the instrument | ⑥ Power Switch |
| | ⑦ Power Port—100 to 240 VAC |

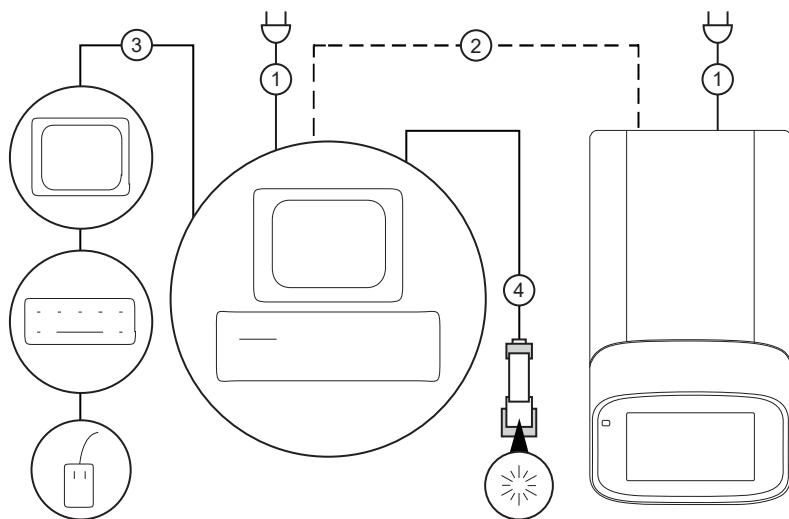


Figure 2 Instrument-to-computer connections (barcode scanner connected to the computer)

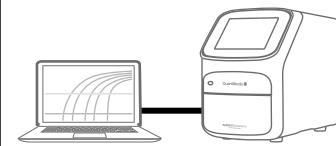
Minitower configuration

- 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.

Computer-to-instrument configuration

IMPORTANT! For HID use, the QuantStudio™ 5 Real-Time PCR System has been validated for a direct (computer-to-instrument) configuration. During installation, a Thermo Fisher Scientific service representative can set up only a direct configuration.

Direct configuration
<ul style="list-style-type: none">• A computer provided by Thermo Fisher Scientific with the HID Real-Time PCR Analysis Software• Computer-to-instrument connection:<ul style="list-style-type: none">– Direct, wired connection between the computer and the instrument using an Ethernet cable



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, 7000	QuantStudio™ 5 Real-Time PCR System (with 0.2-mL 96-Well Sample Block) with firmware v1.3.x Instrument-to-computer connection
mDNS, 7443	QuantStudio™ 5 Real-Time PCR System (with 0.2-mL 96-Well Sample Block) with firmware v1.5.1 Instrument-to-computer connection
mDNS, 5353	Instrument discovery

General procedures to operate the instrument

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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.



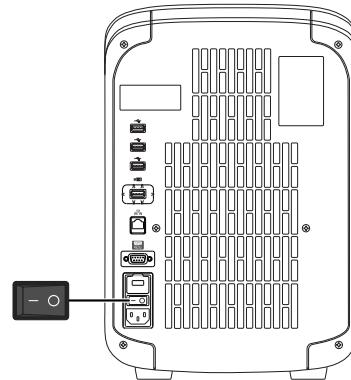
CAUTION! Use flat caps for tubes. Rounded caps can damage the heated cover.

Power on the instrument

1. Touch anywhere on the touchscreen to determine if the instrument is in sleep mode. If the home screen is displayed, the instrument is already powered on.
2. If the home screen does not display, power on the instrument by pressing the switch on the rear panel.

If left unattended, the instrument automatically enters sleep mode (enabled by default) to conserve power.

Note: To customize the sleep mode setting, touch  **Settings ▶ Instrument Settings ▶ Sleep Mode.**



Power off the instrument

The instrument operates in low-power mode when not in use. However, the instrument can be powered off completely so that the components use no power.

Note: To power off the instrument for >1 week, see page 65 .

1. Power off the instrument using the power switch on the back of the instrument.
2. Power off the computer.

Sign in

Create an instrument profile before signing into the instrument. See “Create a new instrument profile” on page 29.

Note: An instrument profile is a user account specifically for the instrument. It is not related to any other user account for the system or software.

1. In the home screen, touch  **Sign In**.
2. Touch **Sign In**, then select your username.
3. Enter your PIN, then touch **Enter**.

Note: To enable access to Thermo Fisher™ Connect, see “Link an instrument profile to the Thermo Fisher™ Connect Platform” on page 30.

Sign out

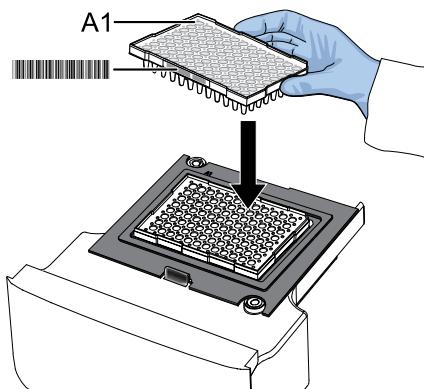
1. In the home screen, touch  **My Profile**.
2. Touch **Sign Out**.

Load and unload plate in the instrument



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

1. Load the plate.
 - a. Touch to eject the instrument drawer.
 - b. Load the plate onto the plate adapter so that:
 - Well A1 of the plate is in the top-left corner of the plate adapter.
 - The barcode faces the front of the instrument.



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

Note: Do not remove the black plate adapter before loading a plate or tube strips. If used, tube strips may fit loosely in the adapter, but the heated cover will apply the appropriate pressure to seat the tube strips securely in the adapter.

- c. Touch to close the instrument drawer.
2. When the run ends, unload the plate.
 - a. Touch to eject the instrument drawer.
 - b. Remove the plate.
 - c. Touch to close the instrument drawer.



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

Note: If the instrument does not eject the plate, contact Support.

View real-time data and plots on the instrument touchscreen

1. In the instrument home screen, during an instrument run, touch or swipe left twice.
2. Touch **Well details**.
3. Touch **Samples**, **Targets**, or **Tasks** to select a graphical representation of each selection.
4. Touch **Close** to return to the home screen.

Adjust the display of real-time plots on the instrument touchscreen

1. In the instrument home screen, during an instrument run, touch or swipe left twice to view real-time data and plots.
2. Touch **Zoom**.
3. Touch or to zoom in or out.
4. Touch the arrows to pan left, right, up, or down on the graph.
5. Touch **Close** to return to the default view.

Transfer EDS files from the instrument home screen

1. In the home screen, when a run ends, touch **Transfer File**.
2. Select the data destination for the EDS file.
3. Navigate to and select a folder.
4. Touch **OK**.
5. Touch **Transfer**.

Note: Touch **Settings** ▶ **Run History** to transfer EDS files at any time.



Configure the instrument and manage instrument profiles

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Initial start up

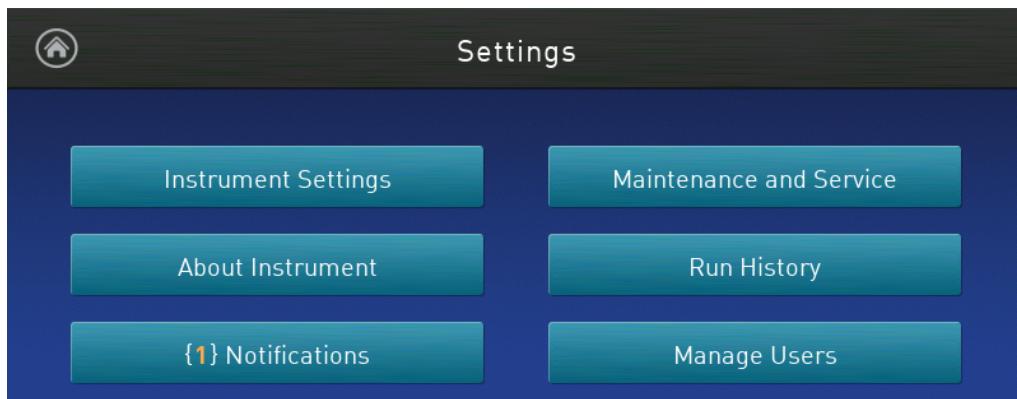
Perform initial start up tasks:

- After initially powering on the instrument (see page 19).
 - After restoring factory defaults (see “Restore factory defaults” on page 40).
1. Ensure that there is a direct, wired connection between the computer and the instrument using an Ethernet cable (see page 17).
 2. Create an administrator instrument profile (see page 28).
 3. (Optional) Manage the instrument name (see page 39).
 4. Set the date and time (see page 39).

Overview of instrument settings (*Administrator*)

Touch  **Settings** in the home screen to configure the instrument settings as needed.

Access to most settings are restricted to administrator instrument profiles.



Options	Description
Instrument Settings	
Instrument Name	Enter a unique instrument name, and (<i>optional</i>) set an instrument avatar.
Sleep Mode	Enable the instrument to enter a sleep mode after a set length of inactivity.
Heated Cover Temperature	Set the idling temperature for the heated cover (before it enters sleep mode).
Date/Time	Set time zone and date and time formats.
Restore Factory Defaults	<p>Restore the instrument to the factory settings.</p> <p>IMPORTANT! Back up the instrument before restoring factory defaults (see “Backup or restore the instrument” on page 60).</p> <p>When you restore an instrument to its factory defaults:</p> <ul style="list-style-type: none"> • The following items are deleted: <ul style="list-style-type: none"> • All instrument profiles • All files stored on the instrument, including all EDS files • All custom dye calibrations, including calibrations for ABY™ and JUN™ dyes • RNase P verification • The following items are <i>not</i> deleted: <ul style="list-style-type: none"> • The most recent valid ROI/uniformity and background calibrations • The most recent system dye calibrations

Options	Description
About Instrument	
About Instrument [1]	Displays the Model Name , IP Address , Serial Number , and Firmware Version .
License Agreement [1]	Displays the End User Software License Agreement and the Limited Product Warranty. You can export the License Agreement to a USB drive.
Notifications [1]	
—	<p>Enable home screen notifications of instrument errors. The number of new, unviewed notifications displays over Settings in the home screen.</p>
Maintenance and Service	
Monitoring	<p>Enable the Remote Monitoring Service to automatically notify Thermo Fisher Scientific support teams in real time of potential instrument issues.</p> <p>The service monitors and sends general <i>instrument</i> data, but the service does not monitor or send <i>customer</i> data.</p>
Instrument Statistics [1]	Displays instrument usage information, including Disk Space Remaining , LED Life , and RNase P Status .
Calibrations	<ul style="list-style-type: none"> • Perform calibrations. <ul style="list-style-type: none"> – ROI and Uniformity – Dye – Custom (including calibrations for background and ABY™ and JUN™ dyes) • View calibration history and set calibration reminders in History and Reminders.
RNase P Verification [1]	Perform instrument performance verification using an RNase P plate.
Self Verification Test [1]	Check the instrument hardware functions.
Log [1]	View and export the Instrument Run Log .
Backup / Restore	<ul style="list-style-type: none"> • Backup the instrument [1] • Restore an instrument backup
Ship Prep Mode [1]	Place the instrument in a safe state for moving or long-term storage.
Run History [1]	
—	<p>Displays the instrument runs and whether the EDS file for the run was transferred.</p> <p>Touch a run to view its details or to transfer or delete (Administrator only) its EDS file.</p>

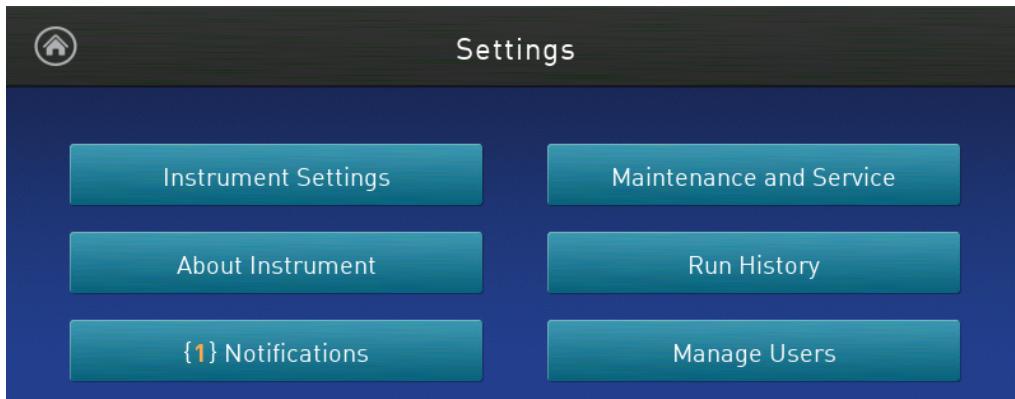
Options	Description
Manage Users	
Sign In Required	Enable only signed-in users to access the instrument for any task, including accessing Settings . Enabling this feature disables the guest profile access to the instrument. Note: Instrument runs must be started from the desktop software, and actions during an instrument run are automatically logged to the guest instrument profile (even if a user was signed into the instrument).
Sign Out Timer	Set the time length of inactivity before a user is automatically signed out.
Manage Profiles	Access the profile information for the instrument.

[1] Also available to standard and guest instrument profiles.

Overview of instrument settings (*Standard or Guest*)

Touch  **Settings** in the home screen to configure the instrument settings as needed.

Access to most settings are restricted to administrator instrument profiles.



Options	Description
About Instrument	
About Instrument	Displays the Model Name, IP Address, Serial Number, and Firmware Version.
License Agreement	Displays the End User Software License Agreement and the Limited Product Warranty. You can export the License Agreement to a USB drive.
Notifications	
—	Enable home screen notifications of instrument errors. The number of new, unviewed notifications displays over Settings in the home screen.
Maintenance and Service	
Instrument Statistics	Displays instrument usage information, including Disk Space Remaining, LED Life, and RNase P Status.
RNase P Verification	Perform instrument performance verification using an RNase P plate.
Self Verification Test	Check the instrument hardware functions.
Log	View and export the Instrument Run Log.
Backup / Restore	Backup the instrument
Ship Prep Mode	Place the instrument in a safe state for moving or long-term storage.
Run History	
—	Displays the instrument runs and whether the EDS file for the run was transferred. Touch a run to view its details and to transfer its EDS file.

Manage instrument profiles

Note: An instrument profile is a user account specifically for the instrument. It is not related to any other user account for the system or software.

To	See
Create a profile	<ul style="list-style-type: none"> “Create an administrator instrument profile during initial start-up” on page 28 “Create a new instrument profile” on page 29
Configure a profile	<ul style="list-style-type: none"> “Edit an instrument profile” on page 29
View or manage all profiles	<ul style="list-style-type: none"> “Manage all instrument profiles” on page 29

Instrument profiles and signed-in users

An instrument profile is a user account specifically for the instrument. It is not related to any other user account for the system or software.

Instrument profile type	Allowed actions
Administrator	All maintenance and administrative tasks, including instrument configuration
Standard	View instrument status, transfer files, and many maintenance tasks (such as RNase P Verification and Self Verification Test)
Guest	View instrument status, transfer files, and many maintenance tasks (such as RNase P Verification and Self Verification Test) Note: All instrument runs and actions during a run are logged to the guest profile (even if a user was signed-in to the instrument when the run was started).

Instrument runs must be started from the desktop software. The instrument will automatically sign-off a signed-in user when an instrument run begins.

Note: To disable guest profile access:  **Settings** ▶ **Manage Users** ▶ **Sign In Required** set to on.

Create an administrator instrument profile during initial start-up

During initial start-up, the user is automatically prompted to create an administrator instrument profile. See “Initial start up”.

- The first instrument profile that is created during installation is given administrator privileges.
- Administrators can grant administrative privileges to other users. See “Manage all instrument profiles” on page 29.

1. Touch **Name**, enter a username, then touch **Done**.
2. Touch **PIN**, enter a four-digit numerical password, then touch **Enter**.

Note: Touch the **Show PIN** checkbox to switch PIN display on or off.

3. Touch **Confirm PIN**, then repeat step 2.
4. Touch **Create profile**.

Create a new instrument profile

1. In the home screen, touch  **Sign In**, then touch **Get Started**.
 2. Touch **Name**, enter a username, then touch **Done**.
 3. Touch **PIN Code**, enter a four-digit numerical password, then touch **Enter**.
-
- Note:** Touch the **Show PIN** checkbox to switch PIN display on or off.
-
4. Touch **Confirm PIN**, then repeat step 2.
 5. Touch **Create profile**.
 6. Sign in to the profile you just created.

Note: To enable access to the Connect Platform, see “Link an instrument profile to the Thermo Fisher™ Connect Platform” on page 30 and “If you link when you are signed in to the instrument” on page 36.

Edit an instrument profile

1. In the home screen, touch  **My Profile**.
-
- Note:** Administrators can also navigate to this screen by touching  **Settings** ▶ **Manage Users** ▶ **Manage Profiles**.
-
2. Touch **Edit**.
 3. Select the fields to edit, then make changes.
 4. Touch **Done**.

Manage all instrument profiles

1. In the home screen, access the **All Profiles** tab.
 - Touch  **My Profile** ▶ **All Profiles**.
 - Touch  **Settings** ▶ **Manage Users** ▶ **Manage Profiles** ▶ **All Profiles**.

A list of users, the date the profile was created, and the user type displays.

2. Select the instrument profile to edit.
3. Edit the profile.
 - To delete the profile, touch **Delete profile** ▶ **Delete**.
 - To reset the PIN, touch **Reset PIN** ▶ **Reset**.

Note:

- The user will be directed to enter a new PIN at the next sign in.
- The PIN can be reset on the instrument for a local instrument profile. It cannot be reset on the instrument for a Thermo Fisher™ Connect Platform profile. The PIN for a Connect Platform profile is reset on the Connect Platform.
- To enable or disable administrative privileges, slide the control to **Administrator** or **Standard**, respectively.

4. Touch **Done**.

Link an instrument profile to the Thermo Fisher™ Connect Platform

Linking your instrument profile to the Thermo Fisher™ Connect Platform (cloud-based) allows you to access the following functions:

- View an instrument status from the cloud.
- Download templates from your cloud storage to the instrument.
- Transfer run data from the instrument to your cloud storage.

To link an instrument profile to the Connect Platform, see the following sections:

- “Recommended order to set up profiles” on page 31
- “Overview of local instrument profiles and Thermo Fisher™ Connect Platform profiles” on page 31
- “Thermo Fisher™ Connect Platform instrument profile roles and functions” on page 32
- “Link a local profile to a Thermo Fisher™ Connect Platform profile” on page 34
- “Unlink a Thermo Fisher™ Connect Platform account” on page 36
- “If you link when you are signed in to the instrument” on page 36
- “If you link when you are not signed in to the instrument” on page 37
- “Change the PIN for a Thermo Fisher™ Connect Platform profile” on page 38

Recommended order to set up profiles

Task	Description
Create a profile for the instrument administrator.	The first profile on the instrument becomes the instrument administrator. See “Create an administrator instrument profile during initial start-up” on page 28.
Select a Thermo Fisher™ Connect Platform administrator.	A Thermo Fisher™ Connect Platform administrator is distinct from an instrument administrator. The first Connect Platform profile to be linked to the instrument is automatically assigned the role of a Connect Platform administrator. It is recommended that the first Connect Platform profile to be linked is the one that should be a Connect Platform administrator. The roles can be updated at a later time on the Connect Platform.
Each person creates a profile.	Create a local instrument profile. Connect Platform-enabled features are not available. <i>(Optional)</i> Link a local instrument profile to a Connect Platform profile.
Assign additional instrument administrators.	Any of the profiles can be assigned the role of instrument administrator.

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

- Local instrument profile
 - Experiment template files and data files are stored on the instrument.
 - Experiment template files and data files can be transferred to the desktop software.
 - Email notifications are not available.
 - Cannot view the instrument status from the Thermo Fisher™ Connect Platform.
 - Separate profiles are required for each instrument if multiple instruments are used.
- Thermo Fisher™ Connect Platform profile
 - Experiment template files and data files are stored on the instrument.
 - Experiment template files and data files can be transferred to the Connect Platform or the desktop software.
 - Email notifications are available.
 - View the instrument status from the Connect Platform.
 - The same profile can be used for multiple instruments.

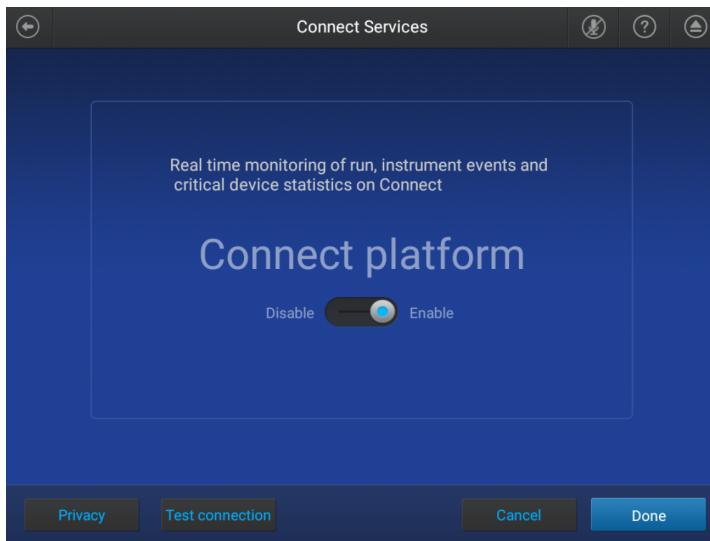
Thermo Fisher™ Connect Platform instrument profile roles and functions

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

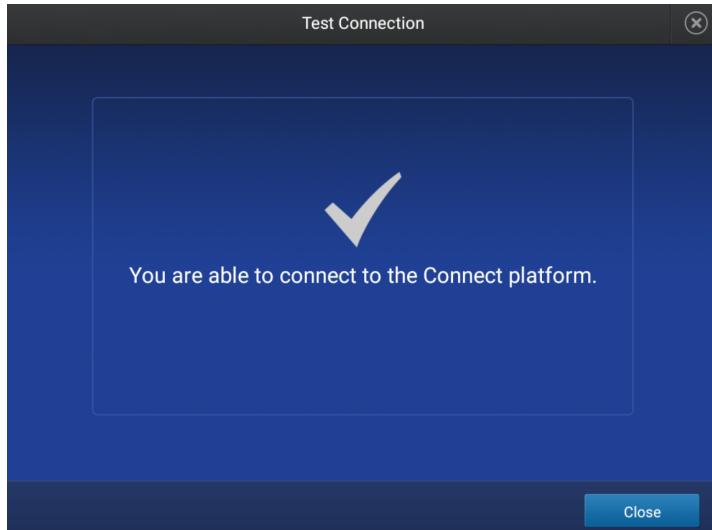
Instrument profile	Location	Functions allowed
Standard	Connect Platform	<ul style="list-style-type: none"> • Create, save, open, import, and run template files • Create and modify run settings • View and export data files
Administrator	Connect Platform	<p>All the permissions of a local administrator profile, plus the following functions performed in the Connect Platform:</p> <ul style="list-style-type: none"> • See a list of all the Connect Platform profiles that are linked to the instrument • Assign Connect Platform administrator roles to one or more users • Remove a user from an instrument • Disconnect the instrument from the Connect Platform • Change the instrument name

Test the connection to the Thermo Fisher™ Connect Platform

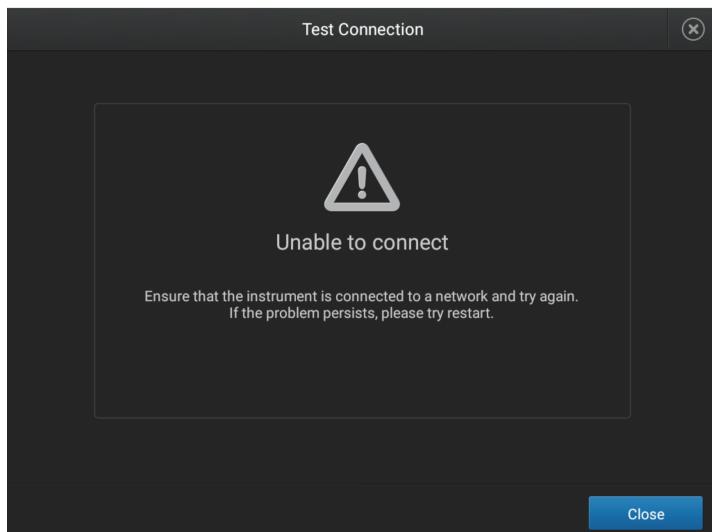
1. In the home screen, tap  **(Settings)** ▶ **Maintenance and service** ▶ **Connect services**.
 The **Connect Services** screen is displayed.



2. Tap **Test connection**.
 If the connection can be established, **You are able to connect to the Connect platform** will be displayed.



If the connection cannot be established, **Unable to connect** will be 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 that you use your 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 Connect Platform account. It will apply to all other instruments when you use your Connect Platform account. This does not change the password when signing in to your Connect Platform account on a browser.

After the PIN is set up on the instrument, it must be changed with your Connect Platform account on a browser, see “Create an administrator instrument profile during initial start-up” on page 28.

The first time the instrument is used with a Connect Platform account, a region must be selected.

1. In the **Sign In** screen, tap **Get started ▶ Create a local instrument file ▶ Connect to your Thermo Fisher™ Connect Platform account**.
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	<p>Note: Before selecting this option, install and sign in to the Connect Platform application on your mobile device.</p> <p>On the instrument:</p> <ol style="list-style-type: none"> 1. Tap  Mobile devices. 2. Hold the camera on your mobile device over the QR code that is displayed on the touchscreen. 3. Tap Close.
 PC	<p>A link code is displayed on the instrument.</p> <p>On a computer:</p> <ol style="list-style-type: none"> 1. Access the Connect Platform. 2. Click Add instrument. 3. Select QuantStudio. 4. 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**.

Link a local profile to a Thermo Fisher™ Connect Platform profile

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

The first time that you use your 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 Connect Platform account. It will apply to all other instruments when you use your Connect Platform account. This does not change the password when signing in to your Connect Platform account on a browser.

After the PIN is set up on the instrument, it must be changed with your Connect Platform account on a browser, see “Change the PIN for a Thermo Fisher™ Connect Platform profile” on page 38.

The first time the instrument is used with a 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 36.

(Optional) Test the connection, see “Test the connection to the Thermo Fisher™ Connect Platform” on page 32.

1. In the home screen, tap  (**Profile**).

The **My Profile** screen is displayed.

2. Tap **Connect ▶ Link Account**.

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	<p>Note: Before selecting this option, install and sign in to the Connect Platform application on your mobile device.</p> <p>On the instrument:</p> <ol style="list-style-type: none">1. Tap  Mobile devices.2. Hold the camera on your mobile device over the QR code that is displayed on the touchscreen.3. Tap Close.
 PC	A link code is displayed on the instrument. <p>On a computer:</p> <ol style="list-style-type: none">1. Access the Connect Platform.2. Click Add instrument.3. Select QuantStudio.4. 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 Connect Platform application on your computer.

For more information about unlinking a Connect Platform account, see “If you link when you are signed in to the instrument” on page 36.

1. Sign in to your account on the desktop Connect Platform application.
2. In the left pane, click  **(Instrument)**.
3. Select the instrument, then click  **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 instrument profile name.

Phase	Steps that occur
Before you link:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • You link your local instrument profile (see “Link a local profile to a Thermo Fisher™ Connect Platform profile” on page 34). • If this is the first time you link, a 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 Connect Platform account username is <i>User G.</i> • Your local instrument profile (<i>UserABC</i>) is linked to your Connect Platform account (<i>User1@thermofisher.com</i>). • Your Connect Platform instrument profile (<i>User G.</i>) replaces your local instrument profile.
After you link:	<ul style="list-style-type: none"> • Your Connect Platform instrument profile (<i>User G.</i>) and  is displayed in the home screen of the instrument. • Plate files and data files from your local instrument profile can be transferred to the Connect Platform. • New plate files and data files are saved under your Connect Platform instrument profile.

(continued)

Phase	Steps that occur
If your Connect Platform account is unlinked:	<ul style="list-style-type: none"> Your local instrument profile (<i>UserABC</i>) is displayed in the home screen of the instrument. Plate files and data files that were saved locally to the instrument under your Connect Platform instrument profile are accessible under your local instrument profile. Plate files and data files that were saved to DataConnect on the Connect Platform are not accessible from the instrument under your local instrument profile. Plate files and data files are saved under local instrument profile and can be copied to the Connect Platform (see “Transfer EDS files from the instrument home screen” on page 22). 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 profile. Plates and results are accessible when you sign in with either profile.

If you link to the Connect Platform when you are *not* signed in to the instrument:

Phase	Steps that occur
Before you link:	<ul style="list-style-type: none"> In the Sign In screen, you tap Get Started ▶ Connect.
When you link:	<ul style="list-style-type: none"> You link your profile (see “Link the instrument to your Thermo Fisher™ Connect Platform account” on page 33). If this is the first time you link, a 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 Connect Platform account username is <i>User G</i>. Your local instrument profile (<i>User G.</i>) is linked to your Connect Platform account (<i>User1@thermofisher.com</i>). Your Connect Platform instrument profile (<i>User G.</i>) replaces your local instrument profile.
After you link:	<ul style="list-style-type: none"> Your Connect Platform instrument profile (<i>User G.</i>) and is displayed in the home screen of the instrument. Plate files and data files from your local instrument profile can be transferred to the Connect Platform. New plate files and data files are saved under your Connect Platform instrument profile. Your Connect Platform instrument profile name (<i>User G.</i>) is available for selection in the Sign In screen.

(continued)

Phase	Steps that occur
If your Connect Platform account is unlinked:	<ul style="list-style-type: none"> Your local instrument profile (<i>User G.</i>) is displayed in the home screen of the instrument. Plate files and data files that were saved under your 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 Connect Platform. Your local instrument profile name (<i>User G.</i>) is available for selection in the Sign In screen.

IMPORTANT! If you sign in with a local profile, without linking to the Connect Platform, sign out, then link to the 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.

Change the PIN for a Thermo Fisher™ Connect Platform profile

This section describes changing a PIN for a Thermo Fisher™ Connect Platform profile. To change a PIN for a local instrument profile, see “Manage all instrument profiles” on page 29.

1. Sign in to the 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 Connect Platform profile is updated. This change applies to all of the instruments that you access with your Connect Platform profile.

Require instrument profile sign-in

1. In the home screen, touch  **Settings** ▶ **Manage Users** ▶ **Sign In Required**.
2. Slide the control **On**.
Only signed-in users are allowed to access the instrument for any task, including access to **Settings**.
3. Touch **Done**.

Manage the Sign Out Timer

1. In the home screen, touch **Settings** ▶ **Manage Users** ▶ **Sign Out Timer**.
2. Touch the **Edit Time** field, then enter the desired duration of inactivity before automatic user sign out.
3. Touch **Enter**, then touch **Done**.

Manage the instrument name

1. In the home screen, touch **Settings** ▶ **Instrument Settings** ▶ **Instrument Name**.
2. Touch the **Instrument Name** field, enter an instrument name, then touch **Done**.
3. Touch **OK**.

Enable Sleep Mode

1. In the home screen, touch **Settings** ▶ **Instrument Settings** ▶ **Sleep Mode**.
2. Slide the control **On** to enable sleep mode.
3. Touch **Edit Time**, then enter the time length of inactivity before the instrument enters sleep mode.
4. Touch **Enter**, then touch **OK**.

Set the idling temperature for the heated cover

1. In the home screen, touch **Settings** ▶ **Instrument Settings** ▶ **Heated Cover Idle Temperature**.
2. Slide the control **On** to set the idling temperature for the heated cover.
3. Touch the **Edit Temperature** field, then enter the desired idling temperature.
4. Touch **Enter**, then touch **OK**.

Set the date and time

1. In the home screen, touch **Settings** ▶ **Instrument Settings** ▶ **Date/Time**.
2. Select a time zone from the dropdown list.
3. Select a date format.
 - a. Touch **Date Format**, then select the preferred date format.

- b. Touch **Next**, touch the date field, then enter the date.
 - c. Touch **Enter**, then touch **Done**.
4. Select a time format.
 - a. Touch **Time Format**.
 - b. Slide the control to select a 12-hour or 24-hour clock.
 - c. Touch **Next**, touch the time field, then enter the time.
 - d. Touch **Enter**, then touch **Done**.
5. Touch **Done**.

Restore factory defaults

This procedure can only be performed by an Administrator.

IMPORTANT! Back up the instrument before restoring factory defaults (see “Backup or restore the instrument” on page 60).

1. In the home screen, touch  **Settings** ▶ **Instrument Settings** ▶ **Restore Factory Defaults**.
2. Touch **Restore Factory Defaults**.
3. Power **Off**, then power **On** the instrument to apply the change.
 - Instrument profiles and files stored on the instrument are deleted, including all EDS files, RNase P verification, and any custom dye calibrations.
 - The most recent valid ROI/Uniformity, Background, and system dye calibrations are not deleted.

After restoring factory defaults, perform initial start-up tasks. See “Initial start up”.

Enable Remote Monitoring Service

Note: Enabling the **Remote Monitoring Service** allows the instrument to automatically notify Thermo Fisher Scientific support teams in real time of potential instrument issues. The service monitors and sends general *instrument* data, but the service does not monitor or send *customer* data.

1. In the home screen, touch  **Settings** ▶ **Maintenance and Service** ▶ **Monitoring**.
2. Slide the control **On** to enable the **Remote Monitoring Service**.
3. Touch **OK**.

Update instrument software

IMPORTANT! Update the instrument software only under the specific guidance of your HID Support Representative.

In the home screen:

1. Touch  **Settings** ▶ **Maintenance and Service** ▶ **Software Update**.
2. Touch the location of the update files.
3. When prompted, confirm your request to update the software.

Calibrate and verify instrument performance

■ Calibration and verification schedule	43
■ Calibration descriptions	44
■ View calibration status and set reminders in the instrument	45
■ Perform ROI/uniformity, background, and dye calibrations	45
■ Calibrate dyes for HID-validated workflows	51
■ Perform instrument verification using RNase P plates	55

Calibration and verification schedule

The instrument is factory-calibrated and does not require calibration at installation. To ensure optimal performance, perform calibrations at the recommended frequency.

Note: During instrument installation, the Thermo Fisher Scientific service representative will perform the initial instrument verification using an RNase P plate and calibrate the instrument for the versions of ABY™ and JUN™ dyes used by HID-validated workflows.

IMPORTANT! Perform calibrations and instrument runs under the environmental conditions that are specified in “Environmental requirements” on page 77. Exposure to extreme temperatures can adversely affect the instrument performance and shorten the life span of the instrument components.

To set the calibration frequency for the instrument, touch **Settings** ▶ **Maintenance and Service** ▶ **Calibrations** ▶ **History and Reminders** ▶ **Edit** ▶ **Exp interval** field.

Calibration	Recommended frequency
ROI/Uniformity	<ul style="list-style-type: none">Every two years (recommended)Always perform new Background and Dye calibrations after an ROI/Uniformity calibration. <p>Note: Performing an ROI/Uniformity calibration invalidates all other calibrations.</p>
Background	<ul style="list-style-type: none">Every two years (recommended)Background calibration can also be performed, as needed:<ul style="list-style-type: none">To check for contamination (depends on usage and laboratory conditions).To obtain the most accurate data for the removal of background fluorescence. <p>Note: Performing a Background calibration does <i>not</i> invalidate any other calibration.</p>
Dye	<ul style="list-style-type: none">Every two years (recommended)During a Dye calibration, only the dyes on the given spectral calibration plate are calibrated. <p>Note: Performing a Dye calibration for a given dye plate does <i>not</i> invalidate any other calibration.</p>
RNase P instrument verification	<ul style="list-style-type: none">After performing instrument calibrations (recommended)As needed to confirm instrument performance

Note: To prepare custom dye plates and to perform custom calibrations, see “Calibrate dyes for HID-validated workflows” on page 51.

Calibration descriptions

Calibration description and purpose	Pass Criteria
ROI/Uniformity <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 software uses calibration data to remove background fluorescence during a run. <p>Note: You can also run this calibration to determine if contamination is related to the sample block or the plate.</p>	The plate images for all filters are free of abnormal fluorescence.
Dye <ul style="list-style-type: none"> The software extracts a spectral profile for each dye standard, then produces a set of spectral profiles plotted as fluorescence vs filter. The software uses calibration data to characterize and distinguish the individual contribution of each dye in the total fluorescence signals collected by the instrument. 	Dye spectra peak within the same filter as their group.

View calibration status and set reminders in the instrument

1. In the home screen, touch  **Settings** ▶ **Maintenance and Service** ▶ **Calibrations** ▶ **History and Reminders**.
2. In the **Calibration Reminders** screen, view the status of each calibration type.
3. *(Optional)* Touch a calibration row to view the history of that specific calibration type, then touch **Done**.
4. Touch **Edit** to set the calibration reminder settings. For each calibration type:
 - a. Slide the control **On** to enable the calibration reminder.
 - b. Edit the **Exp interval** and **Remind me** fields.
 - c. Touch **Save**.
5. *(Optional)* To transfer the calibration report, touch **Export** then follow the directions on the screen.
6. Touch **Done**.

Perform ROI/uniformity, background, and dye calibrations

Workflow: Calibration

Note: The ROI and uniformity calibrations use the same calibration plate.

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 dye calibrations for ABY™ and JUN™ dyes (page 51)

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

Prepare a calibration plate

Materials required for calibration plate preparation

- Plate(s) for the calibration that you are performing:
 - ROI plate (the same plate is used for ROI and uniformity calibrations)
 - Background calibration plate
 - Dye calibration plates

Note: We recommend calibrating with all Spectral Dye Calibrations Plates even if you are not using all the dyes in the plates.

Note: Do not discard the packaging for the calibration plates. Each calibration plate can be used up to 3 times if the following conditions are met:

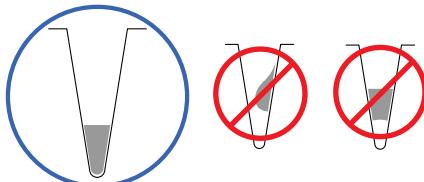
- The plate is stored in its packing sleeve at –15 to –25°C.
 - The plate is used within 6 months after opening.
 - The plate is used before the plate expiry date
-
- Centrifuge with plate adapter; buckets cleaned before use
 - Powder-free gloves
 - Safety glasses

Thaw, vortex, and centrifuge a calibration plate

1. Remove the calibration plate from the freezer, then thaw the plate in its packaging. Keep plates protected from light until you perform the calibration.
 - Thaw each plate for 30 minutes.
 - Use each plate within 2 hours of thawing.

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

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

1. In the instrument home screen:

Calibration	Touch
ROI/Uniformity ^[1]	✳ Settings ▶ Maintenance and Service ▶ Calibrations ▶ ROI and Uniformity
Background ^[2]	✳ Settings ▶ Maintenance and Service ▶ Calibrations ▶ Custom ▶ Background
Dye	✳ Settings ▶ Maintenance and Service ▶ Calibrations ▶ Dye

^[1] Automatically followed by Background calibration.

^[2] Initiate via this route if performing Background calibration only.

2. Follow the instructions on the screen to start the calibration.

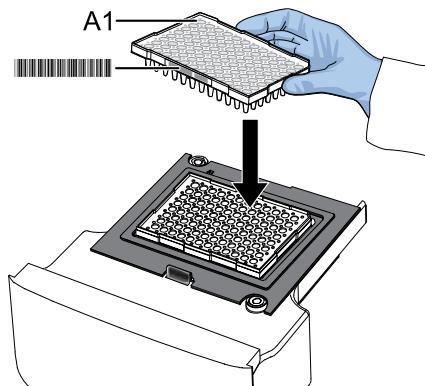
Note: *Dye calibration only:* Select the **Dye Plate** to run, then touch **Next**.

3. Load the plate.

- a. Touch ✳ to eject the instrument drawer.

- b. Load the plate onto the plate adapter so that:

- Well A1 of the plate is in the top-left corner of the plate adapter.
- The barcode faces the front of the instrument.



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

Note: Do not remove the black plate adapter before loading a plate or tube strips. If used, tube strips may fit loosely in the adapter, but the heated cover will apply the appropriate pressure to seat the tube strips securely in the adapter.

- c. Touch ✳ to close the instrument drawer.

4. Touch **Start**.

5. When the run is complete and the screen displays **Calibration Complete**, touch **View Results** to check the calibration status.

Calibration status	Action
Passed	Touch Next to proceed to the next required calibration.
Failed	See “Troubleshoot calibration failure” on page 68.

Note: You can view the calibration images only after the ROI/Uniformity and Background calibrations pass.

6. When the run ends, unload the plate.
 - a. Touch  to eject the instrument drawer.
 - b. Remove the plate.
 - c. Touch  to close the instrument drawer.



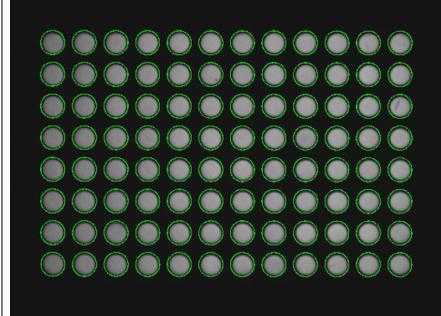
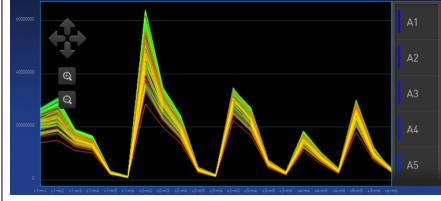
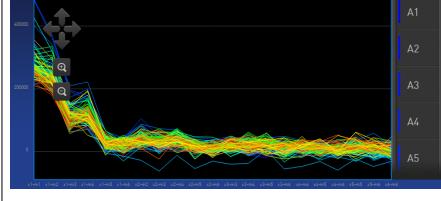
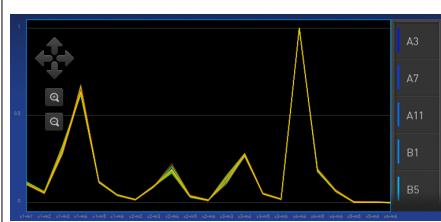
CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the plate temperature can reach 100°C. Allow it to cool to room temperature before handling.

Note: If the instrument does not eject the plate, contact Support.

View calibration images and transfer results to USB

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 **Calibration Status** screen, touch **Details**.
2. In the **Details** screen, touch a calibration type to view its images and plots.

Calibration	Example results indicating successful calibration
ROI	<p>Note: Select the desired filter combination from the Filter Set dropdown list.</p> 
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 peaks at the correct filter. 

3. In the **Calibration Status** screen, touch **Accept Results** or **Reject Results**.
Accepting the results saves the calibration data to the instrument and overwrites existing data.
4. (Optional) Touch **Transfer EDS** to transfer the calibration data to a USB.

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.
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 61).
Reversed	The plate is contaminated. Discard the plate, then perform the calibration using a new calibration plate.

4. If the calibration fails after you decontaminate the sample block and replace the plate, contact Support.

Create a background plate (optional)

Whenever possible, use a background plate listed in Appendix B, “Parts and materials”. 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
- 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.
The recommended volume for a 96-well plate is 10–20 µL.
3. Seal the plate using an optical adhesive cover or optical flat caps.
4. Use the plate for background calibration.

Calibrate dyes for HID-validated workflows

HID-validated workflows use versions of ABY™ and JUN™ dyes that are considered custom dyes for the instrument. These dyes require custom dye calibration.

To calibrate any other custom dye, contact your HID Support Representative.

IMPORTANT! To perform a custom dye calibration for HID-validated workflows, use the following prepared spectral calibration plates:

- ABY™ Spectral Calibration Plate, 96-Well 0.2-mL (Cat. No. 4461591)
 - JUN™ Spectral Calibration Plate, 96-Well 0.2-mL (Cat. No. 4461593)
-

Workflow: Calibrate dyes for HID-validated workflows

Prepare a calibration plate (page 51)



Add the custom dye to the instrument (page 52)



Perform a custom dye calibration (page 53)

Prepare a calibration plate for HID-validated workflows

Materials required for calibration plate preparation

- Plate(s) for the calibration that you are performing:
 - ABY™ Spectral Calibration Plate, 96-Well 0.2-mL (Cat. No. 4461591)
 - JUN™ Spectral Calibration Plate, 96-Well 0.2-mL (Cat. No. 4461593)
-

Note: Do not discard the packaging for the calibration plates. Each calibration plate can be used up to 3 times if the following conditions are met:

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

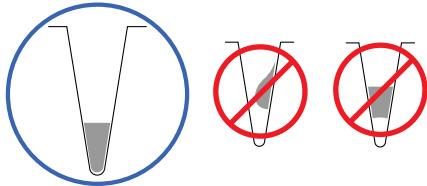
-
- Centrifuge with plate adapter; buckets cleaned before use
 - Powder-free gloves
 - Safety glasses

Thaw, vortex, and centrifuge a calibration plate

1. Remove the calibration plate from the freezer, then thaw the plate in its packaging. Keep plates protected from light until you perform the calibration.
 - Thaw each plate for 30 minutes.
 - Use each plate within 2 hours of thawing.

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

2. While wearing powder-free gloves, remove the calibration plate from its packaging and retain the packaging. Do not remove the optical film.
3. Vortex the plate for 5 seconds, then centrifuge at 750–1,000 × 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.

Add custom dyes to the instrument for HID-validated workflows

1. In the instrument home screen, touch **Settings** ▶ **Maintenance and Service** ▶ **Calibrations** ▶ **Custom** ▶ **Custom Dye**.
2. Touch **Add Custom Dye**.
3. Enter the dye information:

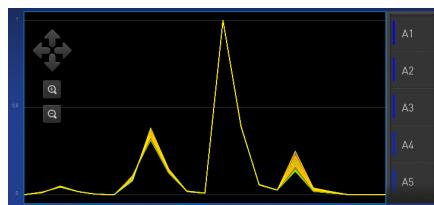
Field/option	Action
Custom Dye Name	Enter the names for the custom dyes: <ul style="list-style-type: none">• ABY-HID• JUN-HID <p>IMPORTANT! Dye names are spacing sensitive.</p>
Type	Select: <ul style="list-style-type: none">• ABY-HID—Reporter• JUN-HID—Reporter

4. Touch **Save**.

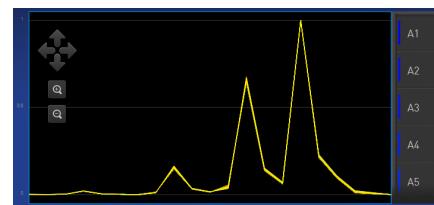
Perform a custom dye calibration for HID-validated workflows

1. Load the plate into the instrument.
2. In the instrument home screen, touch **Settings** ▶ **Maintenance and Service** ▶ **Calibrations** ▶ **Custom** ▶ **Custom Dye**.
3. Touch the custom dye to calibrate.
4. Review the custom dye information, (*optional*) make changes, then touch **Update**.
5. Enter the calibration temperature.
6. (*Optional*) Touch **Reagents**, then enter reagent information.
7. Touch **Start**.
8. When the run is complete and the screen displays **Calibration Complete**, touch **View Results** ▶ **Details**.
9. Review the plot. Passing calibration results show uniform signals with peaks that are aligned with the dye wavelength.

Dye	Peak filter	Filter wavelength (nm)	
		Excitation	Emission
ABY-HID	x3-m3	550 ± 10	587 ± 10
JUN-HID	x4-m4	580 ± 10	623 ± 14



ABY-HID dye calibration plot



JUN-HID dye calibration plot

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

Calibration status	Action
Passed	<ul style="list-style-type: none">Touch Accept Results or Reject Results. <p>Note: Accepting the results saves the calibration data to the instrument and overwrites existing data.</p> <ul style="list-style-type: none">(<i>Optional</i>) Touch Transfer EDS to transfer the calibration data to a USB.
Failed	<ul style="list-style-type: none">Perform the calibration again using a new custom dye plate.See “Troubleshoot calibration failure” on page 68.

11. 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.

Perform instrument verification using RNase P plates

During instrument installation, your HID Support Representative will perform instrument verification. However, perform instrument verification:

- After performing instrument calibrations.
- As needed to confirm instrument performance.

The instrument requires valid ROI/uniformity, background, and dye calibrations to perform instrument 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.	<p>The instrument passes performance specifications if the following inequality is true and the instrument successfully distinguishes between unknown populations A and B.</p> $[(C_{tA}) - 3(\sigma_{CtA})] > [(C_{tB}) + 3(\sigma_{CtB})]$ <p>where:</p> <ul style="list-style-type: none">• C_{tA} = Average C_t of unknown population A• σ_{CtA} = Standard deviation of unknown population A• C_{tB} = Average C_t of unknown population B• σ_{CtB} = 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: PCR master mix, RNase P primers, FAM™ dye-labeled probe, and a known concentration of human genomic DNA template.

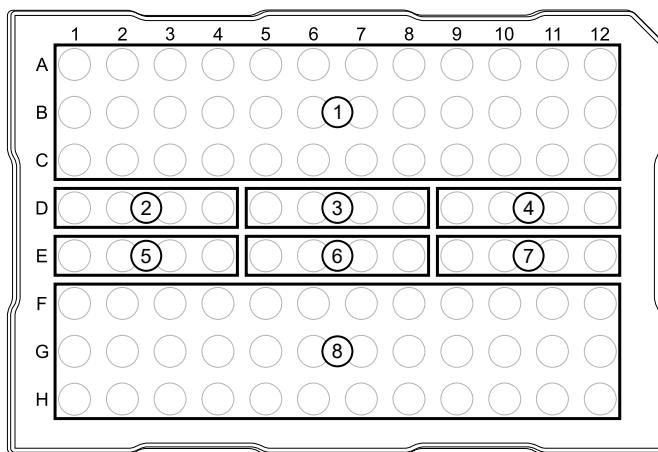


Figure 3 96-well RNase P plate

- | | |
|-------------------------------|------------------------|
| (1) Unknown A (5,000) | (5) STD 5,000 copies |
| (2) NTC (no template control) | (6) STD 10,000 copies |
| (3) STD 1,250 copies | (7) STD 20,000 copies |
| (4) STD 2,500 copies | (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.

$$[(C_{tA}) - 3(\sigma_{CtA})] > [(C_{tB}) + 3(\sigma_{CtB})]$$

- C_{tA} = Average C_t of unknown population A
- σ_{CtA} = Standard deviation of unknown population A
- C_{tB} = Average C_t of unknown population B
- σ_{CtB} = 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 EDS file for the verification in the desktop software.

Prepare an RNase P plate

Materials required for RNase P plate preparation

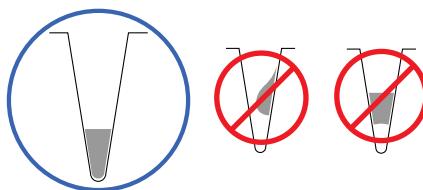
- RNase P instrument verification plate
- Centrifuge with plate adapter; buckets cleaned before use
- Powder-free gloves
- Safety glasses

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.



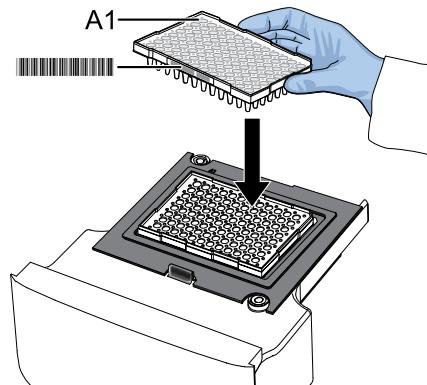
IMPORTANT! Keep the bottom of the plate clean. Fluids and other contaminants on the bottom of the plate can contaminate the sample block and cause an abnormally high background signal.

Perform RNase P verification

1. In the home screen, touch **Settings** **Maintenance and Service** **RNase P Verification**.
2. Load the plate.
 - a. Touch to eject the instrument drawer.

b. Load the plate onto the plate adapter so that:

- Well A1 of the plate is in the top-left corner of the plate adapter.
- The barcode faces the front of the instrument.



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

Note: Do not remove the black plate adapter before loading a plate or tube strips. If used, tube strips may fit loosely in the adapter, but the heated cover will apply the appropriate pressure to seat the tube strips securely in the adapter.

- c. Touch to close the instrument drawer.
3. Touch **Start**.
4. When the run is complete and the screen displays **Verification Complete**, touch **View Results** to confirm the status of the run.

Calibration status	Action
Passed	Instrument is ready for use.
Failed	See “Troubleshoot verification failure” on page 69.

5. In the **RNase P Verification Status** screen, touch:
 - **Accept Results** to save the results to the instrument
 - **Reject Results** to delete the RNase P verification results
 - **Export Results** to export the calibration results to a USB
6. When the run ends, unload the plate.
 - a. Touch to eject the instrument drawer.
 - b. Remove the plate.
 - c. Touch to close the instrument drawer.



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

Note: If the instrument does not eject the plate, contact Support.

■ Backup or restore the instrument	60
■ Decontaminate the sample block	61
■ Replace the instrument fuses	64
■ Store, move, or ship the instrument	65

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.

Backup or restore the instrument

In the home screen:

Touch  **Settings** ▶ **Maintenance and Service** ▶ **Backup/Restore**.

To	Action
Backup	<ol style="list-style-type: none">1. Insert a USB into the front-panel USB port.2. Touch Backup Instrument.3. Touch  USB.4. Enter a backup file name, then touch Done.5. Select which elements to backup, or leave them all selected.6. Touch Backup.
Restore	<ol style="list-style-type: none">1. Insert the USB that contains the backup file into the front-panel USB port.2. Touch Restore a Backup.3. Touch  USB.4. Select the backup file, then touch Restore.

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- μ L) with pipette tips
- Deionized water
- Ethanol, 95% solution
- Na-hypochlorite, (0.1% v/v) solution

Clean the sample block



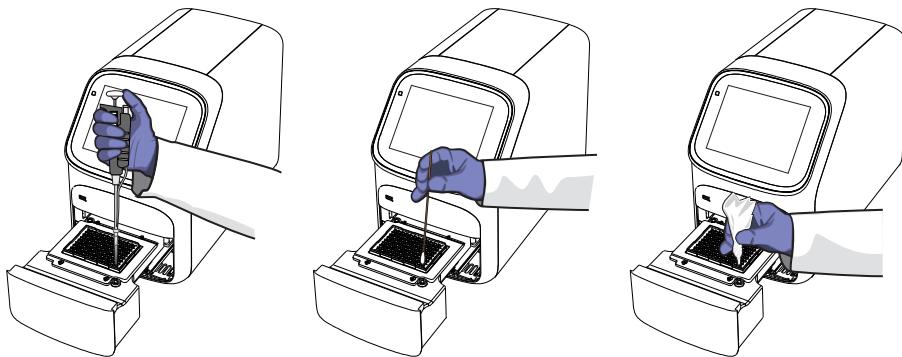
CAUTION! PHYSICAL INJURY HAZARD. During instrument operation, the sample block temperature can reach 100°C. Allow it to cool to room temperature before handling.

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 50).
2. Prepare the instrument and access the sample block:
 - a. Power off and unplug the instrument, then allow it to cool for 15 minutes.

- b. Touch  to eject the instrument drawer.
3. Rinse the contaminated wells with deionized water (see “Detailed procedures for cleaning the sample block” on page 63).



4. Close the drawer and test the sample block for contamination:
 - a. Push the instrument drawer back in to the instrument.
 - b. Plug in, then power on the instrument.
 - c. Perform a background calibration to confirm that you have eliminated the contamination.
5. If the contamination remains, clean the contaminated wells using a 95% ethanol solution:
 - a. Repeat step 2 – step 3.
 - b. Clean the contaminated wells using a 95% ethanol solution (see “Detailed procedures for cleaning the sample block” on page 63).
 - c. Repeat step 3 – step 4 to rinse the sample block with deionized water and to confirm that you have eliminated the contamination.

IMPORTANT! Always use deionized water to rinse wells after cleaning with bleach or ethanol solution.
6. If the contamination still remains, clean the contaminated wells using a Na-hypochlorite (0.1% v/v) solution:
 - a. Repeat step 2 – step 3.
 - b. Clean the contaminated wells using a Na-hypochlorite (0.1% v/v) solution (see “Detailed procedures for cleaning the sample block” on page 63).
 - c. Repeat step 3 – step 4 to rinse the sample block with deionized water and to confirm that you have eliminated the contamination.

IMPORTANT! Always use deionized water to rinse wells after cleaning with Na-hypochlorite or ethanol solution.
7. If the contamination continues to remain, contact Support.

Detailed procedures for cleaning the sample block

IMPORTANT! Use these cleaning procedures *only* in conjunction with the complete decontamination procedure (see “Decontaminate the sample block” on page 61).

- 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 Na-hypochlorite (0.1% v/v) solution.
 - a. Pipet a small volume of Na-hypochlorite (0.1% v/v) 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



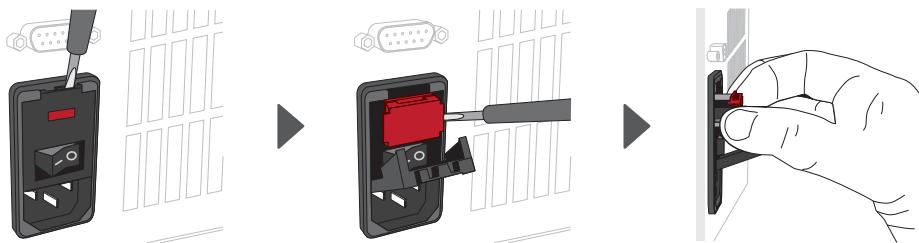
CAUTION! FIRE HAZARD. For continued protection against the risk of fire, replace fuses only with listed and certified fuses of the same type and rating as those currently in the instrument.

Materials required

- Fuses (2) – 10A, Time-Lag T, 250VAC, 5 × 20mm
- Safety glasses
- Powder-free gloves
- Screwdriver, flathead

Replace the fuses

1. Power off and unplug the instrument, then allow it to cool for 15 minutes.
2. Using a flat-head screwdriver, unscrew and remove the fuse holder.



3. Remove each fuse from its fuse holder and inspect it for damage. Carbon typically coats the inside of failed fuses.

Good	Failed
	

4. Replace each failed fuse.

Note: The voltage and amperage ratings are on the fuse holder.

5. Install the fuse holder back into the instrument.
6. 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, contact Support.

Store, move, or ship the instrument

Prepare the instrument to store, move, or ship

In the home screen:

1. Touch  **Settings** ▶ **Maintenance and Service** ▶ **Ship Prep Mode** ▶ **Next**.
2. Touch  to eject the instrument drawer.
3. Load the packing plate or an empty plate, then touch  to close the drawer.
4. Touch **Lock Block**.
5. Power off the instrument using the power switch on the back of the instrument.

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 kg (77 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.

Return the instrument for service

The service process requires 2 to 3 weeks.

Before returning the instrument for service, perform the following tasks.

1. Back up the instrument (see “Backup or restore the instrument” on page 60).
2. In the home screen, touch  **Settings** ▶ **Instrument Settings** ▶ **Reset Factory defaults**.
3. Set the instrument to **Ship Prep Mode** (see “Prepare the instrument to store, move, or ship” on page 65).

To return the instrument for service, perform the following tasks.

1. Contact your local customer care center or technical support group to obtain a copy of the Certificate of Instrument Decontamination, a service notification, a service call number, and packaging materials (if required).
2. Follow the instructions in the form to decontaminate the instrument.

IMPORTANT! The instrument must be decontaminated before packing it for shipping.

3. Complete and sign a copy of the Certificate of Instrument Decontamination.
4. Fax the Certificate of Instrument Decontamination to the customer care center.
5. Pack the instrument in the provided packaging and follow the instructions in the table below.

Prepare	Include	Exclude
<p>1. Transfer any data files from the instrument.</p> <p>2. Load an empty plate in the sample block.</p> <p>3. Use the touchscreen to place the instrument in ship mode.</p> <p>Note: The empty plate and ship mode protects the internal components of the instrument during transport.</p>	<ul style="list-style-type: none"> • Instrument • Completed and signed Certificate of Instrument Decontamination <p>Note: The instrument will not be accepted for service without a hard copy of the Certificate of Instrument Decontamination.</p>	Any accessories, including: <ul style="list-style-type: none"> • Power cord • Ethernet cable • USB drive • Wireless adapter <p>Note: If included with the instrument, these items will be disposed of during service and not returned.</p>

6. Attach the postage provided with the Certificate of Instrument Decontamination to the box, then ship the instrument to the designated facility.



Troubleshooting

Instrument troubleshooting

Observation	Possible cause	Recommended action
Insufficient disk space message	Insufficient disk space to save a run.	<ol style="list-style-type: none">1. In the home screen, touch Settings ▶ Run History ▶ Manage.2. Delete or transfer experiments from the instrument.
The touchscreen is black	The instrument is in sleep mode.	Touch anywhere on the instrument touchscreen.
	The instrument is not powered on.	If you touch the instrument touchscreen and it remains black, check if the instrument is powered on. The power switch is located on the rear panel of the instrument.
		If the instrument does not power on, check that the instrument is properly plugged in. If the instrument does not power on and the instrument is properly plugged in, contact Support.
Forgot PIN for instrument profile	Non-administrator forgot instrument profile PIN.	See “Manage all instrument profiles” on page 29.
	Administrator forgot instrument profile PIN.	Have another administrator reset the PIN for the forgotten-PIN profile (see “Manage all instrument profiles” on page 29).
		If there is not another administrator profile on the instrument, you must restore factory defaults (see “Restore factory defaults” on page 40).

Troubleshoot calibration failure

Observation	Possible cause	Recommended action
Calibration failed	The plate was improperly prepared.	<p>Ensure the following:</p> <ul style="list-style-type: none"> • 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 plate is damaged or contaminated.	<p>Check for damage, improper plate seal, or contamination.</p> <p>Order a replacement plate. If the replacement plate fails, contact Support.</p>
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 50.
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.	<p>Repeat the calibration with the plate properly prepared.</p> <p>If the calibration fails again, order a replacement plate. If the replacement plate fails, contact Support.</p>



Troubleshoot verification failure

Observation	Possible cause	Recommended action
Verification failed	The plate was improperly prepared.	Ensure the following: <ul style="list-style-type: none">• The correct plate was used for the verification performed.• The plate was properly thawed.• The plate was properly centrifuged.• The plate was properly sealed.
	The plate is damaged or contaminated.	<p>Check for damage, improper plate seal, or contamination.</p> <p>Order a replacement plate. If the replacement plate fails, contact Support.</p>
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 may indicate fluorescent contaminants on the plate or the sample block.	<p>Examine the bottom of the reaction plate. If there is contamination, prepare a new plate and run the experiment again.</p> <p>Identify the location of contamination on the plate or sample block.</p> <ol style="list-style-type: none">1. Obtain a background plate.2. Follow the procedures that are described in “Identify contamination” on page 50.
Verification failed but plate is undamaged	The incorrect plate was used for verification.	Use the correct RNase P plate for verification.
	The plate was improperly prepared.	<p>Repeat the verification with a new properly prepared plate.</p> <p>Note: The verification procedure is an experiment run, so each RNase P plate can only be used once.</p> <p>If the verification fails again, order a replacement plate. If the replacement plate fails, contact Support.</p>



Parts and materials

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■ Consumables (96-well, 0.2-mL format)	71
■ Accessories	72
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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.



Consumables (96-well, 0.2-mL format)

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™ 96-Well Tray/Retainer Set for Veriti™ Systems	10 trays	4381850
MicroAmp™ Optical 96-Well Reaction Plate	10 plates	N8010560
	500 plates	4316813
MicroAmp™ Optical 96-Well Reaction Plate with Barcode	20 plates	4306737
	500 plates	4326659
MicroAmp™ EnduraPlate™ Optical 96-Well Clear Reaction Plates with Barcode	20 plates	4483354
	500 plates	4483352
MicroAmp™ EnduraPlate™ Optical 96-Well Clear GPLE Reaction Plates with Barcode	20 plates	4483348
	500 plates	4483351
MicroAmp™ EnduraPlate™ Optical 96-Well Fast Clear Reaction Plates with Barcode	20 plates	4483485
MicroAmp™ Optical Adhesive Film Kit	1 kit	4313663
MicroAmp™ Optical Film Compression Pad (<i>Optional, used for some applications</i>)	5 each	4312639

Instrument verification or calibration plate	Cat. No.
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
Spectral calibration plates for dyes used with HID-validated workflows	
ABY™ Spectral Calibration Plate, 96-Well 0.2-mL	4461591
JUN™ Spectral Calibration Plate, 96-Well 0.2-mL	4461593

Accessories

Item	Amount	Cat. No.
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

General-use materials and consumables

The following general-use materials and consumables are required to calibrate, maintain, and operate the instrument.

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.

Material/Consumable	Source
Centrifuge with 96-well plate buckets	MLS
Cotton or nylon swabs and lint-free cloths	MLS
Ethanol, 95% solution	MLS
Optical clear adhesive film for PCR	MLS
Na-hypochlorite, 0.1% v/v solution	MLS
Pipettors, 100-µL and 200-µL (with pipette tips)	MLS
Powder-free gloves	MLS
Safety glasses	MLS
Screwdriver, flathead	MLS
Tissue, lint-free	MLS
Deionized water	MLS



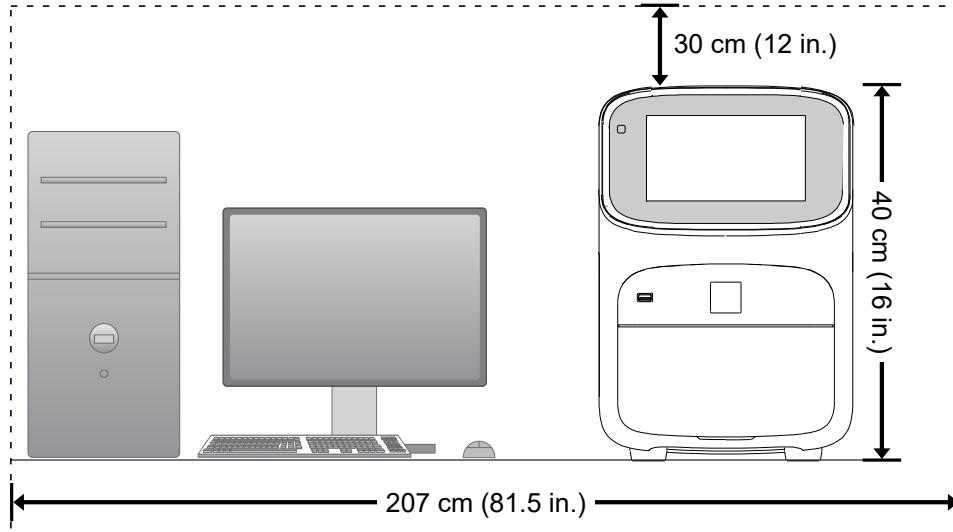
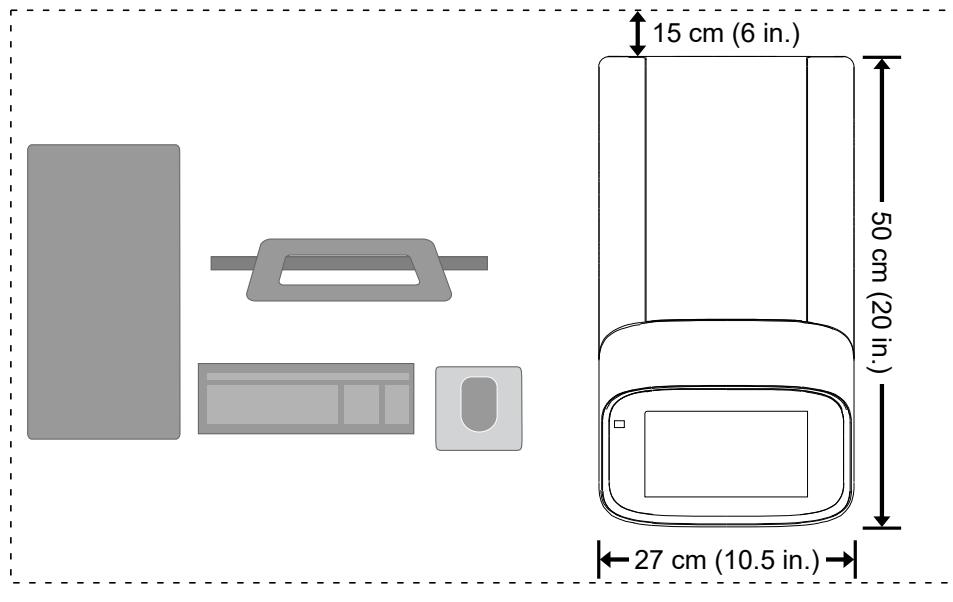
Instrument specification and layout

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Configured system dimensions

Allow space for the configured instrument. A typical setup with a co-located minitower computer is shown below.

Note: Dimensions are rounded to the nearest whole or half unit.





Instrument and computer connections

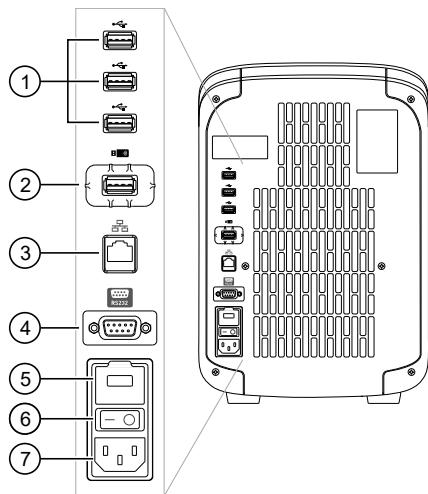


Figure 4 Instrument back panel

- | | |
|---|-----------------------------------|
| ① USB ports | ④ RS232 Port—For service use only |
| ② WiFi USB port—Not applicable | ⑤ Fuse Cover |
| ③ Ethernet Port—RJ45 port for 100/1,000 Mbps Ethernet communication with the instrument | ⑥ Power Switch |
| | ⑦ Power Port—100 to 240 VAC |

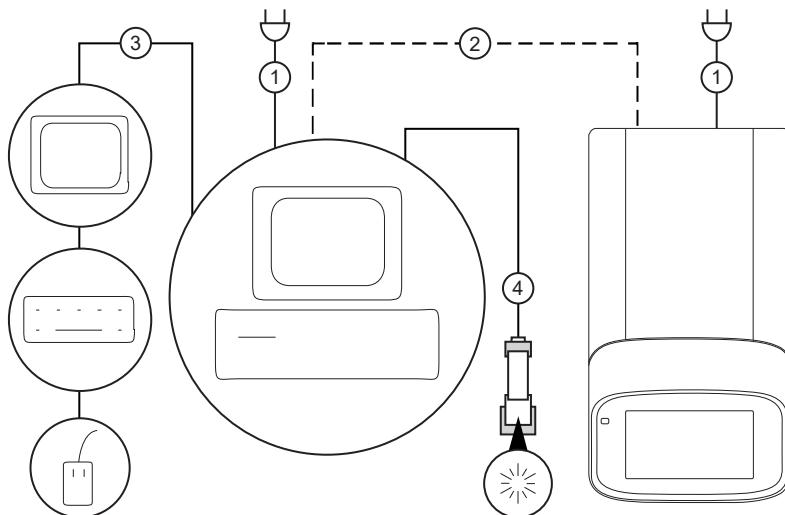


Figure 5 Instrument-to-computer connections (barcode scanner connected to the computer)

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.

Instrument 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	Top	Front	Sides	Back
Instrument	30 cm (12 in.)	30 cm (12 in.)	15 cm (6 in.)	15 cm (6 in.)
Computer	—	15 cm (6 in.)	—	15 cm (6 in.)

Electrical requirements



WARNING! For safety, the power outlet used for powering the instrument must be accessible at all times. See “Instrument clearances” 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.



WARNING! Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of the equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Electric receptacle with grounding capability
- Maximum power dissipation: ~960 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 $\pm 10\%$ VAC ^[1]	10 A	50/60 Hz	960 W
Computer (laptop)	100–240 $\pm 10\%$ VAC	10 A	50/60 Hz	90 VA
Computer (desktop)	100–240 $\pm 10\%$ VAC	10 A	50/60 Hz	125 VA
Monitor				65 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

Table 2 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.
Altitude	Between sea level and 2000 m (6500 ft) above sea level
Operating conditions	<ul style="list-style-type: none">Humidity: 15–80% relative humidity (noncondensing)Temperature: 15°C to 30°C (59°F to 86°F) <p>Note: For optimal performance, avoid rapid or extreme fluctuations in room temperature.</p>
Storage and transport conditions	<ul style="list-style-type: none">Humidity: 20–80% relative humidity (noncondensing)Temperature: –30°C to 60°C (–22°F to 140°F)
Thermal output	During operation, the net thermal output, based on the actual current draw of the instrument, is expected to be approximately 960 W (3275 Btu/h).
Vibration	Ensure that the instrument is not adjacent to strong vibration sources, such as a centrifuge, pump, or compressor. Excessive vibration will affect instrument performance.
Pollution degree	The instrument has a Pollution Degree rating of II. The instrument may only be installed 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. The noise output of the instrument is ≤ 60 dB when running.
Other conditions	Ensure the instrument is located away from any vents that could expel particulate material onto the instrument components. Avoid placing the instrument and computer adjacent to heaters, cooling ducts, or in direct sunlight.

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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.

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

(continued)

Symbol	English	Français
	Caution, risk of electrical shock	Attention, risque de choc électrique
	Moving parts	Parties mobiles
	Caution, hot surface	Attention, surface chaude
	Potential biohazard	Danger biologique potentiel
	Ultraviolet light	Rayonnement ultraviolet
	Potential slipping hazard	Danger de glisser potentiel
	On	On (marche)
○	Off	Off (arrêt)
○/○	On/Off	On/Off (marche/arrêt)
○ ⊖	Standby	En attente
⊖	Earth (ground) terminal	Borne de (mise à la) terre
	Protective conductor terminal (main ground)	Borne de conducteur de protection (mise à la terre principale)
~	Terminal that can receive or supply alternating current or voltage	Borne pouvant recevoir ou envoyer une tension ou un courant de type alternatif
~ ⊖	Terminal that can receive or supply alternating or direct current or voltage	Borne pouvant recevoir ou envoyer une tension ou un courant continu ou alternatif

(continued)

Symbol	English	Français
	<p>Do not dispose of this product in unsorted municipal waste</p> <p>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.</p>	<p>Ne pas éliminer ce produit avec les déchets usuels non soumis au tri sélectif.</p> <p>MISE EN GARDE ! Pour minimiser les conséquences négatives sur l'environnement à la suite de l'élimination de déchets électroniques, ne pas éliminer ce déchet électronique avec les déchets usuels non soumis au tri sélectif. Se conformer aux ordonnances locales sur les déchets municipaux pour les dispositions d'élimination et communiquer avec le service à la clientèle pour des renseignements sur les options d'élimination responsable.</p>

Conformity symbols

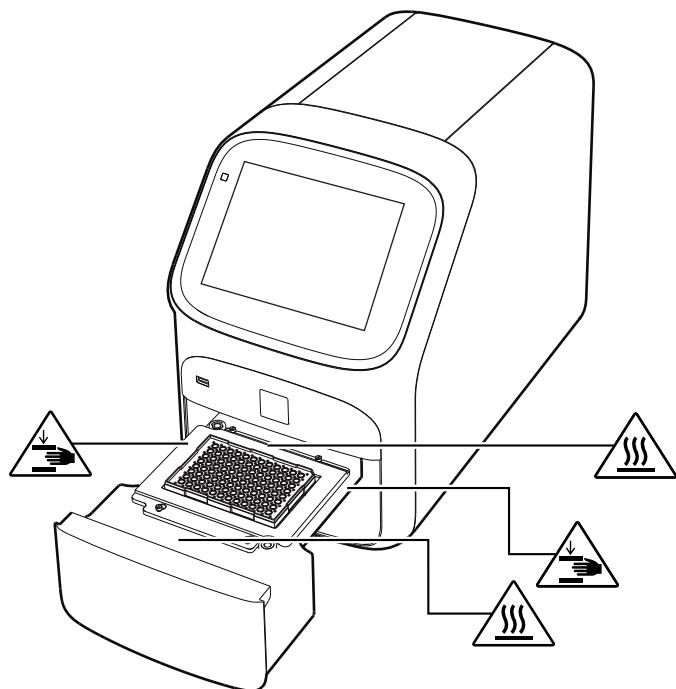
Conformity mark	Description
	Indicates conformity with safety requirements for Canada and U.S.A.
	Indicates conformity with European Union requirements for safety and electromagnetic compatibility.
	Indicates conformity with Australian standards for electromagnetic compatibility.

Safety alerts on this instrument

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

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

Location of safety labels on the instrument



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.

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.



WARNING! Do not attempt to lift or move the instrument without the assistance of others. Use appropriate moving equipment and proper lifting technique, improper lifting may result in serious injury.

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.



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

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



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



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

Cleaning and decontamination



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

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

Safety and electromagnetic compatibility (EMC) standards

The instrument design and manufacture complies with the following standards and requirements for safety and electromagnetic compatibility.



Safety compliance

Reference	Description
EU Directive 2014/35/EU	European Union “Low Voltage Directive”
IEC 61010-1 EN 61010-1 UL 61010-1 CSA C22.2 No. 61010-1	<i>Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements</i>
IEC 61010-2-010 EN 61010-2-010	<i>Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-010: Particular requirements for laboratory equipment for the heating of materials</i>
IEC 61010-2-081 EN 61010-2-081	<i>Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes</i>

EMC

Reference	Description
Directive 2014/30/EU	European Union “EMC Directive”
EN 61326-1/ IEC 61326-1	<i>Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements – Part 1: General Requirements</i>
AS/NZS CISPR 11	<i>Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment</i>
ICES-001, Issue 4	<i>Industrial, Scientific and Medical (ISM) Radio Frequency Generators</i>
FCC Part 15 Subpart B (47 CFR)	<i>U.S. Standard Radio Frequency Devices</i>

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.

Environmental design

Reference	Description
Directive 2012/19/EU	European Union “WEEE Directive” – Waste electrical and electronic equipment
EU Directive 2011/65/EU & Commission Delegated Directive (EU) 2015/863	European Union “RoHS Directive” – Restriction of hazardous substances in electrical and electronic equipment
Directive 2006/66/EC	European Union “Battery Directive”
GB/T 26572	Requirements of concentration limits for certain restricted substances in electrical and electronic products.

China EEP Hazardous Substances Information						
Component Name	QuantStudio™ 1 Real-Time PCR Instrument (96-Well 0.2-mL Block)					
	Hazardous Substances					
	(Pb)	(Hg)	(Cd)	(Cr(VI))	(PBB)	(PBDE)
PCBA	X	O	O	O	O	O

SJ/T11364. This table is compiled according to SJ/T 11364 standard.

O: GB/T26572.

Indicates that the concentration of the hazardous substance in all homogeneous materials for the part is below the relevant threshold of the GB/T 26572 standard.

X: GB/T26572.

Indicates that the concentration of the hazardous substance in at least one homogenous material of the part is above the relevant threshold of the GB/T 26572 standard.

Chemical safety



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

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



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)*, 5th Edition, HHS Publication No. (CDC) 21-1112, Revised December 2009; found at:
www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf
- World Health Organization, *Laboratory Biosafety Manual*, 3rd Edition, WHO/CDS/CSR/LYO/2004.11; found at:
www.who.int/publications/item/9789240011311



Documentation and support

Related documentation

Document	Pub. No.
<i>QuantStudio™ 5 Real-Time PCR Instrument Site Preparation Guide (for Human Identification)</i>	MAN0016701
<i>QuantStudio™ 5 Real-Time PCR Instrument User Guide (for Human Identification)</i>	MAN0017162
<i>HID Real-Time PCR Analysis Software User Guide</i>	MAN0009819

Obtain information from the Help system

The instrument has a Help system that describes how to use each feature of the touchscreen. Touch  on the instrument touchscreen to access the Help system.

Customer and technical support

For support:

- **In North America**—Send an email to HIDTechSupport@thermofisher.com, or call **888-821-4443 option 1**.
- **Outside North America**—Contact your local support office.

For the latest services and support information for all locations, go to thermofisher.com/support to obtain the following information.

- Worldwide contact telephone numbers
- Product support
- Order and web support
- Safety Data Sheets (SDSs; also known as MSDSs)

Additional product documentation, including user guides and Certificates of Analysis, are available by contacting Customer Support.

Limited product warranty

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

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