LightCycler®

Roche

LightCycler® PRO System

Quick Reference Guide

Publication version 2.0

Software version 1.2

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0	July 2023	First version
1.1	1.1	April 2024	Quick Reference Guides for “Generating data for research purposes” and “Establishing an analysis package” have been updated.
2.0	1.2	October 2024	General improvements

Revision history

Edition notice

This publication is intended for users of the LightCycler® PRO System.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **User Assistance** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Software reference
- Configuration information
- Background information

There is also a User Assistance available for the LightCycler® PRO Development Software.

The **User Guide** focuses on routine operation and maintenance. The content is organized according to the normal operation workflow.

The **Quick Reference Guide** gives a brief introduction to important routine tasks.

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When you use the User Assistance online, viewing events (topics viewed and searches performed) and IP addresses are logged.
The data collected is for Roche internal use only and is never forwarded to third parties. It is anonymized, and after 1 year, it is automatically deleted.

Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

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To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Store all publications in a safe and easily accessible place.

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Approvals

The LightCycler® PRO System meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.
To view the full text of the 2014/53/EU declaration of conformity, go to the **navify**® Portal global website (*navifyportal.roche.com*) and choose the eLabDoc link. If you are unable to access **navify**® Portal, contact a Roche Service representative.

Compliance with the applicable directives is provided by means of the declaration of conformity.

The following marks demonstrate compliance:

For in vitro diagnostic use.

Complies with the provisions of the applicable EU regulations.

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eLabDoc

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Table of contents

Quick Reference Guide

In this section

About the Quick Reference Guide

The LightCycler® PRO System supports several workflows for setting up runs:

- Generating data for research purposes
- Establishing an analysis package
- Routine workflow

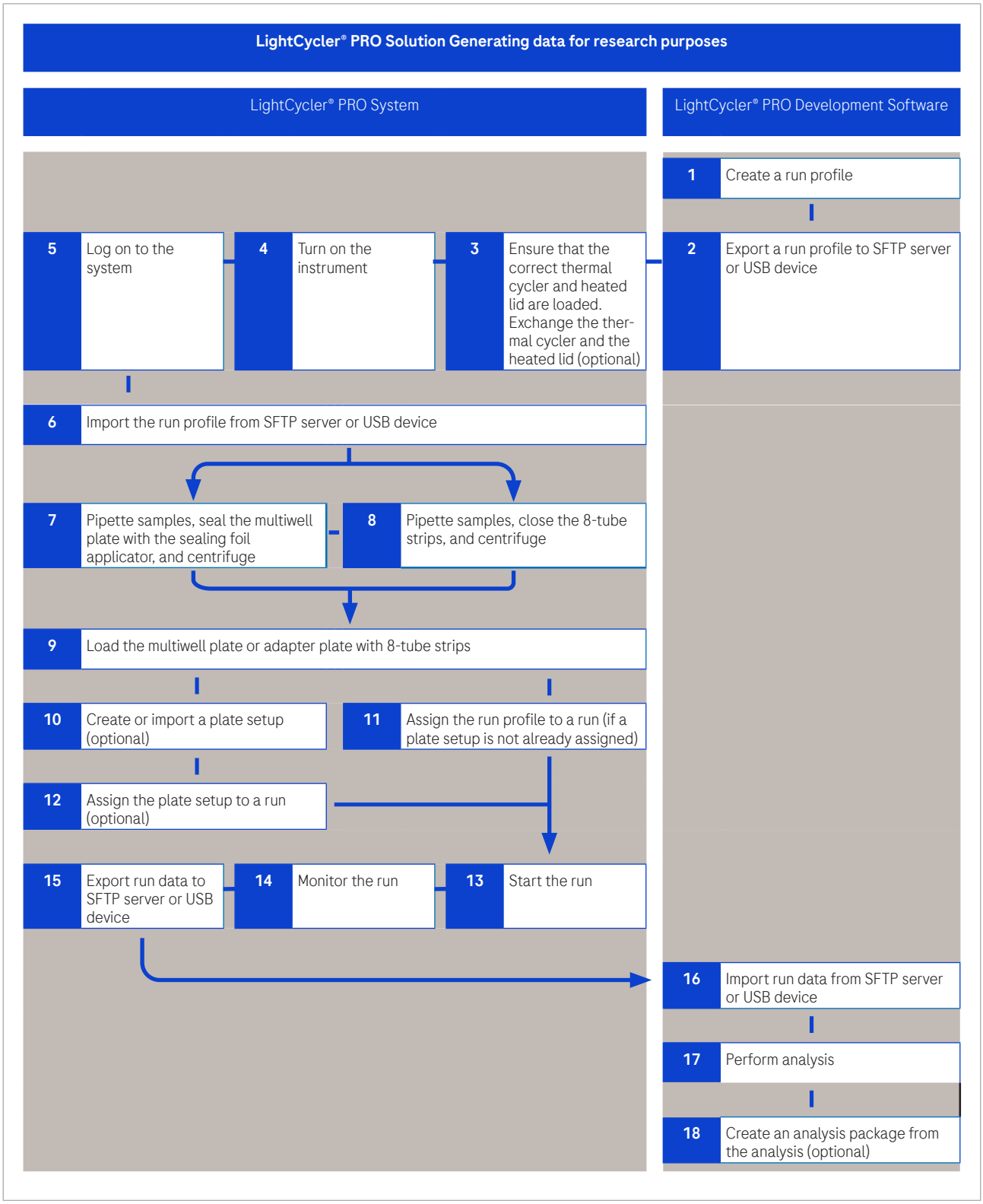
Not every step is needed in each workflow.

The following table summarizes the different workflows.

For detailed information, refer to the corresponding tasks described in the user documentation.

Generating data for research purposes

Generating data for research purposes



Steps	User action
1 Create a run profile. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Using the development software, choose the **Run profiles** app. 2. Choose the **Create** button. 3. Add all your programs. 4. Define your settings. 5. To add one or more detection formats, choose the **Detection format** button. 6. Choose the **Release** or **Save** button. When the **Release** button is selected, no more changes are possible.
2 Export a run profile to an SFTP server or a USB device. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Using the development software, choose the **Run profiles** app. 2. Select the run profile you want to export. 3. Choose the **Export** button.
3 Ensure that the correct thermal cycler and heated lid are loaded. Exchange the thermal cycler and the heated lid, if required.	1. Open the front flap. 2. Move the locking lever to the upper position. 3. Pull out the thermal cycler and load the new thermal cycler. 4. Move the locking lever to the lower position. 5. Press the manual release mechanism and keep it pressed. 6. Pull out the heated lid. 7. Push the new heated lid above the thermal cycler. 8. Release the manual release mechanism and check that it is in the vertical position. 9. Close the front flap.
4 Turn on the instrument.	At the front of the instrument, press the power button. Startup can take up to 5 minutes.
5 Log on to the system.	On the logon screen, enter your credentials.

Quick Reference Guide - Generating data for research purposes

Steps		User action	
6	Import the run profile from an SFTP server or a USB device.	1.	Choose the **Run profiles** app.
		2.	Choose the **Import** button.
		3.	Choose the run profile you want to import. If the run profile is in draft status, it can be further modified on the instrument.
		4.	Choose the **Import** button.
7	Pipette samples, seal the multiwell plate with the sealing foil applicator, and centrifuge. or	1.	Pipette your samples into the multiwell plate.
		2.	Remove the protective layer from the sealing foil.
		3.	Cover the multiwell plate with the adhesive side of the sealing foil and firmly press using the sealing foil applicator.
		4.	Remove both extremities.
		5.	Centrifuge the multiwell plate.
8	Pipette samples, close the 8-tube strips, and centrifuge.	1.	Pipette your samples into the 8-tube strips.
		2.	Close the tubes by firmly pressing the 8-cap strip into place. Make sure the tubes are closed properly.
		3.	Install the 8-tube strips on the adapter plate.
		4.	Centrifuge the 8-tube strips on the adapter plate on the top of the 96-well plate.
9	Load the multiwell plate or adapter plate with 8-tube strips.	1.	In the **Overview** panel, choose the **Open loading drawer** button.
		2.	Load the multiwell plate or 8-tube strips (symmetrically placed on the adapter plate).
		3.	On the user interface, choose the **Close loading drawer** button.

Quick Reference Guide - Generating data for research purposes

Steps	User action
10 Create a plate setup (optional): • Creating a plate setup by assigning orders manually well by well. • Creating a plate setup by importing orders and assigning manually to wells. • Synchronizing plate setups with host. • Importing a plate setup. • Assigning orders automatically to the plate. or	1. Choose the **Plates** app. 2. Refer to the specific steps in each procedure.
11 Assign the run profile to a run (if a plate setup is not already assigned). The run profile can be automatically detected when you load a plate with a barcode that matches the plate ID of an existing plate setup.	1. Choose the **Overview** app. 2. In the **Run workflow** panel, below **Run profile**, choose the ⊕ icon. 3. Assign the run profile.
12 Assign the plate setup to a run (optional). The plate setup is automatically assigned when you load a plate with a barcode that matches the plate ID of an existing plate setup.	1. Choose the **Overview** app. 2. In the **Run workflow** panel, below **Plate setup**, choose the ⊕ icon. 3. Assign the plate setup.
13 Start the run.	1. In the **Overview** panel, choose the **Start run** button.
14 Monitor the run.	1. Choose the **Overview** app. 2. Choose the **View run data** button. 3. Check fluorescence curves in real time. If required, choose the **Abort run** button.
15 Export run data or customer data to an SFTP server or a USB device.	1. Choose the **Results** app. 2. Select your run data 3. Choose the **Export** button. 4. Choose an export option.
16 Import run data to the development software from an SFTP server or a USB device. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Choose the **Projects** app. 2. Create or choose your project. 3. Import your run data from the instrument.

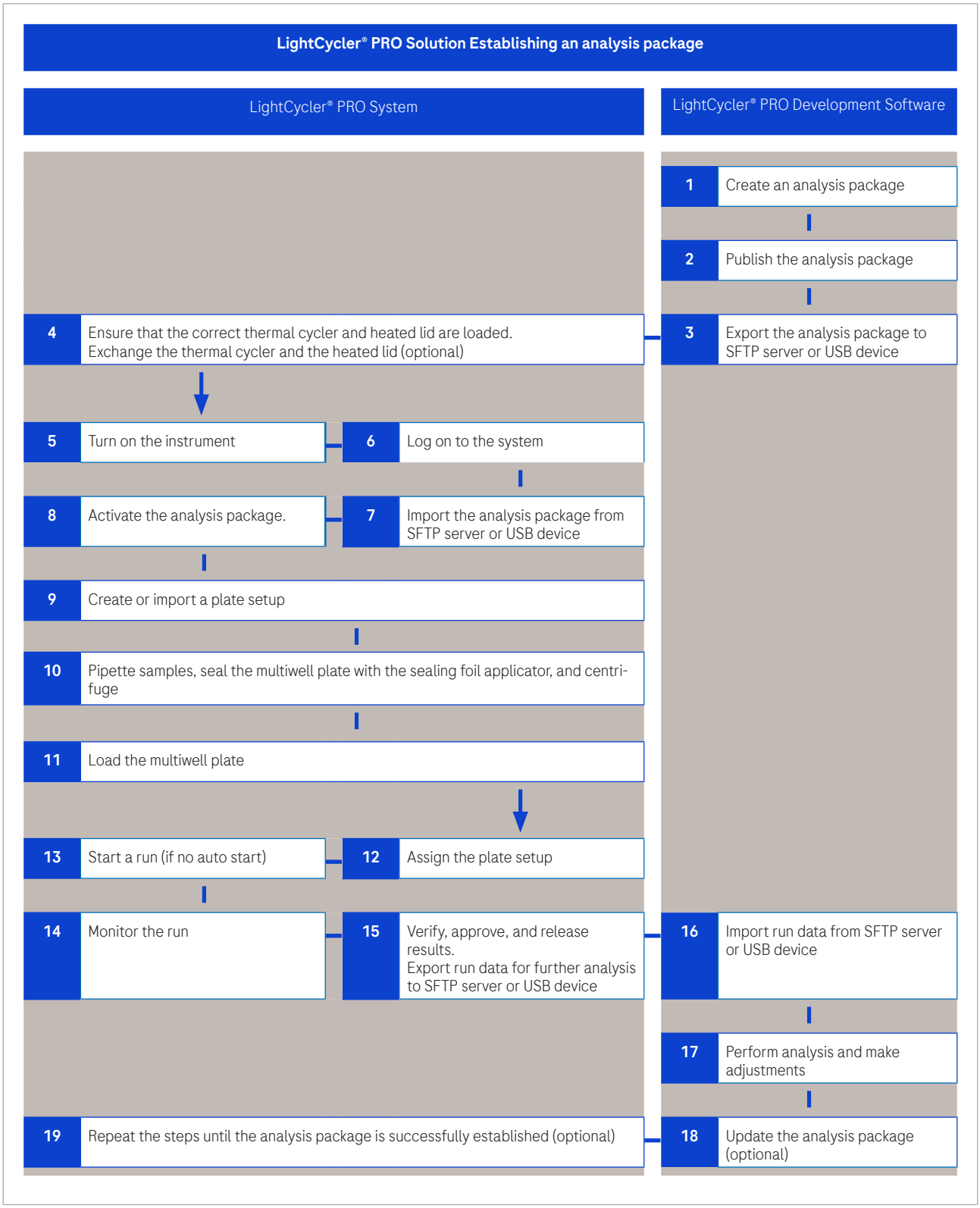
Quick Reference Guide - Generating data for research purposes

Steps	User action
17 Perform an analysis and make adjustments. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Choose the **Projects** app. 2. Create or choose your project. 3. Create a new analysis or perform an analysis based on an analysis package. 4. Define the analysis settings. 5. Recalculate your analysis.
18 Create an analysis package from the analysis (if desired, performing an analysis not necessary). This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Perform your analysis. 2. Define your analysis settings. 3. Create your analysis package.

Quick Reference Guide - Generating data for research purposes

Establishing an analysis package

Establishing an analysis package



Steps	User action
1 Create an analysis package. The analysis package can be created after generating data for research purposes (see previous workflow). This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Choose the **Analysis package** app. 2. Create your analysis package.
2 Publish the analysis package. If the analysis package is published in the status "in validation", it cannot be edited anymore. It can be used on the instrument, but sample results will be flagged to indicate that the analysis package is not finalized yet. If the analysis package is in Released status, it is fully ready to use. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Choose the **Analysis package** app. 2. Publish your analysis package in the status "in validation".
3 Export the analysis package to an SFTP server or a USB device. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Using the development software, choose the **Analysis package** app. 2. Select the run profile you want to export. 3. Choose the **Export** button.
4 Ensure that the correct thermal cycler and heated lid are loaded. Exchange the thermal cycler and the heated lid, if required.	1. Open the front flap. 2. Move the locking lever to the upper position. 3. Pull out the thermal cycler and load the new thermal cycler. 4. Move the locking lever to the lower position. 5. Press the manual release mechanism and hold it pressed. 6. Pull out the heated lid. 7. Push the new heated lid above the thermal cycler. 8. Release the manual release mechanism and check that it is in the vertical position. 9. Close the front flap.

Quick Reference Guide - Establishing an analysis package

Steps		User action
5	Turn on the instrument.	At the front of the instrument, press the power button. Startup can take up to 5 minutes.
6	Log on to the system.	On the logon screen, enter your credentials.
7	Import and install the analysis package from an SFTP server or a USB device.	1. Choose the **Analysis package** app. 2. Choose the **Import and install** button. 3. Select the analysis package you want to import and choose the **Import** button.
8	Activate the analysis package.	1. Choose the **Analysis package** app. 2. Select the analysis package you want to activate and switch on the toggle button.
9	Create a plate setup: • Creating a plate setup by assigning orders manually well by well. • Creating a plate setup by importing orders and assigning manually to wells. • Synchronizing plate setups with host. • Importing a plate setup. • Assigning orders automatically to the plate. The analysis package is assigned by creating the plate setup.	1. Choose the **Plates** app. 2. Refer to the specific steps in each procedure.
10	Pipette samples, seal the multiwell plate with the sealing foil applicator, and centrifuge.	1. Pipette your samples into the multiwell plate. 2. Remove the protective layer from the sealing foil. 3. Cover the multiwell plate with the adhesive side of the sealing foil and firmly press using the sealing foil applicator. 4. Remove both extremities. 5. Centrifuge the multiwell plate.
11	Load the multiwell plate.	1. In the **Overview** panel, choose the **Open loading drawer** button. 2. Load the multiwell plate or 8-tube strips (symmetrically placed on the adapter plate). 3. On the user interface, choose the **Close loading drawer** button.

Quick Reference Guide - Establishing an analysis package

Steps	User action
12 Assign the plate setup. The plate setup is automatically assigned when you load a plate with a barcode that matches the plate ID of an existing plate setup.	1. In the **Overview** panel next to plate setup choose the ⊕ icon. 2. Choose the plate setup. 3. Choose the **Assign** button.
13 Start a run (if no auto start).	1. In the **Overview** panel, choose the **Start run** button.
14 Monitor the run.	1. Choose the **Overview** app. 2. Choose the **View run data** button. 3. Check fluorescence curves in real time. If required, choose the **Abort run** button.
15 Verify, approve, release, and export the run data to an SFTP server or a USB device. If the analysis package is published in the status "in validation", sample results will be flagged to indicate that the analysis package is not finalized yet.	Depending on the results settings: 1. Choose the **Results** app. 2. Verify the results. 3. Approve the target results (1 or 2 levels) or overwrite the target results. The hierarchy of approval is as follows: melting standard results, internal controls results, other controls results, unknown results. It depends on the analysis type. 4. Release sample, controls, and standard results. 5. Export the run data for further analysis on the development software or as customer data export for further analysis with your own tools.
16 Import run data to the development software from an SFTP server or a USB device. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Choose the **Projects** app. 2. Create or choose your project. 3. Import your run data from the instrument.
17 Perform your analysis and make adjustments. This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Choose the **Projects** app. 2. Create or choose your project. 3. Create your analysis. 4. Define your analysis settings. 5. Recalculate your analysis.
18 Update the analysis package (optional). This step is performed using the development software. For more information, refer to the LightCycler® PRO Development Software User Assistance.	1. Perform your analysis. 2. Define your analysis settings. 3. Create your analysis package.

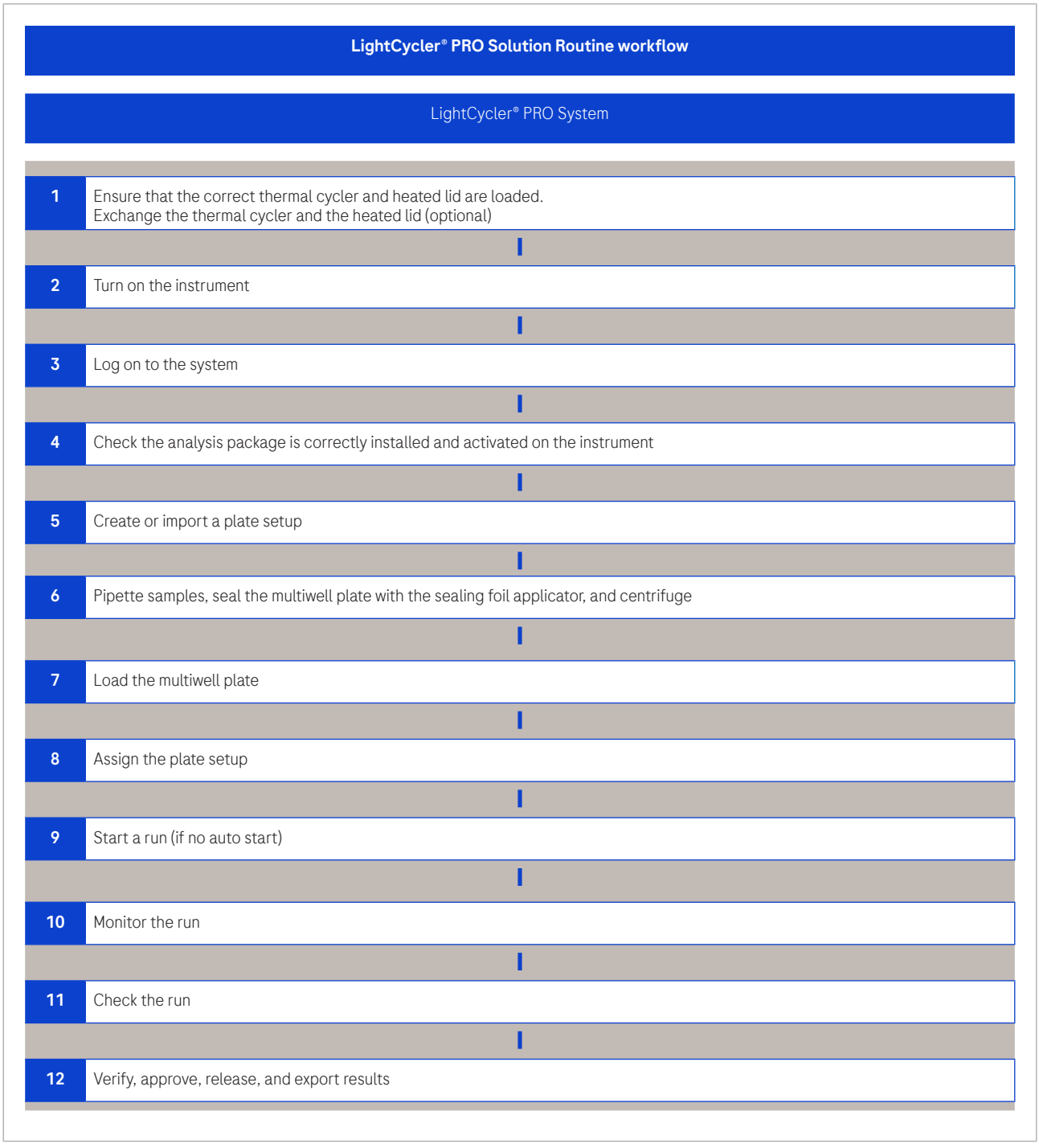
Quick Reference Guide - Establishing an analysis package

Steps		User action
19	Repeat the above steps until the analysis package is successfully established (optional).	When the analysis package is successfully established, it should be published as "Released".

Quick Reference Guide - Establishing an analysis package

Routine workflow

Routine workflow



Steps		User action
1	Ensure that the correct thermal cycler and heated lid are loaded. Exchange the thermal cycler and the heated lid, if required.	1. Open the front flap. 2. Move the locking lever to the upper position. 3. Pull out the thermal cycler and load the new thermal cycler. 4. Move the locking lever to the lower position. 5. Press the manual release mechanism and keep it pressed. 6. Pull out the heated lid. 7. Push the new heated lid above the thermal cycler. 8. Release the manual release mechanism and check that it is in the vertical position. 9. Close the front flap.
2	Turn on the instrument.	At the front of the instrument, press the power button. Startup can take up to 5 minutes.
3	Log on to the system.	On the logon screen, enter your credentials.
4	Check the analysis package is installed and activated on the instrument.	1. Choose the **Analysis package** app. 2. Check that your analysis package is installed. 3. Check that your analysis package is activated.
5	Create a plate setup: • Creating a plate setup by assigning orders manually well by well. • Creating a plate setup by importing orders and assigning manually to wells. • Synchronizing plate setups with host. • Importing a plate setup. • Assigning orders automatically to the plate.	1. Choose the **Plates** app. 2. Refer to the specific steps in each procedure.

Quick Reference Guide - Routine workflow

Steps		User action
6	Pipette samples, seal the multiwell plate with the sealing foil applicator, and centrifuge.	1. Pipette your samples into the multiwell plate. 2. Remove the protective layer from the sealing foil. 3. Cover the multiwell plate with the adhesive side of the sealing foil and press firmly using the sealing foil applicator. 4. Remove both extremities. 5. Centrifuge the multiwell plate.
7	Load the multiwell plate.	1. In the **Overview** panel, choose the **Open loading drawer** button. 2. Load the multiwell plate. 3. On the user interface, choose the **Close loading drawer** button.
8	Assign the plate setup. The plate setup is automatically assigned when you load a plate with a barcode that matches the plate ID of an existing plate setup.	1. In the **Overview** panel next to plate setup choose the ⊕ icon. 2. Choose the plate setup. 3. Choose the **Assign** button.
9	Start a run (if no auto start).	1. In the **Overview** panel, choose the **Start run** button.
10	Monitor the run.	1. Choose the **Overview** app. 2. Choose the **View run data** button.
11	Check the run.	1. On the **Overview** panel, choose the **View run data** button.
12	Verify, approve, release, and export the results to an SFTP server or a USB device. If the analysis package is published in the status "in validation", sample results will be flagged to indicate that the analysis package is not finalized yet.	Depending on the results settings: 1. Choose the **Results** app. 2. Verify the results. 3. Approve the target results (1 or 2 levels) or overwrite the target results. The hierarchy of approval is as follows: melting standard results, internal controls results, other controls results, unknown results. It depends on the analysis type. 4. Release sample, controls, and standard results. If a host connection is set up, results are sent to the host. 5. Export the run data to the development software as necessary.

Quick Reference Guide - Routine workflow

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