

# Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit INSTRUCTIONS FOR USE

High-throughput RNA extraction and real-time RT-PCR detection  
of SARS-CoV-2 RNA

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Revision	Date	Description
B.0	14 July 2022	<ul style="list-style-type: none"> <li>• Saliva was added as a specimen; the workflow was updated to incorporate saliva specimen type and the use of the Spectrum Solutions™ SDNA-2000 Saliva Collection Device.</li> <li>• The workflow was updated to remove automatic lidding for sample extraction plate transfer between Module 1 and Module 2.</li> <li>• The workflow was updated to account for partial runs (&lt;4 plates per run), COVID-19 Interpretive Software Driver to version 1.2, and Tecan™ FluentControl™ Software update to version 3.0.</li> <li>• The Amplitude™ Solution workflow instructions were updated for ease of use and clarity throughout.</li> <li>• The Module 1 and Module 2 computer descriptions were updated to include Microsoft™ Defender.</li> <li>• The Amplitude™ High-Throughput Consumable Package 1 Reagent Kit Cat. No. was updated.</li> <li>• The amounts of plastics supplied in Amplitude™ High-Throughput Consumable Package 3 Plastics were updated (see page 28).</li> <li>• “Required materials not supplied” on page 30 was updated to include Spectrum Solutions™ SDNA-2000 Saliva Collection Device.</li> <li>• The list of required materials not supplied was updated (see “Required materials not supplied” on page 30).</li> <li>• New information about Amplitude™ Beacon was added in “Amplitude™ Beacon” on page 15 and Appendix G, “Amplitude™ Beacon configuration”.</li> <li>• “Additional reagents and consumables” on page 29 was updated.</li> <li>• “Assay limitations” on page 32 was updated.</li> <li>• “Warnings and precautions” on page 36 was updated.</li> <li>• “In-use reagent stability” on page 40 was updated.</li> <li>• A footnote was added for barcode length specifications in “Sample tube barcode requirements” on page 62.</li> <li>• “Power on the A25 Refrigerated Circulator” on page 58 was updated.</li> <li>• Module 1 and Module 2 daily system care was moved to be performed before each shift, instead at the end of each shift.</li> <li>• “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82 was updated.</li> <li>• A note was added in step 1 in “Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation” on page 87.</li> <li>• “Thaw Module 2 reagents” on page 110 was updated.</li> <li>• A warning to remove lids from 150 µL MCA Disposable Tip boxes was added in “Replenish reagents in the Momentum™ Software” on page 119 and “Load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck” on page 125.</li> <li>• Guidance to prevent reagent contamination, invalid results, mold growth on the instrument deck, and damage to the instrument was added in “Load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck” on page 125.</li> <li>• A caution statement was updated in “Monitor the Module 2 run” on page 134.</li> <li>• A warning was added in “Review the unanalyzed real-time RT-PCR data” on page 150.</li> <li>• Maintenance task requirements in Chapter 9, “Perform regular maintenance” were updated.</li> <li>• “Prepare an RNA elution plate balance” on page 154 was added.</li> <li>• Appendix A, “Troubleshooting” was updated to reflect instrument and system upgrades.</li> <li>• Description of Module 1 SampleManager LIMS™ Software CSV output error codes was added (see “Module 1 SampleManager LIMS™ Software CSV output errors” on page 228).</li> <li>• Appendix C, “Performance characteristics for Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit” was updated.</li> </ul>

Revision	Date	Description
B.0 (continued)	14 July 2022	<ul style="list-style-type: none"> <li>• “Module 1 SampleManager LIMS™ Software CSV output errors” on page 228 was added.</li> <li>• “Module 1 automation information” on page 241 was updated.</li> <li>• “Sample and control positions in the tube runners” on page 236 was updated to label tube runner positions on the grid.</li> <li>• Appendix J, “Cleaning and decontamination” was added.</li> <li>• Appendix K, “Safety”, “Safety and electromagnetic compatibility (EMC) standards” on page 264, and “Biological hazard safety” on page 270 were updated.</li> <li>• “Related documentation” on page 271 was updated.</li> <li>• “Download a Safety Data Sheet (SDS)” on page 272 was added.</li> <li>• Contact information for removal/disposal of the Amplitude™ Solution was added (see page 272).</li> <li>• The manufacturing address was updated.</li> </ul>
A.0	19 March 2021	New document for the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit.

The customer is responsible for compliance with regulatory requirements that pertain to their procedures and uses of the instrument.

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

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# About this guide



**CAUTION! ABBREVIATED SAFETY ALERTS.** Hazard symbols and hazard types specified in procedures may be abbreviated in this document. For the complete safety information, see the “Safety” appendix in this document.

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**IMPORTANT!** Before using this product, read and understand the information in the “Safety” appendix in this document.

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## Purpose

This guide provides system information and user workflow instructions for the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit. This guide is not intended to be used for system workflows or instrument maintenance outside of the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit workflow. For comprehensive operating or maintenance instructions, see the guides listed in “Related documentation” on page 271.

## Prerequisites

- The Amplitude™ Solution must be installed by a Thermo Fisher Scientific Field Service Engineer.
- Operators must be trained on the platform before using the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit.



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## Intended Use

The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and nasal swab specimens from individuals suspected of COVID-19 by their healthcare provider.

The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit is also for use with saliva specimens collected using Spectrum Solutions™ SDNA-2000 Saliva Collection Device from individuals suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal swab, nasal swab, and saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within Canada and its territories are required to report all test results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

Automated, high-throughput testing with the TaqPath™ COVID-19 High-Throughput Combo Kit is performed using the Thermo Fisher Scientific Amplitude™ Solution. The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the system workflow and *in vitro* diagnostic procedures.

## Product description

The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit is an automated, high-throughput real-time PCR testing system that detects SARS-CoV-2 RNA in human samples. The system is designed to perform up to 8,000 tests in a 24-hour period. Multiple full-time employees are required to supply and support the system (see “Amplitude™ Solution operator requirements” on page 36). For more information about the system, including ordering information, see [thermofisher.com/amplitude](https://thermofisher.com/amplitude).

The modular system supports sample-to-result testing, and includes the following features:

- Automated isolation of RNA from human samples and preparation of real-time RT-PCR reactions
- Presence/absence detection of SARS-CoV-2 viral RNA using the TaqPath™ COVID-19 High-Throughput Combo Kit
- Automated sample registration, tracking, and delivery of analysis results using SampleManager LIMS™ Software
- Instrument control and inventory management using Momentum™ Workflow Scheduler Software
- Assured supply of assays and consumables
- Comprehensive system support, including:
  - An installation concierge to manage installation, performance checks, and training
  - A dedicated customer success manager to assist with workflow applications, software, and instrument components
  - 24/7 support via telephone or email and live troubleshooting assistance (in-person or remote)

### Amplitude™ Solution Module 1

Module 1 of the Amplitude™ Solution consists of a Tecan™ Fluent™ 1080 Automation Workstation that prepares samples and reagents for transfer to Module 2.

During a run, the Tecan™ Fluent™ 1080 Automation Workstation performs the following:

- Processes up to 376 barcoded sample tubes per run.
- Transfers an aliquot from each sample tube and the reagents into the well of a KingFisher™ Deep-Well 96 Plate with Barcode (sample extraction plate). One sample extraction plate is prepared for each set of 94 samples, with a maximum of 4 sample extraction plates for a full-capacity run of 376 samples.

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**Note:** As part of the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit, Module 1 uses reagents from the TaqPath™ COVID-19 High-Throughput Combo Kit and the Amplitude™ High-Throughput Consumable Package 1 Reagent Kit.

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- Automatically scans barcodes on sample tubes and sample extraction plates, then transfers the information to the SampleManager LIMS™ Software for tracking.

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**Note:** The Amplitude™ Solution does not perform sample accessioning. If required, perform sample accessioning according to guidelines established by your laboratory prior to processing the samples on Module 1. After testing, the results can be ported into your laboratory system.

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Two trained Module 1 technicians load consumables, reagents, and samples; start runs; perform regular system maintenance; and transfer the sample extraction plates to Module 2 for RNA extraction and subsequent real-time RT-PCR.

Tecan™ FluentControl™ Software monitors the reagent and consumable inventories and controls the Tecan™ Fluent™ 1080 Automation Workstation via the instrument touchscreen. The Tecan™ FluentControl™ Software can be accessed on the Module 1 computer or on the Tecan™ Fluent™ 1080 Automation Workstation touchscreen.

For more information, see “Module 1 overview” on page 67.

## Amplitude™ Solution Module 2

Module 2 of the Amplitude™ Solution includes the instruments, software, reagents, and materials for automated RNA extraction, real-time RT-PCR, and reporting of results.

- **Automated Workflow**—The Momentum™ Workflow Scheduler Software controls the flow of materials between the stations and instruments and monitors consumable and reagent inventories. A Spinnaker™ Microplate Robot transfers various plates between the module components. The system automatically scans the 1-D barcodes on all of the system plates, then sends the information to the SampleManager LIMS™ Software for tracking.
- **RNA Extraction**—Four KingFisher™ Presto Purification Systems extract RNA from the samples using reagents from the MagMAX™ MVPII HT Module 2 Sample Prep Kit.
- **Real-time RT-PCR**—A Tecan™ Fluent™ 780 Automation Workstation transfers sample RNA, controls, and RT-PCR reagents to MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plates with Barcode. Real-time RT-PCR is performed using two Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR Systems.  
For information about the TaqPath™ SARS-CoV-2 High-Throughput qPCR Assay and controls used during real-time RT-PCR, see “TaqPath™ COVID-19 High-Throughput Combo Kit” on page 15.
- **Analysis and Results**—The real-time RT-PCR data is automatically analyzed by the COVID-19 Interpretive Software Driver to determine the presence or absence of SARS-CoV-2 RNA, then the results are automatically transferred to and stored in the SampleManager LIMS™ Software for review.

For a complete list of Module 2 components, see “Module 2 layout and components” on page 19.

Two trained Module 2 technicians start runs and monitor reagents and consumables using Momentum™ Workflow Scheduler Software, load consumables and reagents, and perform regular system maintenance.

## TaqPath™ COVID-19 High-Throughput Combo Kit

The TaqPath™ COVID-19 High-Throughput Combo Kit includes the assays and controls for a multiplex real-time RT-PCR test for the qualitative detection of SARS-CoV-2 RNA in patient specimens collected using nasopharyngeal swab, anterior nasal swab, or saliva from individuals suspected of COVID-19 by their healthcare provider.

The kit includes the following components:

- **TaqPath™ COVID-19 Module 2 Assay Kit**—Multiplexed assays that contain 3 primer/probe sets specific to 3 different SARS-CoV-2 genomic regions (ORF1ab, N gene, and S gene) and primers/probe for bacteriophage MS2
- **TaqPath™ COVID-19 Module 1 MS2 Phage Control**—An internal process control for RNA extraction
- **TaqPath™ COVID-19 Control**—An RNA control that contains targets specific to the SARS-CoV-2 genomic regions targeted by the assays

## Amplitude™ Beacon

The Amplitude™ Beacon is configured during installation with options to activate in response to errors and, optionally, warnings. The Amplitude™ Beacon can be configured to produce a flashing light and, optionally, a sound. If you have questions about your configuration, consult Priority Support. For information on the use of the beacon, including light modes and alarms, see Appendix G, “Amplitude™ Beacon configuration”.

# Amplitude™ Solution layout and instrument components

## Module 1 Tecan™ Fluent™ 1080 Automation Workstation components

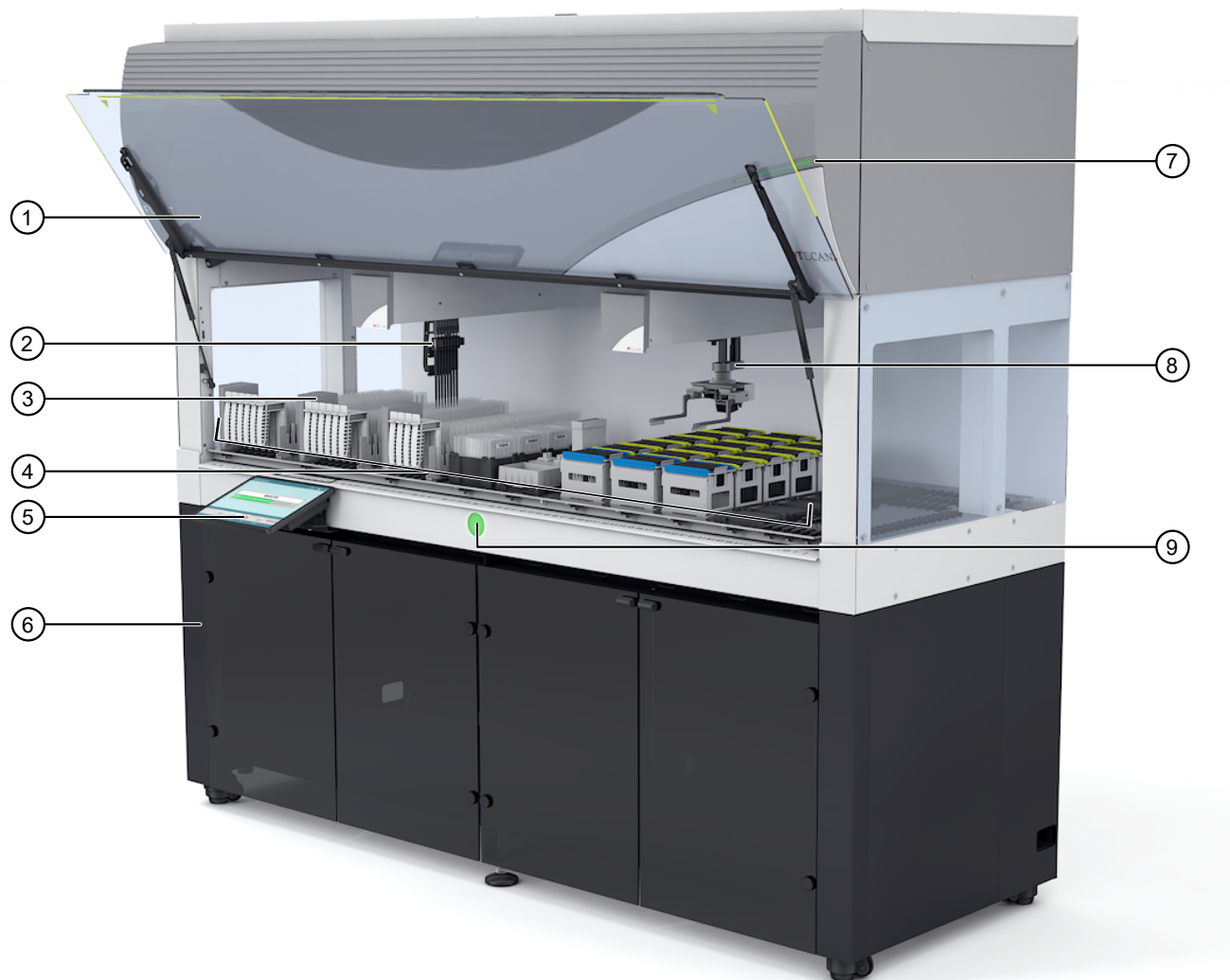


Figure 1 Tecan™ Fluent™ 1080 Automation Workstation

- |  |  |
|--|--|
| ① Front Safety Panel                                   | ⑥ Cabinet  |
| ② Flexible Channel Arm™ with Air System liquid handler | ⑦ Top status lamp                                  |
| ③ Tecan™ FluentID™ Tube Barcode Scanner × 3            | ⑧ Robotic Gripper Arm (RGA) Plate and Tube Gripper |
| ④ Deck   | ⑨ Power status lamp                                |
| ⑤ Touchscreen  |  |



Number	Component	Description
1	Front Safety Panel	The front safety panel opens to allow direct access to the robotic arms and to the elements on the instrument deck. If a run is in process, an interlock device prevents the front safety panel from being opened.
2	Flexible Channel Arm™ with Air System (Air FCA) liquid handler	8-channel liquid handler that uses an air displacement system to pipette liquids. The Air FCA is configured with disposable tip adapters.
3	Tecan™ FluentID™ Tube Barcode Scanner	Scans sample tube barcodes as tube runners are loaded onto the deck. For sample tube barcode requirements, see “Sample tube barcode requirements” on page 62.
4	Deck	Working area of the instrument that contains samples, reagents, and consumables. For a detailed view of the deck layout, see “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82.
5	Touchscreen	Functions as the primary operator interface for Module 1.
6	Cabinet	Houses the external power supply and a waste bin.
7	Top status lamp	The status lamp indicates the instrument status by means of different color, steady or flashing lights. The top status lamp is only active when the instrument software is running. See “Tecan™ Fluent™ Automation Workstation instrument status lamps” on page 221.
8	Robotic Gripper Arm (RGA) Plate and Tube Gripper	Robotic arm with gripper head and gripper finger that transports plates between deck positions. The RGA is equipped with a horizontal scanner for plate barcodes.
9	Power status lamp	The status lamp indicated the instrument status by means of different color, steady or flashing lights. See “Tecan™ Fluent™ Automation Workstation instrument status lamps” on page 221.

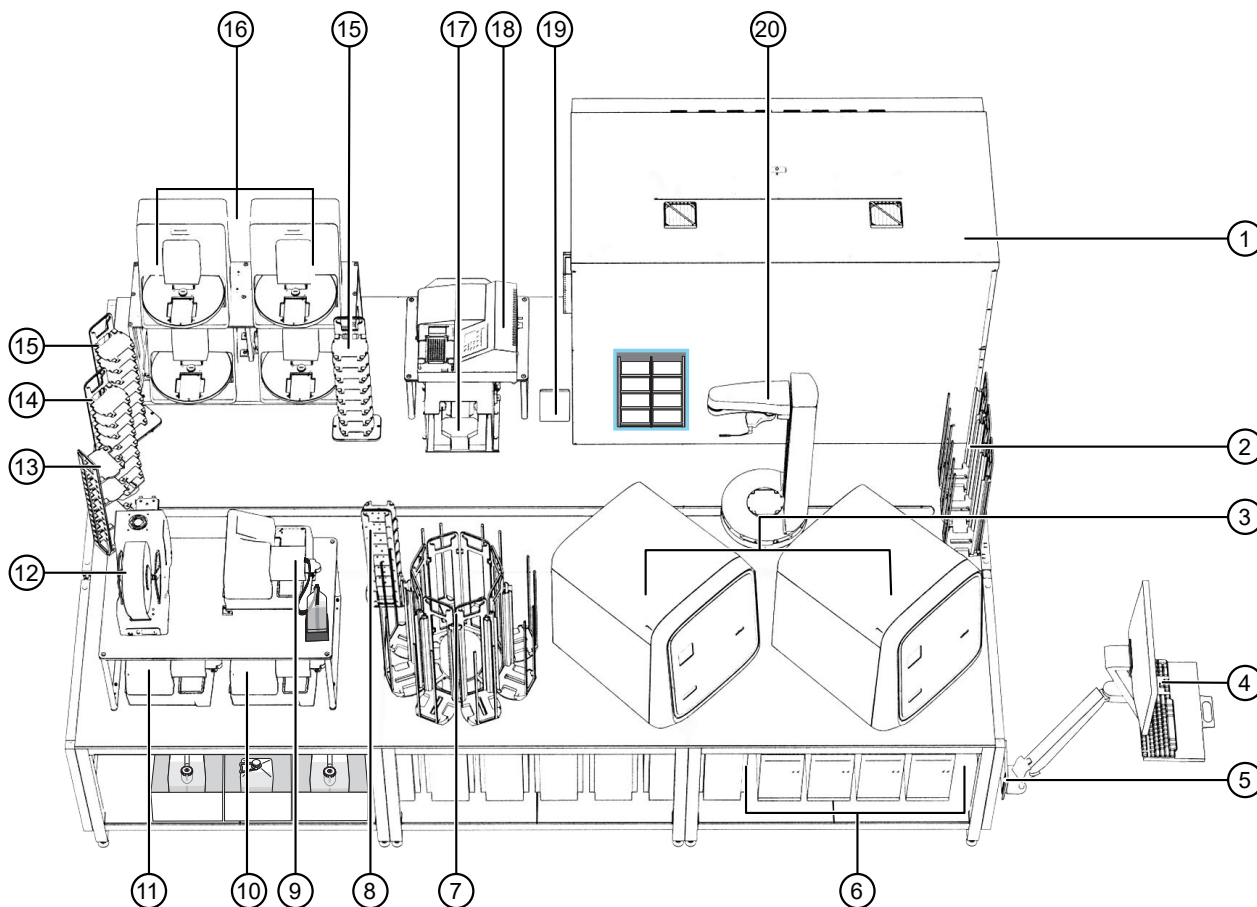
(continued)

Number	Component	Description
—	(Not pictured) Tecan™ Fluent™ 1080 Automation Workstation computer	<p>Runs the Tecan™ FluentControl™ Software v3.0.</p> <p>Also used to access the Module 1 Load Indicator timer in the SampleManager LIMS™ Software Web Client.</p> <p>Microsoft™ Defender v4.1 is installed on this PC. It is not recommended to modify Microsoft™ Defender settings or install alternate antivirus software, as this may interfere with the functioning of the Amplitude™ Solution. The following Microsoft™ Defender settings are in place to accommodate the Amplitude™ Solution:</p> <ul style="list-style-type: none"> <li>• Auto-update is disabled</li> </ul>
—	(Not pictured) Hand-held scanner	Used by the technician to scan the reagent barcodes when loading the bottles onto the Tecan™ Fluent™ 1080 Automation Workstation deck.

## SampleManager LIMS™ Software computer

The system includes a computer that runs the desktop version of the SampleManager LIMS™ Software Version 12.2. SampleManager LIMS™ Software can also be accessed on the other system computers using the Web Client. For more information about the SampleManager LIMS™ Software, see Appendix E, “SampleManager LIMS™ Software”.

## Module 2 layout and components



**Figure 2** Module 2 layout and components

For descriptions of the Module 2 components and their functions, see Table 1 on page 20.

- |   |   |
|---|---|
| ① Tecan™ Fluent™ 780 Automation Workstation with the Thermo Scientific™ A25 Refrigerated Circulator | ⑪ Multidrop™ Combi Reagent Dispenser 2 (Combi 2)  |
| ② RNA Elution Plate Stacker × 4   | ⑫ ALPS™ 3000 Automated Microplate Heat Sealer     |
| ③ QuantStudio™ 7 Flex Real-Time PCR System × 2  | ⑬ Hotel Input (incoming sample extraction plates) |
| ④ Module 2 computer station   | ⑭ Hotel Output (outgoing RNA elution plates)      |
| ⑤ (Not pictured) Spinnaker™ Microplate Robot Mini-Hub Control Puck                                  | ⑮ In-process plate staging hotel × 2              |
| ⑥ Computers   | ⑯ KingFisher™ Presto Purification System × 4      |
| ⑦ Wash Plate Stacker Carousel   | ⑰ Agilent™ Microplate Centrifuge                  |
| ⑧ Hotel for RT-PCR reaction plate balance   | ⑱ BioTek™ ELx405™ Select Microplate Washer        |
| ⑨ Multidrop™ Combi Reagent Dispenser 1 (Combi 1)  | ⑲ Solid waste chute                               |
| ⑩ Multidrop™ Combi Reagent Dispenser 3 (Combi 3)  | ⑳ Spinnaker™ Microplate Robot on BenchTrak        |

Table 1 Module 2 layout and components

Number	Component	Description
1	Tecan™ Fluent™ 780 Automation Workstation	<p>Transfers sample RNA and TaqPath™ COVID-19 High-Throughput Combo Kit reagents to MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plates with Barcode for real-time RT-PCR.</p> <p>Includes a computer that runs the Tecan™ FluentControl™ Software v3.0. The computer can be accessed using the Module 2 computer station. Microsoft™ Defender v4.1 is installed on this PC. It is not recommended to modify Microsoft™ Defender settings or install alternate antivirus software, as this may interfere with the functioning of the Amplitude™ Solution. The following Microsoft™ Defender settings are in place to accommodate the Amplitude™ Solution:</p> <ul style="list-style-type: none"> <li>• Auto-update is disabled</li> </ul> <p>For more information about the Tecan™ Fluent™ 780 Automation Workstation, see “Module 2 Tecan™ Fluent™ 780 Automation Workstation components” on page 23.</p>
	(Not pictured) Thermo Scientific™ A25 Refrigerated Circulator	Chills the reagents on the Tecan™ Fluent™ 780 Automation Workstation.
2	RNA Elution Plate Stacker × 4	Holds 40 (10 per stack) KingFisher™ Deep-Well 96 Plates with Barcodes with tip combs inserted (RNA elution plates).
3	Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System × 2	Performs real-time RT-PCR.

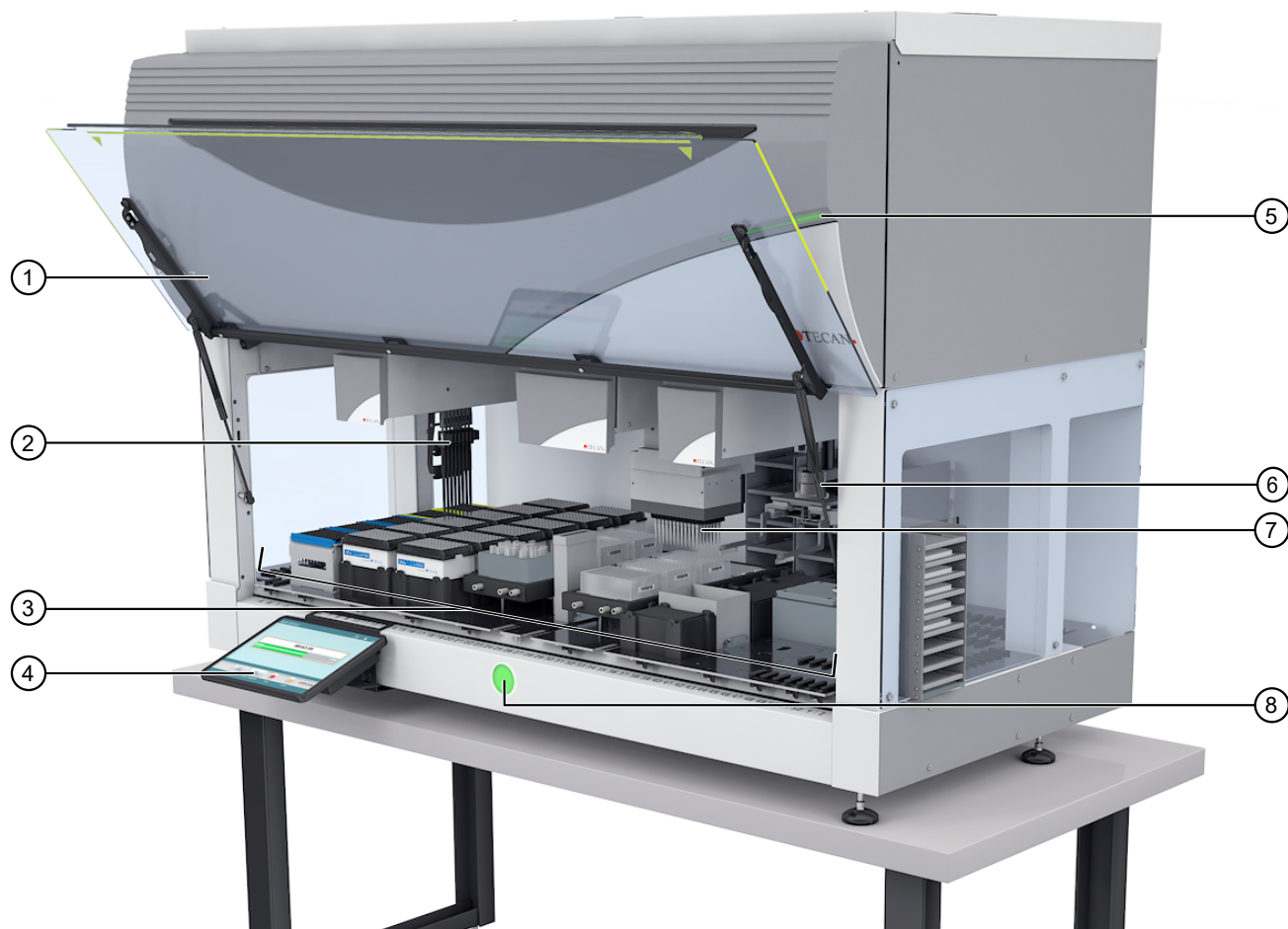
Table 1 Module 2 layout and components (continued)

Number	Component	Description
4	Module 2 computer station	<p>Computer interface that is used to control Module 2.</p> <p>Displays the following computer desktops:</p> <ul style="list-style-type: none"> <li>• Momentum™ Workflow Scheduler Software 6.1 computer, also runs the following software: <ul style="list-style-type: none"> <li>– COVID-19 Interpretive Software Driver v1.2</li> <li>– BioTek™ Liquid Handling Control Software 2.2</li> <li>– FILLit™ Software 2.0 for Multidrop™ Combi Reagent Dispensers</li> <li>– BindIt™ Software 4.0 for KingFisher™ Purification Systems</li> </ul> </li> </ul> <p><b>Note:</b> The operator does not interact directly with the COVID-19 Interpretive Software Driver, FILLit™ Software, or BindIt™ Software.</p> <ul style="list-style-type: none"> <li>• QuantStudio™ 7 Flex Real-Time PCR System 1 computer, running the QuantStudio™ Real-Time PCR Software v1.7</li> <li>• QuantStudio™ 7 Flex Real-Time PCR System 2 computer, running the QuantStudio™ Real-Time PCR Software v1.7</li> <li>• Tecan™ Fluent™ 780 Automation Workstation computer, running the Tecan™ FluentControl™ Software v3.0. Microsoft™ Defender v4.1 is installed on this PC. It is not recommended to modify Microsoft™ Defender settings or install alternate antivirus software, as this may interfere with the functioning of the Amplitude™ Solution. The following Microsoft™ Defender settings are in place to accommodate the Amplitude™ Solution: <ul style="list-style-type: none"> <li>– Auto-update is disabled</li> </ul> </li> </ul> <p>For information about switching between the computer desktop displays, see “Initialize Module 2 if offline” on page 98.</p>
5	(Not pictured) Spinnaker™ Microplate Robot Mini-Hub Control Puck	Powers on, energizes, resets, or shuts off the Spinnaker™ Microplate Robot.
6	Computers	Computers accessed using the Module 2 computer station.
7	Wash Plate Stacker Carousel	Holds 80 × KingFisher™ Deep-Well 96 Plate with Barcode for use during the RNA extraction wash steps.
8	Hotel for RT-PCR reaction plate balance	Holds the balance plate for the real-time RT-PCR reaction plate.
9	Thermo Scientific™ Multidrop™ Combi Reagent Dispenser 1 (Combi 1)	Dispenses MagMAX™ HT Elution Solution for RNA extraction.
10	Thermo Scientific™ Multidrop™ Combi Reagent Dispenser 3 (Combi 3)	Dispenses Wash 2 (80% ethanol) for RNA extraction.

Table 1 Module 2 layout and components (continued)

Number	Component	Description
11	Thermo Scientific™ Multidrop™ Combi Reagent Dispenser 2 (Combi 2)	Dispenses MagMAX™ HT Wash Solution (Wash 1) for RNA extraction.
12	Thermo Scientific™ ALPS™ 3000 Automated Microplate Heat Sealer	Seals the MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plates with Barcode for real-time RT-PCR and the outgoing RNA elution plates.
13	Hotel Input	Holds incoming sample extraction plates.
14	Hotel Output (outgoing RNA elution plate)	Holds outgoing RNA elution plates.
15	In-process extraction plate staging hotel × 2	Holds in-process plates that are loaded and unloaded by the Spinnaker™ Microplate Robot.
16	Thermo Scientific™ KingFisher™ Presto Purification System with 96 Deep Well Head × 4	Extracts sample RNA.
17	Agilent™ Microplate Centrifuge	Centrifuges real-time RT-PCR reaction plates and RNA elution plates.
18	BioTek™ ELx405™ Select Microplate Washer	Separates liquid waste for disposal.
19	Solid waste chute	Provides access to the solid waste bin.
20	Thermo Scientific™ Spinnaker™ Microplate Robot on BenchTrak	Moves plates between the various devices.

## Module 2 Tecan™ Fluent™ 780 Automation Workstation components



- ① Front Safety Panel
- ② Flexible Channel Arm™ with Air System liquid handler
- ③ Deck
- ④ Touchscreen

- ⑤ Top status lamp
- ⑥ Robotic Gripper Arm (RGA) Plate and Tube Gripper
- ⑦ MultiChannel Arm™ liquid handler
- ⑧ Power status lamp

Number	Component	Description
1	Front Safety Panel	The front safety panel opens to allow direct access to the robotic arms and to the elements on the instrument deck.  If a run is in process, an interlock device prevents the front safety panel from being opened.
2	Flexible Channel Arm™ with Air System (Air FCA) liquid handler	8-channel liquid handler that uses an air displacement system to pipette liquids. The Air FCA is configured with disposable tip adapters.
3	Deck	Working area of the instrument that contains samples, reagents, and consumables.
4	Touchscreen	Functions as the operator interface for Tecan™ Fluent™ 780 Automation Workstation maintenance tasks.
5	Top status lamp	The status lamps indicate the instrument status by means of different color, steady or flashing lights.  The top status lamp is only active when software is running.  See “Tecan™ Fluent™ Automation Workstation instrument status lamps” on page 221.
6	Robotic Gripper Arm (RGA) Plate and Tube Gripper	Robotic arm with gripper head and gripper finger that transports plates between deck positions.  The RGA is equipped with a horizontal scanner for plate barcodes.
7	MultiChannel Arm™ liquid handler	384-channel liquid handler that uses an air displacement system to pipette liquids. All pipetting head channels aspirate and dispense simultaneously. The pipetting head is configured with disposable tips adapters.
8	Power status lamp	The status lamps indicate the instrument status by means of different color, steady or flashing lights.  See “Tecan™ Fluent™ Automation Workstation instrument status lamps” on page 221.



## Order Amplitude™ Solution reagents and consumables

The ordering of the Amplitude™ Solution reagents and consumables is managed by your Sales Representative in accordance with your laboratory Supply Agreement.

If you need assistance with an existing order, contact Customer Care at [amplitude.cs@thermofisher.com](mailto:amplitude.cs@thermofisher.com).

The following reagent and consumable kits are available to use with the system:

Component	Amount	Cat. No.	Sub-kits
TaqPath™ COVID-19 High-Throughput Combo Kit	20,000 reactions	A49869	TaqPath™ COVID-19 Module 1 MS2 Phage Control × 3
			TaqPath™ COVID-19 Module 2 Assay Kit × 3
			TaqPath™ COVID-19 Control × 3
			TaqPath™ COVID-19 Module 2 Control Dilution Buffer × 3
Amplitude™ High-Throughput Consumable Package 1 Reagent Kit	20,000 reactions	A49598	MagMAX™ MVPII HT Module 1 Sample Prep Kit × 3
			MagMAX™ MVPII HT Module 2 Sample Prep Kit × 3
			TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX) × 3
			TaqPath™ HT Module 2 Empty Mixing Tubes (5-mL) × 3
Amplitude™ High-Throughput Consumable Package 3 Plastics	40,000 reactions	A49663	Amplitude™ Plastics Combo Kit 1
			Amplitude™ Plastics Combo Kit 2
			Nunc™ Microplate Lids <sup>[1]</sup>

<sup>[1]</sup> Nunc™ Microplate Lids are provided to manually cover sample extraction plates for transfer from Module 1 to Module 2, if needed, in accordance with the guidelines established by your laboratory.

For information about other system reagents and consumables, see “Additional reagents and consumables” on page 29.

## Contents and storage

### TaqPath™ COVID-19 High-Throughput Combo Kit contents and storage

The TaqPath™ COVID-19 High-Throughput Combo Kit (Cat. No. A49869) contains sufficient reagents for 20,000 reactions.

The ordering of the Amplitude™ Solution reagents and consumables is managed by your Sales Representative in accordance with your laboratory Supply Agreement.

**Table 2 TaqPath™ COVID-19 High-Throughput Combo Kit contents and storage (Cat. No. A49869)**

Contents		Amount	Storage <sup>[1]</sup>
TaqPath™ COVID-19 Module 1 MS2 Phage Control		6 × 10 mL per kit; 3 kits included	–30°C to –10°C
TaqPath™ COVID-19 Module 2 Assay Kit	TaqPath™ COVID-19 HT qPCR Assay	6 × 1,600 µL per kit; 3 kits included	–30°C to –10°C
	2-mL tubes <sup>[2]</sup>	6 tubes per kit; 3 kits included	15°C to 30°C
TaqPath™ COVID-19 Control		3 × 25 µL per kit; 3 kits included	≤–70°C
TaqPath™ COVID-19 Module 2 Control Dilution Buffer		3 × 750 µL per kit; 3 kits included	–30°C to –10°C

<sup>[1]</sup> See label for expiration date.

<sup>[2]</sup> Empty plastic tubes used for the serial dilution of the TaqPath™ COVID-19 Control in the TaqPath™ COVID-19 Module 2 Control Dilution Buffer.

## Amplitude™ High-Throughput Consumable Package 1 Reagent Kit contents and storage

The Amplitude™ High-Throughput Consumable Package 1 Reagent Kit (Cat. No. A49598) contains sufficient reagents for 20,000 reactions. The Amplitude™ High-Throughput Consumable Package 1 Reagent Kit consists of the following kit components:

- 3 × MagMAX™ MVPII HT Module 1 Sample Prep Kit
- 3 × MagMAX™ MVPII HT Module 2 Sample Prep Kit
- 3 × TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX)
- 3 × TaqPath™ HT Module 2 Empty Mixing Tubes (5-mL)

The ordering of the Amplitude™ Solution reagents and consumables is managed by your Sales Representative in accordance with your laboratory Supply Agreement.

**Table 3 MagMAX™ MVPII HT Module 1 Sample Prep Kit contents and storage**

Contents	Amount	Storage <sup>[1]</sup>
MagMAX™ HT Binding Solution	3 × 800 mL	15°C to 25°C
MagMAX™ HT Binding Beads	3 × 30 mL	
MagMAX™ HT Water	3 × 20 mL	
MagMAX™ HT Proteinase K	3 × 20 mL	

<sup>[1]</sup> See label for expiration date.

**Table 4 MagMAX™ MVPII HT Module 2 Sample Prep Kit contents and storage**

Contents	Amount	Storage <sup>[1]</sup>
MagMAX™ HT Wash Solution	3 × 1,500 mL	15°C to 25°C
MagMAX™ HT Elution Solution	1 × 700 mL	
MagMAX™ HT Water	3 × 20 mL	

<sup>[1]</sup> See label for expiration date.

**Table 5 TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX) contents and storage**

Contents	Amount	Storage <sup>[1]</sup>
TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX)	6 × 10 mL	-30°C to -10°C

<sup>[1]</sup> See label for expiration date.

**Table 6 TaqPath™ HT Module 2 Empty Mixing Tubes (5-mL) contents and storage**

Contents	Amount	Storage
TaqPath™ HT Module 2 Empty Mixing Tubes (5-mL)	25 tubes	15°C to 25°C

## Amplitude™ High-Throughput Consumable Package 3 Plastics contents

Amplitude™ High-Throughput Consumable Package 3 Plastics (Cat. No. A49663) contains enough plates, reservoirs, and tip combs to perform 40,000 reactions using the Amplitude™ Solution.

The ordering of reagents and consumables for use with the Amplitude™ Solution is managed by your Sales Representative in accordance with your laboratory Supply Agreement.

Amplitude™ High-Throughput Consumable Package 3 Plastics includes the following components:

**Table 7 Amplitude™ Plastics Combo Kit 1 contents**

Contents	Amount
<b>Plates</b>	
KingFisher™ Deep-Well 96 Plates with Barcodes	50 per pack × 36 packs
MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plates with Barcode	20 plates per pack × 6 packs
<b>Tip combs</b>	
KingFisher™ 96 tip combs for deep-well magnets	100 per pack × 5 packs

**Table 8 Amplitude™ Plastics Combo Kit 2 contents**

Contents	Amount
<b>Tips</b>	
200 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	24 racks per case (2,304 tips) × 3 cases
1,000 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	24 racks per case (2,304 tips) × 23 cases
150 µL MultiChannel Arm™ (MCA) Disposable Tips Rack	40 racks per case (3,840 tips) × 11 cases
<b>Reservoirs</b>	
Axygen™ Single Well High Profile Reagent Reservoir	25 reservoirs per case × 2 cases
Axygen™ Multi Well Low Profile Reagent Reservoir	25 reservoirs per case × 1 case

**Table 9 Nunc™ Microplate Lids contents**

Contents	Amount
Nunc™ Microplate Lids	60 per pack × 8 packs

## Additional reagents and consumables

The ordering of reagents and consumables is managed by your Sales Representative in accordance with your laboratory Supply Agreement. The reagents and consumables listed in Table 10 are ordered in a 2-month supply. The 2-month supply for your laboratory will depend on your testing throughput:

- **1 shift per day**—The system is idle overnight and weekends (up to 6 runs per day or up to 24 plates per day).
- **3 shifts per day**—The system is continuously operational with no idle time (approximately 20 runs per day or ~20–80 plates per day).

**IMPORTANT!** The required amounts listed in Table 10 assume that each run includes 4 plates, or 376 samples. If running <4 plates per run, reagent and consumable usage rate can vary from system to system.

Your Sales Representative will help to set up the reagent and consumable orders for your laboratory. If you need assistance with an existing order, contact Customer Care at [amplitude.cs@thermofisher.com](mailto:amplitude.cs@thermofisher.com).

**Note:** Shipments of 80% Ethanol are managed by Customer Care to ensure compliance with local regulations and your laboratory storage capacity. Depending on local regulations and your laboratory storage capacity, this 2-month supply may arrive in multiple shipments.

**Table 10** Additional reagents and consumables

Reagent or consumable	Required amount <sup>[1]</sup>	Approximate 2-month supply <sup>[1]</sup>
80% Ethanol (4 L bottle)	2 bottles (8 L) per 18 runs	<b>1 shift per day</b> — 30 bottles (120 L)
		<b>3 shifts per day</b> — 136 bottles (544 L)
Bead Mix Baffle (for Binding Bead Mix trough)	1 baffle per shift	<b>1 shift per day</b> — 12 boxes (5 baffles/box)
		<b>3 shifts per day</b> — 36 boxes (5 baffles/box)
Oil Level Sensor (for silicone oil trough)	1 sensor per shift	<b>1 shift per day</b> — 12 boxes (5 sensors/box)
		<b>3 shifts per day</b> — 36 boxes (5 sensors/box)
Silicone oil (500 mL bottle)	1 bottle per 6 runs	<b>1 shift per day</b> — 44 bottles
		<b>3 shifts per day</b> — 204 bottles
Multidrop™ Combi long standard tube dispensing cassette (tubing length 200 cm) <sup>[2]</sup>	<b>1 shift per day:</b> <ul style="list-style-type: none"> <li>• 1 cassette every 11 days</li> <li>• 1 cassette every 18 days</li> </ul>	<b>1 shift per day</b> — 7 cassettes
	<b>3 shifts per day:</b> <ul style="list-style-type: none"> <li>• 1 cassette every 4 days</li> <li>• 1 cassette every 6 days</li> </ul>	<b>3 shifts per day</b> — 27 cassettes

Table 10 Additional reagents and consumables (continued)

Reagent or consumable	Required amount <sup>[1]</sup>	Approximate 2-month supply <sup>[1]</sup>
Multidrop™ Combi standard tube dispensing cassette 5-pack	1 shift per day— 1 cassette/144 days	1 shift per day—1 pack
	3 shifts per day— 1 cassette/50 days	3 shifts per day—1 pack
Clear Seal Heat Sealing Film for the ALPS™ 3000 Automated Microplate Heat Sealer	1 roll per 980 runs	1 shift per day—1 roll
		3 shifts per day—2 rolls

<sup>[1]</sup> Assuming 4 plates per run.

<sup>[2]</sup> This type of cassette is used for dispensing two different reagents.

## Required materials not supplied

Unless otherwise indicated, all materials are available through [thermofisher.com](https://www.thermofisher.com). "MLS" indicates that the material is available from [fisherscientific.com](https://www.fisherscientific.com) or another major laboratory supplier.

Item	Source
<b>Equipment</b>	
Laboratory freezers <ul style="list-style-type: none"> <li>• -30°C to -10°C</li> <li>• ≤ -70°C</li> </ul>	MLS
Laboratory refrigerator (4°C)	MLS
Biological safety cabinet (BSL-2)	MLS
Bench or table for staging reagents and plates during Module 2 operation	MLS
Flammable liquid safety storage cabinet for storage of 80% Ethanol	MLS
(Optional) Incubator for heat inactivation of samples <sup>[1]</sup>	MLS
Laboratory mixer, vortex or equivalent	MLS
Microcentrifuge	MLS
Centrifuge, with a rotor that accommodates standard microplates	MLS
Analytical balance (resolution of 0.01 mg)	MLS
Multichannel adjustable pipette (capable of dispensing 20 µL)	MLS
Step stool (used to reach the ALPS™ 3000 Automated Microplate Heat Sealer)	MLS
Tube racks for 50-mL conical tubes	MLS
Enclosed container for transfer of sample extraction plates from Module 1 to Module 2	MLS

(continued)

Item	Source
3.57 mm hex wrench	MLS
Compressed air	MLS
<b>Tubes, plates, and other consumables</b>	
Spectrum Solutions™ SDNA-2000 Saliva Collection Device	SDNA-2000
Barcodes for sample tubes (see “Sample tube barcode requirements” on page 62)	MLS
Additional caps for sample tubes (13 mm, 16 mm, or 17 mm)	MLS
(Optional) Sterile tubes to transfer sample if original tubes contain collection swabs: <ul style="list-style-type: none"> <li>• 12–14 mm diameter, 140 mm height</li> <li>• 15–17 mm diameter, 140 mm height</li> <li>• 16–18 mm diameter, 140 mm height</li> </ul>	MLS
(Optional) Sterile, disposable transfer pipettes to transfer sample if original tubes contain collection swabs	MLS
MicroAmp™ Optical Adhesive Film	<a href="#">4311971</a>
Parafilm™ film	MLS
(Optional) Mixing container for Binding Bead Mix (if mixing for <6 runs in 24 hours)	MLS
50-mL conical tubes	MLS
25-mL liquid reservoir	MLS
Autoclavable Biohazard Bags, 55 gal (100 bags)	ACLB142848 <a href="#">grainger.com</a>
<b>Reagents</b>	
Deionized water	MLS
70–80% Ethanol for cleaning <sup>[2]</sup>	MLS
(Optional) Additional reagents for cleaning (see Appendix J, “Cleaning and decontamination”)	MLS

<sup>[1]</sup> For more information, see “Sample inactivation guidelines” on page 63.

<sup>[2]</sup> Do not use the Wash 2 80% Ethanol for cleaning procedures. The volume of 80% Ethanol that is ordered for Wash 2 does not include sufficient coverage to use for cleaning purposes.

## Assay limitations

- The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit performance was established using anterior nasal swab, nasopharyngeal swab, and saliva samples only. Specimen types other than anterior nasal swab, nasopharyngeal swab, or saliva should not be tested with the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit.
- The performance of this test was not evaluated in an asymptomatic patient population of individuals suspected of COVID-19 by their healthcare providers.
- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
- Saliva must be collected, transported, and stored according to the Spectrum Solutions™ SDNA-2000 Saliva Collection Device instructions for use.
- The workflow for the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit must be performed according to the specified methods listed in this procedure.
- False-negative results may arise from:
  - Improper sample collection
  - Degradation of the SARS-CoV-2 RNA during shipping/storage
  - Specimen collection after SARS-CoV-2 RNA can no longer be found in the specimen matrix
  - Using unauthorized extraction or assay reagents
  - The presence of RT-PCR inhibitors
  - Mutation in the SARS-CoV-2 virus
  - Failure to follow instructions for use
- False-positive results may arise from:
  - Cross contamination during specimen handling or preparation
  - Cross contamination between patient samples
  - Specimen mix-up
  - RNA contamination during product handling
- The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit cannot rule out diseases caused by other bacterial or viral pathogens.
- Certain mutations may affect detection of individual targets with the TaqPath™ COVID-19 HT Kit, including the B.1.1.7 (Alpha) and B.1.1.529 (Omicron) variants of SARS-CoV-2 which may exhibit positive results for the N and ORF1ab targets and negative results for the S-gene target. If such a pattern of detection is observed, further characterization of the specimen by sequence analysis should be considered.
- Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Negative results do not preclude infection with SARS-CoV-2 virus and should not be the sole basis of a patient management decision.



- Laboratories are required to report all test results to the appropriate public health authorities.
- Laboratories should include test reports to healthcare providers.

## Samples and controls

Patient samples must be collected according to appropriate laboratory guidelines. The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit can be used with patient samples collected via nasopharyngeal swab, anterior nasal swab, or saliva..

Store patient samples according to applicable regulatory guidelines.

The following positive and negative test controls are used with the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit to ensure that test results are interpreted accurately:

Control	Used to monitor	Assays
Positive Control (TaqPath™ COVID-19 Control)	RT-PCR reaction setup and reagent integrity	All three SARS-CoV-2 assays
MS2 Phage Control (TaqPath™ COVID-19 Module 1 MS2 Phage Control)	RNA extraction	MS2 assay
Negative Control	Cross-contamination during RNA extraction and RT-PCR reaction setup	All three SARS-CoV-2 assays
		MS2 assay

## Amplitude™ Solution workflow

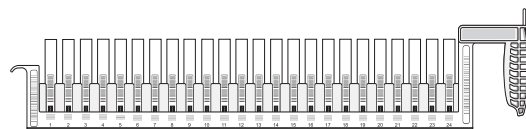
## Amplitude™ Solution workflow



20 m

**Chapter 5, Prepare sample tube runners**

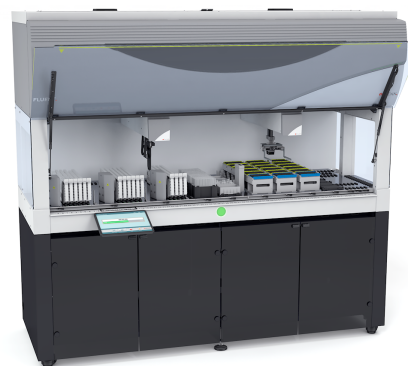
A Module 1 technician loads up to 376 sample tubes into the Tecan™ sample tube runners.



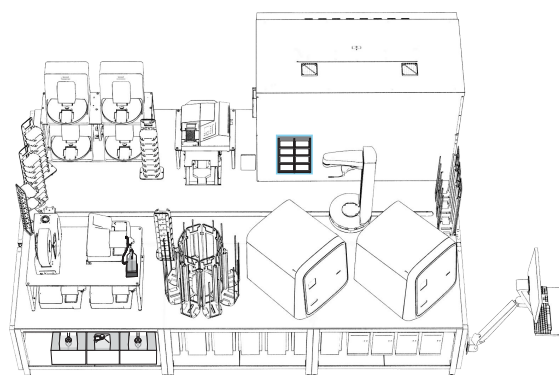
1 h

**Chapter 6, Perform a Module 1 run**

During a Module 1 run, the Tecan™ Fluent™ 1080 Automation Workstation transfers samples and reagents for RNA extraction to deep-well plates. For more information, see “Module 1 workflow” on page 69.

2 h  
15 m**Chapter 7, Perform a Module 2 run**

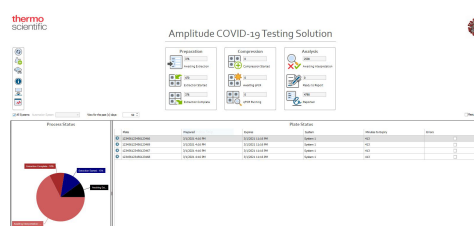
During a Module 2 run, the automated system performs RNA extraction and real-time RT-PCR. The results are analyzed and sent to the SampleManager LIMS™ Software for review. For more information, see “Module 2 workflow” on page 97.



15 m

**Chapter 8, Review results (automated workflow)**

Analyzed real-time RT-PCR results are automatically transferred to the SampleManager LIMS™ Software for review, authorization, and archival. Once authorized, results are exported as a CSV file.



Variable

**Chapter 9, Perform regular maintenance**

Regular maintenance tasks are performed daily, weekly, monthly, and as needed.



# Before you begin

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- In-use reagent stability ..... 40

## Network and password security requirements

### Network configuration and security

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

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

### Password security

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

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

## Amplitude™ Solution operator requirements

Running the Amplitude™ Solution at maximum throughput requires multiple full-time technicians per shift. Additional supervisory personnel is required for consumables stocking, equipment maintenance, sample management, and results analysis. The functions and training required for the technicians are described in the following table.

Operator	Functions and training
Module 1 technician	<ul style="list-style-type: none"> <li>Performs functions under Biosafety Level 2 (BSL2) conditions, frequently in a biosafety cabinet and in full personal protective equipment (PPE)</li> <li>Operates Module 1, and performs regular maintenance and cleaning tasks</li> <li>Applies barcodes to sample tubes</li> <li>Uncaps and places sample tubes in tube runners before each Module 1 run</li> <li>Removes sample tubes from tube runners after each Module 1 run, then recaps and stores the tubes</li> <li>Must have BSL2 training and certification, and training for operating Module 1</li> </ul>
Module 2 technician	<ul style="list-style-type: none"> <li>Performs functions under Biosafety Level 1 (BSL1) conditions, with typical laboratory conditions, precautions, and PPE</li> <li>Operates Module 2, and performs regular maintenance and cleaning tasks</li> <li>Must have training for typical BSL1 laboratory tasks and operating Module 2</li> </ul>

## Warnings and precautions

The system and assay should only be operated by qualified and trained staff to avoid cross-contamination and the risk of erroneous results. For information about operator roles and requirements, see “Amplitude™ Solution operator requirements” on page 36.

- Samples and controls should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.
- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious samples.
- Always use pipette tips with aerosol barriers. Visually inspect tips to ensure filters are present. Tips that are used must be sterile and free from DNases and RNases.
- Do not eat, drink, smoke, or apply cosmetic products in the work areas.
- Modifications to assay reagents, assay protocol, or instrumentation are not permitted.
- Reagents must be stored and handled as specified in “Contents and storage” on page 26.
- Do not use system consumables or reagents after the indicated expiry date.
- Do not use the Amplitude™ Solution instruments offline to perform any tasks outside of the Amplitude™ workflow.
- Dispose of waste in compliance with local, state, and federal regulations.
- Safety Data Sheets are available upon request.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.

- For *in vitro* diagnostic use.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2 RNA, not for any other viruses or pathogens.

## About Module 2 emergency stop buttons

In the event of an emergency, hit one of the five emergency stop buttons to immediately stop the Spinnaker™ Microplate Robot. In the event of an emergency stop activation, individual instruments complete their current processes, then halt until the system is reset. The emergency stop is also triggered if the following occur:

- The technician accidentally hits an emergency stop button.
- The technician opens a system access door when the **Check in** function is not enabled by the Momentum™ Workflow Scheduler Software.
- The technician places an object in the path of the Spinnaker™ Microplate Robot.
- The technician does not empty the Module 2 solid waste, causing waste to accumulate and interfere with the Spinnaker™ Microplate Robot.

If an Emergency Stop button is pressed or triggered, you must reset the system before you can proceed (“Reset Module 2 after an emergency stop” on page 39).

If the Module 2 process cannot be recovered after the emergency stop, you must rerun the samples from Module 1, using the remaining sample in the stored sample tubes.



**CAUTION!** If the emergency stop is accidentally pressed, loss of sample can occur if reactivation takes too long.

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**Note:** In the event that an emergency requires an immediate safety disconnect of an individual instrument on Module 2, power cords at the system or instrument level can be used as safety disconnects.

---

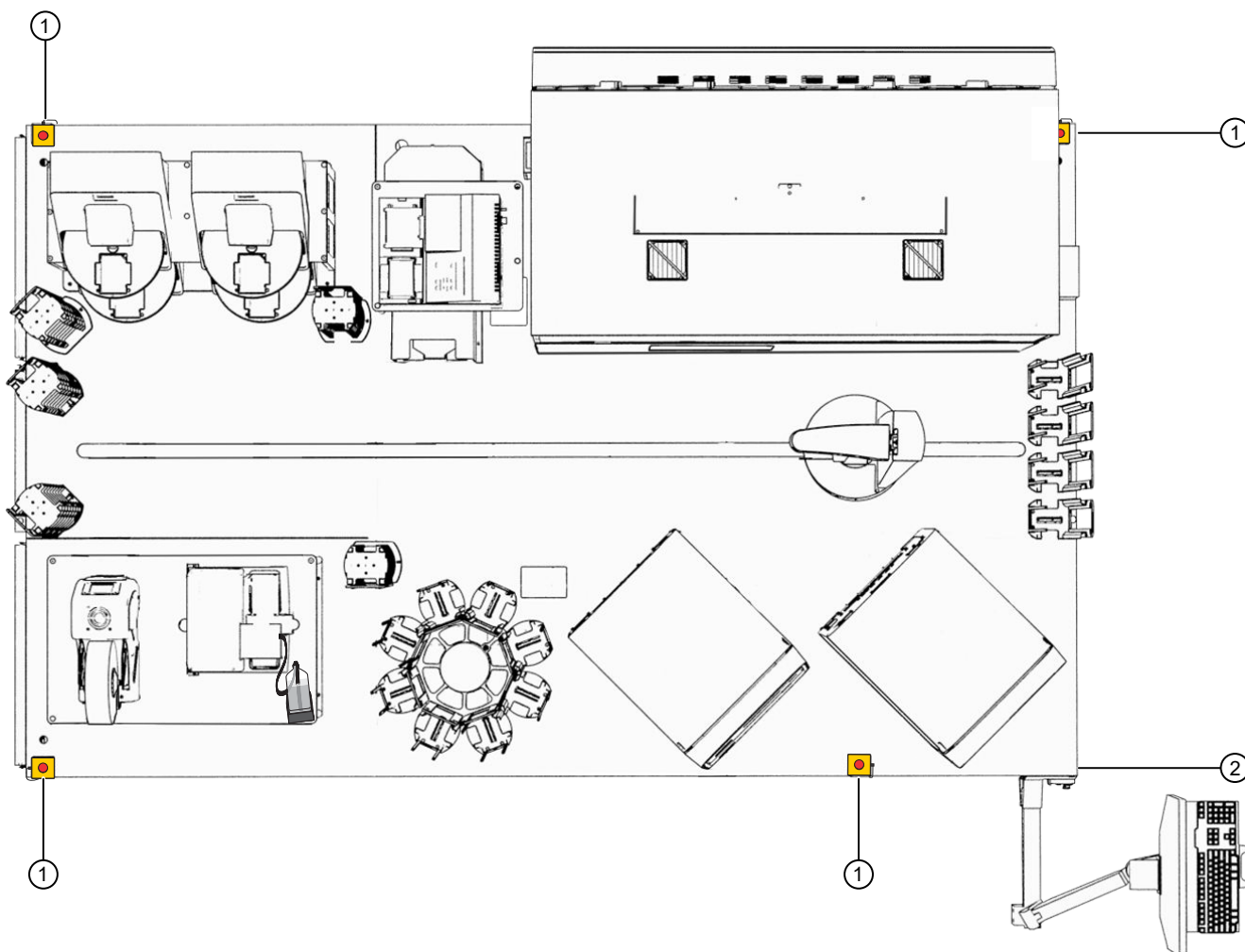
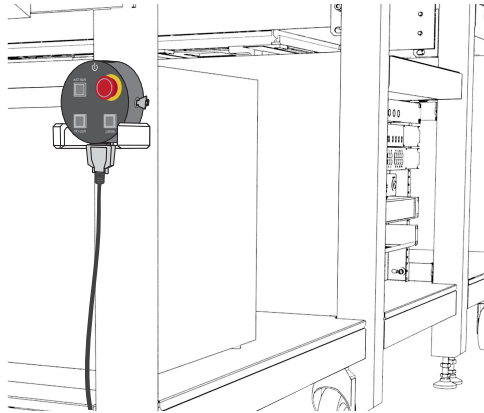


Figure 3 Locations of the Module 2 Emergency Stop buttons

- ① Emergency Stop button
- ② Spinnaker™ Microplate Robot Control Puck with Emergency Stop button

## Reset Module 2 after an emergency stop

1. Ensure that the situation which required the emergency stop has been resolved and that there are no existing hazards.
2. On the Mini-Hub Control Puck, turn the emergency stop (E-Stop) button clockwise until it pops back out.



The Mini-Hub Control Puck is mounted on the side of the table near the Module 2 computer station.

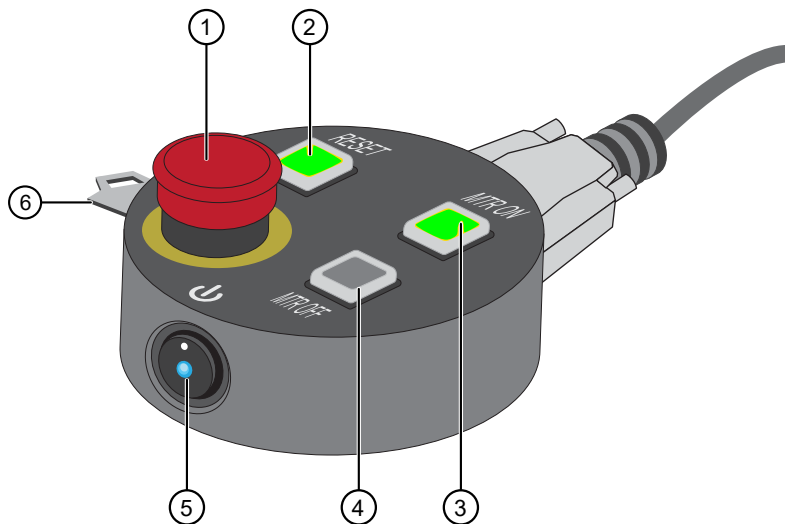


Figure 4 Mini-Hub Control Puck

- |                                     |                                       |
|-------------------------------------|---------------------------------------|
| ① Emergency Stop (E-Stop) button    | ④ Motor Off ( <b>MTR OFF</b> ) button |
| ② Reset ( <b>RESET</b> ) button     | ⑤ Power button                        |
| ③ Motor On ( <b>MTR ON</b> ) button | ⑥ Mode key-switch                     |

The power button glows blue, and the **RESET** and **MTR OFF** buttons glow red, indicating that the power to the motors is stopped.

3. Press **RESET**, then press **MTR ON** to energize the Spinnaker™ Microplate Robot.  
The **MTR ON** and **RESET** buttons glow green and the **MTR OFF** button goes dark, indicating that power to the robot motors is on.

4. On the Module 2 computer station, in the Momentum™ Software, click **Resume** or **Retry** in response to the displayed error message.
5. If necessary, in the Momentum™ Software, confirm the status of the Spinnaker™ Microplate Robot.

If the Module 2 process cannot be recovered after the emergency stop, you must rerun the samples from Module 1, using the remaining sample in the stored sample tubes.

## Ensure that you have the required materials

Before you begin preparing and running samples, ensure that you have all of the required materials to complete the desired number of runs on both Module 1 and Module 2.

- Module 1 required samples, reagents, and consumables (page 68)
- Module 2 required sample input, reagents, and consumables (page 94)

## In-use reagent stability

For stability information for reagents stored at room temperature, refer to the packaging of each reagent.

**Table 11** In-use reagent stability

Reagent	Stability information
Binding Bead Mix (prepared by customer)	Once the MagMAX™ HT Binding Solution and MagMAX™ HT Binding Beads are combined, the mix is stable for 24 hours after preparation. Store capped at room temperature (up to 30°C).
TaqPath™ COVID-19 Module 1 MS2 Phage Control	Once thawed, the TaqPath™ COVID-19 Module 1 MS2 Phage Control is stable for up to 14 days at room temperature (up to 30°C) or in the Tecan™ Fluent™ 1080 Automation Workstation reagent carrier (9°C). Perform a maximum of 5 freeze-thaw cycles.
TaqPath™ COVID-19 HT qPCR Assay	The assay is stable for up to 14 days at room temperature (up to 30°C) or in the Tecan™ Fluent™ 780 Automation Workstation reagent carrier (9°C).
TaqPath™ COVID-19 Control (undiluted)	The undiluted positive control reagent is stable for up to 48 hours at room temperature (up to 30°C) or in the Tecan™ Fluent™ 780 Automation Workstation reagent carrier (9°C). Perform a maximum of 5 freeze-thaw cycles.
Diluted TaqPath™ COVID-19 Control	Once diluted as part of the Module 2 process in the Tecan™ Fluent™ 780 Automation Workstation reagent carrier, the dilute positive control is stable for up to 14 days at up to 30°C or in the Tecan™ Fluent™ 780 Automation Workstation reagent carrier (9°C).



Table 11 In-use reagent stability (continued)

Reagent	Stability information
TaqPath™ COVID-19 Module 2 Control Dilution Buffer	The dilution buffer is stable for up to 14 days at room temperature (up to 30°C) or in the Tecan™ Fluent™ 780 Automation Workstation reagent carrier (9°C).
TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX)	The master mix is stable for up to 14 days at room temperature (up to 30°C) and in the Tecan™ Fluent™ 780 Automation Workstation reagent carrier (9°C).
Purified sample RNA	Once extracted, purified sample RNA is stable at room temperature (up to 30°C) for 1 hour, 4°C for 48 hours, and at -30°C to -10°C or at ≤ -70°C for up to 8 weeks.  Perform a maximum of 3 freeze-thaw cycles.
Assembled sample extraction plate	After the completion of the Module 1 process, the assembled sample extraction plate is stable for up to 7 hours at room temperature (up to 30°C).
Assembled RT-PCR plate	After completion of the compression process, the assembled RT-PCR plate is stable for up to 25 minutes at room temperature (up to 30°C).

# 3

## Power the system on or off

- Power on the Tecan™ Fluent™ 1080 Automation Workstation (Module 1) ..... 42
- Power on the Module 2 instruments and computers ..... 43
- Power off the Tecan™ Fluent™ 1080 Automation Workstation (Module 1) ..... 48
- Power off Module 2 instruments and computers ..... 49
- Perform a total system shutdown ..... 53
- Restart the system after a total shutdown ..... 55

We recommend that you power the system off, then restart at least once weekly.

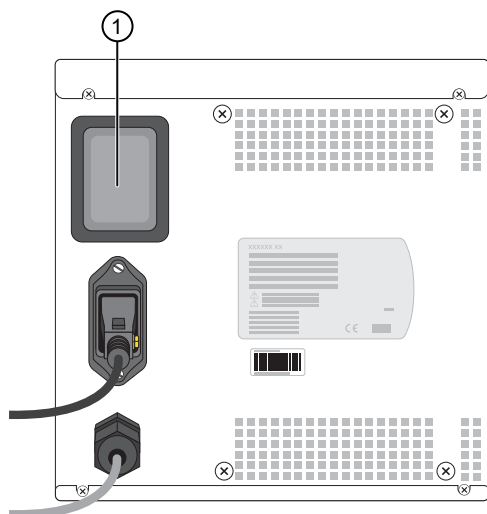
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**IMPORTANT!** Do not power off the system power strips, A25 Refrigerated Circulator chiller, or the uninterruptible power supply (UPS) units that are located under the Lab Automation Robotic Testing Platform during the weekly system power cycle. To power off the power strips and UPS units as part of a total system shutdown, see “Perform a total system shutdown” on page 53. Only perform a total system shutdown if there is a planned power outage to the laboratory.

---

### Power on the Tecan™ Fluent™ 1080 Automation Workstation (Module 1)

1. Power on the Tecan™ Fluent™ 1080 Automation Workstation using the switch on the rear of the external power supply in the instrument cabinet.



① Power switch

When the instrument is powered on, the power status lamp lights up blue.

2. Power on the Tecan™ Fluent™ 1080 Automation Workstation computer, then enter the Windows™ username and password.
3. On the Tecan™ Fluent™ 1080 Automation Workstation computer, double-click the Tecan™ FluentControl™ Software icon to start the software.

## Power on the Module 2 instruments and computers

For information about the location of Module 2 components, see “Module 2 layout and components” on page 19.

1. Power on the Module 2 computers:

Obtain the Windows™ username and password from the administrator for your laboratory.

- Momentum™ Workflow Scheduler Software computer
- QuantStudio™ 7 Flex Real-Time PCR System 1 computer
- QuantStudio™ 7 Flex Real-Time PCR System 2 computer
- Tecan™ Fluent™ 780 Automation Workstation computer

2. Press the switch on the back panel of each QuantStudio™ 7 Flex Real-Time PCR System to power on.
3. Press the switch on the back panel of the Multidrop™ Combi Reagent Dispenser to power on.  

---

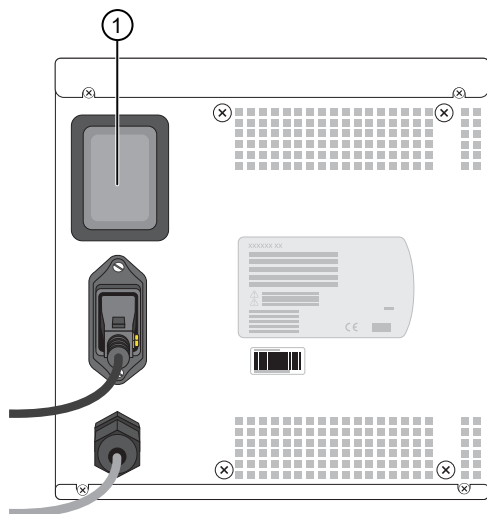
**IMPORTANT!** You must prime each Multidrop™ Combi Reagent Dispenser after powering on (see “Power on each Multidrop™ Combi Reagent Dispenser” on page 44).

---
4. Press the switch on the back panel of the ALPS™ 3000 Automated Microplate Heat Sealer to power on.
5. Press the switches on the side panels of each KingFisher™ Presto Purification System to power on.
6. Press the switch on the back panel of the BioTek™ ELx405™ Select Microplate Washer to power on.
7. Press the switch on the back panel of the Agilent™ Microplate Centrifuge to power on.
8. Press the switches on the back panels of the A25 Refrigerated Circulator bath and immersion circulator to power on. Ensure that the A25 Refrigerated Circulator is set to 9°C. For detailed instructions, see “Power on the A25 Refrigerated Circulator” on page 58.



**WARNING!** Failure to set the A25 Refrigerated Circulator to 9°C can result in inaccurate results.

9. Press the switch on the rear panel of the Tecan™ Fluent™ 780 Automation Workstation external power supply to power on.



① Power switch

When the instrument is powered on, the power status lamp will light up blue.

10. Power on the Spinnaker™ Microplate Robot Mover Link and Mini-Hub Control Puck then energize the instrument. For detailed instructions, see “Power on and energize the Spinnaker™ Microplate Robot” on page 47.

Before performing a run on Module 2, you must initialize the system and bring the components under control of the Momentum™ Workflow Scheduler Software (see “Initialize Module 2 if offline” on page 98).

## Power on each Multidrop™ Combi Reagent Dispenser

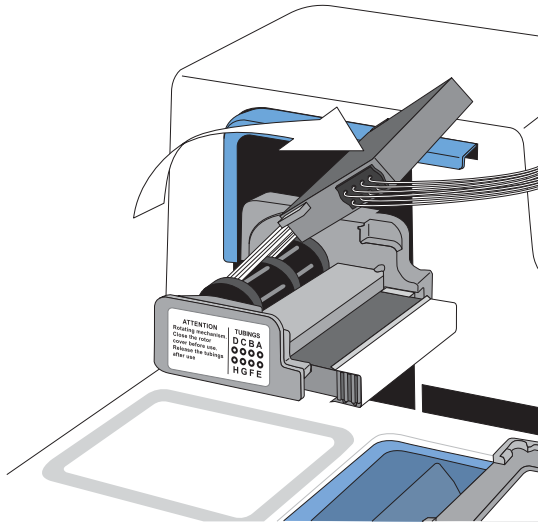
The following procedure is required when the Multidrop™ Combi Reagent Dispenser is powered on after being powered off.

1. For each Multidrop™ Combi Reagent Dispenser, move the tubing bundle from an empty bottle into the appropriate reagent vessel.

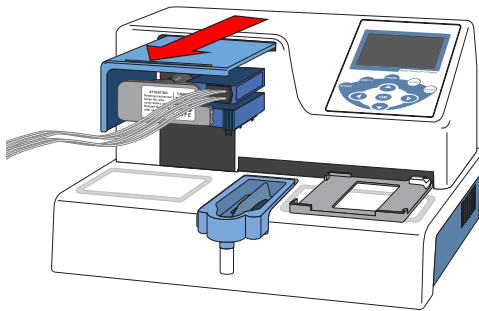


**CAUTION!** Ensure that you place the tubing bundle in the correct reagent vessel, and that there are no kinks in the tubing. Improper placement or kinks in the tubing can cause false negatives or invalid results.

2. Move the dispensing cassette to the engaged position on the Multidrop™ Combi Reagent Dispenser.



3. Pull forward the rotor cover over the rotor and dispensing cassette.



4. Turn on the power switch located at the left back panel of the instrument.

5. For each Multidrop™ Combi Reagent Dispenser, press and hold **PRIME** for the duration listed in the following table.

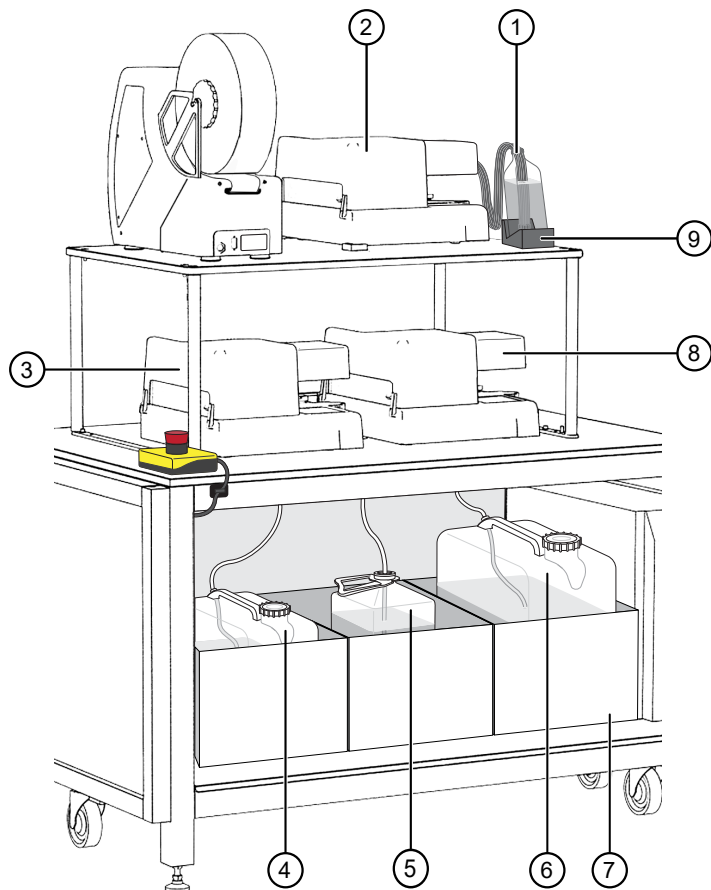


Figure 5 Multidrop™ Combi Reagent Dispenser instrument and reagent locations and reagents

- ① MagMAX™ HT Elution Solution
- ② Combi 1 (dispenses MagMAX™ HT Elution Solution)
- ③ Combi 2 (dispenses MagMAX™ HT Wash Solution)
- ④ Wash 1 (MagMAX™ HT Wash Solution) carboy
- ⑤ Waste carboy
- ⑥ Wash 2 (80% Ethanol) carboy
- ⑦ Weighted drawer with scales
- ⑧ Combi 3 (dispenses Wash 2)
- ⑨ MagMAX™ HT Elution Solution bottle scale

**IMPORTANT!** Ensure that you prime each Multidrop™ Combi Reagent Dispenser for the duration listed. Failure to adequately prime the instruments can affect performance.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	

## Power on and energize the Spinnaker™ Microplate Robot

The Mini-Hub Control Puck is mounted on the side of the table near the Module 2 computer station.

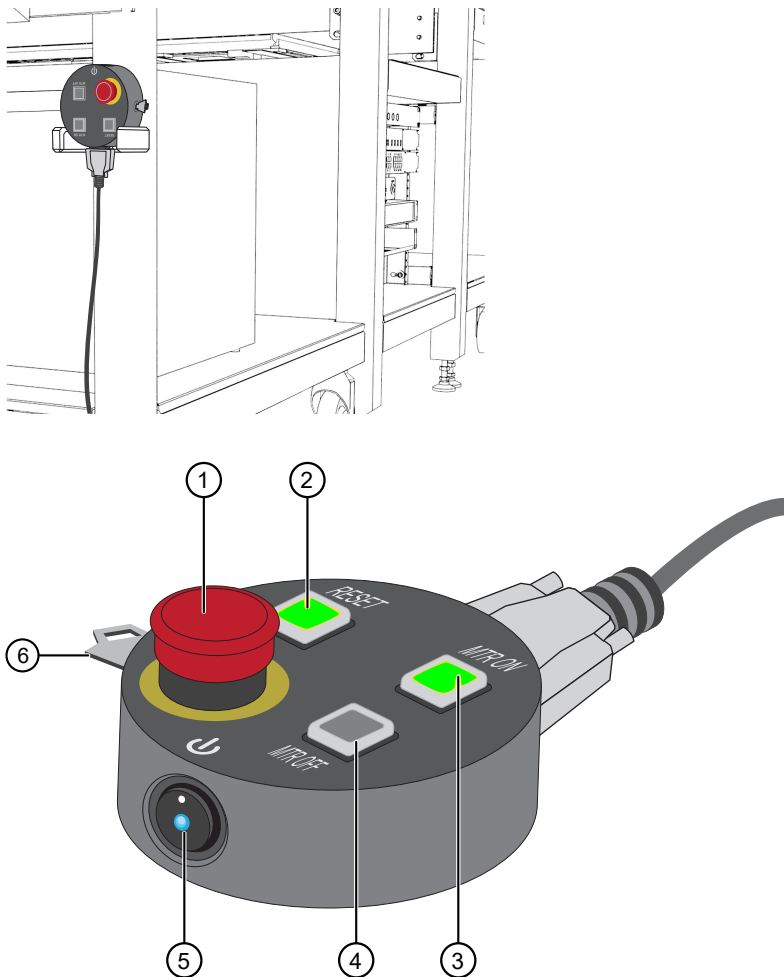


Figure 6 Mini-Hub Control Puck

- |                                     |                                       |
|-------------------------------------|---------------------------------------|
| ① Emergency Stop (E-Stop) button    | ④ Motor Off ( <b>MTR OFF</b> ) button |
| ② Reset ( <b>RESET</b> ) button     | ⑤ Power button                        |
| ③ Motor On ( <b>MTR ON</b> ) button | ⑥ Mode key-switch                     |

The power button glowing blue and the **RESET** and **MTR OFF** buttons glowing red indicates that the power to the robot motors is stopped.

1. On the Mini-Hub Control Puck, ensure that the E-Stop button is not pressed in. If the E-stop button is pressed in, turn it clockwise until the button springs back out.
2. Press the **MTR ON** button to energize the Spinnaker™ Microplate Robot.  
The **MTR ON** and **RESET** buttons glow green and the **MTR OFF** button goes dark, indicating that power to the robot motors is on.

## Power off the Tecan™ Fluent™ 1080 Automation Workstation (Module 1)



**CAUTION!** Ensure that there are no more incoming samples and that all Module 1 operations are complete before powering off the instrument.

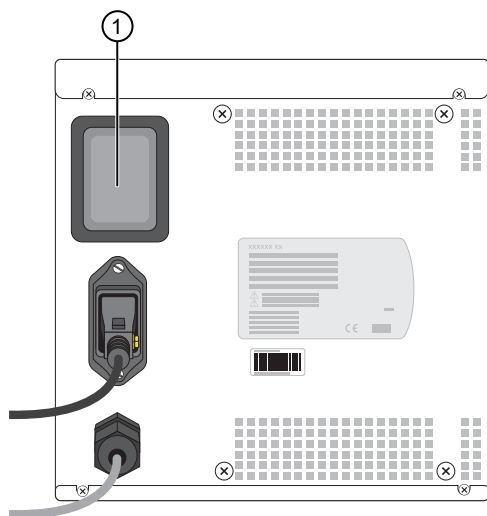
1. On the Tecan™ Fluent™ 1080 Automation Workstation computer, close out of the Tecan™ FluentControl™ Software by clicking **X** in the upper right corner.

---

**Note:** Make sure that all of the Tecan™ FluentControl™ Software dialog windows are closed out before you power off the Tecan™ Fluent™ 1080 Automation Workstation.

---

2. To power off, press the switch on the rear of the external power supply in the instrument cabinet.



① Power switch

3. Wait until the instrument status lamps turn off, then power off the Tecan™ Fluent™ 1080 Automation Workstation computer.



## Power off Module 2 instruments and computers

---

**IMPORTANT!** Only power off the instruments listed in this section during the weekly power cycle. Do not power off the system power strips, A25 Refrigerated Circulator chiller, or the uninterruptible power supply (UPS) units that are located under the Lab Automation Robotic Testing Platform. To power off the power strips and UPS units as part of a total system shutdown, see “Perform a total system shutdown” on page 53. Only perform a total system shutdown if there is a planned power outage to the laboratory.

---



**CAUTION!** Ensure that there are no more incoming sample extraction plates and that all Module 2 operations are complete before taking the system offline and powering off the instruments.

For information about the location of instruments in Module 2, see “Module 2 layout and components” on page 19.

1. On the Module 2 computer station, in the Momentum™ Software **Work Manager Dashboard**, click **Start/Stop** to take the instruments offline and out from Momentum™ Software control, then close the Momentum™ Software.
2. Close the QuantStudio™ Real-Time PCR Software and server windows.

---

**IMPORTANT!** Failure to close out of the QuantStudio™ Real-Time PCR Software and server before shutting down the instruments can lead to communication issues.

---

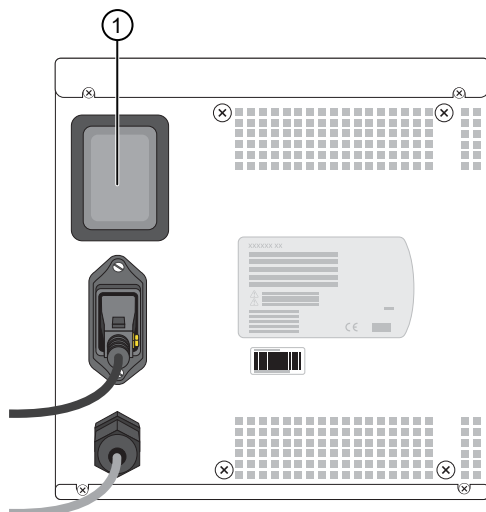
3. Press the switch on the back panel of each QuantStudio™ 7 Flex Real-Time PCR System to power off.
4. Press the switch on the back panel of the ALPS™ 3000 Automated Microplate Heat Sealer to power off.
5. Press the switches on the side panels of each KingFisher™ Presto Purification System to power off.
6. Press the switch on the back panel of the Agilent™ Microplate Centrifuge to power off.
7. Press the switch on the back panel of the BioTek™ ELx405™ Select Microplate Washer to power off.
8. Press the switch on the back panel of the A25 Refrigerated Circulator bath to power off.
9. Close the Tecan™ FluentControl™ Software and server windows.

---

**Note:** Make sure that all of the Tecan™ FluentControl™ Software dialog windows are closed out before you power off the Tecan™ Fluent™ 780 Automation Workstation.

---

10. Press the switch on the rear panel of the Tecan™ Fluent™ 780 Automation Workstation external power supply to power off.



① Power switch

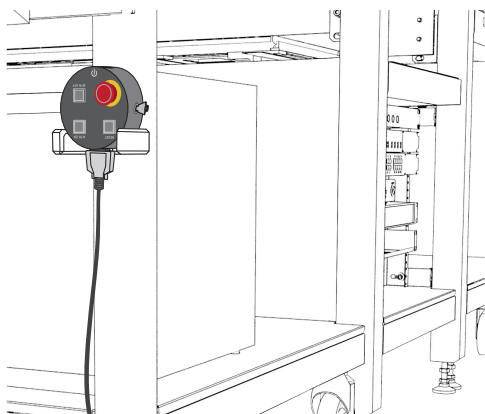
11. To power off the following instruments, follow the instructions to prepare the instrument before shutting it down.
- Spinnaker™ Microplate Robot—See “Power off the Spinnaker™ Microplate Robot” on page 51.
  - Multidrop™ Combi Reagent Dispenser—See “Power off each Multidrop™ Combi Reagent Dispenser” on page 52
12. On the Module 2 computer station, power off the following computers:
- Momentum™ Workflow Scheduler Software computer
  - QuantStudio™ 7 Flex Real-Time PCR System 1 computer
  - QuantStudio™ 7 Flex Real-Time PCR System 2 computer
  - Tecan™ Fluent™ 780 Automation Workstation computer

**Note:** To switch the desktop display, select the computer in the remote desktop application or use the following shortcuts:

Desktop to display	Shortcut
Module 2 computer station (including Momentum™ Software)	Ctrl Ctrl 1
QuantStudio™ 7 Flex Real-Time PCR System 1	Ctrl Ctrl 2
QuantStudio™ 7 Flex Real-Time PCR System 2	Ctrl Ctrl 3
Tecan™ Fluent™ 780 Automation Workstation	Ctrl Ctrl 4

## Power off the Spinnaker™ Microplate Robot

The Mini-Hub Control Puck is mounted on the side of the table near the Module 2 computer station.



On the Mini-Hub Control Puck, press **MTR OFF** button.

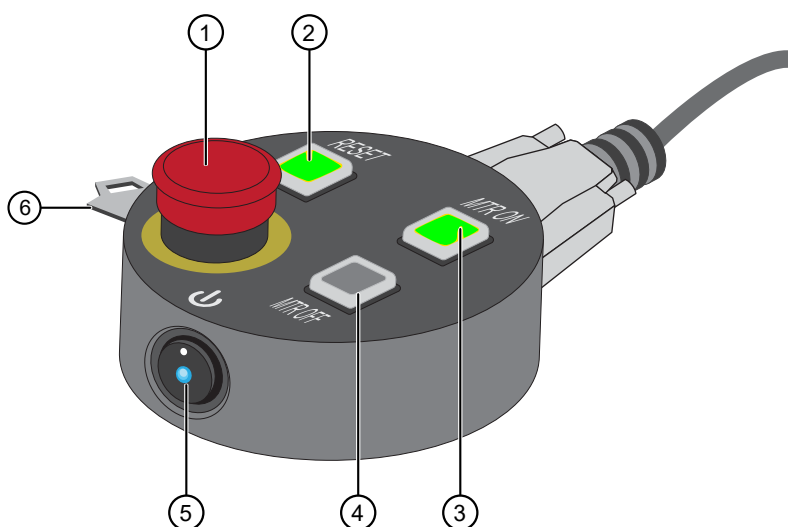


Figure 7 Mini-Hub Control Puck

- |                                     |                                       |
|-------------------------------------|---------------------------------------|
| ① Emergency Stop (E-Stop) button    | ④ Motor Off ( <b>MTR OFF</b> ) button |
| ② Reset ( <b>RESET</b> ) button     | ⑤ Power button                        |
| ③ Motor On ( <b>MTR ON</b> ) button | ⑥ Mode key-switch                     |

The **MTR OFF** and **RESET** buttons glow red and the **MTR ON** button goes dark, indicating that the power to the motors is stopped.

## Power off each Multidrop™ Combi Reagent Dispenser

Power off each Multidrop™ Combi Reagent Dispenser once a week, or if the instruments will be idle for more >24 hours. To prepare the instruments to be idle for <24 hours, see “Prepare each Multidrop™ Combi Reagent Dispenser to be idle” on page 144.

Power off one Multidrop™ Combi Reagent Dispenser at a time.

1. Remove the tubing bundle from the reagent vessel, then place the tubing bundle in an empty container.
2. Press and hold **Prime** for the duration listed in the table.

**IMPORTANT!** Make sure that the reagent is dispensing from all 8 tips of the Multidrop™ Combi Reagent Dispenser.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	

3. Move the tubing bundle to a bottle with at least 100 mL of fresh deionized water, then press and hold **PRIME** for the duration listed in the table.

**Note:** If there is not a large enough bottle available, two 50-mL conical tubes of water could be used instead, with the priming time split between them.

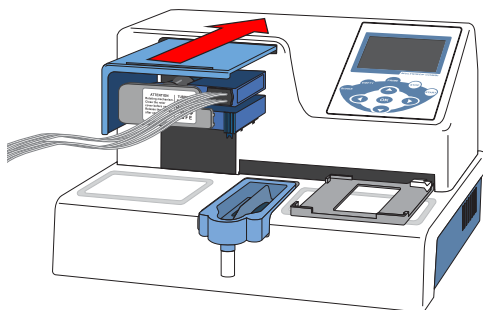
Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	30 seconds
Combi 3 (dispenses Wash 2)	

4. Lift the tubing bundle from the water surface, then press and hold **PRIME** for the duration listed in the table.

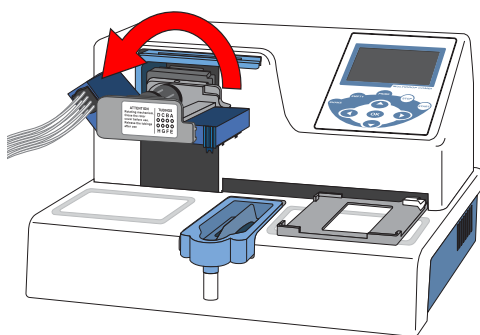
Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	10 seconds
Combi 2 (dispenses Wash 1)	25 seconds
Combi 3 (dispenses Wash 2)	

5. Place each tubing bundle in a clean empty container.

6. Push back the rotor cover to expose the dispensing cassette.



7. Place the dispensing cassette in the rest position.



8. Power off the Multidrop™ Combi Reagent Dispenser using the switch on the left back panel.
9. Wipe the instrument surfaces with a soft cloth or lint-free wipe moistened with deionized distilled water, a mild detergent, or 70% ethanol.
10. Repeat step 1 to step 9 with each remaining Multidrop™ Combi Reagent Dispenser.

## Perform a total system shutdown

---

**IMPORTANT!** Only perform a total system shutdown if there is a planned power outage to the laboratory or building (for example, due to construction).

---

1. Power off the Module 1 Tecan™ Fluent™ 1080 Automation Workstation and computer (see “Power off the Tecan™ Fluent™ 1080 Automation Workstation (Module 1)” on page 48).
2. Power off the Module 1 uninterruptible power supply (UPS) unit.
3. Unplug the Module 1 UPS power cord from the wall outlet.
4. Power off the Module 2 instruments and computers (see “Power off Module 2 instruments and computers” on page 49).

5. Power off the Module 2 power strips for each circuit (CCT1–CCT7).

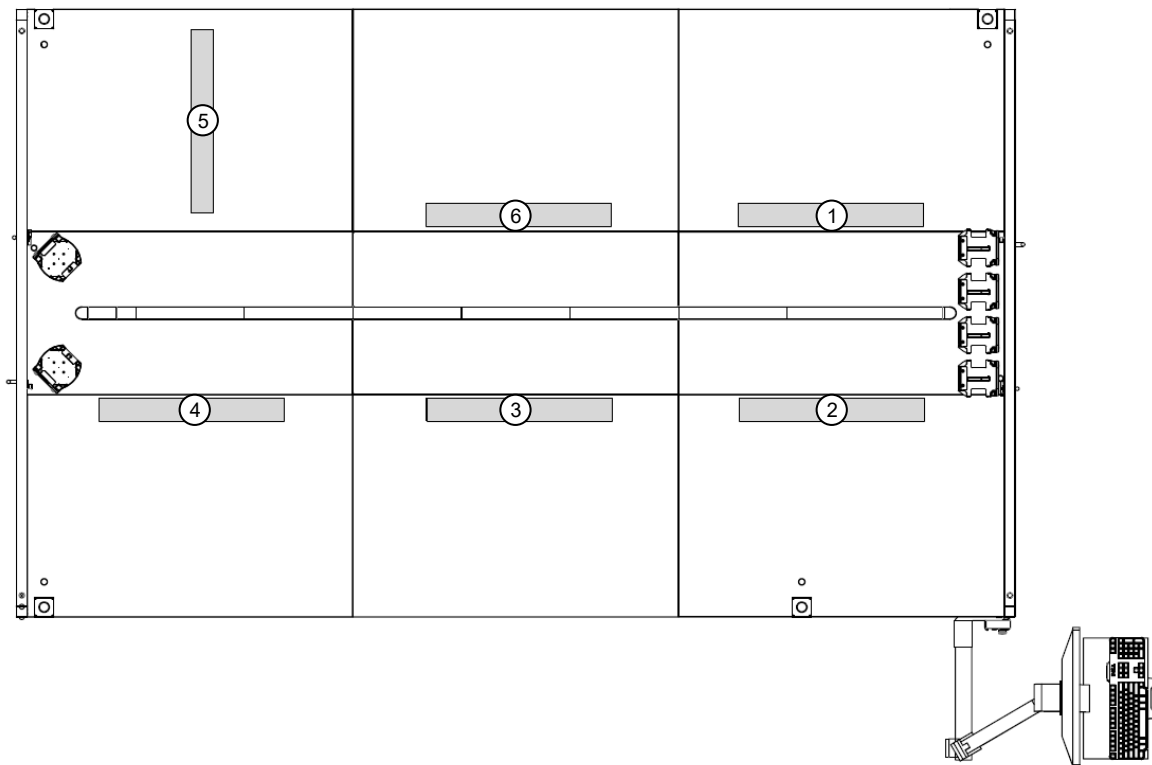


Figure 8 Module 2 power strip layout

- |                    |                    |
|--------------------|--------------------|
| ① CCT1 power strip | ④ CCT4 power strip |
| ② CCT2 power strip | ⑤ CCT5 power strip |
| ③ CCT3 power strip | ⑥ CCT7 power strip |

6. Power off the Module 2 UPS units for each circuit (CCT1–CCT7).

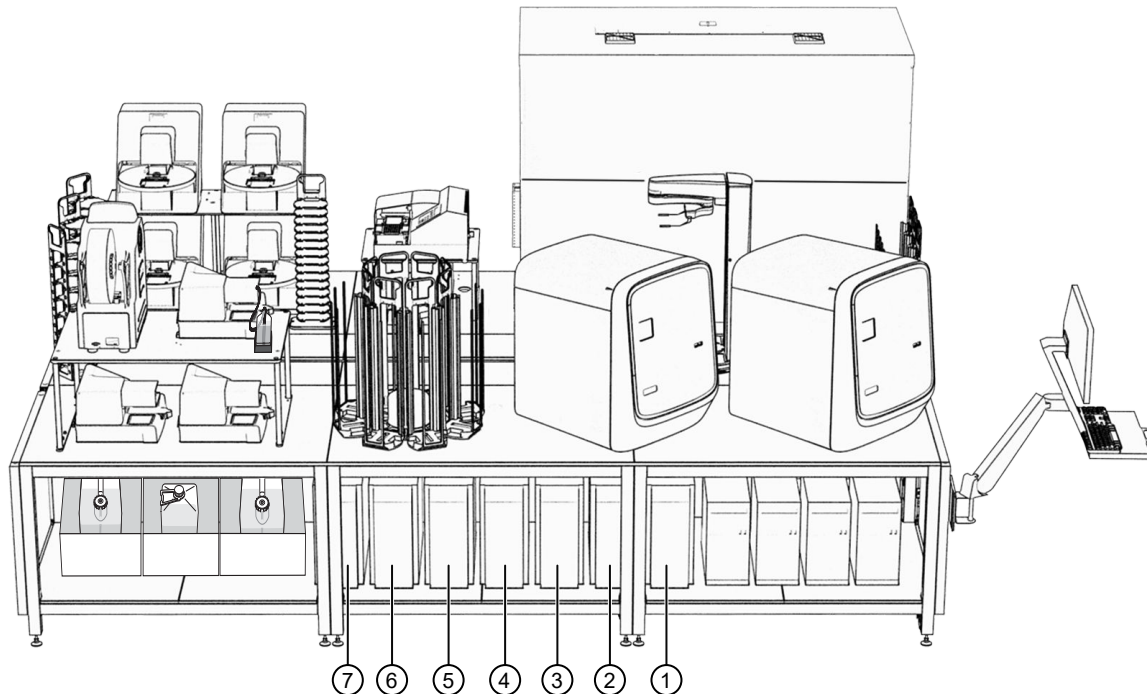


Figure 9 Module 2 UPS positions

- |               |               |
|---------------|---------------|
| ① UPS1 / CCT1 | ⑤ UPS5 / CCT5 |
| ② UPS2 / CCT2 | ⑥ UPS6 / CCT6 |
| ③ UPS3 / CCT3 | ⑦ UPS7 / CCT7 |
| ④ UPS4 / CCT4 |               |

7. Unplug all of the Module 2 power cords from the wall outlets.

## Restart the system after a total shutdown

---

**IMPORTANT!** Only perform a total system shutdown if there is a planned power outage to the laboratory or building (for example, due to construction).

---

1. Plug in the Module 1 uninterruptible power supply (UPS) power cord to the wall outlet, then power on the Tecan™ Fluent™ 1080 Automation Workstation and computer (see “Power on the Tecan™ Fluent™ 1080 Automation Workstation (Module 1)” on page 42).
2. Plug in all of the Module 2 power cords to the wall outlets.

3. Power on the Module 2 uninterruptible power supply (UPS) units for each circuit (CCT1–CCT7).

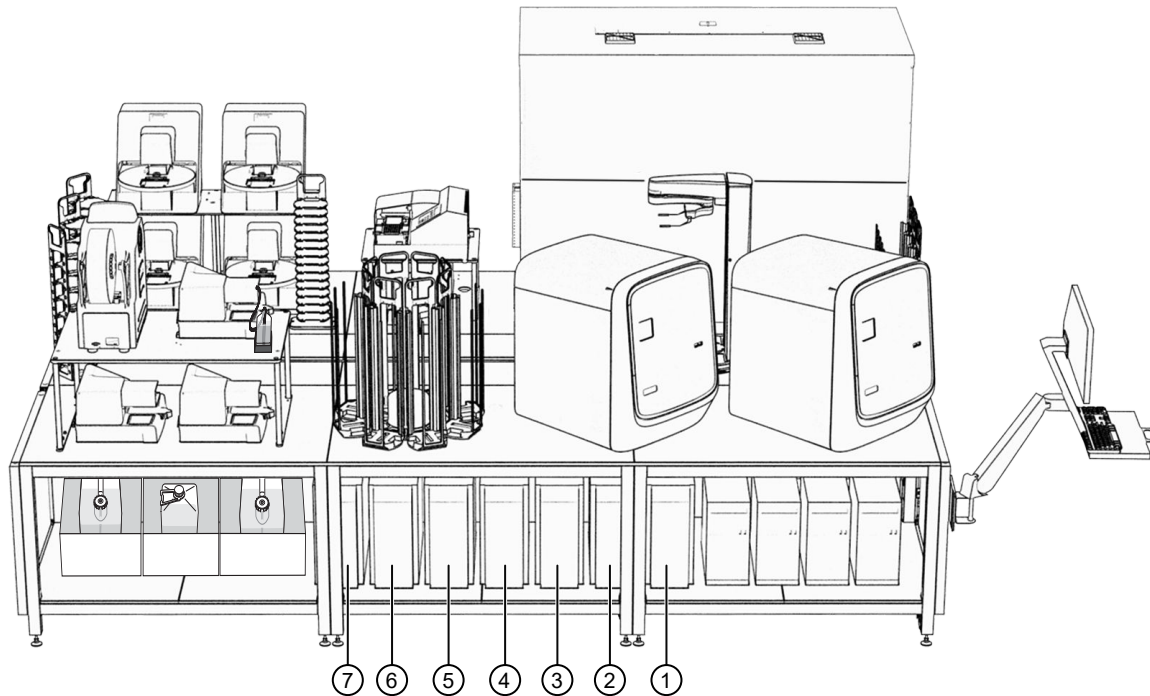


Figure 10 Module 2 UPS positions

UPS units are

- ① UPS1 / CCT1
- ② UPS2 / CCT2
- ③ UPS3 / CCT3
- ④ UPS4 / CCT4

- ⑤ UPS5 / CCT5
- ⑥ UPS6 / CCT6
- ⑦ UPS7 / CCT7



4. Power on the Module 2 power strips for each circuit (CCT1–CCT7).

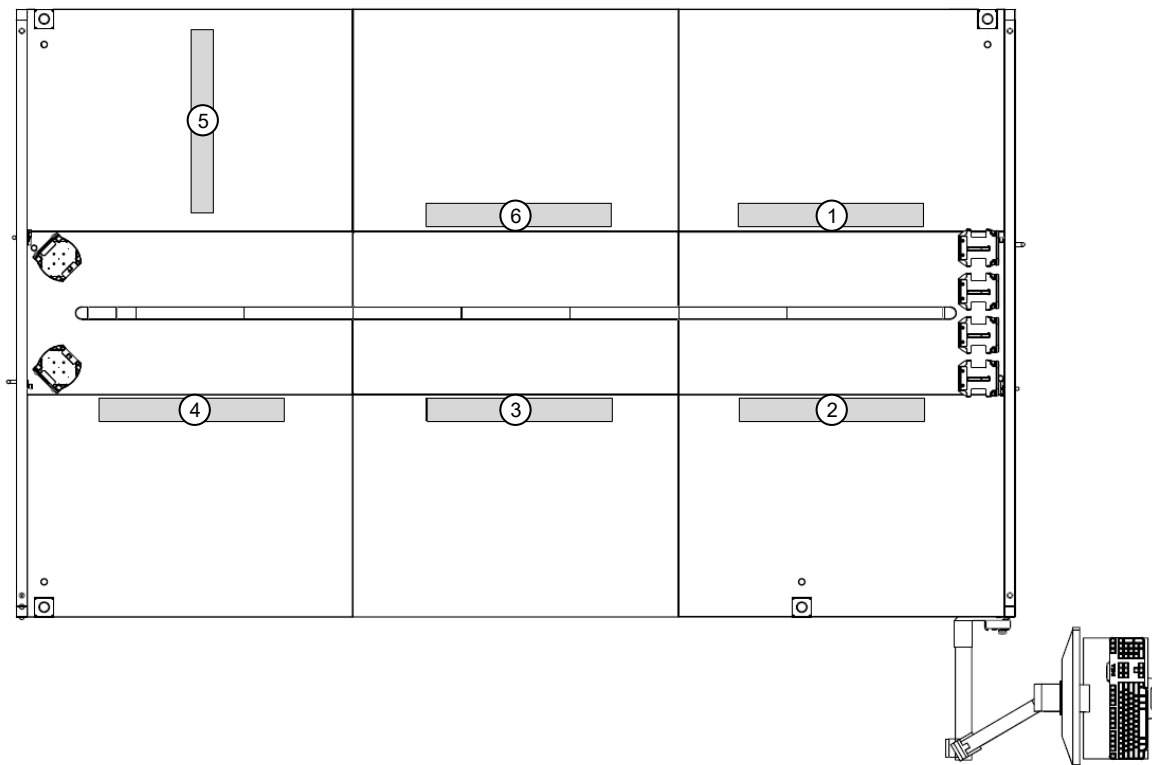


Figure 11 Module 2 power strip layout

- |                    |                    |
|--------------------|--------------------|
| ① CCT1 Power strip | ④ CCT4 Power strip |
| ② CCT2 Power strip | ⑤ CCT5 Power strip |
| ③ CCT3 Power strip | ⑥ CCT7 Power strip |
5. Power on the Module 2 instruments and computers, then sign in (see “Power on the Module 2 instruments and computers” on page 43).

## Power on the A25 Refrigerated Circulator



**WARNING!** Failure to set the A25 Refrigerated Circulator to 9°C can result in inaccurate results.

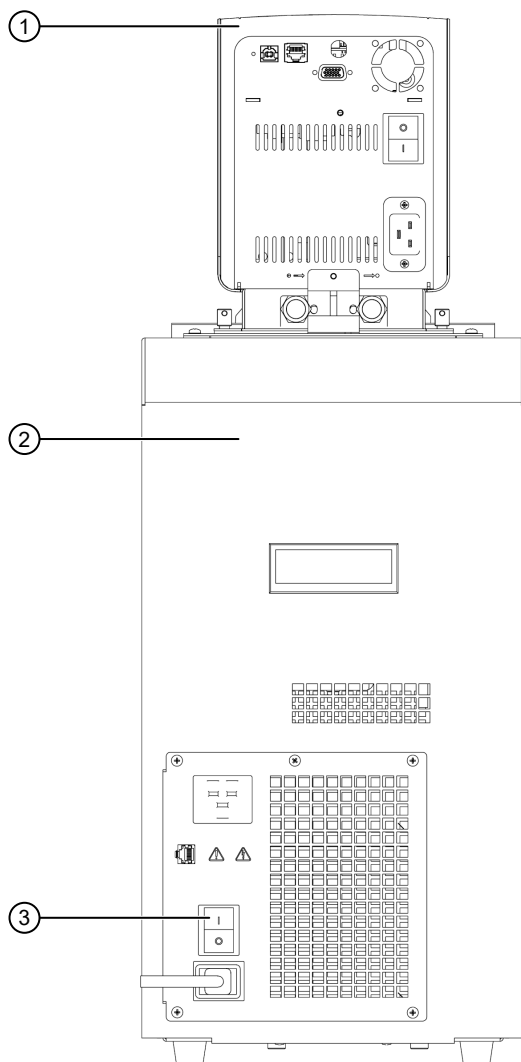
1. Ensure that the A25 Refrigerated Circulator bath is filled with deionized water (see “Maintain the A25 Refrigerated Circulator bath reservoir” on page 180).

---

**IMPORTANT!** Do not power on the A25 Refrigerated Circulator unless the water bath is full.

---

2. Press the power switch on the back panel of the bath.



**Figure 12** A25 Refrigerated Circulator back panel view

- ① Immersion circulator
- ② Bath
- ③ Bath power switch

3. Check the display to confirm that the set point for water bath temperature is **9.0°C**. If the water bath set point is not at 9°C, contact Priority Support.

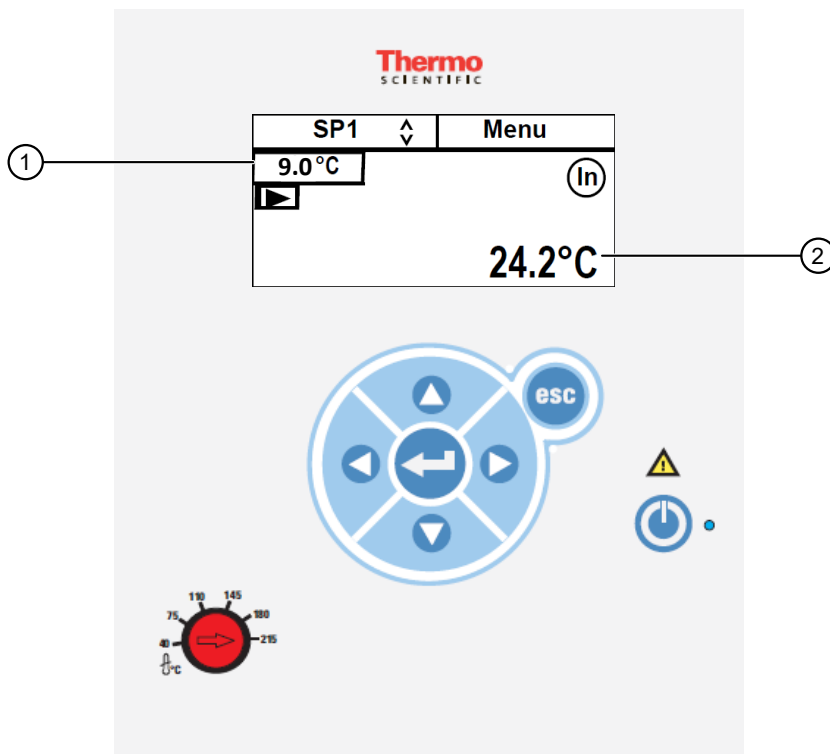


Figure 13 A25 Refrigerated Circulator display

- ① Set point for water bath temperature
- ② Current water bath temperature

---

**Note:** The pump starts immediately but it can take up to 30 seconds before the refrigerated bath compressor starts. If restarting quickly after powering off the instrument, then the compressor may take up to 10 minutes before it starts.

---

# 4

## Prepare samples

### Sample collection, transport, and storage



**CAUTION!** Handle all samples and controls as if they are capable of transmitting infectious agents.

For nasopharyngeal and anterior nasal swabs in viral transport medium (VTM or UTM), store samples at 2–8°C for up to 72 hours after collection. If a delay in testing is expected, store samples at  $\leq -70^{\circ}\text{C}$ .

Saliva specimens collected using the Spectrum Solutions™ SDNA-2000 Saliva Collection Device can be stored at room temperature for up to 21 days.



**WARNING!** The Spectrum Solutions™ SDNA-2000 Saliva Collection Device is not compatible with bleach. Do not bleach specimens or pipette tips used with this device. Do not use bleach solution for liquid handler deck decontamination. For more information, see the SDS for this device.

### Instructions for saliva collection

Collect saliva samples as described in the instructions provided with the Spectrum Solutions™ SDNA-2000 Saliva Collection Device. We recommend that you follow best practices to minimize the presence of inhibitors in the saliva.

---

**IMPORTANT!** Do NOT eat, drink, smoke, or chew gum for 30 minutes before giving your saliva sample.

---

1. **Fill the tube with saliva to the black wavy line:** Fill the tube until your saliva (not including bubbles) is at or just above the wavy line.

---

**IMPORTANT!** Do NOT overfill.

---

2. **Replace the funnel with the fluid cap:** Remove the funnel from the tube. Screw on the enclosed cap **tightly** to release the solution that will stabilize the DNA in your saliva.
3. **Firmly screw the cap down to release the solution and seal the tube:** You will know it works when the blue solution from the cap is released into the tube. Firmly tighten the cap to ensure that the cap and the tube are completely sealed.
4. **Shake the tube for at least 5 seconds:** This will ensure that your sample thoroughly mixes with the stabilizing solution.

# 5

## Prepare sample tube runners

- Requirements for sample tubes ..... 61
- Sample inactivation guidelines ..... 63
- Prepare tube runners for Module 1 ..... 63
- Load sample tubes into tube runners ..... 65

### Requirements for sample tubes

- Only use sample tubes meeting the specifications listed in the table below:

Tube runner type	Tube diameter range		Maximum tube height	Tube bottom type
	Minimum	Maximum		
13 mm, 32-position	12 mm	14 mm	140 mm	Skirted, internal conical only
16 mm, 26-position	15 mm	17 mm	140 mm	Skirted, internal conical only
17 mm, 24-position	16 mm	18 mm	140 mm	Non-skirted, external conical <i>or</i> Skirted, internal conical

#### IMPORTANT!

- For each Module 1 run, all sample tubes must be within the same diameter range. Individual tube heights can vary, but should not exceed 140 mm.
  - For each Module 1 run, all sample tubes must be loaded in the same type of tube runner. Tube runner types cannot be mixed within a run.
- 
- Ensure that you have the minimum volume of sample required for the sample tube size.

Sample tube size	Minimum volume required
12–14 mm	0.5 mL
15–17 mm	1 mL
16–18 mm	1 mL

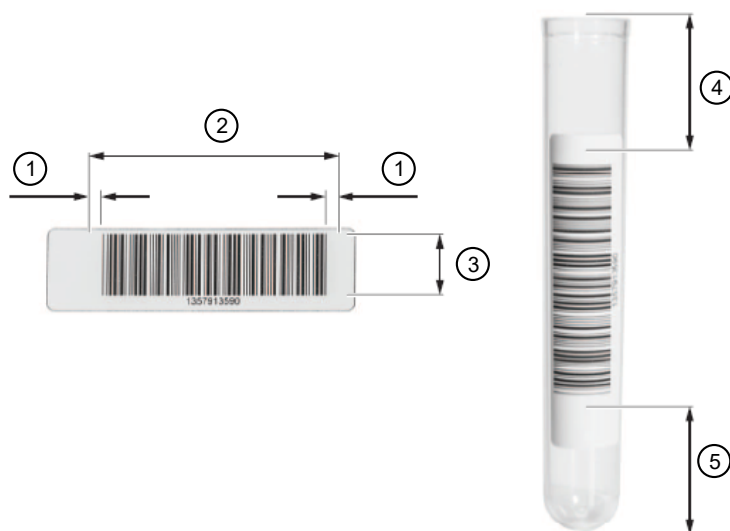
- All sample tubes, including the Spectrum Solutions™ SDNA-2000 Saliva Collection Device, must be barcoded with a unique ID (see “Sample tube barcode requirements” on page 62).

**Note:**

- Due to their positioning, Spectrum Solutions™ SDNA-2000 Saliva Collection Device barcodes cannot be scanned reliably by the Amplitude™ Solution system. Therefore, we recommend applying your own barcodes as described in “Sample tube barcode requirements” on page 62.
  - The Amplitude™ Solution does not perform sample accessioning. If required, perform sample accessioning according to guidelines established by your laboratory prior to processing the samples on Module 1. After testing, the results can be imported into your laboratory system.
- 
- For sample collection devices containing swabs, the swabs must be removed from sample tube before loading into the tube runners. Alternatively, the sample can be transferred to a fresh, barcoded sample tube that is then loaded into an appropriate runner type.
  - The Amplitude™ Solution is configured to run samples in multiples of 94. In other words, each run must include 94, 188, 282, or 376 sample tubes. If the number of sample tubes used in a run is not divisible by 94, you must include additional empty, barcoded tubes to fill any empty positions in the tube runners.

## Sample tube barcode requirements

Use barcodes according to the specifications recommended for the Tecan™ FluentID™ Tube Barcode Scanner.



**Figure 14** Barcode label placement on sample tube

- ① Quiet zone
- ② Barcode length (includes quiet zone)
- ③ Barcode height
- ④ Barcode label position from the top of the sample tube (including the quiet zone)
- ⑤ Barcode label position from the bottom of the sample tube (including the quiet zone)

Table 12 Tube barcode specifications

Tube barcode specification	Value
Density	≥6.6 mils
Barcode height	≥8 mm
Barcode length <sup>[1,2]</sup>	≤80 mm
Number of characters	≤64 characters
Grade	A, B, and C for Code 128
Barcode label position from the top of the sample tube	≥14 mm
Barcode label position from the bottom of the sample tube	≥20 mm

<sup>[1]</sup> Includes a blank space on either side of the barcode that is 10 times the narrow bar width, or 2.5 mm, whichever is greater.

<sup>[2]</sup> To change the barcode length, contact Priority Support or your Field Service Engineer. Changing the barcode length requires updating the Tecan™ Fluent™ 1080 Automation Workstation barcode settings by your Field Service Engineer.

## Sample inactivation guidelines

Follow the sample inactivation guidelines and requirements established by your laboratory and local regulatory bodies. If your laboratory inactivates samples, do so before you begin the Module 1 workflow.

Chemical inactivation is not recommended and may interfere with test results.

## Prepare tube runners for Module 1

**Note:** The number of required tube runners and the control positions depend on the size of the sample tubes and the number of plates used in a run.

1. Ensure that you have the correct tube runner type for your tube size and the correct number of tube runners for the number of sample extraction plates used in a run.

Sample tube size	Tube runner type	Number of plates used per run	Number of tube runners used per run
12–14 mm	13 mm, 32-position	1	3
		2	6
		3	9
		4	12
15–17 mm	16 mm, 26-position	1	4
		2	8
		3	12
		4	16

(continued)

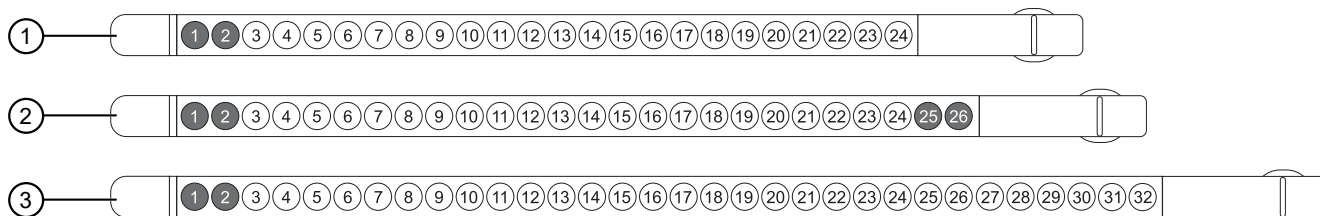
Sample tube size	Tube runner type	Number of plates used per run	Number of tube runners used per run
16–18 mm	17 mm, 24-position	1	4
		2	8
		3	12
		4	16

**IMPORTANT!** Tube runners must be loaded from left to right, as indicated by the Tecan™ FluentControl™ Software.

- Place plug inserts in position 1 (Negative Control) and position 2 (Positive Control) in 1–4 tube runners (depending on the number of sample extraction plates used).

The plug inserts block positions 1 and 2 in the tube runner to prevent insertion of a sample tube. When plated, these positions are used for the Negative Control and Positive Control (see Appendix H, “Sample and control positions in tube runners and plates”).

**Note:** We recommend labeling the tube runners that contain plugs in the control positions so that they are easily identifiable when loading them on the Tecan™ Fluent™ Automation Workstation Tecan™ Fluent™ 1080 Automation Workstation deck. Control tube runners must be loaded at specific grid positions on the deck (see “Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation” on page 87).



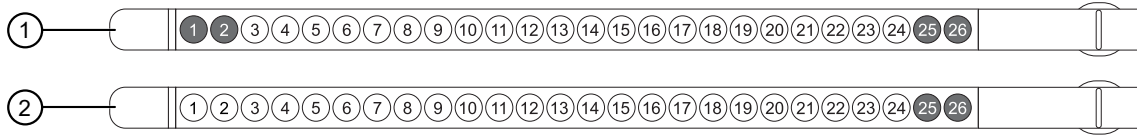
**Figure 15** Plug insert positions in control tube runners

- 17 mm, 24-position control tube runner (16–18 mm tubes)—Plugs in positions 1 and 2
- 16 mm, 26-position control tube runner (15–17 mm tubes)—Plugs in positions 1, 2, 25, and 26
- 13 mm, 32-position control tube runner (12–14 mm tubes)—Plugs in positions 1 and 2

- Depending on the number of sample extraction plates used, place plug inserts in positions 25 and 26 in 4, 8, 12, or 16 of the 26-position (15–17 mm tubes) tube runners (including the control tube runners).

The plug inserts block positions 25 and 26 of the 26-position (15–17 mm tubes) to prevent insertion of sample tubes.





**Figure 16 Plug insert positions in 16 mm, 26-position tube runners (15–17 mm tubes)**

- ① 16 mm, 26-position control tube runner (15–17 mm tubes)—Plugs in positions 1, 2, 25, and 26
- ② 16 mm, 26-position tube runner (15–17 mm tubes)—Plugs in positions 25 and 26

## Load sample tubes into tube runners



**CAUTION!** Handle all samples and controls as if they are capable of transmitting infectious agents. Keep the tube runners in the BSL-2 biological safety cabinet until they are all ready to be loaded into the Tecan™ Fluent™ 1080 Automation Workstation (see “Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation” on page 87).

Before you begin, prepare the tube runners (for more information, see “Prepare tube runners for Module 1” on page 63).



**WARNING!** A spill can result in cross-contamination of samples. For information on decontamination and biological hazard safety, see Appendix K, “Safety”.

1. In a BSL-2 biological safety cabinet, uncap the sample tubes, then discard the caps.

---

**Note:** New caps are put on the sample tubes after the Module 1 run is complete.

---

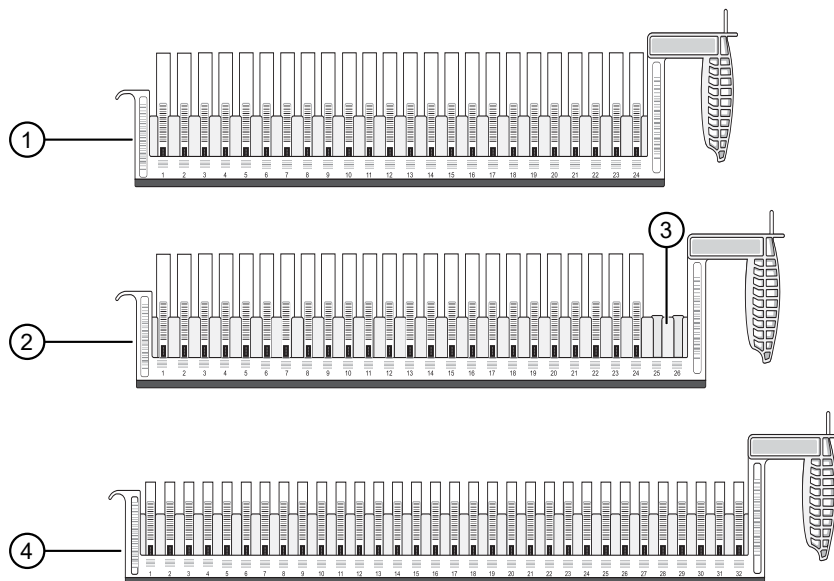
2. Place the uncapped sample tube into the open positions in the prepared tube runners.

---

**IMPORTANT!** Do not place tubes in positions that have a plug insert (see “Prepare tube runners for Module 1” on page 63).

---

3. Ensure that the barcode on each sample tube is aligned facing left and that the full barcode is visible in the scanning window of the tube runner.



**Figure 17** Tube runners with sample tube barcodes facing left and visible in the scanning window

- ① 17 mm, 24-position tube runner (16–18 mm tubes)
- ② 16 mm, 26-position tube runner (15–17 mm tubes); includes plug inserts in positions 25 and 26
- ③ Plug inserts in positions 25 and 26
- ④ 13 mm, 32-position tube runner (12–14 mm tubes)

# 6

## Perform a Module 1 run

■ Module 1 overview .....	67
■ Module 1 required samples, reagents, and consumables .....	68
■ Module 1 workflow .....	69
■ Before you begin—Module 1 .....	70
■ Prepare Module 1 reagents .....	72
■ View the SampleManager Module 1 Load Indicator .....	74
■ Start the method on the Tecan™ Fluent™ 1080 Automation Workstation .....	75
■ Load the Tecan™ Fluent™ 1080 Automation Workstation deck .....	82
■ Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation .....	87
■ Monitor the Module 1 run .....	90
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■ Unload the tube runners .....	91
■ Prepare the Tecan™ Fluent™ 1080 Automation Workstation for the next shift or to be idle .....	92

### Module 1 overview

Module 1 operation is controlled by the Tecan™ FluentControl™ Software, via the Tecan™ Fluent™ 1080 Automation Workstation touchscreen.

During Module 1 operation:

- Technicians load prepared sample tube runners, reagents, and consumables on the Tecan™ Fluent™ 1080 Automation Workstation deck and start runs.
- Depending on the number of samples in a run, the instrument prepares 1–4 sample extraction plates containing the following components:
  - 200 µL of sample from the sample tubes
  - MagMAX™ HT Proteinase K
  - TaqPath™ COVID-19 Module 1 MS2 Phage Control
  - Binding Bead Mix
  - Silicone oil
- The Tecan™ Fluent™ 1080 Automation Workstation scans the barcodes on sample tubes and sample extraction plates, then registers the information with the SampleManager LIMS™ Software for sample tracking.

Technicians also need to perform regular Module 1 maintenance. For the regular maintenance task list and schedule, see Chapter 9, “Perform regular maintenance”.

For more information about the automated steps in Module 1, see “Module 1 automation information” on page 241.

## Module 1 required samples, reagents, and consumables

For information about the location of the required materials in the deck layout, see “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82.

Required samples, reagents, and consumables	Usage (Reload frequency)	See
<b>Sample input</b>		
Barcoded sample tubes in sample carrier racks	94, 188, 282, or 376 samples per run	page 87
<b>Tips and Plates</b>		
KingFisher™ Deep-Well 96 Plate with Barcode (sample extraction plates)	1–4 plates per run	page 82
1,000 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	15 racks per 12 plates	
200 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	3 racks per 18–24 plates	
Axygen™ Multi Well Low Profile Reagent Reservoir (for MagMAX™ HT Proteinase K/TaqPath™ COVID-19 Module 1 MS2 Phage Control)	1 reservoir per 18–24 plates <sup>[1]</sup>	
Axygen™ Single Well High Profile Reagent Reservoir (for Binding Bead Mix)	1 reservoir per 18–24 plates <sup>[1]</sup>	
Axygen™ Single Well High Profile Reagent Reservoir (for silicone oil)	1 reservoir per 18–24 plates <sup>[1]</sup>	
<b>Reagents<sup>[2,3]</sup></b>		
MagMAX™ HT Binding Beads	1 bottle per 18–24 plates	page 73
MagMAX™ HT Binding Solution	1 bottle per 18–24 plates	
TaqPath™ COVID-19 Module 1 MS2 Phage Control	2 bottles per 18–24 plates	page 82
MagMAX™ HT Proteinase K	1 bottle per 18–24 plates	
MagMAX™ HT Water	1 bottle per 18–24 plates	
Silicone oil	1 bottle per 18–24 plates	

<sup>[1]</sup> Replaced daily, if running <18–24 plates.

<sup>[2]</sup> See “In-use reagent stability” on page 40.

<sup>[3]</sup> Reagent consumption and reload frequency depend on the number of sample extraction plates used per run and vary from system to system.

## Module 1 workflow

### Module 1 workflow (approximately 1 hour)

#### Before you begin—Module 1 (page 70)

- Ensure that you have all of the required materials.
- Perform Tecan™ Fluent™ 1080 Automation Workstation daily system care.
- Prepare the Tecan™ Fluent™ 1080 Automation Workstation.

#### Prepare Module 1 reagents (page 72)

Ensure that you prepare reagents before they need to be reloaded.

- Thaw TaqPath™ COVID-19 Module 1 MS2 Phage Control (page 72)
- Prepare the Binding Bead Mix (page 73)

#### View the SampleManager Module 1 Load Indicator (page 74)

Before each run, confirm that it is time to load Module 1.

#### Start the method on the Tecan™ Fluent™ 1080 Automation Workstation

To start a run, select the appropriate method for your sample type and sample tube size.

#### Load the Tecan™ Fluent™ 1080 Automation Workstation deck (page 82)

Every run, follow the instrument touchscreen prompts to load the reagents and consumables as required.

- **Every run**—Binding Bead Mix, silicone oil, and KingFisher™ Deep-Well 96 Plates with Barcodes
- **Every 12 plates**—1,000 µL FCA Disposable Tips
- **Every 18–24 plates**—All reagents and consumables

#### Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation (page 87)

Every run, load the tube runners containing the sample tubes when prompted by the instrument touchscreen.

#### Monitor the Module 1 run (page 90)

During each run, monitor the run progress on the instrument touchscreen.

#### Transfer sample extraction plates from Module 1 to Module 2 (page 90)

After a run is complete, immediately transfer the sample extraction plates to Module 2.

#### Unload the tube runners (page 91)

After transferring the sample extraction plates to Module 2, unload the tube runners when prompted by the instrument touchscreen.

## Module 1 workflow (approximately 1 hour)

### Prepare the Tecan™ Fluent™ 1080 Automation Workstation for the next shift or to be idle (page 92)

At the end of each shift, empty tip waste.

## Before you begin—Module 1

At the beginning of each shift, complete the following tasks:

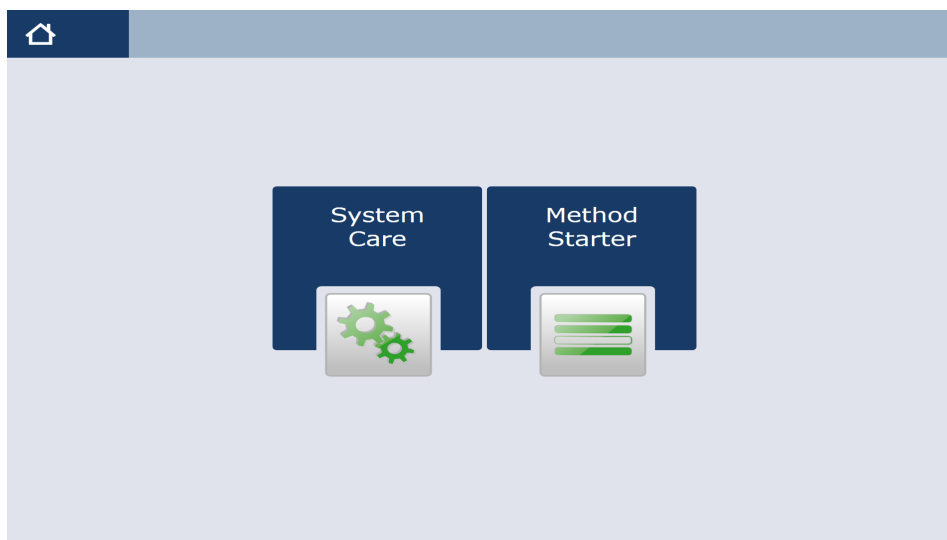
- Ensure that you have all of the required materials (see page 68).
- Perform Tecan™ Fluent™ 1080 Automation Workstation daily system care (see page 70).
- Prepare the Tecan™ Fluent™ 1080 Automation Workstation (see page 71).

## Perform Tecan™ Fluent™ 1080 Automation Workstation daily system care



**WARNING!** Failure to conduct Tecan™ Fluent™ 1080 Automation Workstation system care when prompted can result in inaccurate results or loss of the sample.

1. In the Tecan™ Fluent™ 1080 Automation Workstation touchscreen home screen, tap **System Care**.



2. In the **System Care** screen, select the **DailySystemCare** method.
3. Follow the on-screen prompts to perform the following tasks:



**CAUTION!** Do not use bleach for the **DailySystemCare** cleaning.

- Clean disposable tip cones with an ethanol wipe
- Empty disposable tip waste
- Check the waste chute is in the proper position
- Check that the gripper fingers on the RGA are straight and level

## Prepare the Tecan™ Fluent™ 1080 Automation Workstation

Perform before every shift.

1. Ensure that the Tecan™ Fluent™ 1080 Automation Workstation and computer are powered on.
2. On the Tecan™ Fluent™ 1080 Automation Workstation desktop computer, double-click the Tecan™ FluentControl™ Software to open.
3. On the Tecan™ Fluent™ 1080 Automation Workstation desktop computer, select a user profile, enter the password, then click **OK**.

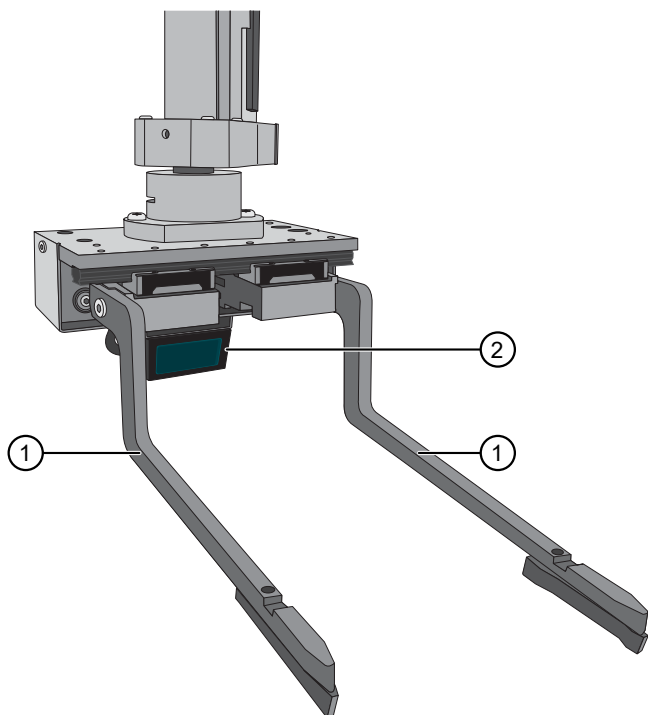
4. Inspect the RGA gripper fingers for misalignment and damage.
  - Ensure that RGA gripper fingers are level and the screws are not loose. If the RGA gripper fingers are misaligned, loosen the RGA gripper finger screws with the T20 wrench, adjust the fingers to level, then tighten the screws with the T20 wrench.

---

**Note:** Tighten the RGA gripper finger screws securely, but do not overtighten.

---

- If the RGA gripper fingers are bent, damaged, or you are unable to align them, contact Support.



- ① RGA gripper fingers
- ② RGA gripper barcode scanner

5. Check the tip waste level, then empty if needed (see “Empty the Tecan™ Fluent™ 1080 Automation Workstation tip waste” on page 92).

## Prepare Module 1 reagents

### Thaw TaqPath™ COVID-19 Module 1 MS2 Phage Control

For every 24 sample extraction plates, thaw 2 bottles of the TaqPath™ COVID-19 Module 1 MS2 Phage Control at room temperature (up to 30°C). For in-use stability information, see “In-use reagent stability” on page 40.



## Prepare the Binding Bead Mix

Prepare the Binding Bead Mix as needed within the specified stability window.

---

### IMPORTANT!

- Use the Binding Bead Mix within 24 hours of preparation (see “In-use reagent stability” on page 40).
  - If not performing back-to-back runs, replace the Binding Bead Mix before each run.
- 

1. Vortex one bottle of MagMAX™ HT Binding Beads for a minimum of 15 seconds to ensure that the bead mixture is homogeneous.
2. Combine the appropriate volumes of MagMAX™ HT Binding Beads and MagMAX™ HT Binding Solution for the required number of sample extraction plates and runs intended.
  - For full-capacity back-to-back runs (6 runs, consisting of 4 sample extraction plates each), pour all of the MagMAX™ HT Binding Beads directly into the bottle of MagMAX™ HT Binding Solution.
  - For all other plate and run configurations, combine the appropriate volumes of MagMAX™ HT Binding Beads and MagMAX™ HT Binding Solution in a secondary mixing container that can be closed.

---

**Note:** To reduce reagent loss, the secondary mixing container size should not exceed 500 mL when preparing the Binding Bead Mix for a single run. If you are scaling up the Binding Bead Mix preparation for multiple runs and the mix volume exceeds 500 mL, you can split up the formulation into another secondary mixing container.

---

**Table 13** Required volumes of MagMAX™ HT Binding Beads and MagMAX™ HT Binding Solution per run

Number of plates	MagMAX™ HT Binding Beads <sup>[1]</sup>	MagMAX™ HT Binding Solution <sup>[2]</sup>
1	2.6 mL	68.9 mL
2	3.6 mL	94.4 mL
3	4.5 mL	120 mL
4	5.5 mL	145.5 mL

<sup>[1]</sup> Fill volume=30 mL

<sup>[2]</sup> Fill volume=800 mL

---

**IMPORTANT!** Keep the bottle of MagMAX™ HT Binding Beads and the bottle of MagMAX™ HT Binding Solution to scan when prompted by the Tecan™ Fluent™ 1080 Automation Workstation touchscreen.

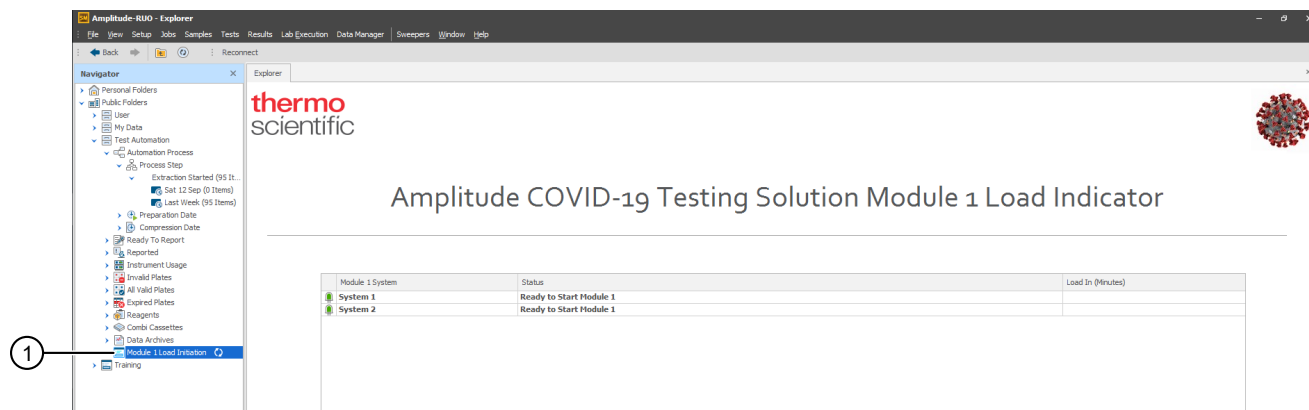
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3. Mix well by inversion, then store the Binding Bead Mix at room temperature until ready to use (see “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82).

## View the SampleManager Module 1 Load Indicator

The SampleManager Module 1 Load Indicator tells you when to start a Module 1 run.

1. On the Tecan™ Fluent™ 1080 Automation Workstation computer, navigate to the SampleManager LIMS™ Software web client.
2. In the SampleManager LIMS™ Software **Navigator** pane, select **Public Folders** ▶ **Test Automation** ▶ **Module 1 Load Initiation**.



- ① Navigation to the Module 1 Load Indicator screen

3. Review the system status in the Module 1 Load Indicator status table.

Column	Description
<b>Module 1 System</b>	Indicates the system to which the Module 1 belongs, if more than one system is in use. Each system consists of one Module 1 and one Module 2.
<b>Status</b>	● <b>Ready to Start Module 1</b> —Start the Module 1 run. RNA extraction has commenced in Module 2, a new Module 1 run can begin.
	● <b>Extraction Plates Assembled, Ready for Module 2 Check in</b> —The Module 1 run is complete. Transfer the plates to Module 2 and prepare Module 1 for another run.
	● <b>System Down: Check Module 2 Status, Do Not Start Module 1</b> —There is an error in Module 2. Do not start the Module 1 run until the issue is resolved and the system is prepared to accept additional plates.
<b>Load In (Minutes)</b>	● <b>Module 2 In-use</b> —The SampleManager LIMS™ Software can be configured to allow a delay in the Module 1 run start. If this delay is enabled, the count in minutes until Module 1 can be loaded is displayed.

When indicated, start the Module 1 run (see “Start the method on the Tecan™ Fluent™ 1080 Automation Workstation” on page 75).

## Start the method on the Tecan™ Fluent™ 1080 Automation Workstation




**WARNING!** Only start a run on Module 1 when indicated by the SampleManager LIMS™ Software Module 1 Load Indicator.

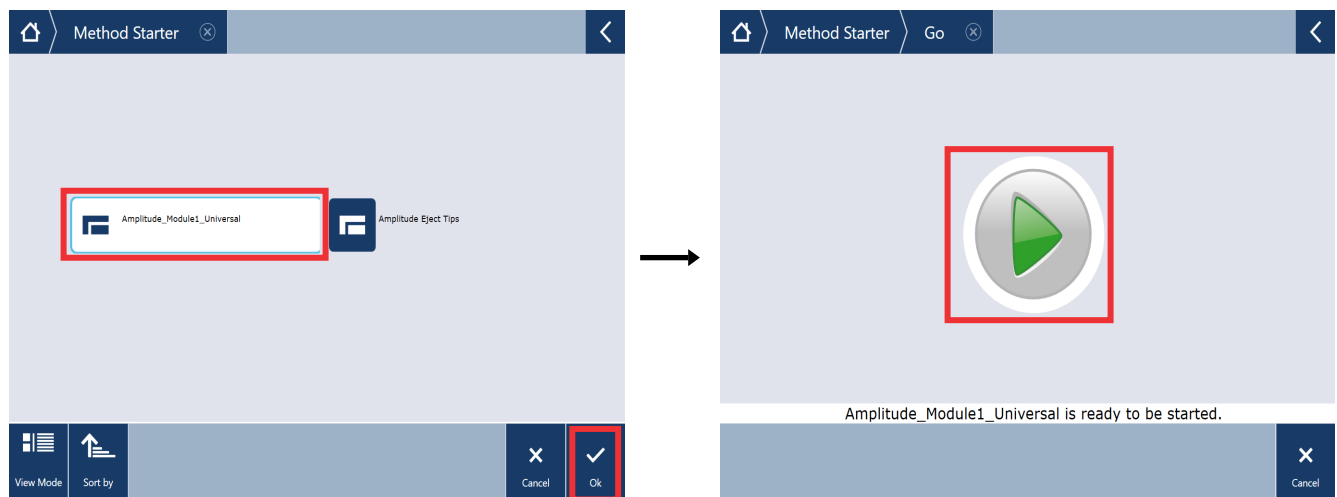
Follow the recommended system workflow for your specimen type:

- Nasal—“Start the method on the Tecan™ Fluent™ 1080 Automation Workstation – nasopharyngeal and anterior nasal swab specimens” on page 75
- Saliva—“Start the method on the Tecan™ Fluent™ 1080 Automation Workstation – saliva specimens” on page 78

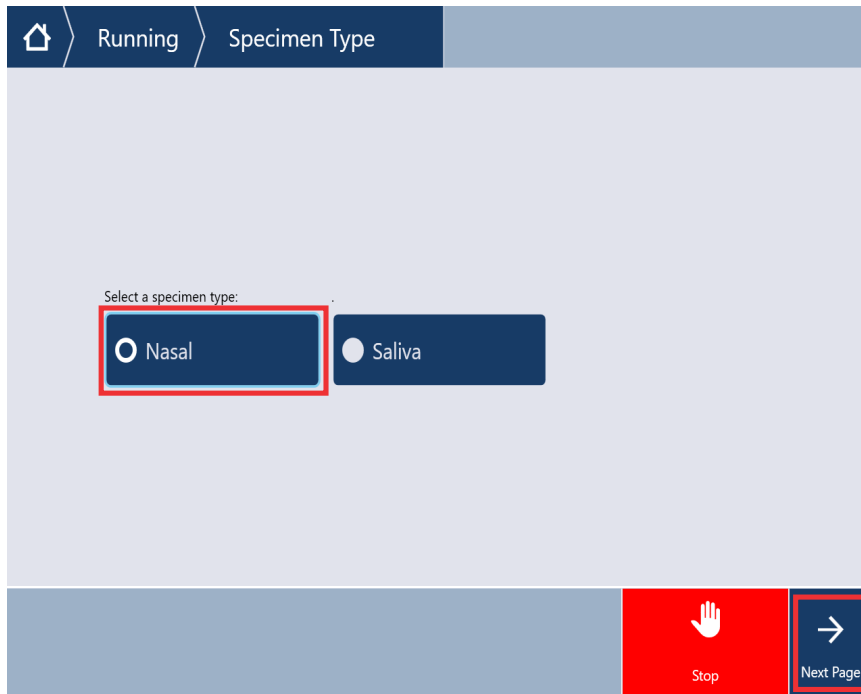
**IMPORTANT!** Barcode scanning only takes place after the method is started. Ensure that the deck is clear of tube runners before you start the method. The tube runners must only be loaded when the prompt is displayed on the touchscreen.

### Start the method on the Tecan™ Fluent™ 1080 Automation Workstation – nasopharyngeal and anterior nasal swab specimens

1. On the Tecan™ Fluent™ 1080 Automation Workstation computer, in the SampleManager LIMS™ Software web client, confirm that it is time to load Module 1 (see “View the SampleManager Module 1 Load Indicator” on page 74).
2. In the Tecan™ Fluent™ 1080 Automation Workstation touchscreen home screen, tap **Method Starter**.
3. In the **Method Starter** screen, tap **Amplitude\_Module1\_Universal**, tap ✓ **OK** to select the method, then in the **Method Starter ▶ Go** screen, tap  to start the method.



4. In the **Running** ▶ **Specimen Type** screen, tap to select **Nasal**, then tap **Next Page**.

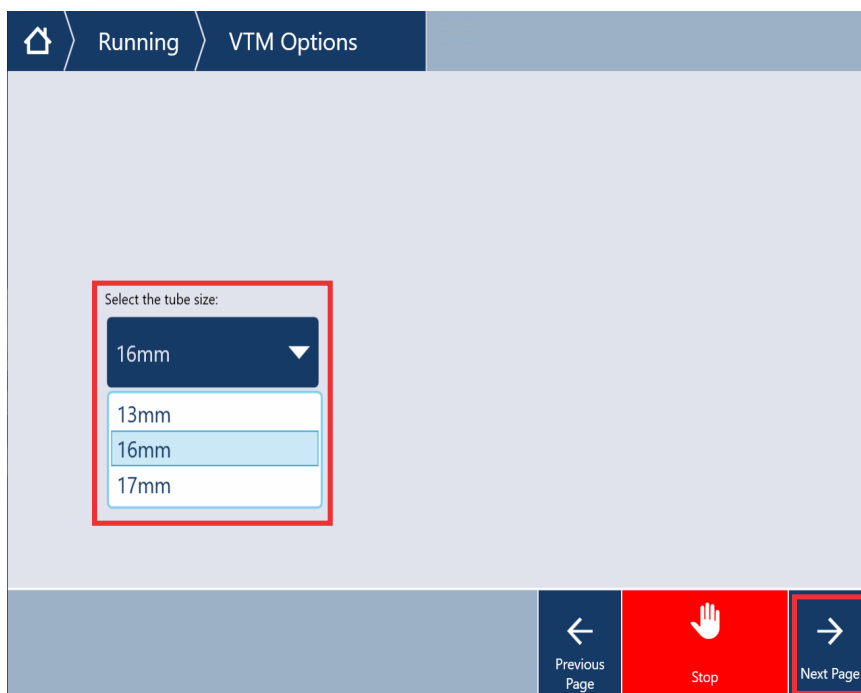


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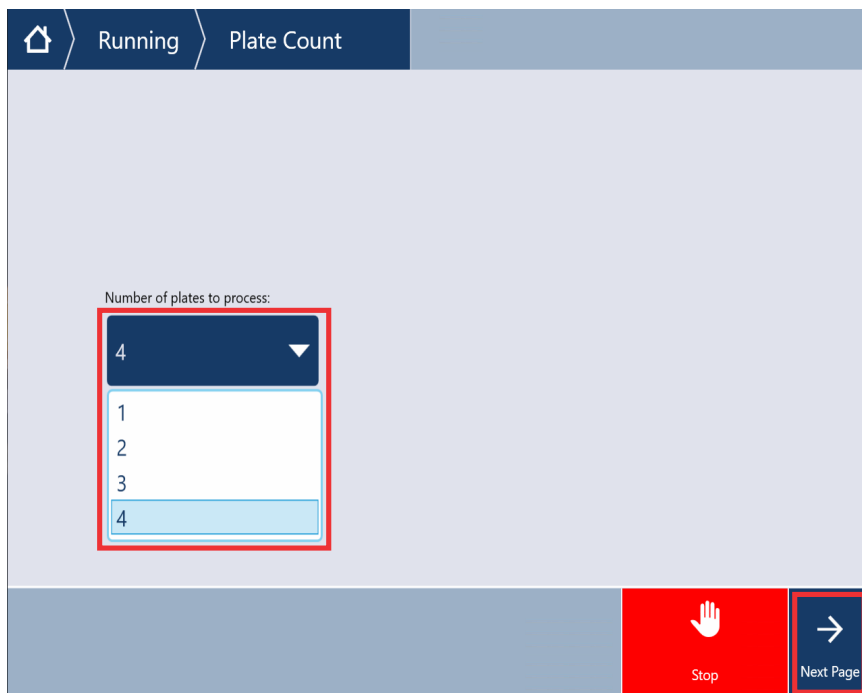
**IMPORTANT!** Multiple method options may be available depending on the script provided to your laboratory. Make sure to select the specimen type specific to your sample.

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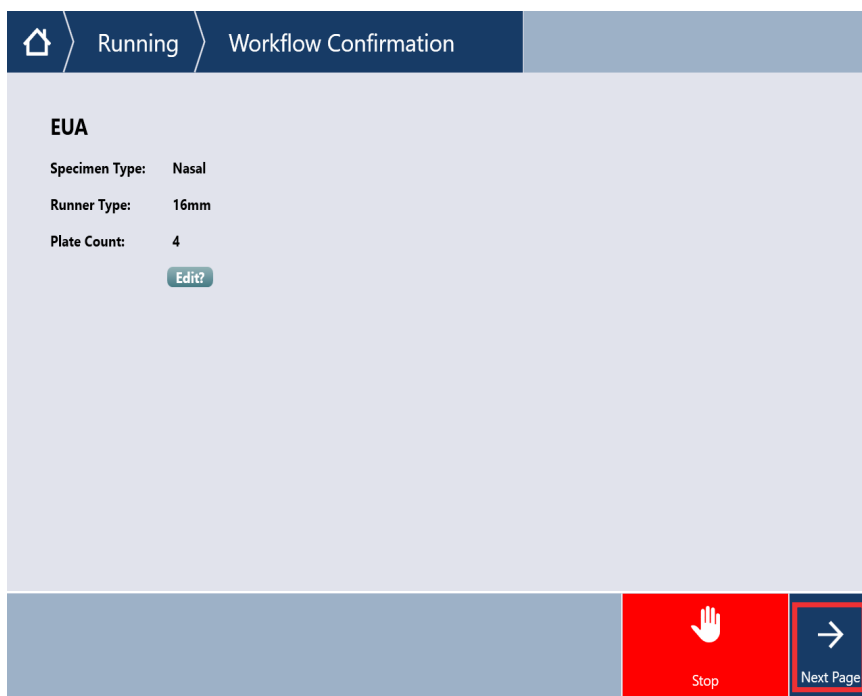
5. In the **Running** ▶ **VTM Options** screen, select the appropriate tube runner type from the dropdown list, then tap **Next Page**.



6. In the **Running ▶ Plate Count** screen, select the number of plates to process from the dropdown list, then tap **Next Page**.




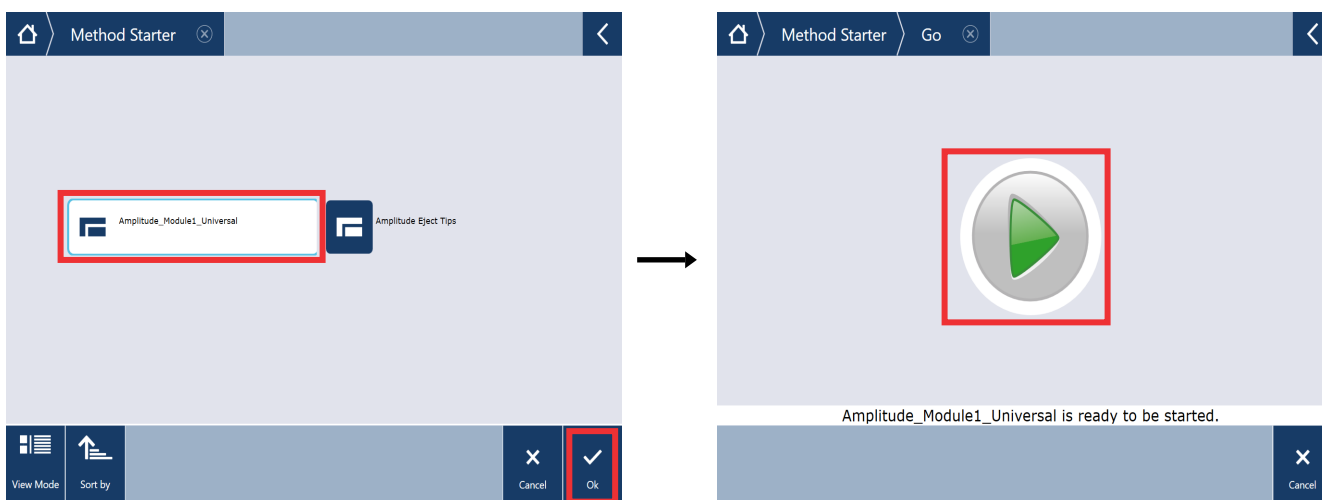
7. In the **Running ▶ Workflow Confirmation** screen, verify your method settings, then tap **Next Page**. If you need to edit your selections, tap **Edit?**.



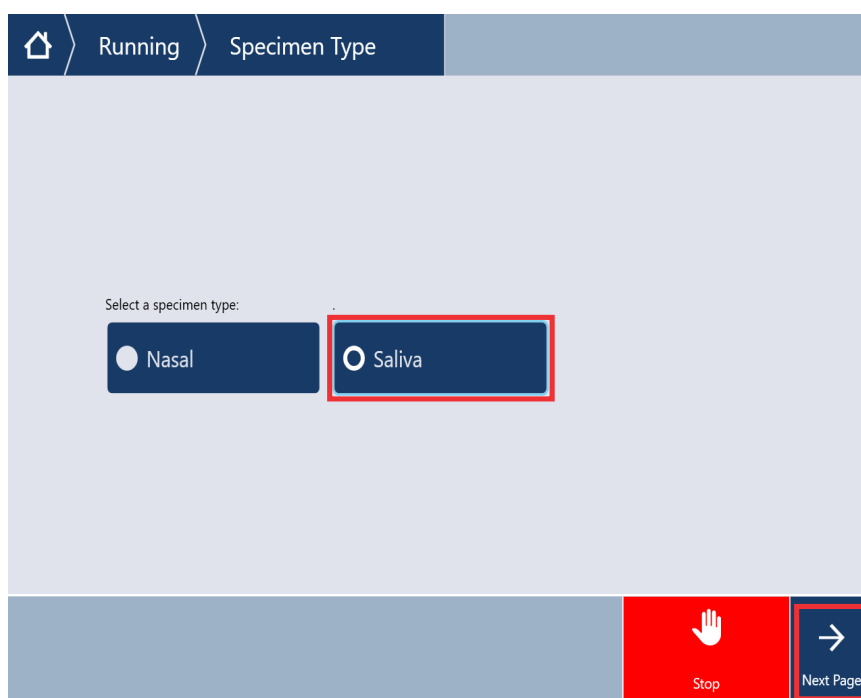
Follow the onscreen prompts to continue setting up the Tecan™ Fluent™ 1080 Automation Workstation, then proceed to “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82.

## Start the method on the Tecan™ Fluent™ 1080 Automation Workstation – saliva specimens

1. On the Tecan™ Fluent™ 1080 Automation Workstation computer, in the SampleManager LIMS™ Software web client, confirm that it is time to load Module 1 (see “View the SampleManager Module 1 Load Indicator” on page 74).
2. In the Tecan™ Fluent™ 1080 Automation Workstation touchscreen home screen, tap **Method Starter**.
3. In the **Method Starter** screen, tap **Amplitude\_Module1\_Universal**, tap ✓ **OK** to select the method, then in the **Method Starter ▶ Go** screen, tap  to start the method.



4. In the **Running ▶ Specimen Type** screen, tap to select **Saliva**, then tap **Next Page**.

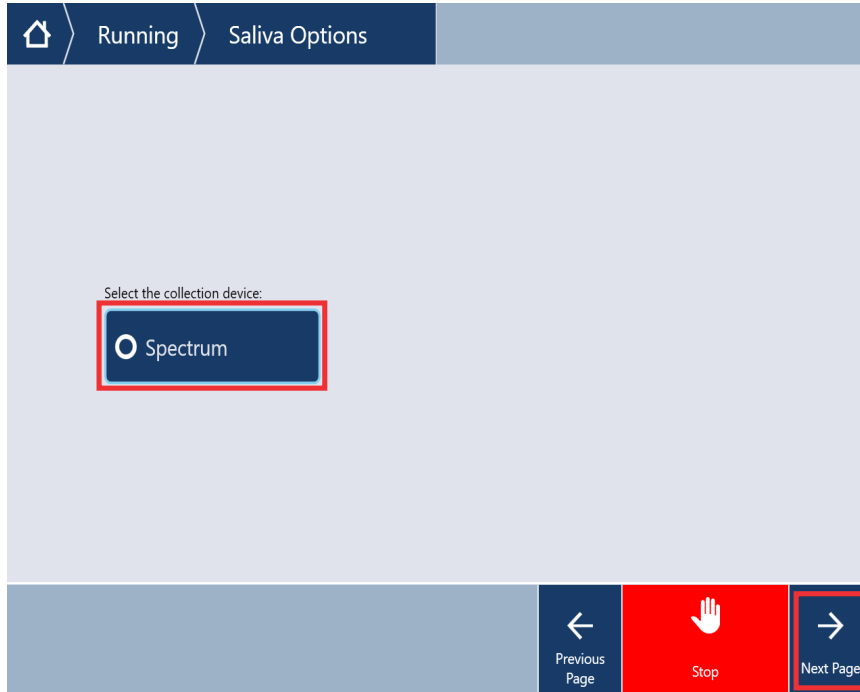


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**IMPORTANT!** Multiple method options may be available depending on the script provided to your laboratory. Make sure to select the specimen type specific to your sample.

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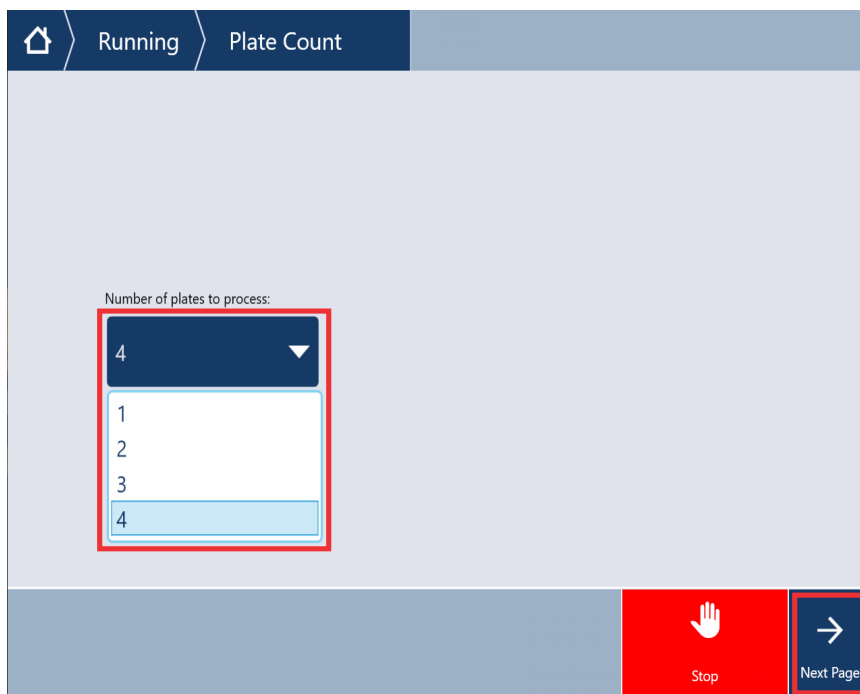
5. In the **Running ▶ Saliva Options** screen, tap to select **Spectrum**, then tap **Next Page**.



6. In the **Running ▶ Confirm Selection of Spectrum Saliva Tube** screen, confirm that the **Spectrum** saliva tube is selected and meets tube specifications that are described in the screen, then tap **Confirm**.

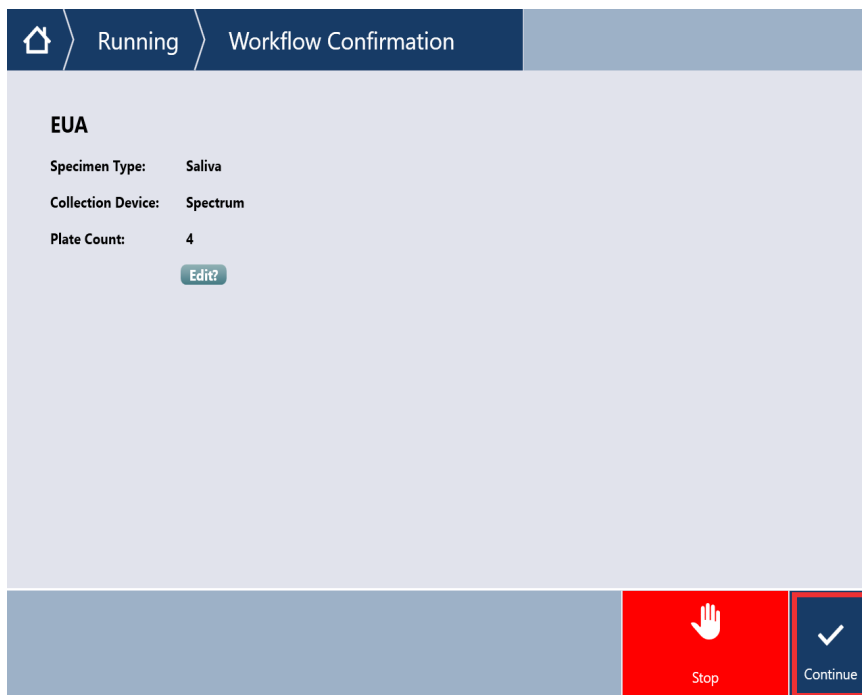


7. In the **Running ▶ Plate Count** screen, select the number of plates to process from the dropdown list, then tap **Next Page**.





8. In the **Running ▶ Workflow Confirmation** screen, verify your method settings, then tap ✓ **Continue**. If you need to edit your selections, tap **Edit?**.



The protocol provides an additional feature for tube-to-plate sample transfer verification via liquid level detection. If a sample transfer is not verified, the sample will be flagged, and the sample result will not be reported.

Follow the onscreen prompts to continue setting up the Tecan™ Fluent™ 1080 Automation Workstation, then proceed to “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82.

## Load the Tecan™ Fluent™ 1080 Automation Workstation deck

**IMPORTANT!** Start the method on the Tecan™ Fluent™ 1080 Automation Workstation, then load reagents and consumables in the correct deck positions when prompted by the instrument touchscreen. Failure to do so can result in reduced throughput.

1. Open the Tecan™ Fluent™ 1080 Automation Workstation access door.
2. Follow the touchscreen prompts to fill the empty deck.

The order in which the consumables and reagents are refilled and reload frequency is summarized in the following table. The reload frequency is dependent on the number of sample extraction plates used per run and varies from system to system.

Load the empty deck	Reload frequency			
	Every run	Every shift	Every 12 plates	Every 18–24 plates
Load 1,000 µL FCA Disposable Tips Rack × 15			X	X
Load 200 µL FCA Disposable Tips Rack × 3				X
Add new Binding Bead Mix trough <sup>[1]</sup> and Bead Mix Baffle		X		
Fill Binding Bead Mix trough	X		X	X
Add new silicone oil trough <sup>[1]</sup> and Oil Level Sensor		X		
Fill silicone oil trough	X		X	X
Add new MagMAX™ HT Proteinase K/TaqPath™ COVID-19 Module 1 MS2 Phage Control mixing trough <sup>[2]</sup>				X <sup>[3]</sup>
Load MagMAX™ HT Proteinase K in reagent carrier (see Figure 21 on page 86)				X
Load MagMAX™ HT Water in reagent carrier (see Figure 21 on page 86)				X
Load TaqPath™ COVID-19 Module 1 MS2 Phage Control × 2 in reagent carrier (see Figure 21 on page 86)				X
Load KingFisher™ Deep-Well 96 Plates with Barcodes × 4	X		X	X

<sup>[1]</sup> Axygen™ Single Well High Profile Reagent Reservoir

<sup>[2]</sup> Axygen™ Multi Well Low Profile Reagent Reservoir

<sup>[3]</sup> If running <18–24 plates per day, replace daily.

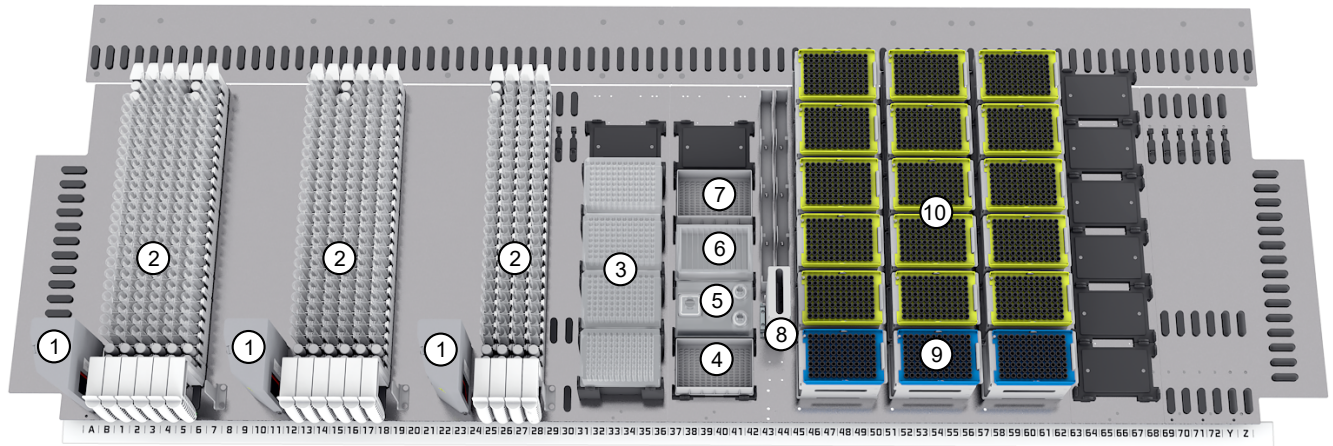


Figure 18 Tecan™ Fluent™ 1080 Automation Workstation deck layout

- ① FluentID™ Barcode Scanner × 3
- ② Tube runners containing ≤376 uncapped sample tubes
- ③ KingFisher™ Deep-Well 96 Plate with Barcode (1–4 sample extraction plates)
- ④ Binding Bead Mix reservoir (Axygen™ Single Well High Profile Reagent Reservoir)
- ⑤ Reagent carrier rack
- ⑥ MagMAX™ HT Proteinase K/TaqPath™ COVID-19 Module 1 MS2 Phage Control reservoir (Axygen™ Multi Well Low Profile Reagent Reservoir)
- ⑦ Silicone oil reservoir (Axygen™ Single Well High Profile Reagent Reservoir)
- ⑧ Tip waste chute
- ⑨ 200 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack × 3
- ⑩ 1,000 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack × 15

- a. **(Every 12 plates, or every 3 full-capacity runs of 4 plates/run)** In the **Load 1000ul yellow tips and 200ul blue tips into racks** screen, follow the prompts to load 15 × 1,000 µL FCA Disposable Tips Rack.

**IMPORTANT!** Visually inspect tips for missing filters and replace as needed.



**CAUTION!** Switching the positions of the 1,000 µL FCA Disposable Tips Rack and 200 µL FCA Disposable Tips Rack on the deck may result in loss of samples and system downtime due to the need for syringe replacement.

- b. **(Every 18–24 plates, or every 6 full-capacity runs of 4 plates/run)** In the **Load 1000ul yellow tips and 200ul blue tips into racks** screen, follow the prompts to load 3 × 200 µL FCA Disposable Tips Rack.

**IMPORTANT!** Visually inspect tips for missing filters and replace as needed.

- c. **(Every shift)** In the **Load reagents and mixing trough** screen, follow the prompts to replace both the used Binding Bead Mix trough and the silicone oil trough with a new Axygen™ Single Well High Profile Reagent Reservoir. Make sure to assemble the troughs with the appropriate inserts before loading onto the instrument deck:
- Insert the Bead Mix Baffle into the Binding Bead Mix trough.
  - Insert the Oil Level Sensor into the **left** side of the silicone oil trough.

---

**IMPORTANT!** When assembled correctly with the troughs, the text stamped on the inserts should be legible and oriented the correct side up (see Figure 19).

---

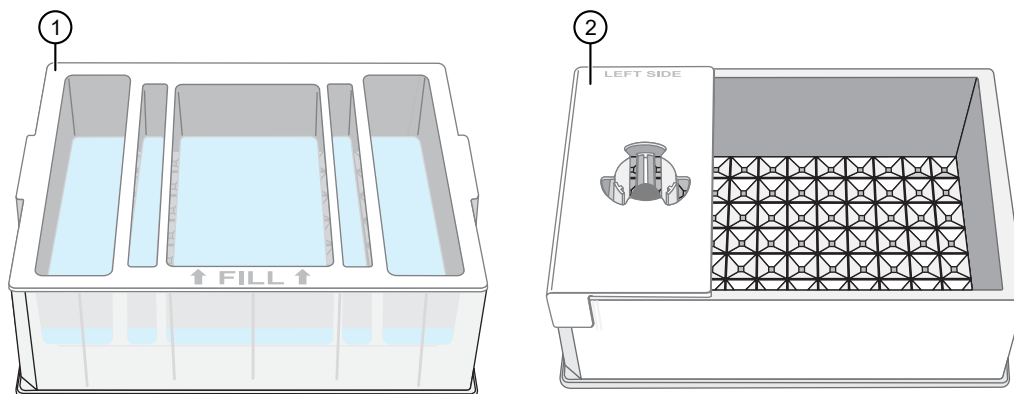


Figure 19

① Bead Mix Baffle

② Oil Level Sensor

- d. **(Every 18–24 plates, or every 6 full-capacity runs of 4 plates/run)** In the **Load reagents and mixing trough** screen, follow the prompts to scan the barcodes on the bottles of MagMAX™ HT Binding Beads and MagMAX™ HT Binding Solution that were used to prepare the Binding Bead Mix.

- e. **(Every run)** In the **Load reagents and mixing trough** screen, follow the prompts to invert the bottle of Binding Bead Mix 10 times to ensure that the mixture is homogenous, then pour the Binding Bead Mix into the middle compartment of the trough.
- For full-capacity back-to-back runs (6 runs, consisting of 4 sample extraction plates each), fill the trough up to the fill line.
  - For all other plate and run configurations, fill the trough with volume specified in Table 13.

**Note:** If there is a significant delay between Module 1 runs (e.g., >2 hours), we recommend using a new Binding Bead Mix trough to prevent aggregation of the MagMAX™ HT Binding Solution, which can lead to liquid detection errors.

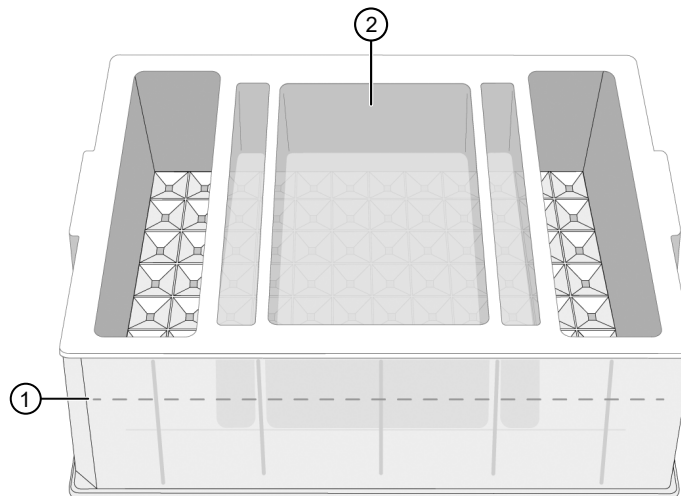


**WARNING!**

- Binding Bead Mix serves to inactivate virus in the sample extraction plate. Any misuse that leads to failure to add the Binding Bead Mix to the sample extraction plate wells can lead to increased risk of exposure to infectious material.
- Improper or overly vigorous mixing of the Binding Bead Mix can lead to invalid results or increased risk of exposure to infectious material. Minimize foaming during the mixing process.



**CAUTION!** Ensure that you add the Binding Bead Mix to the correct trough. Adding the reagent to the incorrect trough can lead to invalid results.



**Figure 20** Binding Bead Mix trough

- ① Trough fill line
- ② Middle compartment for adding the Binding Bead Mix

- f. **(Every run)** In the **Load reagents and mixing trough** screen, follow the prompts to pour the silicone oil to the trough fill line.



**CAUTION!** Ensure that you add the silicone oil to the correct trough. Adding the reagent to the incorrect trough can lead to invalid results.

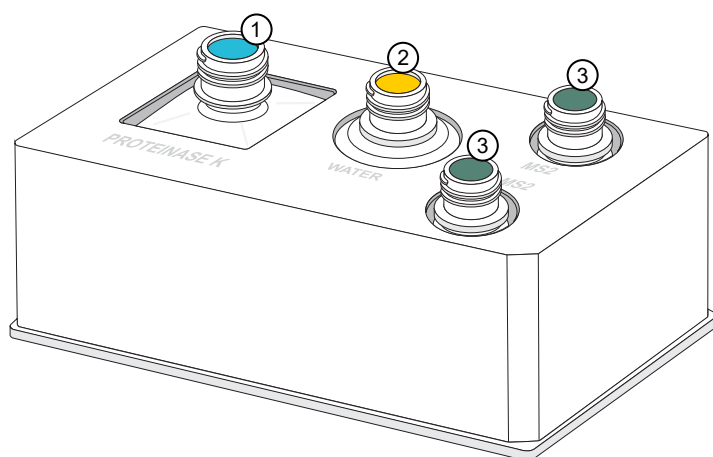
- g. **(Every 18–24 plates, or every 6 full-capacity runs of 4 plates/run)** Follow the prompts to replace the used MagMAX™ HT Proteinase K/TaqPath™ COVID-19 Module 1 MS2 Phage Control mixing trough with a new Axygen™ Multi Well Low Profile Reagent Reservoir.
- h. **(Every 18–24 plates, or every 6 full-capacity runs of 4 plates/run)** Follow the prompts to scan the reagents, then load the reagent carrier.

**Note:** Before removing the reagent bottle cap, gently tap the reagent bottle on the bench to ensure the liquid is collected at the bottom of the container.



**CAUTION!** Only scan, then load new, full bottles of reagents.

Reagent	Amount
MagMAX™ HT Proteinase K	1 bottle
MagMAX™ HT Water (for Negative Control)	1 bottle
TaqPath™ COVID-19 Module 1 MS2 Phage Control	2 bottles



**Figure 21** Module 1 reagent carrier positions

- ① MagMAX™ HT Proteinase K
- ② MagMAX™ HT Water
- ③ TaqPath™ COVID-19 Module 1 MS2 Phage Control × 2

- i. **(Every run)** In the **Load deepwell extraction plates** screen, follow the prompts to load 1–4 × KingFisher™ Deep-Well 96 Plate with Barcode.

After all of the reagents and consumables are reloaded, follow the touchscreen prompts to load the tube runners (see “Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation” on page 87).

## Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation

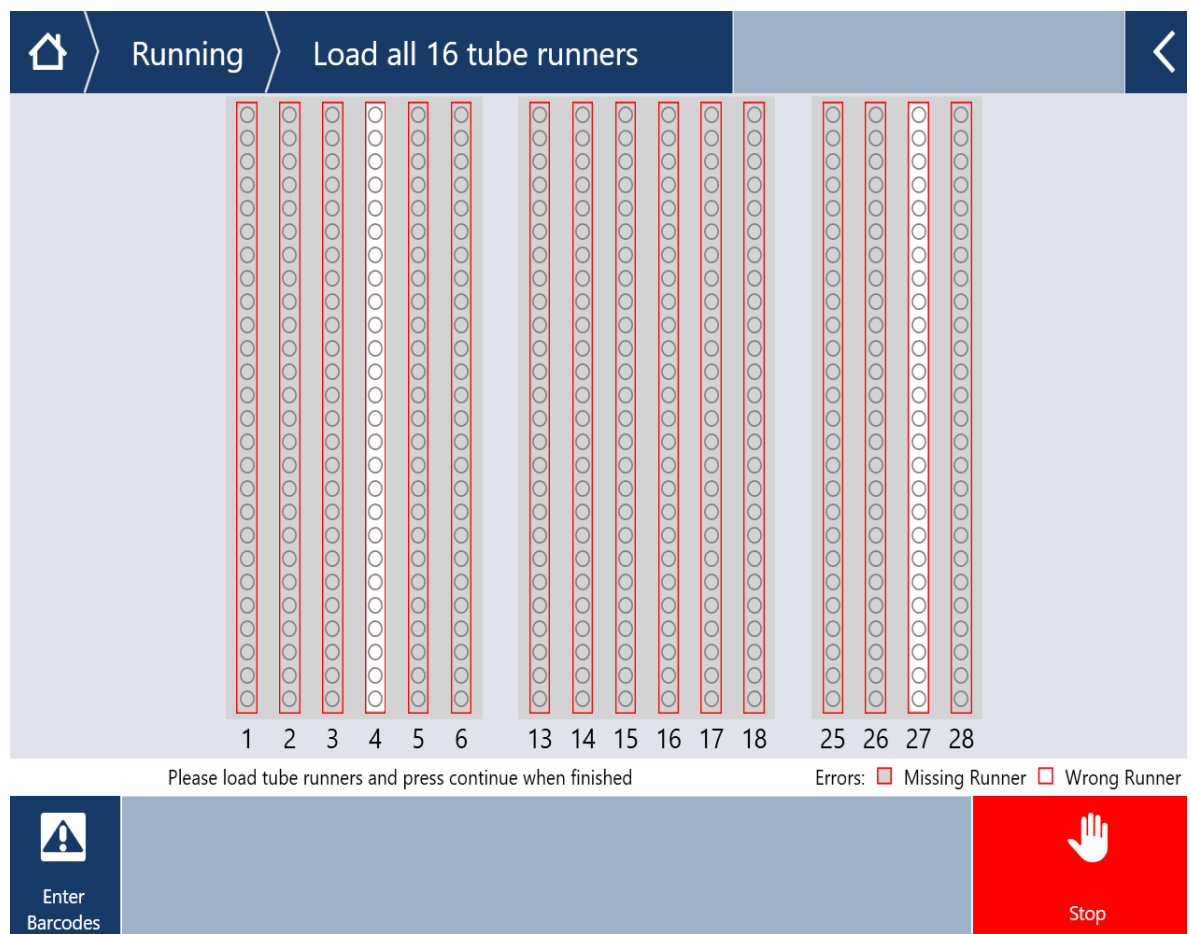
**IMPORTANT!** Start the method before you load the tube runners. Only load the tube runners when prompted by the Tecan™ Fluent™ 1080 Automation Workstation touchscreen.

1. When prompted on the Tecan™ Fluent™ 1080 Automation Workstation touchscreen to load the tube runners, confirm that the light-emitting diodes (LEDs) at the tube runner grid positions are flashing blue.

For more information, see “Tecan™ Fluent™ 1080 Automation Workstation barcode scanner LED indicators” on page 220.

**Note:**

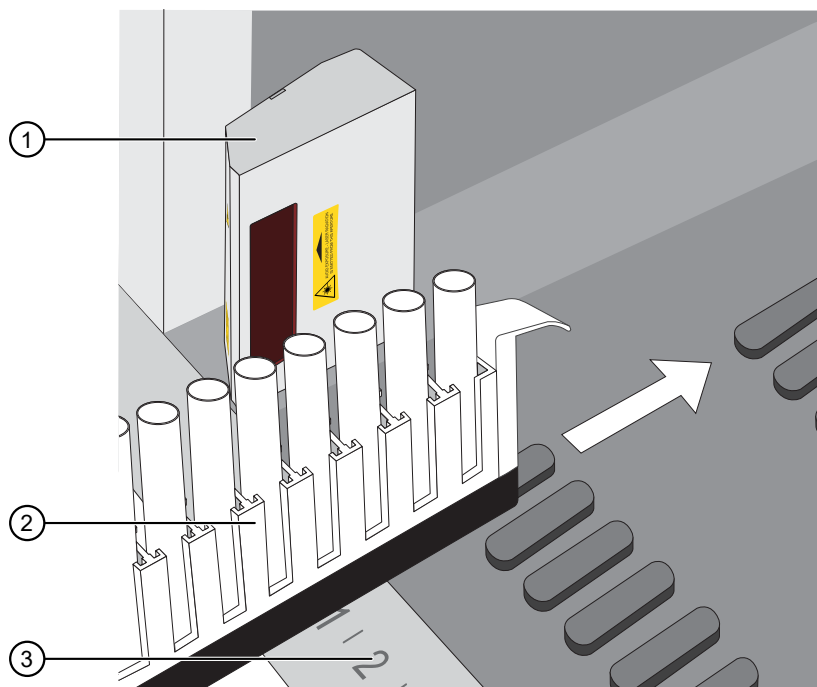
- When handling tube runners, you can support the end of a runner using the finger hook.
- Do not use any runner that appears to have damage or cracking, or if the handle is loose. Replace the damaged runner.



2. Ensure that the barcode on each sample tube is facing left and visible in the scanning window (see Figure 17 on page 66).

- Align the first control tube runner with position 1 on the deck grid, then slowly push the tube runner forward on the deck to the stop position.

**Note:** The tube runners that contain the control plug positions must be inserted at specific grid positions on the deck (see Table 14 on page 88).



**Figure 22** Load the tube runner

- Tecan™ FluentID™ Tube Barcode Scanner
- Sample tubes in tube runner, barcodes facing left
- Numbers indicating grid position on the deck

**Table 14** Deck grid positions for tube runners

Tube runner size	Deck grid positions	
	Tube runners with controls	All tube runners
13 mm, 32-position control tube runner (12–14 mm tubes)	1, 4, 13, and 16	1–6 and 13–18
16 mm, 26-position control tube runner (15–17 mm tubes)	1, 5, 15, and 25	1–6, 13–18 and 25–28
17 mm, 24-position control tube runner (16–18 mm tubes)		

The Tecan™ FluentID™ Tube Barcode Scanner scans each barcode as the tube runner is pushed forward on the deck.



- On the touchscreen, review the status for each tube runner and tube barcode to ensure that all of the barcodes in the tube runner were successfully scanned.

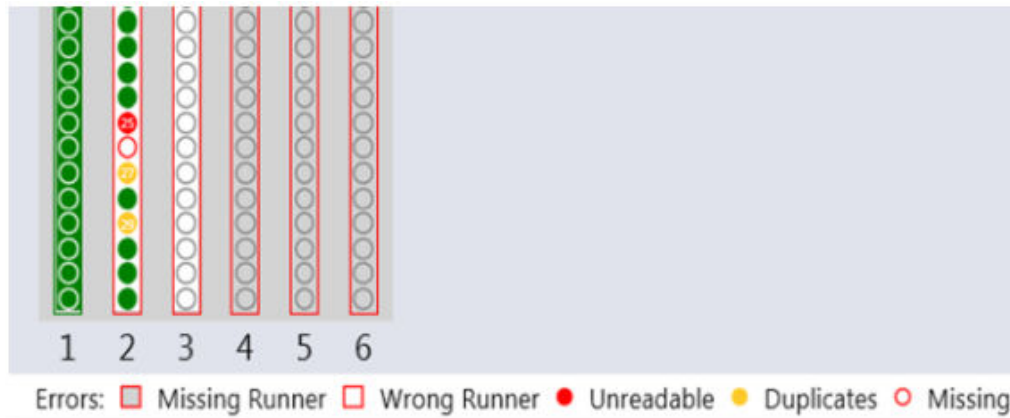


Figure 23 Tube runner and barcode status indicator

Indicator color	Meaning
<b>Tube runner indicator (rectangle)</b>	
Green	All of the barcodes for the tubes in the tube runner were scanned successfully.
White with red outline	The tube runner loaded in the grid position is incorrect.
Grey with red outline	The tube runner for the grid position is missing.
<b>Individual tube indicator (circle)</b>	
Green	The tube barcode was scanned successfully.
Red	The tube barcode was scanned unsuccessfully.
Orange	The tube barcode is a duplicate.
White with red outline	The tube is missing.

- In the event of a barcode scanning error, follow the touchscreen prompts to correct the error. If necessary, unload the tube runner, correct the problem, then slowly reload the tube runner.

**Note:** If scanning of an individual sample tube fails after multiple attempts to reload the same runner, the tube can be scanned manually. Without removing the runner from the deck, locate and lift the tube out of the runner. On the Tecan™ Fluent™ 1080 Automation Workstation touchscreen, tap **Enter Barcode**, then select the dark blue box to open the keyboard. Use the hand-held scanner to scan the barcode on the tube, then click **OK**.

- Following the touchscreen prompts, load the remaining tube runners, ensuring that the control tube runners are loaded at the correct deck positions.
- Once all of the tube runners are loaded successfully, close the front safety panel.
- Tap **Continue** on the touchscreen to continue the run.

## Monitor the Module 1 run

1. Monitor the progress of the run on the Tecan™ Fluent™ 1080 Automation Workstation touchscreen.
2. If the instrument encounters an error, follow the Tecan™ Fluent™ Automation Workstation recovery protocol prompts on the touchscreen.

---

**IMPORTANT!** If a sample failure is detected during preparation of the Module 1 sample extraction plates, then the sample is not registered with the system. An error message is attached to the job in the SampleManager LIMS™ Software and a notification email is sent to the distribution list (see “Review jobs in SampleManager LIMS™ Software for sample preparation error messages” on page 148).

---

When the run is finished, confirm that all of the sample extraction plates that you are using (up to 4 plates) have been registered in SampleManager LIMS™ Software, then transfer the sample extraction plates to Module 2 (see “Transfer sample extraction plates from Module 1 to Module 2”).

---

**Note:** A full-capacity run that uses 4 sample extraction plates takes ~50 minutes to complete. If running <4 plates, the time to completion is reduced.

---

## Transfer sample extraction plates from Module 1 to Module 2

Before you begin, confirm that all of the sample extraction plates that you are using (up to 4 plates) are registered in SampleManager LIMS™ Software, then make sure to transfer the plates to Module 2 within the 7 hour expiration window.



**WARNING!** You must check the sample extraction plates into Module 2 within 7 hours of the completion of the Module 1 run. To ensure that plates are within the established stability window, Module 2 does not accept sample extraction plates that are more than 7 hours old for check-in.

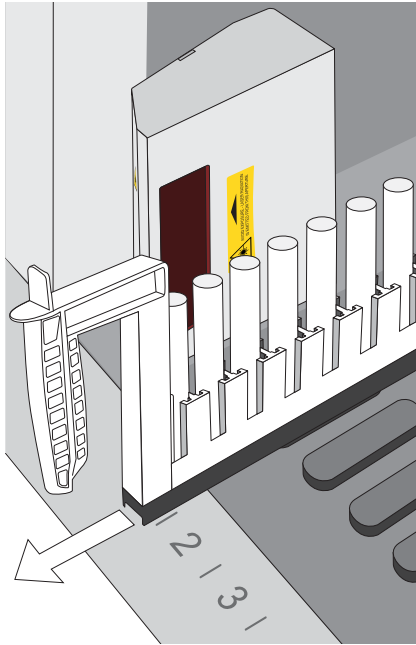
1. On the Tecan™ Fluent™ 1080 Automation Workstation touchscreen, tap ✓ **OK** to confirm that the run is complete.
2. Remove the sample extraction plates from the Tecan™ Fluent™ 1080 Automation Workstation deck, then follow the guidelines established by your laboratory to cover and/or place the plates in an enclosed secondary container for transport to Module 2.
3. Transfer the sample extraction plates to Module 2.

## Unload the tube runners

**Note:** We recommend two technicians for this task:

- One technician to remove the tube runners
- One technician to transfer the tube runners to a biological safety cabinet, then recap the sample tubes

1. To unload a tube runner, pull the runner back horizontally at the level of the deck. Ensure that the tube runner is clear of the grid alignment channels before lifting the runner.



**Figure 24** Unload the tube runners from the Tecan™ Fluent™ 1080 Automation Workstation

2. Immediately place the tube runner in a BSL-2 biological safety cabinet.
3. Repeat step 1 and step 2 for the remaining tube runners.
4. On the Tecan™ Fluent™ 1080 Automation Workstation touchscreen, confirm that unloading of the tube runners is complete.
5. In the biological safety cabinet, remove the sample tubes from the tube runner, capping each tube with a new cap as it is removed.

Store the sample tubes according to the procedures established by your laboratory.

## Prepare the Tecan™ Fluent™ 1080 Automation Workstation for the next shift or to be idle

- At the beginning of each shift, run the Tecan™ Fluent™ 1080 Automation Workstation **DailySystemCare** method (see page 70).
- At the end of each shift, empty the Tecan™ Fluent™ 1080 Automation Workstation tip waste (see page 92).



**WARNING!** Failure to empty tip waste and conduct Tecan™ Fluent™ 1080 Automation Workstation system care when prompted can result in lower throughput, inaccurate results, or loss of the sample.

---

**Note:** If the system will be idle for more than 18 hours (for example, for a weekend), we recommend that you power off all of the components.

---

### Empty the Tecan™ Fluent™ 1080 Automation Workstation tip waste

Empty the Tecan™ Fluent™ 1080 Automation Workstation tip waste at the end of every day or shift.

---

**IMPORTANT!** Empty the tip waste according to the schedule. Failure to do so can result in a lower throughput.

---

1. Open the Tecan™ Fluent™ 1080 Automation Workstation cabinet.
2. Remove the full biohazard bag, then dispose of it according to your laboratory guidelines.
3. Insert a new biohazard bag in the bin.
4. Close the Tecan™ Fluent™ 1080 Automation Workstation cabinet.

# 7

## Perform a Module 2 run

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■ Monitor the Module 2 run	134
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### Module 2 overview

Module 2 operation is controlled via the Momentum™ Workflow Scheduler Software on the Module 2 computer station.

During Module 2 operation, the following tasks are performed:

- Technicians load sample extraction plates, replenish reagents and consumables and unload the outgoing RNA elution plates.
- The sample extraction plates are processed, with an output of one RNA elution plate that contains purified sample RNA for each sample extraction plate used (up to 4 plates maximum).
- The Tecan™ Fluent™ 780 Automation Workstation prepares the real-time RT-PCR plates, including 10 µL of purified sample RNA transferred from the RNA elution plates.
- The Tecan™ Fluent™ 780 Automation Workstation and Spinnaker™ Microplate Robot scan the plate barcodes, then register the information with the SampleManager LIMS™ Software for sample tracking.
- Real-time RT-PCR is performed, then the results are analyzed and transferred to the SampleManager LIMS™ Software for review.

Technicians also need to perform regular Module 2 maintenance. For the regular maintenance task list and schedule, see Chapter 9, “Perform regular maintenance”.

For more information about the automated steps in Module 2, see Chapter 9, “Perform regular maintenance”.

## Module 2 required sample input, reagents, and consumables

The following tables list the required sample input, reagents, and consumables based on the action being completed in the Momentum™ Software: **Check in**, **Replenish reagents**, or **Replenish consumables**.

Momentum™ Software prompts to reload reagents and consumables as required. The required amount of reagents and consumables as well as reload frequency is dependant on the number of sample extraction plates used.

**Table 15 Check in—Required sample input**

Required sample input	Usage (Reload frequency)	See
<b>Hotel Input (Position 1, Figure 25 on page 96)</b>		
Sample extraction plates from Module 1	1–4 plates per run	page 130

**Table 16 Replenish reagents—Required reagents and consumables**

Required reagents and consumables	Usage (Reload frequency)	See
<b>Tecan™ Fluent™ 780 Automation Workstation (Position 2, Figure 25 on page 96)</b>		
TaqPath™ COVID-19 HT qPCR Assay	1 tube/3 runs or 1 tube/12 plates	page 125
TaqPath™ COVID-19 Control	1 tube/22 plates	
TaqPath™ COVID-19 Module 2 Control Dilution Buffer	1 tube/22 plates	
TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX)	1 tube/3 runs or 1 tube/12 plates	
MagMAX™ HT Water	1 bottle/24 plates	
1,000 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	3 racks/18 runs	
200 µL Flexible Channel Arm™ (FCA) Disposable Tips Rack	3 racks/18 runs	
150 µL MultiChannel Arm™ (MCA) Disposable Tips Rack	12 racks/12 plates	
2-mL tubes	2 tubes/6 runs	
TaqPath™ HT Module 2 Empty 5 mL Mixing Tubes	6 tubes/6 runs	

**Table 16 Replenish reagents—Required reagents and consumables (continued)**

Required reagents and consumables	Usage (Reload frequency)	See
<b>Multidrop™ Combi Reagent Dispenser × 3 (Positions 6-8, Figure 25 on page 96)</b>		
MagMAX™ HT Elution Solution (used with Combi 1)	1 bottle/72 plates	page 127
MagMAX™ HT Wash Solution (Wash 1, used with Combi 2)	3 bottles/72 plates	
80% Ethanol (Wash 2, used with Combi 3)	2 bottles/72 plates	

**Table 17 Replenish consumables—Required consumables**

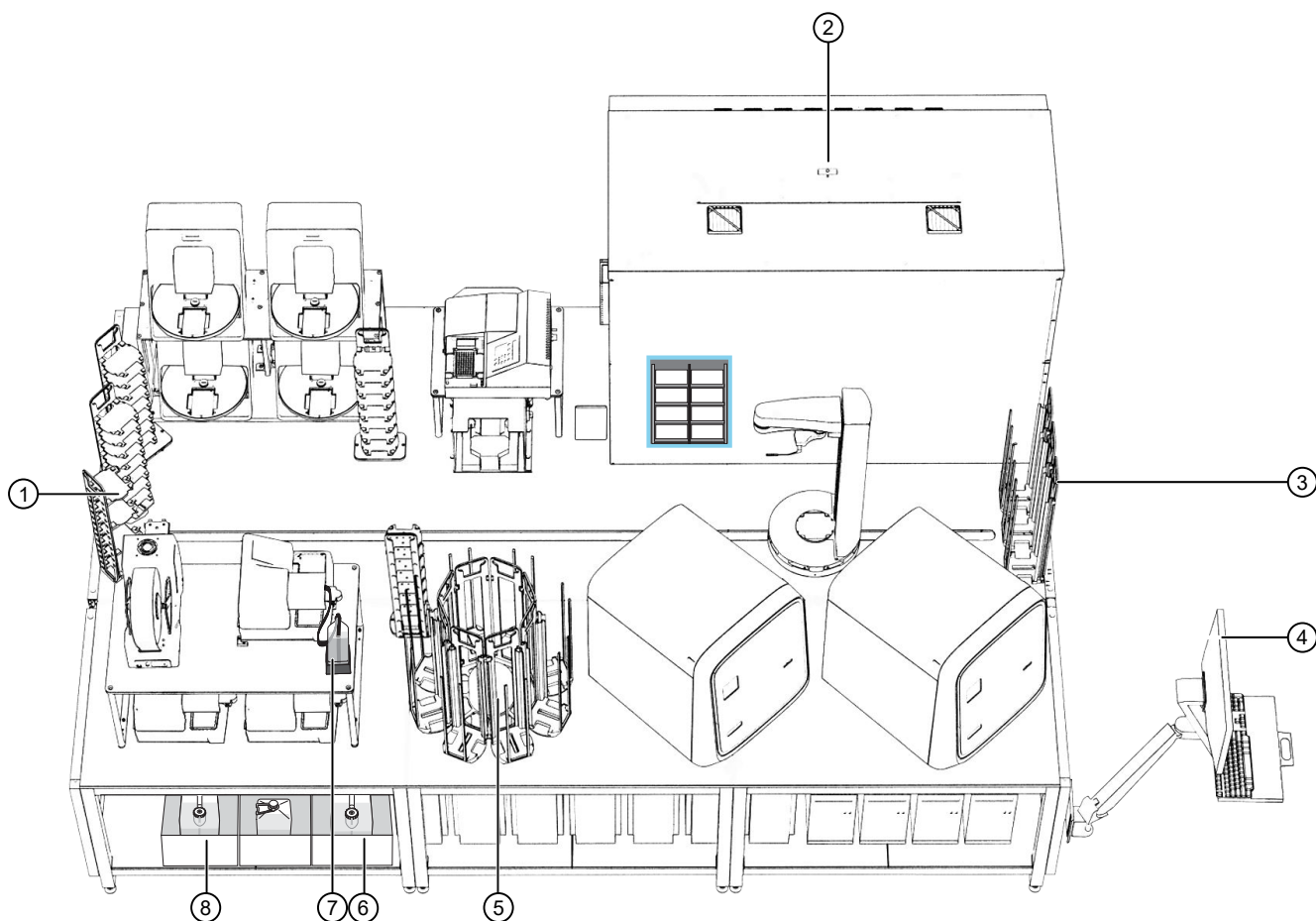
Required consumables	Usage (Reload frequency)	See
<b>Tecan™ Fluent™ 780 Automation Workstation (Position 2, Figure 25 on page 96)</b>		
MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode	6 plates/6 runs	page 125
<b>RNA Elution Plate Stackers (Position 3, Figure 25 on page 96)</b>		
KingFisher™ Deep-Well 96 Plate with Barcode (RNA elution plates)	10–40 plates/10 runs <sup>[1]</sup>	page 115
KingFisher™ 96 tip comb for deep-well magnets (for RNA elution plates)	10–40 tip combs/10 runs <sup>[2]</sup>	
<b>Wash Plate Stacker Carousel (Position 5, Figure 25 on page 96)</b>		
KingFisher™ Deep-Well 96 Plates with Barcodes (wash plates)	20–80 plates/10 runs <sup>[3]</sup>	page 115

<sup>[1]</sup> 1 RNA elution plate per sample extraction plate per run

<sup>[2]</sup> 1 KingFisher™ 96 tip comb for deep-well magnets for each KingFisher™ Deep-Well 96 Plate with Barcode

<sup>[3]</sup> 2 wash plates per sample extraction plate per run

## Locations for loading Module 2 incoming samples, reagents, and consumables



**Figure 25** Locations for loading Module 2 incoming samples, reagents, and consumables

- |   |  |
|---|--|
| ① Hotel Input for Module 1 sample extraction plates   | ⑥ Wash 2 (80% Ethanol) carboy (reagent dispensed by Multidrop™ Combi Reagent Dispenser 3)              |
| ② Tecan™ Fluent™ 780 Automation Workstation   | ⑦ MagMAX™ HT Elution Solution (reagent dispensed by Multidrop™ Combi Reagent Dispenser 1)              |
| ③ RNA Elution Plate Stacker × 4—Used to hold prepared RNA elution plates                                      | ⑧ Wash 1 (MagMAX™ HT Wash Solution) carboy (reagent dispensed by Multidrop™ Combi Reagent Dispenser 2) |
| ④ Module 2 computer station—Used to replenish required materials in the Momentum™ Workflow Scheduler Software |  |
| ⑤ Wash Plate Stacker Carousel—Used to hold wash plates  |  |



## Module 2 workflow

The following workflow outlines tasks that need to be performed during daily operation of the system. For the regular maintenance task list and schedule, see Chapter 9, “Perform regular maintenance”.

### Module 2 workflow (approximately 2 hours 15 minutes)

#### Initialize Module 2 if offline (page 98)

If Module 2 was just powered on, or is offline, complete the following tasks:

- Initialize each QuantStudio™ 7 Flex Real-Time PCR System (page 99)
- Initialize the Tecan™ Fluent™ 780 Automation Workstation (page 101)
- Open the Momentum™ Software (page 102)

#### Before you begin—Module 2 (page 103)

Before you begin each shift, ensure that you have all of the required materials, then prepare the following instruments for use, as required:

- Perform Tecan™ Fluent™ 780 Automation Workstation daily system care (page 104)
- Inspect the Tecan™ Fluent™ 780 Automation Workstation and A25 Refrigerated Circulator (page 106)
- Engage and prime each Multidrop™ Combi Reagent Dispenser if idle (page 107)

#### Thaw Module 2 reagents (page 110)

Ensure that you thaw the Module 2 reagents before they need to be reloaded.

#### Prepare the RNA elution plates (page 110)

Every 10 runs, prepare 10–40 RNA elution plates before they need to be reloaded. Each run uses 1–4 plates.

#### Reload Module 2 consumables (page 111)

As needed, replenish consumables in the Momentum™ Software, then reload in the correct location.

- RT-PCR Plates—**Every 6 runs**
- Wash plates and RNA elution plates—**As needed**
- Replenish consumables in the Momentum™ Software (page 112)
- Physically load the consumables in the correct location:
  - Physically load the RNA Elution Plate Stackers and Wash Plate Stacker Carousel (page 115)
  - Load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck (page 125)

#### Perform Module 2 pre-run connectivity and plate checks (page 116)

- Check network drive mapping and connectivity (page 116)
- Check QuantStudio™ connectivity and plate (page 117)

## Module 2 workflow (approximately 2 hours 15 minutes)

- Check the centrifuge plate (page 118)

### Bring all Module 2 devices online (page 118)

Before every run, ensure that all of the Module 2 devices are online.

### Reload Module 2 reagents (page 119)

As needed, replenish reagents in Momentum™ Software, then reload in the correct location.

- **Every 12 plates**—150 µL MCA Disposable Tips
- **Every 72 plates**—200 µL FCA Disposable Tips, 1,000 µL FCA Disposable Tips, and Multidrop™ Combi Reagent Dispenser reagents
- **As needed**—RT-PCR reagents and consumables
- Replenish reagents in the Momentum™ Software (page 119).
- Physically load the consumables in the correct location:
  - Load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck (page 125)
  - Refill the Multidrop™ Combi Reagent Dispenser reagents (page 127)

### Check in Module 1 sample extraction plates and start a run (page 130)

To start a run, load the sample extraction plates, then check in using the Momentum™ Software.

### Monitor the Module 2 run (page 134)

During each run, monitor the run progress in the Momentum™ Software.

### Unload outgoing RNA elution plates from the Hotel Output (page 135)

After a run is complete, unload the outgoing RNA elution plates when prompted in the Momentum™ Software.

### Prepare Module 2 for the next shift or to be idle (page 136)

After every shift, empty system waste and perform regular maintenance as needed.

## Initialize Module 2 if offline

If Module 2 was just powered on or is offline you must complete the following tasks using the Module 2 computer station:

1. Initialize each QuantStudio™ 7 Flex Real-Time PCR System (page 99)
2. Initialize the Tecan™ Fluent™ 780 Automation Workstation (page 101)
3. Open the Momentum™ Software (page 102)

All of the computers are accessed using the Module 2 computer station. To switch the desktop display to a different computer, use the following keyboard shortcuts:

Desktop to display	Shortcut
Momentum™ Software computer, also runs the following software: <ul style="list-style-type: none"> <li>• BioTek™ Liquid Handling Control Software</li> <li>• FILLit™ Software for Multidrop™ Combi Reagent Dispensers</li> <li>• BindIt™ Software for KingFisher™ Purification Systems</li> </ul>	<b>Ctrl Ctrl 1</b>
QuantStudio™ 7 Flex Real-Time PCR System 1 computer	<b>Ctrl Ctrl 2</b>
QuantStudio™ 7 Flex Real-Time PCR System 2 computer	<b>Ctrl Ctrl 3</b>
Tecan™ Fluent™ 780 Automation Workstation computer	<b>Ctrl Ctrl 4</b>

**Note:** To use a shortcut, press **Ctrl** twice in a row, then press the indicated number.



**WARNING!** Any Tecan™ Fluent™ 780 Automation Workstation error messages should be managed through the Momentum™ Software, not the Tecan™ Fluent™ 780 Automation Workstation touchscreen.

## Initialize each QuantStudio™ 7 Flex Real-Time PCR System

Each QuantStudio™ 7 Flex Real-Time PCR System must be initialized if Module 2 was just powered on or if the system is offline.



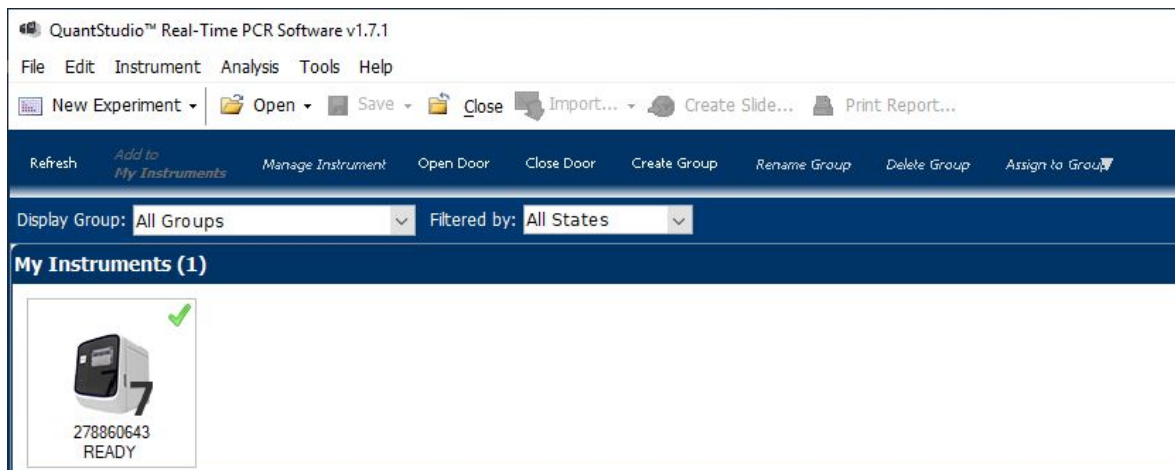
**CAUTION!** Do not independently operate the instruments via the instrument controls.

1. On the Module 2 computer station, use the **Ctrl Ctrl 2** shortcut to open the QuantStudio™ 7 Flex Real-Time PCR System 1 computer desktop.
2. On the QuantStudio™ 7 Flex Real-Time PCR System 1 desktop, double-click the QuantStudio™ Real-Time PCR Software icon.

3. In the QuantStudio™ Real-Time PCR Software, in the **Run** pane, click **Instrument Console**.



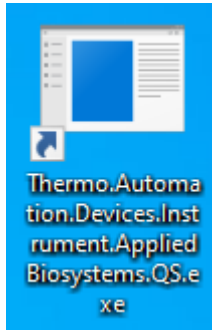
4. In the **My Instruments** pane, confirm that the QuantStudio™ 7 Flex Real-Time PCR System status is **READY**.



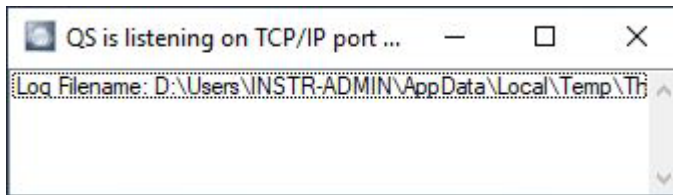
5. Minimize the QuantStudio™ Real-Time PCR Software window.

**IMPORTANT!** Do not close the QuantStudio™ Real-Time PCR Software, only minimize it.

6. On the QuantStudio™ 7 Flex Real-Time PCR System 1 desktop, double-click the shortcut to open the QuantStudio™ server.



The QuantStudio™ server dialog box opens, indicating that the server is communicating with the Momentum™ Software.

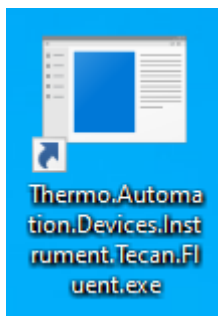


7. Use the **Ctrl Ctrl 3** shortcut to switch to the QuantStudio™ 7 Flex Real-Time PCR System 2 computer desktop.
8. Repeat step 2 to step 6 for the QuantStudio™ 7 Flex Real-Time PCR System 2.

## Initialize the Tecan™ Fluent™ 780 Automation Workstation

The Tecan™ Fluent™ 780 Automation Workstation must be initialized if Module 2 was just powered on or if the system is offline.

1. On the Module 2 computer station, use the **Ctrl Ctrl 4** shortcut to open the Tecan™ Fluent™ 780 Automation Workstation computer desktop.
2. On the Tecan™ Fluent™ 780 Automation Workstation computer desktop, double-click the Tecan™ server icon.



3. Open the Tecan™ FluentControl™ Software.
4. Use the **Ctrl Ctrl 1** shortcut to switch back to the Momentum™ Workflow Scheduler Software computer desktop view.

## Open the Momentum™ Software

If the system was just powered on, complete the following tasks before opening the Momentum™ Software:

- Initialize each QuantStudio™ 7 Flex Real-Time PCR System (page 99)
- Initialize the Tecan™ Fluent™ 780 Automation Workstation (page 101)

For more information using the **Work Manager Dashboard** to operate Module 2, see Appendix F, “Momentum™ Software Work Manager Dashboard screen”.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. Double-click the Momentum™ Software icon to open the software.
3. In the **Momentum Security** dialog box, enter the username and password, then click **Login**.

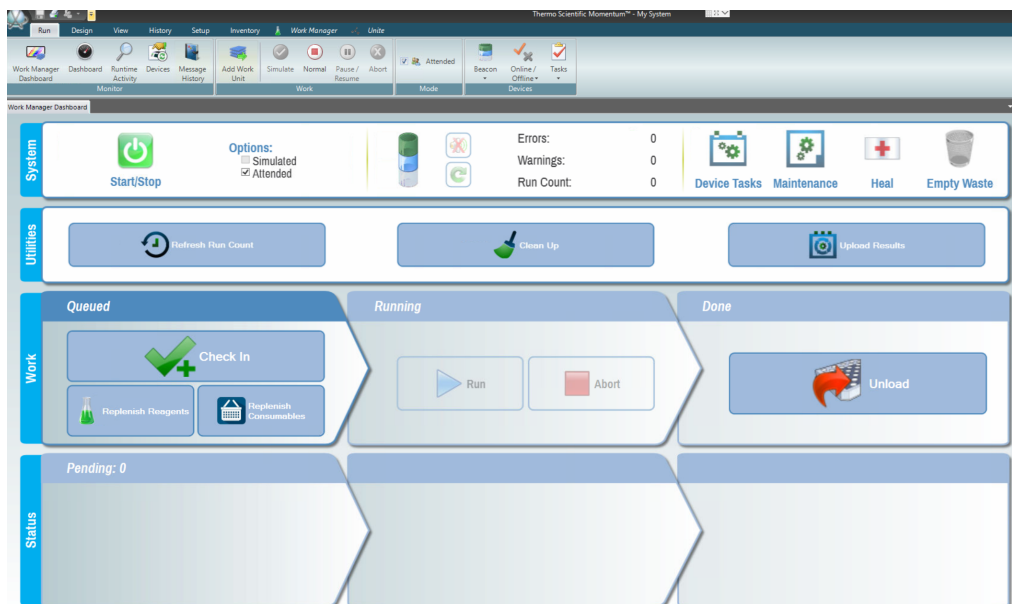
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**IMPORTANT!** If you forget your password or get locked out of the software, contact your laboratory administrator.

---

4. In the Momentum™ Software home screen, in the **Run** menu pane, click **Work Manager Dashboard**.

The **Work Manager Dashboard** opens.



## Before you begin—Module 2

At the beginning of each shift, complete the following tasks, if needed:

Task	Frequency	
	1 shift per day	3 shifts per day
“Perform Tecan™ Fluent™ 780 Automation Workstation daily system care” on page 104	Perform at the beginning of the day.	Perform at the beginning of each shift.
Ensure that you have all of the required materials to complete the desired number of runs (see “Module 2 required sample input, reagents, and consumables” on page 94).	Perform at the beginning of the day.	Perform at the beginning of every shift.
Inspect the Tecan™ Fluent™ 780 Automation Workstation and A25 Refrigerated Circulator (page 106).		
Engage and prime each Multidrop™ Combi Reagent Dispenser if idle (page 107).	Engage and prime all 3 instruments after powering on or at the beginning of the day.  Prime the Wash 1 Multidrop™ Combi Reagent Dispenser if idle for >3 hours <sup>[1]</sup> .	Engage and prime all 3 instruments after powering on.  Prime the Wash 1 Multidrop™ Combi Reagent Dispenser if idle for >3 hours <sup>[1]</sup> .

<sup>[1]</sup> The technician is responsible for monitoring the time the instrument is idle.

## Perform Tecan™ Fluent™ 780 Automation Workstation daily system care



**WARNING!** Failure to maintain the system as described in this guide can result in lower throughput, inaccurate results, or loss of sample.

If Tecan™ Fluent™ 780 Automation Workstation is "online" in Momentum™ Software, take the Tecan™ Fluent™ 780 Automation Workstation "offline" before proceeding with system care or maintenance.

1. In the Tecan™ Fluent™ 780 Automation Workstation touchscreen home screen, tap **System Care**.

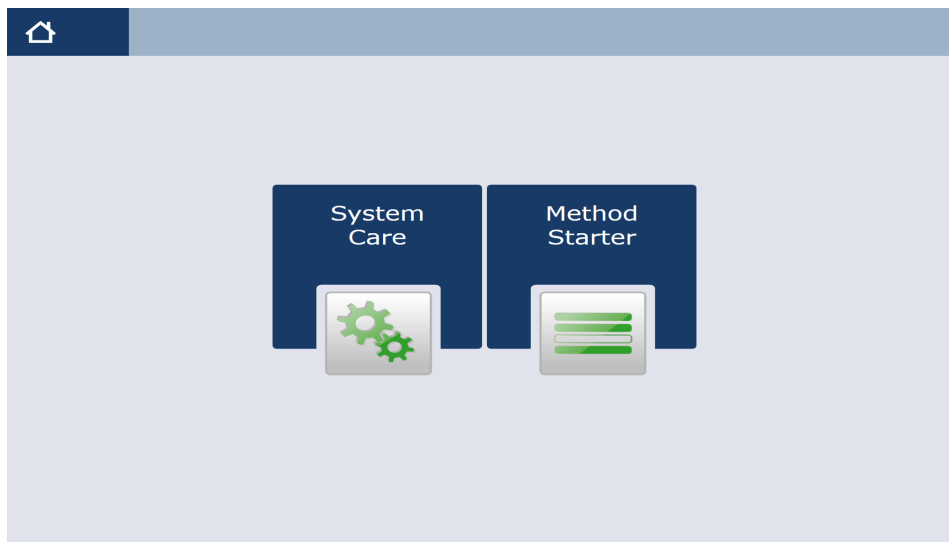


Figure 26 Tecan™ Fluent™ 780 Automation Workstation touchscreen home screen

2. In the **System Care** screen, select the **DailySystemCare** method.
3. Follow the on screen prompts to perform the following tasks:



**CAUTION!** Do not use bleach for the **DailySystemCare** cleaning.

- Clean disposable tip cones with an ethanol wipe
- Empty disposable tip waste
- Check that the MCA adapter head is clean
- Check that the gripper fingers on the RGA are straight and level



## Refresh run count

When RT-PCR reagents and consumables are replenished or every time you reload RT-PCR reaction plates and TaqPath™ HT Module 2 Empty 5 mL Mixing Tubes, you must perform the following processes:

- Execute the **Refresh Run Count** process to reset the run counter to zero and force the Tecan™ Fluent™ 780 Automation Workstation to dilute the positive control in the next run.
  - After the **Refresh Run Count** process is complete, barcode scan and replenish RT-PCR reagents and consumables.
1. In the Momentum™ Software **Work Manager Dashboard**, click **Refresh Run Count**, then click **OK** in the dialog box to begin the process.
  2. Barcode scan and replenish all reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck, including RT-PCR reagents and consumables.
  3. Ensure that there are 6 RT-PCR plates present in the hotel on the Tecan™ Fluent™ 780 Automation Workstation deck, then check in the plates as described in “Replenish consumables in the Momentum™ Software” on page 112.

---

**Note:** If the **Refresh Run Count** process does not begin immediately, check if all work units have been completed. If a work unit is currently running, you must wait until the run is finished for the **Refresh Run Count** process to begin.

---

## Inspect the Tecan™ Fluent™ 780 Automation Workstation and A25 Refrigerated Circulator

Inspect the Tecan™ Fluent™ 780 Automation Workstation and A25 Refrigerated Circulator before every shift.

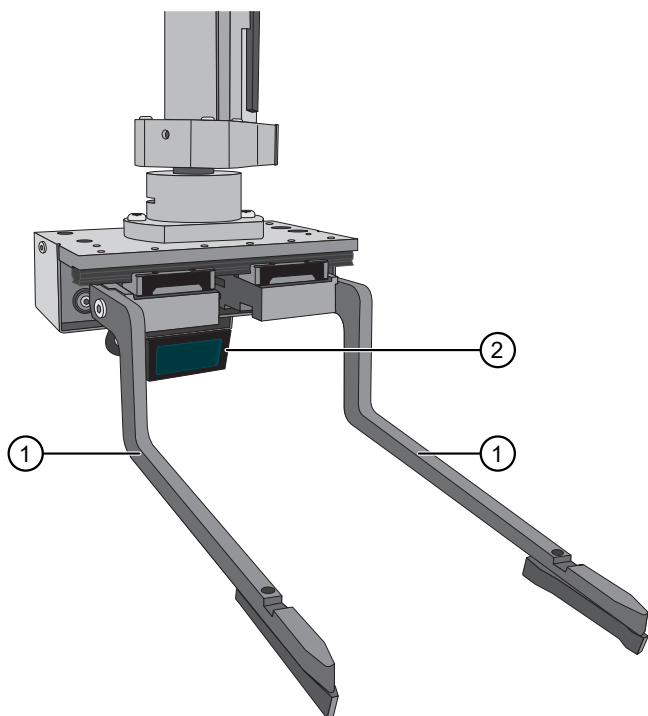
1. Ensure that the Tecan™ Fluent™ 780 Automation Workstation is powered on and initialized (see “Initialize the Tecan™ Fluent™ 780 Automation Workstation” on page 101).
2. On the Tecan™ Fluent™ 780 Automation Workstation, inspect the RGA gripper fingers for misalignment and damage.
  - Ensure that RGA gripper fingers are level and the screws are not loose. If the RGA gripper fingers are misaligned, loosen the RGA gripper finger screws with the T20 wrench, adjust the fingers to level, then tighten the screws with the T20 wrench.

---

**Note:** Tighten the RGA gripper finger screws securely, but do not overtighten.

---

- If the RGA gripper fingers are bent, damaged, or you are unable to align them, contact Support.



- ① RGA gripper fingers
- ② RGA gripper barcode scanner

3. Under the Tecan™ Fluent™ 780 Automation Workstation table, check the tip waste level, then empty if needed.

For more information, see “Empty the Tecan™ Fluent™ 780 Automation Workstation tip waste” on page 137.

4. Visually inspect the Tecan™ Fluent™ 780 Automation Workstation chiller tubing and clamps to ensure they are secure and that there are no leaks.
5. Ensure that the A25 Refrigerated Circulator is powered on and set to 9°C.  
For more information, see “Power on the A25 Refrigerated Circulator” on page 58.



**WARNING!** Failure to set the A25 Refrigerated Circulator to 9°C can result in inaccurate results.

## Engage and prime each Multidrop™ Combi Reagent Dispenser if idle

If idle, use this procedure to engage and prime each Multidrop™ Combi Reagent Dispenser (Combi1-Combi3).


---


**Note:** The technician is responsible for monitoring the time the instruments are idle.

---

**IMPORTANT!** Wash 1 forms bubbles in the Multidrop™ Combi long standard tube dispensing cassette tubes if left idle for >3 hours. Momentum™ Software automatically primes Wash 1 Multidrop™ Combi Reagent Dispenser (Combi 2) 3 hours after a run. Do not prime Combi 2 again, if >3 hours have elapsed since the last run.

---

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to each Multidrop™ Combi Reagent Dispenser (Combi1–Combi3) to take them offline.
  - **Combi1** (dispenses Elution Solution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

The  icon is grayed out, indicating that the instruments are offline. Leave the window open while you refill the reagents.

- On the first Multidrop™ Combi Reagent Dispenser, move the dispensing cassette to the engaged position.

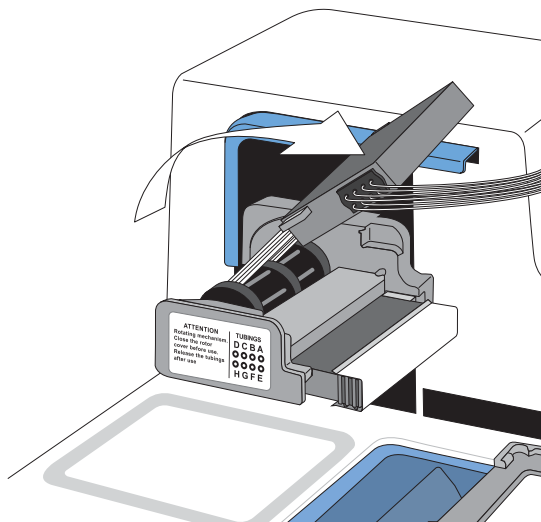


Figure 27 Engage the dispensing cassette

- Pull the cover over the rotor.

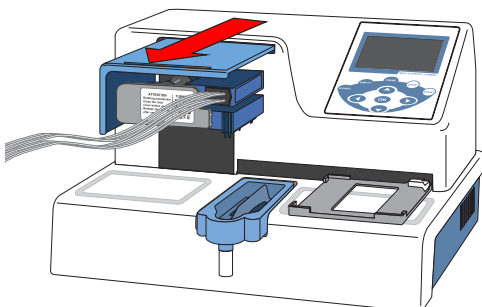


Figure 28 Pull the cover of the rotor

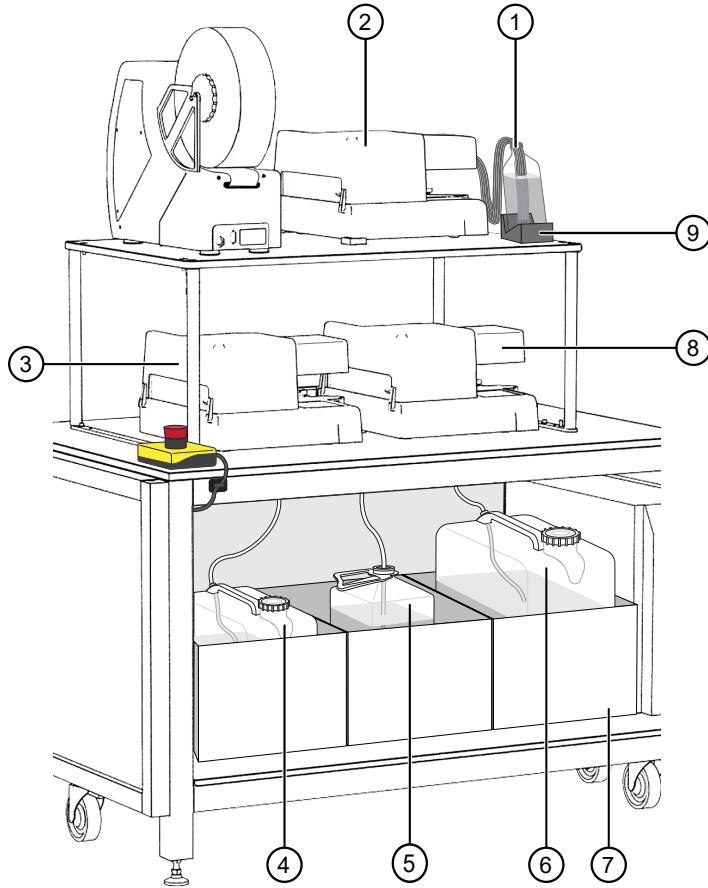
- On the Multidrop™ Combi Reagent Dispenser keypad, press and hold **Prime** for the duration listed in the following table.

**IMPORTANT!** Ensure that you prime each Multidrop™ Combi Reagent Dispenser for the duration listed. Failure to adequately prime the instruments can affect performance.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	





**WARNING!** Ensure that the liquid runs steadily from all of the cassette dispensing tips by the end of the recommended prime duration. Failure to do so can lead to false negative or invalid results.



**Figure 29 Multidrop™ Combi Reagent Dispenser instrument and reagent locations and reagents**

- |   |  |
|---|--|
| ① MagMAX™ HT Elution Solution                     | ⑥ Wash 2 (80% Ethanol) carboy              |
| ② Combi 1 (dispenses MagMAX™ HT Elution Solution) | ⑦ Weighted drawer with scales              |
| ③ Combi 2 (dispenses MagMAX™ HT Wash Solution)    | ⑧ Combi 3 (dispenses Wash 2)               |
| ④ Wash 1 (MagMAX™ HT Wash Solution) carboy        | ⑨ MagMAX™ HT Elution Solution bottle scale |
| ⑤ Waste carboy                                    |  |

7. Repeat step 4 to step 6 for each Multidrop™ Combi Reagent Dispenser reagent.
8. If you took each Multidrop™ Combi Reagent Dispenser offline in step 2, in the Momentum™ Software **Device Tasks** window, click  next to each Multidrop™ Combi Reagent Dispenser to bring it back online.
  - **Combi1** (dispenses Elution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

The  icon is green, indicating that the instruments are online.

9. Click **Done** to close the **Device Tasks** window.

## Thaw Module 2 reagents

Thaw Module 2 reagents as needed. For information about reagent reload frequency, see “Module 2 required sample input, reagents, and consumables” on page 94.

Thaw the following reagents:

---

**IMPORTANT!** Ensure that thaw time plus use time remain within the specified stability window (see “In-use reagent stability” on page 40).

---

- From the TaqPath™ COVID-19 High-Throughput Combo Kit:
    - TaqPath™ COVID-19 HT qPCR Assay
    - TaqPath™ COVID-19 Module 2 Control Dilution Buffer
    - TaqPath™ COVID-19 Control
  - From the Amplitude™ High-Throughput Consumable Package 1 Reagent Kit:
    - TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX)
- 

**Note:**

- Gently invert or mix the reagents prior to use.
  - Ensure that each reagent is localized to the bottom of the tube or bottle.
- 

## Prepare the RNA elution plates

Every 10 runs, prepare one RNA elution plate for each sample extraction plate used (a minimum of 10 plates and a maximum of 40 plates for 10 runs). Each run uses 1–4 plates. For example, if you use one sample extraction plate per run, prepare 10 RNA elution plates for 10 runs. For full-capacity runs of 4 sample extraction plates per run, prepare 40 RNA elution plates for 10 runs.

1. Depending on the number of sample extraction plates used per run, ensure that you have 10–40 each of the following: KingFisher™ 96 tip comb for deep-well magnets and KingFisher™ Deep-Well 96 Plate with Barcode.

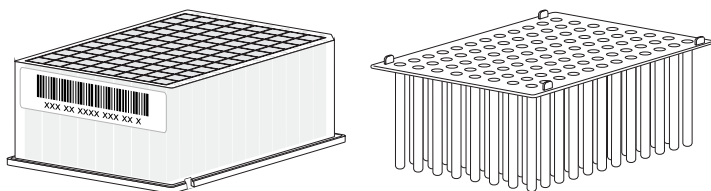


Figure 30 KingFisher™ 96 tip comb for deep-well magnets and a KingFisher™ Deep-Well 96 Plate with Barcode

2. Place a KingFisher™ 96 tip comb for deep-well magnets in each KingFisher™ Deep-Well 96 Plate with Barcode.

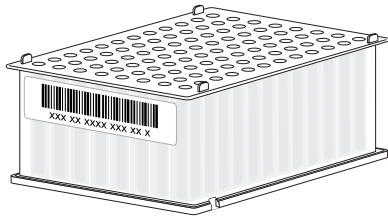


Figure 31 KingFisher™ 96 tip comb for deep-well magnets placed in a KingFisher™ Deep-Well 96 Plate with Barcode

After you replenish the RNA elution plates in the Momentum™ Software, load the prepared plates in the RNA Elution Plate Stackers (see “Physically load the RNA Elution Plate Stackers and Wash Plate Stacker Carousel” on page 115).

## Reload Module 2 consumables

Before starting a run, reload Module 2 consumables, if needed. If you do not have the minimum consumables in the inventory before the run, the Momentum™ Software will not allow the run to proceed.

Reloading Module 2 consumables is a two part process:

1. Replenish the consumables in the Momentum™ Software (see “Replenish consumables in the Momentum™ Software” on page 112).
2. Physically load the consumables in the correct location in the system (see “Physically load the RNA Elution Plate Stackers and Wash Plate Stacker Carousel” on page 115).

---

**IMPORTANT!** When you update the quantity of reagents and consumables in the Momentum™ Software, you must always physically load the reagent or consumable in the correct location in Module 2. Failure to maintain alignment between the information that is entered in the Momentum™ Software and the reagents and consumables that are physically loaded in the system can delay the run by causing errors that require the run to be aborted.

---



**CAUTION!** Do not place anything inside Module 2 except for the designated reagents and consumables. Load the reagents and consumables only at the specified positions. If items are placed in the path of the Spinnaker™ Microplate Robot, the system will perform an emergency stop.



**WARNING!** Only interact with Module 2 at the designated access points, as described in this guide. Do not circumvent the Module 2 barrier walls.

## Replenish consumables in the Momentum™ Software

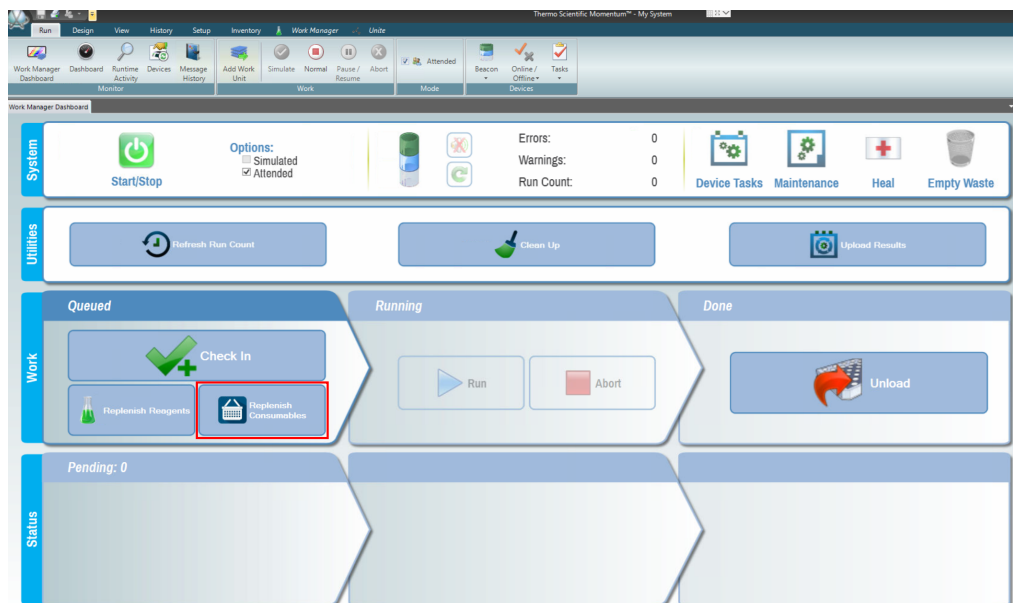
In the Momentum™ Software, click **Replenish Consumables** to view and update the quantities of the Module 2 consumables before a run. The software will not allow you to start a run if the consumables need to be replenished.

- Replenish the real-time RT-PCR plates every 6 runs.
- Replenish the RNA elution plates and wash plates as needed.

**Note:** Module 2 deck can accommodate a maximum of 40 RNA elution plates and 80 wash plates. One RNA elution plate and 2 wash plates are required for each sample extraction plate used in a run.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, click **Replenish Consumables**.

**IMPORTANT!** If the **Replenish Consumables** button is inactive (grayed out), then the system cannot be paused to replenish and reload consumables. Wait until the **Replenish Consumables** button is active to proceed.



The **Consumable Containers Replenishment** window opens.



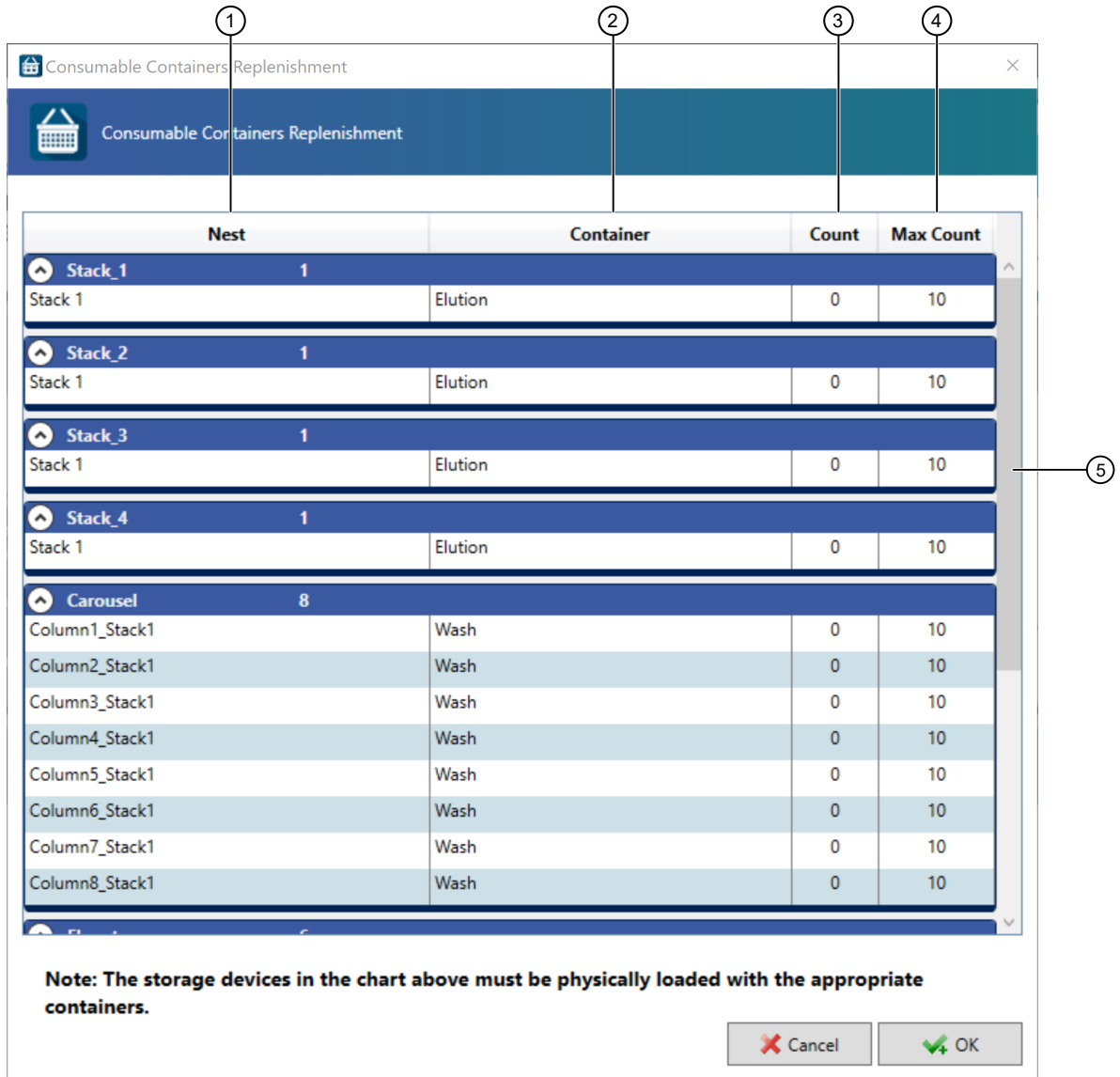


Figure 32 Consumable Containers Replenishment window

- ① **Nest** column—Consumable location
- ② **Container** column—Consumable name
- ③ **Count** column—Current number of the consumable available
- ④ **Max Count** column—Maximum number of the consumable that can be loaded at a time
- ⑤ Scroll bar—Scroll to see all of the consumables

3. To update the current number of a consumable, double-click the number to be updated in the **Count** column, then use the arrow and delete keys to adjust the entry. Repeat for all of the consumables.

Nest	Container (consumable)	Count	Reload frequency
Nest section: <b>Stack_1</b> Row: <b>Stack 1</b>	Elution <sup>[1]</sup>	10	Every 10 runs <sup>[2]</sup>
Nest section: <b>Stack_2</b> Row: <b>Stack 1</b>		10	
Nest section: <b>Stack_3</b> Row: <b>Stack 1</b>		10	
Nest section: <b>Stack_4</b> Row: <b>Stack 1</b>		10	
Nest section: <b>Carousel</b> Rows: <b>Column1_Stack 1–Column8_Stack 1</b>	Wash <sup>[3]</sup>	10 per row 80 total	
Nest section: <b>Fluent</b> Rows: <b>Hotel_PCR_Nest_1–Hotel_PCR_Nest_6</b>	PCR_Plate <sup>[4]</sup>	6	Every 6 runs

<sup>[1]</sup> RNA elution plate (KingFisher™ Deep-Well 96 Plate with Barcode with tip comb inserted)

<sup>[2]</sup> Assuming full-capacity runs of 4 plates per run. If running <4 plates per run, reload frequency will vary.

<sup>[3]</sup> Wash plates (KingFisher™ Deep-Well 96 Plate with Barcode)

<sup>[4]</sup> MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode

4. After all of the consumable counts are updated, click **OK**.

Load the plates in the correct Module 2 location:

- Real-time RT-PCR plates—See “Load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck” on page 125.
- RNA elution plates and wash plates—See “Physically load the RNA Elution Plate Stackers and Wash Plate Stacker Carousel” on page 115.

## Physically load the RNA Elution Plate Stackers and Wash Plate Stacker Carousel

Depending on the number of sample extraction plates used, reload 1–4 RNA elution plates with tip combs into the RNA Elution Plate Stackers and 2–8 wash plates into the Wash Plate Stacker Carousel for each run that you will perform that day (see Figure 25 on page 96). One RNA elution plate and 2 wash plates are required for each sample extraction plate used.



### CAUTION!

- Ensure that you have the minimum number of required plates on the Module 2 table. Not having the minimum number of required plates can affect throughput.
- Ensure that the total number of plates in the stackers matches the total number of plates entered in the Momentum™ Software.

---

**IMPORTANT!** Do not forget to place the tip combs in the plates before loading in the stackers (see “Prepare the RNA elution plates” on page 110).

---

1. Open the system door to access the RNA Elution Plate Stackers.





**CAUTION!** Do not open the system access doors except as part of the Momentum™ Software **Check In, Unload** or **Replenish Consumables** processes. When the **Check In, Unload** or **Replenish Consumables** buttons are inactive (grayed out), opening the access doors can result in an unrecoverable process, requiring the user to rerun all samples currently on Module 2.

2. Unload, then unlock the first RNA Elution Plate Stacker.
3. Load up to 10 RNA elution plates.





**CAUTION!** Ensure that the RNA elution plates are properly seated in the stacker with the barcode facing toward the interior of Module 2.

4. Close and lock the stacker, then reinstall it in the correct position.
5. Load the remaining RNA Elution Plate Stackers (up to a maximum of 40 RNA plates), then close the system access door.
6. If the system is online, in the Momentum™ Software **Work Manager Dashboard**, click **Device Tasks**, then click  next to **Carousel** to take it offline  
The  icon is grayed out, indicating that the carousel is offline. Leave the window open while you reload the carousel.
7. Unlock the first stacker from the Wash Plate Stacker Carousel.

8. Load up to 10 wash plates (KingFisher™ Deep-Well 96 Plate with Barcode).



**CAUTION!** Ensure that each KingFisher™ Deep-Well 96 Plate with Barcode is properly seated in the stackers with the notched corner/A1 well facing toward the center of the carousel.

9. Close and lock the stacker, then reinstall in the carousel.
10. Reload the 7 remaining Wash Plate Stacker Carousel stackers with wash plates (KingFisher™ Deep-Well 96 Plate with Barcode) as needed, up to a maximum of 80 wash plates in the carousel.
11. If you took the Wash Plate Stacker Carousel offline to reload, in the Momentum™ Software **Device Tasks** window, click  next to **Carousel** to bring it back online. The  icon is green, indicating that the carousel is online.

## Perform Module 2 pre-run connectivity and plate checks

- Before each Module 2 run—check network drive mapping and connectivity (see “Check network drive mapping and connectivity” on page 116).
- Before the first Module 2 run of the day:
  - Check QuantStudio™ connectivity and confirm that there is no plate in the tray (see “Check QuantStudio™ connectivity and plate” on page 117).
  - Confirm that there is no plate in the centrifuge (see “Check the centrifuge plate” on page 118).

### Check network drive mapping and connectivity

1. In the Momentum™ Workflow Scheduler Software computer and each QuantStudio™ 7 Flex Real-Time PCR System computer, open the **File Explorer**, then confirm that the network drives are listed and connected, as indicated by the green icons.

The Momentum™ Workflow Scheduler Software should display the following drives:

- Temp (\\10.24.24.1)
- Automation Folder (\\QS71-System ID)
- Automation Folder (\\QS72-System ID)
- ProgramData (\\LQH1-System ID)


The QuantStudio™ 7 Flex Real-Time PCR System computer should display the following drives:

- Temp (\\10.24.24.1)
- Automation Folder (\\QS71-System ID)
- Automation Folder (\\QS72-System ID)

---


**Note:** Additional drives may also be mapped. If so, ensure that these additional drives are also connected.

---

2. If any of the drives display , click once on the folders to re-connect the drives.
3. If any of the drives are missing or unable to connect, contact Priority Support.

## Check QuantStudio™ connectivity and plate

1. In the Momentum™ Workflow Scheduler Software, take the QuantStudio™ instruments offline.
2. In the **Run** tab, click **Tasks ▶ QuantStudio1 ▶ Open Tray**.  
The adapter tray on **QuantStudio1** opens.
3. Visually confirm there is no plate in the tray.
4. In the Momentum™ Workflow Scheduler Software, in the **Run** tab, click **Tasks ▶ QuantStudio1 ▶ Close Tray** to close the tray.
  - If the adapter tray does not open, proceed to step 5.
  - If there is a plate in the adapter plate, proceed to step 6.Otherwise, proceed to step 7.
5. If the adapter tray does not open, power cycle the QuantStudio™ 7 Flex Real-Time PCR System computer and instrument in the following order:
  - a. Close the server on the QuantStudio™ 7 Flex Real-Time PCR System computer.
  - b. Close out of the QuantStudio™ software.
  - c. Power down the QuantStudio™ 7 Flex Real-Time PCR System computer.
  - d. Press the green power button on the bottom left of the QuantStudio™ instrument touchscreen.
  - e. Power off the QuantStudio™ instrument using the switch on the back of the instrument, then wait one minute.
  - f. Power on the QuantStudio™ 7 Flex Real-Time PCR System computer.
  - g. Power on the QuantStudio™ instrument.
  - h. Open the QuantStudio™ Real-Time PCR Software, then double-click **Instrument Console**.
  - i. Confirm that the instrument is connected as indicated by a green check icon (✓). If the instrument is not connected, as indicated by a red “X” icon (✗), click the instrument icon and wait for it to connect. If the instrument does not connect, contact Priority Support.
  - j. Open the QuantStudio™ server.
  - k. After power cycling, repeat step 2–step 4.
6. If there is a plate in the adapter tray, physically remove the plate from the tray, then manually unload the plate from **Inventory** in the Momentum™ Workflow Scheduler Software:
  - a. In the **Inventory** tab, select the **Inventory** icon.
  - b. In the **Location** column, identify if there is a plate listed in **QuantStudio1:Nest**. If there is a plate listed in **QuantStudio1:Nest**, right-click in the row of the plate, then select **Manual Unload**.

- c. In the **Unload Containers** message window, click  **Verify**.
7. Repeat step 1–step 4 for **QuantStudio2**.

## Check the centrifuge plate

1. In the Momentum™ Workflow Scheduler Software, take the centrifuge offline.
2. In the **Run** tab, click **Tasks** ▶ **Centrifuge** ▶ **Open Door at Bucket 1**.
3. Once the door is open, visually inspect the instrument to confirm that there is no plate.
4. If there is a plate inside the instrument, click **Clean Up** in the Momentum™ Software **Work Manager Dashboard** to remove the plate.

If the plate is not removed during the clean up process, contact Priority Support.

## Bring all Module 2 devices online

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**IMPORTANT!** Before bringing Module 2 devices online, ensure that all buckets are empty in the centrifuge and that there are no plates in the QuantStudio™ instruments (see “Perform Module 2 pre-run connectivity and plate checks” on page 116).

---

- **If the system is offline**—On the Module 2 computer station, in the Momentum™ Software **Work Manager Dashboard**, click **Start/Stop** to bring the Module 2 devices online and under control of the Momentum™ Software.

---

**IMPORTANT!** Do not close the server dialog boxes that open when the devices are brought under the control of the Momentum™ Software.

---

- **If an individual device was taken offline**—In the Momentum™ Software **Work Manager Dashboard**, click **Device Tasks**, then click  next to the instrument to bring it online.

## Reload Module 2 reagents

Before starting a run, reload Module 2 reagents, if needed. If you do not reload the required reagents before a run, the Momentum™ Software will prompt you to do so before you can check in sample extraction plates.

Reloading Module 2 reagents is a two part process:

1. Replenish the reagents in the Momentum™ Software (see “Replenish reagents in the Momentum™ Software” on page 119).
2. Physically load the reagents in the correct location in the system (see “Physically load the RNA Elution Plate Stackers and Wash Plate Stacker Carousel” on page 115 and “Load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck” on page 125).

---

**IMPORTANT!** When you update the quantity of reagents and consumables in the Momentum™ Software, you must always physically load the reagent or consumable in the correct location in Module 2. Failure to maintain alignment between the information that is entered in the Momentum™ Software and the reagents and consumables that are physically loaded in the system can delay the run by causing errors that require the run to be aborted.

---



**CAUTION!** Do not place anything inside Module 2 except for the designated reagents and consumables. Load the reagents and consumables only at the specified positions. If items are placed in the path of the Spinnaker™ Microplate Robot, the system will perform an emergency stop.



**WARNING!** Do not circumvent the Module 2 barriers. Only interact with the system at the designated access points.

## Replenish reagents in the Momentum™ Software

As needed, replenish reagents in Momentum™ Software, then reload in the correct location.

Continuous operation:

- Every 12 plates (or every 3 full-capacity runs of 4 plates/run)— replenish 150 µL MCA Disposable Tips.
- Every 72 plates (or every 18 full-capacity runs of 4 plates/run) or if prompted by the Momentum™ Software— replenish 200 µL FCA Disposable Tips, 1,000 µL FCA Disposable Tips, and Multidrop™ Combi Reagent Dispenser reagents.
- As needed— replenish RT-PCR reagents and consumables.

When a new positive control dilution is required (see “In-use reagent stability” on page 40), replenish the following reagents:

- TaqPath™ COVID-19 Control
- TaqPath™ COVID-19 Module 2 Control Dilution Buffer
- 2-mL empty tubes

If RT-PCR reagents are replenished when the run counter is not at 1:

- Replenish RT-PCR reagents and consumables, 150  $\mu$ L MCA Disposable Tips, 200  $\mu$ L FCA Disposable Tips, and 1,000  $\mu$ L FCA Disposable Tips.
- Execute the **Refresh run count** process in the Momentum™ Software (see “Refresh run count” on page 105).

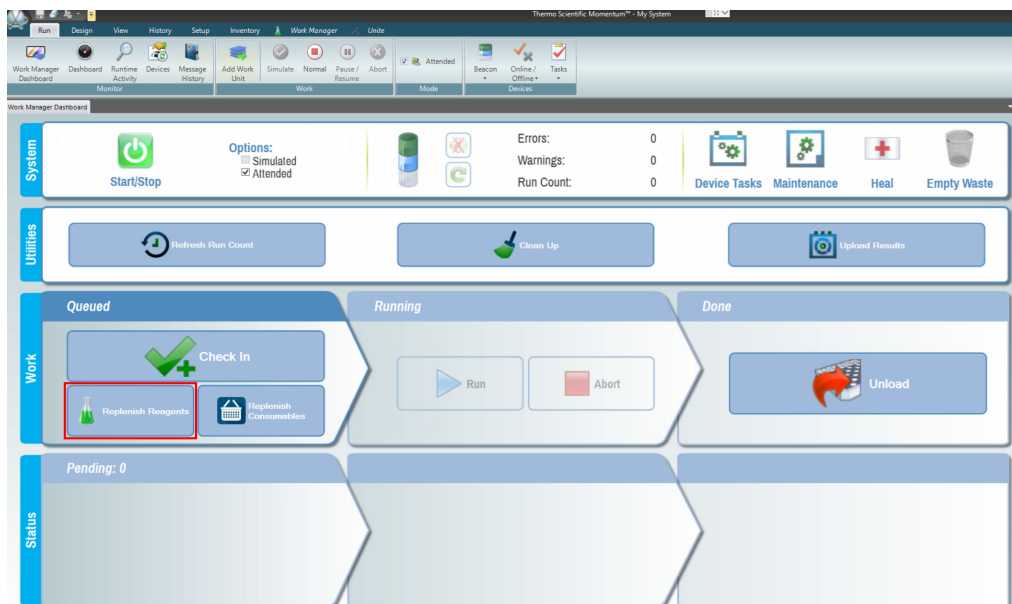


### WARNING!

- Failure to execute the **Refresh run count** process when the positive control, dilution buffer, and 2-mL empty tubes are loaded onto the Tecan™ Fluent™ 780 Automation Workstation reagent carrier will result in an aborted process.
- Ensure that you have physically reloaded 150  $\mu$ L MCA Disposable Tips after performing the **Refresh run count**. Failure to do so can result in invalid results.
- Make sure to remove lids from **all** 150  $\mu$ L MCA Disposable Tip boxes on the deck before beginning a run. Failure to do so can result in invalid results.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, click **Replenish Reagents**.

**IMPORTANT!** If the **Replenish Reagents** button is inactive (grayed out), then the system cannot be paused to replenish and reload reagents. Wait until the **Replenish Reagents** button is active to proceed.





3. Enter the operator names in the dialog box.

The screenshot shows a dialog box titled "Momentum Message" with a close button (X) in the top right corner. Below the title bar is a dark teal header with a question mark icon and the text "Enter Operator Names". The main area contains two text input fields. The first is labeled "Operator 1" and is empty. The second is labeled "Operator 2" and contains the placeholder text "Enter Name". At the bottom of the dialog are three buttons: "OK", "Log Off", and "Cancel".

The **Replenish Reagents** window opens.

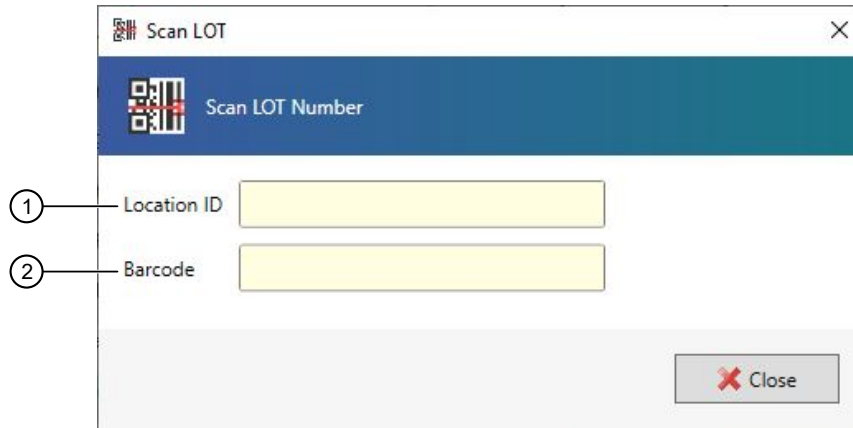
4. In the **Replenish Reagents** window, click **Scan**.

Location	Location ID	Property	Lot Number Prefix	Lot Number (Scanned)	Vol / Qty Remaining	Replenish Date	Units
Combi_1	S2-COMBI1-ELU	MagMax HT Elution Solution	91B29880F9	00123456	68	2/1/2021 6:15:18 PM	Sets
Combi_1	S2-COMBI1-CASSI	Multidrop standard tube dispens	9124072670	832808427	3819	9/14/2020 3:30:55 PM	Sets
Combi_2	S2-COMBI2-W1	MagMax HT Wash Solution	91B32440F4	00123456	68	2/1/2021 6:15:37 PM	Sets
Combi_2	S2-COMBI2-CASSI	Combi2 Multidrop long standard	9124072677	832810918	363	9/14/2020 3:39:31 PM	Sets
Combi_3	S2-COMBI3-W2	80% Ethanol	1PT08204K7	204870	5	9/16/2020 1:50:53 AM	Sets
Combi_3	S2-COMBI3-CASSI	Combi3 Multidrop long standard	9124072677	832808856	219	9/16/2020 1:52:13 AM	Sets
Tecan Deck	S2-qPCR-ASSAY-T	TaqPath™ COVID-19 HT qPCR Ass	91A50750	2008001	5	2/1/2021 6:01:13 PM	Sets
Tecan Deck	S2-MASTERMIX-TI	TaqPath® 1-Step Multiplex Maste	91A50772	0012345	5	2/1/2021 6:04:54 PM	Sets
Tecan Deck	S2-HT-WATER-TEC	MagMax™ HT Water	91R05846F11	00123456	5	2/1/2021 6:06:37 PM	Sets
Tecan Deck	S2-5ML-TUBE-TEC	5mL HT Module 2 Empty Mixing	91A50893	S2-5ML-TUBE-TEC	5	2/1/2021 6:05:51 PM	Sets
Tecan Deck	S2-HT-IVT-RNA-C	TaqPath™ COVID-19 Control	91966128	237095	5	2/1/2021 6:14:47 PM	Sets
Tecan Deck	S2-HT-CTRL-DILN	TaqPath™ HT Ctrl. Dil. Buffer	91A50751	2007002	5	2/1/2021 6:00:46 PM	Sets
Tecan Deck	S2-2ML-TUBE-TEC	2 mL HT Module 2 Empty Tubes	S2-2ML-TUBE-	S2-2ML-TUBE-TEC	5	2/1/2021 6:16:04 PM	Sets
Tecan Deck	S2-1000uL-FCA-TI	1000 uL FCA Disposable Tips Rack	S2-1000uL-FCA-	S2-1000uL-FCA-TI	17	2/1/2021 5:59:49 PM	Sets
Tecan Deck	S2-200uL-FCA-TIP	200 uL FCA Disposable Tips Rack	S2-200uL-FCA-	S2-200uL-FCA-TIP	17	2/1/2021 5:59:53 PM	Sets
Tecan Deck	S2-200uL-MCA-TIP	200 uL MCA Disposable Tips Rack	S2-200uL-MCA-	S2-200uL-MCA-TIP	2	2/1/2021 6:00:00 PM	Sets
Tecan Deck	S2-WORKING-DW	Deep Well Plate in Tecan	S2-WORKING-	S2-WORKING-DW	5	2/1/2021 6:00:04 PM	Sets
Alps 3000	S2-CLEAR-SEAL-AL	Alps Clear Seal	S2-CLEAR-SEA	S2-CLEAR-SEAL-AL	759	9/4/2020 12:30:05 PM	Sets

Figure 33 Replenish Reagents window

- ① **Location** column—Reagent location
- ② **Location ID** column—Reagent location ID is scanned before reagent barcode
- ③ **Property** column—Reagent name
- ④ **Lot Number Prefix** and **Lot Number Scanned** column—Reagent identification and barcode information
- ⑤ **Vol / Qty Remaining** column—The amount of reagent remaining; automatically updates when new reagent barcodes are scanned
- ⑥ **Replenish Date** column—The date and time that the reagent barcode was scanned

The **Scan LOT** dialog box opens.



- ① **Location ID** field—Location barcode information
- ② **Barcode** field—Reagent barcode information

5. With the **Scan LOT** dialog box open, use the hand-held scanner to scan the Location ID barcode, then reagent barcode for the first reagent. Repeat for all of the required reagents.



**CAUTION!** Only scan, then load new, full bottles of reagents.



**CAUTION!** If the Location ID barcode and the reagent barcode do not match you will receive an error message. To remove the error message, close, then re-open the **Scan** dialog box. If you do not remove the error message, the Momentum™ Software will not allow you proceed.

**Note:** **S#** denotes the system on which the reagents and consumables are being used. For example, if your laboratory has two systems, reagents and consumables can be used on **S1** or **S2**.

Replenish the empty deck	Quantity	Reload frequency		
		Every 3 runs	Every 6 runs	Every 18 runs
<b>Tecan™ Fluent™ 780 Automation Workstation reagents and consumables</b>				
<b>S#-200µL-MCA-TIPS-TECAN</b> — 150 µL MCA Disposable Tips Rack	12 racks	X	X	X
<b>S#-qPCR-ASSAY 1-TECAN</b> or <b>S#-qPCR-ASSAY 2-TECAN</b> — TaqPath™ COVID-19 HT qPCR Assay <sup>[1]</sup> in position 1 or position 2	1 or 2 tubes	X	X	X
<b>S#-HT-IVT-RNA-CTRL-TECAN</b> — TaqPath™ COVID-19 Control <sup>[1]</sup>	1 tube		X	X
<b>S#-HT-CTRL-DILN-BUFFER-TECAN</b> — TaqPath™ COVID-19 Module 2 Control Dilution Buffer <sup>[1]</sup>	1 tube		X	X
<b>S#-MASTERMIX 1-TECAN</b> or <b>S#-MASTERMIX 2-TECAN</b> — TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX) <sup>[2]</sup> in position 1 or position 2	1 or 2 bottles	X	X	X
<b>S#-HT-WATER-TECAN</b> — MagMAX™ HT Water	1 bottle		X	X

(continued)

Replenish the empty deck	Quantity	Reload frequency		
		Every 3 runs	Every 6 runs	Every 18 runs
<b>S#-2ML-TUBE-TECAN</b> —2-mL tubes	2 tubes	as needed		
<b>S#-5ML-TUBE-TECAN</b> —TaqPath™ HT Module 2 Empty 5 mL Mixing Tubes	6 tubes		X	X
<b>S#-WORKING-DWP-TECAN</b> —KingFisher™ Deep-Well 96 Plate with Barcode (PCR reaction mix working plate)	1 plate		X	X
<b>S#-1000µL-FCA-TIPS-TECAN</b> —1,000 µL FCA Disposable Tips Rack	3 racks			X
<b>S#-200µL-FCA-TIPS-TECAN</b> —200 µL FCA Disposable Tips Rack	3 racks			X
<b>Multidrop™ Combi Reagent Dispenser reagents (Combi1–Combi3)</b>				
<b>S#-Combi1-Elu</b> —MagMAX™ HT Elution Solution	1 bottle			X
<b>S#-Combi2-W1</b> —MagMAX™ HT Wash Solution (Wash 1)	3 bottles			X
<b>S#-Combi3-W2</b> —80% Ethanol (Wash 2)	2 bottles			X

<sup>[1]</sup> Vortex, then centrifuge briefly<sup>[2]</sup> Mix gently by inversion

6. After all of the reagents that need to be replenished are scanned, click **Close**.  
The **Vol / Qty Remaining** column updates for the scanned reagents.

7. In the **Replenish Reagents** window, click **Submit IDs**.

Physically load the reagents in the correct Module 2 location (see “Reload Module 2 reagents” on page 119).

## Load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck

Every 3, 6, and 18 runs, load reagents and consumables on the Tecan™ Fluent™ 780 Automation Workstation deck.

**IMPORTANT!** Before you load the deck, ensure that the current temperature of the A25 Refrigerated Circulator water bath is 9°C. Failure to maintain the water bath at 9°C can affect results.

Refer to the following figure when loading the deck:

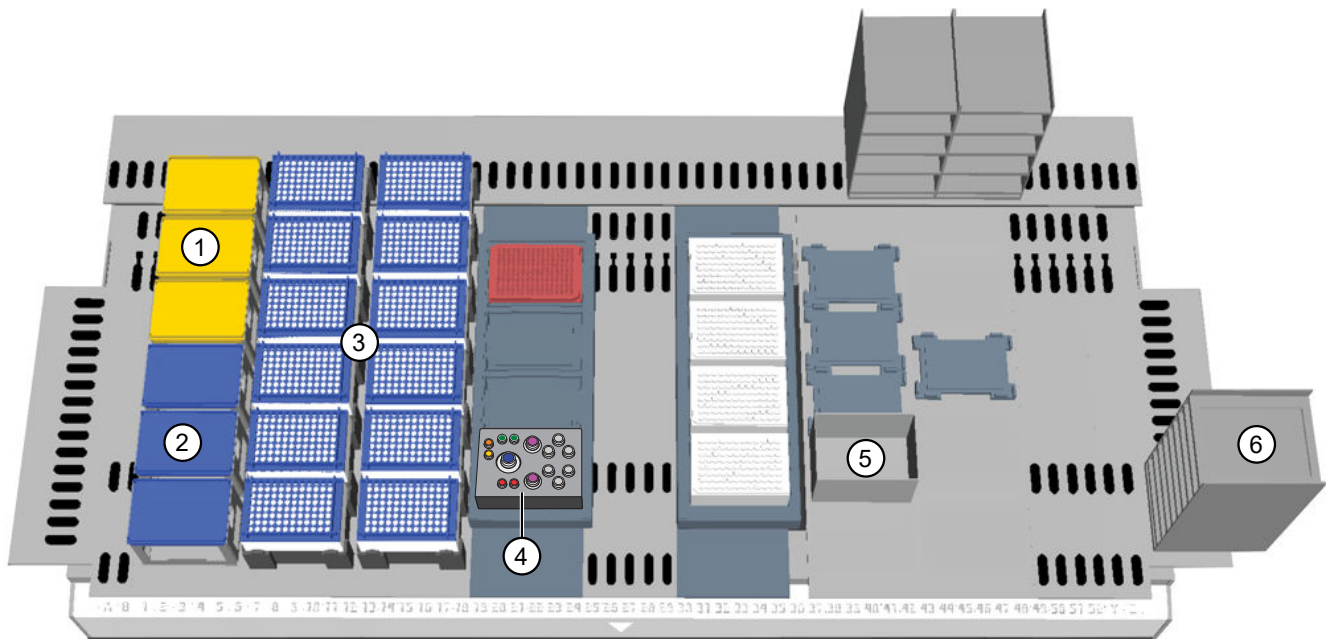


Figure 34 Tecan™ Fluent™ 780 Automation Workstation deck layout

- |  |  |
|--|--|
| ① 1,000 µL FCA Disposable Tips Rack ×3 | ⑤ Tip waste chute  |
| ② 200 µL FCA Disposable Tips Rack ×3   | ⑥ Hotel for MicroAmp™ Optical 384-Well Reaction Plates with Barcodes |
| ③ 150 µL MCA Disposable Tips Rack ×12  |  |
| ④ Reagent carrier (see Figure 35)      |  |

**Note:** In humid conditions, the cold block on the Tecan™ Fluent™ 780 Automation Workstation deck may collect condensation. Periodically wipe off any condensation that collects on the cold block.



**CAUTION!** Ensure that reagents and consumables loaded on the deck matches the information entered in the Momentum™ Software.

1. Open the Tecan™ Fluent™ 780 Automation Workstation access door.
2. **(Every 12 plates, or every 3 full-capacity runs of 4 plates/run)** Discard each empty 150 µL MCA Disposable Tips Rack, then load each 150 µL MCA Disposable Tips Rack (× 12) in **Position 3**.

**IMPORTANT!** Visually inspect tips for missing filters and replace as needed.



**WARNING!** Make sure to remove lids from **all** 150 µL MCA Disposable Tip boxes on the deck before beginning a run. Failure to do so can result in invalid results and damage to the instrument.

3. **(Every 6 runs)** Load a MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode (× 6) in the top 6 nests of the hotel at **Position 6**.

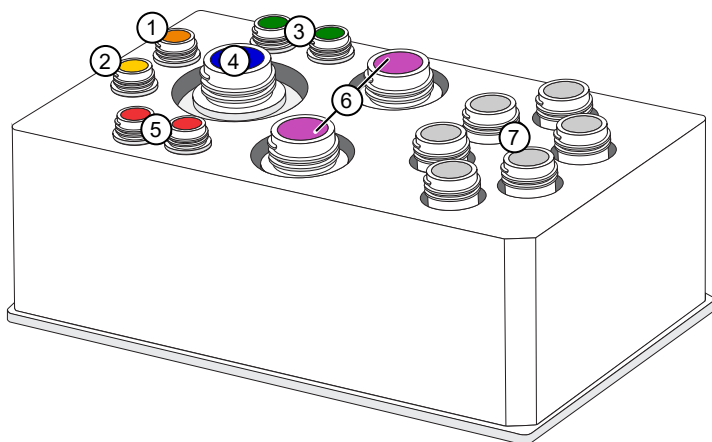


**CAUTION!** Ensure that each MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode is seated properly in the grooves of the hotel nests with the plate barcodes facing in toward the Tecan™ Fluent™ 780 Automation Workstation deck.



**WARNING!** Dry any moisture from the Tecan™ Fluent™ 780 Automation Workstation deck and reagent block to prevent fluid accumulation and potential mold growth.

4. Discard empty reagent vials, then load the reagent carrier according to the diagram. Make sure to uncap the reagent vials after loading.



**Figure 35** Module 2 reagent carrier layout

- |   |   |
|---|---|
| ① TaqPath™ COVID-19 Control   | ⑤ 2 × TaqPath™ COVID-19 HT qPCR Assay   |
| ② TaqPath™ COVID-19 Module 2 Control Dilution Buffer  | ⑥ 2 × TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX)                   |
| ③ 2 × 2-mL tubes (used to dilute the TaqPath™ COVID-19 Control in the TaqPath™ COVID-19 Module 2 Control Dilution Buffer) | ⑦ 6 × TaqPath™ HT Module 2 Empty 5 mL Mixing Tubes (used to mix the PCR reaction) |
| ④ MagMAX™ HT Water  |   |

**CAUTION!**

- If removing partially used reagents from the Tecan™ Fluent™ 780 Automation Workstation deck for later reuse, make sure to place colored reagent caps on the correct vials. Failure to do so can lead to invalid results, incorrect reagent placement, and/or reagent contamination when vials are replaced in the carrier.
- If replacing partially used reagents on the Tecan™ Fluent™ 780 Automation Workstation deck, verify the correct reagent positioning based on the vial labels. Placing vials in incorrect positions can lead to invalid results and damage to the instrument.

5. **(Every 72 plates, or every 18 full-capacity runs of 4 plates/run, or if prompted by the Momentum™ Software)** Replace each 1,000 µL FCA Disposable Tips Rack (× 3) and 200 µL FCA Disposable Tips Rack (× 3).
  - a. Discard each partially empty 1,000 µL FCA Disposable Tips Rack, then load each 1,000 µL FCA Disposable Tips Rack (× 3) in **Position 1**.
  - b. Discard each partially empty 200 µL FCA Disposable Tips Rack, then load each 200 µL FCA Disposable Tips Rack (× 3) in **Position 2**.

---

**IMPORTANT!** Visually inspect tips for missing filters and replace as needed.

---



**CAUTION!** Ensure that the tip racks are seated properly in the correct position on the deck.

6. After all of the reagents and consumables are loaded on the deck, close the Tecan™ Fluent™ 780 Automation Workstation access door.


## Refill the Multidrop™ Combi Reagent Dispenser reagents


Every 18 runs, replenish the Multidrop™ Combi Reagent Dispenser reagents in the Momentum™ Software, then physically refill them (“Replenish reagents in the Momentum™ Software” on page 119).

---

**IMPORTANT!** You must also replenish the dispensing cassettes on the Multidrop™ Combi Reagent Dispenser according to the frequency of use (see “Physically replace the Multidrop™ Combi dispensing cassettes” on page 164). The dispensing cassettes require replacement more frequently than the Momentum™ Software prompts you to replace them.

---

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to each Multidrop™ Combi Reagent Dispenser (Combi1–Combi3) to take them offline.
  - **Combi1** (dispenses Elution Solution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

The  icon is grayed out, indicating that the instruments are offline. Leave the window open while you refill the reagents.

4. Refill the reagents.

---

**Note:** Once a month, when refilling the reagents, switch out the carboys for Wash 1 and Wash 2 with clean, dry carboys so that you can clean them (see “Switch out and clean the Multidrop™ Combi carboys for Wash 1 and Wash 2” on page 173).

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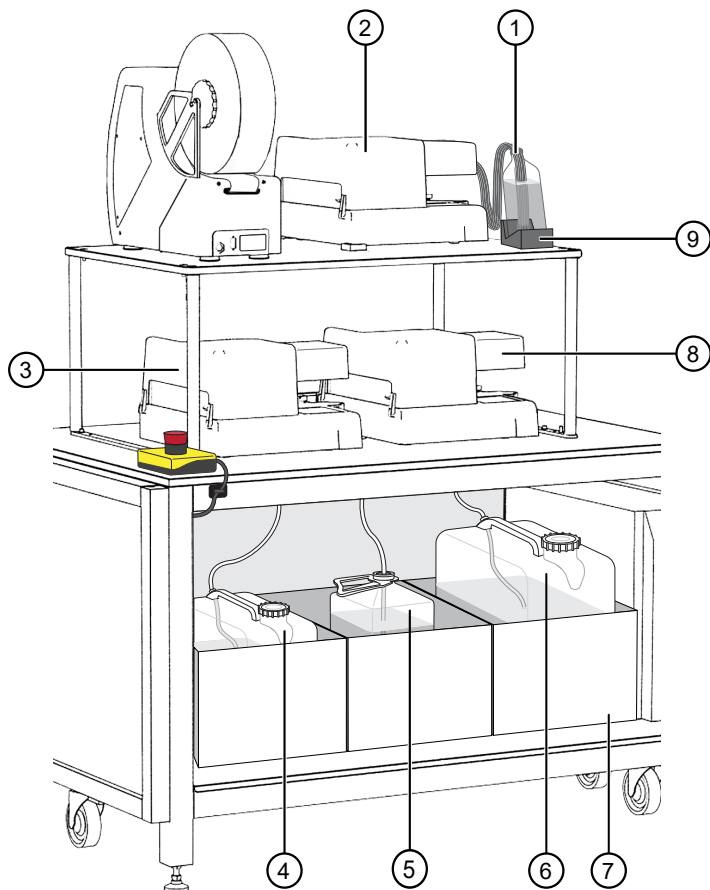
**IMPORTANT!** It is mandatory that you use carboys provided with the Amplitude™ Solution as the scales are calibrated for use with these carboys only. Using any other containers can lead to invalid results.

---



**CAUTION!** Ensure that you pour the MagMAX™ HT Wash Solution (Wash 1) and 80% Ethanol (Wash 2) in the correct carboy.





**Figure 36 Multidrop™ Combi Reagent Dispenser instrument and reagent locations and reagents**

- ① MagMAX™ HT Elution Solution
- ② Combi 1 (dispenses MagMAX™ HT Elution Solution)
- ③ Combi 2 (dispenses MagMAX™ HT Wash Solution)
- ④ Wash 1 (MagMAX™ HT Wash Solution) carboy
- ⑤ Waste carboy
- ⑥ Wash 2 (80% Ethanol) carboy
- ⑦ Weighted drawer with scales
- ⑧ Combi 3 (dispenses Wash 2)
- ⑨ MagMAX™ HT Elution Solution bottle scale

Reagent	Description
MagMAX™ HT Elution Solution	Remove the tubing bundle weight from the used MagMAX™ HT Elution Solution bottle, then place in the new MagMAX™ HT Elution Solution bottle. Wrap the bottle top with Parafilm™ film to prevent evaporation.
MagMAX™ HT Wash Solution (Wash 1)	Remove the Wash 1 carboy lid, then pour 3 bottles of MagMAX™ HT Wash Solution into the Wash 1 carboy. Tightly close the carboy lid.
80% Ethanol (Wash 2)	Remove the Wash 2 carboy lid, then pour 2 bottles of 80% Ethanol into the Wash 2 carboy. Tightly close the carboy lid.


- On each Multidrop™ Combi Reagent Dispenser keypad, press and hold **PRIME** for the duration listed in the following table.


**IMPORTANT!** Ensure that you prime each Multidrop™ Combi Reagent Dispenser for the duration listed. Failure to adequately prime the instruments can affect performance.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	



**WARNING!** Ensure that the liquid runs steadily from all of the cassette dispensing tips by the end of the recommended prime duration. Failure to do so can lead to false negative or invalid results.

- If you took each Multidrop™ Combi Reagent Dispenser offline in step 2, in the Momentum™ Software **Device Tasks** window, click  next to each instrument to bring them back online.
  - Combi1** (Elution)
  - Combi2** (Wash 1)
  - Combi3** (Wash 2)

The  icon is green, indicating that the instruments are online.

- Click **Done** to close the **Device Tasks** window.

## Check in Module 1 sample extraction plates and start a run

Depending on the number of sample extraction plates used, check in 1–4 Module 1 sample extraction plates in the Momentum™ Software, then load the plates in the Hotel Input to start a run.

- On the Module 2 computer station, in the Momentum™ Software **Work Manager Dashboard**, click **Check in**.

**IMPORTANT!** If the **Check in** button is inactive (grayed out), then the system cannot be paused to check in and load the sample extraction plates. Wait until the **Check in** button is active to proceed.

- Open the system door to access the Hotel Input.



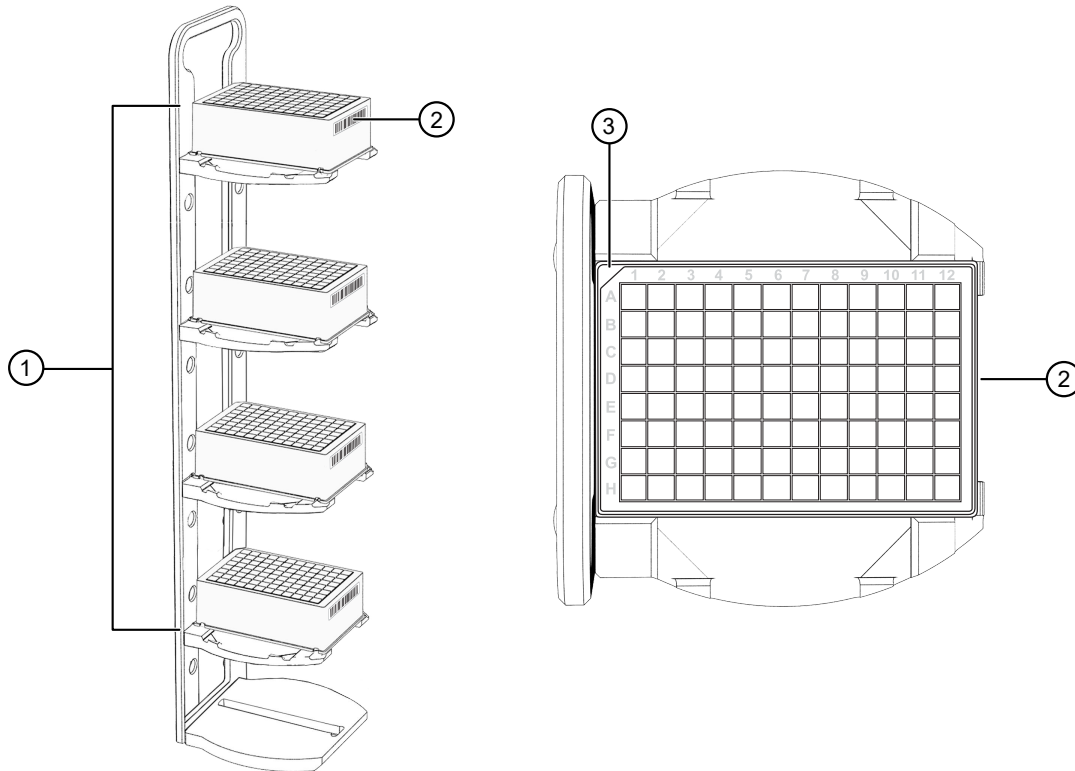
**CAUTION!** Do not open the system access doors except as part of the Momentum™ Software **Check In, Unload** or **Replenish Consumables** processes. When the **Check In, Unload** or **Replenish Consumables** buttons are inactive (grayed out), opening the access doors can result in an unrecoverable process, requiring the user to rerun all samples currently on Module 2.

3. Remove, then discard any sample extraction plate lids which may be used in your laboratory to transfer the sample extraction plates to Module 2.

**IMPORTANT!** Ensure that you remove plate lids. Failure to do so causes failure of the KingFisher™ Presto Purification System.

4. Place the sample extraction plates in the Hotel Input nests 1–4.

**Note:** Depending on the number of sample extraction plates used, some Hotel Input nests may remain empty.



**Figure 37** Hotel Input for incoming sample extraction plates

- ① Hotel Input nests 1–4
- ② The barcode on the sample extraction plate
- ③ The A1/notched corner of the sample extraction plate



**CAUTION!** Ensure that each plate is properly seated in its nest with the barcode facing toward the interior of Module 2.

5. Close the system door.

6. On the Mini-Hub Control Puck, press **MTR ON**, then **RESET**.

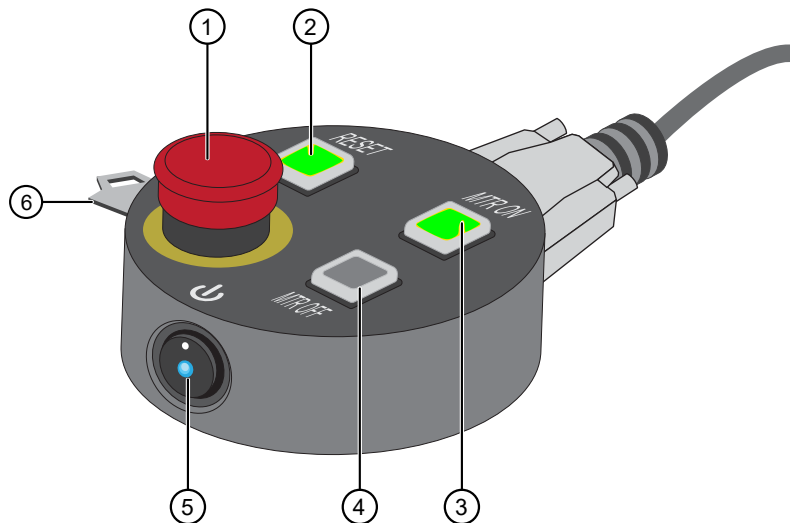


Figure 38 Mini-Hub Control Puck

- ① Emergency Stop (E-Stop) button
- ② Reset (**RESET**) button
- ③ Motor On (**MTR ON**) button
- ④ Motor Off (**MTR OFF**) button
- ⑤ Power button
- ⑥ Mode key-switch

The **MTR ON** and **RESET** buttons glow green and the **MTR OFF** button goes dark, indicating that power to the robot motors is on.

7. In the Momentum™ Software **Check In Input Containers** window, in the **Hotel\_Input** nest table, assign the sample extraction plate to a nest using the dropdown list in the **Container** column.

Nest	Container (sample extraction plate)
Nest 1	Extraction_1
Nest 2	Extraction_2
Nest 3	Extraction_3
Nest 4	Extraction_4

Momentum: Check In Input Containers

Check In Input Containers

Operator 1

Operator 2

Device:

Location	Property	Vol / Qty Remaining	Vol / Qty Required	Units
Combi_1	MagMax HT Elution Solution	40	1	Sets
Combi_1	Multidrop standard tube dispens	3626	1	Sets
Combi_2	MagMax HT Wash Solution	20	1	Sets
Combi_2	Combi2 Multidrop long standard	169	1	Sets
Combi_3	80% Ethanol	32	1	Sets
Combi_3	Combi3 Multidrop long standard	35	1	Sets
Tecan Deck	TaqMan™ SARS-CoV-2 HT qPCR /4		1	Sets
Tecan Deck	TaqPath® 1-Step Multiplex Maste	4	1	Sets
Tecan Deck	MagMax™ HT Water	4	1	Sets
Tecan Deck	5mL HT Module 2 Empty Mixing T	4	1	Sets
Tecan Deck	TaqMan® SARS-CoV-2 HT IVT RN	4	1	Sets
Tecan Deck	TaqMan® HT Control Dilution Bur	4	1	Sets
Tecan Deck	2 mL HT Module 2 Empty Tubes	4	1	Sets
Tecan Deck	1000 uL FCA Disposable Tips Rack	10	1	Sets
Tecan Deck	200 uL FCA Disposable Tips Rack	10	1	Sets
Tecan Deck	200 uL MCA Disposable Tips Rack	4	1	Sets
Tecan Deck	Deep Well Plate in Tecan	4	1	Sets
Alps 3000	Alps Clear Seal	553	5	Sets

Pending Input Containers:  Pending Output Containers:

Nest	Container	Qty	Assay
Nest 1	Extraction_1	1	COVID19
Nest 2	None	0	
Nest 3	None	0	
Nest 4	None	0	

Figure 39

- ① Required reagent table —Displays the required volume or quantity of a reagent or consumable that is required for the run.
- ② Hotel Input nest assignment table

As each sample extraction plate is assigned to the Hotel Input nests, the software displays the volume of reagents and number of consumables required for the run.

**Note:** If you do not have sufficient reagents for the run, you will need to replenish them before the Momentum™ Software will allow you to check in the sample extraction plates.



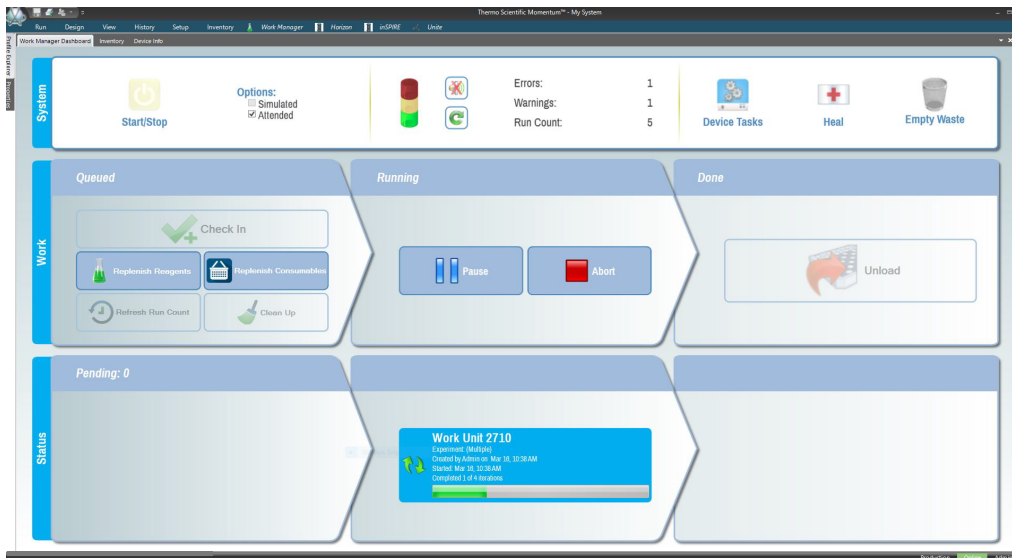
**WARNING!** If you do not have the minimum required consumables on the Module 2 deck, the run can be invalidated.

8. Click **Start Check in**.

The Module 2 run starts.

## Monitor the Module 2 run

- During a Module 2 run, monitor the progress of the run in the Momentum™ Software **Work Manager Dashboard**.



- If an error message displays during a Module 2 run, resolve the issue, then restart the run if paused.



**CAUTION!** If a Module 2 run is paused for too long, loss of sample or false negative results may occur. If a process cannot be recovered, you must rerun the samples starting in Module 1.

- Do not abort a Module 2 mid-run, unless necessary.



**CAUTION!** If you quit a run before completion, loss of sample may occur. If a process cannot be recovered, you must rerun the samples starting in Module 1.

## Unload outgoing RNA elution plates from the Hotel Output



**CAUTION!** Do not open the system access doors except as part of the Momentum™ Software **Check In, Unload** or **Replenish Consumables** processes. When the **Check In, Unload** or **Replenish Consumables** buttons are inactive (grayed out), opening the access doors can result in an unrecoverable process, requiring the user to rerun all samples currently on Module 2.

1. On the Module 2 computer station, in the Momentum™ Software **Work Manager Dashboard**, click **Unload**.

---

**IMPORTANT!** If the **Unload** button is inactive (grayed out), then the system cannot be paused to remove the RNA elution plates. Wait until the **Unload** button is active to proceed.

---

2. Open the system door to access the Hotel Output.
3. Remove the RNA elution plates, then close the system door. Store the RNA elution plates according to your laboratory guidelines.
4. In the Momentum™ Software **Unload Containers** window, click **Verify** to confirm that the RNA elution plates were removed.

## Reset Module 2 after an aborted run

If a Module 2 run must be aborted, click **Clean Up** in the Momentum™ Software **Work Manager Dashboard** to clear the system of plates associated with the aborted run.

Plates from the aborted run are cleared from all areas of the system **except** the QuantStudio™ 7 Flex Instruments and the Tecan™ Fluent™ 780 Automation Workstation. Be sure to check both QuantStudio™ 7 Flex Instruments and Tecan™ Fluent™ 780 Automation Workstation for plates from the aborted run before proceeding with the next Module 2 run.



**WARNING!** Failure to run the **Clean Up** process and remove plates from the QuantStudio™ 7 Flex Instruments and the Tecan™ Fluent™ 780 Automation Workstation after an aborted run can result in damage to instruments and the need to abort the subsequent run.

If you need to replace reagents on the Tecan™ Fluent™ 780 Automation Workstation, make sure to execute the **Refresh Run Count** process before checking in new reagents. For more information, see “Refresh run count” on page 105.

## Prepare Module 2 for the next shift or to be idle

To prepare Module 2 for the next shift or to be idle you must perform the following tasks:



**WARNING!** Failure to maintain the system as described in this guide can result in lower throughput, inaccurate results, or loss of sample.

- Empty Module 2 waste, as needed:

**IMPORTANT!** Failure to empty waste on schedule can result in lower throughput.

Task	Frequency	
	1 shift per day	3 shifts per day
“Empty the Tecan™ Fluent™ 780 Automation Workstation tip waste” on page 137	Empty at the end of the day.	Empty at the end of each shift.
Empty Module 2 solid waste (page 137)		
Empty the BioTek™ ELx405™ Select Microplate Washer liquid waste (page 138)		
Empty the Multidrop™ Combi Reagent Dispenser waste (page 141)	Check daily, empty weekly.	Check at the end of the shift, empty weekly.

- Perform the following maintenance tasks, as needed:

Task	Frequency	
	1 shift per day	3 shifts per day
Disengage the Multidrop™ Combi dispensing cassettes (page 143)	Disengage if the dispensing cassettes will be idle for > 3 hours.	
Prepare each Multidrop™ Combi Reagent Dispenser to be idle (page 144)	Prepare at the end of the day.	Prepare if the instruments will be idle for 4–24 hours.
Refill the BioTek™ ELx405™ Select Microplate Washer water (page 139)	Check daily, refill every 2 weeks.	Check every shift, refill every 2 days.
Power off the KingFisher™ Presto Purification Systems	Power off at the end of the day.	Power off weekly.

**Note:** If the system will be idle for more than 18 hours (for example, for a weekend), we recommend that you use that opportunity to perform the weekly system shut down.



## Empty the Tecan™ Fluent™ 780 Automation Workstation tip waste

Empty the Tecan™ Fluent™ 780 Automation Workstation tip waste at the end of every shift.

---

**IMPORTANT!** Empty the tip waste according to the schedule. Failure to do so can result in a lower throughput.

---

1. Remove the tip waste bin from under the Tecan™ Fluent™ 780 Automation Workstation.
2. Remove the biohazard bag, then dispose of it according to your laboratory guidelines.
3. Insert a new biohazard bag in the bin.
4. Place the tip waste bin back under the Tecan™ Fluent™ 780 Automation Workstation tip waste chute.

## Empty Module 2 solid waste

Empty Module 2 solid waste after every shift.

---

**IMPORTANT!** Failure to physically empty the solid waste after indicating that it has been emptied in the Momentum™ Software schedule can result in lower throughput.

---

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the **Work Manager Dashboard**, click **Empty Waste**.
3. In the **Empty Waste** dialog box, click **OK**.
4. Remove the full biohazard bag from the solid waste bin.
5. Seal, then dispose of the waste according to procedures established by your laboratory.
6. Place a new biohazard bag in the solid waste bin, then replace the bin under the trash chute.

## Empty the BioTek™ ELx405™ Select Microplate Washer liquid waste

Empty the BioTek™ ELx405™ Select Microplate Washer liquid waste after each day or shift.



---

**IMPORTANT!** Failure to empty the BioTek™ ELx405™ Select Microplate Washer waste on schedule can result in the instrument halting operation.

---

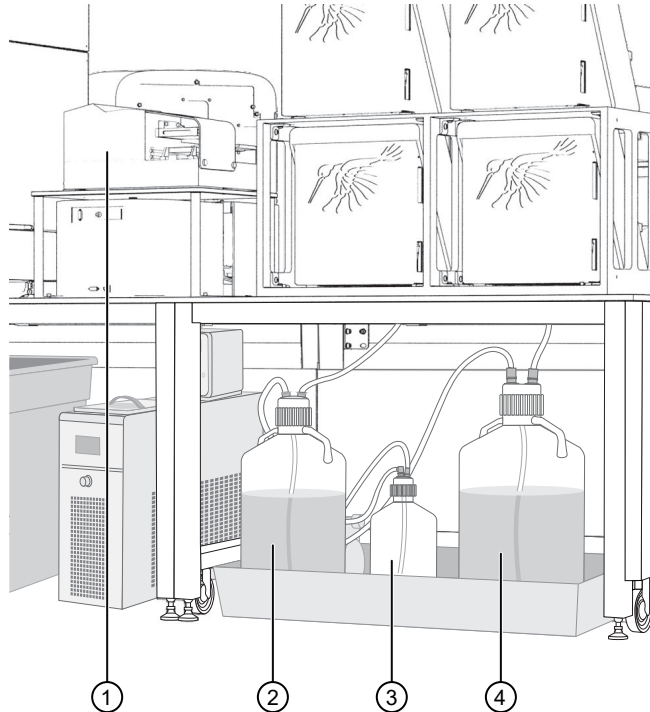
**Note:** If you accidentally bump the BioTek™ ELx405™ Select Microplate Washer liquid waste carboy, the waste sensor can be triggered. If this occurs, empty the liquid waste.

---

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to **ELx405** to take the instrument offline.  
The  icon is grayed out, indicating that the instrument is offline. Leave the window open while you empty the waste.
4. Using the quick connect, disconnect the tubing from the cap of the BioTek™ ELx405™ Select Microplate Washer waste carboy.



**WARNING!** If full, the BioTek™ ELx405™ Select Microplate Washer waste carboy weighs up to 50-lbs.





- ① BioTek™ ELx405™ Select Microplate Washer
- ② Water carboy
- ③ Waste overflow carboy
- ④ Waste carboy

5. Remove the carboy cap, then dispose of the liquid waste according to your laboratory guidelines.
6. Recap, then reconnect the empty waste carboy.

---

**IMPORTANT!** Ensure that the cap is closed tightly. Failure to securely close the cap will prevent the vacuum from working and will stop the run.



---

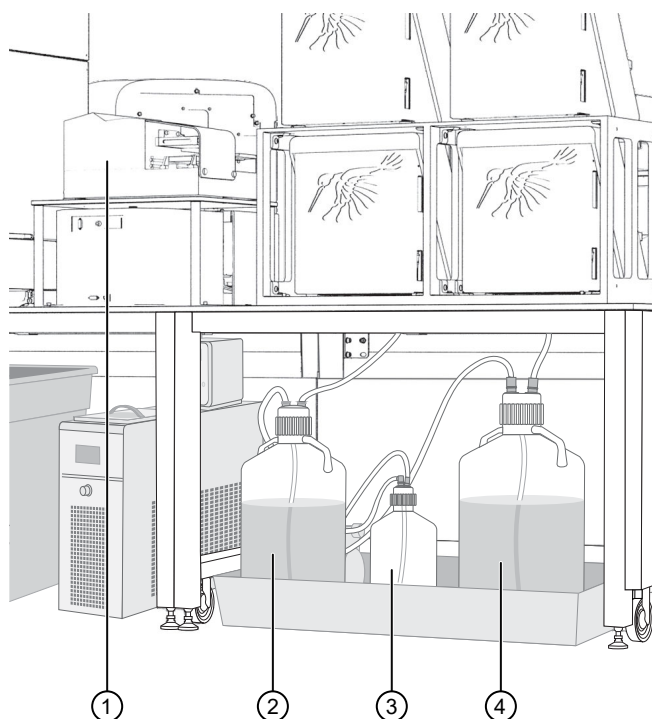
7. If fluid collects in the waste overflow bottle, dispose of the rinse waste according to your laboratory guidelines, then thoroughly rinse the level switch assembly and bottle.
8. In the Momentum™ Software **Device Tasks** window, click  next to **ELx405** to bring the instrument online.  
The  icon is green, indicating that the instrument is online.

## Refill the BioTek™ ELx405™ Select Microplate Washer water

Check the BioTek™ ELx405™ Select Microplate Washer water level daily, then refill according to the following schedule:



- **1 shift per day**—Refill every two weeks.
- **3 shifts per day**—Refill every two days.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to **ELx405** to take the instrument offline.  
The  icon is grayed out, indicating that the instrument is offline.
4. Click **Done**.
5. Disconnect the quick connect tubing from the cap of the BioTek™ ELx405™ Select Microplate Washer dispensing bottle.




- ① BioTek™ ELx405™ Select Microplate Washer
- ② Water bottle
- ③ Waste overflow carboy
- ④ Waste carboy


6. Remove the bottle cap, then fill the bottle with deionized water.
7. Replace the cap and tubing, ensuring that the tubing extends to the bottom of the bottle and that it is not kinked.
8. On the Momentum™ Software computer desktop, open the BioTek™ Liquid Handling Control Software.
9. In the BioTek™ Liquid Handling Control Software, click **File ▶ Open ▶ ELx405 ▶ Select**.

10. Select the **Prime\_200** protocol, then click **Run**.
11. When the **Prime\_200** protocol is complete, close the BioTek™ Liquid Handling Control Software.
12. In the Momentum™ Software **Device Tasks** window, click  next to **ELx405** to bring the instrument online.  
The  icon is green, indicating that the instrument is online.

## Empty the Multidrop™ Combi Reagent Dispenser waste

Check the Multidrop™ Combi Reagent Dispenser waste after every shift and empty weekly.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to each Multidrop™ Combi Reagent Dispenser (Combi1–Combi3) to take them offline.
  - **Combi1** (dispenses Elution Solution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

The  icon is grayed out, indicating that the instruments are offline. Leave the window open while you empty the waste.

4. Remove the tubing from the Multidrop™ Combi Reagent Dispenser waste carboy.

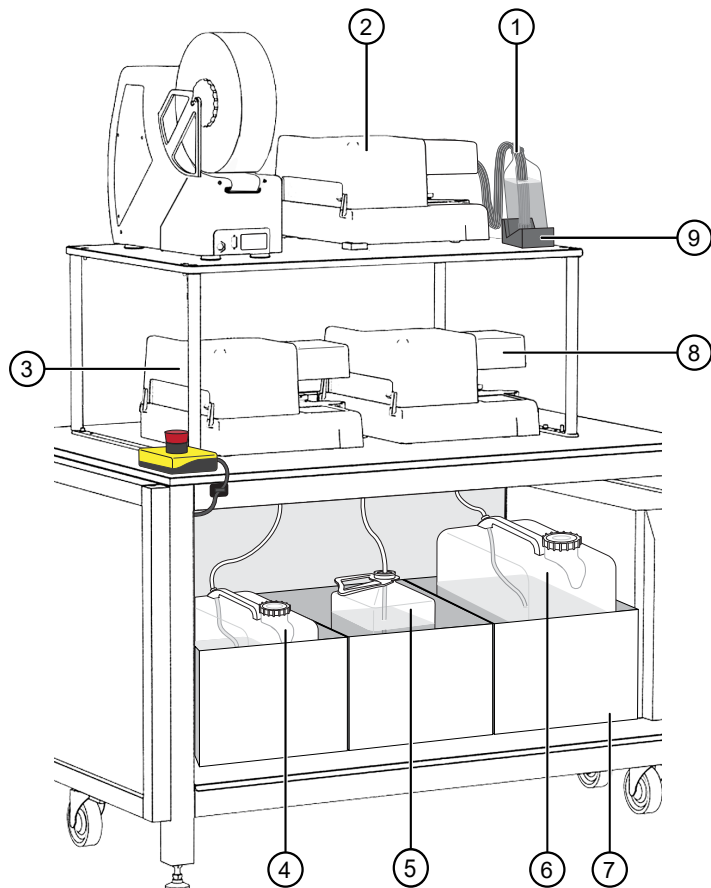


Figure 40 Multidrop™ Combi Reagent Dispenser instrument and reagent locations and reagents


- |   |  |
|---|--|
| ① MagMAX™ HT Elution Solution                     | ⑥ Wash 2 (80% Ethanol) carboy              |
| ② Combi 1 (dispenses MagMAX™ HT Elution Solution) | ⑦ Weighted drawer with scales              |
| ③ Combi 2 (dispenses MagMAX™ HT Wash Solution)    | ⑧ Combi 3 (dispenses Wash 2)               |
| ④ Wash 1 (MagMAX™ HT Wash Solution) carboy        | ⑨ MagMAX™ HT Elution Solution bottle scale |
| ⑤ Waste carboy                                    |  |


5. Dispose of the liquid waste according to your laboratory regulations.
6. Put the waste carboy back in its location, then place the tubing in the carboy.

---

**IMPORTANT!** It is mandatory that you use carboys provided with the Amplitude™ Solution as the scales are calibrated for use with these carboys only. Using any other containers can lead to invalid results.

---

7. In the Momentum™ Software **Device Tasks** window, click  next to each Multidrop™ Combi Reagent Dispenser (Combi1–Combi3) to bring them online.
- **Combi1** (dispenses Elution Solution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

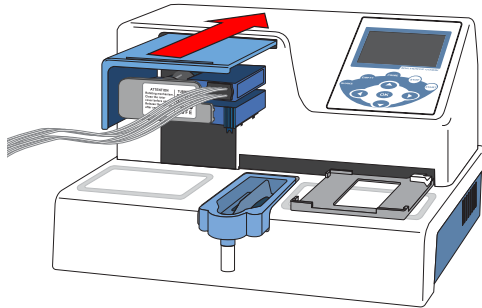
The  icon is green, indicating that the instruments are online.

## Disengage the Multidrop™ Combi dispensing cassettes

Use this procedure if a Multidrop™ Combi Reagent Dispenser will be idle for >3 hours. If the Multidrop™ Combi Reagent Dispenser will be idle overnight, see “Prepare each Multidrop™ Combi Reagent Dispenser to be idle” on page 144.

1. For the first Multidrop™ Combi Reagent Dispenser, push back the cover to expose the rotor and dispensing cassette.

Figure 41 Push back the Multidrop™ Combi Reagent Dispenser cover



2. Move the dispensing cassette to the rest position.

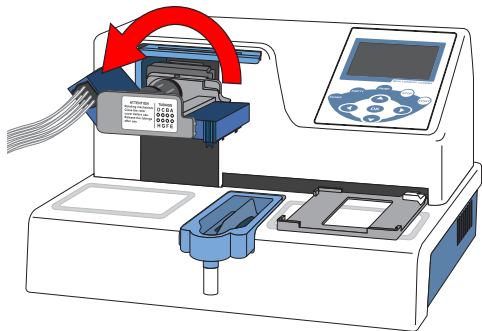


Figure 42 Move the dispensing cassette to the rest position

3. Repeat step 1 to step 2 for each Multidrop™ Combi Reagent Dispenser.


## Prepare each Multidrop™ Combi Reagent Dispenser to be idle


Use this procedure if a Multidrop™ Combi Reagent Dispenser will be idle for 4–24 hours. If the instruments will be idle for >24 hours, power them off.

---

**IMPORTANT!** Ensure that you prime each Multidrop™ Combi Reagent Dispenser for the duration listed. Failure to adequately prime the instruments can affect performance.

---

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to the Multidrop™ Combi Reagent Dispensers to take them offline.
  - **Combi1** (dispenses Elution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

The  icon is grayed out, indicating that the instruments are offline. Leave the window open while you prepare the instruments to be idle.

4. For the first Multidrop™ Combi Reagent Dispenser, remove the tubing bundle from the reagent vessel, then wipe down with 70–80% ethanol.
5. Place the tubing bundle weight in a clean, empty container.
6. On the Multidrop™ Combi Reagent Dispenser keypad, press and hold **Prime** for the duration listed in the following table:

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	

7. Move the tubing bundle weight to a bottle with at least 100 mL of fresh deionized water, ensuring that all portions of the tubing that were previously submerged in the reagent are submerged in the deionized water.

---

**Note:** If there is not a large enough bottle available, two 50-mL conical tubes of deionized water can be used instead, with the priming time split between them.

---



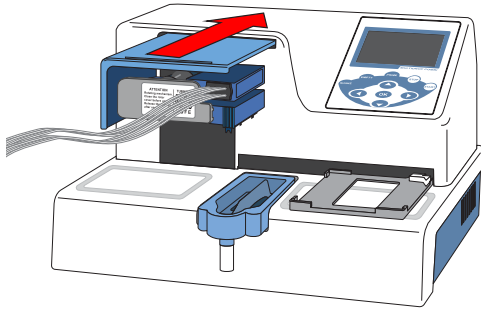
8. On the Multidrop™ Combi Reagent Dispenser keypad, press and hold **PRIME** for the duration listed in the following table.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses Elution Solution)	15 seconds
Combi 2 (dispenses Wash 1)	30 seconds
Combi 3 (dispenses Wash 2)	

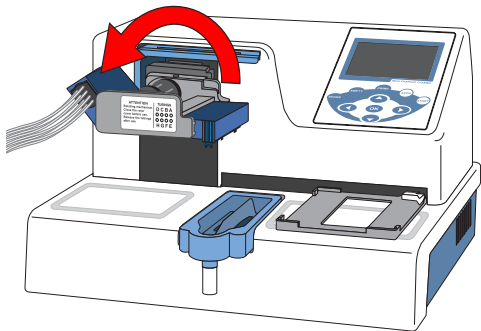
9. Lift the tubing bundle weight from the deionized water surface, then press and hold **PRIME** for the duration listed in the following table.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses Elution Solution)	10 seconds
Combi 2 (dispenses Wash 1)	25 seconds
Combi 3 (dispenses Wash 2)	

10. Place the tubing bundle weight in a clean, empty 50 mL conical tube.  
11. Push back the rotor cover to expose the dispensing cassette.



12. Place the dispensing cassette in the rest position.



13. Repeat step 4 to step 12 for each remaining Multidrop™ Combi Reagent Dispenser.



# Review results (automated workflow)

- Automated results process ..... 146
- Interpretation of the results ..... 147
- Review jobs in SampleManager LIMS™ Software for sample preparation error messages .... 148
- Review the unanalyzed real-time RT-PCR data ..... 150

Your laboratory may allow manual review and authorization of the sample test results (see Appendix E, “SampleManager LIMS™ Software”).

## Automated results process

**Authorized laboratories are required to add the following statement to their laboratory test report to the healthcare provider:**

**The test has been validated.**

1. The real-time RT-PCR data is automatically analyzed, then the results are sent to the SampleManager LIMS™ Software.
2. The SampleManager LIMS™ Software archives the results and transfers the results as a CSV file to the designated location.
3. Review the results in the CSV file (see “Interpretation of the results” on page 147).

---

**Note:** If a batch is **INVALID**, SampleManager notifies users by email that the plate failed.

---

## Interpretation of the results

### Quality control and validity of results

All control wells must pass for the real-time RT-PCR plate results to be considered valid. Validation of results is performed automatically based on the performance of the Positive and Negative Controls.

The following  $C_t$  cutoff values for assay targets are used during interpretation of the results:

**Table 18**  $C_t$  cutoff values for assay targets

Sample	Target $C_t$ cutoff	Result
Positive Control	MS2— $C_t$ values are >37	Valid Positive Control.
	Viral targets— $C_t$ values are ≤37	
Negative Control	MS2— $C_t$ values are ≤32	Valid Negative Control.
	Viral targets— $C_t$ values are >37	
Clinical samples	MS2— $C_t$ values are ≤32	For interpretation of the test results, see Table 19 on page 147.
	Viral targets—Positive $C_t$ values are ≤37	

### Interpretation of test results

The results for each assay target are used to determine the status and result for the sample, as indicated in the table:

**Table 19** Interpretation of test results

ORF1ab	N gene	S gene	MS2	Status	Result	Action
NEG	NEG	NEG	NEG	INVALID	NA	Repeat test. If the repeat result remains invalid, consider collecting a new specimen.
NEG	NEG	NEG	POS	VALID	SARS-CoV-2 Not Detected	Report results to a healthcare provider. Consider testing for other viruses.
Only one SARS-CoV-2 target = POS			POS or NEG	VALID	SARS-CoV-2 Inconclusive	Repeat test. If the repeat result remains inconclusive, additional confirmation testing should be conducted if clinically indicated.
Two or more SARS-CoV-2 targets = POS			POS or NEG	VALID	Positive SARS-CoV-2	Report results to a healthcare provider.

## Review jobs in SampleManager LIMS™ Software for sample preparation error messages

**IMPORTANT!** We recommend that you review all jobs in the SampleManager LIMS™ Software for error messages.

If the SampleManager LIMS™ Software detects a sample failure during Module 1 sample extraction plate preparation, then the following occur:

- The sample with the error is not registered in the system and will not appear in the subsequent QuantStudio™ 7 Flex Real-Time PCR System EDS file or analysis results CSV file.
- The SampleManager LIMS™ Software sends an email containing the **Preparation plate** number and well information to the appropriate distribution group.

**Note:** The email distribution list for failure notifications is set up during system installation.

- A note containing the failure error message is appended to the job in the SampleManager LIMS™ Software.

**Note:** The **Preparation plate** (sample extraction plate) number provided in the notification email is included in the job name.

For more information on Module 1 SampleManager LIMS™ Software CSV output error codes, see “Module 1 SampleManager LIMS™ Software CSV output errors” on page 228.

1. In the SampleManager LIMS™ Software menu, select **Jobs** ▶ **Open Jobs**.
2. In the **Jobs Header** tab, identify the job or jobs that contain an attached error message.

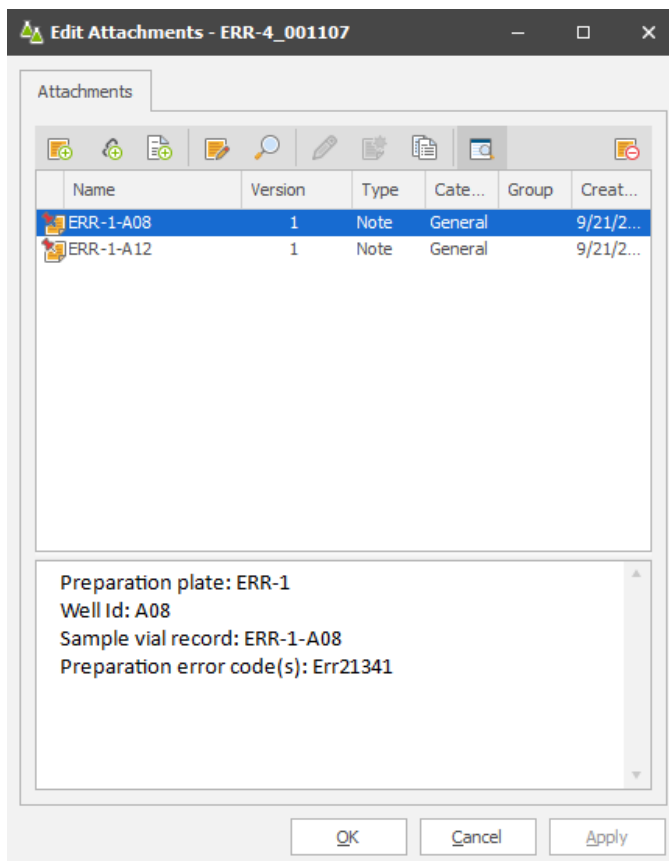
Job name	Browse description	Has attachments
ERR-4_001107	ERR-4 09/21/2020 00:00:00	Yes
P01-4_001105	P01-4 09/19/2020 00:00:00	No
QC05-4_001109	QC05-4 09/21/2020 00:00:00	No

**Figure 43** Job with an attached error message

- ① Job with an attached error message

Action	Description
Search for all jobs that contain an attached error message.	Sort jobs using the <b>Has attachment</b> column. To display the <b>Has attachment</b> column: <ol style="list-style-type: none"> <li>1. Right-click the <b>Browse description</b> column header.</li> <li>2. Select <b>Add/Remove</b> ▶ <b>Has attachment</b>.</li> </ol>
Search for a specific job using the <b>Preparation plate</b> (sample extraction plate) number provided in the notification email.	Enter the <b>Preparation plate</b> number in the search field, then click <b>Find</b> .

3. To review the error message for a job, right-click on the job name, then select **Edit Attachments**.
4. In the **Edit Attachments** window, review the error messages.



Retest the samples that had the failure error.

## Review the unanalyzed real-time RT-PCR data

If you need to review the unanalyzed real-time RT-PCR data file (EDS file) for troubleshooting purposes, the EDS file is stored in the SampleManager LIMS™ Software or on the QuantStudio™ 7 Flex Real-Time PCR System. The EDS file must be reviewed in a compatible real-time RT-PCR software.

To access the file in the SampleManager LIMS™ Software, contact your customer success manager for assistance.

To access the file in the QuantStudio™ 7 Flex Real-Time PCR System, see the instrument user guide.



**WARNING!** Do not derive interpretive results from EDS files, as wells with associated errors that could lead to false results are not excised from EDS files. Use interpretive results only from SampleManager LIMS™ Software, the CSV file it exports, or your laboratory's LIMS.



# Perform regular maintenance

- Regular maintenance task overview ..... 151
- Prepare an RNA elution plate balance ..... 154
- Prepare and reload an RT-PCR plate balance ..... 154
- Multidrop™ Combi Reagent Dispenser regular maintenance ..... 157
- BioTek™ ELx405™ Select Microplate Washer regular maintenance ..... 176
- Tecan™ Fluent™ Automation Workstations regular maintenance ..... 177
- QuantStudio™ 7 Flex Real-Time PCR System regular maintenance ..... 181
- Load sealing film in the ALPS™ 3000 Automated Microplate Heat Sealer ..... 186
- Heal the Spinnaker™ Microplate Robot ..... 190



**WARNING!** Failure to maintain the system as described in this guide can result in lower throughput, inaccurate results, or loss of sample.

Other maintenance tasks are performed by the Thermo Fisher Scientific Field Service Engineer during preventative maintenance visits. Operators are prohibited from performing maintenance tasks other than those specified in these instructions for use.

## Regular maintenance task overview

Regular maintenance is required as part of the normal operation of the Amplitude™ Solution. The frequency of regular maintenance tasks varies based on the system usage:

- **1 shift per day**—The system is idle overnight and weekends (6 runs per day).
- **3 shifts per day**—The system is continuously operational with no idle time (approximately 20 runs per day).

Momentum™ Workflow Scheduler Software is configured to display reminders for the required maintenance tasks for each instrument as needed.

**Table 20 Maintenance tasks that are performed daily**

Task	Description	
	1 shift per day	3 shifts per day
Perform Tecan™ Fluent™ 1080 Automation Workstation daily system care (page 70)	Perform daily at the beginning of the day.	Perform daily at the beginning of each shift.
Perform Tecan™ Fluent™ 780 Automation Workstation daily system care (page 104)	Perform daily at the beginning of the day.	Perform daily at the beginning of each shift.
Maintain the A25 Refrigerated Circulator bath reservoir (page 180)	Check water level daily and fill as needed. Clean the reservoir as part of the filling procedure.	
Refill the BioTek™ ELx405™ Select Microplate Washer water (page 139)	Check the water daily, refill every 2 weeks.	Check the water daily, refill every 2 days.

**Table 21 Maintenance tasks that are performed weekly**

Task	Description	
	1 shift per day	3 shifts per day
Replace dispensing cassettes for Combi 2 (Wash 1) and Combi 3 (Wash 2): <ul style="list-style-type: none"> <li>Physically replace the Multidrop™ Combi dispensing cassettes (page 164)</li> </ul>	The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassettes when required. The replacement frequencies listed below are estimates: <ul style="list-style-type: none"> <li>Combi 2 (Wash 1) dispensing cassette: 18 days</li> <li>Combi 3 (Wash 2) dispensing cassette: 11 days</li> </ul>	The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassettes when required. The replacement frequencies listed below are estimates: <ul style="list-style-type: none"> <li>Combi 2 (Wash 1) dispensing cassette: 6 days</li> <li>Combi 3 (Wash 2) dispensing cassette: 4 days</li> </ul>
Power the system on or off (page 42)	Power off weekly.	Power off weekly.
Prepare an RNA elution plate balance (page 154)	Prepare a new balance plate weekly.	
Prepare and reload an RT-PCR plate balance (page 154)	Prepare a new balance plate weekly.	
Perform Tecan™ Fluent™ 1080 Automation Workstation weekly system care (page 178)	Perform weekly.	
Perform Tecan™ Fluent™ 780 Automation Workstation weekly system care (page 179)	Perform weekly.	



**Table 21** Maintenance tasks that are performed weekly (continued)

Task	Description	
	1 shift per day	3 shifts per day
Delete files on the QuantStudio™ 7 Flex Instruments and the computers (page 181)	Perform weekly.	
Ensure that the seal roll is tightly secured on the ALPS™ 3000 Automated Microplate Heat Sealer spool	If the seal roll is loose, re-install and tighten as described in “Load sealing film in the ALPS™ 3000 Automated Microplate Heat Sealer” on page 186.  Check weekly.	

**Table 22** Maintenance tasks that are performed monthly

Task	Description
Perform a gravimetric volume check on the Elution Solution Multidrop™ Combi Reagent Dispenser (see Perform a Multidrop™ Combi Reagent Dispenser gravimetric volume check (page 171))	Perform monthly.
Clean the Tecan™ Fluent™ 1080 Automation Workstation arm guide (page 179)	
Clean the Tecan™ Fluent™ 780 Automation Workstation arm guide (page 180)	
Switch out and clean the Multidrop™ Combi carboys for Wash 1 and Wash 2 (page 173)	
Perform an instrument self test on the QuantStudio™ 7 Flex Real-Time PCR Systems (page 185)	
Perform the background calibration on the QuantStudio™ 7 Flex Real-Time PCR Systems (page 181)	

**Table 23** Maintenance tasks that are performed every 49+ days

Task	Description	
	1 shift per day	3 shifts per day
Replace the Multidrop™ Combi Elution Solution dispensing cassette: <ul style="list-style-type: none"> <li>Physically replace the Multidrop™ Combi dispensing cassettes (page 164)</li> </ul>	The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassette when required. The replacement frequency listed is an estimate.  Replace every 144 days.	The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassette when required. The replacement frequency listed is an estimate.  Replace every 50 days.
Load sealing film in the ALPS™ 3000 Automated Microplate Heat Sealer (page 186)	Replace every 980 runs (140 days).	Replace every 980 runs (49 days).

Table 24 Maintenance tasks that are performed as needed

Task	Description
Clean the Multidrop™ Combi Reagent Dispenser cassette tips (page 175)	Perform if you touch the cassette tips, or if the reagent is not dispensing freely out of each cassette tip.
Heal the Spinnaker™ Microplate Robot (page 190)	Heal if the robot is mishandling plates.

## Prepare an RNA elution plate balance

Prepare a new balance plate for the RNA elution plate weekly.

Run the **Elution-50ul.pcombi** protocol offline from Combi 1 to fill each well of a KingFisher™ Deep-Well 96 Plate with Barcode with 50 µL of MagMAX™ HT Elution Solution.

---

**Note:** RNA elution plate balance preparation will impact the expected usage and reload frequency of the MagMAX™ HT Elution Solution.

---

## Prepare and reload an RT-PCR plate balance

Prepare a new balance plate for centrifugation of the prepared real-time RT-PCR reaction plate weekly.

1. Add 12.5 µL of water to each well of a MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plates with Barcode.
2. Seal the plate with MicroAmp™ Optical Adhesive Film.
3. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
4. In the Momentum™ Software **Work Manager Dashboard**, click **Replenish Consumables**.

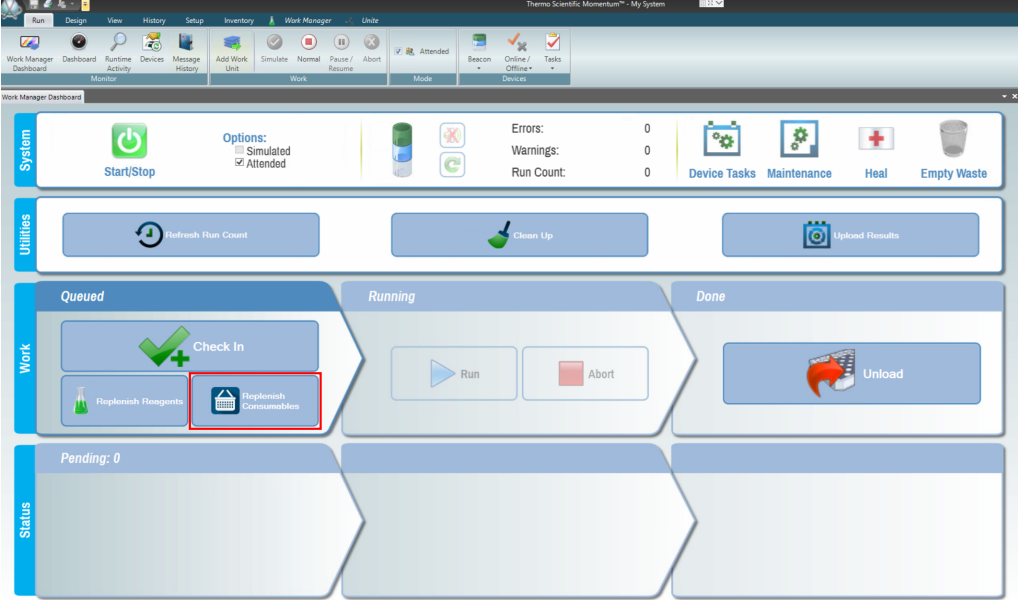
---

**IMPORTANT!** If the **Replenish Consumables** button is inactive (grayed out), then the system cannot be paused to replenish and reload consumables. Wait until the **Replenish Consumables** button is active to proceed.

---

**Note:** If this is the first run after powering on the system, or if the system is offline, we recommend that you wait to bring the system online until the consumables are replenished in the software and loaded in the correct location in Module 2. If the system is offline, you may be required to take the device offline before loading the consumable in Module 2.

---



The **Consumable Containers Replenishment** window opens.

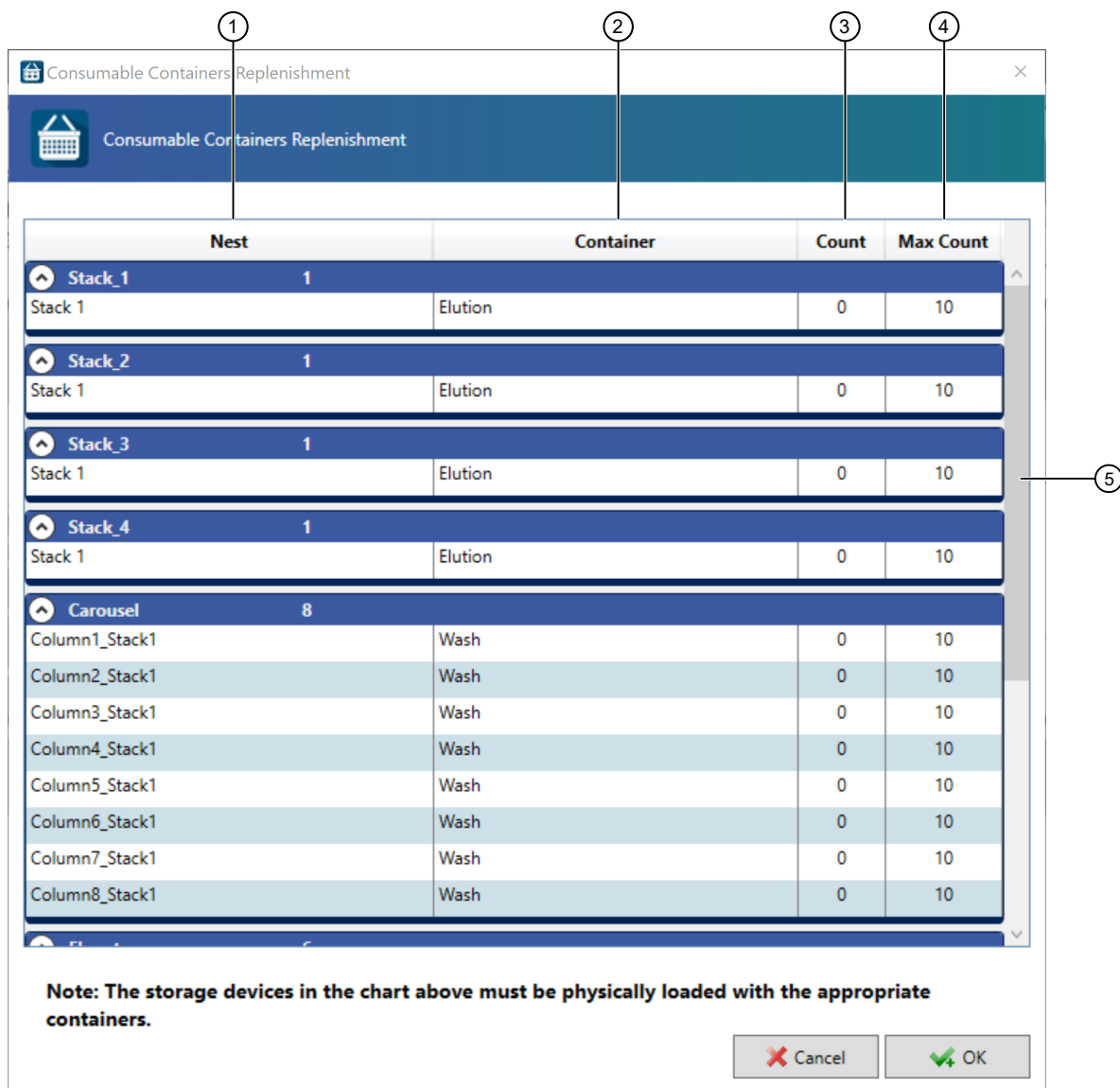


Figure 44 Consumable Containers Replenishment window

- ① **Nest** column—Consumable location
  - ② **Container** column—Consumable name
  - ③ **Count** column—Current number of the consumable available
  - ④ **Max Count** column—Maximum number of the consumable that can be loaded at a time
  - ⑤ Scroll bar—Scroll to see all of the consumables
5. Click **OK**.
  6. Physically load the plate in the hotel for RT-PCR reaction plate balance. For system layout information, see “Module 2 layout and components” on page 19.

## Multidrop™ Combi Reagent Dispenser regular maintenance

Table 25 Multidrop™ Combi Reagent Dispenser regular maintenance tasks

Task	Frequency
Engage and prime each Multidrop™ Combi Reagent Dispenser if idle (page 107)	Engage and prime the instruments if idle.  <b>IMPORTANT!</b> Wash 1 forms bubbles in the dispensing cassette tubes if left idle for >3 hours. You must always prime the Wash 1 Multidrop™ Combi Reagent Dispenser if idle for >3 hours.
Disengage the Multidrop™ Combi dispensing cassettes (page 143)	Disengage the dispensing cassettes if they will be idle for >3 hours.
Prepare each Multidrop™ Combi Reagent Dispenser to be idle (page 144)	Prepare if the instruments will be idle for 4–24 hours (for example, overnight).
Empty the Multidrop™ Combi Reagent Dispenser waste (page 141)	Check daily and empty according to the frequency of use: <ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Empty every 19 days.</li> <li>• <b>3 shifts per day</b>—Empty every 7 days.</li> </ul>
Replace the Wash 1 dispensing cassette (see Physically replace the Multidrop™ Combi dispensing cassettes (page 164)).	The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassettes when required. The replacement frequencies listed below are estimates: <ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Replace every 18 days.</li> <li>• <b>3 shifts per day</b>—Replace every 6 days.</li> </ul>
Replace the Wash 2 dispensing cassette (see Physically replace the Multidrop™ Combi dispensing cassettes (page 164)).	The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassettes when required. The replacement frequencies listed below are estimates: <ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Replace every 11 days.</li> <li>• <b>3 shifts per day</b>—Replace every 4 days.</li> </ul>
Switch out and clean the Multidrop™ Combi carboys for Wash 1 and Wash 2 (page 173)	Clean the carboys for Wash 1 and Wash 2 monthly.
Perform a gravimetric volume check on the Elution Solution Multidrop™ Combi Reagent Dispenser (see Perform a Multidrop™ Combi Reagent Dispenser gravimetric volume check (page 171)).	Perform monthly.

Table 25 Multidrop Combi Reagent Dispenser regular maintenance tasks (continued)

Task	Frequency
Replace the Elution Solution dispensing cassette (see Physically replace the Multidrop™ Combi dispensing cassettes (page 164)).	The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassettes when required. The replacement frequencies listed below are estimates: <ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Replace every 143 days.</li> <li>• <b>3 shifts per day</b>—Replace every 50-days.</li> </ul>
Clean the Multidrop™ Combi Reagent Dispenser cassette tips (page 175)	Clean as needed.

## Replace a Multidrop™ Combi Reagent Dispenser dispensing cassette

The Momentum™ Workflow Scheduler Software will prompt you to replace the Multidrop™ Combi Reagent Dispenser dispensing cassettes when required. The replacement frequencies listed in the following table are estimates:

Multidrop™ Combi Reagent Dispenser	Dispensing cassette type	Estimated replacement frequency <sup>[1]</sup>	
		1 shift per day	3 shifts per day
Combi 1 (dispenses MagMAX™ HT Elution Solution)	Multidrop™ Combi standard tube dispensing cassette	Every 143 days	Every 50 days
Combi 2 (dispenses Wash 1)	Multidrop™ Combi long standard tube dispensing cassette	Every 18 days	Every 6 days
Combi 3 (dispenses Wash 2)		Every 11 days	Every 4 days

<sup>[1]</sup> The replacement frequency will depend on usage.

Replacing the dispensing cassettes is a two part process:

1. Replenish a Multidrop™ Combi Reagent Dispenser dispensing cassette (page 160)
2. Physically replace the Multidrop™ Combi dispensing cassettes (page 164)

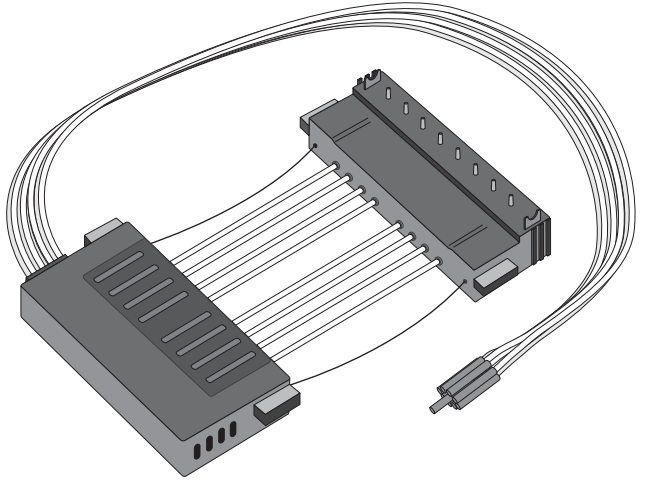
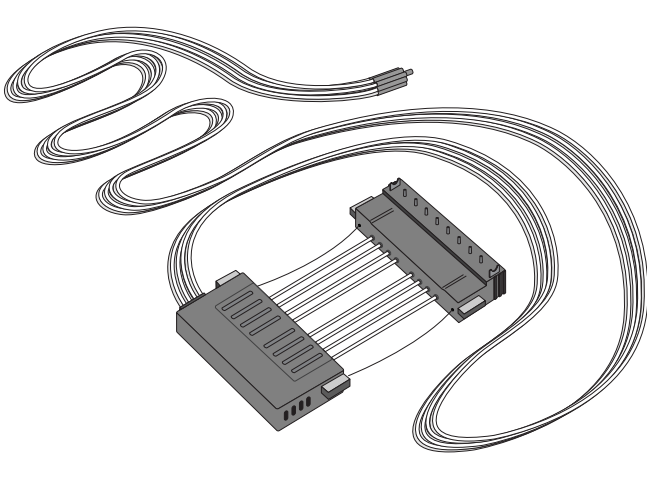
---

**IMPORTANT!** When you update the quantity of reagents and consumables in the Momentum™ Software, you must always physically load the reagent or consumable in the correct location in Module 2. Failure to maintain alignment between the information that is entered in the Momentum™ Software and the reagents and consumables that are physically loaded in the system can delay the run by causing errors that require the run to be aborted.

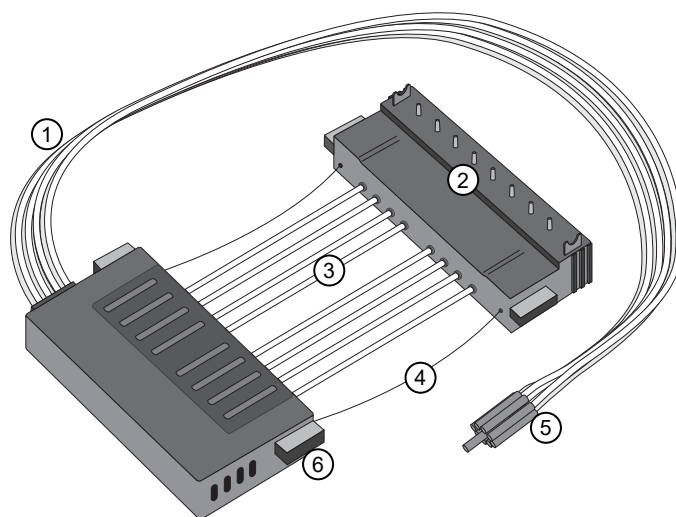
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## About Multidrop™ Combi Reagent Dispenser dispensing cassettes

The system uses two types of Multidrop™ Combi Reagent Dispenser dispensing cassettes:

Multidrop™ Combi standard tube dispensing cassette Used by Combi 1 (dispenses Elution Solution)	Multidrop™ Combi long standard tube dispensing cassette Used by Combi 2 (dispenses Wash 1) and Combi 3 (dispenses Wash 2)
	

A Multidrop™ Combi Reagent Dispenser dispensing cassette includes the components shown in the following figure:



**Figure 45** Parts of a dispensing cassette

- ① Tubing bundle
- ② Tips
- ③ Tubes
- ④ Tension limiting wire
- ⑤ Tubing bundle weight
- ⑥ Tab

## Replenish a Multidrop™ Combi Reagent Dispenser dispensing cassette

The Momentum™ Workflow Scheduler Software will prompt you to replace the dispensing cassettes when required. The replacement frequencies listed in the following table are estimates:

Multidrop™ Combi Reagent Dispenser	Estimated replacement frequency <sup>[1]</sup>	
	1 shift per day	3 shifts per day
Combi 1 (dispenses MagMAX™ HT Elution Solution)	Every 143 days	Every 50 days
Combi 2 (dispenses Wash 1)	Every 18 days	Every 6 days
Combi 3 (dispenses Wash 2)	Every 11 days	Every 4 days

<sup>[1]</sup> The replacement frequency will depend on usage.

1. Ensure that you are using the correct dispensing cassette for the Multidrop™ Combi Reagent Dispenser.

Multidrop™ Combi Reagent Dispenser	Dispensing cassette
Combi 1 (dispenses MagMAX™ HT Elution Solution)	Multidrop™ Combi standard tube dispensing cassette
Combi 2 (dispenses Wash 1)	Multidrop™ Combi long standard tube dispensing cassette
Combi 3 (dispenses Wash 2)	

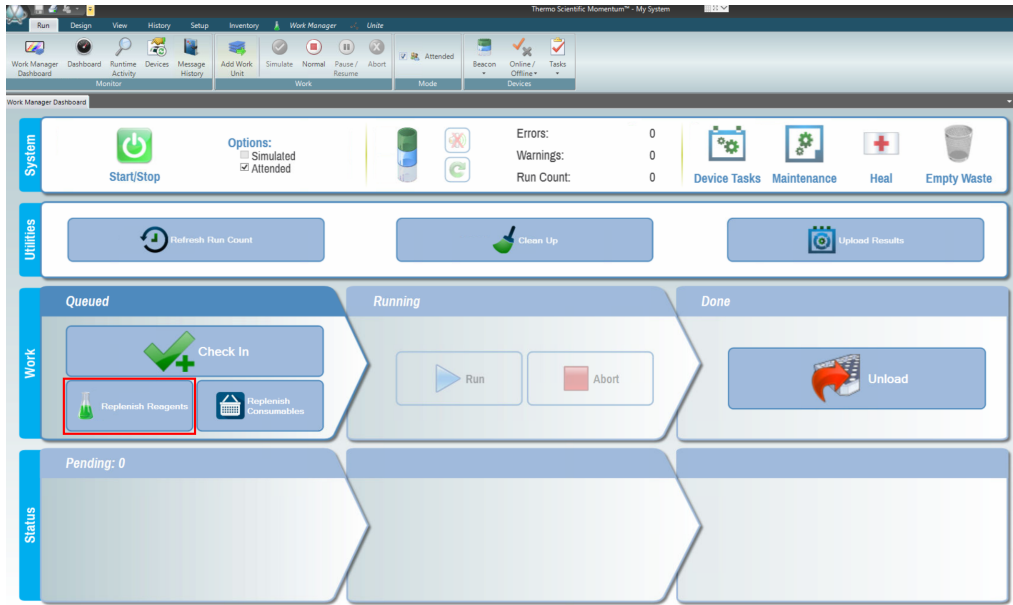
2. On the Module 2 computer station, in the Momentum™ Software **Work Manager Dashboard**, click **Replenish Reagents**.

---

**IMPORTANT!** If the **Replenish Reagents** button is inactive (grayed out), then the system cannot be paused to replenish and reload reagents. Wait until the **Replenish Reagents** button is active to proceed.

---





3. In the **Replenish Reagents** window, click **Scan**.

Momentum: Replenish Reagents



Operator 1

Operator 2

	Location	Location ID	Property	Lot Number Prefix	Lot Number (Scanned)	Vol / Qty Remaining	Replenish Date	Units
	Combi_1	S1-COMBI1-ELU	MagMax HT Elution Solution	91B29880F7	00944064	72	9/8/2020 8:36:31 PM	Sets
①	Combi_1	S1-COMBI1-CASSE	Multidrop standard tube dispensi	9124072670	832808427	1456	9/8/2020 8:43:34 PM	Sets
	Combi_2	S1-COMBI2-W1	MagMax HT Wash Solution	91B32440F2	00946177	72	9/8/2020 8:43:20 PM	Sets
②	Combi_2	S1-COMBI2-CASSE	Combi2 Multidrop long standard	9124072677	832810049	144	9/8/2020 8:43:07 PM	Sets
	Combi_3	S1-COMBI3-W2	80% Ethanol	http://fishersci	204870	72	9/8/2020 8:49:56 PM	Sets
③	Combi_3	S1-COMBI3-CASSE	Combi3 Multidrop long standard	9124072677	832808873	72	9/8/2020 8:42:52 PM	Sets

- ① **Combi1-Cassette**—Multidrop™ Combi standard tube dispensing cassette
- ② **Combi2-Cassette**—Multidrop™ Combi long standard tube dispensing cassette
- ③ **Combi3-Cassette**—Multidrop™ Combi long standard tube dispensing cassette

The **Scan LOT** dialog box opens.

Scan LOT

Scan LOT Number

① Location ID

② Barcode

Close

- ① **Location ID** field—Location barcode information
- ② **Barcode** field—Reagent barcode information

4. Use the hand-held scanner to scan the Location ID barcode that is located next to the appropriate Multidrop™ Combi Reagent Dispenser, then scan the barcode on the dispensing cassette.

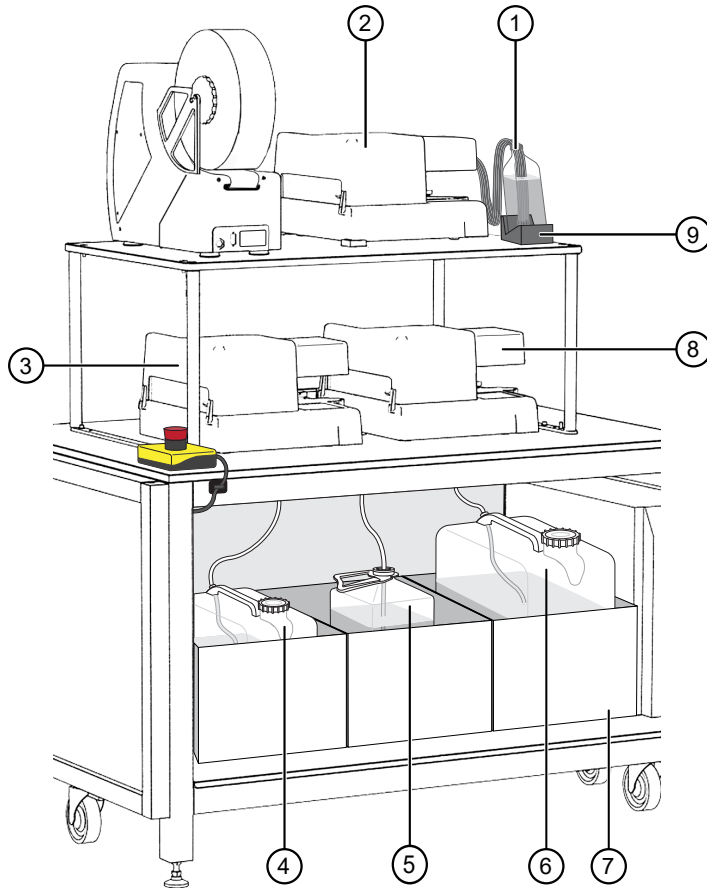


Figure 46 Multidrop™ Combi Reagent Dispenser instrument and reagent locations and reagents

- |   |  |
|---|--|
| ① MagMAX™ HT Elution Solution                     | ⑥ Wash 2 (80% Ethanol) carboy              |
| ② Combi 1 (dispenses MagMAX™ HT Elution Solution) | ⑦ Weighted drawer with scales              |
| ③ Combi 2 (dispenses MagMAX™ HT Wash Solution)    | ⑧ Combi 3 (dispenses Wash 2)               |
| ④ Wash 1 (MagMAX™ HT Wash Solution) carboy        | ⑨ MagMAX™ HT Elution Solution bottle scale |
| ⑤ Waste carboy                                    |  |

**IMPORTANT!** If the Location ID barcode and the dispensing cassette barcode do not match you will receive an error message.

5. On the Module 2 computer station, in the Momentum™ Software **Scan LOT** dialog box, click **Close**.
6. In the Momentum™ Software **Replenish Reagents** screen, click **Submit IDs**.


Immediately replace the dispensing cassette on the Multidrop™ Combi Reagent Dispenser (see “Physically replace the Multidrop™ Combi dispensing cassettes” on page 164).


## Physically replace the Multidrop™ Combi dispensing cassettes

Ensure that you are using the correct dispensing cassette for the Multidrop™ Combi Reagent Dispenser.

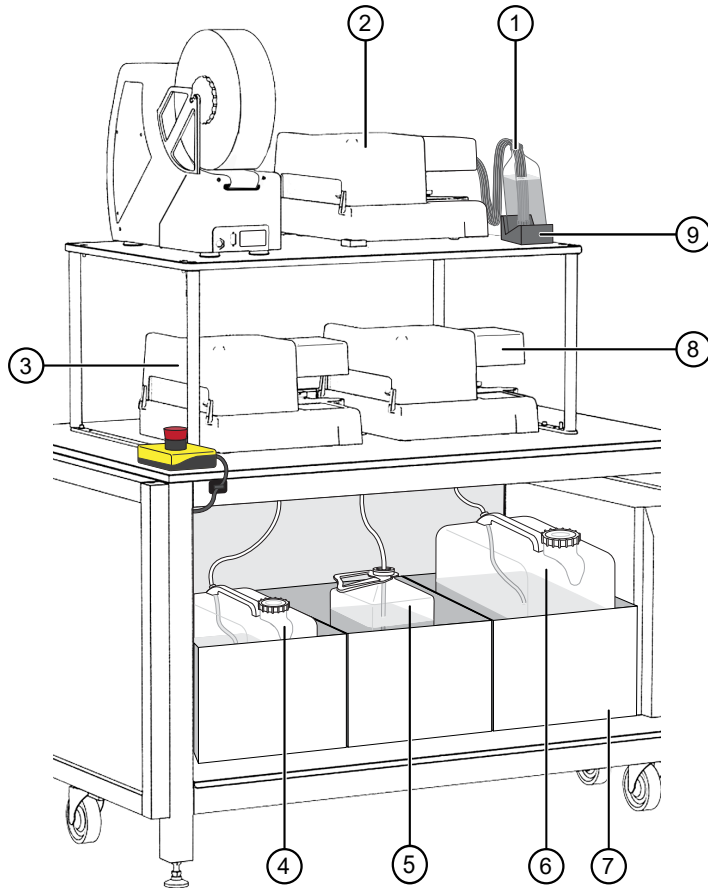
Multidrop™ Combi Reagent Dispenser	Dispensing cassette
Combi 1 (dispenses MagMAX™ HT Elution Solution)	Multidrop™ Combi standard tube dispensing cassette
Combi 2 (dispenses Wash 1)	Multidrop™ Combi long standard tube dispensing cassette
Combi 3 (dispenses Wash 2)	

**IMPORTANT!** Only use the Multidrop™ Combi standard tube dispensing cassette or Multidrop™ Combi long standard tube dispensing cassette, as indicated. The dispensing cassettes have black plastic covers.

1. On the Module 2 computer station, in the Momentum™ Software **Work Manager Dashboard**, click **Device Tasks**.
2. In the **Device Tasks** window, click  next to the Multidrop™ Combi Reagent Dispenser to take it offline.
  - **Combi1** (dispenses Elution Solution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

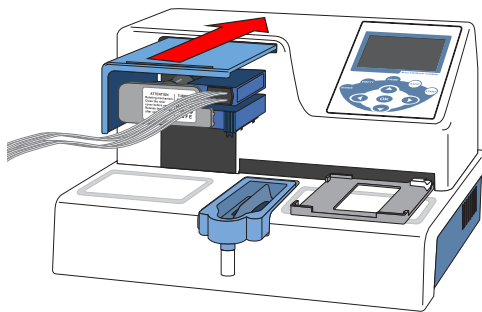
The  icon is grayed out, indicating that the instrument is offline. Leave the window open while you replace the dispensing cassette.
3. Remove the tubing bundle from the reagent bottle or carboy.
4. Press and hold **PRIME** for 5 seconds (Elution Solution) or 20 seconds (Wash 1 and Wash 2).

5. On the appropriate Multidrop™ Combi Reagent Dispenser, push back the rotor cover to expose the rotor and dispensing cassette.

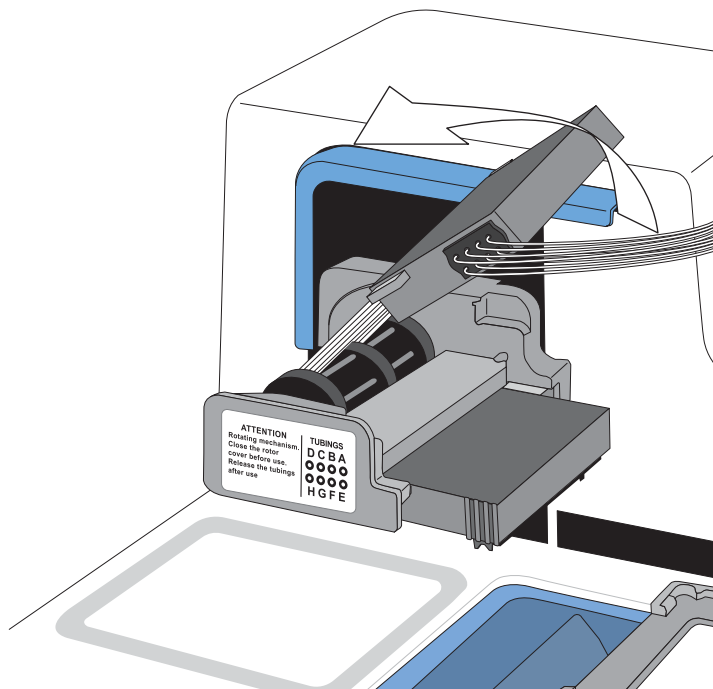


**Figure 47 Multidrop™ Combi Reagent Dispenser instrument and reagent locations and reagents**

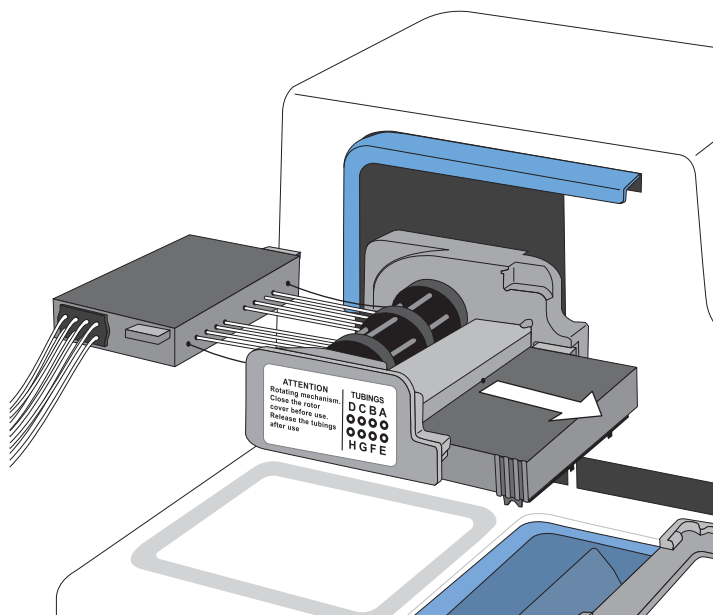
- |   |  |
|---|--|
| ① MagMAX™ HT Elution Solution                     | ⑥ Wash 2 (80% Ethanol) carboy              |
| ② Combi 1 (dispenses MagMAX™ HT Elution Solution) | ⑦ Weighted drawer with scales              |
| ③ Combi 2 (dispenses MagMAX™ HT Wash Solution)    | ⑧ Combi 3 (dispenses Wash 2)               |
| ④ Wash 1 (MagMAX™ HT Wash Solution) carboy        | ⑨ MagMAX™ HT Elution Solution bottle scale |
| ⑤ Waste carboy                                    |  |



6. Remove the used dispensing cassette.
  - a. Using your left hand, slide the tube-part of the dispensing cassette out of the slots, then lift and pull it back over the pump body.



- b. Using your right hand, slide the tip-part of the dispensing cassette out of the slots.

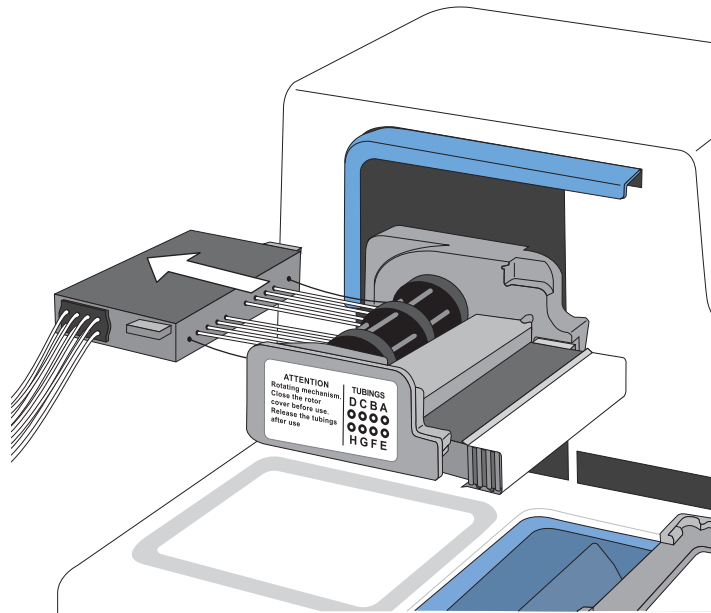


- c. Using both hands, carefully slide the dispensing cassette out from under the pump rotor.
  - d. Remove the tubing bundle from the reagent bottle or carboy, then discard the dispensing cassette.

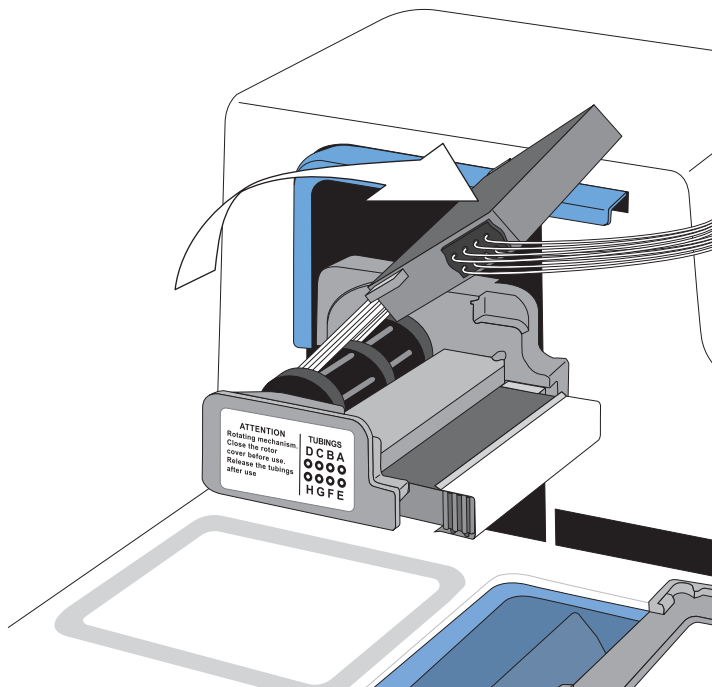
7. Remove the new dispensing cassette from the package, then orient it correctly for insertion.

**IMPORTANT!** Do not remove the metal tip cover.

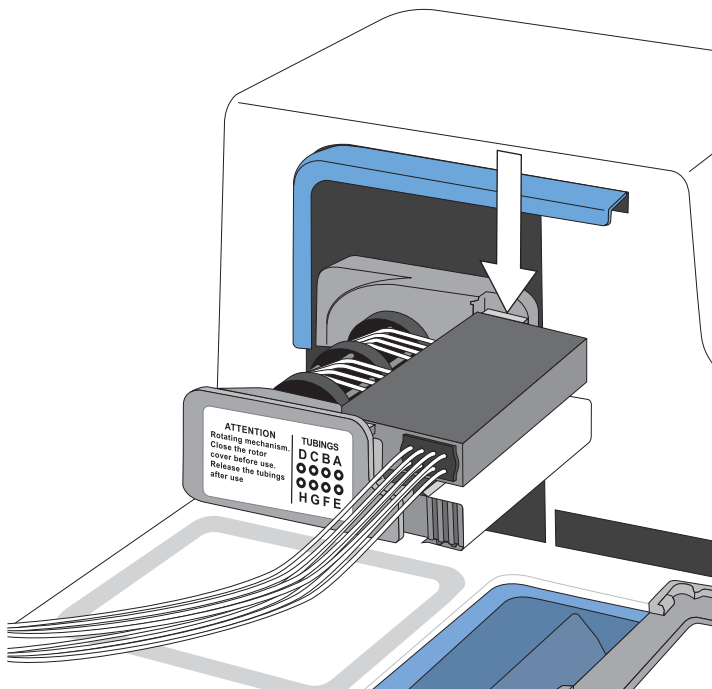
- In your right hand, hold the tip-part of the dispensing cassette with the tips pointing down.
  - In your left hand, hold the tube-part of the dispensing cassette with the tube pointing toward you.
8. Carefully place the eight tubes below the pump rotor, then slide the tabs on the tip-part of the dispensing cassette into the appropriate slots of the pump body. Ensure that the tubes are freely placed below the pump rotor and the tension limiting wires below the rotor shaft.



9. Pull the tube-part of the dispensing cassette up and around the pump rotor, until it is doubled over and nearly on top of the front of the cassette.



10. Insert the tabs into the slots.

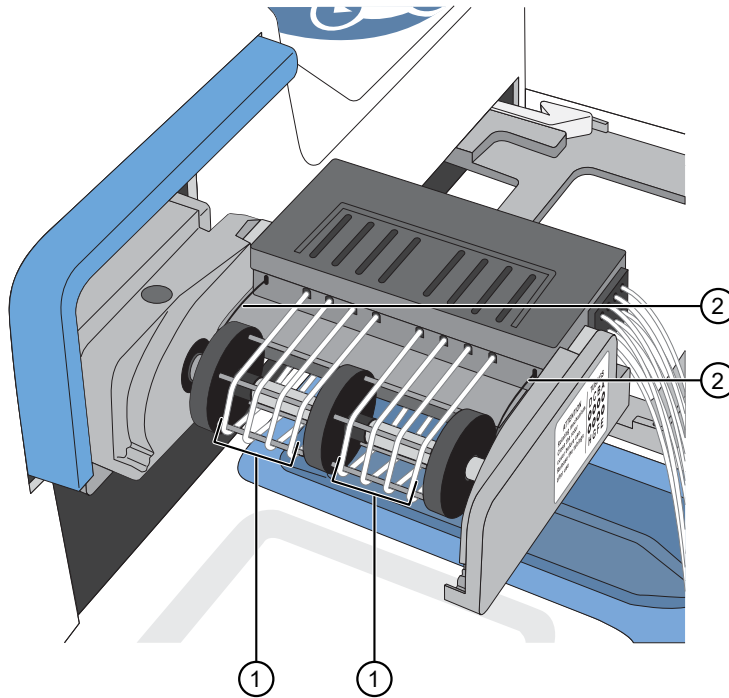




11. Ensure that all the tubes are evenly placed on the rotor needles, four tubes on each half of the pump rotor.



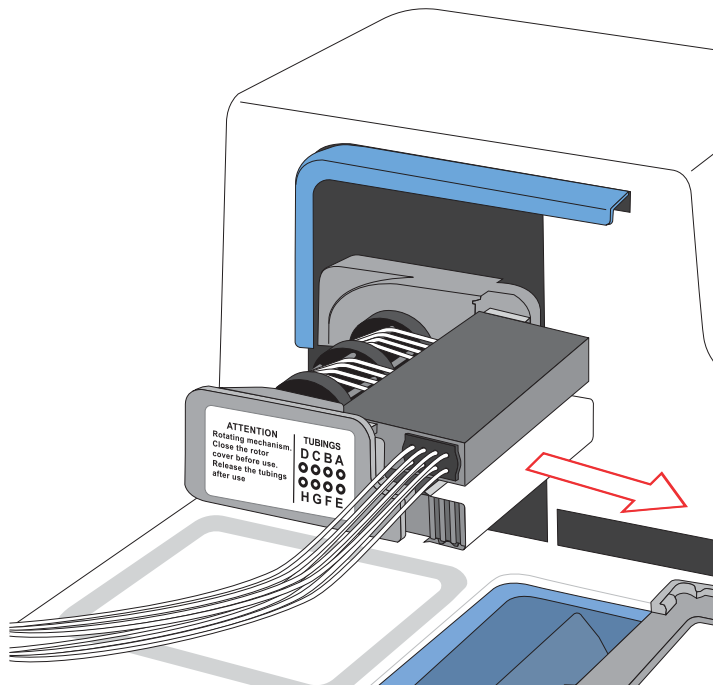
**CAUTION!** Ensure that you correctly align tension limiting wires around the rotor. Failure to do so may result in damage to the dispensing cassette and false negative results.



- ① Tubes evenly placed around the pump rotor
- ② Tension limiting wires with a loose fit around the motor shaft

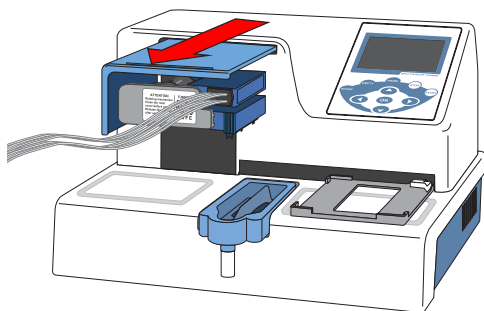
12. Ensure that the tension limiting wires have a loose fit around the rotor shaft and are not on the rotor needles.

13. Pull the tip protection off from the dispensing cassette.



**WARNING!** Do not touch the cassette dispensing tips. Touching dispensing tips can result in false negative results.

14. Pull the cover over the rotor.



15. Place the tubing bundle weight into the bottom of the reagent vessel.



**CAUTION!** Ensure that you place the tubing bundle in the correct reagent vessel, and that there are no kinks in the tubing. Improper placement or kinks in the tubing can cause false negatives or invalid results.

16. Press and hold **PRIME** for the duration listed in the following table.

**IMPORTANT!** Ensure that you prime each Multidrop™ Combi Reagent Dispenser for the duration listed. Failure to adequately prime the instruments can affect performance.




Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	



**WARNING!** Ensure that the liquid runs steadily from all of the cassette dispensing tips by the end of the recommended prime duration. Failure to do so can lead to false negative or invalid results.

## Perform a Multidrop™ Combi Reagent Dispenser gravimetric volume check

Perform a gravimetric volume check on Combi 1 Multidrop™ Combi Reagent Dispenser, which dispenses Elution Solution, every month.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to **Combi1** to take it offline. The  icon is grayed out, indicating that the instrument is offline. Leave the window open while you perform the check.
4. If needed, on the Multidrop™ Combi Reagent Dispenser, press and hold **PRIME** until the dispensing cassette tubing is filled.
5. Record the weight of an empty KingFisher™ Deep-Well 96 Plate with Barcode.
6. Place weighed plate onto the plate carrier of the Multidrop™ Combi Reagent Dispenser.
7. On the Multidrop™ Combi Reagent Dispenser, in the **Main** tab, select  **Plate type**, then press **OK**.

8. In the **Plate type** menu, select **96 DW**.

① **Plate type** menu



Multidrop™ Combi Reagent Dispenser	Combi 1 (dispenses Elution Solution)
Protocol name	96-Elution-50
Target volume per well	50 µL
Target plate weight	4.8 g
Maximum plate weight	5.1 g
Minimum plate weight	4.5 g

9. In the **Main** menu, select **abc** **Save and Edit Protocol**.

10. In the **Save and Edit Protocol** menu, select **96-Elution-50**, then press **OK**.





Figure 48

① **Save and Edit Protocol** menu

11. Press **START** to start the protocol.

12. When the protocol is complete, weigh the plate on the analytical balance, subtract the empty plate weight, then confirm that the difference is within the acceptable range:

Multidrop™ Combi Reagent Dispenser	Combi 1 (Elution Solution)
Target volume per well	50 µL
Target plate weight	4.8 g
Maximum plate weight	5.1 g
Minimum plate weight	4.5 g


- **If the mass is below the acceptable weight**—Rerun the test to confirm that the weight was not light due to bubbles in the tubing. If the plate is light again, replace the cassette, then rerun the test.
  - **If the mass is above the acceptable weight**—Replace the cassette, then rerun the test.
13. On the Module 2 computer station, in the Momentum™ Software **Device Tasks** window, click  next to **Combi1** to bring the instrument online.  
The  icon is green, indicating that the Multidrop™ Combi Reagent Dispenser is online.
14. Click **Done**.


## Switch out and clean the Multidrop™ Combi carboys for Wash 1 and Wash 2

Every month, switch out, then clean the Multidrop™ Combi carboys for Wash 1 and Wash 2 when refilling the reagents.



**WARNING!** Do not clean the carboys with bleach. Toxic gas may form.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to each Multidrop™ Combi Reagent Dispenser to take them offline.
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

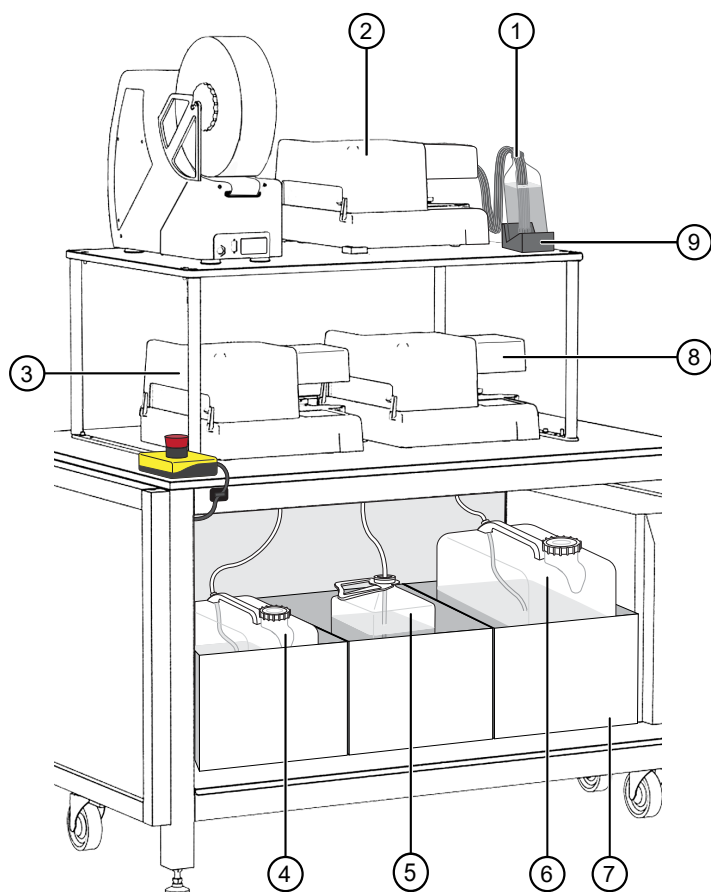
The  icon is grayed out, indicating that the instruments are offline. Leave the window open while you swap out the carboys and refill the reagents.

- When you go to refill the reagents, switch out the current Wash 1 and Wash 2 carboys with clean carboys. For instructions about refilling the carboys, see “Refill the Multidrop™ Combi Reagent Dispenser reagents” on page 127.

**IMPORTANT!** It is mandatory that you use carboys provided with the Amplitude™ Solution as the scales are calibrated for use with these carboys only. Using any other containers can lead to invalid results.



**CAUTION!** Ensure that you place the tubing bundle in the correct reagent vessel, and that there are no kinks in the tubing. Improper placement or kinks in the tubing can cause false negatives or invalid results.




**Figure 49** Multidrop™ Combi Reagent Dispenser instrument and reagent locations and reagents


- |   |  |
|---|--|
| ① MagMAX™ HT Elution Solution                     | ⑥ Wash 2 (80% Ethanol) carboy              |
| ② Combi 1 (dispenses MagMAX™ HT Elution Solution) | ⑦ Weighted drawer with scales              |
| ③ Combi 2 (dispenses MagMAX™ HT Wash Solution)    | ⑧ Combi 3 (dispenses Wash 2)               |
| ④ Wash 1 (MagMAX™ HT Wash Solution) carboy        | ⑨ MagMAX™ HT Elution Solution bottle scale |
| ⑤ Waste carboy                                    |  |

- Inspect the carboys for mold or contaminants and discard if found.
- Rinse the carboys with 70-80% Ethanol, then rinse with water and allow to dry.

## Clean the Multidrop™ Combi Reagent Dispenser cassette tips

Use this procedure if the Momentum™ Workflow Scheduler Software displays an error message indicating that the Multidrop™ Combi Reagent Dispenser cassette tips are clogged.

1. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
2. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
3. If the system is online, click **Device Tasks**, then click  next to the Multidrop™ Combi Reagent Dispenser to take it offline.
  - **Combi1** (dispenses Elution Solution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

The  icon is grayed out, indicating that the instrument is offline. Leave the window open while you clean the cassette tips.

4. Remove the tubing bundle for the affected cassette from the reagent bottle or carboy, and place in a clean, empty 50-mL conical tube.
5. On the Multidrop™ Combi Reagent Dispenser, press and hold **Empty** for 5 seconds.
6. Remove the tubing bundle weight from the conical tube, pour out the liquid in the conical tube, the place the tubing bundle weight back into the empty conical tube.
7. Fill a 25-mL reservoir with deionized water.
8. Place the reservoir under the dispensing cassette tips so that the tips are completely submerged in the deionized water, then press and hold **Empty** until there is only air coming out of the tubing bundle.
9. Place the tubing bundle weight into the bottom of the reagent vessel.



**CAUTION!** Ensure that you place the tubing bundle in the correct reagent vessel, and that there are no kinks in the tubing. Improper placement or kinks in the tubing can cause false negatives or invalid results.


10. Press and hold **PRIME** for the duration listed in the following table.

**IMPORTANT!** Ensure that you prime each Multidrop™ Combi Reagent Dispenser for the duration listed. Failure to adequately prime the instruments can affect performance.

Multidrop™ Combi Reagent Dispenser	Prime duration
Combi 1 (dispenses MagMAX™ HT Elution Solution)	5 seconds
Combi 2 (dispenses Wash 1)	20 seconds
Combi 3 (dispenses Wash 2)	



**WARNING!** Ensure that the liquid runs steadily from all of the cassette dispensing tips by the end of the recommended prime duration. Failure to do so can lead to false negative or invalid results.

11. If the liquid does not run steadily from all of the tips, replace the dispensing cassette (see “Physically replace the Multidrop™ Combi dispensing cassettes” on page 164).
12. If you took the Multidrop™ Combi Reagent Dispenser offline in step 2, in the Momentum™ Software **Device Tasks** window, click  next to the Multidrop™ Combi Reagent Dispenser to bring it back online.
  - **Combi1** (dispenses Elution Solution)
  - **Combi2** (dispenses Wash 1)
  - **Combi3** (dispenses Wash 2)

The  icon is green, indicating that the Multidrop™ Combi Reagent Dispenser is online.

13. Click **Done** to close the **Device Tasks** window.

## BioTek™ ELx405™ Select Microplate Washer regular maintenance



**WARNING!** Internal Voltage. Turn off and unplug the BioTek™ ELx405™ Select Microplate Washer for all cleaning operations.

Task	Frequency
Empty the BioTek™ ELx405™ Select Microplate Washer liquid waste (page 138)	<ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Empty 2-4 times per week</li> <li>• <b>3 shifts per day</b>—Empty 1-2 times per day</li> </ul>
Refill the BioTek™ ELx405™ Select Microplate Washer water (page 139)	<ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Check daily, refill every 2 weeks</li> <li>• <b>3 shifts per day</b>—Check daily, refill every 2 days</li> </ul>
Power off the BioTek™ ELx405™ Select Microplate Washer	Power off weekly.



## Tecan™ Fluent™ Automation Workstations regular maintenance

**Table 26** Module 1 Tecan™ Fluent™ 1080 Automation Workstation regular maintenance tasks

Task	Frequency
Prepare the Tecan™ Fluent™ 1080 Automation Workstation (page 71)	<ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Perform at the beginning of the shift.</li> <li>• <b>3 shifts per day</b>—Perform at the beginning of the shift.</li> </ul>
Perform Tecan™ Fluent™ 1080 Automation Workstation daily system care (page 70)	<ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Perform at the beginning of the shift.</li> <li>• <b>3 shifts per day</b>—Perform at the beginning of the shift.</li> </ul>
Perform Tecan™ Fluent™ 1080 Automation Workstation weekly system care (page 178)	Perform weekly.
Power off the Tecan™ Fluent™ 1080 Automation Workstation (Module 1) (page 48)	Power off weekly.
Clean the Tecan™ Fluent™ 1080 Automation Workstation arm guide (page 179)	Clean monthly.

**Table 27** Module 2 Tecan™ Fluent™ 780 Automation Workstation regular maintenance tasks

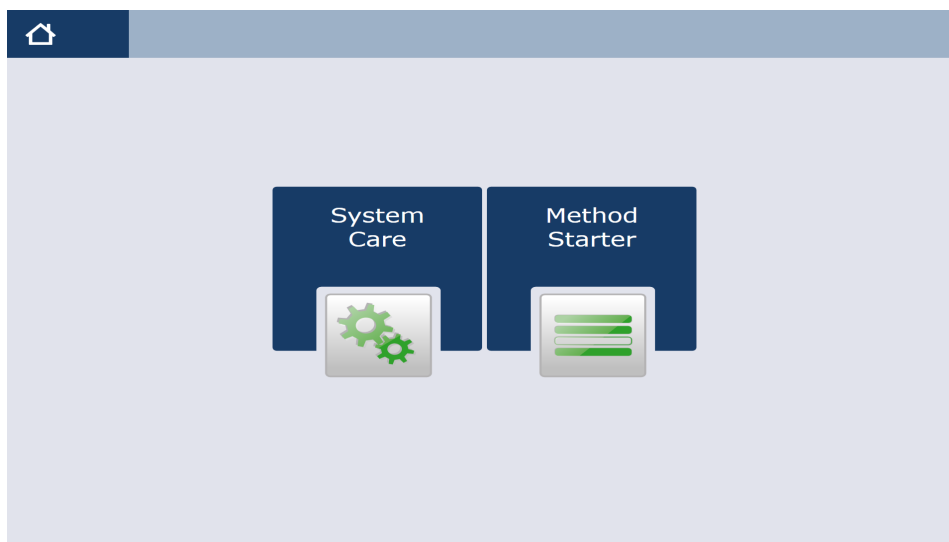
Task	Frequency
Inspect the Tecan™ Fluent™ 780 Automation Workstation and A25 Refrigerated Circulator (page 106)	<ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Perform at the beginning of the shift.</li> <li>• <b>3 shifts per day</b>—Perform at the beginning of the shift.</li> </ul>
Maintain the A25 Refrigerated Circulator bath reservoir (page 180)	<ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Check daily, fill as needed.</li> <li>• <b>3 shifts per day</b>—Check daily, fill as needed.</li> </ul>
Perform Tecan™ Fluent™ 780 Automation Workstation daily system care (page 104)	<ul style="list-style-type: none"> <li>• <b>1 shift per day</b>—Perform at the end of the shift.</li> <li>• <b>3 shifts per day</b>—Perform at the end of the shift.</li> </ul>
Perform Tecan™ Fluent™ 780 Automation Workstation weekly system care (page 179)	Perform weekly.

Table 27 Module 2 Tecan Fluent 780 Automation Workstation regular maintenance tasks (continued)

Task	Frequency
Power off the Tecan™ Fluent™ 780 Automation Workstation (page 49)	Power off weekly.
Clean the Tecan™ Fluent™ 780 Automation Workstation arm guide (page 180)	Clean monthly.

## Perform Tecan™ Fluent™ 1080 Automation Workstation weekly system care

1. On the Tecan™ Fluent™ 1080 Automation Workstation touchscreen home screen, tap **System Care**.



2. In the **System Care** screen, select the **WeeklySystemCare** method.
3. Follow the on screen prompts to perform the required weekly system care.

## Clean the Tecan™ Fluent™ 1080 Automation Workstation arm guide

Clean the Tecan™ Fluent™ 1080 Automation Workstation arm guide monthly.

1. Clean the arm guide roller on the arm guide with a cotton swab.

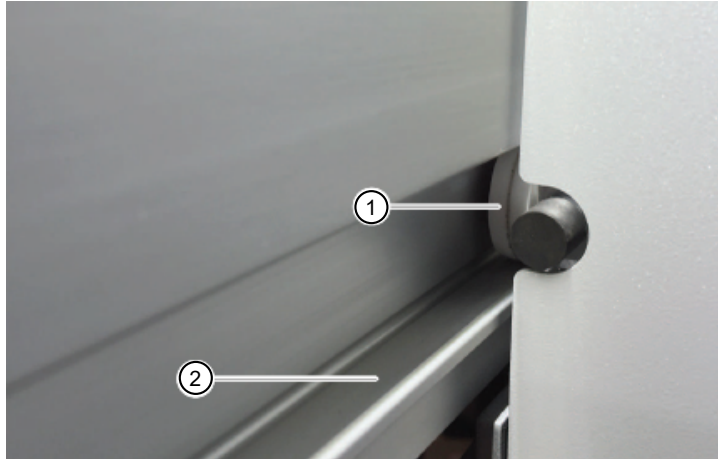


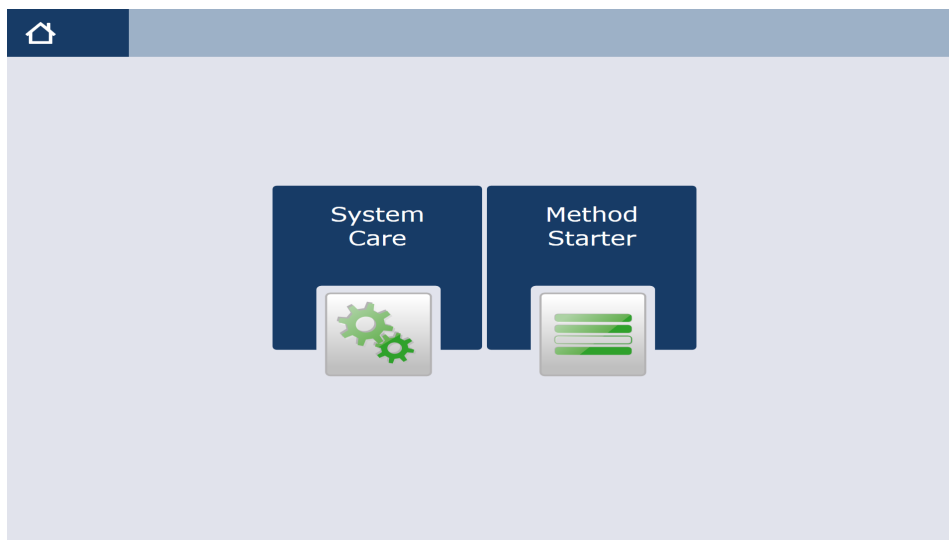
Figure 50 Tecan™ Fluent™ 1080 Automation Workstation arm guide

- ① Arm guide roller
- ② Arm rails

2. Clean the arm rails with a lint-free cloth.

## Perform Tecan™ Fluent™ 780 Automation Workstation weekly system care

1. On the Tecan™ Fluent™ 780 Automation Workstation touchscreen home screen, tap **System Care**.



2. In the **System Care** screen, select the **WeeklySystemCare** method.
3. Follow the on screen prompts to perform the required weekly system care.

## Clean the Tecan™ Fluent™ 780 Automation Workstation arm guide

Clean the Tecan™ Fluent™ 780 Automation Workstation arm guide monthly.

1. Clean the arm guide roller on the arm guide with a cotton swab.

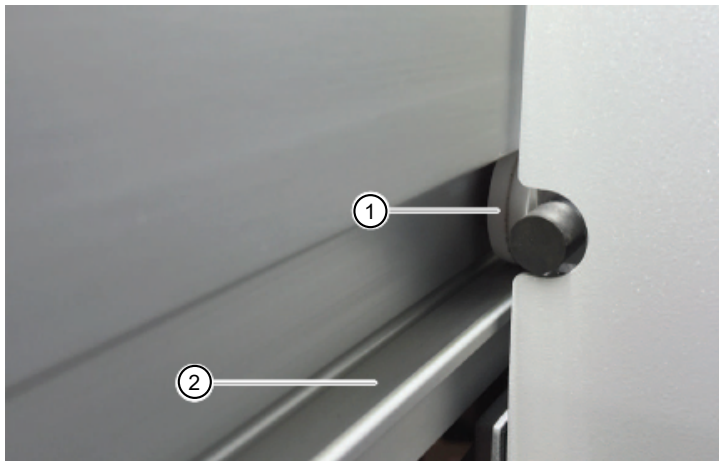


Figure 51 Tecan™ Fluent™ 780 Automation Workstation arm guide

- ① Arm guide roller
- ② Arm rails

2. Clean the arm rails with a lint-free cloth.
3. Clean the upper surface of the guide rail on the MCA arm guide with a lint-free cloth.

## Maintain the A25 Refrigerated Circulator bath reservoir

Check the water level in the A25 Refrigerated Circulator reservoir daily, and fill as needed.

Before you begin, ensure that the reservoir drain port on the front of the bath is closed and that all plumbing connections are secure.

1. Remove the A25 Refrigerated Circulator lid.
2. Use deionized water and a soft cloth to clean the reservoir and built-in components.
3. Fill the reservoir with deionized water, then replace the lid.

## QuantStudio™ 7 Flex Real-Time PCR System regular maintenance



Task	Frequency
Delete files on the QuantStudio™ 7 Flex Instruments and the computers (page 181)	Once a week.
Perform the background calibration on the QuantStudio™ 7 Flex Real-Time PCR Systems (page 181)	Once a month.
Perform an instrument self test on the QuantStudio™ 7 Flex Real-Time PCR Systems (page 185)	Once a month.

The following maintenance is performed by the Thermo Fisher Scientific Field Service Engineer during preventative maintenance visits:

- ROI Calibration
- Background Calibration
- Uniformity Calibration
- Dye Calibration
- Normalization Calibration
- RNase P Verification
- Lamp replacement

### Delete files on the QuantStudio™ 7 Flex Instruments and the computers

Delete files weekly.

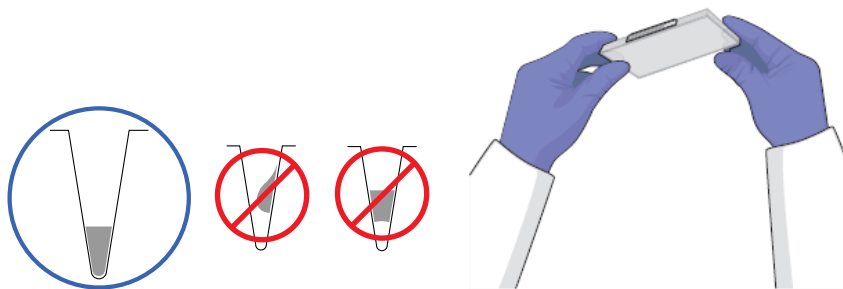
1. Delete the files from the computers, according to the operating system.
2. In the **Main Menu** of the instrument touchscreen, touch **Collect Results**.
3. From the list of experiments, touch **Select All** if you want to delete all experiments or touch the individual experiments of interest that you want to delete.
4. Once all files that you want to delete are selected, touch  **Delete**.
5. When asked to confirm the deletion, touch **OK**.
6. Touch  to return to the **Main Menu**.

### Perform the background calibration on the QuantStudio™ 7 Flex Real-Time PCR Systems

Perform the background calibration on the QuantStudio™ 7 Flex Real-Time PCR Systems once a month.

1. Prepare a background calibration plate.
  - a. Add 20 µL of deionized water to each well of a MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plates with Barcode.
  - b. Seal the plate with MicroAmp™ Optical Adhesive Film.

- c. Confirm that the deionized water in each well of the calibration plate is at the bottom of the well. If not, centrifuge the plate for 2 minutes at <1500 rpm.




---

**IMPORTANT!** Do not allow the bottom of the plate to become dirty. Fluids and other contaminants that adhere to the plate bottom can contaminate the sample block and cause an abnormally high background signal.


---

2. In the QuantStudio™ Real-Time PCR Software **Home** tab, click **Instrument Console**.
3. In the **Instrument Console**, select the icon for your instrument, then click **Manage Instrument**.

---

**Note:** If the **Manage Instrument** button is inactive, add your instrument to the **My Instruments** group.

---


4. In the **Instrument Manager**, start the calibration:
  - a. Click  **Maintenance**, then click **Background**.
  - b. In the **Background Calibration** screen, click **Start Calibration**.
5. Click **Next**, then prepare for the calibration as instructed.
6. At the bottom of the **Setup** tab, enter the reagent information for the calibration plate.

**Reagent Information**

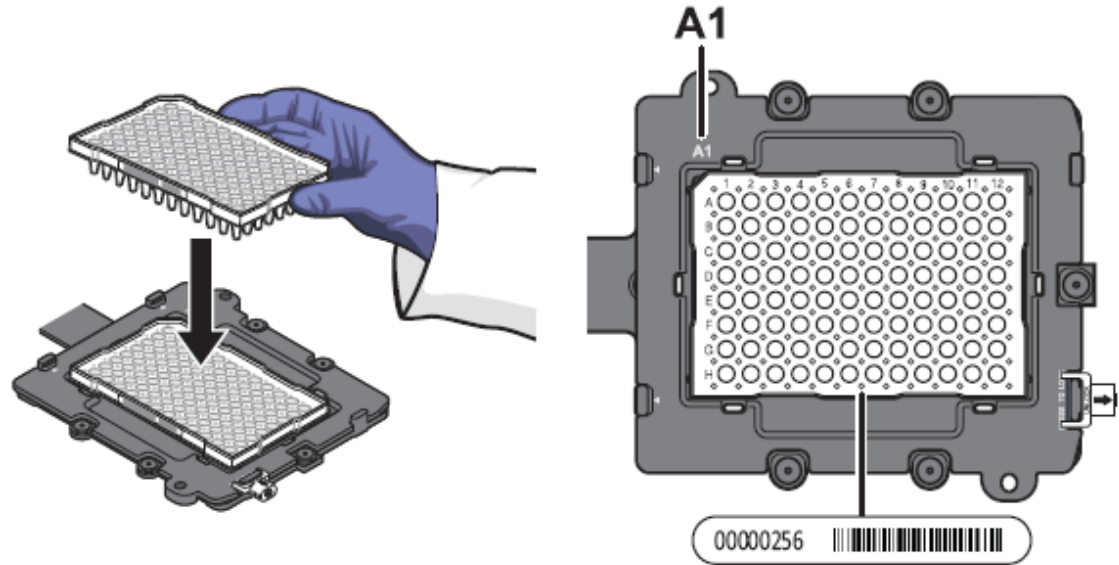
Plate Barcode	Reagent Name	Reagent Part Number	Reagent Lot Number	Reagent Expiration Date

Check the box when the background calibration plate has been loaded, and when you have ensured you have entered all reagents information correctly

Instrument Con... 287880008 x

7. Load the calibration plate into the instrument:
  - a. From the instrument touchscreen, tap  to eject the instrument tray.


- b. Load the calibration plate into the plate holder 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!** Plates should be loaded and unloaded by operators who have been warned of the moving parts hazard and have been adequately trained.

---

- c. From the instrument touchscreen, tap  to close the instrument tray.
8. After loading the plate, start the calibration:
- In the **Setup** tab, select **Check the box when the background calibration plate has been loaded**, then click **Next**.
  - From the **Run** screen, click **Start Run**.

---

**IMPORTANT!** Do not attempt to open the access door during the run. The door is locked while the instrument is in operation.

---

**Note:** Before starting the calibration, the instrument may pause (up to 10 minutes) to allow the heated cover to reach the required temperature.

---

9. When the run is complete and the QuantStudio™ Real-Time PCR Software displays the **Analysis** screen, confirm the status of the calibration. The analysis status indicates the success of the calibration, where *passed* indicates that the run produced viable calibration data and *failed* indicates that the run did not produce data or that the data it collected is unusable.

Analysis status	Action
Passed	Click <b>Next</b> .
Failed	Troubleshoot the failed calibration (see the <i>QuantStudio™ 6 and 7 Flex Real-Time PCR Systems (v1.6.1 or later) Maintenance and Administration Guide</i> (Pub. No. MAN0018828)).

**Note:** Abnormal spectra or abnormally high background fluorescence can indicate the presence of contamination on the plate or sample block, which can cause the calibration to fail.

10. Select the **QC** tab to review the quality check summary. The QC status indicates the quality of the calibration data, where **Passed** indicates that all wells produced data that passed the quality check, and **Failed** indicates that one or more wells produced spectra that deviate significantly from the other wells on the plate.

**Note:** If the calibration failed, the **QC** tab can provide information regarding the cause of the failure.


11. Unload the calibration plate:
- After the calibration, tap  on the touchscreen to eject the plate.

**Note:** If the instrument does not eject the plate, remove it as explained in the *QuantStudio™ 6 and 7 Flex Real-Time PCR Systems (v1.6.1 or later) Maintenance and Administration Guide* (Pub. No. MAN0018828).

- Remove the plate from the instrument tray and discard it.



**WARNING! PHYSICAL INJURY HAZARD.** During instrument operation, the plate temperature can reach 100°C. Allow the consumable to cool to room temperature before removing.

- Tap  on the instrument touchscreen to close the instrument tray.
12. From the **Background Calibration** screen, click **Finish** to complete the calibration, then click **Yes** when prompted to save the results.
13. (Optional) Click **Print Report** in the upper right corner of the screen to print a summary of the calibration results for your records.

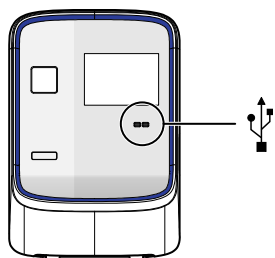


## Perform an instrument self test on the QuantStudio™ 7 Flex Real-Time PCR Systems

Perform an instrument self test on the QuantStudio™ 7 Flex Real-Time PCR Systems monthly.

You can use the QuantStudio™ 7 Flex Real-Time PCR System touchscreen to perform a comprehensive self test of the QuantStudio™ 7 Flex Real-Time PCR System subsystems. After the self test is complete, the QuantStudio™ 7 Flex Real-Time PCR System generates two files that provide a detailed summary of the instrument condition and function. In the event of a problem, you can save the results files to a USB drive and email them to Technical Support for a diagnosis.

1. From the main menu of the instrument touchscreen, touch **Tools**, then touch **Run Self Test**.
2. From the **Self Test** screen, touch  **Start Self Test**, then wait for the test to complete.
3. (Optional) When the QuantStudio™ 7 Flex Real-Time PCR System completes the self test, save the results to a USB drive:
  - a. Plug a USB drive into the USB port below the touchscreen.



---

**IMPORTANT!** Do not use the USB ports on the rear panel of the QuantStudio™ 7 Flex Real-Time PCR Systems. The rear USB ports are for use by Thermo Fisher Scientific personnel to service the instrument.


---

- b. Touch  **Save**.

---

**IMPORTANT!** Do not remove the USB drive from the QuantStudio™ 7 Flex Real-Time PCR System until instructed.

---

- c. When the QuantStudio™ 7 Flex Real-Time PCR System finishes writing the results to the USB drive, touch **OK**, then remove the USB drive.
4. Touch  to return to the main menu.

## Load sealing film in the ALPS™ 3000 Automated Microplate Heat Sealer

The Momentum™ Software notifies the operator when it is time to load a new roll of Clear Seal Heat Sealing Film (4900 plates or 980 Module 2 runs).



**WARNING!** Failure to replace the sealing film when prompted or to follow sealing film replacement instructions can result in inaccurate results and system contamination.

1. Ensure the ALPS™ 3000 Automated Microplate Heat Sealer is powered on.





**CAUTION!** The instrument should be cool when loading the film to eliminate possible injury.

2. Ensure that you have a step stool to access the ALPS™ 3000 Automated Microplate Heat Sealer.

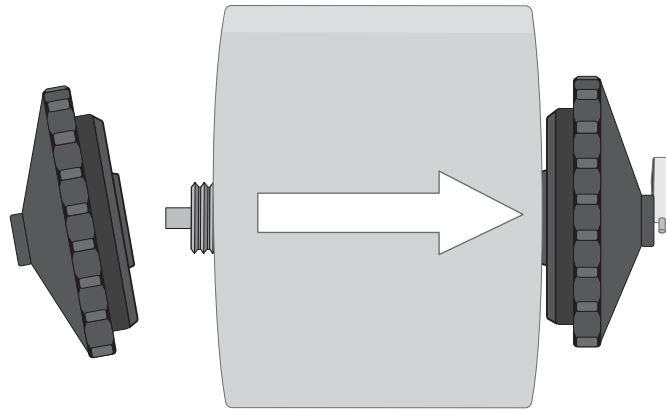
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**IMPORTANT!** Do not attempt to move the instrument to gain access.

---

3. On the Module 2 computer station, use the **Ctrl Ctrl 1** shortcut to open the Momentum™ Software computer desktop.
4. In the Momentum™ Software **Work Manager Dashboard**, confirm that the system is offline.
5. If the system is online, click **Device Tasks**, then click  next to the **ALPS300** to take the instrument offline.  
The  icon is grayed out, indicating that the instrument is offline. Leave the window open while you replace the sealing film.
6. On the instrument screen, tap **Settings**, then tap **Load**.  
The foil gripper and foil clamp open.
  - If you are reloading the seal, proceed to step 10.
  - If you are replacing the seal roll, proceed to step 7.
7. Load the new roll of Clear Seal Heat Sealing Film on to the spool.
  - a. Remove the spool from the support bracket.
  - b. Unscrew the side of the spool, then discard the used Clear Seal Heat Sealing Film.

- c. Holding the spindle with the pin in your right hand, load the new roll of Clear Seal Heat Sealing Film onto the spool rod so that film is unrolling over the top of the roll, away from you.



- d. Hand-tighten the spindle and ensure that the seal roll is tightly secured.

**IMPORTANT!** There should NOT be any space between the spindles and the seal roll.

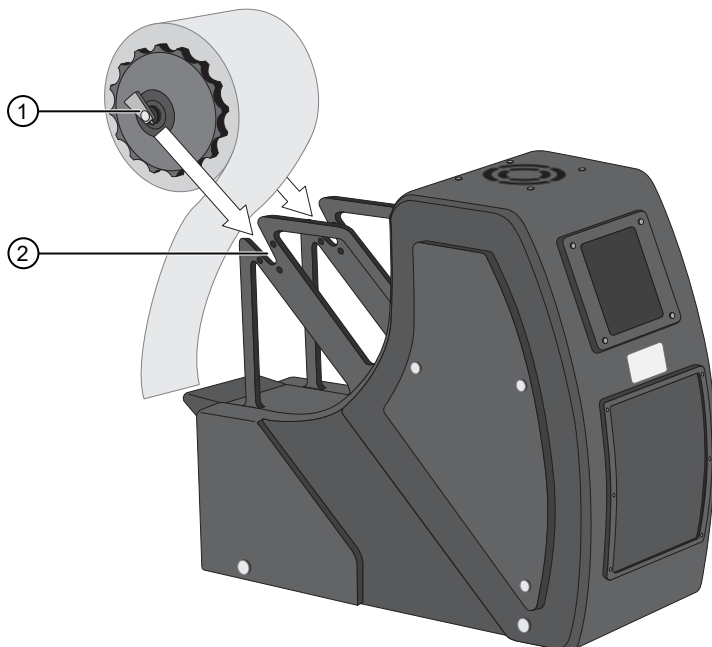
**CORRECT**



**INCORRECT**

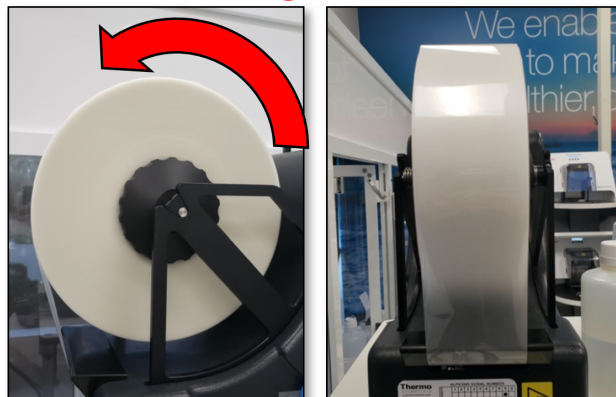


8. Load the spool with the roll of Clear Seal Heat Sealing Film into the support bracket, ensuring that the pin on the spindle inserts correctly into the hole on the bracket.

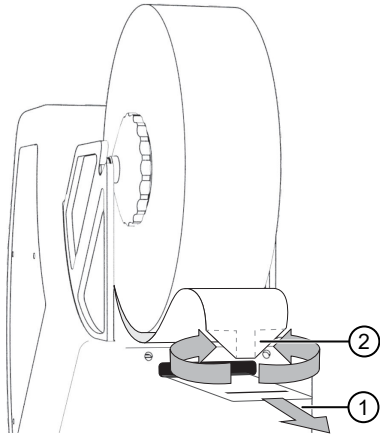


- ① Spindle with pin
- ② Bracket with pin hole

9. Confirm that the seal roll is loaded in the correct orientation on the instrument.

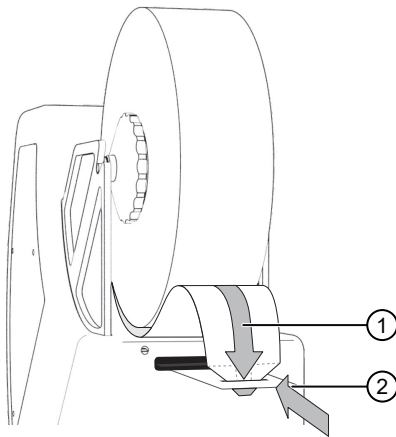
**CORRECT****INCORRECT**

10. From the front of the instrument, place the foil loading tool flat on the plate shuttle with no plate present, then slide the foil loading tool carefully through the instrument and out through the back.



- ① Slide the foil loading tool in from the front of the instrument, and out the back.
- ② Fold or cut the end of the foil into a point.

11. Turn the roll of the Clear Seal Heat Sealing Film to provide slack to feed through the instrument.
12. Fold or cut the end of the foil into a point.
13. Insert folded point into the slot in the loading tool, ensuring that the foil is not twisted.





14. Carefully pull the foil loading tool back through the instrument, ensuring that it is sitting flat and central.
15. Remove foil from the loading tool, then center the foil in the foil gripper.
16. Keep the foil taut and tap **Trim** on the touchscreen. Make sure to maintain a tight grip on the seal during trimming. Discard the trimmed piece of foil.

---

**IMPORTANT!** After trimming, make sure pull the excess seal away from the instrument **quickly** before the door closes.

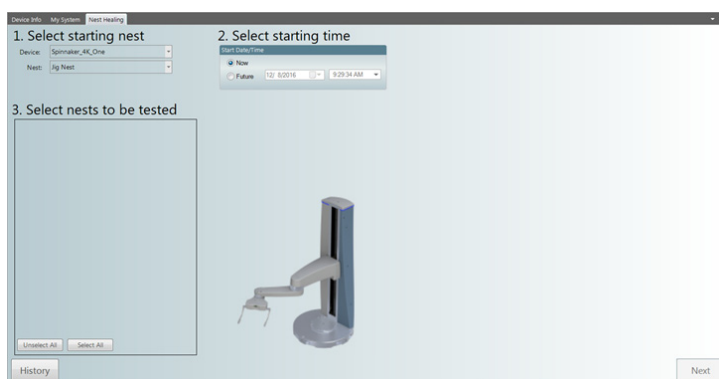
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17. Place an empty PCR plate onto the instrument, then select **Seal** on the touchscreen. Confirm that the seal is centered on the plate and covers all of the wells.
18. On the Module 2 computer station, in the Momentum™ Software **Device Tasks** window, click  next to **ALPS3000** to bring the instrument online.  
The  icon is green, indicating that the instrument is online.

## Heal the Spinnaker™ Microplate Robot

Heal the Spinnaker™ Microplate Robot if it is mishandling plates. During regular maintenance, the location of a nest in relation to the Spinnaker™ Microplate Robot may change. Healing is used to evaluate the difference between the nest's known (taught) location and its new location, and to reteach the Spinnaker™ Microplate Robot

1. On the Module 2 computer station in the Momentum™ Software **Work Manager Dashboard**, click **Heal**.  
The **Nest Healing** window opens.



2. Select the starting location for the Smart Jig. In most cases, this will be the jig nest.
3. Select the time when the healing session will start.
4. Select the check box for each nest location that will be healed during this session, then click **Next**.
5. Place the Smart Jig in the selected starting location.
6. Ensure that there are no containers in the nest(s) that will be healed, then click **Next**.  
The **Run Monitor** opens.
7. Click **Run** to start the healing session.  
The results for each nest location and the progress of the healing run are displayed in the **Run Monitor**.

After the healing session is completed, the Smart Jig is returned to its starting location and a summary of the session is displayed.



# Troubleshooting

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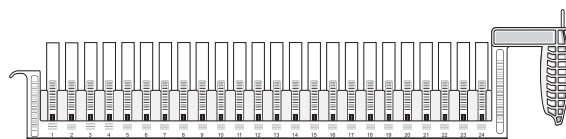
## Module 1—Tecan™ Fluent™ 1080 Automation Workstation

Observation	Possible cause	Recommended action
Tecan™ Fluent™ 1080 Automation Workstation pauses mid-run	Pressure is out of range (Error: "Pressure out of range").	<p>Follow the prompts on the Tecan™ Fluent™ 1080 Automation Workstation touchscreen to select <b>Retry once with New Tip</b>.</p> <p>If the error continues to occur, power-cycle Module 1, assess the function of in-line filters, then recover the run:</p> <ol style="list-style-type: none"> <li>1. Power off the Tecan™ Fluent™ 1080 Automation Workstation (see page 48).</li> <li>2. Power on the Tecan™ Fluent™ 1080 Automation Workstation (see page 42).</li> <li>3. Perform daily system care to check the in-line filters (see page 70). If needed, replace the in-line filter as described in <i>Tecan™ Fluent™ Operating Manual</i> (Pub. No. 399706).</li> <li>4. In the <b>TouchTools</b> screen, select <b>Method Recovery</b>, then click <b>Run Recovery</b> to recover the run.</li> </ol> <p>For assistance, contact Priority Support .</p>

Observation	Possible cause	Recommended action
Tecan™ Fluent™ 1080 Automation Workstation pauses mid-run (continued)	The FCA1 in-line filter test failed (Error: "FCA1 Inline filter test failed for channel(s) X. The affected channels have been deactivated for further use. Please replace inline filters and retry the test to reenable the channels").	Replace the in-line filter as described in <i>Tecan™ Fluent™ Operating Manual</i> (Pub. No. 399706), then rerun the daily system care, which includes the test to re-enable the channels (see page 70).  <b>Note:</b> The replacement filters are in the Tecan™ accessory box.
	FCA tips are not properly ejected.	<ol style="list-style-type: none"> <li>1. Clean the black sleeves and gold disposable tip cones on the Flexible Channel Arm™ with ethanol, then power-cycle Module 1 (see page 48 and page 42).</li> <li>2. Tighten the disposable tip cone where the tips are not properly ejecting.</li> <li>3. If the problem persists, an FCA ejection mechanism calibration may be required. For assistance, contact Priority Support.</li> </ol>
	Persistent liquid level detection error occurs. This error can be caused by a loose tip.	Perform the daily system care, which will prompt you to check the tightness of the disposable tip cone (see page 70). If the problem persists, contact Priority Support.
	The technician fails to remove the bottle cap from the liquid reagents before placing in the reagent carrier on the Tecan™ Fluent™ 1080 Automation Workstation deck, causing impact with and breakage of the disposable tips.	Open door and remove broken tips, then uncap the reagent. Close the door and choose the retry option. Select the <b>Eject mounted tip</b> option.
	The technician misaligns the KingFisher™ Deep-Well 96 Plates with Barcodes, Binding Bead Mix trough, silicone oil trough, or Proteinase K/MS2 Phage Control mixing trough on the Tecan™ Fluent™ 1080 Automation Workstation deck.	Align the reagents properly. Open door and remove broken tips, then uncap the reagent. Close the door and choose the retry option. Select the <b>Eject mounted tip</b> option.



Observation	Possible cause	Recommended action
Tecan™ Fluent™ 1080 Automation Workstation pauses mid-run <i>(continued)</i>	The Tecan™ Fluent™ 1080 Automation Workstation RGA gripper fingers become misaligned, causing the gripper arm to crash.	Perform the daily system care, following the prompts on the Tecan™ Fluent™ 1080 Automation Workstation to realign the fingers, then restart the process. If the Tecan™ Fluent™ 1080 Automation Workstation cannot recover the process, cancel the run. Remove the sample tube runners from the deck, then perform the daily system care. Restart the method. When prompted by the touchscreen, replace the reagents and consumables, then load the sample tube runners.
	The Tecan™ Fluent™ 1080 Automation Workstation gripper head rotation becomes misaligned, causing the gripper fingers to crash.	Power-cycle Module 1 (see page 48 and page 42). If desired, perform method recovery: click <b>Method Starter</b> , then click <b>Start from recovery point</b> . If the issue persists, contact Priority Support.
"Pressure out of range" errors occur during the aspiration or dispensation of the Binding Bead Mix	The Binding Bead Mix was not mixed sufficiently.	<ul style="list-style-type: none"> <li>• Freshly prepare the Binding Bead Mix for each run.</li> <li>• Change the Binding Bead Mix trough between each run.</li> <li>• Mix the beads by inverting the bottle of Binding Bead Mix 10 times prior to pouring the mix into the trough and starting a run.</li> </ul>
Tecan™ Fluent™ 1080 Automation Workstation does not pipette silicone oil into one or more wells	An FCA tip does not pipette silicone oil into one or more wells, with no accompanying error displayed on the Tecan™ Fluent™ 1080 Automation Workstation. All other pipette tips correctly dispense oil into the wells. This can be caused by a loose tip.	<ol style="list-style-type: none"> <li>1. Abort the run.</li> <li>2. Perform daily system care, which will prompt you to check the tightness of the disposable tip cone (see page 70).</li> <li>3. Perform the Module 1 run from the beginning.</li> </ol> If the issue persists, contact Priority Support.
Sample tube barcode read failure	The tube runner was inserted too quickly or not smoothly enough.	Remove the tube runner, wait for the LED indicator light to blink blue, then slowly reinsert the tube runner.
	Sample tube incorrectly positioned in the carrier.	Reposition the sample tube in the runner with tube barcodes facing left and visible in the scanning window. Reload the tube runner on the Tecan™ Fluent™ 1080 Automation Workstation (see "Load the tube runners in the Tecan™ Fluent™ 1080 Automation Workstation" on page 87).



## Module 2—General

Observation	Possible cause	Recommended action
Module 2 encounters and error and pauses mid-run	Spinnaker™ Microplate Robot is not accurately picking up plates from a stack/hotel or instrument nest.	If the problem persists, contact Priority Support to dispatch a Field Service Engineer for reattach.
	<p>Error message: "The Thermo Scientific Mover Spinnaker Mover Task encountered an error. One or more errors have occurred on the mover, the mover is not powered. Error caused by a door opening or an e-stop engaged".</p> <p>The error message includes a list of items to verify, as well as the following actions: <b>Resume the Transfer operation, Take the "Spinnaker" device offline, Abort this iteration of the experiment, and Abort Work.</b></p>	<p>On the Mini-Hub Control Puck, press the <b>RESET</b> button, then press the <b>MTR ON</b> button to reset (the buttons should change to green, see Figure 4). On the Module 2 computer station, in the Momentum™ Software, click <b>Stop</b> in response to the displayed error message.</p> <p>The error message should clear and the Spinnaker™ Microplate Robot should be able to resume. If the error does not clear or the Mini-Hub Control Puck buttons do not change to green, verify that all of the emergency stops around the system are not engaged by turning the E-Stop button on each emergency stop clockwise until it pops back out (see "About Module 2 emergency stop buttons" on page 37). If resetting the Mini-Hub Control Puck does not resolve the issue, restart Momentum™ Software. You may need to force quit the software through Task Manager. If prompted to recover the last known good repository, select <b>Do Not Recover</b>.</p>
	The technician misaligns the wash plates in the carousel, causing the Multidrop™ Combi Reagent Dispenser cassette tips to crash into the wash plate.	Remove the misaligned plate from the Multidrop™ Combi Reagent Dispenser. Wipe up any liquid spilled on the Multidrop™ Combi Reagent Dispenser. Inspect the dispensing cassette for damage, then replace if necessary. Place new wash plate on the Multidrop™ Combi Reagent Dispenser, with barcode facing toward the Spinnaker™ Microplate Robot. Resume the process in the Momentum™ Software.

Observation	Possible cause	Recommended action
<p>Spinnaker™ Microplate Robot stops in front of the centrifuge instead of transferring the real-time RT-PCR plate to the QuantStudio™ 7 Flex Real-Time PCR System</p>	<p>Communication between Momentum™ Software and QuantStudio™ 7 Flex Real-Time PCR System failed; pre-run checklist was not completed or followed incorrectly.</p>	<ol style="list-style-type: none"> <li>1. Open the QuantStudio™ 7 Flex Real-Time PCR System computer desktop (press <b>Ctrl+Ctrl+2</b> for computer 1, or <b>Ctrl+Ctrl+3</b> for computer 2).</li> <li>2. Restart the QuantStudio™ 7 Flex Real-Time PCR System computer. If the computers will not restart, press <b>Ctrl+Alt+Del</b> to start the Task Manager, then end the program.</li> <li>3. Power off the QuantStudio™ 7 Flex Real-Time PCR System: first use the <b>ON/OFF</b> button on the touchscreen, then once the touchscreen is black, turn off using the ON/OFF button located on the back of the instrument.</li> <li>4. While the computer is restarting, power on the QuantStudio™ 7 Flex Real-Time PCR System. If an error message appears on the QuantStudio™ 7 Flex Real-Time PCR System computer desktop and the QuantStudio™ Real-Time PCR Software does not start, restart the computer again and turn off and on the QuantStudio™ 7 Flex Real-Time PCR System.</li> <li>5. Wait for the QuantStudio™ Real-Time PCR Software to start and the server is listening. Ensure that the instrument is <b>Ready</b>.</li> <li>6. Return to Momentum™ Software (<b>Ctrl+Ctrl+1</b>). You will see an error message.</li> <li>7. Select the option that takes the QuantStudio™ 7 Flex Real-Time PCR System offline. You will get another error message.</li> <li>8. Select the option to bring the QuantStudio™ 7 Flex Real-Time PCR System online and restart. The Spinnaker™ Microplate Robot will start to move and bring the plate to QuantStudio™ 7 Flex Real-Time PCR System.</li> </ol>

Observation	Possible cause	Recommended action
The Thermo Fisher™ Multidrop™ Combi Reagent Dispenser "CombiX" Run Protocol operation did not complete	Issue is encountered with Multidrop™ Combi Reagent Dispenser.	On the Multidrop™ Combi Reagent Dispenser, inspect the dispensing cassette for damage, then replace if necessary. Place a new wash plate on the Multidrop™ Combi Reagent Dispenser, with barcode facing toward the Spinnaker™ Microplate Robot. Resume the process in the Momentum™ Software.
Module 2 does not accept reagent check in	Incorrect reagent location barcode scanned <i>or</i> incorrect reagent scanned.	Check correspondence of reagent location and reagent. Some reagents have dual location barcodes. Ensure that the correct location barcode among the dual barcodes is scanned, otherwise the scan will overwrite the inventory for the other bottle without updating the inventory for the intended bottle.  For positive control, dilution buffer, assay, and master mix, ensure that the reagent is EUA-labeled.

## Module 2—KingFisher™ Presto Purification System

Observation	Possible cause	Recommended action
KingFisher™ Presto Purification System encounters Error 34: "Cannot run magnets down"	Typically precedes Error 4: "Head position error" if tip comb was grabbed incorrectly. Also may happen if tip combs were too rigid or if a KingFisher™ Deep-Well 96 Plate with Barcode carrying the tip comb was placed incorrectly into the KingFisher™ Presto Purification System nest.	<ol style="list-style-type: none"> <li>1. In Momentum™ Software, take the KingFisher™ Presto Purification System offline.</li> <li>2. On the KingFisher™ Presto Purification System, press the "down arrow" key, then select <b>Tip Check</b>.</li> <li>3. Verify that the metal pin opens and closes on the sides of the tip comb.</li> <li>4. If the pin is not functioning correctly, contact Priority Support.</li> </ol>
KingFisher™ Presto Purification System encounters "Head position error"	Previous KingFisher™ Deep-Well 96 Plate with Barcode misplacement.	Power cycle the KingFisher™ Presto Purification System. Follow Momentum™ Software prompts to take the KingFisher™ Presto Purification System offline, bring the KingFisher™ Presto Purification System back online, then retry. A few options are available to skip the error, described in "Skip on KingFisher™ Presto Purification System error" on page 197. If the error persists, contact Priority Support.

## Skip on KingFisher™ Presto Purification System error

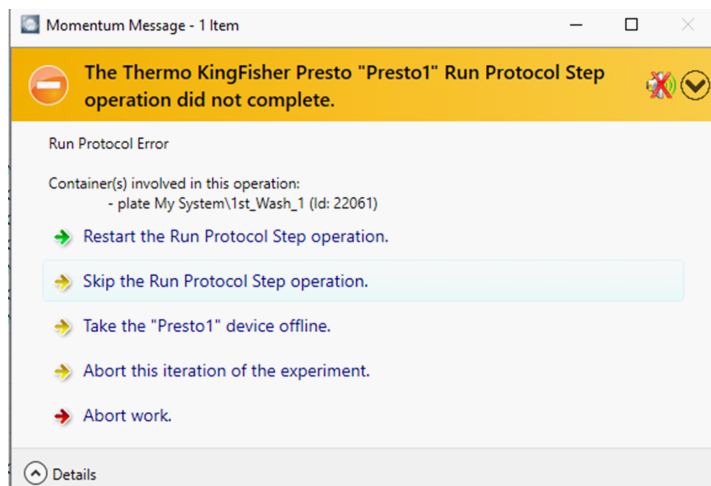
### Error: The Thermo KingFisher Presto "Presto1/2/3/4" Run Protocol Step operation did not complete

You can select one of the following options to skip the error:

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**IMPORTANT!** Do **NOT** select **Abort this iteration of the experiment**.

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Option	Description
<p><b>Restart the Run Protocol Step operation</b></p>	<p>This option can only be used <u>once</u>. If the error occurs again, you must select <b>Skip the Run Protocol Step operation</b> or <b>Abort work</b>.</p> <p><b>IMPORTANT!</b> Repeated protocol step restarts may impact results.</p>
<p><b>Skip the Run Protocol Step operation</b></p>	<p>This option will skip the error and continue the run to completion. The extraction plate that caused the error as well as all downstream operations that are associated with the plate will be skipped.</p>

(continued)

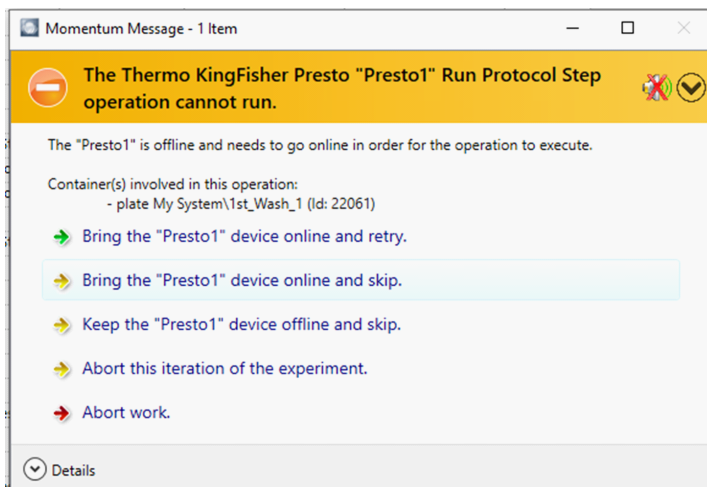
Option	Description
<p><b>Abort work</b></p>	<p>This option will cause the run to be aborted immediately. When the run aborts, take the KingFisher™ Presto Purification System that caused the error offline, power cycle the KingFisher™ Presto Purification System, bring the device online, then restart the run from Module 1 for this set of samples. For more information, see “Reset Module 2 after an aborted run” on page 135.</p> <p><b>IMPORTANT!</b> Ensure that you have sufficient sample volume for a repeat run.</p>
<p><b>Take the "Presto 1/2/3/4" device offline</b></p>	<p>Momentum™ Workflow Scheduler Software takes the device offline. After the device is taken offline, power cycle the KingFisher™ Presto Purification System.</p> <p>Once the KingFisher™ Presto Purification System power cycle is complete, the following prompt will appear: <b>The Thermo KingFisher Presto "Presto1/2/3/4" Run Protocol Step operation cannot run.</b> To continue, use the options listed below.</p>

**Prompt: The Thermo KingFisher Presto "Presto1/2/3/4" Run Protocol Step operation cannot run**

You can select one of the following options to skip the error:

**IMPORTANT!**

- Do **NOT** select **Keep the "Presto1/2/3/4" device offline and skip.**
- Do **NOT** select **Abort this iteration of the experiment.**



Option	Description
Bring the "Presto1/2/3/4" device online and retry	This option will bring the KingFisher™ Presto Purification System online to retry operation. This option can only be used <u>once</u> . If the error occurs again, you must select <b>Bring the "Presto1/2/3/4" device online and skip</b> or <b>Abort work</b> .  <b>IMPORTANT!</b> Repeated protocol step restarts may impact results.
Bring the "Presto1/2/3/4" device online and skip	This option will bring the KingFisher™ Presto Purification System online, then skip the plate and all downstream operations that are associated with the plate.
Abort work	This option will cause the run to be aborted immediately. When the run aborts, take the KingFisher™ Presto Purification System that caused the error offline, power cycle the KingFisher™ Presto Purification System, bring the device online, then restart the run from Module 1 for this set of samples. For more information, see “Reset Module 2 after an aborted run” on page 135.  <b>IMPORTANT!</b> Ensure that you have sufficient sample volume for a repeat run.

## Module 2—Tecan™ Fluent™ 780 Automation Workstation

Observation	Possible cause	Recommended action
Tecan™ Fluent™ 780 Automation Workstation encounters an error: "Failed to initialize"	Tecan™ Fluent™ 780 Automation Workstation was shut down and/or restarted improperly.	Power cycle the Tecan™ Fluent™ 780 Automation Workstation following the correct shutdown/restart order.
		Ensure that the robotic arms are spaced out and the RGA is at least 15 inches away from the side panel before initializing. If Tecan™ Fluent™ 780 Automation Workstation fails to initialize, contact Priority Support.
Tecan™ Fluent™ 780 Automation Workstation encounters an error	FCA tips are not properly ejected.	<ol style="list-style-type: none"> <li>1. Clean the black sleeves and gold disposable tip cones on the Flexible Channel Arm™ with ethanol, then power-cycle Module 2 (see page 49 and page 43).</li> <li>2. Tighten the disposable tip cone where the tips are not properly ejecting.</li> <li>3. If the problem persists, an FCA ejection mechanism calibration may be required. For assistance, contact Priority Support.</li> </ol>

Observation	Possible cause	Recommended action
Tecan™ Fluent™ 780 Automation Workstation encounters an error (continued)	The Tecan™ Fluent™ 780 Automation Workstation RGA gripper fingers become misaligned, causing the gripper arm to crash.	Perform the daily system care, following the prompts on the Tecan™ Fluent™ 1080 Automation Workstation to realign the fingers, then restart the process. If the Tecan™ Fluent™ 1080 Automation Workstation cannot recover the process after performing the daily system care, contact Priority Support.
Tecan™ Fluent™ 780 Automation Workstation encounters RGA "R-axis" errors and/or collision error (even though there was no collision)	Faulty or failing slip ring on the RGA.	Power cycle the Tecan™ Fluent™ 780 Automation Workstation (see page 49 and page 43), then re-initialize. If problems persist, contact Priority Support.
Tecan™ Fluent™ 780 Automation Workstation error: "The Tecan Fluent "Fluent" RunMethod operation did not complete: the run was stopped due to a hardware error"	Tecan™ Fluent™ 780 Automation Workstation encountered a hardware error during a run.	Contact Priority Support.

## Momentum™ Workflow Scheduler Software / SampleManager LIMS™ Software

Observation	Possible cause	Recommended action
Job start error in Module 2 Momentum™ Software	All plate files were not swept to SampleManager LIMS™ Software.	<ol style="list-style-type: none"> <li>1. If all plates are not in SampleManager LIMS™ Software, try restarting the sweeper (from the Windows™ Start menu, navigate to <b>Windows™ Administrative Tools ▶ Services</b>, then right-click <b>SampleManager File Sweeper</b> to restart. If restarting the sweeper fails, proceed to step 2.</li> <li>2. Manually register the plates in SampleManager LIMS™ Software (see "Manually register sample extraction plates" on page 227).</li> <li>3. In Momentum™ Software, navigate to the <b>Inventory</b> tab (<b>Inventory ▶ Inventory</b>). Highlight the plates in <b>Hotel Input</b>, right-click the highlighted plates, then select <b>Manual Unload</b>.</li> <li>4. Proceed with checking the plates back in.</li> </ol>
Module 2 check in error due to mandatory devices offline	One or more instruments required for the run is offline.	Bring the instrument that is mentioned in the error dialog online and retry the check in.



Observation	Possible cause	Recommended action
Module 2 run will not start due to expired sample extraction plates	Sample extraction plates were not transferred from Module 1 to Module 2 within 7 hours of the completion of the Module 1 process.	Re-run the samples on Module 1, confirm that all plates have been swept to SampleManager, then transfer the new sample extraction plates to Module 2 for processing.
Module 2 keyboard is unresponsive	The batteries are discharged.	Replace the batteries. If problem persists, contact Priority Support.
	The USB is unplugged.	Check the USB connection. If problem persists, contact Priority Support.
	KVM connection is lost.	Power cycle the KVM: pull the cord out from the back, wait 15 seconds, then plug the cord back in. Repeat for the mouse.
Module 2 Y-axis error <b>Details:</b> Centrifuge has moved an elution plate from centrifuge "Bucket 1" nest to the centrifuge "Transfer Nest", but the "Transfer operation not complete" error is displayed.	The centrifuge and Momentum™ Software are not communicating correctly.	Select the "Manually Complete the Transfer Operation", then after the run is complete, power cycle the centrifuge and Momentum™ Software computer.

## Module 2—ALPS™ 3000 Automated Microplate Heat Sealer

Observation	Possible cause	Recommended action
ALPS™ 3000 Automated Microplate Heat Sealer encounters "Error 10: No Foil" <b>Details:</b> If there is a "No Foil" error or similar that results in the PCR plate not being sealed, a <b>Retry</b> option in Momentum™ Software is prompted and acceptable within the expiry time frame tracked by the software.	If there is a "No Foil" error or similar that results in the PCR plate not being sealed, a retry in Momentum™ Software is prompted and acceptable within the expiry time frame tracked by the software.	Reload the seal (see "Load sealing film in the ALPS™ 3000 Automated Microplate Heat Sealer" on page 186), then test the alignment of the seal with 3 plates prior to sealing the PCR plate. If prompted, select <b>Retry</b> in Momentum™ Software.
		Check the air pressure gauge. Readings lower than 80–82 psi can also lead to this error. If the air pressure is sufficient and error persists after reloading the seal, contact Priority Support.
Module 2 encounters error and pauses mid-run <b>Details:</b> (ALPS™ 3000 Automated Microplate Heat Sealer error)	Error on the ALPS™ 3000 Automated Microplate Heat Sealer.	Reload the seal (see "Load sealing film in the ALPS™ 3000 Automated Microplate Heat Sealer" on page 186).



## Module 2—QuantStudio™ 7 Flex Real-Time PCR System

Observation	Possible cause	Recommended action
The QuantStudio™ 7 Flex Real-Time PCR System run is not able to initiate	Network or connection error.	Contact Priority Support for assistance.

## Module 2—BioTek™ ELx405™ Select Microplate Washer

Observation	Possible cause	Recommended action
BioTek™ ELx405™ Select Microplate Washer error: "Run file protocol operation did not complete"	The waste switch detects a full bottle.	If waste has not been emptied, empty the waste. If waste has been emptied, check tubing connectors to ensure that they are in the correct positions and firmly attached. Ensure that the overflow carboy is empty and that the float sensor attached to the level switch assembly within the bottle is not stuck in the "raised" position. If the float is stuck, adjust the sensor so that it moves freely. In Momentum™ Software, select <b>Restart the run file protocol operation</b> to continue.

## Module 2—Momentum™ Workflow Scheduler Software connections



Observation	Possible cause	Recommended action
Momentum™ Software cannot connect to KingFisher™ Presto Purification System	KingFisher™ Presto Purification System server window was closed.	When the system is brought online in Momentum™ Software, four server windows appear for the four systems. If one of these four server windows is closed, the KingFisher™ Presto Purification System cannot communicate with Momentum™ Software. Do not close the server windows, only minimize them. If one or more windows are closed, take the KingFisher™ Presto Purification Systems offline, then bring them back online. The server windows will appear.




Observation	Possible cause	Recommended action
Momentum™ Software cannot connect to BioTek™ ELx405™ Select Microplate Washer	BioTek™ ELx405™ Select Microplate Washer server window was closed.	When the system is brought online in Momentum™ Software, a server window for BioTek™ ELx405™ Select Microplate Washer appears. If this window is closed, the BioTek™ ELx405™ Select Microplate Washer cannot communicate with Momentum™ Software. Do not close the server window, only minimize it. If the window is closed, take the BioTek™ ELx405™ Select Microplate Washer offline, then bring it back online. The server window will appear. If communication with Momentum™ Software is not established, check the physical connection cables.
Momentum™ Software cannot connect to Agilent™ Microplate Centrifuge	Agilent™ Microplate Centrifuge server window was closed.	When the system is brought online in Momentum™ Software, a server window for Agilent™ Microplate Centrifuge appears. If this window is closed, the Agilent™ Microplate Centrifuge cannot communicate with Momentum™ Software. Do not close the server window, only minimize it. If the window is closed, take the Agilent™ Microplate Centrifuge offline, then bring it back online. The server window will appear.

Observation	Possible cause	Recommended action
Momentum™ Software cannot connect to or bring QuantStudio™ 7 Flex Real-Time PCR System online	QuantStudio™ 7 Flex Real-Time PCR System server window and/or QuantStudio™ Real-Time PCR Software was closed.	<p>On the QuantStudio™ 7 Flex Real-Time PCR System computer, ensure that the QuantStudio™ Real-Time PCR Software is open and that the instrument is connected. Make sure to open the automation server. Repeat for both QuantStudio™ 7 Flex Real-Time PCR System instruments. Be sure to only minimize the server window, DO NOT CLOSE. If either the server window or the QuantStudio™ Real-Time PCR Software is not open, open, then bring the QuantStudio™ 7 Flex Real-Time PCR System online.</p>
		<p>If all drives are connected and both the server and QuantStudio™ Real-Time PCR Software are open, yet the QuantStudio™ 7 Flex Real-Time PCR System is not online in Momentum™ Software, perform the following procedure to power cycle the QuantStudio™ 7 Flex Real-Time PCR System:</p> <ol style="list-style-type: none"> <li>1. On the QuantStudio™ 7 Flex Real-Time PCR System computer for the impacted instrument, close the server window, then close the QuantStudio™ Real-Time PCR Software.</li> <li>2. Power off the QuantStudio™ 7 Flex Real-Time PCR System using the touchscreen.</li> <li>3. Press the switch on the back panel of the QuantStudio™ 7 Flex Real-Time PCR System to power on.</li> <li>4. Open the QuantStudio™ Real-Time PCR Software.</li> <li>5. On the instrument console, check to make sure the QuantStudio™ 7 Flex Real-Time PCR System is connected in the QuantStudio™ Real-Time PCR Software.</li> <li>6. Bring the QuantStudio™ 7 Flex Real-Time PCR System back online in Momentum™ Software.</li> </ol> <p>If the problem persists, power-cycle the QuantStudio™ 7 Flex Real-Time PCR System computer and the QuantStudio™ 7 Flex Real-Time PCR System as described above, then power cycle the Momentum™ Software computer before you bring the QuantStudio™ 7 Flex Real-Time PCR System back online in Momentum™ Software.</p>

Observation	Possible cause	Recommended action
Momentum™ Software cannot connect to or bring Tecan™ Fluent™ Automation Workstation online	Tecan™ Fluent™ Automation Workstation server window and/or Tecan™ FluentControl™ Software was closed.	On the Tecan™ Fluent™ Automation Workstation computer, ensure the Tecan™ FluentControl™ Software is open and connected to the instrument. Verify that the automation server is launched. Be sure to only minimize the server window, DO NOT CLOSE. If either the server window or the Tecan™ FluentControl™ Software is not open, open, then bring the Tecan™ Fluent™ Automation Workstation online. If this action does not resolve the problem, power cycle the Tecan™ Fluent™ Automation Workstation, the Tecan™ Fluent™ Automation Workstation computer, and the Momentum™ Software computer.

## Troubleshooting—Other

Observation	Possible cause	Recommended action
False negative result	The technician tampers with the results in the CSV file.	 <b>WARNING!</b> Do not alter the results in the CSV file.
	The technician runs a plate that was partially spilled.	Do not run plates that have partially spilled. If a partial spill occurs, discard the plate, then clean the spill according to the established procedures for your laboratory. Rerun the samples using the remaining sample in the tube.
	The technician loads insufficient volume of MagMAX™ HT Proteinase K.	Only load a full bottle of MagMAX™ HT Proteinase K in the Module 1 reagent carrier.   <b>CAUTION!</b> Only scan, then load reagents that are at full volume. If a reagent is not at full volume when it is loaded in the system then the reagent may run out mid-run, resulting in lower throughput, inaccurate results, or loss of sample.
	The Combi 1 (Elution) Multidrop™ Combi Reagent Dispenser dispensing cassette tubing is kinked.	Replace the Multidrop™ Combi dispensing cassette, prime the Multidrop™ Combi Reagent Dispenser, then rerun the samples starting in Module 1.
	Technician fails to prime the Combi 1 (Elution) Multidrop™ Combi Reagent Dispenser.	Prime the Multidrop™ Combi Reagent Dispensers, then rerun the samples starting in Module 1.

Observation	Possible cause	Recommended action
False negative result (continued)	The technician did not replace the Combi 1 (Elution) Multidrop™ Combi Reagent Dispenser dispensing cassette on schedule.	Replace the dispensing cassette, then rerun the samples starting in Module 1.   <b>WARNING!</b> Do not touch the cassette dispensing tips. Touching dispensing tips can result in false negative results.
	The technician touched the tips of the Combi 1 (Elution) Multidrop™ Combi Reagent Dispenser dispensing cassette.	Clean the dispensing cassette tips (see “Clean the Multidrop™ Combi Reagent Dispenser cassette tips” on page 175). Replace the dispensing cassette if needed, then rerun the samples starting in Module 1.   <b>WARNING!</b> Do not touch the cassette dispensing tips. Touching dispensing tips can result in false negative results.
	Interruption during processing in Momentum™ Workflow Scheduler Software may result in beads left in the air for too long during user error handling or user interaction. If subsequent processing is resumed with dry beads, result sensitivity may be impacted, potentially leading to false negative results.	Abort runs where processing is paused while beads are suspended in the air. Rerun the samples starting from Module 1.
False positive test result	The technician tampers with the results in the CSV file.	 <b>WARNING!</b> Do not alter the results in the CSV file.
	The technician runs a plate that was partially spilled.	Do not run plates that have partially spilled. If a partial spill occurs, discard the plate, then clean the spill according to the established procedures for your laboratory. Re-run the samples using the remaining sample in the tube.
In-line filter check fails	Filter needs to be replaced	Replace the in-line filter as described in <i>Tecan™ Fluent™ Operating Manual</i> (Pub. No. 399706), or contact Priority Support for further assistance.
Results do not show up in SampleManager LIMS™ Software	Network or input error.	Contact Priority Support for assistance.

Observation	Possible cause	Recommended action
Sample barcode missing from results	Insufficient volume of sample was aspirated in Module 1.	Review sample error messages in the SampleManager LIMS™ Software (see “Review jobs in SampleManager LIMS™ Software for sample preparation error messages” on page 148). Inspect the original sample tubes to ensure sufficient sample volume is available and the sample is not unusually viscous. Rerun the sample on Module 1 or obtain new sample if sufficient volume is not available or the sample is too viscous.
KingFisher™ Deep-Well 96 Plate with Barcode: barcode is unreadable	Barcode is positioned incorrectly or is not able to be scanned.	Ensure the barcode is positioned facing the scanner (to the right). If the barcode is unreadable when positioned correctly, replace with a new KingFisher™ Deep-Well 96 Plate with Barcode, then press <b>Continue</b> . If the whole box of KingFisher™ Deep-Well 96 Plates with Barcodes does not scan, report the lot number to technical support.
All of the samples in a run are invalid	Technician swapped the Binding Bead Mix and silicone oil on the Module 1 Tecan™ Fluent™ 1080 Automation Workstation deck.	Discard the contaminated troughs, then replace with new troughs (see “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82). Refill the Binding Bead Mix and silicone oil in the correct positions, then rerun the invalid samples starting in Module 1.
	Technician improperly formulated the Binding Bead Mix.	Discard the contaminated Binding Bead Mix trough, then replace with a new trough (see “Load the Tecan™ Fluent™ 1080 Automation Workstation deck” on page 82). Re-prepare the Binding Bead Mix (see “Prepare the Binding Bead Mix” on page 73), then rerun the invalid samples starting in Module 1.
	MS2 Phage control error not detected on Module 1.	Rerun the batch of sample tubes.
	Technician loaded insufficient quantity of TaqPath™ COVID-19 Control in the Module 2 Tecan™ Fluent™ 780 Automation Workstation.	Discard all reagents on the Tecan™ Fluent™ 780 Automation Workstation deck. Replenish the reagents in the Momentum™ Workflow Scheduler Software, then physically reload the reagents on the deck (see “Reload Module 2 reagents” on page 119). Execute the <b>Refresh run count</b> process (see “Refresh run count” on page 105). Rerun the invalid samples starting in Module 1.

Observation	Possible cause	Recommended action
All of the samples in a run are invalid <i>(continued)</i>	Technician replenished the quantity of the TaqPath™ COVID-19 Control in the Momentum™ Workflow Scheduler Software but did not physically load reagent on the Module 2 Tecan™ Fluent™ 780 Automation Workstation deck.	Add the TaqPath™ COVID-19 Control tube to the Module 2 Tecan™ Fluent™ 780 Automation Workstation deck, then rerun the invalid samples starting in Module 1.
	Technician swapped the dispensing cassette tubing for the Combi 2 (Wash 1) and Combi 3 (Wash 2) carboys.	Swap out the contaminated carboys and fill the clean carboys with fresh reagent. Replace the dispensing cassette, prime the Multidrop™ Combi Reagent Dispensers, then rerun the invalid samples starting in Module 1.
	Technician did not place tubing bundle weight in the bottom of the Multidrop™ Combi Reagent Dispenser carboys.	Place tubing bundle weight correctly in bottom of carboy, prime Multidrop™ Combi Reagent Dispenser, then rerun the invalid samples starting in Module 1.
	The dispensing cassette tubing of a Multidrop™ Combi Reagent Dispenser is kinked.	Replace the Multidrop™ Combi dispensing cassette, prime the Multidrop™ Combi Reagent Dispenser, then rerun the invalid samples starting in Module 1.
	Technician failed to perform scheduled preventive maintenance on the Multidrop™ Combi Reagent Dispensers.	Perform preventive maintenance including primes as specified (see “Multidrop™ Combi Reagent Dispenser regular maintenance” on page 157), then rerun the invalid samples starting in Module 1.
	Technician swapped the reagents between Combi 2 (Wash 1) and Combi 3 (Wash 2) carboys.	Swap out the contaminated carboys and fill the clean carboys with fresh reagent. Replace the dispensing cassette, prime the Multidrop™ Combi Reagent Dispensers, then rerun the invalid samples starting in Module 1.
	Module 2 ran out of MagMAX™ HT Wash Solution (Wash 1), 80% Ethanol (Wash 2), or MagMAX™ HT Elution Solution unexpectedly due to more than the expected number or length of primes.	Check the MagMAX™ HT Wash Solution (Wash 1), 80% Ethanol (Wash 2), and MagMAX™ HT Elution Solution liquid levels. Refill if necessary, then rerun the invalid samples starting in Module 1. Ensure that you prime the Multidrop™ Combi Reagent Dispensers at the times and for the durations indicated in this guide.
More than a few samples in a run are invalid	The system ran out of reagents or consumables mid-run.	Reload all of the samples and reagents for the system, then execute the <b>Refresh run count</b> process (see “Refresh run count” on page 105). Rerun the invalid samples as part of a full 376-sample batch.
	Technician failed to prime the Multidrop™ Combi Reagent Dispensers.	Prime the Multidrop™ Combi Reagent Dispensers, then rerun the invalid samples starting in Module 1.



Observation	Possible cause	Recommended action
More than a few samples in a run are invalid <i>(continued)</i>	Technician replenished the Multidrop™ Combi Reagent Dispenser reagents in the Momentum™ Workflow Scheduler Software but did not physically reload the Multidrop™ Combi Reagent Dispenser carboys.	Check the Multidrop™ Combi Reagent Dispenser reagent levels, then refill if necessary, ensuring to prime for the indicated times. Rerun the invalid samples starting in Module 1.
	Technician touched the Multidrop™ Combi Reagent Dispensers dispensing cassette tips.	Clean the Multidrop™ Combi Reagent Dispenser dispensing cassette tips (see “Clean the Multidrop™ Combi Reagent Dispenser cassette tips” on page 175). Replace the dispensing cassette if needed, then rerun the invalid samples starting in Module 1.
	Technician did not perform the Module 1 Tecan™ Fluent™ 1080 Automation Workstation system care when prompted. Contamination accumulates around the pipette heads, causing incorrect fluid volumes.	Perform the Tecan™ Fluent™ 1080 Automation Workstation system care, paying special attention to the cleanliness of the pipette heads. Rerun the invalid samples as part of a full 376-sample batch.



# Additional instructions for labs

- Authorized laboratories using the TaqPath™ COVID-19 High-Throughput Combo Kit will include with result reports of the TaqPath™ COVID-19 High-Throughput Combo Kit all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the TaqPath™ COVID-19 High-Throughput Combo Kit will use the kit as outlined in the *Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit Instructions for Use*. Deviations from the procedures, including the instruments, extraction methods, clinical specimen types, control materials, other ancillary reagents, and materials required to perform the TaqPath™ COVID-19 High-Throughput Combo Kit are not permitted.
- Authorized laboratories that receive the TaqPath™ COVID-19 High-Throughput Combo Kit must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Authorized laboratories using the TaqPath™ COVID-19 High-Throughput Combo Kit will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the test and report to Thermo Fisher Scientific ([techservices@thermofisher.com](mailto:techservices@thermofisher.com); 1 800 955 6288) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.
- All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit and use the test in accordance with the labeling.
- Thermo Fisher Scientific, its authorized distributor(s), and authorized laboratories using the TaqPath™ COVID-19 High-Throughput Combo Kit will ensure that any records associated with this test are maintained until otherwise notified by Health Canada. Such records will be made available to Health Canada for inspection upon request.



# Performance characteristics for Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit

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Analytical performance of the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit was evaluated as described in the following sections.

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**Note:** The Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit uses the same reagents and multiplex assay as the previously-qualified TaqPath™ COVID-19 RT-PCR Kit. For information about the performance characteristics of the TaqPath™ COVID-19 RT-PCR Kit, see *TaqPath™ COVID-19 Combo Kit Instructions for Use* (Pub. No. MAN0019211).

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## Limit of detection bridging study

A limit of detection (LoD) bridging study was performed with the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit and the previously qualified TaqPath™ COVID-19 Combo Kit on the QuantStudio™ 7 Flex Real-Time PCR System (384-well).

Banked, pooled COVID-19 negative nasopharyngeal swab samples were spiked with gamma-irradiated SARS-Related Coronavirus 2 at several concentrations, then processed through the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit workflow.



The LoD bridging study established that the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit achieved the same LoD and similar performance as the previously qualified TaqPath™ COVID-19 Combo Kit on the QuantStudio™ 7 Flex Real-Time PCR System (384-well).

**Table 28** Limit of detection bridging study results

Sample concentration	Replicate <sup>[1]</sup>	C <sub>t</sub> <sup>[2]</sup>				Interpretation	% Positive <sup>[1]</sup>
		ORF1ab	N	S	MS2		
9X LoD (2,250 GCE/mL)	1	27.646	28.294	28.635	26.058	Positive	100%
	2	27.736	28.160	28.507	25.815	Positive	
	3	27.621	28.093	28.410	25.564	Positive	
3X LoD (750 GCE/mL)	1	28.881	29.411	30.540	25.600	Positive	100%
	2	29.157	30.183	30.387	26.062	Positive	
	3	29.147	29.721	30.382	25.911	Positive	
1X LoD (250 GCE/mL)	1	31.567	31.812	32.947	26.282	Positive	100%
	2	31.381	31.805	33.418	25.839	Positive	
	3	30.999	31.344	32.108	25.640	Positive	
0.33X LoD (83.3 GCE/mL)	1	Undet.	32.504	35.345	25.494	Positive	66%
	2	29.772	33.006	36.283	25.423	Positive	
	3	Undet.	34.876	Undet.	25.481	Inconclusive <sup>[3]</sup>	
0.11X LoD (27.8 GCE/mL)	1	Undet.	Undet.	Undet.	25.716	Negative	0%
	2	Undet.	37.245	Undet.	25.893	Negative	
	3	Undet.	Undet.	Undet.	26.210	Negative	
0X LoD (0 GCE/mL)	1	Undet.	Undet.	Undet.	23.797	Negative	0%
	2	Undet.	Undet.	Undet.	25.677	Negative	
	3	Undet.	Undet.	Undet.	25.619	Negative	
Positive Control	N/A	28.084	28.830	29.213	Undet.	Valid	N/A
Negative Control	N/A	Undet.	Undet.	Undet.	27.496	Valid	N/A
	N/A	Undet.	Undet.	Undet.	27.758	Valid	N/A
	N/A	Undet.	Undet.	Undet.	27.549	Valid	N/A
	N/A	Undet.	Undet.	Undet.	28.386	Valid	N/A

<sup>[1]</sup> NA—Not Applicable.

<sup>[2]</sup> Undet.—Undetermined. No amplification was detected.

<sup>[3]</sup> Inconclusive tests were not repeated. All positive results occurred on the first test.



## Limit of detection confirmation study – swab specimens

The Limit of Detection (LoD) of 250 GCE/mL was confirmed using contrived specimens comprising of inactivated SARS-CoV-2 virus spiked at 1X LoD and 3X LoD into pooled clinical nasopharyngeal specimens negative for SARS-CoV-2. Sample extraction, detection, and analysis was performed with both the TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 High-Throughput Combo Kit workflows to verify that the LoD is maintained across systems at 250 GCE/mL ( $\leq 10$  GCE/reaction) using the same spike-in material, inactivated SARS-CoV-2 virus. At both concentrations tested, 1X and 3X LoD, 20 replicates were performed with each workflow; additional replicates were performed at 0X LoD to confirm the negative status of the nasopharyngeal clinical specimens. All controls were reported as valid. The results demonstrated equivalent detection at 1X and 3X LoD, detecting 20 out of 20 replicates across both workflows at both tested concentrations.

## Limit of detection confirmation study – preserved saliva specimens

For this study, the LoD was determined via a probit analysis of a target dilution series using contrived specimens spiked with inactivated SARS-CoV-2 virus at 12 different input concentrations (0, 12.5, 25, 50, 75, 100, 125, 187.5, 250, 500, 1,000, and 1,500 GCE/mL final concentration in the Spectrum Solutions™ SDNA-2000 Saliva Collection Device) using raw pooled clinical saliva specimens, which were confirmed negative for SARS-CoV-2. Sample extraction, detection, and analysis were performed using the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit workflow. The 95% call rate was extrapolated using the probit analysis approach per CLSI EP17-A2. Two lots of kit reagents and 2 lots of inactivated virus were used. The RT-qPCR reactions were performed on 2 different QuantStudio™ 7 Flex Real-Time PCR Systems and the study was performed over 2 consecutive days. In addition, a second site (Thermo Fisher Scientific, South San Francisco) performed additional runs to provide data from a second site and a second Amplitude™ Solution system. Probit fitting established the LoD for SARS-CoV-2 target in saliva samples stabilized in Spectrum Solutions™ SDNA-2000 Saliva Collection Devices to be 172 GCE/mL, 95% CI [140, 212].



## Cross-contamination study

A cross-contamination study was performed with a surrogate assay to assess the potential for well-to-well cross contamination when using the Amplitude™ Solution workflow. Alternating positive ( $10^6 \times \text{LoD}$ ) and negative samples were set up across the extraction plates and then processed through the full assay workflow to evaluate cross contamination.

Results from the combined data points of four runs show that 100% of contrived positive sample replicates (752/752) produced a positive result and 99.7% of contrived negative sample replicates (562/564) produced a negative result.

Table 29 Cross-contamination study results

Run	Sample	Number of Replicates	Number of Replicates with Expected Results	Average $C_t$	Standard Deviation $C_t$	% Passed
1	Positive	188	188	18.717	0.411	100%
	Negative	188	187	35.5	N/A <sup>[1]</sup>	99.5%
2	Positive	188	188	18.976	0.329	100%
	Negative	188	188	N/A <sup>[1]</sup>	N/A <sup>[1]</sup>	100%
3	Positive	188	188	18.637	0.393	100%
	Negative	188	188	N/A <sup>[1]</sup>	N/A <sup>[1]</sup>	100%
4	Positive	188	188	18.239	0.442	100%
	Negative	188	187	35.8	N/A <sup>[1]</sup>	99.5%

<sup>[1]</sup> Not Applicable

## Reactivity (Inclusivity)

*In silico* analysis was executed using 1,116,456 complete SARS-CoV-2 genomes in the GISAID database as of 07 May 2021. 1,116,456 strains were evaluated based on melting temperature analysis. A positive is called when at least two assays show a melting temperature higher than the annealing temperature. A positive was called for 1,098,871 SARS-CoV-2 strains out of 1,116,456 (98.4%). Evaluation of assay components that do not match 100% to target sequences indicated that most of the primer or probe mismatches are unlikely to impact assay function, thus the TaqPath™ COVID-19 High-Throughput Combo Kit is expected to be highly inclusive for SARS-CoV-2 strain detection.



## Cross-reactivity

*In silico* analysis of the following forty-nine (49) organisms was performed.

**Table 30** Organisms used for *in silico* cross-reactivity analysis

Human coronavirus 229E	Rhinovirus/Enterovirus
Human coronavirus OC43	Parechovirus
Human coronavirus HKU1	<i>Candida albicans</i>
Human coronavirus NL63	<i>Corynebacterium diphtheriae</i>
SARS-coronavirus	<i>Legionella</i> (non-pneumophila)
MERS-coronavirus	<i>Bacillus anthracis</i> (Anthrax)
Adenovirus	<i>Moraxella catarrhalis</i>
Human Metapneumovirus (hMPV)	<i>Neisseria elongata</i> and <i>Neisseria meningitidis</i>
Parainfluenza 1	<i>Pseudomonas aeruginosa</i>
Parainfluenza 2	<i>Staphylococcus epidermidis</i>
Parainfluenza 3	<i>Streptococcus salivarius</i>
Parainfluenza 4	<i>Leptospira</i> sp.
Influenza A	<i>Chlamydophila pneumoniae</i>
Influenza B	<i>Chlamydophila psittaci</i>
Influenza C	<i>Coxiella burnetii</i> (Q-Fever)
Enterovirus	<i>Staphylococcus aureus</i>
Respiratory Syncytial Virus A	<i>Haemophilus influenzae</i>
Respiratory Syncytial Virus B	<i>Legionella pneumophila</i>
<i>Bordetella pertussis</i>	<i>Mycobacterium tuberculosis</i>
<i>Mycoplasma pneumoniae</i>	<i>Streptococcus pneumoniae</i>
<i>Pneumocystis jirovecii</i> (PJP)	<i>Streptococcus pyogenes</i>
<i>Porphyromonas gingivalis</i>	<i>Streptococcus mutans</i>
<i>Bacteroides oralis</i>	<i>Eikenella</i> sp.
<i>Nocardia</i> sp	Adenovirus (e.g. C1 Ad. 71)

Among the tested organisms, *Neisseria elongata* showed homology for the forward and reverse primers and probe for the N gene. The forward primer showed ≥80% homology while the reverse primer and probe showed 36% homology. The N gene reverse primer and probe show low homology, therefore the likelihood of non-specific amplification is low.



Blast analysis showed  $\geq 80\%$  homology for one assay component (forward primer, reverse primer, or probe) for select isolates. Despite  $\geq 80\%$  homology of one assay component for select isolates, there is no anticipated amplification because hybridization of all three assay components are necessary to generate a signal. We also found multiple instances where different assay components had  $\geq 80\%$  homology to different isolates of the same species. For example, *Bacillus anthracis* strain AFS029987 had  $\geq 80\%$  homology to the ORF1ab forward primer while strain MCCC 1A01412 had  $\geq 80\%$  homology to the ORF1ab reverse primer. Since these are two different organisms, amplification is not likely to occur. The *in silico* analysis indicates that significant amplification of non-target sequences that result in cross-reactivity or potentially interfere with detection of SARS-CoV-2 is not likely to occur.

## Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit comparator studies

The performance of the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit (Amplitude™ Solution) was compared against three previously-qualified tests: TaqPath™ COVID-19 Combo Kit, Roche cobas® SARS-CoV-2 Test, and Quidel® Lyra™ SARS-CoV-2 Assay.

The Amplitude™ Solution is intended to be an automated, high-throughput version of the TaqPath™ COVID-19 Combo Kit manual workflow, and both workflows have the same LoD (see “Limit of detection bridging study” on page 211). When comparing the workflows, the Percent Positive Agreement (PPA) and Negative Percent Agreement (NPA) both exceeded the 95% threshold, as expected when comparing tests with the same sensitivity.

The Roche cobas® SARS-CoV-2 Test Instructions for Use (IFU) reports a higher sensitivity compared to the Amplitude™ Solution and TaqPath™ COVID-19 Combo Kit. When comparing the Roche cobas® SARS-CoV-2 Test to the Amplitude™ Solution, the PPA was 85.3%, while the NPA exceeded 95%. The PPA was below the 95% threshold due to low-positives being called "Negative" by the Amplitude™ Solution, but this variation was as expected due to the different sensitivities of the tests.

The Quidel® Lyra™ SARS-CoV-2 Assay IFU reports a lower sensitivity compared to the Amplitude™ Solution and TaqPath™ COVID-19 Combo Kit. When comparing the Quidel® Lyra™ SARS-CoV-2 Assay to the Amplitude™ Solution, the PPA exceeded 95%, while the NPA was 84.9%. The NPA was below the 95% threshold due to low-positives being called "Positive" by the Amplitude™ Solution and "Negative" by the Quidel® Lyra™ SARS-CoV-2 Assay, but this variation was also expected due to the different sensitivities of the tests.

### Comparator study with the Roche cobas® SARS-CoV-2 Test and the TaqPath™ COVID-19 Combo Kit

The performance of the Amplitude™ Solution was compared to the previously qualified TaqPath™ COVID-19 Combo Kit and the third-party Roche cobas® SARS-CoV-2 Test.

A total of 200 mixed positive and negative SARS-CoV-2 specimens, consisting of 10 anterior nasal swabs and 190 nasopharyngeal swabs, were evaluated using the three different tests and their associated workflows.





When comparing the Amplitude™ Solution with the TaqPath™ COVID-19 Combo Kit, the PPA and NPA were both 100.00%. "Inconclusive" calls by the Amplitude™ Solution and the TaqPath™ COVID-19 Combo Kit were excluded from analysis.

**Table 31 Concordance results: Amplitude™ Solution vs. TaqPath™ COVID-19 Combo Kit**

Call	Number of samples	Concordance results <sup>[1]</sup>
True Positive	42	PPA: 100.00%
False Negative	0	
True Negative	151	NPA: 100.0%
False Positive	0	

<sup>[1]</sup> "Inconclusive" calls by the Amplitude™ Solution (n=4) and the TaqPath™ COVID-19 Combo Kit (n=3) were excluded from analysis. One sample was called "Inconclusive" by both tests.

When comparing the Amplitude™ Solution to the Roche cobas® SARS-CoV-2 Test, the PPA was 85.3% and the NPA was 99.2%. For the Roche cobas® SARS-CoV-2 Test, only "Result for SARS-CoV-2RNA is Detected" and "SARS-CoV-2 RNA is Not Detected" calls were included in the analysis; "Invalid" and "Presumptive Positive" calls were excluded from analysis. "Inconclusive" calls from the Amplitude™ Solution were also excluded from analysis.

**Table 32 Concordance results: Amplitude™ Solution vs. Roche cobas® SARS-CoV-2 Test**

Call	Number of samples	Concordance results <sup>[1]</sup>
True Positive	29	PPA: 85.3%
False Negative	5	
True Negative	118	NPA: 99.2%
False Positive	1	

<sup>[1]</sup> "Presumptive Positive" calls (n=10) and "Invalid" calls (n=33) by the Roche cobas® SARS-CoV-2 Test were excluded from analysis, as were "Inconclusive" calls (n=4) by the Amplitude™ Solution. One excluded sample was called both "Inconclusive" and "Presumptive Positive".

### Comparator study with the Quidel® Lyra™ SARS-CoV-2 Assay and the TaqPath™ COVID-19 Combo Kit

The performance of the Amplitude™ Solution was compared to the previously qualified TaqPath™ COVID-19 Combo Kit and the third-party Quidel® Lyra™ SARS-CoV-2 Assay.

A total of 85 mixed positive and negative SARS-CoV-2 specimens, consisting of 10 anterior nasal swabs and 75 nasopharyngeal swabs, were evaluated using the three different tests and their associated workflows.



When comparing the Amplitude™ Solution to the TaqPath™ COVID-19 Combo Kit, the Positive Percent Agreement (PPA) was 100.0% and the Negative Percent Agreement (NPA) was 96.0%. "Inconclusive" calls by the Amplitude™ Solution were excluded from analysis.

**Table 33 Concordance results: Amplitude™ Solution vs. TaqPath™ COVID-19 Combo Kit**

Call	Number of samples	Concordance results <sup>[1]</sup>
True Positive	31	PPA: 100.00%
False Negative	0	
True Negative	48	NPA: 96.0%
False Positive	2	

<sup>[1]</sup> "Inconclusive" calls by the Amplitude™ Solution (n=4) were excluded from analysis.

When comparing the Amplitude™ Solution to the Quidel® Lyra™ SARS-CoV-2 Assay, the PPA was 95.8% and the NPA was 84.9% with "Inconclusive" calls by the Amplitude™ Solution excluded from analysis. There were 8 samples that the Amplitude™ Solution called "Positive" but the Quidel® Lyra™ SARS-CoV-2 Assay called "Negative", impacting the NPA. Of the 8 samples, 7 were also called "Positive" by the TaqPath™ COVID-19 Combo Kit, indicating that these samples were likely "True Positives" that were below the LoD of the Quidel® Lyra™ SARS-CoV-2 Assay.

**Table 34 Concordance results: Amplitude™ Solution vs. Quidel® Lyra™ SARS-CoV-2 Assay**

Call	Number of samples	Concordance results <sup>[1]</sup>
True Positive	23	PPA: 95.8%
False Negative	1	
True Negative	45	NPA: 84.9%
False Positive	8	

<sup>[1]</sup> Inconclusive calls by the Amplitude™ Solution (n=4) were excluded from analysis.

## Clinical evaluation with saliva specimens

The clinical performance of the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit was evaluated by testing a total of 300 saliva samples collected under the supervision of a healthcare provider using the Spectrum Solutions™ SDNA-2000 Saliva Collection Device. Saliva specimens were collected from symptomatic and suspected of COVID-19 patients who consented to enroll in the study from August 18, 2020 to November 1, 2020. A corresponding nasopharyngeal (NP) swab was collected within 10 minutes of saliva collection by a healthcare provider. The NP swab was collected in either viral transport medium or 0.9% saline and transported with the saliva samples collected in the Spectrum Solutions™ SDNA-2000 Saliva Collection Device to the laboratory under ambient conditions. The NP swab was tested using a highly sensitive FDA authorized molecular assay.

Results for the paired NP swabs were used as the comparator method for calculating positive and negative percent agreement (PPA and NPA).



Of the 300 saliva specimens tested using the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit, 11 (3.7%) had invalid results. These residual clinical specimens had insufficient volume for additional repeat testing as instructed in the standard operating procedure and were excluded from the analysis. The remaining 289 specimens were used for comparative analysis as denoted in Table 35.

**Table 35 Clinical evaluation results**

Amplitude™ Solution result	NP swab FDA authorized assay result		
	Positive	Negative	Total
Positive	136	7	142
Negative	2	144	146
Total	138 <sup>[1]</sup>	151	289
Positive Percent Agreement	98.6% (95% CI, 94.9%–99.6%)		—
Negative Percent Agreement	95.4% (95% CI, 90.7%–98.1%)		

<sup>[1]</sup> An inconclusive result for the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit occurs when only one of three SARS-CoV-2 targets tests as positive. Two comparator positive samples and one negative sample tested as inconclusive using the Amplitude™ Solution with the TaqPath™ COVID-19 High-Throughput Combo Kit. Inconclusive results were considered discrepant results between the candidate and comparator assays. There was insufficient residual volume for additional testing.



# Tecan™ Fluent™ Automation Workstations

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## About the Tecan™ FluentControl™ Software

For information about the Tecan™ FluentControl™ Software:

- See the software product manuals—Navigate to the **Docs** folder in the Tecan™ FluentControl™ Software installation folder.
- Open the Help—With the Tecan™ FluentControl™ Software running on the Module 1 computer, do one of the following:
  - Press the **F1** key.
  - From the main menu bar, select **Help ▶ Open**.

## Tecan™ Fluent™ 1080 Automation Workstation barcode scanner LED indicators

The Module 1 Tecan™ Fluent™ 1080 Automation Workstation includes three Tecan™ FluentID™ Tube Barcode Scanners, each with dedicated deck grid positions for tube runners.

**Table 36** Tube runner deck grid positions

Tube runner size	Tube runner deck grid positions	
	Tube runners with controls	All tube runners
13 mm, 32-position control tube runner (12–14 mm tubes)	1, 4, 13, and 16	1–6 and 13–18
16 mm, 26-position control tube runner (15–17 mm tubes)	1, 5, 15, and 25	1–6, 13–18 and 25–28
17 mm, 24-position control tube runner (16–18 mm tubes)		

Each tube runner grid positions includes an LED light that indicates the barcode scanner status.

Color	Description
White	The barcode scanner is on, but not yet initialized.
Blue flashing	The instrument is ready for tube runner loading or unloading.
Green	All of the tube barcodes for the tube runner were successfully scanned. Do not remove the tube runner.
Red flashing	There is an error with the tube runner. See the error message and required action displayed on the instrument touchscreen.
No light	The barcode scanner is idle or off.

## Tecan™ Fluent™ Automation Workstation instrument status lamps

The Tecan™ Fluent™ Automation Workstation instrument status lamps indicate the status of the instrument using different colors, and steady or flashing lights. The top status lamp (software status lamp) is only active when the software is running.

Color	Mode	Instrument status
—	Off	The instrument is powered off.
White	"Heartbeat"	The instrument is powered on and the Tecan™ FluentControl™ Software is connected. No module is initiated.
White (power lamp only)	Continuous	The instrument is powered on but the Tecan™ FluentControl™ Software is not connected.
Blue (color scheme of instrument touchscreen)	"Heartbeat"	<b>Idle mode</b> —All modules are initialized and the instrument is ready to run a method. If idle for >1 hour the instrument will switch to standby mode. <b>Standby mode</b> —All axes are braked, and the arms cannot be moved manually. To activate the instrument, run a method.
Yellow	Continuous	<b>Teach mode</b> —The instrument “learns” positions. In this mode the user can move the robotic arms manually.
Green	Continuous	<b>Production mode</b> —A method is running.
	Flashing	<b>Active stop</b> —This is an intentional pause triggered by the runtime controller or by opening a safety panel. The instrument pauses to allow user interaction with the deck. The operator can resume the method.
Red	Flashing	<b>Error state</b> —The Tecan™ Fluent™ Automation Workstation control computer screen or the touchscreen displays an error message.
Green	Flashing	<b>User prompt</b> —A method is running.



# SampleManager LIMS™ Software

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## Sign in to the SampleManager LIMS™ Software

The following procedure uses the desktop version of the SampleManager LIMS™ Software. You can also access the SampleManager LIMS™ Software via the Web Client.

To sign in to the SampleManager LIMS™ Software database, you must have the following information from your system administrator:

- Username
- Password
- The name of the server that you want to connect to

1. On the SampleManager LIMS™ Software computer, double-click the SampleManager icon.

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**Note:** Alternatively, you can open SampleManager from the Windows™ **Start** menu: Select **All Programs** ▶ **Thermo SampleManager** ▶ **SampleManager**.

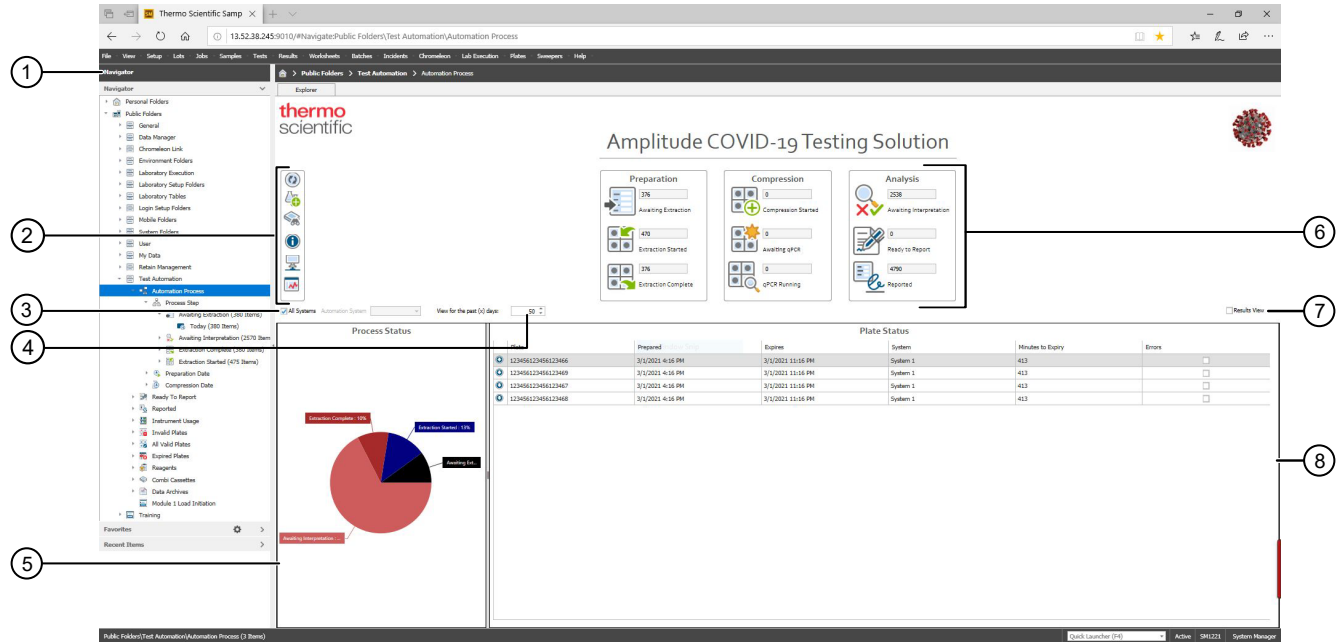
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The **SampleManager Login** window appears.

2. Enter your username and password, select the appropriate server, then click **Login**.  
The **Amplitude COVID-19 Testing Solution** screen appears. For more information, see “SampleManager Amplitude COVID-19 Testing Solution screen” on page 223.

## SampleManager Amplitude COVID-19 Testing Solution screen

The **Amplitude COVID-19 Testing Solution** screen is referred to as the **Automation Process** screen in the navigation pane.



**Figure 52 Overview of the SampleManager Amplitude COVID-19 Testing Solution screen**

- ① Displays SampleManager folders and screens.
- ② Toolbar; see “Amplitude COVID-19 Testing Solution screen toolbar” on page 223.
- ③ If you have multiple Amplitude™ Solution systems, allows you to view data for all systems at once, or view data for an individual system. Each system consists of one Module 1 and one Module 2.
- ④ Allows you to view data over time. The default is the past 50 days of data.
- ⑤ Pie chart of all Module 2 processes.
- ⑥ Tracks the Module 2 workflow; see “Amplitude COVID-19 Testing Solution pane” on page 225.
- ⑦ Replaces the **Plate Status** pane with the **Results** pane; see “Results pane” on page 226.
- ⑧ Displays test results or expiration information for the sample extraction plates prepared on Module 1; see “Plate Status pane” on page 224.

### Amplitude COVID-19 Testing Solution screen toolbar

Item	Description
	<b>Refresh</b> Updates the data displayed in the screen.
	<b>Sample Registration</b> Allows you to manually register sample extraction plates prepared on Module 1. You will be prompted to select the CSV file generated by the Tecan™ Fluent™ 1080 Automation Workstation on Module 1. <b>Note:</b> Manual registration is only required if Module 1 fails to automatically export a CSV file to the SampleManager LIMS™ Software. See “Manually register sample extraction plates” on page 227.



(continued)

Item		Description
	<b>Archive Data Search</b>	Allows you to search for archived data.  The archiving agent saves the EDS, EDT, and CSV files for each sample to a ZIP file, then moves the ZIP file to a server or cloud account. If the sample data needs to be reviewed at a later date, users can download the ZIP file to their own computer.
	<b>Data Archiving Event Viewer</b>	Displays the activities of the archiving agent running on the Momentum™ Workflow Scheduler Software computer.
	<b>Data Archiving Agent Status</b>	Displays the status of the archiving agent that runs on the Momentum™ Workflow Scheduler Software computer.  <ol style="list-style-type: none"> <li>1. <b>Starting</b>—Service is starting.</li> <li>2. <b>Waiting</b>—Waiting for the next scheduled sweep time.</li> <li>3. <b>Sweeping</b>—Looking for new files to archive.</li> <li>4. <b>Stopped</b>—Service not running on Momentum machine.</li> <li>5. <b>Disabled</b>—Sweeping disabled.</li> </ol>
	<b>Data Archiving Capture Source Status</b>	Displays an overview of the number of archives that have been performed.

### Plate Status pane

The **Plate Status** pane displays expiration information for the sample extraction plates prepared on Module 1. Module 1 exports a CSV file to the SampleManager LIMS™ Software. SampleManager uses the CSV file to perform the following functions:

- Register the sample extraction plates.
- Calculate expiration information, based on the **Prep Time** determined by Module 1.

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**Note:** If you do not see the **Plate Status** pane, deselect the **Results View** checkbox in the **Amplitude COVID-19 Testing Solution** screen.

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Item	Description
<b>Plate</b>	The barcode for the sample extraction plates currently on the Tecan™ Fluent™ 1080 Automation Workstation (≤4 plates).
<b>Prepared</b>	The date and time that the sample extraction plates were prepared. This is the <b>Prep Time</b> determined by Module 1.
<b>Expires</b>	The date and time that the sample extraction plates will expire. If the plate barcodes are scanned into Module 2 after the expiration date and time, the plates are invalid, and the RNA extraction will be cancelled.  <b>Note:</b> By default, the sample extraction plates expire after 7 hours from the <b>Prep Time</b> determined by Module 1.



(continued)

Item	Description
<b>System</b>	The Amplitude™ Solution system that the plate is being run on. Each system consists of one Module 1 and one Module 2.
<b>Minutes to Expiry</b>	<p>A countdown timer that displays the number of minutes from the current time until the expiry time in the <b>Expires</b> column.</p> <p><b>Note:</b> By default, users receive an email notification when the countdown reaches 15 minutes. An Administrator can configure the countdown time and the email notifications; see “Configure SampleManager settings” on page 227.</p>

### Amplitude COVID-19 Testing Solution pane

The **Amplitude COVID-19 Testing Solution** pane tracks the Module 2 workflow: RNA extraction, eluate transfer, real-time RT-PCR, and analysis. The Thermo Scientific™ Spinnaker™ Microplate Robot automatically moves plates between the various devices on Module 2.

Item	Description
<b>Preparation</b>	<p>Displays the number of samples at each RNA extraction step.</p> <ul style="list-style-type: none"> <li>• <b>Awaiting Extraction</b>—The number of samples on the Hotel Input that are waiting to start the RNA extraction process.</li> <li>• <b>Extraction Started</b>—The number of samples undergoing the RNA extraction process on the KingFisher™ Presto Purification System. The KingFisher™ Presto system can process up to 4 sample extraction plates.</li> </ul> <p><b>Note:</b> During extraction, users can open the SampleManager <b>Module 1 Load Indicator</b> to see when they can load prepared sample extraction plates from Module 1 onto Module 2. See “View the SampleManager Module 1 Load Indicator” on page 74.</p> <ul style="list-style-type: none"> <li>• <b>Extraction Complete</b>—The number of samples that have completed the RNA extraction process.</li> </ul>
<b>Compression</b>	<p>Displays the number of samples at each compression and real-time RT-PCR step.</p> <ul style="list-style-type: none"> <li>• <b>Compression Started</b>—The number of samples undergoing compression. Compression is when the Tecan™ Fluent™ 780 Automation Workstation transfers eluate from up to 4 sample extraction plates to a single MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode.</li> <li>• <b>Awaiting qPCR</b>—The number of samples waiting for real-time RT-PCR. The compression has completed and the real-time RT-PCR run has been initiated.</li> <li>• <b>qPCR Running</b>—The number of samples undergoing real-time RT-PCR on the QuantStudio™ 7 Flex Real-Time PCR Systems.</li> </ul>



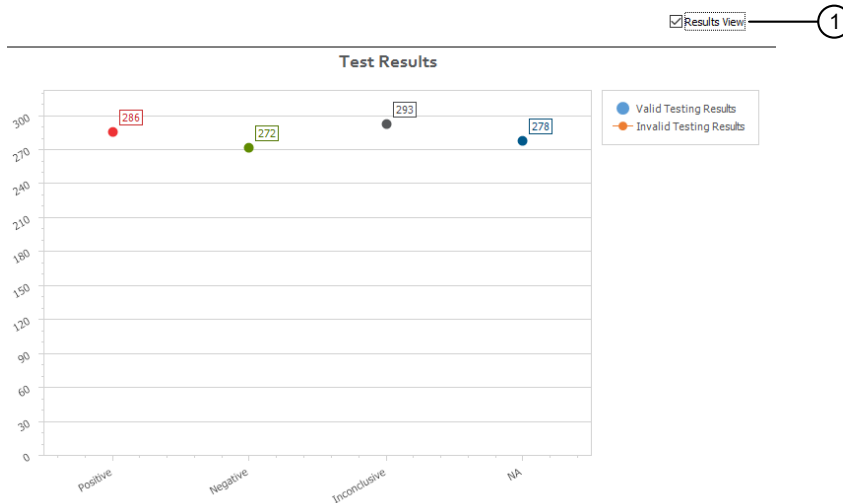
(continued)

Item	Description
Analysis	<p>Displays the number of samples at each analysis step.</p> <ul style="list-style-type: none"> <li>• <i>(Manual workflows only)</i> <b>Ready to Report</b>—The number of samples that have been analyzed but require the results (CSV file) to be manually released. An Administrator can configure the type of workflow (see “Configure SampleManager settings” on page 227).</li> <li>• <i>(Automated workflows only)</i> <b>Reported</b>—The number of samples that have been analyzed and the results (CSV file) automatically released. An Administrator can configure the type of workflow (see “Configure SampleManager settings” on page 227).</li> </ul>

## Results pane

The **Results** pane displays the results for all samples that have completed analysis.

**Note:** To display the **Results** pane, select the **Results View** checkbox in the **Automation Process** screen.




① **Results View** checkbox

Item	Description
Test Results	A series point chart that displays results for Valid Plates and Invalid Plates. The chart displays the counts for <b>Positive</b> , <b>Negative</b> , <b>Inconclusive</b> , and <b>NA</b> (invalid test result).

## Configure SampleManager settings

An Administrator can configure the following settings:

Setting	Description
<b>Plate Status pane</b>	
Prepared Plate Expiration interval	By default, the sample extraction plates expire after 7 hours from the Prep Time entered into Module 1.   <b>WARNING!</b> Do not change the Prepared Plate Expiration interval. Changing the interval can cause invalid test results.
Notification of Expiring Plates	Configure the expiration time for the sample extraction plates.  By default, users receive an email notification when the countdown reaches 15 minutes.
<b>Amplitude™ Solution pane</b>	
Analysis	Automated or manual workflow <ul style="list-style-type: none"> <li>Manual workflow (Ready to Report)— Sample results (CSV file) must be manually released.</li> <li>Automated workflow (Reported)— Sample results (CSV file) are automatically released.</li> </ul>

For detailed information, see the **SM (Admin) Configuration** training within SampleManager.

## Manually register sample extraction plates

The Amplitude™ Solution is designed as an automated workflow, but if necessary, sample extraction plates can be registered manually. For more information, see the **SM (Admin) Jobs** training within SampleManager.

1. On the Tecan™ Fluent™ 1080 Automation Workstation computer, open an internet browser to access SampleManager web client, then sign in.
2. Navigate to **Public Folders ▶ Test Automation ▶ Automation Process**.
3. Click **Register Prepared Plate** (under the **Refresh** button), then click **OK**.
4. Navigate to the **Amplitude** folder.  
There should be 4 new files.
5. Select one file, open it, then click **OK**.

6. Repeat step 3–step 5 for the remaining 3 plates that just came off the Tecan™ Fluent™ 1080 Automation Workstation.

---

**Note:** If some plates were swept automatically but not all, sweep only the plates that were not automatically swept.

---

7. When finished, open **Public Folders** from the desktop of the Tecan™ Fluent™ 1080 Automation Workstation computer, navigate to the **Amplitude** folder, then move the plates that you just manually swept into the **Archives** folder.

This will save the run, but customers will need to work with Priority Support to resolve the automatic sweeping issue.

## Manually review and authorize test results

Use this procedure to manually review and authorize test results before export.

1. In the **Automation Process** screen, click **Ready to Report**  
The **Ready to Report** folder opens.
2. In the **Ready to Report** folder, navigate to the folder with the plate of interest (organized by date), then select the plate.
3. Select a sample, then right-click to open the **Result display** dialog box.
4. Review the results (see “Interpretation of the results” on page 147).
5. When you are done reviewing the results, close the **Result display** dialog box.
6. Select all of the test samples (**Ctrl-A**) or select some of the test samples (**Shift-Select**).
7. Right-click, then select **Process ▶ Authorize**.
8. Click **OK** to authorize the selected sample test results.

## Module 1 SampleManager LIMS™ Software CSV output errors

The Module 1 SampleManager LIMS™ Software CSV output has 3 columns with different error code types.

- Column C – Status error codes (Thermo Fisher Scientific defined; see “Module 1 SampleManager LIMS™ Software CSV output: Status error codes” on page 229)
- Column G – Aspiration error codes (Tecan™ defined; see “Module 1 SampleManager LIMS™ Software CSV output: Aspiration and Dispense error codes” on page 230)
- Column H – Dispense error codes (Tecan™ defined; see “Module 1 SampleManager LIMS™ Software CSV output: Aspiration and Dispense error codes” on page 230)

	A	B	C	D	E	F	G	H	I
1	Operator: user								
2	MS2 Lot Number: 2010006:2010006								
3	Magnetic Beads Lot Number: 01033109								
4	Binding Solution Lot Number: 01031879								
5	Proteinase K Lot Number: 01029145								
6	Sample Prep Water Lot Number: 01029848								
7	Silicone Oil Lot Number: 205351								
8	Instrument ID: 2011015052								
9	Method: Amplitude_Module1_13mm_v2.0.2-EUA								
10	Preparation Time: 2021-06-01 22:52:31								
11									
12	WELL	SAMPLE	STATUS	PLATE	TIME	INSTRUMENT	ASPIRATION ERROR	DISPENSE ERROR	
13	A01	NC3	0	95040456000839400	6/1/2021 22:52	2011015052			
14	B01		No pipett	95040456000839400	6/1/2021 22:52	2011015052	No pipetting	No pipetting	
15	C01	M911026	2	95040456000839400	6/1/2021 22:52	2011015052	8388610	0	
16	D01	M912039	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
17	E01	M911001	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
18	F01	M911007	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
19	G01	M911023	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
20	H01	M911020	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
21	A02	M911020	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
22	B02	M911001	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
23	C02	M911024	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
24	D02	M911025	8	95040456000839400	6/1/2021 22:52	2011015052	8388609	2	
25	E02	M911018	2	95040456000839400	6/1/2021 22:52	2011015052	8388610	0	
26	F02	M912000	8	95040456000839400	6/1/2021 22:52	2011015052	8388609	2	
27	G02	M912021	8	95040456000839400	6/1/2021 22:52	2011015052	8388609	2	
28	H02	M911022	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
29	A03	M912039	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
30	B03	M912029	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
31	C03	M912033	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
32	D03	M911024	8	95040456000839400	6/1/2021 22:52	2011015052	8388609	2	
33	E03	M912036	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
34	F03	M911023	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
35	G03	M912032	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	
36	H03	M911019	0	95040456000839400	6/1/2021 22:52	2011015052	0	0	

SampleManager LIMS™ Software parses column C looking for a non-zero status. If a non-zero status is located, that sample is truncated from the final analysis.

## Module 1 SampleManager LIMS™ Software CSV output: Status error codes

The status column code is generated from Tecan™ FluentControl™ Software as 3 types of validation are being completed during sample processing.

Validation	If validation fails
Volume verification	Status Error = 1
Aspiration error check	Status Error = 2
Dispense error check	Status Error = 5

Volume verification occurs in the deep-well plate immediately after sample dispense. The Air FCA liquid handler will detect liquid in the sample plate and check against a threshold to determine if the sample transfer was successful.

If a validation fails during sample processing, a status error code is defined by Tecan™ FluentControl™ Software and all error codes are added together to be reported as a single number. For example, if there is no sample in the sample tube, the instrument should report an aspiration error [status error 2],

report a dispense error [status error 5] during dispense, and fail volume verification [status error 1], thus reporting **8** in the **STATUS** column for that sample.

## Module 1 SampleManager LIMS™ Software CSV output: Aspiration and Dispense error codes

The Aspiration and Dispense columns are provided for troubleshooting purposes and are defined by Tecan™. The instrument errors are reported as a combination of errors encountered. For example, Aspiration error 8388610 would be a combination of error 838608 (went to Z-max after liquid transfer error) and error 2 (not enough liquid was detected).

Error code	Description
1	No liquid was detected.
2	Not enough liquid was detected.
4	Clot was detected.
8	A diluter error occurred during pipetting.
16	A barcode could not be read by the scanner.
32	The same labware was scanned again and the scanned barcode did not match the previously scanned barcode.
64	An identical barcode was scanned at an unexpected grid position.
128	Contact Tecan™ Expertline.
256	Liquid Arrival Check, liquid error: the dispensed volume was outside of the tolerance specified in the liquid class.
512	Liquid Arrival Check, technical error: timeout or hardware malfunction such as balance overload.
1024	The PMP option detected a tip orifice occlusion (for example, clot aspirated).
2048	The PMP option detected a dispense error.
4096	The user entered the barcode manually after a scanning error.
8192	The user chose RETRY after a barcode scanning error.
16384	The user chose IGNORE after a barcode scanning error.
32768	Contact Tecan™ Expertline.
65536	The diluter was initialized after a diluter error.
131072	The diluter was deactivated after a diluter error.
262144	Retried after a PMP error.
524288	Ignored after a clot error.
1048576	Continued after a clot error.

(continued)

Error code	Description
2097152	Retried after a liquid transfer error.
4194304	Air pipetted after a liquid transfer error.
8388608	Went to Z-max after a liquid transfer error.
16777216	Nothing pipetted after a liquid transfer error.
33554432	The PMP option detected a system error.
67108864	The PMP option detected an aspirate failure.
134217728	Contact Tecan™ Expertline.
268435456	Contact Tecan™ Expertline.
536870912	Empty Tips performed over this well.
1073741824	Rack has been removed and replaced.

## Manually export results

1. In the **Automation Process** screen, click **Ready to Report**  
The **Ready to Report** folder opens.
2. Select a single, authorized test to export, right-click, then select **Test Export Results**.
3. Select a destination folder, then save as a CSV file.



**WARNING!** Do not alter the test results in the CSV file.

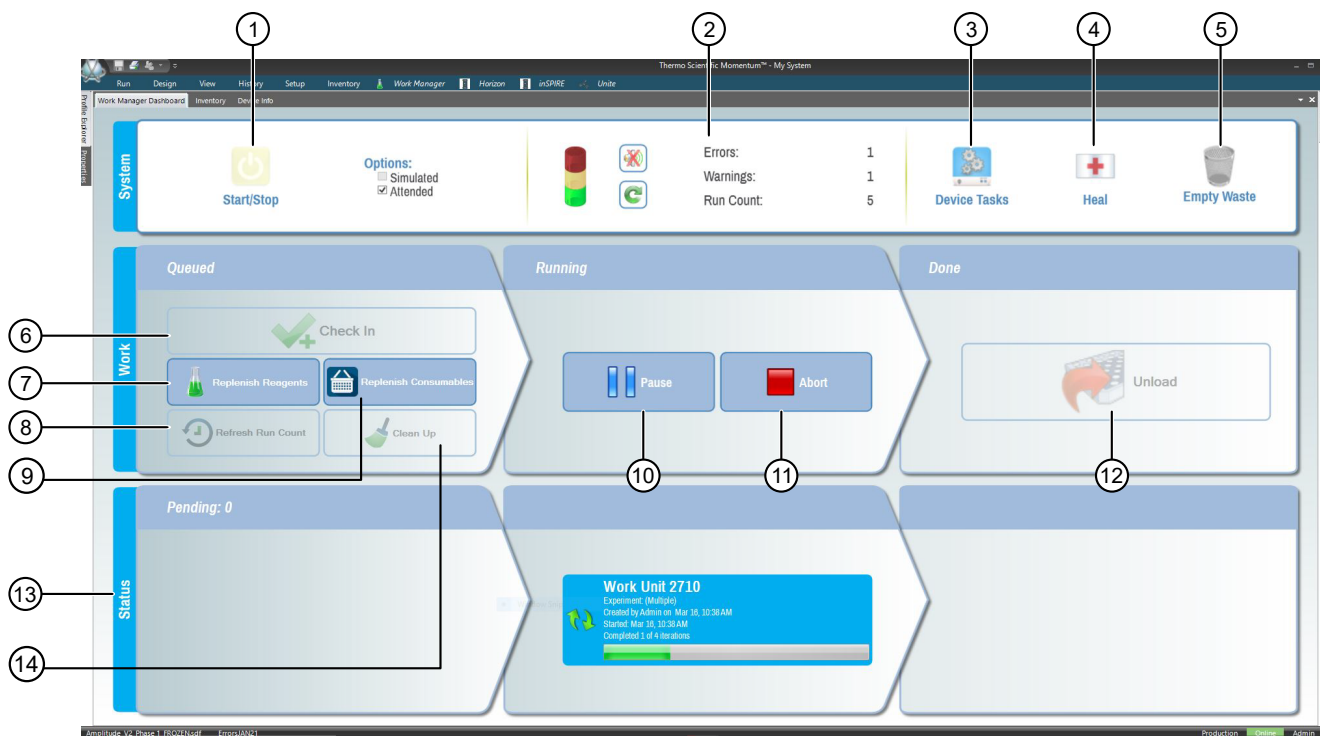
## For more information

This appendix contains brief information about the SampleManager LIMS™ Software. For detailed information, see the following resources within the SampleManager LIMS™ Software:

- Software training materials
- Software Help:
  - Press the **F1** key.
  - From the main menu bar at the top of the SampleManager window, select **Help ▶ Contents**.
  - Click a **Help** button.



# Momentum™ Software Work Manager Dashboard screen



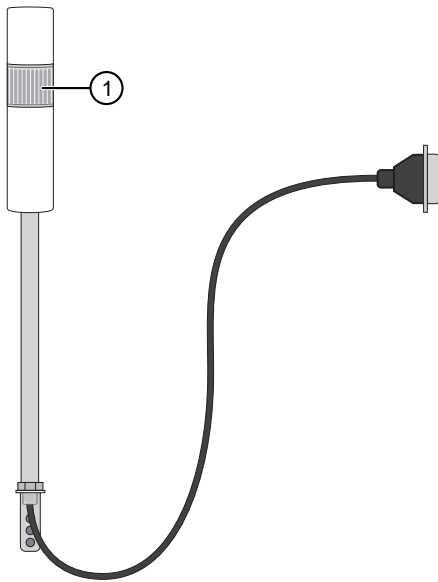
- ① **Start/Stop**—See “Bring all Module 2 devices online” on page 118
- ② Review Errors and Warnings
- ③ **Device Tasks**—Take individual devices online or offline
- ④ **Heal**—See “Heal the Spinnaker™ Microplate Robot” on page 190
- ⑤ **Empty Waste**—See “Empty Module 2 solid waste” on page 137
- ⑥ **Check in**—See “Check in Module 1 sample extraction plates and start a run” on page 130
- ⑦ **Replenish reagents**—See “Reload Module 2 reagents” on page 119
- ⑧ **Refresh Run Count**—See “Refresh run count” on page 105.
- ⑨ **Replenish consumables**—See “Reload Module 2 consumables” on page 111
- ⑩ **Pause**—Pause a current run
- ⑪ **Abort**—Abort a current run
- ⑫ **Unload**—See “Unload outgoing RNA elution plates from the Hotel Output” on page 135
- ⑬ **Status** pane—See pending, running, or finished run information
- ⑭ **Clean Up**—Clear the system of plates associated with the aborted run





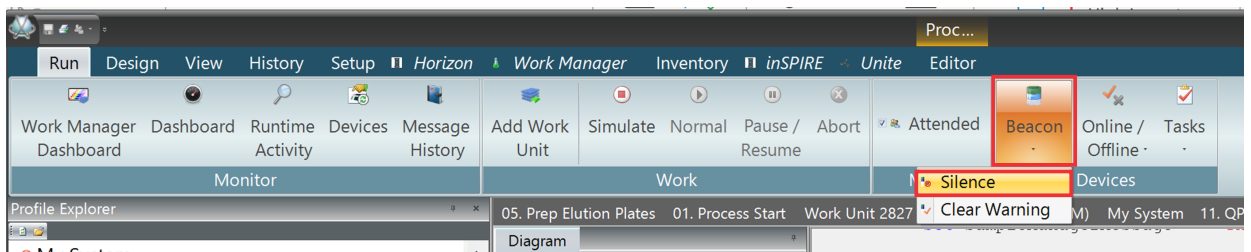
# Amplitude™ Beacon configuration

The Amplitude™ Beacon is configured during installation with options to activate in response to errors and, optionally, warnings. The beacon can be configured to produce a flashing light and, optionally, a sound. If you have questions about your configuration, consult Priority Support.



① Beacon light

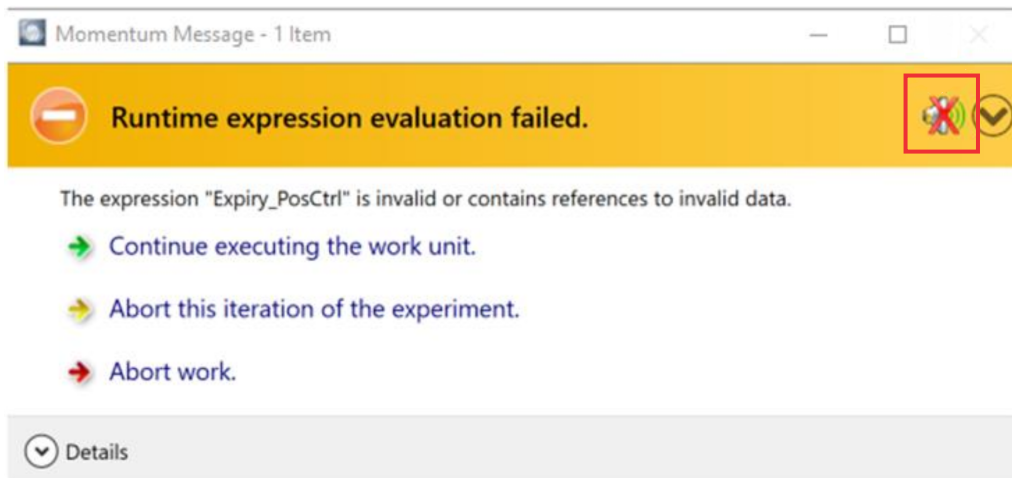
After an error activates the beacon, you can silence the beacon by selecting **Beacon ▶ Silence** from the **Run** tab in Momentum™ Software.



The beacon light will continue to be activated until the error is resolved.

If the beacon is enabled for both errors and warnings, and a warning activates the beacon, you can silence the beacon by selecting **Beacon ▶ Silence** from the **Run** tab in Momentum™ Software. The beacon sound and light can be cancelled by selecting **Beacon ▶ Clear Warning**.

When an error message appears on the screen, you can silence the beacon by clicking the **Silence Alarm** icon. The beacon light will continue to be activated until the error is resolved.



If the beacon is enabled for both errors and warnings, a solid light (and optionally, a solid siren) will be activated for errors and a pulsing light (and optionally, a pulsing siren) will be activated for warnings. If the beacon is enabled for errors only, a pulsing light (and optionally, a pulsing siren) will be activated for errors.

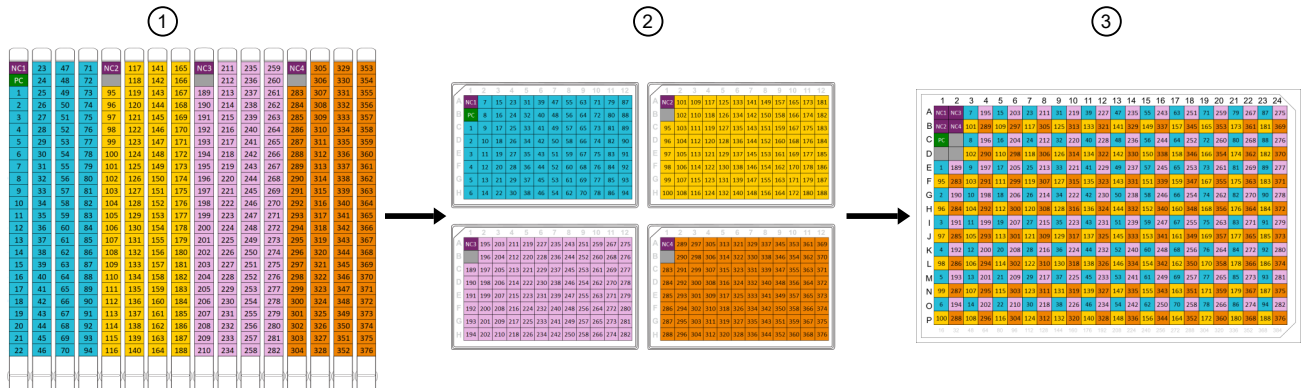


# Sample and control positions in tube runners and plates

- Sample and control positions in the tube runners ..... 236
- Sample and control well positions in the sample extraction plates ..... 239
- Sample and control well positions in the real-time RT-PCR plate ..... 240

Use the figures in this appendix to map the position of a sample in the tube runner to the corresponding well positions in the sample extraction plates and the real-time RT-PCR plate. The figures in this appendix reflect full-capacity runs of 376 samples.

**Note:** The Amplitude™ Solution is configured to run samples in multiples of 94. In other words, each run must include 94, 188, 282, or 376 sample tubes. If the number of sample tubes used in a run is not divisible by 94, you must include additional empty, barcoded tubes to fill any empty positions in the tube runners.



- ① Tube runners (see “Sample and control positions in the tube runners” on page 236)
- ② Sample Extractions Plates (see “Sample and control well positions in the sample extraction plates” on page 239)
- ③ Real-time RT-PCR plate (see “Sample and control well positions in the real-time RT-PCR plate” on page 240)



## Sample and control positions in the tube runners

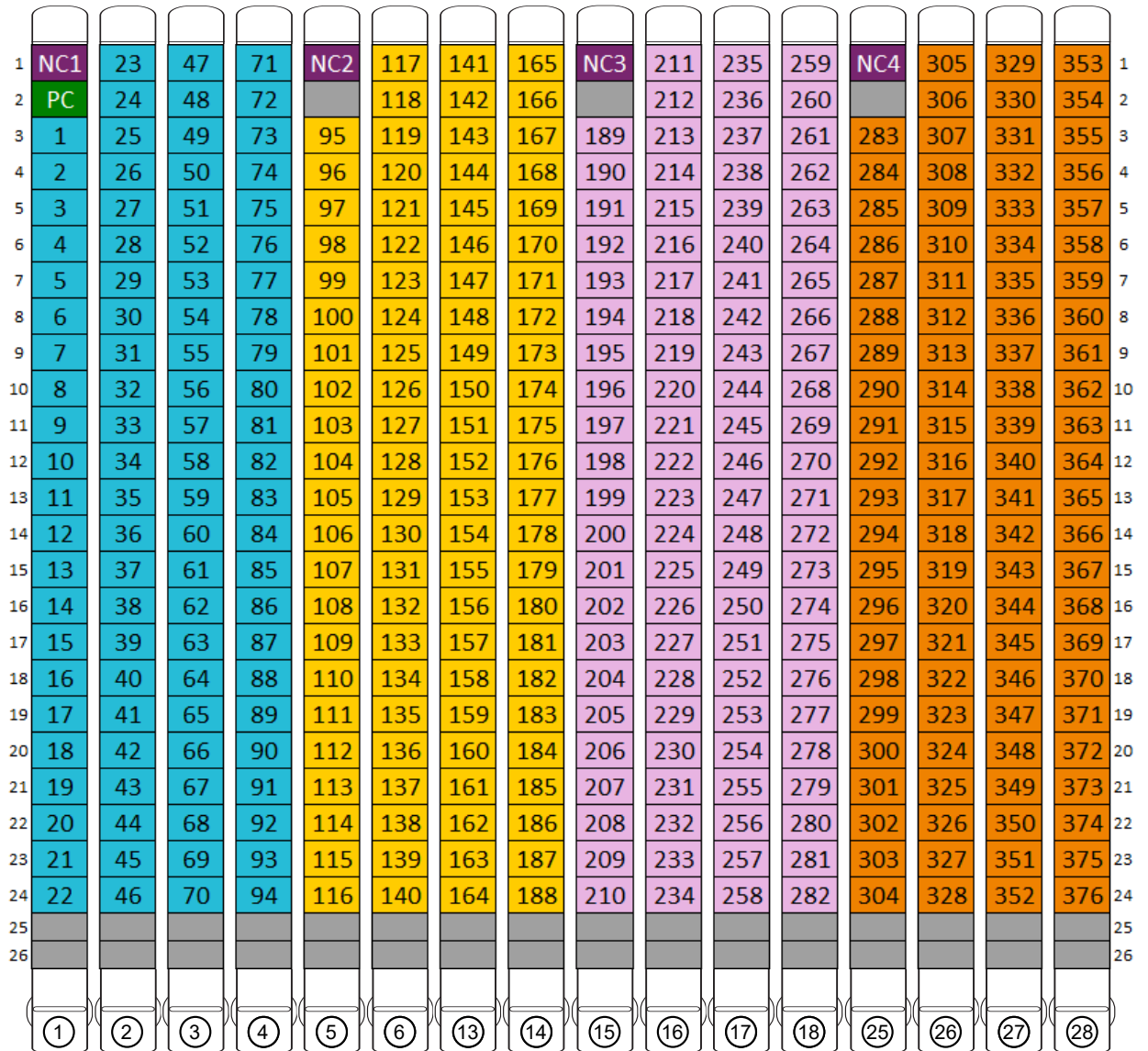
### 17 mm, 24-position tube runner (16–18 mm tubes)

1	NC1	23	47	71	NC2	117	141	165	NC3	211	235	259	NC4	305	329	353	1	
2	PC	24	48	72		118	142	166		212	236	260		306	330	354	2	
3	1	25	49	73	95	119	143	167	189	213	237	261	283	307	331	355	3	
4	2	26	50	74	96	120	144	168	190	214	238	262	284	308	332	356	4	
5	3	27	51	75	97	121	145	169	191	215	239	263	285	309	333	357	5	
6	4	28	52	76	98	122	146	170	192	216	240	264	286	310	334	358	6	
7	5	29	53	77	99	123	147	171	193	217	241	265	287	311	335	359	7	
8	6	30	54	78	100	124	148	172	194	218	242	266	288	312	336	360	8	
9	7	31	55	79	101	125	149	173	195	219	243	267	289	313	337	361	9	
10	8	32	56	80	102	126	150	174	196	220	244	268	290	314	338	362	10	
11	9	33	57	81	103	127	151	175	197	221	245	269	291	315	339	363	11	
12	10	34	58	82	104	128	152	176	198	222	246	270	292	316	340	364	12	
13	11	35	59	83	105	129	153	177	199	223	247	271	293	317	341	365	13	
14	12	36	60	84	106	130	154	178	200	224	248	272	294	318	342	366	14	
15	13	37	61	85	107	131	155	179	201	225	249	273	295	319	343	367	15	
16	14	38	62	86	108	132	156	180	202	226	250	274	296	320	344	368	16	
17	15	39	63	87	109	133	157	181	203	227	251	275	297	321	345	369	17	
18	16	40	64	88	110	134	158	182	204	228	252	276	298	322	346	370	18	
19	17	41	65	89	111	135	159	183	205	229	253	277	299	323	347	371	19	
20	18	42	66	90	112	136	160	184	206	230	254	278	300	324	348	372	20	
21	19	43	67	91	113	137	161	185	207	231	255	279	301	325	349	373	21	
22	20	44	68	92	114	138	162	186	208	232	256	280	302	326	350	374	22	
23	21	45	69	93	115	139	163	187	209	233	257	281	303	327	351	375	23	
24	22	46	70	94	116	140	164	188	210	234	258	282	304	328	352	376	24	
	①	②	③	④	⑤	⑥	⑬	⑭	⑮	⑯	⑰	⑱	⑲	⑳	㉑	㉒	㉓	㉔

- Negative Control (NC)
- Positive Control (PC)
- Plug position (no sample or control)
- Samples 1–94
- Samples 95–188
- Samples 189–282
- Samples 283–376
- ① Tube runner position on the deck grid



**16 mm, 26-position tube runner (15–17 mm tubes)**



- Negative Control (NC)
- Positive Control (PC)
- Plug position (no sample or control)
- Samples 1–94
- Samples 95–188
- Samples 189–282
- Samples 283–376
- # Tube runner position on the deck grid



**13 mm, 32-position tube runner (12–14 mm tubes)**

1	NC1	31	63	NC2	125	157	NC3	219	251	NC4	313	345	1
2	PC	32	64		126	158		220	252		314	346	2
3	1	33	65	95	127	159	189	221	253	283	315	347	3
4	2	34	66	96	128	160	190	222	254	284	316	348	4
5	3	35	67	97	129	161	191	223	255	285	317	349	5
6	4	36	68	98	130	162	192	224	256	286	318	350	6
7	5	37	69	99	131	163	193	225	257	287	319	351	7
8	6	38	70	100	132	164	194	226	258	288	320	352	8
9	7	39	71	101	133	165	195	227	259	289	321	353	9
10	8	40	72	102	134	166	196	228	260	290	322	354	10
11	9	41	73	103	135	167	197	229	261	291	323	355	11
12	10	42	74	104	136	168	198	230	262	292	324	356	12
13	11	43	75	105	137	169	199	231	263	293	325	357	13
14	12	44	76	106	138	170	200	232	264	294	326	358	14
15	13	45	77	107	139	171	201	233	265	295	327	359	15
16	14	46	78	108	140	172	202	234	266	296	328	360	16
17	15	47	79	109	141	173	203	235	267	297	329	361	17
18	16	48	80	110	142	174	204	236	268	298	330	362	18
19	17	49	81	111	143	175	205	237	269	299	331	363	19
20	18	50	82	112	144	176	206	238	270	300	332	364	20
21	19	51	83	113	145	177	207	239	271	301	333	365	21
22	20	52	84	114	146	178	208	240	272	302	334	366	22
23	21	53	85	115	147	179	209	241	273	303	335	367	23
24	22	54	86	116	148	180	210	242	274	304	336	368	24
25	23	55	87	117	149	181	211	243	275	305	337	369	25
26	24	56	88	118	150	182	212	244	276	306	338	370	26
27	25	57	89	119	151	183	213	245	277	307	339	371	27
28	26	58	90	120	152	184	214	246	278	308	340	372	28
29	27	59	91	121	153	185	215	247	279	309	341	373	29
30	28	60	92	122	154	186	216	248	280	310	342	374	30
31	29	61	93	123	155	187	217	249	281	311	343	375	31
32	30	62	94	124	156	188	218	250	282	312	344	376	32

- Negative Control (NC)
- Positive Control (PC)
- Plug position (no sample or control)
- Samples 1–94
- Samples 95–188
- Samples 189–282
- Samples 283–376
- # Tube runner position on the deck grid



# Sample and control well positions in the sample extraction plates

①

	1	2	3	4	5	6	7	8	9	10	11	12
A	NC1	7	15	23	31	39	47	55	63	71	79	87
B	PC	8	16	24	32	40	48	56	64	72	80	88
C	1	9	17	25	33	41	49	57	65	73	81	89
D	2	10	18	26	34	42	50	58	66	74	82	90
E	3	11	19	27	35	43	51	59	67	75	83	91
F	4	12	20	28	36	44	52	60	68	76	84	92
G	5	13	21	29	37	45	53	61	69	77	85	93
H	6	14	22	30	38	46	54	62	70	78	86	94

②

	1	2	3	4	5	6	7	8	9	10	11	12
A	NC2	101	109	117	125	133	141	149	157	165	173	181
B		102	110	118	126	134	142	150	158	166	174	182
C	95	103	111	119	127	135	143	151	159	167	175	183
D	96	104	112	120	128	136	144	152	160	168	176	184
E	97	105	113	121	129	137	145	153	161	169	177	185
F	98	106	114	122	130	138	146	154	162	170	178	186
G	99	107	115	123	131	139	147	155	163	171	179	187
H	100	108	116	124	132	140	148	156	164	172	180	188

③

	1	2	3	4	5	6	7	8	9	10	11	12
A	NC3	195	203	211	219	227	235	243	251	259	267	275
B		196	204	212	220	228	236	244	252	260	268	276
C	189	197	205	213	221	229	237	245	253	261	269	277
D	190	198	206	214	222	230	238	246	254	262	270	278
E	191	199	207	215	223	231	239	247	255	263	271	279
F	192	200	208	216	224	232	240	248	256	264	272	280
G	193	201	209	217	225	233	241	249	257	265	273	281
H	194	202	210	218	226	234	242	250	258	266	274	282

④

	1	2	3	4	5	6	7	8	9	10	11	12
A	NC4	289	297	305	313	321	329	337	345	353	361	369
B		290	298	306	314	322	330	338	346	354	362	370
C	283	291	299	307	315	323	331	339	347	355	363	371
D	284	292	300	308	316	324	332	340	348	356	364	372
E	285	293	301	309	317	325	333	341	349	357	365	373
F	286	294	302	310	318	326	334	342	350	358	366	374
G	287	295	303	311	319	327	335	343	351	359	367	375
H	288	296	304	312	320	328	336	344	352	360	368	376

- ① Sample extraction plate 1
- ② Sample extraction plate 2
- ③ Sample extraction plate 3
- ④ Sample extraction plate 4

- Negative Control (NC)
- Positive Control (PC)
- Empty well
- Samples 1–94
- Samples 95–188
- Samples 189–282
- Samples 283–376



## Sample and control well positions in the real-time RT-PCR plate

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
A	NC1	NC3	7	195	15	203	23	211	31	219	39	227	47	235	55	243	63	251	71	259	79	267	87	275
B	NC2	NC4	101	289	109	297	117	305	125	313	133	321	141	329	149	337	157	345	165	353	173	361	181	369
C	PC		8	196	16	204	24	212	32	220	40	228	48	236	56	244	64	252	72	260	80	268	88	276
D			102	290	110	298	118	306	126	314	134	322	142	330	150	338	158	346	166	354	174	362	182	370
E	1	189	9	197	17	205	25	213	33	221	41	229	49	237	57	245	65	253	73	261	81	269	89	277
F	95	283	103	291	111	299	119	307	127	315	135	323	143	331	151	339	159	347	167	355	175	363	183	371
G	2	190	10	198	18	206	26	214	34	222	42	230	50	238	58	246	66	254	74	262	82	270	90	278
H	96	284	104	292	112	300	120	308	128	316	136	324	144	332	152	340	160	348	168	356	176	364	184	372
I	3	191	11	199	19	207	27	215	35	223	43	231	51	239	59	247	67	255	75	263	83	271	91	279
J	97	285	105	293	113	301	121	309	129	317	137	325	145	333	153	341	161	349	169	357	177	365	185	373
K	4	192	12	200	20	208	28	216	36	224	44	232	52	240	60	248	68	256	76	264	84	272	92	280
L	98	286	106	294	114	302	122	310	130	318	138	326	146	334	154	342	162	350	170	358	178	366	186	374
M	5	193	13	201	21	209	29	217	37	225	45	233	53	241	61	249	69	257	77	265	85	273	93	281
N	99	287	107	295	115	303	123	311	131	319	139	327	147	335	155	343	163	351	171	359	179	367	187	375
O	6	194	14	202	22	210	30	218	38	226	46	234	54	242	62	250	70	258	78	266	86	274	94	282
P	100	288	108	296	116	304	124	312	132	320	140	328	148	336	156	344	164	352	172	360	180	368	188	376

- Negative Control (NC)
- Positive Control (PC)
- Empty well
- Samples 1–94
- Samples 95–188
- Samples 189–282
- Samples 283–376





# Module 1 and Module 2 automation information

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## Module 1 automation information

The Tecan™ Fluent™ 1080 Automation Workstation performs the following steps:

1. Mixes MagMAX™ MVP II HT Proteinase K and TaqPath™ COVID-19 Module 1 MS2 Phage Control.
2. Transfers Binding Bead Mix to every well in each KingFisher™ Deep-Well 96 Plate with Barcode used.
3. Transfers Proteinase K/MS2 Phage Control mix to every well in each KingFisher™ Deep-Well 96 Plate with Barcode used, except well B1.
4. Transfers 200 µL of each sample from the sample tube to a well in a KingFisher™ Deep-Well 96 Plate with Barcode.
5. Adds 200 µL of silicone oil to every well in each KingFisher™ Deep-Well 96 Plate with Barcode used.

To track the sample from the tube runner position to the real-time RT-PCR plate, see Appendix H, “Sample and control positions in tube runners and plates”.

## Module 2 automation information

1. Spinnaker™ Microplate Robot loads KingFisher™ 96 Deep-Well Plates with KingFisher™ 96 tip comb for deep-well magnets onto KingFisher™ Presto Purification Systems.
2. Spinnaker™ Microplate Robot loads sample extraction plates onto KingFisher™ Presto Purification Systems.
3. Spinnaker™ Microplate Robot moves plates between KingFisher™ Presto Purification System, Multidrop™ Combi Reagent Dispensers to perform Wash 1 and Wash 2 and the BioTek™ ELx405™ Select Microplate Washer to remove liquid waste.
4. Spinnaker™ Microplate Robot moves RNA elution plates between the Multidrop™ Combi Reagent Dispensers, Agilent™ Microplate Centrifuge, and KingFisher™ Presto Purification System to elute sample RNA and the BioTek™ ELx405™ Select Microplate Washer to remove liquid waste.
5. Spinnaker™ Microplate Robot loads 1–4 RNA elution plates onto Tecan™ Fluent™ 780 Automation Workstations.



6. Tecan™ Fluent™ 780 Automation Workstation transfers the following components to 1 MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode:
  - RNA from RNA elution plates
  - TaqPath™ COVID-19 HT qPCR Assay
  - MagMAX™ HT Water
  - TaqPath™ HT Module 2 1-Step Multiplex Master Mix (No ROX)
  - TaqPath™ COVID-19 Control diluted by the Tecan™ Fluent™ 780 Automation Workstation in TaqPath™ COVID-19 Module 2 Control Dilution Buffer
7. Spinnaker™ Microplate Robot moves the MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode to ALPS™ 3000 Automated Microplate Heat Sealer to seal, then Agilent™ Microplate Centrifuge to remove bubbles.
8. Spinnaker™ Microplate Robot moves MicroAmp™ EnduraPlate™ Optical 384-Well Clear Reaction Plate with Barcode to QuantStudio™ 7 Flex Real-Time PCR System.
9. Spinnaker™ Microplate Robot moves four RNA elution plates to the ALPS™ 3000 Automated Microplate Heat Sealer, then to Hotel Input for pickup.



# Cleaning and decontamination

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This appendix describes a recommended cleaning and decontamination procedure to be performed on the Amplitude™ Solution system. The procedure references material in the *World Health Organization’s (WHO) Laboratory Biosafety Manual*: [www.who.int/csr/resources/publications/biosafety/](http://www.who.int/csr/resources/publications/biosafety/).

## Safety

For chemical safety and biohazard guidelines, refer to Appendix K, “Safety”. Read the Safety Data Sheets (SDSs) for all chemicals used in the cleaning and decontamination procedure and follow handling instructions. Appropriate personal protective equipment such as gloves, eye goggles, and face mask must be worn at all times while carrying out this procedure.

The customer is responsible for compliance with regulatory requirements that pertain to their procedures and uses of the instrument.

## When to perform cleaning and decontamination

In accordance with the standard laboratory practices, cleaning and decontamination may be required whenever any of the following occur:

- Initial installation, uninstallation, relocation of the Amplitude™ Solution system or any instrument associated with the system.
- Before the instrument is serviced at your facility or is sent for repair, maintenance, trade-in, disposal, or termination of a loan. In this case, request decontamination forms from customer service.

- Incident (e.g. spillage of samples or plates):
  - The severity of the incident must be analyzed in accordance with the local facility regulations. The level of contamination will determine if area decontamination or a comprehensive system decontamination is needed.
  - For general area cleaning and decontamination instruction, follow the steps outlined in area decontamination procedure.
  - For specific instrument decontamination, the instructions for cleaning and decontamination can be found in the specific instrument's user manual. Use the following table to help locating the required documents.
  - Organic material growth is observed in the Module 2 Tecan™ Fluent™ 780 Automation Workstation cold block.
  - A high rate of suspected false-positive results is encountered, potentially due to:
    - A high level of dust
    - Amplicon contamination

In these cases, the scope of decontamination should be determined based on the available data as well as the current facility and maintenance cleaning policy.

- Preventive measure: with the detection of potential amplicon and other environmental contamination, cleaning and decontamination of the system should be performed. The scope of decontamination should be determined based on available data as well as the current facility cleaning and maintenance policy.

Number	Instrument	Manufacture user manual	Chemical incompatibility <sup>[1]</sup>
1	Tecan™ Fluent™ 780 Automation Workstation	<i>Tecan™ Fluent™ Operating Manual</i> , Pub. No. 399706, EN, V1.6	N/A
2	Tecan™ Fluent™ 1080 Automation Workstation	<i>Tecan™ Fluent™ Operating Manual</i> , Pub. No. 399706, EN, V1.6	N/A
3	Agilent™ Microplate Centrifuge	<i>Microplate Centrifuge with Loader User Guide</i> Part No. G5405-90002, Revision C, April 2016	Do not use abrasive, corrosive cleaning agents. Do not use metal brushes.
4	Thermo Scientific™ KingFisher™ Presto Purification System	<i>Thermo Scientific™ KingFisher™ Presto User Manual</i> , Pub. No. N17413, Rev. A.0	N/A
5	Thermo Scientific™ ALPS™ 3000 Automated Microplate Heat Sealer	<i>ALPS™ 3000 Automated Laboratory Plate Sealer User Manual</i>	Do not use acetone or abrasive cleaners.
6	Applied Biosystems™ QuantStudio™ 7 Flex Real-Time PCR System	<i>QuantStudio™ 6 and 7 Flex Real-Time PCR Systems MAINTENANCE AND ADMINISTRATION</i> , Pub. No. MAN0007992, Rev. 2	N/A

(continued)

Number	Instrument	Manufacture user manual	Chemical incompatibility <sup>[1]</sup>
7	Thermo Scientific™ Multidrop™ Combi Reagent Dispenser	<i>Thermo Scientific™ Multidrop™ Combi User Manual</i> , Cat. no. N5616, Rev. 1.7	Advise against formaldehyde.
8	BioTek™ ELx405™ Select Microplate Washer	<i>ELx405™ Microplate Washer Operator's Manual</i> , Part No. 7101000, Rev. L	Do not use DMSO or other organic solvents.
9	Thermo Scientific™ Spinnaker™ Microplate Robot on BenchTrak	See “Thermo Scientific™ Spinnaker™ Microplate Robot on BenchTrak decontamination procedure” on page 247	N/A

<sup>[1]</sup> N/A = not applicable

## Cleaning and decontamination agents



**WARNING!** Heating elements that are included in the Amplitude™ Solution system can produce hazards related to explosion and release of toxic flammable gases. Do not supply consumables or reagents to the system other than those described in this manual.



**CAUTION!** Do not use bleach for decontamination, as it may produce hazardous gases upon contact with reagents used by the Amplitude™ Solution system.

The following table lists commonly used disinfection and decontamination agents that are compatible with Amplitude™ Solution system. Alternatives with the equivalent active ingredients may be considered.

Table 37 Laboratory cleaning agents

Agent	Description	Recommended concentration
DI water	Distilled or deionized water	N/A
Alcohol	Active against vegetative bacteria, fungi and lipid-containing viruses but not against spores. Their actions on non-lipid viruses are variable. Alcohols are flammable and must not be used near open flames.	Ethanol, 70%–80% Isopropanol, 70%
Peroxide	At 3-6% concentration, hydrogen peroxide is effective against most microbes and the effectiveness increases with higher concentration and exposure time. However, due to its corrosive property, do not exceed the recommended concentration and exposure time as listed. Corrosiveness can affect skin and mucous membranes. Safety precautions should be used when dealing with the chemical.	Hydrogen peroxide, 3–6% To effectively remove organic growths including microbes, fungi, spores and molds: soak the affected areas in hydrogen peroxide for 10 to 20 minutes.

Table 38 Commercial decontamination agents

Product name	Active ingredient	Vendor
DNA AWAY™	Sodium Hydroxide, 1%	Thermo Scientific™
RNase AWAY™	Sodium Hydroxide, 1%	Thermo Scientific™

## Decontamination procedure

The following procedure may be used for decontamination prior to moving or servicing instruments, following spillage of plates or sample tubes, for removal of dust contamination of the system, or for cleaning organic growth from the Module 2 Tecan™ Fluent™ 780 Automation Workstation cold block. This procedure may be superseded by local laboratory policies and procedures, provided they are in accordance with the warnings and compatibility information provided in these instructions for use. The success of the decontamination procedure may be evaluated based on PCR measurements of swabs from affected areas (for spillage or dust removal), or based on visual inspection (for removal of organic growth from the Module 2 Tecan™ Fluent™ 780 Automation Workstation cold block). This procedure is not guaranteed to provide sterilization.



**WARNING!** Before applying any cleaning or decontamination agents, disconnect power from all instrumentation in the area. To fully disconnect power either detach or unplug the power cord, positioning the instrument such that the power cord is accessible.



**WARNING! GENERAL CHEMICAL HANDLING.** Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing). Minimize contact with chemicals. Minimize inhalation of chemicals.



**WARNING! Potential Biohazard.** Depending on the samples used on this instrument, the surface may be considered a biohazard. 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 laboratory requirements before working with potentially biohazardous materials.

1. Power off and unplug all instruments and computers prior to using cleaning agents.
2. Cover all ports and openings with a cap or plug.
3. Discard all the used and unused consumables or reagents that are currently on the system.
4. Wear all applicable personal protective equipment. Ensure the area is well-ventilated.

5. Apply a freshly-made solution of lab-grade hydrogen peroxide, 3–6% to the contaminated surfaces:

---

**Note:** Do not use hydrogen peroxide at concentrations higher than 3–6%. If only higher-concentration hydrogen peroxide solutions are available, dilute to 3–6% before use.

---

- a. A spray dispenser may help to ensure complete coverage of larger areas. Do not use a spray dispenser on Tecan™ instruments.
  - b. Dispense the solution onto a lint-free wipe (such as WypAll™) to reach less accessible areas.
  - c. Dip cotton tip swab into solution and apply to impacted small components and surfaces.
6. Keep the surfaces soaked with hydrogen peroxide for no more than 20 minutes. Wipe dry. Fizzing will occur.
  7. After 10 minutes, use a non-abrasive brush to physically remove any remaining visible contamination, growth, or stains. Wipe dry.
  8. Clean all decontaminated surfaces with purified water to remove residue and wipe dry. Repeat this step as many times as needed until no residue is left.
  9. Clean all surfaces using a lint-free wipe and 70–80% ethanol or 70% isopropanol. Let air-dry.

For cleaning and decontamination of the Spinnaker™ Microplate Robot and Module 2 as well as tube runners, use the following procedures:

- “Thermo Scientific™ Spinnaker™ Microplate Robot on BenchTrak decontamination procedure” on page 247.
- “Tecan™ FluentID™ tube runners decontamination procedure” on page 248.

## Thermo Scientific™ Spinnaker™ Microplate Robot on BenchTrak decontamination procedure

1. In the Momentum™ Software **Work Manager Dashboard**, take the Spinnaker™ Microplate Robot offline.  
The Spinnaker™ Microplate Robot should move to a “safe” position next to an access door on the Amplitude™ Solution system. The output/input hotel racks may be removed as required to reach the Spinnaker™ Microplate Robot.
2. Leave the Spinnaker™ Microplate Robot on the BenchTrak, power off and unplug all instruments and computers.
3. Discard all used and unused consumables and reagents currently on the system.
4. Wear all applicable personal protective equipment. Ensure the area is well-ventilated.
5. Clean all visible surfaces with a lint-free wipe dampened with 70%–80% ethanol or 70% isopropanol solution. Focus on the plate grippers and the Spinnaker™ Microplate Robot nest. Let air dry.



6. Spray DNA AWAY™, RNase AWAY™, or 6% hydrogen peroxide on all visible surfaces with focus on the plate grippers and the nest. Leave on for one minute. Wipe the wet surfaces thoroughly using a lint-free wipe.
7. (Optional) Repeat step 6 with another decontamination solution as needed. Do not combine or mix solutions.
8. Spray DI water on all surfaces and wipe clean to remove any residue.
9. Apply 70–80% ethanol or 70% isopropanol. Let air-dry.

## Tecan™ FluentID™ tube runners decontamination procedure



**CAUTION!** Tube runners are NOT autoclavable.

1. Remove tube runners from the instrument deck.
2. Wipe the tube runners with 70% ethanol.
3. Rinse the tube runners with DI water.
4. Allow the tube runners to dry thoroughly before placing them back on the instrument deck.





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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](https://www.thermofisher.com/support).

## Symbols on this instrument










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

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

## Standard safety symbols

Symbol and description	
	<b>CAUTION!</b> Risk of danger. Consult the manual for further safety information.
	<b>CAUTION!</b> Risk of electrical shock.
	<b>CAUTION!</b> Hot surface.
	<b>CAUTION!</b> Potential biohazard.
	<b>CAUTION!</b> Ultraviolet light.


## Additional safety symbols

Symbol and description	
	<b>CAUTION!</b> Moving parts.
	<b>CAUTION!</b> Moving parts.
	<b>CAUTION!</b> Moving parts.
	<b>CAUTION!</b> Moving parts.
	<b>CAUTION!</b> Moving parts.
	<b>CAUTION!</b> Piercing hazard.
	<b>CAUTION!</b> Sharp edges.
	<b>CAUTION!</b> Potential slipping hazard.
	<b>CAUTION!</b> Potential overhead hazard.





- Vor Service - oder Wartungsarbeiten Netzstecker ziehen
- Prior to any repair or maintenance job disconnect mains power cord
- Avant tout type d'intervention, retirer la prise de raccordement au secteur et lire attentivement le manuel
- Prima di eseguire qualsiasi lavoro di manutenzione o servizio, disconnettere il cavo di alimentazione dalla presa di corrente
- Antes de cualquier intervención de servicio o mantenimiento apagar y desconectar el instrumento

**Model** Instrument Fluent 780  
**REF** 30042021 00  
 20991231  
**SN** 9912123456  
**U,f** 24V ==  
**P** 1500W



**TECAN.**

Tecan Schweiz AG  
 Steedstrasse 103  
 CH-8708 Männedorf  
 Switzerland

Doc. No. 3985361 V2.0

Related Patents: [www.tecan.com/patents](http://www.tecan.com/patents)



Figure 54 Tecan™ Fluent™ Automation Workstation type plate

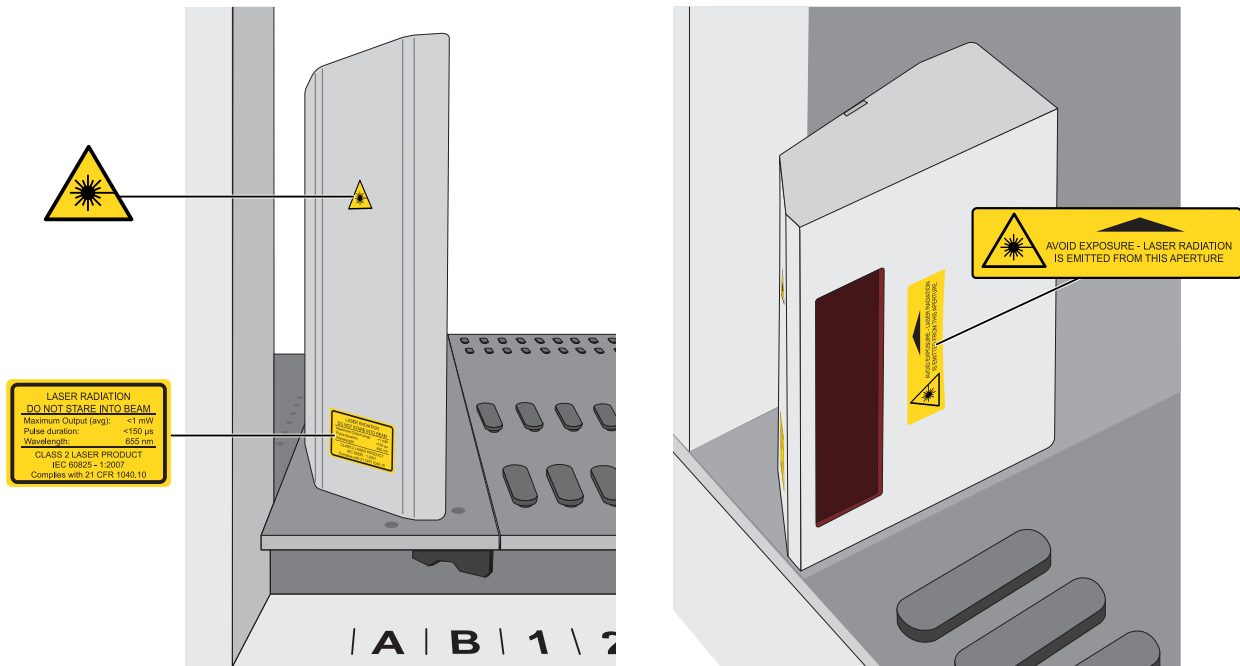


Figure 55 Safety labels on the Tecan™ FluentID™ Tube Barcode Scanner

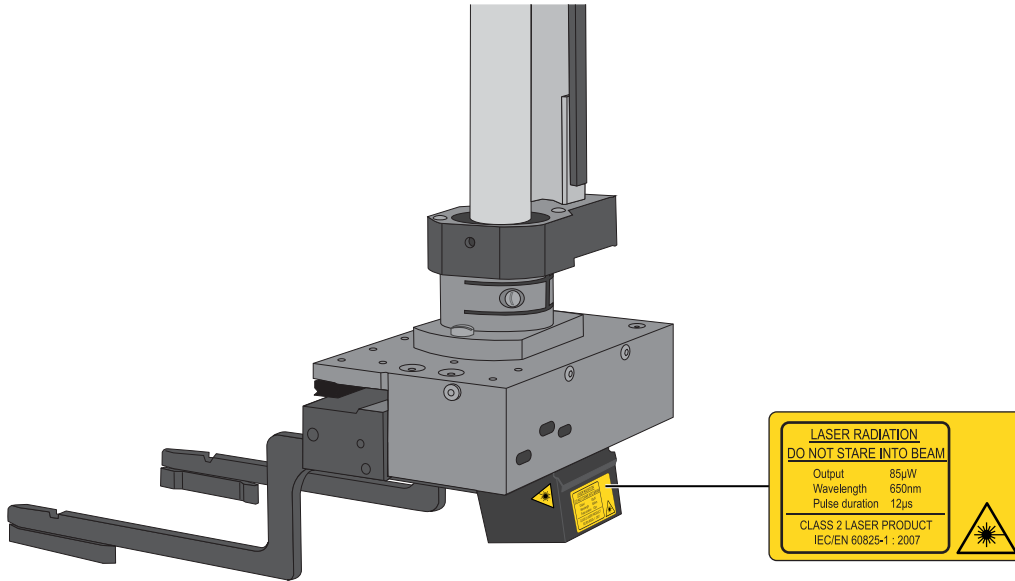


Figure 56 Safety labels on the barcode scanner on the robotic gripper arm

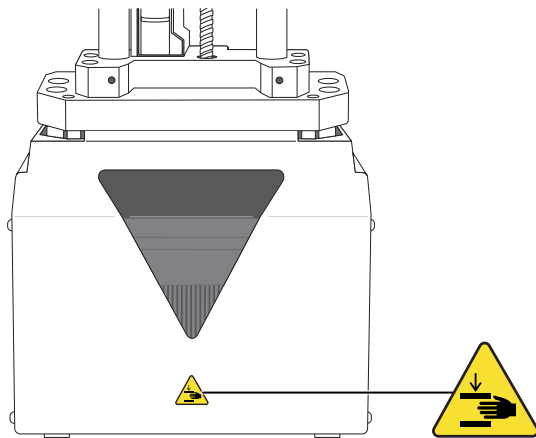


Figure 57 Safety labels on the MultiChannel Arm™

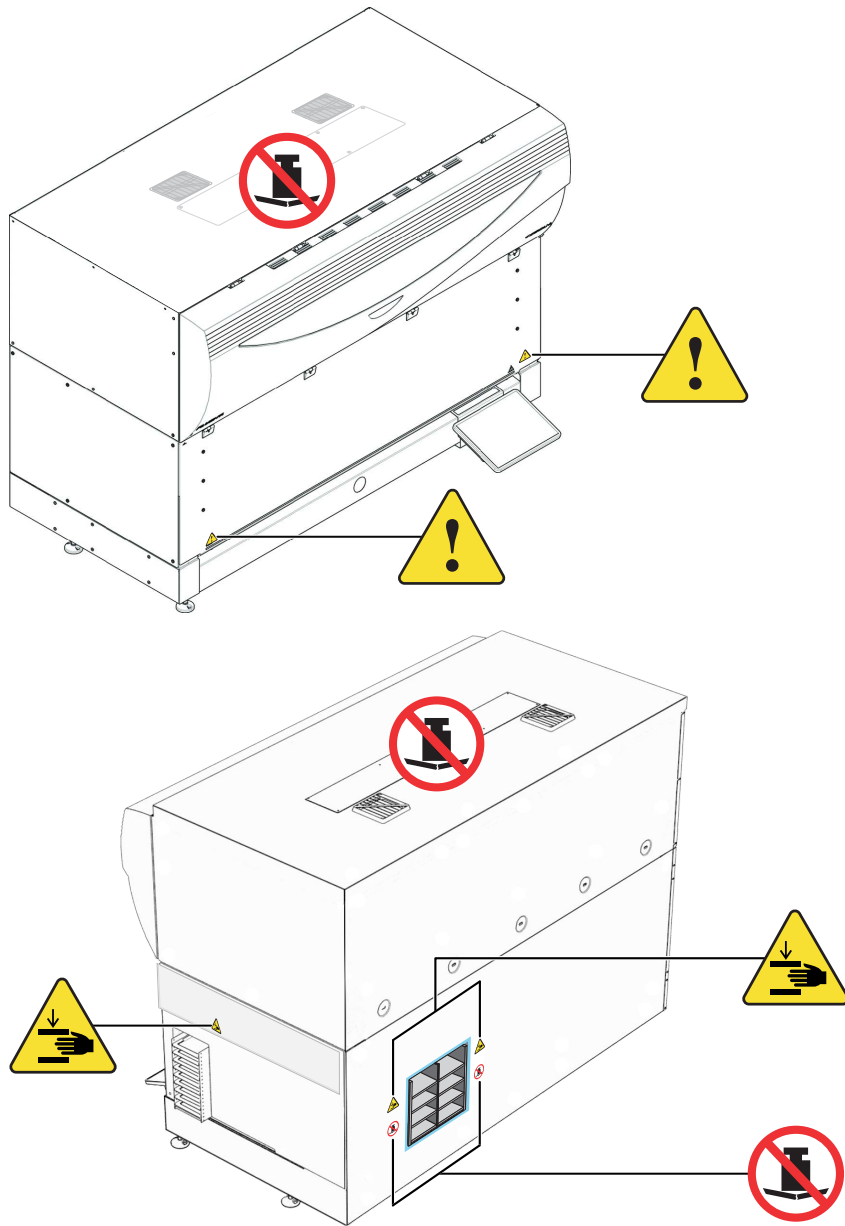


Figure 58 Tecan™ Fluent™ 780 Automation Workstation

### Location of safety labels—Module 2 system instruments

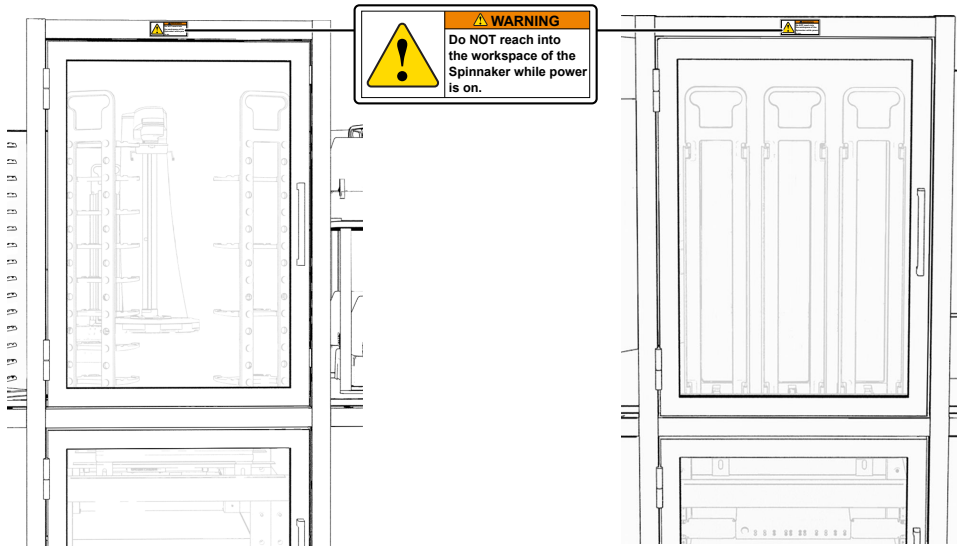


Figure 59 Module 2 system doors

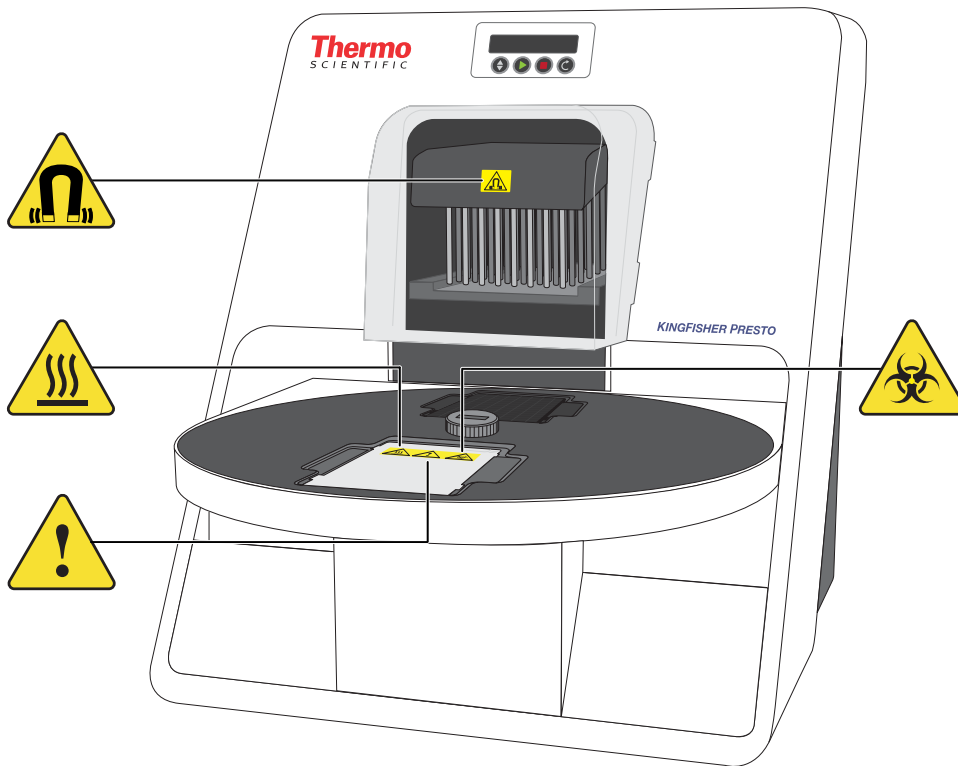
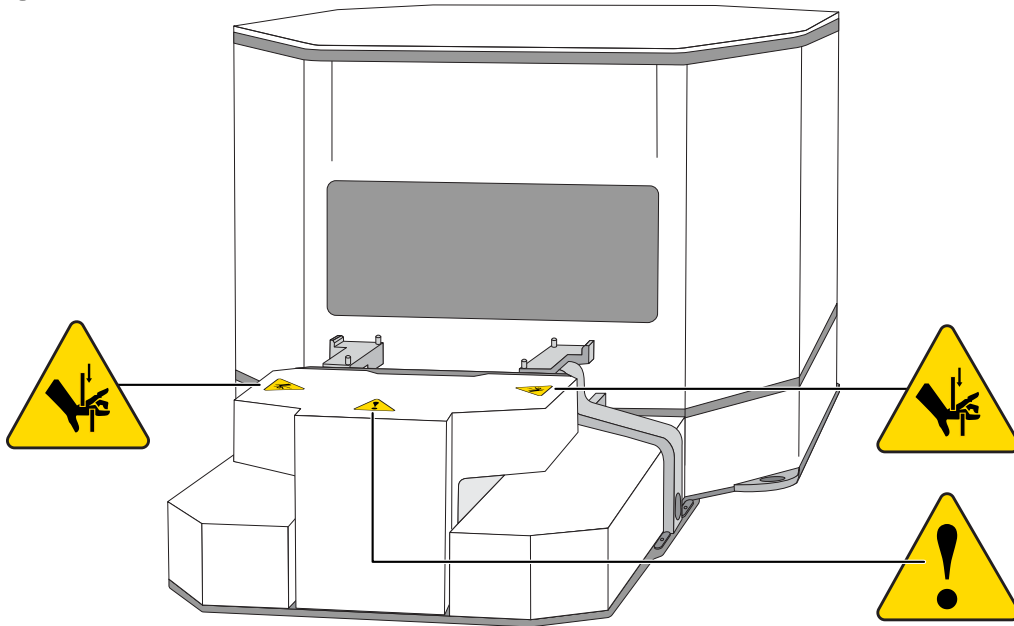


Figure 60 KingFisher™ Presto Purification System

①



②

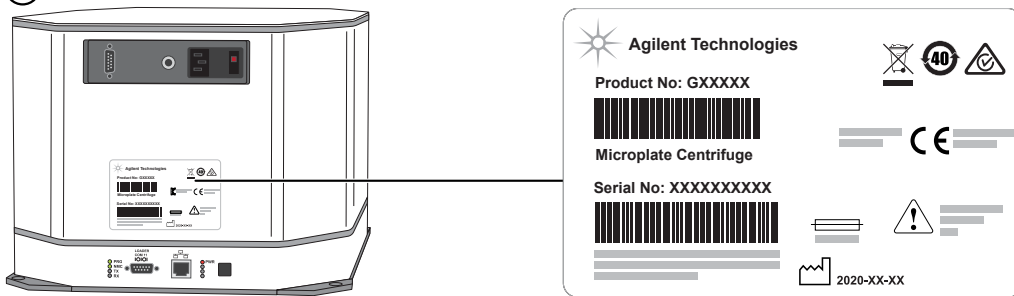


Figure 61 Agilent™ Microplate Centrifuge

- ① Front view
- ② Rear view



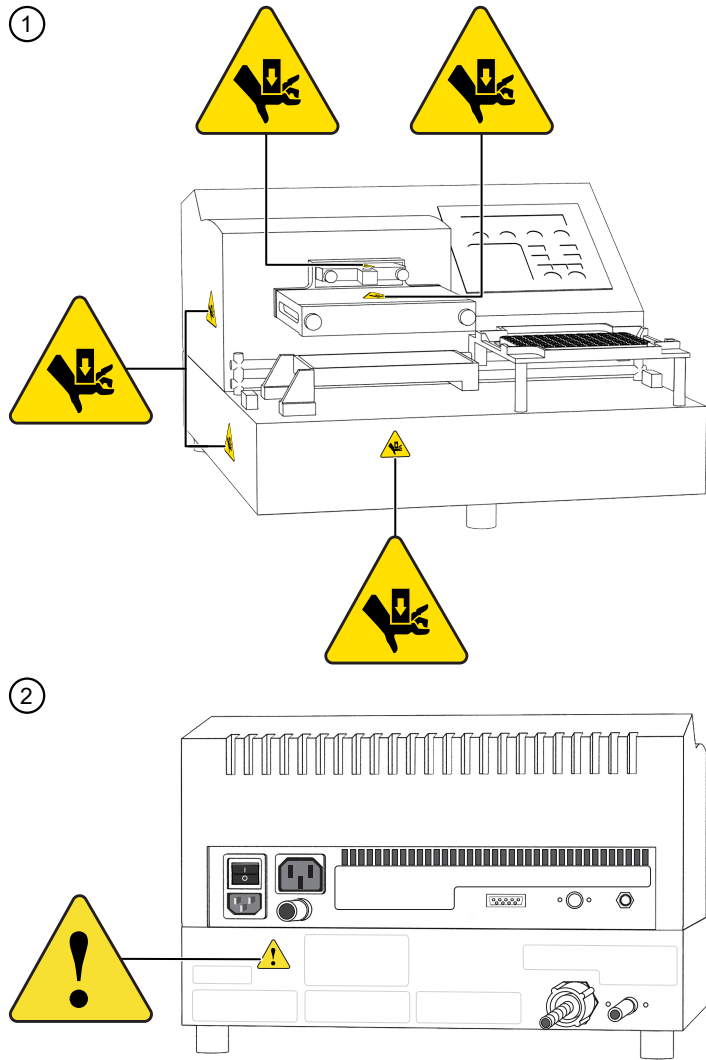


Figure 62 BioTek™ ELx405™ Select Microplate Washer

- ① Front view
- ② Rear view

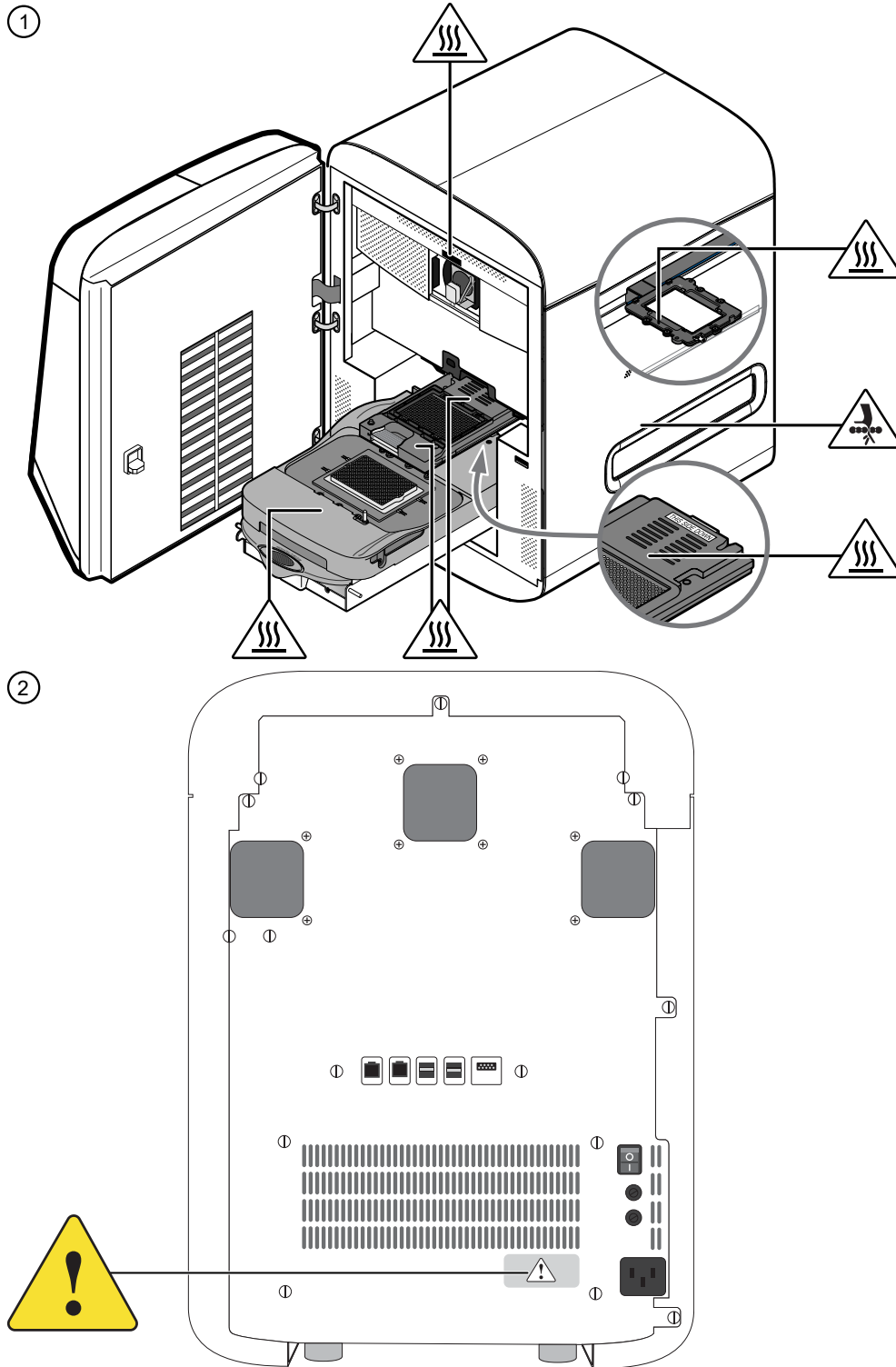


Figure 63 QuantStudio™ 7 Flex Real-Time PCR System

- ① Front view
- ② Rear view

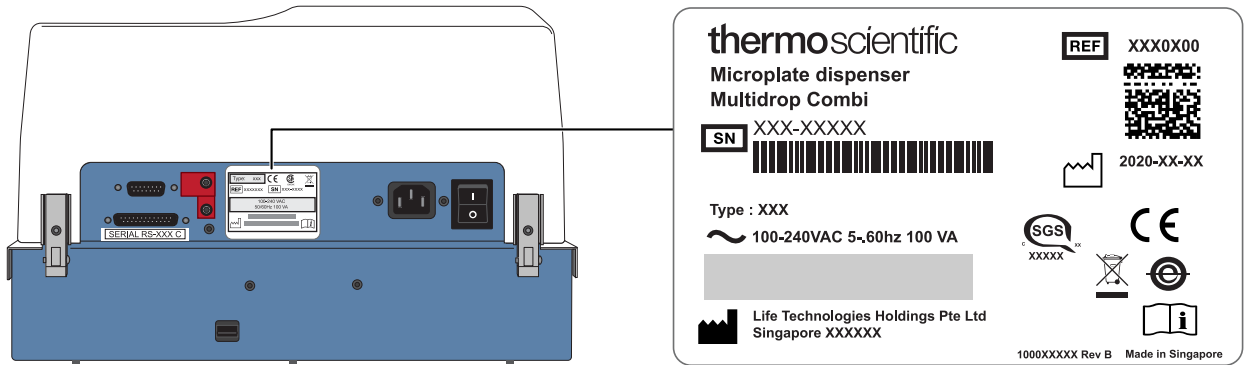


Figure 64 Multidrop™ Combi Reagent Dispenser

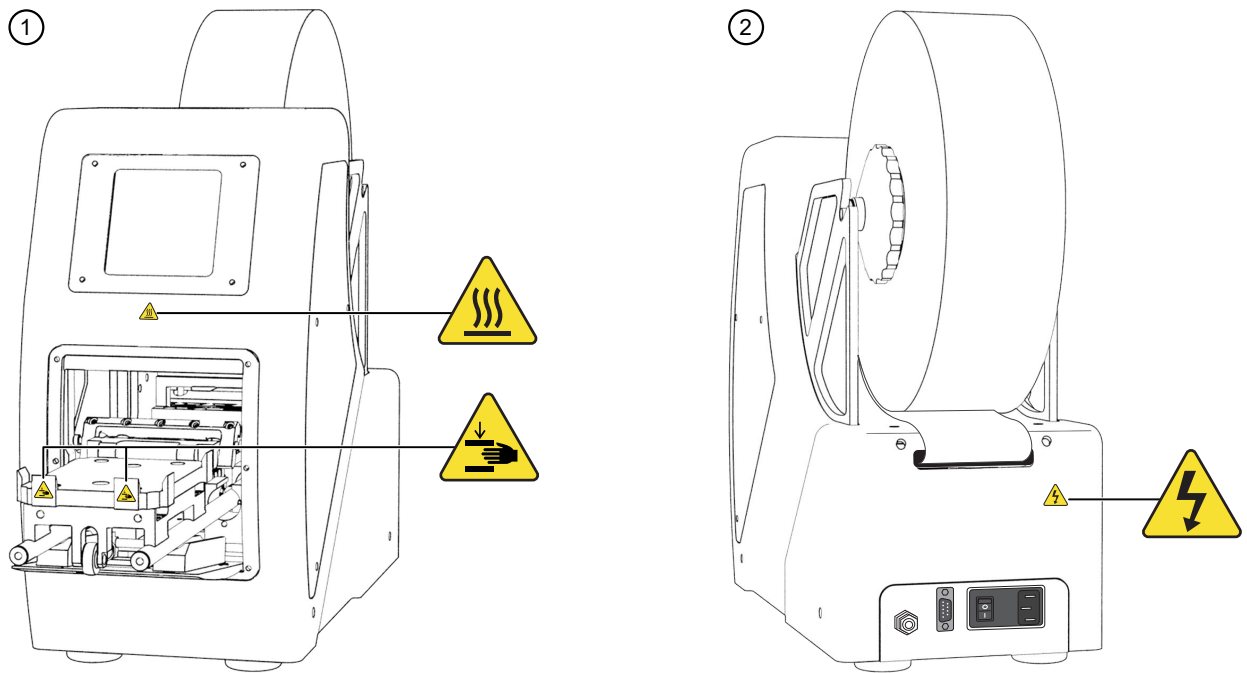


Figure 65 ALPS™ 3000 Automated Microplate Heat Sealer

- ① Front view
- ② Rear view

## Control and connection symbols

Symbols and descriptions	
	On (Power)
○	Off (Power)





(continued)

Symbols and descriptions	
	Earth (ground) terminal
	Protective conductor terminal (main ground)
	Direct current
	Alternating current
	Both direct and alternating current

## Conformity symbols

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

(continued)

Conformity mark	Description
 	Indicates conformity with requirements for safety with Japanese requirements.
	Indicates conformity with the WEEE Directive 2012/19/EU.   <b>CAUTION!</b> To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

## Safety 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

For complete safety information for each instrument that is used in the Amplitude™ Solution workflow, consult the individual instrument Instructions for Use or User Manual.



## 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.
- Ensure that sources of flame or ignition are kept away from ethanol.

Instruments are not considered user-serviceable, except as provided in these Instructions for Use. See individual instrument Instructions for Use for fuse ratings for individual instruments.

## Physical injury



**CAUTION! Moving and Lifting Injury.** The instruments are 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 instruments 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 instruments. Disconnect power before servicing.



**WARNING!** Heating elements that are included in the Amplitude™ Solution system can produce hazards related to explosion and release of toxic flammable gases. Do not supply consumables or reagents to the system, other than those described in these Instructions for Use.

## 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! Voltage Selector Switch.** Before installing the instrument, verify that the voltage selector switch is set for the supply voltage. This will prevent damage to the instrument, reduce risk of fire, and enable proper operation.



**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.



**WARNING!** For safety, the power outlets for the system components must be accessible at all times. Do not block access to the power outlets associated with Module 1, Module 2, or individual instruments.

## Instrument component and accessory disposal

To minimize negative environmental impact from disposal of electronic waste, do not dispose of electronic waste in unsorted municipal waste. Follow local municipal waste ordinances for proper disposal provision and contact customer service for information about responsible disposal options.

## Laser safety



**WARNING! LASER HAZARD.** Under normal operating conditions, the Tecan™ Fluent™ 1080 Automation Workstation is categorized as a Class 1 laser product. However, removing the protective covers and (when applicable) defeating the interlock(s) may result in exposure to the internal Class 2(II) laser. Lasers can burn the retina, causing permanent blind spots. To ensure safe laser operation:

- Never look directly into the laser beam.
- Do not remove safety labels, instrument protective panels, or defeat safety interlocks.
- The system must be installed and maintained by a Thermo Fisher Scientific Technical Representative.
- Remove jewelry and other items that can reflect a laser beam into your eyes or those of others
- Wear proper eye protection and post a laser warning sign at the entrance to the laboratory if the laser protection is defeated for servicing
- DO NOT operate the laser when it cannot be cooled by its cooling fan; an overheated laser can cause severe burns on contact.

The following table lists laser safety symbols and alerts that may be present on the instrument.

Alert	
	<b>CAUTION! LASER HAZARD, Bar Code Scanner.</b> The bar code scanner included with the instrument system is a Class 2 laser. To avoid damage to eyes, do not stare directly into the beam or point into another person's eyes.
	<b>CAUTION!</b> Class 2(II) visible and/or invisible laser radiation present when open. Do not stare directly into the beam or view directly with optical instruments.
	<b>DANGER!</b> Class (III) visible and/or invisible laser radiation present when open . Avoid exposure to beam.
	<b>DANGER!</b> Class 4(IV) visible and/or invisible laser radiation present when open . Avoid eye or skin exposure to direct or scattered radiation.

## Safety and electromagnetic compatibility (EMC) standards

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






## Safety standards

Reference	Description
IEC 61010-1:2010+A1 UL 61010-1:2012 R7.19 CAN/CSA C22.2 No. 61010-1-12 + GI1 + GI2 (R2017) + A1	Safety requirements for electrical equipment for measurement, control, and laboratory use - part 1: general requirements.
IEC 61010-2-010:2019 UL 61010-2-010:2019 CSA C22.2 No. 61010-2-010:19	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-081:2019 UL 61010-2-081:2019 CSA C22.2 No. 61010-2-081:19	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
IEC 61010-2-101:2018 UL 61010-2-101:2019 CSA C22.2 No. 61010-2-101:19	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment



## EMC standards

Reference	Description
IEC 61326-1:2020	<p><i>Electrical equipment for measurement, control and laboratory use — EMC requirements Part 1: General requirements</i></p> <p>This product has been designed and tested to CISPR11 Class A. It is suitable for use in a professional, healthcare, or laboratory environment.</p>
IEC 61326-2-6:2020 <sup>[1]</sup>	<p><i>Electrical equipment for measurement, control and laboratory use — EMC requirements Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment</i></p> <p>It is the user’s responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order for this device to perform as intended.</p> <p>Keep mobile phones at least 2 meters (6 feet) away from the Amplitude™ Solution system.</p> <p>The Amplitude™ Solution system complies with the emission and immunity requirements of IEC 61326-2-6.</p> <p> <b>WARNING!</b> This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.</p> <p>This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.</p> <p>It is advised that the electromagnetic environment should be evaluated prior to operation of the device.</p> <p>Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.</p>
CISPR 11:2019	<p><i>Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement</i></p>

(continued)

Reference	Description
FCC Part 15 class "A" (47 CFR)	<p><i>U.S. Standard Radio Frequency Devices</i></p> <p><b>Note:</b> 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.</p> <p>This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.</p> <p>Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.</p>
ICES-001 Issue 5 Class "A"	<p><i>Industrial, Scientific and Medical (ISM) Equipment</i></p> <p>ISED Compliance Label: CAN ICES-001 (A) / NMB-001 (A)</p>
ICES-003 Issue 7 Class "A"	<p><i>Information Technology Equipment (including Digital Apparatus)</i></p>

<sup>[1]</sup> Test levels from IEC 60601-1-2:2014 were applied.

## Environmental design standards

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



## Radio compliance standards

Reference	Description
RFID	<p>FCC Notice (for U.S. Customers):</p> <p>This device complies with Part 15 of the FCC Rules:</p> <p>Operation is subject to the following conditions:</p> <ol style="list-style-type: none"><li>1. This device may not cause harmful interference, and</li><li>2. This device must accept any interference received, Including interference that may cause undesired operation.</li></ol> <p>Changes and modifications not expressly approved by Thermo Fisher Scientific can void your authority to operate this equipment under Federal Communications Commissions rules.</p>
RFID	<p>Canada (English):</p> <p>This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:</p> <p>(1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.</p>
RFID	<p>Canada (Français):</p> <p>Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :</p> <p>(1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage adioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.</p>

## Chemical safety



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

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



**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.



**WARNING!** Do not use bleach on the Amplitude™ Solution system, as it may react with reagents used in the Amplitude™ Solution workflow to produce toxic gas.

For information on cleaning up sample and reagent spills, refer to individual instrument manuals.

## Biological hazard safety



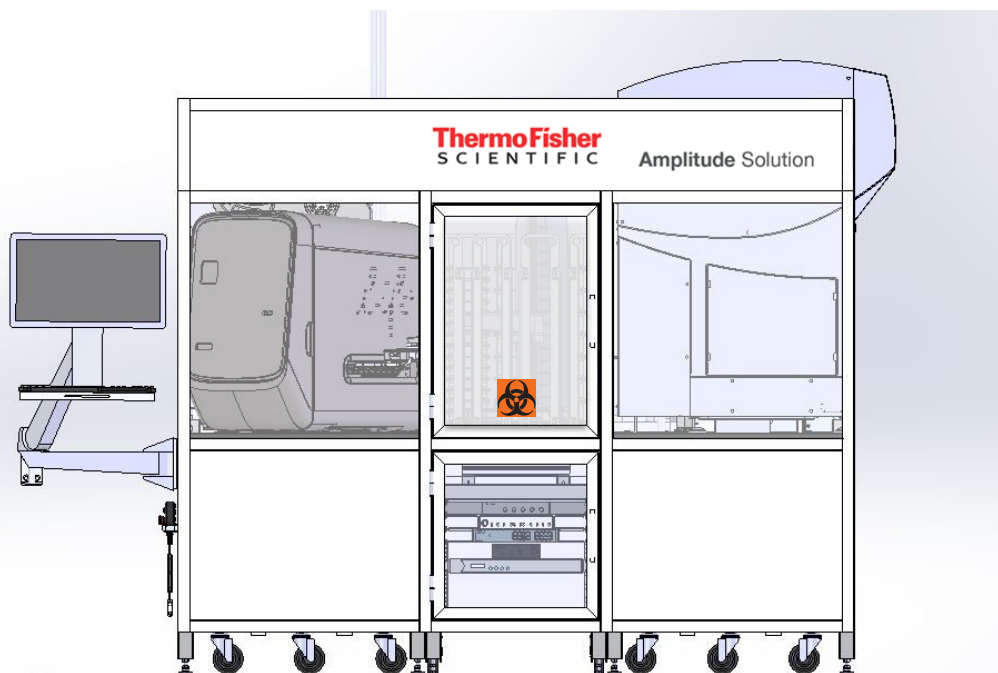
**WARNING! Potential Biohazard.** Depending on the samples used on this instrument, the surface may be considered a biohazard. Use appropriate decontamination methods when working with biohazards.



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

- U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition, HHS Publication No. (CDC) 300859, Revised June 2020  
<https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2020-P.pdf>
- Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs)  
[www.who.int/publications/i/item/9789240011311](http://www.who.int/publications/i/item/9789240011311)

**Note:** When the use of the system includes a biohazard, Thermo Fisher Scientific recommends placing a biohazard label on the Module 2 door as depicted in the following figure.





# Documentation and support

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## Related documentation

Document	Publication Number
<i>Amplitude™ Solution with TaqPath™ COVID-19 High-Throughput Combo Kit—Module 1 Quick Reference</i>	MAN0019429
<i>Amplitude™ Solution with TaqPath™ COVID-19 High-Throughput Combo Kit—Module 2 Quick Reference</i>	MAN0019430
<i>Amplitude™ Solution Site Preparation Guide</i>	MAN0019491
<i>Amplitude Solution Module 2 Help Resource</i>	N/A; directly distributed to customer
<i>QuantStudio™ 6 and 7 Flex Real-Time PCR Systems (v1.6.1 or later) Maintenance and Administration Guide</i>	MAN0018828
<i>QuantStudio™ 6 and 7 Flex Real-Time PCR Systems (v1.6.1 or later) Quick Reference</i>	MAN0018829
<i>QuantStudio™ Real-Time PCR Software Getting Started Guide</i>	4489822
<i>MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (automated extraction) User Guide</i>	MAN0018073
<i>Thermo Scientific™ KingFisher™ Presto User Manual</i>	N17413
<i>Thermo Scientific™ Multidrop™ Combi User Manual</i>	N05616
<i>ALPS™ 3000 Automated Microplate Heat Sealer User Manual</i>	MNLALPS3000
<i>Tecan™ Fluent™ Operating Manual</i>	399706
<i>Tecan™ Fluent™ Reference Manual</i>	399937
<i>Tecan™ Fluent™ Service Manual</i>	399934



## Customer and technical support

For additional information about the system, visit [thermofisher.com/amplitude](https://www.thermofisher.com/amplitude).

For order support, contact Customer Care at [amplitude.cs@thermofisher.com](mailto:amplitude.cs@thermofisher.com).

For technical support, contact [priority.support@thermofisher.com](mailto:priority.support@thermofisher.com) or 1 800 711 6195.

For Certificates of Analysis and Safety Data Sheets (SDSs; also known as MSDSs), visit [thermofisher.com/contactus](https://www.thermofisher.com/contactus).

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

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## Download a Safety Data Sheet (SDS)

1. Go to [thermofisher.com](https://www.thermofisher.com), then select SDS from the **Search All** dropdown list.
2. Search for the product catalog number or REF.
3. Select the product catalog number or REF of interest, select the region and language, then download the SDS.

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

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## Removal or disposal of the Amplitude™ Solution system

For information on removal or disposal of the Amplitude™ Solution system, contact Customer Care.

## 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](https://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](https://www.thermofisher.com/support).



