QlAstat-Dx® Analyzer 1.0 Installation Guide

For use with software version 1.2.x or higher

IVD CE

REF

REF

9002824 (QIAstat-Dx Analyzer 1.0, complete system)

REF 9002814 (QIAstat-Dx Analytical Module)

9002813 (QIAstat-Dx Operational Module)

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Introduction

About this installation guide

This guide provides an overview for installing QIAstat-Dx Analyzer 1.0 instruments.

IMPORTANT: Before using the QIAstat-Dx Analyzer 1.0, it is essential that you read the QIAstat-Dx Analyzer 1.0 User Manual carefully and pay particular attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

Information about installing the QIAstat-Dx Analyzer 1.0 is provided in the following sections:

- Site requirements
- QIAstat-Dx Analyzer 1.0 delivery and components
- Unpacking and installing the QIAstat-Dx Analyzer 1.0
- Installing additional Analytical Modules

WARNING/ CAUTION



Risk of personal injury and material damage

The QIAstat-Dx Analyzer 1.0 is a heavy instrument. To avoid personal injury or damage to the QIAstat-Dx Analyzer 1.0, take care when lifting it and use appropriate lifting methods.

Installation Procedures

Site requirements

Select a flat, dry and clean workbench space for the QIAstat-Dx Analyzer 1.0. Make sure that the space is free of excessive drafts, moisture and dust, as well as protected from direct sunlight, large temperature fluctuations, heat sources, vibration and electrical interference. Refer to the QIAstat-Dx Analyzer 1.0 User Manual for the weight and dimensions of the QIAstat-Dx Analyzer 1.0 and the correct operating conditions (temperature and humidity). The QIAstat-Dx Analyzer 1.0 should have sufficient clearance on all sides to enable proper ventilation and to allow unimpeded access to the cartridge entrance port, the back of the QIAstat-Dx Analyzer 1.0, the power switch, the ON/OFF button, the bar code reader and the touchscreen.

Note: Before installing and using the QIAstat-Dx Analyzer 1.0, refer to the *QIAstat-Dx Analyzer* 1.0 User Manual to become familiar with the QIAstat-Dx Analyzer 1.0 operating conditions.

CAUTION



Impeded ventilation

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the rear of the QIAstat-Dx Analyzer 1.0 and do not block airflow under the unit.

Slits and openings that ensure instrument ventilation must not be covered.

CAUTION



Electromagnetic interference

Do not place or use the QIAstat-Dx Analyzer 1.0 in close proximity of sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these can interfere with proper operation.

QIAstat-Dx Analyzer 1.0 delivery and components

The QIAstat-Dx Analyzer 1.0 is delivered in two separate boxes and includes all the necessary components for setting up and operating the system. The contents of the boxes are described below:

Box 1 contents

Component	Description
	1x Analytical Module
	1x USB storage device
	1x Power cord

	1x Analytical/Analytical Module Bridge
	1x Termination Bridge
	1x Analytical-Operational Module Assembly Tool
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	1x Protective Cover Removal Tool

Box 2 contents

Component	Description
	1x Operational Module
	1x Analytical/Operational Module Bridge

Unpacking and installing the QIAstat-Dx Analyzer 1.0

Carefully unpack the QIAstat-Dx Analyzer 1.0 according to the following steps:

1. Remove the Analytical Module from its box and place it on a level surface. Remove the foam pieces attached to the Analytical Module.

Note: The Analytical Module must be lifted and handled by taking it from the base with two hands, as shown in Figure 1.

WARNING/ CAUTION

Risk of personal injury and material damage



The QIAstat-Dx Analyzer 1.0 is a heavy instrument. To avoid personal injury or damage to the QIAstat-Dx Analyzer 1.0, take care when lifting it and use appropriate lifting methods.

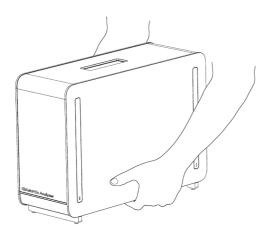


Figure 1. Proper handling of Analytical Module.

2. Remove the protective covers from the side of the Analytical Module using the Protective Cover Removal Tool delivered with the QIAstat-Dx Analyzer 1.0 (Figure 2).

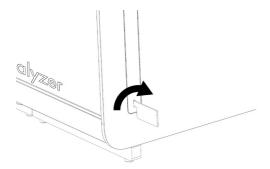


Figure 2. Removing protective covers.

 Remove the Operational Module from its box and attach it to the left side of the Analytical Module. Tighten the screws using the Analytical-Operational Module Assembly Tool delivered with the QIAstat-Dx Analyzer 1.0 (Figure 3).

CAUTION

Risk of mechanical damage

Do not leave the Operational Module without support or resting on the touchscreen, as this may damage the touchscreen.



Figure 3. Attaching the Operational Module to the Analytical Module.

4. Reattach the protective covers on the side of the Analytical Module (Figure 4).



Figure 4. Reattaching the protective covers.

5. Connect the Analytical/Operational Module Bridge at the back of the QIAstat-Dx Analyzer 1.0 to link the Operational and Analytical Modules together (Figure 5).

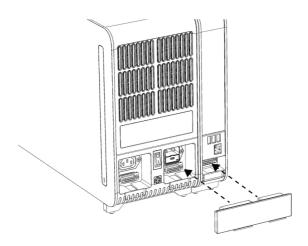


Figure 5. Connecting the Analytical/Operational Module Bridge.

6. Connect the Termination Bridge at the back of the Analytical Module (Figure 6).

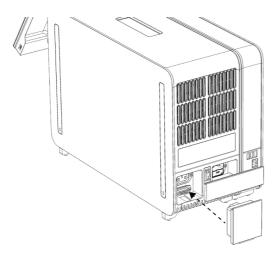


Figure 6. Connecting the Termination Bridge.

7. Connect the power cord that was delivered with the QIAstat-Dx Analyzer 1.0 to the back of the Analytical Module (Figure 7).

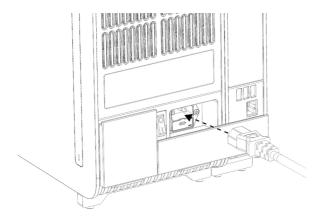


Figure 7. Connecting the power cord.

- 8. Connect the power cord to a power outlet.
- 9. Power ON the instrument by pressing the power switch on the back of the Analytical Module to the "I" position (Figure 8). Confirm that the status indicators of the Analytical and Operational Modules are blue.

Note: If a status indicator is red, there is a malfunction in the Analytical Module. Contact QIAGEN Technical Services.

Note: The instrument must not be positioned so that it is difficult to operate the power switch.

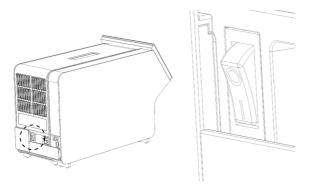


Figure 8. Locating the power switch and setting it to the "I" position.

10. The QIAstat-Dx Analyzer 1.0 is now ready to be configured for its intended use. Refer to Section 6.7 in the QIAstat-Dx Analyzer 1.0 User Manual to configure the system parameters, set the system time and date, and configure the network connection.

Installing additional Analytical Modules

Carefully unpack the additional Analytical Module and install it according to the following steps:

- 1. Prepare the QIAstat-Dx Analyzer 1.0 for installation of the new module:
 - 1a. Power OFF the system by pressing the ON/OFF button on the front of the QIAstat-Dx Analyzer 1.0.
 - 1b. Power OFF the instrument by pressing the power switch on the back of the Analytical Module to the "O" position.
 - 1c. Remove the power cable.
 - 1d. Remove the Termination Bridge from the back of the Analytical Module (Figure 9).

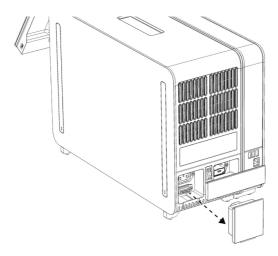


Figure 9. Removing the Termination Bridge.

1e. Remove the protective covers from the side of the Analytical Module, which is where the additional Analytical Module will be attached (Figure 10).

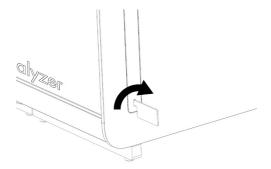


Figure 10. Removing protective covers.

2. Remove the additional Analytical Module from its box and place it on a level surface. Remove the foam pieces attached to the Analytical Module.

Note: The Analytical Module must be lifted and handled by taking it from the base with two hands, as shown in Figure 11, next page.

WARNING/ CAUTION



Risk of personal injury and material damage

The QIAstat-Dx Analyzer 1.0 is a heavy instrument. To avoid personal injury or damage to the QIAstat-Dx Analyzer 1.0, take care when lifting it and use appropriate lifting methods.

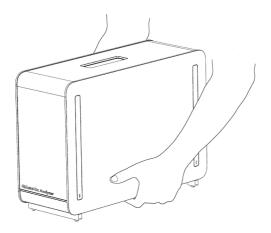


Figure 11. Proper handling of Analytical Module.

3. Remove the protective covers from the side of the Analytical Module using the Protective Cover Removal Tool delivered with the QIAstat-Dx Analyzer 1.0 (Figure 12).

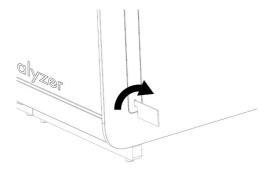


Figure 12. Removing protective covers.

4. Align the additional Analytical Module with the existing Analytical Module. Tighten the screws using the Analytical-Operational Module Assembly Tool delivered with the QIAstat-Dx Analyzer 1.0 (Figure 13).

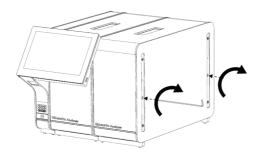


Figure 13. Aligning and attaching the additional Analytical Module.

5. Reattach the protective covers on the side of the additional Analytical Module (Figure 14).

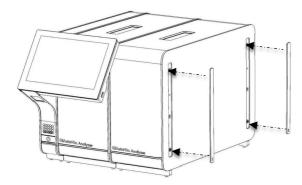


Figure 14. Reattaching protective covers on the additional Analytical Module.

6. Connect the Analytical/Analytical Module Bridge at the back of the QIAstat-Dx Analyzer 1.0 to link the two Analytical Modules together (Figure 15).

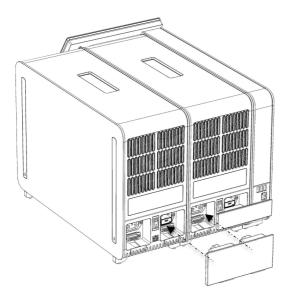


Figure 15. Connecting the Analytical/Analytical Module Bridge.

7. Connect the Termination Bridge at the back of the Analytical Module (Figure 16).

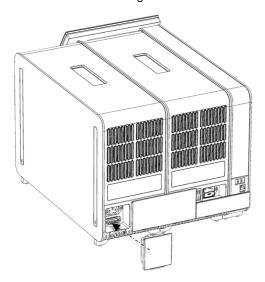


Figure 16. Connecting the Termination Bridge.

8. Connect the power cord that was delivered with the QIAstat-Dx Analyzer 1.0 to the back of the original Analytical Module (Figure 17).

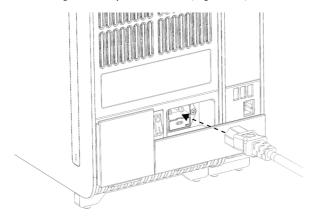


Figure 17. Connecting the power cord.

- 9. Connect the power cord to a power outlet.
- 10. Power ON the instrument by pressing the power switch on the back of the Analytical Module to the "I" position (Figure 18). Confirm that the status indicators of the Analytical and Operational Modules are blue.

Note: If a status indicator is red, there is a malfunction in the Analytical Module. Contact QIAGEN Technical Services.

Note: The instrument must not be positioned so that it is difficult to operate the power switch.

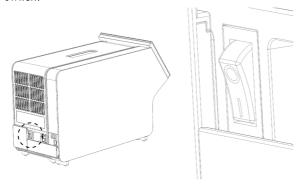


Figure 18. Locating the power switch and setting it to the "I" position.

11. The QIAstat-Dx Analyzer 1.0 is now ready to be configured for its intended use. Refer to Section 6.7 in the QIAstat-Dx Analyzer 1.0 User Manual to configure the system parameters, set the system time and date, and configure the network connection.

Document Revision History

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Document	Revision	History

Revision 1 HB-2637-001

04/2019

Initial release. For use with software version $1.2.x\ or$

higher.

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