applied biosystems

StepOne™ and StepOnePlus™ Real-Time PCR Systems

SITE PREPARATION GUIDE

Publication Number 4376768

Revision E

ThermoFisher SCIENTIFIC

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

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Revision history

Table 1 Revision history of Pub. no. 4376768

Revision	Date	Description
E	January 2016	Minor update in environmental requirements. Update in logos and covers.

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Notice to Purchaser: The purchase of this instrument conveys to the purchaser the limited, non-transferable right to use the purchased instrument only, under intellectual property rights that are owned and/or controlled by Life Technologies and relate specifically to the instrument. Purchase of the instrument includes the right to use the instrument for internal research and to perform services (including the right to report the results of services for a fee) by the purchaser only, but does not convey rights to use any other products, reagents, assays or methods such as the 5' nuclease assay process. The sale of this instrument is expressly conditioned on the purchaser not reselling, repackaging, or distributing this instrument, or any of its components, and no such rights are conveyed expressly, by implication, or by estoppel. For information on obtaining additional rights, please contact **outlicensing@lifetech.com** or Out Licensing, Life Technologies, 5791 Van Allen Way, Carlsbad, California 92008.

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TRADEMARKS

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Preface

How to Use This Guide

Purpose of This Guide

This guide helps you prepare to receive and install the Applied Biosystems StepOne™ or StepOnePlus™ Real-Time PCR System.

Audience

This guide is intended for personnel who will schedule, manage, and perform the tasks required to prepare your site for installation of the StepOne™ and StepOnePlus™ systems.

Assumptions

This guide assumes that you have:

- Familiarity with Microsoft Windows® XP operating system.
- Familiarity with the Internet and internet browsers.
- Knowledge of techniques for handling DNA samples and preparing them for PCR.
- An understanding of data storage, file transfer, and copying and pasting.
- Networking experience, if you plan to integrate the StepOne™ system into your existing laboratory data flow.

Text Conventions

This guide uses the following conventions:

- **Bold** text indicates user action. For example:

  Type **0**, then press **Enter** for each of the remaining fields.
- *Italic* text indicates new or important words and is also used for emphasis. For example:

  Before analyzing, *always* prepare fresh matrix.
- A right arrow symbol (▸) separates successive commands you select from a drop-down or shortcut menu. For example:

  Select **File ▸ Open ▸ Spot Set**.

User Attention Words

Two user attention words appear in the user documentation. Each word implies a particular level of observation or action as described below:

Note: – Provides information that may be of interest or help but is not critical to the use of the product.

IMPORTANT! – Provides information that is necessary for proper instrument operation, accurate chemistry kit use, or safe use of a chemical.

How to Obtain More Information

Related Documentation

The following documentation ships with the StepOne™ and StepOnePlus™ systems:

Document	PN
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Getting Started Guide for Genotyping Experiments	4376786
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Getting Started Guide for Presence/Absence Experiments	4376787
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Getting Started Guide for Relative Standard Curve and Comparative C_T ($\Delta\Delta C_T$) Experiments	4376785
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Getting Started Guide for Standard Curve Experiments	4376784
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Installation, Maintenance, and Networking Guide	4376782
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Installation Quick Reference Card	4376783
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Site Preparation Guide	4376768
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Software Help	—

The following supporting StepOne™ and StepOnePlus™ systems documentation is available for purchase:

Document	PN
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR System Installation Performance Verification Protocol	4376791
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR System Installation Qualification-Operation Qualification Protocol	4376790
Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR System Planned Maintenance Protocol	4376788

Note: For additional documentation, see "How to Obtain Support" on page 7.

Obtaining Information from the Help System

The StepOne™ Software has a Help system that describes how to use each feature of the user interface. Access the Help system by doing one of the following:

- If displayed, click in the toolbar of the StepOne™ Software window
- Select **Help ▸ Contents and Index**
- Press **F1**

You can use the Help system to find topics of interest by:

- Reviewing the table of contents
- Searching for a specific topic
- Searching an alphabetized index

Send Us Your Comments

We welcome your comments and suggestions for improving its user documents. You can e-mail your comments to:

techpubs@appliedbiosystems.com

IMPORTANT! The e-mail address above is only for submitting comments and suggestions relating to documentation. To order documents, download PDF files, or for help with a technical question, go to **http://www.appliedbiosystems.com**, then click the link for **Support**. (See "How to Obtain Support" below).

How to Obtain Support

For the latest services and support information for all locations, go to **http://www.appliedbiosystems.com**, then click the link for **Support**.

At the Support page, you can:

- Search through frequently asked questions (FAQs)
- Submit a question directly to Technical Support
- Order user documents, MSDSs, certificates of analysis, and other related documents
- Download PDF documents
- Obtain information about customer training
- Download software updates and patches

In addition, the Support page provides access to worldwide telephone and fax numbers to contact Technical Support and Sales facilities.

Safety Conventions Used in This Document

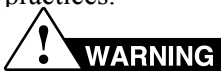
Safety Alert Words

Four safety alert words appear in the user documentation at points in the document where you need to be aware of relevant hazards. Each alert word—**IMPORTANT, CAUTION, WARNING, DANGER**—implies a particular level of observation or action, as defined below.

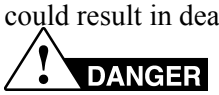
Definitions

IMPORTANT! – Indicates information that is necessary for proper instrument operation, accurate chemistry kit use, or safe use of a chemical.

– 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.



– Indicates a potentially hazardous situation that, if not avoided, could result in death or serious injury.



– Indicates an imminently hazardous situation that, if not avoided, will result in death or serious injury. This signal word is limited to the most extreme situations.

Except for IMPORTANTs, each safety alert word in the document appears with an open triangle figure that contains a hazard symbol. These hazard symbols are identical to the hazard symbols that are affixed to the instruments (see "Safety Symbols" on page 9).

Examples

IMPORTANT! You must create a separate sample entry spreadsheet for each 96-well plate.

CHEMICAL HAZARD. **TaqMan Universal PCR Master Mix** may cause eye and skin irritation. Exposure may cause discomfort if swallowed or inhaled. Read the MSDS, and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves.

PHYSICAL INJURY HAZARD. During instrument operation, the heated cover and sample block can reach temperatures in excess of 100 °C.

ELECTRICAL HAZARD. Grounding circuit continuity is vital for the safe operation. Never operate the instrument with the grounding conductor disconnected.

Symbols on Instruments

Electrical Symbols on Instruments

The following table describes the electrical symbols that may be displayed on the instruments.

Symbol	Description
	Indicates the **On** position of the main power switch.
	Indicates the **Off** position of the main power switch.
	Indicates a standby switch by which the instrument is switched on to the **Standby** condition. Hazardous voltage may be present if this switch is on standby.
	Indicates the **On/Off** position of a push-push main power switch.

Symbol	Description
	Indicates a terminal that may be connected to the signal ground reference of another instrument. This is not a protected ground terminal.
	Indicates a protective grounding terminal that must be connected to earth ground before any other electrical connections are made to the instrument.
	Indicates a terminal that can receive or supply alternating current or voltage.
	Indicates a terminal that can receive or supply alternating or direct current or voltage.

Safety Symbols

The following table describes the safety *s*ymbols that may be displayed on the instruments. Each symbol may appear by itself or with text that explains the relevant hazard (see "Safety Labels on Instruments" on page 10). These safety symbols may also appear next to DANGERS, WARNINGS, and CAUTIONS that occur in the text of this and other product-support documents.

Symbol	Description
	Indicates that you should consult the manual for further information and to proceed with appropriate caution.
	Indicates the presence of a hot surface or other high-temperature hazard and to proceed with appropriate caution.

Symbol	Description
	Indicates the presence of moving parts and to proceed with appropriate caution.
	Indicates the presence of an electrical shock hazard and to proceed with appropriate caution.
	Indicates the presence of a laser inside the instrument and to proceed with appropriate caution.

Environmental Symbols on Instruments

The following symbol applies to all electrical and electronic products placed on the European market after August 13, 2005.

Symbol	Description
	**Do not dispose of this product as unsorted municipal waste.** Follow local municipal waste ordinances for proper disposal provisions to reduce the environmental impact of waste electrical and electronic equipment (WEEE). **European Union customers:** Call your local Customer Service office for equipment pick-up and recycling. See **http://www.appliedbiosystems.com** for a list of customer service offices in the European Union.

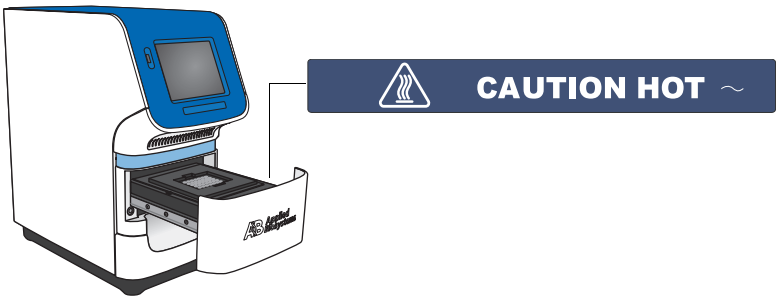
Safety Labels on Instruments

The following CAUTION, WARNING, and DANGER statements may be displayed on the instruments in combination with the safety symbols described in the preceding section.

English	Francais
CAUTION Hazardous chemicals. Read the Material Safety Data Sheets (MSDSs) before handling.	**ATTENTION** Produits chimiques dangeureux. Lire les fiches techniques de sûreté de matériels avant la manipulation des produits.
CAUTION Hazardous waste. Refer to MSDS(s) and local regulations for handling and disposal.	**ATTENTION** Déchets dangereux. Lire les fiches techniques de sûreté de matériels et la régulation locale associées à la manipulation et l'élimination des déchets.
CAUTION Hot surface.	**ATTENTION** Surface brûlante.
DANGER High voltage.	**DANGER** Haute tension.
WARNING To reduce the chance of electrical shock, do not remove covers that require tool access. No user-serviceable parts are inside. Refer servicing to qualified service personnel.	**AVERTISSEMENT** Pour éviter les risques d'électrocution, ne pas retirer les capots dont l'ouverture nécessite l'utilisation d'outils. L'instrument ne contient aucune pièce réparable par l'utilisateur. Toute intervention doit être effectuée par le personnel de service qualifié de Thermo Fisher Scientific.
CAUTION Moving parts.	**ATTENTION** Parties mobiles.
DANGER Class 3B (III) visible and/or invisible LED radiation present when open and interlocks defeated. Avoid exposure to beam.	**DANGER** Rayonnement visible ou invisible d'un faisceau LED de Classe 3B, (III) en cas d'ouverture et de neutralisation des dispositifs de sécurité. Evitez toute exposition au faisceau.

Location of Warning

The StepOne™ and StepOnePlus™ instruments contain a warning label at the location shown below:



General Instrument Safety

WARNING **PHYSICAL INJURY HAZARD.** Using the instrument in a manner not specified by Thermo Fisher Scientific may result in personal injury or damage to the instrument.

Moving and Lifting the Instrument

CAUTION **PHYSICAL INJURY HAZARD.** The instrument is to be moved and positioned only by the personnel or vendor specified in the applicable site preparation guide. If you decide to lift or move the instrument after it has been installed, do not attempt to lift or move the instrument without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques. Improper lifting can cause painful and permanent back injury. Depending on the weight, moving or lifting an instrument may require two or more persons.

Moving and Lifting Standalone Computers and Monitors

WARNING Do not attempt to lift or move the computer or the monitor without the assistance of others. Depending on the weight of the computer and/or the monitor, moving them may require two or more people.

Things to consider before lifting the computer and/or the monitor:

- Make sure that you have a secure, comfortable grip on the computer or the monitor when lifting.
- 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.
- Instead of lifting the object from the packing box, carefully tilt the box on its side and hold it stationary while someone slides the contents out of the box.

Operating the Instrument

Ensure that anyone who operates the instrument has:

- Received instructions in both general safety practices for laboratories and specific safety practices for the instrument.
- Read and understood all applicable Material Safety Data Sheets (MSDSs). See "About MSDSs" on page 13.

Cleaning or Decontaminating the Instrument

CAUTION Before using a cleaning or decontamination method other than those recommended by the manufacturer, verify with the manufacturer that the proposed method will not damage the equipment.

Chemical Safety

Chemical Hazard Warning

WARNING **CHEMICAL HAZARD.** Before handling any chemicals, refer to the Material Safety Data Sheet (MSDS) provided by the manufacturer, and observe all relevant precautions.

WARNING **CHEMICAL STORAGE HAZARD.** Never collect or store waste in a glass container because of the risk of breaking or shattering. Reagent and waste bottles can crack and leak. Each waste bottle should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position. Wear appropriate eyewear, clothing, and gloves when handling reagent and waste bottles.

Chemical Safety Guidelines

To minimize the hazards of chemicals:

- Read and understand the Material Safety Data Sheets (MSDSs) provided by the chemical manufacturer before you store, handle, or work with any chemicals or hazardous materials. (See "About MSDSs" on page 13.)
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing). For additional safety guidelines, consult the MSDS.
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with adequate ventilation (for example, fume hood). For additional safety guidelines, consult the MSDS.
- Check regularly for chemical leaks or spills. If a leak or spill occurs, follow the manufacturer's cleanup procedures as recommended in the MSDS.
- Comply with all local, state/provincial, or national laws and regulations related to chemical storage, handling, and disposal.

About MSDSs

Chemical manufacturers supply current Material Safety Data Sheets (MSDSs) with shipments of hazardous chemicals to *new* customers. They also provide MSDSs with the first shipment of a hazardous chemical to a customer after an MSDS has been updated. MSDSs provide the safety information you need to store, handle, transport, and dispose of the chemicals safely.

Each time you receive a new MSDS packaged with a hazardous chemical, be sure to replace the appropriate MSDS in your files.

Obtaining MSDSs

The MSDS for any chemical supplied by us is available to you free 24 hours a day. To obtain MSDSs:

1. Go to **https://docs.appliedbiosystems.com/msdssearch.html**
2. In the Search field of the MSDS Search page:
   a. Type in the chemical name, part number, or other information that you expect to appear in the MSDS of interest.
   b. Select the language of your choice.
   c. Click **Search**.
3. To view, download, or print the document of interest:
   a. Right-click the document title.
   b. Select:
      - **Open** – To view the document
      - **Save Target As** – To download a PDF version of the document to a destination that you choose
      - **Print Target** – To print the document
4. To have a copy of an MSDS sent by fax or e-mail, in the Search Results page:
   a. Select **Fax** or **Email** below the document title.
   b. Click **RETRIEVE DOCUMENTS** at the end of the document list.
   c. Enter the required information.
   d. Click **View/Deliver Selected Documents Now**.

Note: For the MSDSs of chemicals not distributed by us, contact the chemical manufacturer.

Chemical Waste Safety

Chemical Waste Hazard

CAUTION **HAZARDOUS WASTE.** Refer to Material Safety Data Sheets and local regulations for handling and disposal.

WARNING **CHEMICAL WASTE HAZARD.** Wastes produced by the instruments are potentially hazardous and can cause injury, illness, or death.

WARNING **CHEMICAL STORAGE HAZARD.** Never collect or store waste in a glass container because of the risk of breaking or shattering. Reagent and waste bottles can crack and leak. Each waste bottle should be secured in a low-density polyethylene safety container with the cover fastened and the handles locked in the upright position. Wear appropriate eyewear, clothing, and gloves when handling reagent and waste bottles.

Chemical Waste Safety Guidelines

To minimize the hazards of chemical waste:

- Read and understand the Material Safety Data Sheets (MSDSs) provided by the manufacturers of the chemicals in the waste container before you store, handle, or dispose of chemical waste.
- Provide 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.)
- Minimize contact with chemicals. Wear appropriate personal protective equipment when handling chemicals (for example, safety glasses, gloves, or protective clothing). For additional safety guidelines, consult the MSDS.
- Minimize the inhalation of chemicals. Do not leave chemical containers open. Use only with adequate ventilation (for example, fume hood). For additional safety guidelines, consult the MSDS.
- Handle chemical wastes in a fume hood.
- After emptying a waste container, seal it with the cap provided.
- Dispose of the contents of the waste tray and waste bottle in accordance with good laboratory practices and local, state/provincial, or national environmental and health regulations.

Waste Disposal

If potentially hazardous waste is generated when you operate the instrument, you must:

- Characterize (by analysis if necessary) the waste generated by the particular applications, reagents, and substrates used in your laboratory.
- Ensure the health and safety of all personnel in your laboratory.
- Ensure that the instrument waste is stored, transferred, transported, and disposed of according to all local, state/provincial, and/or national regulations.

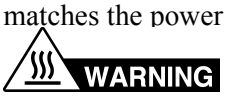
IMPORTANT! Radioactive or biohazardous materials may require special handling, and disposal limitations may apply.

Electrical Safety

ELECTRICAL SHOCK HAZARD. Severe electrical shock can result from operating the StepOne™ and StepOnePlus™ systems without their instrument panels in place. Do not remove instrument panels. High-voltage contacts are exposed when instrument panels are removed from the instrument.

Fuses

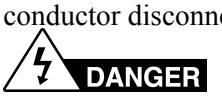
FIRE HAZARD. Improper fuses or high-voltage supply can damage the instrument wiring system and cause a fire. Before turning on the instrument, verify that the fuses are properly installed and that the instrument voltage matches the power supply in your laboratory.



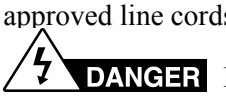
FIRE HAZARD. For continued protection against the risk of fire, replace fuses only with fuses of the type and rating specified for the instrument.

Power

ELECTRICAL HAZARD. Grounding circuit continuity is vital for the safe operation of equipment. Never operate equipment with the grounding conductor disconnected.



ELECTRICAL HAZARD. Use properly configured and approved line cords for the voltage supply in your facility.



ELECTRICAL HAZARD. Plug the instrument into a properly grounded receptacle with adequate current capacity.

Overvoltage Rating

The StepOne™ and StepOnePlus™ systems has an installation (overvoltage) category of II, and is classified as portable equipment

Biological Hazard Safety

General Biohazard

BIOHAZARD. Biological samples such as tissues, body fluids, infectious agents, and blood of humans and other animals have the potential to transmit infectious diseases. Follow all applicable local, state/provincial, and/or national regulations. Wear appropriate protective equipment, which includes but is not limited to: protective eyewear, face shield, clothing/lab coat, and gloves. All work should be conducted in properly equipped facilities using the appropriate safety equipment (for example, physical containment devices). Individuals should be trained according to applicable regulatory and company/institution requirements before working with potentially infectious materials. Read and follow the applicable guidelines and/or regulatory requirements in the following:

- U.S. Department of Health and Human Services guidelines published in *Biosafety in Microbiological and Biomedical Laboratories* (stock no. 017-040-00547-4; **http://bmbl.od.nih.gov**)

- Occupational Safety and Health Standards, Bloodborne Pathogens (29 CFR§1910.1030; **http://www.access.gpo.gov/ nara/cfr/waisidx_01/ 29cfr1910a_01.html**).
- Your company's/institution's Biosafety Program protocols for working with/handling potentially infectious materials.

Additional information about biohazard guidelines is available at:

http://www.cdc.gov

LED Safety Requirements

To ensure safe LED operation:

- The system must be maintained by a Thermo Fisher Scientific Technical Representative.
- All instrument panels must be in place on the instrument while the instrument is operating. When all panels are installed, there is no detectable radiation present. If any panel is removed when the LED is operating (during service with safety interlocks disabled), you may be exposed to LED emissions in excess of the Class **3B** rating.
- Do not remove safety labels or disable safety interlocks.

Workstation Safety

Correct ergonomic configuration of your workstation can reduce or prevent effects such as fatigue, pain, and strain. Minimize or eliminate these effects by configuring your workstation to promote neutral or relaxed working positions.

CAUTION MUSCULOSKELETAL AND REPETITIVE MOTION HAZARD. These hazards are caused by potential risk factors that include but are not limited to repetitive motion, awkward posture, forceful exertion, holding static unhealthy positions, contact pressure, and other workstation environmental factors.

To minimize musculoskeletal and repetitive motion risks:

- Use equipment that comfortably supports you in neutral working positions and allows adequate accessibility to the keyboard, monitor, and mouse.
- Position the keyboard, mouse, and monitor to promote relaxed body and head postures.

Safety and Electromagnetic Compatibility (EMC) Standards

U.S. and Canadian Safety Standards

The StepOne™ and StepOnePlus™ systems has been tested to and complies with standard:

UL 61010-1 / CAN/CSA C22.2 No. 61010-1, "Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements."

FDA "Radition Control for Health and Safety Act of 1968 Performance Standard 21 CFR 1040.10 and 1040.11," as applicable.

Canadian EMC Standard

This instrument has been tested to and complies with ICES-001, Issue 4: "Industrial, Scientific, and Medical Radio Frequency Generators."

European Safety, RoHS Directive, and EMC Standards

Safety

This instrument meets European requirements for safety (Low Voltage Directive 2014/35/EU). This instrument has been tested to and complies with standards EN61010-1, "Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements."

EN 61010-2-010, "Particular Requirements for Laboratory Equipment for the Heating of Materials."

EN 61010-2-081, "Particular Requirements for Automatic and Semi-Automatic Laboratory Equipment for Analysis and Other Purposes."

EN 60825-1, "Radiation Safety of Laser Products, Equipment Classification, Requirements, and User's Guide.

EMC

This instrument meets European requirements for emission and immunity (EMC Directive 2014/30/EU). This instrument has been tested to and complies with standard EN 61326 (Group 1, Class B), "Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements."

This instrument meets European RoHS Directive 2011/65/EU.

Australian EMC Standards

This instrument has been tested to and complies with standard AS/NZS CISPR 11, "Limits and Methods Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radio-frequency Equipment."

Site Preparation Tasks 1

This chapter describes the tasks to perform before you install the Applied Biosystems StepOne™or StepOnePlus™ Real-Time PCR System.

This chapter includes the following topics:

Overview

Prepare your site for the installation according to the instructions in this chapter. Checklists are provided in Chapter 2, "Checklists."

Site Preparation Schedule

To minimize the time between the shipment arrival and system installation:

1. Complete the site preparation tasks (Chapter 1).
2. Fill out the corresponding checklists (Chapter 2).

Site Preparation Process

The general site preparation tasks and a suggested sequence for completing the tasks are summarized in Figure 1-1. The sequence can vary, but always:

- Review this guide first.
- Unpack and store the chemical installation kit as soon as you receive it.

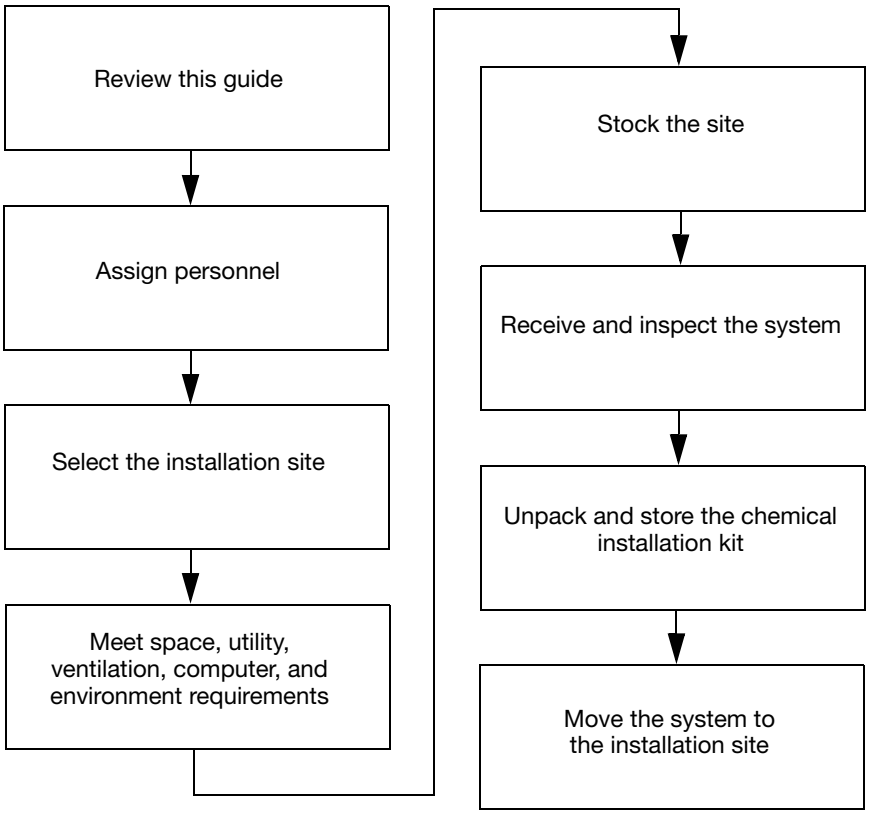


Figure 1-1 Site preparation tasks and their suggested sequence

Assigning Personnel

Laboratory Safety Representative

The laboratory safety representative should be familiar with laboratory safety procedures and know the location of all the safety equipment.

Tasks and Personnel

Table 1-1 summarizes specific site-preparation tasks and suggests the personnel to accomplish the tasks. Use the table to help schedule and manage the site-preparation process.

Table 1-1 Suggested personnel tasks

Personnel	Tasks
Site Preparation/ Installation Coordinator	• Reviews the site preparation guide for safety information and system requirements. • Coordinates personnel and tasks. • Orders required materials. • Chooses the site. • Reviews checklists with applicable personnel to verify that the site is properly prepared. • Receives and inspects the system. • Stores the Chemical Installation Kit. • Schedules the installation and informs personnel of the installation date, if applicable. • Ensures that the site is clear of unnecessary material on the installation day.
Laboratory Safety Representative	• Reviews the site preparation guide for safety information. • Ensures that the required safety practices and equipment are in place. • Is available to assist with unpacking and setup.
Laboratory Personnel/ Primary Users	• Review safety information. • Ensure that all customer-provided materials for installation are present at the site.
Facilities Personnel	• Ensure that installation requirements are met for: – Space at the installation site – Building clearances – Temperature and humidity – Electrical supply – Computer – Safety and installation materials • If possible, move the crated system to the site before the installation date.
Network or IT Specialist (if the system will be connected to a network)	• Ensures that one active, tested local area network (LAN) connection is in place before the scheduled installation date. • Ensures that network hardware is compatible with an RJ45-type connector. • If necessary, supplies additional cables. • Is available during installation to connect the system to the network. • If applicable, provides and installs a network or dedicated printer.

Selecting the Site

When deciding where to install the instrument, refer to the following sections for site requirements:

- "Space Requirements" on page 1-4
- "Environmental Requirements" on page 1-7
- "Ventilation Requirements" on page 1-8
- "Electrical Requirements" on page 1-8
- "Computer Requirements" on page 1-9
- "Safety and Materials" on page 1-11

IMPORTANT! The site cannot be designated BioSafety Level 3 (BSL-3) or BioSafety Level 4 (BSL-4) to be eligible for support. We do not install, service, or repair instruments in areas designated BSL-3 or BSL-4.

Space Requirements

Instrument

Space requirements depends on your StepOne™ or StepOnePlus™ system purchase. Possible layouts:

- Standalone - Instrument is not directly connected to a computer running StepOne™ software. Use the standalone layout when the computer and the StepOne™ or StepOnePlus™ instrument will be placed in separate locations.
- Colocated - Instrument is connected to a computer by the StepOne™ or StepOnePlus™ system cable. Use the colocated layout when both the computer and the StepOne™ or StepOnePlus™ instrument will be placed together in the same location.

Note: You can choose to connect the StepOne™ or StepOnePlus™ system to a network. See the *Applied Biosystems StepOne™ and StepOnePlus™ Real-Time PCR Systems Installation, Maintenance, and Networking Guide* on connecting the StepOne™ or StepOnePlus™ system to an Ethernet network.

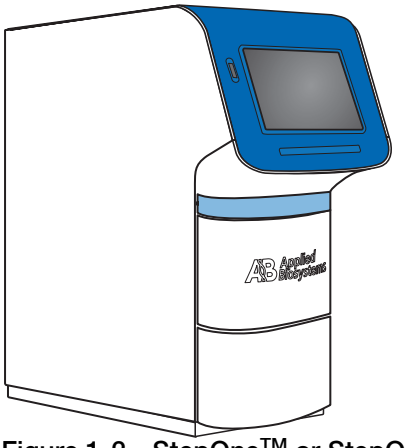


Figure 1-2 StepOne™ or StepOnePlus™ Real-Time PCR System

System Components

If your purchase included a computer, then the StepOne™ or StepOnePlus™ system includes the:

- StepOne™ or StepOnePlus™ instrument
- (*Optional*) Tower computer, monitor, keyboard, mouse, and control pad

  or

  Laptop computer with mouse

Note: In some countries, the StepOne™ or StepOnePlus™ system may be purchased without a computer. See your local representative for more information.

Layout Requirements

Requirements:

- Avoid placing the system adjacent to heaters, cooling ducts, or in direct sunlight.
- Place away from any vibrating equipment such as a refrigerator or centrifuge. It should not share bench space with vibrating equipment.
- Place the computer within 2 m (6 ft) of the instrument in the colocated layout.
- Position the monitor, keyboard, and accessories to allow for proper ergonomics during use.

Figures 1-3 shows layout examples for the StepOne™ or StepOnePlus™ Real-Time PCR System. For details on the StepOne™ or StepOnePlus™ Real-Time PCR System space requirements, see Figure 1-4 on page 1-6 and Figure 1-5 on page 1-7.

Standalone system

System with colocated computer

Figure 1-3 Examples of a standalone or colocated layout (*not to scale*)

Dimensions and Weights

The table below indicates dimensions and weights of the system components, and computer components, if you ordered a computer system. Ensure that the installation site (floor space and/or bench space) can accommodate the dimensions and support the weights.

Component	Width	Depth	Height	Weight
StepOne™ or StepOnePlus™ system	24.6 cm (9.70 in.)	48.5 cm (19.11 in.)	51.80 cm (20.40 in.)	≈23.58±0.45 kg (53 ±1 lbs)
Computer, mini tower	18.7 cm (7.35 in.)	43.8 cm (17.24 in.)	41.1 cm (16.18 in.)	14.29 kg (31.50 lbs)

Component	Width	Depth	Height	Weight
• Monitor	37.2 cm (14.64 in.)	18.2cm (7.16 in.)	45.8 cm (18.03 in.)	6.39 kg (14.08 lbs)
• Keyboard	45.7 cm (18 in.)	17.8cm (7 in.)	5.1 cm (2 in.)	.68 kg (1.5 lbs)
Computer, laptop	33.8 cm (13.3_in.)	27.3 cm (10.75 in.)	3.58 cm (1.4 in.)	≈2.38 to 2.6 kg (5.24 to 5.73) lbs)

Required Clearances

Required clearances for the StepOne™ or StepOnePlus™ Real-Time PCR System are summarized below and illustrated in Figure 1-4 and Figure 1-5.

- **Clearance on all sides** – At least 15.2 cm (6 in.) of clearance for ventilation, service access, and cable routing. Allow space for easy access to the back and sides.
- **Vertical clearance** – At least 30.5 cm (12 in.) of unobstructed vertical clearance above the top of the StepOne™ or StepOnePlus™ system to allow the top to be lifted during service.

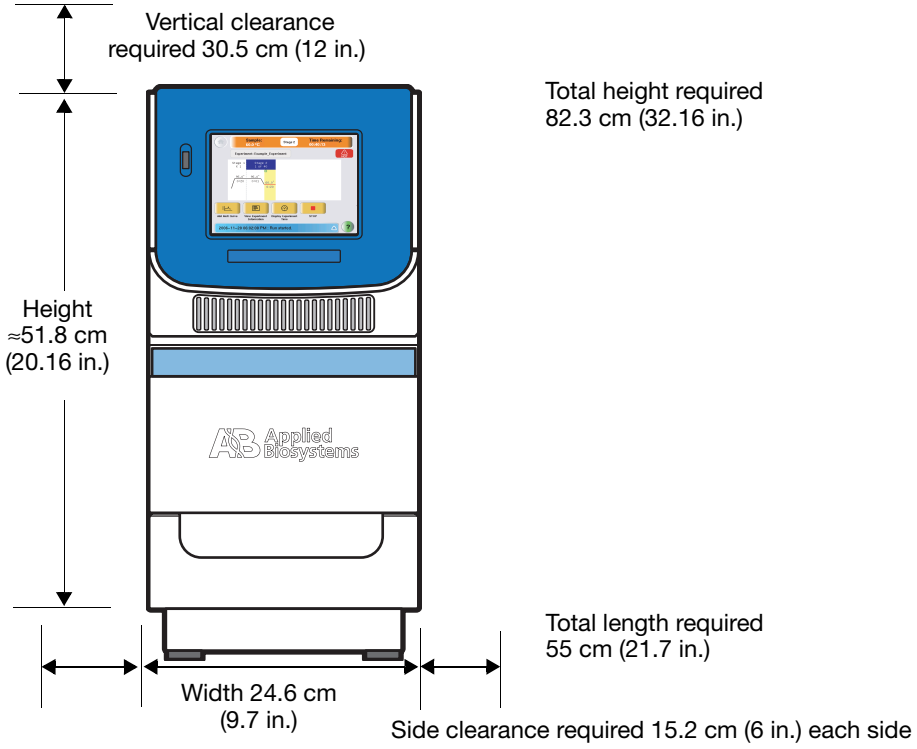


Figure 1-4 Space requirements front view (not to scale)

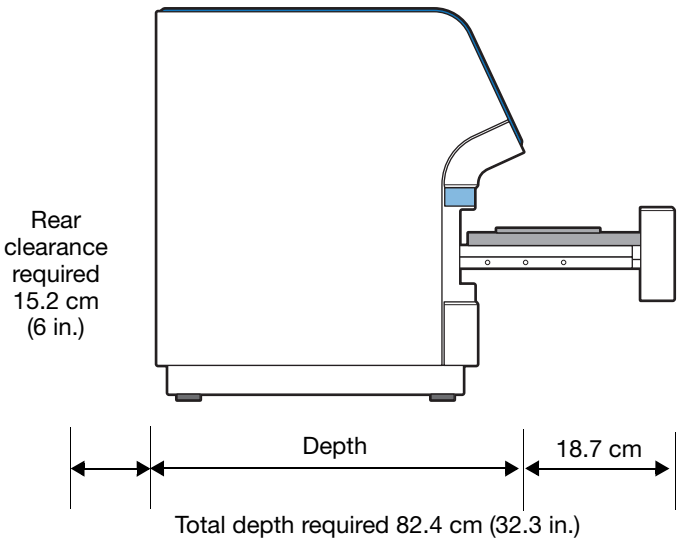


Figure 1-5 Space requirements side view (not to scale)

Environmental Requirements

Altitude

The StepOne™ or StepOnePlus™ system is for indoor use only and for altitudes not exceeding 2000 m (6562 ft) above sea level.

Temperature and Humidity Requirements

Ensure that the installation site is maintained under the following conditions:

Condition	Acceptable Range
Temperature	15 to 30 °C (59 to 86 °F) Maximum change of less than 15 °C per 24 hours
Temperature, transportation and storage	-30 to 60 °C (-22 to 140 °F)
Humidity	15 to 80% relative humidity, noncondensing
Humidity, transportation and storage	20 to 80% relative humidity

Fluctuations between day and night temperatures can cause system instability. For a stable environment, see “Laptop computer with mouse” on page 1-5.

Pollution

The StepOne™ or StepOnePlus™ Real-Time PCR System has a Pollution Degree rating of II. It may be installed in an environment that has nonconductive pollutants only, such as dust particles or wood chips. Typical environments with a Pollution Degree II rating are laboratories and sales and commercial areas.

Ventilation Requirements

Venting Hot-Air-Only Exhaust

Hot-air exhaust is vented from the StepOne™ or StepOnePlus™ system through the hot-air waste port on the back panel. The hot air exhaust is designed to dissipate heat produced by the instrument. The maximum thermal output of the StepOne™ or StepOnePlus™ instrument is 1540 Btu/h (451.3 W). Consult your facilities department to determine if the laboratory ventilation system can maintain room temperature with this level of thermal output. If it can maintain room temperature during instrument operation, the hot-air exhaust port can be vented directly to room air.

Electrical Requirements

Disconnecting Power

In case of emergency, you must be able to immediately disconnect the main power supply to the instrument.

Power Connectors and Receptacles

The StepOne™ or StepOnePlus™ system is shipped to customers with 5 different power connectors to fit various country configurations. These connectors require standard 15 A wall receptacles with proper grounding. Do not use extension cords.

Current Leakage Specification

The instrument meets the specification of 3- 3.5mA. Sites that test to ensure that current leakage is no more than 500 uA may want to purchase an isolation transformer to ground the instrument.

System Electrical Requirements

The StepOne™ or StepOnePlus™ system can be configured for operating voltages between nominal voltages of 100VAC and 240VAC at 50 or 60 Hz. The StepOne™ or StepOnePlus™ system is rated 900 Watts max. During installation, your installation coordinator configures the system for the proper input voltage.

CAUTION–Do not unpack or plug in any components until the appropriate person has configured the system for the proper operating voltage.

Table 1-2 provides electrical specifications for the StepOne™ or StepOnePlus™ system. For all indicated input voltages, a 15 A circuit is required.

Table 1-2 Electrical specifications

Input Voltage (VAC)	Frequency (Hz)	Nominal Current Draw (A)	Power (W)
100	50/60	4.79	479
120	50/60	3.94	473

Table 1-2 Electrical specifications

Input Voltage (VAC)	Frequency (Hz)	Nominal Current Draw (A)	Power (W)
220	50/60	2.07	455
240	50/60	1.84	442

Power Line Regulator

In areas where the supplied power is subject to voltage fluctuations exceeding ±10% of the nominal value, a power line regulator may be required. High or low voltages can adversely affect the electronic components of the instrument.

Computer Requirements

Minimum

We recommend the following minimum requirements for your computer system:

- Pentium IV processor
- USB port (1.1 or 2.0)
- 500 MHz
- 20 GB available on hard drive
- 512 MB of RAM
- Windows® XP operating system
- Computer:
  - UL 60950-1 listed laptop computer
    or
  - UL 60950-1 listed combination of a tower computer and monitor
- Ethernet network interface adaptor (10BASE-T)

Software for Colocated Computer

The computer, if provided by Thermo Fisher Scientific, has the Microsoft® Windows® XP operating system with Service Pack 2 and Internet Explorer 6.x+ or Netscape Navigator 6.x+.

No antivirus software is provided because customer preferences and network requirements vary. Therefore, you need to install antivirus software of your choice to protect the computer against viruses.

CAUTION Do not install on the colocated computer additional software other than antivirus software. Changes to the configured software could void the instrument warranty and cause the system to be nonoperational.

Network Requirements

LAN Connection

If the StepOne™ or StepOnePlus™ Real-Time PCR System will be connected to a LAN, an active, tested LAN connection must be in place before your installation date. Due to differences in network connections, we cannot configure the system to access a specific network. For network issues, see your company IT department.

Network Cables

The computer if supplied is factory configured for the TCP/IP protocol. The product includes a fast Ethernet adapter (10/100baseT) with an RJ45-type connector and one 1.8 -m (6 -foot) Ethernet cable.

Printer Requirements

The StepOne™ or StepOnePlus™ Real-Time PCR System can use a network or a dedicated printer. A dedicated printer is directly connected to the colocated computer.

Safety and Materials

Safety Practices

IMPORTANT! The site must not be designated BioSafety Level 3 (BSL-3) or BioSafety Level 4 (BSL-4) to be eligible for Thermo Fisher Scientific support. We do not install, service, or repair instruments in areas designated BSL-3 or BSL-4.

IMPORTANT! A safety representative from your facility must ensure that:

- Personnel establish and follow all applicable safety practices and policies to protect laboratory personnel from potential hazards.
- All applicable safety devices and equipment are available at all times.

Required Safety Equipment

Your laboratory has specific safety practices and policies designed to protect laboratory personnel from potential hazards that are present. We expect that you will follow all applicable safety-related procedures at all times.

The following safety protection and equipment must be available at the installation site:

- Protection from any sources of hazardous chemicals, radiation (for example, lasers, radioisotopes, radioactive wastes, and contaminated equipment), and potentially infectious biological material that may be present in the area where the installation personnel will work.
- Appropriate fire extinguisher:
  - You are responsible for providing an appropriate fire extinguisher for use on or near the equipment.
  - The types and sizes of fire extinguishers shall be suitable for use on electrical and chemical fires as specified in current codes, regulations, and/or standards, and with approval of the Fire Marshall or other authority having jurisdiction.
  - The installation of appropriate fire extinguishers shall be in addition to other fire-protection systems and not as a substitute or alternative to them.
- Eyewash.
- Safety shower.
- Eye and hand protection.
- Adequate ventilation, including vent line/fume hood, if applicable.
- Biohazard waste container, if applicable.
- First-aid equipment.
- Spill cleanup equipment.
- Applicable MSDSs.

Materials for Installation

Provide the following materials for the installation:

- Safety glasses, lab coats, chemical-resistant, disposable gloves (powder-free)
- Lint-free tissues
- Ethanol, HPLC-grade or better
- 10% Bleach solution
- Water, Milli-Q® grade
- Three sizes of micropipettors and tips
  - 1- to 10-µL
  - 10- to 100-µL
  - 100- to 1,000-µL
- Mini vortexer, centrifuge, and sample tubes

Materials for Routine Operation

StepOne™ or StepOnePlus™ system supplies and consumables are necessary for routine operation of the StepOne™ or StepOnePlus™ system. Before the system is installed, contact the sales representative to order supplies.

Receiving and Inspecting the System

Shipped Contents

The following are included in all StepOne™ or StepOnePlus™ system shipments:

- StepOne™ or StepOnePlus™ instrument
- Accessories:
  - 48-well or 96-well AB plates
  - USB drive
- Chemical installation kit

The following are included if you ordered them:

- Computer, monitor, computer keyboard, mouse, and control pad
  or
- Computer laptop with mouse

Shipped Documentation

Refer to "How to Obtain More Information" on page 6 for a listing of documentation.

Shipping List

Verify that the items shown on the shipping list are the same items that you ordered.

Inspecting Shipping Containers for Damage

Carefully inspect the shipping containers if the shipment was mishandled during transit and report any damage to customer support. Record any damage or mishandling on the shipping documents.

Unpacking and Storing the Chemical Installation Kit

The chemical installation kit is boxed separately from the instrument components. When you receive the shipment, unpack the Chemical Installation Kit immediately. Store the components as specified in the instructions included with the kit.

WARNING **CHEMICAL HAZARD.** Some chemicals used with Thermo Fisher Scientific instruments are potentially hazardous and can cause injury, illness, or death. Read and understand the Material Safety Data Sheets (MSDSs) provided by the chemical manufacturer before you store, handle, work with, or dispose of any chemicals or hazardous materials.

Moving the Crated Instrument to the Laboratory

Moving Schedule

Before the date of installation:

- Clear the installation site of all unnecessary materials.
- If possible, have two people move the crated StepOne™ or StepOnePlus™ instrument from the receiving area to the installation site.
- If possible, move the other shipping containers from the shipping area to the installation site.

Required Building Clearances

The largest container (crate) included with the Applied Biosystems StepOne™or StepOnePlus™ Real-Time PCR System shipment contains the StepOne™ or StepOnePlus™ instrument. To move the crate to the installation site, verify that the building clearances allow passage of the following crate dimensions:

Crate Dimension	Minimum Building Clearance
Height	614 cm (24 3/16 in.)
Length	663 cm (26 1/16 in.)
Depth	608 cm (23 15/16 in.)

Instrument Weight

The StepOne™ or StepOnePlus™ instrument weighs approximately 23.58±0.45 kg (53±1 lbs).

Moving and Lifting the Instrument

CAUTION **PHYSICAL INJURY HAZARD.** If you decide to lift or move the instrument after it has been installed, do not attempt to lift or move the instrument without the assistance of others, the use of appropriate moving equipment, and proper lifting techniques. Improper lifting can cause painful and permanent back injury. Depending on the weight, moving or lifting an instrument may require two or more persons.

During Installation

After your installation personnel uncrate the system, installation and testing of the StepOne™ or StepOnePlus™ system either by your designated installer takes approximately 4 hours.

Checklists 2

This chapter includes the following topics:

Overview

Before using the checklists, read all previous sections in this guide.

Use the checklists in this chapter to ensure that you have made all preparations for installing the system. In the following checklists, date each item after verifying its completion.

Personnel Checklist

For more information, see "Assigning Personnel" on page 1-3.

Date Verified	Designated Personnel
	Site Preparation/Installation coordinator
	Laboratory safety representative
	Laboratory personnel: • To ensure that customer-supplied materials are on hand • Primary users to be trained during installation and to subsequently train other users
	Facilities personnel: • To provide environmental, electrical, and computer site-preparation requirements • Two people to move and position the instrument, if applicable
	Network or IT specialist (only if the system will be connected to a network)

Space and Layout Checklist

For more information, see "Space Requirements" on page 1-4.

Date Verified	Requirements
	Location is away from: • Heating or cooling ducts. • Vibrating equipment, such as a refrigerator or centrifuge on the same benchtop. • Direct sunlight.
	Computer workspace, if applicable, allows for proper ergonomics during use.
	Location accommodates the dimensions and weights specified in "Dimensions and Weights" on page 1-5.
	Location meets the requirements specified in "Required Clearances" on page 1-6.

Environmental Checklist

For more information, see "Environmental Requirements" on page 1-7.

Date Verified	Requirement
	The altitude does not exceed 2000 m (6500 ft) above sea level.
	The conditions specified in "Temperature and Humidity Requirements" on page 1-7 have been met.
	Pollution Degree II – Only nonconductive pollutants, if any, are present.

Ventilation Checklist

For more information, see "Ventilation Requirements" on page 1-8.

Date Verified	Requirement
	Instrument Hot-Air Exhaust Venting
	One of the following conditions exists: • Facilities personnel have certified that the normal room ventilation system can maintain room temperature if the maximum thermal output of the system (see "Venting Hot-Air-Only Exhaust" on page 1-8) is vented directly into the room air. • A suitable venting device such as a fume hood or fume dust is available to vent the hot air exhaust from the instrument space.

Electrical Checklist

For more information, see “Electrical Requirements” on page 1-8.

Date Verified	Requirement
	The main power supply to the instrument can be immediately disconnected.
	Appropriate grounded power receptacles are available.

Computer and Networking Checklist

For more information, see “Computer Requirements” on page 1-9.

Date Verified	Requirement
Antivirus Software	
	Appropriate antivirus software is available for loading on the system computer.
Networking (If the system will be connected to a network)	
	One active, tested LAN connection is available.
	Network hardware is compatible with an RJ45-type connector. See “Network Requirements” on page 1-10.
	For a colocated computer - If the network connection is more than 1.8 m (6 ft) from the system, a Category 5 RJ45 cable of the required length is available.
Printer	
	A network printer or a dedicated printer and necessary print drivers are available.

Safety Checklist

For more information, see “Safety Practices” on page 1-11.

Date Verified	Requirement
	The site is not designated BioSafety level 3 (BSL-3) or BioSafety level 4 (BSL-4) to be eligible for installation, service, and repair.
	Safety practices and policies to protect laboratory personnel from potential hazards are in place and are followed.
	Protection from any sources of hazardous chemicals, radiation (for example, lasers, radioisotopes, radioactive wastes, and contaminated equipment), and potentially infectious biological material is in place.
	Appropriate fire extinguisher
	Eye and hand protection
	Eyewash
	Safety shower
	Vent lines/fume hood, if applicable
	Biohazard waste container, if applicable
	First-aid equipment
	Spill cleanup equipment
	MSDSs readily available

Materials Checklist

For more information, see “Safety and Materials” on page 1-11.

Date Verified	Requirement
	Materials for General Installation
	Safety glasses and lab coats
	Chemical-resistant disposable gloves (powder free)
	Lint-free tissues
	Ethanol, HPLC-grade or better
	10% Bleach solution
	Water, Milli-Q grade
	Three sizes of micropipettors and tips: • 1- to 10-µL • 10- to 100-µL • 100- to 1000-µL
	A mini vortexer, centrifuge, and sample tubes
	Materials for Routine Operation
	Materials for routine operation after the installation are available or have been ordered (see “Materials for Routine Operation” on page 1-12).

System Receipt and Inspection Checklist

For more information, see "Receiving and Inspecting the System" on page 1-13.

Date Verified	Action
	Verified that items on the packing list are those that were ordered. Otherwise, reported to customer support discrepancies in the packing list.
	Opened and stored the Chemical Installation Kit components as specified in the kit operating instructions.
	Received the system and inspected the shipping containers for mishandling or damage.
	Reported to customer support: • Any damage to the shipping containers • Tip indicators or shock indicators that show evidence of mishandling during transit

Moving the Crated Instrument Checklist

For more information, see "Moving the Crated Instrument to the Laboratory" on page 1-14.

Date Verified	Item
	The measured building clearances can accommodate the StepOne™ or StepOnePlus™ system crate dimensions (see "Required Building Clearances" on page 1-14). If the crate dimensions exceed building clearances, contact customer support.
	Moved all the *crated* equipment to the laboratory before the date of the installation. **WARNING** **PHYSICAL INJURY HAZARD**. Do not attempt to lift or move any boxed or crated items unless you have received related training. Incorrect lifting can cause painful and sometimes permanent back injury. Use proper lifting techniques when lifting or moving items. No attempt should be made to lift the instrument.
	Cleared the installation site of all unnecessary materials.

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