

TECHNICAL MANUAL

Maxwell[®] CSC Instrument with Version 2.X Software Operating Manual

Instructions for use of the Maxwell[®] CSC Instrument,
Model Number AS4000.



This product is for sale in the United States
and Canada Only.

Note: Please ensure that all sealing tape
and any residual adhesive are removed from
the Maxwell[®] CSC system cartridges before
placing the cartridges into the instrument.



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Maxwell[®] CSC Instrument

All technical literature is available at: www.promega.com/protocols/
Visit the web site to verify that you are using the most current version of this Technical Manual.
E-mail Promega Technical Services if you have questions on use of this system: techserv@promega.com

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1. Introduction

1.A. Maxwell® CSC Instrument Purification Procedure

The Maxwell® Clinical Sample Concentrator (CSC) Instrument^(a) provides automated nucleic acid purification for a range of clinical sample types. The Maxwell® CSC Instrument is intended for professional use only. The purification methods use sample lysis and binding to paramagnetic particles as the primary separation principle. Up to 16 samples can be prepared in a single run.

The automated steps performed by the Maxwell® CSC Instrument include:

- Sample lysis in the presence of a specially formulated Lysis Buffer
- Binding of nucleic acids to paramagnetic particles
- Washing of the bound target molecules away from other cellular components
- Elution of the product

The instrument is controlled by a graphical user interface running on a tablet PC. The Maxwell® CSC Instrument has the ability to record and report sample tracking and method run data. A bar code reader is supplied with the Maxwell® CSC Instrument and is used for starting method runs and capturing bar code information for samples and reagents. The Maxwell® CSC Instrument provides reports of the data gathered for instrument operations, and the reports can be printed and exported to an administrator-specified storage location or a USB drive for transfer to a separate computer. To start a run the user scans the bar code of the reagent kit to be processed; this selects the appropriate protocol to be run. After entering the sample tracking information, the user follows the recommended protocol for the Maxwell® CSC kit and prepares the deck tray of the instrument as instructed. The cartridges are placed into the instrument, and the method is automatically run. Use of the instrument does not require any special training. However, training is available as part of Operational Qualification, which is offered separately (see Section 9.B)

1.B. Product Intended Use

The Maxwell® CSC Instrument is intended for use, in combination with Maxwell® CSC reagent kits, as an in vitro diagnostic (IVD) medical device to perform automated isolation of nucleic acids. The nucleic acid isolated using the Maxwell® CSC Instrument is suitable for direct downstream analysis by standard amplification methods. These methods include a variety of polymerase chain reaction (PCR) tests for human in vitro diagnostic purposes.

The Maxwell® CSC Instrument is not intended for use as part of a specific in vitro diagnostic test. The Maxwell® CSC Instrument is intended for professional use only. Diagnostic results obtained using the nucleic acids purified with this system must be interpreted in conjunction with other clinical or laboratory data.



1.C. Product Use Limitations

The Maxwell[®] CSC Instrument is not intended for use with reagent kits other than Maxwell[®] CSC reagent kits or with samples other than those defined within the intended use and product limitations of the specific Maxwell[®] CSC reagent kit being used.

The user is responsible for establishing performance characteristics necessary for downstream diagnostic applications. Appropriate controls must be included in any downstream diagnostic applications using nucleic acids purified using the Maxwell[®] CSC Instrument.

1.D. Maxwell[®] CSC Instrument Features

- Easy-to-use and easy-to-maintain system operation
- Standardized nucleic acid sample preparation workflow
- Comprehensive technical support
- System controlled via tablet PC
- Reporting functionality
- Bar code reader included
- Preprogrammed methods for nucleic acid purification
- UV lamp to aid in sanitizing the instrument

1.E. Maxwell[®] CSC Instrument Specifications

Processing Time:	40–60 minutes (depending on sample type and method)
Number of Samples:	Up to 16
Weight:	23lb (10.43kg)
Dimensions (W × D × H):	13 × 18 × 13 inches (330.2 × 457.2 × 330.2mm)
Power Requirements:	95–240VAC, 50–60Hz, 2.5A
Fuse:	2.5A, time-lag fuse
UV Bulb:	Average lifetime approximately 6,000 hours, length 135.9mm, diameter 16mm, 4W, 0.17A current, 29V, Spectral Peak F 253.7, UV output 0.9W



1.F. Product Components

PRODUCT	CAT.#
Maxwell® CSC Instrument	AS4000

For In Vitro Diagnostic Use. Includes:

- 1 Maxwell® CSC Instrument
- 1 Tablet PC preloaded with Maxwell® CSC User Interface
- 1 USB cable for connection of the Maxwell® CSC Instrument to the Tablet PC
- 1 Power Cable for Maxwell® CSC Instrument
- 1 Power Cable for Tablet PC
- 1 Maxwell® CSC Deck Tray
- 1 UV Bulb (installed)
- 1 Bar Code Reader
- 1 Tablet PC Holder
- 1 Quick Start Guide
- 1 Setup Guide
- 1 Software Flash Drive for the Maxwell® CSC Instrument

1.G. Inspection

Upon receiving your Maxwell® CSC Instrument, please inspect the package carefully to make sure all components are present and that the instrument has not been damaged in shipping. If any item is damaged, contact Promega Technical Services (e-mail: techserv@promega.com). Standard components are shown in Figure 1.

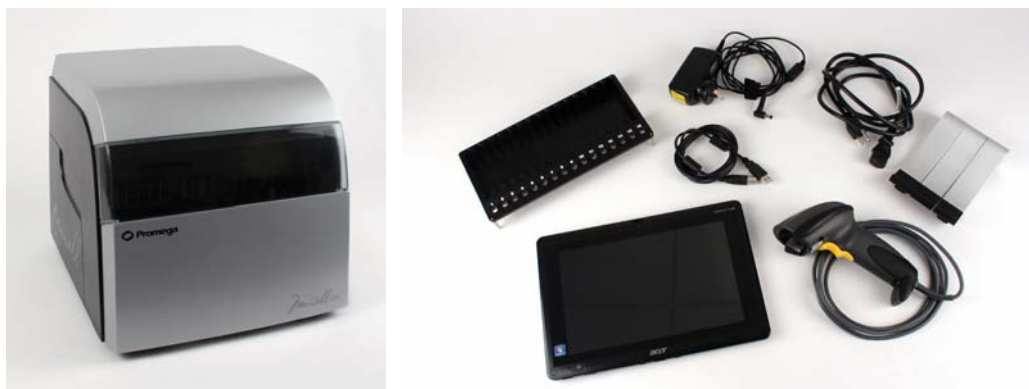








Figure 1. Maxwell® CSC Instrument. Components shown include: deck tray, power cable, USB cable, Tablet PC, Tablet PC Holder and Bar Code Reader for the Maxwell® CSC Instrument.



1.H. Precautions








- Important Safety Instructions. Save these instructions.
- This IVD instrument complies with the EMC emission and immunity requirements described in IEC-61326-2-6 and the safety requirements of IEC 61010-1 and IEC 61010-2-101.
- Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- 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.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper operation.
- Do not use this instrument for anything other than its intended use.
- Always disconnect the power before cleaning or performing routine maintenance.
- Do not disassemble unit.
- Ensure cartridges, elution tubes and plungers have been securely inserted in their correct positions and orientation. Failure to do so may result in damage to the instrument.
- Use only Promega supplied cartridges, plungers and elution tubes. Do not reuse cartridges, plungers or elution tubes.
- If the equipment is used in a manner other than that specified by Promega, the protection provided by the equipment may be impaired.
- Keep hands clear of instrument platform as it moves in and out of the instrument.
- During elution, the heated elution block at the front of the platform becomes very hot. Do not touch.
- To avoid muscle strain or back injury, use lifting aids and proper lifting techniques when removing or replacing the instrument.
- Equipment can be hazardous due to the use of chemical and biohazardous substances.
- Instrument door should be opened and closed only by using the Maxwell® CSC software. Do not manually pry the door open or over-ride the door sensor during protocol operation, as it will result in the protocol being aborted.
- This instrument is intended for use with human samples. Use appropriate personal protective equipment (gloves, safety goggles, lab coat, etc.) for handling and disposing of biohazardous materials.
- Do not attempt to replace the UV lamp. Replacing the UV lamp requires special tools. Contact Promega Technical Services if the UV lamp needs replacement.
- Do not load any additional software programs on the Tablet PC supplied with Maxwell® CSC Instrument. Additional programs may cause the application to slow down.

1.I. Safety Symbols and Marking

Safety Symbols and Markings	
	Danger. Hazardous voltage. Risk of electrical shock.
	Warning. Risk of personal injury to the operator or a safety hazard to the instrument or surrounding area.
	Warning. Pinch point hazard.
	Warning. Hot surface. Burn hazard.
	Warning. Biohazard.
	Warning. UV light hazard. Do not look directly at the UV light.

1.I. Safety Symbols and Marking (continued)

IMPORTANT SAFETY INSTRUCTIONS. SAVE THESE INSTRUCTIONS.

Symbols	Explanation
	Catalog Number
	Serial Number
	Manufacturer
	Consult your local Promega Representative regarding instrument disposal
	CSA Product Certification Mark
	C-TICK EMC Compliance Mark
	In Vitro Diagnostic Medical Device



1.J. Environmental Requirements (Operating, Shipping and Storage Conditions)

Power Requirements:	95–240VAC, 50–60Hz, 2.5A
Temperature:	4°C–50°C (shipping/storage), 15°C–25°C (operation)
Humidity:	Up to 80% relative humidity, non-condensing
Operating Altitude:	<2500 meters

The Maxwell® CSC Instrument is intended for indoor use only. Wipe up spills immediately. To avoid shortening the expected lifespan of the instrument, install in a location that meets the following criteria:

- Locate on a sturdy, level surface.
- Avoid dusty areas.
- Choose a location that has good air circulation and is not exposed to direct sunlight.
- Avoid noisy electrical power sources (e.g., power generators).
- Do not install in a location where there is large temperature variability or high humidity.
- Do not position the instrument so that it is difficult to unplug from the power source.
- Do not place next to heat sources.
- Do not use near flammable gases or liquids.
- Do not place near other electrically sensitive instruments.
- Connect the Maxwell® CSC Instrument and Tablet PC to an uninterrupted power supply (UPS). This is to ensure continued operation during brief power outages that otherwise might result in aborted instrument runs and lost samples.

2. Hardware Overview



Figure 2. Front of Maxwell® CSC Instrument.



Figure 3. Rear view of the Maxwell® CSC Instrument. The rear of the instrument showing the On/Off switch, power cable connector and USB communication port.



Figure 4. Magnetic assembly components and platform. The hardware components inside the Maxwell® CSC Instrument. The magnet and plunger bars, which are used for sample processing, and the platform containing the deck tray are evident.



3. Unpacking the Maxwell[®] CSC Instrument

Allow 10–15 minutes to unpack and set up the instrument. Choose a location with sufficient space to be able to see the components and screen.

1. Cut and remove the straps around the box (Figure 5).



Figure 5. Maxwell[®] CSC Instrument Box with straps.

2. Once the straps are cut, cut the tape on the flaps of the box to open the upper shipping box.
3. Open the flaps and remove the accessories box from the packaging (Figure 6).



Figure 6. The accessories box.

4. Remove the upper shipping box by pressing and releasing the 4 white clips. Pinch the white tabs inward and pull them out. The white piece can then be removed from the box (Figure 7).




Figure 7. Remove the white plastic clips that lock the shipping container.

5. Remove the Upper shipping box (Figure 8).



Figure 8. Upper shipping box removed.

6. Carefully remove the instrument from the box, and place the instrument on a flat stable surface. Leave at least 7.5 inches (19cm) of clearance in front of the instrument to allow the instrument door to open without hindrance.
 7. Remove the plastic bag from around the instrument.
-  Save the packaging material in case the instrument needs to be returned for service or repair later.



4. Setting up the Maxwell[®] CSC Instrument

4.A. Setting Up the Maxwell[®] CSC Instrument

1. Manually open the door of the Maxwell[®] CSC Instrument and carefully remove the two foam pieces from inside the instrument (Figure 9).



Figure 9. Remove the two foam pieces from inside the instrument.

The Maxwell[®] CSC Instrument door is spring-loaded and will close itself once the foam pieces are removed from the inside of the instrument.

4.B. Setting Up the Tablet PC

1. Open the accessories box. The tablet PC, Tablet PC holder, bar code reader and USB card are contained in the box (Figure 10). The tablet PC contains the operating software for the instrument.



Figure 10. Contents of the accessories box.

2. Remove the Tablet PC and Tablet power cable from the box.
3. Remove the Tablet PC holder from its packaging, and place it on top or adjacent to the Maxwell® CSC Instrument (Figure 11).



Figure 11. Tablet PC holder.



4.B. Setting Up the Tablet PC (continued)

4. Raise the middle leg of the Tablet PC holder, and place the Tablet PC on the Tablet PC holder as shown in Figure 12.



Figure 12. Tablet PC holder on top of the Maxwell® CSC Instrument.

5. Connect the Tablet PC power cable and the USB cable to the Tablet PC. Connect the other end of the Tablet PC power cable to a power outlet. We recommend connecting the Tablet PC to an uninterruptible power supply.



Figure 13. Tablet PC installed on the Maxwell® CSC Instrument.

6. Connect the other end of the USB cable to the back of the Maxwell[®] CSC Instrument (Figure 14).



Figure 14. Connect the Tablet PC to the back of the Maxwell[®] CSC Instrument.

7. Connect the Maxwell[®] CSC power cable to the back of the Maxwell[®] CSC Instrument.
8. Connect the bar code reader to the second USB port on the bottom left of the tablet PC.



Figure 15. Maxwell[®] CSC Instrument with the Tablet PC and bar code reader installed.

9. The Maxwell[®] CSC Instrument is now ready to use.



4.C. Switching On the Maxwell[®] CSC Instrument

Once all the foam pieces have been removed and the Tablet PC set up, you can connect the instrument to a power outlet. The power switch is located next to the power cable connection on the back of the instrument. Ensure that the On/Off switch is in the off position. Plug the power cord into a wall outlet. See Section 1.E. for power requirements. We recommend connecting the Maxwell[®] CSC to an uninterruptible power supply. Switch instrument on using the On/Off switch. Connect the Tablet PC power cord into a wall outlet.

Press the Tablet PC power switch located on the side of the Tablet PC to turn the Tablet PC “ON”. Every time the instrument is powered on, it will perform a self-diagnostic test. The deck, plunger bar and magnetic rod assembly are moved to check operation.



Figure 16. On/Off Switch.

4.D. Shutting Down the Maxwell[®] CSC Instrument

Shut Down Instrument

1. Shut down the software by pressing the X in the upper left corner of the ‘Home’ screen (Figure 17).
2. Shut down the Tablet PC using normal Windows[®] shut down procedure (Start→Shut Down).



Note: The Tablet PC must be shut down at least once a week to allow Windows[®] to reset memory usage.



Figure 17. Maxwell® CSC Home screen.

3. Switch the instrument “OFF” using the On/Off switch. Unplug the instrument. If you need to store the instrument, switch the instrument “OFF”, unplug the instrument and store in a place that meets the environmental requirements described in Section 1.J.


Storing the Tablet PC

When not in use for a prolonged period of time, the Tablet PC should be shut down and unplugged.



4.E. Configuring the Tablet PC

The Maxwell® CSC Tablet PC touch screen allows the user to select options. Most screens contain a series of options. Selections may be made touching the appropriate option on the tablet PC screen.

 Your IT department or site Administrator should configure the Tablet PC according to the IT rules and IT procedures pertinent to your site. The following is a set of guidelines for your IT personnel or site Administrator. Depending on your institution's IT policy, you may or may not be able to configure/change the settings for the Tablet PC. Do not load other programs on the tablet as these may interfere with instrument operation.

The first time you use the Maxwell® CSC Instrument and Tablet PC you should check the configuration of the following options. Settings can be changed later if required by following these instructions again.

Touch Screen

The Maxwell® CSC Tablet PC has a touch screen that can be used to navigate to the various screens. Touching the tablet for 3 seconds is equivalent to a Right Click on a PC.

Date and Time

The date and time set on the Tablet PC are used for the instrument run log to indicate when any given protocol was run on the Maxwell® CSC Instrument. You have to close the Maxwell® CSC software to change the date and time.

1. From the **Start** menu select **Control Panel**.
2. In the 'Control Panel' menu touch the **Date and Time** menu item.
3. First set your time zone by touching the **Change time zone...** button
4. On the 'Time Zone Settings' window select the appropriate time zone for your location and whether you wish the clock to automatically adjust for Daylight Savings Time.
5. Touch the **OK** button to save the time zone settings.
6. You will be returned to the 'Date and Time Settings' window.
7. On the 'Date and Time' window touch the **Change date and time...** button.
8. Set the appropriate date and time for your current location using the calendar and clock setting icons.
9. Touch the **OK** button to save the date and time settings.
10. You will be returned to the 'Date and Time Settings' window. Touch the **OK** button on this window to return to the Control Panel.
11. Close the 'Control Panel' by touching the red **X** button in the upper right corner of the screen.

User Password and Setup

Maxwell® CSC software supports the following user roles.

PromegaAdministrator: PromegaAdministrators have the following capabilities:

- Import methods
- Modify settings (e.g., sanitization time, sample entry, export folder, set instrument name, etc.)
- View audit trail logs

PromegaUser: PromegaUsers have the following capabilities:

- Select and run preloaded methods
- View, export results

PromegaUsers **do not** have access to the following:

- Import new methods
- Modify settings (e.g., sanitization time, sample entry, export folder, set instrument name, etc.)

Assigning User Accounts to Promega Groups

The Maxwell® CSC User Interface employs the Windows® login user access levels as a security tool for adding approved users and associated passwords. New user accounts should be created based on policies governing your site. Only someone with an Administrator account can assign users to Promega groups. You have to close the Maxwell® CSC software to create user accounts.

1. From the 'Start' menu, touch and hold on **Computer** and select **Manage**.

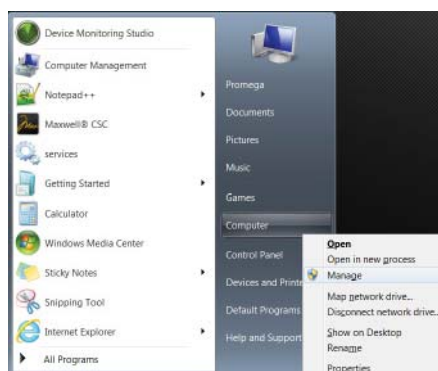


Figure 18. Touch Start→ Computer and select Manage. Touch the Computer button for three seconds to cause the 'Manage' screen to appear.



4.E. Configuring the Tablet PC (continued)

2. The 'Computer Management' window opens.
3. In the left pane of the 'Computer Management' window touch **Local Users and Groups** and double-tap **Groups**.

Note: If the **Local Users and Groups** menu item is not visible touch the **System Tools** item to expand that menu heading.

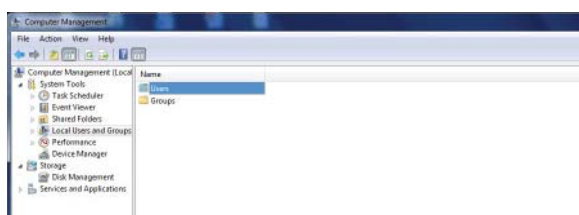


Figure 19. Select Groups from Computer Management Screen.

4. If you want to add Administrators, double-tap **PromegaAdministrators**. A 'PromegaAdministrator' window will open, which can be used to add existing users to the PromegaAdministrators group. Adding Administrators should be done according to the IT rules and IT procedures pertinent to your site. Touch the **Add...** button to add users to the PromegaAdministrators group. In the "Enter the object names to select" area of the window enter the username of the user you wish to add to this group. Touch **OK** on this window and touch **OK** on the 'PromegaAdministrator Properties' window to add users to the PromegaAdministrators group. Close the 'Computer Management' window.

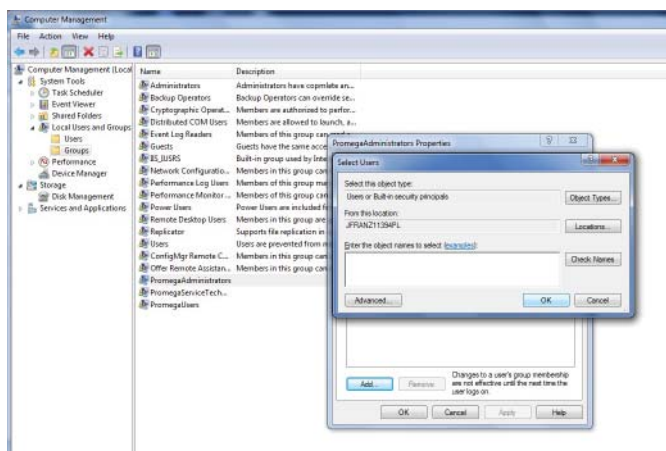


Figure 20. Adding users to PromegaAdministrators group.

5. If you want to add users, double tap **PromegaUsers**. A ‘PromegaUsers’ window will open, which can be used to add existing users to the PromegaUsers group. Adding Users should be done according to the IT rules and IT procedures pertinent to your site. Touch the **Add...** button to add users to the PromegaUsers group. In the “Enter the object names to select” area of the window enter the username of the user you wish to add to this group. Touch **OK** on this window and touch **OK** on the ‘PromegaUser Properties’ window to add users to the PromegaUsers group. Close the ‘Computer Management’ window.

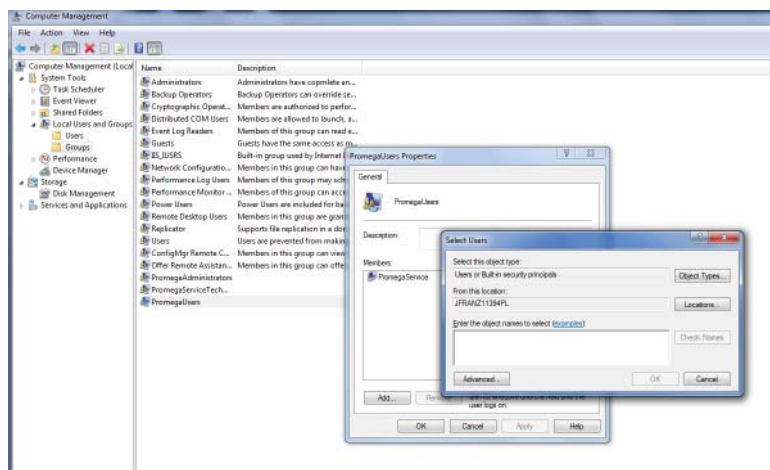


Figure 21. Adding users to the PromegaUsers group.



4.E. Configuring the Tablet PC (continued)

Removing User Accounts

The Maxwell® CSC User Interface employs the Windows® login user access levels as a security tool for adding approved users and associated passwords. Removing existing users can only be performed by someone with Administrator privileges.

1. From the 'Start' menu, select **Computer** and select **Manage** (to get to Manage menu, touch the **Computer** button for 3 seconds).

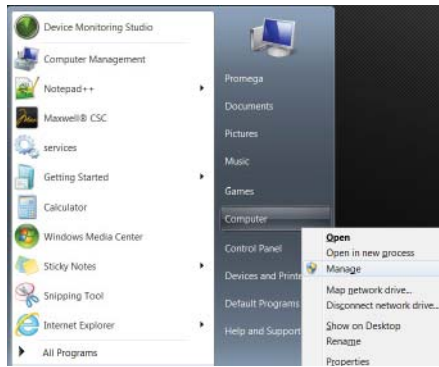


Figure 22. Touch Start to open the start menu, then touch and hold the Computer menu item to access the Manage option.

2. The 'Computer Management' window opens.
3. Touch **Local Users and Groups** and select **Groups**.

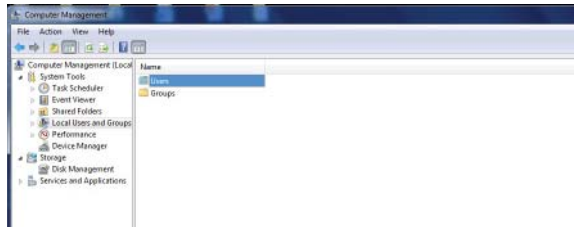


Figure 23. Select Groups from Computer Management Screen.

4. If you want to remove Administrators, double tap 'PromegaAdministrators'. A 'PromegaAdministrators' window will open, which can be used to remove users from the Administrators group. Removing Administrators should be done according to the IT rules and IT procedures pertinent to your site.
5. Select the user you want to remove and touch the **Remove...** button to remove users from the PromegaAdministrators group. Touch **OK** to remove users from the PromegaAdministrators group.

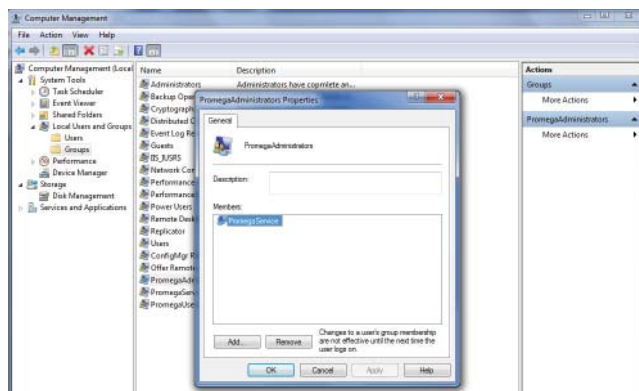


Figure 24. Removing users from the PromegaAdministrators group.

6. If you want to remove users, double tap **PromegaUsers**. A 'PromegaUsers' window will open, which can be used to remove users from the PromegaUsers group. Select the user to be removed and touch the **Remove...** button, to remove users from the PromegaUsers group. Touch **OK** to remove users from the PromegaUsers group.



4.F. Maxwell® CSC User Interface Screens

Set Instrument Name

Administrators can set the instrument name by touching the **Instrument Name** button from the ‘Administrator Page’ window (Figure 25; Home→Settings→Administrator). Administrators can use the on-screen keyboard to manually enter the instrument name (Figure 26). The instrument name should be entered following the procedures and rules at your site.

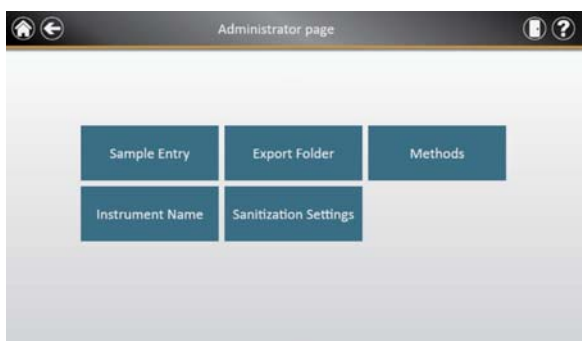


Figure 25. Administrator Page Window.



Figure 26. Instrument Name Window. Administrators can manually enter the instrument name from the instrument name window.



User Interface Home Screen

The 'Home' screen of the Maxwell® CSC User Interface is the main launching pad for interaction with the functionalities built into the Maxwell® CSC Graphical User Interface. The 'Home' screen (Figure 27) contains four buttons:

- **Start.** Pressing the **Start** button on the Maxwell® CSC User Interface screen will begin the process of preparing a protocol run on the Maxwell® CSC Instrument.
- **Results.** The **Results** button takes users to the 'Reports' Screen where it is possible to review, print, and export any of the run reports from previous chemistry and service processes.
- **Sanitize.** Pressing the **Sanitize** button activates the UV light in the Maxwell® CSC Instrument for the time specified by the instrument administrator. During the sanitization procedure it is possible to access reports, settings, and even start the procedure of setting up a new protocol processing run as long as these functions do not proceed to an interruption of the sanitization procedure. Functions that are not allowed during sanitization include opening the door, instrument self test, instrument cleanup, and proceeding past bar code entry for a protocol processing run.
- **Settings.** Accesses the 'Settings' window, which includes functions to: view Instrument Info, perform an instrument **Self Test**, remove plungers with **Clean Up**, export all log files with **Export Logs**, and change instrument settings with **Administrator** (only available to users with Administrator level access).

The Instrument name appears in the title bar of the user interface. The following navigation buttons are displayed across the top of the user interface window:

- **Exit.** When pressed will exit the Maxwell® CSC User Interface software and returns users to the Windows® Operating System.
- **Door.** This button toggles the open/closed status of the door on the Maxwell® CSC Instrument.
- **Help.** Pressing the **Help** button will activate the context-sensitive help for the current page of the Maxwell® CSC User Interface.



4.F. Maxwell[®] CSC User Interface Screens (continued)



Figure 27. Maxwell[®] CSC Home screen.

Within the user interface for the Maxwell[®] CSC Instrument it is possible to modify the following options. Settings can be changed later if required by following these instructions again.

Bar Code Options/Sample Entry

The method run by the Maxwell[®] CSC Instrument is determined by the Maxwell[®] CSC Kit being used. Each kit label contains a method bar code that tells the Instrument which method to run. The default setting for bar code entry is to request sample bar codes and kit bar codes. The Maxwell[®] CSC User Interface uses kit bar code entry as the mechanism for choosing which instrument protocol should be run for a given kit. Sample and kit bar code entry as well as cartridge selection are mandatory in the user interface. It is also possible to configure the Maxwell[®] CSC software for entry of cartridge ID, elution tube ID, and two additional administrator-defined bar code fields. Administrators can also determine whether the bar codes for any of these additional fields should match the sample ID bar code for a given cartridge position.

To configure the bar code entry options for the software perform the following steps:

1. From the 'Home' screen of the Maxwell[®] CSC User Interface (Figure 28) touch the **Settings** button.
2. On the 'Settings' screen select the **Administrator** button. If the current operator logged into the Tablet PC has administrator access rights the Settings screen (Figure 29) will display an **Administrator** button. By touching the **Administrator** button the administrator will gain access to functions that determine the performance characteristics of the Maxwell[®] CSC User Interface and Instrument.
3. From the Maxwell[®] CSC 'Administrator' page (Figure 30) touch the **Sample Entry** button.

4. The 'Sample Entry Settings' window is shown in Figure 31. On this screen the options for *Sample ID* and *Lot Number* are grayed out and checked as these are mandatory settings. The administrator can choose whether to also require the entry of *Cartridge ID* (bar code added to the sample processing cartridge by the user) and/or *Elution Tube ID* (bar code on the elution tube). Administrators can also define and label up to two custom bar code entry fields if desired. If any of these options is enabled the administrator has the option to choose whether the bar codes scanned for the indicated fields are required to match the *Sample ID*. This is useful for ensuring that all bar code values match for any given sample processing position on the instrument deck tray.
5. After the Sample Entry Settings are configured as desired touch the **Save** button to save these settings and return to the 'Administrator' page.
6. To return to the 'Home' screen touch the **Home** button in the upper left corner of the 'Administrator' page.



Figure 28. Maxwell® CSC Home screen. Selecting **Settings** opens the Maxwell® CSC 'Settings' screen from which bar code entry options can be configured.



4.F. Maxwell® CSC User Interface Screens (continued)

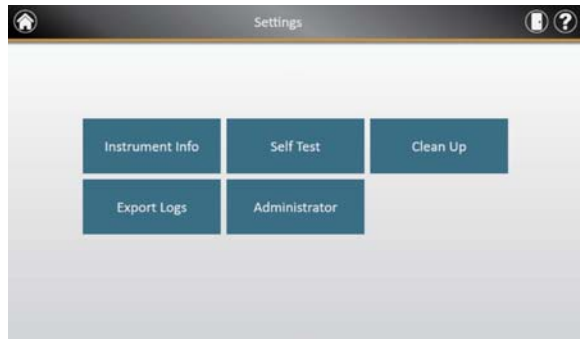


Figure 29. Maxwell® CSC Settings screen. From this screen you can access Administrator settings for the Maxwell® CSC Instrument options.

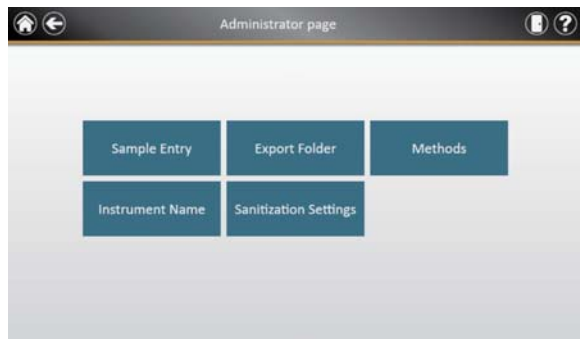


Figure 30. Maxwell® CSC Administrator page. The 'Administrator' page is only visible to administrators and gives access to sample entry and additional options.

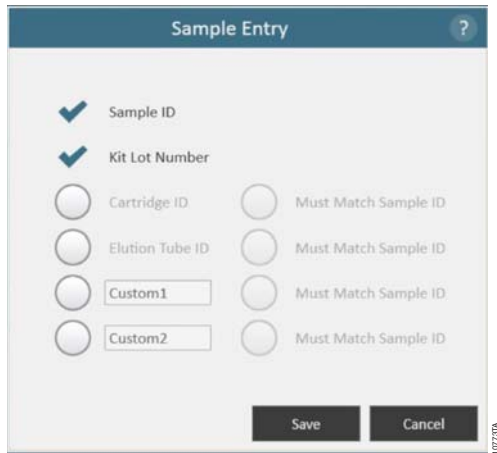


Figure 31. Maxwell® CSC Sample Entry window. This window gives the administrator the ability to configure the software for the bar code entry requirements necessary prior to performing a sample processing protocol. In addition to the required Sample ID and Kit Lot Number bar codes, optional fields can be enabled including Cartridge ID, Elution Tube ID, and two administrator-definable custom fields. The administrator can choose whether any of the optional fields are required to match the Sample ID for each processing position on the instrument.

Export Folder

The Administrator can select the folder where the protocol run reports can be exported. From the ‘Home’ screen of the Maxwell® CSC User Interface (Figure 28) touch the **Settings** button. On the ‘Settings’ screen select the **Administrator** button. If the current operator logged into the Tablet PC has administrator access rights the ‘Settings’ screen (Figure 29) will display an **Administrator** button. By touching the **Administrator** button the administrator will gain access to functions that determine the performance characteristics of the Maxwell® CSC User Interface and Instrument. From this screen touch the **Export Folder** button and select the folder (Figure 32) where the protocol run reports will be saved. Each colored box on the screen corresponds to the folders available in the particular directory. For example, in Figure 33, report files are exported to C:\Exports. To change the export folder settings, navigate to the corresponding folder by touching the buttons. For example, to change export folder settings to a new folder called ‘AS4000’, touch the “C:\” button. Then touch the **AS4000** button. Notice that the export folder path now shows “Drive\C:\AS4000\” as shown in Figure 34. Touch the **Save** button to save the changes to export settings or touch the **Cancel** button to cancel the changes (Figure 34).



4.F. Maxwell® CSC User Interface Screens (continued)

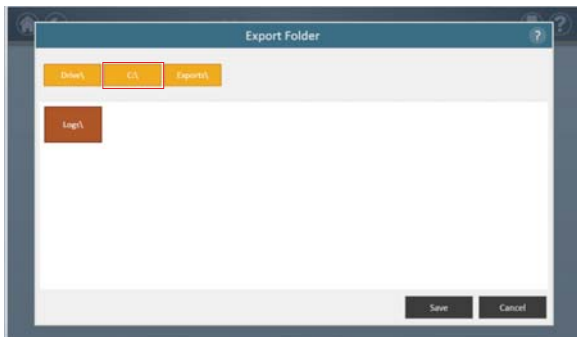


Figure 32. Export folder settings that can be changed by the Administrator.

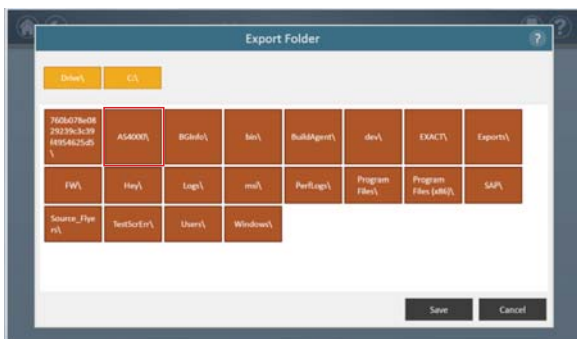


Figure 33. Changing export folder settings to a different folder.

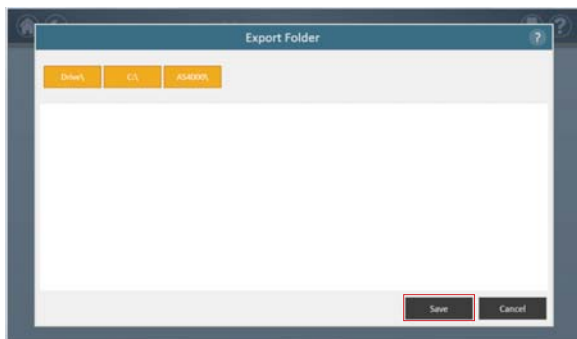


Figure 34. Touch 'Save' to save the settings for the new export folder.

Sanitization Settings

The Administrator can set the Sanitization settings by touching the **Sanitization Settings** button from the 'Administrator' page window (Figure 35; Home Screen → Settings → Administrator). On the 'Sanitization Settings' window the Administrator can specify the Sanitization settings (in minutes) and other settings such as *Sanitize after extraction* and/or *Sanitize on instrument startup* for a specified amount of time (Figure 36).

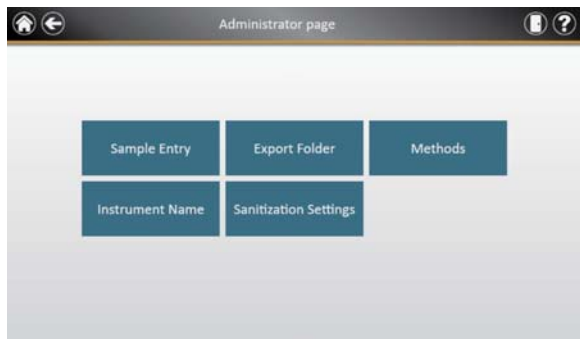


Figure 35. Administrator Page window. The Administrator can set the Sanitization settings by touching the **Sanitization Settings** button from the 'Administrator' page window.

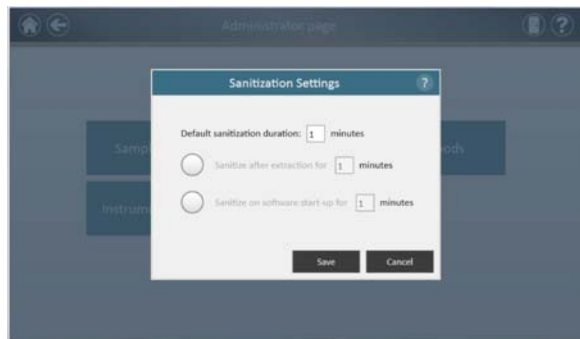


Figure 36. The Sanitization Settings window. The Administrator can specify the Sanitization settings (in minutes) and other settings such as Sanitize after extraction and/or Sanitize on instrument startup for a specified amount of time.



4.F. Maxwell® CSC User Interface Screens (continued)

Methods

Administrators can view all of the methods installed on this instrument or import new methods by touching the **Methods** button on the 'Administrator' page window (Figure 35). The 'Methods' window displays a list of the currently installed methods in the user interface including the name, version number, and catalog number for each method.

As Promega provides new purification kits, new protocol methods can be added to the Maxwell® CSC instrument. Occasionally, an existing protocol method may have to be updated. Only Administrators can add new protocol methods or update existing methods. Administrators can download new protocol methods for new purification kits or updated existing protocol methods from the Promega web site (www.promega.com) onto a USB drive that can be used to transfer the method to the Tablet PC using the Tablet's USB port. The Administrator can import the methods using the **Methods** button on the 'Administrator' page window (Figure 35) to bring up the 'Methods' Window. In the 'Methods' Window, the Administrator can touch the **Select Import Package** button to import new protocol methods (Figure 37). After navigating to the appropriate package file the Administrator can touch the **OK** button and the contents of the package file will be imported. Once the import is completed a message indicating the method was successfully imported is shown. If an updated method is imported for an existing kit, the new method will replace the original one. The current path that has been set is indicated at the top of the window. Any folders present within the default path are displayed in the main portion of the window, and package files are displayed as blue rectangles.

Administrators can download updated Maxwell® CSC Software from the Promega web site. Promega will provide instructions on how to update the Maxwell® CSC Software. Each method has an associated version number. The version number can be accessed by Administrators. If you need to reinstall a previous method, you will need to use the package file that contains that version. After importing a new kit and associated method, the Maxwell® CSC software database is updated, allowing users to scan the new kit bar code and have the new method automatically loaded.



Figure 37. Methods window. This window displays a list of the methods that are currently installed in the Maxwell[®] CSC User Interface. Touching the ‘Select Import Package’ displays a file path for navigating to a particular file (Figure 39). This file will be used to import a new or updated method/kit pair.

Self Test

You can run a “Self Test” by touching the **Self Test** button from the Maxwell[®] CSC ‘Settings’ screen (Figure 38). On touching the **Self Test** button, the Maxwell[®] CSC Instrument will perform a routine test (Figure 39) to confirm that instrument functions including initialization of the deck tray, plunger bar and magnet bar, motion of these systems, and the instrument heater are operating within acceptable performance ranges. Performing the Self Test will result in the generation of a system report that details the Pass/Fail status of the tests that are performed. Following the Self Test the software automatically opens this report.

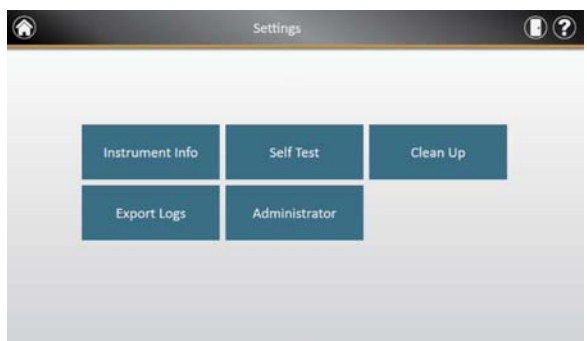


Figure 38. Maxwell[®] CSC Settings screen. From this screen you can perform Self Test for the Maxwell[®] CSC Instruments.



4.F. Maxwell[®] CSC User Interface Screens (continued)

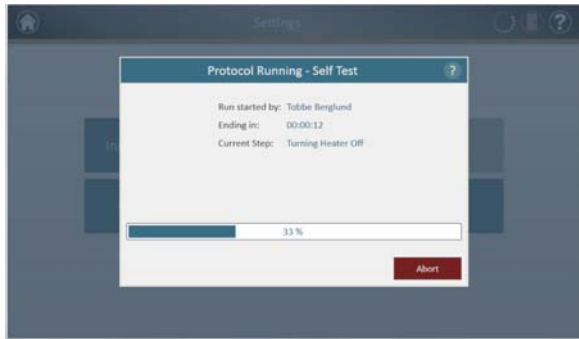


Figure 39. Self-test protocol being executed.

Clean Up

You can run a “Clean Up” procedure to ensure that all the plungers are appropriately unloaded after a protocol run. If your protocol run was aborted or had issues with plunger loading or unloading, the **Clean Up** procedure should be run. Clean Up does not clean the instrument and should not be confused with the Sanitization method. You can run a “Clean Up” by touching the **Clean Up** button from the Maxwell® CSC ‘Settings’ screen (Figure 40). Plungers can only be unloaded from the magnetic rods if a cartridge is in place. Place a cartridge (without a plunger) at each position on the deck tray that did not unload a plunger properly during the run. On touching the **Clean Up** button, you will be presented with a clean up checklist (Figure 41) with the following list:

- *Confirm that cartridges are present at positions for which plungers are still present on the plunger bar.*
- *Plungers are not present in any cartridges in the deck tray.*
- *Deck tray has been placed in the instrument.*

You will have to select **Confirm** on every item of the checklist (Figure 41) before you can start the clean up procedure. After you confirm the checklist items, touch the **Start** button to start the cleanup process. The Maxwell® CSC Instrument will go through the Clean Up process and will generate and display the system report from the Clean Up process. If plungers are not ejected after several clean up attempts the operator should contact Promega Technical Services (techserv@promega.com; 1-800-356-9526) to determine the next appropriate steps.



Figure 40. Maxwell® CSC Settings screen. From this screen you can perform “Clean Up” for the Maxwell® CSC Instrument.



4.F. Maxwell® CSC User Interface Screens (continued)

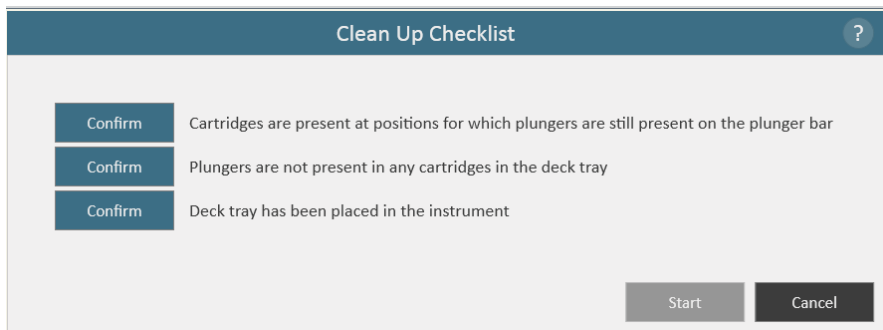


Figure 41. Clean Up Checklist screen. This screen presents you with a checklist prior to cleanup.

Instrument Calibration

The Maxwell® CSC Instrument is calibrated at the manufacturing site prior to use. No user calibration is necessary.

5. Operating the Maxwell® CSC Instrument

5.A. Preprogrammed Methods

The preprogrammed methods supplied with the Maxwell® CSC Instrument can be used to purify nucleic acids from a variety of clinical sample types. The sample type and type of nucleic acid purified are determined by the Maxwell® CSC reagent kit used. Please refer to your specific Maxwell® CSC Purification Kit Technical Manual for information on sample preparation and handling. Scanning of the kit bar code is used as the mechanism for protocol selection as well as confirmation that the kit being used is within the expiration date. Based on the administrator settings in the user interface it is minimally necessary to enter bar code information for the sample ID prior to initiating sample processing. If you are using sample ID bar codes on cartridges and elution tubes, we recommend that you scan the bar code for each one immediately before placing it in the deck tray.

5.B. Starting a Protocol

1. Prepare samples for nucleic acid extraction following the instructions provided in the Technical Manual for the specific Maxwell® CSC reagent kit. From the 'Home' screen (Figure 42) select the **Start** button to begin the process of running a protocol.



Figure 42. Maxwell® CSC Home screen. Selecting the **Start** button begins the process of running a protocol on the Maxwell® CSC Instrument.

2. You will be presented with a screen that will ask you to scan the bar code on the kit box. You can scan the bar code on the kit box indicated by the *Scan Here* label (Figure 43). Alternatively, touch the **text box** (Figure 44) to manually enter the bar code information using the touchscreen. Maxwell® CSC accepts bar codes in the following format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format (example: AS13213221872012-05, where the product catalog number is AS1321, the kit lot number is 322187 and the expiration date is 2012-05). Only if the bar code entered has this format will the **OK** button become active. Once the bar code is correctly entered, touch the **OK** button to get to the Cartridge Setup screen. You can touch the **Back** button to return to the 'Home' screen. Scanning or entering the bar code automatically selects the protocol to be run.



5.B. Starting a Protocol (continued)

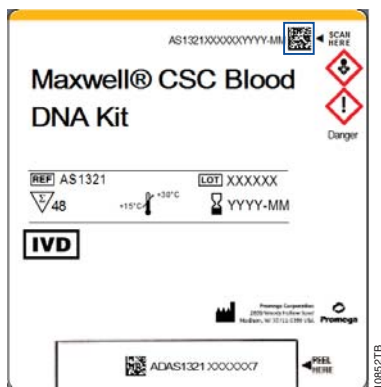


Figure 43. Kit label indicating bar code to scan. Shown in the blue box is the bar code to scan on the kit label for starting a purification run.



Figure 44. Scan Bar Code screen. Scanning the bar code automatically selects the protocol on the Maxwell® CSC Instrument.

3. There are two potential error modes that can occur with bar code scanning:
 - a. If the kit lot has passed the specified expiration date a user prompt will appear explaining that the kit has passed its expiration date and cannot be run. This kit should not be used, and the user should select another kit that is within its specified expiration date to use for the run.
 - b. If the scanned product catalog number does not have a nucleic acid purification method associated with it on this instrument, a user prompt will appear indicating that the software does not have a protocol for this catalog number. Upon selecting the OK button on the user prompt, the software will return to the 'Home' screen. Please contact Promega Technical Services (e-mail: techserv@promega.com) or visit: www.promega.com/resources/tools/maxwellcscmethod to get the most updated information on the available methods.

4. After scanning the bar code, you will be presented with a 'Cartridge Setup' screen (Figure 45) that allows you to specify the positions on the deck tray that will be occupied by cartridges and to enter identification information for each sample.
 - a. Deselect empty positions by touching the blue rectangle for each position that will not be used. The unused positions will turn gray with no data shown. The inclusion or exclusion of any given sample processing position is only used for reporting purposes to indicate how many samples were processed and in which position they were processed on the instrument.
 - b. Once cartridge positions are selected, you must enter all sample tracking information required by the administrator to proceed. Minimally required information is Sample ID and Kit lot number. However, administrators may also require entry of cartridge bar codes, elution tube bar codes, and other information required by two additional administrator-defined fields. All of the required information must be entered for all selected cartridge positions before the **Proceed** button becomes active.
 - Touch the black box below a cartridge position to enter bar code information for the selected position (Figure 46). If cartridge and elution tube bar codes are required, we recommend that these are scanned immediately before placing the cartridge or elution tube in the deck tray.
 - Tap twice on the **Sample ID** box to enter the sample information manually.
 - Multiple kit lots can be entered for a run by touching multiple black box positions and scanning an additional kit bar code (next to the Scan here label). Touching the arrow on the right or left side of the information entry area will move to the next available cartridge position. When entering multiple kit lot numbers the bar code needs to conform to the format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format (example: AS13213221872012-05 where the product catalog number is AS1321, the kit lot number is 322187 and the expiration date is 2012-05). The scanned bar code will be checked to make sure it has the same product catalog number as the originally scanned kit and that the kit is within the expiration date. An error message is displayed if the Kit is expired, or if the kit is not supported by the instrument.

Note that positions with incomplete information will display a red circle with an exclamation point in the top of the blue rectangle. The **Proceed** button will be gray and not active while required information is missing.

Once all information is correctly entered, touch the **Proceed** button to prepare the instrument for this extraction run.

Important. There are two bar codes on the kit label. Enter the bar code at the top of the label. You will receive an error message if you scan the wrong bar code.

5.B. Starting a Protocol (continued)

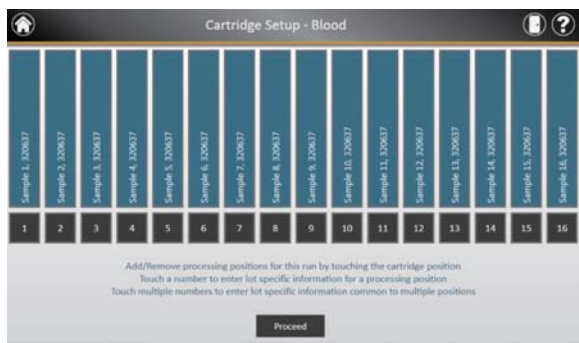


Figure 45. Cartridge Setup screen. At the top of this screen the selected protocol is indicated. This screen allows the user to select which cartridge positions will be processed. To select/deselect a cartridge position touch the blue rectangle for any given position.

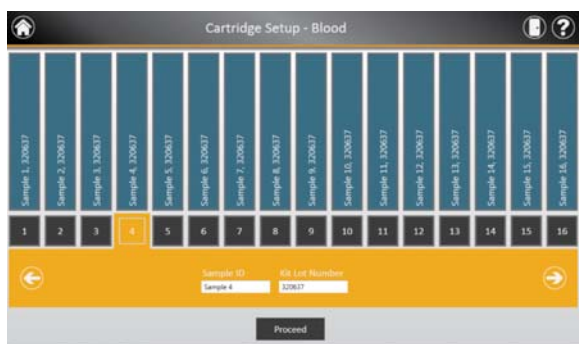


Figure 46. Bar code and kit lot input screen. By selecting the black box at the bottom of any cartridge position, sample ID and kit lot information can be entered for that position. Touching the arrow on the right side of the entry area will move to the next available cartridge position. Selecting multiple positions can be used to enter kit lot information for multiple cartridge positions.

5. After all desired information has been entered for the cartridges and samples that will be processed touch the **Proceed** button to move to the 'Door' screen (Figure 47). Press the OK button to open the Maxwell[®] CSC Instrument door.

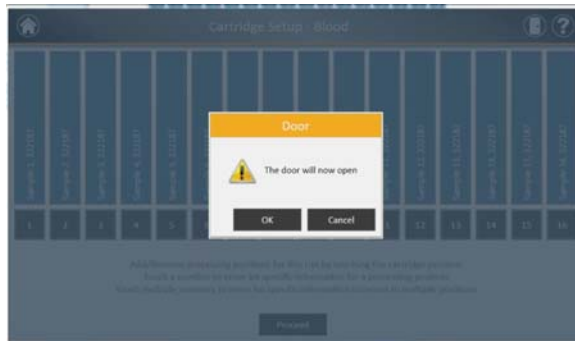


Figure 47. Door open screen. Informs the user that the Maxwell® CSC Instrument door will open.

6. You will be presented with an 'Extraction Checklist' screen (Figure 48). This checklist indicates the steps that need to be performed prior to starting an extraction process. You must confirm that all checklist items have been correctly performed before the **Start** button becomes active. Touch the **Cancel** button to return to the 'Cartridge Setup' screen.



Figure 48. Extraction Checklist screen. This screen indicates the steps that will need to be performed to prepare the instrument for processing the selected samples. Preprocessing steps are not indicated on the 'Extraction Checklist' and should be performed prior to this stage according to the technical manual for the kit being processed.



5.B. Starting a Protocol (continued)

7. Set up the deck tray and instrument as indicated on the 'Extraction Checklist' screen. The steps necessary for setting up the instrument are:
 - Sample preprocessing is complete. Sample preprocessing, if required, is described in the Technical Manual for the specific Maxwell® CSC reagent kit.
 - Place cartridges at the selected positions in the deck tray (Figure 49). Press down firmly to snap the cartridges in place at both ends. There should be an audible snap.



Figure 49. Place the cartridges in the deck tray, and press firmly to snap them in place.

- Completely remove seals from all cartridges.
- Place elution tubes at the selected positions in the deck tray.
- Add the appropriate volume of elution buffer to each elution tube (see the Maxwell® CSC reagent kit Technical Manual for the correct volume to use).
- Add preprocessed sample to well #1 (nearest the clip end) of the cartridge
- Ensure no plungers from the previous run(s) are present on the plunger bar inside the instrument. If there are plungers present, go to Section 5.C for instructions for plunger removal.
- Place a plunger in the last well (closest to the elution tube) of each cartridge.
- Place the deck tray in the instrument as shown in Figure 50. Ensure that the deck tray is completely seated inside the instrument.

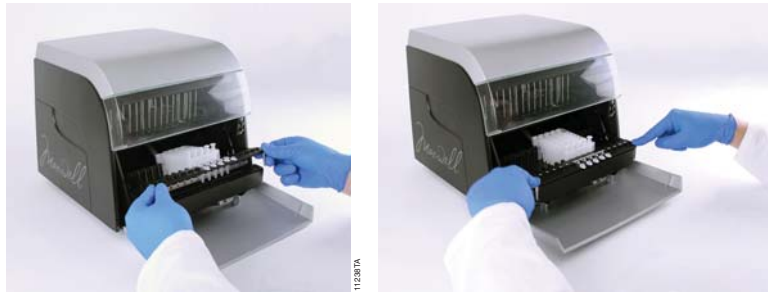


Figure 50. Place the deck tray in the instrument.

After performing each step touch the **Confirm** button next to that step to indicate that it has been performed. Only after all of the checklist items have been confirmed will the **Start** button become active (Figure 51). Touch the **Start** button to begin the purification or touch the **Cancel** button to return to the previous screen.

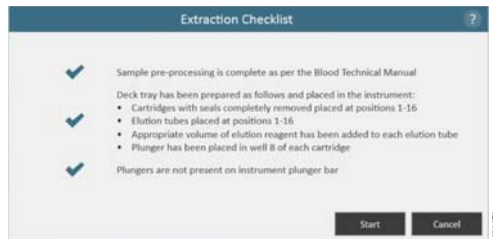


Figure 51. Completed Extraction Checklist. When all checklist items have been confirmed, the **Start** button will become active. Touch the **Start** button to begin the processing run or the **Cancel** button to return to the sample information entry screen.

Note: The reagent cartridges are designed to be used with potentially infectious substances. Users should wear the appropriate protection (i.e., gloves, goggles, etc.) when handling infectious substances. Users should adhere to their institutional guidelines for the handling and disposal of all infectious substances used with this system.

Important. The plungers must be placed in the correct starting position. If the instrument goes through a run with the magnetic rods unprotected, the magnetic rod assembly must be thoroughly cleaned (see Section 6.B) and the cartridges containing the samples discarded. The samples will be lost.



5.B. Starting a Protocol (continued)

8. While the protocol runs, you will see the ‘Protocol Running’ screen (Figure 52). The title bar of the ‘Protocol Running’ screen indicates the protocol currently being run. This screen displays:

- The name of the user who started the protocol run.
- An estimate of the time remaining until the end of the run.
- A description of the current step being performed.
- A progress bar showing the percent completion of the progress.

If you wish to abort the current run, touch the **Abort** button in the lower right corner of the screen. Please note that any samples being processed will be lost if a run is aborted.

9. Protocols can end through one of three mechanisms:

- The protocol completes successfully.
- The protocol is aborted by the user.
- An instrument error.

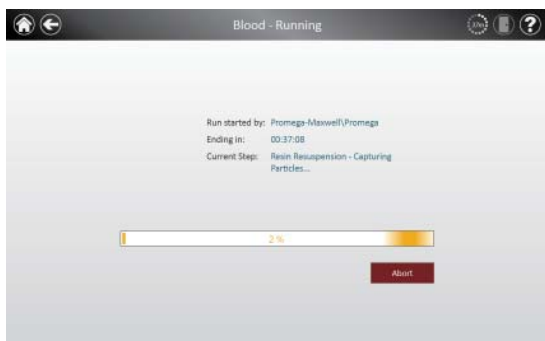


Figure 52. Protocol Running screen. The ‘Protocol Running’ screen is displayed during a protocol run. This screen indicates what protocol is currently being run at the top of the screen. Also indicated on this screen are the user who started the run, an approximate indication of when the run will end, a description of the current method step and a progress bar showing the percent completion of the progress. If you wish to abort the current run, touch the **Abort** button in the lower right corner of the screen.

Protocol Completes Successfully

When the protocol completes successfully the 'Protocol Running' window will change to indicate that the protocol has been completed (Figure 53). After a protocol is complete the Current Step will be listed as *Completed*. Touch the **Open Door** button to open the door of the Maxwell[®] CSC Instrument.

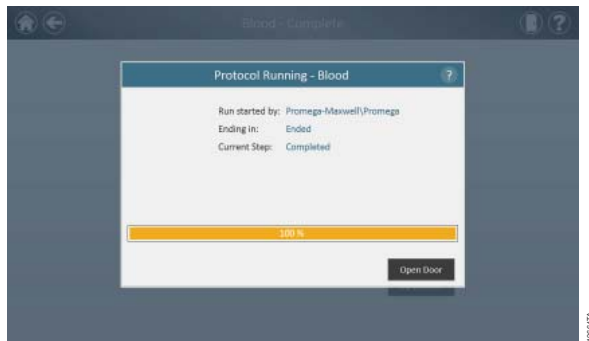


Figure 53. Protocol Running window after completion of the protocol. Upon completion of the currently running protocol, the 'Protocol Running' window indicates 100% completion in the run progress bar. The Current Step changes to Completed after a run is finished. After a protocol is completed you can touch the **Open Door** button to open the door of the Maxwell[®] CSC Instrument to remove the deck tray.

Close the caps of the elution tubes, and remove the tubes from the tray (Figure 54). Verify that all the cartridges have a plunger in well #8. Remove the deck tray by gripping the tray firmly by the elution tube position, lifting up the tray and pulling it out (see Figure 55). The deck tray may be warm to the touch after a run is completed. Exercise caution while removing the deck tray. If there were cartridges missing plungers, proceed to Section 5.C to remove them. The extracted nucleic acid is present in the elution tubes. Remove the cartridges and plungers from the Maxwell[®] CSC Deck Tray. Used cartridges and plungers should be disposed of appropriately according to your institution's procedures for hazardous and biohazardous waste. Do not reuse reagent cartridges, Plungers or Elution Tubes.



5.B. Starting a Protocol (continued)



Figure 54. Closing the elution tube caps.

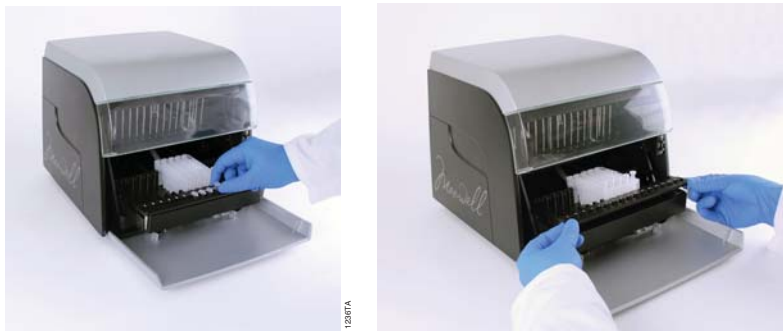


Figure 55. Removing the elution tubes and the deck tray.

After the door is opened, the 'Report View' window (Figure 59) will be presented to you. If the administrator has required that UV sanitization be performed after a purification run, the user will be prompted to confirm that no samples or eluates are present in the instrument prior to the UV sanitization (see Section 5.E).

User Aborts Protocol

If the protocol is aborted by the user, the 'Protocol Running' window will indicate that the protocol has been aborted (Figure 56). After a protocol is aborted, the Current Step will be listed as Aborted by user. After Aborting the protocol, you can press the **Open Door** button to bring up the 'Clean Up' window (Figure 57).

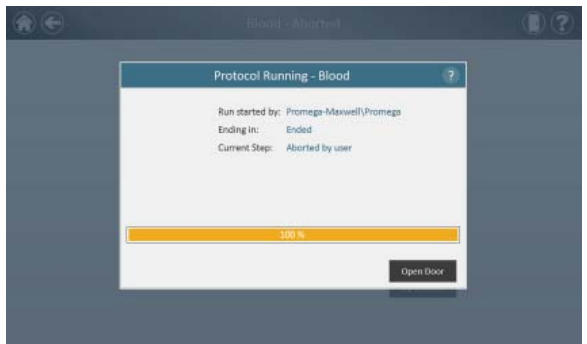


Figure 56. Protocol Running window after protocol abort. If a protocol is aborted by the user or due to an instrument error, the 'Protocol Running' window changes to indicate that the protocol has been aborted and specifies the reason next to the Current Step: title. After a protocol is aborted you can touch the **Open Door** button to run the Clean Up procedure. An aborted run (initiated by the user or due to instrument error) will result in the loss of all the samples. Do not attempt to re-purify samples from an aborted run.

Instrument Error

If the protocol is aborted due to instrument error, the 'Protocol Running' window will change to indicate that the protocol has been aborted (Figure 56) and will display an error message.

After a protocol is aborted the Current Step will list the reason for aborting the protocol.



5.C. Clean Up

After Aborting the protocol, you can press the **Open Door** button to bring up the ‘Clean Up’ window (Figure 57).

The ‘Clean Up’ window asks you to check to see if plungers are still engaged on the plunger bar. If the plungers are not engaged, remove the deck tray from the instrument and touch the **Skip Cleanup** button to continue. On pressing the **Skip Cleanup** button, you will be presented with the extraction report (Figure 58).

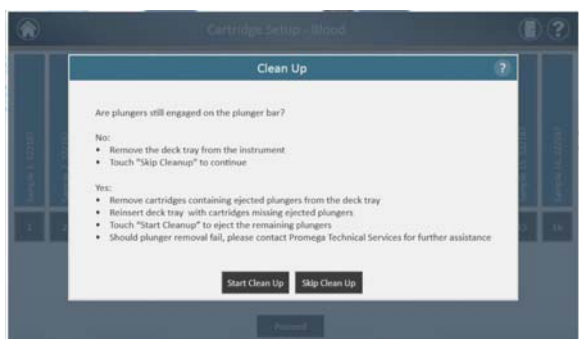


Figure 57. Clean Up window after protocol abort/instrument error. If a protocol is aborted by the user or due to an instrument error, the ‘Clean Up’ window is displayed that asks the users to **Start** or **Skip Clean Up** depending on whether the plungers are still engaged or disengaged from the plunger bar.

If some or all of the Plungers are still engaged on the plunger bar, you must perform the following steps to remove the plungers before another purification run can be performed:

- Remove cartridges containing ejected plungers from the deck tray.
- Reinsert the deck tray with the remaining cartridges (those missing ejected plungers).
- Touch the **Start Cleanup** button to eject the remaining plungers .

After the Clean Up is successful, you can press the **Open Door** button and remove the deck tray. You will be presented with the ‘Report View’ window.

If the plunger clean up fails, you should contact Promega Technical Services for further assistance.

Results

After pressing the **Open Door** button in the 'Protocol Run' window, the 'Report View' screen is displayed (Figure 58). This screen displays the sample tracking and protocol specific information for the current instrument run. Included in this report are the sample tracking information recorded prior to starting the protocol, the final status of the protocol (Completed or Aborted), the time the protocol run was started, the length of time the protocol took to process, the operator ID and the Maxwell[®] CSC Instrument details (software version, firmware version, instrument name, serial number, etc.).



Figure 58. Report View screen. The 'Report View' screen displays the sample tracking and protocol-specific information for the current instrument run. Included in this report are the sample tracking information recorded prior to starting the protocol, the final status of the protocol (Completed or Aborted), the time the protocol run was started, the length of time the protocol took to process, the operator ID and additional instrument information. In the lower left corner of the screen is an **Export** button that will be used for exporting report information.

Using the buttons on the left side of the Report View window, you can

- Print Reports
- Zoom in reports
- Zoom Out reports
- View the reports in Actual Size
- Fit the Report to screen width
- View the Whole Page of the report

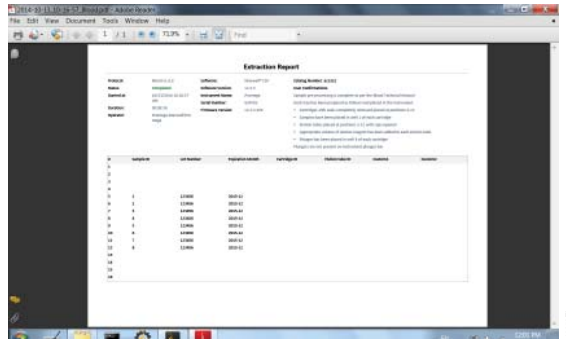


Figure 61. Example of a file in the PDF format.

5.D. Running Reports

From the ‘Home ‘screen (Figure 62) of the user interface, it is possible to view sample tracking reports and service reports on the instrument by pressing the **Results** button. The ‘Results’ screen displays a listing of all of the reports for the protocols, service, and system tasks that have been run on the system (Figure 63). The user can filter reports by date range by touching the buttons on the left side to view reports for runs completed today, this week, this month, the past 3 months, the past 6 months, this year or all Maxwell® CSC Instrument runs completed over the life of the instrument. In addition, reports can be filtered to show only certain report types by touching the **Extraction**, **Service**, **System**, or **All Types** buttons on the left side of the view. Touch the column headers to sort the report based on column contents. Touch the desired report entry to see a detailed view of the report data (Figure 64). All reports can be exported to the administrator-specified Export Folder by touching the **Export All** button in the lower left corner of the view.



Figure 62. Maxwell® CSC Home screen. Selecting **Results** opens the Maxwell® CSC ‘Reports’ screen from which extraction reports from all extraction runs, service activities, and system activities can be viewed.



4 Results				
Today	Date/Time	Name	Type	By
This Week	10/13/2014 10:16:57 AM	Blood	Extraction	Promega-Maxwell/Prom...
This Month	10/13/2014 10:11:58 AM	Blood	Extraction	Promega-Maxwell/Prom...
3 Months	10/13/2014 9:45:47 AM	Blood	Extraction	Promega-Maxwell/Prom...
6 Months	10/13/2014 7:10:03 AM	Blood	Extraction	Promega-Maxwell/Prom...
This Year				
All				
Extraction				
Service				
System				
All Types				
Export All				

Figure 63. Reports screen. The ‘Reports’ screen lists the extraction reports from all of the protocols that have been run. Touch any given report listing to see a detailed view of the report data from that protocol run.

Extraction Report				
Print	Protocol: Blood 12.1.0	Software: Maxwell® 121	Calibration Number: 43333	View Calibration
Zoom In	Reactor: C10000001	Software Version: 12.1.0	Serial Number: 010770	View Calibration
Zoom Out	Report#: 10/13/2014 10:16	Software Version: 12.1.0	Serial Number: 010770	View Calibration
Actual Size	Operator: Promega-Maxwell/Promega	Software Version: 12.1.0	Serial Number: 010770	View Calibration
Fit to Width				View Calibration
Whole Page				View Calibration
Export				View Calibration

Figure 64. Extraction Report. An example of the sample tracking information present in an extraction report as well as Exporting reports.

5.E. Sanitizing

You can Sanitize the instrument from the 'Home' screen (Figure 65) by touching the **Sanitize** button. Make sure all samples have been removed from the instrument and all spills have been cleaned prior to initiating the UV sanitization protocol. You will be presented with a sanitization checklist (Figure 66) that informs you on how long the UV sanitization will take. It will also ask you to confirm that no samples or eluates are present in the instrument prior to running Sanitization. After you confirm, the **Start** button is enabled. Touch the **Start** button to Start UV sanitization.



Figure 65. Home screen. Selecting the **Sanitize** button begins the process of Sanitizing the Maxwell® CSC Instrument.



5.E. Sanitizing (continued)

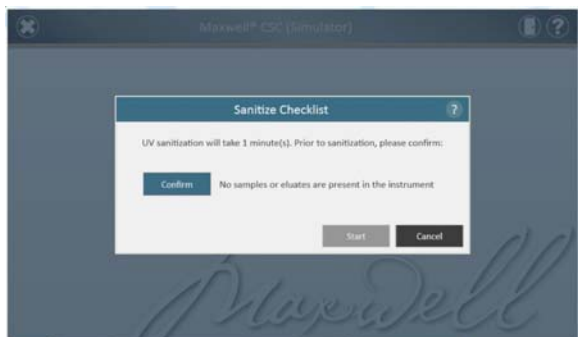


Figure 66. Sanitize Checklist screen. The sanitization checklist informs you on how long the UV sanitization will take. It will also ask you to confirm that no samples or eluates are present in the instrument prior to running Sanitization.

After Sanitization is completed, you will see a flashing indicator:

Touch the **indicator** to view the Sanitization report.

Note: UV radiation is useful in decontamination due to its ability to inactivate biological molecules. UV treatment is not a substitute for cleaning. Using the UV Sanitization protocol alone may not provide sufficient decontamination.


6. Cleaning and Maintenance

The Maxwell® CSC Instrument has no user-serviceable parts and is designed to require minimal maintenance. However, it is important to clean the instrument after every use. If samples or reagents have been spilled, it is important to clean the instrument immediately to avoid damage or contamination of samples.

Most parts of the Maxwell® CSC Instrument have an anodized coating, which forms a durable, easily cleaned barrier on the metal. Always turn off and unplug the instrument before cleaning.

6.A. General Care


Wipe up any spills immediately. After each use, wipe off the magnetic rod assembly, plunger bar, inside platform, and the outside of the instrument using a cloth dampened with 70% ethanol. Do not use other solvents or abrasive cleaners.

 **Important.** Wear gloves or use other protective means. If the instrument is used with biohazardous materials, dispose of any cleaning materials used in accordance with your institutional guidelines.

- Clean the Maxwell® CSC Instrument after every use.
- Keep the vents in the back of the machine clear of dust.
- Do not remove the Maxwell® CSC Instrument case for cleaning. This will void the warranty.
- Do not use a spray bottle to soak instrument surfaces with large volumes of liquid.
- Never allow liquids to remain on instrument surfaces for extended periods of time.
- Keep all moisture away from the heated elution tube slots to prevent damaging the heating elements.

6.B. Cleaning the Hardware

If the plungers are inadvertently omitted during a run or placed in the wrong starting position, the machine may go through a run with the magnetic rods unprotected. If this happens, the magnetic rod assembly needs to be cleaned.


 **Important.** Wear gloves or use other protective means. If the instrument is used with biohazardous materials, dispose of any cleaning materials used in accordance with your institutional guidelines.

1. To clean the magnetic rod assembly, wipe with a damp, soft cloth. You also can wipe the assembly with 70% ethanol. Removal of paramagnetic particles from the magnetic rod assembly will require multiple wipes. Wrapping the damp cloth around a magnet (such as a stir bar) will make the removal of magnetic particles much easier.
2. If the magnetic rod assembly cannot be cleaned, please contact Promega Technical Services for assistance.



6.C. Dealing with Spills

Wipe up any spills immediately. If the reagent spills in the instrument, wipe up visible material with a cloth. Dried material should be wiped up with a wet paper towel. Note that the reagents contain hazardous materials; therefore dispose of paper towels according to your institutional guidelines. Wipe well once visible material is removed. In case of spills in the instrument where there is a potential biohazard, wipe up the spill with paper towels and wash the spill area with a detergent solution such as Steris® LpH® following the manufacturer's instructions. Dispose of towels used according to your institutional guidelines for biohazardous waste.

 **Important.** Bleach reacts with guanidine thiocyanate, which is used in Maxwell® CSC reagent cartridges, and should not be added to any sample waste containing lysis solutions. Bleach should not be used to clean Maxwell® CSC reagent spills.



7. Troubleshooting

For questions not addressed here, please contact your local Promega Branch, Office or Distributor. See the Promega Web site, www.promega.com, to find your nearest Promega branch or distributor. Contact information available at: **www.promega.com**. E-mail: **techserv@promega.com**

Symptoms	Causes and Comments
Instrument does not unload the plungers	<p>If the Plungers are still engaged on the plunger bar, perform the following steps:</p> <ul style="list-style-type: none"> • Remove cartridges containing the ejected plungers from the deck tray. • Reinsert the deck tray with cartridges without the ejected plungers. • From the 'Home Screen' touch the Settings button and select Clean Up. Confirm checklist items and follow onscreen prompts to attempt to unload plungers. <p>If the plunger cleanup fails, contact Promega Technical Services for further assistance.</p>
Tablet PC touch screen does not appear to be working	<p>Verify that the plug is securely connected to the Tablet PC.</p> <p>Verify that the instrument is plugged into the USB port on the Tablet PC.</p> <p>Restart the Maxwell® CSC Tablet and launch Maxwell® CSC software.</p> <p>If the issue is not resolved, contact Promega Technical Services (techserv@promega.com).</p>
Cannot get beyond the 'Scan bar code' screen	<p>Be sure that you are scanning the correct bar code (as shown in Figure 44).</p> <p>Be sure that you are using the correct kit.</p> <p>Be sure that the kit has not expired.</p> <p>If you still experience problems, contact Promega Technical Services (techserv@promega.com).</p>
Cannot change the sanitization time or load new protocols	<p>Only system administrators have the ability to change certain instrument functionality. If you are not a system administrator, please contact your system administrator.</p>
Power failure during run	<p>In the event of a power failure, turn the instrument and the Tablet PC OFF. When power is resumed, turn the instrument and Tablet PC back ON. Check to see whether plungers are loaded on the plunger bar. If so run Clean Up protocol from the Settings Menu and follow prompts to safely remove the plungers. After plungers have been unloaded remove the deck tray from the instrument if it is still present.</p>



7.A. Errors and Warnings

Error	Explanation
Initialization Failure: Access Denied, not a valid Promega User, Please contact your system administrator	Promega User not set up correctly. Please contact your administrator/IT personnel to resolve this issue.
USB Device is not found; is it turned Off or disconnected	Tablet PC is not connected to the instrument or Tablet PC is OFF or the instrument is OFF. Check to see if Tablet PC is connected to the instrument or Turn ON the Tablet PC or turn ON the instrument. If error still persists, contact Promega Technical Services
Open Door detected during Operation	Door open was detected during operation. Depending on when this happened, samples may or may not be salvageable. Press Continue and let the run finish. If error still persists, contact Promega Technical Services
Protocol: Aborted By user	User aborted protocol.
An error occurred during cartridge placement verification. Ensure cartridges are fully seated	Instrument detected cartridges were not fully seated in the tray. Reseat the cartridges in the tray. If error still persists, contact Promega Technical Services.
Door Sensor Tripped	Door sensor trip detected. Contact Promega Technical Services.
Door failed to open successfully	Door failed to open. Contact Promega Technical Services.
A previous instrument task is still active. Please try again later	User tried to do something when previous run was active. Wait for the current process to complete before trying. If error still persists, contact your IT administrator or Promega Technical Services.
Previous session has timed-out, device disconnected?	Connection was lost during previous instrument operation or USB was unplugged during a run and then plugged back in. Check to see that the USB cable is connected to the instrument or no one unplugged the USB cable while the instrument operation was running. If error still persists, contact Promega Technical Services.

7.A. Errors and Warnings (continued)

Warnings	Explanation
Warning: Failed to Start Extraction: Self-Test has not passed	Instrument self-initialization has not passed. Contact Promega Technical Services.
Warning: Startup Diagnostics: Abort of previous run detected	Instrument detected that previous run was aborted. Check to see whether plungers are loaded on the plunger bar. If so run Clean Up protocol from the Settings Menu and follow prompts to safely remove them. After plungers have been unloaded remove the deck tray from the instrument if it is still present.
Warning: Startup Diagnostics: Firmware version change detected	User warning informing user that the firmware version change has been detected.



8. Appendix

8.A. Service

We recommend that the Maxwell® CSC Instrument be serviced once a year.

8.B. Returning the Maxwell® CSC Instrument for Service

The Maxwell® CSC Instrument is designed to provide years of consistent performance with little maintenance. If a problem arises with your instrument, please contact Promega or your local Promega representative for support. Visit the Promega Web site at www.promega.com for the contact information for the Promega branch or distributor nearest you. If further action is required, repair options will be presented and a return authorization number assigned if necessary. Promega is not responsible for instrumentation returned without an authorization number. When you ship the instrument for service, please remember to:

- Obtain return authorization from Promega.
- Decontaminate the instrument (see Section 10 for decontamination instructions).
- Affix a signed and dated Certificate of Decontamination inside the lid of the shipping box in which the instrument is returned (see Section 10). Failure to complete and attach the Certificate of Decontamination will result in a decontamination charge.
- Use the original packaging to ensure that no damage will occur to the instrument during shipping.
- Any damage will incur additional charges. Return all of the accessories with the instrument, including the bar code reader and Tablet PC.

Note: If the original packaging is lost or damaged, contact Promega or your local Promega representative for replacement packaging.

8.C. Repacking the Maxwell® CSC Instrument

Preparation of the Maxwell® CSC Instrument Prior to Repacking:

- Ensure that the cartridges and elution tubes are removed from the instrument platform.
- Switch off and unplug the instrument. Ensure that computers and bar code readers have been disconnected.

Repacking the Maxwell® CSC Instrument

Note: If you do not have the original Maxwell® CSC Instrument packaging, please contact Promega Technical Services or your local Promega representative to order Maxwell® CSC Instrument packaging.

Ship the Maxwell® CSC Instrument only with Promega packaging to avoid any damages.

8.C. Repacking the Maxwell® CSC Instrument (continued)

1. Turn the instrument OFF and unplug it from the outlet.
2. Open the instrument door and manually push the deck to the back of the instrument.
3. Manually bring the plunger bar (Figure 67) down to cover the magnetic tips.

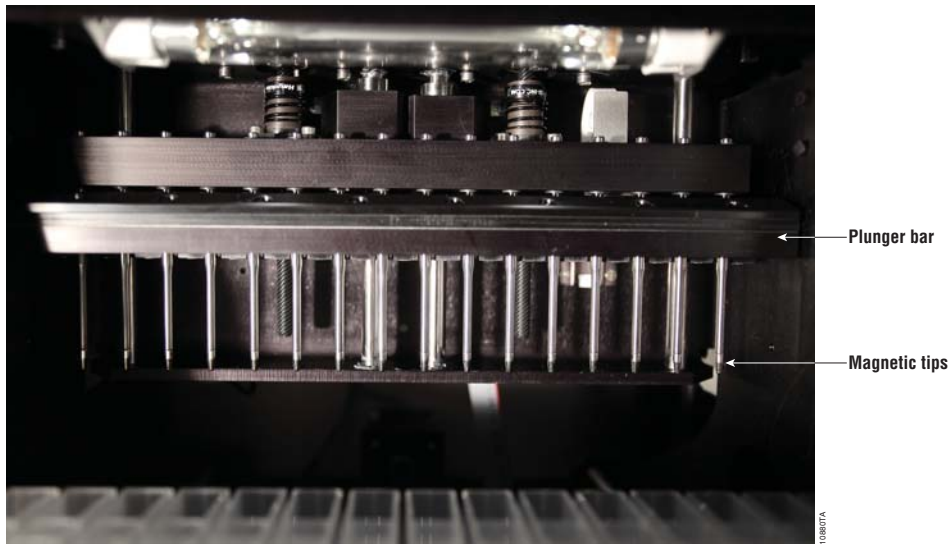


Figure 67. Plunger Bar.

4. Place the die cut foam as shown in Figure 9.
5. Slide the other die cut foam to lock the deck and the plunger bar as shown in Figure 9. You may have to manually move the plunger bar so that it is flush with the foam. The two die cut foams prevent the plunger bar and deck from moving during shipping. Note that the instrument door will not close completely with the foam in place. This is by design. Do not try to force the door to close, or the door can break.
6. Place the instrument back in the plastic bag.



8.C. Repacking the Maxwell® CSC Instrument (continued)

7. Place the instrument in the bottom foam packaging material. The instrument will only fit properly into the bottom foam piece in one orientation (Figure 68). **Note:** Plastic bag used for shipping not shown for photo clarity.



Figure 68. Maxwell® CSC Instrument in correct orientation in the box.

8. Place the top foam packaging over the top of the instrument as shown (Figure 69).



Figure 69. Foam packing on top of box.

8.C. Repacking the Maxwell® CSC Instrument (continued)

9. Place the accessories box on top of the packing foam. Affix the Certificate of Decontamination on top of the accessories box.
10. Add the shipping container top.
11. Lock the shipping container using the four white plastic clips.



Figure 70. Using white plastic clips to lock the shipping container.

12. Close the flaps on the shipping container top, and secure them with packing tape.



13. Secure the top and bottom pieces of the shipping container with nylon shipping straps. If you don't have nylon straps for the instrument, please contact Promega Technical Services, and a set will be sent to you.



Figure 71. Nylon straps on shipping container.

14. Seal the box securely. Write the return authorization number provided to you by Promega or your local Promega representative on the outside of the shipping box.

8.D. Instrument Disposal

Contact your local Promega Representative for disposal of the instrument. Please follow your institutional requirements to handle the disposal of accessories. Instrument should be decontaminated prior to disposal.



9. Warranties, Service Agreements and Related Products

9.A. Warranty

Upon purchase of the Maxwell® CSC, the instrument will be covered by a one year Premier Warranty: The Premier Warranty covers all parts, labor and shipping to and from our depot repair location as well as your choice of a loaner instrument within 1 working day or on-site repair by a factory-trained service technician arriving within 2 business days. We will repair your instrument and return it to you performing to original factory specifications. It also includes one Preventive Maintenance visit.

9.B. Warranty and Service Agreement Options

Maxwell® CSC Premier Service Agreement Cat.# SA1120

The Premier Service Agreement includes all parts, labor and shipping to and from our depot repair location as well as your choice of a loaner instrument within 1 business day or on-site service visit by a factory-trained service technician within 2 business days. Additionally, it includes one annual preventive maintenance visit per year which can be performed by returning the instrument to an authorized service center or by an on-site visit by a service technician. Additional Preventive Maintenance visits are available separately.

Maxwell® CSC Preventive Maintenance Cat.# SA1130

In order to keep the system operating at peak performance, Promega recommends that Maxwell® CSC instruments receive a Preventive Maintenance check after 12 months of use. During this procedure, our qualified service personnel test the instrument, check parts for wear and replace them as needed. Additionally, the system is aligned and performance is verified. Documentation for your files is provided.



**Maxwell® CSC Installation Qualification and Operational Qualification
Cat.# SA1140, SA1150, SA1160**

The Installation Qualification service product includes a series of formal instrument checks, delivers written documentation of instrument functionality, and demonstrates that everything ordered with the instrument is supplied and installed at the customer's laboratory. The service product involves a site visit to perform:

- Installation by qualified Promega personnel
- Inspection of shipping containers, instrument, and accessories
- Comparison of items received vs. items on PO
- Inspection of laboratory conditions
- Review of all hazards and precautions with users
- Confirmation/installation of correct firmware version
- Recording and documenting installation and actions

The Operational Qualification service product demonstrates that the instrument functions according to its operational specifications. The service product involves a site visit to perform:

- Run operational verification tests
- Document test results
- Train customer(s) to operate the instrument
- Train customer(s) to use the log book
- Complete customer specific log book, instrument sticker and OQ documentation



9.B. Warranty and Service Agreement Options (continued)

Limited Warranty and Service Guidelines

Pursuant to this Warranty, Promega warrants to the original purchaser of the Promega Maxwell® CSC Instrument, that Promega will provide the parts and labor required for service and repair of the instrument for one year from the date of purchase. Your Warranty includes the option for: 1) depot repair with a loaner instrument to be used during your instrument's repair, or 2) on-site repair by a factory-trained technician. If you elect depot repair, the instrument is to be safely packed and shipped to Promega at Promega's expense. Promega will return the repaired or replaced unit to you at Promega's expense within 3 business days after the repair is complete. This Warranty may be renewed, in one-year terms, provided the renewal is requested prior to the expiration of the current Warranty or Service Agreement.

Promega agrees, as its sole responsibility under this Warranty, and upon prompt notice of a defect, to repair or replace (at Promega's discretion) any instrument discovered to be defective within the term of this Warranty. Expendable items are not covered by this Warranty. This Warranty does not include repair or replacement necessitated by accident, neglect, misuse, unauthorized repair or modification of the instrument.

This Warranty and the remedies set forth herein are exclusive and in lieu of all other express or implied warranties (including implied warranties of merchantability, fitness for a particular purpose and noninfringement), and no other warranties shall be binding upon Promega. In no event, shall Promega be liable for any special, incidental or consequential damages resulting from the use or malfunction of this instrument or the system with which it is used.

The instrument may not be returned without a proper Return Authorization Number from Promega and certificate of decontamination, as described in this manual.

Out of Warranty Service

Contact Promega or your local Promega representative. We will be happy to assist you by telephone at no charge. Repair service will be quoted prior to any work being performed.

9.C. Related Product

Product	Size	Cat.#
Maxwell® CSC Blood DNA Kit	48 preps	AS1321
Maxwell® CSC DNA FFPE Kit	48 preps	AS1350
Maxwell® CSC RNA FFPE Kit	48 preps	AS1360

For In Vitro Diagnostic Use. This product is only available in certain countries.

For the most up-to-date list of related products, visit:

<https://www.promega.com/products/instruments/maxwell-csc-system-for-ivd-use/>



10. Certificate of Decontamination

Disinfection and decontamination are required prior to shipping the instrument and accessories for repair. Returned Instruments must be accompanied by a signed and dated Certificate of Decontamination, which must be attached to the outside packaging of the instrument.

To disinfect and decontaminate: Wipe off the magnetic rod assembly, plunger bar, inside platform, and inside and outside surfaces using a cloth dampened with 70% ethanol, then a cloth dampened with a 1–2% bleach solution in deionized water. Follow immediately with a cloth dampened with deionized water to remove any residual bleach from the instrument surfaces. Repeat the procedure as many times as required to effectively disinfect and decontaminate the instrument.

Failure to confirm disinfection and decontamination will result in decontamination charges before the instrument will be serviced.

Select either (A) or (B):

- A. I confirm that the returned items have not been contaminated by body fluids or by toxic, carcinogenic, radioactive, or other hazardous materials.
- B. I confirm that the returned items have been decontaminated and can be handled without exposing personnel to health hazards.

Circle the type of material used in the instrument: Chemical Biological Radioactive**

Briefly describe the decontamination procedure performed:

Date: _____

Place: _____

Signature: _____

Name (block capital letters): _____

** The signature of a Radiation Safety Officer is also required if the instrument was used with radioactive materials.

This instrument is certified by the undersigned to be free of radioactive contamination.

Date: _____

Place: _____

Signature: _____

Name (block capital letters): _____



It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

®U.S. Pat. Nos. 7,721,947 and 7,891,549 and other patents pending.

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Products may be covered by pending or issued patents or may have certain limitations. Please visit our Web site for more information.

All prices and specifications are subject to change without prior notice.

Product claims are subject to change. Please contact Promega Technical Services or access the Promega online catalog for the most up-to-date information on Promega products.

