



Promega

Technical Manual

Maxwell® CSC Instrument Operating Manual



This Technical Manual contains the instructions for use of the Maxwell® CSC Instrument, Model Number 9800-000, Catalog 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.

IVD

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Part# TM373

Maxwell® CSC Instrument Operating Manual

All technical literature is available on the Internet at: www.promega.com/protocols/
 Please visit the web site to verify that you are using the most current version of this Technical Manual.
 Please contact Promega Technical Services if you have questions on the use of this product. Email: techserv@promega.com

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1. Introduction

1.A. Maxwell® CSC Instrument Purification Procedure

The Maxwell® Clinical Sample Concentrator (CSC) Instrument 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 decontamination of instrument

1.E. Maxwell® CSC Instrument Specifications

Processing Time:	20–40 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.

1.1. 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
	Test Certification
	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. Install the instrument on a clean, level surface. 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.

2. Hardware Overview



Figure 2. Front of Maxwell® CSC Instrument.

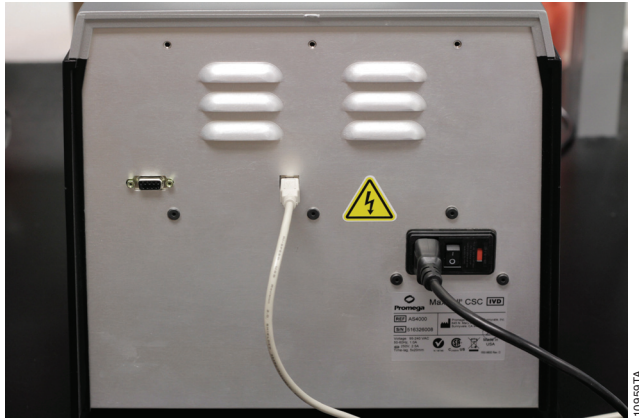


Figure 3. Rear view of the Maxwell® CSC Instrument. The rear of the instrument showing the On/Off switch, power cable connector and USB communication port.



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

1. Remove the top pad from the shipping container. Remove the accessories (i.e., bar code reader, deck tray, USB cable, Tablet PC holder, and power cable) from the shipping container.



Figure 5. Contents of Maxwell[®] CSC Instrument Accessory Box.

2. Remove the top foam from the shipping container.



Figure 6. Top foam removed.

3. Remove the Tablet PC box from the shipping box.



Figure 7. Tablet PC ready to be removed.

3. Unpacking the Maxwell® CSC Instrument (continued)

4. Remove the instrument from the shipping box.
5. Check that all the parts have been included (Figure 1).
6. Set the Maxwell® CSC Instrument on a flat, level, solid surface in a dust-free location with good air circulation.

 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

Manually open the door of the Maxwell® CSC Instrument and carefully remove the two foam pieces from inside the instrument.



Figure 8. 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 tablet PC box. The tablet PC comes with a tablet power cable. The tablet PC contains the operating software for the instrument.



Figure 9. Tablet PC.

2. Remove the Tablet power cable from the tablet PC box.



Figure 10. Tablet PC cords.

3. Remove the Tablet PC from the box.



Figure 11. Tablet PC.

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

4. Remove the Tablet PC holder from its packaging and place it on top or adjacent to the Maxwell® CSC Instrument.



Figure 12. Tablet PC holder.

5. Raise the middle leg of the Tablet PC holder and place the Tablet PC on the Tablet PC holder as shown in Figure 13.



Figure 13. Tablet PC holder on top of the Maxwell® CSC Instrument.

6. 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 14. Tablet PC installed on the Maxwell® CSC Instrument.

7. Connect the other end of the USB cable to the back of the Maxwell® CSC Instrument (Figure 15).



Figure 15. Connect the Tablet PC to the back of the Maxwell® CSC Instrument.

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



Figure 16. Maxwell® CSC Instrument with the Tablet PC and bar code reader installed.

10. 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.

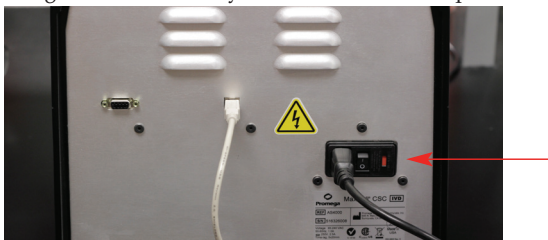


Figure 17. On/Off Switch.

4.D. Shutting Down the Maxwell® CSC Instrument

Shut Down Instrument

1. 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.H.
1. Shut down the software by pressing the 'x' in the upper left hand corner of the Home screen.
2. Shut down the Tablet PC using normal Windows® shut down procedure (Start->Shut Down).



Figure 18. Maxwell® CSC Home screen.

Shut Down the Tablet PC

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

If the Tablet PC is switched on but is not connected to a power supply, it will go to Sleep mode after 15 minutes of inactivity. This does not happen if the Tablet PC is connected to a power supply.

4.E. Configuring the Tablet PC

In the instructions below, screen names are presented in bold type, and on-screen options are presented in *italics*. 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 normal 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 hand 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 pre-loaded 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.)

4.E. Configuring the Tablet PC (continued)

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**”.

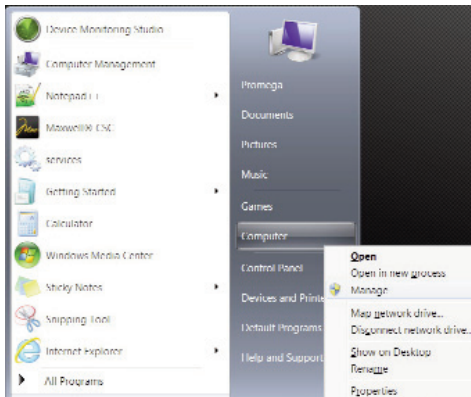


Figure 19. Touch Start→Computer and select Manage. Touch the Computer button for three seconds to cause the Manage screen to appear.

2. The **Computer Management** window opens.
3. In the left-hand 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.

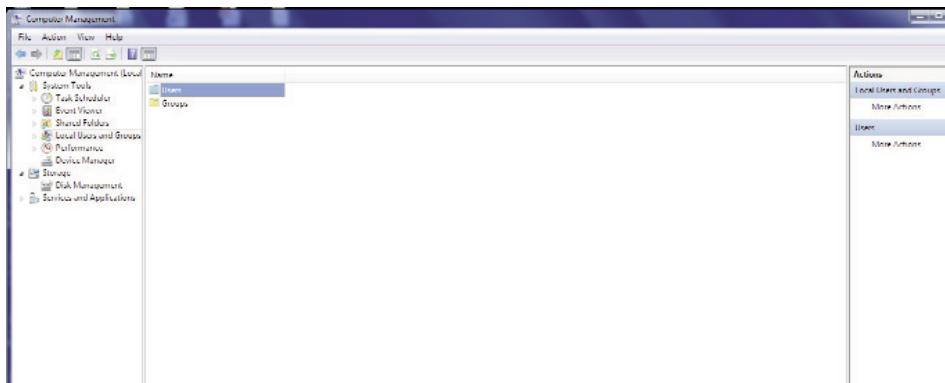


Figure 20. Select Groups from Computer Management Screen.

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.

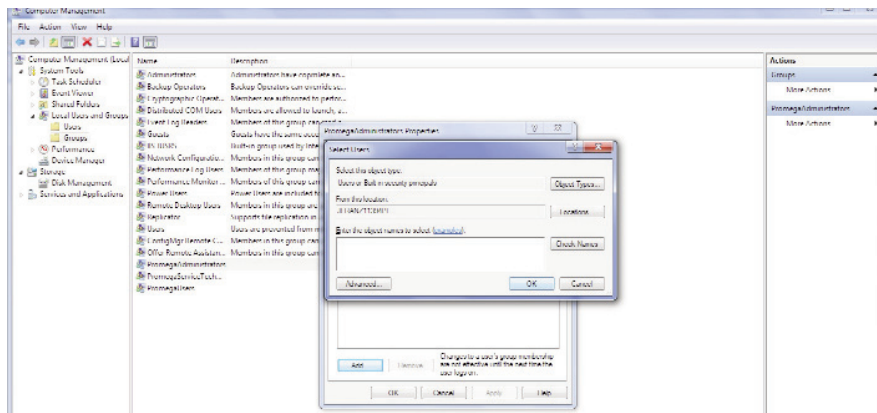


Figure 21. Adding users to PromegaAdministrators group.

5. If you want to add users, touch **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.

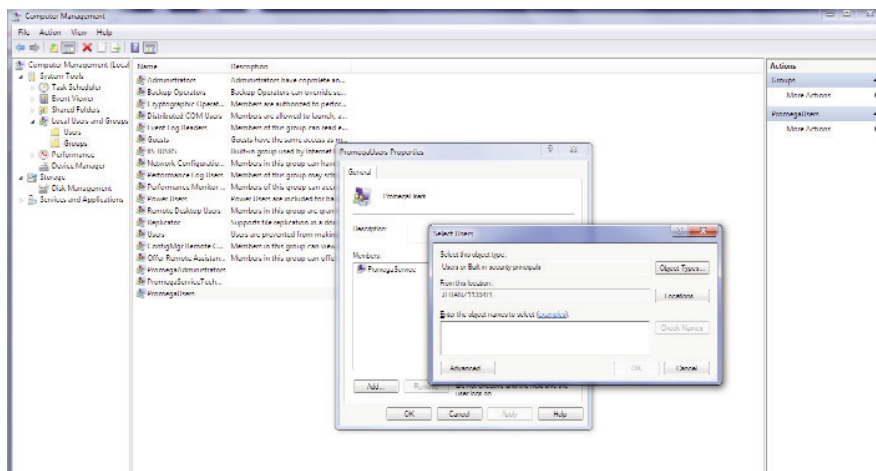


Figure 22. Adding users to the PromegaUsers group.

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).

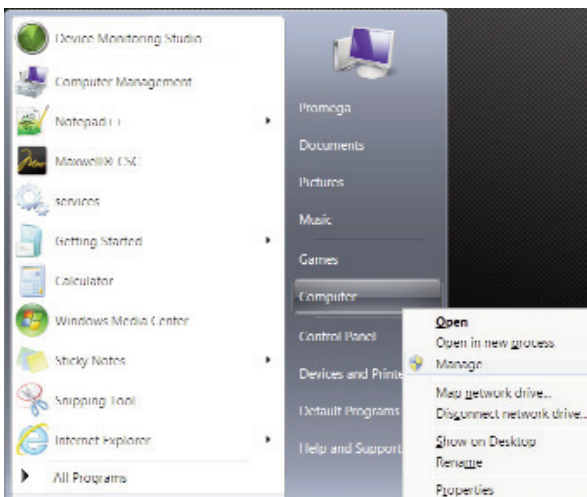


Figure 23. Touch on Start→Computer and touch and hold on Manage.

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

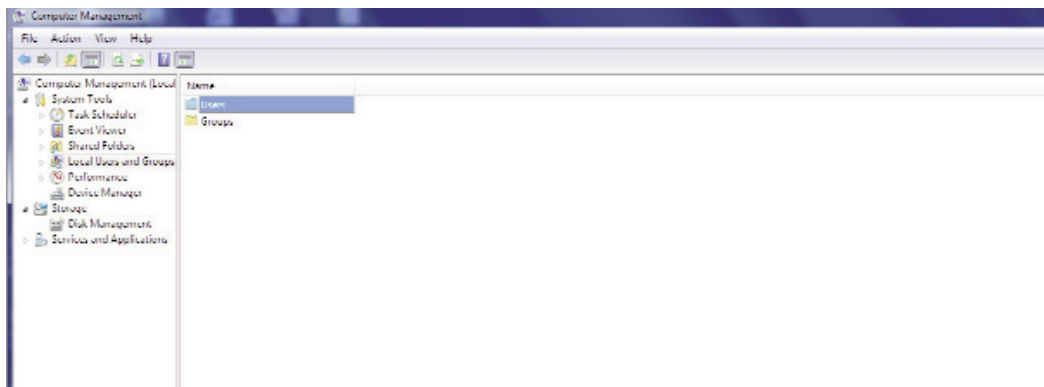


Figure 24. Select Groups from Computer Management Screen.

4. If you want to remove Administrators, touch '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.

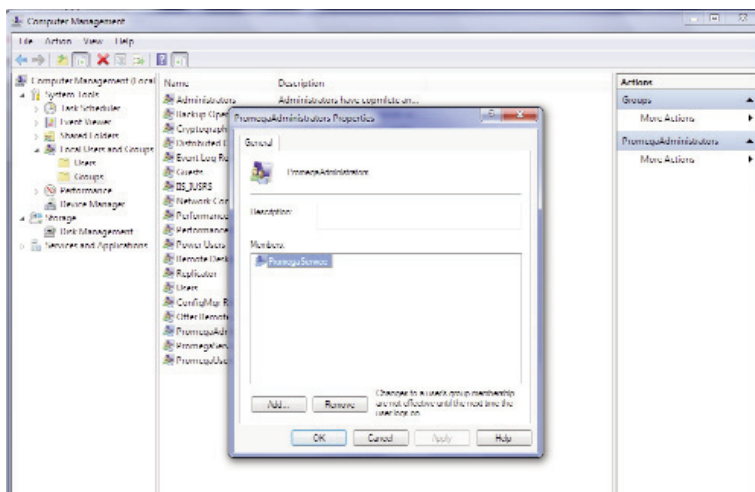


Figure 25. Removing users from the PromegaAdministrators group.

6. If you want to remove users, touch **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.

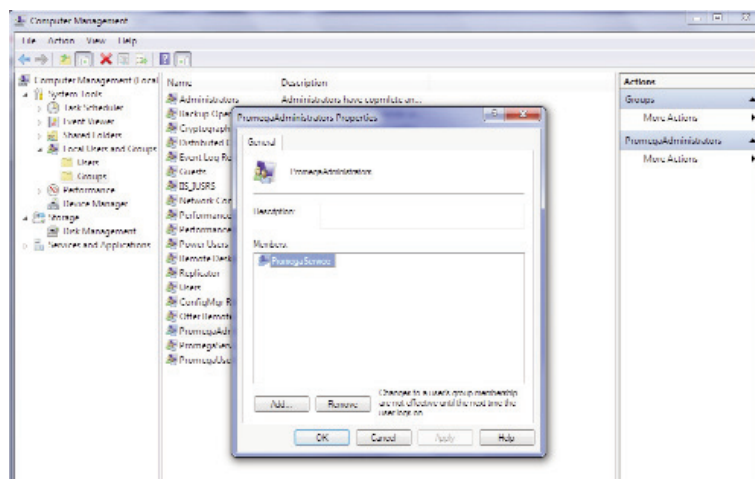


Figure 26. Removing users from the PromegaUsers group.

4.E. Configuring the Tablet PC (continued)

Set Instrument Name

Administrators can set the instrument name by touching the instrument name button from the Administrator Page window (Figure 27; Home→Settings→Administrator). Administrators can use the on-screen keyboard to manually enter the instrument name (Figure 28). The instrument name should be entered following the procedures and rules at your site.

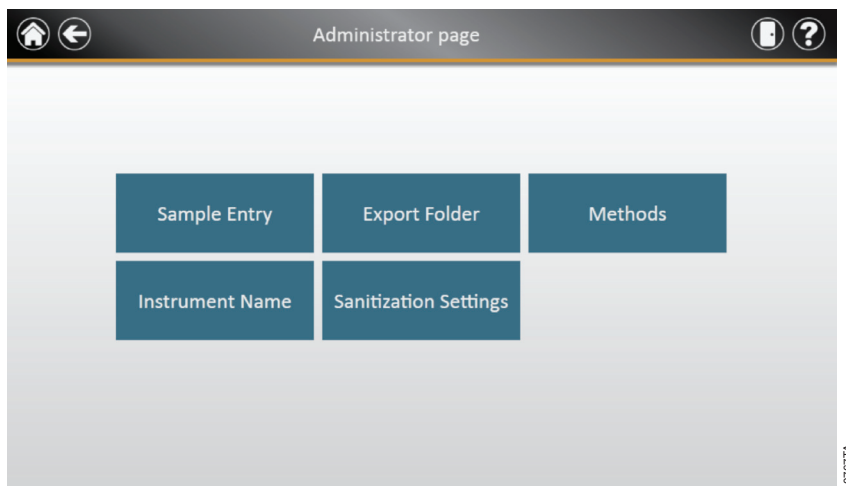


Figure 27. Administrator Page Window.

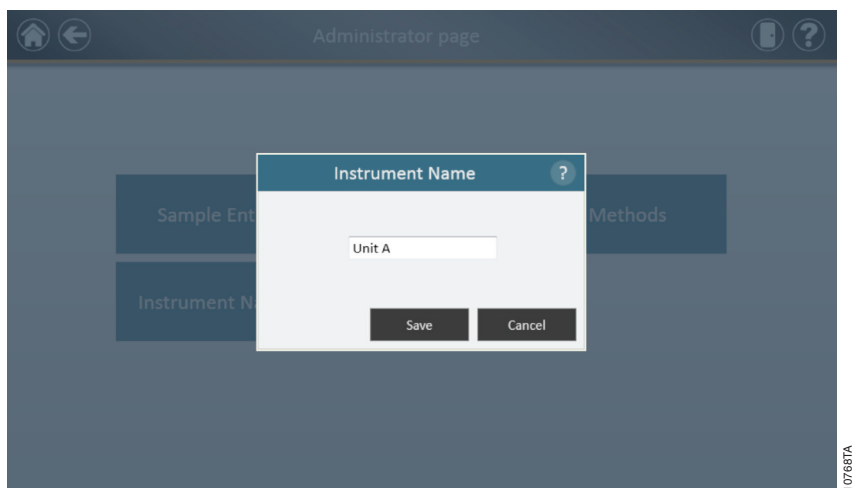


Figure 28. Instrument Name Window. Administrators can manually enter the instrument name from the instrument name window.

4.F. Maxwell® CSC User Interface Screens

Tablet PC Home Screen

The Home screen on the Tablet PC is the main launching pad for interaction with the functionalities built into the Maxwell® CSC Graphical User Interface. The Home screen (Figure 29) 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.
- **Reports.** The reports 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)

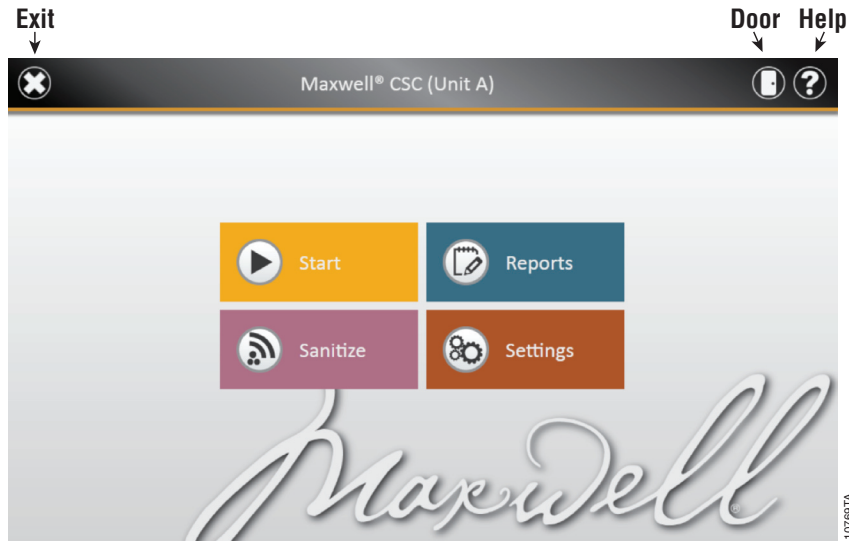


Figure 29. Maxwell® CSC Home screen.

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 30) 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 31) 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 32) touch the **Sample Entry** button.
4. The Sample Entry Settings window is shown in Figure 33. 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 hand corner of the Administrator page.



Figure 30. 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)

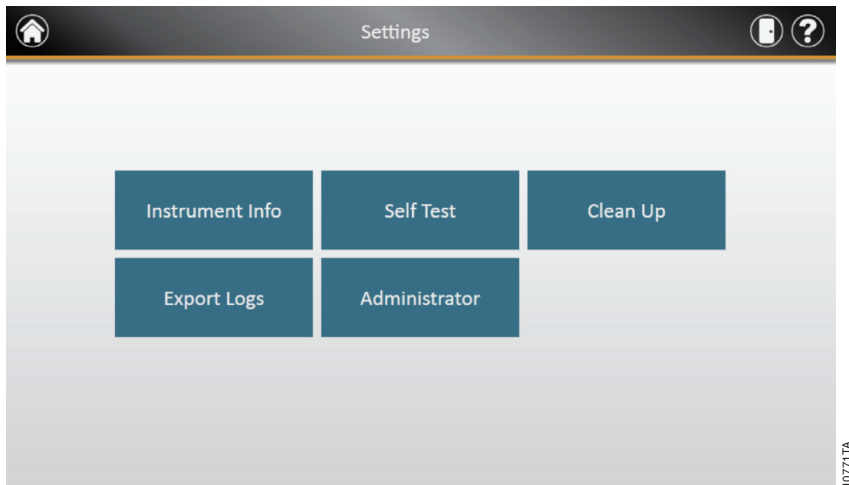


Figure 31. Maxwell® CSC Settings screen. From this screen you can access Administrator settings for the Maxwell® CSC Instrument options.

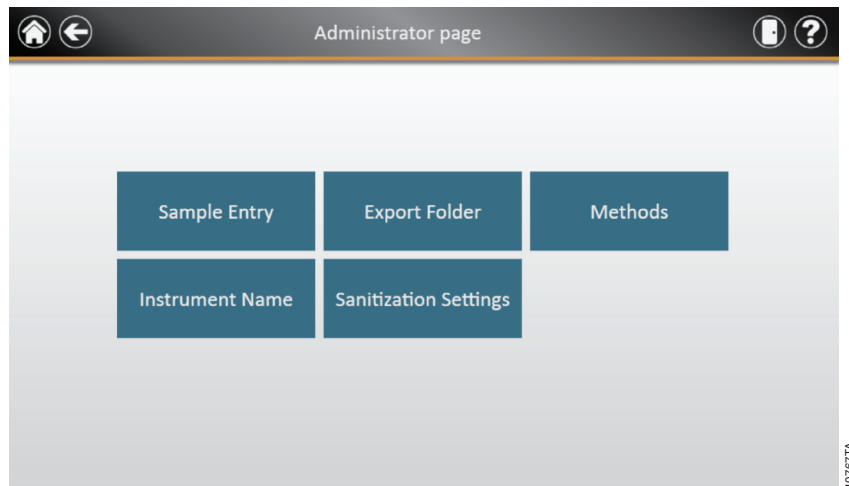


Figure 32. Maxwell® CSC Administrator page. The Administrator page is only visible to administrators and gives access to sample entry and additional options.

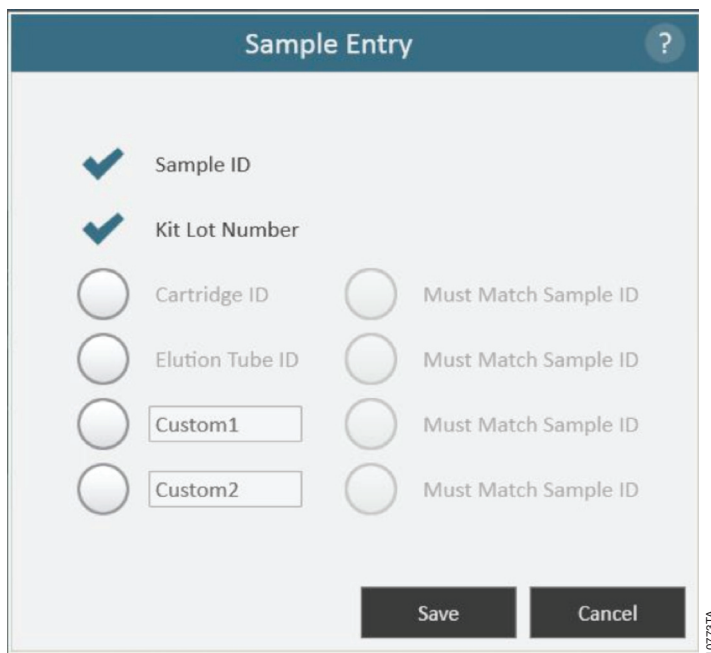


Figure 33. Maxwell® CSC Sample Entry window. This window gives the administrator the ability to configure the software for the bar code entry requirements necessary prior to performing a sample processing protocol. In addition to the required Sample ID and Kit Lot Number bar codes, optional fields can 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. Touch the **Export Folder** button and select the folder (Figure 34) 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 34, 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 reports', touch the "C:\". Then touch the **AS4000** button. Notice that the export folder path now shows "Drive\C:\AS4000\" as shown in Figure 35. Touch the **Save** button to save the changes to export settings or touch the **Cancel** button to cancel the changes (Figure 36).

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

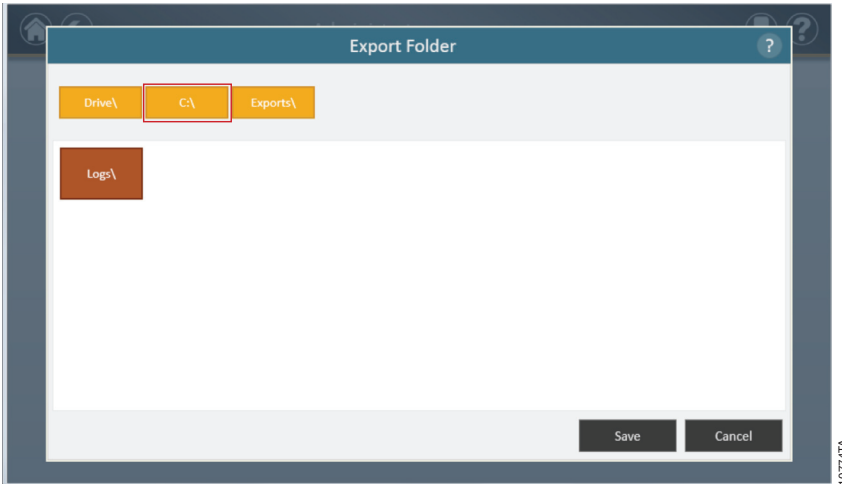


Figure 34. Export folder settings that can be changed by the Administrator.

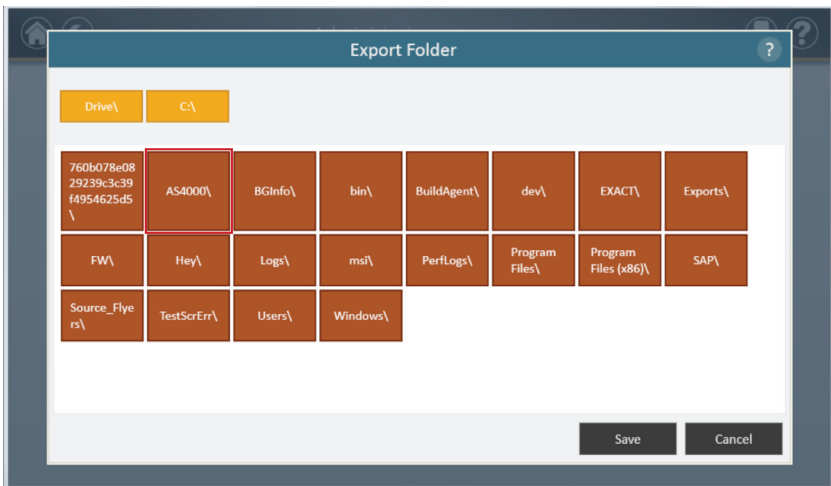


Figure 35. Changing export folder settings to a different folder.

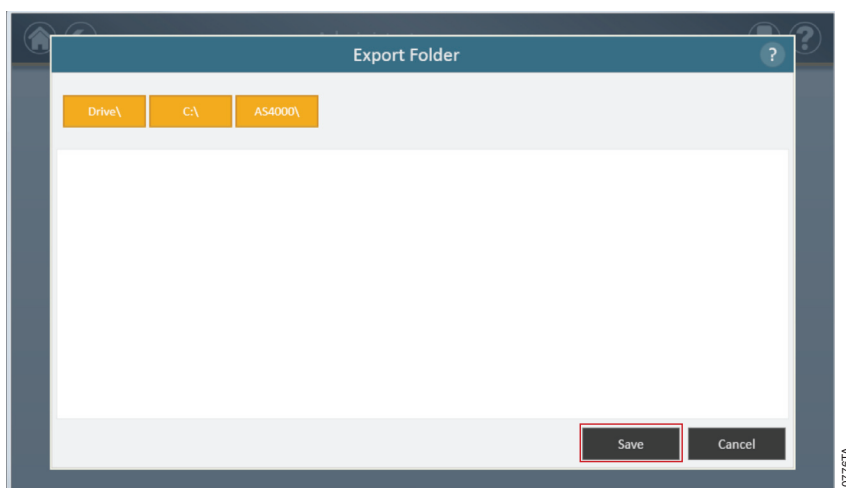


Figure 36. Touch 'Save' to save the settings for the new export folder.

Sanitization Settings

The Administrator can set the Sanitization settings by touching the **Sanitization Settings** button from the Administrator Page window (Figure 37). 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 38).

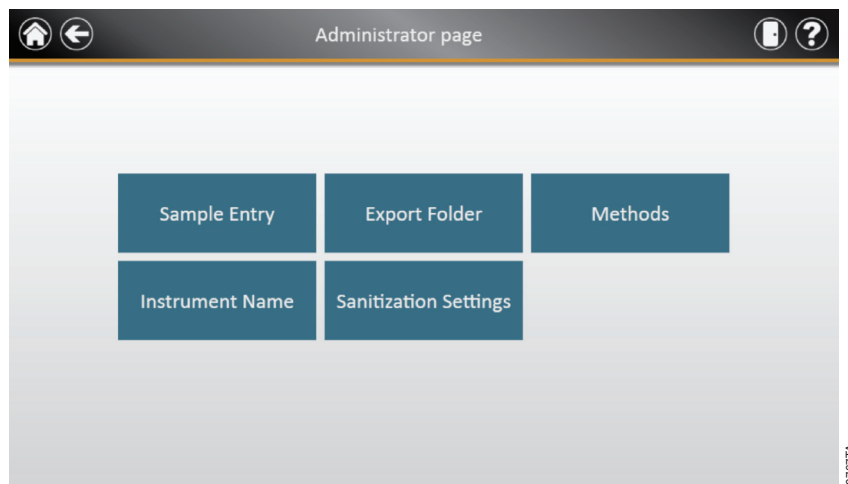


Figure 37. Administrator Page window. The Administrator can set the Sanitization settings by touching the 'Sanitization Settings' button from the Administrator Page window.

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

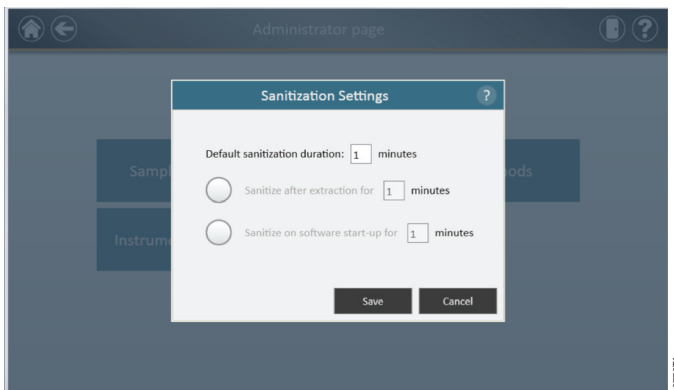


Figure 38. The Sanitization Settings window. The Administrator can specify the Sanitization settings (in minutes) and other settings such as Sanitize after extraction and/or Sanitize on instrument startup for a specified amount of time.

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 37). 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 37) 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 39). After navigating to the appropriate package file the Administrator can touch the OK button and the contents of the package file will be shown on the screen with an Import button next to each protocol included in the package file. The Administrator will need to touch Import for each method they want to update on the instrument (Figure 40). 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.

Promega will send notification of any software updates to the Maxwell® CSC Software. 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.

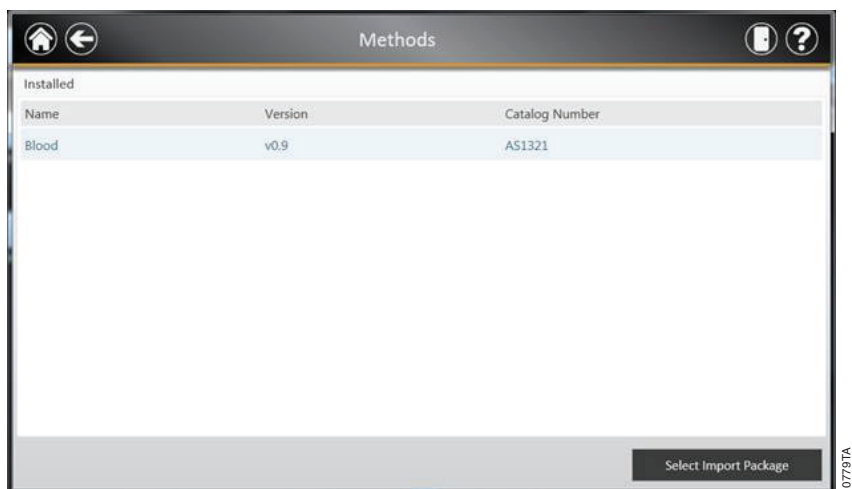


Figure 39. Methods window. This window displays a list of the methods that are currently installed in the Maxwell® CSC User Interface. Touching the ‘Select Import Package’ displays a file path for navigating to a particular file (Figure 40). This file will be used to import a new or updated method/kit pair.

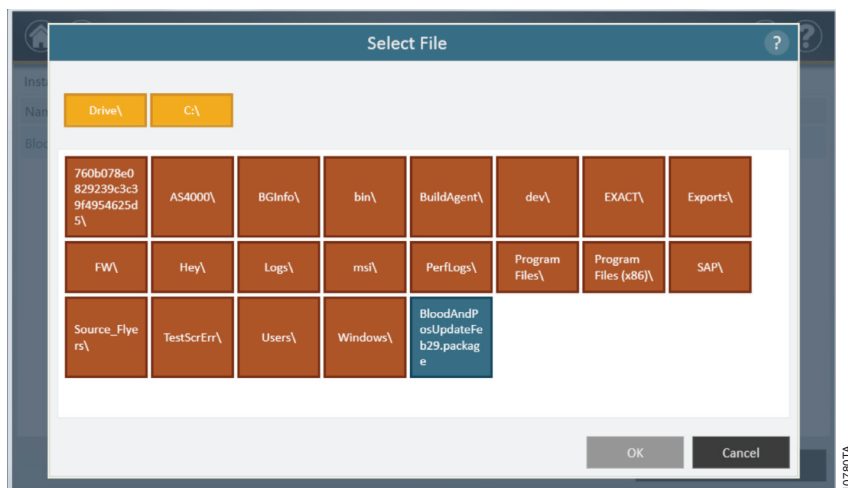


Figure 40. Select file for importing. This figure shows the screen for selecting new method import file (indicated as the package file shown in the blue box). If a method file is imported for an existing kit, the method will replace the original one. If you want to reinstall the previous method, you will need to use the package file that contains the previous method. If administrators import a brand new kit and associated method, then new entries will be made in the database, allowing users to run additional chemistries on the instrument.

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

Self Test

You can run a 'Self Test' by touching the **Self Test** button from the Maxwell® CSC Settings screen (Figure 41). On touching the **Self Test** button, the Maxwell® CSC Instrument will perform a routine test (Figure 42) 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.

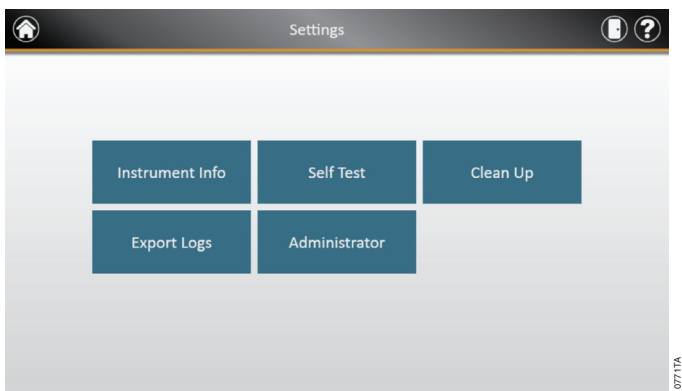


Figure 41. Maxwell® CSC Settings screen. From this screen you can perform Self Test for the Maxwell® CSC Instruments.

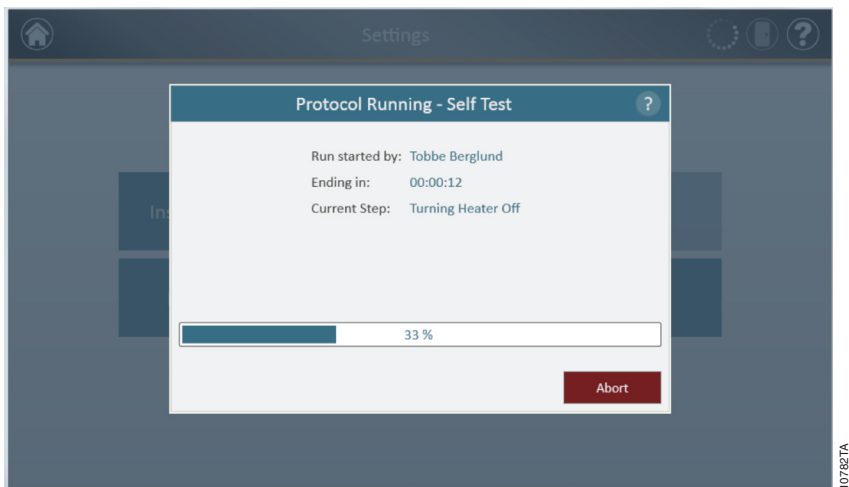


Figure 42. Self-test protocol being executed.

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 43). 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 44) 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, 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.

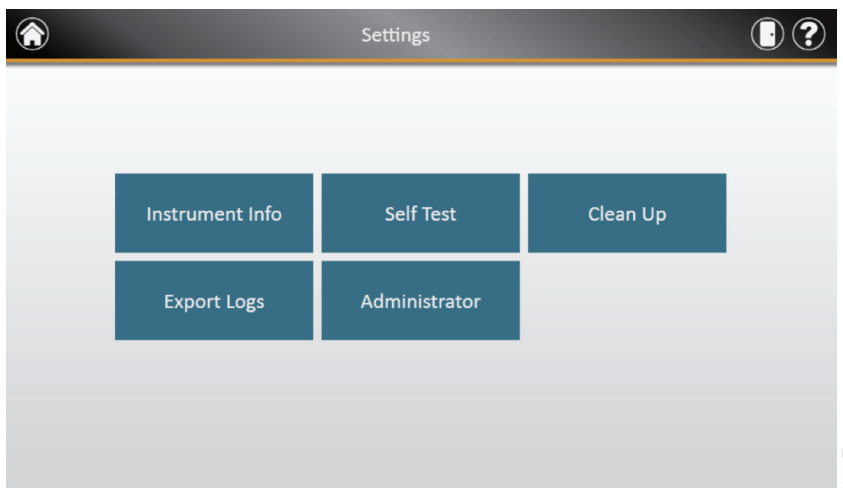


Figure 43. Maxwell® CSC Settings screen. From this screen you can perform "Clean Up" for the Maxwell® CSC Instrument.

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

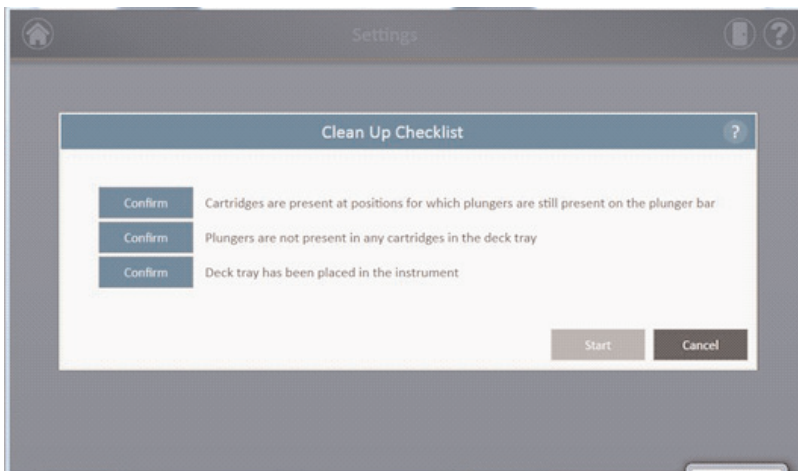


Figure 44. Clean Up Checklist screen. This screen presents you with a checklist prior to cleanup.

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 45) select the **Start** button to begin the process of running a protocol.



Figure 45. 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 46). Alternatively, touch the **text box** (Figure 47) to manually enter the bar code information using the keyboard. 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)

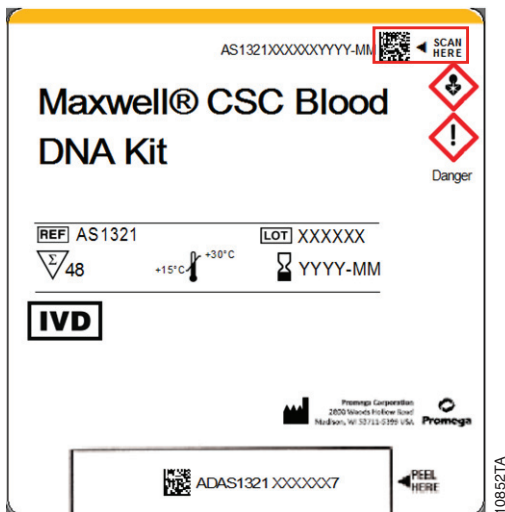


Figure 46. Kit label indicating bar code to scan. Shown in the red box is the bar code to scan on the kit label for starting a purification run.

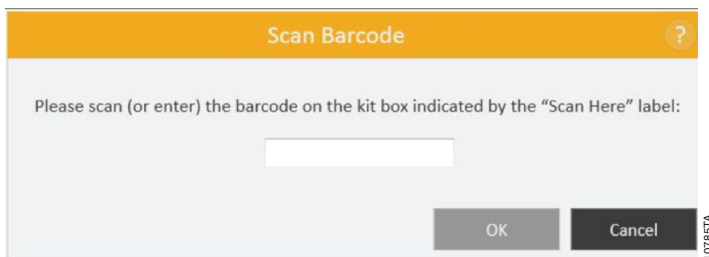


Figure 47. Scan Bar Code screen. Scanning the bar code automatically selects the protocol on the Maxwell® CSC Instrument.

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) to get the most updated information on the available methods.

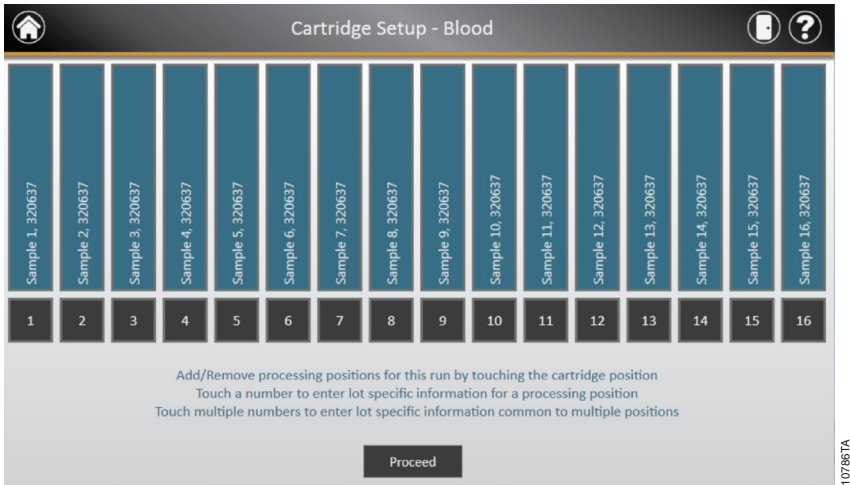
4. After scanning the bar code, you will be presented with a Cartridge setup screen (Figure 48) that allows you to specify the positions on the deck tray that will be occupied by cartridges and to enter identification information for each sample.
 - a. Deselect empty positions by touching the blue rectangle 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 49). 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.

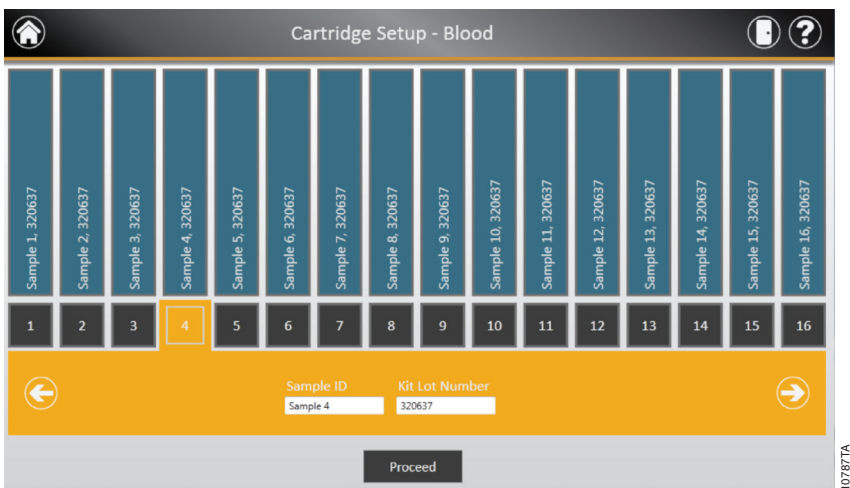
 **Important.** There are two bar codes on the kit label. Enter the bar code at the top of the label. You will receive an error message if you scan the wrong bar code.

5.B. Starting a Protocol (continued)



10786TA

Figure 48. 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.



10787TA

Figure 49. 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.

- 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 50). Press the **OK** button to open the Maxwell® CSC Instrument door.

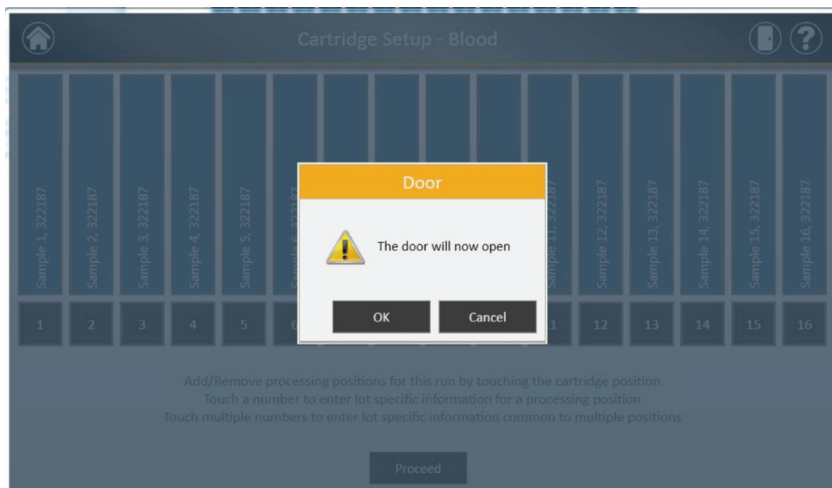


Figure 50. Door open screen. Informs the user that the Maxwell® CSC Instrument door will open.

- You will be presented with an Extraction Checklist screen (Figure 51). 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.

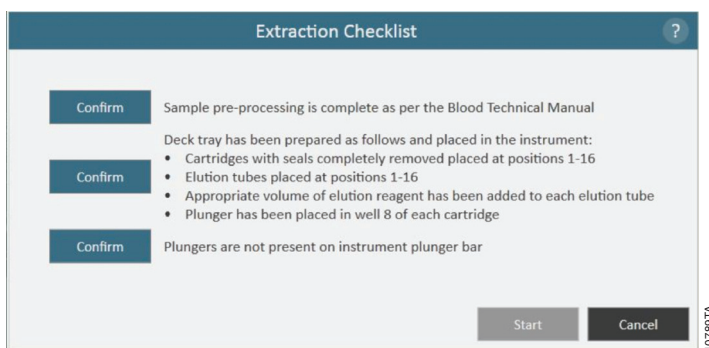


Figure 51. Extraction Checklist screen. This screen indicates the steps that will need to be performed to prepare the instrument for processing the selected samples. Preprocessing steps are not indicated on the Extraction Checklist and should be performed prior to this stage according to the technical 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 pre-processing is complete, sample pre-processing, 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 52). Press down firmly to snap the cartridges in place. There should be an audible snap.

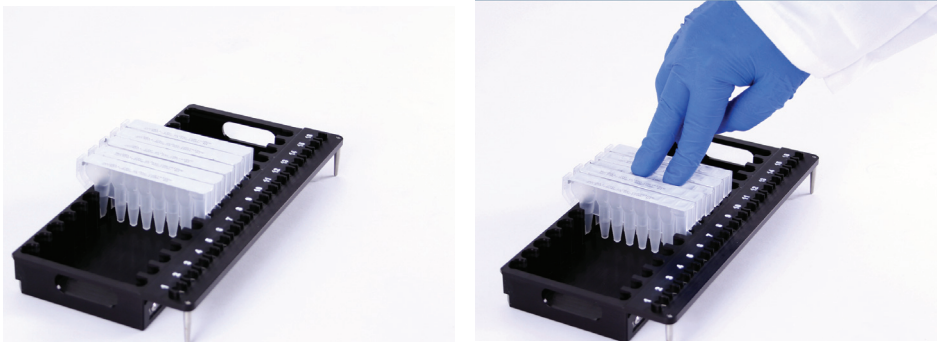


Figure 52. Place the cartridges in the deck tray, and press firmly to snap them in place.

- 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 instruction 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 53. Ensure that the deck tray is completely seated inside the instrument.

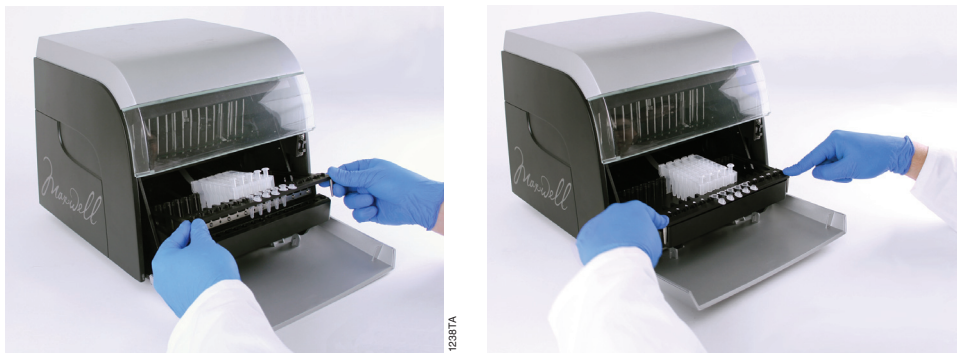


Figure 53. Place the deck tray in the instrument.

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 54). Touch the **Start** button to begin the purification or touch the **Cancel** button to return to the previous screen.

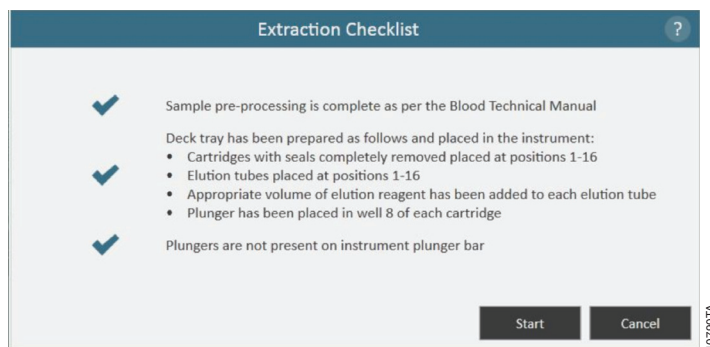


Figure 54. Completed Extraction Checklist. When all checklist items have been confirmed, the Start button will become active. Touch the ‘Start’ button to begin the processing run or the ‘Cancel’ button to return to the sample information entry screen.

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.

8. While the protocol runs, you will see the Protocol Selected screen (Figure 55). The title bar of the Protocol Selected 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 hand corner of the screen. Please note that any samples being processed will be lost if a run is aborted. We do not recommend using the **Open Door** button to interrupt (abort) the current run.

9. Protocols can end through one of three mechanisms:
 - The protocol completes successfully.
 - The protocol is aborted by the user.
 - An instrument error.

5.B. Starting a Protocol (continued)

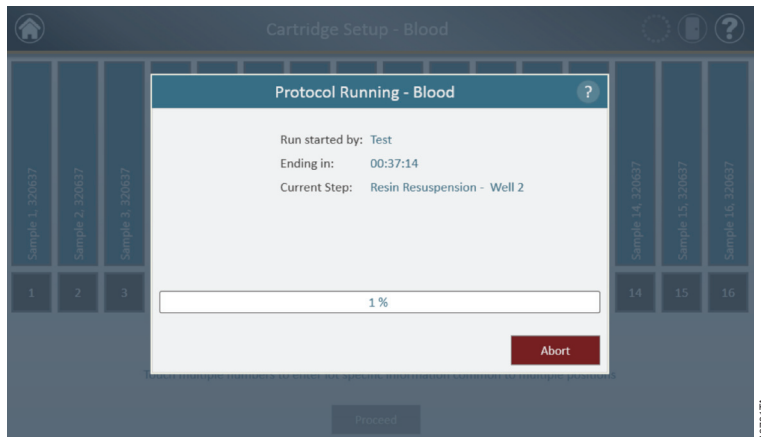


Figure 55. Protocol Selected screen. The Protocol Selected screen is displayed during a protocol run. This screen indicates what protocol is currently being run at the top of the screen. Also indicated on this screen are the user who started the run, an approximate indication of when the run will end, 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 hand corner of the screen.

Protocol Completes Successfully

When the protocol completes successfully the Protocol Selected window will change to indicate that the protocol has been completed (Figure 56). 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.

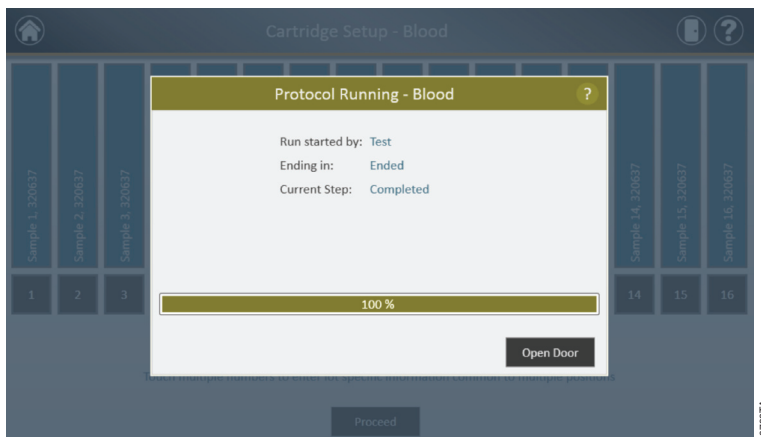


Figure 56. Protocol Selected window after completion of the protocol. Upon completion of the currently running protocol, the Protocol Selected window changes to a green title bar and a 100% completion in the run progress bar. The Current Step changes to Completed after a run is finished. After a protocol 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 57). 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 58). 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.



Figure 57. Closing the elution tube caps.



Figure 58. Removing the elution tubes and the deck tray.

After the door is opened, the Report View window (Figure 62) 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).

5.B. Starting a Protocol (continued)

User Aborts Protocol

If the protocol is aborted by the user, the Protocol Selected window will change to indicate that the protocol has been aborted (Figure 59). 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 61).

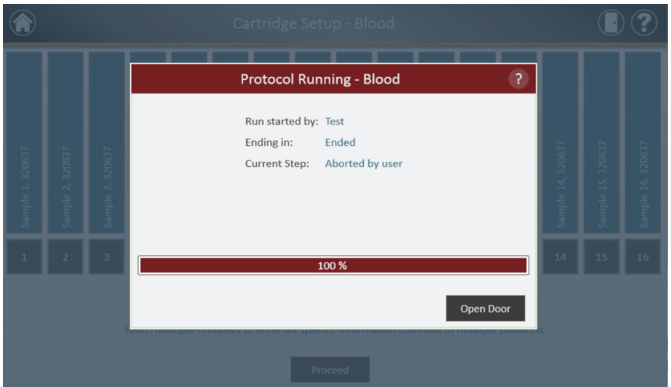


Figure 59. Protocol Selected window after protocol abort. If a protocol is aborted by the user or due to an instrument error, the Protocol Selected window changes to a red title bar and run progress bar. The Current Step changes to Aborted by user. After a protocol is aborted you can touch the 'Open 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 Selected window will change to indicate that the protocol has been aborted (Figure 60) and will display an error message.

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

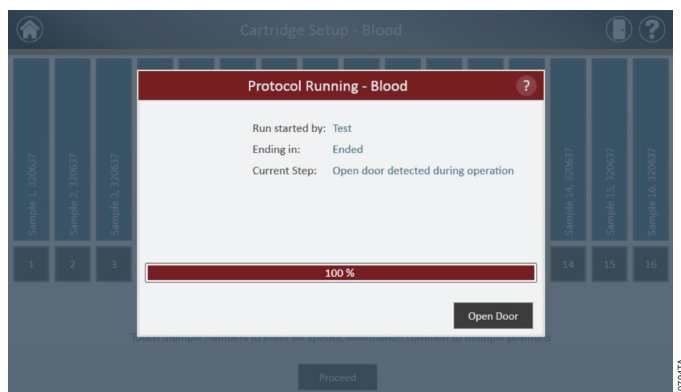


Figure 60. Protocol Selected window after protocol abort. If a protocol is aborted due to an instrument error, the Protocol Selected screen changes to a red title bar and run progress bar. The Current Step lists the reason for Aborting the protocol. An aborted run (initiated by the user or due to instrument error) will result in the loss of all the samples. Do not attempt to re-purify samples from an aborted run.

5.C. Clean Up

After Aborting the protocol, you can press the **Open Door** button to bring up the Clean Up Window (Figure 61).

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 61).

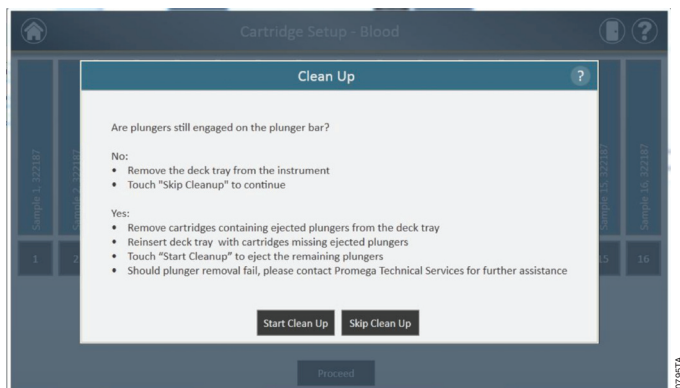


Figure 61. Clean Up window after protocol abort/instrument error. If a protocol is aborted by the user or due to an instrument error, the Clean Up window is displayed that asks the users to 'Start' or 'Skip Clean Up' depending on whether the plungers are still engaged or disengaged on the plunger bar.

5.C. Clean Up (continued)

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.

Reports

10. After pressing the **Open Door** button in the Protocol Run Window, the Report View screen is displayed (Figure 62). 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.*).



Report View

Extraction Report

Protocol: Blood v1.9
 Status: Completed
 Started at: 5/15/2012 11:08:25 AM
 Duration: 00:37:45
 Operator: Test

Software: Maxwell® CSC
 Software Version: 1.1
 Instrument Name: Unit A
 Serial Number: 123
 Firmware Version: 3.29.0

Catalog Number: A51290
 User Confirmation:
 Sample prep processing is complete as per the Blood Technical Manual
 Deck tray has been prepared as follows and placed on the instrument:
 • Cartridge with well completely removed placed at position 1, 26
 • Bottom tubes placed at positions 1, 26
 • Appropriate volume of elution reagent has been added to each elution
 • Plunger has been placed in well 8 of each cartridge
 Plungers are not present on instrument plunger bar

#	Sample ID	Lot Number	Exp. Month	Cartridge ID	Bottom Tube ID	Cutoff1	Cutoff2
1	Sample 1	320637	05/2012				
2	Sample 2	320637	05/2012				
3	Sample 3	320637	05/2012				
4	Sample 4	320637	05/2012				
5	Sample 5	320637	05/2012				
6	Sample 6	320637	05/2012				
7	Sample 7	320637	05/2012				
8	Sample 8	320637	05/2012				
9	Sample 9	320637	05/2012				
10	Sample 10	320637	05/2012				
11	Sample 11	320637	05/2012				
12	Sample 12	320637	05/2012				
13	Sample 13	320637	05/2012				

10796 TA

Figure 62. 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 hand corner of the screen is an 'Export' button that will be used for exporting report information.

Using the buttons on the left hand 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

In the lower left hand corner of the screen is an **Export** button that can be used for exporting report information to a USB drive for transfer to other devices. Use the **Export** button to export the report to the path specified in the Settings (Figure 63).

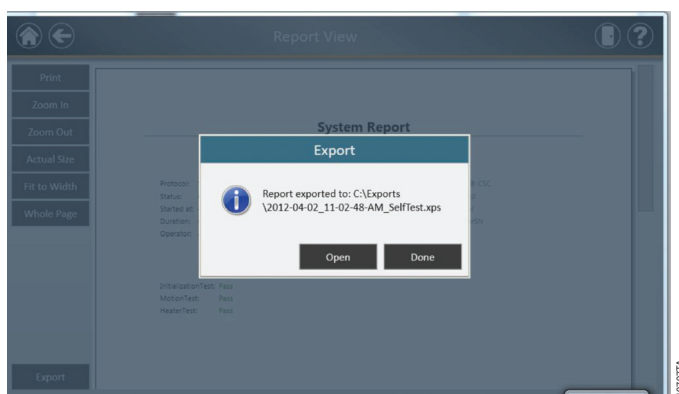
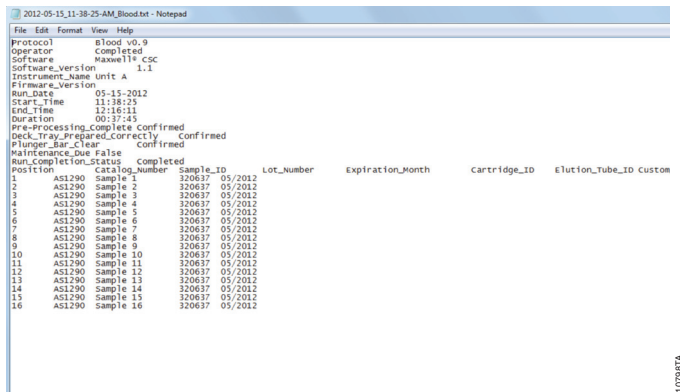


Figure 63. Export screen. When users press the Export button, the report is exported to the path specified in 'Settings'.

Touch the **Open** button to navigate to where the report is exported. The Maxwell® CSC Instrument exports reports in the .xps format as well as tab-separated format. You can use the XPS viewer to view the report. If you do not wish to view the report, press the **Done** button.

5.C. Clean Up (continued)

By using the export button, the files will be exported to the folder designated by the Administrator. You can use the tab-separated format file (*.txt) with Laboratory Information Managements Systems (e.g., LIMS). Touch the Open button to navigate to where the report is exported. The Maxwell® CSC Instrument provides two report files, one in the .xps format and one in tab-separated format. An example of the tab-separated format file is shown in Figure 64.



```

2012-05-15,11:38:25-AM_Blood.txt - Notepad
File Edit Format View Help
Protocol Blood v0.9
Operator completed
Software Maxwell® CSC
Software_Version
Instrument_Name Unit A 1.1
Firmware_Version
Run_Date 05-15-2012
Start_Time 11:38:25
End_Time 12:16:11
Duration 00:37:45
Pre-Processing_Complete Confirmed
Deck_Tray_Prepared_Correctly Confirmed
Plunger_Bar_Clear Confirmed
Maintenance_Due False
Run_Completion_Status completed
Position Catalog_Number Sample_ID Lot_Number Expiration_Month Cartridge_ID Elution_Tube_ID Custom
1 AS1290 Sample 1 320637 05/2012
2 AS1290 Sample 2 320637 05/2012
3 AS1290 Sample 3 320637 05/2012
4 AS1290 Sample 4 320637 05/2012
5 AS1290 Sample 5 320637 05/2012
6 AS1290 Sample 6 320637 05/2012
7 AS1290 Sample 7 320637 05/2012
8 AS1290 Sample 8 320637 05/2012
9 AS1290 Sample 9 320637 05/2012
10 AS1290 Sample 10 320637 05/2012
11 AS1290 Sample 11 320637 05/2012
12 AS1290 Sample 12 320637 05/2012
13 AS1290 Sample 13 320637 05/2012
14 AS1290 Sample 14 320637 05/2012
15 AS1290 Sample 15 320637 05/2012
16 AS1290 Sample 16 320637 05/2012
  
```

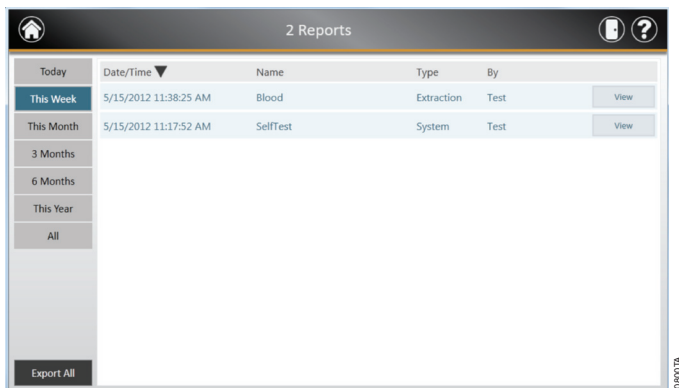
Figure 64. Example of a file in the tab-separated format.

5.D. Running Reports

From the Home screen (Figure 65) of the user interface, it is possible to view sample tracking reports and service reports on the instrument by pressing the **Reports** button. The Reports screen displays a listing of the extraction reports for the protocols that have been run (Figure 66). You can view reports by touching the buttons on the left hand 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. Touch the column headers to sort the report based on column contents. Touch the **View** button to see a detailed view of the report data from that protocol run (Figure 67).



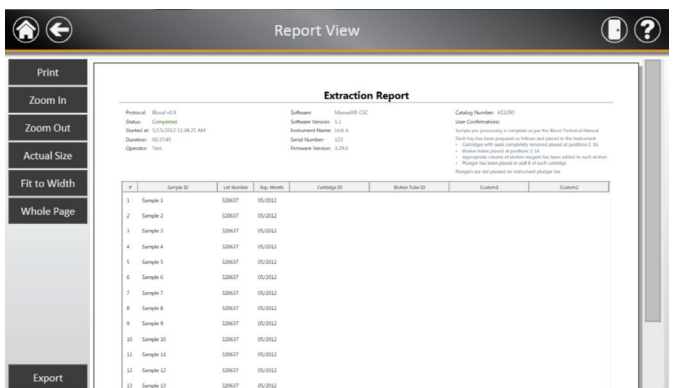
Figure 65. Maxwell® CSC Home screen. Selecting 'Reports' opens the Maxwell® CSC Reports screen from which extraction reports from all protocol runs can be viewed.



Today	Date/Time ▼	Name	Type	By	
This Week	5/15/2012 11:38:25 AM	Blood	Extraction	Test	View
This Month	5/15/2012 11:17:52 AM	SelfTest	System	Test	View
3 Months					
6 Months					
This Year					
All					

Export All

Figure 66. View 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

Protocol: Blood 010
 Status: Completed
 Started on: 5/15/2012 11:38:25 AM
 Operator: Test

Software: iScan4000-CDC
 Software Version: 0.1
 Instrument Name: LIA-A
 Serial Number: 003
 Firmware Version: 1.2163

Cartridge Number: 002280
 User Confirmation:

Sample pre-processing is complete as per the Blood Technical Manual
 The following have been prepared in a folder and placed in the instrument:
 • Cartridge with each cartridge containing plates of platelets (3 x 6)
 • Station value plate of platelets (3 x 6)
 • Sample collection plate of platelets (3 x 6)
 • All sample values of platelets reports have been added to each station.
 • Please has been placed in each of 30 each cartridge.
 Reports are not present on instrument storage list.

#	Sample ID	Lot Number	Exp. Month	Cartridge ID	Station Value ID	Custom3	Custom2
1	Sample 1	320637	05/2012				
2	Sample 2	320637	05/2012				
3	Sample 3	320637	05/2012				
4	Sample 4	320637	05/2012				
5	Sample 5	320637	05/2012				
6	Sample 6	320637	05/2012				
7	Sample 7	320637	05/2012				
8	Sample 8	320637	05/2012				
9	Sample 9	320637	05/2012				
10	Sample 10	320637	05/2012				
11	Sample 11	320637	05/2012				
12	Sample 12	320637	05/2012				
13	Sample 13	320637	05/2012				

Figure 67. 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 68) by touching the **Sanitize** button. Make sure all samples have been removed from the instrument prior to initiating the UV sanitization protocol. You will be presented with a sanitization checklist (Figure 69) 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 68. Home screen. Selecting the 'Sanitize' button begins the process of Sanitizing the Maxwell® CSC Instrument.

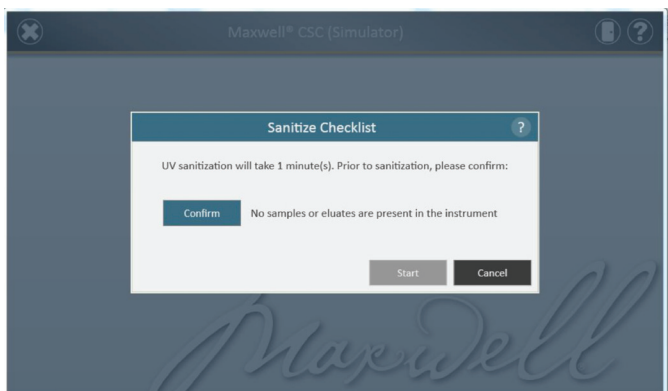


Figure 69. Sanitize Checklist screen. The sanitization checklist informs you on how long the UV sanitization will take. It will also ask you to confirm that no samples or eluates are present in the instrument prior to running Sanitization.

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.

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.
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
Clean Up does not unload the plunger	<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. • Touch the 'Start' button to eject the remaining plungers. <p>If the plunger cleanup fails, you should 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 46).</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 OFF the instrument and the tablet PC. 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

7.A. Errors and Warnings (continued)

Error	Explanation
Touch Sensor Interlock failure	Plunger sensor failure detected. 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.
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 to the outside of the package 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.
2. Open the instrument door and manually push the deck to the back of the instrument.
3. Manually bring the plunger bar (Figure 70) down to cover the magnetic tips.

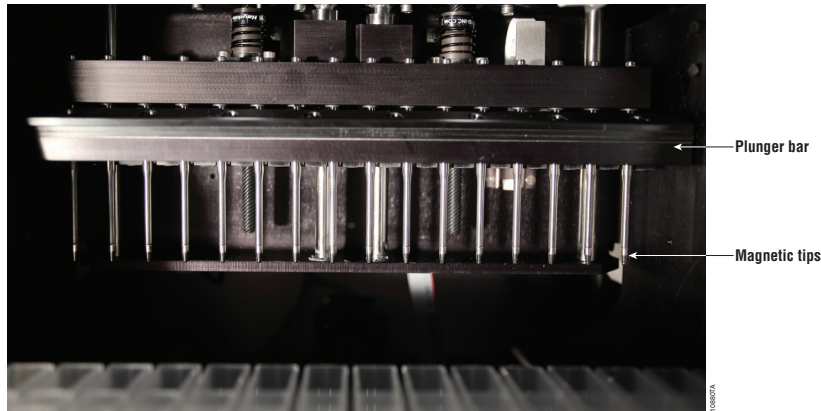


Figure 70. Plunger Bar.

4. Place the die cut foam as shown in Figure 8.
5. Slide the other die cut foam to lock the deck and the plunger bar as shown in Figure 8. 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.

7. Place the instrument in the shipping box. The instrument can only fit in the box in one direction. The back of the instrument should go in the specially designed notch. Ensure that the top of the instrument is facing the top of the open box.

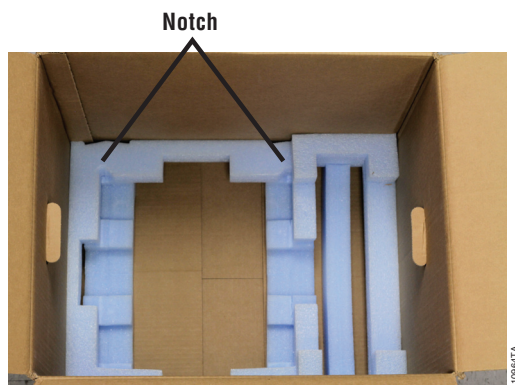


Figure 71. Maxwell® CSC Instrument in correct orientation in the box.

8. Place the top foam packaging over the top of the instrument as shown (Figure 72).



Figure 72. Foam packing on top of box.

9. Repack all the Maxwell® CSC Instrument accessories in the original boxes and place on top of the instrument box.



Figure 73. The instrument accessories box is placed on top.

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

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

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® 16 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

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) onsite 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.

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

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

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

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.