

Maxwell® CSC Instrument IVD Mode Operating Manual

Instructions for Use of Model Number AS6000
running IVD Mode

For use in RUO Mode, see the *Maxwell® CSC RUO Mode Software Manual #TM573*.
Ensure that all sealing tape and any residual adhesive are removed from the Maxwell® CSC reagent cartridges before placing the cartridges into the instrument.



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All technical literature is available at: **www.promega.com/protocols/**

Visit the website to verify that you are using the most current version of this Technical Manual.

Email Promega Technical Services if you have questions on use of this system: **techserv@promega.com**

1 Introduction

1.1 Principle of the Method

The Maxwell® Clinical Sample Concentrator (CSC) Instruments^(a) provide automated nucleic acid purification for a range of 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 selecting method runs and capturing bar code information for samples and reagents. The Maxwell® CSC Instrument provides reports of the data gathered during 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 12.2).

1.2 Product Intended Purpose/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 from specimens derived from the human body. The specimen type is determined by the specific Maxwell® CSC reagent kit used. 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 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.

1.3 Product Use Limitations

The Maxwell® CSC Instrument is only available in certain countries.

When used in IVD mode, 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.

1.4 Maxwell® CSC Instrument Features

- Easy-to-use and easy-to-maintain system operation
- Standardized 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

1.5 Maxwell® CSC Instrument Specifications

Processing Time:	40–60 minutes (depending on sample type and method)
Number of Samples:	Up to 16
Weight:	24.2lb (11kg)
Dimensions (W × D × H):	13 × 13.6 × 11.8 inches (330.2 × 345.2 × 299.7mm)
Power Requirements:	95–240VAC, 50/60Hz, 1.0A
Fuse:	250VAC, 2.5A, time-lag fuse (AC250V, T2.5AL, 5 × 20mm)
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

1.6 Product Components

PRODUCT	CAT. #
Maxwell® CSC Instrument	AS6000

For In Vitro Diagnostic Use. Includes:



- 1 Maxwell® CSC Instrument
- 1 Tablet PC preloaded with Maxwell® CSC Application Software
- 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® RSC/CSC Deck Tray
- 1 UV Bulb (installed)
- 1 Bar Code Reader
- 1 Tablet PC Holder
- 1 Stylus
- 1 Quick Start Guide
- 1 USB card for the Maxwell® CSC Instrument

1.7 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 (email: techserv@promega.com). Standard components are shown in Figure 1.

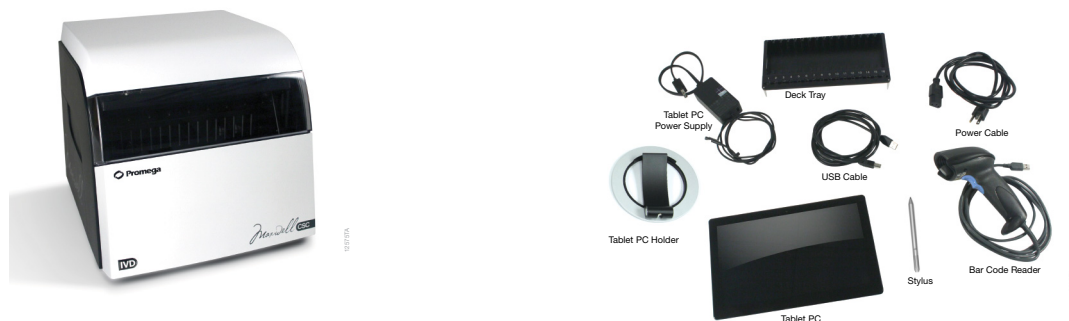


Figure 1. Maxwell® CSC Instrument. Components shown include: deck tray, power cables, USB cable, Tablet PC, Tablet PC Holder, stylus and Bar Code Reader for the Maxwell® CSC Instrument.

1.8 Precautions









Important Safety Instructions. Save these instructions.










- 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.
- 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 designed purpose.
- Always disconnect the power to the instrument and the Tablet PC 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 override the door sensor during protocol operation, as it will result in the protocol being aborted.
- This instrument is intended for use with potentially biohazardous materials. Use appropriate personal protective equipment (gloves, safety goggles, lab coat, etc.) for handling and disposing of biohazardous materials.
- 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.

1.9 Safety Symbols and Marking

Important Safety Instructions. Save these instructions.

Safety Symbols and Markings		
	Danger. Hazardous voltage. Risk of electrical shock.	Danger. Tension dangereuse. Risque de choc électrique.
	Warning. Risk of personal injury to the operator or a safety hazard to the instrument or surrounding area.	Avertissement. Risque de préjudice corporel pour l'opérateur ou risque de danger pour l'appareil ou la zone environnante.
	Warning. Pinch point hazard.	Avertissement. Risque de pincement.
	Warning. Hot surface. Burn hazard.	Avertissement. Surface chaude. Risque de brûlure.
	Warning. Biohazard.	Avertissement. Risque biologique.
	Warning. UV light hazard. Do not look directly at the UV light.	Avertissement. Risque de lampe UV. Ne regardez pas directement en direction de la lampe UV.

SYMBOLS KEY

Symbols	Explanation	Symbols	Explanation
	In Vitro Diagnostic Medical Device		Authorized Representative
	Serial Number		Catalog Number
	Manufacturer		Conformité Européenne
	It is important to understand and follow all laws regarding the safe and proper disposal of electrical instrumentation. Consult your local Promega Representative regarding instrument disposal		Consult instructions for use
	Important information		

The equipment has been tested and demonstrates compliance to EN IEC 61326-1:2021; EN IEC 61326-2-6:2021; EN 55011:2016/A2:2021; EN IEC 61000-6-1:2019; EN IEC 61000-6-4:2019; EN IEC 61000-3-2:2019+A1:2021; EN 61000-3-3:2013+A2:2021; IEC 61000-3-3:2013+A2:2021; IEC 61326-1:2020; IEC 61326-2-6:2020; BS EN IEC 61326-1:2021; BS EN IEC 61326-2-6:2021; BS EN 55011:2016+A2:2021; BS EN IEC 61000-6-1:2019; BS EN IEC 61000-6-4:2019; FCC PART 15 SUBPART B, Class A; and ICES-003 Issue 7. The equipment may cause radio interference, in which case you may need to take measures to mitigate the interference.

1.10 Environmental Requirements (Operating, Shipping and Storage Conditions)

Power Requirements:	95–240VAC, 50/60Hz, 1.0A
Temperature:	+4°C to +50°C (shipping/storage), +15°C to +25°C (operation)
Humidity:	Up to 80% relative humidity, noncondensing
Operating Altitude:	<2,000 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, instrument-to-tablet USB communication port and three additional USB communication ports for peripherals (e.g., Bar Code Reader).

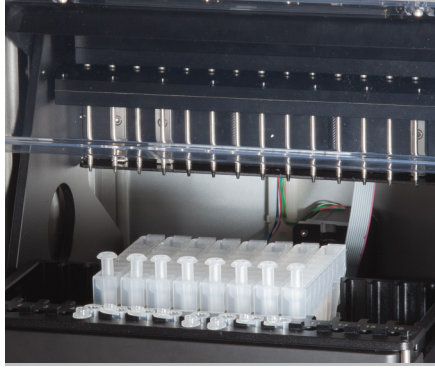


Figure 4. Magnetic assembly components and platform. The hardware components inside the Maxwell® CSC Instrument. The magnet and plunger bars, which are used for sample processing, and the platform containing the deck tray are evident.

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 and identify the contents.



**Follow
These
Steps**

1. Cut the tape on the flaps of the box to open the shipping box.
2. Open the flaps and remove the accessories box from the packaging (Figure 5).



Figure 5. The accessories box.

3. Remove the upper packing material and carefully remove the instrument from the box (Figure 6).



Figure 6. Remove the upper packing material.

4. 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.
5. 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

4.1 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 7).



Figure 7. 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.

2. Open the accessories box. The Tablet PC, Tablet PC Holder, Bar Code Reader and USB card are contained in the box (Figure 8). The Tablet PC contains the operating software for the instrument.



Figure 8. Contents of the accessories box.

3. Remove the Tablet PC and Tablet PC power cable from the box.
4. Remove the Tablet PC Holder from its packaging, and place it on top or adjacent to the Maxwell® CSC Instrument (Figure 9).



Figure 9. Tablet PC Holder.

5. Raise the leg of the Tablet PC Holder (as shown in Figure 10), and place the Tablet PC on the Tablet PC Holder.



Figure 10. 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 11. 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 12).



Figure 12. 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. Ensure that the On/Off switch on the back of the instrument is in the off position. Connect the other end of the Maxwell® CSC power cable to a power outlet. We recommend connecting the Maxwell® CSC power cable to an uninterruptible power supply.
9. Connect the Bar Code Reader to one of the two USB ports on the back of the Maxwell® CSC Instrument.



Figure 13. Maxwell® CSC Instrument with the Tablet PC and Bar Code Reader installed.

10. The Maxwell® CSC Instrument is now ready to use. Please refer to the Maxwell® CSC Tablet PC Configuration Manual #TM484 for instructions on configuring the tablet PC for use and Section 5.B. for instructions on configuring the Maxwell® CSC software.

4.2 Switching On the Maxwell® CSC Instrument

Switch the Maxwell® CSC Instrument on using the On/Off switch on the back panel of the instrument (Figure 14).

Press the power switch located on the top of the Tablet PC to power on the Tablet PC. Before first use, configure the Tablet PC following the instructions provided in the *Maxwell® CSC Tablet PC Configuration Manual #TM484*. If prompted based on the Tablet PC settings, sign into the Tablet PC.

Note: The profile used to sign into the Tablet PC must be assigned to either the PromegaUsers or PromegaAdministrators group in the Windows® operating system to be able to run the Maxwell® CSC software. See the *Maxwell® CSC Tablet PC Configuration Manual # TM484* for information on assigning Windows® user accounts to these groups. From the 'Desktop' screen, touch the Maxwell® CSC IVD icon to start the Maxwell® CSC in IVD Mode software. Every time the software is started, the instrument will perform a self-diagnostic test. The deck, plunger bar and magnetic rod assembly are moved to check operation.



Figure 14. On/Off Switch.

4.3 Instrument Calibration

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

4.4 Shutting Down the Maxwell® CSC Instrument

4.4.1 Shut Down Instrument

1. Shut down the software by touching the **X** in the upper left corner of the 'Home' screen (Figure 15). From any other screen within the Maxwell® CSC software, touch the **Home** button in the upper left portion of the Maxwell® CSC software to return to the 'Home' screen.
2. Shut down the Tablet PC. Touch the **Start** button at the bottom left hand side of the screen, touch the Power icon, and select **Shut Down**.



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



Figure 15. Maxwell® CSC 'Home' screen.

3. Switch off the instrument using the On/Off switch on the back panel of the Maxwell® CSC Instrument. Unplug the instrument. Store the instrument in a place that meets the environmental requirements described in Section 1.10.

4.4.2 Storing the Tablet PC

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

5 Maxwell® CSC IVD Mode User Interface Screens

5.1 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 16) contains four buttons:

- **Start.** Touching the **Start** button on the Maxwell® CSC 'Home' screen will begin the process of preparing a protocol run on the Maxwell® CSC Instrument (see Section 6.2).
- **Results.** The Results button takes users to the 'Results' Screen where it is possible to review, print and export any of the run reports from previous chemistry and service processes (see Sections 6.4 and 6.5).
- **Sanitize.** Touching the **Sanitize** button activates the UV light in the Maxwell® CSC Instrument for the time specified in the administrator settings (see Section 5.3). During the sanitization procedure, access reports, settings and start setting up a new protocol processing run, as long as these functions do not interrupt 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 run (see Section 6.6).
- **Settings.** The Settings button accesses the 'Settings' screen, 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 to the Maxwell® CSC software; see Sections 5.2 and 5.3).



Figure 16. Maxwell® CSC Software 'Home' screen.

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 screen:

- **Exit.** [White X in the upper left corner of the screen] When touched, the Maxwell® CSC User Interface software will close and return users to the Windows® Operating System.
- **Back.** [Left-facing arrow in the upper left corner of the screen] When available, touching the **Back** button will return the interface to the screen accessed prior to the current screen.
- **Door.** [Door icon in the upper right corner of the screen] This button toggles the open/closed status of the door on the Maxwell® CSC Instrument.
- **Help.** [Question mark in the upper right corner of the screen] Touching the **Help** button will activate the context-sensitive help for the current screen of the Maxwell® CSC User Interface.

5.2 User Interface Settings

Within the software for the Maxwell® CSC, all users can access instrument-specific information and functions. In addition, users with Administrator-level access to the Maxwell® CSC software can modify software options to tailor the behavior of the software to the needs of their laboratory. The following sections describe the functions that are accessible from the **Settings** button on the 'Home' screen of the Maxwell® CSC software.

5.2.1 Settings Button

Figure 17 displays the 'Settings' screen for the Maxwell® CSC software. This screen is accessed by touching the **Settings** button on the 'Home' screen (Figure 16). The appearance of the 'Settings' screen is tailored to the access level that the Windows® user account has within the Maxwell® CSC software. A Windows® user account with user-level access to the Maxwell® CSC software will see the following buttons: **Instrument Info**, **Self Test**, **Clean Up** and **Export Logs**. A Windows® user account with administrator-level access to the Maxwell® CSC software will additionally see an **Administrator** button. From this screen the user can access the instrument functionalities described below.

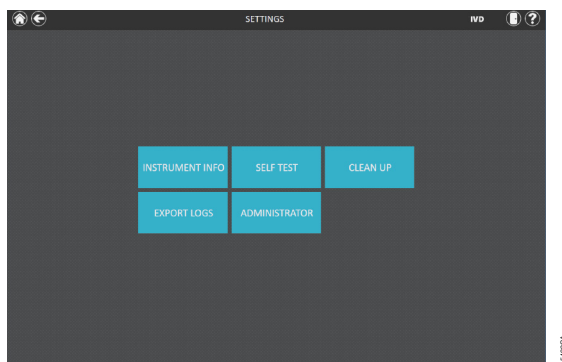


Figure 17. Maxwell® CSC 'Settings' screen. From this screen various instrument-specific functions can be accessed. The **Administrator** button will be displayed only for Windows® user accounts with administrator-level access to the Maxwell® CSC software.

5.2.2 Instrument Information

Touch the **Instrument Info** button to display software, firmware, calibration and other instrument-specific information for this Maxwell® CSC instrument on an 'About Maxwell® CSC' screen (Figure 18). The information shown on this screen includes:

- Software Version – the current software version installed on the Tablet PC.
- Software Revision – the revision number of the software version installed on the Tablet PC.
- Instrument Name – the name that an administrator has assigned to this instrument.
- Serial Number – the serial number of the Maxwell® CSC instrument connected to the Tablet PC.
- Firmware ID – the current firmware version installed on this Maxwell® CSC Instrument.
- Firmware Revision – the revision number of the firmware version installed on the Maxwell® CSC Instrument.
- FPGA ID – the current FPGA version installed on this Maxwell® CSC Instrument.
- FPGA Revision – the revision number of the FPGA version installed on the Maxwell® CSC Instrument.
- Tray Calibration Value – the calibration value for the tray axis on the Maxwell® CSC Instrument.
- Plunger Calibration Value – the calibration value for the plunger bar axis on the Maxwell® CSC Instrument.
- Magnet Calibration Value – the calibration value for the magnet bar axis on the Maxwell® CSC Instrument.

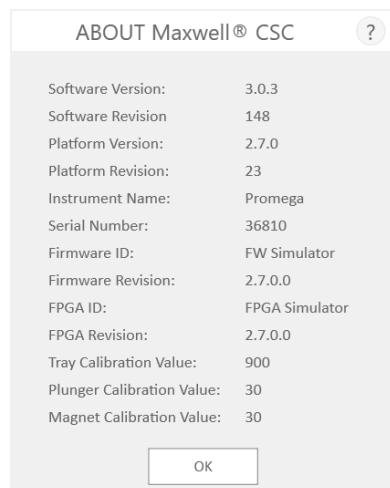


Figure 18. 'About Maxwell® CSC' screen. Instrument- and software-specific information are displayed on the 'About Maxwell® CSC' screen.

5.2.3 Self Test

You can run a Self Test by touching the **Self Test** button from the Maxwell® CSC 'Settings' screen (Figure 19). On touching the **Self Test** button, the Maxwell® CSC Instrument will perform a routine test (Figure 20) 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.

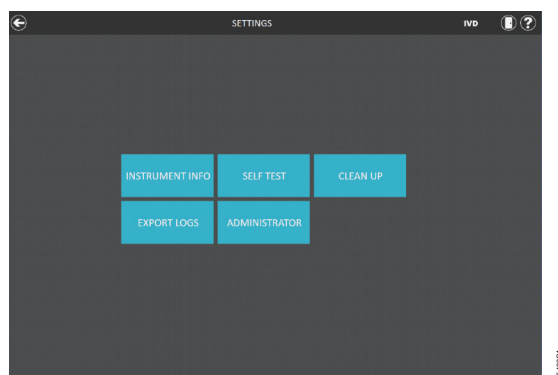


Figure 19. Maxwell® CSC 'Settings' screen. From this screen, you can perform Self Test for the Maxwell® CSC Instruments.

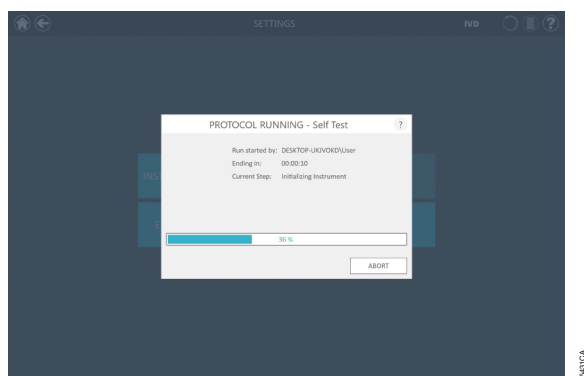


Figure 20. Self-test protocol being executed.

5.2.4 Clean Up

Clean Up attempts to unload plungers from the instrument plunger bar if any have not been 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 21) [From the 'Home' screen touch the **Settings** button to access the 'Settings' screen]. Plungers can only be unloaded from the plunger bar if a cartridge is present beneath the plunger to be unloaded. 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 22):

- 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.

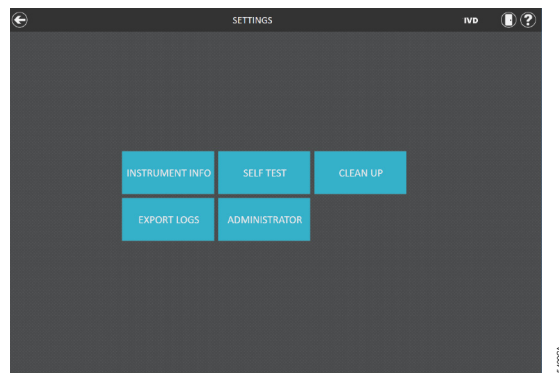


Figure 21. Maxwell® CSC 'Settings' screen. From this screen you can perform a Clean Up procedure to unload any plungers left on the plunger bar after an unsuccessful protocol run.

You will have to select **Confirm** on every item of the checklist (Figure 22) before you can start the cleanup procedure. After you confirm the checklist items, touch the **Start** button to start the cleanup process. The Maxwell® CSC Instrument will perform the Clean Up process and will generate and display the system report from the Clean Up process. If plungers are not ejected after several cleanup attempts the operator should contact Promega Technical Services (email: techserv@promega.com) to determine the next steps.

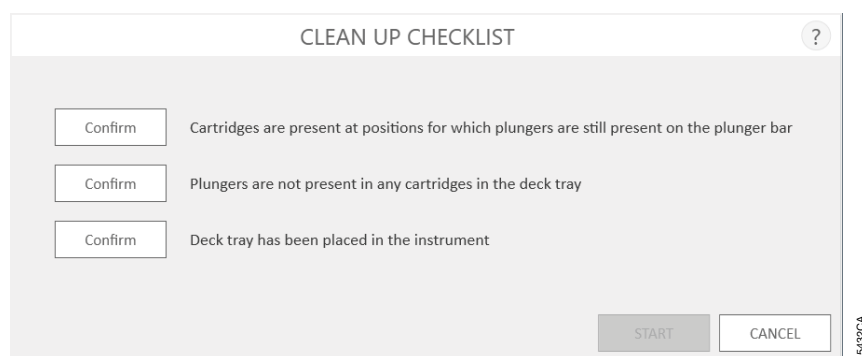


Figure 22. 'Clean Up Checklist' screen. This screen presents you with a checklist of items which must be confirmed prior to starting the cleanup procedure.

5.2.5 Export Logs

The Export Logs button will export instrument logs for troubleshooting purposes. If in the course of troubleshooting an instrument problem you are directed to export logs to send to Promega Technical Services, touch this button to generate instrument-specific log files.

1. Touch the **Export Logs** button to display the 'Export Folder' screen (Figure 23, Panel A). This screen allows the operator to select the path to which the instrument logs should be exported (the default export path for instrument logs is C:\Exports\Logs).
2. Using the Yellow and Red rectangle buttons you can select the folder location where the instrument logs will be saved. The current path is indicated by the yellow rectangles at the top of the 'Export Folder' screen. Any folders present within the selected directory are displayed as red rectangles in the white portion of the screen. Touch the **Drive** button to navigate to the drive location of the desired folder. Touch red folder buttons to navigate to the desired folder location.
3. Once a path has been defined, touch the **Save** button to export logs to the specified path, or touch **Cancel** to return to the 'Settings' screen without exporting logs.
4. After touching **Save**, the 'Export' screen will be displayed indicating that the log files were successfully exported to the path that was specified (Figure 23, Panel B).
5. On the 'Export' screen you can touch **Open** to open a file browser showing the folder location of the exported files. Touch **Done** to close the 'Export' screen and return to the 'Settings' screen.

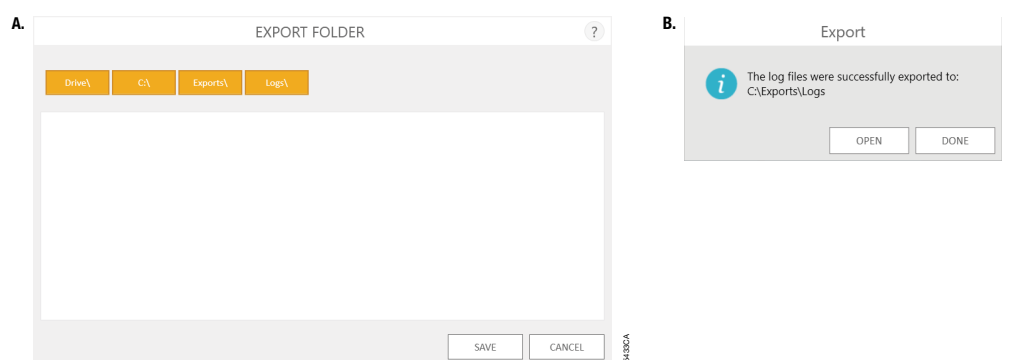


Figure 23. Export Logs. **Panel A.** The 'Export Folder' screen is displayed after touching the **Export Logs** button. Specify a path to which the instrument log files should be exported. Touch **Save** to export instrument logs to the specified location or **Cancel** to return to the 'Settings' screen without exporting logs. **Panel B.** After instrument log files are exported, the 'Export' screen is displayed indicating that logs have been saved to the specified path. Touch **Open** to view the folder location of the exported instrument log files. Touch **Done** to exit the 'Export' screen and return to the 'Settings' screen.

5.3 Administrator Settings

Software settings for the Maxwell® CSC software can be accessed by Windows® user accounts with administrator-level access to the Maxwell® CSC software using the **Administrator** button on the 'Settings' screen. From the 'Settings' screen touch the **Administrator** button to open the 'Administrator page' screen.

Note: From the 'Home' screen touch the **Settings** button and then the **Administrator** button to open the 'Administrator page' screen.

The functions available from the 'Administrator page' screen allow users with administrator-level access to the Maxwell® CSC software to customize the behavior of the Maxwell® CSC IVD Mode software to the needs of their laboratory. Buttons on the 'Administrator page' screen allow the administrator to: set Sample Tracking requirements, define the Export Folder to which exported reports will be saved, manage Methods installed in the software, define an Instrument Name for this Maxwell® CSC instrument, and set the required sanitization behavior and durations for UV light treatment on the Maxwell® CSC instrument. The behavior of each button on the 'Administrator page' screen is detailed here. Follow these instructions to adapt the behavior of the Maxwell® CSC software to the needs of the laboratory, or refer to any individual subsection to address a specific setting.

Note: Administrator settings made within the IVD Mode are only applied when running the Maxwell® CSC software in IVD Mode.

Navigation Note: The instructions for each subsection below assume that the operator is starting from the 'Administrator page' screen in the Maxwell® CSC software. Follow the instructions below to access the 'Administrator page' screen when starting from the 'Home' screen in the software.

1. To return to the 'Home' screen from any other screen, touch the **Home** button in the upper left corner of the screen. From the 'Home' screen of the Maxwell® CSC User Interface (Figure 24), touch the **Settings** button.

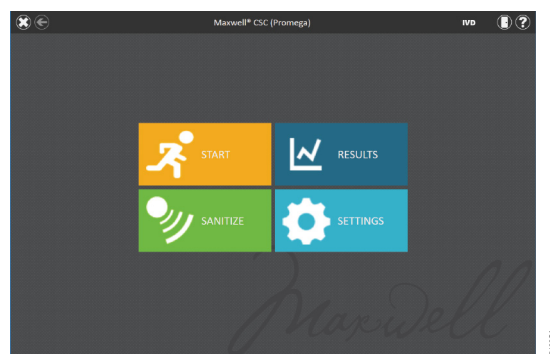


Figure 24. Maxwell® CSC 'Home' screen. Selecting **Settings** opens the Maxwell® CSC 'Settings' screen.

2. If the current operator signed into the Tablet PC has administrator access rights within the Maxwell® CSC software, the 'Settings' screen (Figure 25) will display an Administrator button. On the 'Settings' screen select the **Administrator** button to proceed to the 'Administrator page' screen (Figure 26).

Note: If the Administrator button is not visible, sign out of the Windows® operating system with this user and sign in with user credentials that have administrator access rights within the Maxwell® CSC software.

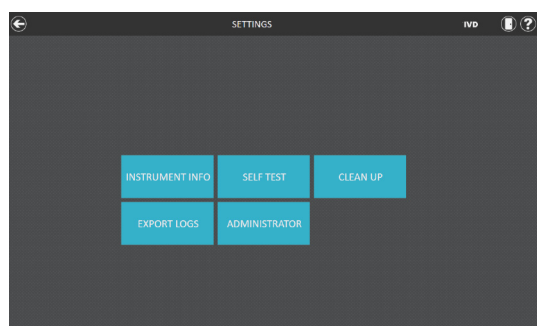


Figure 25. Maxwell® CSC 'Settings' screen. The **Administrator** button will only be visible if the operator currently signed in has administrator rights within the Maxwell® CSC software.

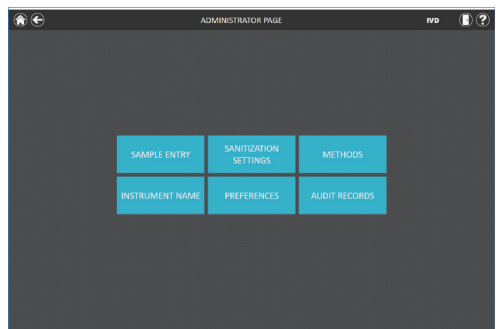


Figure 26. Maxwell® CSC 'Administrator page' screen. The 'Administrator page' screen gives access to customize the behavior of several aspects of the Maxwell® CSC system.

5.3.1 Sample Entry

The 'Sample Entry' screen allows you to define the required bar code values that need to be input by any operator when running a Maxwell® CSC protocol. Kit bar code entry, as well as sample ID entry for every cartridge position selected during a protocol run, is mandatory in the user interface. You can customize the required sample tracking fields in the Maxwell® CSC software such that operators must enter cartridge ID, elution tube ID, and/or two additional administrator-defined bar code fields. A checkbox next to each of these fields can be used to specify whether the bar codes entered for any of these fields is required to match the sample ID bar code for a given cartridge position.

In addition, the software can be set to warn operators if duplicate sample identifiers have been entered for a run by checking the box next to "Warn on duplicates". If duplicate bar codes are detected within a run, the software will display a warning message before starting the extraction of samples.

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

1. From the Maxwell® CSC software 'Administrator page' screen (Figure 26), touch the **Sample Entry** button.
2. The 'Sample Entry' screen is shown in Figure 27. On this screen the options for Sample ID and Lot Number are always checked as these are mandatory settings. You can choose whether to 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). You can also define and label up to two custom bar code entry fields if desired. Enable any of these fields by touching the box to the left of the specified field name. Once enabled the box will contain a check mark.

If any of these options is enabled, then you can 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. Enable the bar code matching option for any of these additional enabled bar code fields by touching the box to the left of the "Must match Sample ID" text for that field. Once enabled the box will contain a check mark.

Figure 27. Maxwell® CSC 'Sample Entry' screen. Use this screen to configure the bar code information that must be entered for each sample prior to performing a sample processing protocol. Use the "Warn on duplicates" option to display a warning when multiple cartridges within a run have identical Sample ID information. For any of the optional fields, you can specify whether the bar code information entered is required to match the Sample ID for each processing position on the instrument.

3. The software can be configured to warn the user if duplicate bar codes are detected within a run. The warning does not prevent the user from processing samples, but allows the user to identify potential errors in bar code scanning. To enable this feature, check the "Warn on duplicates" check box.
4. After the Sample Entry settings are configured as desired touch the **Save** button to save these settings and return to the 'Administrator page' screen.

5.3.2 Sanitization Settings

The Maxwell® CSC instrument contains a UV light that can help aid in sanitization of the instrument. You can specify when UV light treatment of the instrument should be performed, and the duration of the UV treatment.

1. From the 'Administrator page' screen touch the **Sanitization Settings** button to open the 'Sanitization Settings' screen.
2. Three sanitization settings are present on the 'Sanitization Settings' screen (Figure 28). These are described below:
 - a. Default sanitization duration—This setting defines the duration of the UV treatment (in minutes) performed when the **Sanitization** button on the 'Home' screen is touched.
 - b. Sanitize after extraction for (OPTIONAL)—This setting defines the duration of UV treatment (in minutes) that will be automatically performed after completion of a protocol run.
 - c. Sanitize on software start-up for (OPTIONAL)—This setting defines the duration of UV treatment (in minutes) that will be automatically performed when the Maxwell® CSC software is started.

3. Touch the text box next to “Default sanitization duration” to open the on-screen number pad. Enter in the number of minutes to be used for UV sanitization when the **Sanitization** button on the ‘Home’ screen is touched. Touch the **OK** button on the on-screen number pad to accept the duration value or touch the **Cancel** button on the on-screen number pad to discard changes.
4. To enable either of the optional UV sanitization options, touch the box next to the desired option. A checkmark will be visible in the box next to the enabled option and the text box associated with the option will become active. Touch the text box associated with the desired option to open the on-screen number pad. Enter in the number of minutes of UV sanitization to be performed for the desired option. Touch the **OK** button on the on-screen number pad to accept the duration value or touch the **Cancel** button on the on-screen number pad to discard changes.
5. Once all UV sanitization options have been set, touch the **Save** button to accept and save the settings. To discard any changes to the UV sanitization options, touch the **Cancel** button. Touching either button will result in a return to the ‘Administrator page’ screen.

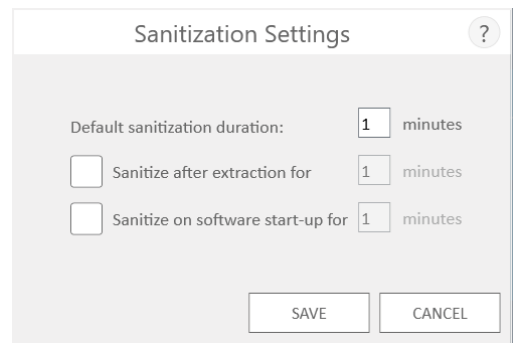


Figure 28. The ‘Sanitization Settings’ screen.

5.3.3 Methods

The ‘Methods’ screen displays a list of the currently installed methods in the user interface including the name, version number, method type (IVD or RUO) and catalog number for each method. There are no configuration settings for the Maxwell® CSC software present on the ‘Methods’ screen (Figure 29).

1. If you desire to view the methods currently installed in the Maxwell® CSC software, touch the **Methods** button from the ‘Administrator page’ screen.
2. Touch the **Back Arrow** in the upper left hand corner of the screen to return to the ‘Administrator page’ screen.

As Promega provides new purification kits for use with the Maxwell® CSC Instrument, new protocol methods can be added to the Maxwell® CSC Instrument. Occasionally, an existing protocol method may have to be updated. Only operators with administrator-level access to the Maxwell® CSC software can add new protocol methods or update existing methods. Administrators can download new protocol methods for new purification kits or updated existing protocol methods for existing purification kits from the Promega website:

www.promega.com/resources/software-firmware/maxwell-maxprep/maxwell-cscsoftware-firmware-methods/

5.3.4 Importing a Method

Methods are provided as files with a .package extension. Follow the instructions below to import a method into the Maxwell® CSC software.

1. Save the method (.package) file on the Tablet PC attached to the Maxwell® CSC.
2. If not already running, start the Maxwell® CSC software (in either IVD Mode or RUO Mode) by double-touching the desired software icon on the desktop.
3. Navigate to the 'Methods' screen ('Home' → **Settings** → **Administrator** → **Methods**).
4. Touch the **Select Import Package** button on the bottom right side of the screen to open the 'Select File' browser screen.
5. Within the 'Select File' screen, navigate to the location at which you saved the method (.package) file. The current path will be shown in yellow boxes along the top of the window. Touch any aspect of the path to navigate to the desired folder. Touch the **Drive** button to select the drive in which to search. Folders within the current path are shown as red rectangles on the left side of the screen. Valid method (.package) files will be shown as blue rectangles (yellow when selected) on the right side of the screen.
6. Select the blue rectangle(s) corresponding to the desired (.package) file(s) to highlight it, then touch the **OK** button.
7. A pop-up window will indicate successful import of the method(s) into the software. If import was successful, the new method file(s) will appear in the list of method files on the 'Methods' screen.

Note: Both IVD and RUO methods can be imported into the Maxwell® CSC IVD software, but only IVD methods can be run in the Maxwell® CSC IVD software.

Name	Version	Type	Catalog Number
Maxwell CSC RBE Blood	v1.02	ND	A57100
Blood	v1.02	ND	A57100
Maxwell R CSC TYPE RBE KIT	v1.04	ND	A57100
Maxwell R CSC TYPE DAB Kit	v1.04	ND	A57100

Figure 29. 'Methods' screen. This screen displays a list of the methods that are currently installed in the Maxwell® CSC software. For each method you can view the name of the method, the version number of the method, method type (IVD or RUO) and the catalog number of the Maxwell® CSC Reagent kit for this method.

5.3.5 Preferences

Administrators can view preferences available in the Maxwell® CSC IVD Mode software by touching the **Preferences** button on the 'Administrator Page' screen. The 'Preferences' screen displays a set of three tabs that can be used by the administrator to adapt the functionality of the software to the need of the laboratory (Figure 30).

Below are listed the tabs and associated preferences that can be set and a description of their functions.

'Common Settings' tab

The 'Common Settings' tab on the 'Preferences' screen (Figure 30) provides administrators the ability to specify the following options:

- **"Allow deletion of results":** When checked, this box will allow users to delete extraction report files from the local database of run reports.
- **"Auto Export":** Report files can be automatically exported to an administrator-defined location at the end of instrument runs. Check the "Auto Export" box to enable this function, and then touch the text box below this option to specify the path to which exported results files should be saved. An 'Export Folder' screen will open with the current path specified in yellow rectangles. Touch any aspect of the path to navigate to the desired folder. Touch the **Drive** button to select the drive in which to search. Folders within the current path will be shown as red rectangles in the main area of the screen. Results will be exported to the specified drive location as PDF and tab-delimited text files.

- **Imported Data Modifications:** Beneath this header are check boxes to specify whether approvals are required to make changes to the imported sample tracking information. The options available are:

“Admin Approval Required”: Check this box if modifying or removing samples to the imported tracking information require entering the credentials by an operator with administrator-level rights to the Maxwell® CSC software.

“User Approval Required”: Check this box if modifying or removing samples to the imported tracking information require entering the credentials of the current operator logged into the Tablet PC.

When navigating away from the ‘Preferences’ screen, a prompt is displayed allowing the administrator to save any changes that have been made. Touch the **Save** button to save any changes and navigate away from the ‘Preferences’ screen. To leave the ‘Preferences’ screen without saving changes, touch the **Don’t Save** button. Touch the **Cancel** button to return to the ‘Preferences’ screen without saving changes.

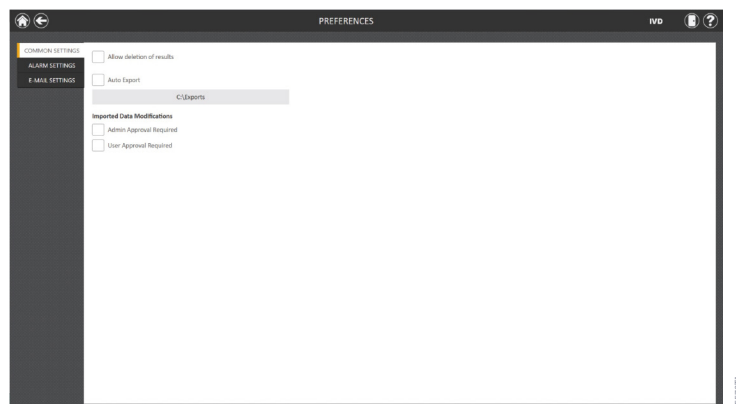


Figure 30. ‘Common Settings’ tab on the ‘Preferences’ screen. From the ‘Common Settings’ tab, the administrator can specify software and export behaviors. Additionally, the approvals required to make changes to sample deck tray layouts retrieved from the Sample Data Import function can be set.

‘Alarm Settings’ tab

The ‘Alarm Settings’ tab on the ‘Preferences’ screen (Figure 31) provides administrators the ability to specify whether the software will provide audible alarms for completed extraction method runs and error states. Available options are:

- “Play sound when extraction is completed”: Check this box to have the Tablet PC generate a sound when an extraction method run is completed. Use the increase/decrease volume rocker switch on the edge of the tablet to adjust the Tablet PC volume.
- “Play sound on error”: Check this box to have the Tablet PC generate a sound if an error occurs during an extraction method run on the instrument. Use the increase/decrease volume rocker switch on the edge of the tablet to adjust the Tablet PC volume.

When navigating away from the 'Preferences' screen, a prompt is displayed allowing the administrator to save any changes that have been made. Touch the **Save** button to save any changes and navigate away from the 'Preferences' screen. To leave the 'Preferences' screen without saving changes, touch the **Don't Save** button. Touch the **Cancel** button to return to the 'Preferences' screen without saving changes.

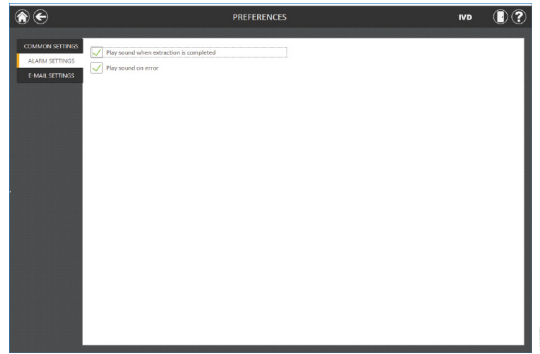


Figure 31. 'Alarm Settings' tab on the 'Preferences' screen. From the 'Alarm Settings' tab, the administrator can specify whether audible alarms should be played on completion of an extraction run or on error.

'E-mail Settings' tab

The 'E-mail Settings' tab on the 'Preferences' screen (Figure 32) is where e-mail server details are specified and where administrators can determine when and to whom e-mail notifications will be sent. It is necessary to fill out the user and server information on the 'E-mail Settings' tab, and that the Tablet PC has network access to the e-mail server in order to use e-mail notifications. Required e-mail server information on the left side of the screen includes:

- **User Name:** The name of the user for the e-mail account from which e-mail notifications will be sent.
- **E-mail:** The e-mail account from which e-mail notifications will be sent.
- **Password:** The password for the e-mail account from which e-mail notifications will be sent
- **SMTP Server:** The SMTP server address for the e-mail account
- **Port:** The port that should be used for the SMTP server
- **SSL Encrypted Connection:** Checkbox indicating whether the e-mail account uses an SSL Encrypted connection

Note: Contact your IT department to provide the information required to complete e-mail settings.

On the right side of the screen the administrator can specify under what conditions and to whom e-mail notifications will be sent. Options include:

- “Send mail when extraction is completed”: Check this box to have e-mails automatically sent to the specified e-mail addresses when an extraction run has been completed.
- “Send mail on error:” Check this box to have e-mails automatically sent to the specified e-mail addresses if an error state occurs during an extraction run.
- “E-mail Recipients:” Enter the e-mail address(es) separated by a space that will act as the distribution list for e-mail notifications under the conditions that have been selected.

Upon completing the entries for e-mail settings, you can test the validity of the settings by touching the **Test Connection** button. Touching this button will attempt to send a test e-mail to the e-mail account and e-mail recipients designated by the settings on this page.

When navigating away from the ‘Preferences’ screen, a prompt is displayed allowing the administrator to save any changes that have been made. Touch the **Save** button to save any changes and navigate away from the ‘Preferences’ screen. To leave the ‘Preferences’ screen without saving changes, touch the **Don’t Save** button. Touch the **Cancel** button to return to the ‘Preferences’ screen without saving changes.

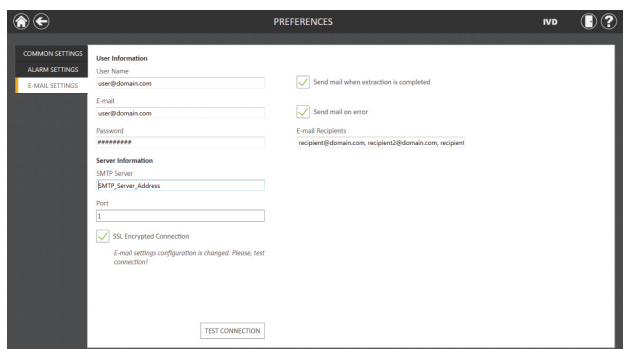


Figure 32. ‘E-mail Settings’ tab on the ‘Preferences’ screen. From the ‘E-mail Settings’ tab the administrator can specify e-mail server settings, under what conditions e-mail notifications should be sent, and the distribution list to which e-mails should be sent. Use the **Test Connection** button to check the settings entered on this screen.

5.3.6 Audit Records

The Maxwell® CSC software contains a full audit trail of all functions which have been performed on the instrument. Operators with administrator-level access to the Maxwell® CSC software have access to view and export the audit records from the instrument through the Audit Records button on the 'Administrator page' screen. The 'Audit Records' screen displays a listing of all of the functions that have been performed on the instrument (Figure 33). You can filter the audit records by touching the buttons on the left side to view records for runs completed today, this week, this month, the past 3 months, the past 6 months, this year, or all functions performed over the life of the instrument. Touch the column headers to sort the records based on column contents. Touch the desired row to see the audit message from that particular record.

Administrators can export all audit records for the selected date range by touching the **Export** button at the bottom left corner of the screen and specifying a location to which the exported information should be saved.

1. Touch the **Export** button on the 'Audit Records' screen.
2. Using the Yellow and Red rectangle buttons you can select the folder location where the method run reports will be saved. The current path is indicated by the yellow rectangles at the top of the 'Export Folder' screen. Any folders present within the selected directory are displayed as red rectangles in the main portion of the screen. Touch the **Drive** button to navigate to the drive location of the desired folder. Touch red folder buttons to navigate to the specified folder location.
3. Once the desired file path has been specified, touch the **OK** button to save the new export folder setting or touch the **Cancel** button to cancel any changes. After touching either **OK** or **Cancel** you will be returned to the 'Audit Records' screen.

	DATE/TIME	STATUS	OPERATOR	OPERATION	CONTENT/MESSAGE
TODAY	5/4/2019 5:53:27 PM	Success	DESKTOP-UXVJ0KZ\user	Export Result	Blood Test exported
THIS MONTH	5/4/2019 5:53:27 PM	Success	DESKTOP-UXVJ0KZ\user	Export Result	Blood PDF exported
SIX MONTHS	5/4/2019 5:05:33 PM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
THIS YEAR	5/2/2019 1:43:03 PM	Success	DESKTOP-UXVJ0KZ\user	Export Result	voidRNA Plasma and Serum (RUO) Test exported
ALL	5/2/2019 1:43:03 PM	Success	DESKTOP-UXVJ0KZ\user	Export Result	voidRNA Plasma and Serum (RUO) PDF exported
	5/2/2019 10:22:47 AM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	5/2/2019 10:19:59 AM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	4/30/2019 11:21:53 AM	Success	DESKTOP-UXVJ0KZ\user	Export Result	Blood Test exported
	4/30/2019 11:21:53 AM	Success	DESKTOP-UXVJ0KZ\user	Export Result	Blood PDF exported
	4/30/2019 9:14:05 AM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	4/30/2019 9:07:21 AM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	4/30/2019 4:03:10 PM	Success	DESKTOP-UXVJ0KZ\user	Export Result	Maxwell CSC RNA Blood Test exported
	4/30/2019 4:03:10 PM	Success	DESKTOP-UXVJ0KZ\user	Export Result	Maxwell CSC RNA Blood PDF exported
	4/30/2019 2:46:36 PM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	4/30/2019 2:46:07 PM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	4/30/2019 2:45:53 PM	Success	DESKTOP-UXVJ0KZ\user	Part Number	QINQMDNA
	4/30/2019 2:45:57 PM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	4/30/2019 2:45:28 PM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
	4/30/2019 2:45:10 PM	Success	DESKTOP-UXVJ0KZ\user	Application start	Application Start
EXPORT	5/4/2019 5:53:27 PM	Success	DESKTOP-UXVJ0KZ\user	Export Result	Blood Test exported

Figure 33. 'Audit Records' screen. A user-readable record of events which have occurred in the Maxwell® CSC software can be viewed and exported to a specified drive location from the 'Audit Records' screen.

5.3.7 Instrument Name

A unique identifying name for the Maxwell® CSC Instrument can be defined. This name will be shown on the title bar of the Maxwell® CSC software 'Home' screen and will be recorded in protocol run reports.

Notes:

- a. Saving an instrument name will force a restart of the Windows® Operating System.
 - b. You cannot specify different instrument names in RUO Mode and IVD Mode for a single Maxwell® CSC Instrument.
1. From the 'Administrator page' screen, touch the **Instrument Name** button to open the 'Instrument Name' screen.
 2. On the 'Instrument Name' screen, touch the text box to enable the on-screen keyboard.
 3. Use the on-screen keyboard to manually enter the desired name for this instrument (Figure 34). The instrument name should be entered following the procedures and rules at your site.
 4. Once the desired name has been entered, touch the **OK** or the **Enter** button on the on-screen keyboard to return to the 'Instrument Name' screen.
 5. Touch the **Save** button to save the instrument name you have entered. **Saving the instrument name will enforce a restart of the Windows® Operating System.** After saving, an informational screen will be displayed indicating that "Windows will now restart". Touch the **OK** button to restart the operating system.
 6. If you do not wish to save any changes to the instrument name, touch the **Cancel** button to return to the 'Administrator page' screen.

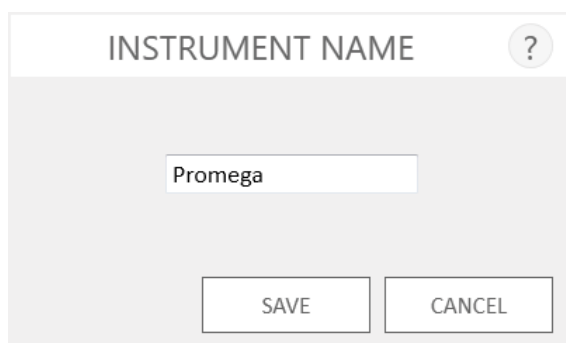
The image shows a software interface for setting an instrument name. It has a light gray background. At the top, there's a header bar with the text "INSTRUMENT NAME" in a bold, sans-serif font. To the right of this text is a small circular icon containing a question mark. Below the header bar is a large, light gray rectangular area. In the center of this area is a white rectangular text input field. The word "Promega" is typed into this field. Below the input field, there are two rectangular buttons side-by-side. The left button is labeled "SAVE" and the right button is labeled "CANCEL". Both buttons have a thin black border. In the bottom right corner of the screen, there is a small vertical text label "13440CA".

Figure 34. 'Instrument Name' screen. Use this screen to manually enter a name for this Maxwell® CSC Instrument. Saving the instrument name will enforce a restart of the Windows® Operating System.

6 Operating the Maxwell® CSC Instrument in IVD Mode

6.1 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 method bar code on the kit label 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, entering bar code information for the sample ID is needed prior to initiating sample processing (See Section 5.3). 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.

6.2 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 35), select the **Start** button to begin the process of running a protocol.



Figure 35. 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 the 'Scan barcode' screen (Figure 36) that will ask you to scan the bar code on the kit box. The method bar code on the kit box is in the top right hand corner of the Maxwell® CSC reagent kit label (Figure 37). Alternatively, touch the text box on the 'Scan barcode' screen to manually enter the bar code information using the on-screen keyboard. Maxwell® CSC accepts bar codes in the following format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format (example: AS13213221872018-05, where the product catalog number is AS1321, the kit lot number is 322187 and the expiration date is 2018-05). The OK button will only become active if the bar code is entered with this format. The text to enter is shown to the right of the method bar code in the top right hand corner of the Maxwell® CSC reagent kit label. Do not use the information from the bar code at the bottom of the label. 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. If a Maxwell® CSC kit has multiple workflows with multiple methods, scanning or entering the bar code will bring up a method selection screen that displays all the available methods for that kit. Touch the desired workflow method to highlight it and then touch the **Proceed** button next to the method.

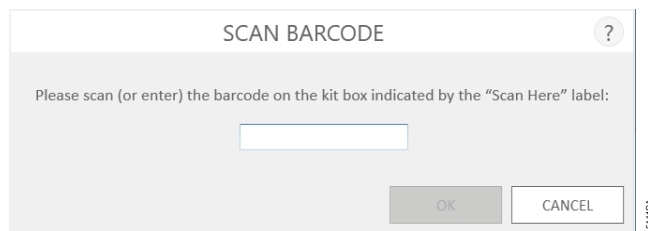


Figure 36. 'Scan Barcode' screen. Scanning the method bar code automatically selects the protocol on the Maxwell® CSC Instrument.



Figure 37. Kit label indicating bar code to scan. Scan the bar code, shown in the upper right of the kit label, to start a purification run.

3. There are three potential error modes that can occur with bar code scanning:
 - a. If the kit lot has passed the specified expiration date, an information screen 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 has a purification method associated with it on this instrument, but the purification method is incompatible with the current software mode, an information screen will appear indicating that the method is incompatible with the current software mode. To run this method, shut down the Maxwell® CSC software and double-tap the Maxwell® CSC software icon for the appropriate mode to use with the desired purification kit.
 - c. If the scanned product catalog number does not have a nucleic acid purification method associated with it on this instrument, an information screen will appear indicating that the software does not have a protocol for the scanned catalog number. Upon selecting the **OK** button on the information screen, the software will return to the 'Home' screen. To get the most updated information on the available methods, please contact Promega Technical Services (email: techserv@promega.com) or visit: www.promega.com/resources/software-firmware/maxwell-maxprep/maxwell-cscsoftware-firmware-methods/
4. After scanning the bar code, you will be presented with a 'Cartridge Setup' screen (Figure 38) 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. Identification information may be entered manually (option 1) or using the sample data import function (option 2).

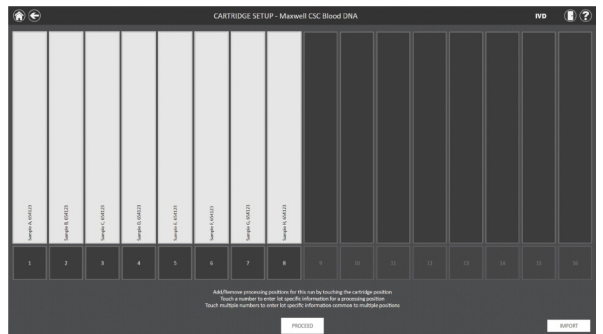


Figure 38. 'Cartridge Setup' screen. At the top of this screen the selected protocol is indicated. This screen allows the user to select which cartridge positions will be processed. To select or deselect a cartridge position, touch the long rectangle for any given position.

Option 1: Manual Entry

- a. Select empty positions at which cartridges will be processed by touching the long rectangle for each position that will be used. 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 up to two additional administrator-defined fields. All of the required information must be entered for all selected cartridge positions before the Proceed button becomes active.
- c. Touch the black box below a cartridge position to scan or manually enter the bar code information for the selected position (Figure 40). 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.
- d. Touch the **Sample ID** and additional required sample tracking information text boxes to enter or scan the sample information. After a bar code is scanned, the software will automatically move to the next empty bar code field for a position. Once all sample identifier information for a cartridge is entered, the software will automatically move to the next cartridge with empty bar code fields. 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.

Option 2: Sample Import

- a. To import sample bar code information from an external file, touch the **Import** button. This will bring up the 'File' tab of the 'Sample Data Import' screen (Figure 39, Panel A).
- b. From the 'File' tab of this screen, apply a filter to display .xlsx files, or .csv, .txt, .tsv files, or .xls files, or any file format. From this tab, select the path where the sample information file is located.
- c. Using the yellow and red rectangle buttons, you can select the folder location where the import file is located. The current path is indicated by the yellow rectangles at the top of 'Sample Data Import' screen. Any folders present within the selected directory are displayed as red rectangles in the main portion of the screen. Touch the **Drive** button to navigate to the drive location of the desired folder. Touch the red buttons to navigate to the desired folder location.
- d. Once a path has been defined, select the desired file, and touch the **Open** button to automatically move to the 'Data' tab on the 'Sample Data Import' screen (Figure 39, Panel B).

- e. The 'Data' tab on this screen allows you to identify the information present in each column of the file. A table displaying the columns of data found in the import file is shown in the main portion of the screen. Select the type of data present in each column of the file using the drop-down menu at the top of each column. The Cartridge position and Sample ID are minimally required; however other categories can be the Cartridge ID bar code, Elution Tube ID bar code or up to two administrator-defined fields. To use these categories, they must be checked in the Sample Entry section of the software. See Section 5.3.1, Sample Entry for more information. For columns that should be ignored during import, select **X** from the drop-down menu.

If your import file has a header row that provides titles for the information in each column, check the "Header" box on the right side of the table to ignore the Header row during import. When the "Header" box is checked, the first row of the table will be shaded light blue.

All selections made on the 'Data' tab are saved and become the default values selected the next time sample data is imported.

- f. Once all data fields are identified, touch the **Accept** button to perform the import of data from the file. An 'Import' screen will be displayed summarizing the results of the sample import, including the number of samples that were present in the file and the data source for the import file. Touch **OK** to dismiss the 'Import' screen.
- g. Touch **OK** to dismiss the 'Sample Data Import' screen and apply the imported information to the 'Cartridge Setup' screen.
- h. At the 'Cartridge Setup' screen, the imported sample information is present. The screen will be locked for editing. If sample information must be edited manually, touch the **Enable Editing** button, and confirm by touching **Continue**. See Option 1 for manual entry instructions.
- i. If sample bar code information is required by the Administrator, but was not present in the imported file, a red exclamation point will be displayed at the top of the cartridge positions missing the required bar code information. The missing information can be entered manually or by importing from an external file containing all of the required sample bar code information.

Note: Positions with incomplete information will display a red circle with an exclamation point at the top of the gray rectangle when required data is missing or cartridges do not meet expiration date requirements specified by the administrator. Touch the red exclamation point icon for a description of the issue with a given cartridge position. Note that The **Proceed** button will be gray and inactive while required information is missing. If information is missing after sample import, touch the **Enable Editing** button and acknowledge the action by touching the **Continue** button.

Multiple kit lots can be entered for a run by touching or swiping across multiple black box positions and touching the Kit Lot Number text box to display a 'Scan Barcode' screen. Scan or enter the bar code information for the kit lot that is being used for the selected cartridge positions. 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: AS13213221872018-05, where the product catalog number is AS1321, the kit lot number is 322187 and the expiration date is 2018-05). 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, if the kit does not match the selected method, or if the kit is not supported by the instrument.

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. Scan the bar code at the top of the label (Figure 37). You will receive an error message if you scan the wrong bar code.

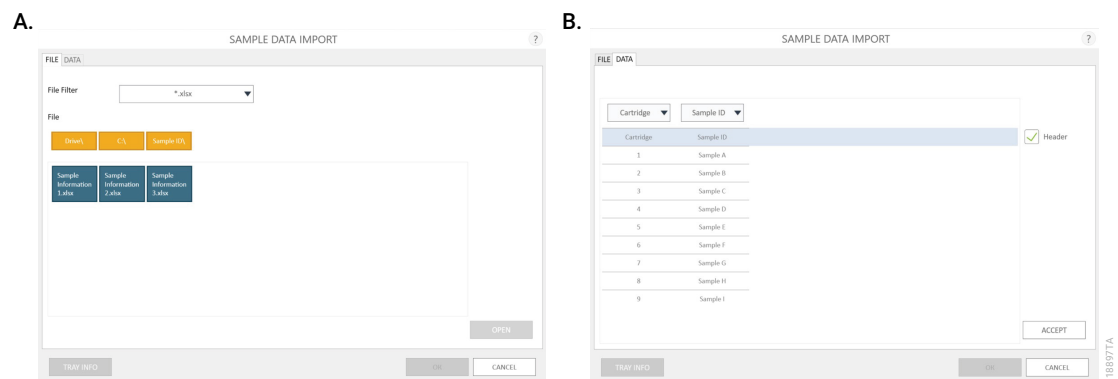


Figure 39. 'Sample Data Import' screen. Panel A. The 'File' tab is displayed after touching the **Import** button. Select the file filter and navigate to the file location where the sample import file is located. Touch the desired blue box file and touch the **Open** button to open up the 'Data' tab and view the sample ID information in the file or touch **Cancel** to return to the 'Cartridge Setup' screen. **Panel B.** The 'Data' tab is displayed after touching the **Open** button. Select the Sample ID categories for the imported data, as well as check if a Header row is present. If data is present that should not be imported, select **X** for the column category. When finished, touch the **Accept** button to apply the information to the 'Cartridge Setup' screen.

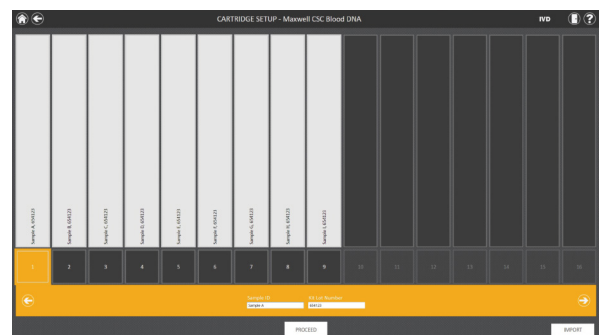


Figure 40. Bar code and kit lot input. By selecting the numbered box at the bottom of any cartridge position, sample ID and kit lot information can be scanned or manually entered for that position. Touching the arrow on the right side of the entry area will move to the next available cartridge position. 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 (Figure 40) to move to the 'Door' screen (Figure 41). Touch the **OK** button to open the Maxwell® CSC Instrument door.

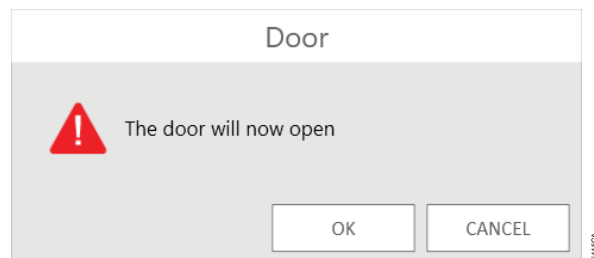


Figure 41. 'Door' screen. Informs the user that the Maxwell® CSC Instrument door will open.

- You will be presented with an 'Extraction Checklist' screen (Figure 42). 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.

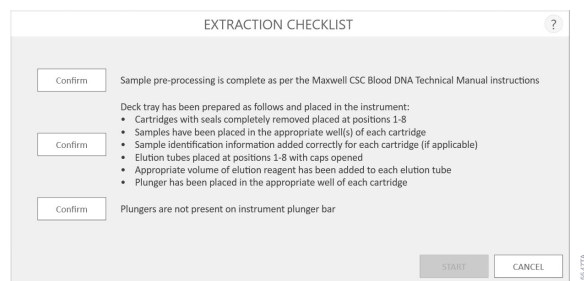


Figure 42. 'Extraction Checklist' screen. This screen indicates the steps that will need to be performed to prepare the instrument for processing the selected samples. Preprocessing steps are not indicated on the 'Extraction Checklist' and should be performed prior to this stage according to the technical manual for the kit being processed.

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 43). Press down firmly to snap the cartridges in place at both ends. There should be an audible snap.

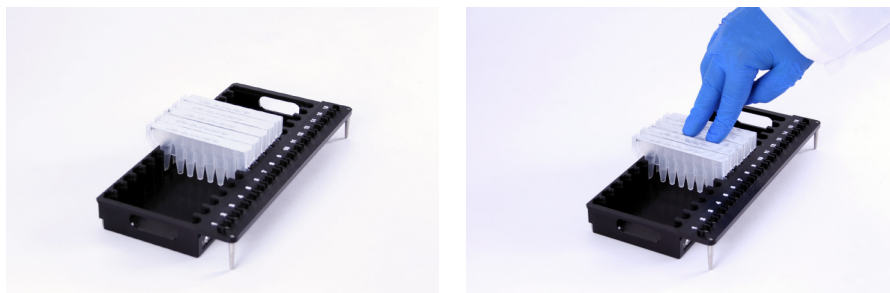


Figure 43. Place the cartridges in the deck tray, and press firmly to snap them in place.

- Completely remove seals from all cartridges.
 - Place elution tubes at the selected positions in the deck tray.
- Note:** Bar code labels should not be wrapped around the outside of the elution tubes before the tubes are inserted into 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 the appropriate well(s) 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 6.3 for instructions for plunger removal.
 - Place a plunger in the last well (closest to the elution tube) of each cartridge.
 - Confirm the sample identification information for each cartridge (if applicable).
 - Place the deck tray in the instrument as shown in Figure 44. Angle the back of the deck tray into the instrument as shown and then press down on the front of the deck tray to seat the elution tubes into the heater position. Ensure that the deck tray is completely seated inside the instrument.

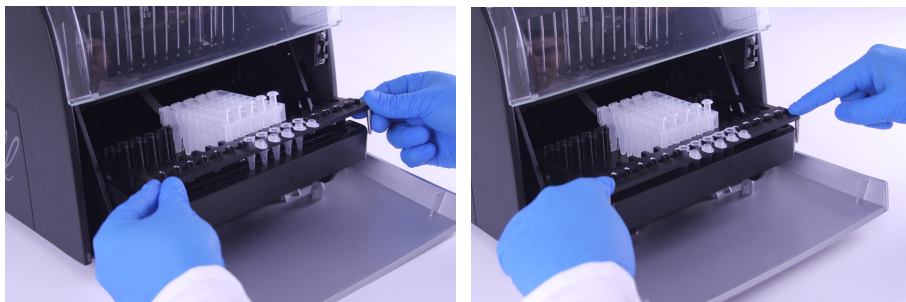


Figure 44. Place the deck tray in the instrument.

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 45). Touch the **Start** button to begin the purification or touch the **Cancel** button to return to the 'Cartridge Setup' screen.

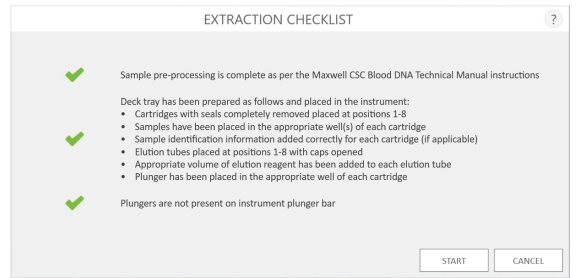


Figure 45. Completed Extraction Checklist. When all checklist items have been confirmed, the **Start** button will become active. Touch the **Start** button to begin the processing run or the **Cancel** button to return to the sample information entry screen.



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 7.2) and the cartridges containing the samples discarded. The samples will be lost.

8. While the protocol runs, you will see the 'Protocol Running' screen (Figure 46). 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 run.

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 occurs.

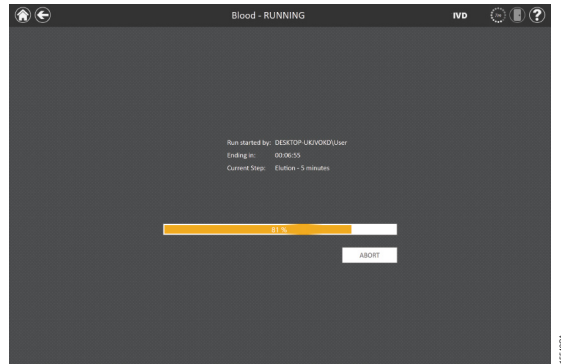


Figure 46. 'Protocol Running' screen. The 'Protocol Running' screen is displayed during a protocol run. This screen indicates what protocol is currently being run at the top of the screen. Also indicated on this screen are the user who started the run, an approximate indication of when the run will end, a description of the current method step and a progress bar showing the percent completion of the run. If you wish to abort the current run, touch the **Abort** button in the lower right corner of the screen.

6.2.1 Protocol Completes Successfully

When the protocol is completed successfully, the 'Protocol Running' screen will change to indicate that the protocol has been completed (Figure 47). After a protocol is complete, "Current Step" will be listed as "Completed". Touch the **Open Door** button to open the door of the Maxwell® CSC Instrument.

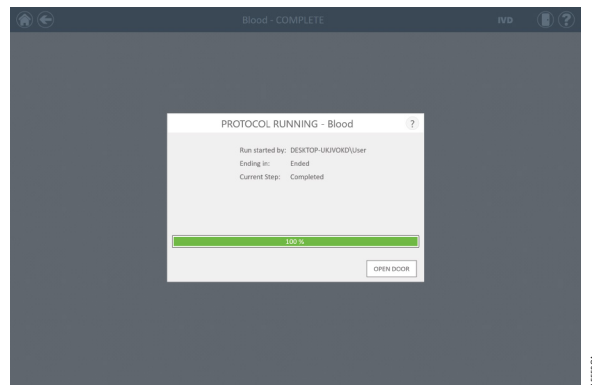


Figure 47. 'Protocol Running' screen after completion of the protocol. Upon completion of the currently running protocol, the 'Protocol Running' window indicates 100% completion in the run progress bar. "Current Step" changes to "Completed" after a run is finished. After a protocol is completed, touch 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 48). 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 49). 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 6.3 to remove them. The extracted nucleic acid is present in the elution tubes. If the method being run is a sequential protocol, follow the on-screen instructions and applicable extraction technical manual to continue the run. If the method is not a sequential protocol, 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 48. Closing the elution tube caps.



Figure 49. Removing the elution tubes and the deck tray.

After the door is opened, the 'Report View' screen (Figure 52) will be presented. If the administrator settings require 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 6.6).

6.2.2 User Aborts Protocol

If the protocol is aborted by the user, the 'Protocol Running' screen will indicate that the protocol has been aborted (Figure 50). After a protocol is aborted, the "Current Step" will be listed as "Aborted by user". After Aborting the protocol, you can touch the **Open Door** button to bring up the 'Clean Up' screen (Figure 51).

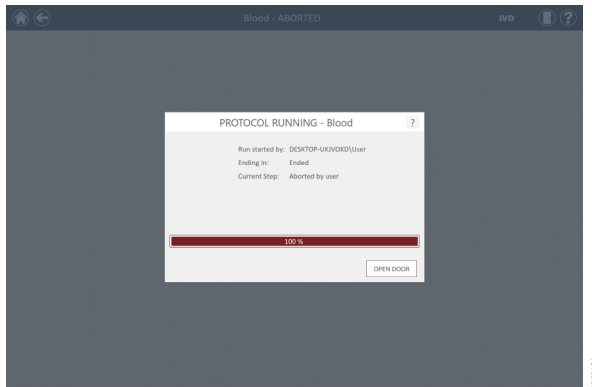


Figure 50. 'Protocol Running' screen after protocol abort. If a protocol is aborted by the user or due to an instrument error, the 'Protocol Running' screen changes to indicate that the protocol has been aborted and specifies the reason next to the "Current Step". After a protocol is aborted, touch the **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 repurify samples from an aborted run.

6.2.3 Instrument Error

If the protocol is aborted due to instrument error, the 'Protocol Running' screen will change to indicate that the protocol has been aborted (Figure 50) and will display an error message.

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

6.3 Clean Up

After Aborting the protocol, you can touch the **Open Door** button to bring up the 'Clean Up' screen (Figure 51).

The 'Clean Up' screen asks you to check whether the 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 Clean Up** button to continue. On touching the **Skip Clean Up** button, you will be presented with the extraction report (Figure 52).

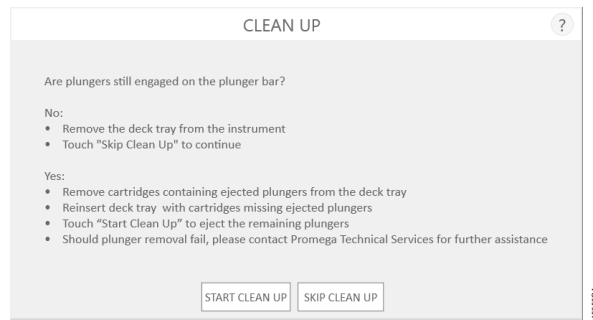


Figure 51. 'Clean Up' screen after protocol abort/instrument error. If a protocol is aborted by the user or due to an instrument error, the 'Clean Up' screen is displayed with a choice of **Start** or **Skip Clean Up**, depending on whether the plungers are still engaged or disengaged from the plunger 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 Clean Up** button to eject the remaining plungers .

After the Clean Up is successful, you can touch the **Open Door** button and remove the deck tray. You will be presented with the 'Report View' screen.

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

6.4 Results

After touching the **Open Door** button in the 'Protocol Run' screen, the 'Report View' screen is displayed (Figure 52). 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, software mode, instrument name, serial number, etc.).

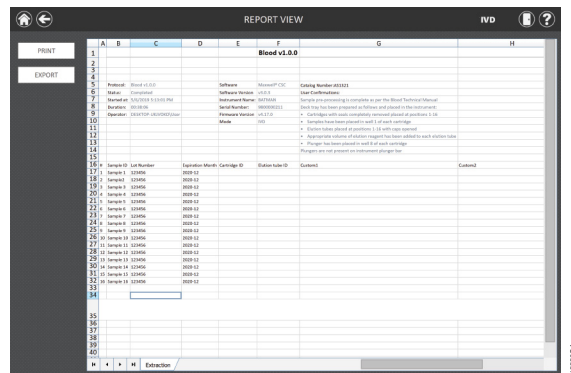


Figure 52. 'Report View' screen. The 'Report View' screen displays the sample tracking and protocol-specific information for the current instrument run. Included in this report are the sample tracking information recorded prior to starting the protocol, the final status of the protocol (Completed or Aborted), the time the protocol run was started, the length of time the protocol took to process, the operator ID and additional instrument information.

On the left side of the screen are a Print and an Export button that can be used for printing the report or exporting report information (Figure 53). Touch the **Export** button to navigate to the folder location where the report should be exported, and then touch the **Save** button. Using the Yellow and Red rectangle buttons, you can select the folder location where the reports will be saved. The current path is indicated by the yellow rectangles at the top of the 'Export Folder' screen. Any folders present within the selected directory are displayed as red rectangles in the main portion of the screen. Touch the **Drive** button to navigate to the drive location of the desired folder. Touch red folder buttons to navigate to the specified folder location. The Maxwell® CSC software exports both a printable (*.pdf) and a tab delimited (*.txt) format of the reports. The tab-delimited-text format file may be useful in combination with a Laboratory Information Management System (e.g., LIMS). An example of the tab-delimited report format is shown in Figure 54 and an example of the printable PDF format is shown in Figure 55.

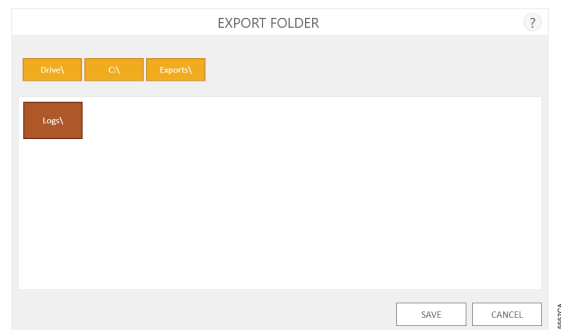


Figure 53. 'Export Folder' screen. When the **Export** button is touched, the user will be asked to navigate to the file location where report files should be saved.

Touch the **Open** button to navigate to the folder location where the report has been exported. If you do not wish to view the report, touch the **Done** button to return to the 'Report View' screen.

```

#000000011 2019-05-06 17:13:01 Bloodlet - Notepad
File Edit Format View Help
Blood v1.0.0

Software: Maxwell® CSC
Software Version: v1.0.0
Instrument Name: 6617668
Serial Number: 000000011
Firmware Version: v4.17.0
Mode: IVD

Protocol: Blood v1.0.0
Status: Completed
Started at: 5/6/2019 5:13:01 PM
Duration: 00:18:06
Operator: DESECTOP-UCXKODUser

# Sample ID Lot Number Expiration Month Cartridge ID Elution tube ID Custom1 Custom2
1 Sample 1 123456 2020-12
2 Sample 2 123456 2020-12
3 Sample 3 123456 2020-12
4 Sample 4 123456 2020-12
5 Sample 5 123456 2020-12
6 Sample 6 123456 2020-12
7 Sample 7 123456 2020-12
8 Sample 8 123456 2020-12
9 Sample 9 123456 2020-12
10 Sample 10 123456 2020-12
11 Sample 11 123456 2020-12
12 Sample 12 123456 2020-12
13 Sample 13 123456 2020-12
14 Sample 14 123456 2020-12
15 Sample 15 123456 2020-12
16 Sample 16 123456 2020-12

```

Figure 54. Example of a report in the tab-delimited format.

#	Sample ID	Lot Number	Expiration Month	Cartridge ID	Elution tube ID	Custom1	Custom2
1	Sample 1	123456	2020-12				
2	Sample 2	123456	2020-12				
3	Sample 3	123456	2020-12				
4	Sample 4	123456	2020-12				
5	Sample 5	123456	2020-12				
6	Sample 6	123456	2020-12				
7	Sample 7	123456	2020-12				
8	Sample 8	123456	2020-12				
9	Sample 9	123456	2020-12				
10	Sample 10	123456	2020-12				
11	Sample 11	123456	2020-12				
12	Sample 12	123456	2020-12				
13	Sample 13	123456	2020-12				
14	Sample 14	123456	2020-12				
15	Sample 15	123456	2020-12				
16	Sample 16	123456	2020-12				

Figure 55. Example of a report in the PDF format.

6.5 Running Reports

From the 'Home' screen (Figure 56) of the Maxwell® CSC software, view sample tracking reports and service reports on the instrument by touching the **Results** button. The 'Results' screen displays a listing of all of the reports for the protocol run in the Maxwell® CSC IVD Mode software, as well as service and system tasks that have been run on the system (Figure 57). Any reports which have resulted from an aborted run will be identified with a red circle containing an exclamation point. The user can filter reports by date range by touching the buttons on the left side to view reports for runs completed today, this month, 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 58). To export a selection of extraction reports to a user-specified drive location, touch the check-box next to the desired extraction report(s), and touch the **Export** button in the lower left corner of the screen. The **Export All** button in the lower left corner of the screen will export all displayed results to a drive location specified by the user.

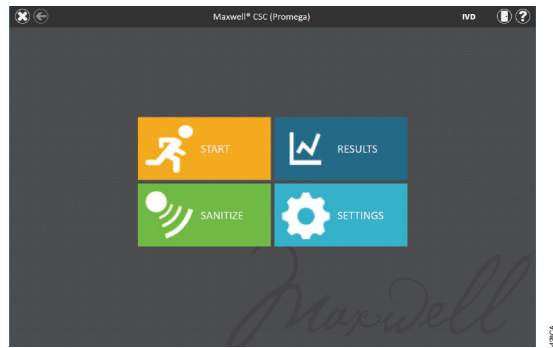


Figure 56. Maxwell® CSC 'Home' screen. Selecting **Results** opens the Maxwell® CSC 'Results' screen from which extraction reports from all extraction runs, service activities and system activities can be viewed.

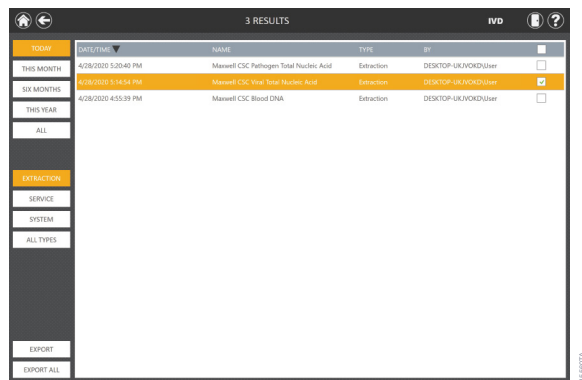


Figure 57. 'Results' screen. The 'Results' screen lists the extraction reports from all of the extraction protocols run in the Maxwell® CSC IVD Mode software, as well as service and system protocols run on this instrument. Reports which have resulted from an aborted run will be identified with a red circle containing an exclamation point. Touch any given report listing to see a detailed view of the report data from that protocol run.

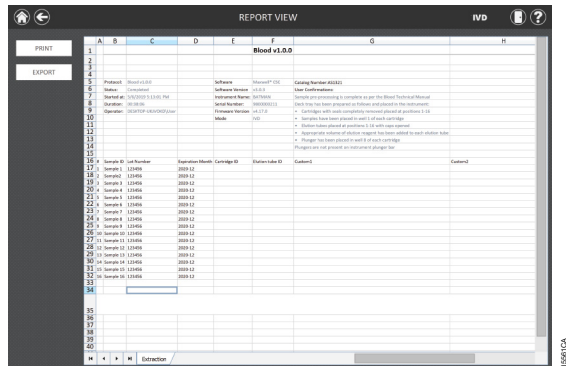


Figure 58. Extraction Report. An example of the sample tracking information present in an extraction report.

6.6 Sanitizing

You can manually perform a UV light treatment of the instrument from the 'Home' screen (Figure 59) 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 60) 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 perform UV sanitization.

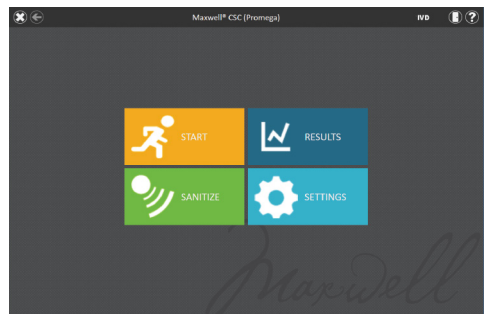


Figure 59. 'Home' screen. Selecting the **Sanitize** button begins the process of performing a UV light treatment of the Maxwell® CSC Instrument.

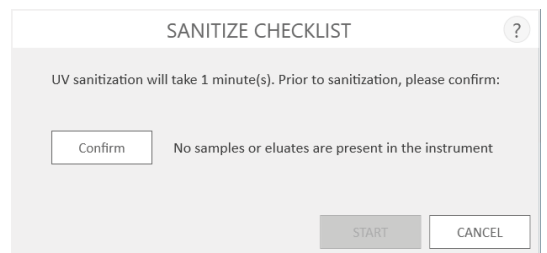



Figure 60. 'Sanitize Checklist' screen. The sanitization checklist indicates the duration of the UV sanitization process. It will also ask you to confirm that no samples or eluates are present in the instrument prior to running Sanitization.

After Sanitization is completed, you will see the following icon appear in the title bar. 

Touch the icon to view the Sanitization report.

Note: UV radiation is useful in sanitization 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. Follow the cleaning guidelines in Section 7.

7

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, 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.

7.1 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.

7.2 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.

7.3 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. Do not use bleach to clean the Maxwell® CSC Instrument. 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.

8

Analytical Performance Evaluation

Analytical performance for the Maxwell® CSC Instrument (Cat.# AS6000) was evaluated in combination with the Maxwell® CSC Blood DNA Kit, Maxwell® CSC RNA Blood Kit, Maxwell® CSC DNA FFPE Kit and Maxwell® CSC RNA FFPE Kit using human whole blood or FFPE tissue samples as appropriate for the specific kit. Average yield and percent coefficient of variation (% CV) were obtained from eluates across three runs on a single instrument and across three separate instruments.

8.1 Reproducibility

Table 1. Reproducibility Within and Across Instrument Runs. Inter- and intra-run reproducibility was determined by running eight replicates of whole blood samples or six replicates of FFPE tissue samples, as appropriate for the Maxwell® CSC kit used, in three separate runs on a single instrument. Sample types and test methods were as follows: 1. DNA was extracted from 300µl samples of whole blood and yield evaluated by absorbance spectroscopy; 2. RNA was extracted from 2.5ml samples of whole blood and yield evaluated by absorbance spectroscopy; 3. DNA was extracted from human colon sections and yield evaluated by qPCR; 4. RNA was extracted from human breast sections and yield evaluated by RT-qPCR.

Maxwell® CSC Kit	Run Number	Intra-Run % CV	Inter-Run % CV
1. Blood DNA	1 (n = 8)	4.0	2.9
	2 (n = 8)	2.5	
	3 (n = 8)	2.2	
2. RNA Blood	1 (n = 8)	9.2	11.8
	2 (n = 8)	17.7	
	3 (n = 8)	7.2	
3. DNA FFPE	1 (n = 6)	5.0	6.7
	2 (n = 6)	4.2	
	3 (n = 6)	7.9	
4. RNA FFPE	1 (n = 6)	17.4	14.2
	2 (n = 6)	7.3	
	3 (n = 6)	7.2	

Table 2. Reproducibility Within and Across Instruments. Three kits were selected as a representative sampling of chemistries to assess instrument reproducibility. Inter- and intra-instrument reproducibility was determined by running eight replicates of whole blood samples or six replicates of FFPE tissue samples, as appropriate for the Maxwell® CSC kit used, on three separate Maxwell® CSC instruments. The average and standard deviation for the purified nucleic acid yield were calculated for replicates in each instrument to determine intra-instrument variability and for replicates in all three runs to determine inter-instrument variability. Sample types and test methods were as follows: 1. DNA was extracted from 300µl samples of whole blood and yield evaluated by absorbance spectroscopy; 2. RNA was extracted from 2.5ml samples of whole blood and yield evaluated by absorbance spectroscopy; 3. DNA was extracted from human colon sections and evaluated by qPCR.

Maxwell® CSC Kit	Instrument Number	Intra-Run % CV	Inter-Run % CV
1. Blood DNA	1 (n = 8)	4.0	3.5
	2 (n = 8)	3.0	
	3 (n = 8)	3.3	
2. RNA Blood	1 (n = 8)	9.2	13.5
	2 (n = 8)	9.4	
	3 (n = 8)	14.7	
3. DNA FFPE	1 (n = 6)	5.0	5.3
	2 (n = 6)	4.1	
	3 (n = 6)	5.6	

8.2 Cross Contamination

DNA was purified from eight replicates of 300µl of female and male whole blood samples processed in alternating deck positions of the Maxwell® CSC Instrument using the Maxwell® CSC Blood DNA Kit. An SRY target on the Y chromosome was used to identify potential cross contamination of female samples with male DNA from neighboring samples. When female whole blood samples were processed in deck positions adjacent to male whole blood samples, female samples exhibited no detectable Y-chromosomal DNA.

9

Clinical Performance Evaluation

Clinical performance was evaluated by an external clinical laboratory. DNA was extracted from human whole blood samples by two separate users using the Maxwell® CSC Instrument and Maxwell® CSC Blood DNA Kit and tested for amplifiability in a relevant in vitro diagnostic test. DNA extracted from the same samples using the extraction method the laboratory typically uses (laboratory reference extraction method) was tested at the same time for comparison purposes.

For additional performance data, please see applicable Maxwell® CSC Reagent Technical Manuals.

9.1 DNA Amplification

Table 3. DNA Amplification. DNA was purified from 16 separate human whole blood specimens using the Maxwell® CSC Blood DNA Kit and the laboratory reference extraction method and tested in a COLD-PCR JAK2 V617F assay targeting the wild-type gene. For Maxwell® purifications, an input blood volume of 50µl and an elution volume of 100µl were evaluated. All samples from both methods amplified with a C_q value <15 cycles.

Blood Samples	Amplification	
	Maxwell® CSC	Laboratory Reference Method
16	All samples amplified	All samples amplified

Table 4. Tester-to-Tester Reproducibility. DNA was purified from 16 separate human whole blood specimens by two different users of the Maxwell® System. An input blood volume of 300µl and an elution volume of 50µl were used for eight of the samples (TS-1 to TS-8) and an input blood volume of 50µl and elution volume of 100µl used for the other eight samples (TS-9 to TS-16) to ensure the full range of input blood volumes and elution volumes allowed by the Maxwell® CSC Blood DNA Kit were covered. The extracted DNA was tested in a COLD-PCR JAK2 V617F assay targeting the wild-type gene and the C_q values obtained by each tester compared. The results were concordant between the two testers.

Blood Sample	Input Sample and Elution Volumes (Maxwell® CSC)		Average C_q	
	Input Sample Volume (µl)	Elution Volume (µl)	Tester 1	Tester 2
TS-9	50	100	12.94	12.87
TS-10	50	100	12.73	13.97
TS-11	50	100	13.34	13.34
TS-12	50	100	14.26	13.41
TS-13	50	100	14.64	14.39
TS-14	50	100	13.19	13.15
TS-15	50	100	12.84	13.15
TS-16	50	100	12.02	14.07
TS-1	300	50	12.62	12.05
TS-2	300	50	12.52	12.83
TS-3	300	50	12.73	12.43
TS-4	300	50	12.82	13.42
TS-5	300	50	12.71	20.38
TS-6	300	50	12.43	12.60
TS-7	300	50	12.77	12.64
TS-8	300	50	12.07	12.83

9.2 Cross Contamination

DNA purification was performed on eight different 300µl whole blood samples and eight negative control water samples in alternating deck positions to assess any cross contamination between samples in the same instrument run. The resulting eluates were tested by qPCR to determine if any contaminating DNA was present in the negative controls, using a JAK2 V617F amplification assay targeting the wild-type gene. No DNA was detected in the negative controls demonstrating that no detectable cross contamination occurred during the instrument run.

Following completion of the other studies described here in Section 9, Clinical Performance Evaluation, the external lab decontaminated and cleaned the instrument following the procedure described in Section 7 of this manual. DNA purification was then performed on 16 negative control samples (water) using the Maxwell® CSC Instrument and Maxwell® CSC Blood DNA Kit, and eluates from each sample were tested by qPCR to determine if any contaminating DNA was present, using a JAK2 V617F amplification assay targeting the wild-type gene. No DNA was detected in the negative controls, demonstrating that the instrument cleaning instructions are effective at preventing contamination carryover from previous instrument runs.

10 Troubleshooting

For questions not addressed here, please contact your local Promega Branch, Office or Distributor. See the Promega website to find your nearest Promega branch or distributor. Contact information available at: www.promega.com. Email: 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> <p>Remove any cartridges containing the ejected plungers from the deck tray.</p> <p>Reinsert the deck tray with cartridges without ejected plungers.</p> <p>From the 'Home' screen touch the Settings button and select Clean Up. Confirm checklist items and follow on-screen prompts to attempt to unload plungers.</p> <p>If the plunger clean up fails, contact Promega Technical Services for further assistance: techserv@promega.com</p>
Tablet PC touch screen does not appear to be working	<p>Verify that the power supply 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>

Symptoms	Causes and Comments
Cannot get beyond the 'Scan bar code' screen	Be sure that you are scanning the correct bar code (see Figure 37).
	Be sure that you are using the correct Maxwell® CSC kit.
	Be sure that the kit has not expired.
	If you still experience problems, contact Promega Technical Services.
Cannot change the sanitization time or load new protocols	Only operators that have administrative-access rights in the Maxwell® CSC software have the ability to change certain instrument functionality. If the current operator signed into the tablet PC does not have administrator-access rights to the Maxwell® CSC software, have the operator sign out and then sign back into the tablet using a Windows® user profile that has administrator-level rights within the Maxwell® CSC software. Start the Maxwell® CSC software and attempt to make the desired Maxwell® software setting changes.

10.1 Errors and Warnings

Error	Explanation
<Method Name> is incompatible with the current operation mode.	The user is attempting to run an RUO method in the Maxwell® CSC IVD software. This method type must be run using the Maxwell® CSC RUO software. Close the Maxwell® CSC IVD software, open the Maxwell® CSC RUO software, and run the desired RUO method.
Initialization Failure: Access Denied, not a valid Promega User, Please contact your system administrator.	The current Windows® user profile signed into the tablet PC does not have access rights to run the Maxwell® CSC software. See TM484 for information on assigning access rights for the Maxwell® CSC software to a Windows® user profile.

Error	Explanation
USB Device is not found; is it turned Off or disconnected?	Tablet PC is not connected to the instrument or the instrument is OFF. Check to see if Tablet PC is connected to the instrument or restart 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. If this error occurs during a protocol run the run will abort and samples will be lost. Touch Continue to have the instrument attempt to complete the protocol abort process. If error still persists, contact Promega Technical Services
Protocol: Aborted By user.	User aborted protocol. Samples will be lost.
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 performing the desired action. If error still persists, contact 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' screen 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.

Any serious incident that occurred in relation to the device that led to, or might lead to, death or serious injury of a user or patient should be immediately reported to the manufacturer. Users based in the European Union should also report any serious incidents to the Competent Authority of the Member State in which the user and/or the patient is established.

10.2 Use of a USB Flash Drive

- When using a USB flash drive, do not insert or remove the flash drive from the USB ports on the back of the Maxwell® CSC instrument while a protocol is running.
- Since USB flash drives may vary from vendor to vendor or from type to type, incompatibilities can occur. If your USB flash drive is not detected after a few seconds or if you encounter any issues with the USB flash drive, shut down and restart the tablet and the instrument, and try a different brand of USB flash drive.
- If the tablet controller becomes unresponsive after inserting a USB flash drive, shut down the tablet and remove the USB drive, then restart the tablet and the instrument.

11 Appendix

11.1 Service

We recommend that the Maxwell® CSC Instrument receives a yearly preventive maintenance service.

11.2 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 website: 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 13 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 13). 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.

11.3 Repacking the Maxwell® CSC Instrument

11.3.1 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 and tablet PC. USB cords from the tablet PC and bar code reader have been disconnected from the USB ports on the back of the Maxwell® CSC instrument.

11.3.2 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 damage.

1. Open the instrument door and manually push the deck to the back of the instrument.
2. Manually bring the plunger bar (Figure 61) down to cover the magnetic tips.

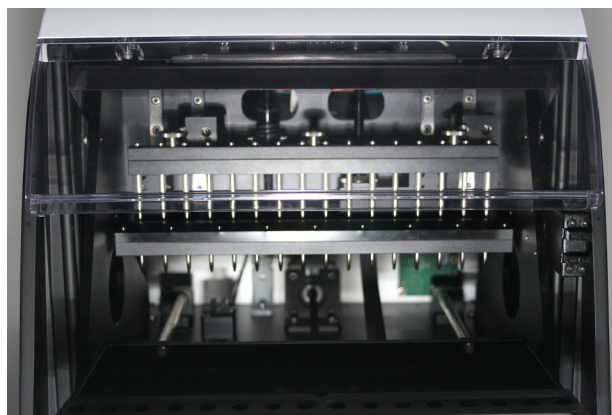


Figure 61. Plunger Bar.

3. Place the die cut foam as shown in Figure 7.
4. Slide the other die cut foam to lock the deck and the plunger bar as shown in Figure 7. 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.
5. Place the instrument back in the plastic bag.

6. Place the instrument in the bottom foam packaging material. The instrument will only fit properly into the bottom foam piece in one orientation (Figure 62).



Figure 62. Maxwell® CSC Instrument in correct orientation in the box.

7. Place the top foam packaging over the top of the instrument as shown (Figure 63).



Figure 63. Foam packing on top of box.

8. Place the accessories box on top of the packing foam. Affix the Certificate of Decontamination on top of the accessories box (Figure 64).



Figure 64. Maxwell® CSC Instrument in correct orientation in the box.

9. Close the flaps on the shipping container top, and secure them with packing tape.
10. Write the return authorization number provided to you by Promega or your local Promega representative on the outside of the shipping box.

11.4 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.

12 Warranties, Service Agreements and Related Products

12.1 Warranty

Upon purchase of the Maxwell® CSC Instrument, the instrument will be covered by a one year Standard Warranty. The Standard Warranty covers all parts, labor and shipping to and from our depot repair location as well as your choice of a loaner (where available). We will repair your instrument and return it to you performing to original factory specifications.

12.2 Warranty and Service Agreement Options

Maxwell® CSC Premier Warranty Upgrade Cat.# SA1111

The Premier Warranty Upgrade 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 (where available) or on-site service visit by a factory-trained service technician within 2 business days (where available). 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 Premier Service Agreement

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 (where available) or on-site service visit by a factory-trained service technician within 2 business days (where available). 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.

Different options for Maxwell® CSC Premier Service Agreement are available as shown below.

Product Name	Cat.#
1-Year Maxwell® CSC Premier Service Agreement	SA1120
2-Years Maxwell® CSC Premier Service Agreement	SA1123
3-Years Maxwell® CSC Premier Service Agreement	SA1124

Maxwell® CSC Standard Service Agreement

The Standard Service Agreement covers all parts, labor and shipping to and from our depot repair location as well as a loaner instrument upon request. If your Maxwell® CSC needs repair, we will provide a box for shipment of the instrument back to our service facility. We will repair the instrument and return it performing to the original factory specifications. Preventative Maintenance visits are available separately.

Different options for Maxwell® CSC Standard Service Agreement are available as shown below.

Product Name	Cat.#
1-Year Maxwell® CSC Standard Service Agreement	SA1110
2-Years Maxwell® CSC Standard Service Agreement	SA1121
3-Years Maxwell® CSC Standard Service Agreement	SA1122

Maxwell® CSC Preventative Maintenance Cat.# SA1130

To keep the system operation 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

Product Name	Cat.#
Maxwell® CSC Instrument Installation Qualification	SA1140
Maxwell® CSC Instrument Operational Qualification	SA1150
Maxwell® CSC Instrument Installation Qualification/ Operational Qualification	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 Installation Qualification service product involves a site visit to:

- 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 by a Promega Service Representative 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) on-site repair by a factory-trained technician (where available). 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. The Maxwell® CSC instrument maintenance can be transitioned to a Premier or Standard Service Agreement option, provided the renewal is requested prior to the expiration of the current Service Agreement or the one-year Warranty provided upon purchase of a new instrument.

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.

12.3 Related Products

PRODUCT	SIZE	CAT.#
Maxwell® CSC Blood DNA Kit	48 preps	AS1321
Maxwell® CSC RNA Blood Kit	48 preps	AS1410
Maxwell® CSC DNA FFPE Kit	48 preps	AS1350
Maxwell® CSC RNA FFPE Kit	48 preps	AS1360
Maxwell® CSC Whole Blood DNA Kit	48 preps	AS1820
Maxwell® CSC Viral Total Nucleic Acid Purification Kit	48 preps	AS1780
Maxwell® CSC Genomic DNA Kit	48 preps	AS1850
Maxwell® CSC Pathogen Total Nucleic Acid Kit	48 preps	AS1860
RSC/CSC Deck Tray	1 each	SP6019
Elution Magnet, 16-Position	1 each	AS4017

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

13 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 inside 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. Follow immediately with a cloth dampened with deionized water. 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 radio-active materials.

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

Date: _____

Place: _____

Signature: _____

Name (block capital letters): _____

14 Summary of Changes

The following changes were made to the 10/24 revision of this document:

1. Made edits to Sections 1.6, 1.8 and 6.5.
2. Updated Sections 1.9, 5.3, 6.2, 12.1 and 12.3.
3. Moved document into a new template, including updating the cover page.

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.

^(a)U.S. Pat. Nos. 7,721,947 and 7,891,549, European Pat. No. 2033144 and Japanese Pat. Nos. 5519276 and 5654519.

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Products may be covered by pending or issued patents or may have certain limitations. Please visit our website 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.

