



Maxwell[®] CSC 48 Instrument IVD Mode Operating Manual

Instructions for Use of Model Number AS8000
when running IVD Mode

For use in RUO Mode, see the *Maxwell[®] CSC 48 RUO Mode Software Manual #TM628*.
Ensure that all sealing tape and any residual adhesive are removed from the Maxwell[®] CSC reagent
cartridges before placing the cartridges into the instrument.



INSTRUCTIONS FOR
USE OF PRODUCT
AS8000



TM623 | Revised 10/24



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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

1.1 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 48 Instrument is intended for use by laboratory professionals. The purification methods use sample lysis and binding to paramagnetic particles as the primary separation principle. Up to 48 samples can be prepared in a single run.

The automated steps performed by the Maxwell® CSC 48 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 through a graphical user interface running on a Tablet PC. The Maxwell® CSC 48 Instrument has the ability to record and report sample tracking and method run data. A bar code reader is supplied with the Maxwell® CSC 48 Instrument and is used for selecting methods and capturing bar code information for samples and reagents. The Maxwell® CSC 48 Instrument provides reports of the data gathered for instrument operations; reports can be printed and exported to a storage location or a USB drive for transfer to a separate computer. To start a run, the user scans the method bar code of the reagent kit to be processed. After entering the sample tracking information, follow the recommended protocol for the Maxwell® CSC reagent kit and prepare the deck trays of the instrument as instructed. Place the deck trays containing prepared cartridges into the instrument, and the method will run automatically. Using the instrument does not require any special training; however, training is available as part of Operational Qualification (OQ; see Section 12.2).

1.2 Product Intended Purpose/Intended Use

The Maxwell® CSC 48 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 48 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 48 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 48 Instrument is only available in certain countries. When used in IVD mode, the Maxwell® CSC 48 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 with the Maxwell® CSC 48 Instrument.

1.4 Maxwell® CSC 48 Instrument Features

- Easy-to-use and easy-to-maintain system operation
- Standardized sample preparation workflow
- System controlled via Tablet PC
- Reporting functionality
- Preprogrammed methods for nucleic acid purification
- Included Bar Code Reader
- UV lamp to aid in sanitization of instrument
- Integrated Vision system for confirming proper deck tray preparation
- Integral USB hub for easy connection to accessory devices
- Comprehensive technical support

1.5 Maxwell[®] CSC 48 Instrument Specifications

Processing Time:	40–60 minutes (depending on sample type and method)
Number of Samples:	Up to 48
Weight:	~60lb (~27kg)
Dimensions (W × D × H):	21 × 21 × 14 inches (533.4 × 533.4 × 355.6mm)
Power Requirements:	100–240VAC, 50/60Hz, 4A
Fuse:	250VAC, 4A, low breaking capacity, time-lag fuse (AC250V, T4AL, 5 × 20mm)
UV Bulb:	Average lifetime approximately 9,000 hours, length 212.1mm, diameter 16mm, 6W, 0.17A current, 42V, spectral peak F 253.7, UV output 1.7W
Installation Category II	
Pollution Degree 2	

1.6 Product Components

PRODUCT	CAT.#
Maxwell® CSC 48 Instrument	AS8000

For In Vitro Diagnostic Use. Includes:



- 1 Maxwell® CSC 48 Instrument
- 1 Tablet PC preloaded with Maxwell® CSC 48 Application Software
- 1 USB Cable for connection of the Maxwell® CSC 48 Instrument to the Tablet PC
- 1 Power Cable for Maxwell® CSC 48 Instrument
- 1 Power Cord for Tablet PC
- 1 Power Adapter for Tablet PC
- 1 Maxwell® RSC/CSC 48 Front Deck Tray
- 1 Maxwell® RSC/CSC 48 Back Deck Tray
- 1 UV Bulb (installed)
- 1 Bar Code Reader
- 1 Tablet Mount Attachment Pieces
- 1 2.5mm Hex Wrench
- 1 Stylus
- 1 Quick Start Guide
- 1 Setup Guide

1.7 Inspection

Upon receiving your Maxwell® CSC 48 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). Included components are shown in Figure 1.



Figure 1. Maxwell® CSC 48 Instrument. Components shown include: Deck Tray (Front; A), Deck Tray (Back; B), Tablet PC (C), USB Cable (D), Tablet PC Power Adapter (E), communication cable for the Bar Code Reader (F), Power Cord for Tablet PC (G) and Bar Code Reader (H).

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) because 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 blocks at the front and middle of the platform become hot. Do not touch.
- To avoid muscle strain or back injury, use lifting aids and proper lifting techniques when removing or replacing the instrument.
- Instrument door should be opened and closed only by using the Maxwell® CSC 48 software. Do not manually pry the door open or override the door sensor during operation because it will result in the method being aborted.
- This instrument can be used with potentially biohazardous samples. Use appropriate personal protective equipment (gloves, safety goggles, lab coat, etc.) for handling and disposing of biohazardous materials.
- Do not load any additional software programs on the Tablet PC supplied with Maxwell® CSC 48 Instrument. Additional programs may cause the application to slow down.
- Contact Promega Technical Services if the UV lamp needs replacement.

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

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:	100–240VAC, 50/60Hz, 4A
Temperature:	4–50°C (shipping/storage), 15–25°C (operation)
Humidity:	Up to 80% relative humidity, non-condensing
Operating Altitude:	<2,000 meters

The Maxwell® CSC 48 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 electrically noisy 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 48 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.

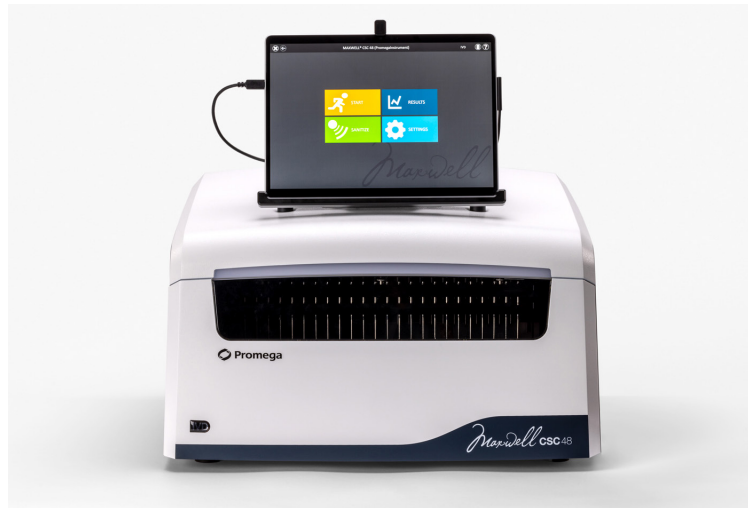


Figure 2. Front of the Maxwell® CSC 48 Instrument.

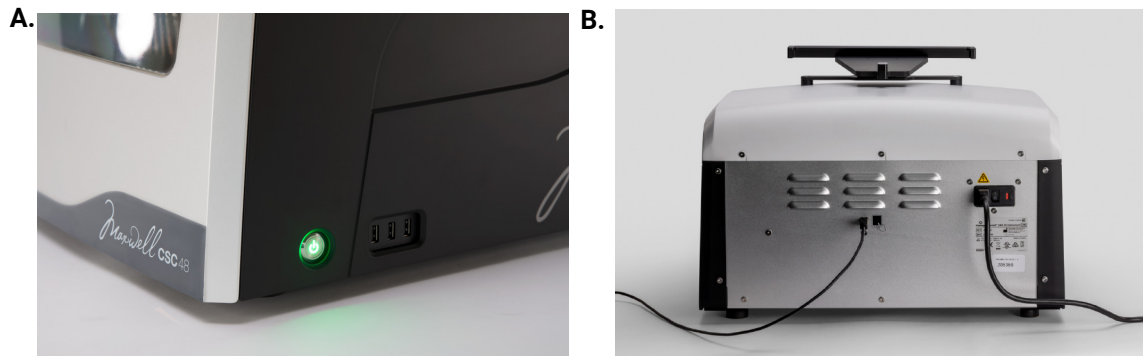


Figure 3. Side and Rear views of the Maxwell® CSC 48 Instrument. Panel A. The side of the instrument showing the On/Off switch and the 3-port USB hub for accessories such as the Bar Code Reader. **Panel B.** The rear of the instrument showing the power cable connector and USB communication port for the Tablet PC.

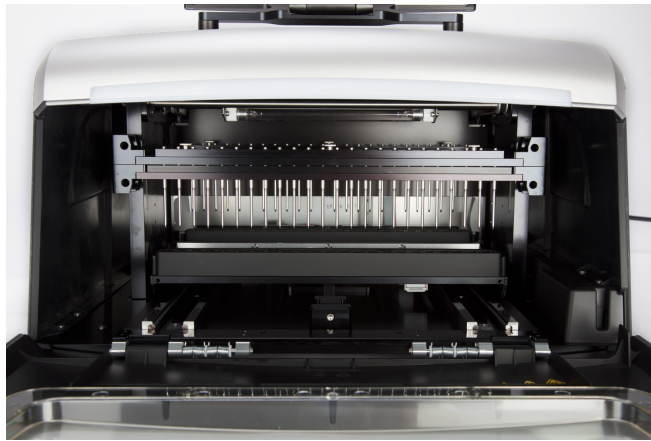


Figure 4. Magnetic assembly components and platform. The hardware components inside the Maxwell® CSC 48 Instrument. The magnet and plunger bars, which are used for sample processing, and the platform, which holds the deck trays, are evident.

Unpacking the Maxwell[®] CSC 48 Instrument

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



Follow These Steps

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



Figure 5. The accessories box.



Save the packaging material in case the instrument needs to be returned for service or repair.

4. Remove the four plastic clips from around the base of the shipping container. To do this, pinch the inner plastic pieces of the clip and pivot the inner portion of the clip vertically; then pull the entire plastic clip out from the base of the box. Slide the top portion of the shipping box off the base. Remove the side foam pieces from the instrument. Carefully remove the instrument from the box (Figure 6).

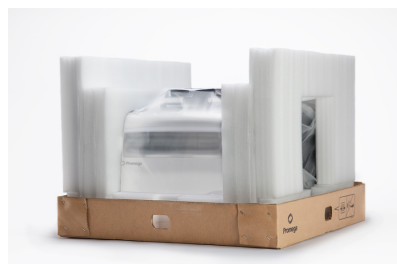


Figure 6. Remove the upper packing material.

5. 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.
6. Remove the plastic bag from around the instrument.

3.1 Setting Up the Maxwell® CSC 48 Instrument

1. Manually open the instrument door and carefully remove the foam piece from the inside front of the instrument (Figure 7, Panel A). The Maxwell® CSC 48 Instrument door is spring-loaded and will close itself automatically.
2. Unscrew the four shipping screws from the sides of the front magnet and plunger bar (Figure 7, Panel B).
3. Slide the magnet and plunger bars downward, and remove the top foam piece from the instrument (Figure 8)

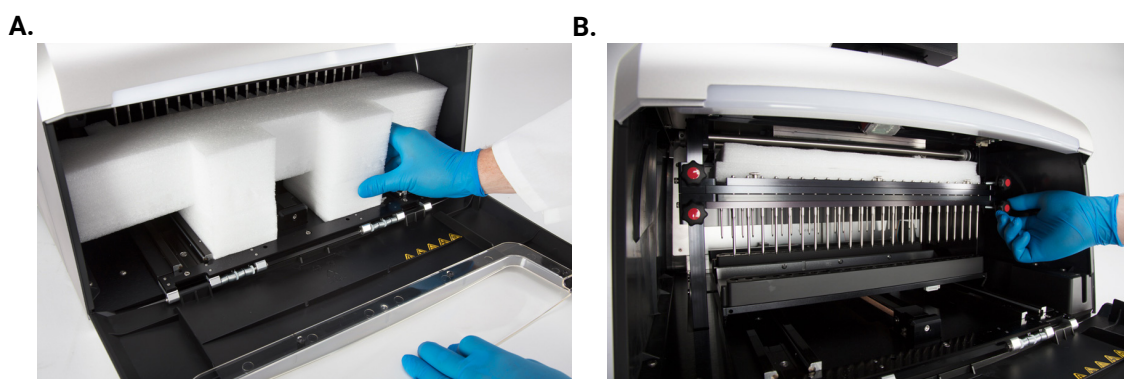


Figure 7. Removing the two foam pieces from inside the instrument. Panel A. Remove the front foam piece. **Panel B.** Remove the four shipping screws from the sides of the front magnet and plunger bars.

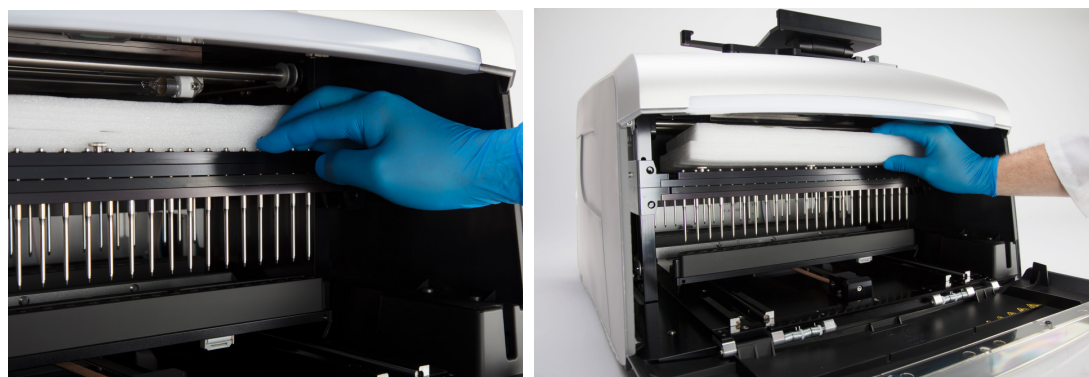


Figure 8. Removing the top foam from the instrument. Move the magnet and plunger bars downward to remove the top foam piece.

Preparing the Maxwell[®] CSC 48 Instrument for Use

4

4.1 Setting Up the Tablet PC

1. Open the accessories box. The Tablet PC and Bar Code Reader are contained in the box. The Tablet PC contains the operating software for the instrument.
2. Remove the Tablet PC from the accessories box.
3. Raise the tablet holder as shown in Figure 9.



Figure 9. Tablet PC Holder.

4. Using the 2.5mm Hex Wrench, remove the Tablet Mount Attachment Piece from the top of the tablet holder. Slide the Tablet PC into the tablet holder. Secure the Tablet PC in the tablet holder by using the 2.5mm Hex Wrench to screw the Tablet Mount Attachment Piece into place at the top of the tablet holder.

5. Connect the Tablet PC Power Cable to the Tablet PC. Plug the other end of the Tablet PC power cable into a power outlet. We recommend connecting the Tablet PC to an uninterruptible power supply. Connect the USB cable to the USB slot on the Tablet PC. Attach the other end of the USB cable to the port on the back of the instrument as shown in Figure 10.



Figure 10. Connecting the Tablet PC to the back of the Maxwell® CSC 48 Instrument.

6. Connect the Maxwell® CSC 48 Power Cable to the back of the Maxwell® CSC 48 Instrument (Figure 10). Connect the Bar Code Reader to a USB port on the right front side of the Maxwell® CSC 48 Instrument.

Optional: To connect the Maxwell® CSC 48 to an internal network, plug a USB Ethernet Adapter (Cat.# AS8403) into a USB port on the right front side of the Maxwell® CSC 48 Instrument. Connect an ethernet cable (not included) to the USB Ethernet Adapter and an ethernet port.



Figure 11. Maxwell® CSC 48 Instrument with the Tablet PC.

7. The Maxwell® CSC 48 Instrument is now ready to use.

4.2 Switching on the Maxwell® CSC 48 Instrument

Following the unpacking and installation described in Section 4.1, you can connect the Maxwell® CSC 48 Instrument to a power outlet. The instrument has two power switches: a rocker switch that is located next to the power cable connection on the back of the instrument (Figure 12, Panel A), and a power button located on the right front side of the instrument (Figure 12, Panel B). Ensure that the rocker switch on the back of the instrument is in the "Off" position. Plug the Maxwell® CSC 48 power cable into a wall outlet. See Section 1.5 for power requirements. We recommend connecting the Maxwell® CSC 48 Instrument to an uninterruptible power supply. Switch the rocker switch on the back of the instrument to the "On" position.

Press the power button on the right front side of the Maxwell® CSC 48 instrument to turn the instrument "On". Press the Tablet PC power switch located on the top of the Tablet PC to turn the Tablet PC "On". Start the Maxwell® CSC 48 IVD Application Software. Every time the instrument application software is started, the Maxwell® CSC 48 will perform a self-diagnostic test. The deck, plunger bar and magnetic rod assembly are moved to check operation, and the heater performance is evaluated.

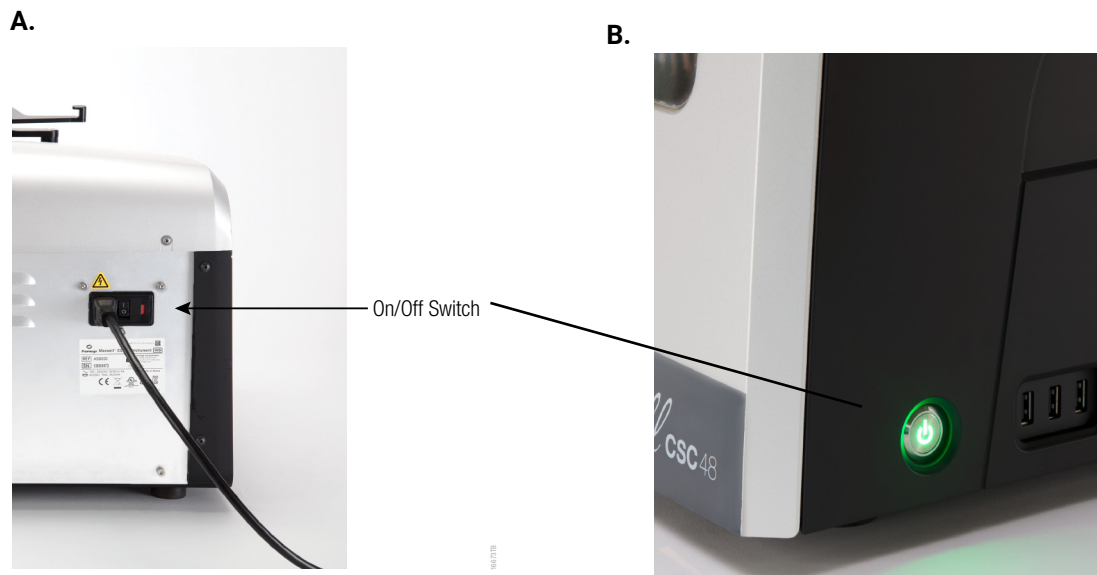


Figure 12. Instrument power switch and power button. Panel A. Rocker On/Off power switch on the back of the instrument. **Panel B.** Power button on the right side of the instrument.

4.3 Shutting Down the Maxwell® CSC 48 Instrument

4.3.1 Shutting Down Instrument

1. Shut down the software by pressing the **X** in the upper left corner of the 'Home' screen. From any other screen in the software, touch the **Home** button at the upper left corner of the screen to return to the 'Home' screen.
2. Turn the Maxwell® CSC 48 instrument off by pressing and holding the power button on the right front side of the instrument for 3 seconds. Switch the rocker switch on the back of the instrument to the off position. Unplug the instrument. If you need to store the instrument, after following the steps above, store in a place that meets the environmental requirements described in Section 1.10.
3. Shut down the Tablet PC using the Windows® 10 shut-down procedure: Touch the Windows® icon in the lower left corner of the screen, touch the power icon on the left side of the Windows® menu and choose Shut Down.

4.3.2 Storing the Tablet PC

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

4.4 Configuring the Tablet PC



Your IT department or site Administrator should configure the Tablet PC according to the IT rules and IT procedures pertinent to your site.

The Maxwell® CSC 48 Instrument is controlled by Maxwell® CSC 48 software running on a Tablet PC. The Tablet PC should be configured to meet the needs of your site, including setting date and time, adding users, specifying access levels for users, connecting to a network and adding network printers. Instructions for configuring the Tablet PC can be found in the *Maxwell® CSC Tablet PC Configuration Manual #TM484*.

5.1 'Home' Screen









The 'Home' screen is the main launching pad for interaction with the functionalities built into the Maxwell® CSC 48 User Interface. The 'Home' screen (Figure 13) contains four buttons:

START	Pressing the Start button on the Maxwell® CSC 48 'Home' screen will begin the process of preparing an extraction method run on the Maxwell® CSC 48 Instrument. See Section 6.2, Starting a Method.
RESULTS	The Results button takes users to the 'Results' screen where it is possible to review, print and export any of the local run reports from previous chemistry and service processes. See Section 6.4, Results, and Section 6.5, Running Reports.
SANITIZE	Pressing the Sanitize button activates the UV light in the Maxwell® CSC 48 Instrument for the time specified in the administrator settings (see Sanitization Settings in Section 5.3). During the sanitization procedure it is possible to access reports, settings, and even start the procedure of setting up a new extraction method run as long as these functions do not proceed to an interruption of the sanitization procedure. Functions that are not allowed during sanitization include opening the door, instrument self test, instrument clean up, and proceeding past bar code entry for an extraction method run. See Section 6.6, Sanitizing.
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 48 software). See Section 5.2, User Interface Settings, and Section 5.3, Administrator Settings.



Figure 13. Maxwell® CSC 48 software 'Home' screen. The Instrument name appears in the title bar of the user interface.

The following navigation and informational buttons are displayed in the title bar at the top of the user interface screen:

	Home	From any screen other than the 'Home' screen, touch this icon to return to the 'Home' screen.
	Exit	From the 'Home' screen, pressing this icon will close the Maxwell® CSC 48 User Interface software and return to the Windows® Operating System.
	Back	When active, pressing the Back button will return the interface to the screen accessed prior to the current screen.
	Running	When visible, this icon indicates that the instrument is currently performing a process (e.g., system protocol, extraction method run). The time to completion of the current process is indicated in the center of the icon.
	Sanitization Done	After UV sanitization is complete, this icon will be displayed in the title bar. Touch the icon to view the sanitization report.
	Sanitization Error	This icon indicates that there was an error during UV sanitization. Touch the icon to view the sanitization report, which will indicate the error state that was encountered.
	Door	This icon toggles the open/closed state of the door on the Maxwell® CSC 48 Instrument.
	Help	Pressing this icon will activate the context-sensitive help for the current screen of the Maxwell® CSC 48 User Interface.

5.2 User Interface Settings

Within the software for the Maxwell® CSC 48 Instrument, it is possible for all users to access instrument-specific information and functions. In addition, users with Administrator-level access to the Maxwell® CSC 48 software can modify software options to tailor the behavior of the software to the needs of their laboratory. Below are sections that describe the functionalities that are accessible from the **Settings** button on the 'Home' screen of the Maxwell® CSC 48 software.

Figure 14 displays the 'Settings' screen for the Maxwell® CSC 48 software. This screen is accessed by touching the **Settings** button on the 'Home' Screen (Figure 13). The appearance of the 'Settings' screen is tailored to the Maxwell® CSC 48 software access level assigned to the Windows® user account (see the *Maxwell® CSC Tablet PC Configuration Manual #TM484* for information on configuring user accounts). A Windows® user account with user-level access to the Maxwell® CSC 48 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 48 software will additionally see an **Administrator** button. From this screen the operator can access the instrument functionalities described below.

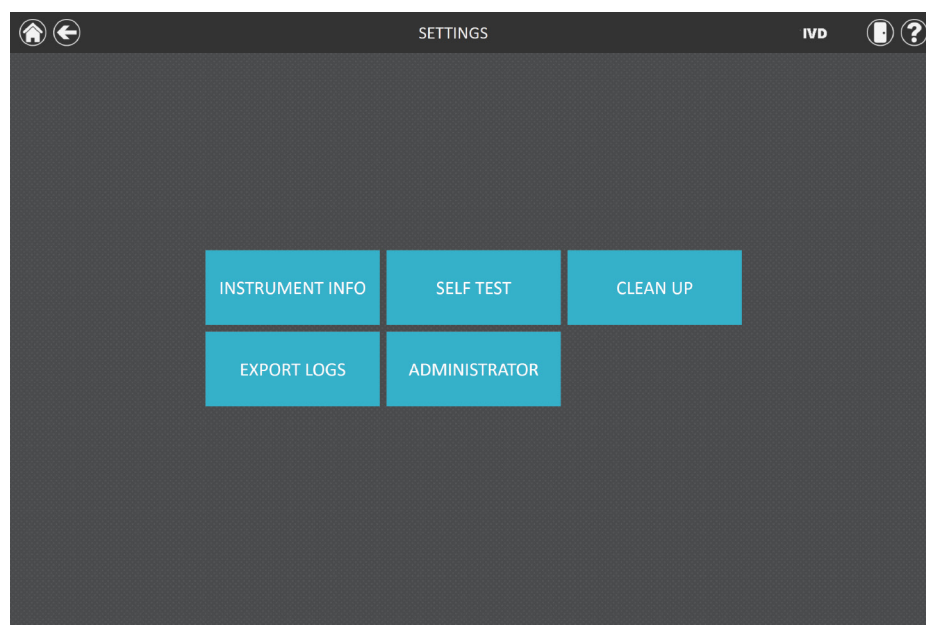


Figure 14. Maxwell® CSC 48 'Settings' screen. From this screen various instrument-specific functions can be accessed. The **Administrator** button will be displayed only for Windows® user accounts with administrator-level access to the Maxwell® CSC 48 software.

5.2.1 Instrument Info

Touch the **Instrument Info** button to display software, firmware, calibration and other instrument-specific information for this Maxwell® CSC 48 instrument on an 'About Maxwell® CSC 48' screen (Figure 15). The information shown on this screen includes:

- **Software Version:** the current software version that is installed on the Tablet PC
- **Software Revision:** the revision number of the software version installed on the Tablet PC
- **Platform Version:** the current platform version that is installed on the Tablet PC
- **Platform Revision:** the revision number of the platform 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 48 Instrument connected to the Tablet PC
- **Firmware ID:** the current firmware version installed on this Maxwell® CSC 48 Instrument
- **Firmware Revision:** the revision number of the firmware version installed on the Maxwell® CSC 48 Instrument
- **FPGA ID:** the current FPGA version installed on this Maxwell® CSC 48 Instrument
- **FPGA Revision:** the revision number of the FPGA version installed on the Maxwell® CSC 48 Instrument
- **Tray Calibration Value:** the calibration value for the tray axis on the Maxwell® CSC 48 Instrument
- **Plunger Calibration Value:** the calibration value for the plunger bar axis on the Maxwell® CSC 48 Instrument
- **Magnet Calibration Value:** the calibration value for the magnet bar axis on the Maxwell® CSC 48 Instrument

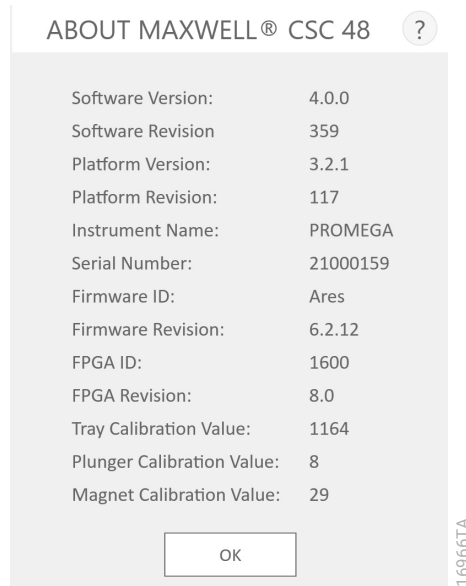


Figure 15. 'About Maxwell® CSC 48' screen. Instrument- and software-specific information is displayed on the 'About Maxwell® CSC 48' screen.

5.2.2 Self Test

You can perform a check of instrument functions by touching the **Self Test** button from the Maxwell® CSC 48 'Settings' screen (Figure 16). On touching the **Self Test** button, the Maxwell® CSC 48 Instrument will perform a routine test 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.

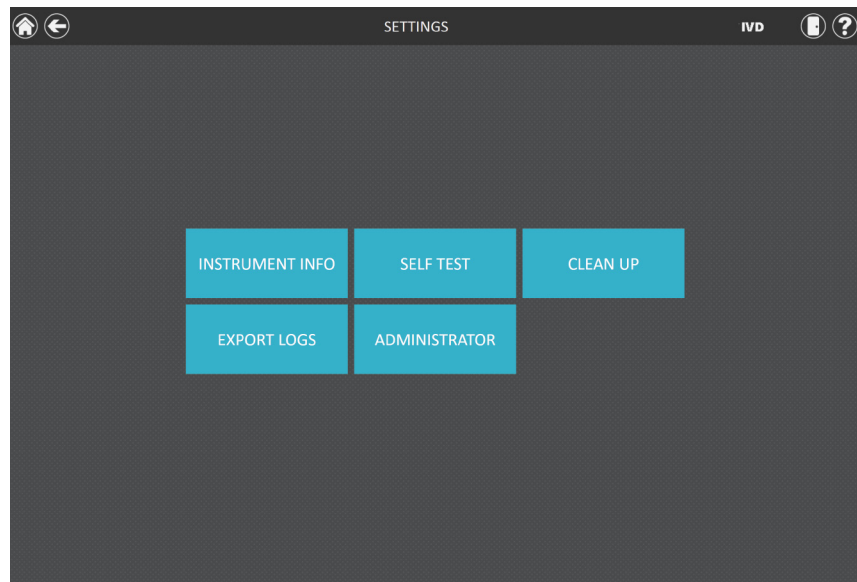


Figure 16. Maxwell® CSC 48 'Settings' screen. From this screen you can perform a **Self Test** for the Maxwell® CSC 48 Instrument.

5.2.3 Clean Up

Clean Up attempts to unload plungers from the instrument plunger bar if any have not been appropriately unloaded after a method run. If your method 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 48 'Settings' screen (Figure 17) [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' screen (Figure 18).

This screen presents you with a checklist of items that must be performed before attempting to unload plungers.

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

You will have to select **Confirm** on every item of the checklist (Figure 22) before you can start the clean up procedure. After you confirm that each of the checklist items has been performed, touch the **Start** button to start the Clean Up process. The Maxwell® CSC 48 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 clean up attempts, the operator should contact Promega Technical Services (techserv@promega.com; 1-800-356-9526) to determine the next appropriate steps.

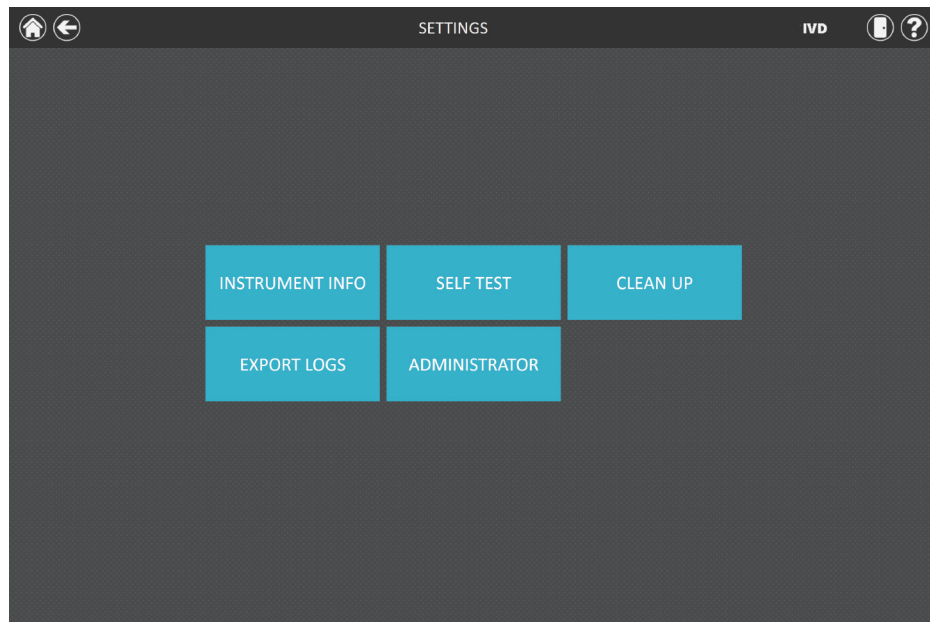


Figure 17. Maxwell® CSC 48 'Settings' screen. From this screen you can press **Clean Up** to unload any plungers left on the plunger bar after an unsuccessful method run.

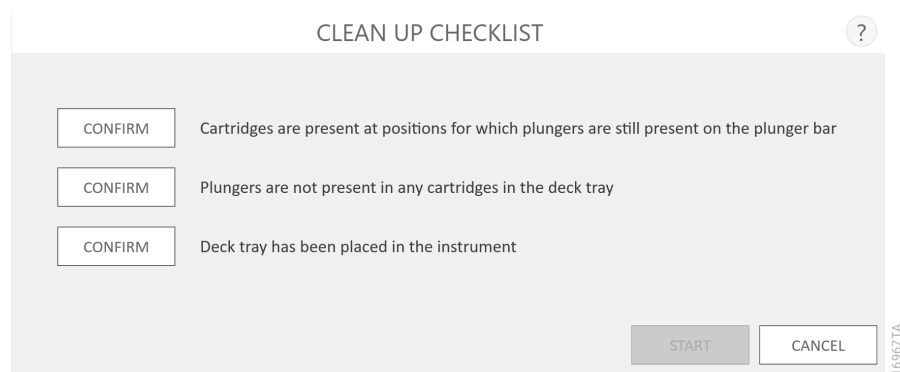


Figure 18. 'Clean Up Checklist' screen. This screen presents you with a checklist of items that must be performed and confirmed before attempting to unload plungers.

5.2.4 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 19, 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\.)
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 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 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 pressing **Save**, the 'Export' screen will be displayed, indicating that the log files were successfully exported to the path that was specified (Figure 19, Panel B).
5. On the 'Export' screen you can press **Open** to open a Windows® File Browser showing the folder location of the exported files. Press **Done** to close the 'Export' screen and return to the 'Settings' screen.

Instrument logs will be exported as a zip file to the path that was specified by the operator. The zip file of the logs should be retrieved from the specified location and sent to a Promega Technical Services representative for further troubleshooting.

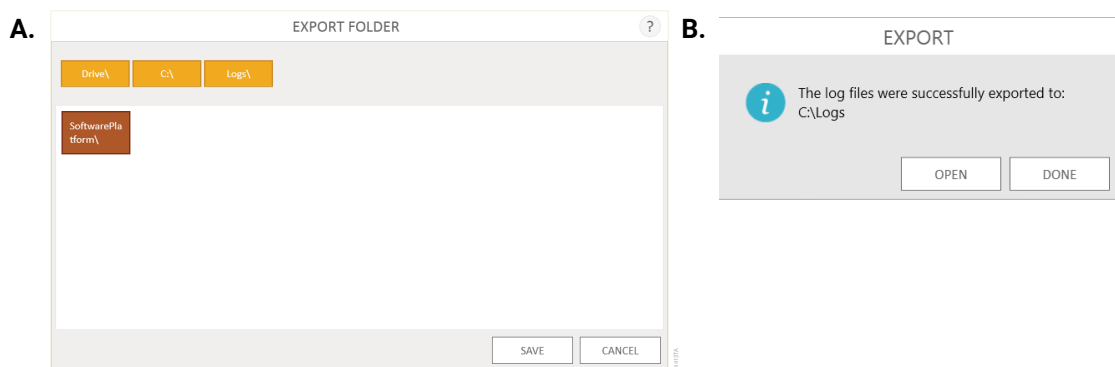


Figure 19. Export Logs. Panel A. The 'Export Folder' screen is displayed after touching the **Export Logs** button. Specify a path to which the instrument log files should be exported. Touch **Save** to export instrument logs to the specified location or **Cancel** to return to the 'Settings' screen 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. Press **Done** to exit the 'Export' screen and return to the 'Settings' screen.

5.3 Administrator Settings



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

Software settings for the Maxwell® CSC 48 software can be accessed by Windows® user accounts with administrator-level access to the Maxwell® CSC 48 software using the **Administrator** button on the 'Settings' screen. From the 'Settings' screen, touch 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 48 software to customize the behavior of the Maxwell® CSC 48 software to the needs of their laboratory. Buttons on the 'Administrator Page' screen allow the administrator to: set **Sample Entry** bar code tracking requirements, configure **Sanitization Settings** for UV light treatment, manage **Methods** installed in the software, configure **Preferences** for the Maxwell® CSC 48 software, view user-readable **Audit Records** and define an **Instrument Name** for this Maxwell® CSC 48 Instrument. The behavior of each button on the 'Administrator Page' screen is detailed below. Follow the instructions to adapt the behavior of the Maxwell® CSC 48 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 48 software in IVD Mode.

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 48 User Interface (Figure 20), touch the **Settings** button.



Navigation Note: The instructions for each subsection below assume that the operator is starting from the 'Administrator Page' screen in the Maxwell® CSC 48 software. Follow the instructions below to access the 'Administrator Page' screen when starting from the 'Home' screen in the software.



Figure 20. Maxwell® CSC 48 'Home' screen. Selecting **Settings** opens the Maxwell® CSC 48 'Settings' screen.

2. If the current operator logged into the Tablet PC has administrator access rights within the Maxwell® CSC 48 software, the 'Settings' screen (Figure 21) will display an **Administrator** button. On the 'Settings' screen, select the **Administrator** button to proceed to the 'Administrator Page' screen (Figure 22).



Note: If the **Administrator** button is not visible, log out of the Windows® operating system with this user and log in with user credentials that have administrator access rights within the Maxwell® CSC 48 software.

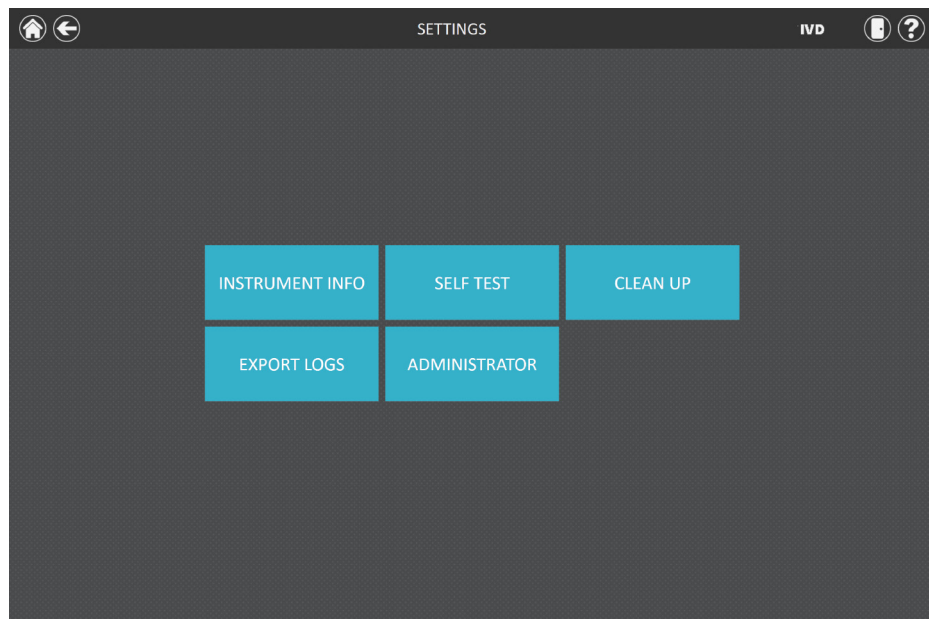


Figure 21. Maxwell® CSC 48 'Settings' screen. The **Administrator** button will only be visible if the currently logged in operator has administrator-level rights within the Maxwell® CSC 48 software.

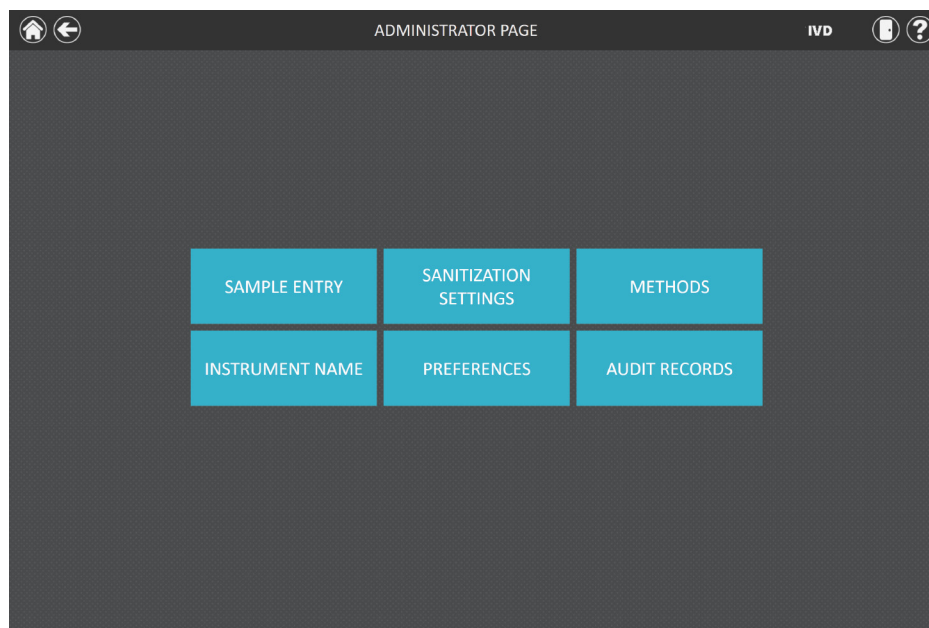


Figure 22. Maxwell® CSC 48 'Administrator Page' screen. The 'Administrator Page' screen is only visible to administrators and gives access to customize the behavior of several aspects of the Maxwell® CSC 48 system.

5.3.1 Sample Entry

The 'Sample Entry' screen allows the administrator to define the required bar code values that need to be input by any operator when running a Maxwell® CSC 48 method. Kit bar code as well as Sample ID for every cartridge position selected during a protocol run are mandatory in the user interface. The required sample tracking fields can be customized in the Maxwell® CSC 48 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 sample extraction.

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

1. From the Maxwell® CSC 48 software 'Administrator Page' screen (Figure 22), touch the **Sample Entry** button.
2. The 'Sample Entry' screen is shown in Figure 23. The options for Sample ID and Kit Lot Number are always checked on this screen because these are mandatory settings. Choose whether to require the entry of Cartridge ID (bar code added to the sample processing cartridge by the user), Elution Tube ID (bar code of the elution tube) or both. If desired, you can also define and label up to two custom bar code entry fields. 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 custom bar code options is enabled, then you can choose whether the bar codes scanned for the indicated fields are required to match the Sample ID. This requirement can ensure 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 23. Maxwell® CSC 48 'Sample Entry' screen. Use this screen to configure the bar code information that must be entered for each sample prior to performing an extraction method. 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, it is possible to 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 identifies potential errors in bar code scanning for the user. 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 48 Instrument contains a UV light that can help aid in sanitization of the instrument. It is possible to specify the duration of the UV treatment and when UV light treatment of the instrument should be performed.

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 24). 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 pressed.
 - b. Sanitize after extraction for (**optional**): This setting defines the duration of UV treatment (in minutes) that will be automatically performed after completion of an extraction method 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 48 software is started.
3. Touch the text box next to "Default sanitization duration:" to open the on-screen number pad. Enter the number of minutes to be used for UV sanitization when the **Sanitization** button on the 'Home' screen is pressed. 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 additional UV sanitization options, touch the check box next to the desired option. A check mark will be visible in the check 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 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.

The screenshot shows a dialog box titled "SANITIZATION SETTINGS" with a help icon in the top right corner. The settings are as follows:

Setting	Value	Unit
Default sanitization duration:	1	minutes
<input type="checkbox"/> Sanitize after extraction for	1	minutes
<input type="checkbox"/> Sanitize on software start-up for	1	minutes

At the bottom of the dialog are two buttons: "SAVE" and "CANCEL".

Figure 24. 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 and catalog number for each method. From the 'Methods' screen the administrator can view, import and delete methods from the Maxwell® CSC 48 software (Figure 25).

1. If you desire to view the methods currently installed in the Maxwell® CSC 48 software, touch the **Methods** button from the 'Administrator Page' screen.
2. Touch the **Back** icon in the upper left corner of the screen to return to the 'Administrator Page' screen.

Importing and Deleting Methods

As Promega provides new purification kits for use with the Maxwell® CSC 48 instrument, new extraction methods can be added to the Maxwell® CSC 48 software. Occasionally, an existing extraction method may have to be updated. Only administrators can add new extraction methods or delete or update existing methods. Administrators can download new or updated extraction methods from the Promega website at:

www.promega.com/resources/software-firmware/maxwell-maxprep/maxwell-csc-48-methods/

Methods are provided as files with a .package extension. Follow the instructions below to import a method into the Maxwell® CSC 48 software.

1. Save the method (.package) file on the Tablet PC attached to the Maxwell® CSC 48.
2. If not already running, start the Maxwell® CSC 48 software (in either IVD Mode or RUO Mode) by double-touching the 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. Click the blue rectangle(s) corresponding to the desired (.package) file(s) to highlight it, then press the **OK** button.
7. A popup 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 48 IVD software, but only IVD methods can be run with the Maxwell® CSC 48 IVD software mode.

To delete a method from the Maxwell® CSC 48 software, touch the **X** on the right side of the method list entry to delete it. A 'Warning' screen will be shown asking whether the file should be permanently deleted. Select **Delete** to permanently remove the file from the Maxwell® CSC 48 software or **Cancel** to return to the 'Methods' screen without deleting the method.

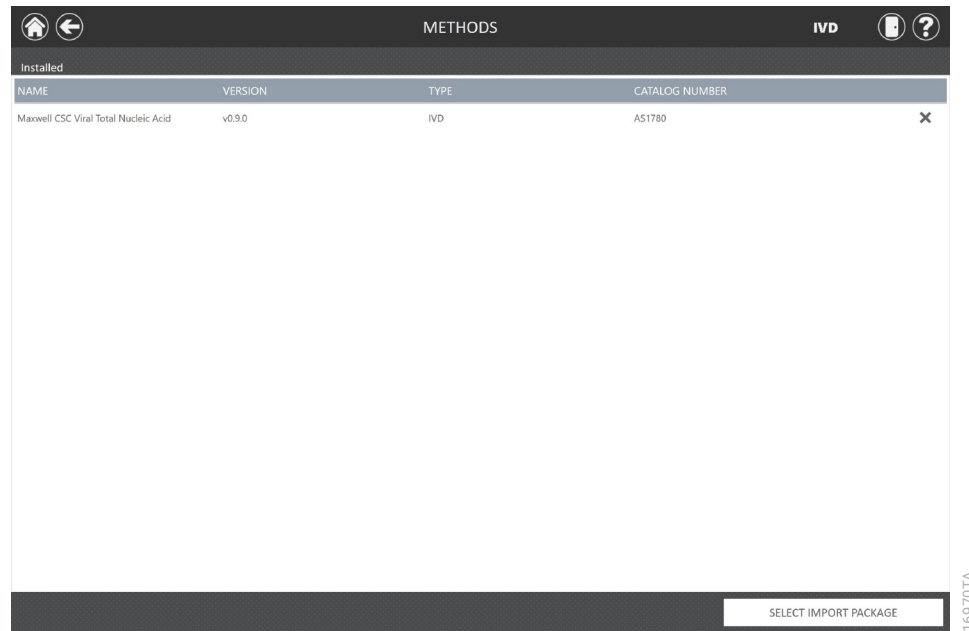


Figure 25. 'Methods' screen. This screen displays a list of the methods currently installed in the Maxwell® CSC 48 software. For each method you can view the name of the method, the version number of the method, method type (IVD or RUO), and the catalog number of the chemistry kit for the method. Methods can be deleted from the software by touching the **X** on the right side of the method list item. Import new methods using the **Select Import Package** button.

5.3.4 Preferences

Administrators can view preferences available in the Maxwell® CSC 48 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 needs of the laboratory (Figure 26).

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 26) provides administrators the ability to specify the following options:

- "Allow deletion of results": When checked, this box will allow administrators to delete extraction report files from the local database of run reports.
- "Use Vision system": The Maxwell® CSC 48 contains a Vision system camera that provides a check of sample number, cartridge position and deck tray setup. Turning off the camera will remove this functionality, relying solely on the user to manually specify number of cartridges, cartridge positions and appropriateness of the deck tray setup (presence of cartridges at specified deck tray positions, presence of plungers in cartridge well #8, presence of open elution tubes). In the checked state, the Vision system camera function is on, while in the unchecked state, the camera is turned off.
- "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 modifications or removals of samples to the imported tracking information require entry of credentials by an operator with administrator-level rights to the Maxwell® CSC software.
 - "User Approval Required": Check this box if modifications or removals of samples to the imported tracking information require entry of 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.

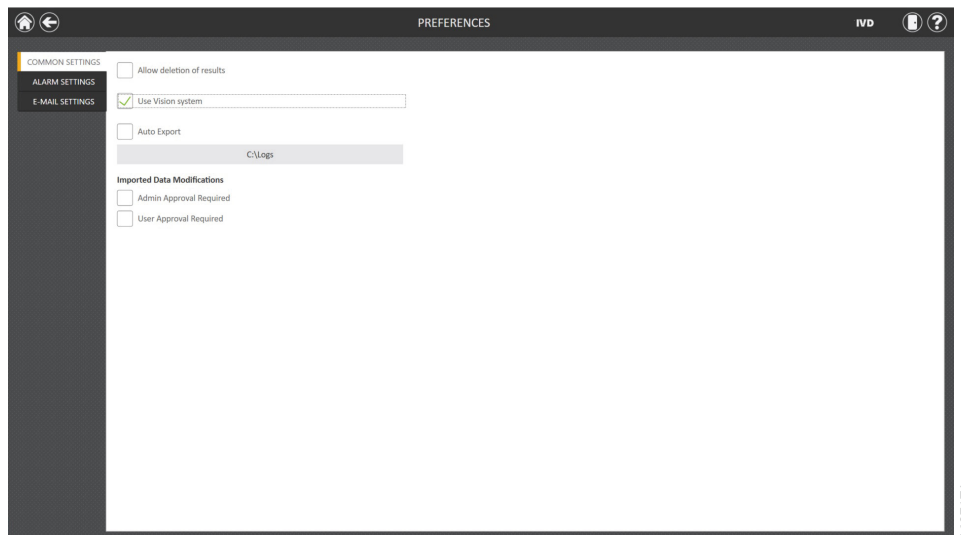


Figure 26. Common Settings' tab on the 'Preferences' screen. From the 'Common Settings' tab, the administrator can specify software and export behaviors as well as use of the Vision system camera. Additionally, you can set the approvals required to make changes to sample deck tray layouts retrieved from the Sample Data Import function.

'Alarm Settings' Tab

The 'Alarm Settings' tab on the 'Preferences' screen (Figure 27) 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.

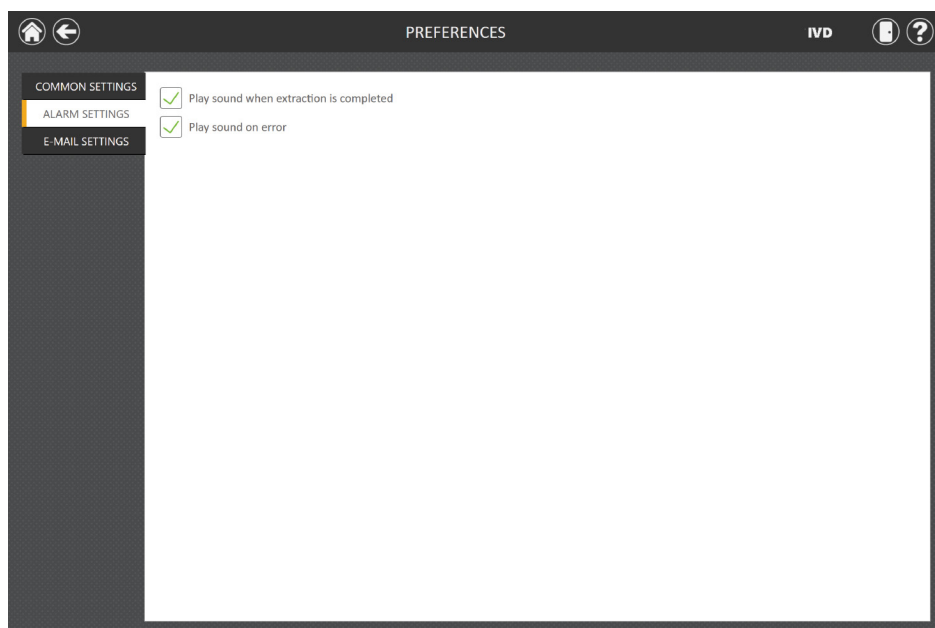


Figure 27. 'Alarm Settings' tab on the 'Preferences' screen. From the 'Alarm Settings' tab, the administrator can specify whether audible alarms should be played on completion of an extraction run or on error.

'E-mail Settings' Tab

The 'E-mail Settings' tab on the 'Preferences' screen (Figure 28) 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:** Check box 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 pressing the **Test Connection** button. Pressing 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.

The screenshot shows the 'PREFERENCES' screen with the 'E-MAIL SETTINGS' tab selected. The interface includes a sidebar with navigation options: COMMON SETTINGS, ALARM SETTINGS, and E-MAIL SETTINGS. The main content area is divided into sections:

- User Information:**
 - User Name: user@domain.com
 - Send mail when extraction is completed
- E-mail:**
 - E-mail: user@domain.com
 - Send mail on error
 - Password: #####
 - E-mail Recipients: recipient@domain.com recipient2@domain.co
- Server Information:**
 - SMTP Server: SMTP.Server.Address
 - Port: 1
 - SSL Encrypted Connection

At the bottom of the screen, there is a 'TEST CONNECTION' button and a status message: "E-mail settings configuration is changed. Please, test connection!". A vertical ID number '16973TA' is visible on the right edge of the screen.

Figure 28. '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.

5.3.5 Audit Records

The Maxwell® CSC 48 software contains an audit trail of functions that have been performed. Administrators 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 functions that have been performed in the software (Figure 29). You can filter the audit records by touching the buttons on the left side to view records from today, this month, 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.

DATE/TIME	STATUS	OPERATOR	OPERATION	CONTEXT/MESSAGE
3/24/2020 2:12:38 AM	Success	DESKTOP-UKJVOKD\User	Application start	Application Start
3/24/2020 2:11:50 AM	Success	DESKTOP-UKJVOKD\User	Application exit	Application Exit
3/24/2020 2:06:47 AM	Success	DESKTOP-UKJVOKD\User	Application start	Application Start
3/24/2020 2:05:00 AM	Success	DESKTOP-UKJVOKD\User	Application exit	Application Exit
3/24/2020 1:58:20 AM	Success	DESKTOP-UKJVOKD\User	Application start	Application Start
3/24/2020 12:10:33 AM	Success	DESKTOP-UKJVOKD\User	Application start	Application Start
3/23/2020 11:29:59 PM	Success	DESKTOP-UKJVOKD\User	Imported protocol	Maxwell CSC Viral Total Nucleic Acid Promega.Metadata...
3/23/2020 11:29:59 PM	Success	DESKTOP-UKJVOKD\User	Imported kit	AS1780
3/23/2020 10:43:55 PM	Success	DESKTOP-UKJVOKD\User	Application start	Application Start
3/23/2020 10:32:24 PM	Success	NT AUTHORITY\SYSTEM	ImportPackage	Package 'Maxwell48.Service' v3.1.0.0
3/23/2020 10:32:23 PM	Success	NT AUTHORITY\SYSTEM	ImportPackage	Package 'Maxwell48' v3.1.0.0

Figure 29. 'Audit Records' screen. A user-readable record of events that have occurred in the Maxwell® CSC 48 software can be viewed by the administrator and exported to a specified drive location from the 'Audit Records' screen.

1. Touch the **Export** button on the 'Audit Records' screen.
2. Using the Yellow and Red rectangle buttons, you can select the folder location (Figure 30) 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.

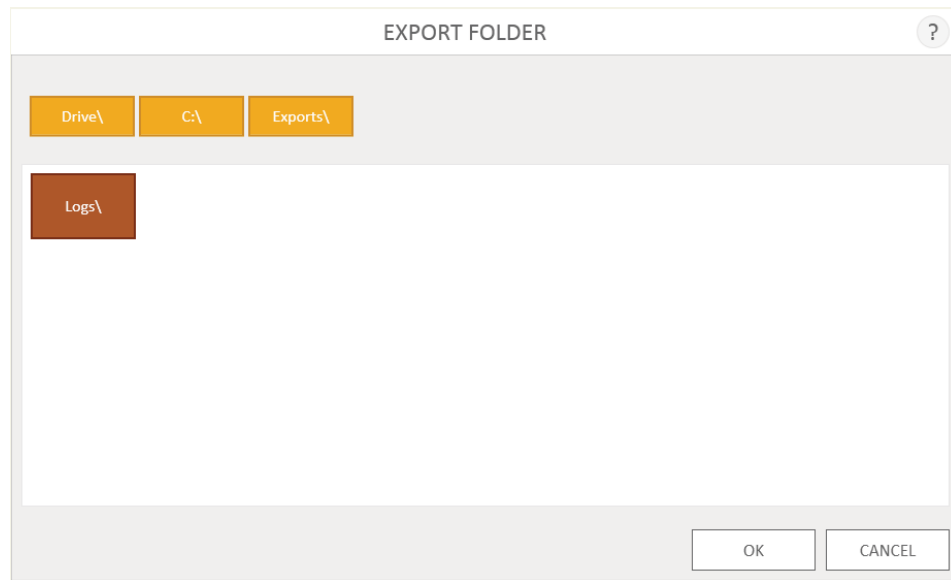


Figure 30. 'Export Folder' screen. From the 'Export Folder' screen you can set the folder location to which all displayed audit records will be exported.

5.3.6 Instrument Name

It is possible to define a unique identifying name for the Maxwell® CSC 48 Instrument. This name will be shown on the title bar of the Maxwell® CSC 48 software 'Home' screen and will be recorded in method 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 the RUO Mode and IVD Mode for a single Maxwell® CSC 48 instrument
1. From the 'Administrator Page' screen, touch the **Instrument Name** button to open the 'Instrument Name' screen (Figure 31).
 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. 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.

- If you do not wish to save any changes to the instrument name, press the **Cancel** button to return to the 'Administrator Page' screen.



Saving the instrument name will enforce a restart of the Windows® Operating System.

INSTRUMENT NAME ?

Maxwell CSC 48

SAVE CANCEL

16975TA

Figure 31. 'Instrument Name' screen. Use this screen to manually enter a name for this Maxwell® CSC 48 Instrument.

6.1 Preprogrammed Methods

The preprogrammed methods available for the Maxwell® CSC 48 Instrument can be used to perform extractions for a variety of clinical sample types. The sample type and type of molecule extracted are determined by the Maxwell® CSC reagent kit used. Please refer to your specific Maxwell® CSC reagent kit Technical Manual for information on sample preparation and handling. Scanning the method bar code on the reagent kit label will select the appropriate protocol for that kit as well as confirm that the kit being used is within its expiration date.

Based on the administrator settings in the user interface, the user is required to enter sample ID information prior to initiating sample processing. If you are using sample identifiers on cartridges and elution tubes, we recommend that you enter or scan the optional user-supplied bar codes for each one immediately before placing it in the deck tray(s).

6.2 Starting a Method

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 32), select the **Start** button to begin the process of running an extraction method.



Figure 32. Maxwell® CSC 48 'Home' screen. Selecting the **Start** button begins the process of running an extraction method on the Maxwell® CSC 48 Instrument.

2. You will be presented with the 'Scan barcode' screen (Figure 33) 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 34). Alternatively, touch the text box on the 'Scan barcode' screen to manually enter the bar code information using the on-screen keyboard. Maxwell® software requires manual entry of bar codes in the following format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format (example: AS17803221872018-05, where the product catalog number is AS1780, the kit lot number is 322187 and the expiration date is 2018-05). Only if the bar code entered has this format will the **OK** button become active. The text to enter is shown to the right of the method barcode in the top right corner of the Maxwell® CSC reagent kit label. Do not use the information from the barcode 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.

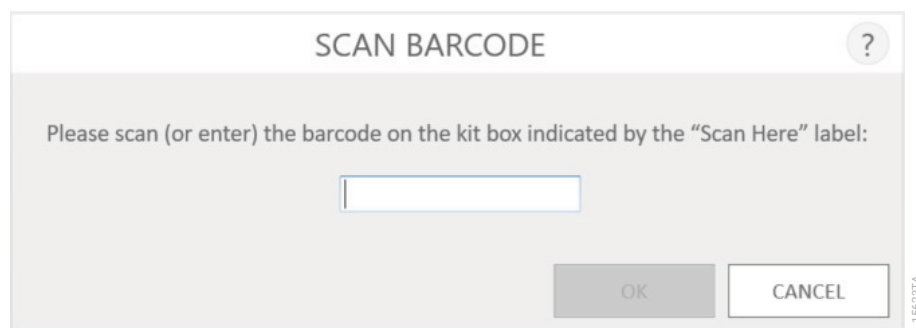


Figure 33. 'Scan Barcode' screen. Scanning the method bar code automatically selects the protocol on the Maxwell® CSC 48 Instrument.



Figure 34. Kit label and bar code to scan. Scan the bar code shown in the red box to start a purification run.

3. There are two potential error modes that can occur when scanning the bar code:
 - a. If the kit lot has passed the specified expiration date, a user prompt will appear explaining that the kit has passed its expiration date and cannot be run. This kit should not be used, and the user should select another kit that is within its specified expiration date to use for the run.
 - b. If the scanned product catalog number 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 48 RUO software and double-tap the Maxwell® CSC 48 IVD software icon to use with the desired purification kit.
 - c. If the product catalog number does not have a purification method associated with it on this instrument, a user prompt will appear indicating that the software does not have a method for this catalog number. Upon pressing the **OK** button on the user prompt, the software will return to the 'Home' screen. Please contact Promega Technical Services (techserv@promega.com) to get the most up-to-date information on the available methods.
4. After the scanning bar code, you will be presented with a 'Cartridge Setup' screen (Figure 35) 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. Each deck tray of 24 samples will be displayed on a separate screen for sample entry. Toggle between the front (positions 1–24) and back (positions 25–48) deck trays using the **Front** and **Back** buttons in the lower left area of the screen. Identification information can be entered manually (option 1) or using the sample data import function (option 2).

Option 1: Manual Entry

- a. Select cartridge positions that will be processed by touching the long rectangle for each position that will be used. If the Vision system is activated on your system (see Preferences in Section 5.3.4), the processing positions specified on the deck trays as well as the correct setup of the deck trays are confirmed by the system.
- 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 36). 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.

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 37, Panel A).
- b. From the 'File' tab of this screen, a file filter can be applied to display .xlsx files, or .csv, .txt, .tsv files, or .xls files, or any file format. This tab then allows the operator to 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 37, Panel B).

- e. The 'Data' tab on this screen allows the user 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 under 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 you import sample data.

- f. Once all data fields are identified, tap the **Accept** button to import 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.

Notes:

- 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. 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: AS17803221872018-05, where the product catalog number is AS1780, 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. 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.

Important: There are two bar codes on the kit label. Scan the bar code at the top of the label. You will receive an error message if you scan the wrong bar code (see Figure 34).



Important: There are two bar codes on the kit label. When entering product and lot information, use the data contained in the bar code at the top of the label. You will receive an error message if you enter data from the wrong kit.

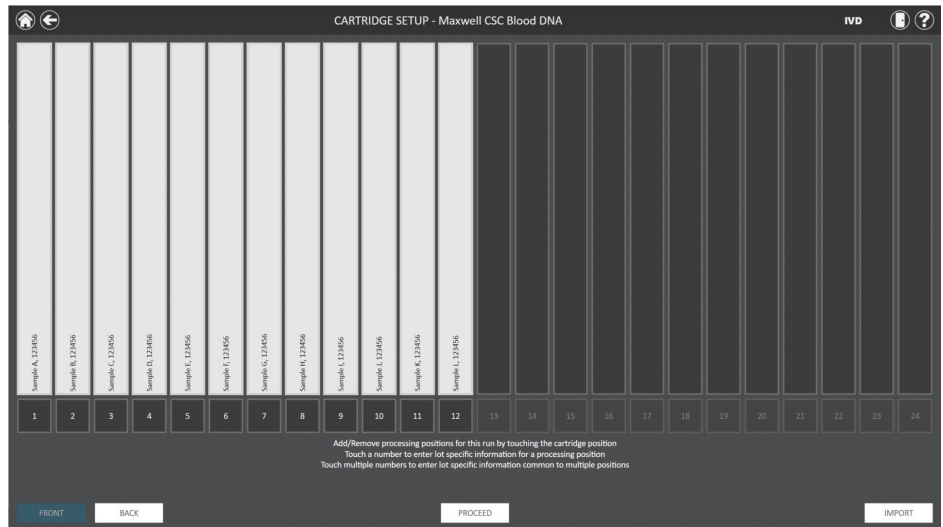


Figure 35. 'Cartridge Setup' screen. At the top of this screen the selected method is indicated. This screen allows the user to select which cartridge positions will be processed. To select/deselect a cartridge position touch the long rectangle for any given position. Use the **Front** and **Back** buttons to toggle between views of the front (positions 1–24) and back (positions 25–48) deck trays.

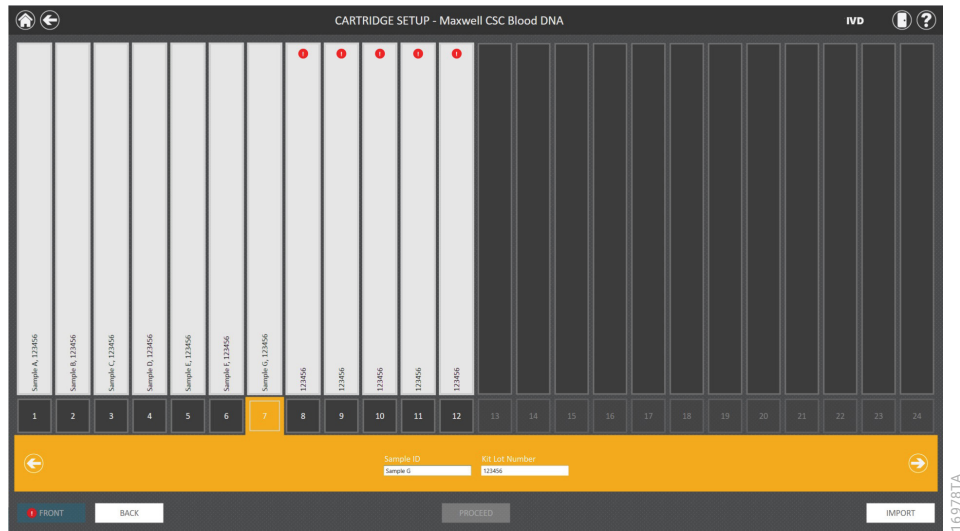


Figure 36. Bar code and kit lot input. By selecting the numbered box at the bottom of any cartridge position, sample ID and kit lot information can be scanned or manually entered for that position. Touching the arrow on the right side of the entry area will move to the next available cartridge position. Selecting multiple positions can be used to enter kit lot information for multiple cartridge positions.

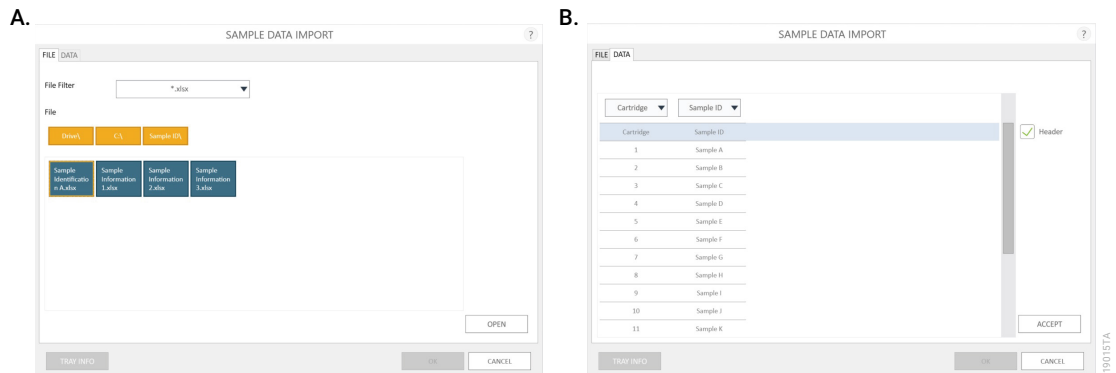


Figure 37. 'Sample Data Import' screen. Panel A. The 'File' tab is displayed after touching the **Import** button. Select the file filter and navigate to the file location where the sample import file is located. Touch the desired blue box file and touch the **Open** button to open up the 'Data' tab and view the sample ID information in the file or **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.

5. After all required information has been entered for the cartridges and samples that will be processed, touch the **Proceed** button to display the 'Door' prompt (Figure 38). Press the **OK** button to open the Maxwell® CSC 48 Instrument door.

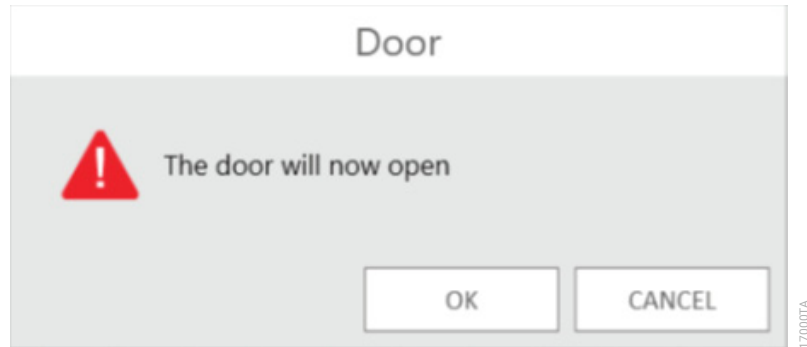


Figure 38. 'Door' screen. Informs the user that the Maxwell® CSC 48 Instrument door will open.

6. You will be presented with an 'Extraction Checklist' screen (Figure 39). 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.
- 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 trays (Figure 40). Press down firmly to snap the cartridges in place at both ends. There should be an audible click.

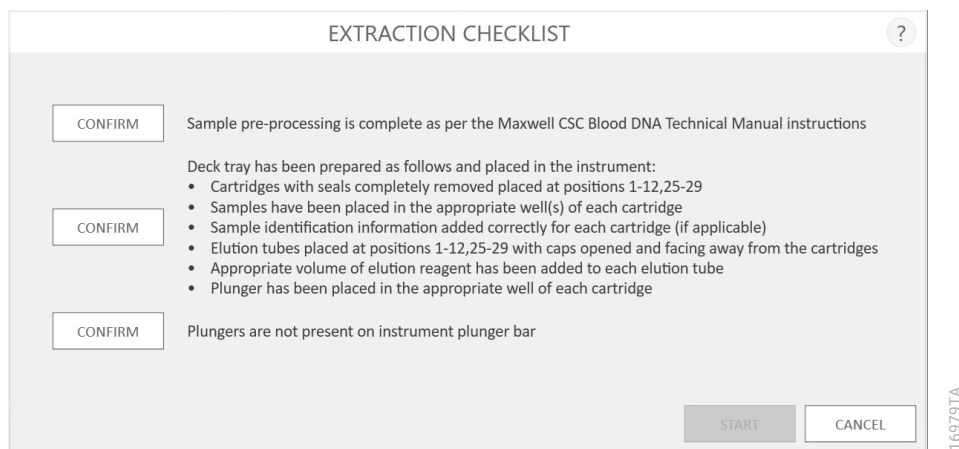


Figure 39. 'Extraction Checklist' screen. This screen indicates the steps that must be performed to prepare the deck trays prior to processing the selected samples. Individual preprocessing steps are not indicated on the Extraction Checklist and should be performed prior to this stage according to the technical manual for the kit being processed.



Figure 40. Placing the cartridges in the Deck Tray and pressing firmly to snap them in place.

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

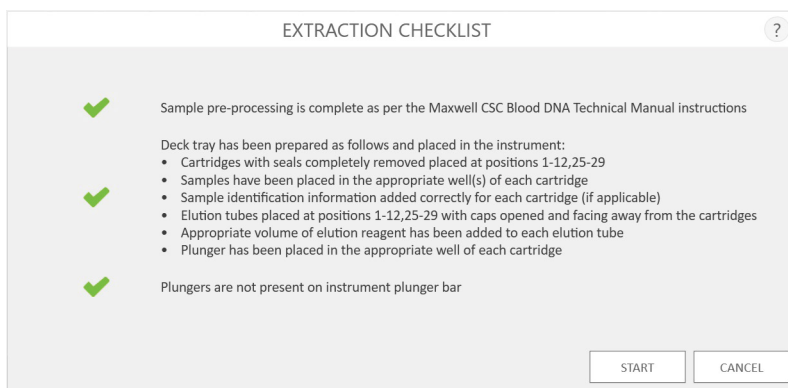


Figure 41. Completed Extraction Checklist. When all checklist items have been confirmed, the **Start** button will become active. Touch the **Start** button to begin the processing run or the **Cancel** button to return to the sample information entry screen.



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

- Completely remove seals from all cartridges.
- Place elution tubes at the selected positions in the deck trays.
- 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). Leave the elution tube lids open.
- 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 Clean Up in Section 5.2, User Interface Settings, 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 trays in the instrument with the Back tray on the back deck position and Front tray on the front deck position as shown in Figure 42. The deck trays for the instrument are keyed so that they will only fit in their appropriate deck position within the instrument. Hold the deck tray by the sides to avoid dislodging cartridges from the deck tray. Ensure that the deck tray is placed in the Maxwell® Instrument with the elution tubes closest to the door. Angle the back of the deck tray downward and place into the instrument so that the back of the deck tray is against the back of the instrument platform. Press down on the front of the deck tray to firmly seat the deck tray on the instrument platform. If you have difficulty fitting the deck tray on the platform, check that the deck tray is in the correct orientation. Ensure the deck tray is level on the instrument platform and fully seated. After all of these steps have been performed, touch the **Start** button to begin the purification, or touch the **Cancel** button to return to the previous screen.

Important: The plungers must be placed in the well closest to the elution tubes. If the instrument goes through a run with the magnetic rods unprotected, the magnetic rod assembly must be thoroughly cleaned (see Section 7.2, Cleaning the Hardware), and the cartridges containing samples discarded. The samples will be lost.



Figure 42. Placing the deck tray in the instrument.

6. If the Vision system is active on your system, when the deck tray is retracted after pressing **Start**, the Vision system will scan the deck trays to confirm deck tray setup. The Vision system will check that cartridges are present at all active cartridge positions, plungers are present at well #8 in the cartridges, elution tubes are present and open for every cartridge position. If there are any discrepancies in deck tray setup, a 'Machine Vision Error' screen is displayed indicating that errors need to be resolved before the extraction run can proceed. Press the **Door Open** button to extend the deck tray and return to the 'Cartridge Setup' screen, or press **Cancel** to return to the 'Cartridge Setup' screen without extending the deck tray. On the 'Cartridge Setup' screen, any positions of concern will be noted with an exclamation mark in a red circle. The **Front** and **Back** buttons on the screen will also display the exclamation mark in a red circle to indicate if there are issues on either deck tray. Touch the exclamation mark in the red circle at any cartridge position to display a message indicating the issues that were observed by the Vision system.

Resolve all issues with the cartridge setup on the deck trays. After all issues have been resolved, touch the **Proceed** button to rescan the deck trays and start the run.

7. While the extraction method runs, you will see the 'Running' screen (Figure 43). The title bar of the 'Running' screen indicates the method currently being run. This screen displays:
- The name of the user who started the method 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 method.

It is possible to perform some instrument functions (e.g., viewing reports) during an extraction run by touching the **Home** button and selecting a function. Touch the rotating timer icon in the title bar from any other screen to return to the 'Running' screen while a method is running. If you wish to abort the current run, touch the **Abort** button in the lower right corner of the screen.

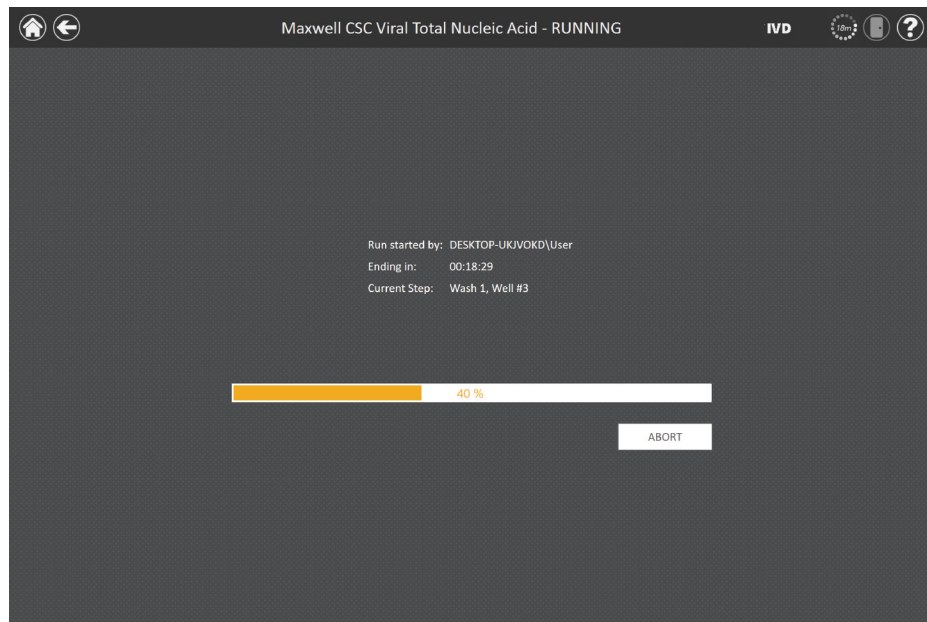


Figure 43. Method 'Running' screen. The method 'Running' screen is displayed during an extraction method run. This screen indicates what method is currently being run at the top of the screen. Also indicated on this screen are the user who started the run, an approximate indication of when the run will end, a description of the current method step and a progress bar showing the percent completion of the method. If you wish to abort the current run, touch the **Abort** button.

8. Method runs can end through one of three mechanisms:

- The method completes successfully.
- The method is aborted by the user.
- An instrument error occurs that aborts the method.



Note: Any samples being processed will be lost if a run is aborted.

6.2.1 Method Completes Successfully

When the method completes successfully, the method 'Running' screen will indicate that the extraction method has been completed (Figure 44). After a method is complete the Current Step will be listed as *Completed*. Touch the **Open Door** button to open the door of the Maxwell® CSC 48 Instrument.

PROTOCOL RUNNING - Maxwell CSC Viral Total Nucleic Acid ?

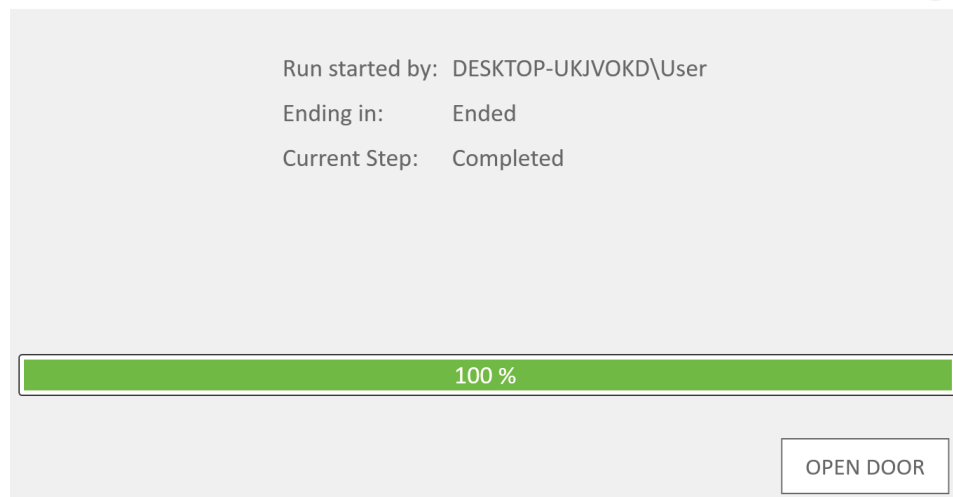


Figure 44. 'Protocol Running' screen after method completion. Upon completion of the currently running extraction method, the progress bar will show 100% completion. The Current Step changes to Completed after a run is finished. After a method is completed, you can touch the **Open Door** button to open the door of the Maxwell® CSC 48 Instrument and remove the deck trays.

Close the caps of the elution tubes, and remove the tubes from the deck trays (Figure 45). Verify that all the cartridges have a plunger in well #8. Remove the deck trays by gripping them firmly by the elution tube position, lifting up and pulling each tray out (see Figure 46). The deck trays may be warm to the touch after a run is completed. Exercise caution while removing the deck trays. If there were cartridges missing plungers, proceed to Section 6.3 to remove them by running the Clean Up method. The extracted material 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® RSC/CSC 48 Deck Trays.



Important: 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 45. Closing the elution tube caps.

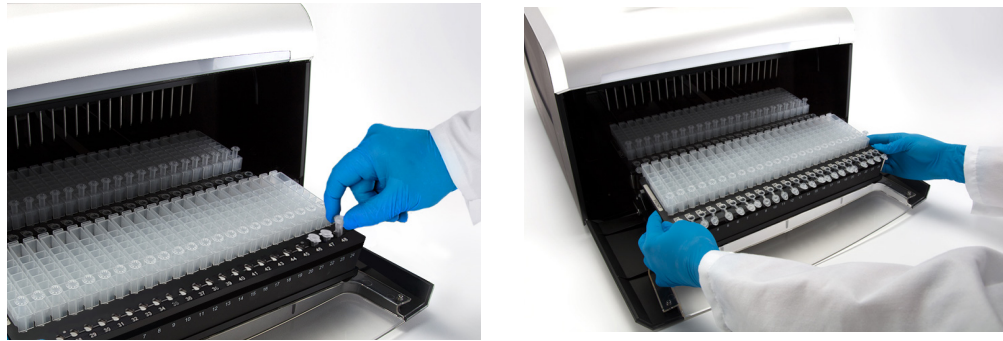


Figure 46. Removing the elution tubes and deck trays.

After the door is opened, the 'Report View' screen (Figure 47) will be presented. If the administrator has required that UV sanitization be performed after a purification run, the user will be prompted to confirm that no samples or eluates are present in the instrument prior to the UV sanitization (see Section 6.6, Sanitizing).

Position	Catalog Number	Sample ID	Lot Number	Expiration Month	Cartridge ID	Elution Tube ID	Custom1
1	as1780	v	123456	2020-12			
2	as1780	c	123456	2020-12			
3	as1780	x	123456	2020-12			
4	as1780	z	123456	2020-12			
5	as1780	m	123456	2020-12			
6	as1780	n	123456	2020-12			
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
21							
22							
23							
24							
25							
26							
27							
28							
29							
30							
31							
32							
33							
34							
35							
36							
37	as1780	b	123456	2020-12			

Figure 47. 'Report View' screen. A run report is displayed after the completion of an extraction run.

6.2.2 User Aborts Method



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.

If the method is aborted by the user, the 'Protocol Running' screen will indicate that the method has been aborted (Figure 48). After a method is aborted, the Current Step will be listed as Aborted by user. After aborting the method, press the **Open Door** button. The Vision system (if enabled) will determine whether plungers have been unloaded successfully, and if not, will attempt to unload them. Otherwise the 'Clean Up' screen (Figure 49) will be displayed.

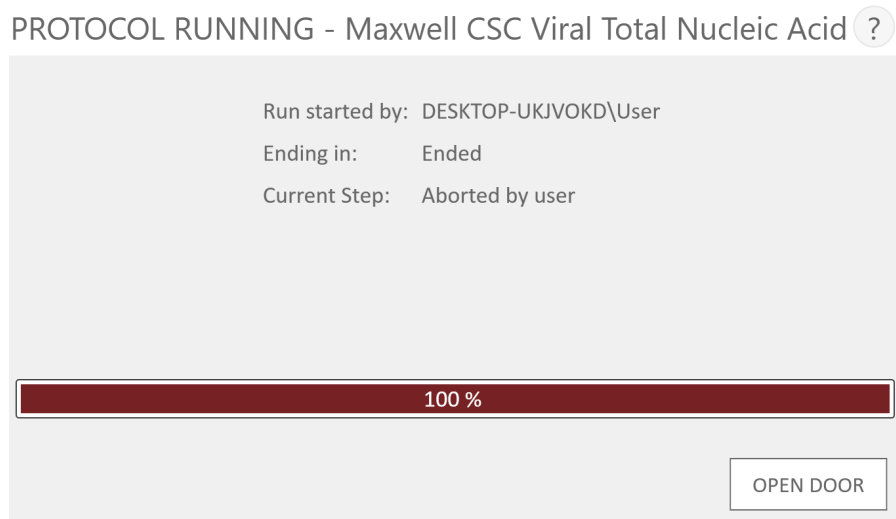


Figure 48. 'Protocol Running' screen after abort by the user. If a method is aborted by the user, the 'Protocol Running' screen will display a progress bar of 100%, and Current Step is shown as Aborted by user. After a method is aborted, press the **Open Door** button.

6.2.3 Instrument Error



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.

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

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

6.3 Clean Up

If a method has been aborted, press the **Open Door** button. The Vision system (if enabled) will determine whether plungers have been unloaded successfully, and if not, will attempt to unload them. Otherwise the 'Clean Up' screen (Figure 49) will be displayed.

The 'Clean Up' screen requests the user check if plungers are still engaged on either the front or back plunger bar. If the plungers are not engaged, remove the deck trays from the instrument and touch the **Skip Clean Up** button to continue. After pressing the **Skip Clean Up** button, you will be presented with the extraction report (Figure 50).

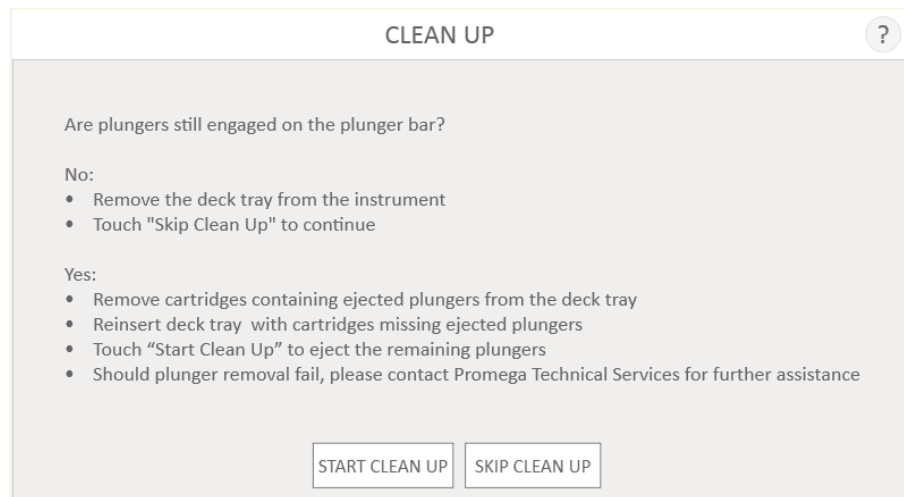


Figure 49. 'Clean Up' screen after abort/instrument error. If an extraction method is aborted by the user or due to an instrument error and the Vision system has been disabled, the 'Clean Up' screen is displayed and asks you to **Start Clean Up** or **Skip Clean Up**, depending on whether the plungers are still engaged on the plunger bar.

If some or all of the plungers are still engaged on the front or back 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 trays.
- Reinsert the deck trays with the remaining cartridges (those missing plungers).
- Touch the **Start Clean Up** button to eject the remaining plungers.

After the Clean Up is successful, you can press the **Open Door** button and remove the deck tray.

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

6.4 Results

The 'Report View' screen is displayed after the **Open Door** button is pressed (Figure 50). Run reports can be accessed later by selecting the **Results** button on the Maxwell® CSC 48 'Home' screen.

This screen displays the sample tracking and method-specific information for the current instrument run. Included in this report are the sample tracking information recorded prior to starting the method, the final status of the method (Completed or Aborted), the time the method run was started, the length of time the method took to process, the operator ID and the Maxwell® CSC 48 Instrument details (software version, firmware version, instrument name, serial number, etc.).

1	A	B	C	D	E	F	G
2	Extraction Report Maxwell CSC Viral Total Nucleic Acid v0.9.0						
3							
4							
5	Software	MAXWELL® CSC 48				Operator	DESKTOP-UKV0KXD\User
6	Software Version	v1.1.9				Run Date	3/24/2020 User Confirmations:
7	Instrument Name	PROMEGA				Start Time	12:17:53 AM Sample pre-processor
8	Instrument Serial No	20000021				End Time	12:48:40 AM Deck tray has been p
9	Firmware Version	v6.2.12				Duration	00:30:47 Cartridges with se
10	Mode	IVD				Run Status	Completed
11							• Samples have bee
12	Position	Catalog Number	Sample ID	Lot Number	Expiration Month	Cartridge ID	Elution Tube ID
13	1	as1780	v	123456	2020-12		
14	2	as1780	c	123456	2020-12		
15	3	as1780	x	123456	2020-12		
16	4	as1780	t	123456	2020-12		
17	5	as1780	m	123456	2020-12		
18	6	as1780	n	123456	2020-12		
19	7						
20	8						
21	9						
22	10						
23	11						
24	12						
25	13						
26	14						
27	15						
28	16						
29	17						
30	18						
31	19						
32	20						
33	21						
34	22						
35	23						
36	24						
37	25						
		as1780	b	123456	2020-12		

Figure 50. 'Report View' screen. The 'Report View' screen displays the sample tracking and method-specific information for the current instrument run. Included in this report are the sample tracking information recorded prior to starting the method, the final status of the method (Completed or Aborted), the time the method run was started, the length of time the method took to process, the operator ID and additional instrument information. Buttons are present on the left side of the screen to **Print** and **Export** report information.

Using the buttons on the left side of the 'Report View' screen you can:

- **Print** reports to a printer that can be accessed by the Tablet PC.
- **Export** reports in tab-delimited text file format as well as PDF format (Figure 51).

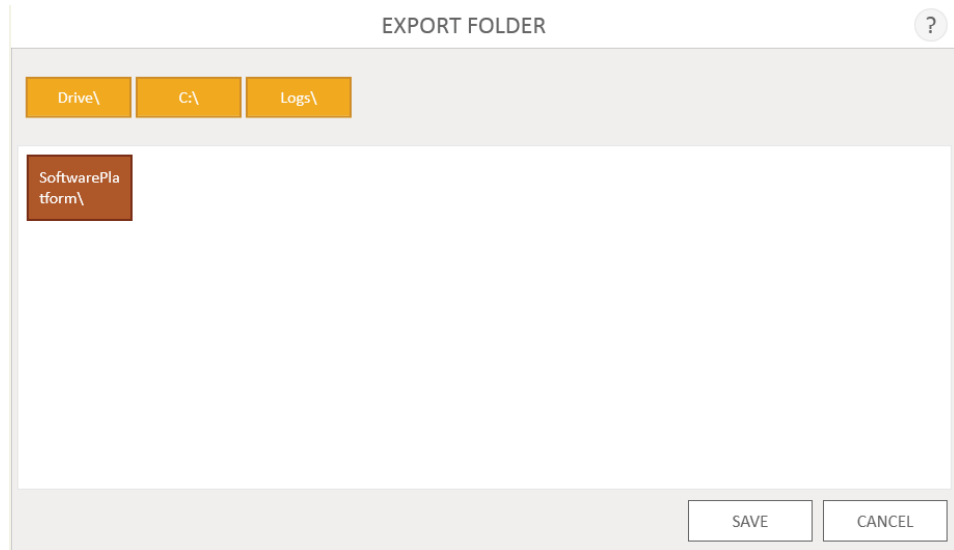


Figure 51. 'Export Folder' screen. When the **Export** button is pressed, the user will be asked to navigate to the file location where report files should be saved.

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 48 Instrument exports reports in tab-separated text format as well as .pdf format.

You can use the tab-separated format file (*.txt) with Laboratory Information Management Systems (i.e., LIMS). An example of the tab-separated format file is shown in Figure 52 and an example of the printable PDF format is shown in Figure 53.

```

Maxwell CSC Viral Total Nucleic Acid v0.9.0
Software          MAXWELL® CSC 48
Software Version  v3.1.0
Instrument Name    PROMEGA
Instrument Serial No 20000021
Firmware Version  v6.2.12

Operator          DESKTOP-UKJYOKD\User
Run Date          3/24/2020
Start Time        4:02:10 AM
End Time          4:33:01 AM
Duration          00:30:50
Run Status        Completed

Position  Catalog Number  Sample ID  Lot Number  Expiration Month  Cartridge ID  Elution Tube ID  Custom1  Custom2
1         AS1780          SAM01     321654     2020-12
2         AS1780          SAM02     321654     2020-12
3         AS1780          SAM03     321654     2020-12
4         AS1780          SAM04     321654     2020-12
5         AS1780          SAM05     321654     2020-12
6         AS1780          SAM06     321654     2020-12
7         AS1780          SAM07     321654     2020-12
8         AS1780          SAM08     321654     2020-12
9
10
11
--
    
```

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Figure 52. Example of an exported text file in the tab-separated format.

Extraction Report								
Software	MAXWELL® CSC 48	Operator	DESKTOP-UKJYOKD\User	User Confirmations:				
Software Version	v3.1.0	Run Date	3/24/2020	Sample pre-processing is complete as per the Maxwell CSC Viral Total Nucleic Acid Technical Manual				
Instrument Name	PROMEGA	Start Time	4:02:10 AM	Deck tray has been prepared as follows and placed in the instrument:				
Instrument Serial No	20000021	End Time	4:33:01 AM	<ul style="list-style-type: none"> Cartridges with seals completely removed placed at positions 1-8 Samples have been placed in well 1 of each cartridge Elution tubes placed at positions 1-8 with caps opened and facing away from the cartridges Appropriate volume of elution reagent has been added to each elution tube Plunger has been placed in well 8 of each cartridge 				
Firmware Version	v6.2.12	Duration	00:30:50					
Mode:	IVD	Run Status	Completed					
Position	Catalog Number	Sample ID	Lot Number	Expiration Month	Cartridge ID	Elution Tube ID	Custom1	Custom2
1	AS1780	SAM01	321654	2020-12				
2	AS1780	SAM02	321654	2020-12				
3	AS1780	SAM03	321654	2020-12				
4	AS1780	SAM04	321654	2020-12				
5	AS1780	SAM05	321654	2020-12				
6	AS1780	SAM06	321654	2020-12				
7	AS1780	SAM07	321654	2020-12				
8	AS1780	SAM08	321654	2020-12				
9								
10								

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Figure 53. Example of a report in the PDF format.

6.5 Running Reports

From the 'Home' screen (Figure 54) of the user interface, it is possible to view sample tracking reports and service reports on the instrument by pressing the **Results** button. The 'Results' screen displays a listing of the extraction reports for the methods that have been run in the Maxwell® CSC 48 IVD Mode software (Figure 55). Use the **Today, This Month, Six Months, This Year** or **All** buttons on the left side of the screen to filter the list of displayed reports by time period. Use the **Extraction, System** and **All Types** buttons on the left side of the screen to filter the displayed reports by report type. Touch the column headers to sort the reports based on column contents. Touch the desired row to see a detailed view of the report data from that method run (Figure 56). 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 54. Maxwell® CSC 48 'Home' screen. Selecting **Results** opens the Maxwell® CSC 48 'Results' screen from which extraction reports from all method runs can be viewed.

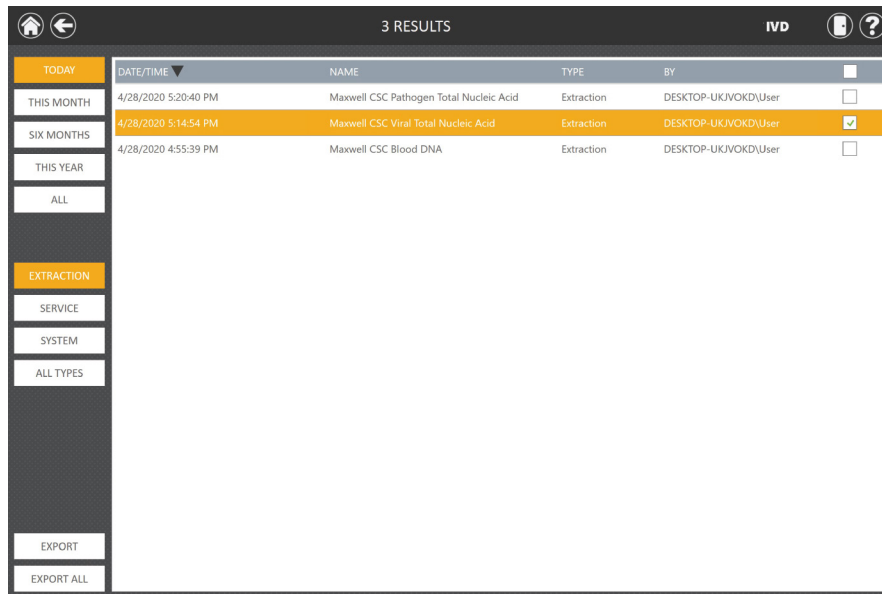


Figure 55. 'Results' screen. The 'Results' screen lists the reports from all of the methods that have been run. Touch any given report listing to see a detailed view of the report data from that method run. Filter the displayed results using the **Extraction, System** or **All Types** buttons on the left side of the screen. Selecting a date range button on the left side of the screen will filter the reports displayed based on their date. To export a selection of reports to a user-specified drive location, touch the check box next to the method runs of interest and touch the **Export** button. Touch the **Export All** button to export all displayed reports to a user-specified drive location.

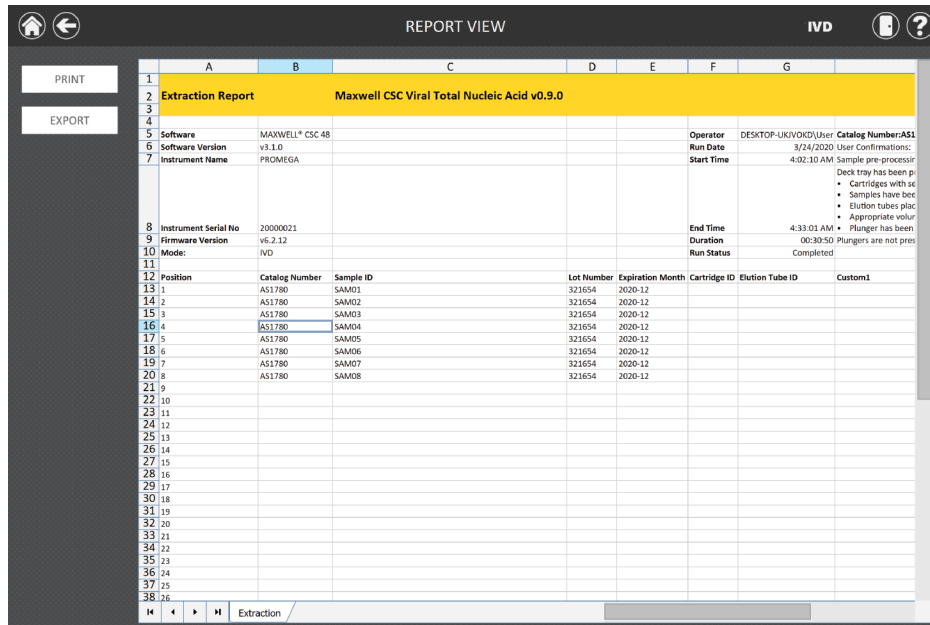


Figure 56. Extraction report. An example of the sample tracking information present in an extraction report.

6.6 Sanitizing

Touch the **Sanitize** button on the 'Home' screen (Figure 57) to perform a UV sanitization of the instrument. 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 58) 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. Once you confirm, the **Start** button is enabled. Touch the **Start** button to start UV sanitization.



Figure 57. 'Home' screen. Selecting the **Sanitize** button begins the process for UV treatment of the Maxwell® CSC 48 Instrument.

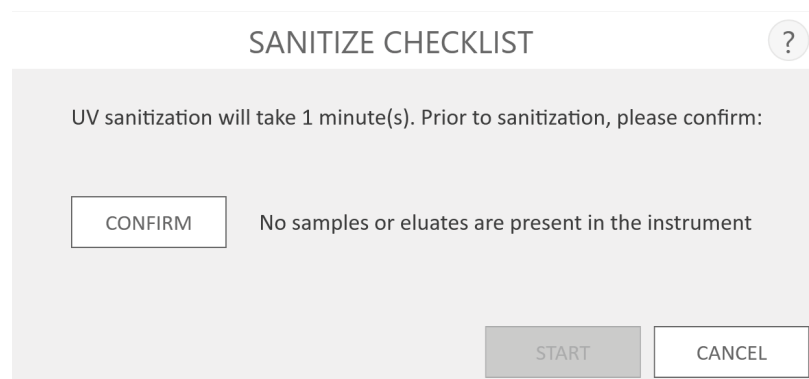


Figure 58. 'Sanitize Checklist' screen. The sanitization checklist indicates how long the UV sanitization will take. Confirm that no samples or eluates are present in the instrument prior to running Sanitization.

After Sanitization is completed, you will see one of the following icons in the title bar:

	Sanitization completed successfully. Touch the icon to view the Sanitization report (Figure 59).
	An error occurred during sanitization. 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.

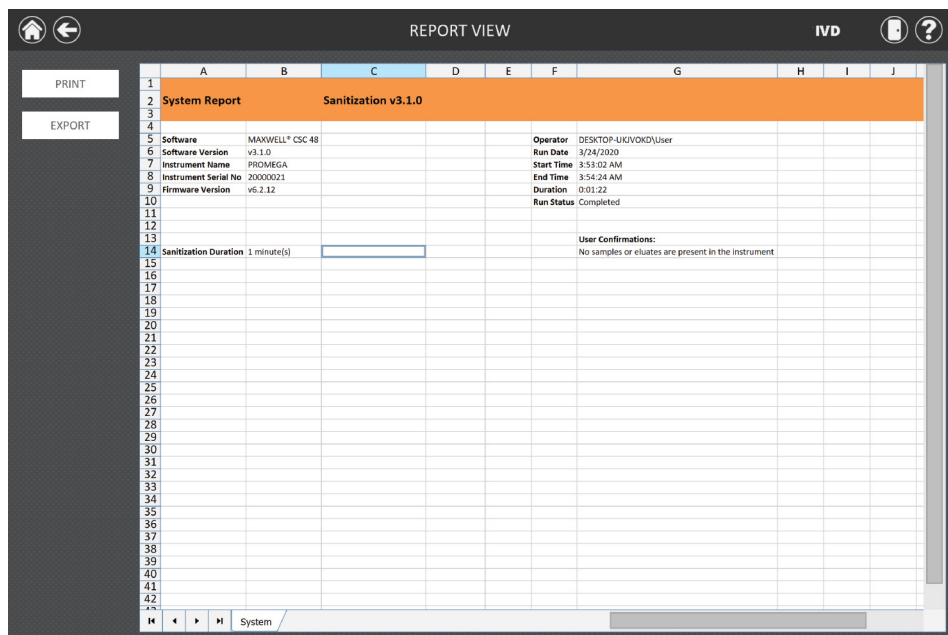


Figure 59. Example Sanitization Report. The sanitization report will be displayed after completion of sanitization.

Cleaning and Maintenance

The Maxwell® CSC 48 Instrument has no user-serviceable parts and is designed to require minimal maintenance. However, it is important to clean the instrument after every use. If samples or reagents have been spilled, it is important to clean the instrument immediately to avoid damage or contamination of samples.

Most parts of the Maxwell® CSC 48 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



Important.

Wear gloves and appropriate personal protective equipment. If the instrument is used with biohazardous materials, dispose of any cleaning materials used in accordance with your institutional guidelines.

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 cloths dampened with 70% ethanol. Do not use other solvents or abrasive cleaners.

- Clean the Maxwell® CSC 48 Instrument after every use.
- Keep the vents in the back of the machine clear of dust.
- Do not remove the Maxwell® CSC 48 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 assemblies need to be cleaned.

1. To clean the back magnetic rods, we highly recommend to first remove the front magnetic rod assembly.
2. Open the instrument door by touching the **Door** icon in the title bar of the software. Remove deck trays from the instrument.
3. Turn off the instrument by pressing and holding the power button on the right side of the instrument for three seconds.
4. Unscrew the three knob screws on the top of the front magnetic rod assembly (the screws cannot be fully removed from the magnet bar). Slide the magnet bar downward toward the deck of the instrument.
5. Pull the magnetic rod assembly upward while angling the assembly toward the front of the instrument (Figure 60) to remove the magnet bar. Slide the magnet and plunger bar upward so you have access to the back magnet rod assembly.
6. To clean the magnetic rod assemblies, wipe with a soft cloth dampened with 70% ethanol. Removal of paramagnetic particles from the magnetic rod assembly will require multiple wipes. The damp cloth may be wrapped around a magnet to facilitate removal of magnetic particles.
7. If the magnetic rod assemblies cannot be cleaned, please contact Promega Technical Services for assistance.
8. After cleaning the magnetic rod assemblies, replace the front magnetic rod by angling the magnetic rod assembly into the front magnet bar and reattaching the three knob screws.
9. Turn the instrument back on by pressing the power button on the right side of the instrument.

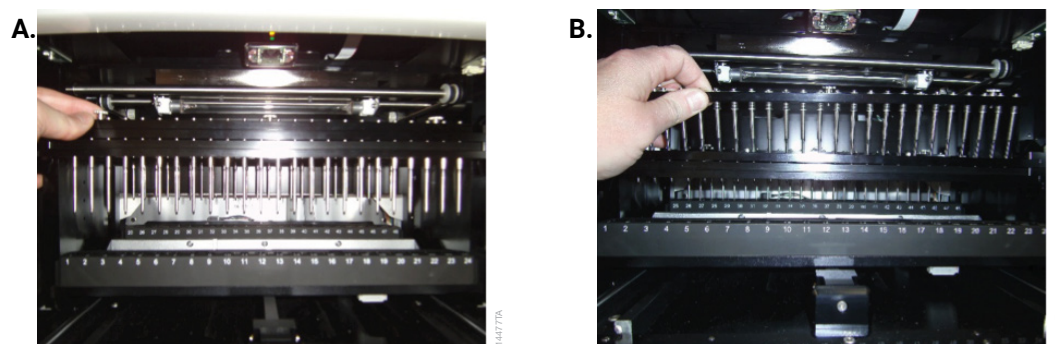


Figure 60. Removing the front magnetic rod assembly. Panel A. Loosen the three thumbscrews that hold the magnetic rod assembly on the magnet bar. **Panel B.** Move the deck forward and slide the magnet bar down. Slide the magnetic rod assembly up and forward to remove it from the magnet bar.

7.3 Dealing with Spills

**Important.**

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

Wipe up any spills immediately. If any material spills in the instrument, wipe up the material using a cloth dampened with 70% ethanol. Note that the reagents contain hazardous materials; therefore dispose of the cleaning materials 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.

Analytical Performance Evaluation

Analytical performance for the Maxwell® CSC 48 Instrument was evaluated in combination with the Maxwell® CSC Blood DNA, Maxwell® CSC RNA Blood, Maxwell® CSC DNA FFPE and Maxwell® CSC RNA FFPE Kits using human whole blood samples or human FFPE tissue samples as appropriate for the specific kit. Average yield and percent coefficient of variation (% CV) were calculated for eluates across three runs on a single instrument and one run on each of three separate instruments.

8.1 Reproducibility

Table 1. Reproducibility within and across instrument runs. Inter- and intra-run reproducibility was determined by running a minimum of 16 replicates of whole blood samples or 16 replicates of FFPE tissue samples, as appropriate for the Maxwell® CSC kit used, in 3 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 tissue sections and yield evaluated by RT-qPCR.

Maxwell® CSC Kit	Run Number	Intra-Run % CV	Inter-Run % CV
1. Blood DNA	1 (n = 24)	3.3	5.1
	2 (n = 16)	6.2	
	3 (n = 16)	4.5	
2. RNA Blood	1 (n = 16)	7.7	8.0
	2 (n = 16)	7.7	
	3 (n = 16)	7.9	
3. DNA FFPE	1 (n = 16)	7.4	10.3
	2 (n = 16)	8.5	
	3 (n = 16)	11.0	

Maxwell® CSC Kit	Run Number	Intra-Run % CV	Inter-Run % CV
4. RNA FFPE	1 (n = 16)	15.2	18.7
	2 (n = 16)	23.6	
	3 (n = 16)	11.0	

Table 2. Reproducibility Within and Across Instruments. Inter- and intra-instrument reproducibility was tested using the Maxwell® CSC Blood DNA Kit, and was determined by running 16 replicates of whole blood, 300µl each, on three separate Maxwell® CSC 48 Instruments. DNA yield was determined by absorbance spectroscopy, and average yield and standard deviation were used to calculate % CV for replicates on each instrument to determine intra-instrument variability, and for replicates across all three instruments to determine inter-instrument variability.

Maxwell® CSC Kit	Run Number	Intra-Instrument % CV	Inter-Instrument % CV
Blood DNA	1 (n = 16)	4.5	4.5
	2 (n = 16)	3.2	
	3 (n = 16)	3.4	

8.2 Cross Contamination

DNA was purified from 8 replicates of female and male whole blood samples, 300µl each, processed in alternating deck positions on both the front and back decks of the Maxwell® CSC 48 instrument using the Maxwell® CSC Blood DNA Kit. qPCR of a Y-chromosome target was utilized 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.

Clinical Performance Evaluation

Clinical performance of the Maxwell® CSC 48 Instrument was evaluated at an external clinical laboratory to test performance of the instrument in the typical user environment. Nucleic acid was extracted from plasma, serum, saliva and viral transport medium using the Maxwell® CSC 48 Instrument and Maxwell® CSC Viral Total Nucleic Acid Kit, eluted in 50µl and tested for amplifiability in a relevant in vitro diagnostic test. Nucleic acid extracted from the same samples using the extraction method the laboratory typically uses (laboratory reference method) was tested in the same assay for comparison purposes.

9.1 Extraction of Nucleic Acids from Different Sample Types

Table 3. SARS-CoV-2 Viral RNA Purification from Universal Transport Medium Samples. Viral total nucleic acid was purified from ten positive and ten negative SARS-CoV-2 UTM samples using the Maxwell® CSC Viral Total Nucleic Acid Purification Kit and a Maxwell® CSC 48 Instrument using 200µl of sample. Viral RNA was also purified from the same samples using the laboratory reference method. Nine of ten positive samples and ten of ten negative samples matched results between the Maxwell® System and laboratory reference method. All Maxwell® samples matched the presumed sample status, which was based on a previous SARS-CoV-2 test run on the sample.

Presumed SARS-CoV-2 Status	Maxwell® System	Laboratory Reference Method	Maxwell® Matches Reference Method	Maxwell® Matches Presumed Status
9 positive	9 positive	9 positive	Yes	Yes
1 positive	1 positive	1 negative	No	Yes
10 negative	10 negative	10 negative	Yes	Yes

Table 4. SARS-CoV-2 Viral RNA Purification from Saliva Samples. Viral total nucleic acid was purified from ten positive and ten negative SARS-CoV-2 saliva samples using the Maxwell® CSC Viral Total Nucleic Acid Purification Kit on a Maxwell® CSC 48 Instrument using 200µl of sample. Viral RNA was also purified from the same samples using the laboratory reference method. All results matched between the Maxwell® System and laboratory reference method. All Maxwell® System samples matched the presumed sample status, which was based on a previous SARS-CoV-2 test run on the sample.

Presumed SARS-CoV-2 Status	Maxwell® System		Laboratory Reference Method	Maxwell® Matches Reference Method	Maxwell® Matches Presumed Status
	100µl Plasma Input	300µl Plasma Input	300µl Plasma Input	300µl Plasma Input	300µl Plasma Input
10 positive	10 positive	10 positive	10 positive	Yes	Yes
10 negative	10 negative	10 negative	10 negative	Yes	Yes

Table 5. Dengue Virus RNA Purification from Plasma Samples. Viral total nucleic acid was purified from ten positive and ten negative Dengue fever virus plasma samples using the Maxwell® CSC Viral Total Nucleic Acid Purification Kit on a Maxwell® CSC 48 Instrument. The Maxwell® CSC Viral Total Nucleic Acid Purification System can be used with plasma input volumes from 100–300µl. Two input plasma volumes were therefore used for positive samples to demonstrate that RNA extracted across the range of input volumes could be amplified. RNA was also purified from the same samples using the laboratory reference method. Ten of ten positive samples and eight of ten negative samples had matching results for the Maxwell® System and laboratory reference method. All Maxwell® samples matched the presumed sample status, which was based on a previous Dengue fever virus test run on the sample.

Presumed Dengue Virus Status	Maxwell® System		Laboratory Reference Method	Maxwell® 300µl Input Matches Reference Method	Maxwell® Matches Presumed Status
	100µl Plasma Input	300µl Plasma Input	300µl Plasma Input	300µl Plasma Input	300µl Plasma Input
10 positive	10 positive	10 positive	10 positive	Yes	Yes
8 negative	NT*	8 negative	8 negative	Yes	Yes
2 negative	NT*	2 negative	2 positive	No	Yes

NT*: Not tested.

Table 6. Cytomegalovirus (CMV) DNA Purification from Plasma Samples. Viral total nucleic acid was purified from ten positive and ten negative CMV plasma samples using the Maxwell® CSC Viral Total Nucleic Acid Purification Kit on a Maxwell® CSC 48 Instrument. The Maxwell® CSC Viral Total Nucleic Acid Purification System can be used with plasma input volumes from 100–300µl. Two input plasma volumes were therefore used for positive samples to demonstrate that DNA extracted across the range of input volumes could be amplified. Viral DNA was also purified from the same samples using the laboratory reference method. Results for all samples matched between the Maxwell® System and laboratory reference method. All Maxwell® samples matched the presumed sample status, which was based on a previous CMV test run on the sample.

Presumed CMV Status	Maxwell® System		Laboratory Reference Method	Maxwell® 300µl Input Matches Reference Method	Maxwell® Matches Presumed Status
	100µl Plasma Input	300µl Plasma Input	300µl Plasma Input		
10 positive	10 positive	10 positive	10 positive	Yes	Yes
10 negative	NT*	10 negative	10 negative	Yes	Yes

NT*: Not tested

Table 7. Dengue Fever Virus RNA Purification from Serum Samples. Viral total nucleic acid was purified from ten positive and ten negative Dengue fever virus serum samples using the Maxwell® CSC Viral Total Nucleic Acid Purification Kit on a Maxwell® CSC 48 Instrument. The Maxwell® CSC Viral Total Nucleic Acid Purification System can be used with serum input volumes from 100–300µl. Two input serum volumes were therefore used for positive samples to demonstrate that RNA extracted across the range of input volumes could be amplified. Viral RNA was also purified from the same samples using the laboratory reference method. Results for all samples matched between the Maxwell® System and laboratory reference method. All Maxwell® System samples matched the presumed sample status, which was based on a previous Dengue fever virus test run on the sample.

Presumed Dengue Virus Status	Maxwell® System		Laboratory Reference Method	Maxwell® 300µl Input Matches Reference Method	Maxwell® Matches Presumed Status
	100µl Plasma Input	300µl Plasma Input	300µl Plasma Input		
10 positive	10 positive	10 positive	10 positive	Yes	Yes
10 negative	NT*	10 negative	10 negative	Yes	Yes

*NT: Not tested.

Table 8. Reproducibility of RNA Purification. Viral total nucleic acid was purified from ten positive and ten negative Dengue fever virus plasma samples using the Maxwell® CSC Viral Total Nucleic Acid Purification Kit on a Maxwell® CSC 48 Instrument by two testers using 300µl of input sample volume. All sample results were concordant between the testers.

Presumed Dengue Virus Status	Maxwell® System		Tester A Result Matches Tester B Result
	Tester A	Tester B	
10 positive	10 positive	10 positive	Yes
10 negative	10 negative	10 negative	Yes

9.2 Cross Contamination

Viral DNA extraction was performed on 300µl samples of nine negative and ten positive CMV plasma samples placed in alternating deck positions on the Maxwell® CSC 48 Instrument. Eluates were tested by qPCR to determine if any contaminating CMV viral DNA was present in the negative samples indicating that cross contamination between samples had occurred during the instrument run. No CMV DNA was detected in the negative CMV plasma samples, indicating no cross contamination between samples.

Following DNA extraction from positive CMV samples, the laboratory performed decontamination and cleaning of the instrument following the procedure described in Section 7. Nucleic acid extraction was then performed on nine negative CMV plasma samples using the decontaminated Maxwell® CSC 48 Instrument and Maxwell® CSC Viral Total Nucleic Acid Purification Kit. Eluates from each sample were tested by qPCR to determine if any contaminating CMV DNA remained in the instrument from a previous run. No CMV DNA was detected in any of the eluates.

For questions not addressed here, please contact your local Promega Branch Office or Distributor. Contact information available at: www.promega.com. Email: techserv@promega.com

Symptoms	Causes and Comments
Clean Up function does not unload the plunger	<p>If plungers are still engaged on the plunger bars, perform the following steps:</p> <ul style="list-style-type: none"> • Remove any cartridges containing the ejected plungers from the deck trays. • Reinsert the deck trays with cartridges that do not have ejected plungers. • Touch the Start button to eject the remaining plungers. <p>If the plunger clean up fails, contact Promega Technical Services for further assistance.</p>
Tablet PC touch screen does not appear to be working	<p>Verify that the power supply is securely connected to the Tablet PC.</p> <p>Restart the Tablet PC and launch Maxwell® CSC 48 software.</p> <p>If the issue is not resolved, contact Promega Technical Services for further assistance.</p>
Cannot change the sanitization time or import new methods	<p>Only operators with administrator-level access to the Maxwell® CSC 48 software have the ability to change certain functions. If you do not have administrator-level access, contact your site administrator.</p>
Power failure during a run	<p>In the event of a power failure, turn off the instrument (using the rocker switch on the back of the instrument) and the Tablet PC. When power has returned, turn the instrument and Tablet PC back on. Check to see whether plungers are loaded on the plunger bar. If so, run Clean Up from the 'Settings' Menu and follow prompts to safely remove the plungers. After plungers have been unloaded, remove the deck tray from the instrument if it is still present. An aborted run (due to power failure) will result in the loss of all the samples. Do not attempt to repurify samples from an aborted run.</p>

Error 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 48 IVD software. This method type must be run using the Maxwell® CSC 48 RUO software. Close the Maxwell® CSC 48 IVD software, open the Maxwell® CSC 48 RUO software, and run the desired RUO method.
Initialization Failure: Access Denied, not a valid Promega User, Please contact your system administrator	Promega User not set up correctly in Windows® Operating System. Consult the <i>Maxwell® CSC Tablet PC Configuration Manual #TM484</i> and/or contact your administrator/IT personnel to resolve this issue.
USB Device is not found; is it turned off or disconnected?	Tablet PC is not connected to the instrument, Tablet PC is off or the instrument is off. Check to see if the Tablet PC is connected to the instrument. Turn on the Tablet PC and turn on the instrument. If the Tablet PC and instrument are powered on, connected by the USB cable and this problem persists, cycle power on the instrument and reboot the Tablet PC. If error persists, contact Promega Technical Services.
Open door detected during operation	Open door was detected during operation. The run will be aborted and samples will be lost. If error persists, contact Promega Technical Services.
Protocol: Aborted By User	User aborted the method. An aborted run (initiated by the user) will result in the loss of all the samples. Do not attempt to repurify samples from an aborted run.
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 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 while previous run was active. Wait for the current process to complete. If error persists, contact your IT administrator or Promega Technical Services.
Previous session has timed-out, device disconnected?	Connection was lost during previous instrument operation or USB was unplugged during a run and then plugged back in. Check to see that the USB cable is connected to the instrument or that no one unplugged the USB cable while the instrument operation was running. If error persists, contact Promega Technical Services.
Warning: Failed to Start Extraction: Self-Test has not passed	Instrument self-initialization has not passed. Contact Promega Technical Services.

Error Warnings (continued)

Error	Explanation
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 from the 'Settings' Menu and follow prompts to safely remove them. After plungers have been unloaded, remove the deck tray from the instrument.
Warning: Startup Diagnostics: Firmware version change detected	User warning informing user that a firmware version change has been detected. Contact Promega Technical Services.

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.

10.1 Use of a USB Flash Drive

- When using a USB flash drive, insert it before running any method and do not remove it until the method is finished.
- Do not insert or remove a USB flash drive while instrument 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 and restart the tablet and the instrument.

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.

Notes

11.1 Service

We recommend that the Maxwell® CSC 48 Instrument receives a yearly preventive maintenance service.

11.2 Returning the Maxwell® CSC 48 Instrument for Service

The Maxwell® CSC 48 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 at www.promega.com for the contact information for the Promega branch or distributor nearest you. If further action is required, repair options will be presented and a return authorization number assigned if necessary. Promega is not responsible for instrumentation returned without an authorization number. When you ship the instrument for service, please remember to:

- Obtain return authorization from Promega.
- Decontaminate the instrument (see Section 13 for decontamination instructions).
- Include a signed and dated Certificate of Decontamination inside the package 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 scanner 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 48 Instrument

11.3.1 Preparation of the Maxwell® CSC 48 Instrument Prior to Repacking:

- Ensure that the cartridges and elution tubes have been removed from the instrument platform.
- Turn off the instrument by pressing and holding the power button on the side of the instrument for three seconds. Switch the rocker switch on the back of the instrument to the Off position and unplug the instrument. Shut down the Tablet PC, and ensure that Tablet PC and bar code reader are disconnected.

11.3.2 Repacking the Maxwell® CSC 48 Instrument

Note: If you do not have the original Maxwell® CSC 48 Instrument packaging, please contact Promega Technical Services or your local Promega representative to order Maxwell® CSC 48 Instrument packaging.

Ship the Maxwell® CSC 48 Instrument only with Promega packaging to avoid any damages.

1. Turn the instrument off and unplug it from the outlet.
2. Open the instrument door and manually push the deck to the back of the instrument.
3. Manually slide the plunger bar and magnet bar (Figure 61) down to insert the upper die-cut foam.

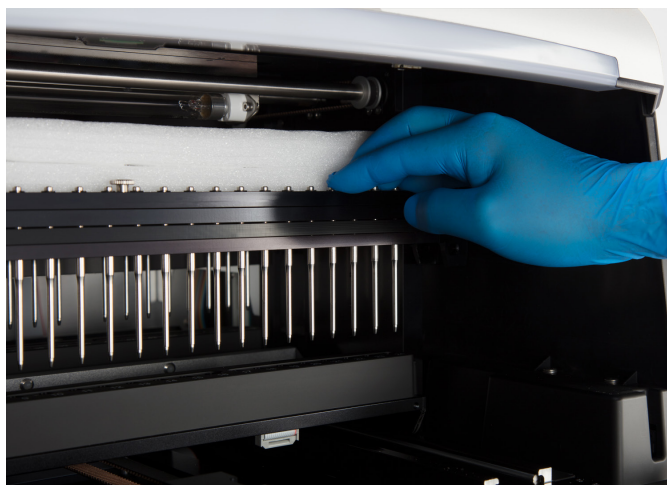


Figure 61. Slide Plunger and Magnet Bars down, and insert upper die-cut foam.

4. Place the upper die-cut foam as shown in Figure 62.



Figure 62. Placement of upper die-cut foam.

5. Manually move the plunger bar and magnet bar (Figure 63) up to attach the shipping screws.



Figure 63. Placement of plastic stoppers. Move the magnet and plunger bars up, and secure the four shipping screws on both sides of the magnet and plunger bars.

6. Secure the four shipping screws by screwing them in on both sides of the magnet and plunger bars as shown in Figure 63.

7. Insert the front die cut foam into the instrument so that the serrated edge covers the magnet rods (Figure 64).

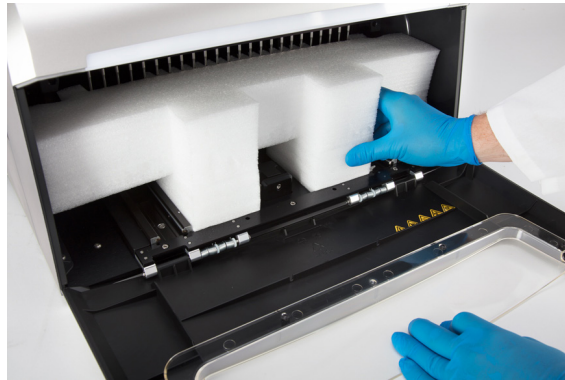


Figure 64. Insert the front die-cut foam. Make sure the serrated edge covers the magnet rods.

8. Place the instrument in the plastic bag.
9. Place the instrument in the bottom foam packaging material. The instrument will only fit properly into the bottom foam piece in one orientation (Figure 65).



Figure 65. Maxwell® CSC 48 Instrument in correct orientation in the box.

10. Place the side foam pieces on either side of the instrument (Figure 65). Slide the box around the instrument and secure with the four plastic clips. Insert the clips into the holes at the base of the box, and then press the tab into the clip to secure it (Figure 66).



Figure 66. Placement of the four plastic clips around the base of the shipping box.

11. Place the accessories box on top of the packing foam (Figure 67). Affix the Certificate of Decontamination on top of the accessories box.



Figure 67. Maxwell® CSC 48 Instrument repackaged in the shipping box.

12. Close the flaps on the shipping container top, and secure them with packing tape.
13. 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 and country-specific requirements to handle the disposal of accessories. Instrument must be decontaminated prior to disposal.

12.1 Warranty

Upon purchase of the Maxwell® CSC 48 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 48 Premier Warranty Upgrade Cat.# SA1450

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 48 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 48 Premier Service Agreement are available as shown below.

Product Name	Cat.#
1-Year Maxwell® CSC 48 Premier Service Agreement	SA1452
2-Years Maxwell® CSC 48 Premier Service Agreement	SA1403
3-Years Maxwell® CSC 48 Premier Service Agreement	SA1404

Maxwell® CSC 48 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 48 needs repair, we will provide a box for shipment of the instrument back to our service facility. We will repair it and return it performing to original factory specifications. Preventive Maintenance visits are available separately.

Different options for Maxwell® CSC 48 Standard Service Agreement are available as shown below.

Product Name	Cat.#
1-Year Maxwell® CSC 48 Standard Service Agreement	SA1451
2-Years Maxwell® CSC 48 Standard Service Agreement	SA1401
3-Years Maxwell® CSC 48 Standard Service Agreement	SA1402

Maxwell® CSC 48 Preventive Maintenance Cat.# SA1456

To keep the system operation at peak performance, Promega recommends that Maxwell® CSC 48 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 functionality is verified. Documentation for your files is provided.

Maxwell® CSC 48 Installation Qualification and Operational Qualification

Product Name	Cat.#
Maxwell® CSC 48 Instrument Installation Qualification	SA1457
Maxwell® CSC 48 Instrument Operational Qualification	SA1458
Maxwell® CSC 48 Instrument IQ/OQ Package	SA1459

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. This service product must be delivered by a Promega representative who is certified to perform the Installation Qualification. The service product involves a site visit to perform:

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

The Operational Qualification service product demonstrates that the instrument functions according to its operational specifications. This service product must be delivered by a Promega representative who is certified to perform the Operational Qualification. The service product involves a site visit to perform:

- Running operational verification tests
- Documenting all calibration and test results
- Training customer(s) to operate the instrument
- Training customer(s) to use the log book
- Completing 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 48 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 a depot repair is elected, the instrument should 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 48 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. 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.#
Bar Code Reader, Maxwell® Systems	1 each	AS3200
Maxwell® RSC/CSC 48 Front Deck Tray	1 each	AS8401
Maxwell® RSC/CSC 48 Back Deck Tray	1 each	AS8402
Elution Magnet, 24-position	1 each	AS4018
USB-A Ethernet Adapter	1 each	AS8403

Maxwell® CSC Reagent Kits

PRODUCT	SIZE	CAT.#
Maxwell® CSC Blood DNA Kit	48 preps	AS1321
Maxwell® CSC DNA FFPE Kit	48 preps	AS1350
Maxwell® CSC RNA FFPE Kit	48 preps	AS1360
Maxwell® CSC RNA Blood Kit	48 preps	AS1410
Maxwell® CSC Viral Total Nucleic Acid Purification Kit	48 preps	AS1780
Maxwell® CSC Whole Blood DNA Kit	48 preps	AS1820
Maxwell® CSC Genomic DNA Kit	48 preps	AS1850
Maxwell® CSC Pathogen Total Nucleic Acid Kit	48 preps	AS1860

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

Certificate of Decontamination

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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 accessories box inside the instrument packaging.

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 follow these decontamination guidelines, sign and return the Decontamination Form 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.

Select the type of material used in the instrument:

- Chemical Biological
- Radioactive**

Briefly describe the decontamination procedure performed:

Date: _____

Place: _____

Signature: _____

Name (block capital letters): _____

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

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

Date: _____

Place: _____

Signature: _____

Name (block capital letters): _____

Title: _____

Summary of Changes

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

1. Updated Sections 1.8, 1.9, 5.3, 6.2, 6.5 and 12.
2. Replaced document font.

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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