

Maxwell® CSC 48 RUO Mode Software Manual

Instructions for Use with Catalog Number AS8000
when running in RUO Mode

For use in IVD Mode, see the *Maxwell® CSC 48 Instrument IVD Mode Operating Manual #TM623*.



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

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

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

1 Introduction

1.1 Maxwell® CSC 48 Instrument Purification Procedure

The Maxwell® CSC 48 RUO Mode software can be used to run the Maxwell® CSC 48 Instrument in Research Use Only (RUO) Mode for automated nucleic acid purification from a variety of research sample types using specific Maxwell® RSC reagent kits. The Maxwell® CSC 48 Instrument is designed for use by laboratory professionals. The extraction 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:

- Lysing samples in the presence of a specially formulated Lysis Buffer
- Binding the nucleic acids to paramagnetic particles
- Washing the bound target molecules away from other cellular components
- Eluting the nucleic acids

The instrument is controlled through a graphical user interface running on a Tablet PC. The Maxwell® CSC 48 RUO Mode software has the ability to record and report sample tracking and method run data. The included Bar Code Reader is used with the Maxwell® CSC 48 Instrument to start method runs and capture bar code information for samples and reagents. The Maxwell® CSC 48 RUO Mode software 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 bar code of the reagent kit to be processed; this selects the appropriate protocol to be run. After entering the sample tracking information, the user follows the recommended protocol for the Maxwell® RSC reagent kit and prepares the instrument deck trays as instructed. The deck trays containing prepared cartridges is placed into the instrument, and the method is automatically run. Use of the instrument does not require any special training. However, training is available as part of Operational Qualification, which is offered separately (refer to the *Maxwell® CSC 48 Instrument IVD Mode Operating Manual #TM623*).

1.2 Product Use

The Maxwell® CSC 48 RUO Mode software is intended for research use only. It is designed to be used in combination with the Maxwell® CSC 48 Instrument and Maxwell® RSC reagent kits to perform automated isolation of nucleic acids from research samples.

When run in RUO Mode, the Maxwell® CSC 48 is intended for research use only and not for use in diagnostic procedures.

1.3 Product Use Limitations

The Maxwell® CSC 48 RUO Mode software is not intended for use with reagent kits other than Maxwell® RSC reagent kits, nor with samples other than those defined within the product limitations of the specific Maxwell® RSC reagent kit being used.

1.4 Maxwell® CSC 48 Instrument RUO Mode Features

- Easy-to-use and easy-to-maintain system operation
- Standardized sample preparation workflow
- Compatibility with samples preprocessed using the Maxprep® Liquid Handler
- Integration with Portal sample tracking software
- Comprehensive technical support
- System controlled via Tablet PC
- Reporting functionality
- Preprogrammed extraction methods for automated nucleic acid purification
- UV lamp to aid in decontamination of instrument
- Integrated Vision system for confirming proper deck tray preparation
- Integral USB hub for easy connection to accessory devices

For more information on the Maxwell® CSC 48 Instrument specifications and product components as well as Warranties, Service Agreements and Related Products, refer to the *Maxwell® CSC 48 Instrument IVD Mode Operating Manual #TM623*.

1.5 Precautions











Important Safety Instructions for the Maxwell® CSC 48 Instrument. Save these instructions.

- Changes or modifications to the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- Do not use the device in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper operation.
- Do not use the 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 cartridges, plungers and elution tubes supplied with the appropriate Promega kit.
- Do not reuse cartridges, plungers or elution tubes.
- If the equipment is used in a manner other than that specified by Promega, the protection provided by the equipment may be impaired.
- Keep hands clear of instrument platform as it moves in and out of the instrument.
- During elution, the heated elution block at the front of the platform becomes very hot. Do not touch.
- To avoid muscle strain or back injury, use lifting aids and proper lifting techniques when removing or replacing the instrument.
- Instrument door should be opened and closed only by using the instrument software. Do not manually pry the door open or override the door sensor during protocol operation, as it will result in the protocol being aborted.
- The instrument can be used with potentially biohazardous materials. 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.

1.6 Safety Symbols and Marking on the Maxwell® CSC 48 Instrument

Important Safety Instructions. Save these instructions.

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

Symbols	Explanation
	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.
	Test Certification
	Conformité Européenne
	Lot Number
	Important Information

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

2

Maxwell® CSC 48 RUO Mode User Interface

2.1 Maxwell® CSC 48 RUO Mode User Interface Screens



Your IT department or site Administrator should configure the Tablet PC according to the IT rules and IT procedures pertinent to your site. Guidelines are found in the *Maxwell® CSC Tablet PC Configuration Manual*.

The Maxwell® CSC 48 instrument is controlled by 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. This Technical Manual can be downloaded at:

www.promega.com/protocols

To access the Maxwell® CSC 48 RUO Mode:

1. Press the **X** in the upper right corner of the 'Home' screen to close the Maxwell® CSC 48 software.
2. Double-touch the Maxwell® CSC 48 RUO icon on the tablet desktop to open the Maxwell® CSC 48 RUO Mode software.

2.2 'Home' Screen

The 'Home' screen is the main launching pad for interaction with the functionalities built into the Maxwell® CSC 48 RUO Mode User Interface. The 'Home' screen (Figure 1) contains four buttons:






START	Pressing the Start button on the 'Home' screen will begin the process of preparing an extraction method run on the Maxwell® CSC 48 Instrument. See Section 3.2, 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 3.5, Reports, and Section 3.6, 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 Section 2.4, Sanitization Settings). 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 3.7, Sanitize.
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 2.3, User Interface Settings, and Section 2.4, Administrator Settings.



Figure 1. '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 RUO Mode 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.
	Portal	When visible, the Portal icon indicates that the Maxwell® CSC 48 RUO Mode software is connected to the Portal software.

	Portal Error	When visible, the Portal icon with a red circle containing an exclamation point indicates that the connection to the Portal software has been lost. Results from the last run will be exported to the Portal software when the connection is restored. Disable Portal sample tracking to run methods until connection is returned, then reactivate Portal sample tracking.
	Quantus	When visible, the Quantus icon indicates that a Quantus™ Fluorometer is connected to the instrument and can be used for quantitation of eluted nucleic acids.
	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.
	RUO	This icon indicates that the Maxwell® CSC 48 software is running in RUO Mode.

2.3 User Interface Settings

Within the RUO Mode 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 RUO Mode software.

Figure 2 displays the 'Settings' screen for the Maxwell® CSC 48 RUO Mode software. This screen is accessed by touching the **Settings** button on the 'Home' Screen (Figure 1). 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 Technical Manual #TM484*. 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.

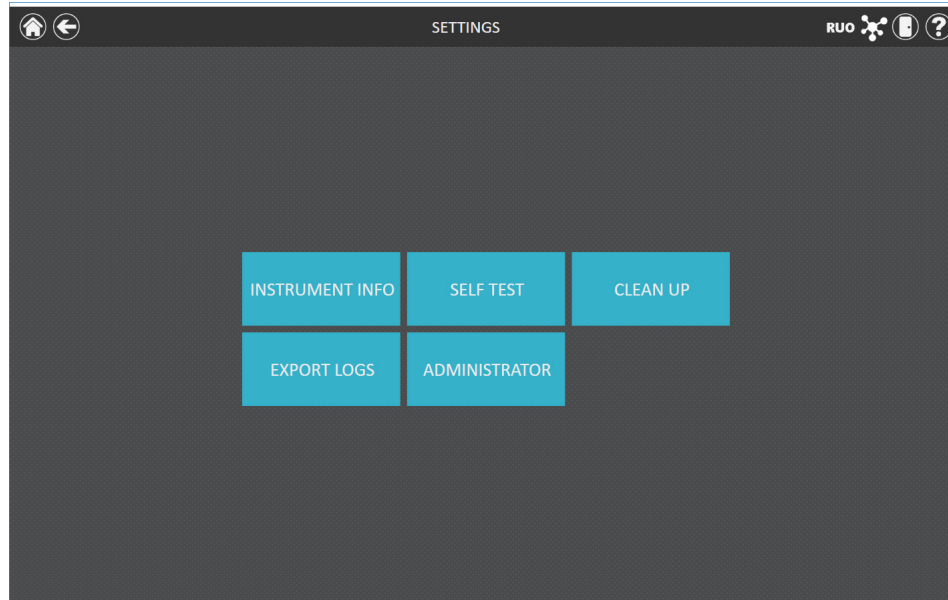


Figure 2. 'Settings' screen. From this screen, various instrument-specific functions can be accessed. The **Administrator** button will be displayed only for Windows® user accounts with administrator-level access to the Maxwell® CSC 48 software.

2.3.1 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 3). 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
- **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 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

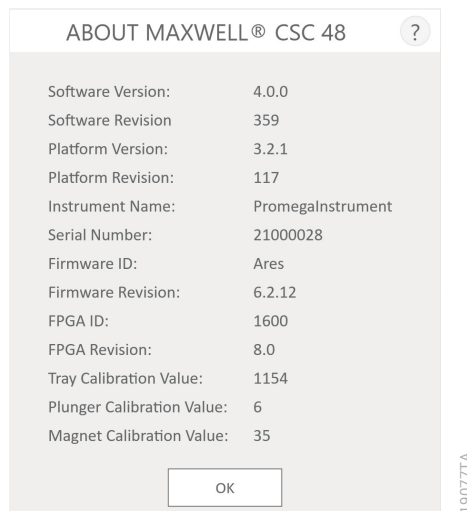


Figure 3. 'About Maxwell® CSC 48' screen. Instrument- and software-specific information are displayed on the 'About Maxwell® CSC 48' screen.

2.3.2 Self Test

You can perform a check of instrument functions by touching the **Self Test** button from the 'Settings' screen (Figure 4). 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.

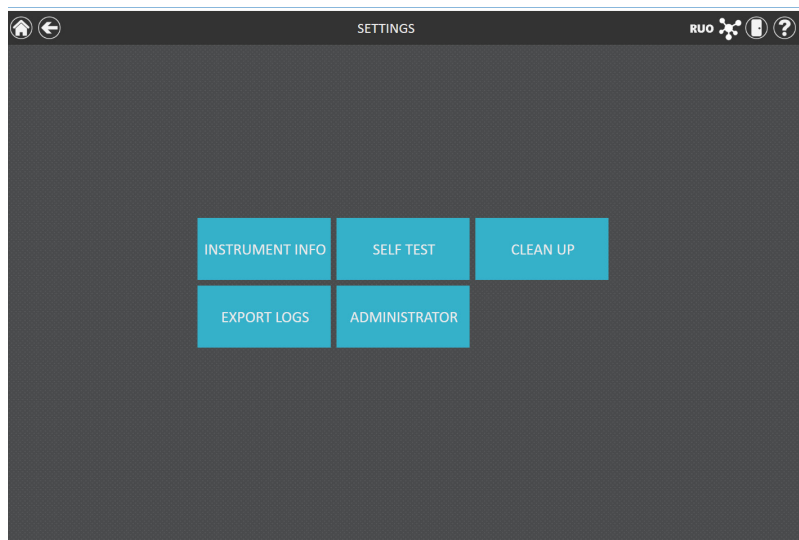


Figure 4. 'Settings' screen. From this screen you can perform a **Self Test** for the Maxwell® CSC 48 Instrument.

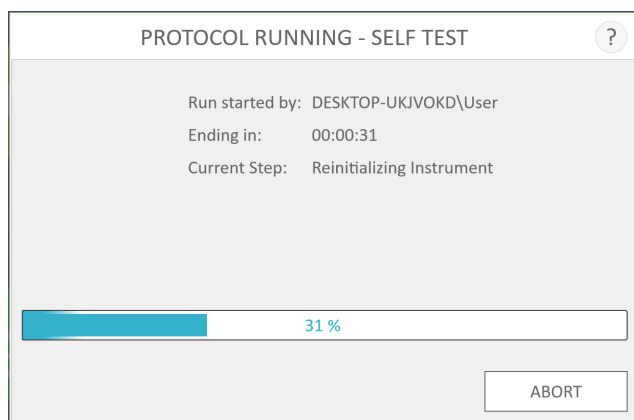


Figure 5. Self Test protocol being executed.

2.3.3 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 'Settings' screen (Figure 6; 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.

After touching the **Clean Up** button, and if the Vision system is activated on the system, the door of the instrument will open and the deck tray will be scanned to ensure that at least one cartridge is present in the deck trays and that no plungers are present in any cartridge. If the Vision system detects an error in deck tray setup, an error will be displayed indicating issues observed in deck tray setup and Clean Up will be aborted. Remove any cartridges containing plungers before touching **Clean Up** again. Next, you will be presented with a 'Clean Up Checklist' screen (Figure 7).

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

After you confirm that each of the checklist items has been performed, touch the **Start** button to start the cleanup 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 (e-mail: techserv@promega.com) to determine the next appropriate steps.

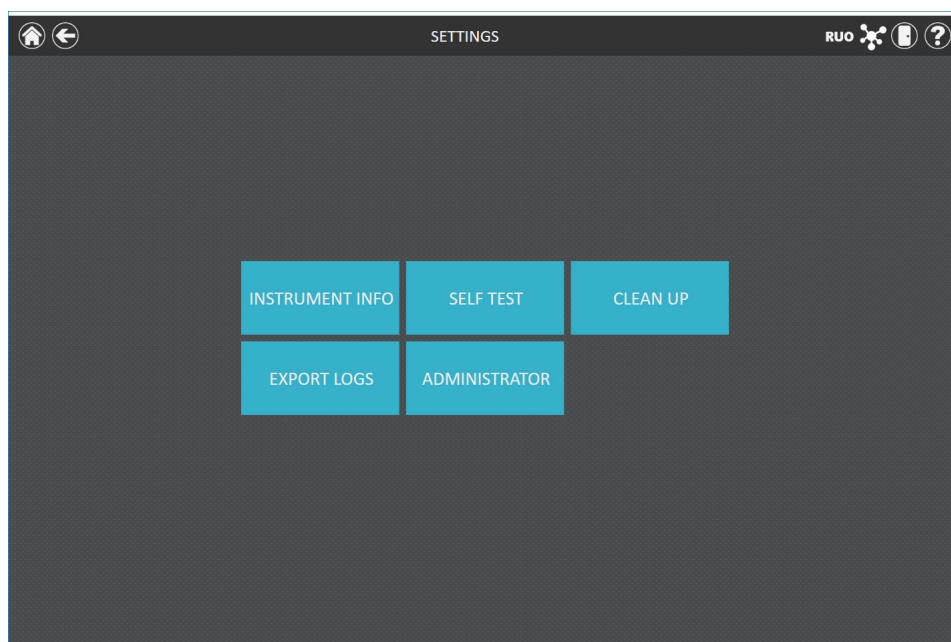


Figure 6. 'Settings' screen. From this screen you can press **Clean Up** to unload any plungers left on the plunger bar after an unsuccessful method run.

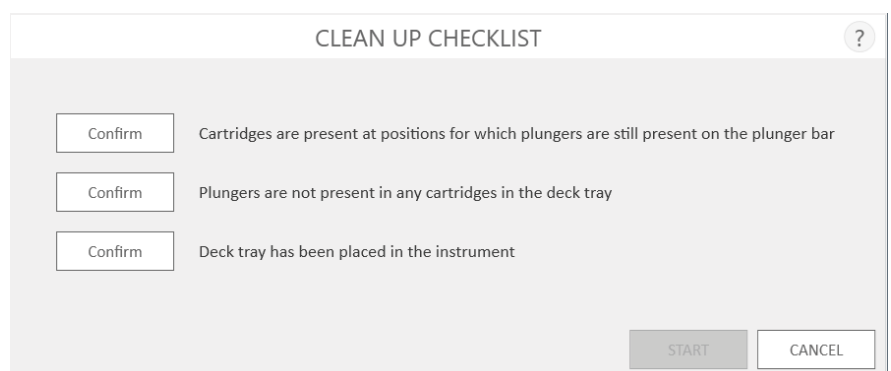


Figure 7. 'Clean Up Checklist' screen. This screen presents you with a checklist of items that must be performed before attempting to unload plungers.

2.3.4 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 8, Panel A). This screen allows the operator to select the path to which the instrument logs should be exported.
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 8, 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.

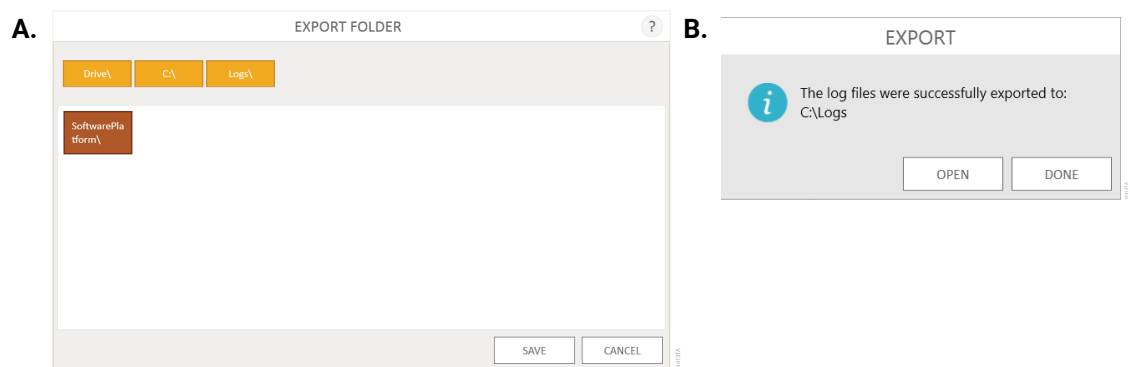


Figure 8. Export Logs. Panel A. The 'Export Folder' screen is displayed after touching the **Export Logs** button. Specify a path to which the instrument log files should be exported. Touch **Save** to export instrument logs to the specified location or **Cancel** to return to the 'Settings' screen without 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.

2.4 Administrator Settings



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



Navigation Note: The instructions for the following subsections assume that the operator is starting from the 'Administrator Page' screen in the Maxwell® CSC 48 RUO Mode software. Follow the instructions on the right to access the 'Administrator Page' screen when starting from the 'Home' screen in the software.

Software settings for the Maxwell® CSC 48 RUO Mode 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 RUO Mode 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 RUO Mode 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 RUO Mode software to the needs of the laboratory, or refer to any individual subsection to address a specific setting.

Note: Administrator settings made within the RUO Mode are only applied when running the Maxwell® CSC 48 software in RUO 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 RUO Mode User Interface (Figure 9), touch the **Settings** button.



Figure 9. 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-level access rights within the Maxwell® CSC 48 software, the 'Settings' screen (Figure 10) will display an **Administrator** button. On the 'Settings' screen, select the **Administrator** button to proceed to the 'Administrator Page' screen (Figure 11).

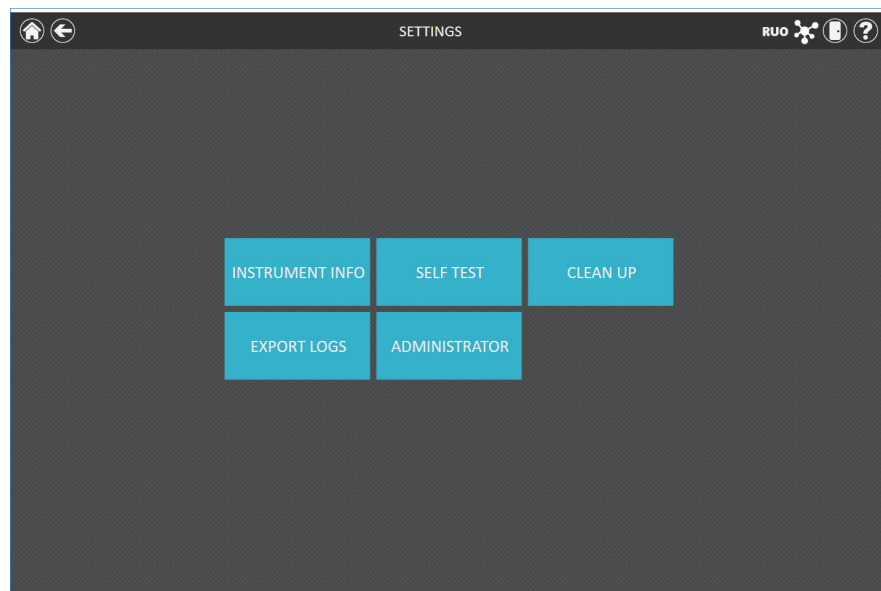


Figure 10. 'Settings' screen. The **Administrator** button will only be visible if the currently logged-in operator has administrator-level rights within the Maxwell® CSC 48 software.

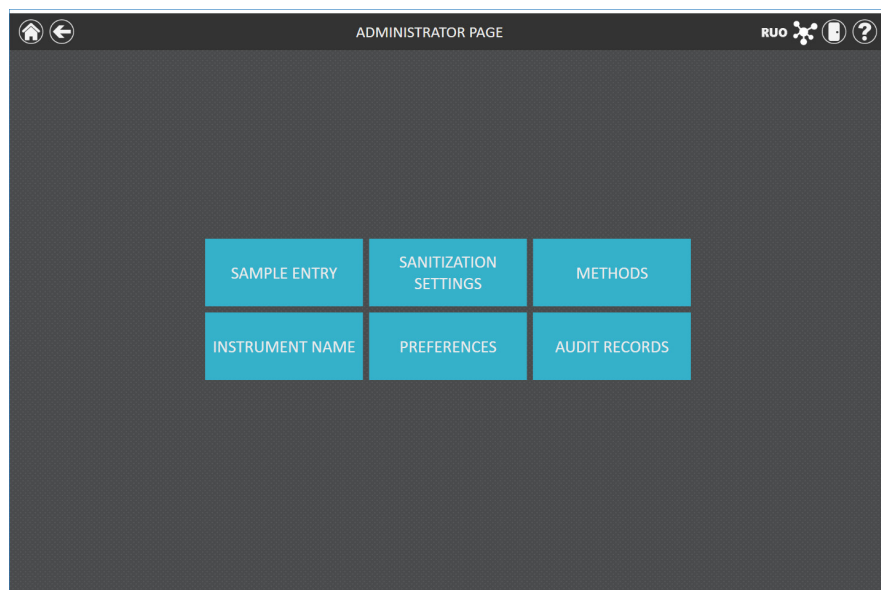


Figure 11. 'Administrator Page' screen. The 'Administrator Page' screen is only visible to administrators and gives access to customize the behavior of several aspects of the Maxwell® CSC 48 system.

2.4.1 Sample Entry

Maxwell® CSC 48 RUO Mode software has two modes for sample tracking: Portal sample tracking and local sample tracking. In Portal mode (see Section 2.4.5, Preferences), all sample tracking information is reported locally in individual run reports in the software and to the Portal software for tracking of samples between instrument modules. When Portal mode is activated (see Section 2.4.5, Preferences), entry of sample identifiers is required, while collecting other sample tracking information is optional. If Portal mode is turned off, the Maxwell® CSC 48 RUO Mode software will only report sample tracking information locally to run reports in the Maxwell® CSC 48 RUO Mode software.



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 RUO Mode software.

The 'Sample Entry' screen allows the administrator to define the required bar code values that need to be entered by any operator when running a Maxwell® CSC 48 RUO Mode method.

Sample tracking fields that can be required by the administrator include: Kit Lot Number, Sample ID, Cartridge ID, Elution Tube ID and two additional administrator-defined bar code fields. A check box next to each of these fields can be used to specify whether the bar codes entered for any of these fields is required to match the Sample ID bar code for a given cartridge position. In addition, the software can be set to warn operators if duplicate sample identifiers have been entered for a run by checking the box next to "Warn on duplicates". If duplicate bar codes are detected within a run, the software will display a warning message before starting the extraction of samples.

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

1. From the Maxwell® CSC 48 RUO software 'Administrator Page' screen (Figure 11), touch the **Sample Entry** button.
2. The 'Sample Entry' screen is shown in Figure 12. Choose whether to require the entry of Kit Lot Number, Sample ID, Cartridge ID (bar code added to the sample processing cartridge by the user) and Elution Tube ID (bar code of the elution tube). It is possible to 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.

When the check box next to the Sample ID field is checked, the "Warn on duplicates" check box becomes active. Check the box next to the "Warn on duplicates" field to warn users that the deck trays contain identical Sample ID information for two or more samples within a run. Enabling this option will not prevent a run from proceeding because of duplicate Sample IDs; it will simply result in a warning before extraction begins for informational purposes.

If any option other than Sample ID and Kit Lot Number is enabled, you can choose whether the bar codes scanned for the indicated fields are required to match the Sample ID. This is useful for ensuring that all bar code values match for any given sample processing position on the instrument deck tray. Enable the bar code matching option for any of these additional enabled bar code fields by touching the box to the left of the "Must Match Sample ID" text for that field. Once enabled, the box will contain a check mark.



Note: When the Maxwell® CSC 48 RUO Mode software is connected to the Portal software (see Section 2.4.5, Preferences) the "Sample ID" and "Kit Lot Number" fields are required.

SAMPLE ENTRY ?

<input checked="" type="checkbox"/> Sample ID	<input type="checkbox"/> Warn on duplicates
<input checked="" type="checkbox"/> Kit Lot Number	
<input type="checkbox"/> Cartridge ID	<input type="checkbox"/> Must Match Sample ID
<input type="checkbox"/> Elution Tube ID	<input type="checkbox"/> Must Match Sample ID
<input type="checkbox"/> Custom1	<input type="checkbox"/> Must Match Sample ID
<input type="checkbox"/> Custom2	<input type="checkbox"/> Must Match Sample ID

SAVE CANCEL

Figure 12. '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. When Portal software is enabled, Sample ID is a required bar code entry field. Use the "Warn on duplicates" option to display a warning when multiple cartridges within a run have identical Sample ID information. For any of the optional fields, you can specify whether the bar code information entered is required to match the Sample ID for each processing position on the instrument.

3. After the Sample Entry settings are configured as desired, touch the **Save** button to save these settings and return to the 'Administrator Page' screen.

2.4.2 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 13). These are described below:
 - a. Default sanitization duration: This setting defines the duration of the UV treatment (in minutes) performed when pressing the **Sanitization** button on the 'Home' screen.
 - b. Sanitize after extraction for (**optional**): This setting defines the duration of UV treatment (in minutes) that will be automatically performed after completing 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 starting the Maxwell® CSC 48 RUO Mode software.

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.

Sanitization Settings

Default sanitization duration: 1 minutes

☐ Sanitize after extraction for 1 minutes

☐ Sanitize on software start-up for 1 minutes

SAVE CANCEL

156387A

Figure 13. The ‘Sanitization Settings’ screen.

2.4.3 Methods

The ‘Methods’ screen displays a list of all currently installed methods in the Maxwell® CSC 48 software (both IVD and RUO Modes) including the name, version number, method type (IVD or RUO) 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 14).

1. If you desire to view all 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.

2.4.4 Importing and Deleting Methods

As Promega provides new Maxwell® nucleic acid purification kits for use with the Maxwell® CSC 48 Instrument, new extraction methods can be added to the Maxwell® CSC 48 RUO Mode 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 extraction methods for new Maxwell® kits or updated extraction methods for existing Maxwell® kits from: www.promega.com/resources/software-firmware/maxwell-maxprep/maxwell-csc-48-methods/

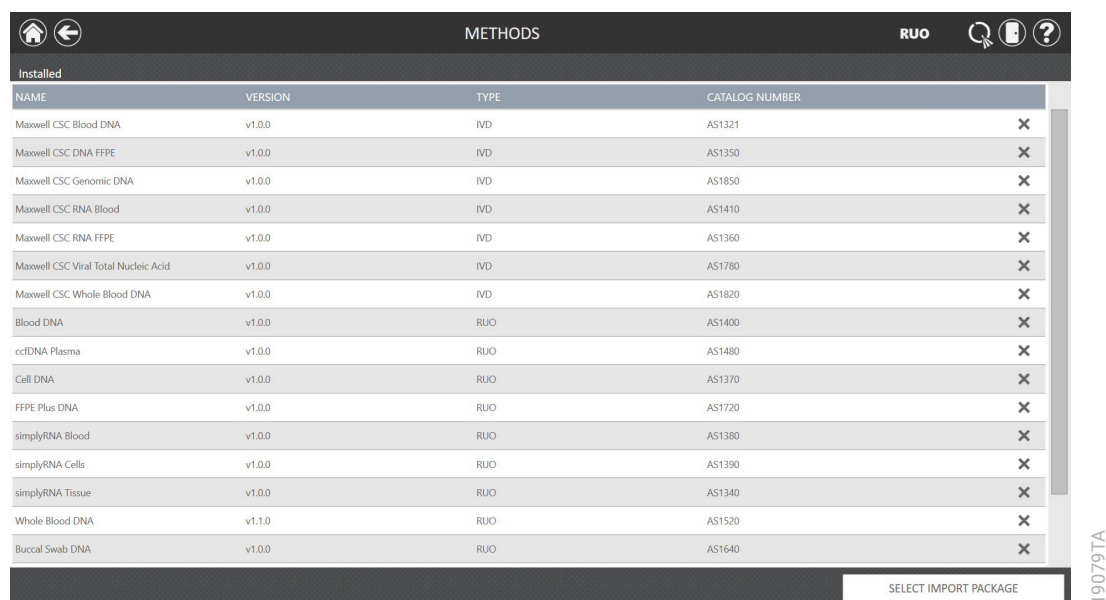
Methods are provided as files with a .package extension. Maxwell® CSC 48 method package files can be imported for IVD mode methods. Maxwell® RSC 48 method package files can be imported for RUO mode methods. Follow the instructions below to import a method into the Maxwell® CSC 48 software.



Note: Both IVD and RUO methods can be imported when in the Maxwell® CSC 48 RUO Mode software. Only RUO methods can be run in the Maxwell® CSC 48 RUO Mode software. Only IVD methods can be run in the Maxwell® CSC 48 IVD Mode software.

1. Save the method (.package) file on the Tablet PC attached to the Maxwell® CSC 48 instrument.
2. If not already running, start the Maxwell® CSC 48 RUO Mode software by double-touching the Maxwell® CSC 48 RUO 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 pop-up window will indicate successful import of the method(s) into the software. If import was successful, the new method file(s) will appear in the list of method files on the 'Methods' screen.

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.



METHODS			
Installed			
NAME	VERSION	TYPE	CATALOG NUMBER
Maxwell CSC Blood DNA	v1.0.0	IVD	AS1321
Maxwell CSC DNA FFPE	v1.0.0	IVD	AS1350
Maxwell CSC Genomic DNA	v1.0.0	IVD	AS1850
Maxwell CSC RNA Blood	v1.0.0	IVD	AS1410
Maxwell CSC RNA FFPE	v1.0.0	IVD	AS1360
Maxwell CSC Viral Total Nucleic Acid	v1.0.0	IVD	AS1780
Maxwell CSC Whole Blood DNA	v1.0.0	IVD	AS1820
Blood DNA	v1.0.0	RUO	AS1400
ccDNA Plasma	v1.0.0	RUO	AS1480
Cell DNA	v1.0.0	RUO	AS1370
FFPE Plus DNA	v1.0.0	RUO	AS1720
simplyRNA Blood	v1.0.0	RUO	AS1380
simplyRNA Cells	v1.0.0	RUO	AS1390
simplyRNA Tissue	v1.0.0	RUO	AS1340
Whole Blood DNA	v1.1.0	RUO	AS1520
Buccal Swab DNA	v1.0.0	RUO	AS1640

SELECT IMPORT PACKAGE

Figure 14. '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 this 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.

2.4.5 Preferences

Administrators can view preferences available in the Maxwell® CSC 48 RUO Mode software by touching the **Preferences** button on the 'Administrator Page' screen. The 'Preferences' screen displays a set of four tabs that can be used by the administrator to adapt the functionality of the software to the needs of the laboratory (Figure 15).

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

Note: Preference settings made in the Maxwell® CSC 48 RUO Mode software only apply to the Maxwell® CSC 48 RUO Mode software. Independent Preferences settings can be made in the Maxwell® CSC 48 IVD Mode software. Available preferences vary by software.

'Common Settings' Tab

The 'Common Settings' tab on the 'Preferences' screen (Figure 15) provides administrators the ability to specify the following options:

- **Allow use of expired kits:** Checking this box allows users to run methods with kits that have passed their expiration date. When this box is unchecked, the software will not allow expired kits to be used for any extraction runs.
- **Allow deletion of results:** When checked, this box will allow users to delete extraction report files from the local database of run reports.
- **Save aborted runs:** When this box is checked, the software will save local run reports for all instrument functions regardless of why they were aborted. If left unchecked, any instrument functions that have been aborted will not generate a local run report.
- **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.
- **Export to PDF:** Checking this box will create a PDF version of exported results in addition to the tab-delimited text file version of the results.
- **Export to Excel:** Checking this box will create an Excel® version of exported results in addition to the tab-delimited text file version of the results.
- **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 as tab-delimited text files. If the options for Export to PDF and/or Export to Excel have been enabled, reports will also be exported in the selected format(s) to the specified drive location.
- **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 48 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.

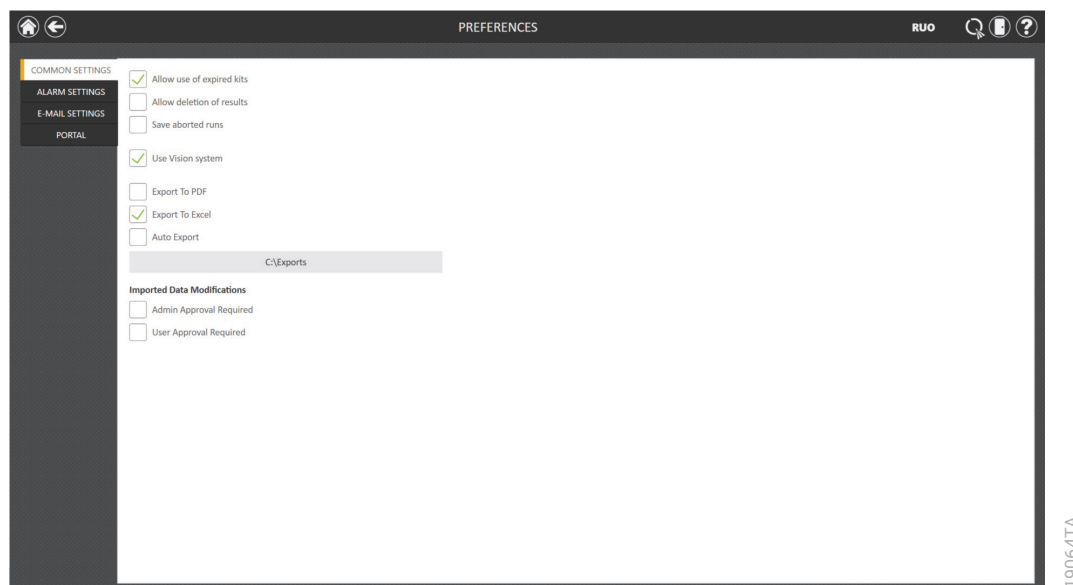


Figure 15. 'Common Settings' tab on the 'Preferences' screen. From the 'Common Settings' tab, the administrator can specify software and export behaviors as well as use of the Vision system camera. Additionally, the approvals required to make changes to sample deck tray layouts retrieved from the Portal software or the Sample Data Import function can be set.

'Alarm Settings' Tab

The 'Alarm Settings' tab on the 'Preferences' screen (Figure 16) 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.

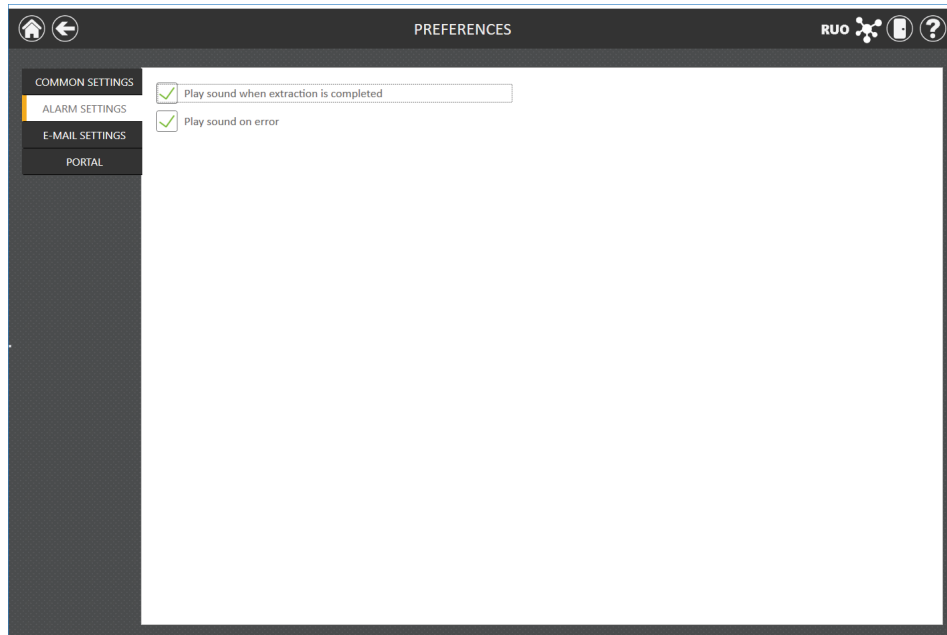


Figure 16. 'Alarm Settings' tab on the 'Preferences' screen. From the 'Alarm Settings' tab, the administrator can specify whether audible alarms should be played on completion of an extraction run or on error.

'E-mail Settings' Tab

The 'E-mail Settings' tab on the 'Preferences' screen (Figure 17) is where e-mail server details are specified and where administrators can determine when and to whom e-mail notifications will be sent. You need to fill out the user and server information on the 'E-mail Settings' tab, and the Tablet PC requires network access to the e-mail server 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 left sidebar contains 'COMMON SETTINGS', 'ALARM SETTINGS', 'E-MAIL SETTINGS' (highlighted), and 'PORTAL'. The main content area is divided into two columns. The left column contains 'User Information' (User Name: user@domain.com), 'E-mail' (user@domain.com), 'Password' (masked with asterisks), 'Server Information' (SMTP Server, SMTP.Server.Address, Port: 25), and a checked 'SSL Encrypted Connection' checkbox. The right column contains two checked checkboxes: 'Send mail when extraction is completed' and 'Send mail on error', followed by an 'E-mail Recipients' field containing 'recipient1@domain.com recipient2@domain.com'. A message at the bottom states 'E-mail settings configuration is changed. Please, test connection!'. A 'TEST CONNECTION' button is located at the bottom center.

Figure 17. '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.

'Portal' Tab

The 'Portal' tab (Figure 18) presents settings for use of the Portal software to connect multiple instrument modules for the purposes of sample tracking and data sharing. Information on this tab will determine whether your system communicates with the Portal software and define the server information necessary to connect to the Portal software. Modifications to sample tracking information retrieved from the Portal software (additions or removals of samples to be processed) can be set to require User or Administrator approvals in the 'Common Settings' tab.

Figure 18. 'Portal' tab on the 'Preferences' screen. The information entered on the 'Portal' tab determines whether Portal Sample Tracking is enabled on your system and allows entry of the communications settings necessary to connect to the Portal software.

If you wish to share sample tracking and other method-specific data between multiple modules, check the 'Enable Portal Sample Tracking' check box on this tab. By default the Portal software is installed on the PC connected to a Maxprep® Liquid Handler (Cat.# AS9105 and AS9205). To allow your system to communicate with Portal software, enter the following information:

- **Server name:** Name of the server hosting the Portal software (Default = Computer Name\PromegaPortal)
- **Database:** Name of the SQL database containing Portal information (Default = Portal)
- **User name:** User name necessary to access the Portal software (Default = PortalLogin)
- **Password:** Password necessary to access the Portal software (Default = PortalLogin)
- **Use Windows Authentication:** A check box that when checked, uses the Windows® login information for the User name and Password to access the Portal software (Default = unchecked).

Once the Portal software connection information has been entered, press the **Test Connection** button to determine whether the Maxwell® CSC 48 RUO Mode software can successfully connect to the Portal software using the information supplied. A message will be displayed indicating whether the connection was successful. If unsuccessful, confirm that the connection information was correctly entered and try again.

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.

2.4.6 Audit Records

The Maxwell® CSC 48 RUO Mode 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 19). 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.

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

DATE/TIME	STATUS	OPERATOR	OPERATION	CONTEXT/MESSAGE
6/10/2024 12:29:21 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	Whole Blood DNA Promega.Metadata.Versioning
6/10/2024 12:29:20 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1340
6/10/2024 12:29:20 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1520
6/10/2024 12:29:19 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	simplyRNA Tissue Promega.Metadata.Versioning
6/10/2024 12:29:19 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	simplyRNA Cells Promega.Metadata.Versioning
6/10/2024 12:29:19 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1390
6/10/2024 12:29:19 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	simplyRNA Blood Promega.Metadata.Versioning
6/10/2024 12:29:19 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1380
6/10/2024 12:29:18 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	RNA FFPE Promega.Metadata.Versioning
6/10/2024 12:29:18 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1440
6/10/2024 12:29:17 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	Pathogen Total Nucleic Acid Promega.Metadata.Version...
6/10/2024 12:29:17 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1890
6/10/2024 12:29:17 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	miRNA Tissue Promega.Metadata.Versioning
6/10/2024 12:29:17 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1460
6/10/2024 12:29:16 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1720
6/10/2024 12:29:16 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	FFPE Plus DNA Promega.Metadata.Versioning
6/10/2024 12:29:16 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1880
6/10/2024 12:29:16 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	Genomic DNA Promega.Metadata.Versioning
6/10/2024 12:29:15 PM	Success	DESKTOP-BNG11ML\user	Imported protocol	Fecal Microbiome DNA Promega.Metadata.Versioning
6/10/2024 12:29:15 PM	Success	DESKTOP-BNG11ML\user	Imported kit	AS1700

Figure 19. 'Audit Records' screen. A user-readable record of events that have occurred in the Maxwell® CSC 48 RUO Mode software can be viewed by the administrator and exported to a specified drive location from the 'Audit Records' screen.

EXPORT FOLDER

Drive\ C:\ Logs\

SoftwarePlatform\form\

SAVE CANCEL

Figure 20. 'Export Folder' screen. From the 'Export Folder' screen you can set the folder location to which all displayed audit records will be exported.

2.4.7 Instrument Name



Note: You are unable to specify different instrument names in RUO Mode and IVD Mode for a single Maxwell® CSC 48 Instrument.

You can 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.

1. From the 'Administrator Page' screen, touch the **Instrument Name** button to open the 'Instrument Name' screen (Figure 21).
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.
6. 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.

Figure 21. 'Instrument Name' screen. Use this screen to enter a name for this Maxwell® CSC 48 instrument.

3 Operating the Maxwell® CSC 48 Instrument

3.1 Preprogrammed Methods

The preprogrammed extraction methods available for the Maxwell® CSC 48 Instrument when running in RUO Mode can be used to perform nucleic acid purifications from a variety of sample types using research use only Maxwell® RSC kits. The sample type and type of molecule extracted are determined by the Maxwell® RSC reagent kit used. Please refer to your specific Maxwell® RSC reagent kit Technical Manual for information on sample preparation and handling. Two mechanisms for selecting a method to run are enabled in the Maxwell® CSC 48 RUO Mode software:

- Scanning the bar code on a Maxwell® RSC reagent kit box. This will select the appropriate installed method for that kit.
- When in Portal mode, scanning the bar codes on the top of the deck trays will retrieve information from the Portal software to automatically select the appropriate installed method based on the preprocessing method that was run on a Maxprep® Liquid Handler.

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

3.2 Starting a Method

1. Either manually or using the Maxprep® Liquid Handler, prepare samples for nucleic acid purification following the instructions provided in the Technical Manual for the specific Maxwell® RSC reagent kit. From the 'Home' screen (Figure 22), select the **Start** button to begin the process of running an extraction method.



Figure 22. 'Home' screen. Selecting the **Start** button begins the process of running an extraction method on the Maxwell® CSC 48 Instrument.

3.2.1 Portal Mode

If the Maxwell® CSC 48 RUO Mode software is connected to the Portal software, the 'Scan Trays' screen will be displayed (Figure 23, Panel A). Touch the appropriate text box and scan the bar code on the top of the deck tray. After entering the bar code information for the deck tray, press the **Continue** button to query the Portal software for Maxprep® Liquid Handler preprocessing information associated with this deck tray.

The 'Preprocessing Info' screen (Figure 23, Panel B) will be displayed summarizing the information found for the deck tray bar code. If preprocessing information for this deck tray has been found, the summary will contain:

- **Barcode:** The deck tray bar code entered.
- **Date Modified:** Date and time at which the preprocessing was performed. Date information will be indicated in red text if the preprocessing was performed prior to the current date.
- **Kit ID:** The catalog number of the kit used for preprocessing.

If no valid preprocessing information was found associated with this deck tray, the 'Preprocessing Info' screen will indicate that no information was found.

- To perform an extraction using the information associated with this deck tray from a prior Maxprep® Liquid Handler preprocessing method, press the **Continue** button. The sample identifiers and kit information from that preprocessing method will be imported into the Maxwell® CSC 48 RUO Mode software. The 'Cartridge Setup' screen will be displayed for the appropriate extraction method that matches the preprocessing method. All sample identifier information entered during the preprocessing method run on the Maxprep® Liquid Handler will be displayed for each cartridge.

If no preprocessing information was found, or to abandon the information that was found associated with this deck tray, press the **New** button. Alternatively, press the **Cancel** button to return to the 'Home' screen. When starting a new method, scan the bar code for the desired kit to select a method. All kit lot and sample tracking information will have to be entered on the 'Cartridge Setup' screen for this run. If a Maxwell® reagent kit supports multiple workflows with multiple methods, scan or enter the bar code information to bring up a method selection screen displaying all the available methods associated with that kit prior to migrating to the 'Cartridge Setup' screen. Touch the desired workflow method to highlight it and touch the **Proceed** button.

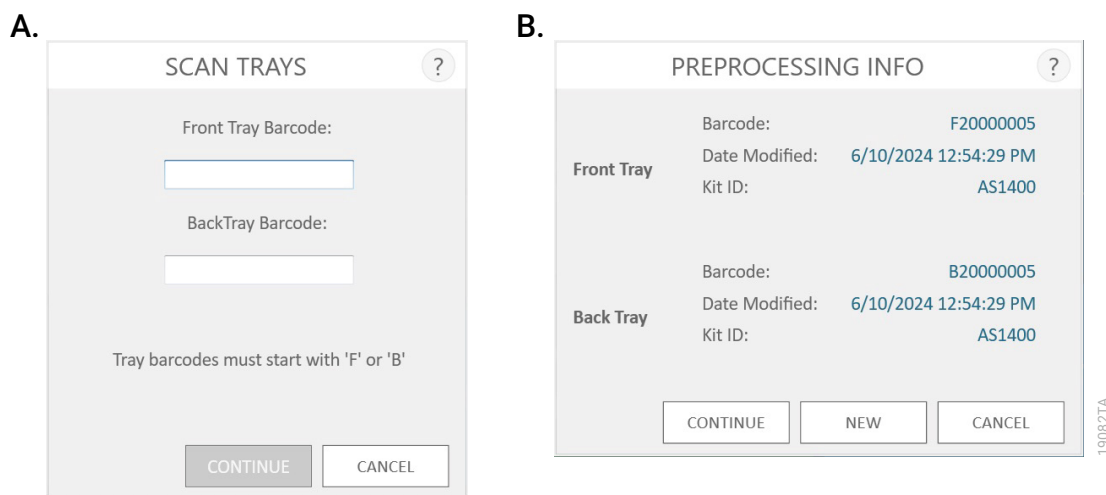


Figure 23. Portal mode requires scanning of deck tray bar codes. Panel A. When starting a run in Portal mode, scan the bar codes on the front and back deck trays to retrieve information about any prior preprocessing method performed on a Maxprep® Liquid Handler. **Panel B.** A summary of any preprocessing information retrieved from Portal for the indicated deck tray is presented on the 'Preprocessing Info' screen. Press **Continue** to start an extraction method using the information retrieved for this deck tray. If no preprocessing information is found, or if you do not wish to use the information that was found, touch the **New** button to start an extraction. All kit lot and sample identifier information will have to be entered for the extraction run.

3.2.2 Local Mode

On the 'Scan Barcode' screen (Figure 24), scan the bar code on the Maxwell® RSC reagent kit box indicated by the Scan Here label (Figure 25), or enter the bar code information using the keyboard. Maxwell® CSC 48 requires manual entry of bar codes in the following format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format (example: AS13303221872018-05, where the product catalog number is AS1330, the kit lot number is 322187 and the expiration date is 2018-05). Only if the bar code entered has this format will the corresponding extraction method be selected and the 'Cartridge Setup' screen displayed. Scanning or entering the bar code information from a kit will select the method to be run (assuming it is installed in the software) and will also record kit lot and expiration date information for the extraction run report. If a Maxwell® RSC reagent kit supports multiple workflows, scan or enter the bar code information to bring up a method selection screen with each of the available workflows to select. Touch the desired workflow method to highlight it and then touch the **Proceed** button.

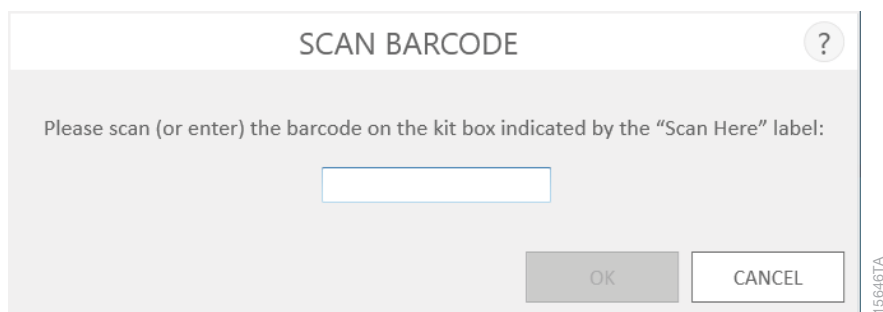


Figure 24. Entering a kit barcode. Scan the Maxwell® RSC reagent kit bar code to select the method corresponding to that kit. When running in Portal mode, information retrieved from the Portal software (if any) will automatically select the appropriate extraction method for the preprocessing method that was performed on the Maxprep® Liquid Handler.

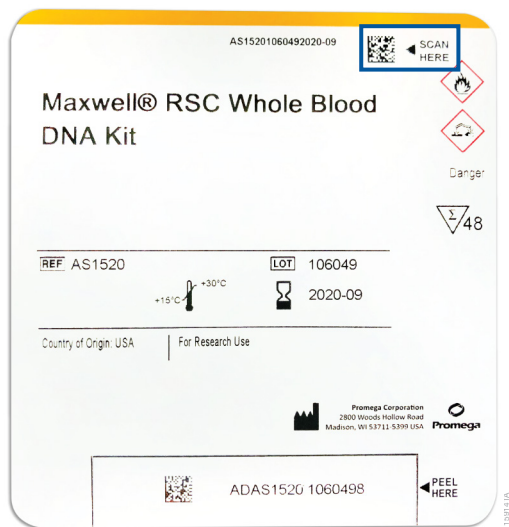


Figure 25. Kit label indicating bar code to scan. Shown in the blue box is the bar code to scan on the kit label for starting an extraction run.



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 (Figure 25). You will receive an error message if you enter data from the wrong kit.

3. There are three potential error modes that can occur when using Portal or the reagent kit bar code information to select a method:
 - 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. An administrator option can be set to allow the use of expired reagent kits on the system (see Section 2.4.5, Preferences). If the administrator has allowed the use of expired kits, a user prompt will appear indicating that the kit has passed the expiration date but the method will be allowed to continue.
 - b. If the product catalog number does not have an extraction 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 (e-mail: techserv@promega.com) to get the most updated information on the available methods.
 - c. If the product catalog number is for a Maxwell® CSC 48 IVD kit, a user prompt will appear indicating that it is incompatible with this mode of operation. Upon pressing the **OK** button on the user prompt, the software will return to the 'Home' screen. Close the Maxwell® CSC 48 RUO Mode software and double-tap the Maxwell® CSC 48 IVD icon on the desktop to open the Maxwell® CSC 48 IVD Mode software in order to run this kit.
4. After selecting an extraction method, you will be presented with the 'Cartridge Setup' screen (Figure 26) on which you specify the positions on the Maxwell® CSC 48 deck trays that will be occupied by cartridges and enter sample tracking information for each sample. Toggle between the front (positions 1–24) and back (positions 25–48) deck trays using the **Front** and **Back** buttons in the lower left of the screen.

Note: If running in local mode with the Vision system enabled and no sample tracking options selected, no cartridge positions will need to be selected. The user will be prompted to open the door of the instrument. Proceed to Step 5.

When running in Portal mode, cartridge positions will be automatically selected and sample tracking information associated with the scanned deck tray will be automatically populated at each cartridge position based on the information that was entered during preprocessing on a Maxprep® Liquid Handler. The 'Cartridge Setup' screen will be locked for editing and provides the user a chance to review existing sample tracking data. Press the **Enable Editing** button to edit or remove cartridge information retrieved from the Portal software. Cartridge positions can be added to the deck trays without pressing the **Enable Editing** button. Based on administrator settings (see Section 2.4.5, Preferences) it may be necessary to enter user or administrator credentials to proceed if Portal data has been edited.

When running in local mode, cartridge positions and identification information may be entered manually (option 1) or using the sample data import function (option 2).



Note: A red exclamation point icon is displayed at the top of cartridge positions when required data is missing or cartridges do not meet expiration date requirements specified by the administrator. Touch the red exclamation point icon for a description of the issue with a given cartridge position.

Option 1: Manual Entry

- a. Select cartridge positions by touching the long rectangle for each position that will be used. If the Vision system is activated on your system (see Section 2.4.5, Preferences), the processing positions specified on the deck trays as well as the correct setup of the deck trays are confirmed by the system. If the Vision system is deactivated, the processing positions specified on the deck trays are only used for reporting purposes to indicate how many samples were processed and in which positions they were processed on the instrument.
- b. Once cartridge positions are selected, you must enter all administrator-specified sample tracking information to proceed (Figure 28). Administrators may configure sample tracking information of sample identifiers such as Sample ID, Kit Lot Number, cartridge ID, elution ID and other information required by two additional administrator-defined fields. All of the required information must be entered for all selected cartridge positions before the **Proceed** button becomes active.
- c. Touch the black box below a cartridge position to enter sample identifier information for the selected position. If cartridge and elution tube bar codes are required, we recommend that these are entered 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 27, 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, 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 27, 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 data type present in each column of the file using the drop-down menu at the top of each column. The Cartridge position is minimally required, however other categories can be the Sample ID bar code, 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 2.4.1, Sample Entry for more information. For columns that should be ignored during import, select **X** from the drop-down menu.

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

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

- f. Once all data fields are identified, touch 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.

Note: Positions with incomplete information will display a red circle with an exclamation point at the top of the gray rectangle. Touch the red circle with an exclamation point to display a message indicating the required information that is missing for that position. 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 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 manually, the bar code needs to conform to the format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format

(example: AS13303221872018-05 where the product catalog number is AS1330, the kit lot number is 322187 and the expiration date is 2018-05). Additional kit lots must be consistent with the product catalog number for the method, and will be assessed for expiration date.

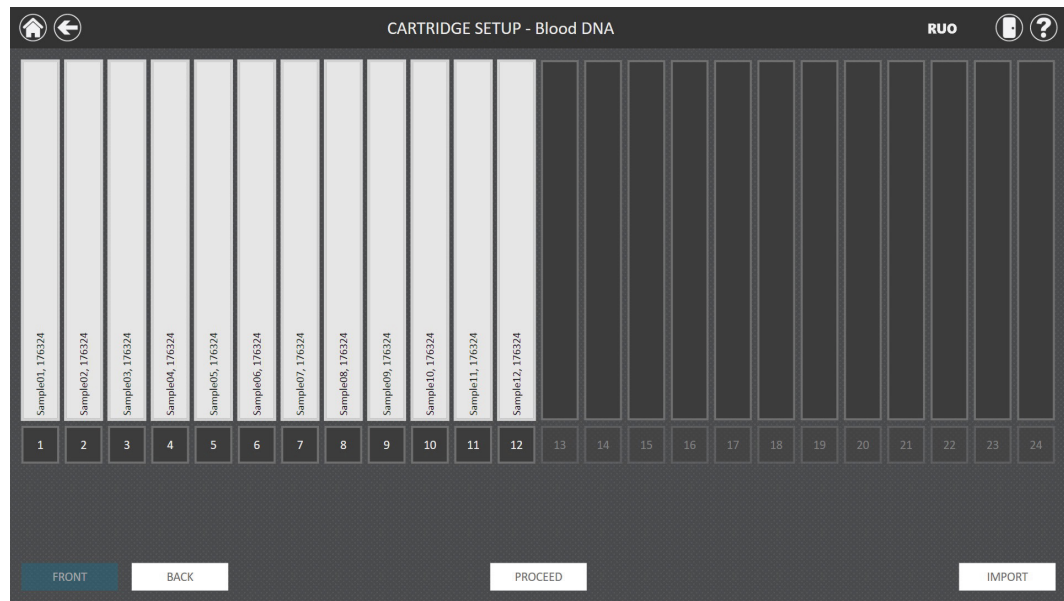


Figure 26. 'Cartridge Setup' screen. At the top of this screen the selected method is indicated. This screen allows the user to select which cartridge positions will be processed. To select or deselect a cartridge position, touch the long rectangle for any given position. Use the **Front** and **Back** buttons to toggle between views of the front (positions 1–24) and back (positions 25–48) deck trays. Touch the **Import** button to open the 'Sample Data Import' screen and import the deck tray layout from an external file.

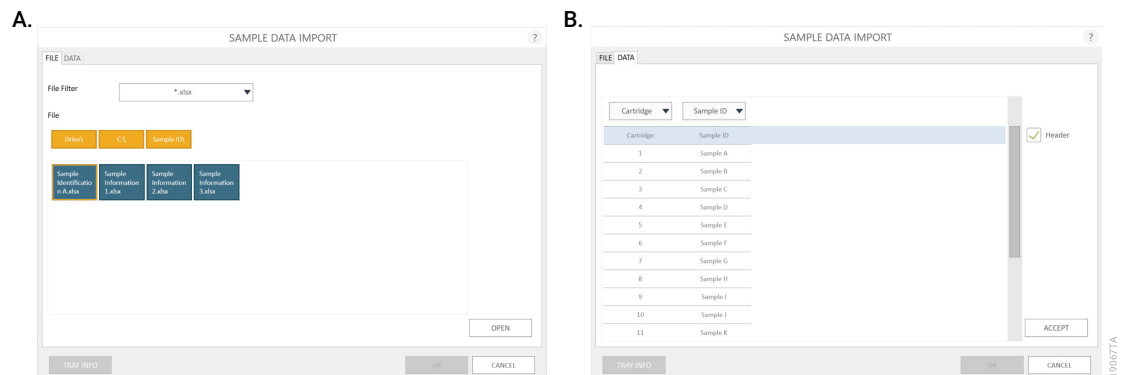


Figure 27. Sample Data Import. Panel A. The 'File' tab is displayed after touching the **Import** button. Select the file filter and navigate to the file location where the sample import file is located. Touch the desired blue box file and touch the **Open** button to open up the 'Data' tab and view the sample ID information in the file or **Cancel** to return to the 'Cartridge Setup' screen. **Panel B.** The 'Data' tab is displayed after the **Open** button is touched. 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, press the **Accept** button to apply the information to the 'Cartridge Setup' screen.

The screenshot shows the 'CARTRIDGE SETUP - Blood DNA' interface. It features a grid of 24 cartridge positions. The first 8 positions are labeled 'Sample A, 154095' through 'Sample H, 154095'. The next 4 positions (9-12) are labeled '154095'. The remaining 12 positions (13-24) are empty. A red exclamation mark is displayed at the top of each of the first 12 positions. Below the grid is an orange bar with two input fields: 'Sample ID' and 'Kit Lot Number', both containing the value '154095'. At the bottom of the screen are four buttons: 'FRONT', 'BACK', 'PROCEED', and 'IMPORT'.

Figure 28. Sample tracking entry. The sample tracking entry fields on the 'Cartridge Setup' screen are administrator-configurable. If your administrator has activated sample tracking (example above is for Sample ID and Kit Lot Number), select the black box at the bottom of any cartridge position and enter the Sample ID and kit lot information for that position. Touching the arrow on the right side of the entry area will move to the next available cartridge position. Select multiple positions (by swiping across the positions to be selected) to enter kit lot information for multiple cartridge positions. If sample tracking has been enabled, all required values must be entered (using the on-screen keyboard or bar code reader) prior to proceeding. Positions with incomplete information will display a red circle with an exclamation point at the top of the gray rectangle. Touch the red circle with an exclamation point to display a message indicating the required information that is missing for that position.

5. After all required information has been entered, touch the Proceed button to display the 'Door' prompt. Press the **OK** button to open the Maxwell® CSC 48 Instrument door.
6. You will be presented with an 'Extraction Checklist' screen (Figure 29). After performing each checklist item, touch the **Confirm** button next to that item to indicate that it has been performed. Only after all of the checklist items have been confirmed will the **Start** button become active.

EXTRACTION CHECKLIST ?

CONFIRM

CONFIRM

CONFIRM

Sample pre-processing is complete as per the Blood DNA Technical Manual instructions

Deck tray has been prepared as follows and placed in the instrument:

- Cartridges with seals completely removed placed at positions 1-12,25-29
- Samples have been placed in the appropriate well(s) of each cartridge
- Sample identification information added correctly for each cartridge (if applicable)
- Elution tubes placed at positions 1-12,25-29 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 the appropriate well of each cartridge

Plungers are not present on instrument plunger bar

START

CANCEL

19069TA



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.

Figure 29. '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.

The steps necessary for setting up the instrument are:

- Sample preprocessing is complete. Sample preprocessing, if required, is described in the Technical Manual for the specific Maxwell® RSC reagent kit. Preprocessing can be performed manually or using the Maxprep® Liquid Handler.
- Place cartridges at the selected positions in the deck tray. Press down firmly to snap the cartridges in place at both ends. There should be an audible click.
- Completely remove seals from all cartridges.
- Place elution tubes at the selected positions in the deck tray.
- Add the appropriate volume of elution buffer to each elution tube (see the Maxwell® RSC 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 Section 2.3.3, Clean Up, for instructions to remove plungers.
- 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).



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, and the samples will be lost.

- Place the deck trays in the instrument with the Back tray on the back deck position and Front tray on the front deck position. 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 (Figure 30). 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.

Touch the **Start** button to begin the extraction, or touch the **Cancel** button to return to the 'Cartridge Setup' screen.



Figure 30. Placing the deck tray in the instrument.

- 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 proper 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.



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

8. While the extraction method runs, you will see the 'Running' screen (Figure 31). 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.

Some instrument functions (e.g., viewing reports) can be performed 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.

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

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

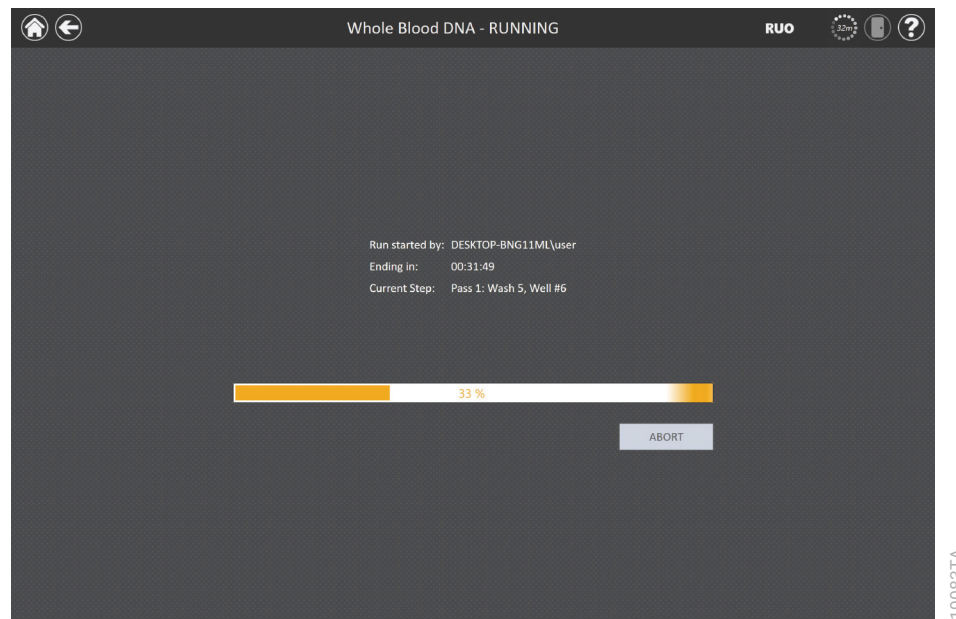


Figure 31. Method 'Running' screen. The method 'Running' screen is displayed during an extraction method run. This screen indicates what method is currently being run at the top of the screen. Also indicated on this screen are the user who started the run, an approximate indication of when the run will 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.

3.2.3 Method Completes Successfully

When the method completes successfully the method 'Protocol Running' screen will indicate that the extraction method has been completed (Figure 32). 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.

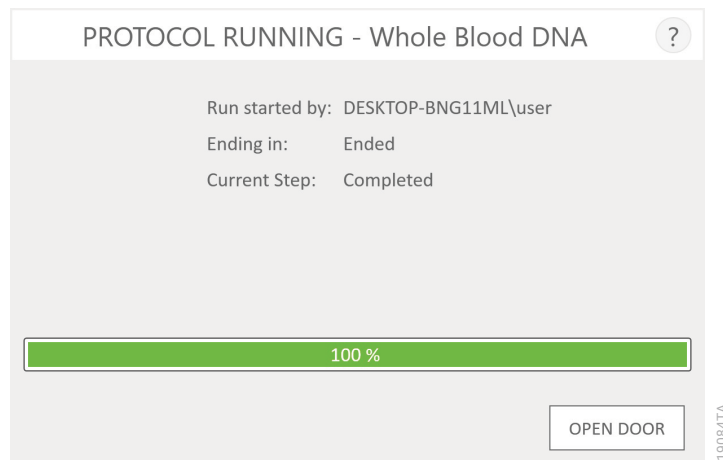


Figure 32. 'Protocol Running' screen after method completion. Upon completion of an extraction method, the progress bar will show 100% completion. The Current Step changes to "Completed" after a run is finished. After a method is complete, you can touch the **Open Door** button to open the door of the Maxwell® CSC 48 Instrument.



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.

Close the caps of the elution tubes, and remove the tubes from the deck tray (Figure 33, Panel A). Verify that all the cartridges have a plunger in well #8. Remove the deck tray by gripping firmly by the elution tube position, lifting up and pulling the tray out (Figure 33, Panel B). The deck tray may be warm to the touch after a run is completed. Exercise caution while removing the deck tray. If there were cartridges missing plungers, proceed to Section 3.3 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 to continue the run. If the method is not a sequential protocol, remove the cartridges and plungers from the Maxwell® CSC 48 deck trays.

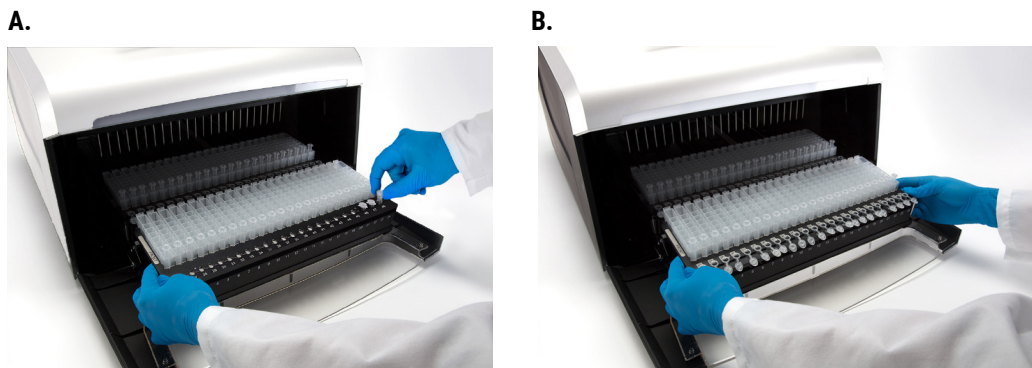


Figure 33. Post-run actions. Close the elution tube caps and remove elution tubes (**Panel A**), then remove the deck tray from the instrument (**Panel B**).

After the door is opened, the 'Report View' screen (Figure 34) will be presented. If the administrator has required that UV sanitization be performed after an extraction 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 3.7, Sanitize).

REPORT VIEW													RUO					
Extraction Report																		
Blood DNA v1.0.0																		
Protocol													MAXWELL® CSC 48			Catalog Number: A51400		
Run Status													Software Version			v4.0.0 User Confirmations:		
Operator													Instrument Name			PRIME/CARBONIZANT		
Run Date													Instrument Serial No			23000047		
																</		

3.2.4 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 35). 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 37) will be displayed.

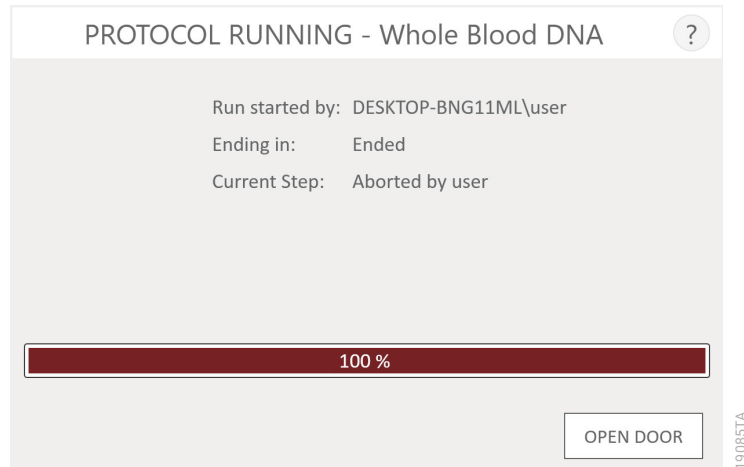


Figure 35. 'Protocol Running' screen after abort by the user. If a method is aborted by the user, the 'Protocol Running' screen will display a progress bar of 100%, and Current Step is shown as "Aborted by user". After a method is aborted, press the **Open Door** button.

3.2.5 Instrument Error

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.

3.3 Clean Up



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 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 36) will be displayed.

The 'Clean Up' screen requests the user check if plungers are still engaged on the plunger bar. If the plungers are not engaged, remove the deck tray from the instrument and touch the **Skip Clean Up** button to continue. On pressing the **Skip Clean Up** button, you will be presented with the extraction report (Figure 42).

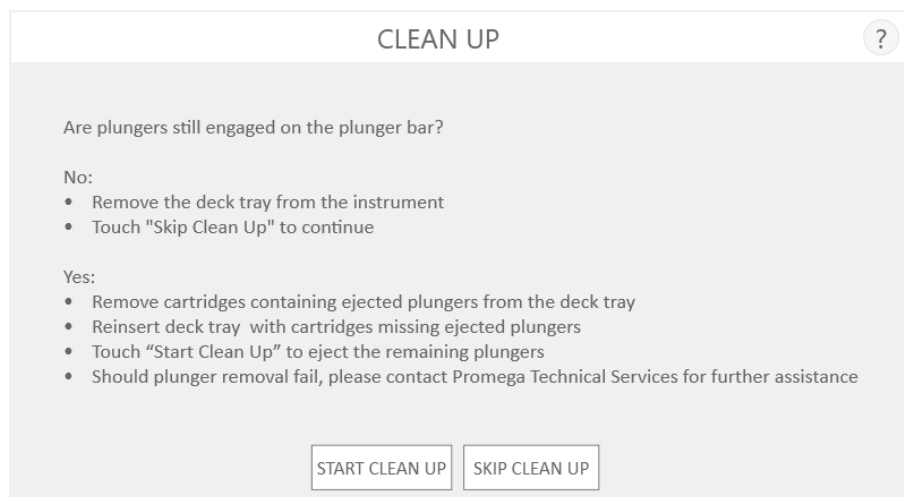


Figure 36. 'Clean Up' screen after abort/instrument error. If an extraction method is aborted by the user or due to an instrument error and the Vision system has been disabled, the 'Clean Up' screen is displayed and asks you to **Start Clean Up** or **Skip Clean Up**, depending on whether the plungers are still engaged on the plunger bar.

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

- Remove cartridges containing ejected plungers from the deck tray.
- Reinsert the deck tray 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.

3.4 Quantitating with the Quantus™ Fluorometer

If a Quantus™ Fluorometer is attached to the instrument, results from the Quantus™ Fluorometer can be appended to completed run reports on the Maxwell® CSC 48 Instrument in RUO mode.

For integrated quantitation using the Quantus™ Fluorometer, unpack the Quantus™ Fluorometer as described in the *Quantus™ Fluorometer Operating Manual #TM396*, and then connect the USB cable to a USB port on the right front side of the Maxwell® CSC 48 Instrument. Refer to the *Quantus™ Fluorometer Operating Manual #TM396* for the operating instructions. To quantitate nucleic acids and generate results that can be added to the run report, the Quantus™ Fluorometer must be calibrated and used with an appropriate fluorescent dye.

If the Quantus™ Fluorometer is correctly connected and ready to run, the “Q” logo will be displayed in the upper right corner of the title bar (Figure 37), and the display on the Quantus™ Fluorometer will be active.



Figure 37. Maxwell® CSC 48 'Home' screen. When the Quantus™ Fluorometer is correctly connected to the Maxwell® CSC 48 instrument, the “Q” logo is displayed in the upper right corner of the title bar.

Prior to quantification, verify the Quantus™ Fluorometer has the appropriate protocol selected. If the Quantus™ Fluorometer needs calibration or the mode needs to be changed, consult the *Quantus™ Fluorometer Operating Manual #TM396*.

1. When a Maxwell® CSC 48 RUO Mode run is completed, the run report will be displayed (Figure 38). To append quantitation data to an existing Maxwell® CSC 48 RUO Mode run report, select **Results** from the 'Home' screen. On the 'Results' screen, select the run report to which quantitation data should be added.

REPORT VIEW									
Blood DNA v1.0.0									
1	Extraction Report								
2	Blood DNA v1.0.0								
3									
4	Protocol	Blood DNA v1.0.0			Software	MAXWELL® CSC 48 Catalog Number: AS1400			
5	Run Status	Completed			Software Version	v4.0.0 User Confirmations:			
6	Operator	PROMEGA/chenchen			Instrument Name	PROMEGA/INSTRUMENT			
7	Run Date	5/3/2024			Instrument Serial No	23000047			
8	Deck tray has been prepared as follows and placed in the instrument:								
9	Start Time	2:47:03 PM			Firmware Version	v6.2.12			
10	End Time	3:22:51 PM			Mode	v6.2.12			
11	Duration	00:35:49			Plungers are not present on instrument plunger bar (RUO)				
12	Position	Catalog Number	Sample ID	Lot Number	Expiration Month	Cartridge ID	Elution Tube ID	Custom1	Custom2
13	1	AS1400	Sample A	154095	2030-12				
14	2	AS1400	Sample B	154095	2030-12				
15	3	AS1400	Sample C	154095	2030-12				
16	4	AS1400	Sample D	154095	2030-12				
17	5	AS1400	Sample E	154095	2030-12				
18	6	AS1400	Sample F	154095	2030-12				
19	7	AS1400	Sample G	154095	2030-12				
20	8	AS1400	Sample H	154095	2030-12				
21	9	AS1400	Sample I	154095	2030-12				
22	10	AS1400	Sample J	154095	2030-12				
23	11	AS1400	Sample K	154095	2030-12				
24	12	AS1400	Sample L	154095	2030-12				
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	AS1400	Sample M	154095	2030-12				
38	26	AS1400	Sample N	154095	2030-12				
39	27	AS1400	Sample O	154095	2030-12				
40	28	AS1400	Sample P	154095	2030-12				
41	29	AS1400	Sample Q	154095	2030-12				
42	30								
43	31								
44	32								
45	33								
46	34								

Figure 38. 'Report View' screen. Touch the **Quantitate** button in lower left corner of a run report to associate quantitation values read by a Quantus™ Fluorometer with samples from this run.

2. Select **Quantitate** on the lower left corner of the screen to display the 'Quantus Measurement' screen (Figure 39).
3. The 'Measure Sample Selection' screen will display on the Quantus™ Fluorometer.
4. Select the sample you wish to quantitate by touching the sample number that represents the elution position on the Maxwell® CSC 48 RUO Mode Software. You can toggle between samples on the front and back deck trays using the **Front** and **Back** buttons on the lower left corner of the screen.

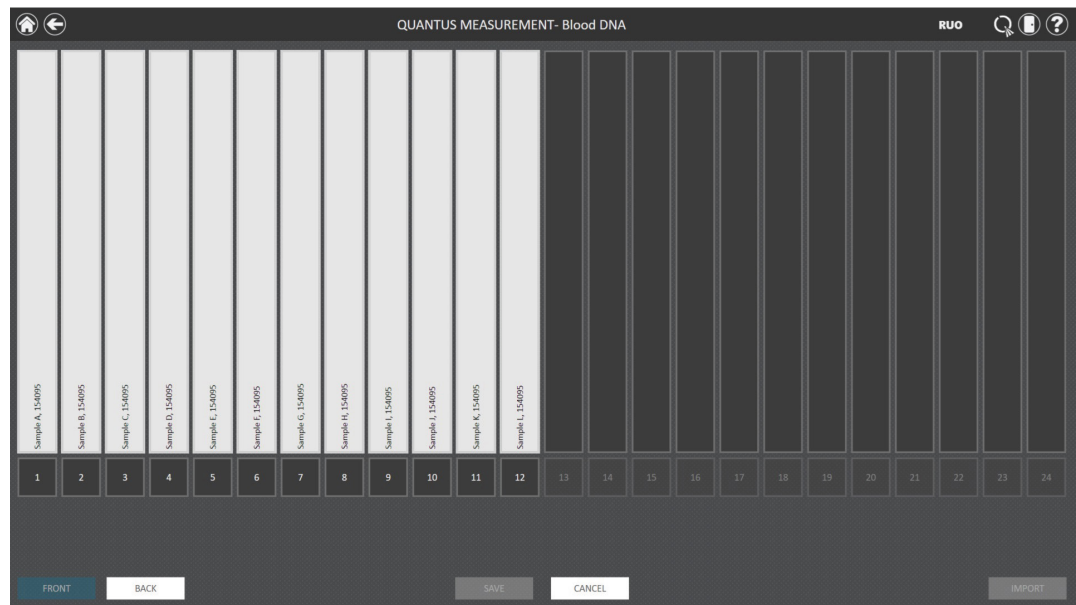


Figure 39. Quantus™ measurement. From this screen, select the sample position (black square below the cartridge) for which you would like to quantitate the sample with a Quantus™ Fluorometer. Toggle between front and back deck trays using the **Front** and **Back** buttons in the lower left corner of the screen.

5. Open the Quantus™ Fluorometer lid by pressing down on the lower right corner of the sample lid.
6. Place the sample to be quantitated (consult the *Quantus™ Fluorometer Operating Manual* #TM396 for instructions on adding sample to dye) into the Quantus™ Fluorometer, and close the lid.
7. After quantitation is complete, a result will be displayed to the right of the sample identifier on the 'Quantus Measurement' screen (Figure 40).

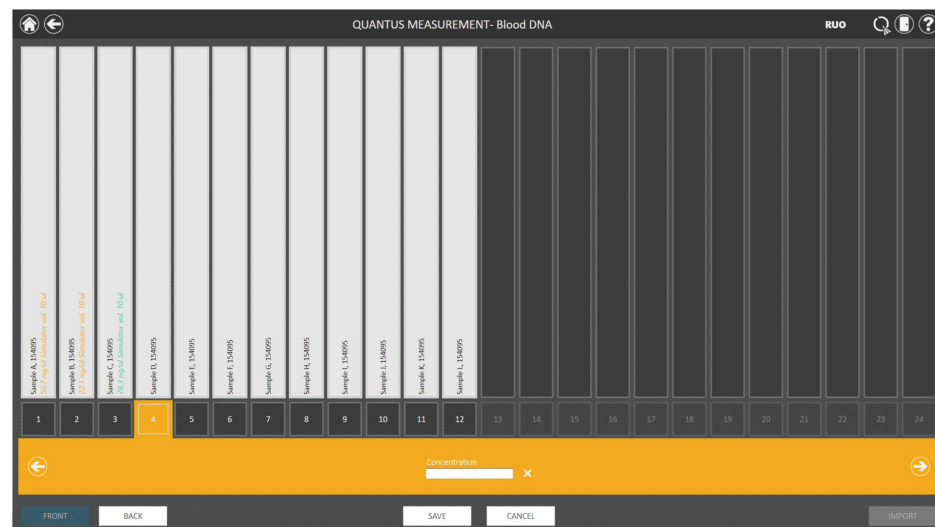


Figure 40. 'Quantus Measurement' screen. After making a quantitation measurement with the Quantus™ Fluorometer, the quantitation value is displayed to the right of the sample identifier.

8. Press down on the lower right corner of the Quantus™ Fluorometer lid to open the Quantus™ and remove the quantitated sample.
9. Discard the sample per your institutional disposal regulations.
10. After a sample has been quantitated, the selection will shift to the next sample. To manually move between samples, either press the arrow buttons on the lower right or left of the 'Quantus Measurement' screen or touch the sample number.
11. Insert the next sample into the Quantus™ Fluorometer and repeat Steps 6–10 until all the samples are quantitated.
12. When all samples have been quantitated, select the button in the center bottom of the 'Quantus Measurement' screen. To discard quantitation data and return to the 'Report View' screen, press the button.
13. A dialog box for the quantitation parameters will pop up (Figure 41). Enter the name of the kit used to quantitate the sample and a description of the standard used for calibration.
14. After entering the information, touch the **OK** button or **Cancel** to return to the 'Quantus Measurement' screen.
15. The quantitation data will be stored, and the run report will be displayed.

QUANTITATION PARAMETERS ?

Kit Used

Standard Used

OK CANCEL

144457A

Figure 41. 'Quantitation Parameters' screen. Enter the name of the kit used to quantitate the sample and a description of the standard used for calibration.

3.5 Reports

The 'Report View' screen is displayed after pressing the **Open Door** button on the 'Protocol Running' screen (Figure 42). Run reports can be accessed later by selecting the **Results** button on the Maxwell® CSC 48 RUO Mode 'Home' screen (Section 3.6).

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, software mode, instrument name, serial number, etc.).

Protocol	Blood DNA v1.0.0	Software	MAXWELL® CSC 48 Catalog Number: AS1400
Run Status	Completed	Software Version	v8.0.0 User Confirmations:
Operator	PRIMEGA/Genetion	Instrument Name	PRIMEGA/INSTRUMENT Sample pre-processing is complete as per the Blood DNA Technical Manual Instructions
Run Date	5/1/2024	Instrument Serial No.	73000047
Start Time	2:47:03 PM	Firmware Version	v8.2.12
End Time	3:22:52 PM	Mode	RUO
Duration	00:35:49		
Catalog Number	Sample ID	Lot Number	Expiration Month
AS1400	Sample A	154095	2030-12
AS1400	Sample B	154095	2030-12
AS1400	Sample C	154095	2030-12
AS1400	Sample D	154095	2030-12
AS1400	Sample E	154095	2030-12
AS1400	Sample F	154095	2030-12
AS1400	Sample G	154095	2030-12
AS1400	Sample H	154095	2030-12
AS1400	Sample I	154095	2030-12
AS1400	Sample J	154095	2030-12
AS1400	Sample K	154095	2030-12
AS1400	Sample L	154095	2030-12
AS1400	Sample M	154095	2030-12
AS1400	Sample N	154095	2030-12
AS1400	Sample O	154095	2030-12
AS1400	Sample P	154095	2030-12
AS1400	Sample Q	154095	2030-12

Figure 42. 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, or **Quantitate** to associate quantitation data with the report.

Sample quantitation results can be added to a report using an integrated Quantus™ Fluorometer by selecting **Quantitate** in the bottom left of the screen. See Section 3.4 for instructions on operating the Quantus™ Fluorometer.

Quantitation results can be reviewed (if collected and saved) by touching the 'Quantitation' tab (Figure 43) on the bottom of the Run report.

Position	Elution Tube ID	Concentration (ng/ul) 1
1	Sample A	121
2	Sample B	137.9
3	Sample C	143
4	Sample D	150
5	Sample E	175
6	Sample F	189.9
7	Sample G	145.3
8	Sample H	186.8
9	Sample I	153
10	Sample J	185.4
11	Sample K	157
12	Sample L	165
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31	Sample M	187.2
32	Sample P	167.3
33	Sample Q	133.4
34		
35		
36		
37		
38		
39		
40		
41		
42		
43		
44		
45		
46		
47		
48		
49		
50		
51		
52		

Figure 43. Quantitation report tab. The quantitation report tab shows sample quantitation data gathered using the Quantus™ Fluorometer.

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 Microsoft Excel® format and/or PDF format, depending on administrator settings (Figure 44).

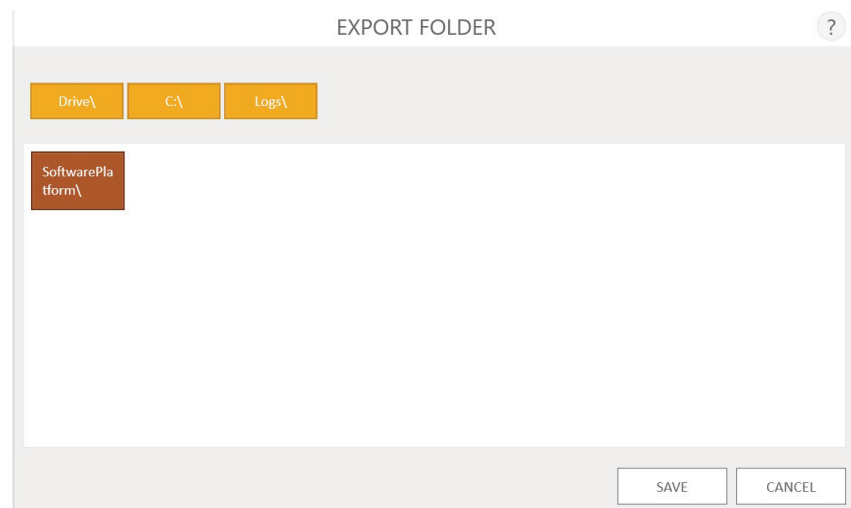
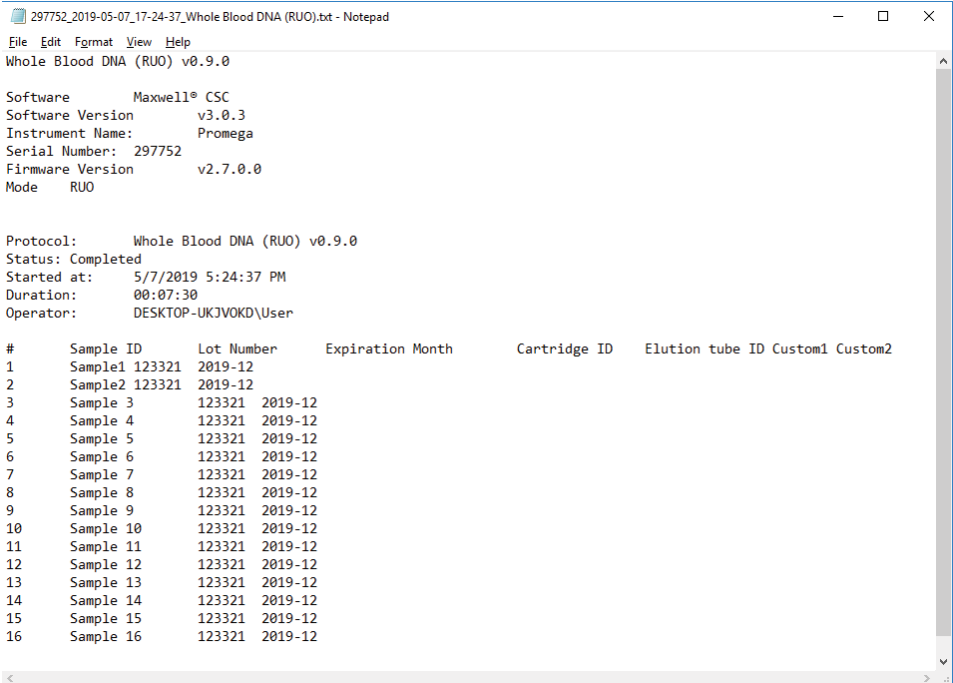


Figure 44. 'Export Folder' screen. When the **Export** button is pressed, the user will be asked to navigate to the file location where report files should be saved.

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 RUO Mode software exports reports in tab-separated text format as well as .xlsx format and .pdf format, depending on administrator settings. You can use the Excel® viewer or PDF viewer to view the report.

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 45.



297752_2019-05-07_17-24-37_Whole Blood DNA (RUO).txt - Notepad

File Edit Format View Help

Whole Blood DNA (RUO) v0.9.0

Software Maxwell® CSC
 Software Version v3.0.3
 Instrument Name: Promega
 Serial Number: 297752
 Firmware Version v2.7.0.0
 Mode RUO

Protocol: Whole Blood DNA (RUO) v0.9.0
 Status: Completed
 Started at: 5/7/2019 5:24:37 PM
 Duration: 00:07:30
 Operator: DESKTOP-UKJVOKD\User

#	Sample ID	Lot Number	Expiration Month	Cartridge ID	Elution tube ID	Custom1	Custom2
1	Sample1	123321	2019-12				
2	Sample2	123321	2019-12				
3	Sample 3	123321	2019-12				
4	Sample 4	123321	2019-12				
5	Sample 5	123321	2019-12				
6	Sample 6	123321	2019-12				
7	Sample 7	123321	2019-12				
8	Sample 8	123321	2019-12				
9	Sample 9	123321	2019-12				
10	Sample 10	123321	2019-12				
11	Sample 11	123321	2019-12				
12	Sample 12	123321	2019-12				
13	Sample 13	123321	2019-12				
14	Sample 14	123321	2019-12				
15	Sample 15	123321	2019-12				
16	Sample 16	123321	2019-12				

Figure 45. Example of an exported text file in the tab-separated format.

3.6 Running Reports

From the 'Home' screen (Figure 46) 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 RUO Mode software (Figure 47). 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 48). Records can be deleted from the software by touching the **X** icon to the right of the desired report row, assuming this has been allowed by the administrator (Section 2.4). 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 46. 'Home' screen. Selecting **Results** opens the 'Results' screen from which extraction reports from all method runs can be viewed.

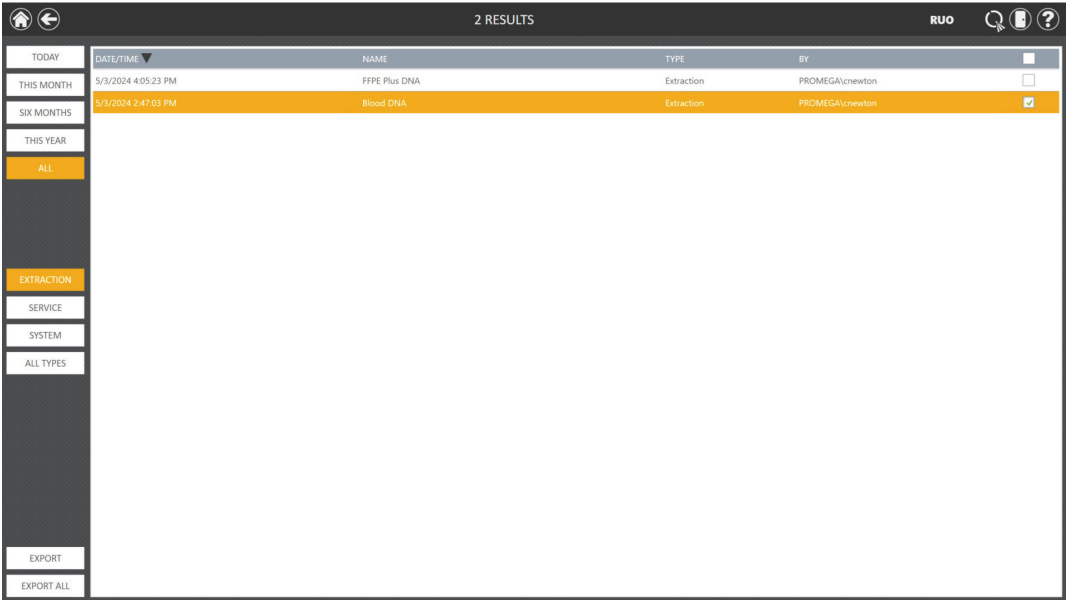


Figure 47. 'Results' screen. The 'Results' screen lists the reports from all of the methods that have been run in the Maxwell® CSC 48 RUO Mode software. Touch any given report listing to see a detailed view of the report data from that method run. Filter the displayed results using the **Extraction, 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. Press the **Export All** button to export all displayed reports to a user-specified drive location.

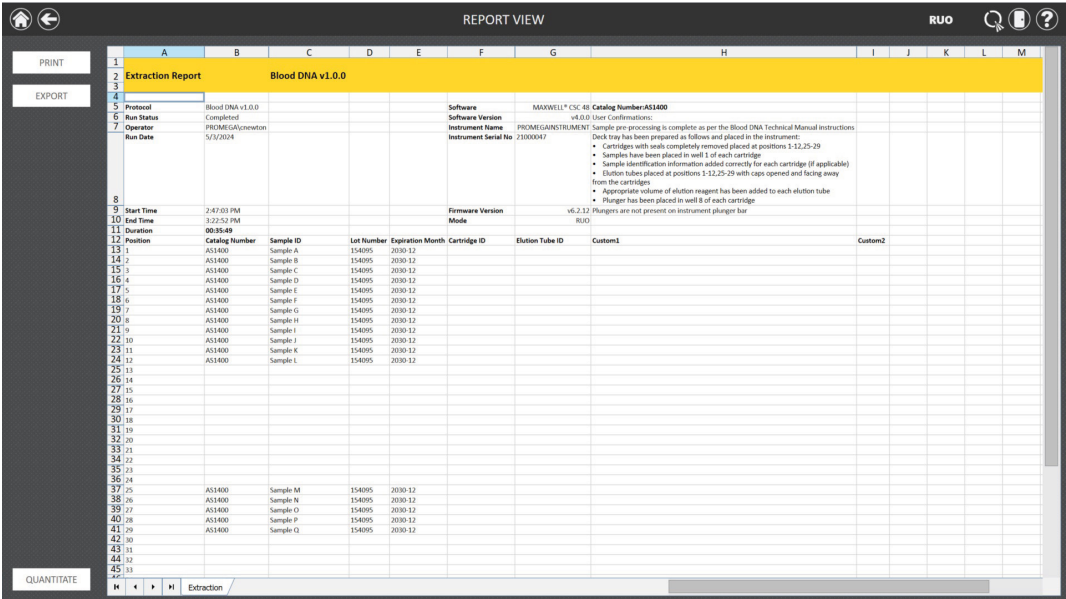


Figure 48. Extraction report. An example of the sample tracking information present in an extraction report.

3.7 Sanitize

Touch the **Sanitize** button on the 'Home' screen (Figure 49) to perform a UV sanitization of the instrument. Make sure all samples have been removed from the instrument prior to initiating the UV sanitization protocol. You will be presented with a sanitization checklist (Figure 50) that informs you on how long the UV sanitization will take. It will also ask you to confirm that no samples or eluates are present in the instrument prior to running Sanitization. After you touch the **Confirm** button, the Start button is enabled. Touch the **Start** button to start UV sanitization.



Figure 49. 'Home' screen. Selecting the **Sanitize** button begins the process for UV treatment of the Maxwell® CSC 48 Instrument.

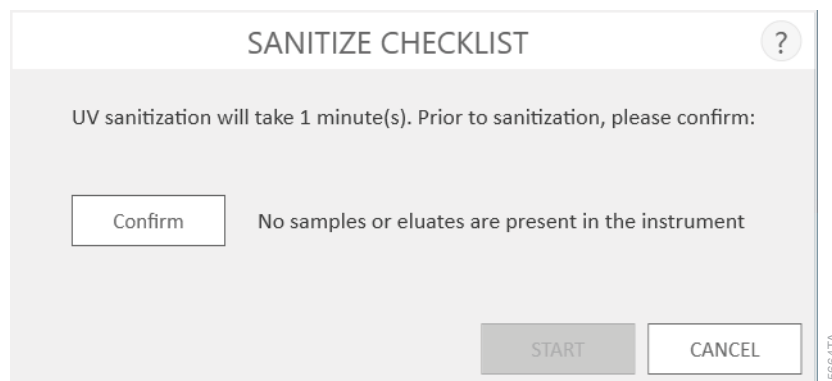




Figure 50. 'Sanitize Checklist' screen. The sanitization checklist indicates how long the UV sanitization will take. Confirm that no samples or eluates are present in the instrument prior to running Sanitization.

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 51).
	An error occurred during sanitization. Touch the icon to view the Sanitization report.

Note: UV radiation is useful in decontamination due to its ability to inactivate biological molecules. UV treatment is not a substitute for cleaning. Using the UV Sanitization protocol alone may not provide sufficient decontamination. For more information on cleaning the instrument, refer to the *Maxwell® CSC 48 Instrument IVD Mode Operating Manual #TM623*.

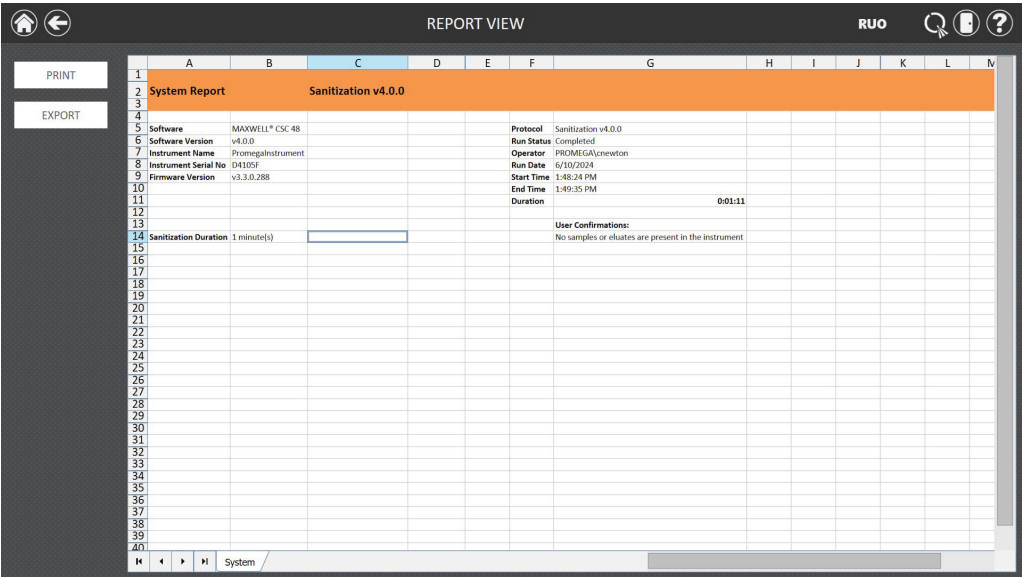


Figure 51. Example Sanitization Report. The sanitization report will be displayed after completion of sanitization.

4

Summary of Changes

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

1. Updated Sections 1.4, 1.6, 2.2, 3.1, 3.4 and 3.5.
2. Made changes to Sections 2.4 and 3.2.
3. Added new Section 3.4 and renumbered subsequent sections.
4. Moved document to a new template.
5. Made minor text edits and formatting changes.

^{a)}It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

^{b)}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.

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