

# Maxwell® FSC Instrument Operating Manual

Instructions for Use of Catalog Number AS4600



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

Introduction

### Maxwell® FSC Instrument Extraction Procedure 1.1

DNA extraction is a critical step in the overall workflow of the forensic laboratory. The resulting DNA needs to be of sufficient yield and purity for optimal downstream STR results. The forensic field has unique challenges due to the sample types that are routinely encountered. These can vary from pristine reference samples to difficult casework samples, such as blood stains, semen, hair, cigarette butts or touch samples. Additionally, the number of samples being processed continues to increase, requiring higher throughput options.

The Maxwell® Forensic Sample Concentrator (FSC) Instrument(a) eliminates many of the manual, labor-intensive steps of current DNA extraction methods. The instrument also provides consistent results by reducing the variability inherent in manual sample processing. It contains preprogrammed extraction methods and is designed for use with prefilled reagent cartridges. The instrument can process up to 16 samples in 30 minutes, and the purified DNA can be used directly in STR amplifications for forensic profile analysis of database and reference samples or can be quantitated prior to STR amplification of casework samples. The Maxwell® FSC Instrument, combined with the appropriate compatible Maxwell® reagent kits, provides an automated DNA extraction system that results in high-yield, inhibitor-free DNA from a wide variety of sample types.

The Maxwell® FSC Instrument is a particle handler that uses paramagnetic particles as an extraction medium to bind and wash nucleic acids. It provides high-purity nucleic acid that is compatible with standard amplification methods. The automated steps performed by the Maxwell® FSC Instrument include:

- Binding nucleic acids to paramagnetic particles
- Washing the bound nucleic acids to remove other cellular components
- Eluting the target nucleic acid

The instrument is controlled through a graphical user interface running on a tablet PC. The Maxwell® FSC Instrument has the ability to record and report sample tracking and method run data. The included Bar Code Reader can be used with the Maxwell® FSC Instrument to start method runs and capture bar code information for samples and reagents. The Maxwell® FSC Instrument provides reports of the data gathered for instrument operations; reports can be printed and exported to a storage location or a USB drive for transfer to a separate computer. To start a run, the user selects the appropriate method or 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® FSC reagent kit and prepares the deck tray of the instrument as instructed. The Deck Tray containing prepared cartridges is placed into the instrument, and the method is automatically run. A readable log of all functions performed by users on the instrument can be accessed and exported to a specified drive location by administrators. For troubleshooting purposes, users can export full instrument logs from the instrument to a specified drive location. Use of the instrument does not require any special training. However, training is available as part of Operational Qualification, which is offered separately (see Section 10.2).

### 1.2 Product Use

The Maxwell® FSC Instrument is exclusively designed to be used with Maxwell® FSC or Maxwell® RSC reagent kits to perform automated isolation of nucleic acids.

The Maxwell® FSC Instrument is for research use only.

### Product Use Limitations 1.3

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

### Maxwell® FSC Instrument Features 1.4

- Easy-to-use and easy-to-maintain system operation
- Standardized sample preparation workflow
- Integration with the Quantus™ Fluorometer (optional)
- Comprehensive technical support
- System controlled via tablet PC
- Reporting functionality
- Included bar code reader
- Preprogrammed extraction methods
- UV lamp to aid in decontamination of instrument
- Integrated USB hub for easy connection to accessory devices

### 1.5 Maxwell® FSC Instrument Specifications

Processing Time:	30-70 minutes (depending on sample type and method)
Number of Samples:	Up to 16
Weight:	24.2lb (11kg)
Dimensions (W $\times$ D $\times$ H):	13 × 13.6 × 11.8 inches (330.2 × 345.2 × 299.7mm)
Power Requirements:	100-240VAC, 50/60Hz, 2.5A
Fuse:	250VAC, 2.5A, low breaking capacity, time-lag fuse (AC250V, T2.5AL, 5 × 20mm)
UV Bulb:	Average lifetime approximately 6,000 hours, length 135.9mm, diameter 16mm, 4W, 0.17A current, 29V, spectral peak F 253.7, UV output 0.9W
Installation Category II	
Pollution Degree 2	

### 1.6 **Product Components**

PRODUCT CAT.# Maxwell® FSC Instrument AS4600

### Includes:

- 1 Maxwell® FSC Instrument
- 1 Tablet PC preloaded with Maxwell® FSC Application Software
- 1 USB Cable for connection of the Maxwell® FSC Instrument to the Tablet PC
- 1 Power Cable for Maxwell® FSC Instrument
- 1 Power Cords for Tablet PC
- 1 Maxwell® FSC Deck Tray
- 1 UV Bulb (installed)
- 1 Bar Code Reader
- Tablet PC Holder
- 1 Quick Start Guide
- 1 Setup Guide

Note: Country-specific power cords for the Maxwell® FSC Instrument and Tablet PC are provided, but not included within the instrument packaging.

# 1.7 Inspection

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

Included components are shown in Figure 1.



**Figure 1. Maxwell® FSC Instrument.** Components shown include: Deck Tray, Power Cable, USB Cable, Tablet PC, Tablet PC Power Cords, Tablet PC Holder, Stylus and Bar Code Reader for the Maxwell® FSC Instrument. Separate from the box containing the Maxwell® FSC Instrument, country-specific power cords for the instrument and Tablet PC are also provided.

### **Precautions** 1.8



### Important Safety Instructions. Save these instructions.

- Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This equipment has been designed and tested to CISPR 11 Class A. It may cause radio interference, in which case you may need to take measures to mitigate the interference.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper operation.
- Do not use this instrument for anything other than its designed purpose.
- Always disconnect the power to the instrument and the Tablet PC before cleaning or performing routine maintenance.
- Do not disassemble unit.
- Ensure cartridges, elution tubes and plungers have been securely inserted in their correct positions and orientation. Failure to do so may result in damage to the instrument.
- Use only Promega Maxwell® FSC or Maxwell® RSC branded and supplied cartridges, plungers and elution tubes.
- Do not reuse cartridges, plungers or elution tubes.
- If the equipment is used in a manner other than that specified by Promega, the protection provided by the equipment may be impaired.
- Keep hands clear of instrument platform as it moves in and out of the instrument.
- · During elution, the heated elution block at the front of the platform becomes very hot. Do not touch.
- To avoid muscle strain or back injury, use lifting aids and proper lifting techniques when removing or replacing the instrument.
- Instrument door should be opened and closed only by using the Maxwell® FSC software. Do not manually pry the door open or override the door sensor during protocol operation, as it will result in the protocol being aborted.
- · This instrument 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® FSC Instrument. Additional programs may cause the application to slow down.

### Safety Symbols and Marking 1.9

# Important Safety Instructions. Save these instructions.

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

Symbols	Explanation
REF	Catalog Number
SN	Serial Number
	Manufacturer
X	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.
(€	CE Compliance Marked
LOT	Lot Number
<u>(!)</u>	Important Information

### Environmental Requirements (Operating, Shipping and 1.10 Storage Conditions)

Power Requirements:	100-240VAC, 50/60Hz, 2.5A
Temperature:	4-50°C (shipping/storage), 15-25°C (operation)
Humidity:	Up to 80% relative humidity, non-condensing
Operating Altitude:	<2,000 meters

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

- Locate on a sturdy, level surface.
- Avoid dusty areas.
- Choose a location that has good air circulation and is not exposed to direct sunlight.
- Avoid electrically noisy power sources (e.g., power generators).
- Do not install in a location where there is large temperature variability or high humidity.
- Do not position the instrument so that it is difficult to unplug from the power source.
- Do not place next to heat sources.
- Do not use near flammable gases or liquids.
- Do not place near other electrically sensitive instruments.
- · Connect the Maxwell® FSC Instrument and Tablet PC to a power outlet. We recommend that you plug the instrument and Tablet PC into an uninterruptible power supply.



Figure 2. Front of the Maxwell® FSC Instrument.



Figure 3. Rear of the Maxwell® FSC Instrument. The rear of the instrument showing the On/Off switch, power cable connector and USB communication port for the Tablet PC and the three-port USB hub for accessories such as the bar code reader and optional Quantus™ Fluorometer.



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

# Unpacking the Maxwell® FSC Instrument

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

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



Figure 5. The accessories box.

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





Figure 6. Remove the upper packing material.

- 4. Place the instrument on a flat, stable surface. Leave at least 7.5 inches (19cm) of clearance in front of the instrument to allow the instrument door to open without hindrance.
- Remove the plastic bag from around the instrument.



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

# Setting Up the Maxwell® FSC Instrument

### Removing Shipping Materials 4.1

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



Figure 7. Removing the two foam pieces from inside the instrument.

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

### 4.2 Setting Up the Tablet PC

- 1. Remove the Tablet PC from the box.
- 2. Locate the Tablet PC Holder, and place it on top or adjacent to the Maxwell® FSC Instrument.



Figure 8. Tablet PC Holder.

3. Raise the leg of the Tablet PC Holder (Figure 9), and place the Tablet PC on the Tablet PC Holder as shown in Figure 10.



Figure 9. Tablet PC Holder on top of the Maxwell® FSC Instrument.

4. Connect the Tablet PC Power Cord to the Tablet PC. Plug the other end of the Tablet PC power cord into a power outlet. We recommend connecting the Tablet PC to an uninterruptible power supply.



Figure 10. Tablet PC installed on the Maxwell® FSC Instrument.

5. Connect the USB Cable to the Tablet PC and plug the other end of the USB Cable to the back of the Maxwell® FSC Instrument (Figure 11).



Figure 11. Connecting the Tablet PC to the back of the Maxwell® FSC Instrument.

6. Connect the bar code reader to any of the USB ports on the back of the Maxwell® FSC Instrument (Figure 12).



Figure 12. Maxwell® FSC Instrument with the Tablet PC and bar code reader.

- 7. **Optional:** Follow this step if you have purchased the Quantus™ Fluometer (Cat.# E6150) for use with your Maxwell® FSC Instrument. For integrated quantitation using the Quantus™ Fluorometer, unpack the fluorometer as described in the Quantus™ Fluorometer Operating Manual #TM396, and then connect the USB cable to a USB port on the bottom left of the back of the Maxwell® FSC Instrument (Figure 11).
- Connect the Maxwell® FSC Power Cable to the back of the Maxwell® FSC Instrument.
- 9. The Maxwell® FSC Instrument is now ready to use.



Note: For instructions on how to configure the Tablet PC, consult the Maxwell® Windows® 10 Tablet PC Configuration Manual #TM586 at www.promega.com/ protocols

## 4.3 Switching On the Maxwell® FSC Instrument

Once all the foam pieces have been removed and the Tablet PC set up, you can connect the instrument to a power outlet as per the following instructions. The power switch is located next to the power cable connection on the back of the instrument. Ensure that the On/Off switch is in the Off position. Plug the power cord into a wall outlet. See Section 1.5 for power requirements. We recommend connecting the Maxwell® FSC Instrument to an uninterruptible power supply. Switch on the instrument using the On/Off switch. Plug the Tablet PC Power Cord into a wall outlet.

Press the Tablet PC power switch located on the top of the Tablet PC to turn on the Tablet PC. Start the Maxwell® FSC Application Software. Every time the instrument software is started, the instrument will perform a self-diagnostic test. The deck, plunger bar and magnetic rod assembly are moved to check operation.



Figure 13. The On/Off switch.

# 4.4 Shutting Down the Maxwell® FSC Instrument

### 4.4.1 Shutting Down Instrument

- 1. Shut down the software by pressing the **X** in the upper left corner of the 'Home' screen.
- 2. Switch off the instrument using the On/Off switch. Unplug the instrument. If you need to store the instrument, switch off the instrument, unplug the instrument and store in a place that meets the environmental requirements described in Section 1.10.
- 3. Shut down the Tablet PC using the Windows® shut down procedure.



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® Windows® 10 Tablet PC Configuration Manual #TM586.



Figure 14. Maxwell® FSC Home screen.

### 4.4.2 Storing the Tablet PC

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

## 4.5 Maxwell® FSC User Interface Screens

Your Maxwell® FSC instrument is controlled by Maxwell® FSC 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® Windows® 10 Tablet PC Configuration Manual #TM586. This Technical Manual can be downloaded at: www.promega.com/protocols

### 'Home' Screen 5.1

The 'Home' screen is the main launching pad for interaction with the functionalities built into the Maxwell® FSC User Interface. The 'Home' screen (Figure 15) contains four buttons:

START	Pressing the <b>Start</b> button on the Maxwell® FSC 'Home' screen will begin the process of preparing an extraction method run on the Maxwell® FSC Instrument. See Section 6.2, Starting a Method.
RESULTS	The <b>Results</b> button takes users to the 'Results' screen where it is possible to review, print and export any of the local run reports from previous chemistry and service processes. See Section 6.5, Reports, and Section 6.6, Running Reports.
SANITIZE	Pressing the <b>Sanitize</b> button activates the UV light in the Maxwell® FSC Instrument for the time specified in the administrator settings (see Section 5.3.2, 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 6.8, Sanitize.
SETTINGS	The <b>Settings</b> button accesses the 'Settings' screen, which includes functions to: view <b>Instrument Info</b> , perform an instrument <b>Self Test</b> , remove plungers with <b>Clean Up</b> , export all log files with <b>Export Logs</b> and change instrument settings with <b>Administrator</b> (only available to users with Administrator level access to the Maxwell® FSC software). See Section 5.2, User Interface Settings, and Section 5.3, Administrator Settings.



Figure 15. Maxwell® FSC software 'Home' screen.

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

	Home	From any screen other than the 'Home' screen, touch this icon to return to the 'Home' screen.
	Exit	From the 'Home' screen, pressing this icon will close the Maxwell® FSC User Interface software and return to the Windows® Operating System.
	Back	When active, pressing the <b>Back</b> button will return the interface to the screen accessed prior to the current screen.
1 <i>m</i>	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® FSC 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.
C <sup>2</sup>	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® FSC Instrument.
?	Help	Pressing this icon will activate the context-sensitive help for the current screen of the Maxwell® FSC User Interface.

### 5.2 **User Interface Settings**

Within the software for the Maxwell® FSC Instrument, it is possible for all users to access instrument-specific information and functions. In addition, users with Administrator-level access to the Maxwell® FSC 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® FSC software.

Figure 16 displays the 'Settings' screen for the Maxwell® FSC software. This screen is accessed by touching the Settings button on the 'Home' Screen (Figure 15). The appearance of the 'Settings' screen is tailored to the Maxwell® FSC software access level assigned to the Windows® user account, see Maxwell® Windows® 10 Tablet PC Configuration Technical Manual, #TM538. A Windows® user account with user-level access to the Maxwell® FSC 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® FSC software will additionally see an Adminstrator button. From this screen the operator can access the instrument functionalities described below.



Figure 16. Maxwell® FSC '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® FSC software.

#### 5.2.1 Instrument Info

Touch the **Instrument Info** button to display software, firmware, calibration, and other instrument-specific information for this Maxwell® FSC instrument on an 'About Maxwell® FSC' screen (Figure 17). 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® FSC instrument connected to the Tablet PC
- Firmware ID: the current firmware version installed on this Maxwell® FSC instrument
- Firmware Revision: the revision number of the firmware installed on the Maxwell® FSC instrument
- FPGA ID: the current FPGA version installed on this Maxwell® FSC instrument
- FPGA Revision: the revision number of the FPGA version installed on the Maxwell® FSC instrument
- Tray Calibration Value: the calibration value for the tray axis on the Maxwell® FSC instrument
- Plunger Calibration Value: the calibration value for the plunger bar axis on the Maxwell® FSC instrument
- Magnet Calibration Value: the calibration value for the magnet bar axis on the Maxwell® FSC instrument

### ABOUT MAXWELL® FSC Software Version: 3.0.3 Software Revision 47 Platform Version: 2.6.0 Platform Revision: 48 Instrument Name: Simulator 631003 Serial Number: Firmware ID: FW Simulator 2.5.5.0 Firmware Revision: FPGA ID: **FPGA Simulator** FPGA Revision: 2.5.5.0 Tray Calibration Value: 900 Plunger Calibration Value: 30 Magnet Calibration Value: 30

Figure 17. About Maxwell® FSC' screen. Instrument- and software-specific information are displayed on the 'About Maxwell® FSC' screen.

#### 5.2.2 Self Test

You can perform a check of instrument functions by touching the Self Test button from the Maxwell® FSC 'Settings' screen (Figure 18). On touching the Self Test button, the Maxwell® FSC 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 18. Maxwell® FSC 'Settings' screen. From this screen, you can perform a Self Test for the Maxwell® FSC Instrument.

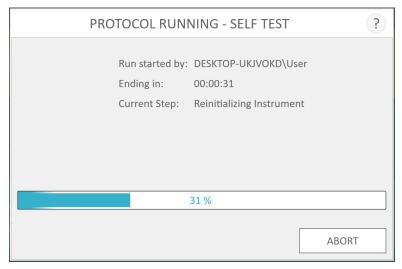


Figure 19. Self Test protocol being executed.

#### 5.2.3 Clean Up

Clean Up attempts to unload plungers from the instrument plunger bar if any have not been appropriately unloaded after a method run. If your method run was aborted or had issues with plunger loading or unloading, the Clean Up procedure should be run. Clean Up does not clean the instrument and should not be confused with the Sanitization method.

You can run a Clean Up by touching the Clean Up button from the Maxwell® FSC 'Settings' screen (Figure 20) [from the 'Home' screen touch the Settings button to access the 'Settings' screen]. Plungers can only be unloaded from the plunger bar if a cartridge is present beneath the plunger to be unloaded. Place a cartridge (without a plunger) at each position on the deck tray that did not unload a plunger properly during the run. On touching the Clean Up button, you will be presented with a 'Clean Up Checklist' screen (Figure 21):

- 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® FSC Instrument will perform the Clean Up process and will generate and display the system report from the Clean Up process. If plungers are not ejected after several clean up attempts the operator should contact Promega Technical Services (techserv@promega.com or 1-800-356-9526) to determine the next appropriate steps.



Figure 20. Maxwell® FSC 'Settings' screen. From this screen, you can press Clean Up to unload any plungers left on the plunger bar after an unsuccessful method run.

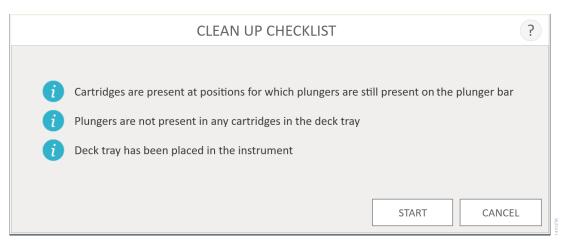


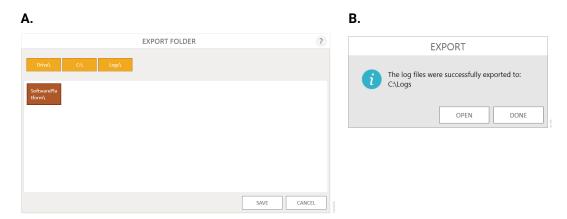
Figure 21. 'Clean Up Checklist' screen. This screen presents you with a checklist of items that must be performed before attempting to unload plungers.

### 5.2.4 **Export Logs**

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

- 1. Touch the **Export Logs** button to display the 'Export Folder' screen (Figure 22, 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 22, Panel B).
- 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 22. Export Logs. Panel A.** The 'Export Folder' screen is displayed after touching the **Export Logs** button. Specify a path to which the instrument log files should be exported. Touch **Save** to export instrument logs to the specified location or **Cancel** to return to the 'Settings' screen without exporting logs. **Panel B.** After instrument log files are exported, the 'Export' screen is displayed, indicating that logs have been saved to the specified path. Touch **Open** to view the folder location of the exported instrument log files. Press **Done** to exit the 'Export' screen and return to the 'Settings' screen.

## 5.3 Administrator Settings



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



### **Navigation Note:**

The instructions for the following subsections assume that the operator is starting from the 'Administrator Page' screen in the Maxwell® FSC software. Follow the instructions on the right to access the 'Administrator Page' screen when starting from the 'Home' screen in the 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® FSC software. Software settings for the Maxwell® FSC software can be accessed by Windows® user accounts with administrator-level access to the Maxwell® FSC 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® FSC software to customize the behavior of the Maxwell® FSC 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® FSC software, view user-readable **Administrative Log** and define an **Instrument Name** for this Maxwell® FSC instrument. The behavior of each button on the 'Administrator Page' screen is detailed below. Follow the instructions to adapt the behavior of the Maxwell® FSC software to the needs of the laboratory, or refer to any individual subsection to address a specific setting.

 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® FSC User Interface (Figure 23), touch the **Settings** button.



Figure 23. Maxwell® FSC 'Home' screen. Selecting Settings opens the Maxwell® FSC 'Settings' screen.

2. If the current operator logged into the Tablet PC has administrator access rights within the Maxwell® FSC software, the 'Settings' screen (Figure 24) will display an **Administrator** button. On the 'Settings' screen, select the **Administrator** button to proceed to the 'Administrator Page' screen (Figure 25).

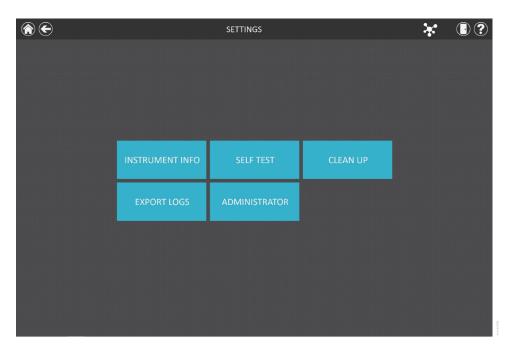


Figure 24. Maxwell® FSC 'Settings' screen. The Administrator button will only be visible if the currently logged in operator has administrator-level rights within the Maxwell® FSC software.



Figure 25. Maxwell® FSC '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® FSC system.

#### 5.3.1 Sample Entry

Maxwell® FSC has two modes for sample tracking: Portal sample tracking and local sample tracking. In Portal mode (see Section 5.3.5, 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 5.3.5), Entering sample identifiers is required, while collecting other sample tracking information is optional. If Portal mode is turned off, the Maxwell® FSC software will only report sample tracking information locally to run reports in the Maxwell® FSC 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® 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® FSC software 'Administrator Page' screen (Figure 25), touch the Sample Entry button.
- The 'Sample Entry' screen is shown in Figure 26. 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). You can 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® FSC software is connected to the Portal software (see Section 5.3.5) the "Sample ID" field is required.

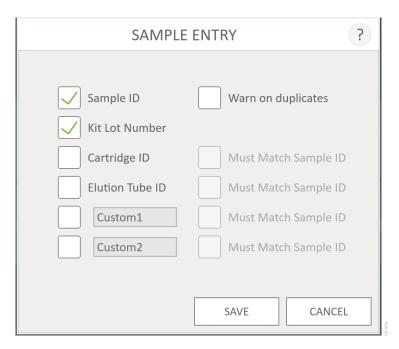


Figure 26. Maxwell® FSC 'Sample Entry' screen. Use this screen to configure the bar code information that must be entered for each sample prior to performing an extraction method. When Portal software is enabled, Sample ID is a required bar code entry field. Use the "Warn on duplicates" option to display a warning when multiple cartridges within a run have identical Sample ID information. For any of the optional fields, you can to 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.

#### 5.3.2 Sanitization Settings

The Maxwell® FSC instrument contains a UV light that can help aid in sanitization of the instrument. You can 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.
- Three sanitization settings are present on the 'Sanitization Settings' screen (Figure 27). These are described below:
  - a. Default sanitization duration: This setting defines the duration of the UV treatment (in minutes) performed when the Sanitization button on the 'Home' screen is pressed.
  - Sanitize after extraction for (optional): This setting defines the duration of UV treatment (in minutes) that will be automatically performed after completion of an extraction method run.
  - Sanitize on software start-up for (optional): This setting defines the duration of UV treatment (in minutes) that will be automatically performed when the Maxwell® FSC software is started.

- 3. Touch the text box next to 'Default sanitization duration:' to open the on-screen number pad. Enter the number of minutes to be used for UV sanitization when the Sanitization button on the 'Home' screen is pressed. Touch the **OK** button on the on-screen number pad to accept the duration value or touch the **Cancel** button on the on-screen number pad to discard changes.
- To enable either of the additional UV sanitization options, touch the checkbox 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.
- 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 'Adminstrator Page' screen.

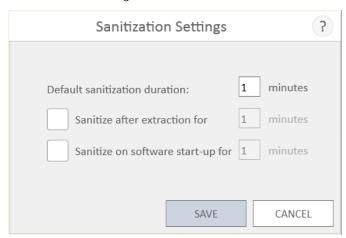


Figure 27. The 'Sanitization Settings' screen.

#### 5.3.3 Methods

The 'Methods' screen displays a list of the currently installed methods in the user interface including the name, version number, and catalog number for each method. From the 'Methods' screen the administrator can view, import, and delete methods from the Maxwell® FSC software (Figure 28).

- 1. If you desire to view the methods currently installed in the Maxwell® FSC 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.

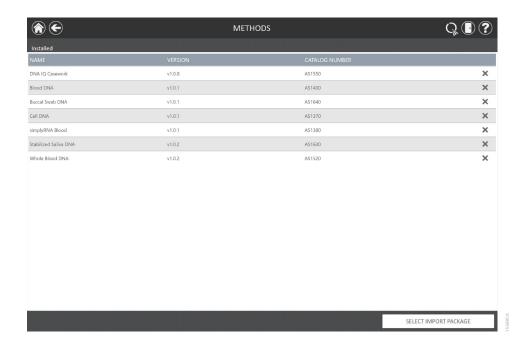
#### 5.3.4 Importing and Deleting Methods

As Promega provides new nucleic acid purification kits for use with the Maxwell® FSC instrument, new extraction methods can be added to the Maxwell<sup>®</sup> FSC software. Occasionally, an existing extraction method may have to be updated. Only administrators can add new extraction methods or delete or update existing methods. Both Maxwell® FSC and Maxwell® RSC method package files can be imported into the Maxwell® FSC software. Administrators can download new extraction methods for new nucleic acid purification kits or updated extraction methods for existing nucleic acid purification kits at: www.promega.com/resources/ software-firmware/maxwell-maxprep/maxwell-rsc-fsc-software-firmware-methods/

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

- 1. Save the method (.package) file on the Tablet PC attached to the Maxwell® FSC.
- 2. If not already running, start the Maxwell® FSC software by double-touching the software icon on the desktop.
- 3. Navigate to the 'Methods' screen (Home → Settings → Administrator → Methods).
- 4. Touch the **Select Import Package** button on the bottom right side of the screen to open the 'Select File' browser screen.
- 5. Within the 'Select File' screen, navigate to the location at which you saved the method (.package) file. The current path will be shown in yellow boxes along the top of the window. Touch any aspect of the path to navigate to the desired folder. Touch the **Drive\** button to select the drive in which to search. Folders within the current path are shown as red rectangles on the left side of the screen. Valid method (.package) files will be shown as blue rectangles (yellow when selected) on the right side of the screen.
- 6. Click the blue rectangle(s) corresponding to the desired (.package) file(s) to highlight it, then press the **OK** button.
- 7. A 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® FSC 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<sup>®</sup> FSC software or Cancel to return to the 'Methods' screen without deleting the method.



**Figure 28. 'Methods' screen.** This screen displays a list of the methods currently installed in the Maxwell® FSC software. For each method you can view the name of the method, the version number of the method, 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.

# 5.3.5 Preferences

Administrators can view preferences available in the Maxwell® FSC 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 29).

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

# 'Common Settings' tab

The 'Common Settings' tab on the 'Preferences' screen (Figure 29) 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
- **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 checkboxes 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® FSC 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.

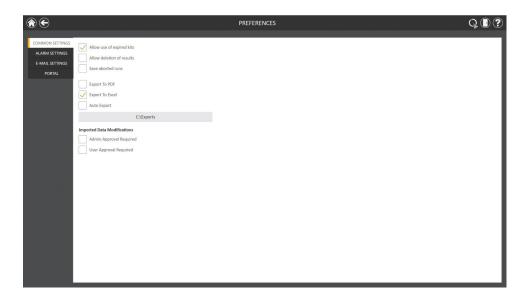


Figure 29. 'Common Settings' tab on the 'Preferences' screen. From the 'Common Settings' tab, the administrator can specify software and export behaviors. Additionally, you can set the approvals required to make changes to sample deck tray layouts retrieved from the Portal software or the Sample Data Import function.

# 'Alarm Settings' tab

The 'Alarm Settings' tab on the 'Preferences' screen (Figure 30) 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.

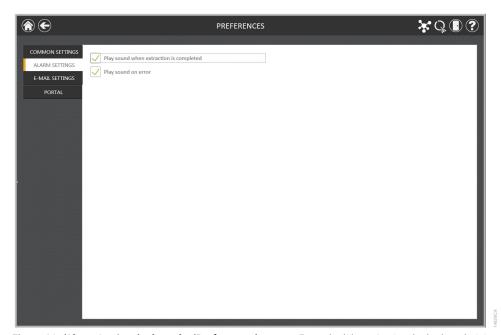


Figure 30. 'Alarm Settings' tab on the 'Preferences' screen. From the 'Alarm Settings' tab, the administrator can specify whether audible alarms should be played on completion of an extraction run or on error.

# 'E-mail Settings' tab

The 'E-mail Settings' tab on the 'Preferences' screen (Figure 31) is where e-mail server details are specified and where administrators can determine when and to whom e-mail notifications will be sent. It is necessary to fill out the user and server information on the 'E-mail Settings' tab, and that the Tablet PC has network access to the e-mail server in order to use e-mail notifications. Required e-mail server information on the left side of the screen includes:

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

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

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

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

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

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

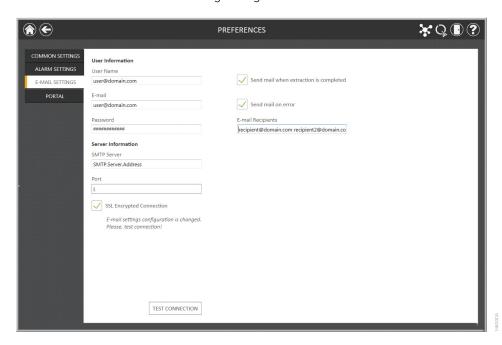
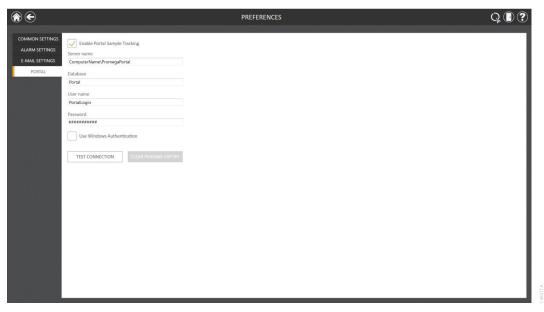


Figure 31. 'E-mail Settings' tab on the 'Preferences' screen. From the 'E-mail Settings' tab, the administrator can specify e-mail server settings, under what conditions e-mail notifications should be sent, and the distribution list to which e-mails should be sent. Use the **Test Connection** button to check the settings entered on this screen.

### 'Portal' tab

The 'Portal' tab (Figure 32) 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 32. '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.



Note: Contact Promega Technical Services (techserv@ promega.com) for information on using Portal when no Maxprep® Liquid Handler is available.

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). In order for 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 software-specific information has been entered, press the **Test Connection** button to determine whether the Maxwell® FSC 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.

#### 5.3.6 Administrative Log

The Maxwell® FSC software contains a record of functions that have been performed. Administrators have access to view and export the Administrative Log from the instrument through the **Administrative Log** button on the 'Administrator Page' screen. The 'Administrative Log' screen displays a listing of functions that have been performed in the software (Figure 33). You can filter the 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 message from that particular record. Administrators can export all 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 'Administrative Log' screen.
- Using the Yellow and Red rectangle buttons you can select the folder location (Figure 34) 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 'Administrative Log' screen.

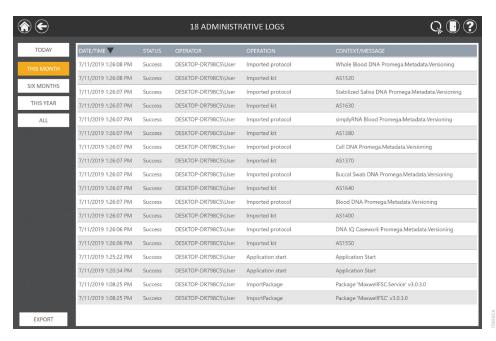


Figure 33. 'Administrative Log' screen. A user-readable record of events that have occurred in the Maxwell® FSC software can be viewed by the administrator and exported to a specified drive location from the 'Administrative Log' screen.

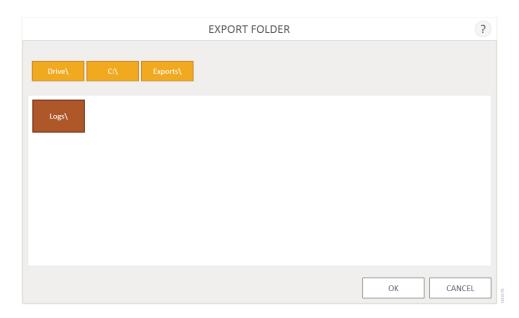


Figure 34. 'Export Folder' screen. From the 'Export Folder' screen, you can set the folder location to which all displayed records will be exported.

#### 5.3.7 Instrument Name

You can define a unique identifying name for the Maxwell® FSC instrument. This name will be shown on the title bar of the Maxwell® FSC 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 35).
- 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.
- Touch the **Save** button to save the instrument name you have entered. Saving the instrument name will enforce a restart of the Windows® Operating System. After saving, an informational screen will be displayed indicating that "Windows will now restart". Touch the **OK** button to restart the operating system.
- If you do not wish to save any changes to the instrument name, press the Cancel button to return to the 'Administrator Page' screen.



Figure 35. 'Instrument Name' screen. Use this screen to enter a name for this Maxwell® FSC instrument.



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

# Operating the Maxwell® FSC Instrument

# Preprogrammed Methods 6.1

The preprogrammed methods available for the Maxwell® FSC Instrument can be used to perform extractions for a variety of sample types. The sample type and type of molecule extracted are determined by the Maxwell® FSC or Maxwell® RSC reagent kit used. Please refer to your specific Maxwell® reagent kit Technical Manual for information on sample preparation and handling. Three mechanisms for selecting a method to run are enabled in the Maxwell® FSC software:

- Manual selection from the list of installed methods corresponding to Maxwell® reagent kits can be used for method selection as well as confirmation.
- · Scanning the bar code on a Maxwell® FSC or Maxwell® RSC reagent kit box will select and highlight the appropriate installed method for that kit with subsequent confirmation by the
- 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 and highlight the appropriate installed method based on the preprocessing method that was run on a Maxprep® Liquid Handler with subsequent confirmation by the user.

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.

## 6.2 Starting a Method

Either manually or using the Maxprep® Liquid Handler, prepare samples for extraction following the instructions provided in the Technical Manual for the specific Maxwell® FSC or Maxwell® RSC reagent kit. From the 'Home' screen (Figure 36), select the Start button to begin the process of running an extraction method.



Figure 36. Maxwell® FSC 'Home' screen. Selecting the Start button begins the process of running an extraction method on the Maxwell® FSC Instrument.

#### 6.2.1 Portal Mode

If the instrument is in Portal mode the 'Scan Trays' screen will be displayed (Figure 37, 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 37, 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 (deck tray bar code must start with an 'A' identifying it as an FSC deck tray)
- 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® FSC software. The 'Methods' screen will be displayed and the appropriate extraction method that matches the preprocessing method will be filtered from the list of installed methods. Touch the method and press the **Proceed** button to open the 'Cartridge Setup' screen. All sample identifier information entered during the preprocessing method run on the Maxprep<sup>®</sup> 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 this deck tray, press the **New** button. Alternatively, press the **Cancel** button to return to the 'Home' screen. When starting a new method, follow the instructions below for Local Mode to select a method. All kit lot and sample tracking information will have to be entered on the 'Cartridge Setup' screen for this run.

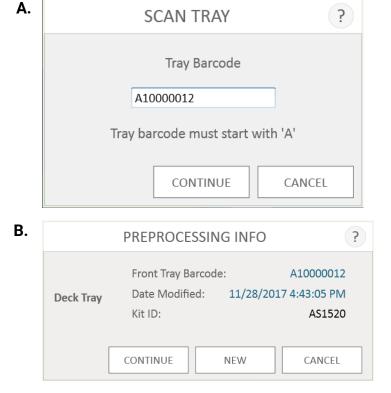


Figure 37. Portal mode requires scanning of deck tray bar codes. Panel A. When starting a run in Portal mode, scan the bar code on the FSC deck tray to retrieve information about any prior preprocessing method performed on a Maxprep® Liquid Handler. Panel B. A summary of any preprocessing information 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.

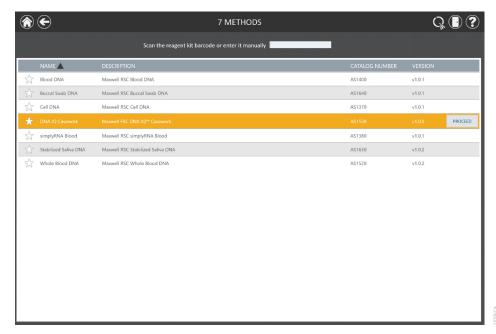
#### 6.2.2 Local Mode

On the 'Methods' screen, select the method from the list that matches the kit name and workflow or catalog number. Alternatively, you can scan the bar code on the Maxwell® FSC or Maxwell® RSC reagent kit box indicated by the Scan Here label (Figure 38), or touch the text box at the top of the screen (Figure 39) to manually enter the bar code information using the keyboard. Maxwell® software requires manual entry of bar codes in the following format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format (example: AS15503221872018-05, where the product catalog number is AS1550, 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 filtered, selected and the **Proceed** button on the right side of the method become active. If a kit has multiple method workflows, the bar code will filter all of the applicable methods. Select the desired workflow and the **Proceed** button on the right side of the method will become active.

Once the bar code is correctly entered, touch the **Proceed** button to access the 'Cartridge Setup' screen. You can touch the **Back** button to return to the 'Method Selection' screen. 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.



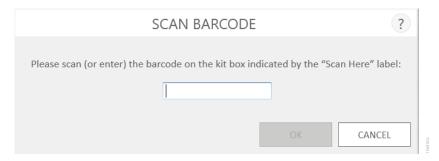
Figure 38. Kit label indicating bar code to scan. Scan the bar code in the blue box, upper right of the kit label, to start an extraction run.



**Figure 39. Selecting a method.** Pressing the method line selects the extraction method on the Maxwell® FSC Instrument. Alternatively, a Maxwell® FSC or Maxwell® RSC reagent kit bar code can be scanned or manually entered to filter and select the method corresponding to that kit. When running in Portal mode, information retrieved from the Portal software (if any) will automatically filter the list to include only the appropriate extraction method for the preprocessing method that was performed on the Maxprep® Liquid Handler.

- 3. There are two potential error modes that can occur when using Portal or the Maxwell® FSC 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 you 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 5.3.5, 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 (**techserv@promega.com**) to get the most updated information on the available methods.

After a method has been selected, one of two screens will appear. If sample tracking of the kit lot and expiration date is required and you are running in Local Mode, the 'Scan Barcode' screen (Figure 40) is displayed. Scan or enter the bar code information for a kit within expiration date. Maxwell® software requires manual entry of bar codes in the following format: Product Catalog Number, Kit Lot Number, Expiration Date in year-month format (example: AS15503221872018-05, where the product catalog number is AS1550, the kit lot number is 322187 and the expiration date is 2018-05). Only if the bar code entered has this format will the **OK** button become active. If bar code information from a Maxwell® FSC reagent kit was scanned or manually entered to select a method, or if you are running in Portal Mode and this information was entered during preprocessing, this information will be automatically recorded and this screen will not be displayed. If sample tracking of kit information is not required, the 'Cartridge Setup' screen is displayed.



**Figure 40. 'Scan Barcode' screen.** When sample tracking of the lot and expiration date of the Maxwell® FSC or Maxwell® RSC reagent kit is required, this screen will be presented so that the information can be manually entered after a method is selected. If a kit bar code was scanned to select a method, or if you are running in Portal Mode, this information will automatically be recorded and this screen will not be displayed.

4. After selecting an extraction method, you will be presented with the 'Cartridge Setup' screen (Figure 41) on which you specify the positions on the Maxwell® FSC deck tray that will be occupied by cartridges and enter sample tracking information for each sample. 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. Based on administrator settings (see Section 5.3.5, 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).

# **Option 1: Manual Entry**

- a. Select cartridge positions by touching the long rectangle for each position that will be used. The processing positions specified on the deck tray 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 42). 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.
- 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.
- Touch the Sample ID and additional required sample tracking information text boxes to enter or scan the sample information manually. 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 42, 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.
- Using the yellow and red rectangle buttons, you can select the folder location where the import file is located. The current path is indicated by the yellow rectangles at the top of 'Sample Data Import' screen. Any folders present within the selected directory are displayed as red rectangles in the main portion of the screen. Touch the Drive\ button to navigate to the drive location of the desired folder. Touch the red buttons to navigate to the desired folder location.
- d. Once a path has been defined, select the desired file, and touch the **Open** button to automatically move to the 'Data' tab on the 'Sample Data Import' screen. (Figure 42, Panel B)

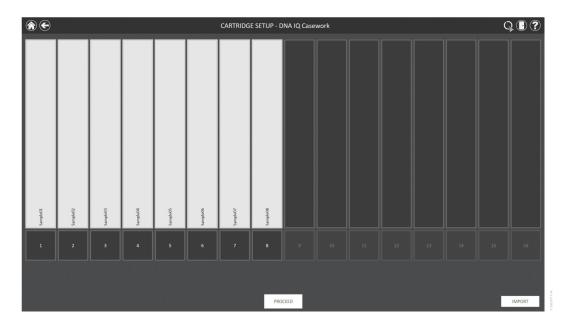
- The 'Data' tab on this screen allows the user to identify the information present in each column of the file. A table displaying the columns of data found in the import file is shown in the main portion of the screen. Select the type of data present in each column of the file using the drop-down menu at the top of each column. The Cartridge position is minimally required, however other categories can be the Sample ID bar code, Cartridge ID bar code, Elution Tube ID bar code and up to two administratordefined fields. To utilize these categories, they must be checked in the Sample Entry section of the software. See Section 5.3.1, Sample Entry for more information. For columns that should be ignored during import, select **X** from the drop-down menu. If your import file has a header row that provides titles for the information in each column, check the Header box on the right side of the table to ignore the Header row during import. When the Header box is checked, the first row of the table will be shaded light blue. All selections made on the 'Data' tab are saved and become the default values selected the next time you import sample data.
- Once all data fields are identified, tap the Accept button to perform the import of data from the file. An 'Import' screen will be displayed summarizing the results of the sample import including the number of samples that were present in the file and the data source for the import file. Touch **OK** to dismiss the 'Import' screen.
- Touch **OK** to dismiss the 'Sample Data Import' screen and apply the imported information to the 'Cartridge Setup' screen.
- 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.
- 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.

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: AS15503221872018-05 where the product catalog number is AS1550, the kit lot number is 322187 and the expiration date is 2018-05).



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



**Figure 41. '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.

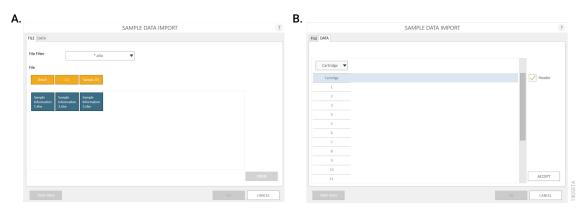
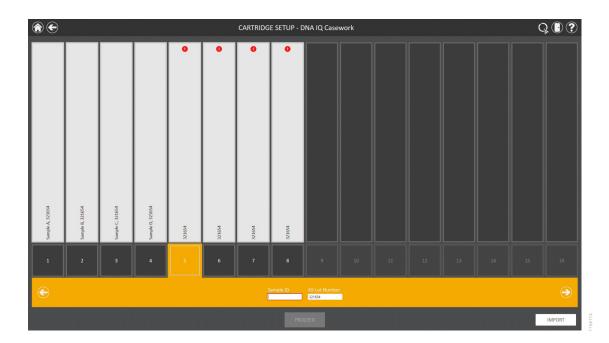


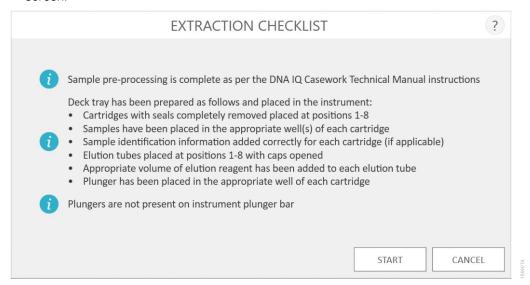
Figure 42. Sample Data Import. Panel A. The 'File' tab is displayed after touching the Import button. Select the file filter and navigate to the file location where the sample import file is located. Touch the desired blue box file and touch the Open button to open up the 'Data' tab and view the sample 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, touch the Accept button to apply the information to the 'Cartridge Setup' screen.



**Figure 43. 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 onscreen keyboard or via optional 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® FSC Instrument door.

6. You will be presented with an 'Extraction Checklist' screen (Figure 44). Confirm that the deck tray and instrument have been prepared as indicated on the 'Extraction Checklist' screen.





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

Figure 44. '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® FSC or 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 (Figure 45). 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® FSC or 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.



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

- Ensure no plungers from the previous run(s) are present on the plunger bar inside the instrument. If there are plungers present, go to Section 6.3, Clean Up, for instructions for plunger removal.
- Place a plunger in the last well (closest to the elution tube) of each cartridge.
- Confirm the sample identification information is accurate for each cartridge (if applicable).
- Place the deck trays in the instrument as shown in Figure 46. Hold the deck tray by the sides to avoid dislodging cartridges. Ensure that the deck tray is placed in the Maxwell® instrument with the elution tubes closest to the door. Angle the back of the deck tray downward and place into the instrument so that the back of the deck tray is against the back of the instrument platform. Press down on the front of the deck tray to firmly seat the deck tray on the instrument platform. If you have difficulty fitting the deck tray on the platform, check that the deck tray is in the correct orientation. Ensure the deck tray is level on the instrument platform and fully seated.

After all of these steps have been performed, touch the **Start** button to begin the extraction, or touch the **Cancel** button to return to the previous screen.





Figure 45. Placing the cartridges in the Deck Tray and pressing firmly to snap in place.





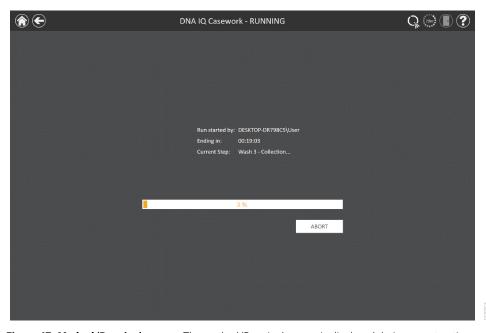
Figure 46. Placing the deck tray in the instrument.

- 7. While the extraction method runs, you will see the 'Running' screen (Figure 47). 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.

You can perform some instrument functions (e.g., viewing reports, associating quantitation data with reports using an optional integrated Quantus $^{\text{\tiny{M}}}$  Fluorometer) 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.



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



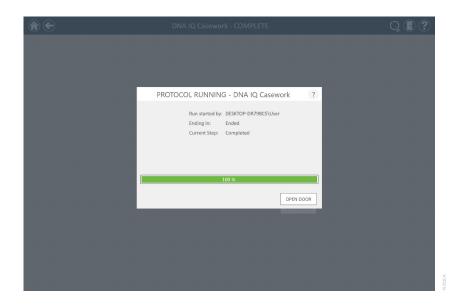
**Figure 47. Method 'Running' screen.** The method 'Running' screen is displayed during an extraction method run. This screen indicates what method is currently being run at the top of the screen. Also indicated on this screen are the user who started the run, an approximate indication of when the run 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.



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

# 6.2.3 Completes Successfully

When the method completes successfully the method 'Running' screen will indicate that the extraction method has been completed (Figure 48). 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® FSC Instrument.

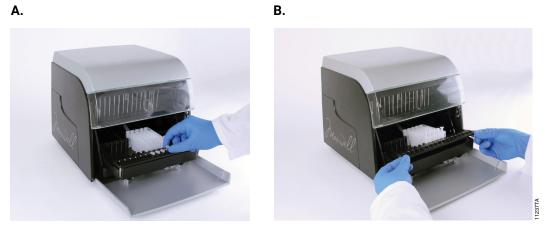


**Figure 48. 'Protocol Running' screen after method completion.** Upon completion of an extraction method, the progress bar will show 100% completion. The Current Step changes to Completed after a run is finished. After a method is complete, you can touch the **Open Door** button to open the door of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



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 49, 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 49, 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 6.3 to remove them by running the Clean Up method. The extracted material is present in the elution tubes. If the method being run is a sequential protocol, follow the on-screen instructions and applicable extraction technical manual to continue the run. If the method is not a sequential protocol, remove the cartridges and plungers from the Maxwell® FSC deck tray.



**Figure 49. 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 50) 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 6.8, Sanitize).

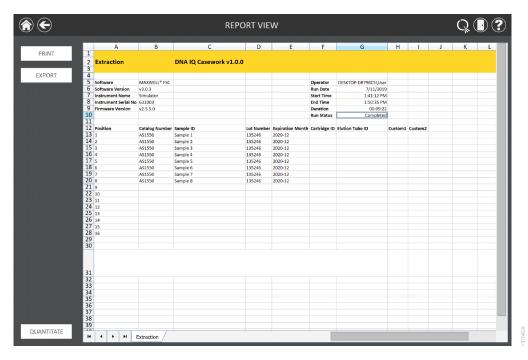


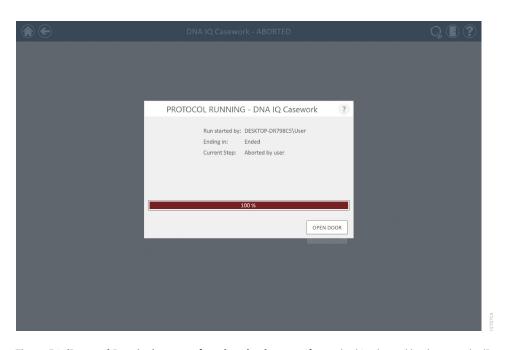
Figure 50. 'Report View' screen. A run report is displayed after the completion of an extraction run.

# 6.2.4 User Aborts Method



An aborted run (due to power failure or other unexpected error) may result in the loss of all samples. While original performance expectations cannot be guaranteed, a partial recovery of the sample(s) may be possible. Please contact **Technical Services** for troubleshooting quidance before attempting to repurify samples.

If the method is aborted by the user, the 'Protocol Running' screen will indicate that the method has been aborted (Figure 51). 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 'Clean Up' screen (Figure 52) will be displayed.



**Figure 51. 'Protocol Running' screen after abort by the user.** If a method is aborted by the user, the 'Protocol Running' screen will display a progress bar of 100%, and Current Step is shown as "Aborted by user". After a method is aborted, press the **Open Door** button.

# 6.2.5 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.

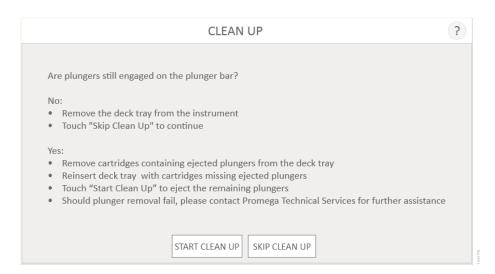
# 6.3 Clean Up



An aborted run (due to power failure or other unexpected error) may result in the loss of all samples. While original performance expectations cannot be guaranteed, a partial recovery of the sample(s) may be possible. Please contact **Technical Services** for troubleshooting guidance before attempting to repurify samples.

If a method has been aborted, press the **Open Door** button. The 'Clean Up' screen (Figure 52) 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 50).



**Figure 52. 'Clean Up' screen after abort/instrument error.** If an extraction method is aborted by the user or due to an instrument error, 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.

# 6.4 Optional: Quantitating with the Quantus™ Fluorometer

If attached to the instrument, results from the Quantus™ Fluorometer can be appended to completed run reports on the Maxwell® FSC Instrument.

Setting up the Quantus™ Flurorometer is covered in Section 4.2.

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<sup> $^{\text{M}}$ </sup> Fluorometer is correctly connected and ready to run, the "Q" logo will be displayed in the upper right corner of the title bar (Figure 53), and the display on the Quantus<sup> $^{\text{M}}$ </sup> Fluorometer will be active.



**Figure 53. Maxwell® FSC 'Home' screen.** When the Quantus™ Fluorometer is correctly connected to the Maxwell® FSC, the "Q" logo is displayed in the upper right corner of the title bar.

Prior to quantification, verify the Quantus<sup>M</sup> Fluorometer has the appropriate protocol selected. If the Quantus<sup>M</sup> Fluorometer needs calibration or the mode needs to be changed, consult the Quantus<sup>M</sup> Fluorometer Operating Manual #TM396.

1. When a Maxwell® FSC run is completed, the run report will be displayed (Figure 54). To append quantitation data to an existing Maxwell® FSC run report, select Results from the 'Home' screen. On the 'Results' screen, select the run report to which quantitation data should be added.

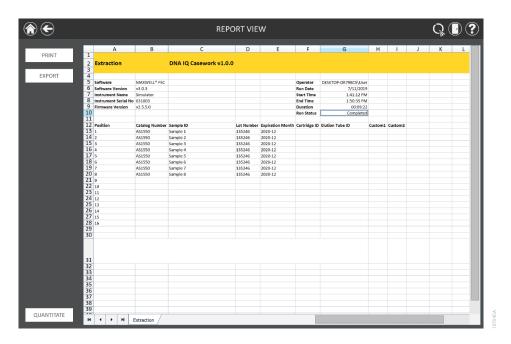
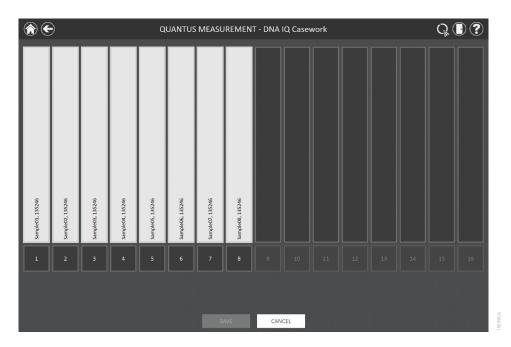


Figure 54. 'Report View' screen. Touch the Quantitate button in lower left corner of a run report to associate quantitation values read by the Quantus™ Fluorometer with samples from this run.

- 2. Select **Quantitate** on the lower left corner of the screen to display the 'Quantus Measurement' screen (Figure 55).
- 3. The 'Measure Sample Selection' screen will display on the Quantus™ Fluorometer.
- Select the sample you wish to quantitate by selecting the sample number that represents the elution position on the Maxwell® FSC Instrument.



**Figure 55. Quantus™ Measurement.** From this screen, select the sample position (black square below the cartridge) for which you would like to quantitate the sample with the Quantus™ Fluorometer.

- 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 and Fluorescent Dye Protocol* 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 56).



**Figure 56. '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 **Save** button in the center bottom of the 'Quantus Measurement' screen. To discard quantitation data and return to the 'Report View' screen, press the **Cancel** button.
- 13. A dialog box for the quantitation parameters will pop up (Figure 57). 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.

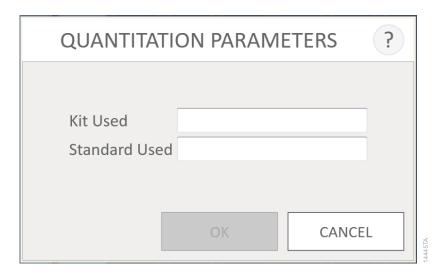
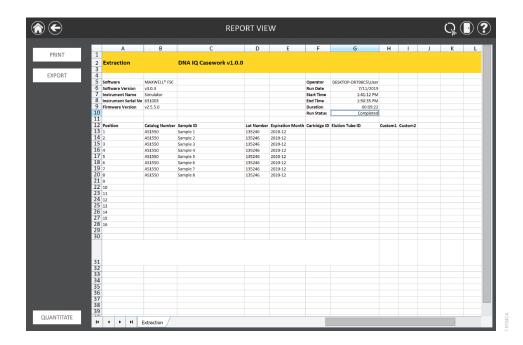


Figure 57. 'Quantitation Parameters' screen. Enter the name of the kit used to quantitate the sample and a description of the standard used for calibration.

### 6.5 Reports

The 'Report View' screen is displayed after pressing the **Open Door** button on the 'Protocol Running' screen (Figure 58). Run reports can be accessed later by selecting the Results button on the Maxwell® FSC 'Home' screen.

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



**Figure 58. 'Report View' screen.** The 'Report View' screen displays the sample tracking and method-specific information for the current instrument run. Included in this report are the sample tracking information recorded prior to starting the method, the final status of the method (Completed or Aborted), the time the method run was started, the length of time the method took to process, the operator ID and additional instrument information. Buttons are present on the left side of the screen to **Print and Export** report information, or **Quantitate** to associate quantitation data with the report.

Sample quantitation results can be added to a report using an integrated Quantus $^{\text{\tiny{M}}}$  Fluorometer by selecting **Quantitate** in the bottom left of the screen. See previous section for Quantus $^{\text{\tiny{M}}}$  Fluorometer operation.

Quantitation results can be reviewed (if collected and saved) by touching the 'Quantitation' tab (Figure 59) on the bottom of the Run report.

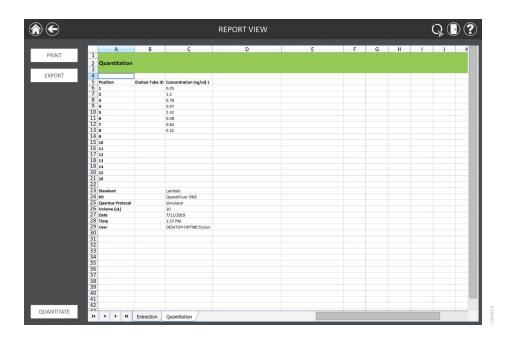


Figure 59. Quantitation report tab. The quantitation report tab shows sample quantitation data gathered using the Quantus™ Fluorometer.

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 60).
- Quantitate samples (optional) and associate the results with this report. This choice will only be displayed if a Quantus™ Fluorometer is plugged into one of the USB ports on the back of the Maxwell® FSC Instrument.

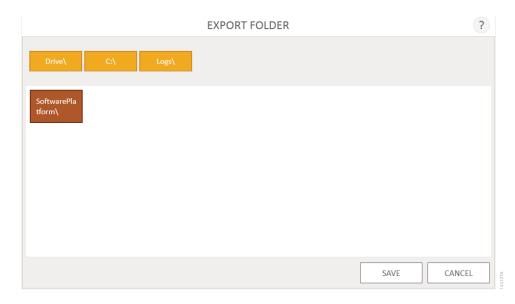


Figure 60. 'Export Folder' screen. When the Export button is pressed, the user will be asked to navigate to the file location where report files should be saved.

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® FSC Instrument 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 61.

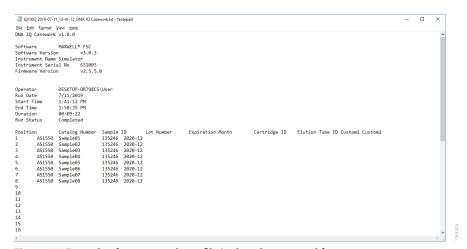


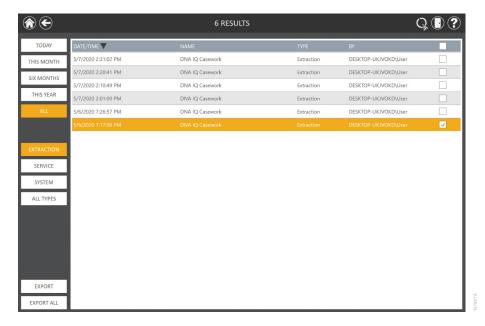
Figure 61. Example of an exported text file in the tab-separated format.

# 6.6 Running Reports

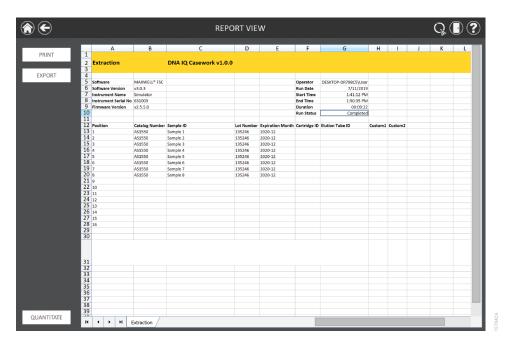
From the 'Home' screen (Figure 62) of the user interface, you can view sample tracking reports and service reports on the instrument by pressing the **Results** button. The 'Results' screen displays a listing of the extraction reports for the methods that have been run (Figure 63). Use the **Today**, **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 64). 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 5.3). To export a selection of extraction reports to a user-specified drive location, touch the checkbox next to the desired extraction report(s), and then 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 62. Maxwell® FSC 'Home' screen.** Selecting **Results** opens the Maxwell® FSC 'Results' screen from which extraction reports from all method runs can be viewed.



**Figure 63. 'Results' screen.** The 'Results' screen lists the reports from all of the methods that have been run. Touch any given report listing to see a detailed view of the report data from that method run. Filter the displayed results using the **Extraction, System** or **All Types** buttons on the left side of the screen. Selecting a date range button on the left side of the screen will filter the reports displayed based on their date. Press the **Export All** button to export all displayed reports to a user-specified drive location.



**Figure 64. Extraction report.** An example of the sample tracking information present in an extraction report.

#### 6.7 Sanitize

Touch the Sanitize button on the 'Home' screen (Figure 65) 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 66) that informs you on how long the UV sanitization will take. It will also ask you to confirm that no samples or eluates are present in the instrument prior to running Sanitization. Touch the Start button to start UV sanitization.



Figure 65. 'Home' screen. Selecting the Sanitize button begins the process for UV treatment of the Maxwell® FSC Instrument.

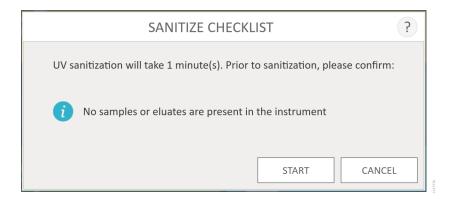


Figure 66. 'Sanitize Checklist' screen. The sanitization checklist indicates how long the UV sanitization will take. Confirm that no samples or eluates are present in the instrument prior to running Sanitization.

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 66).



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. Follow the cleaning guidelines in Section 7.

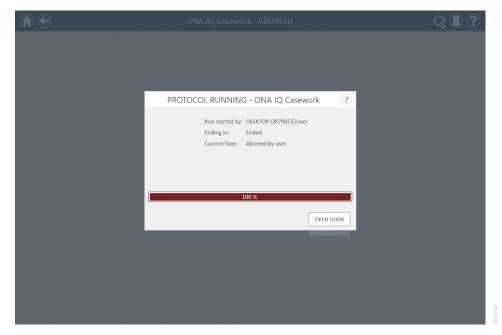


Figure 67. Example Sanitization Report. The sanitization report will be displayed after completing sanitization.

# Cleaning and Maintenance

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

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

## 7.1 General Care



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

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

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

# 7.2 Cleaning the Hardware

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

- 1. To clean the magnetic rod assembly, wipe with a soft cloth dampened with 70% ethanol. Removal of paramagnetic particles from the magnetic rod assembly will require multiple wipes. The damp cloth may be wrapped around a magnet to facilitate removal of magnetic particles.
- 2. If the magnetic rod assembly cannot be cleaned, please contact Promega Technical Services for assistance.

# 7.3 Dealing with Spills



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

Wipe up any spills immediately. If any material spills in the instrument, wipe up the material using a cloth dampened with 70% ethanol. Note that the reagents contain hazardous materials; therefore dispose of the cleaning materials according to your institutional guidelines. Wipe well once visible material is removed. In case of spills in the instrument where there is a potential biohazard, wipe up the spill with paper towels and wash the spill area with a detergent solution such as Steris LpH® following the manufacturer's instructions. Dispose of towels used according to your institutional guidelines for biohazardous waste.

# Troubleshooting

For questions not addressed here, please contact your local Promega Branch, Office or Distributor. Contact information available at: **www.promega.com** or e-mail:

## techserv@promega.com

Symptoms	Causes and Comments
Clean Up function	If plungers are still engaged on the plunger bars, perform the following steps:
does not unload the plunger	Remove cartridges containing the ejected plungers from the deck tray
	Reinsert the deck tray with cartridges that do not have ejected plungers.
	Touch the <b>Start</b> button to eject the remaining plungers.
	If the plunger clean up fails, contact Promega Technical Services for further assistance.
Tablet PC touch	Verify that the power supply is securely connected to the Tablet PC.
screen does not appear to be working	Verify that the instrument is plugged in to the USB port on the Tablet PC.
	Restart the Tablet PC and launch Maxwell® FSC software.
	If the issue is not resolved, contact Promega Technical Services for further assistance.
Cannot change the sanitization time or import new methods	Only operators with administrator-level access to the Maxwell® FSC software have the ability to change certain functions. If you do not have administrator-level access, contact your site administrator.
Power failure during a run	In the event of a power failure, turn off the instrument (using the rocker switch on the back of the instrument) and the Tablet PC. When power has returned, turn the instrument and Tablet PC back on. Check to see whether plungers are loaded on the plunger bar. If so, run <b>Clean Up</b> from the 'Settings' Menu and follow prompts to safely remove the plungers. After plungers have been unloaded, remove the deck tray from the instrument if it is still present. <b>An aborted run (due to power failure or other unexpected error) may result in the loss of all samples. While original performance expectations cannot be guaranteed, a partial recovery of the sample(s) may be possible. Please contact Technical Services for troubleshooting guidance before attempting to repurify samples.</b>

# **Errors and Warnings**

Error	Explanation
Initialization Failure: Access Denied, not a valid Promega User, Please contact your system administrator	Promega User not set up correctly in Windows® Operating System. Consult the Maxwell® Windows® 10 Tablet PC Configuration Manual #TM586 and/or contact your administrator/IT personnel to resolve this issue.
USB Device is not found; is it turned off or disconnected?	Tablet PC is not connected to the instrument, Tablet PC is off or the instrument is off. Check to see if the Tablet PC is connected to the instrument. Turn on the Tablet PC and turn on the instrument. If the Tablet PC and instrument are powered on, connected by the USB cable and this problem persists, cycle power on the instrument and reboot the Tablet PC. If error still persists, contact Promega Technical Services.
Open door detected during operation	Open door was detected during operation. The run will be aborted and samples will be lost. If error persists, contact Promega Technical Services.
Protocol: Aborted By User	User aborted the method.  An aborted run (due to power failure or other unexpected error) may result in the loss of all samples. While original performance expectations cannot be guaranteed, a partial recovery of the sample(s) may be possible. Please contact Technical Services for troubleshooting guidance before attempting to repurify samples.
An error occurred during cartridge placement verification. Ensure cartridges are fully seated	Instrument detected cartridges were not fully seated in the tray. Reseat the cartridges in the tray. If error still persists, contact Promega Technical Services.
Door sensor tripped	Door sensor trip detected. Contact Promega Technical Services.
Door failed to open successfully	Door failed to open. Contact Promega Technical Services.
A previous instrument task is still active. Please try again later.	User tried to do something while previous run was active. Wait for the current process to complete. If error persists, contact your IT administrator or Promega Technical Services.
Previous session has timed-out, device disconnected?	Connection was lost during previous instrument operation or USB was unplugged during a run and then plugged back in. Check to see that the USB cable is connected to the instrument or that no one unplugged the USB cable while the instrument operation was running.  If error still persists, contact Promega Technical Services.
Warning: Failed to Start Extraction: Self-Test has not passed	Instrument self-initialization has not passed. Run the <b>Self Test</b> from the 'Settings' screen. If the problem persists, Contact Promega Technical Services.

Error	Explanation
Warning: Startup Diagnostics: Abort of previous run detected	Instrument detected that previous run was aborted. Check to see whether plungers are loaded on the plunger bar. If so, run <b>Clean Up</b> from the 'Settings' Menu and follow prompts to safely remove them. After plungers have been unloaded, remove the deck tray from the instrument.
Warning: Startup Diagnostics: Firmware version change detected	User warning informing user that a firmware version change has been detected. Contact Promega Technical Services.

#### 8.1 Use of a USB Flash Drive

- · When using a USB flash drive, insert it before running any method and do not remove it until the method is finished.
- Do not insert or remove a USB flash drive while instrument is running.
- Since USB flash drives may vary from vendor to vendor or from type to type, incompatibilities can occur. If your USB flash drive is not detected after a few seconds or if you encounter any issues with the USB flash drive, shut down and restart the tablet and the instrument, and try a different brand of USB flash drive.
- If the tablet controller becomes unresponsive after inserting a USB flash drive, shut down and restart the tablet and the instrument.

# Instrument Service

## 9.1 Service

We recommend that the Maxwell® FSC Instrument receive a yearly preventive maintenance service.

# 9.2 Returning the Maxwell® FSC Instrument for Service

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

- Obtain return authorization from Promega.
- Decontaminate the instrument (see Section 11 for decontamination instructions).
- Include a signed and dated Certificate of Decontamination inside the package in which the instrument is returned (see Section 11). Failure to complete and attach the Certificate of Decontamination will result in a decontamination charge.
- Use the original packaging to ensure that no damage will occur to the instrument during shipping.
- Any damage will incur additional charges. Return all of the accessories with the instrument, including the bar code reader and Tablet PC.



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

#### 9.3 Repacking the Maxwell® FSC Instrument

#### 9.3.1 Preparing the Maxwell® FSC Instrument Prior to Repacking:

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

#### 9.3.2 Repacking the Maxwell® FSC Instrument

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

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

- 1. Turn the instrument off and unplug it from the outlet.
- Open the instrument door and manually push the deck to the back of the instrument.
- Manually slide the plunger bar (Figure 68) down to cover the magnetic tips.



Figure 68. Plunger bar.

- 4. Place the die cut foam as shown in Figure 69.
- 5. Slide the other die cut foam to lock the deck and the plunger bar as shown in Figure 69. You may have to manually move the plunger bar so that it is flush with the foam. The two die cut foams prevent the plunger bar and deck from moving during shipping. Note that the instrument door will not close completely with the foam in place. This is by design. Do not try to force the door to close, or the door can break.
- 6. Place the instrument back in the plastic bag.



Figure 69. Placement of die cut foam in the Maxwell® FSC.

- 7. Place the instrument in the bottom foam packaging material. The instrument will only fit properly into the bottom foam piece in one orientation (Figure 70, Panel A).
- 8. Place the top foam packaging over the top of the instrument as shown (Figure 70, Panel B).

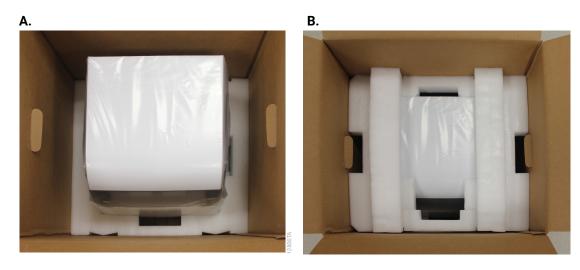


Figure 70. Repacking the Maxwell® FSC. Maxwell® FSC Instrument in the correct orientation in the box (Panel A). Foam packing on top of box (Panel B).

9. Place the accessories box on top of the packing foam. Affix the Certificate of Decontamination on top of the accessories box (Figure 71).



Figure 71. Accessories box on top of packing foam. Affix Certificate of Decontamination to the top of the accessories

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

#### Instrument Disposal 9.4

Contact your local Promega Representative for disposal of the instrument. Please follow your institutional and country-specific requirements to handle the disposal of accessories. Instrument must be decontaminated prior to disposal.

# 10 Warranties, Service Agreements and Related Products

## 10.1 Warranty

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

# 10.2 Warranty and Service Agreement Options

### Maxwell® FSC Premier Warranty Upgrade Cat.# SA3101

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

#### Maxwell® FSC Standard Service Agreement

The Standard Service Agreement covers all parts, labor and shipping to and from our depot repair location as well as a loaner instrument upon request. The Standard Service Agreement is available in 1-Year, 2-Year or 3-Year coverage periods. If your Maxwell® FSC needs repair, we will provide a box for shipment of the instrument back to our service facility. We will repair it and return it performing to original factory specifications. PM visits are available separately.

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

Product Name	Cat. #
1-Year Maxwell® FSC Standard Service Agreement	SA3102
2-Year Maxwell® FSC Standard Service Agreement	SA3110
3-Year Maxwell® FSC Standard Service Agreement	SA3111

### Maxwell® FSC Premier Service Agreement

The Premier Service Agreement includes all parts, labor and shipping to and from our depot repair location as well as your choice of a loaner instrument within 1 business day (where available) or on-site service visit by a factory trained service technician within 2 business days (where available). The Premier Service Agreement is available in 1-Year, 2-Year or 3-Year coverage periods. Additionally, it includes one annual Preventive Maintenance per year which can be performed by returning the instrument to an authorized service center or by an on-site visit by a service technician. Additional PM visits are available separately.

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

Product Name	Cat. #
1-Year Maxwell® FSC Premier Service Agreement	SA3103
2-Year Maxwell® FSC Premier Service Agreement	SA3112
3-Year Maxwell® FSC Premier Service Agreement	SA3113

## Maxwell® FSC Preventive Maintenance Cat.# SA3104

In order to keep the system operation at peak performance, Promega recommends that Maxwell® FSC instruments receive a Preventive Maintenance check after 12 months of use. During this procedure, our qualified service personnel test the instrument, check parts for wear and replace them as needed. Additionally, the system is aligned and functionality is verified. Documentation for your files is provided. The preventive maintenance service is performed by returning the instrument to an authorized service center.

## Maxwell® FSC Installation Qualification and Operational Qualification

Product Name	Cat. #
Maxwell® FSC Installation Qualification	SA3105
Maxwell® FSC Operational Qualification	SA3106
Maxwell® FSC Installation Qualification/Operational Qualification	SA3107

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

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

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

- Running operational verification tests
- Documenting all calibration and test results
- Training customer(s) to operate the instrument
- Training customer(s) to use the log book
- Completing customer-specific log book, instrument sticker and OQ documentation

#### 10.2.1 Limited Warranty and Service Guidelines

Pursuant to this Warranty, Promega warrants to the original purchaser of the Promega Maxwell® FSC Instrument that Promega will provide the parts and labor required for service and repair of the instrument for one year from the date of purchase. Your Warranty includesdepot repair with a loaner instrument (where available) to be used during your instrument's repair. The instrument is to be safely packed and shipped to Promega at Promega's expense. Promega will return the repaired or replaced unit to you at Promega's expense within 3 business days after the repair is complete. Instrument coverage and protection may be renewed through one-, two-, or three-year service agreements, provided the renewal is requested prior to the expiration of the current Warranty or Service Agreement.

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

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

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

## 10.2.2 Out of Warranty Service

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

## 10.3 Related Products

PRODUCT	SIZE	CAT.#
Bar Code Reader, Maxwell® Systems	1 each	AS3200
Maxwell® Elution Magnet, 16-Position	1 each	AS4017
Maxwell® RSC 48 System	1 each	AS8500
Quantus™ Fluorometer	1 each	E6150
Maxwell® FSC Deck Tray	1 each	AS4016
Maxprep® Liquid Handler, RSC Carriers	1 each	AS9105
USB Ethernet Adapter	1 each	AS8403

1 1 Certificate of Decontamination

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

To disinfect and decontaminate: Wipe off the magnetic rod assembly, plunger bar, inside platform, and inside and outside surfaces using a cloth dampened with 70% ethanol. Follow immediately with a cloth dampened with deionized water. Repeat the procedure as many times as required to effectively disinfect and decontaminate the instrument.

Failure to follow these decontamination guidelines, sign and return the Decontamination Form will result in decontamination charges before the instrument will be serviced.

Select either (A) or (B):
<ul> <li>A. I confirm that the returned items have not been contaminated by body fluids or by toxic, carcinogenic, radioactive, or other hazardous materials.</li> </ul>
☐ B. I confirm that the returned items have been decontaminated and can be handled without exposing personnel to health hazards.
Select the type of material used in the instrument:
☐ Chemical Biological
☐ Radioactive**
Briefly describe the decontamination procedure performed:
Date:
Place:
Signature:
Name (block capital letters):
** The signature of a Radiation Safety Officer is also required if the instrument was used with radioactive materials.
This instrument is certified by the undersigned to be free of radioactive contamination.
Date:
Place:
Signature:
Name (block capital letters):
Title:

# 12 Summary of Changes

The following change was made to the 10/24 revision of this document:

- 1. Updated Sections 1.1, 1.4, 4.4, 5.3, 6.2, 6.3, 10.2 and 10.3.
- 2. Revised Figures 29, 32, 41, 42, 43, 44 and 63.
- 3. Made general text and formatting edits.

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

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

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

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

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

