

Maxwell® 16 IVD Instrument Technical Manual



In Vitro Diagnostic
Medical Device



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INSTRUCTIONS FOR
USE OF PRODUCT
AS3050



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1. Introduction

A. Intended Use of the Maxwell® 16 IVD Instrument (Cat.# AS3050)

The Maxwell® 16 IVD Instrument is intended for use as an IVD accessory, when used in the IVD mode with the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015) or the Maxwell® 16 Viral Total Nucleic Acid Purification System (Cat.# AS1155). The instrument is used in combination with the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015) to perform automated isolation of genomic DNA from human whole blood or buffy coat samples. Samples collected in blood collection tubes treated with EDTA, heparin or citrate can be used. The instrument is used in combination with the Maxwell® 16 Viral Total Nucleic Acid Purification System (Cat.# AS1155) to perform automated isolation of viral total nucleic acid from human plasma or serum samples.

The nucleic acid isolated using the Maxwell® 16 IVD Instrument is suitable for direct downstream analysis by standard amplification methods. These methods include a variety of polymerase chain reaction (PCR) tests for human in vitro diagnostic purposes.

The Maxwell® 16 IVD Instrument is not intended for use as part of a specific in vitro diagnostic test. The Maxwell® 16 IVD Instrument is intended for professional use only. Diagnostic results obtained using nucleic acid purified with this system must be interpreted in conjunction with other clinical or laboratory data.

The Maxwell® 16 IVD Instrument is intended for use in the following countries only: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Canada, and the United Kingdom.

B. Product Use Limitations

The Maxwell® 16 IVD Instrument is not intended for use with clinical samples from body fluids or tissues other than blood, plasma or serum. It is not intended for use with nonhuman samples.

The performance of the Maxwell® 16 IVD Instrument when used in combination with the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015) has been evaluated by isolating DNA from 300µl samples of whole blood or 250µl samples of buffy coat prepared from 2.5ml of whole blood obtained from healthy individuals with a white blood cell (WBC) count ranging from 4.2×10^6 to 1.2×10^7 WBC/ml.

The performance of the Maxwell® 16 IVD Instrument and the Maxwell® 16 Viral Total Nucleic Acid Purification System (Cat.# AS1155) has been evaluated by isolating viral total nucleic acid from 300µl of plasma samples containing virus ranging from 10,000 copies to 1 million copies/ml of sample.

The user is responsible for establishing performance characteristics necessary for downstream diagnostic applications. Appropriate controls must be included in any downstream diagnostic applications using nucleic acid purified using the Maxwell® 16 IVD Instrument.

The Maxwell® 16 IVD Instrument does not actively track samples. Maxwell® Sample Track software allows the user to assign matching identification codes to the cartridge and elution tube used for a particular sample only for the purposes of tracking the sample through the Maxwell® 16 IVD Instrument run. The user is responsible for sample tracking.

Compliance with EU Directive 98/79/EC on in vitro diagnostic medical devices has been demonstrated for, and only applies to, use of the Maxwell® 16 IVD Instrument (Cat.# AS3050) in the IVD mode with the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015) or the Maxwell® 16 Viral Total Nucleic Acid Purification System (Cat.# AS1155).

C. Maxwell® 16 IVD Purification Procedure

The Maxwell® 16 IVD Instrument provides automated nucleic acid purification from up to 16 samples using lysis to release nucleic acid and binding nucleic acid to paramagnetic particles as the primary separation principle. It has two modes for different elution volumes. The Standard Elution Volume (SEV) mode, used for the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015), allows elution in a volume of 300µl. The Low Elution Volume (LEV) mode, used for the Maxwell® 16 Viral Total Nucleic Acid Purification System (Cat.# AS1155), allows elution in a volume of 50µl. The Maxwell® 16 IVD Instrument provides high-purity nucleic acid that is compatible with standard amplification methods.

The automated steps performed by the Maxwell® 16 IVD Instrument include:

- Sample lysis in the presence of a chaotropic agent, detergent and/or alcohol
- Binding of nucleic acids to paramagnetic particles
- Washing of the nucleic acid bound to the particles away from other cellular components
- Elution of the product

The instrument contains a touch screen for navigating, programming and running the instrument. It has a UV lamp to aid with decontamination. The Maxwell® 16 IVD Instrument, in association with the Maxwell® Sample Track software, has the ability to record and provide run data. It has a USB port that can be used to attach a bar code reader, allowing sample and reagent information to be entered using bar codes. The Maxwell® 16 IVD Instrument can report the data gathered for each run, and the report can be sent to a computer.

The user selects the protocol to be run, collects the selected bar code information (optional) and places the samples into the reagent cartridges. The cartridges are placed into the machine and the door shut. The user then starts the run, which automatically performs the protocol.

The elution temperature of the samples is regulated by a heating system that is controlled by the protocol.

Maxwell® Sample Track is a communications program that allows downloading and printing of the run data (see Technical Manual #TM314).

Maxwell® 16 IVD Instrument Features

- Compliant with the following EU Directives:
 - 98/79/EC In vitro Diagnostic Medical
 - 2004/108/EC Electromagnetic Compatibility
 - 2006/95/EC Low Voltage Directive
- Easy-to-use and easy-to-maintain system operation that standardizes nucleic acid sample preparation workflow in the clinical laboratory
- Comprehensive technical support
- System controlled via multi-language LCD.
- UV lamp to aid in decontamination of instrument
- Reporting functionality
- Optional Maxwell® Sample Track software available

D. Maxwell® 16 IVD Instrument Specifications

Processing Time: depending on sample type and method used, less than 60 minutes

Number of Samples: up to 16

Weight: 19.4kg (42.7lb)

Dimensions (W × D × H): 325.5 × 438.2 × 326.5mm (12.8 × 17.3 × 12.9 inches)

Power Requirements: 100–240VAC, 50/60Hz, 2.1A

Fuse: 3A time-lag fuse

UV Bulb: Average lifetime approx. 3000 hours, length 134.5mm, diameter 15.5mm, 4.5W, 0.17A current, 29V, Spectral Peak 253.7, UV output 0.8W.

E. Product Components

AS3050 Maxwell® Series Instruments Include:










- 1 Maxwell® 16 IVD Instrument
- 1 power cable
- 1 UV lamp bulb
- 1 SD card
- 1 SD card reader package (contains SD card reader and cable)
- 1 CD containing the technical manual

- 1 Quick Start Guide
- 1 Bar Code Reader
- 1 CD Containing Sample Track Software and manual
- 1 RS-232 Cable for firmware upgrades or data export to serial printer
- 1 RS-232/USB Adaptor for data export to computer
- 1 SEV cartridge rack
- 1 SEV magnetic elution rack
- 1 LEV cartridge rack



The Maxwell® IVD Instrument is supplied preconfigured in the IVD mode and with the LEV hardware.

Table 1. Symbol Key.

Symbol	Explanation
	In Vitro Diagnostic Medical Device
	Conformité Européenne
	Important
	Manufacturer
	Authorized Representative
	Consult your local Promega Representative regarding instrument disposal
	
	Catalog Number
	Serial Number

F. Inspection

Upon receiving your Maxwell® 16 IVD Instrument, please inspect the package carefully to make sure all accessories are present and that the instrument has not been damaged in shipping. If any item is damaged contact Promega Technical Services. Standard accessories are shown in Figure 1.



Figure 1. Maxwell® 16 IVD Components. Components shown include: bar code reader cable, bar code reader, SEV and LEV cartridge racks, SEV elution rack, power cord, UV bulb, SD card reader and cable, SD card, RS-232/USB adaptor cable, RS-232 cable. Not pictured: Quick Start Guide, CD containing Technical Manual and CD containing Sample Track Software. The bar code reader and bar code reader cable are provided in a separate box.

G. Precautions

Important Safety Instructions. Save these instructions.

Table 2. Safety Symbols and Markings.

Symbol	Explanation
	Danger. Hazardous voltage. Risk of electrical shock.
	Warning. Risk of personal injury to the operator or a safety hazard to the instrument or surrounding area.
	Warning. Pinch point hazard.
	Warning. Hot surface. Burn hazard.
	Warning. Lifting hazard.
	Warning. Biohazard.
	Warning. UV light hazard. Do not look directly at the UV light.
	Warning. Wear Gloves When Handling.
	Warning. It is important to understand and follow all laws regarding the safe and proper disposal of electrical instrumentation and components. Please contact your local Promega Representative for disposal of the instrument. Please follow your institutional requirements for disposal of the accessories.

- Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case you may need to take measures to mitigate the interference.
- Do not use this device in proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), because these may interfere with the proper operation.

- Do not use this instrument for anything other than its intended use.
- Always disconnect the power before cleaning or performing routine maintenance.
- Do not disassemble unit.
- Do not override the door sensor. Moving parts may cause personal injury.
- 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.
- After each run, verify that the plungers have been completely removed from the magnet rods before pressing Run/Stop to extend the platform.
- Use only Promega Maxwell® 16 cartridges and plungers designed for use with the appropriate hardware configuration of the instrument.
- Do not reuse cartridges, plungers or elution tubes.
- Wear gloves when handling the UV bulb, for example during insertion and removal of the bulb. Do not operate the UV lamp if the instrument door is open.
- Use only Promega-supplied UV bulbs (Cat.# SP1080).
- 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. The Maxwell® 16 IVD Instrument weighs 19.4kg (42.7lb) and should be handled by two people.
- Equipment can be hazardous due to the use of chemical and biohazardous substances.
- The UV bulb contains mercury and must be disposed of properly. To dispose of a bulb, please follow your institutional requirements for clean up and disposal of mercury.

H. Environmental Requirements (Operating, shipping and storage conditions)

Power Requirements: 100–240VAC, 50–60Hz, 2.1A

Temperature: 5–40°C

Humidity: up to 80% relative humidity

The Maxwell® 16 IVD Instrument is intended for indoor use only. Wipe up spills immediately. Install the instrument on a clean, level surface. To avoid shortening the expected lifespan of the instrument, install in a location that meets the following criteria:

- Locate on a sturdy, level surface.
- Avoid dusty areas.
- Choose a location that has good air circulation and is not exposed to direct sunlight.
- Avoid noisy electrical power sources (e.g., power generators).
- Do not install in a location where there is large temperature variability or high humidity.
- Position the instrument so that it is easy 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.

2. Hardware Overview

Figures 2 and 3 show the front of the Maxwell® 16 IVD instrument.



Figure 2. Front of Maxwell® 16 IVD Instrument.



Figure 3. The touch screen and the keypad for use in navigating through the various screen displays for the Maxwell® 16 IVD Instrument. The same button selections are available on the keypad and the screen. Both sets of buttons can be used to navigate within and between screens. The Back and Run/Stop buttons allow navigation between screens. The Up and Down buttons are for navigation within a screen.

The RS-232 serial port can be used to connect to a computer using the supplied RS-232 cable. If your computer does not have an RS-232 port, a Tripp Lite® connector is included and can be used to connect the Maxwell® 16 IVD Instrument to a USB port on the computer using the adaptor attached to the RS-232 cable.

The USB Connector port is for a bar code reader and only allows bar code data to be imported into the Maxwell® 16 IVD Instrument. Connect the USB plug from the bar code reader to the instrument using this port. Data cannot be exported from this connector port.

Note: Do not link a computer or printer to the USB port.

The SD Card slot is used to update firmware. A blank SD Card is supplied with the Maxwell® 16 IVD Instrument.

This card can be used to transfer firmware to the Maxwell® 16 IVD Instrument from a computer (See Section 11.A). We recommend that you keep the SD card in the instrument to avoid misplacing it.



Figure 4. Power On/Off switch on the back of the Maxwell® 16 IVD Instrument. A 3 amp time-lag fuse is located next to the power switch. This picture shows the back of the instrument with the On/Off switch and the power cable connection.

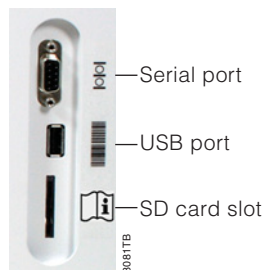


Figure 5. Communications ports on the side of the instrument. This side view shows the communication ports for the instrument. The USB port is used to attach the bar code reader.

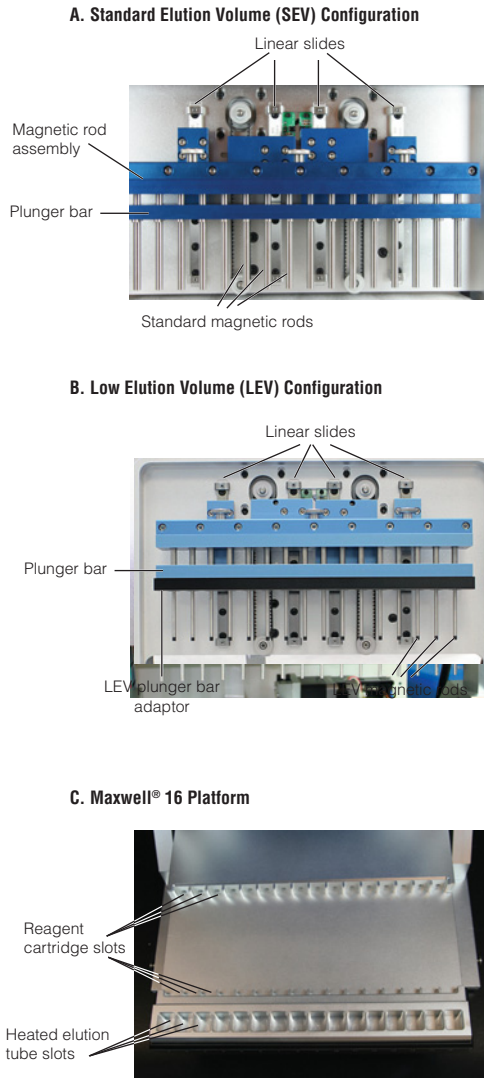
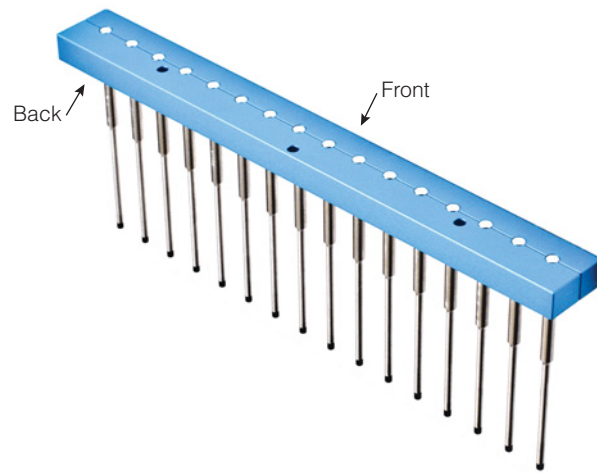


Figure 6. Magnetic assembly components and platform.

Figure 6 shows the hardware components inside the machine. The Magnetic Rod Assembly varies depending on the configuration (SEV or LEV). Figure 6, Panel A, shows the SEV hardware configuration indicating the slides, which allow the Plunger to move up and down; the Magnetic Rod Assembly, which holds the magnets in place; and the Plunger Bar, which contains the Magnetic Rods. Figure 6, Panel B, shows the LEV hardware configuration that incorporates an Adaptor to hold the LEV Magnetic Rods and LEV Plunger Bar. Figure 6, Panel C, shows the Platform indicating the slots where the SEV cartridges and elution tubes are placed. For LEV, the cartridge sample rack containing the LEV cartridges is placed on the Platform (rack not shown).

Orientation of the Magnetic Rod Assembly



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Figure 7. Orientation of Magnetic Rod Assembly. The orientation of the Magnetic Rod Assembly, with the screw holes facing the back of the instrument.

Figure 7 shows the correct orientation of the Magnetic Rod Assembly. The screw holes face the back, and the magnetic rods sit toward the front of the instrument. If the rod assembly needs to be removed for cleaning (see Section 8) and replaced, ensure that this orientation is retained.

3. Unpacking and Setting Up the Maxwell® 16 IVD Instrument

A. Unpacking

1. Remove the accessory box, power cord and literature package from the shipping container. Slide the instrument out of the box. **Note:** Do not lift the instrument out of the box by the door handle.
2. Remove the foam packaging from the sides of the instrument and remove the clear plastic cover.
3. Check that all the parts have been included (Figure 1).
4. Set the Maxwell® 16 IVD Instrument on a flat, level, solid surface in a dust-free location with good air circulation. If possible, move the instrument back from the edge of the surface to prevent inadvertently bumping the open door.



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

B. Removing the Magnetic Rod Assembly/Plunger Bar Platform Shipping Anchors

1. Ensure that the instrument is turned off and unplugged.
2. The Magnetic Rod Assembly, Plunger Bar and Platform are anchored in place during shipment to prevent movement of and damage to these parts.
Note: If the instrument has been switched on before removing the shipping anchors, you will hear the motors grinding as they attempt to perform instrument calibration. If this occurs, immediately turn off and unplug the instrument and remove the shipping anchors. This will not result in permanent damage to the instrument.
3. Open the instrument door and locate the Magnetic Rod Assembly/Plunger Bar and Platform shipping anchor thumbscrews, labeled with red stickers (Figures 8 and 9). Remove them.

! **Important.** Save the shipping anchor thumbscrews in case the instrument needs to be returned for service or repair at a later date.

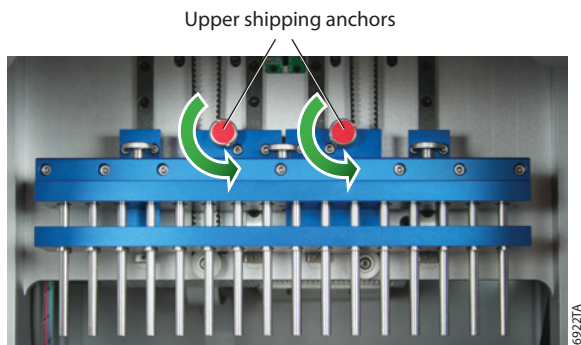


Figure 8. Upper shipping anchors.

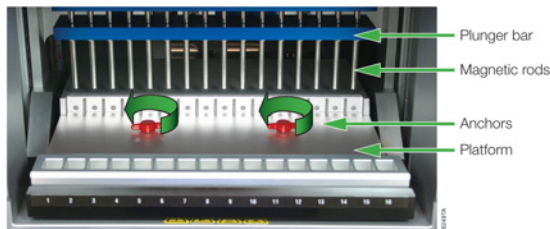


Figure 9. Platform shipping anchors.

C. UV Bulb Installation

To prevent damage to the UV bulb, wear gloves—do not touch the bulb with bare hands. Oil from your hands can compromise the bulb and shorten its lifespan. Remove the UV bulb from the box and wrapping. The bulb may rattle if shaken; this is normal. Locate the UV lamp socket, which

is located on the ceiling of the instrument just inside the door. Slide the bulb into the socket (see Figure 11). Twist the bulb a quarter turn until it is firmly in place. The UV bulb has an average life of 3000 hours. The Maxwell® 16 IVD Instrument will warn you when the accumulated UV bulb usage reaches 2950 hours, and we recommend that you change the bulb at that point. Replacement bulbs can be purchased from Promega (Cat.# SP1080).

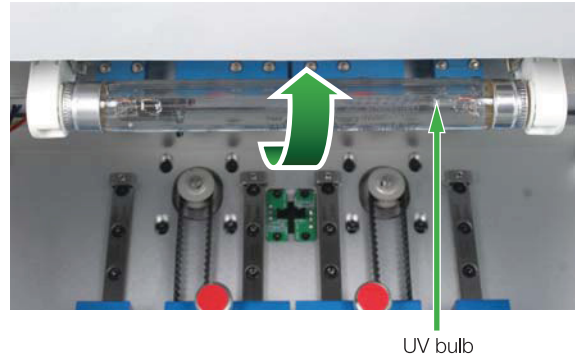


Figure 10. UV bulb in the power supply.

To replace the bulb, locate the old bulb in the UV lamp holder, which is located on the ceiling of the instrument just inside the door (see Figure 11). Wear gloves—do not touch the bulb with your bare hands. Twist the bulb a quarter turn until it can slide out. Place the new bulb into UV lamp socket and twist a quarter turn until it is firmly in place.

Your Maxwell® 16 IVD Instrument is now ready for operation.

D. Maxwell® Sample Track

To use the Maxwell® Sample Track software, you need to load the software onto a computer that will be connected to the Maxwell® 16 IVD Instrument. See the Technical Manual supplied with the software for more information. To install the software, place the CD containing the Maxwell® Sample Track software in the CD drive of your computer, and follow the on-screen instructions.

During installation, the Maxwell® Sample Track program will check to see if Microsoft® Windows® Installer Version 3.1 and Microsoft® .NET Framework Version 2.0 are installed on your computer. If necessary, the Maxwell® Sample Track installer will prompt you to install these applications, which are supplied on the Maxwell® Sample Track CD. Once the software is loaded, connect the computer to the RS-232 port of the Maxwell® 16 IVD Instrument using the RS-232 cable. **Do not connect your computer to the USB port on the Maxwell® 16 IVD Instrument.** If your computer does not have an RS-232 port, use the supplied Tripp Lite® adaptor to connect the USB port of the computer to the RS-232 cable. To use the Tripp Lite® adaptor, you must first load the driver from the

minidisk in the Tripp Lite® box. Place the minidisk in the CD drive of your computer and follow the instructions supplied in the Tripp Lite® instruction manual.

Connect the bar code reader to the USB port on the side of the instrument.

E. Operational Setup

Using the Touch Screen

Note: In the instructions below for touch screen setup and use, screen names are presented in **bold type**, and on-screen options are presented in *italics*.

The Maxwell® 16 IVD touch screen allows the user to select options. Most screens contain a series of navigation buttons that allow the user to scroll up and down easily between options. The touch screen buttons are the same as those on the keypad (see Figure 3), and they perform the same functions. Selection may be made using either set of buttons. The Run/Stop button is located on the bottom right of the touch screen.

Switching on the Instrument

Once the shipping anchors and all the packaging materials have been removed, the UV bulb has been installed and the peripherals attached, you can connect the instrument to a power outlet. Ensure that the On/Off switch is in the off position. The power switch is located next to the power cord connection on the back of the instrument (Figure 4). Connect the power cord to the back of the Maxwell® 16 IVD Instrument, and plug the power cord into a wall outlet. See Section 1.H for power requirements. Switch instrument on using the On/Off switch.

Every time the instrument is powered on, it will perform a self-diagnostic test before opening the **Home** screen. The Platform, Plunger Bar and Magnetic Rod Assembly are moved to check operation, and the UV light is briefly switched on to ensure that the bulb is functioning.

Shut down procedure: Switch the instrument off, using the On/Off Switch located on the back of the instrument (Figure 4). Unplug the instrument.

If you need to store the instrument, switch the instrument off and unplug it. Be sure to store the instrument in the appropriate environmental conditions. See Section 1.H.

Configuring the Instrument Using the Maxwell® Wizard

The Maxwell® Wizard starts the first time the instrument is switched on and guides you through the initial setup. This Wizard will help you to set up the instrument configuration to best meet your needs. During setup you can set the following parameters: Language, Touch screen settings, Date/Time, UV Lamp run options, Sample Tracking, Instrument Name and Approved Users. Settings can be changed later if required (see Section 7.B).

The Wizard runs through the following options screens. You can select the appropriate option as needed.

1. **Languages.** The default language is English. If you wish to change the language, choose from the list in the **Select Language** screen. You may need to scroll down to the option needed. Once you have selected a language, press the Run/Stop button.



Figure 11. The **Select Language** screen. Once you have selected a language, press the Run/Stop button.

2. **Touch Screen.** You will need to calibrate the Touch Screen after shipping.

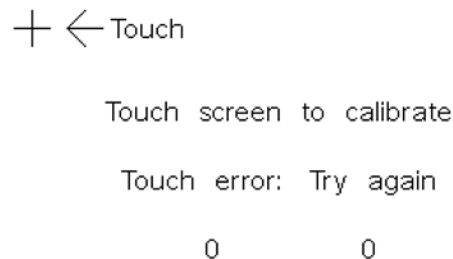


Figure 12. **Calibrating the Touch** screen. To calibrate the screen touch the "+" symbols in the order they are presented. A confirmation screen will open.



Figure 13. Confirmation screen for the Touch screen. Touch all four boxes, if all change color, press the Run/Stop button on the instrument keypad. If they do not all change color, press the back arrow button and repeat the calibration and confirmation.

The "Touch Screen Configuration Successful" message indicates that the calibration was successful, and the Wizard can continue.

3. **Date/Time.** Select the **Date/Time** screen to set the current date and time. In the initial screens, select the date and time formats. In the final **Date/Time Setup** screen, set the current time and date. Selecting each of the screen options opens a keypad for adding numerical values.

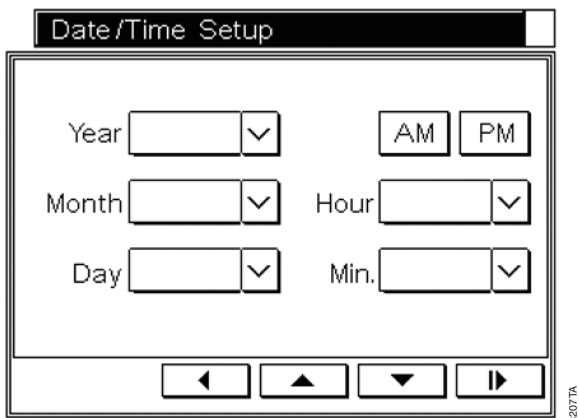


Figure 14. Date/Time Setup screen.

4. **UV Lamp.** You can program the Maxwell® 16 IVD instrument to turn on the UV lamp automatically. It can be set to turn on after each run or after start up, or it can be set to remain off.

The treatment time can be set in increments of 10 minutes for up to 10 hours. We recommend UV treatment for at least 1 hour. The UV lamp can also be turned on from the Setup menu (see Section 8.D).

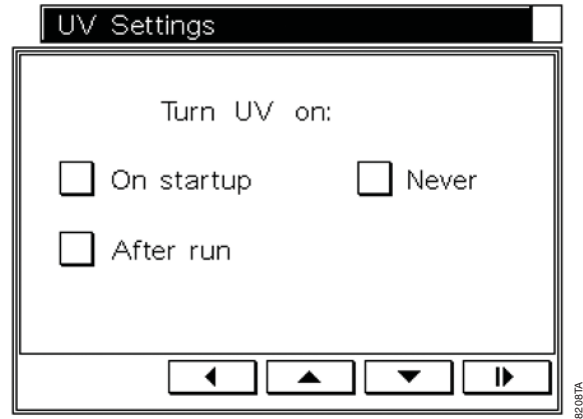


Figure 15. UV Settings screen. Select the desired option on the UV screen, and then set the time for UV treatment.

5. **Sample Tracking** If you choose "Tracking options-on", you will be able to choose the run report parameters to track in the **Barcode Options** screen.

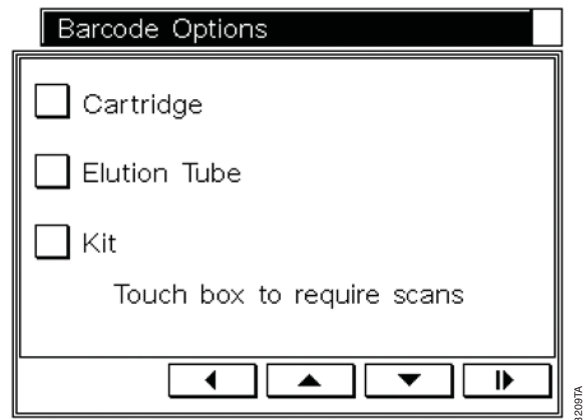


Figure 16. Barcode Options screen. Select the options to be reported.



Important. The options chosen must be entered during the run setup. Options not chosen will be displayed on the Barcode Input screen during run setup (Section 5), but you will not be able to scan bar code data for these options.

6. **Name Maxwell® 16 IVD Instrument.** This option allows the user to assign a unique identifier to the Maxwell® 16 IVD Instrument that can be used to identify the instrument on reports.

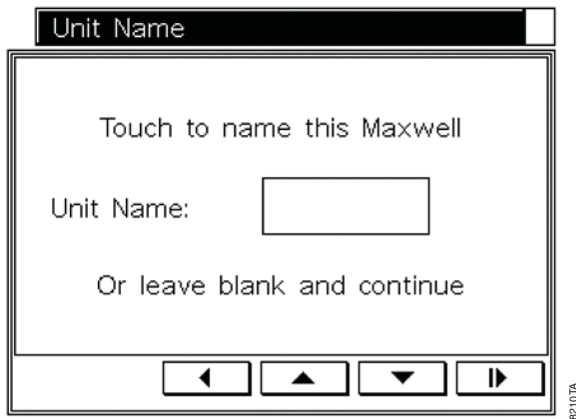


Figure 17. Unit Name screen. Touching the screen to name an instrument will open a keyboard to add a unique identifier.

- User and PIN Setup.** This option is a security tool for adding approved users and associated Personal Identification Numbers (PIN). This will require users to add a PIN when they use the instrument. If you choose "Yes", the **Select User** screen opens. The screen is initially populated with numbers. Select a number and then press the Run/Stop button.

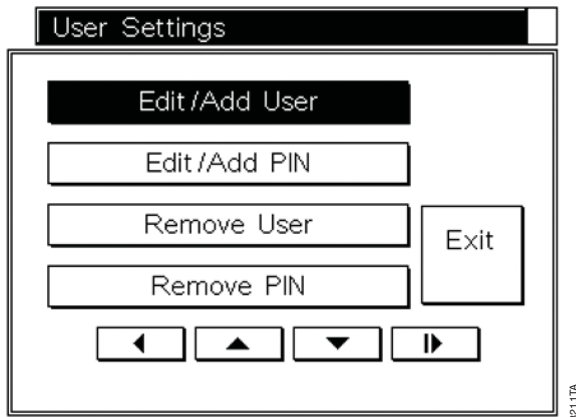


Figure 18. User Settings screen.

In the **User Settings** screen, select *Edit/Add User*, press the Run/Stop button, and add the user name using the keyboard.

Note: The user name is limited to 15 characters.

Once the user name has been added, press the Run/Stop button.

The Wizard will return to the **User Settings** screen. A PIN can be added for each user for security. PIN protection requires the user to enter a PIN to perform a purification run. The PIN is four digits. The list of users and associated PINs can be modified as described in Section 7.B. Keep a separate list of all users and associated PINs in case a PIN is forgotten.

An administrative password is included in the Welcome Letter, sent with the instrument, which is used to access all PIN-protected options. If you lose your Administrative PIN, contact Promega technical services.

To add a PIN, select *Edit/Add PIN* in the **User Settings** screen. A keypad will open. Add the desired PIN, and press the Run/Stop button. Confirm the PIN, and press the Run/Stop button.

In the **User Settings** screen, selecting *Exit* will take you to the **User Setup Complete** screen, where you can choose to add more users. Selecting *Yes* will return you to the **Select User** screen, where the added user is highlighted. Select another number, and repeat the process to add another user and PIN. Repeat until all of the users and PINs are added, then select the *Exit* button, in the **User Setup Complete** screen. Select *No* to end the Wizard. A maximum of 10 users can be added.

The Wizard will indicate that it is finished and will restart the instrument. Upon restart the instrument will perform a self-diagnostic test prior to opening the **Home** screen. The Platform, Plunger Bar and Magnetic Rod Assembly are moved to check calibration, and the UV light is briefly switched on to ensure the bulb is functioning.

During the diagnostic test, the firmware version is displayed on the screen. If you need to update to a new firmware version, see Section 11.

If you have chosen to run the UV lamp each time the instrument is switched on, the UV lamp will come on and run for the specified time. You will have the option to cancel this treatment.



Important. Do not open the door if the UV lamp is on.

UV lamp will not operate with door open.

The **Home** screen contains the menu options that allow access to all of the functions available for the instrument and displays the hardware mode (SEV or LEV).

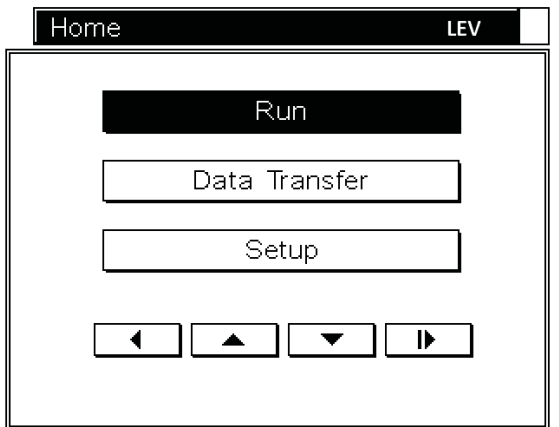


Figure 19. Home screen. Selecting *Run* allows a purification run to be set up and performed (see Section 5). Selecting *Data Transfer* allows the transfer of run data from the instrument to a computer if you are using the Maxwell® Sample Track software (see Section 6), or it allows deletion of run data from the instrument. Selecting *Setup* opens the Maxwell® 16 Configuration screen.

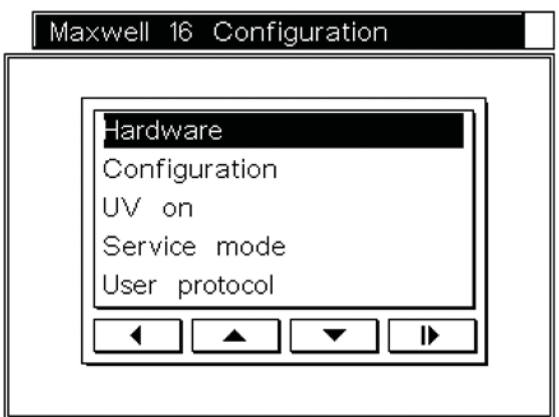


Figure 20. Maxwell® 16 Configuration screen. The functions to change the hardware (*Hardware*) and firmware (*Configuration*) settings (see Section 7) are accessible from this screen. Also, the UV lamp may be run from this screen (*UV on*; Section 8). This screen provides access to the Service functions (*Service mode*; Section 11.B). User protocols also may be set up from this screen by selecting *User protocol*.

4. Hardware Mode

The hardware mode chosen for each run depends on the purification protocol being used. Please refer to the Technical Bulletin or Manual for the Maxwell® 16 Blood DNA Purification System or the Maxwell® 16 Viral Total Nucleic Acid Purification System for further information on the hardware mode setting required.

The existing hardware mode (SEV or LEV) setting is displayed in the upper right hand corner of the **Home** screen. The instrument displays the hardware mode entered and does not sense the hardware installed. Always verify that the hardware installed matches what is displayed on

the **Home** screen. Make sure that the hardware and hardware mode are appropriate for the purification kit being used. If the installed hardware is not correct for the kit being used, remove the installed Magnetic Rod Assembly and replace it with the appropriate Magnetic Rod Assembly (see Section 7.A).

If the installed hardware does not match the hardware mode displayed, turn the machine off, and install the appropriate hardware with the machine turned off. When the machine is powered up after the installation, the installed hardware will match the hardware mode displayed on the **Home** screen.

5. Operating the Maxwell® 16 IVD Instrument

A. Setting Up Runs

Setting Up a Run in the SEV Mode

Verify that the **Home** screen indicates SEV and that SEV hardware is present. Select *Run*. If you configured the instrument to record users, a list of the user names added will be shown. Select the appropriate user, and add the matching PIN (if appropriate).



Important. Compliance with the EU Directive 98/79/EC on in vitro diagnostic medical devices has been demonstrated for, and only applies to, use of the Maxwell® 16 IVD Instrument (Cat.# AS3050) in the IVD mode with the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015) and the Maxwell® 16 Viral Total Nucleic Acid Purification System (Cat.# AS1155).



Important. The instrument is the provided set in the IVD mode. The instrument also contains preloaded research methods. Further information on how to access research methods can be found in Section 12.

1. You can select methods for purifying DNA from blood or buffy coat samples using the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015). Select the desired protocol on the touch screen, and press the Run/Stop button.

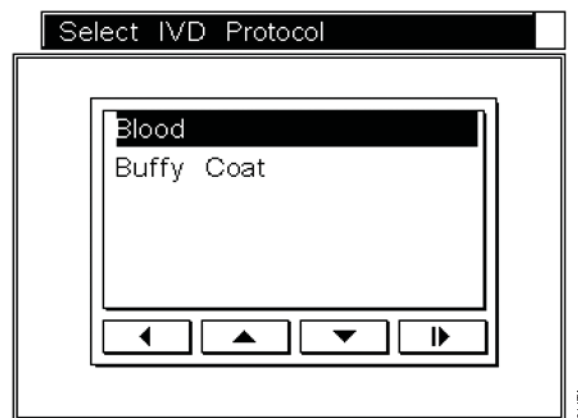


Figure 21. Select IVD Protocol screen for the SEV mode.

2. A **Verification** screen indicates which protocol has been chosen.

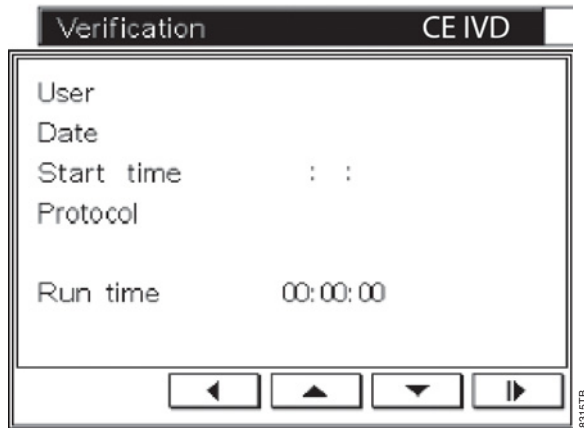


Figure 22. Verification screen.

3. If the correct protocol is shown, press the Run/Stop button. The **SEV Set Up** screen will appear. The instrument door will open, and the platform will extend, ready for sample loading.

Important. At this point there are different paths forward, depending on whether the run data reporting options are being used. See Section 5.B for more information. Proceed to Section 5.C for instructions on starting the run.

Setting Up a Run in the LEV Mode

1. Verify that the **Home** screen indicates LEV and that the LEV hardware is installed. Select *Run*. If you configured the instrument to record users, a list of user names will be shown. Select the appropriate user, and enter the matching PIN, if appropriate. Press the Run/Stop button. The Viral option is available.

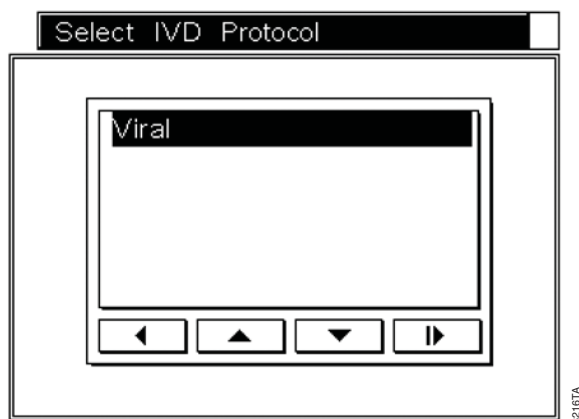


Figure 23. Select IVD protocol screen for the LEV mode.

2. Press the Run/Stop button. A **Verification** screen indicates which protocol has been chosen.

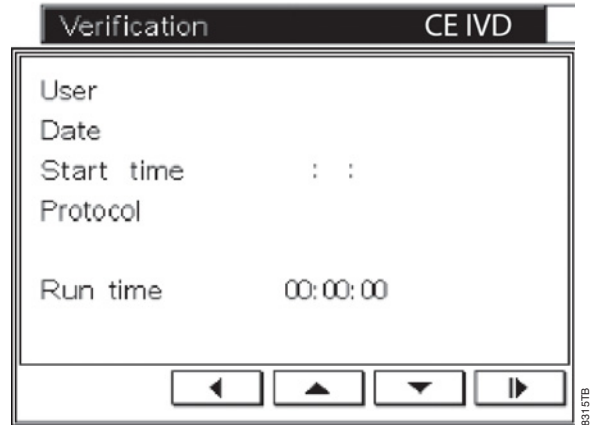


Figure 24. The LEV Verification screen.

3. If the correct protocol is shown, press the Run/Stop button. The **LEV Set Up** screen will appear. The instrument door will open, and the platform will extend, ready for sample loading.

Important. At this point there are different paths forward, depending on whether the run data reporting options are being used. See section 5.B for more information. Proceed to Section 5.C to start the run.

B. Setting Up Samples and Collecting Input Data

Setting Up Samples: No Run Data Reporting

Please refer to your specific Maxwell® 16 Purification Kit Technical Bulletin or Manual for detailed instructions regarding hardware mode, sample preparation, cartridge setup, and purification method.

The Maxwell® 16 reagent cartridges are designed to be used with potentially infectious substances. Users should wear the appropriate protection (i.e., gloves, goggles, etc.) when handling infectious substances. Users should adhere to their institutional guidelines for the handling and disposal of all infectious substances used with this system.

For an SEV run, the cartridges must be placed on the platform in the instrument. For an LEV run, the cartridges can be set up on the removable LEV rack and the rack placed on the platform in the instrument. The plungers are placed in the appropriate chamber as indicated on the **SEV Set Up** or **LEV Set Up** screen.

Important. The plungers must be placed in the correct starting position. If the instrument goes through a run with the magnetic rods unprotected, the magnetic rod assembly must be removed and cleaned (see Section 8.B) and the cartridges containing the samples discarded.

Setting Up Samples for Run Data Reporting

Maxwell® Sample Track software (Section 3.D) allows users to track samples throughout the run. A sample can be linked to a particular run, time and date, and the Maxwell® 16 purification kit used (catalog and lot numbers). Within

that run, the sample can be linked to: 1) the pretreatment tube (if used); 2) the cartridge used; 3) the sample position within the Maxwell® 16 IVD Instrument where the cartridge was placed; and 4) the elution tube used to collect the eluate.

The sample and kit information are entered into the Maxwell® 16 Instrument during sample setup using a bar code reader. To collect the sample information with a bar code reader, you must use matching bar code labels on the sample tube, pretreatment tube (if applicable), Maxwell® 16 cartridge, and elution tube. The bar code labels are placed on the tubes and cartridge before adding the sample. For SEV, the bar codes are scanned as you place the cartridge containing the sample into the Maxwell® 16 Instrument. For LEV, bar codes are scanned before placing the cartridge in the LEV cartridge rack.

Note: Bar codes containing more than 29 characters are not compatible with the Maxwell® 16 IVD Instrument.

Bar code information can be collected from the bar code on the Maxwell® 16 purification kit label. The bar code supplies the kit catalog number, lot number and expiration date. Run information also can be added manually to provide a tracking record.

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

Capturing Run Data with a Bar Code Reader

After you have completed the steps in Section 5.A, the door on the instrument will be open, and the platform will extend. The **Barcode Input** screen displays the information to be collected. The options displayed depend on the options chosen during setup.

! **Important.** If you configured the instrument to collect run information, you must input the information to the Barcode Input screen chosen to perform the run.

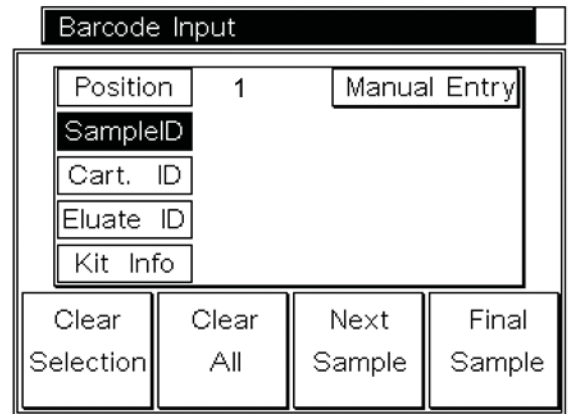


Figure 25. The Barcode Input screen.

1. This screen indicates the cartridge position on top, and the *SampleID* option is highlighted. Position 1 is the initial position. For empty sample positions, select *Next Sample* repeatedly until the required sample position is reached.
2. Scan the bar code label on the sample tube or pretreatment tube. The bar code data is added on the screen next to the *Sample ID* option.
3. For SEV methods, scan the cartridge to which the sample will be added; the cartridge bar code data will appear on the screen next to the *Cart.ID* option. Add the sample to the associated cartridge. Place the cartridge in the instrument platform position corresponding to the *Position* number on the screen. Scan the elution tube bar code, and place the tube in the elution tube slot at the front of the platform next to the appropriate cartridge. The bar code data will appear on the screen next to the *Eluate ID* option. Review the scanned data. All three codes should match. If they do not match, you can reselect the option to change and rescan the information.
4. For LEV methods, scan the cartridge to which the sample will be added; the cartridge bar code data will appear on the screen next to the *Cart.ID* option. Place the cartridge in the cartridge rack. Add the sample to the cartridge. Scan the elution tube bar code, and place the tube in the elution tube slot at the front of the cartridge rack next to the appropriate cartridge. The bar code data will appear on the screen next to the *Eluate ID* option. Review the scanned data. All three codes should match. If they do not match, you can reselect the option to change and rescan the information.
5. Scan the kit box bar code label. The bar code data will appear on the screen next to the *Kit Info* option. If the kit expiration date has passed, an error message will be displayed, and a different kit lot must be used. If

more than one kit lot is to be used, the new kit lot number can be scanned when the first cartridge and elution tube from the new kit are added to the cartridge rack.

Note: Kit lot numbers will automatically advance to the next sample position. If a new kit lot number is used, delete the incorrect lot information and scan the correct information or enter manually.

6. On-screen data can be removed from each option by highlighting the option and selecting the *Clear Selection* option. All of the data can be removed by selecting the *Clear All* option.
7. Select *Next Sample*. For empty sample positions, select *Next Sample* repeatedly until the required sample position is reached.
8. Repeat Steps 2 to 5 for the new sample and associated cartridge and elution tube, and place them in the required positions. Select the *Next Sample* option. Repeat until all samples are loaded.
9. If there are fewer than 16 samples, select *Final Sample* when all of the samples are loaded. This will open the **Verify Scanned Data** screen. This screen allows you to review the bar code data entered.

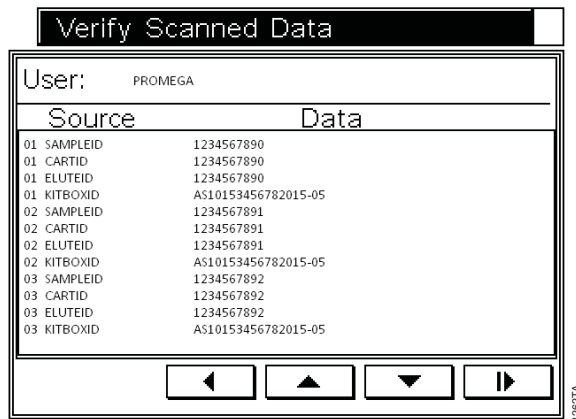


Figure 26. Verify Scanned Data screen.

Capturing Run Data Manually

You can collect run data manually. After you have completed the steps in Section 5.A, the door on the instrument will open, and the platform will extend.

1. In the **Barcode Input** screen, select the *SampleID* option to add information. Select *Manual*. Use the keyboard to type in the data required. The data will appear on the screen next to *Sample ID*.
2. Select the *Cart.ID* option, and the cartridge to which the sample will be added; select *Manual*. Use the keyboard to type in the data required. The data will appear next to *Cart.ID*.
3. For SEV methods, add the sample to the associated cartridge and place the cartridge in the instrument position corresponding to the *Position* number on the screen. Select the *Eluate ID* option, and select *Manual*. Use the keyboard to type in the data required. The data will appear on the screen next to *Eluate ID*. Place the tube in the appropriate elution tube slot at the front of the platform next to the cartridge. Review the data. All data should match. If they do not match, you can reselect the option to change the information.
4. For LEV methods, select the *Cart.ID* option and the cartridge to which the sample will be added. Select *Manual*. Use the keyboard to type in the data required. The data will appear on the screen next to *Cart.ID*; place the cartridge into the cartridge rack. Add the sample to the cartridge. Select the *Eluate ID* option, and select *Manual*. Use the keyboard to type in the data required. Place the tube in the appropriate elution tube slot at the front of the cartridge rack next to the cartridge. Review the data. All data should match. If they do not match, you can reselect the option to change the information.
5. Select the *Kit Info* option, and select *Manual*. Add the kit information using the keyboard. The data appear on the screen next to *Kit Info*. Check that the kit expiration date has not passed.
6. On-screen data can be removed from each option by highlighting the option and selecting the *Clear Selection* option. All of the data can be removed by selecting the *Clear All* option.
7. Select *Next Sample* to move to the next position. The appropriate *Position* number will be displayed, and the kit box information will be carried over to the next position screen. You will not need to add the kit box data each time. If more than one kit lot is used, the new kit lot number can be added once the cartridge and elution tube from the new kit have been added to the rack.
10. If any incorrect data are identified for a sample, you can use the navigation buttons to return to the **Barcode Input** screen where Position 01 will be shown. Select *Next Sample* to navigate to the required sample and add the appropriate information.
11. For SEV methods, once all of the data have been verified, press the Run/Stop button to start a run.
12. For LEV methods, once all of the data have been verified, place the cartridge rack into the instrument, and press the Run/Stop button to start a run.

8. Repeat Steps 2 to 5 for the next sample and associated cartridge and elution tube and place in the required position. Select *Next Sample*. Repeat until all samples are loaded.
9. If there are less than 16 samples select *Final Sample* when all of the samples are loaded. This will open the **Verify Scanned Data** screen. This screen will allow you to review the data. If any incorrect data are identified for a sample, you can use the navigation buttons to return to the **Barcode Input** screen where Position 01 will be shown. Use *Next Sample* to navigate to the required sample, and add the appropriate information.
10. For SEV runs, once all of the data have been verified, press the Run/Stop button to start a run.
11. For LEV runs, once all of the data have been verified, place the cartridge rack into the instrument, and press the Run/Stop button to start a run.

C. Performing a Sample Purification Run

Follow the on-screen instructions for SEV or LEV setup.

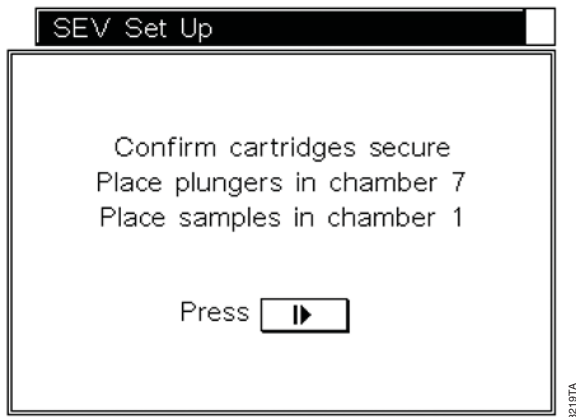


Figure 27. SEV Set Up screen.

Once all of the samples and plungers have been loaded, close the door. The run will begin automatically.



Figure 28. LEV Set Up screen.

Once all of the samples and plungers have been loaded, close the door. The run will begin automatically.



Important. The plungers must be placed in the correct starting position. If the instrument goes through a run without plungers, the magnetic rod assembly must be removed and cleaned (see Section 8.B). The cartridges containing the samples must be discarded.

During the run, the **Processing** screen will display the current run step and the run time remaining. The instrument will automatically perform periodic self-diagnostic tests to verify that the platform, plunger bar and magnetic rod assembly are within calibration during the purification procedure. If the instrument detects that any of these parts are not within calibration during a run, the method will pause and display *Calibration Error*.

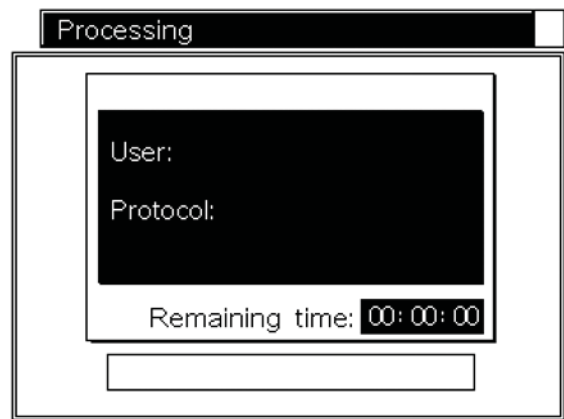


Figure 29. Processing screen.

If a calibration error occurs, note the Error Code Number displayed on the touch screen and refer to the Troubleshooting section (Section 9) for more information. If you are in the middle of a run, you can choose to continue the purification procedure or to abandon the run.

Continuing the run will not damage the Maxwell® 16 IVD Instrument but may result in suboptimal recovery of nucleic acid from the samples. Refer to the Troubleshooting section for a detailed list of error codes. To cancel the run, press the *Run/Stop* button on the instrument keypad to stop the run, and follow the on screen instructions.

At the end of the run, the touch screen will display a message that the method has ended. The export of run data occurs before the samples are removed from the instrument (see Section 6).



Figure 30. End screen.

After the run is complete, open the instrument door and check that all of the plungers have been ejected from the magnetic rod assembly. If a plunger is still attached, push it down gently by hand to remove it. Select the *Run/Stop* button to extend the platform. Remove the elution tubes to the Magnetic Elution Tube Rack (for SEV protocols) to remove any residual particles. The eluted sample can then be transferred to a storage tube.

! **Important.** To avoid particle transfer after SEV runs, use a pipette tip to aspirate samples from the captured particles on the side of the blue elution tube.

D. Post-Run UV Light Treatment

If you have configured your instrument to perform a UV light treatment at the end of each run, that treatment will start *when the door is closed*. Ensure that the samples are removed before closing the door and starting the UV light treatment to avoid damage to the nucleic acid. You also can cancel the UV treatment at any time.

6. Run Reports

If the instrument has been configured for the Maxwell® Sample Track software and connected to the computer or printer, you can export or print a run report at the end of the run. By convention, run data files are named as the run date and finishing time.

A. Data File Transfer at the End of a Run

At the end of a Maxwell® 16 IVD instrument run, the **Data Transfer** screen opens to allow run data export. If *No* is selected, the run data are saved for subsequent retrieval and not exported. If *Yes* is selected, the **File Output** screen opens.

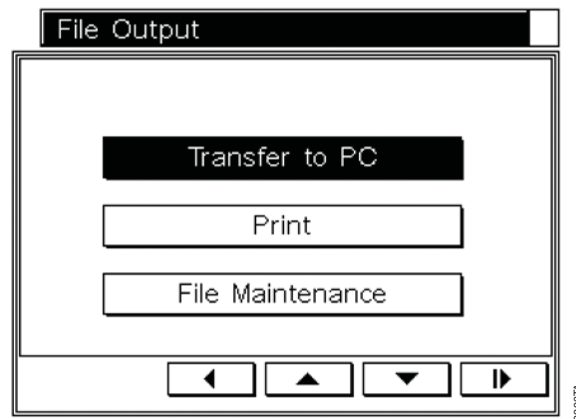


Figure 31. File Output screen.

The *Transfer to PC* option allows the computer containing Maxwell® Sample Track to import the data from the Maxwell® 16 IVD Instrument. When import is complete, the file name will appear, and the **Data Transfer** screen can be closed by pressing the *Run/Stop* button. The imported file can be saved to the computer with a different name and in a different format (see Technical Manual #TM314 for details).

The *Print* option opens the **Select File** screen where files can be selected for printing.

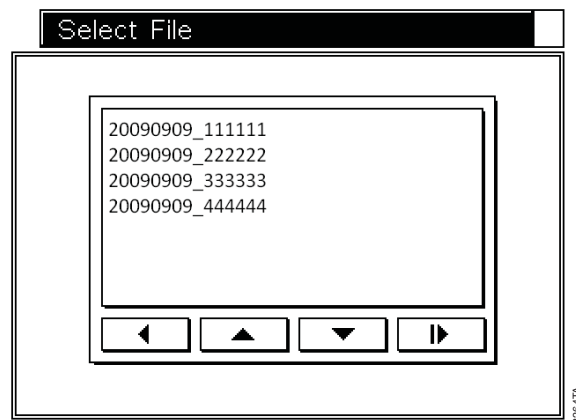


Figure 32. Select File screen.

To print the run data, ensure that the printer is set to receive data and is switched on. Select the file to be printed. You will be notified that the file was sent to the printer. Once printing is complete, press the *Run/Stop* button to close the **File Sent** screen.

B. Data File Transfer at a Later Time

Files may be exported at a later time using the *Data Transfer* option on the **Home** screen. Selecting this option opens the **File Output** screen. Selecting *Transfer to PC* allows transfer as described in the previous section.

C. Data File Management

The files stored on the Maxwell® 16 IVD Instrument can be exported using Maxwell® Sample Track. This does not remove the file from the instrument. To remove any unneeded files use the *Data Transfer* option on the **Home** screen. In the **File Output** screen, select *File Maintenance*, and enter the Administrator PIN. In the **Select File** screen the list of files will be displayed. Select the file to be deleted, and press the forward arrow button. The file will be deleted after confirmation.

7. Changing Configuration Parameters

The instrument configuration can be changed at any time except during a run. In the **Home** screen, select *Setup*, which opens the **Maxwell® 16 Configuration** screen. Here you can choose the parameter that you wish to change.

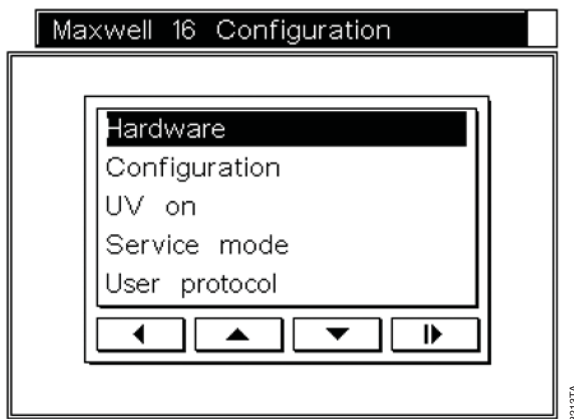


Figure 33. Maxwell® 16 Configuration screen.

A. Changing the Hardware

! **Important.** Do not reconfigure the instrument hardware while samples or reagent cartridges are in place on the instrument platform. Clean the instrument thoroughly following the instructions in Section 8 before removing the existing hardware. Wear gloves when changing the hardware to avoid exposure to any potential contaminants.

Changing from SEV to LEV Hardware

1. Select *Hardware* on the **Maxwell® 16 Configuration** screen.
2. Follow the on-screen instructions. First, open the door.
3. The Magnetic Assembly will move down to allow you to remove the Magnetic Rod Assembly. Do not push down on the Magnetic Rod Assembly if the instrument is powered on.
4. Unscrew the three thumbscrews (boxes in Figure 34) on top of the Magnetic Rod Assembly.

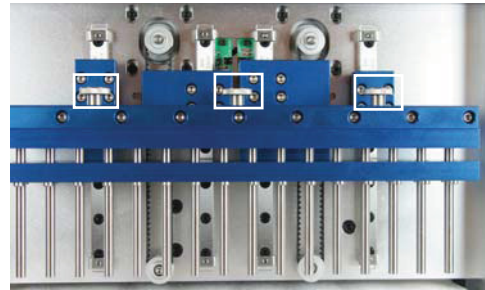


Figure 34. SEV Magnetic Rod Assembly and thumbscrews.

5. Gently lift the SEV Magnetic Rod Assembly, and remove it.

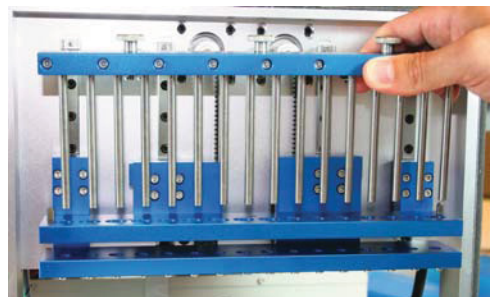


Figure 35. Removing the SEV Magnetic Rod Assembly.

6. Insert the black LEV Plunger Bar Adaptor onto the bottom of the remaining arm. Make sure that the side containing the screws faces upward. Several magnets will "click" and hold the LEV Plunger Bar Adaptor in place once it is attached. The LEV Plunger Bar Adaptor should then be fairly difficult to remove.

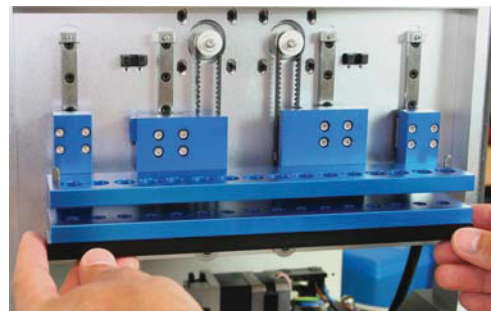


Figure 36. Inserting the LEV Plunger Bar Adaptor.

7. Insert the black LEV Magnetic Rod Assembly in the correct orientation. The screws should be facing toward you. Press firmly to place the LEV Magnetic Rod Assembly in position. It will fit tightly in place.

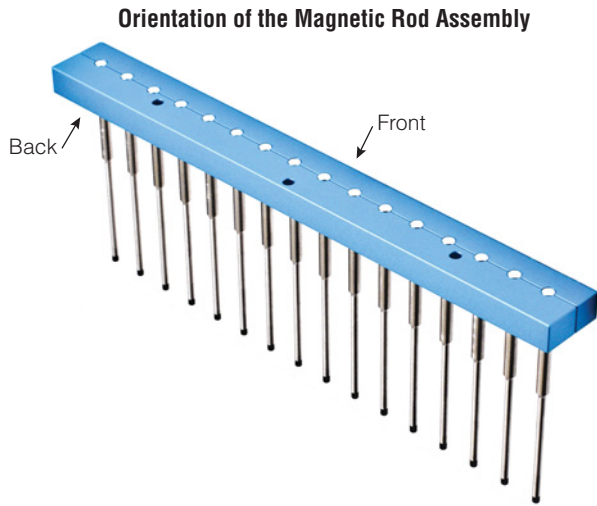


Figure 37. Orientation of the Magnetic Rod Assembly.

8. Secure the LEV Magnetic Rod Assembly with the three thumbscrews from the SEV Magnetic Rod Assembly, and hand-tighten.
9. Close the door as indicated on screen. The screen will indicate that the hardware has been changed. The firmware indicates a hardware change once the door is closed whether or not you actually completed the physical hardware change. Confirm that the hardware shown on the screen display matches the physical hardware installed. If the screen does not match the physical hardware installed, turn the instrument off, install the appropriate hardware and restart the machine. The hardware indicated on-screen should match the physical hardware installed.

⚠ Important. When the Home screen is accessed, it will indicate the new hardware mode. Always confirm that the hardware mode shown matches the physical hardware installed. Running the instrument if the hardware mode shown does not match the physical hardware installed will damage the instrument.

Changing from LEV to SEV Hardware

1. Select *Hardware* on the Maxwell® 16 Configuration screen.
2. Follow the on-screen instructions. First, open the door.
3. The Magnetic Assembly will move down to allow you to remove the Magnetic Rod Assembly. Do not push on the Magnetic Rod Assembly if the instrument is powered on.
4. Unscrew the three thumbscrews (boxes shown in Figure 38) on top of the Magnetic Rod Assembly.

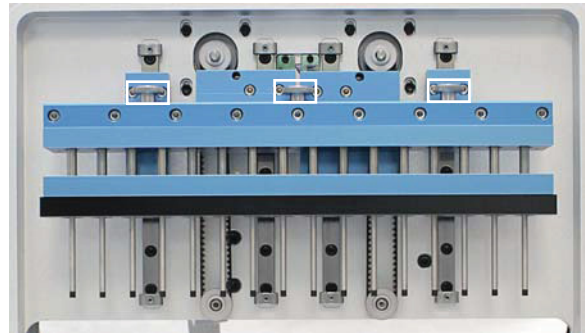


Figure 38. LEV Magnetic Rod Assembly and thumbscrews.

5. Gently lift the LEV Magnetic Rod Assembly, and remove it. Pull down on the LEV Plunger Bar Adaptor to release the magnets that hold it in place. **Note:** Pull down at an angle so that the back of the magnet is released first.
6. Remove the black LEV Plunger Bar Adaptor.

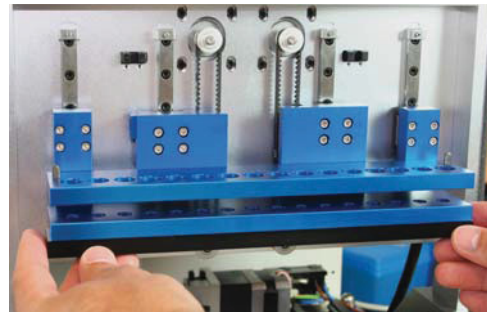


Figure 39. Removing the LEV Plunger Bar Adaptor.

7. Insert the SEV Magnetic Rod Assembly. The set screws should be facing toward you. Press firmly to place the Magnetic Rod Assembly in position. It will fit tightly into place.

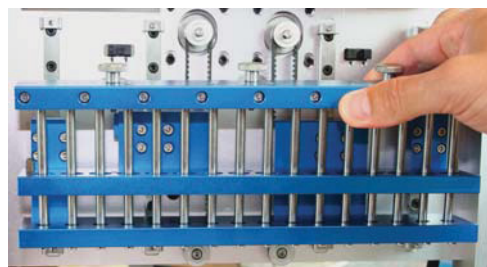


Figure 40. Installing the SEV Magnetic Rod Assembly.

8. Secure the SEV Magnetic Rod Assembly with the three thumbscrews, and hand-tighten.

- Close the door; the screen will indicate that the hardware change was successful. Confirm that the hardware mode shown matches the physical hardware installed. If the screen does not match the physical hardware installed, turn the instrument off, install the appropriate hardware and restart the machine. The hardware indicated on-screen should match the physical hardware installed.

Important. When the Home screen is accessed, it will indicate the new hardware mode. Always confirm that the hardware mode shown matches the physical hardware installed. Running the instrument if the hardware mode shown does not match the physical hardware installed will damage the instrument.

B. Changing the Instrument Firmware Configuration

Resetting the Maxwell® Wizard

The Maxwell® Wizard can be reset. Select *Setup* in the **Home** screen, and *Service mode* in the **Maxwell® 16 Configuration** screen. Enter the Administrator PIN. In the **Utilities Menu** screen, select *Reset Wizard*. Two options are available. Selecting *Wizard only* resets the Wizard. The Wizard will run upon restart, and all user and user protocol information will be retained. Selecting the *All Settings* option in the **Reset Wizard** screen resets the Wizard and removes all users and user protocols.

Important. Removing all settings takes a few minutes. Please wait.

Changing Configuration Settings

To change a subset of parameters, select *Configuration* from the **Maxwell® 16 Configuration** screen.

Important. You may need to scroll down the screen to see all of the options.

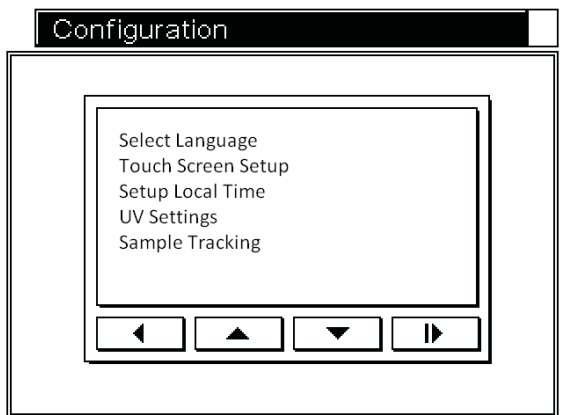


Figure 41. Configuration screen.

- 1. IVD/Research.** Select "IVD/Research" to choose to run either IVD or Research protocols (Section 12).
- 2. Changing the Language.** Select the *Select Language* option in the **Configuration** screen, and select the required language. The display will change over to the selected language.
- 3. Recalibrating the Touch screen.** Select the *Touch Screen Setup* option in the **Configuration** screen. Follow the screen calibration method described in Section 3.E.
- 4. Changing the Date/Time.** The Maxwell® 16 IVD Instrument does not track leap years or daylight saving time. Select the *Setup Local Time* option in the **Configuration** screen. To update, follow the date/time setup method described in Section 3.E.
- 5. Changing the UV Treatment Settings.** Selecting the *UV Settings* option in the **Configuration** screen allows you to set the UV settings in the Maxwell® 16 IVD Instrument as described in Section 3.E.
- 6. Changing the Sample Tracking Settings.** Selecting the *Sample Tracking* option in the **Configuration** screen allows you to change the sample tracking options.
- 7. User Setup.** Selecting this option allows you to add or remove users and PINs.

Adding, Changing or Removing Users and PINs

To add new operators, in the **Maxwell® 16 Configuration** screen, select *User Setup* (you may have to scroll down the screen to select this option). In the **User Name Setup** screen, select a name, and press the Run/Stop button. Select *Add/Edit User*; a keyboard will be displayed, and a new user name can be added. Follow the on-screen instructions to add the new user (also see Section 3.E). Note that the user name is limited to 15 characters.

To add a new PIN, select *Add/Edit PIN* in the **User Name Setup** screen. Add a PIN as described in Section 3.E.

To remove a PIN, select *User Setup* from the **Maxwell® 16 Configuration** screen. Highlight the user name in the "Users" screen and select it. Enter the current PIN. Select the *Remove PIN* option, and press the Run/Stop button. The PIN will be removed.

8. Cleaning and Maintenance

The Maxwell® 16 IVD Instrument is designed to require minimal maintenance. However, it is important to clean the instrument at regular intervals. If samples or reagents have been spilled, it is important to clean the instrument immediately to avoid damage. Most parts of the Maxwell® 16 IVD Instrument have an anodized coating, which forms a durable, easily cleaned barrier on the metal.

Always turn off and unplug the instrument before cleaning.

A. General Care

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



Important. Wear gloves or other protective means. If the instrument is used with biohazardous materials, dispose of any cleaning materials used in accordance with your institutional guidelines.

- Keep the cooling vents in the back of the machine clear of dust.
- Do not remove the Maxwell® 16 IVD 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 sit on instrument surfaces for extended periods of time.
- Keep all moisture away from the heated elution tube slots to prevent damage to the heating elements.
- If the linear slides for the platform need to be cleaned, use only a dry paper towel. If they have been contaminated with any liquid, wipe off excess liquid and follow the lubrication guidelines in Section 8.F, or contact Promega Technical Services for assistance.

B. Cleaning the Hardware

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

1. To remove the hardware, see Section 7.A.
2. To clean the Magnetic Rod Assembly, wipe with a damp, soft cloth. You also can wipe the assembly with 70% ethanol. Removing paramagnetic particles from the Magnetic Rod Assembly will require multiple wipes.
3. If the Magnetic Rod Assembly cannot be cleaned, please contact Promega for assistance.
4. Replace the Magnetic Rod Assembly, and firmly tighten the three thumbscrews.
5. Ensure that the hardware mode displayed on the **Home** screen matches the hardware that is installed in the instrument.

C. Dealing with Spills

Wipe up any spills immediately. If the reagent spills in the instrument, wipe up visible material with a cloth. Dried material should be wiped up with a wet towel. Note that

the reagents contain hazardous materials; therefore dispose of towels according to your institutional guidelines. Wipe well once visible material is removed.

In case of spills in the instrument where there is a potential biohazard, wipe up the spill with towels and wash the spill area with a detergent solution such as Steris® Environ® pH, following the manufacturer's instructions. Dispose of towels used according to your institutional guidelines for biohazardous waste.

UV-treat the instrument.



Important. Bleach reacts with guanidine thiocyanate and should not be added to any sample waste containing lysis solutions.

D. Decontamination Using the UV Lamp

UV radiation is useful in decontamination due to its ability to inactivate biological molecules. The Maxwell® 16 IVD Instrument is equipped with a UV lamp that can be used to treat the interior of the instrument with UV light, after cleaning, to help with decontamination. UV treatment is not a substitute for cleaning. Using the UV lamp treatment alone may not provide sufficient decontamination.

To turn on the UV lamp manually, navigate to the **Home** screen, and select the *Setup* option. In the **Maxwell 16 Configuration** screen select *UV On*. In the **UV Decontamination** screen select *Yes*. Set the amount of time you would like to run the lamp. The recommended setting is 1 hour. The maximum setting is 10 hours.

E. Replacing the UV Bulb

Wear gloves. Do not touch the bulb with your bare hands; this can transfer oils from your hand to the glass and compromise the bulb. The UV bulb has an average life of 3000 hours. The Maxwell® 16 IVD Instrument will warn you when the accumulated UV bulb usage reaches 2950 hours, and we recommend that you change out the bulb at this point. Replacement bulbs can be purchased from Promega (Cat.# SP1080).

To replace the bulb, locate the old bulb in the UV lamp socket which is just inside the door on the ceiling of the instrument. See Figure 11. Twist the bulb a quarter turn until it can slide out. Place the new bulb into UV lamp socket as described in Section 3.C.

The UV bulb contains mercury and must be disposed of properly. To dispose of a bulb, please follow your institutional requirements for clean up and disposal of mercury.

F. Periodic Maintenance

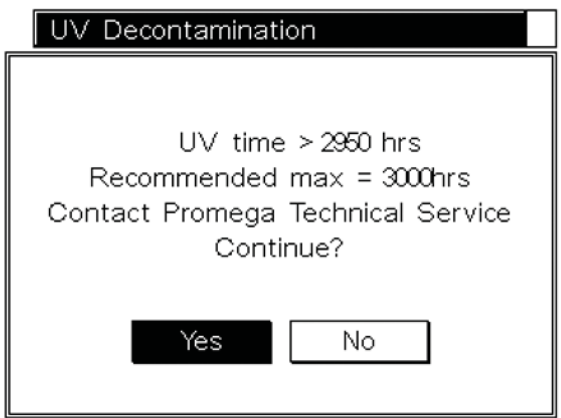

Linear Slides: If the linear slides become sticky, they may be lubricated with light machine oil. Use a cotton swab, and apply only as much as is needed to make the heads and plate slide easily. Do not get oil on the black drive belts.

Belts: Inspect the belts periodically. If excessive wear or excessive slack is noted, contact Promega or your local Promega representative, and arrangements will be made to service the instrument.

9. Troubleshooting

If you have questions that are not covered in this troubleshooting section, contact Promega Technical Services. See the Promega Web site, www.promega.com, to find your nearest Promega branch or distributor.

Symptoms	Causes and Comments
The instrument is making an unusual, rapid clicking noise when it is turned on.	<ul style="list-style-type: none"> Verify that the Magnetic Rod Assembly/Plunger Bar shipping anchors and Platform shipping anchors have been removed. Sensors may need to be cleaned. Contact Promega or your local Promega representative for assistance with sensor cleaning. Look for obstructions that may be preventing a head from moving through its full range of motion (for example, plungers in the tracks of the deck).
The touch screen does not light up when the instrument is turned on.	<p>If you cannot hear the motors running:</p> <ul style="list-style-type: none"> Check that the unit is plugged into a working electrical outlet. Verify that the plug is securely connected to the back of the instrument. A 3-amp time-lag fuse protects the instrument electronics and is located next to the power switch. If the fuse is blown, identify and correct the cause. Never replace this fuse with a fuse rated for higher than 3A. Contact Promega or your local Promega representative for service. <p>If you can hear the motors running:</p> <ul style="list-style-type: none"> Either a cable has become disconnected from the LCD screen, or the LCD screen is broken or damaged. Contact Promega or your local Promega representative for service.
Wrong language displayed.	If the wrong language is displayed, the Language Setup screen can be accessed by switching the instrument off and on. In the Home screen press the up arrow four times on the instrument keypad. This will open the Select Language screen, and the desired language can be selected.
Touch Screen is out of calibration.	If the touch screen is out of calibration and the display is not centered correctly, you can correct it by turning the instrument off and on. When the Home screen is displayed, press the back arrow on the instrument keypad four times. This will take you directly to touch screen setup where you can recalibrate. If you still experience problems after recalibration, contact Promega or your local Promega representative for service.
Slight variations in run time observed.	The instrument checks the temperature within the elution slots. If the temperature is not high enough, the instrument waits for the correct temperature before continuing the run. This means that there may be slight variations in run time.

Symptoms	Causes and Comments
<p>UV lamp errors.</p>	<ul style="list-style-type: none"> After 2950 hours of accumulated lamp time, the following error message appears. <div data-bbox="787 310 1344 724" data-label="Image">  </div> <p>Figure 42. UV Lamp Time This message means that the UV bulb has reached the limit of its rated life span, and it should be replaced. See Section 8.E.</p> <ul style="list-style-type: none"> If you see the error message below, the bulb may not be present or installed properly (see Figure 11). If the bulb is installed properly, this may mean that the bulb is not functioning. It should be replaced. See Section 8.E. <div data-bbox="787 949 1344 1362" data-label="Image">  </div> <p>Figure 43. UV Lamp Error</p>
<p>The machine makes unusual noises during the run.</p>	<p>The machine will make some noise during a typical run. Unusual (or louder than usual) noises may indicate that the heads are not moving freely. Typically this is caused by an obstruction, which should be removed, but may be due to inadequate lubrication. Continued operation under these conditions can cause damage to the instrument. Heads that are not moving freely may be lubricated with light machine oil. Do not get oil on the drive belts. Use a small amount of oil on a cotton swab. If this does not correct the problem, contact Promega or your local Promega representative for service.</p>
<p>Heater error at the elution step.</p>	<p>The unit is not up to temperature. If the run was paused or the door was opened, interlocks turn the heater off. After the run is restarted and the door is closed, the heater should restart, and the instrument should reach the set point temperature. If it hasn't reached the set point in a few minutes, there may be a problem with the heater. Contact Promega or your local Promega representative for service. A heater problem may affect yield.</p>

Symptoms	Causes and Comments
Installed hardware does not match the displayed hardware mode.	Turn the machine off and install the appropriate hardware. When the machine is powered up after the installation, the installed hardware will match the hardware mode displayed on the Home screen.
Plungers are not completely stripped off the rods at the end of the run.	<ul style="list-style-type: none"> • Check that plungers are clear of the magnetic rod assembly before extending the platform out from inside the instrument. If the problem occurs consistently, check that the magnetic rods are clean. Wipe them down carefully with a damp cloth. • Do not reuse plungers; plungers that are reused may not be completely removed at the end of the run. If plungers are consistently left on by the instrument, contact Promega or your local Promega representative for service.
The buttons do not work.	Please contact Promega or your local Promega representative. Do not use spray cleaner on the keypad or touch screen, because it can damage the keypad or touch screen.
When I close (or open) the door, the program does not advance.	There may be a problem with the door sensor. Please contact Promega or your local Promega representative for service.
Expected methods are not shown on the LCD screen.	<ul style="list-style-type: none"> • Verify that the firmware setup is correct. Refer to Section 3.E. • Verify that the instrument is in the proper hardware mode (SEV or LEV).
Calibration error: Error Code 1	Error Code 1 indicates a Platform error. (A picture of the instrument platform is shown in Figure 6.) Open the door and verify that there are no obstructions in the slide channels, in the rear, or in front of the platform that prevent it from moving back and forward freely. Remove any obstruction and continue the run. If the error persists, turn the instrument off, wait a few seconds and turn the instrument back on. Start the run again, add the bar code data and rerun the samples. If the calibration error persists, please contact Promega or your local Promega representative for service.
Calibration error: Error Code 2	<p>Error code 2 indicates a Plunger Bar calibration error (A picture of the plunger bar is shown in Figure 6.)</p> <ul style="list-style-type: none"> • Verify that there are no solid particulates inside Well #1 of the cartridge. Solid particulates that are not easily macerated may obstruct the plunger from moving freely to the bottom of Well #1 during processing. • Ensure the cartridges are seated properly onto the platform. • If the error occurs during plunger loading, ensure the hardware configuration matches the firmware settings. • Verify that the shipping anchors have been removed. Refer to Section 3.B. • Verify that the instrument is in the proper hardware mode (SEV or LEV). • After verification, continue the run. If the error persists, turn the instrument off, wait a few seconds, then turn the instrument back on. Start the run again, add the bar code data, and rerun the samples. If the calibration error persists, please contact Promega or your local Promega representative for service.
Calibration error: Error Code 3	<p>Error Code 3 indicates a Magnetic Rod Assembly problem.</p> <ul style="list-style-type: none"> • Verify that the shipping anchors have been removed. Refer to Section 3.B. • Verify that the instrument is in the proper hardware mode (SEV or LEV). • Verify that the Magnetic Rod Assembly is attached properly. Refer to Section 3.B.

Symptoms	Causes and Comments
	<ul style="list-style-type: none"> After verification, continue the run. If the error persists, turn the instrument off, wait a few seconds, then turn the instrument back on. Start the run again, add the bar code data, and rerun the samples. If the calibration error persists, please contact Promega or your local Promega representative for service.
Power failure occurs during the instrument run.	<p>To recover your samples after a power failure, first ensure that the particles are in one of the wells of the cartridge and are not attached to the plunger. If the power failure occurred at a point where the magnetic particles were captured on the outside of the plungers, manually move the plungers up and down in the wells to wash the particles off. Switch the instrument on. Note the UV light will not come on when the instrument is switched on under these conditions. If you have scheduled the UV lamp to come on after instrument initialization, cancel the UV treatment to avoid losing the sample. In the Home screen restart the run from the beginning. Add new plungers during run set up.</p> <p>Note the power outage will prevent the UV light coming on during initialization, and it will also cancel any programmed UV treatment until a successful run has been completed. Cycle the power after a run has been successfully completed to re-initialize the UV system.</p>
Update of firmware from the SD Card is not successful.	To update the firmware you must use the supplied 1GB SD card. Other 1GB SD cards may work, but Promega does not support other SD cards. It is recommended that you leave the SD card in its slot when not in use to prevent losing it.
Need to cycle power on the instrument.	If you need to cycle the power, it is extremely important to remove any samples from the instrument before cycling the power on the instrument because the UV lamp comes on as part of the startup diagnostic tests.

10. Warranties, Service Agreements and Related Products

A. Warranty Information

Limited Warranty and Service Guidelines

Promega warrants to the original purchaser that the Promega Maxwell® 16 IVD Instrument will be free from defects in materials and workmanship for a period of one year from the date of delivery. Promega agrees, as its sole responsibility under this limited warranty and upon prompt notice of a defect, to repair or replace (at Promega's discretion) any instrument discovered to be defective within the warranty period. Expendable items are not covered by this warranty. This warranty does not include repair or replacement necessitated by accident, neglect, misuse, unauthorized repair or modification of the instrument. The instrument may not be returned without a proper Return Authorization Number from Promega, as described below.

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

In addition to the standard limited warranty that comes with the Maxwell® 16 IVD Instrument, a premier warranty and various service agreement options are available for purchase. If you purchased a premier warranty or service agreement your Maxwell® 16 IVD Instrument, please refer to those specific terms. See Section 10.B.

To obtain service during the warranty period, please take the following steps:

- Write or call the company that sold you the instrument and describe as precisely as possible the nature of the problem.
- Carry out minor adjustments or tests as suggested by your technical contact.
- If the instrument is still not functioning properly, YOU MUST OBTAIN A PROMEGA RETURN AUTHORIZATION NUMBER.
- Before returning the instrument, you will be responsible for cleaning it and providing a Certificate of Decontamination to Promega in accordance with instructions.
- After obtaining a Return Authorization Number and signing the Certificate of Decontamination, pack the instrument carefully (damage incurred in shipping due to improper packaging is not Promega's responsibility), write the Return Authorization Number on the outside of the package and ship it to the address provided by your technical contact.

- Shipping to and from Promega will be paid by Promega pursuant to directions to be provided. The instrument will be repaired free of charge for all customers within their warranty period.
- Under no circumstance can an instrument be returned without proper authorization. This authorization is needed to ensure that the problem is not a minor problem that can be easily handled in your laboratory and to determine the nature of the problem so that repairs can be handled appropriately.

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, if needed, will be billed at a flat rate to be agreed upon in advance. Your invoice will include shipping.

B. Warranty and Service Agreement Options

Maxwell® 16 Premier Warranty

Cat. # SA2000

If uptime is critical, the Premier Warranty can be purchased as an upgrade to the standard warranty. The Premier Warranty provides you with your choice of temporary replacement instrument within 24 hours or on-site repair by a factory-trained service technician. Like the standard warranty, it covers all parts, labor and shipping to and from our depot repair locations, and it also provides a temporary replacement instrument while your instrument is being repaired. Additionally, this option includes one preventive maintenance visit during the term of the agreement.

Maxwell® 16 Standard Service Agreement

Cat.# SA2010

After the warranty period is over, you can continue to receive the same comprehensive service and support from Promega as you did when your system was under warranty. The Standard Service Agreement covers all parts, labor and shipping to and from our depot repair location as well as a temporary replacement instrument upon request. If your Maxwell® 16 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.

Maxwell® 16 Premier Service Agreement

Cat. # SA2015

Our Premier Service Agreement provides maximum flexibility and uptime. The agreement covers all parts, labor and shipping charges. You can use our depot repair and receive a temporary replacement instrument in 24 hours, or you can elect to have one of our service technicians service it in your laboratory. Additionally, the Premier Service Agreement includes one annual preventive maintenance visit.

Maxwell® 16 Preventive Maintenance

Cat.# SA2020

To keep your instrument at peak performance, Promega recommends that the Maxwell® 16 instruments receive a preventive maintenance check after every 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 instrument is aligned and performance is verified.

C. Related Products and Instrument Accessories

Table 3. DNA Purification Kits (SEV)

Product	Size	Cat.#
Maxwell® 16 Blood DNA Purification System ¹	48 preps	AS1015

¹IVD.

Table 4. Viral Purification System

Product	Size	Cat.#
Maxwell® 16 Viral Total Nucleic Acid Purification System ¹	48 preps	AS1155

¹IVD.

Table 5. Instrument Accessories

Product	Size	Cat.#
Maxwell® 16 LEV Cartridge Rack (for use with LEV configuration)	1 each	AS1251
Maxwell® 16 LEV Magnet (for use with LEV configuration)	1 each	AS1261
Maxwell® 16 LEV High Strength Magnetic Rod Assembly and Plunger Bar Adaptor (for use with LEV configuration)	1 each	SP1070
Maxwell® 16 SEV Cartridge Rack (for use with SEV configuration)	1 each	AS1201
Maxwell® 16 SEV Magnetic Elution Rack (for use with SEV configuration)	1 each	AS1202
Bar Code Reader for Maxwell® 16	1 each	AS3200
Thermal Serial Printer and Cable Universal Power	1 each	E2821
LEV plungers	50 each	AS6101
SEV plungers	50 each	AS5201
LEV Elution Tubes	50 each	AS6201
SEV Elution Tubes	50 each	AS5101
UV Bulb	1 each	SP1080

11. Appendix I

A. Updating Firmware

As Promega provides new purification kits, new versions of firmware may be required. The firmware version installed on your instrument can be verified by turning the machine off and then on again. The initial screen will display the version number of the firmware loaded on the instrument. Please note the firmware version currently installed on your instrument before contacting Promega or your local Promega representative for new firmware.

Firmware is updated using an SD card reader in the Maxwell® 16 IVD Instrument SD slot. Download the updated firmware from the Promega web site as main.bin onto a computer. Place the SD card in the computer's SD card slot, and download the updated firmware to the SD card. If you do not have an SD card reader on your computer, use the enclosed SD card reader to download the updated firmware to the SD card through a USB port on your computer.

Place the SD card containing the firmware into the SD slot on the instrument; make sure the instrument door is closed, and turn the instrument off and on. The instrument will install the firmware and the Maxwell® 16 IVD Instrument screen will indicate that the firmware is being updated, and it go through the diagnostic checks. During the diagnostic checks, the instrument will display the new firmware version. When installation is complete, the **Home** screen will open. If the firmware was loaded successfully, the main.bin file will be deleted from the SD card.

With the Maxwell® Sample Track software you also can update the firmware through the RS-232 port on the back of the instrument. Firmware can be updated from any computer running Microsoft Windows® XP or Vista. See Sample Track Software Technical Manual #TM314 for details.

B. Service

The Maxwell® 16 IVD allows you to print the service history of the instrument. In the **Home** screen, select *Setup*. In the **Maxwell 16 Configuration** screen, select *Service Mode*, and enter the Administrative PIN that is supplied in the Welcome letter to access the **Utilities Menu** screen.



Figure 44. Utilities Menu screen.

In the **Utilities Menu** screen, select *Service Report* to view and print a current service report. The report will list the report date, the Instrument Serial Number, the date last service and preventative maintenance were performed, the number of run cycles the instrument has performed, the total number of hours the UV lamp has run and the firmware version.

You also can print the service report using the Maxwell® Sample Track Software. See Technical Manual #TM314, which describes how to do this.

The **Utilities Menu** screen allows the following options:

- *Run Count* shows the number of times the instrument has been run.
- *UV Bulb Time* shows the number of hours the bulb has been run. If you are replacing the bulb (See Section 8.E.), you may reset the number of hours to zero by selecting the *Yes* option in the UV bulb screen.
- *Reset Name* allows you to rename the instrument. Use the Run/Stop button to add the new name.
- *Reset Wizard* opens the **Reset Wizard** screen.

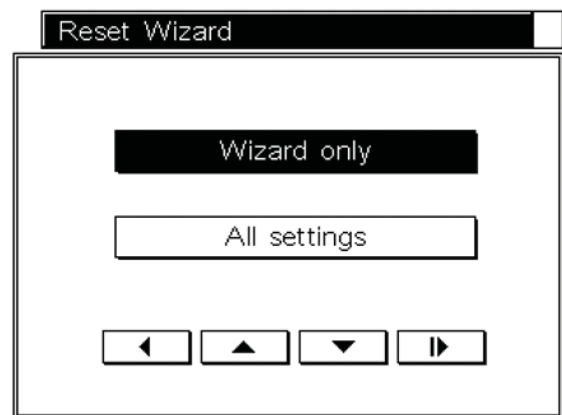


Figure 45. Reset Wizard screen.

If you select *Wizard Only*, after confirmation the Wizard will reset, and when the instrument restarts, the Wizard begins.

Selecting *All Settings* will remove all custom settings as well as reset the Wizard.

These are the parameters that can be changed in your facility. For any other service see the Warranty information in Section 10.

C. Instrument Return

The Maxwell® 16 IVD 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 8. for decontamination instructions).
- Affix a signed and dated Certificate of Decontamination to the outside of the package in which the instrument is returned (see last page of this manual). 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.
Note: If the original packaging is lost or damaged, contact Promega or your local Promega representative for replacement packaging.
- Repack the instrument according to the following instructions:

Preparation of the Maxwell® 16 IVD Instrument Prior to Repacking

- Ensure that the cartridges and elution tubes are removed from the instrument platform.
- Ensure that the instrument is turned off and is not plugged in. Ensure that computers and bar code readers have been disconnected.
- Remove the UV bulb. Dispose of the UV bulb according to your institution's guidelines. Do not return the UV bulb with the instrument.

Anchoring the Platform, Magnetic Rod Assembly and Plunger Bar

- By hand, carefully push the platform back into the instrument as far as it will go. Replace the Platform Shipping Anchor thumbscrews (Figure 10) and tighten by hand to anchor the platform in place for shipment.
- By hand, gently lower the plunger bar and magnetic rod assembly down as far as it will go. Replace the Magnetic Rod/Plunger Bar shipping anchor thumbscrews and tighten by hand (Figure 9).

Repacking the Maxwell® 16 IVD Instrument

- Place the instrument back into the plastic bag.
- Place the two foam packaging protectors on the sides of the instrument.
- Slide the instrument into the small inside shipping box. Ensure that the top of the instrument is facing the top of the open box.
- Slide the small inside shipping box containing the instrument into the large outside shipping box.
- Repack the Maxwell® 16 IVD Instrument accessories into the original box and place on top of instrument in box.
- Place the Power Cable into the box.
- Affix the Certificate of Decontamination on the outside of the shipping box. Write the return authorization number provided to you by Promega or your local Promega representative on the outside of the shipping box. Seal the box securely.

D. Instrument Disposal

Contact your local Promega Representative for disposal of the instrument. Please follow your institutional requirements to handle the disposal of accessories.

12. Appendix II: Research Methods

This section of the Technical Manual discusses use of the Maxwell® 16 IVD Instrument for Research applications. Compliance with EU directive 98/79/EC on in vitro diagnostic medical devices has been demonstrated for, and only applies to, use of the Maxwell® 16 IVD Instrument (Cat.# AS3050) in the IVD mode with the Maxwell® 16 Blood DNA Purification System (Cat.# AS1015) and the Maxwell® 16 Viral Total Nucleic Acid Purification System (Cat.# AS1155).

The Maxwell® 16 IVD Instrument (Cat.# AS3050) is configured for use in the IVD Mode. Research protocols can be run only after the instrument has been reconfigured in the Research Mode. The instrument is not compliant with the IVD directive when used in the research mode.

A. Selecting Research Methods (Research Use Only)

The Maxwell® 16 IVD Instrument has a number of preprogrammed methods that can be used to purify DNA, RNA and protein. These methods must be accessed through the *IVD* option in the **Configuration** screen. Select *IVD*.

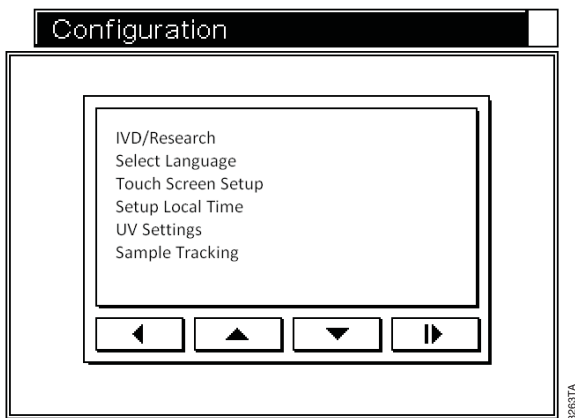


Figure 46. Configuration screen.

Select *IVD Protocol* or *Research Protocol* as needed. Press the Run/Stop button. This will open the **Select Method** screen.

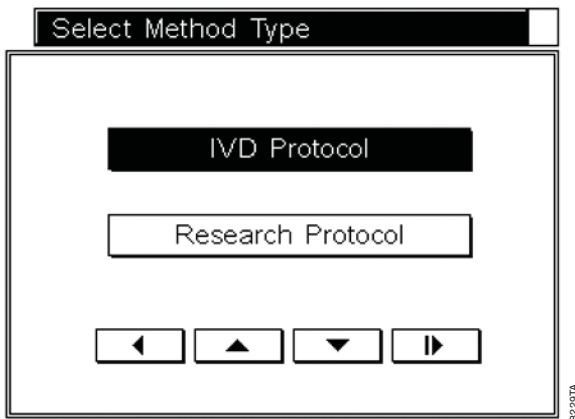


Figure 47. Select Method screen.



Important. The selection you make will be the future default setting. In IVD Mode, the Research Methods will not be available. In the Research Mode, the IVD methods will not be available.

If you choose *Research Protocol*, you will be warned that you will not be in IVD mode. The instrument is not compliant with the IVD Directive when used outside of the IVD mode.



Figure 48. IVD Warning screen.

B. Preprogrammed Research Methods

The preprogrammed methods supplied can be used to purify DNA, RNA and Protein, and the options available differ between the SEV and LEV mode. The protocol to be used can be chosen during run set up.

Setting up a Run in the SEV Mode

1. The **Home** screen must indicate SEV. Select *Run*. Select the User, and add the matching PIN if appropriate. Pressing the Run/Stop button opens the **Protocols** screen. From this screen you can run a research protocol.

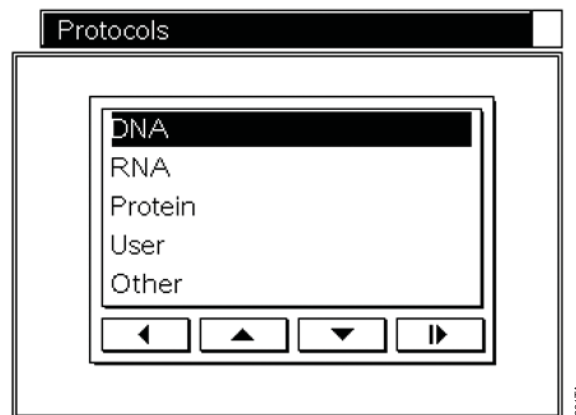


Figure 49. Protocols screen.

2. • Select desired protocol listed in the Maxwell® 16 reagent kit technical manual (e.g., Choose *Protein* to purify polyhistidine-tagged protein from cells using the Maxwell® 16 Polyhistidine Protein Purification Kit Cat.# AS1060).
- Select *User* to access and run custom protocols. Instructions for setting up customized protocols are presented in Section 12.C. Select the method required.
- Select *Other* to access specialized protocols for *Homogenization* or *Fixed Yield DNA* and to access a *Demo* option.

Homogenization allows limited homogenization of some types of tissue samples prior to running the purification method. See Section 12.D.

Fixed Yield DNA purifies a limited amount of DNA, allowing for a reproducible amount of DNA to be captured between samples.

The *Demo* protocol is for demonstration purposes only and should not be used.

Please contact Promega Technical Services at techserv@promega.com for more information on these specialized options.

3. A confirmation screen allows you to verify that the correct selection has been made. If correct, press the Run/Stop button, and you will be prompted to open the door to load the samples. Press the forward arrow button. This will open the door, and the cartridge rack will extend, ready for sample loading. Follow the steps in Section 5 to gather the run data and perform the run. Follow the steps in Section 6 to generate the run reports.

Setting Up a Run in the LEV Mode

1. The **Home** screen must indicate LEV. Select *Run*. Select the *User*, and add the matching PIN if appropriate. Pressing the Run/Stop opens the **Protocols** screen, allowing you to select from the following protocol options in the LEV mode:

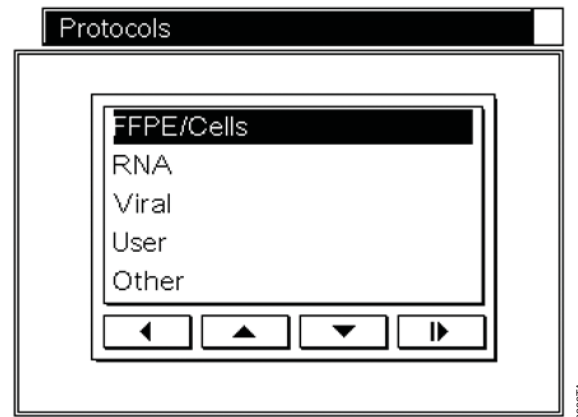


Figure 50. Protocols screen.

2. • Select the desired protocol listed in the Maxwell® 16 reagent kit technical manual (e.g., Choose *Viral* to purify viral total nucleic acid from serum or plasma using the Maxwell® 16 LEV Viral Total Nucleic Acid Kit Cat.# AS1150).
- Select the *User* option to access and run custom protocols. Instructions for setting customized protocols are presented in Section 12.C. Select the method required.
- Select the *Other* option to access a specialized protocol for *Fixed Yield DNA* and to access a *Demo* option.

Fixed Yield DNA allows purification of a limited amount of DNA, allowing for a reproducible amount of DNA to be captured between samples.

The *Demo* protocol is for demonstration purposes only and should not be used.

Please contact Promega Technical Services at techserv@promega.com for more information on these specialized options.

3. A confirmation screen allows you to verify that the correct selection has been made. If correct, press the Run/Stop button, and you will be prompted to open the door to load the samples. Press the forward arrow button. This will open the door, and load the rack with the samples. Follow the steps in Section 5 to gather the run data and perform the run. Follow the steps in Section 6 to generate the run reports.

C. User-Defined Research Methods (Research Use Only)

The Maxwell® 16 IVD Instrument allows the generation and use of customized user-defined methods for research use only. You can generate a method that optimizes purification from challenging sample types or unique applications. User-defined sample processing times for lysis, binding, drying and elution can be set. In addition, the number of cycles can be customized for particular

samples. The new run parameters can be saved on the instrument as a user method. The potential benefits and disadvantages of changing any of these parameters are listed below. The actual effect of any change will must be determined through user testing. The user will need to optimize parameters.

Potential Effects of Changing Run Parameters

Changing Lysis Time: This is the amount of time that the plunger mixes the sample before addition of MagneSil® particles to the sample.

- *Potential Benefits:* Complete lysis of the sample is necessary to recover DNA, RNA or protein. The optimal lysis time for a specific sample type depends on the time required to adequately lyse the samples. Some samples will not require additional lysis time after preprocessing, while other samples will benefit from an extended lysis time.
- *Potential Disadvantages:* Extended lysis times could result in the formation of precipitates, which may interfere with purification and downstream applications.

Increasing Binding Time: This is the amount of time that is allowed for binding the MagneSil® particles containing the nucleic acid or protein.

- *Potential Benefits:* Maximal recovery requires efficient binding of the target molecules to the magnetic particles. Increased binding time can increase binding of the target molecule
- *Potential Disadvantages:* Increased binding times may increase carryover of detergents, contaminants and other components that may affect purity or inhibit downstream applications.

Increasing Drying Time: This is the amount of time prior to elution that the particles are air-dried.

- *Potential Benefits:* Excess alcohol from the wash buffers can interfere with downstream applications such as gel electrophoresis, PCR and enzymatic reactions. Increasing the drying time can remove excess alcohol from the target.
- *Potential Disadvantages:* Over drying can reduce recovery of the target molecules from the MagneSil® particles.

Increasing Elution Time: This is the amount of time that the plunger is used to mix particles in the elution buffer.

- *Potential Benefits:* Efficient recovery of the target molecules requires removal from the MagneSil® particles. Extending the elution time can enhance the removal of the target molecules from the MagneSil® particles.
- *Potential Disadvantages:* Excess elution time can result in the release of detergents and other components that may inhibit the downstream applications. Also, elution buffer could evaporate during long heated elution times.

Increasing Number of Cycles: This is the number of times the entire process will be repeated.

- *Potential Benefits:* Increasing this can result in greater recovery of target molecules.
- *Potential Disadvantages:* Increasing this can result in the transfer of detergents, contaminants and other components that may inhibit downstream applications.

Default Maxwell® Instrument Settings for Preprogrammed Methods

The values for the Maxwell® 16 IVD Instrument preprogrammed methods are given in Table 6 for LEV and Table 7 for SEV. These can be used as a guide for selecting values for custom methods

Table 6. Default LEV Method Parameters (RNA).

Step	RNA
Lyse	3.00 minutes
Bind	2.00 minutes
Dry	3.00 minutes
Elute	5.00 minutes
Cycles	1

Setting a User-Defined Method

1. To set up the custom method select *Setup* in the **Home** screen. In the **Maxwell® 16 Configuration** screen, select *User Protocols*.

Table 7. Default SEV Method Parameters.

Step	DNA from Blood or Cells	DNA from Tissue	DNA from Buffy Coat	RNA from Tissue or Cells	Protein (all sample types)
Lyse	1.67 minutes	10.00 minutes	1.67minutes	0.25 minutes	1.50 minutes
Bind	1.50 minutes	1.50 minutes	1.50 minutes	3.00 minutes	1.50 minutes
Dry	3.00 minutes	3.00 minutes	7.00 minutes	2.00 minutes	0 minutes
Cycles	2	2	2	2	2

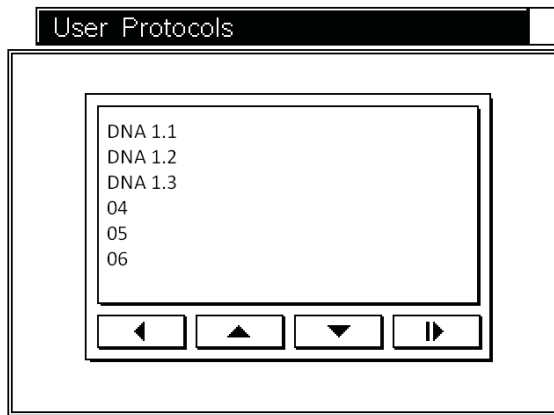


Figure 51. User protocols.

- In the **User Protocols** screen, select a number, then press the the Run/Stop button.

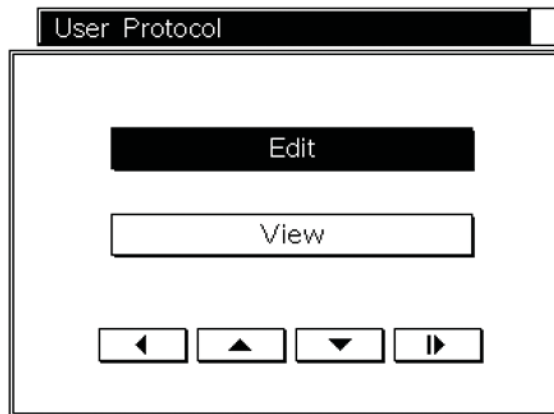


Figure 52. User Protocol screen.

- In the **User Protocol** screen, select *Edit*. The **Choose A Method** screen will appear; choose *RNA*, *DNA* or *Protein* (SEV) or *DNA*, *RNA* or *Total NA* (LEV).

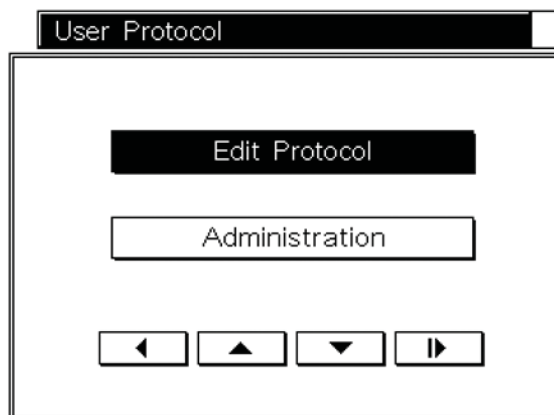


Figure 53. User Protocol screen. Edit user-defined protocols.

- In the **User Protocol** screen, select *Edit Protocol* and press the Run/Stop button. The following screen will open and allow you to edit run parameters.

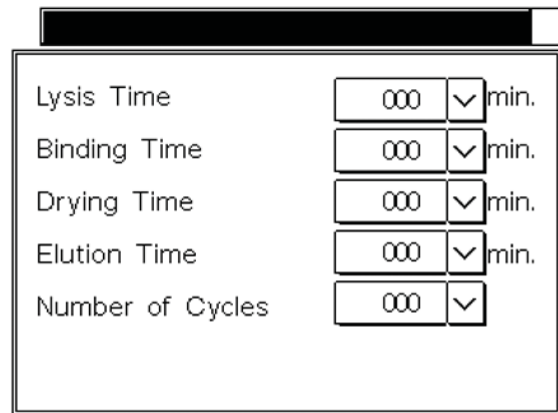


Figure 54. Editing run parameters.

- Lysis Time*. Select the down arrow and add the new value. Press the Run/Stop button. The maximum time that can be added is 60 minutes; the minimum is zero minutes.

Binding Time. Select the down arrow and add the new value. Press the Run/Stop button. The maximum time that can be added is 60 minutes; the minimum is zero minutes.

Drying Time. Select the down arrow and add the new value. Press the Run/Stop button. The maximum time that can be added is 60 minutes; the minimum is zero minutes.

Elution Time. Select the down arrow, and add the new value. Press the Run/Stop button. The maximum time that can be added is 60 minutes; the minimum is zero minutes.

Number of Cycles. Select the down arrow, and add the new value. Press the Run/Stop button. The maximum number of cycles that can be added is 3; the minimum is 1.

- Once the user method parameters are defined, the new method can be named and a PIN added. PIN protection can prevent inadvertent changes. After changing the parameters press the forward arrow button to open the **User Protocol Options** screen

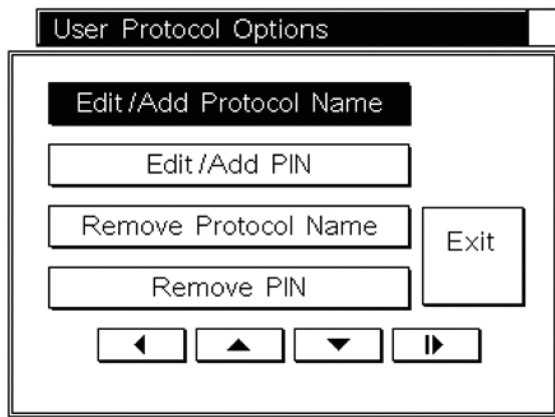


Figure 55. User Protocol Options screen.

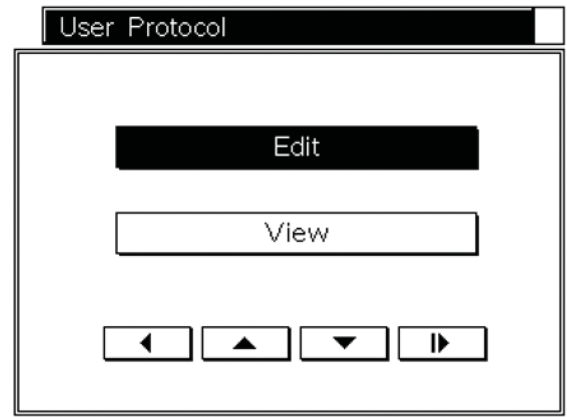


Figure 56. User Protocol screen.

- To name a method, select *Edit/Add Protocol Name*, and use the keyboard to enter the method name. Select the Run/Stop button to return to the **User Protocol Options** screen.
- A PIN, which must be entered to edit the method, can be added. The PIN can contain up to four digits. It is recommended that you keep a separate list of all methods and associated PINs. In the *User Protocol Options* screen, select the *Edit/Add PIN* option. Using the keypad, enter the PIN and then press the Run/Stop button. Confirm the PIN, and press the forward arrow button again. An administrative password is included in the Welcome Letter, received with the instrument, which is used to access all PIN-protected options.

The Maxwell® 16 IVD Instrument allows storage of 10 custom SEV and 10 custom LEV methods. If there are 10 existing custom methods, more custom methods can be added by changing an existing method.

Changing an Existing User-Defined Method

- To change an existing custom method, select *Setup* in the **Home** screen. In the **Maxwell® 16 Configuration** screen, select *User Protocol*. This opens the **User Protocols** screen with the list of protocols. Select the existing custom protocol to be changed, and press the Run/Stop button. In the **User Protocol** screen, select *Edit* and the Run/Stop button.

- In the **User Protocol** screen, select *View* to see the parameters for an existing method. Select *Edit*, and enter the correct PIN, if the method is PIN-protected.

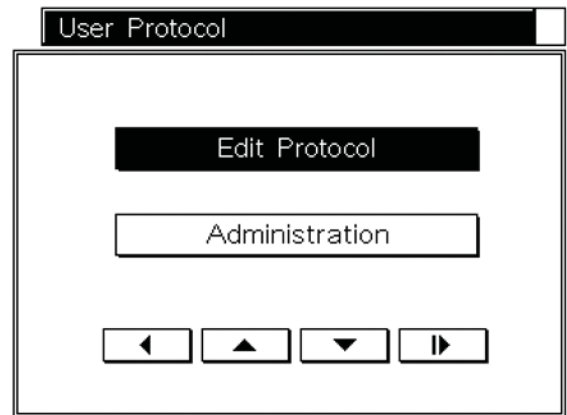


Figure 57. Edit Protocol

- Selecting *Edit Protocol* opens a screen that displays the current method name is listed on the left of the title bar and the current method type on the right. **To change the purification method type (e.g. from DNA to RNA), select the method listed in the screen header.** This will open the **Choose a Method** screen where you can choose *DNA*, *RNA* or *Protein* (SEV) or *DNA*, *RNA* or *Total NA* (LEV). Select the parameter to be changed, and change as described in Section 11.C.

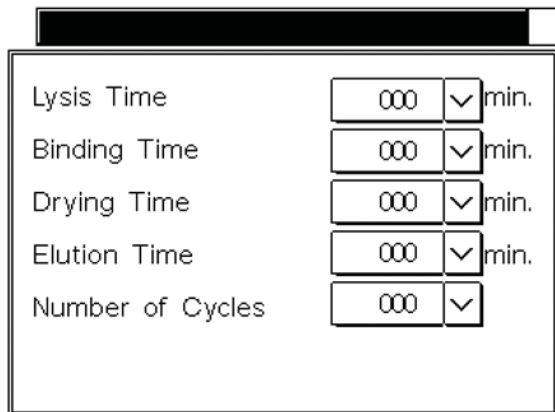


Figure 58. Edit run parameters.

- To change a custom method name or PIN in the **User Protocols** screen, select the existing custom protocol name to be changed, and press the Run/Stop button. In the next **User Protocols** screen, select *Edit*. If the method is PIN-protected, enter the PIN. In the next **User Protocol** screen select *Administration* to open the **User Protocol Options** screen.

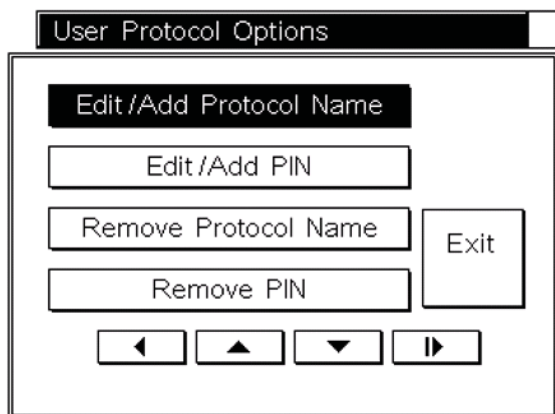


Figure 59. User Protocol Options

- To change the protocol name, select *Edit/Add Protocol Name*; use the keyboard to enter the new name.
To change a protocol PIN, select *Edit/Add PIN*, and use the keypad screen to add and confirm the new PIN.
To remove the protocol name or PIN, choose *Remove Protocol Name* or *Remove PIN*. After confirming that you wish to remove a name or PIN, the instrument will remove these settings.
The user-defined methods may be run by selecting *User* in the **Protocols** screen during run set up in the Research Mode.

D. Homogenization Method

The SEV mode has an option that allows homogenization of tissue samples prior to running the purification method. This method must be user-validated to match the tissue sample type. In the method, a small volume of lysis buffer is added to an elution tube, and the tube containing the plunger is placed in the elution well. Homogenization occurs in this tube. Extra plungers and elution tubes are needed for this method.

Guidelines for Using the Homogenization Method

- Volume of Lysis Buffer:** This depends whether the sample floats in the lysis buffer. If the sample floats, use 200µl of lysis buffer in the SEV mode. If the sample sinks, use 300µl in the SEV mode.
- Sample Heating:** The sample can be heated during homogenization to enhance the release of nucleic acid. The user decides whether this is required.
- Homogenization Time:** The user must establish homogenization time.

Running Homogenization Methods.

In the **Protocols** screen, select *Other* followed by *Homogenization*.

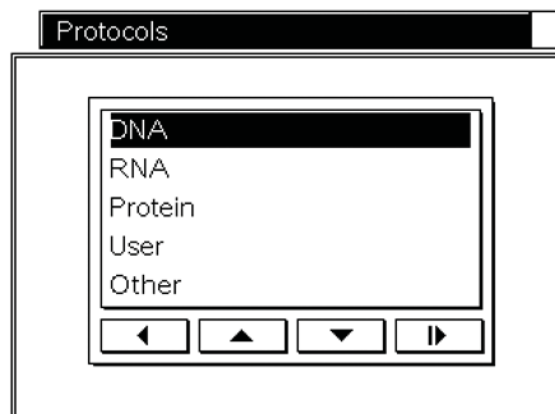


Figure 60. SEV Protocols screen.

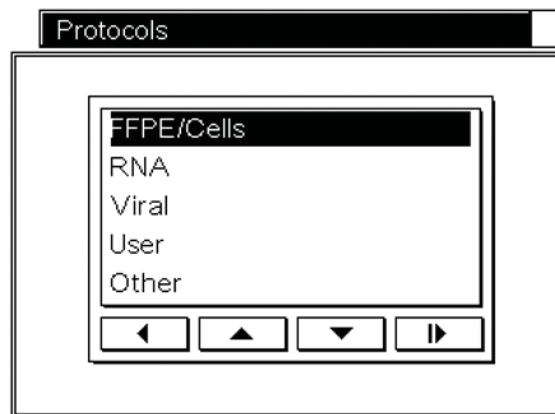


Figure 61. LEV Protocols screen.

For SEV mode, insert the sample and lysis buffer into the elution tube, and place the elution tube into the elution rack. Place the plunger in the tube and press the Run/Stop button.

After the homogenization steps are complete, the nucleic acid may be isolated using the appropriate purification method.

E. Related Research Products

Table 8. DNA Purification Kits SEV

Product	Size	Cat.#
Maxwell® 16 Blood DNA Purification Kit	48 preps	AS1010
Maxwell® 16 Cell DNA Purification Kit	48 preps	AS1020
Maxwell® 16 Tissue DNA Purification Kit	48 preps	AS1030
Maxwell® 16 Mouse Tail DNA Purification Kit	48 preps	AS1120

Table 9. DNA Purification Kits LEV

Product	Size	Cat.#
Maxwell® 16 Cell LEV DNA Purification Kit	48 preps	AS1140
Maxwell® 16 FFPE Tissue LEV DNA Purification Kit	48 preps	AS1130
Maxwell® 16 FFPE Plus LEV DNA Purification Kit	48 preps	AS1135
Maxwell® 16 LEV Blood DNA Purification Kit	48 preps	AS1290
Maxwell® 16 Buccal Swab LEV DNA Purification Kit	48 preps	AS1295

Table 10. RNA Purification Kits SEV

Product	Size	Cat.#
Maxwell® 16 Total RNA Purification Kit	48 preps	AS1050

Table 11. RNA Purification Kits LEV

Product	Size	Cat.#
Maxwell® 16 Tissue LEV Total RNA Purification Kit	48 preps	AS1220
Maxwell® 16 Cell LEV Total RNA Purification Kit	48 preps	AS1225
Maxwell® 16 LEV simplyRNA Cells Kit	48 preps	AS1270
Maxwell® 16 LEV simplyRNA Tissue Kit	48 preps	AS1280
Maxwell® 16 LEV simplyRNA Blood Kit	48 preps	AS1310

Table 12. Viral Purification Kit

Product	Size	Cat.#
Maxwell® 16 Viral Total Nucleic Acid Purification Kit	48 preps	AS1150

Table 13. Protein Purification Kit

Product	Size	Cat.#
Maxwell® 16 Polyhistidine Protein Purification Kit	48 preps	AS1060

¹For Laboratory Use.

Table 14. Items Available Separately

Product	Size	Cat.#
Maxwell® 16 LEV Cartridge Rack (for use with LEV configuration)	1 each	AS1251
Maxwell® 16 LEV Magnet (for use with LEV configuration)	1 each	AS1261
Maxwell® 16 LEV High Strength Magnetic Rod Assembly and Plunger Bar Adaptor (for use with LEV configuration)	1 each	SP1070
Maxwell® 16 SEV Cartridge Rack (for use with SEV configuration)	1 each	AS1201
Maxwell® 16 SEV Magnetic Elution Rack (for use with SEV configuration)	1 each	AS1202
LEV Plungers	50 each	AS6101
SEV Plungers	50 each	AS5201
LEV Elution Tubes	50 each	AS6201
SEV Elution Tubes	50 each	AS5501

13. Certificate of Decontamination

The final page of this manual is a Certificate of Decontamination that should be completed and attached to the outside packaging of the instrument before it can be returned.

(a)Patent Pending.

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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.

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13. Certificate of Decontamination

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

To disinfect and decontaminate: Wipe off the magnetic rod assembly, plunger bar, inside platform, and inside and outside surfaces using a cloth dampened with 70% ethanol then a cloth dampened with a 1–2% bleach solution in deionized water. Follow immediately with a cloth dampened with deionized water to remove any residual bleach from the instrument surfaces. Repeat the procedure as many times as required to effectively disinfect and decontaminate the instrument.

Failure to confirm disinfection and decontamination will result in decontamination charges before the instrument will be serviced.

Select either (A) or (B):

- A. I confirm that the returned items have not been in contact with body fluids or toxic, carcinogenic, radioactive, or other hazardous materials.
- B. I confirm that the returned items have been decontaminated and can be handled without exposing personnel to health hazards.

Circle the type of material used in the instrument: Chemical Biological Radioactive**

Briefly describe the decontamination procedure performed:

Date: _____

Place: _____

Signature: _____

Name (block capital letters): _____

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

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

Date: _____

Place: _____

Signature: _____

Name (block capital letters): _____