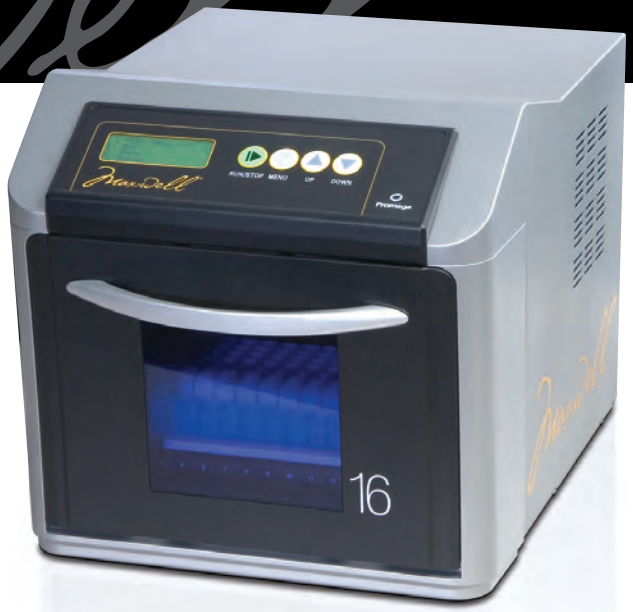
Maxwell® 16 INSTRUMENT



Maxwell® 16 Clinical Instrument Operating Manual

PROMEGA
Madison, WI USA
608-274-4330

IVD
In Vitro Diagnostic
Medical Device

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

INSTRUCTIONS FOR USE OF PRODUCT
AS2050

PRINTED IN USA. 2/08

Part# TM300

Promega

Maxwell® 16 Clinical Instrument Operating Manual

All technical literature is available on the Internet at: www.promega.com/tbs/
Please visit the web site to verify that you are using the most current version of this Technical Manual.
Please contact Promega Technical Services if you have questions on the use of this product. Email: techserv@promega.com

I. Introduction

I.A. Intended Use of the Maxwell® 16 System (Cat.# AS2050 and AS1015)

The Maxwell® 16 System, which consists of the Maxwell® 16 Clinical Instrument[a] (Cat.# AS2050) and the Maxwell® 16 Blood DNA Purification Kit[b,c] (Cat.# AS1015), is used to perform automated isolation of DNA from human whole blood or buffy coat samples. Samples collected in blood collection tubes treated with EDTA, heparin or citrate can be used with the Maxwell® 16 System. The nucleic acid isolation methodology used by the Maxwell® 16 System produces DNA 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 System is not intended for use as part of a specific in vitro diagnostic test.

The Maxwell® 16 Clinical Instrument displays the CE conformity marking to identify it as fulfilling the requirements of the Low Voltage Directive, Electromagnetic Compatibility Directive, and the In Vitro Diagnostic Medical Device Directive and associated harmonized standards.

The Maxwell® 16 System is intended for professional use only. Diagnostic results obtained using DNA purified with this system must be interpreted in conjunction with other clinical or laboratory data.

Product Use Limitations

The Maxwell® 16 System is not intended for use with tissue samples or samples from body fluids other than blood. It is not intended for use with non-human samples or for purification of RNA.

The Maxwell® 16 System performance has been evaluated by isolating DNA from 300µl whole blood samples, or 250µl buffy coat samples, obtained from healthy individuals with a white blood cell count ranging from 4.2×10^6 to 1.2×10^7.

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

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 Instrument (Cat.# AS2050) in the clinical mode with the Maxwell® 16 Blood DNA Purification Kit (Cat.# AS1015).

I.B. Maxwell® 16 Blood DNA Purification Procedure

The Maxwell® 16 Clinical Instrument provides automated nucleic acid purification from up to 16 samples using cell lysis and binding of magnetized silica particles to nucleic acid as the primary separation principle. Used in conjunction with the Maxwell® 16 Clinical Instrument, the Maxwell® 16 Blood DNA Purification Kit (Cat.# AS1015) provides high purity DNA extraction from blood and buffy coat samples. The purified DNA is eluted in a 300µl volume.

The automated steps performed by the Maxwell® 16 System include:

- Sample lysis in the presence of a chaotropic agent and detergent
- Binding of nucleic acids to magnetized silica particles
- Washing of the bound particles away from other cellular components
- Elution of nucleic acids into a formulation that can be added directly to standard PCR.

The user selects the clinical protocol as prompted by the Maxwell® 16 Instrument, places samples into the reagent cartridges, places the cartridges onto the instrument platform and closes the door. The user then starts the instrument, which automatically performs all the steps in the protocol, allowing the user to walk away and do other work.

The temperature of samples is regulated by a heating system that is controlled by the protocol. The extracted nucleic acid can be used for PCR amplification.

Maxwell® 16 System Features:

- Compliant with the following EU Directives:
  98/79/EC In vitro Diagnostic Medical Devices.
  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.
- The system is controlled via a multi-language LCD readout and the default operational mode is clinical SEV blood. Additional operational modes and kits are available for Research and Forensic applications (See Appendix II).

I.C. Maxwell® 16 Instrument Specifications

Processing Time:	30–40 minutes
Number of Samples:	up to 16
Standard Configuration:	300µl elution volume
Weight:	18.9kg
Dimensions (W × D × H):	325.5 × 438.2 × 326.5mm
Power Requirements:	100–240VAC, 50–60Hz, 2.1A

I.D. Product Components and Symbol Key

Product	Cat.#
Maxwell® 16 Clinical Instrument	AS2050

Includes:

- 1 Maxwell® 16 Instrument
- 1 Power Cable
- 1 RS-232 Cable for Firmware Upgrades
- 1 CD Containing the Technical Manual
- 1 Quick Start Guide

IVD In Vitro Diagnostic Medical Device

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Product	Cat.#
Maxwell® 16 Clinical SEV Hardware Kit	AS2250

Required for configuration of the Maxwell® 16 Instrument in SEV (standard elution volume) format for clinical use. Includes:

- 1 Standard Magnetic Rod/Plunger Bar Assembly
- 1 Maxwell® 16 Cartridge Rack
- 1 Maxwell® 16 Magnetic Elution Rack

Symbol Key

Symbol	Explanation	Symbol	Explanation
IVD	In Vitro Diagnostic Medical Device	EC REP	Authorized Representative
CE	Conformité Européenne		Consult your local Promega Representative regarding instrument disposal
!	Important	REF	Catalog number
PROMEGA Madison, WI USA 608-274-4330	Manufacturer	SN	Serial number

I.E. Inspection

Upon receiving your Maxwell® 16 Instrument, please inspect the package carefully to make sure all accessories are present. Standard accessories are shown in Figure 1

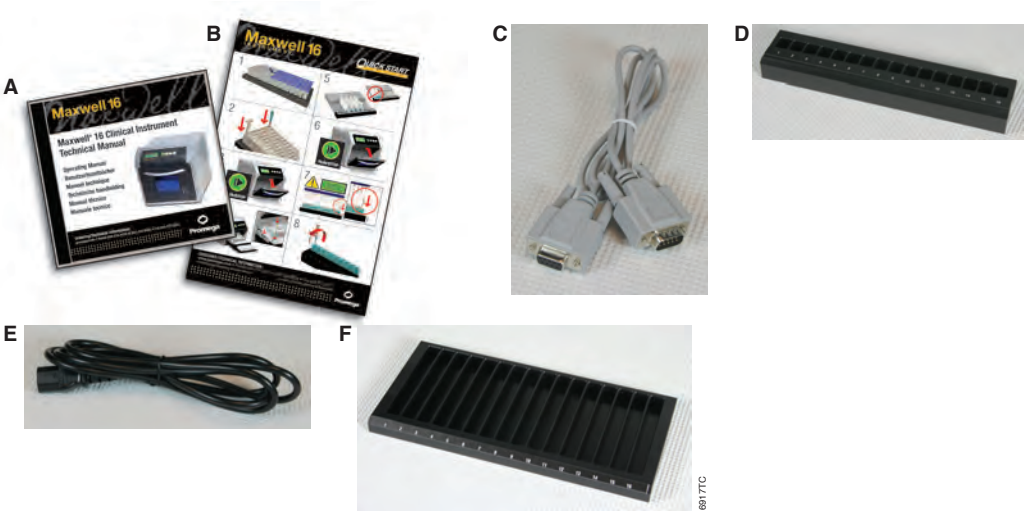


Figure 1. Maxwell® 16 Instrument (AS2050) accessories. A. Operating Manual (provided on CD). B. Quick Start Guide; C. RS-232 Cable for firmware upgrades; D. Maxwell® 16 Magnetic Elution Rack; E. Power Cable; F. Maxwell® 16 Cartridge Rack.

I.F. Precautions

IMPORTANT SAFETY INSTRUCTIONS. SAVE THESE INSTRUCTIONS.

Safety Symbols and Markings	
	Danger. Hazardous voltage. Risk of electrical shock.
	Warning. Risk of personal injury to the operator or a safety hazard to the instrument or surrounding area.
	Warning. Pinch point hazard.
	Warning. Hot surface. Burn hazard.
	Warning. Lifting hazard.
	Warning. Biohazard.
	Warning. It is important to understand and follow all laws regarding the safe and proper disposal of electrical instrumentation. 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 close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional RF sources), as these may interfere with the proper operation.

It is recommended that the user evaluate the electromagnetic environment of the instrument prior to operation.

IMPORTANT SAFETY INSTRUCTIONS. SAVE THESE INSTRUCTIONS.

Safety Precautions	
	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 instrument.
	Do not reuse cartridges or plungers.
	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 Instrument weighs 18.9kg (41.7lb) and should be handled by two people.
	Equipment can be hazardous due to the use of chemical and biohazardous substances.

I.G. Environmental Requirements

Power Requirements:	100–240VAC, 50–60Hz, 2.1A
Temperature:	5–40°C
Humidity:	up to 80% relative humidity

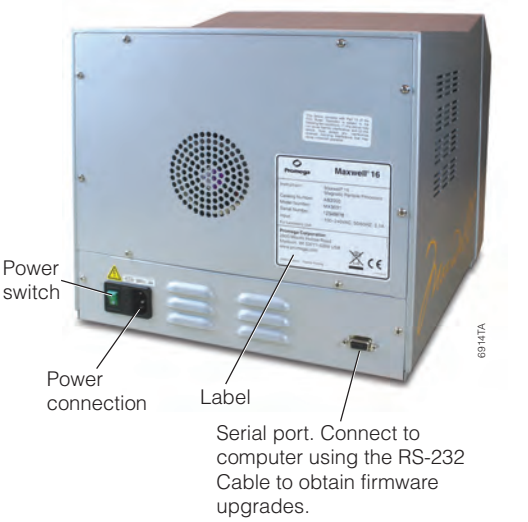
The Maxwell® 16 Instrument is intended for indoor use only. Wipe up spills immediately. Install the instrument on a clean, level surface. To avoid shortening the expected lifespan of the instrument, install in a location that meets the following criteria:

- 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.
- Do not position the instrument so that it is difficult to unplug from the power source.
- Do not place next to heat sources.
- Do not use near flammable gases or liquids.
- Do not place near other electrically sensitive instruments.

II. Hardware Overview

Maxwell® 16 Instrument Front

Maxwell® 16 Instrument Back



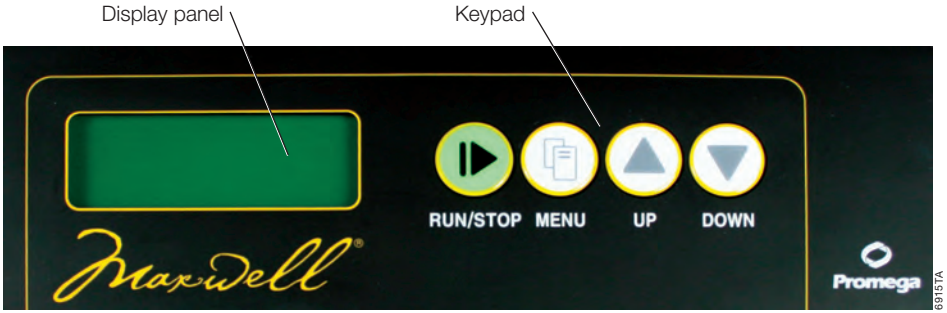


Figure 2. Maxwell® 16 Instrument display panel. The LCD display panel and keypad, including Run/Stop, Menu, Scroll Up and Scroll Down buttons, are shown.

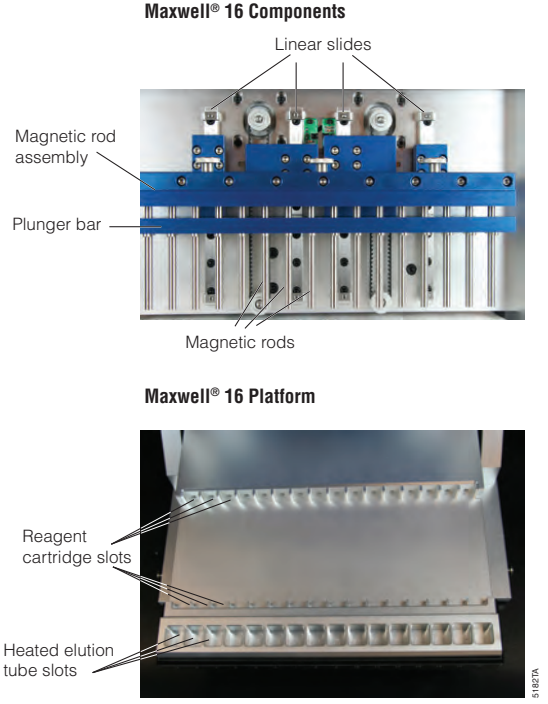


Figure 3. Maxwell® 16 components. Standard (SEV) configuration magnetic rod assembly and plunger bar, and Maxwell® 16 platform.

III. Unpacking and Setting Up the Maxwell® 16 Instrument

III.A. Setup

1. Remove the accessories and literature from the shipping container. Slide the Maxwell® 16 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 parts have been included. Refer to Figure 1 for a list of parts.

4. Set the Maxwell® 16 Instrument on a flat, level, solid surface in a dust-free location with reasonable 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 at a later date.

III.B. Removal of Magnetic Rod Assembly/Plunger Bar and Platform Shipping Anchors

1. **Ensure that the instrument is turned off and is not plugged in.**

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: Do not plug in or turn on the machine before removing the shipping anchors. Turning on the Maxwell® 16 Instrument before the shipping anchors are removed will cause a lot of noise but will not result in permanent damage to the instrument. If this occurs, immediately turn off and unplug the instrument. Proceed with removal of the shipping anchors.

3. Open the instrument door.

4. Locate the Magnetic Rod Assembly/Plunger Bar shipping anchor thumbscrews labeled with red stickers (Figure 4). Unscrew and remove these shipping anchor thumbscrews.

5. Locate the Platform shipping anchor thumbscrews with the red stickers (Figure 4). Unscrew and remove the Platform shipping anchor thumbscrews.

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

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

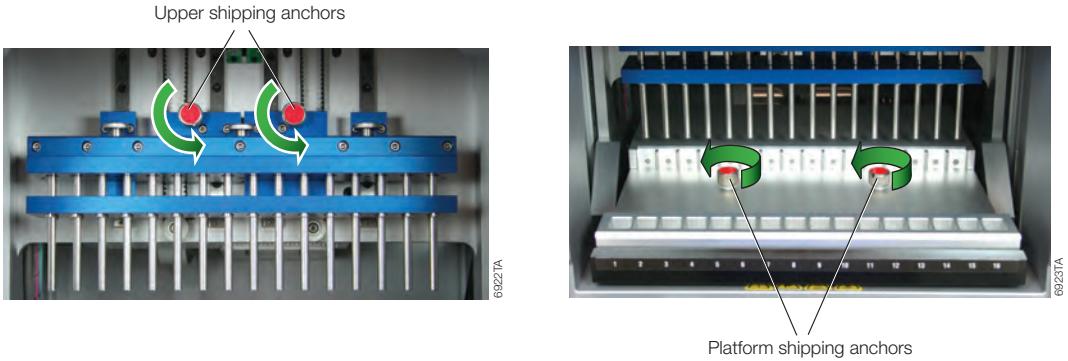


Figure 4. The upper (magnetic rod assembly/plunger bar) shipping anchors and the platform shipping anchors on the Maxwell® 16 Instrument.

III.C. Operational Mode Setup

(i) Plugging the Instrument into the Power Outlet

1. Once the Magnetic Rod Assembly/Plunger bar shipping anchors, Platform shipping anchors and all packaging materials have been removed, you can connect the instrument to a power outlet.
2. Ensure that the power switch is in the off position. The power switch is located next to the power cord connection on the back of the instrument.
3. Connect the power cord to the back of the Maxwell® 16 Instrument.
4. Plug the power cord into a wall outlet. See Section I.G for power requirements.
5. Close the door.
6. Turn the instrument on.
7. Once turned on, the instrument will display the firmware version number and operational mode setting, and proceed through a self-check.
8. Connecting to the serial port on the back of the instrument is not required. Store the RS-232 Cable in a location near the instrument for future use.

(ii) Hardware Configuration and Operational Mode Setup Requirements

The Maxwell® 16 Instrument has multiple operational modes, depending on the purification procedure and the Maxwell® 16 Purification Kit being used. Compliance with Directive 98/79/EC on in vitro diagnostic medical devices has only been demonstrated for, and only applies to, use of the Maxwell® 16 Instrument (Cat.# AS2050) in clinical mode with the Maxwell® 16 Blood DNA Purification Kit (Cat.# AS1015). Table 1 lists the hardware configuration and operational mode requirements for the Maxwell® 16 Blood DNA Purification Kit. The Maxwell® 16 Instrument (Cat.# AS2050) is supplied configured for use in clinical mode with SEV hardware.

Table 1. Hardware Configuration and Operational Mode Setup Requirements.

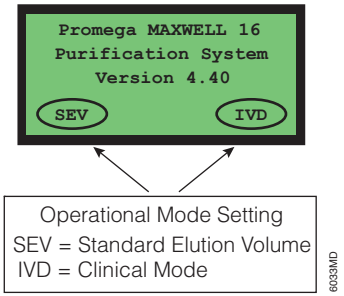
Maxwell® 16 Kit	Purification Procedure	Firmware Operational Mode	Hardware Configuration
Maxwell® 16 Blood DNA Purification Kit	gDNA	Clinical	Standard Elution Volume (SEV)

Failure to use the operational mode required for your selected hardware configuration will cause damage to the instrument.

(iii) Setting the Maxwell® 16 Instrument Operational Mode

1. Make sure the instrument door is closed and turn on the Maxwell® 16 Instrument. The screen will display both the firmware version number and the current operational mode setting. The Maxwell® 16 Instrument (Cat.# AS2050) is supplied configured for use in clinical mode with SEV hardware.

2. Verify that the operational mode is displayed as shown in the image on the right. If the operational mode is not as shown here, you will need to change the instrument setting (see Appendix II, Section VIII.A(ii) "Changing the Maxwell® 16 Instrument Operational Mode").



Compliance with Directive 98/79/EC on in vitro diagnostic medical devices has not been demonstrated for use of the Maxwell® 16 Instrument with reagent kits other than Cat.# AS1015, or with methods other than those provided in the clinical mode.

(iv) Changing the Maxwell® 16 Instrument Display Language

1. Go to the "Menu" screen. The instrument will default to the Menu screen at start-up.
2. Select "Setup". This will open the language screen.
3. Scroll up or down and select the language required.
4. Once the language is selected press "Run/Stop", and then return to Menu. The display should now be in your selected language.

IV. Operating the Maxwell® 16 Instrument

IV.A. Navigation

The system firmware will prompt you through initiation of a purification run. Follow the directions displayed on the LCD screen. Use the "Scroll Up" and "Scroll Down" buttons to move the cursor to the desired position. Once the cursor is moved to the desired position in the list, press the "Run/Stop" button to make the selection. At any time during the selection process, you may press the "Menu" button to return to the beginning.

IV.B.Operational Qualification

With instrument power on:

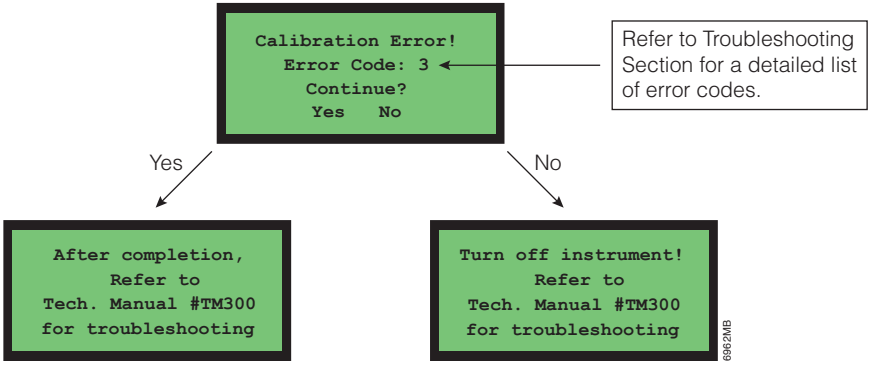
Each time you turn the instrument on, it will automatically go through a self-diagnostic test during which the platform, plunger bar and magnetic rod assembly are moved to check that the instrument is functioning properly. Upon completion of this test, the screen will display either "Diagnostic Check Successful" or "Calibration Error".

During instrument runs:

During runs, the instrument will automatically do 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".

If calibration error occurs:

If a calibration error occurs, you will see the "Calibration Error" screen. Note the Error Code Number displayed on the LCD screen, and refer to the Troubleshooting section of this manual (Section VI.C) for more information on each Error Code. If you are in the middle of a run, you can choose to continue the purification procedure or abandon the run by turning off the instrument. Continuing the run will not damage the Maxwell® 16 Instrument but may result in suboptimal recovery of purified nucleic acid.



IV.C. Sample Purification

Placement of sample cartridges in the Maxwell® 16 Instrument is illustrated in Figure 5. Please refer to the *Maxwell® 16 Blood DNA Purification Kit Technical Manual* (#TM301) for detailed instructions on cartridge and sample preparation and purification.

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 when used with this system.

The Maxwell® 16 reagent cartridges contain potentially hazardous chemicals. Users should wear protective gloves when handling the reagent cartridges. Users should follow their institutional guidelines for disposal.

Figure 5. Placement of sample cartridges into the Maxwell® 16 Instrument. Sample cartridges are placed in the Maxwell® 16 Cartridge Rack. The sample cartridges are then removed from the Maxwell® 16 Cartridge Rack and placed onto the instrument platform.

IV.D. Minimizing Cross-Contamination

Users should follow standard laboratory procedures to avoid cross-contamination of samples. Wear gloves during all procedures, and change gloves often. Use aerosol-resistant pipet tips when transferring samples to minimize the potential for cross-contamination.

V. Periodic Cleaning and Maintenance

The Maxwell® 16 Instrument requires 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 to avoid damage. Most parts of the Maxwell® 16 Instrument have an anodization coating, which forms a durable, easily cleaned barrier with the metal.

Always turn off and unplug the instrument before cleaning.

V.A. General Care

- Wipe up any spills immediately.
- After each use, clean the instrument by wiping off the magnetic rod assembly, plunger bar, and platform using a cloth dampened with deionized water or 70% ethanol. Do not use other solvents or abrasive cleaners.

Note: Wear gloves. If the instrument is used with biohazardous materials, dispose of any cleaning materials used in accordance with your institutional guidelines.

- Periodically wipe the outside of the instrument using a cloth dampened with deionized water or 70% ethanol.
- Keep the cooling vents in the back of the machine clear of dust.
- Do not remove the Maxwell® 16 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 (see Figure 3, Section II) 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 V.C., or contact Promega Technical Services for assistance.
- If any of the hardware accessories need to be cleaned (i.e., cartridge or elution racks), wipe them with a cloth dampened with deionized water or 70% ethanol.

V.B. Removal of Magnetic Rod Assembly

If the plungers are inadvertently left out 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 must be removed for cleaning.

1. Turn off the power and unplug the instrument. This will release the motors so that the heads can be gently moved to allow easier access to the magnetic rod assembly.
2. Gently and slowly, with constant pressure on both the right and left side, push the plunger bar and the magnetic rod assembly down to their lowest positions. Do not push the plunger bar and magnetic rod assembly too fast. Doing so could result in damage to the instrument's electronics.
3. Unscrew and remove the three thumbscrews on top of the magnetic rod assembly (Figure 6).

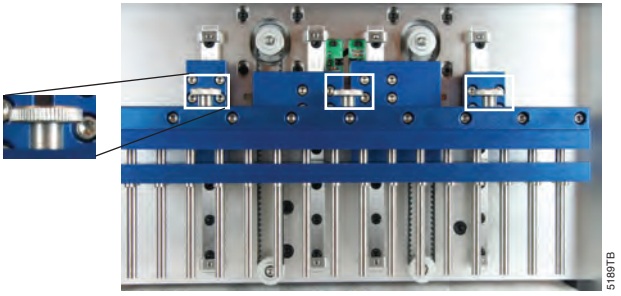


Figure 6. The thumbscrews on the top of the magnetic rod assembly.

4. Once the three thumbscrews are removed, gently lift up the magnetic rod assembly to remove it.
5. To clean the magnetic rod assembly, wipe with a soft paper towel dampened with deionized water or 70% ethanol. Removal of paramagnetic particles from the magnetic rod assembly will require multiple wipes with a damp cloth.
6. If the magnetic rod assembly cannot be cleaned, please contact Promega for assistance.
7. Replace the magnetic rod assembly, and firmly tighten the three thumbscrews.

V.C. 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.

VI. Troubleshooting

VI.A. General Troubleshooting

Symptoms	Causes and Comments
Expected method not available.	Instrument configuration has been changed to Research or Forensic mode. Confirm the configuration by turning the instrument off and then on again (See Section VIII.A). To change the operational mode and hardware settings, follow the directions in Section VIII.A(ii), selecting "Clinical" from the Operational Setup screen, and "SEV" from the Hardware Setup screen.
The instrument is making an unusual, rapid clicking noise when it is turned on.	• Verify that the Magnetic Rod Assembly/Plunger Bar shipping anchors and Platform shipping anchors have been removed. • One of the machine sensors might have a dust particle interfering with it. Contact Promega or your local Promega representative for assistance with sensor cleaning.
The LCD screen does not light up when the instrument is turned on.	If you **cannot** hear the motors running: • 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 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 an amperage higher than 3A. • Contact Promega or your local Promega representative for service. If you **can** hear the motors running: • 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.
The machine makes unusual noises during the run.	The machine will make some noise during a typical run. Unusual (or louder than usual) noises may indicate that the heads are sticking. Continued operation under these conditions can cause damage to the instrument. Heads that are sticking may be lubricated with **light** machine oil. Do not get any 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.
Heater error at the elution step.	The electrical heating system is not working properly. Contact Promega or your local Promega representative for service.
Plungers are not completely stripped off the rods at the end of the run.	Always be careful to 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. If plungers are consistently left on, contact Promega or your local Promega representative for service.

Symptoms	Causes and Comments
The buttons don't work.	Some of the buttons are ignored during processing. If a button is not working consistently, please contact Promega or your local Promega representative. Do not use spray cleaner on the keypad, as it can seep in and short out the keyboard.
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.
The machine runs but does not advance to the "Run" screen.	A sensor for one of the heads may be failing, or a belt may be slipping. Please contact Promega or your local Promega representative for service.
Poor sample quality, low yield or low purity.	See the troubleshooting section of the Technical Manual supplied with your Maxwell® 16 Purification Kit for more information.
Expected methods are not shown on the LCD screen.	Verify the firmware setup. Refer to Section III.C.
Can I change the steps in a protocol?	No. Contact Promega or your local Promega representative for firmware upgrades. As new purification kits become available, new automated methods will be offered. Reagents are predispensed and optimized to work with the preprogrammed automated methods.

VI.B. Power Failure

Power failure occurs during instrument run.	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 off the particles. Then manually remove the plungers from the instrument and restart the purification, from the beginning, with new plungers.

VI. Troubleshooting (continued)

VI.C. Error Messages

Symptoms	Causes and Comments
Calibration error: **Error Code 1.**	Error Code 1 indicates a Platform calibration error. • Verify that there are no obstructions behind or in front of the platform that prevent it from moving back and forward freely. • Turn the instrument off, wait a few seconds, then turn the instrument back on. If the calibration error persists, please contact Promega or your local Promega representative for service.
Calibration error: **Error Code 2.**	Error code 2 indicates a Plunger Bar calibration error. • Verify that there are no solid particulates inside Well #1 of the cartridge. Solid particulates 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. Select "No" after the "Continue?" prompt on the LCD screen (see Section IV.B). • Verify that the shipping anchors have been removed. Refer to Section III.B. • Turn the instrument off, wait a few seconds, then turn the instrument back on. If the calibration error persists, please contact Promega or your local Promega representative for service.
Calibration error: **Error Code 3.**	Error code 3 indicates a Magnetic Rod Assembly calibration error • Verify that the shipping anchors have been removed. Refer to Section III.B. • Verify that the Magnetic Rod Assembly is attached properly. Refer to Section VIII.B. • Turn the instrument off, wait a few seconds, then turn the instrument back on. If the calibration error persists please contact Promega or your local Promega representative for service.
One of the following error messages appears in English. "Error!" "Low Temp Detect" "Press Run/Stop key" "Time: 00h 00m 00s" "Temp Sensor check!" "By agitation" "Press Run/Stop key" "Waiting!" "Heating the Block"	These messages indicate that a thermocouple is detecting a temperature issue. Pressing the Run/Stop key will clear these errors, and the run will continue without heat. DNA yield will be reduced. If you choose to continue the run, check the quality of the purified DNA before using it in downstream diagnostic applications. Contact Promega or your local Promega representative for service.

VII. Appendix I: Firmware Updates, Instrument Return, and Warranty Information

VII.A. Updating Firmware

As Promega releases 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 service or for new firmware.

Firmware is updated using the RS-232 port on the back of the instrument. Firmware can be updated from any computer (Microsoft Windows® 95 or higher) with an available serial port.

For clinical use, firmware version 4.40 or greater is required. Do not install firmware versions below 4.40.

1. Plug the provided RS-232 Cable into the back of the instrument and into a serial port on your computer. Note whether the cable is plugged into COM1 or COM2.
2. Obtain the firmware upgrade program from Promega or your local Promega representative. Save the unzipped file to your hard drive, and follow the directions provided with the new firmware.
3. Double-click on the file icon to open the download program. Select the COM port into which the RS-232 Cable is connected. Click the "Download" button, and wait until the program is complete. The instrument should reset itself. Turn the unit off and then back on again. The screen will display the new firmware version. Disconnect the RS-232 Cable from the computer. The RS-232 Cable may be left plugged into the instrument if desired.

Please contact Promega or your local Promega representative for assistance if you encounter any problems during the firmware upgrade process.

VII.B. Instrument Return

The Maxwell® 16 Instrument is designed to provide consistent performance with little maintenance. If a problem arises with your instrument, please contact Promega or your local Promega representative for support. If further action is required, repair options will be presented and a return authorization assigned if necessary. **Promega is not responsible for instrumentation returned without an authorization number.** When you ship the instrument for service, please remember to:

1. Obtain return authorization from Promega.
2. Decontaminate the instrument (see Section VII.D for Decontamination Instructions).
3. Affix a signed and dated Certificate of Decontamination to the outside of the package in which the instrument is returned (see Section VII.D). **Failure to complete and attach the Certificate of Decontamination will result in a decontamination charge.**
4. 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.
5. Repack the instrument according to the following instructions:

VII.B. Instrument Return (continued)

Preparation of the Maxwell® 16 Instrument Prior to Repacking

1. Ensure that the cartridges and elution tubes are removed from the instrument platform.
2. Ensure that the instrument is turned off and is not plugged in.
3. Decontaminate the instrument.

Anchoring the Platform, Magnetic Rod Assembly and Plunger Bar

1. By hand, carefully push the platform back into the instrument as far as it will go. Replace the Platform shipping anchor thumbscrews (Figure 4, Section III.B) and tighten by hand to anchor the platform in place for shipment.
2. 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 4, Section III.B).

Repacking the Maxwell® 16 Instrument

1. Place the instrument into the plastic bag.
2. Place the two foam packaging protectors on the sides of the instrument.
3. Slide the instrument into the small inside shipping box. Ensure that the top of the instrument is facing the top of the open box.
4. Slide the small inside shipping box containing the instrument into the large outside shipping box.
5. Repack the Maxwell® 16 Instrument accessories.
    a. Rewrap the Cartridge Preparation Rack and Magnetic Elution Tube Rack in bubble wrap and place on top of the instrument.
    b. Place the RS-232 Cable (in a reclosable bag) into the box.
    c. Place the Power Cable into the box.
6. 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.

VII.C. Instrument Disposal

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

VII.D. 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 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): _____

VII.E. Warranty Information

Limited Warranty and Service Guidelines

Promega warrants to the original purchaser that the Promega Maxwell® 16 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 Instrument, extended and premium warranties are available for purchase. If you purchased an extended or premium warranty for your Maxwell® 16 Instrument, please refer to those specific warranty terms.

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

1. Write or call the company that sold you the instrument and describe as precisely as possible the nature of the problem.
2. Carry out minor adjustments or tests as suggested by your technical contact.
3. If the instrument is still not functioning properly, YOU MUST OBTAIN A PROMEGA RETURN AUTHORIZATION NUMBER.
4. Before returning the instrument, you will be responsible for cleaning it and providing a Certificate of Decontamination to Promega in accordance with instructions.
5. 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.
6. 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.
7. 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.

VIII. Appendix II: Research and Forensic Applications of the Maxwell® 16 System

This section of the Technical Manual discusses use of the Maxwell® 16 System for Research and Forensic applications. Operation of the instrument in Research and Forensic modes, or with kits other than Cat.# AS1015, has not been demonstrated to comply with EU Directive 98/79/EC on in vitro diagnostic medical devices.

The Maxwell® 16 Clinical Instrument (Cat.# AS2050) is supplied configured for use in clinical mode with SEV (Standard Elution Volume) hardware. When used for research or forensic applications, the instrument may be configured with SEV or LEV (Low Elution Volume) hardware for different elution volume preferences. See Section VIII.B for instructions on how to configure your instrument in SEV or LEV format.

VIII.A. Operational Mode Setup Requirements

The Maxwell® 16 Instrument has multiple operational modes, depending on the procedure and the purification kit used. Table 2 lists the hardware configuration and operational mode requirements for the Maxwell® 16 Purification Kits. Please refer to the Technical Manual supplied with your specific purification kit for further information on the operational mode required.

Table 2. Hardware Configuration and Operational Mode Setup Requirements for Research and Forensic Applications.

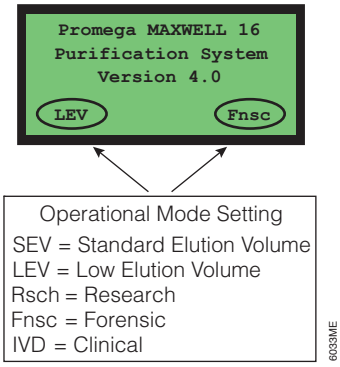
Maxwell® 16 Kit	Purification Procedure	Firmware Operational Mode	Hardware Configuration
Maxwell® 16 gDNA Purification Kits (Cat.# AS1010, AS1020, AS1030)	gDNA	Research (Rsch)	Standard Elution Volume (SEV)
Maxwell® 16 Polyhistidine Protein Purification Kit (Cat.# AS1060)	Polyhistidine-Tagged Protein	Research (Rsch)	Standard Elution Volume (SEV)
Maxwell® 16 Total RNA Purification Kit (Cat.# AS1050)	Total RNA	Research (Rsch)	Standard Elution Volume (SEV)
Maxwell® 16 LEV Total RNA Purification Kits (Cat.# AS1220, AS1225)	Total RNA	Research (Rsch)	Low Elution Volume (LEV)
DNA IQ™ Reference Sample Kit for Maxwell® 16 (Cat.# AS1040)	Forensic gDNA Reference Samples	Forensic (Fnsc)	Standard Elution Volume (SEV)
DNA IQ™ Casework Sample Kit for Maxwell® 16 LEV (Cat.# AS1210)	Forensic gDNA Casework Samples	Forensic (Fnsc)	Low Elution Volume (LEV)

Please ensure that you select the operational mode that is required for your hardware configuration. Failure to use the correct operational mode and hardware configuration will cause damage to the instrument.

VIII.A. Operational Mode Setup Requirements (continued)

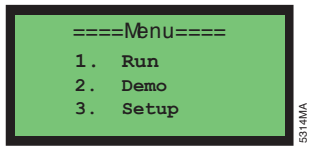
(i) Setting the Maxwell® 16 Instrument Operational Mode

1. Make sure the instrument door is closed and turn on the Maxwell® 16 Instrument. The screen will display both the firmware version number and the current operational mode setting.
2. Verify that the current operational mode displayed matches the operational mode required by both the installed hardware and the purification kit to be used (see Table 2).
3. If the operational mode displayed does not match the operational mode required by the purification kit, you will need to change the instrument setting (see (ii) below, "Changing the Maxwell® 16 Instrument Operational Mode").



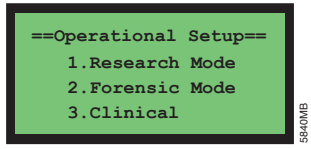
(ii) Changing the Maxwell® 16 Instrument Operational Mode

1. Press the "Menu" button to get to the Menu screen.
2. Scroll down to move the cursor to "Setup". Press "Run/Stop" to select "Setup".

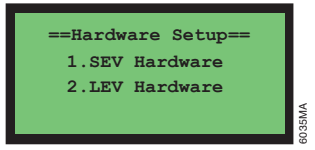


3. Scroll up/down to move the cursor to the desired operational mode. Press "Run/Stop" to select.

Refer to Table 2 for information on the operational mode required for research and forensic Maxwell® 16 Purification Kits.

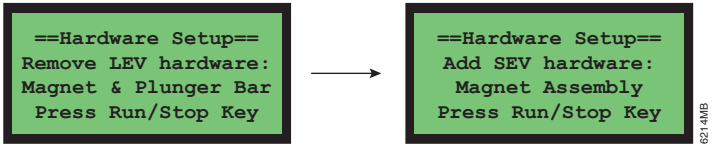


4. Scroll down to move the cursor to the desired hardware mode. If the instrument is configured with the Standard Elution Volume hardware, select "SEV". If the instrument is configured with the Low Elution Volume hardware, select "LEV". Press "Run/Stop" to select.

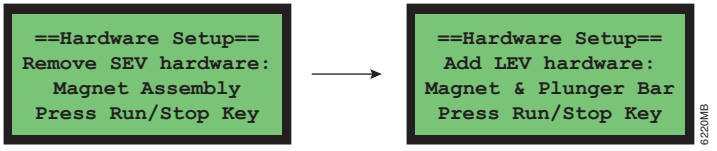


5. If the hardware mode in the firmware has changed, the following LCD screens will appear, prompting the user to change the hardware. Failure to change the hardware will result in damage to the instrument. Directions for changing the hardware are provided in Section VIII.B.

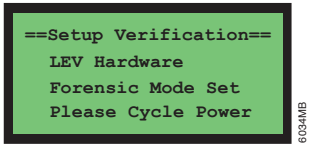
   If changing from LEV to SEV, the following screens will appear:



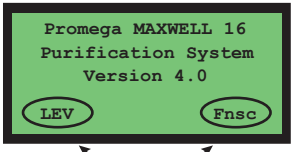
   If changing from SEV to LEV, the following screens will appear:



6. The display will show the operational mode selected. Turn the instrument off and then on to cycle the instrument power.
   Note: The selected operational mode or hardware setting will not be applied until you cycle the power.



7. When you turn the instrument back on, verify the instrument's operational mode setting on the display screen.



Operational Mode Setting

SEV = Standard Elution Volume
LEV = Low Elution Volume
Rsch = Research
Fnsc = Forensic
IVD = Clinical

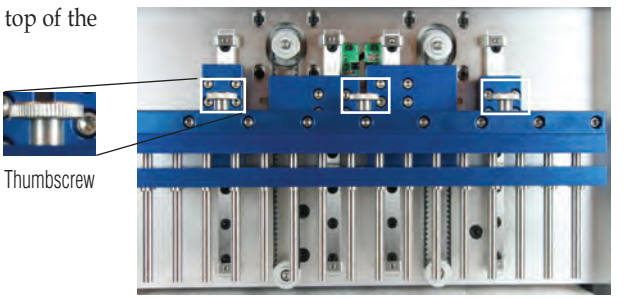
VIII.B. Reconfiguring the Maxwell® 16 Instrument Hardware

The Maxwell® 16 Instrument can be configured in SEV (Standard Elution Volume) or LEV (Low Elution Volume) format for different sample elution volume preferences. To reconfigure your instrument for a different elution volume preference, you will need the appropriate Conversion Kit (see Section VIII.C). The Maxwell® 16 Instrument (Cat.# AS2050) is supplied in SEV format. To convert an SEV instrument to LEV format, the LEV Conversion Kit for Maxwell® 16 (Cat.# AS1250) is required.

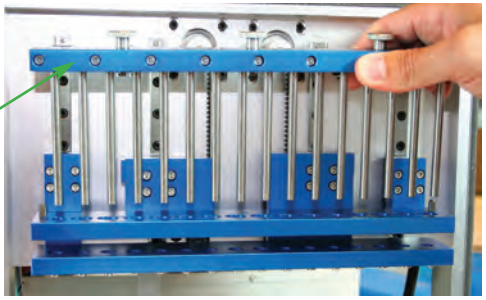
(i) Changing from Standard to LEV Configuration

Note: Do not reconfigure the instrument while samples or reagent cartridges are in place on the instrument platform. To avoid potential exposure to contaminants, clean the instrument according to the instructions in Section V.A before you begin.

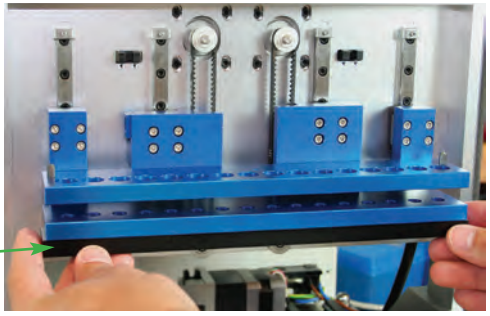
1. Ensure that the power is turned off and the instrument is unplugged. This will release the motors so that the heads can be gently moved to allow easier access to the hardware assemblies.
2. Gently and slowly, with constant pressure on both the right and left side, push the blue Plunger Bar and the blue Magnetic Rod Assembly down to their lowest positions. **Do not push too fast**, as this could cause damage to the instrument's electronics.
3. Unscrew the three thumbscrews on top of the magnetic rod assembly.



4. Gently lift up the SEV Magnetic Rod Assembly and remove it.

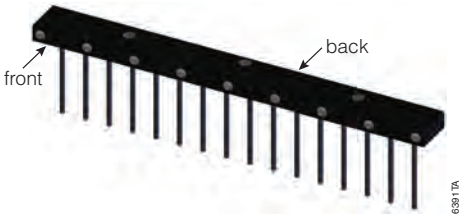


5. Insert the black LEV Plunger Bar Adaptor onto the bottom of the remaining arm. Make sure that the side containing the screws faces upward. Several magnets will "click" and hold the LEV Plunger Bar Adaptor in place once it is attached. The LEV Plunger bar should then be fairly difficult to remove.

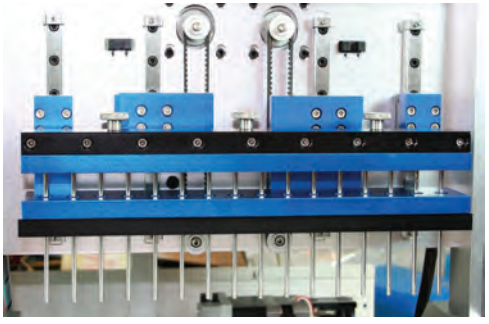


6. Insert the black LEV Magnetic Rod Assembly. The screws should be facing toward you. Press firmly to place the LEV Magnetic Rod Assembly in position. It will fit tightly into place.

Orientation of the Magnetic Rod Assembly



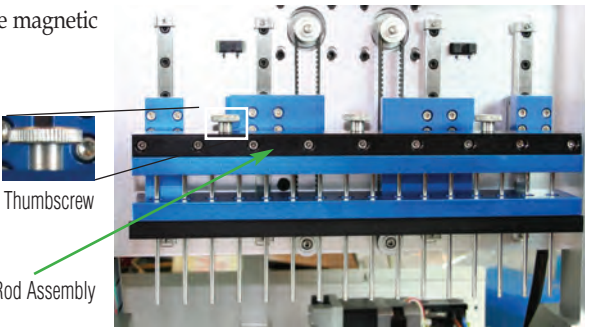
7. Secure the LEV Magnetic Rod Assembly with the three thumbscrews from the standard magnetic rod assembly, and hand-tighten. Complete the configuration by updating the Firmware to the LEV setting (Section VIII.A).



Failure to change the instrument firmware operational mode from SEV to LEV will cause damage to the instrument.

(ii) Changing from LEV to Standard Configuration

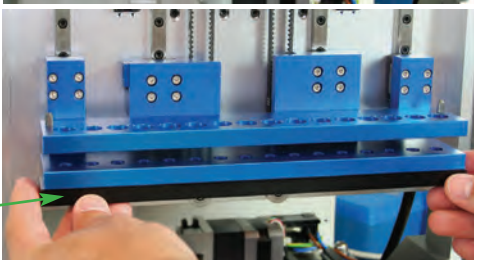
1. Ensure that the power is turned off and the instrument is unplugged. This will release the motors so that the heads can be moved gently to allow easier access to the hardware assemblies.
2. Gently and slowly, with constant pressure on both the right and left sides, push the black LEV Magnetic Rod Assembly down to the lowest position. **Do not push too fast**, as this could result in damage to the instrument's electronics.
3. Unscrew the three thumbscrews on top of the magnetic rod assembly.
4. Gently lift up the LEV Magnetic Rod Assembly to remove it.



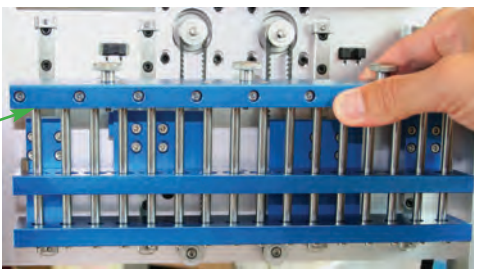
5. Pull down on the LEV Plunger Bar Adaptor to release the magnets that hold it in place.

   Hint: Pull down at an angle so that the back of the magnet is released first.

   Remove the black LEV Plunger Bar Adaptor.



6. Insert the blue SEV Magnetic Rod Assembly.



7. Secure the Magnetic Rod Assembly with the three thumbscrews, and hand-tighten.
8. Complete the configuration by updating the Firmware to the SEV setting (Section VIII.A).

Failure to change the instrument firmware operational mode from LEV to SEV will cause damage to the instrument.

VIII.C. Instrument Accessories and Purification Kits for Research and Forensic Use

DNA Purification Kits

Product	Size	Cat.#
Maxwell® 16 Blood DNA Purification Kit	48 preps	AS1010

For Laboratory Use. Sufficient for 48 automated isolations from up to 400µl whole blood samples.

Product	Size	Cat.#
Maxwell® 16 Cell DNA Purification Kit	48 preps	AS1020

For Laboratory Use. Sufficient for 48 automated isolations from tissue culture or bacterial cells.

Product	Size	Cat.#
Maxwell® 16 Tissue DNA Purification Kit	48 preps	AS1030

For Laboratory Use. Sufficient for 48 automated isolations from up to 50mg tissue samples.

RNA Purification Kits

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

For Laboratory Use. Sufficient for 48 automated isolations from tissue, cells or blood sample types.

Product	Size	Cat.#
Maxwell® 16 Tissue LEV Total RNA Purification Kit	48 preps	AS1220

For Laboratory Use. Sufficient for 48 automated isolations from up to 25mg tissue samples.

Product	Size	Cat.#
Maxwell® 16 Cell LEV Total RNA Purification Kit	48 preps	AS1225

For Laboratory Use. Sufficient for 48 automated isolations from up to 1×10^6 tissue culture cells.

Forensic or Paternity Lab-Related Products

Product	Size	Cat.#
DNA IQ™ Reference Sample Kit for Maxwell® 16	48 preps	AS1040

Sufficient for 48 automated isolations from forensic or paternity reference sample types.
For Research Use Only. Not for use in diagnostic procedures.

Product	Size	Cat.#
DNA IQ™ Casework Sample Kit for Maxwell® 16	48 preps	AS1210

Sufficient for 48 automated isolations from forensic casework sample types.
For Research Use Only. Not for use in diagnostic procedures.

Protein Purification

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

Sufficient for 48 automated isolations.

VIII.C. Instrument Accessories and Purification Kits for Research and Forensic Use (continued)

Instrument Accessories

Product	Cat.#
LEV Conversion Kit for Maxwell® 16	AS1250

Required to configure the Maxwell® 16 Instrument in LEV (low elution volume) format. Includes:

- 1 LEV Magnetic Rod Assembly
- 1 LEV Plunger Bar Adaptor
- 1 Maxwell® 16 LEV Cartridge Rack
- 1 Quick Start Guide

Product	Cat.#
Maxwell® 16 LEV Cartridge Rack (for use with LEV configuration)	AS1251
Maxwell® 16 Cartridge Rack (for use with standard configuration)	AS1201
Maxwell® 16 Magnetic Elution Rack (for use with standard configuration)	AS1202

[a]Patent Pending.

[b]U.S. Pat. Nos. 6,027,945, 6,368,800 and 6,673,631, Australian Pat. No. 732756, European Pat. No. 1 204 741 and Mexican Pat. No. 209436 have been issued to Promega Corporation for methods of isolating biological target materials using silica magnetic particles and simultaneous isolation and quantitation of DNA. Other patents are pending.

[c]Australian Pat. No. 730718, Singapore Pat. No. 64532 and Korean Pat. No. 486402 have been issued to Promega Corporation for an improved filtration system and method. Other patents are pending.

Maxwell is a registered trademark of Promega Corporation. DNA IQ is a trademark of Promega Corporation.

Products may be covered by pending or issued patents or may have certain limitations. Please visit our Web site for more information.

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

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

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2/08

Maxwell® 16
INSTRUMENT

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