

Hematek® Slide Stainer

Operating Manual

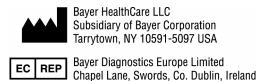




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If the system is used in a manner differently than specified by Bayer HealthCare, the protection provided by the equipment may be impaired. See warning and hazard statements.

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Section 1: Introduction

General Description and Intended Use

The Hematek® Slide Stainer, shown in Figure 1-1. *Hematek Slide Stainer* is a fully automated, bench-top instrument designed specifically for the staining of hematology slides for in vitro diagnostic use. This self-contained precision instrument accepts, conveys, fixes, stains, and delivers dry blood smear preparations that are spread on standard thickness 25-mm x 75-mm or 1" x 3" glass slides. The slides are stained at the rate of one slide per minute.

Two conveyor spirals move the slides along the platen. Three sensing switches are triggered sequentially as the slide moves along the platen. Each switch activates its respective solution pump, which meters and delivers the stain, buffer, or rinse into the capillary space between the slide and platen. After staining and rinsing have been accomplished, the slide is dried by a flow of air from a low velocity blower and it is then deposited in a slide drawer.

Optimal results with the Hematek Slide Stainer are obtained by using one of the Hematek Stain Paks. The Stain Pak consists of one bottle each of stain, buffer, and rinse solutions, and is designed for easy installation and removal from the instrument.

NOTE

Only Hematek Stain Paks should be used with the Hematek Slide Stainer. Use of other stain packs or solutions may void the warranty.

Theory of Operation

The Hematek Slide Stainer is designed to produce stained slides of consistent quality in a continuous process. This is accomplished by having a fixed length of time in each of the three phases of stain, buffer, and rinse, as well as a predetermined ratio of stain-to-buffer volumes in the buffer phase.

A properly stained slide is the result of an interactive process involving the pump volumes, the mixing process, and the stain-to-buffer ratio. A minimum ratio of 1:2 is recommended; however, if the platen is filling properly, good mixing is occurring, and the stained slides are acceptable under the microscope, the stain-to-buffer ratio should not be adjusted.



Figure 1-1. Hematek Slide Stainer

Physical Characteristics

Figure 1-2. *Circular Bubble Level and Leveling Feet*, shows the physical characteristics of the Hematek Slide Stainer, including the circular bubble level and the leveling feet.



Figure 1-2. Circular Bubble Level and Leveling Feet

- 1 Circular Bubble Level
- 2 Leveling Feet

Circular Bubble Level



CAUTION

Do not move the circular bubble level from its location directly behind the operating lever. Proper leveling is essential for optimal mixing of the stain and buffer.

The circular bubble level is a water bubble gauge with an inscribed circle that can be observed through the clear plastic lid of the instrument. The level is located on the instrument panel to the left of the reagent pumps, directly behind the operating lever. It is used to ensure the Slide Stainer is in a level position.

Levelers

The feet under the front corners of the instrument act as levelers and may be adjusted to raise or lower the instrument to a level position. Observe the circular bubble level to verify that the feet have been properly adjusted and the instrument is level.

Slide Transport System

Figure 1-3. *Slide Transport System* and Figure 1-4. *Slide Transport and Staining System* show the slide transport system, including the conveyor spirals, the platen, the platen guide rails, and the slide drawer.

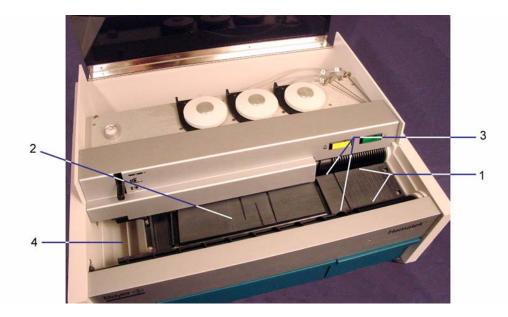


Figure 1-3. Slide Transport System

- 1 Conveyor Spirals
- 2 Platen
- 3 Platen Guide Rails
- 4 Slide Drawer

Conveyor Spirals

The conveyor spirals are two parallel spirals with opposing grooves. Slides to be stained are fitted separately into the opposing grooves, which move the slides across the staining surface. When loading slides onto the instrument, the side covered by the blood smear is faced to the left of the operator, with the feathered edge to the back of the instrument. Slides are moved by the conveyor spirals side by side, from right to left, first at the vertical plane, then at the horizontal plane with the blood smear facing downward toward the platen.

Platen

The platen spans the entire front of the instrument, between the conveyor spirals. The outside ridges of the platen are elevated guide rails, which give support to the slides as they are moved along the platen. It is a precision-machined component made from a high-performance plastic polymer material and is designed specifically for two main functions:

- 1. It maintains the exact volumes of the required solutions within a capillary space between the platen and the slide.
- 2. It provides a mixing system for the stain and buffer.

The platen also provides the necessary time interval after the rinsing step for proper drying of the slides before they are deposited in the slide drawer. A trough around the perimeter of the platen allows for drainage of used solutions into the waste tank below.

Slide Drying System

The dryer is a blower type fan that runs continuously when the instrument is in operation. The airflow serves to cool the mechanical components inside the Slide Stainer, as well as to dry the slides.

Slide Drawer

The slide drawer is located below the left end of the platen. It receives the slides as they drop from the platen after being stained, rinsed, and dried. The drawer will hold 100 slides. See Figure 1-4. *Slide Transport and Staining System*.

Waste Tank

The waste tank is located underneath the platen and collects used and overflow staining solutions. The waste tank should be emptied and rinsed once each day and whenever a new Stain Pak is installed. Refer to Section 5: *Maintenance* for more information.

Staining System

Figure 1-4. *Slide Transport and Staining System*, Figure 1-5. *Staining Systems*, and Figure 1-6. *Sensing Switches*, illustrate the staining system, including the volume control panel, pump assemblies, pump cap, pump arm, pump tubing, and cannula.



Figure 1-4. Slide Transport and Staining System

- 1 Slide Drawer
- 2 Waste Tank
- 3 Volume Control Panel

Volume Control Panel

The volume control panel tips out from the right front corner of the instrument and contains three graduated adjustment knobs. The volume of reagent being delivered can be adjusted by rotating the respective control dial clockwise to increase the volume or counterclockwise to decrease the volume.

Solution Pumps

The instrument has three pump assemblies, one for each solution. Each assembly consists of a pump motor, four rollers that are attached to the underside of a pump cap, and a pump arm. All work together to maintain a constant metering speed to provide consistent volumes of stain, buffer, and rinse, even though the line voltage may fluctuate. The amount of solution pumped is electronically adjusted through the use of the volume control knobs.

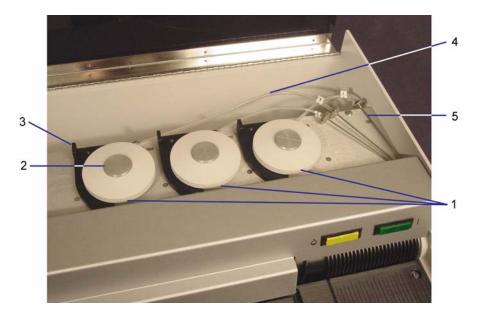


Figure 1-5. Staining Systems

- 1 Pump Assemblies
- 2 Pump Cap
- 3 Pump Arm
- 4 Pump Tubing
- 5 Cannula

Pump Tubing and Cannulas



CAUTION

Use only the Hematek Pump Tube Set with the Hematek Slide Stainer. Use of other tubing may result in incorrect measurement and improper staining, buffering, and rinsing.

The pump tubing is provided as a set of three separate pieces of tubing. Notice that each pump tube is identified with a number and symbol, which corresponds to the reagent carried by the tubing:

- 1 for stain
- 2 for buffer
- 3 for rinse

Each tube has a clear plastic cuff that fits snugly up to the pump arm and holds the tube in position without slippage. The tubing is a special type of rubber that is resistant to leaching and brittleness. The special diameters and lengths of the tubing assure precise measurement of solutions. Each pump tube is connected to a cannula that is inserted into the appropriate bottle in the Stain Pak. Three cannulas are provided with the Hematek Slide Stainer. With proper routine cleaning, the cannulas can be used for an extended period of time.

Sensing Switches

The sensing switches are three finger-like devices located just above the back edge of the platen. When contacted, the respective sensing switch is activated, which tells the instrument that a slide is in position for the pump to run. After a specific time delay, the pumping motor for the specific reagent is activated. The solution pumps are set so that precise volumes of stain, buffer, and rinse are delivered to their respective areas on the platen. Each reagent is delivered through its respective cannula and tubing network to the platen orifice. The capillary space between the slide and the platen is then filled with the measured volume of reagent.

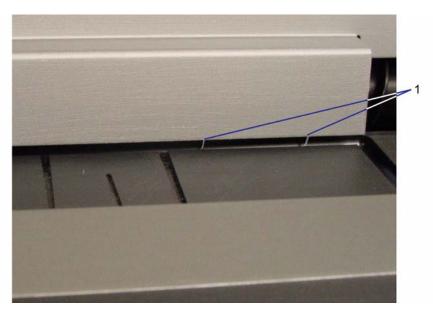


Figure 1-6. Sensing Switches

1 Sensing Switches

Electrical System

Figure 1-7. *Electrical System* and Figure 1-8. *Electrical System–Rear of Instrument* illustrate the components of the electrical system.



Figure 1-7. Electrical System

- 1 Operating Lever
- 2 Power Light
- 3 Low Stain Light

Operating Lever

The operating lever is a multiple function, bar-shaped lever located at the front left side of the instrument, near the top. The three positions of the lever are labeled and their related functions are as follows:

- **UNLOCK** releases the pressure of the reagent pump arms against the pump tubing.
- LOCK locks the reagent pump arms into their proper position against the pump tubing.
- **PRIME** provides an override control to allow the pumps to run continuously so the tubes can be primed with solutions and cleared of air bubbles. The lever must be held continuously in the **PRIME** position. When released, it returns automatically to the **LOCK** position.

POWER Light

The green **POWER** light is located at the right side of the instrument near the top. When the instrument is turned on, the light illuminates.

LOW STAIN Light

The yellow **LOW STAIN** light is to the left of the **POWER** light. It is off under usual operating conditions; however, when the Hematek Stain Pak contains sufficient reagents to stain only about 20 slides, a weight-sensing device activates the circuit and illuminates the light. The Stain Pak should be replaced at this time.

Power Module

The power module is located on the rear of the instrument; on one side of the module is the panel that contains the line cord receptacle, fuse, and power switch. The power module converts the line current coming into the instrument to 12 volts DC, which is the voltage within the instrument.

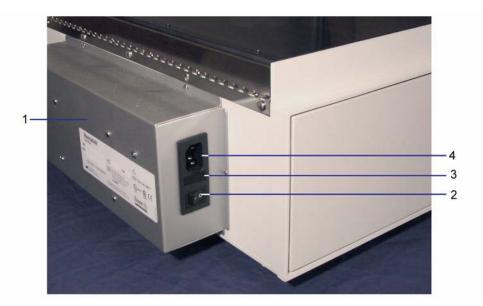


Figure 1-8. Electrical System-Rear of Instrument

- 1 Power Module
- 2 ON / OFF Switch
- 3 Fuse Holder
- 4 Line Cord Receptacle

Line Cord Receptacle

The line cord connects into the line cord receptacle, which is located at the top of the panel on the power module.

Fuse Holder

The fuse holder, in the center of the panel, holds the fuse that protects against serious electrical overload. A spare fuse is also located in the fuse holder.

ON / OFF Switch

The **ON / OFF** Switch is located at the bottom of the panel and controls all power to the instrument.

Specifications

| Power Requirements | 100 - 230 VAC ± 10%, 50/60 Hz, 0.75 Amps |
|----------------------|---|
| Fuse Rating | 250 Volt, 1.0 Amps, 5mm x 20mm, Type T |
| Line Leakage Current | <5 milliamperes Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL 1262 and CSA 22.2 No. 151. |
| Dimensions | Depth - 43.4 cm (17.1 in) Width - 47.0 cm (18.5 in) Height - 19.0 cm (7.5 in) |
| Weight | 17.7 kg (39 lbs) |
| Throughput | Stains 1 slide per minute |

Disposal of System Waste and Supplies

Laws and regulations enacted to protect the environment and to encourage resource conservation require the disposal of hazardous and biohazardous wastes in a specified manner. Some of the wastes from the Hematek Slide Stainer can be classified as hazardous or biohazardous wastes. It is essential that the laboratory take appropriate steps to determine the laws and regulations applicable to their disposal and to effect compliance. If it is necessary to sample instrument wastes and effluent in order to evaluate compliance with applicable regulations, the laboratory should contact a local licensed biohazardous waste disposal firm for assistance.

The principal wastes associated with the use of the Hematek Slide Stainer are pump and underplaten tubing, effluents from the staining operation, and the container for stain, buffer, and rinse.

Slides with human specimens, control materials, and all reagents, should also be handled and disposed of in accordance with the prevailing regulations and guidelines of agencies with jurisdiction over the laboratory. Refer to the product label and to Material Safety Data Sheets for details concerning any special precautions related to the handling of Hematek Stain Pak containers. Material Safety Data Sheets are available from Bayer.



BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to Appendix A, page A-1 for recommended precautions when working with biohazardous materials.

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Section 2: Installation

Overview

This section provides detailed installation and setup instructions for the Hematek Slide Stainer. The installation steps must be followed correctly to ensure proper installation, operation, and service. Read this Operator's Guide carefully before attempting to operate the instrument. Follow all instructions carefully.

The Hematek Slide Stainer is a precision instrument and must be handled accordingly. Rough handling or dropping of the instrument will disturb or damage internal components. Always handle the instrument with care.

Environmental Factors

As with all sensitive electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Temperature should be held relatively constant to obtain the highest degree of operating stability. The ambient temperature range for operating the instrument is 18°C to 30°C (64°F to 86°F). The ambient operating humidity range is 20% to 85% relative humidity.

Place the instrument in a well-ventilated area, avoiding exposure to corrosive vapors or temperature extremes. Be sure it is near a power source that meets the electrical requirements (voltage) specified on the rating label located on the rear of the instrument. Avoid proximity to open windows, sinks, ovens, hot plates, open burners, radiators, and dry ice baths. The instrument should not be used in an explosive atmosphere.

NOTE

The preparation of slides under certain high humidity conditions may result in the appearance of incomplete drying artifacts affecting the red blood cells. The amount of artifact may vary with sample and thickness of smear.

Unpacking

Before opening the shipping carton, inspect it for visible signs of damage. Use the following steps to unpack the instrument.

- 1. Carefully remove the Hematek instrument and supplies from the shipping carton. The following items are provided with the instrument:
 - Hematek pump tube set
 - · Hematek cannula set
 - · operating manual
 - line cord
 - warranty card for use by US customers only
 - FedEx PRP label for use by US customers only
- 2. If the instrument shows any visible signs of damage, immediately file a complaint with the carrier.
- 3. Retain the shipping carton for further use. If the instrument ever needs to be shipped, the shipping carton will afford the best protection. In the U.S., retain the FedEx PRP label.
- 4. After the instrument has been unpacked, place it on a firm, level work surface in the designated work are by lifting the instrument by its frame.

Instrument Setup

Complete the following procedures to ensure proper installation and performance of your Slide Stainer.

Level the Instrument



CAUTION

Do not move the circular bubble level from its location directly behind the operating lever. Proper leveling is essential for optimal mixing of the stain and buffer.

- 1. Raise the hinged lid of the instrument and locate the circular bubble level.

 The circular bubble level is located on the instrument panel to the left of the reagent pumps, directly behind the operating lever.
- 2. Adjust the two feet located under the front corners of the instrument to raise or lower the instrument to a level position.



Figure 2-1. Leveling the Instrument

3. Observe the circular bubble level to indicate when the feet have been properly adjusted and the instrument is level. The bubble in the level should be centered within the inscribed circle.

NOTE

If necessary, make a final leveling check and adjustment by watching the flow of the waste fluids during staining. Fluids should flow evenly to the drain hole at the left-front corner of the waste trough.

Plug the Line Cord into an Outlet



CAUTION

Be sure the outlet supplies the proper voltage for your instrument. Refer to the rating label located on the rear of the instrument to determine the proper voltage rating

Plug the appropriate end of the line cord into the instrument and the other end into an appropriately grounded AC electrical outlet.

Performance Check (Prior to Installing Tubing)

- 1. Turn the instrument on by pressing the **ON / OFF** switch, located on the left side of the power module at the rear of the instrument, to the **ON** position.
 - The green **POWER** light illuminates, the fan starts, and the conveyor spirals slowly revolves.
- 2. Inspect the slide dryer area for noticeable airflow.
- 3. Place five blank slides into the grooves on the right side of the conveyor spirals. Be sure the slides are positioned in opposing slots, parallel to the inscribed lines on the platen.
- 4. Allow the slides to automatically feed onto the platen.
- 5. As the slides move down the platen, make sure the leading edge of the slides contact and activate each of the three sensing switch fingers, located along the back wall of the platen above the platen trough.
 - As each switch is activated, the appropriate pump activates and you are able to observe the pump cap rotating.
- 6. If the instrument functions properly in these steps, continue with the instrument setup procedures.
- 7. If a problem occurred, contact the your local technical support provider or distributor. Refer to Section 8: *Service, Supplies, and Replacement Parts* for more information.

Install the Pump Tubing

- Remove the three cannulas and pump tube sets from their packaging.
 Notice that each pump tube is identified with a number, which corresponds to the reagent carried by the tubing:
 - 1 for stain
 - 2 for buffer
 - 3 for rinse
- 2. Attach the labeled end of each pump tube to a cannula.

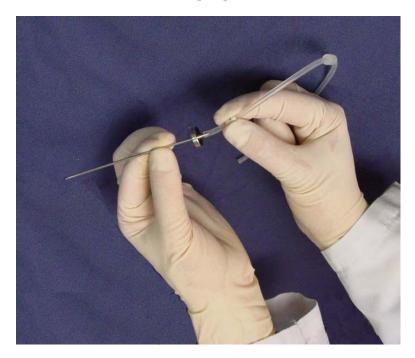


Figure 2-2. Attaching Pump Tubing to Cannula

- 3. Push the operating lever down to the **UNLOCK** position.
- 4. Extend each new tube to its respective pump (in numerical order from right to left) and thread the end of the tubing into the hole in the pump arm.
- 5. Push the thumb tab on the pump arm to the extreme left and push the tubing through until the plastic cuff is flush against the pump arm.



Figure 2-3. Threading Tubing through Pump Assembly

NOTE

If you encounter difficulty in threading the tubing through the pump housing, lift the operating lever to **PRIME** for just a few seconds. This will cause the rollers inside the pump housing to rotate slightly and relieve the interference. Then return the operating lever to the **UNLOCK** position.

- 6. Release the pump arm.
- 7. Repeat steps 4 and 5 for the other two pumps.

- 8. Connect each tube to its proper recessed nipple, located on the backside of the circuit board housing.
- 9. Be sure that at least 7 mm (0.25 in.) of tubing is connected to the nipple for a secure connection.



Figure 2-4. Attaching Pump Tubing to Nipple

NOTE

If it is difficult to connect the tube to its nipple, use forceps or hemostats to grasp and attach the tubing.



CAUTION

Take care to not damage the tubing when using forceps or hemostats.

Install the Stain Pak

- 1. Remove the perforated tabs from the Hematek Stain Pak. Insert the carton, with the **STAIN** bottle to the right, into the well at the rear of the instrument.
- 2. Make sure the carton is all the way down and resting on the tray at the bottom of the well. The carton should be level when properly installed.

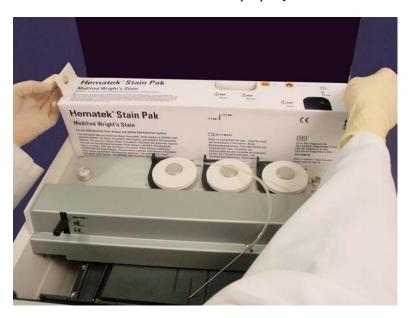


Figure 2-5. Installing the Stain Pak

3. Insert the appropriate cannula into its respective bottle by puncturing the center of the indentation on the bottle.



Figure 2-6. Installing Cannula into Stain Pak Bottle

4. Remove the cannula, turn it 1/4 turn, and insert it again into the same puncture.

The double puncture creates a slightly larger hole for venting.

NOTE

If additional venting is desired, a second hole can be made in the top of the bottle, near the indentation. A 20-gauge needle can be placed into the hole, if needed.

- 5. Push the cannula down until the guard at the top touches the plastic container.
- 6. Repeat steps 3 through 5 for each bottle.

Inspect Waste Tank and Slide Drawer

Inspect the waste tank and slide drawer for proper positioning below the platen. Each should be pushed completely into its respective cavity in the front of the instrument so it is flush with the control panel on the right front corner.

Familiarize Yourself with the Instrument

Before beginning normal instrument use, carefully review Section 3: *Operating Instructions*, and Section 5: *Maintenance*, to become familiar with operating techniques and instrument cleaning requirements.

Check Pump Volumes

Check the pump volumes and adjust them if necessary by following the procedures in *Pump Volume Adjustment* on page 6-14 and *Volume and Ratio Determination* on page 6-17. Do this before staining any patient slides for clinical evaluations.

Fill Out and Mail Warranty Registration Card - U.S. Only

Locate the serial number on top of the power module at the rear of the instrument. Write the installation date and instrument serial number on the Warranty Registration Card packed with the instrument. Also, write the installation date and serial number in the spaces provided on the Manufacturer Warranty page at the end of this manual and in the *Hematek Preservice Checklist* in Appendix A. Completely fill out the Warranty Registration Card and mail it.

| Section 3: Operating Instructions | <i>3-3</i> |
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| Load the Blood Smear Slides | 3-5 |
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| Clean the Tubing after Use | 3-7 |
| Turn the Instrument Off at the End of the Day | 3-7 |
| Stain Pak Replacement | |

Section 3: Operating Instructions

Following initial installation (see Section 2: *Installation*), the Hematek Slide Stainer is ready for routine operation. Carefully read this section before beginning any slide staining.

General Guidelines for Optimal Staining

- Use high quality slides. Do not use slides of variable thickness. Bevel-edged slides should not be used, as they may break in the instrument.
- Make sure the blood smears are thoroughly dry before placing on the instrument for staining.
- Clean the stain tubing with methanol after each run, especially if the Slide Stainer is not to be used for one hour or more.
- Keep the staining grooves and guide rails clean, as instructed in *Cleaning the Platen* on page 5-3. Use only methanol to clean.
- Change the pump tubing and underplaten tubing on a routine basis. Refer to *Replacement of the Pump Tubing* on page 6-7 and *Replacement of the Underplaten Tubing* on page 6-11 for recommended frequency.
- Check the alignment of the sensing switch fingers, as instructed in step 5 of *Check and Correct Instrument Operation Prior to Pump Volume Adjustment* on page 6-15.

Operating Procedures



CALITION

Use Hematek Stain Paks only. Other solutions may contain non-dissolved or particulate materials.

Start the Instrument

1. Turn the instrument on by pressing the **ON / OFF** switch, located on the left side of the power module at the rear of the instrument, to the **ON** position.

The green **POWER** light will illuminate, the fan will start, and the conveyor spirals will begin to slowly revolve.

NOTE

When the Hematek Stain Pak contains sufficient reagents to stain only about 20 slides, the yellow **LOW STAIN** light will illuminate to indicate the need for replacement of the Stain Pak. Refer to *Stain Pak Replacement* on page 3-7.

Prime the Tubing

1. Lift the stainer-operating lever to the **PRIME** position and hold in this position until the stain, buffer, and rinse reagents all flow evenly through their tubes to the platen without any air bubbles.

NOTE

If the tubing is new and does not prime easily, it may be necessary to assist the priming initially. Continue holding the operating lever in the **PRIME** position and push the pump arm inwards (toward the pump) until the reagent fills the tubing, then release the pump arm. It may also be helpful to pinch the tubing several times with the fingers, pinching in the area between the cannula and the pump.



Figure 3-1. Priming the Tubing

2. Release the lever, which will return automatically to the **LOCK** position.



CAUTION

Always wipe the platen from right to left. Damage to the position or shape of the sensing switch fingers may result from not following recommended cleaning practices. Check the position of the fingers after cleaning as described in step 5 of *Check and Correct Instrument Operation Prior to Pump Volume Adjustment* on page 6-15.

3. After priming, wipe the platen with a soft disposable, lint-free absorbent cloth or tissue.

Load the Blood Smear Slides



BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to Appendix A, page A-1 for recommended precautions when working with biohazardous materials.

1. Prime the platen.

The platen should be primed and wetted with reagents in order to ensure optimal results on the specimen slides.

2. Mark blank or old blood smear slides as priming slides (for example, label them with the name **PRIME**).

You can reuse these priming slides



CAUTION

Slides must be inserted into the spiral grooves so they are parallel to the slide loading lines inscribed on the platen. If slides are not placed correctly in the spiral grooves, breakage can occur.

3. Load two to four priming slides and allow them to be transported across the platen ahead of the patient slides.



Figure 3-2. Priming the Platen

4. Load the patient slides.

Place the properly prepared slides into the grooves of the conveyor spirals with the blood smear side facing to the left of the operator and the feathered edge of the blood smear toward the back of the instrument.



Figure 3-3. Loading the Blood Smear Slides

Stain the Smears

As the slides move along the platen, first vertically, then horizontally with the blood smear side down, the instrument performs the following steps.

1. Three sensing switches are triggered sequentially.

Each switch senses the slide and passes the information to another switch, which activates its respective solution pump as long as a slide is detected. The solution pumps meter and deliver the stain, buffer, and then rinse into the capillary space between the slide and platen.

NOTE

If the reagents overflow, as opposed to filling the capillary space between the platen and slide, or if you obtain improper staining results, the reagent pumps may need adjustment. Refer to *Pump Volume Adjustment* on page 6-14 for more information.

- 2. After staining and rinsing have been accomplished, the slide is dried by a flow of air from a low velocity blower.
- 3. The slide is delivered into the slide drawer, ready for examination.

NOTE

If the instrument is accidentally unplugged or there is a power failure during operation, it may be necessary to remove the slides on the platen and reprocess them.

Clean the Tubing after Use

If no slides are to be processed for an extended period (one hour or more), it is recommended that the stain tubing be cleaned with methanol as described in *Cleaning the Stain Tubing and Cannula* on page 5-4. Push the operating lever down to the **UNLOCK** position to relieve the pressure against the pump tubing. You must re-prime the tubing and the platen before processing any more slides.

Turn the Instrument Off at the End of the Day



CAUTION

Always clean the instrument after daily use. See *Daily Cleaning* on page 5-3. If using frosted-end slides, it is especially important to clean the front guide rail on a regular and frequent basis. This is because the stain may spread across the frosted portion of the slide to the front rail. If allowed to accumulate, slide breakage may occur.

- 1. At the end of the day, clean the platen and stain tubing, and empty the waste tank.
- 2. Push the operating lever to the **UNLOCK** position.
- 3. Turn the instrument off.

Stain Pak Replacement

If the **LOW STAIN** light illuminates when the instrument is first turned on or while slides are being processed, a new Hematek Stain Pak is needed. Follow these steps to replace the Stain Pak.



CAUTION

After replacement of the Stain Pak, the instrument must always be primed to remove any air bubbles that may be present.

- 1. Remove the three cannulas from the used Stain Pak and lift the empty carton out of the well at the rear of the instrument.
- 2. Remove the perforated tabs from the new Stain Pak carton.
- 3. Insert the carton with the **STAIN** bottle to the right into the well at the rear of the instrument.
 - Make sure the carton is all the way down and resting on the tray at the bottom of the well. The carton should be level when properly installed.
- 4. Vent each bottle and insert the cannulas as described in *Install the Stain Pak* on page 2-10.

NOTE

Check the cannulas with each new Stain Pak and replace them if they appear bent or damaged.

5. Empty the waste tank into an appropriate receptacle and rinse it with water after each Stain Pak replacement. See *Emptying the Waste Tank* on page 5-6.

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Section 4: Specimens

Overview

The Hematek Slide Stainer is designed specifically for the automatic staining of peripheral blood smears that have been prepared on standard 25 mm x 75 mm or 1" x 3" glass slides. Blood smears that are stained according to instructions will provide the examiner with high quality differential staining characteristics for all cytologic blood components. See Section 3: *Operating Instructions* for staining instructions.

Peripheral Blood Smears



BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to Appendix A, page A-1 for recommended precautions when working with biohazardous materials.

It is crucial to start with a properly prepared blood smear in order to obtain the best results on the stained slide. The following suggestions are recommended:

- Use high quality slides that are new and thoroughly cleaned.
- Slides must be free of oil and grease.
- Do not touch the slide surfaces with the fingers or against the skin of the patient.
- Protect blank slides from moisture and high humidity, as well as contamination by dust, flies, and other insects.
- Store the slides covered in a cool, dry place.
- Never use oxalated or heparinized blood for making blood smears.
- EDTA is the anticoagulant of choice.
- Protect blood smears from excessive heat (such as radiators and ovens), water splatters, and high humidity.

Use the following procedure to prepare a blood smear.

1. Remove the cap from a tube of well-mixed anticoagulated whole blood. EDTA is the anticoagulant of choice.

NOTE

Blood should be kept at room temperature prior to preparing the smear. Adaquate mixing requires approximately 20 inversions prior to blood film preparation.

2. Place a drop of well-mixed blood near one end of a high quality slide. Hold a second spreader slide at about a 45-degree angle and approach the drop of blood. Allow the blood to spread almost to the width of of the slide edge. Then rapidly and smoothly push the spreader slide to the opposite end of the slide, pulling the blood behind it.

NOTE

The angle and speed at which the blood drop is spread determines the thickness or thiness, and length of the blood film.

3. The 'feather' end of the blood film should be at least 1.57 cm (5/8 inch) from the opposite end of the slide to avoid extending beyond the platen surface and contact with the staining reagents.

Do not allow the smear to touch the edges of the slide as large cells tend to accumulate there. This may mechanically effect the distribution of the cell types.

Since frosted-end glass slides limit the spreading area, extra care is needed when preparing a blood film.

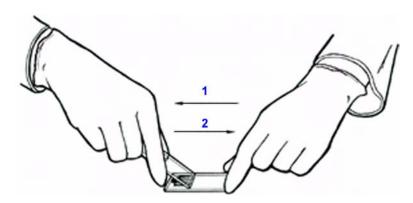


Figure 4-1. Making a Blood Smear

- 1 Approach
- 2 Draw Out
- 4. Allow the smear to dry thoroughly before staining. See Section 3: *Operating Instructions* for staining instructions.

After staining the slide, take the following precautions.

- Examine stained slides as soon as possible.
- Protect stained slides from direct sunlight and store them in a cool, dry place.

Bone Marrow Smears



BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to Appendix A, page A-1 for recommended precautions when working with biohazardous materials.

Many laboratories stain bone marrow smears with the same stain as is used for blood smears. The procedure involves using the "squash" technique for smear preparation and staining the slide once or twice on the Hematek Slide Stainer. The following procedure has been verified as giving clinically useful staining results on bone marrow slides; however, the stain quality is dependent upon the thickness and evenness of the bone marrow smear. A thick smear is more likely to require a second pass through the instrument than a thinner smear; an uneven smear will not stain uniformly.

- 1. Use bone marrow smears that have been prepared using the "squash" technique. Be sure the smear is thoroughly dry before staining.
- 2. Place the slide onto the Hematek Slide Stainer and stain according to instructions in Section 3: *Operating Instructions*.
- 3. Remove the slide after it has been stained and examine it under high power (dry) for the staining quality.
 - Do not use any oil on the slide for this examination.
- 4. If the slide is under-stained, place it on the slide stainer again and stain it a second time. In rare instances, a third staining may be necessary.
 - When using the Hematek Modified Wright Stain Pak (Part No. 4481), the bone marrow smears must be stained twice; one pass through the instrument is generally insufficient to produce distinct nuclear intensity. A third pass generally does not increase or decrease the quality of the staining.
 - When using the Hematek Modified Wright-Giemsa Stain Pak (Part Number 4405), a single staining is generally sufficient for most bone marrow smears. The smear may become over stained, with the appearance of precipitate and nuclear artifacts, on slides stained two or more times.
- 5. Thoroughly clean the platen after staining bone marrow slides to remove the greasy residue that can be left on the platen by the fat droplets in the marrow

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| Weekly Cleaning | 5-6 |
| Cleaning Drain Troughs and Rear Guide Rail | |
| Decontamination and Removal from Operation | 5-9 |

Section 5: Maintenance

The Hematek Slide Stainer is a precision instrument, designed to provide trouble-free operation with a minimum of maintenance.



BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to Appendix A, page A-1 for recommended precautions when working with biohazardous materials.

General Cleaning

Keep the exterior surfaces of the instrument free of dust at all times. If needed, the exterior may be cleaned using a damp cloth and mild detergent. A small amount of methanol may be used to clean stain from the instrument.

Daily Cleaning

It is vitally important to clean the platen and tubing at least once each day in order to maintain consistently high quality staining results. It is also important to empty the waste tank at the end of each day.

Cleaning the Platen

After staining a large number of blood smears, precipitated stain solution tends to accumulate in the mixing grooves of the platen. This precipitate must be removed at regular intervals. Daily cleaning of the platen is imperative; after each run is optimal. Cleaning is especially important if bone marrow slides have been stained because the fat droplets can leave a greasy residue on the platen. Use the following procedure to clean the platen:

- 1. Turn the instrument off.
- 2. Carefully flood the working area of the platen with methanol. Avoid splashing the methanol.



CALITION

Always wipe the platen from right to left. Damage to the position or shape of the sensing switch fingers may result from not following recommended cleaning practices. Check the position of the fingers after cleaning as described in step 5 of *Check and Correct Instrument Operation Prior to Pump Volume Adjustment* on page 6-15.

3. After priming, wipe the platen with a soft, disposable, lint-free absorbent cloth or tissue.

Wipe from right to left only.



Figure 5-1. Cleaning the Platen



CAUTION

If using frosted-end slides, it is especially important that the front guide rail be cleaned on a regular and frequent basis. This is because the stain may spread across the frosted portion of the slide to the front rail. If allowed to accumulate, slide breakage may occur.

4. Thoroughly clean the mixing grooves and the front guide rail.

Cleaning the Stain Tubing and Cannula

The tubing carrying the stain should be cleaned at least once daily (or after each run), as described in the following procedure:

1. Remove the stain, buffer, and rinse cannulas from the Stain Pak bottles.

NOTE

The buffer and rinse cannulas and tubing do not require cleaning. These cannulas are removed so the buffer and rinse solutions are not wasted while the stain tubing is being cleaned.

- 2. Using the prime function, purge the stain from the tubing.
 - a. Place the stain cannula, with tubing attached, into a small container of methanol and lift the operating lever to **PRIME**.



Figure 5-2. Rinsing the Stain Tubing

- b. Holding the lever in this position, continue to pump methanol through the stain tubing until it is thoroughly rinsed and clear solution appears on the platen.
- 3. After the stain tubing has been cleaned, remove the cannula from the methanol and continue to prime until the tubing is emptied of all methanol



CAUTION

Always wipe the platen from right to left. Damage to the position or shape of the sensing switch fingers may result from not following recommended cleaning practices. Check the position of the fingers after cleaning as described in step 5 of *Check and Correct Instrument Operation Prior to Pump Volume Adjustment* on page 6-15.

4. Carefully wipe the platen with a soft, disposable, lint-free absorbent cloth or tissue. Wipe from right to left only.

Emptying the Waste Tank

Empty the waste tank once each day, as well as after installing a new Stain Pak. To avoid spilling the contents while emptying the waste tank, carefully pull the tank away from the instrument, supporting the bottom of the tank to hold it level during removal. After emptying into an appropriate receptacle, rinse the waste tank with water and reinstall it into the instrument.



Figure 5-3. Removing the Waste Tank

Weekly Cleaning

Clean the drain troughs and the rear guide rail on a weekly basis.

Cleaning Drain Troughs and Rear Guide Rail

The back and front drain troughs of the stainer function as drains for excess stain, and residues from the reagents that may accumulate and interfere with proper drainage. The recommended procedure for proper cleaning is as follows:

- 1. Turn the instrument off and remove the line cord from the AC electrical outlet.
- 2. Raise the lid of the instrument.
- 3. Loosen the two thumbscrews that are inserted through the notches in the back of the circuit board cover.



Figure 5-4. Location of Thumbscrews

4. Carefully raise the circuit board cover so the back trough is completely exposed and easily accessible.



Figure 5-5. Raising the Circuit Board Cover

- Move the panel up and back, out of the way.
 The circuit board cover is connected to the instrument by the two connectors of the LOW STAIN and POWER lights. Rotate the panel carefully so the connectors are not pulled loose.
- 6. Flood both the front and back troughs with methanol to loosen any precipitated stain that may be present. Take care not to splash methanol onto the circuit board.

7. Using an applicator stick with a cotton swab attached, wipe from right to left along the length of the back and front troughs to remove the entire excess residue.



Figure 5-6. Cleaning the Back Trough

8. Clean other exposed areas that might be accidentally stained, including the rear guide rail, in the same careful manner.

NOTE

Ensure that you do not scratch the platen.

- 9. Return the circuit board cover to its normal position, between the circuit board panel and the back edge of the screws, and tighten the two thumbscrews.
 - Be sure the panel is not resting on top of the screw heads before tightening.

Decontamination and Removal from Operation



BIOHAZARD

Wear personal protective equipment. Use universal precautions. Refer to Appendix A, page A-1 for recommended precautions when working with biohazardous materials.

Use this procedure to remove the Hematek system from operation for extended periods and prior to packing and shipping the system to another location or to an off-site service facility.

- 1. Remove and dispose of all slides in the appropriate receptacle.
- 2. Follow the first five steps of the *Replacement of the Pump Tubing* on page 6-7, procedure to empty and remove the pump tubing and discard it in an appropriate waste container.
- 3. Lift the used Hematek Stain Pak carton out of the well at the rear of the instrument.
- 4. Follow steps 3 through 8 of the *Replacement of the Underplaten Tubing* on page 6-11 to turn off the instrument and remove the underplaten tubing. Discard it in an appropriate waste container.
- 5. Clean the platen with methanol, always wiping from right to left.
- 6. Empty the waste tank, fill with 10% solution of household bleach and water, empty the solution, and then rinse the tank with regular water.
- 7. Clean the exterior surfaces of the instrument with a damp cloth and mild detergent. A small amount of methanol may be used to clean stain from the instrument.
- 8. Screw the front feet all the way up.

The instrument is now ready for storage or for packing and shipping.

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Section 6: Minor Replacements and Adjustments

This section is provided as an aid for performing minor replacements and adjustments on the Hematek Slide Stainer. Fully review and understand the procedures before attempting them, and they must be performed with care. For any adjustments or replacements other than those given in this section, or if any procedure appears to be too complex, refer to *Supplies and Replacement Parts* on page 8-7, for instructions on service for your instrument.

Fuse Replacement

Use the following procedure to replace the instrument line fuse for all voltage instruments. The fuse is 1.0 amp, 5mm x 20mm, Type T (Part No. 40151108).

- 1. Turn the instrument off and remove the line cord from the AC electrical outlet.
- 2. Using a small, blade-type screwdriver, pry the fuse cover open.



Figure 6-1. Opening the Fuse Cover

- 3. Pull the fuse holder out of the instrument.
- 4. Remove the fuse from the holder and discard it into an appropriate waste container.



Figure 6-2. Replacing the Fuse



CAUTION

Use only the specified fuse to avoid damage to the instrument.

- 5. Replace the defective fuse with an identical fuse, snapping it into place. Fuse specifications are in Section 1: *Introduction*, while ordering information is in Section 8: *Service, Supplies, and Replacement Parts*.
 - A spare fuse, located in the small, enclosed compartment in the fuse holder, is shipped with the instrument. Push the fuse out of the compartment using a small screwdriver.
- 6. With the flat side up, return the fuse holder to its position in the instrument.
- 7. Firmly press the fuse cover until it snaps into place and is flush with the power module plate.

Replacement of Light Assemblies

Use the following procedure to replace the Power Light Assembly (Part No. 94000787) or Low Stain Light Assembly (Part No. 94001073).

- 1. Turn the instrument off and remove the line cord from the AC electrical outlet.
- 2. Raise the lid of the instrument.

3. Loosen the two thumbscrews that are inserted through the notches in the back of the circuit board cover.



Figure 6-3. Location of Thumbscrews

4. Lift the panel from the front wall, exposing the printed circuit board and the connectors for the **LOW STAIN** and **POWER** lights.



Figure 6-4. Raising the Circuit Board Cover

5. Disconnect the wires from the circuit board for the light that is to be replaced.

Using a small, blade-type screwdriver, loosen the two small screws located on the top of the connector (the screws will not come out completely), then pull on the connector wires to remove them from the connector.

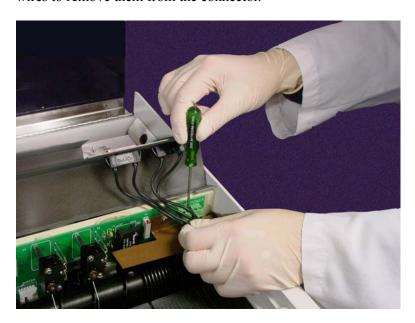


Figure 6-5. Removing the Connector Wires

6. Unsnap the burned-out light assembly from the circuit board cover by pinching together the two plastic retaining tabs on the light assembly.
If the tabs are too stiff, use a screwdriver to press against one side, then push that edge partially through the opening. Repeat with the other side.



Figure 6-6. Unsnapping the Light Assembly

- 7. Discard the burned-out light assembly into an appropriate waste container.
- 8. Insert the new light assembly into the circuit board cover, threading the wires through the opening from the front of the cover and pressing firmly on the light until it snaps into place.
- 9. Insert the connector wires into the holes on the connector on the printed circuit board. Each wire can go into either hole.
- 10. Tighten the small screws to just past finger tight.
- Return the circuit board cover to its normal position, between the circuit board panel and the back edge of the screws, and tighten the two thumbscrews.
 Be sure the panel is not resting on top of the screw heads before tightening.
- 12. Replace the line cord into the AC electrical outlet and turn the instrument on to check the light operation.

Replacement of the Pump Tubing

If any one of the three pumps fails to deliver the proper amount of solution at the adjusted volume setting, it is recommended that all pump tubes be replaced. Regular flushing of the stain tubing with methanol prolongs the life of the tubing. All pump tubes should be replaced after three Stain Paks have been used. If regular cleaning is not performed, or if usage is very heavy, the tubing should be changed more frequently. Use the following procedure to replace the pump tubes with new ones in the Hematek Pump Tube Set (Part No. 4482A).

- 1. Remove the three cannulas from the Stain Pak.
- 2. Raise the operating lever to the **PRIME** position until the reagents are pumped out of the tubes.



Figure 6-7. Priming the Tubing

- 3. Push the operating lever down to the **UNLOCK** position.
- 4. Disconnect each pump tube from its cannula and from the recessed nipple located in the wall in front of the pumps.



Figure 6-8. Removing Tubing from Cannula



Figure 6-9. Removing Tubing from Nipple

- 5. Remove each tube from the pump assembly.
 - a. Push the thumb tab on the pump arm to the left as far as possible.
 - b. While holding the thumb tab in this position, pull the plastic cuff on the tube until the tube is completely removed from the pump arm.
 - c. Discard the tube in an appropriate waste container.



Figure 6-10. Removing Tubing from Pump Assembly

Remove the new tubes from the Hematek Pump Tube Set.
 Each tube is numerically coded to correspond with the numbers shown on the Stain Pak.

| Tube | Code |
|-------------|------|
| stain tube | 1 |
| buffer tube | 2 |
| rinse tube | 3 |

- 7. Attach the coded end of the new tube to its respective cannula.
 - a. Replace the cannula if it appears damaged or bent using the Hematek Cannula Set (Part No. 4483A).
 - b. If you are re-using any cannulas, make sure the cannula previously used for stain is used *only* with the stain tubing.

- 8. Insert tubing into the pump assembly.
 - a. Extend the new tube to its respective pump and thread the end into the hole in the pump arm.
 - b. Push the thumb tab to the extreme left, as before, and push the tube through until the plastic cuff is flush against the pump arm.
 - c. Release the pump arm.

NOTE

If you encounter difficulty in threading the tubing through the pump housing, lift the operating lever to **PRIME** for just a few seconds. This will cause the rollers inside the pump housing to rotate slightly and relieve the interference.



Figure 6-11. Inserting Tubing into Pump Assembly

9. Connect the tube to its proper recessed nipple.

NOTE

If difficulty is encountered in connecting a tube to its nipple, use forceps or a hemostat to grasp and attach the tube.



CAUTION

Take care to not damage the tubing when using forceps or hemostats.

10. Replace the cannulas into their respective reagent bottles.

11. Prime the pumps until the solution in each tube is clear of all air bubbles.

NOTE

New tubing is sometimes difficult to prime the first time and may need assistance. While holding the operating lever in the **PRIME** position, push the pump arm inwards (toward the pump) until the reagent fills the tubing, then release the pump arm. It may also be helpful for you to pinch the tubing several times with your fingers, pinching in the area between the cannula and the pump arm.

12. Verify the pump timings and reset the volume controls if necessary. See *Pump Volume Adjustment* on page 6-14.

Replacement of the Underplaten Tubing

The underplaten tubing is the tubing between the spout under the platen and the nipple behind the circuit board. The buffer and rinse tubing should be replaced after approximately ten Stain Paks have been used. The stain tubing needs to be changed more frequently, especially if it is not regularly flushed with methanol. Depending on usage and cleaning patterns, the stain tubing may need to be changed as often as after every four Stain Paks. Use the following procedure to replace the underplaten tubing with new tubing in the Hematek Underplaten Tubing pack (Part No. 4484A).

- 1. Remove the three cannulas from the Stain Pak.
- 2. Raise the operating lever to the **PRIME** position until the reagents are pumped out of the tubes.



Figure 6-12. Priming the Tubing

- 3. Turn the instrument off and remove the line cord from the AC electrical outlet.
- 4. Raise the lid of the instrument.

5. Loosen the two thumbscrews that are inserted through the notches in the back of the circuit board cover.



Figure 6-13. Location of Thumbscrews

- Carefully rotate the panel up and back.
 The circuit board cover is connected to the instrument by the two connectors of the LOW STAIN and POWER lights. Rotate the panel carefully so the connectors are not pulled loose.
- 7. Disconnect the **LOW STAIN** and **POWER** lights from the circuit board, as directed in step 5 of *Check and Correct Instrument Operation Prior to Pump Volume Adjustment* on page 6-15 in this section.

8. Disconnect the stain tubing from the nipple that is located behind the circuit board.



Figure 6-14. Disconnecting Underplaten Tubing from Nipple

- 9. Remove the waste tank and reach underneath the platen through the waste tank area.
- 10. Disconnect the stain tubing from the platen by pulling the tubing free from behind the circuit board, and then disconnect it from the spout under the platen.



Figure 6-15. Removing the Underplaten Tubing

- 11. Select one of the new sections of underplaten tubing and connect it to the stain-tubing nipple behind the circuit board.
 - Make sure at least 7 mm (1/4 inch) of tubing is connected onto the nipple.
- 12. Thread the tubing behind the circuit board through the channels provided until it extends under the platen.

13. Connect the tubing to the stain spout under the platen, and then check all connections to make sure the tubing is securely in place.

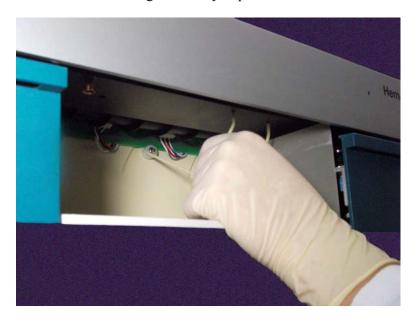


Figure 6-16. Connecting Underplaten Tubing to Platen Spout

- 14. Repeat steps 8 through 13 for the buffer and rinse tubing.

 Connect each tubing section to the appropriate nipple behind the circuit board and then connect the tubing to the appropriate spout under the platen.
- 15. Place the waste tank back in the instrument.
- 16. Connect the **LOW STAIN** and **POWER** lights to the circuit board, as directed in this section.
- 17. Return the circuit board cover to its normal position, between the circuit board panel and the back edge of the screws, and tighten the two thumbscrews.
 - Be sure the panel is not resting on top of the screw heads before tightening.

Pump Volume Adjustment

The Hematek Slide Stainer is designed to produce stained slides of consistent quality in a continuous process. This is accomplished by having a fixed length of time in each of the three phases of stain, buffer, and rinse, as well as a predetermined ratio of stain-to-buffer volumes in the buffer phase.

The stain-to-buffer ratio is adjustable to provide ratios of at least 1:2 to 1:3. This feature allows the user flexibility in obtaining the desired stain results. A small change in the stain-to-buffer ratio can result in either lighter or darker staining. The amount of reagent pumped in each of the three phases is adjustable through the use of the volume control knobs located in the front control panel.

Check and Correct Instrument Operation Prior to Pump Volume Adjustment

Follow these steps to check and correct instrument operation when slides are not satisfactory or pump volumes do not appear to be optimum. If any of these steps correct the situation, you do not need to adjust the pump volumes.

- 1. Replace both sets of tubing.
 - Refer to *Replacement of the Pump Tubing* on page 6-7 and *Replacement of the Underplaten Tubing* on page 6-11.
- 2. Clean the platen, including the front and back drain troughs, and make sure that there is no residue in any mixing groove.
 - Refer to *Cleaning the Platen* on page 5-3 for instructions to clean the platen and the drain troughs.
- 3. Observe the circular bubble level to make sure the instrument is level to provide optimal buffer mixing.
 - If leveling is required, follow the *Level the Instrument* on page 2-5.
- 4. Make sure the Stain Pak has been vented.
 - Refer to *Install the Stain Pak* on page 2-10.
- 5. Check the adjustment of the sensing switch fingers.
- 6. Observe several slides as they move across the platen and visually ensure all of the following events occur and they are activating the pumps at the proper time.
 - The stain pump should be activated after approximately 1/2 of the slide width has passed over the stain orifice.
 - The buffer pump should be activated after about 3 mm (1/8 inch) of the slide has crossed over the buffer orifice.
 - The rinse pump should be activated just as the leading edge of the slide crosses over the rinse orifice.
- 7. If the starting times for each phase are not correct, follow the procedure in this section.

Adjust the Stain, Buffer, and Rinse Volumes

Optimal staining results are achieved when the Hematek Slide Stainer is properly adjusted. Normally, proper adjustment of the instrument can be determined by observation of the amount of stain and buffer required to fill the capillary gap between the slide and the surface of the platen. If the proper amounts of stain and buffer are being pumped, proper mixing of the reagents will occur, resulting in uniform staining of blood smears. Use the following procedure to adjust the pump volumes.

- 1. Locate the pump volume control knobs, which are located in the control panel on the front-right corner of the instrument.
 - Each knob contains a centering catch on, which provides a central reference point. The instrument is manufactured to give a stain-to-buffer ratio of approximately 1:2.5 and a rinse volume of approximately 1.0 mL/slide when each knob is at the centering catch.

Volume is lowest when a knob is turned fully counterclockwise and highest when turned fully clockwise.

Volume increments are marked on each knob:

- Stain and buffer knobs: Each evenly labeled increment changes the volume by approximately 0.1 mL per 10 slides (0.01 mL/slide).
- Rinse knob: Each evenly labeled increment changes the volume by approximately 0.5 mL per 10 slides (0.05 mL/slide).
- 2. Prime the instrument by placing the operating lever in the **PRIME** position and holding it there until solution is being pumped at all three stations (stain, buffer, and rinse).
- 3. Wipe the platen after priming, wiping from right to left only.
- 4. Prime the platen by loading five priming slides and allowing them to be transported across the platen.

This procedure primes and wets the platen to achieve proper surface tension characteristics.

- 5. Adjust the stain volume as follows:
 - a. Run five blood smear slides across the platen immediately following the priming slides.
 - b. Adjust the stain control knob so the stain just fills, but does not overfill, the capillary space between the platen and the slide.
 - c. If the slide is receiving an inadequate amount of stain, adjust the control knob clockwise.
 - d. If overflow of solution is visible on either side of the slide or an excess of stain is visible hanging over the front beveled edge of the platen, adjust the stain control knob counterclockwise.

The adjustment is correct when proper fill has been achieved on two consecutive slides.

- 6. Adjust the buffer volume as follows:
 - a. If there has been a gap of more than two consecutive slides across the platen since the stain volume adjustment, re-prime the platen with three priming slides.
 - b. Run five blood smear slides across the platen immediately following the priming slides.

When the slide passes the buffer section of the platen, mixing of the stain and buffer occurs because of the mixing grooves. This is where the proper stain-to-buffer ratio is most important. The slide looks under filled as it travels over the mixing grooves because the capillary gap is slightly greater.

7. Adjust the buffer control knob so the stain-buffer mixture just fills the capillary space under the slide when the slide is past the mixing grooves and onto the smooth portion of the platen, just before the rinse area.

Ensure that the stain-buffer mix does not extend out from either side of the slide.

NOTE

As the slide moves along, the buffer should pulse from the buffer orifice and move around the two mixing grooves for complete mixing of the stain and buffer. Too much stain and/or buffer will reduce the pulsing action, causing inconsistent staining across the slide. If partial flooding occurs, it should quickly re-drain as the slide continues to move across the grooves. Complete flooding of the second groove may indicate an excessive volume of either the stain or buffer.

- 8. Adjust the rinse volume as follows:
 - a. Examine the slides under a microscope.
 - b. If adjustment is necessary, use the rinse control knob to make the correction.
 - c. If excess stain is left on the slide appearing as precipitation under the microscope, increase the rinse volume.
 - d. If the staining is pale due to over washing, reduce the rinse volume.

NOTE

Any change in the rinse setting may cause a slight color change due to the small amount of methanol in the rinse.

- 9. Recheck the adjusted pump volumes:
 - a. Prime the platen with three priming slides.
 - b. Run at least three blood smears to ensure that the capillary spaces between the platen and slide fill completely with stain at the stain area and with stain-buffer mixture just before the rinse area.

NOTE

Occasional small voids may occur on the slide after proper filling. These voids are acceptable and will not adversely affect stain quality. Do not try to compensate for small voids by increasing the stain volume. Doing so may upset the optimum stain-to-buffer ratio and may affect the stain intensity.

Volume and Ratio Determination

Once adjustments have been made that appear visually to be giving appropriate slide results, the pump volumes and stain-to-buffer ratio can be measured as follows:

- 1. Remove the waste tank and disconnect the underplaten tubing leading to the stain, buffer, and rinse spouts on the platen.
- 2. Place the tubing ends into a beaker or other small container, and prime by using the operating lever.
- 3. As soon as all three-pump tubes have been primed and are free of air, place the free end of the stain and buffer tubes into separate 10 mL graduated cylinders. Place the free end of the rinse tube into a 25 mL graduated cylinder.

4. Process 10 blank slides and record the volume of stain, buffer, and rinse solution pumped into each cylinder. The following should be noted:

The stain-to-buffer ratio should be approximately 1:2 to 1:3, (i.e., the volume of buffer should be about 2 to 3 times that of the stain).

Example:

1.6 mL of stain per 10 slides = 0.16 mL/slide 4.1 mL of buffer per 10 slides = 0.41 mL/slide $0.41 \div 0.160 = a$ ratio of 1:2.56 between stain and buffer

The rinse volume should be approximately 10 mL for the 10 slides.

A properly stained slide is the result of an interactive process involving the pump volumes, the mixing process, and the stain-to-buffer ratio. A minimum ratio of 1:2 is recommended; however, if the platen is filling properly, good mixing is occurring, and the stained slides are acceptable under the microscope, the stain-to-buffer ratio should not be adjusted.

5. When the determinations are complete, reconnect the three tubes to their appropriate spouts and replace the waste tank.

Sensing Switch Fingers Adjustment

The sensing switch fingers must be properly positioned in order to accurately activate the reagent pumps. If the reagents are not being dispensed, check the location of the fingers. Not following recommended cleaning practices may force the sensing switch fingers out of adjustment. Use the following procedure to adjust the sensing switch fingers.

- 1. Turn the instrument off and remove the line cord from the AC electrical outlet.
- 2. Raise the clear plastic lid on the instrument.
- 3. Loosen the two thumbscrews that are inserted through the notches in the back of the circuit board cover.



Figure 6-17. Location of Thumbscrews

4. Carefully rotate the panel up and back.

The circuit board cover is connected to the instrument by the two connectors of the **LOW STAIN** and **POWER** lights. Rotate the panel carefully so the connectors are not pulled loose.

5. Check the location of each of the sensing switch fingers for the following two criteria: Each finger should point straight down into the center of the back trough of the platen, without touching the bottom.

If it is not, bend the finger slightly forward or backward as necessary, as directed below.

The sensing switch should be activated before the finger is lifted over the top surface of the slide.

6. Lay a slide lengthwise along the back edge of the platen and slowly push the slide from right to left past the sensing switch finger, listening for a slight click as the sensing switch is activated.

If the click is not occurring before the finger has been lifted onto the top of the slide, bend the finger slightly to the right, as directed below.



Figure 6-18. Checking for Adjustment of Sensing Switch Fingers

7. If adjustment to a sensing switch finger is necessary, support the wire near the center and carefully bend the lower part of the wire.

If bending to the right, bend the wire no more than 7 mm (1/4 in.) past perpendicular.



Figure 6-19. Adjusting the Sensing Switch Finger

8. Verify the final adjustment of each of the sensing switch fingers by processing several slides across the platen as in Step 5 of *Check and Correct Instrument Operation Prior to Pump Volume Adjustment* on page 6-15.

If these adjustments do not result in correct timing, contact your local technical support provider or distributor.

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Section 7: Troubleshooting

The Hematek Slide Stainer is designed to give trouble-free operation when the directions for operating and cleaning the instrument are followed. If a problem occurs, refer to troubleshooting pointers in this section for help in solving the problem.

Checklist for Quality of Stained Blood Smears

When stained blood smears do not have the desired quality, the first tendency is to assume the staining reagents or the stainer is at fault. Frequently, however, other factors are the cause of the poorly stained blood smears. The following checklist can help isolate the problem when you question the quality of stained blood smears.

| Are the pump volumes properly adjusted? Improper settings may lead to poorly stained blood smears. |
|--|
| Is the blood old or does it contain an incorrect anticoagulant? Use fresh blood (less than 8 hours old), EDTA is the anticoagulant of choice. |
| Was the blood thoroughly mixed before making the smear? |
| Is the blood smear too thick, too thin, or spread unevenly? |
| Does the feathered edge of the smear end at least 3 mm (1/8 inch) from the end of the slide? |
| Was the blood smear thoroughly dry before staining? |
| Are the slides clean? Even new slides are not necessarily clean. |
| Are the slides flat? Variable thickness of a given slide may cause uneven staining. |
| Have the Hematek Stain Pak containers been vented? Venting is necessary for even delivery of the stain, buffer, and rinse reagents. |
| Has the reagent tubing on the Hematek Slide Stainer been primed before staining the slides? Air bubbles in the tubing will cause poorly stained smears. |
| Has the platen been primed and wetted before running blood smears? Process two to four blank slides across the platen to wet the platen surface before each run of blood smears. |
| Is the stain tubing, cannula, nipples, or orifice plugged? Daily cleaning of the stain tubing is recommended to prevent plugging. |
| Are the platen and grooves clean and free of residue? A dirty platen or grooves will result in uneven, low-quality staining. |
| Is the microscope clean and adequately illuminated? A dirty microscope or inadequate lighting may give the impression of a poorly stained blood smear. |
| |

Troubleshooting Chart

The following instrument troubleshooting chart lists possible problems relating to electrical and mechanical operations that could occur during instrument operation. Probable causes and recommended corrective actions are also included, so that many isolated problems can be quickly corrected. When dealing with any problem with the Hematek Slide Stainer, it is essential to determine which portion of the system is the source of the trouble. A systematic approach should be employed to isolate the problem.

If additional assistance is required concerning an instrument problem, copy and complete the *Hematek Preservice Checklist* in Appendix A, and contact your local technical support provider or distributor.

Only Hematek Stain Paks should be used with the Hematek Slide Stainer. Do not use any other stain solution. For problems or questions concerning the Stain Paks, contact your local technical support provider or distributor.

| Symptom | Possible Cause | Corrective Action |
|--|---|--|
| Unit fails to turn on when the main instrument power switch is turned ON | Instrument not plugged into wall outlet or instrument | Ensure line cord is plugged into outlet and instrument |
| | Line fuse is blown | Unplug the unit and replace the fuse. Refer to <i>Fuse</i> Replacement on page 6-3. |
| | Circuit breaker tripped in electrical circuit of building | Reset the circuit breaker |
| | Instrument electrical failure | Contact your local technical support provider or distributor |
| Green POWER light fails to illuminate but drive, pump, and fan motors operate | Light is burned out | Replace light assembly. Refer to <i>Replacement of Light Assemblies</i> on page 6-4. |
| | Open circuit in associated wiring | Contact your local technical support provider or distributor |

(Continued)

| - | | |
|---|---|---|
| Pumps run but do not deliver solution during or after priming | Stain Pak is empty or near empty | Replace with a new Hematek Stain Pak. Refer to <i>Install the Stain Pak</i> on page 2-10. |
| | Tubing has accidentally been pulled off platen nipple | Place tubing back on the nipple |
| | Cannula openings are clogged | Remove cannulas from solution bottles and clean away debris with cloth and alcohol |
| | Pump tubing is collapsed from use, or is perforated | Replace pump tubing. Refer to Replacement of the Pump Tubing on page 6-7. |
| | Underplaten tubing (from the circuit board area to the platen) is clogged with foreign matter | Replace with new tubing. Refer to <i>Replacement of the Underplaten Tubing</i> on page 6-11. |
| Yellow LOW STAIN light is not functioning properly | Stain Pak is not properly positioned in the well | Reposition the Stain Pak so it moves freely up and down on the right end |
| | Light is burned out | Replace light assembly. Refer to <i>Replacement of Light Assemblies</i> on page 6-4. |
| | Light switch is not operating correctly | Contact your local technical support provider or distributor for information on adjusting the switch |
| | Switch or associated circuit is defective | Contact your local technical support provider or distributor |
| Improper mixing action between stain and buffer on platen | Instrument is not properly leveled | Adjust the front feet of the instrument so the bubble is centered in the circular bubble level. Refer to <i>Level the Instrument</i> on page 2-5. |
| | Inadequate pump volume setting | Refer to <i>Pump Volume Adjustment</i> on page 6-14. Contact your local technical support provider or distributor if unable to adjust properly. |
| | | (Continued) |

(Continued)

| Uneven staining | Mixing grooves on the platen are dirty | Clean mixing grooves. Refer to <i>Cleaning the Platen</i> on page 5-3. |
|-----------------|--|--|
| | Too much stain or buffer solution is being pumped causing poor mixing of stain and buffer | Refer to Pump Volume Adjustment on page 6-14 |
| | Slides are of variable thickness | Replace slides |
| Pale staining | Proper stain-to-buffer ratio has not been achieved | Refer to <i>Volume and Ratio</i> Determination on page 6-17 |
| | Stain volume is adjusted too high. Increasing stain volume may decrease stain intensity | Refer to <i>Pump Volume Adjustment</i> on page 6-14 |
| | Rinse volume is too high | Refer to Volume and Ratio Determination on page 6-17 |
| | Deteriorated or outdated Stain Pak | Replace Stain Pak |

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Section 8: Service, Supplies, and Replacement Parts

When problems arise during operation of the Hematek Slide Stainer, refer first to Section 7: *Troubleshooting*. Avoid problems by carefully following proper operating and cleaning procedures.

When to Call for Service

A call for assistance is appropriate under the following circumstances:

- If the problem cannot be solved by performing the steps described in the *Troubleshooting Chart* on page 7-4.
- If additional assistance is required concerning an instrument or reagent problem.
- If the problem is beyond the scope of this manual.

Before calling for service, copy and complete the *Hematek Preservice Checklist* in Appendix B.

For Service

To contact the legal representative for Bayer within the European community, contact the Bayer Authorized Representative. For service, contact your local technical support provider or distributor.

Bayer Authorized Representative

Bayer Diagnostics Europe Limited

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Returning the Instrument for Repair, Exchange, Replacement, or Loaner

When instructed to return the instrument to Bayer for repair, exchange, replacement or the return of a loaner, follow these steps:

- 1. Move the **ON / OFF** switch to the **OFF** position.
- 2. Follow all steps in *Decontamination and Removal from Operation* on page 5-10.
- 3. If you received a new instrument replacement, complete the warranty card. If no warranty card was included with the instrument, Bayer automatically transferred it to the replacement instrument.
- 4. Pack the instrument in the original bag and container, or order a shipping kit (Part Number 95002737) from your local technical support provider or distributor. If applicable, be sure to include the completed warranty card for a new unit.
- 5. Seal the container securely.
- 6. Return the container to your local technical support provider or distributor.

For U.S. returns only:

- Following the directions on the label, complete the FedEx PRP label that was included in the original shipping container.
- Affix the completed label to the sealed container.
- Contact the closest FedEx Ground Customer Service Center for pickup. Call 1-800-238-5355 for the FedEx phone number.
- Retain your copy of the FedEx Ground PRP number and provide the driver with the
 original label. If FedEx does not receive the instrument, you will need this number
 to avoid being billed.
- For additional assistance, call 1-877-229-3711.

NOTE

If Bayer does not receive your defective instrument within 15 days, you will be billed for the replacement.

Supplies and Replacement Parts

To obtain the best results with the Hematek Slide Stainer, use only Hematek brand supplies.

Hematek Stain Pak - Modified Wright's Stain



WARNING

Toxic! Danger of very serious irreversable effects. Toxic by inhalation. toxic in contact with skin. Toxic if swallowed. Keep container tightly closed. Avoid contact with skin. Wear suitable protective clothing and gloves. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Contains: methanol. Highly Flammable! Keep away from sources of ignition. No smoking.

The Stain Pak contains a polychrome methylene blue-eosin stain and specially prepared buffer and rinse solutions. The Stain Pak is contained in a single carton that fits easily into the well inside the Slide Stainer. Also supplied are buffer and rinse solutions that have been optimally designed for use on the Hematek system. Each Stain Pak contains sufficient solutions to stain approximately 1000 slides.

Hematek Stain Pak - Modified Wright-Giemsa Stain



WARNING

Toxic! Danger of very serious irreversable effects. Toxic by inhalation. toxic in contact with skin. Toxic if swallowed. Keep container tightly closed. Avoid contact with skin. Wear suitable protective clothing and gloves. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Contains: methanol. Highly Flammable! Keep away from sources of ignition. No smoking.

This is a modified Wright-Giemsa stain for laboratories that prefer a Giemsa stain component for preparation of their blood smears. This Stain Pak contains a modified polychrome methylene blue-eosin stain based on the original stain proposed by Romanowsky. Also supplied are buffer and rinse solutions that have been optimally designed for use on the Hematek system. Each Stain Pak contains sufficient solutions to stain approximately 1000 slides.

Hematek Cannula Set

The Cannula Set is available as a replacement item. The cannulas are positioned in the Stain Pak bottles and connected to the pump tubing.

Hematek Pump Tube Set

The Pump Tube Set consists of three tubes, each labeled with an identifying number specific to the reagent to be carried in the tubing. Each tube is a specific diameter and length to ensure precise measurement of the reagents. The tubing is made of a special type of rubber that is resistant to leaching and brittleness.

Hematek Underplaten Tubing

The Underplaten Tubing is available for periodic replacement. The tubing set consists of three tubes of equal diameter and length and, therefore, are not specific to a reagent.

Ordering Information for Supplies and Replacement Parts

To order the following Hematek brand products, contact your local technical support provider or distributor.

| Part Number | Description |
|-------------|---|
| 4481 | Hematek Stain Pak – Wright's Stain |
| 4405 | Hematek Stain Pak – Wright-Giemsa Stain |
| 4482A | Hematek Pump Tube Set |
| 4483A | Hematek Cannula Set |
| 4484A | Hematek Underplaten Tubing |

In the United States, the following replacement parts are available by calling toll free 1-877-229-3711. Outside of the United States, contact your local technical support provider or distributor.

| Part Number | Description |
|-------------|---|
| 40151108 | Line fuse – 1.0 amp, 5mm x 20mm, Type T |
| 94000787 | POWER Light Assembly (Green) |
| 94001073 | LOW STAIN Light Assembly (Yellow) |

Appendix A: List of Symbols

Symbols Used With This System

The following table explains the symbols used on the Hematek Slide Stainer, on the Stain Pak, and in this document.

Symbol



Description

This symbol alerts you to a potential biohazard.

All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

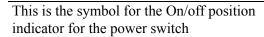
The operator should follow the recommendations to prevent the transmission of infectious agents in health-care settings as recommended for potentially infectious specimens in *Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue, 2d edition; Approved Guideline (1997)* Document M29-A, National Committee for Clinical Laboratory Standards (NCCLS). This document contains complete information on user protection and it can be used as reference material for instructions on laboratory safety.

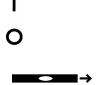


These symbols are used for both Warning and Cautions.

A warning indicates the risk of personal injury or loss of life

A **caution** indicates the possibility of loss of data or damage to or destruction of equipment.





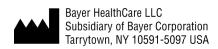
This is the symbol for the **prime** position of the stainer operating lever.

This is the symbol for the **unlock** position of the stainer operating lever



This is the symbol for the **lock** position of the stainer operating lever

| ∱ STN | Identifies Hematek stain. |
|----------------------------------|---|
| 2 BUF | Identifies Hematek buffer. |
| (3) RNS | Identifies Hematek rinse. |
| 1 | Indicates that there is power to the instrument. |
| ۵ | Indicates low stain. |
| 」 添付文書参照 | This symbol indicates that you should consult the instructions for use. |
| \Rightarrow | This is the fuse symbol. |
| LISTED Laboratory Equipment 5N48 | This symbol indicates that the product is UL approved for safety (United States). |
| (1) ® | This symbol indicates that the product is CSA approved for safety (Canada). |
| (€ | This symbol indicates that the product complies with the applicable directives of the European Union. |
| SN | This symbol indicates the serial number of a part or product. |
| Rev. | This symbol indicates the revision letter of a part or product. |
| REF | This symbol indicates the number used for ordering a part or product. |



This symbol indicates the name and location of the product manufacturer.



This symbol indicates the manufacturer's authorized representative within the European community.



This symbol indicates an *in vitro* diagnostic device.

Appendix B: Hematek Preservice Checklist

| For reference, record the following information | on. | | |
|---|----------------------------|-----------|-------------|
| Instrument Serial Number | | | |
| Installation Date | | | |
| | | | |
| | | Yes | No |
| Has Section 7, Troubleshooting, been reviewed | ed? | | |
| In the unit plugged into a live AC electrical of | outlet? | | |
| Does the POWER light illuminate when the p | ower switch is ON ? | | |
| Has the line fuse been checked and replaced | if defective? | | |
| Is the slide drying system operating properly | ? | | |
| Are the conveyor spirals operating? | | | |
| Is the LOW STAIN light operating properly? | | | |
| Do all three stations pump reagent properly? | | | |
| Do all stations pump reagent at the proper tin | ne? | | |
| Is the instrument level? | | | |
| Has the platen been cleaned each day? | | | |
| Has the stain tubing been cleaned each day? | | | |
| Are the sensing fingers properly adjusted? | | | |
| When was the pump tubing last changed? | | | |
| When was the underplaten tubing last changed? | Stain: | | |
| | Buffer/Rinse: | | |
| Stain Pak Information (Check one) | Wright's | Wright-G | iemsa 🗖 |
| | Lot #: | Exp. Date | |
| Give a brief description of the problem: | | | |

Appendix C: Hematek Manufacturer's Warranty

| Keep this sheet in the operat | ing manual for future reference. |
|-------------------------------|----------------------------------|
| Record the following inform | ation: |
| Original Purchaser | |
| Instrument Serial Number | |
| Instrument Model Number | |
| Installation Date | |

Hematek Slide Stainer Manufacturer's Warranty

(United States Only)

Bayer HealthCare LLC ("Bayer") warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for a period of one (1) year from the later of the date of original purchase or installation (except as noted below). During the stated one-year period, Bayer shall replace with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective.

This warranty is subject to the following exceptions and limitations:

A 90-day warranty will be extended for non-mechanical parts.

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost, and Bayer shall not be required to make any repairs or replace any parts, which are necessitated by abuse, accidents, alteration, misuse, neglect, maintenance by other than Bayer, or failure to operate the instrument in accordance with instructions. Further, Bayer assumes no liability for malfunction or damage to instruments caused by the use of reagents other than reagents manufactured or recommended by Bayer.

Bayer reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

Disclaimer of Warranties

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE WHICH ARE EXPRESSLY EXCLUDED, AND IS THE ONLY WARRANTY GIVEN BY BAYER.

Limitation of Liability

IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service, purchaser must contact Bayer's Technical Care Center by calling toll free 1-877-229-3711, for assistance and/or instructions for obtaining repair of this instrument.

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