

# Cardinal Health™ Single Slide Automated Gram Stainer

Instructions for Use Manual

REF CHB-AGS



**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and  
100% Black.**

AMS1800062

Rev. 0 2018-06

## Table of Contents

Specifications.....	5
1.0 INTRODUCTION.....	6
2.0 WORK AREA REQUIREMENTS.....	7
3.0 RECEIVING AND UNPACKING.....	7
4.0 MATERIALS REQUIRED BUT NOT PROVIDED.....	7
5.0 GRAM STAIN KITS.....	7
5.1 General Information.....	7
5.2 Ordering Information.....	7
5.3 Reagent Kit Installation.....	7
6.0 OPERATIONS INSTRUCTIONS.....	8
6.1 Instrument Anatomy.....	8
6.2 Specimen Slide Preparation.....	8
6.3 Instrument Preparation.....	9
6.4 Stain Operation.....	10
7.0 QUALITY CONTROL.....	12
7.1 Quality Control Checks.....	12
7.2 Self Calibration Errors.....	12
8.0 CONSUMABLES.....	12
8.1 Gram Stain Kit Registration.....	12
8.2 Pump Replacement Tube Procedure.....	13
8.3 Register New Pump Replacement Tube Kit.....	14

9.0 MAINTENANCE .....	14
9.1 Wash Cycle.....	14
9.2 Bleach Cycle .....	15
9.3 Scrub Cycle.....	16
9.4 Cuvette Swabbing.....	17
9.5 Deionized Water Disinfectant.....	17
9.6 Refilling the Water Supply .....	18
9.7 Maintenance Summary.....	18
10.0 IDLE DELAYS.....	18
10.1 Setting the Sleep Delay.....	19
11.0 UNIT SHUT DOWN.....	19
11.1 Unit Shut Down Instructions .....	19
12.0 SERVICES AND SUPPLIES.....	20
13.0 SAFETY DATA SHEETS .....	20
14.0 REFERENCES .....	21
15.0 Single Slide Automated Gram Stainer Warranty .....	21
16.0 Maintenance Logs.....	22
Single Slide Automated Gram Stainer Training Checklist.....	23

## Congratulations!

You have made an excellent choice for your Lab. Cardinal Health™ thanks you for the trust you have placed in our products and services.

This operating manual has been designed to help you gain an understanding of the operation and application of our Single Slide Automated Gram Stainer. For optimal utilization of all functions, we recommend that you thoroughly study this manual prior to beginning operation.

This manual has been prepared as an aid for all operations and maintenance, which can be carried out in your facility.

## The Cardinal Health™ Quality Management System

This product is manufactured by Hardy Diagnostics for Cardinal Health in accordance with its quality management system, which complies with the U.S. Food and Drug Administration's (FDA's) Quality Systems Regulation (QSR) and current Good Manufacturing Practices (cGMP) contained in Title 21 Part 820 of the Code of Federal Regulations (CFR). The company's manufacturing establishments are registered, and its medical devices are listed with the FDA. In addition, Hardy Diagnostics' quality management system is certified to ISO 13485 for medical devices

### Unpacking and Inspecting

Carefully unpack the Single Slide Automated Gram Stainer and accessories. Check for damage incurred during transit. Keep all packing material until you are sure the unit operates properly. Any damage to the shipping box should be reported to the responsible carrier. These instructions must be followed for us to guarantee our full support of your claim for protecting against loss from concealed damage. The form required for filing such a claim will be provided by the carrier.

**Important:** Keep this operating manual for future use.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and  
100% Black.**

AMS1800062

Rev. 0 2018-06

## SPECIFICATIONS

<b>Dimensions/Weight</b>	Width 30.5 cm (12.0 in.) Height 40.6 cm (16.0 in.) Depth 33.0 cm (13.0 in.) Weight 12.24 Kg (27.0 lbs.)
<b>Power Requirements</b>	Input: 100-240 VAC, 8-4A, 47-63Hz
<b>Temperature, Ambient Operation</b>	15-30C
<b>Humidity</b>	0 to 95%, without condensation
<b>Operator Adjustments</b>	Individual adjustable stain times on both short and long cycles Adjustable sleep mode Adjustable audible sound volume control
<b>Operator Entry</b>	Moisture proof, touch screen
<b>Standards</b>	IEC-61010-1:2010 (Third Edition) EN55022; CISPR 22:2005/A1: 2005: Class A CFR 47, Part 15, Subpart B, Class A, 2008 ICES-003 Issue 4, 2004 CAN/CSA-CEI/IEC CISPR 22;02, Class A EN55024: 2010 EN 61326-1: 2006
<b>Warranty</b>	One Year Standard

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and  
100% Black.**

AMS1800062

Rev. 0 2018-06

## 1.0 INTRODUCTION

This Operation Manual is provided to guide the user in all aspects of unit set-up, operational use, and user-level maintenance of the Cardinal Health™ Single Slide Automated Gram Stainer unit.

The Single Slide Automated Gram Stainer is a microscope slide stainer capable of automatically performing a Gram stain sequence on a slide containing biological specimen for *in vitro* diagnostic use. An on-board computer, running software specially designed to accomplish correct Gram stain results for any type of sample, controls the entire staining process.

The Single Slide Automated Gram Stainer software provides a series of menus for operator control of the unit. By pressing a key corresponding to a menu item, the operator directs program flow to the various logic paths of the software. All program functions are accessed in this manner.

### Operator Responsibility – Safety Instructions

The Single Slide Automated Gram Stainer ensures safe operation when installed, operated, and maintained according to common safety regulations. This section describes the potential dangers that may arise when operating the Single Slide Automated Gram Stainer.

It is the operator's responsibility to be properly qualified to operate the Single Slide Automated Gram Stainer. The operator and personnel are also advised to refer to this Operating Manual and the set-up letter that is packaged with the unit. If you require additional assistance, please call (800) 266-2222 (ext. 2) to be connected with Cardinal Health™ Technical Support serviced by QuickSlide™.

In addition, the operator is to be familiar with good laboratory practices and safety precautions.

### Explanation of Symbols

**I** - Power On  
**O** - Power Off

 - **Caution:** Refer to marked paragraphs

 - **Not Made with Natural Rubber Latex**

 - **In Vitro Diagnostic Medical Device**

### Background – Gram's Staining Technique

The Gram staining method, named after Hans Christian Gram, the Danish bacteriologist who originally devised it in 1882, is one of the most important staining techniques in microbiology. It is usually the first test performed for the presumptive identification of bacteria. The primary stain of the Gram's method consists of staining with crystal violet which is then fixed with iodine. The microorganisms that retain the crystal violet-iodine complex appear purple under microscopic examination and are commonly classified as Gram positive. Others that are not stained by crystal violet, due to a decolorization, step are referred to as Gram negative, and appear red as a result of counter-staining with safranin.

Gram staining is based on the ability of the bacteria cell wall to retain the crystal violet dye during treatment with acetone-alcohol. The cell wall for Gram positive microorganisms have a higher peptidoglycan and lower lipid content than Gram negative bacteria. Bacteria cell walls are stained by the crystal violet. Iodine is then added as a mordant to form the crystal violet-iodine complex so that the dye cannot be removed easily. Subsequent treatment with an acetone-alcohol decolorizer, which is a solvent, dissolves the lipid layer from the Gram negative cells. The removal of the lipid layer enhances the leaching of the primary crystal violet stain from the cells into the surrounding solvent. In contrast, the solvent dehydrates the thicker Gram positive cell walls, closing the pores as the cell wall shrinks during dehydration. As a result, the diffusion of the violet-iodine complex is blocked, and the bacteria remain stained purple. The length of the decolorization step is critical in differentiating the Gram positive bacteria from the Gram negative bacteria. A prolonged exposure to the decolorizing agent will remove all the stain from both types of bacteria. Some Gram positive bacteria may lose the stain easily and, therefore, appear as a mixture of Gram positive and Gram negative bacteria (Gram variable). Finally, a counter-stain of safranin is applied to the smear to give decolorized Gram negative bacteria a red or pink color.

The decolorization step is especially critical and must be timed correctly; the crystal violet stain is removed from both Gram positive and negative cells if the decolorizing agent is left on too long. This can be particularly problematic for smears of varying thickness – thicker smears require longer exposure for proper decolorization than thinner smears. This is the most sensitive and variable step of the procedure, and requires experience to know just how much to decolorize manually. Many labs performing manual Gram stains have considerable quality control problems for this reason.

#### Art specifications:

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 2.0 WORK AREA REQUIREMENTS

### IMPORTANT!

The Single Slide Automated Gram Stainer unit requires a level counter top surface of a minimum of 12 inches wide by 13 inches deep with a height clearance of 16 inches. The Gram Stain Kit (Cat. No. CHB-AGS-SK) and a container filled with deionized water should be positioned at the same level as the instrument immediately on the left side connected by the tubing coming out of the machine. Do not place reagents below the instrument.

The Single Slide Automated Gram Stainer has one tube that drains all of the waste fluids. The Single Slide Automated Gram Stainer unit drain line can be placed down a drain or into another disposal container to accommodate the waste fluids according to your facility and local regulations.

The Single Slide Automated Gram Stainer consumes less than 400 watts of power and uses an external power supply module that is supplied with 47- 63 Hz, 100-240V, 8-4A line power. The unit requires power from a grounded outlet. The Single Slide Automated Gram Stainer overvoltage category is II, the transient overvoltage is 1440 volts, and the pollution category is 2. The IP protection is IP20.

The Single Slide Automated Gram Stainer is installed with tubing sets to connect the instrument to the reagents. The reagent supply line is equipped with a cannula (rigid tube) to immerse in the reagent supply container. Labels attached to those lines indicate which reagent is to be used with each line. The line labeled as DI Water needs to be immersed in the water supply container to supply the machine with available water.

## 3.0 RECEIVING AND UNPACKING

Unpacking and set-up assistance for the Single Slide Automated Gram Stainer may be obtained by calling the Cardinal Health™ Technical Support Department serviced by QuickSlide™ at (800) 266-2222 (ext. 2) during the hours of 8a.m. – 5p.m, Pacific Time, Monday through Friday.

The external power supply is a Class I supply that must be connected to an earthed (grounded) main power outlet. Failure to connect the Single Slide Automated Gram Stainer as specified will prevent the electrical safety protection features to function as designed.



The power supply is equipped with one attached power cord and one removable power cord. The attached power cord is equipped with a connector that plugs into the Single Slide Automated Gram Stainer rear panel receptacle near the power switch. The removable power cord adapts the IEC style connector on the power supply to the local standard AC outlet. The cord supplied by Cardinal Health™ is appropriate for the country of operation.

## 4.0 MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies, such as Gram's Iodine, Stabilized Dropper Bottle (Cat. No. CHB-GS-DI), Microscope Slide Charged Adhesion Frosted 25mmX75mm 1mm (Cat. No. M6143), Cuvette Swabs (Cat. No. CHB-GS-CS), and Gram Stain QC Slides (Cat. No. CHB-GS-QC), Gram Stain Kit (Cat. No. CHB-AGS-SK), System Cleaner (Cat. No. CHB-AGS-SC), and Replacement Tubing (Cat. No. CHB-AGS-RT)

## 5.0 GRAM STAIN KITS

### 5.1 General Information

The Single Slide Automated Gram Stainer accomplishes automatic Gram staining by a systematically staining, rinsing, decolorizing, and counter-staining the provided biological specimen. It is critical for the success of this automated process that the unit utilizes the Gram Stain Kit (Cat. No. CHB-AGS-SK) from Cardinal Health™.

**NOTE:** For quality control purposes, Gram Stain Kits are labeled with a Kit Number, Lot Number, and Expiration Date. These values are used to track and identify the Gram Stain Kit used in the unit, and are entered into the system as part of the Gram Stain Kit Registration procedure as explained in section 8.1.

### 5.2 Ordering Information

The Single Slide Automated Gram Stainer software monitors consumption of the Gram Stain Kit. When starting each Stain Cycle, the system displays a count of the remaining number of stain cycles available in the current kit. This remaining count should be carefully monitored so that fresh reagents may be ordered and available when needed.

### 5.3 Gram Stain Kit Installation

The Single Slide Automated Gram Stainer reagents are supplied to the unit through tubes connected to the individual reagent containers. Each tube is clearly labeled with a color coded tag, and the tube cannula must be inserted into the correct reagent container. Tubes are also provided for connection to a deionized water container and to a waste fluid drain. Use care to ensure that these lines are properly connected before use of the Single Slide Automated Gram Stain unit.

#### Art specifications:

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 6.0 OPERATION INSTRUCTIONS

### 6.1 Instrument Anatomy

The basic anatomy of the Single Slide Automated Gram Stainer consists of four parts as described below:

**Display screen** – the screen that prompts which buttons to select for procedure steps.

**Key Pad** – the twelve button key pad used to select process options on the instrument.

**Cuvette** – holds the slide during the staining process.

**Front panel** – covers the reagent supply pumps and waste drain pumps.

### 6.2 Specimen Slide Preparation

**6.2.1** If the culture is to be taken from a Petri dish or a slant culture tube, first add a drop or a few loops full of water on the slide and aseptically transfer a minute amount of a colony on the Petri dish. Transfer a drop of the suspended culture to be examined on a slide with an inoculation loop. Note that only a very small amount of culture is needed; a visual detection of the culture on an inoculation loop already indicates that too much is taken. If staining a clinical specimen, smear a very thin layer onto the slide, using a wooden stick. Do not use a cotton swab as the cotton fibers may appear as artifacts. The smear should be thin enough to dry completely within a few seconds. The stains will not penetrate thickly applied specimens, making interpretation very difficult.

**6.2.2** Spread the culture with an inoculation loop to an even thin film over a circle of 1.5 cm in diameter, approximately the size of a dime.

**Position the smear at least 3/4" below the frosted area. Labels should not extend below the frosted area.**

**6.2.3** Fixing the specimen causes the cells to adhere to the glass slide to make possible the subsequent rinsing of the smear with water without a significant loss of cells. This can be accomplished by methanol fixation. **For best results, it is required that the methanol method be used, rather than heat, since it is superior in preventing lysis, distortion, or damage to the cells in clinical material.** Red and white cells will not be harmed, whereas heat will distort or disrupt the cells. Passing the slide over a flame is also not recommended.

Methanol fixed slides have been shown to retain two to ten times as many cells than with heat fixation.(1) In addition, Gram positive bacteria are much less likely to become over-decolorized when fixed with methanol rather than heat.(2)

**Methanol Fixation Procedure:** Air-dry the specimen. If a heat block must be used, do not set the temperature above 40°C, and do not leave the slides on the block for over an hour. It is extremely important that the specimen does not get damaged by excessive heat. Once fully dried, fix by submerging the slide into a Coplin jar filled with methanol. Please ensure that the methanol covers the whole smear. Drain off remaining methanol without rinsing by tapping the bottom edge of the slide to paper towel and allow slide to air dry. Do not apply heat after the methanol dries.

**NOTE:** Because the slide preparation technique can vary from institution to institution and technique is not always controllable (i.e., differences in smear thickness, fixation techniques, drying time, specimen adherence to different types and brands of slides, etc.) rare instances of carryover from slide to slide have been reported. The chance of this can be minimized by carefully following the instructions in this manual.

**NOTE:** For best results with this instrument use glass slides that are positively charged such as Cardinal Health™ Microscope Slide Charged Adhesion Frosted 25mm x 75mm 1mm (Cat. No. M6143) to increase specimen adhesion to the glass slide. The adhesion of the specimen can be variable, depending on the specimen type, volume and its thickness. Lack of adhesion is most notable in blood or bloody culture smears, so it is mandatory to use chemically treated slides that produce a positive electrical charge in order to enhance the specimen's attachment to the slide. Excessively thick smears can lead to a sloughing off of cells from the slide. So it is important to prepare smears that are relatively thin with some transparency. Software and fluid flow design have been engineered to minimize the occurrence, but rare occasions of carryover may still be possible depending on the differences in the user's slide and slide preparation techniques. It is recommended to reconfirm the presence of low numbers of bacteria in traditionally sterile specimens (such as spinal or joint fluid) with manual staining and culture results.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 6.3 Instrument Preparation

**6.3.1** Remove the screws to open the front panel that is covering the pump tube rollers, and attach all eight orange pump tubes around their pump rollers. When installing a new pump Replacement Tube kit (Cat. No. CHB-AGS-RT) refer to section 8.2 for detailed instructions.

**6.3.2** Ensure all reagent supply tubes are properly inserted into the correct reagent containers. Once your machine is powered on, refer to section 8.1 for Gram Stain Kit registration instructions.

**NOTE:** For quality control purposes, Gram Stain Kits are labeled with a Kit Number, Lot Number, and an Expiration Date. These values are used to track and identify the Gram Stain Kit used in the unit as Single Slide Automated Gram Stainer software monitors the consumption of the Gram Stain Kit.

**6.3.3** Position the waste line for proper disposal of waste fluids into a designated waste container that is empty.

**NOTE:** Waste disposal regulations vary according to jurisdiction. Please dispose of waste according to your facility and local regulations.

**6.3.4** Confirm that deionized water is present in the supply container and make sure that the DI Water supply tube is submerged.

In order to prevent contamination, the deionized water must have stabilized gram's iodine disinfectant (Cat. No. CHB-GS-DI) added to the container following this schedule, whichever comes first:

1. Every time the water container is refilled with deionized water.
2. Every 20 days of operation.

This is completed by adding **10 drops of disinfectant per gallon of deionized water** into the water container.

## 6.4 Stain Operation

**6.4.1** Plug the power cord into the back of the machine next to the power switch.

**6.4.2** Turn the system **power switch ON**.

During the power up process, the system identification screen is briefly displayed.

Once the system completes loading, the Self-Test procedure validates the operational parameters and prepares the unit for use. Upon normal completion of the Self-Test, the Main Menu is displayed and the machine is ready to use.

**6.4.3** Press **[1]** on the key pad to select the **RUN** menu.

The Main Menu displays the current date and time as well as the total lifetime number of cycles that have been run on the unit.



**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

**6.4.4 Press [1] on the key pad to select GRAM STAIN.**

Reagent volume and expiration dates are checked at this time to assure staining operation may be completed. Detection of reagent shortage or expiration yields a warning message describing the reagent status.



**NOTE:** The Gram Stain command will fail to start if the instrument is due for a required Bleach or Scrub cleaning cycle.

**6.4.5 Select a Stain Delay Option.**

Select one of the two stain delays **1- Gram Stain (SHORT)** or **2- Gram Stain (LONG)** by pressing the [1] or [2] key on the key pad to choose the desired stain delay times for the run.



There are two sets of pre-programmed stain delay times, a short or a long option. The soak times for crystal violet, Gram's iodine, and safranin are determined by this selection. Note that the three soak times (for CV, GI and SAF) of each of the three sets may be altered as desired by the facility administrator. The default settings are:

	<b>Short</b>	<b>Long</b>
Crystal Violet (CV)	40	60
Gram's Iodine (GI)	40	60
Safranin (SAF)	40	60

**NOTE:** The decolorize only option omits all staining entirely, and provides a means for decolorizing ONLY.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

#### 6.4.6 Loading the slide.

When the screen prompt reads **Load Slide**, lower the slide gently into the cuvette. Load the slide with the specimen side facing out (towards the operator).



**NOTE:** Do not allow the slide to drop and abruptly hit the “Slide Stop” within the cuvette because the slide can chip or break. Broken glass in the instrument is not covered under warranty and the customer will be responsible for repairs and shipping. For assistance in the case of a broken slide, call Cardinal Health™ Technical Support serviced by QuickSlide™ at (800) 266-2222 (ext. 2) before attempting to remove any broken glass.

The Single Slide Automated Gram Stainer employs one cuvette for the entire Gram stain process, the crystal violet staining, Gram’s iodine fixing, decolorizing, and safranin counter-staining all takes place within this cuvette.

**6.4.7 Press any key** on the key pad, except [ \* ], to commence the Automated Gram staining. The unit may now be left unattended as the slide is stained. When the final rinse step has finished, the machine will make an audible alert to notify the operator that the stain is complete and the slide can be removed.

**NOTE:** Pressing the [ \* ] key will abort the Gram stain process and return immediately to the Run Menu.

## 7.0 QUALITY CONTROL

### 7.1 Quality Control Checks

The quality and validity of the Gram stain process of the Single Slide Automated Gram Stainer may be periodically verified by staining a slide prepared with any known sample material. This slide may be stained using exactly the same procedures used for any specimen slide. The processed specimen slide may then be viewed to confirm proper Gram stain technique and results. Quality Control slides may be purchased from Cardinal Health™ under catalog number CHB-GS-QC.

### 7.2 Self Calibration Errors

The Single Slide Automated Gram Stainer employs a “self-calibration” test during every staining cycle to verify proper system operation. This test confirms that the optical sensor response is within a valid specified range. Out-of-Range measurements automatically cause interruption of a staining cycle and operator notification of the error condition. After problem resolution, staining operations will resume from the point of interruption. This self-check provides additional assurance of accurate system performance.

## 8.0 CONSUMABLES

### 8.1 Gram Stain Kit Registration

The Single Slide Automated Gram Stainer software monitors consumption of the Gram Stain Kit, each kit will last for 110 cycles. Follow the steps listed below to install a new Kit when needed.

**8.1.1 Press [ 1 ]** on the key pad to select **Run**

**8.1.2 Press [ 4 ]** on the key pad to select **Purge**

**8.1.3 Press [ \* ]** on the key pad to exit back to the Main Menu

**8.1.4 Remove the cannulas** from the reagent bottles and wipe them with an alcohol pad.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

**8.1.5** Open the new Gram Stain Kit and insert the labeled cannula into the corresponding reagent bottles.

**8.1.6** From the Main Menu, **Press [ 2 ]** on the key pad to select **SET-UP**.

**8.1.7 Press [ 2 ]** on the key pad to select **Consumables**

**8.1.8 Press [ 1 ]** on the key pad to select **Review Reagents**.

This display will show the current kits information.

**8.1.9 Press [ 1 ]** on the key pad to select **Change Kit**

The display will now show the preregistration menu. At this menu, the instrument reminds the operator that a Scrub Cycle is required before the installation of a new reagent kit. Refer to section 9.3 for details on how to run a Scrub Cycle. Once the Scrub has completed, the old reagent bottles may be replaced with new ones.

**8.1.10** Once the blinking cursor appears next to the Kit Number, use the key pad to enter in the Kit Number as it reads on the new reagent kit label.

**8.1.11** Using the key pad, enter in the Lot Number and Expiration Date into the appropriate fields as it reads on the new reagent kit label.

**8.1.12 Press [ # ]** on the key pad to select **Accept** and save the kit registration information.

**8.1.13 Press [ \* ]** on the key pad **once**

**8.1.14 Press [ 1 ]** on the key pad to **Update Reagent Log** and activate the kit.

Entry of invalid numbers or numbers from a previously used Gram Stain Kit, will result in the display of an error message.

## 8.2 Pump Replacement Tube Procedure

All eight pump tubes must be replaced to ensure proper function of the Single Slide Automated Gram Stainer at least every six months, depending on frequency of use. The Single Slide Automated Gram Stainer keeps track of the number of tubing cycles remaining, and will notify when a new pump tube kit is necessary. Each replacement tubing kit will last 1,100 cycles, see section 9.0 for routine maintenance.

**8.2.1 Press [ 1 ]** on the key pad to select **Run**

**8.2.2 Press [ 4 ]** on the key pad to select **Purge**, repeat this step **twice** to make sure all of the reagents are emptied from the tubes.

**8.2.3** Turn the unit **OFF**

**8.2.4 Open the front panel** by removing the four thumb screws.

All eight pump tubes and rollers will be displayed. It is recommended to replace one tube at a time from left to right to keep correct tube placement.

**Art specifications:**

IFU/Manual - 8"Wx10"H

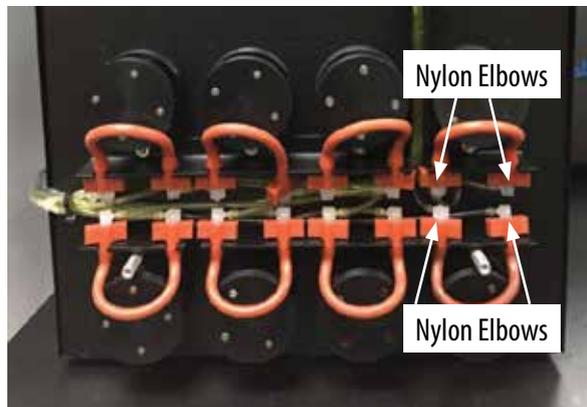
**Do not alter art or size.**

**All art prints PMS 185 Red and  
100% Black.**

AMS1800062

Rev. 0 2018-06

**8.2.5** Remove the two white nylon elbows from each of the orange pump tubes.



**8.2.6** Remove the orange pump tube from the pump roller and bracket.

**8.2.7** Install the new orange pump tube into the bracket and onto the roller.

**8.2.8** Insert the two nylon elbows into the new pump tube.

**8.2.9** Turn the unit **ON** and replace the front panel.

### **8.3 Register New Pump Replacement Tube Kit**

**8.3.1** From the Main Menu, **Press [ 2 ]** on the key pad to select **SET-UP**.

**8.3.2 Press [ 2 ]** on the key pad to select **Consumables**

**8.3.3 Press [ 2 ]** on the key pad to select **Review Tubing**

**8.3.4 Press [ 1 ]** on the key pad to select **Change Kit**

**8.3.5** Enter the **Kit Serial Number** and **press [ # ]** on the key pad to Accept

**8.3.6** Enter the **Kit Batch Number** and **press [ # ]** on the key pad to Accept

**8.3.7 Press [ \* ]** on the key pad **once**

**8.3.8 Press [ 1 ]** on the key pad to **Update Tubing Log**

**8.3.9 Press [ \* ]** on the key pad to return to the Main Menu

**8.3.10 Press [ 1 ]** on the key pad to select **Run**

**8.3.11 Press [ 3 ]** on the key pad to select **Prime**

The unit is now ready to run samples.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and  
100% Black.**

AMS1800062

Rev. 0 2018-06

## 9.0 MAINTENANCE

### 9.1 Wash Cycle

The Wash feature for the Single Slide Automated Gram Stainer is required every 20 slides or every 8 days. The unit runs water and decolorizer through the cuvette and with agitation cleans the internal surface of the cuvette and tubing.

9.1.1 Press [ 1 ] on the key pad to select **Run**

9.1.2 Press [ 2 ] on the key pad to select **Clean Cuvette**

9.1.3 Press [ 1 ] on the key pad to select **Wash Cuvette**



9.1.4 Press **any key** on the key pad to run the Wash Cycle

When complete, there will be an audible alert notifying the technician that the machine is ready to resume staining.

### 9.2 Bleach Cycle

The Bleach feature for the Single Slide Automated Gram Stainer is required every month or 600 cycles, whichever occurs first. The unit runs a 10% bleach solution through the reagent and water lines to clean the internal surface of the tubing and to prevent debris build up in the waste line.

9.2.1 Press [ 1 ] on the key pad to select **Run**

9.2.2 Press [ 4 ] on the key pad to select **Purge**

9.2.3 Remove the reagent lines (Crystal Violet, Gram's Iodine, and Safranin) from their stain containers, and **wipe off** the residual reagents from the ends of the cannulas or rinse them off in water.

9.2.4 In the same water container that supplies the instrument with water, **make a 10% bleach solution**.

9.2.5 **Submerge** all three of the reagent lines and the D.I. Water line into the DI water container that is full of a **10% bleach solution**.

9.2.6 Press [ \* ] on the key pad to return to the Main Menu

9.2.7 Press [ 1 ] on the key pad to select **Run**

9.2.8 Press [ 3 ] on the key pad to select **Prime**

9.2.9 Press [ \* ] on the key pad to return to the Main Menu

9.2.10 Press [ 1 ] on the key pad to select **Run**

9.2.11 Press [ 1 ] on the key pad to select **GRAM STAIN**

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

**9.2.12 Press [ 2 ]** on the key pad to select **Gram Stain (LONG)**

**9.2.13** Place a clean, blank slide in the cuvette when the screen prompt reads **Load Slide**

**9.2.14 Press any key** on the key pad, except [ \* ], to commence the Bleach Cycle

**9.2.15** When the cycle is complete, Press [ \* ] on the key pad to return to the Main Menu

**9.2.16 Press [ 1 ]** on the key pad to select **Run**

**9.2.17 Press [ 4 ]** on the key pad to select **Purge**

**9.2.18 Press [ \* ]** on the key pad to return to the Main Menu

**9.2.19 Empty the 10% bleach solution** from the DI Water container, and **refill the water** container with fresh, supplemented deionized water (refer to section 9.5).

**9.2.20** Wipe off and place **all of the cannulas** into the water container now full of fresh deionized water.

**9.2.21 Press [ 1 ]** on the key pad to select **Run**

**9.2.22 Press [ 3 ]** on the key pad to select **Prime**

**9.2.23 Press [ \* ]** on the key pad to return to the Main Menu

**9.2.24 Press [1]** on the key pad to select **Run**

**9.2.25 Press [1]** on the key pad to select **GRAM STAIN**

**9.2.26 Press [ 2 ]** on the key pad to select **Gram Stain (LONG)**

**9.2.27** Place a new blank slide in the cuvette when the screen prompt reads **Load Slide**

**9.2.28 Press any key** on the key pad, except [ \* ], to commence the Rinse Cycle

**9.2.29 Press [ \* ]** on the key pad to return to the Main Menu

**9.2.30 Press [ 1 ]** on the key pad to select **Run**

**9.2.31** Lift all of the cannulas out of the water container and place them into the waste container before the next step.

**9.2.32 Press [ 4 ]** on the key pad to select **Purge**

**9.2.33** Wipe off and **replace all of the cannulas** back into their respective reagent and/or water containers.

### **9.3 Scrub Cycle**

The Scrub feature for the Single Slide Automated Gram Stainer is required every 15 days or 600 cycles, whichever occurs first.

The unit will automatically prompt the operator when scrub cycle needs to be run. The total time to run a Scrub Cycle is five minutes.

**9.3.1** From the main menu, **Press [ 1 ]** on the key pad to select **Run**.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and  
100% Black.**

AMS1800062

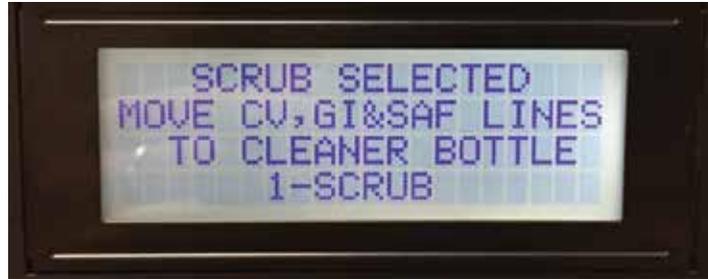
Rev. 0 2018-06

**9.3.2 Press [ 2 ]** on the key pad to select **Clean Cuvette**.

**9.3.3 Press [ 2 ]** on the key pad to select **Scrub Stain Lines**

**9.3.4 Press [ 1 ]** on the key pad to select **Purge**, this will empty the lines of stains.

**9.3.5** Move the Crystal Violet, Gram's Iodine, and Safranin cannulas into one bottle of System Cleaner (Cat. No. CHB-AGS-SC), or a bottle containing at least 500 mL of Decolorizer. The cleaner is used to clean the internal portions of the reagent lines, ports, cuvette, and photo optics of the unit.



**9.3.6 Press [ 1 ]** on the key pad to select **Scrub**

The unit will automatically prime the system cleaner into the reagent lines and then begin the scrub sequence.

**9.3.7** During the scrub sequence use the **Cuvette Swabs** (Cat. No. CHB-GS-CS) to manually scrub any residue build up, off the side of the cuvette chamber.

**NOTE:** When swabbing the cuvette, be cautious not to cause an overflow, as that can affect the integrity of the machine.

**9.3.8** Once the scrub cycle has completed, wipe off the reagent cannulas with an alcohol pad and return the three stain lines to the proper stain bottles.



**9.3.9 Press any key** on the key pad to prime the reagent lines with reagents. The unit will make an audible alert when the Scrub Cycle is complete and ready to resume use.

**NOTE:** To return to the main menu, Press [ \* ] on the key pad.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 9.4 Cuvette Swabbing

The cuvette may build up stain residue over time. To clean it, use a foam cleaning swab (Cat. No. CHB-GS-CS) soaked in alcohol to scrub the walls of the cuvettes. This should be done while the instrument is not in Run Mode, but while a Scrub Cycle is in process. Scrub the cuvette walls with a clean foam swab while decolorizer and water is rinsing the chamber. **Note:** Be careful not to accidentally overflow the cuvette with the submerged swab when performing the wash cycle.

## 9.5 Deionized Water Disinfectant

In order to prevent contamination, the deionized water must have stabilized gram's iodine disinfectant (Cat. No. CHB-GS-DI) added to the container following this schedule, whichever comes first:

1. Every time the water container is refilled with deionized water.
2. Every 20 days of operation.

This is completed by adding 10 drops of disinfectant per gallon of deionized water into the water container.

## 9.6 Refilling the Water Supply

The water can be refilled at any time before the staining process has begun if the water supply is getting low.

**NOTE:** The new water supply must be disinfected using iodine before continuing use, refer to section 9.5 above.

### To refill the water supply, do the following:

- 9.6.1 Remove the water cannula from the water container and place it onto a fresh paper towel or alcohol swab.
- 9.6.2 Fill the water container with fresh deionized water and mix in the drops of Gram's Iodine.
- 9.6.3 Sanitize the water cannula using an alcohol swab and place it back into the water container and screw the lid on tightly.

**Note:** When removing the water cannula, if a column of air is sucked into the cannula, an error message can occur. In order to avoid possible sensor errors caused by air entering into the water cannula, replace the water in the water container before staining a slide.

**Note:** If a separate sterile water container is available, it can be used to pour more deionized water into the original water container without removing the cannula. Be sure to add the drops of Gram's Iodine into the separate sterile water container full of deionized water, before pouring it into the original water container.

## 9.7 Maintenance Summary

Frequency		Maintenance Procedures
Every time the deionized water is refilled (or every 20 days)		• Supplement the fresh deionized water with drops of <b>Gram's Iodine disinfectant</b> (see Section 9.5).
Monthly	Every 600 slides	• Run a <b>Bleach Cycle</b> (see Section 9.2).
Every 8 Days	Every 20 slides	• Run a <b>Wash Cycle</b> (see Section 9.1).
Every 15 days	Every 600 slides	• Run a <b>Scrub Cycle</b> (see Section 9.3). • <b>Swab the cuvette</b> during the Scrub Cycle (see Section 9.4).
Six Months	Every 1,100 slides	• Replace the orange <b>pump tubes</b> (see Section 8.2).

Please utilize the Maintenance Logs to make sure these periodic tasks are completed as scheduled. See section 16.0.

### Art specifications:

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 10.0 IDLE DELAYS

The Single Slide Automated Gram Stainer contains an internal clock that is used to monitor system operations and start a timer to manage the instruments “sleep” time to conserve energy. The software monitors the idle time by observing the elapsed time since the last key on the key pad was pressed. To set a sleep time that works best for your lab, refer to Section 10.1 below. When the machine enters into Sleep Mode the LCD display will turn off and the pump motors will be de-energized.

To exit the Sleep Mode press any key twice on the key pad. This will illuminate the LCD screen and display the Main Menu within 10 minutes as the pump motors are re-energized and the operating system is activated.

The **Stir** operation helps maintain the integrity of the machines cuvette. While the machine is in Sleep Mode or while it is idling, the stir function rotates the pump motors and processes a small amount of decolorizing reagent into and out of the cuvette.

The **Auto-Prime** feature includes a purge of all reagents, followed by a complete prime of the reagent lines. This prevents reagent evaporation in the supply lines and maintains the unit in a ready state without wasting reagents, as each of the reagents is expelled back into the respective reagent container.

### 10.1 Setting the Sleep Delay

**10.1.1 Press [ 2 ]** on the key pad to select **Set- Up**

**10.1.2 Press [ 4 ]** on the key pad to select **Options**

**10.1.3 Press [ 2 ]** on the key pad to select **Idle Delays**

**10.1.4** Next to the **Sleep Delay**, where the blinking cursor is, use the key pad to enter in the desired number of minutes for the instrument to enter the Sleep Mode.

**10.1.5 Press [ # ]** on the key pad to enter the desired delay time and move to the next setting.

**10.1.6** Next to the **Stir Delay**, where the blinking cursor is, use the key pad to enter in the desired number of minutes for the instrument to run a Stir Cycle while the machine is idling.

**NOTE:** It is recommended that the Stir Delay be set to no more than 60 minutes.

**10.1.7 Press [ # ]** on the key pad to enter the desired delay time and move to the next setting.

**10.1.8** Next to the **Auto Prime**, where the blinking cursor is, use the key pad to enter in the desired number of hours after idling that the instrument should automatically prime the reagent lines.

**NOTE:** It is recommended that the Auto Prime be set to no more than 24 hours.

**10.1.9 Press [ \* ]** on the key pad to return to the Options Menu and save the delay times.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 11.0 UNIT SHUT DOWN

### 11.1 Unit Shut Down Instructions

Refer to section 9.3.1 - 9.3.7 for step by step instructions of how to run a Scrub cycle, but **omit the final Prime step.**

#### 11.1.1 Run a Scrub Cycle

**NOTE:** When the screen prompt reads "Replace tubes into proper stains" pull all of the cannulas out of the system cleaner bottle and place them onto a paper towel. Then, press any key to continue.

**NOTE:** For the Scrub procedure it is recommended that the System Cleaner for Single Slide Automated Gram Stainer (Cat. No. CHB-AGS-SC) is used. Alternatively, decolorizer can be used if there is no available system cleaner.

#### 11.1.2 Return to the Main Menu

**11.1.3 Press [ 1 ] on the key pad to select Run then Press [ 4 ] on the key pad to select Purge.**

#### 11.1.4 Turn the system power switch OFF

#### 11.1.5 Remove all eight orange pump tubes from the pump tube rollers

**11.1.5.1 Open the front panel** by removing the four thumb screws.

**11.1.5.2 Gently stretch the tubes** off of the pump rollers without disconnecting the white nylon elbows.



**11.1.6 Replace the front panel** using the four thumb screws.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 12.0 SERVICES AND SUPPLIES

If a problem is encountered that is beyond the scope of this manual or additional assistance is required, contact our Cardinal Health™ Technical Support Team serviced by QuickSlide™ at (800) 266-2222 (ext. 2). Additional supplies for your Single Slide Automated Gram Stainer can be purchased through Cardinal Health.

Catalog Number	Description
CHB-AGS-SK	Gram Stain Kit, 5 x 16 fl. oz.
CHB-GS-QC	QC Slides 50/pack
CHB-AGS-SC	System Cleaner, 2 x 500ml
CHB-AGS-RT	Replacement Tubing Kit, 8 tubes/kit
CHB-GS-CS	Cuvette Cleaning Swabs, 100swabs/kit
CHB-GS-DI	Gram's Iodine for DI Water, 1 bottle
M6143	Microscope Slide Charged Adhesion Frosted 25mmx75mm 1mm

## 13.0 SAFETY DATA SHEETS

Safety Data Sheets (SDS) for any associated reagents kits can be found at [www.mycardinalmsds.com](http://www.mycardinalmsds.com).

## 14.0 REFERENCES

1. Minnerath, J., et al. A Comparison of Heat Versus Methanol Fixation for Gram staining Bacteria, Department of Biology, Santa Mary's University of Minnesota, Winon, MN.
2. Mangels, et al. 1984. Methanol Fixation: An Alternative to heat Fixation of Smears Before Staining. Diagnostic Microbiology and Infectious Disease; 2: 129-137.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

## 15.0 Single Slide Automated Gram Stain Warranty

Cardinal Health utilizes Hardy Diagnostics to repair or replace the instrument under the terms and conditions of this warranty. The liability of Hardy Diagnostics under this warranty, whether in contract, tort, or otherwise, shall not, except as expressly provided herein, exceed Buyer's purchase price on which such liability is based. Please note that:

Repaired units will be given the latest software upgrades.

Shipping charged to and from the buyer will be provided by Hardy Diagnostics.

Travel costs are not included as part of warranty.

Extended warranties do not include the routine replacement of the tube sets.

Hardy Diagnostics shall not be obligated under this warranty if the need for repairs or replacements results from Buyer's or end users' failure to operate and maintain the system as specified in the operating manual. Hardy Diagnostics shall not be responsible for results generated from or damage caused by Buyer's or end users' use of third party reagents or use of third party maintenance services.

This warranty does not cover any claims, actions, losses, damages, demands, liabilities, costs or expenses, including attorney's fees or expenses, whether a suit or other proceeding is initiated or not, which may arise from, but not limited to, the following events: (i) misrepresentations made by Buyer, (ii) any neglect by Buyer or end-users, (iii) Buyer's or end-users' use of products not in compliance with published specifications which are not for their intended purposes, (iv) Buyer's or end-users' modifications or alterations of products, (v) damage from Buyer or end-user misuse, or operation outside of the environmental specifications for the products, (vi) any other act, or failure to act, not in accordance with the terms and conditions of this warranty by Buyer or end user, and (vii) any condition listed below which would invalidate this warranty.

Any of the following conditions shall invalidate the warranty:

Buyer's or end users' failure to properly perform the maintenance required in the operator's manual.

- ii. Repairs by persons other than Hardy Diagnostics service personnel, unless authorized in writing by Hardy Diagnostics personnel.
- iii. Replacements with other than genuine QuickSlide™ parts.
- iv. Buyer's or end users' negligence or negligent operation of the System.
- v. Unauthorized alterations or modifications to the System or software.
- vi. Removal of the protective case without service authorization.
- vii. Use of reagents other than those provided by Cardinal Health.
- viii. Use of microscope slides other than the chemically treated Cardinal Health™ Microscope Slide Charged Adhesion Frosted 25mm x 75mm 1mm (Cat. No. M6143) or Hardy Diagnostic PROBond (Cat. No. PB72) microscope slides with this gram-staining instrument.
- ix. Use of specimen fixation method other than methanol fixation.
- x. Broken glass slides in tubing, cuvettes, or the waste ports as an outcome of buyer or end user negligence.

Buyer waives their Implied Warranty if Buyer fails to use the slides, reagents, and other accessories, as directed by Hardy Diagnostics, with our staining instruments, or fails to follow the defined operating procedures. Use of any unauthorized slides, reagents, or accessories in our staining instruments or failure to follow the defined operating procedures, could produce erroneous results. Hardy Diagnostics is not liable for any damages, financial or otherwise, caused by the use of unauthorized slides, reagents, or accessories, or as a result of not following the defined operating procedures. HARDY DIAGNOSTICS HEREBY EXCLUDES AND IN NO EVENT SHALL BE LIABLE TO BUYER OR END USER FOR SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS.

All other components are covered, granted the user follows the operating instructions. Refer to our Domestic Terms and Conditions at [www.HardyDiagnostics.com/terms-conditions](http://www.HardyDiagnostics.com/terms-conditions) and our International Terms and Conditions at [www.HardyDiagnostics.com/international-terms-conditions](http://www.HardyDiagnostics.com/international-terms-conditions) for additional information.

Hardy Diagnostics represents and warrants to Buyer that all products shipped by Hardy Diagnostics to Buyer, as of the date of such shipment, shall conform in all material respect to the specifications last published at [www.HardyDiagnostics.com](http://www.HardyDiagnostics.com) before the time of shipment of the products.

HARDY DIAGNOSTICS MAKES NO OTHER WARRANTIES TO BUYER, EXPRESS OR IMPLIED, AND HEREBY EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

**How Long Coverage Lasts:** This warranty lasts for a period of twelve (12) months from the time of original instrument shipment, except for products that have an expiration date, in which case the warranty lasts until the expiration date. When an instrument warranty expires or is close to expiration, buyers may purchase up to four (4) successive extended warranty renewals each covering a period of twelve (12) months from the date of purchase of the extended warranty.

**How to Get Service:** In order to be eligible for service under this warranty, the problem must be reported to Hardy Diagnostics in writing within five business days after it becomes apparent while the warranty is in effect, provided an opportunity is afforded for examination by Hardy Diagnostics.

**Governing Law:** This warranty shall be governed by the Uniform Commercial Code as adopted in the State of Wyoming.

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06



# Trainee Name:

## Single Slide Automated Gram Stainer Training Checklist

Refer to the user manual for each item on this checklist. Check the box for each item trained.

Trainee's Initials

- \_\_\_\_\_ Specimen Slide Preparation: Section **6.2**
- \_\_\_\_\_ Loading Slides: Section **6.4.6**
- \_\_\_\_\_ Initiating a Gram Stain: Section **6.4**
- \_\_\_\_\_ Register Reagent Kit: Section **8.1**
- \_\_\_\_\_ General Maintenance: Section **9.7**
- \_\_\_\_\_ Refilling the Water Supply: Section **9.6**
- \_\_\_\_\_ Wash Cycle Operation: Section **9.1**
- \_\_\_\_\_ Bleach Cycle Operation: Section **9.2**
- \_\_\_\_\_ Scrub Cycle Operation: Section **9.3**
- \_\_\_\_\_ Replacing the Tubing Kit: Section **8.2**

**Trainee Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Trainer Signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and 100% Black.**

AMS1800062

Rev. 0 2018-06

Distributed by:  
**Cardinal Health**  
Waukegan, IL 60085 USA  
2018-06  
cardinalhealth.com  
CHB-AGS

© 2018 Cardinal Health. All Rights Reserved.  
CARDINAL HEALTH and the Cardinal Health LOGO are  
trademarks of Cardinal Health and may be registered in  
the US and/or in other countries.



**Art specifications:**

IFU/Manual - 8"Wx10"H

**Do not alter art or size.**

**All art prints PMS 185 Red and  
100% Black.**

AMS1800062

Rev. 0 2018-06