# USER OPERATION MANUAL





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## **Congratulations!**

You have made an excellent choice for your Lab. Hardy Diagnostics 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 GramPRO 80. 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 QuickSlide<sup>™</sup> Quality Management System

Our devices for the medical laboratory are developed, produced, and distributed according to the requirements of ISO 9001:2008.

#### **Unpacking and Inspecting**

Carefully unpack the GramPRO 80 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.



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## **SPECIFICATIONS**

#### **Dimensions/Weight**

Width 83.8 cm (33.0 in.) Height 40.6 cm (16.0 in.) Depth 31.8 cm (12.5 in.) Weight 20.41 Kg (45.00 lbs.)

#### **Power Requirements**

Input 12 VDC, 15 A, 180 W maximum

For reference, GramPRO80 uses an external power supply module that may be supplied with 60 Hz, 110 VAC or 50 Hz, 230 VAC line power. Standard power cords are supplied to meet local standards.

#### **Temperature, Ambient Operation**

16-32 Degrees C (60-90 Degrees F)

#### Humidity

0 to 95%, without condensation

#### **Operator Adjustments**

Individual adjustable stain times on both short and long cycles Adjustable sleep mode Adjustable audible sound volume control

#### **Operator Entry**

Moisture proof, touch screen

#### Standards

IEC-61010-1:2010 (Third Edition) EN55022; CISPR 22 Ed. 6.0:2008 Class A CFR 47, Part 15, Subpart B, Class A, 2011 ICES-003 Issue 4, 2004 CAN/CSA-CIE/IEC CISPR 22;02 Class A EN61326-1: 2010

### Warranty

One Year Standard

#### **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 QuickSlide<sup>™</sup> GramPRO 80 Automated Multiple Slide Gram stainer unit. The GramPRO 80 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. This instrument accepts standard thickness 1"x3"x1mm PROBond glass slides that are frosted and pre-cleaned.

The GramPRO 80 software provides a series of menus for the 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.

Section 5 of this manual provides quick start instructions for Gram stain operation.

Section 11 of this manual provides a complete overview and description of all the system menus and associated operations.

#### **Operator Responsibility – Safety Instructions**

The GramPRO 80 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 GramPRO 80.

It is the operator's responsibility to be properly qualified to operate the GramPRO 80. The operator and laboratory personnel are advised to refer to this Operating Manual and the set-up letter that is packaged with the unit.

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

#### **Explanation of Symbols**

- | Power On
- O Power Off



Caution – Refer to marked paragraphs in this manual for details.

#### 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. The GramPRO 80 incorporates a patented computerized "electronic eye" to perfectly time the decolorization of every sample regardless of the smear thickness, guaranteeing that all slides are processed correctly every time.

#### 2.0 WORK AREA REQUIREMENTS

#### IMPORTANT!

The GramPRO 80 unit requires a level counter top surface of 34 inches wide by 14 inches deep with a vertical clearance of 18 inches. The Reagent Supply Kit should be positioned at the same level as the instrument on the counter immediately beside or behind the instrument and is connected with tubing. Do not place reagents below the instrument.

The GramPRO 80 unit requires a container filled with deionized water, which is connected with tubing.

Several tubes from the GramPRO 80 unit drain waste fluids. The GramPRO 80 unit should be placed near a drain or other disposal container to accommodate this waste fluid.

The GramPRO 80 consumes less than 180 watts of power and uses an external power supply module that is supplied with 60 Hz, 110 VAC or 50 Hz, 230 VAC line power. The unit requires power from a grounded outlet.

#### There are no special environmental requirements for operation of the GramPRO 80.

The GramPRO 80 is supplied with tubing sets to connect the instrument to the reagents. Connect the luer fittings on the reagent lines to the respective fittings on the instrument of the same color. The other end of 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.

In addition, the DI water gauge line with the green luer fitting is to be immersed in the water supply to indicate available water.

#### **3.0 RECEIVING AND UNPACKING**

Unpacking and set-up assistance for the GramPRO 80 may be obtained by calling the Technical Service Department of QuickSlide<sup>™</sup> at 800-266-2222 during the hours of 8am to 5pm Pacific Time, Monday through Friday.

The GramPRO 80 is for use only with provided external power supply. The power supply ratings are:

 Input
 100-240 VAC, 50/60 HZ, 4.0 A

 Output
 12 VDC, 15 A, 180 W

The external power supply is a Class I supply that must be connected to an earthed (grounded) main power outlet. Failure to connect the GramPRO 80 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 GramPRO 80 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 QuickSlide<sup>™</sup> 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. AGS-AGS-DI-1000), Deionized Water, 5 gallons (Cat. no. <u>9265B640</u>), Methanol (Cat. no. <u>107B128</u>), Bibulous Paper, slide blotting paper (Cat. no. <u>28511007</u>), Coplin Jars (Cat. no. <u>VCJ001</u>), Microscope lens cleaner (Cat. no. <u>Z97</u>), Lens Paper, non-linting (Cat. no. <u>52846001</u>), Clorox® Germicidal Bleach (Cat. no. <u>37001060</u>), Sterile Saline, 0.85% (Cat. no. K59), and Transfer Pipet, Disposable (Cat. no. <u>138020500</u>), Cuvette Swabs (Cat. no. AGS-SW-1001), Gram Stain QC Slides (Cat. no. AGS-00700), Immersion Oil (Cat. no. Z96), Microscope (Cat. no. 1423PH), and PROBond Slides (Cat. No. PB72), are required but not provided.

#### **5.0 REAGENT SUPPLY KITS**

#### 5.1 General information

The GramPRO 80 accomplishes automatic Gram staining by systematically staining, rinsing, decolorizing, and counter-staining the provided biological specimen. It is critical for the success of this automated process that these unique reagents be obtained from QuickSlide™.

**NOTE:** For quality control purposes, Reagent Supply Kits are labeled with Kit Number, Lot Number, and Expiration Date. These values are used to track and identify the Reagent Supply Kit used in the unit, and are entered into the system as part of the Change Reagents procedure as explained in section 10.2.

#### 5.2 Ordering information

The GramPRO 80 software monitors consumption of the Reagent Supply 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. Call QuickSlide™ at 800-266-2222 to order supplies.

#### 5.3 Reagent Kit Installation

The GramPRO 80 reagents are supplied to the unit through tubes connected to the individual reagent containers. Each tube is clearly labeled, 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 GramPRO 80 unit.

#### **6.0 OPERATIONS OVERVIEW**

#### 6.1 Instrument Diagram



The basic anatomy of the GramPRO 80 is identified in the diagram above and will be discussed in the procedures that follow.

Left Upper Panel – houses the LCD touchscreen and computer and covers water pumps.

Right Upper Panel – covers water pumps.

**Dog-House** – covers the cuvette array and gripper mechanism and protects operators from moving parts and accidentally damaging the components while operating.

**Cover Door** – covers the In-Feed Screw and must be closed for slides to progress through the instrument.

In-Feed Screw – progresses the slides into the cuvette array under the Dog-House.

Stat Slide Drawer – allows for the input of a stat slide.

**Out-Feed Screw** – promotes the stained slides out of the Dog-House for pickup and reading.

**Lower Panel** – covers the reagent supply and waste 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 into the designated box on the PROBond slide and aseptically transfer a minute amount of a colony from 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. Position the smear within the blue box in the center of the slide at least 3/4" below the frosted area, and 1/4" from the left and right edges of the slide. This will provide the necessary clearances for GramPRO 80 processing. Take care to avoid placing labels on the slide that might interfere with the GramPRO 80 mechanism. Labels cannot wrap around the sides of the slide and should not extend below the frosted area. Labels may wrap over the top of the slide if fitted tightly and flush onto the slide.

**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.<sup>(1)</sup> In addition, Gram positive bacteria are much less likely to become over-decolorized when fixed with methanol rather than heat.<sup>(2)</sup>

**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 the specimen does not get damaged by excessive heat. Once fully dry, submerge the slide in methanol by dipping in and out of a Coplin jar filled with methanol. If a large number of slides are placed on a tray and treated with methanol via a drip method, pour off excess methanol. Please ensure the methanol covers the whole smear. Do not leave slides submerged in a jar or coated with pooled methanol, since this may damage the coating present on slides treated for better specimen adhesion. Drain off remaining methanol without rinsing by tapping the bottom edge of the slide to a paper towel and allow the slide to air dry. Do not apply heat after the methanol evaporates.

**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 PROBond glass slides (Cat. No. PB72) that are positively charged to increase specimen adhesion to the glass slide. The adhesion of the specimen to the glass slide 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.

#### **6.3 Instrument Preparation**

6.3.1 Ensure all reagent and water supply tubes are properly inserted into the correct containers. Ensure all drain tubes are positioned for proper disposal of waste fluids. Confirm that all lines are properly primed. This is done automatically by the power-on Self-Test process. Ensure that all four reagent bottles and the water container are level with the machine. Reagents cannot be stored below or above the machine while being used.

6.3.2 Confirm correct registration and availability of a Reagent Kit and Tubing Kit. These are also checked automatically by the Self-Test process. Confirm reagent fluids are present in the supply containers.

**NOTE:** For quality control purposes, Reagent Kits are labeled with a Kit Number, Lot Number, and an Expiration Date. These values are used to track and identify the Reagent Supply Kit used in the unit as GramPRO 80 software monitors the consumption of the Reagent Kit.

6.3.3 Confirm deionized water is present in the supply container. In order to prevent contamination, the deionized water must have stabilized gram's iodine disinfectant (Cat. no. AGS-DI-1000) 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.

6.3.4 Confirm the waste container has space for anticipated waste fluids. The software monitors water and waste fluids as displayed in the lower right portion of the screen. The system will provide water or waste error messages when appropriate.

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

6.3.5 Ensure there are no slides in the seven processing cuvettes. The presence of slides (as noted by optical sensors) prevents the device from starting the staining process.

6.3.6 Check for space available in the out-feed screw for the unloading of processed slides. An optical sensor detects slides in any of the last seven positions, and prevents the device from starting the staining process if any are present. Unload slides as necessary.

#### 6.4 Loading Slides

#### 6.4.1 Normal Loading

Hardy Diagnostics requiresPROBond glass slides (Cat. no. PB72) to be used in the GramPRO 80. To load slides, open the clear cover door over the in-feed screw on the left side of the GramPRO 80. Up to 80 slides may be pre-loaded into the instrument before processing starts. *The slides must be positioned with the sample smear side facing to the right side of the instrument.* The slides must be loaded into the screw threads so that the slide is perpendicularly aligned to the screws. Positioning sensors at the load station detect incorrectly loaded slides and provide a message to inform the operator of the load error. The cover door must be closed for processing to commence.

Additional slides may be loaded into the in-feed screw while processing continues. Open the cover door to suspend load operations, and insert additional slides for processing as desired.



Close the cover door to resume load operations. Use care when placing slides in the GramPRO 80. The glass slides have sharp corners that if accidently bumped may result in injury or a broken slide.

#### 6.4.2 STAT Loading

The GramPRO 80 includes a STAT load station to accommodate the immediate loading and processing of a STAT slide. Simply open the STAT Slide Drawer by retracting it from the panel, insert a slide, and then close the STAT Slide Drawer. *Note: The GramPRO 80 must be in Run Mode BEFORE closing the Stat Slide Drawer.* Optical sensors detect the presence of the STAT slide and the system preempts the normal loading sequence, effectively allowing it to "cut in line" ahead of the slides in the normal load queue in the in-feed screw.

#### 6.4.3 Processed Slide Order

Processed slides arrive in the out-feed screw in the same order as they were loaded into the infeed screw, except that any STAT slides will be inserted as encountered. Marking the edges of STAT slides with a Sharpie, or similar marker, can aid in identifying and retrieving processed STAT slides from the out-feed screw. Slides loaded from the STAT drawer are double-spaced in the out-feed screw after processing to aid in identification.

#### 6.5 Stain Processing

The GramPRO 80 employs seven cuvettes for the Gram stain process: two for crystal violet staining (#1 and #2); two for Gram's iodine fixing (#3 and #4); one for decolorizing (#5); and two for safranin counter-staining (#6 and #7). Slides are transported from station to station during the process, moving in sequence from load to crystal violet stain to iodine fix to decolorize to safranin counter-stain and finally to unload, traveling either a route of load to cuvette #1 to #3 to \$5 to #7 to unload, or of load cuvette #2 to #4 to #5 to #6 to unload. The "even cuvettes" and "odd cuvettes" paths are alternated for each new slide.

One of three pre-programmed sets of Stain Delays, (i.e. Short, Medium, or Long Delays) is selected when a run is started. 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:

	Short	Medium	Long
CV	40	50	60
GI	40	50	60
SAF	40	50	60

Decolorization duration is determined automatically (by a patented electronic method) for each slide as it is decolorized. GramPRO 80 processing includes an automatic self-calibration of the decolorizer sensor prior to decolorizing each slide to further ensure the reliability and consistency of the processed result. Self-calibration errors are detected and noted to permit any required corrective action.

Once started, processing can be suspended by entering the **PAUSE SLIDE TRAVEL** command. Loading can be suspended by opening the cover door and resumed by closing the cover door. Loading may also be suspended by entering the **SUSPEND NEW LOADS** command, and then resumed with the **RESUME LOADING** command.

Optical sensors monitor the progress of slides traveling through the sequence of cuvettes. Errors are reported any time a slide is detected in a cuvette that should be empty, or when an empty cuvette is detected that should be occupied. Messages and possible corrective actions are provided for any detected errors.

Fluid level detectors are utilized to ensure the cuvettes are filled with fluid to the proper level.

These detectors ensure the same fill level, even when slides of various thicknesses are batched together in the same run. The fluid detectors are also monitored to confirm the proper presence, or absence, of fluid in the cuvettes at specific points in the processing cycle. Errors detected can indicate an out-of-reagent condition, a clogged line, or a malfunctioning pump. Messages and possible corrective actions are provided for any detected errors.

Completed slides are placed into the out-feed screw for drying. Drying fans are used to dry the slides in about two minutes. An **EJECT** function is available to gain access to completed slides more quickly. Slides loaded from the **STAT** drawer are double-spaced in the out-feed screw after processing to aid in identification.

The last seven slots of the out-feed screw are monitored for the presence of slides. Detection of a slide in these positions triggers a count-down of processing for a maximum of seven more slides (the maximum already loaded and processes) before processing is suspended. Processing resumes after slides are removed from the out-feed screw.

#### 6.6 Quick Guide – Stain Operation

This chapter provides the minimum instruction sequence for staining a slide. See Section 11 for the complete description of the GramPRO 80 system options and capabilities. Reagent and waste disposal tubing must be properly connected for proper unit operation. Enter the listed menu command selections in sequence to initiate a Gram stain operation.

#### 6.6.1Turn 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 (refer to section 11.5) validates system operational parameters and prepares the unit for use. Any error conditions encountered are flagged in the Self-Test Review Menu – please refer to section 11.3.1.1 for error resolution methods. Otherwise, upon normal completion the Main Menu is displayed (refer to section 11.2), continue to next step.

#### 6.6.2 Load slides

Optionally, slides to be stained may now be loaded with the *sample side facing right* into the Load Screw and/or Stat Load Drawer. Slides have sharp corners. Use care when installing slides to avoid injury. *Note: The GramPRO 80 must be in Run Mode BEFORE closing the Stat Slide Drawer.* 

#### 6.6.3 Press RUN

Press the **RUN** command button in the Main Menu to proceed to the Run Menu (refer to section 11.3). *Note: the RUN command will fail to start if the instrument is due for a required Bleach or Scrub cleaning cycle.* 

#### 6.6.4 Select and press RUN SHORT, MEDIUM or LONG STAINS

Press one of the stain command buttons (**RUN SHORT STAINS, RUN MEDIUM STAINS**, or **RUN LONG STAINS**) to select the desired stain delay times for the run.6.6.5Automated Gram staining Process Begins

The unit may now be left unattended as slides are automatically loaded from the Load Screw and/or the Stat Drawer for Gram stain processing. Additional slides may be inserted with the *sample side facing right* as desired into either load location for processing. Staining continues automatically until all available slides have been processed, or the **ABORT** command button is pressed.

#### 6.7 Reagent Kit Replacement

The GramPRO 80 software monitors consumption of the Reagent Kit. Follow the steps listed below to install a new Kit when needed.

From the Main Menu select the **SET-UP** option, then **COMSUMABLES**, and next **NEW REAGENT KIT** to access the preregistration menu. A Scrub Procedure is required before installation of every new reagent kit. This menu reminds the operator that a Scrub is needed, and provides easy direct access to run the Scrub Procedure. Refer to section 10.4 for details about running a Scrub. Once the Scrub has completed, the old reagent bottles may be replaced with new ones.

**NOTE:** Take care to make certain all pick-up cannulas are all inserted into the correct bottles.

Select **REGISTER KIT** to proceed to the Reagent Kit Registration Menu.

Notice the current kit information displayed at the bottom of the screen (in white letters on dark blue background). Displayed are the current Lot Number, Pack Number, and Expiration Date. In turn, enter new values for the Lot Number, Pack Number and Expiration Date using the 10-key and corresponding command entry buttons. When all displayed values match those of the new kit label, select the **REGISTER KIT** command. The system acknowledges valid kit registration by displaying a confirmation message. Entry of invalid numbers results in the display of an error message. The **EXIT** button can be used repeatedly to return to the Main Menu after the new kit has been registered.

#### 7.0 QUALITY CONTROL

#### 7.1 Quality Control Checks

The quality and validity of the Gram stain process of the GramPRO 80 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 QuickSlide<sup>™</sup> by calling (800) 266-2222. Ask for Gram Stain Control Slides (Cat. no. AGS-00700).

#### 7.2 Self Calibration Errors

The GramPRO 80 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 are 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 USAGE TRACKING**

#### **Reagent Consumption**

The GramPRO 80 software monitors consumption of the Reagent Supply Kit. At the start of each Stain Cycle, the system displays a count of the remaining number of cycles available in the current kit. The remaining count should be carefully monitored so that fresh reagents may be ordered and available when needed.

#### **Recommended Cleaning Interval**

The staining cuvettes occasionally require thorough cleaning to remove the stain deposit build-ups that occur after many stain cycles. Two types of cleaning processes are available for the GramPRO 80: Bleach and Scrub. The system issues a reminder messages when it is time to run these cleaning cycles. Performing the Cleaning Cycles resets the recommendation messages. Refer to section 10.0 for instructions.

#### **Total Stain Cycles**

The GramPRO 80 system maintains a Lifetime Cycle counter that simply counts all staining cycles that the instrument performs. The counter can be useful to identify a particular run. It also helps gauge useful life of reagents and components.

#### 9.0 IDLE ACTIVITIES

The GramPRO 80 unit contains an internal clock that is used to monitor system operations. This timer is employed to manage the instrument's "idle" time. The user can specify the intervals for these "idle" functions. See section 11.4.6 for instructions on how to set these delays.

#### **STIR Operation**

Following the expiration of the specified Stir Time delay, the GramPRO 80 performs a Stir operation. The Stir operation includes injecting a small amount of decolorizing reagent and then evacuating the cuvette. This compensates for the tendency of the decolorizing reagent to evaporate, and helps maintain the unit in a ready state. A Stir Time delay of about 180 minutes is recommended.

#### **AUTO-PRIME-ALL Operation**

Since the GramPRO 80 is recommended to remain powered on at all times — except for extended periods of non-operation – an Auto Prime cycle is included to keep the unit ready for use. The Auto-Prime-All is for extended idle periods and includes a purge of all reagents, followed by a complete prime cycle. This operation consumes no reagents as they are purged back into the supply bottles, and subsequently re-primed. The Auto-Prime-All cycle is useful in preventing reagent evaporation in the supply lines, and helps maintain the unit in a ready state. An Auto-Prime-All delay of about 24 hours is recommended.

#### **10.0 MAINTENANCE**

#### **10.1 General Maintenance**

**NOTE**: These maintenance procedures for the GramPRO 80 should be performed at the recommended interval of 1,200 cycles, which is the same duration as a reagent kit, or every 30 days (whichever comes first). This is required for lubrication, cuvette swabbing, and load detection swabbing as described in this section. Using the reagent kit replacement as a reminder to also perform the periodic maintenance procedures is strongly suggested.

#### Gram's lodine Vapors

The Gram's iodine vapors may form a brownish residue on some of the moving parts of the slide transport mechanism. If allowed to accumulate excessively, this residue can hinder proper operation of the mechanism. This is cleaned by following the steps below.

#### Lubrication

Clean away or remove any visible residue from the horizontal threaded screw just above and behind the cuvette assembly. After cleaning, apply three small drops of oil equally spaced along the screw. Use sewing machine oil, immersion oil, 3-in-1 oil, or similar oil to lubricate these parts. Wipe away any excess oil.



Clean any brown residue from the gripper arms and assembly using a swab or tweezers. Apply one drop of oil on each of the two gripper arm hinge pins (front and back). These pins are visible at the front and back of the assembly, inside the cut-out opening just above the arm horizontal slide bracket, as shown here:



#### **Cuvette Swabbing**

The seven cuvettes may build up stain residue over time. To clean them, use a foam swab (Cat. no. AGS-SW-1000) soaked in alcohol to scrub the walls of the cuvettes. This should be performed while the instrument is **idle** or when it **is not** in Run Mode or performing a maintenance cycle. Scrub the cuvettes while the machine is idle, then perform a Wash cycle with deionized water to rinse the cuvette chambers. <u>Note:</u> Before the wash cycle, be sure that there is enough deionized water supply for the unit to complete the cycle.

Over time the top of the cuvettes may accumulate dust. Fans inside the instrument help prevent this buildup, but if the instrument is shut down for an extended period of time it is more likely for dust to settle on the cuvettes. If this is noticed, clean the cuvettes by swabbing them with a foam swab before processing slides.



If the instrument is going to be shut down for an extended period of time, or if it is going to be exposed to a dusty environment (e.g. construction), it is recommended to cover the instrument with plastic until the environment is again suitable for operation.

#### Load Detection Swabbing

The two load detection sensors at the end of the input screw similarly require swabbing using a foam swab soaked in alcohol. These sensors are circled in the picture below.

**NOTE:** If you keep specimen in the designated area in the center of the PROBond slide(section 6.2) you will not see debris build up on these two load detection sensors. If visible debris is found on the sensors, it suggests that proper slide preparation is not being followed.



#### Supply Lines and Tubes

Visually inspect all reagent supply and waste cannulas for any leaks, wear spots, kinks, or other blockages. Also check tubes for any leaks or wear spots. Visually inspect all of the orange pump tubes for any leaks or signs of wear.

#### **10.2 Tubing Kit Replacement**

The GramPRO 80 software monitors the normal wear and aging of the Pump Tubes. These tubes have a useful life of about 12,000 stain cycles or six months, whichever comes first. The system informs the operator when a new Tubing Kit should be installed. Follow the steps listed below to install a new Tubing Kit registration when needed. If further assistance is needed, please contact QuickSlide™ Technical Support at (800)266-2222, ext. 5598.

From the main menu select the **SET-UP** option, then **COMSUMABLES**, and next **NEW TUBING KIT** to access the Tubing Kit Registration Menu.

Notice the current kit information displayed at the bottom of the screen (in white letters on dark blue background). Displayed are the current kit Batch Number and Serial Date.

In turn, enter new values for the Batch Number and Serial Number using the 10-key and corresponding command entry buttons. When all displayed values match those of the new kit label, select the **REGISTER KIT** command. The system acknowledges valid kit registration by displaying a confirmation message. Entry of invalid numbers results in the display of an error message. The **EXIT** button can be used repeatedly to return to the Main Menu after the new kit has been registered.

Prepare the unit for powering down by selecting SHUT DOWN from the Main Menu, and turn off the power switch when instructed. The Shut Down procedure purges all fluids from the unit to enable the replacement of the pump tubes.



#### Remove and replace pump tubes.

Open the upper left door panel (holding the LCD screen) one pump at a time from left to right, replace the pump tube for these three pumps:

- 1. Remove the two nylon elbows from the orange pump tube.
- 2. Remove the orange pump tube from the pump roller and bracket.
- 3. Install the new orange pump tube into the bracket and onto the roller.
- 4. Insert the two nylon elbows into the new pump tube.

Open the upper right door panel and one pump at a time from left to right, replace the pump tubes for these four pumps:

- 1. Remove the two nylon elbows from the orange pump tube.
- 2. Remove the orange pump tube from the pump roller and bracket.

- 3. Install the new orange pump tube into the bracket and onto the roller.
- 4. Insert the two nylon elbows into the new pump tube.

Remove the lower front cover panel and one pump at a time from left to right, replace the pump tubes for these 14 pumps:

- 1. Remove the two nylon elbows from the orange pump tube.
- 2. Remove the orange pump tube from the pump roller and bracket.
- 3. Install the new orange pump tube into the bracket and onto the roller.
- 4. Insert the two nylon elbows into the new pump tube.

Power on the unit. Priming the system is required before normal operations can resume and is done as part of the normal power-on Self-Test procedure. Alternately, the unit may be primed using the **PURGE and PRIME** command on the Run Menu.

#### 10.3 Wash Procedure

**NOTE**: The Wash Procedure for the GramPRO 80 is recommended every **15 days or 600 cycles** and when scrubbing the cuvettes with a swab.. The unit will automatically prompt the operator when the wash cycle should be run.

From the Main Menu select the **RUN** option.

Select **CLEAN UNIT** Menu. Notice the due date and remaining cycle count displayed at the bottom of the screen.

#### Select RUN WASH CYCLE.

The Wash Procedure cleans the GramPRO 80 with water only, using repeated filling and agitation cycles to clean the cuvettes. No lines need be moved for the Wash, and the procedure completes in only about three minutes. The **CLEAN UNIT** Menu is displayed upon completion of the Wash cycle. Select **RUN MENU** to exit and resume normal operations.

#### **10.4 Scrub Procedure**

**NOTE**: The Scrub Procedure for the GramPRO 80 is required **every month** or **1,200 cycles**, whichever occurs first. The unit will automatically prompt the operator when scrub cycle needs to be run. To perform a scrub on the machine, use the system cleaner (Cat. no. MGS80-SC-8000).

From the Main Menu select the **RUN** option.

Select **CLEAN UNIT** Menu. Notice the due date and remaining cycle count displayed at the bottom of the screen.

#### Select RUN SCRUB CYCLE.

Select **PURGE STAIN LINES** to empty stains back into stain bottles.

After purging, move the Crystal Violet, Grams Iodine, and Safranin cannulas into the Decolorizer bottle.

**<u>NOTE</u>**: If the 1,200 reagent kit cycles have depleted and a new reagent kit is being installed after performing the Scrub, then use the remaining decolorizer in the Decolorizer bottle.

**NOTE**: If a new reagent kit is **not** being installed after the Scrub, **do not** use the one gallon

Decolorizer bottle. Instead, a system cleaner bottle (Cat. no. AGS-SC-4000) must be used. Otherwise, the one gallon decolorizer bottle will be compromised with stain.

Select **PRIME STAIN LINES** to prime the system cleaner into the reagent lines.

Select **RUN SCRUB CYCLE** to begin the scrub process sequence. This process takes roughly <u>15</u> minutes.

Select **EXIT SCRUB** after the scrub cycle is complete to initiate a purge cycle to empty cleaner from the stain lines.

After purging, remove the reagent cannulas from the cleaner and wipe off the reagent straws with an alcohol pad before returning the three stain lines to their respective stain bottles.

Select **PRIME STAIN LINES** to prime stains into the line. Once priming is complete, the Run Menu is displayed and the unit is ready for use. Also, refer to Section 11.3.2.2 for further guidance with the Scrub cycle.

Do not run the scrub cycle if the unit is not draining properly. This may cause a major overflow. Call QuickSlide<sup>™</sup> at 1-800-266-2222, ext. 5598 for any questions regarding the scrub procedure.

#### **10.5 Bleach Procedure**

**<u>NOTE</u>**: The bleach procedure for the GramPRO 80 is required once every eight days. If the instrument has been accidentally contaminated by an external source, this procedure can be used to eliminate the contamination.

From the Main Menu select the **RUN** option.

Select **CLEAN UNIT** Menu. Notice the due date and remaining cycle count displayed at the bottom of the screen.

#### Select RUN BLEACH CYCLE.

Select **PURGE RINSE LINES** to empty the water supply back into the water container.

After purging, using the same water container, make a 10% bleach solution in at least 300mL of deionized water. Preparing the bleach solution inside of the original water container will also disinfect the water container. If a separate container is used to supply the 10% bleach, be sure to thoroughly disinfect the original water container before reusing it.

Select **PRIME RINSE LINES** to prime the 10% bleach into the rinse lines.

The instrument will now perform a bleach process to disinfect and scrub the water supply lines and cuvettes. This process takes roughly <u>10</u> minutes. After the procedure is complete, refill your water container with deionized water and add iodine disinfectant per section 10.6 and 10.7.

Select **DISINFECTED** to confirm that the iodine disinfectant has been added to the water supply container.

Now return the rinse lines to the deionized water container.

Select **GO TO PRIME** to prime the supply lines with water.

A wash procedure is automatically run to rinse out any residual bleach solution from the instrument. When it is complete, the display will return to the Clean Unit Menu.

#### **10.6 Deionized Water Disinfectant**

In order to prevent contamination, the deionized water must have stabilized gram's iodine disinfectant (Cat. no. AGS-DI-1000) 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.

#### **10.7 Refilling the Water Supply**

The DI water gauge monitors the deionized water supply in the water container. The water can be refilled at any time, but the system will also present warning notifications in the RUN mode when the water supply is getting low.

**<u>NOTE</u>**: The system must be properly calibrated before the DI water gauge measures the water level accurately. See section 11.4.8 and section 12.6. Also, the new water supply must be disinfected using iodine before continuing use. See section 10.6.

To refill the water supply, do the following:

- Remove both the water cannula and water gauge from the water container and place them onto a fresh paper towel or alcohol swab.
- Fill the water container with fresh deionized water and mix in the drops of Gram's lodine (see section 10.6).
- Sanitize the water cannula and water gauge using an alcohol swab and place them both 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, complete a **PURGE & PRIME** from the Run Menu after refilling the water supply and prior to continuing slide processing.

**<u>Note</u>:** 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 cannulas. Be sure to add the drops of Gram's lodine into the separate sterile water container full of deionized water, before pouring it into the original water container.

#### **10.8 Maintenance Summary**

Frequency		Maintenance Procedures	
Every time th	e deionized	• Supplement the fresh deionized water with drops of Gram's lodine	
water is refille	ed (or every 20	disinfectant (see section 10.6).	
days)			
Weekly		• Run a <b>Bleach Cycle</b> (see section 10.5).	
Every 15	Every 600	• Run a Wash Cycle (see section 10.3).	
days	slides		
Monthly	Every 1,200	• Run a Scrub Cycle (see section 10.4).	
slides		• Clean visible residue from the horizontal threaded screw that moves the	
		gripper arms. Apply three small drops of oil and wipe away any excess (see	
	and	section 10.1).	
		• Clean any residue from the gripper arms. Apply one drop of oil on each of	
	With each	the two pins of the arm (see section 10.1).	
new reagent		• Swab the <b>cuvettes</b> followed by a Wash Cycle (see section 10.1).	
kit • Swab		• Swab the load detection sensors (see section 10.1).	
Six Months	Every 12,000	• Replace the orange <b>pump tubes</b> (see section 10.2).	
	cycles		

Please utilize the Maintenance Logs to make sure these periodic tasks are completed as scheduled. See section 17.0.

#### **11.0 SYSTEM SOFTWARE OPERATION**

This chapter provides a detailed description of the operator interface methods of the GramPRO 80 system.

#### 11.1 Software Operation Overview



#### Figure 11.1 – LCD screen lay-out

An LCD touch-screen device is the basis for a menu-driven system of message displays and operator commands. Figure 1 details the general lay-out and usage of the video screen. The upper left portion of the screen may contain up to 10 menu command buttons. Only active buttons are displayed. An optional keypad for numeric entries may appear in the upper right portion, if appropriate for the current menu. Just above the keypad, in red, the entered digits are displayed. The lower left portion may display normal operational status information in gray text or error messages in red text as needed. The lower right area displays operating parameters and the system date and time.

#### 11.2 Main Menu



Figure 11.2 – Main Menu

The Main Menu is the top-level menu of the system as shown in Figure 11.2 above.

Press RUN for access to automated Gram stain operations.

Press **SET-UP** for instrument calibration and parameter set-up menus.

Press **SELF TEST** to initiate a complete unit self-diagnostic and priming procedure.

Press **SERVICE** to access "service mode" operations (these procedures are accessible to qualified service personnel only).

Press **SHUT DOWN**, and then confirm by pressing **SHUT DOWN** again, to initiate the power down preparation procedure which purges all fluid lines and positioned the gripper assembly for shipment.

#### 11.3 RUN Menu



Figure 11.3 – Run Menu

The Run Menu contains the command buttons to initiate automated Gram stain operations. Select SHORT, MEDIUM, or LONG stain delays by pressing the corresponding button to begin the automated slide staining process and proceed to the PROCESS SLIDES Menu (See Section 11.3.1). Select CLEAN UNIT button to proceed to the Cleaning Menu (see section 11.3.2).

At this menu, command buttons are also available to start procedures to:

**PURGE AND PRIME** – Press this button to run a procedure to purge and prime all fluid pumps and lines.

**PURGE** – Press this button to run a procedure to purge all fluids from the unit. Reagents and water are back-flushed into their supply containers, and all cuvettes and waste lines are emptied into the waste container.

MAIN MENU – Press this button to return to the Main Menu.

#### 11.3.1 Process Slides Menu

GramPRO 80 Automated Stainer		
*** Process Slides	***	
SUSPEND NEW LOADS SLIDE TRAVEL		
EJECT SLIDES PROCE	ORT SSING	
A = 1565 W = 10507 C = 111 cycles= 486 c1[ei] c2[ei] c3[ei] c4[ei] c5[ei] c6[ei] c7[ei] load-n stat-n IN empty-y OUT full-n cover-closed	k	70% H2Orem,31.3psi Drain Waste, P Wait 2016-10-20 10:02:31

Figure 11.3.1 – Process Slides Menu

The Process Slides Menu is displayed whenever the system is in run mode and provides options to:

**SUSPEND NEW LOADS** – Press this button to inhibit loading new slides into cuvette #1. However, processing continues for any slides already in cuvettes.

**PAUSE SLIDE TRAVEL** – Press this button to disable any load, cuvette-to-cuvette, or unload slide transfers.

**EJECT SLIDES** – Press this button to move completed slides to the right, out of the dog-house.

**ABORT PROCESSING** – Press this button to abort all active processing and exit run mode.

While in run mode the GramPRO 80 advances a slide present in the In-Feed screw to the load position and then loads the slide into cuvette #1 or #2 for crystal violet staining. A slide placed into the stat load drawer is given load priority over slides in the In-Feed screw, and is the next slide inserted into the processing stream. Upon step #1 completion, the slide is moved to either cuvette #3 or #4 for Gram's iodine staining, after which the slide is moved to cuvette #5 for decolorizing. The final step is to move the decolorized slide to cuvette #6 or #7 for safranin counter-staining. After counter-staining, the slide is transferred to the Out-Feed screw to be air dried, and the process is complete. This cycle is repeated as long as slides are found in the stat drawer or the In-Feed screw.

#### 11.3.1.1 Process Slides / Run Mode Messages

GramPR	O 80 Automated Stainer		
*** Decolo	Error Recovery	***	
Calibration A= 1042 V slides: c[y] load-y sta	Error N=3284 C=1076 cycles=8253 c2[n] c3[y] c4[n] c5[y] c6[n] c7[n] t-n IN empty-n OUT full-n cove	] r-closed	70% H2Orem,31.3psi Drain Waste, P Wait 2016-10-20 10:02:31

Figure 11.3.1.1 – Process Slides / Run Mode Messages Menu

If a Warning, Alert, or Error event occurs while in run mode the Recovery Menu displays a description and provides an option to access repair functions for the event encountered. For some Error and Alert events slide transfer operations are suspended until the event is acknowledged and repaired, but staining procedures within a cuvette continue as normal. All processing continues as normal for Warning events as they do not require any immediate attention. A **HELP** button may appear in the upper right corner of the screen. **HELP** provides on-screen access to the trouble-shooting and corrective actions section of this manual for the error encountered. After reviewing the help information provided, simply press the **EXIT HELP** button to return to GramPRO 80 system operations to resolve the error condition.

#### 11.3.1.2 Run Mode Message Table

The following table summarizes the warnings, alerts, and errors that may be automatically diagnosed and flagged by the GramPRO 80 operating software. When these occur, the GramPRO 80 will display a message in **BLUE** (informative) or **RED** (more serious alerts and errors) lettering describing the condition encountered. An audible alert (BEEP-BEEP-BEEP) may also accompany the message, and may be repeated periodically until action is taken to resolve the problem. Additionally, a **HELP** button may be displayed in the upper right corner of the screen when an error occurs. This button provides access to on-screen display of trouble-shooting and corrective action suggestions for the

error encountered. **EXIT HELP** then dismisses the help information and resumes system operations. The following table includes the displayed messages and a section reference for descriptions of the underlying causes and suggested corrective actions. Please refer to the indicated chapter of the Operational Trouble-Shooting Guide in Section 12 for more information about Run Mode Messages, and possible causes and solutions.

Description:	Trouble-Shooting Guidelines:	On-Screen HELP:
Provided Warnings		
Cover OPEN	Sec. 12.1	N
LOAD Slide Disabled	Sec. 12.2	N
Slide MOTION Disabled	Sec. 12.3	N
Out-Feed EJECT Busy	Sec. 12.4	N
Scrub REQUIRED	Sec. 12.5	N
SCRUB Soon	Sec. 12.5	N
WASH Soon	Sec. 12.5	N
<u>Alerts</u>		
DI Water Bottle Volume Low	Sec. 12.6	N
Waste Container FULL	Sec. 12.7	N
Reagent Kit Exhausted	Sec. 12.8	N
Tubing Cycles Exhausted	Sec. 12.9	N
Load Position Alert	Sec. 12.10	N
Out-Feed Full Alert	Sec. 12.11	N
<u>Errors</u>		
Calibration Error	Sec. 12.12	Y
Cuvette Stainer Error-Cuv <u>N</u>	Sec. 12.13	Y
Air Pressure LOW Error	Sec. 12.14	Y
Slide Transfer Error	Sec. 12.15	Y
Cuvette <u>N</u> Occupied Error	Sec. 12.16	Y
X Home Operation Error	Sec. 12.17	Y
Z Home Operation Error	Sec. 12.18	Ý

#### 11.3.2 Clean Unit Menu

GramPRO 8	HARDY DIAGNOSTICS			
***	Clean Unit	: Menu	***	
Run Wash	Cycle			
		Set Clean	Interval	
Run Bleac	n Cycle			
Run Scrub	Cycle	RUN M	lenu	
cycles rem	Wash 600	Bleach	Scrub 1200	
due date	2016-11-05	2016-11-19	2016-11-20	
time	12:31	11:41	12:31	70% H2Orem,31.3psi Drain Waste, P Wait
Interval(days)	15	30	30	2016-10-20 10:02:31

Figure 11.3.2 – Clean Unit Menu

The Clean Unit Menu provides options to:

**RUN WASH CYCLE** – Press this button to initiate the GramPRO 80 Wash Cycle (see section 11.3.2.1). During WASH, the cuvettes are cleaned by repeated water rinses.

**RUN BLEACH CYCLE** – Press this button to initiate the GramPRO 80 Bleach Cycle. During BLEACH, the cuvettes and water rinse lines are cleaned with bleach solution. Instructions are given to switch the water supply lines to a bleach solution (refer to section 10.5). Upon completion of the bleach cycle, instructions are given to switch the supply lines back to the water rinse container.

**RUN SCRUB CYCLE** – Press this button to initiate the GramPRO 80 Scrub Cycle. Instructions are given to switch the reagent supply lines to the Cleaner bottle, after which the cuvettes are scrubbed by repeated rinses with the cleaning solution. Upon scrub completion, instructions are given to switch the supply lines back to the reagent bottles. (See section 11.3.2.2 and section 10.4)

SET CLEAN INTERVAL – Press this button to access the Clean Interval Menu (see section 11.3.2.3).

**RUN MENU** – Press this button to return to the Run Menu.

The Wash, Scrub, and Bleach procedures require the cuvettes to be empty, and require sufficient available waste container volume to receive the waste fluids produced. If these conditions are not met, error messages are displayed and the options are inaccessible.

#### 11.3.2.1 Wash Cycle Process

During the **WASH** cycle each of the cuvettes is cleaned by repeated water rinses. The approximate time remaining in the process is displayed on the screen. Upon completion, the Clean Unit Menu is presented (refer to section 10.3 for wash procedure.)

#### 11.3.2.2 Scrub Cycle Process

During the **SCRUB** cycle, the internal surfaces of reagent cannulas, pumps, ports and cuvettes are cleaned. Follow the prompts in the bottom left corner of the screen during the Scrub cycle.

#### 11.3.2.2.1. Pre-Scrub Purge Stain Prompt

GramPRO	80 Automated	Stainer	HARDY
***	Scrub Unit Men	u ***	
Purge St	ain Lines		
	_		
		Exit SCRUB	
Press Purge S	tain Lines button		
to prepare fo	r the SCRUB process		70% H2Orem 31 3nsi
or press Exit	SCRUB		Drain Waste, P Wait
or press Exits	JOROD		2010-10-20 10.02.51

The first requirement before running the Scrub Cycle is to purge the stains from the supply lines back into the reagent bottles.

**PURGE STAIN LINES** – Press the PURGE STAIN LINES to initiate the PURGE operations. Reagent fluids are then back-flushed into the supply bottles, leaving the lines drained and empty.

**EXIT SCRUB** – Press this button to return to the Run Menu.

#### 11.3.2.2.2 Pre-Scrub Prime Cleaner Prompt

GramPRO 80 Autor	nated Stainer		HARDY DIAGNOSTICS
*** Scrub L Prime Stain Lines	Jnit Menu	***	
	Exit SCRUB		
Move CV, GI & SAF supply & press Prime Stain Lines to continue the SCRUB pr or press Exit SCRUB	lines to CLEANER button ocess		70% H2Orem,31.3psi Drain Waste, P Wait 2016-10-20 10:02:31

Figure 11.3.2.2.2 – Pre-Scrub Prime Cleaner Prompt

Next the stain supply lines must be moved from the reagent bottles and place into the one gallon Decolorizer bottle (if the reagent kit is empty) or a System Cleaner bottle where the lines will be primed with Cleaner.

**PRIME STAIN LINES** – Press to initiate the PRIME operations.

**EXIT SCRUB** – Press this button to return to the Run Menu.

#### 11.3.2.2.3 Run Scrub Cycle Prompt



Figure 11.3.2.2.3 – Run Scrub Cycle Prompt

The instrument is now ready to run the Scrub Cycle.

**RUN SCRUB CYCLE** – Press this button to initiate the SCRUB operations.

**EXIT SCRUB** – Press this button to return to purge the Cleaner from the supply lines and proceed to the Scrub Complete Menu (Section 11.3.2.2.5).

#### 11.3.2.2.4 Scrub Unit Process

GramPRO 80 Automated Stainer	HARDY DIAGNOSTICS
*** One Moment Please ***	
Scrub Unit in process	
	70% H2Orem 31 3pri
243 seconds remaining	Drain Waste, P Wait
	2016-10-20 10:02:31

Figure 11.3.2.2.4 – SCRUB Unit in process

During the **SCRUB Unit** cycle each of the cuvettes is cleaned by repeated cleaner and water rinses. The approximate time remaining in the process is displayed on the bottom left side of the screen. Upon completion, the **RUN SCRUB CYCLE** prompt is presented again, enabling running another Scrub Cycle if desired.

#### 11.3.2.2.5 Scrub Complete Menu

GramPRO 80 A	utomated Stainer		
*** Scru Go to Prime	Ib Complete Menu	*** It Kit	
Reagent lines are no You may move the l the reagent bottles go register a new Re	ow evacuated ines back to and PRIME or eagent Kit.		70% H2Orem,31.3psi Drain Waste, P Wait 2016-10-20 10:02:31

Figure 11.3.2.2.5 – Scrub Complete Menu

After running the Scrub Cycle the Cleaner fluid is purged from the lines back into the Cleaner bottle. A new Reagent Kit may be registered if desired. To do so, simply choose New Reagent Kit. The stain supply lines must be cleaned, placed back in the reagent bottles, and primed with reagents for normal operations.

GO TO PRIME – Press to proceed to the Post-Scrub Prime Reagents Prompt (section 11.3.2.2.6).

**NEW REAGENT KIT** – Press to register a new Reagent Kit (section 11.4.2.1).

#### 11.3.2.2.6 Post-Scrub Prime Reagents Prompt

GramPRO 80 Automated Stainer	
*** Scrub Unit Menu *** Prime Stain Lines	
Exit without Prime	
Move CV, GI and SAF Lines to Reagents and press Prime Stain Lines button to complete the SCRUB process or press Exit SCRUB	70% H2Orem,31.3psi Drain Waste, P Wait 2016-10-20 10:02:31

Figure 11.3.2.2.6 – Post-Scrub Prime Reagents Prompt

After running the Scrub Cycle and purging the Cleaner fluid back into the Cleaner bottle, the stain supply lines must be cleaned, placed back in the reagent bottles, and primed with reagents for normal operations.

**PRIME STAIN LINES** – Press to initiate the PRIME operations after cleaning the stain supply cannulas and placing them into their respective reagent bottles.

**EXIT WITHOUT PRIME** – Press to return directly to the Run Menu WITHOUT priming the stain lines. This should only be done when the machine is being shut down before shipment.



CAUTION – stain lines must be primed before running GramPRO 80 staining operations.

#### 11.3.2.3 Clean Interval Menu



Figure 11.3.2.3 – Clean Interval Menu

The Clean Interval Menu provides commands to set the elapsed day intervals for Wash and Scrub notification messages. The Reset due date buttons allow alteration of the next cleaning due dates. To change an interval, first enter the number on the keypad and then press the desired change interval button. The available operations are described below:

**Set Wash Interval** – Press to set the Wash needed notification interval to the entered number of days.

**Set Bleach Interval** – Press to set the Bleach needed notification interval to the entered number of days.

**Set Scrub Interval** – Press to set the Scrub needed notification interval to the entered number of days.

**Reset Wash due date** – Press to reset the next Wash needed notification date to today + the specified interval.

**Reset Bleach due date** – Press to reset the next Bleach needed notification date to today + the specified interval.

**Reset Scrub due date** – Press to reset the next Wash needed notification date to today + the specified interval.

**Exit** – Press to return to Clean Menu.

#### 11.4 SET-UP command button



Figure 11.4 – Set-Up Menu

The Set-Up Menu provides access to all user configurable settings. Selection of the set-up option (by pressing the menu button) proceeds to the menu for that option as listed below:

Stain Delays – Press to proceed to the Stain Delay Menu (see section 11.4.1).

Consumables – Press to proceed to the Consumables Menu (see section 11.4.2).

**Date / Time** – Press to proceed to the Date / Time Menu (see section 11.4.3).

Test Decolorizer – Press to proceed to the Decolorizer Sensor Test Menu (see section 11.4.4).

Speaker Volume – Press to proceed to the Adjust Volume Menu (see section 11.4.5).

Idle Delays – Press to proceed to the Idle Delays Menu (see section 11.4.6).

Soak Delays – Press to proceed to the Soak Delays Menu (see section 11.4.7)

DI Water Gauge – Press to proceed to the DI Water Sensor Calibration Menu (see section 11.4.8).

**Waste Container** – Press to proceed to the Waste Container Menu for repair options (see section 11.4.9).

Main Menu – Press to return to the Main Menu.

#### 11.4.1 Stain Delays Menu



Figure 11.4.1 – Stain Delays Menu

The Stain Delays Menu provides commands to set the stain soak times for reagent in each of three sets of delays: Short, Medium and Long Delays. The available operations are described below:

Select Next Set – Press to alternate the selected set among Short, Medium and Long Delays.

**CV Delay** – Press to set the selected set's Crystal Violet soak time to the keypad numeric entry (in seconds).

**GI Delay** – Press to set the selected set's Gram's lodine soak time to the keypad numeric entry (in seconds).

**SAF Delay** – Press to set the selected set's Safranin soak time to the keypad numeric entry (in seconds).

**Set Auto Retries** – Press to set the number of automatic error retries for Stain Errors (before operator notification).

**Set Manual Retries** – Press to set the maximum number of operator initiated manual retries for Stain Errors.

**Save Stain Delays** – Press to permanently save the currently displayed delays (changes will be lost without saving).

**Exit** – Press to return to Set-Up Menu.

#### 11.4.2 Consumables Menu



Figure 11.4.2 – Consumables Menu

The Consumables Menu provides access to the registration menus for Reagent and Tubing Kits. Select the desired menu by pressing the corresponding button. Press Exit to return to the Set-Up Menu.

#### 11.4.2.1 Reagent Kit Registration Menu



Figure 11.4.2.1 – Reagent Kit Registration Menu

The Reagent Kit Registration Menu allows registration of a new Reagent Kit. In turn, enter each of the five numeric values associated with the kit (lot #, pack #, expiration day, month, and year) on the keypad and then press the corresponding identifier button to enter the value. Once the correct registration data appears in the lower left portion of the screen, press the "**Register Kit**" button. The reagent kit is now being registered and a new allotment of reagent processing cycles is available. Press Exit to return to the Main Menu.

#### 11.4.2.2 Tubing Kit Registration Menu



Figure 11.4.2.2 – Tubing Kit Registration Menu

The Tubing Kit Registration Menu allows registration of a new Tubing Kit. In turn, enter the batch number and the serial number associated with the kit on the keypad and then press the corresponding identifier button to enter the value. Once the correct registration data appears in the lower left portion of the screen, press the "**Register Kit**" button. The tubing kit has now been registered and a new allotment of processing cycles is available. Refer to section 10.2 for instructions as to how to install the new tubing. Press Exit to return to the Main Menu.

#### 11.4.3 Date / Time Menu



Figure 11.4.3 – Date / Time Menu

The Date / Time Menu provides commands to set the GramPRO 80 system clock. Enter the digits of the desired item on the keypad and then press the identifier button to "latch" the entered value. The date / time display in the lower right corner will update to reflect the new date and time. Press Exit to return to the Set-Up Menu.

#### 11.4.4 Test Decolorizer Menu

![](_page_42_Figure_1.jpeg)

Figure 11.4.4 – Decolorizer Sensor Test Menu

The Decolorizer Sensor Test Menu provides command buttons for operations related to the decolorizer sensor. The available operations are described below:

**Calibrate Wet** – Press to run a calibration cycle of the measurement system with the chamber filled with fluid.

**Calibrate Dry** – Press to run a calibration cycle of the measurement system with the chamber filled with air.

Calibrate Both – Press to run a calibration cycle of both wet and dry conditions.

**Initialize Sensor** – Press to run an initialization cycle to prepare the Decolorizer Sensor for operations.

**Purge Decolorizer** –Press to run a procedure to evacuate the cuvette and waste lines in the waste container, and back-flush decolorizer from the supply lines into the decolorizer container.

**Purge and Prime Dec'r** – Press to run a Purge procedure, and then primes the decolorizer supply line to the cuvette.

Turn LED On (Off) – Press to manually control the LED light source in the decolorizer chamber.

**Exit** – Press to return to the calling Menu.

#### 11.4.5 Speaker Volume Menu

![](_page_43_Figure_1.jpeg)

Figure 11.4.5 – Speaker Volume Menu

The Speaker Volume Menu provides commands to adjust and test the speaker volume. To hear a test BEEP from the speaker, press the "Sound Tone" button. To adjust, enter a numeric value on the keypad and then press one of: 1) "**Set Volume**" to set the volume to the level entered; 2) "**Adjust UP**" to increase the volume by the entered amount; or 3) "**Adjust DOWN**" to decrease the volume by the entered amount. Press Exit to return to the Set-Up Menu.

#### 11.4.6 Idle Delays Menu

![](_page_44_Figure_1.jpeg)

Figure 11.4.6 – Idle Delays Menu

The Idle Delays Menu provides commands for setting the various delay times in the GramPRO 80 system. Enter the digits of the desired item on the keypad and then press the identifier button to "latch" the entered value. The display in the lower left corner will update to reflect the new delay time. The available operations are:

**Run Exit Delay** – "Run mode" will exit back to Main Menu following this amount of IDLE time. **Auto Eject Delay** – Processed slides will be ejected from the dog-house following this amount of IDLE time.

**Stir Delay** – The STIR procedure will run following this IDLE time delay (when not in run mode). **Prime All Delay** – The PRIME ALL procedure will run following this IDLE time delay (when not in run mode).

**Auto Eject Slots** – Number of slide positions to move processed slides to the right for Auto Eject. **Manual Eject Slots** – Number of slide positions to move processed slides to the right for Manual Eject.

Save Delays and Exit – Permanently save the displayed Delay times and return to the Set-Up Menu.

#### 11.4.7 Soak Delays Menu

![](_page_45_Figure_1.jpeg)

Figure 11.4.7 – Soak Delays Menu

The Soak Delays Menu provides commands for setting the Soak delay times in seconds for the Wash and Scrub procedures in the GramPRO 80 system. Enter the digits of the desired item on the keypad and then press the identifier button to "latch" the entered value. The display in the lower left corner will update to reflect the new soak delay time. The available operations are described below:

Set Wash Soak – Set the Wash Soak time to the entered number of seconds. Set Scrub Soak – Set the Scrub Soak time to the entered number of seconds Save Soak Delays – Permanently save the displayed soak delay times. Exit – Return to the Set-Up Menu.

#### 11.4.8 DI Water Sensor Calibration Menu

![](_page_46_Figure_1.jpeg)

Figure 11.4.8 – DI Water Calibration Menu

<u>Calibrating the DI Water Sensor should be done if changing the SIZE or VOLUME of the</u> <u>deionized water container.</u> The DI Water Calibration Menu provides command buttons for operations related to the DI water sensor. The available operations are described below:

**Calibrate Empty** – Press to run a calibration cycle of the measurement system with the tube exposed to atmosphere.

**Calibrate Full** – Press to run a calibration cycle of the system with the tube submerged in a full DI Water container.

Update Current – Press to read the measurement sensor and update the display.

Drain All Cuvettes – Press to run a procedure to evacuate all cuvettes into the waste container.

**Purge Rinse Lines** – Press to run a procedure to evacuate all cuvettes and waste lines in the waste container, and back-flushes DI water from the supply lines into the water container.

**Prime Rinse Lines** – Press to prime the DI water supply lines to the cuvettes.

Exit – Press return to the Main Menu.

#### 11.4.9 Waste Container Menu

![](_page_47_Figure_1.jpeg)

Figure 11.4.9 – Waste Container Menu

The Waste Container Menu provides command buttons for operations related to the Waste Container tracking and management system. <u>NOTE</u>: When setting the container size, the number entered must be converted to milliliters (mL). To avoid overfilling the waste container, always enter a volume that is roughly 200mL less than the actual volume that the waste container can hold.

The available operations are described below:

**Empty Container** – Press to reset the available Remaining Volume equal to the Container Volume.

**Set Container Size** (ml) – Press to reset the Container Volume equal to the keypad numeric entry volume in milliliters.

**Exit** – Press to return to the Set-Up Menu.

#### 11.5 Self-Test command button

Pressing the Self-Test command button will initiate a self-test procedure of the GramPRO 80. This procedure includes checks and tests of the complete GramPRO 80 system to confirm operational readiness. A brief outline of the operations included follows:

- 1) Confirm Reagent Kit availability (not expired or consumed)
- 2) Confirm Tubing Kit availability (not expired or consumed)
- 3) Cycle Gripper Arms open, then closed
- 4) Move transfer actuator down slightly and then to fully raised position (z home)
- 5) Move transfer actuator right slightly and then to extreme left end position (x home)
- 6) Confirm operating Air Pressure within limits
- 7) Confirm DI Water availability
- 8) Drain all 7 cuvettes
- 9) Purge all Reagent and Rinse supply lines (back-flush into supply bottles)
- 10) Prime all Reagent supply lines to cuvettes
- 11) Prime all Rinse supply lines to cuvettes
- 12) Drain all 7 cuvettes
- 13) Confirm all 7 cuvettes are dry (fluid detector test)
- 14) Confirm all 7 cuvettes are empty (no slides present)
- 15) Confirm Out-Feed screw has available slots (last 7 not occupied)
- 16) Initiate In-Feed travel-to-load-position if a slide is available

If no errors are encountered by the self-test procedure the Main Menu is displayed and the system is ready to process slides. Otherwise, the Self-Test Review Menu is displayed containing information about any errors. Refer to section 11.5.1 for details about self-test errors.

#### 11.5.1 Self-Test Review Menu

![](_page_49_Figure_1.jpeg)

Figure 11.5.1 – Self Test Review Menu

Any of the seven View Error option buttons may be displayed, depending on the error conditions encountered by the Self-Test procedure. The available options are described below:

**View Consumables Error(s)** – Press to display Low Air Pressure, Reagent Kit, Tubing Kit, and/or DI Water error messages.

**View Motor Error(s)** – Press to display Z-axis, X-axis, In-Feed, and/or Out-Feed motor HOME error messages.

View Pump Error(s) – Press to display Drain, Purge, and/or Prime error messages.

View Wet Cuvette Error(s) – Press to display Wet Cuvette error messages.

View Slide Error(s) – Press to display Slide Present in cuvette error messages.

View In-Feed Error(s) – Press to display In-Feed failure to correctly load error messages.

View Out-Feed Error(s) – Press to display Out-Feed Full error messages.

**Run Self-Test** – Press to initiate the Self-Test procedure.

Main Menu – Press to proceed to the Main Menu.

#### 11.6 Service Mode Access Menu

![](_page_50_Figure_1.jpeg)

Figure 11.6 – Service Mode Access Menu

The Service Mode Access Menu provides access to the Update Software Menu or alternately, a password may be entered in order to place the system into **SERVICE MODE**. Service Mode access is restricted to or under the guidance of qualified service personnel only. Please call QuickSlide<sup>™</sup> Technical Support for guidance at (800)266-2222, ext. 5598.

#### 11.6.1 Software Update Menu

![](_page_51_Figure_1.jpeg)

Figure 11.6.1 – Software Update Menu

The Software Update Menu provides command options to update the various pieces of the GramPRO 80 instrument software system. Software updates can only be accomplish via a portable USB memory device. Please call QuickSlide<sup>™</sup> Technical Support for guidance or software updates at (800)266-2222, ext. 5598.

Exit – Press to return to the Main Menu.

#### **12.0 TROUBLE-SHOOTING GUIDE**

This section is intended as an aide for understanding and resolving warnings, alerts, and errors that may be automatically diagnosed and flagged by the GramPRO 80 operating software. When these occur, the GramPRO 80 will display a message in BLUE (warnings) or RED (alerts and errors) letters describing the condition encountered. An audible alert (BEEP-BEEP-BEEP) may also accompany the message, and may repeated periodically until action is taken to resolve the problem. Additionally, a HELP button may be displayed in the upper right corner of the screen when an error occurs. This button provides access to on-screen display of trouble-shooting and corrective action suggestions for the error encountered. EXIT HELP then dismisses the help information and resumes system operations. The following sections include the displayed messages, descriptions of the underlying causes and suggested corrective actions. For information about a particular notification, please refer to the section noted in this summary table:

Description	Trouble-Shooting Guidelines	On-Screen HELP Provided
Warnings		
Cover OPEN	Sec. 12.1	Ν
LOAD Slide disabled	Sec. 12.2	N
Slide MOTION disabled	Sec. 12.3	N
Out-Feed EJECT Busy	Sec. 12.4	N
Scrub REQUIRED warning	Sec. 12.5	Ν
SCRUB soon warning	Sec. 12.5	Ν
WASH soon warning	Sec. 12.5	N
Alerts		
DI Water Bottle Volume Low	Sec. 12.6	N
Waste Container FULL	Sec. 12.7	N
Reagent Kit Exhausted	Sec. 12.8	N
Tubing Cycles Exhausted	Sec. 12.9	N
Load Position Alert	Sec. 12.10	N
Out-Feed Full Alert	Sec. 12.11	N
Errors		
Calibration Error	Sec. 12.12	Y
Cuvette Stainer Error-Cuv <u>N</u>	Sec. 12.13	Y
Air Pressure LOW Error	Sec. 12.14	Y
Slide Transfer Error	Sec. 12.15	Y
Cuvette <u>N</u> Occupied Error	Sec. 12.16	Y
X Home Operation Error	Sec. 12.17	Y
Z Home Operation Error	Sec. 12.18	Y

#### 12.1 Cover OPEN Warning

Cover Open
(no button, processing automatically resumes when fixed)
In-Feed Screw Cover Door is Open

Discussion:

To ensure ease of alignment when loading slides into the In-Feed Screw the GramPRO 80 unit pauses any advance to the load position while the Cover Door is open, and displays this notification message. To resume normal processing simply close the Cover Door.

Possible Causes:

- In-Feed Cover Door is Open.
- In-Feed Cover Door position sensor failure. Corrective Actions:
- Close Cover door.

If a solution is not found call Tech Service (800-266-2222, ext. 5598) for further assistance.

#### 12.2 Load Slide Disabled Warning

Displayed Message:	LOAD Slide disabled
Recovery Button:	Resume Loading
Event Condition:	Suspend New Loads button was pressed

Discussion:

The **Suspend New Loads** command button allows the operator to pause new slide loading when desired. Press the **Resume Loading** button to resume normal processing.

Possible Causes:

• Suspend New Loads button was pressed.

Corrective Actions:

• Press Resume Loading

#### 12.3 Slide Motion Disabled Warning

Displayed Message:	Slide MOTION disabled
Recovery Button:	Resume Slide Travel
Event Condition:	Pause Slide Travel button was pressed

Discussion:

The **PAUSE SLIDE TRAVEL** command button allows the operator to pause slide travel from station to station when desired. Press the **RESUME SLIDE TRAVEL** button to resume normal processing.

Possible Causes:

• **PAUSE SLIDE TRAVEL** button was pressed.

Corrective Actions:

• Press RESUME SLIDE TRAVEL.

#### 12.4 Out-Feed Eject Busy Warning

Displayed Message:	Out-Feed EJECT Busy
Recovery Button:	
Event Condition:	Out-Feed Eject function already busy

Discussion:

The **EJECT SLIDES** command button allows the operator to advance the Out-Feed Screw when desired to eject processed slides from the housing. This notification message is displayed if the Eject function is already in process.

Possible Causes:

• Out-Feed Eject function already busy.

Corrective Actions:

- No immediate action is required normal processing will continue.
- Await eject completion and press **EJECT SLIDES** if further Out-Feed advance is desired.

#### 12.5 Bleach, Scrub, and Wash Warnings

Displayed Message:	Bleach REQUIRED in days, hrs, mins Bleach REQUIRED, days PAST DUE
	Scrub REQUIRED in cycles Scrub REQUIRED, cycles PAST DUE Scrub Recommended in days, hrs, mins Scrub Recommended, days past due
	Wash Recommended in cycles Wash Recommended, cycles past due Wash Recommended in days, hrs, mins Wash Recommended, days past due
Recovery Button: Event Condition:	Scrub or Wash operation needed soon

Discussion:

The GramPRO 80 recommends periodic automatic cleaning operations. The BLEACH procedure is required every eight days. If the procedure is not run and it becomes past due, the instrument will not enter run mode again until a **BLEACH** cycle is completed. The **WASH** procedure is recommended once for every 600 slides processed or 15 days. The **SCRUB** procedure is required once for every 1,200 slides processed, which coincides with the Reagent Kit replacement interval. If 1,200 slides are not run through the instrument within 30 days, it will recommend a scrub but not require it. These warning notification messages are informational only, and require no immediate action.

Possible Causes:

• WASH, SCRUB, or BLEACH interval almost expired.

Corrective Actions:

- No immediate action required for **WASH**.
- No immediate action required for **SCRUB** unless the procedure has not been run in the last 1,200 cycles.
- Immediate action is required for **BLEACH** when it becomes due.

#### 12.6 DI Water Bottle Volume Low Alert

Displayed Message:	DI Water Bottle Volume Low
Recovery Button:	Refill DI Water
Alert Condition:	DI Water gauge indicates volume below minimum

#### Discussion:

A differential pressure measurement method is used to monitor DI Water availability for the GramPRO 80 unit. Any time the monitored water volume falls below the specified minimum this error notification is presented.

Possible Causes:

- Low DI Water Volume.
- DI Water Gauge sense tube not properly submerged in water bottle.
- DI Water monitor calibration required.

#### Corrective Actions:

After pressing **REFILL DI WATER** to proceed to the **DI Water Sensor Calibration Menu** (section 11.4.8) the following actions may be attempted:

- Check Water supply bottle. If empty, refill bottle with water and Gram's iodine and displayed Percent Water Remaining message in lower right corner of screen should change from red to blue and indicate water is available. Press EXIT and RESUME RUN MODE to continue with normal operations from the point of interruption.
- Check DI Water Gauge sense tube properly submerged in water supply bottle. If not, reposition tube and displayed Percent Water Remaining message in lower right corner of screen should change from red to blue and indicate water is available. Press **EXIT** and **RESUME RUN MODE** to continue with normal operations.
- If water bottle if full, run a new calibration sequence:
  - Remove DI Water Gauge sense tube from bottle.
  - Press CALIBRATE EMPTY to obtain the empty reading.
  - Refill bottle, submerge sense tube to bottom of bottle and press CALIBRATE FULL for full reading.
  - Press **SAVE CALIBRATION** to memorize calibration readings.
- After new calibration, displayed Percent Water Remaining message in lower right corner of screen should change from red to blue and indicate water is available. Press **EXIT** and **RESUME RUN MODE** to continue with normal operations from the point of interruption.
- If a solution is not found call Tech Service (800-266-2222 ext. 5598) for further assistance.

#### 12.7 Waste Container FULL Alert

Displayed Message:	Waste Container FULL
Recovery Button:	Empty Waste
Alert Condition:	Waste container requires emptying

Discussion:

If the Waste Monitoring system is activated, the GramPRO 80 tracks the amount of waste fluid gathered into the waste container. When the accumulated waste volume exceeds the specified maximum this error notification is presented.

Possible Causes:

- High Waste Volume accumulated into container.
- Incorrect total available waste Container Volume specified.

#### Corrective Actions:

After pressing **EMPTY WASTE** to proceed to the **WASTE CONTAINER MENU** (section 11.4.9) the following actions may be attempted:

- If the displayed Container Volume is incorrect for the container in use, enter the correct volume (ml) on the key pad and press SET CONTAINER SIZE. The displayed Percent Waste Full message in the lower right corner should update to reflect the new value.
- If the displayed Container Volume is correct, empty the waste container and press **EMPTY CONTAINER** to update the GramPRO 80 waste accounting. The displayed Percent Waste Full message in the lower right corner should reset to reflect the empty container.
- Press **EXIT** and **RESUME RUN MODE** to continue with normal operations from the point of interruption.

#### 12.8 Reagent Kit Exhausted Alert

Displayed Message:	Reagent Kit Exhausted
Recovery Button:	New Reagent Kit
Alert Condition:	Allotted Reagent Stain Cycles consumed

Discussion:

The GramPRO 80 tracks the number of slide stain operations processed and presents this notification when the Reagent Kit is consumed.

Possible Causes:

• Reagent Kit consumed.

#### Corrective Actions:

After pressing **NEW REAGENT KIT** to proceed to the **REAGENT KIT MANAGEMENT MENU** (Sec 11.4.2.1) the following action is needed:

- Refer to the Registration Sticker on the new Reagent Kit for the following information.
- Enter the Kit Expiration Day on the key pad and press CHANGE EXP DAY.
- Enter the Kit Expiration Month on the key pad and press CHANGE EXP MONTH.
- Enter the Kit Expiration Year on the key pad and press CHANGE EXP YEAR.
- Enter the Kit Lot Number on the key pad and press CHANGE LOT #.
- Enter the Kit Pack Number on the key pad and press CHANGE PACK #.
- Confirm the correct information is displayed in the lower portion of the screen.
- Press **REGISTER KIT**.

- Remove and discard old reagent bottles and insert reagent supply lines into new bottles. *NOTE:* a SCRUB cycle is recommended as soon as practical following the current run.
- Press EXIT and RESUME RUN MODE to continue with normal operations from the point of interruption.

#### 12.9 Tubing Kit Exhausted Alert

Displayed Message:	Tubing Kit Exhausted
Recovery Button:	New Tubing Kit
Alert Condition:	Allotted Tubing Kit Stain Cycles consumed

#### Discussion:

The GramPRO 80 tracks the number of slide stain operations processed and presents this notification when replacement of the Tubing Kit is needed.

Possible Causes:

• Tubing Kit worn – replacement needed.

#### Corrective Actions:

After pressing **NEW TUBING KIT** to proceed to the **TUBING KIT MANAGEMENT MENU** (section 11.4.2.2) the following action is needed:

- Refer to the Registration Sticker on the new Tubing Kit for the following information.
- Enter the Kit Batch Number on the key pad and press CHANGE BATCH #.
- Enter the Kit Serial Number on the key pad and press CHANGE SERIAL #.
- Confirm the correct information is displayed in the lower portion of the screen.
- Press REGISTER KIT.
- Install all replacement pump tubes.
- Press EXIT and RESUME RUN MODE to continue with normal operations from the point of interruption.

#### **12.10 Load Position Alert**

Displayed Message:	Load Position Alert
Recovery Button:	(no button, processing automatically resumes when fixed)
Alert Condition:	Slide inserted incorrectly at the Load Position

#### Discussion:

The GramPRO 80 monitors slides placed in the in-feed screw for proper orientation before attempting to pick up and place the slide into a cuvette. Improper slide loading causes this notification message to be displayed.

Possible Causes:

• Slide inserted incorrectly in the In-Feed Screw.

#### Corrective Actions:

The following action is needed:

- Remove slide from the Load Position and insert correctly into the In-Feed Screw.
- Normal processing of slides from the point of interruption resumes automatically.

#### 12.11 Out-Feed Full Alert

Displayed Message:	Out-Feed Full Alert
Recovery Button:	Retry after FIX
Alert Condition:	Out-Feed sensor indicates screw is FULL

Discussion:

The GramPRO 80 monitors slides contained in the out-feed screw and presents this notification when slides must be removed from the screw.

Possible Causes:

- Out-Feed Screw is full slide removal required.
- Detector light path is blocked or obstructed by external object.

Corrective Actions:

The following action is needed:

- Remove slides from the Out-Feed Screw on the right-hand side of the unit.
- Remove light path obstruction.
- Press RETRY AFTER FIX to resume processing slides from the point of interruption.

#### 12.12 Decolorizer Self-Calibration Error

Displayed Message:	Calibration Error
Recovery Button:	Decolorizer Repair
Error Condition:	Decolorizer Automatic Self-Calibration Failed

#### Discussion:

The GramPRO 80 performs an automatic self-calibration before the decolorization step of every slide run. Both a Dry reference reading and a Wet blank reading are validated to confirm correct decolorizer operation. Should the calibration results fail to meet specified criteria, the operator is notified that corrective action is required by this message.

Possible Causes:

- Decolorizer measurement chamber not primed properly
- · Decolorizer measurement chamber windows excessively dirty
- Decolorizer measurement chamber contains contamination or trash
- Decolorizer reagent supply exhausted
- Decolorizer reagent lines clogged
- Decolorizer reagent pump or pump tube failure
- Decolorizer waste pump or pump tube failure
- Decolorizer LED light source failure

#### Corrective Actions:

After pressing **DECOLORIZER REPAIR** to proceed to the **TEST DECOLORIZER MENU** (section 11.4.4) the following actions may be attempted:

- Check Decolorizer Reagent supply bottle for reagent available.
- Check Decolorizer Reagent supply plumbing for correct connections at bottle and unit.
- Press CALIBRATE BOTH to run a calibration and check result. If "Cal Pass" result, press EXIT to resume from the point of interruption.
- Press **PURGE and PRIME DEC'R** to prime the system. Try **CALIBRATE BOTH** again.

- Press **INITIALIZE SENSOR** to prime the chamber. Try **CALIBRATE BOTH** again.
- Press INITIALIZE SENSOR a second time. Try CALIBRATE BOTH again.
- Check Decolorizer reagent and waste lines are not clogged or leaking.
- Check Decolorizer reagent and waste pumps and tubes are operating correctly.
- Press TURN LED ON and check LED light source turns on.
- Press EXIT, RESUME RUN and then ABORT PROCESSING to end the run.
- Press CLEAN UNIT MENU to try a WASH or SCRUB cleaning cycle.
- If a solution is not found call Tech Service (800-266-2222, ext. 5598) for further assistance.

#### 12.13 Cuvette Stain Error

Displayed Message:	Stain Error- Cuv <u>N</u>
Recovery Button:	Fix Stain Errors - access Stain Error Recovery menu
Error Condition:	Reagent or Rinse dispense volume incorrect

#### Discussion:

The GramPRO 80 employs fluid level detectors on each cuvette to automatically control the volume of fluid dispensed into the cuvette, as the needed volume varies with different sizes of slides. A fill operation that requires a fill volume outside the known minimum to maximum volume limits, or a drain operation that yields a wet cuvette can give rise to this error notification. The displayed message will also include one of these secondary error descriptions:

- Cuvette Dry after MAX Reagent (or Rinse) Fill Steps
- Cuvette Not Wet after Reagent (or Rinse) Fill
- Cuvette not Dry after Drain
- Reagent (or Rinse) Wet out-of-range
- Cuvette Dry out-of-range
- Wet/Dry delta out-of-range

#### Possible Causes:

- Fluid Level Detector sensor blocked or obstructed
- Cuvette <u>N</u> Reagent (or Rinse) supply exhausted
- Cuvette <u>N</u> Reagent (or Rinse) pick-up tubes out of fluid
- Cuvette <u>N</u> Reagent (or Rinse) lines clogged
- Cuvette *N* Reagent (or Rinse) pump or pump tube failure
- Cuvette <u>N</u> Waste pump or pump tube failure
- Cuvette <u>N</u> requires Cuvette Fill Level Calibration

#### Corrective Actions:

- Press Fix Stain Errors to proceed to Stain Error Recovery menu.
- Check labels, sample or obstruction blocking the area 3/4" below the top frosted portion or the outside 1/4" edges of the slide.
- Check DI Water supply available and pick-up tube in fluid.
- Check cuvette <u>N</u> Reagent supply bottle for reagent available and pick-up tube in fluid.
- Check cuvette <u>N</u> Reagent supply plumbing for correct connections at bottle and unit.
- Check cuvette <u>N</u> Rinse (Water) supply plumbing for correct connections at source and unit.
- Check cuvette <u>N</u> Reagent, Rinse and Waste lines are not clogged or leaking.
- Check cuvette <u>N</u> Reagent, Rinse and Waste pumps and tubes are operating correctly.
- Press Fix Cuv <u>N</u> and Continue to RETRY the stain operation after fixing any items listed above.

- Press CV, GI, SAF, or DI Water Purge/Prime to prime reagent or rinse lines.
- Press **Abort Cuv N Slide** and remove slide to abort the stain process for that slide and resume run.
- If a solution is not found press ABORT PROCESSING to exit Run Mode and call Tech Service (800-266-2222, ext. 5598) for help.

#### 12.14 Air Pressure LOW Error

Displayed Message:	Air Pressure LOW Error
Recovery Button:	
Error Condition:	System Air Pressure below Minimum

#### Discussion:

Some components of the GramPRO 80 unit are operated pneumatically. Any time the measured air pressure falls below the specified minimum of approximately 27 PSI this error notification is presented.

Possible Causes:

- Air System Test Port not properly sealed.
- Air Leak present in the system.
- Air Pump failure.
- Air Pressure Gauge failure.

#### Corrective Actions:

The following actions may be attempted:

- Check the Air Test Port (black fitting) on the back of the unit for correct installation of the stopper.
- Check all air line connections and fittings for leaks.
- Confirm air pump operation. The pump should run periodically to maintain air pressure above 20 PSI. (pump running is audible)
- An external gauge may be attached to the Test Port to check pressure.
- After resolving the fault, the system will resume processing from the point of interruption
- If a solution is not found press **ABORT PROCESSING** to exit Run Mode and call Tech Service (800-266-2222, ext. 5598) for further assistance.

#### 12.15 Slide Transfer Error

Displayed Message:	Slide Transfer ERROR from source to destination
Recovery Button:	Retry Transfer or Skip Retry
Error Condition:	Slide Transfer from one station to another failed

#### Discussion:

The GramPRO 80 utilizes optical sensors to detect slides correctly positioned in the many staining stations used for processing slides. The system confirms a slide's correct presence in, or absence from, expected stations at each step along the way. Any deviation from the normal expected positioning sequence triggers this error notification. Upon completion of the transfer attempt, if both the <u>destination</u> and <u>source</u> stations are empty the **Skip Retry** option is provided to allow manual placement of a slide that "missed" the target cuvette somehow. Otherwise, only the Retry **Transfer and ABORT** options are given. The message also indicates which source and destination stations were involved in the failed transfer:

- Slide Transfer ERROR from LOAD to Cuv 1
- Slide Transfer ERROR from LOAD to Cuv 2

- Slide Transfer ERROR from STAT to Cuv 1
- Slide Transfer ERROR from STAT to Cuv 2
- Slide Transfer ERROR from Cuv 1 to Cuv 3
- Slide Transfer ERROR from Cuv 2 to Cuv 4
- Slide Transfer ERROR from Cuv 3 to Cuv 5
- Slide Transfer ERROR from Cuv 4 to Cuv 5
- Slide Transfer ERROR from Cuv 5 to Cuv 6
- Slide Transfer ERROR from Cuv 5 to Cuv 7
- Slide Transfer ERROR from Cuv 6 to Out-Feed
- Slide Transfer ERROR from Cuv 7 to Out-Feed

Possible Causes:

- Gripper failed to grab slide correctly.
- Gripper motion obstructed and failed to travel to source station correctly.
- Gripper failed to extract slide correctly from origination station.
- Gripper motion obstructed and failed to travel to *destination* station correctly.
- Gripper failed to deposit slide correctly in destination station.
- Slide detector optical sensor "view" through slide obstructed.

#### Corrective Actions:

The following actions may be attempted:

- Check for and remove any obstruction (labels?) interfering with Gripper grab action.
- Check for and remove any obstruction interfering with Slide detector optical sensors.
- If both <u>destination</u> and <u>source</u> stations are empty, check for a dropped slide and manually place it into the <u>destination</u> station and press **Skip Retry** to resume normal processing.
- Check for and remove any obstruction interfering with horizontal or vertical transfer motion.
- After resolving a problem, press **Retry Transfer** to resume processing from the point of interruption.
- For errors from the LOAD station, confirm the Gripper opens and closes correctly during the **Retry Transfer** operation. If not, refer to Section 10.1 for Gripper maintenance instructions.

#### 12.16 Cuvette <u>N</u> Occupied Error

Displayed Message:	Cuvette <u>N</u> Occupied ERROR
Recovery Button:	(no button, processing automatically resumes when fixed)
Error Condition:	Slide Transfer attempted to an already occupied station

#### Discussion:

To avoid collisions, the GramPRO 80 always checks that the destination cuvette is unoccupied before moving a slide into the cuvette. If the slide detector indicates the cuvette is not empty a notification is issued, including identification of which cuvette needs to be emptied:

- Cuv 1 Occupied ERROR
- Cuv 2 Occupied ERROR
- Cuv 3 Occupied ERROR
- Cuv 4 Occupied ERROR
- Cuv 5 Occupied ERROR
- Cuv 6 Occupied ERROR
- Cuv 7 Occupied ERROR

Possible Causes:

- Optical slide sensor detector momentarily blocked by an external obstruction. (Maybe a finger or hand got in the way briefly?)
- Slide present in the target cuvette.
- Optical slide sensor detector failure.

Corrective Actions:

The following actions may be attempted:

- Check for and remove a slide from the noted cuvette.
- Check for and remove any obstruction from the optical slide sensor for the noted cuvette.
- After the problem is resolved, processing will automatically resume from the point of interruption.
- If a solution is not found call Tech Service (800-266-2222, ext. 5598) for further assistance.

#### 12.17 X Home Operation Error

Displayed Message:	X Home Operation ERROR
Recovery Button:	Retry after FIX
Error Condition:	Horizontal Axis (X) Motor Failed to find Home Sensor

#### Discussion:

The GramPRO 80 has a HOME sensor for anchoring horizontal axis motion. If the sensor is not detected when expected following a horizontal move, this error notification is presented.

Possible Causes:

- Horizontal motion impeded or obstructed.
- Horizontal axis motor failure.
- Horizontal axis HOME sensor failure.

Corrective Actions:

The following actions may be attempted:

- Check for and remove any impediment or obstruction interfering with horizontal motion.
- Press Retry after FIX for processing to resume from the point of interruption.

#### 12.18 Operation Error

Displayed Message:	Z Home Operation ERROR
Recovery Button:	Retry after FIX
Error Condition:	Vertical Axis (Z) Motor Failed to find Home Sensor

#### Discussion:

The GramPRO 80 has a HOME sensor for anchoring vertical axis motion. If the sensor is not detected when expected following a vertical move, this error notification is presented.

Possible Causes:

- Vertical motion impeded or obstructed.
- Vertical axis motor failure.
- Vertical axis HOME sensor failure.

Corrective Actions:

The following actions may be attempted:

- Check for and remove any impediment or obstruction interfering with vertical motion.
- Press Retry After FIX for processing to resume from the point of interruption.

#### 13.0 Unit Shut Down for Shipping

1-Run the GramPRO 80 system Scrub procedure (from the Main Menu select **RUN / CLEAN UNIT MENU / RUN SCRUB CYCLE**) to clean the unit before moving. Refer to section 10.4. The final PRIME operation at the end of the Scrub procedure should be omitted.

**NOTE:** Recommend using GramPRO 80 Decolorizer or System Cleaner (Cat. no. AGS-SC-4000) for Scrub. After priming, all fluids must be purged from the unit.

2-Remove all orange pump tubes from the pump rollers after the unit has been purged.

3-The unit is now ready for shipping.

#### 14.0 Safety Data Sheets

Safety Data Sheets (SDS) for any associated reagents kits can be found at <u>www.HardyDiagnostics.com</u>.

#### 15.0 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.

#### 16.0 GramPRO 80 Warranty

What Is Covered. Hardy Diagnostics (Seller) represents and warrants to Buyer that all products shipped by Seller to Buyer, as of the date of such shipment, shall conform in all material respect to the specifications last published at www.HardyDiagnostics.com before the time of shipment of the products. SELLER MAKES NO OTHER WARRANTIES TO BUYER, EXPRESS OR IMPLIED, AND HEREBY EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

What Is Not Covered. 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 thereto or 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, or (vi) any other act, or failure to act, not in accordance with the terms and conditions of this warranty by Buyer. SELLER HEREBY EXCLUDES AND IN NO EVENT SHALL BE LIABLE TO BUYER FOR SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS.

For the reliable operation of the QuickSlide instruments, use of the QuickSlide brand of reagents, and for the GramPRO instruments, use of the PROBond slides with superior specimen adhesion, is required. The use of other brands will void this warranty.

**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. Before an instrument warranty expires or is close to expiration, customers 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.

What Hardy Diagnostics Will Do. This warranty provides that Seller will either replace or repair the product upon its return or, alternatively, credit the Buyer's purchase price or a portion of the purchase price for the product upon its return, at Seller's option, and that this remedy is intended to be the sole and exclusive remedy of Buyer.

The liability of Seller 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.

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

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

## 17.0 Maintenance Logs

GramPRO 80 User Maintenance Log															
When re water co every	efilling the ontainer or 20 days	8 Days or Less     15 days or 600 cycles, whichever comes first     30 days or 1,200 cycles whichever occurs first													
Deionized Ioc Disint Proc	Water and dine fectant edure	Blea Proce	ach dure	Wash Cycle		Scrub Procedure		Clean and oil the horizontal threaded screw		Clean and oil the gripper arm		Swab the cuvettes and run a Wash Procedure		Swab the load detection sensors	
Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date	Initials	Date
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	12,000 cycle						
Every 1,200 cycles Every 1,200 cycles or every 6 months whichever occurs first							
Reagent Kit Replacement Tubing Kit Replacement Replacement							
Reagent kit							
Initials Date Lot # Pack/Kit Code #	Expiration Date Initials	Date					
	·						

#### **18.0 Training Checklist**

Trainee Name:

## GramPRO 80 Training Checklist

Refer to the user manual for each item on this checklist. Insert initials for each item trained.

Trainee's Initials

	Specimen Slide Preparation: Section 6.2
	Loading Slides: Section 6.4
	Initiating Run Mode: Section 5.6.3, Section 5.6.4
	Explanation of Stain Processing: Section 6.5
	Explanation of Display During Slide Processing: Section 11.3.1, Section 11.3.1.1
	General Maintenance: Section 10.1
	Registering Reagent Kits: Section 6.7
	Tubing Kit Change: Section 10.2
	Wash Operation: Section 10.3
	Scrub Operation: Section 10.4
	Bleach Operation: Section 10.5
	Deionized Water Disinfectant: Section 10.6
	Refilling the Water Supply: Section 10.7
	Calibrating DI Water Sensor: Section 11.4.8
	Waste Container Management: Section 11.4.9
Trainee Signa	ature: Date:

Trainer Signature:

Date:	