USER OPERATION MANUAL

QUICKSLIDE™ GRAMPRO 1

HARDY DIAGNOSTICS
A Culture of Service™

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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 1. 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. At the end of this user manual, you will find an included Installation Qualification, Operation Qualification, and Performance Qualification (IQ/OQ/PQ) document for your review and records.

The QuickSlide™ Quality Management System

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

Important: Keep this operating manual for future use.

800-266-2222
http://www.HardyDiagnostics.com/
Sales@HardyDiagnostics.com

1.0 Instrument Specifications

Dimensions/Weight	Width 30.5 cm. (12.0 in.) Height 40.6 cm. (16.0 in.) Depth 33.0 cm. (13.0 in.) Weight 12.24 kg. (27.0 lbs.)
Power Requirements	Input: 100-240 VAC, 8-4A, 47-63Hz
Temperature, Ambient Operation	16-32 Degrees C (60-90 Degrees F)
Humidity	0 to 95%, without condensation
Operator Adjustments	Adjustable stain times on both short and long cycles Adjustable sleep mode Adjustable audible sound volume control
Operator Entry	12-key keypad
Standards	IEC-61010-1:2010 (Third Edition) EN55022; CISPR 22:2005/A1: 2005: Class A CFR 47, Part 15, Subpart B, Class A, 2008 ICES-003 Issue 4, 2004 CAN/CSA-CEI/IEC CISPR 22:02, Class A EN55024: 2010 EN 61326-1: 2006
Warranty	One-Year Standard
Symbols	| – Power On O – Power Off  Caution – Refer to marked paragraphs in this manual for details.

2.0 Work Area Requirements

The Reagent Supply Kit (Cat. No. GP1SK) and the container designated for deionized water should be positioned at **the same level** as the instrument. The reagent supply kit should be placed on the left side of the unit. **Do not place reagents above or below the instrument.**

The GramPRO 1 has one tube that drains all of the waste fluids. The GramPRO 1 unit drain line can be placed into a customer designated disposal container to accommodate the waste fluids according to your facility and local regulations.

The GramPRO 1 is pre-installed with a tubing set to connect the instrument to the reagents. Each reagent supply line is equipped with a cannula (rigid tube) to submerge in the reagent supply container. Labels attached to those lines indicate which reagent is to be used with each line. The line labeled as DI Water needs to be immersed in the water supply container to supply the machine with available water (supplemented with Iodine, per **Section 15.5**).

The GramPRO 1 is not to be placed near or under any direct source of bright light, such as under a spotlight, or next to a window. Excessive light may cause the optical sensor to incorrectly calibrate, causing a Detector Calibration Error.

3.0 Introduction

This Operation Manual is provided to guide the user in all aspects of unit set-up, operation, and user-level maintenance of the QuickSlide™ GramPRO 1 Automated Gram Stainer Unit.

The GramPRO 1 is a microscope slide stainer capable of automatically performing a Gram stain sequence on a slide containing biological specimen for *in vitro* diagnostic use. An on-board computer, running software specially designed to accomplish correct Gram stain results for any type of sample, controls the entire staining process.

The GramPRO 1 software provides a series of menus for operator control of the unit. By pressing a key corresponding to a menu item, the operator directs program flow to the various logic paths of the software. All program functions are accessed in this manner.

3.1. Operator Responsibility – Safety Instructions

The GramPRO 1 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 1.

It is the operator's responsibility to be properly qualified to operate the GramPRO 1. The operator and personnel are also advised to refer to this Operating Manual. Please call the Technical Support phone number, (800) 266-2222 option 2 for additional assistance.

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

3.2. 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, steps 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 has 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.

4.0 Materials Required But Not Provided

Standard microbiological supplies may be required, but are not provided. These may include but are not limited to: (* required)

- *GramPRO 1 Reagent Kit (GP1SK)
- Decolorizer bottle (À la carte) (GP1DS)
- Replacement tubing kit (GP1RT)
- Gram Stain QC Slides (QS0700)
- System Cleaner (QS4000)
- *Stabilized Gram's Iodine Dropper Bottle (QS2000)
- *PROBond Slides (PB72)
- Thermo Scientific Polysine Slides
- Cuvette Swabs (QS1001)
- *Methanol (for fixation) (QS1016)
- Coplin Jars (VCJ001)
- Bibulous Paper (28511007)
- Saline, 0.85% (K59)
- Transfer Pipet, Disposable (138020500)
- Immersion Oil, Type A (Z95)
- Immersion Oil, Type B (Z96)
- Microscope lens cleaner (Z97)
- Lens Paper, non-linting (52846001)
- Microscope (MRP5000)

5.0 Ordering Information

If additional supplies are needed, these items can be ordered through Hardy Diagnostics Customer Service. Call (800) 266-2222 (option 1), or go to www.HardyDiagnostics.com. Alternatively, you can contact your preferred distributor.

6.0 GP1SK: GramPRO 1 Reagent Kit

6.1. Reagent Kit – General Information

6.1.1. The GramPRO 1 accomplishes automatic Gram staining by a systematically staining, rinsing, decolorizing, and counter-staining the provided biological specimen. It is critical for the success of this automated process that these unique reagents are obtained from QuickSlide™.

6.1.2. Stain kits must be registered on the GramPRO 1 before use. Reagent Kit Installation / Registration procedure as explained in **Section 14.1**.

6.1.3. Every installed stain kit will load the GramPRO 1 to a total of 110 Stain Cycles. The GramPRO 1 software monitors consumption of the Reagent 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.

NOTES

6.1.3.1. For quality control purposes, Reagent Kits are labeled with a Kit Number, Lot Number, and Expiration Date. These values are used to track and identify the Reagent Kit used in the unit, and are entered into the system as part of the Reagent Kit Installation / Registration procedure as explained in **Section 14.1**.

6.1.3.2. Due to the rate of evaporation for Decolorizer (acetone / alcohol), the supplementary product (Cat. No. GP1DS) may be purchased separate from the Reagent Kit, to replace the Decolorizer bottles if necessary.

6.1.3.3. **DO NOT USE** the QuickSlide System Cleaner (Cat. No. QS4000) in place of the Reagent Kit Decolorizer bottles. The System Cleaner contains a higher concentration of acetone / alcohol, and may cause “over-decolorization” during the Gram Staining process.

6.2. Reagents Kit Components

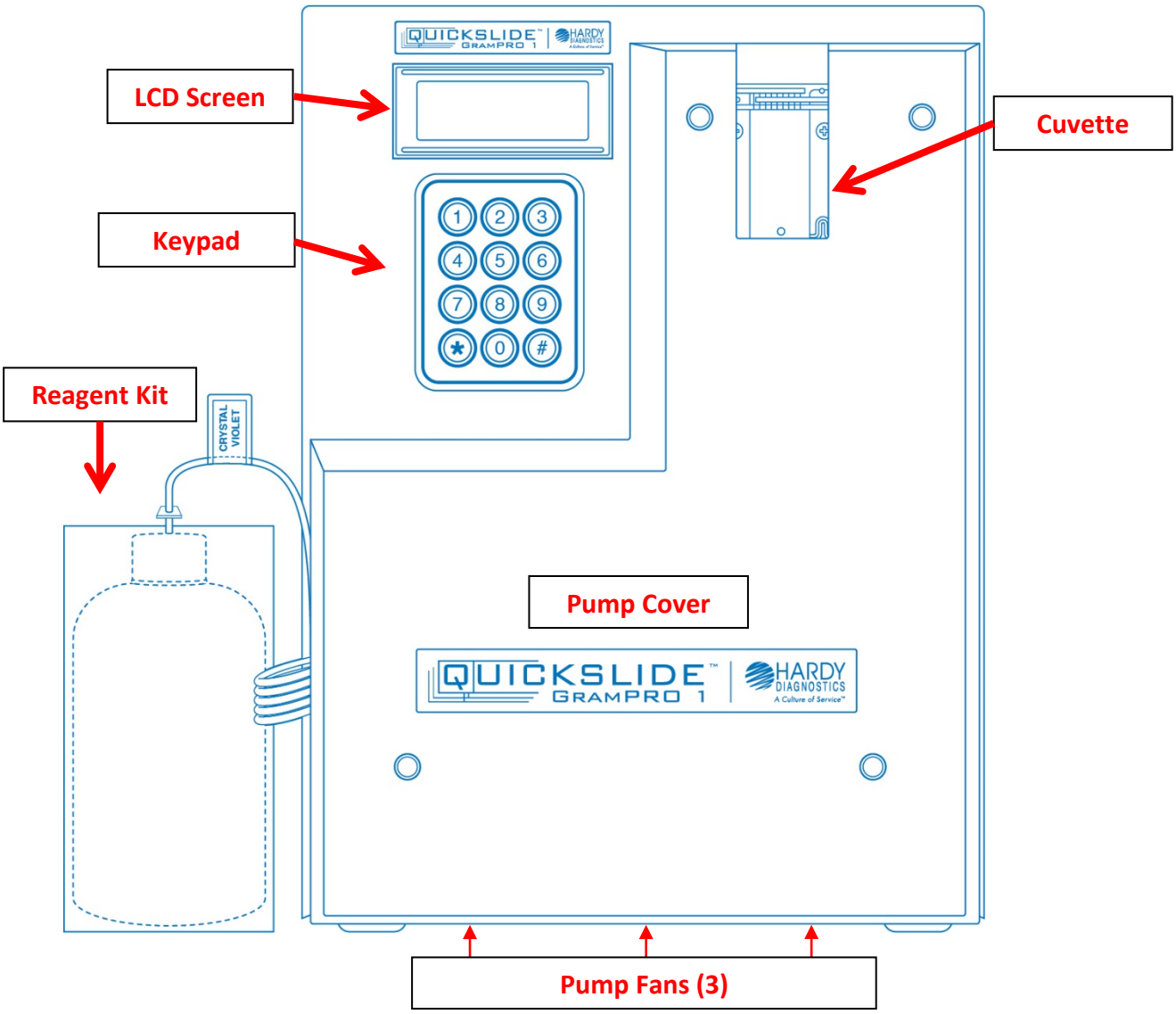
6.2.1. Crystal Violet – 1 bottle

6.2.2. Gram’s Iodine – 1 bottle

6.2.3. Decolorizer, slow – 2 bottles

6.2.4. Safranin (counterstain) – 1 bottle

7.0 GramPRO 1 Layout Diagram



The basic anatomy of the GramPRO 1 is identified in the diagram above.

- **LCD Screen** – The screen that prompts which buttons to select for procedure steps.
- **12-key Keypad** – The twelve button key pad used to select process options on the instrument.
- **Cuvette** – Holds the slide during the staining process.
- **Reagent Kit (GP1SK)** – The kit should sit on the right side of the unit to allow enough slack in the tubing and cannulas to reach inside each bottle comfortably.
- **Pump Cover** – Covers the reagent supply pumps and waste drain pumps.
- **Pump Fans[1] (3)** – Pump fans used to dissipate gram stain fumes.

[1] Units sold after September 16, 2019.

8.0 Specimen Slide Preparation

8.1. Slide Preparation

8.1.1. If the culture is to be taken from a Petri dish or a slant culture tube, first add a drop or a few loops full of water on the slide and aseptically transfer a minute amount of a colony 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.

8.1.2. Spread the culture with an inoculation loop to an even thin film within the blue box in the center of the slide, at least ¾" below the frosted area and ¼" from the left and right edges of the slide. Labels should not extend below the frosted area.

8.1.3. 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.

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

8.2. Methanol Fixation Procedure

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

NOTES

8.2.2. A fresh aliquot of methanol should be dispensed daily for slide preparation.

8.2.3. 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 (using methanol fixation, using the recommended treated slides, and following the maintenance procedures, including the “Wash”, “Scrub” and “Bleach” cycles).

8.2.4. For best results with this instrument use PROBond glass slides (PB72) or Thermo Scientific Polysine Slides to increase specimen adhesion to the glass slide. The adhesion of the specimen can be variable, depending on the specimen type, volume and its thickness. Lack of adhesion is most notable in blood or bloody culture smears, so it is **mandatory** to use chemically treated slides that produce a positive electrical charge in order to enhance the specimen’s attachment to the slide. Excessively thick smears can lead to a sloughing off of cells from the slide. 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 confirm the presence of low numbers of bacteria in traditionally sterile specimens (such as spinal or joint fluid) with manual staining and culture results.

9.0 First Time Instrument Set-Up

Unpacking and set-up assistance for the GramPRO 1 may be obtained by **c**alling the Technical Service Department at (800) 266-2222 option 2 during the hours of 8a.m.-5p.m., Pacific Standard Time, Monday through Friday. Alternatively, you may use the following guide, or view our Hardy Diagnostics YouTube playlist here for additional information.

9.1. Receiving and Unboxing

9.1.1. Carefully unpack the shipment. You will receive each of the following:

a) GramPRO 1

b) Quick start thumb drive

c) User Manual

d) Power Cord

9.1.2. Check for damage incurred during transit. Keep all packing material until you are sure the unit operates properly. Any damage to the shipping box must be reported to the responsible carrier.

9.1.3. These instructions must be followed for us to guarantee our full support of your claim for protecting against loss for concealed damage. The carrier will provide the form required for filing such a claim.

9.2. Installation

9.2.1. Before the GramPRO 1 is powered on, remove the four (4) thumb screws on the front of the unit, and remove the pump cover. This will reveal the eight (8) pump rollers on the unit. Attach all eight (8) orange pump tubes around their designated pump rollers.

9.2.2. Ensure all reagent supply tubes (cannulas) are properly inserted into the correct reagent containers. This should be done by piercing the seal on each reagent bottle with a sterile inoculating needle, and using the cannula to stretch the puncture opening. The bottom of the cannulas must rest at the bottom of their respective reagent bottle.

NOTES:

9.2.2.1. You may use the optional flip-caps that are included in each Reagent Kit (Cat. no. GP1SK) to hold the cannulas.

9.2.2.2. Do not push the cannula *all* the way into the reagent bottle, to where the cannula curves back up the bottle and forms a letter “J”.

9.2.3. Position the waste line for proper disposal of waste fluids into a designated waste container.

NOTE:

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

9.2.4. Confirm that DI water is present in the water supply container and make sure that the DI Water cannula is submerged.

NOTE:

9.2.4.1. To help prevent cross-contamination, the deionized water must be supplemented with stabilized gram's iodine disinfectant (Cat. no. QS2000). This is completed by adding 10 drops of disinfectant per gallon of deionized water into the water container. See **Section 15.5** for additional information.

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

9.2.6. Turn the system power switch ON.

```
AUTO GRAM STAINER
     V 2.1.0

  1-800-266-2222
```

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

```
1 RUN          3 REVIEW
2 SET-UP
       (current sequence)
(time)             (date)
```

9.2.8. Once the system completes loading, the above Main Menu will be displayed.

NOTES:

9.2.8.1. Proceed to **Section 14.1** for reagent kit (Cat. no. GP1SK) registration, and unit priming.

10.0 Menu Navigation

10.1. Main Menu

```
1 RUN        3 REVIEW
2 SET-UP
      (current sequence)
(time)           (date)
```

The Main Menu for the GramPRO 1 will display the time and date on the bottom of the screen, as well as the current cycle sequence. You will be presented with three (3) options. This is considered the starting screen, and all software functions begin from this menu.

10.2. Run Menu

```
1 RUN        3 REVIEW
2 SET-UP
      (current sequence)
(time)           (date)
```

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

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

The nested Run Menu consists of four (4) options, shown above. This menu will give you access to slide staining, preventative maintenance, as well as the ability to prime or purge the unit of the QuickSlide reagent kit (Cat. no. GP1SK). Further information can be found under **Section 11.0**.

10.3. Setup Menu

```
1 RUN        3 REVIEW
2 SET-UP
      (current sequence)
(time)            (date)
```

10.3.1. **Press [2]** on the key pad to select the **SET-UP** menu

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

The nested **Set-Up Menu** consists of four (4) options, shown above. This menu will give you access to manual calibrations, reagent kits registration, tubing kit registration, adjustments to the date and time (as displayed on the **Main Menu**), as well as adjustments to some timing aspects of the unit. Further information can be found under **Section 12.0**.

10.4. Review Menu

```
1 RUN        3 REVIEW
2 SET-UP
      (current sequence)
(time)            (date)
```

10.4.1. **Press [3]** on the key pad to select the **REVIEW** menu.

```
   RESULTS REVIEW
1 STAIN    3 CAL DRY
2 CAL WET
              * EXIT
```

The nested **Review Menu** consists of three (3) options, shown above. This menu allows access to all calibrations per sequence number. This menu is optional, as no further action can be taken as a part of normal unit operation.

11.0 Run Menu: sub-menu navigation

11.1. Gram Stain

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

The Gram Stain sub-menu is where users can access all functionality related to the actual Gram Staining process.

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

```
1-GRAM STAIN (Short)
2-GRAM STAIN (Long)
3-DECOLORIZE ONLY
               * EXIT
```

NOTES

11.1.1.1. Remaining cycles and expiration dates are checked at this time to assure staining operation may be completed. Detection of cycle shortage or reagent/tubing expiration yields a warning message describing the unit's status.

11.1.1.2. The Gram Stain command will also fail to start if the instrument is due for a required Wash Cuvette or Scrub Stain Lines cleaning cycle. These cycles are explained under User Maintenance in **Section15.0**.

11.1.2. Select one of the three (3) stain delay options.

There are two sets of pre-programmed stain delay times, a short or a long option. The soak times for Crystal Violet (CV), Gram's Iodine (GI), and Safranin (SAF) 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. More information can be located in **Section 12.1.3**. The default settings are:

	Short	Long	Decolorize Only
Crystal Violet (CV)	40	60	Varies
Gram's Iodine (GI)	40	60	Varies
Safranin (SAF)	40	60	Varies

NOTES

11.1.2.1. The GramPRO 1 utilizes a patented optical sensor that monitors the decolorizing for you. Therefore, there is no customer facing option to modify the decolorizer time.

11.1.2.2. The “Decolorize Only” option omits all staining entirely, and provides a means for decolorizing ONLY. Selecting this option will act as a Stain Cycle, and deplete the total count remaining by 1.

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

```
 GRAM STAIN SELECTED
CYCLES REMAINING 110
INSERT SLIDE & PRESS
A KEY   (* TO ABORT)
```

NOTES

11.1.3.1. Do not allow the slide to drop and abruptly hit the “Slide Stop” peg within the cuvette. Doing so may cause the slide to chip or break. Broken glass in the instrument is not covered under warranty and the customer will be responsible for the cost of repair and shipping. For assistance in the case of a broken slide, call Technical Support at (800) 266-2222 (option 2) before attempting to remove any broken glass.

11.1.3.2. The GramPRO 1 employs one cuvette for the entire Gram stain process, the Crystal Violet staining, Gram’s iodine fixing, decolorizing, and Safranin counter-staining all takes place within this cuvette.

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

```
STAINING COMPLETE

 REMOVE SLIDE &
 STRIKE ANY KEY
```

NOTE: Pressing the [∗] key will abort the Gram stain process and return to the Run Menu after a DI Water rinse.

11.2. Clean Cuvette

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

The Clean Cuvette sub-menu is where all programmed functions related to User Maintenance can be accessed.

11.2.1. **Press [2]** on the key pad to select **CLEAN CUVETTE**.

```
1-WASH CUVETTE
2-SCRUB STAIN LINES

               * EXIT
```

Please view **Section 15.0** for details on User Maintenance for the GramPRO 1. A summary of all user maintenance can be found under **Section 15.7**.

11.3. Prime Pumps

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

The Prime Pumps function will expel all reagents and DI Water back into their respective containers. During this function, the waste lines will also expel all waste into the designated waste container. The unit will then proceed by priming each reagent line with their respective reagents. This is normally done as a part of a new Reagent Kit Installation and Registration in **Section 14.1**. When the function has completed, the unit will return to the Run Menu.

11.4. Purge

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

The Purge function will expel all reagents and DI Water back into their respective containers. During this function, the waste lines will also expel all waste into the designated waste container. This is normally done as a part of Reagent Kit Installation and Registration in **Section 14.1**, or Unit Shutdown in **Section 16.0**. When the function has completed, the unit will return to the Run Menu

12.0 Set-up Menu: sub-menu navigation

12.1. Calibration

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

12.1.1. **Press [1]** on the key pad to select **CALIBRATION.**

```
1-CALIBRATE DETECTOR
2-SET STAIN DELAYS

    * EXIT
```

12.1.2. Calibrate Detector

12.1.2.1. This function is not accessed as a part of normal unit operation. This function will allow the user to run a manual calibration on the optical sensor. We recommend contacting Hardy Diagnostics's technical support if you receive a Detector Calibration Error as explained in **Section 13.2.1**.

12.1.3. Set Stain Delays

12.1.3.1. This function is not accessed as a part of normal unit operation. This function is used to customize the parameters for the Short Stain and Long Stain cycles. We recommend contacting Hardy Diagnostics's technical support before altering these settings.

12.2. Consumables

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

→

```
1-REVIEW REAGENTS
2-REVIEW TUBING

    * EXIT
```

12.2.1. **Press [2]** on the key pad to select **CONSUMABLES.**

12.2.2. Please view **Section 14.1** for details on how to register and install a new Reagent kit (GP1SK) or a Replacement Tubing Kit (GP1RT).

12.3. Date / Time

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

12.3.1. **Press [3]** on the key pad to select **DATE/TIME.**

```
 SYSTEM DATE / TIME
    TIME HH:MM:SS
   DATE MM/DD/YYYY
1-DATE 2-TIME *EXIT
```

If necessary, the unit's date and time can be modified from this screen. This function will allow the user to do so, by accessing either **[1] DATE** or **[2] TIME**.

12.4. Options

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

12.4.1. **Press [4]** on the key pad to select **OPTIONS.**

```
1-AUDIO ALERT
2-IDLE DELAYS
                * EXIT
```

→

```
  AUDIO ALERT IS ON
1 – AUDIO ALERT OFF
2 – AUDIO ALERT ON
3 - TEST     * EXIT
```

12.4.1. **Press [1]** on the key pad to select **AUDIO ALERT.**

If necessary, the unit's audio functionality may be modified via the software. We do not recommend altering these settings, as the audio alerts serve as helpful reminders to notify the user when to remove the slide from the cuvette.

```
1-AUDIO ALERT
2-IDLE DELAYS

                * EXIT
```

→

```
SLEEP DELAY     5 MIN
STIR DELAY    187 MIN
AUTO PRIME     24 HR
 # ACCEPT     * EXIT
```

12.4.1. **Press [2]** on the key pad to select **IDLE DELAYS.**

The GramPRO 1 contains an internal clock that is used to monitor system operations and start a timer to manage the instruments "sleep" time to conserve energy. The software monitors the idle time by observing the elapsed time since the last key on the key pad was pressed.

12.4.1.1. **Sleep Delay** – When the machine enters into Sleep Mode, the LCD display will turn off and the pump motors will be de-energized. To exit the Sleep Mode press any key once on the key pad. This will illuminate the LCD screen from the previous session. The pump motors will be re-energized and the operating system will be activated. Default time for the Sleep Delay is 5 minutes.

12.4.1.2. **Stir Delay** – This operation helps maintain the integrity of the unit's decolorizer pump tubes. While the machine is in Sleep Mode or while it is idling, the stir function purges and primes the decolorizer pumps. Default time for the Stir Delay is 187 minutes. We recommend this setting not be modified.

12.4.1.3. **Auto Prime** – This operation purges all of the reagents, followed by a complete prime of the reagent lines. This prevents reagent evaporation in the supply lines and maintains the unit in a ready state without wasting reagents, as each of the reagents is expelled back into the respective reagent container. Default time for the Auto Prime is 24 hrs.

13.0 Quality Control and Error Prompts

13.1. Quality Control Checks

The quality and validity of the Gram stain process of the GramPRO 1 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 (Cat. no. QS0700) may be purchased from Hardy Diagnostics. Please refer to **Section 5.0** for ordering information.

13.2. Error Prompts

13.2.1. Self-Calibration Errors

The GramPRO 1 employs a “self-calibration” test during every staining cycle to verify proper system operation. This test confirms that the optical sensor response is within a valid specified range. Out-of-Range measurements automatically cause interruption of a staining cycle and operator notification of the error condition. At this point, the stain cycle will abort. This self-check provides additional assurance of accurate system performance. If a Detector Calibration Error is encountered, the following screen will display:

```
DETECTOR CALIBRATION
 ERROR ENCOUNTERED
STAIN CYCLE ABORTED
              * EXIT
```

For assistance on troubleshooting, please contact QuickSlide Technical Support at (800) 266-2222, option 2.

13.2.2. Invalid Kit Code Error

```
** REAGENT ERROR  **
INVALID KIT NUMBER
```

→

```
** REAGENT ERROR  **
INVALID KIT NUMBER
                * EXIT
```

The GramPRO 1 will display the above Invalid Kit Number Error if a reagent kit has been registered incorrectly. This can happen if any of the numbers in the Kit S/N, Lot Number, or Exp Date have been typed incorrectly. Please be sure that the number is typed exactly as it is shown on the label of the Reagent kit box (Cat. no. GP1SK). If you believe you have received this error by mistake, please contact QuickSlide Technical Support at (800) 266-2222, option 2.

13.2.3. Duplicate Kit Code Error

```
** REAGENT ERROR  **
DUPLICATE NUMBER
```

→

```
** REAGENT ERROR  **
INVALID KIT NUMBER
                * EXIT
```

The GramPRO 1 will display a Duplicate Number Error if it detects that a previously installed reagent kit is trying to be registered again. If you believe you have received this error by mistake, please contact QuickSlide Technical Support at (800) 266-2222, option 2.

14.0 Consumables

14.1. Reagent Kit Installation / Registration

The GramPRO 1 software monitors consumption of the Reagent Kit, each kit will last for 110 cycles. Follow the steps listed below to install a new Kit when needed.

From the Main Menu:

```
1 RUN          3 REVIEW
2 SET-UP
        (sequence number)
(time)             (date)
```

14.1.1. **Press [1] RUN** on the key pad.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE         * EXIT
```

14.1.2. **Press [4] PURGE** on the key pad. You may repeat this step **twice** to make sure all of the reagents are emptied from the tubes.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE         * EXIT
```

14.1.3. **Press [*]** on the key pad to exit back to the Main Menu

```
1 RUN          3 REVIEW
2 SET-UP
        (sequence number)
(time)             (date)
```

14.1.4. **Remove the cannulas** from the reagent bottles and wipe them with an isopropyl alcohol (IPA) pad.

14.1.5. Open the new reagent kit and insert each labeled cannula into the corresponding reagent bottles.

NOTE: **Do not discard the Reagent Kit box**. The label on the new reagent kit contains the Kit Code necessary for registration.

From the Main Menu

```
1 RUN        3 REVIEW
2 SET-UP
       (sequence number)
(time)            (date)
```

14.1.6. **Press [2] SET-UP** on the key pad.

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

14.1.7. **Press [2] CONSUMABLES** on the key pad.

```
1-REVIEW REAGENTS
2-REVIEW TUBING

               * EXIT
```

14.1.8. **Press [1] REVIEW REAGENTS** on the key pad.

```
   REAGENT STATUS
CYCLES REMAINING ###
 EXP DATE MM/DD/YYYY
1-CHANGE KIT    *EXIT
```

This display will show the current kit's information.

14.1.9. **Press [1] CHANGE KIT** on the key pad.

```
KIT S/N   ###-###-###
  LOT NUMBER   ####
 EXP DATE MM/DD/YYYY
# ACCEPT        * EXIT
```

14.1.10. Once the blinking cursor appears next to the Kit S/N, use the key pad to enter in the Kit Number as it reads on the new reagent kit label located on the GP1SK box's label.

14.1.11. **Press [#] Accept** to proceed to the next entry field (Lot Number).

14.1.12. Enter in the Lot Number and Expiration Date into the appropriate fields as it reads on the new reagent kit label.

14.1.13. **Press [#] Accept** on the key pad once the Expiration Date has been entered to move the cursor back to the Kit S/N field.

14.1.14. **Press [*] EXIT** on the key pad once to proceed to the following screen.

```
1-UPDATE REAGENT LOG
2-ABORT UPDATE
```

14.1.15. **Press [1] Update Reagent Log** to save the kit registration information and activate the new kit. Entry of invalid numbers or numbers from a previously used reagent kit will result in the display of an error message.

> **NOTE**: *If an invalid or duplicate error notice is received, please retry this process once more to ensure <u>all fields were entered correctly</u>.* If troubleshooting is required, please contact QuickSlide Technical Support at (800) 266-2222, option 2 for assistance.

14.1.16. When complete, the screen will show the following

```
     REAGENT LOG
  UPDATE CONFIRMED
              * EXIT
```

14.1.17. **Press [*] EXIT** until you return to the Main Menu.

14.2. Pump Tube Replacement Procedure

All (8) pump tubes must be replaced every (6) months to ensure optimal functionality of the GramPRO1. The GramPRO1 keeps track of the number of tubing cycles remaining, and will notify when a new pump tube kit is necessary. Each tubing kit will last 1,100 cycles.

From the Main Menu:

```
1 RUN          3 REVIEW
2 SET-UP
        (sequence number)
(time)             (date)
```

14.2.1. **Press [1] RUN** on the key pad.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

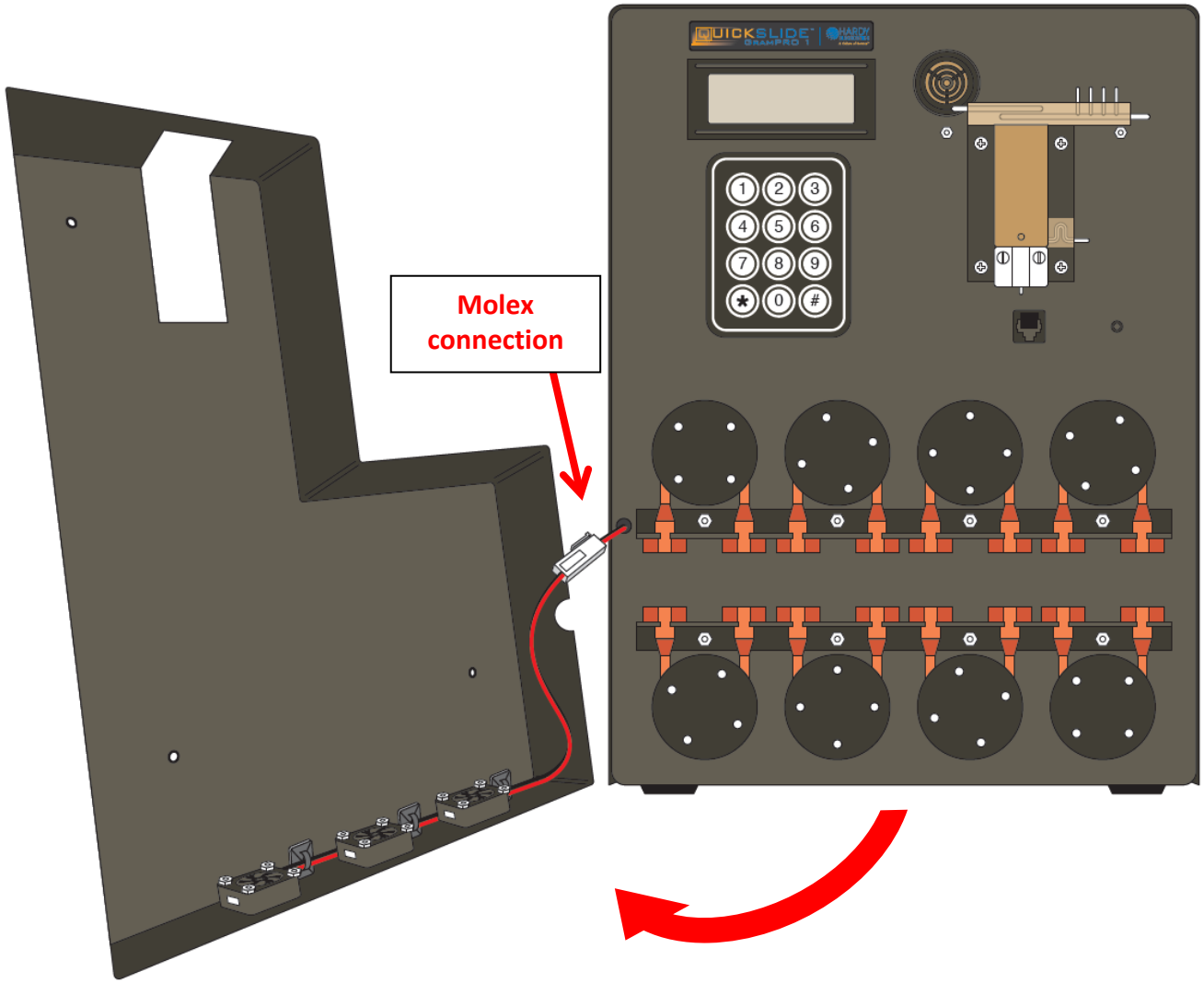
14.2.2. **Press [4] PURGE** on the key pad. You may repeat this step **twice** to make sure all of the reagents are emptied from the tubes.

14.2.3. Power the unit **OFF.**

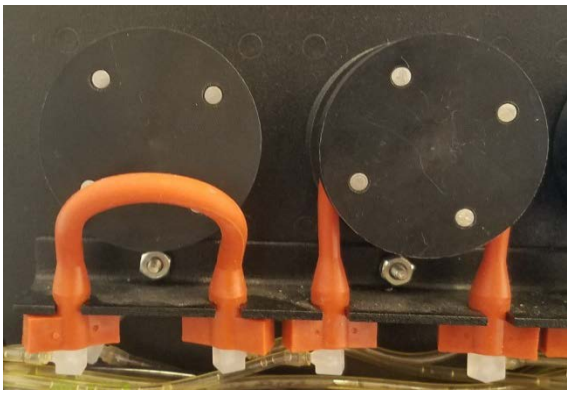
14.2.4. **Open the front panel** by removing the (4) thumb screws. All (8) pump tubes and rollers will be displayed.

14.2.5. For units sold after September 16, 2019, the GramPRO 1 will have the addition of 3 fans attached to the bottom of the pump cover. Please use caution when removing the pump cover by opening the cover on the right side of the unit, as a Molex connection can be found on the left side. The Molex may be disconnected to completely remove the Pump Cover.

14.2.5.1. GramPRO 1 Pump Cover w/ fans



14.2.6. One at a time, starting from Pump #1 (top row, left-most roller), remove the orange pump tube from the pump roller by sliding your finger along the edge of the tube.



14.2.7. When the orange pump tube is off the roller, pull the tube from the bracket.

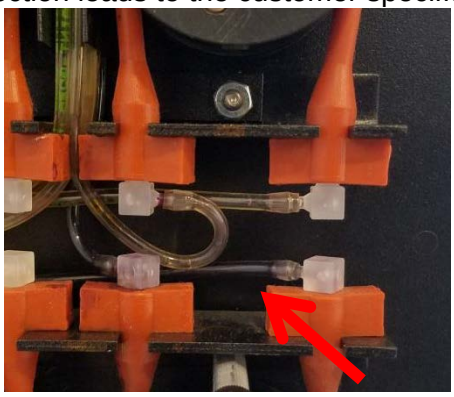
NOTE: It is recommended to replace one tube at a time from left to right to keep correct clear elbow connection placement.

14.2.8. Remove the two white nylon elbows from each end of the orange pump tube.

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

14.2.10. Re-insert the two nylon elbows into the new pump tube.

NOTE: Pump #4 on (top row, right-most roller) must have a looping reservoir for the left polypropylene elbow, which directs from the bottom of the unit's cuvette. This pump is designated for the main waste line of the unit. The right polypropylene elbow connection leads to the customer specified waste container.



14.2.11. **Power the unit ON** and replace the front panel. You must now proceed to **Section 14.4** to register the new pump tubing kit

14.3. GramPRO 1 Tubing Diagram

14.4. Register New Pump Tube Kit

From the Main Menu

```
1 RUN        3 REVIEW
2 SET-UP
       (sequence number)
(time)            (date)
```

14.4.1. **Press [2] SET-UP** on the key pad.

```
1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS
```

14.4.2. **Press [2] CONSUMABLES** on the key pad.

```
1-REVIEW REAGENTS
2-REVIEW TUBING

              * EXIT
```

14.4.3. **Press [2] REVIEW TUBING** on the key pad. The following screen will display how many tubing cycles are allowed on the current tubing set that is installed on the unit. (i.e. a maximum of 1,100 cycles upon each new tubing set/registration).

```
    TUBING STATUS
CYCLES REMAIN   XXXX

1-CHANGE KIT   *EXIT
```

14.4.4. **Press [1] CHANGE KIT** on the key pad.

```
KIT S/N  XXX-XXX-XXX
  BATCH NUMBER XXXX

# ACCEPT       * EXIT
```

14.4.5. Enter the Kit Serial Number and press **[#] ACCEPT** on the key pad.

14.4.6. Enter the **Batch Number** and **press [#] Accept** on the key pad Accept. The cursor will go back to the **KIT S/N** number.

14.4.7. Press [*] EXIT on the key pad once.

```
1-UPDATE TUBING LOG
  2-ABORT UPDATE
```

14.4.8. **Press [1] UPDATE TUBING LOG** on the key pad to save the tubing kit registration information and activate the new kit. Entry of invalid numbers or numbers from a previously used tubing kit will result in the display of an error message.

> **NOTE**: *If an invalid or duplicate error notice is received, please retry this process once more to ensure all fields were entered correctly.* If troubleshooting is required, please contact QuickSlide Technical Support at (800) 266-2222, option 2 for assistance.

```
    TUBING LOG
UPDATE CONFIRMED
            * EXIT
```

14.4.9. **Press [*] EXIT** on the key pad until you return to the Main Menu.

```
1 RUN        3 REVIEW
2 SET-UP
       (sequence number)
(time)          (date)
```

14.4.10. **Press [1] RUN** on the key pad.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE       * EXIT
```

14.4.11. **Press [3] PRIME PUMPS** on the key pad. The unit is now ready to run samples.

15.0 User Maintenance

15.1. Wash Cycle (every 20 slides or 8 days)

The Wash feature for the GramPRO1 is required every 20 slides or 8 days. The unit runs decolorizer and water through the cuvette and with agitation cleans the internal surface of the cuvette and manifold waste line

From the Main Menu:

```
1 RUN          3 REVIEW
2 SET-UP
        (sequence number)
(time)             (date)
```

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

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

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

```
1-WASH CUVETTE
2-SCRUB STAIN LINES

               * EXIT
```

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

```
    WASH SELECTED

REMOVE SLIDE & PRESS
A KEY    (* TO ABORT)
```

15.1.4. **Press any key** on the key pad to start the Wash Cycle. This process should take approximately 3 minutes to complete. When complete, an audible alert will sound, notifying the operator that the machine is ready to resume staining.

15.1.5. **Press [*] EXIT** until you have reached the Main Menu.

15.2. Scrub Cycle (every 600 slides or 15 days)

NOTE: For software version (**V 2.1.0 and above**) the unit will automatically prompt the user to run a Scrub Cycle every 15 days.

NOTE: For software version (**V 2.0.9 and below**), the unit will only prompt the user to run a Scrub Cycle every 30 days. Please follow the below instructions to run a manual Scrub Cycle.

The Scrub feature for the GramPRO1 required every 600 cycles or 15 days, whichever occurs first. The unit will automatically prompt the operator when scrub cycle needs to be run. The total time to run a Scrub Cycle is five minutes.

From the Main Menu:

```
1 RUN          3 REVIEW
2 SET-UP
        (sequence number)
(time)             (date)
```

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

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

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

```
1-WASH CUVETTE
2-SCRUB STAIN LINES

               * EXIT
```

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

```
STAIN LINES MUST BE
 PURGED BEFORE SCRUB

       1-PURGE
```

15.2.4. The unit will now force the user to Purge the unit. This will empty the lines of stains. **Press [1]** on the key pad to select **Purge.**

```
SCRUB SELECTED
MOVE CV,GI&SAF LINES
TO CLEANER BOTTLE
1-SCRUB
```

NOTE: The unit will now instruct the user to move **ONLY** the Crystal Violet, Gram's Iodine, and Safranin cannulas into one bottle of System Cleaner (QS4000), or a container of at least 500mL of Decolorizer. The cleaner is used to clean the internal portions of the reagent lines/hypotubes, manifold waste, cuvette, and photo optic lens of the unit.

NOTE: **Before the Scrub cycle has started**, the user will need to follow **Section 15.4** for Cuvette Swabbing.

15.2.5. **Press [1]** on the key pad to select **Scrub**. The unit will automatically prime the system cleaner into the reagent lines and then begin the scrub sequence.

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

```
SCRUB COMPLETED
REPLACE TUBES INTO
PROPER STAINS
~~ANY KEY~~ TO CONTINUE
```

NOTE: The above Scrub Completed screen will state to press "any key" to continue. Please proceed by **Pressing [1]** on the key pad **to continue** to the next step.

15.2.7. The unit will now prime the reagent lines with reagents. The unit will make an audible alert when the Scrub Cycle is complete and ready to resume use. The screen will show the **Run Menu**.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

15.2.8. **Press [*]** on the key pad to select **EXIT** to return to the Main Menu.

15.3. Bleach Cycle (every 600 slides or 30 days)[2]

We require our users to perform a Bleach cycle for the GramPRO1 every month or 600 slides, whichever occurs first. The user will need to prepare a 10% bleach solution, which will be used to dispense through the reagent and water lines to clean the internal surface of the tubing and to prevent debris build up in the waste line.

From the Main Menu:

```
1 RUN          3 REVIEW
2 SET-UP
        (sequence number)
(time)             (date)
```

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

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

15.3.2. **Press [4]** on the key pad to select **Purge**. When the Purge has completed, the unit will return to the Run Menu.

15.3.3. Remove the reagent lines (Crystal Violet, Gram's Iodine, and Safranin) from their stain containers, **rise off** with water, and **wipe off** with an alcohol pad for any the residual reagents from the ends of the cannulas.

15.3.4. In separate water container, **make a 10% bleach solution**.

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

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

15.3.6. From the Run menu, **Press [3] PRIME PUMPS**. Once the unit has finished priming with the 10% bleach solution, a gram stain cycle will need to be run. When the Prime has completed, the unit will return to the Run Menu.

[2] The GramPRO 1 will not automatically prompt the Bleach cycle to the user.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

15.3.7. From the Run menu, **Press [1] GRAM STAIN.**

```
1-GRAM STAIN (Short)
2-GRAM STAIN (Long)
3-DECOLORIZE ONLY
               * EXIT
```

15.3.8. From the Gram Stain menu, **Press [2] GRAM STAIN (LONG)**.

```
 GRAM STAIN SELECTED
CYCLES REMAINING 110
INSERT SLIDE & PRESS
A KEY    (* TO ABORT)
```

15.3.9. **Press any key** on the key pad, except **[*],** to commence the bleaching process.

```
  STAINING COMPLETE

    REMOVE SLIDE &
    STRIKE ANY KEY
```

15.3.10. **Press any key** when the Gram Stain cycle is complete, the unit will return to the Run Menu.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

15.3.11. From the Run Menu, **Press [4]** on the key pad to select **Purge**. This will expel the 10% bleach solution from the reagent lines and DI water line. When the Purge has completed, the unit will return to the Run Menu.

15.3.12. Wipe off and place **each of the cannulas** back into their respective containers.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

15.3.13. From the Run Menu, **Press [3] PRIME PUMPS**. When the Prime has completed, the unit will return to the Run Menu.

15.3.14. **Press [*]** on the keypad to **EXIT** return to the Main Menu.

15.4. Cuvette Swabbing

Cuvette Swabbing should be done before every Wash Cycle (**Section 15.1**) and Scrub Cycle (**Section 15.2**). The cuvette may build up stain residue over time. To clean it, use a foam swab (QS1001) soaked in alcohol to manually scrub the walls of the cuvette. This should be done **before** the cycle has started.

> **NOTE**: Do not manually scrub the cuvette during the Wash Cycle or Scrub Cycle. Doing so may cause the cuvette to overflow with the submerged swab.

15.5. Deionized Water Disinfectant

In order to prevent contamination, the deionized water must have stabilized Gram's iodine disinfectant (QS2000) 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.

15.6. Refilling the Water Supply

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

> **NOTE:** The new water supply must be disinfected using iodine before continuing use, refer to **Section 15.5** above.

To refill the water supply, do the following:

15.6.1. Remove the water cannula from the water container and place it onto a fresh paper towel or alcohol swab.

15.6.2. Fill the water container with fresh deionized water and mix in the drops of Gram's Iodine.

15.6.3. Sanitize the water cannula using an alcohol swab and place it back into the water container and screw the lid on tightly.

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

15.7. Maintenance Summary[3]

Maintenance Procedures	Frequency	
Supplement the fresh deionized water with 10 drops/gal DI water of **Gram's Iodine disinfectant** (**Section 15.5**).	Every time the DI water is refilled (or every 20 days)	
Run a **Wash Cycle** (**Section 15.1**). **Swab the cuvette** before the Wash Cycle (**Section 15.4**).	8 days	Every 20 slides
Run a **Scrub Cycle** (**Section 15.12**). **Swab the cuvette** before the Scrub Cycle (**Section 15.14**).	15 days	Every 600 slides
Run a **Bleach Cycle** (**Section 15.3**).	(1) Month	Every 600 slides
Replace the orange **pump tubes** (**Section 14.2**).	(6) Months	Every 1,100 slides

15.7.1. **Utilize the Maintenance Log to make sure these periodic tasks are completed as scheduled. See Section 20.0.**

Note: If a problem is encountered that is beyond the scope of this manual or additional assistance is required, contact Hardy Diagnostic's Technical Support team at (800) 266-2222, option 2.

[3] For software version (V 2.1.0 and above), the unit will automatically prompt the user to run a Scrub Cycle every 15 days. For software version (V 2.0.9 and below), the unit will only prompt the user to run a Scrub Cycle every 30 days. Please follow Section 15.2 to run a manual Scrub Cycle.

16.0 Unit Shut Down Procedure

16.1.1. Run a **Scrub Cycle**. Refer to **Section 15.2** for step-by-step instructions of how to run a Scrub cycle, but **omit the final Prime step.**

16.1.2. When the screen prompt reads

```
SCRUB COMPLETED
REPLACE TUBES INTO
PROPER STAINS
ANY KEY TO CONTINUE
```

Pull all of the cannulas out of the system cleaner bottle and place them onto a paper towel. Then, press any key to continue, so the unit will prime air into the lines. When the Prime has completed, the unit will return to the Run Menu.

16.1.3. Place all of the cannulas into an empty waste container.

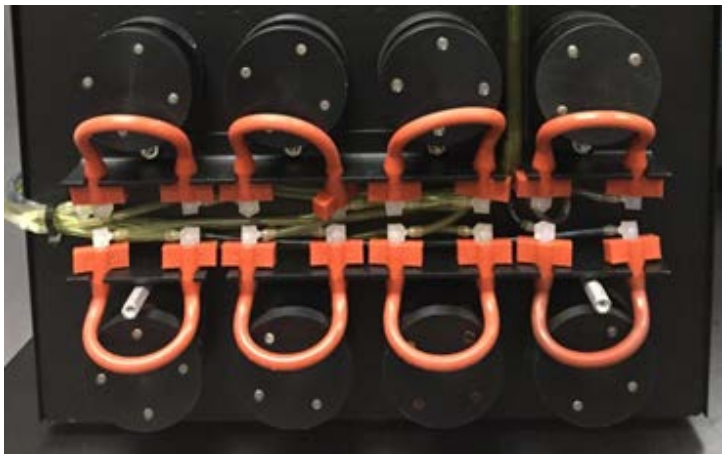
16.1.4. From the Run Menu, **Press [1]** on the key pad to select **Purge**. This will expel any remaining fluid from the lines.

```
1-GRAM STAIN
2-CLEAN CUVETTE
3-PRIME PUMPS
4-PURGE        * EXIT
```

16.1.5. Turn the system **power switch OFF**

16.1.6. **Open the front panel** by removing the (4) thumb screws

16.1.7. Remove all (8) orange pump tubes from the pump tube rollers. Gently **stretch the tubes** off of the pump rollers without disconnecting the white polypropylene elbows.



16.1.8. **Replace the front panel** using the (4) thumb screws.

17.0 Safety Data Sheets

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

18.0 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.

19.0 GramPRO 1 Warranty

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

- Repaired units will be given the latest software upgrades.
- Shipping charged to and from the buyer will be provided by Hardy Diagnostics.
- Travel costs are not included as part of warranty.
- Extended warranties do not include the routine replacement of the tube sets.

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

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

Any of the following conditions shall invalidate the warranty:

i. Buyer's or end users' failure to properly perform the maintenance required in the operator's manual.
ii. Repairs by persons other than Hardy Diagnostics service personnel, unless authorized in writing by Hardy Diagnostics personnel.
iii. Replacements with other than genuine QuickSlide™ parts.
iv. Buyer's or end users' negligence or negligent operation of the System.
v. Unauthorized alterations or modifications to the System or software.
vi. Removal of the protective case without service authorization.
vii. Use of reagents other than those provided by Hardy Diagnostics.
viii. Use of microscope slides other than the chemically treated PROBond (Cat. no. PB72) or Thermo Scientific Polysine microscope slides with any QuickSlide gram-staining instrument.

ix. Use of specimen fixation method other than methanol fixation.
x. Broken glass slides in tubing, cuvettes, or the waste ports as an outcome of buyer or end user negligence.

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

All other components are covered, granted the user follows the operating instructions. Refer to our Domestic Terms and Conditions at www.HardyDiagnostics.com/terms-conditions and our International Terms and Conditions at www.HardyDiagnostics.com/international-terms-conditions for additional information.
Hardy Diagnostics represents and warrants to Buyer that all products shipped by Hardy Diagnostics to Buyer, as of the date of such shipment, shall conform in all material respect to the specifications last published at www.HardyDiagnostics.com before the time of shipment of the products. HARDY DAIGNOSTICS MAKES NO OTHER WARRANTIES TO BUYER, EXPRESS OR IMPLIED, AND HEREBY EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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

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

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

20.0 Maintenance Logs

GramPRO 1 User Maintenance Log

IMPORTANT: For software version (V 2.1.0 and above), the unit will automatically prompt the user to run a Scrub Cycle every 15 days.

IMPORTANT: For software version (V 2.0.9 and below), the unit will only prompt the user to run a Scrub Cycle every 30 days. Please follow Section 15.2 to run a manual Scrub Cycle.

When refilling the water container or every 20 days whichever comes first		20 slides or every 8 days whichever comes first		600 slides or every 15 days whichever comes first		600 slides or every 30 days whichever comes first		Before every Wash Cycle and Scrub Cycle		1,100 cycles or every 6 months whichever comes first			
Deionized Water and Iodine Disinfectant Procedure (**Section 15.5**)		**Wash Cycle** (**Section 15.1**)		**Scrub Cycle** (**Section 15.2**)		**Bleach Cycle** (**Section 15.3**)		**Swab the Cuvette** (**Section 15.4**)		**Replace the Pump Tube Kit** (**Section 14.2**)			
Initials	**Date**	**Initials**	**Date**	**Initials**	**Date**	**Initials**	**Date**	**Initials**	**Date**	**Initials**	**Date**	**Kit Serial Number**	**Kit Lot Number**

Trainee Name: _____

GramPRO 1 Training Checklist

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

Trainee's Initials

_____ Specimen Slide Preparation: **Section 8.1**

_____ Loading Slides: **Section 11.1.3**

_____ Initiating a Gram Stain: **Section 11.1.4**

_____ Register Reagent Kit: **Section 14.1**

_____ Maintenance Summary: **Section 15.7**

_____ Refilling the Water Supply: **Section 15.6, Section 15.5**

_____ Wash Cycle Operation: **Section 15.1**

_____ Scrub Cycle Operation: **Section 15.2**

_____ Bleach Cycle Operation: **Section 15.3**

_____ Replacing the Tubing Kit: **Section 14.2**

_____ Register the Tubing Kit: **Section 14.4**

Trainee Signature: _____Date: _____

Trainer Signature: _____Date: _____