

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.

The QuickSlide™ Quality Management System

Our devices for the medical laboratory are developed, produced, and distributed according to the requirements of ISO 9001:2008. All products are shipped to you from our manufacturing facility located at 3411 McNiel Ave., Suite 302, Wichita Falls, Texas 76308.

Unpacking and Inspecting

Carefully unpack the GramPRO 1 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 or postal authority. 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.

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Important: Keep this operating manual for future use.



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QuickSlide™™, a Division of Hardy Diagnostics
3411 McNiel, #302
Wichita Falls, TX 76308
800-295-9588
www.HardyDiagnostics.com
Sales@HardyDiagnostics.com

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

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 22:2005/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

1.0 Intended Use

The intended use of the QuickSlide™ GramPRO 1 is to automatically perform a Gram stain sequence on a slide containing biological material. An on-board computer with software especially designed to accomplish superior Gram stain results for any type of sample controls the entire staining process.

This Operation Manual is provided to guide the user in all aspects of unit-set up, operational use, and user-level maintenance.

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.

2.0 Operator Responsibility – Safety Instructions

The GramPRO 1 ensures safe operation when installed, operated, and maintained according to common safety regulations. This section explains all the potential dangers that may arise when operating the GramPRO 1 and also specifies the most important safety precautions to prevent mishaps.

The operator is responsible for the qualification of the personnel operating the instruments. The operator and personnel are advised to refer to this Operating Manual and/or call the QuickSlide™ Technical Support phone number for additional assistance.

2.1 Explanation of Safety and Other Alert Symbols



CAUTION:

Describes a possibly dangerous situation. If this is not avoided, slight or minor injuries could result. A warning of possible property damage may also be contained in the test.



NOTE!

Draws attention to something special.



IMPORTANT!

Indicates usage tips and other useful information



ELECTRIC SHOCK HAZARD!

Indicates that electric shock is possible

2.2 Instructions



CAUTION:

- Instrument must to be placed on a level operating surface of 12 inches wide by 18 inches deep with a vertical clearance of 16 inches. Reagent Supply Kit sits on the counter immediately beside the instrument on the left side and is connected with tubing.
- The unit requires a water jug, preferably DI water, which is connected with tubing. A tube from the unit drains waste fluids. The unit should be placed near a drain or other disposal container to accommodate this waste fluid. Handling of waste is up to the user and their facility policies and procedures.



ELECTRIC SHOCK HAZARD!

- The GramPRO 1 consumes less than 400 W of power and may be supplied with **AC INPUT: 100-240V, 8A-4A, 47Hz – 63Hz** line power.
- The GramPRO 1 is intended for indoor use inside a microbiology lab, safe to altitude of up to 2,000 meters, temperature range 5°C to 40°C, humidity of 0-95%, and supply fluctuations of +/- 10%.
- The GramPRO 1 overvoltage category is II, the transient overvoltage is 1440 volts, and the pollution category is 2.
- The IP protection is IP20.
- Each GramPRO 1 comes with a power cord. It is rated to at least 240 volts and 10 amps.

3.0 Instrument Setup



NOTICE: It is recommended that the customer call QuickSlide™ at (800) 295-9588 for setup instructions.

- 3.1. Unbox unit and place in space designated for instrument use.
- 3.2. Remove front cover and stretch orange pump tubes over rollers on all 8 pumps. Replace front cover once finished.
- 3.3. Remove perforated top off of stain kit, leaving bottles in box.
- 3.4. Remove plastic lids from bottles and expose heat seals. **Do not remove heat seals.** Poke a small hole in heat seal using a ball point pen or large gauge needle. The hole should just be big enough to allow cannula to fit into bottle.
- 3.5. Insert each reagent cannula into the correct reagent bottle. Reference the labels off of the reagent bottle and tubing for correct placement.
- 3.6. DI water must be provided by the customer. A container of any size will work, but not having a large opening is preferred to prevent debris from entering the container.
- 3.7. Follow facility or laboratory procedures for waste disposal. If a container is used, make sure to check it once or twice a day to prevent overflow.
- 3.8. Connect the power cord to the power supply on the back of the instrument. It is located at the top right if the user is facing the front of the instrument.
- 3.9. Switch the rocker switch to the “ON” position.
- 3.10. Once screen displays the Main Menu, the following options will appear: 1) RUN, 2) SETUP, and 3) REVIEW. Choose 2) SETUP.
- 3.11. Select Change Reagents by pressing [2] key. The current Reagent Kit information is displayed with an option to Change Reagents:

KIT NUMB	12345689
LOT NUMBER	1234
EXP DATE MM/DD/YYYY	
1-CHANGE REAGENTS *	
KIT NUMB	12345689
LOT NUMBER	1234
EXP DATE MM/DD/YYYY	
# ACCEPT	* EXIT

- 3.12. Notice the blinking cursor marking the Kit Numb field for initial data entry. Enter digits of the kit number. Press [#] key to accept the currently displayed value. Continue with the digit and [#] keys to set lot and expiration date. Press [*] key to accept all displayed fields. The following will display on screen:

1-UPDATE REAGENT LOG
2-ABORT UPDATE

- 3.13. Press [1] key to activate the new Reagent Kit.
- 3.14. An update confirmation message will appear.
- 3.15. Press [*] until the main menu is displayed.
- 3.16. Select [1) RUN].
- 3.17. Select [3) PRIME PUMPS]
- 3.18. Once priming is complete, the machine is ready for use.

4.0 Software Menu System

When the software first starts up, the introductory screen is displayed for 10 seconds, or until a key is pressed. This screen identifies the version of the software currently loaded in the unit.

AUTO GRAM STAINER

V1.0.0

QuickSlide

1-800-295-9588

Once the introductory screen is dismissed, the Main Menu is displayed. This is the launch point of all operations. From any point “below” the Main Menu in the system, you may return to the Main Menu by repeatedly pressing the [*] key at every Menu you visit. The MAIN MENU:

1 RUN 3 REVIEW
2 SET-UP

123
hh:mm:ss mm/dd/year

The Main Menu displays the sequence number of the next staining cycle to be run, and the current time (in military / 24 hour style) and date.

Select 1 of the 3 available options by pressing the corresponding key.

4.1 Main Menu: 1 RUN

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

Pressing [*] will return immediately to the Run Menu.

4.1.1 Run Menu: 1 GRAM STAIN

Select the Gram Stain option by pressing the [1] key.



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

There are two sets of programmable delay times for each of the three reagents. These "short" and "long" delay times may be set individually by the operator for each reagent (see section 4.2.1.2). The "short" or "long" set of delays may be selected here for use during the current staining operation.

The decolorize only option omits all staining entirely, and provides a means for decolorizing ONLY as manually stained sample.

Selection of the Gram stain option results in the following menu:

1-GRAM STAIN (SHORT)
2-GRAM STAIN (LONG)
3-DECOLORIZE ONLY
***EXIT**



NOTE: Pressing [*] will return immediately to the Run Menu

Selection of any of the three options causes the cuvette to be evacuated, and yields this message:

GRAM STAIN SELECTED
CYCLES REMAINING 123
INSERT SLIDE & PRESS
A KEY (* TO ABORT)

The remaining available stain cycle count for the current Reagent Supply Kit is shown. The operator is prompted to load the slide into the cuvette with the specimen side facing out, and press a key when ready to start the selected cycle.

4.1.1.1 Stain Process Step 1: Crystal Violet Stain

The cuvette is filled to the programmed level with Crystal Violet Stain. Following the expiration of the selected (short or long) Crystal Violet stain delay time, the fluid is drained from the cuvette. A Rinse cycle is performed to clean the slide.

4.1.1.2 Stain Process Step 2: Gram's Iodine Stain

The cuvette is filled to the programmed level with Gram's Iodine Stain. Following expiration of the selected (short or long) Gram's Iodine stain delay time, the fluid is drained from the cuvette. A rinse cycle is performed to clean the slide.

4.1.1.3 Stain Process Step 3: Self-Calibration

An automatic self-calibration is run during every stain cycle to confirm proper system operation. Refer to Section 7.2 for a complete description of this process.

4.1.1.4 Stain Process Step 4: Decolorization

Decolorizing reagent is applied to the slide in a pulsing manner. As each successive droplet of run-off fluid exits the slide, it is precisely monitored to determine when sufficient decolorization has been achieved. Upon such determination, the decolorization process is promptly halted. A rinse cycle is performed to clean the slide.



4.1.2 Run Menu: 2 Clean Cuvette

Select the Wash Cuvette option by pressing the 2 key, and the following options appear:

1-WASH CUVETTE
2-SCRUB STAIN LINES

For the SCRUB STAIN LINES function, see section 11.0. To wash the cuvette, press [1]. The following message appears:

WASH SELECTED
REMOVE SLIDE & PRESS
A KEY (* TO ABORT)

The operator is prompted to remove the slide, and press a key when ready to start the wash cycle. Alternately, pressing the [*] key will return immediately to the RUN MENU without performing a wash. A wash consists of completely filling the cuvette with cleaning fluid (acetone-alcohol), allowing it to soak for a moment before agitating, and then evacuating the fluid. The “wash recommended” cycle counter is reset when this wash is done. Program flow returns to the RUN MENU once the wash is finished.



4.1.3 Run Menu: 3 Prime Pumps

Select the Prime Pumps option by pressing the [3] key. To avoid overflows, selection of the Prime function initially causes a Purge cycle to be ran. This assures that all tubing is dry prior to priming. A prime cycle involves running each pump in turn for the programmed duration so as to “prime” the supply lines with fluid and to establish the air gaps required in certain supply line connections. Following the Prime cycle completion, the system is ready for stain operations. Program flow returns to the Run Menu upon completion.



4.1.4 Run Menu: 4 Purge

Select the PURGE option by pressing the [4] key. A Purge cycle starts by completely draining the cuvette of any resident fluid, and pumping this fluid out the waste line to the drain. Once the cuvette is evacuated, all reagent supply lines are purged, or emptied, by back-flushing all fluids into their respective bottles. Program flow returns to the Run Menu upon completion.

4.1.5 Run Menu: *Exit

Pressing [*] will return immediately to the Main Menu.

4.2 Main Menu: 2 Set-Up

1-CALIBRATION
2-CONSUMABLES
3-DATE / TIME
4-OPTIONS * EXIT

Pressing [*] will return immediately to the Main Menu.

4.2.1 Set-Up Menu: 1 CALIBRATION

Select the Calibration option by pressing the [1] key, and the Calibration Menu appears:

1-CALIBRATE DETECTOR
2- STAIN DELAYS
*** EXIT**

Pressing [*] will return immediately to the Set-Up Menu.

4.2.1.1 Calibration Menu: 1 CALIBRATE DETECTOR

The system automatically calibrates the photo sensor every time a staining cycle is run. It is not necessary to manually calibrate the instrument with this option. This option does provide, however, a quick way to confirm the photo detector is operating correctly and can be used as such a test.

Press [1] to select the Calibrate Dector Option, and a Detector Calibration cycle begins.



Detector Calibration Process Step 1 – Wet Reading

The measurement cell is filled with Decolorizer, and the Photo Sensor is activated and monitored for a period of five seconds. The readings obtained are averaged and compared to the stored Calibration Limits values for the Wet condition. If the measured average is within the specified ranges, the Wet Calibration is deemed valid and the cycle continues with the Dry Reading. If not in range, the wet measurement can be repeated a maximum of two more times until the results are in range. If five consecutive attempts yield out-of-range results, the calibration is terminated, and an error notification message is provided:

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

Press [*] key to return to the Photo Detector Menu.



Detector Calibration Process Step 2 – Dry Reading

All fluid is drained from the measurement cell, and the Photo Sensor is activated and monitored for a period of five seconds. The readings obtained are averaged and compared to the stored Calibration Limits values for the Dry condition. If the measured average is within the specified range, the Calibration is deemed valid and the results are stored and displayed. If the measured average is not within the specified range, the dry measurement can be repeated a maximum of two more times until the results are in range. If three consecutive attempts yield out-of-range results, the calibration is terminated, and an error notification message is provided:

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

Press [*] key to return to the Photo Detector Menu.

4.2.1.2 Calibration Menu: 2 STAIN DELAYS

Select the Stain Delays option by pressing the [2] key, and the Stain Delay Menu appears:



**1-SHORT STAIN DELAY
2-LONG STAIN DELAY**

Pressing [*] will return to the Calibration Menu.

The system provides two sets of operator programmable stain delay times. Both a “short” and a “long” delay time may be specified for each of the three staining reagents (Crystal Violet, Gram’s Iodine, and Safranin) used in the Gram Stain process. Either the Short or the Long stain delay set may be selected for staining a particular slide. Use of short delays is sufficient for Saline Prepared samples, while long delays are often better for thick sample preparations. Factory default delays are 40 and 60 seconds, respectively.

4.2.1.2.1 Stain Delay Menu: 1 SHORT DELAYS

Press [1] to select the Short Stain Delay option, and the Current Short Stain Delays Values appear:

**CV TIME 40
GI TIME 40
SAF TIME 40
1-CHANGE DELAYS * EXIT**

Pressing [*] will return to the Stain Delay Menu.

Press [1] to Change the Short Stain Delays, and the Short Stain Delay Edit Menu appears:

CV TIME 40
GI TIME 40
SAFE TIME 40
ACCEPT *EXIT

Notice the blinking cursor marking the CV Time field for initial data entry. Enter digits for CV Time in seconds. Press [#] key to accept the currently displayed value. Continue with digit and [#] keys to set GI and SAF Times. Press [*] key to accept all displayed delay times and program flow returns to Current Short Delay Display.



4.2.1.2.2 Stain Delay Menu: 2 LONG DELAYS

Press [2] to select the Long Stain Delay option, and the Current Long Stain Delays Values appear:

CV TIME 60
GI TIME 60
SAF TIME 60
1-CHANGE DELAYS * EXIT

Pressing [*] will return to the Stain Delay Menu. Press [1] to Change the Long Stain Delays, and the Long Stain Delay Edit Menu appears:

CV TIME 60
GI TIME 60
SAF TIME 60
ACCEPT * EXIT

Notice the blinking cursor marking the CV Time field for initial data entry. Enter digits for CV Time in seconds. Press [#] to accept the currently displayed value. Continue with digit and [#] keys to set GI and SAF Times. Press [*] key to accept all displayed delay times and program flow returns to Current Short Delay Display.

4.2.1.2.3 Stain Delay Menu: * EXIT

Pressing [*] will return to the Stain Delay menu.

4.2.1.3 Calibration Menu: * EXIT

Press [*] to return to the Set-Up Menu.



4.2.2 Set-Up Menu: 2 CONSUMABLES

Select Consumables by pressing the [2] key. Two options are displayed:

1-REVIEW REAGENTS
2-REVIEW TUBING ***EXIT**

Review Reagents by pressing the [1] key. To Review and change Tubing see section 10.0. The Reagent Status is displayed with an option to Change Reagents:

REAGENT STATUS
CYCLES REMAINING 123
EXP DATE MM/DD/YYYY
1-CHANGE KIT ***EXIT**

Press [*] to return to the Set-Up Menu.

4.2.2.1 Change Reagents Menu: 1 CHANGE REAGENTS

Press [1] to activate a new Reagent Kit:

KIT NUMB 12345689
LOT NUMBER 1234
EXP DATE MM/DD/YYYY
ACCEPT *** EXIT**

Notice the blinking cursor marking the Kit Numb field for initial data entry. Enter digits of the kit number. Press [#] to accept the currently displayed value. Continue with digit and [#] keys to set lot and expiration date. Press [*] to accept all displayed fields and see this display:

1-UPDATE REAGENT LOG
2-ABORT UPDATE

Press [1] to activate the Reagent Kit update.
An abort acknowledgement appears. Press [*].

Program flow returns to the Date/Time Menu.

4.2.2.2 Change Reagents Menu: *EXIT

Press [*] to return immediately to the Set-Up Menu.



4.2.3 Set-Up Menu: 3 DATE / TIME

Select Date / Time by pressing the [3] key. The current date and time are displayed with options to change either date or time:

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

Press [*] to return to the Set-Up Menu.

4.2.3.1 Date / Time Menu: 1 SET DATE

Press [1] to change the date, and the following prompt appears:

SET TIME HH/MM/SS
ACCEPT * EXIT

Notice the blinking cursor marking the month field for initial data entry. Enter digits of the desired month. Press [#] to accept the currently displayed month. Continue with digit and [#] keys to set day and year. Program flow returns to the DATE / TIME MENU.

4.2.3.2 Date / Time Menu: 2 SET TIME

Press [2] to change the time, and the following prompt appears:

SET TIME HH:MM:SS
ACCEPT * EXIT

Notice the blinking cursor marking the hour field for initial data entry. Enter digits of the desired hour. Press [#] to accept the currently displayed hour. Continue with digit and [#] keys to set minute and second. Program flow returns to the DATE / TIME MENU.

4.2.3.3 Date / Time Menu: * EXIT

Press [*] to return to the Set-Up Menu.

4.2.4 Set-Up Menu: 4 OPTIONS

Select Options by pressing [4], and the following display appears:

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

Press [*] to return to the Set-Up Menu.

4.2.4.1 Option Menu: 1 AUDIO ALERT

Select Audio Alert by pressing [1], and the following display appears. The top line indicates the current Audio Alert settings.

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

Pressing [1] will turn the Audio Alert setting off.

Pressing [2] will turn the Audio Alert setting on.

Pressing [3] will sound the Audio Alert.

Pressing [*] will return to the Options Menu.

4.2.4.2 Option Menu: 2 IDLE DELAYS

Select Idle Delays by pressing [2], and the following display appears:

```
SLEEP DELAY      xxxx MIN
STIR DELAY       xxxx MIN
AUTO PRIME       xxx HR
# ACCEPT         * EXIT
```

Notice the blinking cursor marking the data entry point. Press numeric keys to enter desired delays. Press [#] to enter desired delays. Press [#] to accept the currently displayed valued. Continue with the numeric and [#] keys until satisfied all three Sleep, Stir and Auto_Prime delay values. Press [*] to update delays and exit to Options Menu.

4.2.5 Set-Up Menu: * EXIT

Press [*] to return to the Main Menu.

4.3 Main Menu: 3 Review



The system maintains a database containing the results of the 100 most recent staining operations, as well as the 50 most recent photo sensor calibration results. Any of these results may be examined by selecting the 3 – Review option provided in the Main Menu. This yields the Results Review Menu:

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

Choose the type of result to review, or press [*] to return to the Main Menu.

4.3.1 Results Review Menu

Upon selection of a run type, the Review Display appears on the screen:

```
MM/DD/YY  HH:MM:SS
Seq-000123  t = 06150
Min=02175  Max = 08643
1-Prev     2 – Next
```

This test result's date and time was obtained and displayed, as is its Sequence Number. The total decolorization time (t) is given in milliseconds. The Min and Max value displayed are the minimum and maximum stabilized photocell readings observed during the operation. These dates are recorded to aid in troubleshooting a malfunctioning system. The contents are displayed in the chronological order of acquisition. The "Prev" and "Next" options permit easy browsing of the selected database. This exported report can be sent in for "off-site" evaluation. Pressing [*] will return immediately to the Results Review Menu.



5.0 Operating Instructions

This section provides the minimum instructions sequence for staining a slide. Reagents must be properly connected and primed for proper unit operation.

5.1 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, 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 1 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.

5.2 Sample Slide Preparation

- 5.2.1 If the culture is to be taken from a Petri dish or a slant culture tube, first add a drop or a few loops full of water on the slide and aseptically transfer a minute amount of a colony on the Petri dish. Transfer a drop of the suspended culture to be examined on a slide with an inoculation loop. Note that only a very small amount of culture is needed; a visual detection of the culture on an inoculation loop already indicates that too much is taken. If staining a clinical specimen, smear a very thin layer onto the slide, using a wooden stick. Do not use a cotton swab as the cotton fibers may appear as artifacts. The smear should be thin enough to dry completely within a few seconds. The stains will not penetrate thickly applied specimens, making interpretation very difficult.
- 5.2.2 Spread the culture with an inoculation loop to an even thin film over a circle of 1.5 cm in diameter, approximately the size of a dime. **Position the smear at least 3/4" below the frosted area, and 1/4" from the left and right edges of the slide to provide the necessary clearances for GramPRO 1 processing.**
- 5.2.3 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. **It is required that the methanol method (Cat. no. AGS-ME-1016) be used, rather than heat, since it is superior in preventing lysis, distortion, or damage to the cells in clinical material.** Red and white cells will not be harmed, whereas heat will distort or disrupt the cells. Passing the slide over a flame is also not recommended.

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

Methanol Fixation Procedure: Air-dry the specimen. A heat source may be used to accelerate the drying process but must be limited to 40 degrees Celsius for no longer than one hour. Higher temperatures and longer durations could compromise the quality of the methanol fix. Once fully dried, place a few drops of methanol on the slide for one minute. Please ensure that the methanol covers the whole smear. Drain off remaining methanol without rinsing and allow slide to air dry. Do not heat before staining.

5.3 Turn system power ON. System ID is displayed:

AUTO GRAM STAINER
V1.0.0
QuickSlide™
1-800-295-9588

5.3.1 Press any key, or wait 10 seconds, to dismiss the ID screen. The Main Menu is displayed:

1 RUN 3 REVIEW
2 SET-UP
142
14:26:38 06/19/2008

5.3.2 Press 1 – Run. The Run Menu is displayed:

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

5.3.3 Press 1 – Gram Stain. The Stain Option Menu is displayed:

1-GRAM STAIN (SHORT)
2-GRAM STAIN (LONG)
3-DECOLORIZE ONLY
***EXIT**

5.3.4 Press 2 – Gram Stain (Long). The Load Slide prompt is displayed:

GRAM STAIN SELECTED
CYCLES REMAINING 92
INSERT SLIDE & PRESS
A KEY (* TO ABORT)

5.3.5 Load the slide with the **specimen side facing out (toward the operator)**. Press a key to start the stain cycle.



CAUTION ⚠: When loading slide into the unit, lower slide gently into the slide holder. If the slide is allowed to drop and abruptly hit the “Slide Stop”, the slide can possibly chip the slide. The slide fragments can clog the waste tubing and cause an overflow. Broken glass in the waste line or cuvette slide holder is not covered under warranty and the customer will be responsible for repairs and shipping. **DO NOT** attempt to remove broken glass by removing tubing, etc. This will further compromise the repair efforts. Call (800) 295-9588 for service questions or repairs.


5.3.6 The slide is automatically stained and decolorized by the system. An audible alarm announces process completion. Remove the slide and wipe the back side of the slide to dry. The front side can be air dried or bottled with bibulous paper (Cat. no: 28511007). Never wipe the specimen side of the slide. The slide is now ready for viewing under the microscope.

6.0 Reagent Supply Kits

6.1 General Information

The system accomplishes automatic Gram staining by a systematically staining, rinsing, decolorizing, and counter-staining the provided biological sample and slide. It is critical for the success of this automated process that the composition of the reagents employed be carefully controlled and be of exceptionally high quality.



NOTICE : To maximize consistently superior performance, the GramPRO 1 requires that only those reagents qualified by QuickSlide be used with the unit.



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.

6.2 Reagent Kit Installation

The instrument reagents are supplied to the unit through tubes connected to the individual reagent containers. Each tube is clearly labeled, and must be inserted into the correct reagent container. Tubes are also provided for connection to a water source and to a waste fluid drain. Use care to insure that these lines are properly connected before use of the unit.

6.3 Waste Collection and Disposal

The waste produced with the machine can be collected in a waste container, or sent directly into a drain. It is up to the user to follow their facility's policy and procedures regarding waste handling. The reagents SDS sheets are located at the end of the manual in section 15.



7.0 Quality Control

7.1 Quality Control Checks

The quality and validity of the Gram stain process of this instrument 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 sample slide. The processed sample slide may then be viewed to confirm proper Gram stain technique and results. Quality Control slides may be purchased from QuickSlide™ by calling (800) 266-2222. Ask for Gram Stain Control Slides (Cat. no. AGS-00700).

7.2 Self-Calibration Errors

The system 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 reported as an error condition, and cause early termination of a staining cycle. This self-check provides additional assurance of accurate system performance.



8.0 Usage Tracking

8.1 Reagent Consumption

The system 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. This remaining count should be carefully monitored so that fresh reagents may be ordered and available when needed. Call (800) 266-2222 to reorder. Ask for QuickSlide™ Gram Stain Reagents (Cat. no. AGS-SK-2000).

8.2 Recommended Wash Interval

The staining cuvette occasionally requires thorough cleaning to remove the stain deposit build-ups that occur after many stain cycles. The system issues a reminder message when it is time to run the cleaning cycle. Performing the Cleaning Cycle resets the recommendation message.

8.3 Total Stain Cycles

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



9.0 Sleep Mode

The 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 4.2.4.2 for instructions for setting these delays.

9.1 SLEEP Mode

The software monitors idle time by observing the elapsed time since the last key was pressed. When this elapsed time exceeds the specified Sleep Time delay, the system enters Sleep Mode. Sleep Mode is distinguished by turning off the LCD display backlight. While in Sleep Mode. The pump motors are de-energized to conserve power and minimize heat. As there is no delay involved in exiting Sleep Mode, the Sleep Time delay should be fairly short, typically about 5-10 minutes. Secondary timers are started for monitoring Stir and Auto-Prime delays when Sleep Mode is entered.

9.2 Exiting SLEEP Mode

The system exits Sleep Mode immediately when a key is pressed. This first key press while in Sleep Mode is NOT acted upon – it simply causes an exit from

Sleep Mode. The system notifies its “awakened” state by illuminating the LCD backlight. Subsequently key presses trigger system operations as normal.

9.3 STIR Operation

Following the expiration of the specified Stir Time delay, the system 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 60 minutes is recommended.

9.4 AUTO-PRIME Operation

For extended idle periods the system may perform an Auto-Prime cycle. The Auto-Prime 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 cycle is useful in preventing reagent evaporation in the supply lines, and helps maintain the unit in a ready state. An Auto-Prime delay of about 24 hours is recommended.



10.0 Pump Tube Replacement Procedure for GramPRO 1

Pump tubes have to be replaced to ensure proper function of the GramPRO 1. The GramPRO 1 keeps track of the number of tubing cycles remaining, and will notify when change is necessary. A new tubing set will last 1,100 cycles. There is no other maintenance involved with tubing other than occasionally checking the pump tubes for flat spots or cracks. This can be done by removing the front cover, and then stretching the orange tubes off of the rollers and visually inspecting them. If a flat spot is discovered, it can be removed by gently rolling the tube between your thumb and forefinger. If a crack is discovered, the tube needs to be replaced.

- 10.1 From main menu-(Select 2 Set-up)
- 10.2 Select [2] Consumables
- 10.3 Select [2] Review Tubing
- 10.4 Select [1] Change Kit
- 10.5 Enter kit S/N and push [#] Accept
- 10.6 Enter kit Batch Number and push [#] Accept
- 10.7 Push [*] to exit
- 10.8 Select [1] Update Tubing Log
- 10.9 [*] to Main Menu
- 10.10 Select [1] Run
- 10.11 Select [4] Purge-Purge Unit 2 Times
- 10.12 Turn unit off
- 10.13 Remove the four thumb screw that secure the pump cover and remove the pump cover.

- 10.14 Remove the nylon elbows from the orange pump tube and replace with a new pump tube. Plug the nylon elbows in the new pump tube on both sides. Change only one pump tube at a time to keep correct tubing placement.
- 10.15 Once all eight pump tubes have been replaced and the nylon elbows have been plugged in, turn the unit on and wait for Main Menu.
- 10.16 Select [1] Run and then select [3] Prime-Check for leaks. Once the unit is primed it is ready to run samples.
- 10.17 Re-install pump cover with the 4 thumb screws.


11.0 GramPRO 1 Scrub Feature



NOTE: The Scrub Feature for the GramPRO 1 required every month or 600 cycles, whichever occurs first. The unit will automatically prompt the operator when scrub cycle needs to be run.

- 11.1 From the main menu, select [1] Run.
- 11.2 Select [2] Clean Cuvette.
- 11.3 Select [1] Purge to empty lines of stains.
- 11.4 Move Crystal Violet, Gram's Iodine, and Safranin lines and cannulas into one bottle of AGS-SC-4000 System Cleaner. The cleaner is used to clean the internal portions of the reagent lines, ports, and photo optics of the unit.
- 11.5 Select [1] to scrub lines. The unit will automatically prime the system cleaner into the reagent lines and then begin the scrub sequence.
- 11.6 After the scrub cycle is complete, wipe off the reagent cannulas with an alcohol pad before returning the three stain lines to the proper stain bottles and press any key. The unit will automatically prime itself and be ready for use after returning to the main menu.



NOTICE : Do not run the scrub cycle if the unit is not draining properly. This will cause a major overflow. Call QuickSlide™ at (800) 295-9588 for any questions regarding the scrub feature.

12.0 GramPRO 1 Warranty

The GramPRO 1 comes with a one (1) year standard warranty from the date of shipment.

- Repaired units will have the latest software upgrades and new tube sets.
- Shipping charged to and from the customer is also covered.

QuickSlide™ shall not be obligated under this warranty if the need for repairs or replacements results from Customer's failure to operate and maintain the System as specified by the operating manual. QuickSlide™ shall not be responsible for results generated from or damage caused by Customer's use of third party reagents or use of third party maintenance services.

Repairs or replacement arising from any of the following shall invalidate the warranty:

- (i) Customer's failure to properly perform the services and maintenance required in the operator's manual for an instrument
- (ii) Repairs by persons other than QuickSlide service personnel
- (iii) Replacements with other than genuine QuickSlide parts
- (iv) Customer's 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

The standard warranty does not cover:

- Routine Maintenance Tube Sets
- Broken glass slides in tubing or the waste ports as an outcome of customer negligence

All other components are covered, granted the user follows the operating instructions.

An extended warranty may be purchased for extended coverage. Visit www.hardydiagnostics.com for more information or call customer service at (800) 266-2222.

13.0 Taking GramPRO 1 Off-Line

13.1 Run scrub cycle



NOTE: Use the GramPRO 1 AGS-SC-4000 System Cleaner. Alternatively, you can use Methanol Alcohol or even hot tap water. If bleach is used, the unit must be rinsed with after the scrub by moving the stain lines from the bleach into water and priming. After this, the unit can be purged out from main menu.

13.2 The orange pump tubes need to be removed off of the rollers after the unit has been purged.

13.3 Now the pump cover can be reinstalled for shipping, etc.

14.0 Service and Supplies

If a problem is encountered that is beyond the scope of this manual or additional assistance is required, contact our QuickSlide™ Technical Support team at (800) 295-9588.

If additional supplies are needed, reagents and tubing kits can be ordered through Hardy Diagnostics' Customer Service. Call (800) 266-2222, or go to www.HardyDiagnostics.com. Alternatively, you can contact your preferred distributor.

Catalog Number	Description
AGS-SK-2000	GramPRO 1 Stain Kit, 5x16 fl. oz.
AGS-00700	QC Slides 50/pack
AGS-SC-4000	System Cleaner, 2x500ml
AGS-TK-3000	Replacement Tubing Kit
AGS-ME-1016	Methanol, 16 fl. oz.

15.0 Safety Data Sheets

Safety Data Sheets (SDS) can be found at www.HardyDiagnostics.com.

16.0 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.