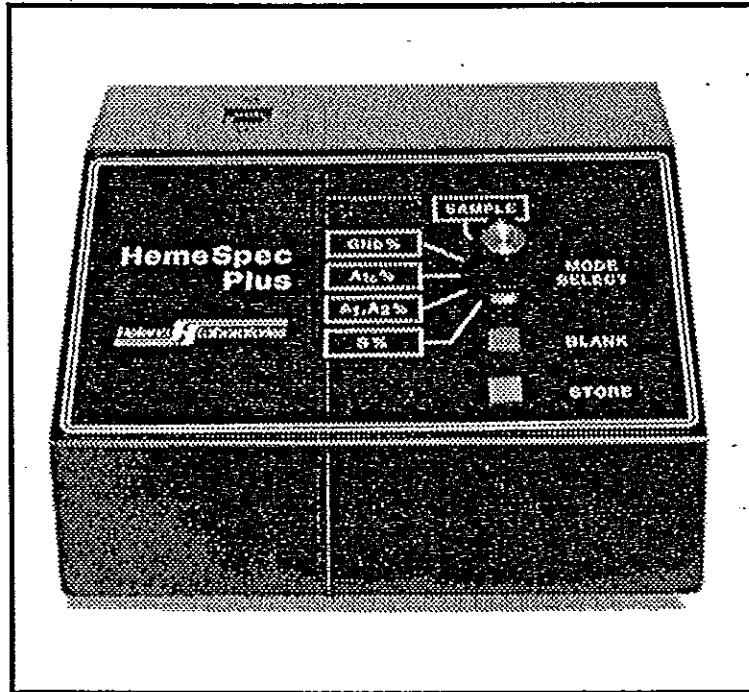


Operator's Manual



HemeSpec Plus

Cat. No. 1103, 110 Vac

Cat. No. 1101, 220 Vac

Helena  **Laboratories**

HemeSpec Plus

Operator's Manual

Cat. No. 1103	110 Vac
Cat. No. 1101	220 Vac

HemeSpec Plus
Operator's Manual

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ONE - Instrument Use and Function

The HemeSpec Plus (Fig. 1-1) is a dedicated colorimeter. It is designed for the automatic calculation of the percentages of glycosylated hemoglobin (GHb), hemoglobin A1, A1c, A2, and hemoglobin S. The HemeSpec Plus is for use only with samples prepared using Helena column methodologies. The HemeSpec Plus is intended for in-vitro diagnostic use only.

The table below lists the reagent kits used with the HemeSpec Plus and the instrument modes for each.

Kit Cat. No. and Name	Mode to Use
5334 Sickle Thal Quick Column TM (A2)	A1, A2%
5334 Sickle Thal Quick Column TM (S)	S%
5341 Beta-Thal HbA2 Quick Column TM	A1, A2%
5344 GLYCO Hb Quick Column TM	A1, A2%
5351 Glyco-Tek Affinity Column	GHb%
5355 Glyco-Tek Renewable Affinity Column	GHb%

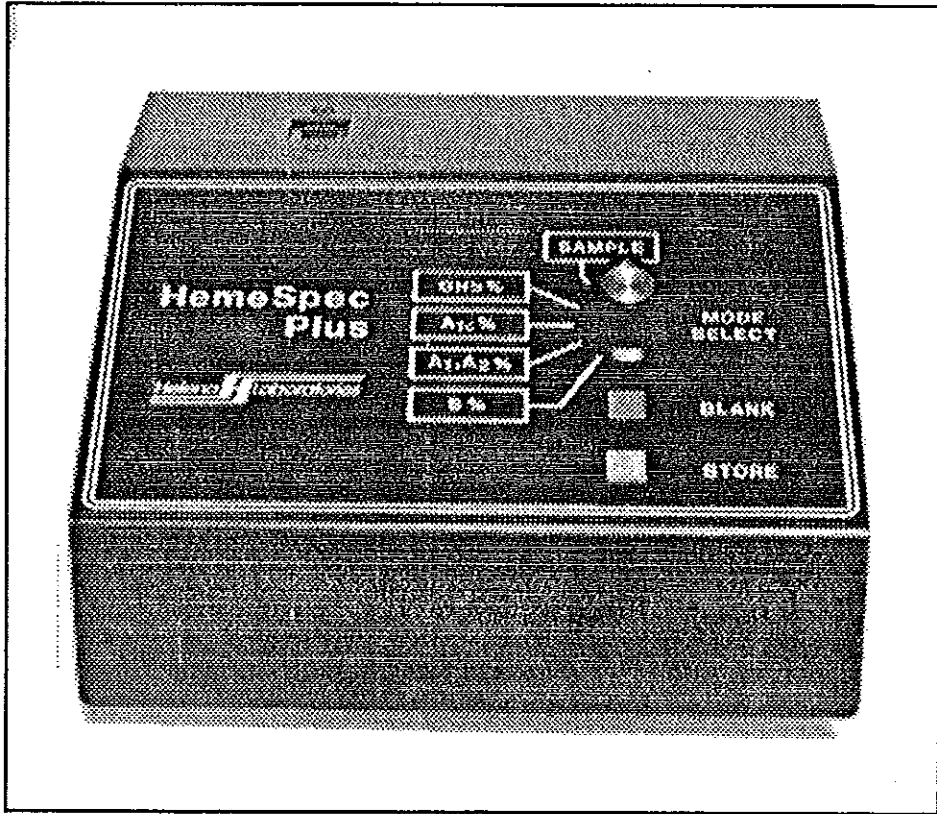


Fig. 1-1. HemeSpec Plus.

TWO - Principles of Operation

The functional units of the HemeSpec Plus are shown in figure 2-1. All user input is through the front panel controls and on/off switch. The tungsten-Krypton lamp illuminates the sample contained in a cuvette in the sample well. Some of the light is absorbed, in proportion to the concentration of the sample. The remaining light passes through a heat absorbing filter and a 415 nm filter and then hits a photocell. The photocell produces a current level in response to the light reaching it. This information is processed by the CPU and a value is displayed.

The displayed result depends on the mode of operation. In the sample mode, the signal is zeroed or the reading from the sample is displayed. In the other four modes, the displayed result is calculated according to one of the following formulas.

$$\text{GHb\%: } \frac{\text{GHb} \times 100}{\text{GHb} + 5(\text{non-GHb})} \quad (\text{Use with Cat. No. 5351, 5355})$$

$$\text{A1c: } \text{---} \quad (\text{Available in Near Future})$$

$$\text{A1,A2\%: } \frac{\text{HbA1,A2} \times 100}{5(\text{Total})} \quad (\text{Use with Cat. No. 5334, 5341, 5344})$$

$$\text{S\%: } \frac{\text{HbS} \times 100}{\text{Total}} \quad (\text{Use with Cat. No. 5334})$$

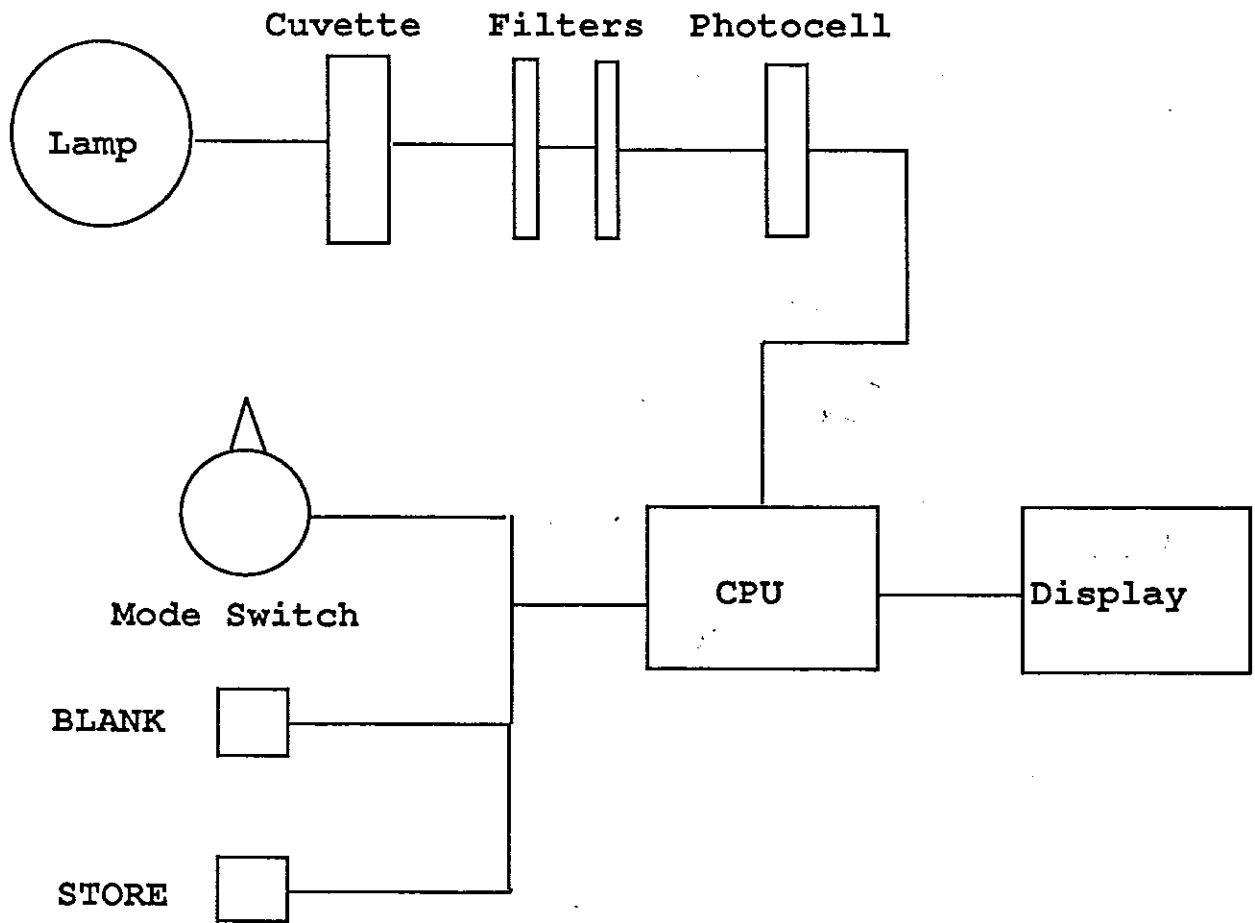


Fig. 2-1. Block Diagram.

THREE - Precautions and Limitations

- 3.1. The entire operator's manual should be read and understood before attempting instrument operation.
- 3.2. Installation is to be performed by the operator.
- 3.3. Provide adequate room at the sides and back of the instrument for good air circulation.
- 3.4. No harsh cleansers, acids, or bases should be used or spilled on inner or outer surfaces. Do not immerse the unit. Always unplug the power cord before cleaning.
- 3.5. For emergency shut down, disconnect the power cord or use the power on/off switch located on the rear of the instrument.
- 3.6. Samples must be read in 1-cm Square Cuvettes, Cat. No. 1104, from Helena Laboratories.
- 3.7. The minimum solution volume for reading is 2.5 mL.
- 3.8. Samples must be prepared by Helena column methodologies only.

FOUR - Hazards

- 4.1. This device contains high voltages which can be extremely dangerous. Turn off the power, disconnect the power cord, and use extreme care when attempting disassembly for cleaning, repair, or adjustments. Do not operate any instrument with the cover removed unless instructed to do so by a qualified service technician directly representing Helena Laboratories, its subsidiaries, or its distributors.
- 4.2. Do not attempt to operate the instrument without plugging the power cord into a grounded wall outlet of the proper voltage and frequency.
- 4.3. Do not touch the lamp before allowing it to cool.
- 4.4. Before turning on the instrument power, ensure that the fuse module (located in the power receptacle) is set for the proper voltage. The voltage rating in effect is the one which is right-side up.

FIVE - Controls and Displays

5.1. Controls

BLANK Button: Zeroes instrument on water blank.

STORE Button: Stores first and second cuvette readings.

MODE SELECT Knob: Selects one of the following modes of operation:

SAMPLE: Shows result of individual sample reading.

GHb%: Use this mode when reading samples to determine GHb for Cat. No. 5351 and 5355

A1c%: (Available in near future)

A1, A2%: Used to read samples to determine HbA1 or HbA2 for Cat. Nos. 5334, 5341, 5344

S%: Used to read samples to determine HbS for Cat. No. 5334

Power On/Off Switch: Located on the back panel. Controls power to the instrument.

5.2. Display

LED display shows results of measurements in various modes.

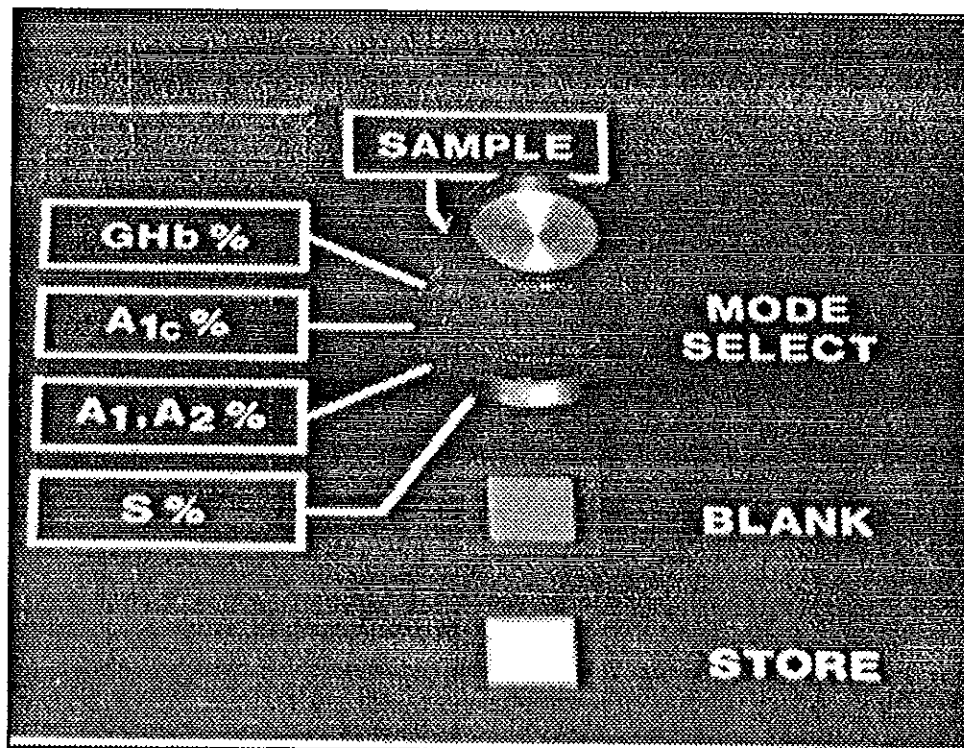


Fig. 5-1. Front Panel.

SIX - Installation Instructions

6.1. Unpacking and Inspection

1. Check all shipping containers for signs of damage. If damage is found, immediately notify the shipping carrier.
2. Carefully unpack the instrument and accessories and remove them from the shipping cartons. The packing material should be removed undamaged, if possible, should repacking be necessary.
3. Remove plastic wrappings from the instrument and accessories. If scissors or a knife are used to cut the plastic or binding tape, take care not to scratch the instrument.
4. Inspect the instrument for any obvious signs of damage. If damage is found, notify the shipping carrier and Helena Laboratories.
5. Inventory all items: If any parts are missing, recheck the packing materials before notifying Helena Laboratories.

Table 6-1. Inventory.

1 HemeSpec Plus
1 Power Cord
100 Cuvettes (Cat. No. 1104)
1 Operator's Manual

6.2. Installation

1. Select an environment free of excessive humidity, dust, and large temperature fluctuations.
2. Place the unit on a level, flat surface. Make sure that there is enough space behind and around it to allow good air circulation.
3. Plug the power cord into a grounded wall outlet of the proper voltage and frequency.

CAUTION: Before turning on the instrument power, ensure that the fuse module (located in the power cord receptacle) is set

SIX - Installation Instructions

for the proper voltage. The voltage rating in effect is the one which is right-side up. If necessary, remove the power cord, withdraw the fuse module by inserting a screwdriver into a slot on the lower right corner of the fuse module. The fuse module is a rectangle labeled 110 and 220, located next to the power cord inlet. When installed, the correct voltage should be displayed right-side up and next to the arrow (at the bottom of the rectangle). Refer to the drawing in figure 10-2. Replace the power cord.

The wall outlet should not be on the same circuit as any large load device such as a refrigerator, compressor, centrifuge, etc. The instrument's circuitry contains filters to reduce the effect of line voltage fluctuations; however, they should still be avoided. If the operator experiences difficulty, it may be necessary to install an isolation transformer.

SEVEN - Operating Instructions

1. Turn on the power.
2. Let the instrument warm up approximately 30 minutes. During this time, run the columns.
3. Fill a cuvette with 2.5 mL purified water, lower it into the sample well with a frosted side toward the front, and turn the knob to the desired test mode.
4. Press the **BLANK** button. The display should now read 0.00 (or -0.00). If not, press **BLANK** again, then withdraw the cuvette. Note the reading on the empty well.
5. Insert the tubes in the following order for the mode in use.

Mode	1st Cuvette	2nd Cuvette	Reagent Kit
GHb%	GHb	non-GHb	Cat. No. 5351, 5355
A1c%	Available in Near Future		
A1,A2%	HbA1,A2	Total	Cat. No. 5334, 5341, 5344
S%	HbS	Total	Cat. No. 5334

Insert the first cuvette into the sample well and press **STORE**, then withdraw the cuvette. Note the reading on the empty well again. If the value has changed, repeat steps 3, 4 and 5.

6. Insert the second cuvette into the sample well and press **STORE**. The result will appear on the display. Record the result before proceeding to the next sample.
7. Repeat steps 5 and 6 for each new set of samples, then turn off the instrument.

EIGHT - Test Functions and Quality Control

The instrument automatically performs a self-test any time the power is turned on. Should the message HSP not appear on the display, see Section Ten, Troubleshooting.

Quality Control of the instrument consists of two parts, a performance check and a linearity check.

8.1. Performance Check

Known dilutions of blood samples or controls serve as a check of instrument performance.

1. Turn on the power and allow it to warm up for 30 minutes. Allow samples and reagents to warm to room temperature.
2. Prepare the sample. If using a glycosylated hemoglobin or A2 control, reconstitute according to package directions (do not make a hemolysate of the control).

Place 20 uL of whole blood or the reconstituted control in 15 mL of distilled water. Agitate well before transferring to two cuvettes.

3. Put the HemeSpec Plus in the appropriate mode.
4. Place a cuvette filled with distilled water in the sample well and press **BLANK**. The display should read 0.00 (or -0.00). If not, press **BLANK** again.
5. Withdraw the cuvette and note the reading on the empty well. The same reading should appear between the first and second cuvette readings when the well is empty, throughout the use of the instrument. Deviation from this number indicates that the instrument should be blanked on distilled water again.
6. Insert the first cuvette prepared in step 2 and press **STORE**. Ignore the reading.
7. Withdraw the cuvette and check the empty well reading. If the number has drifted, reblank the instrument on distilled water and repeat step 6.
8. Insert the second cuvette prepared in step 2 and press **STORE**. The displayed percentage should be within one of the following ranges shown below.

EIGHT - Test Functions and Quality Control

Mode	Percent
GHb%	16.7 +/- 0.4
A1,A2%	20.0 +/- 0.4
S%	100.0 +/- 0.4

9. If the percentages are out of range, repeat steps 6 through 8 using a single cuvette. If still out, leave the cuvette in the sample well and press **STORE** twice. If readings are still out of range, contact Helena Laboratories for assistance.

8.2. Linearity Check

If the instrument readings are off or you think operation is abnormal, conduct the following linearity check.

1. Dilute 50 uL of whole blood with 40 mL of purified water.
2. Prepare a standard curve from the sample prepared above by making the following dilutions of the sample:

Vol. DI Water	+	Vol. Diluted Sample	=	% Standard
10 mL		0 mL		0%
9 mL		1 mL		10%
7 mL		3 mL		30%
5 mL		5 mL		50%
3 mL		7 mL		70%
1 mL		9 mL		90%
0 mL		10 mL		100%

3. BLANK the instrument on purified water with the instrument in SAMPLE mode.
4. Take a reading (in SAMPLE mode) for each dilution, without storing the results.
5. Using standard graph paper, plot the % standard on the horizontal axis and the HemeSpec Plus reading on the vertical axis. The points should result in a straight line. If your results significantly deviate from a straight line, call Helena Laboratories for assistance.

NINE - Performance Specifications

Modes of Operation: Five modes are provided.

SAMPLE: Shows result of sample reading.

GHb%: Determines GHb% (for Cat. No. 5351 or 5355) based on the following formula.

$$\frac{\text{Meas. (GHb)} \times 100}{\text{Meas. (GHb)} + 5(\text{Meas. non-GHb})}$$

A1c%: (Available in Near Future)

A1,A2%: Determines HbA2% or HbA1% (for Cat. Nos. 5334, 5341, 5344) based on the following formula.

$$\frac{\text{Meas. (HbA1,A2)} \times 100}{5(\text{Meas. Total})}$$

S%: Determines S% (for Cat. No. 5334) based on the following formula.

$$\frac{\text{Meas. (HbS)} \times 100}{\text{Meas. Total}}$$

Input Power: 110 Vac, 50/60 Hz, 20 Watts
220 Vac, 50/60 Hz, 20 Watts

Fuses (2): 1/4-A/250-V slow blow

Dimensions: 5-3/8 in (14 cm) High
9-1/4 in (23.5 cm) Wide
9 in (23 cm) Deep

Environment: 15° to 30°C (59° to 86°F)

TEN - Maintenance, Troubleshooting, Warranty

This section describes routine operator maintenance procedures. For instrument calibration or for maintenance not described in this manual, call Helena Laboratories for assistance.

10.1. Maintenance

10.1.1. Fuse Replacement - Ac Line Selection

1. Unplug the power cord at both ends.
2. Use a screwdriver blade to withdraw the fuseblock (Fig. 10-1).
3. Replace the fuse in the holder.
4. Make sure that the fuse holder is oriented properly. The 110 rating should be down (next to the arrow) for 110 V units, the 220 rating should be down (next to the arrow) for 220 V units. Failure to perform this step properly can damage the instrument.
5. Slide the properly oriented holder firmly back in place.
6. Replace the power cord, instrument side first.
7. Turn on the power. If the fuse blows immediately, contact Helena Laboratories for assistance.

10.1.2. Cleaning Spills

Clean spills with a soft cloth or sponge only after turning off the power and unplugging the power cord. Do not use corrosive or abrasive cleansers. Dry the unit before plugging the power cord in.

NOTE: If liquid enters the sample well, unplug the unit and return it to Helena Laboratories. This is not a user-serviceable feature.

10.1.3. Lamp Replacement

1. Turn off the power and unplug the power cord from the instrument and the wall outlet. This is very important.
2. Remove any cuvette from the sample well.
3. Using a No. 1 Phillips screwdriver, remove six screws and lockwashers: two from each side panel and the two bottom screws on the back panel.

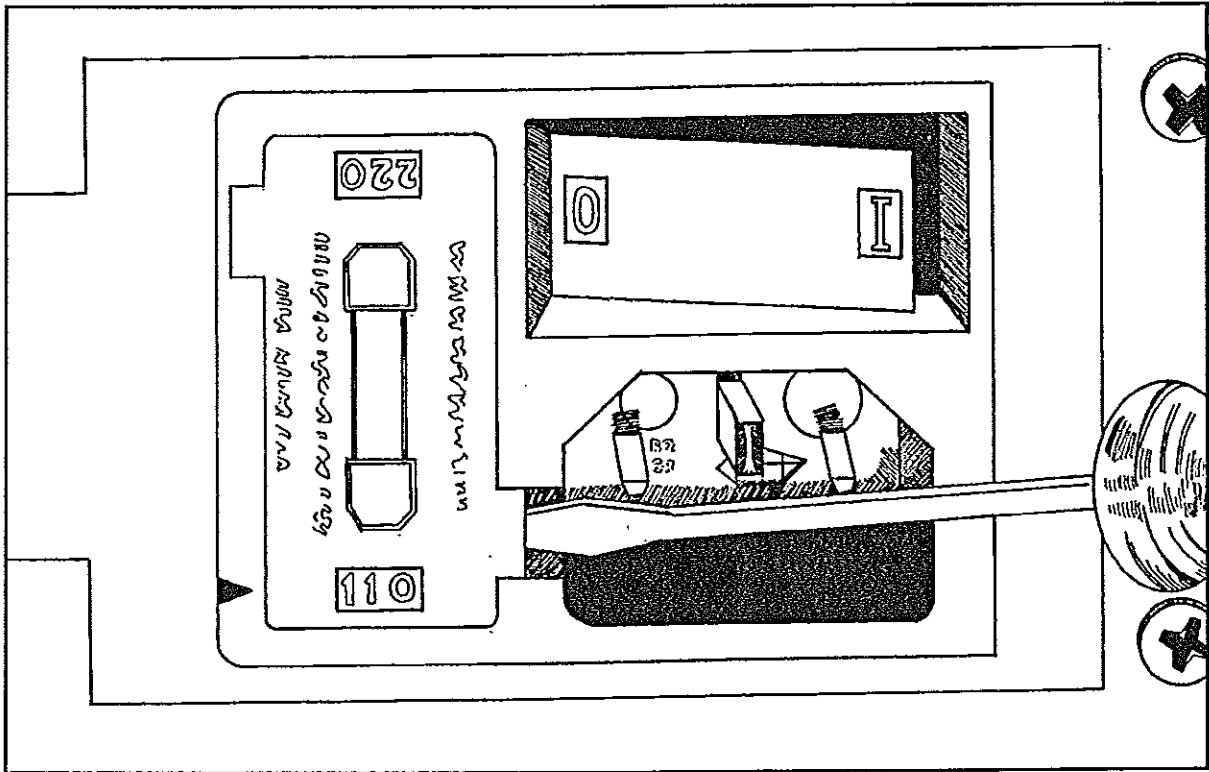


Fig. 10-1. HemeSpec Plus Back.

TEN - Maintenance, Troubleshooting, Warranty

4. Lift the cover off, pulling straight up.
5. Turn the cover on its side, exposing the lamp housing.
6. Remove the two screws and one washer holding on the brace, and remove it. This releases the yellow wire.
7. Remove the two screws and one washer holding on the plate and remove it. This releases the green wire.
8. Withdraw the lamp and replace it with a new lamp (Cat. No. 1106).
9. Replace the plate. Put the lug with the green wire over the lower hole in the plate and fasten with one of the screws. Replace the washer and screw for the upper plate hole and tighten both screws.
10. Replace the brace. Put a screw in the lug which has the yellow wire and then pass the screw through the lower brace hole and into the threaded hole in the lamp block. Put the screw with washer through the upper hole of the brace. Position the brace so that the leaf is in good contact with the center of the lamp base. Tighten the screws.
11. Slide the lid over the base, making sure that all screw tabs are inside.
12. Replace all six screws and washers before tightening screws.
13. Tighten screws.
14. Plug in the power cord at both ends.

TEN - Maintenance, Troubleshooting, Warranty

10.2. Troubleshooting

If the recommended solutions should fail to solve a problem, call Helena Laboratories for assistance.

Table 10-1. Troubleshooting.

Problem	Possible Cause	Solution
No power to instrument when power is turned on	Power cord unplugged	Plug cord into proper wall outlet
	Blown fuse	Replace fuse
Light inside instrument but no readings	Electrical problem	Contact Helena Laboratories for assistance
After zeroing, no readings	Lamp blown	Replace lamp
	Electrical problem	Contact Helena Laboratories for assistance
HSP not displayed at power on	Error found during self-test	Turn power off and on again. If HSP still is not displayed, call Helena Laboratories for assistance
Negative (-) readings on samples	Pressed BLANK button on sample	BLANK again on purified water and repeat readings
Readings of: GHb% = 16.7 +/-0.2 A1,A2% = 20.0 +/-0.2 S% = 100.0 +/-0.2	Used STORE function twice on same cuvette	Repeat readings with proper cuvettes
Other "out of range" numbers recorded	Pressed STORE on purified water or air	Repeat readings with proper cuvettes

TEN - Maintenance, Troubleshooting, Warranty

10.3. Warranty

Helena warrants each new unit to be free from defects in materials and workmanship. Helena's liability under this warranty is limited to servicing and adjusting any unit returned to the factory, servicing and adjusting any unit on site when performed by a Helena service representative, and replacing any defective part. This warranty is effective for 6 months commencing from the date of shipment to the original purchaser and does not cover fuses or faults caused by misuse, abnormal conditions or damage incurred in shipment.

This warranty is made in lieu of all other warranties, expressed or implied, and is limited in any sale to the repair or replacement of the affected component. It does not cover any accessory hardware or software purchased by the operator to modify the unit from the original designed application.

HemeSpec Plus
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Catalog No. 1101, 220 Vac

For Additional Information or Assistance, call your local distributor, or call Helena Laboratories at 800-231-5663 toll free.

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