



# Cascade<sup>®</sup> M

Hemostasis Analyzer



## Operator's Manual

Cat. No. 1710, 120/240 Vac

# **Cascade<sup>®</sup> M**

**Hemostasis Analyzer**

**Operator's Manual**

**Cat. No. 1710, 110/220 Vac**

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**Section 1 - Instrument Use and Function**

Helena's Cascade<sup>®</sup> M (Fig. 1-1) is a Hemostasis Analyzer used for measuring clotting times on samples of human plasma. Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Thrombin Clotting Time (TCT), Fibrinogen and Factor Assays (factors II, V, VII, VIII, IX, X, XI and XII) may be performed using this instrument. The Cascade M is intended for in-vitro diagnostic use only.

The Cascade M is a simplified manual instrument for coagulation measurements. After addition of reagents, activation periods are timed and optical density measurements are performed automatically. Results are automatically quantitated, displayed and printed.

Refer to the procedures supplied with the reagents for information on the following areas:

- Summary
- Principle
- Reagents
- Specimen Collection and Handling
- Reagent Preparation
- Results
- Interpretation of Results
- Bibliography



**Fig. 1-1. Cascade M**

## Section 2 - Principles of Operation

The Cascade M is factory programmed for clotting time analysis. Two cuvettes can be analyzed at a time. The user delivers sample and then reagents into the sample in the cuvettes, and the changes in optical density are monitored and clot times are determined. The reagents are for PT, APTT, Thrombin Clotting Time (TCT), Fibrinogen, and Factor Assays (factors II, V, VII, VIII, IX, X, XI and XII).

The functional units of the Cascade M are shown in Figure 2-1, and include a keypad, display, printer, optics, a 2-channel analog module, thermal sensors and heater, and switch sensors, all controlled and monitored by an internal computer (CPU).

All user input is through the keypad. Key entries are used to select the type of test, start or stop the automatic sequence of operations, run standards, select instrument parameters, and to change displayed menus. The printer can be used automatically or on demand to print test results or quality control records. RS232 outputs are provided for data transfer to external computers.

The computer runs a self-test at power on to detect error conditions or potential problems. If an error is detected, the computer responds by displaying an error message (see Section 10.2, Troubleshooting).

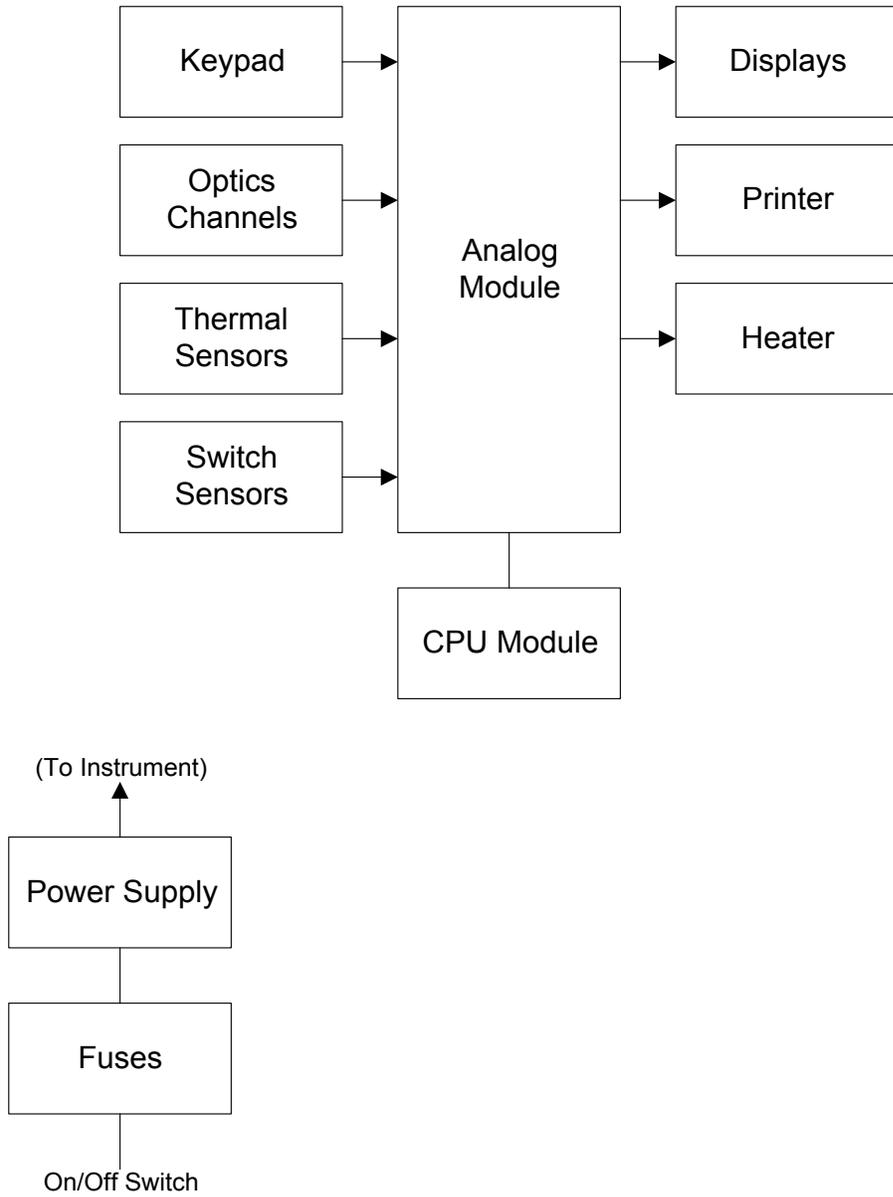


Fig. 2-1. Block Diagram

**Section 3 - Precautions and Limitations**

3.1. The entire operator's manual should be read and understood before attempting instrument operation.

3.2. Refer to the procedure supplied with the reagents for reagent preparation and handling and other information.

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 MAIN POWER CORD BEFORE CLEANING.**

Should an instrument be contaminated by blood or blood derivative, spray any contaminated surface with a commercial virucidal and germicidal agent. Observe where the specimens are used inside the instrument and confine cleaning to that area. Wipe up the residue. These materials contain alcohol and alcohol is a corrosive to metal surfaces.

3.5. Do not expose the instrument to direct sunlight. Do not operate at temperatures above 86°F (30°C) or below 59°F (15°C), or allow prolonged exposure to high humidity.

3.6. Use only Helena reagents designed for use with the Cascade<sup>®</sup> system. Refer to the procedures supplied with the reagents for precautions and limitations specific to the reagents.

3.7. Do not place the instrument near a strong source of electromagnetic interference, such as a centrifuge, x-ray machine, etc.

3.8. For emergency shut down, disconnect the power cord or use the power on/off switch located on the right side of the instrument.

3.9. If the printout is to be part of a permanent record, photocopy it and save the photocopy.

**Section 4 - Hazards**

4.1. This device contains very high voltages, which can be extremely dangerous. Safeguards are built into the instrument to prevent user contact with high voltages; however, **ALWAYS TURN OFF THE POWER, DISCONNECT THE MAIN 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. This information is contained on the serial number plate located on the bottom of the instrument.

4.3. In case of power loss during operation, a power failure detection alarm sounds and the unit must be turned off and on again to reset it. Data in process of being acquired is lost. Discard all cuvettes in the optics wells and replace them with fresh samples.

The instrument contains internal filters, which protect it against power surges. The line fuse also protects the instrument; however, should the fuse blow, replace the fuse and proceed as for power loss, above.

**Section 5 - Installation Instructions**

**WARNING:** Read Section Three (Precautions and Limitations) and Section Four (Hazards) before attempting installation or operation.

**5.1. 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 5-1. Inventory**

- 
- 1 Cascade M
  - 1 Line Power Cord
  - 1 Printer
  - 1 Printer Interface Cable
  - 1 Printer Power Cable
  - 1 Cascade M Printer Paper, Cat. No. 1720
  - 5 Pkgs (100/pkg) Cascade M Cuvettes, Cat. No. 1718
  - 2 Fuses
  - 1 Allen Wrench
  - 1 Dust Cover
  - 1 Cascade M Installation Report
  - 1 Cascade M Quick Procedure Guide
  - 1 Operator's Manual

**Materials Required But Not Provided**

Adjustable Pipettor, 50, 100, 200 µL

**5.2. Installation**

1. Select an environment free of direct sunlight, excessive humidity and dust, and large temperature fluctuations. Ambient temperature should not be above 86°F (30°C) or below 59°F (15°C).
2. Place the Cascade M on a level, flat surface. Make sure that there is enough space behind and around it to allow good air circulation.
3. Put the printer on top of the left side of the Cascade M (Fig. 5-1).
4. Plug the large printer interface cable into the receptacle in back of the printer. Plug the other end into the back of the Cascade M in the receptacle marked "PRINTER CABLE". Secure the clips (Fig. 5-2).
5. Plug the small printer power cable into the receptacle in back of the printer. Plug the other end into the back of the Cascade M in the receptacle marked "PRINTER 5V".
6. Plug the female end of the line power cord into the receptacle in the rear of the Cascade M marked "POWER IN". Plug the other end into a grounded wall outlet of the proper voltage and frequency. This information can be found on the serial number plate located on the bottom of the instrument.

The wall outlets 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.

7. Turn on the printer power switch.
8. Turn on the main power switch. The first menu below appears, followed after initialization of the Cascade M by a second menu.

Cascade M Version #.##		
Please wait, initializing system . . .		

Cascade M Version #.##	37.0C	5.00V
Press ENTER to continue		

9. Press Enter.

### 5.3. Select Parameters

The Cascade M is ready to use as programmed. However, if you wish to change selections for the general system or for tests, you may do so.

#### 5.3.1. General Parameters

1. Press **Util**. The following menu appears.

```
Utility Menu
Select Option: Test Parameters  →
```

2. Press the **right arrow** once. The menu below appears.

```
Utility Menu
Select Option: General Parameters  ←→
```

3. Press Enter. The first *General Parameters* menu appears.

```
Utility Menu
Select Option: Test Parameters  →
```

Move to other categories by pressing the **right/left arrows**. Make selections by pressing the appropriate **keys**, as shown in Fig. 5-3. Press **ESC** to back out of the menus.

**Duplicates/Singles:** Select Yes for duplicate samples of the same patient or control; select No for single samples in channels A and B.

**NOTE:** When running singles, the runs on both channels must be finished before a report can be printed. If only one channel will be run, Abort the other channel.

**Standard Curve Graph Type:** Select Yes to prepare a graph using the Helena method. The Helena Method produces a 4-point standard curve and is normally used with Helena procedures.

Select No to produce a 7-point curve, used when there are a minimum of 3 points and a maximum of 7 points. Seven point curves require longer read times. The read time should be edited under Test Parameters for each test when a seven-point curve will be used. The time selected should be longer than the longest anticipated clot time for that assay.

**Save QC data:** Select Yes to automatically save QC data in the Cascade M memory. Select No to omit saving QC data.

**Export:** Select Yes to automatically export raw data (after each run) to an external computer. Select No if you will not export data. The exported data will output through serial port 1. The format of the data is standard ASCII numbers, with the first number in the stream being the number of raw data points to follow. Each data point is separated by a space, and after 10 characters, a new line character (line feed) is sent. The number of data points is equal to 10 times the read time for the test being run. This data can be used for service analysis.

**Calculate INR:** An INR calculation is included in the software for converting PT clotting time into INR units (International Normalized Ratio). This conversion is based on the particular lot of thromboplastin used. If you do not wish to use INR conversion, select No.

If you are using INR conversion, select Yes.

**INR ISI value:** If using INR conversion, enter the proper ISI value for the lot of thromboplastin to be used here. Press **Del**, type the **numbers**, and press **Enter**. (For values from 0.00 to 9.90 only.)

When you use a new lot of thromboplastin, check the ISI value on the package insert and enter it here, if different.

**INR - Normal Mean Value:** If using INR conversion, you must enter a normal mean PT value for your laboratory here. Press **Del**, type the **numbers**, and press **Enter**. (For values from 0 to 99 only.)

**Calculate APTT Ratio:** For APTT runs, select Yes to calculate the ratio of results divided by the normal mean value (determined in the laboratory) for APTT. Select No to omit APTT ratios.

**APTT - Normal Mean Value:** For APTT runs, you may enter a normal mean APTT value for your laboratory here. Press **Del**,

type the **numbers**, and press **Enter**. This will be used when calculating APTT ratios. (For values from 0 to 99 only.)

### 5.3.2. Test Parameters

1. From the main menu, press **Util**. The following menu appears.

```
Utility Menu
Select Option: Test Parameters  →
```

2. Press **Enter**. The first Test Parameters menu appears.

```
Utility Menu
Select Test from keypad.
```

3. Press the key for the test type you wish to reprogram. Refer to Figure 5-4 to make selections by pressing the appropriate keys. Press **Enter** to edit the parameter shown, press an **arrow key** to go to other parameters. Press **ESC** to back out of the menus.

**NOTE:** The Cascade M is factory programmed and will successfully assay all tests using Helena reagents with the factory programmed settings.

For all parameters, change the numbers shown by pressing **Del**, typing the new **numbers**, and pressing **Enter**.

**Edit Read time:** Read time is the time during which data is collected to detect a clot. Too short a read time will result in no clot (N/C) being detected.

**Edit Blank time:** Blank time is a period at the beginning of an assay when no data is taken. This is done to eliminate interference from premixing reagents, bubbles, etc.

**Note that the maximum detectable clotting time is the blank time plus the read time; for example, a 14 sec. blank time plus an 86 sec. read time equals 100 sec. total.**

**Edit Activation time:** Activation time is the time allowed for activating reagent (in APTT-based assays) to interact with the plasma, and is usually 180 sec. or 300 sec. (refer to APTT reagent procedure, supplied with the reagent).

**Edit Equilibration time:** Equilibration time is the time allowed for the plasma samples to warm to 37°C. It can be set to zero if samples are prewarmed to this temperature.

**Edit Gain:** It is not recommended that the customer change gain settings without contacting Helena Laboratories for assistance. Do this if you are not detecting clots.

**Edit Baseline:** It is not recommended that the customer change baseline settings without contacting Helena Laboratories for assistance. Do this if you get repeated baseline errors.

**Edit Flag:** This is the agreement between the results of duplicate samples in percent. For example, if set to "5", the two channels must be within 5% of each other. If the variance in clot times exceeds this percentage, an asterisk "\*" will be printed by the average results on the report.

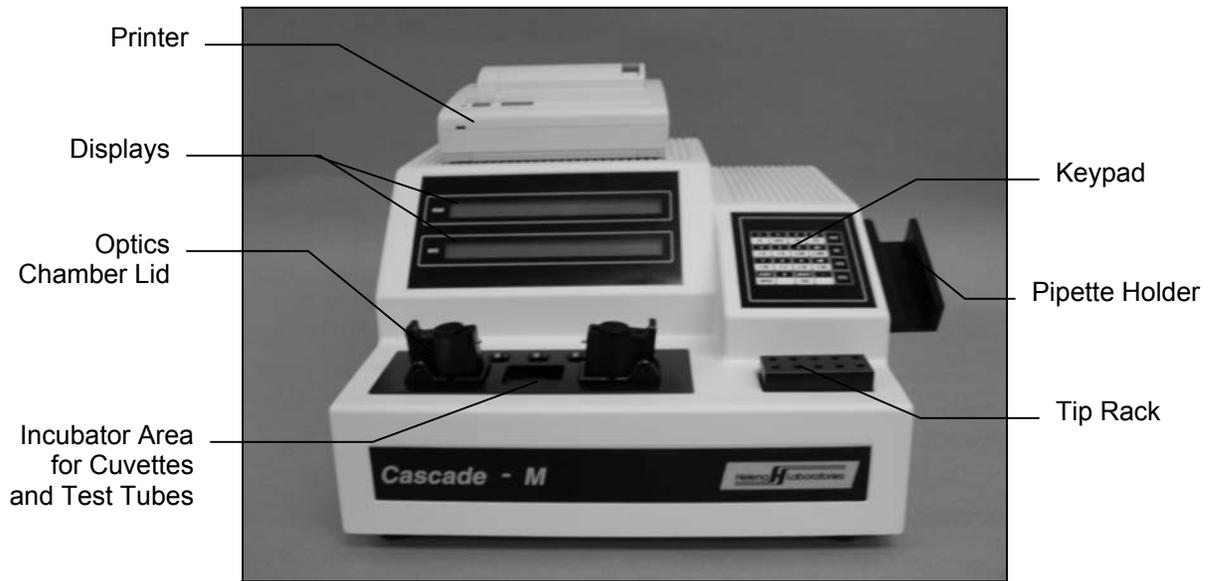


Fig. 5-1. Cascade M

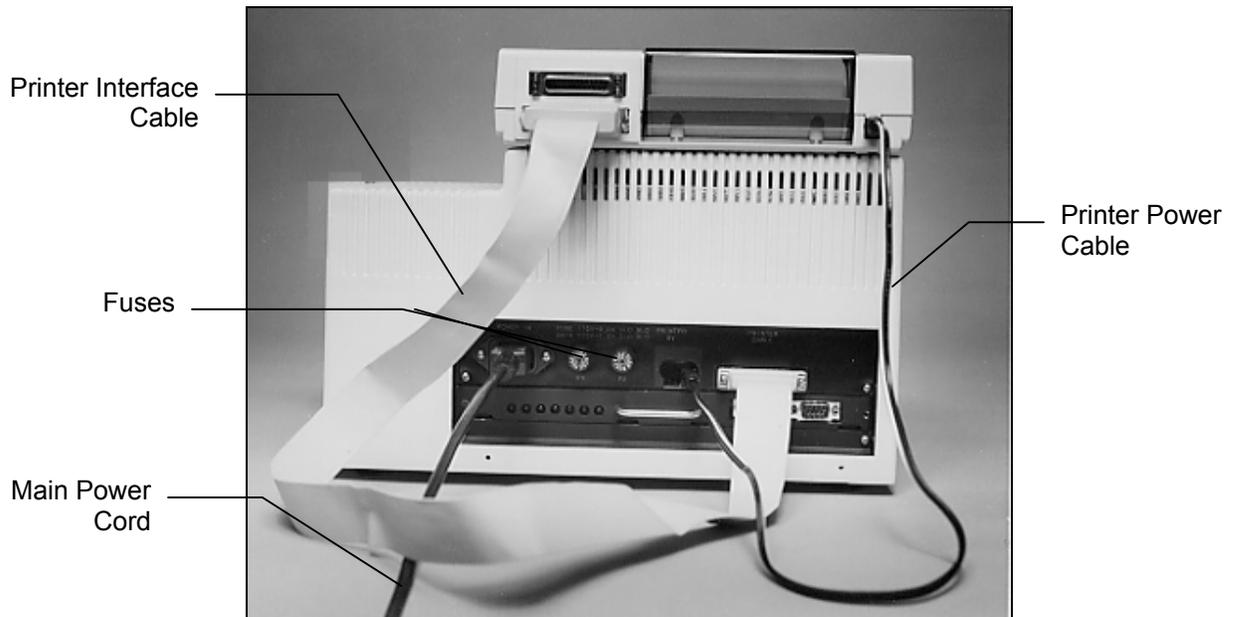
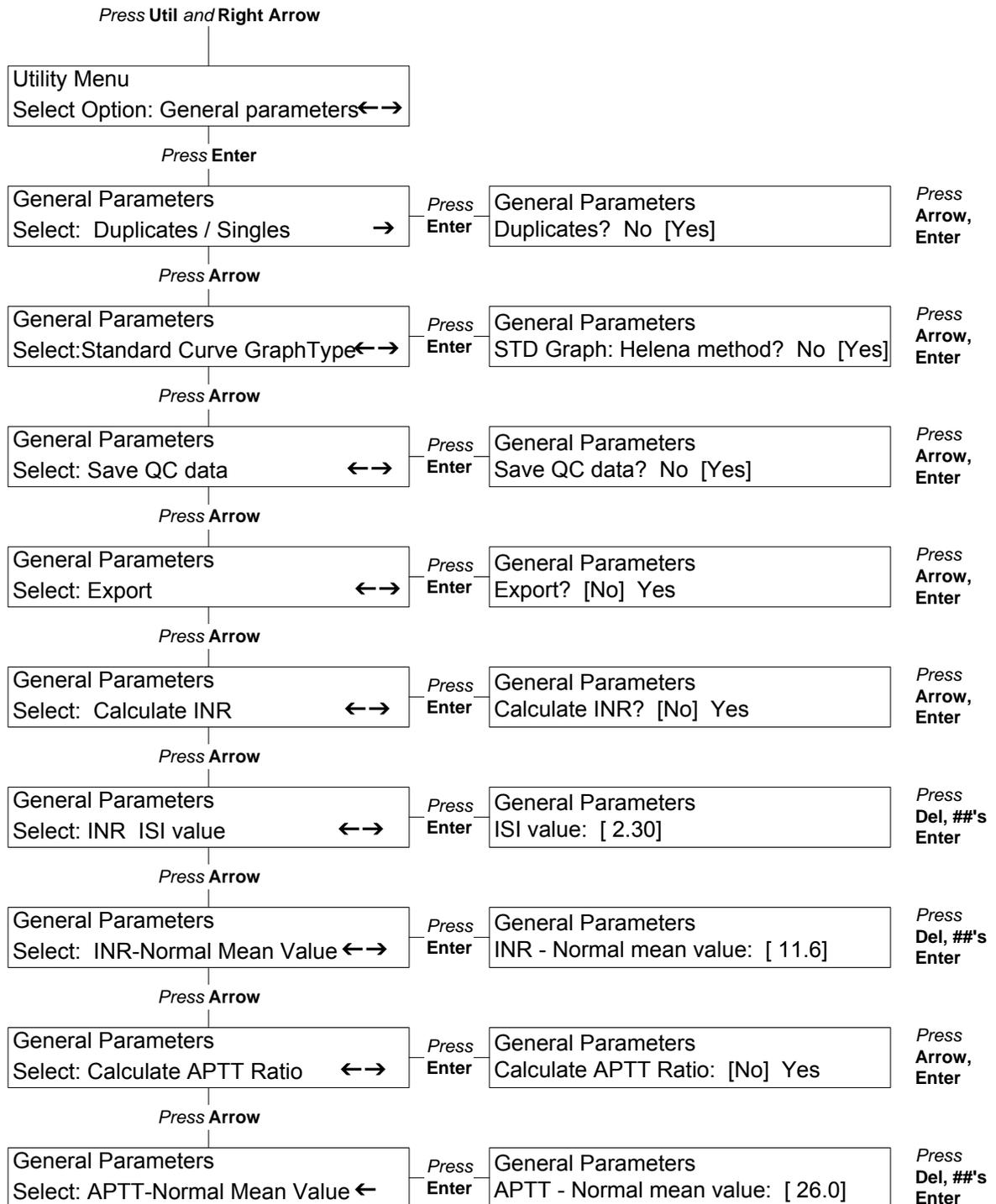


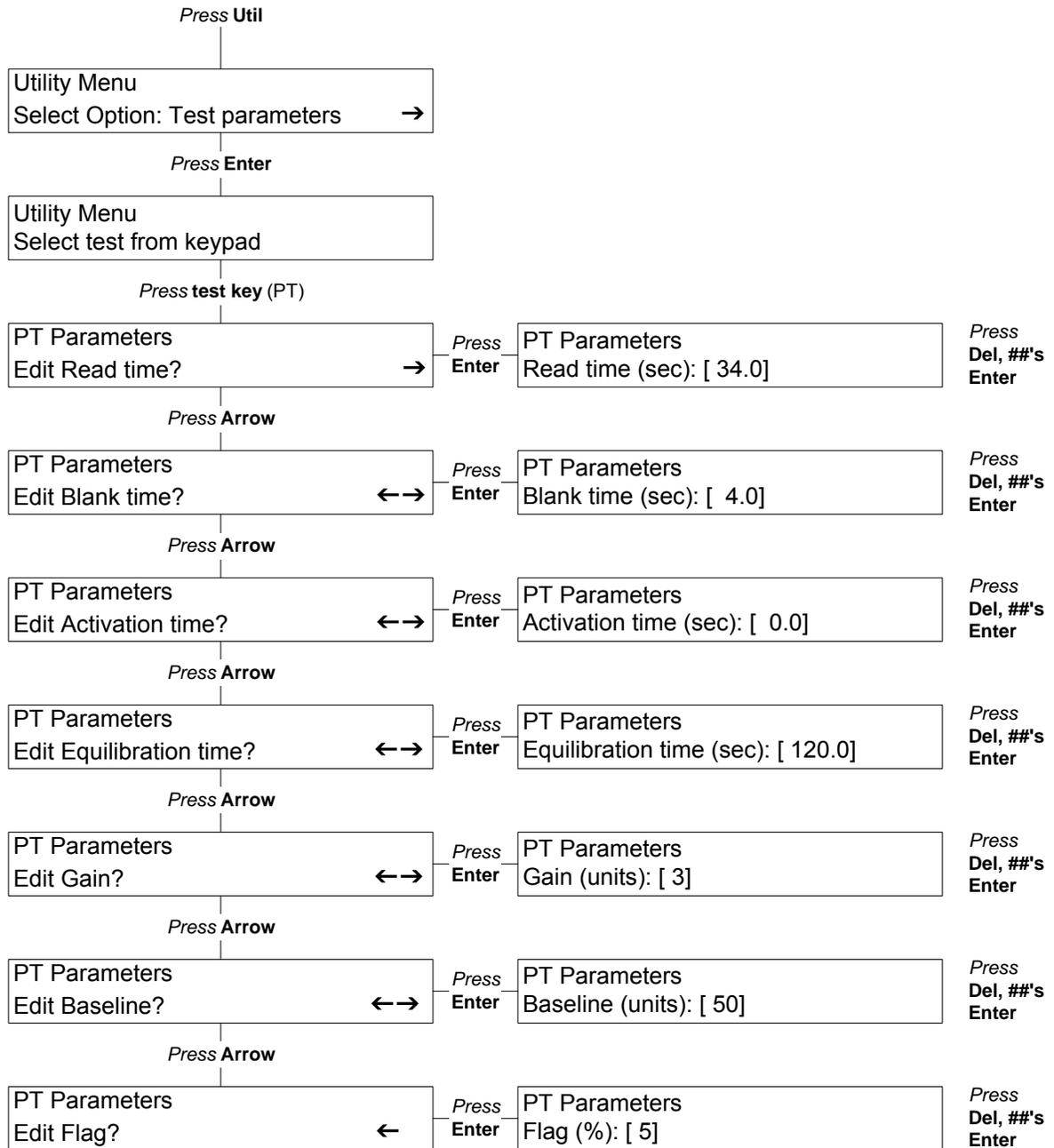
Fig. 5-2. Back of Cascade M

**Note:** To escape from the Utility menu at any point in the program, press Test, Std or QC.



**Fig. 5-3. General Parameters Utility Menus**

**Note:** To escape from the Utility menu at any point in the program, press Test, Std or QC.



**Fig. 5-4. Test Parameters Utility Menus**

**Section 6 - Controls and Displays**

**6.1. Controls**

**Main Power Switch:** Located at right side of the instrument (Fig. 6-1), controls power to Cascade® M and printer (when printer is on).

**Printer Power Switch:** Located on the top right side of the printer, controls power to printer and should always be left on.

**Optics Chamber Lid:** Located on the front top side of the instrument, controls beginning timed functions during a run (Fig. 6-2).

**Keypad:** Includes test selection, function, editing and numerical keys (Fig. 6-3).

**Major Function Keys (Fig. 6-3)**

**Test:** Press to use Test menus and run a test. If reference standard curves have been run, clot times will appear along with mg/dL or percent activity.

**QC:** Press to use QC menus and save data on up to 31 values for each of 3 levels of controls for each test type.

**Std:** Press to use Standard menus and save data on dilutions of reference controls for standard curves. One standard curve is stored for each test type that uses a standard curve.

**Util:** Press to use Utility menus in order to select and save instrument and test parameters.

**Numeric/Test Type Keys (Fig. 6-3)**

Used to select test type after pressing **Test** key, or to enter numeric data as needed. The following tests can be run:

- PT: Prothrombin Time
- APTT: Activated Partial Thromboplastin Time
- Fib: Fibrinogen
- TCT: Thrombin Clotting Time
- F II: Factor II
- F V: Factor V
- F VII: Factor VII
- F VIII: Factor VIII
- F IX: Factor IX

- F X: Factor X
- F XI: Factor XI
- F XII: Factor XII

**Menu/Edit Keys (Fig. 6-3)**

**Start/Enter:** Press **Enter** to select an action or data displayed on a menu, press **Start** to begin a test run.

**Abort/Esc:** Press **Esc** to go back to previous menus, press **Abort** to pause the display during a test run (then choose to abort or continue as shown on the display).

**Del/TCT:** Press **Del** (shared with the TCT test function) to erase data when editing so that data can be written in. Press **TCT** to select that test when running samples.

**Right/Left Arrows:** Press **right arrow** to “scroll” forward through selections within a menu category. Press **left arrow** to “scroll” backward through selections. The arrows shown on the display indicate which direction can be selected.

**Decimal Point ( . ):**  Use to enter a decimal point in numbers.

**Numeric (0-9):** Used to enter numbers during editing or data entry. All except 0 are shared with a test type key.

**6.2. Displays**

Two displays each contain 40 characters in each of 2 lines. The top display is for menus; the bottom display shows run data or other numerical information.

The menu display shows the selection made and instrument status. For example, in the menu below, the test selected is PT and the instrument is running the test.

Menu	Test Menu - PT	37.0C	5.00V
	Running Tests		

Data	A: Reading data	###
	B: Reading data	###

The data display shows the actual point you are in during a test run, and shows run data. In the example above, the instrument is actu-

ally reading data on the test samples, and the numerical results would be shown to the right.

You can make menu selections by pressing buttons on the keypad. To move through a list of options for any menu, press the **right/left arrows**.

For example, the menu below appears when you press the **Test** button. Use the keypad to select the type of test you will run.

Test Selection	37.0C	5.00V
Duplicates - Select test from keypad.		

If you press the APTT button, for example, the menu display will change as shown below.

Test Menu - APTT	37.0C	5.00V
Running Tests		

A: Start sample equilibration
B: Start sample equilibration

The data display will also be activated when you select a test, as seen above. A and B represent the optics channels, with A being the left and B the right channel on the instrument. When the sample cuvette is in the optics chamber, **the user simultaneously presses the optics chamber lid and pipettes the reagent, causing a beep to sound and indicating that you should go to the next step.**

On the following menu, an arrow appears to the right of the menu display. Press the **right arrow** to scroll forward through the displays in this menu.

Utility Menu
Select Option: Test parameters →

Once you begin scrolling through the displays, a two-way arrow appears, indicating that you can press either the right or left arrow to move forward or backward through the menu choices.

Utility Menu
Select Option: General parameters ↔

When you reach the end of the list in the menu, a left arrow is shown, indicating that you can only scroll backward.

Utility Menu
Select Option: Print parameters list ←

When you want to select a displayed option, press **Enter**. If you press Enter while the display above is shown, Cascade M will print a list of test parameters and general parameters for the instrument. If you press Enter while the display below is shown, and realize you made a mistake, press **ESC** to return to it and go on from there.

Utility Menu
Select Option: General parameters ↔

When you have made selections by pressing **Enter**, you can usually “back out” of the selection by pressing **ESC**.

### 6.3. Reports

#### 6.3.1. Test Results

A printout of test data is shown in Figure 6-4. The name of the test and whether duplicates or singles were run are printed at the top. Date, time, temperature (of the incubator) and reference voltage are printed next. The test data follows, with dilution (if any) and clot times for channel A and B. Other pertinent data is also listed, calculated by the instrument. Places for the technician’s initials and for any sample information are provided at the bottom of the printout.

#### 6.3.2. Standard Curve

A typical standard curve is shown in Figure 6-5. Standard curves must be generated using references of known concentration for all Fibrinogen and Factor Assay tests, and for PT if you want results in % activity. The Cascade M automatically refers to a standard curve to determine patient results for these tests.

#### 6.3.3. Levey-Jennings Plot (QC Reports)

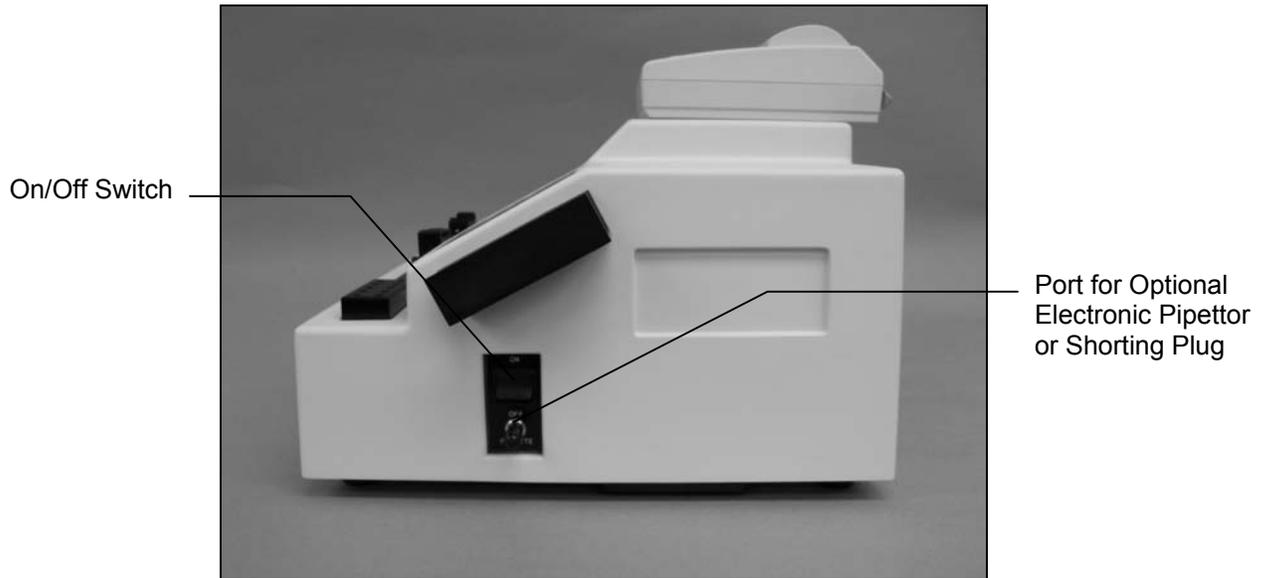
A typical Levey-Jennings Plot of QC data is shown in Figure 6-6. Information for Month-to-Date (MTD) is shown above the graph, and Lot-to-Date (LTD) is listed below the graph.

MTD and LTD information includes the mean, standard deviation, coefficient of variation and number of data points for each level of the control.

The Levey-Jennings plots themselves show the variation from the mean in standard deviations for each data point. The point number, date, ID number and numerical value for each data point are listed to the left of the graph. The graph illustrates the level number of the point and where the point falls in relation to the mean.

#### **6.3.4. System Parameters**

A printout of system parameters (general and test) is shown in Figure 6-7. The instrument can run assays as programmed by the factory, however, system parameters can be altered as described in section 5.3.



**Fig. 6-1. Instrument - Right Side View**



**Fig. 6-2. Simultaneously Press Optics Chamber Lid and Pipette Reagent**

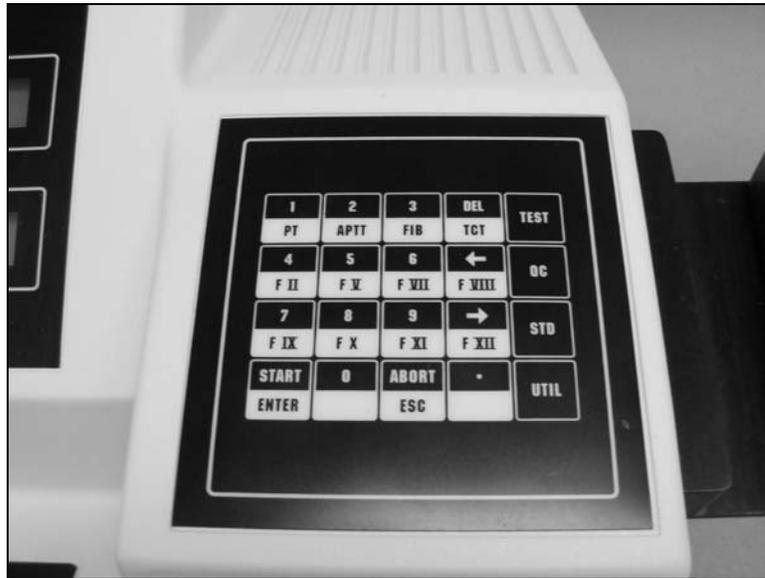


Fig. 6-3. Keypad

Duplicates - Factor IX  
(TEST)

Date : 05-13-93      Temperature : 36.9C  
Time : 15:39:13      Reference : 4.99V

Dilution	A	B	Average	INR	Ratio	%Activity	MG/DL
1:10	52.1	52.4	52.3	N/A	N/A	103.5	N/A

Fig. 6-4. Report Showing Test Data

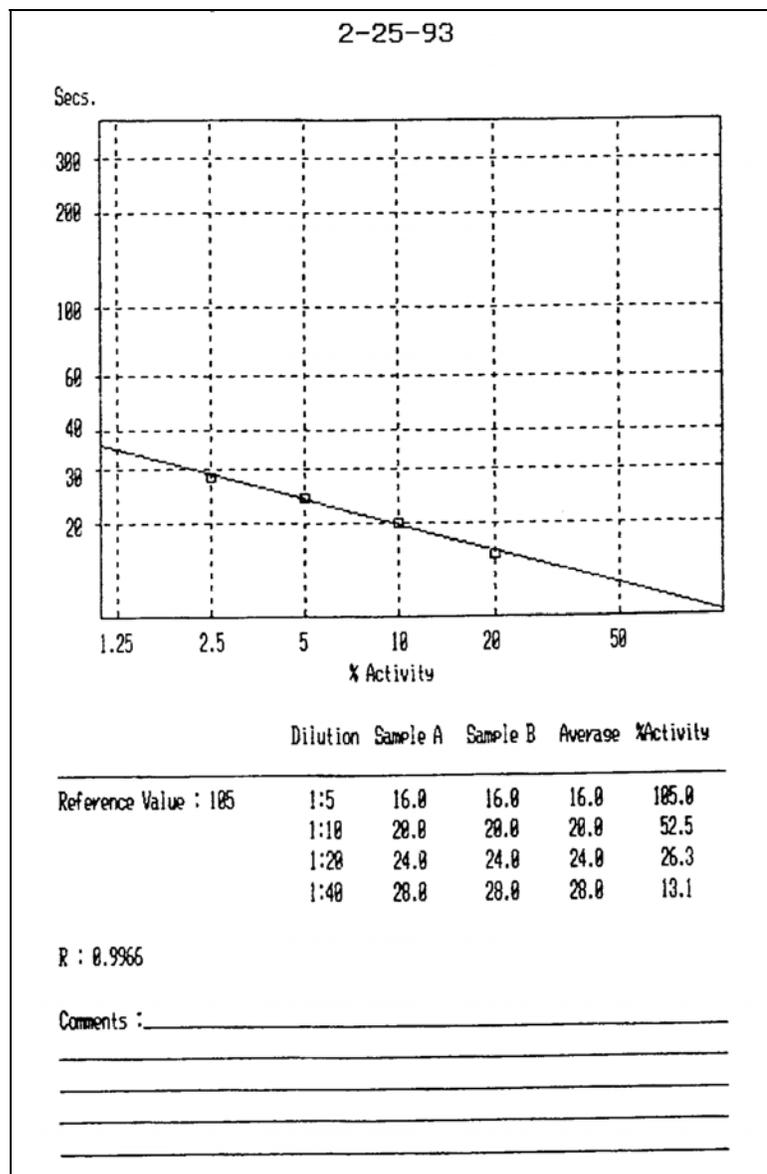


Fig. 6-5. Printout of Standard Curve

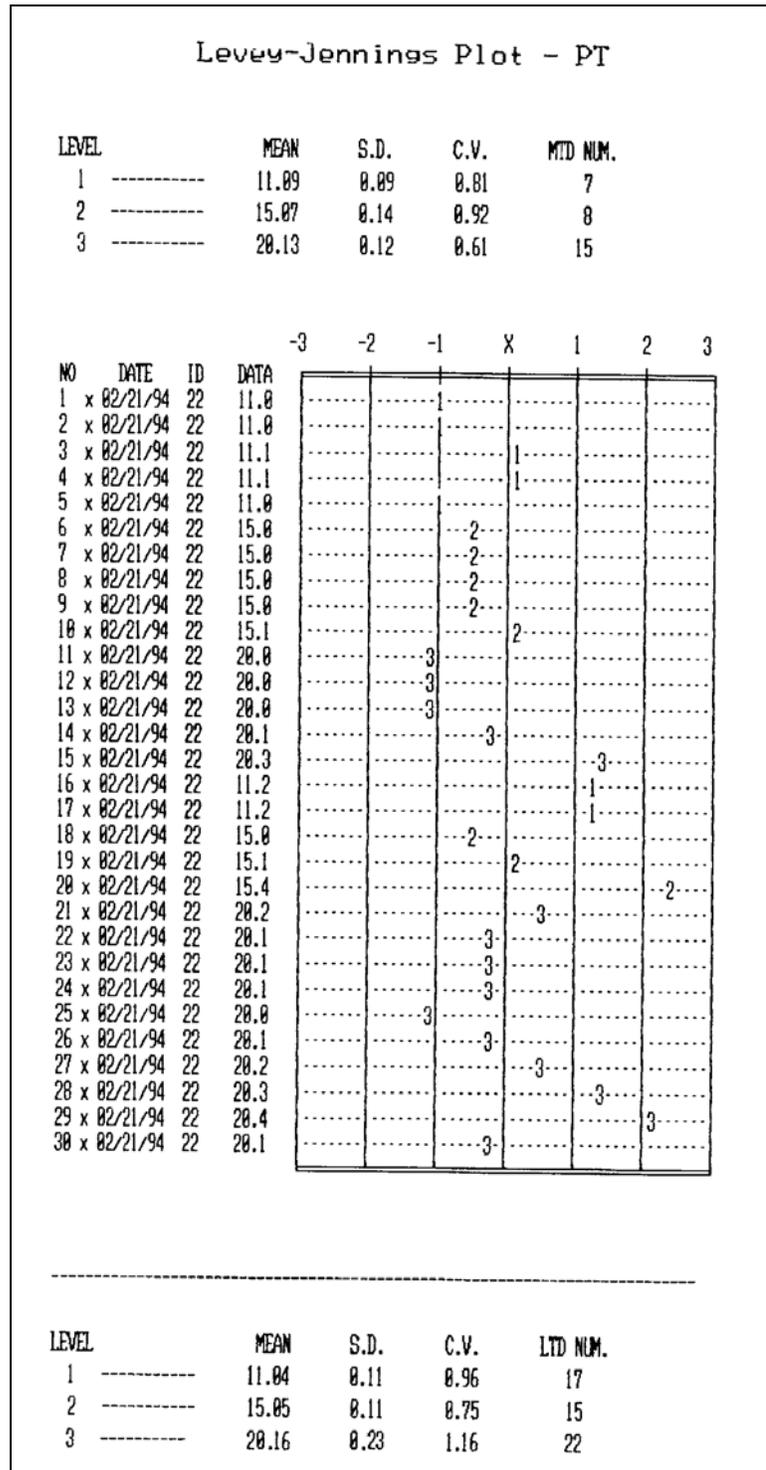


Fig. 6-6. Levey-Jennings Plot of QC Data

```

Cascade - M System Parameters - 2-25-94

General Parameters

Duplicates ..... Yes
STD Graph : Helena method.... Yes
Save QC data ..... Yes
Export ..... No
Calculate INR ..... No
  ISI Value ..... 2.30
  Normal Mean Value ..... 11.6
Calculate APTT Ratio ..... No
  Normal Mean Value..... 26.0
Keypad beep ..... On
Temperature ..... 37.0

Test Parameters

```

Test	Read	Blank	Act.	Eq.	Gain	Baseline	Flas
PT	56.0	4.0	0.0	120.0	3	50	5
APTT	86.0	14.0	100.0	120.0	3	50	5
FIB	43.0	1.5	0.0	120.0	5	20	7
TCT	52.0	8.0	0.0	120.0	4	50	5
F II	34.0	6.0	0.0	120.0	3	50	5
F V	34.0	6.0	0.0	120.0	3	50	5
F VII	34.0	6.0	0.0	120.0	3	50	5
F VIII	86.0	14.0	100.0	120.0	3	50	5
F IX	86.0	14.0	100.0	120.0	3	50	5
F X	34.0	6.0	0.0	120.0	3	50	5
F XI	86.0	14.0	100.0	120.0	3	50	5
F XII	86.0	14.0	100.0	120.0	3	50	5

Fig. 6-7. Printout of System Parameters

## Section 7 - Operating Instructions

### 7.1. Preparation

1. Sample and reagent information for each procedure is given in Table 7-1. For instructions on specimen collection and handling, reagent preparation, and preparation of patient samples and controls, refer to the appropriate sections in the procedures supplied with the reagents.

2. Turn on the main power switch (Fig. 6-1) and allow the instrument to warm up until it stabilizes at 37°C (10 to 20 minutes).

The menus below will appear. Only a short time is required for the instrument to initialize before the second menu appears.

Cascade M Version #.## Please wait, initializing system . . .
--

Cascade M Version #.##      37.0C   5.00V Press ENTER to continue
--

3. Press **Enter** and prepare the reagents you will use. Refer to the procedures provided with the reagents for handling precautions and other information.

4. Pour sufficient amounts of reagents into labeled test tubes.

5. If needed, Thromboplastin and CaCl<sub>2</sub> tubes may be placed in the round holes in the rear of the incubator area. For best equilibration, the liquid levels should not be higher than the top of the well. Alternatively, equilibrate small amounts of reagent in cuvettes in the cuvette warming area between the optical wells.

6. The instrument is normally set up to run tests in duplicates. If single runs are desired, refer to section 5.3.1 to select Singles.

### 7.2. In Case of Power Failure

In case of power loss during operation, a power failure detection alarm sounds. If the power loss was complete, the instrument will automatically reset when the power returns. If power loss was incomplete (low power or brown out), the unit must be turned off and on

again to reset it. **Data in process of being acquired is lost.** Discard all cuvettes and replace them with fresh samples.

### 7.3. Prepare and Load Samples

1. Prepare patient samples and control samples as directed by the procedure supplied with the reagents.

2. Pipette the appropriate amount (see Table 7-1) of patient sample or control into the cuvettes. Avoid forming bubbles in the cuvettes, since they will interfere with optical density readings.

3. Place up to four cuvettes in the central cuvette holder in the incubator for factor assays.

### 7.4. Run Assays

1. If the Test Menu is not already displayed, press the **Test** key. The main test menu appears, below.

Test Menu Duplicates - Select test from keypad
---

2. Press a **Test Type** key for the type of assay you will run.

3. **Refer to Figures 7-1 through 7-6** for operation.

NOTE: Premix the reagent, if required, just before use by aspirating and delivering it repeatedly into the test tube.

NOTE: The delivery of sample and reagents must be done with the pipette tip held **perpendicular** to the chamber lid while holding down the lid. When withdrawing the pipettor, remove it gently from the optical chamber to avoid opening the lid and aborting the test.

4. Each optics chamber is independently operated.

5. At the end of the run, press **Enter** to return to the main test menu.

NOTE: For convenience, the menus on the following pages have both channels at the same stage of operation. The channels are actually totally independent from each other.

For example, the display shown below is a possibility, with channel A finished before channel B has been started. Even though a clot time for channel A is shown, a printout cannot be made until channel B has also been run (or aborted).

A: CLOT AT 12.3 secs.
B: Ready to start equilibration

### 7.5. Abort a Run

1. If you wish to stop operation of a channel during a run, press **Abort**. Operation will stop and the following display will appear.

Test Menu - PT	37.0C	5.0V
Abort channel(s)? [All] A B None		

2. Press **Enter** to abort both channels (*All*), or use the **arrow keys** to select only channel *A* or *B* and press **Enter**. You must rerun the assay for the aborted sample if you abort during a run.

To cancel the abort, press **Abort** again, or use the **arrows** to select *None* and press **Enter**.

**NOTE: An easier way to abort one or two channels is to simply raise the lid over the optical well while reading data.**

### 7.6. Results

Results are displayed at the end of each assay, and printed.

**NOTE: If the printout is to be part of a permanent record, photocopy it and save the photocopy.**

**NOTE: Control values should be within the ranges established by the laboratory for the controls. If they are out of range after a repeat run, there may be a system problem. After consulting Troubleshooting Table 10-2, call Helena Laboratories for assistance.**

Several symbols, listed below, can occur on a printout of test data. Call Helena Laboratories for assistance if these problems persist.

**N/C** (No Clot): The Cascade M did not detect a clot. If a clot is physically present in the cuvette, or if plasma is very dilute (i.e. 1:320, 1.6%), the N/C error occurred due to too short a read time. Edit read time (see section 5.3.2) to lengthen it.

**B/E** (Baseline Error): The sample data fell below the lower range of the optics. This indicates a lack of sample, low reagent addition, improper baseline value, or an empty cuvette. No data is taken.

**O/R** (Overrange): The sample data exceeded the upper range of the optics.

**@** by clot time (i.e. 12.5@): This means that the sample data exceeded the upper range of the optics, but the Cascade M was able to make a clot time determination. The clot time is still valid but high fibrinogen is suspected, and follow up testing is recommended.

**x** (lower case letter "x"): This means that a QC value was manually changed (on a QC sample, only).

**\*** (asterisk): This indicates that the duplicate samples were not within a given percentage of each other (default values of 7% for Fibrinogen and 5% for all others).

**#** (pound sign): This indicates that the test result value was outside of the standard curve limits. This symbol is only used for PT, Fibrinogen, and Factor Assays.

**>** (greater than, i.e. >999.9) Printed on Levey-Jennings plots for excessive values.

Refer to the following sections of the procedure supplied with the reagents for a complete discussion of results and their interpretation: Instruments, Stability of End Product, Results, Expected Values, Performance Characteristics, and Interpretation of Results.

## 7.7. Shut Down

To shut down the instrument:

1. Cap all reagents and controls (do not mix up the caps) and store appropriately.
2. Remove all cuvettes and test tubes and discard in a solid waste container.
3. Turn off the power switch.
4. Clean any spills (see section 10.1.1).

## 7.8. Standard Curves

The Cascade<sup>®</sup> M refers to a standard curve based on known reference values to calculate results for Fibrinogen and Factor Assays or for PT (with results in % activity). Each time a new lot of reagent or control will be used, a new standard curve must be run. One standard curve is stored for each test type.

### 7.8.1. Run Standard

**NOTE:** If you are using a seven point curve, longer read times are required. The read time should be edited during setup of Test Parameters for each test when a seven-point curve will be used. The time selected should be longer than the longest anticipated clot time for that assay. Refer to section 5.3.2.

1. Prepare dilutions of the control according to the instructions provided in the procedure packaged with the control.

2. Follow the instructions in Figure 7-7 to run the curve.

**NOTE:** For a PT % Activity curve, a 75% dilution is not required, although it can be used if desired. If you do not need to use a particular dilution, do not select it when running the standard curve.

3. Repeat until all dilutions have been run.

4. Press **ESC**. The new standard curve is stored for the selected test type.

### 7.8.2. Edit Standard Curve

This feature can be used to reenter a deleted standard curve or to correct an existing curve. Refer to Figure 7-7 to edit standard curves stored in memory.

1. Press **Std**, **right arrow** one time, **Enter**, and **test type key**.

2. Enter the reference value (see insert with control) and press **Enter**. (To clear the number on display, press **Del**, then type the number and press **Enter**.)

3. Press the **arrows** to select the dilution of the point you want to edit, and press **Enter**.

4. At *New:*, type the new value for the point and press **Enter**.

5. Press **ESC** and either repeat steps 3 and 4 as needed, or press **ESC** again when finished.

6. Use the **arrows** to select *Yes* or *No* at *Save the changes?* and press **Enter**.

**NOTE:** To remove a point from a standard curve, print the curve (in order to show all points available). Then delete the curve (as in starting a standard curve run and then aborting the run). Finally, edit in only the points desired.

**This is the only way to remove a point that has been previously run (or edited in). Once a point has been run or edited in, it will remain a part of the curve. Attempting to remove a point by entering 0 sec. of time removes the point from the graph but not from the printout.**

### 7.8.3. Print Standard Curve

Refer to Figure 7-7 to edit standard curves contained in memory.

1. Press **Std**, **right arrow** twice, and **Enter**.

2. Press the **test type key**. The printer will produce a standard curve for the test selected.

**NOTE:** If the printout is to be part of a permanent record, photocopy it and save the photocopy.

## 7.9. Utilities

1. Press **Util**. The following menu appears.

Utility Menu Select Option: Test parameters →
--

**NOTE:** For Test Parameters and General Parameters, see sections 5.3.1 and 5.3.2.

2. Press the right arrow twice to get to the menus shown in Figure 7-8.

### 7.9.1. Set Date/Time for Instrument

Refer to Figure 7-8 for instructions. This will correct the date or time printed on the reports.

### 7.9.2. Set Date Format

Refer to Figure 7-8 for instructions. Use this to redo date format if necessary.

### 7.9.3. Keypad Beep On or Off

Refer to Figure 7-8 for instructions. When on, the keypad will beep every time a button is pressed. When off, the instrument beeps only at various steps of operation.

### 7.9.4. Set Incubator Temperature

**NOTE:** Incubator temperature is factory preset to 37°C. Consult Helena Laboratories before changing.

Refer to Figure 7-8 for instructions. The incubator temperature controls the temperature at which reagents and samples are maintained.

### 7.9.5. Adjust Display Brightness

Refer to Figure 7-8 for instructions. The brightness should be at a comfortable level for the operator, and the background should appear plain blue.

### 7.9.6. Reset to Default Values

Refer to Figure 7-8 for instructions. When you reset to default values, factory programmed values are used for the instrument.

**NOTE:** Reset to default values will reset Yes/No parameter choices to No. The user will have to reselect parameters but numerical values will remain in memory.

### 7.9.7. Print Parameter List

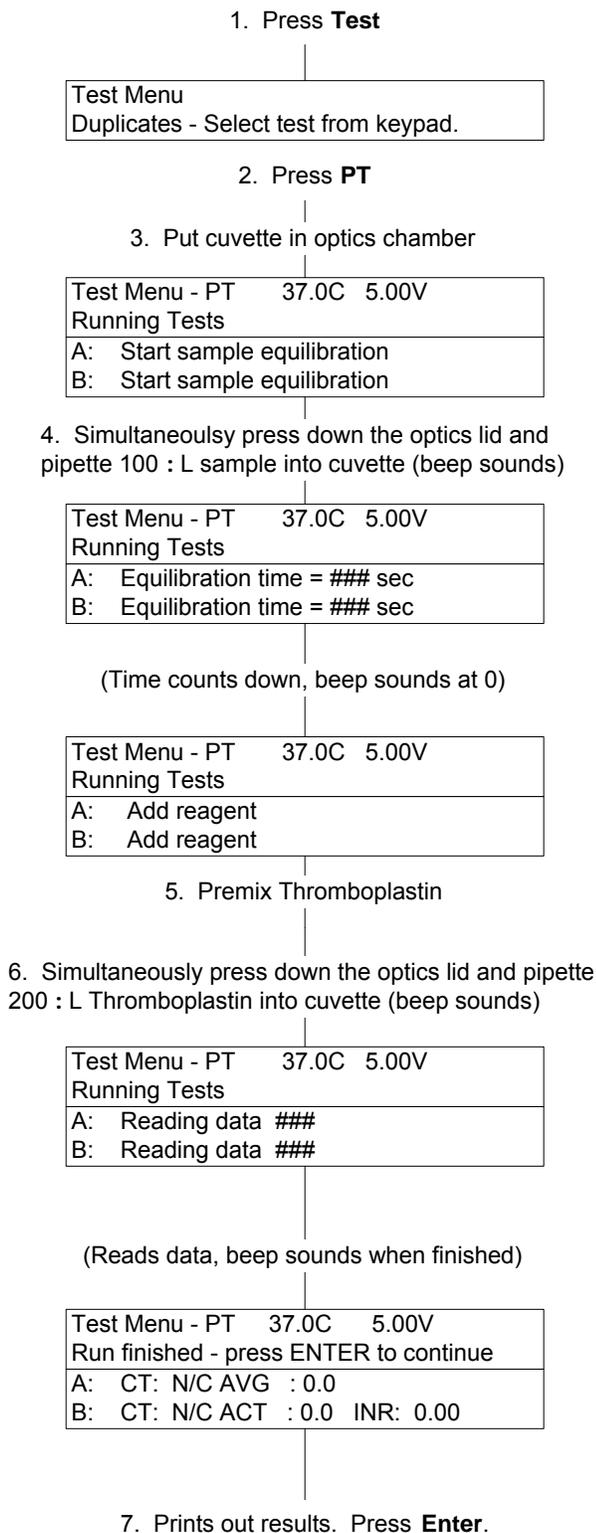
Refer to Figure 7-8 for instructions. The parameter list includes both test parameters and general instrument parameters.

**Table 7-1. Sample and Reagent Information for Factory Programmed Procedures**

<b>Test Type</b>	<b>PT</b>	<b>APTT</b>	<b>Fibrinogen</b>	<b>TCT</b>
Sample Volume	100 µL	100 µL	200 µL	200µL
Reagent Type	Thromboplastin Rgt.	APTT Reagent	Thrombin Rgt.	TCT Rgt
Premix?	Yes	Yes	Yes	Yes
Vol. Added	200 µL	100 µL	100 µL	100µL
Reagent Type	None	Calcium Chloride	None	None
Premix?		No		
Vol. Added		100 µL		

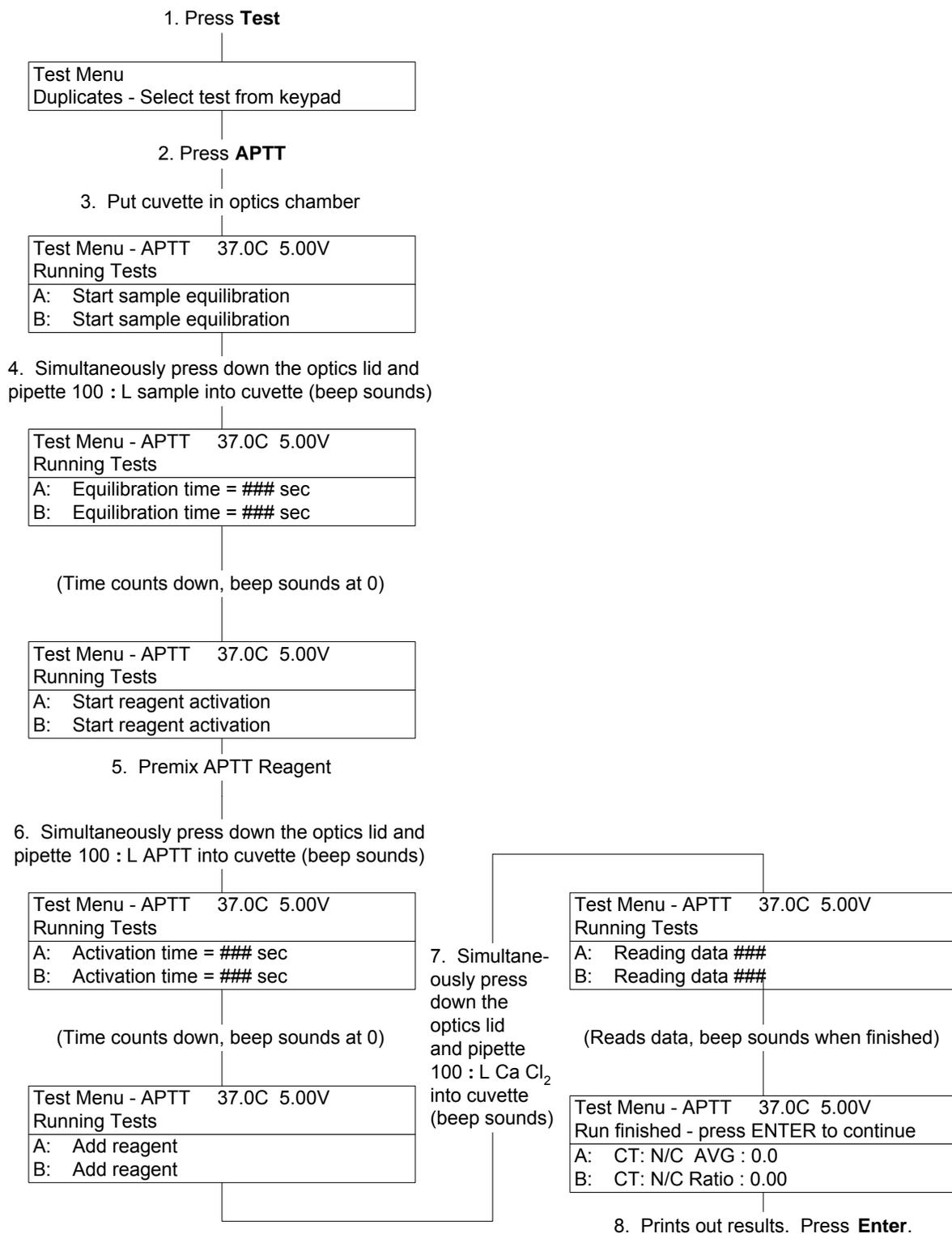
<b>Test Type</b>	<b>Factor Assays</b>	
Reagent Type	Factor Deficient Substrate	Factor Deficient Substrate
Premix?	No	No
Vol. Added	100 µL	100 µL
Sample Type	PT Factors II, V, VII, X	APTT Factors VIII, IX, XI, and XII
Sample Volume	100 µL	100µL
Reagent Type	Thromboplastin Rgt.	APTT Reagent
Premix?	Yes	Yes
Vol. Added	200 µL	100 µL
Reagent Type		Calcium Chloride
Premix?		No
Vol. Added		100 µL

Note: If results are desired in % activity, a standard curve is required (see section 7.8).  
 INR values can also be reported (see section 5.3.1).



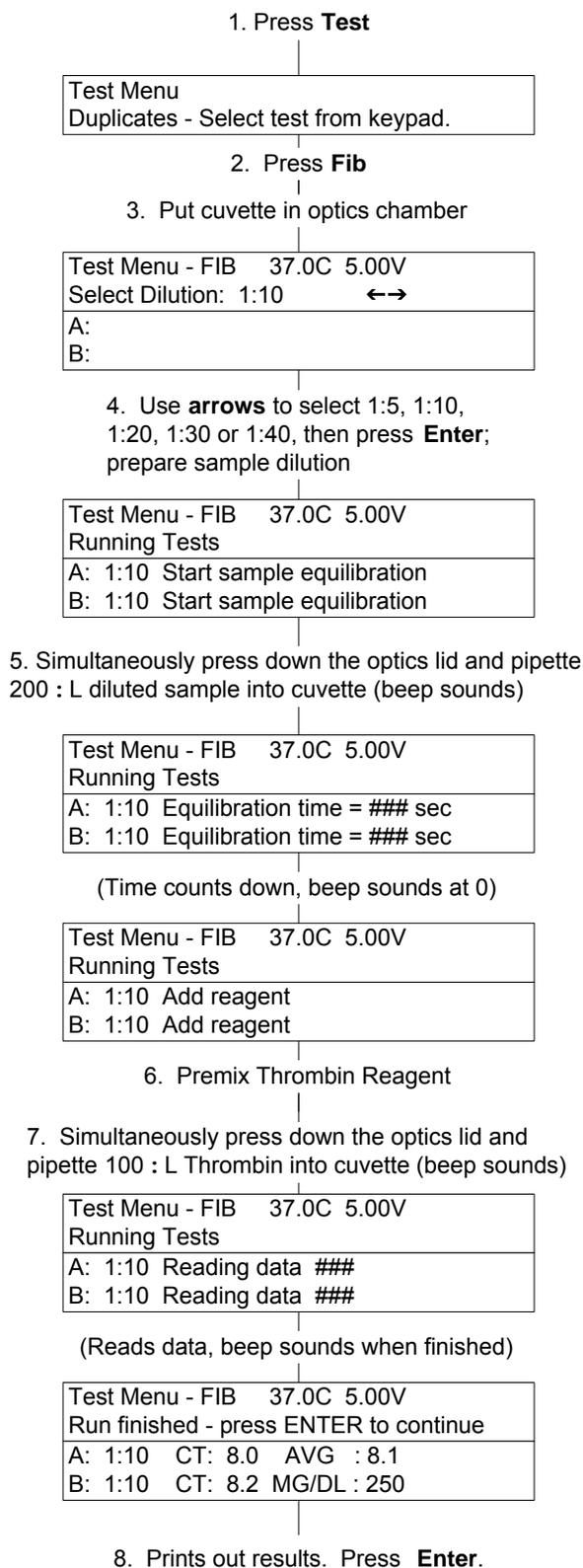
**Fig. 7-1. PT Assay**

**Note: No standard curve needs to be run for this assay.  
If an APTT ration is desired, see section 5.3.1.**



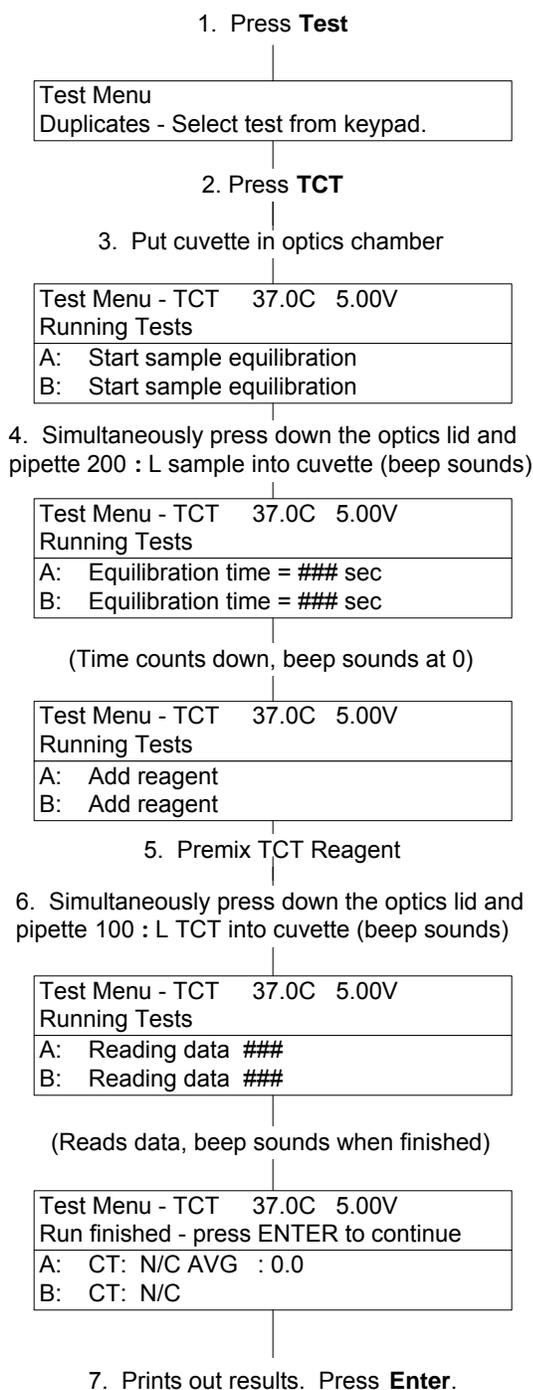
**Fig. 7-2. APTT Assay**

**Note: A standard curve must be run prior to running this assay (see section 7.8 and Helena Fibrinogen Assay Procedure).**



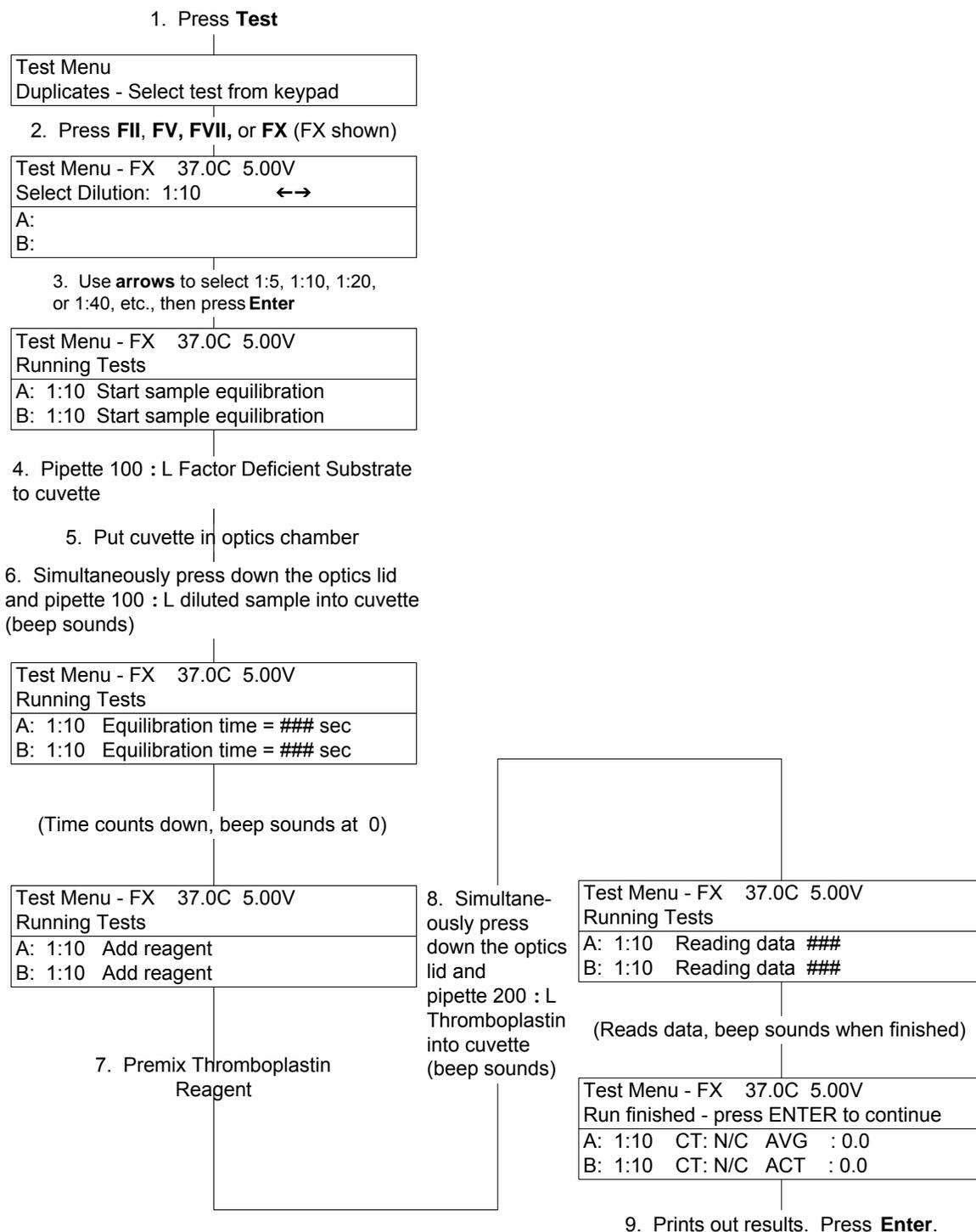
**Fig. 7-3. Fibrinogen Assay**

**Note: No standard curve needs to be run for this assay.**



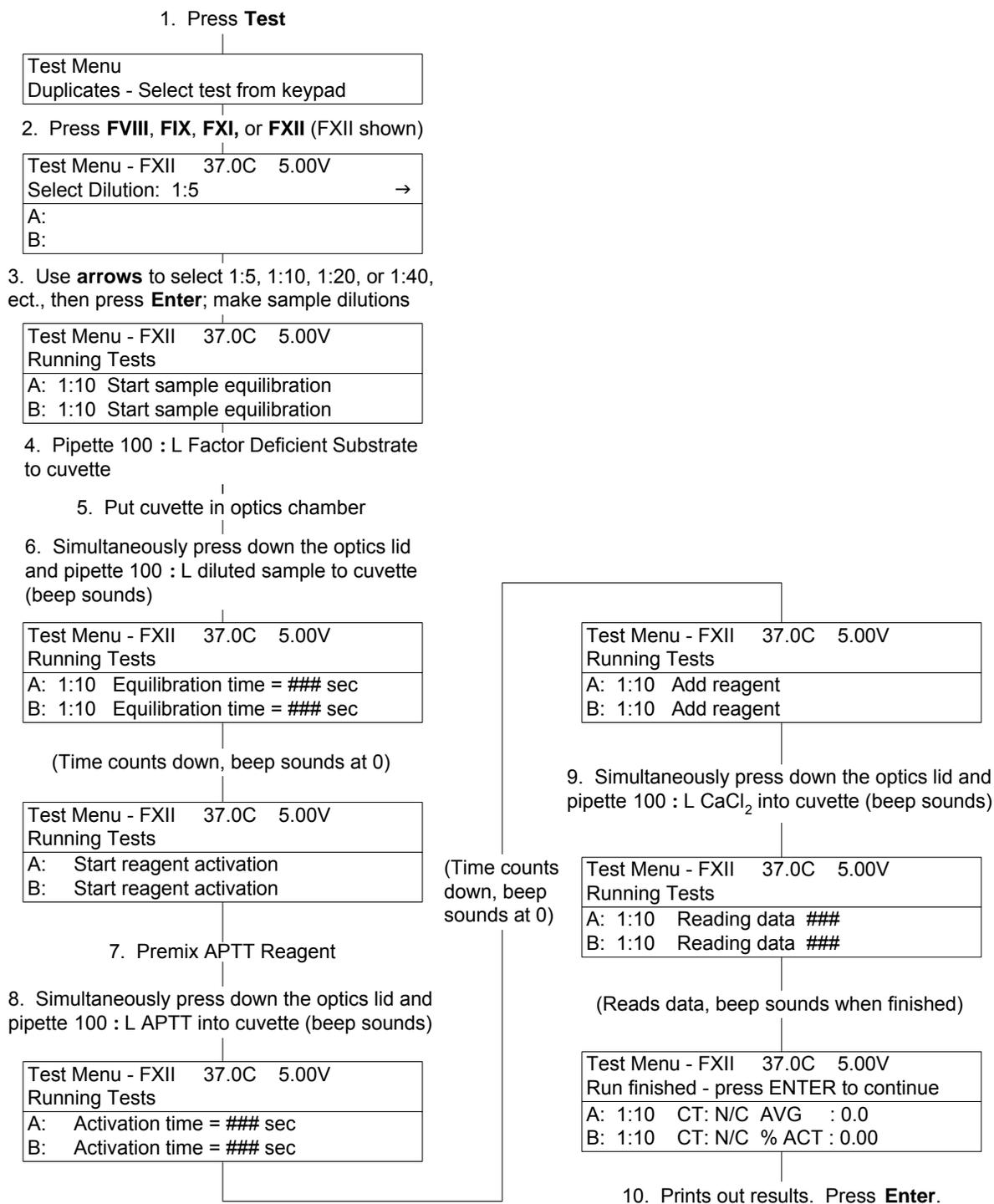
**Fig. 7-4. TCT Assay**

**Note: A standard curve must be run prior to running this assay (see section 7.8 and appropriate Helena Factor Deficient Substrate Procedure).**



**Fig. 7-5. FII, FV, FVII, or FX Assay**

**Note: A standard curve must be run prior to running this assay (see section 7.8 and appropriate Helena Factor Deficient Substrate Procedure).**



**Fig. 7-6. FVIII, FIX, FXI, or FXII Assay**

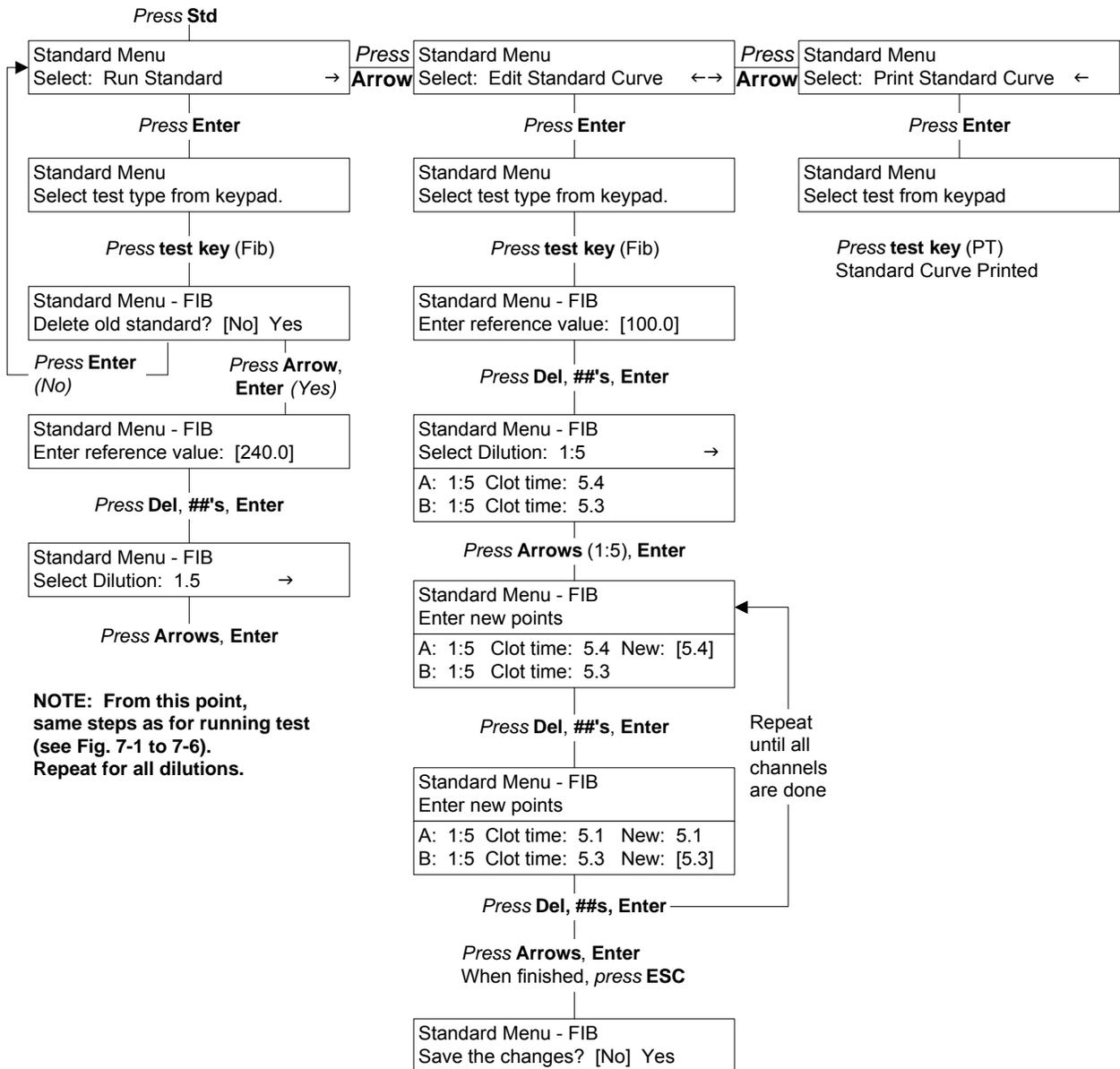


Fig. 7-7. Standards Menus

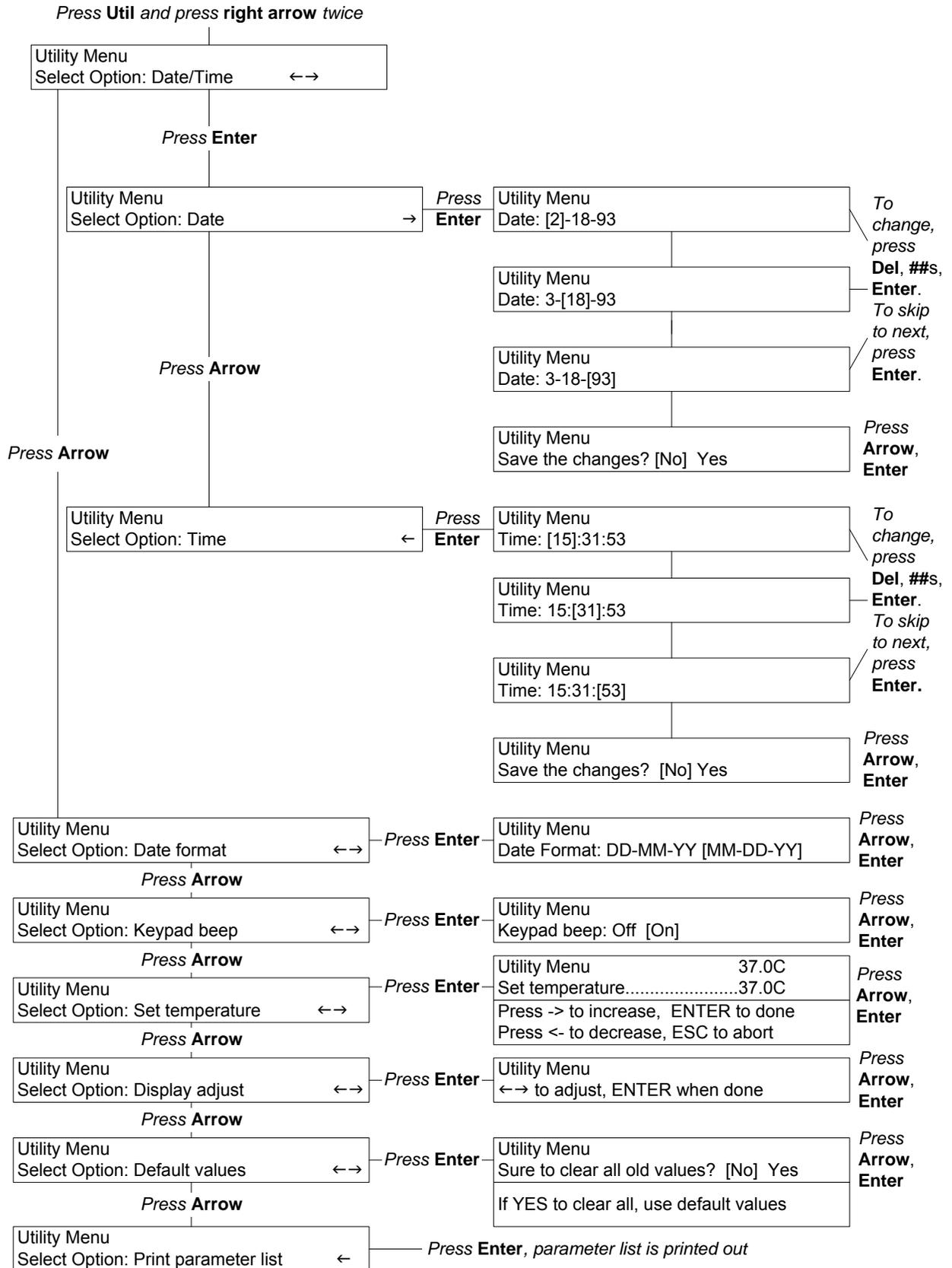


Fig. 7-8. Utility Menus

## Section 8 - Test Functions and Quality Control

The instrument automatically performs a self-test any time the power is turned on. Should an error message appear on the display, see Section 10.2, Troubleshooting.

Each laboratory should establish a quality control program that includes normal and abnormal controls to evaluate the instrument, reagent, and technologist performance. Control data should be compared to the ranges established by the laboratory for the controls. If controls are out of range, appropriate troubleshooting procedures should be followed. Contact Helena Laboratories for further assistance.

The patient data should be compared to the normal range values for the procedure in use and to the laboratory normal range values. Refer to the procedure supplied with the reagents for further information.

QC data is normally stored in battery backed-up memory in the Cascade M.

### 8.1. Run QC Control

Refer to the flowchart in Figure 8-1 to run a QC control.

1. Press **QC**, and use the **arrows** until *Run QC Control* appears, then press **Enter**.

2. Press the **test type key** for the test that the control is used for.

**NOTE:** Before you can run controls for Factor Assay or Fibrinogen tests, you must first run a standard curve for the test.

3. Type in the operator ID and press **Enter**. (To clear the number on display, press **Del**, then type a two-digit **number** and press **Enter**.)

4. Press the **arrows** to select the *LEVEL* of the reference (Level 1 is usually a normal control, levels 2 and 3 are usually abnormal controls) and press **Enter**.

5. *Ready to start* read appears. Run as you would a regular sample.

Whenever you wish, a Levey-Jennings Plot can be printed for each test (see section 8.5). Levey-Jennings plots display data as mean  $\pm 3$  standard deviations with individual data points on the graph. The data are derived from assay results on the QC controls run.

### 8.2. End of Month QC

Refer to the flowchart in Figure 8-1 to print the end of month QC report. When the end of month (EOM) function is selected, data (for up to 31 data points) is erased. You can choose to delete the cumulative mean, SD and CV value, as well as the data points if you will be using a different lot of control. Do **not** delete the mean, SD and CV if you are using the same lot of control and want to keep a continuing record (lot-to-date, LTD).

### 8.3. Delete QC Control

Refer to the flowchart in Figure 8-1 to delete a data point from the QC record.

1. To delete a QC record, press **QC**, press **arrows** to select *Delete QC Control* and press **Enter**.

2. Press the **test type key** for the test that the control is used for.

3. *Delete ONE?* appears. Use the **arrows** to select *Yes* if deleting only one data point, or select *No* if deleting more than one data point, and press **Enter**.

4. To delete a single point, type in the point number and press **Enter**. (To clear the number on display, press **Del**, then type the **number** of the point to be deleted, and press **Enter**.)

To delete a series of points, press **Del**, type the **first number** of the series to be deleted, and press **Enter**. Then press **Del**, type the **second number**, and press **Enter**.

5. *Sure to delete?* appears. Use the **arrows** to select *Yes* (to delete) or *No* (not to delete) and press **Enter**.

### 8.4. Add QC Control

Refer to the flowchart in Figure 8-1 to add a data point to the QC record.

1. To add a point to the Levey-Jennings plot of control data, press **QC**, press **arrows** to select *Add QC Control* and press **Enter**.
2. Press the **test type key** for the test that the control is used for.

**NOTE:** Before you can add a point to a plot for Factor Assays or Fibrinogen, a standard curve must exist for that test.

3. Type in the operator **ID** and press **Enter**. (To clear the number on display, press **Del**, then type the two-digit **number** and press **Enter**.)
4. Press the **arrows** to select the *LEVEL* of the reference (Level 1 is usually a normal control, levels 2 and 3 are usually abnormal controls) and press **Enter**.
5. Press **Del**, then type the **value** and press **Enter**.
6. Repeat steps 4 and 5 until finished, then press **ESC**.
7. *Save the changes?* appears. Press the **arrows** to select *Yes* to save the changes, or *No* to leave the original data unchanged, and press **Enter**.

### 8.5. Print Levey-Jennings Plot

Refer to the flowchart in Figure 8-1 to print a Levey-Jennings plot of QC data **at any time**. Levey-Jennings plots display data as mean  $\pm 3$  standard deviations with individual data points on the graph. The data are derived from assay results on the QC controls run (section 8.1).

1. To make a print out of a Levey-Jennings plot, press **QC**, **arrows** to select *Print Levey-Jennings Plot* and press **Enter**.
2. Press the **test type key** for the test that the control is used for. A printout is produced if there are at least 2 data points. If a QC value was manually changed, an "x" will be printed

by the value. If no points are stored for the test, a message appears instead of a printout being produced.

**NOTE:** If the printout is to be part of a permanent record, photocopy it and save the photocopy.

### 8.6. QC for Assays Using Standard Curves

QC Controls at three levels can be stored for each of the factor assays as well as PT, APTT, TCT and Fibrinogen. These are selected and run just as for other assays. The major difference is that if you choose to edit in data, the number must be entered as clot time in seconds.

For factor assays, the data printed in the Levey-Jennings plot for is the % activity. This is calculated from the clot time entered versus the standard curve stored in the memory. In the case of fibrinogen, the clot time is edited in and the fibrinogen concentration (mg/dL) is calculated from the fibrinogen standard curve and stored.

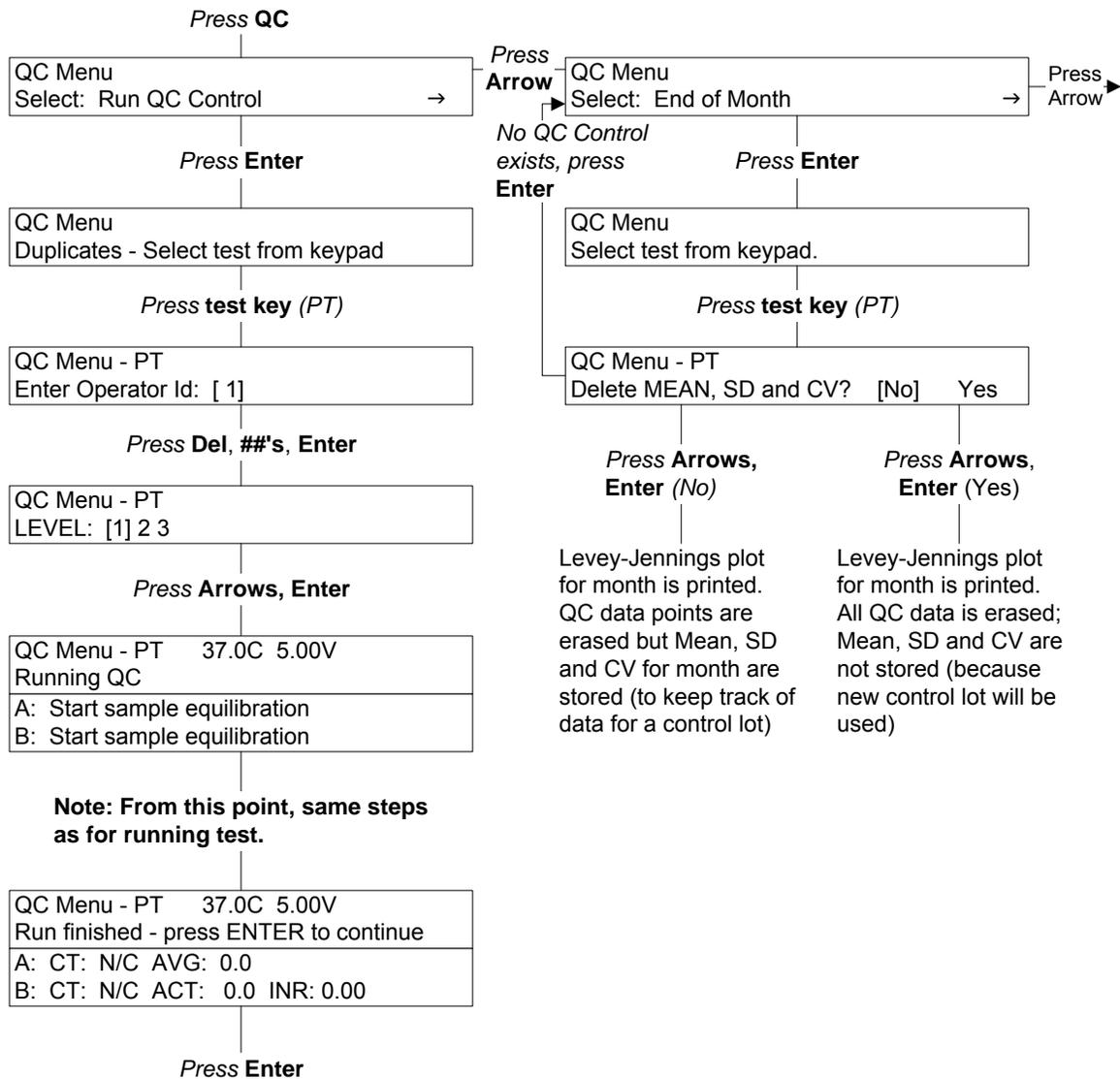
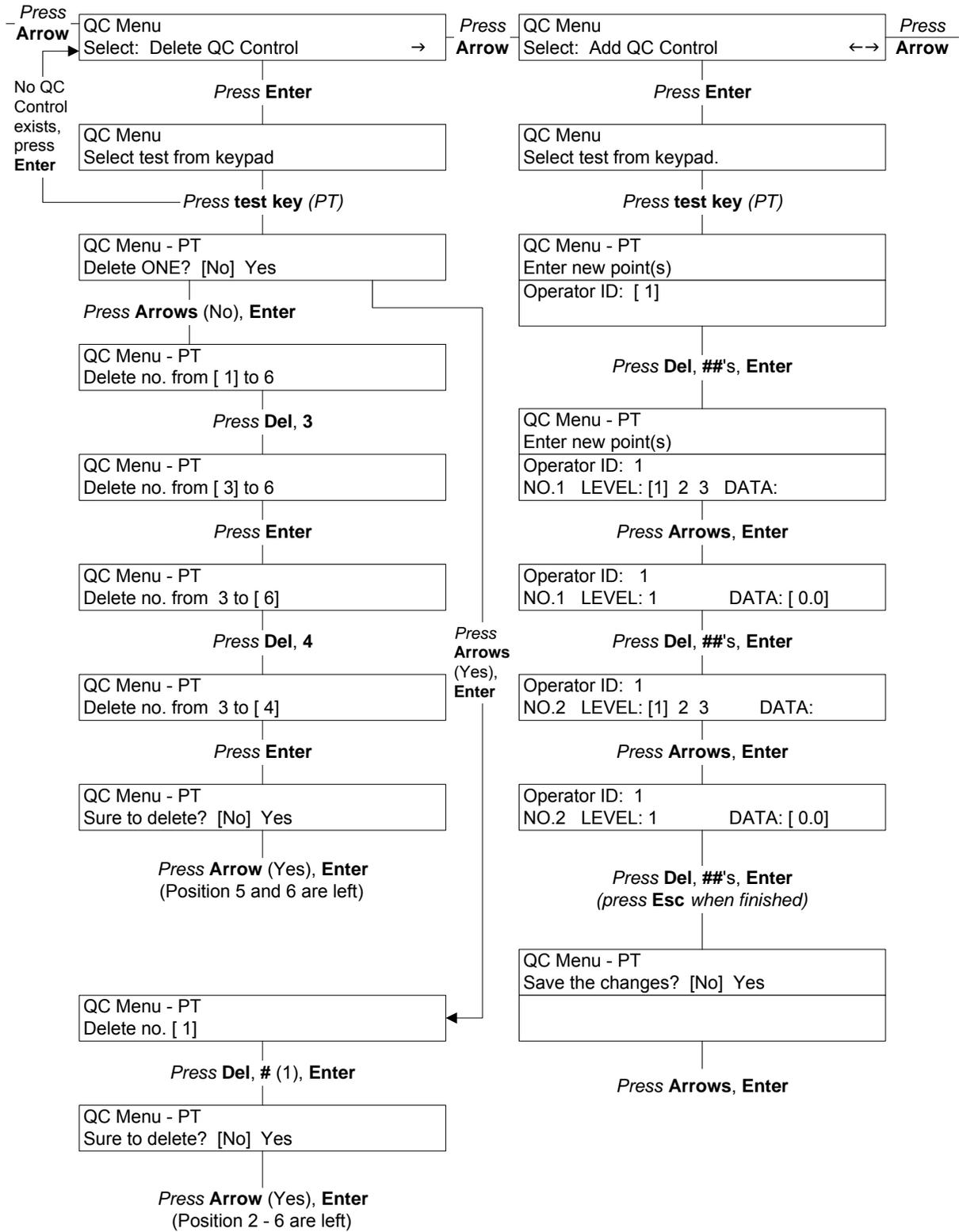
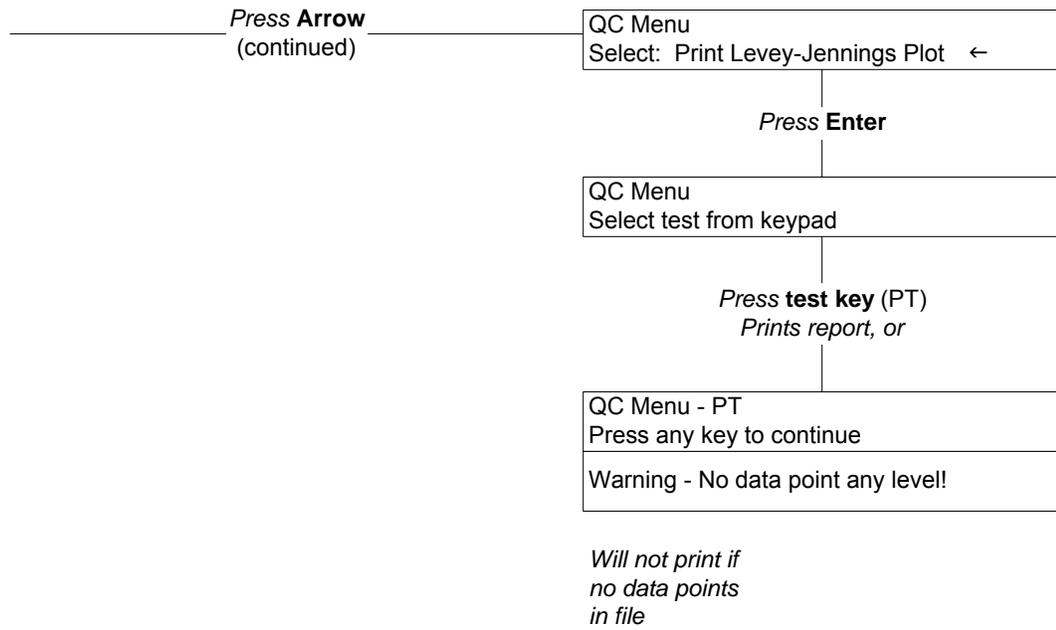


Fig. 8-1. QC Menus

**Note: If more than 31 data points are in any level, Level # - full! Press Enter to continue appears. Press Enter and go to Delete QC Control.**



**Fig. 8-1. QC Menus (cont.)**



**Fig. 8-1. QC Menus (cont.)**

**Section 9 - Performance Specifications****Assays:**

PT (one stage prothrombin time), APTT (activated partial thromboplastin time), fibrinogen, thrombin clotting time (TCT), and factors II, V, VII, VIII, IX, X, XI and XII

**Printed Reports:**

Results printed on 4.5" wide thermal paper (Cat. No. 1720); also standard curves, Levey-Jennings plots (QC) and system parameters can be printed out.

**Incubator Temperature:** 37°C +/- 0.5°C

**Cuvette:**

Disposable cuvettes, maximum cell capacity is 600 µL (Cat. No. 1718)

**Input Power:**

110/220 Vac, 50/60 Hz, 100 Watts Max.

**Fuses (2):**

110V/220V 3A/250V slo blo

**Dimensions, Assembled:**

8 in. (20 cm) High  
15 in. (38 cm) Wide  
13 in. (33 cm) Deep

**Weight:**

20 lbs (44 kg)

**Environment:**

15° to 30°C (59° to 86°F)

## Section 10 - Maintenance, Troubleshooting, Warranty

### 10.1. Maintenance

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

**Table 10-1. Preventative Maintenance**

<b>Daily:</b>	Check for spills
<b>Weekly:</b>	Clean Injection Ports and Optical Wells
<b>Every Month:</b>	Check the Filter, Clean if Dirty

#### 10.1.1. Cleaning Spills

**AFTER TURNING OFF THE POWER AND UNPLUGGING THE POWER CORD**, clean spills with a cotton swab, soft cloth or sponge. Do not use corrosive or abrasive cleansers. Thoroughly dry the unit before plugging the power cord in.

Should an instrument be contaminated by blood or blood derivative, spray any contaminated surface with a commercial virucidal and germicidal agent. Observe where the specimens are used inside the instrument and confine cleaning to that area. Wipe up the residue. These materials contain alcohol, which is corrosive to metal surfaces.

A spill in the optical well should pour out the hole in the bottom of the well. Clean the inside of the optical well, the bottom of the unit and the bench area.

#### 10.1.2. Clean Injection Ports and Optical Wells

Once a week, or more often if crossover contamination is suspected, clean the injection ports and the optical wells.

1. Open the lids.
2. Clean the ports in the lids with a swab dipped in alcohol. If necessary, ports can be

unscrewed and removed from the lid for cleaning.

3. Use the cotton swab (dipped in alcohol) to rub the inside of the optical wells to remove any internal residue.

4. Close the lids.

#### 10.1.3. Fuse Replacement

Two fuse holders are located on the back panel of the Cascade M next to the power cord (Fig. 10-1).

1. Switch the main power to off and unplug the power cord.

2. Push in and twist the fuse holder counter-clockwise to remove it, and withdraw the old fuse.

3. Replace the fuse with one of the proper rating (see labeling on back).

4. Push the fuse holder firmly into the instrument and twist it clockwise to seat it.

If the fuse blows out immediately after replacement, other causes must be considered. Call Helena Laboratories for assistance.

#### 10.1.4. Replacing Printer Paper

1. Remove the old paper core from the printer.

2. Use scissors to cut a clean leading edge (a triangular point is best) on the new roll of printer paper.

3. Put the new roll in the printer with the roll feeding from the underside toward the front of the printer.

4. Manually feed the paper straight into the slot in the printer and press LF (line feed) until paper catches and moves through the printer.

#### 10.1.5. Cleaning the Filter

One filter is located on the bottom of the Cascade M. Remove the filter and check to see if the filter needs cleaning once a month.

1. Remove any cuvettes and reagents from the top of the instrument.

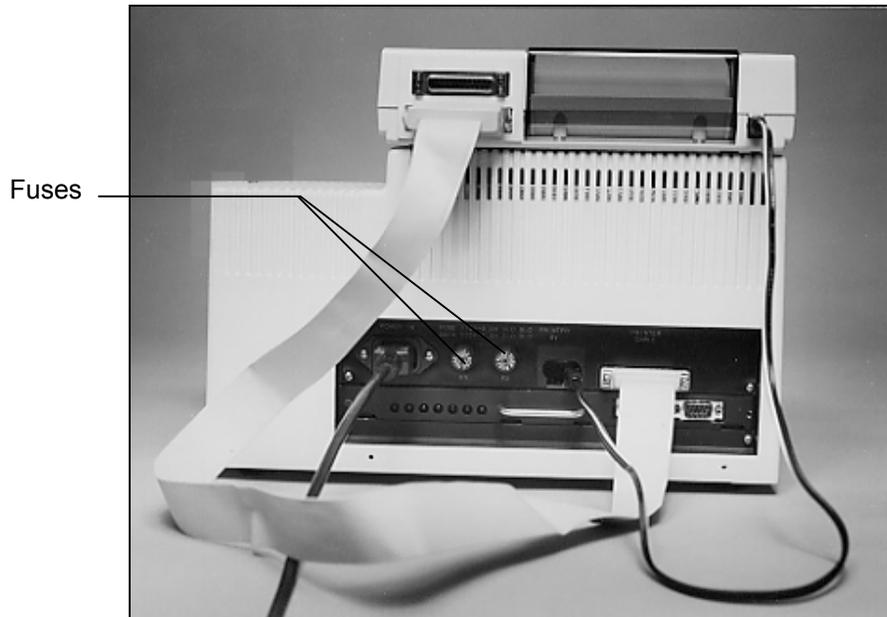
2. Turn off the power and unplug the power cord.
3. Turn the instrument over, exposing the filter.
4. Pull off the cover and then remove the filter.
5. Wash the filter in soap and water.
6. Rinse the filter in water and allow to air dry.
7. Replace the filter and then the cover.
8. Turn the instrument upright, plug in the power cord and turn on the power.
6. Turn the wrench slowly **clockwise**, until the timing process begins.
7. Now turn the wrench 1/8 turn further **clockwise**.
8. Release pressure on the lid switch (and pipettor button), then press the **Abort** key to stop the test in progress.
9. Check the lid switch for proper operation by running another simulated test. If the switch performs satisfactorily, adjustments are complete. If not satisfactory, turn the wrench **clockwise** about 1 turn and repeat steps 1 to 8 until the switch operates correctly.

#### 10.1.6. Momentary Lid Switch Adjustment

In the Cascade M, the lid over each optical channel contains two switches. One is a “momentary” switch, used to begin timing of a process, and the second is a “magnetic” switch, which monitors opening and closing of the lid.

The momentary lid switch may need adjustment if a timer does not start when the lid switch is pressed. (Note that if both channels have this problem at the same time and an electronic pipettor is in use, the switch in the pipettor may be at fault, not the lid switch.)

1. Locate the 0.05” Allen wrench supplied with the instrument. Turn on the power to the Cascade M.
2. Look at the top of the lid switch to be adjusted and find the very small hole on top of the lid, toward the hinge side.
3. Insert the long end of the Allen wrench into the hole and hold it there.
4. Begin a test sequence by pressing **Test** and the **Test Type** buttons. You need not use reagents or cuvettes to simulate a test.
5. If an electronic pipettor is not in use, press down the optics chamber lid. If an electronic pipettor is in use, insert the pipettor into the lid needing adjustment, press and hold down both the pipettor button and the optics chamber lid.



**Fig. 10-1. Back Showing Fuse Location**

## 10.2. Troubleshooting

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

**Table 10-2. Troubleshooting**

<b>Problem</b>	<b>Possible Cause</b>	<b>Solution</b>
No power to instrument	Power cord unplugged	Plug cord into properly grounded wall outlet
	Blown fuse	Replace fuse
Error message is displayed or error	Error found during self-test or operation	Do as directed by the message or see Section 7.6 code is printed for a list of error codes (on results printout). If message returns, or an error code reappears, call Helena Laboratories for assistance
Poor sample duplication	Pipette tip contaminated	Use clean pipette tips for each addition of reagent or sample
	Old reagent	Replace reagent
	Air bubbles in cuvette	Push pipette button more slowly
	Injection port contaminated	Clean port (see section 10.1.2)
No clots indicated	Read time too short	Go to longer read time (see section 5.3.2)
	Low fibrinogen level	Increase gain setting (call Helena Laboratories for assistance)
	No patient sample in cuvette	Add sample to cuvettes
	Old or contaminated reagent	Replace reagent
No displays	Fuse blown	Check fuses, replace if required
	Power supply problem	Call Helena Laboratories
Incubator too hot or cold	Temperature not set to 37°C	See General Parameters (section 5.3.1)
	Electrical problem	Call Helena Laboratories
Timer will not start when lid switch is pressed	The momentary lid switch needs adjustment	Adjust momentary lid switch (section 10.1.6)

**10.3. Warranty**

Helena Laboratories warrants its products to meet Helena's published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be the buyer's exclusive remedies.

In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.

The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

**Section 11 - Symbology**

NOTE: The following symbols may be used in this manual, or on the instrument, to provide information necessary to the user, if applicable.

	Caution, electric shock hazard, high voltages capable of causing personal injury - shut down the instrument and unplug the power cord before touching - do not operate with the cover(s) removed
	Caution, heat hazard - allow heated components to cool before handling
	Caution, general hazard - see Precautions and Hazards (Sections 3 and 4) of Operator's Manual before proceeding
	Direct current
	Alternating current
	Both direct and alternating current
	Ground (earth) terminal
	Protective conductor terminal (grounded conductors)
	Frame or chassis terminal
	Equipotentiality (conductor with all parts at a single potential)
	On (power switch)
	Off (power switch)
	Equipment protected throughout by double insulation or reinforced insulation (equivalent to Class II of IEC 536)

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**Operator's Manual**

**Cascade<sup>®</sup> M**

**For additional information, call Helena  
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