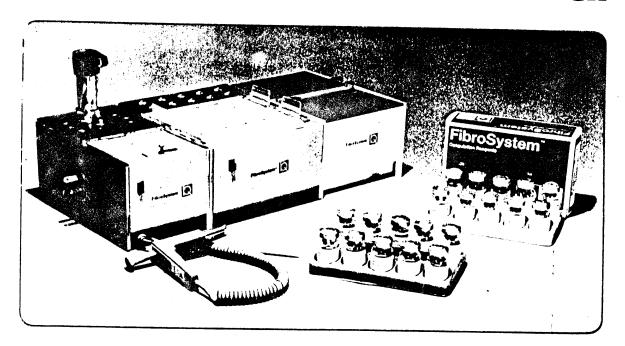
# The FibroSystem Manual



Directions for Use for the FibroSystem® - The Total System for Coagulation Testing

Fibrometer® Precision Coagulation Timer

Catalog Number 60415 NHF

NHRIC Ref. No. H 8292-213413

Thermal Prep Block

Catalog Number 60419

NHRIC Ref. No. H 8292-213513

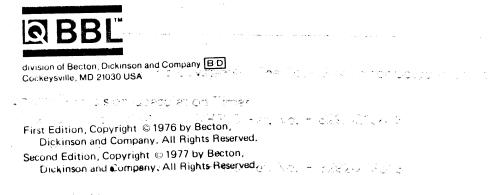
Automatic Electric Pipette

Catalog Number 60420

NHRIC Ref. No. H 8292-213613

#### **TRADEMARKS**

The following are trademarks of Becton, Dickinson and Company — BBL, BART, Fibrometer, FibroPlastin, FibroSystem, FibroTip, FibroTrol, FibroTube and B-D.



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#### **PRECAUTIONS**

Read this manual before testing controls or clinical samples with FibroSystem equipment. This manual has been designed utilizing a step-by-step format. It is meant to provide all the information that is needed to run accurate tests for fibrin formation. Not only will this manual serve as a handy, reference, but also as an important training guide for new personnel.

FOR YOUR PROTECTION, the Fibrometer® Precision Coagulation Timer and the Thermal Prep Block are equipped with a three-wire grounding plug. Used properly, this grounding plug will protect you from shock hazards. Should a two-prong receptacle be encountered, it must be replaced with a properly grounded three-wire receptacle in accordance with the National Electrical Code and local codes and ordinances. This work should be done by a qualified electrician.

DO NOT, under any circumstances, cut or remove the grounding prong from the plug. UNPLUG the power cord before cleaning or performing any of the procedures described in the section entitled, "Trouble Shooting".

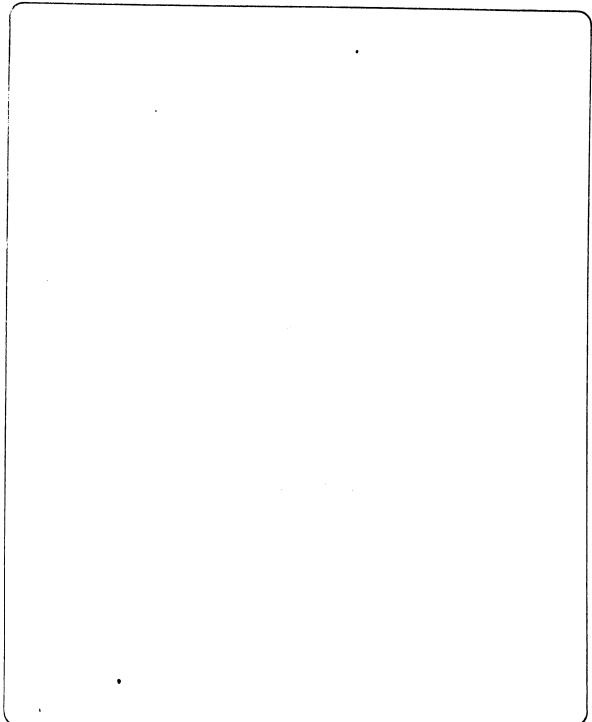
DO NOT perform any servicing except for those items specifically stated and described in this manual. Advice on specific technical problems can be obtained by contacting the Technical Services Department at BBL, Post Office Box 243, Cockeysville, Maryland 21030 or telephone toll-free, (800) 638-8663; in Maryland call (301) 666-0100 collect.

DO NOT open any instrument cover under any circumstances. To do so may invalidate your warranty.

DO NOT remove labels or warning tags from this equipment.

Use FibroSystem Reagents only as directed in the package insert accompanying each product.

# FIBROSYSTEM® - THE TOTAL SYSTEM FOR COAGULATION TESTING



FibroSystem, the registered trademark of Becton, Dickinson and Company, is a total system containing all the equipment, reagents and disposable supplies needed for accurate coagulation testing. The FibroSystem concept provides a reliable method for performing any laboratory test which utilizes a fibrin clot as the end point. Its range of operation includes diagnostic evaluation, monitoring anticoagulation therapy, and measuring the effect of heparin and protamine sulfate on whole blood during open heart surgery, renal dialysis, etc.

#### **EQUIPMENT**

#### 1. Fibrometer® - Precision Coagulation Timer

The major component of the **FibroSystem** is the **Fibrometer** Precision Coagulation Timer. (In this manual, this component will be called the **Fibrometer**.) The instrument is designed to automatically detect fibrin clot formation.

#### 2. Thermal Prep Block

The Thermal Prep Block complements the Fibrometer. This unit is a precise device for prewarming reagents and plasma to testing temperature. Temperature equilibrium is maintained at 37.2 ± 0.5 C in 20 shallow wells and 10 deep wells. The shallow wells will accommodate FibroTube® Coagulation Cups. The deep wells have been designed to hold standard 12 X 75 mm test tubes.

#### 3. Automatic Pipette

The third component in the FibroSystem is the Automatic Pipette, which is capable of dispensing the 0.1 ml and 0.2 ml volumes normally used in coagulation testing. Once plugged into the Fibrometer, the Automatic Pipette will serve a double function. This hand-held pipetting gun will accurately pipette liquids, and it will automatically initiate the Fibrometer clot detecting and timing mechanisms.

#### **DISPOSABLE SUPPLIES**

The recommended reaction cup for use with the Fibrometer and the Thermal Prep Block is the FibroTube Disposable Coagulation Cup. Three factors make these cups an important FibroSystem component. First, they are made to carefully controlled dimensions to ensure that the proper liquid level is maintained in the Fibrometer reaction well. Second, they are made of special materials that allow the proper heat transfer from heating block to liquid. Finally, these cups are one-time disposables which eliminate errors due to contamination.

The recommended pipette tip for use with the Automatic Pipette is the FibroTip TM Disposable Pipette Tip. FibroTip Disposable Pipette Tips should always be used when pipetting with the Automatic Pipette. These chemically clean, disposable tips are easy to use and eliminate the hazards associated with mouth pipetting.

#### BBL® COAGULATION REAGENTS

BBL manufactures a broad line of reagents as part of the FibroSystem. When these reagents are used as directed, any laboratory can conveniently perform the most modern coagulation tests. Complete and detailed procedures for these tests are provided in the package insert which accompanies each product. All personnel should read the insert before using the product. A complete list of BBL coagulation reagents is shown in the chart on the next page.

#### BBL® COAGULATION REAGENTS

40775,76	t	FibroPlastin® Rabbit Brain Thromboplastin with Calcium
40821,22	t	FibroPlastin® II Liquid Rabbit Brain Thromboplastin with Calcium
40777	t	FibroTrol® Citrate Normal Coagulation Control Plasma
40778	t	FibroTrol® Oxalate Normal Coagulation Control Plasma
40779,80	t	FibroLet® Activated Platelet Factor Reagent
40802	t	FibroTrol® 10-20 Citrated Abnormal Range Coagulation Control Plasma Kit
40805	t	FibroTrol® 10-20 Oxalated Abnormal Range Coagulation Control Plasma Kit
40813	t	FibroFac <sup>™</sup> Correction Reagent Kit
40823		BART TM Reagent
40631	t	Platelet Factor Reagent
40636	t	Prothrombin-Free Plasma, Bovine Source
40637		Sodium Oxalate, 0.1 Molar
40662		Calcium Chloride, 0.0032 Molar
40638		Calcium Chloride, 0.02 Molar
40639		Calcium Chloride, 0.025 molar
40640	†	Thromboplastin Generation Kit (for performing the Thromboplastin Generation Time Test)

40641,42 †\* ThromboTest® Owren Prothrombin Time Reagent

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<sup>\*</sup> Trademark of Nyegaard & Co., A/S, Oslo, Norway

<sup>†</sup> Refrigerate. Store at 2 to 8C.

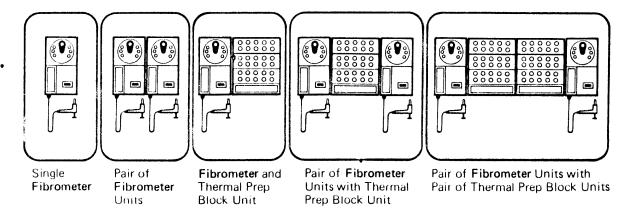


Figure 1-1 The Modular Concept

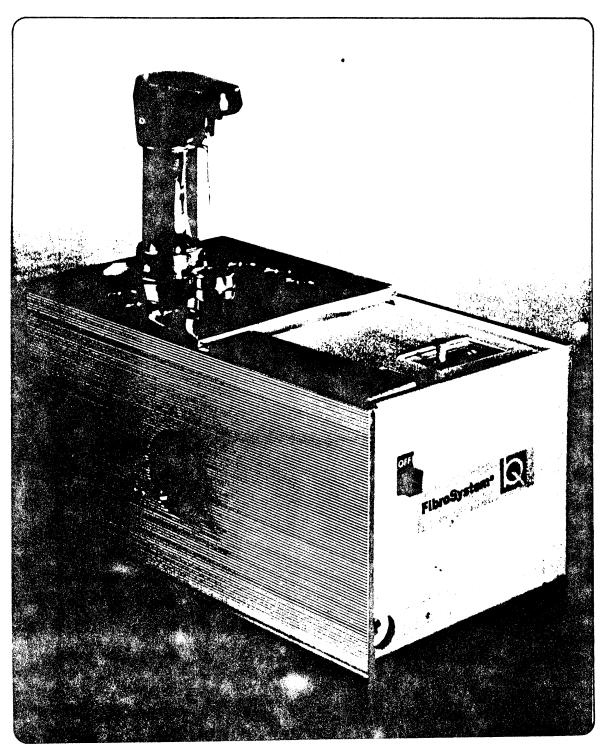
#### THE MODULAR CONCEPT

Due to the small amount of electricity used by the **FibroSystem** components and their special design features, modular combinations are possible. Built into opposite sides of both the **Fibrometer** and the Thermal Prep Block are special polarized three-pronged plugs and receptacles. This means that any of these machines can be plugged into any other **Fibrometer** or Thermal Prep Block. The first machine will obtain power from one three-wire line cord plugged into a wall receptacle. At the same time, line power will pass on to the second machine now plugged into the first. If a third machine were to be plugged into the second, it too would receive power. This modular concept will not overload a circuit because of the small amount of electricity actually being used by each machine. For example, a system composed of two **Fibrometer** Timers and two Thermal Prep Blocks would use a maximum current of 3.0 amperes.

The modular concept is expanded still further by plugging the Automatic Pipette cord directly into the connector on the front of the Fibrometer.

Examples of modular combinations are shown in Figure 1-1.

• SECTION TWO
THE FIBROMETER® PRECISION COAGULATION TIMER



#### THE FIBROMETER® PRECISION COAGULATION TIMER

#### USE

The Fibrometer Precision Coagulation Timer is an electro-mechanical instrument that will determine the presence of a fibrin clot. The Fibrometer is both a clot sensing device and a timer. Each unit also contains constant temperature warming and reaction wells. This basic design allows the Fibrometer to be used as the primary piece of equipment in most of the coagulation determinations now in common use.

#### PRINCIPLES OF OPERATION

Historically, those wishing to perform coagulation determinations utilized the wire loop manual method for measuring the critical clotting end point. The Fibrometer was designed to mechanically replicate this proven manual method (1,2). Now after more than ten years of successful use and millions of field determinations, the Fibrometer is a time-tested device.

The Fibrometer is a rugged unit which ensures the quality performance demanded by modern laboratory standards. When used for tests ending with fibrin formation, this machine is capable of sustained accuracy, consistency and reproducibility.

The performance characteristics and specifications are detailed on the following page.

#### THE FIBROMETER® PRECISION COAGULATION TIMER

Performance Characteristics and Specifications

Heating Temperature  $37.2 \pm 0.5 \text{ C}$ 

Detector Cycle Time 0.5 sec.

Machine Resolution ± 0.5 sec.

Timing Range 0.0 to 999.9 sec. •

Standard Deviation\* 0.3 sec. for times under 25.0 sec.

0.6 sec. for times over 25.0 sec.

Dilution Curves\* Curves established using the Fibrometer have the same

characteristics as those obtained by visual methods.

Test Volumes 0.3 ml and 0.4 ml

Patient Sample Size 0.1 ml or 0.2 ml of patient's plasma, whole blood, or

occasionally serum

Liquid Heating Times Refrigerated fluids: 5 minutes

Room temperature liquids: 3 minutes

Dimensions and Weights Height (probe up) - 178 mm (7")

Width - 102 mm (4") Depth - 184 mm (7.25") Net Weight - 3 Kg (7 lbs.)

Shipping Weight - 4.8 Kg (10.5 lbs.)

Machine Warm-Up Time Approximately 10 minutes

Electrical Specifications 117 volts, 60 Hz, 0.6 amps (Catalog No. 60415)

117 volts, 50 Hz, 0.6 amps (Catalog No. 60416)

<sup>\*</sup> These times are supported by data obtained using the Quick one-stage technique and the Ware-Stragnell modification of Owren's test for Prothrombin and Proconvertin (3,4).

#### COMPONENT PARTS

#### The Probe Unit

The clot detection arm of the Fibrometer is the probe unit. Two probe units are available and may be used interchangeably on any Fibrometer. Each Fibrometer comes with one standard probe, BBL® Catalog No. 60417. This probe is designed to be used with samples having a volume of 0.3 ml. For samples that require 0.4 ml, the user may order a special probe, BBL Catalog No. 60418.

The probe unit is made of a cylindrical body, two sensory electrodes, and a heavy wire called the probe foot, which extends from the base of the assembly. These structures may be seen in Figure 2-1.

The entire probe unit fits smoothly into the probe sleeve with the electrodes positioned directly over the reaction well (Figure 2-2).

Between tests, the probe is placed in the UP position. This allows for easy cleaning, insertion of FibroTube® cups and pipetting.

For details concerning the probe drop and electrode movement, see COMPONENT PART PRINCIPLES OF OPERATION.

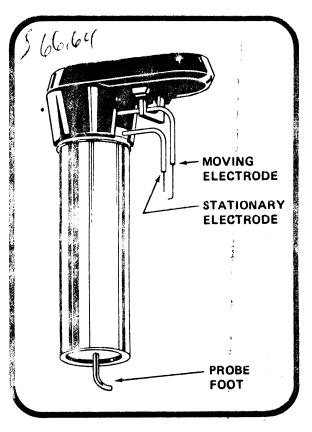


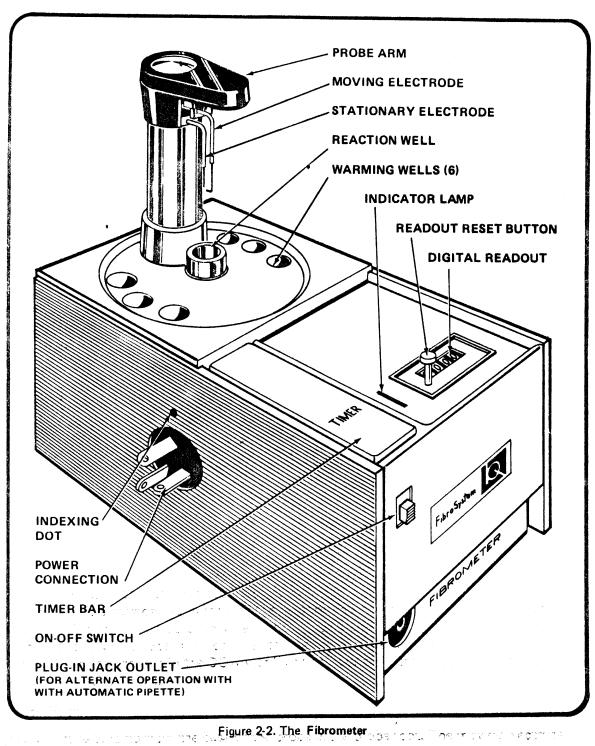
Figure 2-1. The Probe Unit

#### The Electrodes

Two durable metal electrodes, made from #304 stainless steel, are the only parts of the Fibrometer that make contact with the reaction mixture. There is a moving and a stationary electrode. The moving electrode cycles through the reaction mixture by sweeping in an elliptical pattern. A small hook on the tip of this electrode will pick up the initial fibrin thread (monomer). The stationary electrode is responsible for creating an electric potential between the electrodes. When the probe is in the DOWN or "sensing" position, the stationary electrode remains in the reaction mixture.

#### The Probe Foot

The heavy wire extending from the base of the probe is the probe foot. The moving electrode is an extension of this probe foot. A cam raises and lowers the probe foot, thus moving the electrode. The probe foot also is the contact point between the moving electrode and the detection circuit of the Fibrometer.



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The same of the sa The chrome-plated heating block is designed to heat and hold liquids at 37.2  $\pm$  0.5 C. The block itself is composed of metal which has a long thermal constant to ensure that the proper testing temperature will be held. Six prewarming wells and a reaction well are built into the block.

#### The Detection Circuit

The function of the detection circuit is to sense the circuit formed (completed) when a fibrin strand is detected by the moving electrode. When a fibrin strand is detected, the Fibrometer will stop timing and cease mechanical action. If no strand of fibrin is present, there is no flow of current through the detection circuit. However, when a fibrin strand is detected, current flows through the detection circuit and de-energizes a relay. The relay contacts open and stop both the timing and the mechanical operation. The detection circuit may be classified as a bistable or flip-flop transistorized circuit.

#### The Motor and Counting Unit

The Fibrometer contains a synchronous clock motor to run the counting unit and to produce electrode movement. The precise speed of the this motor is regulated by the frequency of the power line. The motor has two shafts. One shaft moves the cam at 60 rpm. The other shaft drives a pulsed counting unit at 600 rpm. This arrangement enables the counting system to have a resolution of 0.1 second.

#### Readout Reset Button

This small red button resets the counter to zero when depressed firmly for at least one second.

#### Indicator Lamp

The function of the indicator lamp is to let the user know when the machine has reached operating temperature. This light will come ON only when operating temperature has been obtained. It will stay ON as long as the machine remains at this temperature.

DO NOT perform Fibrometer tests unless the indicator light is ON.

#### Safety

The Fibrometer is certified for safety by the Los Angeles County Testing Laboratory and is listed by the Canadian Standards Association (CSA).

#### COMPONENT PART PRINCIPLES OF OPERATION

This section should be read and understood completely before beginning routine use of the Fibrometer. The factors outlined and explained below are vital to accuracy.

#### **Heating System**

The heating block contains two mercury thermostats and a heater that will bring liquids in the wells to  $37.2 \pm 0.5$  C. The operation of these thermostats is automatic. The temperature cannot be adjusted by the operator.

This unit will bring liquids at room temperature to approximately 35 C in about ten minutes. At this point, the indicator light comes on and the "fine" control thermostat takes over. This sensitive thermostat will react to a 0.1 C temperature change inside the block and maintain a temperature of  $37.2 \pm 0.5$  C.

#### Mechanical Action - Probe Drop

The Fibrometer can be activated manually by depressing the TIMER bar or automatically when the Automatic Pipette has delivered its last bit of liquid into the reaction cup. There is a built-in delay of 0.5 to 1.8 seconds before the probe drops into the reaction well. The delay allows for the removal of the pipette tip from the reaction cup. This delay will not affect the test results.

After the built-in delay, the sensing probe assembly drops into the reaction well. Before the testing of a sample, the probe is placed in its rest position above the reaction well. In this position, the probe rests upon the probe support lever. This lever is mechanically connected to a solenoid. When the delay circuit energizes the solenoid, the lever snaps back inside the probe sleeve to deprive the probe of its support and causes it to drop. The drop places the electrodes into the proper position inside a **FibroTube** cup in the reaction well.

#### Mechanical Action - Electrode Movement

Movement of the sweeping electrode is supplied by a segmented cam that rotates at 60 rpm and raises the probe foot every 0.5 second. This sweeps the electrode through the reaction mixture every one-half second. The electrode moves in the desired elliptical pattern through the reaction mixture. This can be viewed as a four step process:

- 1) The moving electrode sweeps through the reaction mixture.
- 2) The electrode lifts completely out of the reaction mixture to a point 1.27 mm above the liquid level. (NOTE: This is why the FibroTube cup is of such importance in the FibroSystem. Use of these cups ensures proper liquid level.)
- 3) The electrode becomes electrically active.
- 4) The electrode is returned to the liquid level and sweeps through the reaction mixture to complete an elliptical pattern.

#### Clot Detection

As the initial fibrin strand forms in the reaction mixture, it is picked up on the next sweep of the moving electrode (see Figure 2-3). When this electrode is lifted to a point 1.27 mm above the level of the liquid in the FibroTube cup, a portion of the fibrin strand will remain in the liquid. At this point there is a stationary electrode remaining in the liquid reaction mixture, a moving electrode situated 1.27 mm above the liquid level and a fibrin strand connecting the moving electrode to the reaction mixture.

When the moving electrode is lifted to its position above the liquid level, it becomes electrically active. A fibrin strand will complete the circuit. Current flows from the stationary electrode, through the liquid and through the fibrin strand to the moving electrode. The circuit is completed as current flows from the moving electrode to the cam and detection circuit. The completion of this circuit causes the Fibrometer and its timing device to stop. This is why the Fibrometer is known as a fibrin switch detection device.

Note once again, the level of the liquid in the reaction well is critical. FibroTube cups ensure that the proper liquid level can be maintained.

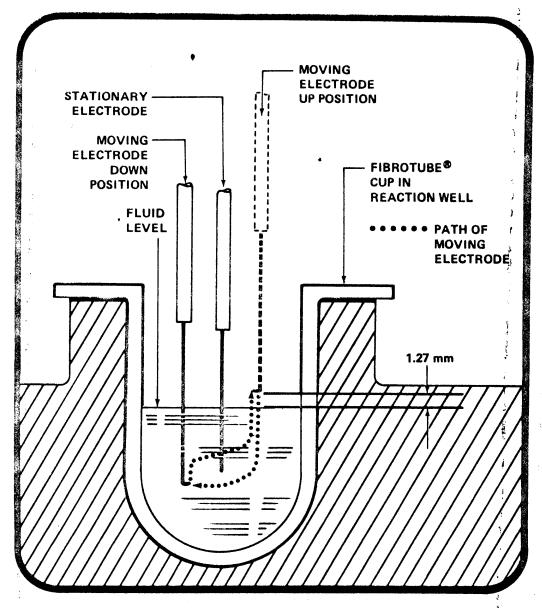


Figure 2-3. Clot Detection

#### INSTALLATION

#### **Equipment Models and Power Ratings**

BBL	60415	Fibrometer	117 volts,	60 Hz, 0.6 amps
*BBL	60416	Fibrometer	117 volts,	50 Hz, 0.6 amps

A dropping transformer, BBL Catalog No. 60575, is available for lowering the 220 volt power source of many countries to 110 volts, thus enabling the user to employ either a 50 or 60 Hz Fibrometer. The frequency (Hz) rating of the Fibrometer must agree with the local line frequency. Up to two Fibrometers and one Thermal Prep Block may be connected to a single transformer.

<sup>\*</sup> This machine is intended for use in countries with 50 cycle (Heftz) alternating current.

#### Laboratory Requirements

The Fibrometer operates on a standard 117-volt A.C. power source which must meet the National Electrical Manufacturers Association standard of 99.5 to 128.7 volts. The outlet must be a standard laboratory three-wire grounded receptacle. Other power sources or outlets may damage the machine. The working environment should be as clean and dust-free as possible, with an ambient temperature between 18 and 32 C (64.4 to 89.6 F).

#### Procedures

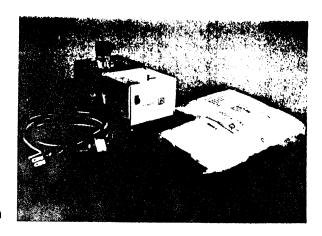
The following procedures are designed to allow you to set up and test your Fibrometer, step-by-step. It is recommended that you test this unit independently of the Thermal Prep Block and the Automatic Pipette. If you plan to connect two Fibrometer timers to a single power source, each unit should be tested independently. If any problems occur as you test your new Fibrometer, please call the BBL Hot Line, toll-free: (800) 638-8663; in Maryland call (301) 666-0100 collect.

 Begin by placing the Fibrometer box with the words, "OPEN THIS END" in the UP position. Take out the packing material and remove the machine.

Included in this one shipping carton are:

- A. One Fibrometer
- B. One line cord
- C. One 0.3 ml probe
- D. 400 FibroTube cups

Visually inspect all items for any indication of shipping damage.



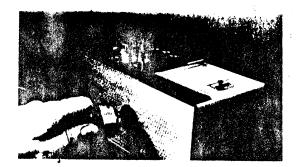
WARNING: The 0.3 ml probe is packed in the DOWN position; i.e., in the probe sleeve. DO NOT turn the Fibrometer over with the probe still in the machine. There is no mechanism to keep the probe from falling out of the well and away from the base.

2. Place the machine on a level bench top that is free from vibration. At this time, it would be wise to decide if additional space is needed for other modules of the Fibro-System.

CAUTION: DO NOT place the Fibrometer on the same bench with a rotary centrifuge, or shaker. Mechanical shaking may separate the mercury column in the sensitive mercury thermostat and impair the ability of the unit to hold the correct operating temperature. Should such a problem occur, see the Section titled, "Trouble Shooting."

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3. Plug the grounded three-wire line cord onto the prongs found on the left side of the Fibrometer. NEVER plug the line cord into the wall receptacle first and then attempt to connect to the machine. Insure proper alignment by matching the red dots found above the prongs on the Fibrometer and on the line cord.



4. Plug the line cord into a standard laboratory three-wire grounded receptacle. DO NOT use any other receptacle or modify the line cord to fit any other type of receptacle.

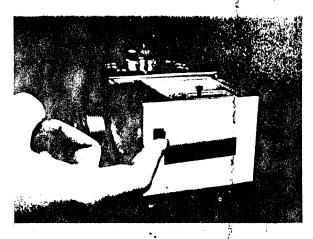
# WARNING: AN UNGROUNDED RECEPTACLE CAN CONSTITUTE A SHOCK HAZARD FOR THE OPERATOR!

Remember to reduce the variables in the testing of all equipment. At this point, test only one Fibrometer. After completion of this test, proceed to test additional Fibrometer Timers, Thermal Prep Blocks and Automatic Pipettes.

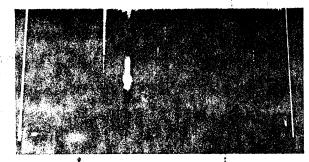
#### **Operating Instructions**

The following instructions are for a test run of the Fibrometer. The test being utilized is the Prothrombin Time Test. Be sure to run this test several times to be certain the Fibrometer is properly detecting and timing fibrin strand formation. If a problem is noted in these test runs, please call BBL Technical Services, toll-free: (800) 638-8663; in Maryland call (301) 666-0100 collect.

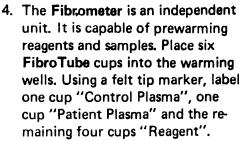
1. Put the Fibrometer power switch in the ON position (switch up).

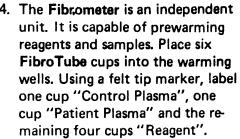


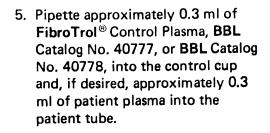
2. Wait approximately ten minutes for the machine to reach proper operating temperature. The indicator light will come on and remain on as long as the machine is at the correct operating temperature.

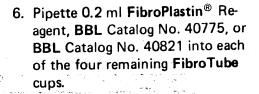


3. Raise the probe arm to the UP (rest) position. When the machine is not in use, the probe should be left in the DOWN position to protect the electrodes from accidental damage. Please note that the probe cannot be forced down into the probe sleeve. One must switch on the machine and depress the Timer Bar to drop the probe into the DOWN position.

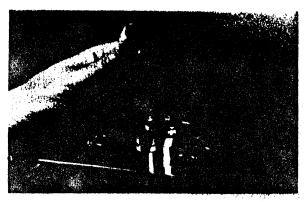


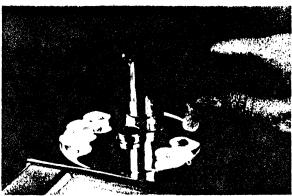


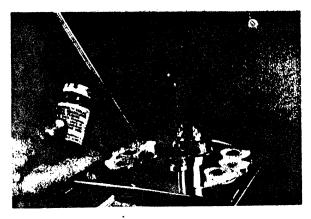




NOTE: The use of FibroPlastin Reagent is recommended. This is the reagent used by BBL to calibrate all Fibrometer Timers at the factory.

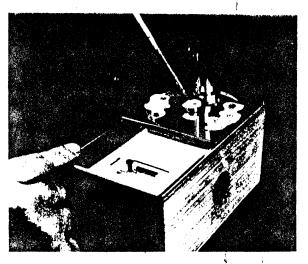






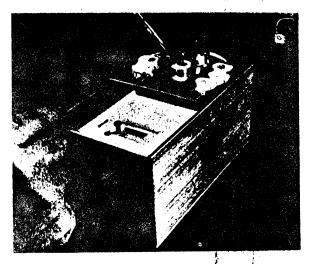


- 7. Allow three minutes for room temperature liquids to come to operating temperature in the warming wells. Five minutes will be necessary for refrigerated liquids.
- 8. Place one FibroTube cup with FibroPlastin into the center (reaction) well.
- Pipette 0.1 ml of FibroTrol Control Plasma into the cup and simultaneously press the Timer Bar.

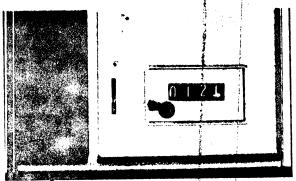


NOTE: With the Automatic Pipette, there is no need to press the Timer Bar. When the Automatic Pipette switch is ON, the Fibrometer action is begun automatically as the last bit of liquid is expelled from the pipette.

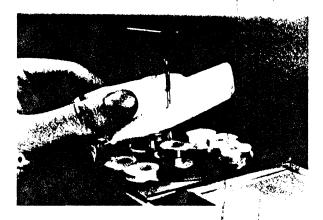
10. The probe should drop and the moving electrode should begin its elliptical sweeping pattern through the reaction mixture. A clicking sound will be heard. This is normal.



11. The digital readout and electrode action will stop when a fibrin strand is detected. Read and record the time required for fibrin strand detection. If the **Fibrometer** has properly detected the formation of the first fibrin strand, the time shown on the digital readout should be from eleven to thirteen seconds.

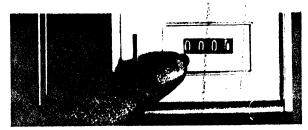


12. Lift the probe arm up to the rest position. The electrode should be wiped dry with a <u>lint-free</u> laboratory grade absorbent tissue or bibulous paper.



NOTE: This tissue or paper MUST be lint-free. The electrode must be free of fint and all other forms of contamination for proper fibrin strand detection. A distilled water wash directed from a wash bottle may be used to clean the electrodes. If an acid wash is desired, use 1.0% phosphoric acid followed by a distilled water rinse. The use of other acids may pit the electrode.

13. Set the timer to zero by firmly depressing the red reset button for at least one second.



14. Repeat the Prothrombin Time Test, Steps 7 through 13.

#### **Pipetting Hints**

Proper and consistent pipetting is necessary for sustained accuracy. Regardless of which system you use, the Automatic Pipette or standard pipetting, adopt the following procedure:

- A) Rest the pipette on the lip of the cup that is closest to the center of the Fibrometer.

  DO NOT let the tip touch the opposite side wall or the reaction mixture.
- B) When dispensing, insert the pipette tip at least 1/4 of the way into the **FibroTube** cup.
- C) Aim the tip at the back bottom of the FibroTube cup.
- D) Eject the material smoothly and without splashing.

DO NOT allow the liquid being pipetted to run down the side wall. This will cause an unequal liquid level and result in an erroneous, short end point.

AVOID PIPETTING CONTAMINATION: The same pipette or FibroTip can be used for pipetting each aliquot of a reagent or sample. A different pipette or FibroTip MUST be used for each plasma specimen.

#### **OPERATING HINTS AND PRECAUTIONS**

The Fibrometer Precision Coagulation Timer is designed for In Vitro Diagnostic Use; all directions should be read and followed carefully.

WARNING: Every human blood sample represents a potential HEPATITIS DANGER.

Observe proper precautions against this infectious hazard whenever handling plasma, serum or whole blood specimens. (5)

#### **Electrodes**

The stationary and moving electrodes should be aligned in a vertical position, parallel to one another. Even though spacing is not critical, gross distortions should be corrected. If the electrodes become bent, carefully realign them so that they are both vertical and parallel to one another.

As noted, lint contamination of the electrodes will result in erroneous, short coagulation times. Use lint-free laboratory-grade absorbent tissue or bibulous paper.

#### **Mechanical Operation**

The Timer bar must be pressed firmly to ensure proper probe activation. The timer reset button must be depressed firmly for at least one second to reset the digital mechanism. Failure to do so may cause slipping or jumping of the timer wheels.

#### Wires and Outlets

Separate modular units with care. Electrical safety procedures always recommend that the power cord be unplugged before connecting or disconnecting modular units.

When machines are in a modular arrangement, keep them on a level surface and be sure to avoid twisting the connectors.

#### Cups

FibroTube cups are single use disposables manufactured by BBL. The liquid level in the reaction well is critical to the operation of the Fibrometer.

#### Reagent Quality

FibroSystem Reagents are recommended for the best test results. However, any properly produced and correctly standardized reagent and control plasma will work with the Fibrometer.

#### Reagent Volume

The Fibrometer comes with a probe calibrated for use with exactly 0.3 ml of liquid. A 0.4 ml probe is available for use in tests requiring this volume. To ensure proper liquid levels, it is recommended that FibroTube cups be utilized for all tests. To ensure correct volume delivery, use the Automatic Pipette, BBL Catalog No. 60420.

#### **Temperature Warnings**

Thromboplastin reagents should never be left at 37.2 C for more than four hours. Plasma should not be left at this temperature for more than twenty minutes.

#### **MAINTENANCE**

The Fibrometer is designed with user convenience in mind. There is a minimum of maintenance required. The timing mechanism is factory-sealed and never requires lubrication. There are no zero calibrations, threshold settings, temperature controls, or day-to-day adjustments necessary with the Fibrometer. All that is required of the user are a few simple procedures, as outlined below.

#### **Electrode Care**

Protein build-up can significantly alter test times. Remove all dust, debris and testing contamination from the electrodes. Clean electrodes of foreign material by wiping the electrodes with lint-free tissue or paper, or rinse with distilled water by using a wash bottle.

#### Warming and Reaction Wells

Periodically, remove accumulated dust and debris with a slightly dampened cotton swab. Dirt or debris will raise the level of the FibroTube cup. This in turn will raise the level of the liquid in the reaction well and drastically alter the coagulation time measurements. Check the well each day before use.

#### Probe Column

No portion of the probe assembly should ever be lubricated. The materials and mechanism of this probe are designed to operate dry. After approximately 1,000 probe drops, the post hole and the probe column must be wiped with a lintless soft tissue. This should be done, even if no dirt accumulation is visible. Should dirt be allowed to accumulate in the post hole, it must be wiped clean with a tissue moistened in 70% isopropyl alcohol. DO NOT use any other solvent.

#### **Top Surfaces and Case**

Use a dry or slightly dampened cloth to remove dust, water or plasma stains. This should be done daily. Remember that all blood, plasma and serum is a potential hepatitis hazard.

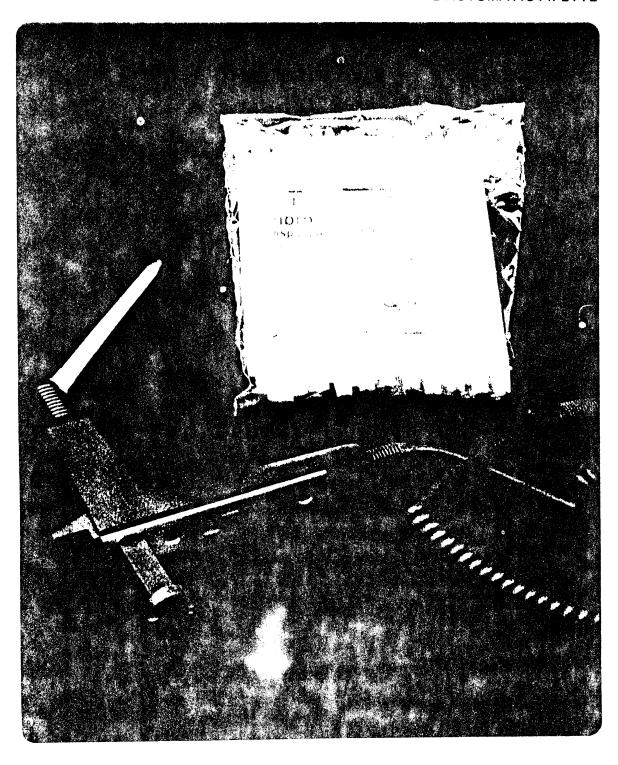
#### Internal Mechanism

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The internal mechanism should not be touched except in specific instances as described in the section titled "Trouble Shooting." All internal arms, levers, and movable parts are designed to operate dry. The motor is permanently sealed and lubricated. To open this unit may invalidate your warranty.

SECTION THREE
THE AUTOMATIC PIPETTE



#### THE AUTOMATIC PIPETTE

USE

The Automatic Pipette (BBL® Catalog No. 60420) is a hand-held pipetting device manufactured specifically to function with the Fibrometer®. This device mechanically dispenses aliquots of liquid. A quick and simple adjustment will allow the Automatic Pipette to take up and deliver either 0.1 or 0.2 ml aliquots. Careful design and rigid testing assure the user of accuracy well within the ± 5% volumetric accuracy required for coagulation studies.

#### PRINCIPLES OF OPERATION

The Automatic Pipette is a modular FibroSystem unit. When connected to a Fibrometer, the pipette will electrically activate the Fibrometer at the same moment in each test. When the final bit of activating reagent is dispensed into the FibroTube® Cup, there is a built-in 0.5 to 1.8 second delay which is followed by the automatic dropping of the Fibrometer probe arm. Sweeping and timing activities will begin automatically.

The Automatic Pipette has a dual Purpose:

- 1. Switch OFF it is a conventional pipetting device
- 2. Switch ON it dispenses liquid and activiates the Fibrometer

The Automatic Pipette is constructed of a light-weight, chemical resistant plastic. All mechanical parts of the pipette are enclosed by this protective plastic. The liquid aliquot is held in and dispensed from a FibroTip<sup>TM</sup> Disposable Tip (BBL Catalog No. 70314). This special disposable tip, seated in the gun, has been designed to prevent liquid from touching the pipetting apparatus. Only the tip, a disposable item, touches any of the samples or reagents used in coagulation studies. This keeps cleaning and maintenance of the Automatic Pipette to a minimum. The cleaning procedures are to be performed after every two months of use.

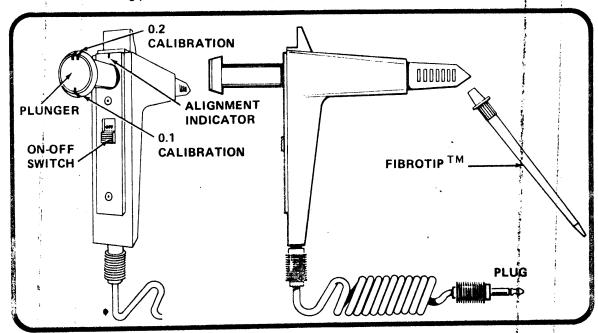


Figure 3-1 The Automatic Ripette

The Automatic Pipette is under warranty for ten years or until the product is no longer a part of the BBL line - whichever is the longest. This warranty covers defects in materials and workmanship. The warranty does not cover abuse. Replacement units can be obtained by calling the Technical Services Department: (800) 638-8663 toll-free; in Maryland call (301) 666-0100 collect.

#### **OPERATING INSTRUCTIONS**

The Automatic Pipette is supplied ready for use. It comes complete with an electric cord and a supply of 200 FibroTip Disposable Coagulation Tips.

#### Independent Testing:

The following seven steps are designed to test the Automatic Pipette without activating the Fibrometer:

 The Pipette is designed to be cradled in the hand with the forefinger on the top rest. This allows for maximum flexibility and control when dispensing. Many users prefer to hold the Pipette in "handgun" fashion. Either approach will produce the same results. A few simple tests will determine which is most comfortable for the operator.

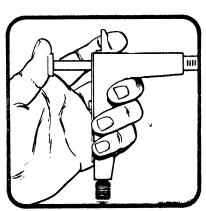


Figure 3-2

- 2. Insert the plug on the end of the pipette cord into the jack located at the lower left front of the Fibrometer.
- 3. Seat a FibroTip onto the forward end of the pipette. Use a firm turning motion, as shown here.

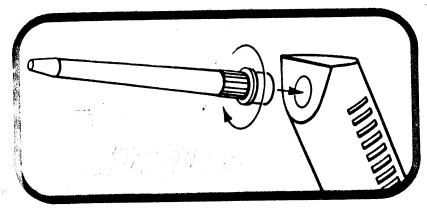


Figure 3-3

4. To adjust for the volume of pick up and delivery, turn the plunger in either direction to align the calibration notches with the alignment indicator. One notch equals 0.1 ml, two notches equals 0.2 ml.

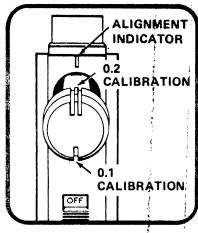
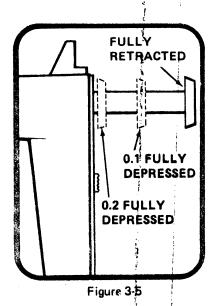


Figure 3-4

5. With the Fibrometer switch in the ON position and the Pipette switch in the OFF position, fully depress the plunger. Insert the tip into the liquid reservoir.

NOTE: Be sure to fully depress the plunger before the tip is placed into the liquid. This will prevent aeration of the liquid and the subsequent formation of error-producing air bubbles.



- 6. Allow the plunger to retract fully and pick up the aliquot of liquid into the **FibroTip**. It is a good practice to "touch off" the tip against the side wall of the liquid reservoir to insure that droplets do not cling to the exterior of the tip.
- 7. Dispense the liquid into a FibroTube Cup by completely depressing the plunger. The FibroTip should be inserted 1/4 of the way into the FibroTube Cup while resting against the lip closest to the pipette as shown below in Fig. 3-6. After ejecting the liquid, be sure to withdraw the pipette tip before releasing the plunger.

NOTE: DO NOT let the FibroTip touch the opposite side wall of the FibroTube Cup. An unequal liquid level will result if the liquid is allowed to run down the side wall. This will yield an erroneous end point.

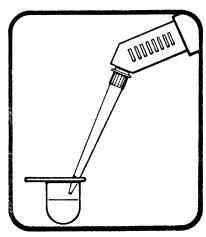


Figure 3-6

#### Testing With The Fibrometer:

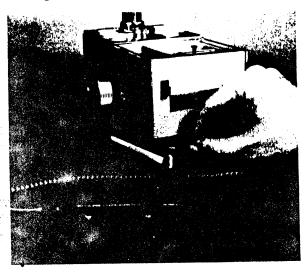
The previous instructions apply to pipetting when the user does not wish to start the Fibrometer action. To activate the Fibrometer, flip the Pipette switch to ON before dispensing the final aliquot of liquid (CaCl<sub>2</sub>, plasma, etc.). Electrical contact is made at the end of the plunger stroke; i.e., the instant the final bit of liquid is dispensed.

Assuming the Fibrometer has been tested independently, the following is a guide for a Prothrombin Time Test protocol in which the automatic action of the Pipette may be tested.

- 1. Begin by preparing the Fibrometer for the Prothrombin Time Test:
  - A. Plug the Fibrometer into a standard grounded three prong outlet.
  - B. Switch ON the Fibrometer.
  - C. Wait for the indicator light to come ON (approximately 10 minutes).
  - D. Raise probe to the UP position.
  - E. Place six FibroTube cups into the warming wells. Label one cup "Control Plasma", one cup "Patient Plasma", and the remaining four cups "Reagent".
- 2. Insert a FibroTip into the Pipette.
- Insert the plug on the Pipette cord into the lower left front jack of the Fibrometer.

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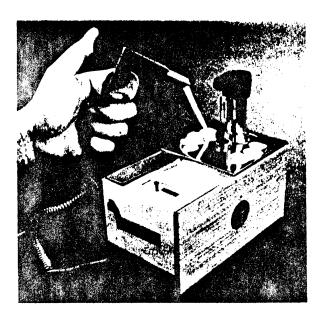
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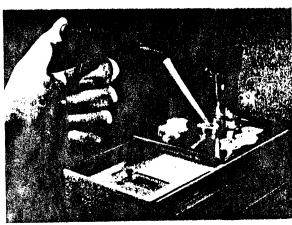
- 4. Turn the pipette plunger so that the 0.2 ml calibration notches align with the indicator.
- 5. Depress the plunger and fill the tip with 0.2 ml of FibroTrol® Control Plasma (BBL Catalog No. 40777 or BBL Catalog No. 40778). Remember to depress the plunger fully before inserting tip into the reagent and then allow the plunger to retract fully to be certain of picking up the correct volume.
- 6. Deliver 0.2 ml of FibroTrol into the FibroTube Cup labelled "Control Plasma".
- 7. Reset the pipette to the 0.1 ml mode.
- 8. Fill FibroTip with 0.1 ml of FibroTrol.
- 9. Deliver 0.1 ml of FibroTrol to the FibroTube Cup labelled "Control Plasma" containing 0.2 ml of the reagent. This cup will now contain 0.3 of FibroTrol reagent.
- 10. The same procedures can be done with patient plasma, if desired. Be sure to REPLACE the FibroTip with a new tip before going from FibroTrol to patient plasma.
- 11. Replace FibroTip with a new tip.
- 12. Set the Pipette into the 0.2 ml mode. Fill the FibroTip and deliver 0.2 ml of Fibro-Plastin® Reagent (BBL Catalog No. 40775 or BBL Catalog No. 40821) into one of the cups labelled "Reagent". Repeat this process for each of the three remaining "Reagent" cups.
- NOTE: It is not necessary to change FibroTip Tips as long as you are pipetting the same concentration of a given reagent. In Step 12, the same FibroTip can be used to fill and dispense the FibroPlastin into each of the four cups.
  - 13. Allow three minutes for room temperature liquids to come to operating temperature. Five minutes will be necessary for refrigerated liquids.
- 14. Place one FibroTube Cup with 0.2 ml of FibroPlastin into the center (reaction) well.
- 15. Replace the FibroTip.
- 16. Adjust the Pipette to the 0.1 ml mode.
- 17. With the Pipette switch in the OFF position, depress the plunger fully and insert the tip into the FibroTrol liquid.
- 18. Allow the plunger to retract fully to pick up the 0.1 ml aliquot.
- 19. Move the Pipette switch to ON.



20. Insert the FibroTip into the FibroTube Cup containing 0.2 ml of FibroPlastin Reagent. The FibroTip should be 1/4 of the way into the cup and resting on the lip closest to the pipette.

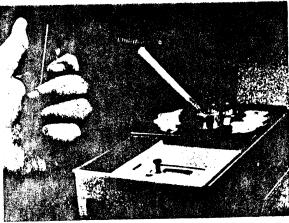


21. With the Pipette switch ON, dispense the 0.1 ml of FibroTrol into the 0.2 ml of FibroPlastin.



NOTE: There will now be a 0.5 to 1.8 second built-in delay. This will in no way invalidate the test results.

22. The probe arm of the Fibrometer will automatically drop. Sweeping action and timing will now begin automatically. The time for the first fibrin strand detection in the FibroTrol plus FibroPlastin reaction mixture should be between ten and thirteen seconds for 100% plasma.



23. Repeat the above test to verify the results. Then test the patient's plasma.

#### **PRECAUTIONS**

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For Laboratory Use.

#### TIP CONTAMINATION

The most common mistake made by the user of any automatic pipette is the failure to replace disposable tips when going from one reagent or concentration to another. In the Prothrombin Time Test, the recommended tip replacement schedule is:

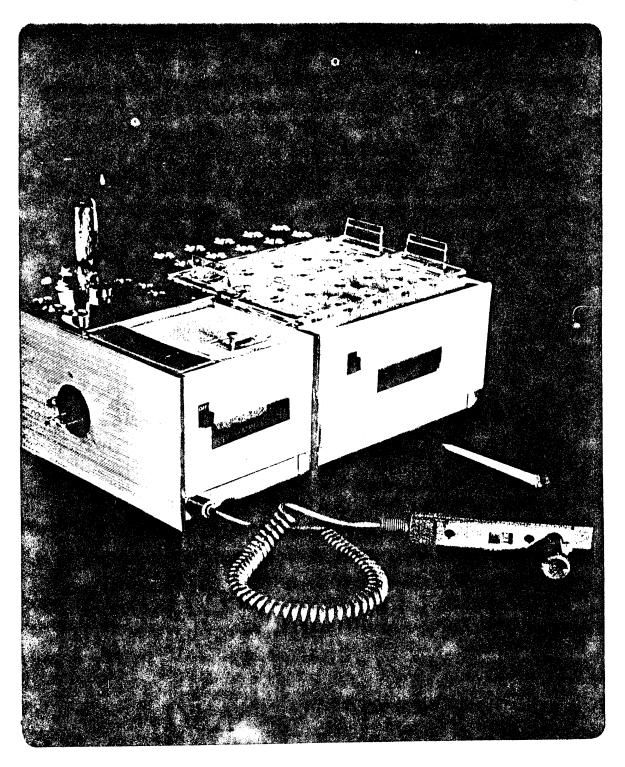
- a) One tip for the FibroTrol
- b) A new tip if patient's plasma is to be tested
- c) A new tip for the FibroPlastin Reagent
- d) A new tip to dispense the FibroTrol aliquot (0.1 ml) into the FibroPlastin

CAUTION: Any tip coming into contact with patient serum, plasma or whole blood is a potential HEPATITIS DANGER. Avoid personal and environmental contamination. Discard all FibroTip Tips with the same care as used for any contaminated pipette.

## ADDITIONAL DESIGN CHARACTERISTICS

- After depressing the plunger to dispense, some liquid will remain in the FibroTip. This
  condition was compensated for during the calibration of the pipette. This liquid DOES
  NOT affect the accuracy of the Automatic Pipette.
- 2. The material being pipetted never contacts with the plunger or barrel assembly. No daily disassembly or cleaning is required. To minimize maintenance problems, the plunger is molded from a chemical resistant plastic, and has a neoprene rubber "O" ring and a stainless steel barrel coupling.
- 3. Once the **Fibrometer** action has been initiated, the Pipette switch can be moved to OFF without affecting the **Fibrometer**. This feature permits additional dispensing of reagents while the **Fibrometer** is in operation.

SECTION FOUR
THE THERMAL PREP BLOCK



#### THE THERMAL PREP BLOCK

**USE** 

An integral component of the FibroSystem® is the Thermal Prep Block.

This precision instrument has been designed for prewarming large numbers of cups and tubes containing reagents and patient specimens for Fibrometer® testing.

#### PRINCIPLES OF OPERATION

The Prep Block provides thirty wells for prewarming. Twenty shallow wells are constructed to hold FibroTube® cups and ten deep wells exist for 12 x 75 mm test tubes. The Prep Block ensures that liquids are prewarmed to the required 37.2 ± 0.5 C before testing. When used as directed, this instrument is an efficient and convenient device for warming large quantities of all liquids to be used in the tests run with the Fibrometer.

The thermal control system of the Prep Block has a very narrow differential. It should never require adjustment. Solid state circuitry maintains the temperature specified in liquids in both the shallow and deep wells as long as the ambient temperature is between 18 and 32 C.

By utilizing the modular concept, a single operator can significantly increase ease of operation and work output. The following set-up is suggested:

- 1. Begin with two Fibrometer Timers and one Thermal Prep Block.
- 2. Connect a Fibrometer to each side of the Prep Block.
- 3. The removable plastic trays of the Prep Block can be pre-filled with reagents and refrigerated.
- 4. The instruments can be brought to operating temperature and the trays of reagents can be placed over the shallow wells.
- 5. The reagents can be brought to the testing temperature in five minutes. During this time, additional trays can be readied and refrigerated.
- 6. Continuous testing and reagent warm-up can now begin with no risk of deterioration due to prolonged heating of reagents.

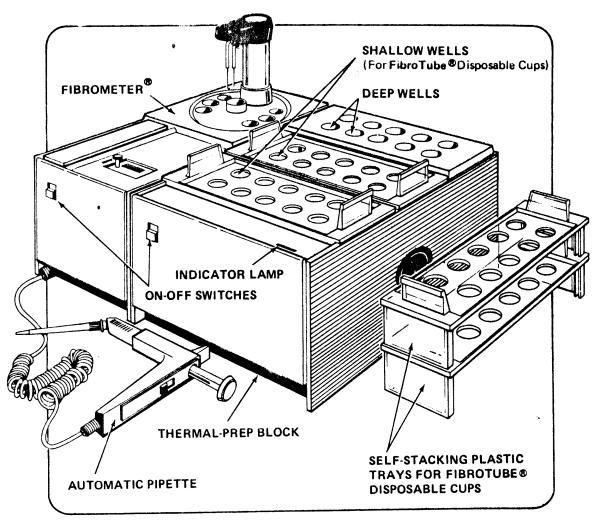


Figure 4-1 The Complete System

#### THERMAL PREP BLOCK

### **Performance Characteristics and Specifications**

Temperature Range

37.2 ± 0.5 C

**Volumes** 

Up to 0.5 ml in FibroTube ® Cups in twenty shallow

wells

Up to 3.0 ml in 12 x 75 mm test tubes in ten deep

wells

**Dimensions and Weights** 

Height - 102 mm (4")

Width - 159 mm (6.25") Length - 184 mm (7.25") Net Weight - 2.9 kg (6.45 lb) Shipping Weight - 4 kg (9.0 lb)

Block Warm-Up Time

Approximately fifteen minutes

Liquid Warm-Up Time

Refrigerated liquids: five minutes

Room temperature liquids: three minutes

**Electrical Specifications** 

117 volts, 50 or 60 Hz, 0.6 ampere

#### COMPONENT PART PRINCIPLES OF OPERATION

#### Heating System

A heating circuit, regulated by a precise mercury thermostat, holds the warming block at  $37.2 \pm 0.5$  C.

#### Heating Block

An epoxy coated, durable aluminum block provides precision heat transmission to liquids anywhere in the block.

#### Indicator Lamp

When the unit is plugged in and the switch is in the ON position, the neon indicator light will come on immediately. The indicator light will remain on to indicate the heating circuit is functioning. When the warming block reaches a temperature of  $37.2 \pm 0.5$  C, the thermostat will switch out and the light will go off. When the thermostat calls for heat, the indicator light will come back on.

NOTE: The action of the Thermal Prep Block indicator lamp is not the same as the Fibrometer indicator lamp. In the Fibrometer, the indicator lamp is designed to glow when liquids reach the required temperature. Remember:

- 1. Fibrometer machine ON, light ON, liquids ready for use
- 2. Thermal Prep Block machine ON, light OFF, liquids ready for use

#### **Power Supply**

The Thermal Prep Block may be operated independently by attaching the unit by a three-wire line cord (not supplied) to any approved 110-volt, three-wire grounded receptacle.

Most users connect the Thermal Prep Block directly to the **Fibrometer**. Both of these machines have been designed to operate in a modular arrangement. A single power source will operate both machines. The second machine in line will receive power even when the first machine is switched off.

#### Safety

The Thermal Prep Block is certified for safety by the Los Angeles County Testing Laboratories and is listed by the Canadian Standards Association (CSA).

DO NOT separate or connect the Thermal Prep Block to the **Fibrometer** while the line cord is connected to the power receptacle. A Shock Hazard exists when doing so.

#### INSTALLATION

#### **Equipment Model and Power Rating**

BBL Catalog No. 60419 Thermal Prep Block 117 volts, 50 or 60 Hz, 0.6 amps.

#### **Laboratory Requirements**

The Thermal Prep Block operates on a standard 117 volt A.C. power source which must meet the National Electrical Manufactures Association standard of 99.5 to 128.7 volts. The outlet must be a standard laboratory three-wire grounded receptacle (wall or through the Fibrometer). Other power sources or outlets may damage the machine. The working environment should be as clean and dust-free as possible, with an ambient temperature between 18 and 32 C (64.4 to 89.6 F).

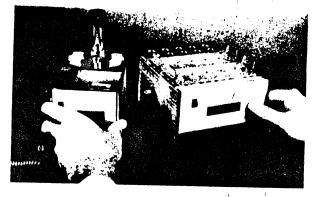
#### **Procedures**

The following procedure is designed to allow you to test your new Thermal Prep Block. It is assumed that the Fibrometer and Automatic Pipette have been tested independently. If any problems occur as you test your new Thermal Prep Block, please call the BBL Hot Line, toll-free: (800) 638-8663; in Maryland call (301) 666-0100 collect.

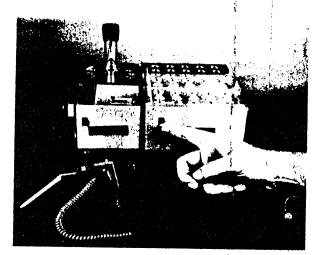
- 1. Begin by placing the Thermal Prep Block box with the words, "OPEN THIS END" in the UP position. Lift out the machine and visually inspect all items for shipping damage.
- 2. Price the machine on a level bench top, which is free from vibrations. If the Prep Block is to be used as a part of a modular system, be sure to leave room for additional pieces of equipment.

3. To utilize the modular plug-in design, set the Prep Block to the right of the Fibrometer. Carefully connect the three-pronged outlet on the right side of the Fibrometer to the receptacle on the left side of the Prep Block.

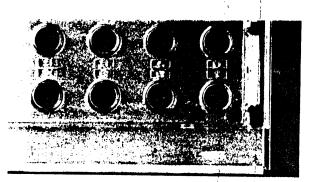
WARNING: DO NOT twist these outlets.



4. Plug in the line cord from the Fibrometer and put the power switch of the Prep Block into the ON position.



5. Wait approximately fifteen minutes for the machine to reach operating temperature. The indicator light will be ON while the machine is warming. At operating temperature, the light will be OFF.



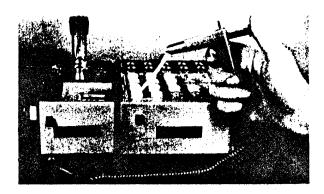
- 6. The Prothrombin Time Test can now be run to test the performance of the Thermal Prep Block.
- A. Check that both instruments are at operating temperature.
  - B. Place four FibroTube cups into one of the removable plastic trays.

    Label one cup FibroTrol® and the remaining three cups

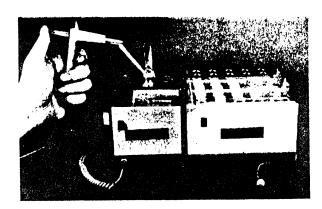
    "Reagent". Place the tray into the well of the Prep Block.



C. Utilizing standard operating procedures with the Automatic Pipette, fill one cup with 0.3 ml FibroTrol and the remaining cups with 0.2 ml FibroPlastin® Reagent.



- D. Wait three minutes for room temperature liquids to arrive at the testing temperature. Allow refrigerated liquids five minutes.
- E. Place one cup with 0.2 ml of FibroPlastin into the center (reaction) well of the Fibrometer. With the Pipette switch ON, deliver 0.1 ml of FibroTrol into the cup.



- F. After the built-in delay, the probe arm of the **Fibrometer** will fall and the sweeping and timing actions will begin. The time for the first fibrin strand detection should be between eleven and thirteen seconds.
- G. Repeat the above procedures to verify the results.

You are ready to begin routine use of the Thermal Prep Block. There are NO temperature settings or day-to-day calibrations necessary with this or any other FibroSystem instrument.

# **OPERATING HINTS**

- 1. Ten FibroTube cups may be placed in one removable plastic tray. Two trays are designed to fit snugly across the shallow wells of the Prep Block. In this position, the cups rest on the spherical bottoms of the wells, just as they would without the trays. The trays do not affect the temperature of the cup and its contents.
- 2. Placing cold liquids in wells adjacent to wells with liquids at 37.2 C does not disturb the thermal equilibrium of the heated liquids.
- 3. Reagents for the next day can be prepared and stored overnight. A box of ten trays (BBL Catalog No. 70313) may be purchased. The required number of cups can be placed in the trays, 0.2 ml of reagent added to each cup, and the readied trays stored overnight at 4 C. The trays are made to be stacked to use less storage space.

### MAINTENANCE

# **PRECAUTIONS**

For Laboratory Use.

The Thermal Prep Block is easy to keep clean. Wipe the metal surfaces and wells with a damp cloth. Be sure to take all necessary precautions to avoid hepatitis dangers when working with human serum, plasma or whole blood. The wells should be wiped periodically.

There are no temperature controls or adjustments of any kind in or on the Prep Block. The heating circuit is extremely stable. If there is a bad component in this circuit, the block will become too hot to hold or will be well below 37 C.

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# **SECTION FIVE**

	STANDARD OPERATING PROCEDURE: PROTHROMBIN TIME TEST
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# PROTHROMBIN TIME TEST

This section contains a step-by-step procedure to test the FibroSystem® equipment in the Prothrombin Time Test. It is recommended that beginning personnel and new users of the Fibro-System work their way through Sections One through Four to independently test equipment and learn procedures.

- 1. Connect one Fibrometer® and one Thermal Prep Block in modular sequence. Place the Fibrometer to the left of the Prep Block. Carefully connect the three-pronged receptacle on the right side of the Fibrometer to the plug on the left side of the Prep Block.
- 2. Connect the line cord to the three-pronged plug on the left side of the Fibrometer. Be certain to match the alignment dots found on both the line cord and the Fibrometer plug.
- 3. Plug the line cord into a standard laboratory grounded three-wire outlet.
- 4. Switch ON the Fibrometer and the Prep Block. Both machines should be at operating temperature in approximately fifteen minutes.
- 5. Lift the Fibrometer probe arm to the UP position.
- 6. Plug the Automatic Pipette cord into the lower left front receptacle of the **Fibrometer**. Leave the Pipette switch in the OFF position.
- 7. Prepare the FibroTrol® test solution. You will need 0.1 ml for each test. Assume that you will run TWO tests. Using the Automatic Pipette, take up 0.2 ml of FibroTrol and dispense into a FibroTube® Cup labeled "Control".\*
- 8. Place this cup into a plastic rack and set over one of the shallow wells in the Prep Block.

  Do this after the Prep Block has reached operating temperature.
- 9. You will need 0.2 ml of FibroPlastin® per test. Assume you are running TWO tests. Using the Automatic Pipette, take up and dispense 0.2 ml of FibroPlastin into one cup labled "Reagent". Repeat this procedure a second time for the second "Reagent" cup.

NOTE: A new FibroTip<sup>TM</sup> should be used for the FibroPlastin. DO NOT use the same tip for FibroTrol and FibroPlastin.

- 10. Place both "Reagent" cups into the rack over a shallow well in the Prep Brock.
- 11. It will take three minutes for room temperature liquids to reach the test temperature (37.2 ± 0.5 C). Allow refrigerated liquids five minutes.
- 12. Once the liquids are at operating temperature, place one "Reagent" cup into the center (reaction) well of the Fibrometer.
- 13. Be certain to replace the **FibroTip** in the Automatic Pipette. Switch the pipette into the 0.1 ml delivery mode. Do this by turning the plunger until the single notch aligns with the indicator mark.
- 14. Take up 0.1 ml of prewarmed FibroTrol with the Automatic Pipette.
- 15. Switch the Automatic Pipette to the ON position.

<sup>\*</sup> It is suggested that you add an additional 0.1 ml of FibroTrol to the control cup to give a total volume of 0.3 ml. This will avoid pipetting the cup dry on the second run.

- 16. Dispense 0.1 ml of FibroTrol into the "Reagent" cup now sitting in the Fibrometer reaction well.
- NOTE: There will be a Built-in 0.5 to 1.8 second delay. This will allow you to remove the FibroTip from the FibroTube cup. This delay does not change the test results.
  - 17. The probe arm of the Fibrometer will drop automatically and begin the sweeping and timing actions.
  - 18. First fibrin strand detection should occur between eleven and thirteen seconds. The Fibrometer will stop timing and electrode activity automatically.
  - 19. Record the time and reset the timer by depressing the red "reset" button for at least one full second; then, lift and clean the probe arm.
  - 20. Replace the FibroTip and discard the FibroTube Cup from the reaction well of the Fibrometer.
  - 21. Repeat the above procedures, Steps 11-20, to verify the results.

WARNING: Be certain to carefully dispose of all tips and cups that contact patient serum, plasma or whole blood. There is a HEPATITIS DANGER when working with these specimens.

NOTE: Be certain to change the FibroTip for each change of liquid or concentration being pipetted. For example, DO NOT use the same tip for both FibroTrol and FibroPlastin.

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PREVENTIVE MAINTENANCE PROCEDURE FOR 60420 & 60422
AUTOMATIC PIPETTES

helpful hints

# **HELPFUL HINTS**

The procedure outlined in this section is designed to prevent tip fall out and leakage when using the BBL® Catalog No. 60420 Automatic Electric Pipette or BBL Catalog No. 60422 Nonelectric Pipette.

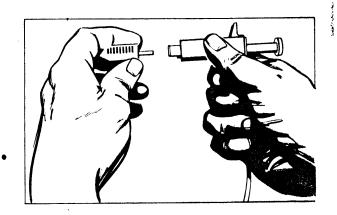
The twisting motion of inserting the disposable plastic pipette tip into the barrel of the pipette may leave bits of plastic adhering to the side walls of the hole in which the tip is inserted. This prevents the tip from seating properly and may result in tip fallout.

Cleaning the "O" ring and cannula is required to prevent deformation of the soft "O" ring as it rides over dirt particles. Deformed, worn or damaged "O" rings may permit air to enter and result in leakage of material from the tip.

BBL Catalog No. 70312 FibroTube® Disposable Plastic Coagulation Cups are specifically recommended for use with the Fibrometer® and Automatic Pipettes because they are designed to provide precisely the liquid level height required by the Fibrometer for accurate operation.

The BBL Catalog No. 70314 FibroTip™ is precisely engineered and rigidly quality controlled for a leakproof fit in the 60420 and the 60422 pipettes.

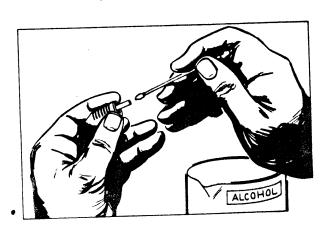
1. Hold the pipette as one would when dispensing. With the other hand, grasp the metal barrel and pull it straight off the pipette.



2. Take the metal barrel to another bench away from the plastic parts. Place a small quantity of acetone on a swab and vigorously scrape around in the hole where the tip is placed. This will clean out the plastic bits which have accumulated from normal usage.



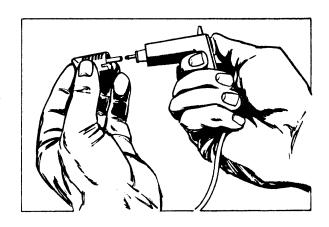
3. Use a fresh swab moistened with alcohol and swab out the center hole in the metal barrel. Use a small swab and keep cleaning until the swab comes away clean. Rinse the barrel and cannula with distilled water to wash out any particles that remain. Dry thoroughly.



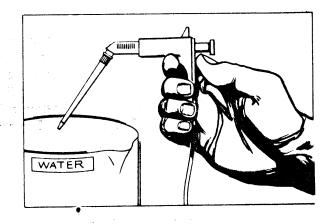
4. Turn the plunger of the pipette to the 0.2 ml setting and depress the plunger fully. This will expose the "O" ring. With a lintless tissue moistened with alcohol, clean the area around the "O" ring and the "O" ring itself. When clean, visually examine the "O" ring for slits, flat spots and other signs of wear. If there is damage, replace the "O" ring or request a replacement from BBL.



5. Place a small amount of silicone grease or petroleum jelly around the "O" ring. With the pipette plunger still depressed, slide the piston and "O" ring into the tube of the metal barrel. Align the barrel so that the notch on the perimeter matches the projection on the pipette. Snap the barrel in place.



6. Work the plunger up and down to lubricate the tube. Take a tip, insert it in the pipette and pick up 0.2 ml of water. Hold the pipette steady for one minute without touching the plunger, watching the end of the tip to see that no drop forms, Repeat on the 0.1 ml setting.



# **SECTION SEVEN**

USE OF FIBROTUBE® DISPOSABLE PLASTIC COAGULATION CUPS WITH THE FIBROMETER® PRECISION COAGULATION TIMER

# helpful hints

# HELPFUL HINTS

The FibroTube Cup is an integral part of the Fibrometer because it precisely and consistently presents the sample to the Fibrometer probe. The FibroTube disposable plastic cup is protected under U.S. Patent #3,219.421. The Patent was granted, based on the dimensions of the FibroTube cup, which enables the cup to perform its precise function in the Fibrometer.

The internal diameter (I.D.) of the FibroTube cup fixes the liquid level at a precise height when a total volume of 0.3 ml is placed within the cup. The spherical radius of the bottom of the FibroTube cup exactly matches the spherical radius of the tube well of the Fibrometer. This fact, in concert with the uniform wall thickness of the FibroTube cup, provides excellent heat transfer from the heating block to the liquid within the cup.

Figure 7-1, shows a cutaway view of the heat block, probe assembly, and associated clot detection apparatus. In this figure, a clot has been detected and the Fibrometer has stopped.

The moving electrode has mechanically caught a fibrin strand during its sweep through the material in the cup and then lifted to a point 1.27 mm above the level of the liquid in the cup.

At this time and only at this time the moving electrode is electrically active.

The probe or electrode foot is contacting the cam carrying the signal that a clot is present, to the cam, cam finger, and detection circuit.

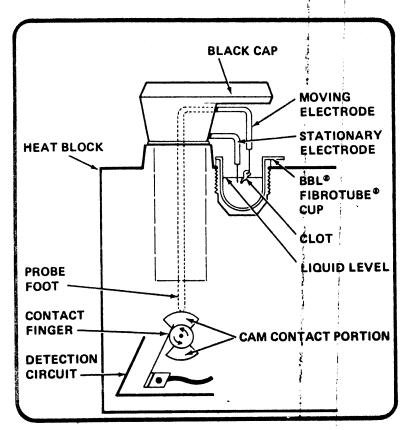


Figure 7-1

In Figure 7-2, the moving electrode is mechanically searching for a fibrin strand. The elliptical path taken by the movable electrode is directed and controlled by the groove in the black cap where the upper portion of the electrode is captivated.

The probe foot is resting on the insulated portion of the cam. The moving electrode is now electrically inactive and cannot conduct. As the cam continues to rotate, the moving electrode is lifted by the contact portion of the cam and the configuration returns to that of Figure 7-1.

NOTE: The moving electrode is alternately in the up or down position every half second, stopping Fibrometer only where there is a clot to complete the circuit.

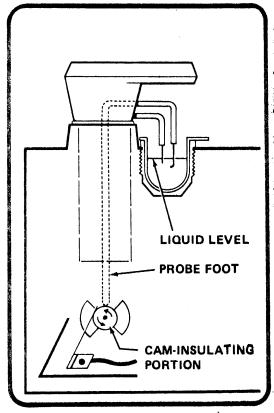


Figure 7-2

Important: If 0.3 ml total volume is placed within a competitive cup whose internal diameter is slightly smaller than the internal diameter of the BBL® FibroTube® cup, the liquid may rise to a higher level and bridge the 1.27 mm gap, thereby closing the circuit causing the Fibrometer to stop almost as soon as the probe electrodes drop into the cup (Figure 7-3). Conversely, if a 0.3 ml total volume is placed within a competitive cup whose internal diameter is slightly larger than the BBL® FibroTube® cup, then the liquid level will be considerably below the level obtained in the BBL® FibroTube® cup. With such a low liquid level, it is possible for the moving electrode to lift the clot above the liquid in the cup breaking the circuit; the Fibrometer will not stop (Figure 7-3). Both of these problems are best rectified by use of BBL® FibroTube® cups.

The problem of short times or a "no detect" condition can also be caused by maladjusted electrodes. Short times can be caused by the moving electrode being lengthened by the cleaning procedure over a period of time. The normal cleaning procedure after each test is to raise the probe to the rest position and wipe the electrodes down with the lintless tissue. Depending upon the length of the time in service and the degree of "squeeze" exerted upon the electrode, it is possible to lengthen the moving electrode by 0.64 or 1.30 mm. This condition can be corrected by holding the probe in your left hand with the black cap toward the ceiling and the electrodes facing your right. At the very bottom of the cylindrical body, you will notice a single heavy wire which comes out straight 6.35 mm then curves; this is the probe foot. Grasp the probe foot with your right hand and pull down with a steady force. While you are pulling down, watch the hook end of the moving electrode. You should see it move slightly forward

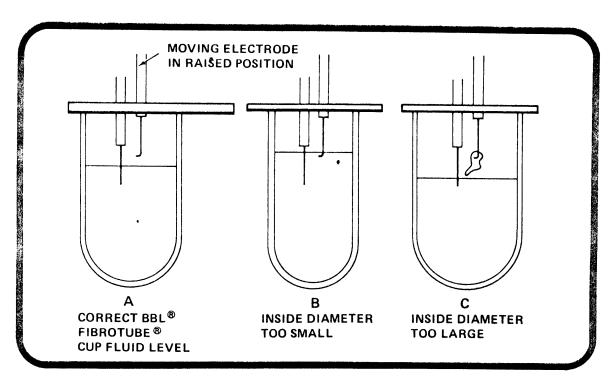


Figure 7-3

and up. This shortens the electrode by 1.30 or 1.93 mm. Test the adjustment by placing 0.3 ml of reagent only in a FibroTube cup in the center well of the Fibrometer. Place the probe in the Fibrometer and press the timer bar so that the probe will drop into the reagent. It should continue to run. In the event that the unit again stops prematurely, the procedure can be repeated one more time. If the problem cannot be resolved, call the BBL Technical Services toll-free Hot Line at (800) 638-8663; in Maryland call (301) 666-0100, collect.

A "no detect" condition can be caused by the accidental bending of the moving electrode away from the stationary electrode. This <u>shortens</u> the electrode causing the "no detect" condition.

If the thin wire section is bent it may be straightened with a pair of forceps. If the thin wire section is straight but the tubing is bent, it can usually be corrected by placing your thumbs against the tubing at the black cap and pressing the tubing against the cap.

Another factor that can cause a "no detect" condition is that the automatic pipette is dirty and not delivering full volume. Cleaning the pipette as described in Section Six, will restore the volumetric accuracy.

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# **SECTION EIGHT** TROUBLE - SHOOTING AND REPAIR

# TROUBLE - SHOOTING AND REPAIR

This Section includes the following:

- 1. Flowcharts for trouble-shooting the Fibrometer®
- 2. Additional problems with the Fibrometer
- 3. Trouble-shooting charts for the Thermal Prep Block
- 4. Trouble-shooting charts for the Automatic Pipette
- 5. Repair procedures for the FibroSystem®

In the past, we have found the following types of individuals doing trouble-shooting and repair:

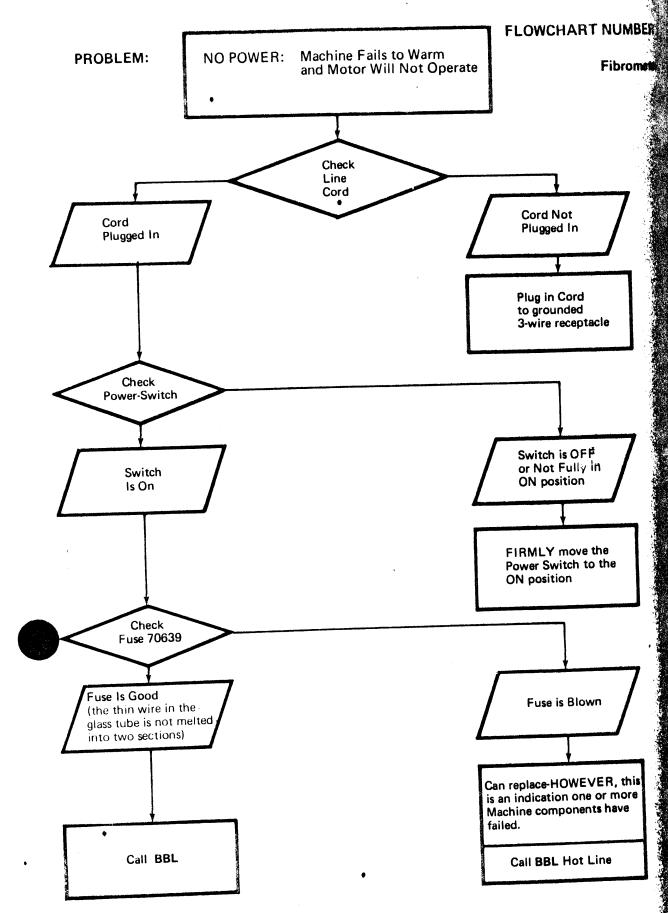
- 1. The technician without any experience beyond operating laboratory equipment. If you fall into this category, DO NOT attempt internal repairs. When working with the Flowcharts, STOP at the large black dot and seek experienced help from the repair technician where you work or through the BBL Hot Line.
- 2. The technician with training to make minor repairs. If you fall into this category, you must be the judge of the level of training you have acquired. Obviously, complex circuit work, thermostat electrical evaluation etc., are more work of the specialist. Whenever you are not sure, consult with the repair technician where you work, or call the BBL Hot Line.
- 3. The trained repair technician. Most repairs on FibroSystem equipment are within the range of activities performed by trained repair personnel. Should there be any questions, call the BBL Hot Line. Our technicians and engineers will be happy to assist you.

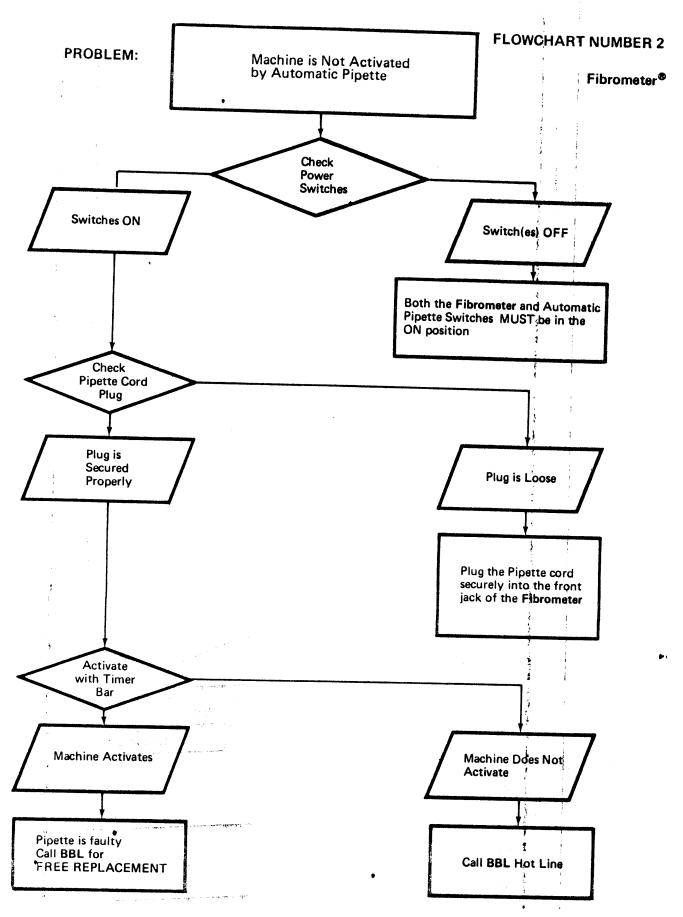
Please note that a wiring diagram and mechanical diagram have been included in this manual. A complete parts list has also been provided.

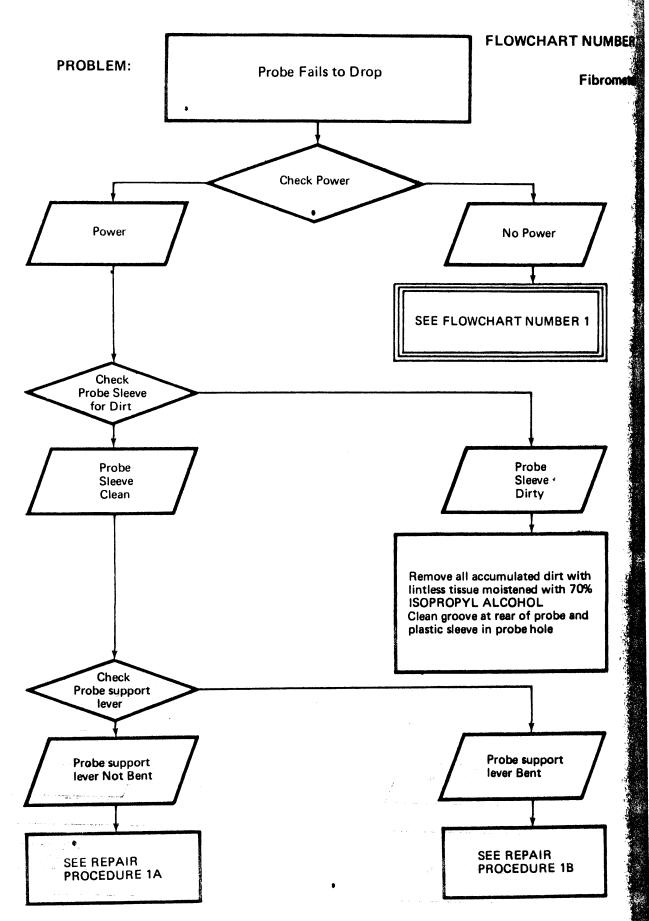
NOTE: BEFORE STARTING ANY REPAIRS, CHECK YOUR WARRANTY.

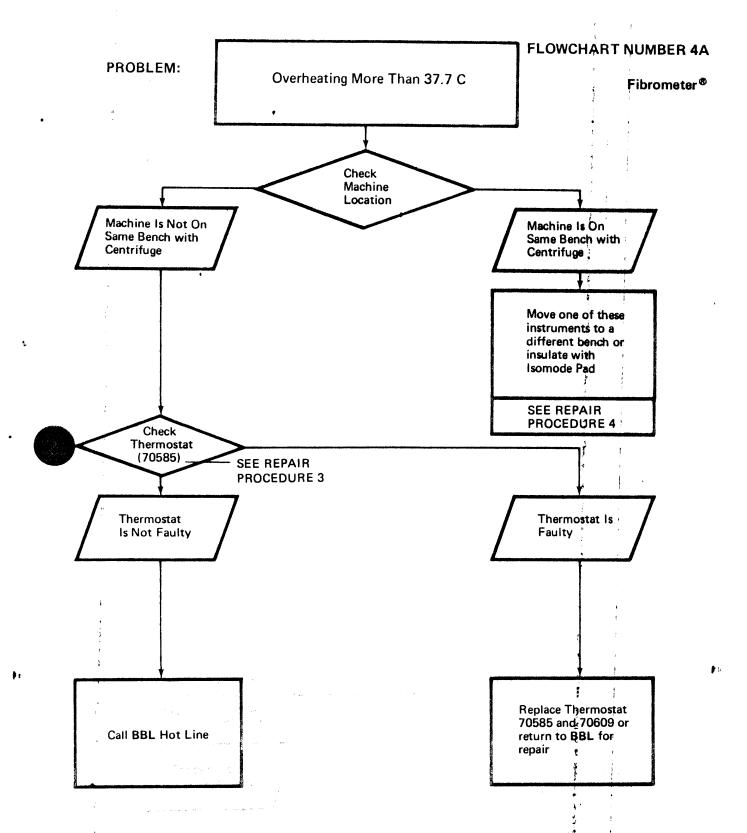
OBSERVE ELECTRICAL SAFETY — UNPLUG THE POWER CORD BEFORE STARTING ANY REPAIRS.

ALSO, WIPE THE MACHINE TO REMOVE ANY PLASMA RESIDUE - A HEPATITIS DANGER EXISTS.

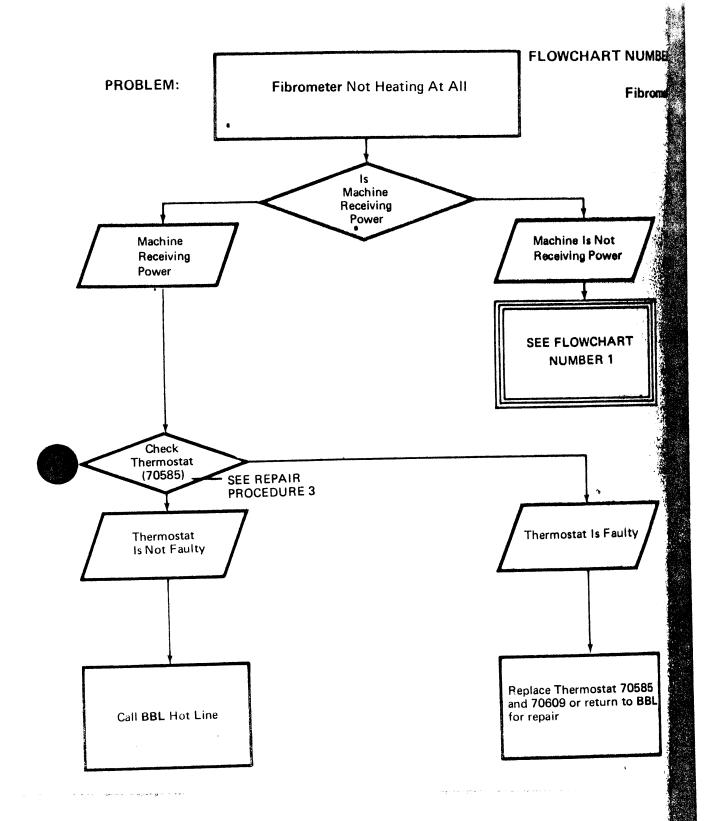




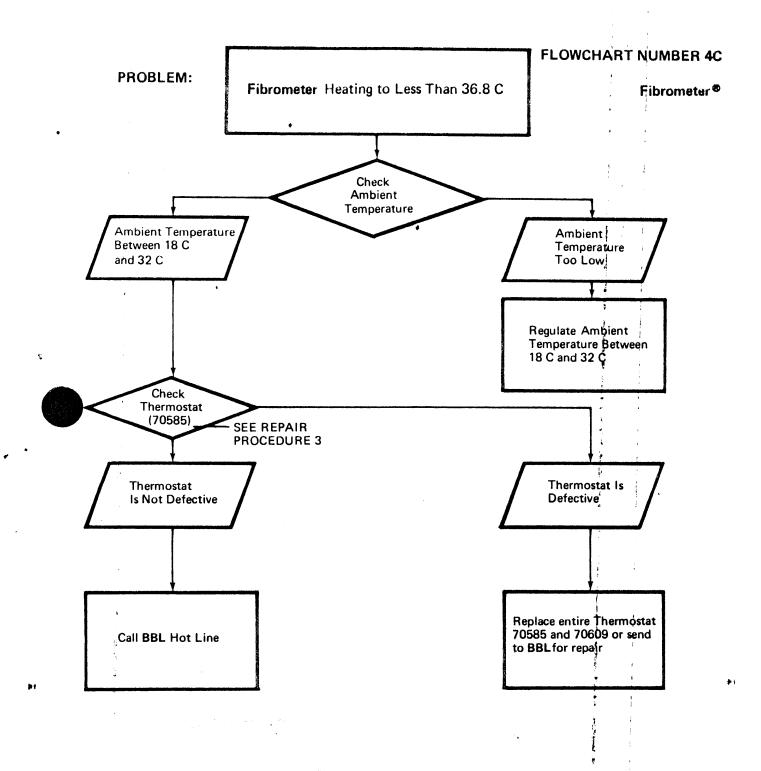


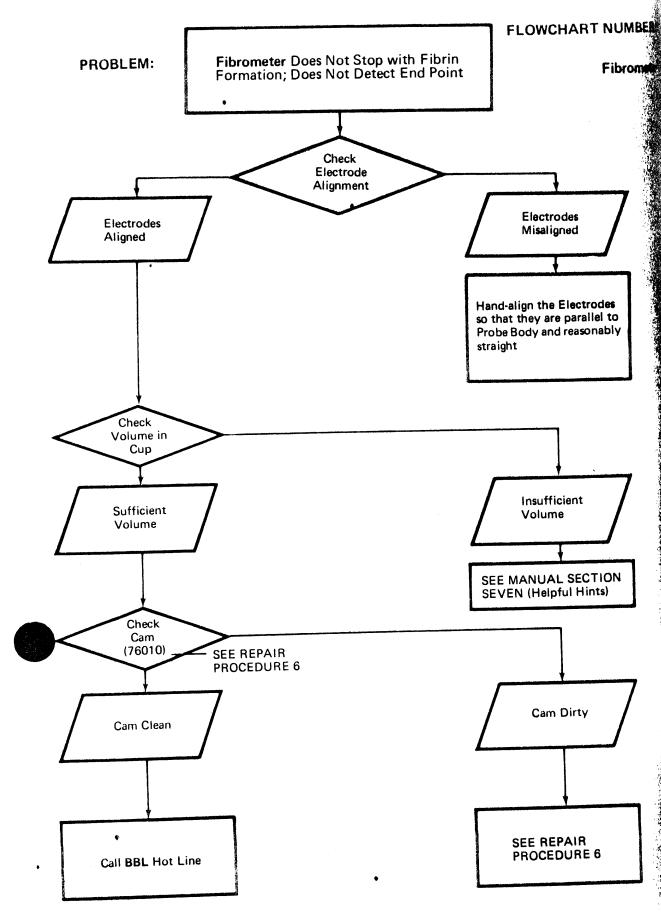


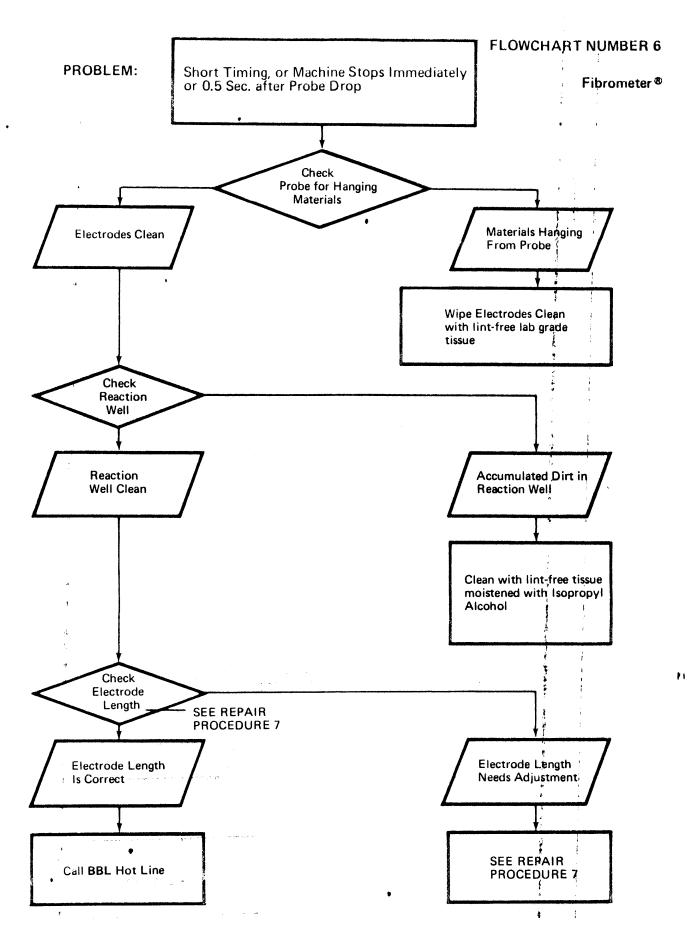
NOTE: If the heating system is faulty the warming block will usually be too hot to touch or will be below 37C. There is little chance of a Prep Block being only one or two degrees off the desired range.



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# **TROUBLE - SHOOTING:**

# FIBROMETER®, ADDITIONAL PROBLEMS

Listed below are problems that may occur with the **Fibrometer**, but have not been covered in the flowcharts.

PROBLEM		
1.	Probe will not remain in the UP Position.	

**Probable Cause:** Bent probe support lever.

2. Erratic End Points

Probable Cause: This condition is rare and is usually a technique, reagent or line voltage problem.

- 3. Sticky Timer or Digit Repetition
- 4. Machine works on Prothrombin Times but does not pick up clot on PTT's.

# **SOLUTION**

- 1. See Repair Procedure #1
- 2a. Any inconsistency in test procedures or reagents will cause erratic timing. See Section II.
- 2b. If the problem is low line voltage, check the Installation Requirements, Section II. In addition, have an electrician periodically check line voltage.
- 3. See Repair Procedures #10 and #11
- 4. See Flowchart #5

TROUBLE - SHOOTING
THERMAL PREP BLOCK

# PROBLEM

1. Machine will not heat

# **Probable Causes:**

- A. Machine not switched ON.
- B. Faulty power connection.
- 2. Erroneous Temperature

# SOLUTION

- 1a. Firmly move the power switch ON.
- 1b. This problem may occur when the Prep Block is connected to the Fibra meter. See Repair Procedure #12.
- 2. The heating element and system of the Prep Block is almost identical to the Fibrometer. See Flowcharts #4A to 4C. Also see Repair Procedure #3.

# TROUBLE - SHOOTING AUTOMATIC PIPETTE

Many of the problems with the Automatic Pipette can be solved by reading Section VI: Helpful Hints.

PROBLEM	SOLUTION		:
<ol> <li>Fibrometer is not activated by the Automatic Pipette.</li> </ol>	1. See Flowchart #2.		1
2. Plunger binds or will not depress fully.			į
Probable Causes:		ž Š	1
A. Dirty cannula B. Worn "O" Ring	2a. See Section VI 2b. See Section VI	} 	1 1 1
3. Leakage of liquid from tip.		÷,	,
Probable Causes:		ļ I	!
A. Worn or defective "O" Ring.	3a. See Section VI		
B. Improper seated or defective tip.	3b. Firmly secure the tip in Check the FibroTip <sup>TM</sup> flaws.	•	
4. Inaccurate delivery		•	į
Probable Causes:		: \ *	,
A. Improper techique B. Defective "O" Ring	4a. See pipetting directions in Section II 4b. See Section VI		

NOTE: READ WARRANTY BEFORE BEGINNING ANY REPAIRS

ONLY TRAINED PERSONNEL SHOULD ATTEMPT INTERNAL REPAIRS

**WARNING: OBSERVE ELECTRICAL SAFETY GUIDELINES** 

# Fibrometer® and Thermal Prep Block

- 1. Probe fails to drop or it will not remain in the UP position.
  - A. Check to see if the machine has a faulty time delay circuit or solenoid.
    - 1) Remove the probe.
    - 2) Activate the machine.
    - 3) Watch for the probe support lever (brass lever on the right hand side of the probe hole) to snap inside the sleeve, out of sight.
    - 4) If the lever does not retract, the machine has a bad time delay circuit or solenoid. Factory repair will be done by BBL. If desired, a faulty solenoid may be replaced with a new solenoid assembly (BBL Catalog Number 76007). The time delay capacitor, if found defective, may be replaced (BBL Catalog Number 70615).
  - B. If the lever does retract, and the probe sleeve has been checked for dirt accumulation, the lever must be out of alignment. The lever arm should extend approximately 1.6 mm into the probe hole beyond the sleeve. If it extends more than 1.6 mm:
    - 1) Use a 6.4 mm blade screwdriver to press the lever back into the cavity. Press until a stop is felt.
    - 2) Carefully apply 2.3 to 4.5 Kg. of pressure to force a slight bend in the lever. The lever is malleable bronze and may easily be bent back if the desired point is overshot.
    - 3) Check the extension. Repeat procedure until the desired 1.6 mm is achieved.
    - 4) If the lever extends less than 1.6 mm, put the screwdriver behind the lever and carefully apply outward pressure until the desired extension is reached.
  - C. The probe will not remain in the UP position if the lever extends less than 1.6 mm beyond the sleeve. (See Step 4 above).
- 2. Measuring the Heat Block Temperature Fibrometer
  - A. Method I:
    - 1) Pipette 0.5 ml of water into a FibroTube <sup>®</sup> Cup and place the FibroTube Cup into the reaction well of the Fibrometer.
    - 2) Allow at least ten minutes for temperature stabilization.
    - 3) Use a #30 copper constant thermocouple and potentiometer type millivoltmeter (preferably one calibrated in C and having a compensated reference junction). Wind a small coil (6.4 mm long) of the thermocouple wire near the hot junction on a 3.2 mm mandrel and insert into the FibroTube Cup.
    - 4) Allow five minutes for stabilization, then read the temperature.
  - B. thod II
    - 1) Pipette 0.5 ml of water into a FibroTube Cup and place the cup into the reaction well.

- 2) Place a small mercury thermometer in the cup (preferably a rectal thermometer for babies).
- 3) Allow five minutes for stabilization, then read the temperature. The reading should be  $98.6 \pm 1.8 \text{ F}$  (37.2  $\pm 0.5 \text{ C}$ ).
- NOTE: A thermistor type thermometer or a large glass thermometer cannot be used. They will conduct heat too rapidly from the small mass of liquid and yield a false low reading.
  - C. A faulty thermostat can be replaced by BBL, or you may order a new thermostat (BBL Catalog Number 70585) and the required phenolic sleeve (BBL Catalog Number 70609).
- 3. Measuring the Heat Block temperature Thermal Prep Block

Follow the steps in Procedure #2. Use a shallow well of the Prep Block (Note: The center well in the second row of deep wells will be slightly warmer than the others).

If you wish to order a new thermostat for the Prep Block, order BBL Catalog Number 76018. If the thermostat is not faulty and tests show a new heat pad is needed, order BBL Catalog Number 76015.

- 4. Extreme overheating Fibrometer or Prep Block
  - A. Make sure these instruments are not on the same bench with a centrifuge. If this is not possible, insert TWO layers of Isomode pad (available from most scientific supply houses) under the FibroSystem® instruments. Let the machines cool to room temperature and attempt operation the next day.
  - B. Check thermostats as described in Procedure #2 (Fibrometer) or Procedure #3 (Prep Block).
- 5. The Fibrometer does not stop after a clot has formed (does not detect an end point).
  - A. Dispense 0.5 ml of reagent into a FibroTube Cup and place the cup into the reaction well.
  - B. Start the Fibrometer and allow the probe to drop.
  - C. Due to the excess of liquid in the FibroTube Cup, the Fibrometer should stop immediately or within 0.5 second after the probe has dropped.
  - D. Check the electrodes for misalignment. They should be parallel to the body and reasonably straight. Hand alignment is all that should be necessary.
  - E. If, in step C, the Fibrometer does not stop, check the cam for dirt accumulation and check for dirty electrodes.
    - 1) Clean electrodes with distilled water. Dry with lintless paper.
    - 2) To clean the cam, see Procedure #6 below.
- 6. Cleaning the Fibrometer Cam Assembly
  - A. Remove probe.

1

- B. Moisten a well-compacted swab with 70% isopropyl alcohol and lower the swab through the probe hole until it rests on the top cam.
- C. Activate the Fibrometer and allow the cam to rotate. Move the swab back and forth to clean the solid portion of the cam. Repeat with fresh swabs moistened with alcohol until all dirt is removed. Test with a Prothrombin Time Test.

- D. If the cam is found to be defective, send the Fibrometer to BBL for factory repair, or replace with BBL Catalog Number 76010, Cam Assembly.
- E. If step C fails and the cam appears satisfactory in its operations, call the BBL Hot Line (800) 638-8663; in Maryland call (301) 666-0100 collect.

# 7. Electrode Length Adjustments

A. Adjustments for short times: Fibrometer stops 0.5 to 3.0 seconds after the probe drops.

NOTE: Before making any adjustments, test with an empty FibroTube Cup. If the machine runs, put 0.2 ml of reagent in the cup and test (use only the 0.2 ml of reagent). If the Fibrometer runs, proceed with adjustments. If it does not run on either of the above tests, call BBL.

- 1) 'Remove the Probe assembly and hold it in your left hand so that the black cap is pointing upwards. See Figure 8-1.
- 2) With your right hand, grab the probe foot (the heavy wire extending down from the base of the probe) and pull down with 0.9 to 1.4 Kg. of pull.
- 3) Watch the hook end of the moving electrode as you pull down on the probe foot. The moving electrode will now be shortened by your pulling action. This should solve most short timing problems.
- 4) Check electrode lengths by TWO methods:
  - a) Replace the probe. Dispense 0.3 ml of reagent only into a FibroTube Cup. Place a cup into the reaction well. With the Fibrometer switch in the ON position, depress the Timer bar to activate the machine. If the probe does not drop and the detection and timing mechanisms do not begin to function, repeat steps 1 and 2. If this does not correct the problem, call BBL, Hot Line (800) 638-8663.
  - b) Perform a final check by running a normal control and an abnormal control to be sure the correct end points are detected.

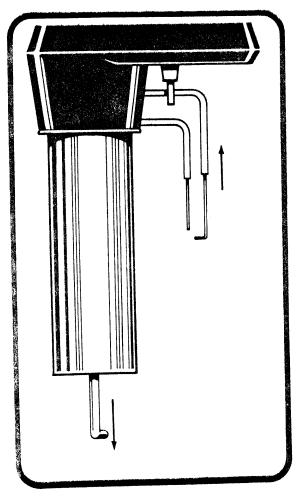


Figure 8-1

- B. Adjustments for no end point or for considerably longer than correct end point.
  - To lengthen the electrode, remove the probe and hold it in your left hand with the black cap to the ceiling and the electrodes facing you.
  - Place your right forefinger on top of the right angle formed by the moving electrode. See Figure 8-2.
  - 3) Place your right thumb on the bottom of the probe foot and apply approximately 1.0 Kg. of upward pressure. This should lengthen the moving electrode.
  - 4) Test the electrode length by allowing the probe to drop into 0.3 ml reagent only. If the machine stops, perform the shortening procedure outlined above. Perform a normal and an abnormal control to be sure that the correct end points are detected. If the problem continues, call the BBL Hot Line.

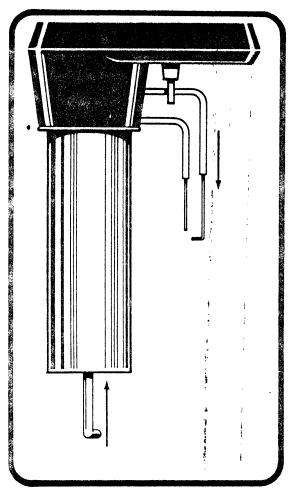


Figure 8-2

- 8. Correct Protimes, will not detect PTT's. See Procedure #5.
- Long PTT and Long PT.
   Problem is a dirty cam. See Procedure #6.
- 10. Digit Repetition

On occasion, a machine will develop a constant display of one of a pair of digits separated by 0.5 second (0.2 and 0.7, 0.3 and 0.8 or 0.4 and 0.9). Even though this state of constant display does not cause results to go beyond the stated accuracy of the machine, many users find this condition to be undesirable. The problem must be corrected at the factory. It should be noted that the length of time a corrected counter will remain operative is unpredictable. For more detail, call Technical Services at BBL.

11. Sticky Timer

If your Fibrometer has a sticky timer, call BBL for a loaner. Hold this loaner for several days until you are sure the procedure outlined below has corrected the problem. The prob-

lem is caused most often by a piece of plastic flash from one gear breaking off and wedging into another gear.

- A. Remove the probe and activate the machine.
- B. Allow the machine to run for two hours. Punch the reset button every fifteen to twenty minutes during this running time. This may cause the bit of plastic that is causing the jamming to drop out.
- C. If this fails, or is only temporary, call the BBL Hot Line.
- D. If your own inspections and tests show that a new counter is required, order BBL Catal Number 70624 and the required hardware noted in the parts list.
- 12. Faulty power connection Fibrometer and Prep Block (Modular).

If the Thermal Prep Block will not heat and the switch is in the ON position:

A. Remove the Fibrometer line cord from the wall receptacle.

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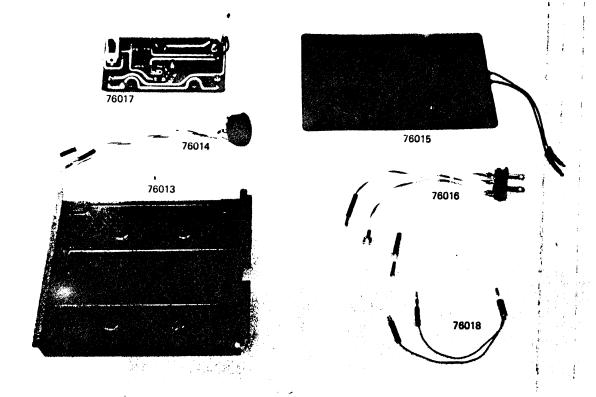
- B. Separate the Prep Block from the Fibrometer.
- C. Plug the female line cord plug directly into the Prep Block. Plug the line cord into the wall receptacle.
  - 1) If the Prep Block works, check the male plug on the Fibrometer. If defective, have BBL repair it. If the Fibrometer was also not receiving power initially, then the female receptacle must also be checked.
  - 2) If the Prep Block still does not function, check the female receptacle. If defective, have BBL repair, or order BBL Catalog Number 76014, Female Plug assembly.

# **Automatic Pipettes**

Repair is not done by BBL. Defective pipettes are replaced. See the repair policy.

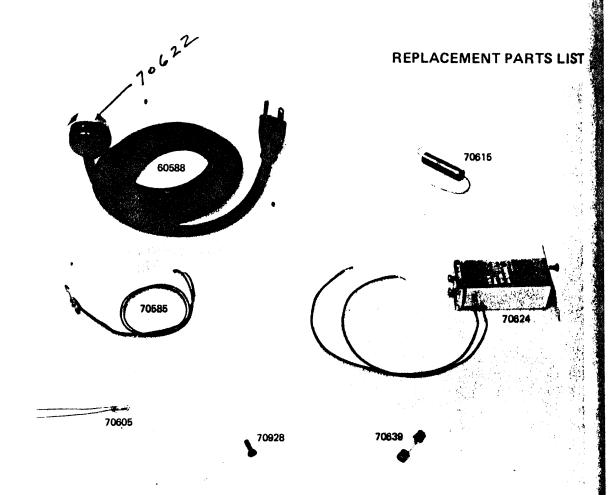
The user will find that most problems with the Automatic Pipette can be solved by following the directions given in Section Seven of this manual.

# REPLACEMENT PARTS LIST



Replacement Parts List: THERMAL PREP BLOCK (60419)

CATALOG NUMBER	DESCRIPTION
76013	Bottom Cover Assembly
76014	Female Plug Assembly
76015	Heat Pad and Lug Assembly
76016 '	Male Plug Assembly
76017	Printed Circuit Board Assembly
76018	Thermostat and Lug Assembly



Replacement Parts List: Fibrometer®(60415)

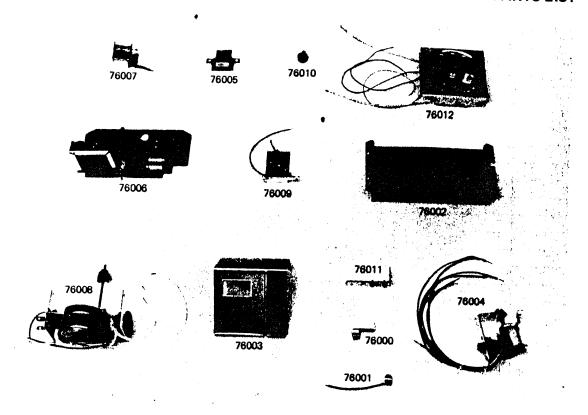
# **CATALOG NUMBER**

# DESCRIPTION

Fibrometer Line Cord
Thermostat
Thermostat Phenolic Sleeve
Light, Indicator
Capacitor, Time Delay, 30 mfd
Counter, Veeder Root
Counter, Trim Plate

Counter, Frim Plate Counter, Shim Counter, Spacer Screw - #4-40 x ½" Washer #4 Fuse 1 ampere Button, Reset

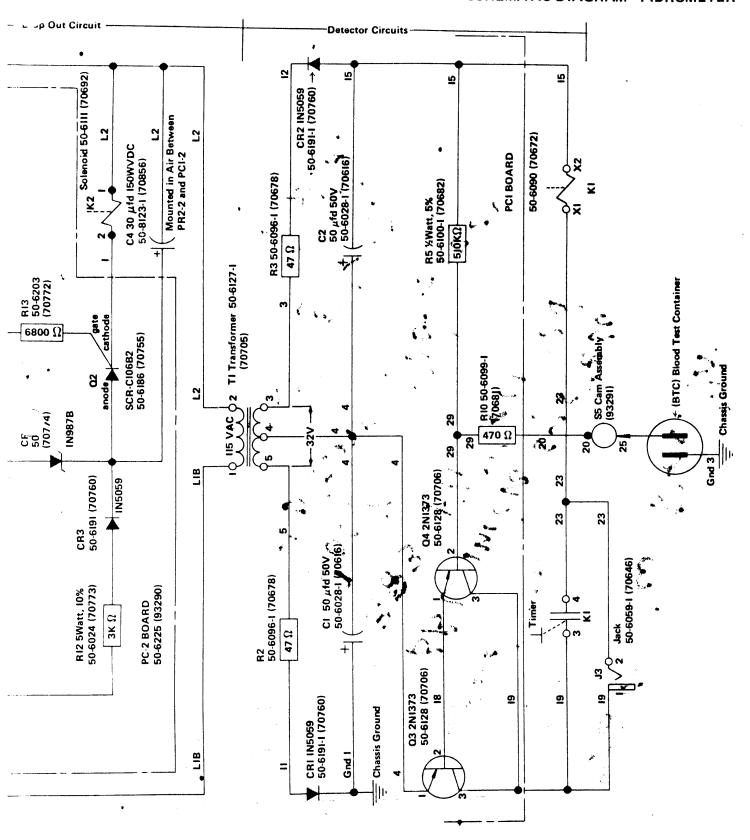
# REPLACEMENT PARTS LIST

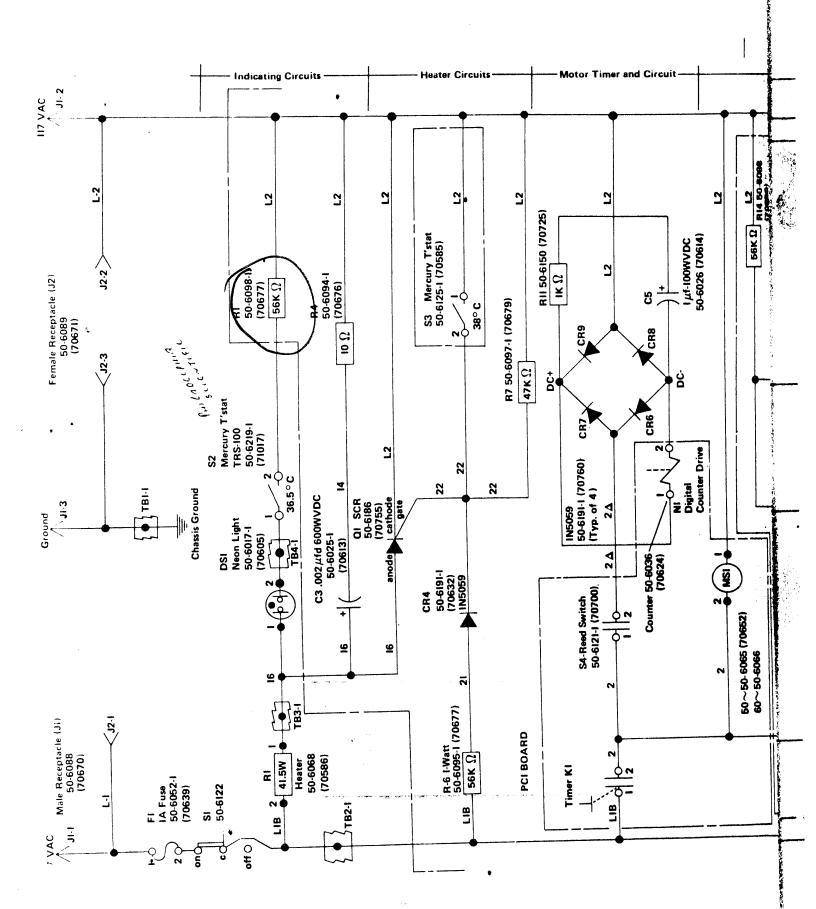


# Replacement Parts List: Fibrometer®(60415)

CATALOG	NUMBER	DESCRIPTION
76000		Fuse Clip and Tie Lug
76001		Fuse Clip and Wire Assembly
76002		Bottom Cover Assembly
76003		Front Cover Assembly .
76004		Relay and Switch Assembly
76005		Printed Circuit Board Assembly - TAR
76006		Printed Circuit Board Assembly - #6
76007		Solenoid Assembly
76008		Motor Assembly, 60 cycle
76009		Reed Switch Assembly
76010	a sandina di Amerika	Cam Assembly
76011		Bearing Bracket Assembly
76012		Heat Block Assembly

# SCHEMATIC DIAGRAM - FIBROMETER®





# WARRANTY AND REPAIR POLICY

**SECTION NINE** 

# Repair Policy

# Fibrometer® and Thermal Prep Block

- 1. Any machine that cannot be repaired as directed by the Trouble Shooting Section (Section Eight) should be returned to BBL for repair. A loaner machine is usually available for immediate shipment on request. Call the toll-free number (800) 638-8663 to arrange for shipment of a loaner machine and repair of your machine. BBL will allow one month from the time the machine is shipped until receipt of the customer's unit for repair. BBL will also allow one month after shipment of the repaired unit for return of the loaner. Failure to meet these dates may result in a delay in shipping a loaner to you when you need it. These loaner Fibrometer Timers and Thermal Prep Blocks are not for sale.
- 2. Please do not ship your unit to BBL until the loaner is received, provided, of course, that a loaner was necessary. Call Technical Services at BBL, (800) 638-8663, to determine if a loaner is needed. The loaner unit will have with it a defective unit return authorization, and a peel-stick BBL address label. Please check off the list of possible defects any which you may have experienced. Add any note you feel may be helpful in repairing the unit. Pack your Fibrometer in the loaner box with the defective-unit return authorization. Seal the box and place the BBL address label on it.
- 3. Do not ship by Parcel Post unless you insure it. Without the insurance slip, there is no chance of tracing the shipment if it is lost.

# **Automatic Pipettes**

BBL does not repair defective Automatic Pipettes; it exchanges them. Refer to the discussion under "Warranty". An exchange unit will be airshipped to you. The defective unit must be returned so that it can be repaired and placed in the exchange pool.

# REFERENCES

- 1. Fewell, R. G., A. Cundy, and G. C. Jenkins, 1972. The One Stage Prothrombin Test: A Comparative Study of Mechanized Prothrombinmeter and Manual Testing. Med. Lab. Tech. 29:147.
- 2. Miale, J. B. 1965. The Fibrometer System of Routine Coagulation Tests. Amer. J. Clin. Pathol. 43:475.
- 3. Sterling, R. E., A. A. Wilcox, A. G. Ware, and M. K. Umehara. 1965. Improved Instrumentation for the Determination of Prothrombin Activity. Clin. Chem. 11:409.
- 4. Barnett, R. N., and C. L. Pinto. 1966. Reproducibility of Prothrombin Time Determinations Between Technologists. Am J. Clin. Pathol. 46:148.
- 5. Viral Hepatitis. 1973. World Health Organization. WHO Tech. Rep. Serv. #512. Page 820.