HEMOCHRON®

Whole Blood Coagulation Systems

OPERATOR'S MANUAL

Models 801 & 401

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For *in vitro* Diagnostic Use

Summary & Explanation

The HEMOCHRON® instruments (Models 401 and 801) are portable, battery operated instruments designed to perform an array of whole blood coagulation tests at any patient location. The Model 401 instrument has one test well for single or sequential test determinations. The Model 801 instrument has two individual test wells allowing for the simultaneous performance of two coagulation tests. It is ideal for running the same test in duplicate or for measuring two different coagulation tests simultaneously. The operation of both the 401 and the 801 Models is the same.

The HEMOCHRON is manufactured and quality assured by skilled technical personnel using high quality test instruments. Our Quality Assurance team uses rigorous standards to evaluate and certify each machine. The HEMOCHRON instrument complies with CSA, L.A. County, and IEC standards as well as many other state and city codes.

Under routine operating conditions, the HEMOCHRON instrument will provide uninterrupted trouble-free service. The HEMOCHRON is sold with a Limited Warranty which is published in this manual.

Principle of the Procedure

There are two pathways which comprise the overall coagulation cascade: The **intrinsic** and the **extrinsic** pathways. There are twelve clotting factors or proteins involved in this cascade scheme. They are numbered I through XIII, excluding factor VI which was incorrectly used to label an extrinsic factor.

The **intrinsic** pathway is so named because all the proteins needed for the entire process are contained within the blood. The following clotting factors are unique to this pathway: XII, XI, IX, and VIII. The **extrinsic** mechanism requires a substance outside of the blood, tissue factor (Factor III), to initiate the pathway. Only Factor VII is unique to this pathway. The **extrinsic** pathway of coagulation is much faster than the **intrinsic**.

Common to both the **intrinsic** and **extrinsic** pathways are Factor X, prothrombin, thrombin, fibrinogen and fibrin.

The HEMOCHRON system allows one to conduct in vitro diagnostic coagulation tests at the patient bedside to ensure accurate assessment of patient hemostasis.

Principle of Operation

The HEMOCHRON instrument was introduced commercially in 1969 as a convenient replacement for the more time-consuming and subjective Lee-White and manual activated clotting time procedures. The Models 401 and 801 provide many features for ease of use and reliability.

The HEMOCHRON system has enjoyed widespread use during cardiopulmonary bypass surgery, hemodialysis, extracorporeal membrane oxygenation, Percutaneous Transluminal Coronary Angioplasty, cardiac catheterization, and critical care. Over 15,000 HEMOCHRON systems have been sold worldwide since its introduction.

The patented HEMOCHRON clot detection mechanism consists of a precision aligned magnet within a test tube and a magnetic detector located within the test well. When a test tube is inserted into the well, the magnetic detector senses a magnet within the test tube as the tube slowly rotates. When the clot begins to form, it causes the magnet to lift within the tube. Since the magnet has been displaced, it is no longer sensed by the instrument's magnetic detector. The instrument gives an audible beep and displays the coagulation time.

The HEMOCHRON system, which includes the instrument plus test kits, has developed over the years to offer an expanding coagulation test menu. At present, the whole blood activated clotting time (ACT) test, activated partial thromboplastin time (APTT) test, prothrombin time (PT) test, fibrinogen assay (FIB), thrombin time (TT) test, heparin neutralizing thrombin time (HNTT) test, high dose thrombin time (HiTT), heparin response test (HRT), protamine response test (PRT), and protamine dose assay (PDA) are available for the HEMOCHRON. New tests are constantly under development. For a complete list of HEMOCHRON tests, contact International Technidyne Corporation.

Features

- Coagulation testing at bedside.
- Uses fresh whole blood.
- Test results within minutes.
- Fully portable system.
- Self-contained rechargeable nickel cadmium batteries.
- Automatic shut-off conserves batteries.
- "Select" button offering several test result conversion and countdown options.
- Low battery indicator on the display screen.
- Automatically monitors internal circuitry and reports problems to display screen (see Trouble-shooting).
- Microprocessor controlled for enhanced reliability.

Convenience Features of the Models 401 and 801

Automatic Shut-Off

If the "Start" button is depressed but no test tube is inserted into the instrument within 60 seconds, the system automatically sounds and displays a **FAULT 08** on the display screen. This feature is designed to conserve the life of the battery by preventing the instrument from running indefinitely.

Select Options

1. *Pre-Warm Option:* Depressing the "Select" button once will begin a 300 second (5 minute) pre-warming of the test well. The display will countdown this 300 second period and the alarm will sound at 0 seconds. The test well will warm up to 37 °C within 20 seconds and maintain that temperature for five minutes.

Note: Some older HEMOCHRON® models use a 180 second Prewarm feature instead of 300 seconds.

2. *APTT Conversion Option:* Before beginning the fresh whole blood OneStep APTT test by HEMOCHRON (A103), depress the "Select" button two times rapidly so that the letters APTT appear on the display screen. Upon completion of the APTT test and prior to removing the APTT test tube from the test well, the operator can obtain a plasma equivalent value of the HEMOCHRON OneStep APTT test result by depressing the "Select" button once. Pressing the "Select" button again will return the HEMOCHRON result and continual pushing of the "Select" button toggles between the two values as long as the test tube is in the well. When the test tube is removed, the instrument will only display the HEMOCHRON whole blood result.

Note: *For differentiation, plasma equivalent values are displayed with a decimal point (123.45) while HEMOCHRON whole blood results do not have a decimal point (123).*

A plasma equivalent result with a flashing **FAULT** annunciator indicates that the result is within the range of the HEMOCHRON OneStep APTT but outside of the range of a routine plasma APTT test. Three dashes (---) will appear on the display screen when a plasma equivalent value is chosen and the actual result is outside of the range of the HEMOCHRON test.

3. *PT Conversion Option:* Before beginning the fresh whole blood PT test by HEMOCHRON (A201 or A203), depress the "Select" button three times rapidly so that the letters **PT** appear on the display screen. Upon completion of the PT test *and prior to removing the PT test tube from the test well*, two correlations can be obtained for the HEMOCHRON PT result.

Depressing the “Select” button one additional time will provide a plasma equivalent PT value. Pressing the button again will provide an INR value (refer to PT package insert for an explanation of INR). Pressing the “Select” button one more time will return the HEMOCHRON PT result and continual pushing of the “Select” button toggles between the three values as long as the test tube is in the well. When the test tube is removed, the instrument will only display the HEMOCHRON result.

Three dashes (---) will appear on the display screen when a plasma equivalent or INR value is chosen and the actual result is outside of the range of both the HEMOCHRON and routine plasma tests.

Note: *For differentiation, plasma equivalent values are displayed with a decimal point (12.3), and are always greater than 10.0, INR values are displayed with a decimal point (1.2) and are always less than 10.0, HEMOCHRON results do not have a decimal point (123).*

Run On Shut Off

The HEMOCHRON instrument will automatically shut itself off once the timer exceeds 1500 seconds. This feature conserves battery life if for any reason an empty HEMOCHRON test tube is inserted and the start button is depressed. A HEMOCHRON test result of greater than 1500 seconds should be considered beyond clinical significance and the test should be immediately repeated.

Self Monitoring

The Models 401 and 801 automatically monitor internal circuitry and report problems to the display screen. Malfunctions will appear on the display screen as an error code or fault. For example, **LO BAT** will appear on the display screen when the battery is running low.

A complete list of **FAULT** codes with an explanation can be found in the TROUBLESHOOTING section of this manual.

Specifications

HEMOCHRON Model	401	801
■ Number of Channels	1	2
■ Timing Range (seconds)	0 - 1500	0 - 1500
■ Incubation Temperature (°C)	37 ± 0.5	37 ± 0.5
■ Incubation Warm-Up Time (sec)	14 - 20	14 - 20
■ Operating Time on Full Battery Charge, All Channels Constant Run (hours)	4 - 6	4 - 6
■ Line Voltage (volts AC ‰ Hz)	120 (100, 220, 230 optional)	120 (100, 220, 230 optional)
■ Power (watts)	6	11
■ Dimensions (w x d x h, cm)	18 x 23 x 12.5	25 x 28 x 15
■ Weight (kg)	1.7	2.6

Operating Instructions

The HEMOCHRON coagulation instrument can be operated either on its self-contained battery or plugged into the appropriate AC outlet. Routine charging and discharging of the nickel cadmium battery will improve its life-span. Coagulation tests can be performed on the HEMOCHRON while it is charging.

The HEMOCHRON is operated by simply depressing the "Start" button to begin the timer. The test well heater is activated at the same time. Depress the "Start" button twice if the instrument is asleep (blank screen). The asleep mode is a conservation feature during battery operation.

The proper operating procedure for individual HEMOCHRON coagulation tests can be found in the respective package inserts. Common to all HEMOCHRON test tubes is the magnet and plastic center post. When a HEMOCHRON test tube is inserted into the test well the magnet positions itself directly above the detector. To assure this positioning, the operator should rotate the test tube two full revolutions clockwise while verifying that the detector light is illuminated.

Once a clot has been detected, a beeping sound will be heard and the clotting time will flash on the display screen. This result will remain flashing on the screen for 15 minutes.

Whenever a **FAULT** is on the HEMOCHRON display screen and a new test is desired, simply depress the "Start" or "Select" button to begin a new test.

Operating Cautions & Limitations

The instrument should be plugged into the proper AC outlet when not in use to maintain the battery power level. To unplug the instrument, firmly grasp the plug and pull. **DO NOT** remove the plug from the outlet by pulling on the cord.

DO NOT force test tubes into the test well. If resistance to insertion or rotation is encountered, gently remove the test tube and examine the test well. Remove any obstruction before attempting further use of the instrument (see Service and Maintenance.)

DO NOT use excessive force in depressing the "Start" or "Select" button.

DO NOT expose the HEMOCHRON instrument to extremes in temperature. Such exposure may affect all types of solid state instrumentation.

DO NOT drop the HEMOCHRON instrument.

As with all microprocessor controlled instrumentation, exposure to static electrical charges should be minimized.

Always plug the instrument into a properly grounded, three pronged receptacle. Do not use non-grounding adaptors.

HEMOCHRON instruments are designed for use only with HEMOCHRON coagulation test tubes. Other commercially available blood collection test tubes or culture tubes lack material and components necessary for clot detection in HEMOCHRON instruments.

In a properly maintained and operated HEMOCHRON instrument, the accuracy and precision of test results are largely dependent upon the quality of the blood specimen used for the test. Factors such as specimen contamination, inappropriate technique, or large temperature variations will adversely affect most coagulation tests.

HEMOCHRON test results should always be scrutinized in light of a specific patient's condition or anticoagulant therapy. Any HEMOCHRON test result exhibiting inconsistency should be repeated or supplemented with additional test procedures.

HEMOCHRON test results greater than 1500 seconds should be considered beyond clinical significance and the test should be immediately repeated. All guidelines pertaining to the handling of fresh whole human blood, such as CDC guidelines, should be strictly adhered to when operating the HEMOCHRON instrument.

Used HEMOCHRON test tubes should be considered contaminated. They should be handled according to individual institutional policies concerning body fluids and the disposal of contaminated materials.

It should be noted that HEMOCHRON equipment is not rated for use in explosion-proof areas.

Use of this equipment other than in accordance with the manufacturer's guidelines is not recommended and is at the sole discretion of the institution.

Performance (Expected Values)

HEMOCHRON Test	Cat No.	Reagent	Blood Volume	Mean Normal (sec)	Range (± 2 SD) (sec)	Use
ACT	CA510/ FTCA510	Diatomaceous Earth	2.0 cc	132 160*	105-167 120-196	Monitoring heparin during cardiovascular surgery.
ACT	K-ACT/ FTK-ACT	Kaolin	2.0 cc	121 132*	91-151 110-154	Monitoring heparin during cardiovascular surgery.
ACT	P214/ P215	Glass	0.4 cc	146	110-182	Monitoring heparin during hemodialysis and ECMO.
APTT	A103	Kaolin & platelet Factor 3 substitute	2.0 cc	123	109-137	OneStep APTT
PT	A201	Thromboplastin	2.0 cc	61	50-72	Monitoring warfarin and extrinsic coagulation screening
PT	A203	Thromboplastin	3.0 cc	61	50-72	Same as A201 except evacuated DirectDraw™ tube
FIB	B101	Thrombin	See Product Insert			Quantitation of functional fibrinogen in whole blood
TT	A301	Thrombin	1.0 cc	46	38-54	Monitoring heparin and fibrinogen function in fresh whole blood.
HNTT	A401	Thrombin Protamine Sulfate	1.0 cc	44	31-56	Assessing fibrinogen function in presence of heparin in fresh whole blood.
HiTT	A501	Thrombin	1.5 cc	43	35-51	Monitoring heparin during cardiovascular surgery.
QC	CPL1/2	Non-Human Plasma	See Product Insert			Quality control of HEMOCHRON ACT test tubes.
QC	Q101	Non-Human Plasma	See Product Insert			Quality control of all non-ACT HEMOCHRON tests.
QC (FIB)	B102	Human Plasma	See Product Insert			Quality Control of HEMOCHRON FIB test tubes

* Expected values for cardiovascular patients are different than for normal, healthy persons with CA510/FTCA510/K-ACT/FTK-ACT tubes.

Please refer to the instruction card and/or package insert included in each box of HEMOCHRON test tubes for details on product use.

Quality Control

Establishing a quality control program is recommended for all in vitro diagnostic products. Routine quality control is recommended for electronic diagnostic instruments such as the HEMOCHRON to assure that no drift has occurred in the calibration settings.The HEMOCHRON instrument and coagulation tests should be quality controlled using two levels of control and performed daily once per shift. Complete records of such quality control must be kept.

The temperature of the HEMOCHRON test well can be verified externally with the use of the HEMOCHRON Temperature Verification Test Tube (HE1001).

Routine quality control testing and tracking should be part of a comprehensive Quality Assurance program. HEMOCHRON products for Quality Control are available to make routine QC convenient and affordable. These products are especially beneficial when an instrument problem is suspected. We recommend that multiple tests be run with HEMOCHRON control plasma before sending an instrument to International Technidyne Corporation for service.

Detector Sensitivity
The sensitivity of the clot detection mechanism can be easily checked on a daily basis.

Procedure
1. If the instrument is asleep (blank display screen), depress the start button twice to begin the timer.

2. Insert an empty HEMOCHRON test tube(s), rotating it gently clockwise twice, verifying illumination of the detector light.

3. Wait 20 seconds, then slowly rotate the entire instrument counterclockwise onto its left side as viewed from the front. At approximately 90 degrees from its normal horizontal position the instrument should sound and flash the time on the display screen.

If the instrument does not perform as described, and QC values are consistently out-of-range, contact the ITC Technical Service Department immediately.

Test Well Temperature

Verified as follows:

1. Charge the HEMOCHRON instrument battery fully.

2. Insert the HE1001 Temperature Verification Tube into the HEMOCHRON test well and depress the START button. The green detector light should illuminate and remain lit for the entire temperature verification procedure. Allow the instrument to come to thermal equilibrium for at least 10 minutes.

3. Without removing the verification test tube from the test well, read the temperature and record the results.

4. Repeat steps 2 and 3 for the second test well. (Not applicable to Models 400/401)

An observed temperature deviation of greater than ± 1 °C from 37 °C suggests the necessity of instrument recalibration. In this circumstance, return the instrument to ITC with a description of the fault.

Note: *Before returning the instrument for temperature recalibration, check the calibration tube thermometer for evidence of mercury column separation and, if necessary, correct as described in the Temperature Verification Tube instruction sheet.*

Service & Maintenance

Inspect and clean the test well and test tube drive collar. Remove residual dried blood or other foreign matter using a 1:10 dilution of household bleach (sodium hypochloride) with moistened cotton swabs.

Apply solution to clean and disinfect areas contaminated with residual dried blood. **DO NOT** use solvents or strong cleaning solutions. They may deform the instrument's plastic components.

Fig. 1. Schematic diagram HEMOCHRON Model 401

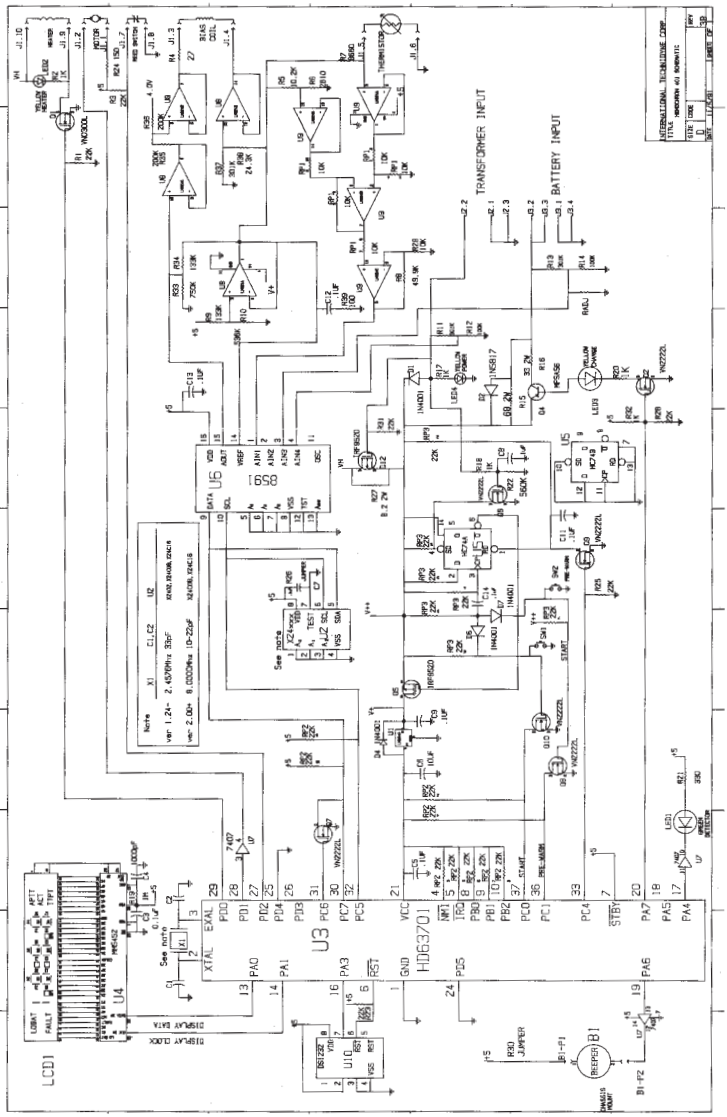


Fig. 2. Schematic diagram HEMOCHRON Model 801

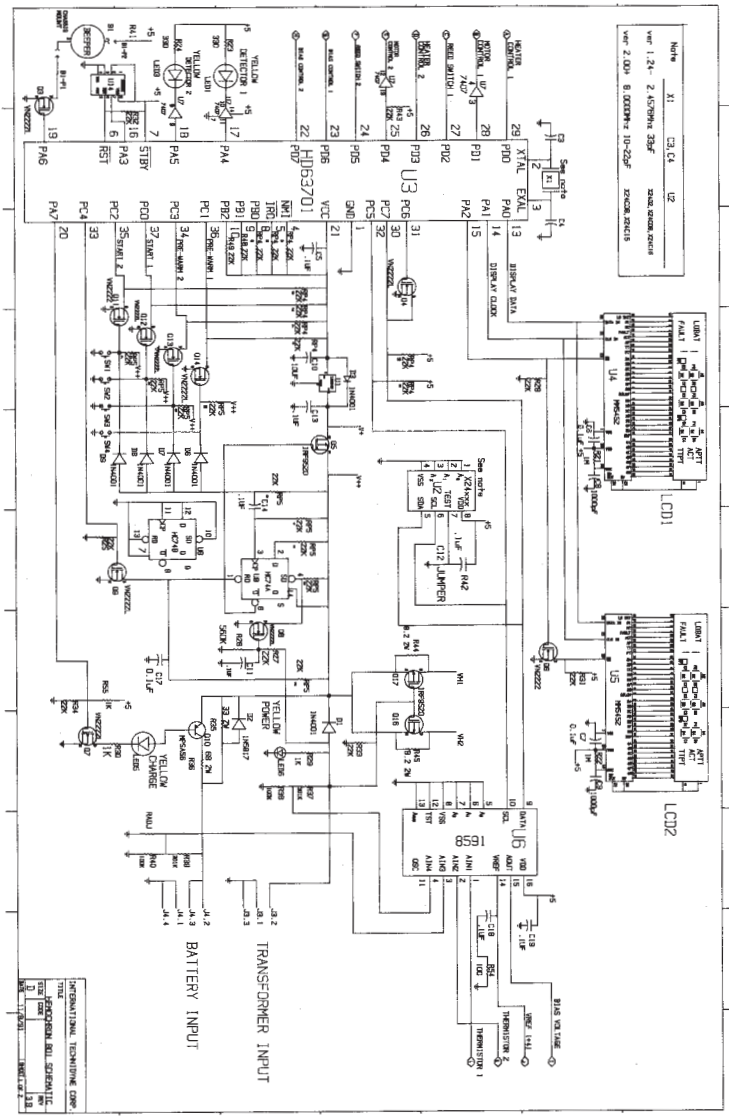


Fig. 3. Schematic diagram HEMOCHRON Model 801

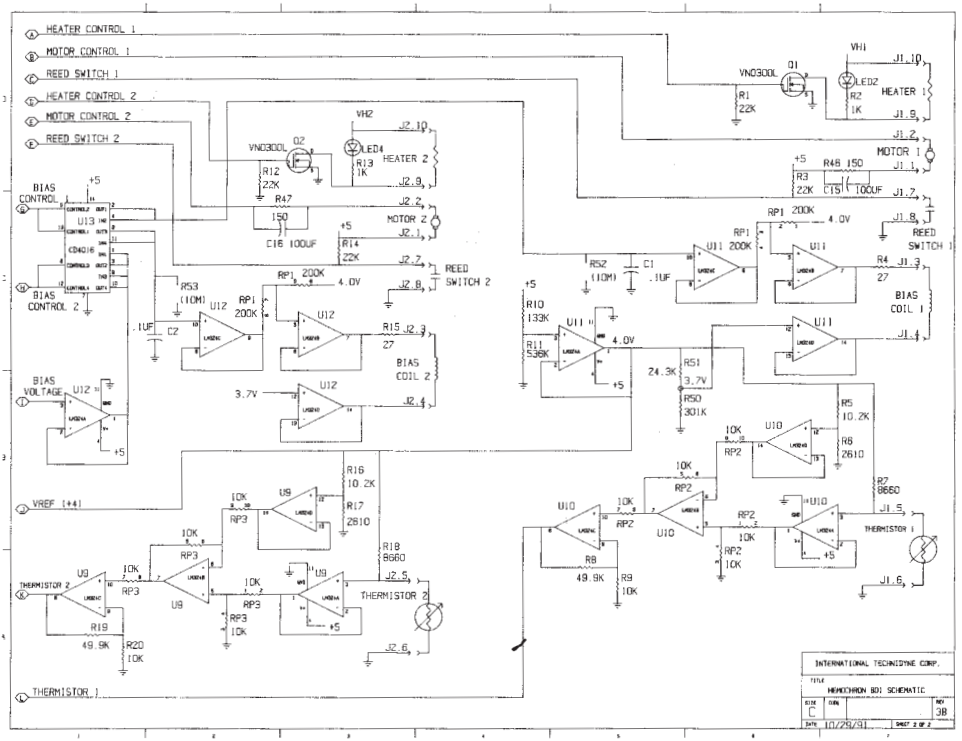


Fig. 4. Component Layout HEMOCHRON Model 401

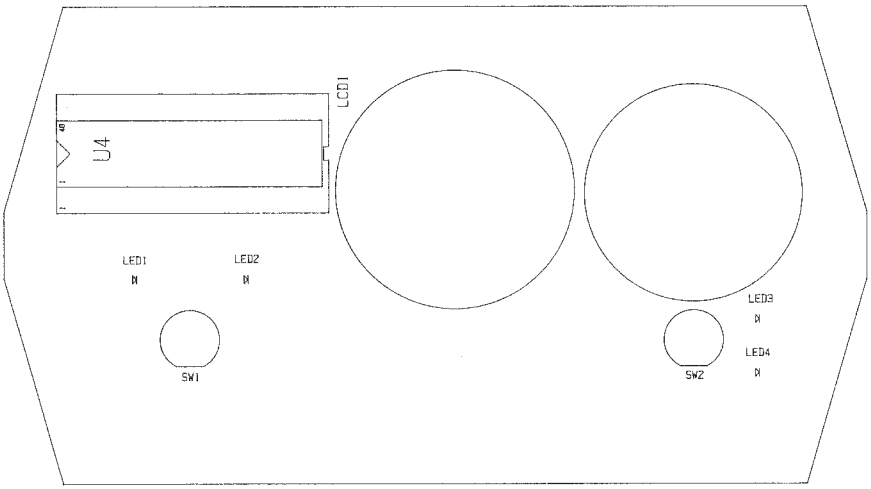


Fig. 5. Component Layout HEMOCHRON Model 401

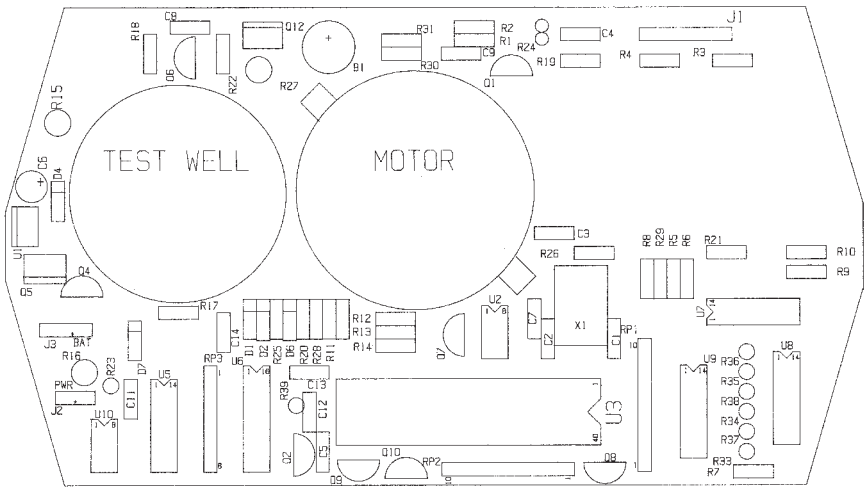


Fig. 6. Component Layout HEMOCHRON Model 801

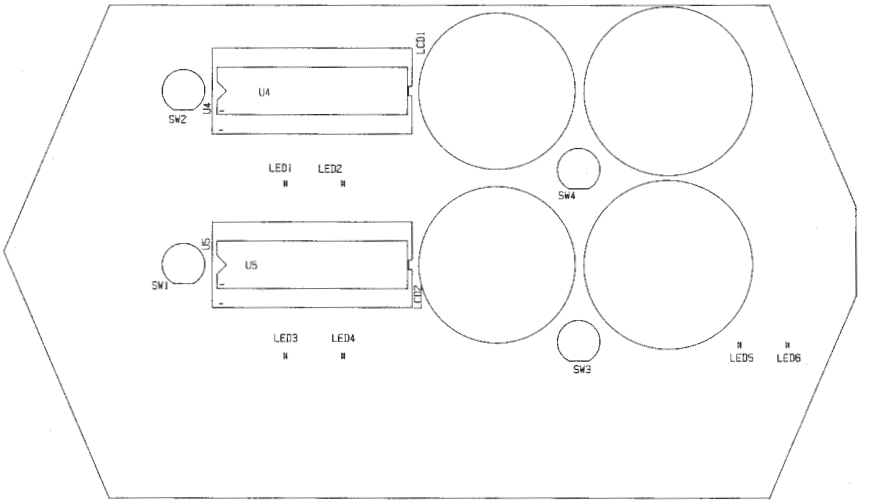


Fig. 7. Component Layout HEMOCHRON Model 801

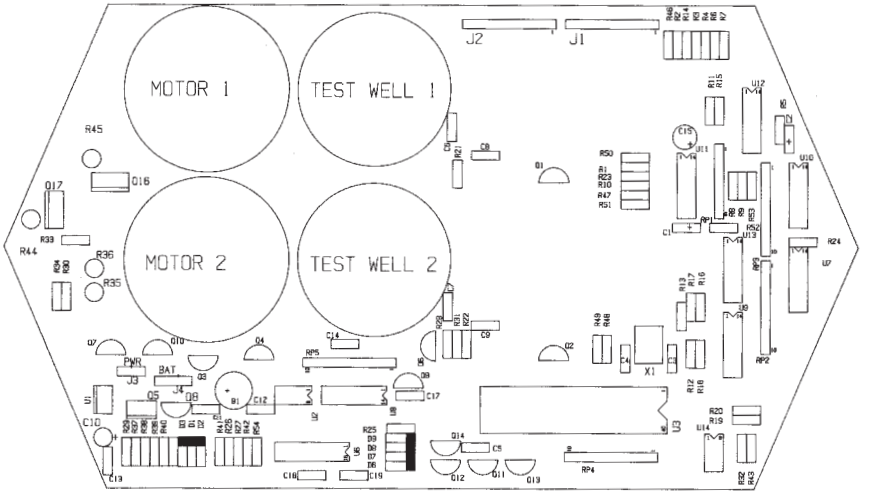


Fig. 8. HEMOCHRON Models 401/801 Power Supply Schematic (115 V, AC)

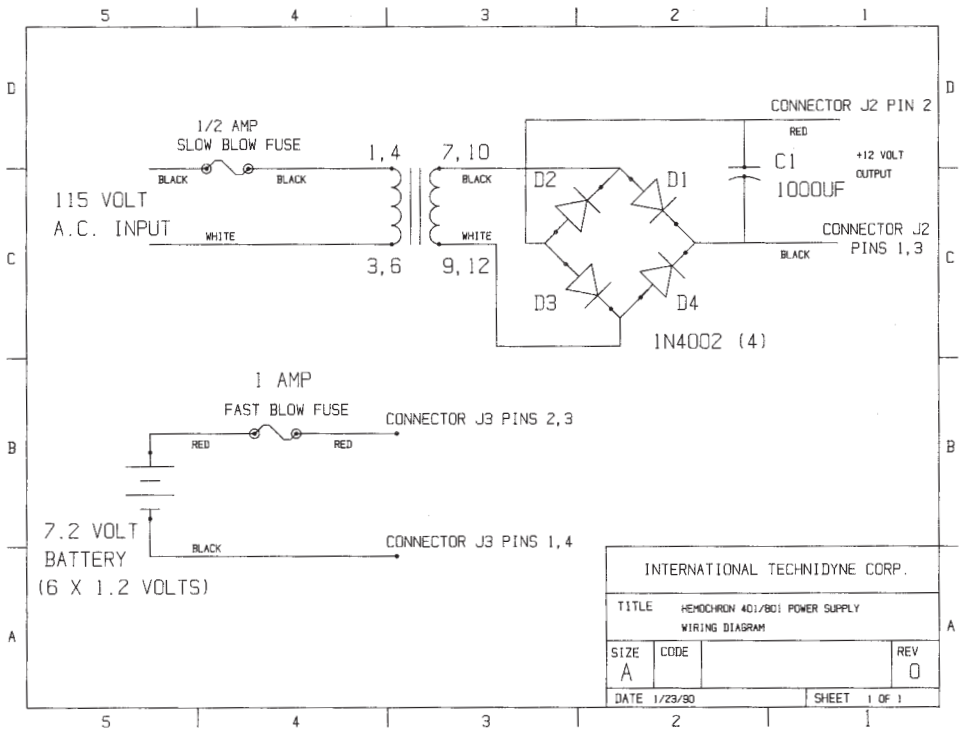
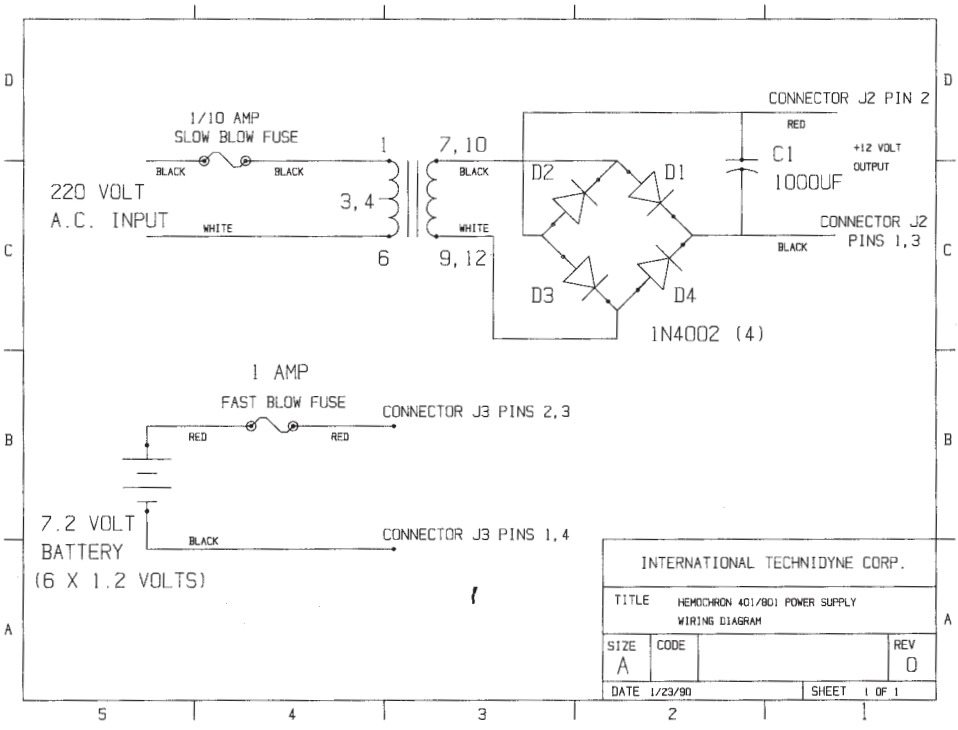


Fig. 8. HEMOCHRON Models 401/801 Power Supply Schematic (220 V, AC)



Service & Maintenance (cont.)

The Models 401 and 801 are almost completely self-monitoring. They automatically monitor internal circuitry and report problems to the display screen. Malfunctions are assigned an error code or fault and are detailed on the instrument's bottom label and in the section on "Troubleshooting".

HEMOCHRON instruments have a fixed calibration system. All HEMOCHRON instruments are fully calibrated before shipping. Calibration status is automatically monitored as noted above. Any calibration error will be signified by a FAULT 04 or 05 on the LCD screen, a shift in clinical results and quality control (QC) values, or a failed detector sensitivity test. After diagnosing a calibration error, immediately contact ITC Technical Service Department.

To optimize battery life, it is recommended that you run the HEMOCHRON on its battery during the day. Plug it into standard AC current overnight to allow the batteries to recharge. The nickel cadmium battery cells work best when they are exercised in this manner.

A fully charged battery will operate the instrument for four to six hours continuously or for approximately eight to twelve hours of clinical use.

The low battery indicator will appear on the display screen to alert you when the battery is running low. At that point, the instrument still has approximately one hour of battery time left to perform coagulation testing. Once this message appears, plug the instrument in at the earliest possible convenience.

The **POWER** light should always be illuminated when the instrument is plugged into AC current. The **CHARGE** light will **only** illuminate during the rapid charge mode which occurs when the batteries are substantially depleted. Otherwise the **CHARGE** light will not illuminate and a trickle charge will be given to the batteries.

When the batteries are drained to the point that valid testing cannot be performed, the instrument will display **FAULT 06** (see Troubleshooting). At this point, the instrument must be plugged in for operation and recharging. Whether or not the instrument's batteries are functional, you will not be inconvenienced by downtime because you may continue to run tests while the instrument is plugged into the AC outlet.

Troubleshooting

Before attempting repairs, perform a careful inspection of the instrument. A visual examination can frequently pinpoint the defect, especially if the unit has been dropped. Get a description of the malfunction and confirm it by running your own test using an empty HEMOCHRON test tube.

Observation	Possible Cause
A. Long Clotting Times	• Too much heparin • Incubator temperature out of range • Incubator circuit or test well malfunction • Test tube does not rotate
B. Short Clotting Times	• Tubes not mixed properly • Tubes not turned twice after green light comes on • Battery may be discharged
C. Battery Will Not Charge	• Fuse(s) blown • Bad cell in battery • Charging circuit malfunction • Defective line cord or plug
D. Segments Missing in Counter	• LCD counters exhibiting missing segments should be returned to the manufacturer for replacement. The complete instrument serial number must accompany such returns
E. Green Light Stays on Even When the Tube is Removed	• Press reset button. If problem persists, contact ITC Technical Service Department
F. Green Detector Light Does Not Illuminate	• Tubes not mixed properly • Tubes not rotated twice after insertion into test well • Detector sensitivity error. Perform detector sensitivity test. If problem persists, contact ITC Technical Service Department
G. Tube Does Not Rotate	• Motor physically damaged (this usually occurs when an instrument has been dropped) • Motor pulley is stripped on the motor shaft • Wires to motor are broken or disconnected • Test well and nameplate are misaligned
H. Unit Does Not Start When Button is Pushed	• Battery discharged • Fuses blown • Push reset button twice

Fault	Definition	Action
01	Test well temperature below acceptable level	Send to ITC for correction
02	Test well temperature above acceptable level	Send to ITC for correction
03	Automatic run-on shut-off Timer exceeded 1500 seconds	Repeat test being performed. If no test being run, no action is necessary
04	Clot detection sensitivity not set	Depress reset button in rear cord compartment. If **FAULT** persists, contact ITC Technical Service Department
05	Bias current calibration error	Contact ITC Technical Service Department
06	Battery error	Charge battery for 12 hours. If **FAULT** persists, replace battery
07	Internal diagnostics error	Depress reset button found in recessed electrical cord holder. If **FAULT** persists, contact ITC Technical Service department.
08	Automatic shut-off	No action necessary
"###" Fault	A flashing test result with the "Fault" label indicates the removal of a HEMOCHRON test tube prior to clot detection.	

Replacement Parts

Electronic components used in the HEMOCHRON are commercially available. If a replacement is required, it may be purchased from your local HEMOCHRON distributor. Mechanical components and battery packs are available from International Technidyne Corporation. The parts list includes the stock number of each available part. This stock number, together with the description of the part, and the model and serial numbers of the instrument, should be included with your order.

HEMOCHRON Model 401 and Model 801 (110 V and 100 V)

Part No.	Description
HE1A	Test Well Assembly
HE2-1	Circuit Board (Model 401)
HE2-2	Circuit Board (Model 801)
HE4A	Motor
HE5-3	Battery Pack (Model 401)
HE5-4	Battery Pack (Model 801)
HE6-3	Transformer (Model 401 and Model 801)
HE8-7	LED - Green
HE8-9	LED - Amber
HE10-1	Fuse (F1), 1 amp AGC
HE11-1	Fuse (F2) 3/16 amp slow blow (Model 401 and 801)
HE11-6A	Fuse Holder
HE12-401	Drive Kit (Model 401) includes: 2 HE12-1 3 HE12-2A 2 HE12-5 2 HE12-9 2 HE12-10A

HEMOCHRON Model 401 and Model 801 (110 V and 100 V)

Part No.	Description
HE12-801	Drive Kit (Model 801) includes: 2 HE12-1 3 HE12-2A 2 HE12-5 2 HE12-9 2 HE12-10A
HE12-1	Motor Drive Pulley
HE12-2A	Idler Pulley (large)
HE12-5A	Drive Belt (Model 401 and Model 801)
HE12-9	Name Plate Drive Bushing
HE12-10A	Test Tube Drive Pull/Collar
HE16-5	Name Plate (Model 401)
HE16-6	Name Plate (Model 801)
HE17	Reset Button

Parts Exclusive to 220 V Model 401 and Model 801

HE6-4A	Transformer (Model 401 and Model 801)
HE11-7A	Fuse Holder
HE11-5A	Fuse (F2) 100 ma (5mm x 20mm) slow blow (Model 401 and Model 801)

Suggested Reading

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Scott JA, Berenstein A, Blumenthal D: Use of the activated coagulation time as a measure of anticoagulation during interventional procedures. Radiology 158:849-850, 1986.

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CE Marking and Related Safety Standards

The HEMOCHRON® instrument complies with the following safety standard regulations:

EN55011 (Mar 1991)	Limits and Methods of Measurement of Ratio Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio Frequency Equipment
EN50082-1 (Jan 1992)	Electromagnetic compatibility - Generic Immunity Standard, Part 1: Residential, Commercial and Light Industry.
EN60601-1-2 (Apr 1993)	Medical Electrical Equipment: Part 1: General Requirement for Safety. Part 2: Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 801-2 (1991)	Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment Part 2: Electrostatic Discharge Requirement
IEC 801-3 (1984)	Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment Part 3: Radiated Electromagnetic Field Requirement
IEC 801-4 (1988)	Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment Part 4: Electrical Fast Transient/Burst Requirements
IEC 801-5 (Draft, 1993)	Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment Part 5: Surge Immunity Requirements

EMC Directive 89/336 EEC

All the relevant documentation is kept and can be requested at the following address:

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