CE

HEMOCHRON® *Response*
Whole Blood Coagulation System

Operator's Manual
English

TABLE OF CONTENTS

This manual is published by International Technidyne Corporation (ITC) for use with the HEMOCHRON *Response* V2.00 or above. Questions or comments regarding the contents of this manual can be directed to the address at the back of this manual or to your ITC representative.

INTENDED USE

The HEMOCHRON® *Response* Whole Blood Coagulation System is a dual-well microprocessor-controlled coagulation testing instrument with an integral test type barcode reader, RS232 communication interface capability, and a printer. The system runs coagulation tests such as Activated Clotting Time (ACT), Activated Partial Thromboplastin Time (APTT), Prothrombin Time (PT) and other specialty tests that are currently available from ITC.

SUMMARY AND EXPLANATION

Events that lead to formation of a blood clot are simplified in coagulation theory into two interactive coagulation cascades. The Activated Clotting Time (ACT), Activated Partial Thromboplastin Time (APTT) and Prothrombin Time (PT) tests are general coagulation screening tests that are used to measure the functionality of these cascades.

The ACT test is the method of choice for monitoring heparin therapy. Administration of heparin to maintain hemostasis during cardiac surgery and cardiac angioplasty procedures can pose significant risk to the patient. Since individual patients can vary as much as twelve-fold in heparin sensitivity, overdosing heparin can result in dangerous bleeding and underdosing heparin can lead to thrombosis.

ACT is performed by adding a clotting activator such as Celite®, silica, kaolin, or glass particles to a blood sample and then measuring the length of time required for clot formation. The particular clotting activator that is used influences the time required for clot formation. Celite (diatomaceous earth) is the standard ACT reagent used for high level heparin monitoring because of its excellent activating properties. However, serine protease inhibitors such as aprotinin that may be administered to certain patients to decrease postoperative bleeding can prolong the Celite activated ACT. When aprotinin is on-board, a kaolin-activated ACT tube should be used.

The APTT test measures the intrinsic coagulation pathway and involves all coagulation factors except factors VII and III (tissue factor). The APTT test improves the earlier PTT test through use of a contact activating substance which standardizes activation of Factor XII to provide a more precise and sensitive assay for low level heparin monitoring.

The PT test measures the extrinsic coagulation pathway and is sensitive to coagulation factors VII, X, V, II, and fibrinogen. PT results may be abnormal in patients with liver disease or Vitamin K deficiency, and the test is widely used to monitor oral anticoagulant therapy.

Under clinical conditions, the coagulation cascade may be affected by either naturally occurring or administered procoagulants or anticoagulants. Endogenous changes in hemostasis, such as disseminated intravascular coagulation, can result in extreme clotting factor depletion. In order to determine which pathway is being affected, a panel of coagulation assays may be performed. Results of these tests are used to diagnose the hemostatic abnormality and to determine the appropriate therapeutic intervention.

PRINCIPLES OF OPERATION

The patented HEMOCHRON clot detection module contains two test wells into which disposable unitized coagulation test tubes can be inserted. The test tubes (provided in a separately purchased test kit) contain reagents for a particular test and a precision magnet. Immediately after the sample is added to the test tube, the START button is pressed, the test tube is agitated, and the test tube is placed into the test well by the operator. There, it is automatically rotated at a controlled speed and incubated at 37 °C ±1.0 °C.

When a fibrin clot begins to form, it causes the magnet in the test tube to be displaced. Two magnetic detectors located in the test well continuously monitor the precise magnet position. When a specific displacement of the magnet occurs, the elapsed time between the beginning of the test and the clot endpoint is displayed as the coagulation time (in seconds). The instrument also emits an audible beep when clot formation occurs, indicating the end of the test.

The coagulation time is displayed on the LCD screen. The operator may choose to print the result (if automatic printing of results is not specified) or simply proceed to the next desired assay.