CE

HEMOCHRON® *Response*
Whole Blood Coagulation System

RxDx® Analysis Module
Heparin and Protamine Dosing

Supplement to HEMOCHRON *Response*
Whole Blood Coagulation System

Operator's Manual
English

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This manual is published by International Technidyne Corporation (ITC) for use with the HEMOCHRON® *Response* ver. 2.00 or higher.

Questions or comments regarding the content of this manual can be directed to the address at the back of this manual or to your ITC representative.

INTENDED USE

The HEMOCHRON® *RxDx*® Analysis Module is a supplementary module for the HEMOCHRON *Response* Whole Blood Coagulation System that provides automated calculations for use during cardiopulmonary bypass surgery and cardiac catheterization procedures.

These calculations are used to determine the doses of heparin to be administered before and during these procedures, the dose of protamine needed to reverse the effects of heparin after the procedure is completed, and the patient's clotting time and residual heparin level after protamine has been administered.

The results that are obtained are saved to an internal database and can be printed or downloaded to a personal computer.

> ***Note**: Refer to the HEMOCHRON Response Whole Blood Coagulation System Operator's Manual for the intended use and instructions for the use of the HEMOCHRON Response Whole Blood Coagulation System.*

SUMMARY AND EXPLANATION

Heparin is used to maintain hemostasis during cardiac surgery and percutaneous coronary interventional (PCI) procedures. However, its administration 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. Therefore, monitoring heparin therapy is vital in guarding against these undesirable side effects.

The doses of heparin to be administered before and during the procedure, the dose of protamine to administer after the procedure, and the patient's clotting time and residual heparin level are determined by running a series of clotting time tests. This series of tests for a patient is referred to as an ***RxDx* case**.

> ***Note**: In this manual, a **case** is the patient information and the series of test results that are associated with a specific patient ID.*

Prior to administration of heparin, an Activated Clotting Time (ACT) and Heparin Response Time (HRT) test are run on the HEMOCHRON *Response* Whole Blood Coagulation System. These tests measure the patient's baseline clotting time and determine how the patient will respond to heparin. The patient blood volume can then be directly entered (if available) or calculated by the system based upon the patient's height, weight and gender. The initial heparin dose (referred to as the bolus heparin dose) is then calculated by the system. During this process, the case is in the **heparin mode**.

Once the patient has received heparin, additional ACT or High Dose Thrombin Time (HiTT) tests are run to measure the coagulation status, determine the efficacy of heparin, and calculate additional heparin doses that may be needed to maintain the target clotting time in the patient. The case is now in the **additional heparin mode**.

After the cardiac surgery or cardiac angioplasty procedure is completed, the effects of administered heparin can be reversed by administration of protamine. Like heparin, protamine must be administered in the correct dose to prevent dangerous bleeding or thrombosis. For this reason, a Protamine Response Time (PRT) test is performed, and the results of this test and the most recent ACT test are used to determine the dose of protamine that is required. The case is now in the **protamine mode**.

Once the protamine has been administered, the patient's clotting time and residual heparin level are measured, using an ACT and a Protamine Dose Assay - Orange (PDA-O) test to determine the post-protamine clotting time and residual heparin level in the patient's blood. Dual Thrombin Time and Heparin Neutralized Thrombin Time (TT/HNTT) tests can also be run after protamine administration to identify the presence of heparin rebound or abnormal fibrinogen function.

Since Celite® (diatomaceous earth) is sensitive to the presence of serine protease inhibitors such as aprotinin, it is recommended that kaolin test tubes are used instead of Celite test tubes when aprotinin is on board.

PRINCIPLES OF OPERATION

Refer to the HEMOCHRON Response Whole Blood Coagulation System Operator's Manual for a complete description of the HEMOCHRON Response Whole Blood Coagulation System.

Once the HEMOCHRON *RxDx* Analysis Module is installed on the HEMOCHRON *Response*, an *RxDx* case is automatically initiated whenever the operator runs an HRT, PRT, or PDA-O test or manually selects the *RxDx* menu.

Each *RxDx* case is tracked by a numeric Patient ID (PID). Once a PID is entered, it is applied to tests in both wells. At the outset of the case, the operator enters the PID plus the patient's height, weight and gender (for calculating blood volume). Calculations performed by the system for determining patient blood volume, bolus heparin dose, additional heparin dose, and protamine dose are summarized below.

Definitions and Terms

The following acronyms and abbreviations are used in this manual, instrument screens and printouts:

ACT	Activated clotting time (FTCA510/FTK-ACT)
AdditionalHepDose/Addl Hep	Additional heparin dose (units)
Base ACT	Baseline ACT (seconds)
Bld Vol, Blood Vol	Blood volume (mL)
Bolus Hep	Bolus heparin dose (units)
CalcDse	Calculated heparin dose (units)
Cur ACT	Most recent ACT result
EstBV	Estimated blood volume (mL)
Hep Gvn	Heparin dose given to the patient (units)
Hep Lvl	Patient heparin level (units/mL or mg/kg)
HiTT	High Dose Thrombin Time
HRT	Heparin Response Time (R-HRT480P/R-HRT480PK)
OID	Operator Identification Number
Pat Info	Patient demographics information
PDA-O	Protamine Dose Assay - Orange (PDAO/PDAOK)
PID	Patient Identification Number
PIN	Operator Personal Identification Number
PostBolusACT	ACT result following bolus heparin dose
ProtDose	Protamine dose (mg)
PRT	Protamine Response Time (R-PRT200/R-PRT200K) (R-PRT400/R-PRT400K)
Pump Hep	Amount of heparin added to the pump (units)
QC	Quality Control
Tot Hep/THep	Calculated total heparin dose given, including bolus dose heparin in the pump and additional heparin given (units)

Blood Volume Calculation

Blood volume can either be directly entered, or it can be calculated from the patient's height and weight. The system automatically calculates the blood volume once values for the patient's height, weight, and gender have been entered, using the algorithm described by Allen, et al.[1] If the patient's blood volume is entered by the operator, that value is used instead.

If the entered weight is less than 20 kg, the message **OUT OF RANGE WEIGHT** is displayed. The blood volume for the patient must then be manually entered.

Bolus Heparin Dose Calculation (Heparin Mode)

The bolus heparin dose is calculated using the baseline ACT, HRT, targeted ACT and patient blood volume, based upon standard dose response techniques described by Bull, et al. [2]

The bolus heparin dose is calculated if the baseline ACT and current HRT values are within these ranges:

- The baseline ACT must be within **70** to **250** seconds.
- The current HRT must be within **200** to **1,500** seconds, and at least **100** seconds greater than the baseline ACT.

***Note**: If a user-entered value is outside these ranges, an error message is displayed. If the calculated bolus heparin dose is greater than 6.7 units per mL of blood volume (or 5 mg/kg by body weight), a warning message is displayed.*

Additional Heparin Dose Calculation (Additional Heparin Mode)

After the bolus heparin dose is administered, any additional heparin doses can be calculated using the current ACT and heparin dose given, as described by Bull, et al. [2]

The additional heparin dose is calculated if the post bolus ACT, baseline ACT, target ACT, and current ACT values are within these ranges:

- The post bolus ACT must be greater than the baseline ACT.
- The target ACT must be greater than the current ACT.

***Note**: If the values are outside these ranges, a message is displayed.*

Protamine Dose Calculation (Protamine Mode)

The protamine dose is calculated using the PRT (or PDA-O), the most recent ACT, targeted ACT value and the patient's blood volume, as described by Bull, et al. [2]

When a PRT test is run, the protamine dose is calculated if the Current PRT and Status ACT values are within these ranges:

- The current PRT must be within **70** to **800** seconds.
- The status ACT must be within **200** to **1,500** seconds and greater than the PRT.

***Note**: If the values are outside these ranges, an error message is displayed.*

When a PDA-O test is run, the protamine dose is calculated if the Current PDA-O and Status ACT values are within these ranges:

- The current PDA-O must be within **70** to **300** seconds.
- The status ACT must be within **150** to **1,500** seconds and greater than the PDA-O.

***Note**: If the values are outside these ranges, an error message is displayed.*

If the calculated protamine dose is greater than **500** mg, a warning message is displayed. If the calculated protamine dose is greater than **800** mg, the message **Dose >800 mg** is displayed in place of the protamine dose.