



QUICK USER GUIDE

FOR

CAPILLARY BLOOD INR TESTING

USING THE

**THROMBI-STAT MC1 WB
INSTRUMENT**

AND

**MANCHESTER CAPILLARY
REAGENT**



INTRODUCTION

The combination of the Hart Biologicals Thrombi-stat MC1WB coagulation instrument and the Hart Biologicals Manchester Capillary Reagent is a well-established method for the efficient and cost-effective measurement of International Normalised Ratio (INR) in patients on Warfarin or other warfarin-like drugs in hospital outpatient clinics or community health centre or pharmacy clinics .

This **Quick User Guide** describes the steps required to:

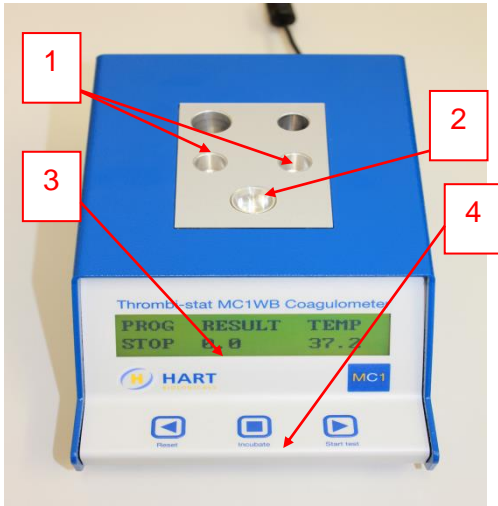
- Prepare the Manchester Capillary Reagent and CPC Control Plasma ready for use
- Prepare the Thrombi-Stat MC1WB instrument ready for use
- Perform pre-clinic Quality Control Testing
- Test patients attending the clinic.

Appendix 1 on Page 9 describes the Blood Collection procedure

Appendix 2 on Page 10 describes the procedure for checking ISI and MNPT values for accurate INR calculation.

Appendix 3 on Page 11 describes the support available to perform local calibration of ISI and MNPT if required.

VIEWS OF THE THROMBI-STAT MC1WB



1. Test Cup pre-warm stations
2. Measuring station for clot time measurement
3. Graphic display showing clot time, INR and test temperature.
4. Reset, Incubation and Start Test keys for instrument operation.
5. Main On/Off power switch
6. Power Supply connection socket
7. RS232 Interface connection for printer or PC connection

VIEWS OF THE MANCHESTER CAPILLARY REAGENT AND

QUALITY CONTROL PLASMA BOXES AND VIALS



- Manchester Capillary Reagent available in 3 convenient pack sizes

HB-1101-FG	5 x 6.0ml vials	-	48 tests per vial
HB-1190-FG	5 x 3.0ml vials	-	24 tests per vial
HB-1133-FG	5 x 1.5ml vials	-	12 test per vial

- Capillary Control Plasmas are available at 3 levels

HB-4411-FG	10 x 0.5ml vials	-	Normal
HB-4412-FG	10 x 0.5ml vials	-	Level 1
HB-4413-FG	10 x 0.5ml vials	-	Level 2

OTHER ITEMS REQUIRED

- Purified water for the reconstitution of control plasmas
- Test cups and balls (pack of 1000). Available from Hart Biologicals, part number HB-1123-FG
- 25ul pipettes for capillary blood sample collection. Available from Hart Biologicals, part number HB-1109-FG
- 125ul pipette for reagent dispensing. Available from Hart Biologicals, part number HB-1110-FG
- Pipette tips suitable for use on the 25ul and 125ul pipettes, part number HB-1172-FG or HB-1116-FG
- Single use lancets for finger prick blood sampling—must be suitable for coagulation sample collection, part number HB-1169-FG or HB-1170-FG
- RAID Express computer dosing software (optional—available as an on-line download). Connects to the Thrombi-stat MC1WB via the RS232 port for automated INR transfer, part number HB-1142-FG

PRE-CLINIC SETUP

- Remove the required quantity of Manchester Capillary Reagent and Reconstitution Fluid vials from the fridge and allow to warm to room temperature—this can be done the night before the clinic day. This is important as the Reagent contains fibrinogen, which can precipitate if it is too cold on reconstitution .
- To reconstitute the Reagent, simply pour the contents of the Reconstitution Fluid in to the lyophilised powder vial. Mix by gentle inversion and allow to stand for at least 15 minutes. Mix well before use and during use.
- Remove the required Capillary Control Plasma from the fridge and allow to warm to room temperature before use. Reconstitute each vial with 0.5ml of purified water and allow to stand for at least 15 minutes. Mix by inversion before use.
- Ensure sufficient test cups, balls, pipette tips and lancets are available for the number of patients expected in the clinic.
- Check that the correct ISI and MNPT are programmed in to the Thrombi-stat MC1WB for accurate INR calculation. These change with each new batch of the Manchester Capillary Reagent. Instructions for checking and changing these values are given in Appendix 2 on Page 10.

CLINIC SETUP

- Switch on the Thrombi-stat MC1WB and allow to warm to 37°C (approximately 15 minutes).
- While the Thrombi-stat MC1WB is warming, reconstitute the required vials of Manchester Capillary Reagent (see Page 6).
- While the Thrombi-stat MC1WB is warming, reconstitute the required vials of QC plasma (see Page 6)—if no dedicated 0.5ml pipette is available, 4 x 125µl dispenses of purified water from the Reagent Pipette can be used.
- While the Thrombi-stat MC1WB is warming, place the required number of test cups to cover the number of patients plus QC testing in to a tray and dispense a ball in to each cup.
- Mix the Manchester Capillary Reagent well and dispense 125µl on to each of the test cups.
- Insert one test cup in to the Measuring Station of the Thrombi-stat MC1WB and allow to warm for 60 seconds.
- Test the QC plasma—if results are in range, continue to test patients.

PATIENT TESTING

- Place 1 test cup in the Measuring Station of the Thrombi-stat MC1WB (see position 2 on Page 3) and allow to warm for 60 seconds before the first test.
- Collect a fresh Capillary Blood Sample (25µl) from the patient.
- Within 15 seconds of blood collection:
 - ⇒ Press 'Reset' on the keypad and the display will flash for 5 seconds.
 - ⇒ While the display is flashing, transfer the blood sample in to the cup containing Manchester Capillary Reagent in the Measuring Station.
 - ⇒ At the same time as transferring the blood sample, press the 'Start Test' button. The timer will start.
- Once the clot is detected, the display will show the INR and the clot time.
- Remove the completed test cup and replace with a fresh one ready for the next patient. Repeat the test procedure for each patient.

APPENDIX 1 – CAPILLARY BLOOD COLLECTION

Sample collection is the most important aspect of accurate INR testing from capillary blood:

Wash Sample Site

- Have the patient wash their hands in warm soapy water, or clean the sample fingertip with an alcohol wipe. Make sure the sample finger is thoroughly dry.

Prepare For Blood Sampling

- Increasing blood flow to the finger will help with the collection of a good drop of blood
- Ensure the hand is warm before sample collection.
- Ask the patient to let the sampling arm hang down by their side.
- Massage the sampling finger from base to tip to ensure good colour of the sample site.

Collect The Sample

- Prepare the lancet
- Perform one last massage of the finger to ensure good colour
- Place the lancet firmly in contact with the skin of the finger and press the trigger button.
- In a single movement, squeeze from the base of the finger to develop a discrete blood drop.
- Carefully collect 25µl of blood and immediately (within 15 seconds of lancet use) transfer to the test cup of the Thrombi-stat MC1WB and start the test.
- If the blood does not flow easily, DO NOT continue to squeeze the finger – this can cause erroneous results.
- Ask patient to apply pressure to the sample site to stop the bleeding.

APPENDIX 2 – CONFIRMATION OF CORRECT ISI AND MNPT VALUES

For correct INR calculation by the Thrombi-stat MC1WB, it is important that the instrument is programmed with the correct ISI and MNPT values at the start of each new batch of reagent. The ISI and MNPT values are supplied in each box of Manchester Capillary Reagent. To check or change the values, undertake the following steps:

- With the machine switched OFF, press the centre 'INCUBATE' button on the keypad while simultaneously switching the POWER button (Number 5 on Page 3) to 'ON'
- Hold the 'INCUBATE' button until 2 'beeps' are heard, then release the 'INCUBATE' button.
- The 'SETTINGS-MENU: INR-Standard' should appear.
- Press the 'INCUBATE' button
- The 'INR Std-Value' screen appears.
- Using the arrow indicators on the 'RESET' and 'START TEST' buttons, change the number to the MNPT value supplied with the Manchester Capillary PT Reagent lot.
- Press the 'INCUBATE' button to accept this value.
- The 'ISI-value' screen now appears.
- Using the arrow indicators on the 'RESET' and 'START TEST' buttons, change the number to the ISI value supplied with the Manchester Capillary PT Reagent lot.
- Press the 'INCUBATE' button to accept this value.
- The 'SETTINGS-MENU' screen appears again.
- Using the arrow indicators on the 'RESET' and 'START TEST' buttons, move to the 'QUIT' screen.
- Press the 'INCUBATE' button to save the entered changes.
- Press the 'RESET' button to confirm 'YES' to Result Calculation
- The Thrombi-stat MC1WB is now ready for use.

APPENDIX 3 – CALIBRATION OF LOCAL ISI AND MNPT VALUES

An advantage of the Thrombi-stat MC1WB system for measuring INR is the ability to align results of the capillary INR method to the laboratory coagulometer INR results if required.

There are a number of ways to do this, and Hart Biologicals can help advise the method most appropriate for your laboratory or clinic.

For more information on the best way to align the Thrombi-stat MC1WB system to your laboratory coagulometer, please contact Hart Biologicals Technical Support at:

Email : technical@hartbio.co.uk

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Note: Because of differences between capillary blood and venous blood, plasma versus whole blood testing and differences between different thromboplastins, undertaking local alignment can improve agreement significantly, but there will always be some differences.

CONTACT DETAILS

For more information on any part of this Quick User Guide, please contact Hart Biologicals Technical Support at:

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