Royal Cornwall Hospitals
NHS Trust

Hemochron POCT ACT Analyser during Vascular Surgery
Standard Operating Procedure

V2.0

April 2025

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Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. The Hemochron Signature Elite Point of Care Testing (POCT) instrument has been approved for use within Vascular anaesthesia to monitor heparin therapy associated with Vascular surgery. The instrument utilizes a mechanical endpoint detection mechanism to detect clot formation occurring within a disposable single-use cuvette to measure the activated clotting time at the low range (ACT-LR).

1.1. The operator inserts a cuvette for the test into the instrument; the cuvette warms to 37°C ± 1.0°C. Following whole blood sample introduction to the cuvette, the instrument precisely measures and transfers 15µL of blood into the cuvette test channel (the remainder of the blood sample is automatically drawn into the waste channel of the cuvette). Sample / reagent mixing, and test initiation are performed automatically and the test sample is moved back and forth at a predetermined rate within the test channel and monitored for clot formation.

1.2. The clot detection mechanism utilises LED optical detectors that are aligned with the test channel of the cuvette. The speed at which the blood sample moves between the detectors is measured and as clot formation begins, blood flow is impeded, and the movement slows. The instrument recognizes that the clot endpoint has been achieved when the movement decreases below a threshold rate. Electronic optical detection of a fibrin clot in the blood sample automatically terminates the test. The instrument's digital timer measures the elapsed time between the start of the test and the clot formation. At the end of the test, the instrument displays the ACT-LR time in seconds.

2. Purpose of this Standard Operating Procedure

2.1. The purpose of this policy is to ensure that consistent procedures are in place throughout the Royal Cornwall Hospitals NHS Trust to reduce to a minimum the risk to patients and staff from errors that may occur from the use of this device.

2.2. This policy is designed to ensure that the POCT systems used within RCHT are managed in accordance with national guidelines and accreditation standards. It is also designed to ensure that the introduction of new POCT technology is appropriate and consistent across the Trust

2.3. The policy has been produced using:

- UKAS: Clinical Pathology Accreditation Guidelines.
- ISO:22870 / ISO:15189.
- Management and Use of IVD Point of Care Test Devices: Medicines and Healthcare Products Regulatory Agency (MHRA), MDA DB2002(3).
- CQC Regulation 15: Premises and Equipment.

3. Ownership and Responsibilities

3.1. Role of the Managers

Line managers are responsible for:

- Ensuring staff are aware of their personal responsibilities with regard to training and the use of Hemochron ACT monitor.
- Ensuring that staff are trained and competent to use POCT devices.
- Keeping records of training and competency.
- Ensure that all users carry out quality control and quality assurance as advised.
- Point of Care Testing Policy.
- Nominating a key person to assist training new users and oversee day to day operation of POCT within their area.

3.2. Role of Individual Staff

All staff members are responsible for:

- They only use POCT equipment after adequate training and if personally confident in their competence to do so.
- Their training and competency records are kept up to date.
- Training and assessment will be undertaken online via the Werfen academy.
- Standard operating procedures are followed, including sample handling, running quality checks, recording results.
- Abnormal or unusual patient results are reported to the person responsible, without delay.
- Problems with a device, or any part of a procedure are reported as soon as possible to the person in charge or the POCT Team/medical physics.
- Sharps and consumables are disposed of immediately and in accordance with Trust Waste Disposal Policy.
- Equipment and workstations are kept clean in accordance with Trust Control of Infection Policy.

4. Standards and Practice

4.1. Quality Control

4.1.1. Method

4.1.1.1. Electronic QC Check (EQC) provides a two-level electronic verification of instrument performance plus a verification of the temperature. If one result fails, the test will stop and all results will be recorded as “failed”. It is required every 8 hours of patient testing, and the Hemochron will lock out operation if it is not performed (if the meter is kept switched on). EQC will be performed automatically if the Hemochron is plugged into the AC/DC power module and is turned on. Routinely, however, the meter is not kept turned on, so EQC should be performed manually on a daily basis. To perform an EQC manually press the QC button followed by the 1 key. When the test is completed, results will be displayed and written to the QC database. Press the CANCEL button to exit the screen. All results of the EQC test should be recorded on the daily QC chart kept with the Hemochron.

4.1.2. Liquid QC Checks

Normal and abnormal liquid quality controls (LQC) are performed:

- With each new shipment / lot of cuvettes.
- Every 30 days.
- When a shift in clinical results is suspected.

4.1.3. Procedure:

4.1.3.1. Remove the ACT-LR test cuvettes and the Direct Check vials (normal and abnormal control material) from the refrigerator; to come to room temperature; this may take up to 60 minutes.

4.1.3.2. Check expiry date on all reagents and visually inspect the control vials to ensure that the glass ampoule is intact.

4.1.3.3. After reagents have reached room temperature, insert an ACT-LR cuvette into the cuvette slot on the side of the Hemochron.

4.1.3.4. If LQC is due, select the QC being run (QC Normal / QC Abnormal). If LQC is not ‘due’ but is being run, press the QC key and select QC Normal / QC Abnormal. If the QC key / level of QC is not selected, the Hemochron will identify the test as a patient test.

4.1.3.5. When LQC is due, the Hemochron will lock-out operation.

4.1.3.6. The Hemochron will signal when ready with an audible tone (beep) and the display will indicate “ADD SAMPLE” and “PRESS START.”

4.1.3.7. Reconstitute the QC dropper vial (begin with the normal level):

4.1.3.8. Remove the top of the plastic seal from the QC vial.

4.1.3.9. Insert the QC vial into the white protective sleeve.

4.1.3.10. Holding the vial upright, tap the QC vial on the table top to settle the inner glass ampoule to the bottom of the vial.

4.1.3.11. Crush the inner glass ampoule by either bending the vial over the edge of a table top or by crushing the vial between two fingers.

4.1.3.12. Immediately repeat the crushing action one to two additional times to ensure complete breakage of the glass ampoule.

4.1.3.13. Quickly invert the dropper vial end to end.

4.1.3.14. While inverting the vial (dropper tip down), use a downward snapping motion of the wrist to ensure the control material flows to the dropper tip.

4.1.3.15. Remove and retain the vial cap.

4.1.3.16. Squeeze the vial to discard the first drop of control material into the vial cap.

4.1.3.17. Immediately dispense as many drops of control material as needed to fill the cuvette sample well flush to the top. Should a large dome extend over the top of the centre sample well, push it over into the outer sample well.

4.1.3.18. Press the START key on the Hemochron.

4.1.3.19. Recap the control vial and remove the vial from the protective sleeve. Discard the vial and vial cap in a sharps bin; retain the protective sleeve for reuse.

4.1.3.20. Wait for a single beep signalling the end of the test. (Two beeps indicate a fault condition).

4.1.3.21. The result is displayed as the Celite equivalent clotting time. Document the QC result. Note: The Hemochron Signature Elite® may be programmed for the result to display as “Pass” or “Fail”.

4.1.3.22. Compare the result with the acceptable range published on the Direct Check package insert in use.

4.1.3.23. Repeat the procedure using the abnormal liquid QC material.

4.2. **Invalid Quality Control result(s)**

When QC results are outside the acceptable range, verify the following immediately:

- Ensure that controls and cuvettes have not expired. If expired, discard and repeat the tests with new reagents / cuvettes.
- Ensure proper Hemochron temperature; perform the instrument temperature verification procedure (EQC).
- Ensure proper technique. The timing from crushing the vial to pressing the START key is critical.
- Ensure adequate cuvette sample volume.
- Check the control material for the presence of clots. If present, repeat the procedure using freshly prepared samples of control material.
- If the procedure is repeated with new reagents / cuvettes and the QC results continue to be outside the acceptable range, DISCONTINUE USE OF THE INSTRUMENT AND REPORT THE FAULT - The Hemochron / cuvettes must NOT be used for patient testing until all control values are within the acceptable range. Document all faults and corrective actions.

[Hemochron Signature Elite QC Testing Guide]

4.2.1. **Method**

4.2.1.1. Identify the patient by asking them to confirm their name and Date of Birth.

4.2.1.2. Turn on the Hemochron by pressing the start button.

4.2.1.3. Insert the ACT-LR cuvette into the cuvette opening on the side of the Hemochron – check the expiry and integrity of the cuvette pouch. The Hemochron will identify the cuvette inserted and display the test name. The Self-Check will be initiated.

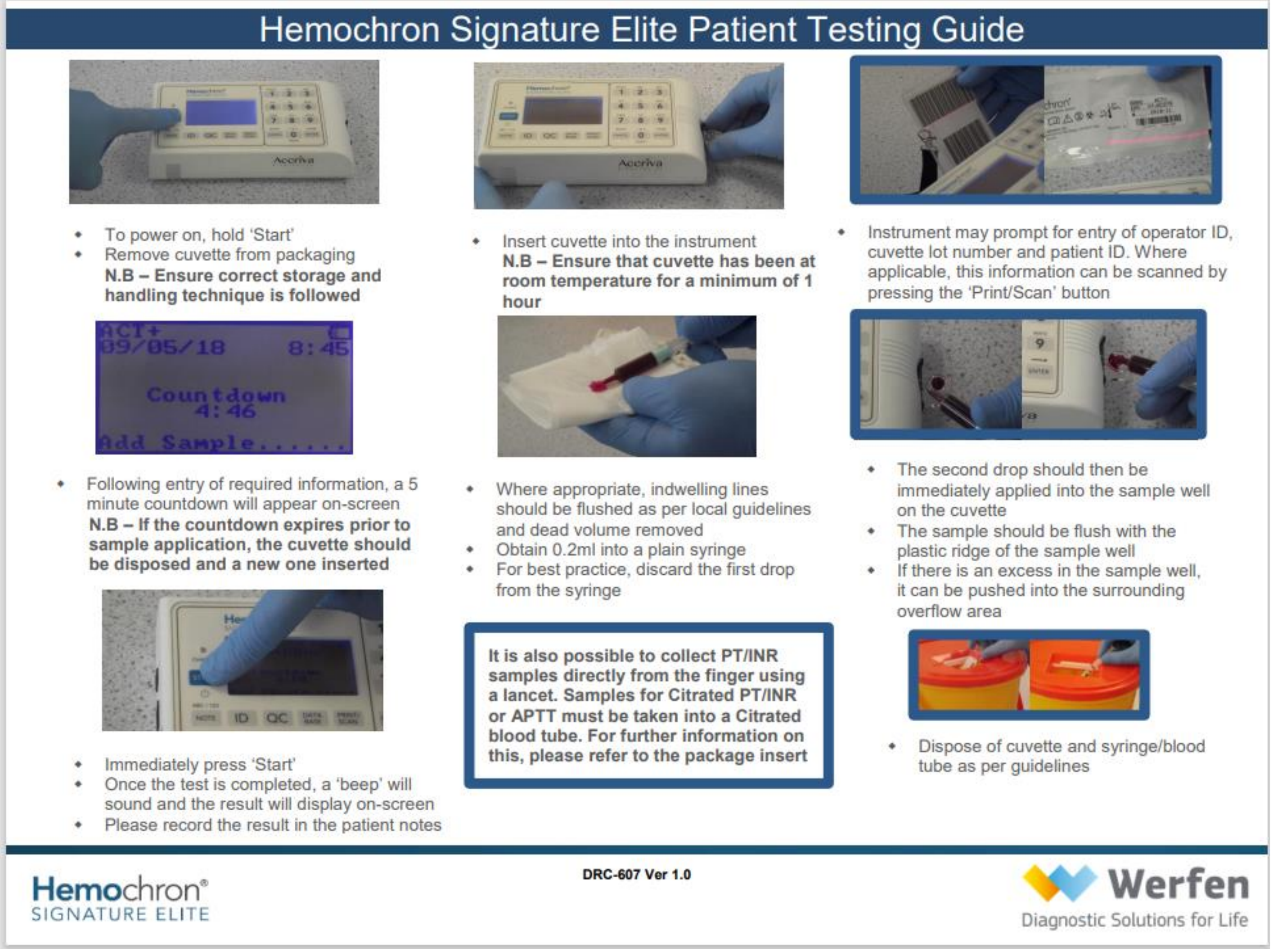
4.2.1.4. Enter or scan the patient’s ID at the PID prompt. If scanned, the PID will be automatically stored. If manually entering the PID, press ENTER until stored is displayed on the screen – CHECK THE DETAILS ARE ACCURATE.

4.2.1.5. The Hemochron will signal when ready with an audible tone (beep) and the display will indicate “ADD SAMPLE” and “PRESS START.” The Hemochron will remain in the ready mode for five minutes. At the end of five minutes, a “START TIMEOUT” will occur indicating that the current cuvette must be discarded, and new cuvette placed in the cuvette opening.

4.2.2. **Collect Sample**

- Observe appropriate RCHT recommendations regarding personal protection.
- Clean the 3-way tap.
- Draw off 5 – 10mls of blood and discard.
- When the machine says, “ADD SAMPLE” Immediately dispense one drop of blood into the sample well of the cuvette. Fill the sample well from the bottom up with whole blood. A sufficient quantity of blood must be added directly to the centre of the sample well to fill it flush to the top. Should a large drop of blood extend over the top of the centre sample well, creating a dome, push it over into the outer sample well. Note: When transferring blood into the sample well:
  - Do NOT force blood into the pin located on the centre of the sample well.
  - Do NOT generate air bubbles in the sample well.
- Press the START key on the Hemochron. Test completion will be indicated by a single beep. The ACT-LR result is automatically converted to a reference Celite ACT result and displayed as the Celite equivalent result in seconds.
- Enter a note(s) if applicable. Up to 2 operator selectable notes can be added to the patient record for each test; the note will be recorded in the final record. A cuvette must be in the Hemochron to enter a note.

- To enter a note, press the NOTE key. Type the number of the predefined note(s) or press the NOTE key repeatedly until the desired note is displayed.
- Press ENTER. Press CANCEL to return to normal operation.
- Write the result into the patient's notes, noting the date, time and name of the person performing the test, as well as the results and their units (seconds).
- Remove the test cuvette and discard appropriately.



Hemochron Signature Elite Patient Testing Guide

4.2.3. Reporting of Results

- All results must be documented in the patient's notes
- A result that exceeds "400 seconds" and reads "out of range Hi" is reported as "greater than 400" if the result is expected.
- If any result is inconsistent with patient therapy, repeat the test.
- If the result is "out of range Lo", repeat the test with a new sample and new cuvette.

4.3. Troubleshooting guide

Hemochron Signature Elite Troubleshooting Guide

Error	Description	Likely Cause	Preventative Action	If Error Persists
STL	Sample too large	Too much sample has been aspirated from the central sample well	If meniscus of blood extends over the central well, push the excess blood into the overflow area using the syringe.	Contact POCT/key user for further support
STS	Sample too small	Insufficient sample has been aspirated from the central sample well	Ensure blood is level with the plastic ridge surrounding the central sample well, volume required is 15uL.	Contact POCT/key user for further support
SNS	Sample not seen	Sample has not reached the front detector in specified time period	Ensure that sample is added within the time period, any air gaps/bubbles will prevent sample aspiration.	Contact POCT/key user for further support
Detector Blocked	Detector blocked (during EQC)	A foreign body (likely a cuvette) is inside the analyser during EQC	Remove the cuvette from the instrument and re-run the EQC, if no cuvette is inserted please call the helpline.	Contact helpline
EQC Fail	EQC failure	The temperature/led intensity required for analysis exceeds the acceptable ranges	Re-run EQC ensuring ambient temperature is acceptable. If there is evidence of blood entering the instrument, see below.	Contact helpline
Visible Blood	Blood forced into instrument	Blood has been forced into the instrument in error	Assess instrument performance by running EQC and LQC. If either fail, the instrument should not be used and service is recommended.	Contact helpline
LQC Fail	LQC failure	LQC result has not fallen within the acceptable range	Ensure vial has been at room temperature for 1 hour and reconstitution is completed to manufacturer requirements.	Refer to QC Quick User Guide
Assay/Machine Locked	Instrument has been Locked	Either the EQC/LQC failure limit has been reached	The instrument will need to be connected to Configuration Manager so it can be unlocked.	Contact POCT/helpline
Access Denied	Operator ID not accepted	Operator ID/barcode has not been granted access to the Hemochron Signature Elite	Ensure user has received training to required local standard. Contact POCT/key user so user can have access authorised.	N/A
Out of Range-Lo	Test result is outside clinical range	Sample has clotted or did not mix in the cuvette correctly	Repeat test with a fresh sample/cuvette ensure sample pre-analytics are completed correctly.	Refer to Patient Quick User Guide/Package Insert
Out of Range-Hi	Test result is outside clinical range	Heparin/citrate contamination or incorrect cuvette used for Heparin dose	Repeat test with a fresh sample/cuvette ensuring sample pre-analytics are completed correctly including dead volume removal.	Refer to Patient Quick User Guide/Package Insert
ACT/INR Query	ACT/INR result is lower than expected	There has been a delay from sample collection to the start of analysis	Repeat test with a fresh sample/cuvette ensuring there is no delay. Ensure the instrument has started the countdown prior to sample collection.	Refer to Patient Quick User Guide/Package Insert

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DRC-608 Ver 1.0

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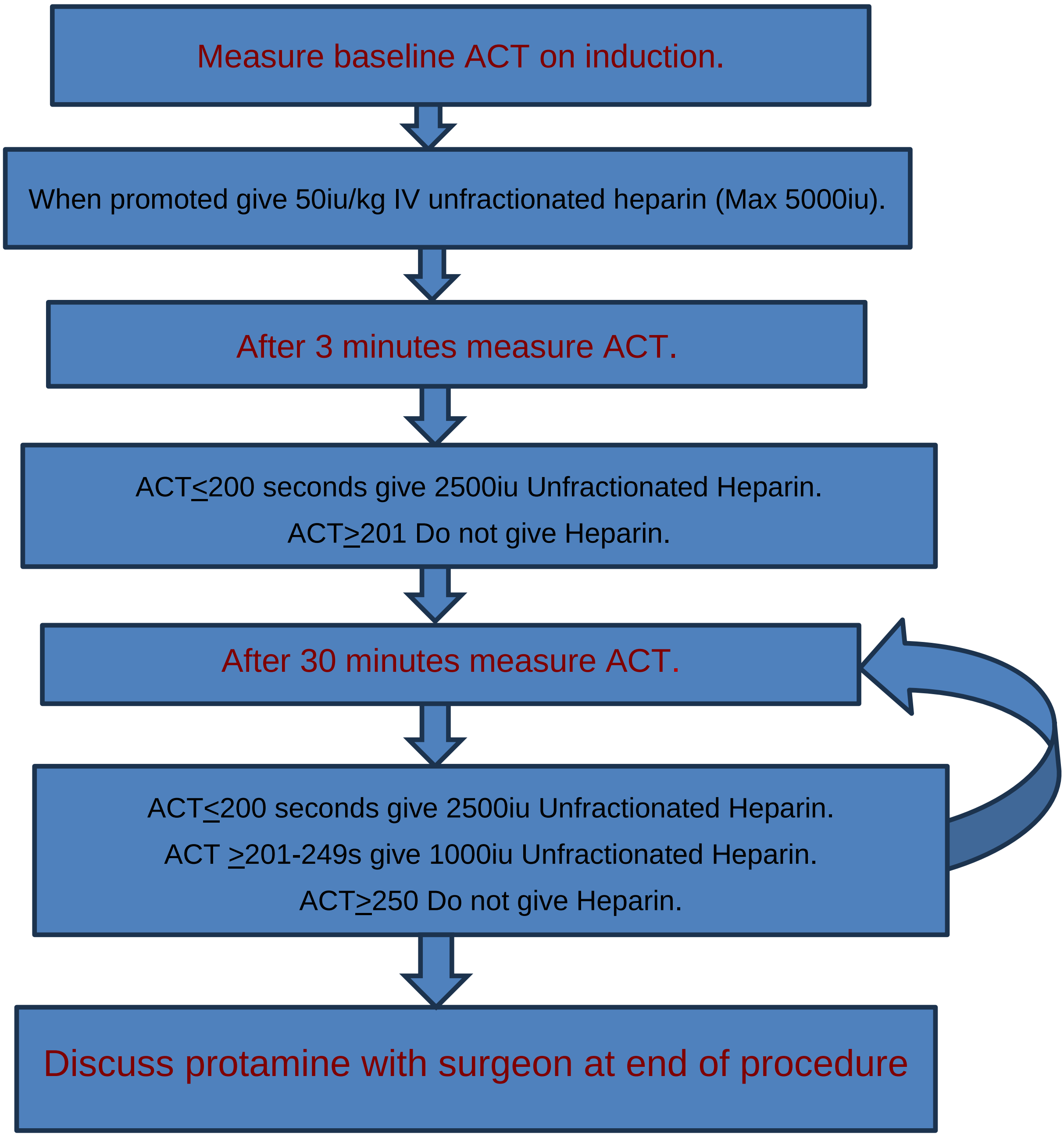
[Hemochron Signature Elite Troubleshooting Guide](#)

4.4. **Heparin Bolus flow chart for Vascular Surgery**



4.4.1. If the ACT at closure is 200-250 sec., 25 mg protamine should be administered. If >250 sec., 50 mg protamine. If 180-200 sec., 10 mg protamine. 5 min. after the administration of protamine, the ACT is measured. The ACT should preferably be below 180 sec. If the ACT is still more than 200 sec., protamine should be administered again.

4.4.2. **Note:** protamine – usually given undiluted, by slow IV injection or infusion at a rate not exceeding 5mg /min. Faster rates are associated with severe hypotension and anaphylactoid reactions. The maximum dose is 50mg over a ten minute period. Total doses exceeding 6mg/kg have an anticoagulant effect).

5. Dissemination and Implementation

5.1. Vascular anaesthesia consultants and ODPs will be trained to perform ACT measurements.

5.2. This document will be freely available on the trust Intranet and its contents discussed at governance and audit meetings.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Quality assurance of ACT monitor
Lead	Dr David Elliott
Tool	Local QC will be undertaken as per manufacturers recommendation. External Quality assessment (EQA) will be performed by NEQAS with 2 samples assessed quarterly.
Frequency	Local QC will be undertaken as per manufacturers recommendation. External Quality assessment (EQA) will be performed by NEQAS with 2 samples assessed quarterly.
Reporting arrangements	Report to Care Group Director of Anaesthesia. Report to Anaesthetic Clinical Governance meeting. Clinical Governance meeting minutes to record outcome and actions identified. POCT committee if necessary.
Acting on recommendations and Lead(s)	Anaesthetic directorate to identify recommendations and actions. Actions to be undertaken and completed within 6 months.
Change in practice and lessons to be shared	Required changes to practice will be identified and action taken within 6 months. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

7. Updating and Review

This Standard Operating procedure (SOP) will be reviewed every three years or sooner if a change in practice or equipment is implemented.

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Hemochron POCT ACT Analyser during Vascular Surgery Standard Operating Procedure V2.0
This document replaces (exact title of previous version):	Hemochron POCT ACT Analyser during Vascular Surgery Standard Operating Procedure V1.0
Date Issued/Approved:	14 April 2025
Date Valid From:	April 2024
Date Valid To:	April 2028
Directorate / Department responsible (author/owner):	Dr David Elliott, Consultant Anaesthetist
Contact details:	David.elliott9@nhs.net
Brief summary of contents:	Standard Operating Procedure for the use of the Hemochron ACT monitor during vascular surgery.
Suggested Keywords:	Anaesthesia, Vascular surgery, Heparin, Clotting ODP, Theatres.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	ACCT Care Group
General Manager confirming approval processes:	Doug Riley
Name of Governance Lead confirming approval by specialty and care group management meetings:	James Masters
Links to key external standards:	None
Related Documents:	None required
Training Need Identified?	Yes- Online training provided by Werfen

Information Category	Detailed Information
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Anaesthetics

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
17/01/2022	V1.0	Initial issue	Dr David Elliott, Consultant Anaesthetist
09/04/2025	V2.0	Reviewed- no changes	Dr David Elliott, Consultant Anaesthetist

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Hemochron POCT ACT Analyser during Vascular Surgery Standard Operating Procedure V2.0
Directorate and service area:	ACCT
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dr David Elliott, Consultant Anaesthetist
Contact details:	David.elliott9@nhs.net

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To Ensure the accurate measurement of activated clotting time in adult vascular surgery patients.
2. Policy Objectives	To Ensure the accurate measurement of activated clotting time in adult vascular surgery patients.
3. Policy Intended Outcomes	To Ensure the accurate measurement of activated clotting time and safe administration of heparin in adult vascular surgery patients.
4. How will you measure each outcome?	Audit and discussion of unexpected intraoperative vascular thrombosis cases at governance and, mortality and morbidity meetings and
5. Who is intended to benefit from the policy?	Adults (including young adults 16+ years) undergoing vascular anaesthesia

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	Workforce: Yes Patients/ visitors: No Local groups/ system partners: No External organisations: No Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Leads for Vascular surgery and anaesthesia.
6c. What was the outcome of the consultation?	No consultation required.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Dr David Elliott, Consultant Anaesthetist.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. References

A Standardized Bolus of 5 000 IU of Heparin Does not Lead to Adequate Heparinization during Non-cardiac Arterial Procedures Orkun Doganer,1,2 Vincent Jongkind,1,2 Jan D. Blankensteijn,2 Kak Khee Yeung,2 and Arno M. Wiersema,1,2 Hoorn and Amsterdam, the Netherlands Ann Vasc Surg 2021; 71: 280–287 https://doi.org/10.1016/j.avsg.2020.07.035

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RCHT Thrombosis Prevention And Anticoagulation Policy.

Guide to Anticoagulant Therapy: Heparin

A Statement for Healthcare Professionals From the American Heart Association

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Originally published19 Jun 2001https://doi.org/10.1161/01.CIR.103.24.2994Circulation. 2001;103:2994–3018

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