

**COPY**

**Summary of Significant Changes at this Revision**

Remove the patient record log  
 Include an abnormal iQC record table for acceptance testing of cartridges.  
 Removal of reference to generic log in , removal of use of printer.

**Purpose and Scope**

The TEG 6 device is a non-invasive diagnostic instrument designed to monitor and analyse the coagulation state of a blood sample in order to assist in the assessment of patient clinical haemostasis conditions.

**Items Required**

TEG6 analyser  
 Citrated Haemonetics cartridges & transfer pipettes  
 Quality control cartridges level 1 & 2  
 Citrate sample tubes  
 Abnormal iQC samples

**Definitions and Abbreviations**

- TEG6 = Thromboelastography
- POCT = Point of Care Testing
- CK = Citrated Kaolin
- CRT = Citrated RapidTEG
- CKH = Citrated Kaolin with Heparinase
- CFF = Citrated Functional Fibrinogen
- R (min) = Reaction time.
- K (min) = The speed of formation of the clot from R time to a specific clot strength
- Angle (deg) = The speed of the clot strengthening
- MA (mm) = Maximum amplitude.
- iQC = Internal Quality Control
- QC = Quality Control
- EQA = External Quality Assurance

**Grade / Qualifications**

Medical staff: All grades  
 Nursing Staff: All Trained operators  
 Health Care Assistants: All trained operators  
 Biomedical Scientists – all grades

**Competencies Required:**

Certificate produced from College of TEG

**Safety Precautions for This Procedure:**

- Training for use of TEG6
- Needle stick injury policy
- Immunizations
- PPE
- Sharps Disposal policy
- Procedure for spillages of body fluids
- Local Health and safety policy
- EQA screened for HIV and Hepatitis
- Analyser cannot be used without valid iQC

**Risk Assessment:**

**Current Version of:** RA/POCT/7 found on the intranet

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STANDARD OPERATING PROCEDURE SOP/POCT/61/2

Title: Haemonetics TEG6 POCT analyser

Effective date: 10/11/2022

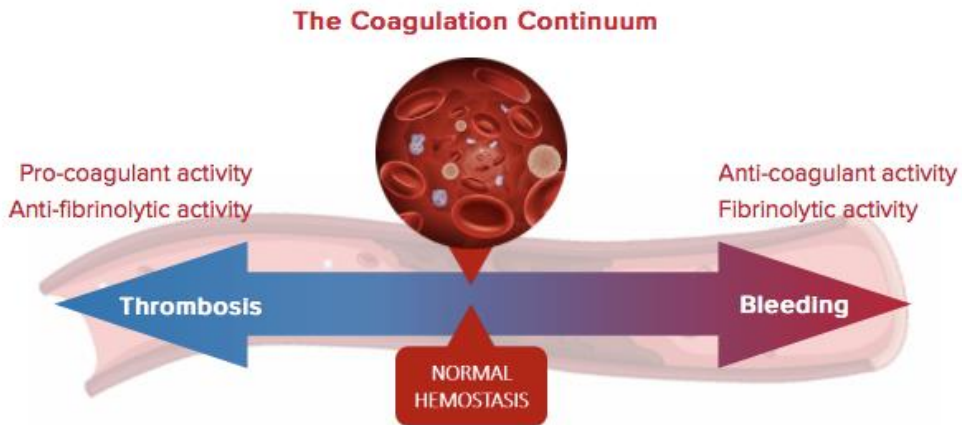
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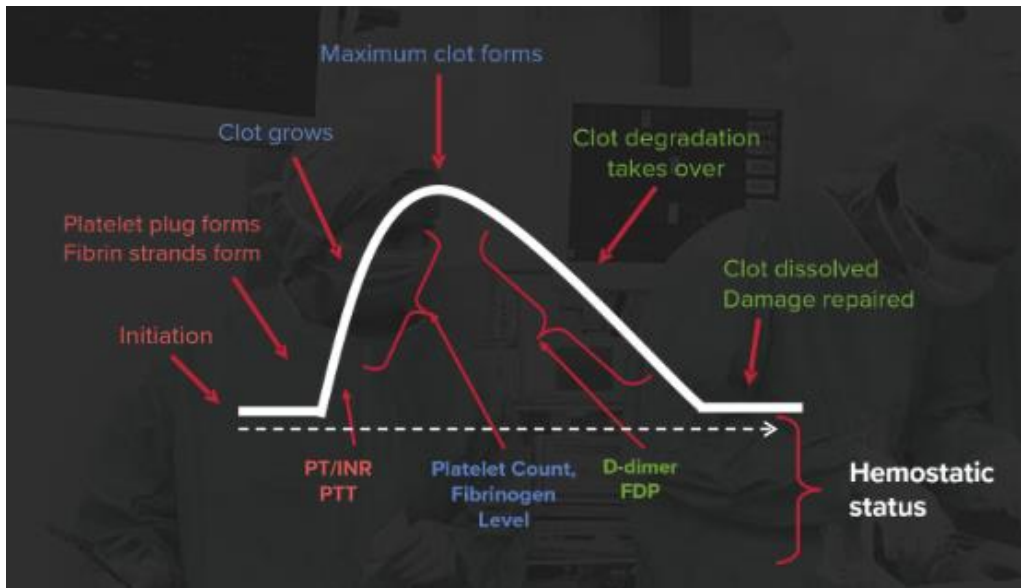
### Clinical Relevance/Purpose and Limitations of the Examination

The TEG 6 device is a non-invasive diagnostic instrument designed to monitor and analyse the coagulation state of a blood sample in order to assist in the assessment of patient clinical haemostasis conditions. The TEG 6 is indicated for use with adult patients. Results from the TEG 6 should not be the sole basis for patient diagnosis but should be considered together with the patient’s medical history, clinical status and, if necessary, other coagulation tests.

Maintaining coagulation haemostasis requires a fine balance of many elements to ensure a patient does not have complications from bleeding or thrombosis.



Traditional coagulation tests are based on the coagulation cascade and provide a limited view of haemostasis not reflecting real time in vivo states.



Viscoelastic testing assesses the dynamic mechanical properties of a clot during its initiation, amplification and propagation and fibrinolysis. The TEG 6 system and the citrated multichannel cartridge are used to test the haemostasis properties of citrated blood samples using 4 different assays/reagents simultaneously:

- a) CK assay – kaolin-activated test methods are used to reduce variability and to reduce the running time of a native whole blood sample
- b) CRT assay – maximally accelerates the clotting process by simultaneously activating the intrinsic and extrinsic coagulation pathways, allowing for maximum clot strength to be reached more quickly
- c) CKH assay – similar to CK but with the addition of heparinase to neutralise the effect of heparin in the blood. If heparin is present the R time for CK will be significantly longer than the R time for CKH
- d) CFF assay – inhibits platelet aggregation, excluding its contribution to clot strength, and thereby measures fibrinogen contribution to clot strength

## 1 Principle and Method of the Procedure Used For the Examination

The TEG system technology is the measurement of clot viscoelasticity using a resonance method. To measure the clot strength with the resonance method, the sample is exposed to a fixed vibration frequency. With LED illumination, a detector measures up/down motion of the blood meniscus. The frequency leading to resonance is identified and then converted to the TEG system readout. Stronger clots have higher resonant frequencies and higher TEG readouts.

**CK principle** - particles of hydrated aluminium silicate shorten coagulation times because kaolin acts as a contact surface activator (intrinsic pathway) which activates Factor XII and platelets and stimulates the reserve clotting ability of a blood sample. Kaolin is combined with  $\text{CaCl}_2$  to neutralise any sodium citrate in the blood.

**CRT principle** – the clotting process is accelerated by simultaneously activating the intrinsic and extrinsic coagulation pathways using a high concentration of kaolin and Tissue Factor.  $\text{CaCl}_2$  is included to neutralise any sodium citrate in the blood.

**CKH principle** – Heparin is commonly used in surgical procedures. The presence of heparin can noticeably increase the R time making it difficult to monitor developing coagulopathies that may be masked by high levels of heparin. The Kaolin with Heparinase assay rapidly and specifically neutralises the anticoagulant effect of heparin. Calcium chloride ( $\text{CaCl}_2$ ) is included to neutralise any sodium citrate in the sample.

**CFF principle** – The functional fibrinogen reagent activates the extrinsic pathway using tissue factor and inhibits platelet aggregation using a platelet inhibitor that binds to GPIIb/IIIa receptors, thereby measuring fibrinogen contribution. Functional fibrinogen is combined with  $\text{CaCl}_2$  to neutralise any sodium citrate in the blood.

### 1.1 Limitations and Interferences

TEG analyser results should always be considered within the clinical context of the individual patient's case. In the event of inconsistencies with the patient's clinical status, samples should be repeated or supplemented with additional clinical information.

**CK** Assay was tested for interference factors according to CLSI EP7-A2. Potential interfering factors tested were Absence of a Discard Tube, Short Draw, Haemolysis, Haemodilution, and epsilon aminocaproic acid (EACA). Only Haemolysis and Haemodilution levels above 20% were found to be interfering factors.

**CRT** assay was tested for interference factors according to CLSI EP7-A2. Potential interfering factors tested were Absence of Discard Tube, Short Draw, Haemolysis, Haemodilution, and epsilon aminocaproic acid (EACA). All Except EACA and Absence of Discard Tube were found to be interfering factors, with Haemodilution being an interfering factor above 30% concentration.

**CKH** assay was tested for interference factors according to CLSI EP7-A2. The potential interfering factor tested was Protamine. Results show that Protamine is an interfering factor at concentrations above 0.062mg/mL.

**CFF** assay was tested for interference factors according to CLSI EP7-A2. The potential interfering factors tested were Heparin and Haemodilution. Heparin was found to be an interfering factor for the Functional Fibrinogen above Heparin concentrations of 1 IU/mL, and Haemodilution was found to be an interfering factor above Haemodilution levels of 40%.

## 2 References and Definitions

### 2.1 References

- TEG6s Hemostasis System User Manual (PDF) EXT/POCT/12
- Package Insert for Haemonetics Citrated Cartridges (PDF) EXT/POCT/13
- Package Insert for Haemonetics quality control cartridges (PDF) EXT/POCT/13
- Package Insert for Haemonetics abnormal quality control (PDF) EXT/POCT/13
- TEG6 Competency: Certificate produced from College of TEG
- TEG iQC log (Appendix 1)
- TEG Abnormal iQC Log (Appendix 2)
- ITU clinical interpretation guidelines can be found on the Critical Care Clinical Guidelines intranet page. (For clinical algorithm, see Appendix 3)
- PAW theatres clinical interpretation guidelines can be found in the Trust major obstetric haemorrhage guideline under Maternity Policies. (For clinical algorithm, see Appendix 4)
- Point of Care Testing Policy (772/2018)
- RUH Medical Equipment Policy (713/2011)

All documents can be found on the intranet on the POCT web page or the respective ward web page.

## 2.2 Definitions

- TEG6 = Thromboelastography
- POCT = Point of Care Testing
- CK = Citrated Kaolin
- CRT = Citrated RapidTEG
- CKH = Citrated Kaolin with Heparinase
- CFF = Citrated Functional Fibrinogen
- R (min) = Reaction time. Time between the start of the test and the beginning of coagulation.
- K (min) = The speed of formation of the clot from R time to a specific clot strength
- Angle (deg) = The speed of the clot strengthening
- MA (mm) = Maximum amplitude. The ultimate strength of the clot
- iQC = Internal Quality Control
- QC = Quality Control
- EQA = External Quality Assurance

## 3 Actions and Methods

### 3.1 Specimen Requirements and Means of Identification

- To ensure accurate results, draw a discard tube first. Use a no-additive tube or citrate tube marked “discard”. Note: using a plain serum tube for the discard is not recommended as these can contain clot activators.
- Patient sample should be collected in 1:9 citrated sample tube that should be completely filled; whole blood is used for analysis.
- Use only 3.2% sodium citrate blue Vacutainer tubes that have been filled completely (until vacuum is exhausted). After collection, gently invert the tube 5 times to mix.
- No additives or preservatives are necessary to maintain the integrity of the sample, but samples should normally be used after 10-minute incubation and within 4 hours of draw.
- In an urgent or emergency situation, when speed of results is a concern, samples may be tested immediately.

### 3.2 Patient Preparation

Routine venepuncture preparation

### 3.3 Environmental and Safety Controls

Refer to risk assessment (QMS/RA/POCT/7)

- Blood samples – dispose of used samples into clinical waste burn bins or sharps bins and wear PPE when handling blood samples.
- Used cartridges - dispose of into clinical waste bags (as per trust policy).
- Used pipettes - dispose of into clinical waste bags (as per trust policy).

- Glass vials - dispose of into yellow sharps bins.
- QC material – potentially hazardous in case of ingestion, inhalation, skin contact and eye contact. It contains animal source material; therefore, it should be treated as potentially infectious. Dispose bottles into clinical waste burn bins.

### 3.4 Required Reagents, Quality Controls, Calibrators and Equipment Preparation

- TEG6 analyser
- Citrated Haemonetics cartridges & transfer pipettes
- Quality control cartridges level 1 & 2
- Citrate sample tubes
- Abnormal iQC (packs of 12 vials) part number 07-662

Consumables (citrated cartridges and iQC cartridges) are controlled and ordered by:

- ❖ The anaesthetic assistant for obstetric emergency cover via materials management team, for PAW theatres.
- ❖ Procurement & equipment lead for critical care services.

#### 3.4.1 Storage

- **TEG6 analyser** must be operated at room temperature (10-32 °C) and although it can be stored at between -20°C and +50°C it must be brought to operating temperature before use.
- **Citrated Haemonetics cartridges** & transfer pipettes must be stored refrigerated at 2-8°C immediately on receipt and prior to use, cartridges do not require a warm up before use. Cartridges are stored in the drugs fridge in ITU and in the Main sock Drug fridge in PAW theatres.
- **Quality control cartridges** (QC) level 1 & 2 must be stored refrigerated at 2-8 °C immediately upon receipt and up until use. QC must be given 10 minutes to equilibrate to room temperature. QC can be stored at room temperature (<25°C) for up to a month (not reconstituted). Reconstituted QC cartridges must be used with 2 hours of reconstitution. iQC is stored in the drugs fridge in ITU and in theatre 9B anaesthetic drug fridge.
- **Abnormal quality control** (for acceptance testing) must be stored refrigerated at 2-8°C, this is a lyophilized plasma reagent that must be reconstituted and used within 2 hours of reconstitution. Abnormal QC is stored in the drugs fridge in ITU and in theatre 9B anaesthetic drug fridge.

### 3.5 Internal Quality Control and Calibration Procedures

#### 3.5.1 Internal Quality Control (IQC)

Quality control samples:

- QC Level 1kit ref. number 07-650
- QC level 2 kit ref. number 07-651



QC Level 1 and 2 come in boxes of 10 cartridges each sealed with a desiccant pack in a foil pouch. Each Cartridge contains single use lyophilised reagent and diluent. Cartridges are stored at 2-8°C in ITU drugs fridge and in theatre 9B anaesthetic drugs fridge. Dispose in clinical waste bins as found in clinical areas.

- One level of iQC material is performed weekly by ward staff.
- Each level of iQC is performed fortnightly.
- IQC results are recorded and reviewed on the analyser itself and on the TEG log.
- A pass is indicated by a green tick

The TEG 6 Analyser performs internal QC checks during a pre-test when the cartridge is inserted as well as throughout the duration of the test. This verifies that all electromechanical and pneumatic functions of the analyser-cartridge combination are operating satisfactorily.

### 3.5.2 iQC Failure

In the event of IQC results fall outside of specified ranges (see iQC kit insert), troubleshoot (see page 15) possible causes then repeat the QC. If QC failure is persistent, refer to a senior member of staff who may decide to perform the opposite level of QC material to establish the source of the error.

In cases of persistent and unresolvable IQC failure the affected TEG6 must not be used for patient analysis and senior staff on the department must be informed and the POCT Co-ordinator notified.

A sign stating 'QC FAILURE – DO NOT USE' will be fixed to the TEG6 device and Haemonetics will need to be contacted.

Haemonetics Customer Support: 08082344817

### 3.5.3 Internal Quality Control Procedure

- Remove the required cartridges from the fridge.
- Switch on device using rocker switch at back left-hand side.
- Log in using your personal username and password then press 'login'.
- Allow QC packs 10 minutes to equilibrate to room temperature
- Ensure contents of diluent vial are tapped down to base of vial before removing lid.
- Carefully remove metal cap from reagent vial and dispose of in sharps bin.
- Slowly remove bung from lyophilised reagent – Aware, strong vacuum! Take care not to allow loss of lyophilised reagent.
- Using a pouring technique add all the diluent to dried QC material, replace bung and gently swirl – **DO NOT INVERT/SHAKE**. Leave to stand for 5 minutes.
- After 5 minutes, gently invert the vial 3 times whilst turning/swirling bottle – **DO NOT SHAKE**. Leave to stand for a further 5 minutes.

- Select 'New QC' on the TEG6 device. Instrument will state 'Preparing'.
- When the cassette entry area illuminates at the front of the device you will be directed to place the cartridge inside.
- Ensure that the cartridge is oriented correctly, as indicated on the screen and so that the sample application well is not inserted into the device.
- Push cartridge in firmly and it will give an audible 'clunk'.
- Once the cassette has been validated hit 'Next', enter lot number of QC, hit 'Next' again.
- Once the 5 minutes post inversions has elapsed use pipette provided to add QC reagent to the opening on the top of the cartridge, fill up to or above the line marked on the left side of the cartridge. Ensuring there are no bubbles
- Hit 'Next'; the test will now run.
- The test will take approximately 20 minutes to complete.
- Once complete, the TEG will ask that the cartridge be removed, remove only when directed to.
- Discard the cartridge.
- The results of the QC analysis will remain on the screen, once they have been recorded hit done, this will take you to the TEG home screen.
- Green ticks depict a pass, a red crosses depict a fail.

Results will be recorded on the analyser and in TEG manager.

#### 3.5.4 Retrieving and Reviewing Previous iQC

1. From the home screen, touch 'stored qc'
2. On the stored QC screen, select the desired test, and touch 'results'
3. On the QC screen for the selected test, view the results
4. Touch 'tracings' to view a graphic representation of the results (if required), touch 'results' to view the results page.
5. Touch 'Home' to return to the Home screen.

#### 3.5.5 Traceability

Expected values for test results are within the reference ranges that were established based on testing, following Clinical and Laboratory Standards Institute (CLSI) publication C28-A3c, Defining, Establishing and Verifying Reference Intervals.

### 3.6 Abnormal Quality Control

Abnormal QC part number 07-662

Abnormal QC comes in a box of 12 vials of lyophilised plasma reagent and 12 vials of diluent water vials. Disposal of vials into clinical waste bins as found in clinical areas.

Abnormal QC should be used to accept citrated cartridges into use on arrival of a new batch (delivery) or when there is a change of lot number of citrated cartridges. The boxes of cartridges from a given batch or/and lot number (if more than one lot number received on one delivery), should be marked as accepted into use with initials and a date. The results of the abnormal QC should be recorded on the Abnormal QC Log (appendix 2).

#### 3.6.1 Procedure for Running Abnormal QC (Acceptance testing)

On delivery of a batch of citrated cartridges the abnormal QC must be analysed on one of these cartridges to demonstrate nothing untoward has occurred to that batch, and that the cartridges are acceptable for clinical use (acceptance testing). If more than one lot-number of cartridges are received, then a cartridge of each lot-number must be acceptance tested.

- Remove one citrated cartridge from the newly delivered batch
- Remove 1 vial of lyophilised plasma control and 1 vial of water diluent, from the fridge to equilibrate to room temperature for 10 minutes
- Ensuring the lyophilised material is at the bottom of the vial remove the seal (dispose into sharps bin)
- Slowly remove bung from lyophilised reagent – Aware, strong vacuum! Take care not to allow loss of lyophilised reagent.
- Slowly pour the water diluent into the lyophilised control vial, take care not to spill any diluent outside of the control vial.
- Stopper on the control vial and shake vigorously until the contents are fully reconstituted.
- Allow to stand for 5 minutes.
- Shake vigorously again and allow to stand for 5 minutes again.
- Tear open the pouch, remove the citrated cartridge.
- From the home screen select 'new qc'
- Insert the cartridge into the slot with the barcode on the left side.
- On the 'confirm test' screen press 'continue'
- After the cartridge pre-test and verification of the assay required press 'next'
- On the 'Test information' screen enter details (lot number of abnormal QC), press 'next'
- Pipette the abnormal QC from the control vial into the cartridge sample port filling to or above the line. Press 'next'
- Results will be displayed as available.
- Record results on abnormal iQC log (appendix 2) compare to reference ranges (found in the abnormal QC kit insert).
- When abnormal QC has passed the boxes of cartridges from the same batch or lot must have, 'accepted into use', the date of passed abnormal QC and the acceptors initials, written on.

### 3.7 External Quality Assessment Schemes

External Quality Assurance (EQA) differs from IQC in that the accuracy of the procedure is not known until after the results have been issued. The user does not know what the results are at the time of analysis and the results are assessed independently.

UKNEQAS blood coagulation is the EQA scheme the TEG6 analysers are registered to.

- NEQAS scheme samples for TEG users are distributed quarterly, received by laboratory and taken to the department for analysis.
- Sample must be analysed as a patient sample (as per Patient Testing 5.1).
- Follow instructions in the NEQAS product insert sheet
- Results should be recorded on the return sheet then returned to POCT coordinator
- Performance report reviewed by POCT coordinator and fed back to department.

Return sheets and reports are stored on ningi (pathology database) and on the equipment module of q-pulse (pathology quality system). The performance is fed back to the ward and discussed at the POCT management meeting. Issues and poor performances will be discussed at the POCT coordinators meeting (held quarterly) and may be raised via Datix reporting system.

## 4 Maintenance

### 4.1 Cleaning the exterior surface of the analyser (This should be carried out weekly or as needed):

1. Turn off the analyser and unplug it from the mains.
2. Put on PPE
3. Using gauze pads soaked in 79-90% isopropyl alcohol or germicidal disposal (Clinell) wipes; thoroughly clean all external surfaces of the TEG analyser including touch screen.

**NOTE:** Avoid getting liquid into the cartridge slot at the front of the analyser or into connectors on the rear panel.

### 4.2 Clean the Filter (For trouble shooting only):

The TEG analyser has a filter assembly mounted at the rear of the unit to filter air as it is drawn into the unit by the fan. This filter should be cleaned or replaced during each scheduled preventive maintenance (PM) procedure. If a temperature error occurs before a scheduled PM, clean the filter using the following instructions:

1. Grasp the edges of the filter cover and pull to remove it.
2. Remove the filter from the cover.
3. Rinse the filter under warm water until it is clean. Do not use soap or any cleaning solution.
4. Squeeze out any excess water, place on a clean cloth, and allow to dry completely.
5. Ensure the filter is 100% dry, and then reinsert the filter into the filter cover.
6. Press the filter cover back onto the analyser.
7. Record the date of maintenance

## 5 Instructions for the Performance of the Examination

### 5.1 Patient Testing

- Log in using your personal username and password then press 'login'.

**Note:** If the data fields appear red, then either the incorrect information has been added or there is missing data. Please note that the username and password are all 'lower case'

- When you have logged-in the home screen will appear. Press 'new test'.

**Note:** Available Options:

- ❖ New test = Perform a new test
- ❖ Stored tests = Review old test results
- ❖ New QC = Perform a new quality control check
- ❖ Stored QC = Review old quality control checks
- Select your patient's ID or add your patient by touching the + button.

**Note:** Once a test has been performed, the patient ID (MRN) will be stored.

- If adding a patient, type your patient ID (use MRN number) and touch 'ok'
- You will then need to ensure you have the appropriate cartridge available – Citrated TEG Cartridges, a sample of blood in a blue citrated tube and a transfer pipette.
- Remove the test cartridge from its sealed pouch and insert when prompted on the screen (cartridge port will flash), put in with the barcode facing left.

**Note:** Blood has **NOT** been put into the cartridge at this point

- The TEG will now 'verify' the Citrated Cartridge

**Note:** Blood has **NOT** been put into the cartridge at this point

- When the TEG has recognised the cartridge, it will demonstrate this on the screen and provide a reminder of the citrated sample tube required as shown. Press 'next'
- Enter 'Test Information', this is not mandatory but is useful to time order TEG results if multiple tests are performed on one patient.

For example:

- ❖ TEG 1 (Baseline)
- ❖ TEG 2 (Time)
- ❖ TEG 3 (Time)
- Press 'next' when ready
- You will now be asked to 'load sample'

- With the cartridge in the cartridge slot fill the sample port with whole citrated blood using a pipette (provided with the cartridges).
- Fill the cartridge with blood above the arrow indicator.
- Press 'next'
- The test will now run, and the results screen will be displayed. Results will be populated as they are generated
- When all parameters have been measured and populated, the test finishes automatically.
- Remove cartridge when prompted, cartridge slot LED will also flash.
- From the results screen press done to return to the home screen. Dispose of cartridge and pipette in any clinical waste bin.

## 5.2 Procedure for Recording and Obtaining Results

### 5.2.1 Recording Results

Press print from the results screen; this then needs to be written into the patient notes to include:

- ❖ Test results
- ❖ Patient ID
- ❖ Time and date of sample
- ❖ Analyser the results were obtained from
- ❖ User performing analysis
- ❖ Confirm the iQC had been run and passed within the past 7 days

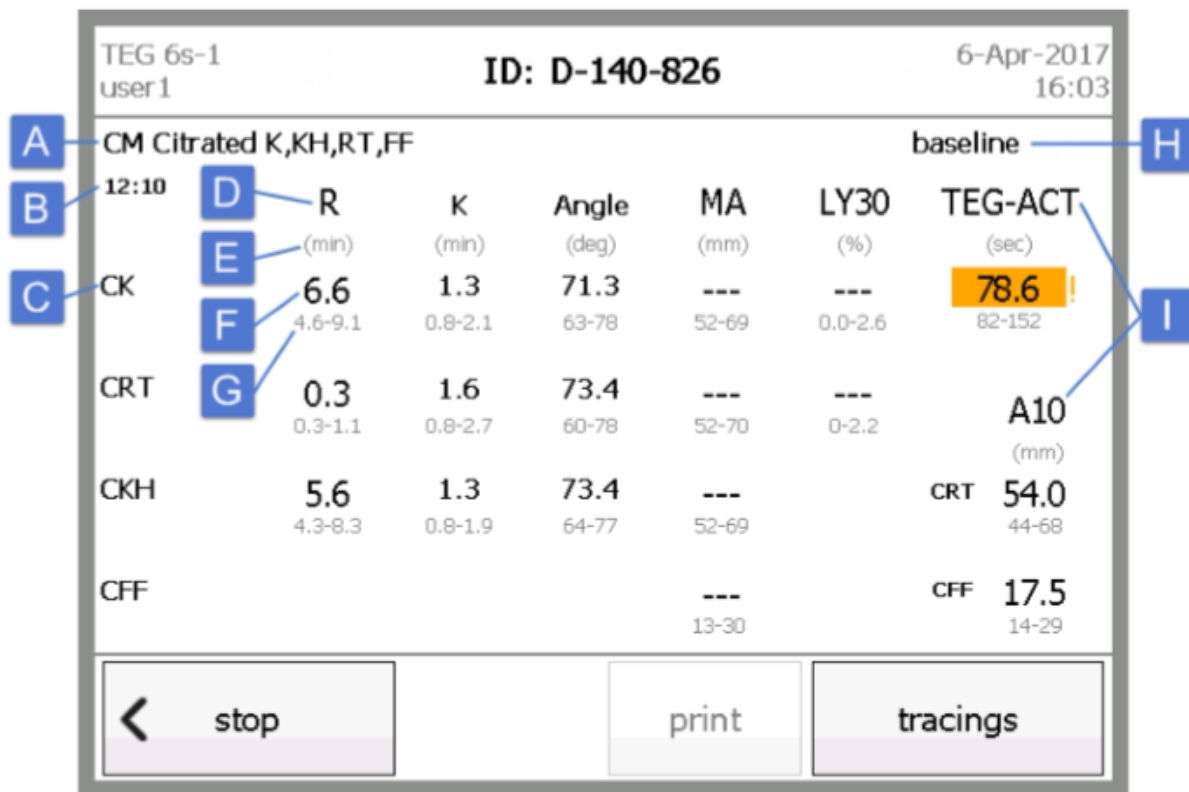
All written information must be checked by a second person for correct transcription.

### 5.2.2 Retrieving previous results

1. From the home screen, touch 'stored tests'
2. On the 'Stored Tests' screen, select the desired test, and touch 'results'
3. On the results screen for the selected test, view the results
4. Touch 'tracings' to view a graphic representation of the results (if required), touch 'results' to view the results page.
5. Touch 'back' to return to the 'Stored Test' screen.
6. Touch 'Home' to return to the Home screen.

### 5.2.3 Results Screens

The following illustration identifies the information that appears on the results screen for an in-progress four-channel test. If a parameter is 'out of range' it will be highlighted in orange.



- A. **Cartridge name:** This is the name that appears on the outside of the cartridge.
- B. **Test timer:** The timer begins when the test starts. Once the assay is complete, the timer stops and is replaced by the date and time that the test started.
- C. **Test name:** Each test name – one per channel – is displayed in the left column. You can touch the test name to display the tracing for the test.
- D. **Test parameters:** The top row displays the primary parameters that are being measured for each test.
- E. **Parameter units:** The units of measure are displayed under each parameter name.
- F. **Parameter values:**
  - The large numbers indicate the results of each test.
  - A parameter displays with dashed lines until it is finalized and a numerical result appears.

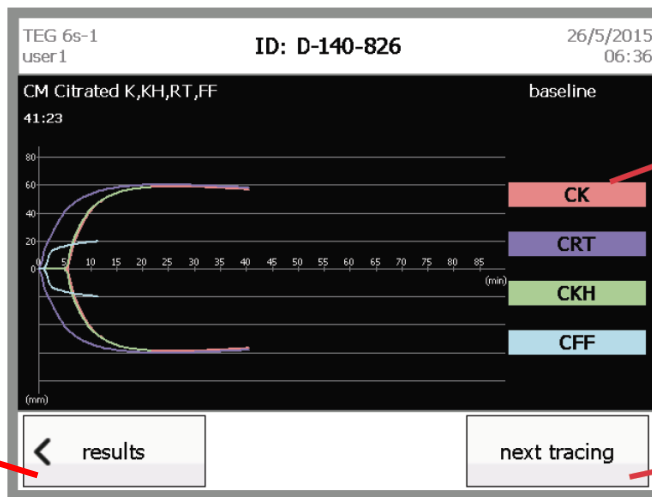
- Not all parameters are applicable or calculated for all tests; any parameter that is not calculated for a test remains blank.
- A parameter displays with an asterisk if it cannot be defined due to the timing or value of the MA parameter.
- If a finalized parameter falls outside of the expected range, it is highlighted in orange and an exclamation mark appears next to the number.

G. **Reference ranges:** The maximum and minimum limits for normal results for each parameter appear under the parameter values.

H. **Test information:** The information that is added for the test in the *Test information* screen displays at the top right of the screen.

I. **Additional parameters:** If additional parameters are calculated for any test, they display in the right column.

Touch “tracings” button to view the graphical representation of the results (see below).



Touch legend to go to individual tracing

or

next tracing

Touch “results” to go back to the numerical results page

#### 5.2.4 Operators:

- Only staff that are trained and considered competent are authorised to use the analyser
- Training is provided via College of TEG (see appendix 5) or face to face with link trainer in department.
- The certificate produced by college of TEG is evidence of completion of training and competency.
- All training and competency should be recorded and accessible to department leads for audit.
- Access details will be held entered and held on TEG manager (see TEG manager SOP)
- User must log in to the TEG using their personal user ID (usually a barcode) and by scanning the generic password barcode on the outside of the analyser.
- Refresher training may be provided by a Link trainer every 2 years.
- Refer to the NMC Professional Conduct Code 2008 and RUH Policies.



## 6 Troubleshooting and Common Errors

### 6.1 Failed iQC Results

- Can indicate a problem with the analyser performance – review iQC performance and repeat iQC using a fresh sample.
- Can be caused by improperly prepared control material or product deterioration.
  - Check lot number and expiry date of iQC match the analyser and the kit insert (ranges specified here)
  - Check storage conditions, temperature control of fridge not breached.
  - Ensure only trained operators are performing the iQC as per SOP.
  - Ensure **all** the diluent is added to the lyophilised reagent and none of this is lost.
  - Check for bubbles before pipetting iQC into the cartridge.
  - Ensure no more than 2hrs have lapsed since reconstitution.

### 6.2 Unexpected or Failed Patient Results

- Repeat patient test with a fresh cartridge
- Ensure bubbles are not pipetted into cartridge
- Review iQC ensure completed within the last week, if not perform iQC to ensure analyser is working correctly.
- Ensure only trained operators are performing the patient test as per SOP
- Check storage conditions, temperature control of fridge not breached.

If the instances above persist the abnormal QC can be prepared and analysed using a citrated cartridge (NOT iQC cartridge) (see 3.6.1) to establish if there may be an issue with the cartridges, if this is the case a new lot of cartridges should be used.

## 7 Reference Limits, Reportable intervals, Reporting and Interpretation

- Only trained staff can operate the analyser, results must be written into patient’s clinical notes (see 4.91 above) by member of staff testing the patient.
- Clinical staff are responsible for the interpretation of the TEG results.

Expected values for test results are within the Reference Ranges for a reference population that were established according to CLSI C28-A3c. The following tables contain the reference range data for each reagent and parameter

### CK Reference Ranges

Citratd Blood Parameter	N	Range
R(Min)	157	4.6 – 9.1
K (Min)	157	0.8 – 2.1
Angle (deg)	155	63 – 78
MA (mm)	151	52 – 69
LY30 ( %)	132	0.0 – 2.6

### CRT Reference Ranges

Citratd Blood Parameter	N	Range
TEG-ACT(sec)	157	82 – 152
R (min)	157	0.3 – 1.1
K (min)	156	0.8 – 2.7
Angle (deg)	154	60 – 78
A10 (mm)	153	44 – 67
MA (mm)	152	52 – 70
LY30 (%)	131	0.0 – 2.2

### CKH Reference Ranges

Citratd Blood Parameter	N	Range
R(Min)	155	4.3 – 8.3
K (Min)	157	0.8 – 1.9
Angle (deg)	154	64 – 77
MA (mm)	154	52 – 69

### CFF Reference Ranges

Citratd Blood Parameter	N	Range
A10 (mm)	153	15 – 30
MA (mm)	151	15 – 32

#### 7.1 Results outside Reportable Intervals

Please refer to the clinical guideline documents (see 2.1)

#### 7.2 Reporting and Interpretation

Please refer to the clinical guideline documents (see 2.1)

## 8 Performance Characteristics

### 8.1.1 Validation and Verification Report

- Full validation is not possible for this analyser. User acceptance into use has been carried out for this analyser - see q-pulse (pathology quality management system) for details.
- See manufacturer's iQC & cartridge kit inserts (EXT/POCT/13)
- See manufacturer's operator's manual (EXT/POCT/12)
- Measurement of uncertainty – to be reviewed following a year of iQC data (see Q-pulse equipment module)

### 8.1.2 iQC Precision

The precision of the TEG System QC Calcium Chloride cartridge with Level 1 and with level 2 was evaluated according to CLSI EP5-A2. Testing was performed for within-device (20-day tests using QC Level 1 & level 2), and multi-site reproducibility tests were performed across three sites, three lots, three operators and three analysers. Results included Coefficient of Variance (CV) values for all precision tests. The CV of the test results was less than 10% for all parameters.

### 8.1.3 CK Precision

The precision of the Kaolin test was evaluated according to CLSI EP5-A2. Testing was performed for within-run (using three donors), within-device (20-day tests using QC Levels 1 and 2), between lots (using three different cartridge lots), and between operator (using five operators). Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analysers. Results included Coefficient of Variance (CV) values for all precision tests. The CV of the test results for the Kaolin Assay was less than 10% for all parameters.

### 8.1.4 CK Sensitivity and Specificity

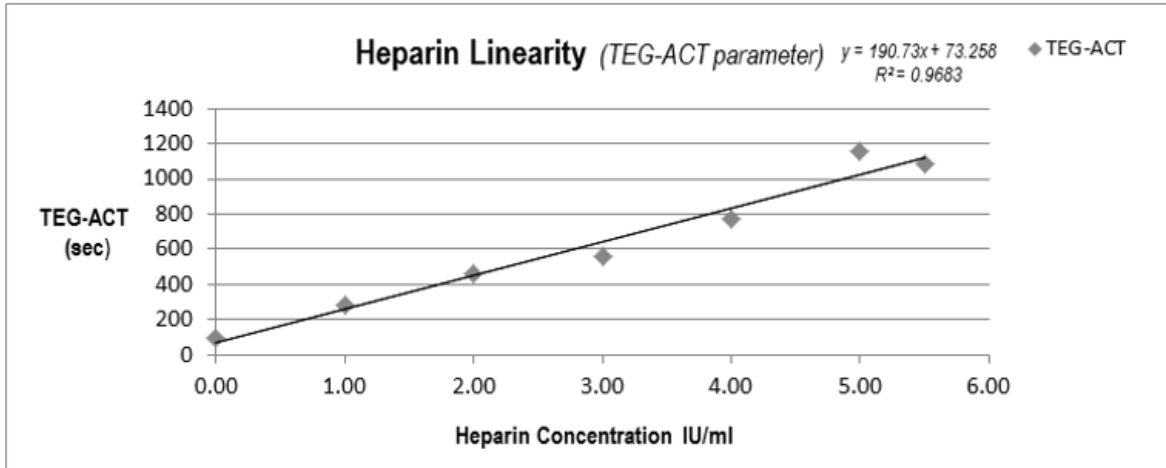
The Kaolin reagent is often used in conjunction with tests performed on blood samples from patients administered with heparin, with the goal of either determining heparin effect (titration of dose) or determining full reversal (post-protamine) of heparin administered. It is, therefore, important that the Clinical Sensitivity and Specificity for the presence of heparin be determined. Five different heparin spiked samples were examined, with concentrations spread across the heparin therapeutic ranges (0.2 to 6.0 IU/mL). 0.2 IU/mL is the lowest therapeutic dose typically used and 6.0 IU/mL represents a typical dose of heparin used when patients are fully heparinized during cardio-pulmonary by-pass. In addition, five (5) non-heparin spiked samples were analysed. Kaolin's sensitivity to Heparin was 100%, with the R parameter elongated and out of range for all concentrations. Specificity was also 100%, with all un-spiked samples having an R parameter within normal range.

### 8.1.5 CRT Precision

The precision of the RapidTEG test was evaluated according to CLSI EP5-A2. Testing was performed for within-run (using three donors), within-device (20-day tests using QC Levels 1 and 2), between lots (using three different cartridge lots), and between operator (using five operators). Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analysers. Results included Coefficient of Variance (CV) values for all precision tests. The CV of the test results for the RapidTEG Assay was less than 13% for the TEG-ACT parameter and less than 10% for the K, Angle and MA parameters.

**8.1.6 CRT Linearity**

RapidTEG was tested for linearity according to CLSI EP6-A. The TEG-ACT parameter was found to be linear with respect to concentrations of Heparin, as shown below.



**8.1.7 CKH Precision**

The precision of the Kaolin with Heparinase test was evaluated according to CLSI EP5-A2. Testing was performed for within-run (using three donors), within-device (20day tests using QC Levels 1 and 2), between lots (using three different cartridge lots), and between-operator (using five operators). Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analysers. Results included Coefficient of Variance (CV) values for all precision tests. The CV for the test results for the Kaolin with Heparinase Assay was less than 10% for the R parameter.

**8.1.8 CKH Neutralization**

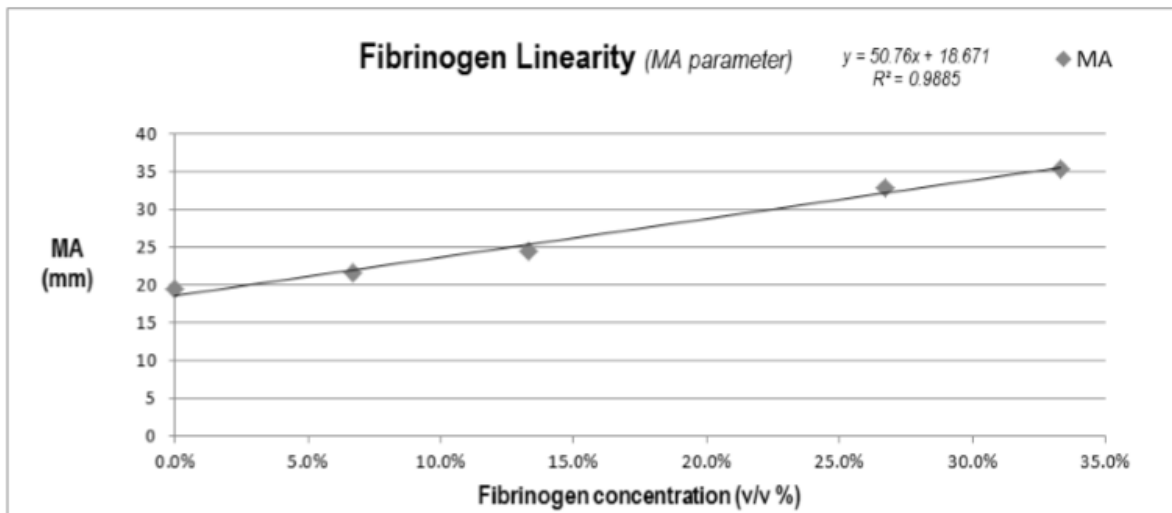
The Kaolin with Heparinase assay was tested to verify that 6 IU of Heparinase per 1 mL of blood will effectively neutralize the effects of both Unfractionated Heparin (UFH) and Low Molecular Weight Heparin (LMWH) on Kaolin-activated citrated whole blood samples. This is the amount of Heparinase used in the Kaolin with Heparinase assay. Tests were performed using UFH and LMWH spiked samples and un-spiked samples that confirmed the neutralization effectiveness of the assay.

**8.1.9 CFF Precision**

The precision of the Functional Fibrinogen test was evaluated according to CLSI EP5-A2. Testing was performed for within-run (using three donors), within-device (20day tests using QC Levels 1 and 2), between lots (using three different cartridge lots), and between-operator (using five operators). Also, multi-site reproducibility tests were performed across three sites, three lots, three operators and three analysers. Results included Coefficient of Variance (CV) values for all precision tests. The CV of the test results for the Functional Fibrinogen Assay was less than 10% for the MA and FLEV parameters.

**8.1.10 CFF Linearity**

The Functional Fibrinogen assay was tested for linearity according to CLSI EP6-A. The MA parameter was found to be linear with respect to concentrations of Fibrinogen, as shown below.



STANDARD OPERATING PROCEDURE SOP/POCT/61/2

Title: Haemonetics TEG6 POCT analyser

Effective date: 10/11/2022

**Appendix 1: TEG iQC Log**

Analyser: TEG 6 SN: \_ \_ - \_ \_ \_ - \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ Analyser Location: \_ \_ \_ \_ \_ \_ \_ \_ \_ \_

**Each column must be completed in full**

Date	iQC level / Lot number	Channel	R	K	Angle	MA	Pass Y/N	Operator	Weekly analyser surface clean complete
		1							
		2							
		3							
		4							
		1							
		2							
		3							
		4							
		1							
		2							
		3							
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		2							
		3							
		4							
		1							
		2							
		3							
		4							

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STANDARD OPERATING PROCEDURE SOP/POCT/61/2

Title: Haemonetics TEG6 POCT analyser

Effective date: 10/11/2022

**Appendix 2: Abnormal iQC log:** Stock Control & Acceptance test Record (see SOP, 3.6)

- Each delivery (batch) of cartridges should have an abnormal control check run
- Each different lot number of box of cartridges within a batch should have an abnormal control check run
- All boxes of cartridges must have ‘accepted into use’, the date control run, and a signature written on the box once the control has passed

Cartridge Delivery Date	Cartridge Box Lot Number	Date Control Performed	Abnormal Control lot number	Parameters	R	K	Angle	MA	iQC Acceptable?	Operator Signature Cartridge box signed & dated
				CK						
				CRT						
				CKH						
				CFF						
				CK						
				CRT						
				CKH						
				CFF						
				CK						
				CRT						
				CKH						
				CFF						
				CK						
				CRT						
				CKH						
				CFF						

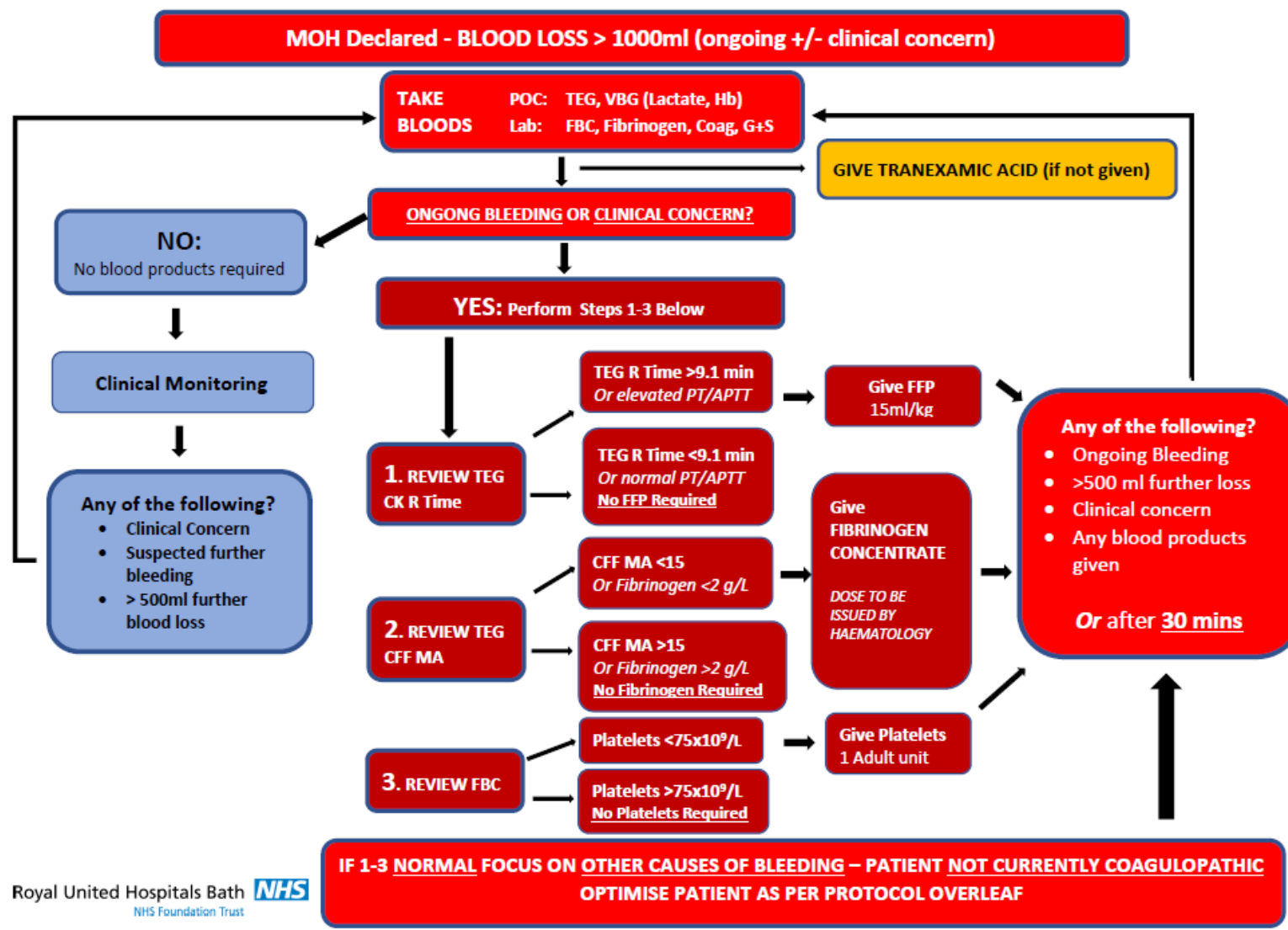
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STANDARD OPERATING PROCEDURE SOP/POCT/61/2

Title: Haemonetics TEG6 POCT analyser

Effective date: 10/11/2022

**Appendix 3:** Major obstetric haemorrhage TEG algorithm (see Major Obstetric haemorrhage guidelines for full details)

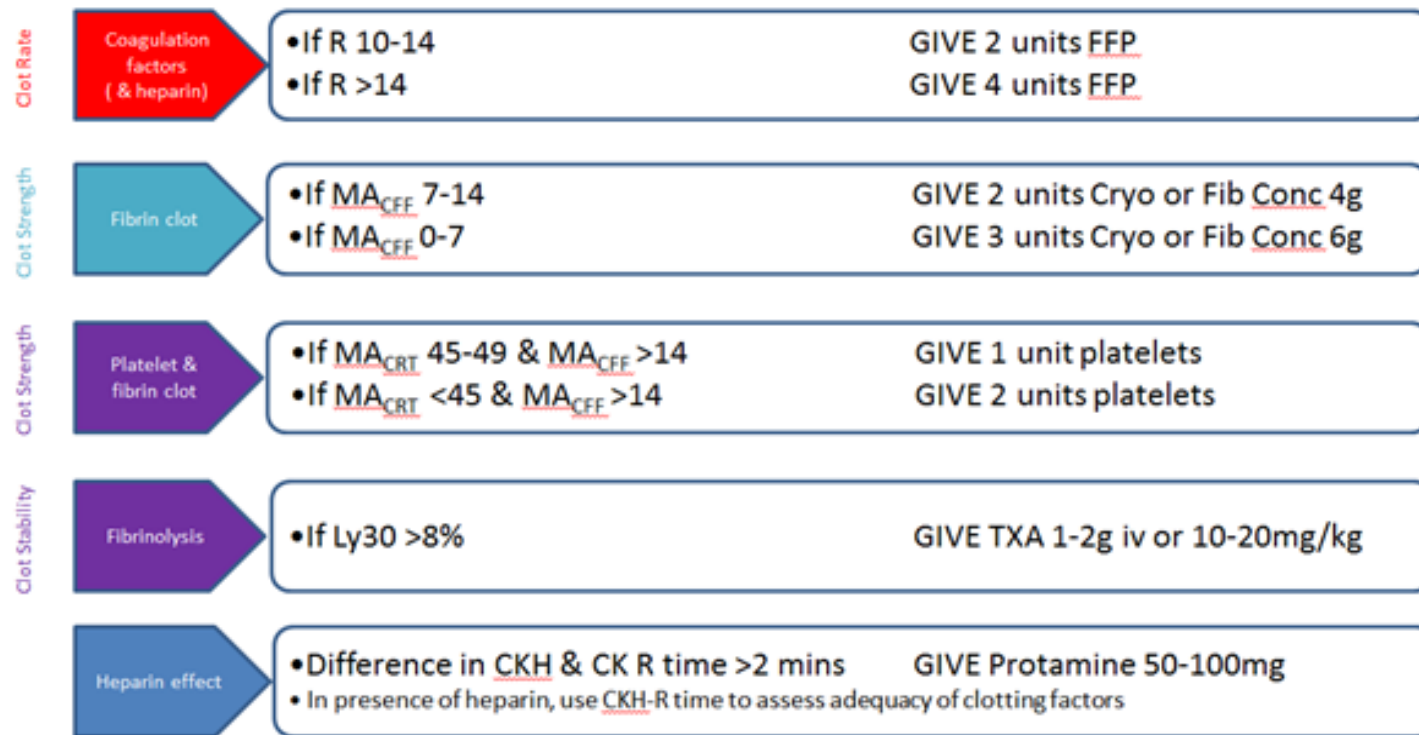


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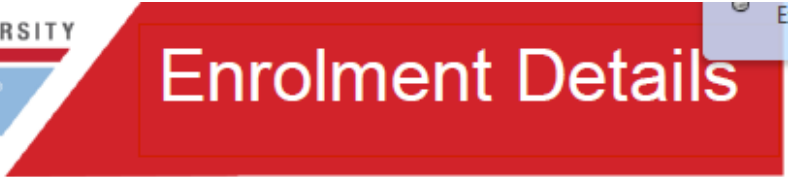
**Appendix 4:** TEG algorithm for non-obstetric patients (see TEG user guide on Critical Care Clinical Guidelines page)

# TEG Algorithm



TEG repeatable 15min after blood products to assess treatment response and to further guide therapy

**Appendix 5:** Access to college of TEG for training and competency assessment.



## Congratulations!!

You have been invited to complete the TEG® online training.

### College of TEG - Training modules

The following training & assessment modules are available now. Further modules are in development.



#### Introductory Operator Training & Assessment

This course will introduce you to the TEG® 6s Analyzer and guide you through best practices for operating the device. This will assist with confidently and competently generating results in a timely fashion, providing complete and accurate hemostasis profiles with ease.



#### Introductory Clinical Training & Assessment

This course will guide you through effectively interpreting TEG® 6s Analyzer results and show you how these results can help make more informed clinical decisions. Pinpointing hemostatic disturbances, better equipping you to monitor and maintain the hemostatic balance of your patients.

### Online Access Instructions

1. Go to <https://tegraining.haemonetics.com>
2. Enter your account details when prompted
  - a. Account Name: RUHBATH
  - b. Account Password: teg146
3. Select desired training module or assessment
4. Enter your first and last name
5. Submit to begin the module
6. Courses take approximately ½ hour
7. Your progress within the module is **tracked**, you may come back to complete.
8. A **certificate** can be printed and/or saved upon successful assessment completion

*Any questions please contact [lisa.kelly@haemonetics.com](mailto:lisa.kelly@haemonetics.com)*

Copy number	Location held
1	Electronically through Q-Pulse.
2	PAW Theatres
3	ITU department
4	Critical Care Intranet web page
5	POCT Intranet web page