POINT OF CARE COAGULATION TESTING

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Royal Victoria Infirmary

Newcastle upon Tyne

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The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Introduction

Declarations of Interest: None

CONTENT

Introduction to POCT

Principles

Interpretation

Treatment

Literature

NUTH Experience

Point Of Care Testing (POCT)

Medical diagnostic testing at (or near) the point of care.

POCT

PROS

- Quick
- Convenient
- Reliable
- Efficient

CONS

- Cost (potentially)
- Quality
- Training
- Workload
- Recording
- Risk of inappropriate decision-making

Point of Care Coagulation Testing (POCCT)

Viscoelastic properties of whole blood clot

Thromboelastography (TEG)	=	Thromboelastometry (ROTEM)

Purported Benefits over Standard Tests

- Measures whole blood, not just plasma
- Looks at clot generation and propagation beyond the point of clot appearance
- Allows comment on clot ‘quality’
- Can identify fibrinolysis

FAST –potential information on clotting status within 5mins of test starting

POCCT vs Standard Lab Tests

POCCT

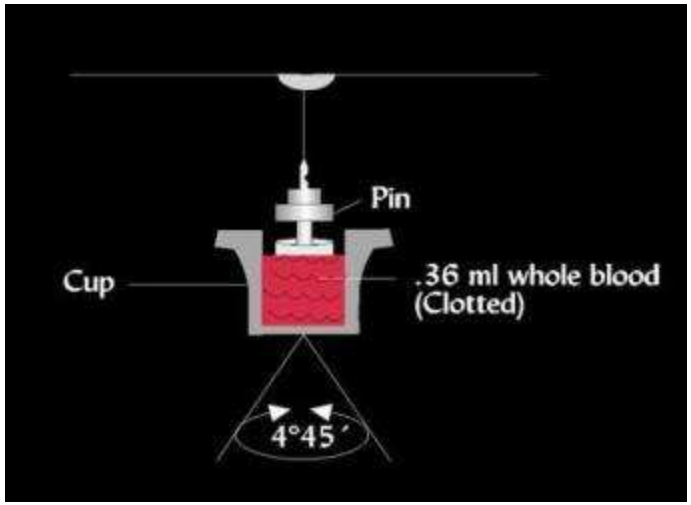
- Whole blood
- Clot beyond first appearance
- Clot quality
- Identify fibrinolysis
- FAST

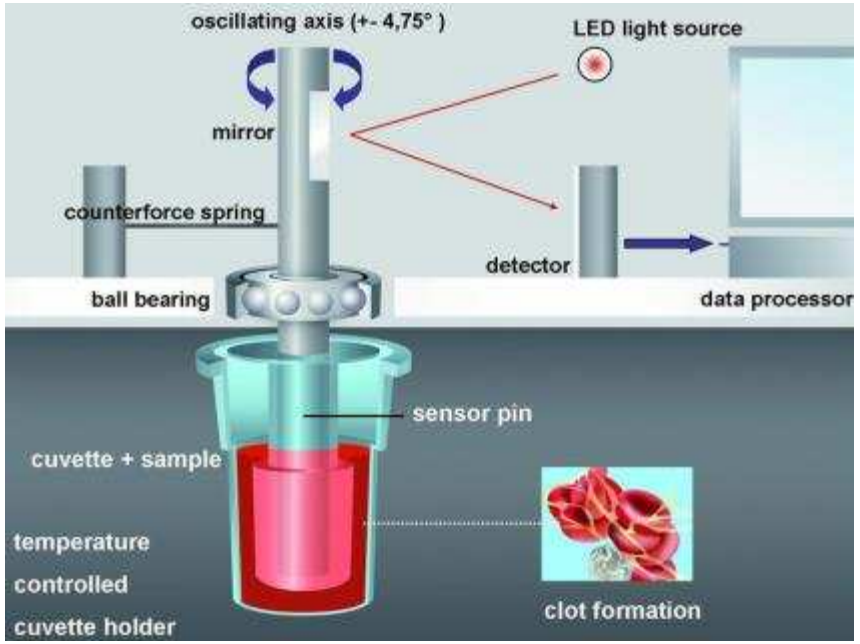
LAB

- Highly standardised
- Trained, professional staff
- Quality control
- Well established
- Complete picture
- Cost

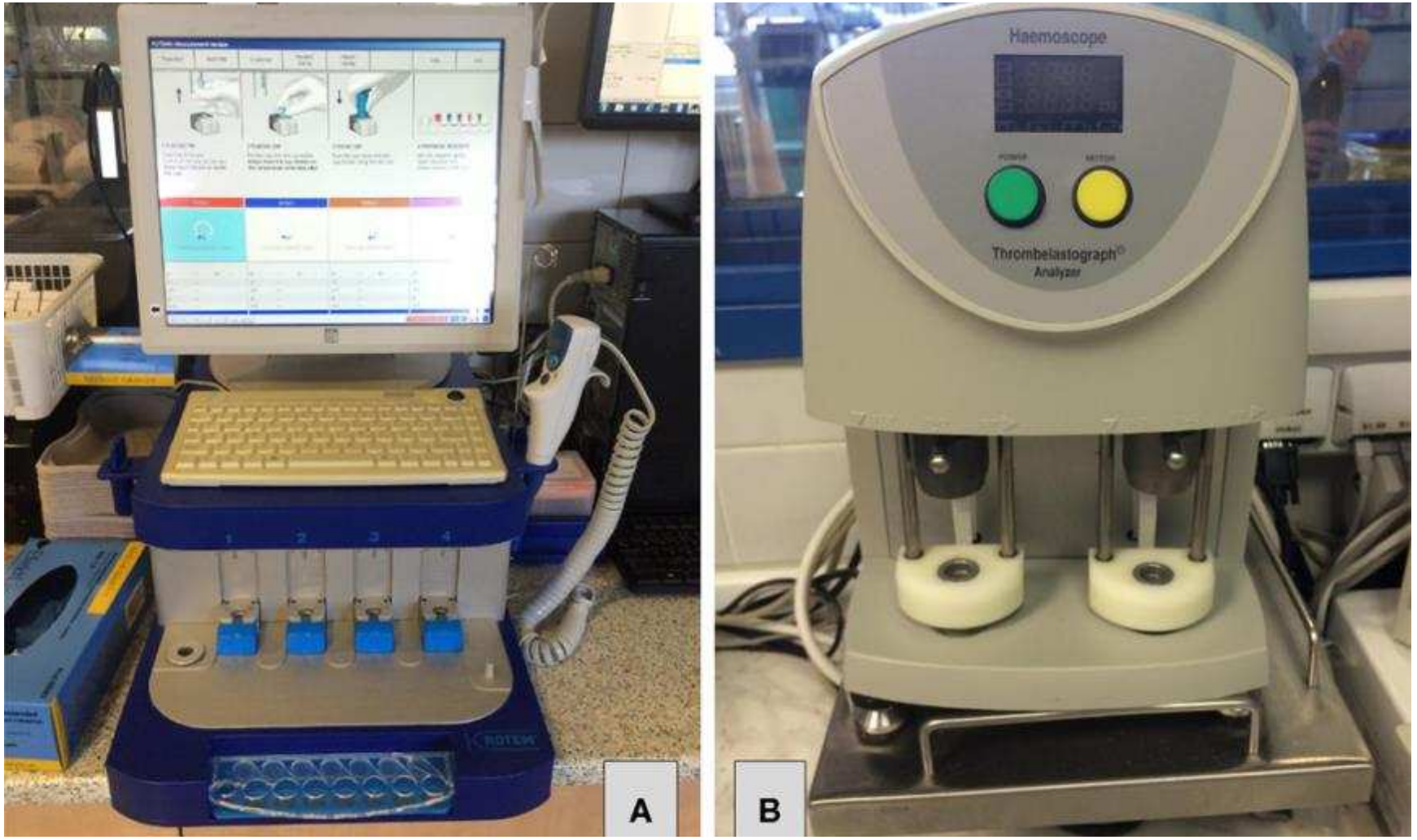
PRINCIPLES

Viscoelasticity





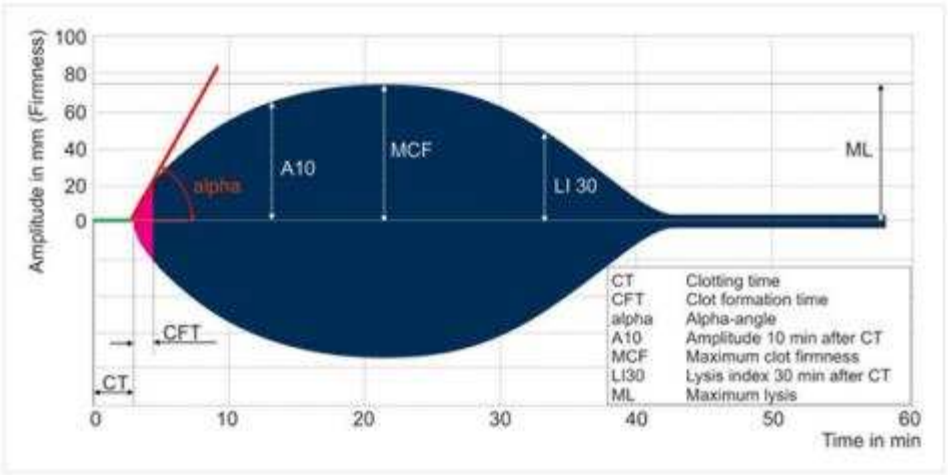
Hardware



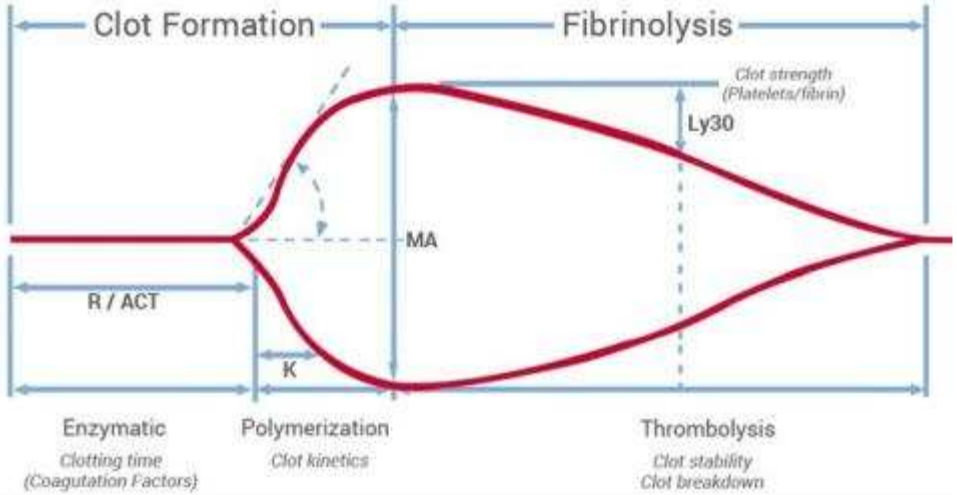

HAEMONETICS
TEG 6s


ROTEM

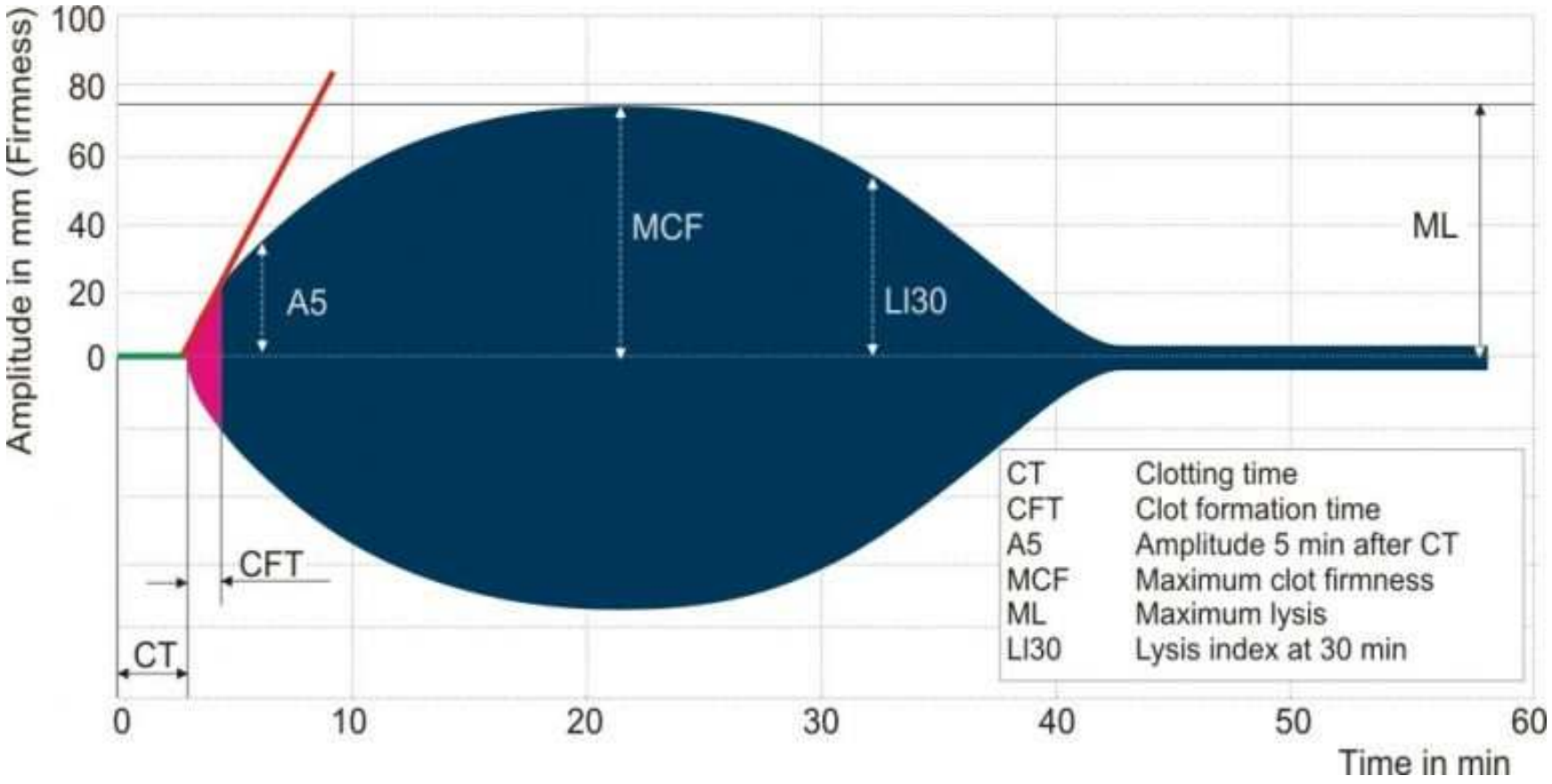
OUTPUTS



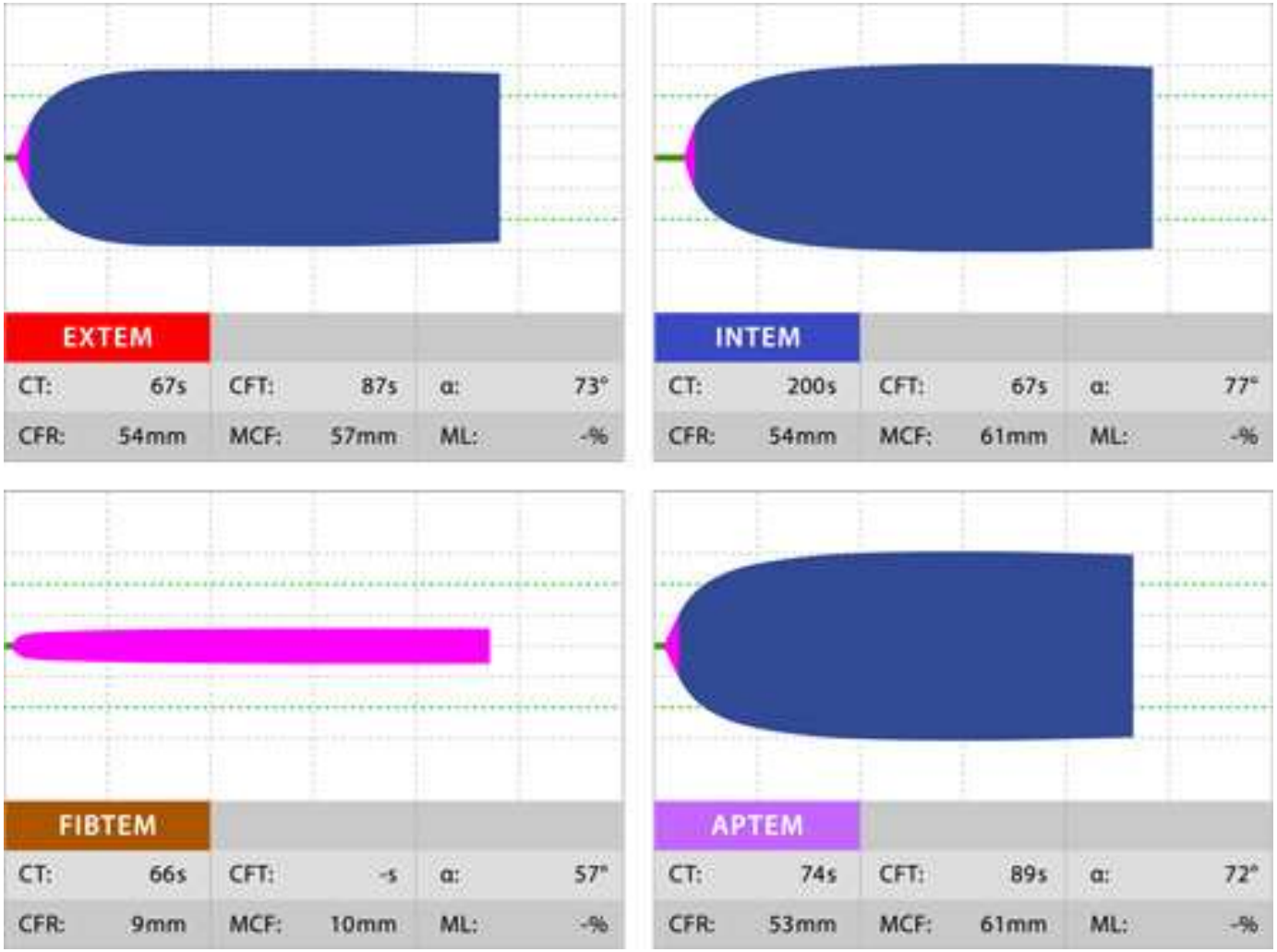
https://www.rotem-usa.com/methodology/rotem-analysis/



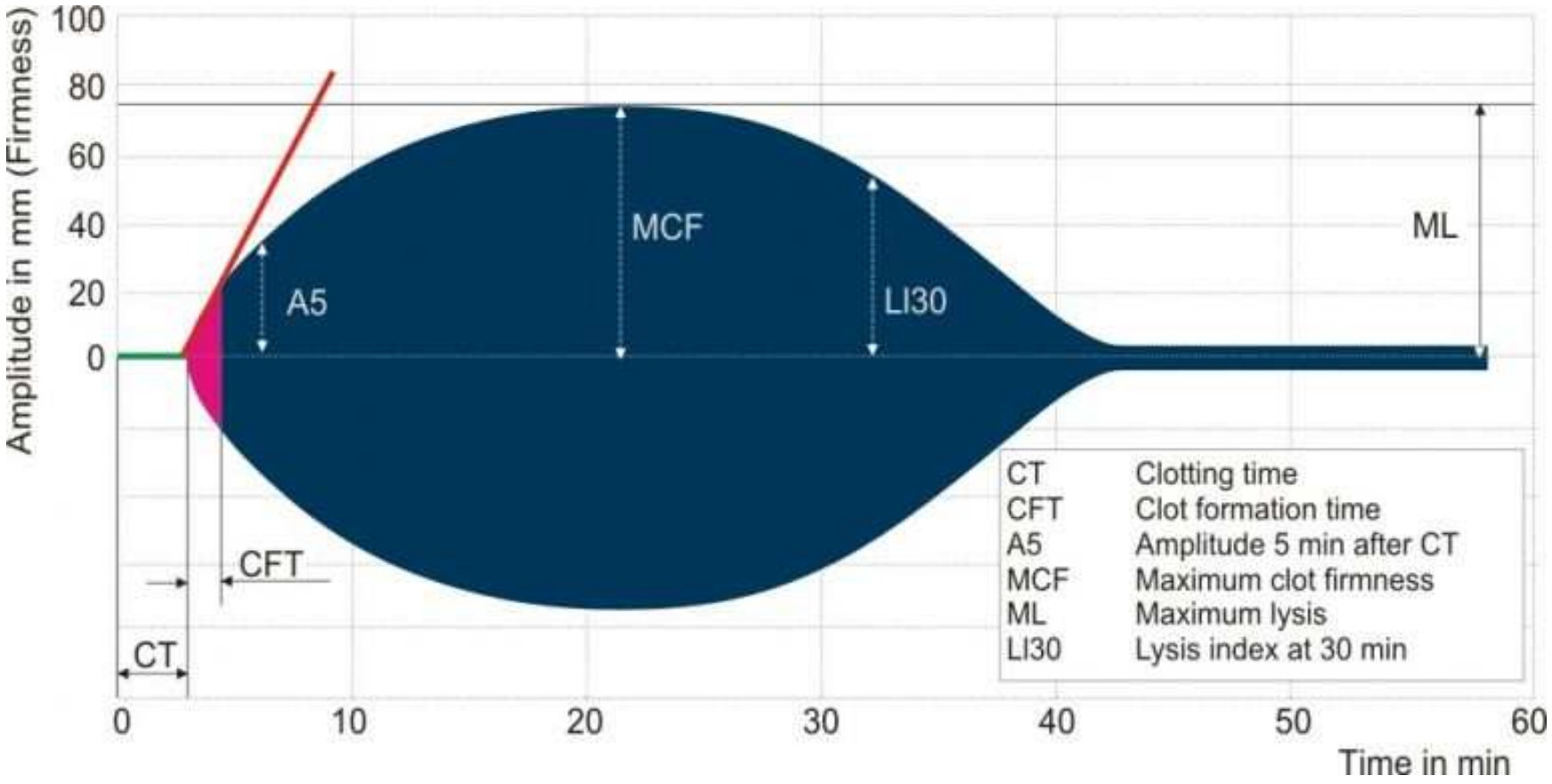
http://teg.haemonetics.com/en-gb


Amplitude in mm (Firmness)
100
80
60
40
20
0
A5
MCF
LI30
ML
CFT
CT
0
10
20
30
40
50
60
Time in min
CT Clotting time
CFT Clot formation time
A5 Amplitude 5 min after CT
MCF Maximum clot firmness
ML Maximum lysis
LI30 Lysis index at 30 min

Panel Testing – Normal results



INTERPRETATION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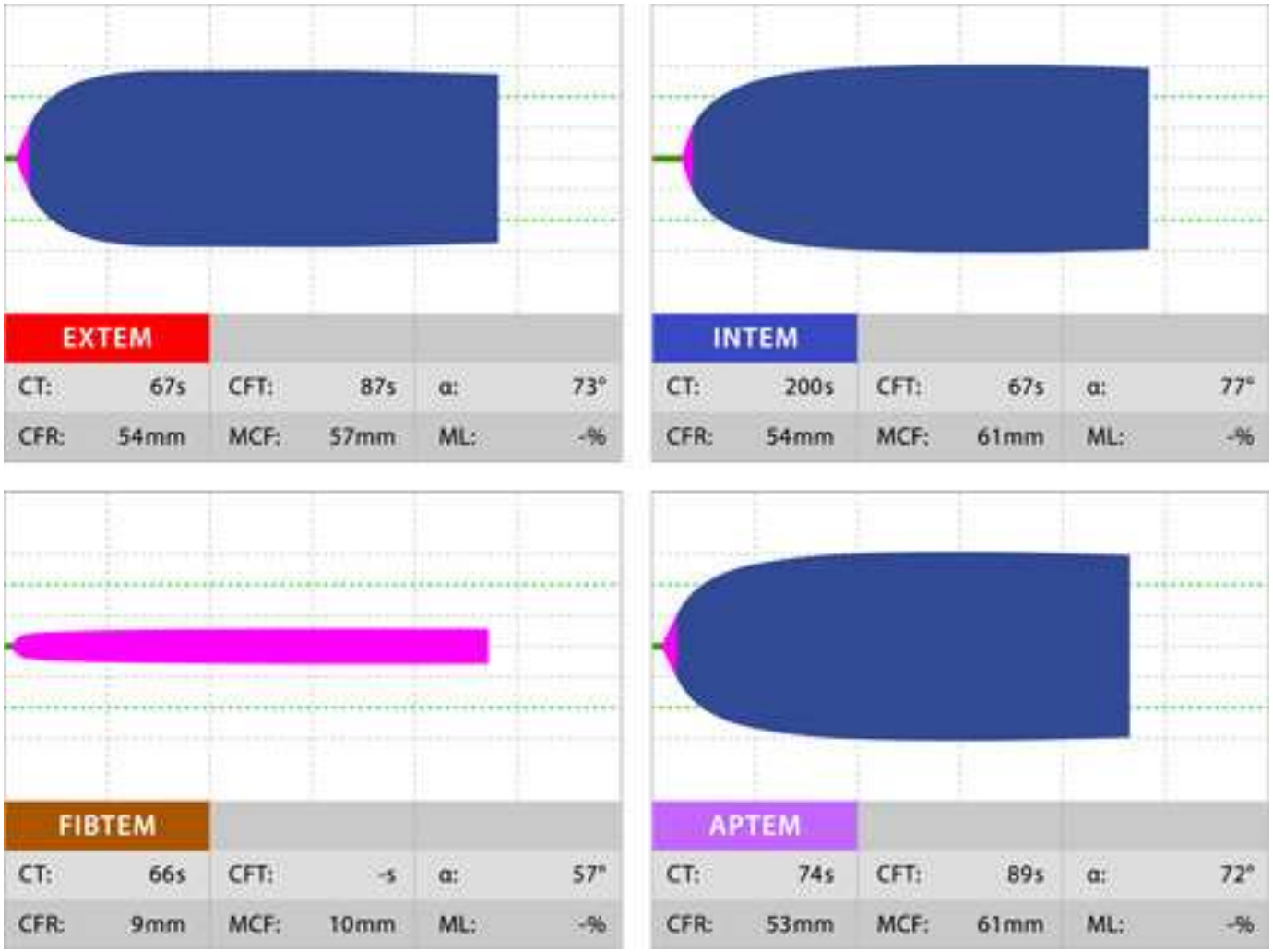
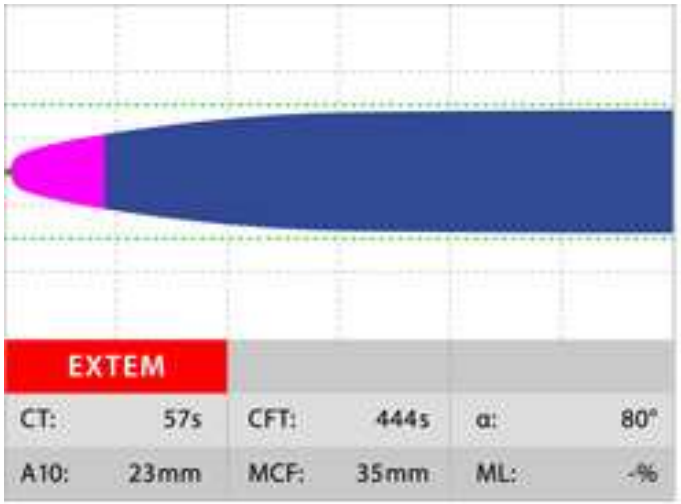
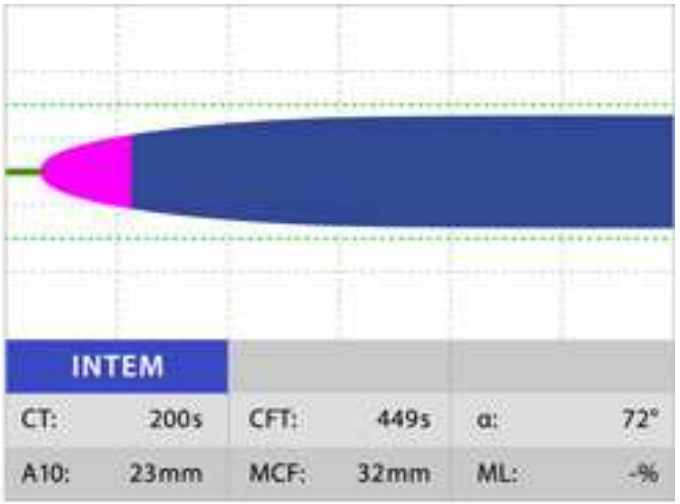
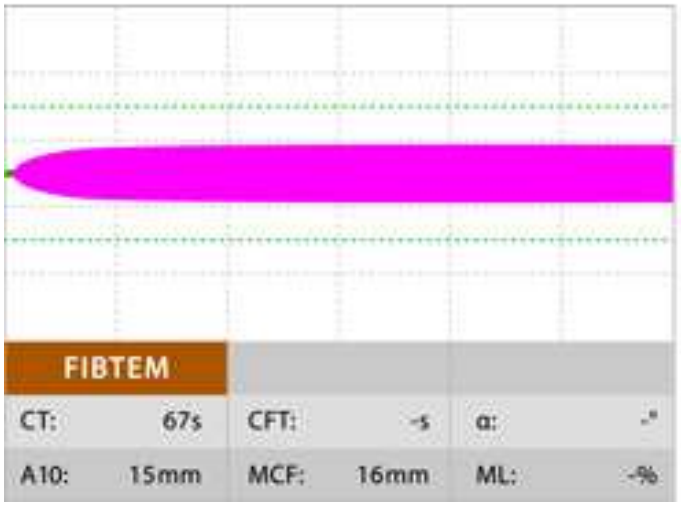

EXTEM
CT: 67s
CFT: 87s
α: 73°
CFR: 54mm
MCF: 57mm
ML: -%
INTEM
CT: 200s
CFT: 67s
α: 77°
CFR: 54mm
MCF: 61mm
ML: -%
FIBTEM
CT: 66s
CFT: -s
α: 57°
CFR: 9mm
MCF: 10mm
ML: -%
APTEM
CT: 74s
CFT: 89s
α: 72°
CFR: 53mm
MCF: 61mm
ML: -%



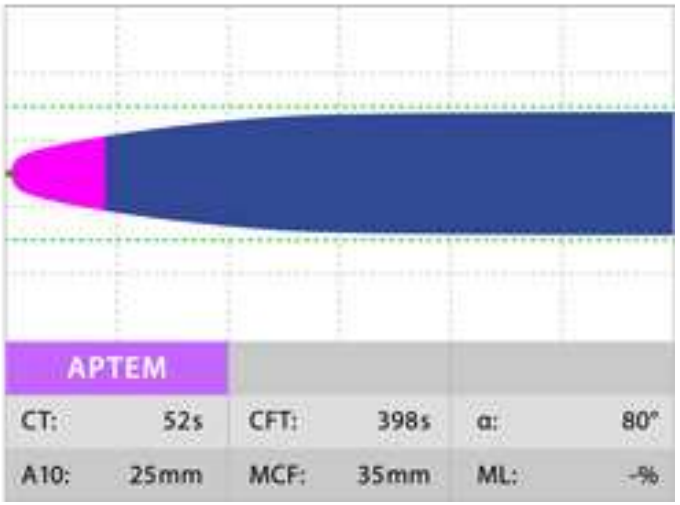
EXTEM					
CT:	57s	CFT:	444s	α:	80°
A10:	23mm	MCF:	35mm	ML:	-%



INTEM					
CT:	200s	CFT:	449s	α:	72°
A10:	23mm	MCF:	32mm	ML:	-%

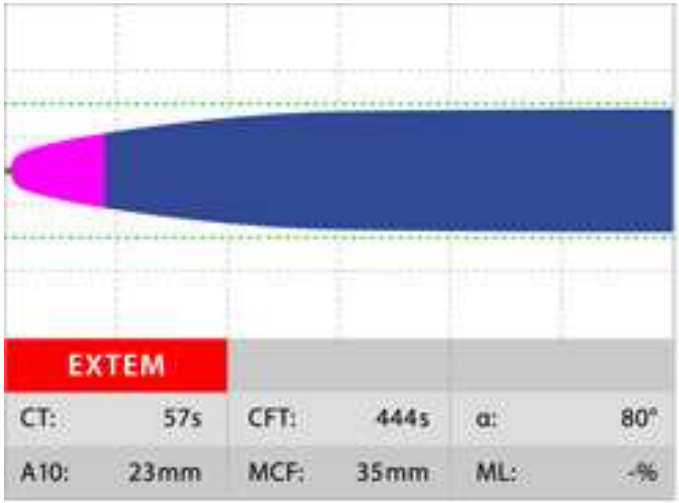


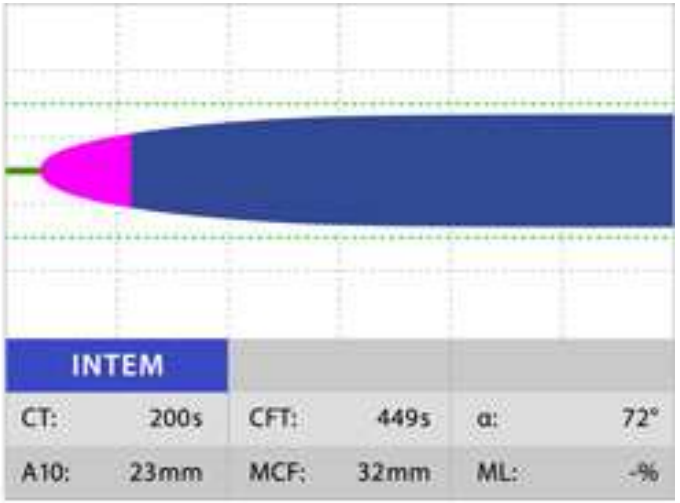
FIBTEM					
CT:	67s	CFT:	-s	α:	-°
A10:	15mm	MCF:	16mm	ML:	-%

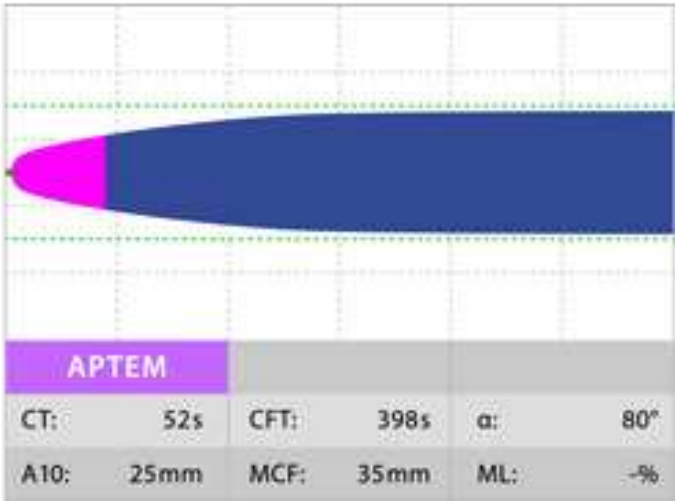


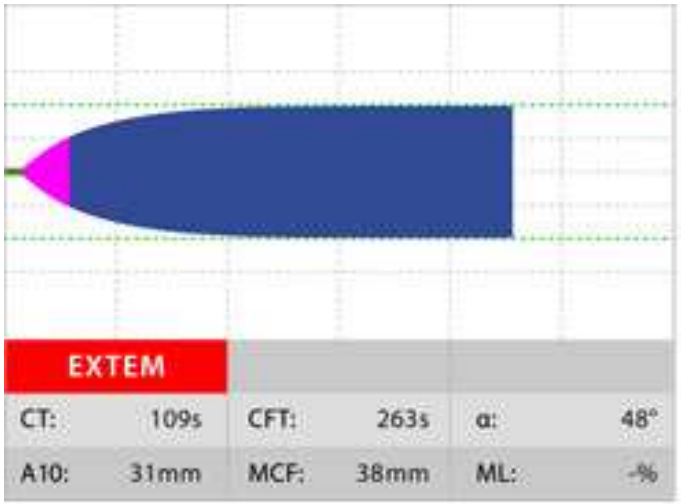
APTEM					
CT:	52s	CFT:	398s	α:	80°
A10:	25mm	MCF:	35mm	ML:	-%

Low Platelets

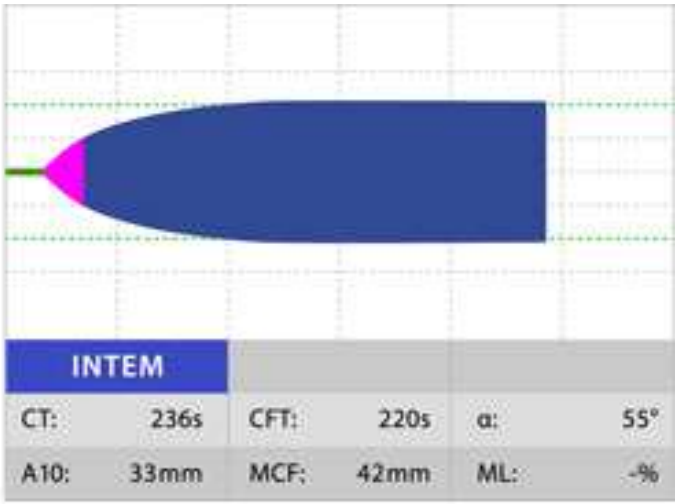






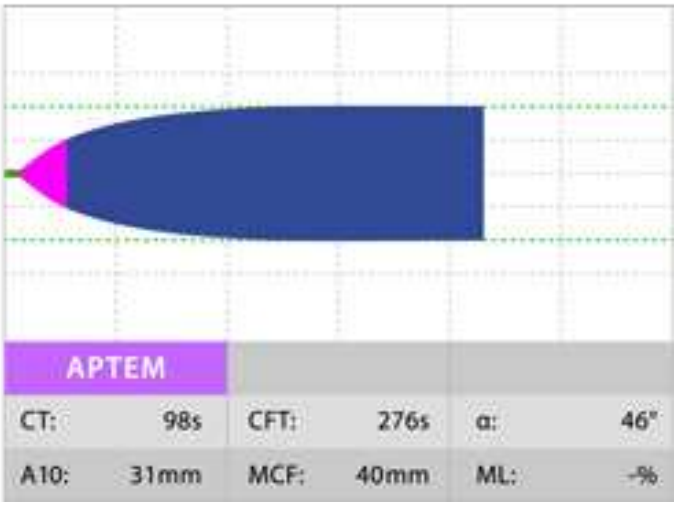


EXTEM					
CT:	109s	CFT:	263s	α:	48°
A10:	31mm	MCF:	38mm	ML:	-%



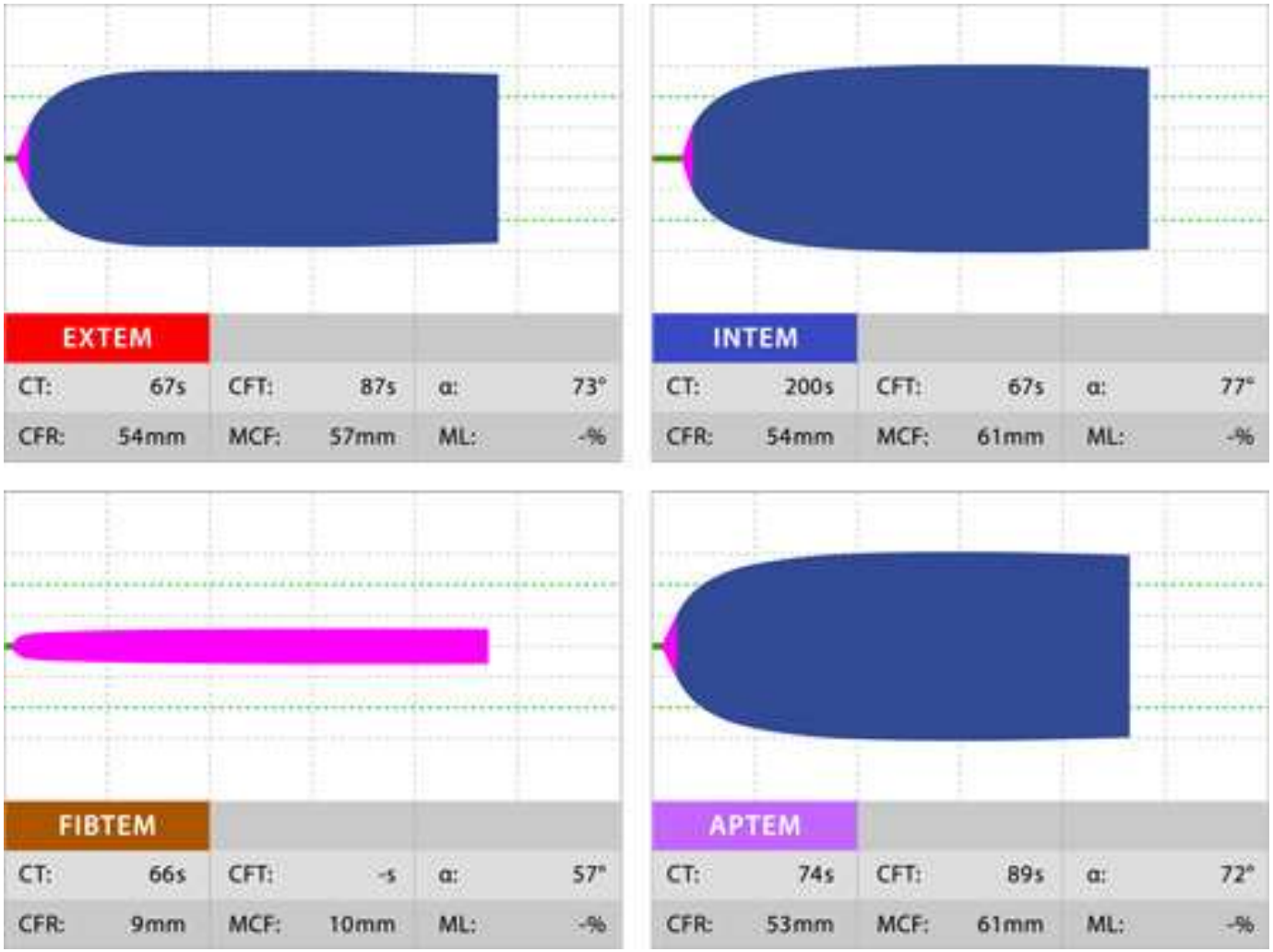
INTEM					
CT:	236s	CFT:	220s	α:	55°
A10:	33mm	MCF:	42mm	ML:	-%

FIBTEM					
CT:	185s	CFT:	-s	α:	-°
A10:	3mm	MCF:	3mm	ML:	-%



APTEM					
CT:	98s	CFT:	276s	α:	46°
A10:	31mm	MCF:	40mm	ML:	-%

Normal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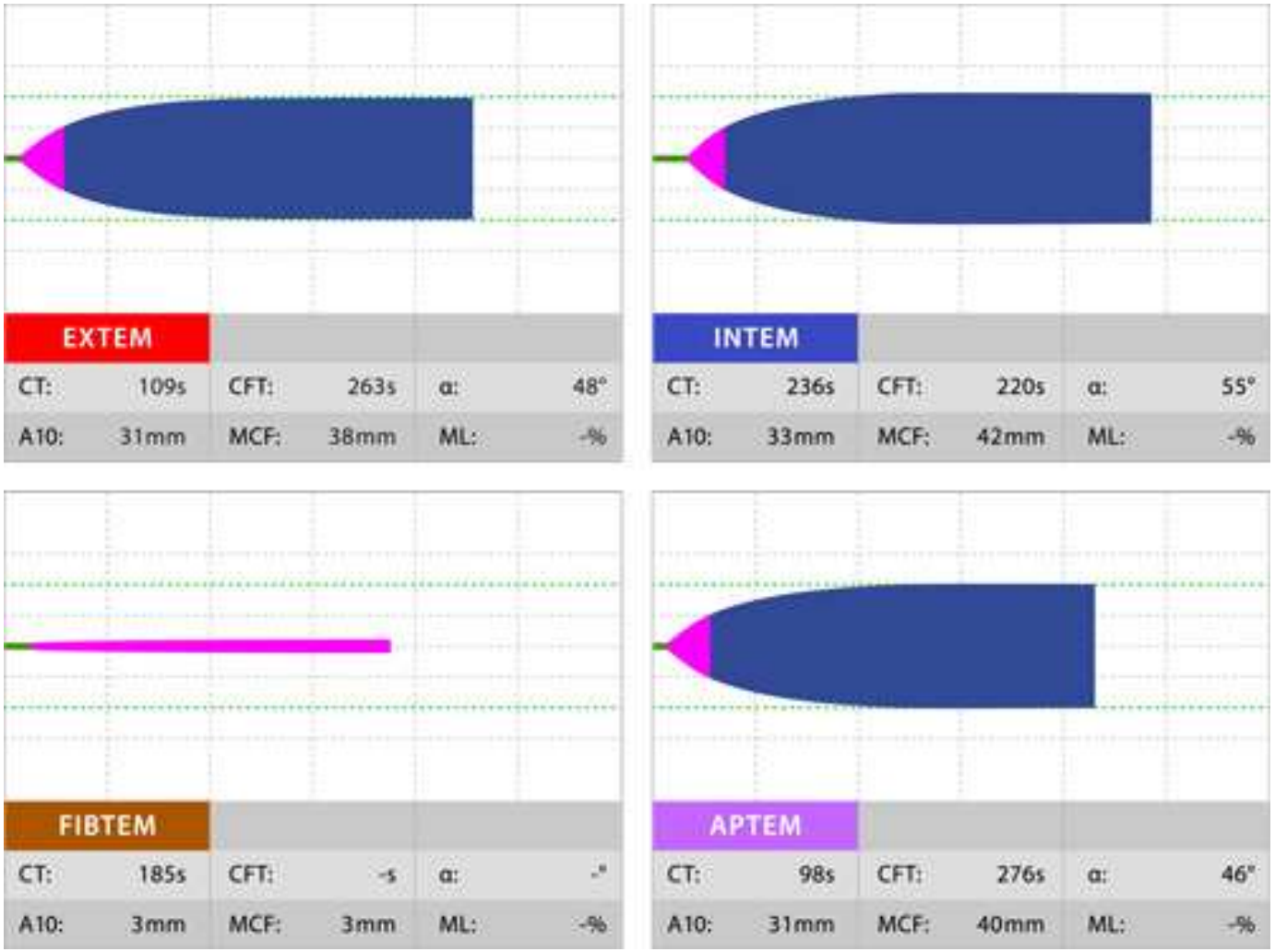
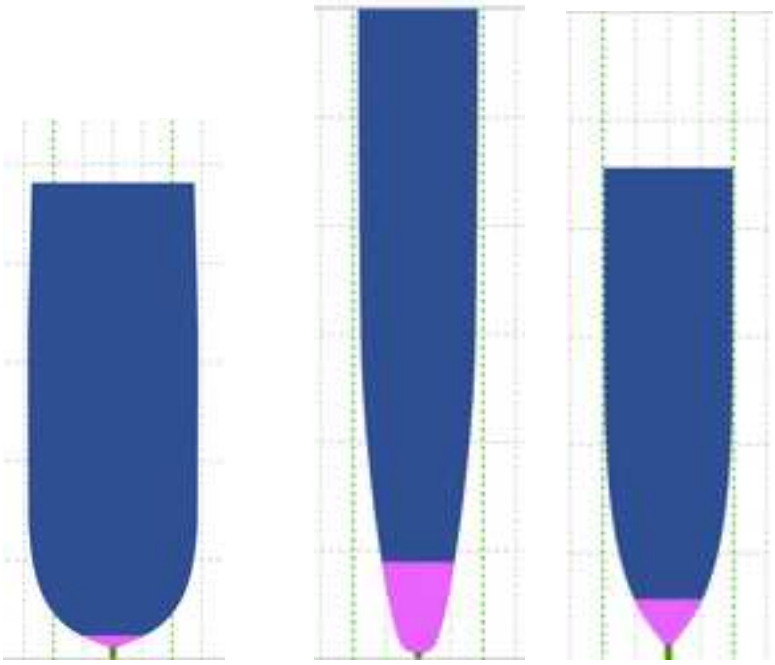
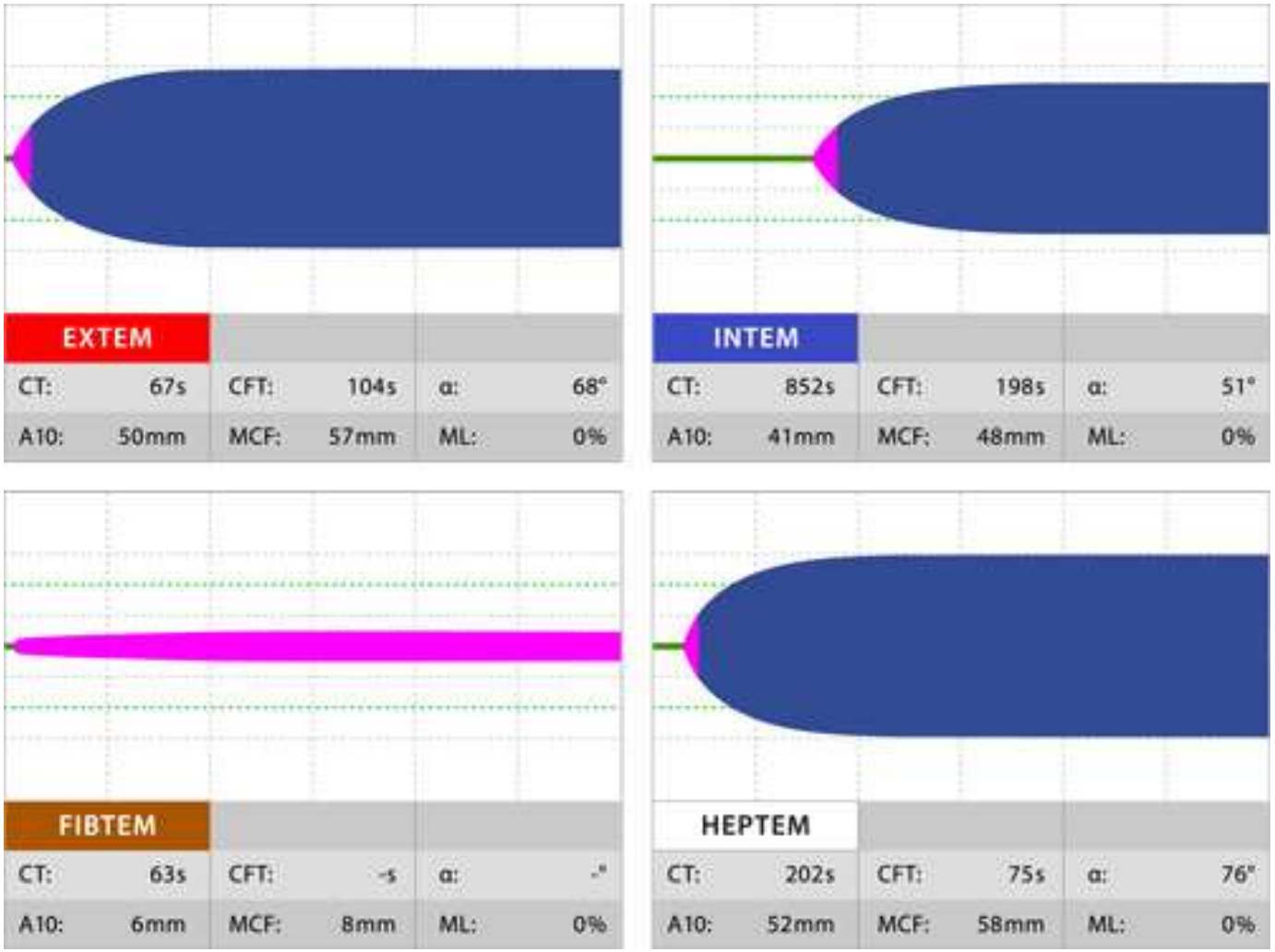
Hypo-fibrinogenaemia






RIESLING (DRY) /
PINOT GRIGIO
CHAMPAGNE
VINTAGE
CHAMPAGNE

Heparin Effect



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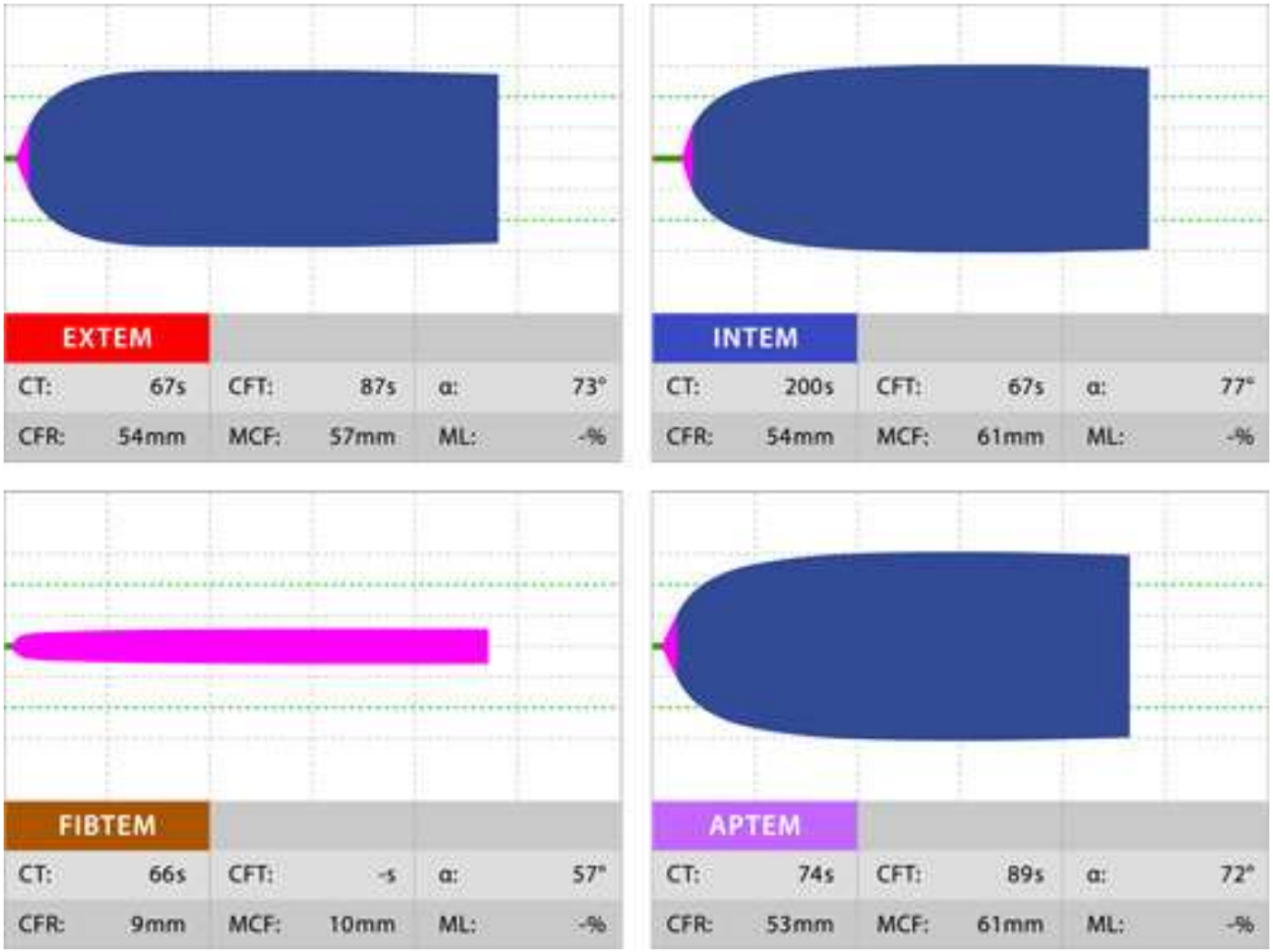
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TREATMENT

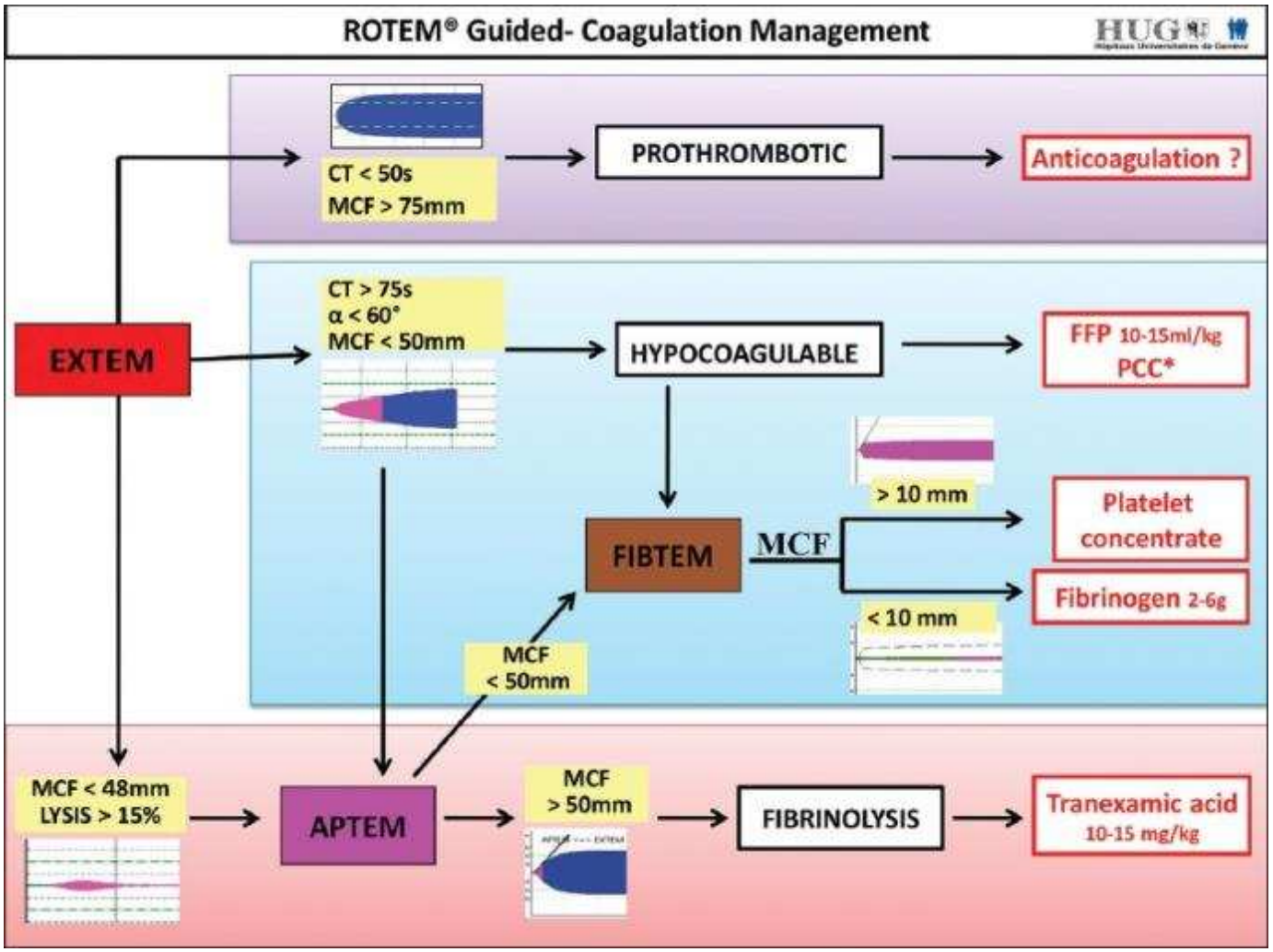
LIMITATIONS AND WARNINGS

- Treatment should be administered according to the clinical picture (e.g. volume & current rate of blood loss)
- Viscoelastic devices are not uniformly sensitive to all disturbances of coagulation status
  - e.g. platelet dysfunction, antiplatelets, LMWHs, warfarin, DOACs
- Pre-existing local protocols should be respected, given current level of evidence for POCCT devices.

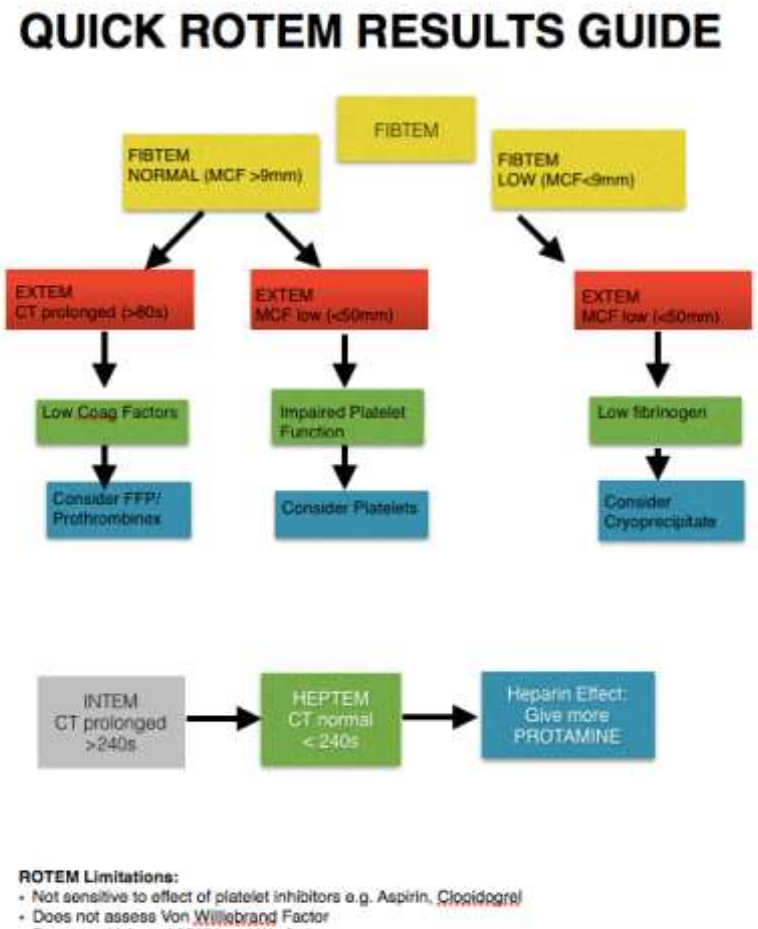
Where is it useful?

- Perioperative
  - Livers, cardiac, unanticipated bleeding
- Trauma
  - Pre- and in-theatre
- Obstetrics
  - PPH
- ITU

Algorithms


ROTEM® Guided- Coagulation Management
HUG
CT < 50s
MCF > 75mm
PROTHROMBOTIC
Anticoagulation ?
EXTEM
CT > 75s
α < 60°
MCF < 50mm
HYPOCOAGULABLE
FFP 10-15ml/kg
PCC*
> 10 mm
FIBTEM
MCF
Platelet concentrate
Fibrinogen 2-6g
< 10 mm
MCF < 50mm
MCF < 48mm
LYSIS > 15%
APTEM
MCF > 50mm
FIBRINOLYSIS
Tranexamic acid
10-15 mg/kg

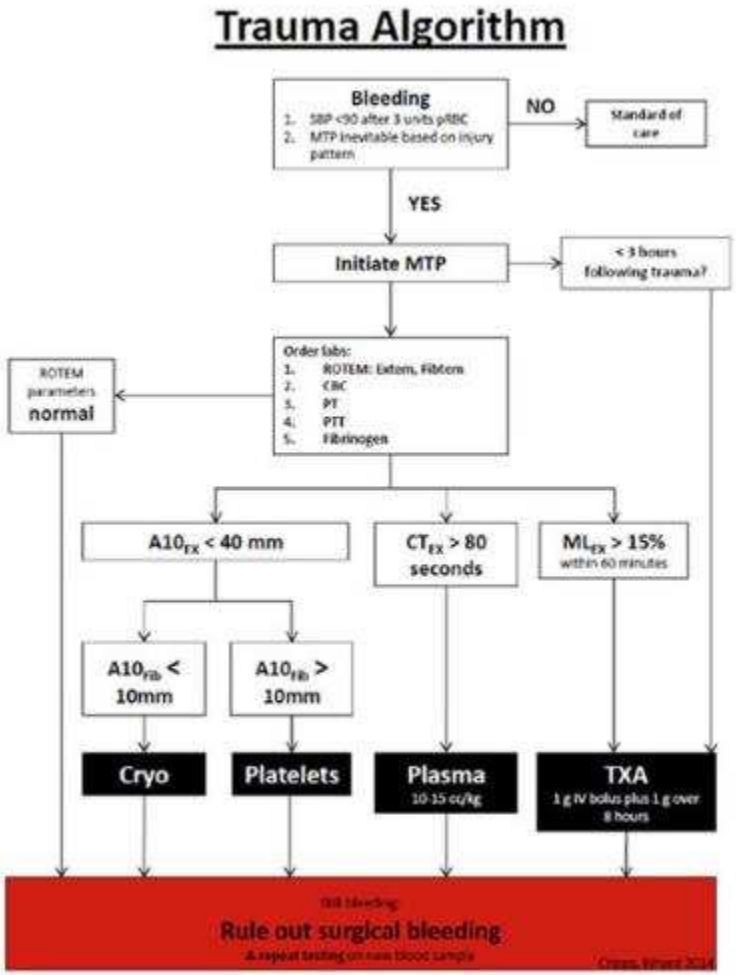
Algorithms



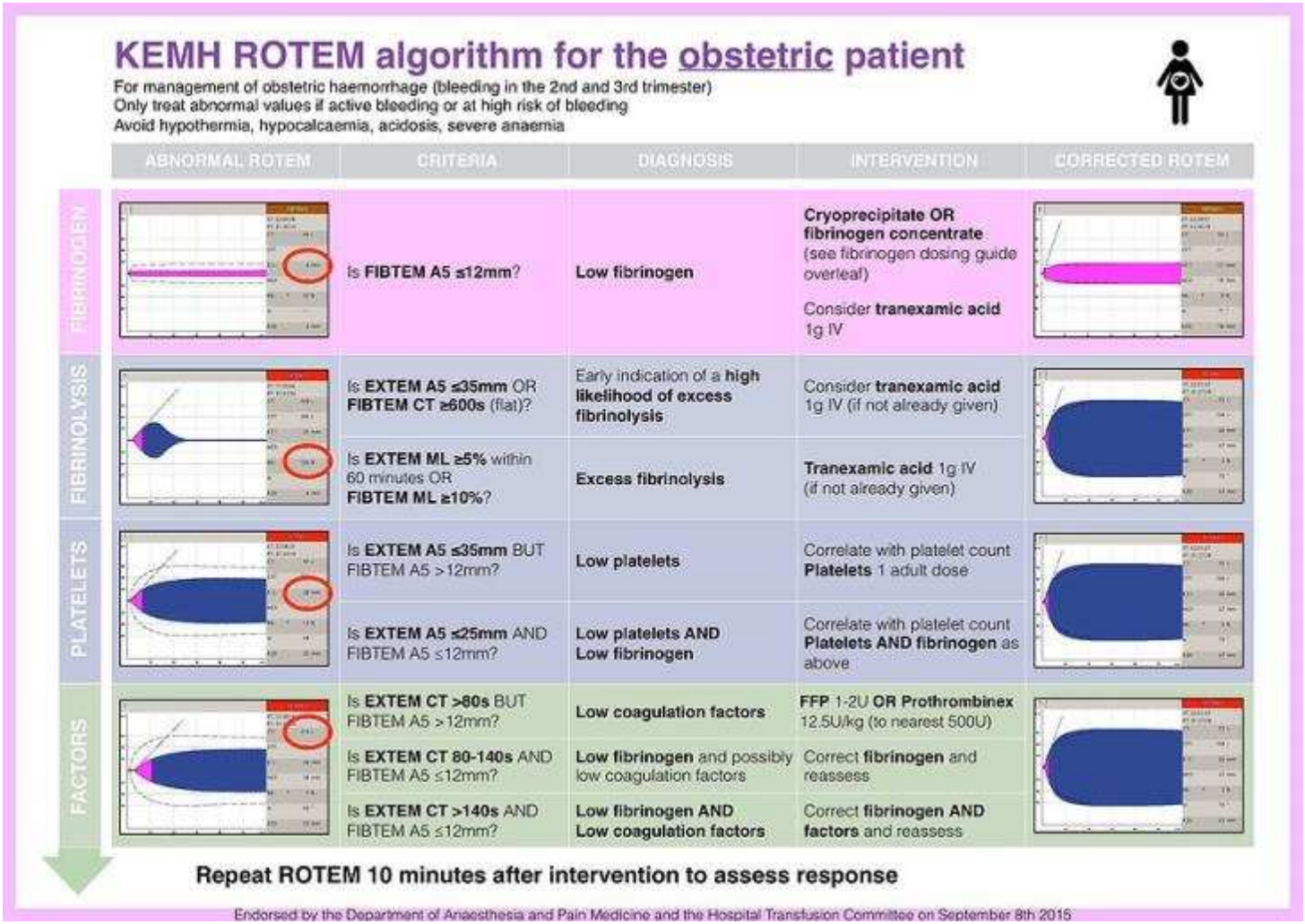
ROTEM Limitations:

- Not sensitive to effect of platelet inhibitors e.g. Aspirin, Clopidogrel
- Does not assess Von Willebrand Factor
- Poor sensitivity to LMWH and Warfarin

Algorithms


Trauma Algorithm
Bleeding
1. SBP <90 after 3 units pRBC
2. MTP inevitable based on injury pattern
NO
Standard of care
YES
Initiate MTP
< 3 hours following trauma?
Order labs:
1. ROTEM: Extem, Fibtem
2. CBC
3. PT
4. PTT
5. Fibrinogen
ROTEM parameters normal
A10EX < 40 mm
CTEX > 80 seconds
MLEX > 15%
within 60 minutes
A10Fib < 10mm
A10Fib > 10mm
Cryo
Platelets
Plasma
10-15 cc/kg
TXA
1 g IV bolus plus 1 g over 8 hours
Rule out surgical bleeding

Algorithms



KEMH ROTEM algorithm for the obstetric patient

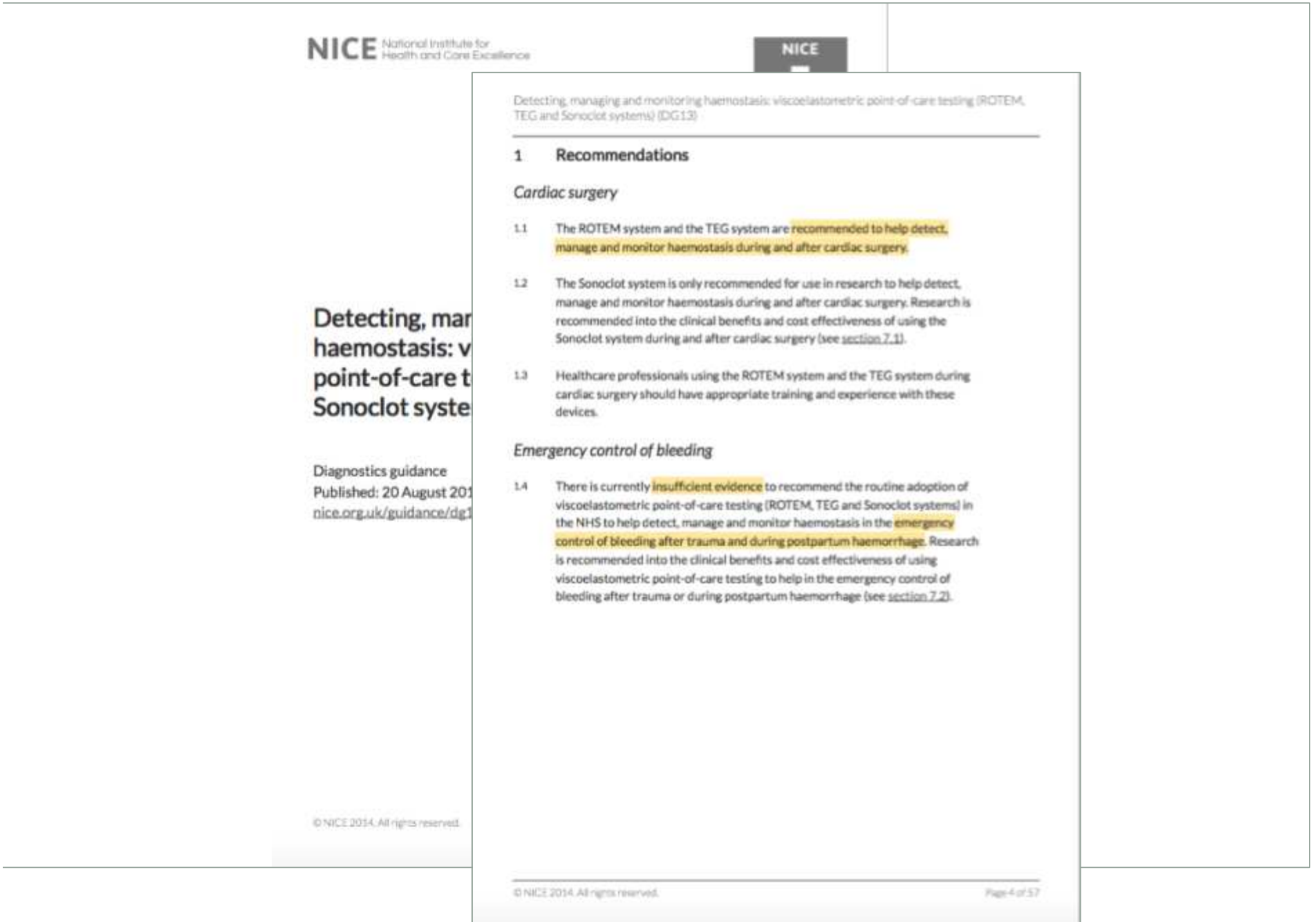
For management of obstetric haemorrhage (bleeding in the 2nd and 3rd trimester)
Only treat abnormal values if active bleeding or at high risk of bleeding
Avoid hypothermia, hypocalcaemia, acidosis, severe anaemia

	ABNORMAL ROTEM	CRITERIA	DIAGNOSIS	INTERVENTION	CORRECTED ROTEM
FIBRINOGEN		Is **FIBTEM A5 ≤12mm**?	**Low fibrinogen**	**Cryoprecipitate OR fibrinogen concentrate** (see fibrinogen dosing guide overleaf) Consider **tranexamic acid** 1g IV	
FIBRINOLYSIS		Is **EXTEM A5 ≤35mm** OR **FIBTEM CT ≥600s** (flat)?	Early indication of a **high likelihood of excess fibrinolysis**	Consider **tranexamic acid** 1g IV (if not already given)	
		Is **EXTEM ML ≥5%** within 60 minutes OR **FIBTEM ML ≥10%**?	**Excess fibrinolysis**	**Tranexamic acid** 1g IV (if not already given)	
PLATELETS		Is **EXTEM A5 ≤35mm** BUT FIBTEM A5 >12mm?	**Low platelets**	Correlate with platelet count **Platelets** 1 adult dose	
		Is **EXTEM A5 ≤25mm** AND FIBTEM A5 ≤12mm?	**Low platelets AND Low fibrinogen**	Correlate with platelet count **Platelets AND fibrinogen** as above	
FACTORS		Is **EXTEM CT >80s** BUT FIBTEM A5 >12mm?	**Low coagulation factors**	**FFP** 1-2U **OR Prothrombinex** 12.5U/kg (to nearest 500U)	
		Is **EXTEM CT 80-140s** AND FIBTEM A5 ≤12mm?	**Low fibrinogen** and possibly low coagulation factors	Correct **fibrinogen** and reassess	
		Is **EXTEM CT >140s** AND FIBTEM A5 ≤12mm?	**Low fibrinogen AND Low coagulation factors**	Correct **fibrinogen AND factors** and reassess	

Repeat ROTEM 10 minutes after intervention to assess response

Endorsed by the Department of Anaesthesia and Pain Medicine and the Hospital Transfusion Committee on September 8th 2015

LITERATURE


NICE National Institute for Health and Care Excellence

NICE

Detecting, mar
haemostasis: v
point-of-care t
Sonoclot syste

Diagnostics guidance
Published: 20 August 201
nice.org.uk/guidance/dg1

1 Recommendations

Cardiac surgery

1.1 The ROTEM system and the TEG system are recommended to help detect, manage and monitor haemostasis during and after cardiac surgery.

1.2 The Sonoclot system is only recommended for use in research to help detect, manage and monitor haemostasis during and after cardiac surgery. Research is recommended into the clinical benefits and cost effectiveness of using the Sonoclot system during and after cardiac surgery (see section 7.1).

1.3 Healthcare professionals using the ROTEM system and the TEG system during cardiac surgery should have appropriate training and experience with these devices.

Emergency control of bleeding

1.4 There is currently insufficient evidence to recommend the routine adoption of viscoelastometric point-of-care testing (ROTEM, TEG and Sonoclot systems) in the NHS to help detect, manage and monitor haemostasis in the emergency control of bleeding after trauma and during postpartum haemorrhage. Research is recommended into the clinical benefits and cost effectiveness of using viscoelastometric point-of-care testing to help in the emergency control of bleeding after trauma or during postpartum haemorrhage (see section 7.2).

Hunt H, Stanworth S, Curry N, Woolley T, Cooper C, Ukoumunne O, Zhelev Z, Hyde C.
Thromboelastography (TEG) and rotational thromboelastometry (ROTEM) for trauma induced coagulopathy in adult trauma patients with bleeding.
Cochrane Database of Systematic Reviews 2015, Issue 2. Art. No.: CD010438.
DOI: 10.1002/14651858.CD010438.pub2.

www.cochranelibrary.com

Objectives

The objective was to determine the diagnostic accuracy of thromboelastography (TEG) and rotational thromboelastometry (ROTEM) for TIC in adult trauma patients with bleeding, using a reference standard of prothrombin time ratio and/or the international normalized ratio.

Authors' conclusions

We found no evidence on the accuracy of TEG and very little evidence on the accuracy of ROTEM. The value of accuracy estimates are considerably undermined by the small number of included studies, and concerns about risk of bias relating to the index test and the reference standard. We recognise that the reference standards of PT and INR are imperfect, but in the absence of embedded clinical consensus these are judged to be the best reflection of current clinical practice. We are unable to offer advice on the use of global measures of haemostatic function for trauma based on the evidence on test accuracy identified in this systematic review. This evidence strongly suggests that at present these tests should only be used for research. We consider more thoroughly what this research could be in the Discussion section.

Wikkelsø A, Wetterslev J, Møller AM, Afshari A.

Thromboelastography (TEG) or thromboelastometry (ROTEM) to monitor haemostatic treatment versus usual care in adults or children with bleeding.

Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD007871.

DOI: 10.1002/14651858.CD007871.pub3.

www.cochranelibrary.com

Objectives

We assessed the benefits and harms of thromboelastography (TEG)-guided or thromboelastometry (ROTEM)-guided transfusion in adults and children with bleeding. We looked at various outcomes, such as overall mortality and bleeding events, conducted subgroup and sensitivity analyses, examined the role of bias, and applied trial sequential analyses (TSAs) to examine the amount of evidence gathered so far.

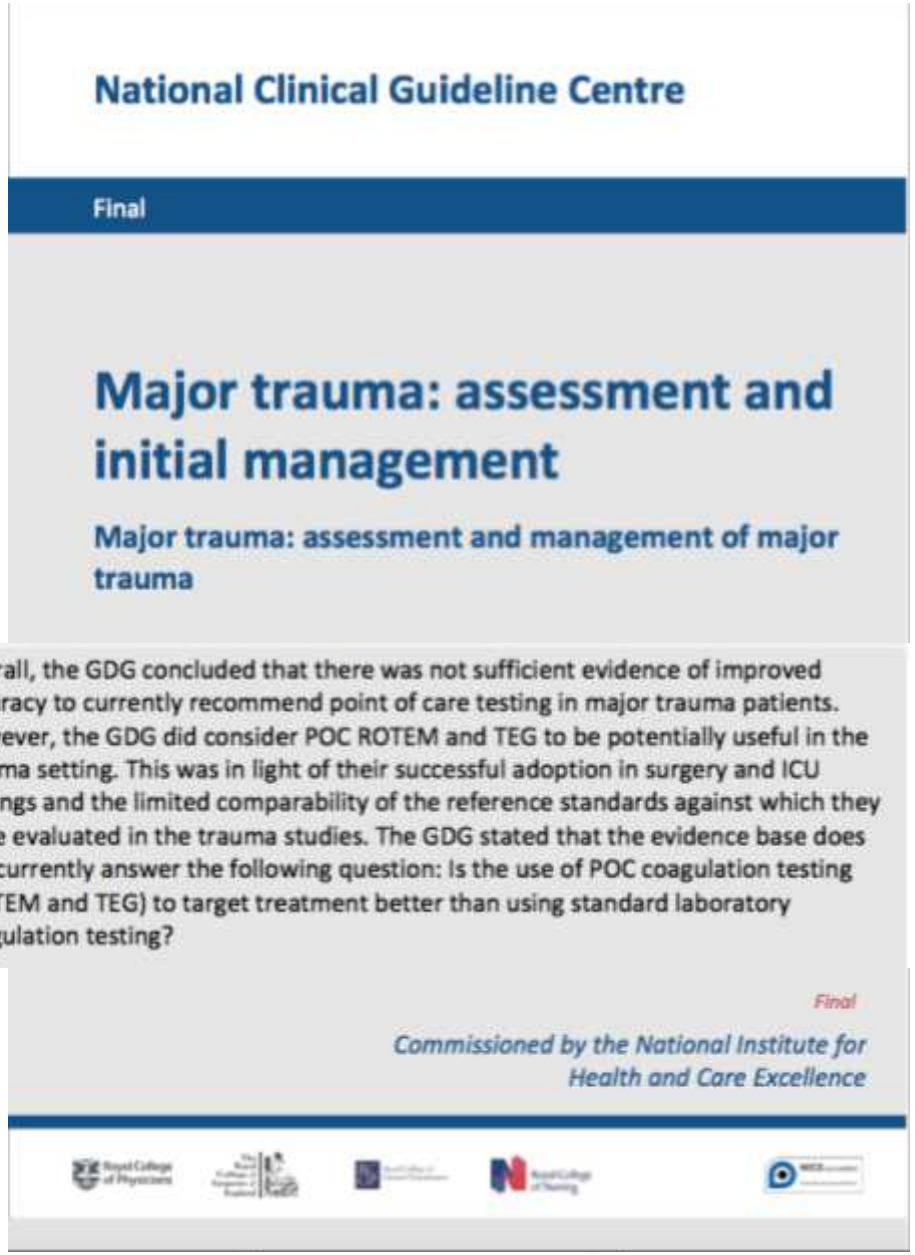
Selection criteria

We included all RCTs, irrespective of blinding or language, that compared transfusion guided by TEG or ROTEM to transfusion guided by clinical judgement, guided by standard laboratory tests, or a combination. We also included interventional algorithms including both TEG or ROTEM in combination with standard laboratory tests or other devices. The primary analysis included trials on TEG or ROTEM versus any comparator.

Authors' conclusions

There is growing evidence that application of TEG- or ROTEM-guided transfusion strategies may reduce the need for blood products, and improve morbidity in patients with bleeding. However, these results are primarily based on trials of elective cardiac surgery involving cardiopulmonary bypass, and the level of evidence remains low. Further evaluation of TEG- or ROTEM-guided transfusion in acute settings and other patient categories in low risk of bias studies is needed.

TRAUMA



National Clinical Guideline Centre

Final

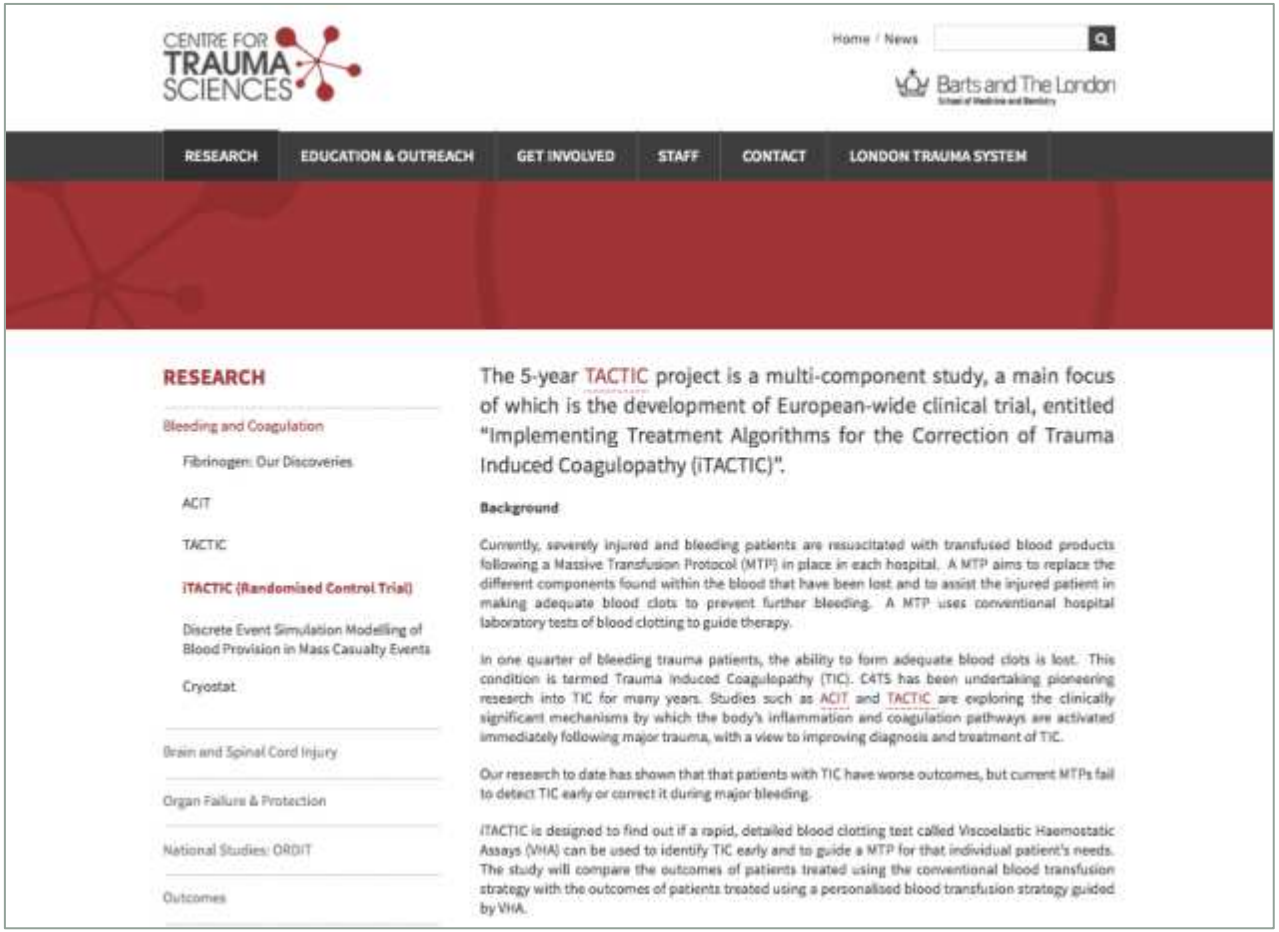
Major trauma: assessment and initial management

Major trauma: assessment and management of major trauma

Other considerations	Overall, the GDG concluded that there was not sufficient evidence of improved accuracy to currently recommend point of care testing in major trauma patients. However, the GDG did consider POC ROTEM and TEG to be potentially useful in the trauma setting. This was in light of their successful adoption in surgery and ICU settings and the limited comparability of the reference standards against which they were evaluated in the trauma studies. The GDG stated that the evidence base does not currently answer the following question: Is the use of POC coagulation testing (ROTEM and TEG) to target treatment better than using standard laboratory coagulation testing?

Final

Commissioned by the National Institute for Health and Care Excellence



http://www.c4ts.qmul.ac.uk/bleeding-and-coalgulation/itactic (Accessed on 9/10/16)

OBSTETRICS

ARTICLE IN PRESS

International Journal of Obstetric Anesthesia (2016) xxx, xxx–xxx

http://dx.doi.org/10.1016/j.ijoa.2016.06.006

ELSEVIER
www.obstetanesthesia.com

CONTROVERSY

Report of a debate held at the Obstetric Anaesthetists' Association Cases and Clinical Challenges Meeting, London, UK, March 2016

Coagulation point-of-care testing on the labour ward should be mandatory

Proposer: R. Collis
Department of Anaesthetics, University Hospital of Wales, Cardiff, UK

OBSTETRICS

Anaesthesia 2015, 70, 166–175 doi:10.1111/anae.12859

Original Article

Introduction of an algorithm for ROTEM-guided fibrinogen concentrate administration in major obstetric haemorrhage

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OUR EXPERIENCE

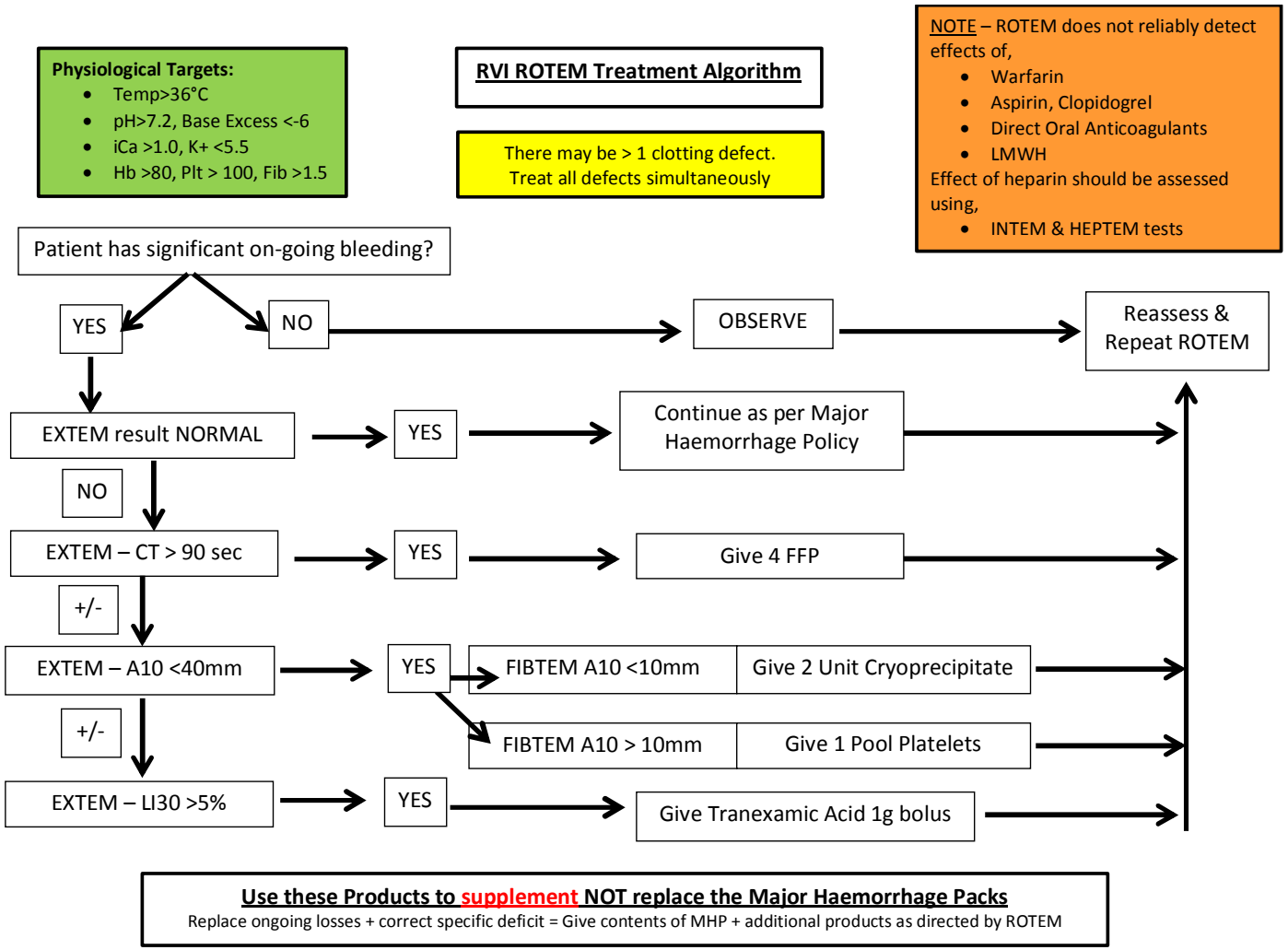
NUTH Experience

- Introduced POCCT end of 2014 after an evaluation period to assess feasibility, reliability and accuracy.

- Trialled TEG 5000, ROTEM Delta in theatre (POCCT), TEG and ROTEM in lab and compared with standard lab tests coag tests.

- Findings
  - Generally good concordance between POCT and lab tests
  - Higher user error for more complicated procedures
  - Sending samples to lab could introduce a delay of **50mins** over POCT

NUTH algorithm



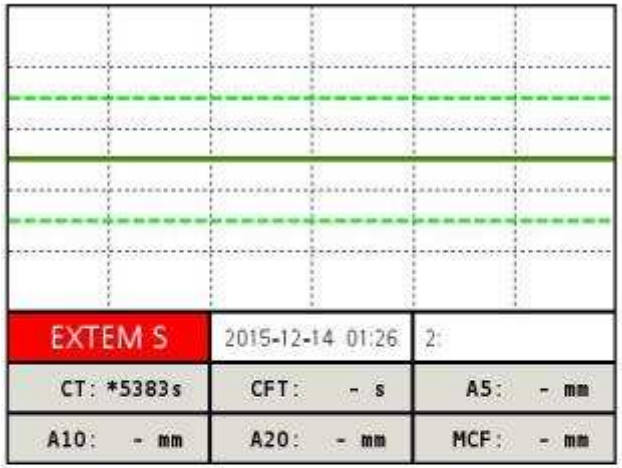
NUTH Experience since…

- Valuable technology, very useful addition to arsenal.
- Can be ‘transfusion-sparing’; imparts confidence that management strategy is correct.
- Speed of testing and results

- **Issues**
  - Training
  - Regular use
  - QC
  - Interpretation
  - IT
  - Interference with MHP

When is it useful?

- To confirm that MHP is addressing specific transfusion requirements of patient (e.g. bleed then DIC)
- In cases of slow, steady transfusions that haven’t reached MHP level
- To exclude ‘anaesthetic’ bleeding
- To confirm that transfusion goals have been achieved



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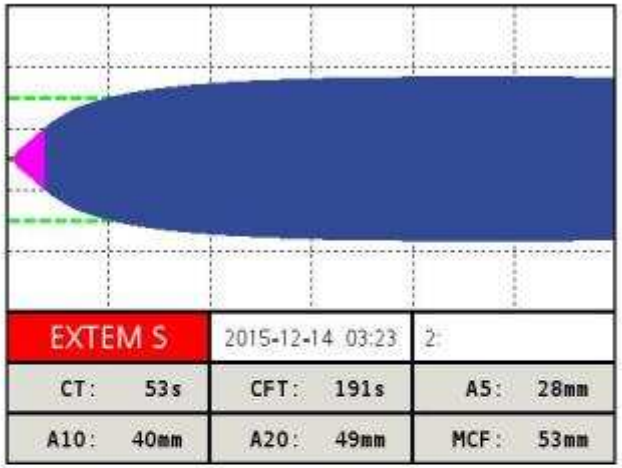
CT: *5383s	CFT: - s	A5: - mm
A10: - mm	A20: - mm	MCF: - mm



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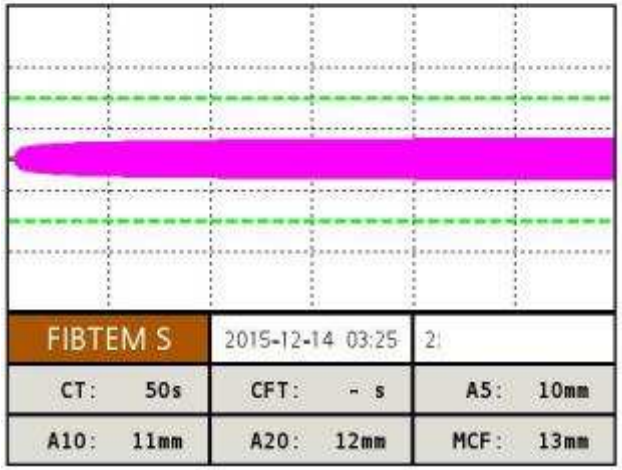
A10: 40mm	A20: 49mm	MCF: 53mm



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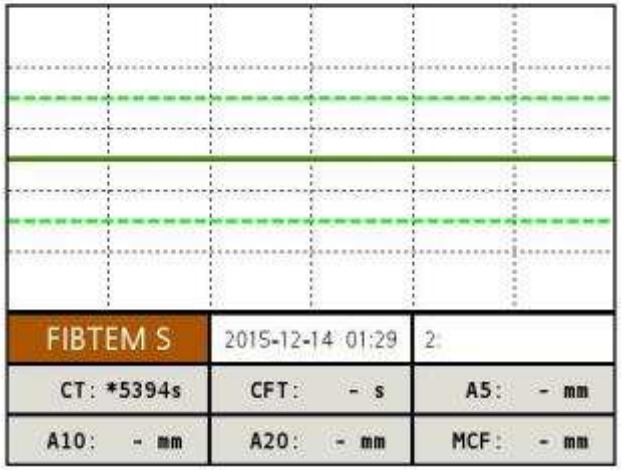
A10: 11mm	A20: 12mm	MCF: 13mm



FIBTEM S	2015-12-14 01:29	2:
CT: *5394s	CFT: - s	A5: - mm
A10: - mm	A20: - mm	MCF: - mm

SUMMARY

- Viscoelastic, POCCT devices offer the prospect of rapid assessment and rational, individually tailored transfusion therapy in the management of major haemorrhage.
- Barriers remain to their effective and efficient use, and in many areas a protocolised transfusion strategy may still produce the best outcomes overall.
- Evidence of effectiveness is lacking still, but it is difficult to imagine these devices will not be more widely used in the near future.

THANK YOU