Application of thromboelastography in clinical practice and how to control quality

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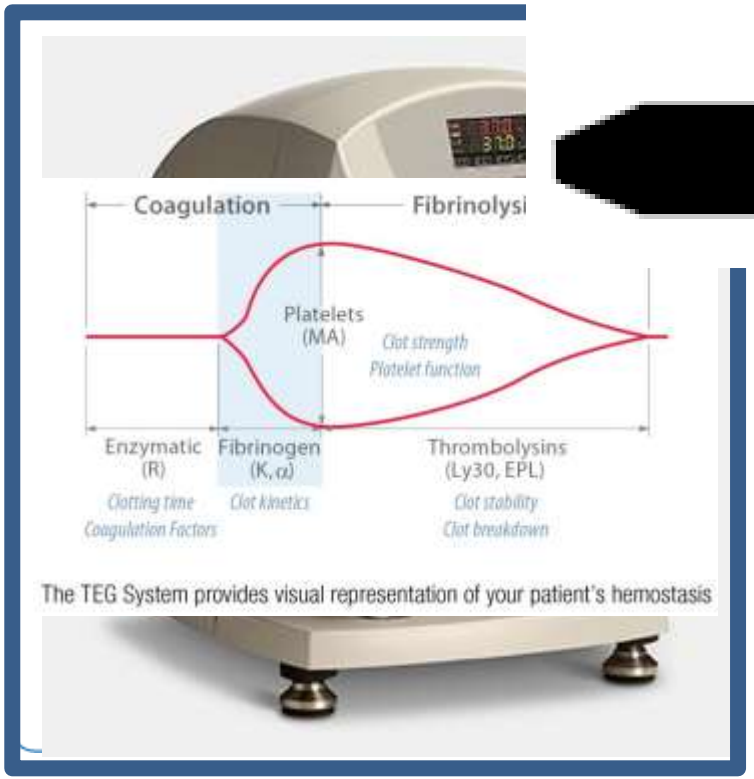
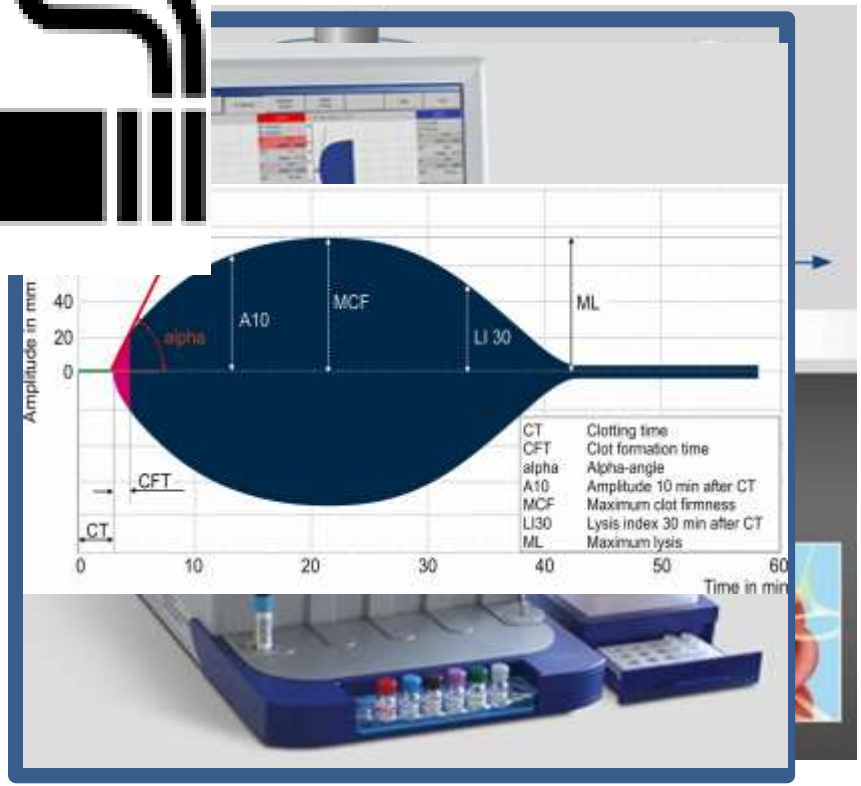
- **AGENDA**

1. **What is trombo-elastometry/graphy (ROTEM/TEG)**
2. **Indication for use: (massive) blood loss**
3. **The road to ROTEM in Maastricht UMC+**
4. **The bridge to Quality aspects**
   - **Internal QC**
   - **External QC → the ECAT pilots 2013 & 2014**

Thrombo-elastography (Hartert, Heidelberg, 1948)

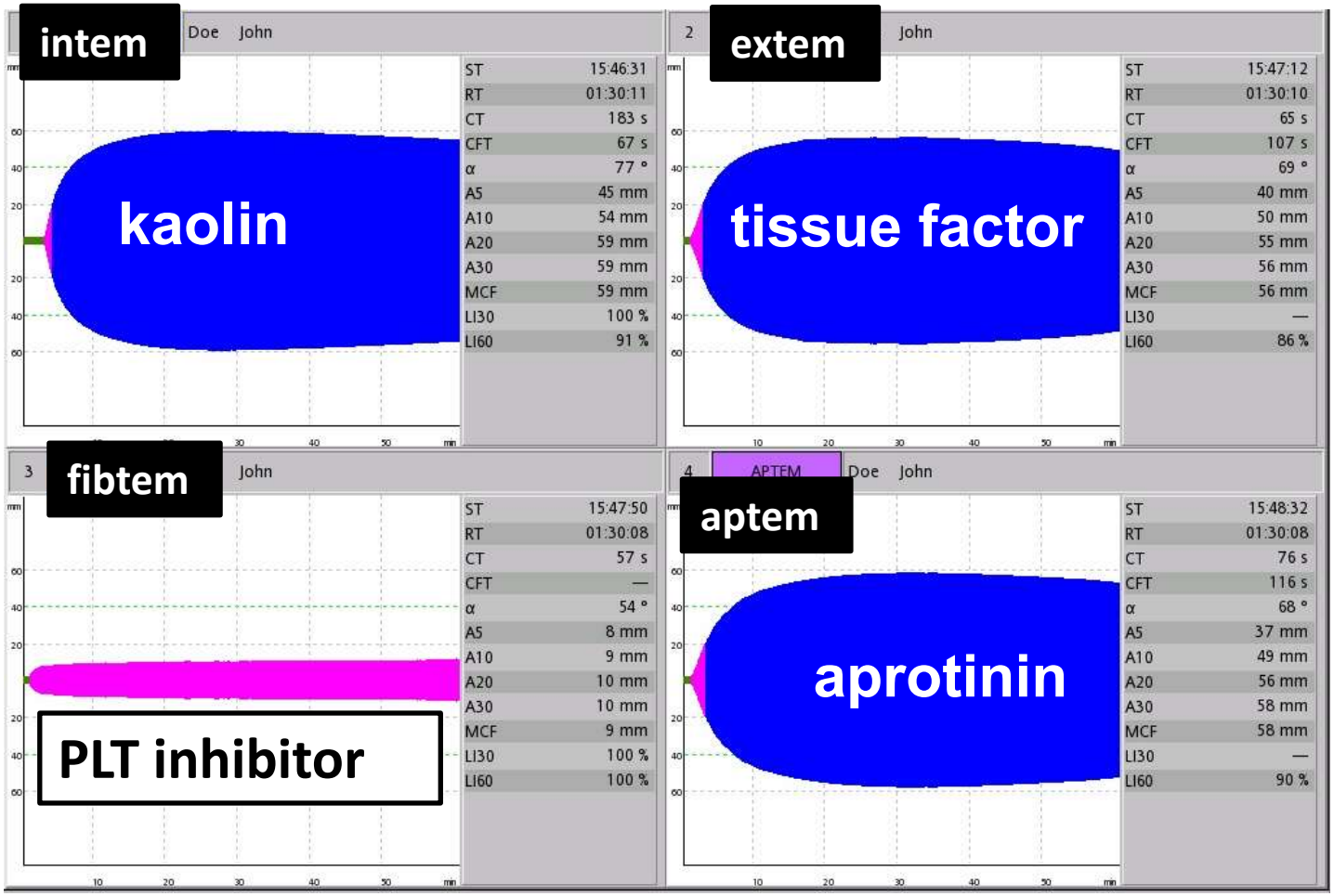
TEG **M**



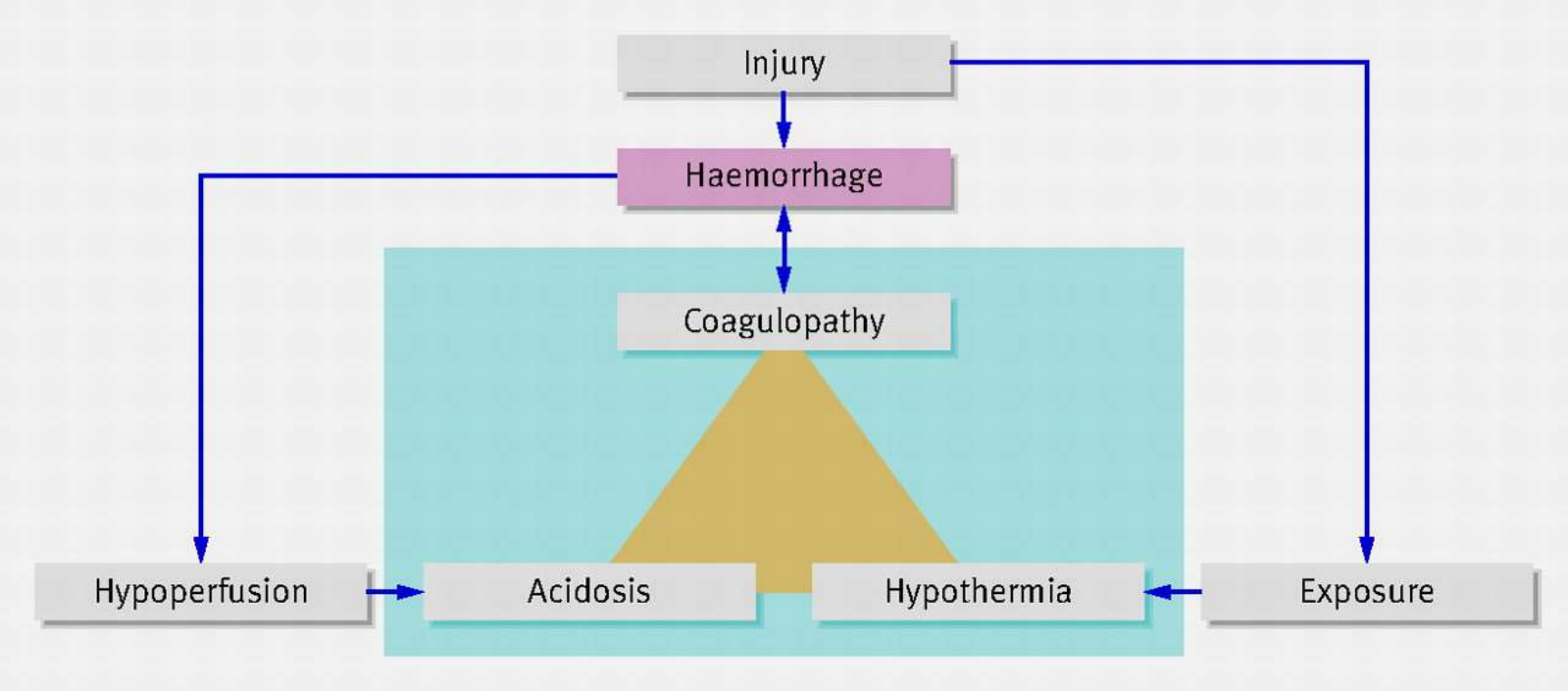


ROTEM	Activator
Extem	Tissue factor
Intem	Kaolin
Fibtem	Tissue factor + platelet inhibitor
Aptem	Tissue factor + aprotinin
Heptem	Kaolin + heparinase

Normal ROTEM pattern
CT, A10, MCF



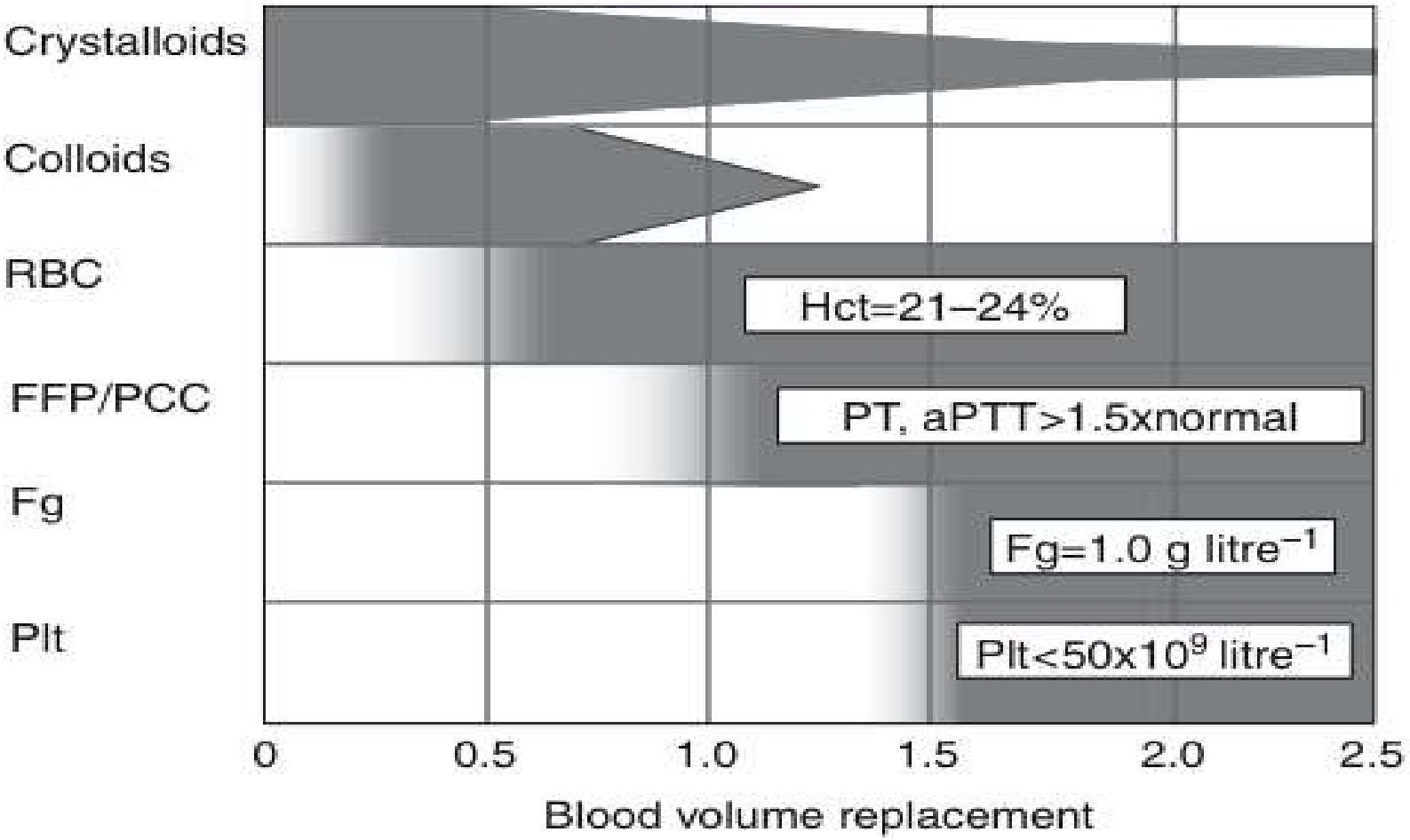
Indications for use
Massive blood loss
Prevent the lethal triad



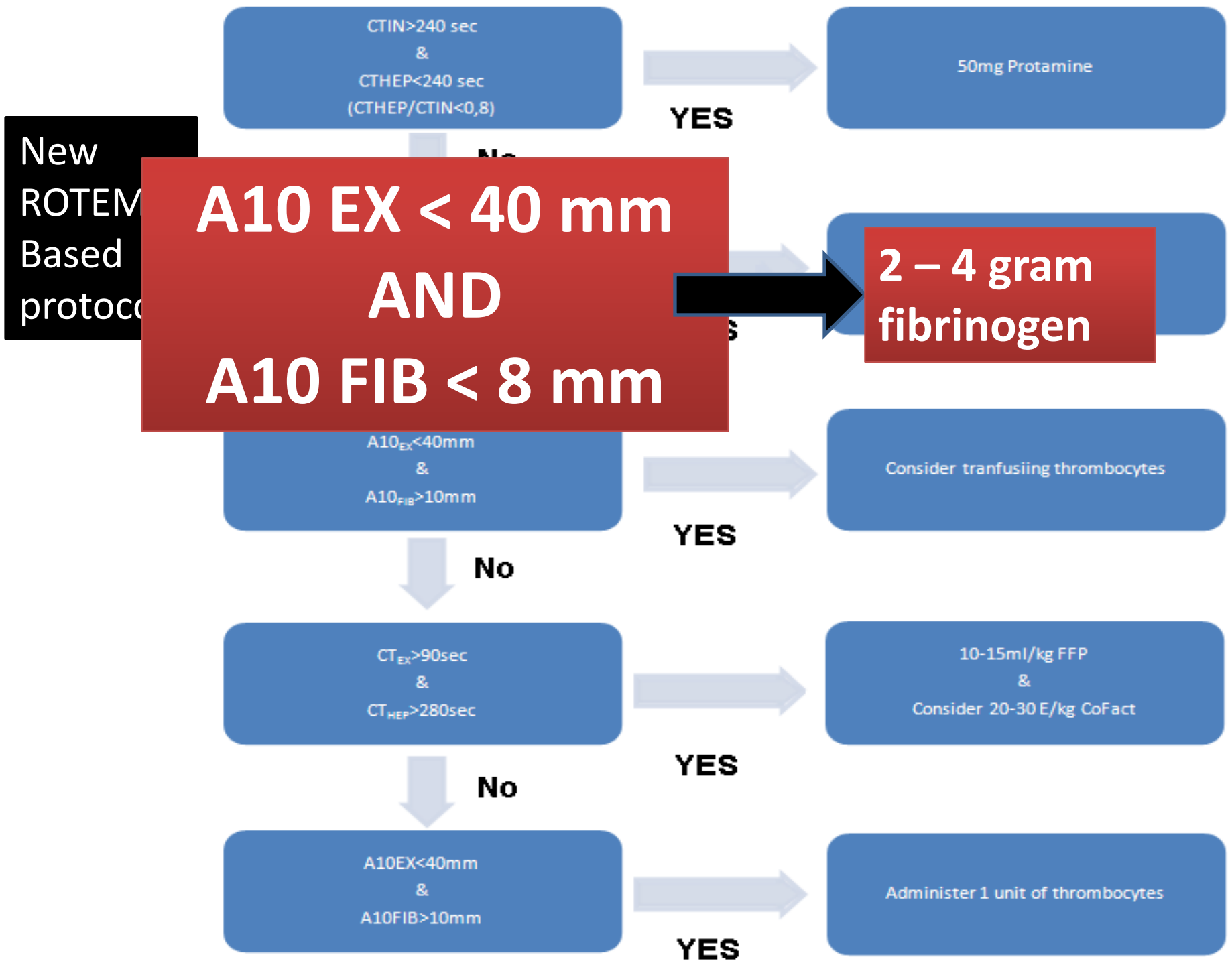
What is needed for treatment of the bleeding patient

1. **Standard procedure for diagnosis of coagulopathy, treatment of massive blood loss, monitoring of treatment.**
2. **Fast laboratory results on hemostasis**
3. **Fast availability of all types of blood products**
4. **Continuous training of staff members on the procedure**

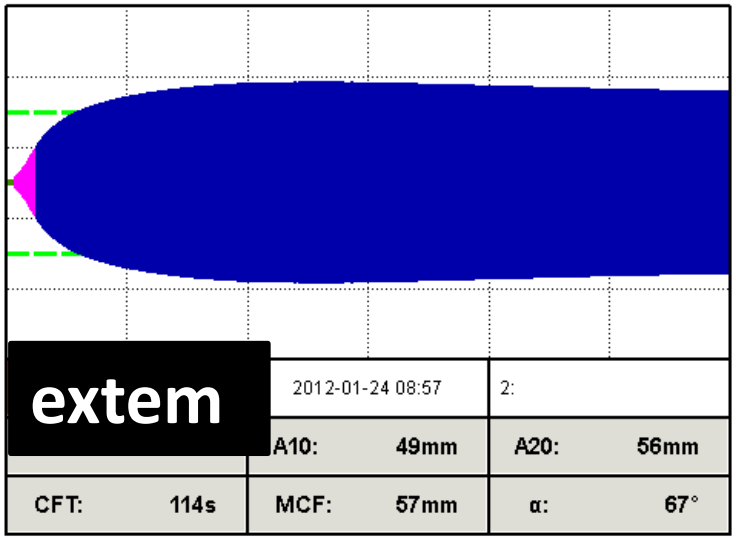
Traditional protocols

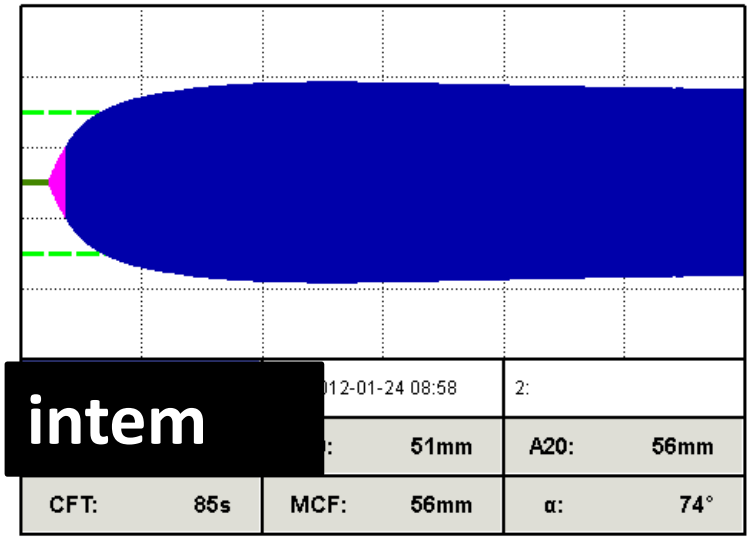


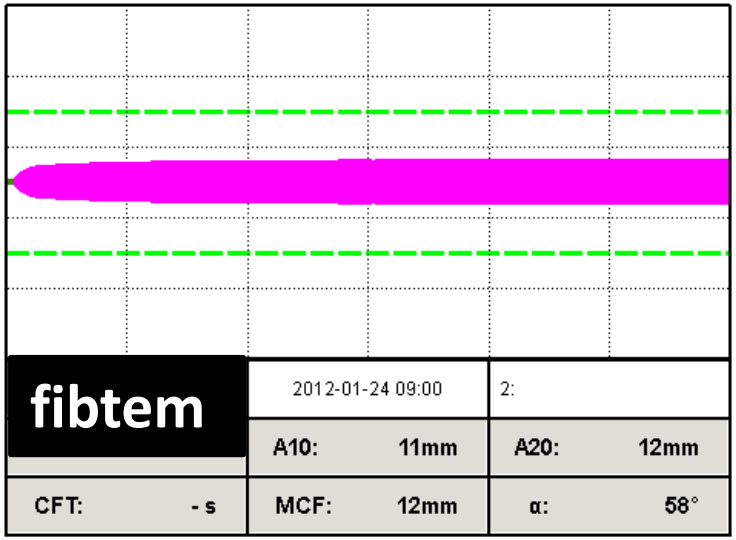
Erber WN Transfus Apheresis Sci 2002;27:83-92

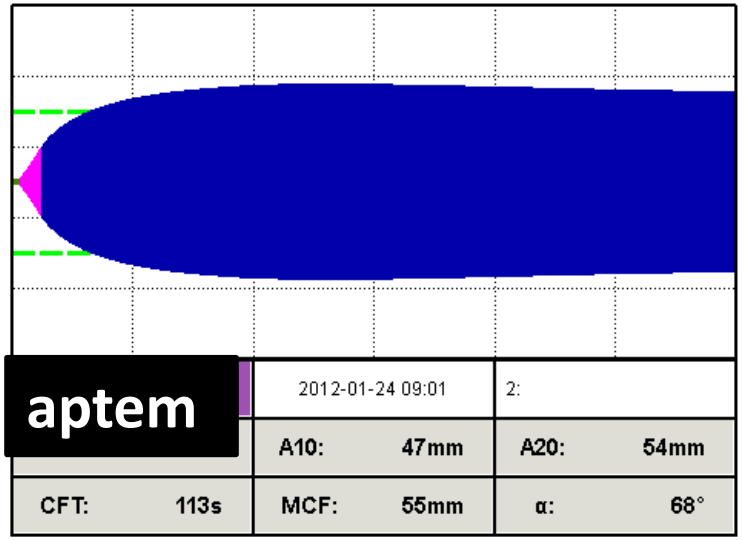

New ROTEM Based protocc
CTIN>240 sec
&
CTHEP<240 sec
(CTHEP/CTIN<0,8)
YES
50mg Protamine
No
A10 EX < 40 mm
AND
A10 FIB < 8 mm
2 – 4 gram fibrinogen
A10EX<40mm
&
A10FIB>10mm
Consider tranfusiing thrombocytes
YES
No
CTEX>90sec
&
CTHEP>280sec
10-15ml/kg FFP
&
Consider 20-30 E/kg CoFact
YES
No
A10EX<40mm
&
A10FIB>10mm
Administer 1 unit of thrombocytes
YES

Patient: ROTEM before Cardiothoracic surgery



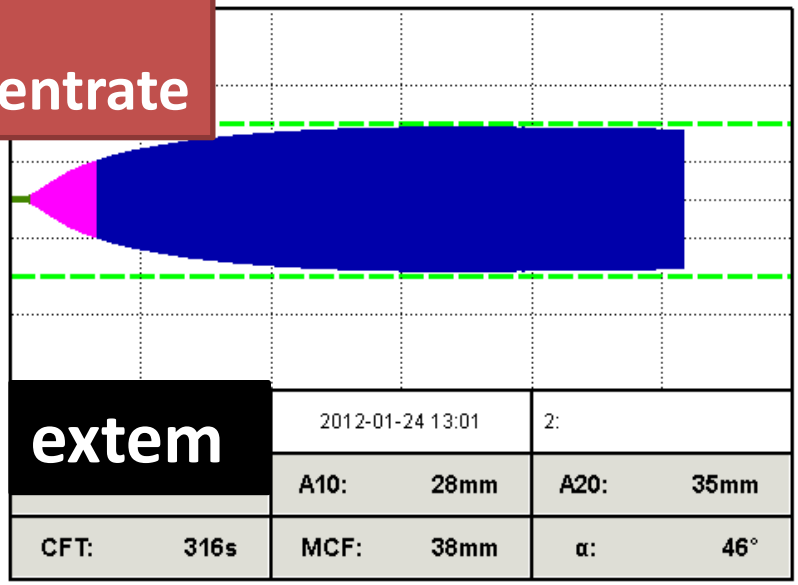




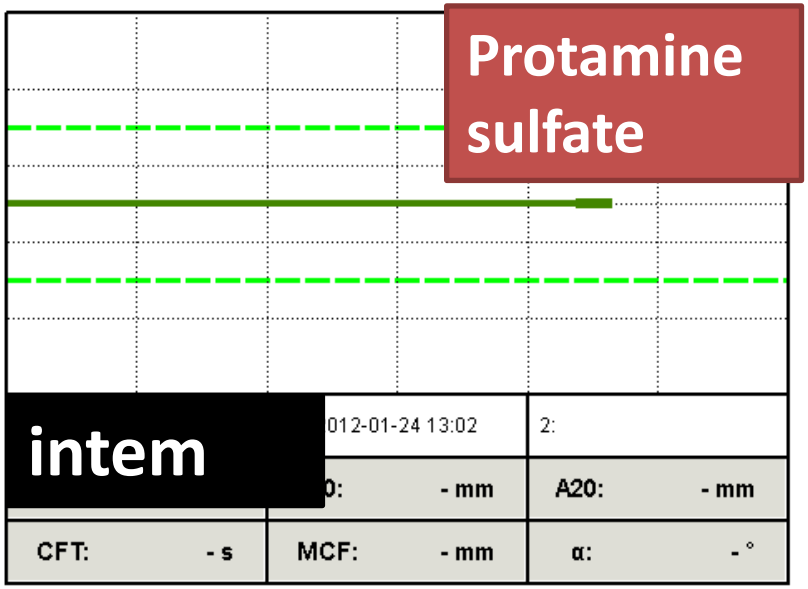


Patient: 4 hours later, at the end of extracorporeal circulation

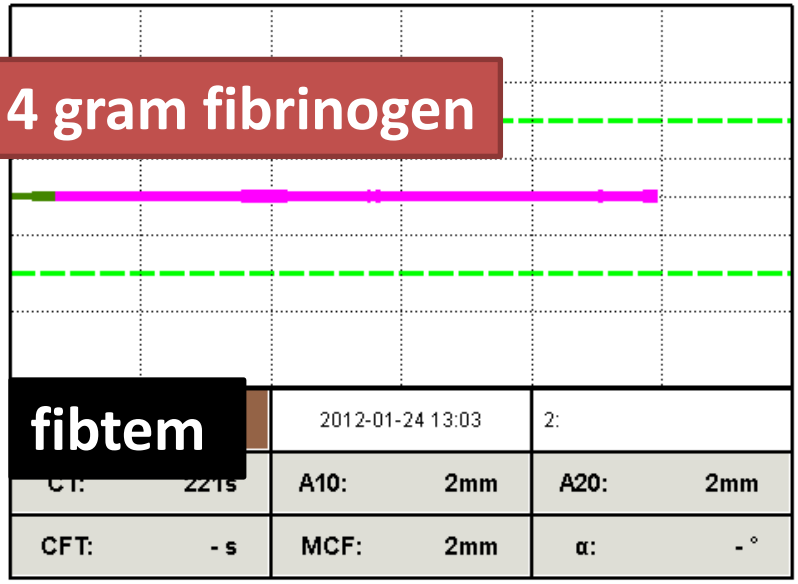
1 Plt concentrate

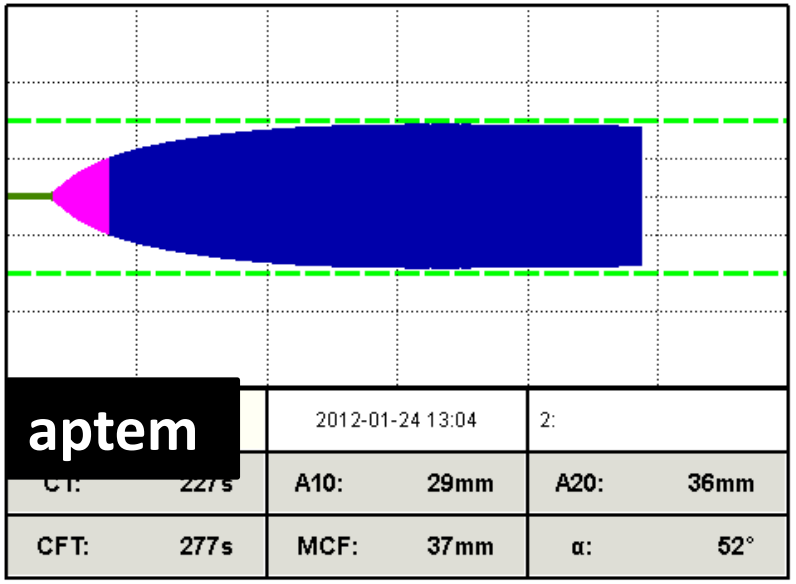


Protamine sulfate



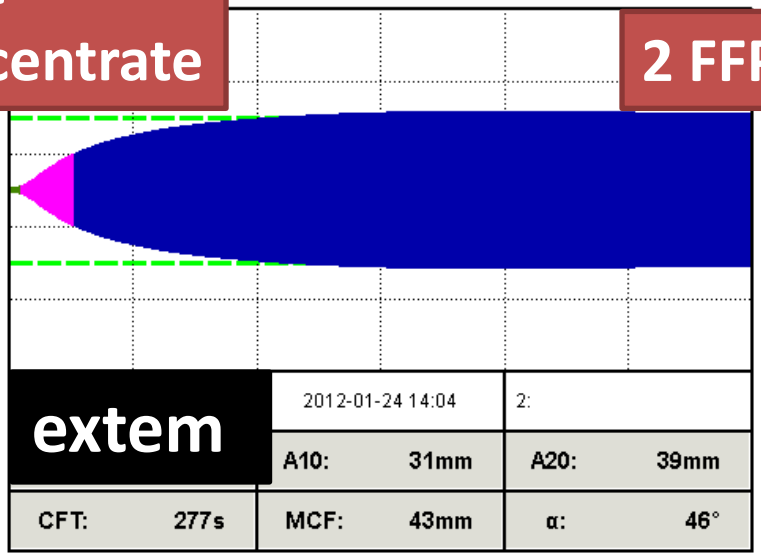
4 gram fibrinogen



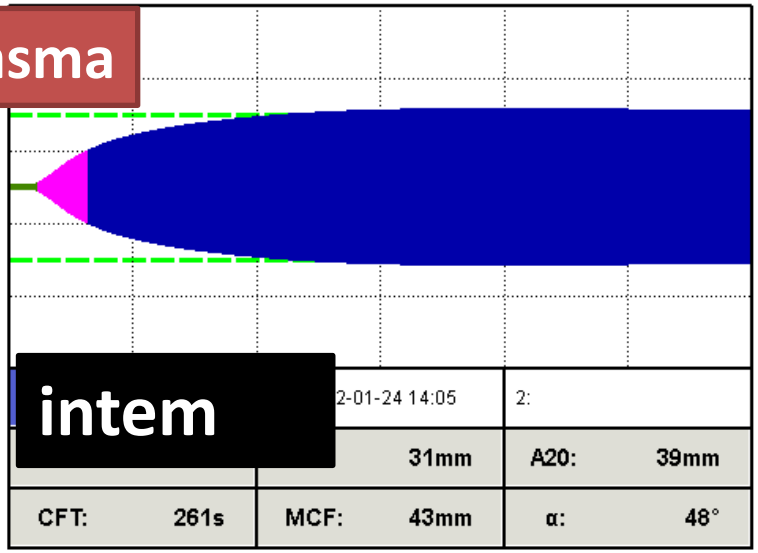


Patient: one hour later after protamine sulfate

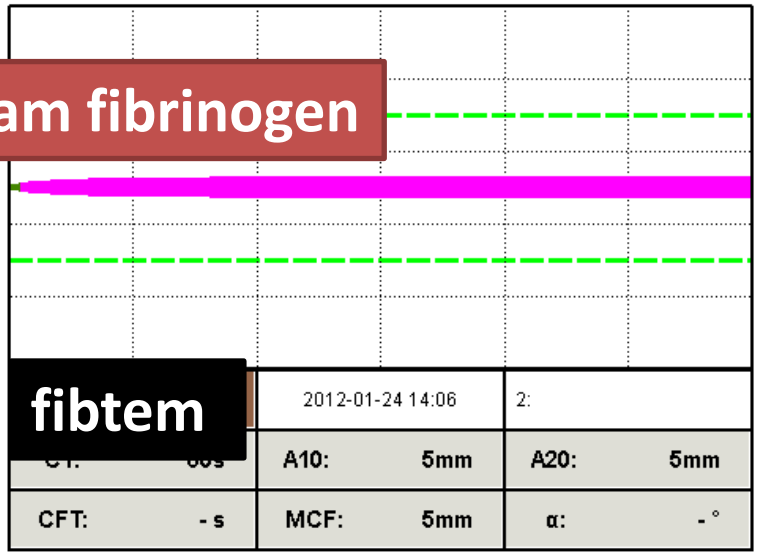
1 Plt concentrate



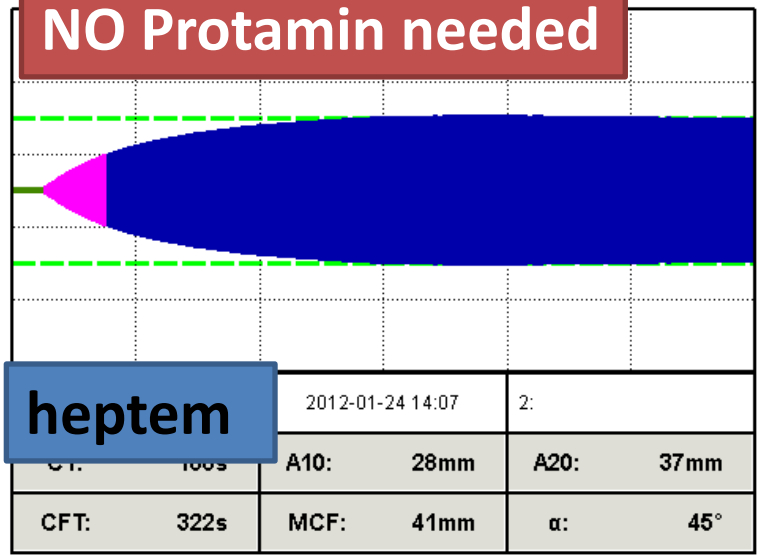
2 FFPlasma



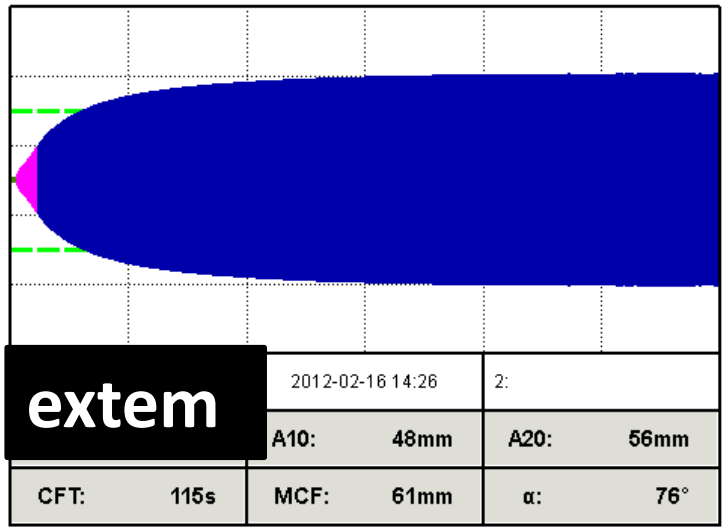
4 gram fibrinogen

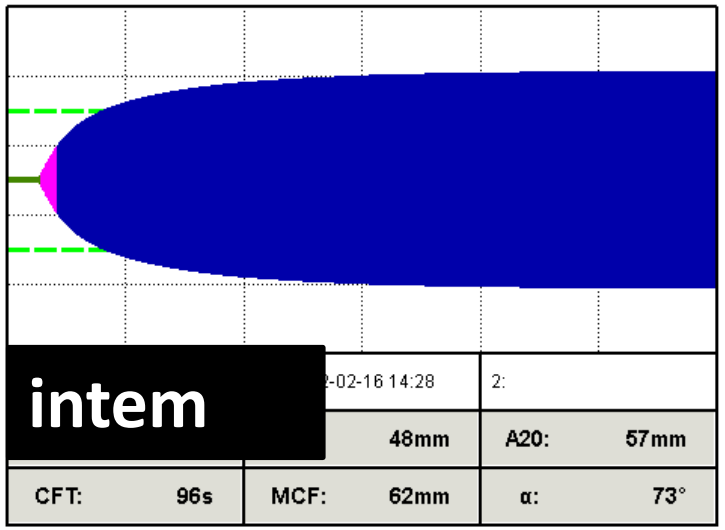


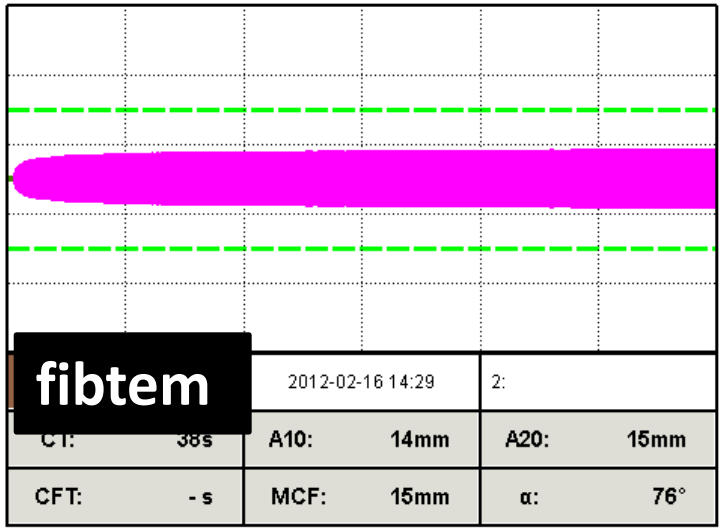
NO Protamin needed

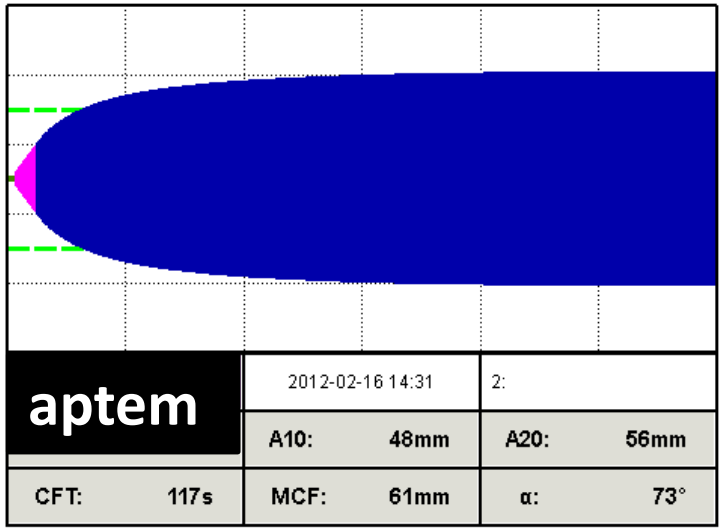


Patient: one hour later on cardiothoracic ICU

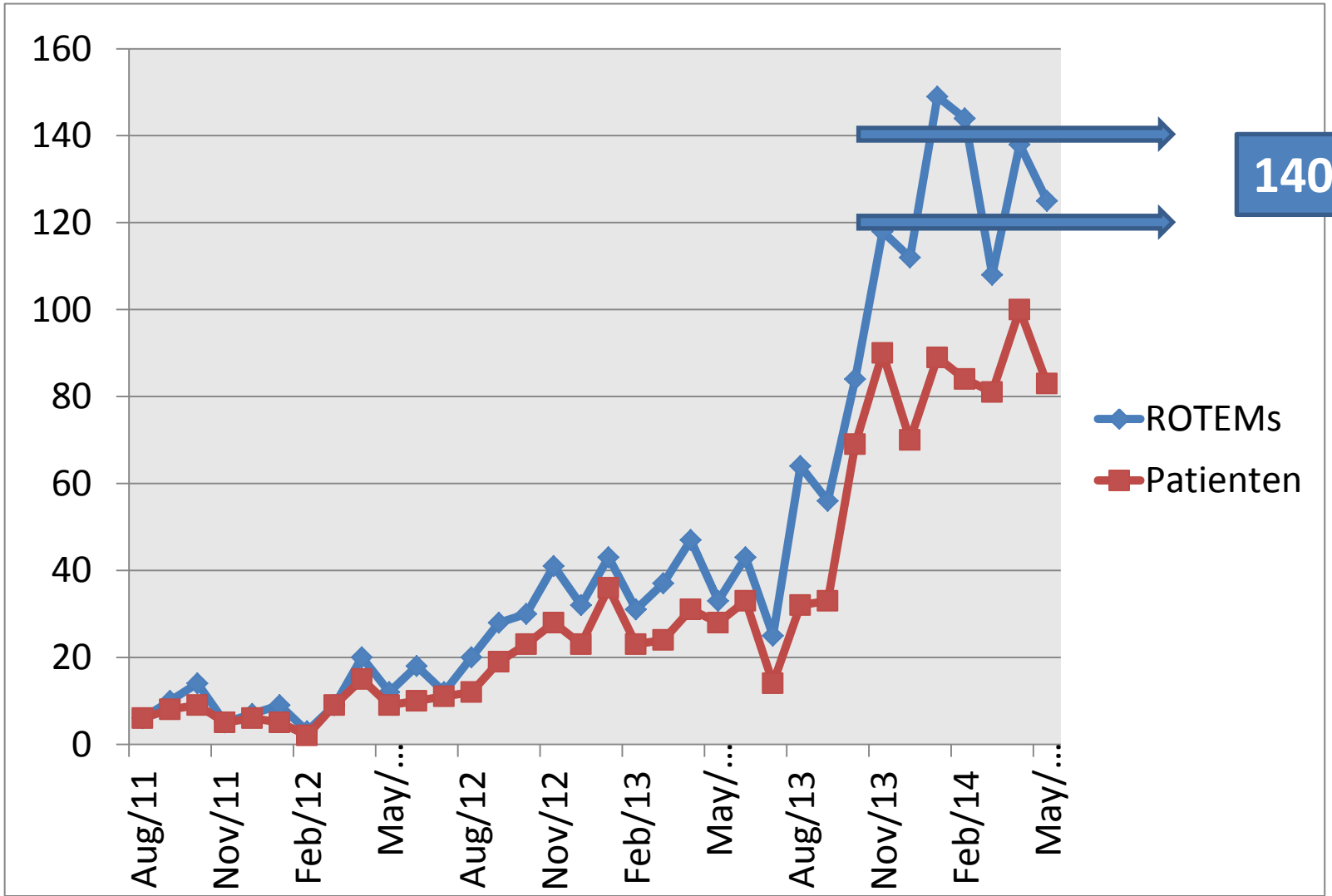








Increasing number of ROTEMS in CTS



Maastricht: Road to ROTEM

2009

Our clinicans were not satisfied……

Blood products were ordered, based on expert opions and not based on protocols or hemostatic test results

PROTOCOLS WERE NOT CLINICALLY USEFULL

GOALS

- FASTER but still RELIABLE and CLINICALLY USEFULL laboratory tests/results

- realistic PROTOCOLS for bleeding patients

WE EXPLORED Tromboelastography 2009

Our road to ROTEM:
started with cardiothoracic surgery ONLY

		2010	2011	2012	2013	2014	2015	2016	2017
CTS	Traditonal								
CTS	Trad + ROTEM								
CTS	ROTEM								

ONE tube of blood gives you information on

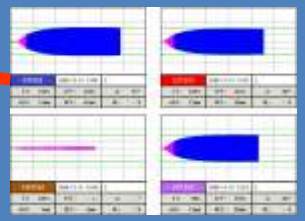
1. Clotting factors and clot formation speed (CT, CFT)
2. Fibrinogen (FIBTEM)
3. Platelet count (PLTEM)
4. Fibrinolysis (APTEM)
5. Heparin (HEPTEM)

- **Hematocrit has to be measured on a bedsite POCT meter (blood gas analyzer)**

CENTRAL LAB

ER

ICU



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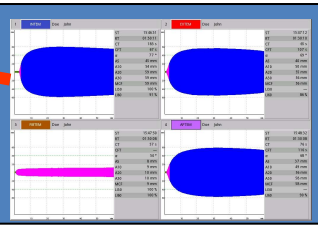


RECOVERY

Delivery ward

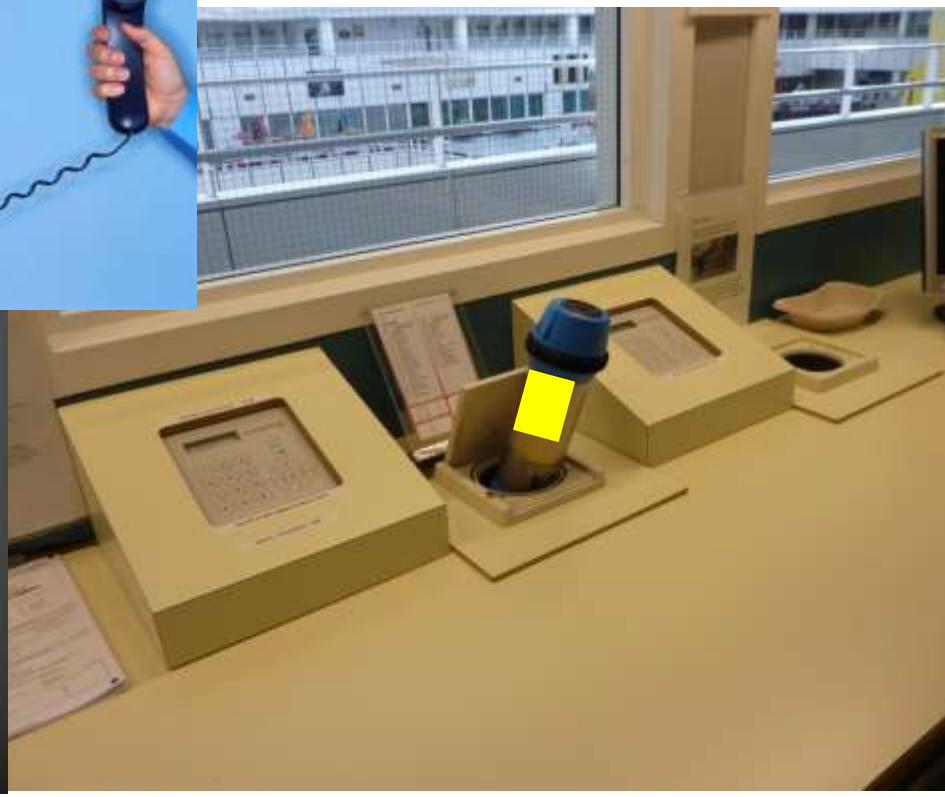
Web-based IT connections

POCT equipment in the central lab: WHY ?

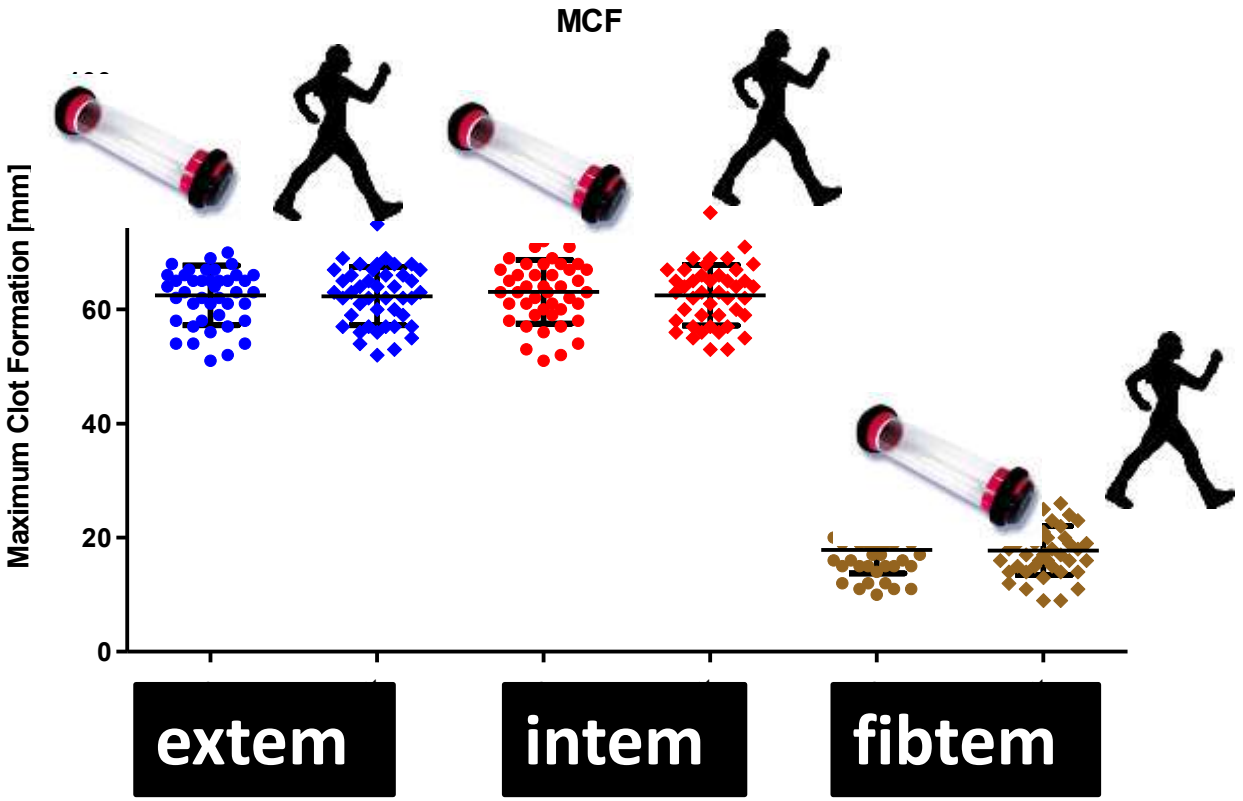
- **Rule of Health Care Inspectorate (IGZ) in The Netherlands and Policy in hospitals**
  - Only use bedside testing when strictly necessary
  - Labresults in the hospital information system
  - All bedside tests are quality controlled by the central lab
  - Staff has to be (re)trained by central lab

- **Good collaboration and communication between anesthesiology, hematology and central laboratory**

Tube transport
(2 stations in OR)

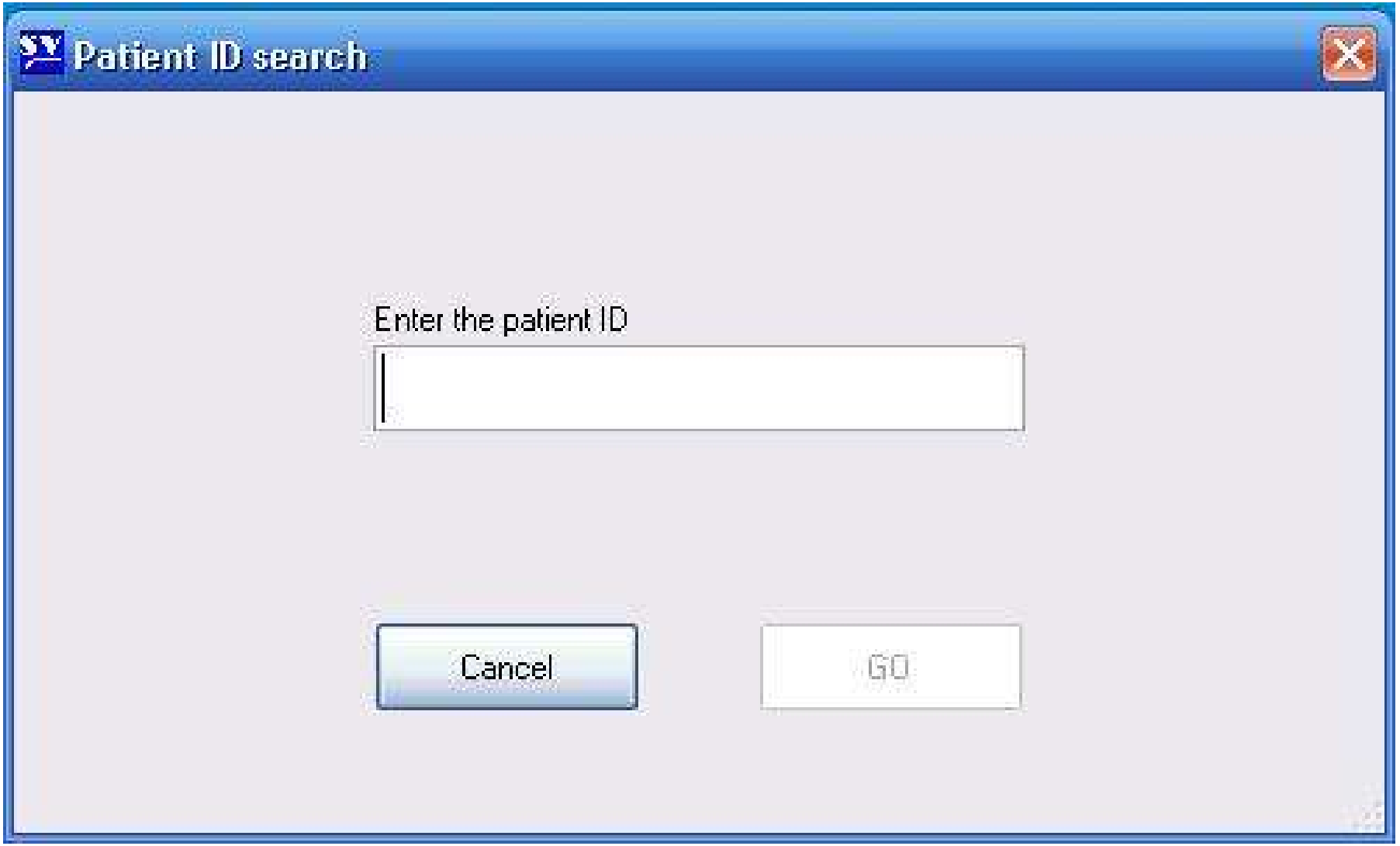


Pneumatic tube transport of ROTEM samples

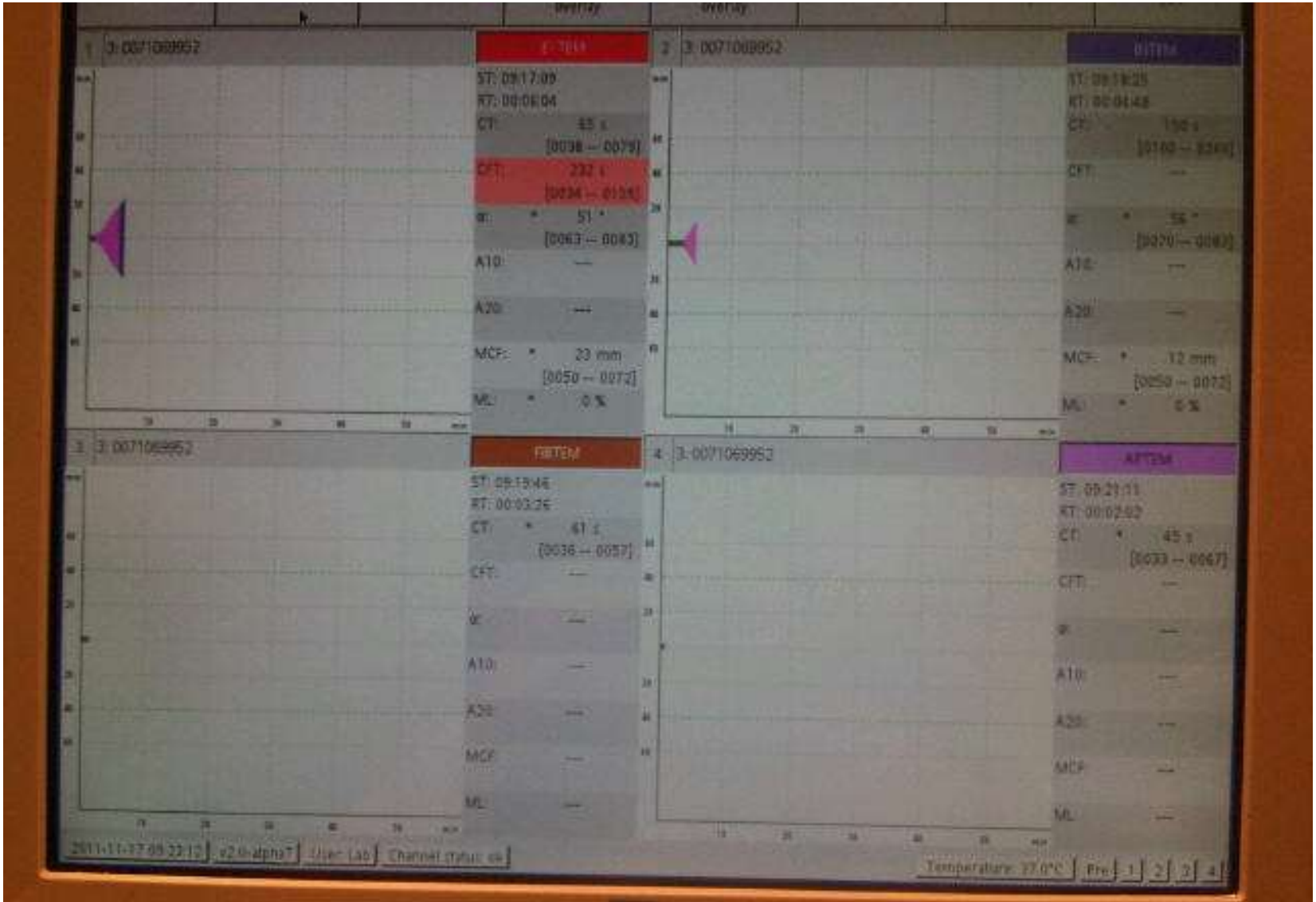


Trained technicians (n=20)

OR: viewer function



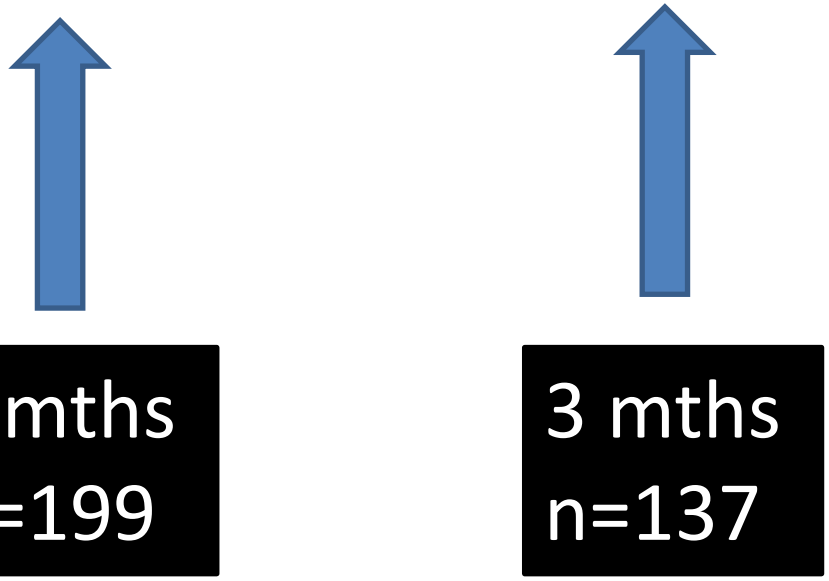
Live viewing AND data in HIS



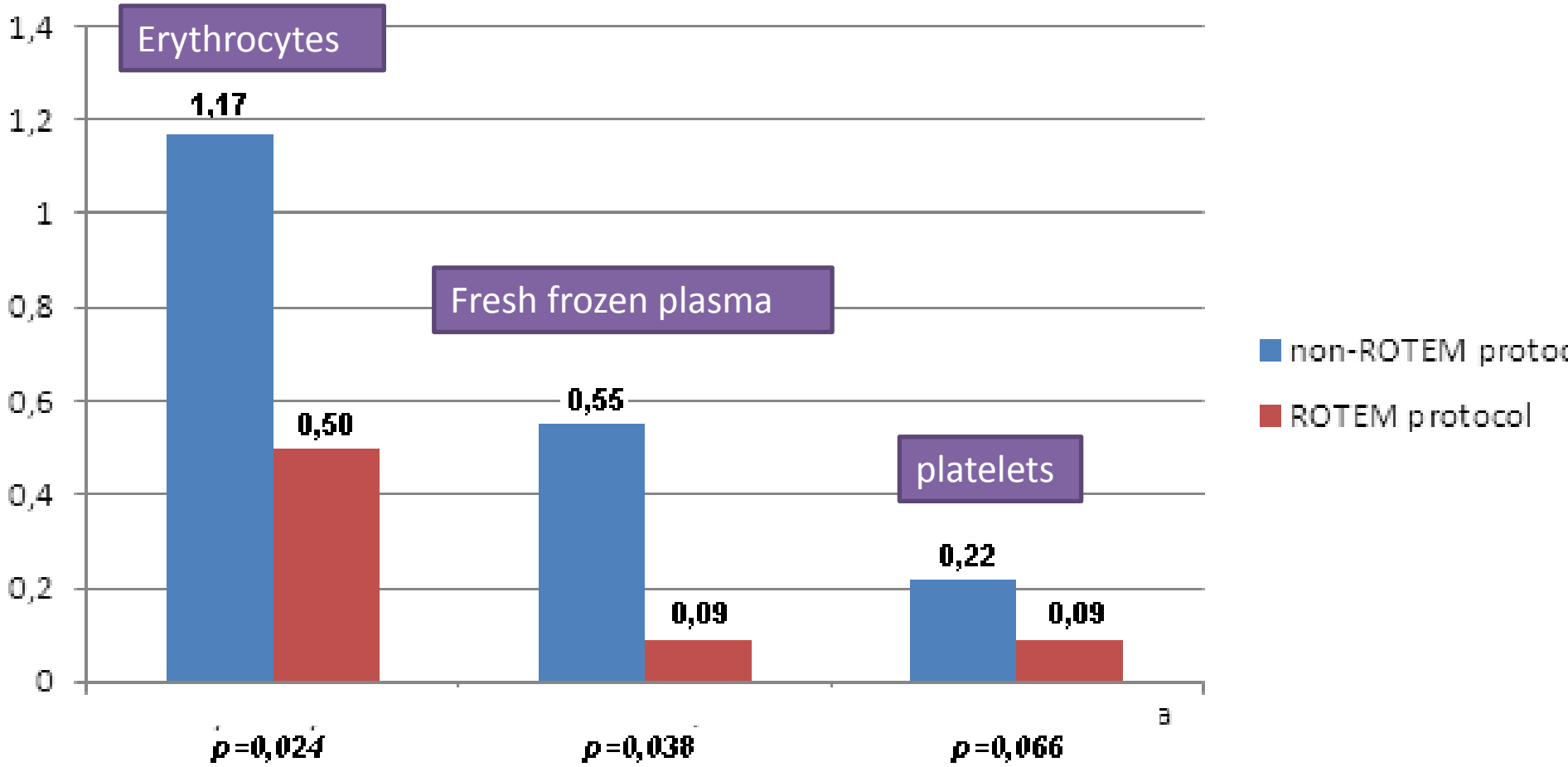
Cardio-OR (6 anesthesiologists and 8 perfusionists)

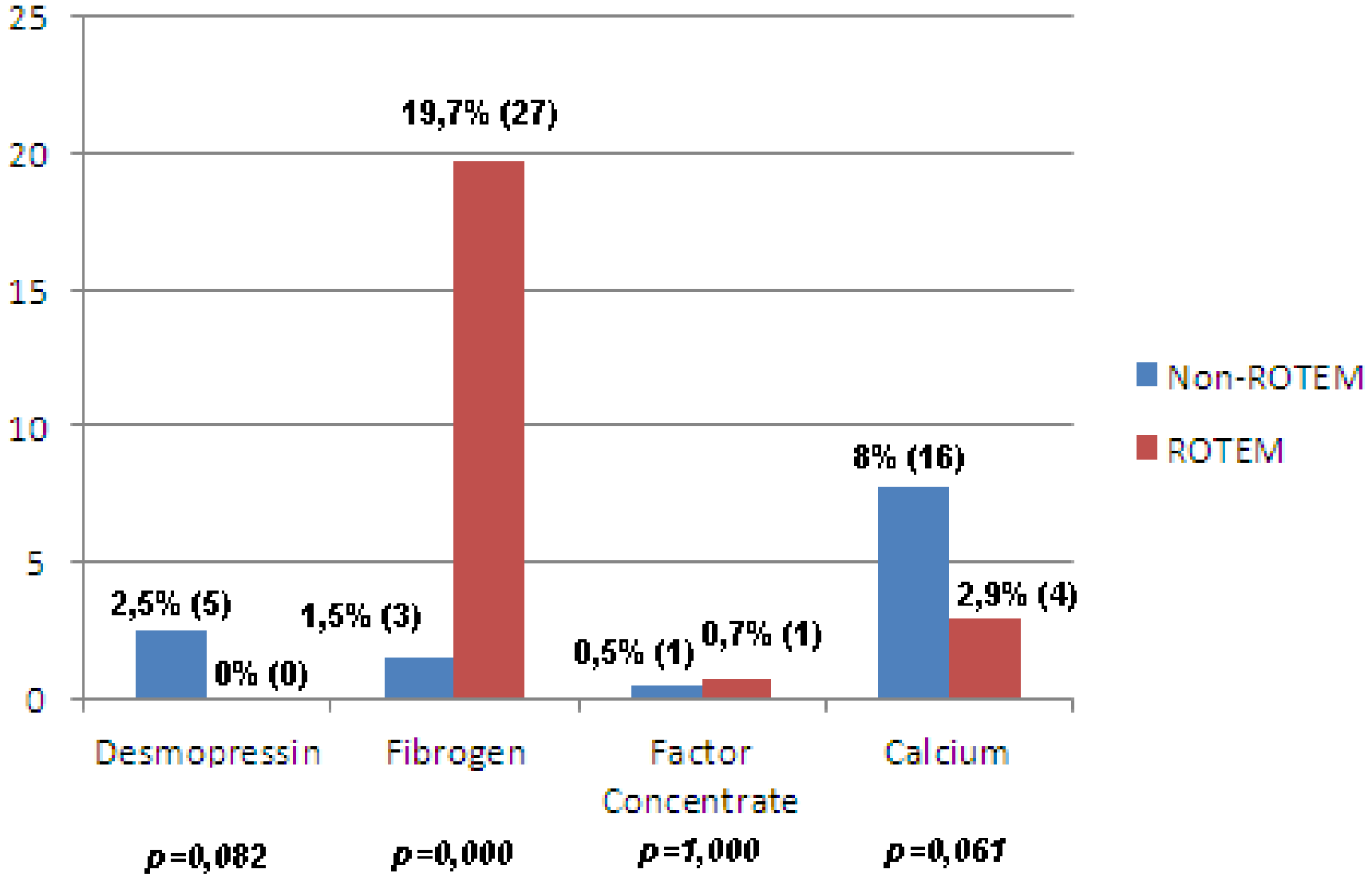
Prospective registry started in 2010

		2010	2011	2012	2013	2014	2015	2016	2017
CTS	Traditonal								
CTS	Trad + ROTEM								
CTS	ROTEM								



Blood products per patient




25
20
15
10
5
0
19,7% (27)
8% (16)
2,5% (5)
0% (0)
1,5% (3)
0,5% (1)
0,7% (1)
2,9% (4)
Non-ROTEM
ROTEM
Desmopressin
Fibrogen
Factor Concentrate
Calcium
p=0,082
p=0,000
p=1,000
p=0,061

Our road to ROTEM continues with PPH, Trauma, General surgery including the prospective registry

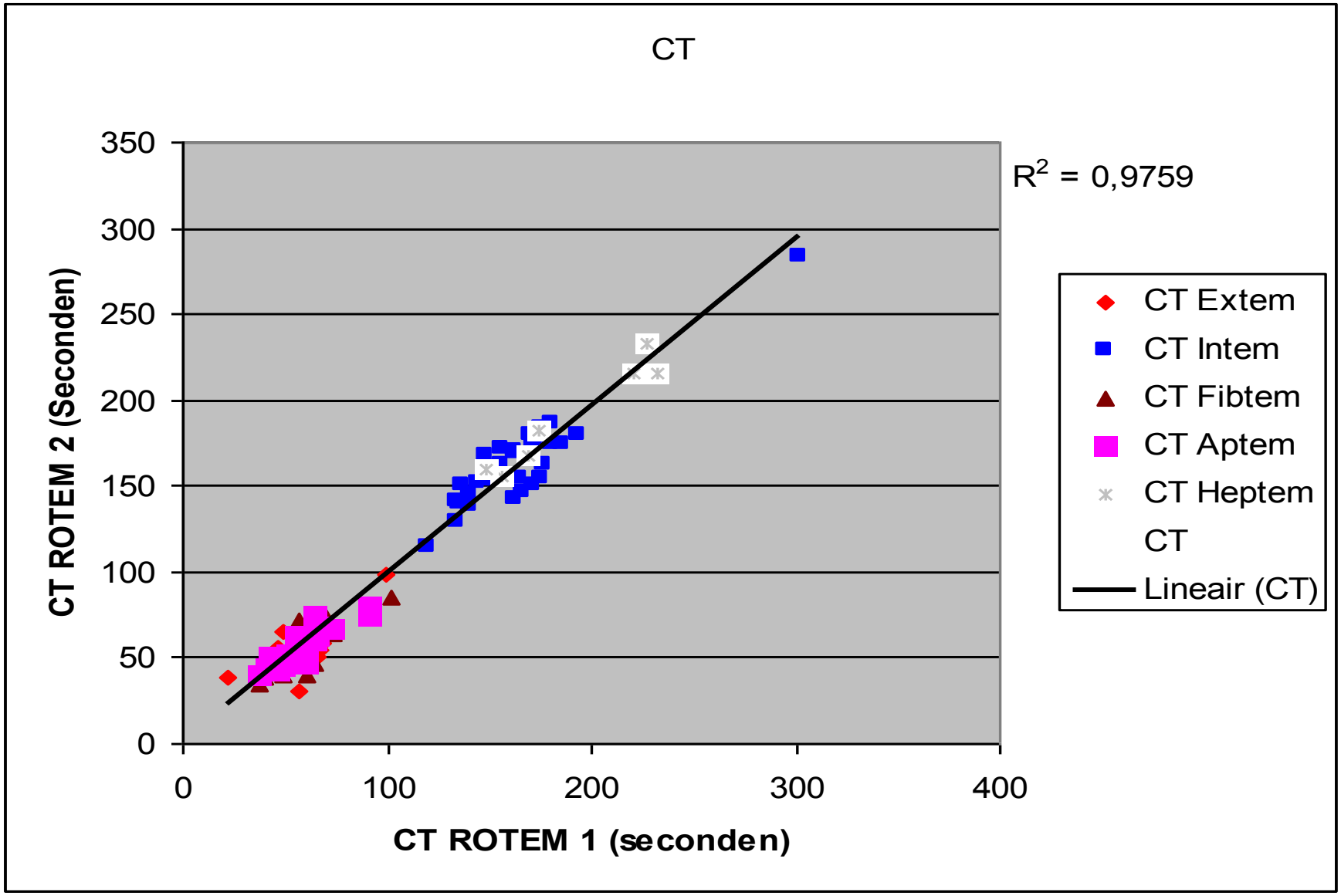
Bridge to Quality aspects

Internal Quality MONTHLY commercial plasma control

Variation is between 1 and 8 %

ROTEM	EXTEM Normal control sample	EXTEM Abnormal control sample	INTEM Normal control sample	INTEM Abnormal control sample
CT	4,3	5,2	2,3	4,2
MCF	3,3	3,1	3,7	7,5

QUALITY CONTROL WEEKLY
human whole blood



External QC ??

ECAT FOUNDATION
External quality Control of diagnostic Assays and Tests
with a focus on Thrombosis and Haemostasis

Literature on precision of TEG or ROTEM was not very promising !

Quality assurance and quality control of thromboelastography and rotational Thromboelastometry: the UK NEQAS for blood coagulation experience.

Kitchen DP et al, Seminar Thromb Hemos 2010

- **Variance between hospitals:**
- **7.1 to 39.9%** for TEG (n=18)
- **7.0 to 83.6%** for ROTEM (n=10)

2 ECAT Pilots: 2013 & 2014

2013	# hospitals	# equipment
ROTEM	5	7
TEG	4	9

2014	# hospitals	# equipment
ROTEM	9	15
TEG	1	2

SAMPLES ECAT 2013 & 2014

Pilot 2013	Pilot 2014	Plasma samples
X	X	Normal Pooled Plasma (2x)
X		Unfractionated Heparin 0.45 IU/mL
	X	Unfractionated Heparin 0.25 IU/mL
X		Plasma with factor XIII level < 5%
X		Abnormal Plasma (30-60%)
	X	Abnormal Plasma (40-60 %)
X		Plasma with factor VIII level < 1%

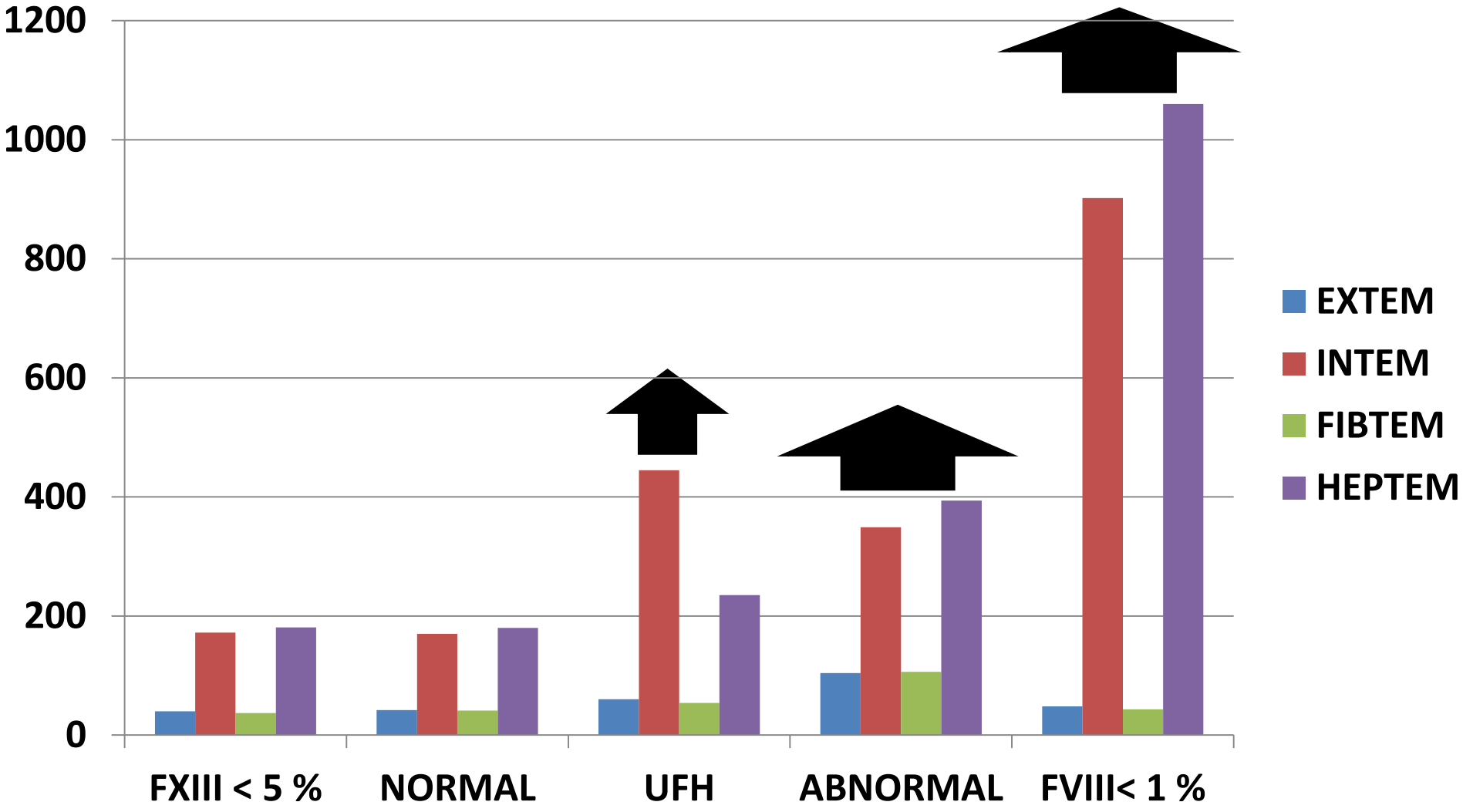
Parameters of first choice:

TEG: R and MA

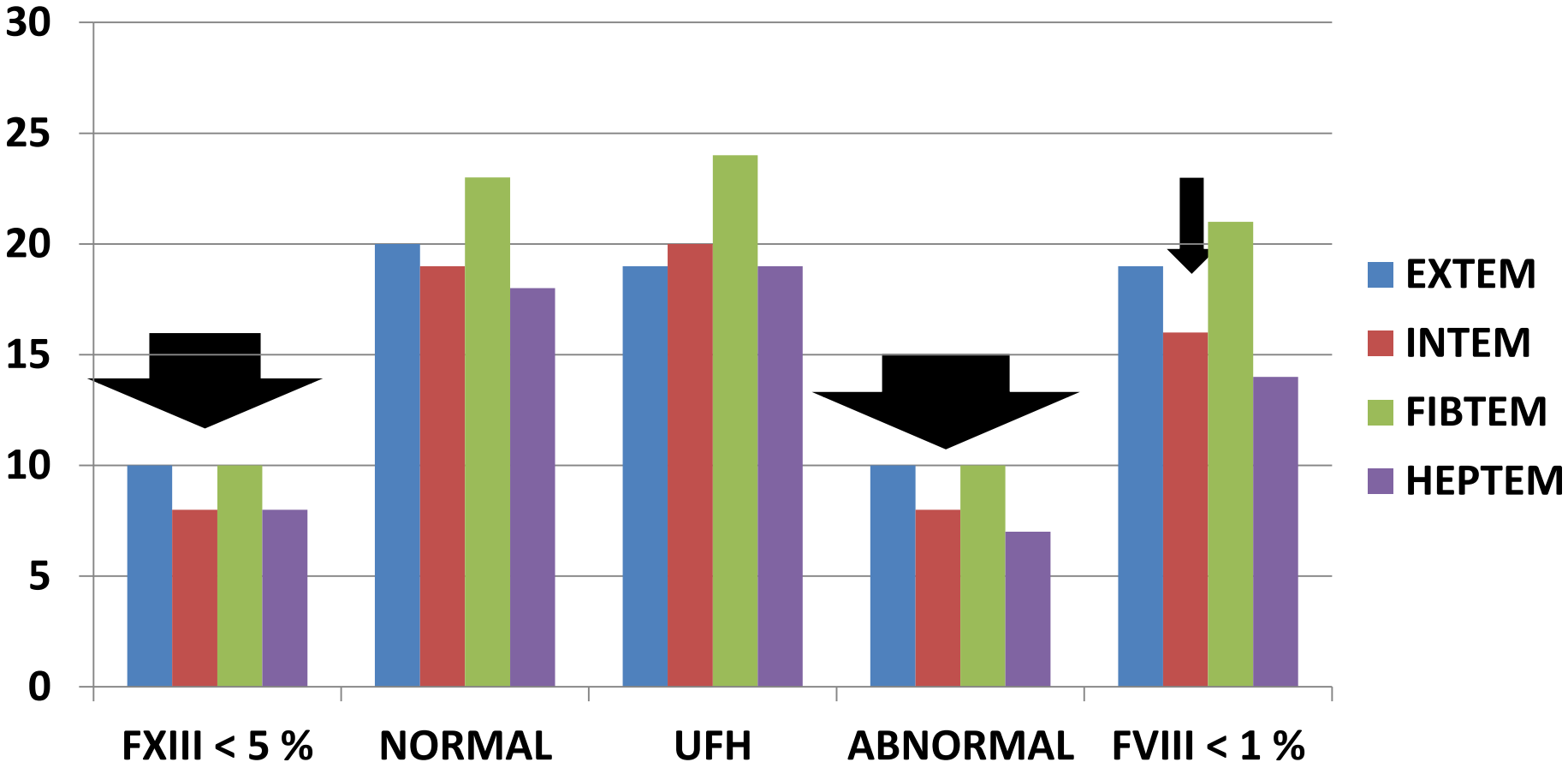
ROTEM: CT and MCF

FIRST ROUND 2013

MEDIAN
Clotting time (sec) CT



MEDIAN
Maximum Clot Firmness (mm) MCF



ROTEM VARIATION BETWEEN HOSPITALS (5/7)

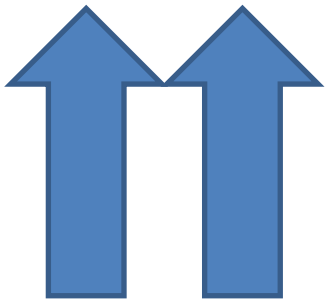
CLOTTING TIME (CT) in CV (%)

	FXIII<5 %	NORMAL	UFH	ABNORMAL	FVIII<1%
EXTEM	4.6	3.5	9.4	10.4	10.7
INTEM	7.4	4.3	7.4	8.0	14.0
FIBTEM	2.9	18.3	8.1	11.5	9.5
HEPTEM	3.2	3.4	4.9	9.1	16.5

SECOND ROUND 2014

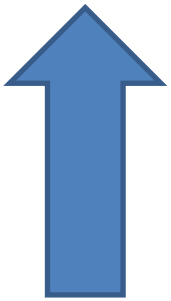
CV % CLOTTING TIME (CT – sec)

	NORMAL	UFH	ABNORMAL
EXTEM	24,0	26,9	19,6
INTEM	13,9	10,3	16,2
FIBTEM	22,5	28.1	36,2
HEPTEM	9,4	9,0	17,0



CV % MCF (mm)

	NORMAL	UFH	ABNORMAL
EXTEM	6,2	4,6	8,3
INTEM	7,9	7,4	16.6
FIBTEM	8,2	9,9	17,9
HEPTEM	12,4	12,2	22,4



NORMAL PLASMA VARIATION 2013 VS 2014

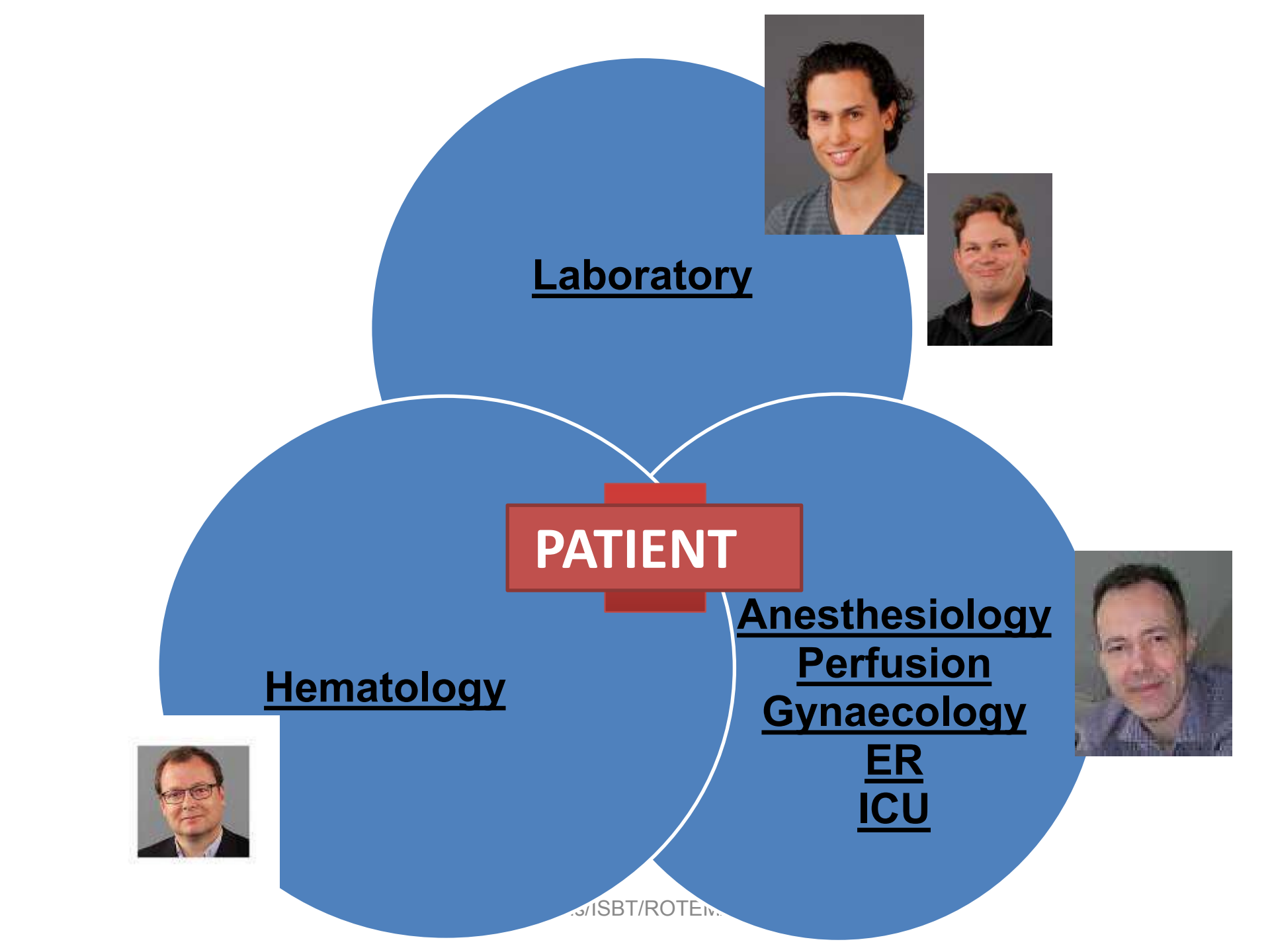
n	5/7	9/15
	2013 Range	2014 Range
CT	sec	sec
EXTEM	40-44	22-67
INTEM	162-188	160-226
FIBTEM	36-58	40-67
HEPTEM	173-190	172-214
MCF	mm	mm
EXTEM	19-22	21-26
INTEM	16-22	19-25
FIBTEM	21-26	21-27
HEPTEM	17-20	16-25

Conclusions on QC-ECAT

- Different abnormal samples can be identified by ROTEM and TEG using plasma
- Clotting time is the most variable parameter

→ up to 20-30 % !

- MCF is more comparable between hospitals
- Variation increased from 2013 to 2014 (with the increase of participants)


Laboratory
PATIENT
Hematology
Anesthesiology
Perfusion
Gynaecology
ER
ICU