

WHAT'S CAUSING THE BLEEDING?
You need to know fast . . .

The key to bleeding control

DIFFERENTIAL DIAGNOSIS

SCREENING (ITEM) (EXTEM*)

NORMAL

No obvious haemostasis disorder
Surgical bleeding likely

ABNORMAL

Haemostasis disorder
Bleeding risk
Haemotherapy required

For targeted therapy:

ADDITIONAL TESTS

Exclusion of suspected primary haemostatic disorder

DIFFERENTIAL DIAGNOSIS

EXTEM* **ITEM** **FIBTEM*** **APTEM*** **HEPTEM**

EXTEM*	ITEM	FIBTEM*	APTEM*	HEPTEM
Factor deficiency?		Fibrin polymerisation problem or fibrinogen deficiency?	Hyperfibrinolysis?	Heparin?
		Platelet disorder?		Other deficiencies masked by heparin?

CONSIDER

Surgical intervention

CONSIDER

FFP	Fibrinogen DDAVP	Antifibrinolytics	Dose change or protamine
Factor concentrates	FFP, Cryo, Platelets		

The ROTEM® system provides a unique set of tests to discriminate between therapeutic options.

*Research use only in the US

Rapid differential diagnosis

Acute peri-operative bleeding can be life-threatening and always requires immediate action. Rapid differential diagnostic information is the basis of targeted therapy. ROTEM® analysis provides valuable results in 5 to 20 minutes and treatment can start instantly. ROTEM® analysis with a new blood sample enables monitoring and fine-tuning of the therapy.

ROTEM® IS FAST

ROTEM® Analysis

Appropriate therapy

Therapy monitoring

Therapy adjustment



< 20 minutes

Comprehensive bleeding management

- pre-operative screening
- peri-operative differential diagnosis
- rapid discrimination between surgical bleeding and coagulopathy
- therapy monitoring and control

Benefits of differential diagnosis

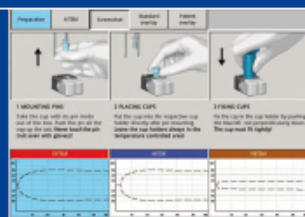
- targeted therapy
- effects of treatment can be monitored immediately
- risks of complications are minimised
- patient benefit becomes measurable

POC coagulation monitoring

ON-SCREEN INSTRUCTIONS



GRAPHICAL USER GUIDE



PIPETTING SEQUENCE



ROTEM® delta – bleeding management for the patient's benefit

In critical bleeding situations, coagulation testing in the laboratory is time consuming and may not correlate to the clinical picture. ROTEM® analysis is performed near the patient and provides information on

- hyperfibrinolysis
- the extent of dilutional coagulopathy
- the requirement for either fibrinogen or platelet substitution
- heparin and protamin dosage monitoring

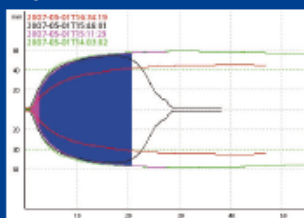
Step by step user guidance – for true POC use

- test preparation steps on screen
- easy to use automated pipette
- reliable results, even in emergency situations

Multi-language support: English, French, German, Italian, Spanish, Swedish and Turkish. Other languages upon request.

RESULT TRACKING AND TRANSFER

THERAPY MONITORING



CONNECTIVITY

ROTEM® delta system	POC
	Direct remote view
	LIS/HIS
	Full data access via information system
LAB	Direct remote view

LEFT Curve overlay of previous results simplifies therapy control.

RIGHT All test results are available in numerical and graphical format. Transfer to LIS/HIS systems or real time view on selected PCs is available. The integrated user management ensures data safety.

Fast and easy operation

REAGENTS FOR DIFFERENTIAL ANALYSIS

REAGENT	MAIN COMPONENTS	INFORMATION
ex-tem®	Tissue factor	Global test for plasmatic coagulation factors, fibrin polymerisation, platelet contribution, hyperfibrinolysis. Low heparin sensitivity.
in-tem®	Contact activator	Global test for plasmatic coagulation factors, fibrin polymerisation, platelet contribution, hyperfibrinolysis. Heparin sensitive.
fib-tem®	Cytochalasin D Ca ⁺⁺	Fibrin status: Identification of polymerisation disorders or deficiency.
ap-tem®	Aprotinin Ca ⁺⁺	Confirmation or exclusion of hyperfibrinolysis.
hep-tem®	Heparinase I Ca ⁺⁺	Screening test in the presence of heparinase; like INTEM, but without heparin influence.

TWO REAGENT LINES – EQUIVALENT RESULTS

SINGLE USE REAGENTS*

For optimal reagent usage
One test per vial
No reagent handling
Just add blood and start test
No reagent wastage

LIQUID REAGENTS

For high volume user
Ready to use
Colour coded
Excellent stability

Each test requires only 300µl of citrated blood.

POC-optimized software

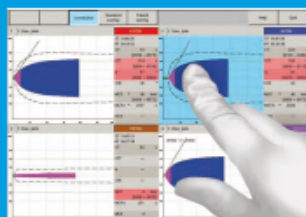
The touch-screen optimized measurement software enhances operation. Elaborate colour coding of the TEMogram curve and flagged out of range numerical results facilitate evaluation, even when looking at the monitor from a distance. Overlay of a patient's TEMogram with a standard curve or the same patient's previous TEMograms further simplify interpretation.

Help system with patient cases from clinical experts

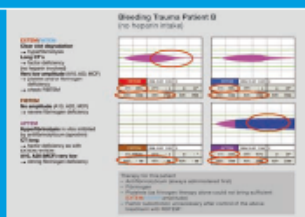
Comprehensive understanding of the patient's coagulation is important for targeted treatment. The on-board learning programme, with cases from experts, helps novices with result evaluation and interpretation. Cases are shown with test results, diagnostic conclusions and applied treatment.

EASY TO HANDLE

CONVENIENT TOUCH SCREEN



INTEGRATED LEARNING PROGRAMME



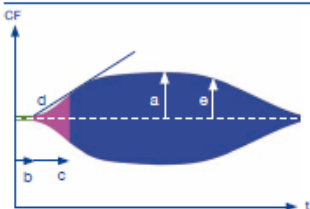
LEFT Touch-screen operation and a consistent colour coding facilitate easy handling and interpretation.

RIGHT The cases shown in the learning programme combine patient history, test results and applied treatment on one concise screen.

The key to cost control

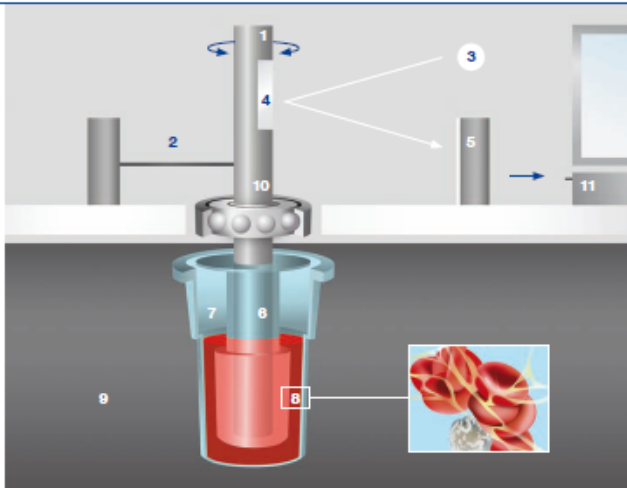
THE TEMOGRAM

ROBUST TECHNOLOGY FOR THE POC



- t time, CF clot firmness
a MCF, maximum clot firmness
b CT, clotting time
c CFT, clot formation time
d alpha angle
e LI30, lysis index

- 1 oscillating axis ($\pm 4,75^\circ$)
2 counterforce spring
3 light beam from LED
4 mirror
5 detector (electronic camera)
6 sensor pin
7 cuvette with blood sample
8 fibrin strands and platelet aggregates
9 temperature controlled cuvette holder
10 ball bearing
11 data processing unit



Technology for the POC

Thromboelastometry is designed to assess clot formation and lysis by a reliable and fast method. The unique ball-bearing stabilized technology enables operation of the system in the busy situation of an operating theatre – even on a trolley.

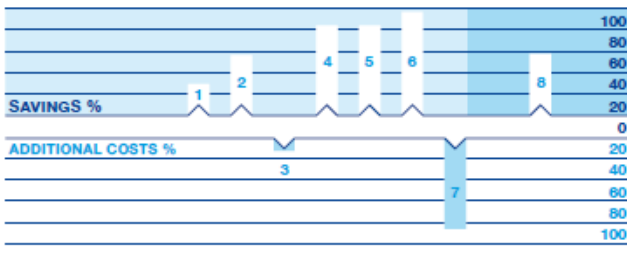
ROTEM® guided therapy – potential cost savings

In addition to better patient care, ROTEM® guided therapy has been shown to effectively save cost. Early targeted treatment leads to better control of bleeding with lower transfusion requirements. Moreover, the reduced platelet transfusion has the additional potential of reducing ICU and hospital stay time.

THE SAVING POTENTIAL of ROTEM® guided therapy*

- 1 RBC
2 Platelets
3 FFP
4 PPSB
5 FXIII
6 FVIIa
7 Fibrinogen
8 Total cost savings

* data with kind permission of
G. Spalding, Heart Centre, Bernau





- First fully integrated Thromboelastometry instrument
- Touch screen operation
- 4 channels
- Dimensions: w 37 cm, l 57 cm, h 57 cm
- Weight app. 22 kg
- 360 watts max
- Measurement insensitive to shock & vibration
- Temperature: 37°C default setting, adjustable between 30-40°C
- Storage temperature 0-50°C
- Rel. humidity 20%-85%
- Altitude up to 2000 m
- Automated pipette
- Pre-warming position for patient samples
- Integrated user administration
- Database holds > 20.000 patient records
- Real-time data viewing via Intranet (password protected)
- Comprehensive database queries
- TEMogram overlay from database and during run
- USB printer (optional)
- Barcode reader (optional)
- User traceability
- LIS/HIS connectivity (including graphs)
- CE marked instrument, reagents and disposables (IVDD 98/79/EC)

BIBLIOGRAPHY

Cost Savings. An audit of red cell and blood product use after the institution of thromboelastometry in a cardiac intensive care unit. L. Anderson, I. Quasim, R. Soutar, M. Steven, A. Macfie and W. Korte. *Transfusion Medicine* 16, 2006, 31-39.

Cost Savings. Cost reduction of perioperative coagulation management in cardiac surgery: value of 'bedside' thromboelastography (ROTEM®). Grit J. Spalding, Martin Hartmupf, Tobias Sierig, Nils Oesberg, Christian Günther Kirschke and Johannes M. Albes. *Eur. J. Cardio-thorac Surg.*, 2007, in press.

Predictivity in Cardiac Surgery. The Predictive Value of Modified Computerized Thromboelastography and Platelet Function Analysis for Postoperative Blood Loss in Routine Cardiac Surgery. Ursula Cammerer, Wulf Dietrich, Tobias Rampf, Siegmund L. Braun, Josef A. Richter. *Anesth. Analg.* 96, 2003, 51-57.

Heparin/Protamine Monitoring. Effects of protamine and heparin can be detected and easily differentiated by modified thromboelastography (ROTEM®). An in vitro study. M. Mittermayr, J. Margreiter, C. Velik-Salchner, A. Klingler, W. Streif, D. Fries and P. Innerhofer. *Br. J. Anaesth.* 95, 2005, 310-316.

Fibrinogen Therapy Control. Efficacy of fibrinogen and prothrombin complex concentrate used to reverse dilutional coagulopathy – a porcine model. D. Fries, T. Haas, A. Klingler, W. Streif, G. Klima, J. Martini, H. Wagner-Berger, P. Innerhofer. *Br. J. Anaesth.* 97 (4), 2006, 460-467.

Fibrinolysis. Management of Fulminant Fibrinolysis During Abdominal Aortic Surgery. Matthias Vorweg, Burkhard Hartmann, Dirk Knüttgen, Monika Carola Jahn, Manfred Doebe. *Journal of Cardiothoracic and Vascular Anaesthesia* 15, 2001, 764-767.

Normal Range. Multi-centre investigation on reference ranges for ROTEM® thromboelastometry. Thomas Lang, Anne Bauters, Siegmund L. Braun, Bernd Pötzsch, Klaus-Werner von Pape, Hans-Jürgen Kolde, Meret Lakner. *Blood Coagulation and Fibrinolysis* 16, 2005, 301-310.

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