tem®

Redefining Bleeding Control

ROTEM® *delta*
ROTEM® *platelet*

Targeted therapy stops the bleeding.

Easy and safe handling
Fast therapeutic decisions
Advanced diagnostic safety

ROTEM®

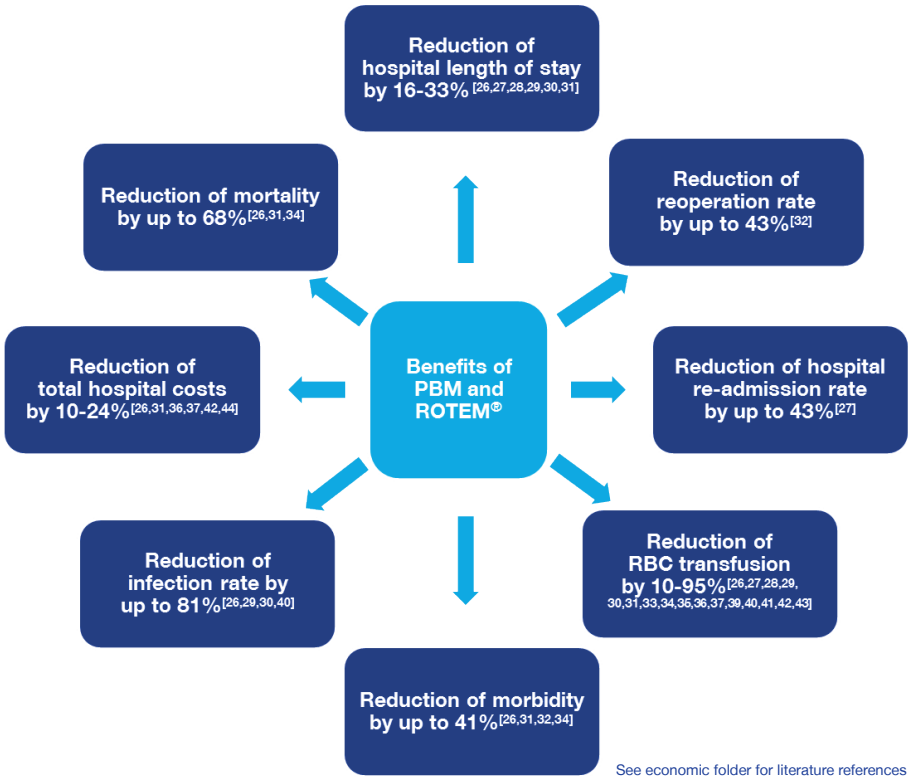
ROTEM® system in clinical use

Ensuring both, the quality and the supply of blood products is becoming increasingly difficult. This is leading to a more rational use of the limited resource “blood“ and to a critical view on the need of blood transfusions.

Blood loss, anaemia and blood transfusions are independent predictors for worse outcomes and patients‘ quality of life. This includes an increase in morbidity and mortality, as well as a prolongation of the average length of hospital stay. In short, transfusions typically lead to avoidable complications and costs.

In this context, the targeted ROTEM®-based bleeding control solution is integral to Patient Blood Management that is predicated on both pre-emptive and reactive blood-saving measures. In fact, WHA 63.12, all 193 WHO member states have been asked to implement the concept of PBM in a timely manner.

ROTEM®- based bleeding control



See economic folder for literature references

ROTEM® *delta* haemostasis analyser

Complicated bleeding situations can occur intra- and post-operatively. They can be life threatening and always require immediate action.
A fast differential diagnosis is vital. It is also the basis of a targeted therapy.

The ROTEM®- analysis offers reliable results within 5-10 minutes and provides critical information about the efficacy of the therapy. Additionally the ROTEM®- analysis enables the monitoring and the course-modification of the therapy as needed.

The result is significantly improved patient outcome and lower healthcare cost per episode with subsequent cost savings benefit.

A comprehensive reagent portfolio provides a differential diagnosis

Liquid reagents	in-tem®	r ex-tem®	fib-tem®	ap-tem®/ t ap-tem®	hep-tem®
Single use reagents	**in-tem® S**	**ex-tem® S**	**fib-tem® S**	**ap-tem® S**	**hep-tem® S**
	Fast assessment of clot formation, fibrin polymerization and fibrinolysis via the intrinsic pathway	Fast assessment of clot formation, fibrin polymerisation and fibrinolysis via the extrinsic pathway	Fast analysis without platelets; qualitative assessment of fibrinogen status	Fast detection of lysis when compared with EXTEM via fibrinolysis inhibition	Specific detection of heparin when compared with INTEM via heparin neutralisation

The ROTEM® *delta* haemostasis analyser measures kinetic changes of the clot elasticity of whole blood samples.
It allows quantitative and qualitative assessment by measuring different parameters of the clot status of the blood sample. A comprehensive set of assays permits a differential diagnosis.

The differential ROTEM®- analysis can be performed at the patient´s point of care and provides information about hyperfibrinolysis, dilutional coagulopathies, substitution of fibrinogen, factors or platelets as well as the control of heparin or protamine dosage.

ROTEM® *platelet*
Proven technologies in one system

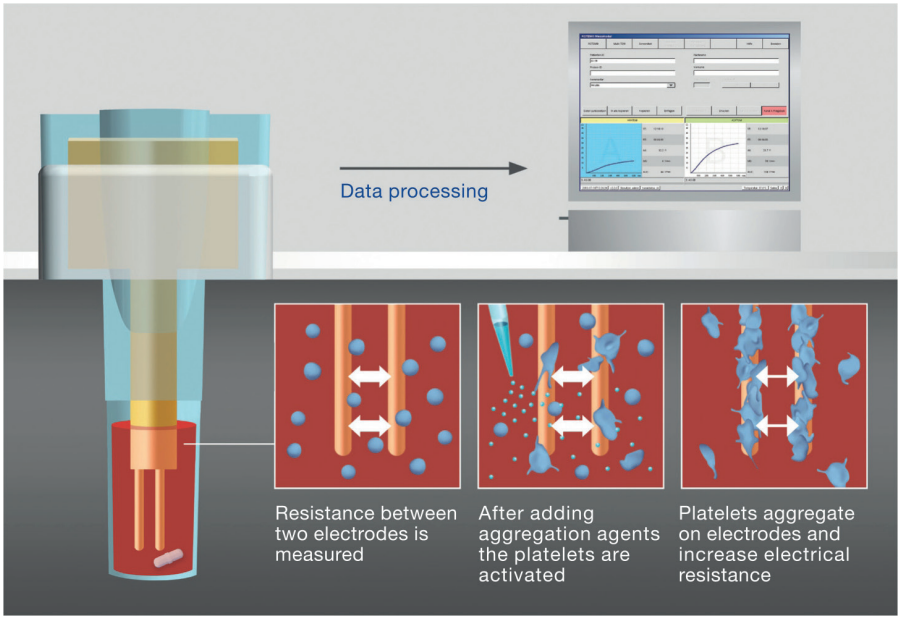
The ROTEM® *platelet* measures platelet aggregation in whole blood samples using impedance aggregometry. The new device is run in conjunction with the ROTEM® *delta*, and is compatible with all existing ROTEM® *delta* models with serial numbers > 2000. The ROTEM® *platelet* characteristics are:

– Dedicated single use cuvettes with electrodes
– 2 channels can be used simultaneously
– Measurement time is 6 min, while allowing for emergency samples
– 3 different parameters are available:
  • A6 (amplitude at 6 min in Ohm)
  • MS (maximum slope of the aggregation graph in Ohm/min)
  • AUC (area under the curve in Ohm*min)

Measurements can be performed on the ROTEM® *platelet* device while running measurements on the ROTEM® *delta* system simultaneously.

Single use reagents	adp-tem®
	e.g. for the detection of ADP receptor blockage (Clopidogrel)
ara-tem®	trap-tem®
e.g. for the detection of cyclooxygenase inhibitors (Aspirin®)	e.g. for the detection of GP IIb/IIIa receptor antagonists (Abciximab)

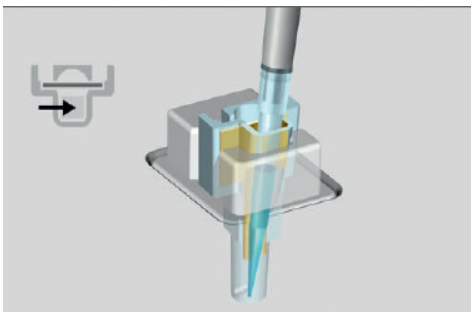
ROTEM® *platelet* detection principle

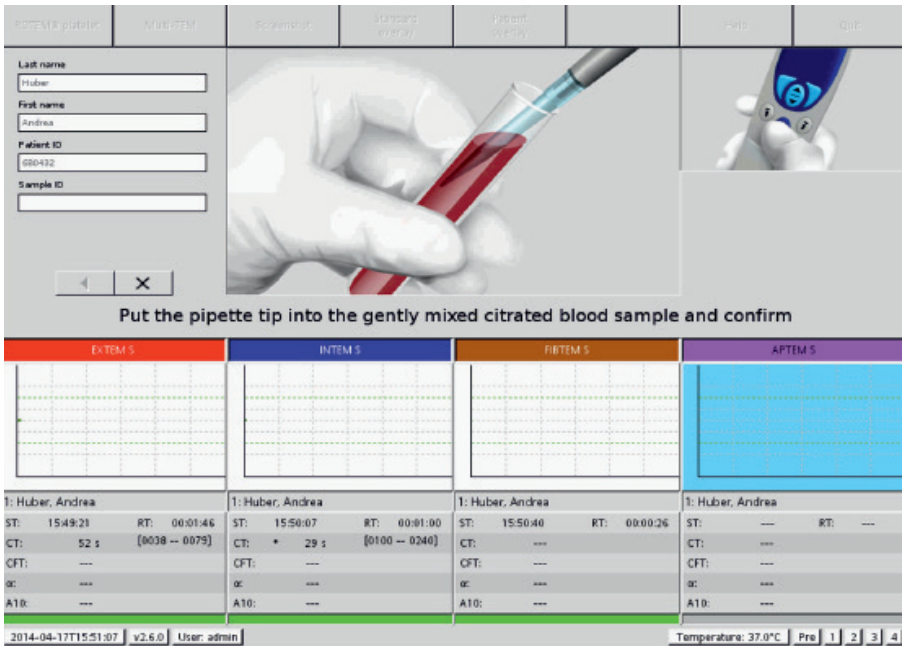


Easy and safe handling

- Single use reagents for fast and reliable results
- Automated pipette for standardised volumes
- Easy operation via touch screen
- Graphical, step-by-step instruction that simplify the test performance
- Integrated learn programme with treatment algorithms and case reports from experts
- Integrated troubleshooting for fast help

Graphical instructions with touch screen





Literature

Haas T, Spielmann N, Mauch J, Madjdpour C, Speer O, Schmugge M, Weiss M, **Comparison of thromboelastometry (ROTEM) with standard plasmatic coagulation testing in paediatric surgery.** British Journal of Anaesthesia 2012 Jan; 108 (1): 36-4.

Theusinger OM, Nürnberg J, Asmis LM, Seifert B, Spahn DR. **Rotation thromboelastometry (ROTEM) stability and reproducibility over time**. Eur J Cardiothorac Surg. 2010 Mar; 37 (3): 677-83.

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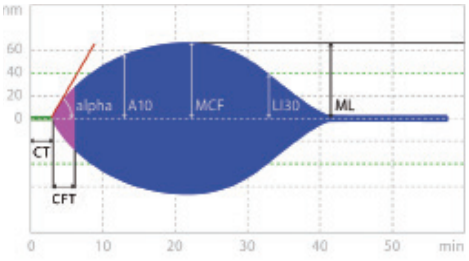
Fast therapeutic decisions

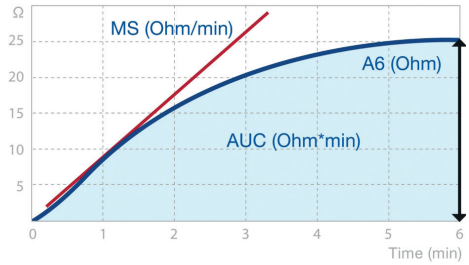
- First results are available within 5 to 10 minutes
- 6 channels: differential diagnosis of coagulopathies
- Simplified interpretation of results via colour coded TEMograms/ aggregation graphs and highlighted abnormal parameter results
- Easy therapeutic control using previous patient results as overlays
- Fast interpretation by overlay of standard curves over running results
- ROTEM® Data solutions enabled by HIS/LIS connection for comprehensive data transfer
- Mobile use via the ROTEM® *trolley*

ROTEM® analysis

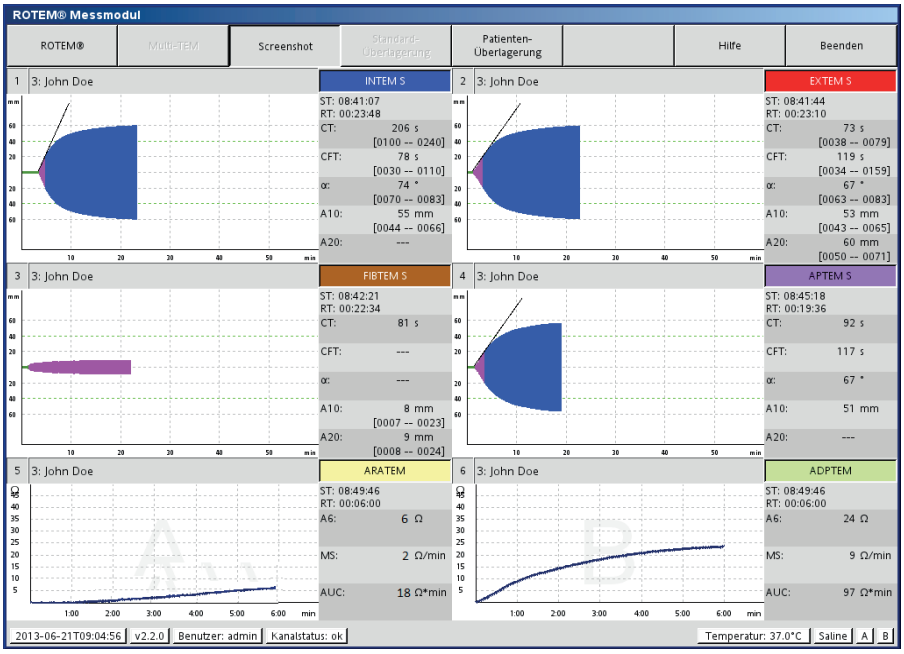


CT Clotting time
CFT Clot formation time
alpha Alpha angle
A10 Amplitude 10 min. after CT
MCF Maximum clot firmness
LI30 Lysis index 30 min. after CT
ML Maximum Lysis

A6 Amplitude 6 min
MS Maximum slope
AUC Area under the curve



TEMograms and aggregation curves of the 6 channels



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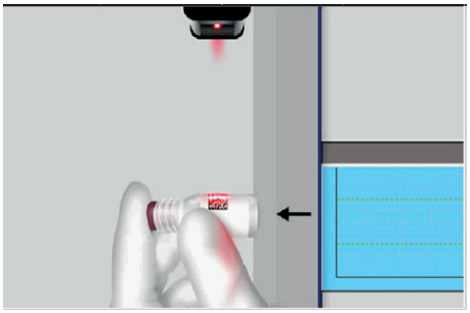
Schöchl H, Maegele M, Solomon C, Görlinger K, Voelckel W. **Early and individualized goal-directed therapy for trauma-induced coagulopathy.** Scand J Trauma Resusc Emerg Med. 2012 Feb 24;20(1):15.

Görlinger K: **Gerinnungsmanagement bei Leberstransplantationen (Coagulation management during liver transplantation).** Hämostaseologie 2006; 26 (Suppl. 1): S64-S76.

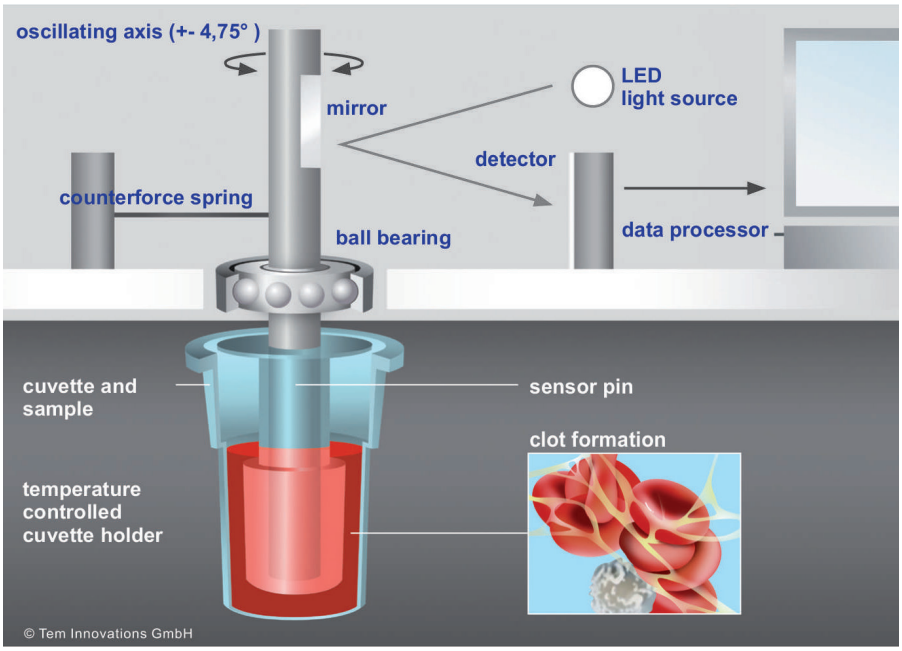
Advanced diagnosis safety

- Instrument handling in a busy operating area enabled by the ball bearing stabilised technology of the ROTEM® thromboelastometry
- Differential diagnosis by the combination of up to 8 different assays
- The barcode scanner prevents the use of wrong or expired reagents
- Quality controls: ROTROL N (Level I); ROTROL P (Level II)
- Simple patient-ID search function for fast and safe real time data transmission

Barcode scanner



ROTEM® technology



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Larsen OH, Fenger-Eriksen C, Christiansen K, Ingerslev J, Sørensen B. **Diagnostic Performance and Therapeutic Consequence of Thromboelastometry Activated by Kaolin versus a Panel of Specific Reagents.** Anesthesiology 2011; 115:294-302

ROTEM®
Data solutions

Data solutions - On-time information. Where it is needed.

All test results are available in numerical and graphical formats. Transfer to LIS/HIS systems or real time transmission to defined PCs is possible. Data protection via integrated password at the user management is ensured.

Data solutions

Data solution
Secure Viewer

Data transmission in real time to remote screens

Data solution
Database Commander

Data management of all connected ROTEM®-sytems on one computer

Data solution
POCcelerator™
CONWORX Technology GmbH

POCcelerator™ manages patient data, QC data, and the transfer of the ROTEM® *delta* results to LIS/HIS

The complete ROTEM® system with ROTEM® *delta* and ROTEM® *platelet* provides an overview about the coagulation status within 10 minutes with information on:

Requirement for factor, fibrinogen or platelet substitution
Detection of platelet function and aggregation
Hyperfibrinolysis
Extent of dilutional coagulopathy
Heparin and protamin dosage monitoring

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