

All INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI – 110029
Department of Surgical Discipline
(Stores Section)

Ref. No. 05/Surgery/Proprietary/2021-22/St.

Dated: 21.06.2021

Subject: Purchase of Viscoelastic Global Coagulation Testing Device (ROHTM) on proprietary basis rates – reg.

The request has been received from the Surgeon of Department of Surgical Discipline for purchase of subject item from M/s Instrumentation Laboratory Tem Innovations GmbH, Martin-Kollar-Strasse 13-1581529 Munich Germany through their authorized distributors M/s Hospimex on proprietary basis. The proposal submitted by M/s Hospimax Healthcare Pvt. Ltd. ,1471-1476, Aggarwal Millenium Tower-II, Plot No. E-4, Netaji Subhash Place, Pitampura, New Delhi 110034 India. PAC certifications are attached herewith.

The above document are being uploaded on AIIMS Website for open information to prospective manufactures to submit their objections/comments, (if any) regarding proprietary nature of the equipment/item within 15 days giving reference No. 26/Surgery/Prop./2019-20/St. The comments should be received in the office of Sr. Stores Officer (Surgery), Department of Surgical Disciplines, Center for Medical Education & Technology (CMET), Educational Hall, 1st Floor, (Near B.B. Dikshit Library), AIIMS, Ansari Nagar, New Delhi-110029 on or before 07/07/2021 up to 04:00 p.m., failing which, it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.


Sr. Stores Officer (Surgery)

Encl: Related documents enclosed.

1. PAC Certificate enclosed.
2. Specification of equipment.

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-110029
DEPARTMENT OF SURGICAL DISCIPLINES

PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

1	The indented goods are manufactured by	Instrumentation Laboratory
2	Item Name	VISCOLEASTIC Global coagulation Testing Device (ROHTM)
3	HSN Code	90279090
4	Reasons/Justification which makes the requirement proprietary:-	<p>1. It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent VISCOLEASTIC Global coagulation Testing Device (ROHTM) System with same quality and specifications which can fulfil the vital requirements of end user.</p> <p>2. It is also certified that it is close system item.</p>

Note: Since, it is a proprietary item, the price may be negotiated before placing the order.



(STORES SECTION)
DEPARTMENT OF SURGICAL DISCIPLINES
ALL INDIA INSTITUTE OF MEDICAL SCIENCES

Sub: Procurement for purchase of VISCOLEASTIC Global coagulation Testing Device (ROHTM) -2 (01 No. for Surgical Block and 01 No. for Deptt. of Anesthesia) Rate reasonability & urgency certificate thereof.

Certified that the following members of the Technical Committee are jointly and individually satisfied that the goods recommended for purchase are of the requisite specification and quality, priced at the prevailing market rate. The subject items are urgently required in surgery block.

A handwritten signature in blue ink, appearing to be 'W. S.', written over two horizontal lines.A handwritten signature in blue ink, appearing to be 'P. S. S.', written in a cursive style.

To whom it may concern

PROPRIETARY CERTIFICATE

2018-04-10

This is to certify that all reagents, consumables & essential accessories like Pipette eLine and spare parts etc. for ROTEM® Thromboelastometry are the proprietary items of Tem Innovations GmbH, with manufacturing plant in Munich, Germany.

These reagents, consumables & essential accessories like Pipette eLine and spare parts etc., along with equipment as per the current information available with us, are not available with any other manufacturer.

Sincerely yours,



.....
Dr. Volker-Joachim Friemert
Director of Quality Assurance and RA, PBM

**Tem Innovations GmbH
Instrumentation Laboratory**

Instrumentation Laboratory
Tem Innovations GmbH
Martin-Kollar-Strasse 13-15
81829 Munich
Germany
Phone: +49 (0) 89 45 42 95 0
Fax: +49 (0) 89 45 42 95 22



**Our Passion.
Your Results.**

IL/2020/Letter1/54

Dt. 02.12.2020

MANUFACTURER'S AUTHORISATION FORM

The HOD,
Surgery Department,
All India Institute of Medical Science,
Ansari Nagar East,
New Delhi-110029

Dear Sir,

Ref: Your TE document No. ROTEM Machine dated 02.12.2020

We, M/s. Instrumentation Laboratory India Pvt. Ltd., Office No. 1471-1476, Aggarwal Millennium Tower-I, Plot No-E-4, Netaji Subhash Place, Pitampura, New Delhi-110034 India, are authorized Indian agent and fellow affiliate of TEM Innovations GmbH, Martin-kollar strabe 13,81829 Munchen, Germany who are manufacturer of Rotem Products (Rotational Thrombo Elastometry). Further TEM Innovations GmbH has been acquired by Instrumentation Laboratory, USA in year 2016. We being the Principal Company in India do hereby authorize M/s. Hospimax Healthcare Pvt. Ltd., having registered office at 109, DDA Building # 5, District Centre, Janakpuri, New Delhi- 110058 and Corporate Office at T-95/A, 2nd Floor, C.L House, Gautam Nagar, Yusuf Sarai Community Centre, New Delhi - 110049 to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also state that we are not participating directly in this bid for the following reason(s): Messrs Hospimax Healthcare Pvt. Ltd., is our authorised distributor for your Institute.

We further confirm that no supplier or firm or individual other than Messrs. Hospimax Healthcare Pvt. Ltd., Regd. Office: #109, DDA Building No. 5, District Centre, Janakpuri, New Delhi- 110058 & Corp. Office: T- 95/A, 2nd Floor, C. L. House, Yusuf Sarai Community Centre, New Delhi-110049 is authorised to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent and the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly.

Yours faithfully,

For Instrumentation Laboratory India Pvt. Ltd.

Pawan Jindal
National Sales Manager

Instrumentation Laboratory India Pvt. Ltd.

Warehouse
Ground Floor, 21 Rama Road,
New Delhi-110015
Tel: +91-11-43088282
Fax: +91-11-43088282

Regd. office :
1471-1476, Aggarwal Millennium Tower-II, plot No. E-4
Netaji Subhash Place, Pitampura, New Delhi-110034 India
Tel: +91-11-49029550, 49029551
Fax: +91-11-49029567
E-mail: info@ilindia.com



TO WHOMSOEVER IT MAY CONCERN**Milano, April, 13 2018**

We, Instrumentation Laboratory, SpA, a Werfen Company, having offices at Viale Monza, 338, 20128 Milano, Italy, declares that Tem International GmbH having manufacturing plant at Martin-Kollar-Straße 13, 81829 München, Germany, proven and reputable manufacturers of Thrombo Elastogram, ROTEM has been acquired by Instrumentation Laboratory, a Werfen Company.

We declare that prior to the aforesaid acquisition, Vijyoti Management & Communications learning Institute Pvt. Ltd(vijyoti), B-8, Sector-27, Noida 201301, Uttar Pradesh was the authorised Distributor of TEM International.

We further declare that post the acquisition, we authorized our affiliate Instrumentation Laboratory India Pvt. Ltd. (IL India) 1471-1476, Aggarwal Millenium Tower - II, Plot No. E-4, Netaji Subhash Place, Pitam Pura, New Delhi - 110034 to be our sole authorised supplier in India and to appoint sub distributors in the territory of India.

Sincerely,


José Zamora
EEMEI Director

Instrumentation Laboratory, SpA
A Werfen Company

*EEMEI - International Division*

To whom it may concern

2018-04-10

We, Tem Innovations GmbH represented by Dr. Volker-Joachim Friemert (Director of QA & RA) with registered office at:

Martin-Kollar-Strasse 13-15
81829 Munich
Germany

hereby confirm that Tem Innovations GmbH is the sole manufacturer of the ROTEM[®] *delta* whole blood coagulation system, and the ROTEM[®] *platelet* whole blood impedance aggregometry module (equipment, reagents and disposables).

The ROTEM[®] *delta* system and ROTEM[®] *platelet* module are categorized as in-vitro diagnostic devices, and meet all applicable requirements of the Directive 98/79/EC (in vitro diagnostic medical devices – Annex III).

Tem Innovations GmbH is certified according to ISO 13485:2003.
According to EU-Directives GMP only applies for pharmaceutical companies.
TEM Innovations GmbH is not a pharmaceutical company, but a manufacturer of medical devices.

Sincerely yours,



Dr. Volker-Joachim Friemert
Director of Quality Assurance and RA, PBM

**Tem Innovations GmbH
Instrumentation Laboratory**

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**Our Passion.
Your Results.**



ROTEM[®] *delta* ROTEM[®] *platelet*

Targeted therapy stops the bleeding.

Easy and safe handling.
Fast therapeutic decisions.
Advanced diagnostic safety.



ROTEM®-based bleeding control.

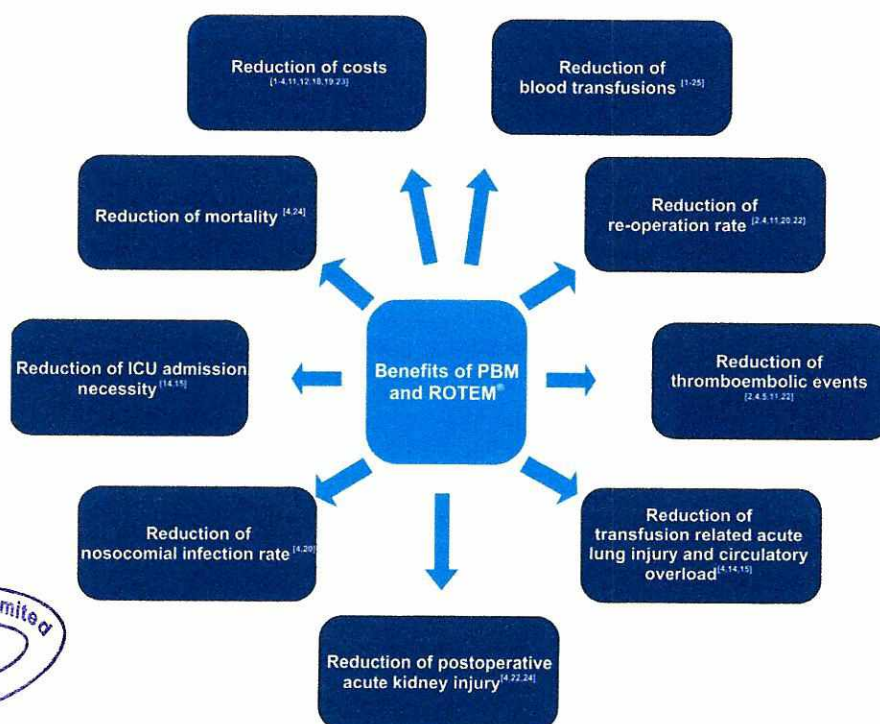


Ensuring both, the quality and the supply of blood products is becoming increasingly difficult. This is leading to a more rational use of the limited resource “blood” and to a critical view on the need of blood transfusions.

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 prolonged stay in hospital. 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 preemptive 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



ROTEM® system in clinical use.



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.

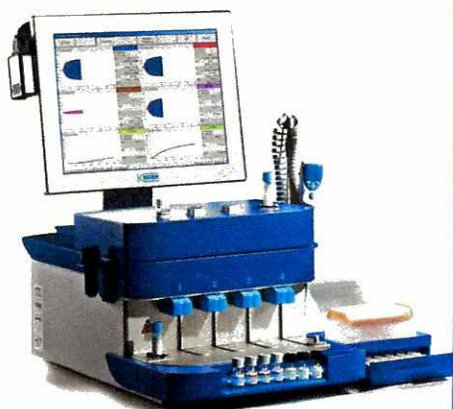
The ROTEM®- analysis offers reliable results within 5-10 minutes and provides critical information about the efficacy of the therapy. Additionally, the ROTEM®- analysis enables continuous monitoring and therefore any therapy changes as needed.

ROTEM® facilitates the management of bleeding episodes as they can occur in major surgery, such as:

- Cardiac and vascular surgery
- Organ transplantation
- Trauma
- Abdominal surgery
- Tumor removal
- Orthopedic
- Obstetrics

and others.

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



The complete ROTEM® system with ROTEM® *delta* and ROTEM® *platelet* can be performed at the patient's point of care and provides a coagulation status overview within 10 minutes of providing information on:

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

Easy and
safe handling.

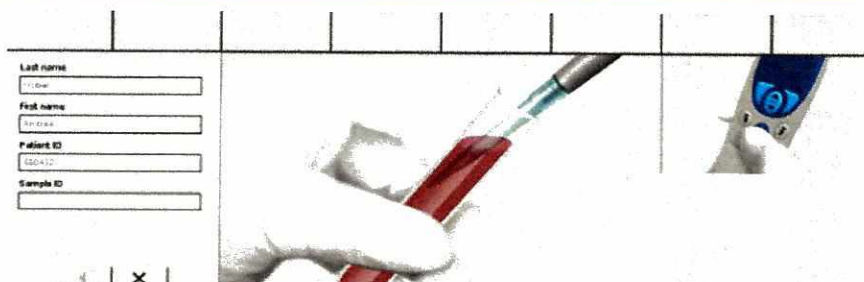


Proven technologies in one system providing flexible solutions for whole blood testing.

- 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

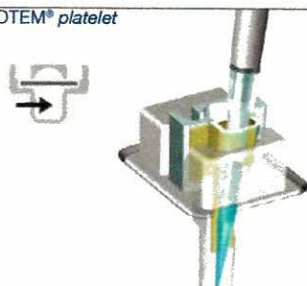
Graphical instructions with touch screen

ROTEM® delta



Put the pipette tip into the gently mixed citrated blood sample and confirm

ROTEM® platelet



APTEM 1	APTEM 2	APTEM 3	APTEM 4
I: Huber, Andrea ST: 15:49:21 RT: 00:01:46 CT: 52 s [0038 - 0079] CFT: --- SE: --- A10: ---	I: Huber, Andrea ST: 15:50:07 RT: 00:01:00 CT: 29 s [0100 - 0240] CFT: --- SE: --- A10: ---	I: Huber, Andrea ST: 15:50:40 RT: 00:00:26 CT: --- CFT: --- SE: --- A10: ---	I: Huber, Andrea ST: --- RT: --- CT: --- CFT: --- SE: --- A10: ---

2014-04-17T15:51:07 v2.6.0 User admin

Temperature 37.0°C Pre 1 2 3 4



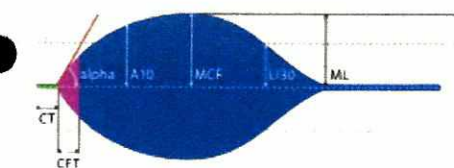
Fast therapeutic decisions.



ROTEM® analysis gives results that can guide optimal treatment and monitors the success of the treatment within minutes.

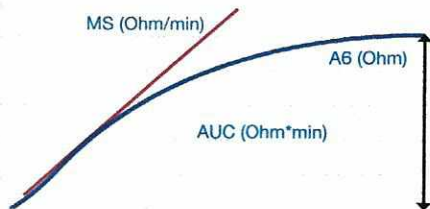
- First results are available within 5 to 10 minutes
- 6 channels: differential diagnosis of coagulopathies
- Simplified interpretation of results via colour coded TEMograms/aggregation graphs and highlighted abnormal parameter results
- Easy therapeutic control using previous patient results as overlays
- 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

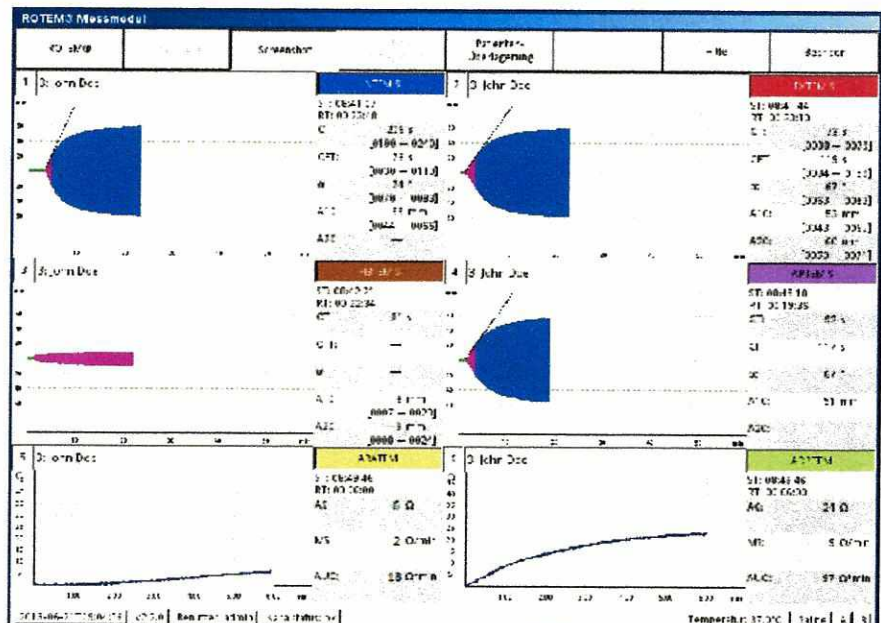


CT Clotting time
CFT Clot formation time
alpha Alpha angle
A10 Amplitude 10 min. after CT
MCF Maximum clot firmness
LI30 Lysis index 30 min. after CT
ML Maximum Lysis

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



TEMograms and aggregation curves of the 6 channels



ROTEM® *delta* haemostasis analyser.



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.

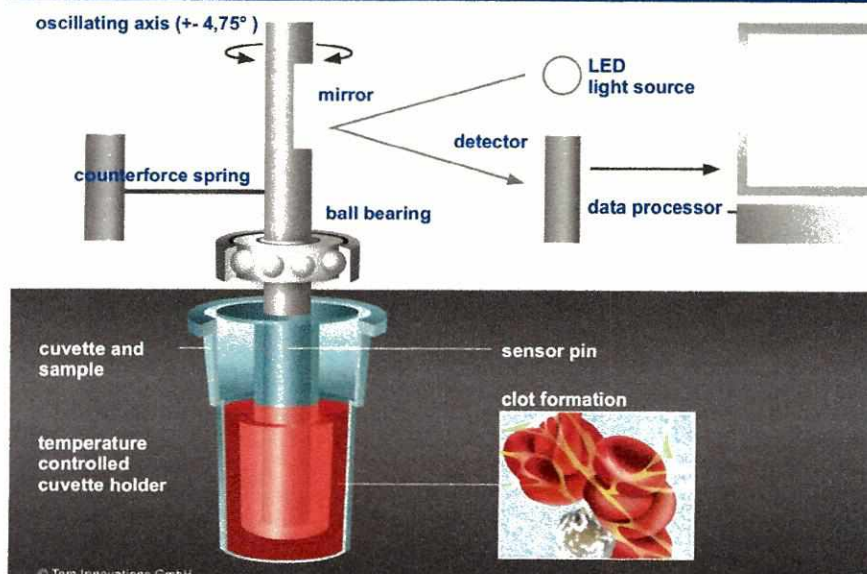
The ROTEM® *delta* features:

- 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) and ROTROL P (Level II)
- Simple patient-ID search function for fast and safe real time data transmission

ROTEM® *delta* comprehensive reagent portfolio

Liquid reagents	in-tem®	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 polymerization and fibrinolysis via the extrinsic pathway	ROTEM® analysis without platelets; qualitative assessment of fibrinogen status	In-vitro fibrinolysis inhibition; assessment of the possible effect of antifibrinolytic drugs (compared to EXTEM)	Specific detection of heparin when compared with INTEM via heparin neutralisation

ROTEM® *delta* technology



ROTEM® platelet module for platelet aggregation.



The ROTEM® platelet measures platelet aggregation in whole blood samples using impedance aggregometry. The 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 features:

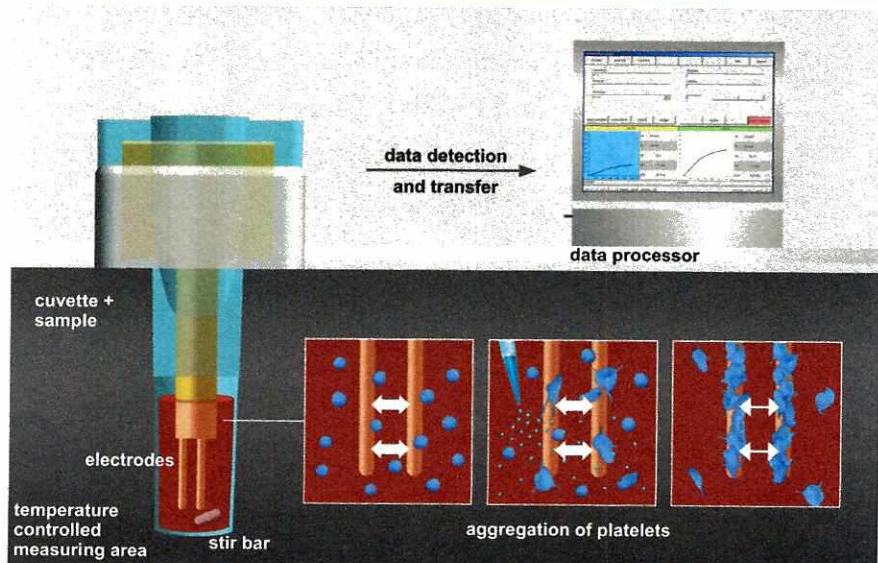
- Dedicated single use cuvettes with electrodes
- 2 channels, which can be used simultaneously
- 6-minute measurement time
- 3 different parameters:
 - AUC (area under the curve in Ohm*min)
 - A6 (amplitude at 6 min in Ohm)
 - MS (maximum slope of the aggregation graph in Ohm/min)

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

ROTEM® platelet reagent portfolio

Single use reagents	adp-tem®	ara-tem®	trap-tem®
	e.g. for the detection of ADP receptor blockage (clopidogrel)	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



ROTEM® Literature.



- Görlinger K, Dirkmann D, Weber CF, Rahe-Meyer N, Hanke AA. **Algorithms for transfusion and coagulation management in massive haemorrhage.** *Anästhesiologie Intensivmedizin* 2011 Feb; 52(2): 145-59.
- Görlinger K, Dirkmann D, Hanke AA, Kamler M, Kottenberg E, Thielmann M, Jakob H, Peters J. **First-line therapy with coagulation factor concentrates combined with point-of-care coagulation testing is associated with decreased allogeneic blood transfusion in cardiovascular surgery: a retrospective, single-center cohort study.** *Anesthesiology*. 2011 Dec;115(6):1179-91.
- Görlinger K, Fries D, Dirkmann D, Weber CF, Hanke AA, Schöchl H. **Reduction of fresh frozen plasma requirements by perioperative point-of-care coagulation management with early calculated goal-directed therapy.** *Transfus Med Hemother* 2012 Apr;39(2):104-13.
- Weber CF, Görlinger K, Meininger D, Herrmann E, Bingold T, Moritz A, Cohn LH, Zacharowski K. **Point-of-care testing: a prospective, randomized clinical trial of efficacy in coagulopathic cardiac surgery patients.** *Anesthesiology*. 2012 Sep;117(3):531-47.
- Spahn DR, Goodnough LT. **Alternatives to blood transfusion.** *Lancet*. 2013 May 25;381(9880):1855-65.
- Alamo JM, León A, Mellado P, Bernal C, Marín LM, Cepeda C, Suárez G, Serrano J, Padillo J, Gómez MÁ. **Is "intra-operating room" thromboelastometry useful in liver transplantation? A case-control study in 303 patients.** *Transplant Proc*. 2013;45(10):3637-9.
- Bolliger D, Tanaka KA. **Roles of thrombelastography and thromboelastometry for patient blood management in cardiac surgery.** *Transfus Med Rev*. 2013 Oct;27(4):213-20.
- Theusinger OM, Stein P, Spahn DR. **Applying 'Patient Blood Management' in the trauma center.** *Curr Opin Anaesthesiol*. 2014 Apr;27(2):225-32.
- Leahy MF, Roberts H, Mukhtar SA, Farmer S, Tovey J, Jewlchow V, Dixon T, Lau P, Ward M, Vodanovich M, Trentino K, Kruger PC, Gallagher T, Koay A, Hofmann A, Semmens JB, Towler S; Western Australian Patient Blood Management Program. **A pragmatic approach to embedding patient blood management in a tertiary hospital.** *Transfusion*. 2014 Apr;54(4):1133-45.
- Fayed NA, Abdallah AR, Khalil MK, Marwan IK. **Therapeutic rather than prophylactic platelet transfusion policy for severe thrombocytopenia during liver transplantation.** *Platelets*. 2014;25(8):576-86.
- Haas T, Görlinger K, Grassetto A, Agostini V, Simioni P, Nardi G, Ranucci M. **Thromboelastometry for guiding bleeding management of the critically ill patient: A systematic review of the literature.** *Minerva Anestesiologica*. 2014 Dec;80(12):1320-35.
- Görlinger K, Kozek-Langenecker SA. **Economic aspects and organization.** In: Marcucci CE, Schoettler P (eds.). *Perioperative Hemostasis: Coagulation for Anesthesiologists*. Springer-Verlag Berlin Heidelberg, 2015: 412-45.
- Nakayama Y, Nakajima Y, Tanaka KA, Sessler DI, Maeda S, Iida J, Ogawa S, Mizobe T. **Thromboelastometry-guided intraoperative haemostatic management reduces bleeding and red cell transfusion after paediatric cardiac surgery.** *Br J Anaesth*. 2015 Jan;114(1):91-102.
- Mallaiah S, Barclay P, Harrod I, Chevannes C, Bhalla A. **Introduction of an algorithm for ROTEM-guided fibrinogen concentrate administration in major obstetric haemorrhage.** *Anaesthesia*. 2015 Feb;70(2):166-75.
- Mallaiah S, Chevannes C, McNamara H, Barclay P. **A reply.** *Anaesthesia*. 2015 Jun;70(6):760-1.
- Karkouti K, McCluskey SA, Callum J, Freedman J, Selby R, Timoumi T, Roy D, Rao V. **Evaluation of a novel transfusion algorithm employing point-of-care coagulation assays in cardiac surgery: a retrospective cohort study with interrupted time-series analysis.** *Anesthesiology*. 2015 Mar;122(3):560-70.
- Corredor C, Wasowicz M, Karkouti K, Sharma V. **The role of point-of-care platelet function testing in pre-dicting postoperative bleeding following cardiac surgery: a systematic review and meta-analysis.** *Anaesthesia*. 2015 Jun;70(6):715-31.
- Whiting P, Al M, Westwood M, Ramos IC, Ryder S, Armstrong N, Misso K, Ross J, Severens J, Kleijnen J. **Viscoelastic point-of-care testing to assist with the diagnosis, management and monitoring of haemostasis: a systematic review and cost-effectiveness analysis.** *Health Technol Assess*. 2015 Jul;19(58):1-228, v-vi.
- Naik BI, Pajewski TN, Bogdonoff DI, Zuo Z, Clark P, Terkawi AS, Durieux ME, Shaffrey CI, Nemergut EC. **Rotational thromboelastometry-guided blood product management in major spine surgery.** *J Neurosurg Spine*. 2015 Aug;23(2):239-49.
- Pearse BL, Smith I, Faulke D, Wall D, Fraser JF, Ryan EG, Drake L, Rapchuk IL, Tesar P, Ziegenfuss M, Fung YL. **Protocol guided bleeding management improves cardiac surgery patient outcomes.** *Vox Sang*. 2015 Oct;109(3):267-79.
- Donohue CI, Mallett SV. **Reducing transfusion requirements in liver transplantation.** *World J Transplant*. 2015 Dec 24;5(4):165-82.
- Deppe AC, Weber C, Zimmermann J, Kuhn EW, Slottosch I, Liakopoulos OJ, Choi YH, Wahlers T. **Point-of-care thromboelastography/thromboelastometry-based coagulation management in cardiac surgery: a meta-analysis of 8332 patients.** *J Surg Res*. 2016 Jun 15;203(2):424-33.
- Straub N, Bauer E, Agarwal S, Meybohm P, Zacharowski K, Hanke AA, Weber CF. **Cost-Effectiveness of POC Coagulation Testing Using Multiple Electrode Aggregometry.** *Clin Lab*. 2016;62(6):1167-78.
- Wikkelso A, Wetterslev J, Möller AM, Afshari A. **Thromboelastography (TEG) or thromboelastometry (ROTEM) to monitor haemostatic treatment versus usual care in adults or children with bleeding.** *Cochrane Database Syst Rev*. 2016 Aug 22;(8):CD007871.
- Karkouti K, Callum J, Wijesundera DN, Rao V, Crowther M, Grocott HP, Pinto R, Scales DC; TACS Investigators. **Point-of-care hemostatic testing in cardiac surgery: A stepped-wedge clustered randomized controlled trial.** *Circulation*. 2016 Sep 21. pii: CIRCULATIONAHA.116.023956. [Epub ahead of print]

Contact

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