CARDO THORACIC & NEURO SCIENCES CENTRE
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
(STORE SECTION, CNC)

Ref.T.No. 15/CNC/CA/2026-27/St. **Date:-04.11.2026**

Subject: - Proposal for procurement of Viscoelastic Global Coagulation Testing Device-01 No. for the department of Cardiac Anesthesia, CNC, AIIMS, New Delhi, on proprietary basis inviting comments -thereof.

*****

Store Section, CNC, AIIMS, New Delhi, is in the process of procuring **Viscoelastic Global Coagulation Testing Device-01**. for the Department of Cardiac Anesthesia, CNC, AIIMS, New Delhi, on a proprietary basis from M/s. Werfen. The proposal submitted by M/s. Werfen along with the Proprietary Article Certificate (PAC), Authorization Letter and other related documents is enclosed herewith.

The above documents are being uploaded on AIIMS Website for open information to invite suggestions/objections/comments, if any, from manufacturers/suppliers regarding the proprietary nature of the equipment/item. Such comments may be submitted within 15 days from the date of issue of this notice by quoting Tender No.15/CNC/CA/2026-27/St The comments/objections should be submitted to the office of the Stores Officer (CNC), Room No. 1, First Floor, New Private Ward, CNC, AIIMS, New Delhi – 110029, on or before 19.11.2026 up to 3:00 PM. Failing which it will be presumed that no other vendor has any objection to the proposed procurement, and the purchase process will be initiated further as per the prescribed procedures.

No suggestions or objections received after 19.11.2026 shall be entertained.

4/11/2026. 4/11/2026

STORE OFFICER, CNC

Encl: Related documents enclosed.

DEPARTMENT OF CARDIAC ANAESTHESIA AND CRITICAL CARE
C.T. CENTRE, A.I.I.M.S., NEW DELHI-110029

Specifications for Viscoelastic Global Coagulation Testing Device

No. of units required: 01

Approximate cost: INR

1. System should be fully automated Cartridge based viscoelastic testing system for rapid monitoring of the entire haemostatic process that evaluates the components related to the activation of the clot, its formation and subsequent retraction.

2. System should have integrated touch screen of 12 inches or more for easy handling and should project all the channels at the same time.

3. Evaluation of the clot formation with and without the presence of platelet inhibitor for the identification of fibrinogen disorders of deficiencies.

4. Should have various tests (activators) to give complete information of bleeding patients like:-
   i. Extrinsic Pathway activation.
   ii. Intrinsic Pathway activation.
   iii. Differentiation between Platelet and Fibrinogen Deficiency.
   iv. Check the Heparin-Protamine dose monitoring.
   v. Identification of Factor deficiency.
   vi. Checking and confirming for hyper firbrinolysis.

5. Should have least possible turnaround time for faster action and provides reliable results within 15-20 minutes.

6. Evaluation of the intrinsic pathway (with and without heparinase, for the additional evaluation of heparin therapy). Aids in the detection of heparin and heparin-like substances. Can help to discriminate between factor deficiency and heparin effect.

7. Should have a software inbuilt to guide the process for running a test.

8. Should give coloured graphs and tables for easy interpretation not overlay.

9. Keyboard with integrated trackball connected to one of the 4 USB slots.

10. Should have sufficient memory to store multiple patients results.

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File No. T.No15/CNC/CA/2026-27/ST (Computer No. 3344322)

11. Test cartridge should remain stable till the expiry period at room temperature, should not require refrigeration.

12. System should have Specific confirmation of hyperfibrinolysis.

13. System should have integrated scanner for sample identification.

14. Test results should be validated using cup and pin movement method.

15. Should allow to create various users password protected to ensure the department wise use.

16. Should have LAN compatibility and should be connected to HIS/LIS system of the hospital.

17. Should be provided with a mobile cart with smooth-rolling castors and locking mechanism so that it can be moved to patients bedside. The card should have drawers to store reagents and disposable items.

18. It should have a stainless steel top of robust quality so as to prevent vibration.

19. Technical staff should be available for a month to teach and train technicians about the functioning, care and maintenance of the equipment.

20. Instrument should be USFDA/CE/ISO approved and reagents should be USFDA/ISO approved.

21. Should be able to connect to printers.

22. Firm should provide UPS with backup of 1 hr and coloured printer to print out reports.

23. It should have 2 years warranty and 8 years CAMC.

24. The cost of any disposables and cartridge etc. should include for 2 years and separate pricing should be quoted in a fixed price for subsequent purchase.

25. The equipment must be of latest state-of-art technology and model.

26. Free demonstration before technical evaluation.

27. Proprietary certificate, if applicable must be provided.

28. There should local technical support team in Delhi/NCR. The defect in the equipment should be solved within 24-48 hours from the time of complain.

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Proprietary Article Certificate (PAC)

(Machinery & Equipment)

(i) The indented goods are manufactured by only one manufacturer, M/s. Tem Innovations GmbH, Munich, Germany

(ii) Item Name: Viscoelastic Global Coagulation testing device

(iii) Model No.: Rotem Sigma

(iv) Vital Technical Performance Parameters required which makes the requirement proprietary[##]

The technology of point of care testing and cartridge based assessment of coagulation parameters is only available with this single company.

(v) No other make or model is acceptable for the following reasons:.....

The Rotem sigma analyser combines innovation with experience. The important advances are i) proven /validated technology, ii) fully automatized and iii) simple and safe handling.

It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfil the vital requirements of end user.

Signature of TSEC

With Name, Designation, Department and Hospital/Institute/DGHS

[##]Note 1: TSEC should clearly mention the vital functional parameters requirements which end user essentially require and are manufactured by only one manufacturer mentioned in Serial No. i.

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Proprietary Article Certificate (PAC)

(for chemicals, spare parts, reagents, consumables etc.)

(i) The indented goods are manufactured by M/s. Tem Innovations GmbH, Munich. Germany

(ii) Item Name: Cartridge kit of Fibtem C, Extem C, Intem C & Aptem C

(iii) Model/Part/Catalogue No.: Rotem Sigma

(iv) Reasons/Justification which makes the requirement proprietary ##. Viscoelastic Global Coagulation testing device manufactured only by M/s. Tem Innovations GmbH

1. It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfil the vital requirements of end user.

2. It is certified that the purchase is proposed to be made on proprietary usage basis because any other material/equipment/instrument chemical, etc. if used will lead to deviation and affect the integrity/accuracy, validity or analysis of the assignment/patient care.

Signature of TSEC

With Name, Designation, Department and Hospital/Institute/DGHS

##Note 1: TSEC should clearly mention that the item in question is required to standardization of machinery or spare parts to be compatible to the existing sets of equipment which is required to be procured only from one manufacturer mentioned in serial no. (i).

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IL/2025/Letter/P170 **Dt. 08.05.2025**

TO WHOM SO EVER IT MAY CONCERN

Proprietary Certificate

This is to Certify that All reagents, consumables, essential accessories and spare parts for ROTEM® Thromboelastometry are proprietary items of Tem Innovations GmbH with manufacturing Plant in Munich, Germany.

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

The Instrument Brand name ROTEM is based on viscoelastic/ Thromboelastometry principle/ Technology, is proprietary in nature.

Sincerely your's

For Instrumentation Laboratory India Pvt. Ltd.

Pawan Jindal
Business Director

Instrumentation Laboratory India Pvt. Ltd.

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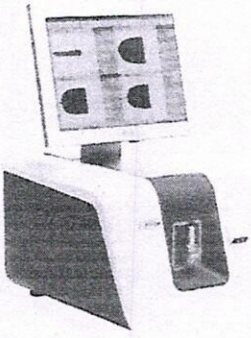
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ROTEM
sigma







Rapid and accurate test results

The ROTEM *sigma* analyzer combines innovation with experience

- Proven technology
- Fully automatized
- Simple and safe handling

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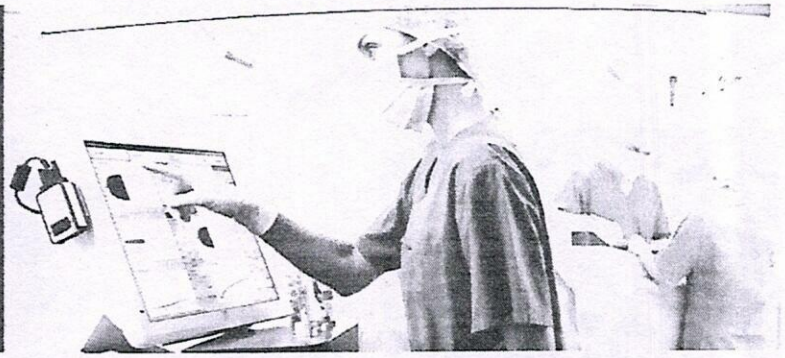
Werfen

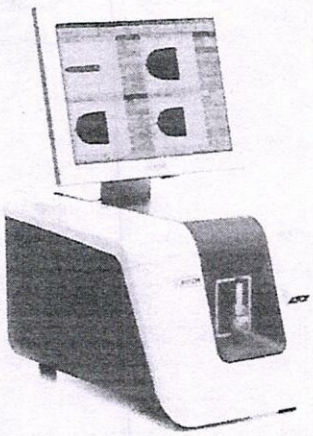
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PRODUCT BROCHURE

Proven technology
Fully automated





ROTEM *sigma* Hemostasis analyzer combines automated functionality with proven ROTEM technology

Closed, easy-to-use system

- Fully automated—no pipetting and test preparation (Figure 1)
- Sample tube fits directly into cartridge, avoiding blood handling (Figure 2)
- Simple cartridge system minimizes operator involvement
- Automated functionality checks before every measurement
- Provides results with prevailing reference ranges
- Large integrated touchscreen allows easy viewing of results
- Cartridges stored at room temperature
- Existing algorithms, recommendations, guidelines and literature are applicable

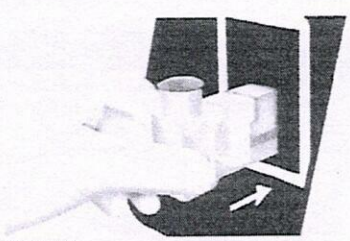


Figure 1

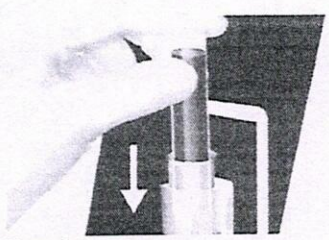


Figure 2

Proven ROTEM thromboelastometry technology provides coagulation status overview within 10 minutes

The ROTEM *sigma* analyzer measures kinetic changes in the clot elasticity of **whole blood samples**. Through measurement of **clot status** parameters, quantitative and qualitative assessment is offered. A comprehensive set of assays allows **differential diagnosis**.

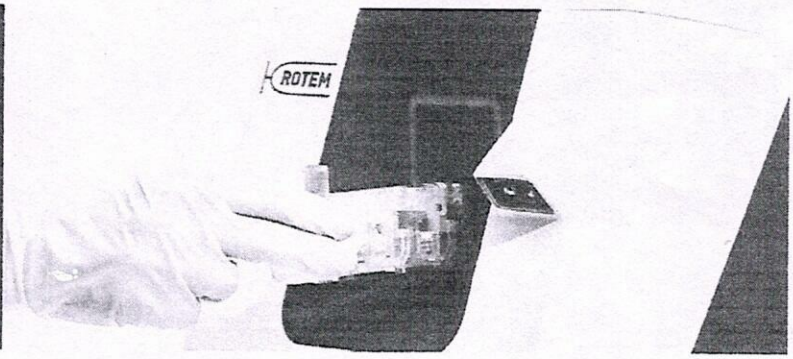
Analysis, performed at the **point of care,** provides essential information about hyperfibrinolysis, dilutional coagulopathies, substitution of fibrinogen, factors or platelet substitution, as well as heparin or protamine dosage control.

2

1

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ROTEM *sigma* cartridges



Rapid, accurate test results when time is crucial

ROTEM *sigma* cartridges

- Detect factor deficiency
- Discriminate between thrombocytopenia and fibrinogen deficiency or fibrin polymerization disorders
- Detect hyperfibrinolysis
- Detect direct FX inhibitors and direct thrombin (FIIa) inhibitor effects

The ROTEM *sigma* cartridge portfolio contains five tests offered in two test combinations: ROTEM *sigma* complete and ROTEM *sigma* complete + hep.

Tests	INTEM C	EXTEM C	FIBTEM C	APTEM C	HEPTEM C
	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	*In-vitro* fibrinolysis inhibition; assessment of the possible effect of antifibrinolytic drugs	Specific detection of heparin when compared with INTEM C via heparin neutralisation

ROTEM *sigma* complete

FIBTEM C EXTEM C INTEM C APTEM C

- Discriminates between hyperfibrinolysis and platelet mediated clot retraction/FXIII deficiency
- Provides *in vitro* assessment of antifibrinolytic drug effect
- Particularly suitable for patients where a diagnosis of fibrinolysis is needed

ROTEM *sigma* complete + hep

FIBTEM C EXTEM C INTEM C HEPTEM C

- Detects heparin and heparin-like substances
- Discriminates between factor deficiency and heparin effect
- Recommended for patients with:
  - Therapeutic heparin effect (*e.g.*, in cardiac and vascular surgery, intensive care patients)
  - Endogenous heparin effect (*e.g.*, in liver transplantations, liver cirrhosis, infections or sepsis)

The extrinsic-based tests (FIBTEM C, EXTEM C and APTEM C) in the ROTEM *sigma* cartridges neutralise heparin in up to 5 IU/ml of whole blood.

3

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