

Admn/Prop/42/2018-AIIMS.JDH

Dated: - 16th October 2018

Subject: Purchase of Rotational Thrombo Elastometry for the department of Anaesthesiology at

AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Rotational Thrombo Elastometry for the department of

Anaesthesiology at AIIMS, Jodhpur from M/s Instrumentation Laboratory Tem Innovation GmbH,

Martin-Kollar-Strasse 13-15, 81829, Munich, Germany on proprietary basis. The proposal

submitted by M/s Shreya Enterprises, Jodhpur and PAC certification by user are attached.

The above document are being uploaded for open information to submit subjection,

comments, if any from any manufacturer regarding proprietary nature of the equipment within

21days of issue giving reference Admn/Prop/42/2018-AIIMS.JDH. The comments should be

received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 06th

November 2018 upto 03:00 PM failing which it will be presumed that any other vendor is having no

comment to offer and case will be decided on merits.

Yours faithfully,

Administrative Officer

Enclosed: Related documents enclosed.



Technical Specifications

Whole Blood Haemostasis System using Rotational Thrombo Elastography as measuring principle for in-vitro diagnostics in the POC (Point of Care). The machine should have:

S.No.	Component	
1	Four independent channels tempered to 37 +/- 1.0 degree centigrade (default physiologic temperature) to	
	i) Shorten the reaction time relevantly	
	ii) Increase the precision	
	iii) Inhibit certain factors (Heparin)	
	iv) Allow differentiation between Fibrin and Platelet contributions to the overall clot	
	v) Allow simultaneous use for multiple patients	
	The work area should serve as a preheating station for cup holders and additionally to contain a sample preheating station.	
	It should have a measuring cell ejector.	
2	Seventeen inches touch screen monitor for easy handling and to give simultaneous results for all 6 (4+2) channels	
3	Barcode reader to scan samples, single use reagents as well as quality controls	
4	Electronic pipette: Software controlled pipetting and mixing of liquids	
5	Should have Pipette and clean ring rod holder with pipette cable guide. Pipette socket	
6	Should have Guiding rods and rails to guide the cup holder and to ensure the proper positioning of the cup under the axis	
7	MC rod holder to hold the MC Rod pro	
8	Curve smoothing algorithm and noise filter to prevent errors due to mechanical or electronic noise	
9	Reagent Jack to hold the reagents during measurement	
10	Keyboard with integrated trackball connected to one of the 4 USB slots in the rear side of the instrument	
11	Additional USB port for data backup	
12	Internal hard disk memory: 500 GB memory	

Quality Controls: To be done on alternate weeks with INTEM and EXTEM with Rotrol N and Rotrol P for one year by the supplier. Cost of Q & C is to be mentioned separately.

Reagents: 10 Vials each for: Intem, Rextem, Fibtem, Heptem and Startem to be supplied. Cost of reagents to be mentioned separately

Consumables to be supplied with installation:

S.No.	Component	Quantity
1	Cups and Pins: To be used for Viscoelastic testing	10 boxes of 20 each
2	Pipetting Tips	10 boxes of 96 single use disposable pipette tips
3	Pipette Filters	10 replacement filters
4	Measuring Cells	100 (cup and pin pro)





Instrumentation Laboratory
Tem Innovations GmbH • Martin-Kollar-Strasse 13-15 • 81829 Munich/Germany

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 –

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. CEO Hans-Martin Combé/Javier Gomez

HRB: 132082 Amtsgericht München Ust.-IdNr: DE 209487304





Instrumentation Laboratory
Tem Innovations GmbH • Martin-Kollar-Strasse 13-15 • 81829 Munich/Germany

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,

Ør. Volker-Joachim Friemert

Director of Quality Assurance and RA, PBM

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Our Passion. Your Results.

CEO Hans-Martin Combé/Javier Gomez HRB: 132082 Amtsgericht München Ust -ldNr: DE 209487304 St.-Nr: 143/185/60952







IL/2018/Letter/P123

Administrative Officer AIIMS, Bansi Industrial Area Phase II Jodhpur-342005 Rajasthan

Ref: Tender No. Admn/Tender/54/2017-AIIMS-JDH

Sub. - Authorization

Dear Sir,

We, M/s. Instrumentation Laboratory India Pvt. Ltd. Office No. 1471-1476, Aggarwal Millenium Tower-II, Plot No.E-4, Netaji Subhash Place, Pitam Pura, New Delhi-110034, India a 100% subsidiary of Instrumentation Laboratory, Spain/USA, who are authorized supplier of Rotem- Rotational Thrombo, having factories at Martin-Kollar strabe 13, 81829 Munchen, Germany, hereby authorize Messrs Vijyoti Management And Communications Learning Institute Private Limited, GF 12, Vardhman Sunrise Plaza, Vasundhara Enclave, New Delhi 110096 to bid, negotiate and conclude the contract with you for the above goods manufactured by us.

No company or firm or individual other than Messrs, Vijyoti Management And Communications Learning Institute Private Limited, GF 12, Vardhman Sunrise Plaza, Vasundhara Enclave, New Delhi 110096 are authorized to bid, negotiate and conclude the contract in regard to this business against this specific tender.

We hereby extend our full guarantee and warranty as per the conditions of tender for the goods offered for supply against this tender by the above firm.

We further authorize them that they can appoint a sub distributor for the supply of reagents and consumables of the equipment to the Institute till the warranty & CMC period of the mentioned tender.

The authorization is valid till the Tender tenure.

Thanking and assuring you of our best service at all times.

Yours sincerely

For Instrumentation Laboratory India Pvt. Ltd.

Pawan Jindal

Nationad Sales Managery India Pvt. Ltd.

Warehouse Ground Floor, 21 Rama Road, New Delhi-110015

Tel.: 011- 45088282 Fax: 011-45088282

Regd.Office : 1471-1476, Aggarwal Millenium Tower-II, Plot No. E-4, Netaji Subhash Place, Pitampura, New Delhi-110034 India Tel.: +91-11- 49029550, 49029551

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E-mail: info-in@werfen.com

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VIJYOTI MANAGEMENT AND COMMUNICATIONS LEARNING INSTITUTE PVT. LTD. GF-12 VARDHMAN SUNRISE PLAZA VASUNDHARA ENCLAVE NEW DELHI - 110096 INDIA

TEL: 91.11.2262.5762 MOB: 91.99104.88637 INFO@/UYOTI.COM | WWW.VIJYOTI.COM

Date- 11th May 2018

To

Administrative Officer

AIIMS, Bansi Industrial Area Phase II

Jodhpur-342005 Rajasthan

Sub- Authorization Letter for supply of Consumables & Reagents.

We M/s Vijyoti Management and Communications Learning Institute Pvt Ltd here by confirm that we are the authorized Distributor of ROTEM in India having our office at GF 12, Vardhman Sunrise Plaza, Vasundhara Enclave, New Delhi 110096. Here by We authorize –

M/s Shreya Enterprises "Shreya" 27, Narpat Nagar [Amar Nagar] , Pal Road, Jodhpur 342008 Rajasthan

for the supply of reagents and consumables to the AIIMS Jodhpur till the validity of the tender as period of 10 yrs. [5 yrs. Warranty & 5 yrs CMC] .

Yours Sincerely,

Vijyoti Management & Communications
Learning Institute Pvt. Ltd.

Vijay G Pande

Authorised Signatory

Managing Director

Registered Office: 344, 4th Floor, Shri Niketan CGHS, Sector 7, Dwarka, New Delhi 110075 Corporate Identity No.: U80200DL2007PTC167698

Branch Office: B-8 Sector 27: Noida 201301 UP, India | Tel: 91.120.434.9412





AND COMMUNICATIONS
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TEL: 91.11.2262.5762 MOB: 91.99104.88637 INFO@/UYOTI.COM | WWW.VIJYOTI.COM

To

Administrative Officer

AIIMS, Bansi Industrial Area Phase II

Jodhpur-342005 Rajasthan

Sub- Freezing price for 2 yrs for consumables & Reagents

Dear Sir /Madam,

We M/s Vijyoti Management and Communications Learning Institute Pvt Ltd here by confirm that we are the authorized Distributor of ROTEM in India and having our office at GF 12, Vardhman Sunrise Plaza, Vasundhara Enclave, New Delhi 110096.

We authorize -

M/s Shreya Enterprises, "Shreya" 27, Narpat Nagar, Pal Road, Jodhpur 342008 Rajasthan for the supply of reagents and consumables to the AIIMS Jodhpur till the validity of the tender.

The price for the reagents and consumables to Aiims , Jodhpur will be fixed for two years from date of installation.

For Vijyoti Management & Communications erely, Learning Institute Pvt. Ltd.

Yours Sincerely,

Vijay G Pande

Managing Director

Registered Office: 344, 4th Floor, Shri Niketan CGHS, Sector 7, Dwarka, New Delhi 110075 Corporate Identity No.: U80200DL2007PTC167698

Branch Office B-8 Sector 27 Noida 201301 UP, India | Tel: 91.120.434.9412





Administrative Officer AIIMS, Bansi Industrial Area Phase II Jodhpur-342005 Rajasthan

Ref :- Tender No. Admn/Tender/54/2017-AIIMS-JDH

Sub- Undertaking for the 5 yrs. Warranty & CMC for 5 yrs.

Dear Sir / Madam,

We, M/s. Instrumentation Laboratory India Pvt. Ltd. Office No. 1471-1476, Aggarwal Millenium Tower-II, Plot No.E-4, Netaji Subhash Place, Pitam Pura, New Delhi-110034, India a 100% subsidiary of Instrumentation Laboratory, Spain/USA, who are authorized supplier of Rotem- Rotational Thrombo, having factories at Martin-Kollar strabe 13, 81829 Munchen, Germany, hereby authorize Messrs Vijyoti Management And Communications Learning Institute Private Limited to maintain Warranty of 5 Yrs. on unit from date of installation & Comprehensive Maintenance Contract (CMC) for the ROTEM Delta machine for next five years from the date of completion of warranty at the Institute.

We are fully responsible for the warranty & CMC period .

Thanking and assuring you of our best service at all times.

Yours sincerely

CIN NO. U26104DL2007FTC159969

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.: 011- 45088282 Fax: 011- 45088282

Regd.Office

Rega. Unice: 1471-1476, Aggarwal Millenium Tower-II, Plot No. E-4, Netaji Subhash Place, Pitampura, New Delhi-110034 India Tel.: +91-11- 49029550, 49029551 Fax: +91-11- 49029567

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TEL: 91.11.2262.5762 MOB: 91.99104.88637 INFO@VUYOTI.COM | WWW.VUYOTI.COM

To

Administrative Officer

AIIMS, Bansi Industrial Area Phase II

Jodhpur-342005 Rajasthan

Sub- Undertaking for the warranty of 5 yrs . & CMC of 5 Yrs.

Dear Sir / Madam,

We M/s Vijyoti Management and Communications Learning Institute Pvt Ltd here by confirm that we are the authorized Distributor of ROTEM in India and having our office at GF 12, Vardhman Sunrise Plaza, Vasundhara Enclave, New Delhi 110096.

Vijyoti Management and Communications Learning Institute Pvt Ltd is the technical channel partner with Instrumentation laboratories in India $\,$ undertake the warranty $\,$ of 5 Yrs of the $\,$ instrument & 5 yrs Maintenance Contract (CMC) of ROTEM Delta machine after completion of warranty.

Yours Sincerely, For Vijyoti Management & Communications Learning Institute Pvt. Ltd.

Vijay G Pande

Managing Director

Registered Office: 344, 4th Floor, Shri Niketan CGHS, Sector 7, Dwarka, New Delhi 110075 Corporate Identity No. U80200DL2007PTC167698

Branch Office: B-8 Sector 27. Noida 201301 UP, India | Tel: 91.120.434.9412







EP 1 627 725 B1

(12)

EUROPEAN PATENT SPECIFICATION

- (45) Date of publication and mention of the grant of the patent: 17.12.2008 Bulletin 2008/51
- (21) Application number: 05017564.5
- (22) Date of filing: 12.08.2005
- (51) Int Cl.: B29C 59/14 (2006.01) B29C 71/04 (2006.01) G01N 33/49 (2006.01)

B29C 59/16 (2006.01) C08J 7/14 (2006.01) G01N 11/16 (2006.01)

(54) Method of treating the surface of a medical device for blood coagulation diagnosis, and such

Verfahren zur Oberflächenbehandlung einer medizinischen Vorrichtung für die Untersuchung der Blutgerinnungsfunktion, sowie eine dergestalte Vorrichtung

Procédé de traitement de surface d'un dispositif médical pour le diagnostic de la coagulation sanguine, et un tel dispositif

- (84) Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI
- (30) Priority: 12.08.2004 GB 0418474
- (43) Date of publication of application: 22.02.2006 Bulletin 2006/08
- (73) Proprietor: C A Casyso AG 4132 Muttenz (CH)
- (72) Inventors:
 - · Schubert, Axel 81377 München (DE)
 - · Wurlitzer, Stefan 85630 Grasbrunn (DE)

- · Glauner, Martin
- 79639 Grenzach-Wyhlen (DE)
- · Calatzis, Andreas 81673 München (DE)
- (74) Representative: Rentsch & Partner Fraumünsterstrasse 9 Postfach 2441 8022 Zürich (CH)
- (56) References cited:

EP-A- 0 404 456 WO-A-02/066958 IE-B- 70 604 US-A- 5 627 079

US-B1-6 417 004

EP-A- 0 629 445 DE-A1- 10 003 093 US-A- 4 341 111 US-A- 5 723 219

Note: Within nine months of the publication of the mention of the grant of the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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(19)

EP 2 208 996 B1

EUROPEAN PATENT SPECIFICATION

- (45) Date of publication and mention of the grant of the patent: 01.09.2010 Bulletin 2010/35
- (51) Int Cl.: G01N 33/49 (2006.01)
- (21) Application number: 09150740.0
- (22) Date of filing: 16.01.2009
- (54) A measuring unit for measuring characteristics of a sample liquid, in particular viscoelastic characteristics of a blood sample

Messeinheit zum Messen der Eigenschaften einer Probenflüssigkeit, insbesondere der viskoelastischen Eigenschaften einer Blutprobe

Unité de mesure des caractéristiques d'un échantillon liquide, en particulier les propriétés viscoélastiques d'un échantillon sanguin

- (84) Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK TR
- (43) Date of publication of application: 21.07.2010 Bulletin 2010/29
- (73) Proprietor: C A Casyso AG 4132 Muttenz (CH)
- (72) Inventors: · Schubert, Axel 81377, München (DE)

- · Romero-Galeano, José Javier 85570, Markt Schwaben (DE)
- · Kessler, Max 81539, München (DE)
- (74) Representative: Peckmann, Ralf Reinhard, Skuhra, Weise & Partner GbR Patent- und Rechtsanwälte Friedrichstrasse 31 80801 München (DE)
- (56) References cited: DE-A1- 2 740 932 GB-A- 2 257 256 US-A- 5 287 732 US-A- 5 777 215

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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(19)



(11)

EP 2 549 928 B1

(12)

EUROPEAN PATENT SPECIFICATION

- (45) Date of publication and mention of the grant of the patent: 03.06.2015 Bulletin 2015/23
- (21) Application number: 11702252.5
- (22) Date of filing: 08.02.2011
- (51) Int Cl.: A61B 5/15 (2006.01) G06F 19/00 (2011.01)
 - A61B 5/145 (2006.01)
- (86) International application number: PCT/EP2011/051803
- (87) International publication number: WO 2011/117017 (29.09.2011 Gazette 2011/39)
- (54) METHOD FOR DETERMINING AT LEAST ONE EVALUATION PARAMETER OF A BLOOD SAMPLE VERFAHREN ZUR BESTIMMUNG VON MINDESTENS EINEM AUSWERTUNGSPARAMETER

PROCÉDÉ POUR DÉFINIR AU MOINS UN PARAMÈTRE D'ÉVALUATION D'UN ÉCHANTILLON SANGUIN

- (84) Designated Contracting States: AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
- (30) Priority: 24.03.2010 EP 10157562
- (43) Date of publication of application: 30.01.2013 Bulletin 2013/05
- (73) Proprietor: C A Casyso AG 4132 Muttenz (CH)
- (72) Inventors:
 - SCHUBERT, Axel 81927 München (DE)
 - BELS. Kevin 81675 München (DE)

- (74) Representative: Isarpatent Patent- und Rechtsanwälte Postfach 44 01 51 80750 München (DE)
- (56) References cited: EP-A1- 1 367 392 EP-A1- 1 394 546 WO-A2-2006/091650 US-A- 6 066 243
 - NIELD L E ET AL: "MRI-based blood oxygen saturation measurements in infants and children with congenital heart disease.", PEDIATRIC RADIOLOGY, vol. 32, no. 7, July 2002 (2002-07), pages 518-522, XP002596496, ISSN: 0301-0449
 - · PRISCO DOMENICO ET AL: "Point-of-Care Testing of Hemostasis in Cardiac Surgery" THROMBOSIS JOURNAL, BIOMED CENTRAL LONDON, GB LNKD- DOI:10.1186/1477-9560-1-1, vol. 1, no. 1, 6 May 2003 (2003-05-06), page 1, XP021018831, ISSN: 1477-9560

928 B1 549 N

Note: Within nine months of the publication of the mention of the grant of the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the

Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

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Instrumentation Laboratory SpA A Werfen Company

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(vijjyoti), 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

Jose Zamora **EEMEAI** Director

Instrumentation Laboratory, SpA

A Werfen Company

Instrumentation Laboratory SpA A Werfen Company

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EEMEAI - International Division