

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

Ref. No. 29/Surgery/Proprietary/2019-20/St.

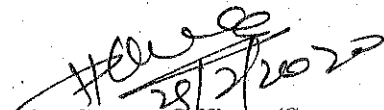
Dated: 29.02.2020

**Subject: Proposal for purchase of Arterial Blood Gas Analyzer Co-oximeter, Electrolyte and Metabolic Analyzer with consumables on proprietary basis and fixing of rates of consumables for 10 years – reg. (Estimated Cost: Rs. 6,43,38,206/-)**

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The request has been received from the HoD, Department of Surgical Discipline for purchase of subject mentioned item from **M/s Nova Biomedical Corporation** through their authorized distributors **M/s Surgitech India** on proprietary basis. The proposal submitted by **M/s Surgitech India, D-23, Flat No. 16, Rajouri Garden, New Delhi 110027 India**. PAC certifications are attached herewith.

The above documents 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. 29/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, 1<sup>st</sup> Floor, (Near B.B Dikshit Library), AIIMS, Ansari Nagar, New Delhi-110029 on or before **18/03/2020 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.

Date: September 2, 2019

To Whom It May Concern:

**PROPRIETARY CERTIFICATE**

Dear Sir/Madam,

Greeting from Nova Biomedical Corporation, USA!

**Nova Biomedical Corporation** a Massachusetts corporation with its principal place of business at 200 Prospect Street, Waltham, Massachusetts 02453-3465 U.S.A., hereby declare the following:

That below mentioned parameters are available in following models:

Models	Measured Parameters
<b>Stat Profile Prime ES</b>	Sodium, Potassium, Chloride, Ionized calcium, <b>Ionised Magnesium</b> , and pH
<b>Stat Profile PRIME PLUS</b>	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Sodium, Potassium, Chloride, Ionized calcium, <b>Ionised Magnesium</b> , Haematocrit, Saturation Oxygen, Haemoglobin, Glucose, Lactate, <b>Blood Urea Nitrogen, Creatinine</b> , Hydro-haemoglobin (HHb), Oxy-haemoglobin (O <sub>2</sub> Hb), Meth-Haemoglobin (MetHb), Carboxy-haemoglobin (COHb), Total haemoglobin (tHb), Fetal Haemoglobin (FHB), Oxygen content (O <sub>2</sub> Ct), Oxygen capacity (O <sub>2</sub> Cap) and Total Bilirubin (tbili)
<b>Stat Profile pHox Ultra Plus</b>	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Sodium, Potassium, Chloride, Ionized calcium, <b>Ionised Magnesium</b> , Haematocrit, Saturation Oxygen, Haemoglobin, Glucose, Lactate, <b>Blood Urea Nitrogen, Creatinine</b> , Hydro-haemoglobin (HHb), Oxy-haemoglobin (O <sub>2</sub> Hb), Meth-Haemoglobin (MetHb), Carboxy-haemoglobin (COHb), Total haemoglobin (tHb), Fetal Haemoglobin (FHB), Oxygen content (O <sub>2</sub> Ct), Oxygen capacity (O <sub>2</sub> Cap) and Total Bilirubin (tbili)

We also confirm that above mentioned models and its consumables are our proprietary products and No company or firm, or individual is authorized to manufacture/market these items worldwide without our consent.

For and on behalf of the Manufacturer  
**NOVA Biomedical Corporation,**

Signed: Kenneth J. Lumm

In the capacity of: **Senior Director, International Sales**

Duly authorized to sign the Authorisation for and on behalf of:  
**Nova Biomedical Corporation**

Nova Biomedical, 200 Prospect Street, Waltham, MA 02454-9141 U.S.A. Tel: 781-894-0800  
www.novabiomedical.com

**ATTESTED**

Notary Public, Delhi

**nova**  
biomedical  
200 Prospect Street  
Waltham, MA 02454 U.S.A.



Date: April 1, 2019

To Whom It May Concern:  
MANUFACTURER CERTIFICATE

Dear Sir/Madam,

Greeting from Nova Biomedical Corporation, USA!!

As one of our many valued customers in India, Nova Biomedical is pleased to announce our distributor arrangement in India.

Nova Biomedical Corporation ("**Nova**"), a Massachusetts corporation with its principal place of business at 200 Prospect Street, Waltham, Massachusetts 02453-3465 U.S.A., hereby declare **Surgitech India**, a corporation formed under the laws of India with its principal place of business at D-23, Flat No-16, Rajouri, Garden, Delhi-110027, INDIA, as our **Exclusive Distributor** for the products listed below in India.

**Products:**

**Blood Gas and Electrolyte Analyser for following model:**

Model: Stat Profile pHox Series, CRT/NOVA Series

Nova Stat Profile Ultra and Critical Care Xpress (CCX)

Prime/ Prime ES and Prime Plus Series

**Blood Analysers for following Model:**

Accessories and Consumables for the above Analyzers

Please also be informed that **Surgitech India** is the **Exclusive Stockist for India** for the **Accessories and Consumables for the above Analyzers**.

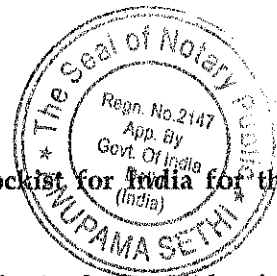
No company or firm or individual other than **Surgitech India**, is authorized to provide after sales support for the installed Nova Analyzer's, provide technical Support, submit new bids and subsequently negotiate and sign the contract with you for Nova business in India for the specific Products listed above on our behalf.

The equipment requires consumables, accessories and kits which are proprietary items of Nova Biomedical, USA. We are enclosing the list of consumables, accessories and kits which are to be used on this machine. All these consumables are proprietary items and will be supplied in your hospital by **Surgitech India** or through any of its sub-distributors "if any".

Further, **Surgitech India** is also authorized to sell, supply, service and distribute the products as listed above and manufactured by Nova Biomedical Corporation on previously supplied and installed Analyzer through any of its sub-distributors "if any" for your institution.

Nova Biomedical, 200 Prospect Street, Waltham, MA 02453-3465 U.S.A. Tel: 781-894-0800  
www.novabiomedical.com

**ATTESTED**  
*Sdhi*  
Notary Public, Delhi

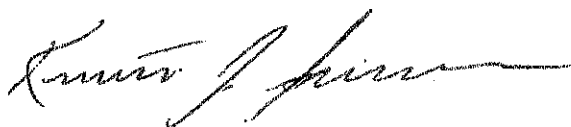


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Nova Biomedical Inc. guarantees the availability of supply of the relevant consumables and warranty support for the duration and term of the contract between you and Surgitech India.

This authorization will supersede any letter previously issued to you on our behalf. Any renewal or extension of this Letter of Authorization must be in writing and executed by a director or officer of Nova Biomedical.

For and on behalf of the Manufacturer  
**NOVA Biomedical Corporation,**

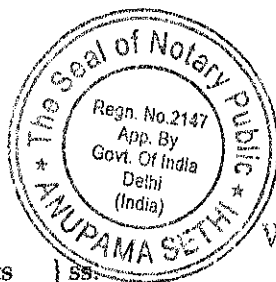


**Signed: Kenneth J. Lumm**

In the capacity of: **Senior Director, International Sales**

Duly authorized to sign the Authorisation for and on behalf of:

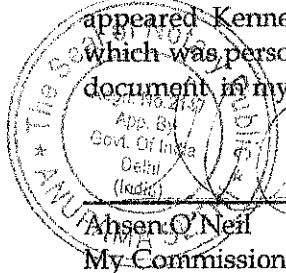
**Nova Biomedical Corporation**



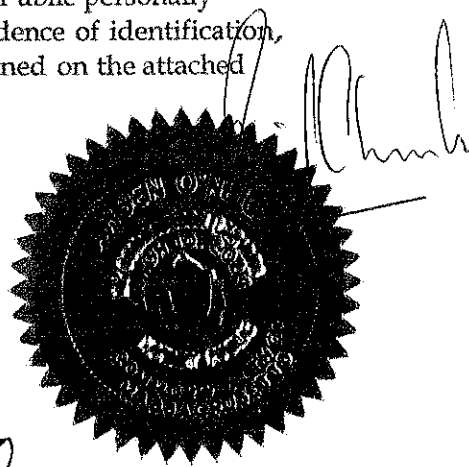
**nova  
biomedical**  
200 Prospect Street  
Waltham, MA 02454 U.S.A.

Commonwealth of Massachusetts }  
County of Middlesex }

On this 1<sup>st</sup> day of April, 2019, before me, the undersigned Notary Public personally appeared Kenneth J. Lumm, proved to me through satisfactory evidence of identification, which was personal knowledge, to be the person whose name is signed on the attached document in my presence.




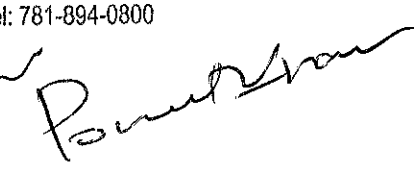
**Anupama Sethi**  
My Commission expires March 15, 2024



**ATTEST**

  
**Notary Public, Delhi**

Nova Biomedical, 200 Prospect Street, Waltham, MA 02453-3465 U.S.A. Tel: 781-894-0800  
[www.novabiomedical.com](http://www.novabiomedical.com)

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(90)

(67)

ALL INDIA INSTITUTE OF MEDICAL SCIENCES  
ANSARI NAGAR, NEW DELHI-110029  
DEPARTMENT OF SURGICAL DISCIPLINE  
Proprietary Article Certificate (PAC) (Machinery & Equipment)

1. The indented goods are manufactured by	M/s Nova Biomedical Corporation.
2. Item Name:	Arterial Blood Gas Analyzer Co-oximeter, Electrolyte and Metabolic Analyzer with consumables
3. Model No:	pHOx Ultra
4. Vital technical performance parameters required which makes the requirement proprietary:	It is the only company who provide magnesium and magnesium is required in critical care setups, management of intestinal obstruction, arrhythmia, and asthma management.
5. No other make or model is acceptable for the following reasons:	<p>The combination of 22 parameters is available with single manufacture only. i.e Nova Biomedical which is useful and required for patient care. the below mentioned parameters are available in the following models:-</p> <p>pH, pCO<sub>2</sub>, pO<sub>2</sub>, Sodium, Potassium, Chloride, Ionized calcium, <b>Ionised Magnesium</b>, Haematocrit, Saturation Oxygen, Haemoglobin, Glucose, Lactate, Blood Urea Nitrogen, Creatinine, Hydro-haemoglobin, (HHb), Oxy-haemoglobin(O<sub>2</sub>Hb), Meth-haemoglobin(MetHb), Crboxy-haemoglobin, Total haemoglobin, Fetal haemoglobin, Oxygen Content (O<sub>2</sub>Ct), Oxygen Capacity (O<sub>2</sub>Ct) and Total Bilirubin (tbili).</p>

It is certified that market survey has been done found that no other manufacture is manufacturing similar/equivalent specification which can fulfill the vital requirement of end user.

Poonam Kanna

V

Anurag

Anil Kumar

**New Generation**

STAT PROFILE®

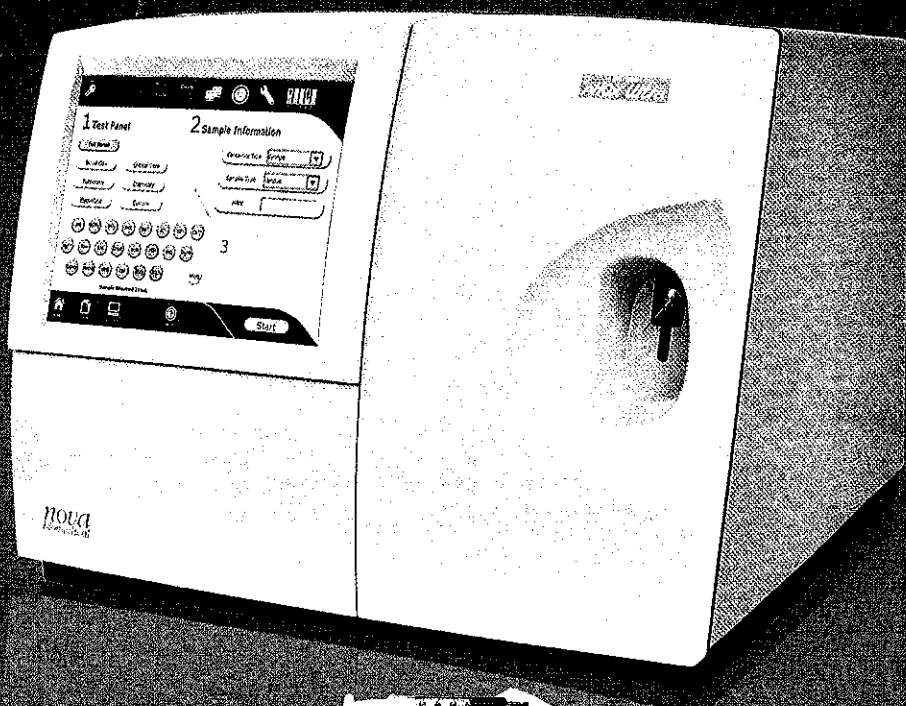
**pHOx® Ultra™**

# Best Value for Critical Care Blood Gas Testing

**One Analyser, Up to  
20 User Selected  
Critical Care Tests**

**New, Simplified  
Operation with  
Easy-to-Use, High  
Resolution Touchscreen**

**Proven pHOx Hardware Platform  
Provides Exceptional Reliability**



**nova**  
biomedical



Lactate

O<sub>2</sub>Hb

COHb

MetHb

HHb

SO<sub>2</sub>%

tBil

# Stat Profile pHox<sup>®</sup> Ultra<sup>™</sup> Specifications

## Critical Care Test Menu:

pH	Direct ISE
PCO <sub>2</sub>	Severinghaus
PO <sub>2</sub>	Amperometric
SO <sub>2</sub> %	Optical, reflectance
Haematocrit	Conductivity/Na <sup>+</sup> correction
Haemoglobin	Multi-wavelength reflectance/ conductivity correction
Na <sup>+</sup>	Direct ISE
K <sup>+</sup>	Direct ISE
Cl <sup>-</sup>	Direct ISE
Ca <sup>++</sup>	Direct ISE
Mg <sup>++</sup>	Direct ISE
Glucose	Enzyme/Amperometric
BUN/Urea	Enzyme/Direct ISE
Creatinine	Enzyme/Amperometric
Lactate	Enzyme/Amperometric

## CO-Oximetry Test Menu:

HHb, deoxyhaemoglobin	O <sub>2</sub> Hb, oxyhaemoglobin
MetHb, methaemoglobin	COHb, carboxyhaemoglobin
tHb, total haemoglobin	SO <sub>2</sub> %, oxygen saturation
O <sub>2</sub> Ct, oxygen content	O <sub>2</sub> Cap, oxygen capacity
tBil, total bilirubin	

## Calculated Tests:

eGFR	a/A	Ca <sup>++</sup> /Mg <sup>++</sup> Ratio
HCO <sub>3</sub> <sup>-</sup>	PO <sub>2</sub> /FIO <sub>2</sub>	Normalised Ca <sup>++</sup>
BE-act	Anion Gap	Normalised Mg <sup>++</sup>
BE-b	SBC	Osmolality
O <sub>2</sub> Ct	Base Excess	O <sub>2</sub> Cap
A	O <sub>2</sub> Saturation	Haemoglobin
A-aDO <sub>2</sub>	BUN/Creatinine Ratio	
pH/PCO <sub>2</sub> /PO <sub>2</sub> Corrected to Patient Temperature		
Respiratory Index (If % FIO <sub>2</sub> value entered)		

## Special Calculated Tests (CO-Oximeter Required):

Tests	Resolution
A-v DO <sub>2</sub>	0.1 mmHg (0.01 kPa)
CaO <sub>2</sub>	0.1 mL/dL (0.01 kPa)
CcO <sub>2</sub>	0.1 mL/dL (0.01 kPa)
P50	0.1 mmHg (0.01 kPa)
C(a-v)O <sub>2</sub>	0.1 mmHg (0.001 kPa)

## Complete Management Reports:

- Calibration Report
- Cartridge Log Report
- Daily Sample Log Report
- Edit Log Report
- Error Log Report
- Maintenance Log Report
- Operator Setup Report
- Patients Report
- Levey-Jennings QC Reports
- QC Corrective Actions Report
- QC Data Report
- QC Statistics Report
- QC Setup Report
- Sample Audit Log Report

## Monitored Interferences:

sHb, sulphaemoglobin (Measured; user alerted if abnormal, > 1.5%)

## Measurement Range:

pH	6.50 - 8.000 (H <sup>+</sup> : 316.23 - 10.00 mmol/L)
PCO <sub>2</sub>	3.0 - 200 mmHg (0.4 - 26.6 kPa)
PO <sub>2</sub>	0 - 800 mmHg (0.0 - 106.4 kPa)
SO <sub>2</sub> %	30 - 100 % (0.3 - 1.00)
Hct	12% - 70%
Hb	4.0 - 24.0 g/dL (2.5 - 14.9 mmol/L)
Na <sup>+</sup>	80 - 200 mmol/L
K <sup>+</sup>	1 - 20 mmol/L
Cl <sup>-</sup>	50 - 200 mmol/L
Ca <sup>++</sup>	0.1 - 2.7 mmol/L
Mg <sup>++</sup>	0.1 - 1.5 mmol/L
Glucose	15 - 500 mg/dL (0.83 - 27.75 mmol/L)
BUN	3 - 100 mg/dL (2.1 - 17.4 mmol/L)
Urea	1.1 - 35.7 mmol/L (6.4 - 214.5 mg/dL)
Creatinine	0.2 - 20 mg/dL (18 - 1765.8 µmol/L)
Lactate	0.3 - 20 mmol/L (2.7 - 178.1 mg/dL)
HHb	0 to 100%
O <sub>2</sub> Hb	0 to 100%
MetHb	0 to 100%
COHb	0 to 100%
SO <sub>2</sub> %	0 to 100%
O <sub>2</sub> Ct	0 to 34.75 vol. %
O <sub>2</sub> Cap	0 to 34.75 vol. %
tBil	0.5 - 35.1 mg/dL
iHb	5 - 25 g/dL
sHb	Alert > 1.5%
BarP	400.0 - 800.0 mmHg (53.3 - 106.7 kPa)

## Other Features:

Full colour 30.7-cm touchscreen, multilingual, QC statistics, onboard data management, automatic sampler, integrated capillary adapter, optional barcode scanner, QC data storage, ASTM and HL7 communication protocols, optional mobile cart with UPS

## Certifications:

Nova Biomedical is in compliance with ISO 13485; 2003, ISO 9001; 2008 and FDA Quality System Regulation  
Safety Tested by TÜV, SUB and CSA  
Meets requirements of the IVDD  
Integrated RiLiBaK compliant QC module

## Typical Sample Volume:

- 60 microliters whole blood micro sample for blood gases/pH
- 105 microliters whole blood for CO-Oximetry with total Bilirubin
- 120 microliters micro sample for full panel without CO-Oximetry
- 150 microliters whole blood sample for full panel without CO-Oximetry
- 210 microliters whole blood sample for full panel with CO-Oximetry

## Physical Specifications:

Height: 43.7 cm (17.22 in) Width: 56.7 cm (22.34 in)  
Depth: 43.8 cm (18.7 in) Weight: 27.7 kg (61 lb)  
without reagent pack

## Electrical Power Requirements:

90-264 VAC, 50/60 Hz, 350 W

## Interfaces:

ASTM Protocol, via serial RS232 TCP/IP, POCT1-A

## Temperature Thermostatting:

37°C ± 0.1°C

## Printer:

Built in thermal

## FDA Labeling:

For in-vitro diagnostic use

## Calibration:

Fully automatic two point calibration every two hours; user-selectable single point calibration every 30 minutes or with each sample. No calibration initiated at any time.

## Acceptable Samples:

Whole blood (heparinised), serum/plasma, arterial, mixed venous, capillary

**nova**<sup>®</sup>  
**biomedical**

**novabiomedical.com**

Specifications subject to change without notice.

**Nova Biomedical Headquarters:** 200 Prospect St., Waltham, MA 02453-3465 U.S.A.: +1-781-894-0800 800-458-5813 FAX: +1-781-894-5915 Int'l FAX: +1-781-899-0417 e-mail: info@novabio.com  
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**Nova Biomedical Canada, Ltd:** 17 - 2900 Argentea Road, Mississauga, Ontario L5N 7X9 Canada TEL: +1-905-567-7700 800-263-5999 FAX: +1-905-567-5496 e-mail: info@novabio.ca  
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**Nova Biomedical U.K.:** Innovation House, Aston Lane South, Runcorn, Cheshire WAZ 3FY United Kingdom TEL: +44-1928 704040 FAX: +44-1928 796792 e-mail: sales@novabiomedical.co.uk

Mg<sup>++</sup>

Glucose

Urea/BUN

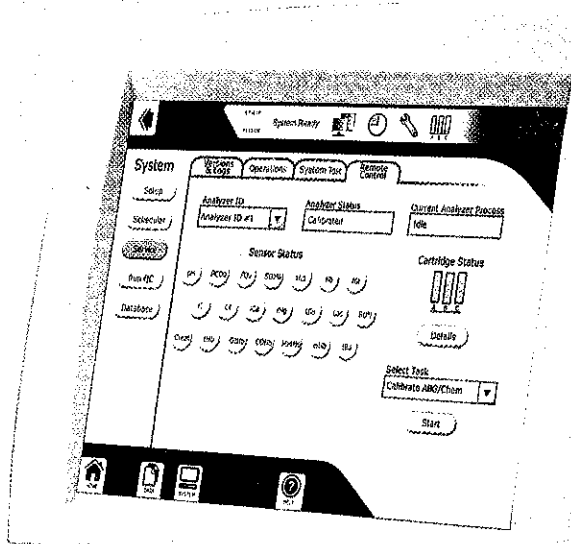
Creatinine

eGFR

Hct

Hb

# Complete Data Management and Connectivity



## Onboard Data Management System

A standard feature of pHox Ultra is a complete, onboard data management system, which allows for data capture and extensive reporting capabilities, including:

- Storage and retrieval of patient results, patient demographics, QC, and authorised users
- Data retrieval by name, ID, date, location, or operator
- Patient, QC, utilisation, and operator reports

## Analyser Networking at No Extra Cost

Multiple pHox Ultra analysers can be networked into a single, common database. A supervisor or authorised operator can access all patient results, QC results, and reports from all analysers. Competitors often offer this capability only as an expensive accessory, adding 30% to 40% to the analyser's cost.

## Remote Setup and Control

pHox Ultra offers comprehensive, time-saving remote setup, control, and review of multiple pHox Ultra analysers. From any point on the LAN, a manager can perform the following functions on a remote analyser:

- Review reagent cartridge and QC cartridge status
- Review instrument calibration status
- Initiate a calibration cycle
- Review QC status
- Initiate a QC cycle
- Enable or disable an analyte
- Enable or disable operator access
- Edit normal ranges, critical ranges, QC ranges, QC frequency, operators, test menu, instrument defaults

## Connectivity

pHox Ultra analysers are compliant with industry standard POCT1-A and ASTM communication protocols for connectivity. These industry standards are used to easily interface pHox Ultra analysers to a wide range of connectivity systems including LIS, HIS, and middleware.

*[Handwritten signatures]*