TECHNICAL COMMITEE EVALUATION REPORT FOR TENDER NO: -184 (Digital Invasive Hemoglobinometer, strips)/APMSIDC/MEDICINE WING/2025-26

Firm Name : ***SENSA CORE MEDICAL INSTRUMENTATION PVT LTD*** **Firm Remarks :**

		Remarks	Documents Submitted by the Firm May Be/May Not Be Considered as per Tender Conditions.
I	Valid manufacturing license in case of Bidder as a Manufacturer / Wholesale Licenses license in case of Bidder as a Distributor. They should submit Drug License copies from statutory body of concerned Licensing authorities of Central/State Government	Yes, Submitted MD-5 Licence bearing No: MFG/IVD/2019/000046 uptod upto 17/8/2030	May be Considered
II	Scanned copy of Valid ISO/BIS/CE/ISI Certificate of manufacturing company. In case of imported products, scanned copy Valid quality Certificate of manufacturing company of foreign company.	Yes, Submitted ISO 13485 Certificate	May be Considered
III	Latest Non-conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted by manufacturer or distributor. Not less than 12 months from the date of commencement of tender.	Yes, Submitted N.C.C issued on 09.02.2026	May be Considered

Firm Name : ***SENSA CORE MEDICAL INSTRUMENTATION PVT LTD***

S.No	*Item Code*	*Item Name*	*Strength*	Priliminary Remarks on Valid Manufacturing License /Valid import license /COPP	Priliminary Evaluation status (Considered-YES, Not-Considered-NO)	Final Remarks on Valid Manufacturing License /Valid import license /COPP	Final Item Status (Considered/ Not-Considered)
1	*T184*	*Digital Invasive Hemoglobinometer, strips and Consumables as per GOI*	*Specifications as per tender document*	Submitted MD-5 Licence bearing No: MFG/IVD/2019/000046 uptod upto 17/8/2030	Yes		

Priliminary Remarks **:**

The firm may be considered for Item code T184

Signature : 17/4/26
Name : T. Vinodh
Designation : DI, Tndl

Final Remarks **:**

Signature :
Name :
Designation :

Technical Evaluation of T No 184 (HB Strips along with Haemoglobinometer)

M/s SENSA CORE MEDICAL INSTRUMENTATION PVT LTD

I. Technical

		Remarks
(I)	Valid manufacturing license in case of Bidder as a Manufacturer / Wholesale Licenses license in case of Bidder as a Distributor. They should submit Drug License copies from statutory body of concerned Licensing authorities of Central/State Government	1. Submitted MD-5 License bearing No. MFG/IVD/2019/000046 for Hb Analyser, Test strips and Control Solutions
(II)	Scanned copy of Valid ISO/BIS/CE/ISI Certificate of manufacturing company. In case of imported products, scanned copy Valid quality Certificate of manufacturing company of foreign company. 2. Submitted	ISO 13485: 2016 Certificate valid upto 24/11/2017
(III)	Latest Non-conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted by manufacturer or distributor. Not less than 12 months from the date of commencement of tender. 3. Submitted	N.C.C issued on 9/02/2018

II. Technical Characteristics

			Additional State requirements	Amendment after pre bid	Technical Preliminary Remarks	Technical Final Remarks
1.	**Working principle**	Reflectance Photometry/ Absorbance Photometry				
2.	**Parameter**	Blood Hemoglobin level				
3.	**Range of Hb estimation**	0-25 gm/dl				
4.	**Volume of blood sample required**	10- 50 µl				
5.	**Sample material**	Capillary or venous whole blood				
6.	**Measuring time**	Less than one minute				
7.	**Calibration**	Auto calibration				
8.	**Accuracy**	Sensitivity more than 90%, Specificity more than 90% and Bias less than 0.5 gm/dl (Limits of agreement) (±1 gm/dl)				
9.	**Publications for verification of accuracy**	Accuracy parameters listed in point 10 should be corroborated by two (2) peer reviewed indexed journals publications. The studies should be community based, done in two different Indian settings by two independent teams of investigators.			The firm submitted two publications. However, the studies were not Community based and no data in two different indian settings	
	User Interface					
10.	**Memory to store data**	500 tests				
11.	**On-screen result display**	LCD or LED display				
12.	**Wireless Connectivity**	Desirable - Bluetooth				
13.	**Data transfer**	Desirable – provision for data transfer to printer and PC	Automated data transfer to portal/app.			
			Data integration/ transfer with State Government mobile applications and dashboards, ABDM compliant			
	Physical Characteristics					
14.	**Dimensions (metric)**	Not more than 15 cm X 10 cm X 20 cm				
15.	**Weight (grams)**	Should not be more than 500 grams				
16.	**Portability**	Should be portable				
	Energy Source					
17.	**Power requirements**	Battery operated work as well on direct connection with electricity source (AC)				
18.	**Battery**	AA batteries/ Lithium rechargeable battery, either inbuilt (with charging cable) or detachable (with external charger)				
		Should be able to perform up to 500 tests on battery when fully charged				
19.	**Automatic shut down**	The device should turn off/sleep mode after 5 minutes of no use				
	Environmental Consideration					
20.	**Working temperature and humidity**	Should be functional and capable of being stored in the temperature range of 5 – 50 degree Celsius and relative humidity of 15% - 90%				

II. Technical Characteristics			Additional State requirements	Amendment after pre bid	Technical Preliminary Remarks	Technical Final Remarks
		Should also be able to work at extreme of temperatures and high humidity				
21.	**User care/ Cleaning**	Easy to disinfect and clean by user including the part of equipment which comes in contact with blood				
		Printed user manual with details of how to clean, disinfect and use the device to be provided along with the device				
		The cleaning material (cloth, solution or any other material required) for the lens and device should be provided with the device				
Specifications of Strips, Accessories, Spare Parts, Consumables						
22.	**Cuvette/ Strip -Working environment**	Stable at temperature 5 – 50 degreeCelsius, and high humidity				
23.	**Cuvette/ Strip-Storage environment**	Should be stable at room temperature of 10 – 40 degreeCelsius, and high humidity				
		Shelf life for storage should be at least two years				
24.	**Auto disabled lancet**	Single use 23 gauze			Licence for Lancet not submitted	
25.	**Carrying Bag**	A compact sling bag with provision for device and all consumable required should be provided to facilitate portability	For every 1500 strips one(01) suitable digital invasive Hemoglobinometer as per mentioned specifications should be supplied with free of cost.			
Quality Control, Standards and Safety						
26.	**Control solutions**	Should be provided along with device. Liquid controls of three range- low, normal and high hemoglobin values			→ Submitted Licence in MD-5 bearing No: MFG/IVD/2019/000046 for Control Solutions	
		Controls should be thermostable at room temperature				
27.	**Certification**	CDSCO ISO 13485 certification	* Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification	**No change, same as tender specification.** CDSCO ISO 13485 certification: * Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification.(GoI specification) *Valid CDSCO manufacturing license of control solution (State Specification) IEC 60601 for electricity safety: *IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference. (GoI specification) *IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.(State Specification) According to notice no. IVD/Misc/196/2020 dated 25 October 2023, haemoglobin analysers are classified into two categories: Class A and Class C. Analysers intended for near-patient testing fall under Class C. The Central Drugs Standard Control Organisation (CDSCO) defines near-patient testing as "Any device that is not intended for self-testing, but is intended to perform testing outside a laboratory environment, generally near, or at the side of the patient by a health professional." As per the notice dated 25th Oct 2023, a Class C CDSCO license is mandatory, as we are doing the testing outside the laboratory, which is not a controlled environment.Standard IEC 61010-2-1:2010 is applicable and critical for IVD devices. It includes user safety from electrical shock and mechanical hazards, as well as safe handling in non-lab environments. It is mandatory for operators using the device in the field. Standard IEC 61010-1:2010 includes basic tests, not IVD-specific. For IVD, standard IEC 61010-2-1:2010 is mandatory.	→ The firm not submitted Licence under clause i.e. MD-9, as per tender condition.	
			*Valid CDSCO manufacturing license of control solution		→ The firm submitted ISO 13485:2016 certificate valid upto 24.11.2027	
		IEC 60601 for electricity safety	IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference			
			IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.			
28.	**Batch testing report**	Batch testing quality assurance report from an accredited agency shall be provided for the device/ cuvette/strip		No change, same as tender specification. Clarification: Batch testing quality assurance will be provided by a laboratory that has an MD-24 license from CDSCO.	← The firm has not submitted Batch Testing Quality Assurance Report	
29.	**User/Customer satisfaction**	Quality assurance recommendation /Certificate by at least two other States based on supply and use of device by those states				

II. Technical Characteristics			Additional State requirements	Amendment after pre bid	Technical Preliminary Remarks	Technical Final Remarks
Service Support						
30.	**Service support**	Contact details of manufacturer, supplier and service agent to be provided				
		Toll free number for service to be printed on the device				
31.	**Training**	Free onsite training for the doctors, CHO, ANM, RBSK teams. At least two trainings (one training at the time of installation and another training after six months, i.e., refresher training)				
32.	**Warranty and on-site AMC**	For 3 years each				
Biomedical Waste Management and Infection control						
33.	**Safe disposal of sharps**	Detailed instructions for safe disposal of all biomedical waste generated (including sharp) during testing should be provided				
34.	**Infection control**	Detailed instruction for minimizing risk of infection transmission during testing by contamination of DIH should be provided				

Preliminary Remarks:

Signature: 11/5/2026

Name: J. Vinodh

Designation: Drugs Inspector, Tenali

1. The firm has submitted manufacturing license (clam-A) in form MD-5, bearing No. MFG/IVD/2019/000046 for Hemoglobin Analyser. However, on per tender condition, license under clam-C i.e form MD-9 is required. Hence, the firm may be considered after submission of license in form MD-9 on per tender condition.
2. The firm submitted manufacturing license in form MD-5 bearing No. MFG/IVD/2019/000046 for Hemoglobin measuring Test strips and

Final Remarks:

Signature:

Name:

Designation:

Hemoglobin Measuring System Control Solutions (Low | Medium | High)

3. The firm has not submitted Batch testing quality assurance report for the device | strip.

4. The firm has not submitted manufacturing license for Lancets.

5. The firm submitted two publications for verification of accuracy. However, the studies were not community based and not done in two different indian settings.

6. The firm submitted valid ISO 13485 and Non Conviction Certificate.

1/5/26

DI, Tenali

Sample Evaluation of T No 184 (HB Strips along with Haemoglobinometer)

M/s SENSA CORE MEDICAL INSTRUMENTATION PVT LTD

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
1.	**Working principle**	Reflectance Photometry/ Absorbance Photometry			Reflectance Photometry	Yes
2.	**Parameter**	Blood Hemoglobin level				Yes
3.	**Range of Hb estimation**	0-25 gm/dl			0 - 25.6	Yes
4.	**Volume of blood sample required**	10- 50 µl			10µl	Yes
5.	**Sample material**	Capillary or venous whole blood			Capillary & Venous	Yes
6.	**Measuring time**	Less than one minute			30sec	Yes
7.	**Calibration**	Auto calibration			Auto/self calibration	Yes
8.	**Accuracy**	Sensitivity more than 90%, Specificity more than 90% and Bias less than 0.5 gm/dl (Limits of agreement) (±1 gm/dl)			Both studies from laboratories, not submitted field studies Hence. cannot considered as Meeting Requirements	NO
9.	**Publications for verification of accuracy**	Accuracy parameters listed in point 10 should be corroborated by two (2) peer reviewed indexed journals publications. The studies should be community based, done in two different Indian settings by two independent teams of investigators.			Not submitted community Based Publications	NO.
User Interface						
10.	**Memory to store data**	500 tests			1000 Test records	Yes
11.	**On-screen result display**	LCD or LED display			LCD	Yes
12.	**Wireless Connectivity**	Desirable - Bluetooth			Bluetooth	Yes
13.	**Data transfer**	Desirable – provision for data transfer to printer and PC	Automated data transfer to portal/app.		Provision for Data transfer to printer. No Automated Data transfer to portal / mobile applet	NO
			Data integration/ transfer with State Government mobile applications and dashboards, ABDM compliant		Data Integration provision Not available No ABDM compliance	NO
Physical Characteristics						
14.	**Dimensions (metric)**	Not more than 15 cm X 10 cm X 20 cm			10 cm × 5.4 cm × 2.5cm	Yes

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
15.	**Weight (grams)**	Should not be more than 500 grams			90 gm	yes
16.	**Portability**	Should be portable			yes	yes
Energy Source						
17.	**Power requirements**	Battery operated work as well on direct connection with electricity source (AC)			Battery and electricity	yes.
18.	**Battery**	AA batteries/ Lithium rechargeable battery, either inbuilt (with charging cable) or detachable (with external charger)			Lithium Rechargeble and Detachable	yes
		Should be able to perform up to 500 tests on battery when fully charged			1000 Tests	yes
19.	**Automatic shut down**	The device should turn off/sleep mode after 5 minutes of no use			5 Min	yes
Environmental Consideration						
20.	**Working temperature and humidity**	Should be functional and capable of being stored in the temperature range of 5 – 50 degree Celsius and relative humidity of 15% - 90%			0 – 50 °C 5 – 95%	yes
		Should also be able to work at extreme of temperatures and high humidity				yes
21.	**User care/ Cleaning**	Easy to disinfect and clean by user including the part of equipment which comes in contact with blood				yes
		Printed user manual with details of how to clean, disinfect and use the device to be provided along with the device				yes
		The cleaning material (cloth, solution or any other material required) for the lens and device should be provided with the device				yes.
Specifications of Strips, Accessories, Spare Parts,						
22.	**Cuvette/ Strip - Working environment**	Stable at temperature 5 – 50 degreeCelsius, and high humidity				yes

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
23.	**Cuvette/ Strip-Storage environment**	Should be stable at room temperature of 10 – 40 degreeCelsius, and high humidity				Yes
		Shelf life for storage should be at least two years				Yes
24.	**Auto disabled lancet**	Single use 23 gauze			Single use 23	Yes
25.	**Carrying Bag**	A compact sling bag with provision for device and all consumable required should be provided to facilitate portability	For every 1500 strips one(01) suitable digital invasive Hemoglobinometer as per mentioned specifications should be supplied with free of cost.			Yes
Quality Control, Standards and Safety						
26.	**Control solutions**	Should be provided along with device. Liquid controls of three range- low, normal and high hemoglobin values				Yes
		Controls should be thermostable at room temperature				Yes
27.	**Certification**	CDSCO ISO 13485 certification	* Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification	**No change, same as tender specification.** CDSCO ISO 13485 certification: * Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification.(GoI specification) *Valid CDSCO manufacturing license of control solution (State Specification) IEC 60601 for electricity safety: *IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference. (GoI specification) *IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.(State Specification) According to notice no. IVD/Misc/196/2020 dated 25 October 2023, haemoglobin analysers are classified into two categories: Class A and Class C. Analysers intended for near-patient testing fall under Class C. The Central Drugs Standard Control Organisation (CDSCO) defines near-patient testing as "Any device that is not intended for self-testing, but is intended to perform testing outside a laboratory environment, generally near, or at the side of the	The Firm not-Submitted class-C MD-9 certificate	NO.
			*Valid CDSCO manufacturing license of control solution		Yes (control solution)	Yes
			IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference		IEC 61010-2-1: 2010 Not Submitted as per Tender IEC 61010-1: 2010 only submitted	NO

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
		IEC 60601 for electricity safety	IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.	patient by a health professional." As per the notice dated 25th Oct 2023, a Class C CDSCO license is mandatory, as we are doing the testing outside the laboratory, which is not a controlled environment.Standard IEC 61010-2-1:2010 is applicable and critical for IVD devices. It includes user safety from electrical shock and mechanical hazards, as well as safe handling in non-lab environments. It is mandatory for operators using the device in the field. Standard IEC 61010-1:2010 includes basic tests, not IVD-specific. For IVD, standard IEC 61010-2-1:2010 is mandatory.		
28.	**Batch testing report**	Batch testing quality assurance report from an accredited agency shall be provided for the device/ cuvette/strip		No change, same as tender specification. Clarification: Batch testing quality assurance will be provided by a laboratory that has an MD-24 license from CDSCO.	Not submitted	NO
29.	**User/Customer satisfaction**	Quality assurance recommendation /Certificate by at least two other States based on supply and use of device by those states			PO s only submitted But not submitted Satisfactory certificate from user	NO.
Service Support						
30.	**Service support**	Contact details of manufacturer, supplier and service agent to be provided				Yes
		Toll free number for service to be printed on the device				Yes
31.	**Training**	Free onsite training for the doctors, CHO, ANM, RBSK teams. At least two trainings (one training at the time of installation and another training after six months, i.e., refresher training)				Yes
32.	**Warranty and on-site AMC**	For 3 years each				Yes
Biomedical Waste Management and Infection control						
33.	**Safe disposal of sharps**	Detailed instructions for safe disposal of all biomedical waste generated (including sharp) during testing should be provided				Yes

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
34.	**Infection control**	Detailed instruction for minimizing risk of infection transmission during testing by contamination of DIH should be provided				Yes

Remarks:

Committee member: 1 Dr. LBS HDevi

Signature:

Name:

Designation: State Nodal officer AHB and SNO.

Committee member: 2

Signature: B.V.Satish

Name: B.V.Satish kumar,

Designation: JD, MHN

committee member 3
signature : Nirmala
Name : DR. NIRMALA GLORY
Designation : SNO RKSK

(2)

TECHNICAL COMMITEE EVALUATION REPORT FOR TENDER NO: -184 (Digital Invasive Hemoglobinometer, strips)/APMSIDC/MEDICINE WING/2025-26

Firm Name : ***Wrig Nanosystems Pvt Ltd***

Firm Remarks :

		Remarks	Documents Submitted by the Firm May Be/May Not Be Considered as per Tender Conditions.
I	Valid manufacturing license in case of Bidder as a Manufacturer / Wholesale Licenses license in case of Bidder as a Distributor. They should submit Drug License copies from statutory body of concerned Licensing authorities of Central/State Government	Submitted Valid Form MD-9 license	may be considered
II	Scanned copy of Valid ISO/BIS/CE/ISI Certificate of manufacturing company. In case of imported products, scanned copy Valid quality Certificate of manufacturing company of foreign company.	Submitted ISO 9001:2015 ISO 13485:2016	may be considered
III	Latest Non-conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted by manufacturer or distributor. Not less than 12 months from the date of commencement of tender.	Submitted Valid NCC	may be considered

Firm Name : ***Wrig Nanosystems Pvt Ltd***

S.No	*Item Code*	*Item Name*	*Strength*	Priliminary Remarks on Valid Manufacturing License /Valid import license /COPP	Priliminary Evaluation status (Considered-YES, Not-Considered-NO)	Final Remarks on Valid Manufacturing License /Valid import license /COPP	Final Item Status (Considered/ Not-Considered)
1	*T184*	*Digital Invasive Hemoglobinometer, strips and Consumables as per GOI*	*Specifications as per tender document*	Submitted Valid medical Device mfg license in Form MD-9	yes, may be considered		

Priliminary Remarks :

The applied item may be considered.

Signature : 17/04/2026

Name : E. Sambasiva Rao

Designation : DI, VGE, CNT

Final Remarks :

Signature :

Name :

Designation :

Technical Evaluation of T No 184 (HB Strips along with Haemoglobinometer)

M/s Wrig Nanosystems Pvt Ltd

I. Technical

		Remarks
(I)	Valid manufacturing license in case of Bidder as a Manufacturer / Wholesale Licenses license in case of Bidder as a Distributor. They should submit Drug License copies from statutory body of concerned Licensing authorities of Central/State Government	Yes. Submitted License in Form MD-9 for Hemoglobin monitoring system Further Valid License in Form MD-5 for Test Strips, Control solution
(II)	Scanned copy of Valid ISO/BIS/CE/ISI Certificate of manufacturing company. In case of imported products, scanned copy Valid quality Certificate of manufacturing company of foreign company.	Yes. provided Valid ISO 9001:2015 certificate Valid ISO 13485: 2016 certificate
(III)	Latest Non-conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted by manufacturer or distributor. Not less than 12 months from the date of commencement of tender.	Yes. provided Valid NCC, dt: 28/07/2025.

II. Technical Characteristics

			Additional State requirements	Amendment after pre bid	Technical Preliminary Remarks	Technical Final Remarks
1.	**Working principle**	Reflectance Photometry/ Absorbance Photometry				
2.	**Parameter**	Blood Hemoglobin level				
3.	**Range of Hb estimation**	0-25 gm/dl				
4.	**Volume of blood sample required**	10- 50 µl				
5.	**Sample material**	Capillary or venous whole blood				
6.	**Measuring time**	Less than one minute				
7.	**Calibration**	Auto calibration				
8.	**Accuracy**	Sensitivity more than 90%, Specificity more than 90% and Bias less than 0.5 gm/dl (Limits of agreement) (±1 gm/dl)				
9.	**Publications for verification of accuracy**	Accuracy parameters listed in point 10 should be corroborated by two (2) peer reviewed indexed journals publications. The studies should be community based, done in two different Indian settings by two independent teams of investigators.			Yes	
	User Interface					
10.	**Memory to store data**	500 tests				
11.	**On-screen result display**	LCD or LED display				
12.	**Wireless Connectivity**	Desirable - Bluetooth				
13.	**Data transfer**	Desirable – provision for data transfer to printer and PC	Automated data transfer to portal/app.			
			Data integration/ transfer with State Government mobile applications and dashboards, ABDM compliant			
	Physical Characteristics					
14.	**Dimensions (metric)**	Not more than 15 cm X 10 cm X 20 cm				
15.	**Weight (grams)**	Should not be more than 500 grams				
16.	**Portability**	Should be portable				
	Energy Source					
17.	**Power requirements**	Battery operated work as well on direct connection with electricity source (AC)				
18.	**Battery**	AA batteries/ Lithium rechargeable battery, either inbuilt (with charging cable) or detachable (with external charger)				
		Should be able to perform up to 500 tests on battery when fully charged				
19.	**Automatic shut down**	The device should turn off/sleep mode after 5 minutes of no use				
	Environmental Consideration					
20.	**Working temperature and humidity**	Should be functional and capable of being stored in the temperature range of 5 – 50 degree Celsius and relative humidity of 15% - 90%				

II. Technical Characteristics			Additional State requirements	Amendment after pre bid	Technical Preliminary Remarks	Technical Final Remarks
		Should also be able to work at extreme of temperatures and high humidity				
21.	**User care/ Cleaning**	Easy to disinfect and clean by user including the part of equipment which comes in contact with blood				
		Printed user manual with details of how to clean, disinfect and use the device to be provided along with the device				
		The cleaning material (cloth, solution or any other material required) for the lens and device should be provided with the device				
Specifications of Strips, Accessories, Spare Parts, Consumables						
22.	**Cuvette/ Strip -Working environment**	Stable at temperature 5 – 50 degreeCelsius, and high humidity				
23.	**Cuvette/ Strip-Storage environment**	Should be stable at room temperature of 10 – 40 degreeCelsius, and high humidity				
		Shelf life for storage should be at least two years				
24.	**Auto disabled lancet**	Single use 23 gauze				
25.	**Carrying Bag**	A compact sling bag with provision for device and all consumable required should be provided to facilitate portability	For every 1500 strips one(01) suitable digital invasive Hemoglobinometer as per mentioned specifications should be supplied with free of cost.			
Quality Control, Standards and Safety						
26.	**Control solutions**	Should be provided along with device. Liquid controls of three range- low, normal and high hemoglobin values				
		Controls should be thermostable at room temperature				
27.	**Certification**	CDSCO ISO 13485 certification	* Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification	**No change, same as tender specification.** CDSCO ISO 13485 certification: * Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification.(GoI specification) *Valid CDSCO manufacturing license of control solution (State Specification) IEC 60601 for electricity safety: *IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference. (GoI specification) *IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.(State Specification) According to notice no. IVD/Misc/196/2020 dated 25 October 2023, haemoglobin analysers are classified into two categories: Class A and Class C. Analysers intended for near-patient testing fall under Class C. The Central Drugs Standard Control Organisation (CDSCO) defines near-patient testing as "Any device that is not intended for self-testing, but is intended to perform testing outside a laboratory environment, generally near, or at the side of the patient by a health professional." As per the notice dated 25th Oct 2023, a Class C CDSCO license is mandatory, as we are doing the testing outside the laboratory, which is not a controlled environment.Standard IEC 61010-2-1:2010 is applicable and critical for IVD devices. It includes user safety from electrical shock and mechanical hazards, as well as safe handling in non-lab environments. It is mandatory for operators using the device in the field. Standard IEC 61010-1:2010 includes basic tests, not IVD-specific. For IVD, standard IEC 61010-2-1:2010 is mandatory.	Yes. The firm submitted class-c license in Form MD-9 and also submitted valid ISO13485:2016 Certificate	
			*Valid CDSCO manufacturing license of control solution		yes. submitted valid license in Form MD-5 for Control Solution	
		IEC 60601 for electricity safety	IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference			
			IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.			
28.	**Batch testing report**	Batch testing quality assurance report from an accredited agency shall be provided for the device/ cuvette/strip		No change, same as tender specification. Clarification: Batch testing quality assurance will be provided by a laboratory that has an MD-24 license from CDSCO.	The firm submitted 03 lots/batch testing reports from M/s Institute of Industrial Research & Toxicology, UP which is approved MDTL.	
29.	**User/Customer satisfaction**	Quality assurance recommendation /Certificate by at least two other States based on supply and use of device by those states				

II. Technical Characteristics			Additional State requirements	Amendment after pre bid	Technical Preliminary Remarks	Technical Final Remarks
Service Support						
30.	**Service support**	Contact details of manufacturer, supplier and service agent to be provided				
		Toll free number for service to be printed on the device				
31.	**Training**	Free onsite training for the doctors, CHO, ANM, RBSK teams. At least two trainings (one training at the time of installation and another training after six months, i.e., refresher training)				
32.	**Warranty and on-site AMC**	For 3 years each				
Biomedical Waste Management and Infection control						
33.	**Safe disposal of sharps**	Detailed instructions for safe disposal of all biomedical waste generated (including sharp) during testing should be provided				
34.	**Infection control**	Detailed instruction for minimizing risk of infection transmission during testing by contamination of DIH should be provided				

Preliminary Remarks:

→ The firm submitted valid medical devide mfs. licens in Form MD-9 for the Hemoglobin monitoring system and valid MD-5 licens for strips, control solution

→ Feather the firm provided valid ISO 13485:2016 certificate, Valid NOC.

→ However, the firm could not produce the valid medical Devide mfs license for Auto disabled lancet 23 gauge.

Hence, the applied item may be considered after submission of Valid medical device mfs license for Autodisabled lancet 23 gauge and also after meeting the others related specifications of the Device (x will the same be verified by the concerned department officials).

Signature:

Name:

Designation:

01/05/2026
DI, VGH, Guntur

Final Remarks:

Signature:

Name:

Designation:

Sample Evaluation of T No 184 (HB Strips along with Haemoglobinometer)

M/s Wrig Nanosystems Pvt Ltd

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
1.	**Working principle**	Reflectance Photometry/ Absorbance Photometry			Reflectance photometry	Yes
2.	**Parameter**	Blood Hemoglobin level				Yes
3.	**Range of Hb estimation**	0-25 gm/dl			0 – 25.5 gm/dL	Yes
4.	**Volume of blood sample required**	10- 50 µl			10 – 12 µL	Yes
5.	**Sample material**	Capillary or venous whole blood			capillary & venous	Yes
6.	**Measuring time**	Less than one minute			with in 60 sec	Yes
7.	**Calibration**	Auto calibration				Yes
8.	**Accuracy**	Sensitivity more than 90%, Specificity more than 90% and Bias less than 0.5 gm/dl (Limits of agreement) (±1 gm/dl)			Sensitivity 92.8 % Specificity 92 % Bias 0.28 gm/dL	Yes
9.	**Publications for verification of accuracy**	Accuracy parameters listed in point 10 should be corroborated by two (2) peer reviewed indexed journals publications. The studies should be community based, done in two different Indian settings by two independent teams of investigators.			peer reviewed, community Based, Two different settings, Indipendt teams – Submitted	Yes.
User Interface						
10.	**Memory to store data**	500 tests			1000 tests	Yes
11.	**On-screen result display**	LCD or LED display			LCD	Yes
12.	**Wireless Connectivity**	Desirable - Bluetooth			Blue tooth	Yes
13.	**Data transfer**	Desirable – provision for data transfer to printer and PC	Automated data transfer to portal/app.		Automated transfer of data	Yes
			Data integration/ transfer with State Government mobile applications and dashboards, ABDM compliant		Data integration with State Government mobile applications & Dashboards, ABDM Compliant	Data integrate from NHA MIS team under development Yes ABDM Compliant
Physical Characteristics						
14.	**Dimensions (metric)**	Not more than 15 cm X 10 cm X 20 cm			13.3 cm X 1.68 cm X 1.5 l	Yes

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15.	**Weight (grams)**	Should not be more than 500 grams			709m	yes
16.	**Portability**	Should be portable			yes	yes
	Energy Source					
17.	**Power requirements**	Battery operated work as well on direct connection with electricity source (AC)			Lithium rechargeable battery - inbuilt & electricity	yes
18.	**Battery**	AA batteries/ Lithium rechargeable battery, either inbuilt (with charging cable) or detachable (with external charger)			Lithium rechargeable Battery	yes
		Should be able to perform up to 500 tests on battery when fully charged			500 cycles	yes
19.	**Automatic shut down**	The device should turn off/sleep mode after 5 minutes of no use				yes
	Environmental Consideration					
20.	**Working temperature and humidity**	Should be functional and capable of being stored in the temperature range of 5 – 50 degree Celsius and relative humidity of 15% - 90%			5-55°c 5%-95% humidity	yes
		Should also be able to work at extreme of temperatures and high humidity				yes
21.	**User care/ Cleaning**	Easy to disinfect and clean by user including the part of equipment which comes in contact with blood				yes
		Printed user manual with details of how to clean, disinfect and use the device to be provided along with the device				yes
		The cleaning material (cloth, solution or any other material required) for the lens and device should be provided with the device				yes
	Specifications of Strips, Accessories, Spare Parts,					
22.	**Cuvette/ Strip - Working environment**	Stable at temperature 5 – 50 degreeCelsius, and high humidity			5-52	yes

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
23.	**Cuvette/ Strip-Storage environment**	Should be stable at room temperature of 10 – 40 degreeCelsius, and high humidity			yes	yes.
		Shelf life for storage should be at least two years			yes	yes.
24.	**Auto disabled lancet**	Single use 23 gauze			Single use 23G	yes
25.	**Carrying Bag**	A compact sling bag with provision for device and all consumable required should be provided to facilitate portability	For every 1500 strips one(01) suitable digital invasive Hemoglobinometer as per mentioned specifications should be supplied with free of cost.			yes
Quality Control, Standards and Safety						
26.	**Control solutions**	Should be provided along with device. Liquid controls of three range- low, normal and high hemoglobin values				yes
		Controls should be thermostable at room temperature			.	yes
27.	**Certification**	CDSCO ISO 13485 certification	* Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification	**No change, same as tender specification.** CDSCO ISO 13485 certification: * Valid CDSCO license duly amended till date for point-of-care and near Patient testing, in-vitro diagnostic testing along with ISO 13485 certification.(GoI specification) *Valid CDSCO manufacturing license of control solution (State Specification) IEC 60601 for electricity safety: *IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference. (GoI specification) *IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.(State Specification) According to notice no. IVD/Misc/196/2020 dated 25 October 2023, haemoglobin analysers are classified into two categories: Class A and Class C. Analysers intended for near-patient testing fall under Class C. The Central Drugs Standard Control Organisation (CDSCO) defines near-patient testing as "Any device that is not intended for self-testing, but is intended to perform testing outside a laboratory environment, generally near, or at the side of the	Submitted class C license in form MD9. and also valid ISO 13485:2016 certificate	yes.
			*Valid CDSCO manufacturing license of control solution			yes
			IEC 60601 specifies the electromagnetic compatibility (EMC) to prevent electromagnetic interference			yes

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		IEC 60601 for electricity safety	IEC 61010-2-1:2010 to protect users, Patients and operators from hazards including electric shock, fire hazards and temperature hazards.	patient by a health professional." As per the notice dated 25th Oct 2023, a Class C CDSCO license is mandatory, as we are doing the testing outside the laboratory, which is not a controlled environment.Standard IEC 61010-2-1:2010 is applicable and critical for IVD devices. It includes user safety from electrical shock and mechanical hazards, as well as safe handling in non-lab environments. It is mandatory for operators using the device in the field. Standard IEC 61010-1:2010 includes basic tests, not IVD-specific. For IVD, standard IEC 61010-2-1:2010 is mandatory.		
28.	**Batch testing report**	Batch testing quality assurance report from an accredited agency shall be provided for the device/ cuvette/strip		No change, same as tender specification. Clarification: Batch testing quality assurance will be provided by a laboratory that has an MD-24 license from CDSCO.	Not submitted	NO.
29.	**User/Customer satisfaction**	Quality assurance recommendation /Certificate by at least two other States based on supply and use of device by those states			P.O. submitted But user satisfaction certificate Not submitted	NO
Service Support						
30.	**Service support**	Contact details of manufacturer, supplier and service agent to be provided			Yes	Yes.
		Toll free number for service to be printed on the device				Yes
31.	**Training**	Free onsite training for the doctors, CHO, ANM, RBSK teams. At least two trainings (one training at the time of installation and another training after six months, i.e., refresher training)				Yes
32.	**Warranty and on-site AMC**	For 3 years each				Yes
Biomedical Waste Management and Infection control						
33.	**Safe disposal of sharps**	Detailed instructions for safe disposal of all biomedical waste generated (including sharp) during testing should be provided				Yes

I. Technical Characteristics			Additional State requirements	Amendment after pre bid	Sample Remarks	Sample status
34.	**Infection control**	Detailed instruction for minimizing risk of infection transmission during testing by contamination of DIH should be provided				yes

Remarks:

Committee member:

Signature:

Name: Dr. LBSH Devi

Designation: State Nodal officer AMB & SLO

Committee member:

Signature: B.V.Satish Kumar

Name: B.V.Satish Kumar

Designation: JD (M&N)

Committee member 3

Signature Nirmala

Name DR. NIRMALA GLORY

Designation : SNO RBSK