
Annex A

***Technical Specifications for High Performance Liquid Chromatography
(HPLC) System***

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Technical Specifications for High Performance Liquid Chromatography (HPLC) System**1. Functional Requirements**

- 1.1 The HPLC system is intended for the measurement of beta-lactam antibiotics in serum or plasma to aid the management of patients to achieve patient-centric doses of beta-lactams.
- 1.2 The HPLC system shall be compatible with commercially-available kits for the purpose of measurement of beta-lactam antibiotics in serum or plasma. The beta-lactam antibiotics of interest are:
 - (a) Ampicillin
 - (b) Cefepime
 - (c) Ceftazidime
 - (d) Meropenem
 - (e) Piperacillin-Tazobactam
 - (f) Linezolid

2. General Requirements

- 2.1 The unit shall be a compact, table-top design, ergonomic, integrated Liquid Chromatography (LC) system, and shall be easy to use with the system functions controlled through a touch-screen.
- 2.2 The system shall have an integrated solvent and sample management platform with spill protection.
- 2.3 The system shall have a quaternary solvent delivery system.
- 2.4 The system shall have thermo-controlled sample and column compartments.
- 2.5 The system shall come with an integrated degasser for all channels.
- 2.6 Samples shall be introduced into the system using an auto sampler.
- 2.7 Column compartment shall be able to detect leakage from the column.
- 2.8 The system shall have a UV detector with variable settings for wavelength.
- 2.9 The system shall have software for instrument control and data management.
- 2.10 The system software shall be able to save different chromatography methods.
- 2.11 The system shall be equipped with self-diagnostic program(s) which can identify and diagnose operational problems and instrument failures.
- 2.12 The system shall be designed for easy access to serviceable parts.
- 2.13 The system shall be easy to clean and maintain. Instrument startup and shutdown shall be programmable.
- 2.14 The system shall be designed to permit future extension or upgrades of both hardware and software to wield more advanced capabilities.



- 2.15 The Contractor shall include the basic user operating manual in their proposal.
- 2.16 The Contractor shall take into consideration the method of waste disposal from the system and suggest the easiest and safest options available.
- 2.17 The Contractor shall provide:
- (a) On-site support during the evaluation and service set-up period.
 - (b) Comprehensive training for any number of operators as required.

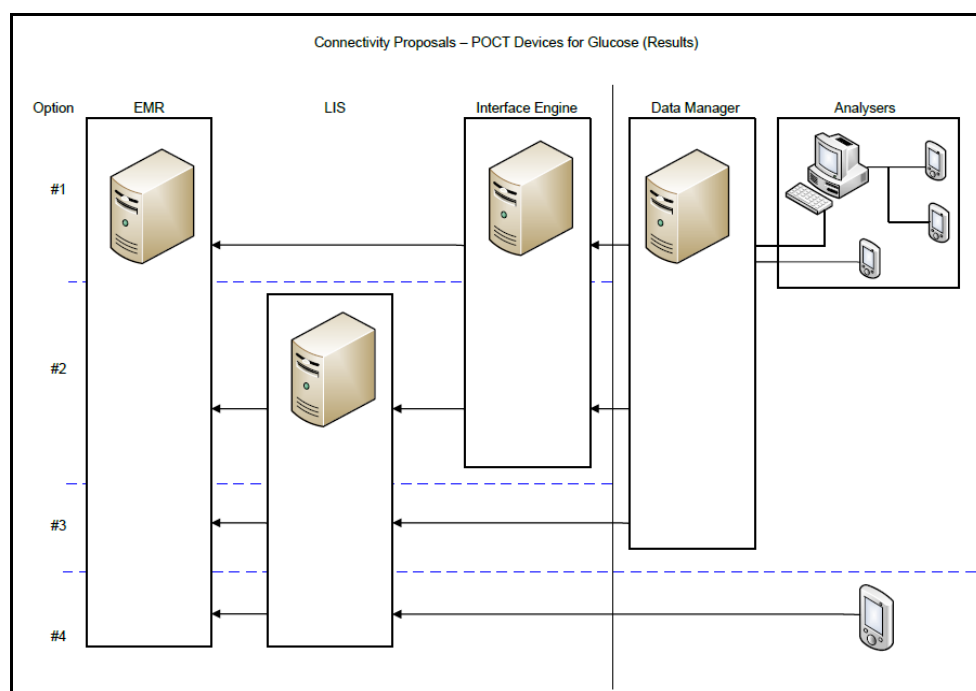
System Integration Requirements

- 2.18 The system software shall be able to communicate with the Laboratory Information System (LIS) in order to:
- (a) Download worklists containing patient details and order information from the LIS.
 - (b) Display the worklists in a format suitable for fuss-free, batch run method assignment.
 - (c) Transmit results from the system to the LIS interface to eliminate the need for manual transcription.
- 2.19 The system shall be interfaced with the Laboratory Information System (LIS) for bi-directional downloading of test orders from the LIS to the system and uploading of results from the system to the LIS. All costs incurred by the Vendor for the connectivity will be borne by the Vendor itself. Please specify the system's communication protocol with LIS.
- 2.20 The proposed system shall have HL7 connectivity capability and should be compliance to the standard HL7 version 2.3.
Note: If the device does not have HL7 Connectivity, please include any other components/connectivity accessories which are required to enable this feature.
- 2.21 The proposed system shall be able to support Secure Shell (SSH) network protocol for secure network services such as Secured File Transfer (SFTP) between computer systems.
- 2.22 Processing of in-coming messages shall provide exception handling such as checking of invalid messages, example handling of duplicate MRN, duplicate result, and invalid result. Rejected messages shall be placed in rejection message queue so that Administrator can take appropriate action to rectify the problem message.
- 2.23 The proposed system shall be able to re-trigger outbound messages.
- 2.24 The proposed system shall be able to re-process inbound failed messages after rejection reason is rectified.
- 2.25 The proposed system shall provide exception reports for users' follow-up actions.
- 2.26 The proposed system shall trigger alert (SMS or Email) when interface is down or where there is a huge number of transactions in the queue waiting to be processed.
- 2.27 The proposed system shall have search function for incoming and outgoing HL7 messages.
- 2.28 The proposed system shall have the ability to view, print or export HL7 Messages.
- 2.29 The proposed system interface must be able to maintain persistent connection with the current Cloverleaf Integration Engine using the existing TCP/IP MLLP socket provided virtual IP addresses. In the event of the Cloverleaf Integration Engine failover from the active node to the passive node, the interface must be able to connect seamlessly without additional configuration needed.

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- 2.30 The proposed solution shall have special dashboard for interface monitoring by operator.
- 2.31 The proposed system shall reconcile results sent with receiving application.
- 2.32 The proposed system shall support inbound messages from HIS for Patient Demographic and registration.
- 2.33 The proposed system shall support outbound messages to HIS for Billing and LIS or EMR for results.
- 2.34 The proposed system shall support wireless connectivity between the Device and the Data management system.
- 2.35 The proposed system shall allow manual patient creation and hospital registration.
- 2.36 The Participating Vendor shall engage the Company's Lab Information System vendor to provide integration solution with the medical device.
- 2.37 The proposed system shall have the following integration options for Outbound Results:



- 2.37.1 Option #1
Results to Electronic Medical Record (EMR) System via Unit Data Manager and Interface Engine.
- 2.37.2 Option #2
Results to Electronic Medical Record (EMR) System via Unit Data Manager, Interface Engine and Lab Information System (LIS).
- 2.37.3 Option #3
Results to Electronic Medical Record (EMR) System via Unit Data Manager and Lab Information System (LIS).

TWaters HPLC Absorbance PQ Teststy

- 2.37.4 Option #4
Results to Electronic Medical Record (EMR) System via Lab Information System (LIS).

Quotes and Offers by Vendor

- 2.38 The Contractor shall quote for outright purchase of:
- 2.38.1 One (1) unit of HPLC system and all related accessories and materials required in order for the system to function as intended.
- 2.38.2 5 years post-warranty preventive maintenance of the system. Refer to the Warranty and Post-Warranty Service Contract section for the requirements.
- 2.39 The Contractor shall provide, at no cost to TTSH, all the necessary materials required for testing during commissioning of the system.
- 2.40 Requirement for service support:
- (a) The Contractor shall have locally-based technical and application support personnel.
 - (b) Service response time within two (2) hours of receiving breakdown notice.
 - (c) Carry out necessary repair within forty eight (48) hours of receiving breakdown notice.
 - (d) Availability of replacement unit within forty eight (48) hours where equipment is not able to be repaired.
 - (e) System downtime of no more than forty eight (48) hours if no replacement parts needed.

3. Electrical Requirements

- 3.1 The system shall operate directly from a 230V $\pm$ 10%, 50 Hertz, single-phase AC supply.
- 3.2 All accessories shall be fully integrated, with a single power plug.
- 3.3 The system shall be protected from transient power disruptions and power surge during use. The disruption shall not affect the performance of the unit.
- 3.4 The system shall be equipped with self-tripping circuit breaker for protection against overload.
- 3.5 The system shall be equipped with a built-in voltage stabiliser and uninterrupted power supply (UPS) for stable, continuous operation. The UPS shall be sufficient to complete on board test.
- 3.6 The system shall have safety catch to secure the line power cord to the unit casing.

4. Safety Requirements

- 4.1 The construction of the unit shall ensure a sufficient degree of protection against safety hazards caused by overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilisation and disinfection.
- 4.2 The enclosure shall be secure and provide adequate protection against moving and electrically energised parts.

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- 4.3 The controls (i.e. switches, knobs, etc.) should be visible and clearly identified, and their function should be self-evident. Device design should prevent misinterpretation of displays and controls settings.
- 4.4 Switches and controls shall be protected against penetration of fluids and accidental setting changes.
- 4.5 The unit shall resist tipping over during use and transport.

5. Technical Requirements

- 5.1 The Contractor shall furnish full technical specifications for the complete system during the submission of documents.

6. Standards

- 6.1 The system shall fully conform to the following:
 - a. IEC/EN 61010-1, General safety requirements for laboratory electrical equipment;
 - b. IEC/EN 61326-1, Standard for Electromagnetic Compatibility – Requirements and tests;
 - c. IEC/EN 61000-4-x series safety requirements and tests for Electromagnetic Compatibility, Immunity;
 - d. IEC/EN 60529 (1989), Degrees of protection provided by enclosures (IP code);
- 6.2 Contractors shall comply with Health Sciences Authority (HSA) Medical Device Regulation requirements and Good Distribution Practice (GDP/MDS) for all classes of medical devices. A copy of the valid HSA registration certificate must be submitted together with the tender submission.
- 6.3 The system shall fully comply with the latest Republic of Singapore Radiation Protection Act and regulations for ultrasound and laser instrument. The nature and extent of such protection shall be to the satisfaction of the HSA/National Environment Agency (NEA) and all costs (if any) incurred to comply with the Regulations shall be borne by the Tenderer. The Contractor shall state whether N2/N3 licences are required.

7. Standard Accessories

- 7.1 All standard accessories, required for normal operation, decontamination and maintenance, shall be listed with itemised prices and included in the unit base prices.
- 7.2 The standard accessories shall include all the necessary items for the proper operation of the unit.
- 7.3 All perishable standard accessories shall be supplied with a minimum shelf life of one (1) year, from the date of delivery to the Company.

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8. Optional Accessories

- 8.1 The optional accessories and consumables available with the unit shall be quoted separately with itemized price.

All Contractors are to comply with all requirements stated in the Company Standard Conditions of Contract - ***SCC.3**.

Failure to comply with any of the above requirements may result in the rejection of the offer.

*** SCC.3 is available from Material Management Department.**

All Tenderers are to acquaint themselves with the detailed requirements set out in SCC.3.

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A. PERFORMANCE SUMMARY FOR HPLC SYSTEM

Contractor : WATERS PACIFIC PTE LTD

Name of System / Unit : Alliance e2695 XC HPLC

Manufacturer / Model : 2018

Year of manufacture : 2019

Year of model 1st sold : 2004

Country of origin : United States of America

Warranty period (Min. 2 years) : 3 YEARS

(The Contractor shall provide a twenty-four (24)-month warranty period, commencing from date of successful completion of commissioning. The Contractor shall replace all original parts including rechargeable battery, provide free labour with unlimited breakdown repair calls and shall also provide regular preventive maintenance as specified in the manufacturer's latest technical manuals or operating manuals during the warranty period at no cost to the Company.)

Contractors shall qualify against each functional performance for its compliance and requirements and provide all specified information and documentation as needed. Where space is insufficient, Contractor may submit the relevant information on separate sheets of paper with references.

Nothing is to be left blank. Where compulsory documents are required, kindly furnish as required to avoid disqualification.

A Performance Summary must accompany each option offered.

No cross-referencing should be used in this performance summary unless specified by the Company.

(*Please delete where applicable)

1. **FULL COMPLIANCE** with technical specifications * ☒ Yes / No

2. **NON-COMPLIANCE** with technical specifications pls state Nil
number only

3. **APPLICATIONS – Indicate* if the system is able to measure the following in serum/plasma:**
 - a. Ampicillin * ☒ Yes / No
Testype text here
 - b. Ceftazidime * ☒ Yes / No
 - c. Cefepime * ☒ Yes / No

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- d. Meropenem * ☒ Yes / No
- e. Piperacillin/Tazobactam * ☒ Yes / No
- f. Linezolid * ☒ Yes / No

4. SOFTWARE

- a. Does the system's software come with instrument control and data management capabilities? * ☒ Yes / No
- b. Is the system's software able to save different chromatography methods? * ☒ Yes / No

5. OVERALL SIZE

- a. Height (H), cm pls specify 57.1
- b. Width (W), cm pls specify 58.4
- c. Depth (D), cm pls specify 64.8

6. **OVERALL WEIGHT, kg** pls specify 59.1

7. **TABLE-TOP MODEL** * ☒ Yes / No

8. OPTIMAL OPERATING TEMPERATURE AND RELATIVE HUMIDITY

- a. Temperature pls specify 4-40 Deg C
- b. Relative humidity pls specify 20-80%

9. SOLVENT AND SAMPLE MANAGEMENT

- a. Does the system have an integrated solvent and sample management platform with spill protection? * ☒ Yes / No

10. SOLVENT DELIVERY SYSTEM

- a. Does the system have a quaternary solvent delivery system? * ☒ Yes / No



11. SAMPLE AND COLUMN COMPARTMENTS

- a. Can the sample compartment temperature be maintained at <10 °C? * ☒ Yes / No
- b. Can the column temperature be maintained at 22 °C? * ☒ Yes / No

12. PRESSURE

- a. Specify the maximum operational pressure of the system. pls specify 5000 psi

13. DEGASSER

- a. Does the system come with an integrated degasser for all channels? * ☒ Yes / No

14. AUTO-SAMPLER

- a. Does the system use auto-sampler to introduce samples into the system? * ☒ Yes / No

15. UV DETECTOR

- a. Does the system come with UV detector that have variable settings for wavelength? * ☒ Yes / No

16. SAFETY LID-LOCKS* ☒ Yes / No**17. TEST AND CONTROL PROGRAM ALARMS*** ☒ Yes / No**18. COLOR LCD TOUCH SCREEN*** ☒ Yes / No**19. BACK-LIT PANEL*** ☒ Yes / No**20. UPGRADABLE SOFTWARE*** ☒ Yes / No**21. ACCESSORIES AND CONSUMABLES**

pls specify

C18 Column

System starter kit



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22. BARCODE READER SYMBOLOGY

- a. List the supported symbologies pls specify Zebra Barcode Printer

23. INTERFACE TO LIS

- a. Bi-directional downloading of test orders from the LIS to the system and uploading of results from the system to the LIS. ☒ Yes / No
- b. Specify the system's communication protocol with LIS. pls specify _____

24. POWER CORD

- a. Safety catch for securing the line power cord (casing interface) to the unit casing * ☒ Yes / No
- b. Type of power plug used, e.g. single phase 13A, 20A, etc. pls specify 13A

25. FUSEHOLDER (if applicable)

- a. Accessible from outer chassis * ☒ Yes / No
- b. Others pls specify _____

26. FLUID-SPILL PROOF

- a. Degree of protection - IP code pls specify _____

27. BATTERY-OPERATED (if applicable)

- a. Battery type pls specify _____
- b. Battery rating pls specify _____
- c. Full charging time pls specify _____

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d.	Battery operating time, hr	pls specify	_____
e.	Built-in charger		* Yes ☒ No
28. ELECTRICAL SAFETY			
a.	Safety Class		* I / II / III
b.	Type of protection		* B / BF / CF
29. STANDARDS OF COMPLIANCE (Certificates of conformity to be provided)			
a.	Can your proposed system comply to international standards such as International Electrotechnical Commission (IEC), British Standards (BS), European Standards (EN), etc?		* ☒ Yes / No
b.	Please specify the type of compliance and its class.	pls specify	_____
c.	Certificate of compliance to each Standard is required (previous compliance for the same model may be accepted as a reference):		
i.	IEC/EN 61010-1, general requirements for electrical measurements, control and laboratory use or equivalent		☒ Yes/No
ii.	IEC/EN 61326-1, Electromagnetic Compatibility		* ☒ Yes No
iii.	IEC/EN 61000-4-x series safety requirements and tests for Electromagnetic Compatibility, Immunity		* ☒ Yes/No
iv.	IEC 60529		* ☒ Yes No
	- IP code	pls specify	_____
v.	Particular requirements for safety and performance of the tendered Article;		☒ Yes/No
	- If yes, pls specify reference standard		_____
vi.	HSA registered		* ☒ Yes No
vii.	CE-marked		* ☒ Yes No
viii.	Others	pls specify	_____

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*** If certificates for the compliance are not provided during the submission, it shall be considered as non-compliance to the standard.**

30. POWER CONSUMPTION

- a. Rating, AC Supply Voltage/Phase pls specify 230 V
- b. Standby Operation, KVA/KW/Amp pls specify Refer to site prep guide
- c. Normal Operation, KVA/KW/Amp pls specify Refer to site prep guide
- d. Heat Dissipation

Equipment	Model	Maximum Heat – Standby Operation	Maximum Heat – Normal Operation

31. WARRANTY & POST-WARRANTY SERVICE CONTRACT (p/s submit with each offer)

Description	Warranty Period	1st year after warranty	2nd year after warranty	3rd year after warranty	4th year after warranty	5th year after warranty

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Frequency of Preventive Maintenance (no of times per year) recommended by manufacturer	Frequency of PM recommended by manufacturer per annum: 1	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Annual Charges for Preventive Maintenance (PM) only (The cost which covers all labour and transportation for providing PM only periodically within a year and corrective maintenance is not included)	Not Applicable	\$ 2550.00	\$ 2550.00	\$ 2550.00	\$ 3060.00	\$ 3060.00
Annual Charges for Preventive Maintenance (PM) and Unlimited Breakdown Repair calls (The cost which covers all labour, transportation, on-site response for providing both PM and corrective maintenance except parts replacement)	Not Applicable	\$ 4700.00	\$ 4700.00	\$ 4700.00	\$ 5640.00	\$ 5640.00

32. SERVICE SUPPORT

- a. **Support Hours** - Does your service & support, irrespective of contracted service or warranty repair, cover after office hours, i.e. after 5.00 pm and weekends?

* Yes ☒ No

S/No	Description	Remark
i)	After office hours	* ☒ Yes / No
ii)	During weekend & public holiday	* ☒ Yes / No
iii)	Labour charge for non-contract service during office hour	\$ 340 480 /hr
iv)	Labour charge for non-contract service after	



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	office hour	\$ <u>720</u> /hr
v)	Labour charge for non-contract service during weekend	\$ <u>720</u> /hr

*** Please attach operating hours for service support for our information. And provide Sales and Service organisation chart for emergency contact.**

- b. **Essential spare parts** support you are stocking to meet TTSH repair/service needs.

Description	Remark
• % of stocked essential spare parts vs total essential spare parts	<u>100</u> %
• Cost of stocked items	\$ <u>NA</u>
• % of stocked essential spare parts vs total system parts	<u>100</u> %
• Years spare parts will continue to be available after the discontinuation of the model purchased by TTSH	<u>10</u> years
• Is replacement unit available?	* ☒ Yes / No
• Can replacement unit be made available within 24 hours?	* ☒ Yes / No

*** Full list of essential spare parts is required. Kindly indicate those that you would be stocking. Non-stocked parts must still be reflected in the full list.**

- c. **TOP 5 Parts** – 5 most expensive spare parts for this unit.

Part No.	Description	Cost (SGD)

- d. **Parts Delivery** for non-stocked items (If parts are to be delivered from overseas, kindly state the turnaround time for delivery to TTSH).

S/No	Description	Remark
i)	Standard delivery	<u>5</u> days
ii)	Courier delivery	<u>3</u> days

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iii)	Air Parcel	<u>3</u> days
iv)	Others	<u>NA</u> days

e. **Service Support**

Description	Remark
• Full on-site support from engineers and application specialists during unit evaluation and service setup period	* ☒ Yes / No
• Frequency of PM (times/year) during warranty period	1
• 24-hour service available	* ☒ Yes / No
• Service response time (hours)	Return call on the same day Onsite support within 48Hrs
• Maximum downtime due to instrument breakdown (hours)	48
• Maximum downtime due to routine maintenance (mins)	300
• Are your Service Engineer(s) trained on the proposed system?	* ☒ Yes / No
- Name of trained personnel	Wong Liang Seng
- Last training date	NA. When there is product replacement.
- Next re-certification date	NA
- Designation	Expert Centre Manager
- Educational qualification	Diploma
- Mobile contact number for backup services	96387993
- Years of service with the employer	8 Yrs
- Factory trained	* ☒ Yes / No

(If personnel are not factory trained, please give details of supervisor or colleague who conducted training and are responsible for work supervision.)

- f. Is a loaner unit available without charges for equipment under repair and awaiting spare parts during and after warranty period? * ☒ Yes / No

If there are charges, please specify:

NA

- g. **Spare Parts list** (Stocked and Non-stocked items) valid for two (2) years after warranty

S/N	Description	Unit Price (SGD)	Stock Item Y/N
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33. TRAINING

a. Does your **in-service training** cover:

Description	Remark
• Equipment operation	* ☒ Yes / No
• General maintenance	* ☒ Yes / No
• Equipment safety verification (for use on patients)	* ☒ Yes / No
• Others, pls specify	

b. Does your **technical training** cover:

Description	Remark
• Installation instructions	* ☒ Yes / No
• System overview with block diagram	TWaters HPLC Absorbance PQ Testype ☒ Yes
• Detailed theory of operation	* ☒ Yes / No

• Detailed preventive maintenance procedures	* ☒ Yes / No
• Detailed calibration and performance checks	* ☒ Yes / No
• Detailed troubleshooting procedures	* ☒ Yes / No
• Overhaul procedures	* ☒ Yes / No
• Others, pls specify	NA

c. **Training Program**

S/N	Content	Duration

- d. Estimated date for technical training to commence after the delivery of the unit / system pls specify 21 days from award date

e. **Trainer's Credentials**

Waters HPLC Absorbance PQ Test	Test type text here	Remark
- Name of Trainer		Chantel Lee
Designation	Waters HPLC Absorbance PQ Test	Application Specialist

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- Educational qualification	Master
- Mobile contact number for backup services	96388038
- Years of service with the employer	4 yrs
- Trained by Manufacturer to service product (pls submit certificates)	* ☒ Yes / No
- Certified by Manufacturer to provide technical training (pls submit certificates)	* ☒ Yes / No
- Date of last technical training received for this product	

34. **AVAILABILITY OF EVALUATION UNIT** ☒ Yes / No

35. **OTHER FEATURES** pls specify _____

36. **REFERENCES FOR THE TENDERED MODEL (LOCAL)**

S/N	Year Purchased	Institution	Contact Person/Number

I hereby certify that all information are true and correct and shall fully comply with all requirements stated in these specifications, unless stated otherwise under the Statement of Non-compliance.

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Signature & Stamp/Seal of the Contractor

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Joanna Ang/Account Manager/96536605

19 December 2019

Name/Designation/Contact number

Date

** Please note that full information shall be provided before the closing date. Insufficient information will not be accepted.

All information must be provided to avoid rejection of offer.

Every page of the Technical & Performance summary must be duly signed, stamped with the company stamp, and returned with the submission.

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Please specify in the format below all areas of non-compliance. Failure to use this format may render the Tender submission liable to rejection. **KINDLY REPRODUCE ADDITIONAL COPIES AS NECESSARY.**

[illegible]

ANNEX A-2 CONTRACTOR CHECKLIST for SUBMISSION OF DOCUMENTS**1. CONFORMITY CERTIFICATES (Important:** Please insert the required certificates after this page – MANDATORY)

- a. IEC/EN 61010-1 * Yes / No
- b. IEC/EN 61326-1 * Yes / No
- c. IEC/EN 61000-4-x * Yes / No
- d. IEC/EN 60529 * Yes / No
- e. Particular requirements for the tendered articles * Yes / No
- f. Other related _____

2. FDA/HSA CLEARANCE

- a. Pre-market notification (510K) * Yes / No
- b. Pre-market approval (PMA) * Yes / No
- c. HSA Registration Number _____

3. MANUFACTURER'S LETTER

- a. Distributor appointment letter ☒ Yes / No
- b. Frequency of preventive maintenance per year recommended by manufacturer ☒ Yes / No

4. PREVENTIVE MAINTENANCE (PM)

- a. Checklist ☒ Yes / No
- b. Procedure for carrying out PM * ☒ Yes / No

5. SPARE PART PRICE LIST

- a. Full list with price valid for 2 years * ☒ Yes / No
- b. Stocked spare parts * Yes ☒ No

6. TRAINING PROGRAMME

- a. Detailed Technical training indicating the number of days and the time required for each segment of the training. * ☒ Yes / No

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b. Operator * ☒ Yes / No

7. REFERENCE LIST

a. Telephone no/contact person * Yes / No

b. Year in which they were supplied _____

8. PERFORMANCE SUMMARY

a. Fully completed * Yes / No
(Performance summary is *INCOMPLETE*
without the **SUBMISSION** of documents!)

9. ORGANISATION CHART * ☒ Yes / No

**10. CERTIFICATES OF TECHNICAL
SERVICE ENGINEERS** * ☒ Yes / No

11. OTHERS

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