

Our Ref.: EOI-KCC/T/H1/036/26/BTS
Tel No.: 3506 5053
Fax No.: 2780 0886



九龍中醫院聯網
Kowloon Central Cluster

30 Gascoigne Road, Kowloon, Hong Kong

9 September 2026

Dear Sir/Madam,

**Invitation for Expression of Interest (EOI)
Supply of Plateletpheresis Collection Sets with On-loan Equipment for
Hong Kong Red Cross Blood Transfusion Service
Kowloon Central Cluster, Hospital Authority**

This letter serves as an invitation to your company to submit an Expression of Interest (EOI) for the supply of Plateletpheresis Collection Sets with On-loan Equipment for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority. A set of EOI document is enclosed herewith for your compilation.

Please complete the attached EOI document in duplicate together with your proposals enclosed in a sealed plain envelope marked "Expression of Interest (EOI) for the supply of Plateletpheresis Collection Sets with On-loan Equipment for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority", "EOI Reference Number: EOI-KCC/T/H1/036/26/BTS" and "Closing Date" on the envelope for easy identification and address to the Chairman of Tender Opening Committee, Cluster Procurement & Supplies Department, Kowloon Central Cluster. All Tenders **must be deposited in the Tender Box situated at 5/F., Block S, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon before 12:00 noon (Hong Kong Time) on 5 October 2026.**

Should you have any query, please contact Mr. Andy LEE, HM(CPSD)1 at 3506 5053 or email to leaps1@ha.org.hk. In case of no offer, please fill in the reply slip with your reason(s) and return to us for our recording purpose.

Thank you.

Yours faithfully,

(Ms. Sandy SZETO)
Cluster General Manager
(Administrative Services)
Kowloon Central Cluster
Hospital Authority



**Expression of Interest (“EOI”)
for
Supply of Plateletpheresis Collection Sets
with On-loan Equipment for
Hong Kong Red Cross Blood Transfusion Service
Kowloon Central Cluster, Hospital Authority
(EOI Ref. : EOI- KCC/T/H1/036/26/BTS)**

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Expression of Interest (“EOI”)
Supply of Plateletpheresis Collection Sets with On-loan Equipment for
Hong Kong Red Cross Blood Transfusion Service
Kowloon Central Cluster, Hospital Authority

1. Purpose

- 1.1 The Kowloon Central Cluster (“KCC”) of the Hospital Authority (“HA”) intends to invite parties (the “Interested Parties”) to indicate their interests and to solicit information/proposals on the supply of Plateletpheresis Collection Sets with On-loan Equipment.
- 1.2 KCC of HA intends to conduct a pre-qualification exercise to enlist from the interested parties, who may be further invited to submit tender proposals after completion of this EOI exercise. The selected candidate(s) of the tender exercise shall supply the Plateletpheresis Collection Sets with On-loan Equipment to HA by entering into contracts with the HA.

2 Background

- 2.1 The HA is planning to procure Plateletpheresis Collection Sets with On-loan Equipment for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority.

3. Objectives

- 3.1 The objectives of this Expression of Interest are to:-
- 3.1.1 invite market feedback, on a noncommittal basis, on the proposed specifications and evaluate to what extent the market can meet the proposed specification;
- 3.1.2 understand the available source of supply being marketed for the supply of Plateletpheresis Collection Sets with On-loan Equipment.
- 3.1.3 ensure there will be suppliers who are of solid experience and capable to enter contract with HA.
- 3.1.4 conduct a pre-qualification exercise to enlist from the interested parties for further invitation to tender exercise.

4. Qualification Requirement and Criteria for Evaluation

- 4.1 Interested parties may respond to this EOI if they comply with the qualification requirement including
- the specification of the Supply of Plateletpheresis Collection Sets with On-loan Equipment for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority as listed in Annex 2.

5. Submission Requirements/Proposals

- 5.1 Interested parties are required to provide to the Hospital Authority the following information and documents:

5.1.1 Particulars of the Interested Party

- (a) Completed application form, as provided in Annex 1, containing basic information of the interested party and its authorized representative together with a declaration.
- (b) Documentary evidence for the compliance of qualification requirements as listed in Annex 2.
- (c) Name and address of the company/business organization.
- (d) Length and nature of business experience including without limitation experience in the performance and/or supply of the products as listed in Annex 2.
- (e) Shareholders/partners of the company/business organization.
- (f) Copies of its audited accounts/financial statements for the past three years. The latest audited accounts/financial statements must be for the period ended no more than eighteen (18) months before the EOI submission date mentioned in paragraph 6.9. The audited accounts/financial statements must include Director's report, Auditor's report, Profit and loss statement/Statement of comprehensive income, Balance sheet/Statement of financial position, Statement of cash flow and Notes to the Accounts/financial statements. The accounts/financial statements shall be prepared on the same basis for each year in accordance with accounting principles generally accepted in the Hong Kong Special Administrative Region and the disclosure requirements of the Companies Ordinance, Cap. 32/Cap. 622 of the laws of Hong Kong (as applicable), or for overseas company the equivalent requirements of the local government.
- (g) A copy of its Memorandum and Articles of Association or other documents evidencing its business status.
- (h) Copies of the organization's Certificate of Incorporation with the Companies Registry (if incorporated), its current business registration certificate and its application form for registration of business.
- (i) Copies of all current license(s) or permit(s) issued in favour of the interested party by the relevant authorities that are required to legally perform and/or supply the product (if applicable).
- (j) Any other market information that the interested party considers relevant to the Supply of Vial, Culture, Aerobic and Anaerobic Bottle with On-loan Equipment.
- (k) Supporting documents and/or brochures/catalogue shall be submitted.

5.1.2 Compliance with the Qualification Requirement

Interested parties should explicitly indicate the compliance of the preliminary specifications and provide comment and/or feedback by completing and returning Annex 2 for HA's consideration.

5.1.3 Indicative Price Proposal

Interested parties should also indicate the price of Plateletpheresis Collection Sets with On-loan Equipment by completing and returning Annex 3.

6. **Expression of Interest**

- 6.1 Submissions from Interested Parties meeting the above requirements will be considered by HA. Submissions or parties not meeting any of the mandatory qualification requirements shall be rejected.
- 6.2 Pre-qualified candidates will be notified separately by HA. The pre-qualification does not indicate or imply any commitment for future engagement of any pre-qualified party(ies) by HA.
- 6.3 HA will issue tender document for the supply of Plateletpheresis Collection Sets with On-loan Equipment to the pre-qualified candidates only and will consider further proposals submitted by such candidates only.
- 6.4 If HA considers that a pre-qualified candidate has ceased to be able to meet any of the qualification requirements, HA may, at its discretion, disqualify such candidate from submitting further proposal at any time prior to acceptance of the proposal.
- 6.5 This EOI does not constitute an invitation to participate in the tender for the supply of Plateletpheresis Collection Sets with On-loan Equipment, nor does this document or any document made available pursuant to this EOI constitute any contract or agreement of any kind whatsoever with HA.
- 6.6 Proposals from interested parties will be considered by the HA in compilation of tender document and specifications for the coming tender.
- 6.7 All costs associated with any submission in response to this invitation shall be entirely the responsibility of the interested party(ies). The HA reserves the right to accept or reject any Expression of Interest at its discretion and without assigning any reason or explanation.
- 6.8 The HA reserves the right to cancel or terminate the process of Expression of Interest and/or “Invitation to Tender” at any time or during any stage of the process without giving the reason for such action. The HA shall not be liable to any party for any loss or damage, cost or expense as a result of such action.
- 6.9 All Expression of Interest in duplicate, with the hard copies and soft copies (saved in CD-ROM), in a sealed envelope marked “Invitation for Expression of Interest for the Supply of Plateletpheresis Collection Sets with On-loan Equipment for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority (EOI ref.: EOI - KCC/T/H1/036/26/BTS)” must be deposited into the Tender Box situated at the following address **on or before 12:00 noon (Hong Kong Time) on 5 October 2026.** Late submission may not be accepted or considered.

Cluster Procurement and Supplies Department (CPSD)
Kowloon Central Cluster, Hospital Authority
5/F, Block S, Queen Elizabeth Hospital,
30 Gascoigne Road, Kowloon

The office hours of Kowloon Central Cluster Procurement and Supplies Department (CPSD) are from Monday to Friday 8:45 a.m. to 1:00 p.m. and 2:00 p.m. to 5:33 p.m., except public holiday. Please deposit your EOI or sample during the office hours.

(Note: Reference number; Description and Closing Date shall be marked on the envelope for easy identification)

6.10 The Tender Closing Time and Tender Closing Date will be extended to 12:00 noon the next working day in Hong Kong (i.e. any day from Monday to Friday which is not a public holiday) under the following situations:

- (i) a black rainstorm signal or tropical cyclone warning signal No. 8 or above or “Extreme Conditions” issued by the Government is still in force between 9:00 am and 12:00 noon on the Tender Closing Date; or
- (ii) it is announced by the Government between 9:00 am and 12:00 noon on the Tender Closing Date that a black rainstorm signal or tropical cyclone warning signal No. 8 or above or “Extreme Conditions” will be issued in Hong Kong between 9:00 am and 12:00 noon on the Tender Closing Date. For the avoidance of doubt, if it is announced by the Government that such signal will be issued at or before a time that falls beyond 12:00 noon on the Tender Closing Date, there will not be any extension of the Tender Closing Time or Tender Closing Date unless the relevant signal is actually issued and is in force between 9:00 am and 12:00 noon on the Tender Closing Date.

7. Presentation / Product Demonstration

Interested party(ies) which have submitted “Expression of Interest” may be invited to give presentation on their proposals / demonstration on their product in person or by other means after the closing date of this EOI exercise.

8. Tentative Procurement Plan

Following the Expression of Interest exercise, it is anticipated that the tentative procurement schedule will be as follows:

- a) Issuance of Invitation to Tender (4Q 2026)
- b) Evaluation of Tender (4Q 2026)
- c) Award of Contract (1Q 2027)

9. Enquiry

Please write to the designated contact person by email or by post for any enquiries concerning this Expression of Interest exercise as detailed below:

Attention : Mr. Andy LEE, Hospital Manager (CPSD)1
Email : leaps1@ha.org.hk
Address : Room 505, 5/F, Block S, Queen Elizabeth Hospital, 30 Gascoigne Road, Kowloon
Tel No.: 3506 5053

Hospital Authority
9 September 2026



Application for the Expression of Interest to the Hospital Authority

**Supply of Plateletpheresis Collection Sets with On-loan Equipment for
Hong Kong Red Cross Blood Transfusion Service
Kowloon Central Cluster, Hospital Authority**

I.	Party	
● Name of Party: _____ ● Registered Address (No. Street, City, Country and Postal Code): _____ _____ - Tel. No.: () _____ Fax No.: () _____ - E-mail: _____		
II.	Representative authorized by the Party	
The following information of the Representative authorized by the Party must be provided: ● Name of the Representative authorized by the Party: _____ ● Position of the Representative authorized by the Party: _____ ● Contact Address (No., Street, City, Country and Postal Code): _____ _____ - Tel. No.: () _____ Fax No.: () _____ - E-mail: _____ ● The Representative must have full authority to commit the Party in this Expression of Interest.		

III. Declaration

- I declare that to the best of my knowledge and belief:
 - (a) the Party is able to meet all of the basic qualification requirements set out in Hospital Authority's invitation for Expression of Interest; and
 - (b) the information and documents submitted by the Party to the Hospital Authority in response to the invitation are true and correct in all material respects.
- I understand that Hospital Authority reserves the right to accept or reject any Expression of Interest at its discretion without giving any reason or explanation.

Signature: _____

Names: _____

Position: _____

For and on behalf of: _____

Date: _____ Company Chop: _____

- This shall be signed by the "Representative Authorized by the Party" named in Section II above.

Qualification Requirement
Supply of Plateletpheresis Collection Sets with On-loan Equipment for
Hong Kong Red Cross Blood Transfusion Service
Kowloon Central Cluster, Hospital Authority
(EOI Reference: EOI-KCC/T/H1/036/26/BTS)

General Rules and Observations

Unless otherwise stated, each item offered shall incorporate the following components / requirements / features. Interested parties must indicate below, point by point, whether their offered goods complies fully with the specification. In addition to indicating 'Yes' or 'No' against each item, interested parties must provide details / data / documentary support if necessary. Interested parties should also indicate if they or their subsidiary companies are the exclusive distributor of any of accessories or ancillary systems in the specification. Failure of the interested parties to comply with the foregoing requirement may jeopardize consideration of their offers.

This EOI calls for the supply of Plateletpheresis Collection Sets with On-loan Equipment for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority.

This EOI exercise will pre-qualify candidate(s) on an **overall basis**.

Please specify the details of the Plateletpheresis Collection Sets with On-loan Equipment to be offered and attach the relevant catalogue / brochure:-

To be completed by Interested Party:

Single Dose Plateletpheresis Collection Sets

Brand : _____

Model : _____

Manufacturer : _____

Country of Origin : _____

Date of Product Launch : _____

Delivery Lead Time : _____

Shelf-life : _____

Double Dose Plateletpheresis Collection Sets

Brand : _____

Model : _____

Manufacturer : _____

Country of Origin : _____

Date of Product Launch : _____

Delivery Lead Time : _____

Shelf-life : _____

On-loan Equipment

Brand : _____

Model : _____

Quantity: _____

Manufacturer : _____

Country of Origin : _____

Date of Product Launch : _____

Reference Clinical Installation Site : _____

Delivery Lead Time : _____

Installation Lead Time : _____

Expected Equipment Lifespan : _____

We or our subsidiary companies are / are not* the exclusive distributor of any of requested items in the specification.

**please delete where appropriate*

Qualification Requirement
Supply of Plateletpheresis Collection Sets with On-loan Equipment for
Hong Kong Red Cross Blood Transfusion Service
Kowloon Central Cluster, Hospital Authority
(EOI-KCC/T/H1/036/26/BTS)

The product offered shall incorporate the following components, requirement & features.

Importance of the clause specified is denoted by:

M – Mandatory

D – Desirable

O – Optional

Tenderers must indicate below, point by point, whether their offer complies fully with the quotation specification. Details must be given should the offered product differ from the specification.

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u>
			<u>(Provide details)</u>	
1.	General Requirement			
1.1.	This exercise calls for supply of single dose and double dose leucodepleted plateletpheresis collection set with On-Loan Equipment for Hong Kong Red Cross Blood Transfusion Service (HKRCBTS).	M		
1.2.	The collection set shall conform to ISO 3826-4:2019 (or latest revision) and other applicable parts of the ISO 3826 series for apheresis blood bag system. The manufacturer shall maintain a Quality Management System certified to ISO 13485:2016 (or latest revision). Equivalent international standards may be considered with evidence of equivalence. Documentation shall be provided in accordance with Clause 2.25.	M		
1.3.	The collection system shall comply with all applicable regulatory requirements for medical devices in the intended market, including but not limited to CE marking (EU MDR 2017/745) or US FDA approval (21 CFR Part 820) or equivalent. Documentation shall be provided in accordance with Clause 2.25.	M		
1.4.	The provided collection machine must accommodate the collection procedure of plateletpheresis and plasmapheresis.	D		
2.	Configuration of Collection Set			
2.1.	The configuration applies to apheresis collection.	M		
2.2.	The set must use a fully automatic closing system for platelet and concurrent plasma collection.	M		
2.3.	All accessories must be integrated into one single collection set unit.	M		
2.4.	A 5 ml sample pouch shall be attached to the platelet collection bag for product sampling within a close system after completion of the procedure.	M		
2.5.	The capacity of each collection bag shall be at least 600 ml.	M		
2.6.	Each collection bag shall have at least 70 cm of tubing attached to facilitate Quality Control (QC) sampling.	M		
2.7.	Configuration of Single Dose Plateletpheresis Collection Set			
2.7.1.	The collection set shall include at least one platelet collection bag and one plasma collection bag.	M		
2.7.2.	Required quantity: 38,000 set.	M		
2.8.	Configuration of Double Dose Plateletpheresis Collection Set			
2.8.1.	The collection set shall include at least two platelet collection bag and one plasma collection bag.	M		
2.8.2.	The collection set is allowed to be converted to a single dose plateletpheresis collection if needed.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
2.8.3.	Required quantity: 8,000 set.	M		
2.9.	Phlebotomy Needle			
2.9.1.	The needle must be 16G to 17G with an ultra-thin wall, silicone-treated, and protected with a hard plastic cap to facilitate bleeding.	M		
2.9.2.	The needle length must be 3.0-4.0 cm with $\pm 10\%$.	M		
2.10.	Needle Protector			
2.10.1.	The protector must be activated with a one-handed technique with audible lock for confirmation.	M		
2.10.2.	The protector materials must be non-toxic, pyrogenic free and latex free.	M		
2.10.3.	The protector must be a smooth cylindrical tube with no protruding flanges, or alternatively a SyslocKL needle guard.	M		
2.10.4.	The needle and hub must be fully retractable within the housing.	M		
2.11.	Blood Sampling Device			
2.11.1.	The sampling device must include a pouch with minimum 40 ml capacity, and preferably with engraving(s) on the pouch.	M		
2.11.2.	The device must include an adaptor/sample tube holder, and fit 13mm and 16mm diameter vacuum tubes.	M		
2.11.3.	The holder must prevent finger pricking by a silicone-coated needle.	M		
2.11.4.	Pre-donation samples must suitable for viral serological and molecular testings with technologies used commonly in blood services, which include but not limited to chemiluminescent immunoassay (CHLIA), enzyme-linked immunoassay (ELISA) and Nucleic Acid Amplification Technology (NAT).	M		
2.12.	Collection Bag and Tubing			
2.12.1.	The plasma collection bag must be compatible with existing rapid freezing equipment in HKRCBTS.	M		
2.12.2.	Brand: AR&E Model: RPF MKIV-60	M		
2.12.3.	Brand: ARROWSMITH & GRANT Model: AG RPF50 MKVI	M		
2.12.4.	The tubing must be compatible with existing sealers. Existing Fresenius Kabi Composeal Mobilea, Macoseal SE160 and Terumo T-seal mobile hand-held sealers and sealers commonly available in the market.	M		
2.12.5.	Tubing must suit Terumo BCT Sterile Connecting Device Model SC-203A and Fresenius Compo Dock Model 902865.	M		
2.12.6.	Sealed tubing must allow manual separation without leakage.	M		
2.12.7.	The set must fit HKRCBTS's packaging system.	M		
2.12.8.	The bag must suit HKRCBTS's blood unit packaging with 270 mm x 200 mm coolants.	M		
2.13.	Quality of Plastics			
2.13.1.	The collection kit must be complied of ISO 10993 and tested for cytotoxicity, sensitization and hemocompatibility. Documentation shall be provided in accordance with Clause 2.25.	M		
2.13.2.	Plastics must be color less and transparent for visual inspection.	M		
2.13.3.	Plastics must maintain hermetic seals.	M		
2.13.4.	Plastics must withstand -80°C to $+37^{\circ}\text{C}$ temperatures.	M		
2.13.5.	Plastics must produce no harmful fumes during heat-sealing and sterile welding.	M		
2.13.6.	The set must be compatible with the tenderer's apheresis machine.	M		
2.14.	Sterility			
2.14.1.	The collection set must be non-pyrogenic.	M		

Clause	Specification	M/ D/ O	Yes	No
			(Please tick where appropriate)	
2.14.2.	The interior fluid pathway must be sterile.	M		
2.14.3.	Sterilization process validation reports must be provided. Documentation shall be provided in accordance with Clause 2.25.	M		
2.14.4.	The sterility must comply with ISO 11139 or an equivalent standard. Documentation shall be provided in accordance with Clause 2.25.	M		
2.15.	Anticoagulant solution			
2.15.1.	The materials of collection set must compatible of plastic collapsible anticoagulant e.g. ACD-A.	M		
2.15.2.	An anticoagulant design spike must be available.	M		
2.16.	Base label			
2.16.1.	Label size and logo format must be made in accordance to the requirement of ISBT 128 blood product labelling symbology.	M		
2.16.2.	The size must be 105mm length and 100mm +/- 5%.	M		
2.16.3.	Label Ink must not leach at any time during storage, warming and thawing, causing cosmetic or toxicity to the content.	M		
2.16.4.	The label must be waterproof (e.g., plastic-coated).	M		
2.16.5.	The label must be compatible with HKRCBTS adhesive labels.	M		
2.16.6.	The label must resist slippage under temperature changes. Cellulose tape for fixing labels is unacceptable.	M		
2.16.7.	The adhesion of the label must comply with ISO 10993, ISO 3826 series, US FDA 21 CFR 175, or an equivalent standard. Documentation shall be provided in accordance with Clause 2.25.	M		
2.16.8.	The label must withstand freezing at -80°C.	M		
2.16.9.	Label glue must not come out during processing, on compression or storage, causing stickiness and trapping undue dirt on blood bag or facilities and device.	M		
2.16.10.	Barcodes must comply with ISO/IEC 15416 for printing quality.	M		
2.16.11.	Barcodes must be readable by HKRCBTS scanning equipment.	M		
2.16.12.	The following information must be included in this section using symbols taken from recognized medical device stand (ISO 15223-1, ISO3826-2 and EN980).	M		
2.16.13.	The identity of blood component that the container is specifically intended for storage.	D		
2.16.14.	The maximum volume of the blood container and/or volume of blood intended to be collected into the container if applicable.	D		
2.16.15.	Do not reuse this container (Single use only).	M		
2.16.16.	Expiry date on collection bag or its package (symbol and text YYYY-MM, preferably YYYY-MM-DD).	M		
2.17.	Log Number Label Sticker for Blood Donation Registration Form			
2.17.1.	Labels must be provided separately with collection kit packaging.	M		
2.17.2.	Labels must be supplied at 120-130% of consignment quantity.	M		
2.17.3.	Labels must include ISBT IST-compliant batch numbers.	M		
2.17.4.	Batch numbers printed by font size 12, bold.	M		
2.17.5.	Batch numbers must be barcoded.	M		
2.17.6.	Barcodes must be readable by HKRCBTS scanning equipment.	M		
2.18.	Shelf-Life of Collection Set			
2.18.1.	Collection set must have a minimum 12-month shelf-life upon receipt by user.	M		
2.18.2.	Sterility report of shelf-life must be provided. Documentation shall be provided in accordance with Clause 2.25.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
2.18.3.	Material stability-reports must be provided. Documentation shall be provided in accordance with Clause 2.25.	M		
2.19.	Collection set Packaging			
2.19.1.	Each set must be individually packed.	M		
2.19.2.	Packaging must maintain sterility and be protected against contamination.	M		
2.19.3.	Packaging must be free of foreign particles or dirt.	M		
2.19.4.	Packaging must be sufficiently water repellent to prevent liquid or moisture from passing through.	M		
2.19.5.	Packaging must contain expiry date.	M		
2.19.6.	Packaging materials must be recyclable where feasible.	M		
2.19.7.	Packaging materials must be biodegradable where feasible.	M		
2.20.	Marking and Labelling			
2.20.1.	Each kit shall be legibly marked with the following information.	M		
2.20.1.1.	The manufacturer's name.	M		
2.20.1.2.	Trade mark or recognized symbol.	M		
2.20.1.3.	A textual description of content.	M		
2.20.1.4.	Manufacture date.	D		
2.20.1.5.	Expiry date.	M		
2.20.1.6.	Lot Number.	M		
2.20.1.7.	Country of Origin.	D		
2.20.1.8.	Indicate "Sterile".	M		
2.20.1.9.	Indicate "For Single Use".	M		
2.20.1.10.	The site of peel-off.	D		
2.20.1.11.	Sterilization indicator.	D		
2.21.	Transportation Container and Labelling			
2.21.1.	Cartons must display the manufacturer's name.	M		
2.21.2.	Cartons must display a trademark or symbol.	M		
2.21.3.	Cartons must describe the content.	M		
2.21.4.	Cartons must show the expiry date.	M		
2.21.5.	Cartons must show the lot number.	M		
2.21.6.	Cartons must show the country of origin.	M		
2.21.7.	Cartons must show the gross weight.	D		
2.21.8.	Cartons must show storage temperature requirements.	D		
2.21.9.	Cartons must protect contents with a water-repellent lining.	D		
2.21.10.	Cartons must be sealed on all six sides with cellulose tape.	D		
2.21.11.	Cartons must have handles for stacking.	D		
2.21.12.	Carton gross weight must not exceed 8 kg (± 1 kg).	M		
2.22.	Plasma Product Requirement	M		
2.22.1.	The plasma must be non-pyogenic and suitable for transfusion and fractionation.	M		
2.22.2.	The system must ensure platelet count for plasma unit must less than $50 \times 10^9/L$. Documentation shall be provided in accordance with Clause 2.25.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
2.22.3.	The system must ensure WBC count less than 1×10^6 /unit in collected plasma. Documentation shall be provided in accordance with Clause 2.25.	M		
2.22.4.	The system must ensure RBC count less than 6.0×10^9 /L in collected plasma. Documentation shall be provided in accordance with Clause 2.25.	M		
2.22.5.	The system must ensure that the Factor VIII level of frozen plasma (after freezing and thawing) stored for one month meets an average of a minimum of 70 IU per 100ml, and that every unit of minimum of 50 IU per 100 ml. Documentation shall be provided in accordance with Clause 2.25.	M		
2.22.6.	The system design must ensure no growth in bacterial surveillance.	M		
2.22.7.	The system design must ensure plasma free of visible hemolysis.	M		
2.22.8.	The system design must ensure residual plasma loss in the collection kit is less than 5% of target collection volume or less than 35ml. Documentation shall be provided in accordance with Clause 2.25.	M		
2.23.	Platelet Product Requirement			
2.23.1.	The platelet count of each unit must not less than 3×10^{11} /unit. Documentation shall be provided in accordance with Clause 2.25.	M		
2.23.2.	The platelet must be non-pyogenic and suitable for transfusion.	M		
2.23.3.	The pH value of platelet must be equal to or greater than 6.2. Documentation shall be provided in accordance with Clause 2.25.	M		
2.23.4.	The system must ensure WBC count less than 1.0×10^6 /unit in collected platelet. Documentation shall be provided in accordance with Clause 2.25.	M		
2.23.5.	The system design must ensure platelet free of visible hemolysis.	M		
2.23.6.	In accordance with BTS donor requirements, the collection duration for double-dose plateletpheresis shall not exceed 90 minutes in at least 90% of collection episodes. Documentation shall be provided in accordance with Clause 2.25.	M		
2.24.	Packaging system requirement			
2.24.1.	The collection bag shall be compatible with the packaging system of HKRCBTS's current materials, including the blood bin (interior dimension: Height 260mm x Width 560mm x Depth 330mm) and coolant (Length 270mm x Width 220mm), to facilitate delivery.	M		
2.24.2.	Using the above materials, each blood bin must securely house 14 to 18 units of collection bags under controlled temperature environment.	M		
2.25.	Documentation			
2.25.1.	Tenderers shall submit with tender copies of 2 set (each set in separate file) of the following documentations for inspection and evaluation or otherwise offers will be considered incomplete and will be jeopardized.	M		
2.25.2.	Certified true copy of Manufacturer Licence, Certificate or Permit issued by the Government or Health Authority of the country of origin to certify that the manufacturer is a legitimate manufacturer in the manufacture of the collection set being offered.	M		
2.25.3.	Certified true copy of Manufacturer's Quality Assurance/Control Report (QCR) and batch-specific Certificate of Sterility of the apheresis collection set being offered. Tenderers are required to submit QCR of the plateletpheresis collection kit manufactured in the most recent batch to serve a sample of the report for the inspection and evaluation, especially in the following areas:	M		
2.25.3.1.	Production Process	M		
2.25.3.2.	Finished goods with batch release	M		
2.25.3.3.	Traceability and lot control	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u>
			(Please tick where appropriate)	
2.25.4.	CE marking certification or US FDA or equivalent approval certification must be provided. (Refer to clause 1.3)	M		
2.25.5.	A true copy of valid ISO 13485:2016 or latest version standard certificate issued by independent and authorized certification institute must be provided. (Refer to clause 1.2)	M		
2.25.6.	Certified true copy of certificate(s) or reports to certify the sterilization company / service provider / self-owned department is qualified to conduct the sterilization for the plateletpheresis collection set being offered and comply with relevant standards, e.g. ISO11135 for Ethylene Oxide Sterilization or ISO11137 for Radiation Sterilization or equivalent. For the outsourced sterilization, certified true copy of ISO 13485:2016 or latest version must be provided. (Refer to clause 2.14.4)	M		
2.25.7.	Certified true copy of valid certificate(s) or reports to certify that the packaging materials of the plateletpheresis collection set comply with ANSI/AAMI/ISO11607:2019 (or latest version) of or equivalent standard which are compatible for sterilization process of the offered product.	M		
2.25.8.	Label adhesion reports must comply with ISO 10993/ISO 3826 /FDA 21 CFR175. (Refer to clause 2.16.7)	M		
2.25.9.	A compliance report or certification demonstrating conformity of the collection set with ISO 3826-4:2019 (or latest revision) and other applicable parts of the ISO 3826 series shall be provided. (Refer to clause 1.2)	M		
2.25.10.	Reports, manual or manufacturer's declaration shall be provided to demonstrate that residual plasma loss in the collection kit is less than 5% of the target collection volume or less than 35 ml (Refer to Clause 2.22.8).	M		
2.25.11.	Reports, manual or manufacturer's declaration shall be provided to demonstrate that WBC count must confirm $<0.9 \times 10^9/L$ due to kit's filtration system.	M		
2.25.12.	Supplier shall submit the Material Data Sheet (MDS) of their offered product.	M		
2.25.13.	Cytotoxicity reports for plastics must be provided. (Refer to Clause 2.13.1)	M		
2.25.14.	Biocompatibility reports must comply with ISO 10993. (Refer to Clause 2.13.1)	M		
2.25.15.	Reports or manufacturer's declaration shall be provided to demonstrate compliance with the following plasma product requirements (Refer to Clauses 2.22.2 to 2.22.5): Platelet count $< 50 \times 10^9/L$ WBC count $< 1 \times 10^6/unit$ RBC count $< 6.0 \times 10^9/L$ Factor VIII level after freezing and thawing (Stored for one month at $<-31^\circ C$): average $\geq 70 IU/100ml$, and every unit $\geq 50 IU/100ml$	M		
2.25.16.	Reports or manufacturer's declaration shall be provided to demonstrate compliance with the following platelet product requirements (Refer to Clauses 2.23.1, 2.23.3 and 2.23.4): Platelet count $\geq 3 \times 10^{11}/unit$ pH value ≥ 6.2 WBC count $< 1.0 \times 10^6/unit$	M		
2.25.17.	Reports or manufacturer's declaration shall be provided to demonstrate that the collection duration for double-dose plateletpheresis does not exceed 90 minutes in at least 90% of collection episodes (Refer to Clause 2.23.6).	M		

Clause	Specification	M/ D/ O	Yes	No
			(Please tick where appropriate)	
2.25.18.	Validation reports shall be provided to demonstrate the sterilization process has been validated. (Refer to Clauses 2.14.3)	M		
2.25.19.	Sterility reports of the shelf-life of the collection set shall be provided (Refer to Clause 2.18.2).	M		
2.25.20.	Material stability reports of the collection set shall be provided (Refer to Clause 2.18.3).	M		
2.25.21.	Supplier shall submit matching table.	M		
2.26.	Product Defect and Recall Mechanism			
2.26.1.	Supplier shall submit plan for product recall mechanism and contingency of replacement.	M		
2.26.2.	Supplier is required to provide information on the product recall mechanism that manufacturing facility/site and tenderer will exercise.	M		
2.26.3.	Supplier must provide a defect investigation with corrective action report within 28 days for cosmetic issue.	M		
2.26.4.	If a single instance of product defect is reported, the supplier is required to propose appropriate follow-up actions and submit a post-testing and evaluation report to the user within 8 weeks. In the event of a second occurrence within the same batch and/or lot, all kits stored at the user's facility must be recalled.	M		
2.26.5.	Supplier must provide replacement by non-affected batch during recall to ensure service continuity.	M		
2.27.	On-Loan Apheresis Collection Equipment			
2.27.1.	The supplier must provide on-loan plateletpheresis collection equipment, and ensuring equipment compliance with ISO 13485 quality management standards, IEC60601-1 or equivalent medical electrical equipment regulations, EU MDR 2017/745 requirements, or US FDA 21 CFR Part 820 standards or equivalent.	M		
2.27.2.	The supplier must provide on-loan apheresis machines to HKRCBTS during the contract period as stated quantity.	M		
2.27.3.	Single dose plateletpheresis – 9.	M		
2.27.4.	Double dose plateletpheresis – 4.	M		
2.27.5.	Equipment offered must be fully automatic. The operator's role shall be limited exclusively to kit installation, input of donor's data, initiation of the procedure, and routine monitoring. No manual manipulation, adjustment, or intervention shall be required during the collection process (e.g., no manual resuspension, offset adjustments, or aggregate management). Acceptable documentation includes manual, reports, internal document or a manufacturer's declaration confirming compliance with this requirement.	M		
2.27.6.	Equipment offered must comply with the safety requirements of IEC60601-1 / IEC61010-1 or equivalent. Acceptable documentation includes reports, internal document or a manufacturer's declaration confirming compliance with this requirement.	M		
2.27.7.	Equipment offered must comply with the electromagnetic compatibility (EMC) requirements of IEC60601-1-2 or IEC 61326-1 or equivalent. Acceptable documentation includes reports, internal document or a manufacturer's declaration confirming compliance with this requirement.	M		
2.27.8.	The equipment must remain operational and within specification throughout the voltage range of 220V +/- 6%, 50Hz +/- 2%, 1-phase A.C. electrical supply.	M		
2.27.9.	Single phase mains operated equipment must be fitted with a power plug suitable for the site condition. The plug shall comply with relevant standards e.g. BS1363 for 13A plug.	M		
2.27.10.	The supplier must provide backup battery to maintain the operation for at least 15 minutes in case no electricity supply.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
2.28.	Safety Feature of Equipment			
2.28.1.	The machine must be equipped with safety feature to avoid ineligible donation of following condition:	M		
2.28.1.1.	HCT < 50	M		
2.28.1.2.	Extracorporeal volume in a single apheresis collection exceeds 15% of donor's total blood volume or other features with same function.	M		
2.28.2.	The collection equipment shall equip with safety feature to avoid wrong entry of platelet count.	M		
2.28.3.	The collection equipment is allowed to set with a post-donation platelet count target of no less than 100,000 platelets/uL. Acceptable documentation includes reports, internal document or a manufacturer's declaration confirming compliance with this requirement.	M		
2.28.4.	The residual red blood cell must less than 30ml after completion of each collection procedure. Acceptable documentation includes reports, internal document or a manufacturer's declaration confirming compliance with this requirement.	M		
2.29.	Other function			
2.29.1.	It shall be capable of detecting less than 1ml droplet leakage from the closed system.	M		
2.29.2.	It shall constantly provide status messages indicating the operation procedure performed.	M		
2.29.3.	A visual and audible alert shall prompt to user if an automatic features is required to be manually overridden.	M		
2.30.	Maintenance Service			
2.30.1.	The supplier must provide regular preventive maintenance (every 6 months) and calibration to ensure the collection systems are operated in acceptable functional standard. Written reports shall be provided to HKRCBTS after each maintenance and calibration.	M		
2.30.2.	The Supplier must carry out safety test on the equipment upon completion of the PM. The safety standard required shall comply with IEC60601-1 / IEC61010-1 safety requirements for electrical medical equipment and relevant collaborative standards.	M		
2.30.3.	Ad hoc repair must be provided free of charge throughout the contractual period and attendance for repair shall be no later than one working day after notice by HKRCBTS.	M		
2.30.4.	The supplier provide guarantee throughout the on-loan period for the equipment supplied, or any part or portion thereof, starting from the date of acceptance of the goods. During the guarantee period all services which include replacement of faulty parts, scheduled and breakdown services by qualified maintenance personnel, shall be provided free of charge.	M		
2.30.5.	The supplier must provide free software and firmware updates for apheresis machines.	M		
2.30.6.	The supplier must notify HKRCBTS of software updates at least 2 weeks in advance and provide free installation service on user agreed schedule.	M		
2.30.7.	If the apheresis product fail to meet the requirement of Quality Control Laboratory of HKRCBTS, the supplier must adjust the machine setting and provide the procedure data within 1 week on request.	M		
2.31.	Inventory and Delivery Requirement			
2.31.1.	For each delivery of less or equal 500 collection kits, there shall be at least 2 different lots number of products.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
2.31.2.	Every lot of apheresis kit upon delivery must be accompanied by a Certificate of Quality/Conformance/Analysis signed by Manufacturer's Quality Director or equivalent to ensure that all delivered goods meet the defined specifications; and also HKRCBTS' Certificate of Acceptance (CoA). Sample layout shall be provided.	M		
2.31.3.	The supplier must retain additional lots as backup for replacement.	M		
2.31.4.	The Supplier shall manage inventory of kits and deliver the kits, on consignments, to specified sites of HKRCBTS on an "as and when required" basis.	M		
2.31.5.	Before incoming evaluation check by HKRCBTS for each consignment of collection kit, the Supplier must conduct preliminary overall appearance check and ensure that the bags are transported and stored in good condition. The Supplier must send 1.5% to 2% of each batch (even though the same batch has been tested acceptable by user before), together with a Certificate of Acceptance (CoA) (Appendix IV) for each batch to the off-site warehouse of HKRCBTS for user's incoming evaluation. During the effective period of this contract, HKRCBTS will sign and return the CoA provided that particular batch passes the incoming evaluation check. In general, the incoming evaluation check would be completed within 14 days of goods receipt. The manufacturing plant should ship a batch (with a particular batch number) of collection kit as a whole to Hong Kong at one time.	M		
2.31.6.	HKRCBTS reserves the right to relocate the warehouse within the territory of Hong Kong.	M		
2.31.7.	The supplier must provide monthly stock status report. The monthly report of stock status (with respect to individual batch information) including stock at hand and outstanding balance shall be sent to HKRCBTS at the beginning of each month. It is preferable to have stock status access through a web-based online query from validated software.	M		
2.31.8.	The frequency of delivery could be every 2-4 weeks and no minimal order shall be imposed.	M		
2.31.9.	The supplier must provide the tolerance of out-ranged storage environment/ state the acceptable transportation environment for the collection kit.	M		
3.	Other Requirement			
3.1.	Production, materials, packing and delivery shall comply with environmental protection standard.	M		
3.1.1.	The Manufacturer is required to comply with any environmental Regulation or Code of Practice and should refer to Appendix II Environmental Guidance for Suppliers for information.	M		
3.1.2.	The Manufacturer shall complete Appendix III Environmental Management Supplier/ Contractor Questionnaire (2 pages) and return to the HKRCBTS with tender return.	M		
3.1.3.	The supplier shall provide recycle of the plastic tray of the apheresis kit.	M		
3.1.4.	The used plastic tray shall be collected once every week if any.	D		
3.1.5.	The Contractor shall supply Hospital Authority (HA) with medical equipment with international directive of Rohs, WEEE, etc. in restriction and control of heavy metal contents, disposition and recyclable options wherever possible, for HA consideration. Detailed information, if any, shall be provided during tender submission.	M		
3.1.6.	If factory inspection on the manufacturing plant of the tenderer is deemed necessary by the HKRCBTS, the tenderer shall provide all necessary assistance to facilitate the inspection to be conducted.	M		
3.1.7.	The Supplier must seek HKRCBTS' approval in advance of introducing changes to the material, process or plant for the System delivered to HKRCBTS; and to seek HKRCBTS' written consent in the change process.	M		

Clause	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> <u>(Provide details)</u>
			(Please tick where appropriate)	
3.1.8.	The whole collection system shall comply fully with the latest regulation requirements for registration of medical devices in Hong Kong.	M		
3.1.9.	If there is/are any other extra feature(s)/device(s) that is/are not specified as requirements by the HKRCBTS as indicated above; but is/are included as part of the System, the Tenderer(s) has to specify such feature(s)/device(s) in the tender return. Whether such feature(s)/device(s) is/are acceptable is subject to assessment of the HKRCBTS.	M		
3.1.10.	HKRCBTS has the absolute discretion to reject offer(s) which contains additional and redundant feature(s), as part(s) of the offered collection system, and described in this specification.	M		
3.2.	Product Evaluation			
3.2.1.	Two free collection kit with product configurations and specifications compatible to tender mandatory requirements, must be submitted together with quotation for evaluation. The samples must be received on or before tender closing time. Offer without sample or late sample submission will NOT be considered.	M		
3.2.2.	The collection kit must undergo the product evaluation which processed by Quality Control Laboratory and fulfil the acceptance criteria.	M		
3.2.3.	At least 24 samples which certified suitable for blood collection, filtration, storage of blood/blood components and subsequent transfusion to humans must be provided on request basis for evaluation. Reasonable amount of further samples shall be provided for evaluation upon request by HKRCBTS.	M		
3.2.4.	The supplier must provide the same collection equipment which mentioned in the tender return for evaluation without additional cost.	M		
3.2.5.	The supplier must provide and support related collection kit and collection equipment with training within one month upon request by HKRCBTS.	M		
3.3.	Training			
3.3.1.	Training materials and manuals (Chinese and English) shall be provided by supplier as required.	M		
3.3.2.	Local comprehensive training shall be provided (minimum of 4 training sessions) to all staff from HKRCBTS as required.	M		
3.3.3.	Local comprehensive training shall be provided (minimum of 4 training sessions) to all staff from HKRCBTS as required if there were software or hardware changes.	M		
3.4.	Data interface			
3.4.1.	The supplier must provide a total solution to enable a bi-directional data interface between the on-loan equipment and HKRCBTS Blood Supply Management System (BSMS). The data interface specification will be provided by the HKRCBTS. The supplier shall be fully responsible for all costs required to establish such data interface with BSMS, which shall include, but not limited to, additional hardware, software and licensing costs. The data interface implementation shall be completed within 12 calendar months after tender is being awarded. Acceptable documentation includes specification, internal document or a manufacturer's declaration confirming compliance with this requirement.	M		
3.4.2.	The on-loan apheresis equipment shall receive donor's information including, but not limited to, donor ID, blood test result etc. from HKRCBTS BSMS for determination of suitable apheresis donation procedure for the donor.	M		
3.4.3.	The equipment must capture the donor donation process information including, but not limited to procedure start time, procedure end time, collection volume, staff code of the operator, etc. from the on-loan apheresis equipment and then transfer to HKRCBTS BSMS through the data interface.	M		
3.4.4.	The supplier shall update the data interface at no additional costs according to the need of end-user during the contract period.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
3.4.5.	The supplier shall provide API (Application Programming Interface) with complete API documentation, at no additional costs, to enable an authorized third-party vendor to collect the required information from the equipment.	M		
3.4.6.	The workstations and servers which have interface with HA / HKRCBTS should comply with the prevailing HA Terms and Conditions for Medical System Networks connecting to HA Network. The HA Terms and Conditions are provided in Appendix A.	M		
3.4.7.	If the solution contains any wireless network connections via radio frequency (RF) transmission, the RF ranges employed by the on-loan equipment shall be approved to be used in Hong Kong bound by Chapter 106 Telecommunications Ordinance. The contractor shall provide information on the mode of wireless transmission and relevant license documents issued by the Communications Authority during tender submission.	M		
3.4.8.	The supplier shall provide active survey reports for every access points (APs) of the wireless network to demonstrate good quality of wireless signals. To avoid of doubt, “active survey” is a wireless survey performed with the survey client associated to the APs and performs all the tasks a typical 802.11 client performs throughout the survey which shall include rate shifting data rates as the RF condition changes and performs retransmissions.	M		
3.4.9.	The supplier shall provide a contingency mechanism to prevent missing of donation record during service interruption, e.g. interface failure.	M		
3.4.10.	The supplier shall resolve the compatibility issue of patches and/or security patches that are classified as “critical” or “high” within a reasonable time as agreed by the HKRCBTS.	M		
3.4.11.	All wireless communications of the on-loan apheresis machine shall be protected with at least the same security level as the WPA2 (Wireless Protected Access 2) protocol with AES algorithms.	M		
3.4.12.	The supplier shall provide quotation of annual maintenance cost of the interface service at the time of tender submission which shall include, but not limited to, hardware, software, licenses that are required to maintain the interface to work properly with the HKRCBTS BSMS.	M		
3.4.13.	The supplier shall provide a reliable anti-virus, anti-spyware, anti-hacking or equivalent solution for the system on offer and regularly update the anti-virus definition. The Seller shall provide supporting documents issued by the equipment manufacturer in case installation of anti-virus, anti-spyware or anti-hacking software may affect normal operation of the equipment. In addition to the document from manufacturer, Seller shall provide a risk mitigation plan for HA’s consideration.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
4.	IT Security Requirements			
4.1.	Data Security Requirements (a) Encryption of Sensitive Data: The Tenderer must ensure that sensitive data, including but not limited to identifiable patient information, downloaded from the System/Equipment to end-user devices, is adequately protected by encryption of a reasonable and industry-accepted standard. (b) Encryption of Stored Data: The Tenderer shall ensure that sensitive data stored within the System/Equipment is preferably encrypted, adhering to current encryption standards. (c) Encryption of Backup Data: All sensitive data stored in backup storage must be encrypted to maintain confidentiality and integrity. (d) Safeguarding Important Data: The Tenderer is required to ensure that all important data, including knowledge and System/Equipment configuration parameters, is safeguarded and preserved through an effective and reliable backup mechanism. (e) Restrictions on Data Export: The Tenderer must ensure that sensitive data is not exported for any purpose unless prior explicit authorization has been obtained from HA. Failure to comply with this requirement may result in legal consequences. (f) Prohibition on Data Transfer via Portable Media: Unless prior authorization has been obtained from HA, it is strictly prohibited to copy or move data from the System/Equipment to the HA network using portable media such as USB drives or CDs. (g) Logging of Sensitive Data: The Tenderer must ensure that sensitive or personal data is not logged unless operationally necessary. If logging is required, the data must be encrypted or secured with restricted access controls.	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
4.2.	Network Connectivity and Security (a) Restricted External Access: The Tenderer shall ensure that there are no non-HA (external) network connections to the System/Equipment unless supported by prior authorization and knowledge from HA. (b) Prohibition on Unauthorized Connections: The System/Equipment must not automatically establish any wireless or wired connections without prior explicit authorization from HA. (c) Secure HA Network Connectivity: For Systems/Equipment residing within HA premises, the Tenderer must ensure secure connectivity to the HA network for information exchange, adhering strictly to HA's security requirements, including but not limited to network segregation by firewall. (d) Endorsement and Compliance: Any network connection for the System/Equipment to the HA network must be endorsed by HA and implemented and operated according to HA's policies, procedures, and guidelines. (e) Security Solutions and Updates: The Tenderer must provide reliable antivirus, anti-spyware, and anti-hacking solutions for the medical Systems/Equipment. The solution should not compromise the normal performance of the Systems/Equipment and should be updated regularly, preferably using HA's virus definitions for daily updates. (f) Account Management: The Tenderer shall ensure each user identity (user-ID) for remote support must uniquely identify only one user. Sharing user account with other individuals is strictly prohibited. Any unauthorized use or access may result in consequences, including termination of the user account.	M		
5.	Tenderer shall declare their offered product(s) the compliance with Radiation Ordinance (Cap. 303) with details in Appendix I.	M		
6.	Tenderer may be invited to provide an in-person demonstration of their proposed products upon request, following the tender closing date, which is tentatively scheduled in Oct 2026 or around 14 days after tender closing date.	M		
7.	Brand & Authorization Documents			
7.1.	Tenderers are required to provide Authorization Letters issued by manufacturers or brand owners of the goods offered in this tender exercise and the authorization letter shall remain valid during contract period.	M		
7.2.	HA reserves the right to obtain Authorization Letters directly from manufacturers or brand owners and to verify the authenticity independently. Please provide contact of manufacturers or brand owners. Name of Contact Person: _____ Email Address: _____ Phone Number: _____	M		

<u>Clause</u>	<u>Specification</u>	<u>M/ D/ O</u>	<u>Yes</u>	<u>No</u> (Provide details)
			(Please tick where appropriate)	
7.3.	If authorization letter provided will be expired before contract end date, Contractors are required actively to provide the update Authorization Letter to HA that 1 month prior to the expiry date of existing Authorization Letter.	M		
7.4.	If applicable, Tenderer must submit a validated laboratory test report(s) from an independent and accredited laboratories/testing centre together with the submission of tender document. A duplicate copy of the report directly sent to the hospital by the laboratory is required if applicable.	M		
7.5.	Tenderer shall provide test report issued by independent accredited laboratory. The laboratory report shall be made available to the Hospital Authority (HA) by one of the following methods: Direct submission by laboratory: the accredited laboratory sends the report directly to HA from the laboratory's official email address. Tenderer submission with verifiable reference: the tenderer submits the report and provides the laboratory's report reference number and/or a persistent verification method so HA can independently verify authenticity.	M		
7.6.	The Contractor shall take or procure to be taken any reasonable action to rectify any reasonable concerns raised by the Authority following inspection or examination.	M		
8.	All the documentary evidence/certifications must be stamped with company chop and/or authorized signature by the issuing party.	M		
9.	All the documentary evidence/certifications must be certified true copy by the tenderer with company chop and/or authorized signature.	M		

Company Chop _____

Compliance with Radiation Ordinance (Cap. 303 of the Laws of Hong Kong)

I/We confirm that:-

- () The offered product(s) contain(s) radioactive substances (RS).
- () The offered product(s) do(es) not contain any radioactive substances (RS).

- () The offered product(s) is an / are irradiating apparatus(es). (IA)
- () The offered product(s) is not / are not irradiating apparatus(es). (IA)

If the offered product is IA or contain any RS, I/we confirm/commit to the following:-

- () I/We have obtained the necessary license from Radiation Board for selling the offered RS/IA product in Hong Kong, **or**
- () I shall/We will obtain the necessary license from Radiation Board for selling the offered RS/IA product in Hong Kong.

Tenderer is required to provide the information of the offered IA/RS product in below space (e.g. type, activity, etc.), if applicable:-

[Please refer to Hong Kong Radiation Ordinance (Cap. 303 of the Laws of Hong Kong) for the definition of RS and IA.]

[() Please tick “✓” where appropriate.]

Company Chop _____

Environmental Guidance for Suppliers, Contractors and Service Providers

BTS is committed to providing safe blood and quality service to hospitals in Hong Kong, and contributing to building a better environment through observance to environmental conservation and protection; we strictly adhere to our Quality-Environmental-Occupational Health and Safety Policies. We have implemented an Integrated Quality-Environmental Management System in accordance with ISO9001:2015 and ISO 14001:2015 and ISO45001:2018 standards and request all our Suppliers, Contractors and other Service Providers to observe the following requirements:-

- Comply with all relevant environmental legislation and other requirements;
- Control the use of materials and resources (e.g. electricity, fuel, chemicals, paper, etc.) wherever appropriate, to be both energy and resource efficient;
- Minimize the production of all kinds of waste where applicable;
- Reuse and recycle materials/waste wherever possible;

For works conducted in HKRCBTS premises, all Suppliers/Contractors/other Service Providers are required to ensure that all waste materials are properly handled, stored and disposed of in an efficient and sensitive manner to ensure that all facilities, equipment, plants and vehicles so deployed are properly maintained and comply with relevant environmental legislation and other requirements.

We hope that our suppliers, Contractors and Service Providers would have a clear corporate environmental policy.

Appreciate if you would complete and return the attached questionnaire. Please contact the HKRCBTS if you have any queries or need assistance.

ENVIRONMENTAL MANAGEMENT SUPPLIER / CONTRACTOR QUESTIONNAIRE

Name of Company:	
Address:	
Tel No:	Fax No:
Email Address:	
Describe	
a) Name of Product(s) or service(s) to which this questionnaire applies:	
b) Special features(s) of above offer(s) related to environmental protection where applicable:	
Name of the person who has prime responsibility for environmental performance:	
Position:	
Are you registered to ISO 14001?	YES / NO
If “yes”, please supply photocopies of	
1) the ISO14001 certificate, and	Copy attached: YES / NO
2) your company Environmental Policy.	Copy attached: YES / NO
<i>Then sign the form in P2 and return it to us.</i>	
If you are NOT ISO14001 certified, please answer the following questions:	
Do you have an Environmental Management System?	YES / NO
Do you have an Environmental Policy?	YES / NO
If “yes”, please send us a copy.	Copy attached: YES / NO

Company Chop _____

Are you currently preparing for ISO 14001 certification?	YES / NO
If “yes”, when do you expect to be approved?	
If “no”:	
Have you defined the environmental Regulations which apply to your organisation?	YES / NO
Have you defined the environmental impacts caused by your activities?	YES / NO
Are there written procedures to control environmental activities, especially emergencies?	YES / NO
Do you measure environmental performance?	YES / NO
Is environmental performance regularly reviewed by senior management?	YES / NO
Do your training plans include environmental training?	YES / NO
Please send us a copy of your statement of environmental impacts, if available.	ENCLOSED / NOT AVAILABLE
Please send us a copy of your list of relevant environmental Regulations, if available.	ENCLOSED / NOT AVAILABLE
Have you given consideration to the environmental impact associated with a) the production of your purchased raw materials, components, etc., and the ultimate disposal of your product? and/or b) the operation or activities of the purchased service?	YES / NO YES / NO

Company Chop _____

Sample of Certificate of Acceptance**CERTIFICATE of ACCEPTANCE**

Brand of filtration system:	
Manufacturer:	
Product description:	
Product code:	
Batch number:	
Manufacturing date:	
Expiry date:	
Remarks:	

This is to certify that the above-mentioned item was tested and found to be acceptable by HKRCBTS.

Approved by:

Name in block letter

**Designation/
HKRCBTS**

Signature

Date of approval:

Appendix A

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***IT Security Requirements for Quotation / Tender -
Procurement of "non-IT" System/Equipment***

Version	Effective Date
16.0	31/07/2026

Document Number	HAHO-ITD-PD-ISP-007-v16
Author	William WONG, HOIT&HI SM(ISO)1
Custodian	William WONG, HOIT&HI SM(ISO)1
Approved/ Endorsed By	ITD
Approval Date	31/07/2026
Distribution List	All HA HOIT&HI Staff / Cluster IT Staff

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Amendment History

Version No.	Date of Amendment	Prepared by	Description
1.0	7/09/2017	Dale Johnstone First draft	ALL
2.0	7/11/2017	Dale Johnstone	Add Appendix C&D
3.0	28/12/2017	Dale Johnstone	Add Appendix E
4.0	13/04/2018	John Tse	Update A.16.3 & A.16.4 in Appendix A
5.0	07/12/2018	William Wong	- Re-format document - Change A.4 Availability in Appendix A - Replace diagram in Appendix B - Add "Privacy Control" in Appendix E
6.0	15/03/2019	William Wong	- Change name in Further Information
7.0	16/12/2019	William Wong	- Update document link "Guidelines on Connecting Medical System Networks (Information Technology Circular 1/2019)" in Reference - Add Note i) & ii) in Appendix A - Add A19.9 in Appendix A
8.0	09/10/2020	John Tse	- Change Medical System networks to External network - Update A.19 in Appendix A - Update Appendix B to "External Network Architecture" - Remove Appendix C and Appendix D - Change Appendix E to Appendix C
9.0	09/12/2020	John Tse	- Update the External Network architecture to indicate building switch is L3 switch - Correct the link for "Guidelines for Cabling System and Network Setup in External Network"
10.0	15/12/2020	John Tse	- Correct the numbering for section 3 - Remove point c) from section 4 (ie. appendix for "Guidelines for Cabling System and Network setup in External network")
11.0	29/12/2020	William Wong	- Update distribution list
12.0	12/7/2021	John Tse	- Restore version 7 until the latest guideline for cabling and network setup is ready
13.0	13/07/2022	Yorky Wong	- Update Reference

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			- Update Further Information contacts - Update A.12.2 and A.20.1 in Appendix A
14.0	15/08/2022	John Tse	- Add the link for “ Guidelines for Cabling System and Network Setup in External Network” in References - Update A.19 to align with “One Network for All” strategy - Update Appendix B to “ External Network Architecture” - Combine Appendix C and D to Appendix C - Change Appendix E to Appendix D
15.0	21/02/2025	ISO1	- Update Reference - Update clause 5 - Update clause 6 Further Information - Add A.10.7 for logging sensitive data - Update A.11.2 for role-based access control - Update A.13.2 for patch management - Update A.15.1 for network segregation - Update A.18.3 for security compliance - Update A.20.1 for data exchange - Add A.21 for public cloud service - Update A9.1, A9.2, A11.5, A19.4 and A19.9 (a) for reference document viewing arrangement - Consolidate Appendix as Part A, B, C and D with updated checklist
		N5	- Update A.19, Appendix Part B and C for the Layer 2 switch
16.0	27/07/2026	ISO1	- Add A.2.3, A2.4, A2.5 for enhanced confidentiality undertaking and account management of tenderer staff - Add A9.4 for the PC security requirements - Update A10.5 and 10.6 for strengthening data export prohibition for any purpose unless prior authorization has been obtained from HA - Update A16.2, A16.3, A16.4 for connecting media or device which was obtained prior authorization from HA during maintenance support - Update A18.3 and Appendix D for Vendor System Security Compliance Report

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IT Security Requirements for Quotation / Tender –

Procurement of “non-IT” System/Equipment

THE TERMS AND DEFINITIONS BELOW ARE GENERAL REQUIREMENTS WHICH APPLY TO THE ACQUISITION AND INSTALLATION OF “NON-IT SYSTEMS” (SYSTEM)/EQUIPMENT WITH HA.

“NON-IT SYSTEMS”/EQUIPMENT IS TECHNOLOGY BEING ACQUIRED BY HA THAT MAINTAINS IT COMPONENTS BUT WHICH IS NOT NORMALLY PROCURED BY HA INFORMATION TECHNOLOGY AND HEALTH INFORMATICS DIVISION (IT&HID).

THERE MAY ADDITIONALLY BE PROJECT SPECIFIC REQUIREMENTS.

SUBJECT OFFICERS OF INDIVIDUAL PROJECTS ARE ADVISED TO CONSULT HA IT&HID DURING THE TENDER SPECIFICATION PREPARATION STAGE.

SUBJECT OFFICERS SHOULD NOTE THAT PROJECTS HAVE TO RESERVE FUNDING FOR SETTING UP AND ESTABLISHING ANY NETWORK CONNECTIVITY THAT WILL BE PERFORMED BY HA IT&HID.

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1. Purpose

The purpose of this document is to provide model IT security related terms and definitions clauses to be used by HA when preparing and evaluating "Requests for Quotations" and "Requests for Tender" for the procurement of non-IT Systems ("Systems")/Equipment.

2. References

- (a) Guidelines for Windows Server Hardening
<http://it.home/doc/HAHO-ITD-GL-T03-010.aspx>
- (b) Guidelines for Connecting External Network in HA (Information Technology Circular 1/2019)
<http://ha.home/circular2/IT-2019-01.pdf>
- (c) Guidelines for Connecting External Network in HA
<http://it.home/doc/HAHO-ITD-GL-N02-001.aspx>
- (d) Guidelines for Host Security Hardening
<http://it.home/doc/HAHO-ITD-GL-T02-001.aspx>
- (e) OWASP Top 10 Vulnerabilities
https://www.owasp.org/index.php/Category:OWASP_Top_Ten_Project
- (f) Malicious Code Protection Requirements for Medical Equipment Maintenance
 (IT Circular 2/2018)
<http://ha.home/circular2/IT-2018-02.pdf>
- (g) Guidelines for Application Security
<http://it.home/doc/HAHO-ITD-GL-ISO-005.aspx>
- (h) Adopting Security Specifications Standard
<http://it.home/doc/HAHO-ITD-SD-ISO-001.aspx>
- (i) Guidelines for Mobile Device Security
<http://it.home/doc/HAHO-ITD-GL-ISO-003.aspx>
- (j) Guidelines for IoT Security
<http://it.home/doc/HAHO-ITD-GL-ISO-008.aspx>
- (k) Guidelines for Cabling System and Network Setup in External Network
<http://it.home/doc/HAHO-ITD-GL-N05-001.aspx>
- (l) Cloud Security Standard
<http://it.home/doc/HAHO-ITD-SD-ISO-004.aspx>
- (m) Guidelines for Vulnerability Management Process
<http://it.home/doc/HAHO-ITD-GL-ISO-001.aspx>
- (n) Guidelines for Security Patch Management
<http://it.home/doc/HAHO-ITD-GL-ISO-013.aspx>

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- (o) Guidelines for Security Requirements for HA PCs and Notebooks
<http://it.home/doc/HAHO-ITD-GL-ISO-009.aspx>

3. Introduction

Tenderer are reminded that:

- (a) the procurement process shall be considering risks that could be introduced to HA as a result of the selection of a System/Equipment;
- (b) details shall be described in the respective Schedule(s) pertaining to "Statement of Compliance" as to how the System/Equipment proposes to implement security requirements, including product names, product specifications and interconnection diagrams;
- (c) an alternative security solution able to achieve the same or better security protection, shall be proposed where any System/Equipment security requirements are unable to be fulfilled due to product design limitations;
- (d) where an alternative security solution is being proposed details shall be included which describe the alternative security solution in an Appendix to the "Statement of Compliance";
- (e) the security requirements outlined in Clause 5 are critical.

4. Overview

4.1 Scope

The scope of these IT security requirements are applicable to all "Requests for Quotations" and "Requests for Tender" for the procurement of non-IT Systems ("Systems")/Equipment in HA.

4.2 Objective

The scope of this document cover security requirements with terms and definitions for procurement of non-IT Systems ("Systems")/Equipment in HA, including data security, application security, network security, server security, client/desktop security, security incident reporting and vendor maintenance and etc.

5. IT Security Requirements

The IT security requirements for all "Requests for Quotations" and "Requests for Tender" within HA with a view to:

- (a) providing "Terms and Definitions" please refer detail noted in Appendix Part A;

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- (b) providing "Network Connection between Vendor Network and HA Network", please refer detail noted in Appendix Part B;
- (c) providing "Failure and Recovery Scenarios in Hospitals for vendor managed L3 network switches", please refer detail noted in Appendix Part C;
- (d) providing "Vendor System Security Compliance Report (Sample)", please refer detail noted in Appendix Part D (The form can be downloaded from <https://hateams.home/~rndKs>)

Note: Appendix is a clean standalone version that can be directly incorporated into tendering document for procurement process. All clauses stated are required whenever applicable.

6. Further Information

Further information and details concerning IT Security Requirements for Quotation / Tender - Procurement of "non-IT" System/Equipment can be obtained by contacting:

- William Wong, SM(ISO)1, 3906 3577, wongwwl@ha.org.hk
- Jackson Lam, SM(N)5, 3969 3123, jackson.lam@ha.org.hk

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Appendix Details of IT Security Requirements

A. Terms and Definitions

These terms and definitions apply to any System/Equipment requiring access to the HA IT network. Additional terms and definitions appear below in "Connectivity of Vendor Managed Network to HA" (A.19) for System/Equipment operated by the Tenderer on a separate self-contained "vendor" network.

Note:

- i) An alternative security solution able to achieve the same or better security protection, shall be proposed where any System/Equipment security requirements are unable to be fulfilled due to product design limitations;*
- ii) where an alternative security solution is being proposed details shall be included which describe the alternative security solution*

Reference Document:

- (a) Guidelines for Windows Server Hardening
<http://it.home/doc/HAHO-ITD-GL-T03-010.aspx>*
- (b) Guidelines on Connecting External Network in HA (Information Technology Circular 1/2019)
<http://ha.home/circular2/IT-2019-01.pdf>*
- (c) Guidelines for Connecting External Network in HA
<http://it.home/doc/HAHO-ITD-GL-N02-001.aspx>*
- (d) Guidelines for Host Security Hardening
<http://it.home/doc/HAHO-ITD-GL-T02-001.aspx>*
- (e) OWASP Top 10 Vulnerabilities
https://www.owasp.org/index.php/Category:OWASP_Top_Ten_Project*
- (f) Malicious Code Protection Requirements for Medical Equipment Maintenance (IT Circular 2/2018)
<http://ha.home/circular2/IT-2018-02.pdf>*
- (g) Guidelines for Application Security
<http://it.home/doc/HAHO-ITD-GL-ISO-005.aspx>*
- (h) Adopting Security Specifications Standard
<http://it.home/doc/HAHO-ITD-SD-ISO-001.aspx>*
- (i) Guidelines for Mobile Device Security
<http://it.home/doc/HAHO-ITD-GL-ISO-003.aspx>*
- (j) Guidelines for IoT Security
<http://it.home/doc/HAHO-ITD-GL-ISO-008.aspx>*

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- (k) *Guidelines for Cabling System and Network Setup in External Network*
<http://it.home/doc/HAHO-ITD-GL-N05-001.aspx>
- (l) *Cloud Security Standard*
<http://it.home/doc/HAHO-ITD-SD-ISO-004.aspx>
- (m) *Guidelines for Vulnerability Management Process*
<http://it.home/doc/HAHO-ITD-GL-ISO-001.aspx>
- (n) *Guidelines for Security Patch Management*
<http://it.home/doc/HAHO-ITD-GL-ISO-013.aspx>
- (o) *Guidelines for Security Requirements for HA PCs and Notebooks*
<http://it.home/doc/HAHO-ITD-GL-ISO-009.aspx>

A.1 Safety

- A.1.1** Tenderer shall ensure the System/Equipment remains secure and malicious code free in accordance with the terms and conditions of the relevant contract.
- A.1.2** Tenderer shall ensure the System/Equipment when being used for healthcare related patient outcomes does not cause danger, risk, harm, injury, or loss to the safety of an individual.
- A.1.3** Tenderer shall ensure the System/Equipment is protected from being used in a manner relied upon by other System/Equipment that could result in danger, risk, harm, injury, or loss to the safety of an individual.
- A.1.4** Tenderer shall ensure the System/Equipment does not create any non-compliance with regulatory or legal frameworks.

A.2 Confidentiality and Privacy

- A.2.1** Tenderer shall ensure the System/Equipment does not capture, store or process sensitive data and/or any data related to any individual, including personal health information, in a manner that allows the data to be made available or disclosed in an unauthorized manner.
- A.2.2** Tenderer shall ensure the System/Equipment provides appropriate authentication controls on privacy control when allowing any user, protocol or other form of connection.
- A.2.3** Tenderer shall ensure that all its staff and appointed sub-contractors and agents involved in the performance of the Services sign a confidentiality undertaking, declaration form, declaration checklist prior to commencing any work in HA onsite and remote access.
- A.2.4** Tenderer shall ensure each user identity (user-ID) for remote support must uniquely identify only one user. . Sharing user account with other individuals is strictly prohibited.

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Any unauthorized use or access may result in consequences, including termination of the user account.

- A.2.5** Tenderer shall ensure to review on the validity and on-going need for each of the User accounts of System/Equipment annually.

A.3 Integrity

- A.3.1** Tenderer shall ensure the System/Equipment preserves the accuracy and completeness (i.e. integrity) of data and the methods used to process and manage this data.
- A.3.2** Tenderer shall ensure the System/Equipment minimises any potential to cause business disruption if the System/Equipment does not operate as expected/planned.
- A.3.3** Tenderer shall ensure the System/Equipment can be accurately relied upon as a result of its function.
- A.3.4** Tenderer shall provide evidence to HA that any source code associated with the System/Equipment is free of common "OWASP Top 10 Vulnerabilities" [Reference Document (e)].

A.4 Availability

- A.4.1** Tenderer shall ensure the System/Equipment will be accessible and usable when needed.
- Tenderer shall ensure the System/Equipment achieves an overall level of availability with reference to the requirement of Uptime under warranty and maintenance support related clause in the Tender Specifications.
- A.4.2** Tenderer shall ensure any System/Equipment interruption with reference to the requirement of Corrective Maintenance under warranty and maintenance support related clause in the Tender Specifications.
- A.4.3** Tenderer shall ensure the System/Equipment provides adequate System/Equipment resilience facilities, including and not limited to redundant hardware components, enabling any faulty components to be switched over to redundant components if applicable.
- A.4.4** Tenderer shall ensure the System/Equipment is supported by uninterruptable power supply (UPS) for maintaining the committed level of System/Equipment availability if applicable.
- A.4.5** Tenderer shall ensure the System/Equipment minimises any disruption if not performing as expected/planned.

A.5 Compatibility

- A.5.1** Tenderer shall ensure the System/Equipment is able to effectively function together with other System/Equipment.

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A.5.2 Tenderer shall ensure the System/Equipment does not adversely interfere with the effective operation of any other System/Equipment.

A.5.3 Tenderer shall ensure the System/Equipment continues to function correctly following any System hardening and security specification requirements imposed by HA.

A.6 Longevity

A.6.1 Tenderer shall ensure the length of effective service of the System/Equipment (i.e. many years) and all of its components will be sufficient to meet the needs of HA.

A.6.2 Tenderer shall ensure the System/Equipment continues to operate beyond the period of time expected by HA.

A.6.3 Tenderer shall ensure updates for patching of vulnerabilities are maintained throughout the System/Equipment's lifetime expected by HA.

A.7 Technological Substitution

A.7.1 Tenderer shall ensure that within the warranty period/maintenance service contract period (if applicable), System/Equipment upgrades are performed, if there is any, without any charge within the contract period.

A.8 Data Sovereignty

A.8.1 Tenderer shall ensure the data processed or stored by the System/Equipment resides in Hong Kong.

A.8.2 Tenderer shall ensure the System/Equipment does not process or store data outside of Hong Kong.

A.8.3 Tenderer shall ensure the System/Equipment is governed by the laws of Hong Kong.

A.9 System Hardening

A.9.1 Tenderer shall ensure the System/Equipment, where using the Microsoft Windows Operating System, hardens all its components and functionality according to "Guidelines for Windows Server Hardening" [Reference document (a), which is available for viewing after signing a non-disclosure agreement with hospital].

A.9.2 Tenderer shall ensure the System/Equipment where using the non-Windows solutions are secured according to "Guidelines for Host Security Hardening" [Reference document (d), which is available for viewing after signing a non-disclosure agreement with hospital].

A.9.3 Tenderer shall ensure the System/Equipment avoids the presence of hard-coded authentication credentials.

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A.9.4 Tenderer shall ensure the PC connecting System/Equipment which meet following security requirements

- (a) Disable default Administrator account, and create another super user account for use instead which should not be granted to end-users
- (b) Enable password-protected screen saver
- (c) File sharing access must not be granted to "Everyone", and should be permitted based on pre-defined access rights if and when needed
- (d) Install endpoint protection software (e.g. MDE) with the latest definition
- (e) Install the latest security patch
- (f) Enable personal firewall for blocking incoming network connections, and disabling vulnerable network services such as LLMNR and NBT-NS
- (g) Install with encryption software for enabling removable media encryption
- (h) Encrypt files and folders containing confidential data, which should be stored in centralized file server instead of local hard disk drive
- (i) Confidential files should only be copied into removable storage devices supporting mandatory encryption
- (j) Enable full disk encryption and power-up password protection for Notebooks

A.10 Data Security

A.10.1 Tenderer shall ensure sensitive data downloaded from the System/Equipment to end-user devices is protected by a reasonable level of encryption.

Note: Sensitive data refers to data including but not limited to identifiable patient information.

A.10.2 Tenderer shall ensure sensitive data stored within the System/Equipment is preferably encrypted.

A.10.3 Tenderer shall ensure sensitive data stored in backup storage is encrypted.

A.10.4 Tenderer shall ensure all important data (knowledge, System/Equipment configuration parameters) stored in the System/Equipment is safeguarded and preserved through an effective backup mechanism.

A.10.5 Tenderer must ensure that sensitive data is NOT exported for any purpose unless prior authorization has been obtained from HA. Failure to comply with this requirement may result in illegal activities.

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A.10.6 Unless prior authorization has been obtained from HA, it is prohibited to copy or move data from the System/Equipment to the HA network using portable media (i.e. USB Drive or CD).

A.10.7 Tenderer shall ensure sensitive or personal data is not logged as much as possible; if there is operational need to log such data, ensure it is encrypted or secured with restricted access control.

A.11 Application Security

A.11.1 Tenderer shall ensure the System/Equipment employs prevalent authentication and authorisation mechanisms at reasonable safety level.

A.11.2 Tenderer shall ensure the System/Equipment supports role-based access control. For example, general user shall be restricted from system administration and setting function, which shall only be performed by authorized users.

A.11.3 Tenderer shall ensure the System/Equipment applies network level encryption.

A.11.4 Tenderer shall ensure the System/Equipment provides comprehensive version control and configuration management mechanisms.

A.11.5 Tenderer shall ensure the System/Equipment conforms to "Guideline for Application Security" [Reference document (g), which is available for viewing after signing a non-disclosure agreement with hospital].

A.12 Malicious Code Protection

A.12.1 Tenderer shall ensure the System/Equipment is protected with the installation of a reputable Anti-Virus program in all servers, PC and Workstation components.

A.12.2 Tenderer shall ensure the System/Equipment is protected with regular updates of the latest virus definitions.

Note: It is highly preferred that Tenderer shall use the same product as HA to have virus definition update automatically.

A.12.3 Tenderer shall be responsible for the on-going support and for keeping the virus definitions and related software up-to-date in all Servers, PCs and workstations.

A.12.4 Tenderer shall ensure virus definitions are updated within 24 hours from the date of release.

A.12.5 Tenderer shall be responsible for the regular scanning of all Servers and PCs in the System/Equipment every three months to ensure that they are not infected by virus, worms and spyware including the on-going support of scheduling and verifying the results of the virus scan.

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A.13 Vulnerability / Patch Management

A.13.1 Tenderer shall maintain ongoing System/Equipment support, including the installation of the latest security patches for the Operating Systems and related software in all System servers, PCs and workstations.

A.13.2 Tenderer shall ensure critically affected security patches are updated as soon as practically possible; for non-critical ones, within twelve months from the date of release.

A.14 Restricted External Access

A.14.1 Tenderer shall ensure that there are no non-HA (external) network connections to the System/Equipment unless supported by prior authorization and knowledge of HA.

A.14.2 Tenderer shall ensure that the System/Equipment does not automatically establish any wireless connections without prior authorisation and knowledge of HA.

A.14.3 Tenderer shall ensure that the System/Equipment does not establish any wired connections without prior authorisation and knowledge of HA.

A.15 HA Network Connectivity

A.15.1 Tenderer shall be responsible, where operational reasons exist, for a System/Equipment residing within HA premises to connect to the HA network for information exchange with HA IT systems, for implementing such network connection in accordance with HA requirements and to ensure all security requirements are strictly adhered to (e.g. network segregation by firewall to ensure security attacks due to the System/Equipment would not directly impact HA).

A.15.2 Tenderer shall ensure any network connection for a System/Equipment to the HA network is endorsed by HA and implemented and operated according to HA policies, procedures and guidelines.

A.15.3 Tenderer shall ensure connectivity of the System/Equipment to the HA network adheres to the network diagram as depicted in **Part B**.

A.16 Maintenance Support

A.16.1 Tenderer shall ensure that when maintenance is performed on the System/Equipment or when accessing the System/Equipment in any remote manner that the tools and software have been confirmed to be free of malicious code.

A.16.2 Tenderer shall ensure that where maintenance on the System/Equipment needs to be performed, that HA is provided with a level of assurance that the vendor has undertaken proactive actions to ensure their connecting media or device (USB stick, portable media, laptops, iPads, etc.) which was obtained prior authorization from HA. It has been scanned

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for malicious code before and after every time that portable media is used to apply changes/updates to the System/Equipment.

- A.16.3** Tenderer shall bring with them a mobile computer (i.e. laptop) which was obtained prior authorization from HA. It contains the latest version of anti-virus software, complete with up-to-date virus signatures to confirm onsite within HA premises that their media to be connected (i.e. USB) is free of malicious code.
- A.16.4** Tenderer shall ensure portable media (USB stick, CD/DVD, etc.) which was obtained prior authorization from HA. It is scanned (in addition to clause A.16.3) on a HA PC to ensure that the media is not infected by virus, worms and spyware before being used to apply changes/updates to the System/Equipment.
- A.16.5** Tenderer shall ensure the vendor provides HA a completed attestation of compliance to confirm the media or device to be connected to the System/Equipment has been scanned for viruses and found to be free of malicious code.
- A.16.6** Tenderer shall perform technical support on-site unless appropriate remote support arrangement is endorsed.
- A.16.7** Tenderer shall erase the sensitive data in the storage devices of the System/Equipment before taking away the equipment for repairing or disposal.
- A.16.8** Tenderer shall sign and fully comply with a non-disclosure confidentiality agreement during on-site and remote support.
- A.16.9** Tenderer should use different portable media (i.e. USB sticks), which have been scanned for malicious code, for each item of medical equipment they need to apply an update to.
- A.16.10** Tenderer shall where not able to use different individual portable media (i.e. USB sticks) for applying changes/updates to multiple items of medical equipment (see clause A.16.10), repeat Clauses A.16.3 and A.16.4 before proceeding to attach/apply the portable media to the second and subsequent items of medical equipment.

A.17 Decommissioning Support

- A.17.1** Tenderer shall ensure that upon decommissioning of the System/Equipment, data exports and data definitions (sometimes known as data dictionary) are provided for all clinical data, and other data as appropriate, in a data structure and format as required by Hospital Authority.
- A.17.2** Tenderer shall provide assistance, as required, for the successful migration of any data to a new replacement System/Equipment(s) as adopted by Hospital Authority.

A.18 Security Incident Reporting and Compliance

- A.18.1** Tenderer shall ensure the System/Equipment provides health-checking and audit logging capabilities.

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A.18.2 Tenderer shall immediately report to the Hospital management and the HA ITS Call Centre any security incident relating to the System/Equipment.

A.18.3 Tenderer shall monitor its security compliance and comply with HA's regular review process with respect to the requirements stipulated in this document. **Part D** provides a sample of a "Vendor System Network Security Compliance Report" which should be used.

A.19 Connectivity of Vendor Managed Network to HA

A.19.1 For Medical Systems, HA will install External Network data ports next to the equipment for connection with the HA Network, or HA will install External Network Wireless LAN for the equipment that supports Wi-Fi for connection with the HA Network.

(Note: Tenderer shall confirm with HA if External Network data ports can be provided)

A.19.2 The External Network data ports are based on the Institute of Electrical and Electronics Engineers (IEEE) 802.3 standards and support 10BASE-T at 10 Mbit/s (IEEE 802.3i), 100BASE-TX Fast Ethernet at 100 Mbit/s (IEEE 802.3u) and 1000BASE-T Ethernet at 1 Gbit/s (IEEE 802.3ab) connections.

A.19.3 The External Network is an Internet Protocol (IPv4) routable network. It supports the following communication protocols, including Internet Protocol (IP), Address Resolution Protocol (ARP), Internet Control Message Protocol (ICMP), Transmission Control Protocol (TCP) and User Datagram Protocol (UDP). The IP address will be assigned by HA.

A.19.4 In case the tenderer cannot use HA-provided External Network data ports, the tenderer shall set up the network and implement the cabling system according to the "Guidelines for Cabling System and Network Setup in External Network" [Reference Document (k) , which is available for viewing after signing a non-disclosure agreement with hospital].

A.19.5 Other than the provision by HA IT&HI as specified in the tender document, if the tenderer considered the HA IT&HI provision not sufficient/applicable to its proprietary Medical Systems, the tenderer may propose additional installation (in such case the additional installation works shall be carried out by the tenderer according to the "Guidelines for Cabling System and Network Setup in External Network" at its own cost [Reference Document (k)]). HA will not bear any additional charges, and the tenderer shall bear all such related costs which shall have been included in the tender price submitted by the tenderer.

A.19.6 Tenderer shall put their servers in Hospital Data Center as far as possible.

A.19.7 Tenderer shall provide the network diagram to illustrate the network architecture if the tenderer follows A.19.4. **Part B.1** illustrates the architecture of External Network for Medical Systems.

A.19.8 Tenderer shall ensure the System/Equipment connecting to the External Network Wireless LAN comply with the following requirements and specifications:

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- (a) Tenderer shall comply with the HA Wi-Fi infrastructure and standard guidelines
- (b) The end devices provided by the tenderer shall support IEEE 802.11a/g/n/ac/ax. For the end devices which support IEEE 802.11ax, they shall be compatible with IEEE 802.11a/g/n/ac
- (c) The end devices provided by the tenderer shall support 2.4GHz channel 1-13 and/or 5GHz channel under U-NII-1, U-NII-2A, U-NII-2C and U-NII-3
- (d) The end devices provided by the tenderer shall support WPA2 with AES encryption and PSK authentication
- (e) The end devices provided by the tenderer shall support DHCP/static IP configuration
- (f) The end devices provided by the tenderer shall support roaming across access points without session drop
- (g) Tenderer shall provide MAC addresses of the end devices for registration and PSK authentication in order to access Wi-Fi network
- (h) Tenderer shall arrange a Wi-Fi connectivity test with users and Hospital/HA IT&HI before the production rollout
- (i) Only 1 common SSID will be provided by HA for all non-IT systems
- (j) Non-IT systems shall use IP addresses as assigned by HA
- (k) IP routable network will be provided for Wi-Fi and wired equipment

A.19.9 For Non-Medical Systems such as Operational Technology (OT), the tenderer shall comply with the following requirements and specifications:

- (a) Tenderer shall set up the network and implement the cabling system according to the "Guidelines for Cabling System and Network Setup in External Network" [Reference Document (k) , which is available for viewing after signing a non-disclosure agreement with hospital].
- (b) Refer to the "Guidelines for Cabling System and Network Setup in External Network" [Reference Document (k), tenderer shall install at least one Layer 2 switch or with resilient when HA requires at the tenderer's cabinet and shall cater for different auto network failover and recovery scenarios according to the network diagrams illustrated in **Part C.1 and C.2**. If Layer 3 switch installation is required, the tenderer shall contact HA IT&HI in advance for consideration.
- (c) Tenderer shall provide the network diagram to illustrate the network architecture. **Part B.2** illustrates the architecture of External Network for Non-Medical Systems.
- (d) HA shall arrange HA Authorized Cabling Contractor to install the backbone cablings and HA Equipment Vendor to install the Gigabit Interface Converters (GBICS) at HA switch in Building Closets for the network connection to the tenderer's switch.

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- (e) HA will not bear any installation and maintenance related charges (except for backbone cabling, i.e. B.4 in **Part B.2**), and the tenderer shall bear all such related costs which shall have been included in the tender price submitted by the tenderer

A.20 Clinical Data Exchange

A.20.1 Tenderer shall ensure seamless electronic data exchange with Hospital Authority corporate systems, complying with Health Level Seven (HL7) version 2.3.1 and above, including support for the HL7 FHIR (Fast Healthcare Interoperability Resources) standard. The data transfer protocols should include MLLP with native HL7, SOAP, or RESTful-based web services with HL7XML, as well as FHIR API interfaces. Additionally, the Clinical Information System (CIS) must have the capability to receive events from and publish events to hospital systems in a timely manner to ensure real-time or near real-time data availability and synchronization. Furthermore, the file server storing clinical report files to be downloaded by the Hospital Authority system must support the SFTP protocol.

A.20.2 Tenderer shall ensure the implementation of electronic data exchange with Hospital Authority corporate systems complies Hospital Authority HL7 Guidelines.

A.20.3 Tenderer shall ensure any electronic message exchange with the Hospital Authority includes reference keys supplied by Hospital Authority corporate systems such as:

- (a) HKID
- (b) Name
- (c) Date of birth
- (d) Sex
- (e) HA case number
- (f) HA system unique patient key

Note: Electronic message exchange is important to ensure high integrity associated with patient identification and automatic mapping to patient records within the Hospital Authority.

A.20.4 Tenderer shall ensure the System/Equipment maintains the existing exchange of patient data with Hospital Authority corporate systems and provides exchange for other data including but not limited to:

- (a) Admit, discharge & transfer, and patient demographics
- (b) Allergy, Adverse Drug Reaction and Alert information
- (c) Clinical order, observations and results
- (d) Multimedia and imagery data

A.20.5 Tenderer shall ensure the System/Equipment automatically updates patient's demographic data upon reception of ADT message.

A.20.6 Tenderer shall ensure ADT information exchanged is in compliance with the latest Hospital Authority HL7 Implementation Guidance.

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A.20.7 Tenderer shall ensure audit logging is provided for all ADT (Admit, Discharge and Transfer) interactions.

A.20.8 Tenderer shall ensure the System/Equipment adopts the preferred Hospital Authority date format.

- (a) For the display of date in frontend screen: DD-MMM-YYYY (e.g. 01-JAN-2014)
- (b) For the display of date-time in frontend screen: DD-MMM-YYYY hh:mm:ss in either 12hr/24hr mode (e.g. 01-Jan-2014 15:30:45)
- (c) For the transfer of date information to HA system: YYYYMMDD (e.g. 20140101)
- (d) For the transfer of date-time information to HA system: YYYYMMDDhhmmss in 24hr mode (e.g. 20140101153045).

Note: This enables user friendliness and system interoperability to be achieved.

A.20.9 Tenderer shall ensure the System/Equipment sends update or delete messages, if necessary, to perform corresponding actions with Hospital Authority corporate systems, with proper authorization mechanism from supervisor and audit trail.

A.20.10 Tenderer shall ensure the System/Equipment provides appropriate feedback to users to indicate the successfulness of message exchange with Hospital Authority corporate systems. (e.g. dashboard system, system alert to users).

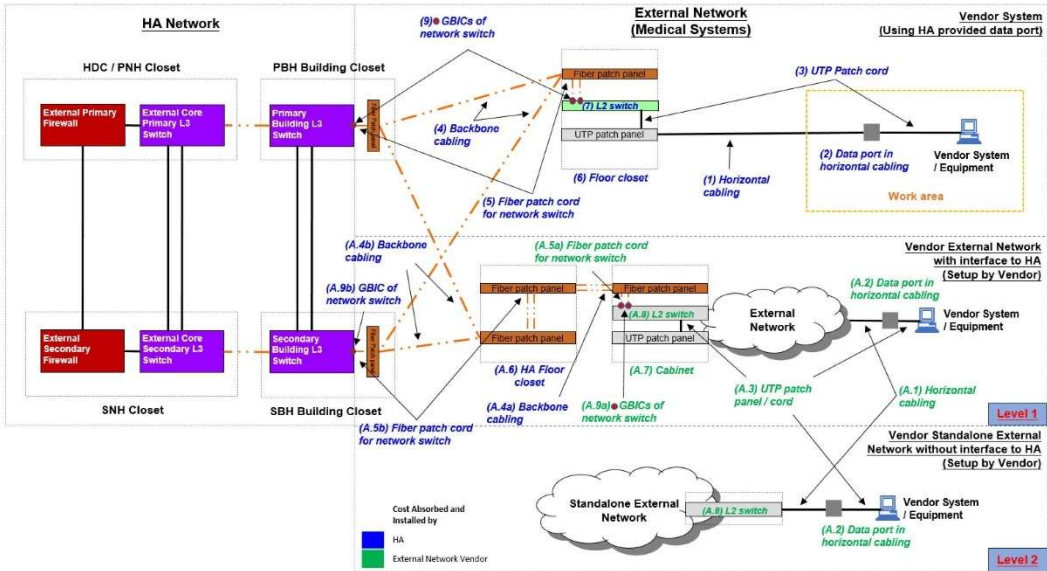
A.21 Public Cloud Service

A.21.1 Tenderer shall ensure the System/Equipment, where using public cloud service (e.g. Software as a Service/SaaS), conforms to "Cloud Security Standard" [Reference document (I), which is available for viewing after signing a non-disclosure agreement with hospital].

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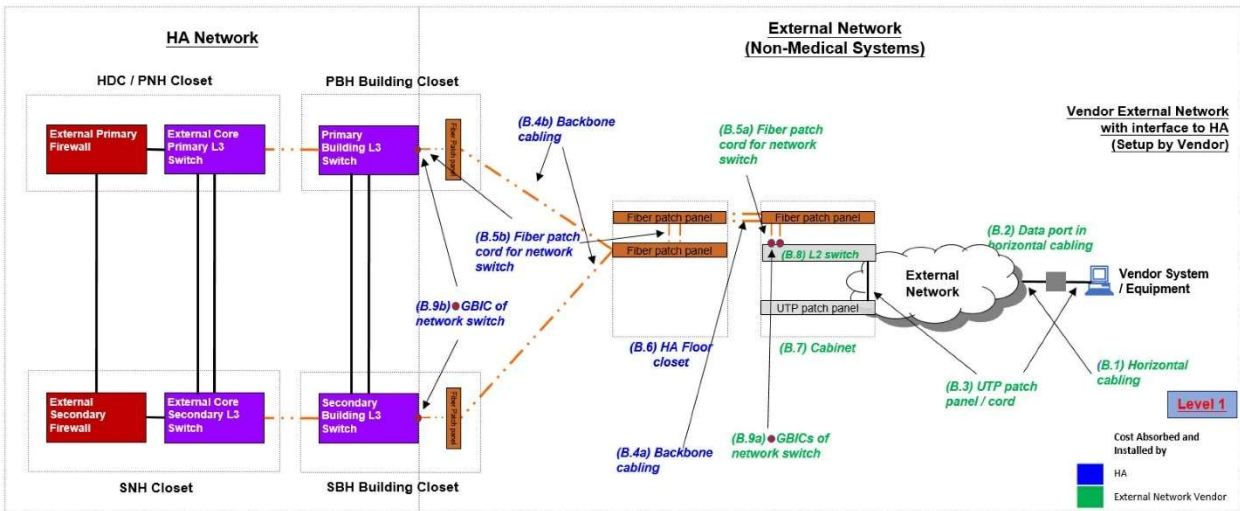
B. External Network Architecture

1) Below diagram illustrates the External Network Architecture for Medical Systems



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2) Below diagram illustrates the External Network Architecture for Non-Medical Systems

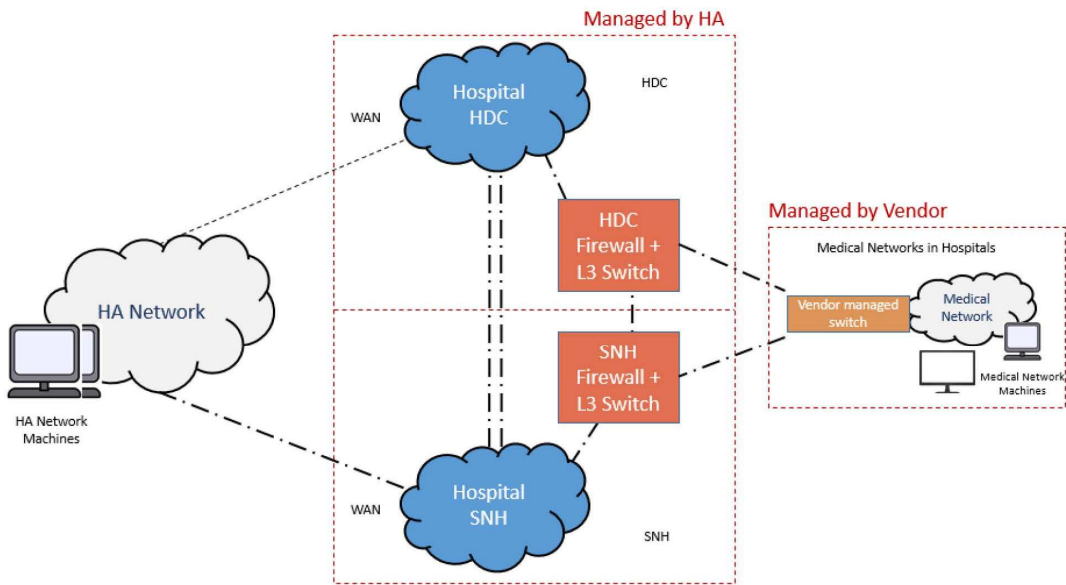


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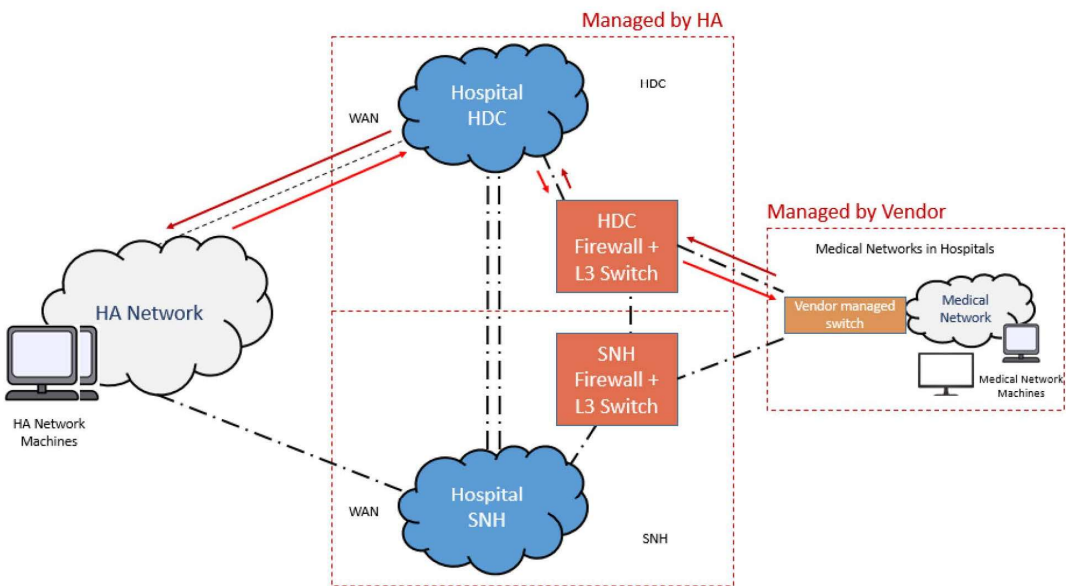
C. Failure and Recovery Scenarios in Hospitals for Vendor Managed Network Switches

C.1 Model A (Single Vendor Managed Layer 2 Switch)

C.1.1 Network Diagram

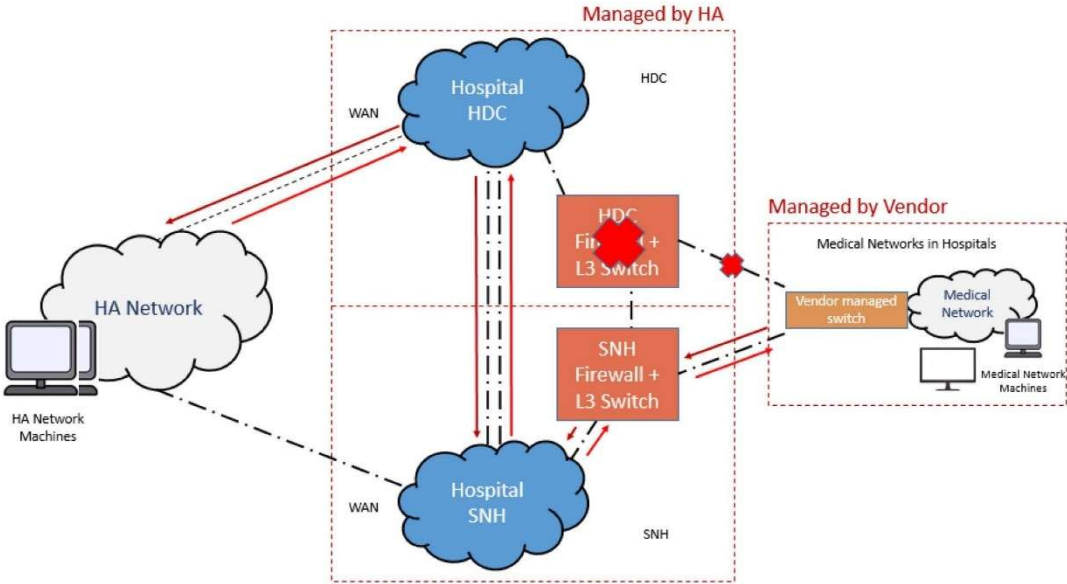


C.1.2 Normal Network Path



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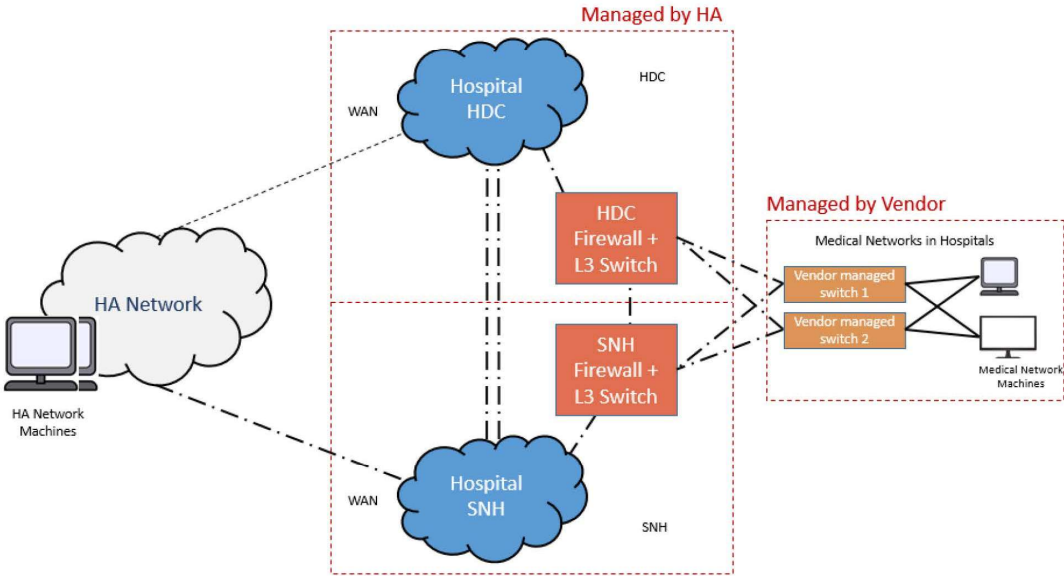
C.1.3 Failure Scenario



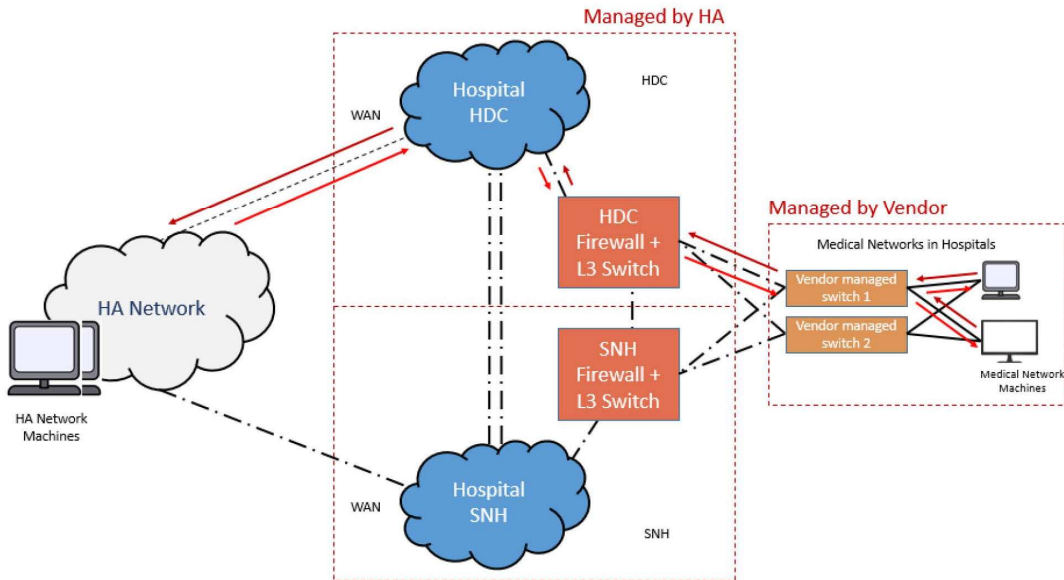
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C.2 Model B (Resilient Vendor Managed Layer 2 Switches)

C.2.1 Network Diagram

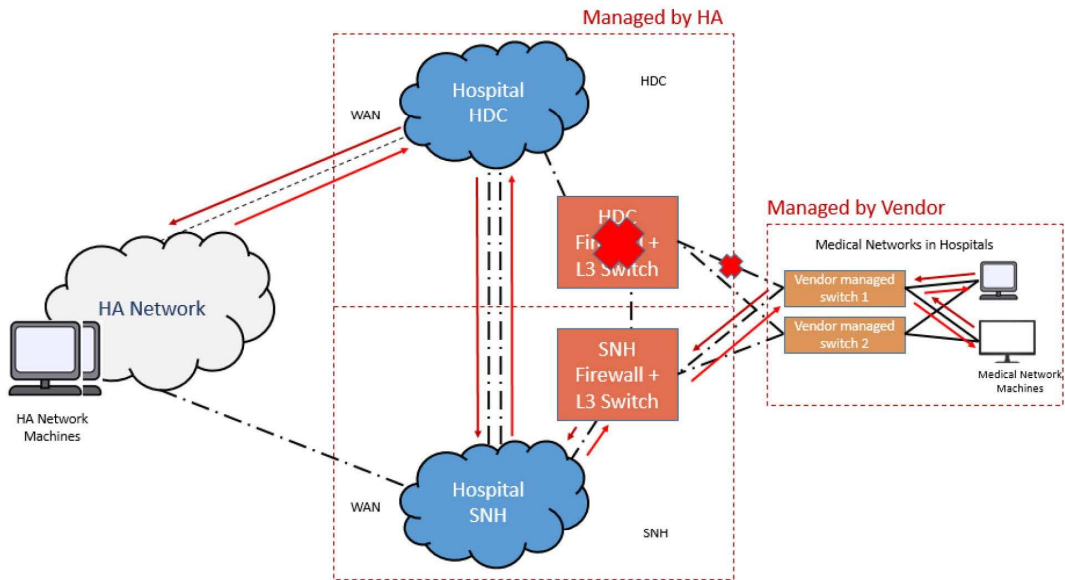


C.2.2 Normal Network Path

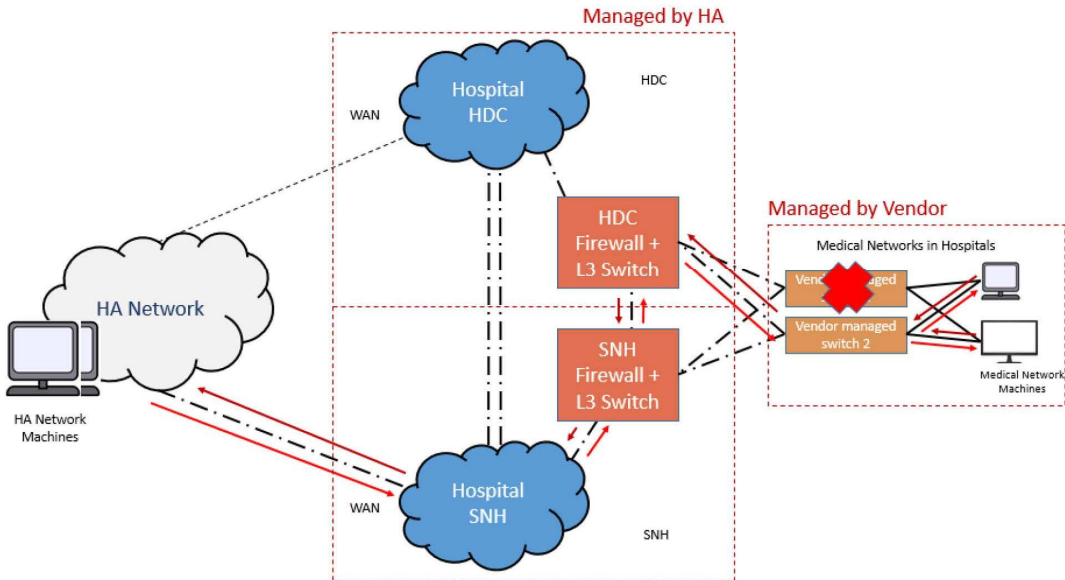


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C.2.3 Failure Scenario B1



C.2.4 Failure Scenario B2



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D. Vendor System Security Compliance Report (Sample)

Hospital: _____ Name of Systems: _____

Installation Location: _____ IP Subnet: _____

Security Requirements for Vendor System/Equipment Installed in HA

Items for Verification with Vendor		Comply (Y/N/NA)	Remark (if "N" or "NA")
A. Data Security (Review in regular basis)			
A1	Confidential data downloaded from the System/Equipment to end-user devices should be encrypted		
A2	Confidential data transferring between the System/Equipment and other HA IT systems should "preferably" be encrypted		
A3	Confidential data stored within the System/Equipment should "preferably" be encrypted		
A4	Confidential data stored in backup storage should be encrypted		
A5	Confidential data must not be exported for any usage unless prior authorisation has been obtained from HA.		
A6	Is the confidential data in System/Equipment and backup being protected from unauthorized access / leakage, including physical security controls? Please specify the controls in "Remark"		
B. Application Security (Review in regular basis)			
B1	The application should support role-based access control		
B2	The application should employ prevalent authentication mechanism at reasonable safety level		
B3	The application should apply network level encryption		
B4	The application should provide health-checking information		
B5	The application should keep audit logs		
B6	Conformance to HA's Guidelines for Application Security		
C. Network Security (Review in regular basis)			
C1	The System/Equipment should not have any network connection to external parties and should not have any unauthorized network connections		

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Items for Verification with Vendor		Comply (Y/N/NA)	Remark (if "N" or "NA")
C2	The System/Equipment network should connect to the network port provided by HA		
C3	The System/Equipment network should use IP addresses as assigned by HA		
C4	Only the authorised network traffic is permitted between the System/Equipment network and HA network		
C5	Formal change request and endorsement process for defining and implementing the network firewall policies		
D. Server Security (Review in regular basis)			
D1	Vendor should implement the server security as described in the Guidelines for Windows Server Hardening and the Guidelines for Host Security Hardening		
D2	Vendor should install into the servers an anti-virus program running with the latest virus definitions		
D3	Vendor should install the latest security patches in the servers		
D4	Vendor should perform a regular scanning in the servers		
E. Client / Desktop Security (Review in regular basis)			
E1	Vendor should implement the security controls at the PCs of the System/Equipment as described in the Guidelines for Security Requirements for HA PCs and Notebooks		
F. Security Incident Reporting (On-going exercise)			
F1	Vendor should immediately report security incidents to Cluster/Hospital management		
G. Vendor Maintenance (Review in regular basis)			
G1	Vendor should erase the data in storage devices before taking away the equipment for repair		
G2	Vendor should perform technical support on-site unless appropriate remote support arrangement is endorsed		
G3	Vendor support staff should sign the non-disclosure confidentiality agreement		
G4	When equipment is required to be taken away for offsite repair, are there ways to remove / erase / protect the confidential data in the equipment form leakage? Please specify the controls in "Remark"		

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Items for Verification with Vendor		Comply (Y/N/NA)	Remark (if "N" or "NA")
H. Privacy Control (Review in regular basis)			
H1	Are there any user authentication controls present in the System/Equipment?		
H2	Is unique user ID being assigned to every user?		
H3	Does the System/Equipment allow setting of complex password such as upper / lower case, alpha, numeric and special characters?		
H4	Does the System/Equipment provide audit trails of user accesses? Please specify the controls in "Remark" .		
H5	Is there any means to synchronize System/Equipment time with a trustworthy time server such as HA time server for accurate system record?		
H6	Perform user account review annually and disable inactive user immediately.		

Assumptions

1. in-direct offline storage should not be used

Full Name of Vendor Staff: _____ Vendor Company: _____

Position of Vendor Staff _____ Company Chop: _____

Signature of Vendor Staff: _____ Date: _____

Indicative Price Proposal

Item No.	Description	Estimated Quantity	F.I.S./Hong Kong Price Including Installation		Delivery Lead Time
			Unit Price (HK\$)	Total Amount (HK\$)	
1	Single Dose Plateletpheresis Collection Sets	38,000 sets			
2	Double Dose Plateletpheresis Collection Sets	8,000 sets			
Our/My EOI offer remains valid for a period of <u>180 days</u> from the closing date of this EOI.					
Notes:					
(a) All indicative prices of optional items must be quoted separately, if any.					

Company Chop _____

No Offer Reply Slip

- Tenderers who do not intend to make offer to this Expression of Interest (EOI) should complete and return this 'No Offer Reply Slip' before the closing date and time as specified below;
- Information provided will be updated for reference in future tender exercise;
- Failure to do so may lead to deletion from the vendor list maintained by the Hospital Authority.

Kowloon Central Cluster
Chairman of Tender Opening Committee

Fax: 2771 0373

Expression of Interest Details

Expression of Interest for the Supply of Plateletpheresis Collection Sets with On-loan Equipment for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority
EOI Ref : EOI-KCC/T/H1/036/26/BTS

Closing Date and Time : before 12:00 noon (Hong Kong Time) on 5 October 2026

With reference to the tender invitation of captioned subject, I regret to advise that I cannot provide the quotation(s) on the following reason(s):

(Please tick against the box where applicable)

☐ The requirement is out of the range of our supply / service. The product(s) we are selling / The service(s) we are providing:

☐ The required tender specifications cannot be met.
(Please specify which mandatory requirement(s) cannot be met)

☐ The delivery date of the goods / service job cannot be met.

☐ Others (Please specify)

_____ (Signature)

_____ (Name in Block Letters)

_____ (Post Title)

_____ (Name of Company)

_____ (Email and Telephone)

_____ (Date)

_____ (Company stamp)