HOSPITAL UiTM PUNCAK ALAM

JABATAN INFRASTRUKTUR

SENARAI SEMAK PROSES PENGUJIAN DAN PERTAULIAHAN (T&C)

1	Empat (4) salinan penghantaran paralatan(*Delivery Order)*	
2	Empat (4) salinan *invoice* pembayaran	
3	Empat (4) salinan pesanan tempatan(*Local Oder)*	
4	Empat(4)salinan sijil pengujian dan pertauliahan(T&C)	
5	Empat (4) salinan kenyataan tawaran (E Procurement Plus)	
6	Salinan keputusan pengujian elektrik peralatan(*Electrical Safety Test)* ***Electrical Safety Test*** **mesti dijalankan di lokasi (T&C).**	
7	Salinan senarai semak *Performace Test Result* **(Dilakukan di lokasi T&C)**	
8	Salinan *Medical Devices Authority* (MDA) Company dan Peralatan	
9	Service manual & Operation Manual	
10	Senarai alat ganti berserta harga yang perlu di ditukar secara berjadual dan tidak berjadual	
11	Kadar harga penyelenggaraan berkala (PPM)	

NOTA :

1. Pihak pengguna harus memaklumkan 14 hari sebelum Proses Pengujian&Pertauliahan(T&C) dilakukan. Sila email permakluman T&C kepada **sitilaila@uitm.edu.my**, **faizolmohtar@uitm.edu.my** dan **bems_z1p3@triplc.com.my** dan **satriaacesbems2@gmail.com**
2. Senarai semak ini harus dilengkapkan semasa proses T&C.
3. Tandakan (✓) pada bahagian yang disediakan.

DISEDIAKAN OLEH (VENDOR)	DISAHKAN OLEH (PENGGUNA)

Tick (✓) where appropriate

PART 1 ASSET DETAILS

HOSPITAL :
LOCATION :
DEPARTMENT :
LOCATION CODE :
ASSET DESCRIPTION :
ASSET NO. :
GMDN & UMDNS TYPE CODE :
BRAND :
MDA RISK CLASSIFICATION :
MODEL :
MANUFACTURER :
MAKE :
SERIAL NO. :
CALIBRATION/ QA REQUIREMENT : ☐ Required ☐ Not Required
(Calibration is not under CC scope, calibration by the supplier shall be one year from Acceptance date)
SOFTWARE VERSION NO. :
MANUFACTURER RECOMMENDED LIFESPAN : years
CALIBRATION/ QA COVERED DURING WARRANTY ☐ YES ☐ NO
(If no, under reimbursable work to user)
POWER SPECIFICATION : (Watt) Volt-Ampere
CALIBRATION / QA FREQUENCY : / years

PART 2 PURCHASE DETAILS

SUPPLIER :
(Bumi-agent/as stated on LPO)
CONTACT PERSON :
ADDRESS :
CONTACT NO. :

AUTHORISED SERVICE AGENT:
(Sole distributor / service warranty provider)
CONTACT PERSON :
ADDRESS :
CONTACT NO. :

LOCAL PURCHASE ORDER NO. :
PURCHASE PRICE : RM
(Itemized price / quantity / type code)

PART 3 WARRANTY DETAILS

PURCHASE DATE :
(LPO date)
PPM FREQUENCY :
(Manufacturer recommendation)
MANUFACTURING DATE :
(Date of equipment is produced)
WARRANTY PPM TENTATIVE DATES :
T&C DATE :
(First T&C Date)
1) 4)
WARRANTY START DATE :
(Acceptance Certificate date for whole system)
2) 5)
WARRANTY END DATE :
3) 6)

PART 4 PHYSICAL INSPECTION

	PASS	FAIL	NA
1. Chassis - verify physical integrity, cleanliness and condition	☐	☐	☐
2. Mount/ Fasteners - verify physical integrity	☐	☐	☐
3. Castor / Brakes - verify proper function and integrity	☐	☐	☐
4. Power Cord/Strain Relief - verify physical integrity (do not accept if no strain relief on the cord or modified plug head)	☐	☐	☐
5. Fittings/ Connectors - check all fittings/connectors	☐	☐	☐
6. Control/Switches - verify proper operation of controls	☐	☐	☐
7. Indicators/ Displays - verify proper illumination and operation	☐	☐	☐
8. Accessories - verify physical integrity	☐	☐	☐
9. Alarms - verify functionality	☐	☐	☐

PART 5 PERFORMANCE TEST (TO BE DONE BY SUPPLIER)

Relevant Performance Test on equipment : ☐ Done ☐ Not Done ☐ Pass ☐ Fail
Performance check of software ☐ Pass ☐ Fail ☐ NA
Performance check of all accessories ☐ Pass ☐ Fail

PART 6 ELECTRICAL SAFETY TEST

Electrical Safety Test (Please attach report) : ☐ Pass ☐ Fail ☐ Not Applicable
(In accordance to MS IEC 60601/ 61010/ 62353)
Equipment Power Cord Classification : ☐ Class I ☐ Class II
Equipment Type : ☐ B ☐ BF CF ☐
(Verify Equipment Type and markings on the equipment)

ASSET NO ►

PART 7 TESTING & COMMISSIONING REQUIREMENTS

Tick (✓) where appropriate

Note: Equipment shall be under exemption until ALL relevant documents are provided

#	Document meets the following requirements	Available	Not Available	Remarks
1	Copy of **PURCHASE AGREEMENT / TENDER DOCUMENT / CONTRACT DOCUMENT / QUOTATION**			
2	Copy of **PURCHASE ORDER (LPO)**			
3	Copy of **DELIVERY NOTE (Delivery Order)** and ensure that;			
	3.1) Physical delivery **MUST** tally with Delivery Note			
	3.2) To specify separately between **Main System**, **Subsystems, Accessories** and **Consumables**			
4	Copy of Notice to Commence / to Stop Service (SNF)			
5	**USER MANUAL / OPERATION MANUAL / APPLICATION MANUAL** *(Hospital copy shall be an original copy)*			
6	**SERVICE / MAINTENANCE MANUAL BOTH SOFTCOPY AND HARDCOPY** with the following;			
	6.1) **INSTALLATION MANUAL**			
	6.2) **PPM MANUAL**			
	6.3) **CIRCUIT DIAGRAM MANUAL**			
	6.4) **SPARE PARTS LIST/MANUAL**			
7	**PPM CHECKLIST** *(as per manufacturer requirement)*			
8	List of tools/test equipment required (during maintenance & calibration)			
9	**CERTIFICATE OF ACCEPTANCE**			
10	Declaration of **CE or IEC conformance** and a copy of **CALIBRATION CERTIFICATE**			
11	A backup copy of **SOFTWARE** for user and **SOFTWARE LICENSE** inclusive of **access key**			
12	Declaration of Previous Recalls / Device Alerts / End of Life Date			
13	**FACTORY PERFORMANCE TEST RESULT**			
14	**QA RESULT & CERTIFICATE**			
15	**MDA SUPPLIER & EQUIPMENT CERTIFICATE**			
16	**ELECTRICAL SAFETY TEST & TEST EQUIPMENT CALIBRATION CERTIFICATE** (during testing and commissioning)			
17	**SERVICE ENGINEER TRAINING CERTIFICATE** (Manufacturer Training)			
18	Response time during warranty period - On call and on Site			
19	**TENTATIVE DATES & SYLLABUS** for User Training			
20	**TENTATIVE DATES & SYLLABUS** for Technical Training			

Remarks:

1. Power cord must strain relief (Medical grade) - if no strain relief on the cord or modified plug head need to replace with medical grade.
2. For radiology equipment, QA and QC test report is compulsory
3. Certificates of installation (JKKP) *if applicable

ASSET NO

PART 8	ITEMIZED LIST			
	List of Subsystems	**Qty**	**Price**	**S/N (if applicable) :**
	a)			
	b)			
	c)			
	d)			
	e)			
	f)			
	g)			
	h)			
	i)			
	j)			
	k)			
	l)			
	List of accessories *(Accessories shall carry the same warranty period as main system, if it is not shall be reimbursable to end user)*	**Qty**	**Price**	**S/N (if applicable) :**
	a)			
	b)			
	c)			
	d)			
	e)			
	f)			
	g)			
	h)			
	i)			
	j)			
	k)			
	l)			
	Plan Preventive Maintenance (PPM)	**Qty**	**Price**	**Remarks**
	a)			

ASSET NO ►

PART 9 TESTING & COMMISSIONING REFERENCE NUMBER AND STATUS

Tick (✓) where appropriate

T&C Work Order No ► _____ T&C Date ► _____

☐ Done ☐ Not Done Remarks : _____

☐ Accepted ☐ Not Accepted (*Refer to Part 10*)

PART 10 DEFECT LIST

Problem/Defect Statement
Remarks
Suggestion

PART 11 DEVICE RISK IDENTIFICATION

***Note: Supplier to declare potential risk associated with the device. (Technical staff and User to confirm and ask for details)*

No	*Identified Risks*	*Risk Control*	*Risk Reporting / Risk Monitoring*

PART 12 TRAINING PROVISION BY SUPPLIER

Technical Training : ☐ Done ☐ Not Done

User training on clinical usage & daily maintenance : ☐ Done ☐ Not Done

Emphasis on Do(s) & Don't(s)

Include decontamination & sterilization procedure

☐ Reschedule Reschedule date : _____

(Please indicate reschedule date)

PART 13 FACILITIES AND LOCATION ASSESMENT

Uninterrupted Power Supply	☐ Not Required	☐ Required and provided	☐ Required but not provided	☐ Remarks :
Back-up Battery	☐ Not Required	☐ Required and provided	☐ Required but not provided	☐ Remarks :
Room Temperature requirement	☐ Not Specified	☐ Comply	☐ Does Not Comply	☐ Remarks:
Room Humidity requirement	☐ Not Specified	☐ Comply	☐ Does Not Comply	☐ Remarks :
Electrical Power Supply	☐ Sufficient	☐ Insufficient	☐ Remarks :	
Compressed Air supply	☐ Sufficient	☐ Insufficient	☐ Remarks :	
Medical Gas Supply	☐ Sufficient	☐ Insufficient	☐ Remarks :	
Water Supply	☐ Sufficient	☐ Insufficient	☐ Remarks :	

ASSET NO ►

PART 14 ATTENDANCE LIST

Venue :

Date :

No	Name	Designation	Department/Company	Contact No.	Signature

VERIFICATION OF TESTING & COMMISSIONING DONE

SUPPLIER SERVICE ENGINEER :	HOSPITAL REPRESENTATIVE :	ENGINEERING REPRESENTATIVE :	CC REPRESENTATIVE :
Name :	**Name :**	**Name :**	**Name :**
Designation :	**Designation :**	**Designation :**	**Designation :**
Date :	**Date :**	**Date :**	**Date :**