September 2013

DRAFT
MEDICAL DEVICE
GUIDANCE DOCUMENT

REQUIREMENTS FOR INSTALLATION, TESTING & COMMISSIONING, AND ACCEPTANCE OF MEDICAL DEVICE

Medical Device Authority
MINISTRY OF HEALTH MALAYSIA

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Preface

Introduction

This guidance document outlines a systematic approach for the installation, testing and commissioning (T&C) and acceptance of medical devices at healthcare facility, aesthetic settings, and premises for wellness programs and related services.

It is intended primarily for use by persons involved in the in healthcare installation, testing and commissioning and acceptance of medical devices. This activity is to minimize risks, ensure safety and complying with intended use of medical devices upon acceptance.

The procedures stated in this document cover the activities in pre-requisite installation, calibration, T&C, issuance of certificate, training and acceptance of medical devices.

GUIDANCE DOCUMENT: REQUIREMENTS FOR INSTALLATION, TESTING & COMMISSIONING, AND ACCEPTANCE OF MEDICAL DEVICE

1 Purpose

This document is intended to:

i. Provide guidance to comply with the requirements under Section 43 - Usage, operation, maintenance, etc., of medical device in the Medical Device Act 737 2012.

ii. Provide guidance on the procedures for installation, T&C and acceptance of medical devices in healthcare facility, aesthetic settings, and premises for wellness programs and related services.

iii. Ensure the medical device is appropriately installed, tested and commissioned by the equipment specialists or competent personnel and accepted in accordance with manufacturer's specification, purchase agreement and statutory requirement.

2 Scope

This Guidance document applies to all products that fall within the definition of a medical device, as defined in GD-01: Definition of Medical Device.

This Guidance Document applies to all medical devices which require installation, T&C and acceptance in healthcare facility, aesthetic settings, and premises for wellness programs and related services.

This guidance document does not apply to all active and non-active implantable medical devices.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Acceptance for active medical device

A process that involves inspection, testing, verification and validation of relevant documents upon the completion of installation (where applicable), T&C, and training of medical device.

3.2 Acceptance for non-active medical device

A process that involves physical inspection, verification, and validation of relevant documents upon the completion of training of medical device.

3.3 Active medical device

Any medical device, operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. *Medical devices* intended to transmit energy, substance or other elements between an active medical device and the patient, without any significant change, is not considered to be active medical device.

3.4 Aesthetic settings

A facility that offers aesthetic services on human.

3.5 Building services

Services that are concerned with aspects of the built environment, i.e. involving air conditioning and mechanical ventilation, electrical, fire services, fire safety, water and waste services, data and communications, security and access control, vertical transportation, acoustics in buildings and energy management.

3.6 Calibration

A procedure used to determine device's accuracy using test equipment whose own accuracy is appropriate and has been verified; and then, as needed, adjusting that device to meet the manufacturer's specification.

3.7 Clinical investigation

Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device to assess the safety and performance of the medical device in question and evaluate whether it is suitable for the purpose(s) and the population(s) for which it is intended.

3.8 Competent technical personnel

A person who possesses a combination of knowledge, skills and behavior utilized to improve performance. More generally, competence is the state or quality of being adequately or well qualified, having the ability to perform a specific job/role in healthcare facility, aesthetic settings, and premises for wellness programs and related services to carry out installation, T&C, acceptance and maintenance of medical devices in accordance to manufacturer's specification and meets the competency requirement as described in competency guideline by Medical Device Authority (MDA).

3.9 Designated device

Medical device specified by the Minister to be a designated medical device by order published in the Gazette. (Medical Device Act 737 2012).

3.10 Designated medical device permit

The permit issued to a person who operate any designated device.

3.11 Equipment specialist

The technical personnel trained by the manufacturer.

3.12 Healthcare facility

Any premises in which one or more members of the public receive healthcare services, which includes:

a) medical, dental, nursing, midwifery, allied health, pharmacy, and ambulance services and any other services provided by healthcare professional;

b) accommodation for the purpose of an service provided;

c) any service for the screening, diagnosis, or treatment of persons suffering from, or believed to be suffering from, any disease, injury or disability of mind and body;

d) any service for preventive and promotion of health purpose;

e) any services provided by any healthcare para-professional;

f) any service for curing or alleviating abnormal condition of the human body by the application of any apparatus, equipment, instrument or device or any other medical technology; or

g) any health-related services.

3.13 Labelling

Includes any written material accompanying the medical device such as instructions for use, operators' manual or any instructions of control feature markings attached to the device or system.

3.14 Major upgrading

Improvement done on the device by adding or replacing major components and / or software.

3.15 Medical device

a) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, intended by manufacturer to be used, alone or in combination, for human beings for the purpose of:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

iii. investigation, replacement or modification, or support of the anatomy or of a physiological process;

iv. support or sustaining life;

v. control of conception;

vi. disinfection of medical devices; or

vii. providing information for medical or diagnostic purpose by means of *in-vitro* examination of specimens derived from the human body,

which does achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; and

b) any instrument, apparatus, implement, machine, appliance, implant, *in-vitro* reagent or calibrator, software, material or other similar or related article, to be used on the human body, which the Minister may, after taking into consideration issues of public safety, public health or public risk, declare to be a medical device by order published in the *Gazette*.

3.16 Medical Device Authority

Authority to control and regulate medical device, its medical device industry and its activities, and to enforce the medical device laws, and for related matters.

3.17 Medical device establishment

Licensed manufacturer, distributor or Authorised Representative (AR) of medical device under Medical Device Act 2012 [Act 737].

3.18 Medical device owner

Any healthcare facility, aesthetic settings, wellness program and any related services of which the medical device belongs to.

3.19 Mobile healthcare facilities

A facility from which ranges of primary health services are provided and where a mobile unit / bus / car provides the resources for the service.

3.20 Professional competent technical personnel

A person who is licensed to practice biomedical engineering in Malaysia after meeting all requirements of the law (Registration of Engineers Act 1967).

3.21 Shop drawing

Detailed construction and fabrication drawings that show the proposed material, shape, size, and assembly of the parts and how the entire unit will be installed.

3.22 Trial evaluation

Medical device put to use for the purpose of evaluation of device performance within a specified time frame.

4 Procedure

For a newly purchased medical device, the medical device establishment shall be responsible to carry out the installation and T&C of the medical device while the medical device owner shall be responsible for the acceptance processes of the medical device as detailed in this document (refer Annex 1).

Medical devices which are leased, on-loan, for trial evaluation, clinical investigation, transferred and undergone major upgrading, shall be installed, tested and commissioned before initial use.

4.1 Pre-requisite

4.1.1 Documentation

4.1.1.1 For the purchase of a new medical device, documentation as listed (but not limited to) below shall be made available to medical device owner by medical device establishment prior to T&C:

a) device registration certificate and Establishment License from MDA;

b) purchase agreement/ tender document/ contract document/quotation;

c) purchase order, T&C date by the medical device establishment;

d) relevant licenses and certificates:

   i. factory test certificate;

   ii. software license (applicable only for software related medical device);

e) List of equipment specialist responsible to carry out the T&C;

f) manuals (user, operation, service, spare part list, list of tool and test equipment required, circuit diagram, planned preventive maintenance manual and checklist as per manufacturer's requirement.);

g) all approval document from regulatory body (where relevant); and

h) as build drawing of site and facility where relevant.

4.1.1.2 For other than newly purchased medical devices such as leased, on-loan, for trial evaluation, clinical investigation, transferred, donated and medical device undergone major upgrading, documentation shall include (but not limited to):

a) device registration certificate and establishment license (if applicable) from MDA;

b) purchase agreement/leased agreement/tender document / quotation (where applicable);

c) purchase order, T&C date by the medical device establishment (where applicable);

d) relevant licenses and certificates:

i. factory test certificate or equivalent certificate;

ii. software license (applicable only for software related medical device);and

iii. installation qualification, if applicable;

e) list of equipment specialist and/or competent personnel responsible to carry out the T&C;

f) manuals (user, operation, service, spare part list, list of tools and test equipment required, circuit diagram, PPM Manual and checklist as per manufacturer requirement);

g) all approval document from regulatory body (where relevant);

h) as build drawing of site and facility where relevant;

i) maintenance history (include quality assurance test details where relevant);

j) a clear statement that the equipment is being resold/donated; and

k) proof of decontamination.

4.1.2 Medical device establishment shall provide written notification of any specific installation and T&C requirements.

4.1.3 For non-active device, only inspection, training and acceptance procedure is required.

4.1.4 For a designated device, all drawings, safety requirements and installation plan shall be submitted for approval to the relevant regulatory authority. The medical device establishment shall only commence with the

installations of the designated device upon receiving the designated device permit from the regulatory authority.

4.1.5 For management of radioactive source; medical device owner shall refer to medical device establishment and regulatory authority.

4.2 Medical device category

Medical devices are categorized into active medical device and non-active medical devices.

Table 1. Examples of active medical devices and non-active medical devices

Medical Device Category	Examples
Active Medical Devices	*Active medical device that **requires installation*** 1. Scanning Systems, Magnetic Resonance Imaging, Full-Body 2. Scanning Systems, Computed Tomography 3. Linear Accelerators *Active medical device that **does not require installation*** 1. Hemodialysis Units 2. Ventilators, Intensive Care 3. Lasers, Carbon Dioxide, Surgical/Dermatologic 4. Defibrillators, External, Automated
Non-active Medical Devices	1. Tongue depressor 2. Examination glove 3. Contact lenses

4.3 Installation

4.3.1 For active medical device that requires installation

4.3.1.1 Installation usually applies when any of the following occurs:

a) substantial assembly work will be required on-site;

b) there are dedicated plumbing, electrical and gas pipeline connection for the equipment; or

c) the device needs to be permanently fixed in place.

4.3.1.2 The medical device owner with medical device establishment input or advice shall ensure site preparation is in accordance to establishment and regulatory requirement.

4.3.1.3 The medical device owner shall ensure that all technical drawings (medical device layout, mechanical and electrical (M&E), civil and structural) is submitted to the relevant authorities / departments for approval prior to installation.

4.3.1.4 Medical device installation layout shall be endorsed by professional competent technical personnel.

4.3.1.5 Medical device establishment shall install the medical device in accordance to manufacturer's technical specification for installation work.

4.3.1.6 All as built drawings shall be made available and submitted to competent technical personnel of medical device owner.

4.3.2 For active medical device which <u>does not require installation</u>

a) The medical device owner, with medical device establishment input or advice shall perform pre-check prior to T&C. The pre-check includes:

   i. availability and sufficient utility i.e.: medical gas, electrical supply (essential/non-essential), water supply;

   ii. appropriate placement area i.e.; ventilation, humidity, room temperature.

4.4 Site preparation

4.4.1 Renovation

4.4.1.1 Medical device owner shall furnish the details of the renovation scope of work and a room data sheet recommended by medical device establishment. A room data sheet provides information on the minimum requirements for the room where the medical device is to be installed. The information shall include room details, room fabric, fittings and furniture, fixtures and equipment with associated services.

4.4.1.2 Medical device owner shall prepare shop drawings (plan and side elevations view) that includes :

a) architectural drawings giving details of the renovation works as stipulated in the scope of work. Details of any partitions or panels required should

include furniture, type of floor finishes, wall finishes and ceiling finishes as recommended by the establishment, local statutory and regulatory requirement;

b) structure drawing shall be endorsed by the professional engineer if required;

c) layout and positioning details of the medical device and related systems as recommended by the establishment and local statutory and regulatory requirement;

d) utilities details to support the installation of medical device and corresponding associated drawing. Refer Table 2.

Table 2. Examples of the utilities details for renovations

No	Examples of utilities	Details to be provided				
1	Cold water	Type of pipe	Pressure	Flow rate	Size (∅)	Location (e.g. from wall, from ceiling, distance, height)
2	Treated water	Type of pipe	Pressure	Flow rate	Size (∅)	Location (e.g. from wall, from ceiling, distance, height)
3	Electrical Supply	Voltage		Phase	Current	Location (e.g. from wall, from ceiling, distance, height)
4	Steam supply	Pressure		Flow rate	Size (∅)	Location (e.g. from wall, from ceiling, distance, height)
5	Medical gases	Type of gas		Pressure	Flow rate	Location (e.g. from wall, from ceiling, distance, height)
6	Drain	Type of pipe		Size (∅)		

4.4.1.3 Medical device owner shall provide a matrix of responsibilities clearly stating the parties responsible to prepare or provide a particular scope of work or utilities required for proper installation of the medical device.

4.4.1.4 Prior to installation, all shop drawings related to installation of the medical device shall be verified by professional competent technical personnel (e.g. competent technical personnel, medical physicist – depending on the type of medical device) and agreed by user.

4.4.1.5 Medical device owner shall carry out the renovation and site preparation works according to the approved scope of work and shop drawings.

4.4.1.6 The renovation and site preparation works shall be supervised by competent technical personnel.

4.4.2 New building / new building extension

4.4.2.1 Medical device owner shall appoint a team of consultants consisting of architects, civil and structural engineers, mechanical and electrical engineers, quantity surveyor and medical device planner. The consultants shall be registered with their respective professional boards or other relevant bodies.

4.4.2.2 All requirements as specified from 4.4.1.2 until 4.4.1.6 of this document shall apply.

4.4.3 Mobile Healthcare Facilities

4.4.3.1 Services provided on fixed routes and at a number of points, which are visited on a regular basis. Some visiting points may involve the use of a room in a building, but the resources (equipment, stocks) are provided from the mobile when the service is available and are not maintained at the visiting point.

4.4.3.2 Medical device owner shall submit a technical report on the suitability of the proposed vehicle from Road Transport Department;

4.4.3.3 Medical device owner shall prepare relevant document that includes:

a) drawings giving details of the retrofitting works required to make the mobile facilities functional for its purpose. Details of any partitions or panels required should include the type of floor finishes, wall finishes and ceiling finishes as recommended by the establishment and relevant authority;

b) layout and positioning details of the medical device and related systems;

c) safety features or harness required as recommended by the medical device establishment and relevant authority; and

d) utilities details such as cold water supply, treated water supply, electrical supply, steam supply, medical gases and drain. Refer Table 2.

4.4.3.4 All drawings shall be approved by user and authorised persons (e.g. competent technical personnel, medical physicist and Road Transport Department – depending on the type of medical device).

4.4.3.5 The mobile medical device owner shall carry out the vehicle renovation and site preparation works according to the approved scope of work and drawings.

4.4.3.6 The mobile medical device owner renovation and site preparation works shall be supervised by the appointed consultants and competent technical personnel.

4.5 Device installation

Site preparation works for the installation of medical device shall be ready prior to installation.

4.5.1 Appointed competent technical personnel by medical device owner shall:

a) verify all relevant documents prior to device installation;

b) ensure the facility is ready prior to installation as required by the manufacturer and relevant statutory requirement, e.g., for mri: the load consideration, rf shielding requirement and power supply requirement;

c) ensure that the installation complies with manufacturer's instruction, approved technical drawings and statutory requirements; and

d) ensure that the installation complies with all safety requirements as required by manufacturer and relevant authority.

4.5.2 Medical device establishment shall ensure only equipment specialist(s) will carry out the installation.

4.6 Calibration

4.6.1 The medical device establishment shall produce the manufacturer's calibration certificate or report for any medical device that *does not* require on-site calibration.

4.6.2 The medical device establishment shall perform the calibration as per manufacturer's specification for any medical device that requires on-site calibration.

4.6.3 Any medical device that requires certified calibration shall be carried out by a recognized and certified calibration laboratory; and medical device establishment shall ensure the calibration is performed as per the manufacturer's specification.

4.6.4 Medical device establishment shall submit calibration test report and calibration certificate of the medical device to the medical device owner.

4.6.5 The calibration certificate of all test equipment used shall also be submitted to the medical device owner.

4.6.6 The calibration test report shall be verified and endorsed by competent technical personnel.

4.6.7 The medical device establishment shall rectify all faults that causes calibration to fail and re-perform the calibration until it passes.

4.7 Testing and commissioning

4.7.1 The medical device owner shall verify that the medical device delivered is in good condition and complete based on the purchase document.

4.7.2 Physical evaluation / visual checks of the medical equipment include observations of:

a) chassis - verify physical integrity, cleanliness and condition;

b) mount / fasteners - verify physical integrity;

c) castor / brakes - verify proper function and integrity;

d) power cord / strain relief - verify that power cord is of medical grade and comes with strain relief;

e) fittings / connectors - check all external fittings/ connectors;

f) control / switches - verify proper operation of controls;

g) indicators / displays - verify for good condition;

h) accessories - verify physical integrity; and

i) labelling - verify correctness.

Refer Annex 2 for sample of testing and commissioning checklist.

4.7.3 T&C is best performed at the very location of which the medical equipment will be placed for use.

4.7.4 Medical device establishment shall operate the medical device to ensure it is functional and ready to be tested.

4.7.5 The competent technical personnel of the medical device owner shall ensure that all required document as listed in Clause 5 and the following is made available during T&C by the medical device establishment:

a) copy of delivery note / delivery order and ensure that;

   i. physical delivery must tally with delivery note;

   ii. to specify separately between main system, subsystems, accessories and consumables;

b) certificate of acceptance;

c) declaration of CE or IEC conformance and a copy of calibration certificate;

d) backup copy of software for user and software license inclusive of access key;

e) declaration of previous recalls / device alerts / end of life date;

f) quality assurance result and certificate;

g) service engineer training certificate (manufacturer training);

h) response time during warranty period - on call and on site;

i) tentative date and syllabus for user training;

j) tentative date and syllabus for technical training;

4.7.6 The medical device establishment is required to perform specific tasks during T&C on the medical device and the task includes:

a) confirmation of items delivered based on purchase document;

b) validation of the specification/parameters using appropriate test equipment;

c) all other relevant safety test to the equipment shall also be conducted and recorded accordingly.

4.7.7 The equipment specialist from medical device establishment shall carry out performance and safety tests as required by the manufacturer, witnessed by competent technical personnel.

4.7.8 A label indicating the medical device passed the electrical safety test shall be affixed at a visible area on the device (Refer to Annex 4).

4.7.9 All results shall be documented, medical device establishment shall keep all documents according to retention period specified by MDA and a copy is submitted to medical device owner.

4.7.10 The competent technical personnel shall verify the performance and safety test carried out by equipment specialist from medical device establishment.

4.7.11 T&C shall be repeated upon rectification of all deficiencies by medical device establishment.

4.8 Inspection of non-active medical device

4.8.1 Medical device owner accepting the device has the discretion to determine when and where the device should be inspected and sampled for conformance to specifications depending upon the risk that failure of that device may pose.

4.8.2 Non-active Medical device shall be inspected by:

a) medical device establishment;

b) medical device owner – material / procurement warehouse; and

c) medical device owner - user.

4.8.3 Medical device owner shall perform general acceptance inspection on random sampling basis for non-active medical device against the purchase order.

4.8.4 Inspection tasks shall include but do not limited to:

a) checking and verifying the product is exactly as ordered and corresponds with the delivery note;

b) verification of quantity, size, consumable items and accessories delivered as stated in the purchase agreement;

c) visual inspection of the device or equipment for physical damage, incompleteness, misassemble, void, wear and / or abuse;

d) check relevant labelling on the device;

e) take note on batch number or lots in the event of a product recall;

f) contamination;

g) disseminate instructions and safety information when necessary.

4.8.5 Rejected medical devices shall be documented, rectified or replaced by the medical device establishment.

4.8.6 Medical device establishment shall provide proof of compliance to the specification in purchase document.

4.8.7 Records of inspection shall be kept by medical device owner.

4.9 Issuance of T&C Certificate

4.9.1 T&C certificate shall be issued by medical device establishment once T&C process is successfully completed. The certificate shall be signed by:

a) medical device establishment;

b) medical device owner; and

c) competent technical personnel.

4.10 Training

4.10.1 Equipment training

a) Medical device establishment shall provide on-site hands-on equipment training.

b) The equipment training module shall include but not limited to:

i. safety precautions in operating the medical device;

ii. proper operation / application including features unique to the particular manufacturer or model of medical device;

iii. user maintenance;

iv. cleanliness and decontamination;

v. operational verification procedures;

vi. recognition and correction of common operational problems;

vii. recognition of defective equipment and potential hazards;

viii. the risk associated with the device.

c) Certificate of attendance shall be issued by medical device establishment to the user upon completion of the training. (Refer Annex 7).

4.10.2 Technical training

a) Medical device establishment shall offer hands-on technical training to the competent technical personnel. The technical training module shall include the abovementioned equipment training module and other module not limited to:

   i. PPM according to manufacturers' specification;

   ii. maintenance competency as defined by MDA.

b) Certificate of competency shall be issued by medical device establishment to the competent technical personnel upon completion of the training.

4.11 Acceptance

4.11.1 Non active medical device

a) Non-active medical device is accepted upon completion of successful inspection and training.

b) The records of acceptance shall be signed by medical device establishment and medical device owner.

4.11.2 Active medical device

a) Competent technical personnel shall perform the tasks that includes, but not limited to:

   i. ensuring the medical device is exactly as ordered and corresponds with the delivery note;

   ii. verifying of quantity, consumable item and accessories delivered as stated in the purchase agreement;

   iii. ensuring the equipment has successfully undergone performance and safety tests;

   iv. checking of relevant labelling on the device;

   v. ensuring the medical device is delivered with a full set of documentation including user and operating manuals, spare part list, schematic diagram, PPM manual and checklist as recommended by manufacturer, validated T&C report and certificate, calibration certificate, training certificate and any other relevant documents). the documents delivered shall be in Malay or English;

   vi. ensuring the medical device technical support information from medical device establishment is submitted (address, person in-charge, telephone number, fax number, medical device registration number and any relevant information);

vii. ensuring the user and technical training on the medical device has been carried out.

b) Upon passing acceptance testing, the medical device shall be labelled (Refer Annex 4) indicating:

i. asset identification; (Refer Figure 1).

ii. warranty information; (Refer Figure 2)

iii. performance test pass label;

iv. electrical safety pass label (where applicable; Refer Figure 3); and

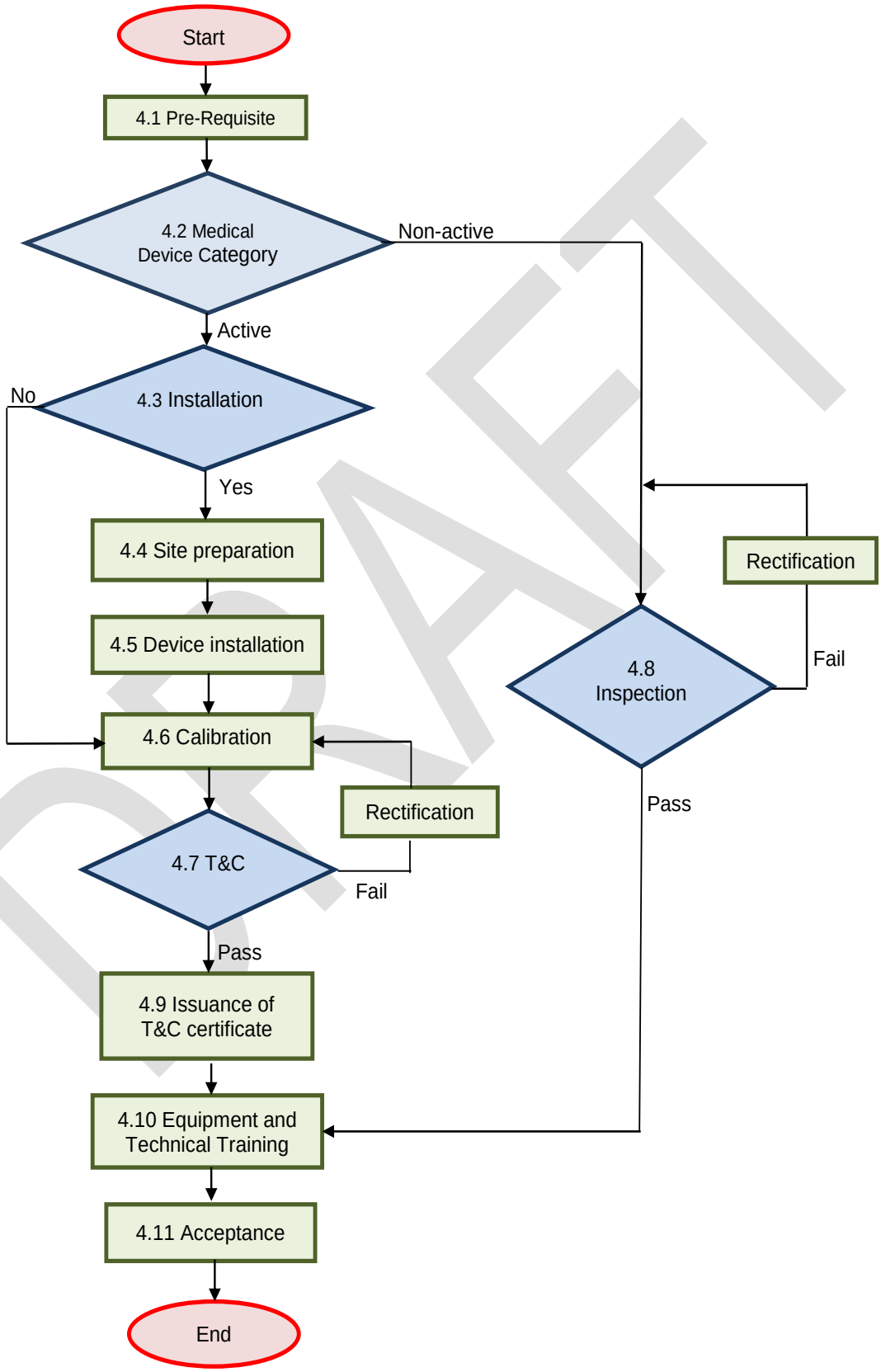
v. next PPM due date.

c) Acceptance certificate (refer Annex 5) shall be issued by medical device establishment once acceptance process is successfully completed. The certificate shall be signed by medical device establishment, medical device owner and competent technical personnel.

d) Warranty period and PPM frequency (within the warranty period) shall be specified in the acceptance certificate.

Annex 1

Flowchart of testing and acceptance of medical device



Annex 2
(informative)

Checklist of testing and commissioning

A. SAMPLE OF TESTING AND COMMISSIONING CHECKLIST

	Biomedical Engineering Maintenance Services **Testing & Commssioning Checklist**	Version 2.00 1st May 2011 Page 1 of 4

Tick (✓) where appropriate

PART 1 ASSET DETAILS

HOSPITAL	:	LOCATION	:
DEPARTMENT	:	LOCATION CODE	:
ASSET DESCRIPTION	:	ASSET NO	:
GMDN & UMDNS TYPE CODE	:	BRAND	:
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)*	
		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 *(Itemized price / quantity / type code)*	: RM

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 except if no strain relief on the cord or modified plug head)	☐	☐	☐

	PASS	FAIL	NA
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	Performance check of software	☐ Pass ☐ Fail
	☐ Pass	☐ Fail	Performance check of all accessories	☐ Pass ☐ Fail

PART 6 ELECTRICAL SAFETY TEST

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

VERIFICATION OF TESTING & COMMISSIONING DONE

SUPPLIER SERVICE ENGINEER :	HOSPITAL REPRESENTATIVE :	CC REPRESENTATIVE :
NAME:	NAME:	NAME:
DESIGNATION:	DESIGNATION:	DESIGNATION:
DATE:	DATE:	DATE:

	Biomedical Engineering Maintenance Services **Testing & Commissioning Checklist**	Version 2.00 1st May 2011 Page 2 of 4

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 on Variation in Service (VNF) and 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** with the following;			
	5.1) **INSTALLATION MANUAL**			
	5.2) **PPM MANUAL**			
	5.3) **CIRCUIT DIAGRAM MANUAL**			
	5.4) **SPARE PARTS LIST/MANUAL**			
8	**PPM CHECKLIST** *(as per manufacturer requirement)*			
9	List of tools/test equipment required (during maintenance & calibration)			
10	**CERTIFICATE OF ACCEPTANCE**			
11	Declaration of **CE or IEC conformance** and a copy of **CALIBRATION CERTIFICATE**			
12	A backup copy of **SOFTWARE** for user and **SOFTWARE LICENSE** inclusive of **access key**			
13	Declaration of Previous Recalls / Device Alerts / End of Life Date			
14	**FACTORY PERFORMANCE TEST RESULT**			
15	**QA RESULT & CERTIFICATE**			
16	**SERVICE ENGINEER TRAINING CERTIFICATE** (Manufacturer Training)			
17	Response time during warranty period - On call and on Site			
18	**TENTATIVE DATES & SYLLABUS** for User Training			
19	**TENTATIVE DATES & SYLLABUS** for Technical Training			

VERIFICATION OF TESTING & COMMISSIONING DONE

SUPPLIER SERVICE ENGINEER :	**HOSPITAL REPRESENTATIVE :**	**CC REPRESENTATIVE :**
NAME:	**NAME:**	**NAME:**
DESIGNATION:	**DESIGNATION:**	**DESIGNATION:**
DATE:	**DATE:**	**DATE:**

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PART 7	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)			

Remarks :

VERIFICATION OF TESTING & COMMISSIONING DONE

SUPPLIER SERVICE ENGINEER :	**HOSPITAL REPRESENTATIVE :**	**CC REPRESENTATIVE :**
NAME:	**NAME:**	**NAME:**
DESIGNATION:	**DESIGNATION:**	**DESIGNATION:**
DATE:	**DATE:**	**DATE:**

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PART 8 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 11)*

PART 9 DEFECT LIST

Problem/Defect Statement

Remarks

Suggestion

PART 10 TRAINING PROVISION BY SUPPLIER

User training on clinical usage & daily maintenance : ☐ Done ☐ Not Done
Emphasis on Do(s) & Dont(s)
Include decontamination & sterilization procedure ☐ Reschedule Reschedule date : _____
(Please indicate reschedule date)

PART 11 FACILITIES AND LOCATION ASSESMENT

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

VERIFICATION OF TESTING & COMMISSIONING DONE

SUPPLIER SERVICE ENGINEER :	HOSPITAL REPRESENTATIVE :	CC REPRESENTATIVE :
NAME:	NAME:	NAME:
DESIGNATION:	DESIGNATION:	DESIGNATION:
DATE:	DATE:	DATE:

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ASSET NO ►

PART 12 ATTENDANCE LIST

Venue :

Date :

No	Name	Designation	Department/Company	Contact No.	Signature

VERIFICATION OF TESTING & COMMISSIONING DONE

SUPPLIER SERVICE ENGINEER :	HOSPITAL REPRESENTATIVE :	CC REPRESENTATIVE :
NAME:	NAME:	NAME:
DESIGNATION:	DESIGNATION:	DESIGNATION:
DATE:	DATE:	DATE:

Annex 3

Checklist of acceptance

	Non-Active Medical Device **Acceptance Checklist**	Version 2.00 1st Nov 2011

Tick (✓) where appropriate

PART 1 ITEMS DETAILS

HOSPITAL	:	LOCATION	:
DEPARTMENT	:	LOCATION CODE	:
DESCRIPTION	:	MANUFACTURER	:
GMDN & UMDNS TYPE CODE	:	BRAND	:
RISK CLASSIFICATION	:	MODEL	:
BATCH NO	:	MAKE	:
MANUFACTURING DATE *(Date of equipment is produced)*	:	RECOMMENDED SHELF LIFE : *(Maximum duration in storage)*	

PART 2 PURCHASE DETAILS

SUPPLIER : *(Bumi-agent/as stated on LPO)* ADDRESS :		CONTACT PERSON CONTACT NO	: :
AUTHORISED SERVICE AGENT: *(Sole distributor / service warranty provider)* ADDRESS :		CONTACT PERSON CONTACT NO	: :
LOCAL PURCHASE ORDER NO :		PURCHASE PRICE	: RM [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]
PURCHASE DATE : *(LPO date)*		DELIVERY REF NO	:
WARRANTY START DATE :		WARRANTY END DATE :	

PART 3 PHYSICAL INSPECTION

Batch Size : Sample Size : Defects Count :

	PASS	FAIL	NA
1. Products conform to the purchase order and other relevant requirements. (for example: correct model number, description, size, type, color, ratings, etc.)	☐	☐	☐
2. Quantity ordered against the quantity shipped or delivered.	☐	☐	☐
3. No damage, breakage, tampered packaging, possible contamination etc.	☐	☐	☐
4.Unit of measurement count is correct (e.g. if the unit of measurement on the purchase order is one dozen, there should be 12 in the package).	☐	☐	☐
5. Delivery documentation (packing list, certifications, etc.) is valid and acceptable.	☐	☐	☐
6. Perishable items are in good condition and expiration dates have not been exceeded/reasonable duration	☐	☐	☐
7. Products are operable or functional.	☐	☐	☐

PART 4 DEFECT LIST

Problem/Defect Statement
Remarks
Suggestion

PART 5 CONCLUSION

☐ Inspection Done	☐ Inspection Not Done
☐ Accepted	☐ Not Accepted
☐ Accepted with reservations	☐ Remarks : _____

PART 6 VERIFICATION OF ACCEPTANCE CHECK DONE

SUPPLIER :	**HOSPITAL REPRESENTATIVE :**
NAME:	**NAME:**
DESIGNATION:	**DESIGNATION:**
DATE:	**DATE:**

Annex 4

Labelling

4.1 Asset label

Figure 1 : Sample of asset label

4.2 Asset under warranty label

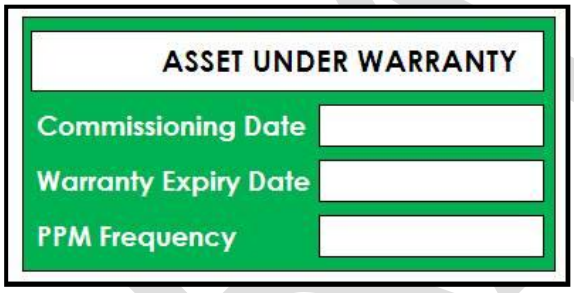

Figure 2 : Sample of Asset under warranty label

4.3 Electrical safety test label

Figure 3 : Sample of electrical safety test label

Annex 5

Acceptance certificate

ACCEPTANCE CERTIFICATE

This is to certify that the following works/installation has been accepted in accordance with the contract specifications to satisfaction :

1) Nature of Works/Installation : _____

2) CONTRACT/TENDER NO. _____

3) HAND OVER DATE : _____
WARRANTY PERIOD : _____

4) INSPECTED/CERTIFIED BY :

CHOP & SIGN : _____ CHOP & SIGN : _____

NAME : _____ NAME : _____

5) HANDED OVER BY : 6) ACCEPTED AND TAKEN OVER BY :

CHOP & SIGN : _____ CHOP & SIGN : _____

NAME : _____ NAME : _____

Annex 6

T&C certificate

TESTING AND COMMISSIONING CERTIFICATE

This is to certify that the following works/installation has been tested in accordance with the contract specifications to satisfaction :

1) Nature of Works/installation :

_____
_____
_____

_____
_____
_____

2) CONTRACT/TENDER NO. _____ 3) TESTING & COMMISSIONING DATE : _____

4) INSPECTED/CERTIFIED/WITNESS BY :

CHOP & SIGN : _____ CHOP & SIGN: _____

NAME : _____ NAME : _____

Annex 7

Certificate of user training

Certificate of Training

This is to certify that

_____

has successfully completed a course in

_____

On the _____ Day of _____ In the Year _____

At: _____.

Signed,

_____

Certificate Provided by www.hooverwebdesign.com