



Creating Markets, Creating Opportunities

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IFC, a member of the World Bank Group, is the largest global development institution focused exclusively on the private sector in developing countries.

We utilize and leverage our products and services—as well as products and services of other institutions in the World Bank Group—to provide development solutions customized to meet clients' needs. We apply our financial resources, technical expertise, global experience, and innovative thinking to help our partners overcome financial, operational, and political challenges.

Clients view IFC as a provider and mobilizer of scarce capital, knowledge, and long-term partnerships that can help address critical constraints in areas such as finance, infrastructure, employee skills, and the regulatory environment.

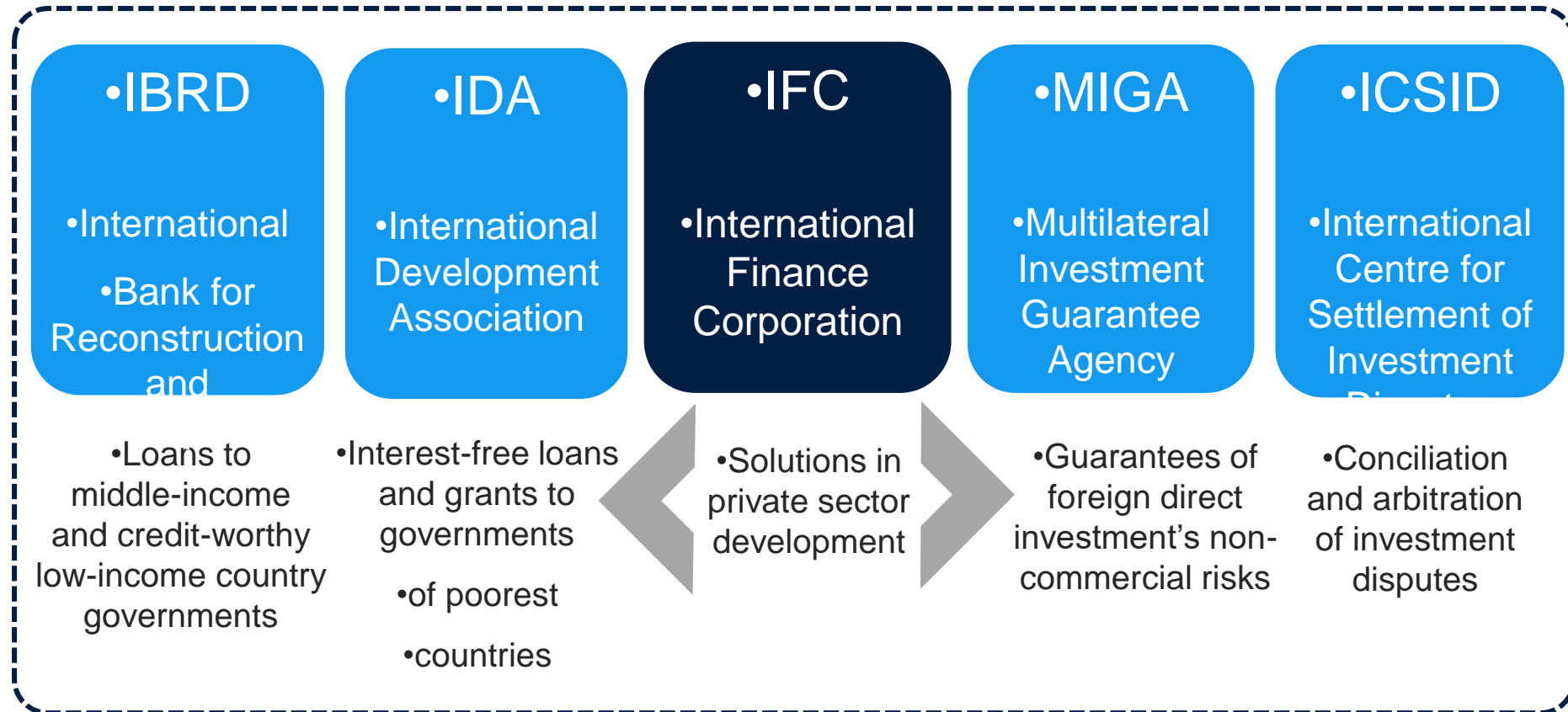
IFC is also a leading mobilizer of third-party resources for its projects. Our willingness to engage in difficult environments and our leadership in crowding-in private finance enable us to extend our footprint and have a development impact well beyond our direct resources.

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Our goals are to
end extreme
poverty by 2030
and boost shared
prosperity in every
developing country

IFC: A MEMBER OF THE WORLD BANK GROUP





Contents

1. IFC - Worldbank Group
2. AMEF – the program
3. AMEF – advisory services



Creating Markets, Creating Opportunities

**Faith Muigai, RN, CNRN
MSN**

- 20 years global health experience in both public and private sectors.
- **S**ector experience in Sub Saharan Africa with focus health policy and healthcare standards, quality and regulation, healthcare health systems strengthening experts, commodity management experts, public private partnerships, health service strategy and delivery.
- In 2019, recognized as an Innovator and Woman in Leadership by the International Finance Corporation (IFC).



Joseph Williamson, DMS

- 35 years of radiology clinical practice
- Extensive experience in Medical Equipment procurement and project planning
- Trained Board Certified Sonologist/Fetal Medicine Imaging
- 20 years consulting in international healthcare markets





Africa Medical Equipment Facility (AMEF)



Creating Markets, Creating Opportunities

www.ifc.org/amef

What is AMEF?



A Financial Facility

To support medical equipment financing for Healthcare SMEs (private hospitals, clinics, pathology labs and diagnostics imaging centers)

Where: 9 countries in West and East Africa



A Risk Sharing Facility (RSF)

US\$150 million RSF established by IFC in partnership with local Partner Financial Institutions (PFIs) and global Original Equipment Manufacturers (OEMs)

Goal: Facilitate HSMEs access up to US\$300 million of loans and leases



AMEF's Value Add

To increase availability of medical equipment in these under-developed healthcare markets by providing HSMEs adequate financing

Goal: Help strengthen healthcare infrastructure in West and East Africa

AMEF Countries



Ivory Coast



Cameroon



Ghana



Tanzania



Senegal



Nigeria



Kenya

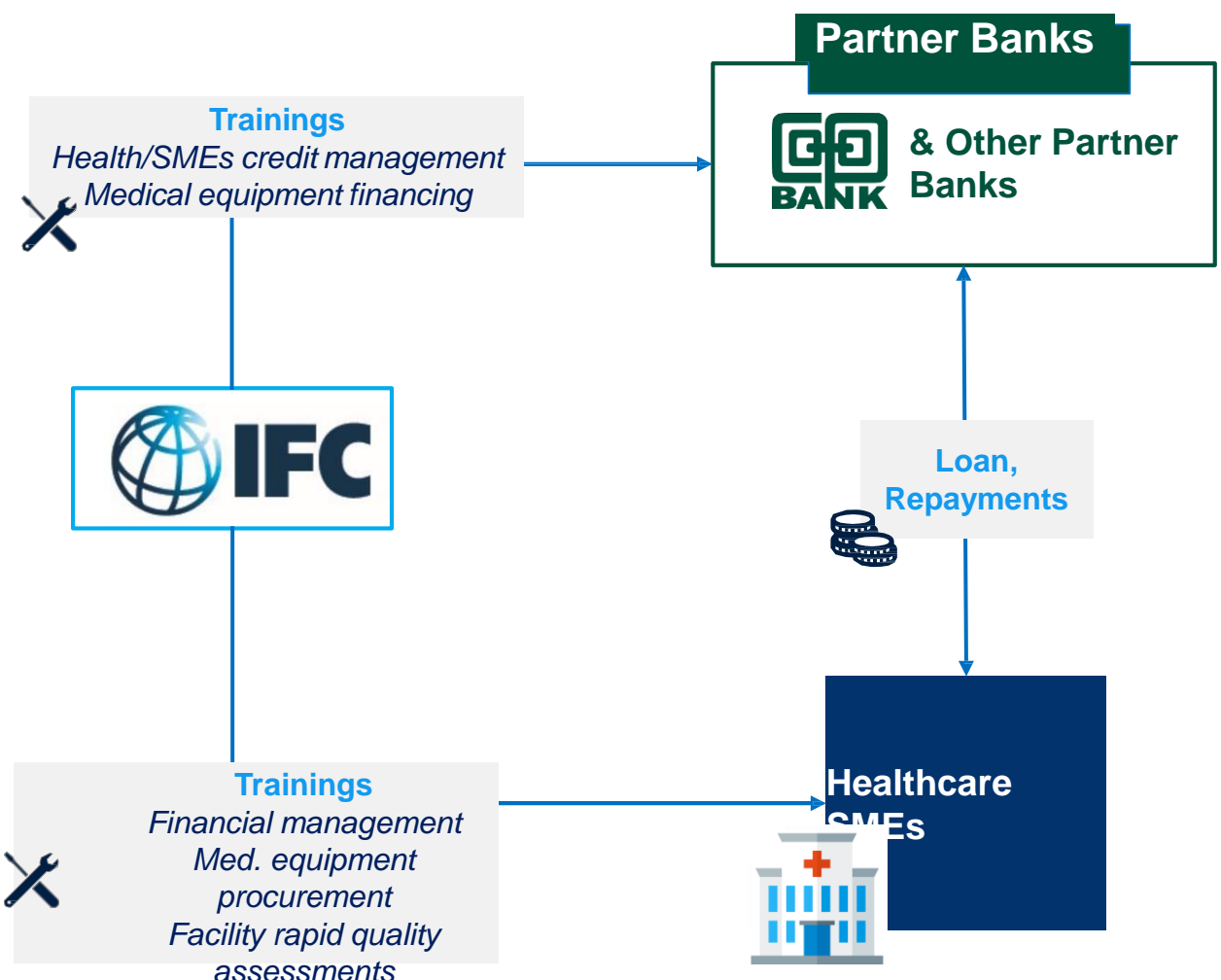


Uganda



Rwanda

Who Does What? How Does it Work?



Partner OEMs

A collection of logos for Partner OEMs, including GE HealthCare, PHILIPS Healthcare, STORZ KARL STORZ-ENDOSKOPE, Wondfo, Elekta, GETINGE, Neusoft Medical Systems, mindray, and BIOMÉRIEUX.





AMEF Advisory Services



Creating Markets, Creating Opportunities

About AMEF

IFC designed a **multi-component advisory program** to address the challenges faced in acquiring medical equipment in Sub-Saharan Africa as a joint initiative between the Financial Institutions Group Advisory, Healthcare Quality Advisory, and the Financial Management Advisory programs.

Countries Covered



Kenya



Ivory Coast

Program Components

1

Component 1: Onboarding, Training, and Implementation Support for Partner FIs

An advisory program will be delivered to banks through (i) a training program to help banks understand the Risk-Sharing Facility eligibility criteria for HSMEs and reporting requirements, and (ii) workshops to develop recommendations on how the Risk-Sharing Facility can be utilized most effectively and assist with building an implementation plan.

2

Component 2: Training & Awareness Building on Medical Equipment Planning, Procurement, Maintenance, and Other Relevant Issues for HSMEs

An advisory program will provide HSMEs with access to necessary information and training materials to facilitate smart decisions on equipment purchasing and operations.

3

Component 3: Financial Management and Business Planning Toolkit

An advisory program will be delivered to HSMEs to strengthen their financial management capacities, particularly around cashflow forecasting, budgeting, and business planning.

Who Can Benefit AMEF? What are the Key Terms?

Who Can Benefit AMEF?

- **Private Hospitals, Clinics, Laboratories, Imaging Centers operating since at least 3 years**
- **Registered Healthcare SMEs/Professionals**
- **Meeting 2/3 criteria of IFC SME definition:**
 - (i) *Revenue: KES 10 million - 1.5 billion*
 - (ii) *Total Assets: KES 10 million - 1.5 billion*
 - (iii) *Staff count: 1 to 300*
- **Looking to purchase medical equipment from an AMEF Partner OEM**
- **Need loan from an AMEF Partner Bank**

What are the Key Terms?

- **Loan Amount:** From KES 500,000 to KES 200,000,000
- **Tenor:** Up to 5 years
- **Grace period:** 3 -6 months moratorium on principal
- **Use of funds:**
 - Purchase of medical equipment
 - Ancillary services (delivery, installation, warranty, maintenance, application/usage trainings)
 - From an AMEF Partner OEM or its duly authorized distributor



Q&A



Creating Markets, Creating Opportunities

YOUR MEDICAL EQUIPMENT PURCHASING JOURNEY



Creating Markets, Creating Opportunities

Medical Equipment Purchasing Experience



Raise your hand if you have experience purchasing medical equipment.

What challenges have you had?

Common challenge: So much to choose from!

Device types

- Over 6,000 distinct device types and entities

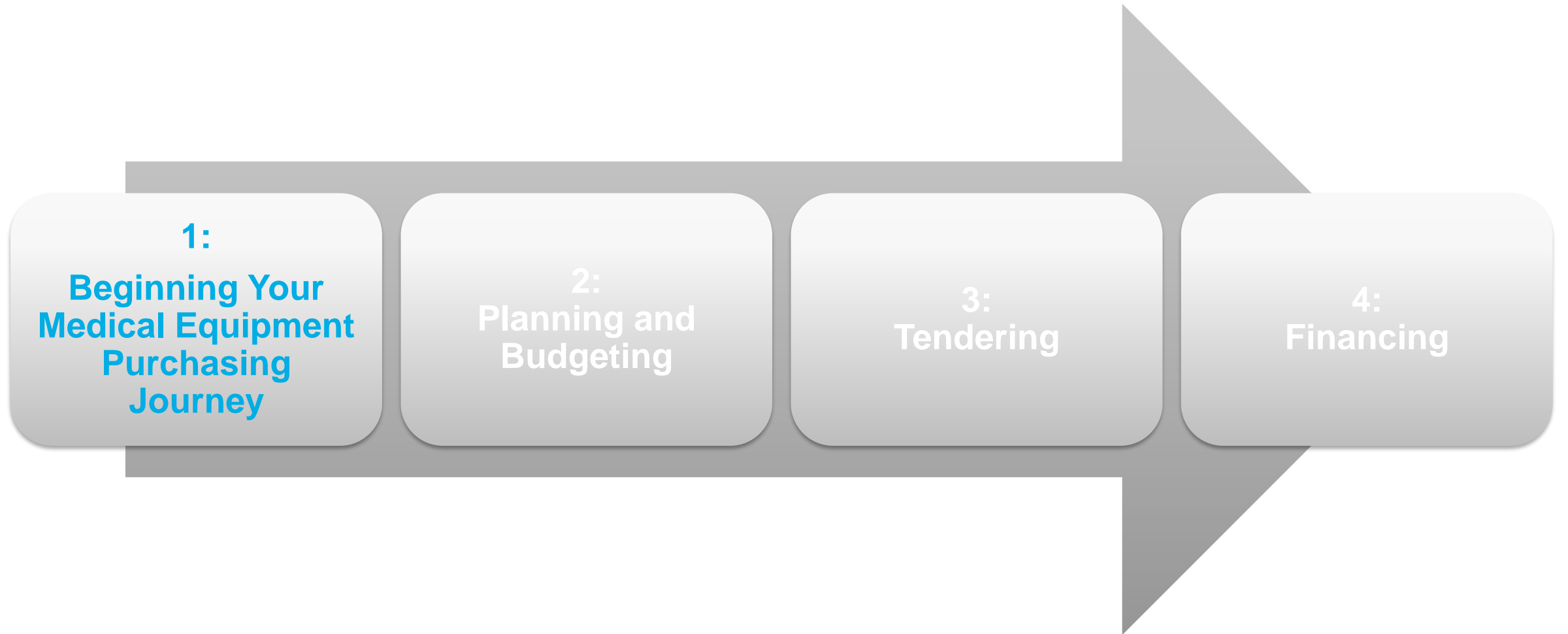
Brands and models

- Over 50,000 brands and models available from over 12,000 manufactures

Sophistication

- Range from simple to sophisticated

The Medical Procurement Journey

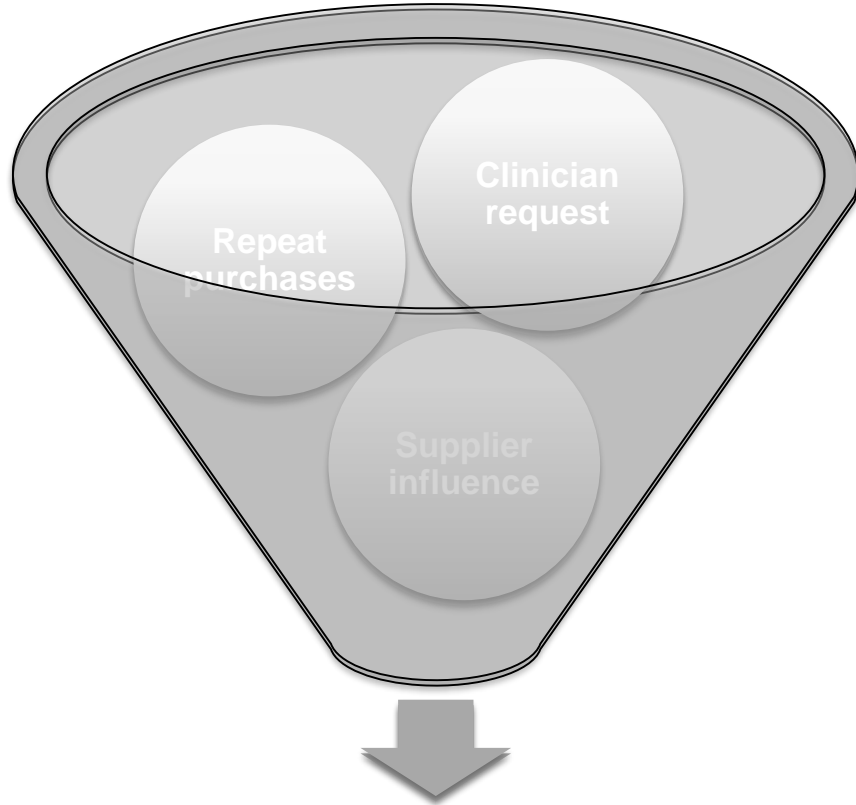


OBJECTIVES

By the end of this session, you will be able to:

1. Describe the medical equipment purchasing journey
2. Gather key information needed for the procurement journey (Needs Assessment Step 1)
3. Understand a procurement needs assessment
4. Plan the budget for a medical equipment procurement
5. Identify key planning and budgeting needs
6. Conduct a procurement needs assessment
7. Plan the budget for a medical equipment procurement
8. Identify key planning and budgeting points in a case study
9. Identify risks in seeking financing
10. Prepare a loan application

Common Purchasing Practices



Often result in:

- X Special clinical requirements not accounted for
- X Staff not trained to handle device
- X Room cannot accommodate device
- X Additional, unaccounted for hidden costs
- X Technology discontinued/obsolete
- X Technology has high number of reported problems

Key Elements to Consider in ME Purchasing

- ✓ Clinical requirements
- ✓ Safe for use by users and patients
- ✓ Current technology
- ✓ Compatibility with existing technologies
- ✓ Cost-effectiveness
- ✓ Space/room requirements
- ✓ Maintenance
- ✓ After-sales servicing by supplier



Your ME Procurement Team

What does your facility's procurement team look like?

Who makes the ME purchasing decision?

- The top leader (owner, CEO, Chairman of the Board)
- The procurement officer/lead
- The finance department lead
- The lead physician providing the intended service

Any Size Medical Facility Should have a Medical Procurement Team That Comprises

- CEO, Medical Director, Owner
- Finance Manager
- Clinical users (physicians, nurses, radiographers, lab technicians)
- Procurement Manager
- IT department representative
- Human Resources representative
- Biomedical engineer



ME Procurement Team Tasks and Responsibilities

- ✓ Initiate procurement process
- ✓ Define clinical needs, features, patient type and patient volume
- ✓ Carry out finance-related work (e.g., calculating total cost of ownership and return on investment)
- ✓ Source for equipment suppliers, conduct tender, communicate with suppliers, evaluate tender outcome
- ✓ Check pre-installation requirement and availability
- ✓ Identify maintenance requirements
- ✓ Identify cybersecurity risk and possible interoperability issues
- ✓ Identify expertise and training requirements
- ✓ Hire expertise where required

Planning for ME Procurement: Needs Assessment Steps



Medical Equipment Purchasing Planning



What could possibly go wrong in purchasing medical equipment?

Planning is:

A systematic approach to determine the clinic/hospital's equipment needs

Planning helps answer these questions:

WHY PLAN?

**What to buy
Why buy
When to buy
How much**

Planning helps to:

**Identify clinical needs
Identify suitable ME type and quantity
Identify key technical requirements to effectively deliver intended clinical service
Facilitate subsequent steps in Needs Assessment process**

Medical Equipment Purchasing Planning Information

What information would you want in order to make this ME procurement?

A. What is the required ME type?

✓ Will it deliver the intended clinical application?

B. What is the key features required?

✓ What is the patient type to be serviced?

✓ What are the technical requirements?

C. What is the intended clinical service or application:

✓ For replacement of existing ME or to support increasing patient volume

✓ For delivering new clinical services or applications



Needs Assessment:

A. What is the intended location?

Adequate space for delivery

Adequate and appropriate space for use

B. What is the estimated patient volume?

Is it replacing the existing ME?

Is it for new service?

Is this purchasing a whole new unit?

C. What is the quantity of ME required?

How many are you replacing?

For new clinical service/additional unit: Guided based on anticipated numbers of patients/day against time to complete the delivery of each procedure

Needs Assessment Steps

1. Collect key information required for planning

2. Determine suitable medical equipment category

3. Identify expertise available/required to operate and maintain medical equipment

4. Perform request for information

5. Perform feasibility study

Case Study: Happy Clinic Step 1



Dr Amanda, the owner of Happy Clinic, would like to start offering a health screening service at her clinic.

She wants to start offering a comprehensive health screening service. She needs a digital X-Ray system for the chest scans.

What information would you need?

Key Information Required for Planning

Stakeholders involved (*name,title*): _____

Discussion date: _____

| No. | Questions | Response |
|-----|---|--|
| a. | What would be the main reason for ME purchase? | <input type="checkbox"/> To replace ME which is beyond economical repair <input type="checkbox"/> To replace ME discontinued by manufacturer <input type="checkbox"/> To deliver new clinical service/application <input type="checkbox"/> To support increasing patient volume <input type="checkbox"/> Others, <i>please specify</i> : _____ |
| b. | What is the intended clinical service/application? <i>*Indicate ALL clinical services/applications intended to be delivered (consider current and future needs).</i> | |
| c. | Where is the location of use (Department, Room)? | |
| | -Is adequate space currently available to support the delivery of clinical service and increase in patient volume? | |
| d. | What is the required ME type? <i>*Perform research to identify suitable equipment type for the intended clinical application.</i> | |
| e. | What are the key features required? <i>*Indicate key technical requirements to deliver intended clinical services/applications (e.g., height-adjustable table, screen size, invasive blood pressure monitoring, 24-hours ECG monitoring, etc.).</i> | |
| | - Patient type <i>*Indicate the type of patients expected to receive the services/applications.</i> | <input type="checkbox"/> Adult <input type="checkbox"/> Pediatric <input type="checkbox"/> Neonates <input type="checkbox"/> Bariatrics |
| f. | What is the estimated patient volume? <i>*Refer to relevant documents/business case study/business plan</i> | |
| g. | What is the quantity of ME required? <i>*Refer to number of ME required to be replaced OR calculate based on anticipated number of patients versus procedure time and device capacity</i> | |

Use the Checklist

Start filling this out for Dr. Amanda's request:

- At the start of the request, she had stated that she wants to start offering a comprehensive health screening service. To do this she needs a digital X-Ray system for the chest scans.
- She thinks she will need it for about 2 adult patients each day.
- She wants it to have a digital detector and she plans to put it in the clinic's X-ray room

Key Information Required for Planning

Stakeholders involved: Dr Amanda (clinic owner)

Date: 1st June 2021

| No. | Questions | Response |
|-----|--|---|
| a. | What would be the main reason for ME purchase? | <input type="checkbox"/> To replace ME which is beyond economical repair <input type="checkbox"/> To replace ME discontinued by manufacturer <input checked="" type="checkbox"/> To deliver new clinical service/application <input type="checkbox"/> To support increasing patient volume <input type="checkbox"/> Others, please specify: _____ |
| b. | What is the intended clinical service/application? <i>*Indicate ALL clinical services/applications intended to be delivered (consider current and future needs).</i> | To perform chest X-ray for health screening |
| c. | Where is the location of use (Department, Room)? -Is adequate space currently available to support the delivery of clinical service and increase in patient volume? | Clinic X-ray Room Yes |
| d. | What is the required ME type? <i>*Perform research to identify suitable equipment type for the intended clinical application.</i> | Digital X-ray |
| e. | What are the key features required? <i>*Indicate key technical requirements to deliver intended clinical services/applications (e.g., height-adjustable table, screen size, invasive blood pressure monitoring, 24-hours ECG monitoring, etc.).</i> - Patient type <i>*Indicate the type of patients expected to receive the services/applications.</i> | Digital Detector <input checked="" type="checkbox"/> Adult <input type="checkbox"/> Pediatric <input type="checkbox"/> Neonates <input type="checkbox"/> Bariatric |
| f. | What is the estimated patient volume? <i>*Refer to relevant documents/business case study/business plan</i> | 2 patients /day |
| g. | What is the quantity of ME required? <i>*Refer to number of ME required to be replaced OR calculate based on anticipated number of patients versus procedure time and device capacity</i> | 1 unit |

Case Study: Happy Clinic Step 1 in Action

- ✓ Estimated the patient volume to be 2 patients per day.
- ✓ Calculated quantity of ME by estimating procedure time and device capacity/day.
 - ✓ Device capacity/day: 8 hours (clinic operation time) x 60 min ÷ 5 mins= 96 scans/day
 - ✓ Therefore, 1 unit of the device will be sufficient to serve the expected volume of 2 patients/day.



What comes next?

1. Collect key information required for planning

2. Determine suitable medical equipment category

3. Identify expertise available/required to operate and maintain medical equipment

4. Perform request for information

5. Perform feasibility study

MEDICAL EQUIPMENT PURCHASING JOURNEY: **PLANNING AND BUDGETING**



Medical Equipment Planning



What are the risks for not properly identifying the suitable ME category?

Risks:

- X Cannot meet full intended use
- X Cannot use at all
- X Frustrated staff
- X Loss of income

Why is it important to identify the suitable ME category?

- ✓ There from **multiple ME categories** for a single equipment type.
- ✓ You need effective delivery of the **intended clinical application**.

Needs Assessment Step 2

| ME Type | ME Category |
|---------------------|--|
| MRI | <ul style="list-style-type: none"> • 1.5T • 3.0T |
| CT Scanner | <ul style="list-style-type: none"> • 16 to 32 slices • 64 slices • 128 slices • ≥256 slices |
| Digital X-Ray | <ul style="list-style-type: none"> • Bucky stand only • Bucky stand and table unit • Mobile X-Ray |
| Ultrasound | <ul style="list-style-type: none"> • General Purpose Ultrasound • Breast Ultrasound • Cardiovascular Ultrasound • OBGYN Ultrasound • Point-of-Care Ultrasound |
| Physiologic Monitor | <ul style="list-style-type: none"> • Vital Signs Monitor • Bedside Monitor • Transport Monitor |

A facility needs to perform full body digital x-ray scanning in supine position



Medical Equipment Planning

What considerations should you make when determining the suitable ME category?

Needs Assessment Step 2

What considerations should you make when determining suitable ME category?

- ✓ Relevant features, functionality and accessories required to deliver the intended clinical application
- ✓ Expected patient type to be served
- ✓ ME versatility

Tasks involved:

1. Perform market research to identify ME categories and its capabilities
2. Select suitable device category that best meets clinical service/application
3. Identify brands and models available in the market






Digital X-Ray Systems

The following table indicate clinical application and typical location of use for different categories of **Digital X-Ray, Ultrasound** and **Patient Monitors**. Price ratio (💰) is provided to illustrate price difference between ME categories of different technology level.

| ME Category | Application | Typical location of use | | | | | | |
|--|--|-------------------------|----------------------------------|--------------|------------------------------------|--------------|-----|-------------------------|
| | | Clinic | Primary Care Hospital (~50 beds) | | Tertiary Care Hospital (>100 beds) | | | |
| | | - | Emergency Dept | Imaging Dept | Emergency Dept | Imaging Dept | ICU | Health Screening Center |
| 1 Bucky Stand Only | Only allows X-ray scanning to be performed in standing or sitting position. Suitable for chest x-ray scanning | ✓ | | ✓ | | | | ✓ |
| 2 Combination of Table Unit & Bucky Stand | Allows full-body head-to-toe scanning to identify fractures/break, tumors in bones; identify arthritis; diagnose pneumonia, identify kidney stones, etc. | | | ✓ | | ✓ | ■ | |
| 3 Mobile X-Ray | Portable x-ray units that can be moved to immobile patients for x-ray scanning | | ✓ | | ✓ | | | ✓ |







Ultrasound Machines

| ME Category | Application | Typical location of use | | | | | | | | | | | |
|---|--|-------------------------|----------------------------------|--------------|---------------|------------------------------------|--------------|-----|-------------------------|---------------|----------------|----|-------------------|
| | | Clinic | Primary Care Hospital (~50 beds) | | | Tertiary Care Hospital (>100 beds) | | | | | | | |
| | | - | Emergency Dept | Imaging Dept | OB/GYN Clinic | Emergency Dept | Imaging Dept | ICU | Health Screening Center | OB/GYN Clinic | Cardiac Centre | OT | Labour & Delivery |
| Point-of-Care Ultrasound with 2D scanning mode Price ratio:   | - Perform all acquisitions and interpretations of image at point-of-care (POC). - Capable of performing all clinical applications of a general-purpose ultrasound in 2D scanning mode. | | ✓ | | | ✓ | | ✓ | | | | | |
| General Purpose Ultrasound with 2D and 3D scanning mode Price ratio:  | Basic scanning to help diagnose the causes of pain, swelling and infection in the body's organ - Examples of general applications include Abdominal scan, Cardiovascular scan, Breast scan, OB/GYN scan, Small parts scan, Musculoskeletal scan, Kidney or Bladder scan, Intraoperative application in surgery (including biopsy procedure) | ✓ | | ✓ | | | ✓ | | ✓ | | | | |

7



2

Ultrasound Machines (Continued)

| ME Category | Application | Typical location of use | | | | | | | | | | | |
|--|---|-------------------------|----------------------------------|--------------|--------------|------------------------------------|--------------|-----|-------------------------|--------------|----------------|----|-------------------|
| | | Clinic | Primary Care Hospital (~50 beds) | | | Tertiary Care Hospital (>100 beds) | | | | | | | |
| | | - | Emergency Dept | Imaging Dept | OBGYN Clinic | Emergency Dept | Imaging Dept | ICU | Health Screening Center | OBGYN Clinic | Cardiac Centre | OT | Labour & Delivery |
| 1 Obstetrics and Gynecology (OB/GYN) Ultrasound with 2D and 3D scanning mode  Price ratio:  | - Has specialized Obstetric Analysis software and interpretation tools specialized for gynecology - Able to obtain detailed organ images in the female pelvic region and perform transvaginal ultrasound. | | | | ✓ | | | | | ✓ | | | ✓ |
| 2 Obstetrics and Gynecology (OB/GYN) Ultrasound with 2D, 4D and 4D scanning mode  Price ratio:  | - Capable to perform all clinical application of a 2D/3D OBGYN Ultrasound and 4D scanning to create a live video effect which is usually used for Obstetric application to capture baby movement inside the womb. | | | | ✓ | | | | | ✓ | | | ✓ |
| 3 Obstetrics and Gynecology (OB/GYN) Ultrasound with 2D, 4D and 5D scanning mode  Price ratio:  | - Capable to perform all clinical application of a 2D/3D/4D OBGYN Ultrasound and perform 5D scanning to give realistic view of baby inside the womb (show baby with reddish/pinkish color). | | | | ✓ | | | | | ✓ | | | ✓ |

Physiological Monitors

1

| ME Category | Application | Typical location of use | | | | | | | | | | | | | | | | |
|---|--|-------------------------|----------------------------------|-------------------|------|------------------------------------|----------|-----|------|----|------|-------------------|-----------|------|-----------|-------------------|--|---|
| | | Clinic | Primary Care Hospital (~50 beds) | | | Tertiary Care Hospital (>100 beds) | | | | | | | | | | | | |
| | | - | Emergency Dept | Outpatient Clinic | Ward | Emergency Dept | Dialysis | ICU | NICU | OT | PACU | Labour & Delivery | Endoscopy | Ward | Sleep Lab | Outpatient Clinic | | |
| Vital Sign monitor Price ratio:  | - Measures basic physiologic parameters and track the status of low-acuity patients. - Typical parameters include NIBP, SpO2, HR and Temperature. | ✓ | ✓ | ✓ | ✓ | ■ | ■ | | | | | | | | | ✓ | | ✓ |
| Transport monitor Price ratio:  | - Measure and display waveforms and numerical data for various parameters during patient transport. - Typical parameters include ECG, NIBP, SpO2, HR, RR, Temperature, IBP and ETCO2. | | ✓ | | | ✓ | | ✓ | ✓ | ✓ | | | | | | ■ | | |

2

Note: Electrocardiography (ECG), Non-invasive blood pressure (NIBP), Pulse oximetry (SpO2), Heart rate (HR), Respiration Rate (RR), End-Tidal Carbon Dioxide (ETCO2), Invasive Blood Pressure (IBP)



Case Study: Happy Clinic

Dr. Amanda, the owner of Happy Clinic, would like to start offering a comprehensive health screening service at her clinic.

She needs a digital X-ray system for the chest scans.

Key Information Required for Planning

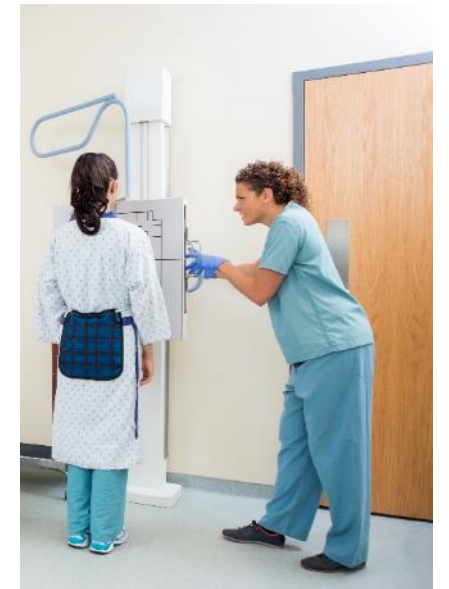
Stakeholders involved: Dr Amanda (clinic owner)

Date: 1st June 2021

| No. | Questions | Response |
|-----|--|--|
| a. | What would be the main reason for ME purchase? | <input type="checkbox"/> To replace ME which is beyond economical repair |
| | | <input type="checkbox"/> To replace ME discontinued by manufacturer |
| | | <input checked="" type="checkbox"/> To deliver new clinical service/application |
| | | <input type="checkbox"/> To support increasing patient volume |
| | Others, please specify: _____ | |
| b. | What is the intended clinical service/application? <i>*Indicate ALL clinical services/applications intended to be delivered (consider current and future needs).</i> | To perform chest X-ray for health screening |
| c. | Where is the location of use (Department, Room)? | Clinic X-ray Room |
| | -Is adequate space currently available to support the delivery of clinical service and increase in patient volume? | Yes |
| d. | What is the required ME type? <i>*Perform research to identify suitable equipment type for the intended clinical application.</i> | Digital X-ray |
| e. | What are the key features required? <i>*Indicate key technical requirements to deliver intended clinical services/applications (e.g., height-adjustable table, screen size, invasive blood pressure monitoring, 24-hours ECG monitoring, etc.).</i> | Digital Detector |
| | - Patient type <i>*Indicate the type of patients expected to receive the services/applications.</i> | <input checked="" type="checkbox"/> Adult <input type="checkbox"/> Pediatric <input type="checkbox"/> Neonates <input type="checkbox"/> Bariatric |
| f. | What is the estimated patient volume? <i>*Refer to relevant documents/business case study/business plan</i> | 2 patients /day |
| g. | What is the quantity of ME required? <i>*Refer to number of ME required to be replaced OR calculate based on anticipated number of patients versus procedure time and device capacity</i> | 1 unit |

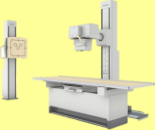
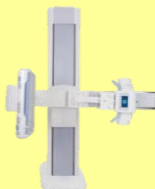

Case Study: Happy Clinic Step 1

- ✓ Compiled information as required in the **Key Information Required for Planning** form
- ✓ Estimated the patient volume
- ✓ Calculated the quantity of ME required



Case Study: Happy Clinic Step 2

- ✓ Conducted **market research** to identify categories of digital X-ray system available in the market.
- ✓ Compiled **brands and model information** on the respective categories.

| Digital X-Ray <small>SEP</small> Category | | Features and Clinical <small>SEP</small> Application Guide | Examples of Brand/model available |
|--|---|--|--|
| Combination of table unit and bucky stand |  | Allows full-body head-to-toe scanning to identify fractures/break, tumors in bones; identify arthritis; diagnose pneumonia, identify kidney stones, etc. | <ul style="list-style-type: none"> • Philips/ CombiDiagnose R90 • GE/ OPTIMA XR646 |
| Bucky stand only |  | Only allows X-ray scanning to be performed in standing or sitting position. Suitable for chest x-ray scanning | <ul style="list-style-type: none"> • Fujifilm FDR Smart f vertical wall stand • Philips/ DigitalDiagnost |
| Mobile X-ray |  | Portable x-ray units that can be moved to immobile patients for x-ray scanning. | <ul style="list-style-type: none"> • Philip/ MobileDiagnost wDR • GE/ AMX 220 |

Where are we in the journey?

1. Collect key information required for planning

2. Determine suitable medical equipment category

3. Identify expertise available/required to operate and maintain medical equipment

4. Perform request for information

5. Perform feasibility study

Medical Equipment Planning

Your new equipment arrived but no one knows how to operate it. What challenges does this cause?

Incorrect operation of ME can cause:

- Incorrect diagnosis
- Patient harm
- Unused equipment
- Broken equipment
- Not meeting intended use



Needs Assessment Step 3

Availability of ME Operator with Sufficient Expertise/Skill

- ✓ Availability of **adequate number of certified/trained staff** based on
 - ME quantity
 - Increase in patient volume and workload

- ✓ Plan to **hire additional number of qualified staff**, if needed
- ✓ Building in the **requirement and cost for additional staff training/education** to manage new ME
- ✓ Consider **internal training on local/international requirements** relevant to the ME



Needs Assessment Step 3

Examples of specialists and knowledge required to operate ME

| ME Type | Specialists | Required knowledge |
|---------------------|---|--|
| MRI, CT, X-Ray | Radiologists, x-ray technologists, medical physicists | <ul style="list-style-type: none">• Trained on radiation safety issues• Optimize radiation dose for a given clinical task and patient group (adult vs pediatric)• Perform quality control tests to ensure equipment is functioning properly. |
| Ultrasound machines | Ultrasound technician/sonographer, physicians, surgeons, radiologists | <ul style="list-style-type: none">• Trained to operate ultrasound machines• Interpret ultrasound images (does not apply to technician/sonographer) |

Needs Assessment Step 3

Availability of Expertise to Maintain ME

- ✓ Check with **in-house Biomedical Engineering team** (BME) for availability of expertise. Obtain estimated annual maintenance cost for ME.
- ✓ **Requirement and cost for additional training/education** for BME staff to maintain ME
- ✓ If in-house BME expertise is not available, consider **outsourcing maintenance work** to ME suppliers. Obtain estimated annual maintenance cost for ME.
- ✓ For outsourcing, **identify the suitable service contract arrangement**

1. Collect key information required for planning

2. Determine suitable medical equipment category

3. Identify expertise available/required to operate and maintain medical equipment

4. Perform request for information

5. Perform feasibility study

✓ Comprehensive service contract

✓ Non-comprehensive service contract

Needs Assessment Step 4



Why is a request for information (RFI) important?

- ✓ To collect information from potential suppliers on specifications and price indications
- ✓ Ensures facilities obtain sufficient information for planning of space and Mechanical, Electrical and Plumbing (MEP) requirements for ME

Tasks involved:

- ✓ Compile supplier contact information for brand and model of equipment type and category
- ✓ Prepare the letter of invitation
- ✓ Contact suppliers for participation in RFI activity
- ✓ Obtain quotations for ME price
- ✓ Obtain quotation for annual maintenance cost

Needs Assessment Step 4

Obtain:

- ✓ Space requirement for the installation and operation of the device
- ✓ Information and cost for technical training
- ✓ ME price
- ✓ Maintenance costs
- ✓ Renovation/installation costs



Where are we in the journey?

1. Collect key information required for planning

2. Determine suitable medical equipment category

3. Identify expertise available/required to operate and maintain medical equipment

4. Perform request for information

5. Perform feasibility study

Medical Equipment Planning

What could happen if you do not perform a feasibility study?

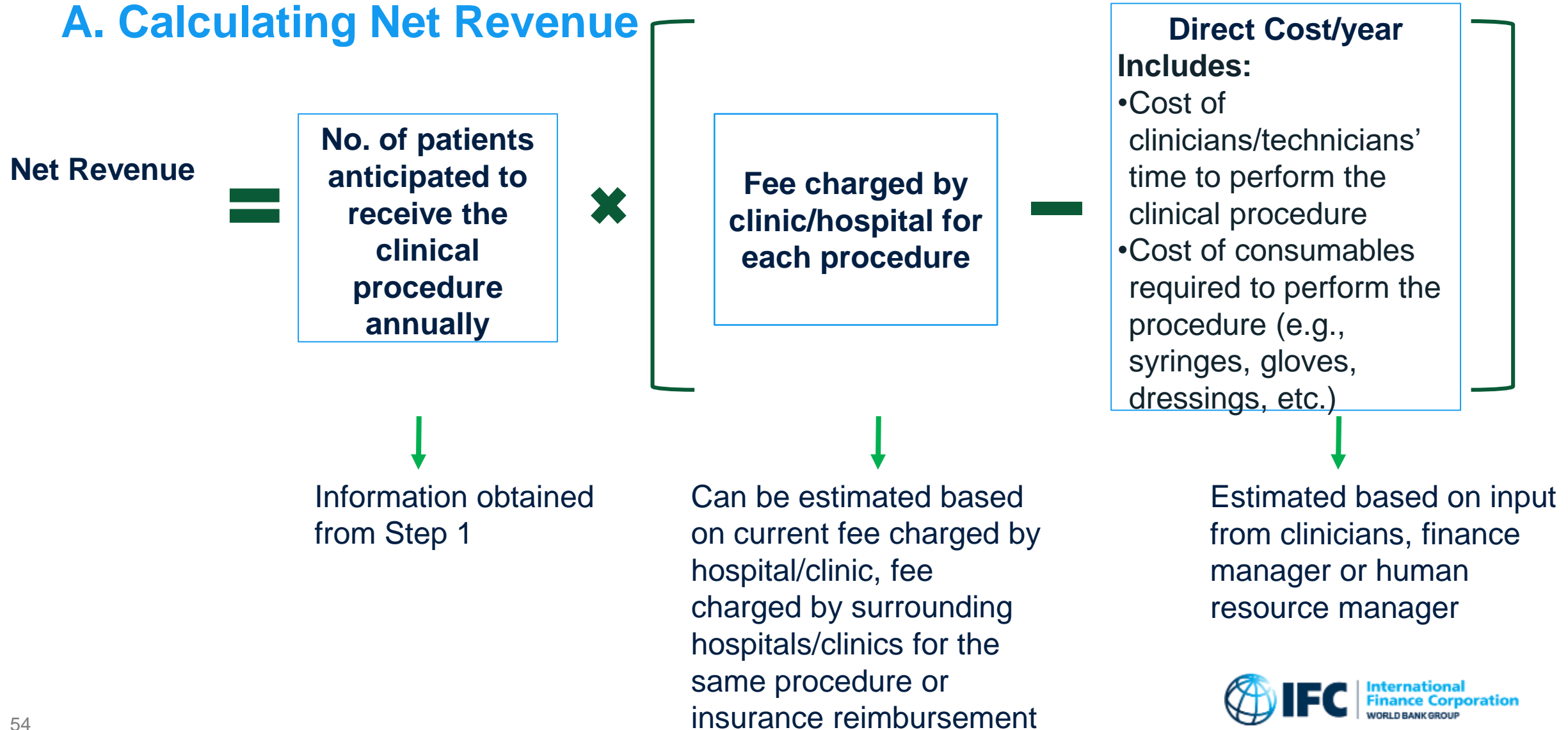
Included in a feasibility study:

- Calculate total net revenue
- Calculate cost of ownership (TCO) for ME
- Calculate return of investment (ROI)



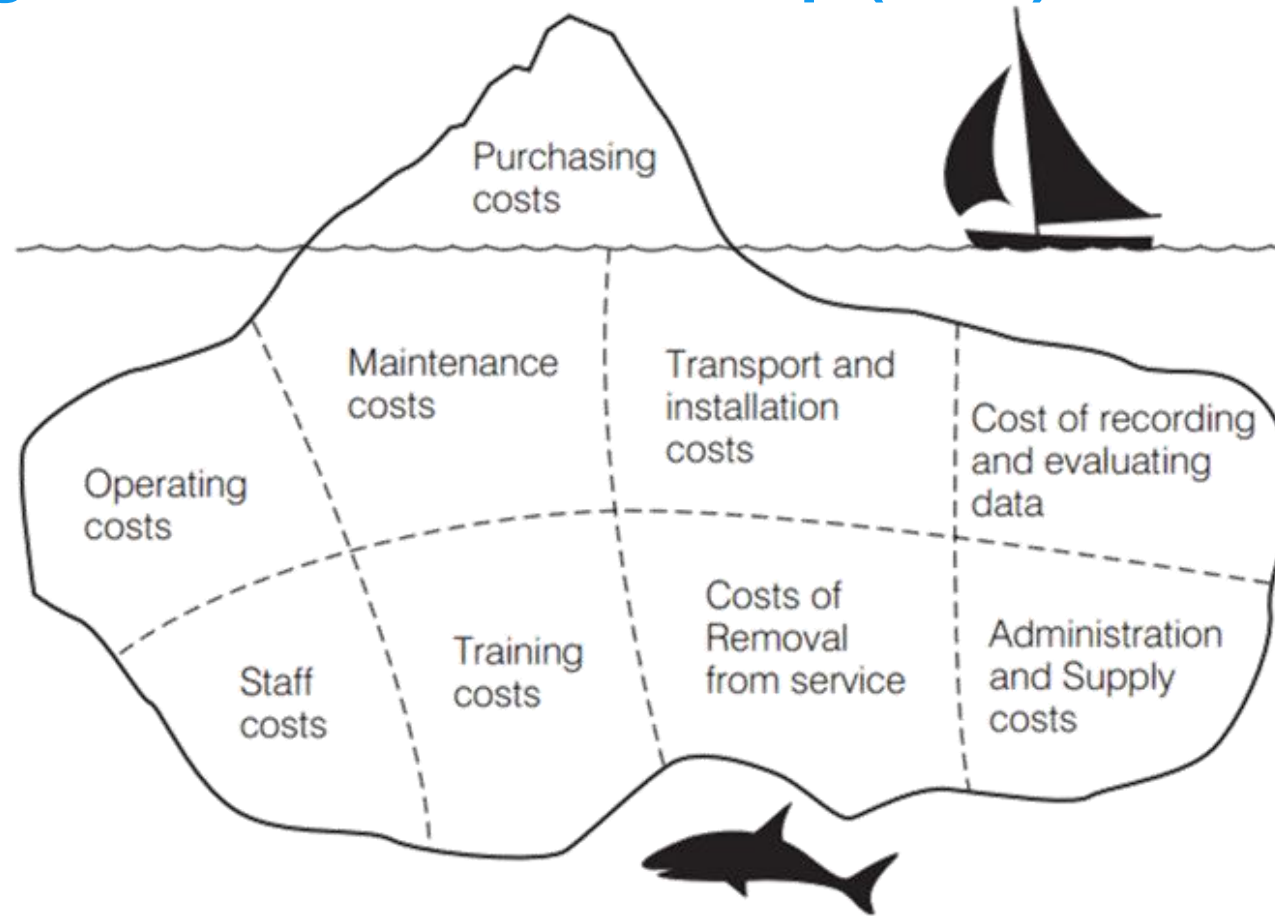
Needs Assessment Step 5

A. Calculating Net Revenue



Needs Assessment Step 5

B. Calculating Total Cost of Ownership (TCO)



Costs to consider when planning to purchasing ME

Needs Assessment Step 5

B. Calculating Total Cost of Ownership (TCO)

B) Calculation of Total Cost of Ownership (TCO) for Medical Equipment

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total over 5 years |
|--|--------|--------|--------|--------|--------|--------------------|
| Device Total Cost of Ownership: | | | | | | |
| 1. Initial Purchase Cost | | | | | | |
| a. Medical equipment purchase price | \$xx | | | | | |
| b. Infrastructure modifications | \$xx | | | | | |
| c. Clinical/ Biomedical staff training | \$xx | | | | | |
| d. | \$xx | | | | | |
| e. | \$xx | | | | | |
| f. | \$xx | | | | | |
| 2. Annual Operational Cost | | | | | | |
| a. Comprehensive service contract cost | \$xx | \$xx | \$xx | \$xx | \$xx | |
| b. Estimated scheduled maintenance cost (if no service contract) | \$xx | \$xx | \$xx | \$xx | \$xx | |
| c. Estimated repair cost (if no service contract) | \$xx | \$xx | \$xx | \$xx | \$xx | |
| d. Consumable cost | \$xx | \$xx | \$xx | \$xx | \$xx | |
| e. Annual re-training cost | \$xx | \$xx | \$xx | \$xx | \$xx | |
| f. Reprocessing cost | \$xx | \$xx | \$xx | \$xx | \$xx | |
| g. | \$xx | \$xx | \$xx | \$xx | \$xx | |
| h. | \$xx | \$xx | \$xx | \$xx | \$xx | |
| Total cost of ownership/ year | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Annualized total cost of ownership over 5 years | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | |

$$\boxed{\text{Total Cost of Ownership (Total over 5 years)}} = \boxed{\text{Initial Purchase Cost}} + \boxed{\text{Annual Operational Cost (Total over 5 years)}}$$

Needs Assessment Step 5

C. Calculating Return of Investment (ROI)

C) Calculation of Profit/Loss and Return on Investment (ROI)

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total over 5 years |
|---|---------|---------|---------|---------|---------|--------------------|
| Total Net Revenue (All procedures) | #VALUE! | #VALUE! | #VALUE! | #VALUE! | #VALUE! | #VALUE! |
| Annualized total cost of ownership over 5 years | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Estimated profit/ loss | #VALUE! | #VALUE! | #VALUE! | #VALUE! | #VALUE! | #VALUE! |
| Cumulative profit/ loss | #VALUE! | #VALUE! | #VALUE! | #VALUE! | #VALUE! | |
| Estimated ROI (%) over 5 years | #VALUE! | #VALUE! | #VALUE! | #VALUE! | #VALUE! | |

Estimated profit/loss = Total Net Revenue (All procedures) – Annualized TCO

Estimated ROI= (Estimated profit/loss ÷ Annualized TCO) x 100

Needs Assessment Step 5

B. Calculating Return of Investment (ROI)

ROI greater than or equal to 0%:

✓ Positive

✓ Client can proceed with next step in procurement process ME.

ROI less than 0%:

✓ Negative

✓ Client should reconsider its decision to purchase the ME.



Case Study: Happy Medical Centre's New Clinic

Due to the increasing patient volume in Happy Medical Centre (50 beds), the CEO (Dr. James) has decided to start an additional clinic.

The new OBGYN clinic will **require an OBGYN ultrasound system**. The following slides demonstrate the steps taken by the medical center in planning for an ultrasound machine.



Case Study: Happy Medical Centre

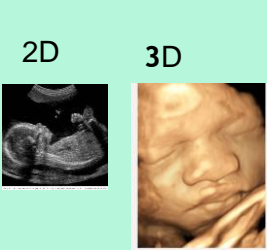


Step 1: Key Information Required for Planning

| Key Information Required for Planning | | | | | | | | | | | | | | |
|--|--|--|-----------------|------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Stakeholders involved (name,title): <u>Dr. James (CEO), John (procurement manager), Emma (physician), Lucas (IT staff), Noah (BME)</u> | | | | | | | | | | | | | | |
| Date: <u>5th June 2021</u> | | | | | | | | | | | | | | |
| No. | Questions | Response | | | | | | | | | | | | |
| a. | What would be the main reason for ME purchase? | <input type="checkbox"/> To replace ME which is beyond economical repair <input type="checkbox"/> To replace ME discontinued by manufacturer <input type="checkbox"/> To deliver new clinical service/application <input checked="" type="checkbox"/> To support increasing patient volume <input type="checkbox"/> Others, please specify : _____ | | | | | | | | | | | | |
| b. | What is the intended clinical service/application? <i>*Indicate ALL clinical services/applications intended to be delivered (consider current and future needs).</i> | To perform fetal scanning and transvaginal scanning | | | | | | | | | | | | |
| c. | Where is the location of use (Department, Room)? | OBGYN Clinic 2 | | | | | | | | | | | | |
| | - Is adequate space currently available to support the delivery of clinical service and increase in patient volume? | Yes | | | | | | | | | | | | |
| d. | What is the required ME type? <i>*Perform research to identify suitable equipment type for the intended clinical application.</i> | OBGYN Ultrasound | | | | | | | | | | | | |
| e. | What are the key features required? <i>*Indicate key technical requirements to deliver intended clinical services/applications (e.g., height-adjustable table, screen size, invasive blood pressure monitoring, 24-hours ECG monitoring, etc.).</i> | Able to create live video effect for fetal scanning | | | | | | | | | | | | |
| | - Patient type <i>*Indicate the type of patients expected to receive the services/applications.</i> | <input checked="" type="checkbox"/> Adult <input type="checkbox"/> Pediatric <input type="checkbox"/> Neonates <input type="checkbox"/> Bariatric | | | | | | | | | | | | |
| f. | What is the estimated patient volume? <i>*Refer to relevant documents/business case study/business plan</i> | <table border="1"> <thead> <tr> <th>Fetal scanning:</th> <th>Transvaginal scanning:</th> </tr> </thead> <tbody> <tr> <td>Year 2022: 100 patients</td> <td>Year 2022: 110 patients</td> </tr> <tr> <td>Year 2023: 200 patients</td> <td>Year 2023: 220 patients</td> </tr> <tr> <td>Year 2024: 300 patients</td> <td>Year 2024: 330 patients</td> </tr> <tr> <td>Year 2025: 400 patients</td> <td>Year 2025: 440 patients</td> </tr> <tr> <td>Year 2026: 500 patients</td> <td>Year 2026: 550 patients</td> </tr> </tbody> </table> | Fetal scanning: | Transvaginal scanning: | Year 2022: 100 patients | Year 2022: 110 patients | Year 2023: 200 patients | Year 2023: 220 patients | Year 2024: 300 patients | Year 2024: 330 patients | Year 2025: 400 patients | Year 2025: 440 patients | Year 2026: 500 patients | Year 2026: 550 patients |
| Fetal scanning: | Transvaginal scanning: | | | | | | | | | | | | | |
| Year 2022: 100 patients | Year 2022: 110 patients | | | | | | | | | | | | | |
| Year 2023: 200 patients | Year 2023: 220 patients | | | | | | | | | | | | | |
| Year 2024: 300 patients | Year 2024: 330 patients | | | | | | | | | | | | | |
| Year 2025: 400 patients | Year 2025: 440 patients | | | | | | | | | | | | | |
| Year 2026: 500 patients | Year 2026: 550 patients | | | | | | | | | | | | | |
| g. | What is the quantity of ME required? <i>*Refer to number of ME required to be replaced OR calculate based on anticipated number of patients versus procedure time and device capacity</i> | 1 unit | | | | | | | | | | | | |

- ✓ A consistent increase in the number of patient seeking OBGYN services
- ✓ The patient volume estimated to grow by
 - ✓ 100 patients for fetal scanning
 - ✓ 110 patients for transvaginal scanning
- ✓ Estimated procedure time for both procedures: 10 minutes
- ✓ Clinic operation time: 8 hours

Case Study: Happy Medical Centre

Step 2: Determine suitable medical equipment category

| Ultrasound Category | | Features and Clinical Application Guide | Examples of Brand/model available |
|---|--|---|--|
| Obstetrics and Gynecology (OB/GYN) Ultrasound (with 2D and 3D scanning mode) |  <p>2D 3D</p> | <ul style="list-style-type: none"> - Has specialized Obstetric Analysis software and interpretation tools specialized for gynecology - Able to obtain detailed organ images in the female pelvic region and perform transvaginal ultrasound that allows internal examination of the organ | <ul style="list-style-type: none"> • Philips / Sparq • GE / LOGIQ F8 |
| Obstetrics and Gynecology (OB/GYN) Ultrasound (with 2D, 3D and 4D scanning mode) |  <p>4D</p> | <ul style="list-style-type: none"> - Capable to perform all clinical application of a 2D/3D OBGYN Ultrasound. - Able to perform 4D scanning to create a live video effect. This scanning mode is usually used for Obstetric application to capture baby movement (e.g., baby smiles) inside the womb. | <ul style="list-style-type: none"> • Philips/ EPIQ 7 • GE/ Voluson S10 |
| Obstetrics and Gynecology (OB/GYN) Ultrasound (with 2D, 3D, 4D and 5D scanning mode) |  <p>5D</p> | <ul style="list-style-type: none"> - Capable to perform all clinical application of a 2D/3D/4D OBGYN Ultrasound. - Able to perform 5D scanning to give realistic view of baby inside the womb. This scanning mode will show baby with reddish/pinkish color. | <ul style="list-style-type: none"> • Samsung / WS80A Elite |



Case Study: Happy Medical Centre

Step 3: Identify Expertise Available/Required to Operate and Maintain Medical Equipment

- ✓ Additional doctor to **serve the patients and operate** the OBGYN ultrasound system
- ✓ Qualifications to operate the ME
 - ✓ Certified OBGYN specialist
 - ✓ Trained to operate ultrasound machine and interpret ultrasound images
- ✓ Has qualified in-house biomedical engineer to maintain the ME

Case Study: Happy Medical Centre

Step 4: Perform Request for Information (RFI)

- ✓ Additional doctor to **serve the patients and operate** the OBGYN ultrasound system
- ✓ Qualifications to operate the ME
 - ✓ Certified OBGYN specialist
 - ✓ Trained to operate ultrasound machine and interpret ultrasound images
- ✓ Has **qualified in-house biomedical engineer** to maintain the ME



Case Study: Happy Medical Centre

BRAND C QUOTATION

DATE
June 29, 2021

QTN No.
1991

Brand C
Salesperson: Mr. WAA
Mobile: 0121234567
Email: waa@brandc.org

Customer
Happy OBGYN Center
ATTN: Mr. LLI
Mobile: 0111122334
Email: LLI@obgynclinic.org

Brand C Model c

| PART NO. | DESCRIPTION OF GOODS | QTY | UNIT PRICE | TOTAL PRICE |
|--------------|---|-----|------------|------------------|
| 777 | OBGYN ultrasound including 2D,3D and 4D modes | 1 | 45,000 | 45,000 |
| 778 | Software package | 1 | 1,000 | 1,000 |
| 779 | Convex transducer | 1 | 3,000 | 3,000 |
| 780 | Endovaginal transducer | 1 | 4,000 | 4,000 |
| 781 | Volume transducer | 1 | 3,200 | 3,200 |
| 782 | Ultrasound gel - 1 Liter | 12 | 10 | 120 |
| 783 | Thermal Paper - 1 roll | 6 | 5 | 30 |
| NA | Service Manual | 1 | 0 | 0 |
| NA | User Training | 1 | 200 | 200 |
| Total | | | | \$ 56,550 |

Payment Terms: 60 days after invoice date
Standard Warranty: 12 months from the date of acceptance test
Delivery Time: 3- 4 months from date of confirmed order

For and on behalf of Brand C
WAA
MR, WAA

Brand D QUOTATION

TO:
[Happy OBGYN Centre](#)
Attn: [Mr. James](#)
Phone: 0111122334
Email: James@happy.org
QUOTATION NO.: U/S6012

DATE: JUNE 12, 2021

| Model No. | Description | Quantity | Unit Price (\$) | Amount (\$) |
|--------------|-------------------------|----------|-----------------|-----------------|
| Model d | OBGYN Ultrasound System | 1 | 38,000 | 38,000 |
| US10-3/4D | 3D and 4D module | 1 | 4,000 | 4,000 |
| US-112 | Curve/Convex Transducer | 1 | 3,200 | 3,200 |
| US-113 | Endovaginal Transducer | 1 | 3,100 | 3,100 |
| US-114 | Volume Transducer | 1 | 3,500 | 3,500 |
| N/A | User Training | 1 | 150 | 150 |
| N/A | Service Manual | 1 | 0 | 0 |
| OP-123 | Ultrasound Gel (1L) | 12 | 5 | 60 |
| OP-234 | Thermal Paper (roll) | 6 | 10 | 60 |
| Total | | | | \$52,070 |

Terms & Conditions:

Payment Term : 80 days after invoice
Standard Warranty : 12 months from the date of acceptance test
Delivery Time : 2 months from date of confirmed order

Prepared by:

Debbie

Mr. Debbie
Mobile: 01299788899
Sales Manager

Case Study: Happy Medical Centre

Equipment Data Sheet from identified supplier indicating space and MEP requirement for the medical equipment

Power supply required is 100-240V

Model c Ultrasound System

Electrical Parameters

AC Voltage

- AC voltage 100-240 V~
- 50 or 60 Hz
- 600 VA

Power must be available through a grounded outlet.

Dimensions

- Width: 59.2 cm (23.3 in)
- Height (with fully extended monitor): 188.6 cm (74.25 in)
- Height (with monitor folded down): 125.7 cm (49.5 in)
- Depth (Maximum extension): 111.8 cm (44 in)
- Depth (Minimum extension): 79.4 cm (31.25 in)
- Weight: 102 kg (225 lb)

Model d Electrical power

- Nominal input voltage: 100-240 VAC, frequency 50/60 Hz
- Nominal 900VA including all options Typical power consumption with 500VA load approx. 1.75A at 230V/50Hz without peripherals

Model d Dimensions and Weight:

- Width:
 - 620mm (24.4 in)
- Depth:
 - 865mm (34.1in)
- Height:
 - Maximum: 1730 mm (68.1 in)
 - Minimum: 1380mm (54.3in)
- Weight: 90 kg, 198 lbs

Case Study: Happy Medical Centre

Step 5: Perform Feasibility Study

| | 2022 | 2023 | 2024 | 2025 | 2026 | Total over 5 years |
|--|------------|-------------|-------------|-------------|-------------|--------------------|
| Fetal scanning | | | | | | |
| a. Anticipated number of patients per procedure | 100 | 200 | 300 | 400 | 500 | |
| b. Average direct cost per procedure | \$100.00 | \$100.00 | \$100.00 | \$100.00 | \$100.00 | |
| c. Fee charged per procedure | \$125.00 | \$125.00 | \$125.00 | \$125.00 | \$125.00 | |
| Net Revenue per procedure <i>- [(c) - (b)] x (a)</i> | \$2,500.00 | \$5,000.00 | \$7,500.00 | \$10,000.00 | \$12,500.00 | |
| Transvaginal scanning | | | | | | |
| a. Anticipated number of patients per procedure | 110 | 220 | 330 | 440 | 550 | |
| b. Average direct cost per procedure | \$125.00 | \$125.00 | \$125.00 | \$125.00 | \$125.00 | |
| c. Fee charged per procedure | \$150.00 | \$150.00 | \$150.00 | \$150.00 | \$150.00 | |
| Net Revenue per procedure <i>- [(c) - (b)] x (a)</i> | \$2,750.00 | \$5,500.00 | \$8,250.00 | \$11,000.00 | \$13,750.00 | |
| Total Net Revenue (All procedures) <i>- Sum of net revenue of all procedures</i> | \$5,250.00 | \$10,500.00 | \$15,750.00 | \$21,000.00 | \$26,250.00 | \$78,750.00 |

Case Study: Happy Medical Centre

| | 2022 | 2023 | 2024 | 2025 | 2026 | Total over 5 years |
|--|-------------|-------------|-------------|-------------|-------------|--------------------|
| Device Total Cost of Ownership: | | | | | | |
| 1. Initial Purchase Cost | | | | | | |
| a. Medical equipment purchase price | \$54,000.00 | | | | | |
| b. Infrastructure modifications | \$0.00 | | | | | |
| c. Clinical/ Biomedical staff training | \$175.00 | | | | | |
| 2. Annual Operational Cost | | | | | | |
| a. Comprehensive service contract cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | |
| b. Estimated scheduled maintenance cost <i>(if no service contract)</i> | \$0.00 | \$5,000.00 | \$5,000.00 | \$5,000.00 | \$5,000.00 | |
| c. Estimated repair cost <i>(if no service contract)</i> | \$0.00 | \$1,000.00 | \$1,000.00 | \$1,000.00 | \$1,000.00 | |
| d. Consumables Cost | \$45.00 | \$45.00 | \$45.00 | \$45.00 | \$45.00 | |
| e. Annual re-training cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 | |
| f. Reprocessing cost | \$500.00 | \$500.00 | \$500.00 | \$500.00 | \$500.00 | |
| Total cost of ownership/ year | \$54,720.00 | \$6,545.00 | \$6,545.00 | \$6,545.00 | \$6,545.00 | \$80,900.00 |
| Annualized total cost of ownership over 5 years | \$16,180.00 | \$16,180.00 | \$16,180.00 | \$16,180.00 | \$16,180.00 | |

Average Cost Calculation from Quotations:
a. Medical equipment purchase price =
 $(\$56,200 + \$51,800) / 2 = \$54,000$
b. Consumable cost = $(\$30 + \$60) / 2 = \$45$
c. User Training = $(\$200 + \$150) / 2 = \$175$

MEDICAL EQUIPMENT PURCHASING JOURNEY: APPLYING FOR FINANCING

What are your facility's risks in getting a loan to purchase medical equipment?



Creating Markets, Creating Opportunities

Risks to financing

ME does not meet your clinical application

Overestimation of patient number and affordability

Lack of expertise to use it

Underestimation of total cost of ownership

ME with hazards/alerts/recalls

Insufficient MEP services, space, room requirements

Medical equipment unused or underutilized



Hospital unable to generate adequate ROI



Hospital defaults on loan

Clinical Application

If the ME does not meet the intended clinical application, what might be the risk(s)?

1.5T



Example 1, Step 1

1 Application Submission Form 1 (Completed by applicant)

| To be completed by Applicant | |
|--|---|
| <u>Application Submission Form 1: Medical Equipment Information</u> | |
| Medical Equipment Type: | <i>Digital X-Ray</i> |
| Medical Equipment Category: | <i>Bucky Stand Only</i> |
| Brand/Model: | <i>Philips DigitalDiagnost</i> |
| Quantity: | <i>1</i> |
| Location of use (Department: Room): | <i>Imaging department: X-Ray Room 1</i> |
| Medical Equipment Purchase Price per unit: | <i>\$50,000</i> |
| Total Medical Equipment Purchase Price: | <i>\$50,000</i> |
| Warranty duration (at least one year): | <i>1 year</i> |
| Clinical application: | <i>Perform full body X-ray scanning</i> |

ME does not meet clinical application

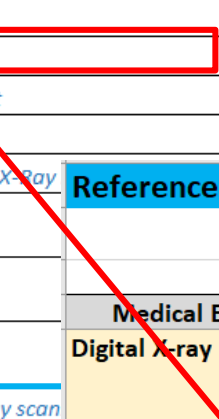
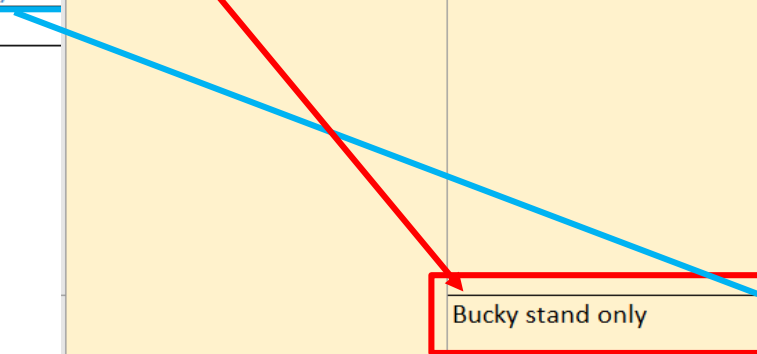
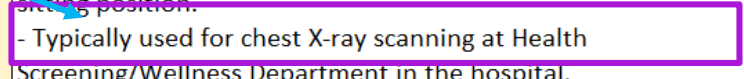
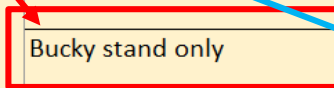
Example 1, Step 2

1 Application Submission Form 1 (Completed by applicant)

| To be completed by Applicant | |
|---|------------------------------|
| Application Submission Form 1: Medical Equipment Information | |
| Medical Equipment Type: | Digital X-Ray |
| Medical Equipment Category: | Bucky Stand Only |
| Brand/Model: | Philips DigitalDiagnost |
| Quantity: | 1 |
| Location of use (Department: Room): | Imaging department: X-Ray |
| Medical Equipment Purchase Price per unit: | \$50,000 |
| Total Medical Equipment Purchase Price: | \$50,000 |
| Warranty duration (at least one year): | 1 year |
| Clinical application: | Perform full body X-ray scan |

2 ME Category Reference Sheet

| Reference document for user (for internal use only) | | |
|---|---|--|
| Medical Equipment Category Reference | | |
| Medical Equipment Type | Medical Equipment Category | Clinical Application |
| Digital X-ray | Combination of table unit and bucky stand | <ul style="list-style-type: none"> - Perform X-ray scanning to identify fractures/break, location of infection and tumors in bones; identify arthritis; diagnose pneumonia, tuberculosis, or lung cancer; identify problems in the digestive tract such as kidney stones. - A complete set of X-ray table and bucky stand allows examination to be performed for all types of patients. - X-ray table unit allows scanning on patient from head to toe in lying (supine or prone) position which is preferred for patient with limited mobility (e.g. elderly, disabled); whereas Bucky stand allows scanning on patient in standing or sitting position. |
| | Bucky stand only | <ul style="list-style-type: none"> - Only allows X-ray scanning to be performed on standing or sitting position. - Typically used for chest X-ray scanning at Health Screening/Wellness Department in the hospital. |
| | Mobile X-ray | <ul style="list-style-type: none"> - Allows X-ray scanning to be performed on patients in Intensive Care Units (ICU), Operating Theaters or Emergency Rooms, where transferring patients to the Radiology Department may be an obstacle. |



ME does not meet clinical application

Example 1, Step 3

3 Loan Application Assessment Checklist (Completed by assessor)

Action by assessor:
 - **REJECT** the loan application

| No. | Assessment Criteria | Assessor's Guide | Y/N | *N/I | Comments |
|-----|---|--|-----|------|---|
| 1.d | Is the indicated ME category suitable to deliver the intended clinical application? | <p>- Utilizing the ME Category Reference Sheet, assessor should check if the indicated ME category is suitable to deliver the intended clinical application. The ME Category Reference Sheet can be used for the purchase of MRI, CT, X-ray and Ultrasounds.</p> <p>- If the indicated ME category is not suitable to deliver the intended clinical application, assessor should reject the loan application.</p> <p><i>Note: For other medical equipment, assessor may verify with supplier/distributor/manufacture if the indicated ME category is suitable to deliver the planned clinical application.</i></p> | N | | ME category proposed (Bucky stand only) cannot carry out full body X-ray scanning |

Example 2, Step 1

1 Application Submission Form 1 (Completed by applicant)

ME does not meet
clinical application

| Application Submission Form 1: Medical Equipment Information | |
|---|--|
| Medical Equipment Type: | <i>Digital X-ray</i> |
| Medical Equipment Category: | <i>Bucky Stand Only</i> |
| Brand/Model: | <i>Philips DigitalDiagnost</i> |
| Quantity: | <i>1</i> |
| Location of use (Department: Room): | <i>Health Screening department: X-Ray Room 1</i> |
| Medical Equipment Purchase Price per unit: | <i>\$50,000</i> |
| Total Medical Equipment Purchase Price: | <i>\$50,000</i> |
| Warranty duration: (at least one year required) | <i>1 year</i> |
| Clinical Application: | <i>Perform chest X-ray scannings</i> |
| | |
| | |

Example 2, Step 2-3

ME does not meet clinical application

1 Application Submission Form 1 (Completed by applicant)

| Application Submission Form 1: Medical Equipment Information | |
|--|---|
| Medical Equipment Type: | Digital X-ray |
| Medical Equipment Category: | Bucky Stand Only |
| Brand/Model: | Philips DigitalDiagnost |
| Quantity: | 1 |
| Location of use (Department: Room): | Health Screening department: X-Ray Room 1 |
| Medical Equipment Purchase Price per unit: | \$50,000 |
| Total Medical Equipment Purchase Price: | \$50,000 |
| Warranty duration: (at least one year required) | 1 year |
| Clinical Application: | Perform chest X-ray scannings |

Loan Application Assessment Checklist (Completed by assessor)

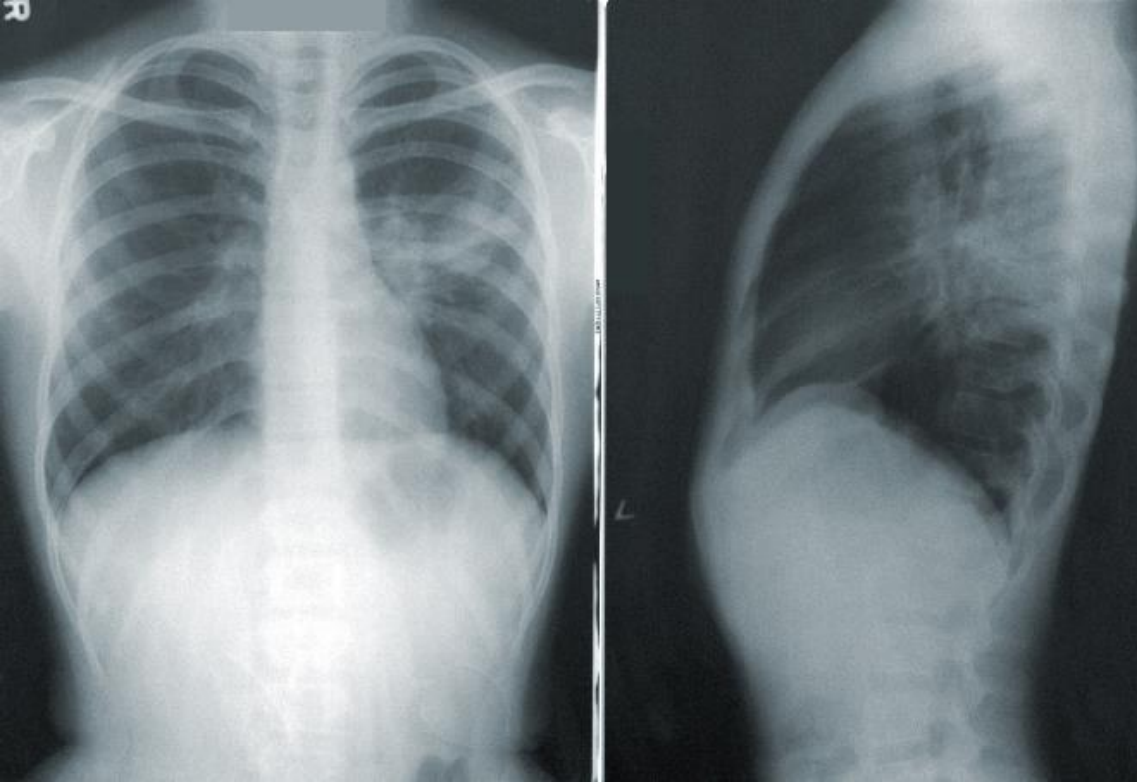
| No. | Assessment Criteria | Assessor's Guide | Y/N | *N/I | Comments |
|-----|---|---|-----|------|----------|
| 1.d | Is the indicated ME category suitable to deliver the intended clinical application? | <p>- Utilizing the ME Category Reference Sheet, assessor should check if the indicated ME category is suitable to deliver the intended clinical application. The ME Category Reference Sheet can be used for the purchase of MRI, CT, X-ray and Ultrasounds.</p> <p>- If the ME category is not suitable to deliver the intended clinical application, assessor should reject the loan application.</p> <p><i>Note: For other medical equipment, assessor may verify with supplier/distributor/manufacturer if the indicated ME category is suitable to deliver the planned clinical application.</i></p> | y | | |

2 ME Category Reference Sheet

| Reference document for user (for internal use only) | | |
|---|---|--|
| Medical Equipment Category Reference | | |
| Medical Equipment Type | Medical Equipment Category | Clinical Application |
| Digital X-ray | Combination of table unit and bucky stand | <p>Perform X ray scanning to identify fractures/break, location of infection and tumors in bones; identify arthritis; diagnose pneumonia, tuberculosis, or lung cancer; identify problems in the digestive tract such as kidney stones.</p> <p>- A complete set of X-ray table and bucky stand allows examination to be performed for all types of patients.</p> <p>- X-ray table unit allows scanning on patient from head to toe in lying (supine or prone) position which is preferred for patient with limited mobility (e.g. elderly, disabled); whereas Bucky stand allows scanning on patient in standing or sitting position.</p> <p>- Only allows X-ray scanning to be performed on standing or sitting position.</p> <p>Typically used for chest X ray scanning at Health screening/Wellness Department in the hospital.</p> |
| | Bucky stand only | |
| | Mobile X-ray | - Allows X-ray scanning to be performed on patients in Intensive Care Units (ICU), Operating Theaters or Emergency Rooms, where transferring patients to the Radiology Department may be an obstacle. |

Overestimate of Patient Number

Overestimation of
patient number and
affordability



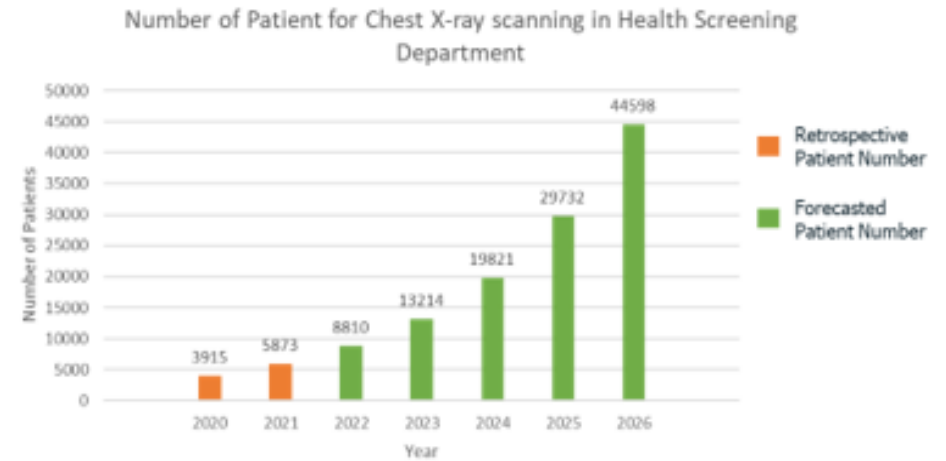
If the facility
overestimates the
number of patients,
what might be the
risk(s)?

Example 1, Step 1: Applicant Overestimated Patient Number

To justify purchasing an additional unit of Bucky Stand, the applicant provided a supporting document illustrating the retrospective patient trend from year 2020 to 2021 and the forecasted patient number from year 2022 to 2026.

1 Supporting Document from Applicant

Happy Medical Center Patient Volume Projection for Year 2022-2026



The graph illustrates the increase of patient number for chest x-ray scanning in Health Screening Department between years 2020 to 2026. In year 2020, 3915 patients underwent chest scanning in the department. In 2021, the department received 5,873 for chest screening.

Based on the retrospective patient number, it is forecasted that there will be a 50% increase in patient number from the year 2022 onwards as there is a 50% increase in patient from year 2020 to 2021.

The existing unit will not be sufficient to serve the increasing patient number foreseen in 2022 onwards. Therefore, it is proposed for the hospital to purchase an additional unit of Bucky Stand to meet the immediate demand expected in 2022 and 2023.

Overestima
patient num
affordab

Example 1, Step 2

2 Loan Application Assessment Checklist (Completed by assessor)

Overestimation of patient number and affordability

1 Supporting Document from Applicant



The forecasted increase of patient volume by 50% per year is not sufficiently supported. 50% growth in patient number from 2020 to 2021, does not provide assurance that there will continue to be a similar growth.

| No. | Assessment Criteria | Assessor's Guide | Y/N | *N/I | Comments |
|-----|---|---|-----|------|--|
| 2 | Application Submission Form 2: Purchase Justification | <ul style="list-style-type: none"> - Check the completeness of the Application Submission Form 2: Purchase Justification. - Check if relevant supporting documents are provided to justify the purchase of ME: <ul style="list-style-type: none"> i. Maintenance report from manufacturer/supplier/distributor indicating the equipment is beyond economical repair (BER); OR ii. Maintenance report from manufacturer indicating the estimated life span of the equipment; OR iii. Letter from manufacturer stating the existing model is discontinued; OR | Y | / | Request applicant to provide further clarification on the forecasted patient number for years 2022 to 2026 |

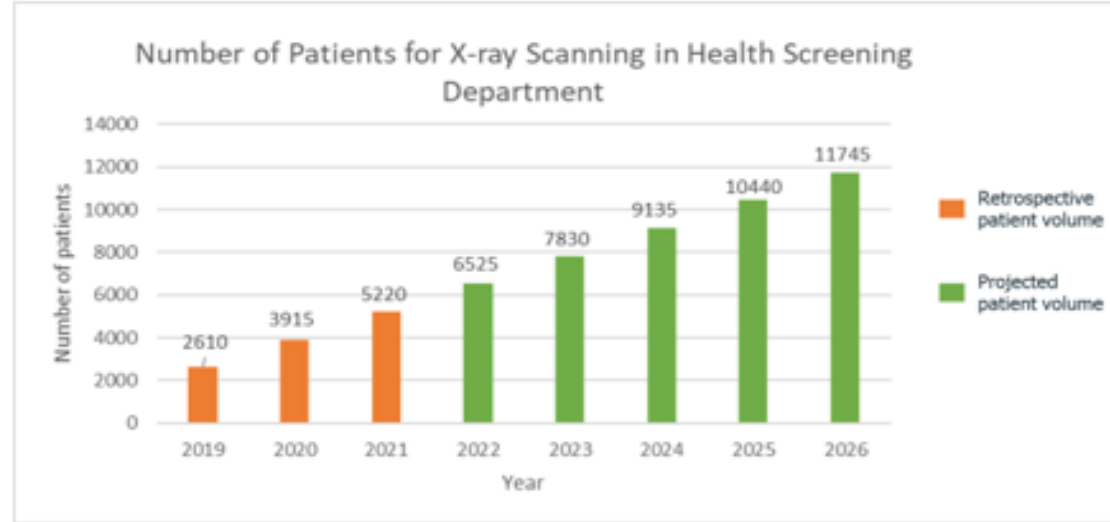
Action by Assessor:
Request applicant to provide additional supporting documents to justify that the patient number will increase by 50% every year from 2022 onwards.

Example 2, Step 1

To justify purchasing an additional unit of Bucky Stand, the applicant provided a supporting document to illustrate the retrospective patient trend from year 2019 to 2021 and the forecasted patient number from year 2022 to 2026.

1 Supporting Document from Applicant Showing the Rise in Patient Number

Happy Medical Center Patient Volume Projection for Year 2022-2026



Overestimation of patient number and affordability

The graph illustrates the increase of patient number for chest x-ray scanning in Health Screening Department between years 2019 to 2026. In 2019, 2610 patients underwent chest scanning in the department, this number reflects 10 patients/day (2610 patients/261 working days in a year). In 2020, the department received 3,915 patients (or 15 patients/day) for chest screening, followed by 5,220 patients in 2021 (or 20 patients/day). This trend shows that there has been a steady increase of about 5 patients/day or 1,305 patients a year (5 patients/day x 261 working days).

Based on this trend, we have forecasted that the patient number will continued to grow by at least 1,305 patients/year (or 5 patients/day). The projection shows that the department will receive 25 patients/day in 2022, 30 patients/day in 2023, 35 patients/day in 2024, 40 patients/day in 2025 and 45 patients/day in 2026.

The department's record as of December 2021 indicates that the existing one unit of Bucky Stand can be used to scan a maximum of 24 patients/day. This unit will not be sufficient to serve the additional patient number the department is forecasted to receive from 2022 onwards. Therefore, it is proposed for the hospital to purchase an additional unit of Bucky Stand to meet the immediate demand expected in 2022 and 2023.

Example 2, Step 2

1 Supporting Document from Applicant Showing the Rise in Patient Number



According to supporting document provided, one unit of Bucky stand can serve a maximum of 24 patients/day. The forecasted patient number/day from year 2022 onwards is >25, justifying the purchase of an additional Bucky Stand.

2 Loan Application Assessment Checklist (Completed by assessor)

Overestimation of patient number and affordability

| No. | Assessment Criteria | Assessor's Guide | Y/N | *N/I | Comments |
|-----|---|---|-----|------|----------|
| 2 | Application Submission Form 2: Purchase Justification | <p>- Check the completeness of the Application Submission Form 2: Purchase Justification.</p> <p>- Check if relevant supporting documents are provided to justify the purchase of ME:</p> <p>i. Maintenance report from manufacturer/supplier/distributor indicating the equipment is beyond economical repair (BER); OR</p> <p>ii. Maintenance report from manufacturer indicating the estimated life span of the equipment; OR</p> <p>iii. Letter from manufacturer stating the existing model is discontinued; OR</p> | Y | | |

Action by Assessor:
Move on to the next assessment section.

Lack of Expertise

Lack of expertise



If the facility lacks the expertise to use the ME, what might be the risk(s)?

Resource: Specialists and Required Knowledge

| ME Type | Specialists | Required knowledge |
|---------------------|---|--|
| MRI, CT, X-Ray | Radiologists, x-ray technologists, medical physicists | <ul style="list-style-type: none">• Trained on radiation safety issues• Optimize radiation dose for a given clinical task and patient group (adult vs pediatric)• Perform quality control tests to ensure equipment is functioning properly. |
| Ultrasound machines | Ultrasound technician/sonographer, physicians, surgeons, radiologists | <ul style="list-style-type: none">• Trained to operate ultrasound machines• Interpret ultrasound images (does not apply to technician/sonographer) |

Example 1, Step 1

1 Supporting Documents from Applicant

Happy Medical Center
Employment Verification Letter

To whom it may concern,

This letter serves to confirm that the following individuals are permanent employees at Happy Medical Centre. Details on the specialists' name, qualifications as well as employment starting date are indicated below for your reference.

| No. | Name | Qualification | Employment Start Date |
|-----|--------------|---|-----------------------|
| 1 | John A | B.Sc (Hons.) in Medical Radiotherapy | 1 January 2018 |
| 2 | Dr. Amanda B | Diploma in X-ray Radiography and Ultra-sonography | 3 June 2019 |

Please do not hesitate to contact me should you require further information.

Yours sincerely,
A.
Head of Human Resource Department
Tel: 0123456789
Email: a@happymedcenter.org

Lack of expertise



Example 1, Step 2

1 Supporting Documents from Applicant



Qualifications and availability provided

2 Loan Application Assessment Checklist (Completed by assessor)

| | | | |
|---|---|---|---|
| 3 | Is a specialist available to operate the medical equipment? | <p>- Check if applicant provided documentation of education, qualification, and experience of the identified specialists.</p> <p>- If the required clinical specialists are not available, check if applicant provided Specialist recruitment plan and/or Training schedule.</p> | Y |
|---|---|---|---|

| ME Type | Specialists | Required knowledge |
|----------------|---|--|
| MRI, CT, X-Ray | Radiologists, x-ray technologists, medical physicists | <ul style="list-style-type: none"> Trained on radiation safety issues Optimize radiation dose for a given clinical task and patient group (adult vs pediatric) Perform quality control tests to ensure equipment is functioning properly. |

Action by Assessor:
Move on to the next assessment section.

Employment Verification Letter

To whom it may concern,

This letter serves to confirm that the following individuals are permanent employees at Happy Medical Centre. Details on the specialists' name, qualifications as well as employment starting date are indicated below for your reference.

| No. | Name | Qualification | Employment Start Date |
|-----|--------------|---|------------------------------|
| 1 | John A | B.Sc (Hons.) in Medical Radiotherapy | 1 st January 2018 |
| 2 | Dr. Amanda B | Diploma in X-ray Radiography and Ultra-sonography | 3 rd June 2019 |

Please do not hesitate to contact me should you require further information.

Yours sincerely,

A.

Head of Human Resource Department

Tel: 0123456789

Email: a@happymedcenter.org

Example 2, Step 1

1 Supporting Document from Applicant

Example 2, Step 2

1 Supporting Document from Applicant

Happy Medical Center
Employment Verification Letter

To whom it may concern,

This letter serves to confirm that the following individuals are permanent employees at Happy Medical Centre. Details on the specialists' name, qualifications as well as employment starting date are indicated below for your reference.

| No. | Name | Qualification | Start Date |
|-----|------------|--|------------------------------|
| 1 | John A. | B.Sc (Hons.) in Medical Radiotherapy | 1 st January 2018 |
| 2 | Dr. Amanda | Diploma in X-ray Radiography and T/fluoroscography | 3 rd June 2019 |

Please do not hesitate to contact me should you require further information.

Yours sincerely,
A.
Head of Human Resource Department
Tel: 0123456789
Email: a@happycenter.org

Specialists' Certificates not provided

2 Loan Application Assessment Checklist (Completed by assessor)

| | | | | |
|---|---|--|---|---|
| 3 | Is a specialist available to operate the medical equipment? | <ul style="list-style-type: none"> - Check if applicant provided documentation of education, qualification, and experience of the identified specialists. - If the required clinical specialists are not available, check if applicant provided Specialist recruitment plan and/or Training schedule. | N | D'd not provide evidence of qualifications. |
|---|---|--|---|---|



Applicant provided employment verification letter, but not evidence of qualifications.

Action by assessor:
Request the applicant to provide copies of specialists' certificates

Underestimation of Operation Costs

Underestimation of operation costs

If the facility underestimates the operational costs of the new ME, what might be the risk(s)?

| B) Calculation of Total Cost of Ownership (TCO) for Medical Equipment | | | | | |
|---|-------------|-------------|-------------|-------------|-------------|
| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| Device Total Cost of Ownership: | | | | | |
| 1. Initial Purchase Cost | | | | | |
| a. Medical equipment purchase price | \$50,000.00 | | | | |
| b. Infrastructure modifications | \$15,000.00 | | | | |
| c. Clinical/ Biomedical staff training | \$500.00 | | | | |
| d. X-ray shield (X-ray apron, vest, apron rack) | \$2,300.00 | | | | |
| 2. Annual Operational Cost | | | | | |
| a. Comprehensive service contract cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| b. Estimated scheduled maintenance cost (<i>if no service contract</i>) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| c. Estimated repair cost (<i>if no service contract</i>) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| d. Consumables Cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| e. Annual re-training cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| f. Reprocessing cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Total cost of ownership/ year | \$65,500.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Annualized total cost of ownership over 5 years | \$13,100.00 | \$13,100.00 | \$13,100.00 | \$13,100.00 | \$13,100.00 |

Underestimation of total cost of ownership

Example 1, Step 1 Annual Operational Cost

1 Application Submission Form 3 (Completed by applicant)

| B) Calculation of Total Cost of Ownership (TCO) for Medical Equipment | | | | | |
|---|-------------|-------------|-------------|-------------|-------------|
| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| Device Total Cost of Ownership: | | | | | |
| 1. Initial Purchase Cost | | | | | |
| a. Medical equipment purchase price | \$50,000.00 | | | | |
| b. Infrastructure modifications | \$15,000.00 | | | | |
| c. Clinical/ Biomedical staff training | \$500.00 | | | | |
| d. X-ray shield (X-ray apron, vest, apron rack) | \$2,300.00 | | | | |
| 2. Annual Operational Cost | | | | | |
| a. Comprehensive service contract cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| b. Estimated scheduled maintenance cost (if no service contract) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| c. Estimated repair cost (if no service contract) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| d. Consumables Cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| e. Annual re-training cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| f. Reprocessing cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Total cost of ownership/ year | \$65,500.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Annualized total cost of ownership over 5 years | \$13,100.00 | \$13,100.00 | \$13,100.00 | \$13,100.00 | \$13,100.00 |

Underestimation of total cost of ownership

Example 1, Step 2

1 Application Submission Form 3 (Completed by applicant)

| B) Calculation of Total Cost of Ownership (TCO) for Medical Equipment | | | | | |
|---|-------------|-------------|-------------|-------------|-------------|
| Device Total Cost of Ownership: | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
| I. Initial Purchase Cost | | | | | |
| a. Medical equipment purchase price | \$0,000.00 | | | | |
| b. Infrastructure modifications | \$15,000.00 | | | | |
| c. Clinical/ biomedical staff training | \$500.00 | | | | |
| d. X-ray shield (X-ray apron, vest, apron rack) | \$2,300.00 | | | | |
| II. Annual Operational Cost | | | | | |
| a. Comprehensive service contract cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| b. Estimated scheduled maintenance cost (if no service contract) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| c. Estimated repair cost (if no service contract) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| d. Consumables Cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| e. Annual re-training cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| f. Reprocessing cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Total cost of ownership/ year | \$65,500.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Annualized total cost of ownership over 5 years | \$13,100.00 | \$13,100.00 | \$13,100.00 | \$13,100.00 | \$13,100.00 |

2 Loan Application Assessment Checklist (Completed by assessor)

| No. | Assessment Criteria | Assessor's Guide | Y/N | INI | Comments |
|-----|---|--|-----|-----|--|
| 4.f | Estimated Total Cost of Ownership (TCO) for the medical equipment - Did the TCO consider the initial purchase cost and its annual operational cost? | - Check if applicant indicated all costs incurred under initial purchase cost and annual operational cost. | N | | Applicant did not indicate any annual operational cost in Form 3 |

Action by assessor:

Request applicant to resubmit Form 3 with the required annual operational cost



Annual operational cost were not indicated in Form 3.

Example 2, Step 1

Underestimation of total cost of ownership

1 Application Submission Form 3: Feasibility Study (Completed by applicant)

B) Calculation of Total Cost of Ownership (TCO) for Medical Equipment

| | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 |
|--|--------------------|---------------|---------------|---------------|---------------|
| Device Total Cost of Ownership: | | | | | |
| 1. Initial Purchase Cost | | | | | |
| a. Medical equipment purchase price | \$50,000.00 | | | | |
| b. Infrastructure modifications | \$15,000.00 | | | | |
| c. Clinical/ Biomedical staff training | \$500.00 | | | | |
| d. X-Ray Shield (X-ray apron, vest, apron rack) | \$2,300.00 | | | | |
| 2. Annual Operational Cost | | | | | |
| a. Comprehensive service contract cost | \$0.00 | \$15,000.00 | \$15,000.00 | \$15,000.00 | \$18,000.00 |
| b. Estimated scheduled maintenance cost (if no service contract) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| c. Estimated repair cost (if no service contract) | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| d. Consumable cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| e. Annual re-training cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| f. Reprocessing cost | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| g. | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| h. | \$0.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |
| Total cost of ownership/ year | \$67,800.00 | \$0.00 | \$0.00 | \$0.00 | \$0.00 |

2 Supplier's Quotation

ABCD

ABCD Servicing Co.
 Tel: +1122334411223
 Fax: +1122334411322
 Email: ABCD@abcd.org

Our Reference: ABCD/Q1/0015 Date: 22/8/2020

Happy Medical Center

Attn: M- POB
 Phone: 0111122334
 Email: POB@happy.org

Dear Sir / Madam,

SERVICE CONTRACT PRICE FOR PHILIPS DR16AG16AGN021

| Type of Maintenance Service | After Warranty Period (\$) | | | | |
|---|----------------------------|----------------------|----------------------|----------------------|----------------------|
| | 1 st Year | 2 nd Year | 3 rd Year | 4 th Year | 5 th Year |
| NON-COMPREHENSIVE —which includes: Preventive Maintenance (2 times per year) + Unlimited breakdown calls OUT WITHOUT SPARE PARTS | 8,000 | 8,000 | 8,000 | 10,000 | 10,000 |
| COMPREHENSIVE —which includes: Preventive Maintenance (2 times per year) + Unlimited breakdown calls INCLUDES ALL THE SPARE PARTS | 15,000 | 15,000 | 15,000 | 18,000 | 18,000 |

TERMS AND CONDITIONS:

- * Contract coverage includes Routine servicing as well as breakdown repair on a 1 year round.
- * Routine servicing includes calibration, performance system check, adjustment, essential wear & tear replacement will be carried out at a pre-informed rate set.
- * Contract coverage does not include the damage or loss caused by mishandling, fires, floods, lightning or cause by failure to meet the specified conditions for this equipment, such as inadequate power supply or unacceptable environmental conditions.
- * The price is only valid when the above contract price is purchase 1 month before the warranty expires.
- * Response time for Breakdown calls within:
 - 2 hours by phone
 - 4 hours at site within 15km radius of City A
 - 12 hours at site outside radius of City A, (Office Hours: 9.00a.m. - 5.00p.m. (Mon-Fri))

Prepared by:

 Mr. JKL
 Mobile: 01122112211

Example 2, Step 2

Underestimation of
total cost of
ownership



For this submission, relevant annual operational costs have been indicated in Form 3 and supported with quotation from supplier/distributor.

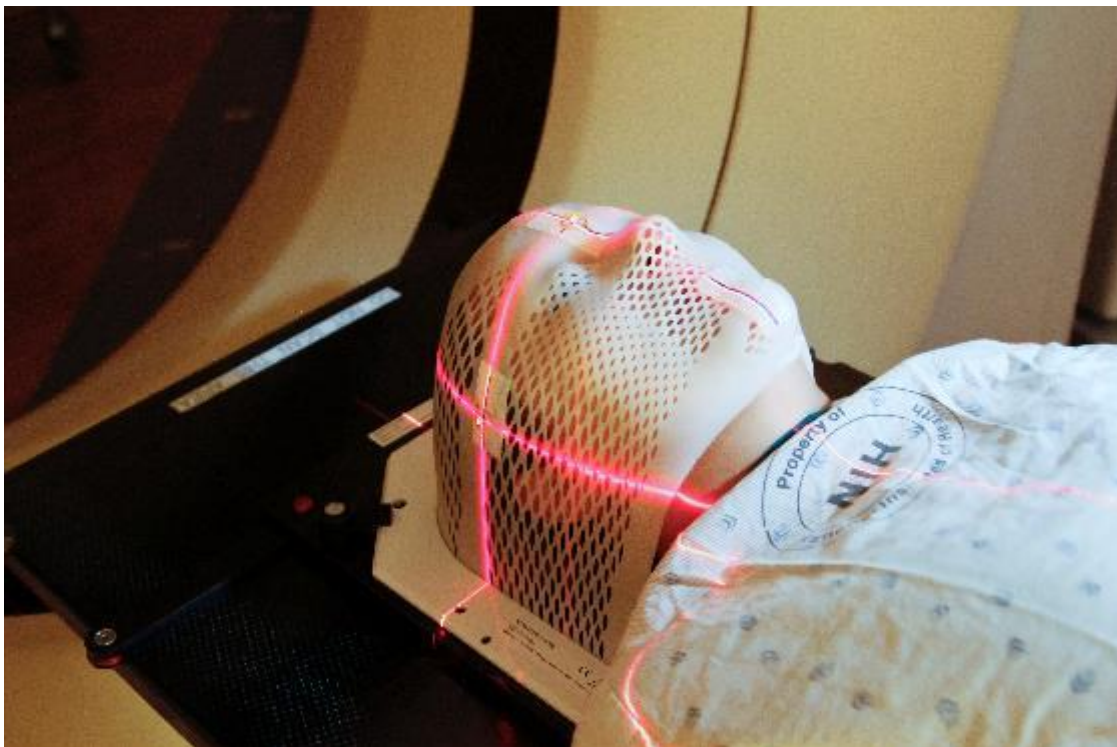
3 Loan Application Assessment Checklist (Completed by assessor)

| No. | Assessment Criteria | Assessor's Guide | Y/N | *N/I | Comments |
|--------|---|--|-----|------|----------|
| 4.f.ii | Are supporting documents from supplier/distributor provided to justify costs indicated under <u>annual operational cost</u> ? | - Review supplier/distributor's quotation for cost of consumables, scheduled maintenance, annual re-training, estimated repair costs, service contract, costs of software updates to ensure accuracy. (Refer to submission of quotation from applicant for Form 3) | Y | | |

ME with Hazards, Alerts, or Recalls

ME with
hazards/alerts/recalls

If there are hazards, alerts, or recalls on an ME, what might be the risk(s)?



Example 1, Step 1

ME with hazards/alerts/recalls

1 Application Submission Form 4: Reported Hazards/Alerts/Recalls (Completed by Applicant)

| Application Submission Form 4: Reported Hazards/Alerts/Recalls | | | | | | | | |
|---|---------|-----------------|--|--|------------------------------------|---|--|---|
| * Applicant to check if there are reports of hazard/alerts/recalls on the medical equipment model intended for purchase in the last 3 years. Copies of hazard/alerts/recalls reports must be attached to this form for bank review. | | | | | | | | |
| Medical Equipment Type intended for purchase | Brand | Model | Are reported hazards/alerts/recalls found on the model in the last 3 years? (Yes/No) | Websites/Sources checked by applicant for hazards/alerts/recalls reports (e.g. USFDA, MHRA, TGA, Bfarm, manufacturer letter, etc.) | Date of hazard/alert/recall report | Reported hazard/alert/recall | Corrective actions taken by manufacturer | Hazard/alert/recall report attached to this form? (Yes/No/Not Applicable) |
| Digital X-Ray | Philips | DigitalDiagnost | Yes | ECRI Alerts | 2nd October 2012 | Mobile Detector Holder Used with DigitalDiagnost Systems: Wireless Portable Detector May Fall | | Yes |

2 Hazards/Alerts Report from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm>

Accession Number: A18829 **ECRI Priority:** High **Published:** 10/02/2012
Channel: Devices **FDA:** Class II **Last Updated:** 10/15/2012
Philips—Mobile Detector Holder Used with DigitalDiagnost Systems: Wireless Portable Detector May Fall

Product Identifier: +

Manufacturer(s):

Philips Healthcare North America, 3000 Minuteman Rd, Andover, MA 01810-1099, United States

Problem:

In an August 13, 2012, Urgent Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM) and the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Philips states that the 4 countersunk screws that attach the wireless portable detector to the mobile detector holder in the above systems may become loose. If the screws become loose and the mechanism fails, the detector may fall off when the holder is rotated 90° clockwise. FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a field correction by Urgent Medical Device Correction letter dated August 13, 2012.

Example 1, Step 2

ME with hazards/alerts/recalls

| Application Submission Form 4: Reported Hazards/Alerts/Recalls | | | | | | | | |
|---|---------|-----------------|--|--|------------------------------------|---|--|---|
| * Applicant to check if there are reports of hazard/alerts/recalls on the medical equipment model intended for purchase in the last 3 years. Copies of hazard/alerts/recalls reports must be attached to this form for bank review. | | | | | | | | |
| Medical Equipment Type intended for purchase | Brand | Model | Are reported hazards/alerts/recalls found on the model in the last 3 years? (Yes/No) | Websites/Sources checked by applicant for hazards/alerts/recalls reports (e.g. USFDA, MHRA, TGA, Bfarm, manufacturer letter, etc.) | Date of hazard/alert/recall report | Reported hazard/alert/recall | Corrective actions taken by manufacturer | Hazard/alert/recall report attached to this form? (Yes/No/Not Applicable) |
| Digital X-Ray | Philips | DigitalDiagnost | Yes | ECRI Alerts | 2nd October 2012 | Mobile Detector Holder Used with DigitalDiagnost Systems: Wireless Portable Detector May Fall | | Yes |



The brand/model of the ME to be purchased was found to have a hazard/alert. No corrective action was indicated in Form 4 for the identified hazard/alert.

3 Loan Application Assessment Checklist (Completed by assessor)

| No. | Assessment Criteria | Assessor's Guide | Y/N | SN/I | Comments |
|-------|--|--|-----|------|---|
| 5 | Is the Application Submission Form 4: Reported Hazards/Alerts/Recalls completed by the applicant? | - Check the completeness of Application Submission Form 4: Reported Hazards/Alerts/Recalls . | Y | | |
| 5.a | Did the applicant check relevant <u>sources/websites</u> to identify reported hazards/alerts/recalls on the ME model? | - Check if applicant indicated <u>sources/websites</u> used to identify reported hazards/alerts/recall on the model. | Y | | |
| 5.b | Does the model have any reported recalls? | - If the model is indicated to have been recalled by the manufacturer, assessor should reject the loan application. | N | | |
| 5.c | Does the model have any reported hazards/alerts? | - If the model indicated for purchase is impacted, check if a copy of hazards/alerts report is submitted. | Y | | |
| 5.c.i | Was a corrective action report or letter from manufacturer indicating that the ME to be purchased will not be impacted provided? | -Check for corrective actions report for the respective hazards/alerts to see if the reported problem has been resolved; OR -Check for letter from manufacturer indicating ME to be purchased is not impacted by the hazards/alerts . | N | | Request applicant to provide a corrective action report/letter from manufacturer indicating model to be purchased in not affected by the hazard/alert during the resubmission of loan application |

Action by Assessor:
Request applicant to provide a corrective action report/letter from manufacturer indicating model to be purchased in not affected by the hazard/alert during the resubmission of loan application.

Example 2, Step 1

1 Complete Application Submission Form 4

Application Submission Form 4: Reported Hazards/Alerts/Recalls

* Applicant to check if there are reports of hazard/alerts/recalls on the medical equipment model intended for purchase in the last 3 years. Copies of hazard/alerts/recalls reports must be attached to this form for bank review.

| Medical Equipment Type intended for purchase | Brand | Model | Are reported hazards/alerts/recalls found on the model in the last 3 years? (Yes/No) | Websites/Sources checked by applicant for hazards/alerts/recalls reports (e.g. USFDA, MHRA, TGA, BfArM, manufacturer) | Date of hazard/alert/ recall report | Reported hazard/alert/recall | Corrective actions taken by manufacturer | Hazard/alert/ recall report attached to this form? (Yes/No/Not Applicable) |
|--|---------|-----------------|--|---|-------------------------------------|---|--|--|
| Digital X-Ray | Philips | DigitalDiagnost | Yes | ECRI Alerts | 2nd October 2012 | Mobile Detector Holder Used with DigitalDiagnost Systems: Wireless Portable Detector May Fall | Users should control the lock mechanism of the holder and if it can be moved without pressing the actuator, the holder should not be rotated clockwise. Philips will secure the 4 countersunk screws with Loctite 243 Threadlockers. | Yes |

2 Hazards/Alerts Report

Accession Number: A18623 ECR Priority: High Published: 16/10/2012
 Channel: Devices FDA: Class II Last Updated: 16/10/2012
 Philips—Mobile Detector Holder Used with DigitalDiagnost Systems: Wireless Portable Detector May Fall

Product Identifier: +

Manufacturer(s):
 Philips Healthcare North America, 3000 Minuteman Rd., Andover, MA 01810-1099, United States

Problem:
 From August 13, 2012, Urgent Field Safety Notice letter posted by the German Federal Institute for Drug and Medical Devices (BfArM) and the UK Medicines and Healthcare Products Regulatory Agency (MHRA), Philips states that the 4 countersunk screws that attach the wireless portable detector to the mobile detector holder in the above systems may become loose. If the screws become loose and the mechanism fails, the detector may fall off when the holder is rotated 90° clockwise. FDA's Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a field correction by Urgent Medical Device Correction letter dated August 13, 2012.

3 Corrective Action Report

Lock mechanism of Mobile Detector Holder

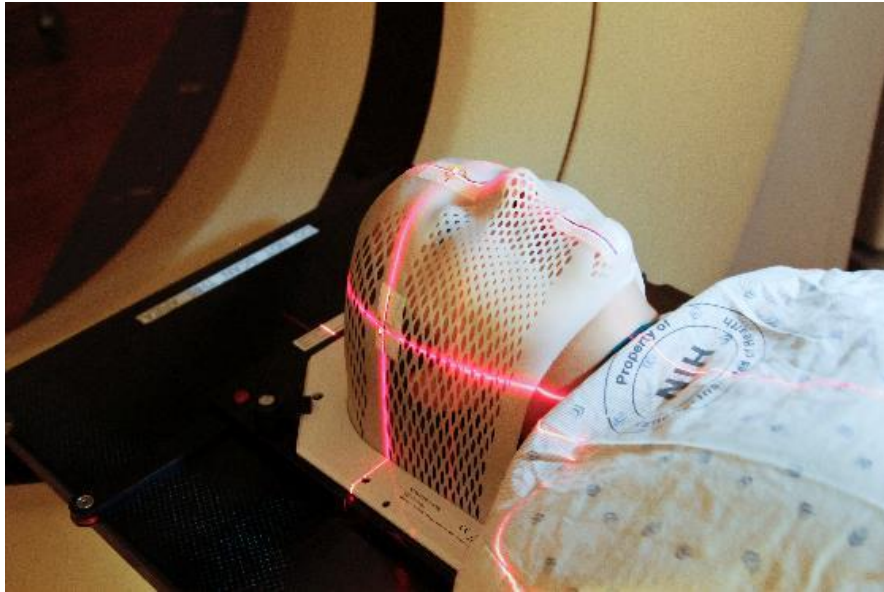
| | |
|--|---|
| AFFECTED PRODUCTS | Mobile Detector Holder for Digital Diagnost (Single Detector, Dual Detector, Release 3) System codes: 712020, 712022, 712025 |
| PROBLEM DESCRIPTION | The Wireless Portable Detector (WPD) is fixed in the Mobile Detector Holder via a lock mechanism. The 4 countersunk screws, that are used to attach the lock mechanism, can become loose. If this happens and the mechanism fails, the detector may fall down when the holder is rotated 90° clockwise. |
| HAZARD INVOLVED | The WPD is not fixed securely inside the Mobile Detector Holder and may fall down. |
| HOW TO IDENTIFY AFFECTED PRODUCTS | This correction applies to all Mobile Detector Holders for Digital Diagnost Systems (Single Detector, Dual Detector, and Release 3) with system codes: 712020, 712022, and 712025. Customers will be notified by a Philips representative in case their Mobile Detector Holder is affected. |
| ACTION TO BE TAKEN BY CUSTOMER / USER | The customer should control the lock mechanism of the Mobile Detector Holder. In case the lock mechanism can be moved without pressing the actuator, the holder should not be rotated clockwise. |
| ACTIONS PLANNED BY PHILIPS | Philips Healthcare will: Secure the 4 countersunk screws, which are used to attach the lock mechanism, with thread locker (e.g. LOCTITE 243). |
| FURTHER INFORMATION AND SUPPORT | If you need any further information or support concerning this issue, please contact your local Philips representative. 1-800-722-9377. Please reference FCO 71200067 when contacting your local Philips representative. |

4 Loan Application Assessment Checklist (Completed by assessor)

| | | | |
|-----|---|--|---|
| 5 | Is the Application Submission Form 4: Reported Hazards/Alerts/Recalls completed by the applicant? | - Check the completeness of Application Submission Form 4: Reported Hazards/Alerts/Recalls . | Y |
| 5.a | Does the model have any reported recalls? | - If the model is indicated to have been recalled by the manufacturer, assessor should <u>reject</u> the loan application. | N |
| 5.b | Does the model have any reported hazards/alerts? | - If the model indicated for purchase is impacted, check if a copy of hazards/alerts report is submitted. | Y |

Insufficient MEP Services, Space, or Room Requirement

Insufficient MEP services, space, room requirements



If there are not sufficient services, space, or room, what might be the risk(s)?

Insufficient MEP services, space, room requirements

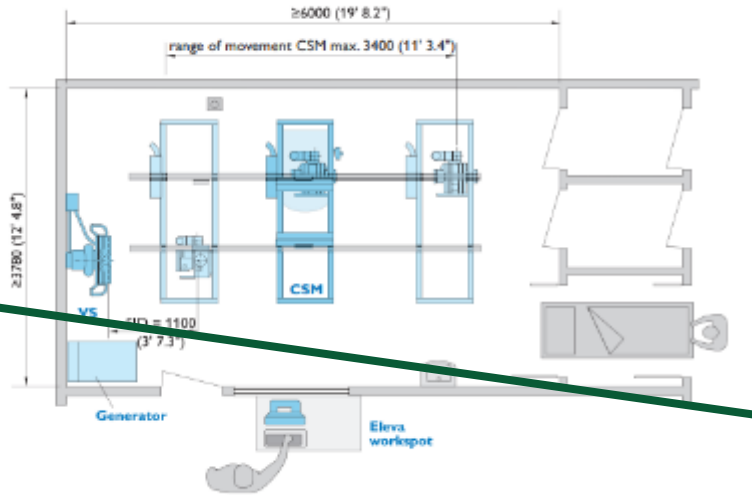
Example 1, Step 1

1 Information on MEP services, space, floor/loading from Manufacturer

Room layouts
Example room layout with fixed detector in vertical stand VS

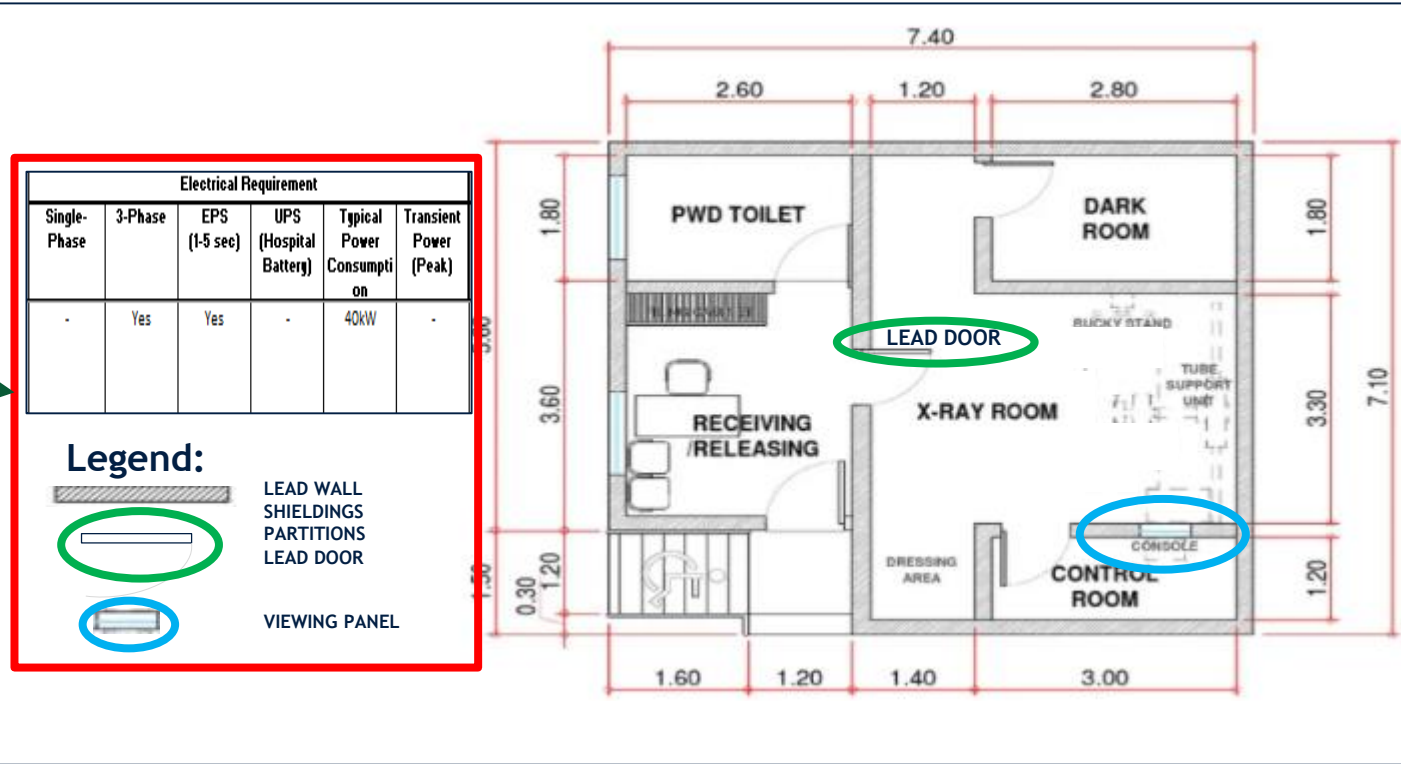
All dimensions in mm (feet/inches)

- Chest Room Requirements:**
- Power supply
 - Lead Wall Shielding
 - Lead Door
 - Viewing Panel



| Generator | 65 kW | 80 kW |
|--------------------------------|---|--------------------------|
| High-voltage generator | The converter generator generates high voltage equivalent to DC voltage | |
| Mains voltage | 400 V / 480 V (±10%); 50 Hz or 60 Hz, 3-phase | |
| Max. mains resistance at 400 V | 0.2 Ohm | 0.2 Ohm |
| Max. mains current at 400 V | 134 A | 160 A |
| Nominal power (IEC) | 65 kW | 80 kW |
| Max. tube voltage | 150 kV | 150 kV |
| Max. tube current (at 80 kV) | 812 mA | 1000 mA |
| Tube support | SRO see tube section | SRO see tube section |
| mAs product | 0.5 mAs to 850 mAs | 0.5 mAs to 850 mAs |
| Exposure times | 1ms to 4s | 1ms to 4s |
| Compatible with VarioFocus | yes | yes |
| Safety | Tube overload protection | Tube overload protection |

2 Schematic drawing of the identified location



Electrical Requirement

| Single-Phase | 3-Phase | EPS (1-5 sec) | UPS (Hospital Battery) | Typical Power Consumption | Transient Power (Peak) |
|--------------|---------|---------------|------------------------|---------------------------|------------------------|
| - | Yes | Yes | - | 40kW | - |

- Legend:**
- LEAD WALL SHIELDINGS
 - PARTITIONS
 - LEAD DOOR
 - VIEWING PANEL



Provided: Information on MEP services and room requirements from manufacturer as well as a schematic drawing of the identified location of use. This indicates that there is a plan for all the requirements needed.

Insufficient MEP services, space, room requirements

3

Loan Application Assessment Checklist (Completed by assessor)

| No. | Assessment Criteria | Assessor's Guide | Y/N | N/A | Comments |
|-----|---|---|-----|-----|----------|
| 6 | Mechanical, Electrical and Plumbing (MEP), Space, Floor/Ceiling Loading capacity needed to operate the medical equipment. | | | | |
| 6.a | Did the applicant provide site planning documents from supplier/distributor indicating the MEP services, space, floor/ceiling loading capacity required for the medical equipment to be operational. Examples of MEP services include: - Electrical requirements (eg. Single-phase power supply, 3-phase power supply and backup power supply). - Ducting requirements (eg. Exhaust, quench pipe), if any - Plumbing requirement (eg. Incoming hot/cold water supply and drainage), if any - Chiller requirement, if any - Medical gas supply (eg. Medical Air, Oxygen, Carbon Dioxide, Nitrogen, Nitrous Oxide, Anaesthetic gas Scavenging system, Surgical air and Vacuum), if any - IT requirement (eg. Data points and interface to information system), if any | - Check if relevant supporting documents from manufacturer (e.g., Equipment data sheet/ Catalogues/ Site planning documents/ Schematic drawings) indicating the MEP services, space, floor/ceiling loading capacity required for the medical equipment to be operational are provided. | Y | | |
| 6.b | Did the applicant indicate if the identified location of use has the required MEP services, sufficient space and floor/ceiling loading capacity for the installation and operation of medical equipment? | - Check if schematic drawing/floor plan or other supporting document indicating that the required MEP services, space, floor/ceiling loading capacity is available at the identified location; - If the required MEP services, sufficient space and floor/ceiling loading capacity is currently not available at the identified location of use, check if a complete project plan that indicates the progression of making the MEP services, space, floor/ceiling loading capacity available at the indicated location of use (this should ideally include architect's schematic drawings/ | Y | | |

Insufficient MEP services, space, room requirements

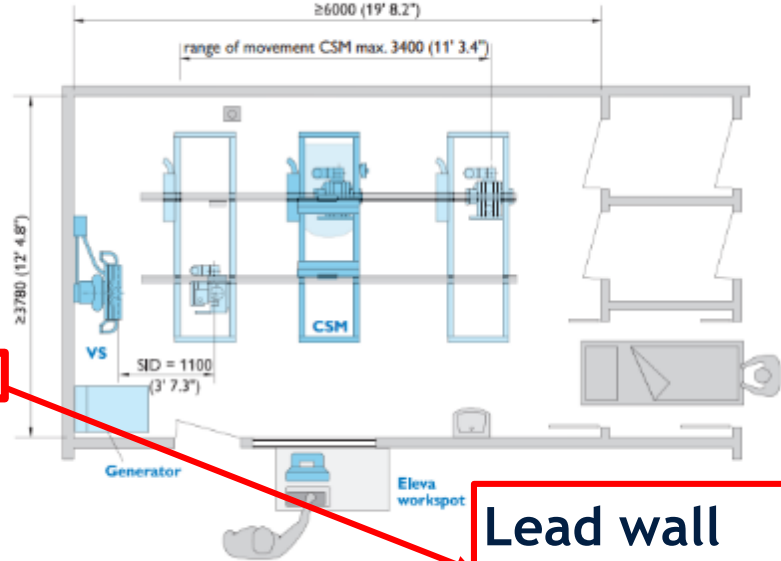
Example 2, Step 2

1 Information on MEP Services/Space/Room Requirements from Manufacturer

Room layouts

Example room layout with fixed detector in vertical stand VS

All dimensions in mm (feet/inches)



Chest Room Requirements:

- Power supply
- **Lead Wall Shielding**
- Lead Door
- Viewing Panel

Lead wall shielding is not in the project plan

2 Project Plan Provided by Applicant

| Task Name | By | Year | 2021 | | | | 2021 | | | | 2021 | | | | | | | | |
|------------------------------|----|------|-------|------|---|---|------|--------|---|---|------|-----------|---|---|---|---------|---|---|---|
| | | | Month | July | | | | August | | | | September | | | | October | | | |
| | | | | Week | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 |
| On-site Meeting | | | █ | █ | █ | █ | | | | | | | | | | | | | |
| Discussion with stakeholders | | | | █ | █ | █ | █ | █ | █ | █ | | | | | | | | | |
| Power Supply Installation | | | | | | | | | | | █ | █ | █ | █ | | | | | |
| Viewing Panel Installation | | | | | | | | | | | | | | | █ | █ | █ | █ | |
| Lead Door Installation | | | | | | | | | | | | | | | █ | █ | █ | █ | |
| Completion | | | | | | | | | | | | | | | | | | █ | |



According to Information on MEP services, space, room requirements from manufacturer, chest room requires lead wall shielding. However, this was not included in the project plan submitted by the applicant.

| Generator | 65 kW | 80 kW |
|--------------------------------|--|--------------------------|
| High-voltage generator | The converter generator generates high voltage | |
| Mains voltage | 400 V / 480 V (±10%); 50 Hz or 60 Hz, 3-phase | |
| Max. mains resistance at 400 V | 0.2 Ohm | 0.2 Ohm |
| Max. mains current at 400 V | 134 A | 160 A |
| Nominal power (IEC) | 65 kW | 80 kW |
| Max. tube voltage | 150 kV | 150 kV |
| Max. tube current (at 80 kV) | 812 mA | 1000 mA |
| Tube support | SRO see tube section | SRO see tube section |
| mAs product | 0.5 mAs to 850 mAs | 0.5 mAs to 850 mAs |
| Exposure times | 1ms to 4s | 1ms to 4s |
| Compatible with VarioFocus | yes | yes |
| Safety | Tube overload protection | Tube overload protection |

Insufficient MEP services, space, room requirements

Example 2, Step 2

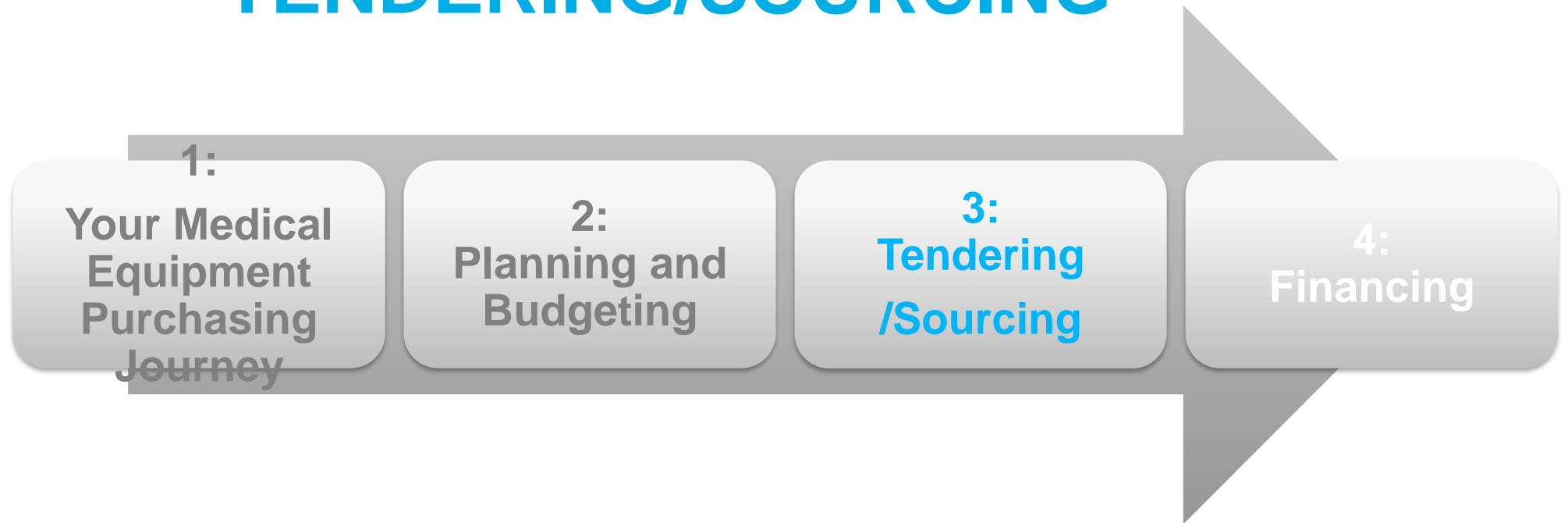
3 Loan Application Assessment Checklist (Completed by assessor)

| No. | Assessment Criteria | Assessor's Guide | Y/N | N/I | Comments |
|-----|---|--|-----|-----|--|
| 6 | Mechanical, Electrical and Plumbing (MEP), Space, Floor/Ceiling Loading capacity needed to operate the medical equipment. | | | | |
| 6.a | <p>Did the applicant provide site planning documents from supplier/distributor indicating the MEP services, space, floor/ceiling loading capacity required for the medical equipment to be operational. Examples of MEP services include:</p> <ul style="list-style-type: none"> - Electrical requirements (eg. Single-phase power supply, 3-phase power supply and backup power supply). - Ducting requirements (eg. Exhaust, quench pipe), if any - Plumbing requirement (eg. Incoming hot/cold water supply and drainage), if any - Chiller requirement, if any - Medical gas supply (eg. Medical Air, Oxygen, Carbon Dioxide, Nitrogen, Nitrous Oxide, Anaesthetic gas Scavenging system, Surgical air and Vacuum), if any - IT requirement (eg. Data points and interface to information system), if any | <p>- Check if relevant supporting documents from manufacturer (e.g., Equipment data sheet/ Catalogues/ Site planning documents/ Schematic drawings) indicating the MEP services, space, floor/ceiling loading capacity required for the medical equipment to be operational are provided.</p> | Y | | |
| 6.b | <p>Did the applicant indicate if the identified location of use has the required MEP services, sufficient space and floor/ceiling loading capacity for the installation and operation of medical equipment?</p> | <p>- Check if schematic drawing/floor plan or other supporting document indicating that the required MEP services, space, floor/ceiling loading capacity is available at the identified location;</p> <p>- If the required MEP services, sufficient space and floor/ceiling loading capacity is currently not available at the identified location of use, check if a complete project plan that indicates the progression of making the MEP services, space, floor/ceiling loading capacity available at the indicated location of use (this should ideally include architect's schematic drawings)</p> | | | <p>Project plan submitted did not indicate plans for lead door installation. Request applicant to resubmit loan application.</p> |

Action by assessor:

Request for a revised project plan to be provided during the resubmission of the loan application.

MEDICAL EQUIPMENT PURCHASING JOURNEY: TENDERING/SOURCING



OBJECTIVES

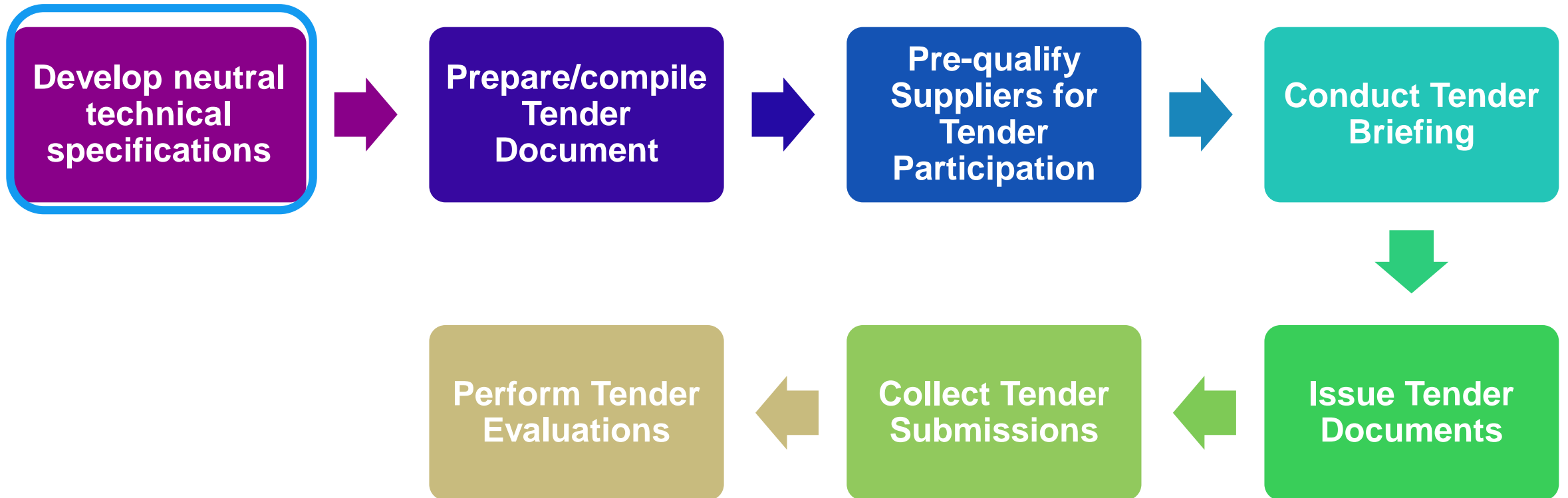
By the end of this session, you will be able to:

Develop neutral technical specifications

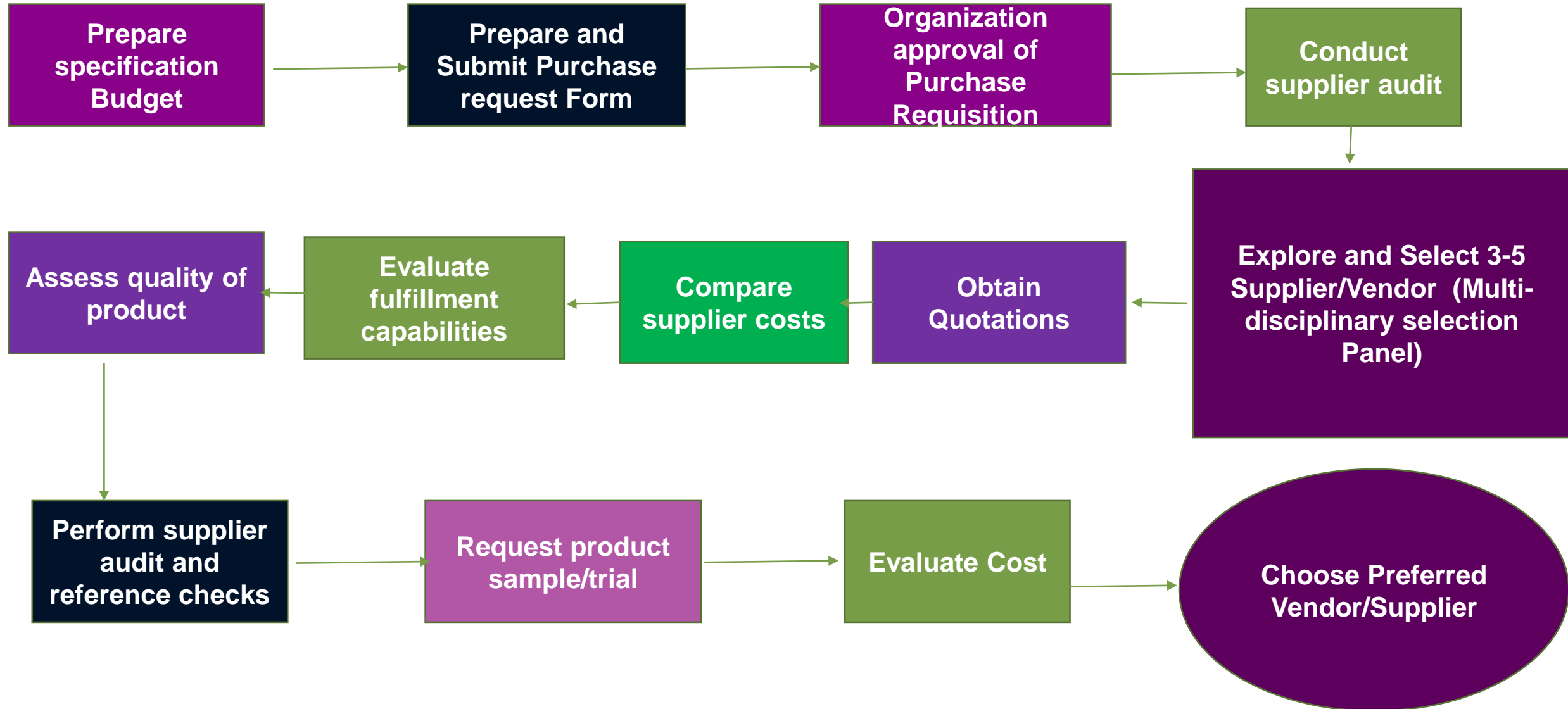
Prepare tender documents

Perform tender evaluations

Tender Process:



Sourcing For Medical Equipment



Neutral Technical Specifications

What makes the specifications neutral?

1. Developing Neutral Technical Specifications

Include specifications for these types of information:

- ✓ Device information
- ✓ Clinical application
- ✓ Technical specifications and features
- ✓ Accessories
- ✓ Start-up consumables
- ✓ Physical attributes
- ✓ Mechanical and electrical requirements
- ✓ Room requirements
- ✓ IT requirements
- ✓ Purchase information
- ✓ After-sales services

1. Development of Neutral Technical Specifications

Developing Neutral Technical Specifications Checklist

| Check | Consideration | Notes |
|-------|--|-------|
| | Device information: specify equipment name, description, location and quality | |
| | Request suppliers to provide: <ul style="list-style-type: none"> • Brand/model name • Device certification • Product brochure and catalogue | |
| | Clinical application: Type of clinical procedures to be delivered with the ME | |
| | Clinical application: type of patient | |
| | Technical requirements for the ME: <ul style="list-style-type: none"> • Configuration • Type • Requirements for each parameter • Self-test function • Alarms system • Display system • User interface • Recorder system • Storage capacity • Safety features | |
| | Accessories required and quantity | |
| | Start-up consumables required and quantity | |
| | Physical attributes <ul style="list-style-type: none"> • Dimensions • weight | |
| | Request suppliers to provide information on mechanical and electrical requirements: <ul style="list-style-type: none"> • Electrical requirements • Battery type • Incoming water and draining requirements • Exhaust ducting requirements • Medical gases requirements | |

| Check | Consideration | Notes |
|-------|---|-------|
| | Request suppliers to provide information on room requirements: <ul style="list-style-type: none"> • Special infrastructure needs • Minimum room size • Minimum ceiling height • Door size • Air conditioning needs • Technical/control room • Audio/visual communication | |
| | Specify IT requirements: Interface with information system <ul style="list-style-type: none"> • Type of networking/connectivity interface • Networked to a central station monitor • Requirement for interfacing peripheral device • System software upgrades • cybersecurity | |
| | Specify purchase information: <ul style="list-style-type: none"> • Budget • Price validity period • Payment terms • Delivery time | |
| | Request suppliers to provide pricing information: <ul style="list-style-type: none"> • Unit price, including duties/taxes, broken down by all items/services includes • Discounts | |
| | Specify the minimum after-sales services required: <ul style="list-style-type: none"> • Warranty duration • Acceptance, testing and commissioning • Frequency of inspection and preventive maintenance • Breakdown response time • Manuals | |

Neutral Technical Specifications



What could result if you do not include after-sales service in your specifications?

2. Prepare Tender Documents

- ✓ Sometimes called **Request for Quotation (RFQ)** / **Request for Proposal (RFP)**
- ✓ Gives information to suppliers about:
 - Description of the medical equipment, clinical application and quantity
 - Technical specification/requirements for the ME
 - Warranty requirement
 - After-Sales Service requirement
 - Other information required from suppliers (e.g., pricing, supporting documents to be submitted, etc.)
 - Rules for the procurement process (when and where to submit, format of submission)
 - Terms and conditions

2. Prepare of Tender Documents

| Criteria | Reason |
|---|---|
| Contact information of person-in-charge in clinic/hospital | For supplier to seek clarification from clinic/hospital during the tender period |
| Fields/form for suppliers to provide contact information | For clinic/hospital procurement team to seek clarification from supplier during tender evaluation process |
| Neutral technical specification | For clinic/hospital to obtain technical information, purchase information, after-sales service information of the proposed model |
| Fields/form for supplier to indicate information on type, quantity and price of accessories, consumables and spare parts expected to be replaced over 5 years | For clinic/hospital to calculate maintenance cost |
| Fields/form for supplier to indicate price and details of post-warranty service contract over 5 years | For clinic/hospital to determine the costs for comprehensive service contract and non-comprehensive service contract over 5 years |
| Fields/form for supplier to indicate installation base | For clinic/hospital to gauge supplier reliability |

2. Prepare of Tender Documents

| Criteria | Reason |
|---|--|
| Company background information such as: <ul style="list-style-type: none"> • A copy of the company's business license • Authorized Distributor letter from manufacturer • Business registration • List of Service Engineers/Technicians, with their qualifications, year of experiences, and base location. | To gauge supplier credibility To determine the after-sales capability of the supplier |
| Field for supplier to indicate ME delivery time | For clinic/hospital to plan for the ME delivery and installation |
| Other supporting documents: <ul style="list-style-type: none"> • Quotations • Catalogues • Service & user manuals | To facilitate referencing of information during tender evaluation |

3. Pre-qualify Suppliers for Tender Participation

✓ Check **credibility of suppliers** by obtaining the following information:

- Financial capability
- Past project experience
- List of installed bases for the device type identified for tendering
- Company registration
- Official distributor letter
- Availability of local technical staff

4. Conduct Tender Briefing

5. Issue Tender Documents



- ✓ Explain the **layout and information required**
- ✓ Suppliers can **clarify any matters**
- ✓ Suppliers should be **present to thoroughly understand the requirements** stipulated in the tender document

6. Collect Tender Submissions from Suppliers

- ✗ Do not accept tender documents submitted **after the stated date and time**
- ✓ Open all tender documents in the presence of an assigned team to avoid possible disputes
- ✓ Check if the supplier **completed all the required forms** in tender documents
- ✓ Ensure **supporting documents** are included



Medical Equipment Tendering Evaluations



How would you go about evaluating tenders?

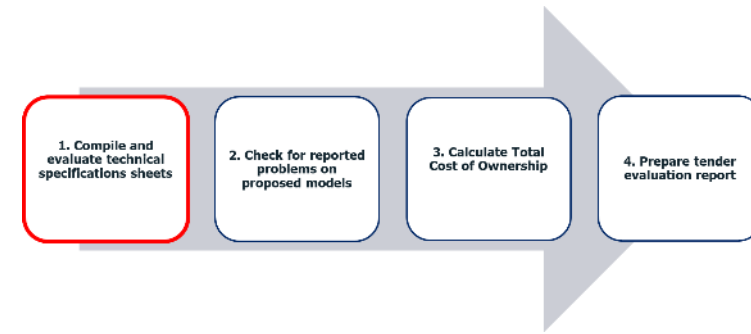
7. Preform Tender Evaluations and Prepare Recommendation Report

- ✓ Identify models that best meet tender requirements
- ✓ Ensure recommended equipment is safe for use
- ✓ Identify models that provides best economic value
- ✓ Exclude suppliers that do not comply to key requirements (e.g., technical specification, warranty period, after sales requirements, etc.)

To allow better understanding of supplier proposed model/s of ME, a physical demonstration on the usability and performance can be requested upon suppliers.

Tender Evaluation

1. Compile and evaluate technical specifications sheets



✓ Consolidation of **Technical Specifications Compliance Sheet** from all suppliers

| Brand/Manufacturer Name | Bidder to specify | Dräger/Dräger | | | KLS martin | | | MAQUET | | |
|--|---|---------------------------|--------|--|-------------------|--------|--|-------------------|--------|--|
| Model Name | Bidder to specify | Dräger Polaris 100 Mobile | | | v10 Mobile | | | LUCEA 100 Mobile | | |
| TECHNICAL SPECIFICATIONS/FEATURES | REQUIRED SPECIFICATIONS | BIDDER'S RESPONSE | | | BIDDER'S RESPONSE | | | BIDDER'S RESPONSE | | |
| | | Yes (v) | No (x) | Bidder to enter responses about their device | Yes (v) | No (x) | Bidder to enter responses about their device | Yes (v) | No (x) | Bidder to enter responses about their device |
| Configuration | Mobile stand with articulating arm suspension | ✓ | | Meet Required clinical application, Brochure Page 3 | Yes (v) | | Mobile | ✓ | | Mobile stand with articulating arm suspension. See LUCEA catalogue, Page 15 |
| Angle of Rotation from Fixed Point, ° | 270° | ✓ | | Meet Required clinical application | Yes (v) | | 360° | | x | Enter Responses Here! |
| Vertical Adjustment Range, cm | ≥80cm | ✓ | | | Yes (v) | | 131 cm | ✓ | | Vertical adjustment range >142 cm. See LUCEA catalogue, Page 17 |
| Castors | Swivel castors with brakeslocks | ✓ | | Trolley is equipped with locking Brakes, Brochure Page 5 | Yes (v) | | brakeslocks for 2 wheels | ✓ | | With swivel castors with brakeslocks, See LUCEA catalogue, Page 18 |
| Number of Lighthead | Single lighthead | ✓ | | Meet Required clinical application | Yes (v) | | 1 lighthead | ✓ | | Single lighthead. See LUCEA catalogue, Page 15 |
| Type of Light Source | LED, Cold light | ✓ | | Yes, LEDs, Brochure Page 6 | Yes (v) | | 2nd generation LEDs | ✓ | | White LEDs type, See LUCEA catalogue, Page 6 |
| Number of LEDs | Bidder to specify | ✓ | | 48 LEDs, Brochure Page 6 | Yes (v) | | 160 of LEDs | ✓ | | 52 LEDs. See LUCEA catalogue, Page 19 |
| LED Lifespan, hr | ≥ 20,000 hours | ✓ | | life time LEDs Approx. 50,000 hours, Pi_9067046 Page 5 | Yes (v) | | >40,000 hrs | ✓ | | LED Lifespan > 60,000 hr. See LUCEA catalogue, Page 15 |
| Illumination Level, Lux at 1m | At least 120,000 lux | ✓ | | Illumination intensity at 1m is 40,000 lux to 160,000 lux, Brochure Page 6 | Yes (v) | | 140,000 lux | ✓ | | Illumination 120,000 lux. See LUCEA catalogue, Page 15 |
| Colour Temperature, K | 3,000K to 5,500K, Adjustable | ✓ | | Colour Temperature 5,000 K or 5,600 K, Brochure Page 6 | Yes (v) | | 3,800K, 300K, 800, Adjustable | | x | Fix colour temperature 4,300K. See LUCEA catalogue, Page 15 |
| Colour Rendering Index (CRI), R _a Value | ≥ 90R _a , Higher R _a value is preferred | ✓ | | Colour Rendering index R9 is 93, Brochure Page 6 | Yes (v) | | CRI = 95, R _a = | ✓ | | Colour rendering index (CRI) : 95 and R _a : 92. See LUCEA catalogue, Page 15 and 20 |
| Field Size Diameter, cm | At least 16cm | ✓ | | Light field diameter 20 cm., Brochure Page 6 | Yes (v) | | 23-33 cm, Adjustable | ✓ | | Field size diameter 22cm. See LUCEA catalogue, Page 15 |
| Field Size Depth, cm | At least 50cm | | x | Fix focus 200mm | Yes (v) | | 129 cm | ✓ | | Depth of illumination (L1+L2 at 20%) 110cm. See LUCEA catalogue Page 15 |
| Field Length, cm | At least 55cm | | x | Fix focus 200mm | Yes (v) | | 51 cm | ✓ | | Depth of illumination (L1+L2 at 20%) 110cm. See LUCEA catalogue Page 15 |

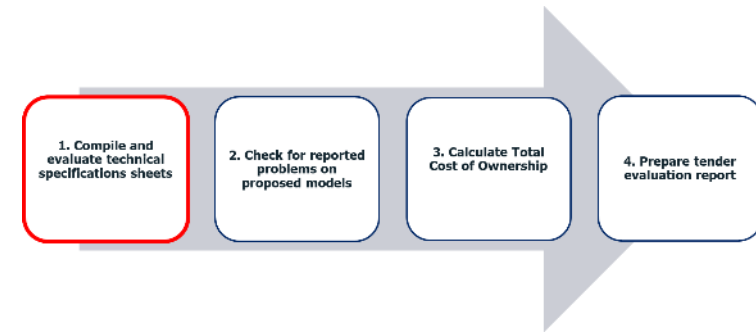
Supplier 1

Supplier 2

Supplier 3

Tender Evaluation

1. Compile and evaluate technical specifications sheets (continued)



✓ Assign weightage and compliance points

- Define and assign **weightage** for each technical specification/requirement based on importance.
 - More important technical specifications: **High weightage** point
 - Less important/generic specifications: **Low weightage** point

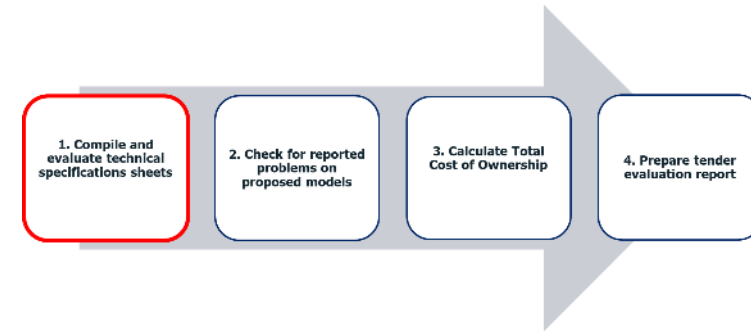
- Define and assign **compliance score/value** based on supplier's response

| Compliance Type | Value (V) |
|--|-----------|
| Exceed Requirement | 2 |
| Comply/Meet Requirement | 1 |
| Partially Comply | 0.5 |
| Unable to Comply/ No Response/ Invalid Reference | 0 |
| Not Applicable | 0 |

| Specification Weightage (WT) | Value |
|------------------------------|-------|
| Key Specification (High) | 3 |
| Generic Specification (Low) | 1 |

Tender Evaluation

1. Compile and evaluate technical specifications sheets (continued)



✓ Assign weightage and compliance points

Weightage point (WT)

Compliance value (V)

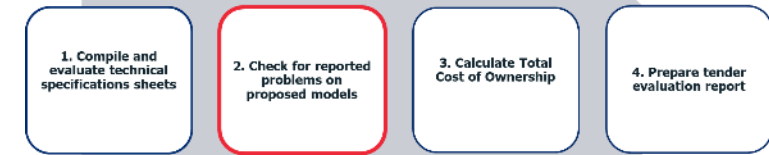
Compliance points (CP)
= Weightage (WT) x Compliance Value (V)

| TECHNICAL SPECIFICATIONS/FEATURES | REQUIRED SPECIFICATIONS | 59.0 | 81.5 | | | | BIDDER'S RESPONSE | | | | 42.0 | |
|--|---|------|------|-------|---------|--------|---|-----|-------|---------|---------|--|
| | | WT | V | CP | Yes (v) | No (x) | Bidder to enter responses about their device | | V | CP | Yes (v) | |
| Configuration | Mobile stand with articulating arm suspension | 3.0 | 1.0 | 3.0 | ✓ | | Meet Required clinical application, Brochure Page 3 | 1.0 | 3.0 | Yes (v) | | |
| Angle of Rotation from Fixed Point, ° | 270° | 1.0 | 1.0 | 1.0 | ✓ | | Meet Required clinical application | 1.0 | 1.0 | Yes (v) | | |
| Vertical Adjustment Range, cm | ≥80cm | 1.0 | 0.0 | 0.0 | ✓ | | | 1.0 | 1.0 | Yes (v) | | |
| Castors | Swivel castors with brakes/locks | 1.0 | 1.0 | 1.0 | ✓ | | Trolley is equipped with locking Brakes, Brochure Page 5 | 1.0 | 1.0 | Yes (v) | | |
| Number of Lighthead | Single lighthead | 3.0 | 1.0 | 3.0 | ✓ | | Meet Required clinical application | 1.0 | 3.0 | Yes (v) | | |
| Type of Light Source | LED, Cold light | 3.0 | 1.0 | 3.0 | ✓ | | Yes, LEDs, Brochure Page 6 | 1.0 | 3.0 | Yes (v) | | |
| Number of LEDs | Bidder to specify | 1.0 | 1.0 | 1.0 | ✓ | | 48 LEDs, Brochure Page 6 | 1.0 | 1.0 | Yes (v) | | |
| LED Lifespan, hr | ≥ 20,000 hours | 1.0 | 1.0 | 1.0 | ✓ | | life time LEDs Approx. 50,000 hours, Pj_9067046 Page 5 | 1.0 | 1.0 | Yes (v) | | |
| Illumination Level, Lux at 1 m | At least 120,000 lux | 1.0 | 1.0 | 1.0 | ✓ | | Illumination intensity at 1 m is 40,000 lux to 160,000 lux, Brochure Page 6 | 1.0 | 1.0 | Yes (v) | | |
| Colour Temperature, K | 3,000K to 5,500K, Adjustable | 1.0 | 1.0 | 1.0 | ✓ | | Colour Temperature 5,000 K or 5,600 K, Brochure Page 6 | 0.5 | 0.5 | Yes (v) | | |
| Technical Specifications Total Compliance Points | | | | 121.0 | | 110.0 | | | 106.0 | | | |
| Compliance Percentage (%) | | | | | | 90.9% | | | 87.6% | | | |

Additional rows to calculate total compliance points scored by suppliers

Tender Evaluation

2. Check for reported problems on proposed models

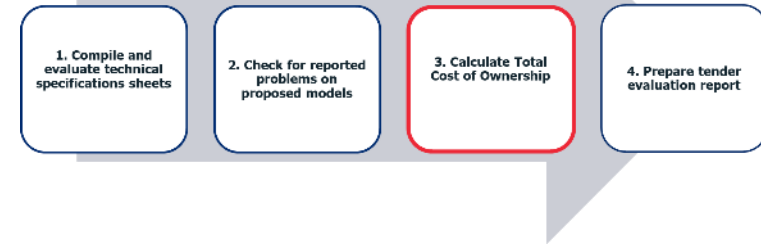


- Check proposed models for **reported problems**
- If the model is impacted by any reported problems, obtain **corrective action letter** from manufacturer
- Check models to ensure that it is **not discontinued by manufacturer**
- Use these websites or sources:
 - USFDA
(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm>)
 - MHRA (https://www.gov.uk/drug-device-alerts?alert_type%5B%5D=device-safety-information)
 - TGA (<https://www.tga.gov.au/current-year-alerts>)
 - Manufacturer letter, etc.
 - PPB
 - KEBS



Tender Evaluation

3. Calculate Total Cost of Ownership



- ✓ Calculate total cost of ownership for each proposed model over a period of 5 years
- ✓ Compare against allocated budget

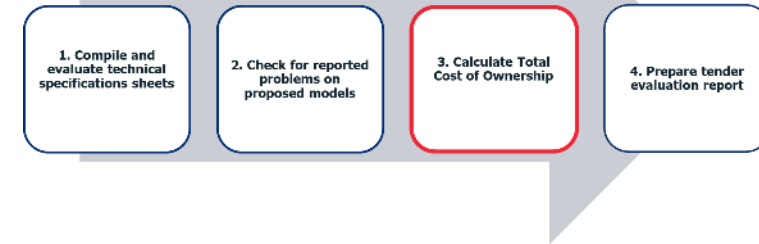
Costs to consider:

- ✓ ME purchase price (includes capital price, accessories, warranty, software, etc.)
- ✓ Infrastructure modification, if applicable
- ✓ Maintenance cost

$$\boxed{\text{TCO}} = \boxed{\text{Costs to Procure}} + \boxed{\text{Costs to Maintain over 5 years}}$$

Tender Evaluation

3. Calculate Total Cost of Ownership (continued)



- ✓ Estimating maintenance costs
- In-house maintenance:**

Calculate total cost of **accessories, spare parts and consumables** expected to be replaced over a period of 5 years

Maintenance service from the supplier:

Determine if comprehensive or non-comprehensive contract arrangement is required.

For comprehensive contract:

(Annual cost for preventive maintenance and repair submitted by supplier in tender document x 5 years) + (Cost of accessories expected to be replaced over a period of 5 years)

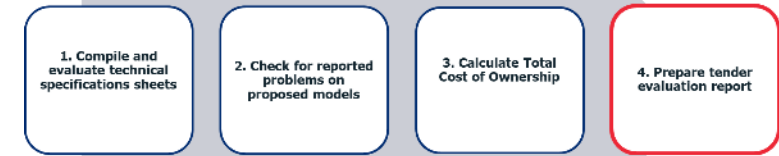
For non-comprehensive contract:

(Annual cost for preventive maintenance submitted by supplier in tender document x 5 years) + (Cost of accessories, spare parts and consumables expected to be replaced over a period of 5 years)

Tender Evaluation

4. Prepare tender evaluation report

- ✓ Description of ME for this tender
- ✓ Information of submitted models and suppliers
- ✓ Evaluation summary indicating:
 - Compliance score of proposed models
 - Key advantages and non-compliances (specifications and other tender requirements)
 - Reported problems found on proposed models
 - Purchase price and TCO against allocated budget
 - Supplier credential
- ✓ Ranking the suppliers based on evaluation findings





What criteria should top ranking suppliers meet?

- High total compliance points and comply to important technical requirements
- No serious problems reported on model
- Purchase price and TCO is within allocated budget
- Comply to other tender requirements (warranty, payment terms, after-sales service, etc.)
- Supplier has good credentials

Case Study: CT Scan Success



Hillcrest Hospital had two CT scan units that within the last year have begun to require more and more maintenance.

Both units are approximately 10 years old and no longer covered by warranty.

The attending radiologists as well as general providers are dissatisfied with the downtime because these units are under frequent maintenance.

Case Study: CT Scan Success

The medical director meet with the chief radiologist as well as the consultant cardiologist and general practitioner.

They determine it is time to replace one or both units.

What should they do first?



Case Study: CT Scan Success

Tendering Process

As part of the procurement process, they form a team to oversee tendering.

The team:

- ✓ the hospital physicist
- ✓ the CAT scan radiologist
- ✓ the chief technologist
- ✓ the head of hospital facility
- ✓ a biomedical engineer
- ✓ The financial manager was consulted to establish **a budget** for the new ME.

The procurement team consulted referring consultants **to assess which technology was mandatory in the new equipment.**

- ✓ **Decision:** Replacing both aging CAT scan machines with one high end 128 slice piece of equipment.
- ✓ **The demand of the cardiology unit:** A 128 sliced CAT scan



Case Study: CT Scan Success

Tendering Process



- ✓ Arranging demonstrations
- ✓ Evaluating the ME through a scoring system
- ✓ Visiting several medical facilities to see the non-portable ME's functioning
- ✓ A decision was made upon the **scoring mechanism**.
- ✓ It was presented to the financial manager and the hospital CEO.

What is your key takeaway for your procurement journey?





HEALTH SECTOR PRESENTATIONS

**Topic: Accessing Financing for
Health Sector- Medical Equipment Solution**



Our Mission Statement



To offer a wide range of innovative financial solutions leveraging on our heavy investment in multi channels, national and regional presence and with focus on excellent customer experience by a highly motivated and talented team.



Our Purpose

A Financial institution predominantly owned by the Kenyan Co-operative movement transforming lives.



Vision

To be the dominant Bank in Kenya and in the Region riding on the unique Co-operative Model, providing innovative financial solutions for distinctive customer experience.

Universal Bank Offering full Corporate and Retail Banking Services

- Term Loans
- Working Capital
- Trade Finance
- Leasing Solutions
- Supply Chain Finance
- Capital Markets

Corporate & institutional
Banking

- Savings Accounts
- Salary Accounts
- Home Loans
- Personal Loans
- Vehicle Loans
- Mco-op – Mobile Banking

Retail
Banking

- Operating Accounts
- Cash Management
- Payment Solutions
- Export Processing
- Import Processing
- FX Solutions
- Internet Banking

Treasury &
Transaction
Banking

- Economic and Industry
Research
- Equity Research
- Investment & Broking Accounts
- Insurance Brokerage

Investment &
Insurance



Our customer touch points Physically and Digitally

178

Branches

8.8M

Account Holders

584

ATMs

16K

Diaspora Banking Customers

17K

Co-op Kwa Jirani Agents

103K

Digital Banking Customers

479

SACCO Front Office Branches

5M

MCo-op Cash Customers

24hr

Contact Center

4,600

Staff



CO-OPERATIVE BANK

We are you



AFRICA MEDICAL FACILITY FEATURES



Target Market

Healthcare providers including clinics, hospitals, medical imaging centers, laboratories etc.

Minimum Eligibility

Active operation for a minimum of 3 years

Profitable for the last 2 years in operation

Good financial standing

Eligibility Criteria

- Meets at least two of the following three criteria:

Annual revenues of between KES 10 Million and KES 1.5 Billion;

Not more than 300 employees;

Total assets of between KES 10 Million and KES 1.5 Billion;



CO-OPERATIVE BANK

We are you



Product Offering

Asset Finance and Leasing Options

Amount

Between KES 500,000 and KES 200,000,000

Criteria

- The eligibility, screening, documentation, analysis, approval, and process flow as per the Bank policy
- Only new models will be financed under the program
- Purchase of equipment from approved Original Equipment Manufacturers (OEMs)

Tenure

Up to 5 years

Financing

Up to 90% for asset finance
Leasing options

Pricing

Competitive pricing offered



CO-OPERATIVE BANK
We are you



Security

- The financed asset will be the primary security
- All risk insurance cover over the financed asset to be provided through the Co-op Bank Bancassurance

Requirements Pricing

- Loan application form
- KYC documents
- AMEF submission form (to be shared by the Bank)
- Financials - > Kes 10 Million- Audited books (3 years), 12 months cashflow projections , management accounts
- Account statement with other banks (last 12 months) for facilities of Kes 10 million and below
- Loan details with other banks; Amount, tenor, outstanding balance, security and repayment schedule
- Company profile
- Relevant business licenses



CO-OPERATIVE BANK
We are you



Application process

- Contact the OEM for an indicative invoice
- Contact the branch/relationship manager
- Site visit/Provide required application documents
- Review/approval process
- Execution of offer letter and related documents
- Disbursement of facility

Turn-around time

- Amounts below Kes 10 million – 3 days
- Amounts above Kes 10 million to Kes 100 million - 7 days
- Amounts above Kes 10 million – 14 days once all documentation has been provided

Other terms

- Leasing will be done under Co-op Bank Fleet Africa Limited
- Service contract with the OEM



Why AMEF?



| | | |
|---------------------|-----------------------|------------------------------|
| Policy | Normal Financing | AMEF Scheme |
| Financing | 60% of the total cost | 90% of the total |
| Interest Rate | 24% | 19.5% |
| Tenor | 36 months | 60 months |
| Appraisal Fee | 3% | 1.5% |
| Security | Title deed | Self-securing |
| After Sales support | None | Available from approved OEMs |



Other Benefits

- Quality Improvement of HSME
- Capacity Building of HSME- Healthcare advisory,
Free Periodic Training
- Access to renowned Original Equipment Manufacturers such as GE, Philips, Karl Storz, Elekta, Biomeriux, Siemens, Mindray, Neusoft among others
- Simplified documentation
- Enhanced processing period (SLAs)
- Access to multiple banking solutions from the bank
- Dedicated relationship team

Health Sector Banking Partnerships

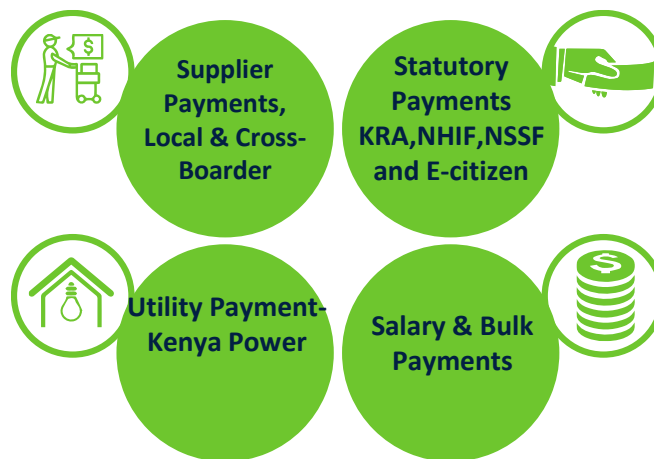


Cash Management Solutions

Collections & Receivable Management



Payments Solutions



Account Management Solutions



Key Capabilities:

Co-op Online | Open Banking API's(Co-op Connect) | e-Commerce(Chapa pay) | B2B Integrations | H2H Payment Integrations | Merchant POS | Remote Cheque Scanners | Cash Deposit Machines |

Healthcare Staff Welfare Partnerships



Salary Accounts & Payroll Processing



Investment advisory/management



Staff Pension Schemes



Staff Savings and Credit Society.



E- Credit (Mobile based loans).



Personal Loans & Credit Cards.



Car loans.



Mortgage loans.





Thank You



In partnership with the
Government of Japan



Date: 29 August 2024

Ethical Principles in Health Care – An introduction

- An IFC and World Bank initiative
- Established in 2019
- A no-fee, collective action initiative helping build transparent, resilient health systems through a set of 10 shared principles that promote ethical decision making and behavior.
- Aimed to help achieve affordable, high-quality healthcare for all
- Participation is voluntary, and signatories implement the principles to the degree they decide and at the pace they choose.

Ten Operating Principles to Ensure Ethical Conduct

- 01 | Respecting Laws and Regulations
- 02 | Making a Positive Contribution to Society
- 03 | Promoting High Quality Standards
- 04 | Conducting Business Matters Responsibly
- 05 | Respecting the Environment
- 06 | Upholding Patients' Rights
- 07 | Safeguarding Information & Using Data Responsibly
- 08 | Preventing Discrimination, Harassment & Bullying
- 09 | Protecting & Empowering Staff
- 10 | Supporting Ethical Practices and Preventing Harm

Through these principles, EPIHC promotes ethical conduct and helps guide decision-making processes for private healthcare providers, payors, investors, and associations

I ETHICAL HEALTHCARE COLLABORATION

Community and Collaboration Efforts

Fostering Ethical Excellence in Healthcare

Encouraging Collaboration

Promotes teamwork among healthcare providers for comprehensive patient care.



Sharing Experiences

Enhances care standards by exchanging insights and best practices.

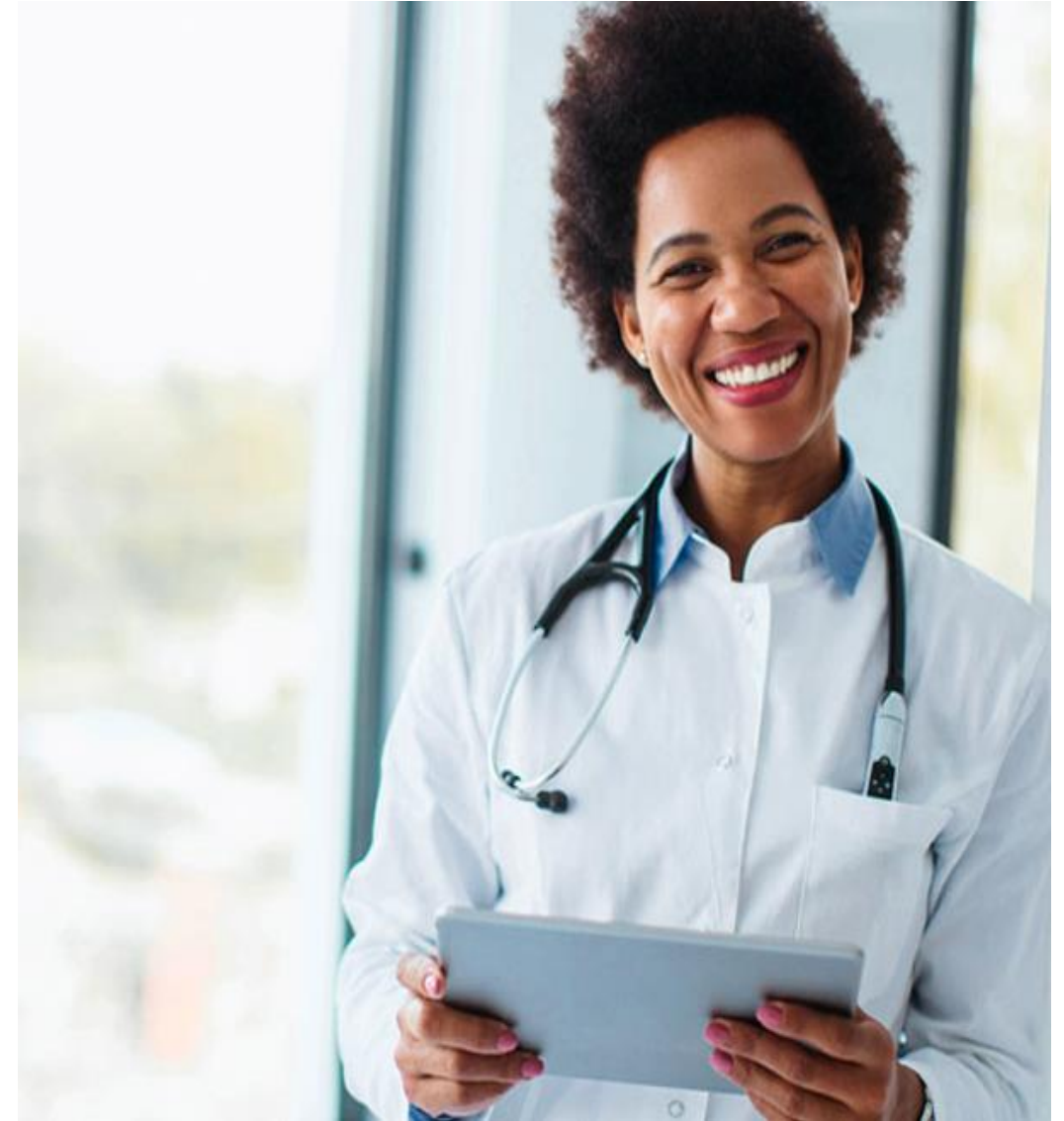
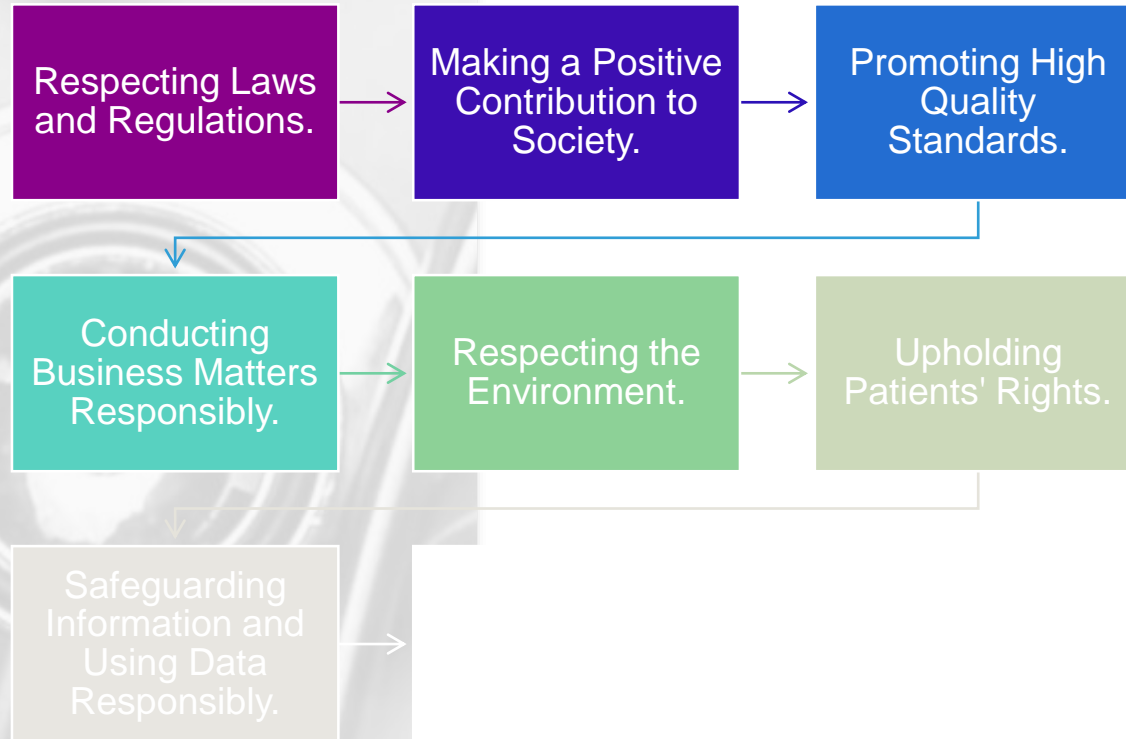


Collective Improvement Goal

Strives for a unified approach to elevate ethical standards in healthcare delivery.



EPIHC – Principles



EPIHC - Who we are:

- Today, EPIHC comprises more than **340+** signatories and nearly **6,000** facilities worldwide in **100+** countries.
- EPIHC's founding signatories below represent diverse regions and business models.

ACIBADEM
HOSPITALS GROUP

EYE

ANDALUSIA
for MEDICAL SERVICES

Apollo
HOSPITALS

MAYO
CLINIC

艾力彼
Asclepius Healthcare

CENTENE
Corporation

FHC 复星医疗
FOSUN
HEALTHCARE

FULLERTON
HEALTH

GEORGIA
HEALTHCARE
GROUP

IFC
International
Finance
Corporation
WORLD BANK GROUP

IVC ROYTERBERG CLINIC
MEDICINA

Medtronic

SAUDI GERMAN HOSPITALS GROUP
مجموعة مستشفيات السعودية الألمانية

QUADRIA
CAPITAL

United Family Healthcare
和睦家医疗

IDH INTEGRATED
DIAGNOSTICS
HOLDINGS

مستشفى العبدلي
ABDALI HOSPITAL
Member of Clemensia Network

LAGOON
HOSPITALS
YEMEN

HHI

IFC
International
Finance Corporation
WORLD BANK GROUP

Creating Markets, Creating Opportunities

Global Distribution of our 340+ members



EPIHC – What can signatories expect?

As an **EPIHC signatory**, your organization demonstrates to the global healthcare community **your commitment to ethics and integrity**. EPIHC offers the following to its signatories:



A specialized assessment tool*

Through this signatories get:

- Free access to a comprehensive self assessment tool to understanding the current level of implementation of the 10 ethical principles in their organizations
- A platform allowing each signatory to identify gaps and opportunities of their own approach and to review their own progress

*Launching in 2024



Tailored resources and trainings

EPIHC offers an access to a plethora of tailored resources:

- World-class trainings from healthcare experts and advocates worldwide
- Online self paced course on the 10 ethical principles*
- EPIHC Resource Library offers blueprints for replicating the ethical successes of its signatories and other experts
- Member-only events: a quarterly meeting to promote knowledge sharing
- Our quarterly newsletter lets you know what's happening with ethics in healthcare



Global visibility and networking

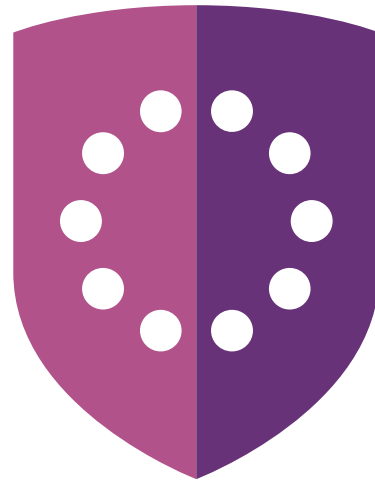
EPIHC creates opportunities for signatories to:

- Connect, collaborate and network through the online EPIHC community or in-person events like the recently concluded IFC healthcare conference in Cape Town
- Participate and drive the agenda on a theme of their choice through Thematic Task Groups
- Empowers member engagement and collaborative impact by providing a platform for sharing knowledge and best practices

EPIHC – How Do You Sign Up?

www.epihc.org

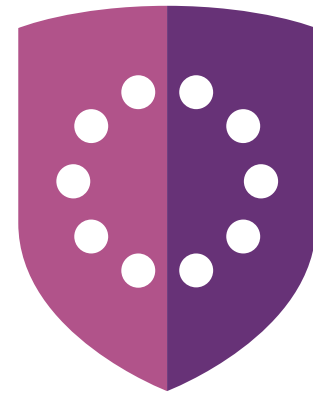
- **Submit on-line application**
- **Await verification of application**
- **Await letter of acceptance from Secretariat**
- Utilize access to resources and support offered by such signatory status.



epihc®

ETHICAL PRINCIPLES IN HEALTH CARE

Thank You!



epihc[®]

ETHICAL PRINCIPLES IN HEALTH CARE