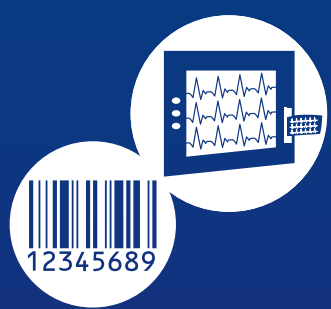
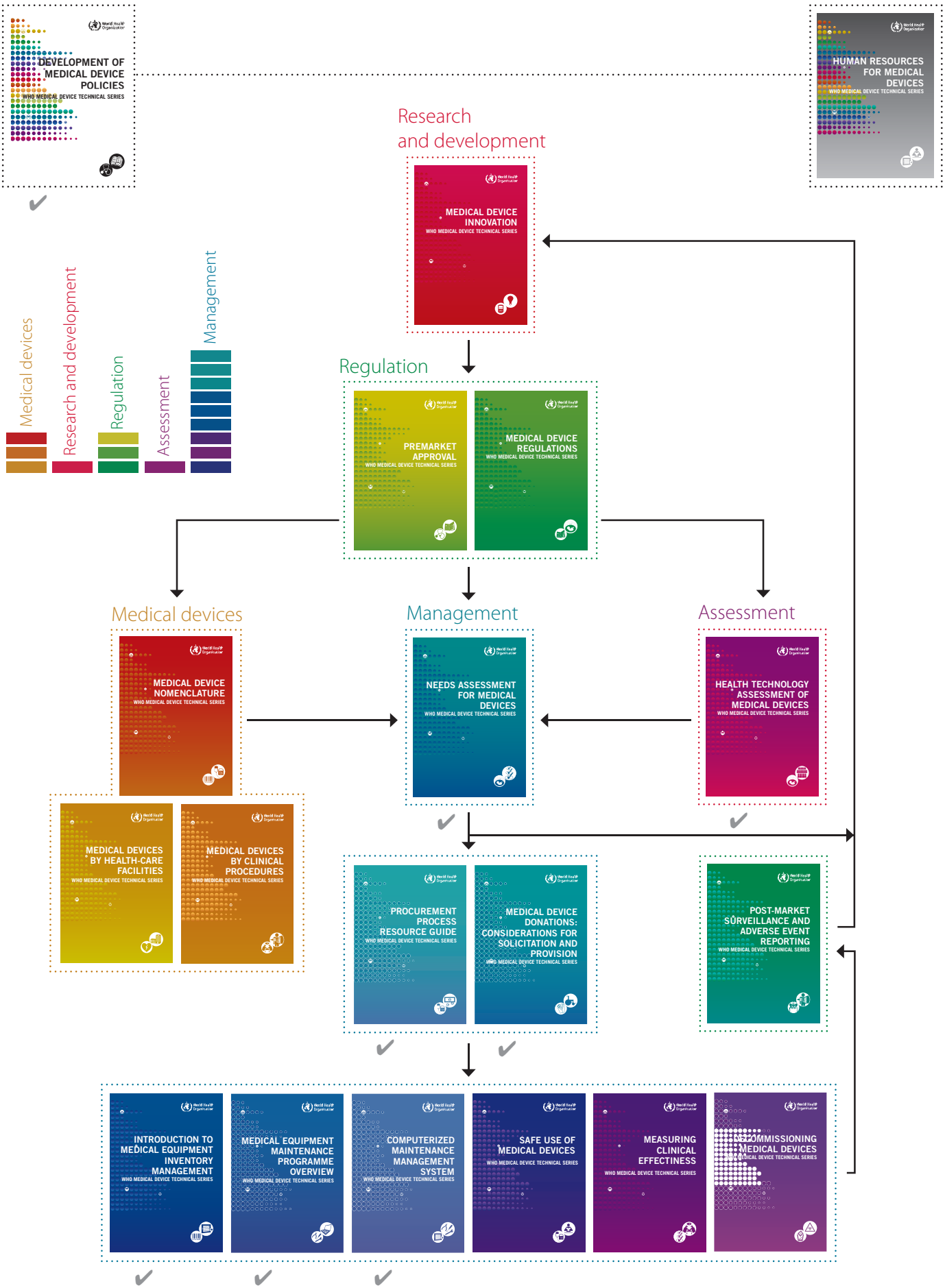
World Health Organization

Introduction to medical equipment inventory management

WHO Medical device technical series



WHO MEDICAL DEVICE TECHNICAL SERIES: TO ENSURE IMPROVED ACCESS, QUALITY AND USE OF MEDICAL DEVICES



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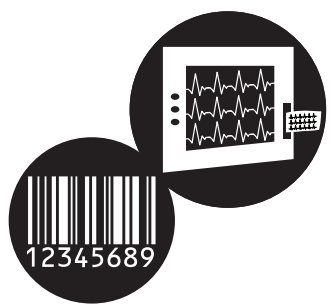

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Contents

Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

- to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;
- to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas:

- policy framework for health technology
- medical device regulations
- health technology assessment
- health technology management
  - needs assessment of medical devices
  - medical device procurement
  - medical equipment donations
  - medical equipment inventory management
  - medical equipment maintenance
  - computerized maintenance management systems
- medical device data
  - medical device nomenclature
  - medical devices by health-care setting
  - medical devices by clinical procedures
- medical device innovation, research and development.

These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.

Maintenance series & external guidance

Three documents in this technical series have been developed specifically to aid a health facility or a national ministry of health to establish or improve a medical equipment maintenance programme. The documents address medical equipment inventory management, maintenance, and computerized maintenance management systems. Each of these documents can be used as a stand-alone document, but together they present all of the factors to consider when developing a medical equipment maintenance programme. Furthermore, a six-volume comprehensive series of manuals for the management of healthcare technology, known as the 'How To Manage' series, exists for people who work for, or assist, health service provider organizations in developing countries and are publicly available.[1]

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health-care technology management (HTM) tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and to help countries develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were discussed further during the First WHO Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level. [2]

All meeting participants and people involved in the development of these documents were asked to complete a declaration of interest form, and no conflicts were identified.

1 Available at http://www.healthpartners-int.co.uk/our_expertise/how_to_manage_series.html

2 *First WHO Global Forum on Medical Devices: context, outcomes, and future actions* is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed March 2011)

Definitions

Recognizing that there are multiple interpretations that exist for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.[3] It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.[4]

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

3 World Health Assembly resolution WHA60.29, May 2007 (http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf, accessed March 2011).

4 Information document concerning the definition of the term "medical device". Global Harmonization Task Force, 2005 (http://www.ghtf.org/documents/sg1/sg1n29r162005.pdf, accessed March 2011).

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Tania O'Connor is currently a consultant and was formerly employed by Johns Hopkins University-TSEHAI and the Black Lion Hospital in Addis Ababa, Ethiopia.

The draft was reviewed by Jennifer Barragan (WHO), Ismael Cordero (ORBIS International), Yadin David (Biomedical Engineering Consultants), Bjorn Fahlgren (WHO), Geeta Mehta (WHO), Iyad Mobarek (WHO), Paul Rogers (WHO) and Binseng Wang (ARAMARK Healthcare LLC) and edited by Inis Communication.

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Declarations of interests

Conflict of interest statements were collected from all contributors and reviewers to the document development. Tania O'Connor declared her former employment with Johns Hopkins University-TSEHAI and Black Lion Hospital (ended in 2009) and Binseng Wang declared his current employment at ARAMARK as remuneration from an organization with an interest related to the subject. Yadin David declared that the International Federation of Medical and Biological Engineering supported his travel to one of the TAGHT meetings. None of these declared conflicts influenced the content of the document.

Acronyms and abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
CMMS	computerized maintenance management system
GIHT	Global Initiative on Health Technologies
GMDN	Global Medical Device Nomenclature
HTM	health/health-care technology management
TAGHT	Technical Advisory Group on Health Technology
UMDNS	Universal Medical Device Nomenclature System
WHO	World Health Organization

Executive summary

Equipment inventory is an essential part of an effective health-care technology management (HTM) system. In order to be effective in assisting with various HTM activities, the inventory must be updated continually so that it provides at any given moment a correct look at the status of medical equipment within the health-care facility. Update points include initial data collection; as information is updated, such as when a new piece of equipment arrives or is retired; and during annual inventory audits. The inventory of medical equipment is used in conjunction with inventories of additional supportive assets, such as consumables, spare parts, and testing and safety tools and equipment. Inclusion of equipment in an inventory is decided through a risk-based analysis in order to ensure appropriate time and resource allocation, and to eliminate unnecessary work. The health-care facility decides on the level of detail of data to be included in its inventory, in order to satisfy its own requirements and according to its own capabilities. Inventory management is done through a paper-based or computer-based system, as determined by the resources available.

Once established, the inventory serves as the foundation for moving forward within the HTM system and ensuring safe and effective medical equipment. The inventory may be used to develop budgets for capital purchases, maintenance and running costs; to build and support an effective clinical engineering department, by allowing for workshop planning, hiring and training of technical support staff, and establishing and maintaining service contracts; to support an effective medical equipment management programme, such as planning preventive maintenance activities and tracking work orders; and to plan the stock of spare parts and consumables. The inventory may also be used to support equipment needs assessment within the health-care facility and to record the purchase, receipt, retirement and discarding of equipment. Facility risk analysis and mitigation, and emergency and disaster planning, are also supported by an inventory.

1 Introduction

Health-care technology has become a critical component of health care, as it enables health-care providers to diagnose, treat, monitor and provide therapy to patients within an appropriate environment of care. Quality management of health-care technology helps ensure that these services are provided in a safe and effective way.

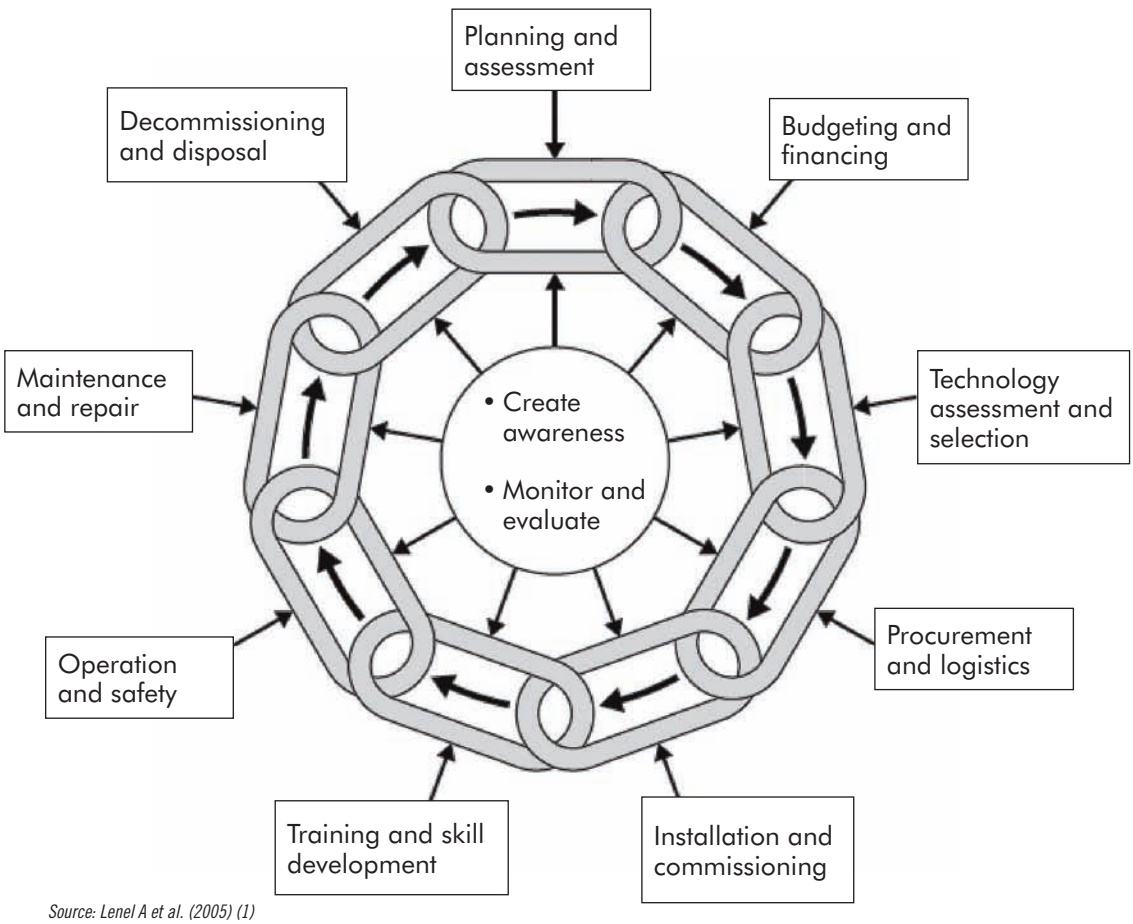
The first step in managing health-care technology is to determine what items are to be managed and to create the health-care technology inventory. The inventory is a working document that is regularly checked and updated to accurately reflect the status of health-care technology assets. When used appropriately, the inventory serves as an important and powerful tool to improve management of many key aspects of health-care technology.

2 Purpose

The purpose of this document is to provide an overview of health-care technology inventory for people working within the health-care field and who wish to understand the topic in greater detail. The reader will benefit from learning about the different types of inventory and the data included in these inventories. Furthermore, the document is intended to illustrate the role of an accurate, detailed inventory in HTM and the importance in ensuring the inventory provides useful information to support informed decision-making.

It is important to understand that maintaining an accurate inventory is not the end of the HTM process. Rather, the inventory serves as an input to the many different activities within the HTM cycle (Figure 1). The role of an equipment inventory in each step of the cycle is discussed in order to emphasize the importance it plays in all facets of HTM.

Figure 1. Health-care technology management cycle



Source: Lenel A et al. (2005) (1)

3 Definition of inventory

An inventory is a detailed itemized list of assets held by an organization or institution. To be worthwhile, an inventory must be continually maintained and updated to reflect the current status of each asset. Depending on the nature of the organization and its associated assets, different details are tracked and updated as changes occur. The goal is to have an accurate, up-to-date record of all assets held by the organization, reflecting the current status at any given moment in time. Within the scope of HTM, an inventory is the first and most important tool for achieving several broad aims:

- A medical equipment inventory provides a technical assessment of the technology on hand, giving details of the type and quantity of equipment and the current operating status.
- The inventory provides the basis for effective asset management, including facilitating scheduling of preventive maintenance and tracking of maintenance, repairs, alerts and recalls.
- The inventory can provide financial information to support economic and budget assessments.
- The inventory is the foundation needed to organize an effective HTM department. Items such as equipment history files and logbooks, operating and service manuals, testing and quality assurance procedures and indicators are created, managed and maintained under the umbrella of the equipment inventory. Furthermore, accessories, consumables and spare parts inventories are directly correlated with the main medical equipment inventory.

4 Types of inventory

Inventories of medical equipment may be maintained at different levels within a country's health-care structure. At the national level, the ministry of health or other overseeing body may keep an inventory of highly sophisticated or regulated equipment, such as devices used in nuclear medicine and devices that emit ionizing radiation. Such inventories may be used to ensure that the proper service is implemented to protect large investments of highly technical equipment and to monitor potential hazards, including radioactive and nuclear exposure. In cases where the state owns the assets, a national or regional/provincial inventory may be implemented.

Most medical equipment inventories, however, are held at the health-care facility level. For smaller organizations, such as a local clinic, the inventory may consist of a few simple items and may be updated very infrequently, if ever. Meanwhile, high-level specialized hospitals may have thousands of items listed in the inventory, with continual updates. Every inventory is unique to reflect the facility's assets; the size and complexity of the inventory will depend on its type and purpose and the scale of the operation.

Many types of medical equipment require consumables and accessories. Therefore, in conjunction with the medical equipment inventory, the health-care facility should maintain a separate inventory of consumables necessary to operate medical equipment *(2)*. These include items such as blood tubing sets, electrodes, electrocardiographic (ECG) paper, conductive gel and reagents. The inventory includes a stock-control system to track details such as quantities and expiration dates so that items remain in stock and are used before they expire. Effective stock control of consumables inventory prevents stock-outs and allows budget estimates to cover the cost of consumables.

An equipment spare parts inventory is another important record that must be maintained in order to ensure safe and effective function of medical equipment. For each medical device, it is important to have a stock of the items that wear over time or need to be replaced regularly, including filters, O-rings and other parts recommended by the manufacturer. In addition, general maintenance materials, such as fuses, screws and electrical wires, must be kept in supply through the use of the inventory. A spare parts inventory can assist in estimating the annual maintenance costs of the medical equipment stock.

Other inventories that could be implemented in support of or related to health-care technology include the following:

- *Workshop tools and test equipment inventory:* Assists the medical equipment maintenance team in keeping tools and test equipment organized, in good working order and in calibration.
- *Industrial and hospital equipment:* Items such as boilers, autoclaves, laundry equipment, generators,

and compressed air, vacuum and medical gas distribution systems, are all necessary to keep the hospital running smoothly and require maintenance. An inventory of such equipment is useful in managing the maintenance of this equipment.

- *Safety equipment:* Keeping an inventory of items such as fire extinguishers, fire hoses, alarms and eyewashes, and performing routine checks to ensure they are in good order, will ensure that they are functional when needed.
- *Radioactive and hazardous materials and waste:* Maintaining an inventory of such materials helps to ensure proper regulation and disposal and prevent unnecessary contamination.

The focus of this document is on medical equipment, consumables, spare parts, workshop tools and test equipment inventories. Discussions of inventories for industrial and hospital equipment, safety equipment, and radioactive and hazardous materials and waste are outside the scope of this document.

5 Items included in an inventory

The main health-care technology asset to be included in an inventory is medical equipment. Such an inventory often remains separate from the main hospital asset inventory, since different information is needed for the purpose of HTM. The responsible department within the health-care facility (such as a medical equipment maintenance department or clinical engineering department) determines which equipment should be included in the inventory. Some organizations choose to include all medical devices in an inventory, including small items such as stethoscopes and thermometers; for larger organizations, however, this may not be practical.

When an organization decides to eliminate some items from the inventory, it establishes a set of criteria by which to include or exclude each item. One method is to implement a risk-based inventory that identifies higher-risk equipment to be included in the inventory and medical equipment management plan, and lower-risk items that may safely be eliminated. The Association for the Advancement of Medical Instrumentation (AAMI), in its widely recognized standard *Recommended practice for a medical equipment management program (3),* requires that inventory inclusion criteria take into account the function of the equipment, the physical risks associated with the equipment, the maintenance requirements of the equipment and the incident history of the equipment. Fennigkoh and Smith (1989)*(4)* created a numerical algorithm to evaluate medical equipment based on equipment function, risk and required maintenance. This algorithm serves as a foundation for many inventory inclusion analyses in health-care facilities worldwide. The algorithm is explained in Appendix A. An adaptation of this algorithm is found in *Medical equipment maintenance programme overview (5)* in this technical series. This adaptation adds the equipment incident history as a consideration, such that equipment with a higher frequency of failures moves up on the risk scale (and thus is more likely to be included in the inventory) and those with a lower frequency of failures moves down on the scale (less likely to be included in the inventory).

Building on Fennigkoh and Smith's model and the idea of a numerical algorithm to determine equipment inclusion in an inventory, many improvements and suggestions have been made to determine how to decide which equipment should be included in an inventory. Wang and Levenson (2000)*(6)* emphasized that the consideration of mission criticality and utilization rates is essential when deciding which equipment should be included in an inventory. Mission criticality identifies how important the equipment is to the overall goal of the hospital. Equipment that is more important to the main mission of the hospital (for example, a piece of laboratory equipment used to perform routine tests) may be more important than high-risk or sophisticated equipment (such as a ventilator) of which there are many units available. Furthermore, utilization rates consider how often a piece of equipment is used. For example, a piece of equipment that is used often and of which there is only one unit has a much higher utilization rate (and thus may be much more important) than a piece of equipment that is used rarely or of which there are several units (for example, defibrillators). Further discussion of this algorithm is included in Appendix A.

Wang et al. (2006) *(7)* discuss further different strategies for determining equipment to be included in an inventory and within a medical equipment management programme. Every healthcare facility has different equipment needs and usage rates, and the department responsible for medical equipment inventory should take all of these factors into consideration when determining which equipment should and should not be included.

Regardless of the method used to determine inventory equipment inclusion, it is important that the responsible department reassesses inventory equipment inclusion often, particularly when mission criticality or utilization rates change.

6 Data included in an inventory

Every health-care facility has different requirements for the information about each item that needs to be included in an inventory. Table 1 shows a list of information that may be included. The minimum information that is typically included is at the top of the table – this provides any department with the information about a piece of equipment that may be needed within even the most basic HTM system. Other useful information that may be considered for inclusion in an inventory is also listed in Table 1.

6.1 Inventory identification number

In a medical equipment inventory, each piece of equipment is assigned a unique number to allow it to be identified from among all other pieces of equipment in the inventory. All information gathered about this piece of equipment in the equipment management process, such as service history, preventive maintenance procedures and schedules, repair history and spare part usage, is linked to this identification number for optimal organization of data.

Once the inventory identification number is assigned, each piece of equipment is labelled with that number.

The clinical engineering department determines the identification numbering and labelling system to be used within the organization. To assist in this decision-making process, three possible numbering systems are described here *(8)*:

- *Sequential numbering:* starting with 1, 2, 3 and continuing sequentially until each item has been assigned a number, every new item is assigned the next available number. This is the simplest method, although it does not give any information about the machine. A master list (and backup) with all allocated numbers is kept in order to assign the next number.
- *Coded numbering:* a code is used to identify unique features about the equipment, with different parts of the code identifying different features of the equipment. An example of a code could be 01-XXX-02, with 01 indicating the machine type (for example, ultrasound machines), XXX indicating the manufacturer, and 02 indicating that the item is the second ultrasound machine by the manufacturer XXX. From the code, a person can instantly know information about the piece of equipment such as the type, manufacturer and the specific machine. Other information can be incorporated into the code, as is deemed useful by the organization. For some organizations, however, this may be seen as complicated or unnecessary. The use of a computerized inventory management system may eliminate the need for such a code, since information about the equipment is easily accessible by typing in the inventory identification number. Other facilities, however, may find a coded numbering system useful. When using such a system, the clinical engineering department needs to agree on the coding system and understand the meaning of the codes.
- *Barcodes:* barcode stickers can be used to label each piece of equipment. With this more advanced system, a barcode reader is necessary to read the inventory identification number

and software programmes are needed to link the barcode to the detailed information about the machine. This can be useful when using a computer-based inventory management system, although it requires the extra barcode reader hardware, a regular supply of stickers and the appropriate computer software. The system is most easily implemented if the inventory identification number associated with the barcode is also included on the inventory sticker/label, which prevents confusion if a barcode reader is not available.

Table 1. Inventory data

Item	Brief description/purpose	Type of inventory
Minimum data included in inventory records		
Equipment identification number	Unique identifier for each piece of equipment	Medical equipment
Type of equipment/ item	Identifies what the item is, using standard and uniform nomenclature, such as the Universal Medical Device Nomenclature System (UMDNS) or Global Medical Device Nomenclature (GMDN)	All
Brief description of equipment/item	Describes the item, including its function/purpose	All
Manufacturer	Identifies the company that makes the item, including the name, address and contact details of the manufacturer	All
Model/part	Unique identifier of the product line (assigned by the manufacturer)	All
Serial number	Unique identifier of the item (assigned by the manufacturer)	All
Physical location within health-care facility	Includes room number or department; allows medical equipment to be located when preventive maintenance is due; may include storeroom information for consumables and spare parts	All
Condition/operating status	Identifies equipment as "in service" or "out of service"; includes reason for being out of service, such as calibration due, preventive maintenance due, under repair, awaiting spare parts or damaged beyond repair	Medical equipment, testing equipment
Power requirements	Clarifies the required power to run the equipment, such as 110V, 220V, 380V or three-phase; may be useful for identifying equipment that requires transformers or other special attention	Medical equipment, testing equipment
Operation and service requirements	Identifies any special requirements needed in operation or service of equipment	Medical equipment
Date inventory performed/updated	Date the equipment was entered into the inventory and the last date the information was updated	All
Maintenance service provider	Lists details of provider including name, contact details and contract details when medical equipment is maintained by an outside service organization (including when under warranty by manufacturer) or peripheral workshop; information on maintenance performed	Medical equipment, testing equipment
Purchase supplier	Used as a point of contact regarding purchase, reorders, warranty replacements, etc.	All

Additional useful information		
Lot number	May be assigned for consumables or reagents manufactured in the same batch; can assist in identifying defects; useful for stock-control systems for consumables	Consumables
Current software and firmware version numbers	Used for equipment run with computer software or electronics (firmware); can be used to identify software- or firmware-related problems	Medical equipment, testing equipment
Department ownership details	Identifies point of contact for notification in service delays, and to schedule preventive maintenance	Medical equipment
Purchase cost	Serves as an input to capital inventory values and for budgeting purposes	All
Purchase date	In the case of capital assets, used to calculate depreciation values or replacement/ obsolescence determination. In the case of consumables or spare parts, may be used to determine usage rates, reorder requirements and expiration dates	All
Warranty expiration date	Useful in tracking warranty validity and expiration	All
Installation date and acceptance testing information and results	Serves as a foundation for the service history record and is used as a reference when troubleshooting	Medical equipment, testing equipment
Safety/risk assessment/ classification	Includes the risk assessment performed (or other rationale, if needed) that determined inclusion of equipment in the inventory; may also be used to determine equipment testing and repair priority	Medical equipment
Preventive maintenance schedule and procedures	Outlines frequency of preventive maintenance intervals and procedures for maintenance	Medical equipment, testing equipment
Calibration dates performed and results, dates due and procedures	Serves as a reference when troubleshooting equipment and ensures equipment is within calibration dates	Medical equipment, testing equipment
Stock and reorder quantities	When used in stock-control systems, serves as a trigger point for reorder when stock numbers reach an identified level	Spare parts, consumables
Associated devices/ systems/accessories/ consumables/spare parts	Identifies important supportive equipment, including any apparatus or accessories required to run a piece of equipment; part numbers for accessories, spare parts and consumables are helpful	Medical equipment, testing equipment
Year of manufacture	Used to calculate the age of the equipment; used with expected equipment lifetime as an input to determine when an item needs to be replaced, retired or discarded	Medical equipment, testing equipment
Expected equipment lifetime	Lists the expected amount of time (typically in years) that a piece of equipment may be safely and effectively in service; may be used as an input to determine when an item needs to be replaced, retired or discarded	All
Operating and service history	May include user or maintenance logbooks (for operation or service), work order or service reports, preventive maintenance reports and other information regarding the operation and service of the equipment; can be used when troubleshooting failures, evaluating purchases of new, similar equipment, and determining when an item needs to be replaced, retired or discarded	Medical equipment, testing equipment
History of recalls and reported hazards	Used to identify and follow up on any potential hazards associated with machine use	Medical equipment, testing equipment
Any other desired information	An inventory is useful to a health-care facility only if it contains important information needed by the facility; therefore, any data fields can be added as deemed necessary	All

7 Inventory management

An inventory is effective only when it is comprehensive and accurate. In order to achieve this, the inventory is updated whenever there is any change or addition of information, and during annual audits and reviews. Inventory management can be classified into three stages:

- *Initial data collection:* For an existing health-care facility, the first and most critical step in establishing an effective HTM programme is to compile an inventory of all medical equipment. In this process, a team of people, including an end-user with knowledge about the equipment and an appropriately qualified and trained technician, engineer or other person responsible for inventory management, visits every department within the facility and checks every piece of equipment, recording every detail required for the inventory. The process of locating every piece of equipment may involve opening drawers and looking in cupboards, closets, store rooms and so on. For many facilities, this process will reveal many pieces of equipment that are obsolete or not repairable, and this may be a good opportunity to dispose of such items. Appendix B includes a sample inventory data collection form. In the case of a new health-care facility, it is prudent that the inventory data are collected before the facility is put into operation. This allows the facility to establish good records from the start, which will set the foundation for an effective HTM system. When the data are collected, they are compiled and included in a paper-based or computer-based inventory management system.
- *Information update:* The equipment inventory is updated whenever there is any change in information for any inventory item. Whenever a new piece of equipment is acquired through purchase or donation, the piece of equipment should be entered into the inventory before it is put into use. Equipment that is leased or borrowed for an extended period of time should also be entered into the inventory. Records of equipment already listed in the inventory should be updated to show any changes, such as a change of location or operating status, updates to software or firmware, and service and repair performed on the machine.
- *Annual audit/review:* Every year, the clinical engineering department (or other responsible party) performs a review of the medical equipment inventory. The purpose of this review is to check that all of the information is accurate and to make any updates and changes as necessary. Similar to the initial inventory data collection process, a team of people visits every department and checks the details of every piece of equipment to ensure they are accurate. Any changes are recorded and then transferred to the main inventory record for the piece of equipment.

8 Computerized systems for inventory management

Although using a paper-based system for inventory is perfectly acceptable, a computer-based inventory system can ease inventory management, especially for larger inventories. The inventory may be integrated into a Computerized Maintenance Management System (CMMS), which generally combines inventory, repair and maintenance history, and work-order control into one system. Other information as needed may also be included in a CMMS.

Computerized maintenance management systems are commercially available or may be customized for a specific need. In many instances, a simple CMMS may be developed using commercially available or free spreadsheet or database software to maintain the basic information noted above. Beyond the aforementioned functions, a CMMS can generate reports in support of management analysis and decisions, including statistical analysis to identify maintenance and failure trends, and to determine solutions such as equipment replacement and required training. A CMMS can also maintain a spare parts inventory, track utilization and automatically trigger reorders. When financial data are included, a CMMS can produce budgeting trends in support of financial forecasts.

A CMMS may have the capability to record all repair and maintenance history for a particular item included in the inventory. Whenever any service is performed on a piece of equipment, it is entered into the system according to the inventory identification number. Any person with access to the system can then see the entire maintenance and service history for the piece of equipment, which may identify failure trends and assist in troubleshooting.

Work-order tracking is another important feature of a robust CMMS program. This tracks all work orders opened for maintenance within an entire clinical engineering department. Some systems have the capability to automatically generate work orders when preventive maintenance is due and may generate device-specific procedures.

More detailed information about CMMS can be found in *Computerized maintenance management system (9)* in this technical series.

9 The inventory as a tool

Once the inventory has been established, it can be a very helpful tool within the clinical engineering department and the health-care facility as a whole. This section illustrates the value of maintaining an effective inventory.

9.1 Forecasting and developing budgets

The equipment inventory can be used to assist in forecasting a variety of budgets. By considering current equipment values (based on local standard depreciation rates), performing a needs assessment, identifying equipment that needs to be replaced, and determining the expected lifetime of equipment, capital budgets can be forecast for the coming years for the purchase of new equipment *(10)*.

Annual service and operating costs associated with the equipment inventory can be used to plan for future annual budgets. Additionally, spare parts and consumables usage can be used to forecast and plan for future stock planning and budgeting.

9.2 Planning and equipping a technical workshop

A workshop with adequate space and the appropriate tools and test equipment is essential to keep equipment running safely and in good order. The equipment inventory is an important input in determining the tools and test equipment required for maintenance and the budget required for acquiring, calibrating and maintaining the instruments *(11)*.

Depending on the technical requirements of the medical equipment maintained in the inventory, the workshop may require various areas dedicated to different types of work. These areas may include an electronics laboratory, workshops for welding and carpentry, storage space for equipment waiting to be repaired, a disinfection area for decontaminating equipment, and space for tools, test equipment, technical literature, protective clothing such as gloves, goggles and overcoats, and storage for hazardous materials.

As tools and test equipment are expensive, it is suggested that a separate inventory is maintained in order to prevent loss of items and to track usage. Additionally, many types of specialized test equipment require periodic calibration to ensure accuracy.

9.3 Determining required staffing

Knowledge of the equipment available can help the clinical engineering department determine the staffing and skill-set needed to keep the inventory of equipment in good running order *(12)*. Medical technology as a whole comprises many different types of technology of varying technical complexity. Assessing the technical expertise needed to maintain equipment in conjunction with the quantities of equipment at each complexity level will allow the manager to hire the appropriate staff with the spectrum of technical skills needed to maintain the equipment.

In addition, the inventory of equipment will enable the organizational management to hire doctors, nurses, technicians and so on with the skill-set required to effectively operate the equipment. In most settings, clinical staff will also be responsible for performing various degrees of maintenance, including

calibration, cleaning, storage and basic tasks such as changing filters and bulbs. In resource-limited settings, equipment users may also play a greater role in inventory management.

9.4 Identifying training needs

After the equipment inventory is established, it can be used in combination with work orders and service history records to identify equipment failures, malfunctions and misuse due to inadequate training. Training deficiencies may be identified by equipment (such as new technology that is difficult to learn to use), by department (such as incorrect application of the technology) and by person (such as where an error is repeated by the same person) *(2)*. It is important to note that training may be for either or both technical and clinical staff. Where clinical staff members are expected to maintain and update equipment inventory records (such as in small clinics and other resource-limited settings), training on inventory record-keeping is essential.

Additionally, the arrival of a new piece of equipment typically sparks a series of training activities within the health-care facility, such as appropriate use and technique (required for clinical staff but also useful for maintenance staff), general maintenance, proper cleaning and storage of the equipment (for both clinical and maintenance staff). For specialized equipment, the initial inventory inclusion data for new equipment can be used to schedule periodic mandatory refresher training sessions for all personnel. Where the hospital or health-care facility has implemented some sort of quality management system, there is the possibility that this system may track and record all training performed (equipment-related or otherwise) and may restrict equipment use and maintenance to those staff members who have been trained. In this case, equipment training and usage will be managed in conjunction with this system.

9.5 Managing service contracts

At times, support from external service providers will be required to undertake the service and repair activities for medical or test equipment. This is often the case for highly specialized equipment and equipment under warranty. The inventory can help identify which equipment needs external service and can also assist in determining the budget required and available for such service.

External service providers may perform servicing on site or may remove equipment from the health-care facility to a workshop off site. It is important for the clinical engineering department to track all activity performed by external service providers and to ensure that all records of service performed are added to the equipment history file to maintain an accurate inventory record. A prudent health-care facility clinical engineering department is vigilant in requiring service reports from external service providers detailing, for example, all work performed and spare parts replaced.

9.6 Running an effective medical equipment management programme

It is imperative for any organization intending to run an effective medical equipment management programme to have and maintain an equipment inventory. The inventory serves as the basis for the programme. Intervals for inspection, testing and maintenance are defined by the initial risk analysis that determines a piece of equipment's

inclusion in the inventory. An organization may also decide to include items in the inventory, for the purpose of tracking, budgeting, etc., that may not require regular maintenance. The facility should make the final determination of what inventory items to include in the medical equipment management programme based on their particular requirements and resources.

Proper organization of technical documents (including user and maintenance manuals) is done under the umbrella of the equipment inventory and service history files and as part of a wider quality assurance programme. Maintenance schedules and procedures are kept with the equipment documentation for easy reference when it is time to perform the procedures. Good organization and documentation of inventory files allows for assessment and assurance of the quality and effectiveness of technical services.

9.7 Planning for spare parts and consumables orders

A medical equipment inventory can help identify the spare parts and consumables required to keep the equipment running. Spare parts and consumables inventories alert the team to order stock so that current reserves are not depleted and service is not stopped. The main functions here are to determine usage rates (number of parts/time) and to establish a reorder level that is sufficient to maintain service during the time required to order and obtain the new parts. When managed correctly, item stock levels are never depleted and service continues uninterrupted.

9.8 Performing needs assessment

It is beneficial for every health-care facility to assess the needs of the facility such that it may work to efficiently provide the treatments and procedures defined within the facility's scope. This assessment typically includes the types and quantities of equipment needed to perform these interventions effectively. This list can then be compared with the current inventory to identify the deficiencies and surpluses within the equipment inventory and to plan how to best meet the needs of the organization. Deficiencies within the inventory may be quantitative (sufficient number of machines to meet the patient demand) or qualitative (relating to performance, integrity, reliability and functionality of the equipment).

This needs assessment can be used in planning for purchasing new equipment or for compiling donation 'wish-lists' to receive relevant donations.

More detailed information on needs assessment can be found in *Needs assessment for medical devices (13)* in this technical series.

9.9 Developing replacement and disposal policies and goals

All equipment has an expected lifetime and will eventually need to be replaced or disposed of. Service histories associated with inventory items can be assessed to determine when equipment is no longer serviceable, relevant, safe or cost-effective. Over time, trends can help to identify the expected lifetime for equipment and cost-effectiveness (or lack of) to keep a piece of equipment in service. This information can help to develop policies for the replacement or disposal of equipment. Subsequently, this information can be used to prepare budgets for new capital purchases, repair services and so on.

9.10 Developing purchasing and donations goals

When equipment is replaced or disposed of, it usually needs to be replaced through purchase or donation *(14)*. Tracking inventory levels and trends over time in conjunction with performing a needs assessment of required technologies can help the health-care facility identify equipment that it needs to acquire. This information can be developed into a purchasing plan, identifying critical equipment that needs to be purchased in the short term, and establishing goals for future acquisition. Additionally, where technology is determined to be lacking, it can be added to a wish-list for donations, which can then be given to charitable organizations to encourage useful and appropriate donations.

More detailed information about procurement and donations can be found in *Procurement process resource guide (15)* and *Medical device donations: considerations for solicitation and provision (16)* in this technical series.

9.11 Performing risk analysis, management and mitigation

In the earlier discussion about inclusion and exclusion of equipment in the equipment inventory, risk analysis was identified as the key determining factor. Once the inventory has been established, analysis of the inventory as a whole can identify potential areas of risk that can be handled and mitigated accordingly. This may include identifying hazardous areas in a hospital (such as radiation areas around imaging departments), creating backup plans in the case of device failures, and the placement of safety equipment throughout a facility (such as installation locations of fire extinguishers).

9.12 Planning for disasters and emergencies

Knowledge of equipment inventory quantity and type can feed into planning for disasters and emergencies to determine the number of patients that can be accepted by a facility during such events. Additionally, it can show what type of treatments it can and cannot provide ahead of time in order to handle an emergency situation most efficiently.

9.13 Making a case for equipment standardization

Assessing an equipment inventory can help to identify potential benefits in standardizing equipment *(14)*. Important items that feed into such a decision are the cost of spare parts (discounts for bulk purchases), failure rates of equipment, lack of expertise of equipment users and maintainers due to variability between different pieces of equipment, and the cost of training users and technical maintenance staff. Assessment might show that standardization would lead to lower spare parts prices, lower costs required for training more individuals on one type of technology, and lower costs for tool and equipment purchases.

More detailed information about planning and equipping a technical workshop, determining the required staffing, identifying training needs, managing service contracts and running an effective medical equipment management programme can be found in *Medical equipment maintenance programme overview (5)* in this technical series.

10 Concluding remarks

Although the basic definition of an inventory is a list of assets, it has been shown that an inventory can be a much more powerful and useful tool. In the case of HTM, the inventory serves as the foundation of the entire HTM cycle, with each item in the cycle depending on the completeness and accuracy of the information. For a health-care facility to have any intention of implementing a high-quality HTM programme, the first and most important step is to perfect the equipment inventory.

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Appendix A

Criteria for medical equipment inventory inclusion

Fennigkoh and Smith model

Each category includes specific sub-categories that are assigned points, which when added together according to the formula listed below, yield a total score from three (3) to twenty (20). Based upon these scores, the equipment is categorized into priority levels.

Categories & point scores

Equipment function

Includes various areas in which therapeutic, diagnostic, analytical and miscellaneous equipment is used.

Category	Function Description	Point score
Therapeutic	Life support	10
	Surgical and intensive care	9
	Physical therapy and treatment	8
Diagnostic	Surgical and intensive care monitoring	7
	Additional physiological monitoring and diagnostic	6
Analytical	Analytical laboratory	5
	Laboratory accessories	4
	Computers and related	3
Miscellaneous	Patient related and other	2

Physical risk associated with clinical application

Lists the potential patient or equipment risk during use.

Description of use risk	Point score
Potential patient death	5
Potential patient or operator injury	4
Inappropriate therapy or misdiagnosis	3
Equipment damage	2
No significant identified risk	1

Maintenance requirements

Describes the level and frequency of maintenance required as noted by the manufacturer or through experience.

Maintenance requirement	Point score
Extensive: routine calibration and part replacement required	5
Above-average	4
Average: performance verification and safety testing	3
Below average	2
Minimal: visual inspection	1

Formula

The formula used to calculate the equipment management (EM) number is:

EM = Function + Risk + Required maintenance

Results

Devices with an EM number 12 or over are included in the inventory.

Devices with an EM number below 12 are not included in the inventory.

Wang and Levenson's algorithms

Equipment management rating

Wang and Levenson's algorithm calculates an "Equipment Management Rating" (EMR), utilizing a mission critical rating from 1 to 10 (with 10 being assigned to equipment most critical to the mission of the health-care organization), combined with Fennigkoh & Smith's values of risk and maintenance. The EMR is calculated as follows:

EMR = "Mission Critical Rating" + 2*Risk + 2*Maintenance

EMR values range from 5 to 30, with 30 indicating the highest rating, and therefore the most important equipment to include in an equipment inventory. The multiplication factor of 2 for risk and maintenance is to give equal weight for all three parameters (risk and maintenance are scaled from 1 to 5).

Adjusted equipment management rating

Wang and Levenson propose an adjusted EMR incorporating equipment utilization (from 0-100%) in the following algorithm:

Adjusted EMR = ("Mission Critical Rating" + 2*Maintenance)*Utilization + 2*Risk

The utilization rate is used to weight both the maintenance values as well as the mission critical rating because a low utilization rate implies less urgency for equipment repairs as well as less criticality for the organization's mission. The risk to patients in case of equipment failure should not be affected by utilization rates, however.

Appendix B

Inventory data collection form

Inventory #_____

Type of equipment:_____

Manufacturer:_____

Model:_____ Serial #:_____

Country of origin:_____ Year of manufacture:_____

Power requirement: ❑ 220V ❑ 110V

Current state/condition: ❑ Operable and in service

❑ Operable and out of service

Reason out of service:_____

❑ Requires maintenance

❑ Not repairable

Requires special disposal? ❑ Yes ❑ No

Spare parts available? ❑ Yes ❑ No

If yes, what, how many, and where are they located? _____

_____

Manuals available:

❑ User manual # of copies _____ Location _____

❑ Service manual # of copies _____ Location _____

❑ Other (specify) # of copies _____ Location _____

_____

Equipment users: ❑ Doctors ❑ Nurses ❑ Lab technicians

❑ Students ❑ Residents ❑ Other (specify) _____

Equipment owner (department), if any: _____

Contact person _____ Phone number: _____

Current location of equipment: _____

Will it move from here? ❑ No ❑ Yes If so, where? _____

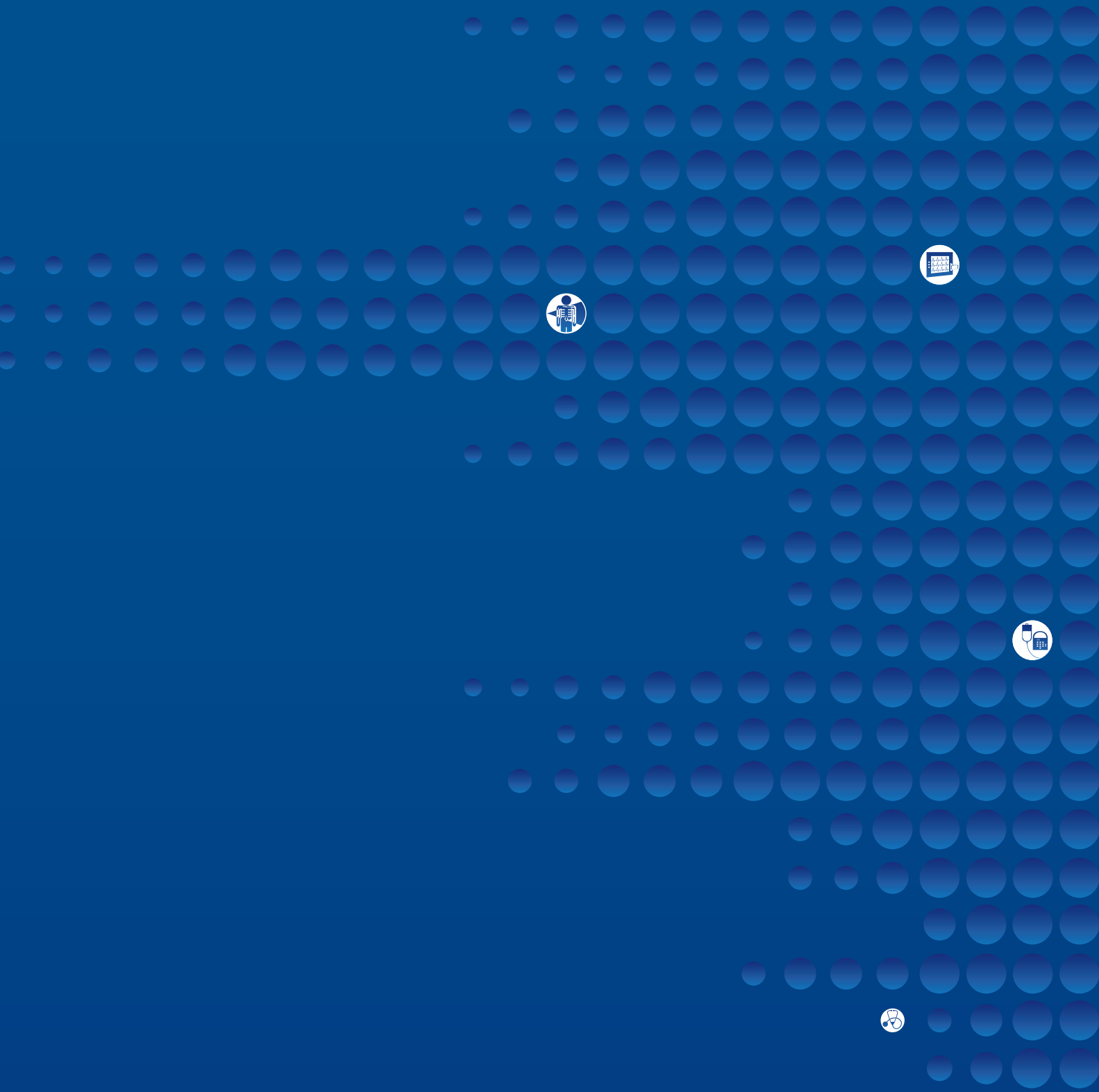
Other notes (use back of paper if more room is needed): _____

_____

_____

_____

_____



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