INTRODUCTION

Healthcare in Uzbekistan is one of the foreground directions of the inclusive social policy implementation which experienced major reform over the past two decades. Uzbekistan has a single statutory health care system, which includes public, private and other forms of non-public actors.

Today over 1,000 inpatient health institutions, 4,000 polyclinics and outpatient institutions, 501 rural outpatient posts, 2,606 RHCs and other health institutions are providing qualified public health services.

The priorities of the government of Uzbekistan, focused on comprehensive modernization of health system, continued gradual and targeted work on further reforming and developing of healthcare system. More attention is being paid to the protection of public health and strengthening of economic and technical base of medical institutions, as well as rendering high-quality medical services at modern requirements. With the purpose of improving the quality of laboratory services, improving the metrological service, improving the efficiency and security of medical services to the population on the basis of improvement of the system of medical equipment maintenance and testing in medical organizations, the Cabinet of Ministers of the Republic of Uzbekistan formed the decision №112 on February 15, 2018 "On measures for improving metrological control of medical laboratory and diagnostic equipment".

Actuality of the theme: Measurements and measuring instruments in the health sector are present in the everyday life of people and are fundamental processes in prevention, diagnosis and treatment of disease. Although medical measurements are only pieces within the complex process of medical decision making in general, they contribute incrementally. Therefore, the accuracy and reliability of medical measurements are of direct consequences for the health of each individual patient.

The purpose and functions of the research: The purpose of the research is to define the level, problems and their solution, optimization of metrological service in the field of medicine.

To achieve the purpose:

- To study and analyze current case of metrological service in the field of medicine;
- To study failures and their effects of blood preasure measurement devices and their effective use;
- To create new optimized functional metrological model for inspection and evaluation of medical devices.

The research object and subject: Object of master thesis is blood preasure measurement devices that are used in the hospitals, clinics and diagnostic centers. Subject of master thesis is metrological service of medical devices.

The research methodology and technique: Experimental, theoretical, and analytical research methods are used during the formation process of metrological service for the measurement device in the field of medicine.

The innovation of the research:

- Problems pertain to the formation of metrological service for medical measurement device are learned and relative solutions are provided;
- Accuracy of medical measurement devices are increased and errors are prevented;
- Metrological model for inspection and evaluation of medical devices is developed.

The importance of the result and practical applications: To improve the illness diagnosis quality by preventing the errors of medical measurement devices that are used in clinics, hospitals and diagnostic centers is considered as a practical importance and applications of master thesis result.

The structure of the thesis: This master thesis includes 3 chapters. Chapter I defines the features and the main directions of the health care system in Uzbekistan, metrological service and measurement requirements. Importance of

blood preasure measurement and blood preasure measurement devices are defined in the chapter II. Results of analytical experiments are given in the chapter III.

The main results of the research: The main result of research is to form the most effective metrological service for medical measurement device.

Shortcoming of conclusion and recommendation: By implementing the suggested metrological model for inspection and evaluation of medical devices, accuracy of medical devices will be provided and quality of medical service will be increased.

CHAPTER I. MEASUREMENT AND MODERN MEDICAL DEVICES IN THE HEALTH CARE SYSTEM.

1.1 The importance of metrological service in the health care system of the Republic of Uzbekistan

Healthcare in Uzbekistan is one of the foreground directions of the inclusive social policy implementation which experienced major reform over the past two decades.

Uzbekistan has a single statutory health care system, which includes public, private and other forms of non-public actors.

The share of national budget expenditures for healthcare is as high as 15,7 percent, and represents 4,1 percent of GDP. It is expected that the total health-care expenditures in the country would grow 3,8 times by 2020, and 8,7 times by 2030. This will result in the increase of the share of health-care expenditures in GDP to 9,8% in 2020 and 10,7% in 2030.

Today over 1,000 inpatient health institutions, 4,000 polyclinics and outpatient institutions, 501 rural outpatient posts, 2,606 RHC and other health institutions are providing qualified public health services [55].

The priorities of the Government of Uzbekistan, focused on comprehensive modernization of health system, continued gradual and targeted work on further reforming and developing of healthcare system. More attention is being paid to the protection of public health and strengthening of economic and technical base of medical institutions, as well as rendering high-quality medical services at modern requirements.

The country features high natural demographic growth rates, which total 1-1,5% per annum according to the projections. Approximately 615,000 newborns are expected annually in the next five years, whereas, 607,800 are expected annually in 2015-2020, and 596,700 annually in 2020-2025. Also absolute

growth of the number of the elderly is expected thanks to the improvement of health services and better living standards [55, 56].

These factors lead to higher demand for new technologies, modern equipment and high quality medications essential for treatment of pediatric diseases, mandatory vaccination of newborns and children, and treatment of diseases typical for the elderly – cardiovascular, oncologic, and neurological diseases. Simultaneously, importance of metrological service in the medicine will increase dramatically.

It has been envisaged to provide 517 medical establishments with modern medical equipment and equipment for utilization of wastes and furniture. The list has been determined on the basis of time sheet for fitting out medical establishments of the district and municipal levels. This will enable to create conditions for full coverage of rural and urban population with quality medical care at the level of primary out-patient and in-patient establishments.

It is planned to furnish medical institutions covered by the project, to the amount of $40 million. This will include X-ray equipment, dental equipment, vehicles for medical establishments located in remote and hard-to-reach areas. It is also planned to procure medical and laboratory furniture, sets of instruments, diagnostic and eye-care equipment and computers.

The Uzbek market for medical technology is almost entirely carried by imports. Also due to the increasing importance of private medical services, the demand for industry products is growing.

Uzbek government approved projects to develop by 2017 of health care services in rural areas to a total value of 5,2 billion soms ($ 2,5 million at the exchange rate of the Central Bank of the country). In particular, organization on the basis of 228 rural health facilities of paid medical, dental services, phytobars and branch pharmacies of "Dori-Darmon" including therapeutic services [56].

The central government's investment program includes the construction of new and modernization of existing medical objects.

Planned investment and loan projects of the Ministry of Health (2015-2018)	Procurement of diagnostic and medical equipment in all regional multi-profile medical centers - Surkhandarya, Andijan, Bukhara, Navoi, Rep of Karakalpakstan (KfW) - 45,5 mill. US$
	Procurement of radiotherapy equipment for Oncological Service of Uzbekistan (Islamic Development Bank loan) – 37 mill US$
	Procurement of modern medical equipment for Republican Specialized Centers (source not identified) – 28 mill. US$
	Procurement of modern medical equipment for district and city health facilities (loan requested from Export-Import Bank of Korea) – 40 mill. US$
	Procurement of x-ray machines and fluorography devices for outpatient services of Tashkent City (loan requested from Export-Import Bank of Hungary)
	Procurement of equipment for Medical University Clinics and Republican Clinical Hospitals (source not identified) – 15 mill US$
	Procurement of laboratory equipment for Sanitary Inspection Centers (source not identified) – 30 mill US$
	Procurement of equipment for emergency ambulance services and emergency medical care (source not identified) – 6 mill. US$

Figure 1. Planned investment and loan projects of the Ministry of Health (2015-2018).

Figure 1 demonstrates planned investment and loan projects of the Ministry of Health in 2015-2018 years. It means that, having this projects implemented completely there will be huge demand for the metrological service of the medical devices.

A number of governmental documents for the development of private entrepreneurship have been adopted in the country. They have given an opportunity to develop the system of private medicine which is the lowest layer in the hierarchy of the Uzbek health system and still in the process of developing.

There are about 4,500 private medical centers in Uzbekistan now. Private and other forms of non-public actors in the health sector comprise pharmacies, physicians working in single practices, and institutions involved in health care delivery or the production and supply of pharmaceuticals or medical equipment.

The private clinics and medical centers are equipped with modern equipment to render qualified medical services to the people, whereas state-run establishments still employ old equipment.

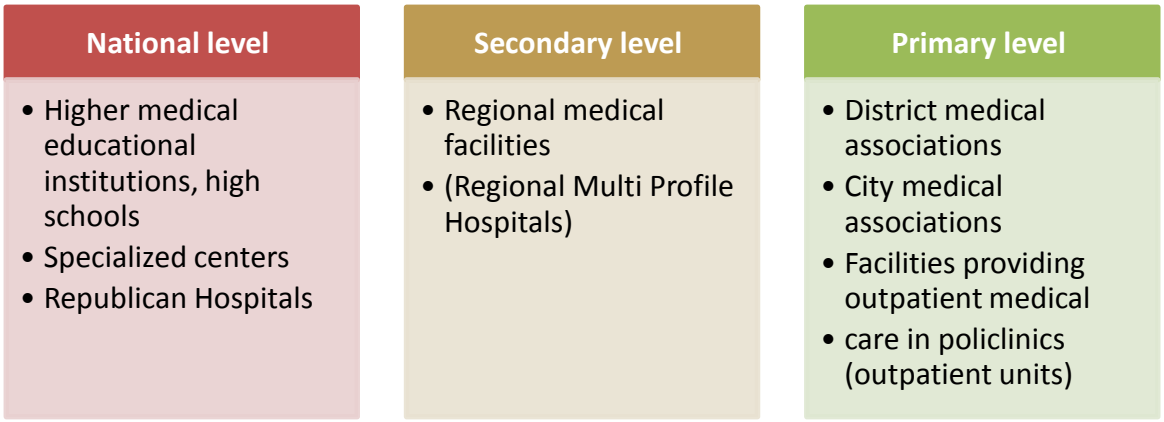
Administratively, they are accountable to the local governments, while financial accountability lies with the local tax departments, to which private providers are required to submit regular financial reports. Private providers are subject to the regulations of "for-profit" (profit-making) entities.

Little public funding is directed towards private health care providers. Private funding is obtained through the delivery of services outside the state-guaranteed basic benefits package of medical services. Financing flows from external sources to the private sector, for which no protocols on expenditure and use of health resources exist.

Private health care providers are exempted from all types of taxes for the first two years, provided they use these savings for investment in their medical and diagnostic equipment.

Health care professionals in Uzbekistan are paid differently, it depends on whether they work in the public or the private sectors. Private health care companies establish salary structures themselves, so that payment mechanisms and salary levels differ from company to company. This is also the case for individual private practices in their employment of health professionals. Reliable data on the private sector are not available.

Figure 2. Uzbekistan: Public Healthcare System



The Ministry of Health of the Republic of Uzbekistan is the central organ for state management of health care and subordinates its activities to the Cabinet of Ministers of the Republic of Uzbekistan.

In recent years, primary health care in Uzbekistan has seen dramatic changes in organization, management and financing. The Soviet multi-tiered system of primary care is being replaced by a two-tiered system, consisting in rural areas of rural physician points (SVPs) and outpatient clinics of central region hospitals.

1.2 Medical devices and their types

The term “medical devices” includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors. The intended primary mode of action of a medical device on the human body, in contrast with that of medicinal products, is not metabolic, immunological, or pharmacological.

Several different international classification systems for medical devices are still in use in the world today. The World Health Organization, with its partners, is working towards achieving harmonization in medical device nomenclature, which will have a significant impact on patient safety. This is particularly important to be able to identify adverse incident reports and recalls.

The Global Harmonization Task Force has proposed the following harmonized definition for medical devices.

‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means [29].

A few years ago, the medical equipment were fully utilized with human participation, which was used only for the control of the patient, the study of internal organs, the performance of ordinary measurements, and the recording of the drug. Stethoscopes, thermometers, and several surgical instruments can be examples for the first medical devices. Today, medical equipment are much more complex and diverse. The reason is that the their functions of sensing, receiving, processing, storing and transmitting data are combined with electronic systems and operate on electrical, mechanical, chemical and radiation sources. Additionally, the need for measurements with high accuracy of the physiological parameters of the disease is becoming an imperative demand while every doctor is giving guidelines for diagnoses and treatments of disease. As a result, the number and type of medical equipment is growing steadily. It can be approved by taking as an example the table of medical device type (Table 1) [19]. Why I am giving huge consideration to the type of medical devices in the master thesis, because increasing the number and type of medical devices effects the quality of metrological service in the field of medicine.

Table 1. Medical Device Type

№	Type of medical device	№	Type of medical device
1	Apparatus and equipment for traumatic and mechanical treatment	**13**	Respiratory and anesthetics, intensive care units, devices and equipment
2	Water treatment equipment	**14**	Pharmacy equipment
3	Instruments, apparatus and equipment for hemorrhage and neurosurgery	**15**	Instruments and tools for laboratory, morphological research, sanitary epidemiology
4	Disinfection equipment	**16**	Endoscopic equipment
5	Clinical Diagnostic Instruments and Apparatus	**17**	Instruments, apparatus and equipment for physiotherapy
6	Cosmetology equipment	**18**	Hearing aids
7	Otorhinolaryngology devices and equipment	**19**	Ophthalmology equipment, apparatus and equipment
8	Medical furniture	**20**	Sterilizing equipment
9	Radiology devices, apparatus and equipment	**21**	Devices, apparatus and equipment for tomography
10	Urology and blood purification apparatus and equipment	**22**	Instruments and tools for dental surgery
11	Functional diagnostic tools, apparatus and equipment	**23**	Laser apparatus and equipment
12	Instruments, apparatus and equipment for obstetrics, gynecology and neonatology		

1.3 Use of standards in medical device regulations

Although a standard can be set and mandated by an authority, the current trend is for the adoption of voluntary standards established by consensus from all interested parties (the stakeholders). The use of voluntary standards originated from the realization that while regulations generally address the essential safety and performance principles, manufacturers and users still need to know detailed specifications pertaining to specific products. The provision of such specifications and detailed requirements for the multitude of devices presents an enormous task for regulatory authorities. Fortunately, the wealth of

voluntary standards already existing or being developed provide such precise specifications. Therefore, requirements that are given in the normative documents and international standards are mentioned as a main parameters of metrological service and successfully used while developing "Metrological model for the inspection and evaluation of medical devices" in these master thesis. I'm going to prove my opinion by describing advantages of standards and their principles.

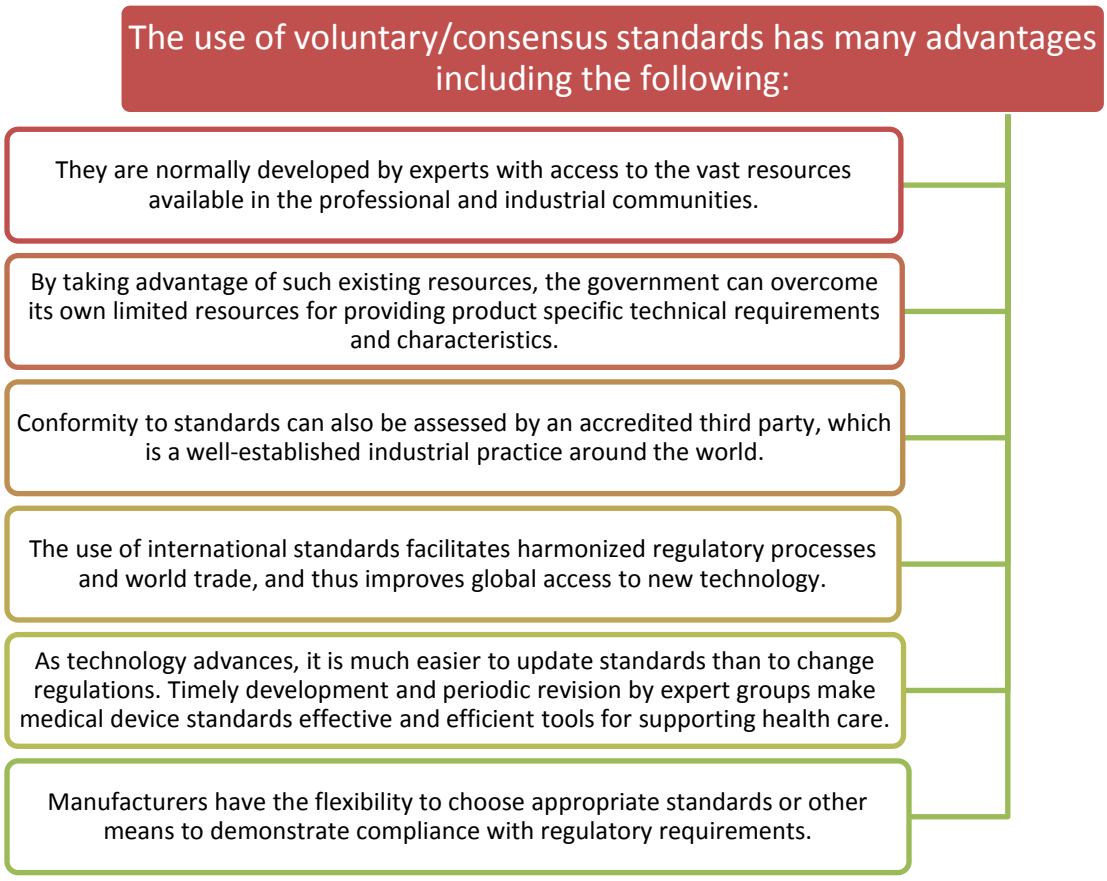


Figure 3. Advantages of use of standards

Regulatory authorities can recognize a standard, fully or partially, provided they clearly specify and publicize their intent. Several standards can also be recognized as a group to satisfy the requirements for a particular device. In some countries, the publication of government-recognized standards mandates product compliance [35].

Medical devices intended for global use should follow international standards. For example, the ISO Technical Report (ISO 16142:2000) lists a number of significant international standards that may be suitable for demonstrating compliance with certain features of the essential principles of safety and performance of medical devices. International standards are a building block for harmonized regulatory processes to assure the safety, quality and performance of medical devices. To achieve this purpose, the following principles are recommended [30]:

• Regulatory Authorities and industry should encourage and support the development of international standards for medical devices to demonstrate compliance with "the Essential Principles of Safety and Performance of Medical Devices".

• Regulatory Authorities developing new medical device regulations should encourage the use of international standards.

• Regulatory Authorities should provide a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating compliance with the Essential Principles.

• When an international standard is not applied or not applied in full, this is acceptable if an appropriate level of compliance with the Essential Principles can be demonstrated.

• While it may be preferable for harmonization purposes to use international standards, it may be appropriate for Regulatory Authorities to accept the use of national/regional standards or industry standards as a means of demonstrating compliance.

• Standards Bodies developing or revising standards for use with medical devices should consider the suitability of such standards for demonstrating compliance with the Essential Principles and to identify which of the Essential Principles they satisfy.

• The use of standards should preferably reflect current, broadly applicable technology while not discouraging the use of new technologies.

• Standards may represent the current state of the art in a technological field. However, not all devices, or elements of device safety and/or performance may be addressed by recognized standards, especially for new types of devices and emerging technologies.

Implementing a full regulatory program can be very expensive and demanding on resources. The work of the GHTF and the trend to use international standards are, in effect, tackling this problem by steering manufacturers more and more toward producing medical devices with uniform standards. The methods and procedures relating to governmental regulations are also converging. These developments create opportunities for countries to establish low-cost programs that promote the safety and performance of medical devices by taking full advantage of what others have already done in this field.

A good approach to setting a clear direction for all stakeholders is to establish a comprehensive national policy or guideline on medical device management. The government can subsequently bring in legislation and enforcement to suit the country's conditions and needs. Five principal activities are identified [30]:

1. Increasing the knowledge of the medical device sector
2. Establishing basic regulatory programs
3. Drafting a comprehensive policy/guideline including the recognition and use of standards
4. Promoting compliance and cooperation
5. Setting priorities for regulatory program development

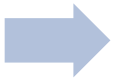
1.4 Measurement requirements and the factors effecting measurement results

To assure adequate space system performance, it is essential that technical requirements be developed, defined and documented carefully. Clearly defined

measurement requirements lead to the high reliability and quality needed to assure successful system performance and mission achievement.

Measurement — The set of operations having the object of determining the value of a quantity. Measurements are subject to varying degrees of uncertainty, the uncertainties need to be estimated, from the estimate, the validity of the measurement can be assessed, the risks associated with decisions based on these measurements quantified, and corrective actions taken to control growth in the measurement uncertainty [25].

The more critical the decision, the more critical the data



The more critical the data, the more critical the **measurement**

Measurements provide data from which decisions are made:

- To continue or stop a process
- To accept or reject a product
- To rework or complete a design
- To take corrective action or withhold it
- To establish scientific fact

The objective of the measurement process for space systems is to monitor the integrity of the performance parameters of space hardware, instrumentation and ground support equipment, and to allow sound decisions for taking actions. The objective of calibration is to determine initial bias errors, correct for these, "and then to monitor and control the growth of measurement uncertainty. This assures that decisions being made about the hardware from the measurement data are made within acceptable risk limits.

In order to achieve high accuracy in measurement, there should be clear concepts about measurement principles. Because these principles describe real meaning of measurement.

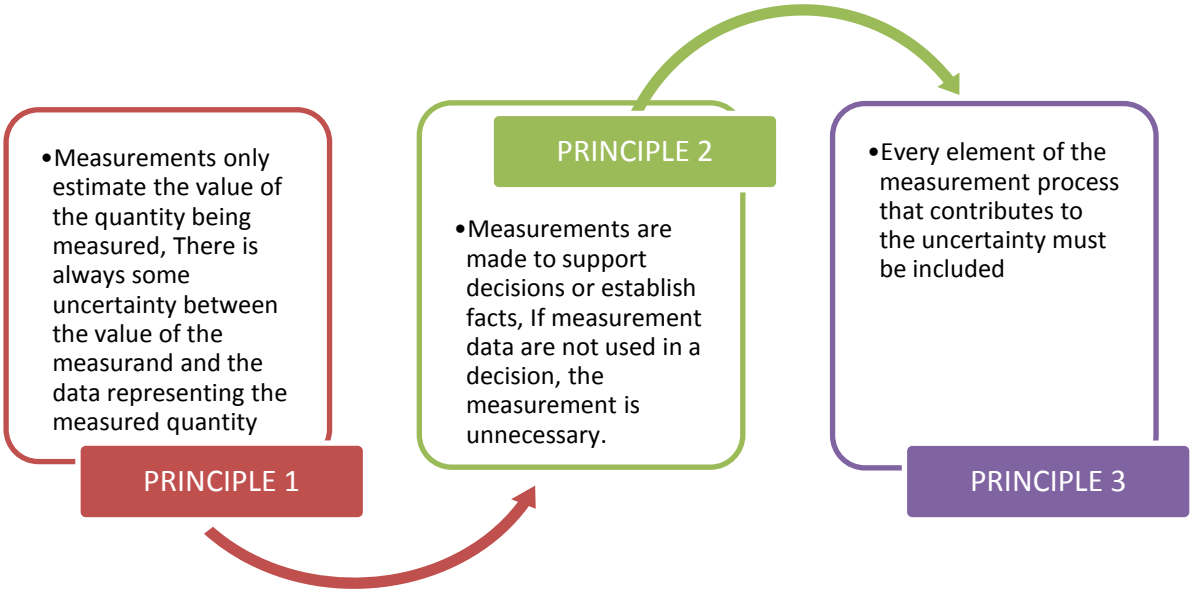


Figure 4. Principles of Measurement

Determining measurement process requirements can be viewed as a ten-stage sequence that flows down in the table [25; 28]:

Table 2. Measurement Requirements Definition Sequence

№	Stage title	Definition
Stage 1	MISSION PROFILE	Define the objectives of the mission, What is to be accomplished? What reliability is needed and what confidence levels are sought for decisions to be made from the measurement data?
Stage 2	SYSTEM PERFORMANCE PROFILE	Define the needed system capability and performance envelopes needed to accomplish the Mission Profile. Reliability targets and confidence levels must be defined.
Stage 3	SYSTEM PERFORMANCE ATTRIBUTES	Define the functions and features of the system that describe the System's Performance profile. Performance requirements must be stated in terms of acceptable system hardware attribute values and operational reliability.
Stage 4	COMPONENT PERFORMANCE ATTRIBUTES	Define the functions and features of each component of the system that combine to describe the System's Performance Attributes. Performance requirements must be stated in terms of acceptable component attribute values and operational reliability.

Stage 5	MEASUREMENT PARAMETERS	Define the measurable characteristics that describe component and/or system performance attributes. Measurement parameter tolerances and measurement risks (confidence levels) must be defined to match system and/or component tolerances and operational reliability.
Stage 6	MEASUREMENT PROCESS REQUIREMENTS	Define the measurement parameter values, ranges and tolerances, uncertainty limits, confidence levels, and time between measurement limits (test intervals) that match mission, system, and component performance profiles (Stages 2, 3 and 4) and the measurement parameter requirements (Stage 5.)
Stage 7	MEASUREMENT SYSTEM DESIGNS	Define the engineering activities to integrate hardware and software components into measurement systems that meet the Measurement Process Requirements, Definition must include design of measurement techniques and processes to assure data integrity.
Stage 8	CALIBRATION PROCESS REQUIREMENTS	Define the calibration measurement parameter values, ranges, uncertainty limits, confidence levels, and recalibration time limits (calibration intervals) that match measurement system performance requirements to detect and correct for systematic errors and/or to control uncertainty growth.
Stage 9	CALIBRATION SYSTEM DESIGNS	Define the integration of sensors, transducers, detectors, meters, sources, generators, loads, amplifiers, levers, attenuators, restrictors, filters, switches, valves, etc., into calibration systems that meet the Calibration Process Requirements. Definition must include design of calibration techniques and processes to assure data integrity.
Stage 10	MEASUREMENT TRACEABILITY REQUIREMENTS	Define the progressive chain of calibration process requirements and designs that provide continuous reference to national and international systems of measurement horn which internationally harmonized systems measurement process control is assured.

Error and uncertainty. Error refers to the difference between the measured value and the true one, while uncertainty is the doubt that exists about the result of any measurement.

Accuracy and precision. If you make several measurements and find that they also agree closely with each other, then they are precise. If they agree closely with the actual value, then they are accurate.

Trueness. Trueness is a similar concept to accuracy, but while accuracy refers to the closeness between an individual measurement and the true value, trueness refers to the closeness of agreement between the average value obtained from a set of test results and the true value.

Bias. Bias is the opposite of trueness – the greater the bias the lower the trueness. So, when a measuring instrument consistently gives readings which are too high or too low, it is said to be biased.

Tolerance. A tolerance is the maximum acceptable difference between the actual value of some quantity, and the value specified for it. For example, if an electrical resistor has a specification of 10 ohms and there is a tolerance of ±10% on that specification, the minimum acceptable resistance would by 9 ohms and the maximum would be 11 ohms.

As usual in science, clear definitions of words are just the start, for those words to be useful, numbers need to be attached to them. It is one of the triumphs of metrology that initially vague concepts like uncertainty can be pinned down in such a way that they can be expressed in numbers [31].

There are a number of factors that either can't be controlled at all, or can only be controlled to a limited extent, and which will influence the result [18; 31].

a) Instruments

While calibrations and preliminary checks can confirm that measuring instruments are behaving as they should before a measurement begins, a number of factors can impair their performance during the measurement itself. Electrical measuring instruments can be affected by electrical noise, either in the form of electromagnetic radiation or disturbances to voltage supplies. Proper earthing of equipment is also important, which can be tricky when several electrical

instruments are involved in the same measurement, in which case common earths may need to be set up and checked, to avoid earth loops.

In some cases the instrument itself can have a significant effect on the thing to be measured – this is always an issue with measurements of tiny quantities but can affect larger-scale measurements too. For instance, acoustic measurements are frequently required to be made in anechoic conditions – that is, environments in which there are no reflections of sound from objects. While chambers can be provided with special wall coverings to scatter and absorb sound waves, the detector itself can be a source of trouble some acoustic reflections.

b) The object to be measured

Hardly anything that is measured is truly stable: many people shrink by over a centimeter over the course of a day, fruit and vegetables slowly dry out and their chemical compositions change as they ripen and rot, colors fade and shift, electrical resistance alters with temperature and so on. Therefore, a consideration of the significance of such changes is important in planning measurements. In some cases, they may be small enough to be disregarded (‘negligible’). In others, they can be corrected for or averaged out. In yet others they can be reduced or halted by controlling the environmental conditions. Sometimes the variation itself is of direct interest, for example in measuring the stability of blood chemistry, the constancy of flow in pipelines or the flicker of light-sources. Measurements which track such changes (rather than simply averaging them out) are referred to as ‘dynamic.’

c) Sampling, and other aspects of the measurement process

The measurement technique needs to be well designed and the people who use it well-trained to get the most out of a measurement. This is especially important in those cases where the thing to be measured varies across space and time – the noise inside a car, the speed of the wind or the temperature of seawater can all be measured very accurately, but the answer will be of no value

unless measurements are made in sufficient numbers, and at appropriate positions and times – that is to say, that they are representative.

Another issue is that some samples can alter after they are taken but before they are measured. Blood, for example, undergoes many changes once it is removed from the body. So, characteristics of blood samples are not necessarily the same as those of in the bloodstream. In cases like this, a combination of appropriate storage, prompt measurement, and knowledge of expected changes is required.

Sometimes there are aspects of the measurement process which cannot be completely controlled or planned, however excellent the people, equipment and procedures may be. In those cases it is essential to make clear what the limitations on the measurement results are.

d) Operator skill

Measurements involve human skills, and there are limits to these, no matter how well trained, diligent or highly-motivated the operator is. Often, setting up the measuring equipment and preparing the thing to be measured is even more challenging than carrying out the measurement itself.

An important consideration here too is that those limits vary widely between individuals, so a measurement which can be carried out to a certain level of uncertainty by one person may be unachievable by another.

e) Environmental factors

The environment – especially its temperature, air-pressure and humidity – can affect the results of measurements of many kinds, by altering the characteristics of the measuring instrument, the thing to be measured, or both. In some cases, for example where mass has to be very accurately determined, the measurement is carried out in chambers under which all these factors are controlled, at a precise temperature and sometimes in a vacuum (and hence zero air pressure and humidity). However, measurements like this are expensive to make, in terms both of the facilities involved and the time required,

Furthermore, many items to be measured, including liquids and living things, don't take kindly to being measured in a vacuum.

In this master thesis, above mentioned factors were considered as a main metrological parameters that effect the accuracy of the medical devices.

1.5 Six guiding principles for the measurement

The number of quantities that can be measured is vast, and the number of measuring instruments is far larger. Length (or distance), for example, might be measured by a tape-measure, a sonar system, or a laser range finder, depending on whether you're a tailor, a submariner or a builder. The number of ways to misuse these devices is also rather large, and this section is an attempt to reduce that number a little.

Figure 5. Six guiding principles for the measurement

All measurements are based on the same approach used to measure doorways, and have been helpfully boiled down (by NPL) to six guiding principles [31].

1. The right measurements

A measurement is made for a reason, and that reason needs to be clearly defined and understood if the measurement is to be a good one. This is of course especially important when the measurement is being carried out for someone else. When a system which involves routinely repeated measurements is being devised (such as a system to measure the sizes of vegetables), a pilot study is a useful first approach, to discover where any problems lie and where improvements can be made to the procedure.

2. The right tools

The measuring instruments used need to be appropriate for the task, in a good state of repair, and calibrated and they need to be used according to the instructions of their owner or manufacturer.

3. The right people

Whoever makes the measurement (sometimes referred to as the 'operator') needs to have received the right instructions and training. For complex measurements, this training will often include formal qualifications. Where a group of operators is involved, their individual roles and responsibilities need to be formally agreed and clearly understood.

4. Regular review

Measuring instruments are often easily damaged and their performance frequently changes as time passes, so they need to be checked. These checks should be carried out at regular intervals rather than just before they are needed, to avoid delays. Since many individual instruments may be involved in making a measurement (to check environmental conditions, for instance), a written schedule is usually essential. In many cases this schedule will include both internal checks and less frequent external assessments. Measurement procedures also need to be reviewed regularly.

5. Demonstrable consistency

A measurement result isn't much use if it's only valid at the place where the measurement is made. For highly accurate measurements, there are often all

sorts of local factors that need to be taken into account if this is to be avoided. The force of gravity, for example, varies by up to 1% from place to place on the Earth's surface (and changes with time too, as a result of the shifting gravitational influences of the Sun and Moon, among other things). In turn, this affects the weights of objects (as measured, for example, by spring balances). So, an assessment of such factors should be made in planning an important measurement. Depending how different those results prove to be, it might again be necessary to make corrections, increase quoted uncertainties, or carry out further investigations.

6. The right procedures

As there are so many factors which need to be addressed to ensure that the result of a measurement is a good one, it's important that important or complex measurements are carried out in accordance with written procedures. Though these might simply be the documents supplied by the manufacturer, these may not be sufficient, especially where a number of different pieces of equipment are involved. An important function of a written procedure is to safeguard health and safety, so it will often be backed up by a risk assessment for this purpose.

Table 3. Checklist

ARE YOU CONFIDENT YOU ARE:	
MAKING THE RIGHT MEASUREMENTS?	☐
USING THE RIGHT TOOLS?	☐
INVOLVING THE RIGHT PEOPLE?	☐
CARRYING OUT REGULAR REVIEWS?	☐
ABLE TO DEMONSTRATE CONSISTENCY?	☐
FOLLOWING THE RIGHT PROCEDURES?	☐

1.7 Validation and calibration

How is it determined whether the people, procedures, equipment and other factors actually are the right ones? The process of checking this is called validation and it takes many forms, but the fundamental approach is to rely on the judgment of experts that all these factors are fit for purpose. These experts usually include people who will be using the measurement results, others with thorough knowledge of the items being measured, and experienced metrologists.

Another key measurement concept is calibration, which is the comparison of an instrument or artefact against a more accurate instrument (or sometimes a well-controlled reference signal or other reference condition), to discover whether it meets the manufacturer's specification. As a result of this comparison, a certificate is produced, which reports the instrument's readings and compares them to a reference value or values [25].

If the results are consistent with the reference values (i.e., any differences between them are within acceptable limits), then no further action is needed. If the results are significantly different, the measuring instrument under test can, in some cases, be adjusted until the results agree, and these adjustments are then recorded on the certificate. (In general, NPL does not make such adjustments, though they are routine in some organizations). Sometimes, calibration corrections are applied to the results, rather than to the instrument.

Depending on the type of weight being calibrated and class of accuracy, NMO may be able to adjust the weight for a customer if its calibration reading is outside the tolerances of legal metrology. However, the customer will then have to pay to have the weight re-calibrated.

In general, measuring instruments are first calibrated by their manufacturer. Sometimes, they are returned periodically to that manufacturer for re-calibration, or they may be calibrated either in house by the owner, or by a calibration laboratory.

Any calibration certificate can only report the behavior of the measuring device at the time the calibration was carried out, but it is usually assumed that the device will remain 'in calibration' – i.e. performing according to its specification – for some specified time-period, such as a year. Of course, when a device has been dropped, miss-used or otherwise badly treated, it will often need to be re-calibrated straight away, and the same applies if it begins behaving oddly. Some instruments also need to be calibrated more often depending on how they are used – flow meters, for example, will need more frequent attention when the fluids they measure are corrosive or erosive.

Conclusions by Chapter I:

Health care in Uzbekistan is developing and government is concentrating on modernization of health system, continued gradual and targeted work on further reforming and developing of healthcare system. As a result there is huge demand for new technologies, modern equipment and high quality medications essential for treatment of diseases. Simultaneously this requires modernization of metrology service in the field of medicine.

Nowadays medical device types is increasing gradually and their functions of sensing, receiving, processing, storing and transmitting data are combined with electronic systems and operate on electrical, mechanical, chemical and radiation sources. What I mean by this is that standards and normative documents which are used for the inspection of medical devices should be modernized according to the today's requirements.

The right measurements, the right tools, the right people, regular review, demonstrable consistency and the right procedures can be reliable aspects for the improvement of quality of metrological service. Therefore, special attention of metrology bodies should be given to these aspects.

CHAPTER II. METHODS OF BLOOD PRESSURE MEASUREMENT AND METROLOGICAL CONTROL OF BLOOD PRESSURE DEVICES.

2.1 Methodological provision

LIST OF IMPORTANT VOCABULARY

Auscultatory method– Technique whereby sounds (known as Korotkoff sounds) are heard over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with the systolic blood pressure and the disappearance of sounds with the diastolic blood pressure in adults. In children under age of 13, "k4" (i.e. 4th phase Korotkoff sound) may be appropriate [24].

Bladder - Inflatable component of the cuff [15].

Cuff - Component of the sphygmomanometer, comprising a bladder and a sleeve, which is wrapped around the limb of the patient [14].

Diastolic blood pressure– Minimum value of the arterial blood pressure as a result of relaxation of the systemic ventricle [24]. It is the lower of two blood pressure measurements, for example, if the blood pressure is 120/80, then 80 is the diastolic pressure.

Durability – ability of the measuring instrument to maintain its performance characteristics over a period of use [13].

Micro-circulation – is the circulation of the blood in the smallest blood vessels, present within organ tissues.

Oscillometric method – Method, wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced [24].

Permissible error – Method, wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced [13].

Pneumatic system – System that includes all pressurized and pressure controlling parts such as cuff, tubing, connectors, valves, transducer and pump.

Systolic blood pressure – Maximum value of the arterial blood pressure as a result of the contraction of the systemic ventricle.

Sleeve – Essentially inelastic part of the cuff that encloses the bladder [15].

Viscosity – resistance of a fluid (liquid or gas) to a change in shape, or movement of neighbouring portions relative to one another.

LIST OF SYMBOLS AND ABBREVATIONS

ACE	Automated Calibration Equipment
AR	Accuracy Ratio
ATE	Automated Test Equipment
BIPM	International Bureau of Weights and Measures
ECG	Electrocardiography
GDP	Gross Domestic Product
GHTF	Global Harmonization Task Force
GMP	Good Manufacturing Practice
ISO	International Organization for Standardization
MAP	Measurement Assurance Program
mmHg	Millimeter of Mercury
NIBP monitors	Non-Invasive Blood Pressure monitors
NPL	National Physical Laboratory
OIML	International Organization of Legal Metrology
QA	Quality Assurance
RHC	Rural Health Clinics
SVP	Rural Physician Point
SI	International System of Units

NORMATIVE REFERENCES

1. The decree of the Cabinet of Ministries of the Republic of Uzbekistan on 15.02.2018 №112 “On measures for improving metrological control of medical laboratory and diagnostic equipment”;

2. ISO 14971:2007 – Medical Devices – Application of risk management to medical devices, Switzerland, ISO;

3. ISO 13485:2003 – Medical devices — Quality management systems. Requirements for regulatory purposes. Second ed. Geneva, Switzerland, ISO

4. International Document OIML D 11:2013 – General requirements for measuring instruments – Environmental conditions;

5. International Document OIML R 16-1:2002 – Non-invasive mechanical sphygmomanometers;

6. International Document OIML R 16-2:2002 – Non-invasive automated sphygmomanometers;

7. IEC 62366:2007 – Medical Devices – Application of usability engineering to medical devices;

8. IEC 62304:2006 – Medical device software—Software life cycle processes. Geneva, Switzerland, IEC.

2.2 Literature review

Jay L. Bacher discussed fundamental concepts of metrology in his The Metrology Handbook in a clear and precise way. Metrology is always changing as scientists, engineers, and technicians learn more about how to make good measurements. In the latter part of the last century, concepts such as uncertainty, quality systems, statistics, and good metrology laboratory management underwent significant changes, resulting in better metrological practice. All this and more is covered in this book [26].

Joseph D. Bronzino has worked on researches that are deeply concerned with the discipline of biomedical engineering, as well as with ethical and

economic issues related to the application of technology to the delivery of health care. Biotechnology, clinical engineering, medical informatics and ethical issues associated with the use of medical technology are analyzed in his The Biomedical Engineering Handbook (second edition). The book consists of many chapters and in the one of them, role and major functions of clinical engineers are well defined [32].

"Medical Device Regulations" manual of WHO describes the nature of medical device safety as a risk management process that must encompass the life span of medical devices from their conception to disposal. A Life Span Diagram facilitates understanding and serves as a memory anchor. Optimum safety and performance require cooperation among all those involved in the life span of a medical device: the manufacturer, importer/vendor, government, user and public – each has a specific role to play in risk management. Besides manual considers the role of the government. The critical elements of the life span of medical devices that require regulatory attention are highlighted. Chapter 6 suggests various steps for governments seeking to establish an affordable regulatory program from the ground up for ensuring the safety and performance of medical devices. The need for knowledge, policies, legislation and enforcement of medical device safety is discussed [30].

Mahmud Omer Mohamed Ali and Eltahir Mohammed Hussein researched together on the theme of "Metrological Model for Inspection and Evaluation of Medical Devices". In their research a metrology model is proposed for inspection and evaluation of medical devices, which provide cost-oriented re-diagnosis rate of non-accuracy of the results. This work focuses on the current situation of medical devices in military hospital and Khartoum hospital, by applying the statistical methods such as the mean, frequencies, percentages and independent T – test. Results obtained by the model reflect the state of medical devices in hospitals. However, the average percentage of standards inspection and evaluation of medical devices which reached at military hospital is (46.8%) and Khartoum hospital is (47,9 %). While, the ratio required to ensure the

efficiency of medical devices scientifically more than (95%) which helps in diagnosis, treatment, monitoring of patients to provide the best healthcare services [43].

“Inspection of Medical Devices” book of Almir Badnjević, Mario Cifrek, Ratko Magjarević, Zijad Džemić describes the applications of physical science, engineering and mathematics in medicine and biology. This book was compiled to be an indispensable resource for professionals working directly or indirectly with medical devices, national metrology institutes, institutes of accreditation and institute of standardization. Just as importantly, it was organized for graduate and postgraduate students in biomedical engineering, electrical engineering, mechanical engineering, hospital engineering and medical physics. “Inspection and Testing of Noninvasive Blood Pressure Measuring Devices” part of the book is more useful for my master thesis and I found reliable information on the blood preasure measurement [24].

H.T.Castrup, W.G.Eicke and others “Metrology - Calibration and Measurement Processes Guidelines” specifically, is not limited to test equipment calibration and measurement standards activities. To provide a realistic assessment of data quality, the total process should be considered. The measurement process is covered from a high level through more detailed discussions of key elements within the process. Emphasis is given to the flow down of project requirements to measurement system requirements, then through the activities that will provide measurements with known quality that will meet these requirements [25].

Medical measurements are present in the everyday life of people and are fundamental processes in prevention, diagnosis and treatment of disease. Therefore, a growing interest lies in the role of metrological decisions and conformity assessment, namely where measurements are in support of health. From this point of view, M. do C´eu Ferreira, professor of Portuguese Institute for Quality, decided to work on the use of medical devices looking to enhance its metrological traceability, highlighting the specific role of metrology in the

field of health care and the impact of legal control in the framework of the medical devices regulation with a measuring function. He proposed a new regulatory approach for medical devices in use, facing the convergence between European policy enforcement and Metrological regulations [34].

"Beginner's Guide to Measurement" of National Physical Laboratory explains the fundamental concepts and basic facts about measurement, and in particular accurate measurement. It includes brief accounts of the role of measurement in modern and historical societies and explains the SI system, its base units and their relation to other units. The various organizations involved in measurement are introduced and their roles in linking all measurements to the SI base units through traceability chains explained. It includes general guidance about practical issues that affect the making of measurements, gives the meanings of key measurement terms, and explains the significance of such fundamental concepts as measurement traceability and calibration [31].

2.3 Importance of blood pressure measurement

The measurement of blood pressure is important in the diagnosis and monitoring of a wide range of clinical conditions. The blood pressure in the circulation is principally due to the pumping action of the heart and other determinants including peripheral vascular resistance, the blood volume and viscosity. The pumping action of the heart generates pulsatile blood flow, which is conducted into the arteries, across the micro-circulation and back via the venous system to the heart. Blood pressure usually refers to the arterial blood pressure in the systemic circulation. Arterial blood pressure is the force blood exerts per unit area on the walls of the arteries as the heart pumps it through the arterial tree. It is one of the vital signs, along with heart rate, oxygen saturation, respiratory rate and body temperature. Blood pressure is usually expressed in terms of the systolic pressure (maximum during one heart beat) over diastolic pressure (minimum in between two heart beats) [55].

Table 4. Classification of blood pressure for adults

Category	Systolic pressure (mmHg)	Diastolic pressure (mmHg)
Normal	90–119	60–79
High normal (Prehypertension)	120–139	80–89
Stage 1 hypertension	140–159	90–99
Stage 2 hypertension	160–179	100–109
Stage 3 hypertension (emergency)	≥ 180	≥ 110
Isolated systolic hypertension	≥ 140	<90

Normal blood pressure at rest for adults is within the range of 100–140 mmHg systolic and 60–90 mmHg diastolic. Hypertension, or high blood pressure is present if the resting blood pressure is persistently at or above 140/90 mmHg for most adults. Table 4 gives one of the most widely used classifications of blood pressure for adults. As of 2015, approximately one billion adults or 22% of the population of the world have hypertension. Arterial hypertension is a major risk factor for heart disease and could lead to severe organ damage. It is often called a “silent killer”, because there are usually no warning symptoms before hypertension strikes a person in the form of a stroke, heart attack, heart failure, eye problems (hypertensive retinopathy) or kidney disease. Therefore it is important to measure blood pressure regularly especially if any of risk factors (family history, smoking, obesity, high sodium intake, stress,) is present [24].

Public awareness of risks associated with high blood pressure and the availability of embedded microcontroller-based systems have resulted in the development of numerous automated devices for noninvasive blood pressure measurement and their widespread use not only in medical facilities, but also in homes and public places. The only way to determine whether someone has high blood pressure is to have it checked regularly. The key to blood pressure control is “good blood pressure measurement”. From the engineering point of view “good” means accurate and reliable. Both medical professionals and general

public users require accurate, safe and reliable blood pressure measuring. A standardized set of recommendations for blood pressure measurement in humans, that, if followed, should lead to accurate estimation of blood pressure, are summarized in.

2.4 Methods for blood pressure measurement

Methods for arterial pressure measurement are usually classified into direct and indirect methods [56]. The first being invasive and the only that measure the "true" pressure. All other methods belong to the group of indirect methods since the pressure is measured noninvasively from outside the body.

2.4.1 Invasive method

Invasive methods imply the insertion of an arterial cannula into a suitable artery and then displaying the measured pressure waveform on a monitor. The arterial cannula is connected to tubing filled with saline, which acts as a coupling medium between the blood in the artery and the external pressure transducer. The liquid within the tubing is in contact with a diaphragm that moves in response to the transmitted pressure wave. The movement is converted to an electrical signal by a transducer. In that way the complete arterial pressure waveform is measured and it is easy to determine systolic and diastolic pressure on a beat-to-beat basis.

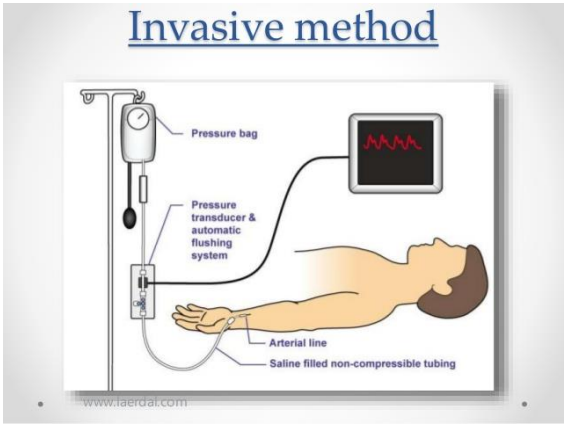


Figure 6. Invasive method

Invasive method is the gold standard of blood pressure measurement giving accurate beat-to-beat information. During the invasive measurement arterial catheter must be short and with the maximum gauge possible; column of saline must be as short as possible; the catheter and tubing must be stiff walled; the transducer diaphragm must be as rigid as possible. Also, a potential source of error may be the incorrect positioning of the catheter or the pressure transducer

positioned at the different level to the patient's heart. The drawbacks of direct methods are that they are invasive and uncomfortable for patients and in long-term use could lead to risks associated with infection, air embolism or thrombosis. Therefore invasive measurement of blood pressure is performed only in clinical environment in patients who are likely to display sudden changes in blood pressure, in whom close control of blood pressure is required, or in patients receiving drugs to maintain the blood pressure.

2.4.2 Noninvasive methods

Noninvasive measurement of arterial pressure is based on the detection of certain characteristic physical phenomena that can be registered at the surface of the body and correlating these phenomena to the arterial pressure. In the majority of noninvasive methods an occlusive cuff is used to obstruct the blood flow normally in the brachial artery. Then during cuff deflation, occurring phenomena are being recorded. In some methods systolic and diastolic pressure can be determined not only during cuff deflation but also during cuff inflation. The process of cuff deflation (or inflation) can be continuous or incremental (stepwise) [24].

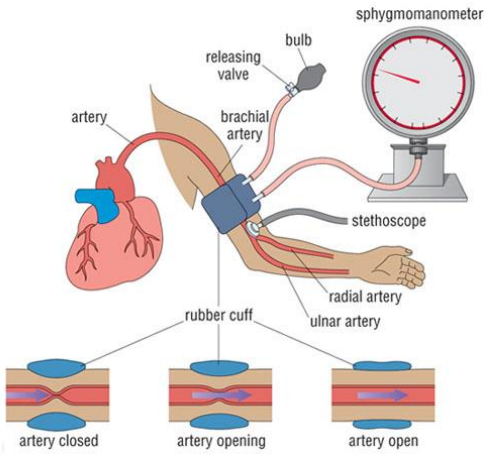


Figure 7. Noninvasive method

Based on the physical principle noninvasive methods for blood pressure measurement are divided into one of the following categories:

- Auscultatory method (Riva-Rocci method, Korotkoff method)
- Oscillometric method
- Palpatory method
- Ultrasound method
- Pulse-wave velocity method (Transit-time method)
- Vascular unloading method
- Arterial tonometry

2.5 Blood pressure measurement equipment

Devices for noninvasive blood pressure measurement, usually known as NIBP monitors, can be classified into three groups. One of them is the group of ambulatory monitors for 24 h recording of arterial pressure during normal activities, similar to ambulatory ECG. These are designed to record the patient's blood pressure at pre-defined intervals over a 24-h period during normal activities and store the data for future analysis. These devices help physicians to diagnose blood pressure disorders and to manage and optimize anti-hypertension therapy. Ambulatory devices are also important to assess the prevalence of "white-coat" hypertension. The second group comprises of bedside and transport monitors. The blood pressure measurement module is usually a part of multiparameter physiological monitor that enables measurement of ECG, SpO2, respiration, body temperature, etc. These make repetitive measurements at set time intervals and often incorporate vital sign parameter alarms. They are designed for bed-side monitoring in a clinical environment and are an expensive option. The third group of blood pressure measuring devices is the largest one comprised of the so-called self-taking NIBP monitors. The characteristic of this group is that these devices are intended for routine measurement at home, office or in public places either by a subject himself or by a physician. These devices are usually very simple and are widely available for an attractive price [46].

According to the way the systolic and diastolic pressure are determined and the way the cuff pressure is controlled three categories of NIBP monitors can be distinguished: non-automatic devices (manual cuff inflation, observer determines characteristic pressures), semiautomatic devices (manual cuff inflation, automatic determination of characteristic pressures) and fully automatic devices (automatic cuff inflation, automatic pressure determination). Typical non-automatic device is mercury sphygmomanometer, typical semi-automatic devices are some older oscillometric blood pressure monitors with manual cuff pump, and the example of the automatic devices are the majority of

oscillometric NIBP monitors available nowadays at the market. Combined auscultatory-oscillometric monitors are also available.

2.5.1 Automated devices, generally using the oscillometric method

The majority of non-invasive automated blood pressure measuring devices currently available use the oscillometric method. The oscillometric method relies on detection of variations in pressure oscillations due to arterial wall movement beneath an occluding cuff. Empirically derived algorithms are employed, which calculate systolic, mean arterial and diastolic blood pressure. Manufacturers develop their own algorithms by studying a population group and may have validated the stated accuracy by performing a clinical trial in accordance with one of the standards. Automated devices, generally using the oscillometric method [24]:

- **Automated (spot-check) device**

This includes an electronic monitor with a pressure sensor, a digital display and an upper arm cuff. An electrically-driven pump raises the pressure in the cuff. When started, the device automatically inflates the cuff to the appropriate level (usually about 30 mmHg above an estimated systolic reading), then deflates the cuff and displays the systolic and diastolic values. Some devices may have a user-adjustable set inflation pressure. The majority calculate these values from data obtained during the deflation cycle, but there are some that use data from the inflation cycle. The pulse rate may also be displayed. These devices may also have a memory which stores the last measurement and previous readings. Battery powered.

- **Wrist device**

This includes an electronic monitor with a pressure sensor, an electrically-driven pump attached to a wrist cuff. Battery powered.

• **Finger device**

This includes an electronic monitor and a finger cuff, or the device itself may be attached to the finger. Battery powered. Uses oscillometric, pulse-wave or plethysmographic methods for measurement.

• **Automatic-cycling NIBP monitor**

This is similar to the spot-check NIBP monitor, but with the addition of an automatic-cycling facility to record a patient's blood pressure at set time intervals. These are designed for bed-side monitoring in a clinical environment where repetitive monitoring of patients and an alarm function is required. These devices may incorporate the ability to measure additional vital signs. The alarm limits can usually be set to alert nursing staff when one or more of the measured patient parameters exceed the pre-set limits. Mains and battery powered.

• **Multi-parameter patient monitors**

These are designed for use in critical care wards and operating theatres and monitor a range of vital signs including blood pressure. May be possible to communicate with a Central Monitoring Station via Ethernet.

• **Ambulatory blood pressure monitor**

This includes an upper arm cuff and an electronic monitor with a pressure sensor and an electrically-driven pump that attaches to the patient's belt. The unit is programmed to record the patient's blood pressure at pre-defined intervals over a 24-h period during normal activities and stores the data for future analysis. Uses electronic auscultatory and oscillometric methods.

2.6 Metrological inspection of non-invasive mechanical and automated sphygmomanometers

Blood pressure measuring equipment should be regularly checked and calibrated. Frequency of inspections and calibrations should meet legislative and regulatory requirements and manufacturer's recommendations. Maintenance recommendations vary depending on the type, frequency and location of use. Faulty cuffs, hoses, aneroid gauges and mercury manometers can all lead to erroneous blood pressure measurements, with significant effects on patient care [24; 44].

Here metrological inspection of non-invasive mechanical sphygmomanometers and non-invasive automated sphygmomanometers are briefly presented based on international recommendations published by OIML. OIML international recommendations are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. The OIML member states shall implement these recommendations to the greatest possible extent.

2.6.1 Non-invasive mechanical sphygmomanometers

OIML R-16-1 specifies general, performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, for non-invasive mechanical sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure. The application of the cuff is not limited to a particular extremity of the human body.

Included within the scope of this recommendation are sphygmomanometers with a mechanical pressure sensing element and display, used in conjunction with a stethoscope or other manual methods for detecting Korotkoff sounds and for cuff inflation. Components of these devices are manometer, cuff, valve for deflation (often in combination with rapid exhaust valve), hand pump or electromechanical pump and connection hoses. These devices may also contain electro-mechanical components for pressure control [14].

Units of measurement

The blood pressure shall be indicated either in kPa or mmHg.

Metrological requirements

Maximum permissible errors of the cuff pressure indication

For any set of conditions within the ambient temperature range of 15 °C to 25 °C and the relative humidity range of 20–85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ±0,4 kPa (±3 mmHg) in case of verifying the first time and ±0,5 kPa (±4 mmHg) for sphygmomanometers in use.

OIML R-16-1 also specifies requirements under storage conditions and under varying temperature conditions.

Technical requirements

Technical requirements for the cuff and bladder

The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents. The optimum

bladder size is one with dimensions such that its width is 40% of the limb circumference at the midpoint of the cuff application, and its length is at least 80%, preferably 100%, of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

Technical requirements for the pneumatic system

Air leakage

Air leakage shall not exceed a pressure drop of 0,5 kPa/min (4 mmHg/min).

Pressure reduction rate

Manually operated deflation valves shall be capable of adjustment to a deflation rate from 0,3 to 0,4 kPa/s (2–3 mmHg/s). Manually operated deflation valves shall be easily adjusted to these values.

Rapid exhaust

During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 to 2 kPa (260–15 mmHg) shall not exceed 10 s.

Technical requirements for the pressure indicating devices

Nominal range and measuring range

The nominal range shall be equal to the measuring range. The nominal range for the cuff gauge pressure shall extend from 0 kPa to at least 35 kPa (0 mmHg to at least 260 mmHg).

Analogue indication

The scale shall be designed and arranged so that the measuring values can be read clearly and are easily recognized. The graduation shall begin with the first scale mark at 0 kPa (0 mmHg). The scale interval shall be: 0,2 kPa for a scale graduated in kPa or 2 mmHg for a scale graduated in mmHg. Each fifth scale mark shall be indicated by greater length and each tenth scale mark shall be numbered. The distance between adjacent scale marks shall be not less than 1,0 mm. The thickness of the scale marks shall not exceed 20% of the smallest scale spacing. All scale marks shall be of equal thickness.

Safety requirements

Resistance to vibration and shock

The sphygmomanometer shall comply with the relevant paragraphs of International Document OIML D 11. After testing, the device shall comply with the requirements of maximum permissible errors of the cuff pressure indication [13].

Mechanical safety

It shall be possible to abort the blood pressure measurement at any time by activating the manual rapid exhaust valve, which shall be easily accessible.

Tamper proofing

Tamper proofing of the manometer shall be achieved by requiring the use of a tool or breaking a seal.

Metrological controls

Requirements related to type approval, verification (initial and subsequent), sealing, marking the device and manufacturer's information are also prescribed.

2.6.2 Non-invasive automated sphygmomanometers

OIML R-16-2 specifies general, performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, for non-invasive electronic or automated sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure. This recommendation only applies to devices measuring at the upper arm, the wrist or the thigh [15].

Units of measurement

The blood pressure shall be indicated either in kilopascals (kPa) or in millimeters of mercury (mmHg).

Metrological requirements

Maximum permissible errors of the cuff pressure indication for any set of conditions within the ambient temperature range of 15–25 °C and the relative humidity range of 20–85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any

point of the scale range shall be ±0,4 kPa (±3 mmHg) in case of verifying the first time and ±0,5 kPa (±4 mmHg) for sphygmomanometers in use.

Maximum permissible errors of the overall system as measured by clinical tests (this is carried out by the manufacturer).

The following maximum permissible errors shall apply for the overall system: maximum mean error of measurement: ±0,7 kPa (±5 mmHg), maximum experimental standard deviation: 1,1 kPa (8 mmHg).

Technical requirements

General

Equipment, or parts thereof, using materials or having forms of construction different from those detailed in this recommendation shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.

Technical requirements for the cuff and bladder

The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents. The optimum bladder size is one with dimensions such that its width is 40% of the limb circumference at the midpoint of the cuff application and its length is at least 80%, preferably 100% of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

Technical requirements for the display

The display shall be designed and arranged so that the information including measuring values can be read and easily recognized. Testing shall be carried out by visual inspection.

If abbreviations are used on the display they shall be as follows: S or SYS: systolic blood pressure (value); D or DIA: diastolic blood pressure (value); M or MAP: mean arterial blood pressure (value). Single letter abbreviations shall be positioned in such a way to avoid confusion with SI units.

Effect of voltage variations of the power source

Internal electrical power source

Changes of the voltage within the working range determined according to Test methods for the effect of voltage variations of the power source on the cuff pressure indication shall not influence the cuff pressure reading and the result of the blood pressure measurement.

Outside this working range no cuff pressure reading and no result of the blood pressure measurement shall be displayed.

External electrical power source

Changes of the voltage within the working range specified by the manufacturer shall not influence the cuff pressure reading and the result of the blood pressure measurement.

Incorrect values resulting from voltage variations outside these limits shall not be displayed.

In the case of any malfunction of the equipment, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0,7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients.

Pneumatic system

Air leakage

Air leakage shall not exceed a pressure drop of 0,8 kPa/min (6 mmHg/min). Pressure reducing system for devices using the auscultatory method the pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0,3–0,4 kPa/s (2–3 mmHg/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of 0,3 kPa/pulse to 0,4 kPa/pulse (2–3 mmHg/pulse) shall be maintained.

Rapid exhaust

During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 to 2 kPa (260–15 mmHg) shall not exceed 10 s. For blood pressure measuring systems having the capability to measure in a neonatal/infant mode, the time for the pressure

reduction from 20 to 0,7 kPa (150–5 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened shall not exceed 5 s.

Zero setting

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereafter. Devices performing zero setting only immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds 0,1 kPa (1 mmHg).

Electromagnetic compatibility

Either electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement. If electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance. Testing should be carried out in accordance with the relevant OIML provisions.

Stability of the cuff pressure indication

The change in the cuff pressure indication shall not be more than 0,4 kPa (3 mmHg) throughout the pressure range after 10,000 simulated measurement cycles.

Pressure indicating device

Nominal range and measuring range

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of blood pressure measurement results outside the nominal range of cuff pressure shall be clearly indicated as out of range.

Digital indication

The digital scale interval shall be 0,1 kPa (1 mmHg). If the measured value of a parameter is to be indicated on more than one display, all the displays shall indicate the same numerical value. Measured numerical values on the display(s), and the symbols defining the units of measurement shall be arranged in such a way so as to avoid misinterpretation. Numbers and characters should be clearly legible.

Signal input and output ports

The construction of the signal input and output ports (excluding internal interfaces, e.g. microphone signal input) relevant to the non-invasive blood pressure measurement shall ensure that incorrectly fitted or defective accessories shall not result in erroneous indication of cuff pressure or erroneous indication of blood pressure.

Alarms

If alarms are used they shall be of at least medium priority.

Safety

Cuff pressure

It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust.

Unauthorized access

All controls which affect accuracy shall be sealed against unauthorized access.

Tubing connectors users of equipment intended for use in environments employing intervascular fluid systems shall take all necessary precautions to avoid connecting the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used.

Electrical safety

Electronic or automated sphygmomanometers shall comply with the relevant national safety regulations.

Resistance to vibration and shock

The sphygmomanometer shall comply with the relevant provisions of OIML D 11. After testing, the device shall comply with the requirements of maximum permissible errors of the cuff pressure indication.

Metrological controls

Requirements related to type approval, verification (initial and subsequent), sealing, marking the device and manufacturer's information are also prescribed.

For each requirement test procedures are also described and test report format is also given in the OIML R 16-2.

In order to speed up the testing procedure in everyday practice blood-pressure simulations are available (e.g. BP Pump 2 NIBP Blood Pressure Simulator by Fluke) as well as Electrical Safety Analyzers to test for IEC60601-1 compliance.

Conclusions by Chapter II

To be suitable for clinical use blood pressure measuring devices must comply with numerous requirements that depend on state legislative. To ensure reliable and accurate blood pressure measurement it is equally important that in hospitals and other medical facilities QA measures have been implemented. It is also necessary to perform routine inspection and calibration of blood pressure manometers, and all automated blood pressure measuring devices used in hospitals and primary care facilities. How often, by whom, and at what cost remain to be decided by responsible authorities. Training of those who use blood pressure measuring devices must be done and kept up to date.

Devices for home use are rarely thoroughly tested. Especially automatic oscillometric blood pressure monitors that are widely available could in some patients show unreliable and highly inaccurate results. It is therefore important to inform patients of the limitation of these devices. These limitations are also present in oscillometric monitors used in clinics, but physicians and nurses could cope with them if properly trained.

CHAPTER III. METROLOGICAL MODEL FOR INSPECTION AND EVALUATION OF MEDICAL DEVICES.

3.1 Risks that affect the medical devices safety

Figure 8 illustrates the major phases in the life span of a medical device from conception and development to disposal and responsible target groups of it's safety. The activity phases are simplified to make it easier to understand the regulatory system. For example, the development phase includes development planning, design verification/validation, prototype testing and clinical trials.

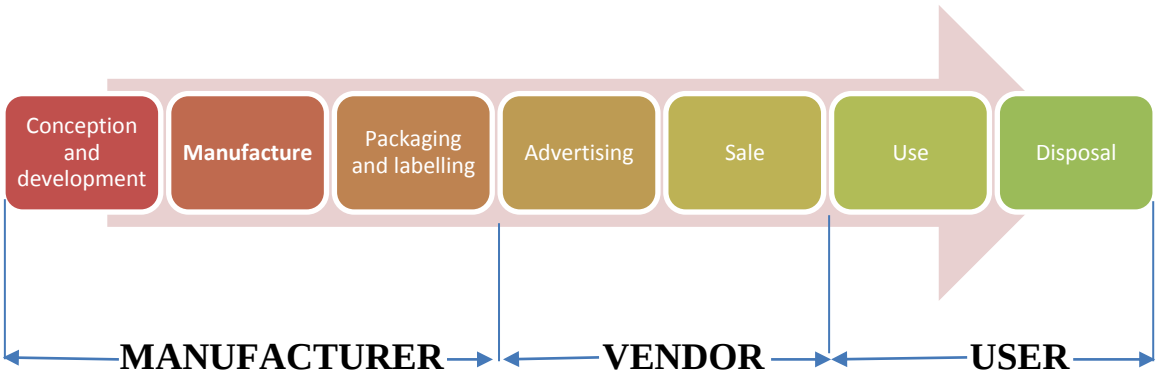


Figure 8. Major phases in the life span of a medical device

In practice, the phases outlined below may overlap and interact. It is important to recognize that any of these phases can affect the safety and performance

of a medical device. Examples of how each phase can create health hazards are described below:

1. Conception and development.

The scientific principles upon which a device is based are fundamental to its safety and performance. The more complex the device, the higher the risk of user error. Soundness of concept and adequacy of design, construction, and testing (including verification, validation and clinical trials) require the scrutiny

of scientific experts to ensure that design parameters and performance characteristics do not impose unwarranted risks.

2. Manufacture.

Good, functional medical devices are produced when the manufacturing process is adequately managed. However, poor manufacturing management can produce inconsistency in the quality of products, such that non-conforming devices can filter through the production line to the market, even when the original prototype has been well-designed. This consideration has led to the development of good manufacturing practice for drugs, biological products and medical devices. Now, GMP is more commonly referred to as "quality systems in manufacturing".

3. Packaging and labelling.

Properly packaged medical devices pose little risk to individuals handling them, even if the medical device is bio hazardous. This highlights the importance of well-designed packaging systems in delivering clean, sterile and protected medical devices to the point of use. Shipping is one of the hazards a medical device and its packaging must survive. Subtle damage can result during transportation and handling unless the total packaging system is designed robustly and can withstand various stresses. Well-sealed packaging is essential for those medical devices that must be maintained sterile. Labelling is crucial in identifying the medical device and specifying instructions for its proper use.

4. Advertising.

Advertisement has the potential to create expectations and powerfully influence the belief in a medical device's capabilities. It is important, therefore, that medical device marketing and advertising are regulated to prevent misrepresentation of a medical device and its performance. Misleading or fraudulent advertising of medical devices may increase sales. However, from the buyer's perspective, the purchase of an inappropriate medical device is

a waste of money that may deprive the patient of more appropriate treatment and could lead to patient or user injury.

5. Sale.

The sale of medical devices by the vendor is a critical stage that leads to the device being put into actual use. If the vendor is not subject to regulation, then there is higher risk of exposing the public to low quality or ineffective devices.

6. Use.

Users of medical devices can have a profound effect on their safety and effective performance. Unfamiliarity with a certain technology or operating procedure, and the use of products for clinical indications outside the scope of those specified in the labelling, can cause device failure even in the absence of any inherent design or manufacturing defects. Within the clinical engineering community it is widely believed that user error underlies at least half of all medical device-related injuries and deaths. The lack of, or inappropriate, calibration and maintenance of medical devices can seriously jeopardize their safety and performance. These issues are often overlooked or underestimated.

7. Disposal.

Disposal of certain types of devices should follow specific and stringent safety rules. For example, devices that are contaminated after use (e.g. syringes) or devices that contain toxic chemicals, can present hazards to people or the environment and must be disposed of properly. It is people who manage each phase in the life span of a medical device, and these people should be identified and called on to participate in ensuring medical device safety.

The ***manufacturer***, as the creator of the device, must ensure that it is manufactured to meet or exceed the required standards of safety and performance. This includes the three phases (design/development/testing, manufacturing, packaging and labelling) that lead to a product being ready for the market.

The ***vendor*** provides the interface between the product and the user. He/she should ensure that the products sold comply with regulatory requirements. With

increasing public interest in health and a competitive marketplace, vendors should be careful to avoid making misleading or fraudulent claims about their products or issuing false compliance certificates.

The ***user*** should make sure that he/she has qualifications and training in the proper use of the device, and is familiar with the indications, contra-indications and operating procedures recommended by the manufacturer. It is crucial that experience gained with medical devices be shared with other users, the vendor and manufacturer to prevent future problems. This can be done by reporting any incidents to a coordinating center from which warnings can be issued.

In conclusion, the ideal conditions that will ensure the safety and performance of medical devices require shared responsibility by all stakeholders. This need for cooperation is illustrated below.

The circle formed by the stakeholders illustrates the shared responsibility. The diamond handshake symbolizes cooperation and two-way communication (2-way arrow), and the star highlights how the fundamental elements for cooperation function best when all stakeholders communicate with each other.

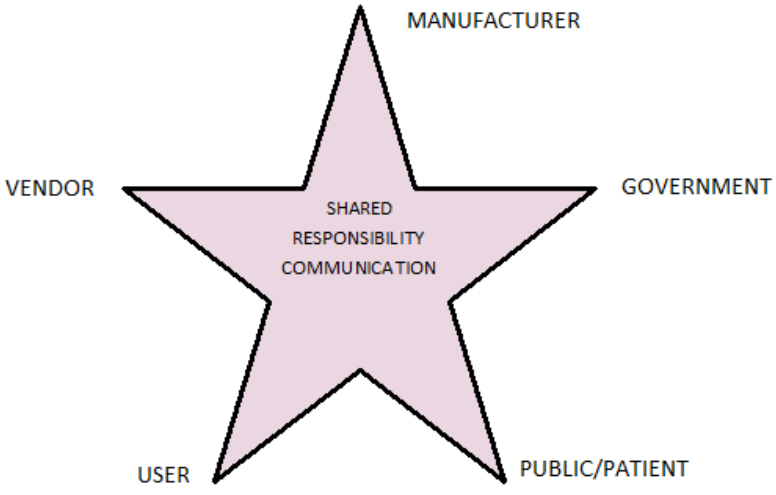


Figure 9. Ideal conditions for ensuring the safety and performance of medical devices

3.2 Metrological model for inspection and evaluation of medical devices

Several researches in area of reliable engineering for medical equipment mainly consider devices in their design or manufacturing stage and suggest many techniques to improve their reliability. Device evaluation helps to determine how the device functions as well as its ability to provide reliable results. Devices have been evaluated to learn how they function. It is important to know the device limitations than to know how it performs against standard specifications. All devices have limitations, and the limitations must be identified prior to adopting the devices, to reduce the risks.

In this master thesis, we learnt metrological service of blood preasure measurement devices in Andijan Testing and Certification Center – State Company. Unfortunately, accuracy of some blood preasure measurement devices is low and they are not conform to the requirements of standard. Then we researched inspection and evaluation system of hospitals, clinics and diagnostic centers for the blood preasure measurement. Because the main nonconformities of medical devices depend on effectiveness of this inspection and evaluation system. Furthermore, medical devices affect directly human health. It means that it's not enough to control accuracy of medical devices only in the comparative period, they should be controlled daily. Therefore we purposed to develop metrological model for inspection and evaluation of medical devices.

The model is designed to determine the effect of inspection and evolution of medical devices in health care, according to recommendations of the World Health Organization, recommendations of metrology specialists and technicians of hospitals, clinics, diagnostic centers and successful practices of other countries' systems. Further, the model has been designed to investigate and evaluate the activities and techniques in departments and sections that working with medical devices in health care, including documents, visual inspection, risk

management, preventive maintenance, corrective maintenance, policies and procedures, vocational performance.

Document model will check instructions and measurement, regulation for documentations.

In the policies and procedures model, policies and procedures relating to equipment and devices will be reviewed to focus on management of medical devices and equipment.

Safety model will review the plans of management including the risks of medical devices equipment and services throughout the facility.

In the performance vocational model activities of biomedical engineers and method of identifying training needs will be studied and checked.

A checklist will be applied to determine the conditions of all items in the visual inspection model.

In the preventive and corrective maintenance model, the basic principles will be reviewed including policies, procedures and manufacture recommendation. Documentation of maintenance, contract services and availability of spare part will be studied.

Table 5. Proposed model documentation

Metrological Model For Inspection And Evaluation Of Medical Devices				
Name of the facility:		Unit:		
Inspector:		Date:		
Documentation				
№	Item	EXISTING	INCOMPLETE	NOT EXISTING
1	Documentation of maintenance service			
2	Documentation of PM(books/logs/forms)			
3	Documentation of calibration			
4	Archiving of medical devices documents			
5	Reporting incidents			
6	Certificate of conformity			
7	List of spare parts and disposables			
8	Medical equipment Inventory list			
9	Daily Record to check medical devices			
10	Record of Equipment out of service			
11	List of devices that need to be repaired			
12	List of Inventory storage devices			
13	Requests for equipment maintenance			
14	Record of risk management			
15	Documentation for training			
16	Documentation of inspections and testing			
17	Annual effectiveness report			

Table 6. Proposed model policies and procedures

Metrological Model For Inspection And Evaluation Of Medical Devices				
Name of the facility:		Unit:		
Inspector:		Date:		
Policies and Procedures				
№	Item	EXISTING	INCOMPLETE	NOT EXISTING
1	Equipment management manual			
2	Policy to create a file for devices			
3	Policies for preventive maintenance			
4	Policy to develop and improve the work of devices			
5	Monitoring of performance indicators			
6	Reporting system			
7	Policies for corrective maintenance			
8	Policies for the Structure and staff			
9	Policies to train operators			
10	Policies to train engineers			

Table 7. Proposed model safety

Metrological Model For Inspection And Evaluation Of Medical Devices				
Name of the facility:		Unit:		
Inspector:		Date:		
Safety				
№	Item	EXISTING	INCOMPLETE	NOT EXISTING
1	Electrical safety standard 3 wire AC line cord or equivalent			
2	Safety electrical wiring			
3	Fire system			
4	Use gloves during maintenance			
5	Electrical grounding systems			
6	Electric generator (ATS)			
7	Electrical safety testing			
8	Environmental safety testing			
9	The warning signs			
10	Cleaning and disinfection devices			
11	Labeling safety signs			
12	Checking temperature in storage			
13	Checking humidity in storage			
14	Appropriate distance between the device and the surfaces			
15	Storage of devices by classification			

Table 8. Proposed model performance vocational

Metrological Model For Inspection And Evaluation Of Medical Devices				
Name of the facility:		Unit:		
Inspector:		Date:		
Performance Vocational				
№	Item	EXISTING	INCOMPLETE	NOT EXISTING
1	Service and maintenance of medical equipment			
2	Development and implementation of medical equipment management plan			
3	Management operating and maintenance manuals			
4	Management of maintenance contracts			
5	Development and implementation of replacement program			
6	Knowledge of international standards or recent recommendations			
7	The ability to investigate incidents of medical devices			
8	Participate in purchase and sale of devices			
9	Receiving and inspection of new devices			
10	Coordinating training on the operation of medical devices			
11	Continues training			

Table 9. Proposed Model For Preventive and Corrective Maintenance

Metrological Model For Inspection And Evaluation Of Medical Devices				
Name of the facility:		Unit:		
Inspector:		Date:		
Preventive and Corrective Maintenance				
№	Item	EXISTING	INCOMPLETE	NOT EXISTING
1	Schedule illustrating dates of periodic maintenance			
2	Providing the necessary consumables for periodic preventive maintenance			
3	Making the card or file for follow-up			
4	PM procedures			
5	Inspection and testing of medical equipment			
6	Calibration of equipment			
7	Failure/user error summary report			
8	Ordering engineers for maintenance			
9	Reporting devices in the warranty period			
10	Maintenance contracts			
11	Delivery system for equipment which has been repaired			
12	Availability of spare parts			
13	Corrective maintenance procedures			
14	Availability of maintenance tools			
15	Calibration after maintenance			

Table 10. Proposed model visual inspection

Metrological Model For Inspection And Evaluation Of Medical Devices				
Name of the facility:		Unit:		
Inspector:		Date:		
Visual Inspection				
№	Item	EXISTING	INCOMPLETE	NOT EXISTING
1	Presence of all accessories required for proper operation			
2	Standard operating procedure (SOP)			
3	Proper operation of the equipment as specified in the manufacturer's service literature			
4	Electrical connectors (jacks, receptacles, plugs)			
5	Alarms			
6	Circuit Breaker/Fuse			
7	Controls/Switches			
8	Indicators/Displays			
9	Audible Signals			
10	Battery Charger			
11	Availability and validity of consumables			
12	Equipment cards			
13	Connecting the device to the grounding system			
14	Calibration stickers			
15	Suitable environment for equipment			
16	Freeing device untimely and extremely from rust			

	corrosion liquids and dust			
17	Doors, knobs and the other of the moving parts are working well			
18	Checking the component holders, clips, and receptacles			
19	Checking the nuts, bolts, screws, and other hardware			

Conclusions and recommendations

Covering a wide range of products, from bandages to the most sophisticated life-supporting products used in diagnosis, prevention, monitoring, and treatment of diseases proper functionality of medical devices is crucial. In particular, it is important in life critical situations, when doctors have no more than 10 min to make a decision according to diagnosis based on readings of medical devices. Unfortunately, between 40,000 and 80,000 patients around the world, die due to the malfunctioning of medical apparatus and over 10,000 patients get seriously injured.

The aspect of accuracy of medical devices in health care systems around the world is regulated by different agencies or by applying international managing standards for health care institutions, which ensure that accuracy of medical devices is checked once a year. On the other hand, the aspect of accuracy of medical devices in a health care system for most countries is left to manufacturers or distributors of medical equipment, allowing them a certain kind of monopoly.

As a part of preventive service, an authorized service center performs also certification of devices. A certification process report is usually a work order document. This document only reports the result of the certification: whether the device passed or failed. The work order document contains neither any information about device output values measurement, nor the reference to the certification standard. From this point of view, we aimed to develop metrological model for the inspection and evaluation of medical devices all the time, not only in the surveillance control. In order to achieve this aim, indicators that affect the accuracy of metrological service of medical devices were learnt as an example of blood preasure measurement devices. As a result, metrological model for the inspection and evaluation of medical devices is developed based on recommendations of the WHO, recommendations of metrology specialists and technicians of hospitals, clinics, diagnostic centers and successful practices of other countries' systems.

In addition to knowledge and experience of medical doctors, correct diagnosis and appropriate patient treatment largely depend on accuracy and functionality of

medical devices. In a large number of serious medical situations proper functionality of medical devices is crucial for patients. Therefore, it is necessary to carry out as strict and independent testing of functionalities of medical devices as possible and to obtain the most accurate and reliable diagnosis and patient treatment.

By implementing the suggested metrological model for inspection and evaluation of medical devices, accuracy of medical devices will be provided and quality of medical service will be increased.

Based on analyzed and learnt knowledge related medical metrological service, following recommendations are given:

A) In order to operate in a competitive marketplace with increasing end-user demands for features and usability, medical device manufacturers operate in a highly regulated environment. Regulatory bodies look for evidence that medical devices are developed under a structured, quality-oriented development process. By following software validation and verification the best practices, manufacturers can not only increase the likelihood that they will meet their compliance goals, they can also enhance developer productivity. One of the most important verification tools that medical device manufacturers can deploy is source code analysis technology. Source code analysis tools provide an automated method to detect a significant number of software bugs or security vulnerabilities early in the development process and before any code is delivered to the testing team.

B) Quality manuals that are complied with ISO/IEC 17025 should be used in every medical laboratories. The laboratory should use the format that is most appropriate for its own needs. Regardless of the format that is used, the quality manual needs to be easy to read and use by all personnel. Many alternative methods exist for quality manuals, including the use of flowcharts. Flowcharts are typically simpler to understand, visual, and therefore are more likely to be used by all personnel. Quality manual should reflect the changes and should reflect the philosophy of how the organization is managed on a day-to-day basis.

C) There should be clinical engineer in every hospitals, clinics and diagnostic centers in order to provide safety and effectiveness of medical devices. Besides, profession of clinical engineering will be main factor for the strengthening the metrological service. Because they will be bridge between metrological organizations and hospitals, clinics, diagnostic centers. From this point of view objectives of clinical engineers are given below:

1. Acquisition, maintenance and repair of the medical equipment.

2. Assisting and overseeing writing specific cations for new equipment.

3. Evaluation and assistance in acquiring new technology for patient care.

4. Coordination of preventive maintenance and repairs by outside service personnel.

5. Evaluation of possible service contracts and outside vendor relationships.

6. Maintaining familiarity with regulatory codes and standards.

7. Collaboration with clinical staff to provide the highest level of patient safety.

8. Ensuring that applicable accreditation standards are met.

9. Ensuring departmental policies and procedures are followed.

10. Managing other projects as assigned.

11. Managing department productivity and performance improvement initiatives.

12. Assistance in the management of the computerized maintenance management system.

13. Ensuring the timely completion and documentation of all maintenance activities.

14. Maintaining the stock of repair parts to ensure appropriate maintenance of equipment.

15. Ensuring timely completion of preventive maintenance.

16. Representing clinical engineering at meetings as assigned.

17. Instructing hospital personnel on safe and proper operation and maintenance of medical equipment.

E) Joint scientific and technical seminars should be organized and hold on periodically. Theme of seminars should be concentrated on the problems of metrological support in the field of health and medical instrument making with the participation of both metrologists (relevant institutions and services of the metrology and the Ministry of Health) and representatives of medical institutions and manufacturing enterprises, as well as relevant representatives of local bodies of state administration and insurance medicine.

F) Expand the scope of control and participation of metrological services and organizations of the State Metrological Service and the Ministry of Health for the whole cycle of a single technological process (development, production, testing, approval, operation, disposal of medical devices).

LITERATURE

1. The Law of the Republic of Uzbekistan on December 28, 1993 “About Metrology”;

2. The Law of the Republic of Uzbekistan on December 28, 1993 “About Standardization”;

3. The Law of the Republic of Uzbekistan on December 28, 1993 “About Certification of Products and Services”;

4. The decree of the Cabinet of Ministries of the Republic of Uzbekistan on 15.02.2018 №112 “On measures for improving metrological control of medical laboratory and diagnostic equipment”;

5. The decree of the President of the Republic of Uzbekistan on 31.10.2016 №2647 “On measures to improve the provision of population with medicines and medical supplies”;

6. The decree of the president of the Republic of Uzbekistan on 28.04.2017 №2935 “On Measures to Improve the Activity of the Uzbek Agency for Standardization, Metrology and Certification”;

7. И.А.Каримов “Мамлакатимизни янада обод этиш ва модернизация қилишни қатъият билан давом эттириш йўлида” 21-том. Тошкент “Ўзбекистон” 2013;

8. И.А.Каримов “Ўзбекистон эришган ютуқ ва марралар биз танлаган ислоҳотлар йўлининг тасдиғидир” 22-том Тошкент “Ўзбекистон” 2014;

9. ISO 14971:2007 – Medical Devices – Application of risk management to medical devices, Switzerland, ISO;

10. ISO 13485:2016 – Medical devices — Quality management systems. Requirements for regulatory purposes. Second ed. Geneva, Switzerland, ISO;

11. IEC 62366:2007 – Medical Devices – Application of usability engineering to medical devices;

12. IEC 62304:2006 – Medical device software—Software life cycle processes. Geneva, Switzerland, IEC;

13. International Document OIML D 11:2013 – General requirements for measuring instruments – Environmental conditions;

14. International Document OIML R 16-1:2002 – Non-invasive mechanical sphygmomanometers;

15. International Document OIML R 16-2:2002 – Non-invasive automated sphygmomanometers;

16. МИ 2124:90 Рекомендация. ГСИ. Манометры, вакуумметры, мановакуумметры, напоромеры, тягомеры и тягонапоромеры показывающие и самопишущие. Методика поверки;

17. Мухаммедов Б.Э. “Метрология, технологик параметрларни ўлчаш усуллари ва асбоблари” Тошкент, “Ўқитувчи”, 1991, 320 бет;

18. Исматуллаев П.Р., Максудов А.Н., Абдуллаев А.Х., Ахмедов Б.М., Аъзамов А.А. “Метрология, стандартлаштириш ва сертификатлаштириш” «Узбекистон» Тошкент-2001й;

19. A.X.Haydarov, B.B.G’oipnazarov, X.N.Berdiyeva “Tibbiyot texnikasiga servis xizmat ko’rsatishni tashkil etish” Toshkent, “Noshir”, 2003, 244 b;

20. Sh.Z.Umarova, M.N.Ziyayeva “Tibbiyot va farmasevtika tovarshunosligi” o’quv qo’llanma, Toshkent-2016;

21. Remizov A.N. “Tibbiyot va biologik fizika” darslik, “O’zbekiston Milliy Ensiklopediyasi” Toshkent-2005;

22. Л.В.Перегудов, М.Х.Саидов, Д.Е. Аликулов “Илмий ижод методологияси”. Ўқув қўлланма.Тошкент “Молия” 2002;

23. А.А.Абдувалиев, В.Б.Латипов, А.С.Умаров, М.Н.Алимов, О.Ш.Ҳакимов, В.И.Хван «Стандартлаштириш, метрология, сертификатлаштириш, сифат» Тошкент 2008;

24. Almir Badnjević, Mario Cifrek, Ratko Magjarević, Zijad Džemić “Inspection of Medical Devices” Springer Nature Singapore Pte Ltd. 2018;

25. H.T.Castrup, W.G.Eicke and others “Metrology - Calibration and Measurement Processes Guidelines”, NASA Reference Publication, June 1994, 316 page;

26. Jay L. Bucher, “The Metrology Handbook” second edition, ASQ Quality Press, USA-2012;

27. Aruna Ranaweera, “Medical Device Risk Management: Practical Overview & Challenges”, October 2, 2012 – San Francisco, CA;

28. Alan S. Morris, “Measurement and Instrumentation Principles” third edition, Reed Educational and Professional Publishing Ltd, 2001, 491p;

29. World Health Organization “Medical equipment maintenance programme overview” Geneva-2011;

30. World Health Organization “Medical Device Regulations” Geneva-2003;

31. National Physical Laboratory “A Beginner’s Guide to Measurement” Queen’s Printer and Controller of HMSO, 2010;

32. Joseph D. Bronzino “The Biomedical Engineering HandBook” second edition, CRC Press LLC, 2000, 3189 p;

33. H. T. Castrup, W. G. Eicke, J. L. Hayes “Metrology – Calibration and Measurement Processes Guidelines” NASA Reference Publication California-1994, 330p;

34. M. do C´eu Ferreira, “The role of metrology in the field of medical devices” International Journal Metrology and Quality Engineering, 2011;

35. Chi˜ao et al., Metrology and Standards Needs for Some Categories of Medical Device, J. Res. Natl. Inst. Stand. Technol. 113, 121–129 (2008);

36. К. В. Подмастерьев, А. В. Дунаев, А. В. Козюра, Е. А. Жеребцов, “Метрологическое обеспечение биомедицинских приборов и технологий для функциональной диагностики”, Метрология в биомедицинской инженерии, 2012;

37. Муравская Наталья Павловна “Актуальные проблемы метрологического обеспечения в медицине” Федеральное государственное

унитарное предприятие Всероссийский научно-исследовательский институт оптико-физических измерений;

38. Нишонов Вохобжон, Ўрмонжонов Боходир “Корхона сифат бошқарув тизимида ахборот технологиялари” “Инновацион ривожланиш муаммолари: илм-фан, таълим ва ишлаб чиқариш ҳамкорлиги” мавзусидаги вазирлик миқъёсидаги илмий-амалий конференция, Андижон – 2016;

39. З.Ю.Мамасадикова, У.Ю.Мамасадикова, В.Х. Нишонов “Акустический метод для контроля подземных объектов”, “Инновацион ривожланиш муаммолари: ишлаб шиқариш, таълим, илм-фан” мавзусидаги вазирлик миқёсидаги илмий-техникавий анжуман, Андижон – 2017;

40. Хамидова Зулфия Аслановна, Нишонов Воҳобжон Хамидулла ўғли “Тиббиёт соҳасида фойдаланилаётган асбоб-ускуналарда юзага келиши мумкин бўлган хавфларни бошқариш” Стандарт журнали, 1 сон, Тошкент – 2018;

41. О.А. Парпиев, В.Х.Нишонов “Инсон мувозанати функцияларини тадқиқ этишда ўлчашларни метрологик таъминоти” “Машинасозлик” илмий хабарномаси, 1 сон, Андижон – 2018;

42. Juraev Zafar, Nishonov Vohobjon, Abdurahimov Jamshid “Metrology service in the field of medicine”, scientific journal “Economics and Finance”, International scientific-practical conference under the theme of “Problems of modern science” Namur, Belgium-2018;

43. Mahmud Omer Mohamed Ali, Eltahir Mohammed Hussein “Metrological Model for Inspection and Evaluation of Medical Devices” Biomedical Engineering Dept., Sudan University of Science and Technology, Khartoum, Sudan, 2014;

44. Almir Badnjević, Dušanka Bošković, Zijad Džemić, “Medical devices in legal metrology”, 4th Mediterranean Conference on Embedded Computing, 2015;

45. Almir Badnjevic, Gurbeta Lejla, Dusanka Boskovic “Measurement in medicine – Past, present, future” conference paper, 2015;

46. R.M. Guerra1, M.C. Meizoso1, and J.R. Ramírez “Influence of the Quality Infrastructure in the Development of Medical Technologies” Springer International Publishing Switzerland, 2015;

47. Gianfranco Parati, Shanthi Mendis “Recommendations for blood pressure measuring devices for office/clinic use in low resource settings”, Department of Clinical Medicine, University of Milano-Bicocca, 2004;

48. Dr. Peter Lee, “Metrology control of medical devices” World Metrology Day Symposium in Peru, 2013;

49. В. М. Лахов, “Проблемы метрологического обеспечения в области здравоохранения”, Госстандарт России, г.Москва;

50. www.iso-org.com

51. www.standart.uz

52. www.management.uz

53. www.lex.uz

54. http://mxkm.uz

55. www.minzdrav.uz/en

56. www.oxymed.uz

APPENDIX

Appendix A Sample policies and procedures

The following samples are provided to support the development of medical equipment maintenance policies and procedures in a hospital, health centre or other health facilities. The samples should be adapted and modified according to the specific needs and circumstances of any given institution, the relevant resource context and local environment.

Appendix A.1 Risk-based biomedical equipment management program

Equipment inclusion criteria have been developed to evaluate each piece of equipment in use at a hospital or health facility. The following details a modifi ed version of the Fennigkoh and Smith model (see reference 6) where a numerical value has been assigned to each device type by classifying its equipment function, clinical application and required maintenance. Adding the number from each subgroup and adding or subtracting a factor based on equipment failure history yields an equipment management (EM) number.

EM number equation:

EM # = Function # + Application # + Maintenance # + History #

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 signifi cant identifi ed 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 verifi cation and safety testing	3
Below-average	2
Minimal: visual inspection	1

Appendix A.2 Initial testing and evaluation

Purpose

To assure that all clinical equipment is inspected prior to its initial use.

Policy

All clinical equipment coming into the hospital is tested before initial use and appropriately added to an inventory. These tests, evaluations and inventories are documented. All clinical equipment falling under the responsibility of the clinical engineering department is covered by this policy, regardless of ownership, and

must pass the incoming inspection before it will be allowed into the hospital. Examples of ownership categories are:

- Rental/leased equipment
- Physician-owned equipment
- Donated/loaned equipment
- Hospital-owned equipment

Procedures

A. Hospital-owned equipment:

1. When notified that new clinical equipment is received in the hospital, the clinical engineering department will initiate a work order.

2. The clinical engineering department will ensure that the new equipment is inspected for:

a. Presence of all accessories required for proper operation.

b. Presence of operators' manuals and technical service manuals, and schematics, if applicable.

c. Proper operation of the equipment. Performance specifications in the manufacturer's service literature should be used if available.

d. Clinical alarm functionality and audibility, if applicable.

e. Passage of electrical safety requirements, if applicable.

f. Inclusion into, or exclusion from, the equipment management program.

g. Compliance on labelling of equipment, to ensure that the equipment has been evaluated for safety and suitability for intended use by a nationally or internationally recognized testing laboratory.

3. If equipment passes all required inspections, the technician will affix a clinical equipment maintenance inspection sticker, or other means of identification, in a visible location on the device.

4. The clinical engineering technician who performs the inspection is responsible for ensuring the completion of the initial inspection documentation. If the technician determines that an in-service orientation/training would be beneficial, the technician will make a recommendation to the hospital education

department or the department manager. Should a manufacturer in-service demonstration be required, the technician will assist in coordinating this effort with the hospital education department.

B.Testing of devices brought in for demonstration or trial evaluation

The hospital is responsible for the safety of all patients, staff, and visitors; equipment for loan, evaluation or demonstration is tested prior to its use in the hospital, unless an emergency dictates otherwise. In this instance, the user should ensure with reasonable certainty that the equipment is in safe working condition before operating. If the equipment is to remain in the hospital subsequent to its emergency use, it must be safety tested by the clinical engineering department.

1. All electrical equipment that passes the clinical engineering safety inspection will have a clinical equipment maintenance sticker affixed in a visible location, or equivalent, indicating that it has been inspected, and is safe for use in the hospital. (Certain battery-operated devices may be excluded from the preventive maintenance program, and will not have a sticker affixed. Devices included in the program, but that do not require regular preventive maintenance, will also receive a "PM Exempt" sticker).

2. Any equipment that fails the clinical engineering safety inspection will be returned to its originating source with a description of the failure. Such equipment/device will be prohibited from being used in the facility until it has been repaired and satisfactorily passes the safety inspection.

C.Equipment intended for use in a clinical laboratory application

Vendor provided equipment in exchange for the purchase of reagents or consumables must be approved by hospital management, the clinical laboratory, or pathology department manager and safety tested prior to being placed into service. Hospital technical staff is not responsible for the maintenance of this equipment.

Appendix A.3 Inspection and preventive maintenance procedure

Equipment to be covered by the program will typically include: life support equipment, laboratory equipment, surgical and critical care equipment, imaging equipment, equipment which could cause patient injury or death if it fails,

equipment required to be maintained by regulations, equipment on an outside vendor maintenance program, equipment under lease where maintenance is part of the lease, and equipment under warranty.

Procedure

1. All equipment due for maintenance needs to be identified one month prior to the maintenance date. The list of maintenance tasks can be generated automatically by a computerized maintenance management system (CMMS), if in place.

2. Parts required for preventive maintenance are ordered and made available for the equipment in this period.

3. The inspection and preventive maintenance (IPM) tasks will be assigned to specific biomedical technicians.

4. Work orders will be generated and distributed to the assigned technicians.

5. Maintenance will be performed in accordance with the established IPM procedure. These IPM procedures will be based on manufacturer's recommendations, industry recommendations and facility experience.

6. The assigned technician will document on the work order the inspections and maintenance performed and any other important observations.

7. When the IPM is completed successfully, the equipment will receive an IPM sticker or other identification denoting its maintenance status.

8. When the IPM and documentation is completed, the work order will be updated in the records and/or the CMMS.

9. If scheduled work cannot be completed (i.e. parts are needed, equipment is in use, equipment cannot be located), the reason is documented on a work order. This work will be followed up at a later date.

10. When scheduled maintenance is performed by an outside vendor, the biomedical engineering department will notify the vendor and schedule the maintenance service. When maintenance and documentation is completed, the work order is subsequently updated in the records and/or the CMMS.

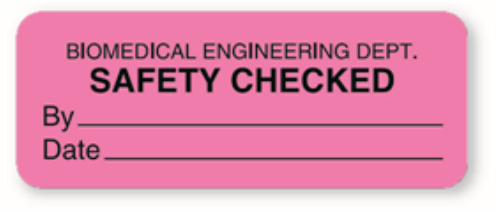
11. Life support equipment due for maintenance but still in use by patients will be scheduled for maintenance after it is removed from the patient. The

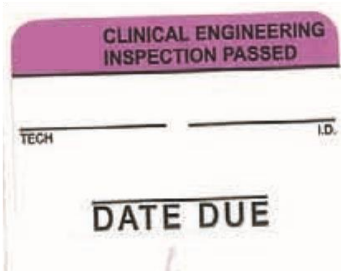
technician will work closely with the clinical department to schedule the maintenance as soon as possible.

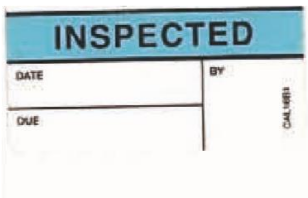
12. Equipment scheduled for IPM but which cannot be located, can be identifi ed as “could not locate” only after a concerted effort to locate the device has been made, the equipment owners have made every attempt to locate it and the biomedical engineering supervisor/manager has approved the device to be marked in this way.

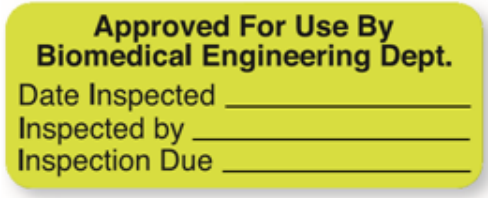
Appendix B.1 Record of inspection

This type of label indicates the date the device was serviced or inspected and may indicate when the next service is due. These tags are sometimes printed in different colors, one for each year or inspection cycle so that it is easier to identify devices that are due for inspection. This tag may be covered with plastic adhesive/cover to protect it from being defaced during the cleaning process.



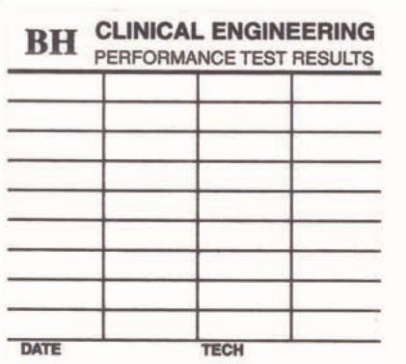


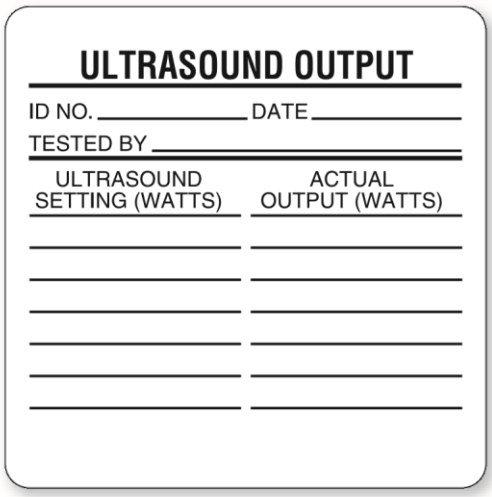


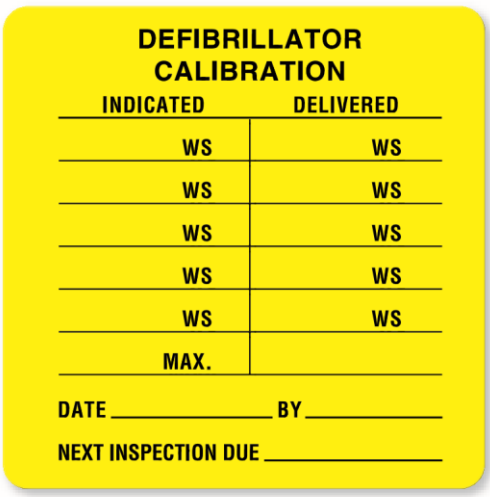


Appendix B.2 Record of inspection (test) results

This label provides space to record the output readings taken during the performance assurance inspection. These can be used to record outputs on many energy-producing devices including ultrasound therapy equipment, lasers, defibrillators, electrocurrent therapy devices, nerve stimulators, etc.

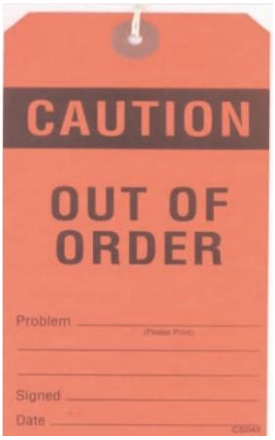


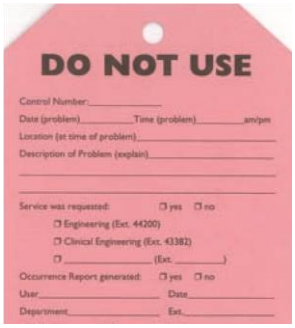




Appendix B.3 Notification of defect

This label is placed on medical equipment that has been inspected by the clinical engineering staff and found to be defective. It is printed on very brightly colored paper to attract the clinician's visual attention and prevent inadvertent use of the device.





Appendix C.1 Planning a maintenance program at a district hospital.

Critical factor	Action	Responsible party
Inventory	• Create an inventory of all medical equipment in the hospital using a computer spreadsheet or simple CMMS software.	Clinical engineering department
Methodology	• Identify current resources • Defi ne maintenance methodologies: – Simple maintenance tasks – hospital staff – critical equipment of greater complexity – service contracts	Clinical engineering department manager
Financial resources	• Plan for service contracts. • Develop the budget for implementing the programme. • Develop the budget for operating the programme. • Identify budget sources.	Clinical engineering department manager

Physical resources	• Plan for build-out of space and acquisition of tools and equipment.	Architect
	• Plan for basic computer resources.	Administrator
Human resources	• Plan additional training for technicians. • Identify managerial capabilities within the hospital for management of the programme. • Develop links to external resources.	Clinical engineering department manager/administrator

Appendix C.2 Managing a maintenance program at a district hospital

Management component	Action	Responsible party
Personnel management	• Assign scheduled and unscheduled work to the repair person. • Monitor hours worked by the technician and timely completion of scheduled and unscheduled work assignments.	Clinical engineering department manager
	• Document work on work order forms and, if available, in the CMMS software.	Technician
Financial management	• Monitor costs associated with service contracts and with work carried out by the technician. • Compare costs to budget, review variances, plan for future budgets.	Clinical engineering department manager
Operational management	• Develop procedures and schedules for inspection and preventive maintenance. • Develop policies for prioritizing corrective maintenance activities. • Monitor services provided under service contracts.	Clinical engineering department manager
	• Work closely with clinicians.	Clinical engineering department manager/technician
Performance monitoring	• Monitor performance measures.	Clinical engineering department manager
Performance improvement	• Compare performance to objectives annually; identify opportunities for improvement.	Clinical engineering department manager

Appendix C.3 Planning a maintenance program within a regional health system

Critical factor	Action	Responsible person
Inventory	• Create inventory of all medical equipment in the system using full-featured CMMS software.	Clinical engineering department
Methodology	• Defi ne maintenance methodologies: – simple and moderate maintenance tasks – hospital staff – critical equipment of greater complexity – service contracts, with “fi rst look” by hospital staff	Clinical engineering department manager
Financial resources	• Identify fi nancial resources (moderate). • Plan for service contracts. • Develop budget for implementing the programme. • Develop budget for operating the programme. • Identify budget sources.	Clinical engineering department manager
Physical resources	• Identify physical resources (some space, tools, and equipment).	Clinical engineering department manager
	• Plan for build-out of space and acquisition of tools and equipment.	Architect
	• Plan for basic computer resources.	Administrator
	• Plan for transportation among hospitals and clinics.	Administrator/transport services offi cer
	• Plan for service request dispatching and clerical support.	Administrator
Human resources	• Identify current human resources (one engineer and a few technicians with varying skills).	Clinical engineering department manager
	• Plan additional general and specialised training for technicians. • Plan management training for the engineer. • Develop links to external resources.	Clinical engineering department manager/administrator

Appendix C.4 Managing a maintenance program within a regional health system

Management component	Action	Responsible person
Personnel management	• CMMS assigns scheduled and unscheduled work using defi ned protocols. • Monitor hours worked by the technical staff and timely completion of scheduled and unscheduled work assignments.	Clinical engineering department manager
	• Technical personnel document work on work order forms and in the CMMS software.	Technician
Financial management	• Monitor costs associated with service contracts and with work carried out by technical staff. • Compare costs to budget, review variances, plan for future budgets.	Clinical engineering department manager
Operational management	• Develop procedures and schedules for inspection and preventive maintenance. • Develop policies for prioritizing corrective maintenance activities. • Monitor services provided under service contracts. • Participate in medical equipment planning, incident investigation and committee activities.	Clinical engineering department manager
	• Work closely with clinicians and conduct customer satisfaction surveys.	Clinical engineering department manager/technician
Performance monitoring	• Monitor performance measures plus additional measures supported by the CMMS. • Manage compliance with applicable standards, performance benchmarking, and implementation of ‘best practices.’	Clinical engineering department manager
Performance improvement	• Prepare written report comparing performance to objectives and identifying opportunities for improvement. • Implement performance improvement initiatives and monitor for success.	Clinical engineering department manager