Metrology in Medical Field

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Abstract:

Medical device calibration and test are one of the emerging, important and critical issues in the field of metrology. The traceability in medical devices and measurements are not powerful enough as much as the traceability in technical and military calibration and measurements. Patient safety is a must for the medical device industry and applications in health sector. Therefore all measurement devices used in medical field must be controlled periodically and all measurements must be standardized as a quality control regimen that guarantees the reliability of medical devices. Test, measurement and calibration of bio-medical equipment are becoming increasingly significant for manufactures, when accuracy in diagnosis and effectiveness in treatment are required as well as patient safety.

In this paper, medical metrology concept has been introduced and critical cases have been outlined. Current situation has been summarized in all over the world by the light of metrology institutes and international organizations. Measurement parameters in medical devices have been investigated and calibration systems, traceability and standards have been given. It is expected that this manuscript will give a clear vison for the importance of accurate measurements in medical field and guide for medical metrology studies.

Keywords: Measurements, medical device, medical metrology, traceability, uncertainty

1. Introduction

Medical metrology can be described as measurements involving measurement, control, verification and calibration activities of measurement, analysis, diagnosis, imaging and treatment devices. Devices used in this field have critical importance because they are used on human and they are multifunctional.

Medical decisions about diseases are usually based on the clinical findings including medical examination and the results of statistical studies that have been obtained from the patients over the years. Medical measurements are important for creating of clinical findings and generating consistent statistical data from large number of patients (Report, 2013; Schreyögg, 2009; Zimmerman, 2014).

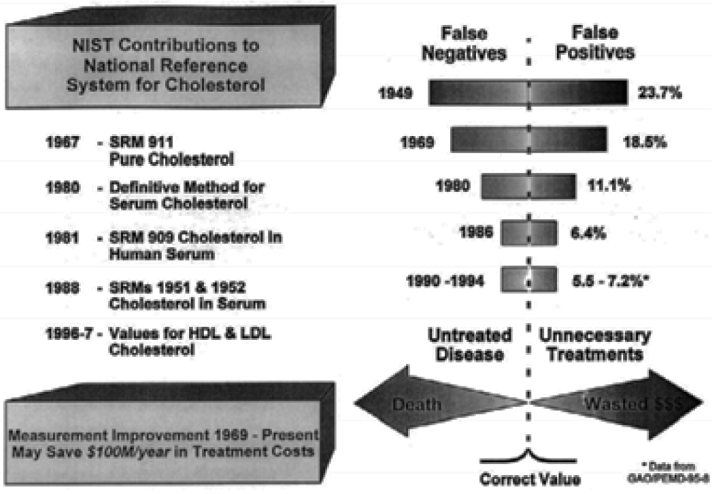
Medical measurements are actually based on the research studies conducted by the work of national metrology institutes. A reliable measurement system can be created by combining metrological instruments and quality assurance systems. Calibrations of the devices and systems used for transferring the measurement values, using of scientifically accepted measurement and calibration methods in measurements and control procedures required by legal metrology are metrological tools that must be used in the system. Objective and transparent system based on quality criteria can be established by using the internationally recognized standards of quality assurance (Karaböce, 2016).

In the field of health, the diversity of devices used in imaging, diagnosis and treatment has been increasing in recent years and its usage is becoming widespread (Squra, 2015; Tooker, 2005; Zaitseva, 2017).

These systems range from a simple thermometer to computerized imaging systems, clinical measurement devices or computer-controlled, highly precise surgical robots. According to the findings and examination findings obtained with these systems, the treatment steps and methods are determined by the physician. Data obtained from measurement systems in audits may be more important than findings from examinations. For example, a hernia that cannot be identified in the examination findings of medical doctor can appear in MR (magnetic resonance) image.

As a result of the measurements, analyzes and tests made in the field of clinical metrology, the direct treatment method can be determined. For example, if a diabetic patient has a high blood sugar level, it is highly likely that he or she will begin insulin therapy. Failure to measure glucose in the blood correctly will result in unnecessary treatment and/or delay in necessary treatment. Damage risk to life on the wrong measurement of glucose in the blood cannot be measured in addition to high amount of expenses. More accurate or small uncertainty in cholesterol in the blood measurements will guarantee the less expenses and correct treatment as can be seen in Figure 1 (NIST; Semerjian, 1999). Definitive and standard methods and development of serum cholesterol standard reference materials (SRMs) will result in saving of treatment costs for misdiagnosed patients and additionally lives through timely and accurate diagnosis.

Figure 1 - Development of accuracy in glucose in the blood measurements.



Source: Semerjian, (1999)

Regular maintenance/repair as well as testing, measurement, verification and calibration must be carried out at regular intervals to ensure correct operation of medical devices during use. Some of the devices and apparatus used for testing, measuring, verifying and calibrating are commercially available. However, it is very important that institutions and organizations that provide services in the field of health as well as all areas should be able to monitor the devices used for diagnosis and treatment to national and/or international standards and to establish a measurement association within the country. It is necessary to carry out studies for the establishment and research of the necessary infrastructure for this traceability (Baura, 2012; Shirmohammadi, 2016).

In order to emphasize the importance of instrument calibrations used in the medical field and to ensure correct calibration, training programs are provided in some universities, public and private institutions, in limited numbers and narrow scope. These training programs should be disseminated. There should be absolute medical metrology among the training programs and uncertainty calculations in the measurements. Training programs should be given to all interested persons, including hospital administrators, calibration laboratory staff and device users.

A regulation on testing, control and calibration of medical devices will create an appropriate environment in order to establish traceability of standards and reliability in medical measurements. In particular, audits should cover technical areas. For example, aspects such as calibration, compliance with a specific standard, traceability of the devices used should be controlled. It is foreseen that the accreditation institution and the pharmaceuticals and medical devices agency should act in coordination with the accreditation of the laboratories that perform medical device calibration.

Collaborative platforms for the collaboration of public institutions, universities and industrial organizations for the design and production of devices such as calibrators, phantoms, analyzers in the medical field are more widely and effectively used.

Scheduled works in the field of medical metrology by national metrology institute (NMI) or designated institute (DI) can be listed as follows:

- Making preliminary study to ensure traceability in national and international standards for diagnostic and therapeutic devices which are serving in the field of health;
- Preliminary studies for the establishment of a measurement unity within the country for devices used in the health field;
- In the field of clinical metrology, investigation of required laboratory infrastructure for validation of measurement method used to verifying measurements, analyses and tests;
- In clinical metrology, planning for the production of reference materials used in chemical measurements;
- Creation of metrology awareness for universities, calibration laboratories and societies which are interested with this subject;
- Comparison and competence testing for the purpose of ensuring measurement unity between laboratories in the country.

The metrological reference values (produced for country and by joining all necessary all international comparisons required for NMI's reference standards and reference materials used in the traceability of medical and clinical devices) are aimed to adapt to the international system.

Examination of written standards, medical and clinical devices, calibration/measurement systems within the feasibility project and information obtained from interviews with related institutions, universities, hospitals and private laboratories must be compiled. With this information, works to be done, calibration/measurement systems to be installed, plans of these calibrators, phantoms and reference materials which are considered of their design and production have to be given.

2. Current Situation in Medical Metrology

Official institutions, universities, biomedical calibration laboratories and private companies operate in specific areas of medical metrology, have variable approaches in this field (Bošnjaković, 2017; Ferreira, 2011; Feldman, 2007). Some private hospitals declaring that they are testing, checking, verifying and calibrating their own devices. Medical calibration units in the Ministry of Health declare that they can test, control, verify and calibrate the medical devices in some hospitals within the capacities of their own portable system. But the traceability and reliability of medical devices is not provided by metrologically. calibrations of instruments used in calibration (such as calibrator, simulator, analyzer and phantom) must be performed by authorized (accredited) and trained persons, using reference measurement standards, according to written standards or methods defined in the literature, if possible in controlled environments.

Some good examples can be given: university hospital's devices are calibrated with the systems in the relevant laboratories where they calibrate their own devices in their systems. But some of them send devices such as simulators, analyzers, etc. used in calibration to an organization that does not have an accreditation certificate (Monteiro, 2017).

As can be seen from the above information, they are doing their own calibrations but the calibration must be done by independent third parties. When the situation is examined in terms of metrological traceability and reliability, it can be said that the calibration of the reference standards should be done by the accredited laboratories or the national metrology organization in the country.

Most hospital's devices cannot be calibrated in real sense. For example, it can be seen that the calibration requirement is fulfilled by attaching only labels and performing non-accredited measurements (Ventola, 2008; Kiekens, 2010). The reasons can be listed as follows:

- Fulfillment of calibration makes possible to receive money from circulating capital fund of the hospital;
- The ignorance or carelessness of the medical doctors or the person concerned who request for calibration;
- There is no regular audit by authorities.

Calibrations of calibrators, simulators, analyzers and phantoms which are used in the test, control, verification and calibration of medical devices are made by the distributors of those devices under the name of maintenance/repair/calibration in health institutes. This process is not correct metrologically and not within the scope of authority and accreditation. NMI must calibrate the calibrator, simulator, analyzer and phantoms with creating references to medical metrology:

- The situation has been established and it has been emphasized that the major of devices used in the medical field are not calibrated or verified metrologically;
- Considering the frequency of use, measurement accuracy and health risk, it has been agreed to assign a calibration period for each device type. In general case, hospital's surgeons are not well aware of the importance of test, control, verification and calibration of medical devices;
- Many manufacturers and distributors have no information about device calibration;
- The biomedical institute or departments of some universities are only more focused on consultancy and education but not calibration and measurement.

For this purpose, training programs should be organized by the NMI and other organizations / universities and participation to these trainings should be encouraged. Most of the calibration companies do not have sufficient coverage in the accreditation certificate.

It has been stated that in the initial installation and licensing stages of ionizing radiation devices which are used in the health field, authorized agencies for ionizing radiation are taking part but later they don't do calibration and measurements. Safety of usage of medical device must be settled in order to avoid tomography, mammography, and X-ray devices produce higher doses from expected doses. Application of excess doses must be prevented in order to break kidney stones with few sessions in lithotripsy laboratories (Hermanek, 2017; Ainsley, 2014; Villarraga-Gomez, 2017).

NMI must ensure the testing, control, verification and calibrations of medical devices in health institutes with reference standards. The suggestions made during the interviews in the field of medical metrology are listed below. The following suggestions should be made to start working at NMI in the light of the recommendations. Calibrators, phantoms and reference materials should be designed and manufactured in NMI. Trainings and workshops emphasizing the importance of medical device calibration should be organized.

Bureau International des Poids et Mesures-the Joint Committee For Traceability in Laboratory Medicine (BIPM – JCTLM) was established in 2002 for the implementation of the European Union Directive 98/79/EC with the cooperation between the Comité International des Poids et Mesures (CIPM), the International Federation of Clinical Chemistry and Medical Laboratories (IFCC) and the International Laboratory Accreditation Association (ILAC). JCTLM contributes to provision of the traceability of the measurements made in the clinical laboratories. The calibrators used by laboratories which are operating in the field of in vitro diagnostics are also inspected. JCTLM activities cover production of primary reference materials and reference measurement procedures/methods, and service for laboratory reference measurement worldwide.

The National Metrology Institute of Turkey (TÜBİTAK UME) has established the traceability of measurement quantities relevant to medicine, to integrate the measurement quantities into the international metrology system through international comparisons and to ensure measurement unity by disseminating traceability to lower level laboratories within the country or abroad through calibration, measurement and test services. The other objective of the laboratory activities is to produce research projects in line with national priorities and the stakeholder demands.

As well as ensuring measurement traceability of the devices used in medicine and reliability studies, the Medical Metrology Laboratory has implemented projects such as calibrator design and production for medical devices and certified reference materials production for autoanalyzers (TUBİTAK UME). In addition to this, the laboratory has also organized trainings for professionals that perform medical device calibrations.

Study areas of the TÜBİTAK UME Medical Metrology Laboratory include:

- Ensuring measurement traceability of the devices used in health field;
- Certified reference materials production for clinical measurements;
- Calibrator design and production for medical devices;
- Practical trainings for professionals perform in medical device calibrations;
- Establishing systems and implementing projects for the application of ultrasonic techniques in the health field;
- Conducting performance tests of hearing aids and headsets;
- Calibration and Measurement Services include;
- Patient Simulator Calibrations;
- Defibrillator/Pacer Analyzer Calibrations;
- Electrical Safety Analyzer Calibrations;
- Pulse-Oximetry Analyzer Calibrations;
- Infusion Pump Analyzer Calibrations;
- Gas Flow Analyzer Calibrations;
- Electrosurgey Analyzer Calibrations;
- Hearing Aid Performance Tests;
- Measurement Systems for Ultrasonic Applications in the Health Field;
- Standard Reference Materials (SRM);

United States National Institute of Standards and Technology (NIST), has medical metrology activities as shown below:

•Optical imaging techniques: With this program, the development of optical imaging techniques in surgeries, in hospitals and in medical applications is planned;

•Electronic-based biosensing, single-molecule metrology;

•Engineering studies that aim to reproduce the organ structures in three dimensions;

•NIST has developed a reference phantom for using in calibration of magnetic resonance imaging systems. 100 contrast agents and reference material placed to inside to sphere as big as human skull (NIST; Chiao, 2008).

The French National Meteorological Institute-Laboratoire National de Métrologie Et D'essais (LNE), expanded his work in health metrology, certification activities are spread to 52 country, 4000 laboratories in the country reported that they provide reference measurement data on biomarker dosage every day according to the 2010's year report (LNE):

•LNE established test laboratory in 1979 year for meet the certification requirement of hospitals and medical device manufacturers in the field of health;

•LNE performs measurements on hearing aids, blood pressure monitors, eye pressure monitors and spirometers in the medical field;

•In addition, LNE's laboratories have the ability to perform the calibrations and tests on medical devices and equipment;

•LNE certifies the medical devices in accordance with ISO 13485, ISO 15378, ISO 15189 and EN 15593 standards;

•Research activities are the development of measurement systems that can detect biomarkers, the development of test methods that can provide monitoring and control of electronic blood pressure gauge, and nano virology.

German Physcalische-Technische Bundesanstalt (PTB) conducts activities in the field of medical device. Main purpose is to improve accuracy and reliability in diagnosis and treatment by creating measurement methods and test procedures and scientifically, industrially and aimed protecting the consumer. The department engages in method development for magnetic resonance imaging (MRI) and spectroscopy (MRS) as seen in Figure 2. In the Medical Physics Department new measurement and testing techniques are being developed and research is being conducted about reference material production. PTB has improved the secondary personal dose Hp (10) standard for X-ray use. The standard is designed as the volume of ionization in a 30 cmx30 cmx15 cm polymethyl methacrylate (PTB; Ittermann, 2015).

Figure 2 - MRI imaging studies at PTB

National Physical Laboratory of United Kingdom (NPL), has research and development studies in the medical field (NPL). Working areas and projects:

•Optical diagnostic tools (Optical Coherence Tomography) and optical tissue phantoms;

•Centre for Biomolecular Metrology (polypeptide structure and function);

•Calibration of ultrasound power for medical devices.

NPL has published studies of patient's treatment, which is at home for long-life and monitoring by tele-care monitoring, and studies of to ensure the reliability of devices used in therapeutic measurements in annual reports.

The Japanese national metrology institute (NMIJ) is working on standardizing medical metrology measurements. For this purpose, NMIJ has created an organization, named "Standardization of Laboratory Medicine Club" and has been carrying out studies especially in the Department of Biomedical Standards and Organic Analytical Chemistry Department (NMIJ; Nakamura, 2010; Tanaka, 2014). NMIJ carried out the studies in the field of medical metrology are medical imaging systems and production of reference materials for clinical laboratories. By organizing workshops in the field of medical metrology; NMIJ ensures that international trends in the sector and new international standards in the medical field are followed.

The South Korean Metrology Institute (KRISS) has established a center in the field of medical measurements (Center for Medical Measurements). Their primary research works are the development of national calibration systems for blood pressure gauges and thermometers which are commonly used in hospitals. Also, the required metrological studies are being carried out in order to establish the traceability of the signals which produced by ECG devices (KRISS).

2.2. International Organizations

The Joint Commission Accreditation for Health Organization (JCAHO) provides accreditation organization in "Hospital management and care services and professional management functions". This movement, which started in health care services in the United States, has been a study that attracts the attention of world countries since 1990.

Joint Commission International (JCI) that is a subdivision of JCAHO works as an institution established to accredit hospitals in the international arena. JCI's mission is to make better and improve the quality of health services in the international arena by providing worldwide accreditation services. "Accreditation Standards for Hospitals" book, which is prepared for the hospitals to be prepared for the accreditation audit by the JCI organization, includes the following headings about accreditation standards for administrative areas:

- •Quality improvement and patient safety;
- •Management, leadership and orientation;
- •Facility management and safety;
- •The quality and training of employees;
- •Prevention and control of infections;
- •Information management.

Approximately 190 hospitals in countries outside the US have received JCI accreditation. JCI generally conducts technical surveys at the hospital to ensure the quality and control of all operations.

Emergency Care Research Institute ECRI activities are for development of methods and standards that will remove risks from patient care and patient safety. ECRI study and research areas are about measurement/calibration systems to be established in the field of medical metrology, calibration/measurement methods and reference materials which will be developed, and the medical devices which are used in hospitals. Institute provides the accurate measurements in the desired level of uncertainty, the sustainability of these measurements through the accreditation system. As a result, ECRI accreditation system will ensure that the clinical, technical and administrative services provided by the health services are guaranteed to give more accurate and safe services.

World Health Organization (WHO), conducts international studies on community health. The United Nations Conference, gathered in San Francisco, USA in 1945, acknowledged that the health of all people has fundamental importance of ensuring peace and security in the world. And it has been accepted that organize a meeting for establishing an "International Health Organization" by Chinese and Brazilian delegates unanimity (WHO).

Some of the tasks, that organization fulfilled to achieve its organizational goals, are listed below:

- •Promote and guide research in the field of health;
- •Facilitate the improvement of the norms of teaching and training of medical staff;
- •Standardize diagnostic methods as needed.

Food and Drug Administration (FDA) is the responsible bureau of food, medicine, biological medical products, blood products, medical instruments, radiation emitting instruments, veterinary instruments and cosmetics in United States Ministry of Health.

Medical devices and medical products are classified according to their potential risk situation due to their design and manufacture, and the degree of danger to human health. FDA categorizes medical devices and medical products to three categories, like class III: high risk products, class II: medium risk products and class I: low risk products.

The European Union has directives for medical devices. These directives including the technical requirements and responsibilities that must be provided during the design and production phase of medical devices before they released:

- •Directive 90/385/EEC regarding active implantable medical devices;
- •Directive 93/42/EEC regarding medical devices;
- •Directive 98/79/EEC regarding in-vitro diagnostic medical devices.

Institute of Physics and Engineering in Medicine (IPEM), aims its members to apply the progress in the field of physics and engineering to the field of medicine and biology, and to increase the knowledge of people in medicine and biology with their education and present these to the use of interested persons.

The European Metrology Research Program (EMRP) and the European Metrology Programme for Innovation and Research (EMPIR) which is being executed under Article 169 of the European Commission include Common Research Projects which have been launched in various "metrology in health" fields between 2007 and 2011. Projects have been conducted 4-5 NMIs/DIs and unfunded partners with a budget of approximately 3 Million Euro in three years.

In the first call of health, 7 projects were supported and completed. The projects completed with the participation of NMIs and DIs are listed below:

- •Breath analysis as a diagnostic tool for early disease detection;
- •Metrology on a cellular scale for regenerative medicine;
- •Increasing cancer treatment efficiency using 3D brachytherapy;
- •External Beam Cancer Therapy;
- •Traceable measurements for biospecies and ion activity in clinical chemistry;
- •Traceability of Complex Biomolecules and Biomarkers in Diagnostics - Effecting Measurement Comparability in Clinical Medicine.

In the second EMRP call of metrology in health, 11 projects were funded and completed:

- •Metrology for a universal ear simulator and the perception of non-audible sound;
- •Metrological characterization of micro-vesicles from body fluids as non-invasive diagnostic biomarkers;
- •Dosimetry for ultrasound therapy;
- •Metrology for the characterization of biomolecular interfaces for diagnostic devices;
- •Metrology for metalloproteins;
- •Metrology for next-generation safety standards and equipment in MRI;
- •Metrology for drug delivery;
- •Metrology for monitoring infectious diseases, antimicrobial resistance, and harmful micro-organisms;

•Metrology for radiotherapy using complex radiation fields;

•Metrology for biomolecular origin of disease;

•Metrology for molecular radiotherapy.

According to success in EMRP programme, a new programme EMPIR calls, launched between 2014 and 2020. Budgets were approximately 2 Million Euro in three years with the partnerships of external partners from universities, research institutions and private companies. 9 metrology in health projects have been initiated already (EURAMET Newsletter Issues 1-12), namely:

•Quantitative measurement and imaging of drug-uptake by bacteria with antimicrobial resistance;

•Role of metals and metal containing biomolecules in neurodegenerative diseases such as Alzheimer's disease;

•Metrology for modern hearing assessment and protecting public health from emerging noise sources;

•Innovative measurements for improved diagnosis and management of neurodegenerative diseases;

•Metrology for multi-modality imaging of impaired tissue perfusion;

•Metrology for clinical implementation of dosimetry in molecular radiotherapy;

•Novel materials and methods for the detection, traceable monitoring and evaluation of antimicrobial resistance;

•Metrology for MR guided radiotherapy;

•Metrology for additively manufactured medical implants.

In response "Metrology for Health" ranks high on the EURAMET agenda. A dedicated Task Group was established in 2013 in order to develop a strategy on how metrological R&D should evolve in the context of EMPIR and the European Union's HORIZON2020. The main objective of the Task Group is to organize the scientific and technical collaboration in health related fields among EURAMET members and associates and to form a coherent and comprehensive approach on metrology for health. In more detail the group's terms of reference ask to:

•Coordinate and to complement the work of EURAMET's Technical Committees in metrology for health;

•Liaise with the Joint Committee for Traceability in Laboratory Medicine (JCTLM) and other groups working in this field;

•Support and act for the development of standards, measurement methods and measurement structures;

•Develop the Strategic Research Agenda for EMPIR;

•Propose research topics for joint research projects and to elaborate road maps for future research and development;

•Disseminate expertise and knowledge on metrology for health through seminars, guides and conferences.

The OIML (The International Organization of Legal Metrology) main goal is harmonization of regulations and metrological controls which are applied by national metrology institutions of member states or related organizations (Ferreira, 2011). There are two basic categories of OIML publications.

OIML Draft Recommendations and Documents are prepared by technical committees or subcommittees which are created by Member States. One of these technical committees is the technical committee of TC 18 Medical Measurement Devices. In this technical committee, subcommittees were formed in different subjects:

•TC 18 – Medical measuring instruments;

•TC 18/SC 1: Blood pressure instruments;

•TC 18/SC 2: Medical thermometers;

•TC 18/SC 4: Bio-electrical instruments;

•TC 18/SC 5: Measuring instruments for medical laboratories.

3. Measurement Parameters and Traceability in Medical Device

A traceability scheme is given in Figure 4 for medical measurements. For example, blood pressure measuring devices (that are individual or engaged to a patient monitor) are calibrated by using patient simulator device that are calibrated routinely in NMSs or DIs. Establishment of similar links to calibrators and so SI/derived SI units maintain the accuracy in the medical measurements.

Patient simulator, defibrillator/pacer, infusion pump simulator, electrosurgery analyzer, electrical safety analyzer, pulse oximeter analyzer and gas flow analyzer are mostly used medical device calibrators. Parameters, measurement ranges and traceabilities were given in Table 1-Table 7 (1).

For example, calibration of infusion pump analyzer has realized according to manufacturer specifications. Before the calibration process, the device flow channels are cleaned by flowing distilled and degassed water with soft detergent by connecting the Syringe3 directly into channels in order to remove any remaining dirt and chemicals residues. This process prevents the formation of unwanted bubbles during calibration. All those connections are completed and filled with water in order to avoid bubbles in the water during calibration as seen in Figure 3. The cleaning process repeated few times until no bubbles left.

Than calibration process is realized by the following:

•First, some amount of distilled and degassed water is injected from reservoir to fill in the Syringe3 as in the ways of red arrows while valves V1, V2 and V3 closed and valve V4 is open;

•Then V4 is closed and V1 opened. The water is sent to calibrated Syringes 2 (and Syringes3 for calibration of 2 channels at the same time) as in the ways of blue arrows until they are full;

•Infusion device has been set to desired flow rates and volumes between 75 ml/hr and 830 ml/hr and at 25 ml and 45 ml volumes according to manufacturer specifications;

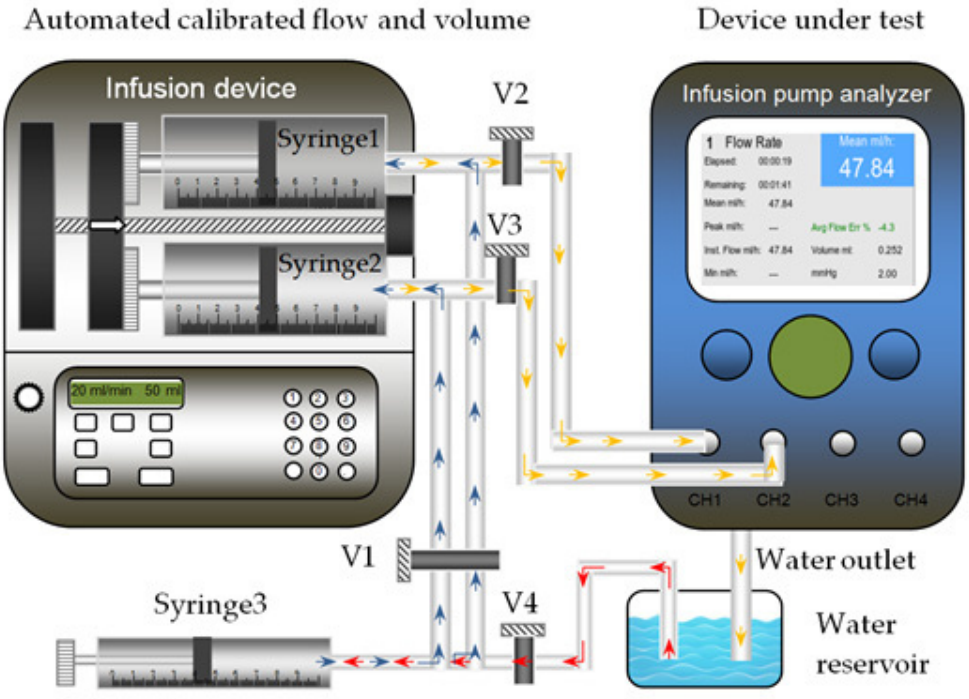
•The process started automatically for each set of measurements. The water is flowed through the channels of infusion pump analyzer as in the ways of yellow arrows while V1, V4 are closed and V2, V3 are opened;

•Pressure tests are realized between 5 PSI and 40 PSI;

•Solenoid valve release test are conducted and value is measured;

•All values are measured and recorded for each measurement at each channel and compared to tolerances and manufacturer specifications.

Figure 3 - Infusion pump analyzer calibration system.



4. Conclusions

Medical metrology concept has been investigated in detail in this paper. Accuracy in medical measurements satisfies the more accurate diagnosis and treatment and less expenditure in health expenses. Even though metrology is an internationally linked activity, current situation shows that each NMI has some kind of studies in medical metrology field that are not harmonized between each other. International organizations (i.e. JCI, ECRI) have individual guidelines for quality control of medical devices but don't directly aims to metrology traceability.

NMIs or DIs have to have a collaborative and multidisciplinary study in order to establish the traceability and equivalence of medical measurements in all over the world. Another important issue becomes to educate and train medical people who are engaged in use of medical devices and measurements. Scheduled works in the field of medical metrology by NMI or DI can be listed as follows:

•Establishment of traceability in diagnostic and therapeutic devices in the field of health;

•Investigation of required laboratory infrastructure for validation of measurement method used to verifying measurements, analysis and tests in clinical measurements;

•Production of reference (or quality control) materials used in clinical measurements;

•Creation of metrology awareness for universities, calibration laboratories and societies which are interested with this subject;

•Intercomparisons and competence tests for the purpose of ensuring measurement unity between laboratories (i.e. NMI, DI or secondary laboratories) in the country and in the world.

References

Ainsley, C.G., Yeager, C.M.(2014), Practical considerations in the calibration of CT scanners for proton therapy, *J Appl Clin Med Phys.* May 8;15(3):4721. doi: 10.1120/jacmp.v15i3.4721, PMID: 24892347.

Baura, G. D. (2012), *Medical Device Technologies: A Systems Based Overview Using Engineering,* Academic Press, 2012, 512 pages.

Bošnjaković, A., Džemić, Z.(2017), Legal Metrology: Medical Devices, *CMBEBIH 2017* pp 583-588, © Springer Nature Singapore Pte Ltd. 2017 583, A. Badnjevic (ed.), CMBEBIH 2017, IFMBE Proceedings 62, DOI: 10.1007/978-981-10-4166-2_88.

Chiao, J. C., Goldman, J.M., Heck, D.A., Kazanzides, P., Peine, W.J., Stiehl, J.B., Yen, D., Dagalakis, N.G.(2008), Metrology and Standards Needs for Some Categories of Medical Devices, *J Res Natl Inst Stand Technol.* Mar-Apr; 113(2): 121–129, PMID: 27096115.

Feldman, M.D., Petersen, A.J., Karliner, L.S., Tice, J.A., (2007). Who is responsible for evaluating the safety and effectiveness of medical devices? The role of independent technology assessment. *J Gen Intern Med.* 23(Suppl 1):57–63.

Ferreira, M. (2011), The role of metrology in medical devices, *OIML Bulletin Volume* L II, Number 4.

Ferreira, M. (2011), The role of metrology in the field of medical devices. *International Journal of Metrology and Quality Engineering* **2(02):**135 – 140, DOI10.1051/ijmqe/2011101.

Food and Drug Administration - FDA, http://www.fda.gov/MedicalDevices/default.htm.

Hermanek, P., Carmignato, S.(2017), Establishment of metrological traceability in porosity measurements by x-ray computed tomography, *Conference: Developments in X-Ray Tomography* XIDOI10.1117/12.2276942

Ittermann, B., Bottauscio, O., Hand, J. Pooter, J., Prez, L., Rabus, H., Seifert, F., Szymanowski, H., Weidemann, G., Zilberti, L.(2015), Metrology for MRI safety, *17th International Congress of Metrology* doi.org/10.1051/metrology/20150009001.

Karaböce, B., Gülmez, Y., Akgöz, M., Kaykısızlı, H., Yalçınkaya, B., Dorosinskiy, L.(2015). Medical metrology studies at TÜBİTAK UME, *17th International Congress of Metrology,* DOI: 10.1051/20150 011.

Karaböce, B. (2016), Metrological approach in medical measurements. *2nd International Conference on Medical Physics and Biophysics.* Barcelona, Spain.

Monteiro, E.C, Leon, L.F.(2015), Metrological Reliability of Medical Devices, *J. Phys.: Conf. Ser.* 2015, 588 012032.

Schreyögg, J., Bäumler, M., Busse, R. (2000), Balancing adoption and affordability of medical devices in Europe. *Health Policy* 92(2-3):218-24, DOI10.1016/j.healthpol.2009.03.016.

Semerjian, H.G., Watters, R.L.(2000), Impact of Measurement and Standards Infrastructure on the National Economy and International Trade. *Measurement* 27, 179–196.

Shirmohammadi, S., Barbé, K., Grimaldi, D., Rapuano, S. and Grassini, S. (2016). Instrumentation and Measurement in Medical, Biomedical, and Healthcare Systems. *IEEE Instrumentation & Measurement Magazine,* pp, 6-12.

Squara, P., Imhoff, M., Cecconi, M. (2015), Metrology in Medicine: From Measurements to Decision, with Specific Reference to Anesthesia and Intensive Care, *Anesth Analg.* **120(1):** 66–75. PMID: 25625255.

Tooker, J. (2005),The Importance of Measuring Quality and Performance in Healthcare, *MedGenMed*. **7(2):** 49, PMID: 16369427.

Zaitseva, E.(2017), *Importance Measures in Reliability Analysis of Healthcare System, Human – Computer Systems Interaction: Backgrounds and Applications 2, Part of the Advances in Intelligent and Soft Computing book series (AINSC, volume 98),* 2017 Springer International Publishing AG. Part of Springer Nature.

Zimmerman, M. (2014),The Importance of Measuring Outcomes in Clinical Practice. *US Psychiatric & Mental Health Congress.* Career, Major Depressive Disorder, Volume: 31Issue: 10.

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Baki Karaböce has been working as a lead researcher in the field of acoustics, vibration, ultrasonic, electrical, mechanical and medical measurements at TÜBİTAK UME (National Metrology Institute) since 1993. He is the founder of the Medical Metrology Research Laboratory and responsible for the metrology in health at UME. He has participated and successfully completed several projects in various periods in 7th Framework and Horizon 2020 program. He has prepared number of book sections, refereeing tasks in congresses and journals, and numerous scientific publications at national and international level. He has served as referee and adviser in TUBITAK TARAL (national funding) projects. He has participated and organized national and international congresses as invited speakers, organizers of sessions and presidencies in congresses. He has chaired the Turkish Acoustical Society. As a proposer and member of the Health Working Group set up at EURAMET (European Metrological Centers Association), he is actively involved in the organization, programming and strategy preparation of all projects. Baki Karaböce is Turkish representative of the EURAMET TC-AUV (Acoustic, Ultrasonic and Vibration) Ultrasonic section. He is an active member of IEC (International Electrotechnical Commission)'s TC87 Ultrasonics group.