CALIBRATION OF MEDICAL EQUIPMENT

4th EAST AFRICAN REGIONAL HEALTHCARE ENGINEERING CONFERENCE & EXHIBITION (EARC 2014)

DATES: 17th to 19th Dec, 2014.
VENUE: HILLTOP HOTEL KIGALI - RWANDA.
THEME: MEDICAL EQUIPMENT MANAGEMENT- A PROACTIVE APPROACH.
SUB THEME: PERFORMANCE MEASUREMENTS AND EFFICIENCY
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Measurements & Calibration of Medical Equipment.

1. Definitions
2. Purposes
3. Methodology
4. Our Role
5. MTRH/KNH Pilots
6. AMEK/UXT Partnership
7. Conclusion
The science of measurements is called **Metrology**.

**Measurement** is the process or the result of determining the ratio of a physical quantity, such as a length or a mass, to a unit of measurement, such as the meter or the kilogram.

**Calibration** is a comparison between measurements, one is set (standard) value and the other measured (practical) value that leads to process of corrective actions when results are out of limits.

**The accuracy** of a measurement system is the degree of closeness of measurements of a quantity to that quantity's true value.
Definitions

The precision of a measurement system, also called reproducibility or repeatability, is the degree to which repeated measurements under unchanged conditions show the same results.

A measurement system is designated valid if it is both accurate and precise.
Example

NIBP measurement supposed to be within tolerance of 5 mmHg, therefore:

± 1 mmHg
± 2 mmHg
± 3 mmHg
± 4 mmHg
± 5 mmHg
By performing the test 3 times:

(a)  
(b)  
(c)  

We notice all the readings within the tolerance but the following points are reasonable:

- Figure (a): with low accuracy and precision is not acceptable and requires calibration
- Figure (b): High Accuracy & precision, Calibration not required
- Figure (c): High precision and low accuracy close to the limit, Calibration is recommended
Purpose of Measurement

The purpose of measurement is to provide information about a quantity of interest - a measurand. For example, the measurand might be the flowrate, potential difference, or energy. Etc.

No measurement is exact. When a quantity is measured, the outcome depends on:

- The measuring system,
- The measurement procedure,
- The skill of the operator,
- The environment, and other effects.
Metrology Basics

- Metrology includes all theoretical and practical aspects of measurement.

- A core concept in metrology is (metrological) traceability, defined as "the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties."

- Traceability is most often obtained by calibration, establishing the relation between the indication of a measuring instrument and the value of a measurement standard.

- Mistakes can make measurements and counts incorrect. Even if there are no mistakes, nearly all measurements are still inexact.
Each instrument should be labeled with the unique identifier (e.g. serial number, model number, location, etc.).

Calibration status of each instrument, the date of calibration, the next calibration date and the identification of person performing calibration should be readily available.

Appropriate systems to document calibration status must include calibration logs and calibration stickers.
Written calibration procedures that use traceable calibration standards and/or calibration equipment.

Qualified individuals (having the appropriate education, training, background and experience) responsible for calibrating & maintaining instrumentation.

Second person check of all calibration tests.

Qualified individuals responsible for monitoring the calibration.

Ensure the calibration program and procedures are reviewed and approved by the Quality Assurance Department.
Records for Calibration

* All calibration records must be retained as per document retention procedures which should include:
  1. “as found” measurements, results of adjustments (“as left”) and appropriate review & approval of all results
  2. Tolerance or limit for each calibration point
  3. Identification of standard or test instrument used
  4. Identification of persons performing the work and checking the results with dates

* Currently we have a management software (MED-@eBASE) which does all the above, it has eliminated all necessary paper work. For more information about the software see me after these.
After Calibration

- Review must ensure the approved activities have been completed and all results have passed the established acceptance criteria.

- Actions to be taken if machines are out of calibration (e.g. contact appropriate service people, label and remove from service).

- Record all calibration & maintenance activities.

- Periodic review of historic calibration & maintenance data to evaluate appropriateness of established frequencies.
4. Our Role

- Establish Quality Control (QC) & Quality Assurance (QA) protocols for medical technology and maintain the CMMS data secured and updated.
- Complete performance assurance and electrical safety testing
- Perform preventive/Scheduled maintenance
- Perform repairs and calibrations
The Moi Teaching and Referral Hospital (MTRH) in Eldoret, a Calibration Laboratory was set up in September 2012. Kenyatta National Hospital (KNH) is in the process of securing the multi-parameter bench that can work similarly to that at MTRH. Currently the bench is able to do the following parameters:

- Pressure (mainly +ve).
- Temperature.
- Mass.
- Speed (Tachometry).
- Conductivity (PH).
- AC/DC.

There are plans to upgrade the laboratory gradually to be able to cater for other parameters as well as analyzing patient monitors among others.
To set up a Calibration Centre of medical equipment for training Biomeds on Calibration related issues and doing the actual calibration of such sophisticated equipment.
7. Conclusion

* Qualification/Calibration are not optional but needed for regulatory compliance

* A strong calibration program ensures:
  * Highly Efficient Lab
  * Reliable Results
  * Quality Product
  * Patient Safety
Due to the challenge AMEK and User Experience Technologies Ltd (UXT) came together and came up with a training center to equip our BMETs and Clinical Engineers with the relevant skills needed to perform credible measurement and calibration of medical equipment. The center is NITA Approved and works hand in hand with KENAS.

The center also partnering with other centers from abroad, offers continuous trainings on touching and emerging issues on healthcare technology

The center is open to serve East Africa as a whole.
Location and Contacts

- The center is located in Nairobi Ngong Rd Bemuda Plaza 4th floor at the UXT Premises.
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