Testing and Calibration of Bio-Medical Equipment

For the health industry, be it hospitals or manufacturers of medical equipment – nothing counts more than the safety of a patient.

NOT surprising therefore that almost all quality conscious hospitals & medical equipment manufacturers have already made periodic testing and calibration of equipments, a permanent feature in their quality control regimen that they strictly adhere to.

WHAT is perhaps also significant is that the common thread across all such organizations is not their size or turnover but their dedication and commitment to quality and continuous improvement.

Testing and calibration of bio-medical equipment to ensure quality control in equipments is becoming increasingly significant today when accuracy in diagnosis and effectiveness in treatment cannot be compromised at all.

Testing and calibration of equipment ensures accuracy, effectiveness and long life of equipments, which ultimately enables one to achieve the highest degree of quality control.

Testing and calibration

- ► Is extremely important in achieving quality control of the highest standard in medical equipment
- ► Is done with the help of specialized testing and calibrating equipment.
- ►Should be done at least once a year
- ►Can be done as per a range of national and international standards including – IEC606.1, EN60601.1, EN60601.2.4 , EN61010 , VDE0751, MDADB9801, HE 95, ANSI/AAMI and more.
- ►Can be done for almost the entire range of medical equipments – including Defibrillators, Pulse Oxymeters , Infusion pumps , Patient Simulators, ventilators , Foetal Monitors, Patient monitors etc.
- ►Should be carried out by trained engineers.
- ►Should be concluded by documenting the test results and issuing a calibration report.

Testing and calibrating equipment

- Are specialized tools that cater to all medical equipments and applications- electrical safety testers, patient simulators, foetal monitor testers, Ventillator testers, SPO2analysers, NIBP analyzers, Electro surgical analyzers, Defibrillator analyzers etc.

- Are versatile, available in various models with numerous optional features, that enable the user to perform testing comprehensively, accurately, effectively, in-depth with great efficiency.

- Provide the option of storing and printing test results with special software packages.

How is testing and calibration done?

Any measuring equipment or device needs to be tested and checked for its accuracy and calibrated whenever the need arises. Testing is done in accordance to domestic standards, very often this means, in accordance with manufacturers specifications, for both safety and performance test. The test results need to be formally documented.

Example - If a defibrillator supply is do be repaired and the manufacturer specifies safety test according to EN60601-2-24 to be performed after the repair of the defibrillator power supply, an EN 60601-2-24 test has to be done and the result has to be documented.

The European Medical Directive Describes in Article 12 (Conformity of systems)

> Any natural or legal person who puts devices together within their intended purpose and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he states that:
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> A) He/she has verified the mutual compatibility of the devices in accordance with the manufacturers instruction and has carried out this operations in accordance with these instructions; and
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> B) He/she has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers; and
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> C) The whole activity is subjected to appropriate methods of internal control and inspection.

OR -

If you install, connect to, or modify medical equipment, you are responsible for making a declaration of conformity. If you perform PM, service, or repair medical equipment you shall follow manufacturer's instruction.

Key parameters for testing and calibrating Bio-Medical Equipment.

(Only a few equipments have been listed below for illustration)

Equipment	Parameters
❖ Defibrillators	- Electrical Safety tests - Biphasic energy measurement - ECG, performance and arrhythmia simulation - Charge and discharge time test - Waveform simulation
❖ Pulse Oxymeter	- Electrical safety tests - O2 Saturation - Heart rate - Pulse amplitude - Selectable pigmentation and ambient light condition
❖ Infusion pump	- Electrical safety tests - Flow rate - Occlusion alarm tests - Pressure
❖ Patient Simulators	- Electrical safety tests - ECG - Blood pressure - Cardiac Output - Respiration - Temperature - Pacemaker recognition
❖ Ventilators	- Tidal Volume - Inspiratory Peak flow - Inspiratory peak pressure - Peep pressure - Minute volume - I/E ratio - Oxygen level - Inspiratory hold Etc
❖ Fetal monitor	- Electrical safety tests - Fetal ECG - Maternal ECG - Uterine activity - TOCO simulation

Today awareness is on the increase in the community and doctors would like to deliver accurate diagnosis and quality care, negating all chances. More and more companies in India now are going in for testing and ensuring that their products meet international standards and safety norms. With medical tourism a reckonable aspect of the industry, India is fast catching up with EU and FDA standards voluntarily rather that with any Government initiative.