NABL 126

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Specific Criteria for Calibration of Medical Devices

ISSUE NO. : 01
ISSUE DATE: 02-Jan-2018

AMENDMENT NO: 01
AMENDMENT DATE: 09-Aug-2019

AMENDMENT SHEET

Sl no	Page No.	Clause No.	Date of Amendment	Amendment made	Reasons	Signature QM	Signature CEO
1	29/ 29	--	09.08.2019	Groupings of Medical devices as ANNEXURE C	Internal review	-Sd-	Sd-
2							
3							
4							
5							
6							
7							
8							
9							
10							

CONTENTS

1. General Requirements

- The purpose of this document is to specify requirements with which a laboratory has to operate and demonstrate its competency to carry out Calibration of Medical Devices in accordance with ISO/IEC 17025:2005, ISO 13485, IEC 60601, IEC 62353, GHTF, (Global Harmonization Task Force)
- To achieve uniformity between the laboratories, assessors and assessment process in terms of maximum permissible error, CMC, measurement uncertainty etc in line with National/International standards.
- To achieve uniformity in selection of equipment's, calibration methods, maintaining required environmental conditions, personnel with relevant qualification and experience.

2. Scope

This specific criterion lays down the requirements for Management system and Technical requirements for Calibration of Medical devices which:

- Needs to demonstrate its ability to consistently provide medical devices that meet customer and applicable statutory and regulatory requirements.
- To enhance customer satisfaction through the effective application of the system and technical requirements, including processes for continual improvement of the system and the assurance of conformity to customer

3. Application

All requirements of this document are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this document cannot be applied due to the nature of an organization and its products, this can be considered for exclusion.

If any requirement(s) of this document is (are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system and appropriate justification shall be recorded, provided such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

4. Personnel, Qualification and Training

4.1 Technical Personnel

Management needs to understand the scope, significance, and complexity of the program

4.1.1 Calibration Personnel: Degree in Electrical / Electronics / Biomedical Engineering/ Instrumentation or equivalent or post graduate in the relevant field, with at least one year experience in the relevant field of calibration or, graduate, Diploma in science with Physics / Electronics/Instrumentation with experience of 3 years in the relevant field of calibration. The personnel shall have relevant knowledge of basic principles of testing, evaluation of calibration results, equipment capabilities and uncertainty of test results & applicable regulations and general requirements expressed in relevant& associated standards.

4.1.2 People involved in metrology should have some of these characteristics: –technical education and experience in the area of job assignment –basic knowledge of metrology and testing/calibration concepts –an understanding of basic principles of measurement disciplines as per product base.

4.2 Authorized Signatory

4.2.1 Qualification required

Authorized Signatory: Degree in Electrical / Electronics /Biomedical Engineering /Instrumentation or equivalent or post graduate in the relevant field, with at least one year experience in the relevant field of calibration. Or, graduate in science with Physics / Electronics/Instrumentation with experience of 5 years in the relevant field of Calibration. The personnel shall have relevant knowledge of basic principles of calibration, evaluation of test results, equipment capabilities and uncertainty of test results & applicable regulations and general requirements expressed in relevant & associated standards.

4.3 Training and experience required

4.3.1 Due to various kinds of medical devices and each being used for different purpose, the authorized calibration engineer should be trained in each of the medical device which he/she is authorized to handle including the aspects of criticality of results, interpretation of data, correctness of data, specific operating ranges expected from the medical device, safety during usage, regulatory requirement to be followed / adhered to etc.

4.3.2 Experience in evaluation of Risk Assessment, Usability Engineering, EMC and Software Life Cycle Management is mandatorily needed. Knowledge of bio-compatibility and sterilization techniques and requirement are expected as needed depending on the product. Training on Emergency Medical preparedness including CPR shall be provided.

5. Accommodation And Environmental Conditions

Laboratory may be offering Medical Calibration services under different categories:

i. Permanent laboratory
ii. Onsite Facility
iii. Mobile Facility

The above category of laboratories may provide following types of services:

5.1.1 Service that intended primarily for working standards, reference standard / reference equipments which are further used for calibration purposes or high accuracy measurements which requires high degree of accuracy and better CMC.

5.1.2 Service that intended primarily for calibration and adjustment of test, measurement and diagnostic equipments to use in such areas as product calibration, manufacturing and servicing.

5.1.3 Accommodation and environmental conditions adversely affect the results of calibration and measurement accuracy unless they are controlled and monitored. Hence, they play a very important role.

5.1.4 The influencing parameters may be one or more of the following i. e. temperature, relative humidity, atmospheric pressure, vibration, acoustic noise, dust particle, air currents/draft, illumination(wherever applicable), voltage fluctuations, electrical earthing, line harmonic distortions and direct sunlight etc., depending on the nature of calibration services provided. The variables described above can play a major factor on calibration results.

5.1.5 The main difference between the permanent laboratory, onsite and mobile calibration services has to do with environmental conditions only. Since the onsite calibration relies on where the service is provided, it affects the results of calibration.

5.1.6 The laboratories are advised to follow the requirement of accommodation and environment depending on the types of services provided as recommended:

- By the manufacturers of the reference equipment
- By the manufacturers of the Unit under calibration
- As specified in the National/ International Standards or guidelines followed for the calibration.

5.1.7 The environmental monitoring equipments used should also meet the requirement of manufacturers' recommendations and specifications as per the relevant standards followed. If, accommodation and environmental conditions are not specified either by manufacturer or by National/International standards / guidelines, the laboratory shall follow the below recommendations.

- The calibration area shall be adequately free from vibrations generated by central air-conditioning plants, vehicular traffic and other sources to ensure consistent and uniform operational conditions. The laboratory shall take all special/ protective precautions like mounting of sensitive apparatus on vibration free tables and pillars etc., isolated from the floor, if necessary.
- The acoustic noise for the calibrations area shall be < 60dB
- The Illumination level of calibration area shall be 250 Lux to 500 Lux

The environmental conditions for the activity of the laboratory shall be such as not to adversely affect the required accuracy of measurement. Facilities shall be provided whenever necessary for recording temperature, pressure and humidity values prevailing during calibration. The atmospheric conditions maintained in the laboratory during calibration shall be reported.

6. Other significant requirements for laboratory

a. The calibration laboratory shall make arrangements for regulated and uninterrupted power supply of proper rating. The recommended voltage regulation level is ± 2% or better, and Frequency variation ± 1 Hz or better on the calibration bench.
b. The reference standards shall be maintained at temperatures specified for their maintenance on order to ensure their conformance to the required level of operation. The laboratory shall take adequate measures against dust and external air pressure.
c. As far as possible, only the staff engaged in calibration activity shall be permitted entry inside the calibration area.
d. The calibration Laboratory shall ensure adequate space for calibration activity without adversely affecting the results with the free movement of personnel.

7. Safety Precautions

7.1 Relevant fire extinguishing equipment for possible fire hazards shall be available in the corridors or convenient places in the laboratory. Adequate safety measures against electrical, chemical fire hazards (fumes/gases), Power backups must be available at the work place. Laboratory rooms/ areas where highly inflammable materials are used/ stored shall be identified. Access to the relevant fire equipment shall be assured near these rooms/ areas.

7.2 Chemical storage area should be highly protected with biosafety cabinets or fume hoods or with fire protection and should be isolated from workplace.

7.3 According to Regulation (EC) No. 1907/2006) a Material safety data sheet (MSDS) should be maintained with any hazardous chemical. Safety data sheets (SDSs) provide useful information on chemicals, describing the hazards the chemical presents, and giving information on handling, storage and emergency measures in case of an accident.

7.4 Proper eye wash and shower facility need to be provided in chemical hazarders handling areas.

7.5 Specification SP 31- 1986, a special publication in the form of a wall chart, giving the method of treatment in case of electric shock, should be followed. The chart shall be placed near the power supply switchgear and at other prominent places as prescribed under Indian Electricity Rules 1956.

7.6 Effective mains earthing shall be provided in accordance with relevant specification IS: 3043. This shall be periodically checked to ensure proper contact with earth rod.

7.7 First aid facility shall be provided in all the work places.

8. Documentation

There must be two copies of the instructions manual and a service manual with the equipment. Instructions manual should be with the equipment, and the other filed with the person responsible in department of the health unit. Service Manual must be obtained for each equipment, in order to provide technical information needed by the clinical engineer for maintenance. This should be a mandatory item in the technical specifications during procurement of equipment as well. IEC 60601-1 determines that all equipment must be accompanied by a description of technique, supplied by the manufacturer.

9. Labeling of Equipment

a) The labeling of equipment must be part of the program implemented by the in-house/outsourced clinical engineering group. Use of series of labels and color code for medical equipment, serving as guide for the development of a system for each health unit may be practiced.

b) Green label (Upto 100 µA) – Safe for use in all areas. In devices that have leads which connect to low impedance, direct wire electrical connection to the conductive system of the heart, lead leakage must be 20 uA or less, and chassis leakage must be 100 uA or less.

c) Blue label (101 to 500 µA) – Not intended for use in patient care areas. Equipment with this label must be used outside a six foot radius from a non-ambulatory patient.

d) Out-of-Service tag. White Tag (red lettering) – Remove from service. If a piece of equipment does not work properly, disconnect it and attach a white tag. This label and applied in any equipment classified as unsafe for reasons determined by the clinical engineer, and calls the attention of medical or nursing staff so that the equipment is not used. When equipment is classified, the supervisor of the unit must be immediately notified and corrective action should be initiated. Examples of these tags are the following data:

- **Patient Care Equipment**
- **Do Not Remove The Label**
- **Inspection date:** **Next inspection:**
- **Technician:**
- **Faulty-Do Not Use**
- **Do Not Remove This Tag**
- **Date: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _**
- **Technician:**
- **Figure –label Models**

9.1 The utilization of tags and a nice visual feature to determine whether the equipment has been inspected. Its not uncommon for vendors, nurses or even get a medical equipment for the health unit without the knowledge of the clinical engineering group, and therefore without your safety inspection. However, while a device is in the health unit, this will be liable if it is used in a patient, and bring any damage to the same.

9.2 Another benefit in the system of tags, and that the medical or nursing staff using the equipment feels safer if it has been inspected. Also, the medical staff or nursing can give return to the people of clinical engineering, if you notice that certain equipment is with your date of inspection due, or not have been inspected. It is important to instill in people the only procedure using labeled equipment, and bring inspection date updated.

10 Special Requirements for Medical Devices Calibration at Different Facility

10.1 **Permanent Laboratory**: A calibration laboratory set up in a dedicated location for an indeterminate amount of time.

10.2 **Site Calibration Facility**: Calibration performed by staff of a laboratory or entity at the customer premises or location outside of a permanent laboratory.

10.3 **Mobile Facility**: Fully equipped, self-contained, transportable calibration facility capable of performing tests/ calibrations under controlled environmental conditions.

Sl.	Equipment	Permanent	Site	Mobile
1.	Incubator	✓	✓	
2.	Autoclave		✓	
3.	Defibrillator	✓	✓	
4.	Suction Pump	✓	✓	
5.	Flow meter with Humidifier	✓	✓	
6.	Pressure Gauge of Oxygen Cylinder	✓	✓	✓
7.	BP Apparatus (Sphygmomanometer)	✓	✓	✓
8.	ECG Unit	✓	✓	
9.	Trans illuminator light source	✓	✓	
10.	Ventilator	✓	✓	
11.	Nebulizer (Electric)	✓	✓	
12.	Syringe Pump	✓	✓	
13.	Infusion Pump	✓	✓	
14.	Radiant Warmer	✓	✓	
15.	Phototherapy	✓	✓	
16.	Pulse Oxymeter	✓	✓	
17.	Weighing scales (baby)	✓	✓	
18.	EEG	✓	✓	
19.	Electro Surgical Unit/ Diathermy Machine/ Cautry Machine.	✓	✓	
20.	Patient Monitors	✓	✓	
21.	Apnea Monitors	✓	✓	
22.	External Pace Maker	✓	✓	
23.	Fetal Monitor	✓	✓	
24.	Feat Doppler	✓	✓	
25.	Infant Incubator	✓	✓	
26.	Electronic Tourniquet	✓	✓	
27.	Therapeutic Ultra sound Machine	✓	✓	
28.	Boyles Apparatus	✓	✓	
29.	Dialysis Machine		✓	
30.	Heart Lung Machine		✓	
31.	Patient Warmer	✓	✓	
32.	OT Table		✓	
33.	OT Light		✓	
34.	Electronic /Mechanical Patient Bed		✓	
35.	CPM Machine	✓	✓	
36.	Therapeutic Stimulator	✓	✓	
37.	Enteral Feeding Pump	✓	✓	
38.	CPAP	✓	✓	
39.	BiPAP	✓	✓	

Note: This list is indicative & non exhaustive

11. Selection of Reference Masters & Standards

Sl.	Equipment /DUC	Relevant Standard	Recommended parameter to measure	Reference Equipment to be used
1.	Patient Monitor	1. IEC 60601-1 2.IEC 60601-1-2 3. Pulse oximetry standard ISO 9919:2005. NIBP and ECG IEC 60601-2-27, IEC 60601-2-34, IEC 60601-2-49	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Basic safety and essential performance requirements of multifunction patient monitoring equipment. For Patient Monitor, Patient Monitor Simulator is required to check and simulate critical parameters like NIBP, Respiration, ECG, IBP ,SPO2 and also to simulate performance waveforms.	Electrical Safety Analyzer& Patient Monitor Simulator.
2.	Syringe Pump	1. IEC 60601-1 2. IEC 60601-1-2 3. IEC 60601-2-24:2012 Medical electrical equipment - Part 2-24	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for the basic safety and essential performance of infusion pumps and controllers, For Syringe Pump critical parameters needs to be measured /Analysed like Flow Rate, Volume Measurement, Pressure Measurement etc.	Electrical Safety Analyzer & Infusion Device Analyzer.
3.	Infusion Pump	1. IEC 60601-1 2. IEC 60601-1-2 3. IEC 60601-2-24:2012 Medical electrical equipment - Part 2-24	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for	Electrical Safety Analyzer& Infusion Device Analyzer.

			the basic safety and essential performance of infusion pumps and controllers, For Syringe Pump critical parameters needs to be measured /Analysed like Flow Rate,Volume Measurement, Pressure Measurement etc	
4.	Autoclave	1.IEC 60601-1 2.IEC 60601-1-2 3.IEC 61010-2-040	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance withregard to electromagnetic disturbances and for electromagnetic emissions 3. specifies safety requirements for electrical equipment intended for sterilization, washing, and disinfection of medical materials	Digital Thermometer &Pressure Calibrator
5.	Defibrillator	1.IEC 60601-1 2.IEC 60601-1-2 3.IEC 60601-2-4	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for the safety of cardiac defibrillator. Defibrillator unit critical Parameters needs to be measured like Energy Measurement, Charge Time, ECG Simulation, Patient test Load (Resistance) , External Pacer Test etc.	Electrical Safety Analyzer & Defibrillator Analyzer
6.	Suction Pump	1. IEC 60601-1 2. ISO 10079-1.	1. General requirements for basic safety and essential performance 2. Specifies safety and performance requirements for electrically powered medical and surgical suction equipment	Electrical Safety Analyzer &Pressure Calibrator.
7.	Laryngoscope	1. ISO 7376:2009	1. General requirements for laryngoscopes used for intubation, and specifies critical dimensions for the handle and lamp of hook-on type laryngoscopes.	
8.	Flowmeter with Humidifier	ISO 8185 and ISO 9360-1/62353	1. General requirements for Flow Test, Temperature Test, Electrical Safety Test	Electrical Safety (if it is electrically operated)Analyzer, Gas Flow

				analyzer, Digital Thermometer.
9.	BP Apparatus (Sphygmomanometer)	1.IEC 60601-2-30:2009 :Medical electrical equipment -- Part 2-30	1. Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers	NIBP Simulator, if it is electrical operated, then Electrical Safety Analyzer is also required.
10.	Ophthalmoscope	1.IEC 60601-1 2.ISO 10942:2006 along with ISO 15004-1 and ISO 15004-2	1. General requirements for basic safety and essential performance 2. specifies minimum requirements and test methods for hand-held direct ophthalmoscopes designed for directly observing the eye fundus	
11.	X-Ray	1.IEC 60601-1 2.IEC 60601-1-2 3. IS 7620:Part 1(1986) 4. IEC 60601-1-3:2008:Medical electrical equipment - Part 1-3 5. IEC 60601-2-54:2009:Medical electrical equipment - Part 2-54 6.IEC 62304 :2006	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Mechanical and Electrical Safety Requirement 4. General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment 5. Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy 6. Medical device software	Electrical Safety Analyzer &Radiology Test Equipment, Radiation Leakage Detector
12.	ECG Unit	1.IEC 60601-1 2. IEC 60601-1-2 3. IEC 60601-2-25, IEC 60601-2-27	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions. 3. Basic safety and essential performance of electrocardiographs, Parameter like ECG Simulation needs to be checked and simulated	Electrical Safety Analyzer&ECG Simulator
13.	Blood Gas analyser	1.IEC 60601-1 2. IEC 60601-1-2	1. General requirements for basic safety and essential	Eectrical Safety Analyzer

		3.IEC 61010-2-081: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081 4.IEC 61010-2-101	performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for automatic and semi-automatic laboratory equipment 4. Particular requirements for in vitro diagnostic (IVD) medical equipment	
14.	Transilluminator light source	1.IEC 60601-1 2.IEC 60601-1-2 3.IEC 60601-2-18: Medical electrical equipment - Part 2-18	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for the basic safety and essential performance of endoscopic equipment	Electrical Safety Analyzer & LUX Meter.
15.	Ventilator	1.IEC 60601-1 2. IEC 60601-1-2 3. IEC 60601-2-12: Medical electrical equipment -- Part 2-12 ,IEC60601-2-13	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for the safety of lung ventilators -- Critical care ventilators, The Vital Parameters of Ventilator machine needs to be analysed and tested are like Bidirectional flow (high- and low-flow ranges), volume, vacuum, pressure, and oxygen-concentration Accuracy measurements, in technical terms, Flow/Volume accuracy (VT, MV, PIF, PEF), Pressure accuracy (PIP, MAP, IPP PEEP), Time accuracy (RR, TI, TE, I:E ratio).	Electrical Safety Analyzer& Gas Flow Analyzer (Ventilator Analyzer)
16.	Nebulizer (Electric)	1.IEC 60601-1 2.ISO 27427:2013	1. General requirements for basic safety and essential performance 2. Anesthetic and respiratory equipment -- Nebulizing systems and components	Electrical Safety Analyzer required(if it Is Electrical Operated)&Gas Flow Analyzer

17.	Radiant Warmer	1. IEC 60601-1 2.IEC 60601-1-2 3. IEC 60601-2-21:2009 &IEC60601-1-19 Medical electrical equipment - Part 2-21 &2-19	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for the basic safety and essential performance of infant radiant warmers, Radiant Warmer machines critical parameters needs to be checked and tested like • Airflow • Sound • Humidity • Air and surface temperature in 6 independent points Optional skin temperature	Electrical Safety Analyzer& Radiant Warmer Analyzer
18.	Semi- Auto analyser	1.IEC 60601-1 2. IEC 60601-1-2 3.IEC 61010-2-081: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081 4.IEC 61010-2-101	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for automatic and semi-automatic laboratory equipment 4. Particular requirements for in vitro diagnostic (IVD) medical equipment	Electrical Safety Analyzer
19.	Self inflating reservoir bag	1. ISO 10651-4:2002 2. IS 6194(1971)	1. Specifies requirements for operator-powered resuscitators intended for use with all age groups and which are portable and intended to provide lung ventilation	
20.	Electrosurgical Unit	1.IEC 60601-1: 2. IEC 60601-1-2 3.IEC 60601-2-2: Medical electrical equipment - Part 2-2: Particular	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic	Electrical Safety Analyzer& Electrosurgical Analyzer/Cautery Analyzer.

		requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	emissions 3. Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories,Electrosurgical/Cautery Machine critical parameters needs to be measured and checked like with precise power, current, frequency, crest factor and load resistance ranges, Automatic power distribution measurement, Return electrode measurement (REM)test including power, Contact quality Monitor test, peak-to-peak voltage, and crest factor, Vessel Sealing Test	
21.	Phototherapy	1. IEC 60601-1 2.IEC 60601-1-2 3. IEC 60601-2-50: Medical electrical equipment - Part 2-50	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for the basic safety and essential performance of infant phototherapy,Phototherapy Analyzer required to test and check measurement of irradiation by simply placing the detection probe under the phototherapy light (fluorescent lamps only). In addition to verifying output power	Electrical Safety Analyzer, Irradiance meter.
22.	Pulse Qximeter	1.IEC 60601-1 2.IEC 60601-1-2 3.ISO 80601-2-61:2011 or ISO 9919:2005Medical electrical equipment -- Part 2-61	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for basic safety and essential performance of pulse oximeter equipment	Electrical Safety Analyser & Pulse Oximeter Simulator

23.	Weighing scales (baby)	IS 2489 (1963)	Weights Test	Weights
24.	Irradiance meter	1. IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	Electrical Safety Analyzer
25.	Basinet	Not applicable	Not applicable	
26.	EEG	1. IEC 60601-1 2. IEC 60601-1-2 3.IEC 60601-2-26: Medical electrical equipment - Part 2-26	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for the basic safety and essential performance of electroencephalographs	Electrical Safety Analyzer
27.	Hematology Analyser	1.IEC 60601-1 2. IEC 60601-1-2 3.IEC 61010-2-081: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081 4.IEC 61010-2-101	1. General requirements for basic safety and essential performance 2. Basic safety and essential performance with regard to electromagnetic disturbances and for electromagnetic emissions 3. Particular requirements for automatic and semi-automatic laboratory equipment 4. Particular requirements for in vitro diagnostic (IVD) medical equipment	Electrical Safety Analyzer.
28.	Infant Incubator	IEC 60601/62353 Relevant standards: IEC 60601-2-20	Electrical Safety Test, Also Incubator Critical parameters needs to be Tested and measured like • Airflow • Sound • Humidity • Air and surface temperature in 6 independent points Optional skin temperature	Electrical Safety Test & infant Incubator Analyzer.
29.	External Pace Maker	IEC 60601/62353,	Rate Accuracy, Output accuracy, Pulse width, Energy	Pace Maker Analyzer
30.	Fetal Monitor	IEC 60601/62353,	Electrical Safety test, Fetal Heart rate accuracy, Maternal Heart rate accuracy, Intrauterine pressure accuracy, Alarm function	Fetal Simulator with Mechanical Fetal Heart.

31.	Therapeutic Ultra sound Machine	IEC 60601-2-5/62353,	Electrical Safety Test, Output accuracy test, Duty cycle, Timer accuracy.	Electrical Safety Analyzer, Ultrasound watt meter, stop watch
32.	Anesthesia Machine	IEC 60601-1/ISO 8835-2,-3,-4-5/62353,	Electrical Safety Test, Flow/Volume accuracy (VT, MV, PIF, PEF), Pressure accuracy (PIP, MAP, IPP PEEP), Time accuracy (RR, TI, TE, I:E ratio), Oxygen Concentration accuracy, Alarm functions, Hypoxic Guard Test.	Electrical Safety Analyzer &Gas Flow analyzer
33.	Dialysis Machine	EN 13867 / IEC 60601-2-16, -2-39/62353,	Electrical Safety Test, Dialysate Conductivity Test, Temperature test, Flow Test, pH Test, Timer test, Pressure test.	Electrical Safety Analyzer, Dialysis Reference meter, Temperature data logger, Pressure data logger
34.	Apnea monitor	IEC 60601-1	Electrical safety test,apneaalarm,Multi parameter test	Multi parameter simulator, Electrical safety analyzer
35.	Electronic Tourniquet	IEC 60601-1	Electrical safety test, pressure test ,Time interval	Electrical safety analyzer, pressure analyzer, stop watch
36.	Boyels apparatus		Pressure gauge test, gas test	Pressure calibration, gas flow analyser
37.	OT table	IEC 60601-1	Electrical safety test, functional test	Electrical safety analyser
38.	OT light		Light intensity test	Lux meter
39.	Electronic/Mechanical bed	IEC 60601-1	Electrical safety test , functional test	Electrical safety analyser
40.	CPM Machine	IEC 60601-1	Electrical safety test, angular test	Electrical safety analyzer, angle measuring device
41.	Therapeutic stimulator	IEC 60601-1	Electrical safety test, functional test	Electrical safety analyzer , wave form analyser
42.	C pap	IEC 60601-1	Electrical safety test, Particular requirements for the safety & performance same as ventilators	Gas flow analyzer with test lung, electrical safety test
43.	Bi pap	IEC 60601-1	Electrical safety test, Particular requirements for the safety &	Gas flow analyzer with

			performance same as ventilators , humidity test	test lung, electrical safety test, humidity tester
44.	Sterile hypodermic syringes for single use – Part 1: Syringe for manual use	IS 10258 ISO 7886-1	Limit for acidity or alkalinity	Electrode pH meter
			Limit for extractable metals	Atomic absorption method
			Test for Air Leakage test Syringe during aspiration and for separation of piston and plunger	*Apparatus for Aspiration test
			Determination of capacity and dead space	Weighing balance capable of determining a difference in mass of 0.2 gm
			Test for Liquid Leakage at Syringe piston under compression	*Apparatus for liquid leakage test
			Test for force required to operate plunger	*Apparatus for determine force to operate plunger
45.	Sterile hypodermic syringes for single use – Part 2: Syringe for use with power – driven syringe pumps	ISO 7886-2	Determination of flow characteristic	*Apparatus for Determination of flow characteristic
			Determination of compliance syringe	*Apparatus for Determination of compliance syringe
46.	Sterile hypodermic syringes for single use – Part 3: Auto-disable syringes for fixed dose immunization	IS 10258 (Part 3) ISO 7886-3	Test for testing auto disable feature	*Apparatus for testing auto disable feature
47.	Sterile hypodermic syringes for single use – Part 4: Syringe with re-use prevention feature	ISO 7886-4	Test for testing for testing re-use prevention feature for RUP syringes	*Apparatus for testing re-use prevention feature
48.	Sterile single use syringes, with or without needle for insulin	IS 12227 ISO 8537	Test for bond between hub and needle tube	*Apparatus for measuring bond between hub and needle tube

49.	Sterile hypodermic needles for single	IS 10654 ISO 7864	Measurement of needle point geometry	Test apparatus (profile projector-micrometer having least count 0.001mm and angle detector having least count 1minute)
			Test for bond between hub and needle tube	*Apparatus for measuring bond between hub and needle tube
			Determination of flow rate through the needle	*Apparatus for Determination of flow rate through the needle
			Test for measuring the penetration force and drag force for needle	*Apparatus for measuring the penetration force and drag force for needle
50.	Stainless steel needle tubing for the manufacture of medical devices	ISO 9626	Test for stiffness of tubing	*Apparatus for stiffness test of tubing capable of applying a force of up to 60 N downward within accuracy of ±0.1N
			Test for resistance of tubing to breakage	*Apparatus for resistance of tubing to breakage capable of applying a force to tubing sufficient to bend it through an angle of up to 25°
51.	Intravascular Catheters – Sterile and single – use catheters-Part 5: Over-needle peripheral catheters	ISO 10555-5	Determination of liquid leakage from vent fitting	*Apparatus for Determination of liquid leakage from vent fitting

52.	Intravascular Catheters – Sterile and single – use catheters- Part 1: General Requirements	ISO 10555-1	Radio-detectability	Radio-detectability test (by X-ray)
			Determining peak tensile force	*Apparatus for Tensile testing (capable of exerting a force of greater than 15 N)
			Liquid leakage under pressure	*Apparatus for Liquid leakage under pressure
			Air leakage in to hub assembly during aspiration	*Apparatus for Air leakage in to hub assembly during aspiration
			Determination of flow rate through catheter	*Apparatus for Determination of flow rate through catheter
			Test for burst pressure under static condition	*Apparatus for assessing high pressure capability
			Power injection test for flow rate and device pressure	*Apparatus for assessing Power injection flow rate and device pressure
53.	Single use container for venous blood specimen collection	ISO 6710	Test for leakage of container	*Apparatus -test for leakage of container
54.			Test for robustness of container	Centrifuge capable of subjecting the base of the container to centrifugal acceleration of 3 000g for 10min.
55.	Sterile single use scalp vein infusion set	IS 16097	Limit for acidity or alkalinity	Electrode pH meter
			Limit for extractable metals	Atomic absorption method

			-Test for bond between wing and needle tube - Test for bond between wing and extension tube	*Apparatus for measuring bond between wing and needle tube/extension tube
56.	Blades , surgical , detachable and handles	IS 3319	Measurement of blade shape and dimension	Test apparatus (profile projector-micrometer having least count 0.001mm and angle detector having least count 1minute)

Note: This list is indicative & non exhaustive

12. Calibration Interval for Medical Devices:

Sl.	**Category of Equipment**	**Interval**
1.	Electric-powered equipment	Annual
2.	Battery-powered equipment	Annual
3.	Powered by mechanical systems, electromechanical or fluid	Annual
4.	Resuscitation equipment or life saving equipment	Quarterly or Biannual
5.	Equipment located in areas of special care	Quarterly or Biannual
6.	Monitoring equipment	Quarterly or Biannual
7.	Equipment that present high risks to users	Quarterly or Biannual

13. Standard Operating Procedure

The elaborate test protocols for each equipment proposed in this work are described in 4 distinct steps which are described below (Additional steps may be proposed if desired by the manufacturer/ client.

Step 1- Relevant qualitative and quantitative tests should include the following:-

- Protection against mechanical risks
- Protection against risk of unwanted or excessive radiation
- Protection against risk of ignition of anesthesia mixtures
- Protection against excessive temperatures
- Abnormal operations and conditions of failure

Step 2- With relevant general rule, with the help of an appropriate electrical safety analyser, and qualified person check/verify the following:-

- Curent consumption
- Insulation Resistance
- Leakage current to the ground
- Leakage current through the Cabinet
- Leakage current through the patient
- Auxiliary current through the patient

The above measures include all tests that can be performed on electro medical equipment as prescribed by the general rule, and that meet the criteria established for this step and the previous one.
The results of the tests mentioned above represent characteristics common to all electro medical equipment. Additionally, each equipment must observe compliance with their particular standard. The nature of the tests varies greatly according to the equipment to be tested; e.g., the tests applied in electrosurgical units are completely distinct from those applied in infusion pumps.

Through this methodology, test protocols developed for electrocardiographs, infusion pumps, syringe pumps, defibrillators and electrosurgical units are attached as suggestive tests. The tests applied in these equipments are listed below:

Electro medical equipment in general

The following tests should be applied:-

- Insulation resistance
- Leakage current to the ground
- Leakage current through the Cabinet
- Leakage current through the patient
- Auxiliary current through the patient

Electrosurgical Units

The following tests should be applied:-

- Insulation resistance
- Leakage current to the ground
- Leakage current through the Cabinet
- Leakage current through the patient
- Auxiliary current through the patient
- Accuracy of the power outlet
- RF leakage current

Defibrillators

The following tests should be applied:-

- Insulation resistance
- Leakage current to the ground
- Leakage current through the Cabinet
- Leakage current through the patient
- Auxiliary current through the patient

- Energy delivered
- Isolation of the high voltage parts
- Energy loss rate
- Battery capacity

Volumetric infusion pumps and syringe pumps
The following tests should be applied:-

- Insulation resistance
- Leakage current to the ground
- Leakage current through the Cabinet
- Leakage current through the patient
- Accuracy of the intermediary and minimum rate infusion without return pressure
- Accuracy of infusion rate

The above tests are only suggestive. The service provider may add new tests.

Similarly the tests for all the equipment intended to be tested under the Scope should be developed.

However the procedures for doing each test needs to be elaborated in the Procedures Manual.

14. SAMPLE SCOPE:

DEFIBRILLATOR CALIBRATION PARAMETERS				
S. No.	**Quantity Measured/**	**Range/Frequency**	**CMC (±)**	**Remarks**
01	Heart Rate Accuracy	±5%		Electrical Safety Analyzer and Defibrillator Analyzer
	Output Accuracy	±15%		
	Output Accuracy Multiple	±15%		
	Output Energy at Max Setting for 10 Chg cycle (Battery Power)	±15%		
	Charge time after 10 discharge cycles (Battery Power)	≤ 15 sec		
	Energy after 60 sec of full charge	≥ 85%		
	Synchronizer Operation	≤ 60 msec		
	Pacer Output Accuracy	±10%		
	Pacer Rate Accuracy	±5%		
**Defibrillator performance for 'Verify units on battery' is verified for its operational integrity*				
INCUBATOR CALIBRATION PARAMETERS				
02	Warm Up Time	±20%		Electrical Safety Analyzer and Incubator Analyzer
	Air Temperature Accuracy	±1 °C		
	Skin Temperature Accuracy	±0.3 °C		

	Temperature overshoot	±2 °C		
	Relative Humidity	±10%		
	High Temperature Protection	±2%		
	Air Flow	≤0.35 m/s		
	Noise Level	≤ 60dB normal Conditions		
		≤ 80 dB alarm activated		
		≥80 dB alarm activated 3 m from Incubator		
**Incubator performance for "Verify Unit on battery, 'Fan Operation', 'Air Temperature Alarms' and 'Skin Temperature Alarms' is verified for its operational integrity.*				
INFUSION PUMP CALIBRATION PARAMETERS				
03	Flow Rate Accuracy	±10%		Electrical Safety Analyzer & Infusion Pump Analyzer
	Volume Accuracy	±10%		
	Occlusion Detection Pressure	±1 psi		
**Infusion Pump performance for "Infusion Complete/KVO'is verified for its operational integrity.*				
EXTERNAL PACEMAKER CALIBRATION PARAMETERS				
04	Rate Accuracy	±5%		Electrical Safety Analyzer and Pacemaker Analyzer
	Output Accuracy	±10%		
	Pulse width	±10%		
**External Pacemaker performance for 'Verify units operate on battery' & 'Alarm Function' is verified for its operational integrity.*				
PATIENT MONITOR CALIBRATION PARAMETERS				
05	Heart Rate Accuracy	±5%		Electrical Safety Analyzer & Patient Monitor Simulator
	Respiration Rate Accuracy	±5%		
	NIBP Leak Test	≤15mmHg/min		
	NIBP Static Pressure Accuracy	±3mmHg		
	NIBP Pressure Relief Test	≤330mmHg		
	Dynamic NIBP Pressure Repeatability	±10mmHg		
	SpO2 Accuracy	±3%		
	Invasive Pressure Accuracy	±5%		
**Patient Monitor performance for 'Verify units operate on battery' & ECG Simulation - (Test for minimum 3 Arythmia's) all leads is verified for its operational integrity.*				
VENTILATOR CALIBRATION PARAMETERS				
06	Volume Accuracy	±10%		Electrical Safety Analyzer, Ventilator & Gas Flow Analyzer
	Respiration Rate	±10%		
	I:E Ratio	±10%		
	Pressure Accuracy	±10%		
	PEEP	±10%		
	Oxygen Accuracy	±2%		

**Ventilator performance for 'Gas Cylinders and Regulators', 'Hose Tubing and Connectors' & 'Alarm Function' is verified for its operational integrity.*				
PHOTOTHERAPY UNIT CALIBRATION PARAMETERS				
07	Volume Accuracy	±5%		Electrical Safety analyzer & Phototherapy Analyzer
	Oxygen Accuracy	≥ 4.5 µW/cm²/nm		
		(≥198 µW/cm²/nm @ 44 nm bandwidth)		
		≤ 40 µW/cm²/nm		
		(≤1760µW/cm²/nm @ 44 nm bandwidth)		
**Phototherapy Unit performance for 'Alarm Function' is verified for its operational integrity.*				

Note: Prior to the calibration of the above said DUC, electrical safety parameters such as Ground Wire Resistance, Chassis Leakage, Patient Leakage Current, Patient Lead Leakage Current, Isolation Test (mains on applied part), Insulation (Optional) 500 V etc. shall be verified as per IEC-60601/62353 and found within limits.

References

- Accreditation of Biomedical Calibration Measurements in Turkey
- Medical Equipment Quality Assurance: Inspection Program Development and Procedures, Instrumentation & Technical Services University of Vermont 280 East Avenue, Suite 2 Burlington, VT 0540, IS/ISO 13485

(ANNEXURE-A)

Sample Report Format

Defibrillator Report Format

MANUFACTURER: _____MODEL: _____

SERIAL NO: _____ TEST CARRIED ON:_____

Reference Equipment's Used: Electrical Safety Analyzer & Defibrillator Analyzer

Equipment details:

Equipments Details	**Model/Make/ Serial No.**	**Calibration Valid till**
Electrical Safety Analyzer		
Defibrillator Analyzer		

DEFIBRILLATOR CALIBRATION PARAMETERS				
S. No.	**Quantity Measured**	**Range/Frequency**	**CMC(±)**	**Remarks**
	Heart Rate Accuracy	±5%		
	Output Accuracy	±15%		
	Output Accuracy Multiple	±15%		
	Output Energy at Max Setting for 10 Chg cycle (Battery Power)	±15%		
	Charge time after 10 discharge cycles (Battery Power)	≤ 15 sec		
	Energy after 60 sec of full charge	≥ 85%		
	Synchronizer Operation	≤ 60 msec		
	Pacer Output Accuracy	±10%		
	Pacer Rate Accuracy	±5%		

**Defibrillator performance for 'Verify units on battery' is verified for its operational integrity.*

Note: Prior to the calibration of this DUC electrical safety parameters such as Ground Wire Resistance, Chassis Leakage, Patient Leakage Current, Patient Lead Leakage Current: Isolation Test (mains on applied part), Insulation (Optional) 500 V etc. verified as per IEC-60601/62353 and found within limits.

Patient Monitor Report Format

MANUFACTURER: _____MODEL: _____

SERIAL NO: _____ TEST CARRIED ON:_____

Reference Equipment's Used: Electrical Safety Analyzer &Patient Monitor Simulator

Equipment details:

Equipment's Details	**Model/Make/ Serial No.**	**Calibration Valid till**
Electrical Safety Analyzer		
Defibrillator Analyzer		

PATIENTMONITORCALIBRATION PARAMETERS				
S. No.	**Quantity Measured/**	**Range/Frequency**	**CMC(±)**	**Remarks**
	Heart Rate Accuracy	±5%		
	Respiration Rate Accuracy	±5%		
	NIBP Leak Test	≤15mmHg/min		
	NIBP Static Pressure Accuracy	±3mmHg		
	NIBP Pressure Relief Test	≤330mmHg		
	Dynamic NIBP Pressure Repeatability	±10mmHg		
	SpO2 Accuracy	±3%		
	Invasive Pressure Accuracy	±5%		

**Patient Monitor performance for 'Verify units operate on battery' & ECG Simulation - (Test for minimum 3 Arythmia's) all leads is verified for its operational integrity.*

Note: Prior to the calibration of this DUC electrical safety parameters such as Ground Wire Resistance, Chassis Leakage, Patient Leakage Current, Patient Lead Leakage Current: Isolation Test (mains on applied part), Insulation (Optional) 500 V etc. verified as per IEC-60601/62353 and found within limits.

(ANNEXURE-B)

Sample Report Format -Electrical Safety

Defibrillator Report Format

MANUFACTURER: _____MODEL: _____

SERIAL NO: _____ TEST CARRIED ON:_____

Reference Equipment's Used: Electrical Safety Analyzer & Defibrillator Analyzer

Equipment details:

Equipments Details	**Model/Make/ Serial No.**	**Calibration Valid till**
Electrical Safety Analyzer		
Defibrillator Analyzer		

Electrical Safety test for Defibrillator As per IEC60601/62353					
Sl.No	**Parameter**	**Permitted Values**	**Measured Values**	**Deviation %**	**Remarks (PASS/FAIL/NA)**
	Ground Wire Resistance	<0.3Ω			
	Chassis Leakage	<100µANC			
		<500µASFC			
	Patient Leakge Current	<100µABandBF			
		<10µACF			
	Patient Lead Leakage Current, Isolation Test (mains on Applied part)	<100µABF			
		<10µACF			
	Insulation (Optional) 500V	<2MΩ			

Patient Monitor Report Format

MANUFACTURER: _____MODEL: _____

SERIAL NO: _____ TEST CARRIED ON:_____

Reference Equipment's Used: Electrical Safety Analyzer &Patient Monitor Simulator

Equipment details:

Equipment's Details	**Model/Make/ Serial No.**	**Calibration Valid till**
Electrical Safety Analyzer		
Defibrillator Analyzer		

Electrical Safety test for Defibrillator As per IEC60601/62353					
Sl. No	**Parameter**	**Permitted Values**	**Measured Values**	**Deviation %**	**Remarks (PASS/FAIL/NA)**
	Ground Wire Resistance	<0.3Ω			
	Chassis Leakage	<100µANC			
		<500µASFC			
	Pateint Leakge Current	<100µABandBF			
		<10µACF			
	Patient Lead Leakage Current, Isolation Test (mains on Applied part)	<100µABF			
		<10µACF			
	Insulation (Optional) 500V	<2MΩ			

(ANNEXURE-C)

GROUPING OF MEDICAL DEVICES

I. Discharge Equipment/Devices

S. No.	Name of Equipment/Device
01	Suction Pump
02	Flow meter with Humidifier
03	Pressure Gauge of Oxygen Cylinder
04	BP Apparatus (Sphygmomanometer)
05	Nebulizer (Electric)
06	Syringe Pump
07	Infusion Pump
08	Enteral Feeding Pump
09	CPAP
10	BiPAP
11	Boyles Apparatus
12	Anesthesia Machine

II. Patient Conditioning/ Maintenance

S. No.	Name of Equipment/Device
01	Incubator
02	Autoclave
03	Defibrillator
04	Ventilator
05	Electro Surgical Unit/ Diathermy Machine/ Cautry Machine.
06	External Pace Maker
07	Electronic Tourniquet
08	Dialysis Machine
09	Heart Lung Machine
10	Patient Warmer
11	OT Table
12	Radiant Warmer
13	Irradiance Meter
14	Phototherapy Unit

III. Monitoring Unit

S. No.	Name of Equipment/Device
01	Patient Monitors
02	Apnea Monitors
03	Fetal Monitor
04	Therapeutic Stimulator
05	Weighing Scale
06	Hematology Analyser

IV. Imaging/Plotters

S. No.	Equipment/Device
01	Trans illuminator light source
02	EEG
03	Fetal Doppler
04	ECG
05	X-Ray Diagnostic Equipment

National Accreditation Board for Testing and Calibration Laboratories
NABL House
Plot No. 45, Sector- 44,
Gurgaon – 122002, Haryana
Tel.: +91-124 4679700
Fax: +91-124 4679799
Website: www.nabl-india.org