CALIBRATION OF MEDICAL DEVICES

Calibration of medical devices is a critical process that ensures these devices provide accurate and reliable measurements. In the healthcare industry, the accuracy of medical devices is paramount for proper diagnosis, treatment, and patient care. Here's a comprehensive overview of the calibration process for medical devices:

1. Definition of Calibration:

- Calibration: The process of comparing the measurement performance of a medical device against a known and traceable standard to ensure accuracy.

2. Importance of Calibration in Healthcare:

- Patient Safety: Inaccurate measurements can lead to incorrect diagnoses and treatments.
- Regulatory Compliance: Adherence to regulatory standards and guidelines (e.g., FDA, ISO 13485).
- Data Integrity: Reliable data is crucial for research, clinical trials, and medical decision-making.
- Equipment Longevity: Regular calibration can extend the lifespan of medical devices.

3. Types of Medical Devices Requiring Calibration:

- Imaging Equipment: X-ray machines, MRI scanners, CT scanners.
- Diagnostic Instruments: Blood pressure monitors, glucose meters, and thermometers.
- Laboratory Instruments: Centrifuges, spectrophotometers, pipettes.

4. Calibration Process Overview:

a. Establishing Traceability:

Ensuring measurements can be traced back to national or international standards.

b. Setting Calibration Standards:

Using calibrated reference standards that are traceable to a recognized authority.

c. Performing Calibration:

Adjusting the medical device to align with the reference standards.

Conducting calibration tests under controlled conditions.

d. Documentation and Record-keeping:

Detailed records of calibration procedures, results, and any adjustments made.

Maintaining a calibration schedule for each device.

5. Common Calibration Methods:

- Bench Calibration: Conducted in a controlled laboratory environment.
- On-site Calibration: Performed at the location where the medical device is used.

6. Key Calibration Parameters:

- Accuracy: How close the device measurement is to the true value.
- Precision: Consistency in repeated measurements.
- Linearity: Ability to provide accurate measurements across a range.
- Sensitivity: Detecting small changes in measurements.

7. Calibration Frequency:

- Determined by regulatory requirements, device usage, and manufacturer recommendations.
- Critical devices may require more frequent calibration.

8. Challenges in Calibration:

- Environmental Factors: Temperature, humidity, and pressure variations.
- Wear and Tear: Aging components affecting device performance.
- Technological Advances: Keeping up with updates and advancements.

9. Benefits of Calibration:

- Enhanced Patient Safety: Accurate measurements lead to proper diagnoses and treatments.
- Compliance with Standards: Meeting regulatory requirements.
- Extended Device Lifespan: Regular calibration can prevent wear and maintain performance.

10. Documentation and Record-keeping:

- Calibration Certificates: Issued after each calibration, specifying results and adjustments.
- Electronic Records: Digital databases for easy accessibility and tracking.

11. Training and Competency:

- Trained Personnel: Ensure that individuals conducting calibration are skilled and knowledgeable.
- Continuous Training Programs: Keeping staff updated on new technologies and procedures.

12. Future Trends:

- Advancements in Technology: Integration of smart sensors for real-time monitoring.
- Predictive Maintenance: Using data analytics to predict when calibration is needed.

13. Conclusion:

- Reinforce the critical role of calibration in maintaining the accuracy and reliability of medical devices.
- Emphasize the impact on patient outcomes and overall healthcare quality.
- Calibration is an ongoing process that contributes significantly to the overall quality and safety of healthcare delivery. Regularly calibrated medical devices play a vital role in providing accurate data for medical professionals to make informed decisions and ensure the well-being of patients.

Project Cost

The total cost includes the following items	Amount / $	Note
Test Equipment		Addition 1 calibration equipment list
Transfer of an internationally accredited calibration company to Kurdistan		
Establishment of national medical device inventory system for MOH		
Laboratory setup		Rent of space and equipment
Vehicles		3 vehicles
Staff Training Program (2 month) 3 trainer came outside		
TOTAL		

LIST OF CALIBRATION TEST DEVICES - 3 SETS

	QTY	Price / $
SET	1	
a. Electrical Safety Tester	1	
i. IEC ISO 60601		
ii. IEC ISO 62353		
b. Patient Simulator	1	
i. EKG		
ii. SPO2		
iii. IBP		
iv. NIBP		
v. EtCO2		
vi. CO		
vii. Respiratory		
viii. Heat		
c. Defibrillator and Pacemaker Analyzer	1	
D. Flow and Gas Analyzer (Breathing Group)	1	
i. Flow Analyzer		
ii. Vaporizer Gas Analyzer		
iii. Test Lung		

	QTY	Price / $
to. Electrocautery Analyzer	1	
f. Incubator - Incubator Analyzer	1	
g. Fetal Maternal Simulator	1	
i. Mechanical Heart		
ii. TOCO adapter cables		
iii. USG Adapter Cables		
h. Infusion Injectomat Analyzer (2 channels)	1	
I. USG Phantom	1	
j. USG Doppler Flow Phantom	1	
k. X-Ray Analyzer		
i. kVp, Dose, mAs, HVL (Conventional and Dental X-ray, Fluoroscopy, Mammography, CT, Angiography)	1	
ii. Radiography and CT Quality Control Phantoms		
X-Ray QA Routine Test Phantom	1	

LIST OF CALIBRATION TEST DEVICES - 3 SETS

	QTY	Price / $
Step wedge and HVL Set	1	
steepness phantom	1	
Fluoroscopy Phantom -	1	
Mammography - 6 Filaments - 6 micro calcifications - 3 groups Low contrast detection"	1	
Mammography - AEC, Detector homogeneity, SNR, CNR	1	
CTDI Phantom	1	
CT Ionization Chamber	1	
CTDI Phantom Holder	1	
MR QA Phantom -	1	
Dental QA Phantom	1	
l. Dialysis Systems Analyzer - pH, conductivity, flow, pressure	1	
m. Pressure Calibrator	1	
n. Temperature Calibrator - 5 channels	1	

	QTY	Price / $
he. Temperature Calibrator		
p. Autoclave Data logger and Validation Software (Pressure Temperature)	1	
q. Audiometer Calibration System (Air-Bone)		
i. Sound pressure Meter Analyzer		
ii. Sound Calibrator		
iii. Artificial Ear + Microphone		
iv. Bone Conduction Measurement Module		
r. Clean Room Validation System		
i. Aerosol Photometer	1	
ii. Particle Counting Device (2 cfm)	1	
iii. Aerosol Generator	1	
iv. Smoke Generator	1	
v. Anemometer	1	
vi. barometer	1	

DEVICES WHICH NEED TO CALIBRATIONS

1	ELECTROPHORESIS
2	PATIENT HEATER
3	BLOCK HEATER
4	PATIENT BED
5	OPERATING TABLE
6	ANESTHESIA DEVICE (INCLUDING VAPORISATOR & PATIENT MONITOR)
7	ASPIRATOR (SURGICAL ASPIRATOR DEVICE)
8	THERMOMETHER
9	BABY OPEN BED (RADIANT HEATER)
10	BENMARI
11	PCR
12	MEDICAL REFRIGERATOR
13	DEFIBRILLATOR DEVICE (ECG + MONITOR)
14	EKG DEVICE
15	ELECTROCOTERIAL DEVICE
16	COMBINED ELECTROTHERAPY DEVICE (FTR)
17	ENDOSCOPY DEVICE (ENDOCAM-LIGHT SOURCE-SHAVER-STROBOSCOPY ETC.)
18	OVEN INCUBATOR DEVICE
19	FLOW METER
20	PHOTOTHERAPY DEVICE
21	PATIENT MONITOR DEVICE
22	INcubator DEVICE
23	NST DEVICE
24	AUTOCLAVE & PLASMA DEVICE
25	PACEMAKER DEVICE
26	PIPETTE - MICRO PIPETTE
27	PULSEOXIMETER DEVICE

DEVICES WHICH NEED TO CALIBRATIONS

28	MORGUE
29	ULTRASOUND (FTR)
30	CENTRIFUGE DEVICE
31	NERVE STIMILATOR
32	TEMPERATURE METER / DATA LOGGER
33	TENSION DEVICE
34	SCALE / WEIGH
35	TENS DEVICE
36	THORACIC DRAINAGE ASPIRATOR
37	PNEUMATIC TURNSTILE
38	VACUUM REGULATOR
39	LAMINAR AIR FLOW
40	THORACIC DRAINAGE ASPIRATOR
41	HOLTERS
42	X-RAY
43	PORTABLE X-RAY
44	MAMMOGRAPHY
45	FLUOROSCOPY
46	ULTRASOUND
47	MRI
48	CT
49	PET/CT
50	GAMMA CAMERA
51	C-SLEEVE
52	ANGIO
53	FUME FURNACE
54	ECO DEVICE
55	INFUSION PUMP
56	PERFUSER

DEVICES WHICH NEED TO CALIBRATIONS

57	BONE DENSITOMETER
58	PUVA
59	TREADMILL
60	EVAPORATOR
61	COLD LIGHT SOURCE
62	ECHOCARDIOGRAPHY (STRONG)
63	OPERATING LAMP
64	OXYGEN BLENDER
65	RF KOTER
66	MICROSCOPE
67	HOTPACK BOILER
68	INFRARUG LAMP
69	BLOOD WARMING
70	BIOSAFETY CABINET
71	LIGASURE KOTER
72	PARAFINE BOILER
73	THERMOHYGROMETER
74	TOUR ENGINE
75	WASHING DEVICE
76	DIALYSIS DEVICE
77	EEG DEVICE
78	EMG DEVICE
79	PHACO VITRECTOMMI
80	AUDIO METER
81	AUTOMATIC INJECTOR PUMP
82	VAPORIZER

Medical devices subject to calibration are listed in three phases.

Phase 1 Devices:

These devices are required to be calibrated every 6 months and their calibration periods cannot be changed. They are prioritized in the calibration measurement sequence.

Examples of these devices include: anesthesia devices, anesthesia ventilators, anesthesia vaporizers, ventilators, respirators, incubators, pacemakers, and automatic pipettes.

Phase 2 Devices:

These devices are also required to be calibrated, but their calibration periods can vary from 6 months to 12 months depending on the frequency of use.

Examples of these devices include: bedside monitors, defibrillators, ECG devices, stress ECG devices, electrocautery devices, and radio frequency devices.

Phase 3 Devices:

These devices are required to be calibrated every 12 months and their calibration periods cannot be changed.

Examples of these devices include: open incubators, endoscopic systems, control manometers, phototherapy devices, physical therapy ultrasound devices, centrifuges, X-ray computed tomography, and X-ray devices.

PHASE 1:

- Anesthesia Devices + Ventilators
- Anesthesia Devices Vaporizers
- Ventilators - Respirators (Adult - Pediatric - Servo - Portable - Transport)
- Baby Incubators (Transport-Intensive Care)
- Pacemakers (External Pacemaker)
- Automatic Micropipettes

PHASE 2:

- Bedside Monitors (Cyb-Byb-Kyb-Kvc-Transport)
- Defibrillators (Biphasic-Monophasic)
- ECG Devices (With and without Comment)
- Stress ECG Devices + Treadmiller
- Electrocoterers (Bipolar-Monopolar-Laparoscopic-Ercp)
- Radio Frequency Devices - Ligasure - Termal Wending

PHASE 3:

Open Incubators (Reanimation Beds)
Pain Pumps (PCA)
Pressure - Blood Bags
Baby Beds (With Radiant Heater)
Body Grades (Axilla-Skin-Rectal-Nasal)
Bainmaries (Water heaters-Thermostatic Baths)
Nutrition Food Pumps (Enteral)
Bottle Sterilizers
Steam Autoclaves - Ebro
Burettes - Beakers - Graves
Surgical & Shaver Motors and Charging Units
Cryo Cufflar

Deep Freezers
Digital Sphygmomanometers
Extractors - Gomcolar
Electric-Mobile-Surgical Aspirators (Curettage)
Electrical Safety Test
Electronic hospital beds (EGT)
Endoscopy Systems
Control Manometers
Injector Pumps (Injectomat-Perfuser)
Ethylene oxides (Temp) -Ebro
Fetal Monitors (NST)
Fibrillators

PHASE 3:

Flash Autoclaves- Pre-washing (Purification) Devices

Formaldehydes (Temp) -Ebro

Phototherapy Devices

FTR Diadinamies

FTR Diathermy

FTR Interfransial - Vacuums

FTR Galvani Faradis

FTR Paraffin - Hotpack Boilers

FTR Tensler

FTR Tractions

FTR Ultrasound Devices

Precision Balance

Patient Body Warmers (KVC)

Hemodynamic Monitors - IBP

Hygrometers

Intra - Aortic Balloon Pumps

Irrigators

Heater - Coolers (KAP)

Thickening-Shaking Devices

Heart - Lung Pumps

Blood Bank Cabinets and Warmers

Lead Aprons (+ Troid)

Dry Air Sterilizer

Food Heaters

PHASE 3:

Manometer + Flowmeter O2 tubes Central System.

Manometers

Vacuum Meters (Turbo)

Negative - Positive Central System Flowmeters

Microbiology Incubators (Pasteur Oven-Oven)

Morgue Cabinets

Temperature Measurements of Kitchen-Cellar Cold Storage Cabinets and Dishwasher

O2 concentrators

Automatic Injectors (KVC)

Automatic Turnstiles (Pneumatic)

Pulseoximeters (Spo2)

Rhythm Holters, Blood Pressure Holters

X Ray Bath Devices (Wet)

Centrifuges (Tabletop - Urine - Hematocrit)

Serum Pumps (Infusion)

Hot-Cold Compresses

Nerve Stimulators

Respiratory Function Tester (Sprometer-SFT)

Milk Drawing Pumps

Blood Pressure Devices (Analog-Mercury-Fixed)

Scale, Scale (Adult, Pediatric) - (Digital-Analog) + Height Meter

Telemetries - Including all consoles

Medical Refrigerators

Medical Purpose Refrigerators Ratings

RADIOLOGY PHASE:

- Ultrasonographs - With Probes (Convex-Vaginal-Linear-Intracavitary)
- ECO- (Echocardiography) - With probes
- X-Ray Mangetic Resonances (MR)
- X-Ray Angio Devices (DSA)
- X-Ray Computed Tomographs (CT)
- X-Ray Bone Densitometers
- X-Ray Devices Digital X-Ray
- X-Ray Equipment Conventional X-Ray
- X-Ray Devices Mammography
- X-Ray Devices Portable Mobile X-Ray
- X-Ray Equipment Scopy (C / U Arm)
- X-Ray Panaromic Jaw X-Ray
- X-Ray Dental X-Ray
- Medical Gas System Complete System Test.