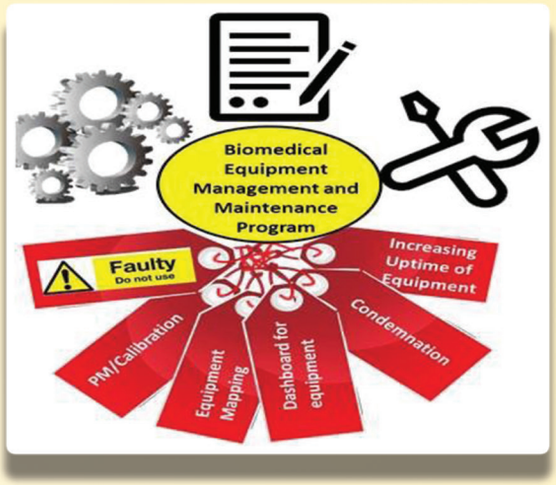
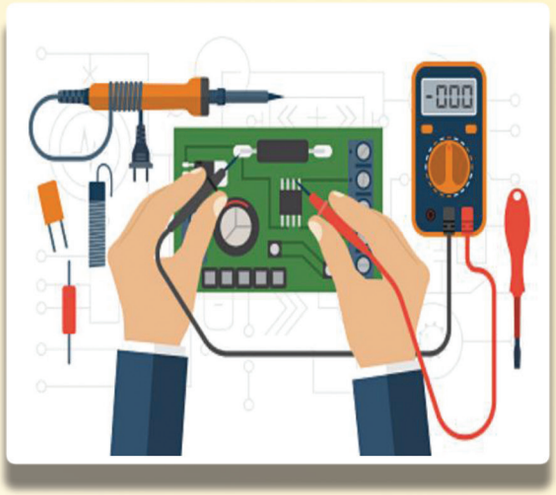
NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

सत्यमेव जयते
Ministry of Health & Family Welfare
Government of India

NHSRC





Guidelines on Equipment Maintenance,Calibration & Testing

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Secretary

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

Message

Successful healthcare delivery depends both on the availability of trained medical personnel and appropriate health technologies. Medical devices are an integral part in the healthcare delivery system. They equip health service providers with the necessary tools to perform their job of providing quality healthcare effectively. Effective and comprehensive equipment maintenance is essential for ensuring the proper functioning of a public health system. It can improve patient outcomes, save costs, increase efficiency, enhance safety, and ensure compliance with regulations.

The National Biomedical Equipment Management & Maintenance Programme (BMMP) launched in 2015 has made significant improvements in public healthcare facilities by ensuring maximum equipment availability and functionality. Few States have adopted good equipment inventory management using in-house online systems and forming facility-level Hospital Equipment Management Committees to undertake equipment audits and identify procurement needs, and hold condemnation boards for obsolete & dysfunctional equipment. Such best practices adopted by a few states should be replicated in all the states for effective biomedical equipment inventory management.

This guidance document is recommended for reference in strengthening the monitoring aspects of equipment maintenance in public health facilities. States/UTs may develop their own SOPs based on the said guidance note and will also help in strengthening the BMMP. I am certain that this technical guidance document would be resourceful for all the States/UTs and contribute to the health systems strengthening.

Date : 14.06.2024
Place : New Delhi

(Apurva Chandra)

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सत्यमेव जयते

आज़ादी का अमृत महोत्सव

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
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Government of India
Ministry of Health and Family Welfare
Nirman Bhawan, New Delhi-110011

MESSAGE

The Ministry of Health and Family Welfare, Government of India launched the National Biomedical Equipment Management and Maintenance Program (BMMP) in the year 2015 for comprehensive maintenance of medical equipment available in public health facilities from the level of Primary Health centre up to the district hospital.

An effective medical equipment maintenance program entails proper planning, timely preventive maintenance & calibration, equipment audit and good asset management. The guidance document on equipment inventory management has been developed as a reference guide for improved programme deliverables.

The guidance document on equipment Maintenance comprehensively addresses the various aspects related to equipment inventory management, asset valuation, and the need for achieving a dynamic medical equipment asset base by carrying out equipment audits with improved in-house equipment monitoring capability under the National Biomedical Equipment Maintenance and Management Program.

I expect all States/UTs to form a Hospital Equipment Management Committee on priority and contextualize this guidance document based on their local requirements to ensure quality equipment maintenance services.

Dated: 18th June, 2024

(Aradhana Patnaik)

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राष्ट्रीय स्वास्थ्य प्रणाली संसाधन केंद्र
Ministry of Health and Family Welfare
Government of India

MESSAGE

Health technologies are essential for a functioning health system. Medical devices are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. It is important, therefore, to ensure that these devices remain reliable, safe, and available for patient care. It is essential to establish a well-structured and well-managed maintenance program.

The National Biomedical Equipment Management and Maintenance Program (BMMP) was launched in the year 2015 with an objective to ensure comprehensive maintenance of equipment linked with upkeep time of 95% for DHs, 90% for CHCs and 80% for PHCs. The program supports States/UTS both in-house and PPP mode to maintain equipment inventory, repair and undertake CMC/AMC for keeping maximum equipment functional in the health facility.

Planning and acquisition of medical equipment is a continuous process. It is imperative to assess its operative functionality and utilisation. The medical technology is changing at rapid pace and maintenance of old and historical equipment at the health facility has become a huge challenge. Periodical equipment survey and equipment audit helps in identifying the dysfunctional equipment and take timely corrective action. For success of the program, however, it is essential that there should be good maintenance service, an efficient system of data collection, and documented policies & procedures governing every aspect of equipment management.

I am sanguine that this guidance document shall be useful resource material for the States/UTS for effective monitoring and implementation of Biomedical equipment management & maintenance programme in the public health facilities.

(Maj Gen (Prof) Atul Kotwal)

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PART 1
Strengthening Equipment Maintenance

The document is to be read in conjunction with the approved Report on Modalities for procurement and Maintenance of Medical Equipment vide DGHS Office Order No. Z-28016/35/2024-PMSSY-IV-Part (1) (8288538) dated 30th August 2024.

Guidelines on Equipment Maintenance

Introduction

1. Medical equipment contributes to the quality of healthcare services on several levels. They play a key role in the diagnosis, the treatment, and the rehabilitation of the medical impairment and diseases. Equipment maintenance includes a set of activities to keep equipment in optimum working condition and consists of periodic inspection, preventive maintenance, calibration and breakdown maintenance. The equipment maintenance objective is to ensure maximum availability with minimum downtime, maximum reliability, extend the useful life of equipment, prevention of wastage of consumables & spares and maximize return on investment.
2. Modern day hospitals are equipment heavy organizations as equipment is an integral part of health technology management and without equipment good patient care is impossible. There is an increasing reliance by the medical community on sophisticated equipment & technology for diagnostic, monitoring and therapeutic activities. Non-functional equipment is a major contributing factor for wasteful expenditure in health facilities. Optimum utilization of equipment requires that the equipment remains in functional order for most of its life. Keeping medical equipment safe and effective will require timely preventive maintenance, calibration and breakdown maintenance services carried out by trained & competent people.
3. Few States have adopted good equipment inventory management using in-house online systems and forming facility level Hospital Equipment Management Committee to undertake equipment audit and identify procurement need, hold condemnation board for obsolete & dysfunctional equipment. Such best practices adopted by a few states should be replicated in all the states for effective biomedical equipment inventory management. The best practices have been included in the ibid guidelines which will help to ensure that equipment being used at the public health facilities, is:
   (a) Suitable for its intended purpose
   (b) Properly understood by appropriately trained users
   (c) Maintained in a safe and reliable condition
4. A good Equipment management Program demands a multidisciplinary equipment management committee at the core of the program which can provide a participatory mechanism for prudent, need based, purchases, planned maintenance with minimum downtime and optimal utilization with maximum returns.

Levels of equipment maintenance

5. The levels of equipment maintenance are:
   (a) By operator (day-to-day maintenance)
   (b) By in-house biomedical engineer
   (c) By OEM trained service engineer or trained BME

National biomedical equipment management and maintenance programme

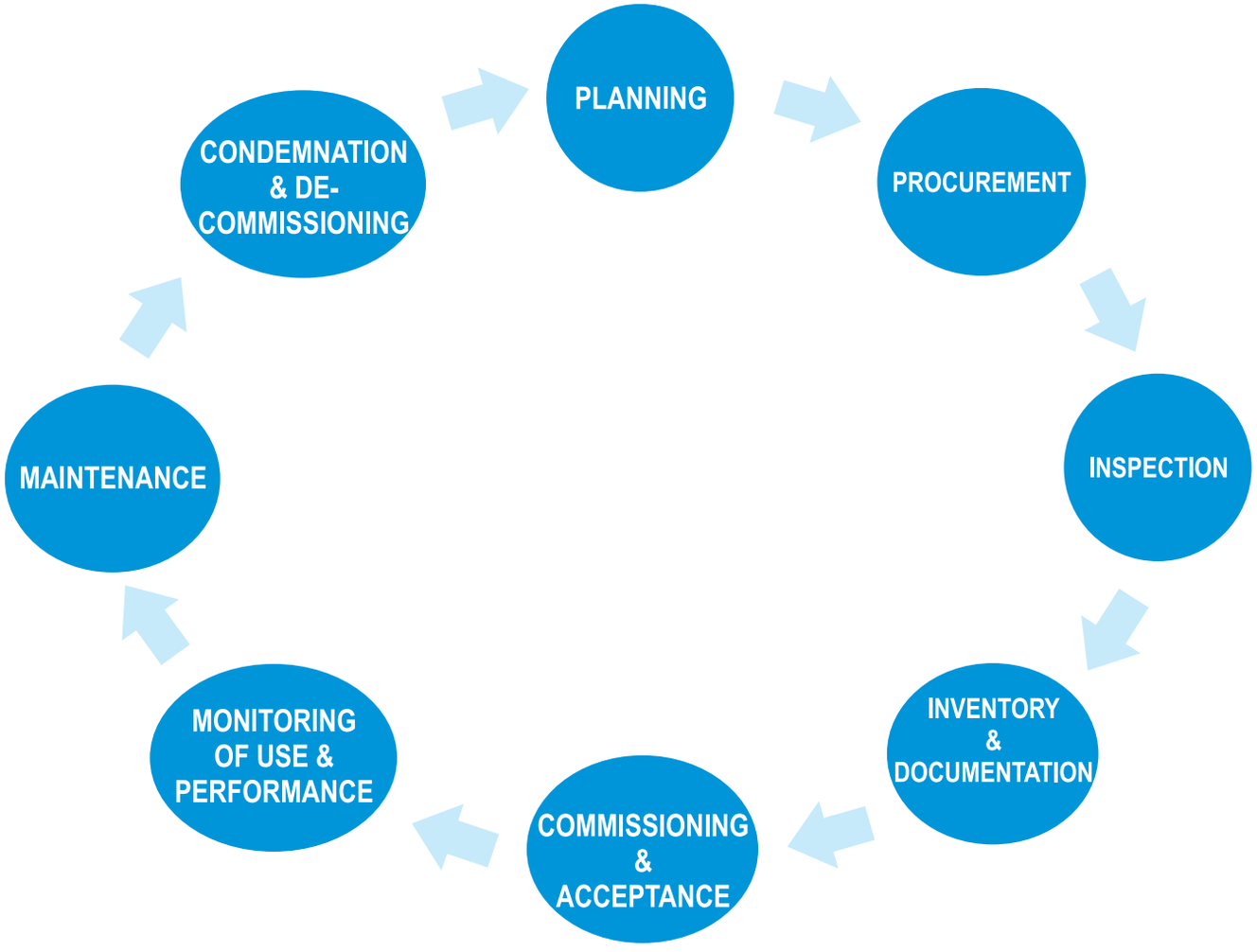
6. The National Biomedical Equipment Management & Maintenance Programme (BMMP) is in operation since 2015. Financial support is provided under National Health Mission to the states/UTs under the programme for equipment maintenance activities and its upkeep, through annual Programme Implementation Plans (PIPs). The services are offered both in the PPP mode or through in-house mode as per the state's requirement.

7. The program envisages to provide support by outsourcing medical equipment maintenance in the PPP mode, to improve the functionality and life of equipment, simultaneously improving healthcare services in public health facilities by reducing the cost of care and improving the quality of care. The program is operational in 30 States and UTs through Outsourcing mode as well as in-house mode. The outsourcing model of service delivery is as per the NHM guidelines on National Biomedical Equipment Management and Maintenance Program. The in–house mode of service delivery is based on maintenance through Original Equipment Manufacturers (OEMs) by engaging through Comprehensive Maintenance Contract (CMC) or Annual Maintenance Contract (AMC).

8. However, in the both the modes of operation, availability of Biomedical Engineer & Technician at the district & facility level is essential for the successful outcome of the Biomedical Equipment Management & maintenance programme. IPHS-2022 has also recommended a post for Biomedical Engineer in the District Hospitals to oversee equipment maintenance as per AMC at public health facilities within the district. The engineer will also be responsible for training of technicians on equipment handling and ensuring calibration of equipment.

Life cycle of medical equipment

9. The delivery of the best healthcare services depends heavily on reliable medical equipment, weather for life support, for diagnosis, for patient monitoring or for the delivery of therapies or teaching and research purposes. The risks associated with the use of medical equipment can only be controlled by managing the whole life cycle of the equipment.



Categorization of medical equipment

10. There is a need to categorize the equipment for mapping the asset base and prioritizing the maintenance activities. One of the suggested methods for categorization of equipment is given below :

Sl. No.	Category of Equipment	Criteria for Categorization
(a)	Sophisticated Electro Medical Equipment	Electro Medical equipment which are costly & sophisticated supplied by OEM and spares easily not available in the local market.
(b)	Electro Medical Equipment	'Plug & Play' medical equipment which do not require OEM intervention and spares available in the local market and the complaints can be resolved by the in-house Biomedical engineer or through the service provider
(c)	Non-Electro Medical equipment	Medical Equipment which does not require electricity for operation and are mechanical in nature and less chances for breakdown. Complaints can be resolved or certified regarding its dysfunctional by the in-house Biomedical Engineer/ Service provider.

11. The summary of the number of equipment categorized as per healthcare facility level based on criticality and Electromedical (Plug & Play) characteristic, as per IPHS-2022 is given below:

Facility Level	Critical	Non-Critical	Electromedical	Non-Electromedical
SC-HWC	Nil	13	Nil	13
PHC-HWC	5	40	17	28
CHC	21	85	69	37
DH	31	112	97	46

12. The list of equipment asset categorization at each level of healthcare as per IPHS-2022 is placed as Annexure 'C' to this document. The List of critical lifesaving medical equipment (Sophisticated Electromedical) approved by MoHFW (Annexure 'B') is reproduced below :

Sl. No.	Equipment Nomenclature	Sl. No.	Equipment Nomenclature
1.	Ventilator	14.	Bio-Chemistry Analyser
2.	CT Scan Machine	15.	Dental Chair (motorised)
3.	MRI machine	16.	Multi Para Monitor
4.	ECG Machine	17.	Emergency Resuscitation Kit
5.	Defibrillator	18.	Anaesthesia Machine
6.	Infusion Pump	19.	Anaesthesia workstation
7.	C-PAP/Bi-PAP machine	20.	Ultrasound Machine
8.	Baby Incubator (Phototherapy)	21.	Mammography Unit
9.	Oxygen Concentrator	22.	X-Ray Machine
10.	Suction Apparatus	23.	Radiant Warmer
11.	ABG Analyser	24.	ELISA Reader
12.	Haemodialysis Machine	25.	Laser Therapy Unit
13.	Haematology Analyser	26.	Any other equipment identified by the State/UT

Hospital equipment management committee (HEMC)

13. For effective monitoring and supervision of the quality of services being provided by the service provider in PPP mode, a Hospital Equipment Management Committee is considered essential. The suggested composition would be as follows:

    (a) MS Hospital/ AMS or MO IC health facility

    (b) Head or Nominated members from clinical specialties

    (c) Biomedical Engineer

    (d) Store in Charge

    (e) Purchase Officer/ Finance Officer

    (f) Nursing Superintendent

14. The HEMC should hold a meeting, at least once in a quarter to discuss regrading the equipment functionality and its maintenance. The HEMC will also undertake the following activities:

    (a) Receive proposals from the respective departments

    (b) Evaluation of the proposals received from the department for procurement/induction of new equipment and the justification provided after need analysis and cost-benefit analysis.

    (c) Receipt, Installation & Commissioning of new equipment at the hospital.

    (d) Training of the user staff in operation & maintenance of the equipment

    (e) Preparation of Equipment Master Maintenance Plan consisting of the scheduled preventive maintenance & calibration of the equipment

    (f) Undertake review of equipment inventory (Equipment census) available and their utilization once in a year. List out functional, dysfunctional & repairable or BER equipment.

    (g) Carry out equipment audit and review the asset base with addition of new equipment and its valuation, deletion of BER/Condemned equipment from the asset base.

    (h) Monitoring the activities of the maintenance service provider (in PPP), complaint management, equipment downtime, and ensuring preventive maintenance & calibration are carried out as per the OEM recommendations.

    (i) Monitor weeding out of the old/obsolete equipment declared beyond economic repairs and recommend proposal for condemnation to the SHS/Md NHM.

    (j) Record achievement of the Key deliverables approved for the BMMP at the facility and forward a copy to the SHS/SNO BMMP/MD NHM office for collation and inclusion in the annual PIPs.

    (k) The committee shall undertake analysis of the records pertaining to equipment breakdown and preventive maintenance logs. They shall also assess the usage and performance of the equipment. The committee shall also suggest measures to optimally utilize the equipment for quality health services.

Equipment audit

15. Equipment audit is a periodic evaluation system to measure the quality of performance of the medical equipment. The focus of the equipment audit should be to assess the current status of the medical equipment, carry out equipment census, analyze the records of breakdown, preventive maintenance, service engineer report, record the feedback from user experience in the usage and performance of the equipment, electrical reasons, if any etc. The equipment audit should clearly bring out the reason for dysfunctional equipment which could be as follows:

(a) Want of minor repairs

(b) Lack of Preventive maintenance

(c) Lack of corrective maintenance

(d) Lack of essential spares

(e) Electrical faults

(f) Unfavorable equipment conditions

(g) Mishandling of equipment by untrained and unskilled manpower

(h) Purchase of equipment without justifiable demand etc

(i) False reporting, willful damage and overuse than rated.

Key deliverables under BMMP for PIPs

16. The key performance indicators for the National Biomedical Equipment Management & Maintenance Programme are as follows:

(a) Equipment CAMC/AMC (in Percentage) : Percentage of equipment covered under comprehensive maintenance contract/Annual maintenance contract.

(b) Numerator : Total No. of equipment covered under warranty/CAMC/AMC **Denominator :** Total No. of equipment held in the inventory.

Equipment upkeep time (in Percentage) : Percentage of equipment uptime at each level of Public Health facility as per BMMP guidelines i.e. (PHC-80%, CHC-90% and DH-95%)

Numerator : Total No. of equipment found functional at the facility during census

Denominator : Total No. of equipment held in the inventory (asset base) at the facility.

Inventory and documentation

17. Inventory management is a key component of equipment management. It provides information to support various aspects of medical equipment. Online inventory management is an ideal option developed in-house or customized by the state. Online inventory helps in analytics and good record keeping. Further, States should also ensure that the admin control of the IT dashboard and safe custody of the server holding BMMP data is secured with the State Health Society/NHM office, in the case of PPP service provider.

18. States where the BMMP is operational, the service provider has an IT dashboard for recording complaints and inventory management. However, for the states where the BMMP is operational in-house, online inventory management & maintenance is always beneficial and should be adopted. Centralized equipment inventory management application like eUPKARAN (equipment management & maintenance system) is more efficient than the traditional paper-pen system for effective BMMP service delivery. The format for the Equipment Logbook and inventory master record is given in Annexure 'E' and 'F' respectively.

Types of maintenance

19. Maintenance of equipment is classified as :

(a) Preventive or scheduled maintenance : This is the maintenance carried out at Predetermined intervals or according to the manufacturer's recommendation to reduce the probability of equipment failure. The major advantage of the preventive maintenance is reduction in equipment downtime, ensures safety of equipment, extended useful life of equipment, availability during emergency.

- Preventive maintenance of all the equipment held at the facility whether in use or not shall be done periodically as per the recommendation of manufacturer/supplier.; so that functioning status of the equipment is known, and the equipment is readily available whenever required.
- In critical areas like casualty, ICU, OT daily inspection of the life saving critical equipment is required and standby active unit should be kept ready so that patient do not suffer in case of equipment failure. BMMP guidelines has the provision for the service provider to supply alternate machine till the equipment downtime for ensuring patient safety and continuity in patient care.
- Availability of good quality spares/ consumables and accessories is essential and helps in prolonging the useful life of equipment.

(b) Breakdown or Corrective Maintenance : This is the maintenance carried out after fault recognition and is intended to put equipment into a state in which it can perform a required function. It is important to analyze the reason for the breakdown/shut down and ensure early rectification. The user should record details of the breakdown/defect/fault and attach label to the faulty equipment so that it is not used by other staff. The user should immediately contact the service engineer/service provider and log his complaint using Toll Free number provided by service provider/OEM for call resolution.

20. The service provider/OEM carrying out the repairs should give a guarantee/ warranty certificate stating that the equipment serviced by them will render trouble free service for a defined period. In case the equipment breakdowns within the warranty period, it should be repaired free of cost.

Maintenance contract

21. The process for fresh maintenance contract (AMC/CMC/Warranty) of the equipment should be initiated 3 (three) months in advance, before the expiry of the warranty/CAMC/AMC period. The necessary concurrence from the finance department of the institution required for the renewal of the contract/fresh contract shall be taken well in advance so that equipment remains functional, and downtime is minimized.

TYPE OF SERVICE	SERVICE CONTRACT	CHARGES
Annual Maintenance Contract (AMC)	AMC starts after expiry of the warranty period. Third party service provider or OEM	Only Service provided. Fixed Charges Renewed every year. Cost of spares used is billed
Comprehensive Maintenance Contract (CMC)	Variable response time Third party service provider or OEM	Service charges included. Minor consumables & spares free of cost
Warranty (Full Service with parts or Replacement)	Quick response available at all times for maintenance & repair	Fixed charges usually embedded in the procurement cost

22. The specialized and lifesaving critical equipment will require comprehensive maintenance contract (CMC) with all the spares included. The procurement of the equipment should preferably be done with 02 years warranty and 08 years CMC. The rates approved for post warranty CMC, will be as per the RFP terms & conditions for the the duration of the contract period and the rate cannot be modified by the vendor, unless there is a clause to do so.

Warranty management

23. Warranty management requires good record keeping and timely renewals. National Biomedical Equipment Management & Maintenance Programme has the provision for the District Biomedical Engineer to monitor the equipment asset base. The asset register must be updated periodically with the arrival of any new equipment and deletion of equipment recommended BER/condemnation. Penalty provisions in the service level agreement must be invoked for non-compliance by the service provider/OEM.

Commissioning and acceptance of the equipment

24. The procurement agency/competent authority should ensure installation and commissioning of the equipment by the manufacturer/supplier at the health facility. The date of the installation should be communicated in advance to the health facility. Requisite power connections, earthing, serviceability of the electrical line, air-conditioning equipment, online voltage regulator/stabilizer etc should be ensured before installation. The process should be monitored by in-house technical staff/user so that any important 'Dos & DON'T's' can be recorded in the maintenance/equipment history log register. The occasion also provides an excellent opportunity for the in-house staff to gain familiarity with the new equipment and get trained in its operation.

Monitoring of use and performance

25. It is important that user should safely use the equipment and also monitors the performance of the equipment. User should immediately register complaint through the TOLL- FREE number provided by the service provider/OEM and monitor the real time breakdown time. The user should maintain a record of all such breakdown and the reason attributed for the same to take future preventive action. The user should undertake visual inspection, power-on/off & performance test, report errors due to equipment failure (calibration) etc. These tasks must be carried out by the user as per the manufacturer's instructions and documented in the equipment logbook. Any discrepancy found, should be brought into notice of the head of department/HEMC for necessary corrective action.

Equipment life

26. The physical life of equipment is identified as service life, which is the time period till the equipment can no longer be operated. This is greatly impacted by the repair & maintenance attention that the machine has been provided over its lifespan. Equipment that has not been given adequate maintenance throughout its lifespan will deteriorate at a faster rate than a machine that was given substantial preventive maintenance.

27. Economic life is based on decreasing ownership costs with the increase in operating costs. The time period that these costs are equivalent is called the economic life. The useful life of a medical equipment is not the same as actual life of an asset. A piece of equipment may last far longer than its estimated useful life but will need higher maintenance resources. In addition, an equipment may become obsolete or require major repairs but still be technically functional but may be a more of liability than a benefit as it may require frequent repair work. In such case when spares are not available in the open market then sustenance becomes less cost effective and should be recommended for condemnation.

Asset management

28. Asset management provide the means through which likely future equipment needs are identified, criteria for prioritising needs are set and informed decisions on spending priorities are made. Decisions based on asset management plans should lead to greater efficiency in the use of medical equipment. A key output from the plan should be a prioritised equipment procurement program, regularly updated, that addresses the most serious and urgent needs of hospitals.

29. The strategies for hospital medical equipment procurement should include scientific need or gap assessment, value based procurement, timely maintenance, repairs, optimum utilization, and timely replacement. Equipment availability, functionality, effective, efficient utility assessment are the bedrock of any equipment management program. Care should be taken to avoid supplier induced demands, indiscriminate use, duplication, and underutilisation of any equipment.

Approach to medical equipment valuation

30. Depreciation represents the decline in value of a piece of equipment due to age, wear, deterioration & obsolescence. Depreciation can result from either physical deterioration occurring from wear & tear of the machine or due to economic decline or obsolescence occurring over the passage of time. There are two common techniques for calculating depreciation.

    (a) Straight Line Method

    (b) Written down Value (WDV) Method

Straight line method

31. Straight-line method also known as constant charge method used for charging depreciation in which depreciation is charged on annual basis. The depreciation charged in this way remains constant throughout the useful life of the asset. The depreciation is calculated by dividing a fixed asset's depreciable base by its useful life. The depreciable base is the difference between an asset's all-in costs and the estimated salvage value at the end of its useful life. With the straight-line depreciation method, the value of an asset is reduced uniformly over each period until it reaches its salvage value.

$$\text{Annual Depreciation Expense} = \frac{(\text{Procurement Cost of the Asset} - \text{Expected residual value})^*}{\text{Useful life of the Asset}}$$

* Residual Value = Expected re-sale value as scrap beyond equipment useful life

Illustration : straight line depreciation method

Public Health Facility purchases an Ultrasound machine for INR 10,00,000 with an estimated expected residual value of INR 10000 after a useful life of 10 years.

The straight-line depreciation for the machine would be calculated as follows :

Calculate annual depreciation expense

(INR 10,00,000 – 10,000) / 10 years = INR 99,000 depreciation amount per year.

Therefore, over the useful life of the asset, the value would depreciate to its salvage value.

Year	Book Value (Beginning of the FY) in INR	Depreciation Value in INR	Book Value in INR (Close of the FY)
1.	10,00,000	99,000	901000
2.	901000	99,000	802000
3.	802000	99000	703000
4.	703000	99000	604000
5.	604000	99000	505000
6.	505000	99000	406000
7.	406000	99000	307000

8.	307000	99000	208000
9.	208000	99000	109000
10.	109000	99000	10000

Written Down Value (WDV) method

32. WDV method is the most common used method of depreciation. In this method a fixed depreciation rate is charged on the book value of asset and book value is decreased each year by subtracting the depreciation amount as calculated. This method is also called reducing balance method. In the WDV method, the amount of depreciation goes on decreasing with time. This method is considered as the most logical method of depreciation and good for high value equipment where the useful life is difficult to predict.

33. For Eg- Asset is purchased at INR 1,00,000 and depreciation rate is 10% then first year depreciation is INR 10,000 (10% of INR 1,00,000), second year depreciation is INR 9,000 (10% of 90,000 [1,00,000 – 10,000]) and third year depreciation is INR 8100 (10% of INR 81,000 [90,000 – 9,000]).

Year	Book Value (Beginning of the FY) in INR	Depreciation Value (10% of cost) in INR	Book Value in INR (Close of the FY)
After First Year	1,00,000	10000	90,000
2	90,000	9000	81000
3	81000	8100	72900
4	72900	7290	65610
5	65610	6561	59049
6	59049	5904	53145
7	53145	5314	47831
8	47831	4783	43048
9	43048	4304	38744
10	38744	3874	34870

34. In view of the above, it is prudent to take the average useful life span of medical equipment as 10 years. However, if well maintained medical equipment may continue to be used for a longer time. Old medical equipment which has serviced beyond its useful life is likely to be technologically obsolete and difficult to support as spare availability in the market is a big challenge. Several high med medical equipment are quite sturdy *e.g.*, CT & MRI machine which do not necessarily face functional obsolescence, as fast as others.

35. For historical equipment (Equipment has outlived its useful life *i.e.*, more than 15 years except high end equipment), the book value calculated at the close of FY using the WDV method would be the asset value and to be taken for asset calculation purpose. In few instances when the cost of the historical equipment or the date of installation is not known and records supporting the same are not available in the health facility, a notional value mutually agreed upon by the state health authority and the service provider, not exceeding the valuation calculated by the WDV method using the discovered cost of the equipment as on the date and the probable age of the equipment may be taken for asset valuation purpose.

36. Statutory Requirements :

    (a) In India Radiology equipment need to be registered with and have operating license from AERB. AERB no longer permits usage of radiology equipment that is older than 10 years. Existing equipment should have de-commissioning approval from AERB to be provided approval for purchase and re-installation. Any equipment which currently does not have AERB license simply cannot be re-installed, so it has

only scrap value. AERB could shut down operations of any unit not in compliance with its radiation safety requirements.

(b) All Ultrasound machines must have PC-PNDT license before purchase and NOC is required from local Health authorities to sell and transfer ultrasound machine.

37. The adoption of effective maintenance practices by hospitals is essential if medical equipment is to function as intended. It is also important to prevent equipment breakdowns that could interrupt the delivery of healthcare services or be potentially harmful to patients or staff. To achieve a good inventory control, the following is recommended :

- Prepare 'Asset Management Plan' with yearly forecasts of funding requirements for the medical equipment.
- Develop a 'Single Master Asset Register', using standard classifications to describe the medical equipment and specified details of the equipment, as per the Guidelines given in National BMMP.
- Develop and use guidelines which reflect industry best practice to periodically assess the life expectancy of the equipment.
- Regularly determine the condition of the medical equipment using a standardized assessment system.
- Undertake yearly equipment census and audit for categorizing the inventory as functional, dysfunctional – needs repair, dysfunctional – beyond economical repair and prepare a list of equipment for condemnation and hold the condemnation board as per the National Biomedical Equipment Management & maintenance programme.

38. Given the sophistication of modern medical equipment, maintenance practices can be very complex, requiring expertise in a broad range of specialities such as electronics, computers, mechanical systems, pneumatics, chemicals and optical systems. Generally, hospitals use a combination of in-house maintenance staff (biomedical or engineering departments) and external maintenance services, such as those provided by the equipment supplier, or a third-party provider.

39. For major items of equipment, virtually all maintenance is carried out under comprehensive service contracts. The service is provided by either the vendor or by multi- vendor service companies. The in-house biomedical engineering department generally provide a first-response service, checking the equipment for simple faults before calling the contractor, and at some hospitals they also monitor the service contracts.

40. An important responsibility for asset managers is to ensure that maximum benefit is derived from their assets. Accordingly, asset managers need to be mindful where, for example, equipment is no longer effective in performing the activities required of it, it is in less than optimum condition, or demand for the services it delivers or supports has reduced. Underutilised equipment should be identified and the reasons for this examined and, as far as possible, rectified.

Training and development

41. Proper training is critical for the safety of patients and the user. The user should be trained in operating the equipment safely, basic knowledge of possible faults, DO's & DON'T's, rectifying minor causes of failure and calibration requirement.

Conclusion

42. A good equipment management program needs to be established at levels of healthcare, which is an essential requirement for patient safety and optimal use of the medical equipment. A proactive HEMC is the key to achieve good equipment maintenance program and functional equipment inventory. For success of the program, however, it is essential that there should be good maintenance service, an efficient system of data collection, and documented policies & procedures governing every aspect of equipment management.

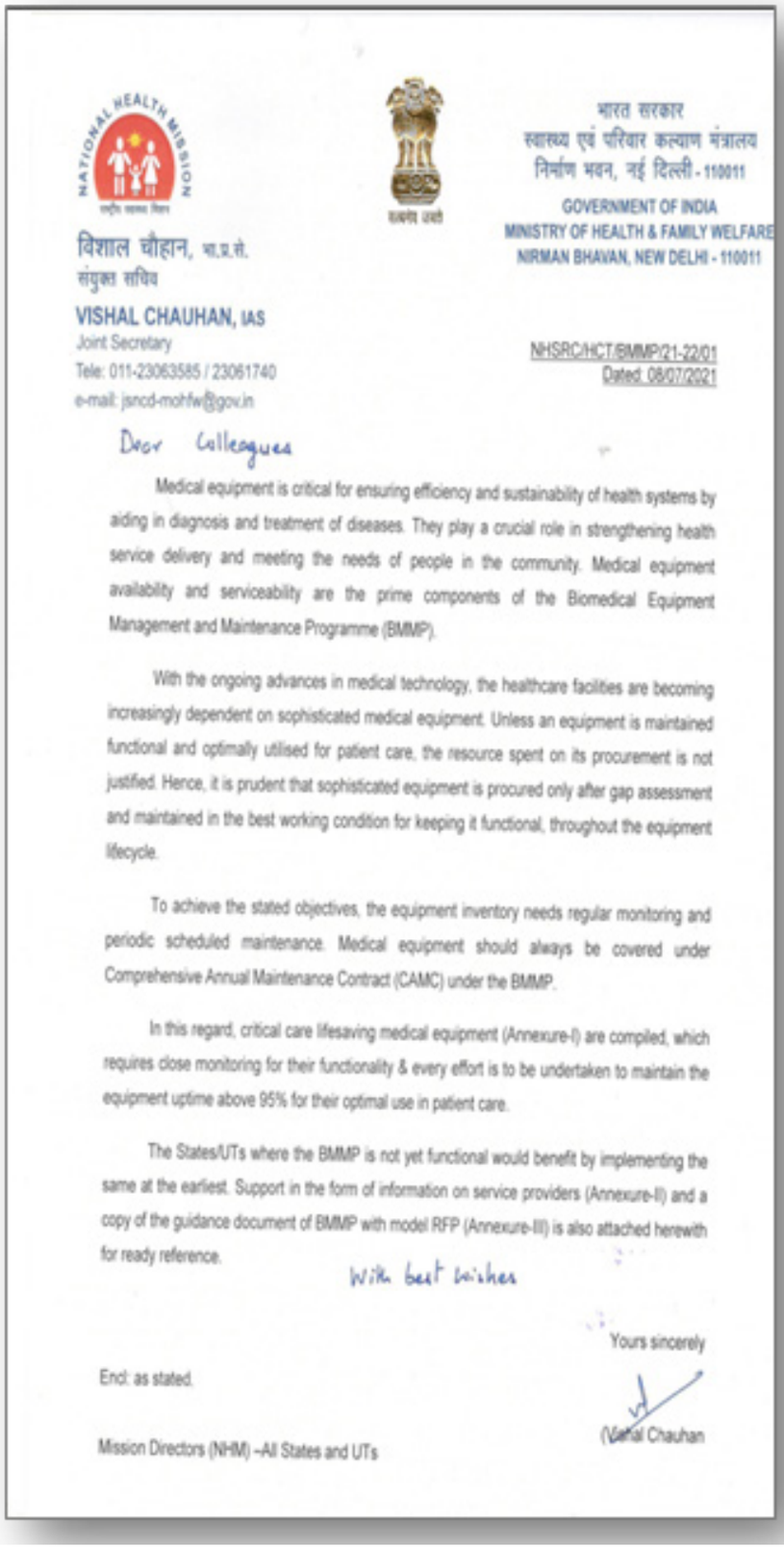
Annexure-A : Preventive Maintenance and Calibration Frequency for Biomedical Equipment Listed under IPHS -2022

Sl. No.	Name of the Equipment	Visits/ year
1.	Arterial Blood Gas Analyser	4/year
2.	Autoclave	4/year
3.	Automated analyser for blood cultures	4/year
4.	Automated coagulation analyser,	4/year
5.	Bubble CPAP with compressor,	4/year
6.	C arm with accessories*	4/year
7.	C.T. Scan Multi slice (64 SLICES)	4/year
8.	Cardiac monitors	4/year
9.	Chemiluminescence Immuno- assay	4/year
10.	Dental chair (complete system)	4/year
11.	Dialysis machine	4/year
12.	Dialyzer reprocessing unit	4/year
13.	Electrolyte analyser	4/year
14.	Electrophoresis machine	4/year
15.	ELISA Reader and Washer	4/year
16.	Flow cytometer.	4/year
17.	Fully automated Biochemistry analyser	4/year
18.	Haematology analyser (5 Part/3 Part)	4/year
19.	HPLC machine,	4/year
20.	Infusion pump	4/year
21.	Mammography unit	4/year
22.	Multi para-Monitor	4/year
23	Phototherapy	4/year
24.	Portable ultrasound	4/year
25.	Radiant warmer,	4/year
26.	Semi-automated Biochemistry analyser	4/year
27.	Surgical diathermy – bipolar	4/year
28.	Transport incubator,	4/year
29.	Transport multi parameter monitor	4/year
30.	Transport ventilator	4/year
31.	Ultrasound machine	4/year
32.	Colour Doppler and Echo	4/year
33.	Ventilator-Adult, Paediatric and Neonatal	4/year
34.	X-ray machine fixed (60 ma/ 100 ma/ 200 ma/ 300 ma/ 500 ma/ 850 ma/ 1000 ma	4/year

35.	ACT machine,	4/year
36.	100 M.A. X-ray machine (Mobile),	2/year
37.	A-Scan Biometer,	2/year
38.	Ambu bag (adult & paediatrics)	2/year
39.	Applanation Tonometer	2/year
40.	Auto- refractometer	2/year
41.	B- Scan Biometer	2/year
42.	Baby weighing scale –Digital,	2/year
43.	Blood warmers	2/year
44.	Bowl Sterilizers – Different Sizes,	2/year
45.	BP Apparatus – Neonatal Cuff,	2/year
46.	Centrifuge	2/year
47.	Cryosurgery unit	2/year
48.	CTG machine	2/year
49.	CTG Monitor	2/year
50.	Defibrillators	2/year
51.	Ear & nasal Suction machine	2/year
52.	EEG Machine	2/year
53.	EMG machine	2/year
54.	ESR analyser	2/year
55.	Examination Light	2/year
56.	Fetal Doppler	2/year
57.	Flash Autoclave	2/year
58.	Foetal Doppler	2/year
59.	Fetoscope	2/year
60.	Fundus Camera	2/year
61.	Glucometer	2/year
62.	Hba1C analyser	2/year
63.	Hemoglobinometer	2/year
64.	Hysteroscopy	2/year
65.	ICU beds	2/year
66.	Interferential therapy	2/year
67.	Intermittent compression device for DVT	2/year
68.	Irradiance Meter	2/year
69.	Keratometer	2/year
70.	Labour bed	2/year
71.	Laryngoscope with 5 Blades (LED),	2/year
72.	Laryngoscopes (LED)	2/year
73.	Microcentrifuge	2/year
74.	Microscope	2/year
75.	Mortuary table (Stainless steel)	2/year
76.	NCV machine	2/year

77.	Nd Yag Laser	2/year
78.	Nebulizer	2/year
79.	Negative Ionizer/air purifier,	2/year
80.	Neonatal Resuscitation Equipment,	2/year
81.	Nucleic Acid Amplification Test (NAAT)	2/year
82.	OCT (Optical Coherence Tomography)	2/year
83.	Operating Microscope	2/year
84.	Ophthalmoscope- Direct,	2/year
85.	Ophthalmoscope- Indirect with 20 D Lens	2/year
86.	OT light	2/year
87.	OT light – Ceiling Double Dome	2/year
88.	OT Table	2/year
89.	Otoscope	2/year
90.	Oxygen Concentrator	2/year
91.	Paediatric ICU Beds	2/year
92.	Paediatrics Resuscitation Equipment	2/year
93.	Phaco Machine	2/year
94.	Portable LED Standing light	2/year
95.	Pulse oximeter with Neonatal Wrap up	2/year
96.	Punch biopsy gun	2/year
97.	Real time Polymerase Chain Reaction	2/year
98.	Slit lamp	2/year
99.	Sphygmomanometer	2/year
100.	Spiro meter	2/year
101.	Streak retinoscope	2/year
102.	Suction Machine (Electrical)	2/year
103.	Suction machine (foot-operated)	2/year
104.	Syringe pump,	2/year
105.	TENS	2/year
106.	Transcutaneous Bilirubinometer	2/year
107.	Turbidimeter	2/year
108.	Ultrasonic nebulizer	2/year
109.	Ultrasound therapy	2/year
110.	VEP machine	2/year
111.	Arthroscope	2/year
112.	Anaesthesia Work Station	2/Year
113.	Weighing machines (Organs)	2/year
114.	Bi-PAP/CPAP	2/year
115.	Dental X-ray machine	2/year
116.	ECG machine	2/year
117.	Electric cautery	2/year

Annexure-B : D O letter from MoHFW on Identification of Critical Equipment



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAWAN, NEW DELHI - 110011

विशाल चौहान, भा.प्र.से.
संयुक्त सचिव

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NHSRC/HCT/BMMP/21-22/01
Dated: 08/07/2021

Dear Colleagues

Medical equipment is critical for ensuring efficiency and sustainability of health systems by aiding in diagnosis and treatment of diseases. They play a crucial role in strengthening health service delivery and meeting the needs of people in the community. Medical equipment availability and serviceability are the prime components of the Biomedical Equipment Management and Maintenance Programme (BMMP).

With the ongoing advances in medical technology, the healthcare facilities are becoming increasingly dependent on sophisticated medical equipment. Unless an equipment is maintained functional and optimally utilised for patient care, the resource spent on its procurement is not justified. Hence, it is prudent that sophisticated equipment is procured only after gap assessment and maintained in the best working condition for keeping it functional, throughout the equipment lifecycle.

To achieve the stated objectives, the equipment inventory needs regular monitoring and periodic scheduled maintenance. Medical equipment should always be covered under Comprehensive Annual Maintenance Contract (CAMC) under the BMMP.

In this regard, critical care lifesaving medical equipment (Annexure-I) are compiled, which requires close monitoring for their functionality & every effort is to be undertaken to maintain the equipment uptime above 95% for their optimal use in patient care.

The States/UTs where the BMMP is not yet functional would benefit by implementing the same at the earliest. Support in the form of information on service providers (Annexure-II) and a copy of the guidance document of BMMP with model RFP (Annexure-III) is also attached herewith for ready reference.

With best wishes

Yours sincerely

Encl: as stated.

(Vishal Chauhan

Mission Directors (NHM) –All States and UTs

DRAFT LIST OF CRITICAL LIFESAVING EQUIPMENT

S. No.	Equipment	Equipment Category
1	Ventilator	Sophisticated Equipment
2	CT Scan	Sophisticated Equipment
3	MRI	Sophisticated Equipment
4	ECG machine	Electromedical Equipment
5	Defibrillator	Electromedical Equipment
6	Infusion Pump	Electromedical Equipment
7	C-PAP/Bi-PAP Machine	Sophisticated Equipment
8	Baby Incubator (Phototherapy)	Electromedical Equipment
9	Oxygen Concentrator	Electromedical Equipment
10	Suction Apparatus	Electromedical Equipment
11	ABG Analyser	Sophisticated Equipment
12	Haemodialysis machine	Sophisticated Equipment
13	Auto Haemato-analyzer	Sophisticated Equipment
14	Auto bio-chemistry analyser	Sophisticated Equipment
15	Dental Chair (PCB)	Sophisticated Equipment
16	Multi para monitor	Electromedical Equipment
17	Emergency Resuscitation Kit	Electromedical Equipment
18	Anesthesia machine	Sophisticated Equipment
19	Anesthesia workstation	Sophisticated Equipment
20	Ultrasound machine	Sophisticated Equipment
21	Mammography unit	Sophisticated Equipment
22	X-Ray machine	Sophisticated Equipment
23	Radiant warmer	Electromedical Equipment
24	ELISA Reader	Sophisticated Equipment
25	Laser Therapy unit	Sophisticated Equipment

Annexure-C : IPHS Asset Categorisation (District Hospital)

Sl. No.	Equipment Name	Critical / Non-Critical	Electromedical / Non-Electromedical
1.	Defibrillator with TCP and AED	critical	Electromedical
2.	Defibrillators	critical	Electromedical
3.	ECG 3 Channel	critical	Electromedical
4.	ECG machine- 12 Channel	critical	Electromedical
5.	ECG Machine- 6 Channel	critical	Electromedical
6.	Infusion Pump	critical	Electromedical
7.	ABG analyser	critical	Electromedical
8.	Anaesthesia Machine	critical	Electromedical
9.	Anaesthesia Workstation	critical	Electromedical
10.	Bi-PAP machine	critical	Electromedical
11.	C.T. Scan Multi slice (64 SLICES)	critical	Electromedical
12.	CPAP Machine	critical	Electromedical
13.	Dialysis Machine	critical	Electromedical
14.	Elisa Reader/washer	critical	Electromedical
15.	Fully automated biochemistry analyser	critical	Electromedical
16.	Haematology analyser (3-part)	critical	Electromedical
17.	Haematology analyser (5 part)	critical	Electromedical
18.	Mammography Unit	critical	Electromedical
19.	Mechanical ventilator	critical	Electromedical
20.	MRI 1.5 Tesla	critical	Electromedical
21.	Multi para monitor for ICU	critical	Electromedical
22.	Neonatal Resuscitation Equipment	critical	Electromedical
23.	Open care Radiant warmer	critical	Electromedical
24.	Oxygen Therapy apparatus/HFNC	critical	Electromedical
25.	Portable x-ray machine-200mA	critical	Electromedical
26.	Suction Machine electrical / Suction machine foot operated	critical	Electromedical
27.	USG Machine- portable ultrasound	critical	Electromedical
28.	X Ray 300 mA	critical	Electromedical
29.	x-ray machine 100 mA (Mobile)	critical	Electromedical
30.	x-ray machine 500 mA	critical	Electromedical
31.	Colour Doppler Ultrasound/	critical	Electromedical
32.	EEG machine	Non-Critical	Electromedical
33.	Mobile Spotlight/ Light for conducting deliveries/ Examination lamp with white light/ Examination light	Non-Critical	Electromedical
34.	Transport Incubator	Non-Critical	Electromedical

35.	Blood warmers	Non-Critical	Electromedical
36.	Electrolyte Analyser	Non-Critical	Electromedical
37.	Electrophoresis Machine	Non-Critical	Electromedical
38.	ESR analyser	Non-Critical	Electromedical
39.	Flame photometer	Non-Critical	Electromedical
40.	Multipara monitor	Non-Critical	Electromedical
41.	Syringe Pump	Non-Critical	Electromedical
42.	TENS Machine	Non-Critical	Electromedical
43.	Transport Ventilator	Non-Critical	Electromedical
44.	Applanation Tonometer	Non-Critical	Electromedical
45.	A- Scan and B scan Biometer	Non-Critical	Electromedical
46.	ACT machine	Non-Critical	Electromedical
47.	Arthroscope	Non-Critical	Electromedical
48.	Auditory Brainstem Response machine	Non-Critical	Electromedical
49.	Auto-refractometer	Non-Critical	Electromedical
50.	Automated blood culture analyser	Non-Critical	Electromedical
51.	automated coagulation analyser	Non-Critical	Electromedical
52.	Bowl Sterlizer	Non-Critical	Electromedical
53.	Bubble CPAP with compressor	Non-Critical	Electromedical
54.	CARM with accessories and Image intensifier	Non-Critical	Electromedical
55.	Chemiluminescence Analyser	Non-Critical	Electromedical
56.	Cryo surgery unit (Co2, N2O)	Non-Critical	Electromedical
57.	Cryo surgery unit (Liquid Nitrogen)	Non-Critical	Electromedical
58.	CTG Machine	Non-Critical	Electromedical
59.	Dental x-ray IOP/OPG	Non-Critical	Electromedical
60.	Dialyzer reprocessing unit	Non-Critical	Electromedical
61.	DVT pump (Deep Vein Thrombosis prevention devices)	Non-Critical	Electromedical
62.	ECMO machine	Non-Critical	Electromedical
63.	Electrical cautery	Non-Critical	Electromedical
64.	Flash Autoclave	Non-Critical	Electromedical
65.	Flow Cytometer	Non-Critical	Electromedical
66.	Fundus Camera	Non-Critical	Electromedical
67.	Horizontal Autoclave	Non-Critical	Electromedical
68.	HPLC Analyzer	Non-Critical	Electromedical
69.	Hysteroscope	Non-Critical	Electromedical
70.	ICU beds	Non-Critical	Electromedical
71.	Interferential therapy/electrotherapy unit	Non-Critical	Electromedical
72.	Keratometer	Non-Critical	Electromedical
73.	Microscope	Non-Critical	Electromedical
74.	Mortuary table (stainless steel)	Non-Critical	Electromedical
75.	NAAT machine	Non-Critical	Electromedical
76.	NCV machine, EMG Machine, VEP Machine	Non-Critical	Electromedical

77.	Nd Yag Laser	Non-Critical	Electromedical
78.	Nebulizer/ Ultrasonic nebulizer	Non-Critical	Electromedical
79.	OCT	Non-Critical	Electromedical
80.	OT light – shadowless lamp – Major (Ceiling Double dome)	Non-Critical	Electromedical
81.	OT light – shadowless lamp – Minor	Non-Critical	Electromedical
82.	OT light standing model/ operating light mobile	Non-Critical	Electromedical
83.	OT Table	Non-Critical	Electromedical
84.	Phaco Machine	Non-Critical	Electromedical
85.	Phototherapy Single Surface LED	Non-Critical	Electromedical
86.	Pneumatic drill and reamer	Non-Critical	Electromedical
87.	RTPCR machine	Non-Critical	Electromedical
88.	Spiro meter	Non-Critical	Electromedical
89.	Surgical diathermy	Non-Critical	Electromedical
90.	Washer Disinfector	Non-Critical	Electromedical
91.	x-ray viewer with LED light	Non-Critical	Electromedical
92.	Water Bath	Non-Critical	Electromedical
93.	Portable/Mini Autoclave	Non-Critical	Electromedical
94.	Operating Microscope	Non-Critical	Electromedical
95.	Ultrasound therapy	Non-Critical	Electromedical
96.	Resuscitation Bed	Non-Critical	Electromedical
97.	slit lamp	Non-Critical	Electromedical
98.	Otoscope	Non-Critical	Non-Electromedical
99.	weighing machine- digital	Non-Critical	Non-Electromedical
100.	weighing machine- organ	Non-Critical	Non-Electromedical
101.	Ear & nasal Suction machine	Non-Critical	Non-Electromedical
102.	Foetal Doppler	Non-Critical	Non-Electromedical
103.	Glucometer	Non-Critical	Non-Electromedical
104.	Goinometer	Non-Critical	Non-Electromedical
105.	Head Lamp	Non-Critical	Non-Electromedical
106.	Hemoglobinometer	Non-Critical	Non-Electromedical
107.	Irradiance Meter	Non-Critical	Non-Electromedical
108.	Ophthalmoscope- Direct	Non-Critical	Non-Electromedical
109.	Ophthalmoscope- Indirect	Non-Critical	Non-Electromedical
110.	Pulse oximeter	Non-Critical	Non-Electromedical
111.	Retinoscope	Non-Critical	Non-Electromedical
112.	THERMOMETER	Non-Critical	Non-Electromedical
113.	Turbidometer	Non-Critical	Non-Electromedical
114.	Vien Finder	Non-Critical	Non-Electromedical
115.	wheel chair	Non-Critical	Non-Electromedical
116.	BP apparatus- Digital/ Sphygmomanometer	Non-Critical	Non-Electromedical
117.	oxygen hood neonatal	Non-Critical	Non-Electromedical

118.	Ambu Bags	Non-Critical	Non-Electromedical
119.	Baby weighing scale	Non-Critical	Non-Electromedical
120.	Bilirubinometer	Non-Critical	Non-Electromedical
121.	BP apparatus- Aneroid/ Sphygmomanometer	Non-Critical	Non-Electromedical
122.	Exercise Couch	Non-Critical	Non-Electromedical
123.	External fixator	Non-Critical	Non-Electromedical
124.	Finger Exerciser web	Non-Critical	Non-Electromedical
125.	Foetoscope	Non-Critical	Non-Electromedical
126.	infantometer	Non-Critical	Non-Electromedical
127.	Labor bed	Non-Critical	Non-Electromedical
128.	Laryngoscope	Non-Critical	Non-Electromedical
129.	Manual Vacuum Aspirator/ Vacuum extractor	Non-Critical	Non-Electromedical
130.	Oxygen cylinder Type D	Non-Critical	Non-Electromedical
131.	Percussion Hammer/ Reflex Hammer	Non-Critical	Non-Electromedical
132.	Proctoscope	Non-Critical	Non-Electromedical
133.	Punctum Dilator	Non-Critical	Non-Electromedical
134.	Shoulder Pulley	Non-Critical	Non-Electromedical
135.	Shoulder Wheel	Non-Critical	Non-Electromedical
136.	stadiometer/ Wall mounted height measuring scale	Non-Critical	Non-Electromedical
137.	Stethoscope	Non-Critical	Non-Electromedical
138.	Tongue depressor	Non-Critical	Non-Electromedical
139.	Tuning fork	Non-Critical	Non-Electromedical
140.	Walking aid for training/ Adjustable Walker/ Reciprocal walker	Non-Critical	Non-Electromedical
141.	Wall ladder finger Exerciser/ shoulder abduction ladder	Non-Critical	Non-Electromedical
142.	Lower & upper extremity cycle/basic ergo meter/ static cycle	Non-Critical	Non-Electromedical
143.	Spiro meter for rehabilitation	Non-Critical	Non-Electromedical

(Community Health Centre)

Sl. No.	Equipment Name	Critical / Non-Critical	Electromedical/ Non-Electromedical
1.	Defibrillators	Critical	Electromedical
2.	Dental chair with accessories	Critical	Electromedical
3.	ECG 3 Channel	Critical	Electromedical
4.	ECG Machine- 12 Channel	Critical	Electromedical
5.	ECG Machine- 6 Channel	Critical	Electromedical
6.	Infusion pump	Critical	Electromedical
7.	3-part Haematology Analyser	Critical	Electromedical
8.	5-part cell counter/ hematology analyser	Critical	Electromedical
9.	USG Machine- portable ultrasound	Critical	Electromedical
10.	Anaesthesia machine	Critical	Electromedical

11.	Anaesthesia workstation	Critical	Electromedical
12.	Elisa Reader & Washer	Critical	Electromedical
13.	Fully automated biochemistry analyser	Critical	Electromedical
14.	Mechanical ventilators	Critical	Electromedical
15.	Oxygen concentrator	Critical	Electromedical
16.	Oxygen Therapy apparatus (High flow nasal Cannula)	Critical	Electromedical
17.	Radiant warmer	Critical	Electromedical
18.	Semi-automated biochemistry analyser	Critical	Electromedical
19.	Suction Machine electrical / Suction machine foot operated	Critical	Electromedical
20.	X-Ray 300 mA	Critical	Electromedical
21.	Obstetric/ Gynaecologic Ultrasound/ Colour doppler ultrasound	Critical	Electromedical
22.	Applanation Tonometer	Non-Critical	Electromedical
23.	Pulse Oximeter - tabletop	Non-Critical	Electromedical
24.	CTG Machine	Non-Critical	Electromedical
25.	Electrolyte analyser	Non-Critical	Electromedical
26.	Electrophoresis machine	Non-Critical	Electromedical
27.	ESR Analyser	Non-Critical	Electromedical
28.	HbA1C Analyser	Non-Critical	Electromedical
29.	TENS machine	Non-Critical	Electromedical
30.	Transport Ventilator	Non-Critical	Electromedical
31.	A- Scan and B-scan Biometer	Non-Critical	Electromedical
32.	Auditory Brainstem Response machine	Non-Critical	Electromedical
33.	Auto- refractometer	Non-Critical	Electromedical
34.	Automated Blood culture system	Non-Critical	Electromedical
35.	Automated coagulation analyser	Non-Critical	Electromedical
36.	Blood Warmer	Non-Critical	Electromedical
37.	Bowl Sterilizers	Non-Critical	Electromedical
38.	Chemiluminescence Analyser	Non-Critical	Electromedical
39.	Cryo surgical unit (Carbon and nitrous oxide)	Non-Critical	Electromedical
40.	Cryo Surgical unit with liquid nitrogen	Non-Critical	Electromedical
41.	Dental X-ray IOP/OPG	Non-Critical	Electromedical
42.	Diathermy Bipolar/ Electrosurgical unit	Non-Critical	Electromedical
43.	Flash Autoclave	Non-Critical	Electromedical
44.	Fundus Camera	Non-Critical	Electromedical
45.	Horizontal Autoclave	Non-Critical	Electromedical
46.	Interferential therapy/ Electrotherapy unit	Non-Critical	Electromedical
47.	Keratometer	Non-Critical	Electromedical
48.	Microscope	Non-Critical	Electromedical

49.	Mobile Spotlight/ Light for conducting deliveries/ Examination lamp with white light/ Examination light	Non-Critical	Electromedical
50.	Multipara monitor	Non-Critical	Electromedical
51.	NCV machine, EMG Machine, VEP Machine	Non-Critical	Electromedical
52.	Nd Yag Laser	Non-Critical	Electromedical
53.	Nebulizer/ Ultrasonic nebulizer	Non-Critical	Electromedical
54.	OCT	Non-Critical	Electromedical
55.	Operating Microscope	Non-Critical	Electromedical
56.	OT light - shadowless lamp - Major (Ceiling Double dome)	Non-Critical	Electromedical
57.	OT light - shadowless lamp - Minor	Non-Critical	Electromedical
58.	OT light standing model/ operating light mobile	Non-Critical	Electromedical
59.	OT Table	Non-Critical	Electromedical
60.	Phaco Machine	Non-Critical	Electromedical
61.	Portable/ Mini Autoclave	Non-Critical	Electromedical
62.	Resuscitation Bed/ ICU bed	Non-Critical	Electromedical
63.	Spirometer	Non-Critical	Electromedical
64.	Surgical Diathermy – Bipolar	Non-Critical	Electromedical
65.	Ultrasound therapy	Non-Critical	Electromedical
66.	Washer Disinfector	Non-Critical	Electromedical
67.	Water Bath	Non-Critical	Electromedical
68	X-ray viewer with LED light/ xray view box	Non-Critical	Electromedical
69.	Slit lamp	Non-Critical	Electromedical
70.	BP Apparatus- Digital/ Sphygmomanometer	Non-Critical	Non-Electromedical
71.	Otoscope	Non-Critical	Non-Electromedical
72.	Weighing Scale- Electronic	Non-Critical	Non-Electromedical
73.	Ear & nasal Suction machine	Non-Critical	Non-Electromedical
74.	Foetal Doppler	Non-Critical	Non-Electromedical
75.	Glucometer	Non-Critical	Non-Electromedical
76.	Goinometer	Non-Critical	Non-Electromedical
77.	Hemoglobinometer	Non-Critical	Non-Electromedical
78.	Ophthalmoscope- Direct	Non-Critical	Non-Electromedical
79.	Ophthalmoscope- Indirect	Non-Critical	Non-Electromedical
80.	Streak retinoscope	Non-Critical	Non-Electromedical
81.	Thermometer	Non-Critical	Non-Electromedical
82.	Turbidometer	Non-Critical	Non-Electromedical
83.	BP Apparatus- Aneroid/ Sphygmomanometer	Non-Critical	Non-Electromedical
84.	Hysteroscopy set	Non-Critical	Non-Electromedical
85.	Ambu bag	Non-Critical	Non-Electromedical

86.	Baby Weighing Scale	Non-Critical	Non-Electromedical
87.	Exercise couch	Non-Critical	Non-Electromedical
88.	Finger exerciser web	Non-Critical	Non-Electromedical
89.	Foetoscope	Non-Critical	Non-Electromedical
90.	Labor bed	Non-Critical	Non-Electromedical
91.	Laryngoscopes	Non-Critical	Non-Electromedical
92.	Lower & upper extremity cycle/basic ergometer/ static cycle	Non-Critical	Non-Electromedical
93.	Manual Vacuum Aspirator/ Vacuum extractor	Non-Critical	Non-Electromedical
94.	Oxygen cylinder Type D	Non-Critical	Non-Electromedical
95.	Percussion hammer/ Reflex Hammer	Non-Critical	Non-Electromedical
96.	Proctoscope	Non-Critical	Non-Electromedical
97.	Punctum Dilator	Non-Critical	Non-Electromedical
98.	Shoulder pulley	Non-Critical	Non-Electromedical
99.	Shoulder wheel	Non-Critical	Non-Electromedical
100.	Spirometer for rehabilitation	Non-Critical	Non-Electromedical
101.	Stadiometer/ Wall mounted height measuring scale	Non-Critical	Non-Electromedical
102.	Stethoscope	Non-Critical	Non-Electromedical
103.	Tongue depressor	Non-Critical	Non-Electromedical
104.	Tuning fork (156 Hz)	Non-Critical	Non-Electromedical
105.	Walking aid for training /Adjustable Walker/ Reciprocal Walker	Non-Critical	Non-Electromedical
106.	Wall ladder finger exerciser/ abduction ladder	Non-Critical	Non-Electromedical

(Ayushman Arogya Mandir - Primary Health Centre)

Sl. No.	Equipment Name	Critical / Non-Critical	Electromedical / Non-Electromedical
1.	3 part Haematology Analyser	Critical	Electromedical
2.	Dental Chair-Basic	Critical	Electromedical
3.	Radiant Warmer	critical	Electromedical
4.	Semi-automated biochemistry analyser	Critical	Electromedical
5.	Suction Machine electrical / Suction machine foot operated	critical	Electromedical
6.	Mobile Spotlight/ Light for conducting deliveries/ Examination lamp with white light/ Examination light	Non-Critical	Electromedical
7.	Pulse Oximeter - tabletop	Non-Critical	Electromedical
8.	Weighing Scale- Electronic	Non-Critical	Electromedical
9.	HbA1C Analyser	Non-Critical	Electromedical
10.	Deep Freezer- Large	Non-Critical	Electromedical

11.	Deep Freezer- Small	Non-Critical	Electromedical
12.	Electrolyte analyser	Non-Critical	Electromedical
13.	ESR Analyser (semi-automated)	Non-Critical	Electromedical
14.	Fully Loaded Dental Chair Electrically Operated	Non-Critical	Electromedical
15.	ILR With Voltage Stabilizer - Small/Large	Non-Critical	Electromedical
16.	Microscope	Non-Critical	Electromedical
17.	Phototherapy unit	Non-Critical	Electromedical
18.	BP apparatus- Digital	Non-Critical	Non-Electromedical
19.	Fetal Doppler	Non-Critical	Non-Electromedical
20.	Glucometer	Non-Critical	Non-Electromedical
21.	Hemoglobinometer	Non-Critical	Non-Electromedical
22.	Ophthalmoscope- Direct	Non-Critical	Non-Electromedical
23.	Ophthalmoscope- Indirect	Non-Critical	Non-Electromedical
24.	Pulse Oximeter- handheld	Non-Critical	Non-Electromedical
25.	Turbidometer	Non-Critical	Non-Electromedical
26.	Oxygen Hood Neonatal	Non-Critical	Non-Electromedical
27.	Ambu Bags (for adult & neonatal)	Non-Critical	Non-Electromedical
28.	Baby Weighing Scale	Non-Critical	Non-Electromedical
29.	BP apparatus- Aneroid	Non-Critical	Non-Electromedical
30.	Examination table	Non-Critical	Non-Electromedical
31.	Exercise Couch	Non-Critical	Non-Electromedical
32.	Finger exerciser web	Non-Critical	Non-Electromedical
33.	Infantometer	Non-Critical	Non-Electromedical
34.	Labor Bed	Non-Critical	Non-Electromedical
35.	Laryngoscope	Non-Critical	Non-Electromedical
36.	Lower & upper extremity cycle/basic ergometer/static cycle	Non-Critical	Non-Electromedical
37.	Manual Vacuum Aspiration (MVA)	Non-Critical	Non-Electromedical
38.	Oxygen cylinder- B type	Non-Critical	Non-Electromedical
39.	Shoulder pulley	Non-Critical	Non-Electromedical
40.	Shoulder Wheel	Non-Critical	Non-Electromedical
41.	Spiro meter for rehabilitation	Non-Critical	Non-Electromedical
42.	Vaccine Carrier with Ice Packs	Non-Critical	Non-Electromedical
43.	Walking aid for training/Adjustable Walker/Reciprocal Walker	Non-Critical	Non-Electromedical
44.	Wall ladder finger exerciser/Shoulder abduction ladder	Non-Critical	Non-Electromedical
45.	Wheel chair	Non-Critical	Non-Electromedical

(Ayushman Arogya Mandir - Sub-Health Centre)

Sl. No.	Equipment Name	Critical / Non-Critical	Electromedical / Non-Electromedical
1.	BP apparatus- Digital/ Sphygmomanometer	Non-Critical	Non-Electromedical
2.	Weighing machine- Electronic	Non-Critical	Non-Electromedical
3.	Hemoglobinometer	Non-Critical	Non-Electromedical
4.	Glucometer	Non-Critical	Non-Electromedical
5.	Thermometer	Non-Critical	Non-Electromedical
6.	BP apparatus- Aneroid/ Sphygmomanometer	Non-Critical	Non-Electromedical
7.	Baby weighing scale	Non-Critical	Non-Electromedical
8.	Stethoscope	Non-Critical	Non-Electromedical
9.	Near Vision chart	Non-Critical	Non-Electromedical
10.	Snellen vision chart	Non-Critical	Non-Electromedical
11.	Stadiometer	Non-Critical	Non-Electromedical
12.	Tuning fork	Non-Critical	Non-Electromedical
13.	Fetoscope	Non-Critical	Non-Electromedical

Annexure-D : Performa for Annual Equipment Inventory Survey

Name of the Health Facility : .....

Level of Healthcare Facility : .....

Details of HEMC Member : .....

Sl. No.	Department	Equipment Nomenclature	Quantity Held (Total)	Equipment Functional Status				Remarks
				Functional	Non-Functional	Repairable	BER	

Annexure-E : Equipment Maintenance Logbook

Sl. No.	Preventive Maintenance/ Calibration	Remarks of Service Engineer	Breakdown (Date/Time)	Rectified on (Date/ Time) by Service Engineer	Total Breakdown Time	Remarks/ Sign of HoD

Annexure-F : Inventory Master Record

Ref ID	Equipment Nomenclature	Qty	Equipment Make/model (Sl. Num)	Date installed/ received	Warranty Valid Till	CAMC/ AMC Valid Till	Current Status / Remarks

PART 2
Testing and Calibration of Biomedical Equipment

Testing and Calibration of Biomedical Equipment

Introduction

1. Calibration of biomedical equipment is a crucial process in the healthcare sector, ensuring the accuracy, precision, reliability, and safety of medical devices and instruments. Precise measurements and consistent functionality of biomedical equipment are of utmost importance, as they directly impact the accuracy of diagnosis, treatment effectiveness, and the overall well-being of patients. Calibration is essential for maintaining the quality of healthcare services, minimizing the risk of errors, and therefore enhancing patient health outcomes.

2. Calibrating instruments and processes are crucial for verifying their accuracy against established standards, ensuring consistent and error-reduced measurements that can be universally accepted. This procedure typically includes comparing the instrument to either primary or secondary standards. In certain cases, calibrating a device against another one with a recognized level of accuracy may be sufficient.

Gaps in the Testing and Calibration of Biomedical Equipment

3. The calibration of biomedical equipment encounters many challenges and shortcomings, in India, which significantly affect the maintenance and management of the equipment.

4. Inaccurate or improperly calibrated equipment can compromise patient safety and reduce the efficacy of medical treatments, highlighting the critical need for improved calibration practices. The Key issues pertaining to the calibration of biomedical equipment include :

   4.1 **Limited Technical Expertise among Service Providers :** Service providers frequently encounter difficulties in calibrating biomedical equipment due to lack of technical knowledge, insufficient training, and resource constraints.

   4.2 **Inadequate Infrastructure :** Many healthcare facilities in India lack the required infrastructure for accurate calibration of medical equipment. This includes a shortage of dedicated calibration laboratories and skilled technical personnel.

   4.3 **Shortage of Skilled Personnel :** There is a scarcity of skilled biomedical engineers and technicians capable of performing precise calibrations.

   4.4 **Lack of Standardization :** There is a lack of standardized guidelines and protocols for the calibration of biomedical equipment. This insufficiency of uniform standards can lead to inconsistencies in equipment performance.

   4.5 **Limited Awareness :** Awareness among healthcare professionals & administrators regarding the importance of regular equipment calibration is limited, resulting in the neglect or postponement of calibration activities.

   4.6 **Disparities in Rural Healthcare :** Rural healthcare facilities often encounter even greater obstacles in calibrating biomedical equipment due to limited access to resources and expertise.

   4.7 **Remote and Challenging Terrains :** Calibration process faces distinctive challenges in the northern and northeastern states due to geographical remoteness, harsh environmental conditions, inadequate connectivity and logistical challenges.

5. The importance of Testing and Calibration is as follows :

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

5.2 **Quality Control :** Testing and calibration helps ensure that medical devices are accurate and effective, and that they last a long time.

5.3 **Patient Safety :** Regular testing and calibration can help prevent incorrect readings, misdiagnoses, and inappropriate treatment plans that could harm patients.

5.4 Testing and Calibration can also help identify if a device is no longer suitable or has declined in quality, so that repairs or replacements can be made. For instance, the X-ray machine emitting radiation beyond the recommended norms by AERB.

Standards in Testing and Calibration of Biomedical Equipment

6. Standards are established sets of guidelines, criteria, or specifications that act as reference benchmarks to guarantee the accuracy, precision, reliability, and traceability of measurements, hence contributing to safety and quality assurance. There are two types of standards : written standard and measurement standard.

6.1 Written standards are often established by global organizations such as International Organization for Standardization (ISO), International Electrochemical Commission (IEC), Institute of Electrical and Electronics Engineers (IEEE), International Laboratory Accreditation Cooperation (ILAC) and others, providing a universally recognized and accepted framework.

6.2 In India, Bureau of Indian Standards (BIS) is an exclusive standardization body for development of Indian Standards (IS), as per the country's requirement. BIS is a member of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).

6.3 BIS has a dedicated division dealing with medical devices under the name "Medical Equipment and Hospital Planning Division (MHD)." At present, 20 committees are operating under MHD and have published more than 1250 Indian Standards on Medical equipment (Product Standard). BIS standards can be accessed from BIS website, know your standards webpage (https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/knowyourstandards/Indian_standards/isdetails/).

6.4 By adhering to written standards, organizations can uphold the quality of their products, comply with regulations, and maintain the reliability of measurements, ultimately building trust and confidence in what they offer. The most widely adopted written quality management standards are IS/ISO 9001:2015 (Quality Management System), IS/ISO/IEC 17025:2017 (General requirements for the competence of testing and calibration laboratories) & IS/ISO/IEC 13485:2016 (Medical Devices- Quality Management Systems, Requirements for regulatory purpose).

6.5 Quality management written standards mandate that laboratories showcase their adherence to a comprehensive quality system encompassing processes, documentation, and quality management. These labs are required to produce technically valid results, considering equipment, procedures, and personnel variables.

6.6 Testing & calibration of medical devices should be based on established standards. For example, for testing and calibration of cardiac defibrillator should be based on IEC 60601-1:2012 (Medical electrical equipment: Part 1 General Requirements for basic safety and essential performance) & IEC 60601-2-4: 2010 (Particular requirements for the basic safety and essential performance, Cardiac defibrillators).

6.7 If there are no relevant Standard of any medical device that has been laid down by BIS or notified by MoHFW, device shall conform to the standard laid down by the *ISO or IEC,* or by any other *pharmacopeial standards*. And in case of the standards which have not been specified by any of the options given above, then the device shall conform to the *validated manufacturer's standards.*

Organizations Contributing to Biomedical Equipment Testing and Calibration

7. In India, medical device regulations (National Medical Device Policy, 2023 and New Drugs, Medical Devices and Cosmetics Bill, 2022) emphasize on the need for quality control and periodic calibration assessments of medical equipment in order to reduce errors associated with these devices.

   7.1 Precise and accurate measurements are crucial for correct diagnoses and critical medical decisions. Conversely, using uncalibrated medical devices can lead to severe errors, resulting in incorrect diagnoses, device failures, and, in some cases, even casualties and fatalities. Therefore, regular testing and calibration of biomedical equipment is essential to ensure accurate and periodic measurements, representing a crucial step in establishing a robust national quality healthcare infrastructure within the healthcare sector.

CSIR-NPL (Council of Scientific and Industrial Research – National Physical Laboratory, www.nplindia.org)

8. CSIR-NPL is mandated to be India's "National Metrology Institute" by the act of Parliament (The Gazette of India) and is custodian of "National Standards of Measurements." CSIR-NPL is responsible for the realization, establishment, up-gradation, maintenance and dissemination of standards at par to international level, providing metrological traceability across the country.

   8.1 The CSIR-NPL, Indian National Metrology Institute contributes to the enhancement of quality control regulations for medical equipment in healthcare sector and boosts the growth of country's biomedical industries and calibration laboratories by:

   (i) Development, operation and maintenance of national standards for biomedical equipment as per relevant national and international standards.

   (ii) Providing testing/calibration services to accredited testing laboratories and other stakeholders within the healthcare industry by disseminating metrological traceability of physical measurements.

   (iii) Providing training/workshop on biomedical calibration and testing.

   (iv) The CSIR-NPL has following facilities for testing/calibration of medical device, medical device simulator/analyser :

   (a) Defibrillator & Defibrillator Analyser calibration facility is established by installing a set-up of a primary standard of defibrillator with its physical parameters traceable to national standards.

   (b) Infusion Device & Infusion Device Analyser calibration facility as per IS 13450 (Part 2/Sec 24): 2009 equivalent to IEC 60601-2-24.

   (c) Non-Invasive Blood Pressure (NIBP) devices calibration/testing system. The system is also established for Regional Reference Standards Laboratories (RRSL) at Varanasi and Faridabad.

   (d) Clinical Thermometer testing/calibration facility. The system is also established at Legal Metrology Department (LMD), Regional Reference Standard Laboratories (RRSL) at Varanasi and Ahmedabad. The facility is also useful for testing clinical glass thermometers and digital thermometers as per national and international standards' requirements.

   (e) ECG Simulator calibration facility.

   8.2 The CSIR-NPL in New Delhi has set up the Centre for Calibration & Testing (CFCT) Section with the primary aim of enhancing the laboratory's Calibration & Testing Services. Testing/Calibration services

provided by CSIR-NPL can be accessed from CSIR-NPL website Calibration and testing webpage. https://www.nplindia.org/index.php/commercial-services/calibration-testing/

National Accreditation Board for Testing and Calibration Laboratories (NABL)

9. NABL is an accreditation body, with its accreditation system established in accordance with ISO/ IEC 17011. It undertakes the assessment and accreditation of testing (including medical), calibration, proficiency testing provider and reference material producer in India and abroad.

10. NABL offers voluntary accreditation services to calibration laboratories in accordance with ISO/IEC 17025. The scope of NABL accreditation services for calibration laboratory encompass multiple disciplines, including Mechanical, Electro-technical, Fluid Flow, Thermal, Optical, Radiological and Medical Devices.

11. NABL provide accreditation to calibration laboratories that adheres to stringent quality and calibration standards and procedure. NABL accreditation signifies a laboratory's competence and capability as per internationally recognized standards, making them integral in ensuring the precision and safety of medical devices in the healthcare sector.

12. NABL provide accreditation to a large number of laboratories while ensuring metrological traceability to SI units. NABL accredited calibration laboratories can be categorized as below:

    12.1 **Tier-1 calibration laboratories :** These would be equivalent to those of Regional Reference Laboratories of Legal Metrology and obtain measurement traceability directly from the CSIR-NPL. Therefore, these Tier-1 laboratories are expected to have much lower measurement uncertainty. Laboratories falling under government and/or private sectors having essential infrastructure can be assigned Tier-1 grade after the approval from CSIR-NPL.

    12.2 **Tier-2 calibration laboratories :** Rest of the laboratories would be accredited under Tier-2, and they will obtain measurement traceability from Tier-1 laboratories. Tier-2 laboratories will disseminate measurement traceability to testing laboratories.

    12.3 In the pursuit of precision and reliability in healthcare, the calibration of medical equipment is of utmost importance. NABL accredited specific calibration laboratories for medical device calibration can be accessed from NABL website laboratory search webpage by selection field as calibration and discipline as medical devices. https://nablwp.qci.org.in/laboratorysearchone

Standardization of Testing and Quality Certification (STQC) Directorate

13. Standardisation Testing and Quality Certification (STQC) Directorate is an attached office of the Ministry of Electronics and Information Technology, Government of India, provides quality assurance services in the area of Electronics and IT through countrywide network of laboratories and centers.

14. The services include Testing, Calibration, IT & e-Governance, Training and Certification to public and private organizations. STQC laboratories are having National / International accreditation and recognitions in the area of testing and calibration.

15. STQC offers calibration services to industry and organizations in the domains: Electro Technical Calibration, Non-Electrical Calibration, High Precision Calibration, Onsite Calibration, and Medical Equipment Calibration.

16. There are 4 regional laboratories, 10 state level laboratories and 2 high precision calibration centres at Delhi and Bangaluru. The STQC laboratories are equipped with the state-of-the-art calibrating facilities. Medical

equipment calibration services are provided by STQC laboratories at ERTL (North) Delhi and ERTL (South) Thiruvananthapuram. https://www.stqc.gov.in/labs-centres

16.1 These laboratories serve as support hierarchy in establishing traceability to the National Standards through their calibration services to electronic & allied industries for electro technical and non-electrical parameters.

16.2 All STQC laboratories have well-established quality system complying with ISO/IEC 17025 and are accredited by NABL (National Accreditation Board for Laboratories).

Location / Site of Testing and Calibration

17. The outcome of calibration and measurement accuracy can be adversely affected by the accommodation and environmental conditions. Hence, they need to be controlled along with other significant factors.

18. The laboratory can provide medical equipment testing and calibration services under different categories:

18.1 Permanent Laboratory : This refers to a testing or calibration laboratory established at a specific location.

18.2 Site Testing/Calibration Facility : Testing/Calibration is conducted by the laboratory's personnel at the client's site or a location other than the permanent laboratory.

18.3 Mobile Facility : This consists of a self-contained, fully equipped testing or calibration facility that is transportable and capable of conducting calibrations under controlled environmental conditions.

Documentation of Calibration Results

19. The result of calibration is documented in calibration certificate or a calibration report. The calibration certificate must also include the associated measurement uncertainty. Information obtained through calibration can be conveyed through a statement, calibration function, calibration diagram, calibration curve, or a calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

20. Calibration Diagram: graphical expression of the relation between indication and corresponding measurement result. This concept pertains to a calibration when the instrumental measurement uncertainty is large in comparison with the measurement uncertainties associated with the quantity values of measurement standards (IEC/ISO Guide99, Definition 4.30).

21. Calibration Curve: expression of the relation between indication and corresponding measured quantity value. A calibration curve expresses a one-to-one relation that does not supply a measurement result as it bears no information about the measurement uncertainty (IEC/ISO Guide99, Definition 4.31).

Calibration Interval

22. A calibration interval is the predefined period between two consecutive scheduled calibrations. The primary purpose is to ensure that the instrument continues to provide accurate and reliable measurements, in accordance with the reference standards or manufacturer's specifications.

23. Establishing and adhering to appropriate calibration intervals is essential for ensuring accuracy and consistency, thereby helping to maintain product quality and regulatory compliance.

24. Some instruments may require more frequent recalibration, while others can go longer between calibrations. Striking a balance is important when establishing a calibration interval.

25. The frequency of calibration may vary depending on factors such as instrument type, manufacturer recommendations, instrument usage, criticality of use, environmental conditions, required accuracy and precision, maximum permissible errors, stability of the equipment and regulatory requirements etc.

26. It is recommended that healthcare facilities consult with equipment manufacturers, regulatory bodies, and local experts to establish appropriate calibration schedules for their specific biomedical equipment and circumstances.

27. Biomedical Equipment at various healthcare facilities (as per IPHS 2022) has been classified according to the calibration requirements, relevant standards, and the reference equipment necessary for calibration along with their suggestive calibration schedule are annexed.

Important Tests for Electro-Medical Equipment

28. The following measures in Step 1 and 2 encompass all tests prescribed by the general rules for electro-medical equipment and adherence to the established criteria. The results of the tests listed below represent characteristics that are common to all electro-medical equipment.

29. Furthermore, each specific equipment must adhere to its specific standard. The nature of the tests varies significantly depending on the type of equipment being tested.

Step 1 - Relevant qualitative and quantitative tests should include the following :
1. Protection against mechanical risks
2. Protection against risk of unwanted or excessive radiation
3. Protection against risk of ignition of anaesthesia mixtures
4. Protection against excessive temperatures
5. 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 :
1. Current Consumption
2. Insulation Resistance
3. Leakage current to the ground
4. Leakage current through the Cabinet
5. Leakage current through the patient
6. Auxiliary current through the patient

30. Tests mentioned below are suggestive in nature, the service provider may add new tests as needed. Additional steps may be proposed if required by the manufacturer or client.

Electro medical equipment in general		**Electrosurgical Units**	
1.	Insulation resistance	1.	Insulation resistance
2.	Leakage current to the ground	2.	Leakage current to the ground
3.	Leakage current through the Cabinet	3.	Leakage current through the Cabinet
4.	Leakage current through the patient	4.	Leakage current through the patient
5.	Auxiliary current through the patient	5.	Auxiliary current through the patient
		6.	Accuracy of the power outlet
		7.	RF leakage current

Defibrillators		Volumetric Infusion Pumps and Syringe Pumps	
1.	Insulation resistance	1.	Insulation resistance
2.	Leakage current to the ground	2.	Leakage current to the ground
3.	Leakage current through the Cabinet	3.	Leakage current through the Cabinet
4.	Leakage current through the patient	4.	Leakage current through the patient
5.	Auxiliary current through the patient	5.	Accuracy of the intermediary and minimum rate infusion without return pressure
6.	Energy delivered	6.	Accuracy of infusion rate
7.	Isolation of the high voltage parts		
8.	Energy loss rate		
9.	Battery capacity		

Conclusion

31. Testing and calibration plays a crucial role in maintaining the accuracy, precision, and reliability of instruments. Beyond being a procedural necessity, testing & calibration of biomedical equipment serves as a cornerstone for ensuring the highest standards in patient care, diagnostics, and treatment within healthcare systems.

32. Biomedical equipment should comply with established standards, as this compliance ensures overall effectiveness and contributes significantly to safety and quality assurance in healthcare practices. Proper documentation of testing & calibration results is essential, serving as a comprehensive record that enables healthcare professionals to track the performance history of biomedical equipment and make well-informed decisions.

33. This document aims to be a valuable resource for healthcare professionals and biomedical engineers, promoting the adoption of best practices in testing & calibration of biomedical equipment and contributing to the delivery of high-quality healthcare services.

List of Equipment that Requires Testing / Calibration

A. For Sub Health Centre (SHC) Level

Sl. No.	List of Equipment at SHC as per IPHS 2022	Reference Equipment for Testing / Calibration
1.	Digital Hemoglobinometer	Auto - Hematology Analyzer (Gold Standard)
2.	Digital Glucometer with test strips	Biochemistry Analyzer (Using Venous Blood Sugar) (Gold Standard)
3.	Digital BP apparatus	Non-Invasive Blood Pressure (NIBP) Simulator https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-simulators/bp-pump-2-nibp-blood-pressure-simulator
4.	Weighing Scale Non-Electronic	Reference Weights with high accuracy https://calibrationweights.in/?gad_source=1&gclid=Cj0KCQjw-ai0BhDPARIsAB6hmP4l49gRyXgaebnlE65UNe_DAAKag2IA-Ip1pTJipTaHualZVBRuBcQaAiWjEALw_wcB
5.	Baby Weighing Scale	Reference Weights with high accuracy https://calibrationweights.in/?gad_source=1&gclid=Cj0KCQjw-ai0BhDPARIsAB6hmP4l49gRyXgaebnlE65UNe_DAAKag2IA-Ip1pTJipTaHualZVBRuBcQaAiWjEALw_wcB

B. For Primary Health Centre (PHC) Level

*Same as equipment mentioned in Sub Health Centre (SC)

Sl. No.	List of Equipment at PHC as per IPHS 2022	Reference Equipment for Testing / Calibration
1.	Radiant Warmer	1. Incubator/Radiant Warmer Analyzer https://helixindia.com/incubator-analyzer/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
2.	Phototherapy Unit	1. Phototherapy Radiometer/ Irradiance meter https://www.flukebiomedical.com/products/biomedical-test-equipment/phototherapy-radiometers/dale40-phototherapy-radiometer 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
3.	Suction Machine	1. Pressure Calibrator https://www.fluke.com/en-us/product/calibration-tools/pressure-calibrators/fluke-718 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/

4.	Binocular Microscope	Stage Micrometre & Calibration Grids https://www.thorlabs.com/newgrouppage9.cfm?objectgroup_id=7502&gad_source=1&gclid=Cj0KCQjws560BhCuARIsAHMqE0HsCEu1XYS_6tY4-SDKzaS2FOk2-7Fgl1sN-0zhXyFM4pDK7oqn_QU4aAgKKEALw_wcB
5.	BP Apparatus Aneroid	Reference Manometer (Mercury Sphygmomanometer or Electronic Manometers) https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-simulators/bp-pump-2-nibp-blood-pressure-simulator
6.	Foetal Doppler	Foetal Simulator with Mechanical Heart https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-simulators/ps320-fetal-simulator
7.	HbA1c Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
8.	Semi-automated analyser	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
9.	Turbidimeter	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2.Turbidity Calibration Standard Solutions traceable to primary standard reference materials
10.	3 Part Hematology Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
11.	Electrolyte Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
12.	ESR Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
13.	Ophthalmoscope	Lux meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941

14.	Pulse Oximeter (handheld)	Pulse Oximeter Simulator/SpO2 Signal Simulator https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-simulators/prosim-spot-light-spo2-pulse-oximeter-tester
15.	Pulse Oximeter (tabletop)	Pulse Oximeter Simulator/SpO2 Signal Simulator https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-simulators/prosim-spot-light-spo2-pulse-oximeter-tester
16.	Spirometer for rehabilitation	3 Litre Precision Calibration Syringe https://vitalograph.com/products/3-liter-precision-calibration-syringe
17.	ILR with voltage stabilizer	1.Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Reference Thermometer/Temperature Data Logger https://as.flukecal.com/products/process-calibration-tools/temperature-calibrators/precision-digital-thermometers/1523-1524- 3.Voltage Calibrator https://www.fluke.com/en-in/learn/blog/temperature-calibration/best-practices-process-temperature-calibration
18.	Deep Freezer	1.Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Reference Thermometer/Temperature Data Logger https://as.flukecal.com/products/process-calibration-tools/temperature-calibrators/precision-digital-thermometers/1523-1524-

C. For Community Health Centre (CHC) Level

*Same as equipment mentioned in Primary Health Centre (PHC)

Sl. No.	List of Equipment at CHC as per IPHS 2022	Reference Equipment for Testing / Calibration
1.	Mechanical ventilator	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Gas Flow Analyzer Ventilator Tester https://www.flukebiomedical.com/products/biomedical-test-equipment/gas-flow-analyzers-ventilator-testers/vt900a-gas-flow-analyzer-ventilator-tester
2.	Transport Ventilator	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Gas Flow Analyzer Ventilator Tester https://www.flukebiomedical.com/products/biomedical-test-equipment/gas-flow-analyzers-ventilator-testers/vt900a-gas-flow-analyzer-ventilator-tester

3.	Defibrillator	1. Defibrillator Analyzer https://www.flukebiomedical.com/products/biomedical-test-equipment/defibrillator-analyzers 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
4.	Electrosurgical unit/ Dia-thermy Bipolar	Electrosurgical Unit Analyzer/Cautery Analyzer https://www.flukebiomedical.com/products/biomedical-test-equipment/electrosurgery-analyzers Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
5.	CTG Machine	1. Foetal Simulator https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-simulators/ps320-fetal-simulator 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
6.	Multipara monitor	1. Patient Monitor Simulator https://helixindia.com/vital-sign-patient-simulator/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
7.	X-Ray 300 mA	1. Phantoms 2. Kilo Peak Voltage Meter (kVp) Meter & Exposure Timer https://www.barc.gov.in/technologies/meter/meterbr.html 3. Radiation Survey Meter https://www.avanttec.net/radiation-survey-meter/ 4. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
8.	Infusion pump	Infusion Pump Analyzer https://www.rigelmedical.com/gb/products/infusion-pump-testing/infusion-pump-analyzers/multi-flo/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
9.	Goniometer	Precision Angle Blocks https://www.fluke.com/en-in/products/calibration-tools/pressure-calibrators
10.	Anaesthesia machine	Gas Flow Analyzer https://www.rigelmedical.com/gb/products/ventilator-testing/gas-flow-analyzers/ Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
11.	Interferential Therapy Unit	Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
12.	NCV EMG Machine & VEP Machine	Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/

13.	Phaco Machine	As per manufacturer's recommendation Electric Safety Analyser https://helixindia.com/electrical-safety-analyzers/
14.	Nd Yag LASER	As per manufacturer's recommendation Electric Safety Analyser https://helixindia.com/electrical-safety-analyzers/
15.	TENS	Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
16.	Ultrasonic Nebulizer	Gas Flow Analyzer https://www.rigelmedical.com/gb/products/ventilator-testing/gas-flow-analyzers/ Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
17.	Ultrasound Therapy	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Ultrasound power meter/watt meter https://www.omnia-health.com/product/digital-ultrasound-wattmeter-power-meter
18.	Oxygen Concentrator	Oxygen Analyzer https://www.indiamart.com/proddetail/oxygen-analyzer-20732065088.html Pressure Testing Gauge https://bajajlifecare.com/product/oxylife-pressure-testing-gauge-for-oxygen-cylinder/ 3. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
19.	Resuscitation Bed/ICU Bed	Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
20.	OT Table	Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
21.	Autoclave (HP Horizontal / Flash/ Portable)	Pressure Calibrator https://www.fluke.com/en-us/product/calibration-tools/pressure-calibrators/fluke-718 2. Temperature Calibrator https://www.fluke.com/en-us/product/calibration-tools/temperature-calibrators/fluke-724
22.	Spirometer	3-Litre Calibration Syringe (Calibration Volume Syringe) https://www.a-msystems.com/p-60-3l-fixed-volume-calibration-syringe.aspx
23.	Obstetric/ Gynaecologic Ultrasound/ Colour doppler ultrasound	1. Ultrasound Phantoms 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 3.Ultrasound Phantom or Calibration Test Object https://www.sunnuclear.com/products/zerdine-ultrasound-phantom

24.	Ophthalmoscope	Lux meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941
25.	Slit lamp	Lux meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941
26.	Streak retinoscope	1. Illuminance/Lux Meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941 2. Distance Vision Chart & Near Vision Chart
27.	Keratometer	1. Calibration Sphere or Test sphere https://www.zeiss.co.in/metrology/products/accessories/machine-accessories/zeiss-reference-spheres-and-calibration-artifacts.html
28 .	A-Scan and B-Scan Biometer	Calibration Sphere https://www.fluke.com/en-in/products/calibration-tools/pressure-calibrators
29.	Automated Coagulation Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
30.	Fundus Camera	1. Illuminance/Lux Meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
31.	Refractometer	1. Auto-refractor Calibration Test Lens Set https://www.nidek-intl.com/product/ophthaloptom/refraction/ref_auto/ark-1s.html 2. Electrical Safety Analyser https://helixindia.com/electrical-safety-analyzers/
32.	OCT	1. OCT Phantom https://www.ardenphotonics.com/products/apl-op01/ 2. Electrical Safety Analyser https://helixindia.com/electrical-safety-analyzers/
33.	Applanation Tonometer	Electrical Safety Analyser https://helixindia.com/electrical-safety-analyzers/
34.	ECG Machine 12 channel	1. ECG Simulator https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-simulators 2. Electrical Safety Analyser https://helixindia.com/electrical-safety-analyzers/
35.	Otoscope	1. Ear Simulator https://www.indiamart.com/proddetail/type-4195-ear-simulator-for-telephonometry-itu-t-type-3-2-coupler-b-k-2853934184848.html?pos=8&pla=n 2. Electrical Safety Analyser https://helixindia.com/electrical-safety-analyzers/

36.	Auditory Brainstem Response Machine	Acoustic Calibrator https://www.noisemeters.asia/help/faq/calibrator/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
37.	5 Part Hematology Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
38.	ESR Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
39.	Fully Automatic Biochemistry Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
40.	ELISA Reader & Washer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
41.	Chemiluminescence Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
42.	Automated Blood Culture System	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/

D. For District Hospital (DH) Level

*Same as equipment mentioned in Community Health Centre (CHC)

Sl. No.	List of Equipment at DH as per IPHS 2022	Reference Equipment for Testing / Calibration
1.	C.T. Scan Multi slice (64 SLICES)	1. CT Phantoms https://www.indiamart.com/proddetail/phantoms-to-ctiq-15090879155.html 2. Radiation Survey Meter https://www.avanttec.net/radiation-survey-meter/ 3. Electric Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
2.	MRI System 1.5 Tesla	1. Phantoms 2. Radio Frequency (RF) Power Meter 3. Electric Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
3.	Mammography Unit	Mammographic Phantoms 2. Radiation Survey Meter https://www.avanttec.net/radiation-survey-meter/ 3. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
4.	Bubble CPAP	1. Gas Flow Analyzer https://www.rigelmedical.com/gb/products/ventilator-testing/gas-flow-analyzers/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
5.	CARM with accessories	1. Phantoms 2. Electric Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
6.	Defibrillator with TCP and AED	1. Defibrillator Analyzer https://www.flukebiomedical.com/products/biomedical-test-equipment/defibrillator-analyzers 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
7.	Hemodialysis Machine	1. Dialysis Reference Meter https://helixindia.com/dialysis-reference-meters/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
8.	Dialyzer reprocessing unit	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Conductivity Meter 3. pH Calibration Solutions (As per manufacturer's recommendation)

9.	Electrical cautery	1. Electrosurgical Generator Analyzer/Cautery Analyzer https://www.flukebiomedical.com/products/biomedical-test-equipment/electrosurgery-analyzers 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
10.	EEG machine	Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
11.	Arterial Blood Gas Analyzer	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. pH Buffers Solutions and Electrolyte Standards (As per manufacturer's recommendation)
12.	ACT machine	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Calibration Plasma and Control Solutions (As per manufacturer's recommendation)
13.	Multi para monitor for ICU	1. Patient Monitor Simulator https://helixindia.com/vital-sign-patient-simulator/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
14.	Bilirubinometer	Bilirubin Standard Solutions (As per manufacturer's recommendation)
15.	CPAP	1. Gas Flow Analyzer https://www.rigelmedical.com/gb/products/ventilator-testing/gas-flow-analyzers/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
16.	RTPCR machine	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
17.	Transport Incubator	1. Incubator Analyzer https://helixindia.com/incubator-analyzer/ 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
18.	DVT pump (Deep Vein Thrombosis prevention devices)	1. Pressure Calibrator https://www.fluke.com/en-us/product/calibration-tools/pressure-calibrators/fluke-718 2. Flow Meter / Calibrator 3. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/

19.	ECMO machine	1. Pressure Calibrator https://www.fluke.com/en-us/product/calibration-tools/pressure-calibrators/fluke-718 2. Temperature Calibrator https://www.fluke.com/en-us/product/calibration-tools/temperature-calibrators/fluke-724 3. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
20.	Flame Photometer	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Standard Solutions (As per manufacturer's recommendation)
21.	Phototherapy Single surface LED	1. Illuminance/Lux Meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
22.	X-Ray machine 500 ma	1. Electrical Safety Analyzer Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Radiology Test Equipment https://humanhealth.iaea.org/HHW/MedicalPhysics/DiagnosticRadiology/DosimetryInstrumentationandCalibration/Radiologicaltestequipmentmeasurementandpractice/index.html 3. Radiation Leakage Detector1 https://instrukart.com/lutron-emf-810-micro-wave-leakage-detector/
23.	Blood Separation /Apheresis Machine	Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
24.	Digital Thermometer	Reference thermometer https://as.flukecal.com/products/process-calibration-tools/temperature-calibrators/precision-digital-thermometers/1523-1524-
25.	Syringe Pump	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Infusion Device Analyzer https://www.flukebiomedical.com/products/biomedical-test-equipment/infusion-pump-analyzers
26.	Slit Pump	1. Illuminance/Lux Meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/

27.	Portable X-Ray	1. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 2. Radiology Test Equipment https://humanhealth.iaea.org/HHW/MedicalPhysics/DiagnosticRadiology/DosimetryInstrumentationandCalibration/Radiologicaltestequipmentmeasurementandpractice/index.html 3. Radiation Leakage Detector1 https://instrukart.com/lutron-emf-810-micro-wave-leakage-detector/
28.	Cell Counter Electronic	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
29.	NAAT Machine	1. Calibrators (Nucleic Acid, qPCR & Fluorescence Standards) As per manufacturer's recommendations 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
30.	Plasma Expressor	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
31.	Irradiance Meter	1. Illuminance/Lux Meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/ 3. NIST-Traceable Standard Light Source https://www.google.com/search?q=NIST-Traceable+Standard+Light+Source&rlz=1C1CHBF_enIN959IN960&oq=NIST-Traceable+Standard+Light+Source&gs_lcrp=EgZjaHJvbWUyBggAEEUYOTIHCAEQIRigAdIBBzg4N2owajSoAgCwAgA&sourceid=chrome&ie=UTF-8
32.	Hysteroscope	1. Illuminance/Lux Meter https://www.fluke.com/en-in/product/building-infrastructure/indoor-air-quality-testing/fluke-941 2. Pressure and Flow calibrators (As per manufacturer's recommendations) 3. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
33.	HPLC Analyzer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/

34.	Flow Cytometer	1. Calibrators and Controls (As per manufacturer's recommendations) 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
35.	Centrifuge	1. Tachometer https://www.testo.com/en-IN/testo-470/p/0563-0470 2. Electrical Safety Analyzer https://helixindia.com/electrical-safety-analyzers/
36.	Bi-PAP Machine	1. Electric Safety Analyser https://helixindia.com/electrical-safety-analyzers/ 2. Gas Flow Analyzer https://www.flukebiomedical.com/products/biomedical-test-equipment/gas-flow-analyzers-ventilator-testers

Note : For all Analysers / Cell Counters / Semi-Auto Analysers / Fully Automatic Analysers, Calibrators & Controls (as per manufacturer's recommendations), and an Electrical Safety Analyzer is required for testing and calibration

Statewise List of NABL Accredited Calibration Laboratories for Biomedical Devices

Sl.No.	State/UT	Address
1.	Andhra Pradesh	**Global Bio Medical Services India, Visakhapatnam** 10-35-5/1, 3rd Floor, Bhanoji Narag, Visakhapatnam, Andhra Pradesh-530002
2.	Delhi	**1. Centre for Calibration & Testing (CFCT), CSIR-National Physical Laboratory, New Delhi** Dr. K. S. Krishnan Road, New Delhi-110012 **2. Quality Certification & Laboratories, New Delhi** Plot No. 10, First Floor, DSIDC Scheme - III, Okhla, Industrial Area, Phase - II, New Delhi- 110020 **3. Kirloskar Technologies (P) Ltd. (Quality Assessment Services), New Delhi** D 97-98 Ground Floor, Lajpat Nagar, Part-1, New Delhi, Delhi-110024
3.	Gujarat	**1. Pramukh Technical & Calibration Centre Pvt. Ltd., Ahmedabad** A/201, Abhishek Complex-2, Ahmedabad, Gujarat- 380016 **2. Electronics and Quality Development Centre (EQDC), Gandhinagar** B 177/178, GIDC Electronics Estate, Sector 25, Gandhinagar, Gujarat-382024 **3. Prism Calibration Centre, Ahmedabad** GF-101,F/101,101 A,B, TF-85 To101, Rudraksh Complex-II, Jashoda Nagar Cross Roads, Phase III GIDC, Vatva, Ahmedabad, Gujarat-382445
4.	Haryana	**Fare Labs Private Limited, Gurgaon** D-18, Infocity Phase-II, Sector-33,Gurgaon, Haryana-122001D-18, Infocity Phase-II, Sector-33, Gurgaon, Haryana-122001
5.	Himachal Pradesh	**National Research and Technology Consortium (C-ACT), Himachal Pradesh** Parwanoo Department of Industries Complex, Sector- 1, Parwanoo, Sector-1, Parwanoo, Himachal Pradesh-173220
6.	Karnataka	**1. Transcaal Engineers India Pvt. Limited, Bengaluru** #116, 3rd Floor, 11th Cross, Margosa Road (3rd Main), Malleswaram, Bengaluru, Karnataka- 560003 **2. Helix Private Limited, Bengaluru** 878, 17th Cross, 9th B Main Road, ISRO Layout, Bengaluru, Karnataka-560078 **3. Oregon Healthcare Pvt. Ltd., Bengaluru** No: 160, 9th Main, 6th Sector, HSR Layout, Bengaluru, Karnataka-560102 **4. Roots Metrology & Testing Laboratory, Bengaluru** 156, Bommasandra Industrial Area, Bommasandra-Jigani Taluk, Bengaluru, Karnataka-560099

7.	Kerala	**1. Hindustan Health Care, Kannur, Kerala** PP - XII 313, Opposite Hp Pump, Padannapalam, Kannur, Kerala-670014 **2. Biomedical Techniques-Calibration Laboratory, Thrissur** II/446, S N Park, Ayyanthole, Thrissur, Kerala-680004 **3. Mecom Services, Aluva, Kerala** 15/582 B, AM Road, St. Mary's Building, South Vazhakulam, Aluva-683105 Kerala
8.	Madhya Pradesh	**Kailtech Test and Research Centre Private Limited, Indore** 141-C, Electronic Complex, Indore, Madhya Pradesh-452010
9.	Maharashtra	**Godrej & Boyce Mfg. Co. Ltd.**, Lawkim Motors Group, Calibration & Inspection, Plant-18 B 1st Floor, Pirojshanagar, Vikhroli (E), Mumbai,Maharashtra-400079 **Creative Electronics and Bio Medicals**, Pimpri S.No.-92/1, Galli No. -4, Pawana Nagar, Kalewadi, Pimpri Chinchwad, Pimpri, Maharashtra-411017 **Autocal Medi Systems**, Pune 48/413, 1 St Floor, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra-411018 **Reliable Technocare Pvt.Ltd. (Medical Division)**, Pune Reliable House, Palazzo Greens, Wing-A, Unit No.101-104,, Vadgaon Maval, Pune -412106, Maharashtra
10.	Manipur	**Necatel Solutions Pvt. Ltd., Imphal** Khurai Thangjam Leikai, Imphal, Manipur-795005
11.	Odisha	**Electro Meter Corporation, Bhubaneswar** Plot No-1294(P), CRP Square, Bhubaneswar, Odisha- 751012
12.	Rajasthan	**Apex Quality Certification Services Pvt. Ltd., Jaipur** 161 Kasturba Nagar, Nirman Nagar, Jaipur, Rajasthan-302019
13.	Tamil Nadu	**1. Sunshine Biomedical Solutions, Chennai** No.68, Poomagal Main Road, Chennai, Tamil Nadu- 600032 **2. Transindia Calibration Services Pvt. Ltd., Tirunelveli** 763/19,Block No 10, KTC Nagar, Kulasekarapatti, Tirunelveli **3. Bio Vision Medical Systems, Chennai** No 49&50, Second Floor, Samuvel Nagar, Chennai, Tamil Nadu-600060 **3. Northlab India Pvt. Ltd., Chennai** Plot No 1 SV Nagar Perumalpattu, Chennai, Tamil Nadu-602024 **5. Centre For Calibration and Testing of Medical Equipment, Chennai** National Hub for Healthcare Instrumentation Development, 2nd Floor, Kalanjiyam Building, Anna University, Chennai, Tamil Nadu-600025 **6. Department of Biomedical Engineering, Christian Medical College, Vellore** #4, IDA Scudder Road, Vellore, Tamil Nadu **7. Vanavil Calibrations Private Limited, Salem** S2,Rishi Maharaj Apartment, Indrani Nagar, Salem, Tamil Nadu-636004 **8. PSG Centre for Industrial Research & Development, Coimbatore** A115, PSG College of Technology, Avinashi Road, Peelamedu, Coimbatore, Tamil Nadu-641004 **9. Sindoori Management Services Private Limited, Chennai** No. 77, Pottipati Plaza, 4th Floor, Nungambakkam High Road, Nungambakkam, Chennai, Tamil Nadu-600034

14.	Telangana	**Trimed Solutions (India) Private Limited, Hyderabad** Plot No. 40 to 43 and 54 to 57, Kavuri Hills, Phase III, Guttala Begumpet, Serilingampally, Hyderabad, Telangana- 500081 **Radian Health Care, Hyderabad** 8-2-310/3A/5, Road Number 14, Nandi Nagar, Banjara Hills, Hyderabad, Telangana- 500034
15.	Uttar Pradesh	**1. Central Institute of Petrochemicals Engineering and Technology (CIPET), Calibration Centre, Lucknow** B-27, Amausi Industrial Area, Lucknow, Uttar Pradesh-226008 **2. AOV International LLP (Medical Devices Calibration Laboratory), Noida** C-22/25, Sector-57,Noida, Uttar Pradesh-201301
16.	West Bengal	**1. Sodexo India Services Private Limited- Calibration Lab, Kolkata** 2nd Floor, EN-7, Biwanath Building, Sector-V, Salt Lake, Kolkata, West Bengal-700091 **2. Measure Techno Lab, Kolkata** 2,B.T.Road, (Jayanti Cinema Complex), Barrackpore, Kolkata, West Bengal-700120 **3. Young Engg. And Calibration Services Pvt Ltd., Howrah** Kamardanga Road, Ichapur, Howrah, West Bengal-711104

Note : States/UTs where accredited NABL calibration labs are not available are advised to avail the nearby state facility and enter into MoU or service level agreement for undertaking equipment calibration. Funds for the same can be projected in PIP under BMMP programme (FMR Code: 184).

Sample Format for Calibration Report

Calibration Protocol & Report or Medical Equipment

Equipment Name : ..... Protect Class/Test : .....

Make : ..... S.No. : .....

Model : ..... Location : .....

Sl. No.	Measurement Parameters		Status	Remarks
1.	Electrical Test	(a) Safety Standards (b) Equipotential ground & Earthing (c) Risk of shock/fire (d) Battery Conditions		
2.	Physical Condition Test	(a) Risk of mechanical damage (b) Power supply unit		
3.	Performance Test	Specific to equipment		
4.	Calibration Test	Specific to equipment		
Formulated By: (Company Name)		Issued By :	User Department :	
Endorsed By :				
Reviewed On :				
Next Review :				

PART 3

List of Equipment at Ayushman Arogya Mandir (Sub Health Centre and Primary Health Centre) as Per IPHS-2022 For Service Delivery of 12 CP-CPHC Packages

List of equipment at PHC and SHC as per IPHS 2022

AT AAM - Primary Health Care

Sl. No.	Equipment	Essential	Desirable
1.	Ambu Bag (Adult & Neonatal)	Essential	
2.	Baby Weighing Scale	Essential	
3.	Binocular Microscope	Essential	
4.	BP Apparatus- Aneroid	Essential	
5.	BP Apparatus-Digital	Essential	
6.	Cell Counter/ Hematology analyser – 3 Part	Essential	
7.	Deep Freezer-Small	Essential	
8.	Deep Freezer-Small-Large	Essential	
9.	Dental Chair-Basic	Essential	
10.	Electrolyte Analyzer		Desirable
11.	ESR Analyzer		Desirable
12.	Examination Table	Essential	
13.	Exerciser Couch/Table	Essential	
14.	Finger Exerciser Web	Essential	
15.	Foetal Doppler	Essential	
16.	Fully Loaded Dental Chair Electrically Operated	Essential	
17.	Glucometer	Essential	
18.	Haemoglobinometer	Essential	
19.	HbA1C Analyser	Essential	
20.	ILR With Voltage Stabilizer-Large	Essential	
21.	ILR With Voltage Stabilizer-Small	Essential	
22.	Infantometer	Essential	
23.	Labor Bed	Essential	
24.	Laryngoscope	Essential	
25.	Lower and Upper Extremity Cycle/Basic Ergometer/Static Cycle	Essential	
26.	Manual Vacuum Aspirator	Essential	
27.	Mobile Spotlight/ Examination light	Essential	
28.	Ophthalmoscope	Essential	
29.	Oxygen Cylinder- B Type	Essential	
30.	Oxygen Hood Neonatal	Essential	
31.	Phototherapy Unit	Essential	
32.	Pulse Oximeter-Finger Tip	Essential	
33.	Pulse Oximeter-Table Top	Essential	
34.	Radiant Warmer	Essential	

35.	Spirometer for Rehabilitation	Essential	
36.	Semi-Automated Biochemistry Analyser	Essential	
37.	Shoulder Abduction Ladder	Essential	
38.	Shoulder Pulley	Essential	
39.	Shoulder Wheel	Essential	
40.	Stethoscope	Essential	
41.	Suction Machine	Essential	
42.	Thermometer	Essential	
43.	Turbidimeter	Essential	
44.	Vaccine Carrier with Ice Packs	Essential	
45.	Weighing Scale	Essential	
46.	Walking Aid for Training- Adjustable walker/ Reciprocal Walker	Essential	
Instruments			
47.	Kelly Pads & blankets	Essential	
48.	Sponge holding forceps	Essential	
49.	Velsellum uterine forceps	Essential	
50.	Equipment for assisted forceps delivery	Essential	
51.	Cusco's Speculum	Essential	
52.	Dental mouth mirror	Essential	
53.	Puncture proof box	Essential	
54.	Cold box	Essential	
55.	Wall ladder Finger exerciser	Essential	

At AAM-Sub Health Centre

Sl. No.	Equipment	Essential / Desirable
1.	Ambu Bag (Paediatric size) with baby mask	Essential
2	BP apparatus- Digital/ Sphygmomanometer	Essential
3.	Baby weighing scale / Hanging Type	Essential
4.	BP apparatus- Aneroid/ Sphygmomanometer	Essential
5.	Examination Lamp	Essential
6.	Examination Table	Essential
7.	Glucometer	Essential
8.	Digital Hemoglobinometer	Essential
9.	Manual Vacuum Aspirator (MVA) / Mucus Extractor	Essential
10.	Near Vision chart	Essential
11.	Nebulizer	Essential
12.	Oxygen Cylinder with Trolley	Essential
13.	Snellen vision chart	Essential
14.	Stadiometer	Essential
15.	Stethoscope	Essential

16.	Suction Machine	Essential
17.	Thermometer	Essential
18.	Tuning fork	Essential
19.	Vaccine Carrier with Ice pack box, tracking bag and tickler box	Essential
20.	Weighing Scale - Electronic	Essential
Instruments / Consumables		
21.	Sahli's Hemoglobinometer	Essential
22.	Kelly Pads & blankets	Essential
23.	Sponge holding forceps	Essential
24.	Velsellum uterine forceps	Essential
25.	Equipment for assisted forceps delivery	Essential
26.	Cusco's Speculum	Essential
27.	IV Stand	Essential
28.	Foetoscope	Essential
29.	Tongue Depressor	Essential
30.	LED Torch/ Flashlight	Essential
31.	Measuring Tape	Essential
32.	Dental Mouth mirror	Essential
33.	Ice pack box	Essential
34.	Minor Treatment Instruments like Trays, Forceps, Cord Cutting Scissors (Curved Blunt/ Flat), Needle holder etc.	Essential

Equipment Required for Operationalisation of 12 CPHC Packages

I. Care in Pregnancy and Child-Birth

Sl. No.	Equipment List
1.	Haemoglobinometer
2.	Ambu bag- Adult and neonatal
3.	BP apparatus (Digital/ Aneroid)
4.	Cord cutting scissor (Umbilicus – Blunt)
5.	Cover slips
6.	Delivery kit
7.	Fetoscope
8.	Glucometer
9.	Instrument tray
10.	Microscope
11.	Microscope glass slides
12.	Mucus extractor
13.	Oxygen cylinder
14.	Stadiometer
15.	Surgical scissors
16.	Thermometer
17.	Vaccine carrier Ice pack box
18.	Weighing machine (Adult & Baby)
19.	Accessories: Urine test kit, RDT test Kit, Pregnancy Test kit, HIV TRI-DOT
20.	Labor bed
21.	Foetal Doppler
22.	Radiant Warmer
23.	7 Delivery trays (Forceps delivery kits, Episiotomy Kit, Cusco's speculum, Cord Cutting Scissors (Curved/ Blunt/ Flat), Needle holder etc)
24.	Pulse Oximeter (Adult & Neonatal)
25.	Nebuliser
26.	Baby weighing Scale
27.	Baby measuring scale
28.	Phototherapy Unit
29.	Emergency Resuscitation Kit- Baby

30.	Oxygen Concentrator
31.	LED Mobile Examination Light
32.	Suction Machine (Electric & Foot-operated)
33.	Kelly Pads & Blankets
34.	IV Set with Stand

II. Neonatal and Infant Health Care Services

Sl. No.	Name of Equipment
1.	Ambu bag- Adult and neonatal
2.	BP apparatus (Digital/ Aneroid)
3.	Cold Box
4.	Deep Freezer
5.	Glucometer
6.	ILR
7.	Neonatal mask size 0,1
8.	Overhead warmer
9.	Oxygen Hood Neonatal
10.	Pencil torch
11.	Pulse oximeter
12.	Puncture proof box
13.	Radiant warmer
14.	Stadiometer
15.	Suction Machine (Electric & Foot-operated)
16.	Thermometer
17.	LED Torch
18.	Vaccine carrier Ice pack box
19.	Vision charts
20.	Weighing machine (Adult & Baby)
21.	Nebuliser
22.	LED Phototherapy Unit
23.	Room Thermometer
24.	Neonatal Stethoscope

25.	Oxygen Hood (Neonatal / Infant Size)
26.	Measuring Tape
27.	Neonatal Resuscitation Kit with Neonatal Laryngoscope with Blades
28.	Oxygen cylinder/ Oxygen Concentrator
29.	LED Mobile Examination Light
30.	Examination Table
31.	Syringe Hub cutter
32.	Instruments like Dressing tray, stainless steel 300x200x30 mmm, Kidney basin, stainless steel
33.	Infantometer

III. Childhood and Adolescent Health Services

Sl. No.	Name of Equipment
1.	BP apparatus (Digital/ Aneroid)
2.	Vaccine carrier Ice pack box
3.	Deep Freezer
4.	Examination table
5.	Haematology Analyzer
6.	Hemoglobinometer
7.	ILR
8.	Pulse Oximeter
9.	Stadiometer
10.	Stethoscope
11.	Thermometer
12.	Weighing Scale (Adult & Baby)
13.	Consumables: HIV TRI-DOT
14.	Laryngoscope set, neonate
15.	Stadiometer
16.	Suction Machine (Electric & Foot-operated)
17.	LED Mobile Examination Light
18.	Syringe Hub cutter
19.	Ambu bag with mask (paediatric and adult size)
20.	Nebulizer

21.	X-ray view box
22.	Measuring Tape

IV. Family Planning, Contraceptive Services and other Reproductive Health Care Services

Sl. No.	Name of Equipment
1.	Bed
2.	BP apparatus (Digital/ Aneroid)
3.	Examination Table
4.	Foetal Doppler
5.	Normal Delivery kit
6.	Oxygen cylinder
7.	Seven trays: Delivery, episiotomy, EMR drug, medicine, MVA, PPIUCD, Baby
8.	Speculum
9.	Weighing Scale- Electronic
10.	Consumables: Pregnancy test kits etc
11.	Basket of Choice (ANTARA, MAYA, IUCD/ PPIUCD/ PAIUCD etc)

V. Management of Communicable Diseases including National Health Programmes

Sl. No.	Name of Equipment
1.	Microscope with Slide Box (20-25 slides)
2.	Digital Thermometer
3.	Weighing machine (Adult & Baby)
4.	Consumables: Rapid test kits Malaria, Dengue rapid test kit, Kala azar Rapid Test Kits, HIV test (Antibodies 1/2 and HIV 1/2), Hepatitis B surface antigen test, HCV Antibody Test (Anti HCV)
5.	Refrigerator
6.	Micropipette (20ul/ 200 ul/ 1000 ul)
7.	Semi biochemistry analyser
8.	Cell counter/ 3 part haematology analyser
9.	Needle Holder and stitch remover
10.	Instruments like Kidney Tray, Steel Tray, Surgical Scissors, etc)

VI. Management of Common Communicable Diseases, and OPD for acute illness and minor ailments

Sl. No.	Name of Equipment
1.	BP apparatus (Digital/ Aneroid)
2.	Glucometer
3.	Pulse Oximeter
4.	Semi-automated biochemistry analyser
5.	Spirometer for rehabilitation
6.	Stethoscope
7.	Thermometer
8.	Turbidometer
9.	Binocular Microscope
10.	Microscope with Slide Box (20-25 slides)

VII. Screening, Prevention, Control and Management of Non-Communicable Diseases

Sl. No.	Name of Equipment
1.	Cusco's speculum
2.	Dental Mouth mirror
3.	LED Mobile Examination Light
4.	Examination Table
5.	Glucometer
6.	BP apparatus (Digital/ Aneroid)
7.	LED Torch
8.	Wooden disposable spatula
9.	Consumables: Gluco-strips, Gloves, cotton swabs, distilled water, dilute acetic acid (5%), (freshly prepared), wooden sticks, gauze, normal saline solution, wooden blades wooden sticks, gauze, normal saline solution, wooden blades, urine test
10.	Autoclave
11.	IV Set with Stand
12.	ECG Machine – 12 Channel
13.	Oxygen Cylinder

14.	Pulse Oximeter
15.	Stethoscope
16.	Semi-automated biochemistry analyser
17.	Cell counter/ 3 part haematology analyser
18.	Urine dipsticks (strip based testing)
19.	Kit for VIA examination

VIII. Oral Healthcare

Sl. No.	Name of Equipment
1.	Dental chair with all accessories
2.	Mouth mirror
3.	Needle holder/ artery forceps
4.	Tissue holding forceps
5.	Torch
6.	Tweezer
7.	Wooden spatula
8.	Consumables: Cement carriers, needle, suturing material, scissors, curved haemostat, scalpel, blade no 11 & 15
9.	Autoclave (electronic)
10.	Extraction forceps

IX. Care for Common Ophthalmic and ENT problems

Sl. No.	Name of Equipment
1.	Ophthalmoscope
2.	Stainless steel tray with sterile cottons/ swabs/ gloves
3.	Snellen & Near Vision Charts
4.	LED head lamp
5.	Lid speculum
6.	Nasal Speculum
7.	Tongue depressor
8.	LED Torch
9.	Trial frame (adult and child) with Trial set
10.	Tuning fork – 512 Hz
11.	Otoscope
12.	Head Light

X. Screening and Basic Management of Mental Health Ailments

Sl. No.	Equipment List
1.	Patient Health Questionnaire (PHQ-9)
2.	Hamilton Depression Scale
3.	Beck Depression Inventory (BDI)

XI. Elderly and Palliative Health Care Services

Sl. No.	Equipment List
1.	Glucometer
2.	Torch
3.	Forceps
4.	BP apparatus (Digital/ Aneroid)
5.	Stethoscope
6.	Tongue Depressors
7.	Charts for Exercise Guidance
8.	Wheelchair
9.	Lower and Upper Extremity Cycle/Ergometer
10.	Spirometer for Breathing Exercises
11.	Shoulder Wheel
12.	Wall Ladder Finger Exerciser
13.	Finger Exerciser Web
14.	Free Weights (0.5 kg, 1 kg, 1.5 kg)
15.	Shoulder Pulley
16.	Adjustable and Reciprocal Walkers
17.	Exercise Couch with Accessories
18.	Colored Floor Patterns for Gait Training
19.	Light-weight foldable stool
20.	Positioning Chart for Special Patients
21.	Pulse Oximeter
22.	Snellen & Near Vision Chart
23.	Haemoglobinometer
24.	Glucometer

25.	Thermometer
26.	Dressing Trays
27.	Consumables: Scissors, gauze pieces, syringes and needles
28.	Ambu bag- Adult and neonatal
29.	Bed
30.	Examination Table
31.	Exercise Bicycle
32.	Nebuliser
33.	Ophthalmoscope
34.	Otoscope
35.	Walking Stick
36.	X-ray Viewing box

XII. Management of Common Emergencies, Burns and Trauma

Sl. No.	Name of Equipment
1.	Ambu bag- Adult and neonatal
2.	IV Stand
3.	Medicine Trolley with emergency drugs(e.g. Adrenaline, Hydrocortisone)
4.	Multipara Monitor (to monitor Heart Rate, BP, SPO2, ECG, Temp.)
5.	Oxygen Cylinder (to be used during Transport of patients for investigation or shifting)
6.	Pulse Oximeter
7.	Suction Machine (Electric & Foot-operated)
8.	Temporary splints for fractures
9.	Warmer (warm air blower to prevent hypothermia)
10.	Consumables: Philadelphia Cervical collar, Neck stabilization device, spine board, IV cannula, drip set, IV fluids, IO needle, Pressure dressing, Tourniquet (Adult & paediatric), Suturing set, Urinary catheter, Uro-bag, Oxygen cannula, mask, non-rebreather mask, airway adjuncts
11.	LED Mobile Examination Light

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