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Ministry of Health

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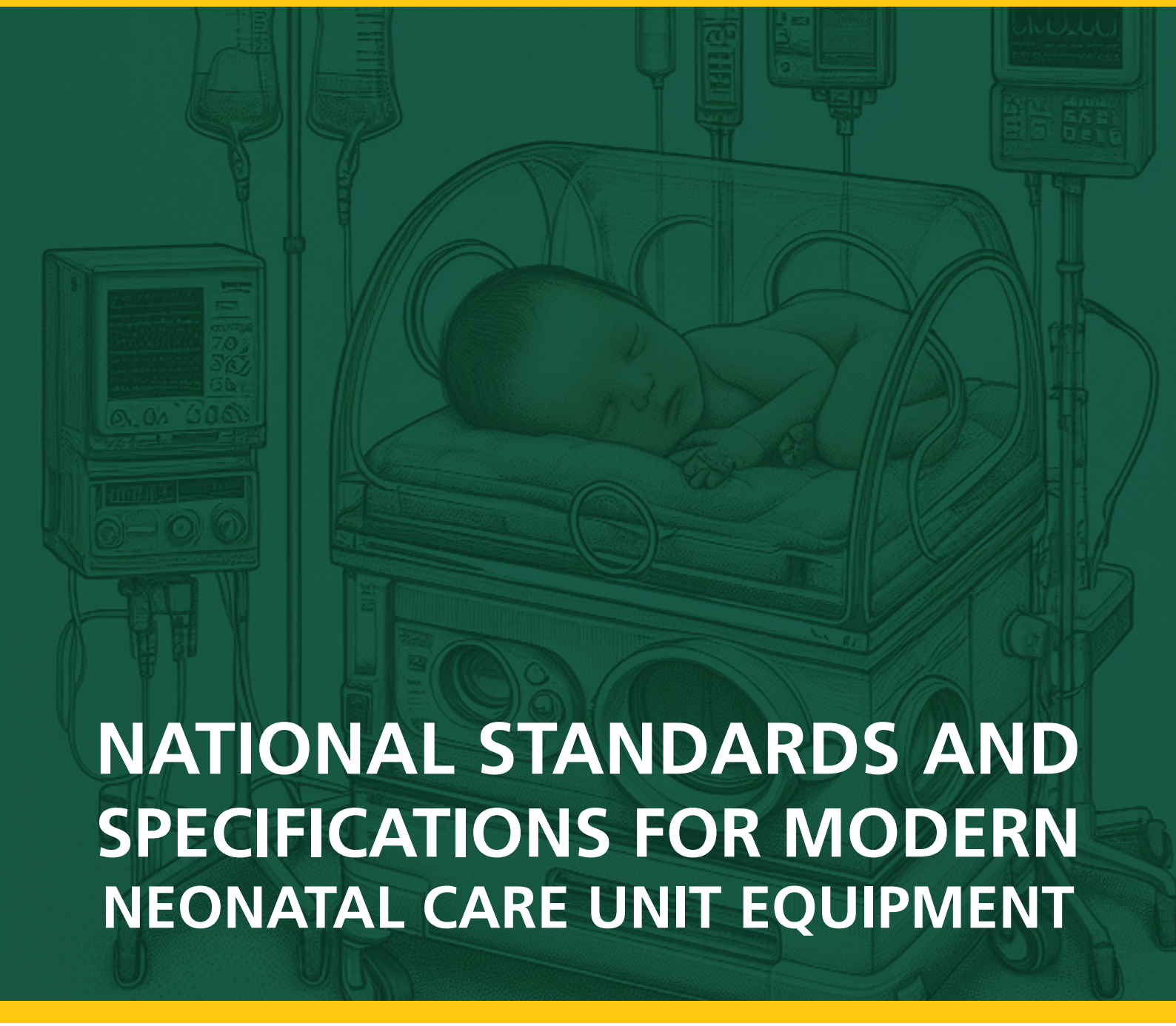

NATIONAL STANDARDS AND SPECIFICATIONS FOR MODERN NEONATAL CARE UNIT EQUIPMENT

NATIONAL GUIDE

2024

PREFACE

This document establishes a guideline for national neonatal care standards, serving as a reference for hospital management in the delivery of care for neonates in Palestine. Recognizing the unique challenges and opportunities within the Palestinian healthcare system, this guideline serves as a comprehensive reference for hospital management to ensure the delivery of exemplary care for neonates. In the development of this guideline, a wide range of stakeholders, including medical experts, hospital administrators, and healthcare policymakers – have been consulted. This collaborative approach has been instrumental in creating a well-rounded and practical set of standards. Its overall goal is not only to address current needs but also to lay a foundation for continual improvement and alignment with international best practices in neonatal care.

This guideline is designed for application across both governmental and private healthcare sectors, as well as by donors. It provides comprehensive information essential for medical planners, biomedical engineers, medical professionals, hospital owners, and directors. Additionally, it serves as a crucial resource for all health personnel engaged in establishing or upgrading neonatal care units. It encompasses detailed specifications on medical equipment, workflow processes, and infrastructural considerations. It aims to enhance operational efficiency and optimize financial resources while prioritizing the highest value in patient care. Specific attention has been given to designs, dimensions, and civil work aspects, offering valuable insights for medical planners and biomedical engineers.

Furthermore, the guideline is designed to be a dynamic document, adaptable to the evolving landscape of medical technology and healthcare needs in Palestine. It is subject to review and approval by the Palestinian Ministry of Health's (MoH) Engineering Unit, ensuring compliance with national standards. Hospitals and healthcare providers are required to obtain MoH approval before implementing these guidelines, ensuring a unified approach to neonatal care across all facilities.

Our vision is a future where every neonate in Palestine receives the highest standard of care, supported by state-of-the-art facilities and highly skilled medical professionals. We believe this guideline is a significant stride towards that future, benefiting not just the medical community but every family and newborn in our nation.

ACKNOWLEDGEMENTS

This document represents the culmination of persistent effort and unwavering dedication from a multitude of individuals whose contributions have been invaluable. We extend our deepest gratitude the National Committee for Standards and Specifications of Neonatal Intensive Care Unit (NICU) Medical Equipment and professionals listed below. Their expertise, insights, and tireless commitment have been instrumental in shaping this guideline into a comprehensive and effective tool for neonatal care standards. This guide is a testament to the significant efforts of the National Committee for Equipment Standards, neonatologists, engineers, and other professionals who, with the support of UNICEF – State of Palestine, led this crucial initiative.

We sincerely acknowledge the invaluable inputs and field insights provided during the drafting and revision of this document. Special thanks are due to those who diligently worked to establish firm standards and specifications for medical equipment, as well as to the members of the national committee who meticulously reviewed, revised, and finalized the draft.

- **Engineer Majed Wahdan,** Head of Biomedical Engineering Unit, MoH, Head of the National Committee
- **Dr. Hadeel Al-Masri,** Head of Women Health and Development Unit, MoH
- **Engineer Thaer Bleibleh**, Head of Engineering and Maintenance Unit, MoH
- **Engineer Abdel Salam Hamdan,** Biomedical Engineering Department, MoH
- **Engineer Allam Tahayna,** Engineering and Construction Unit, MoH
- **Engineer Ahmad Basheer,** Biomedical Engineering Department, MoH
- **Dr. Amir Atawneh,** Neonatologist, Al-Makassed Islamic Charitable Hospital
- **Dr. Elias Habash,** Juzoor for Health and Social Development
- **Engineer Ibrahim Elyyan,** Juzoor for Health and Social Development
- **Engineer Mahmoud Sandouka,** Juzoor for Health and Social Development

Special thanks to Caritas Baby Hospital - Bethlehem for the kind cooperation and support in giving the opportunity to make real photos for the equipment that were used in this guide.

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- **Dr Hatem Khammash,** Head of Neonatal Unit, Makassed Islamic Charitable Hospital
- **Dr. Nabil Barqouni,** Head of Gaza Neonatal Network

We extend our sincere gratitude to UNICEF for supporting the preparation of this guide, made possible through a generous contribution from the Norwegian government. Their support has been pivotal in enabling the comprehensive development and dissemination of these vital standards.

INVITATION FOR FEEDBACK AND ENGAGEMENT

These standards are the product of collaboration among professional engineers with over 20 years of experience in medical equipment and planning, esteemed architectural firms, state planning agencies, and seasoned medical professionals. This diverse expertise ensures that the standards meet both technical precision and practical applicability.

We recognize that the field of neonatal care is continually evolving, and so must our standards. Therefore, we warmly welcome and value your feedback. Whether it's suggestions for modifications, additions, or insights into the impact these standards are having on neonatal unit design and care, your input is crucial for ongoing refinement.

We are keen to understand how these standards are being applied in practice and their effect on neonatal care. Please feel free to contact us with your experiences, insights, and suggestions. Your engagement is key to ensuring that these standards remain relevant, practical, and effective in advancing neonatal care.

ACRONYMS & ABBREVIATIONS

AAP	American Academy of Pediatrics
AC	Alternating Current
AKI	Acute Kidney Injury
Cath lab	Catheterization Laboratory
CPAP	Continuous Positive Airway Pressure
cmH2O	Centimeters of Water
CRRT	Continuous Renal Replacement Therapy
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
ECMO	Extracorporeal Membrane Oxygenation
ENAP	Every Newborn Action Plan
ETT	Endotracheal Tube
FDA	United States Food and Drug Administration
FO	FO
FPD	Flat Panel Detector
Hb	Hemoglobin
Hct	Hematocrit
HD	High Definition

HFNC	High flow nasal cannula
HFV	High Frequency Ventilation
HIS	Hospital Information System
ISO	International Organization for Standardization
IT	Information Technology
IV	Intravenous
LCD	Liquid Crystal Display
LED	Light Emitting Diode
LIS	Laboratory Information System
MoH	Palestinian Ministry of Health
NICU	Neonatal Intensive Care Unit
NIV	Non-Invasive Ventilation
PACS	Picture Archiving System
PCO2	Partial Pressure of Carbon Dioxide
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
PO2	Partial Pressure of Oxygen
PSIG	Pounds per square inch gauge
SpO2	Oxygen Saturation
UMDNS	Universal Medical Device Nomenclature System
UNICEF	United Nations Children's Fund

FOREWORD BY THE MINISTER OF HEALTH

Serious and concerted efforts have must be made to address the needs of newborns in their first days of life to reduce neonatal morbidity and mortality in Palestine. Standard preventive interventions within the neonatal unit environment of healthcare facilities remain the cornerstone in addressing newborn morbidity and mortality.

There is always room for improvement in the provision and delivery of services for both essential newborn care and the care of sick newborns in existing neonatal units in Palestine.

The Palestinian Ministry of Health, in its endeavor to achieve the highest standards of healthcare, is undertaking several programmatic and institutional strengthening measures. Developing standards for medical equipment used in neonatal care units is one such programmatic intervention, aiming at improved neonatal healthcare services and the overall health of the Palestinian population.

Medical devices are a very important part of healthcare, and their use is increasing by the day. Providing essential standards for medical equipment in neonatal units is a critical component of strengthening health infrastructure. However, rapidly changing technologies, the complexity associated with medical equipment, and the high costs of procurement make the selection of appropriate and cost-effective equipment a challenging task.

The Ministry of Health provides support to health providers in improving the quality of health services and enhancing the necessary infrastructure, including medical equipment. Ensuring adequate, safe, and appropriate medical equipment at all levels of health facilities remains a focus of the Ministry of Health.

I am happy to note that the National Health System, under the guidance of national experts and with the active participation of partners, has filled an important technical gap by providing technical specifications for commonly used medical devices in neonatal units. I am confident that specifications meeting adequate standards of safety and accuracy will be very useful for the health system in undertaking appropriate and cost-effective procurement, efficient utilization, and maintenance of medical devices.

I hope that this reference guide will contribute to the improvement of newborn care in Palestine and ensure that advanced medical technologies are available and efficiently used to provide the best possible services for all children at the beginning of life.

Minister of Health

Dr. Maged Awni Abu Ramadan

ABOUT THIS WORK

The development of equipment specifications was inspired by the "Every Newborn Action Plan" (ENAP). This initiative is part of a strategic plan to prepare and equip every neonatal unit and Neonatal Intensive Care Unit (NICU) in Palestine with the best and most suitable medical equipment to meet the needs of our newborns and improve neonatal care services.

This guide aims to provide health decision-makers, directors, biomedical engineers, and health providers working in neonatal care units with a reference for equipment standards and specifications. It considers the healthcare situation in Palestine and is adapted for use across public, civil society, and private sectors. The guide offers detailed specifications for commonly used medical devices in neonatal units, along with tips for their utilization and maintenance. It aligns with the latest evidence-based science and advanced medical technologies to support the standards of neonatal care services, aiming to achieve better newborn health outcomes. Moreover, it focuses on the most efficient and cost-effective service provision, considering the limited availability of resources.

Great efforts have been made to ensure that the specifications are as generic and technically appropriate as possible. Key considerations such as cost, utility, domestic market availability, maintenance, and patient safety have been paramount in the preparation of this guide. Using these reference specifications for procurement will help reduce costs, maintenance issues, and procurement lead time. Regular updates are essential to incorporate new research findings and experiences.

We believe that quality healthcare for newborns in Palestine is achievable. This guide represents a significant step forward in that direction.

STANDARDS

National Standards Compliance

The guideline adheres to internationally recognized standards, including the International Electrotechnical Commission's IEC 60601 and IEC 62353 for medical electrical equipment, as well as the International Organization for Standardization (ISO) 9001 standard for quality management systems.

DEFINITIONS OF NICU

There is no unified national standard defining a NICU. While some states have established levels of care, others rely on informal or non-existent classification systems. The American Academy of Pediatrics (AAP) has defined NICU levels primarily based on the availability of specialized equipment and staff. However, these units often provide both intensive and step-down or intermediate care.

For the purpose of this document, newborn intensive care is defined as care for medically unstable or critically ill newborns who require constant nursing, complex surgical procedures, continual respiratory support, or other intensive interventions. Intermediate care, on the other hand, caters to ill infants needing less constant nursing, but does not exclude respiratory support. In facilities where an intensive care nursery is available, the intermediate nursery functions as a 'step down' unit from the intensive care area. In cases where hospitals accommodate infants with varying levels of acuity in the same area, the design standards of intensive care should be applied to ensure maximum clinical flexibility.

NICU departments are categorized as follows, taking into consideration the situation and needs in Palestine:

- Area A: Observation Room
- Area B: Neonatal Intensive Care
- Area C: Intermediate Care
- Area D: Isolation Room
- Area E: Emergency Room
- Area F: Milk Preparation
- Area G: Breast Feeding

SAMPLE NICU LAYOUT

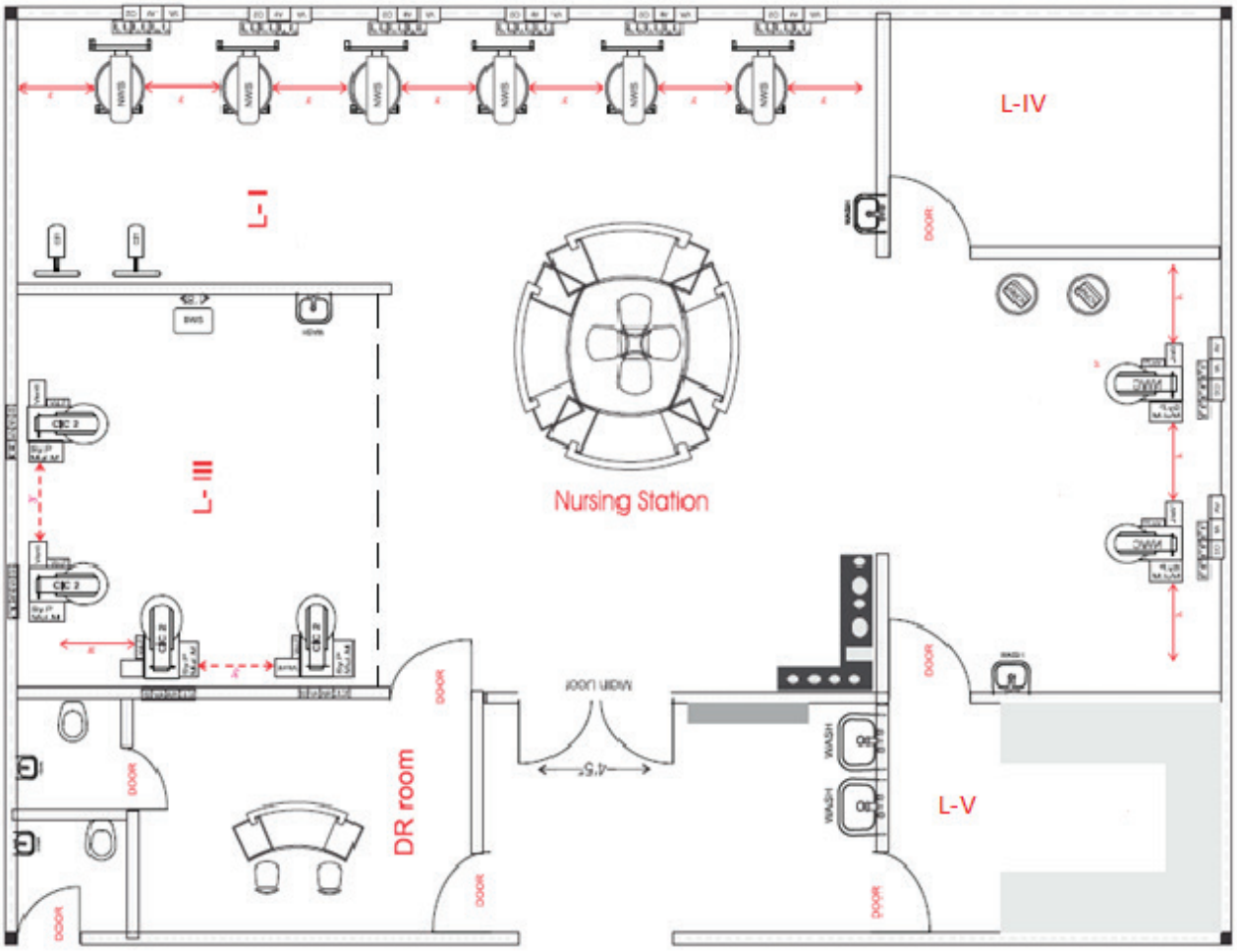


Figure 1: Sample Layout for NICU

* This architectural design is provided SOLELY for clarification. Applicable standards should be adhered to when designing a new NICU Unit.

An architect should design the unit while considering the following factors:

- Unit configuration and NICU location within the hospital
- Minimum space requirements, including clearance and privacy for the infant space
- Electrical and gas supply needs, along with mechanical requirements
- Airborne infection isolation room(s)
- Family entry, reception area, and handwashing stations
- General and staff support spaces

- Family transition room(s) and family support space
- Support space for ancillary services and administrative space
- Ambient and procedure lighting in infant-care areas, as well as illumination of support areas
- Daylighting considerations
- Floor, wall, and ceiling finishes
- Furnishings
- Ambient temperature and ventilation
- Acoustic environment
- Safety and infant security measures
- Access to nature and other positive distractions

Additional considerations:

- High Purity Oxygen Supply is required for the NICU.
- The expected lifetime of medical equipment ranges from 7 to 10 years at maximum. Replacement and disposal should comply with national regulations and guidelines.
- Lighting and environmental conditions should be carefully designed in accordance with ISO standards.

Annex 1 provides examples of specific NICU room and facility layouts.

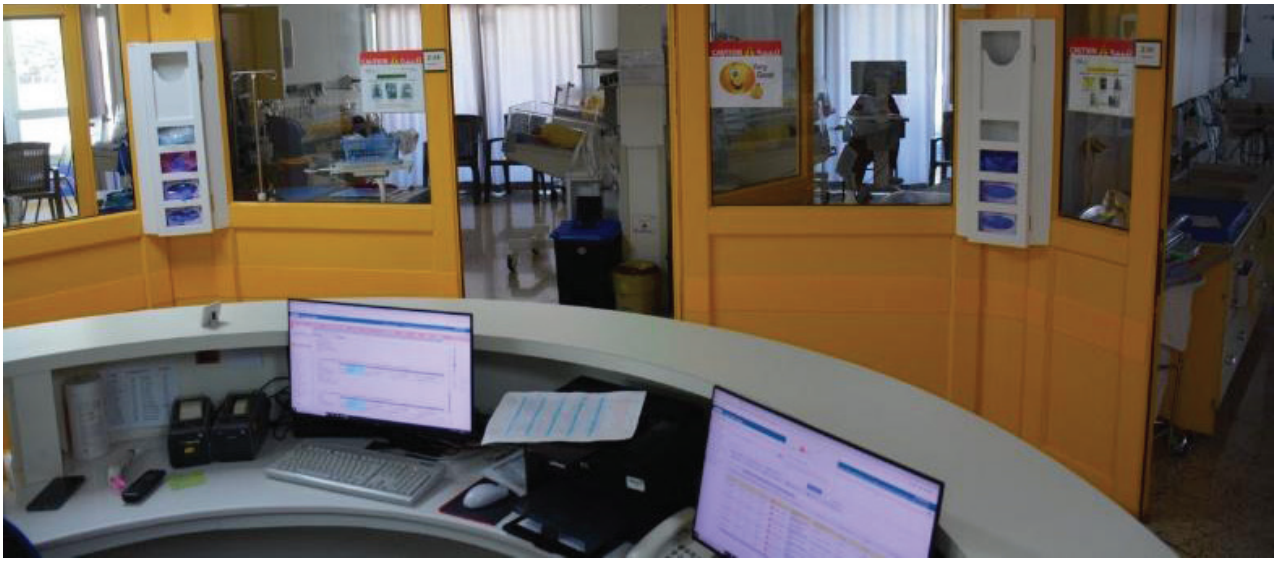
SCOPE OF EACH UNIT WITH EQUIPMENT LIST

Area A: Observation Room

Normal Neonatal Care

Scope: This is usually administered by the mother in the postnatal ward, under the supervision of a nurse and doctor, and requires minimal medical care or nursing advice.

- Minimal Dimensions for each Unit: 2.8 m Height x 1.2m Width x 2m Length.
- Ventilation System: Normal atmospheric pressure with a fresh air source.
- Temperature: A stable air temperature of 25°C is optimal, with a maximum deviation of 2 degrees.
- Humidity: Relative humidity should be maintained between 30% to 60%, ensuring that there is no condensation on the walls.



List of Equipment:

1.	Pulse Oximeter
2.	Vital Sign Monitor
3.	Scale
4.	HIS Access
5.	Baby Cot
6.	Radiant Warmer
7.	Bilirubinometer
8.	Heating / Cooling Mattress
9.	Labeling System
10.	Noise Level Detector

* Quantities to be determined according to the number of beds and maximum patient capacity.

Area B: Neonatal Intensive Care

Scope:

Care in the special care nursery is provided for seriously ill neonates who require intensive management by skilled nursing and medical staff.

- Minimal Dimensions for each Unit: Height 2.8m x Width 1.9m x Length 2m.
- Ventilation System: Maintain positive pressure, air treatment unit with HEPA filter, 30% fresh air.
- Temperature: A stable air temperature of 24°C is optimal, with a maximum allowable deviation of ±2°C.
- Humidity: Maintain relative humidity between 30% to 60%, ensuring there is no water condensation on the walls.

List of Equipment:

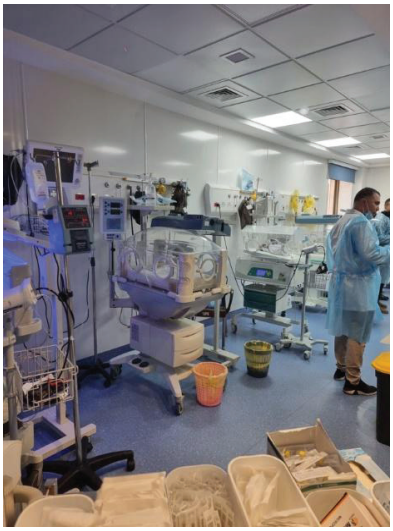
1	Bed Head Unit	21	High Frequency Ventilator
2	Transport Monitor	22	High Flow Oxygen Therapy Machine
3	Open System Incubator	23	Ventilation Humidifier
4	Closed System Incubator	24	Scale
5	Open-Closed System Incubator	25	Ultrasound machine
6	Hemodynamic Monitor with Central Station	26	Cerebral Function Monitor
7	Syringe Pump	27	Transport Incubator
8	Infusion Pump	28	Medication Trolley
9	Defibrillator	29	Emergency Trolley

10	Phototherapy machine	30	Oxygen Flow Meter
11	Bilirubinometer	31	Oxygen Air Mixer
12	Examination Lamp	32	Suction Unit
13	Pulse Oximeter	33	Access to HIS
14	Vein Viewer	34	Access to PACS
15	Mobile Digital X-ray machine	35	Glucometer
16	ECMO Machine	36	Noise Level Detector
17	Dialysis Machine for Infants	37	Oxygen Monitor
18	Vital Sign Monitor	38	Blood Gas Analyzer
19	Conventional Neonatal Ventilator	39	Water Distillator
20	Bubble CPAP Machine	40	Heating-Cooling System

* Quantities to be determined according to the number of beds and maximum patient capacity.

Area C: Intermediate Care Room (Special Care Nursery)

Scope:



Care provided in the special care nursery includes observation, treatment and monitoring that is more extensive than normal routine but does not require the full resources of intensive care.

- Minimal Dimensions for each Unit: Height 2.8m x Width 1.2m x Length 2m.
- Ventilation System: Positive pressure, air treatment unit with HEPA filter, 30% fresh air (ASHRAE 170-2017 table 7.1).
- Temperature: The stable air temperature should be maintained at 24°C, with a maximum deviation of ±2°C.
- Humidity: The relative humidity should be between 30% to 60%, ensuring there is no condensation on the walls.

List of Equipment:

1	Open System Incubator	11	Access to HIS
2	Closed System Incubator	12	Access to PACS
3	Ambient Oxygen Monitor	13	Bubble CPAP/CPAP Machine/ NIV
4	Vital Sign Monitor	14	Diagnostic Light Source
5	SCALE	15	Oxygen Flow meter
6	Infusion Pump	16	Oxygen Blender
7	Syringe Pump	17	Bed Head Unit
8	Phototherapy Unit	18	Noise Level Detector
9	Blood gas Analyzer	19	Bed Head Unit
10	Bilirubinometer		

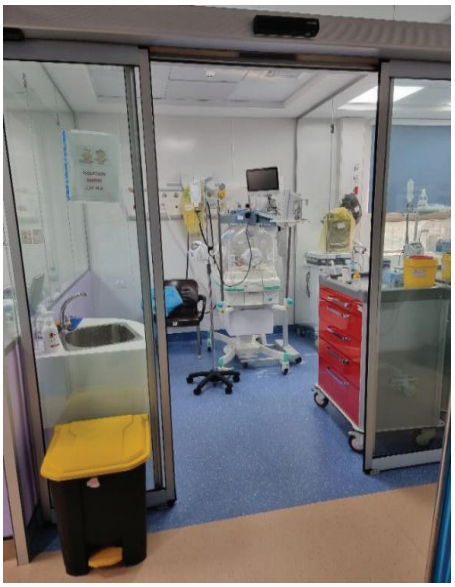
* Quantities to be determined according to the number of beds and maximum patient capacity.

Area D: Isolation Room

Scope:

This unit is designed for patients at risk of infection or with low immunity.

- Minimal Dimensions for each Unit: 2.8 m Height, 3m Width, 2.5m length.
- Minimal Dimensions for each Unit: Height 2.8 m, Width 3 m, Length 2.5 m.
- Ventilation System: The system must maintain negative pressure with a source of fresh air. Recycling of air is prohibited, and the system must be separate from the unit (negative pressure, air treatment unit with HEPA filter, 100% fresh air) (ASHRAE 170-2017 table7.1).
- Temperature: The optimal stable air temperature is 25°C, with a maximum deviation of ±2°C.
- Humidity: Relative humidity should be maintained between 30% to 60%, with no condensation on the walls.



List of Equipment:

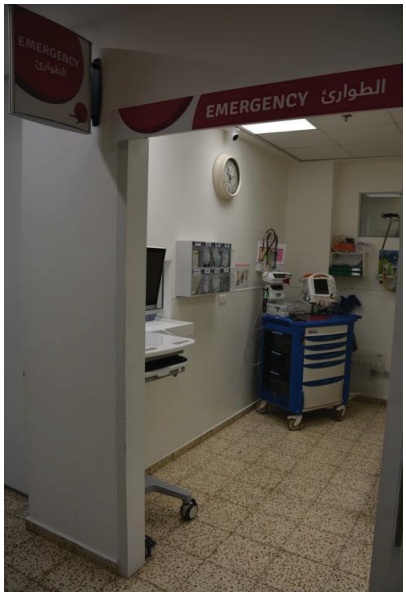
1	Bed Head unit	8	Ventilation Humidifier
2	Open-Closed System Incubator	9	Oxygen Flow Meter
3	Hemodynamic Monitor	10	Oxygen Air Mixer
4	Syringe Pump	11	Suction Unit
5	Infusion Pump	12	Access to HIS
6	Examination Lamp	13	Access to PACS
7	Conventional Neonatal Ventilator	14	Emergency Trolley

* Quantities to be determined according to the number of beds and maximum patient capacity.

Area E: Emergency Room

Scope:

The Emergency Room is designed for rapid admission and immediate response to emergency cases before transfer.



List of Equipment:

1	Open System Incubator with resuscitation Module
2	Neopuff
3	Defibrillator
4	Emergency Trolley complete
5	Transport Incubator
6	Syringe Pump
7	ICU Monitor
8	Access to HIS
9	Access to PACS
10	Bed Head Unit

* One Unit for Each Hospital is required.

Area F: Milk Preparation Room

Scope:

The Milk Preparation Room is used to prepare the necessary nutrition for the babies in different areas.

* Milk Lab Overview

List of Equipment:

1	Medical Refrigerator
2	washer disinfector
3	Milk Bottle Sterilizer (Autoclave)
4	Fume Hood
5	Labeling System
6	Breast Pump
7	Milk warmer (water bath)
8	Water Distillator

Area G: Breast Feeding Room

Scope:

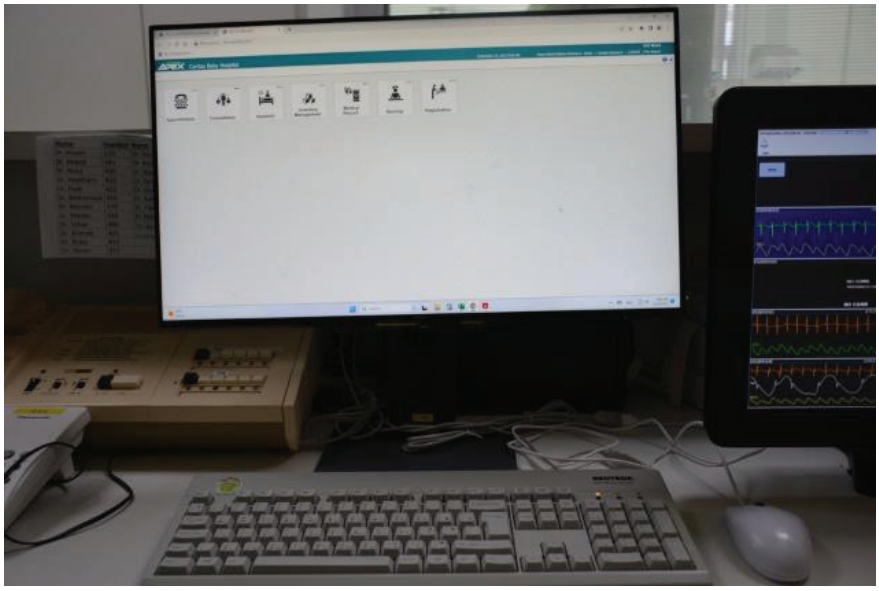
Area where the mother feeds her baby under observation.

List of Equipment:

1	Medical Refrigerator
2	Breast Milk Pump
3	Milk warmer (water bath)

SPECIFICATIONS OF EACH MEDICAL EQUIPMENT

1. Access to Hospital Information (HIS)



Purpose:

Online computer-based software connected to a central data management system for:

- Storing all patient data.
- Admitting and discharge patients.
- Adding orders.
- Reviewing patient history.
- Reviewing patient tests and exams.
- Adding notes.
- Adding reports.
- Recording all patient data coming from third-party devices, such as patient monitors, ventilators etc…

Principles of Operation:

- The system is computer-based software, interfere between biomedical engineers and information technology (IT).
- Special training is required for both IT and biomedical engineers.

Supplies requirements:

- Electrical source 220 V,50 Hz, socket.

Safety & Product Standards:

- N/A.

Technical Specifications:

- In accordance with the Data Management System installed at the hospital.
- IT Specialist required.

System Configuration Accessories, Spares and Consumables:

- As per the Hospital System.

Documentations:

- Operating manual.
- Service manual.
- Quick guide to basic operation.

Training Needed:

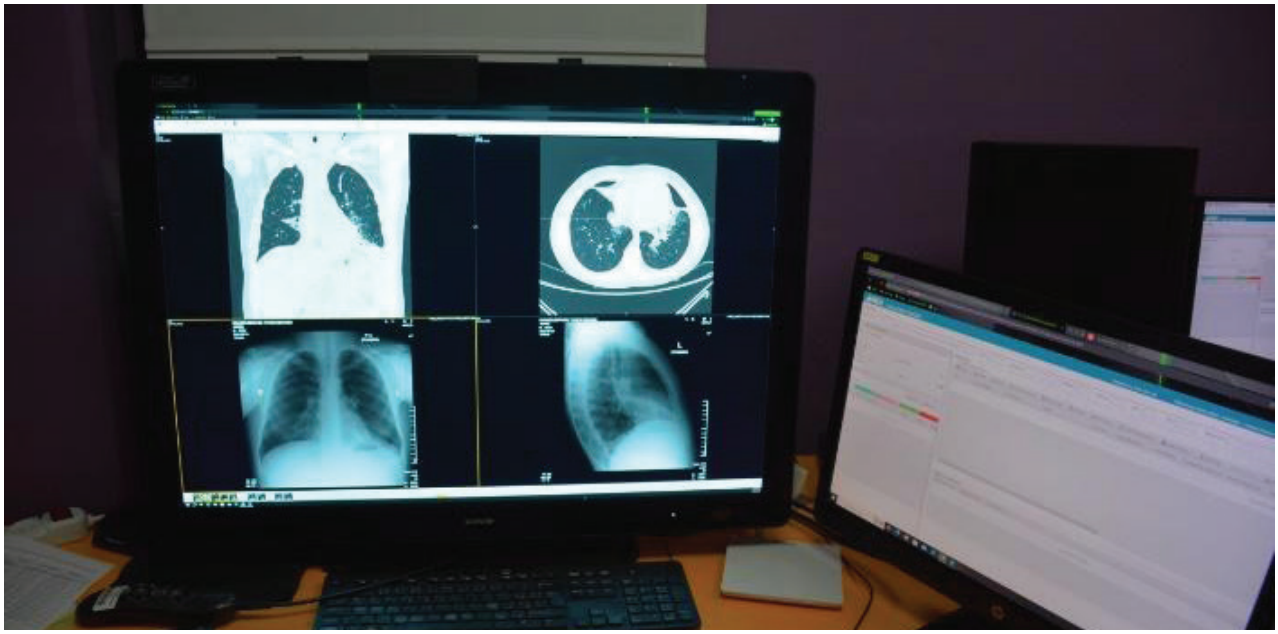
- Operation training.
- Clinical training.
- Service training.

Preventive Maintenance and Periodic Tests:

"Always test to according to the standards and/or the manufacturers' service manual."

2. Access to Picture Archiving System (PACS)

Purpose:



Full high definition (HD) medical online computer-based software that connects to a central data management system, where all patient imaging data is stored

- Review Mobile X-ray Data (Conventional Radiology).
- Review Fluoroscopic Images.
- Review CT Images.
- Review Cath lab Images.

Principles of Operation:

Computer-based software where all Digital Imaging and Communications in Medicine (DICOM) format images can be retreated, manipulated, and stored for medical decisions.

Supplies requirements:

Electrical source 220 V,50 Hz, socket.

Safety & Product Standards:

- N/A

Technical Specifications:

- As per the Data Management System installed at the hospital.
- IT Specialist required.

System Configuration Accessories, Spares and Consumables:

- As per the Hospital System.

Documentations:

- Operating manual.
- Service manual.
- Quick guide to basic operation.

Training Needed:

- Operation training.
- Clinical training.
- Service training.

Preventive Maintenance and Periodic Tests:

"Always test to according to the standards and/or the manufacturers' service manual."

3. Oxygen Hood

Universal Medical Device Nomenclature System (UMDNS): 12-027

Technical Specifications:

- Dome shape.
- Canopy placed over the head and shoulders.
- Provide oxygen at a higher level than normal.
- Set of Reusable Hoods.
- Includes all sizes.
- Autoclavable polycarbonate material.
- Clear plastic shell encompasses the baby's head.
- 100% Pure Virgin Plastic.
- Is tolerated by babies.
- Allows easy access to chest, trunk and extremities.
- Trauma free silicone neck adjustment flap.
- Trauma free silicone neck adjustment flap.
- System Configuration Accessories, Spares and Consumables
- System as specified.
- Oxygen tube.

4. Baby Cot

Technical Specifications

- Height adjustable mechanically by gas spring from 65-90cm approx.
- Mechanical tilting with spring.
- Trendelenburg ± 14°.
- Powder coating polyester stand.
- Plastic baby crib.
- Crib dimension 65*60 cm approximately.
- Weight limit not less than 15 kg.
- 4 castors with brake mechanism.
- Includes foam mattress with washable cover.

System Configuration Accessories, Spares and Consumables:

- Crib.
- Stand.
- Foam mattress.

5. Bed Head Unit

Technical Specifications:

- Bedhead services for medical gasses, electrical power, nurse call.
- Vertical / Horizontal according to site.
- With integral equipment mounting pole/rail.
- Services to include:
- 2 x Medical Air Outlet.
- 2 x Oxygen Outlet.
- 2 x Vacuum Outlet.
- 2 x Data Socket.
- 4 x Power Socket.
- 2 x Power (UPS) Socket.
- 1 x Ground.
- 1 x Nurse call.
- 1 x AVSU
- 1 x Alarm
- *Medical Gas HTML 02-01 Code

6. Bilirubinometer

Universal Medical Device Nomenclature System (UMDNS): 16-166

Technical Specifications:

- Hand-held direct reading for total serum in mg/dl or µmol/l.
- Premature baby measurable (more than 1000 g).
- Non-invasive.
- The meter work by directing light into the skin of the neonate and measuring jaundice.
- Principle of measurement by detecting signal from the skin.
- Not less than 400 times measurements per fully charged battery.
- Long life bulb life, not less than 100000.
- Measuring methods.
- Determine yellowness of subcutaneous tissue by using two optical paths to measure optical density difference at two wavelengths.
- Measurement Range: 0-25 mg/dl.
- Accuracy: ± 1.5 mg/dl.
- Digital Liquid Crystal Display (LCD) display.
- Light source Xenon or LED.
- Silicon photodiode Sensors.
- Including Original Charger and Should be provided with Carry bag.
- Power input to be 220-240VAC, 50Hz.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Battery charger.
- Carry bag.

7. Blood Gas Analyzer

Universal Medical Device Nomenclature System (UMDNS): 15-709

Technical Specifications:

- Measured Parameters: pH, PCO2, PO2, SO2, Hct and Hb.
- Sample type: Whole blood.
- Accepts small sample for infants.
- Sample throughput: up to 30 per hour.
- Calibration method: fully automatic.
- Automatic calibration.
- With QC lockout.
- Color display type.
- Programmable data management.
- Data Storage Capability.
- Printer: built in thermal printer.
- Interface capability: RS232C (standard).
- Capable to be connected to HIS, LIS

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Startup kit.

8. Breast Pump

Universal Medical Device Nomenclature System (UMDNS): 10-485

Technical Specifications:

- Manual Single breast pump.
- Lightweight, portable design.
- With Personal breast shield that reduces pressure on the breast and optimize milk flow, 105-degree angle, oval shape, and soft rim, better fitting breast shield for optimal comfort while pumping and more milk per session.
- Easily fits into handbag, perfect for traveling.
- Uses 2 Phase technology to mimic natural baby sucking behavior at the mother's breast.
- Ergonomic swivel handle.
- Bottle stand helps prevent spills.
- Easy to use and clean.

System Configuration Accessories, Spares and Consumables:

- Breast Pump as specified.
- Breast Shield.
- 5-Oz/150mL Breast Milk Bottle with Lid and Stand.

9. Bubble CPAP Machine

Technical Specifications:

Air-oxygen blender:

- Oxygen concentration range should be 21 – 100%.
- Accuracy: ±3% full scale.
- Gas supply pressure: 30 – 75 PSIG.
- Flow range: 1 – 15 L/ min.
- It should be supplied with air & oxygen hose at least 5 meters in length with suitable adaptors.
- Blender should be United States Food and Drug Administration (FDA) and CE /BIS certified.

CPAP Generator:

- Capable to deliver nasal/ nasopharyngeal Continuous Positive Airway Pressure (CPAP) and heated humidified high gas flow through nasal cannula /mask (>2 LPM).
- CPAP generator with pressure range 3 to10 cm of water, accuracy: ±1 cm of H2O.
- Gas flow range: 1 – 15 LPM.
- Pressure release valve: safety valve mechanism to release excessive pressure.
- Reservoir (Bubble chamber) capacity: >300 ml.
- Generator tube: graduations in the tube should be clearly readable from a distance of 6 feet, and it should be snugly fitting into the chamber and the chamber should be transparent for checking water level.
- Equipment mounting stand: should be supplied with a stand with clamps for mounting blender, bubble chamber and humidifier.
- Soft anatomically shaped nasal prongs.

- Alarms for: Low/high Temperature, Tube open, Flow increase/decrease alarm, O2 pressure low alarm, Air pressure low alarm.
- Power 220-230 volts 50 Hz.

Humidifier:

- Servo controlled
- Should be capable of supplying fully saturated gas at 370C.
- Flow resistance <20 cm H2O L/ sec.
- Temperature range: 310°C – 400°C, ± 20°C.
- Digital display of temperature.
- Capable of ambient humidity compensation.
- Should be compatible with both reusable & disposable chambers and circuits.
- Must have water level indicator in the chamber.
- Minimum warm up time: <30 min
- Servo humidifier should be US FDA and European CE /BIS certified.

System Configuration Accessories, Spares and Consumables:

- Air-oxygen blender.
- CPAP generator.
- Humidifier including reusable chamber, temperature probe, heater wire with adaptor.
- Mounting stand.
- Patient circuits.
- Nasal interface including nasal prongs, and masks of different sizes.
- Head bonnet of different sizes.
- 5 ml test lung.

10. Cerebral Function Monitor

Universal Medical Device Nomenclature System (UMDNS): 17-412

Technical Specifications:

Compact:

- Continuous real time bedside monitoring of cerebral function in preterm and term babies.
- Should provide amplitude integrated EEG record of overall electro cortical background activity of brain.
- Should display one channel EEG in real time with adjustable speed and amplitude, should use 3 electrodes to measure single channel amplitude EEG.
- Real time and review modes.
- CFM, impedance, and an EEG display.
- Shows trends and transient events.
- Onscreen indication/alarm for abnormal conditions (impedance, interference) or device malformation.
- Built in safeguard for interruption in power supply, self-calibration check, and lead-off alarm.
- Should have on screen display of at least three hours of cerebral function monitoring trace.
- It should be capable of continuously recording for up to 30 days.

- Battery backup for 60 minutes.
- Including built-in printer.
- Should have internal memory to store data for 20000 hrs of monitoring to maintain complete patient file management.
- Should be simple and easy to operate with LCD touch screen display.
- Should have facility to customize markers, display style, language, operation mode, print traces & patient information display as per user preference.
- Should provide color coded alerts and status messages for caution & action to be taken.
- Should be supplied with viewer software to transfer & view the data to any Microsoft window PC, print & capture images.
- Should have facility to select different combination of graphs for print.
- Should have RS 232 interface & serial IO port for Network / Ethernet connection.
- Should have inbuilt handle for easy transportation.

System Configuration Accessories, Spares and Consumables:

- Cerebral Function Monitor as specified.
- Trolley with locking castors.
- Including built-in printer.
- Cable and Electrodes.
- EEG paste and Disposables/reusables.
- Thermal paper

11. Closed System Incubator

Universal Medical Device Nomenclature System (UMDNS): 17-432

Technical Specifications:

- Mobile neonatal incubator for infants in NICU.
- Microprocessor controlled equipment.
- Double wall transparent shield, X-ray compatible.
- Completely tip-up frontal access hatch Double Sided Sliding tray with Kangaroo Mode or Similar.
- Variable height hood.
- Mechanical one step cradle tilting, up to 12 degrees.
- Double Temperature control, skin 34-36°C and air modes Ambient -37°C.
- Temp accuracy 99%.
- Dual skin temperature monitoring.
- Humidity control 30% to 85%.
- Two side-access panels.
- At least 4 access doors with covers and at least 6 separate tubing ports with related covers.
- Left and right Tubing grommets on both front and rear.
- Adjustable bed tilt with mattress.
- IV pole with 4 hooks included.
- Sliding out an integrated X-ray tray.
- Patient removable bed/mattress: 55 cm (length) x 34 cm (wide) approx.

- Mattress made by a material flame retardant, washable, antibacterial and resistant to: corrosion, water, detergent soap. X-ray compatible.
- At least 2 Drawer big size included.
- Shelf for monitor is included.
- Mobile equipment with at least 4 castor anti-static and rust-free wheels and two brakes.
- Alarms: visual and audible for air flow, Skin temperature, Air temperature, sensors failure, Air circulation failure, Power failure with possibility to silence audible alarm.
- Noise level inside < 45 dB.
- Micro air intake filter 99.9% efficiency.
- Digital displays for air and skin temperatures, humidity and oxygen %.
- Oxygen servo control Module (Oxygen monitor), Price separately.
- Humidity servo control Module, Price separately.
- Including: temp probes, sensors, (filters (Set of 5 boxes)).

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Mattress.
- Oxygen servo control Module.
- Humidity servo control Module.
- Temperature skin probe.
- Temperature air probe.
- Air filter.

12. Ventilators, Intensive Care, Neonatal / Pediatric

Universal Medical Device Nomenclature System (UMDNS): 14-361

Technical Specifications:

High-end neonatal ventilator with HFV (Optional) with Non-Invasive Ventilation (NIV) Capabilities, on trolley with wheels and brake facility, Humidifier: Autoclavable humidifier chamber, Circuit Support arm.

General Requirements:

- The ventilator should be microprocessor controlled designed for neonatal use with possibility to upgrade with additional features.
- Continues flow, pressure limited, time cycled ventilator
- Should be able to ventilate patients with body weight from 400 grams to 25 kg
- Should have battery back-up for the ventilator with integrated rechargeable battery for a Minimum of 60 min operation.
- Should have integrated high resolution LCD screen minimum 12”color display with touch screen facility for real-time display of scalar (Pressure, flow and volume against time) and loop (Pressure-volume, volume-flow and pressure-flow). Graphic display of at least 3 waveforms together out of choice of flow, volume and pressure versus time with a facility to freeze these waveforms. Facility for loops together with a facility to freeze the same.
- Should have an integrated electronic blender for blending Air & Oxygen
- Monitoring of flow: At the Y piece or at Expiration Port with facility to activate or deactivate it.
- The flow sensor should be reusable and autoclavable.

- Should have device checking mechanism where it can determine and display the compliance and resistance of the system, determine leakage in the patient hose system and checking of valves, gas supply system, flow sensors etc.
- Should have an automatic leak compensation facility that provide sensitive triggering even with changing ET-Tube leaks
- Should have graphical as well as tabular trend facility of data up to 24 Hrs.
- Digital display of FiO2, peak pressure, mean airway pressure, CPAP/PEEP (Positive End Expiratory Pressure), Expiratory tidal volume, expiratory minute volume, total frequency, spontaneous frequency, lung function monitoring including compliance, resistance, lung distention coefficient, (C2O/C), Lung time constant, rate volume ratio etc.
- Should have a built-in logbook for recording events like various alarms.
- Integrated monitoring: Integrated volume and pressure monitoring i.e. monitoring of PEEP Pmax, Pmean and VT, VTspont, MV and MVleak. The volume monitoring should have NTPD to BTPS correction.
- Monitoring of I:E, frequency and Spontaneous Frequency.
- Should measure parameters in HFOV such as DCO2, VtHF, MVim and Vtim.
- Ventilator should have following features in Pressure support/volume Guarantee.
- It should be possible to give leakage adapted inspiratory trigger during pressure support to spontaneously breathing patients with a set volume guarantee.
- Volume guarantee should be regulated with lowest possible airway pressure within a set PIP.
- It should be possible to adjust the Volume Guarantee manually as per patient requirement
- The ventilator should have automatic compensation for leakage and should monitor and display leakages
- The ventilator should show trends of important parameters for evaluation of patient improvement.
- Ventilator should be supplied with good quality medical air compressor
- The servo Controlled Heated Wire Humidifier should be supplied along with Reusable patient circuit. The humidifier must be FDA approved.
- Battery back-up (at least 30 minutes) Battery should be integrated and should provide backup to both ventilator & Air compressor.
- Should be supplied with ultrasonic nebulizer which should have capability to deliver particle size of <3 micron and to be used in both off and on line with ventilator.

Ventilation Modes required:

- IMV/IPPV.
- CPAP including non-invasive ventilation.
- SIMV, SIPPV/Assist control.
- High frequency oscillatory ventilation which is oscillating diaphragm based (optional).
- Volume targeted/guarantee mode of ventilation with ability to deliver and monitor tidal volume as low as 1-2 ml (Range 2 ml to 50 ml).
- Pressure support mode of ventilation.
- Apnea back-up ventilation.

Setting Range:

- Trigger flow/volume, leak adapted.
- PIP 10 to 80 cm H20.
- PEEP/CPAP 0 to 25 mbar.
- I:E ratio 1:0 to 1:10.
- Insp. Time 0.1 to 2 Sec.
- Exp. Time 0.2 to 30 Sec.
- Frequency Up to 200 BPM.
- Base Flow (VIVE) 1 to 30 LPM.
- Synchronization Patient synchronization with adjustable flow trigger.
- High frequency amplitude 1-100%.
- Integrated blender for Oxygen 21% to 100%.
- Integrated nebulization facility.
- Integrated monitoring of FiO2.
- Audiovisual alarms with advisory on-screen message.
- MV high/Low, Apnea, tube obstruction, FiO2 high/low high PIP, low PEEP/CPAP, fail to cycle, gas supply low, power failure, ventilator inoperative, alarm log book.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- 2 hose sets for conventional reusable neonatal ventilator circuit.
- 5 hose sets of disposable conventional neonatal ventilator circuit.
- 1 hose set for reusable HF ventilation.
- Bacterial filters.
- Flow sensors.
- Oxygen cell.
- Oxygen connecting hose.
- Air connecting hose.
- Test lung.
- Heater wire.
- Temperature probe.
- Expiratory valve.
- Nasal interface with nasal mask and nasal prongs and bonnet Or Suitable Nasal Cannula.

13. Defibrillator

Universal Medical Device Nomenclature System (UMDNS): 11-134

Technical Specifications:

- Biphasic type.
- Semiautomatic and manual modes.
- External defibrillation Energy setting Level: 10-270 J.
- Internal defibrillation Energy setting Level: 5-50 J.
- Paddle: External (adult, child).
- Recharging time: Not more than 10 sec when fully charged battery or AC plugged in operation.
- Thermal Printer: Built in, with Thermal Head, auto start when charging and discharging, Start/ Stop buttons, uses standard Defibrillators thermal paper.
- ECG synchronous and asynchronous
- Lead selected to be displayed
- AED mode included.
- External Pace maker.
- Demand, fixed rate pacing modes.
- Pacing rate 50-150 ppm
- Output current 0-140mA
- Pulse width 20msec min.
- Fully defibrillator protection on the input
- Detects pace maker pulses.
- Heart rate: 25-300 bpm.
- Lead fault indicator.

- ECG recorder.
- Summary Feature.
- Nearly 7” LCD TFT Monitor to display Heart rate, ECG wave, ALARMS and other device features like battery, AC, Filter Lead, etc.
- Memory not less than 30 ECG strips of 20 sec.
- Defibrillator can operate on AC or battery modes.
- Power:220 V AC 50/60HZ.
- Operating time: Min 50 Discharge.
- Charging method AC/DC.
- Charging time: 5hr max. the lower time will be rated.
- Low battery indication.
- Audible and Visual Alarms to indicate: Arrhythmia, No ECG signal, Heart rate Low/High, Low Battery, Charging and Discharging Tunes.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Original manufacturer Trolley.
- Dust Cover.
- Rechargeable battery.
- Chart Paper.
- Electrode Jell.
- 3 and 5 ECG cables.
- External paddles (adult and child).

14. Electrocardiograph

Universal Medical Device Nomenclature System (UMDNS): 16-231

Technical Specifications:

- Good brand name.
- Leads: 12 standard leads acquired simultaneously and continuously.
- Number of Channels: Three real times continuous with rhythm, interpretation and measurements.
- ECG interpretation Analysis.
- Resting ECG Mode.
- Computerized measurements 12-lead analysis.
- Programs for adult & pediatric.
- Arrhythmia: detection of arrhythmia events.
- HRV: acquisition and processing of heart rate variation.
- Parameter Calculation.
- ECG analysis and measurements programs.
- HRV: heart rate variation.
- Memory storage not less than 100 patients.
- Pacemaker recognition: recognize pulse in accordance with current IEC standards.
- Internal Defibration protection.

- Recording speed: 5,10,25 or 50mm/sec.
- LCD DISPLAY: backlight graphic display around 5˝.
- Display channel: 3, 6 ,12.
- Operation modes: Auto or Manual.
- Copy button for generating multiple copies.
- Thermal printer.
- Rechargeable battery.
- Battery power capacity not less than two hours.
- Power Supply: 220V AC 50/60Hz.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Original manufacturer Trolley.
- Dust Cover.
- Rechargeable battery.
- Chart Paper.
- Electrode Jell.
- 3 and 5 and 12 ECG cables.

15. Emergency Trolley Complete

Universal Medical Device Nomenclature System (UMDNS): 10-647

Technical Specifications:

- Strong steel structure painted with epoxy powder.
- One-piece top with border, without sharp corners.
- Equipped with 3medium drawers and 1 large drawer and one small drawers with partitions, with silent sliding and end-run block, lockable.
- Lockable drawer for dangerous drugs.
- Mobile on 4 castors with break mechanism.
- Oxygen tank holder.
- With IV pole holder.
- With Backboard.
- With waste container.
- With Defibrillator swing arm.
- Mobile on antistatic rubber castors with break mechanism.
- Size: around 60 x 50 x 100 cm approx.
- Ergonomic push handle.
- Bumpers at lower corners

- Complete with:
- O2 cylinder complete with regulator flow meter and mask.
- Diagnostic set.
- Laryngoscope.
- Fully catheters 8 sizes 10 each.
- Ambo bag set silicon infant, child, adult.
- Dressing set (specify).
- Endotracheal tube 8 sizes 10 each.

System Configuration Accessories, Spares and Consumables:

- Emergency trolley.
- Backboard.
- Waste container.
- With Defibrillator swing arm.
- IV pole.
- O2 cylinder complete with regulator flow meter and mask.
- Diagnostic set.
- Laryngoscope.
- Fully catheters 8 sizes 10 each.
- Ambo bag set silicon infant, child, adult.
- Dressing set (specify).
- Endotracheal tube 8 sizes 10 each.

16. Examination Lamp

Universal Medical Device Nomenclature System (UMDNS): 12-276

Technical Specifications:

- Compact light head.
- LED bulb.
- Light intensity: ≥20,000Lux 0.5m
- Adjustable focus by handle.
- Field size: 10-17 cm.
- Adjustable height: 60-100 cm.
- Cold light reflector.
- Lamp life: not less than 3000hr.
- Color temperature: 3,700K approx.
- Including transformer.
- Mobile on 4 castors.
- Mains power: 220 V, 50Hz.

17. Glucometer

Universal Medical Device Nomenclature System (UMDNS): 16-488

Technical Specifications:

- Hand-held type Glucometer.
- Battery operated.
- Memory up to 10 measurements.
- Sticks method measurements.
- Code of sticks interring is available.
- Indication of high and low measurements.
- Case is included.
- One box of sticks and punctures is included.
- Operating instructions is included.

System Configuration Accessories, Spares and Consumables:

- Glucometer.
- One box of sticks and punctures Waste container.
- Case is included.

18. Warming Mattress

Universal Medical Device Nomenclature System (UMDNS): 10-414

Technical Specifications:

- Consist of control unit, Hose, washable protective hose cover, blankets and trolley.
- Microprocessor controlled.
- Applications: Operating room. ICU, CCU, Pediatric
- Can operate with full range of blankets for all applications in operating room.
- Mattress control unit can be set to any temperature between Ambient-43 °C with 0.2°C accuracy.
- With automatic cut off safety thermostat, When the temperature reaches a predetermined maximum, the thermostat turns off the heater circuit, high limit of 53°C to prevent thermal injuries.
- Control: Touchpad.
- Display: LED.
- Indicators for temperature and working hours.
- Hose length: not less than 1.5meter.
- Audible and visual alarm for high temperature.
- Carbon fiber material accounts for X-rays.
- Silent with noise level not more than 55dB.

- Warm up time not more than 5 sec.
- Filtration system 0.2 µm HEPA filter.
- Power :230-240 V, 50 Hz.
- Stainless Steel trolley with castors.
- The following reusable/disposable blankets must be priced separately, in case of disposable please mention no of pieces /box:
- Pediatric - Neonatal.

System Configuration Accessories, Spares and Consumables:

- Warming Mattress.
- Mounting stand.
- Hose.
- Blanket.

19. Hemodynamic Monitor

Universal Medical Device Nomenclature System (UMDNS): 27-872

Technical Specifications:

- Type: Compact.
- Neonatal Configuration.
- Display: color up to 6 waves simultaneously.
- Not less than 10-inch TFT display.
- Wall mounted with CGX variable height mount.
- Parameters:
- ECG:
- Leads: 3 and 5 lead (I, II, III, aVR, aVL, aVF, V1-V6).
- Gain:4 Gain Selections Including 0.5 and 1.
- ST included.
- Safety: ESU and defibrillator protection.
- Pacer detection/rejection.
- Respiration:
  - Through ECG.
  - Up to 150 bpm.
  - Resolution 1bpm.
- Heart rate:
  - User selectable source (ECG, NIBP, pleth).
  - 20-300bpm with accuracy less than 2%.

- Temp:
  - One channel.
  - 20-45°C degrees with resolution less than 1°C.
- NIBP:
  - One channel.
  - Oscillating during inflation.
  - Pediatric rang 30-150mmHg with resolution of 1mmHg.
  - Neonate rang 20-150mmHg with resolution of 1mmHg.
- SPO_2:
  - One channel.
  - Dual wavelength LED.
  - Range 1%-99% with resolution of 1%.
  - Trend for 24 hours.
- Alarms: audible and visual with silence feature.
- Wave form speed 6.25, 12.5, 25 and 50 mm/sec.
- Printer is included.
- Power: 220V, 50Hz.
- Battery rechargeable not less than 2 hours.
- Include all accessories.

System Configuration Accessories, Spares and Consumables:

- Monitor.
- Wall mounting kit.
- 3 ECG cable complete included.
- 2 sets of lead wires included.
- 2 different Temp. probes.
- NIBP cuff and hose for neonate.
- SPO2 sensor for neonate.

20. High Flow Oxygen Therapy Machine

Universal Medical Device Nomenclature System (UMDNS): 12-700

Technical Specifications:

- High flow nasal cannula therapy device (HFNC) is a kind of oxygen therapy device that directly transports a certain oxygen concentration of air oxygen mixed with high flow gas to patients through a soft nasal cannula.
- It shall operate from the mains supply/ central oxygen supply, inbuilt air source.
- It should be single system for treating pediatric and infant patients.
- It should be complaint for use on patients in ICU, wards and emergency department oxygen therapy.
- It shall have LCD/LED display to monitor for temperature, flow rate, Therapy air FiO2, mode of operation and fault error.
- Inbuilt flow generator capable of delivering wide range of flows:2-25 liters in pediatric mode.

- Inbuilt Air/O2 blending and FiO2 monitoring, facility to deliver wide range of oxygen concentration (FiO2) from 21 to 100%.
- It should have inbuilt Air source
- It should have integrated heated humidifier with temperature control range of 31°C to 37°C.
- It should have Visual and audible alarm indication for: High/Low oxygen, temperature, power failure etc.
- Should be supplied with heated wire patient breathing tube and nasal cannula of different sizes.
- Pediatric nasal cannula should be made of kink proof material with adhesive pads to stick on skin.
- It should commonly be used on tracheostomy patients and covid patients.
- System shall come with appropriate trolley, basket/drawer and tubing holder set.

System Configuration Accessories, Spares and Consumables:

- High Flow Oxygen Therapy Machine.
- Stand.
- Tubing Holder Set.
- Servo control auto heated humidifier with accessories.
- Oxygen hose.
- Nasal cannula for pediatric –1 pcs each.
- Heating circuit- 1 pcs each.
-

21. High Frequency Ventilator

Universal Medical Device Nomenclature System (UMDNS): 18-793

Technical Specifications:

- Advance ventilator with SIMV/AC/PS/ Targeted volume with HFO.
- Modular type ventilators, ventilator and HFO in same machine and using the same circuit, and can be switched between ventilation modes and HFO, HFO module should be priced separately.
- The ventilator should be microprocessor controlled designed for neonatal use with possibility to upgrade with additional features.
- Continues flow, pressure limited, time cycled ventilator design.
- Ventilator modes: should have following modes available in the unit:
  - IMV/IPPV.
  - CPAP including non-invasive ventilation.
  - SIMV, SIPPV/Assist-control.
  - Volume targeted/guarantee mode of ventilation with ability to deliver and monitor tidal volume as low as 1-2 ml (Range 2 ml to 50 ml).
  - Pressure support mode of ventilation.
  - Apnea back-up ventilation.
  - Non-Invasive Ventilation (NIV).
  - High frequency oscillatory ventilation which is oscillating diaphragm based.
  - High and Low flow oxygen therapy.
- Should have integrated high resolution LCD screen minimum 12" color display with touch screen facility.
- Graphic display of at least 3 waveforms together, flow, volume and pressure versus time with a facility to freeze these waveforms.

- Facility for 3 loops together with a facility to freeze.
- Should have graphical as well as tabular trend facility of data up to 24 hours.
- Digital display of FiO2, peak pressure, mean airway pressure, CPAP/PEEP, Expiratory tidal volume, expiratory minute volume, total frequency, spontaneous frequency, lung function monitoring including compliance, resistance, lung distention coefficient, (C20/C), Lung time constant, Rate volume ratio etc.
- Should have built-in logbook for recording events like various alarms.
- Integrated monitoring: Integrated volume and pressure monitoring i.e., monitoring of PEEP Pmax, Pmean and VT, VTspont, MV and MVleak. The volume monitoring should have NTPD to BTPS correction.
- Monitoring of I: E, frequency and Spontaneous Frequency.
- Trigger Flow/ volume, leak adapted.
- Synchronization Patient synchronization with adjustable flow trigger.
- Integrated blender for Oxygen.
- Integrated nebulization facility.
- Integrated monitoring of FiO2.
- Monitoring of flow: At the Y piece with facility to activate or deactivate it.
- Should measure parameters in HFOV such as DCO2, VtHF, MVim and Vtim, in the monitors with HFO.
- Ventilator should have following features in Pressure Support/ Volume Guarantee:
    - It should be possible to give leakage adapted inspiratory trigger during pressure support to spontaneously breathing patients with a set volume guarantee.
    - Volume guarantee should be regulated with lowest possible airway pressure within a set PIP.
    - It should be possible to adjust the Volume Guarantee manually as per patient requirement.
- Audiovisual alarms with advisory on-screen message: MV high/Low, Apnea, tube obstruction, FiO2 high/low high PIP, low PEEP/CPAP, fail to cycle, gas supply low, power failure, ventilator inoperative, alarm log book.
- The ventilator should have automatic compensation for leakage and should monitor and display leakages.
- The ventilator should show trends of important parameters viz. CR, FiO2, MAP etc. for evaluation of patient improvement.
- The Servo Controlled Heated Wire Humidifier should be supplied along with Reusable patient circuit. The humidifier must be FDA approved.
- Battery back-up (at least 30 minutes) Battery should be integrated and should provide backup to both ventilator & Air compressor in case of compressor included.
- Should be supplied with ultrasonic nebulizer which should have capability to deliver particle size of < 3 micron and to be used in both off and on line with ventilator.
- Should have permanent Electronic O2 Sensor. Company will provide life time warranty on Oxygen Sensor.
- Ventilator should have Up gradation facility with EtCO2 (EtCO2 priced separately).

- Machine should have facility to set exp flow different than inspiratory flow to help in ETCO2 flush.

System Configuration Accessories, Spares and Consumables:

- Ventilator as specified.
- Trolley with wheels and brake facility.
- Integral medical air compressor (if ordered).
- Humidifier: Autoclavable humidifier chamber (2 with each ventilator).
- Circuit support arm.
- 2 hose sets for conventional reusable neonatal ventilation circuit.
- 5 hose sets of disposable conventional neonatal ventilation circuit.
- 1 hose set for reusable HF ventilation.
- Bacterial filters.
- Flow sensors (20 sets with each ventilator).
- Oxygen cell.
- Oxygen connecting hose.
- Air connecting hose.
- Test lung with Heater wire (3 each).
- Temperature probe (3 each).
- Expiratory valve (2 with each).
- Nasal interface (3 in number) with nasal mask (4 each of all sizes) and nasal prongs (4 each of all sizes) and bonnet (5 each of only preterm size).

22. Hood

Universal Medical Device Nomenclature System (UMDNS): 15-279

Technical Specifications:

- Laminar flow.
- Class II.
- Glass front screen.
- 316 stainless steel work surfaces.
- Chamber dimension: not less than 580D × 1190W × 700H.
- Filter efficiency: 99.999, for particles>0.3 micro
- Air volume: 300 m³/hours.
- Air velocity: 0.4 m/sec.
- Including HEPA filter.
- Vertical sterile flow.
- Lighting: 800LUX at work surface.
- UV sterilization.
- Deep sink 14x12x6 inch is included.
- Hot and cold-water supply.
- Power supply: 220V AC, 50Hz.
- Exhaust system complete including duct to connect between the cabinet and the room exhaust around 2-meter length, resistance for chemicals, with suitable suction motor.
- Gas inlet is included.
- Stand type with base.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Stand.

23. Washer Disinfector

Universal Medical Device Nomenclature System (UMDNS): 21-171

Technical Specifications:

- Completely stainless steel with a double wall for thermo-acoustic insulation.
- The inside covering, washing arms and filters are all manufactured in stainless steel AISI 316.
- Steam condenser.
- Water softener built in.
- Drying with hot air.
- Microprocessor control.
- LCD display.
- Audible and Visual alarms.
- Single door with automatic door lock during washing cycle.
- Detergent and chemical additive dispenser.
- Compartment for storage of chemical additive.
- Pre and main filters, the main is HEPA not less than 99.99%.
- Number: 2 dosing pumps.
- Power supply: 220V /50 Hz.
- Including:
  - Three level rack with washing arms QTY1.
  - Din basket QTY6 with covers.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Trolley with wheels and brake facility.
- Three level rack.
- Din basket QTY6 with covers.
- Startup chemicals (acid and alkaline).

24. Infant Scale

Universal Medical Device Nomenclature System (UMDNS): 13-462

Technical Specifications:

- Professional infant scale for clinical and hospital use.
- High quality and easy-care housing with anti-tilt infant tray.
- Electronic scale with a large weighing tray.
- Should have capacity weighing range of 0 - 20 kg with an accuracy of ±5.
- Weighing unit: Standard display in grams.
- Internal damping system compensates for movements.
- Pan material: Fiber resistant plastic (coated).
- Pan size: 630 x 300 mm ±25mm.
- Display: Bright LED or LCD display for easy viewing.
- Should have functions TARE, Auto-HOLD and Automatic switch-off
- Insulation should be Protection Class II approved.
- Should be light weight and has a handle for easy transportation.
- The scales are only cleaned with normal disinfectants.
- Should have operated by battery or power supply.
- Battery operated or by transformer.
- Battery backup: At least 3 hours.
- Should have a measuring rod and a head positioner
- Should be supplied with detachable Baby Measuring Rod with measuring range: 35 – 80 cm with graduation of 1 mm.

System Configuration Accessories, Spares and Consumables:

- Scale as specified.
- Measuring rod.
- Head positioner.
- Transformer.

25. Infusion Pump

Universal Medical Device Nomenclature System (UMDNS): 13-215

Technical Specifications:

- Open system.

Configuration:

- Pump mechanism: Linear peristaltic.
- Number of channels:1.

Display:

- Data displayed: Rate, infused volume, total volume, medication name, duration, battery capacity, pressure limit.

Pump Capabilities:

- Flow range, mL/Hr.: 0.1-999.9.
- Increments, ml :0.1.
- KVO rate, mL/Hr. :1-5.
- Accuracy, %: ±5.
- Volume to be infused: 1-9999ml in 1ml increment.
- VTBI selector, mL: 0.1-9,999.
- Fluid resistant.
- Front-panel lockout.
- The pump must be protected of harmful ingress of water; IP XX Code document must be submitted with the offer.
- The supplier will be responsible for changing the pump Free of Charge in case of damage due to ingress of water.

IV Set:

- Open system infusion pump.
- Set type: Standard, PVC.
- Free-flow protection: Required.

Alarms & Indicators:

- Occlusion upstream.
- Occlusion downstream.
- Pressure, psi: ≤15.
- Real-time display.
- Flow error.
- Air in line.
- Drop sensor.
- System malfunction.
- Empty reservoir.
- Set disengaged.
- Door open.
- Infusion complete.
- Low battery.

Audible Alarm:

- Volume control.
- Momentary silence.

Others:

- Event log included.
- Power requirements, VAC (Hz): 220 (50/60).
- Battery: built in.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Infusion bump stand with counter weight.
- Startup kit of infusion tubes, (one box of 20).

26. Medical Labelling System

Scope:

Medical labeling system is a thermal printer providing medical wristbands contains Barcoded Patient Information such as:

- Date of birth.
- Mother Name.
- And any other useful information's the hospital admission decides to add.

Technical Specifications:

- Reliable direct thermal printer.
- Easy to load cartridge.
- ONLY antimicrobial-coated wristbands.
- Capable to print water proof wristbands.
- independent print system and if necessary, PC should be included with applicable software.
- 22V 50 Hz power supply.
- Prices of wristbands, thermal paper and printer head should be added.

27. Medical Refrigerator

Scope:

- Reliable medical refrigerator is used to keep the Breast Milk in a well-controlled environment for future usage.

Technical Specifications:

- Microprocessor/Digital temperature control.
- It should have galvanized sheet steel construction, white powder coated and adjustable feet.
- Vertical, frost free CFC free.
- Capacity: from 400-450-liter single glass door with key lock.
- Temperature range: should be from 2°C to 8°C throughout the chamber.
- Should have digital display for the temperature
- Number of shelves: 8 shelves.
- Isolated of high grade pressure-foam materials.
- Automatic defrosting and condensed melt water evaporator.
- Re-circulating air-cooling system.
- Control panel with thermometer, main switch and temperature selection.
- Hermetically enclosed, low noise, vibration proof compressor.
- Visual and acoustic signal alarm system.
- Full Stainless steel interior / anticorrosion.
- Monitoring temperature for 24/7.
- Power supply: 220V 50 Hz.

28. Medication Trolley

Universal Medical Device Nomenclature System (UMDNS): 10-644

Technical Specifications:

- Made of steel sheet frame and powder painted.
- Top compact laminated to prevent from chemicals.
- Strong rubber for protection surrounds bottom.
- The cart must have five drawers.
- Four drawers 4 inches in height and one bottom drawer 11 inches high.
- The top drawer must have drawer divider kit which can be adjusted for various uses.
- Have a bin system for holding each residents' medications within an individual bin.
- Side rails on top 3 sides.
- Hand for movement.
- 4 castors with 2 brakes.
- Dimension: 720 * 410 * 1020H mm approx.
- IV rod height adjustable included.
- Waste Container included.
- Slide Out Writing Surface included.
- Must be able to attach sharps container.

System Configuration Accessories, Spares and Consumables:

- Cart as specified.
- Measuring rod.
- Waste Container.
- Slide Out Writing Surface.

29. Milk Bottle Sterilizer (Autoclave)

Universal Medical Device Nomenclature System (UMDNS): 13-746

Technical Specifications:

- Fully automated.
- Stainless steel body.
- LCD display.
- Capacity: not less than 20 places.
- Overheating protection.
- Pressure and temperature controlled and monitored.
- Pressure and temperature alarms.
- Safety valve is included.
- Drain.
- Timer and buzzer are available.
- Power supply: three phase, 380VAC.
- Including holder for bottles.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Baskets for milk bottles.

30. Milk Warmer (Water Bath)

Universal Medical Device Nomenclature System (UMDNS): 15-108

Technical Specifications:

- Analogue with polypropylene tank ambient to 90˚C.
- Inner Material: stainless steel 304
- Capacity (L): 17.5 liters tank capacity.
- Graduated thermostat in 5°C divisions from 20-90˚C.
- Accuracy (degree Celsius): 1° C
- Heating time: 40 minutes.
- Heater power: 0.75 Kw.
- Tank Dim: 410x240x80 (LxWxD) Approx.
- Complete with cover.
- Voltage 220 V AC.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Baskets for milk bottles.

31. Mobile Digital X-Ray Machine

Universal Medical Device Nomenclature System (UMDNS): 13-272

Technical Specifications:

- Digital mobile X-ray system for general purpose exams.
- Compact, easily transportable with articulated/telescopic arm suitable for bedside X-ray with maximum positioning flexibility in any patient position, the angles in various planes to be specified by the manufacturer.
- The unit should be a digital system with flat panel detector.

Generator:

- Must be microprocessor controlled high frequency, output 30 KW or above.
- It should have a digital display of mAs and kV and an electronic timer.
- KV range: 40kV to 130kV or more.
- Max. current: 300 mA or more.
- Please specify mA and seconds separately and not mAs alone.
- Shortest exposure time: should be 1ms or less.

X-ray Tube:

- Output should match the output of the generator.
- It must have a rotating anode with 3000 rpm or more.
- Focal spot size should be less than 1mm.
- Mention the heat storage capacity of the anode.

Flat panel detector:

- Should be Wireless, with original protective cover with handle.
- The flat detector should be of the size around 200 X 250 mm or more.

- The detector pixel matrix size should be 2K x 2K or more.
- The machine should have a detector storage compartment.
- The image viewing time after exposure should not be more than 15 sec.

Battery:

- The machine should be able to run on mains as well as on battery supply
- Please specify number of exposures which can be done on battery
- The battery should also provide power for the motor to move the machine
- The battery should be able to be charged from a normal 15A 230V single phase pocket in less than 6 hours

Workstation:

- The machine should have an integrated workstation with a TFT touch screen.
- The workstation should enable to view the image, and provide post processing. features, using touch screen.
- The post processing features should include, zoom, contrast and brightness adjustment, storage of image with a memory of at least 2000 images.
- The touch screen size should be at least 15 inches.

Connectivity:

- The machine should be fully network ready.
- It should be possible to transfer images and patient data from and to hospital network using LAN connectivity and wireless LAN.

Others:

- The tube stand must be fully counter balanced with rotation in all directions.
- The unit must have an effective braking system for parking, transport and emergency braking.
- All cables should be concealed in the arm system.
- The exposure release switch should be detachable with a cord of at least 5 meters. Exposures with remote control should be possible.
- Detector/tube/generator, should be manufactured in the same manufacturer.

Power Line Connection:

- Should operate on single phase power supply with plug in facility to any standard wall outlet.
- Automatic adaptation to line voltage 200 to 240 Volts.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Flat Panel Detector (FPD).
- Lead apron 0.5mm lead equivalence.
- Thyroid guard.

32. T-piece Resuscitator

Universal Medical Device Nomenclature System (UMDNS): 13-360

Technical Specifications:

- Delivers controlled, consistent, and precise pressures
- Should be manually operated, gas-powered resuscitator with consistent Peak Inspiratory Pressure (PIP) and Positive End Expiratory Pressure (PEEP) to infants.
- Should accept and deliver oxygen concentrations from 21% to 100%.
- T-piece circuits should be connected to infant resuscitation masks or endotracheal tubes.
- The gas flow outlet should allow easy and secure connection of the T-piece circuit and humidified T-piece circuit.
- Manometer range: -10 to 80 cmH20; ± 2% accuracy.
- Maximum pressure relief: 8L/min 5 to 70 cmH20.
- Peak Inspiratory Pressure: 5L/min 2 to 70 cmH20, 8L/min 3 to 72 cmH20, 10L/min 4 to 73 cmH20, 15L/min 8 to 75 cmH20.
- Input gas flow range: 5L/min (minimum) to 15L/min (maximum).

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Original trolley.
- Gas supply line – 3 Nos.
- Disposable infant resuscitation T-piece circuit – 10 Nos.
- Disposable infant resuscitation T-piece mask – 10 Nos.
- Disposable humidifier T-piece circuit with heated wire – 10 Nos.

33. Noise Level Detector

Technical Specifications

- Digital Sound Level Meter.
- Handheld.
- LCD Display Measuring 30-130Db.
- 9V Battery.
- Large, clear display with back-light.
- A and C frequency weighting.
- Fast and Slow time weighting.
- Maximum and Minimum sound level readings.
- Hold button holds the currently displayed level.
- Simple push-button operation.
- Display: 4 Digit LCD with back light, update rate 0.5 s.
- Indicators: Low battery, freq. & time weighting, min/max.
- Battery Life: About 50 hours (alkaline battery).
- Resolution / Accuracy 0.1dB / ±1.5 dB (ref 94 dB @ 1 kHz).
- Frequency Range: 31.5 Hz to 8 kHz.
- Level Range: 30 to 130 dB(A), 35 to 130 dB(C).
- Frequency Weighting A and C.
- Microphone: 1/2" electret condenser.
- Time Weighting: Fast (125 ms) and Slow (1 s).
- Dynamic Range: 50 dB.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Wind Shield.
- Carrying Case.
- Battery.

34. Open System Incubator

Universal Medical Device Nomenclature System (UMDNS): 18-857

Technical Specifications:

- Mobile on 4 castors with break mechanism.
- Microprocessor control for temperature with built in Temp. sensor.
- Audible and visual alarms for temperature (low and high) sensors, power failure with alarm silence feature.
- Display for skin and control temperatures.
- Tiltable warmer head to easy use of mobile x- ray.
- Examination lamp included.
- Removable sides for easy access to baby.
- Basinet Trendelenburg ±25° at least.
- Washable and hypoallergenic mattress included.
- Oxygen and suction outlets (Regulator Controlled).
- With X-ray cassette tray.
- Monitor shelf and holder are included.
- 2 drawers are included.

- Lateral rail for accessories is included.
- Handles for movement.
- Including:
  - Heating Element QTY of 2.
  - Skin Temperature sensor QTY of 2.
  - Oxygen flowmeter with humidifier.
  - Suction complete (regulator, safety bottle, collection bottle and tubing).
  - IV pole.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Skin Temperature sensor.
- Oxygen flowmeter with humidifier.
- Suction complete.
- IV pole.
- Mattress.

35. Open System Incubator with Resuscitation Module

Universal Medical Device Nomenclature System (UMDNS): 18-857

Technical Specifications:

- Microprocessor control for temperature.
- Mobile infant radiant warmer with fixed height bassinet.
- Antistatic 4 castors, 2 with brakes.
- Bassinet tilt of up to 10º at least.
- Mattress padding foam high density approx. 21-25 kg/m3.
- Mattress should be sealed waterproof, washable, resistant to cleaning with chlorine-based solution and flame retardant.
- Side boards transparent acrylic, drop down and lockable.
- Integrated X-ray tray.
- Under Table 2 storage drawers for emergency drugs, equipment storage etc.
- Side rails allow for mounting of accessories.
- Monitor shelf and holder.
- Handles for movement.
- Hood suspended above the table integrates heating element and overhead light & should have 90 Degree swivel facility to enable taking X-rays.
- Heating element emitter with parabolic reflector and protected by metal grid.
- Control unit allows skin temperature preset (visual digital indicator) and drives radiant heater output (servo and manual).
- Integrated timer: 1 to 60 min, with count up feature.
- Temperature range, skin 34ºC to 38ºC (use pre-settable).
- Monitoring of skin temperature by means of sensor, range: 30°C to 42ºC.
- Heater output: 0 to 100% in increments of 5%.

- Control unit: audiovisual alarms according to timer and temperature presents avoiding overheating.
- Should alarm & display reports systems errors, sensor failure like absence of power, failure of heater, permanence of full heater power beyond 10-15 minutes, high temperature, low temperature, absence of sensor, dislodgement of sensor.
- Should automatically shut off with manual mode after certain period (say 15 minutes).
- Power requirement: 220V / 50 Hz AC.
- Power consumption: 650-1000W.
- Should have oxygen blender with flow-meter and suction.
- Should be supplied with inbuilt T-Piece Resuscitator:
- Automated device for resuscitation of babies.
- Able to set PIP (5-50cmH2O) and PEEP (1-10cmH2O).
- Manometer able to display real time pressure delivery (0 to 80 cmH2O).
- Adjustable pressure relief valve: 5-70 cmH2O.
- Pressure safety valve.
- Able to use face mask as well as ETT.
- Able to deliver free flow of oxygen.
- Non-electric powered.
- FDA or European CE Certified.
- Should be supplied with 10 nos. of Reusable Circuits and 10 nos. of face masks of different sizes (Exact sizes to be mentioned in supply order).

System Configuration Accessories, Spares and Consumables:

- System as specified.
- T-Piece Resuscitator.
- Skin Temperature sensor.
- Oxygen flowmeter with humidifier.
- Suction complete.
- IV pole.
- Mattress.

36. Open-Closed System Incubator

Universal Medical Device Nomenclature System (UMDNS): 12-113

Technical Specifications:

- Full-featured incubator and a radiant warmer in one, Double-sided Sliding tray with Kangaroo Mode or Similar.
- Integrated Plexiglass double-wall.
- Should have advanced servo-controlled microprocessor-based system.
- Height Adjustable by foot mechanism from both sides of the incubator.
- Changing from closed incubator to open resuscitator by touch button.
- Slide out AND rotating by 360° mattress.
- Mattress tilt angle: 12°, continuously variable.
- Pressure-diffusing mattress.
- Large, drop down, removable doors, patient access from either side of the bed.
- Full Color Touch Display: 10.4" Centralized control screen.
- With big storage drawer.
- With monitor shelf.
- Mobile equipment with at least 4 castor anti-static and rust-free wheels and two brakes.
- Eight Tubing access ports.
- Bi-Directional Airflow.
- Baby (Servo) Temperature Control: 35-38°C in 0.1° increments.
- Air Temperature Control: 20-39°C in 0.1° increments.
- Manual Radiant Power Control: 0-100% in 5% increments.
- Servo Humidity Control Range: 30-95% relative humidity in 5% increments.
- Servo-controlled Oxygen delivery, Control Range: 21% to 65%.

- Low noise fan Average 40 dBa.
- Data collection: RS-232.
- Electrostatic filter for dust.
- Alarm: Audible and visual for temperature, humidity, oxygen, sensors and probes, main supply.
- Alarm sound level: Adjustable audible levels.
- IV pole with 2 hocks included.
- The incubator included all sensors, probes, filters to work as specified.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Skin Temperature sensor.
- Air Temperature sensor.
- IV pole.
- Mattress.
- Filters.

37. Oxygen/Air Mixer

Universal Medical Device Nomenclature System (UMDNS): 12-876

Technical Specifications:

- Scope of application: Premature infants, newborns, infants.
- Equipped with double cone shape proportion valve and 2 level self-balance pressure stabilize the device, ensure the constant concentration of the output mixed air-oxygen.
- Separated adjustment of oxygen concentration and the flow quantity, so they will not affect each other.
- Alarming system of differential pressure is equipped.
- During alarm safety valve starts automatically, and produce the mixed gas continuously to ensure the safety of the patients.
- Safe, accurate and stable, especially for newborns and premature infants, providing safe and reliable oxygen.
- Total flow maximum: 30 LPM.
- Oxygen concentration adjustment: 21% to 100%; Accuracy: <±5%.
- Pressure difference: when it is over 0.1MPa, alarm goes off.
- Input gas pressure: 0.3 MPa~0.4 Mpa.
- With switchable bleed-function.
- Audible warning in case of gas failure.
- Oxygen % monitor included.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Hanging tools to rail or pole.
- Mobile stand with counter weight.

38. Oxygen Flow Meter

Universal Medical Device Nomenclature System (UMDNS): 24-782

Technical Specifications:

- Wall/Direct or Rail mounted type as requested.
- Consists of: flow meter, Humidifier and gas specific male adapter.

Flow meter:

- OHIO type connector.
- Back-pressure compensated is available.
- Unbreakable.
- From 0 to 15 l/min.

Humidifier:

- Capacity: 500 cc.
- Autoclavable.
- Built-in safety relief valve prevents over pressure.

Complete with:

- Mask and tube are included.
- Nasal tube is included.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Humidifier.
- Mask and tube.
- Nasal tube is included.

39. Oxygen Monitor

Universal Medical Device Nomenclature System (UMDNS): 12-861

Technical Specifications:

- Microprocessor based Oxygen Monitor.
- Constructed from high impact resistant materials.
- Ideally suited for use in Neonatology, Respiratory care, and Anaesthesia applications.
- Large high bright LED display.
- Accurate oxygen sensor.
- Low Power draw allows the units to operate continuously for 20 hours in the rechargeable battery.
- Audio and Visual indications for Low battery alarm, Sensor Fail alarm, Calibration error alarm.
- Oxygen sensor providing superior long-term stability and accuracy.
- Measuring range: 21%-100%.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Cable.
- T-Piece.
- Oxygen cell.

40. Phototherapy Unit

Universal Medical Device Nomenclature System (UMDNS): 15-731

Technical Specifications:

- Phototherapy Unit for treatment of hyper bilirubinemia in the newborn.
- Material: Mild steel.
- Applicable with Baby Incubators, Open Beds, Warmers and Bassinets.
- High Density Light Power with Fan-less LED Technology.
- Tilting head.
- Applicable with Baby Incubators, Open Beds, Warmers and Bassinets.
- Wavelength: 400 to 500 nm.
- Easy to Use, User Interface with Colorful Touch Screen (4.3" colorful TFT touch screen).
- On /off switch for all or half lamps.
- UV shield.
- Changeable Screen Angle.
- Quick Treatment Start and Stop.
- Programmable Treatment Duration and Resetting.
- 5 Levels of Light Intensity.
- Max Light Intensity (40cm) 120 µw/cm2nm (+-10%).
- Min Light Intensity (40cm) 33 µw/cm2nm (+-10%).
- Effective Area: 45 cm x 20 cm.

- Single Touch for High(max.) Density Treatment.
- LED Life Time Counter (0-99999).
- End of Treatment Warning and Auto Stop.
- Easy to Use Pneumatic Height Adjustment.
- Horizontal Angle Adjustment (360°).
- Durable, Reliable, Sophisticated Base Unit.
- Low Energy Consumption.
- Width: 75 cm approx.
- Depth: 80cm approx.
- Height Adjustable. 100cm to 140cm approx.
- Mobile on 4 castors with break mechanism.
- Power supply: 220Vac,50Hz.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Eye protection one box.

41. Pulse Oximeter

Universal Medical Device Nomenclature System (UMDNS): 22-855

Technical Specifications:

- Hand-held and not finger type with Motion Artifact Reduction and Low Perfusion detection.
- Adult/Infant Operation
- Two Parameters: SPO2, Pulse Rate.
- Waveform: SP02 waveform-PLETH
- Display screen:160 x128 dot matrix color LCD screen, Display area: 42mmx33mm.
- Parameter Specifications:
- 1-SpO2:
- SpO2 range: 1-99%.
- Accuracy: 2-3%.
- Resolution: 1%.
- 2-Pulse Rate (PR).
- Range: 0 bpm ~250bpm.
- Resolution: l bpm.
- Accuracy: 2bpm.
- Storage/Review trend data not less than 1000 groups.
- History data uploading to PC for review, printing or storage.
- Audio and visual alarm when parameters exceeded and sensor-off.
- Built-in rechargeable not less than 8 hour running time.
- Battery capacity indicator. Automatic shutdown for power saving.
- With adult SpO2 sensor.
- With child/neonate rap SpO2 sensor with extension cable.
- Trend for last 10 min on screen.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Cable.
- Sensor wraps for infant.

42. Radiant Warmer

Universal Medical Device Nomenclature System (UMDNS): 17-956

Technical Specifications:

- Made of quartz heater provides uniform warmth rapidly all over the bed.
- The height of the heater unit is adjusted for different bed heights.
- T-shaped base.
- Convenient handle for transportation.
- The control panel is ergonomically designed using soft touch keys.
- Display indicates the temperature.
- Battery backup that indicates the temperature even during power failures.
- Drawers are provided for storing items.
- Power: 220V,50Hz.

System Configuration Accessories, Spares and Consumables:

- System as specified.

43. Suction Unit

Universal Medical Device Nomenclature System (UMDNS): 10-211

Technical Specifications:

- It consists of suction regulator and suction container.
- Vacuum for medical care.
- Standard pressure: 600 mmHg.
- Maximum pressure: 760 mmHg.
- Noise: below 60db in 1m streets.
- Lightweight construction.
- High impact plastic body.
- Screw lid.
- Easy to clean.
- Appling unique anti-overflow system.
- Color coded gauge.
- One touch bottle cover separator.
- Handle is included.
- Unbreakable polycarbonate collection bottle not less than 1400 c.c.
- Wall or rail mounted type according to need.
- OHIO or Din type connector according to hospital outlet.

- Safety bottle.
- All connecting tubes between bottles are included.
- Including vacuum regulator with vacuum gauge.
- Including plate holder and clamp.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Safety bottle.
- Collection jar.
- Hanging accessories (plate holder and clamp).
- Rail.
- Tubes.

44. Syringe Pump

Universal Medical Device Nomenclature System (UMDNS): 13-217

Technical Specifications:

- Microprocessor controlled syringe pump.
- Control panel with 15cm LCD screen with simultaneous display of 10 alpha-numeric infusion parameters: delivery speed; delivered volume; dosage unit; remaining infusion time; occlusion alarm level; current pressure; drug name; drug concentration; battery status; syringe type and size; pump status.
- Capable of working with the commonly available 5, 10, 20 and 50/ 60 mL syringes.
- Automatic detection of syringe size & proper fixing.
- Flow rate setting ranges:
  - 0.01- 150 mL/h (for 5 mL syringes)
  - 0.01 - 300 mL/h (for 10-, 20- and 30-mL syringes)
  - 0.01 - 1200 mL/h (for 50/60 mL syringes)
- Volumetric flow rate accuracy with dedicated syringes better than +/- 2%, and +/- 5% with common syringes.
- Bolus rate should be programmable to 300 – 1200 ml/hr. or more with infused volume display.
- Anti-bolus system to reduce pressure on sudden release of occlusion
- Should have KVO
- Event logging system
- Availability of a medications database with at least 200 medications selectable for download to pump
- Should have programmable occlusion pressure for low, medium and high levels.
- Should have following Audio-Visual Alarms:
  - Near End (pre alarm before end of infusion) .

- End of Infusion.
- Syringe Empty.
- KVO.
- Occlusion.
- Syringe not installed or dislocated.
- Drive Disengaged.
- AC Power failure or Mains disconnection.
- Low Battery (pre-Alarm before full battery discharge.
- System/internal function error.

- 220/230 V AC and 50/60 Hz power supply.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Rolling stand, counter weighted.
- Mounting device/ Docking Station for two.

45. Transport Incubator

Universal Medical Device Nomenclature System (UMDNS): 12-114

Technical Specifications:

- Servo controlled Air/Baby modes.
- Double wall hood and double-sided tray movement.
- Air temperature control from 23-38 with 0.5ºC accuracy and safety lock.
- Air temperature display 20-38.5ºC.
- Skin temperature display 30-38ºC.
- Double door and opening from both sides.
- Digital Display: On/standby, Battery status, Heater power, Baby and air temperature ° C, Alarm indicators.
- With collapsible stand for ambulance loading.
- With adapter cable for 12-volt automatic supply.
- 4 Casters with brake.
- Alarms for: air flow, probes, high temp, low temp, power failure.
- Visual indicators for battery power status, power source and system alarm status.
- Noise level inside ≤60dB.
- Air filter can remove >99% of airborne particles greater than 0.5-micron diameter.
- Humidity: 50 to 70 percent humidity in the patient hood for up to 12 Hours.
- 1 Iris port.
- 6 tubing ports.
- Examination lamp, must be included.

- Ability to mount infusion pumps.
- Suitable mounting system for Ventilator and Monitor.
- Power requirements (220VAC. 50-60Hz), 12 V DC.
- Battery to operate incubator at least one hour with full heater power and min charging time.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- O2 cylinder with proper flowmeter.
- O2 cylinder holder.
- Built in batteries and mains charger.
- IV pole.
- Set of air filters (min 20).
- Temperature air probe.
- Skin temp. probe.
- Rechargeable Batteries.

46. Transport Monitor

Universal Medical Device Nomenclature System (UMDNS): 17-588

Technical Specifications:

Compact:

- Display: Color LCD up to 6 waves simultaneously
  - Not less than 10-inch TFT
  - Resolution 640x480 pixels
  - Speed 12.5, 25,50mm/sec.
- Parameters: ECG, NIBP, SpO2, Respiration, two temperatures
- ECG:
  - Leads: 3/5 lead (I, II, III, aVR, aVL, aVF, V1-V6).
  - Gain: 4 Gain Selections Including 0.5 and 1.
  - ST included.
  - Safety: ESU and defibrillator protection.
  - Pacer detection/rejection.
- NIBP:
  - One channel.
  - Oscillating during inflation.
  - Adult range: 30-300mmHg with resolution of 1mmHg.
  - Pediatric range: 30-150mmHg with resolution of 1mmHg.
  - Neonate range: 20-150mmHg with resolution of 1mmHg.

- SPO2:
  - One channel.
  - Dual wavelength LED.
  - Range: 1%-99% with resolution of 1%.
- Respiration:
  - Through ECG.
  - Up to 150 BPM.
  - Resolution: 1 BPM.

- Temp:
  - Tow channel.
  - 20-45°C degrees with resolution less than 1ºC.
- Heart rate:
  - User selectable source (ECG, NIBP, pleth).
  - 20-300 bpm with accuracy less than 2%.
- Trend for 24 hours.
- Alarms: audible and visual with silence feature.
- Wave form speed: 6.25, 12.5, 25 and 50 mm/sec.
- Printer is included.
- Power: 220V, 50Hz.
- Battery rechargeable not less than 2 hours.

System Configuration Accessories, Spares and Consumables:

- System as specified
- Hanging Accessories (Clamp / Stand)
- 5 and 3 ECG cable complete
- 2 sets of lead wires included
- 2 different Temp. probes
- NIBP cuff and hose (2 sizes for infant and neonate)
- SPO^2 sensor (2 sizes for infant and neonate).

47. Ultrasound Machine

Universal Medical Device Nomenclature System (UMDNS): 15-976

Technical Specifications:

- Application: General abdomen, pediatrics, cardiology and small parts.
- Developmental dysplasia of the hip (DDH) screening.
- Scanning model: Convex, Linear, and Micro-convex.
- Imaging Mode: B, 2B, B/M, M.
- Monitor: not less than15-inch non-reflection filter, with Swivel and tilt possibility.
- 8 segment TGC adjustment.
- Gray scale levels: 256.
- Scanning frequency: 3.5 up to 10 MHz.
- Max. display depth: min. 200 mm.
- Memory: not less than 50 frames.
- Two probe connectors at least.
- Measurements B-Mode: Distance, length, area/circumstance (manual/auto), volume, angle, ellipse.
- Measurements M-Mode: heart rate, time, velocity, distance.
- With multi-measurement possibility, in. 5 measurement in each image.
- Image orientation: right/left; top/bottom, real time /frozen.
- Information: all patient relevant data (ID, date, time, examiner, etc.).

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Trolley.
- B/W Printer.
- Linear probe.
- Convex probe.
- U/S Gel.

48. Vein Viewer

Universal Medical Device Nomenclature System (UMDNS): 15-957

Technical Specifications:

- Infrared Vein Locator.
- The product should be able to define the subcutaneous veins for the purpose of cannulation.
- It should make it easy to identify the valves in the veins.
- It should be light weight, not more than 300grams.
- It should be small and easy to be hand held.
- It should function on the principle of class 2 red laser light. The veins should stand out in the light background.
- It should comply to IEC/EN 60825-1 laser safety norms.
- It should have an inverse display, with veins appearing lighter compared to background.
- The battery should last at least 3 hours.
- It should be supplied with the battery charger.
- The battery should be displayed on the screen.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Charger.
- Mounting kit.

49. Vital Signs Monitor

Universal Medical Device Nomenclature System (UMDNS): 25-209

Technical Specifications:

- Mobile SpO2/NIBP.
- Pediatric/Infant Operation.
- SpO2 range:1-99%.
- Accuracy :2-3%.
- Resolution :1%.
- Pulse Rate Range :20-300BPM.
- Pressure range: 30 –300 mmHg Pediatric, 20-150 mmHg neonate.
- Resolution :1mmHg, Accuracy: +/-2%.
- Automatic measurement cycle adjustable.
- Alarms: Low SpO2, high SpO2, Low Pulse, high Pulse, Low pressure, and high pressure.
- Alarm Silence: Available.
- Memory :24hrs data storage.
- Power: 220 V AC 50/60HZ.
- Battery: more than 5 hrs. lead acid.
- Digital display for SpO2, heart rate and pressure.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Pediatric and infant SpO2 Reusable finger probes are included (2 sets for each size).
- NIBP cuffs and hoses are included for Pediatric and infant (2 sets for each size).
- Original Stand with Counter Weight Is Included.

50. Dialysis Machine for Infants

Universal Medical Device Nomenclature System (UMDNS): 23-426

Technical Specifications:

- Machine should be microprocessor controlled.
- Delivers continuous renal replacement therapy (CRRT) for pediatric patients weighing 2.5–10 kgs.
- Cardio-renal pediatric dialysis emergency machine.
- For patients with acute kidney injury (AKI) and fluid overload (FO).
- Provides CRRT treatment for pediatric patients.
- Enabling CVVH, CVVHD, and SCUF treatments.
- High-precision scales monitor fluid balance.
- Three-rollers Peristaltic pumps.
- Small catheter use.
- Extracorporeal volume 32 ml or 41 ml.
- Monitors fluid output with a +/- 30 g range over 24 hours.
- System scales have sensitivity of +/- 1 g.
- Blood pump flow rate: 2–50 mL/min Increments: 1 mL/min.
- Infusion/dialysis pump flow rate: Up to 10 mL/min (Depending on selected modality).
- Effluent pump- flow rate: Up to 15 mL/min (Depending on selected modality).
- Peristaltic pumps with cradle movements, instead of rotors, support small circuit lines.
- Should have high resolution LCD Display with backlight. Must have touch screen for ease of usage.
- Display information on the screen must be user friendly and containing numerical and graphical information for assisting the user.

- Safety features must be available like Closed System Design, Volumetric Ultrafiltration, Volumetric Concentrate Dilution, Start-up test and Self tests.
- Shall have audio visual alarms on limit violation of conductivity, blood leak, air leak, trans membrane pressure alarms, dialysis temperature alarm, dialysis can empty alarm, end of disinfection alarm, bypass alarm and blood pump stop alarm.
- Must have diagnostic program for checking components like individual valves, pumps and closed loop tightness.
- Unit should have temperature control range from 35.0 to 39.0 °C and temperature alarm limits of 34.0 to 40.0 °C.

System Configuration Accessories, Spares and Consumables:

- System as specified.
- Original trolley.
- Warmer.
- Hemofiltration/Hemodialysis Kits.
- Pre-assembled blood sets.
- Dialysate Bag / Fluid Bag.
- Non-sterile waste bag.
- Syringe.
- Warmer tubing set.

CLEANING, DISINFECTION, AND STERILIZATION

General Guidelines

Extreme caution and diligence must be exercised when cleaning and disinfecting equipment, as it represents a significant source of infection and falls under personal responsibility. The following safety procedures must be followed:

- Remove all jewellery (rings, wristwatches) and fake nails and any other impediment to cleaning.
- At a minimum, wear appropriate personal protective equipment (PPE) such as gloves and a plastic apron during cleaning and disinfection. The use of eye protection and a surgical mask is recommended.
- Do not begin the cleaning process until you have confirmed that the equipment is disconnected from the patient and completely devoid of any patient remains from the treatment procedure.
- Make sure that the equipment is disconnected from any electrical power source.
- Confirm that all exposed wiring on the equipment is covered and safe.
- Verify there are no breaks or protruding parts on the equipment before you begin cleaning.
- Equipment should not be returned to service until it is confirmed as completely dry from any liquids used during cleaning.
- Cleaning and disinfection must occur in an area separate from patients, staff, and visitors. A dedicated, isolated cleaning area is preferred.
- The following cleaning and disinfection procedures must be followed unless otherwise specified by the manufacturer.

Cleaning and Disinfection Process

- **Cleaning:** Thoroughly clean the equipment using an antiseptic solution diluted in clean water, ensuring all surfaces are free of visible dirt and debris.
  - **Purpose:** To remove visible dirt, debris, and organic matter from equipment and surfaces.
  - **Rationale:** Cleaning reduces the load of contaminants and prepares surfaces for effective disinfection or sterilization. It is a critical first step as the presence of debris can reduce the effectiveness of disinfectants and sterilizing agents.
- **Disinfection:** Disinfect all surfaces by wiping them with a 0.5% disinfectant solution. Allow the solution to remain on the surfaces for 10 minutes or as per the manufacturer's instructions.
  - **Purpose:** To eliminate most pathogenic microorganisms (except bacterial spores) on surfaces and equipment using chemical agents.
  - **Rationale:** Disinfection is essential for reducing the risk of infection by killing or inactivating bacteria, viruses, and fungi. This step is particularly important for non-critical items that come into contact with intact skin, such as bedside equipment and surfaces in healthcare settings.
- **Sterilization:** autoclave surgical instruments and other items that come in contact with sterile tissues, ensuring they are free from any contamination.
  - **Purpose:** To completely eliminate all forms of microbial life, including bacteria, viruses, fungi, and bacterial spores, typically through methods such as autoclaving, dry heat, or chemical sterilants.
  - **Rationale:** Sterilization is crucial for surgical instruments and devices that penetrate sterile tissues or the vascular system. It ensures that no viable microorganisms remain, thereby preventing infection during invasive procedures.

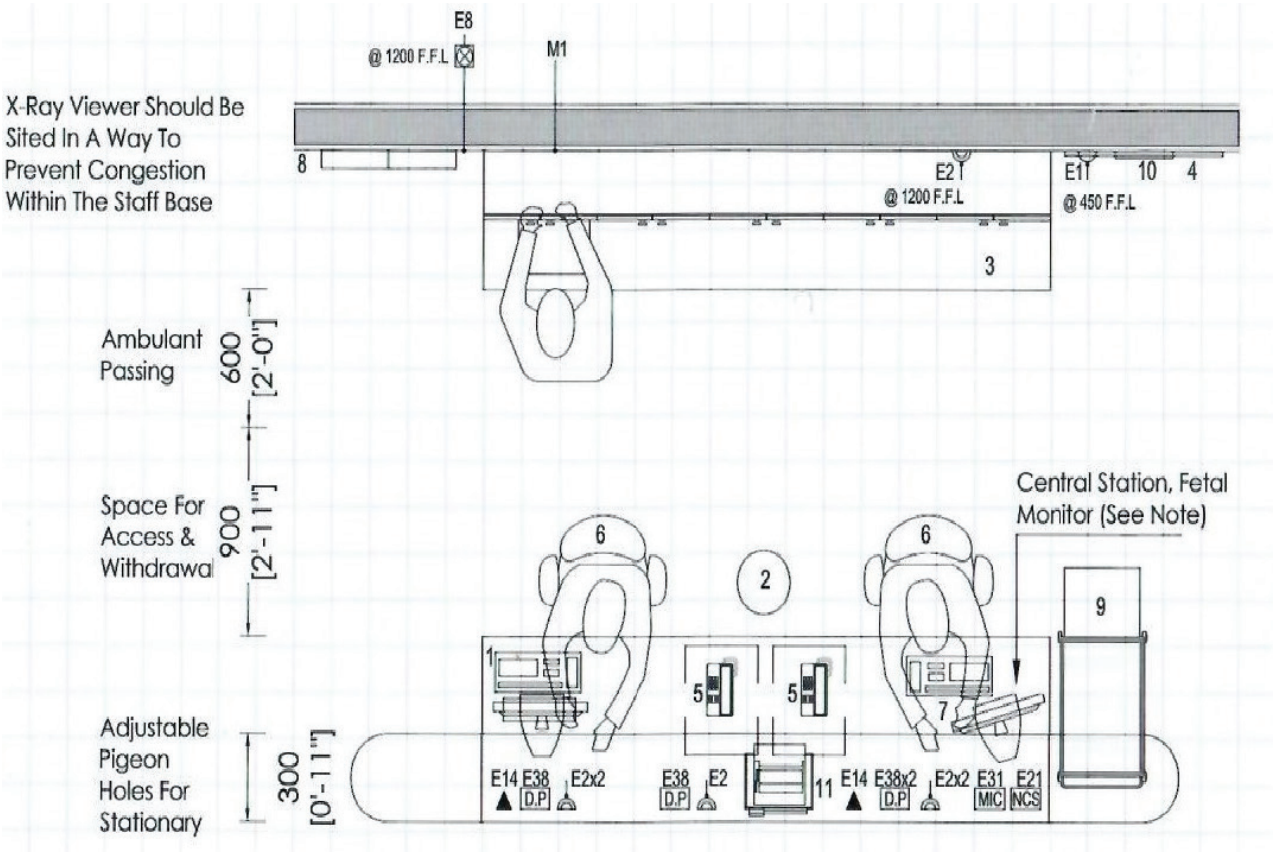
- Ensure the equipment is completely dry before proceeding with any servicing or use.
- Dispose of all waste from the cleaning process in accordance with hospital protocols and infection control guidelines.
- Upon completion, label equipment with the completion date and the signature of the person responsible for cleaning and disinfecting.

TESTING AND QUALITY ASSURANCE (QA)

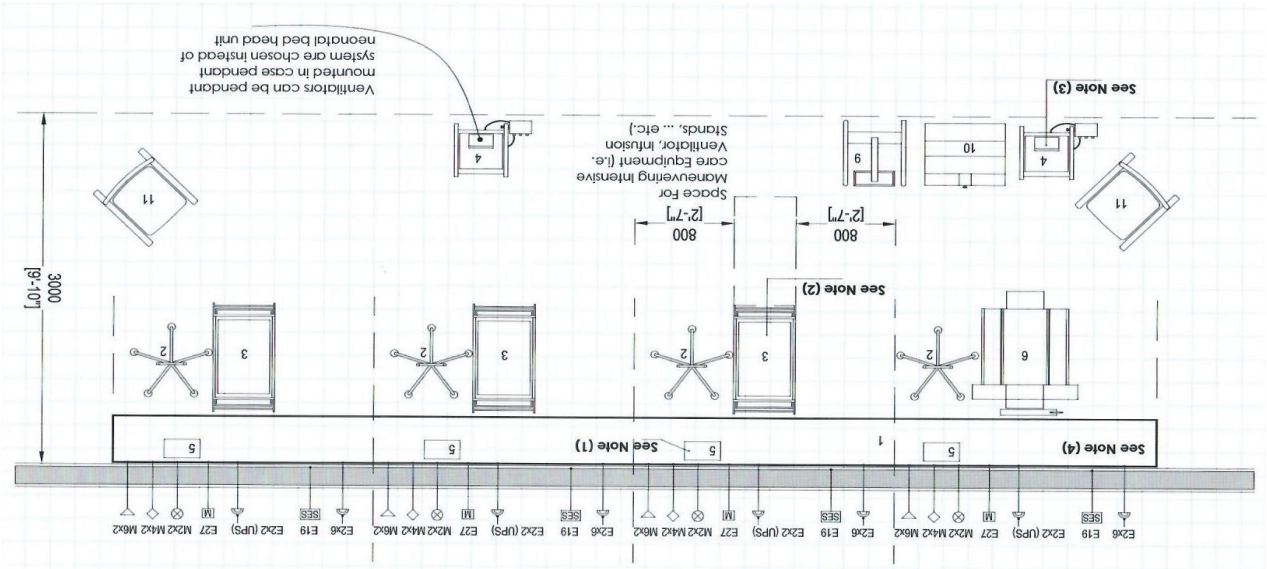
In a separate electronic file

Annex 1: NICU Layout

Neonatal Unit -Staff Base



The central station monitors to be connected to the neonatal physiologic monitors at the head unit of each monitor.



Neonatal I.C.U.

General:

- Glazed observation windows shall be provided to permit the viewing of infants from adjacent nurseries or control area; however, the exact location of the windows will be dependent upon the design of the neonatal care, and its location in relation to the nurse station and other support facilities.
- Hand wash basin shall be provided in the room.

To consider the following:

- **Note (1)**

The neonatal physiologic monitors to be connected to the central station monitor at the staff base.

- **Note (2)**

The number of incubators will vary according to local needs, depending on the level of neonatal care being provided within the hospital, therefore only a typical layout for the incubators are provided.

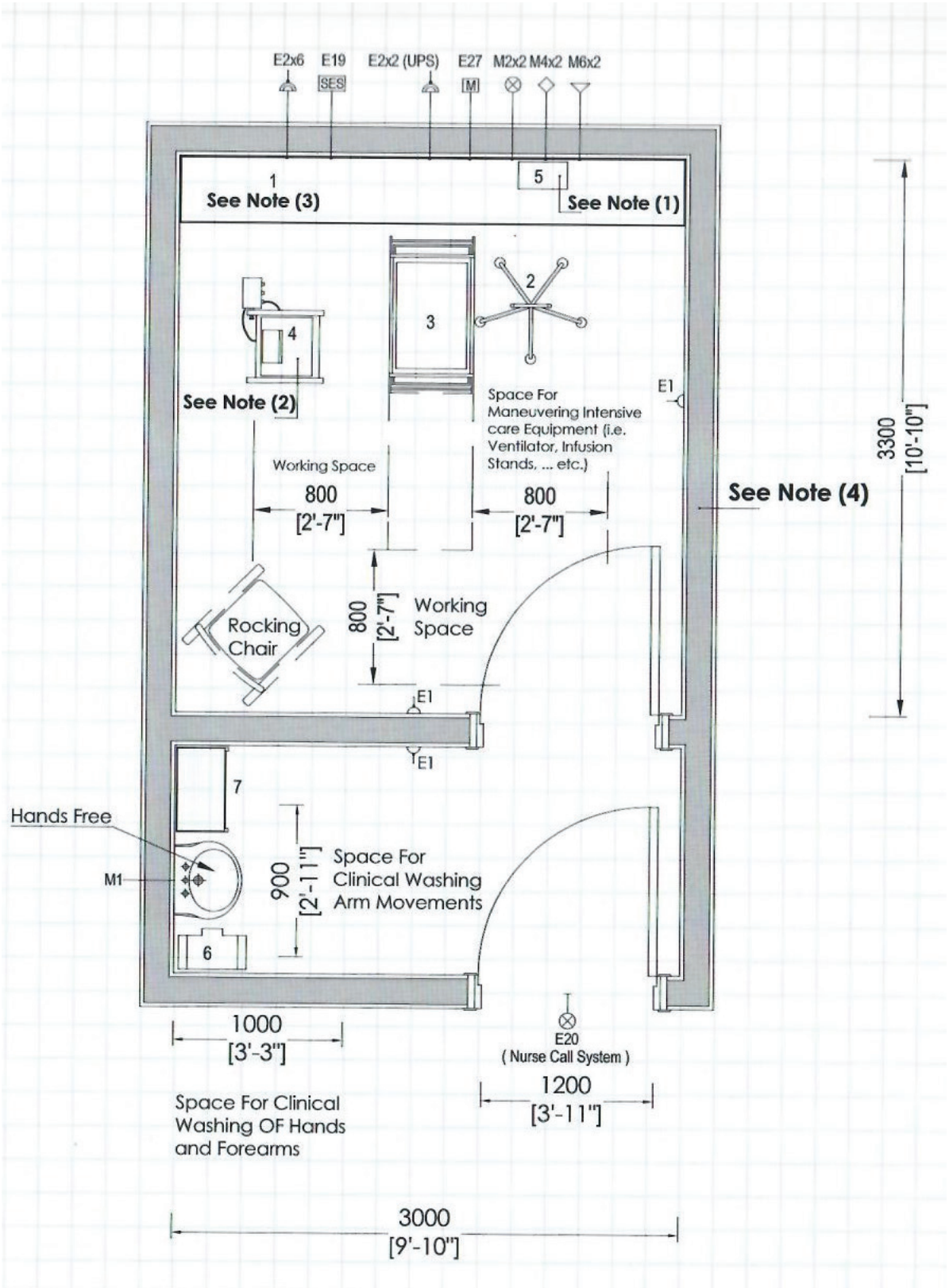
- **Note (3)**

Intensive care equipment will be brought from the store nearby when needed.

- **Note (4)**

The type of bed head unit is subject to project team/ clients' choice; it is becoming increasingly popular to provide a more domestic environment in the whole department.

Neonatal I.C.U. (Isolation)



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The type of bed head unit is subject to project team/ clients' choice, it is becoming increasingly popular to provide a more domestic environment in the whole department.

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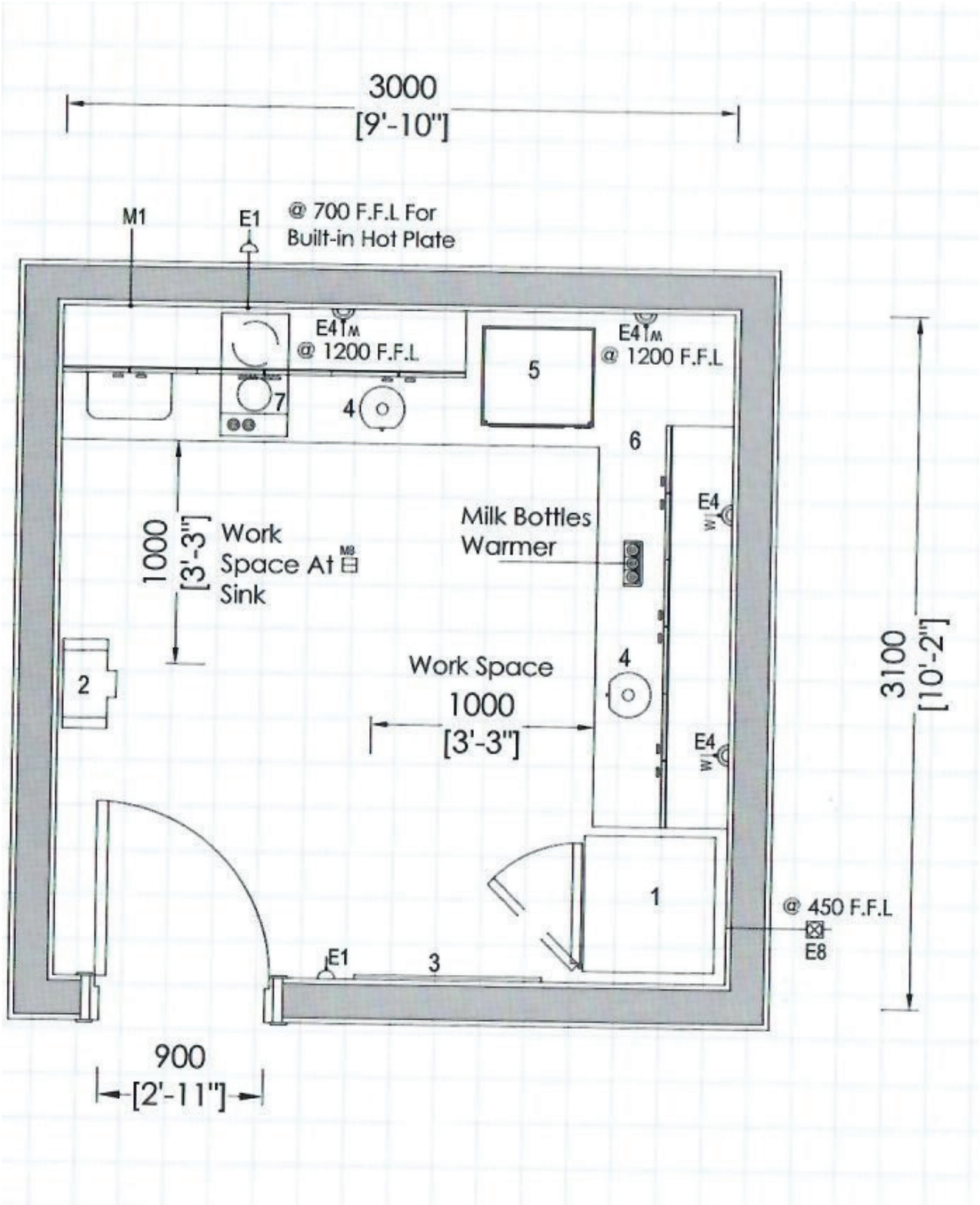
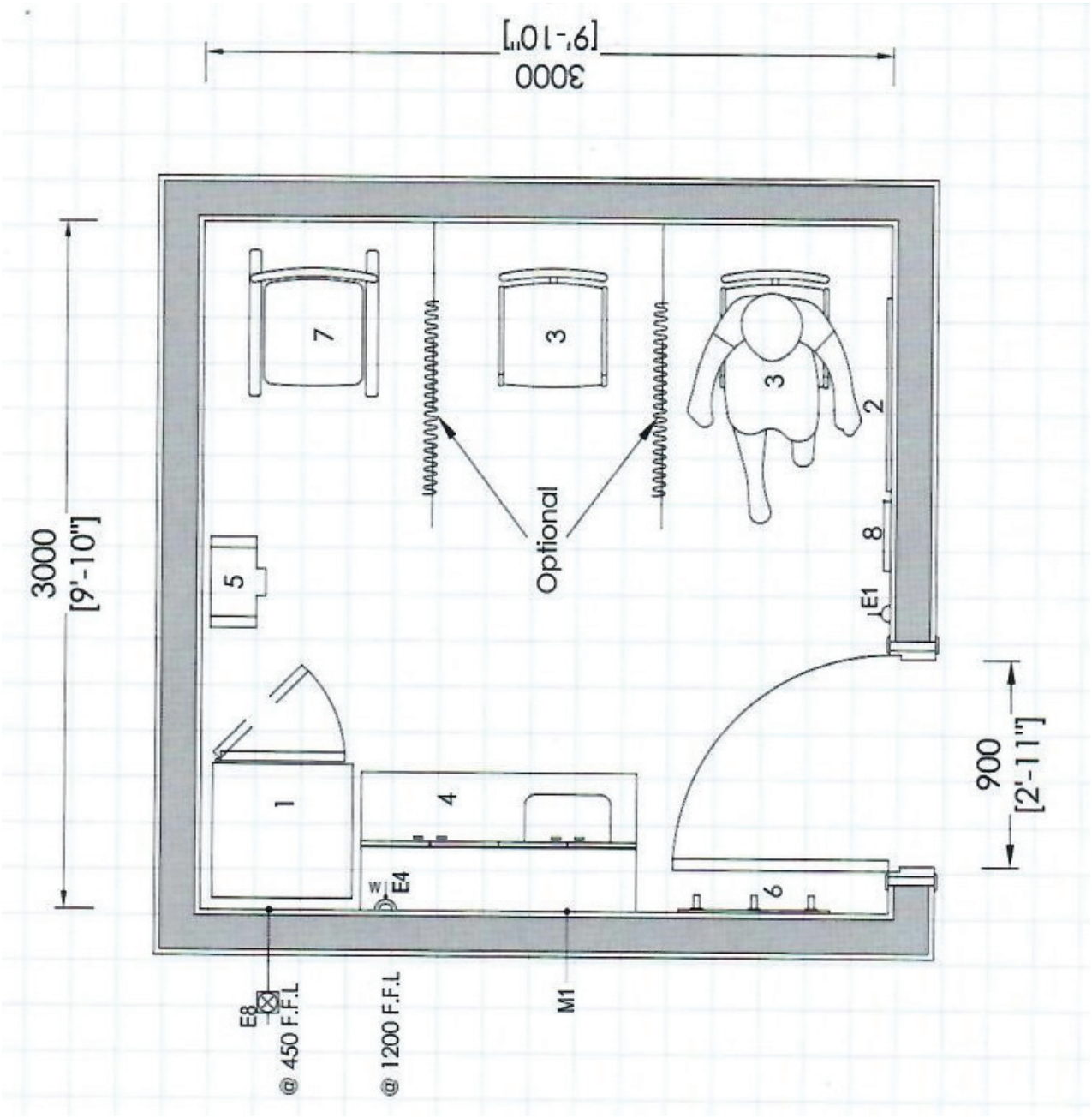
Glazed observation windows shall be provided to permit the viewing of infants from adjacent nurseries or control area; however, the exact location of the windows will be dependent upon the design of the insulation room, and its location in relation to the nurse station and other support facilities.

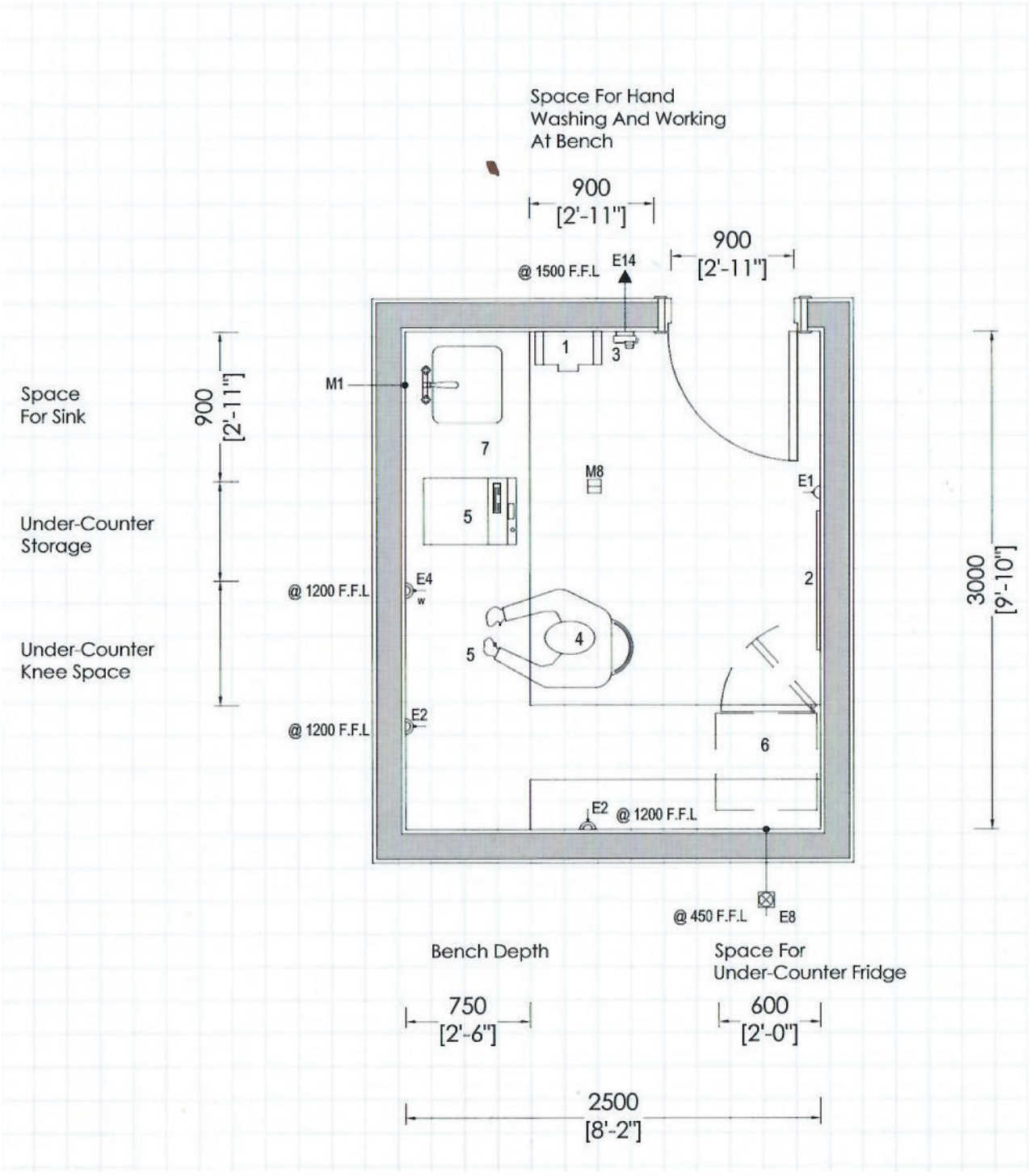
Neonatal Unit - Milk Kitchen

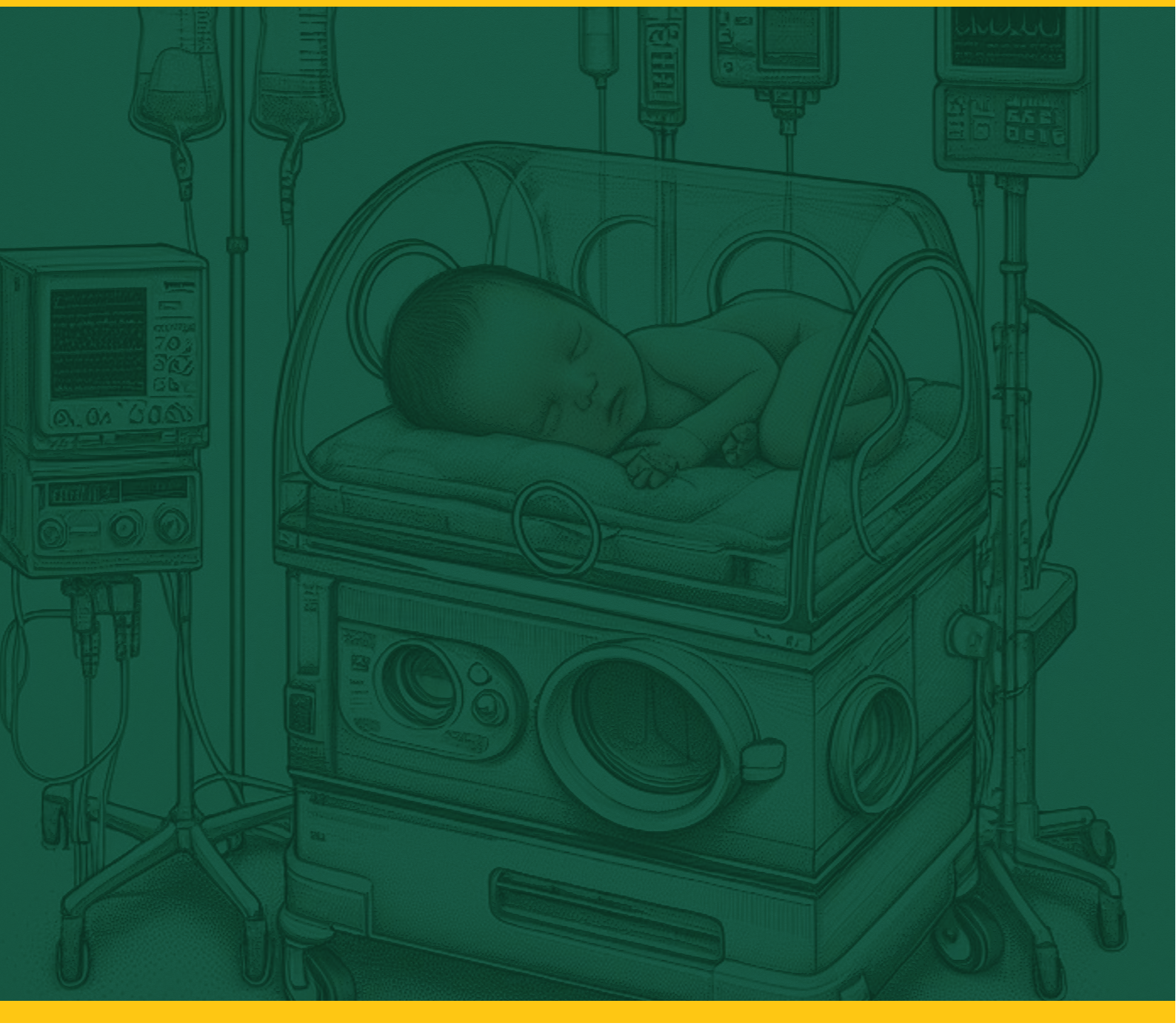


Neonatal Unit - Feeding Room



Neonatal Unit – Laboratory





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