

Lot 1-PHOTOTHERAPY

NAME AND CODING		
GMDN name		Phototherapy units/systems
GMDN code(s)		CT 2066
GENERAL		
1. USE		
1.1	Clinical purpose	Emits in the main radiation spectrum in the range between 400 nm and 550 nm for reducing the concentration of Bilirubin
1.2	Used by clinical department/ ward	New born stabilisation unit, SNCU
1.3`	Overview of functional requirements	a) Provides filtered light using radiant electric lights, not fibreoptics. b) Infant supported securely in bassinette below bulbs. c) Monitors hours of radiant light exposure.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Phototherapy should be based on LED technology, which after filtering should provide, a light of wavelength approximately 450 to 470 nm with peak wavelength of 450-460nm range. 2. Irradiance to be minimum 35 μW/cm2/nm at 40 cm height and UV should not exceed 10-4 W/m2 in 180nm to 400nm. 3. Digital Hour meter showing total exposure time for current patient to be clearly visible by operator. 4. Effective light field >700 cm2. 5. Lamp life should be minimum 20000 hours for LED and should have timer to indicate its usage. 6. Over temperature safety cut out to be included. 7. Up, down and tilting of head should be possible. 8. The unit should be mounted with castor wheels with brakes. 9. Variation in intensity over 5-6 hours < 10%. 10. The irradiance ratio (min to max) shall be greater than 40 % on mattress. 11. Green indicator light shall be provided to indicate that equipment is ready for normal use. 12. Interruption and a restoration of the power supply do not change preset values. LED heat can be reduced by natural cooling. 13. LED should be protectred from free fall. 14. It should not topple on 10 deg inclined angle. 15. The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.

		<p>16. There should be intuitive method to indicate the light surface is at the appropriate treatment distance.</p> <p>17. Mobile stand with movable castors and height adjustment facility along with easy swivelling of source box. Unit can be used along with Infant care trolley, Radiant Warmer and Incubator.</p>
2.2	Settings	UP/DOWN adjustment of Over Head Unit; The phototherapy unit should be able to provide effective treatment for beds and incubators of varying heights (generally 1.0 to 1.6m). Adjustment of light intensity may be provided.
2.3	User's interface	Manual
2.4	Software and/or standard of communication(where ever required)	LED Display and inbuilt software
2.5	Others	
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	minimum spec: 1650mm Height X 750mm Width X 500mm Length
3.2	Weight (lbs, kg)	<20 kg
3.3	Configuration	<p>Clear cabinet for observation of infant.</p> <p>Infant bassinette to be an integral unit which should be detachable.</p> <p>Unit to provide shielding of infant in the event of bulb breakage.</p> <p>Bulb mount to have angle adjustment of at least 30 degrees.</p> <p>All surfaces to be made of corrosion resistant materials.</p> <p>Light unit tilting facility and height adjustment facility.</p>
3.4	Noise (in dBA)	<60dBA
3.5	heat dissipation	The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.
3.6	Mobility, portability	Minimum 3 castors and atleast 2 with brakes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	Power Requirements	220 to 240V, 50 Hz
4.2	Battery operated	NA
4.3	Tolerance (to variations, shutdowns)	± 10% of input AC
4.4	Protection	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	Power consumption	Should not be more than 160 W
4.6	Other energy supplies	Mains cable to be at least 2.5m length
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional)	<p>Complete set of replacement tubes to allow 3 months' continuous operation</p> <p>Two replacement sets of fuses, if replaceable type used.</p>
5.2	Spare parts (main ones)	No spares required
5.3	Consumables / reagents (open, closed system)	Total 500 nos. Infant eye masks of both available sizes (term and pre term babies).
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.

7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international	<p>Should be FDA / CE approved product</p> <p>Shall meet IEC-60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Or Equivalent BIS)</p> <p>Should meet IEC 60601-1:2005 standard requirements</p> <p>Shall meet IEC 60601-2-50: 2009 Medical Electrical Equipment - Part 2-50: Particular Requirement for the basic safety and essential performance of infant phototherapy equipment;</p> <p>Manufacturer should be ISO 13485 certified</p>
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	Certificate of Calibration and inspection from the factory.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided
8.4	Others	
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years for the machine and 20,000 hours for LEDs
9.2	Maintenance tasks	Maintenance manual detailing complete maintaining schedule
9.3	Service contract clauses, including prices	Local clinical staff to affirm completion of installation
9.4	Others	
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	<p>Advanced maintenance tasks required shall be documented</p> <p>User, technical and maintenance manuals to be supplied in English language.</p> <p>List to be provided of equipment and procedures required for local calibration and routine maintenance</p>
10.2	Other accompanying documents	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided
11.2	Recommendations or warnings	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.