LED phototherapy for neonatal jaundice

Country of origin | India

Health problem addressed

Neontal jaundice (hyperbilirubinemia) occurs in at least 60% of term infants. If untreated, it can cause irreversible brain damage. Phototherapy equipment for treatment currently available have frequent bulb replacement needs, expensive bulb replacement costs and experience frequent breakdown in remote, rural areas.

Product description

The device emits light through an array of high-powered light emitting diodes (LEDs). These LEDs have been specifically selected to emit a narrow wavelength of blue light (dominant wavelength 458nm) that maximises the rate of bilirubin breakdown. The arrangement of the LEDs along with the optics have been designed to provide uniformity of light on the patient, while minimizing unwanted spill and glare outside the treatment surface. The device provides the ability to cater the treatment to the patient by allowing the caregiver to choose a high intensity (45µw/nm/cm^2) or low intensity (22 µw/nm/cm^2) setting.

Developer's claims of products benefits

Most phototherapy devices on the market use tubelights or compact fluorescent (CFL) bulbs to provide phototherapy. Many of these do not provide adequate intensity or uniform coverage. Moreover, these tubelights have to be replaced frequently - every 1000 hours. This is often not feasible due to high replacement costs and availability in markets.

This device is easy to use for the caregiver, has a low total cost of ownership, is designed to be rugged and reliable, and provides excellent clinical outcomes. The uniformity, intensity and wavelength of emitted light results in a 28% increase in bilirubin breakdown. It utilizes only 20W of power, which is great for electricity savings as well as for the environment. It can be used with most commercially available photovoltaic systems, or potentially car batteries connected to inverters. It is simple to use with only two buttons - on/off and high/low. Lamps last for 50,000 hours, which provides 6 years of night and day use.

Suitability for low-resource settings

The device is specifically designed for low resource settings. It is designed to be rugged: e.g. all moving mechanical parts such as fans have been removed from the lamphead. The cost of ownership is highly minimized by having LEDs that last 50,000 hours - 6 years of night & day use, and 50 times that of bulbs. It also uses only 20W of power. Over 2000 units have been deployed in low-resource settings.

Almost one third of the device's sales in India have been to Tier 2 or 3 towns. It has been awarded the Oxford Analytica validation Healthymagination certificate for product that improves access, betters quality and reduces cost of care. The Federation of Indian Chambers of Commerce and Industry have awarded it the prestigious Healthcare Excellence Award in 2012 for innovation to solve pressing healthcare challenges in India.

Operating steps

The device is simple to use. After installation, it has to be plugged into mains power (100-240V). There are then only two buttons - On/Off and High/Low to vary the intensity. Black screws on top can be unfastened to remove the lamp head for placement on an incubator. The height of the lamp can be adjusted by unscrewing a ring in center of the pole.

Regulatory status

It conforms with the requirements of Medical Devices Directive 93/42/EEC - BSI CE 0086 mark. It is also certified ISO 13485. It has US FDA 510K clearance (K120168). It is ROHS compliant and a WEEE certificate is available.

Use and maintenance

User: Physician, nurse, midwife

Training: None

Maintenance: None

Environment of use

Settings: Rural, urban settings, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)

Requirements: Continuous power supply (100-240V)

Product specifications

Dimensions (mm): 530 x 550 x 1700 (maximum height)

Weight (kg): 10

Consumables: None

Life time: 7 years

Shelf life: 2 years (6 months without any operation)

Retail Price (USD): 1200 with considerable variation between countries

List price (USD): 1500

Other features: Mobile, capital equipment

Year of commercialization: 2011

Currently sold in: 122 countries. Emerging market countries include Bahamas, Bolivia, Costa Rica, Czech Republic, Ecuador, Egypt, Gabon, Ghana, Hungary, India, Indonesia, Mexico, Moldova, Myanmar, Peru, Philippines, Poland, Romania, South Africa, Thailand, Tunisia, Vietnam.

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