Phototherapy for neonatal jaundice treatment

Country of origin | Brazil

Health problem addressed
Neonatal Jaundice (Hyperbilirubinemia) is a frequent issue in newborns. Approximately 60% of newborns become clinically jaundiced. It is a clinical condition generally benign and reversible if properly treated, but its exacerbated intensification may generate serious sequelae into the central nervous system, which may lead patient to death.

Product description
Phototherapy is an efficient mean to treat Hyperbilirubinemia. By emitting blue light over the patient's skin, it converts toxic bilirubin molecules in the blood into less toxic isomeric forms, by photo-oxidation and photoisomerization. The device uses high power LEDs for treatment and negligible emission of UV / IR radiation.

Product functionality
The phototherapy uses a set of 5 high power LEDs, positioned 30 cm above the patient. The treatment uses high radiation emitted at the blue range of the spectrum, from 400 to 550 nm (the most recommended for Jaundice treatment). The device also provides extra functions, such as integrated radiometer and treatment time counter.

Developer’s claims of product benefits
Traditional devices use fluorescent or halogen lamps, or many conventional LEDs. Lamps may require filters to attenuate UV / IR rays and have a low life expectancy (around 2.000h). Conventional LEDs are low power devices. To work effectively, hundreds of LEDs must be used, making the phototherapy complex and prone to failure. The proposed technology uses only 5 high power LEDs, which is equivalent to more than 250 conventional LEDs. The result is a compact, highly efficient, long life time (20.000 h) and low cost phototherapy. It provides new resources: output radiation level adjustment, embedded radiometer and irradiance measurement reports. In addition, it is compact, saving space in the intensive care unit.

Operating steps
Place the device over the newborn, 30 cm away. Turn it on and press ‘Menu’ to go to the irradiance level screen. Set the irradiance using the ‘up’/’down’ keys and press ‘Enter’ to confirm. Be sure the newborn is exposed to the light at the chest and abdomen area. Protect the newborn’s eyes.

Development stage
The product is being manufactured and commercialized. It has been fully validated and clinically tested. Studies verify that the blue high power LEDs are more efficient for Jaundice treatment. The market confirms those studies. It has the Brazilian ANVISA regulatory approval, the CE marking and it is currently obtaining the UL recognition approval.

Future work and challenges
Promoting the technology’s ease-of-use, efficient treatment system and affordable cost in low and middle income countries is the greatest challenge. Assistance herein is required, e.g. through workshops by professionals to explain the importance and advantages and to make users familiar with new functions that improve the treatment quality, like the embedded radiometer and the timer.

User and environment
User: Nurse, physician
Training: Concept presentation (2 hours training).
Maintenance: Technician

Environment of use
Setting: Secondary (general hospital), tertiary (specialists hospital)
Requirements: Power supply (100 to 240 Vac), 50 or 60Hz; ambient temperature between 18°C and 28°C; air humidity between 10% and 95%; eye protection for the patient.

Product specifications
Dimensions (mm): 230 x 116 x 50
Weight (kg): 1
Consumables: Eye protector
Other features: Portable and reusable. It utilizes software.
Year of commercialization: 2005

Currently sold in: Algeria, Australia, Bolivia, Brazil, Colombia, Costa Rica, Ecuador, Spain, Finland, France, Indonesia, Iran, Iraq, Jamaica, Lithuania, Malaysia, Mexico, Nicaragua, Paraguay, Peru, Poland, Portugal, Russia, Syria, Sudan, Sweden, Uruguay, Venezuela, Vietnam, Yemen.

Contact details
Djalma Luiz Rodrigues
Email rukanin.massaro@uol.com.br
Telephone +55 11 2412 3743
Fax +55 11 2412 3743
http://www.who.int/medical_devices

Please see disclaimer on following page
Disclaimer

Eligibility for inclusion in the compendium has been evaluated by EuroScan member agencies, WHO Collaborating Centres, and WHO. However, the evaluation by EuroScan member agencies, WHO Collaborating Centres, and WHO has been solely based on a limited assessment of data and information submitted in the developers’ applications and, where available, of additional sources of evidence, such as literature search results or other publicly available information. There has been no rigorous review for safety, efficacy, quality, applicability, nor cost acceptability of any of the technologies. Therefore, inclusion in the compendium does not constitute a warranty of the fitness of any technology for a particular purpose. Besides, the responsibility for the quality, safety and efficacy of each technology remains with the developer and/or manufacturer. The decision to include a particular technology in the compendium is subject to change on the basis of new information that may subsequently become available to WHO.

WHO will not be held to endorse nor to recommend any technology included in the compendium. Inclusion in the compendium solely aims at drawing stakeholders’ attention to innovative health technologies, either existing or under development, with a view to fostering the development and availability of, and/or access to, new and emerging technologies which are likely to be accessible, appropriate and affordable for use in low- and middle-income countries.

WHO does not furthermore warrant or represent that:

1. the list of innovative health technologies is exhaustive or error free; and/or that
2. the technologies which are included in the compendium will be embodied in future editions of the compendium; and/or that
3. the use of the technologies listed is, or will be, in accordance with the national laws and regulations of any country, including but not limited to patent laws; and/or that
4. any product that may be developed from the listed technologies will be successfully commercialized in target countries or that WHO will finance or otherwise support the development or commercialization of any such product.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage, use of personal data, or other prejudice of any kind whatsoever that may arise as a result of, or in connection with, the procurement, distribution and/or use of any technology embodied in the compendium, or of any resulting product and any future development thereof.

Developers whose technology has been included in the compendium shall not, in any statement of an advertising, commercial and/or promotional nature, refer to their participation and/or inclusion in the compendium. In no case shall the latter use the WHO name and/or the emblem, or any abbreviation thereof, in relation to their business or otherwise.