



Health Technology Review	
Technology Ref.:	HTA23040
Technology Name:	TRANSCUTANEOUS BILIRUBIN METER (BILICARE)
Approvals by International Bodies:	CE Marked
Company name:	HESSA MEDICAL EQUIPMENTS CO LLC
Agent in UAE:	R.K. MURTHY
Email:	<a href="mailto:rkmurthy@hessamed.com">rkmurthy@hessamed.com</a>

<b>Short Description of the Technology:</b>	<p>Transcutaneous bilirubin (TcB) is a measurement of the yellow color of the blanched skin and subcutaneous tissue, not of the serum, and is used as a screening tool to help determine at risk infants and whether the TSB should be measured. TcB measurements are being used with increasing frequency in hospital nurseries and in some outpatient settings. They have the advantage of providing instantaneous information and probably reduce the likelihood of missing the diagnosis of significant hyperbilirubinemia or kernicterus. The shortening of newborn hospital stays after birth and the observation that kernicterus is still occurring has drawn attention to the importance of identifying and monitoring the jaundiced newborn infant. The use of TcB screening is deemed to be more accurate than visual assessment and reduces the number of blood tests for bilirubin determination, without compromising detection of infants with elevated TSB values</p>
---	---

<b>Health Technology Assessment Team Recommendation:</b>	<b>Approved</b>
<b>Summary of Review:</b>	
<p>The technology is a point of care device to analyses the light reflected by the skin and subcutaneous tissues to assess the risk of neonatal hyperbilirubinemia. This non-invasive method is easy, safe, and convenient for measuring neonatal jaundice. It has been used in different countries but not yet approved by FDA. The accuracy of the BiliCare System has been validated in clinical studies.</p>	
<b>Advantages</b>	<b>Disadvantages</b>
Efficacy; Can accurately define a level of bilirubin in preterm infants at a gestational age of 24 weeks and more	To be used by healthcare professionals only
Easy to use; The device can be operated with one hand, both by right- and left-handers	Fairly new technology needs more testing and more patient's population studies with larger neonatal populations (although current available studies results is reassuring).
Long-term storage of results provides trending of patient data.	
CE marked with no history of device recall or	

failure could be found.	
The Bilicare device can be used on all skin tones and bilirubin measurements on newborns do not depend upon thickness of the ear.	
The specified parameters of the Bilicare device do not change over time since Bilicare uses LED technology	

We recommend an **approval of using this technology** with the following conditions:

1. Approval on using the technology "TRANSCUTANEOUS BILIRUBIN METER (BILICARE)" by healthcare professionals in healthcare facilities.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

**Moreover**, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

#### Technology Image





### **Population, setting and intended user for Technology “BILICARE DEVICE”**

- **Population/ Intended User;**
  - For screening infants for hyperbilirubinemia.
- **To be performed by:**
  - By healthcare professionals.
- **Clinical Setting:**
  - Healthcare facilities.
- **Condition of use:**
  - As per Doctor recommendation.
- **Exclusion criteria:**
  - Other conflicting medical issues.