

Picterus® Jaundice Pro as a screening tool for neonatal jaundice: a validation study across three study sites.

Picterus AS, May 2025, revised September 2025

Disclaimer: The data presented herein are unpublished and are not yet subjected to formal peer review or public distribution. These findings are preliminary and may be subject to further analysis or revisions.

Key notes:

- Picterus® Jaundice Pro (Picterus JP) is a medical device designed to screen for neonatal jaundice using a smartphone app and a Picterus® Calibration Card. The device can be used by both parents and healthcare professionals, allowing for early detection and monitoring of jaundice even when the newborn is at home.
- This document presents the results from 3 different studies assessing Picterus JP performance in 475 newborns with various skin tones.
- Results show that Picterus JP has a high correlation with the gold standard total serum bilirubin test, ensuring reliable screening results.
- Picterus JP demonstrated high sensitivity and specificity in identifying newborns at risk of developing severe neonatal jaundice, ensuring timely intervention and reducing the risk of severe jaundice.
- Picterus JP showed a high decision accuracy for identifying newborns requiring further follow-up for diagnosis of neonatal jaundice with a blood test:
 - All the newborns who needed phototherapy (diagnosed by TSB) were correctly identified using Picterus JP screening.
 - Picterus JP demonstrated great potential to avoid unnecessary blood draws and effectively screen for neonatal jaundice.
- These benefits highlight the potential of Picterus JP as a safe, effective, and accessible tool for screening, ultimately improving newborn health outcomes.

Table of Contents

1. Background	3
2. Aim	3
3. Methods	3
4. Study participants	4
5. Data collection	4
5.1 Total Serum Bilirubin	4
5.2 Picterus JP.....	4
6. Statistical analysis	4
7. Results	5
8. Decision accuracy.....	6
9. Performance characteristics of Picterus JP	8
10. Conclusion	9
11. References.....	9

1. Background

Neonatal jaundice is a condition where newborns have yellowish skin due to high levels of bilirubin in their blood. It affects 60-80% of newborns within the first 48 to 72 hours after birth (1). While it is usually harmless, about 1 million newborns develop severe jaundice each year, which can cause serious problems if undetected or untreated. When bilirubin levels get too high, it can affect the newborns brain and cause permanent damage. Therefore, early detection, monitoring and treatment is important (2-5).

The standard test for neonatal jaundice diagnosis is the total serum bilirubin (TSB) test, which requires a blood sample and lab facilities. Non-invasive devices like transcutaneous bilirubinometers (TcB) can detect high bilirubin levels without needing a blood sample (6). However, these devices are expensive and not always available in health facilities or for home visits (7-11). Many newborns are already at home when signs of jaundice start, typically around 48 hours after birth. As a result, visual examination is often used to check for neonatal jaundice both in the hospital and at home, but this method is not fully reliable and requires experience (1, 12, 13).

Picterus® Jaundice Pro (Picterus JP) is a medical device that uses a smartphone to screen for neonatal jaundice. It is approved for use by both parents and healthcare professionals. The device uses a smartphone app and a Picterus® Calibration Card to estimate bilirubin levels from images of the skin of a newborn's chest (Figure 1). The Picterus® Calibration Card adjusts for different light conditions and camera sensors.



Figure 1 Picterus® Jaundice Pro app and Picterus® Calibration Card

2. Aim

There are several publications (14-18) on the development and validation of the Picterus JP device; since publication of these studies, however, the product has been significantly developed and improved. In this paper we present the latest findings from studies conducted across various countries evaluating the performance of Picterus JP.

3. Methods

We included three cross-sectional studies conducted at different sites: two in the United States (US) and one in Mexico (Table 1).

Table 1 Overview of clinical study sites, data collection period and included newborns

Study site and country	Data collection period	Newborns (n)
Intermountain Medical Center, McKay-Dee Hospital, and Utah Valley Hospital USA	February-July, 2024	234
University of Chicago USA	March-October, 2024	79
Hospital General Zona 1 Oaxaca Mexico	February 2023-June 2024	162
Total		475

4. Study participants

Newborns included in the analysis met the following criteria: age between 1 to 14 days, gestational age of at least 35 weeks, birth weight of 2000 g or more and requiring a blood sampling either for clinically suspected jaundice or other clinical indication.

Newborns were excluded if they had a condition or treatment that affected skin colour or appearance, other than jaundice. Infants receiving or previously receiving phototherapy were also excluded.

5. Data collection

Data were collected under the ambient conditions found in each of the settings. The following data on each newborn was collected: day and time of birth, birth weight, and gestational age.

All procedures were performed within a span of 60 minutes.

5.1 Total Serum Bilirubin

TSB levels were measured with a blood sample obtained by either heel prick or venous puncture. Samples were immediately processed at the hospitals' laboratory by trained personnel.

5.2 Picterus JP

To perform a Picterus JP scan, the Picterus Calibration Card was placed on a flat part of the newborn chest and an image set, consisting of 3 images with and 3 without flash, was automatically captured on a smartphone using the Picterus JP app.

6. Statistical analysis

We determined the decision accuracy from Picterus JP results to identify newborns requiring further follow-up for diagnosis of neonatal jaundice by TSB. Results were plotted against the phototherapy threshold charts for newborns with one or more hyperbilirubinemia neurotoxicity risk factors, as outlined in the AAP 2022 guidelines for managing hyperbilirubinemia in newborns with a gestational age of 35 weeks or more (19). This chart was chosen to ensure a more conservative approach, because we lacked specific information on individual risk factors for some of the newborns. For this report, TSB

levels and Picterus JP bilirubin results were categorized according to the AAP guidelines recommendations for further follow-up for diagnosis of neonatal jaundice by TSB based on TcB results as:

- a. Positive: Falling above 250 $\mu\text{mol/L}$ (14.6 mg/dL) or within 0-50 $\mu\text{mol/L}$ (0-3 mg/dL) below phototherapy threshold or above it.
- b. Negative: Falling below 250 $\mu\text{mol/L}$ (14.6 mg/dL) or more than 50 $\mu\text{mol/L}$ (3 mg/dL) below phototherapy threshold.

Additionally, a sub analysis of the newborns with positive TSB results was conducted to determine the accuracy of Picterus JP to identify newborns requiring phototherapy.

Moreover, the correlation between Picterus JP bilirubin results and TSB levels were evaluated using Pearson's r . Bland-Altman analysis was conducted to evaluate potential bias in the difference between Picterus JP results and TSB, as well as to evaluate confidence intervals for the difference. Analyses were performed using GraphPad Prism. Additionally, Picterus JP accuracy was assessed by calculating sensitivity and specificity for a threshold of 250 $\mu\text{mol/L}$ based on TcB thresholds commonly used to confirm the diagnoses with TSB, as recommended in several clinical guidelines for neonatal jaundice (19-21).

7. Results

475 newborns were included in the data analysis. Birth weight, gestational age, TSB levels and Picterus JP bilirubin values are shown in Table 2.

Table 2 Clinical characteristics of newborns (n = 475)

	Mean	SD	Min-Max
Birthweight (grams)	3215	489	2040-4990
Gestational age (weeks)	38.4	1.4	35-42
Age at inclusion (hours)	60.8	48.3	24-319
TSB ($\mu\text{mol/L}$)	156.3	70.8	17-511
(mg/dL)	9.1	4.1	1-29.8
Picterus JP ($\mu\text{mol/L}$)	169.7	80	49-362
(mg/dL)	9.9	4.6	2.8-21.1

SD: standard deviation, Min: minimum, Max: maximum, TSB: Total Serum Bilirubin, Picterus JP: Picterus® Jaundice Pro, $\mu\text{mol/L}$: micromoles per litre, mg/dL: milligram per deciliter

Figure 2 shows the skin tone demographic from the combined clinical studies. A calibrated r-channel value is affected by the melanin content of a newborn's skin and is determined from Picterus JP images. Since transcutaneous bilirubin assessments are affected by the presence of melanin (8, 22), we aimed to include a range of skin tones in the clinical studies. The r-channel values in this data set range from 0.12 to 0.53; lower values indicate darker skin. Examples of newborn skin tones for r-channel values below and above a threshold are shown.

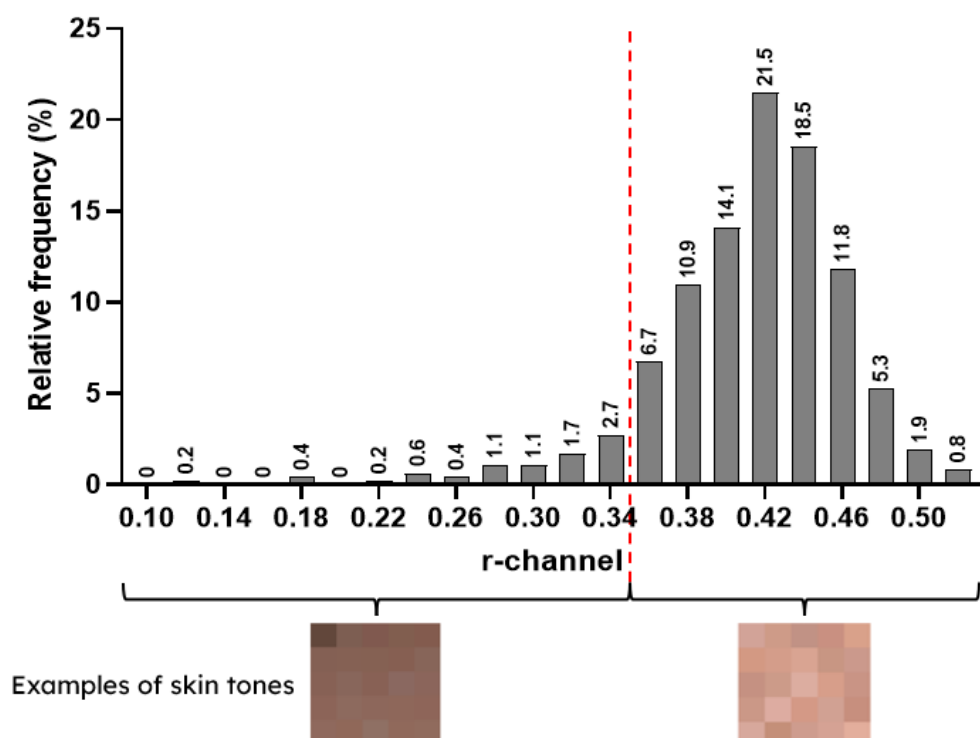


Figure 2 Skin tone distribution from the combined clinical studies. The calibrated r-channel value (x-axis) from Picterus® Jaundice Pro images was used to approximate the skin tone of the newborns. The relative frequency (y-axis) for each r-channel value is shown. A cut-off of 0.37 has been indicated, and examples of skin tones below and above this threshold value are shown.

8. Decision accuracy

The decision accuracy in Table 3 shows the effectiveness of Picterus JP as a screening tool for neonatal jaundice according to the gestational age corrected phototherapy guidelines for one or more neurotoxicity risk factor, as defined by the AAP (2022). Newborns with Picterus JP results categorized as negative are recommended to have a follow-up Picterus JP scan. Newborns with Picterus JP results categorized as positive are recommended to get a TSB before a clinical decision for phototherapy is made. Table 4 shows the effectiveness of Picterus JP to identify newborns requiring phototherapy among newborns with a positive TSB result.

Table 3 Decision accuracy for Picterus JP

*Gestational age corrected phototherapy threshold for one or more neurotoxicity risk factor as defined by the AAP guidelines 2022.

TSB: Total Serum Bilirubin, Picterus JP: Picterus Jaundice Pro, $\mu\text{mol/L}$: micromoles per litre, mg/dL : milligrams per decilitre

		TSB POSITIVE		Total
		YES	NO	
PICTERUS JP POSITIVE	YES	98	91	189
	NO	33	253	286
Total		131	344	475

*Gestational age corrected phototherapy threshold for one or more neurotoxicity risk factor as defined by the AAP guidelines 2022.

TSB: Total Serum Bilirubin, Picterus JP: Picterus Jaundice Pro, $\mu\text{mol/L}$: micromoles per litre, mg/dL : milligrams per decilitre

Table 4 Accuracy of Picterus JP to identify newborns requiring phototherapy among newborns with TSB positive result.

		Requiring phototherapy		Total
		YES	NO	
Picterus JP Positive	YES	34	64	98
	NO	0	33	33
Total		34	97	131

*Gestational age corrected phototherapy threshold for one or more neurotoxicity risk factor as defined by the AAP guidelines 2022.

TSB: Total Serum Bilirubin, Picterus JP: Picterus Jaundice Pro, $\mu\text{mol/L}$: micromoles per litre, mg/dL : milligrams per decilitre

A summary of the decision accuracy results:

- Picterus correctly recommended follow-up with TSB in 98/131 (74%) of newborns requiring follow-up with TSB.
- Picterus correctly recommended follow-up with TSB in 34/34 (100%) of newborns requiring phototherapy.
- Picterus correctly ruled-out severe jaundice (would not have recommended follow-up with TSB) in 253/344 (73%) of newborns not requiring follow-up with TSB.
- Picterus recommended TSB in 91/344 (26%) of newborns not requiring TSB (unnecessary blood-draw).

9. Performance characteristics of Picterus JP

Figures 3 and 4 show the correlation and Bland-Altman plots for Picterus JP and TSB results of the combined clinical trials ($n = 475$). There was a strong statistical correlation between Picterus JP results and TSB (Pearson's $r = 0.80$) (Figure 3). The Bland-Altman plot shows that Picterus JP tends to overestimate higher bilirubin values, which is a built-in safety feature of the device (Figure 4). The overall bias was $13 \mu\text{mol/L}$ (0.8 mg/dL) and standard deviation of the bias was $47.6 \mu\text{mol/L}$ (2.8 mg/dL), which is similar to the performance characteristics reported for traditional TcB devices (8). Applying a threshold of $250 \mu\text{mol/L}$ (14.6 mg/dL), the sensitivity was 94% and specificity was 84% (48 positive cases).

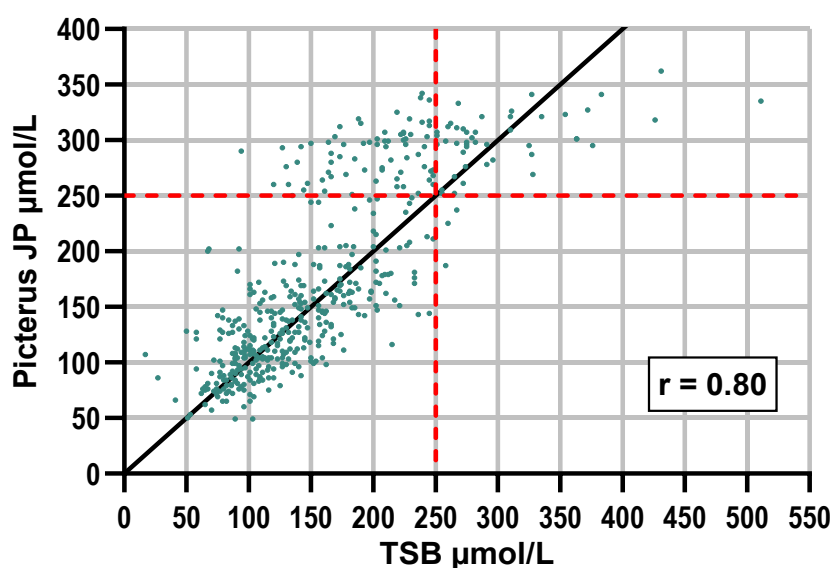


Figure 3 Pearson's correlation (r) between Picterus JP (y-axis) and TSB (x-axis) in $\mu\text{mol/L}$. The black line is the line of identity, and the red dotted lines represent the bilirubin threshold to define neonatal jaundice requiring further evaluation. Picterus JP: Picterus® Jaundice Pro; TSB: total serum bilirubin; $\mu\text{mol/L}$: micromoles per litre; r : Pearson's correlation coefficient

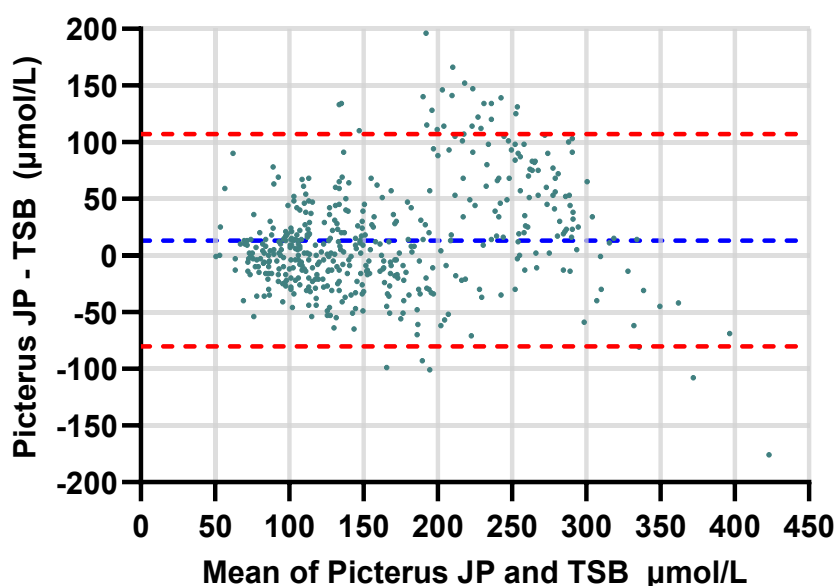


Figure 4 Bland-Altman plot of Picterus JP and TSB. X-axis shows the mean of Picterus JP and TSB; y-axis shows the differences between Picterus JP-TSB; The blue dotted line represents the mean difference between Picterus JP-TSB ($13 \mu\text{mol/L}$), the red-dotted lines represent the 95% limits of agreement. Picterus JP: Picterus Jaundice Pro; TSB: total serum bilirubin; $\mu\text{mol/L}$: micromoles per litre

10. Conclusion

The findings underscore the clinical value of Picterus JP as a reliable and accessible screening tool for neonatal jaundice. With excellent decision accuracy, high correlation to TSB levels and strong sensitivity and specificity Picterus JP effectively identifies newborns who require follow-up testing while also minimizing unnecessary blood draws. Importantly, the device did not miss any newborns who later required phototherapy, highlighting its safety in guiding early clinical decisions. Picterus JP offers a promising solution to support both healthcare providers and families in the early detection and management of neonatal jaundice, ultimately contributing to better health outcomes for newborns.

11. References

1. Olusanya BO, Kaplan M, Hansen TWR. Neonatal hyperbilirubinaemia: a global perspective. *Lancet Child Adolesc Health*. 2018;2(8):610-20.
2. Olusanya BO, Ogunlesi TA, Slusher TM. Why is kernicterus still a major cause of death and disability in low-income and middle-income countries? *Arch Dis Child*. 2014;99(12):1117-21.
3. Bhutani VK, Wong RJ, Vreman HJ, Stevenson DK. Bilirubin production and hour-specific bilirubin levels. *J Perinatol*. 2015;35(9):735-8.
4. Bhutani VK J-HL. The clinical syndrome of bilirubin-induced neurologic dysfunction. *Semin Perinatol*. 2011;2011(35):101-3.
5. Bhutani VK, Zipursky A, Blencowe H, Khanna R, Sgro M, Ebbesen F, et al. Neonatal hyperbilirubinemia and Rhesus disease of the newborn: incidence and impairment estimates for 2010 at regional and global levels. *Pediatr Res*. 2013;74 Suppl 1:86-100.
6. Okwundu CI, Olowoyeye A, Uthman OA, Smith J, Wiysonge CS, Bhutani VK, et al. Transcutaneous bilirubinometry versus total serum bilirubin measurement for newborns. *Cochrane Database of Systematic Reviews*. 2023(5).
7. Cohen RS, Wong RJ, Stevenson DK. Understanding neonatal jaundice: a perspective on causation. *Pediatr Neonatol*. 2010;51(3):143-8.
8. Engle WD, Jackson GL, Engle NG. Transcutaneous bilirubinometry. *Seminars in Perinatology*. 2014;38(7):438-51.
9. Van den Esker-Jonker B, den Boer L, Pepping RMC, Bekhof J. Transcutaneous Bilirubinometry in Jaundiced Neonates: A Randomized Controlled Trial. *Pediatrics*. 2016;138(6):e20162414.
10. Dräger. Products and Solutions 2024 [cited 2024. Available from: <https://www.draeger.com/en-us/SearchResults?s=Dr%C3%A4ger+Jaundice+Meter+JM-105>.
11. UNICEF. Supply Catalogue [cited 2024. Available from: <https://supply.unicef.org/s0002644.html>.
12. Greco C, Arnolda G, Boo N-Y, Iskander IF, Okolo AA, Rohsiswatmo R, et al. Neonatal Jaundice in Low- and Middle-Income Countries: Lessons and Future Directions from the 2015 Don Ostrow Trieste Yellow Retreat. *Neonatology*. 2016;110(3):172-80.
13. Riskin A TA, Kugelman A, Hemo M, Bader D. Is Visual Assessment of Jaundice Reliable as a Screening Tool to Detect Significant Neonatal Hyperbilirubinemia? *J Pediatr*. 2008;152(6):782-7.
14. Vartdal G. Development of a Smartphone-based diagnostic Tool for Jaundice. In: Stokke BT, Randeberg LL, Aune A, Ramstad T, editors.: NTNU; 2014.
15. Jimenez Diaz G. Validation of a new smartphone app to assess neonatal jaundice in a Mexican population. [Master thesis]. Trondheim, Norway: Norwegian University of Science and Technology; 2019.
16. Aune A, Vartdal G, Bergseng H, Randeberg LL, Darj E. Bilirubin estimates from smartphone images of newborn infants' skin correlated highly to serum bilirubin levels. *Acta Paediatrica, International Journal of Paediatrics*. 2020;109(12):2532-8.

17. Tusoy J, Odland JØ, Aune A, Jimenez-Diaz G. A mHealth application as a screening tool for neonatal jaundice in Filipino neonates [Master thesis]: Norwegian University of Science and Technology; 2022.
18. Aune A, Vartdal G, Jimenez Diaz G, Gierman LM, Bergseng H, Darj E. Iterative Development, Validation, and Certification of a Smartphone System to Assess Neonatal Jaundice: Development and Usability Study. *JMIR Pediatrics and Parenting*. 2023;6:e40463.
19. Kemper AR, Newman TB, Slaughter JL, Maisels MJ, Watchko JF, Downs SM, et al. Clinical Practice Guideline Revision: Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation. *Pediatrics*. 2022;150(3).
20. Amos RC, Jacob H, Leith W. Jaundice in newborn babies under 28 days: NICE guideline 2016 (CG98). *Archives of disease in childhood - Education & practice edition*. 2017;102(4):207-9.
21. Diagnóstico y Tratamiento de la Ictericia Neonatal. Guía de Práctica Clínica: evidencias y recomendaciones. 2019 ed. Mexico: CENETEC; 2019.
22. Maisels MJ, Ostrea EM, Jr., Touch S, Clune SE, Cepeda E, Kring E, et al. Evaluation of a new transcutaneous bilirubinometer. *Pediatrics*. 2004;113(6):1628-35.