



Instructions for Use English



Picterus® Jaundice Pro
Version 16.0



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0297

This product complies with the
relevant requirements of the
Regulation (EU) 2017/745

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1. INTRODUCTION

This document is the user guide for Picterus® Jaundice Pro, a medical device designed by Picterus AS. Picterus AS is a limited liability company incorporated under the laws of Norway. Its registered address is Kjøpmannsgata 61, 7011, Trondheim, Norway.

Picterus® Jaundice Pro assists in screening and follow up of neonatal jaundice. With its unique technology, Picterus® Jaundice Pro can calculate bilirubin concentration in the blood from images taken of a small part of the skin of a newborn's chest.

Bilirubin is a yellow colored waste product formed when red blood cells are broken down in the body. Neonatal jaundice or hyperbilirubinemia occurs when a newborn has high levels of bilirubin in the blood, which can have severe consequences if not treated appropriately. Picterus® Jaundice Pro has been clinically tested and proven to be reliable when used correctly. Picterus® Jaundice Pro is easy and fast to use. By using the Picterus® Calibration Card and installing the Picterus® Jaundice Pro app, one can screen newborns for neonatal jaundice in just minutes.



IMPORTANT INFORMATION: Pay special attention to these Instructions for Use and information in the app as they are important for the correct use of Picterus® Jaundice Pro. Failure to do so could compromise the quality of the result.

2. INTENDED USE

The Picterus® Jaundice Pro is intended to assist in screening and follow up of neonatal jaundice.

2.1 Intended Users and Environment

The medical device is intended to support authorized healthcare providers, parents and/or caregivers (lay persons) of newborns in the assessment of neonatal jaundice. The medical device is intended for use as a screening and control device together with other clinical signs and laboratory measurements. Assessments shall never be made using Picterus® Jaundice Pro and the Picterus® Calibration Card alone. In cases where the bilirubin values from the Picterus® Jaundice Pro app indicate hyperbilirubinemia, the bilirubin levels of the newborn must always be confirmed by other methods, such as serum bilirubin, before treatment is established. Picterus® Jaundice Pro and the Picterus® Calibration Card are designed for use in clinical and home settings.

2.2 Warnings and Precautions

WARNING: Do not use the device for diagnostic purposes.

WARNING: Do not at any time delay seeking medical advice, stop treatment and/or disregard medical advice due to the information contained in the Picterus® Jaundice Pro app.

WARNING: Do not use Picterus® Jaundice Pro in populations, lighting conditions, or environment not covered by the intended use and/or indications for use. Incorrect use may result in wrong estimation of bilirubin and missed detection of jaundice.

WARNING: Do not initiate a scan without verifying that the correct newborn profile is selected. Using the wrong profile may result in an incorrect bilirubin value.

WARNING: Do not interpret the result without considering its assignment to Group A or Group B.

Interpretation of the results should be conducted according to the characteristics outlined in Section 6: SAFETY AND PERFORMANCE. Please note the higher uncertainty in the performance of Group A.

WARNING: Do not use Picterus® Jaundice Pro if the newborn's skin is wet and/or has been recently treated with skin cream, oil, powder, etc. Always make sure that the newborn's skin is dry and clean.

CAUTION: Always consult and communicate the Picterus bilirubin result, including the unit, to a healthcare provider.

CAUTION: Always use Picterus® Jaundice Pro under adequate lighting conditions.

CAUTION: Always make sure that your mobile phone camera lens is clean and not obstructed by anything, for example hair, shadows, finger, or other objects. If the lens is dirty, wipe it carefully with a soft cloth.

CAUTION: Do not disable, modify, "hack" or otherwise interfere with the proper functioning of this software.

CAUTION: Do not install or use the Picterus® Jaundice Pro app on a device with non-original ('jailbroken' or 'rooted') software.

3. DEVICE ACCESSIBILITY

To use Picterus® Jaundice Pro, please ensure that:

- ✓ You have access to the Picterus® Calibration Card which needs to be used together with the smartphone application Picterus® Jaundice Pro.
- ✓ Your mobile phone is connected to the internet.
- ✓ The Picterus® Jaundice Pro app is designed for use on modern smartphones, but some models may have issues. For more information and a list of tested phone models, please visit picterus.com/devices.

4. USING PICTERUS® JAUNDICE PRO

4.1 Indications

Only use the app on newborns who:

- a. Are born with a gestational age over 37 weeks.
- b. Have a birth weight of at least 2000 grams.
- c. Are between 24 hours and 14 days old.

4.2 Contraindications

Do NOT use the app on newborns with:

- a. Jaundice appearing within the first 24 hours of life.
- b. Current or previous treatment involving phototherapy (light therapy) or prolonged exposure to sunlight because safety assessment for this patient group has not been performed. Light can alter the relationship between bilirubin levels in the blood and skin, affecting the accuracy of the result.
- c. A condition or treatment that affects skin color or appearance, excluding jaundice, such as skin diseases or extremely dry skin that appears cracked or peeled. The skin must be intact.

Additionally, do NOT use the device for monitoring newborns at high risk for rapidly rising bilirubin levels due to confirmed or suspected underlying conditions, including but not limited to:

- Hemolytic disease.
- G6PD deficiency.
- Cephalohematoma or birth trauma.
- Red blood cell disorders.

4.3 Please Note before using the Picterus® Calibration Card

1. The Picterus® Calibration Card (Figure 1) is a single patient multi-use card. Discard the card after final use according to local regulations.
2. Handle the Picterus® Calibration Card with clean hands.
3. Avoid exposure of the Picterus® Calibration Card and packaging to:
 - a. Direct sunlight.
 - b. Blood spills, water, and other fluids.
 - c. Skin lotions or greasy substances.
 - d. Mechanical stress such as folds and scratches.
4. Storage of Picterus® Calibration Card:
 - a. Keep protected when not in use. Avoid possible exposure to substances that could affect the color of the patches or damage the card as described in the section above.
 - b. Do not store above 35°C.
 - c. The card is valid for 5 years from the manufacturing date. Look for the manufacturing date symbol on the back of the card packaging.
5. Be sure to:
 - a. Use the Picterus® Calibration Card within the valid expiration date.
 - b. Use the card **as is** from the manufacturer.
 - c. Handle the card using the marked area. Do not cover the colors around the hole on the Picterus® Calibration Card when using it.

6. When using the Picterus® Calibration Card:
 - a. Make sure that the card is lying flat against the skin of the newborn's chest. Check that there are no shadows inside the Picterus® Calibration Card's hole or across the color patches.

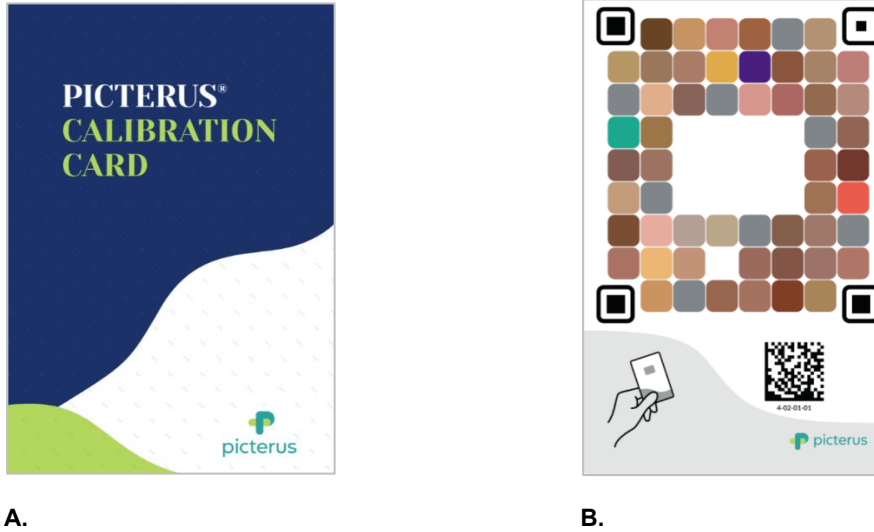


Figure 1. Illustration of the Picterus® Calibration Card*: A. Packaging. B. Picterus® Calibration Card.

*Design of the card and packaging may vary.

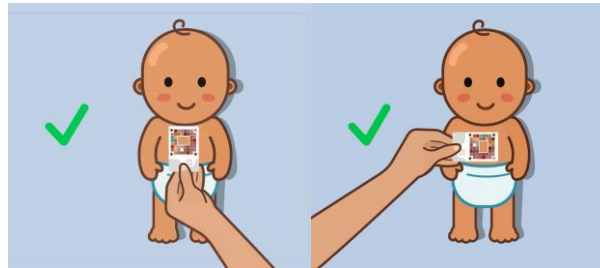
4.4 Download Picterus® Jaundice Pro App

1. Download the Picterus® Jaundice Pro app on your mobile phone. Any requests for update of the software will be shown in the display when the Picterus® Jaundice Pro app is opened. Please update your Picterus® Jaundice Pro app to continue.
2. Start using the Picterus® Jaundice Pro app (see sections 4.5 and 4.6).

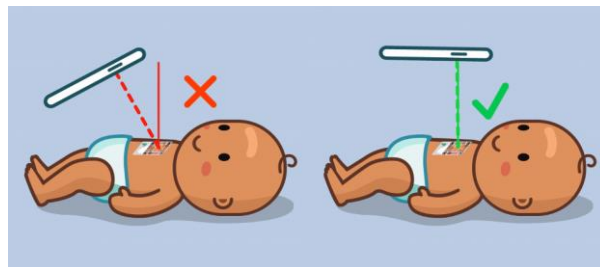
4.5 How to use

- 1) Open the Picterus® Jaundice Pro app, and go through the initial steps presented in the app.
- 2) Register a newborn profile from the home screen or from the main menu (☰), 🧒 Newborn Profiles:
 - a) Tap “+” to add a new profile.
 - b) Enter the following information:
 - i) 🧒 a profile name to later identify each profile
 - ii) 📄 birth weight in grams
 - iii) 🕒 gestational age in weeks
 - iv) 📅 date of birth
 - v) 🕒 time of birth
 - c) Tap Register to add the newborn profile.
 - d) Return to the home screen.

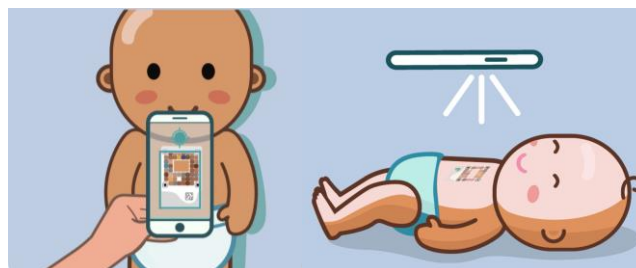
- 3) Before starting a scan, make sure that the active newborn profile is correct. To change the active newborn profile, select the correct newborn from the Newborn Profiles menu and confirm your selection, or create a new profile. The active profile name will be displayed on the home screen, during the scan, and with the result.
- 4) Pull open the Picterus® Calibration Card packaging using the notch on the side.
- 5) Remove the Picterus® Calibration Card from the packaging by carefully breaking the perforations. Be careful not to bend the card or touch the color patches.
- 6) Place the Picterus® Calibration Card on a flat section on the bare skin of the upper chest of the newborn. Make sure that the whole card is in contact with the skin. You can also place the card sideways on the newborn.



- 7) Hold the phone steady and straight above the Picterus® Calibration Card approximately 20-30 cm above the newborn.



- 8) Match the rectangle displayed on the app screen with the outer edge of the Picterus® Calibration Card. When the camera is in the correct position, the app will automatically start capturing images. The app needs six images of good quality - three without flash and three with flash. Do not move the phone until all six images have been captured.



- 9) Wait for the result. The level of bilirubin is shown in mg/dL or $\mu\text{mol/L}$, depending on which unit you have chosen in the app settings. The calculated value will be automatically assigned to group A or B (see section 6).



- 10) Consult a healthcare professional regarding the Picterus result; communicate the result together with its units (mg/dL or $\mu\text{mol/L}$) and the group (A or B). Healthcare professionals shall perform actions according to national guidelines for follow-up and treatment of neonatal jaundice.
- 11) To view, share or delete results, tap the menu icon \equiv at the top left of the home screen and tap History. Select the newborn profile you want to review. Selecting the newborn profile on the history page does not affect the active profile for performing a scan.

4.6 Picterus® Jaundice Pro App Settings

To manage settings:

1. Open the Picterus® Jaundice Pro app.
2. Tap the menu \equiv at the top-left of the Picterus® Jaundice Pro app.
3. Select Settings:
 - a. Select country of use.
 - b. Select the language.
 - c. Select if you are a healthcare professional (yes or no).
 - d. Select the bilirubin unit of the result mg/dL (milligrams per deciliter) or $\mu\text{mol/L}$ (micromole per liter).
 - e. Select the shutter sound (on or off).

5. CLINICAL BENEFIT

Picterus® Jaundice Pro has a better performance than visual assessment to identify newborns with significant jaundice who require a blood test to determine total serum bilirubin (TSB).

We recommend that Picterus® Jaundice Pro is used with respect to our clinical data and in conjunction with other clinical signs and laboratory measurements.

6. SAFETY AND PERFORMANCE

Picterus® Jaundice Pro has undergone extensive testing in multiple clinical studies. Picterus results were compared with total serum bilirubin (TSB). The time between the Picterus Scan and blood draw for TSB was within 60 minutes.

The Picterus® Jaundice Pro app automatically assigns results to group A or B, depending on the measured skin characteristics, as shown in Figure 2. Notice that screens display colors differently and the actual colors may vary slightly. The newborn's assigned group is presented along with the result. For newborns with skin characteristics close to the threshold between groups A and B, it can be expected that results are assigned to one group or another for repeated scans.

Results shown in Figure 3 are based on clinical studies including participants across the full range of skin tones. The statistics from these studies are presented in Table 1. Please note the higher uncertainty in performance of group A.

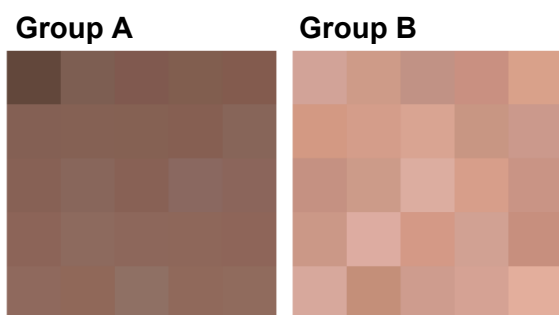


Figure 2: Examples of skin characteristics of Group A, and Group B.

Table 1: Performance Characteristics of Picterus Jaundice Pro vs TSB.

	Group A & B combined	Group A	Group B
Sensitivity (Threshold 250 $\mu\text{mol/L}$, 14.6 mg/dL)	95 %	80 %	100 %
Specificity (Threshold 250 $\mu\text{mol/L}$, 14.6 mg/dL)	84 %	71 %	85 %
Pearson's correlation coefficient (r)	0.82	0.46	0.87
Average error / bias (Picterus - TSB)	12.9 $\mu\text{mol/L}$ 0.8 mg/dL	14.0 $\mu\text{mol/L}$ 0.8 mg/dL	12.8 $\mu\text{mol/L}$ 0.8 mg/dL
Standard deviation of the error (SD)	47.8 $\mu\text{mol/L}$ 2.8 mg/dL	88.0 $\mu\text{mol/L}$ 5.2 mg/dL	41.5 $\mu\text{mol/L}$ 2.4 mg/dL
Range of Picterus® Jaundice Pro			
Clinical range (observed values)	49 – 342 $\mu\text{mol/L}$ 2.9 – 20.0 mg/dL	84 – 315 $\mu\text{mol/L}$ 4.9 – 18.4 mg/dL	49 – 342 $\mu\text{mol/L}$ 2.9 – 20.0 mg/dL
Technical range (device limits)	0 - 500 $\mu\text{mol/L}$ 0 - 29.2 mg/dL	0 - 500 $\mu\text{mol/L}$ 0 - 29.2 mg/dL	0 - 500 $\mu\text{mol/L}$ 0 - 29.2 mg/dL
Safety and accuracy of Picterus® Jaundice Pro			
Clinical Data	<p>The standard deviation shown above is based on the average of data from 3 clinical studies. The value can be affected by variables such as age, skin color, lighting conditions, and smartphone performance.</p> <p>We recommend that Picterus® Jaundice Pro is used in conjunction with other clinical signs and laboratory measurements.</p>		
Limits of agreement	<p>Limits of agreement are calculated as $(2 \times \text{SD} + \text{bias})$. This calculation results in 92.3 % of the results in Group A and 92.5 % of the results in Group B falling within the range defined by the limits of agreement. Each result will be presented to the user in the app along with its group.</p>		

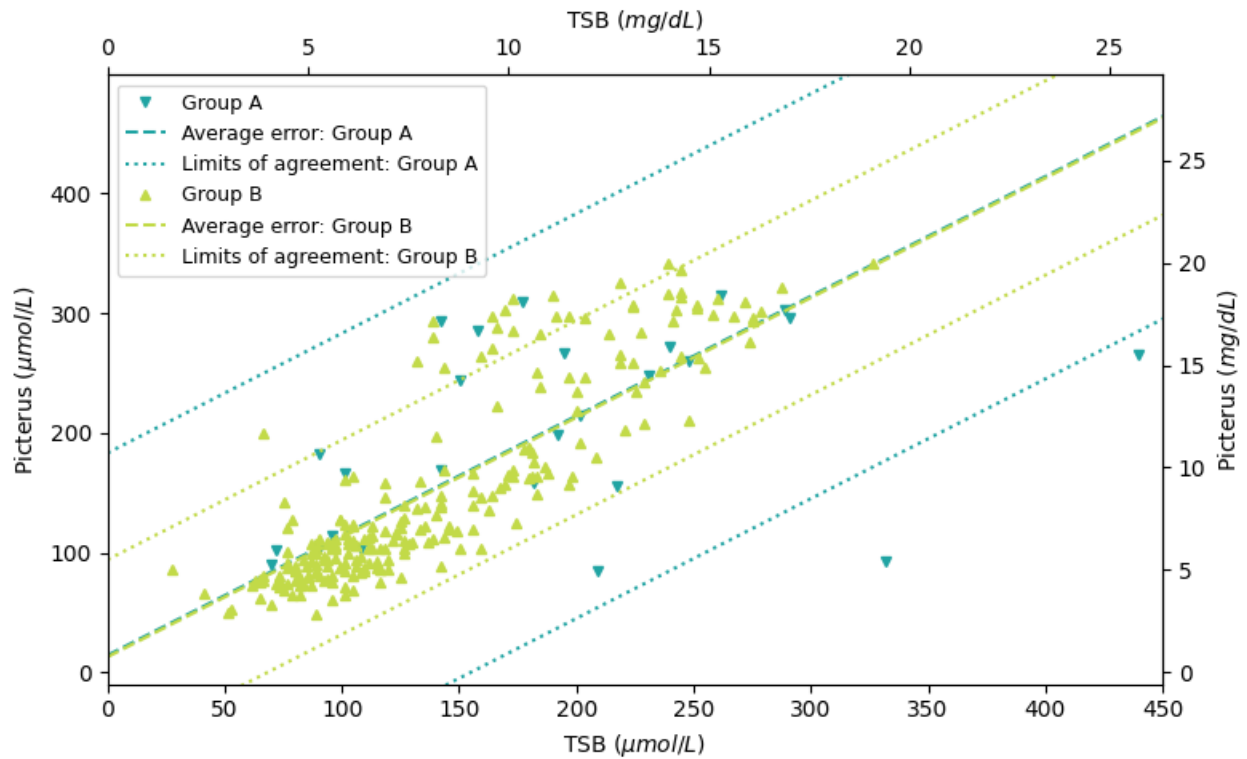


Figure 3: Correlation between Total Serum Bilirubin (TSB) on the x-axis and the bilirubin value provided by Picterus® Jaundice Pro on the y-axis (n= 266 in total). Values are demonstrated in micromol per litre ($\mu\text{mol/L}$) on the left-side and lower scale, and in milligram per deciliter (mg/dL) on the right-side and upper scale. The dashed line in the middle indicates the average error between the TSB and Picterus results. Group A results (n=26) are presented in blue (\blacktriangledown) and group B results (n=240) in green (\blacktriangle). The limits of agreement are represented as ($2 \times \text{SD} + \text{bias}$).

7. DATA COLLECTION AND PRIVACY

Picterus® Jaundice Pro handles personal data. For details on how your information is collected, used and protected please refer to our Privacy Policy.










The application does not automatically log out or close after displaying a result. If the mobile device remains unlocked and the application is running, results will stay visible. To ensure data security and prevent unauthorized access, users should: 1) log out after use, 2) lock the mobile device, 3) follow institutional security and data protection protocols where applicable.





8. SUPPORT

If you encounter problems using the Picterus® Jaundice Pro app or Picterus® Calibration Card, please read the Frequently Asked Questions on www.picterus.com. For questions regarding the app and cards, contact Picterus AS at contact@picterus.com.

9. SYMBOLS

Please, carefully read the precautions with symbols, to ensure that Picterus® Jaundice Pro and the Picterus® Calibration Card are used in the best conditions.

	<p>MANUFACTURER</p>
	<p>DATE OF MANUFACTURE Indicates the date when the medical device was manufactured.</p>
	<p>CE MARK Indicates the manufacturer's declaration that the product is in compliance with the European Medical Device Regulation 2017/745.</p>
	<p>UPPER LIMIT OF TEMPERATURE Indicates the upper limit of temperature to which the medical device can be safely exposed.</p>
	<p>KEEP DRY Indicates that medical equipment must be protected from moisture.</p>
	<p>DO NOT EXPOSE TO SUNLIGHT Picterus® Calibration Cards must not be exposed to sunlight.</p>
	<p>CAUTION</p>
	<p>BATCH CODE Indicates the manufacturer's batch code so that the batch or lot can be identified.</p>
	<p>CATALOGUE NUMBER Indicates the manufacturer's catalogue number so that the medical device can be identified.</p>

	CONSULT ELECTRONIC INSTRUCTIONS FOR USE
	INDICATING THAT THE ITEM IS A MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	SINGLE PATIENT Indicates a medical device that may be used multiple times (multiple procedures) on a single patient.

10. NOTICE

If, during the use of Picterus® Jaundice Pro, you have a reason to believe that a serious incident occurred, please report it to Picterus AS and to your national authority. The manufacturer cannot be held responsible for any problems with Picterus® Jaundice Pro if the instructions have not been followed.

Picterus® is a registered trademark owned by Picterus AS, Norway.

11. TECHNICAL INFORMATION

The CE mark on a medical device indicates that the product conforms with the provisions in the Medical Device Regulations (EU) 2017/745.



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