

Frequently Asked Questions Picterus® Jaundice Pro

The Patient

1. What is neonatal jaundice and why is it so important to measure it?

Neonatal jaundice or hyperbilirubinemia occurs when a newborn has high levels of bilirubin in the blood. Bilirubin is a yellow waste product formed when the hemoglobin of red blood cells are broken down in the body. We are all constantly renewing our red blood cells, with approximately 2.4 million red blood cells being produced every second in adults. The large amount of bilirubin resulting from this process is handled by the liver, which performs some chemical transformations to it and excretes it out of the body.

Due to the constant ongoing breakdown of red blood cells, there is always some bilirubin in our blood. This is, however, not dangerous for adults. The reason for this is both because the bilirubin levels are not very high and because the blood brain barrier is fully developed, which stops the bilirubin from entering the brain. This is however not the case for newborns. While still in the womb, fetuses have to get the oxygen from the blood of their mothers through the placenta. In order to be able to extract the oxygen from their mothers' blood, the fetuses have a special kind of hemoglobin, called fetal hemoglobin, which binds the oxygen stronger than adult hemoglobin. This hemoglobin is however not useful when the baby is born and starts breathing air. At birth, a process is therefore started where the breakdown of red blood cells is accelerated in order to change from fetal hemoglobin to adult hemoglobin. This breakdown of a large number of red blood cells in turn creates a lot of bilirubin. In addition, the liver is not fully formed for some newborns, reducing their ability to excrete the produced bilirubin. The blood brain barrier for some newborns is also not fully formed, making it possible for the bilirubin to leak into the brain and this can be very dangerous. Neonatal jaundice is a common and temporary finding in newborns. It is present in 60 to 80% of neonates, i.e., 84 to 112 million cases yearly worldwide, usually without severe consequences. Neonatal jaundice commonly manifests 48 to 72 hours after birth and resolves in 3 to 7 days. However, one in ten newborns can develop significant neonatal jaundice which requires close monitoring and eventually, treatment. Lack of detection of this condition can lead to extremely high levels of bilirubin that might cross the blood brain barrier.

The User

2. Who is allowed to use the app?

The Picterus® Jaundice Pro App is intended for use in hospitals, health stations or home visits **by authorized health personnel**. By "authorized health personnel", it means health care professionals as defined by local law, often defined as health personnel with a formalized education and authorization, including but not limited to doctors, nurses, and other health professionals with specialization within pediatric, midwifery and pediatric nursing.

3. Can parents use the app?

The Picterus® Jaundice Pro App is currently not intended for use by non-health care personnel.

4. Can I use the app on all newborns?

Picterus® Jaundice Pro **can only be used** on newborns who:

- Are born with gestational age between 37-42 weeks.
- Have a birth weight between 2500 – 4500 gr.
- Are between 1-14 days old.
- Have parents with skin color, according to Fitzpatrick, Scale 1 to 4 in Figure 1.

The six Fitzpatrick skin types and associated hair and eye color are classified from very light (1) to very dark skin (6), as shown below. The Picterus® Jaundice Pro App is only valid for skin type 1 to 4.



Figure 1 Fitzpatrick skin type scale

Picterus® Jaundice Pro App **must not be used** on newborns who:

- Have pathological jaundice.
- Are highly likely to develop pathological jaundice as a result of incompatible blood type or hemolytic jaundice.
- Have other medical conditions that require medical treatment.
- Have received phototherapy.
- Have had the chest region exposed to sunlight over the last 24 hours. Sunlight changes the relationship between the amount of bilirubin in the blood and the skin and can thus make the measurements less accurate.

5. Can I only do the measurement on the newborn's chest?

Yes, pictures must only be taken on the infant's chest as shown in the instructions for use. The skin must be clean, intact, and dry. It must not have been lubricated with skin cream, oil etc. The skin must not be affected by any skin condition or skin disease other than jaundice.

6. Do I need to do the measurement on fixed timepoints?

Measurements with Picterus® Jaundice Pro App can be taken at any point between 1-14 days of age of the newborn.

7. I don't understand the results. How do I know what to do based on the number the app gives me?

Please seek medical advice. Estimated values given from this equipment should **not** be used for diagnosis. It does not replace the need for follow-up of health personnel. Do not rely solely on the results and always consider the overall condition of the patient.

The Picterus® Jaundice Pro App

8. How can I download the App?

Download the Picterus® Jaundice Pro App from Google Play on your mobile phone. Follow the instructions as stated in Google Play.

9. Does the App work on all mobile phones?

Picterus® Jaundice Pro can currently only be used on phones validated by Picterus AS. To see which phones are validated, please visit

<https://picterus.com/picterus-jaundice-pro-validated-devices/> .

10. Do I have to be connected to the internet?

Yes, to be able to use the Picterus® Jaundice Pro, your mobile phone must be connected to the internet.

11. Do you have tips for doing the measurement?

Please follow section 4.2 of the Picterus® Jaundice Pro Instruction for Use. Moreover: - The measurements are easier to perform when the baby is calm, for example, by using the App after feeding.

- Babies often move with their arms. Ask one of the parents or somebody else to hold their hands.
- Take the photos in good light conditions and avoid shadows. This reduces the number of error messages.
- Make sure you use the sticker on the back of the Picterus Calibration Card.

12. I get a failure message while doing the measurement. How is that possible?

Failure messages are very often shown due to rejection of a measurement. This is a safety measure to avoid inaccurate measurements. Rejection of a measurement can happen due to low quality of the image e.g., too little light. If you get a failure message, try the measurement again by, for example, turning on an extra light or measuring the newborn in a different place. Moreover, shadows should be avoided when doing the measurement. Furthermore, try using some of the suggestions stated in question 11.

13. Sometimes the app crashes. How is that possible?

There can be many reasons that the app crashes and our technical team is constantly working on improvements. If the app crashes, please close the app, restart it and try the measurement again.

14. Is the flash used during taking the images harmful for the newborn? Picterus® Jaundice Pro IFU shows the right positioning of the camera which is above the sternum thus the camera flash doesn't aim directly at the eyes. Moreover, no undesirable side effect has been reported in the relevant literature nor were found in the Picterus® Jaundice Pro clinical studies related to the use of a smartphone to obtain images of newborn's skin.

15. How does Picterus AS handle the data in the App?

Picterus AS does not collect or process personal or sensitive personal information. For further details please read The Picterus Privacy Policy

<https://picterus.com/picterus-jaundice-pro-privacy-policy/>

The Picterus Calibration Card

16. Can I use the Picterus Calibration Card twice?

Picterus[®] Calibration Card is a single-use card and needs to be disposed of after use.

17. Is the sticker on the back of the Picterus Calibration Card harmful? The sticker on the back of the Picterus[®] Calibration Card is intended and approved to be used on skin.

18. How can I order new Picterus Calibration Cards?

For inquiries, please contact us via email sales@picterus.com.

19. How do I get in contact when I have further questions?

For questions, please contact Picterus AS on contact@picterus.com.