

Terms and Conditions

1. Introduction

Welcome to Picterus website and Picterus® Jaundice Pro smartphone application an online information and communication service provided by Picterus AS («Picterus» or «We» or «Us»), subject to your agreement with all these terms and conditions («Terms»). Picterus AS is a limited liability company incorporated under the law of Norway and has its registered address at Havnegata 7, 7010 Trondheim, Norway.

Postal Address is Postboks 1284 Torgarden 7462 Trondheim, Norway.

Picterus AS may modify these Terms at any time, and such modifications shall be effective immediately upon posting the modified Terms on the Picterus® Jaundice Pro and website. We will ask you to acknowledge that you have received the modified Terms prior to your usage of Picterus® Jaundice Pro.

If you do not accept these updated Terms or do not wish to be bound by changes following posted notices that you should discontinue the use of the Picterus® Jaundice Pro. If you do not agree with all the Terms, do not use the Service. Please review all the Terms and the Instructions for Use carefully before using the Picterus® Jaundice Pro. In addition to these Terms, Picterus® Jaundice Pro is also governed by our Privacy Policy.

2. Intent of Picterus® Jaundice Pro

Picterus AS provides the following Services:

- The Picterus® Jaundice Pro
- The website www.picterus.com

The Picterus® Jaundice Pro is intended to assist the healthcare professional in screening for neonatal jaundice by optical measurement of bilirubin levels from pictures of the newborn's chest, where the Picterus® Calibration Card is placed. The equipment is intended to support authorized health personnel in their assessment of neonatal jaundice, not as a standalone equipment for the diagnosis and/or control of hyperbilirubinemia. Assessments shall never be made based on the Picterus® Jaundice Pro and/or the calibration card alone. Picterus® Jaundice Pro is only to be used on phones validated by Picterus AS. To see which phones are validated, please visit <https://picterus.com/picterus-jaundice-pro-validated-devices/>.

The Picterus® Jaundice Pro 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 paediatric, midwifery and paediatric nursing.

The Picterus® Jaundice Pro can only be used together with Picterus® Calibration Card which is developed and certified by Picterus AS. The instructions for use describe how to handle the Picterus® Calibration Card.

3. Please Note before Using the Picterus® Jaundice Pro

Picterus recommends you to carefully read the Instruction for Use before you use the Picterus® Jaundice Pro.

1. The app should only be used by you personally. Don't lend the app to others. This is because you cannot be sure that the person you are lending the app to knows how to use the app safely.
2. Indications: Only use the app on newborns who:
 - a. Are born with gestational age between 37-42 weeks.
 - b. Have birth weight between 2500 – 4500 gr.
 - c. Are between 1-14 days old.
 - d. **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). The Picterus® Jaundice Pro App is **only** valid for skin type 1 to 4.
3. The equipment is not intended as a standalone device for the diagnosis of hyperbilirubinemia. It is intended for use as a screening and control device with other clinical signs and laboratory measurements.
4. Do not use the app on newborns who:
 - a. Have pathological jaundice.
 - b. Are highly likely to develop pathological jaundice because of incompatible blood type or haemolytic jaundice.
 - c. Have other medical conditions that require medical treatment.
 - d. Have received phototherapy.
 - e. 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. This equipment should only be used as intended, described in the intended use section above. The manufacturer is not responsible for events caused by improper use of the application.
6. The pictures must only be taken on the infant's chest. 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.
7. The Picterus® Jaundice Pro shall be used under adequate lighting.

4. Data collection and data privacy

Picterus AS does not process personal or sensitive personal data. Picterus® Jaundice Pro only takes images of a small part of the skin on the chest of the newborn and requires no personally identifiable data. For further information on how we collect your data, we refer to our Privacy Policy.

5. Health Follow Up Policy

At Picterus we are constantly improving our services by performing research activities. As part of research activities; we may perform checks on the photos to verify the accuracy of Picterus® Jaundice Pro. Important information will be communicated through updates in the app.

6. No Warranties

You understand and agree that the services of Picterus® Jaundice Pro and the content or information contained on or provided by Picterus® Jaundice Pro is provided on an “as is” basis. Picterus AS does not make any express or implied warranties, representations, or endorsements whatsoever (including without limitation warranties of title or non-infringement, or the implied warranties of merchantability or fitness for a particular purpose) regarding the service or any merchandise, information or service provided through the service. In addition, Picterus AS does not guarantee that use of Picterus® Jaundice Pro will be free from technological difficulties including, but not limited to, unavailability of information, downtime, service disruptions, viruses or worms and you understand that you are responsible for implementing sufficient procedures and checkpoints to satisfy your requirements for accuracy of data input and output.

7. Discontinuance of Picterus® Jaundice Pro

Picterus AS reserves the right to modify, discontinue, temporarily or permanently, the services, or any part thereof, at any time, with or without notice. When appropriate, Picterus AS will give you a proportional refund.

8. Disclaimer, Limitations, and Exclusions of Liability

- The Picterus® Jaundice Pro is a medical device that has been tested according to international standards. With its unique technology, Picterus® Jaundice Pro can measure bilirubin concentration in the blood from images taken of a small part of the skin of a newborn's chest. The Picterus® Jaundice Pro is intended for use only by authorized health professionals. The Picterus® Jaundice Pro has been clinically tested and proven to be accurate when used correctly. The Picterus® Jaundice Pro is easy and fast to use. By using phones validated by Picterus AS, the Picterus® calibration card and the installed Picterus® Jaundice Pro app, one can measure bilirubin concentrations in newborns in just minutes.
- The Picterus® Jaundice Pro can measure bilirubin concentration in the blood from images taken of a small part of the skin of a newborn's chest, where the Picterus Calibration Card is placed. The equipment is intended to support authorized health personnel in their assessment of neonatal jaundice, not as a standalone equipment for the diagnosis and/or control of hyperbilirubinemia. Assessments shall never be made based on the Picterus® Jaundice Pro and/or the calibration card alone. The Picterus® Jaundice Pro Software nor the Picterus® calibration card shall not be used nor relied on solely for any diagnostic or treatment purposes and do not for instance, but not limited to, replace blood samples. Any reliance by you is at your own discretion and risk.
- Picterus AS makes no representation or warranties relating to the information contained in the online and in-app library. We do not warrant that the medical information on the Picterus® Jaundice Pro will be available, complete, completely accurate, up to date.
- Notwithstanding the foregoing, Picterus AS reserves the right, but is not obligated, to refuse to post any content and/or remove your access to Picterus® Jaundice Pro.

- We have no responsibility or liability for any kind of action that you do or do not take because of or despite the information on the Picterus® Jaundice Pro. If you are experiencing a medical emergency or have any concern about the newborn condition in any way you should seek immediate medical attention. You should not delay seeking medical advice, stop treatment, or disregard medical advice because of the information contained in the Picterus® Jaundice Pro.
- Picterus AS does not guarantee correct functioning of Picterus® Jaundice Pro if you use Picterus® Jaundice Pro while you are subject to a contra-indication for the use.
- Our liability in connection with Picterus® Jaundice Pro shall be limited to direct damages or (in case of insurance coverage) the amount paid under our insurance policy, unless it concerns liability:
 - for death or personal injury resulting from gross negligence.
 - for damage resulting from fraud or fraudulent misrepresentation.
 - which based on the applicable law cannot be limited.
- To the extent that our website and the information on our website are provided free of charge, we will not be liable for any loss or damage of any nature.
- We will not be liable to you in respect of any losses arising out of any event or events beyond our reasonable control.
- Picterus® Jaundice Pro for personal use only. Therefore, we will not be liable to you in respect of any business losses, including (without limitation) loss of or damage to profits, income, revenue, use, production, anticipated savings, business contracts, commercial opportunities, or goodwill.
- You agree that you will not bring any claim personally against our officers or employees in respect of any losses you suffer in connection with the website or these Terms (this will not, of course, limit or exclude the liability of the limited liability entity itself for the acts and omissions of our officers and employees).
- We shall not be liable for any content you publish on social media by using a social media plugin on our website.

9. Copyright and Trademark Information

The mark "Picterus" and the «P» logo are trademarks and/or service marks of Picterus. The content and design of Picterus® Jaundice Pro are protected by international copyright laws. You may not copy, reproduce, republish, upload, post, display, transmit, or frame any of these materials without prior written consent from the copyright owners, except that you may view, download, display and print a single copy of these materials on a single computer for personal, non-commercial use only, so long as: you do not alter or modify the materials in any way; you include all applicable notices and disclaimers (including copyright notices); and you do not use the materials in a way that suggests an association with Picterus AS or an affiliated Picterus AS entity. You understand and agree that title to these materials shall not pass to you or any other user.

10. Consumer rules

Depending on your country, consumer protection rules may apply. We recommend you take note of these.

11. Payment Terms and Conditions

The prices will be specified in the applicable order confirmation via email. Invoice payment deadline is according to the order confirmation. Payment shall be made to the bank account nominated in writing by Picterus AS. If you believe that there has been an error in billing or you are entitled to a refund, please contact us at sales@picterus.com.

12. Picterus Sales Support

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

The contract between Picterus AS and the customer shall be deemed to have been made in Norway and shall be governed in all aspects to Norwegian law. The customer shall submit to the jurisdiction of the Norwegian court.