



Instructions for Use English



Picterus® Jaundice Pro
Version 5.0



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

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IMPORTANT: 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/> .

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 and has its registered address at Havnegata 7, 7010 Trondheim, Norway. Postal Address is Postboks 1284 Torgarden 7462 Trondheim, Norway.

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.



IMPORTANT INFORMATION: Pay special attention to these Instructions for Use as they are important for the correct use of the Picterus® Jaundice Pro. If you do not follow the instruction carefully, you may not get the right bilirubin measurement.

2. INTENDED USE

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.

2.1 Intended Users and Environment

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 pediatric, midwifery and pediatric nursing.

2.2 Warnings

1. 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.
2. The equipment is intended for use as a screening and control device together with other clinical signs and laboratory measurements. In cases where the bilirubin estimates in the

Picterus® Jaundice Pro app indicates hyperbilirubinemia, the specific bilirubin levels of the newborn must always be confirmed by other methods, such as serum bilirubin, before treatment is established.

3. You should 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.
4. Do not install or use the Picterus® Jaundice Pro app on a device with non-original ('jailbroken' or 'rooted') software.
5. Do not disable, modify, "hack" or otherwise interfere with the proper functioning of this software.

3. DEVICE ACCESSIBILITY

To use the Picterus® Jaundice Pro, please ensure that:

- ✓ Your mobile phone is connected to the internet.
- ✓ Your mobile phone camera lens is clean and not obstructed by anything, for example hair, shadows, finger, other objects. Wipe the lens carefully with a soft cloth if it is dirty.

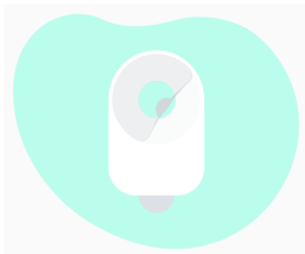
4. USING PICTERUS® JAUNDICE PRO

4.1 Picterus® Jaundice Pro App and Download

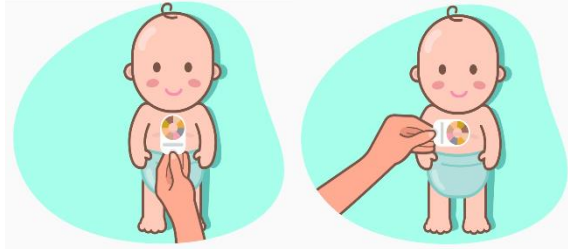
1. Download the Picterus® Jaundice Pro App from Google Play on your mobile phone. Any request for update of the software will be shown in the display when the Picterus® Jaundice Pro App is opened. Please update your application to continue.
2. Read the Terms and Conditions, and if you confirm that you have read and understood the Terms, tap the "agree" button.
3. Take out the Picterus® Calibration Card from the packaging.
4. Open the Picterus® Jaundice Pro App and read the Instructions for Use.
5. Start using the Picterus® Jaundice Pro App (see section 4.2).

4.2 Quick Guide for Measurement

1. Open Picterus® Jaundice Pro App.
2. Perform initial instructions (if the app is used for the first time).
3. Remove the protection from the sticker on the back side of the card.



4. Place the Picterus® calibration card on the chest over the sternum of the newborn. Make sure the sticker holds the card in place. You can place the card sideways on the child.



5. Hold the phone steady and straight above the calibration card approximately 20-30 cm above the newborn.



6. Match the circle displayed on the phone with the outer circle of the calibration card. When the camera is correctly placed, the app will automatically start capturing images. The app needs six images of good quality - three without flash and three with flash. If an image is not of good enough quality, the app will automatically recapture that image. Do not remove the phone until it is indicated on the screen that all 6 images have been captured. Wait for the result.




7. The estimated level of bilirubin in the blood is expressed in the legal units' mg/dL or $\mu\text{mol/L}$.



8. Based on the bilirubin measurement, perform actions according to national guidelines for follow-up and treatment of neonatal jaundice.

4.3 Estimate History and Settings

To see the estimates history and manage settings:

1. Tap the menu  at the top-left of the Picterus[®] Jaundice Pro App
2. Select Estimate History: The Estimate History section displays a measurement log, sorted by date, with the most recent measurement at the top.
3. Select Settings:
 - a. Select the Language.
 - b. Select the bilirubin unit of measurement (mg/dL or $\mu\text{mol/L}$).
 - c. Select the Shutter Sound (on or off).
 - d. Select the display mode (system default, on or off).

4.4 Please Note before Using the Picterus[®] Jaundice Pro App

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), as shown below. The Picterus[®] Jaundice Pro App is **only** valid for skin type 1 to 4.

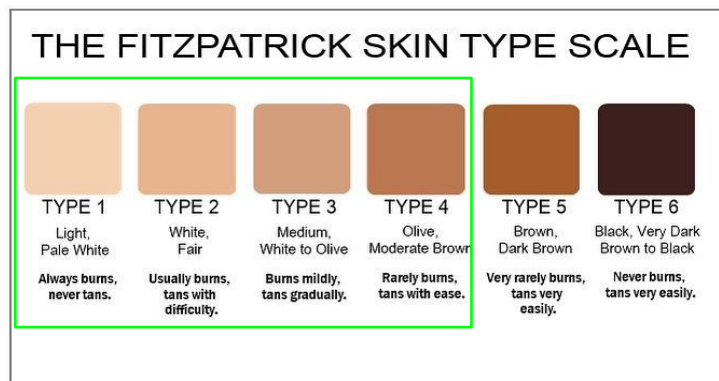


Figure 1 Fitzpatrick skin type scale

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 as a result of incompatible blood type or hemolytic 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 as shown above. 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.

4.5 Please Note before using the Picterus® Calibration Card

1. Picterus® Calibration Card is a single-use card and needs to be disposed of after use.
2. Protect calibration cards and card packaging from:
 - a. Direct sunlight.
 - b. Blood spills, water, and other fluids.
 - c. Mechanical stress such as folds and scratches.
3. Storage of Calibration Cards:
 - a. Keep calibration cards in the appropriate packaging and make sure the card is not scratched or has any spots.
 - b. The card is valid for 12 months after production date.

4. Be sure to:
 - a. Use the card **as is** from the manufacturer.
 - b. Do not cover the colors around the circle on the calibration board when using it.
 - c. When using the calibration card, make sure there is no shadow inside the hole. To avoid this, make sure that the card is firmly attached to the newborn skin by the back sticker.



Figure 2 Picterus® Calibration Card



CAUTION: 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.









5. PROBLEM SOLVING





For questions regarding the app and cards, contact Picterus AS on contact@picterus.com. If you encounter problems using the Picterus® Jaundice Pro app and Picterus® calibration card, follow the instructions in the troubleshooting guide below or contact us at contact@picterus.com.

Problem	Solution
Picterus® Calibration card is broken. For example, have stains or are scratched.	Contact Picterus AS to order a new card.
Picterus® Calibration cards have expired.	Contact Picterus AS to order a new card.
Camera has poor quality.	Use a mobile phone with better camera quality.
Lighting conditions are too poor.	Pictures must be taken in one well-lit room but does not require daylight.

6. SYMBOLS

Please, carefully read the precautions with symbols, to ensure that the software and calibration card are used in best conditions.

	MANUFACTURER
	USE BEFORE Indicates the date when the medical device will not be used after.
 0297	CE MARK Indicates the manufacturer's declaration that the product is in compliance with the Medical Device Regulation 745/2017.
	KEEP DRY Indicates that medical equipment must be protected from moisture.
	DISPOSE IN GARBAGE CONTAINER
	DO NOT EXPOSE TO SUNLIGHT Calibration cards must not be exposed to sunlight.
	CAUTION
	BATCH CODE Indicates the manufacturer's batch code so that the batch or lot can be identified.

	CONSULT INSTRUCTION FOR USE
	INDICATING THAT THE ITEM IS A MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	SINGLE USE SYMBOL Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

7. ERROR MESSAGES

ERROR MESSAGE DISPLAYED IN THE APP
The Picterus® Jaundice Pro Server encountered an error. Please try again.
It seems you are not imaging newborn skin where the newborn's parents have Fitzpatrick skin types 1 to 4.
Your Picterus® Calibration Card has expired. Please try again with a new Picterus® Calibration Card.
Color calibration could not be performed correctly. Please ensure you have a clean and undamaged Picterus® Calibration Card, avoid shadows across the card, or increase the light intensity, then try again.
The barcode could not be found in the images. Please make sure your Picterus® Calibration Card is clean and undamaged and no obstacles are covering the barcode.
Please download an updated version of the application.

8. NOTICE

For customers in the European Union: if, in the course of 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 the Picterus® Jaundice Pro if the instructions have not been followed.

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

9. 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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