BAYOOCARE

LEGAL MANUFACTURER

BiliPredics

Operating Instructions EN

The following operating instructions refer to software version:

V1.4.x

CE 0123

Version: 2025-10-02 Index 03

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1. SYMBOLS AND ABBREVIATIONS

1.1. Symbols for labeling

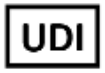
Symbol	Meaning
	Manufacturer
	Distributor
	Indicates the date on which the medical device was manufactured (software version date of publication)
	Medical device
	Product name
	Software version
	CE conformity marking and identification number of the notified body involved in the conformity assessment procedure
	Please refer to the electronic instructions for use (PDF). Download: bayoocare.com
	Information / Informal note
	Action prompt, work step
	One-time product identification

Table 1: Symbols for labeling

1.2. Symbols used in the software

Symbol	Meaning
	Optical measurement / non-invasive / transcutaneous bilirubin value / TcB
	Total serum bilirubin / TSB
	Marker for TcB (if no chart options are enabled)
	Marker for TSB (if no chart options are enabled)
	Measurement value outside of valid range (if no chart options are enabled)
	Marker for TcB (with chart options enabled)
	Marker for TSB (with chart options enabled)
	Measurement value outside of valid range (with chart options enabled)
	Generate PDF document
	Add
	Confirm
	Cancel
	Add
	Calendar

Symbol	Meaning
	Edit
	Delete
	Start phototherapy
	Discontinue phototherapy
	Mandatory condition not met
	Information / Informal note
	Warning

Table 2: Symbols used in the software

2. DEFINITIONS OF TERMS AND ABBREVIATIONS USED

2.1. Definitions of terms

This section defines basic terms that will be used below.

Term	Explanation
Bilirubin measurement	Includes: • Time of measurement • Bilirubin value • Unit of measurement • Type of measurement
Bilirubin progression	Dynamic progression of bilirubin values over a specified period of time
Patient / Newborn	Equivalent terms used in the document. For better readability, the generic masculine form is used, but it refers to both female and male patients.

Table 3: Definition of terms

2.2. Abbreviations used

Abbreviation	Explanation
TcB	Transcutaneous bilirubin value
TSB	Total serum bilirubin
AAP 2022 Guidelines	American Academy of Pediatrics (2022) “Clinical Practice Guideline Revision: Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation”
NICE Guideline	National Institute for Health and Care Excellence (2023). “Jaundice in newborn babies under 28 days”. Clinical guideline.

Table 4: Abbreviations used

3. INTENDED USE

BiliPredics is software to predict bilirubin progression in newborns.

BiliPredics can predict bilirubin progression in the first week of life up to 60 hours after the last measurement. Bilirubin (in µmol/l or mg/dl) is represented as a graph in a diagram depending on postnatal age (in hours).

3.1. Indication

BiliPredics supports the indication "Screening and/or Prevention of Hyperbilirubinemia" in newborns with a gestational age of ≥ 34 weeks.

3.2. Contraindication

The following general risk factors are contraindicated:

- Phototherapy before the first bilirubin measurement
- Neonatal cholestasis (congenital or acquired liver dysfunction of various causes during the neonatal period)
- Hydrops fetalis (congenital severe anemia due to Rh or blood group incompatibility, infections, or cardiovascular malformations)
- Neonatal sepsis
- Severe asphyxia (Apgar1 Score < 4)
- Hypoxic ischemic encephalopathy
- Malformations of the digestive tract and/or the liver
- Systemic antibiotic treatment
- Congenital metabolic diseases

3.3. User

BiliPredics is intended for use exclusively by medical professionals (users).

4. SAFETY INFORMATION

4.1.Safety notice classification

The safety instructions and important usage instructions in this document are classified based on risk.

▶ Familiarize yourself with the meanings of the classifications before using the software.

NOTE!

Indicates a potentially harmful situation.

If it is not avoided, it can lead to loss or compromise of data.

4.2. Safe use

To use BiliPredics safely, follow the notes below:

▶ Read these operating instructions and keep them for future reference.

	The operating instructions are also permanently integrated into BiliPredics and can be accessed at any time.
	If you need a hard-copy printed version of the user manual, please contact BAYOOCARE GmbH using the help function in the tool or using the contact information (see Section 13). We will send you a copy as soon as possible.

▶ Use BiliPredics exclusively in accordance with its intended use (see Section 3).

▶ The user is responsible for the proper entry of data and values.

▶ Perform the function test according to Section 10 to check the proper operation of the BiliPredics software.

4.3. Predictable misuse

NOTE!

Use of the results for therapy decision-making

- Do **not** use the BiliPredics results for making treatment decisions.

4.4. General warnings

4.4.1. Incidents

- Report any events to the relevant authority **and** to BAYOOCARE GmbH in accordance with the regulations applicable in your country.
- Use the form in the software help function to send a report to BAYOOCARE GmbH.

4.4.2. Malfunctions

- Report any malfunctions to BAYOOCARE GmbH.
- Use the form in the software's help function.

5. SPECIFICATIONS AND OPERATION

5.1. Minimum technical requirements



BiliPredics can be used with a desktop PC or a tablet (Standard Mode & Lite Mode) as well as on a mobile device (Lite Mode only). Please note the different controls for desktop or mobile use in the instructions for use.

To use BiliPredics, you will need a device with the following characteristics:

- PC with input devices or tablet PC
- Internet connection (DSL with 1 Mbit/s or better)
- Up-to-date browser (Google Chrome, Microsoft Edge, Mozilla Firefox), not more than 6 months old
- Processor: 1 GHz or higher
- RAM: 1 GB or more
- Monitor resolution depends on scaling: at least 1376 x 786 pixels or higher

For mobile use of BiliPredics (available only in Lite and On-Demand Mode), you will need a device with the following characteristics:

- Screen size: at least 4.7″
- Screen resolution: at least 1080 x 1920 pixels at a DPR of 3 (viewport size 360 x 640 pixels)
- Internet connection (1 Mbit/s or better)
- Up-to-date browser (Google Chrome, Microsoft Edge, Mozilla Firefox, Safari), not more than 6 months old
- Operating system: iOS 15 or higher, Android 9 or higher
- Processor: 2 GHz or higher
- RAM: 2 GB or more
-

5.2. Minimum medical requirements

To enable prediction of bilirubin progression, the following medical parameters for the patient have to be input into BiliPredics:

Data required	Acceptance criteria for the specified values
Time of bilirubin measurement(s)	1 to 120 hours after birth
Gestational age in weeks and days	34+0 to 42+6
Weight at birth	1500 to 5000 g
For a gestational age ≤ 36+6	at least 1500 g
For a gestational age ≥ 37+0	at least 2500 g
Delivery mode	Vaginal or cesarean
Measured TSB or TcB values	One or more measured value(s)
Data in mg/dl	1 – 18
Data in µmol/l	17.1 – 307.8

Table 5: Minimum requirements and acceptance criteria for data to predict bilirubin progression

Limits for prediction
No prediction is made if the specified values are outside the stated acceptance criteria.
Please also consider the bilirubin limits based on postnatal age as outlined in Section 7.3.1.

5.3. Computer model used to predict bilirubin progression

The algorithm used in BiliPredics is based on a mathematical computer model that predicts the progression of bilirubin as a function of postnatal age. This model consists of a differential equation with medically and physiologically motivated components that reflect the production and elimination of bilirubin in the body.

In healthy individuals, the production and elimination of bilirubin are in balance, resulting in constant bilirubin values. In premature or full-term infants, production may be increased and elimination may be reduced in the first few days of life. This leads to increased bilirubin values in the first few days of life. After reaching the peak of bilirubin progression, production and elimination gradually return to a healthy balance. This leads to a subsequent decrease until bilirubin is normalized.

The bilirubin progression for this newborn is predicted based on one or more bilirubin measurements, as well as individual medical parameters of the newborn such as gestational age, birth weight, and delivery mode. In the algorithm, the mathematical model is first calibrated using a statistical method (Bayesian estimation) based on the individual values input. As a result, each newborn requires individual adjustment.

Details about the mathematical computer model can be found in the Patent “EP 3688473 B1” or “US 11,656,234 B2”.

6. USING BILIPREDICS

NOTE!

Data compromise

Access to the system by unauthorized persons can lead to data loss or manipulated patient data and system settings!

- If you have received access data, change the initial password to a personal password after logging in for the first time.
- Make sure that your personal password is known only to you. Change your password immediately if it could have become known to another person.
- Use a sufficiently complex password that cannot be easily guessed.
- Enter your personal password manually each time you log in, without saving it in the browser.
- Log out from BiliPredics when you are not using BiliPredics any longer.

6.1. BiliPredics operating modes

BiliPredics offers two main operating modes, the Standard Mode and the Lite Mode. Data entry in Standard Mode is done step by step and requires entering the exact time of birth and the exact times of the measurements. Lite Mode, on the other hand, allows for simultaneous entry of multiple measurements and requires only the postnatal age at the time of the measurement (see Table 6).

ℹ	Please note the respective limitations and differences between the modes when deciding which BiliPredics mode to use!
ℹ	Switching between modes after installation is not possible and will require complete reinstallation.

The differences between Standard Mode and Lite Mode are as follows:

- Different data fields and entry options (see Table 6)
- Additional verification step before saving data (Standard Mode only)
- Different additional options:
    - Connection to the hospital information system (Standard Mode only)
    - Use on mobile devices (Lite Mode only)
    - On-Demand Mode (only available as a variant of Lite Mode)

On-Demand Mode: If permanent storage of patient data and measurements is not required, you can select On-Demand Mode as a variant of Lite Mode. The patient data that has been

entered cannot be retrieved later. If you want to perform a new analysis for the patient, you will have to completely re-enter the data.

> Which mode was selected during installation can be found under the “Info” menu item in the software footer bar.

Information	Standard Mode	Lite Mode	
		Lite Mode	On-Demand Mode
Patient name			
Patient ID			
Date of birth			
Time of birth			
Weight at birth			
Delivery mode			
Gestational age			
Risk factors			
Bilirubin measurements			
	only entry of respective individual measurements	option to enter set of measurements	option to enter set of measurements
	date and time	postnatal age at time of measurement	postnatal age at time of measurement
Application environment	desktop	desktop & mobile	desktop & mobile

Table 6: Difference between BiliPredics operating modes.
Legend: saved in patient file; not retrievable; retrievable.

6.2. Controlling BiliPredics

When using BiliPredics, there are differences in individual control elements between use on a desktop or use on mobile devices.

Please note the **different control elements** when you use BiliPredics on a **mobile device**.

They are marked in these instructions for use with the symbol .

6.3. Logging in to BiliPredics without a connection to the hospital information system

▶ Log in with your personal data to use BiliPredics.

The necessary information in the login dialog are:

- Client name of your facility
- Your personal username
- Your personal password

You will be provided with the initial login data.

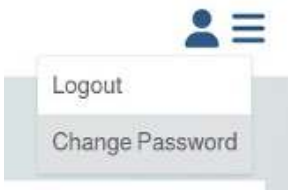
6.3.1. Changing the password

▶ Log in to BiliPredics with your personal data when you want to change the password.

▶ Select the “Change Password” function using the arrow symbol next to your username.



Figure 1: Accessing the password manager in desktop view



► Click on “ ” at the top edge of the screen to open the selection.

► Click on “Change password”.

▶ Enter your current password.

▶ Enter a new password that meets the specified minimum requirements.

▶ Re-enter your new password for security purposes.

6.3.2. Password recovery

If you forget your personal password, you can assign a new password.

- Open the login dialog

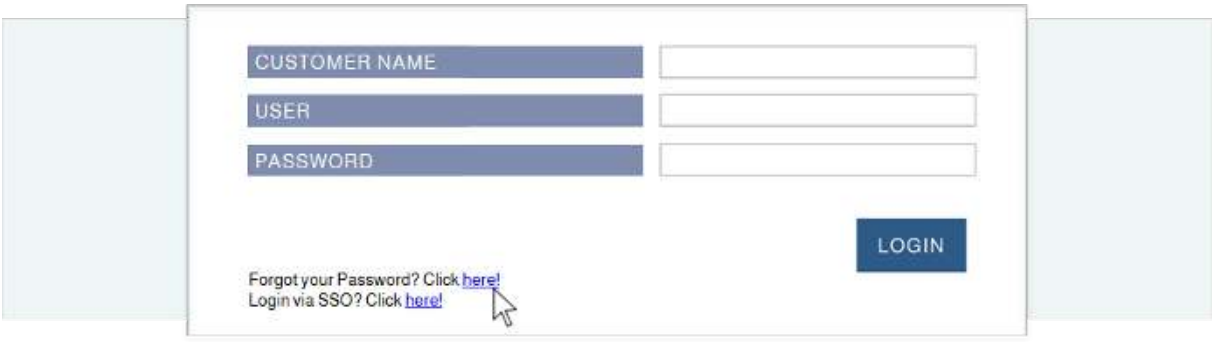


Figure 2: Login dialog

- Click on the link “here”.
- Enter your customer name.
- Enter your username.
- Submit the request.

An email will be sent to the email address associated with the user.

- Check the inbox of the associated email account.
- Follow the instructions in the email to reset your password.

6.4. Logging in to BiliPredics with a connection to the hospital information system

If BiliPredics is connected to your hospital information system and authentication is activated through your hospital information system:

- Input the client name of your facility in BiliPredics

You will be redirected to your authentication provider. After successful authentication, you will be returned to BiliPredics.

6.5. Logging out from BiliPredics

To log out from BiliPredics:

▶ Select the “Logout” function using the arrow symbol next to your username



Figure 3: User logout in desktop view



► Click on “ ” at the top edge of the screen to open the selection.
► Click on “Logout” to log out from BiliPredics.

7. DATA ENTRY IN STANDARD MODE

See Section 8 for how to enter data in Lite Mode.

7.1. Viewing patient data

After logging in, you will find yourself in the patient overview, also known as the dashboard.

The patient overview shows the patients of your facility stored in BiliPredics. By default, patients who were born within the last 30 days will be shown. You can set this value during installation or afterwards. Please contact our customer support for assistance with this.

The patient overview can be accessed at any time by clicking on “DASHBOARD” at the top of the screen.



Figure 4: DASHBOARD button in the patient information (Standard Mode)

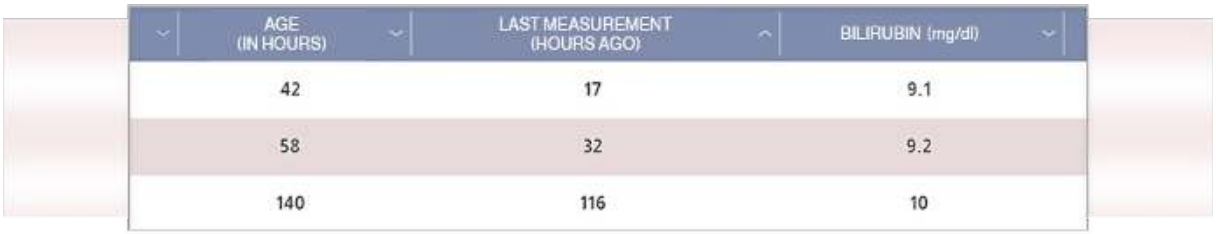
The following information is shown for each patient:

- Patient ID
- Patient name
- Date and time of birth
- Current age (in hours)
- Hours elapsed since the last bilirubin measurement
- Bilirubin value at last measurement

By default, the patient overview is sorted by the time of birth, with the youngest patients shown first.

7.1.1. Adjusting the sorting order in patient overview

- By clicking on the arrow symbol, select the column according to which you want to sort the entries.
- Click on the arrow symbol in the column again to reverse the sorting order.



AGE (IN HOURS)	LAST MEASUREMENT (HOURS AGO)	BILIRUBIN (mg/dl)
42	17	9.1
58	32	9.2
140	116	10

Figure 5: Excerpt from the patient overview table (Standard Mode)

7.1.2. Finding patients

Patients are searched based on the patient ID or the patient's name.

- Enter the patient ID, name, or parts of it into the respective search field of the patient overview (see Figure 6).

After each input, only the patients that match this input data will be shown.

To show all patients again, reset all the filters.

- Select “RESET FILTER” to delete all entered filter criteria.

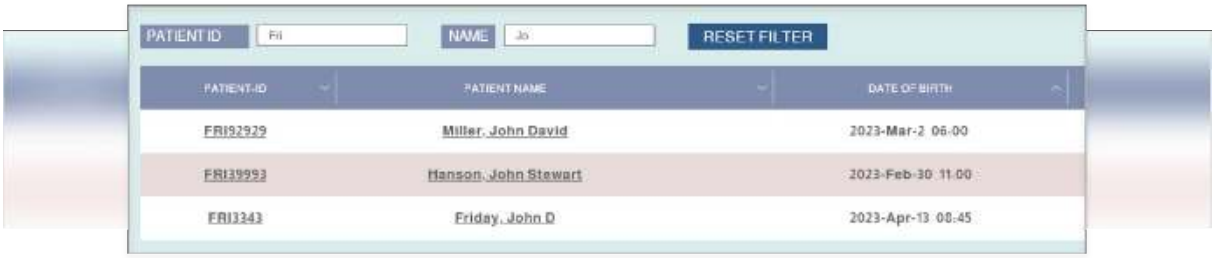


Figure 6: Patient filter function in the dashboard (Standard Mode)

7.1.3. View patient information

Accessing the detailed information of an individual patient:

▶ Click on the respective patient ID or the patient's name.

The patient information page is divided into 3 sections:

- Patient data
- Measurement data
- Diagram area with various options

On the patient information page, you have the following options:

- Adjust patient data (*) [see Section 7.2.4]
- Delete patient data completely from the system [see Section 7.2.5]
- Add, adjust, or delete bilirubin value(s) (*) [see Section 7.3]
- Show bilirubin rate of increase [see Section 9.3]
- Show prediction of bilirubin progression [see Section 9.3]
- Show nomograms per Bhutani and NICE guidelines [see Section 9.4]
- Show phototherapy thresholds [see Section 9.4]
- Show zones of discharge recommendations [see Section 9.4]
- Record start and end of phototherapy [see Section 9.6]
- Generate report [see Section 9.7]

For detailed information, please refer to the referenced sections.

(*) Bilirubin values and patient data can be changed only if there is no connection to the hospital information system.

7.2. Entering and editing patient data

7.2.1. Adding new patients

To add new patients:

▶ Select the “ADD NEW PATIENT” button in the patient overview (dashboard).



Figure 7: “ADD NEW PATIENT” button on the dashboard (Standard Mode)

The input mask for patient data appears.

7.2.2. Entering patient data without a connection to the hospital information system

The following information is needed to enable a prediction for bilirubin progression:

- Patient ID
- Date and time of birth
- Gestational age on day of birth
- Weight at birth
- Delivery mode (vaginal or cesarean)
- Presence of risk factors (per the AAP 2022 Guidelines)

▶ Enter the **Patient ID** in the input mask that appears.

> See APPENDIX II “Assigning Patient IDs” for the rules for entering the Patient ID.

▶ Enter the **date of birth** using one of these options:

- Choose the date directly from the past days, OR
- Enter the date in the format “YYYY-MM-DD” OR
- Select the date using the calendar tool

▶ Enter the **time of birth** in 24-hour format “hh:mm”.

▶ Select the **gestational age** in weeks and days.

▶ Enter the **weight at birth** in grams.

▶ Select whether **hyperbilirubinemia neurotoxicity risk factors** are present.

Select "Yes" if at least one of the following risk factors for hyperbilirubinemia neurotoxicity according to the AAP 2022 guidelines are present:

- Albumin < 3.0 g/dL
- Isoimmune hemolytic diseases (including positive direct antiglobulin test), G6PD deficiency, or other hemolytic diseases
- Sepsis
- Significant clinical instability in the past 24 h

Select "No" if none of the risk factors listed are present.

> Selecting "No" leads to higher threshold values under the AAP 22 thresholds and the AAP 22 zones for discharge recommendations. That means, for example, that phototherapy is recommended only at a higher bilirubin value.

Select "Unknown" if you cannot clinically assess whether there are risk factors for hyperbilirubinemia neurotoxicity.

> When "Unknown" is selected, the AAP 22 thresholds, the AAP 22 zones for discharge recommendations, and the discharge recommendations are not available. Select "Yes" or "No" instead if you want to use these functions.

▶ Enter the patient name in the **name fields** (last name, first name, and middle name). You have the option to enter up to 40 characters for each. Numbers are not allowed.

> You can identify missing or invalid information by a red border.

▶ Click “CONFIRM” after entering all known information.

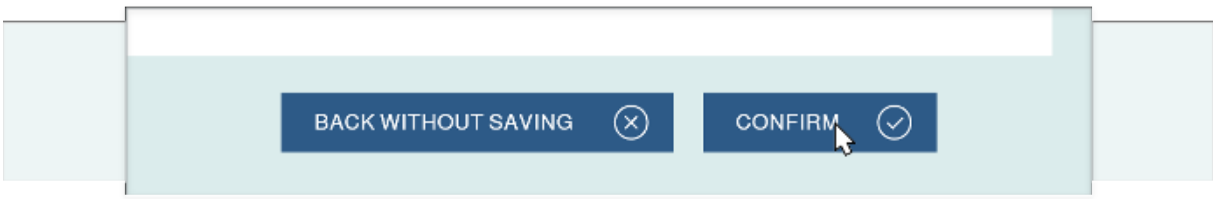


Figure 8: Confirm the patient data entry (Standard Mode)

▶ Check the information shown for accuracy

▶ Confirm the entries by clicking “SAVE”

> You can make changes by clicking “BACK WITHOUT SAVING” and going back to the input screen.

7.2.3. Entering patient data with a connection to the hospital information system

If BiliPredics is connected with your hospital information system, you can import patient data. These patient data will be updated with every access through the hospital information system.

To import data on a patient:

▶ Enter the “Medical Record Number (MRN)”

▶ Select “Load patient”

The patient data fields are automatically filled with the data from the hospital information system.

▶ Click “CONFIRM” (see Figure Figure 8)

▶ Check the information shown for accuracy

▶ Confirm the entries with “Save”

> You can make changes by clicking “BACK WITHOUT SAVING” and going back to the input screen.

7.2.4. Editing patient data

NOTE!

Data loss

- Save entered data and values before closing the software.

If there is no connection to a hospital information system, you can edit the data of existing patients.

- Open the patient information on the respective patient
- Select the “EDIT PATIENT DATA” function there



Figure 9: “EDIT PATIENT DATA” button in patient information

- Edit the patient data in the input mask, if necessary. The same conditions apply as when adding a new patient.

You can change the date and time of birth only if no bilirubin value has been entered for this patient.

- After all adjustments are made, select “Confirm” to accept the changes.

If you make adjustments to patient data that have an impact on the prediction of bilirubin progression, you will be warned with a corresponding message.



Figure 10: "Changed Data" Warning

- Check to make sure the changes are correct.

New information is shown in the respective field, with the previous content shown in addition next to or below the corresponding field.

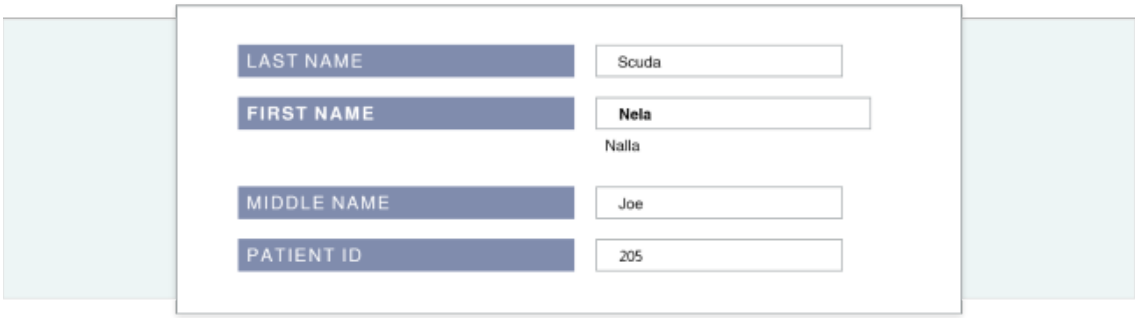


Figure 11: Comparison of changed data (Standard Mode)

- Confirm the adjustments by selecting "Save" if all the information is correct.

> You can make changes by clicking "BACK" and going back to the input screen.

7.2.5. Deleting patient data

To delete patient data from the system:

- Select the "recycle bin" symbol
- Confirm deletion if you are certain that the patient's record should be deleted

7.3. Adding and editing bilirubin measurements

7.3.1. Adding a bilirubin measurement

NOTE!

Using the browser's autofill function

Automatically filled fields may contain incorrect entries for the patient. This can lead to an **anomalous prediction**.

- ▶ Do NOT use the browser's automatic fill functions (“autocomplete” or “autofill”) when entering measurement values!

NOTE!

Data loss

- ▶ Save entered data and values before closing the software.

If there is no connection to the hospital information system, there are two options to add a bilirubin measurement for a patient.

- ▶ Select the “ADD MEASUREMENT” function in the patient overview for the corresponding patient, OR

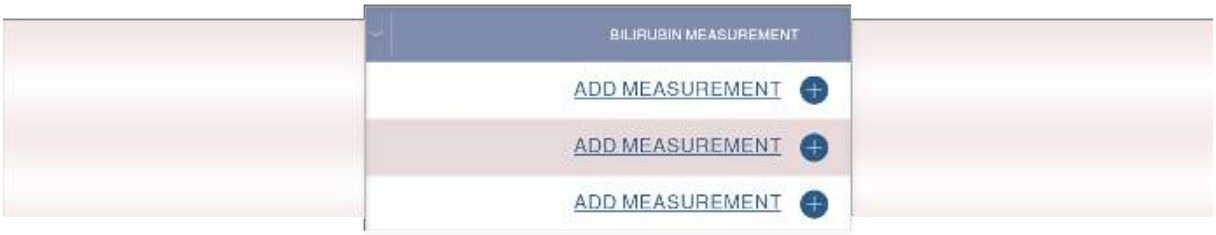


Figure 12: Excerpt from the patient overview on the dashboard (Standard Mode)

- ▶ Select “ADD BILIRUBIN MEASUREMENT” in the patient information of the corresponding patient



Figure 13: “ADD BILIRUBIN MEASUREMENT” button in the patient information (Standard Mode)

- ▶ Check the patient data shown next to the input mask for the bilirubin value

▶ Enter the time of measurement

- date and time

▶ Enter the measured bilirubin value

- in mg/dl or µmol/l, as desired
- rounded to one decimal point
- required minimum value: 1.0 mg/dl or 17.1 µmol/l

▶ Select the type of measurement being performed, TSB or TcB

The maximum value to obtain a prediction of bilirubin progression depends on the postnatal age of the patient.

Postnatal age in hours	**Maximum bilirubin value**	
	mg/dl	**µmol/l**
between ≥ 8 and ≤ 60	15.0	256.5
between > 60 and ≤ 72	16.0	273.6
between > 72 and ≤ 84	17.0	290.7
between > 84 and ≤ 120	18.0	307.8

Table 7: Maximum permissible bilirubin value entries depending on postnatal age

	Measurement values higher than the maximum values can also be entered; however, in that case, the bilirubin progression cannot be predicted.
	You can identify missing or invalid information by a red border. After entering all the data, proceed to the confirmation.

▶ Check the information shown for accuracy

▶ Confirm the entries by selecting “SAVE”

ℹ	You can make changes by clicking “BACK WITHOUT SAVING” and going back to the input screen.
ℹ	If there is a connection to the hospital information system, the bilirubin measurements will be automatically imported into the system when the patient is added and will be updated every time the patient is accessed. That is, new bilirubin measurements will be automatically inserted and old possibly incorrect measurements will be updated or removed.

7.3.2. Editing an existing bilirubin measurement

NOTE!

Using the browser's autofill function

Automatically filled fields may contain incorrect entries for the patient. This can lead to an **anomalous prediction**.

- ▶ Do NOT use the browser's automatic fill functions (“autocomplete” or “autofill”) when entering measurement values!

NOTE!

Data loss

- ▶ Save entered data and values before closing the software.

If there is no connection to the hospital information system, you can edit already entered bilirubin measurements for a patient.

- ▶ Open the patient information on the respective patient
- ▶ Click on the measurement value to be changed in the measurement table
  - time,
  - date, OR
  - “Edit” icon

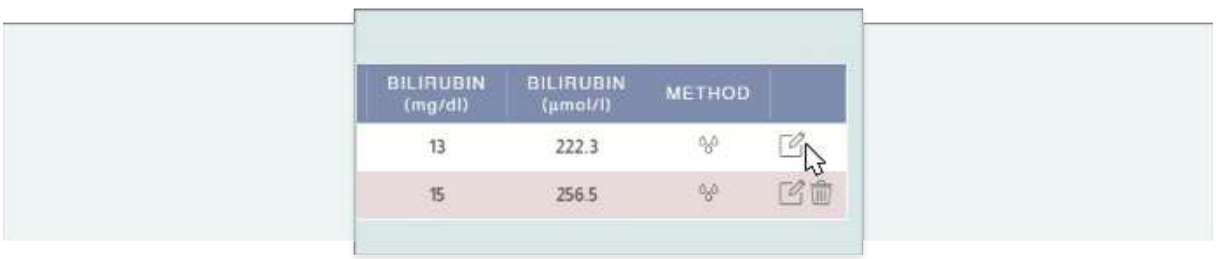


Figure 14: Excerpt from the measurement value table in the patient information (Standard Mode)

	You can edit the measurement information in the input mask. The same conditions apply as when entering a new bilirubin measurement.

- Enter the changes
- Continue to the confirmation
- Check the changes shown for accuracy

	New information is shown in bold, with the previous content shown in addition next to or below the corresponding field.

- Confirm the changes by selecting “SAVE” if all the information is correct.

	You can make additional changes by going back to the input screen.
	If there is a connection to the hospital information system, the bilirubin measurements will be automatically imported into the system when the patient is added and will be updated every time the patient is accessed. That is, new bilirubin measurements will be automatically inserted and old possibly incorrect ones will be updated or removed.

8. DATA ENTRY IN LITE MODE

ℹ	See Section 7 for how to enter data in Standard Mode.
ℹ	If you selected **On-Demand Mode** during installation, the **dashboard is not available** and you will start directly at the patient data and measurement value input screen. Entries cannot be saved to a patient file! **Skip directly to Section 8.4** *Data entry in On-Demand Mode*.
ℹ	Please note the **different control elements** when you use BiliPredics on a **mobile device**. They are marked in these instructions for use with the symbol .

8.1. Viewing patient data

After logging in, you will find yourself in the patient overview, also known as the dashboard.

The patient overview shows the patients of your facility stored in BiliPredics. By default, patients who were born within the last 30 days will be shown. You can set this value during installation or afterwards. Please contact our customer support for assistance with this.

The patient overview can be accessed at any time by clicking on “DASHBOARD” at the top of the screen.



Figure 15: "DASHBOARD" button in the patient information (desktop view in Lite Mode)



►Click on “☰” at the top edge of the screen to open the selection.
► Click on “Dashboard” to get to the patient overview.

The following information is shown for each patient:

- Patient ID
- Weight at birth
- Gestational age
- Time (postnatal age) and measurement value from last bilirubin measurement

By default, the patient overview is sorted by the time of patient creation, with the most recently created patients shown first.

8.1.1. Adjusting the sorting order in patient overview

▶ By clicking on the arrow symbol, select the column according to which you want to sort the entries.

▶ Click on the arrow symbol again to reverse the sorting order.

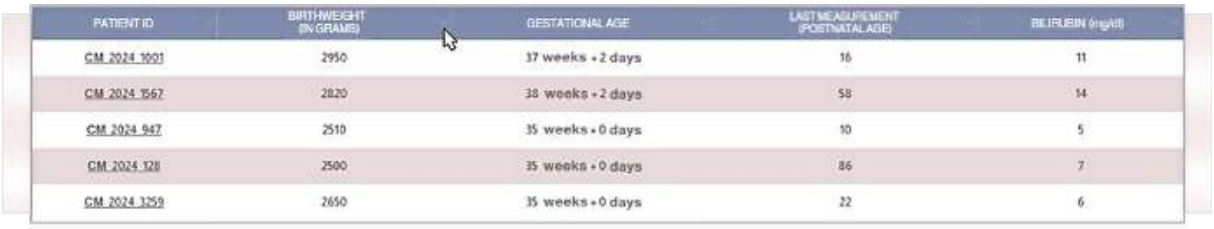


Figure 16: Excerpt from the patient overview table on the dashboard (desktop view in Lite Mode)

8.1.2. Finding patients

Patients are searched for using the Patient ID.

▶ Enter the patient ID or parts of it into the patient overview (dashboard) search field.

After each input, only the patients that match this input data will be shown.

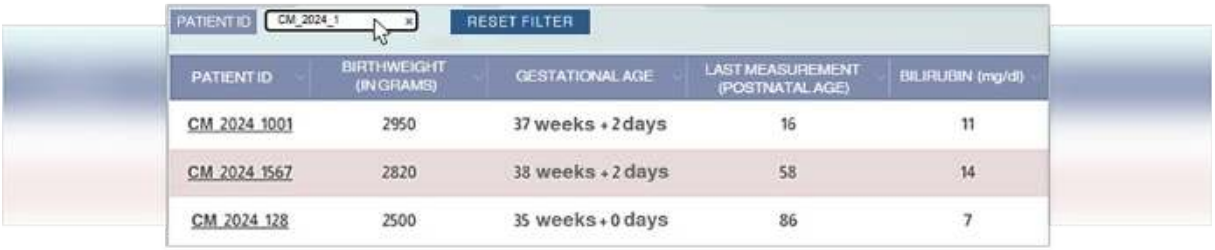


Figure 17: Patient filter function on the dashboard (desktop view in Lite Mode)

To show all patients again, reset the filter.

▶ Select “RESET FILTER” to delete the filter criterion.

8.1.3. View patient information

Accessing the detailed information of an individual patient:

▶ Click on the respective patient ID for the patient.

The patient information page is divided into 3 sections:

- Patient data
- Measurement data
- Diagram area with various options

On the patient information page, you have the following options:

- Adjust patient data (*) [see Section 8.2.2]
- Delete patient data completely from the system [see Section 8.2.3]
- Add, adjust, or delete bilirubin value(s) (*) [see Section 8.3]
- Show bilirubin rate of increase [see Section 9.3]
- Show prediction of bilirubin progression [see Section 9.3]
- Show nomograms per Bhutani and NICE guidelines [see Section 9.4]
- Show phototherapy thresholds [see Section 9.4]
- Show zones of discharge recommendations [see Section 9.4]
- Record start and end of phototherapy [see Section 9.6]
- Generate report [see Section 9.7]

For detailed information, please refer to the referenced sections.

(*) Bilirubin values and patient data can be changed only if there is no connection to the hospital information system.

8.2. Entering and editing patient data

8.2.1. Adding new patients

To add new patients:

- Select the “ADD NEW PATIENT” button in the patient overview (dashboard).



Figure 18: “ADD NEW PATIENT” button on the dashboard (desktop view in Lite Mode)

The input mask for patient data appears.

- Enter the **Patient ID** in the input mask that appears

> See APPENDIX II “Assigning Patient IDs” for the rules for entering the Patient ID.

- Enter the **weight at birth** in grams.
- Enter the **delivery mode**.
- Select the **gestational age** in weeks and days.
- Select whether **hyperbilirubinemia neurotoxicity risk factors** are present.

  Select “Yes” if at least one of the following risk factors for hyperbilirubinemia neurotoxicity according to the AAP 2022 guidelines are present:

  - Albumin < 3.0 g/dl
  - Isoimmune hemolytic diseases (including positive direct antiglobulin test), G6PD deficiency, or other hemolytic diseases
  - Sepsis
  - Significant clinical instability in the past 24 h

Select “No” if none of the risk factors listed are present.

> Selecting “No” leads to higher threshold values under the AAP 22 thresholds and the AAP 22 zones for discharge recommendations. That means, for example, that phototherapy is recommended only at a higher bilirubin value.

Select “Unknown” if you cannot clinically assess whether there are risk factors for hyperbilirubinemia neurotoxicity.

> When “Unknown” is selected, the AAP 22 thresholds, the AAP 22 zones for discharge recommendations, and the discharge recommendations are not available. Select “Yes” or “No” instead if you want to use these functions.

▶ Check the information shown for accuracy

> You can identify missing or invalid information by a red border.

▶ Confirm the entries by clicking “SAVE”

8.2.2. Editing patient data

NOTE!

Data loss

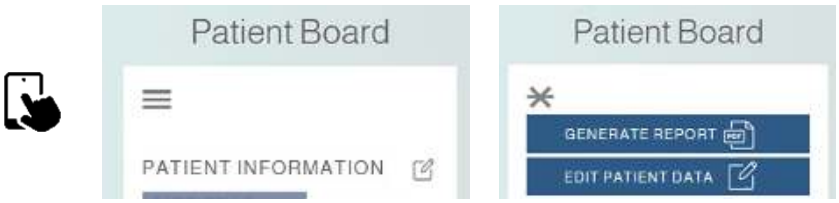
▶ Save entered data and values before closing the software.

▶ Open the patient information on the respective patient

▶ Select the “EDIT PATIENT DATA” function there



Figure 19: “EDIT PATIENT DATA” button in the patient information (desktop view in Lite Mode)



►Click on “☰” in the Patient Board to show the options.

▶ Edit the patient data in the input mask, if necessary. The same conditions apply as when adding a new patient.

▶ After all adjustments have been made and checked, select “SAVE” to accept the changes.

If you make adjustments to patient data that have an impact on the prediction of bilirubin progression, you will be warned with a corresponding message.

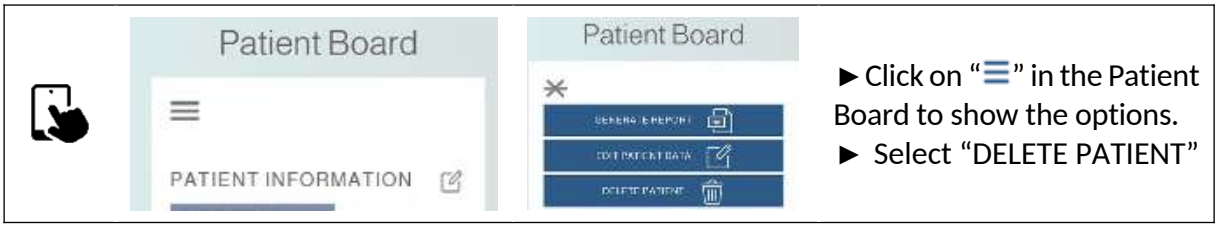


Figure 20: “Changed Data” Warning

8.2.3. Deleting patient data

To delete patient data from the system:

- ▶ Select “DELETE PATIENT” in the patient information.
- ▶ Confirm the deletion if you are certain that the patient's record should be deleted.



► Click on “☰” in the Patient Board to show the options.
► Select “DELETE PATIENT”

8.3. Adding and editing bilirubin measurements

8.3.1. Adding a bilirubin measurement

NOTE!

Using the browser's autofill function

Automatically filled fields may contain incorrect entries for the patient. This can lead to an **anomalous prediction**.

- ▶ Do NOT use the browser's automatic fill functions (“autocomplete” or “autofill”) when entering measurement values!

NOTE!

Data loss

- ▶ Save entered data and values before closing the software.

If there is no connection to the hospital information system, there are two options to add a bilirubin measurement for a patient.

- ▶ Select the “ADD MEASUREMENT” function in the patient overview for the corresponding patient, OR

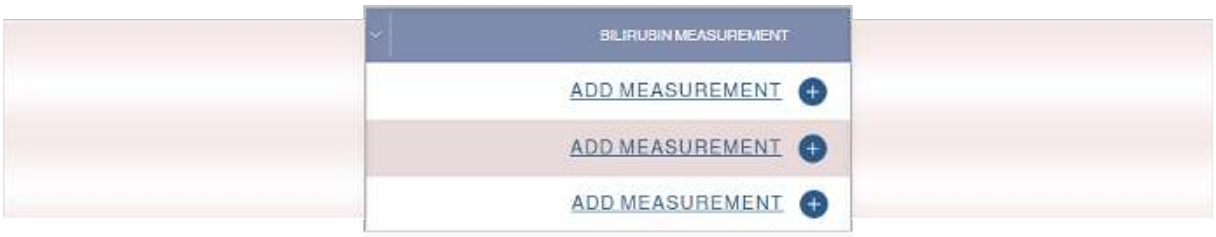
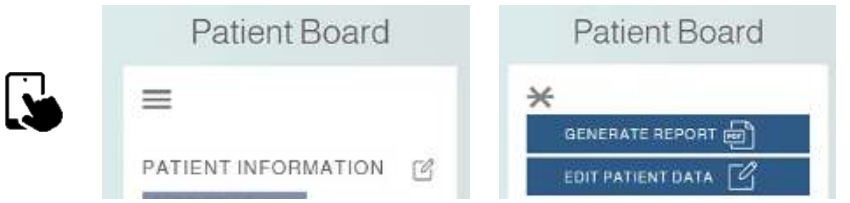


Figure 21: “ADD MEASUREMENTS” buttons in the patient overview on the dashboard (desktop view in Lite Mode)

- ▶ Select “EDIT PATIENT DATA” in the patient information for the corresponding patient



Figure 22: “EDIT PATIENT DATA” button in the patient information (desktop view in Lite Mode)



►Click on "☰" in the Patient Board to show the options.
► Select "EDIT PATIENT DATA".

- ▶ Check the patient data shown next to the input mask for the bilirubin value
- ▶ Enter the time of measurement
  - PNA in hours
- ▶ Enter the measured bilirubin value
  - in mg/dl or µmol/l, as desired
  - rounded to one decimal point
  - required minimum value: 1.0 mg/dl or 17.1 µmol/l
- ▶ Select the type of measurement being performed, TSB or TcB

The maximum value to obtain a prediction of bilirubin progression depends on the postnatal age of the patient.

Postnatal age in hours	**Maximum bilirubin value**	
	mg/dl	**µmol/l**
between ≥ 8 and ≤ 60	15.0	256.5
between > 60 and ≤ 72	16.0	273.6
between > 72 and ≤ 84	17.0	290.7
between > 84 and ≤ 120	18.0	307.8

Table 8: Maximum permissible bilirubin values depending on postnatal age

ℹ	Measurement values higher than the maximum values can also be entered; however, in that case, the bilirubin progression cannot be predicted.
ℹ	You can identify missing or invalid information by a red border. After entering all the data, proceed to the confirmation.

- ▶ Check the information shown for accuracy

▶ Confirm the entries by selecting “SAVE”

> If there is a connection to the hospital information system, the bilirubin measurements will be automatically imported into the system when the patient is added and will be updated every time the patient is accessed. That is, new bilirubin measurements will be automatically inserted and old possibly incorrect measurements will be updated or removed.

8.3.2. Editing an existing bilirubin measurement

NOTE!

Using the browser's autofill function

Automatically filled fields may contain incorrect entries for the patient. This can lead to an **anomalous prediction**.

▶ Do NOT use the browser's automatic fill functions (“autocomplete” or “autofill”) when entering measurement values!

NOTE!

Data loss

▶ Save entered data and values before closing the software.

If there is no connection to the hospital information system, you can edit already entered bilirubin measurements for a patient.

▶ Open the patient information for the respective patient
- Click on the “Edit” icon of the measurement value table OR
- Click on “EDIT PATIENT DATA”

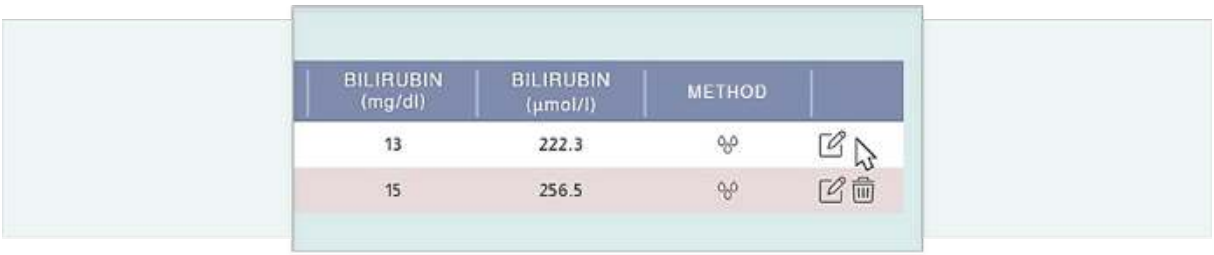


Figure 23: “Edit measurement value” button in the patient information (desktop view in Lite Mode)

> You can edit the measurement information in the input mask. The same conditions apply as when entering a new bilirubin measurement.

- Enter the changes
- Check the changes shown for accuracy
- Confirm the changes by selecting “Save” if all the information is correct.

> If there is a connection to the hospital information system, the bilirubin measurements will be automatically imported into the system when the patient is added and will be updated every time the patient is accessed. That is, new bilirubin measurements will be automatically inserted and old possibly incorrect ones will be updated or removed.

8.4. Data entry in On-Demand Mode

> The patient and measurement data required to predict bilirubin progression must be entered in full in each case in this mode. There is no option available to access saved data.

You will be taken directly to the data input mask after logging in.

- Select the weight unit for the birth weight
- Enter the patient’s birth weight
- Select the delivery mode
- Enter the patient’s gestational age
- Enable the check box for risk factors IF there are any
- Set the measurement value units once for all measurements
- Enter the bilirubin measurement(s) with the corresponding measurement times (PNA in hours), measurement values, and measurement methods
- Check to make sure the entered data is correct
- Select “SAVE” to calculate the prediction



Figure 24: Input screen in On-Demand Mode (desktop view)

Once you have selected “SAVE”, the software takes you directly to the prediction overview for the patient. The overview provides information on noteworthy measurement values, a prediction of the bilirubin value progression (see Section 9), recommendations per the AAP 2022 Guidelines, and a graphic representation of the value progression prediction (see Section 9.4).

9. PREDICTION OF BILIRUBIN PROGRESSION



Detailed explanations on how to determine the maximum predictive time for bilirubin progression can be found in Appendix I.

9.1. Input rules for bilirubin measurements

There are three input rules regarding bilirubin measurements to obtain a prediction of bilirubin progression.

Rule 1: Prediction period with a maximum length of 30 hours

If a TSB measurement is available between 8 and 72 hours after birth, a maximum prediction of 30 hours after the last measurement is possible.

Rule 2: Prediction period with a maximum length of 48 hours

If any measurement is taken between 8 and 72 hours after birth, and another measurement is taken between 24 and 120 hours after birth, with an interval of at least 8 hours, a maximum prediction of 48 hours after the last measurement is possible. There is an exception for two TSB measurements; see the following Rule 3.

Rule 3: Prediction period with a maximum length of 60 hours

If a TSB measurement is taken between 8 and 72 hours after birth, and another TSB measurement is taken between 24 and 120 hours after birth, with an interval of at least 8 hours, a maximum prediction of 60 hours after the last measurement is possible.

Figure 25 shows input rules 1-3.

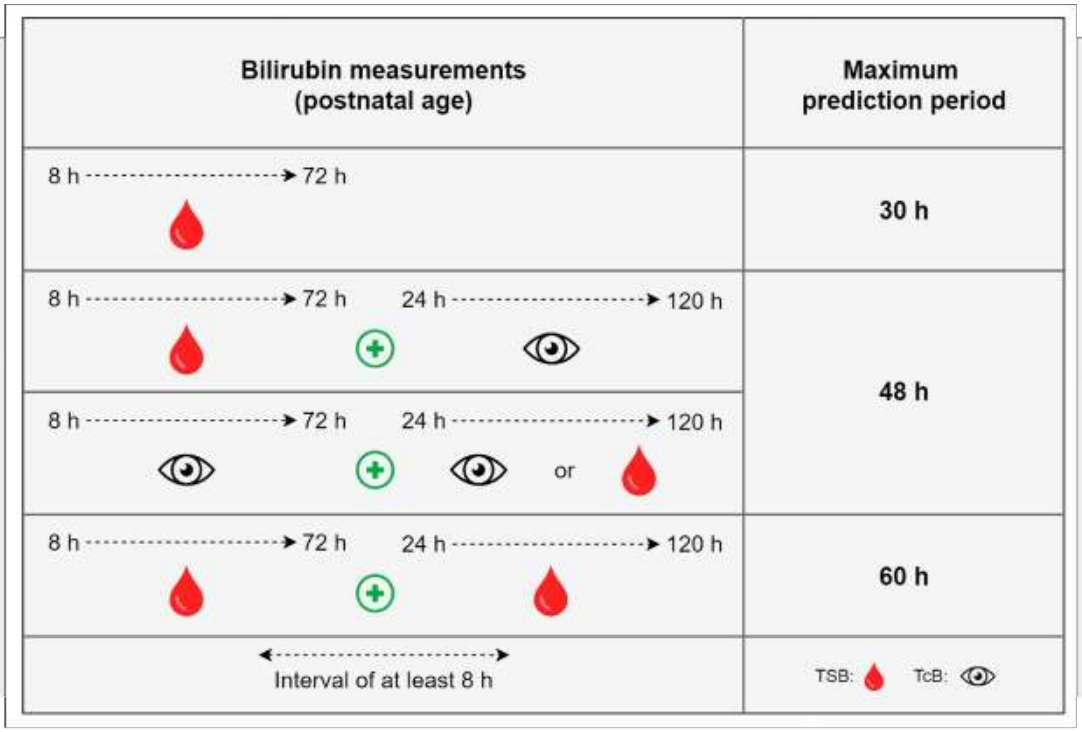


Figure 25: Summary of the three input rules

9.2. Invalid bilirubin measurements

Bilirubin measurements that fall below or exceed the defined limits (see Section 7.3.1), are shown in gray. Once at least one bilirubin measurement has been marked as invalid, the bilirubin progression can no longer be predicted.

9.3. Viewing prediction of bilirubin progression

You can show the prediction of a patient's bilirubin progression.

▶ Open the patient information for the respective patient.
A chart displays showing the bilirubin values already recorded.

> In On-Demand Mode, the overview appears with the chart automatically once the entered data is confirmed.

▶ Select “Show prediction” below the chart

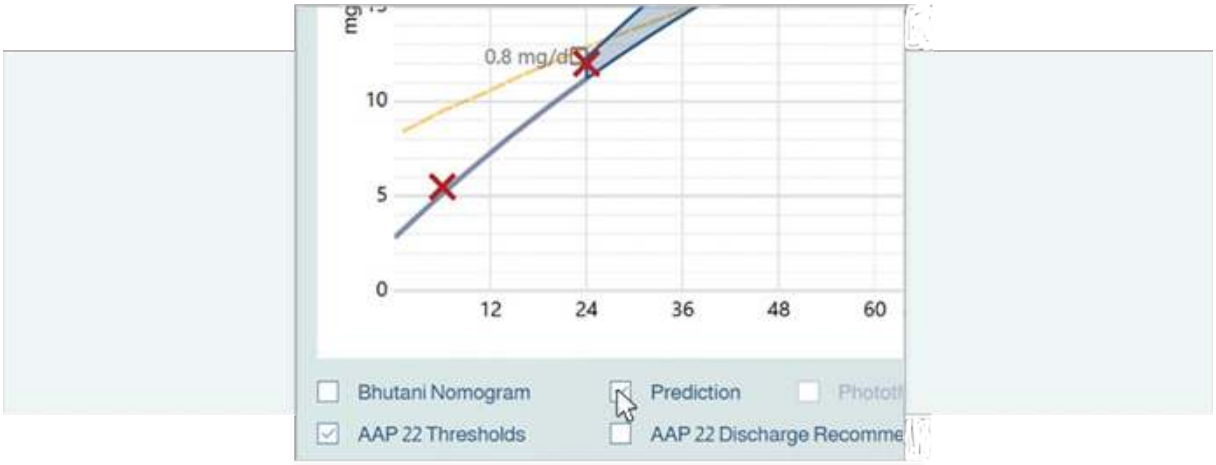


Figure 26: Enabling the prediction of bilirubin progression

If this option is not available (button is grayed out), the recorded bilirubin values do not allow for prediction (see Section 9.2).

▶ Check if you can meet the requirements by taking another measurement.

If the requirements are met, BiliPredics provides a prediction of bilirubin progression up to:

- a maximum of 60 hours after the last measurement (depending on the number and type of measurements, see Appendix I) and
- a maximum of 144 hours after birth

The predictive accuracy of bilirubin progression may vary due to individual changes (e.g., biological factors) or measurement errors in the laboratory.

▶ Only use bilirubin measuring devices with CE and/or FDA approval for bilirubin measurement that have a maximum measurement accuracy of +/- 7%.

The prediction of bilirubin progression (in mg/dl and µmol/l) is shown as a graph in the diagram depending on postnatal age (in hours). TSB measurements are represented in the diagram with a red cross, and TcB measurements are represented with a blue cross. The following information is shown in this case:

① Prediction of bilirubin progression based on previous measurements (in the example, three red crosses)

② Start of prediction from the last measurement and start of the clinically relevant safety range, indicated by a vertical line at +10%

③ End of the prediction period and end of the clinically relevant safety range, indicated by a vertical line at +25%

④ Upper limit of the clinically relevant safety range over the prediction period, increasing from +10% to +25%

⑤ Clinically relevant safety range represented as an area over the prediction period

⑥ Prediction range given by the two predicted bilirubin values from +0% to +25% at the end of the prediction period

⑦ Display of bilirubin increase rate

⑧ Display of current actual age (available only in Standard Mode)



Figure 27: Example of prediction chart

- Move the mouse pointer over any point of a graph (prediction, threshold lines, or nomogram line) to display the exact value.



Figure 28: Display of detailed information in the charts

9.4. Nomograms based on the AAP 2022 Guidelines, Bhutani, NICE Guideline, and other displayed information

9.4.1. AAP 2022 thresholds and nomogram zones

Various nomograms and further information based on the AAP 2022 guidelines can be shown in BiliPredics:

- Select “Show AAP 22 Thresholds” to show the phototherapy thresholds based on gestational age and the indicator for existing hyperbilirubinemia neurotoxic risk factors according to the AAP 2022 guidelines (see ① in Figure 29).
- Choose “Show AAP 22 Risk Nomogram Zones” to show the different zones of discharge recommendations according to the AAP 2022 guidelines (see ② in Figure 29).
  - The bilirubin increase rate is shown, see ③ in Figure 29.
  - The difference from the phototherapy threshold based on the last bilirubin measurement is shown; see ④ in Figure 29.



Figure 29: Example of AAP guidelines

9.4.2. Nomogram curves according to Bhutani and the NICE guidelines

Bhutani nomograms and thresholds according to the NICE guideline can be shown in BiliPredics:

- Select “Show Nomogram Curves” to show the Bhutani nomogram (see ① in Figure 30).
- Select “Show NICE Guidelines” to show the phototherapy threshold and the exchange transfusion threshold based on the gestational age according to the NICE guideline (see ② in Figure 30).



Figure 30: Example of nomogram curves according to Bhutani and the NICE guideline

9.5. Discharge recommendations and phototherapy recommendations

Recommendations for further monitoring of bilirubin progression using measurements, phototherapy, patient observations, or for discharging the patient are shown directly above the chart.

> Discharge recommendations are displayed only if the AAP 22 thresholds or the AAP 22 zones for discharge recommendations have been enabled in the chart options and no phototherapy has been initiated yet.

A colored background behind the discharge recommendation reflects which nomogram zone (per the AAP 2022 Guideline) the most recent measurement value is in.



Figure 31: Example of compact display of recommendations above the chart

- Click on the speech bubble next to the discharge recommendation for detailed information.

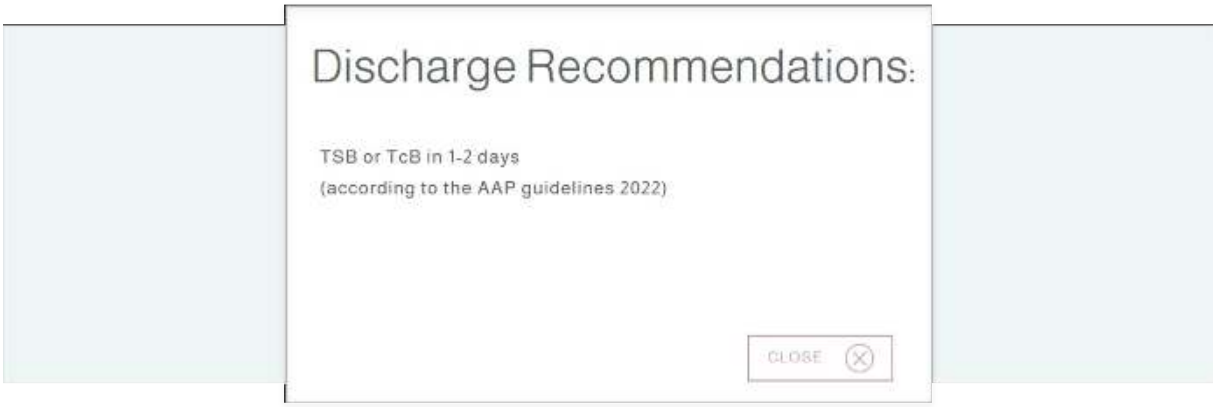


Figure 32: Example of recommended measures related to patient discharge

9.6. Documenting phototherapy

If the patient is receiving phototherapy, it can be documented in BiliPredics.

To record the phototherapy:

▶ Select “START PHOTOTHERAPY” in the patient information.



► You can also click on the “Play” symbol to record the start of phototherapy.

▶ Enter the therapy start time

▶ Confirm your entry by selecting “OK”

The start of phototherapy and the bilirubin threshold value for ending phototherapy (see ① and ② in Figure 33) are displayed in the chart using blue lines.

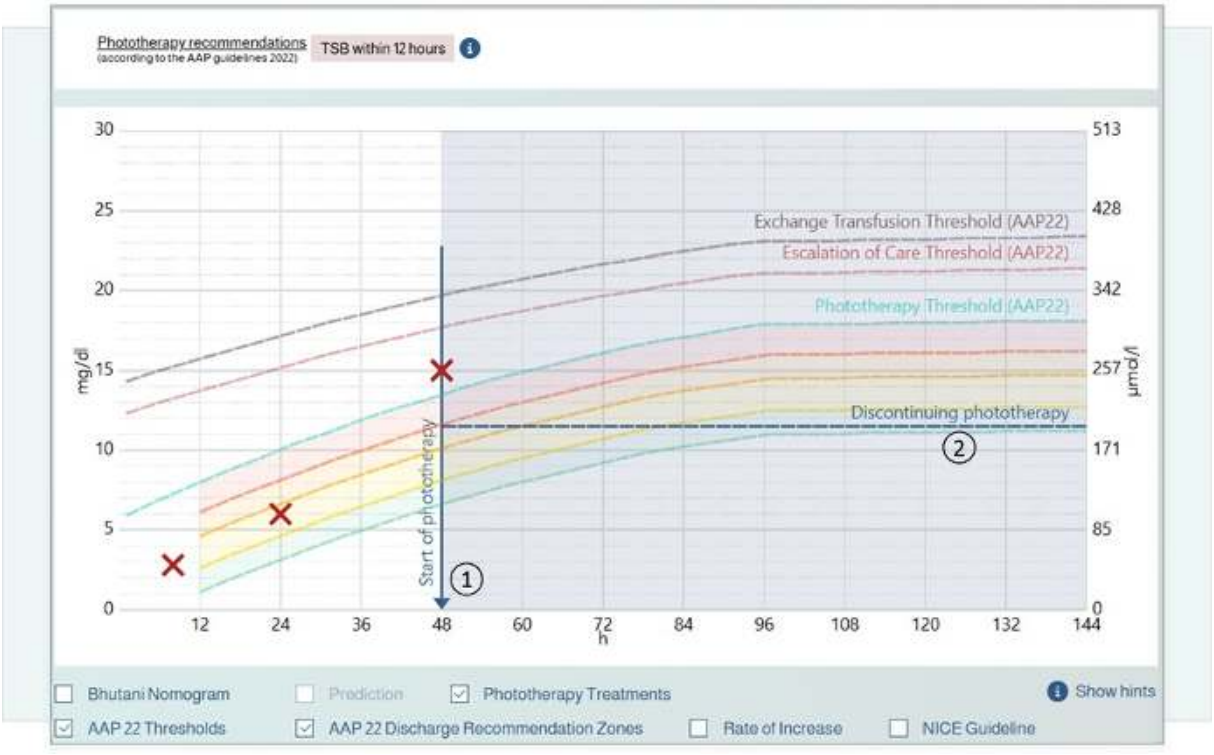


Figure 33: Example of started phototherapy

If phototherapy is discontinued, you can enter that as well in the prediction overview:

▶ Select “DISCONTINUE PHOTOTHERAPY” in the patient information.



► You can also click on the “Stop” symbol to record the end of phototherapy.

▶ Enter the therapy end time

▶ Confirm your entry by selecting “OK”

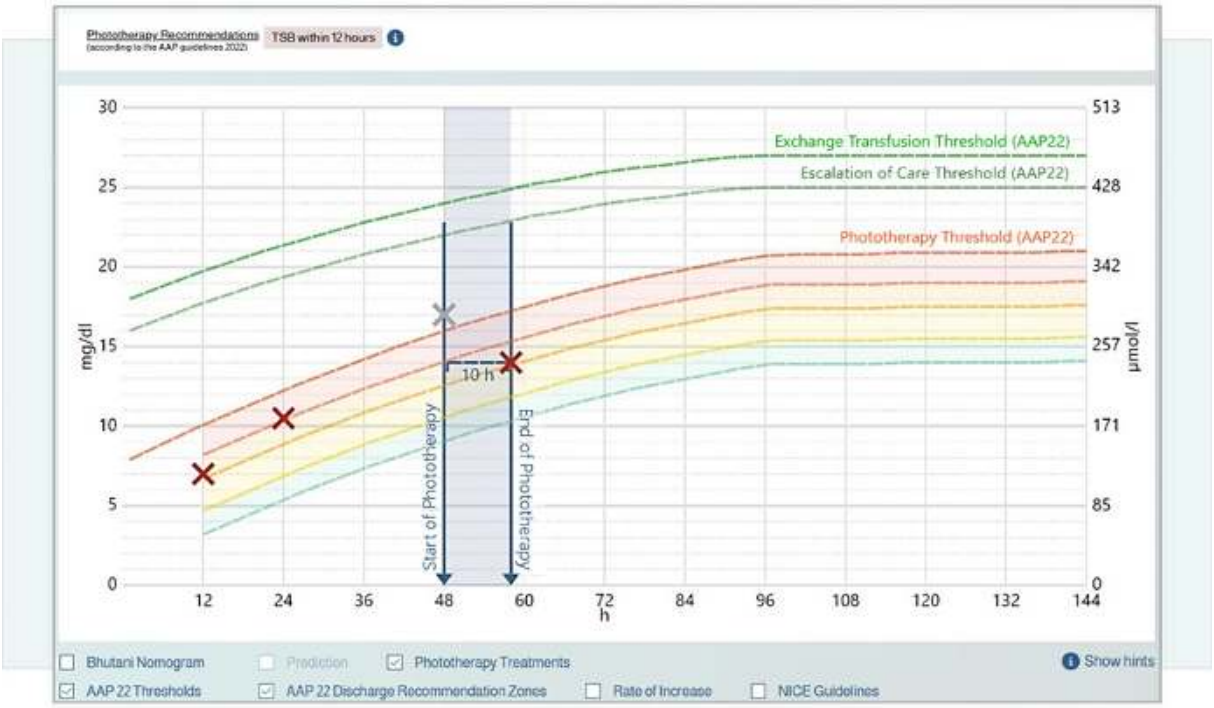


Figure 34: Example of ended phototherapy

9.7. Generate report

You can generate a report with the following contents:

- the patient information
- all bilirubin measurements recorded
- the predicted bilirubin progression

▶ In the Patient Board for the respective patient, select the function “CREATE REPORT” or “REPORT”

The report will be shown as a PDF file in a new browser window. From there, you can download or print the report.

9.8. Warnings for measurements

As soon as a test criterion for a measured value is over or under the limits, a warning will be shown in the form of a warning symbol.

▶ Click on the warning symbol shown to see more details.

The individual details of the test criteria will now be explained in more detail.

Test criterion for minimum and maximum weight values

The permissible measurement values depend on the postnatal age of the measurement. Please refer to Section 7.3.1.

Test criterion for minimum and maximum measurement time points

The allowable postnatal age range at the time of the measurements is 1 to 120 hours. If the results are outside of this range, the bilirubin measurement will be marked as invalid and no further bilirubin results can be shown. Furthermore, a warning message will be shown.

Plausibility check of consecutive bilirubin measurements

If two consecutive bilirubin measurements have the same value, a warning will be generated and the measurement value to be compared will be shown next to the last measurement.

Test criterion: rate of increase

The rate of increase between the measurements is calculated.

The prediction of bilirubin progression depends on postnatal age and the determined rate of increase. If the results fall over or under the limits for the rate of increase, no prediction will be made. A warning message displays if the limits for the rate of increase are exceeded.

Postnatal age of the patient	**Rate of increase in mg/dl/h**	**Effect**
1 - 120 hours	≥ 1.5 or ≤ -1.5	• No prediction of bilirubin progression possible • Any later measurement will be shown in gray (invalid) on the diagram • Warning in the table
24 - 120 hours	**≥ 0.2** mg/dl/h	• Warning in the table
1 - 24 hours	**≥ 0.3** mg/dl/h	• Warning in the table

Table 9: Test criterion: rate of increase of the bilirubin value
(Legend: "<" less than; ">" greater than; "≥" greater than or equal to; "≤" less than or equal to)

10. FUNCTION TEST

NOTE!

Using BiliPredics with malfunction(s)

Using BiliPredics software that is not functioning error-free can lead to **anomalous predictions**.

- ▶ Do not use the software if it is not functioning properly.
- ▶ Report any malfunctions to BAYOOCARE GmbH.
- ▶ Use the form in the software's help function.

To check whether the BiliPredics software is working properly, you can perform a function test.

- ▶ Enter the following data for a test patient:

Parameter	Input value
Date of birth	e.g., 2022-10-04
Time of birth	11:30 a.m.
Gestational age	39+0
Weight at birth	3070 g
Delivery mode	Cesarean
First measurement	10/05/2022 11:30 a.m. 7 mg/dL TSB (24 hours after birth)
Second measurement	10/06/2022 11:30 a.m. 10.4 mg/dl TSB (48 hours after birth)

Table 10: Test data for function test

The diagram of the bilirubin progression prediction should correspond to Figure 35 and the values:

Prediction value at 108h 14.8 mg/dL to 18.5 mg/dL

If the comparison does not match:

- Do not continue to use the software to predict bilirubin progression
- Report the error to BAYOOCARE GmbH



Figure 35: Expected result of function test

11.CYBERSECURITY

The operator is responsible for providing appropriate security information and a secure environment outside of the software system covered here (e.g., security of the operating system, browser, restricted physical access to certain areas of the software system's usage environment). This includes ensuring the maintenance of security during the operation and use of the software system.

> No special training or skills related to cybersecurity are required for the use of the software.

Duties of the operator:

- Make sure that the necessary security levels are guaranteed for the operating environment, including the required infrastructure, such as the latest browser version, network, physical access, and up-to-date malware software (see also Section 5.1)
- Use best-practice security standards
- Make sure that the staff is properly trained and available for security issues
- Make sure that the system is used in accordance with the manufacturer's guidelines and security requirements.
  Among others, these include:
  - No physical access by unauthorized users
  - Setting access rights via user roles
  - Compliance with password guidelines by users (see also Section 6)
  - Disabling functions/applications that are not used and do not contribute to security (also relevant outside the software system, e.g., applications in the runtime environment)
  - Do not use mobile devices when using the software
- Make sure that health data and personal data are also protected outside of the software system (e.g., exported files or printed reports from the software)
- Make sure that the prescribed maintenance is carried out as required, including accepting the installation and provision of security updates/patches by the manufacturer
- Inform the manufacturer and the competent authority of the Member State in which the user and/or patient is located immediately of any suspected security incident

In the document “Technical and Organizational Measures” provided by the manufacturer, you will find further information on:

- Security-by-default principle
- Data storage
- Security checks for data protection
- Planned updates/patches
- Latest software version
- Description of the backup and update procedure by the manufacturer
- Recording of log files for security events
- Use of automatic analysis software
- Security event reports from software

12. HELP

If you have any questions or problems, use the help function in the software to get assistance. You can find it in the footer of the application.

13. CONTACT INFORMATION

	**BAYOOCARE GmbH** Europaplatz 5 64293 Darmstadt, Germany Phone: +49 6151 8618-0 Email: info@bayoocare.com bayoocare.com
	**NeoPredics USA, Inc. (US)** 110 E Broward Blvd #1700 Fort Lauderdale, FL 33301, USA Phone: +1 (954) 315-3884

APPENDIX I

EXPLANATIONS ON HOW TO DETERMINE THE MAXIMUM PREDICTION PERIOD FOR BILIRUBIN PROGRESSION

The number of recorded bilirubin values, the type of bilirubin values, and the timing of the measurements performed affect the maximum prediction period of bilirubin progression from the last measurement. BiliPredics basically offers three different lengths (30, 48, and 60 hours) for the prediction period.

The maximum prediction period is determined based on a lead and support concept. In short, all entered bilirubin measurements are categorized as either Lead or Support. For the Lead Bilirubin measurements, the maximum prediction period is determined using three rules.

Rule 1: Prediction period with a maximum length of 30 hours

If a TSB measurement is available between 8 and 72 hours after birth, a maximum prediction of 30 hours after the last measurement is possible.

Rule 2: Prediction period with a maximum length of 48 hours

If any measurement is taken between 8 and 72 hours after birth, and another measurement is taken between 24 and 120 hours after birth, with an interval of at least 8 hours, a maximum prediction of 48 hours after the last measurement is possible. There is an exception for two TSB measurements; see the following Rule 3.

Rule 3: Prediction period with a maximum length of 60 hours

If a TSB measurement is taken between 8 and 72 hours after birth, and another TSB measurement is taken between 24 and 120 hours after birth, with an interval of at least 8 hours, a maximum prediction of 60 hours after the last measurement is possible.

Additional notes for further bilirubin measurements

If further bilirubin measurements are available, they do not affect the length of the already determined maximum prediction period, but they are used to predict the bilirubin progression and thus support the prediction. These so-called support bilirubin measurements can be taken at any time between 1 and 120 hours after birth. The above stated condition regarding the minimum 8-hour interval in the rules for lead measurements does not apply to support bilirubin measurements. The distance between the lead and support for bilirubin measurement or the distance between support and additional support for bilirubin measurement is arbitrary.

APPENDIX II

ASSIGNING PATIENT IDS

The **Patient ID** must meet the following conditions:

- Unique for each patient
- Length between 1 and 40 characters
- Do not use any special or control characters ".", "\", or Unicode characters U+007F - U+009F
- Allowed special characters are, for example:

Character	Description
;	Semicolon
,	Comma
/	Slash
?	Question mark
:	Colon

Character	Description
@	At sign
&	And
=	Equals sign
+	Plus
$	Dollar

Table 11: Allowed special characters for the patient ID