# BIOSENCY

# **Bora**connect®

Web platform & mobile application for healthcare professionnals

**User manual** 



Bora connect<sup>®</sup> version 2.8.3 Bora-connect\_IFU\_2.8.3 - June 2023

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# About this user manual

This manual is a user guide for the Bora connect® platform and mobile application intended to be used by healthcare professionals.

#### s WARNINGS

#### **INSTRUCTION FOR USE**

Please do not use Bora connect<sup>®</sup> without first reading and understanding all the instructions contained within this manual.

The use of the Bora connect® medical device by customers is conditioned by training in its use by Biosency's teams.

The installation, configuration, and use of Bora connect® do not require specific computer skills.

Please always use Bora connect<sup>®</sup> in accordance with the instructions contained within this manual. Failure to follow the instructions in this manual may result in malfunctions.

Bora connect® should only be used in combination with the accessories supplied by Biosency: Bora band® standard kit BB-100 (wearable device used for measuring the physiological parameters of patients), Bora connect for Home BC4H, Bora connect for Study BC4S (mobile applications that transfer the data from and to Bora band®).

To ensure safe and optimal use of the device, please carefully read the precautions for use and warnings marked with an **s** symbol.

# **Intended use**

Bora connect® is a web-based platform for healthcare professionals intended to:

- E Transfer and display device information and physiological parameters that have been transmitted remotely from the patient's device(s). It is intended to support the medical follow-up of patients with respiratory insufficiency.
- E Provide information for monitoring physiological conditions, state of health or illnesses of patients with respiratory insufficiency. Information can include visual notifications for patients who are outside of thresholds previously defined in Bora connect® by the healthcare professional.

Bora connect® is also available as a mobile application.

Bora connect® is intended to be used in combination with Bora band®.

Bora connect® is intended to be used in combination with one of the following patient's mobile applications: Bora connect mobile (patient's account), Bora connect for Home, Bora connect for Study.

# **Target population and intended users**

Bora connect® is intended to display the physiological parameters of patients suffering from chronic respiratory

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disease. The patients are adults with a satisfactory blood supply. Physiological parameters are collected by Bora band®, a wearable device.

Medical staff have access to patient physiological data through to Bora connect®.

The client structure (e.g., home healthcare provider) has access to Bora band® status information (device in use or available for use, battery level, etc.) using Bora connect®.

# **Contraindications**

#### s WARNINGS

#### ALARM

Do not use Bora connect® when alarms are required.

#### CONTINUOUS MONITORING

Do not use Bora connect® for continuous monitoring purposes. Bora connect® is intended to be used in combination with devices that periodically record physiological parameters.

Bora connect® does not trigger an alarm and does not allow for continuous readings.

Bora connect® is not designed to continuously monitor patient vital signs.



# Warnings

E Do not use Bora connect® without first reading and understanding all the instructions contained within this manual.

EDo not use Bora connect® when alarms are required.

- E Do not use Bora connect® for continuous monitoring purposes.
- E Do not use Bora connect® with accessories other than those supplied by Biosency: Bora band Model BB-100, Bora connect for Home BC4H, Bora connect for Study BC4S.
- Elnstall only one of these applications at the patient's side: Bora connect mobile, Bora connect for Home or Bora connect for Study. Otherwise, the data collection by Bora connect® could be disrupted.

# **Precautions**

- EPlease always use Bora connect® in accordance with the instructions contained within this manual. Failure to follow the instructions in this manual may result in malfunctions.
- E Bora connect® should only be used in combination with the accessories supplied by Biosency.

EBora connect® is intended to be used in combination with Bora band®.

- EInformation for a safe combination of Bora connect® with Bora band® are available in Bora band® user manual. This must be carried out by a qualified professional
- ETo benefit from the latest developments, make sure you are using the latest version of Bora connect® mobile application.
- ETo benefit from the latest developments, make sure the patient is using the latest version of Bora connect mobile, Bora connect for Home or Bora connect for Study.
- E It is recommended to carry on a risk analysis of your IT-network with the identification, analysis, evaluation, and control of all risks related to Bora connect® installation and operation.
- E It is important to check all technical prerequisites described in the section <u>Technical prerequisite</u> and the information related to cybersecurity described in the section <u>Cybersecurity</u> and necessary for Bora connect® operation in case of any change in your IT-network.
- E If a new risk is detected, please contact the Biosency's support team by the mean described in the section <u>Support</u>.
- E Please store your login information (username and password) securely and remember to secure access to your smartphone with a pin code or biometric recognition. This will prevent an unauthorized and/ or malicious third party from accessing your data. Your connection information is strictly personal and must not be transmitted to a third party.



Bora connect® allows to monitor patient's physiological parameters, to manage visual notification on patient's physiological data, to export patient's physiological data, to launch survey campaign, to manage bora bands fleet and to manage patients, doctors, and home healthcare providers accounts. Depending on your role, you may not be able to manage bora bands fleet, patients, doctors, and home healthcare providers accounts. Please refer to the Bora connect® administrator of your structure.

Bora connect® offers different pages:

- EDashboard: a list of all the patients of the structure, with a visual indication if an alert condition is reached
- E **Patients :** a list of all the patients of the structure, and pre-set filters (favorites, no data for 24 hours, with bora band, no bora band®)
- E Doctors: a list of all the doctors, and services, linked to the structure
- E Home healthcare providers: a list of all health actors

EBora bands: a list of all Bora band® allocated to the structure

- E Surveys: a list of all the survey
- E Roles: a list of all roles, access of Bora connect® pages depends on user role
- E Settings: your personal data, consult data privacy and bora connect label.

Bora connect® web platform is available at this address: <u>https://bora-connect.com</u>. Bora connect® mobile application is available on Google Play Store and Apple App Store.

# Accessories, information for a safe combination

#### s WARNINGS

#### COMPATIBLE ACCESSOIRIES

Do not use bora connect® with accessories other than those supplied by Biosency: Bora band Model BB-100, Bora connect for Home BC4H, Bora connect for Study BC4S.

### Bora band®

Bora connect® is intended to be used in combination with Bora band®.

Device	Description
Poro bond@ standard kit PR 100	Bora band standard kit, wearable device used for measuring
Dora Danue Standard Rit DD-100	the physiological parameters of patients

Information for a safe combination of Bora connect® with Bora band® are available in Bora band® user manual. This must be carried out by a qualified professional.



### Patient mobile application

#### s WARNINGS

#### PATIENT'S MOBILE APPLICATION

Install only one of these applications at the patient's side: Bora connect mobile, Bora connect for Home or Bora connect for Study. Otherwise, the data collection by Bora connect could be disrupted.

#### s **PRECAUTIONS**

#### VERSION OF BORA CONNECT MOBILE, FOR HOME AND FOR STUDY

To benefit from the latest developments, make sure the patient is using the latest version of Bora connect mobile, Bora connect for Home or Bora connect for Study.

Bora connect® needs a mobile application to be installed at the patient's side: Bora connect® mobile, Bora connect for Home or Bora connect for Study. Only one of these applications shall be installed at the patient's side. This must be carried out by a qualified professional.

Device	Description
BC4H	Bora connect for Home, patient's mobile applications that transfer the data from and to Bora band®
BC4S	Bora connect for Study, patient's mobile applications that transfer the data from and to Bora band®, and collect answer to survey
BC mobile (patient account)	Bora connect mobile for patient, patient's mobile applications that transfer the data from and to Bora band®, allows the patient to consult their data, and collect answer to survey

Information for a safe combination of Bora band® with the mobile applications are available in Bora band® user manual.

# Bora connect® identification

Bora connect® version is displayed at the bottom left of the application, it is preceded by the word «version». Bora connect® Unique Device Identifier is displayed on the "Settings" page, it is preceded by the symbol **UDI**.



#### s **PRECAUTIONS**

#### **IT NETWORK**

The execution of Bora connect® on your IT-network could result in previously unidentified risks to patients, users or third parties. Therefore, a risk analysis of your IT-network is recommended with the identification, analysis, evaluation and control of all risks related to Bora connect® installation and operation. In addition, it is important to check all technical prerequisites described in the section <u>Technical prerequisite</u> and the information related to cybersecurity described in the section <u>Cybersecurity</u> and necessary for Bora connect® operation in case of any change in your IT-network. If a new risk is detected, please contact the Biosency's support team by the mean described in the section <u>Support</u>.

Bora connect® platform is a web-based platform, bora connect® is not installed on your computer. Bora connect® web platform is available at this address: <u>https://bora-connect.com</u>.

Bora connect mobile application can be installed in the same way as any other mobile applications, depending on how your mobile phone works. Bora connect mobile application is available on Google Play Store and Apple App Store.

# **Technical prerequisites**

#### Bora connect web

- Processor: 1.4 GHz
- RAM: 2 Go
- Browsers: current major version of Chrome or Safari
- Resolution: min. 1920\*1080
- Internet connection with access to https://bora-connect.com

#### Bora connect mobile application

- Processor: 1.4 GHz
- RAM: 2 Go
- Bluetooth®: 4.2 (Bluetooth Low Energy)
- OS: Android version N-5 (or iOS version N-3) where N is the last version
- Networks: Wifi with web access or 3G or 4G or 5G
- Resolution: 360 x 640 pixels



# Bora connect<sup>®</sup> onboarding



In the next part, we will assist you to onboard with Bora connect®:

- E You will log in Bora connect® for the first time
- E You will set a patient in remote monitoring
- E You will consult patient measurements graphs

# **1** How to log in Bora connect<sup>®</sup> for the first time?

#### s **PRECAUTIONS**

#### BORA CONNECT IDENTIFIERS

Please store your login information (username and password) securely and also remember to secure access to your smartphone with a pin code or biometric recognition. This will prevent an unauthorized and/or malicious third party from accessing your data. Your connection information is strictly personal and must not be transmitted to a third party.

Once your Bora connect® account has been created by your administrator, you will receive a verification email. **Remember to check your spam.** 

Click on the link in the email to define your account password.

Your password must be at least 8 characters in length, contain at least 3 of the following 4 types of characters:

- 1. Lower case (a-z)
- 2. Upper case (A-Z)
- 3. Numbers (i.e. 0-9)
- 4. Special characters (e.g. !@#\$%^&\*)





2 After defining your password, you will be redirected to the login page.

Enter your login (which is your email address), your newly defined password and validate.

3 During your first connection, you will need to enter a mobile phone number to enable MFA (multifactor authentication). Select your country code and enter your mobile phone number. You will immediately receive a SMS containing a one-time use code.

4 Enter the one-time use code received by SMS. The multifactor authentication will be required at least once per week unless you voluntary disconnect from Bora connect®.

5 If this is your first connection, you will get a recovery code on the platform that you can use in case you need to login without your phone device. This recovery code can be used only once. Please store this recovery code in a safe place.





6 Last step, you are required to consent to the processing of your personal data on Bora connect® platform.

	How is my personal data processed?
Contant of the modifications of 05/04/22 :	
· Update of the company's capital	
Deplacement of "BOBA Connect Solution" By "BOBA CAB	d Salution"
Contant of the modifications of 06/22/2021 :	
Update of the company's capital	
- Users of the salution may be natified of the modification of	f the TOS by email or via BOBA Connect
CENERAL TERMS OF USE	
OF THE BORA CARE SOLUTION	
Goder, 2550 Saine Chippole, France, and shich is regulatere Benefan, any use of the BOBA CASE Solution implets the	d with the and Congress larger outer matter (2016) 2016 2021 2023 denses. New Derivative shared is a "BOGCOY"
The GCU come into force with respect to the User on the da	by of their acceptance from the spening page of the User Account which is personal to him.
tagree to the collection and processing of my data	(mit)

Congratulation, you are now logged into the Bora connect® platform.

ø	Jacques POCHENIN Antoine	Doracomect
۵	Dashboard	Dashboard
8	Patients	Q. Search for a patient By alert type 🕘 🕲 🕲 🔘
ų,	Dectors	Ms MarksTipART V Perr BOTTIRO O O O
*	HHCPs	Mr. Mailer Council 9 9 Perril Diffitio 9 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
٥	BORA Bands	Ms Careline GRVTR. 19 Carlos RUZ ZARON 19 C 10 C
₽	Surveys	
0	Tales	

Head to the second part of the user manual to get details on each menu. The next section will guide you on how to start the remote monitoring for a patient.

# 2 Patient remote monitoring

To enable patient remote monitoring, start by creating the patient account.

Remote monitoring allows you to get visual notifications when a patient vital sign reach a specific limit that you have configured.

### How to start a new patient' session?

In the patients menu, click on the "Add" button.



2 Fill the patient information to create the account. The patient will receive a verification email and will be able to setup his account. The account process for the patient is identical to yours. Click on the <u>setup</u> button. The patient will immediately receive a verification email.

K BACK Add patient	
Primary doctor	
Search doctors:	
SHOW HEL DOCTORESERVICES	
Identity	
Cender:	Lastname :
Firstname :	
Birth date :	
Birth place :	
Language:	
Contact	
E-Mail:	
Prefix	Plane number:



Doctor			
Pierre BOTTERO		۲	*
Gregory KEYES	$\odot$	۲	*

4 Select the monitoring device which will be equipped on the patient and click on the "Next" button.

	Boraconnect	
K BACK Assign a BORA Band to Catherine CG-FLG		
Q Search	Stage V3 Choose a sensor to assign	
Model	Serial number	
BB-100	BBBAAC	
BB-100	BBBAAA	
BB-100	B36ACZ	
BB-100	B36AFG	
BB-100	B36AEA	
Display 50 C elements per page	Previous page 1 Next page	5 elements in total

**5** Configure alerts on patient's measurements you would like to monitor.

Note that by default alerts are disabled, you have to manually activate alerts that you want to see in the dashboard.

Enable alerts and customize them according to your needs (e.g alerts settings).

DACK Assign a BORA Dand to Ortherine CG-F	EG			
		Stage 2/3		
	Confi	gure alerts for the ses	sion	
🕕 astroneticone transforme	<ul> <li>Number of measurements</li> <li>Windows</li> </ul>	to least lan 30 company	() Wearing be wistherables- time	than 60% of the
🗇 Guygert satural on	ster tree 1 €	0	🕞 Kespiratory rete	0
CREATE AN ALERT				
	(PREVIOUS)	) 🗥 🚾	XT	

6 Verify the selected device and the alerts configuration and confirm to start patient remote monitoring.

BACK Assign a BORA Band to Catherine C	S-FLG
	Stage 3/3
	Summary
Wristband to be assigned: BB-100 B36	AFG
Patient to equip: Catherine CG-FLG	
2 configured alerts:	
Oxygen saturation	Heart rate
Add a session start comment:	
	(PREVIOUS)

**7** Note that you can modify patient's alerts afterward in the «Alerts Setup» section of the patient details page.

& Patient informations
♣ Alerts configuration
ື່ງ Alerts and comments history
Measures



### How to customize an alert?

There are 2 types of alerts available:

1. **Technical alerts** that cannot be customized, related to the wearing of the bracelet, the number of measurements taken and the data transmission.

2. **Clinical alerts** related to respiratory rate, heart rate and oxygen level that can be customized (possibility to combine several alerts and to configure them with a threshold trigger based on a fixed limit or on the evolution of the patient's baseline.

#### ETechnical alerts

Last connection more than 48h ago	
Number of measurements less than 30 over past 48 hours	
Wearing the wristband less than 60% of the time	

If the device did not connect with Bora connect® in the last 48h ago, this alert will be raised

If the number of one vital sign is less than 30 over past 48h, this alert will be raised

If the wristband was used less than 60% of the time, this alert will be raised

#### **EClinical alerts**

You can either customize an already existent alert or create a new one.





To customize a clinical alert, click on the 🖉 button.

To create a new alert click on this button.





When you click on the button "new condition", you will have to choose which type of condition you wish to add:



A condition based on one or two fixed terminal (s) (ex: Alert raised when saturation is below 95%).

Note that the median is calculated over 48 hours.

A condition based on one or two terminal(s) calculated on a variation from the patient's baseline (ex: Alert raised when HR has a variation of 20% compared to the baseline).

Note that the median is calculated over 48 hours and the baseline is calculated as the median over the last 15 days.



Note that in case several conditions are created in the same alert, it is possible to choose to trigger the alert if all conditions are met or only if one of the conditions is met.

In this example, the alert will be raised if oxygen saturation is inferior or equals 92% **OR** respiratory rate is superior or equals 30 cpm.



### How to stop a patient monitoring session?

To stop patient remote monitoring, simply click on the <b>Stop monitoring session</b> button.	
Last connection date : Wednesday, October 20, 2021 2:00 AM	B36AAV
Monitoring period : 02/07/2023 (16 days) * Stop monitoring session	
& Patient informations	

### How to visualize the alerts?

Head to the Dashboard menu to check for patient alerts.

Patients whose features have triggered an alert are signaled with a red indicator at the top of the dashboard.

		M	s Aline EXA-AFI		
ď	Harper LEE une de		Bora connect		
Ż	Dashboard	Dashboard			
8	Patients	Q Search for a patient	Filter by alert type 🛛 💿 💿		
ų,	Doctors	Ms. Marie MF-3FM	'é Gregory ×EVES	6000	۲
		Mr. Antoine EXA-40	S Pierre BOTTERO	<b>6 0 0 0</b>	۲
*	HHCPs	Ms. Anne EXA-AEV	Se Pierre DOTTERO	6 💿 🖸 🚳	•
		Mr. Adrien EXA-ALO	Verine BOTTERO	O O O	0
2	BORA Bands	Ms. Amending EXA ABL	S Pierre BOTTERO	6 6 0 6	۲
Þ	Surveys	Mr. A ban EXA-AE7	G Pierre DOTTERO	6000	۲
-		Ma Aine FXA-AFI	6 Pierre BOTTERO	6000	0
Ø	Roles	Mr. Adam EXA AET	6 Pierre BOTTERD	0000	•

Depending on the parameters involved, the alert symbol enabled differs:

0	Alert is related to a technical problem: wearing the bracelet < 60% of the time, low data feedback (>30 over 48h sliding), no connection for 48h
Oz	Alert is related to the patient's oxygen level
<b>(20)</b>	Alert is related to the patient's heart rate
<i>(</i> 7)	Alert is related to the patient's respiratory rate



It is possible to filter by type of alert to see only those that interest you.

Dashboard			
Q Search for a patient	Filter by alert type	000	
Ms Aline EXA-AFI		Å	Pierre BOTTERO
Mr Michel POLNANEF		Å	Pierre BOTTERO
Mr Pierre PETIT		ĥ	Carlos RUIZ ZAFON
Ms Caroline GENTIL		Å	Carlos RUIZ ZAFON

**BIOSENCY** 

### How to resolve an alert?

Click on a patient for whom an alert is raised. You will see the patient's alert history and comments written by other health actors to help you get a tracking history of actions.



2 Active alerts are red colored and resolved alert are greyed out

3 Click on the core button (adding a comment is mandatory) then click on the corre button to close the alert. 4 The alert has been closed and is now grayed out.

-	Harper LEE	Alert and comment history for Al Alert number: 1	Boraconnect ine EXA-AFI	8
	09/07/2022 9:25 AM	Last connection more than /8h age	0000	
	04/10/2022 12:23 AM	Number of measurements less than 30 over past 48 hours	0000	
	03/31/2022 1:23 AM	Respiratory rate		
	03/25/2022 3:23 AM	Respiratory rate		<b>(</b> )
	03/24/2022 7:23 AM	Respiratory rate		(E) 🚱
	_			

Note: You can close multiple alerts at the same time with the D button at the top left.

Tick the alerts you wish to close and click on the close naces button.

0	Harper LEE Breads		t Alert and comment history for Alit Alert number: 1	Boraconnect ne EXA-AFI	×
	<ul> <li>O9/07/2022 9:26 /</li> </ul>	M O	Last connection more than 48h ago	8000	
	04/10/2022 12:23	м 🔶	Number of measurements less than 30 over past 48 hours	000	
	03/31/2022 1:23	м 🔶	Respiratory rate		
	03/25/2022 3:23		Respiratory rate		
	03/24/2022 7:23	м	Respiratory rate		a la
					CLOSE () ALERT)

### How to comment an alert / follow up a patient history?





2 Your comment will appear under the alert.

(	Harber LEE	Doraconnect Alert and comment history for Aline EXA-AFI Alert number:1	->
	09/07/2022 9:26 AM 💿	Last connection more than 48h ago S S S S Context (D)	
	04/10/2022 12:23 AM	Number of measurements less than 30 over past 48 hours	
	03/31/2022 1:23 AM	Respiratory rate 💿 💿 💿 🕒	
	03/25/2022 3:23 AM	Respiratory rate	tal
	03/24/2022 7:23 AM	Respiratory rate	- 1
			- 1
	_		-





How to visualize the clinical data related to the alert?

Click on the *w* button to to view the patient data related to the alert.





### How to disinfect a wristband Bora band @?

When ending a remote monitoring session, the Bora band® used during the session will automatically be set to the "To disinfect" status.



Select the Bora band® to disinfect in the list.



Click on the button to begin the disinfection process.



3 In the next screen, confirm that you have executed each step to complete the disinfection.

You can optionally add comment.

Click on the	SUBMIT	but
confirm the disinfect	tion.	

on to

Once you have disinfected your Bora band®, they are available for the next monitoring session.

K BACK 3 BORA Band(s) selected
Mark BORA Bands as disinfected :
The BORA Band was disinfected.
The BORA Band wristband was replaced.
The BORA Band package was checked. It contains a user manual, a quick tutorial, a spare wristband and a charger.
The BORA Band package, spare wristband, charger, user manual and tutorial were checked.
Comment
SUEMD
Mark BORA Bands as disinfected :
The BORA Band was disinfected.
The BORA Band wristband was replaced.
The BORA Band package was checked. It contains a user manual, a quick tutorial, a spare wristband and a charger.
The BORA Band package, spare wristband, charger, user manual and tutorial were checked.

This is the end of patient remote monitoring section. In the next part, you will see graph visualization.



# **3** Patient measurements

Bora connect® allows you to consult patient measurements. Go to the patient detail page by clicking on the 
button.

For a patient equipped with a Bora band®, you will have access to oxygen level, respiratory rate, heart rate, activity duration and number of steps.

### How to set up the Bora connect® interface clinical data?

Bora connect has 2 types of graphs available:



Standard mode

To switch between the different mode, go to graph parameters by clicking on the button.





r Yann LE C	UILLOU		
nents histo	ry		
	PDF export		Advanced parameters
	MONTH	WEEK	DAY
	12/18/2020 - 0	1/17/2021	0
ţţţţ	۽ مول ا		Synthesis Measures 28/31 days 3rd quartile 96.8 % Median 94.7 % Ist quartile 91.8 %
State	andard		and quartile median 1st quartile
O Ad	vanced		95th percentile 3rd quartile median 1st quartile 5th percentile

Select the preferred mode:



You can modify the order of the graphs display by a simple drag & drop operation in the list below

ſ	Modify displayed graphs	
~	■ Oxygen saturation	
	■ Respiratory rate	
	≡ Heart rate	-
	Temperature	
	≡ Activity	-
	≡ Steps count	-

You can also enable or disable the display of specific graph. Simply click on the <

#### STANDARD MODE

Below is the representation of heart rate of a patient in standard mode.





Below is the representation of oxygen level of a patient in advanced mode. Measurements are represented with a boxplot.



#### DISPLAY CONFIGURATION

View :	MONTH	WEEK	DAY
Measures :	(245)	ġ.	J

The display menu allows to switch between month, week, or day view.

You can also display only diurnal or nocturnal values to focus specific period of the day.

24h	Default mode: all values are displayed
淤	Diurnal mode display measurements taken from 8:00am to 11:00pm
$\bigcirc$	Nocturnal mode display measurements taken from 11:00pm to 8:00am



#### **GRAPH NAVIGATION**

Click on the date picker button to select a period to display



### How to export a PDF from the platform?

1 Click on the 🗾 button to	YOUR PATIENTS Mr Yann LE GUILLOU
export measurements.	Alerts and comments history
	Measures
	Parameters Watchfulness O2 (%) PDF export Advanced parameters
	Display View: MONTH WEEK DAY
2 Select the period of	K BACK Export health data for Yann LE GUILLOU
measurements you wish to export:	Select the period to export
<ul> <li>Complete : to export all patient measurements</li> </ul>	<ul> <li>Complete</li> <li>By sessions</li> </ul>
• By sessions : select among the different monitoring session of the patient	
<ul> <li>By dates: select a start date and an end date</li> </ul>	05/29/2020     01/09/2023   Anonymize the export ?  The patient's name will be replaced by their initials, age and gender.
	Comment



3 You can anonymize the	K BACK Export health data for Yann LE GUILLOU
PDF export. Simply click on the	
button Anonymize the export ? 🤍	Select the period to export
Patient's name will be replaced	Compare     By sessions
by their initials, age and gender.	-
You can type a specific com- ment which will be included in the PDF export.	By dates:         Starting date:         o5/29/2020         OV/09/2023    Anonymize the export ? <ul> <li>The patient's name will be replaced by their initials, age and gender.</li> <li>Comment</li> <li>Export of last monitoring session</li> </ul>



After a short while, you will receive a PDF export in your mailbox. Below is a sample PDF export:

-	Complete		
0	By sessions		
0	By dates		
	Starting date : 05/29/2020	Ending date : 01/09/2023	
And The	onymize the export ?	laced by their initials, age and gender.	
And The	onymize the export ?   patient's name will be rep ment	laced by their initials, age and gender.	
And The	onymize the export ?	laced by their initials, age and gender.	





The PDF export will use your current graph settings for the PDF file. Modify your current display settings to alter the PDF export.

### How to create a survey on Bora connect®?

1 You can submit a survey to patients who uses Bora connect® mobile application.

Go to the survey menu to create a survey campaign. Click on the button

Surveys						ADD
Q Search						
Name	Туре	Starting date	Ending date	Frequency		
VQ11	BPCO-VQ11	Mar 2, 2022	Mar 4, 2022	Weekly	0	
VQ11	BPCO-VQ11	Mar 2, 2022	Mar 2, 2022	Daily	0	
Fibrosis patient follow-up	BPCO-VQ11	Feb 4, 2022	Feb 4, 2022	Every two days	۲	
Fibrosis patient follow-up	Direct	Feb 4, 2022	Feb 4, 2022	Monthly	0	
Dr Le Guillou VQ11	BPCO-VQ11	Sep 20, 2021	Oct 21, 2021	Weekly	0	
COPD VQ11	BPCO-VQ11	Jun 11, 2021	Jul 13, 2021	Weekly	$\bigcirc$	
Exascore follow-up	Exascore	May 19, 2021	May 22, 2021	Daily	$\odot$	
Survey Direct	Direct	Apr 12, 2021	Apr 12, 2021	Daily	$\odot$	
EXASCORE clinical study	Exascore	Feb 10, 2021	Feb 11, 2021	Daily	$\odot$	
Rennes hospital	BPCO-VQ11	Aug 31, 2020	Aug 31, 2020	Weekly	$\odot$	
Respiratory study	BPCO-VQ11	Jun 26, 2020	Jun 26, 2020	Daily	0	
BPCO follow-up	BPCO-VQ11	Jun 22, 2020	Jul 1, 2020	Weekly	$\bigcirc$	
BPCO clinical study	BPCO-VQ11	Apr 2, 2020	Apr 4, 2020	Daily	$\bigcirc$	
Display 50 elements per page			Previous page 1 Next page	8		13 elements in total

2 Enter a name for the survey, select your survey type and its frequency.

C BACK Add a survey			
Name :			
Type :		<ul> <li>Frequency :</li> </ul>	*
Starting 81/12/2023		Ending date :	
Patients list			
Q Search			
Cender	Firstname	Lastname	Birth date
Ms	Perelle	Cécile	Feb 16, 1949
Mr	Adam	LABROSSE	Oct 18, 1976
Mr	Jean	JF-JFM	Sep 22, 1967
Mr	Ferdinand	FB-JFM	Apr 29, 1963
Mr	Aubin	SAHALOR	Sep 9, 1939
Mr	Thierry	TB-JFM	Nov 13, 1957
Ms	Anne	AP-JFM	Oct 4, 1966
Ms	Annie	AMD-FLG	Jul 11, 1938

3 types of surveys are available:

Direct	۲
BPCO-VQ11	0
Exascore	0

Select the frequency of the survey:

Daily	۲
Every two days	0
Weekly	0
Monthly	0



**3** Select a starting and ending date:

K BACK Add a survey	
Name :	
Type :	Frequency :
Starting date : 01/12/2023	Ending date :
Patients list	

Finally, select the patients who will receive the survey. Click on the patients in the list.

Click on <u>the button to</u> confirm the survey creation.

K BACK Add a survey			
Name :			
Type :		<ul> <li>Frequency :</li> </ul>	*
Starting date :		Ending date :	
0/12/2023			
Patients list			
Q Search			
Gender	Firstname	castname	Birth date
MS	Perelle	Cecile	PeD 10, 1949
Mr	Adam	LABROSSE	OCT 18, 1976
Mr	Jean	JF-JFM	Sep 22, 1967
Mr	Ferdinand	FB-JFM	Apr 29, 1963
Mr	Aubin	SAHALOR	Sep 9, 1939
Mr	Thierry	TB-JFM	Nov 13, 1957
Ms	Anne	AP-JFM	Oct 4, 1966
Ms	Annie	AMD-FLG	Jul 11, 1938
Mr	Corectio	CRIEIC	Mar 18, 1975
	Corentan	08-100	

**5** The next time a patient open Bora connect mobile, a survey notification will appear and ask the patient to complete the survey.





#### Patient can answer the survey on his phone



	BEGIN					
•	• • • • • • •	• •			• • • • • • • • •	
111	0	<		111	0	<

6 You can consult patient answers in his detailed page below the graph measures.

Quality of life			
Date	Туре	Score	
06/09/2020	Direct	14	۲
09/18/2020	Exascore	18	0
09/22/2020	Exascore	16	•
02/09/2022	Exascore	23	•
02/09/2022	Exascore	15	•

Click on the Solution to consult patient answers for each survey

<b>ल</b> :	Charles NGOR liosency	Boraconnect
٢	Dashboard	¢ BACK
8	Patients	6 rest
Ŷ,	Doctors	Firstname : Charles NGOR Date : 18/09/2020
*	HHCPs	Quality questionnaire of life BPCO-EXASCORE
٥	BORA Bands	The following statements assess your current respiratory condition. - No discomfort
	Surveys	Discrete or moderate discomfort     Important, but bearbaile discomfort     Very important discomfort difficult to tolerate     Intelerable discomfort.
0	Roles	For each of the questions to be followed, point out your level of discomfort.
鹵	Structures	1.1 spit a lot 3
		2. I feel tense 3
		3. My cough exhausts me 2
۹	• 100%	4. I become withdrawn on me 3
		5. I feel blocked 2
۰	Settings	6. I find it difficult to concentrate
G	Logout	7. I get breathless by eating or speaking 1
Version :	2.8.1-staging	8. Fam anxious 3



# Doctor

In case you would like to add a doctor, please contact Biosency support.

Doctors L	ist							
Q Search	1							
Firstname	Lastname	Gender	E-Mail		Professional ID	Phone number	Creation date	
Pierre	Bottero	Mr	pierre.bottero.bi	o@yopmail.com		+33622334455	Feb 21, 2020	0
Carlos	Ruiz Zafon	Mr	carlos.ruiz.zafon	.bio@yopmail.com	112049191	+33103954815	Mar 4, 2020	$\bigcirc$
Alex	LeMedecin		alex.lemedecin.l	bio@yopmail.com			Dec 15, 2020	$\bigcirc$
Display 50 e	lements per page			Prev	vious page 1 Next page			3 elements in total
Services L	.ist							ADD
Q Search	i							
Name		Description		Creation date				
Service 1				Jan 6, 2021	0		0	
Service3		Fibrosis servi	ce	Jan 8, 2021	0		0	
Service 1-2				Jan 6, 2021	0		0	
Remote servi	ce			Dec 14, 2021	0		0	
Display 50 e	lements per page			Prev	vious page 1 Next page			4 elements in total



# **Services list**

You can create a service which regroups multiple doctors. A service can then be associated to a patient. All doctors in the service will then be able to consult the patient data.

To create a service, click on the	ADD	button
-----------------------------------	-----	--------

Services List						ADD
Q Search						- I
Name	Desc	cription	Creation date			
Service 1			Jan 6, 2021	0		0
Service3	Fibro	osis service	Jan 8, 2021	٢		0
Service 1-2			Jan 6, 2021	$\begin{tabular}{ c c c c } \hline \hline & \hline \\ \hline \\$		0
Remote service			Dec 14, 2021	$\begin{tabular}{ c c c c } \hline \hline & \hline \\ \hline \\$		0
Display 50 element	ts per page		Previous page 1 Ne	ext page		4 elemerts in
K BACK Add a	a service					
Name :					←	
Description :						
Doctors List						
<b>Q</b> Search						
Firstname	Lastname	Gender	E-Mail	Professional ID	Prefix	Phone number
Pierre	Bottero	Mr	pierre.bottero.bio@yopmail.com		+33	622334455
Carlos	Ruiz Zafon	Mr	carlos.ruiz.zafon.bio@yopmail.com	112049191	+33	103954815
Alex	LeMedecin		alex.lemedecin.bio@yopmail.com			
Display 50 elemen	nts per page		Previous page 1 Net	xt page		3 elements in tot
ADD						

Enter a name for the service. An optional description can be added.



#### Select the doctors to add to the service by clicking items in the list

K BACK Add a s	service					
Name :						
Description :						
Doctors List						
<b>Q</b> Search						
E Firstname	Lastname	Gender	E-Mail	rofessional ID	Prefix	Phone number
Pierre	Bottero	Mr	pierre.bottero.bio@yopmail.com	K	+33	622334455
Carlos	Ruiz Zafon	Mr	carlos.ruiz.zafon.bio@yopmail.com	112049191	+33	103954815
Alex	LeMedecin		alex.lemedecin.bio@yopmail.com			
Display 50 elements	per page		Previous page 1 Nex	t page		3 elements in total
ADD						

Click on the \_\_\_\_\_ button to confirm the service creation.

# **HHCPs**

This page allows you to manage the creation of HHCP accounts. Click on \_\_\_\_\_ the button to add a new HHCP account.

#### Health actors

<b>Q</b> Search								
Firstname	Lastname	Gender	E-Mail	Phone number	Creation date	Author		
Harper	LEE	Mr	harper.lee.bio@yopmail.com	+33655468990	Feb 4, 2020		0	
Charles	Italian	Mr	charles.italian@yopmail.com		Jun 7, 2022	Harper LEE	$\bigcirc$	0
Sylvain	Italian	Mr	sylvain.italian@yopmail.com		Jun 7, 2022	Harper LEE	0	0
Yannick	Nouet	Mr	yannick.nouet@biosency.com		May 19, 2021	Gilles GIANNOLI	$\bigcirc$	0
Sylvain	Magnin	Mr	sylvain.magnin@biosency.com		Apr 8, 2021	Harper LEE	0	0
Haloui	Houda	Ms	houda.haloui@gmail.com		Feb 3, 2021	Harper LEE	0	0
Gilles	Giannoli	Mr	mbr.biosency@yopmail.com		Feb 3, 2021	Harper LEE	$\bigcirc$	0
Chantal	ASTARAC	Ms	chantal.astarac@yopmail.com	+33644553377	May 4, 2020	Harper LEE	$\bigcirc$	0
Jean	BAMBOIS	Mr	jean.bambois@yopmail.com	+33644556678	May 4, 2020	Harper LEE	$\bigcirc$	0
Charles	Ngor	Mr	charles@biosency.com		Jul 22, 2021	Harper LEE	$\bigcirc$	0
Jiggles	Mister	Mr	mr.jiggles@yopmail.com		Apr 12, 2022	Harper LEE	$\bigcirc$	0
Billy	Soptekeu	Mr	bsoptekeu@yopmail.com		Apr 12, 2022	Harper LEE	$\bigcirc$	0
Billy	SOPTEKEU	Mr	bsoptekeu@intermedcon.com		Apr 8, 2022	Harper LEE	$\bigcirc$	0
azur	02	Mr	azur.o2@yopmail.com		Feb 15, 2022	Harper LEE	$\bigcirc$	0
Laura	Colin	Ms	laura.colin@biosency.com		Sep 7, 2021	Harper LEE	$\bigcirc$	0
Edith	PIAF	Ms	epiaf@hotmail.fr	+33	Mar 2, 2022	Harper LEE	0	0



K BACK Add a health actor	
Gender :	
Language :	•
Lastname :	
Firstname :	
E-Mail :	
Prefix :  Phone number :	
Role :	•
ADD	

Select a role for the HHCP account.

Role :	
StructurePharmacist	0
StructureTechnician	0
External role	0
Admin role	0
Technician role	0

Roles can be configured in the Roles page. Roles allows you to grant specific permissions for HHCP users.

Click on \_\_\_\_\_ the button to add the HHCP user.



# Roles

This page allows to manage the creation of roles for HHCP users. Roles allows you to grant specific permissions for HHCP users.



Roles list	ADD
Q Search	
Name	Description
StructurePharmacist	Structure pharmacist
StructureTechnician	Structure technician
External role	o / 1 ()
Admin role	0 0 D
Technician role	O O O O
Display 50 elements per page	Previous page 1 Next page 5 elements in otal
Name : Description : Select permissions	
Name	Description
Patients management	Access patients list Create a patient Start or stop a monitoring session Access BORA Band Bist Access BORA Band details Access a patient's data Access doctors list Update a patient Create a service Update a service Delete a service Access the list of doctors in a service Access services list
Patients deletion	Access patients list Access a patient's data Delete a patient



Select the permissions you want to grant to this new role by clicking on items in the list.

К ВАСК Add a role	
Name :	
Description :	
Select permissions	
Q Search	
Name	Description
Patients management	Access patients list Create a patient Start or stop a monitoring session Access BORA Band details Access BORA Band details Access a patient's data Access doctors list Update a patient Create a service Update a service Delete a service Access the list of doctors in a service Access services list
Patients deletion	Access patients list Access a patient's data Delete a patient
Patients and surveys related data	Access patients list Access questionnaires on the patient's quality of life Access a patient's answers to a questionnaire on their quality of life Access a patient's data
Doctors related data	Access patients list Access doctors list Access a doctor's details and his list of patients the doctor is following Create a service Update a service Delete a service Access the list of doctors in a service Access services list

Click on the

button to confirm the creation of the role.



# **Bora band**®

This page allows you to manage your Bora band®.

Bora band® are classified in 4 states:

Available	Bora band® is ready to be assigned to a patient
Assigned	Bora band® is currently assigned to a patient
To disinfect	Bora band® must be disinfected before being allowed to be assigned
	to a new patient
In maintenance	Bora band® is under investigation or being repaired by Biosency

BORA Bands					
Q Search					
Available					
Model		Serial number			
BB-100		B38ABT		()	)
BB-100		B36AAH		()	
Display 50 v elements pe	er page		Previous page 1 Next page		2 elements in total
Assigned					
Model	Serial number	Patient	Assignment date		
BB-100	C17ABH	Marie STUART	02/04/2020	• •	
BB-100	C17BDB	Michel POLNAREF	11/10/2021		
Display 50 🗸 elements pe	er page		Previous page 1 Next page		2 elements in total
To disinfect					
Model					
BB-100		B37BBT		٥	)
Display 50 🗸 elements pe	er page		Previous page 1 Next page		1 elements in total
In maintenance					
Model	Serial number	Mainte	enance status	Comment	
No data					
Display 50 v elements pe	er page		Previous page 1 Next page		0 elements in total

Click on the 📀 button to assign the Bora band® to a patient.



Click on the O button to consult details of a Bora band®.

vailable				
<b>N</b> odel	Serial number			
BB-100	B38ABT		٢	0
BB-100	ВЗбААН		٢	0
play 50 v elements per page		Previous page 1 Next page		
ВАСК			<del>(                                    </del>	
30RA Band details				
Model: BB-100 Serial number: BBBAAA		Status: Maintenance status: Allocation date:	Available None 06/19/2020	
		1		)
BORA Band events	Message	1		Author
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BORA Band events Date 12/14/2022 3:31:59 PM 12/14/2022 3:30:41 PM 12/14/2022 3:30:27 PM 11/10/2022 1:205:28 PM 11/10/2022 1:205:28 PM 09/06/2022 4:01:03 PM 04/07/2022 9:45:45 AM	Message Disinfected BORA Band BORA Band removing End of monitoring session for Thierry M BORA Band assignment Beginning of monitoring session for Th Disinfected BORA Band BORA Band removing End of monitoring session for Adam E) BORA Band assignment Beginning of monitoring session for Adam E) Disinfected BORA Band	I IARTIN Iierry MARTIN GA-AET		Author Harper LEE Harper LEE Sylvain MAGNIN Sylvain MAGNIN Harper LEE

You can consult the details of the Bora band®: model, serial number, status, date of allocation to your structure.

An event table list all events of the Bora band® (assignment to patient, status modification).



# **Settings**

This allows you to manage your personal data and settings.

► CE2797

You can edit your identity, email address, and modify the interface language. Click on the **UPDATE** button to confirm changes.

### Multi-factor authentication

Click on the **RESET THE PAIRED DEVICE** button to reset the phone number associated to your account (the phone number which receives the one-time password code during authentication). A new phone number will be requested the next time you login to Bora connect.

### Password

Click on the REQUEST PASSWORD CHANCE button to request a password change. You will receive an email which contains a reset password link.



### Forgotten your password?

If you wish to change your password or you have forgotten your password, you can request a change password in the login page.

Click on "Don't remember your password?". An email containing a reset password link will be sent to you.

If you have trouble with changing your password, contact Biosency support (see at the end of the user manual).





# Meanings of figures, symbols, and abbreviations

	Click to start a monitoring session
	Click to end a monitoring session
0	Click to consult
\$	Click to add as a favorite
*	Click to add remove from favorite
0	Click to delete
	Click to modify
B	Click to duplicate
RR (CPM)	Respiratory rate (Cycle per minute)
HR (BPM)	Heart rate (Beat per minute)
SpO2 (%)	Oxygen saturation (percentage)
Act (h)	Activity duration (hour)
0	A technical alert is active
Θ	Technical alert is not active
02	An oxygen level alert is active
	Oxygen level alert is not active
<b>S</b>	A heart rate alert is active
	Heart rate alert is not active
(A)	A respiratory rate alert is active
	Respiratory rate alert is not active
	Add a comment on an alert
Д.	Consult patient graphs on date of alert
0	Select several alerts for closing

# Logout from bora connect

Use the "Logout" button at the bottom-left of the application.

Logout

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# Bora connect<sup>®</sup> software update and maintenance

Bora connect® platform is automatically updated when a new version is available. A communication is made by Biosency ahead of the update if there is an interruption of service or to present new functionalities.

#### s **PRECAUTIONS**

#### VERSION OF BORA CONNECT MOBILE

To benefit from the latest developments, make sure you are using the latest version of Bora connect® mobile application.

Bora connect® mobile application displays a notification at the connection if a new version is available in the store.



# Data storage

Bora connect® data is encrypted and hosted by a certified health data hosting provider.

For data storage, Bora connect® uses a 256-bit AES-256-GCM key format to secure the data.

Data retention period is defined in the privacy policy available in the section Personal data Protection Policy of the website: <u>doc.bora-connect.com</u>.

Personal data are archived for 5 years after the end of the contract. After then, they are deleted.

Connection logs are stored for 1 year. After then, they are deleted.

About Bora connect® mobile application, no personal data are stored on the phone device. Personal data are loaded on the RAM memory during application use and are deleted afterward.



# **Data access**

# Healthcare workers and professionals

Connect to the Bora connect® platform or mobile application:

- to view your patients' data.
- to view the status of your Bora bands fleet.

# **Patients**

Patient can connect to Bora connect® platform or mobile application: to check the status of their Bora band®, and to consult their physiological data.

Patient can connect to bora connect for home or study to check the status of their Bora band®.



For our warranty and support conditions, please refer to our general subscription conditions -available at <u>doc.</u> <u>bora-connect.com</u> - in the following paragraphs:

DURATION OF SUBSCRIPTION-CONTRACTS-- RENEWAL - TERMINATION

CONDITIONS SPECIFIC TO THE PROVISION OF THE BORA CONNECT PLATFORM; paragraph support function

# **Guarantee exclusion**

For our warranty and exclusion conditions, please refer to our general subscription conditions in the following paragraphs:

RESPONSIBILITIES, GUARANTEES AND EXCLUSIONS

# Incidents

Any serious incident which occurs in connection with Bora connect® should be reported to the manufacturer and the competent authority of the Member State where the patient resides.

# Support

In case of issue, contact Biosency at support@biosency.com or at 0 800 910 073.



Bora connect platform is a web-based platform, Bora connect® is not installed on your computer.

Bora connect mobile application, Bora connect for Home and Bora connect for Study can be uninstalled in the same way as any other applications, depending on how your mobile phone works. In general, a long press on the application's logo brings up a menu allowing you to uninstall the application.



# Cybersecurity

This chapter provides a set of precautions and warnings to guard against cybersecurity risks. In order to guarantee the confidentiality, integrity and security of your personal data, you are strongly advised to read the information below.

Please consult this page which contains device residual risks, an overview of the security management of our platform, useful information for the safe use of the medical device and recommendations to protect yourself from cybersecurity risks:

https://doc.bora-connect.com

### Security options

Bora connect® is a web platform. Security updates are deployed automatically. There are no specific security options for the use Bora connect®. Refer to the security recommendation section in <u>https://doc.bora-connect.com</u>

### Auditing and logging

Bora connect® has the ability to reliably audit activity on the device. Bora connect® creates additional audits logs for any action in the platform. Data subject is identified for each personally identifiable information event in the log.

### Security impact

In case of Bora connect® should fail to maintain security, the following impact to patient care would be the interruption of his remote monitoring which would only cause a delay in patient care.



# **Specifications**

### Performance

For measurements accuracy please refer to the device's instruction for use.

Data		Display range	Display accuracy
Measurements			
Oxygen saturation		70% - 100% Sp0 <sub>2</sub>	±1%
Heart Rate		35 – 240 bpm	±1bpm
Respiratory Rate		10 – 50 cpm	±1cpm
Temperature		10 – 43 °C	±0,1°C
Activity		0 – 24 h	±1min
Step		0 – 2 <sup>63</sup> -1 steps	±1step
Median & quartil	es		
Oxygen saturation		70% - 100% Sp0 <sub>2</sub>	±1%
Heart Rate		35 – 240 bpm	±1bpm
Respiratory Rate		10 – 50 cpm	±1cpm
Temperature		10 – 43 °C	±0,1°C
Activity		0 – 24 h	±1min
Step		0 – 2 <sup>63</sup> -1 steps	±1step
	1		
Lifespan	3 yeai	ſS	

### Conformity

Software	IEC 62304
	IEC 82304-1



# **Clinical benefits**

Improving the quality of life is a possible clinical benefit of setting up remote monitoring with the Bora band® and Bora connect®. The clinical parameters displayed on Bora connect® can be used by practitioners to optimize respiratory assistance prescriptions, and also allow the monitoring and maintenance of improvements during respiratory rehabilitation.

Preventing the worsening of chronic respiratory pathologies is a possible clinical benefit of using Bora connect® in combination with Bora band®. Changes in the clinical parameters displayed by Bora connect® may be an alert criteria for a future deterioration in a patient's state of health.



Bora band® and Bora connect® are registered trademarks of Biosency in France and Europe.





This chapter describes the symbols that are used on the product or its packaging.

	Please consult the user guide before using the device.
$\bigotimes$	No alarm trigger.
<b>CE</b> <sub>2797</sub>	CE mark indicating compliance with current medical devices regulations. Notified body: BSI NL.
MD	Medical device.
UDI	Unique device identifier
	Manufacturer and date of manufacture.





