

BIOSENCY

Caring anytime, anywhere

Boraconnect®



Web platform & mobile application
for healthcare professionals and
stakeholders

User manual



Bora connect® version 3.0
Bora-connect_IFU_3.0_A September 2024

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Introduction

About this user manual

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

WARNINGS


USER MANUAL

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

Customers must first undergo training provided by the Biosency teams on how to use the Bora connect® medical device before operating it.

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

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.

To guarantee that the device is used in the best conditions, please carefully read the precautions for use and warnings marked by the  symbol.

Intended use

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

- transfer and display device information and physiological parameters that have been remotely transferred from the patient's device. The platform is designed to support medical monitoring of patients with chronic respiratory diseases.
- provide information for monitoring the physiological conditions, state of health or diseases of patients with chronic respiratory disease. Information can include visual notifications for patients who are outside thresholds previously defined in Bora connect by the healthcare professional.

Bora connect® is intended for use with compatible oximeters, heart rate sensors, respiratory rate sensors and Non-Invasive Ventilation remote monitoring software.

Bora connect® is also available as a mobile application.

Please refer to the "Accessories, information for optimal use" section for compatible accessories and devices.

The client organization (e.g. homecare provider) has access to Bora band® status information (device in use or available, battery level, etc.) through Bora connect®.

Contraindications

WARNINGS

ALARM

Do not use Bora connect[®] when alarms are required.

CONTINUOUS MONITORING

Do not use the 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.

Target population


Bora connect[®] is destined to be used by healthcare professionals and home healthcare provider staff.

Warnings and precautions

Warnings

- Do not use the Bora connect® without first reading and understanding all the instructions contained within this manual.
- Do not use Bora connect® when alarms are required.
- Do not use Bora connect® for continuous monitoring purposes.
- Do not use Bora connect® with accessories other than those provided by Biosency: Bora band® Model BB-100, Bora connect for Home BC4H, Bora connect for Study BC4S, Data feedback terminal.
- Install only one of these applications for patient use: Bora connect® mobile application, Bora connect for Home or Bora connect for Study. Otherwise, the collection of data by Bora connect® may be disrupted.

Precautions

- 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.
- The Bora connect® platform must only be used with accessories or devices provided by Biosency or its partners.
- To ensure the safe and optimal use of the device, please carefully read all the precautions for use and warnings marked by the  symbol.
- Bora connect® is intended to be used in combination with compatible accessories and devices.
- The information for safely combining the Bora connect® with Bora band® is available in the Bora band® user manual. This operation must be carried out by a qualified professional.
- To use the latest upgrades, make sure to use the latest version of the Bora connect® mobile application.
- To use the latest upgrades, make sure that the patient is using the latest version of Bora connect® mobile, Bora connect for Home, Bora connect for Study or the data feedback terminal.
- It is recommended to perform a risk analysis of your computer network by identifying, analysing, evaluating, and checking all of the risks related to the installation and use of the Bora connect®.
- It is important to check all the technical prerequisites outlined in the [Technical prerequisites](#) section and the cyber security information described in the [Cyber security](#) section and required for the Bora connect® to function in case of a change in your computer network.
- If a new risk is detected, please contact Biosency customer service as described in the [Assistance](#) section.
- Please safely save your connection information (username and password) and do not forget to secure access to your smartphone with a pin code or biometric recognition. This will prevent unauthorised and/or malicious third parties from accessing your data. Your connection information is strictly personal and must not be transmitted to a third party.

Accessories and devices, information for optimal use

WARNING

COMPATIBLE ACCESSORIES

Do not use Bora connect[®] with accessories or devices other than those provided by Biosency or its partners:

- **Bora band[®]** BB-100 standard kit (wearable device used for measuring patient physiological parameters)
- **Mobile application** that transfers data to and from the Bora band[®]: Bora connect for Home BC4H or Bora connect for Study BC4S
- **Data feedback terminal** (NGDF) that transfers data to and from the Bora band[®]
- **Software for remote monitoring of Non-Invasive Ventilation systems: AirView[™]**

Bora band[®]

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

Device	Description
Bora band [®] BB-100 standard kit	Bora band [®] standard kit (wearable device used for measuring patient physiological parameters)

Information on the safe combination of the Bora connect[®] with the Bora band[®] is available in the Bora band[®] user manual. This operation must be carried out by a qualified professional.

Patient data feedback

WARNING

PATIENT'S MOBILE APPLICATION

If a mobile application is used, install only one of these applications for patient use: Bora connect[®] mobile, Bora connect for Home or Bora connect for Study. Otherwise, the collection of data by Bora connect[®] may be disrupted.

PRECAUTIONS

VERSION OF BORA CONNECT[®] MOBILE, FOR HOME AND FOR STUDY

To use the latest upgrades, make sure that the patient is using the latest version of Bora connect[®] mobile, Bora connect for Home or Bora connect for Study.

Bora connect® requires a data feedback device to be installed alongside the patient:

- A mobile application: Bora connect® mobile, Bora connect for Home or Bora connect for Study. Only one of these applications should be installed for patient use. This operation must be carried out by a qualified professional.
- An NGDF data feedback terminal.


Device	Description
BC4H	Bora connect for Home, the patient’s mobile application that transfers data to and from the Bora band®.
BC4S	Bora connect for Study, the patient’s mobile application that transfers data to and from the Bora band® and collects the responses to the quality of life survey.
BC mobile (Patient account)	Bora connect® mobile for the patient, the patient’s mobile application that transfers data to and from the Bora band®, allows the patient to consult their data and collect responses to the quality of life survey.
NGDF data feedback terminal	New Gateway Device Firmware data feedback terminal, the patient feedback terminal that transfers data to and from the Bora band.

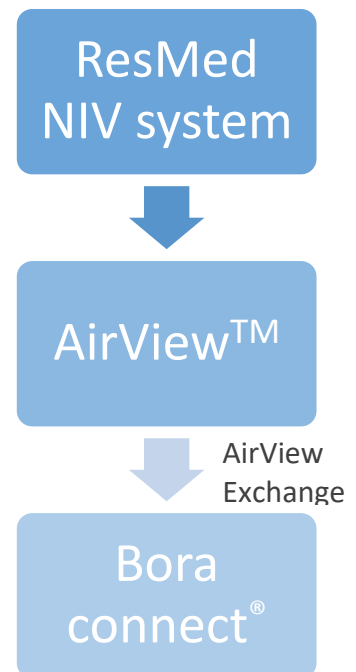
Information on the optimal use of the Bora band® with data feedback devices are available in the Bora band® user manual.

Software for remote monitoring of Non-Invasive Ventilation systems: AirView™

Bora connect® can be associated with Resmed’s AirView™ remote monitoring software. Clinical and technical parameters from the Resmed NIV device are first sent to the AirView™ platform, then transmitted to Bora connect® via the AVX (AirView™ Exchange) software brick, enabling the Bora connect® platform to display the data.

Information for pairing a NIV device with the Bora connect® is available in [the chapter "Pairing in devices"](#). This operation must be carried out by a qualified professional.

 It should be noted that to make the pairing possible, the transmission of data from the AirView™ platform to the Bora connect® must be authorised.



Bora connect® installation

PRECAUTIONS

COMPUTER NETWORK

The operation of Bora connect® on your computer network may lead to previously unidentified risks for patients, users or third parties. It is recommended to perform a risk analysis of your computer network by identifying, analysing, evaluating and checking all of the risks related to the installation and use of the Bora connect®. It is important to check all the technical prerequisites outlined in the [Technical prerequisites](#) section and the cyber security information described in the [Cyber security](#) section and required for the Bora connect® to function in case of a change in your computer network. If a new risk is detected, please contact the Biosency support team as described in the [Support](#) section.

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

The Bora connect® mobile application is installed just like any other mobile app, depending on your mobile phone's operating mode. The Bora connect® mobile application is available at the Google Play Store and the Apple App Store.

Technical prerequisites

Bora connect® web

- Processor: 1.4 GHz
- RAM: 2 GB
- Up-to-date browser supporting HTML5
- Resolution: min. 1920*1080
- Internet connection with access to:
 - <https://bora-connect.com>
 - <https://bora-connect.com>
 - <https://auth.bora-connect.com>
 - <https://psc.esante.gouv.fr/auth>
 - <https://insi.bora-connect.com>
 - <https://airview.resmed.eu/patients>



Bora connect® mobile application

- Processor: 1.4 GHz
- RAM: 2 GB
- Bluetooth®: 4.2 (Bluetooth Low Energy)
- Operating system: Android version N-5 (or iOS version N-3) with N being the latest version
- Networks: Wi-Fi with web, 3G, 4G or 5G access
- Resolution: 360 x 640 pixels








Important to note:

All the sections relating specifically to Bora connect® use with:

- The NIV module will be marked with the icon
- The Bora band module will be marked with the icon
- The module including French requirements for Digital Medical devices will be marked with the icon

The other, unannotated sections are valid regardless of which modules are activated.



Bora connect® enables:

- start remote monitoring sessions
-  • monitor patient physiological parameters
-  • monitor the patient's BVS³ score
-  • monitor the patient's NIV parameters
- configure and visualise alerts on patient physiological data
- export patient physiological data
- manage the accounts of patients, healthcare professionals and healthcare stakeholders
-  • start a patient survey
-  • manage the fleet of Bora band® wristbands




Depending on your role, you may not be able to manage the Bora band® fleet or the accounts of patients, healthcare professionals and healthcare stakeholders. Please refer to the Bora connect® administrator of your organisation.

Bora connect® offers different tabs:

- ▶ **Dashboard:** a list of all the organisation's patients, with a visual indication if a patient's status reaches an alert level.
- ▶ **Patients:** a list of all the organisation's patients with predefined filters (favourites, monitoring in process, not equipped).
- ▶ **Healthcare professionals:** a list of all the healthcare professionals and services connect to the organisation.
- ▶ **Healthcare stakeholders:** a list of all healthcare stakeholders except for healthcare professionals, involved in the patient's treatment.
- ▶  **Bora bands:** a list of all of the Bora bands® assigned to the organisation.
- ▶  **Surveys:** a list of all the surveys.
- ▶ **Roles:** a list of all the roles. Access to the Bora connect® pages depends on the user's role .
- ▶ **Parameters:** your personal data, consult the data privacy section and the Bora connect® label.

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

Bora connect® identification



The version of Bora connect® is displayed in the lower left of the application and is preceded by the word "version". The Bora connect® unique device identifier is displayed on the "Parameters" page and is preceded by the  symbol.

Use Bora connect[®] to manage a remote monitoring session

In this section, you will see the steps to follow during your first time using Bora connect[®]. This tutorial will teach you how to:

- ▶ Connect to Bora connect[®]
- ▶ Add a patient
- ▶ Start a remote monitoring session
- ▶ Configure alerts
- ▶ Monitor and export the collected data

These different points are arranged in chapters as shown below:

- 1 Start out on Bora connect[®]**
 - Connection via email
 - Connection via Pro Santé Connect. 
 - Add a patient file
 - List of patients
- 2 Start a remote monitoring session**
 - Step 1: Link device(s)
 - Step 2: configure alerts for the session
 - Step 3: start the remote monitoring session
- 3 Monitor the collected data**
 - Use the clinic dashboard and alerts
 - Reading and configuring of graphs
 - Report export
 - Create a survey 
- 4 Stop a remote monitoring session**

Refer to [the second part of the user manual](#) for details on each tab.

1 Start out on Bora connect®

After creating your Bora connect® account, you will receive a verification email from your administrator.

i If you are a healthcare professional, you will receive your email on your MSSanté email address.

Click on the link embedded in the email to create your account's password (remember to check your spam folder).

Your password must contain at least **10** characters and at least 3 of the 4 types of the following characters:

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

After creating your password, you will be redirected to the connection page.

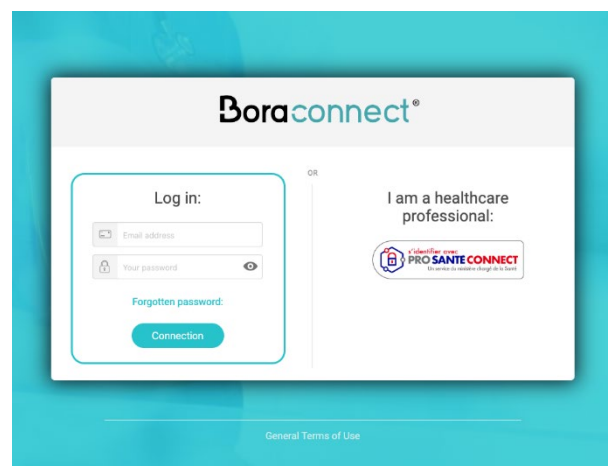
Connection via email

1 Enter your email address (which is your username), then your newly created password and confirm.

When you connect for the first time, you have to enter a phone number to activate the two-factor authentication.

Boraconnect®

Welcome
Your BORA Connect account has been created.
You can now define your password by clicking here.



2 Select your country code and enter your mobile or landline number.

Choose whether you want to receive the code by text message or voice call (the code is given orally).

By clicking “Continue”, you will receive your one-time code.

Boraconnect®

Secure Your Account

Enter your country code and phone number to which we can send a 6-digit code:

France, FR, +33

Enter your phone number

How do you want to receive the code?

Text message Voice call

Continue

Try another method

3 Enter the one-time code received.

Two-factor authentication will be required at least once every 6 months.

Boraconnect®

Verify Your Identity

We've sent a text message to:

+33 Edit

Enter the 6-digit code*

Continue

Didn't receive a code? Resend or get a call

Try another method

If it is your first time logging in, you will receive a recovery code on the platform that you can use in case you need to connect without your mobile phone.

i This recovery code can only be used once.

4 Keep this recovery code in a safe place.

Boraconnect®

Almost There!


Copy this recovery code and keep it somewhere safe. You'll need it if you ever need to log in without your device.

WJ77FX1KWB0202FLD358AK2B

Copy code

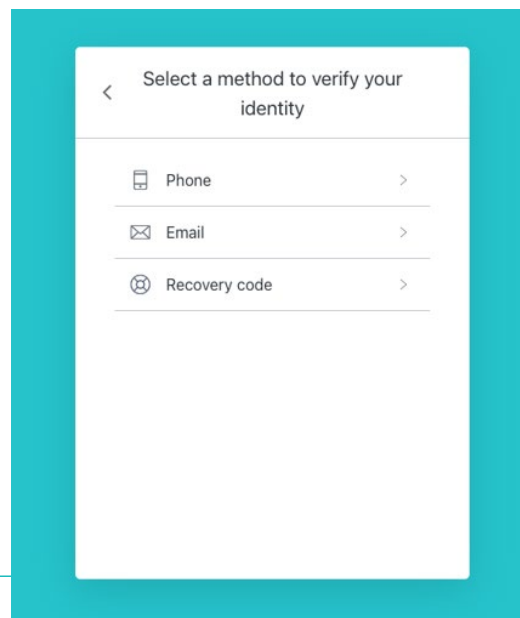
I have safely recorded this code

Continue

 When you next log in, you will be able to choose several ways of connection. By default you are asked to log in with a phone number. By selecting "Try another method" you will be able to choose between:

- Telephone (voice call or SMS)
- Email
- Recovery code

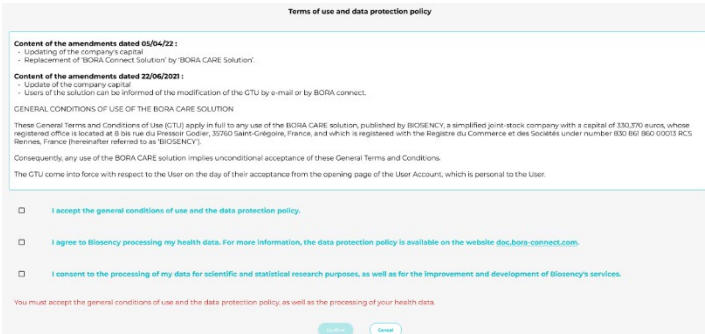
PRECAUTIONS



BORA CONNECT® LOGIN DETAILS

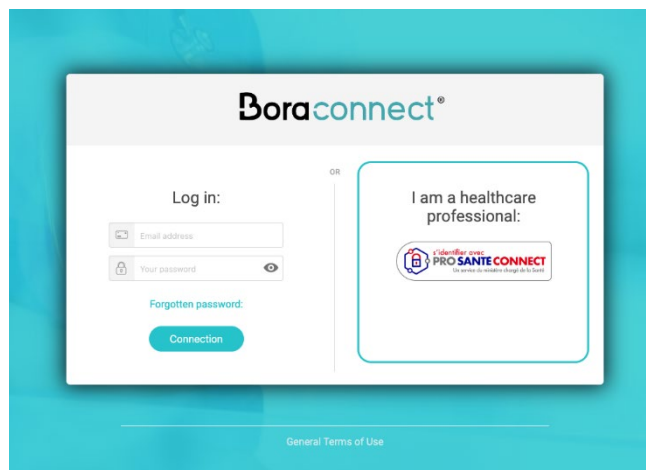
Please safely save your connection information (email address and password) and do not forget to secure access to your smartphone with a pin code or biometric recognition. This will prevent unauthorised and/or malicious third parties from accessing your data. Your connection information is strictly personal and must not be transmitted to a third party.

5 For the last step, you will be required to **consent to the processing of your personal data** on the Bora connect® platform.

A screenshot of a consent screen titled "Terms of use and data protection policy". It contains several sections of text, including "Content of the amendments dated 05/04/22:", "Content of the amendments dated 22/06/2021:", and "GENERAL CONDITIONS OF USE OF THE BORA CARE SOLUTION". Below the text are three checkboxes, each followed by a line of text: "I accept the general conditions of use and the data protection policy.", "I agree to Biosency processing my health data. For more information, the data protection policy is available on the website doc.bora-connect.com.", and "I consent to the processing of my data for scientific and statistical research purposes, as well as for the improvement and development of Biosency's services." At the bottom, there is a red warning line: "You must accept the general conditions of use and the data protection policy, as well as the processing of your health data." and two buttons labeled "Accept" and "Decline".

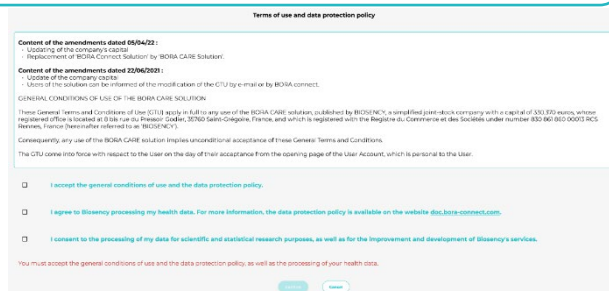
6 Congratulations, you are now connected to the Bora connect® platform.

If you are a **healthcare professional**, you can **1** connect directly via Pro Santé Connect with your RPPS number.



i In case you are unable to connect via Pro Santé Connect, you can still connect using your email address and password ([see the Connection via email section](#)).

2 You will then be required to **consent to the processing of your personal data** on the Bora connect® platform.



3 Congratulations, you are now connected to the Bora connect® platform.

i If you have already connected to the platform with your Bora connect® login details, then you will be asked for your Bora connect® login details the first time you connect via Pro Santé Connect. This will allow your existing account to be linked to your Pro Santé Connect account.

The following section will show you how to add a patient file.

Add a patient file

To begin adding a patient, go to the **“Patients” tab** in the side menu, then click on the button **“+ Add”**.



The patient addition file is divided into several categories according to the monitoring type selected. The following categories are shown in all cases:




- Monitoring type
- Patient identity
- Patient contact
- Patient address
- Patient national identification number
- Physicians and services

As part of the remote monitoring package ( / ), two additional categories are shown:

- Prescription
- Social security and supplemental health insurance information




1 The first step in creating a patient file consists of choosing the monitoring type by indicating:

▶ The device(s) to be linked with the patients:

-  NIV (Ventilation)
-  Bora Band® (connected wristband)
-  If the patient is undergoing oxygen treatment (this information is only optional and does not have an impact on the patient’s current care on the platform)


▶  +  If the monitoring is done as part of a remote monitoring package

1/ Monitoring type

 NIV Ventilation  Bora band Connected wristband  Patient undergoing O2 treatment

Remote monitoring package : Yes No

2 Fill in the patient identity file, including all the following information:

- Sex (obligatory)
- Birth name (obligatory)
- Name used
- First name(s) given at birth
- First name given at birth (obligatory)
- First name used
- Date of birth (obligatory)
- Jurisdiction code of birthplace (obligatory) 
- Language (obligatory)

2/ Patient identity

Sex : *	<input type="text"/>	Name used :	<input type="text"/>
Birth name : *	<input type="text"/>	First name(s) given at birth :	<input type="text"/>
1st First name given at birth : *	<input type="text"/>	First name used :	<input type="text"/>
Date of birth : *	<input type="text"/>	Place of birth code : *	<input type="text"/>
Place of birth : *	<input type="text"/>	Language : *	<input type="text"/>

3 Enter the patient contact information: email (obligatory) and telephone number.

3/ Patient contact

E-Mail *

Prefix	Telephone number
<input type="text"/>	<input type="text"/>

4 Complete the information concerning the patient address.
The "postal code", "town/city" and "country" fields are optional.

i Email address of a trusted third party can be used.

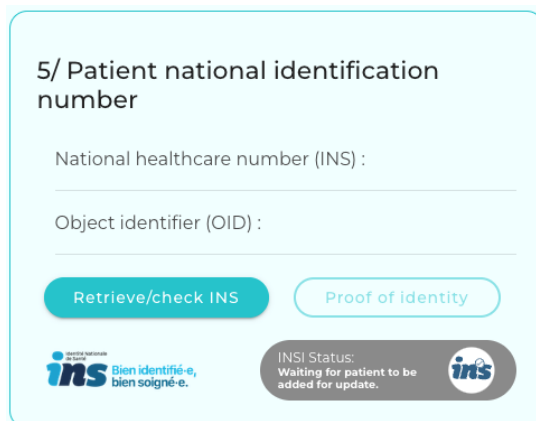
4/ Patient address

Street number	Complements
<input type="text"/>	<input type="text"/>
Street name	<input type="text"/>
ZIP/postal code	Town
<input type="text"/>	<input type="text"/>
Country	<input type="text"/>

To access the INS service, the software must be installed. Refer to [annex 1](#) to follow the installation steps.

5 The "patient national identification" category is for:

- Pressing on the "retrieve/check INS" button to retrieve the patient's INS/OID number using the information entered in the obligatory fields of "2/ Patient identity" category.
- You can also indicate that proof of identity was shown to you by clicking on "Proof of identity".



5/ Patient national identification number

National healthcare number (INS) :

Object identifier (OID) :

Retrieve/check INS Proof of identity

ins Bien identifié-e, bien soigné-e. INSI Status: Waiting for patient to be added for update. **ins**

Depending on the information recovered from the INS, five results are possible:

- The INS status is "provisional identity" (default status) when one of the two following cases is true:
 - The "questionable identity", "fictitious identity" or "homonymous identity" attribute was ticked
 - The INS was not recovered and no highly trusted proof of identity was stated as being presented
- The INS status is "recovered identity" when one of the two following cases is fulfilled:
 - The INS or OID were recovered
 - None of the three "questionable identity", "fictitious identity" or "homonymous identity" attributes was ticked
 - No highly trusted proof of identity was stated as being presented
- The INS status is "confirmed identity" when one of the three following cases is fulfilled:
 - The INS or OID was not recovered
 - None of the three "questionable identity", "fictitious identity" or "homonymous identity" attributes was ticked
 - A highly trusted proof of identity was stated as being presented
- The INS status is "qualified identity" when one of the three following cases is fulfilled:
 - The INS or OID were recovered
 - None of the three "questionable identity", "fictitious identity" or "homonymous identity" attributes was ticked
 - A highly trusted proof of identity was stated as being presented
- "An error has occurred" message is displayed. In this case, follow the following instructions:
 - Verify that the entered identity traits are correct
 - Restart the INS recovery/verification process
 - If the error continues, contact Biosency support (see [Warranty and Assistance](#))



These two verifications (INS recovery + proof of identity) are not obligatory when creating the patient file and have no influence on reimbursement access. They can be done by the medical secretariat or later on by the medical assistant.

These verifications help qualify the INS and strengthen the patient's identification safety and reliability.

These verifications do not have to be renewed.

6

Enter the patient's prescribing physician. The service or other physician's associated with the patient's care can also be indicated.

6 / Physicians and services

Prescribing physician *

Other healthcare professionals and services



If you are a healthcare professional, you must provide information on your patient's home structure. You will be automatically added to the "other healthcare professionals and services" category so that you can access the patient's record even if you are not the prescribing physician.

6 / Physicians and services

Affiliated structure : *

Démo BB + BF + BVS3 FR

Prescribing physician *

Select the prescribing physician

Other healthcare professionals and services

Marguerite Labrosse

7

If you want, you can add an additional information field to your patient record by clicking on the "Add an information field" button:

7 / Additional information

+ Add an information field

To add a field, you must:

- Give the field a name
- Enter the information you wish to add
- Click on the validate button on the right

7 / Additional information

Field name : *

Information : *

+ Add an information field

Once a field has been added, you can edit it at any time by clicking on the edit button to the right of the field.

You can also delete the field by clicking on the "trash can" icon to the right of the field.

7 / Additional information

Name of caregiver

Ms. Marguerite Dupont

+ Add an information field

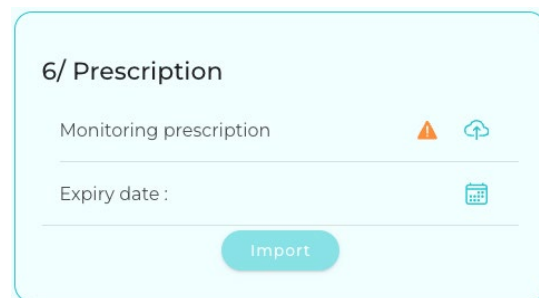
7 Attach the patient's prescription in category "6/ Prescription information" by:

- Selecting the prescription document
- Entering the prescription expiry date
- Clicking on "Import"

Entering the expiry date allows you to be notified, on Bora connect®, 15 days before the expiry date, then when the prescription has expired.

i The length of the initial prescription cannot exceed 3 months. The length of the renewal prescription cannot exceed 6 months.

Once the prescription has been imported, it appears in the prescription table.

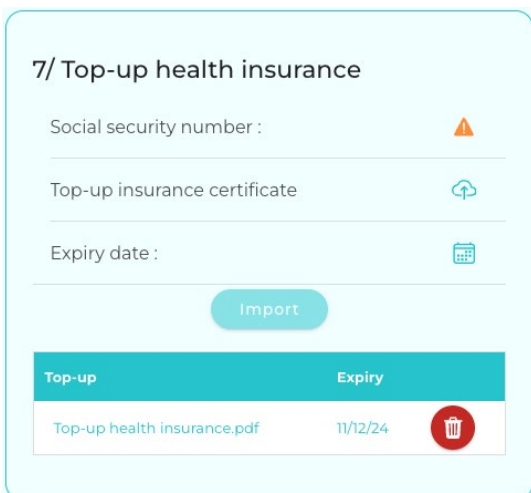



Prescription	Expiry	
prescription.pdf	11/12/24	


8 Fill in the category "7/ Social security and supplementary health insurance information" by:


- Inserting the patient's social security number
- Enclosing the complementary health insurance certificate
- Indicate the expiry date of the complementary health insurance

In the same way, once the mutual insurance certificate has been imported, it appears in the "mutual insurance certificate" table.



Top-up	Expiry	
Top-up health insurance.pdf	11/12/24	

As long as the fields shown above are not filled in, a warning icon  appears next to the document import field.

 Accepted file formats are: jpeg, png, pdf.

! Failure to download these documents does not block patient creation, but does prevent the patient from exercising his or her reimbursement rights.

Once all categories have been completed, click on "Add" at the bottom of the page to finalize patient creation.

List of patients

By going to the **“Patients”** tab on the side menu, you can visualise all of the patients whom you are responsible for.

These patients are put in groups on a table based on their status:

- Favorites
- Monitoring in process
- Not equipped




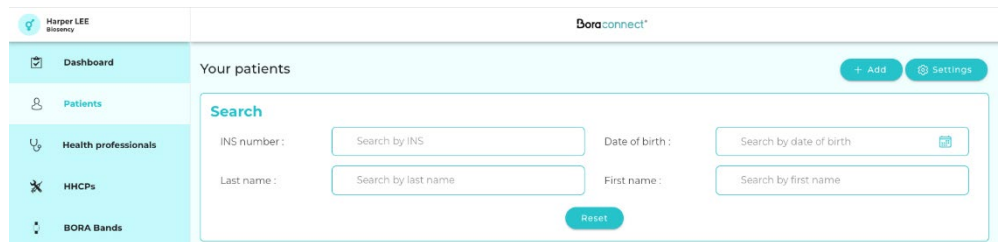
All the tables can be seen by default. You can conceal certain tables by clicking on the button, which slides the status name to the left.

Filter by patient status

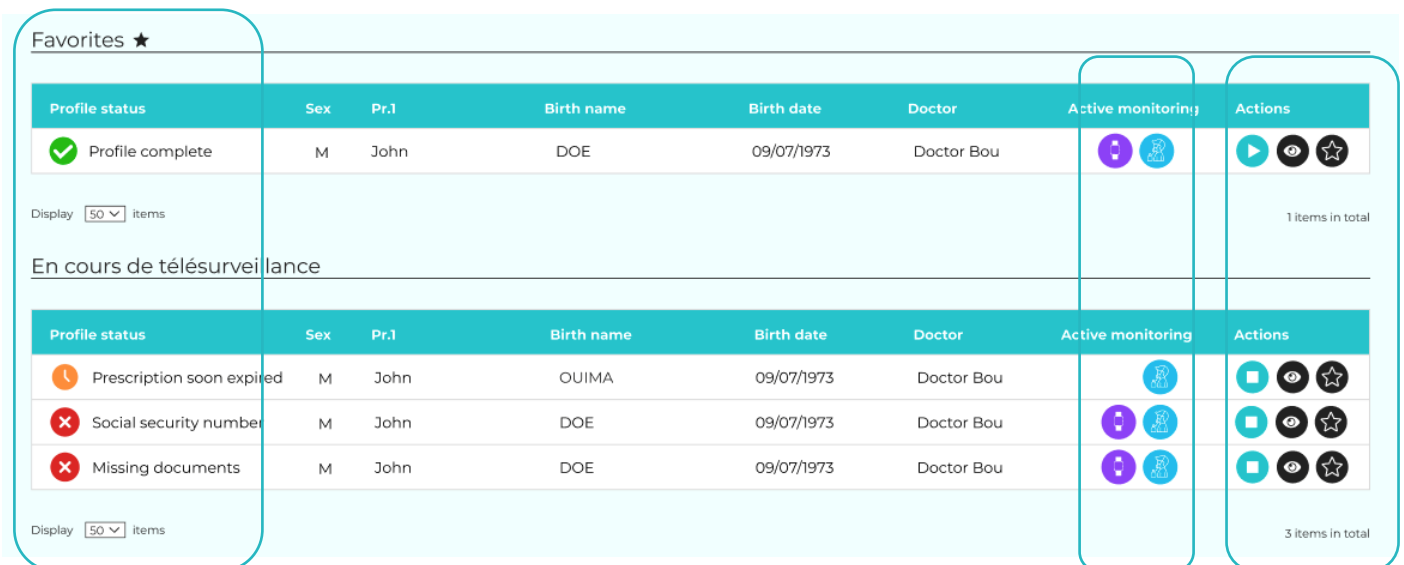
Filter by patient status: Favorites Monitoring in process Not equipped

If you are searching for a specific patient, you can use one or more of the following fields in the search box:

- INS  AGENCE DU NUMERIQUE EN SANTE
- Last name
- Date of birth
- First name





The list of patients is shown on a table with several information columns, including:









Profile status	Sex	Pr.1	Birth name	Birth date	Doctor	Active monitoring	Actions
Profile complete	M	John	DOE	09/07/1973	Doctor Bou		
Prescription soon expired	M	John	OUIA	09/07/1973	Doctor Bou		
Social security number	M	John	DOE	09/07/1973	Doctor Bou		
Missing documents	M	John	DOE	09/07/1973	Doctor Bou		

- **Active monitoring:** displays the type of device(s) currently being used in the remote monitoring session:

-  when a measuring device is connected to the patient
-  when a NIV device is connected to the patient




- **Profile status:** displays profile statuses and alerts the user to incomplete profiles that need to be investigated


-  **Missing documents**: The prescription and social security number are missing.
-  **Prescription**: the prescription is missing.
-  **Social security number**: The social security number is missing.
-  **Prescription**: The prescription has expired.
-  **Prescription**: The prescription expires in less than 15 days.
-  **Profile complete**: The prescription and social security number are completed and not expired.



You can manage these statuses on the page of the patient concerned by resolving the problems mentioned. For example, by updating the documents relating to a status indicating that the prescription is about to expire. Once the problem is corrected the status will update automatically.

- **Actions:** the user can click on different buttons to:

- Start/Stop the remote monitoring session 
- Directly view the patient data on the graphs 
- Put the patient among the favourites 

 When a patient account is created, an e-mail is sent to the e-mail address entered in the patient file. This e-mail allows the patient to create a password and log in, so that he can give his consent to Biosency to process his data, and to view his data if he so wishes.


2





Start a remote monitoring session

Once the patient account has been created, you can start a remote monitoring session. Remote monitoring provides you with visual notifications when the vital signs of a patient reach a specific limit that you have configured.

Start a session

You can start a remote monitoring session for a patient in two ways:

- ▶ From the “Patients” tab on the line of the patient whom you want to start the remote monitoring session for, by clicking on the button in the  “Actions” column

Profile status	Sex	Pr.1	Birth name	Birth date	Doctor	Active monitoring	Actions
 Profile complete	ND	D	PATIENT	07/04/2024	Pierre BOTTERO		  

- ▶ From the patient file, by clicking on the “Start a session” button


Three **steps are must then be completed to start a remote monitoring session.**

Step 1: Link device(s)


You can link one or more devices to the patient to start the remote monitoring session: a NIV device and/or a measuring device (connected wristband).



Linking a NIV device

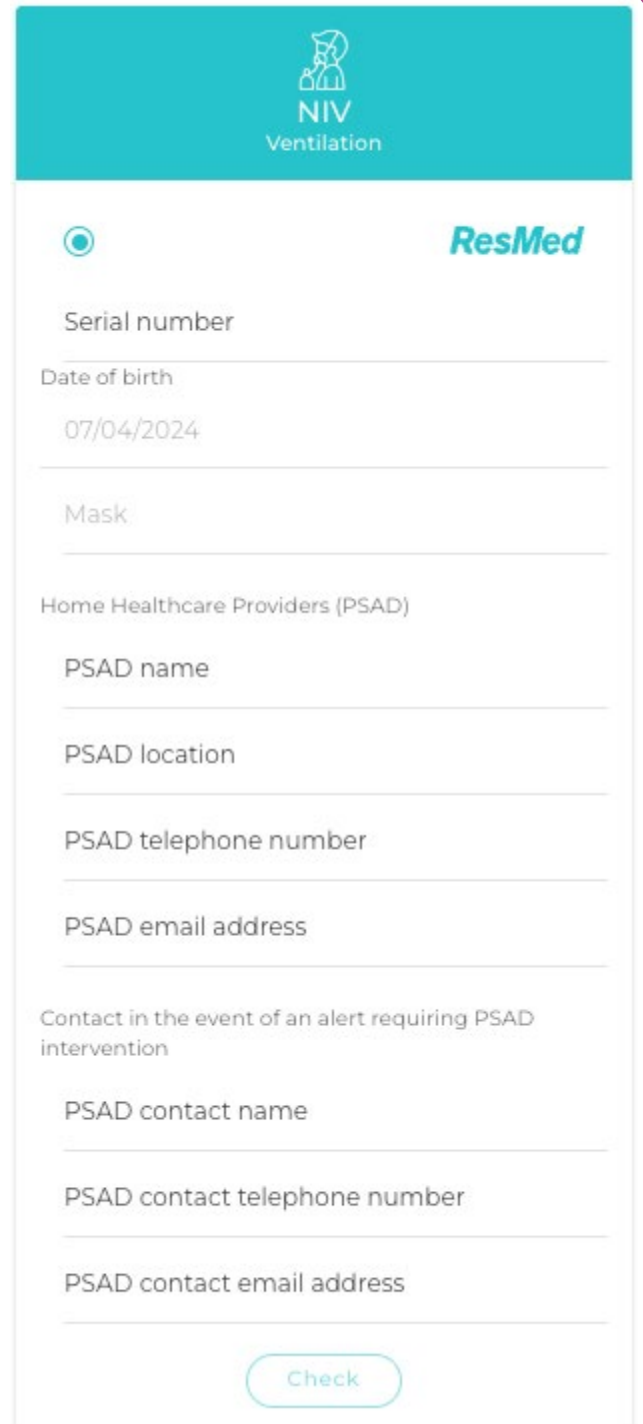
To link a NIV device, click on  then:

- ▶ Select the manufacturer brand
- ▶ Enter the NIV device's serial number
- ▶ Indicate the type of mask used


 The patient's date of birth is pre-filled by the information provided when the patient file was created.

You can then enter the information relating to the healthcare provider agency as well as the point of contact in charge of the installation.

This information is not obligatory to validate the device link-up but it is recommended for having a reference contact in case of any problems.



NIV Ventilation



Serial number

Date of birth
07/04/2024

Mask

Home Healthcare Providers (PSAD)

PSAD name

PSAD location

PSAD telephone number

PSAD email address

Contact in the event of an alert requiring PSAD intervention

PSAD contact name

PSAD contact telephone number

PSAD contact email address

Once all of the information has been entered, click on the button to register the device.

Three types of messages can appear:

- A message indicating the success of the verification

The link with the NIV machine was successful!

Verification successful

CLOSE

- A message indicating a verification failure linked to an entry error by the user (patient's date of birth or serial number)

The NIV device has not been found. **Please check the "serial number" of the device and the patient's "date of birth" fields.**

If necessary, contact the service provider in charge of the NIV device .

CLOSE

Verification failed (incorrect information)

- A message indicating a verification failure linked to the device's non-activation on the AirView™ platform or missing access authorisation for the AirView™ data.

The NIV device has been found. However, to be made available, the device must be activated in AirView and data access must be authorised.

Please contact the provider in charge of the patient, to verify that **the NIV device has been activated in AirView** or that **Bioency has been authorised to access AirView data.**

CLOSE

Verification failed (connection not established)



Linking a measuring device

To link a measuring device, click on and then:

[Link Bora band](#)

- ▶ Enter the serial number or select it from the list that is displayed when you click on the field

Then click on [Submit](#) to confirm the link-up.

Once the device has been linked, click "Step 2" to go on to the next step.

Step 2: Configure alerts for the session

There are two types of alerts:

- Technical alerts related to data transmissions and to the use of measuring devices.
- The processing alerts related to:
 - Vital signs and their combination (BVS³[®] score)
 - The operation and use of NIV devices

BVS³[®] score

The Bora Vital Sign Standard Score (BVS³[®]) is designed as an additional tool to assess the vital signs of patients remotely monitored by the Bora Care solution. It was developed to facilitate the early identification of deterioration in the condition of patients with respiratory failure (e.g. detection of COPD exacerbations).

It aims to provide a detailed and tailor-made assessment of the evolution of the patient's respiratory status hour by hour and after at least 3 days of follow-up. It is calculated in standard deviations (σ) and indicates the divergence of the vital signs measured in real life by the Bora band (heart rate, respiratory rate, SpO₂) compared to their average over the duration of the follow-up.

An alert is activated as soon as the score exceeds a predetermined and clinically validated threshold, allowing 85% of COPD exacerbations to be detected with 10% false positives (3 days on average) before they occur¹.

Interpretation of results

The BVS³[®] score ranges between 0 σ and 10 σ , with values:

- Between 0 σ (minimum value) -- 3 σ - indicating that the patient's vital signs over the last hour are very close to the patient's baseline: no significant difference (<3 σ) from the last 15 days.-
- Between 3 σ - 10 σ (maximum value) indicating that the patient's vital signs over the last hour are significantly deviated ($\geq 3 \sigma$) from the last 15 days.-

By default, the alert threshold is¹ set to 3.0 σ in the Bora connect[®] platform.

Calculation mode

The BVS³[®] score:

- is **not** calculated if, over an hour, none of the 3 vital signs (HR / FR / SpO₂) is available
- is calculated, and therefore displayed:
 - if, over the last 5 days, at least an average of 40% of one-hour windows (48 out of a possible 120) contain at least 1 vital sign measurement (HR/FR/SpO₂).-

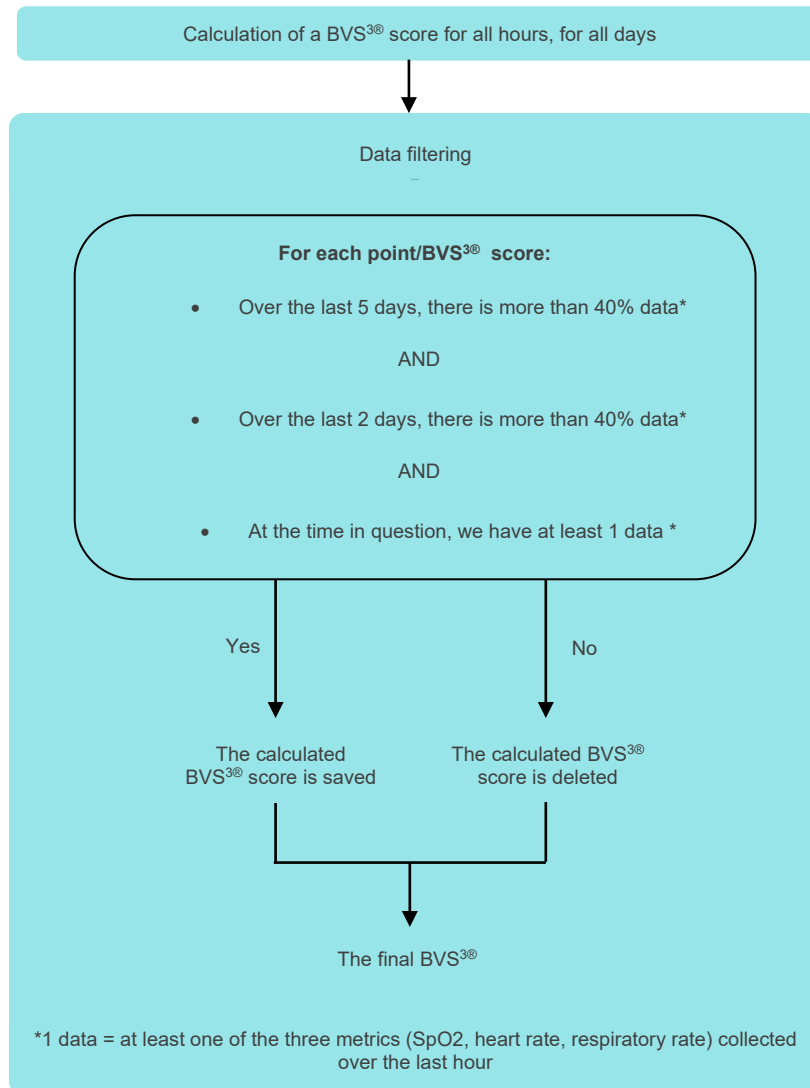
AND

- If, over the last 2 days, at least an average of 40% of one-hour windows (21 out of 48 possible) contain at least 1 vital sign measurement (HR/FR/SpO₂).-

¹ "Le Guillou et al."Vital Signs Remote Patient Monitoring in Real-Life for Early Detection of Acute Exacerbations of Chronic Obstructive Pulmonary Disease."American Thoracic Society, 2023"

In practical terms, you need to wait around 3 days for the first BVS³® score to be calculated at the start of a telemonitoring session, the number varying according to the number of one-hour windows containing at least 1 vital sign measurement.

The method of calculating the BVS³® score is as follows:



PRECAUTIONS

- The BVS³® is not intended to replace a thorough medical evaluation but rather serves as a complement by providing an indication of changes in patients' physiological parameters. Healthcare professionals should use their clinical judgment to interpret alerts and make appropriate decisions based on the patient's specific context.
- Failure to calculate BVS³® due to an insufficient number of vital sign measurements may result in a lack of BVS³® alert. Healthcare professional will ensure that this lack of data is compared with other available individual data available (HR, RR, SpO₂).

Available Alerts

Depending on the device(s) linked to the patient in the previous step, the alerts presented by default will be different:



Linked NIV device



Linked measuring device

Technical alerts



No data transmission for more than 48 hours



Low measurement



Infrequent wearing of wristband



Non-transmission of data for more than 48 hours

Processing alerts



Use



AHI



Heart rate



Respiratory rate



Leakages



Respiratory rate



SpO2



BVS³ > 3 σ



Tidal volume



IE



Spontaneous cycling



Spontaneous trigger



SpO2

Default Alerts

Depending on the device(s) associated with the patient in the previous step, several alerts will be configured and activated by default at the start of the session:





Linked NIV device




Linked measuring device

Technical alerts

 No data transmission for more than 48 hours

 Low measurement feedback

 Infrequent wearing of

 Non-transmission of data for more than 48 hours

Processing alerts

 Use


 Leaks 95th percentile


 Use

 IAH AHI

 Respiratory rate

 BVS³ > 3 σ

 Alert activated by default

 Alert activated by default and cannot be deactivated

The threshold of these alerts and their activation remain configurable at all times except:

- For the "BVS³" alert whose threshold cannot be changed
- For the "Median Leaks" alert which cannot be deactivated (requirement imposed by the Haute Autorité de Santé)
- For the alert "No data transmission for more than 48 hours" which cannot be deactivated (requirement imposed by the Haute Autorité de Santé) when a NIV device is associated with the patient

Use the slide button to activate or deactivate a type of alert. 

Click on the button to modify an alert. 

Personalised alerts

In addition to the processing alerts already available, new personalised processing alerts can be configured by pressing the button [+ Create an alert](#)

To add a new alert, you can add one or more conditions, by clicking “New condition”.

Alert creation

Trigger condition(s)

[New condition](#)

Alert name : *

For each of the conditions, you must:

- Choose the observed parameter

Condition 1

Observation parameters

Observed data Oxygen saturation	Observed metric Daily median	Observation window 2 consecutive day(s)
------------------------------------	---------------------------------	--

Type of threshold
1 fixed threshold

Threshold configuration

O ₂ Oxygen saturation	Operator ≤	Threshold 92 %
----------------------------------	---------------	-------------------

Summary of the condition

The condition is met if the **daily median** value of the **oxygen saturation** is **less than or equal to 92 %**, on **2 consecutive days**

[Delete](#)

Condition 1

Observation parameters

Observed data Oxygen saturation	Observed metric Daily median	Observation window 2 consecutive day(s)
------------------------------------	---------------------------------	--

Type of threshold
1 fixed threshold

Threshold configuration

O ₂ Oxygen saturation	Operator ≤	Threshold 92 %
----------------------------------	---------------	-------------------

Summary of the condition

The condition is met if the **daily median** value of the **oxygen saturation** is **less than or equal to 92 %**, on **2 consecutive days**

[Delete](#)

- Choose the observation window:
 - the default value is 2 consecutive days, i.e. the alert will be displayed if the configured condition is maintained for 2 consecutive days.

The value of the observation window can be changed to a value:

- Between 1 and 7 consecutive days for parameters reported by the Bora band wristband
- Between 1 and 30 consecutive days for parameters reported by respiratory assistance machines



The "NIV median leak" alert is an alert imposed by the HAS reference framework for patients under remote monitoring. The observation window must be between 3 and 7 consecutive days.

- Select the type of threshold:

Condition 1

Observation parameters

Observed data Oxygen saturation	Observed metric Daily median	Observation window 2 consecutive day(s)
------------------------------------	---------------------------------	--

Type of threshold
1 fixed threshold

Threshold configuration

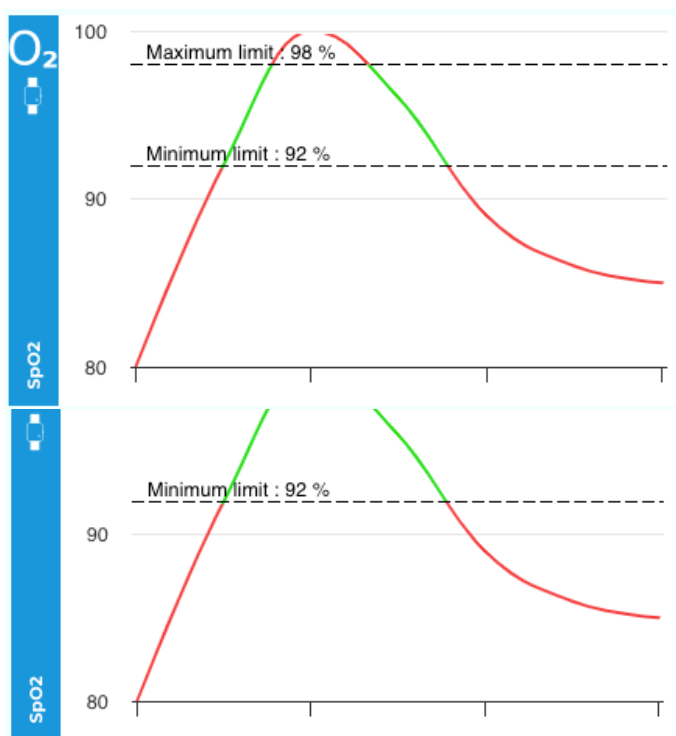
O ₂ Oxygen saturation	Operator ≤	Threshold 92 %
----------------------------------	---------------	-------------------

Summary of the condition

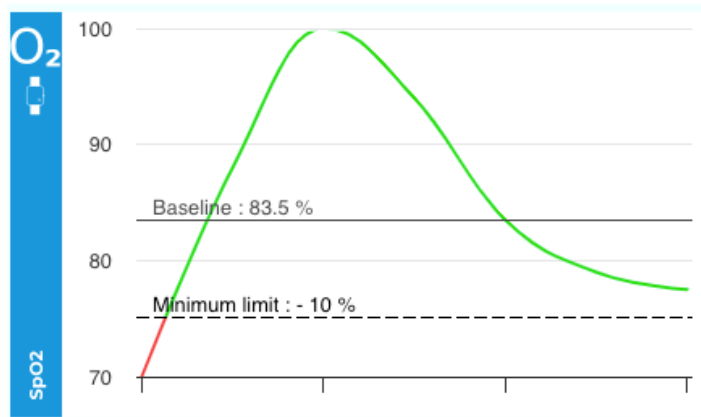
The condition is met if the **daily median** value of the **oxygen saturation is less than or equal to 92 %**, on **2 consecutive days**

Delete

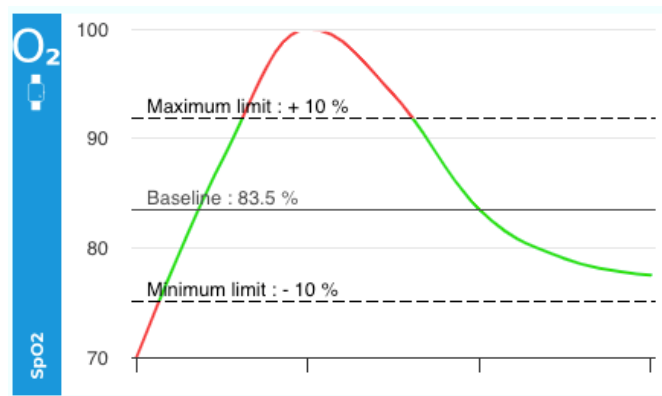
- 1 fixed threshold: the condition is met if the configured fixed threshold is exceeded (e.g.: Saturation \geq 92% SpO₂)
- 2 fixed thresholds: the condition is met if the observed parameter goes beyond the two set thresholds (e.g.: Saturation is \leq 92% OR \geq 98%)



- 1 variable threshold: the condition is met if the observed parameter exceeds the chosen threshold. **The threshold value is not fixed.** (e.g.: Saturation increases by 10% compared to the baseline corresponding to the median over the last 15 days)



- 2 variable thresholds: the condition is met if the observed parameter exceeds the defined thresholds. **The thresholds are not fixed** (e.g.: saturation increases by 10% or decreases by 10% compared to the baseline corresponding to the median over the last 15 days)



- Configure the thresholds:

Condition 1 ^

Observation parameters

Observed data	Observed metric	Observation window
Oxygen saturation	Daily median	2 consecutive day(s)

Type of threshold

1 fixed threshold

Threshold configuration

O₂

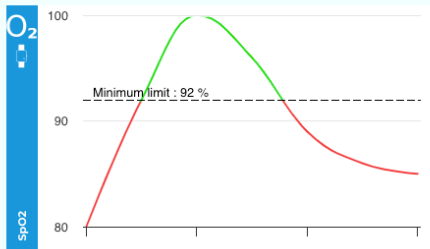
Oxygen saturation

Operator ≤

Threshold 92 %

Summary of the condition

The condition is met if the **daily median** value of the **oxygen saturation** is **less than or equal to 92 %**, on **2 consecutive days**



Delete

Once the condition is set, a summary is available on the right side of the window: in the graph the red part indicates the regions where the alert is triggered

The screenshot shows the configuration for 'Condition 1'. It is divided into three main sections:

- Observation parameters:** Observed data is 'Oxygen saturation', Observed metric is 'Daily median', and Observation window is '2 consecutive day(s)'. The Type of threshold is '1 fixed threshold'.
- Threshold configuration:** The metric is 'Oxygen saturation', the Operator is ' \leq ', and the Threshold is '92 %'.
- Summary of the condition:** A text box states: 'The condition is met if the **daily median** value of the **oxygen saturation** is **less than or equal to 92 %**, on **2 consecutive days**'. Below this is a line graph showing SpO2 levels over time. A horizontal dashed line at 92% is labeled 'Minimum limit: 92 %'. The graph shows a green curve that rises above 92% and then falls below it. The portion of the curve that falls below the 92% line is highlighted in red, indicating when the alert is triggered. A 'Delete' button is located at the bottom right of the summary box.

It is possible to set several conditions; By clicking on "New condition" you can add another condition to your alert.

The 'Alert creation' form includes a 'Trigger condition(s)' section with a 'New condition' button. Below this is an 'Alert name : *' field with a red asterisk indicating it is required.

Once the conditions are set, you must name the alert. This name will be used to describe the alert when it is triggered.

i If you create an alert with several conditions, you must choose whether to trigger the alert if all the conditions are met or only if one of the conditions is met.
Example: the alert will be activated if oxygen saturation is less than or equal to 92% **OR** if the heart rate is less than or equal to 35 bpm or greater than or equal to 100 bpm.
The alert will be activated if: One of these conditions is met All these conditions are met

! The conditions attached to different devices cannot be combined.

You can confirm the creation of the alert by pressing the **Create the alert** button.

Once this step has been finalised, you can click "Next" to move on to the last step, the start of the remote monitoring session.

Step 3: start the remote monitoring session

This last step allows you to confirm the summary of the information entered with:

- The assigned devices
- The patient to equip
- The configured alerts

A session start comment can be added.

Stage 3/3

Summary

Device(s) to be assigned: A32AAD (BB-100)

Patient to equip: D PATIENT

5 configured alerts:

- Last connection more than 48h ago
- Wearing the wristband less than 60% of the time
- vv
- Number of measurements less than 30 over past 48 hours
- BVS¹ (Risk of COPD exacerbation in the next 10 days)

Add a session start comment:

Previous Start



Note that you can modify these patient alerts later on in the “alerts configuration” section on the patient details page.

Alerts configuration

Technical alert(s)

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

Treatment alerts configuration

- O₂ Test multi condition
- Respiratory rate
- Heart rate
- O₂ Test multi condition 2
- O₂ Oxygen saturation
- BVS¹ (Risk of COPD exacerbation in the next 10 days)

+ Create an alert

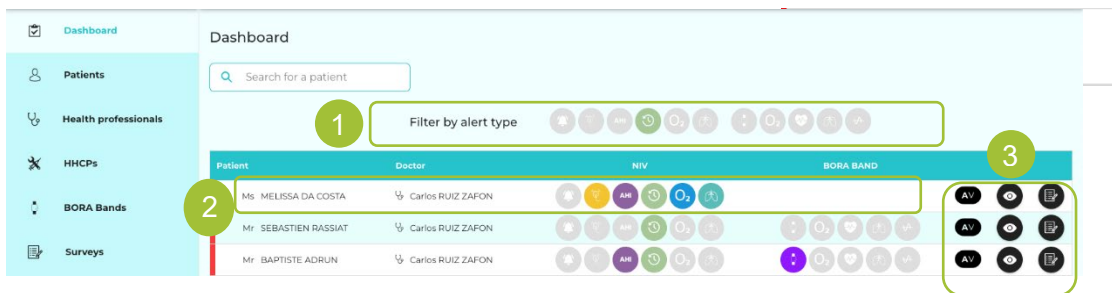
3 Monitor the collected data

Once the remote monitoring session has started, you can monitor the data uploaded to Bora Connect®.

Use the clinic dashboard and alerts

Go to the “Dashboard” tab on the side menu.

The clinic dashboard centralises all the patients and sets them up in a hierarchy through the alert system.



The patients who have characteristics that triggered an alert are noted by a red indicator at the top of the dashboard.

The patients are arranged by chronological order based on the arrival of their alerts (from the most recent to the oldest).



1 By default, the entire list of patients can be seen. The list can be filtered by alert type:



By clicking on one or more of the icons seen on the "filter by alert type" bar, you can filter the list, keeping only the patients that have an active alert for the type that you selected.

For example, by clicking on the two following icons, only the patients that have an active alert for use uploaded by the NIV device or for heart rate uploaded by a measuring device will be visible. The two alerts are not combined, patients with one or the other will be displayed.



The alert filter tool bar differs depending on the activated modules ( and / or  AGENCE DU NUMÉRIQUE EN SANTÉ);



Linked NIV device



Linked measuring device

Alerts related to technical problems



Technical problem:
No data transmission for more than 48 hours



Technical problem:

- Wearing the wristband < 60% of the time
- Low data feedback (< 30 measurements over 48 hours)
- No connection for 48 hours

Alerts related to processing



Excessive unintentional leaks



AHI



Use



Oxygen level of patient



Patient respiratory rate



Oxygen level of patient



Heart rate



Patient respiratory rate



BVS³® Score > 3 σ

1 The names of the alerts are visible when you place your cursor over the icons.



2 Click on the name of a patient for whom an alert has been triggered. A window opens, detailing in chronological order the patient's alerts and the comments written by other healthcare stakeholders to help you obtain a record of actions.


The alerts can be active (framed in red) or closed (greyed line).

The following information appears for each alert:


- The date and time of the alert
- The type of alert
- The comments associated with the alert

To see the comments associated with the alert, click on the arrow. The displayed information includes: the comment and its date and author.







To view the alert directly on the patient's graphs, click on the  button. You will then be sent to the patient file.

Click on the  button to add a comment.



Click on the  button to close out the alert. A comment must be added to validate the closure of the alert.

Once the alert has been closed, it will be greyed out.

 You can close several alerts at the same time by using the  button located in the upper left. Tick the alerts that you want to close and click on the  button.

 An alert is active again only when all alerts of the same type are closed off. We advise you to close off an alert once the issue has been raised and addressed, in order to avoid alerts being re-triggered continuously.

 You can view the alert directly on the patient's graphs by clicking on the  button

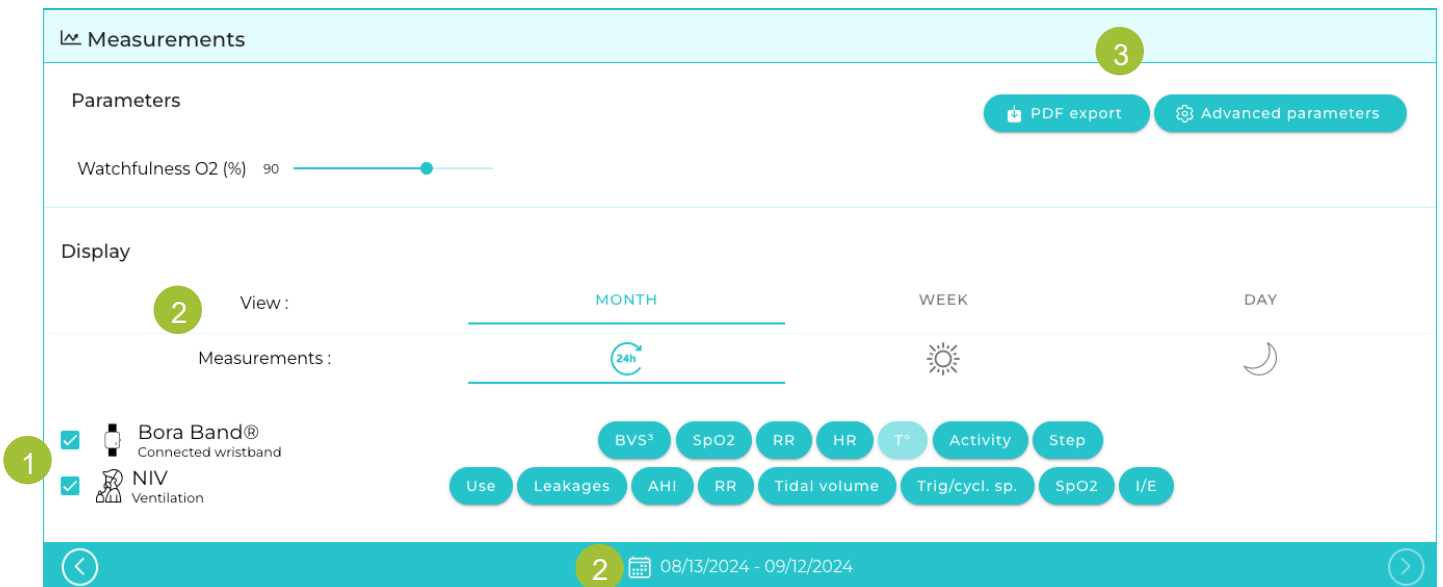
 To access the patient's account on the AirView™ platform, click on the  button.

Reading and configuring of graphs

Bora connect® allows you to consult the parameters uploaded by the devices linked with the patients.

To access the patient file, click on the information line corresponding to the desired patient on the “Patient” tab.

The graphs are available in the “measurements” category in the patient file.



1 Depending on the devices linked to the patients, the graphs that can be displayed differ. Tick the device(s) whose uploaded parameters you want to view. Click on the buttons AHI/RR/etc. to go directly to the corresponding graph.

All the graphs are displayed by default.

2 You can personalise the graph display by selecting:



- A type of view:
 - Monthly view
 - Weekly view
 - Daily view
- Time scale
 - 24-hour view (default view)
 - Daytime view (8 a.m. To 11 p.m.)
 - Nighttime view (11 p.m. To 8 a.m.)

Only available for patients with a Bora Band linked to their profile



You can select the desired month/week/day by scrolling through the calendar dates.


3 Click "Advanced settings" to:

- Manage the display order of the graphs: the graphs are listed in the order of display. To change it, click on the  button of the graph that you want to reposition and press down for the time it takes to move the graph to the right position.
- Select the graphs to display/hide using the  button
- Select standard or advanced display mode. **It should be noted that the advanced mode is only available for the data relating to a Bora Band.**

The data are displayed as a histogram or a curve depending on their typology.

The name of the datum displayed is listed the left of the graph.

An overview box for graphs, located on the right, display:

- The number of days with measurements
- The median of values over the selected time period
- The 95th percentile over the selected time period
- The 5th percentile over the selected time period
- A button  to access the patient's AirView™ account for more details on the daily measurements (valid only for the patients linked to a NIV device)



3

Modify displayed graphs

- BVS³
- Oxygen saturation
- Respiratory rate
- Heart rate
- T° skin
- Activity
- Steps count

Display mode

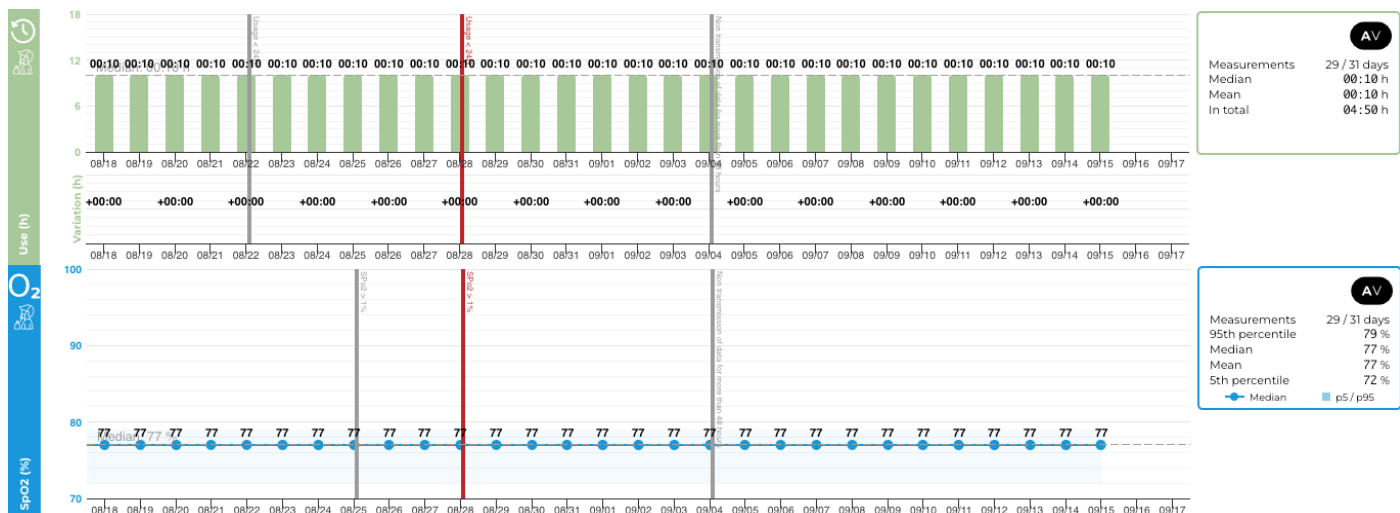
Standard

Advanced

Display values

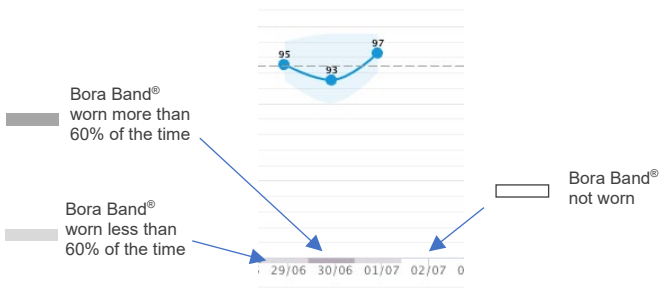
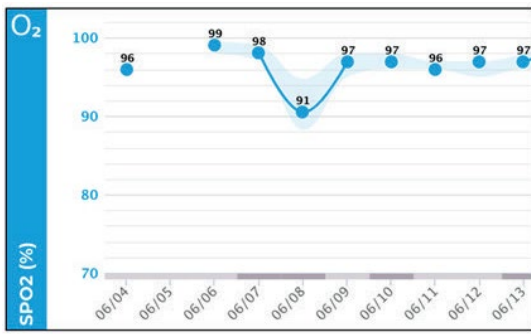
Display median line

Submit Close

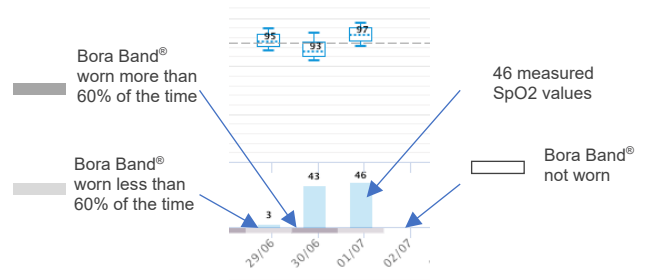
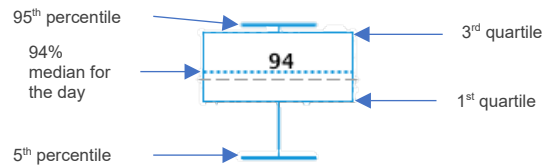
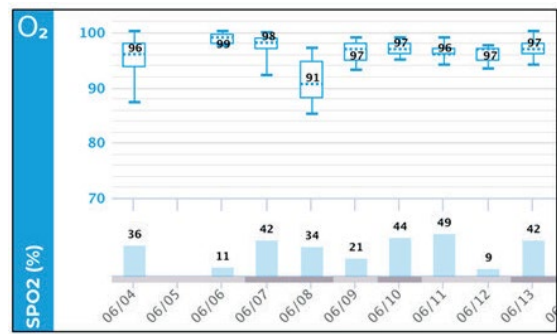


Depending on the mode selected in the advanced settings, the measurements display will be different:

Standard mode

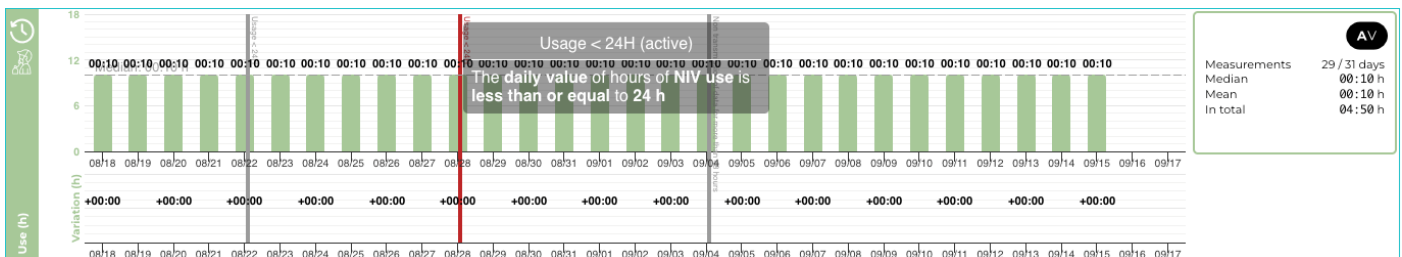


Advanced mode



The raised **alerts** are directly visible on the graphs from the date they were triggered. They appear as a **red bar** when they are **active** and as a **grey bar** when they are **closed**.

By positioning your cursor on the alert bar, you will be able to see the details of the alert.



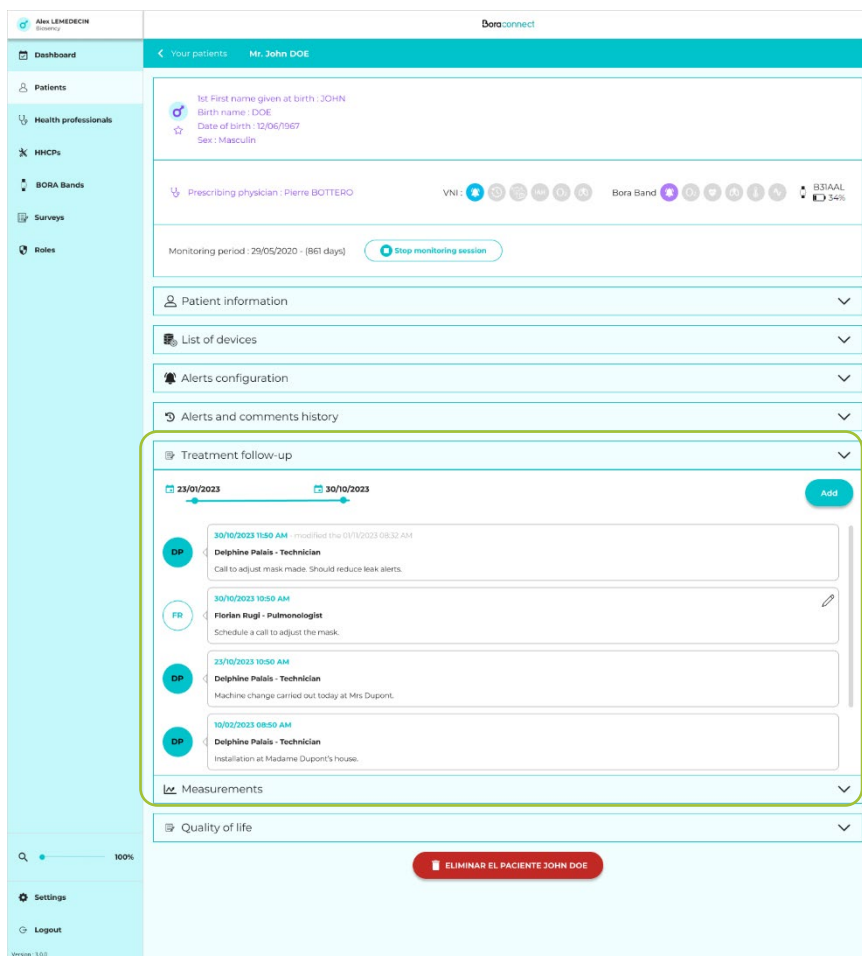
i On the histogram measurements for use, the fragmentation of the usage appears when the users go over the graph.

Therapeutic follow-up

The therapeutic follow-up aims to allow the patient to be monitored through notes filled in by the actors and professionals involved in his or her care pathway.

The therapeutic follow-up table is visible from the patient file under the "Therapeutic follow-up" tab. It brings together all the notes entered since the launch of the remote monitoring session. The notes are:

- Arranged in chronological order (from newest to oldest)
- Editable by the author only
- Composed of the following information:
 - Date the note was added (and date of last modification if applicable)
 - First Name Last Name and medical specialty / Role of the author of the note
 - Contents of the note



There are three ways to add a briefing note:

- From an alert comment: if you want the comment to appear in the therapeutic follow-up, click on "I want to integrate this note into the patient's therapeutic follow-up table".

- From the dashboard: you can click on the button  to open the therapeutic follow-up chart.

- From the patient file, therapeutic follow-up tab:

If the note is added from the dashboard or from the patient file, a window will open containing:

- First Name Last Name and medical specialty / Role of the author of the note
- Date added
- Comment (to be filled in to validate the addition of the note)

Report export

1 To receive the collected data report (summary) by email, click on the “export PDF” button.

2 Select the measurement period that you want to export:

- Complete: to export all the patient’s measurements
- By session: select from the patient’s different remote monitoring sessions
- By date: select a start date and finish date

← Back Export health data for D PATIENT

Select the period to export

Complete

By sessions

Select monitoring sessions ▼

By dates

Starting date : 07/18/2024 Ending date : 08/19/2024


Anonymize the export ?

Display additional information:

First name(s) given at birth INSEE Birth. Name used First name used

Comment

Submit

 In day mode, you cannot export more than 15 days.

3 You can make the PDF export anonymous. You only need to click on the Anonymize the export ? button. The patient’s name will be replaced by their initial, age and sex.

You can choose to add additional information to the export header.

You can enter a specific comment that will be included in the export.

← Back Export health data for D PATIENT

Select the period to export

Complete

By sessions

Select monitoring sessions ▼

By dates

Starting date : 07/18/2024 Ending date : 08/19/2024

Anonymize the export ?

Display additional information:

First name(s) given at birth INSEE Birth. Name used First name used

Comment

Submit

Click on the “submit” button to start the PDF export.

← Back **Export health data for D PATIENT**

Select the period to export

Complete

By sessions

Select monitoring sessions ▼

By dates

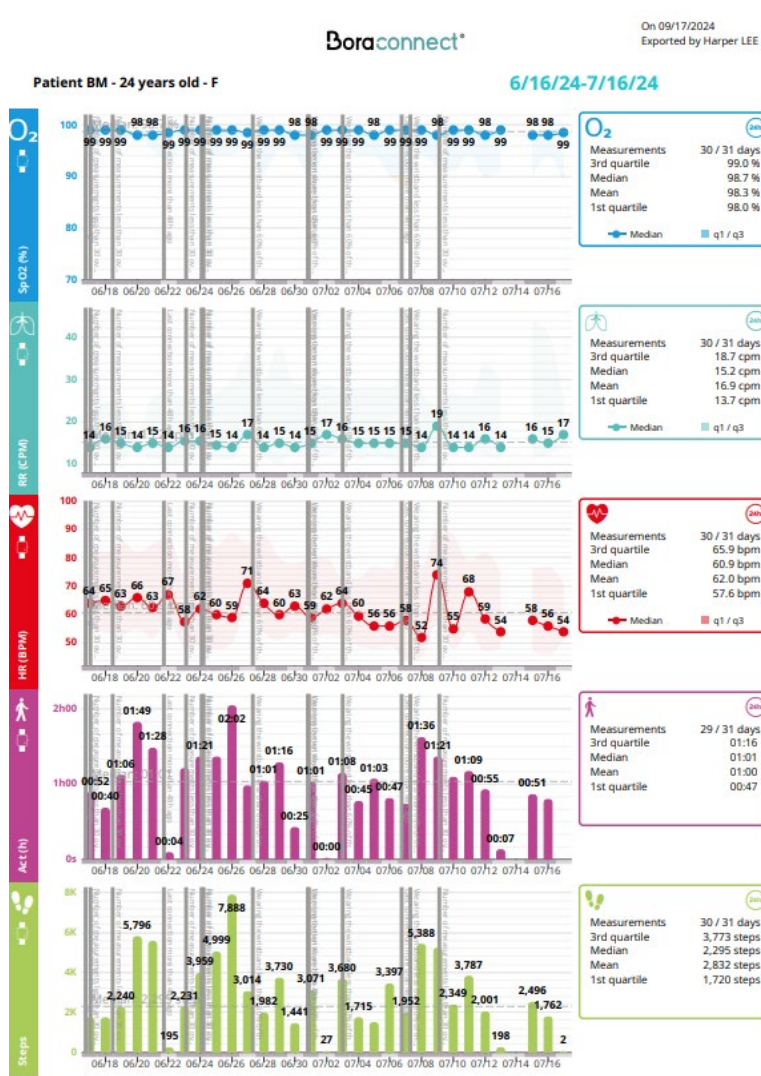
Starting date: 07/18/2024 Ending date: 08/19/2024

Anonymize the export ?
The patient's name will be replaced by their initials, age and gender.

Comment

Submit

After a brief moment, you will receive a PDF export in your inbox. You will find a PDF export example below:

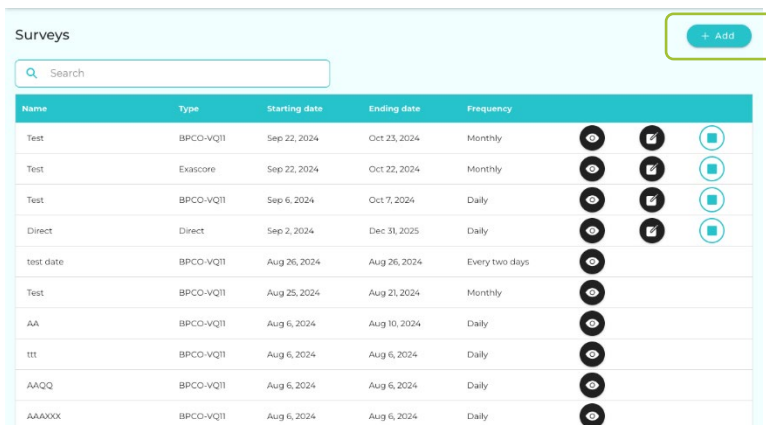


i The PDF export will use your current graph parameters for the PDF file. Modify your current display parameters to modify the PDF export.

Create a survey

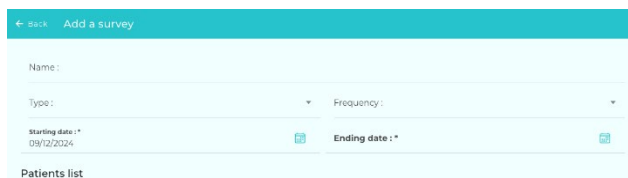
You can then send a survey to the patients who use the Bora Connect® Mobile application. **This tab is only available for users who have the activated Bora Band® module.**

1 Go to the “surveys” tab to create survey campaign for the patients. Click on the “add” button.



Name	Type	Starting date	Ending date	Frequency			
Test	BPCO-VQ11	Sep 22, 2024	Oct 23, 2024	Monthly			
Test	Exascore	Sep 22, 2024	Oct 22, 2024	Monthly			
Test	BPCO-VQ11	Sep 6, 2024	Oct 7, 2024	Daily			
Direct	Direct	Sep 2, 2024	Dec 31, 2025	Daily			
test date	BPCO-VQ11	Aug 26, 2024	Aug 26, 2024	Every two days			
Test	BPCO-VQ11	Aug 25, 2024	Aug 21, 2024	Monthly			
AA	BPCO-VQ11	Aug 6, 2024	Aug 10, 2024	Daily			
ttt	BPCO-VQ11	Aug 6, 2024	Aug 6, 2024	Daily			
AAQQ	BPCO-VQ11	Aug 6, 2024	Aug 6, 2024	Daily			
AAAXXX	BPCO-VQ11	Aug 6, 2024	Aug 6, 2024	Daily			

2 Enter a name for the campaign and select the survey type and its frequency. Select a start date and finish date.



3 types of surveys are available:

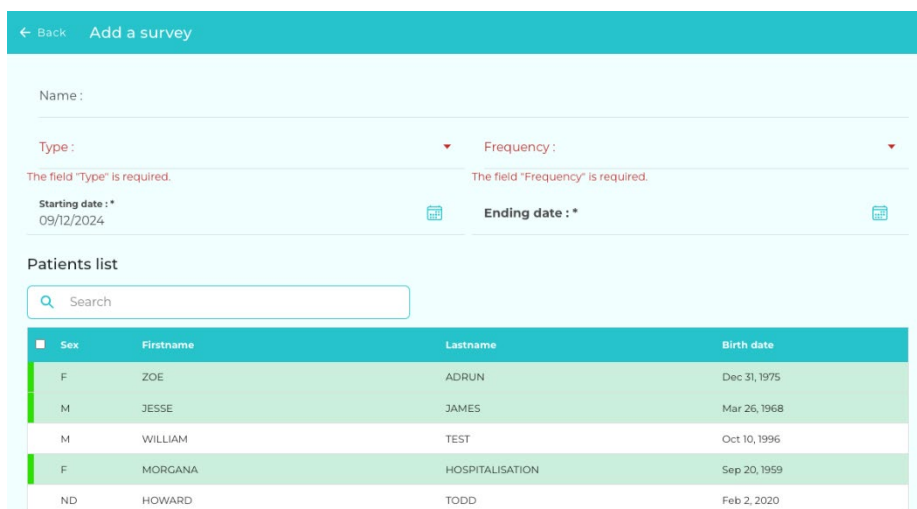
- Direct
- BPCO-VQ11
- Exascore

Select the survey’s frequency:

- Daily
- Every two days
- Weekly
- Monthly

3 Then, select the patients who will receive the survey. Click on the patients on the list.

Click on the button  to confirm the campaign’s creation.



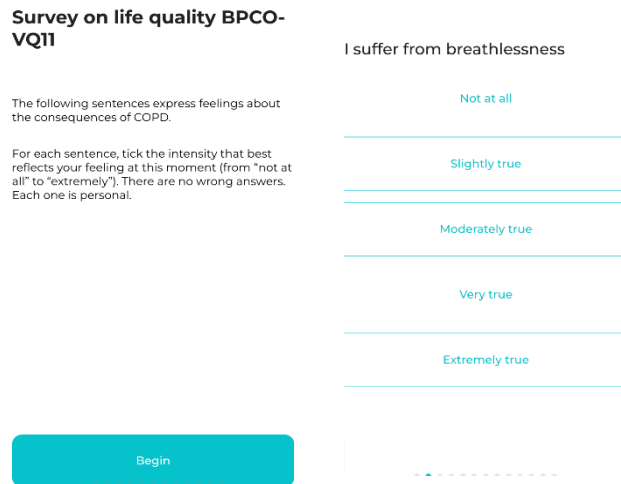
Patients list

Sex	Firstname	Lastname	Birth date
F	ZOE	ADRUN	Dec 31, 1975
M	JESSE	JAMES	Mar 26, 1968
M	WILLIAM	TEST	Oct 10, 1996
F	MORGANA	HOSPITALISATION	Sep 20, 1959
ND	HOWARD	TODD	Feb 2, 2020

4 The next time that a patient will open the Bora Connect® mobile application, a notification will appear and ask the patient to answer the survey.

i Patients using a Bora connect for home or Bora connect for study mobile application cannot access the survey feature.

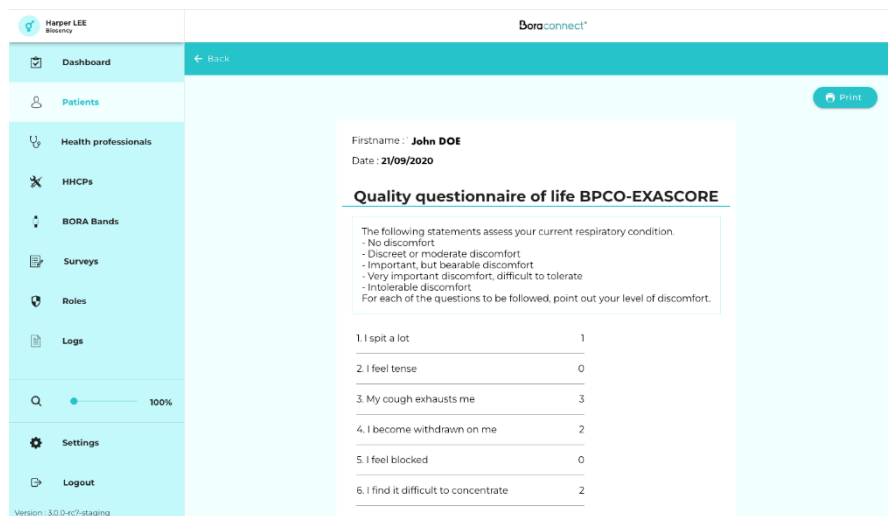
5 Patients can respond on their smartphone:



6 You can consult the patient’s response in their file in the “quality of life” category.

Quality of life			
Date	Type	Score	
09/02/2023	BPCO-VQ11	15	👁️
09/03/2023	BPCO-VQ11	37	👁️
09/04/2023	BPCO-VQ11	31	👁️
09/15/2023	Exascore	16	👁️

7 Click on the 👁️ button to consult the responses of the patient to each survey.



4 Stop a remote monitoring session

A remote monitoring session can be stopped from:

- The list of patients ("Patients" tab) using the "stop" button

Profile status	Sex	Pr.1	Birth name	Birth date	Doctor	Active monitoring	Actions
Profile complete	M	John	DOE	09/07/1973	Doctor Bou		

- The patient file by clicking on the button



Harper LEE
Biosency

Boraconnect*

← Back Stop monitoring for M B31AAL

Monitoring session start comment

Monitoring session end comment

Stop monitoring session

A remote monitoring session can be stopped by clicking on the button "Stop monitoring session". A comment can be linked to this action.

Harper LEE
Biosency

Boraconnect*

← Back Stop monitoring for M B31AAL

Monitoring session start comment

Monitoring session end comment

Stop monitoring session

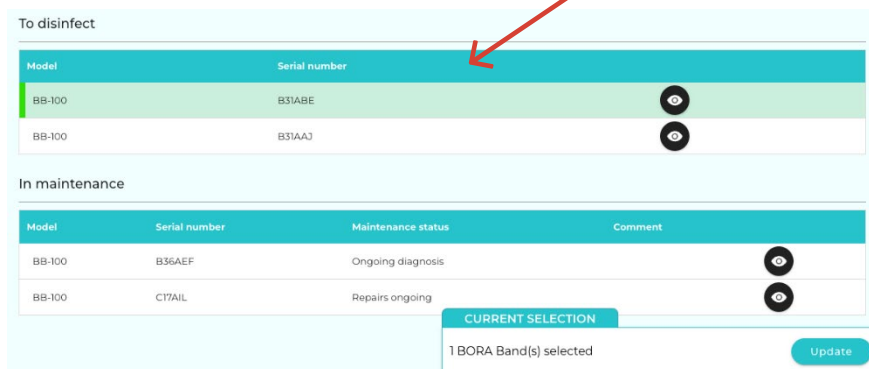
When the session is closed all the devices are automatically disconnected.

When starting the next session, the user has to link up new devices again.

At the end of a remote monitoring session, the Bora band® wristband used for the session will be automatically set to the status “to be disinfected”.

For the Bora band® wristband to be assigned to a new patient, you need to confirm that the Bora band® wristband has been disinfected.

- 1 Go to the “Bora Band” tab and select the Bora band® wristband(s) to be disinfected on the list.



The screenshot shows a web interface with two main sections: "To disinfect" and "In maintenance".

To disinfect

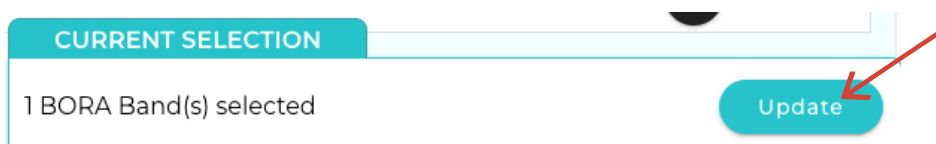
Model	Serial number	
BB-100	B31ABE	
BB-100	B31AAJ	

In maintenance

Model	Serial number	Maintenance status	Comment	
BB-100	B36AEF	Ongoing diagnosis		
BB-100	C17AIL	Repairs ongoing		

Below the tables, there is a "CURRENT SELECTION" box containing "1 BORA Band(s) selected" and an "Update" button. A red arrow points to the "Update" button.

- 2 Click on the button to start the disinfection procedure.



This is a close-up of the "CURRENT SELECTION" box from the previous screenshot. It shows the text "1 BORA Band(s) selected" and a teal "Update" button. A red arrow points to the "Update" button.

← Back 1 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

Submit

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.


3 On the next screen, confirm that you performed each step to finish the disinfection. You can also add a comment.


4 Press the button  to confirm disinfection.


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

The different Bora connect[®] tabs

Healthcare professionals

This page displays all the healthcare professionals who are associated with your organisation. You can consult the detailed information concerning the healthcare professional by clicking on the button. 

If the  module is activated, you can add a healthcare professional account by entering the professional's RPPS number.


If the  module is not activated and you wish to add a healthcare professional, please contact Biosency customer service.













Services List + Add


List of services

You can create a service that combines several healthcare professionals. A service can then be linked to a patient. All of the service's healthcare professionals can then consult the patient's data.

Click on the  button to create a service.

Services List 

Name	Description	Creation date			
Service3	Test Yann	Jan 8, 2021			
Service 4		Dec 14, 2021			
Réanimation	Faux Service	Aug 29, 2023			
Animation	Faux Service	Aug 29, 2023			

 **Add a service**

Name :


Description :

List of healthcare professionals

<input type="checkbox"/>	Firstname	Lastname	Gender	E-Mail	Professional ID	Prefix	Telephone number
<input type="checkbox"/>	Pierre	Bottero	Mr	pierre.bottero.bio@yopmail.com			6234567
<input type="checkbox"/>	Carlos	Ruiz Zafon	Mr	carlos.ruiz.zafon.bio@yopmail.com		+33	103954815

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

Select the healthcare professionals to be added to the service by clicking on the elements on the list.


 **Add a service**

Name :

Description :

List of healthcare professionals

<input type="checkbox"/>	Firstname	Lastname	Gender	E-Mail	Professional ID	Prefix	Telephone number
<input checked="" type="checkbox"/>	Pierre	Bottero	Mr	pierre.bottero.bio@yopmail.com			6234567
<input type="checkbox"/>	Carlos	Ruiz Zafon	Mr	carlos.ruiz.zafon.bio@yopmail.com		+33	103954815


Click on the  button to confirm the service's creation.

Healthcare stakeholders

You can use this page to manage the account creation of the healthcare stakeholders. Healthcare stakeholders refer to healthcare non-professionals who participate in the patient’s care.

Click on the  button to add a new account.

Health actors



Firstname	Lastname	Gender	E-Mail	Telephone number	Creation date	Author	Actions
Harper	Lee		harper.lee.bio@yopmail.com	611223344	Feb 21, 2020		
Eline	Hervoir	Ms	eline.hervoir@biosency.com	+33104956869	Nov 3, 2020		
admin	hhcp	Mr	hhcp.admin@yopmail.com		Nov 23, 2020		
hhcpadmin	eticeo	Mr	eticeo.hhcpadmin@yopmail.com		Nov 24, 2020		
Freeze	Mister	Mr	mister.freeze.bio@yopmail.com		Dec 15, 2020		
Raphaël	Cottancin	Mr	raphael.cottancin@biosency.com		Jan 24, 2022	Charles NGOR	
Sylvain	Le Liepvre	Mr	sll@biosency.com		Mar 29, 2022	Charles NGOR	
Nobbs	Mr	Mr	nobbs.bio@yopmail.com		Jan 14, 2021	Charles NGOR	
dark	vador	Mr	d.v.bio@yopmail.com	12345678	Dec 20, 2022	Harper LEE	
Émilie	BUSQUE	Ms	jadeb@hokla.com		Feb 17, 2023	Charles NGOR	

[← Back](#) **Add a health actor**

Gender : *

Language : *


Lastname : *

Firstname : *

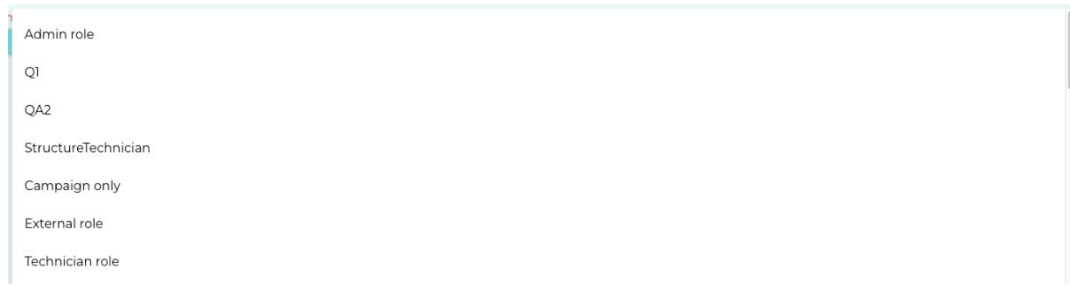
E-Mail : *

Prefix Telephone number :


Role : *



Select a role for the healthcare stakeholder's account.



The roles can be configured in the Roles page. The roles allow you to grant specific permissions to the healthcare stakeholders.

Click on the button  to add the healthcare stakeholder.

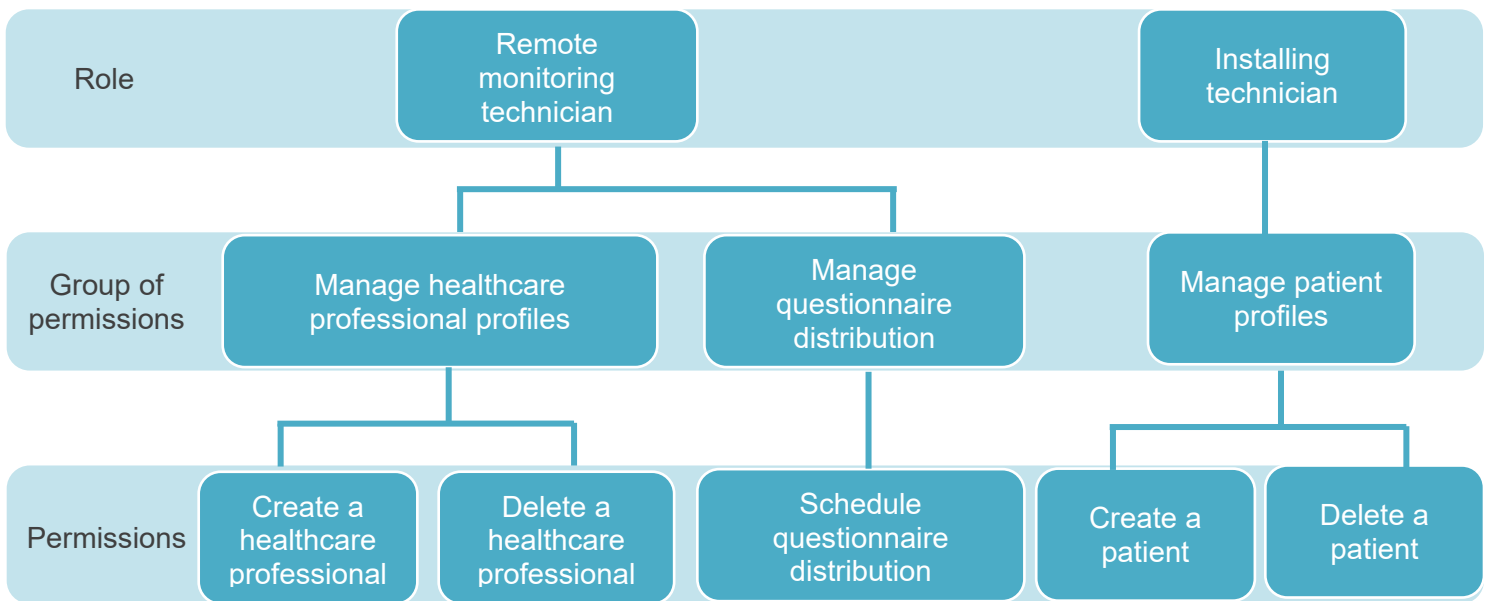
Roles

An organisation is made up of several roles:

- Healthcare administrator
- Healthcare stakeholder
- Healthcare professional (grouped together by service)
- Patient

Each user has a role among the four roles shown above.

Each role can access one or more groups of permissions. Each group of permissions contains one or several permissions. The following example summarises this division:




The healthcare administrator is created by a Biosency administrator. They have access to all of the available permissions, in addition to those for managing (creating/deleting) the accounts of healthcare professionals and stakeholders. This role cannot be changed.

Healthcare professionals only have access to the files of the patients who have been assigned to them. This role cannot be changed.

Healthcare stakeholders have a configurable role. This means that a different role can be assigned to each healthcare stakeholder profile created.

































Default roles are available. These roles are managed in the "Roles" tab.

On this page you can:

- View the available default roles
- Create a new role by clicking the  button

Roles list + Add

Search

Name	Description	Actions
Admin role		   
Q1		   
QA2		   
StructureTechnician	Structure technician	   
Campaign only		   
External role		   
Technician role		   
Super Admin role	Full Access	   

← Back **Add a role**

Name:

Description:

Select permissions

Search

Name	Description
Patients management	<ul style="list-style-type: none"> Access patients list Create a patient Start or stop a monitoring session Access BORNA Bands list Access BORNA 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	<ul style="list-style-type: none"> Access patients list Access a patient's data Delete a patient
Patients and surveys related data	<ul style="list-style-type: none"> Access patients list Access surveys on the patient's quality of life Access a patient's answers to a survey on their quality of life Access a patient's data
Doctors related data	<ul style="list-style-type: none"> Access patients list Access doctors list Access a doctor's details and his/her list of patients Create a service Update a service Delete a service Access the list of doctors in a service Access services list

To add a new role, you need to click on the groups of permissions that you want to grant on the list.

← Back **Add a role**

Name:

Description:

Select permissions

Search

Name	Description
Patients management	<ul style="list-style-type: none"> Access patients list Create a patient Start or stop a monitoring session Access BORNA Bands list Access BORNA 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	<ul style="list-style-type: none"> Access patients list Access a patient's data Delete a patient
Patients and surveys related data	<ul style="list-style-type: none"> Access patients list Access surveys on the patient's quality of life Access a patient's answers to a survey on their quality of life Access a patient's data
Doctors related data	<ul style="list-style-type: none"> Access patients list Access doctors list Access a doctor's details and his/her list of patients Create a service Update a service Delete a service Access the list of doctors in a service Access services list

Click on the **Add** button to confirm the role's creation.

You can from then on use this role for each healthcare stakeholder that is created.











You can use this page to manage your Bora band® fleet in case the module is activated.

Bora band® wristbands are given 4 types of status:





- ▶ Available: The wristband is ready to be assigned to a patient.
- ▶ Assigned: The wristband is currently assigned to a patient.
- ▶ To disinfect: The wristband must be disinfected before it can be assigned to a new patient.
- ▶ In maintenance: The wristband is being inspected or repaired by Biosency.

BORA Bands



Available

Model	Serial number		
BB-100	B31ABW		
BB-100	C17AUE		
BB-100	B31AAQ		
BB-100	A32AAD		
BB-100	A44AAK		



Assigned

Model	Serial number	Patient	Assignment date		
BB-100	B31ABH	Thierry ROUSSEL	04/05/2022		
BB-100	B31AAF	Henri LECOMTE	12/18/2020		

To disinfect



Model	Serial number	
BB-100	B31ABE	
BB-100	B31AAJ	

In maintenance

Model	Serial number	Maintenance status	Comment
BB-100	B36AEF	Ongoing diagnosis	
BB-100	C17AIL	Repairs ongoing	

Click the  button to assign the wristband to a patient.

Click the  button to consult the details of the Bora band® wristband.

Available		
Model	Serial number	
BB-100	B31ABW	 
BB-100	C17AUE	 
BB-100	B31AAQ	 
BB-100	A32AAD	 
BB-100	A44AAK	 



BORA Band details

Model: BB-100 Serial number: B31ABW	Status: Maintenance status: Allocation date:	Available None 11/17/2023
--	--	---------------------------------

BORA Band events

Date	Message	Author
08/13/2024 9:16:39 AM	Disinfected BORA Band	Harper LEE
07/25/2024 4:04:13 PM	BORA Band removing End of monitoring session for Margareth ATWOOD	Harper LEE
07/25/2024 3:50:53 PM	BORA Band assignment Beginning of monitoring session for Margareth ATWOOD	Harper LEE
07/10/2024 1:50:32 PM	Disinfected BORA Band	Harper LEE
06/12/2024 4:23:34 PM		Harper LEE
02/19/2024 2:02:39 PM		Gregory HOUSE
02/12/2024 1:38:33 PM	Disinfected BORA Band	Harper LEE
02/12/2024 1:37:47 PM	BORA Band removing End of monitoring session for Sylvain LE LIEPVRE	Harper LEE

You can consult the details of the Bora band® wristband: model, serial number, status, and date assigned to your organisation.

A table of events lists all of the Bora band® events (assignment to patient, status change).

Parameters

This section allows you to manage your data and personal parameters. All of the regulatory information and use information are available at the top of the page.

The screenshot displays the user interface for Bora connect®. At the top left, there are logos for MD and UDI, followed by the product name and version: "Bora connect® Version: 3.0.0-rc7-staging" and the website "www.biosency.com". A UDI number is also provided: "(01)03770024064018(8012)v3.0.0-rc7-staging". To the right, the Biosency company information is listed: "BIOSENCY 13 rue Claude CHAPPE Bât. A Oxygène 35510 Cesson-Sévigné France 2024-09". Below this, there is a QR code and CE 2797 certification marks. A note states: "Instructions for use are available electronically at: www.doc.bora-connect.com. A hard copy of the instructions can be provided within 7 days (upon request) by contacting Biosency at support@biosency.com".

The main section is titled "Personal data" and contains the following fields:


- Gender: * Other (dropdown menu)
- Language: * English (dropdown menu)
- Lastname: * Lee
- Firstname: * Harper
- E-Mail: * harper.lee.bio@yopmail.com
- Prefix: None
- Telephone number: 611223344

Below the personal data fields is an "Update" button. Underneath, there is an "Authentication" section with two buttons: "Reset the paired device" and "Request password change". At the bottom of the form is a "Privacy" link.

You can change your identity and email address and change the interface language.


Click on the  button to confirm the changes.

Multi-factor authentication

Click the  button to reset the telephone number associated with your account (the telephone number that receives a one-time code during the authentication process).

You will be asked for a new telephone number the next time you connect to Bora connect®.

Password

Click on the  button to ask to change your password. You will receive an email that contains a link for resetting your password.

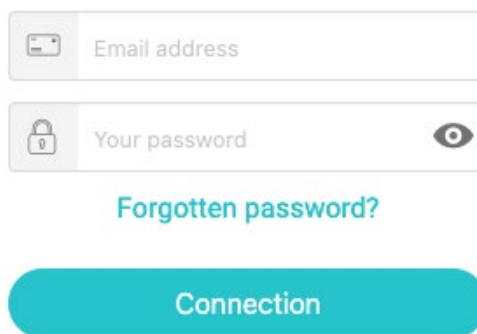
Did you forget your password?

If you want to change your password or if you have forgotten it, you can request to change your password on the connection page.

Click on "Forgotten password?". You will be sent an email that contains a link for resetting your password email.

If you have problems changing your password, [contact Biosency customer service](#) (see the end of the user manual).

Log in:



The login form consists of two input fields stacked vertically. The first field is labeled 'Email address' and has a small envelope icon on the left. The second field is labeled 'Your password' and has a lock icon on the left and an eye icon on the right. Below the password field is a teal link that says 'Forgotten password?'. At the bottom of the form is a large teal button with the text 'Connection' in white.

Meaning of figures, symbols and abbreviations

	Click to start a remote monitoring session
	Click to end a remote monitoring session
	Click to consult
	Click to add as a favourite
	Click to add or remove favourites
	Click to delete
	Click to change
	Click to duplicate
	Click to add a note to the therapeutic follow-up
RR (CPM)	Respiratory rate (cycle per minute)
HR (BPM)	Heart rate (beats per minute)
SpO2 (%)	Oxygen saturation (percentage)
Act (hr.)	Length of activity (hour)
 	One/no technical alert linked to a NIV device has been raised
 	One/no technical alert linked to a measuring device is active
 	One/no technical alert for an excessive unintentional leak is active
 	One/no alert linked to usage is active
 	One/no alert linked to the Apnoea-Hypopnoea Index (AHI) is active
 	One/no oxygen level alert is active
 	One/no heart rate alert is active
 	One/no respiratory rate alert is active
 	One / No BVS ³ > 3 σ alert is active
	Add a comment to an alert
	Consult patient data relevant to the alert
	Select several alerts to close out



Consult the patient file on AirView™

Bora connect® disconnection

Use the “Disconnection” button at the bottom left of the application.

 Logout

Updates and maintenance of the Bora connect[®] software

The Bora connect[®] platform is automatically updated when a new version is available. Biosency informs users before the application's update to warn of a potential service disruption or to present new associated features or upgrades.

PRECAUTIONS

VERSION OF BORA CONNECT[®] MOBILE

To use the latest upgrades, make sure to use the latest version of the Bora connect[®] mobile application.

The Bora connect[®] mobile application displays a notification to the connection if a new version is available for upload.

Data storage

The Bora connect® data are encrypted and hosted by a certified healthcare data host.

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

The length of data conservation is defined in the privacy policy available in the section Personal data protection policy of the website: doc.bora-connect.com.

The personal data are archived for 5 years after the end of the contract. After this period, they are deleted.

The connection record is kept for 1 year. After this period, it is deleted.

With regards to the Bora connect® mobile application, no personal data is stored on the mobile phone. The personal data are held in the RAM memory when the application is being used and are deleted afterwards.

Healthcare professionals and stakeholders

Connect to the Bora connect[®] platform or mobile application to see:

- ▶ your patients' data
- ▶ the status of your Bora band[®] fleet.

Patients

The patient can connect to the Bora connect[®] platform or mobile application to:

- ▶ check the status of their Bora band[®]
- ▶ consult their physiological data.

Patients can connect to Bora connect for home or for study to check the status of their Bora band[®]. The patient cannot view the BVS³[®] score or alerts.

Warranty and assistance

To learn about our warranty and assistance terms and conditions, please refer to our general subscription terms and conditions, available on doc.bora-connect.com.

Warranty exclusions

To learn about our warranty and exclusion conditions, please refer to our general subscription terms and conditions in the next section:

LIABILITIES, WARRANTIES AND EXCLUSIONS

Incidents

Any serious incident which occurs in connection with the Bora connect® must be reported to the manufacturer and to the competent authority of the country in which the patient resides.

Assistance

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

Software uninstalling and decommissioning

Bora connect® is a web platform and is not installed on your computer.

The Bora connect® mobile application, Bora connect for Home and Bora connect for Study can be uninstalled in the same way as any other application according to how your mobile phone operates. In general, pressing and holding on the application's logo will show a menu from which the application can be uninstalled.

This chapter presents a set of precautions and warnings to guard against cyber security 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 the device's residual hazards, an overview of our platform's safety management, information helpful for using the medical device safely and recommendations for protecting yourself against cyber security risks:

<https://doc.bora-connect.com>

Security options

Bora connect[®] is an online platform. Security updates are performed automatically. There are no specific security options for using Bora connect[®]. Review the section on security recommendations at

<https://doc.bora-connect.com/security-description-BC/en>

Verification and Logging

Bora connect[®] can reliably audit the activity on the device. Bora connect[®] creates additional audit logs for any action on the platform. The person concerned is identified in the log for each personally identified information.

Impact on security

In the event where Bora connect[®] were unable to maintain the platform's security, the subsequent impact on the care of patients would involve the interruption of their remote monitoring, which would only delay the patients' care.

Technical characteristics

Performance

For the measurement accuracy, please refer to the device's user manual.

Bora Band®

Data	Display range	Display accuracy
Measurements		
Oxygen saturation	70% - 100% SpO ₂	± 1%
Heart rate	35 – 240 bpm	± 1 bpm
Respiratory rate	10 – 50 cpm	± 1 cpm
Temperature	10 – 43°C	± 0.1°C
Activity	0 – 24 hrs.	± 1min
Step	0 – 2 ⁶³ -1 step	± 1 step
Median and quartiles		
Oxygen saturation	70% - 100% SpO ₂	± 1%
Heart rate	35 – 240 bpm	± 1 bpm
Respiratory rate	10 – 50 cpm	± 1 cpm
Temperature	10 – 43°C	± 0.1°C
Activity	0 – 24 hrs.	± 1min
Step	0 – 2 ⁶³ -1 step	± 1 step

Lifespan	3 years
-----------------	---------

Remote monitoring software

Manufacturer	NIV remote monitoring software designation	Method of Integration	Conclusion
ResMed	AirView™	AVX API	All clinical and technical parameters from NIV remote monitoring software and displayed on Bora Connect® are accurate.

For further information on the accuracy and performance of ResMed NIV devices, please refer to the user manual of the corresponding device, available on the page <https://www.resmed.fr/professionnels-de-sante/centre-de-ressources/guides-utilisation-et-declarations-de-conformite/> category “ventilation device”.

BVS³[®]

The clinical performances of the BVS³[®] score are as follows:

Parameter	Designation	Results
Time	Mean time anticipation before the exacerbation occurs	3 days
Sensitivity	Sensitivity of BVS ³ [®] – Likelihood of detecting real exacerbations	85.7%
Specificity	Specificity of BVS ³ [®] – Likelihood of detecting false exacerbations	90.9%

Conformity

Standards related to software	IEC 62304 IEC 82304-1
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Clinical benefits table

Improving the quality of life is a possible clinical benefit of setting up remote monitoring with Bora connect[®] with Bora band[®] or compatible Non-Invasive Ventilation. The clinical parameters displayed on Bora connect[®] can be used by practitioners to optimise respiratory assistance prescriptions, monitor patients and maintain improvements during respiratory rehabilitation.

Preventing the aggravation of chronic respiratory pathologies, and (re)hospitalisation, is a possible clinical benefit of using Bora connect[®] in combination with Bora band[®] or compatible Non-Invasive Ventilation. Changes in the clinical parameters displayed by the Bora connect[®] may be an alert criteria for a future deterioration in a patient's state of health.

The following clinical benefits are documented when Bora Connect[®] is connected to Bora band[®] or compatible Non-Invasive Ventilation.

Clinical benefits table

Benefits	Quality of Life improvement	
	Acceptance of physical training in rehabilitation	Patient reassurance
Population	BPCO, OSAS	BPCO, OSAS
Source	eMEUSE clinical trial	
Results	84% (95% confidence interval: [75% - 93%]) of patients taking a personalized physical training in pulmonary rehabilitation with Bora care [®] solution did not quit the Program.	95% of patients (95% CI: [91% - 99%]) were reassured by the Bora Care [®] solution

Benefits	Patient care improvement		
	Patient compliance		
Population	BPCO	BPCO, OSAS	Chronic Respiratory Diseases

Source	DACRE clinical study Brinchault, G., et al. "Évolution des signes vitaux en vie réelle de patients BPCO: facteurs préventifs d'une réadmission après une hospitalisation pour exacerbation sévère—étude clinique en vie réelle DACRE." Revue des Maladies Respiratoires Actualités 15.1 (2023): 70.	eMEUSE clinical trial Le Guillou, Y., et al. "Vital Signs Remote Patient Monitoring in Real-life for Early Detection of Acute Exacerbations of Chronic Obstructive Pulmonary Disease." C15. EMERGING COPD DIAGNOSTICS AND TREATMENTS. American Thoracic Society, 2023. A4496-A4496.	APOR clinical study
Results	Mean patient compliance of 90% (95% CI: [87% - 92%]).	Mean patient compliance of 90% (95% CI: [87% - 92%]).	Mean patient compliance of 90% (95% CI: [82% - 93%])








Benefits	Patient care improvement		
	Patient care improvement: Prevention of (re) hospitalization with remote monitoring with Bora Band®	Prevention of BPCO exacerbations with remote monitoring with Bora Band®	Detection of wrong oxygenotherapy prescription and generation of a new O2 prescription and/or prescribe another exam
Population	BPCO	BPCO	Chronic Respiratory Diseases
Source	DACRE clinical study Brinchault, G., et al. "Évolution des signes vitaux en vie réelle de patients BPCO: facteurs préventifs d'une réadmission après une hospitalisation pour exacerbation sévère—étude clinique en vie réelle DACRE." Revue des Maladies Respiratoires Actualités 15.1 (2023): 70.	eMEUSE clinical trial Le Guillou, Y., et al. "Vital Signs Remote Patient Monitoring in Real-life for Early Detection of Acute Exacerbations of Chronic Obstructive Pulmonary Disease." C15. EMERGING COPD DIAGNOSTICS AND TREATMENTS. American Thoracic Society, 2023. A4496-A4496.	APOR clinical study
Results	Respiratory rate correlates with readmission (0.607, p-value=0.010). Heart rate correlates with readmission (0.416, p-value=0.097)	The BVS ³ ® > 3 alert makes it possible to detect COPD exacerbations on average 3 days before their occurrence with a sensitivity of 85.7% and a specificity of 90.9%	Bora Care® is useful to confirm the O2 prescription, or detect a wrong O2 prescription and generate a new O2 prescription, or prescribe another exam in 54% of the cases (95% confidence interval: [25% - 81%]).

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Symbols

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

	Please consult the user's guide before using the device.
	No alarm triggered.
	EC marking that indicates its compliance with the current regulations on medical devices. Notified body: BSI NL
	Medical device.
	Unique identifier for the device.
	Manufacturer and date of manufacture.
	Name and address of the registered branch of the Swiss representative.

Manufacturer contact details



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