BIOSENCY

Bora connect®

Web platform and mobile application
for healthcare professionals and stakeholders

User manual

Bora connect® version 2.10
Bora-connect_IFU_2.10_B – April 2024

Table of contents

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 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®.

Indication for use and target population

Bora connect ® is indicated for remote monitoring of adult patients with a chronic respiratory disease and equipped with a compatible medical device enabling data transmission.

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.

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

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

Intended users

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.
- 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.
- The Bora connect® is intended to be used in combination with compatibles 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 the Bora connect® mobile application, Bora connect for Home or Bora connect for Study.
- 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 AND DEVICES

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

Bora band®

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

Device	Description
Bora band® BB-100 standard kit	Bora band® standard kit, device worn on the wrist and used to measure 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's mobile application

⚠ WARNING

PATIENT'S MOBILE APPLICATION

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 the installation of a mobile application for patient use: 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.

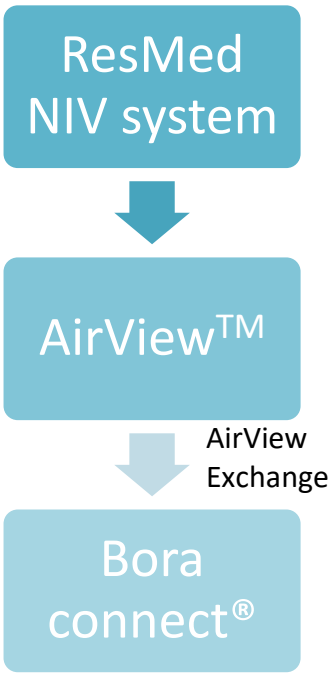
Device	Description
BC4H	Bora connect for Home, the patient's mobile application that transfers data to and from the Bora band®:
BC4S	Bora connect for Study, the patient's mobile application that transfers data to and from the Bora band® and collects the responses to the quality of life questionnaire.
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 response to the quality of life questionnaire.

Information on the optimal use of the Bora band® with the mobile applications is 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.

⚠ 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
- Browser: Up-to-date browser supporting HTML5
- Resolution: min. 1920*1080
- Internet connection with access to :
  - https://bora-connect.com
  - https://auth.bora-connect.com
  - https://api.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

Bora connect® presentation

Important to note:

- 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 AGENCE DU NUMÉRIQUE EN SANTÉ

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 NIV parameters
- monitor the patient's BVS3 score
- 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
-  **Questionnaires:** a list of all the questionnaires
- **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". Bora connect® unique device identifier is displayed on the "Parameters" page and is preceded by the UDI 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: Pair devices
- Step 2: configure alerts for the session
- Step 3: start the remote monitoring session

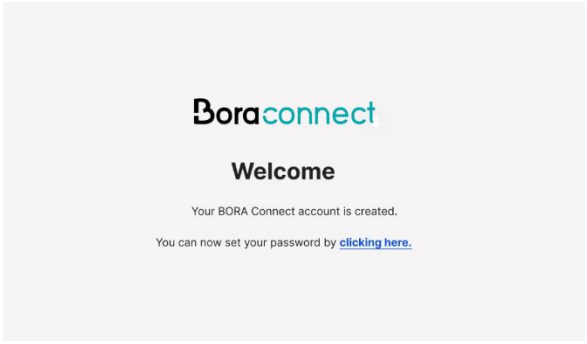
3 Monitor the collected data

- 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.

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



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.)

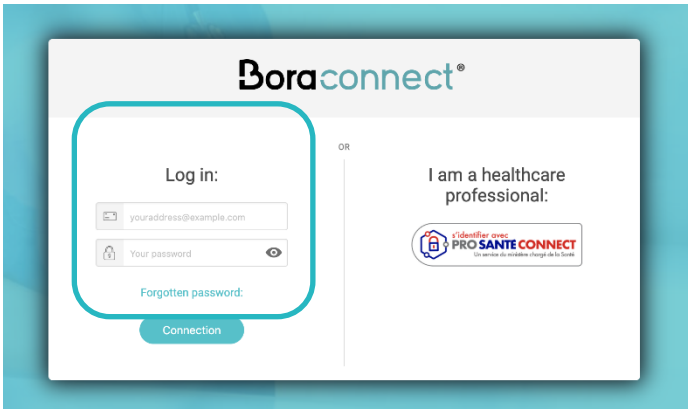
Your password must contain at least 10 characters and at least 3 of the 4 types of the following characters:

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

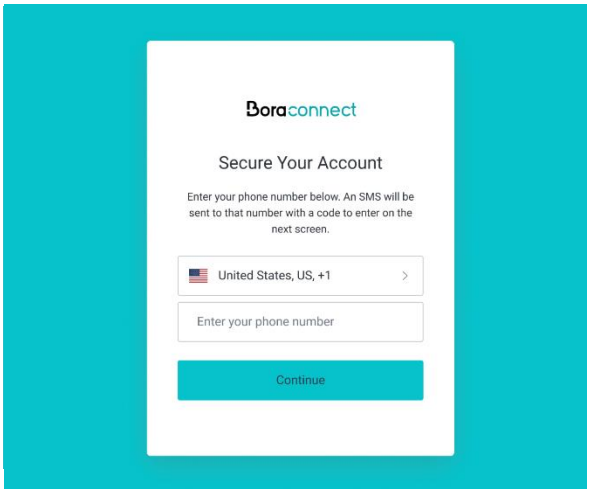
After creating your password, you will be redirected to the connection page.

Connection via email

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

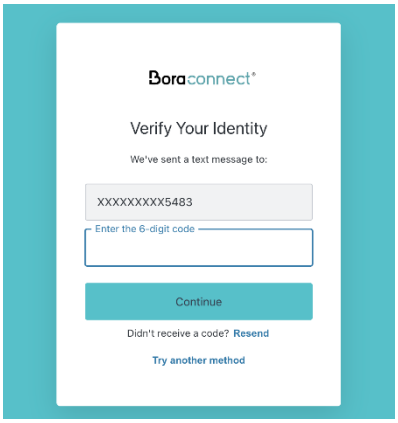


When you connect for the first time, you have to enter a mobile phone number to activate the two-factor authentication.



2 **Select your country code** and **enter your mobile phone number**.

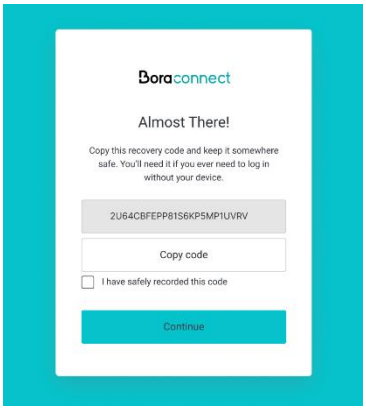
You will immediately receive a SMS containing a single-use code.



3 **Enter the single-use code received by SMS**.

The two-factor identification will be required at least once per week, unless you willingly disconnect from Bora connect®.

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



ⓘ This recovery code can only be used once.

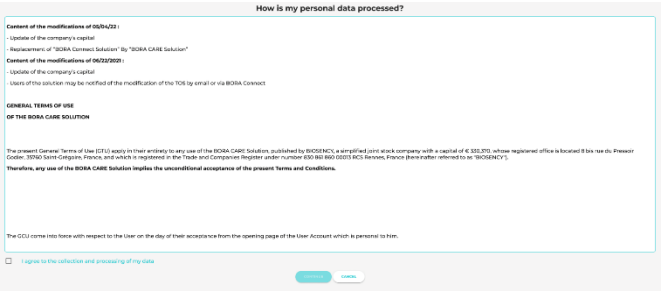
4 **Keep this recovery code in a safe place**.

⚠ PRECAUTIONS

BORA CONNECT® LOGIN DETAILS

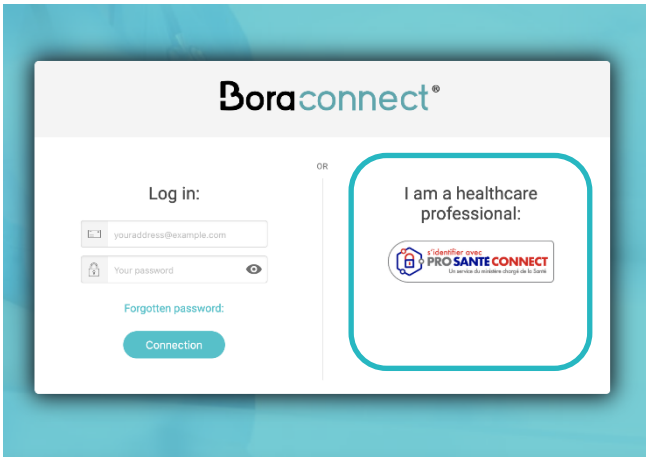
Please safely save your connection information (email address and password) and do not forget to secure access to your smartphone with a pin code or biometric recognition. This will prevent unauthorised and/or malicious third parties from accessing your data. Your connection information is strictly personal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



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

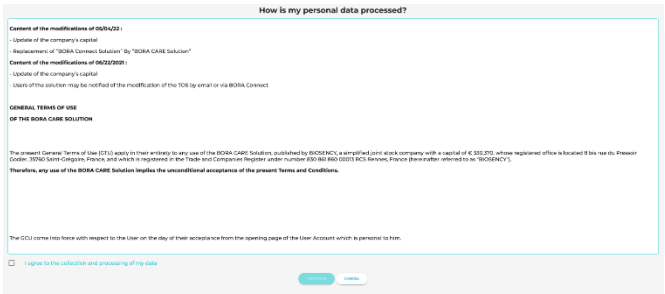
Connection via Pro Santé Connect



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

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.



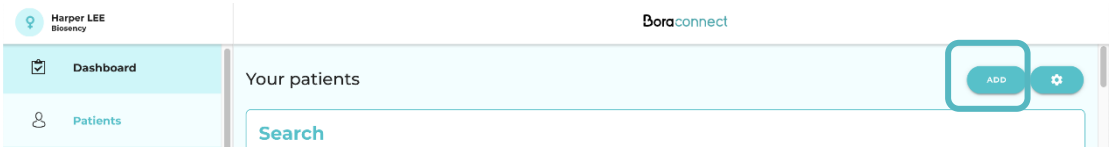
3 Congratulations, you are now connected to the Bora connect® platform.

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

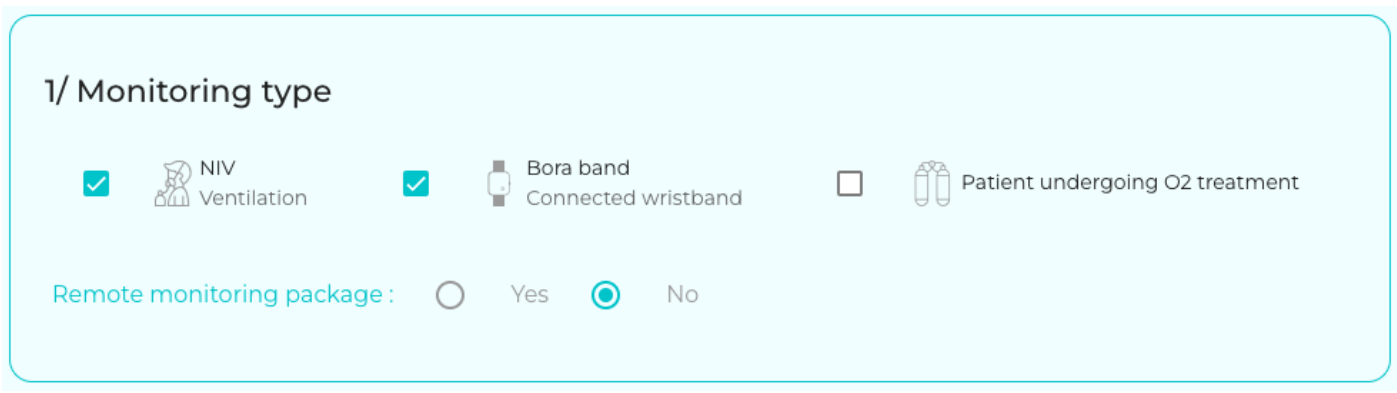
As part of the remote monitoring package (/), two additional categories are shown:

- 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:

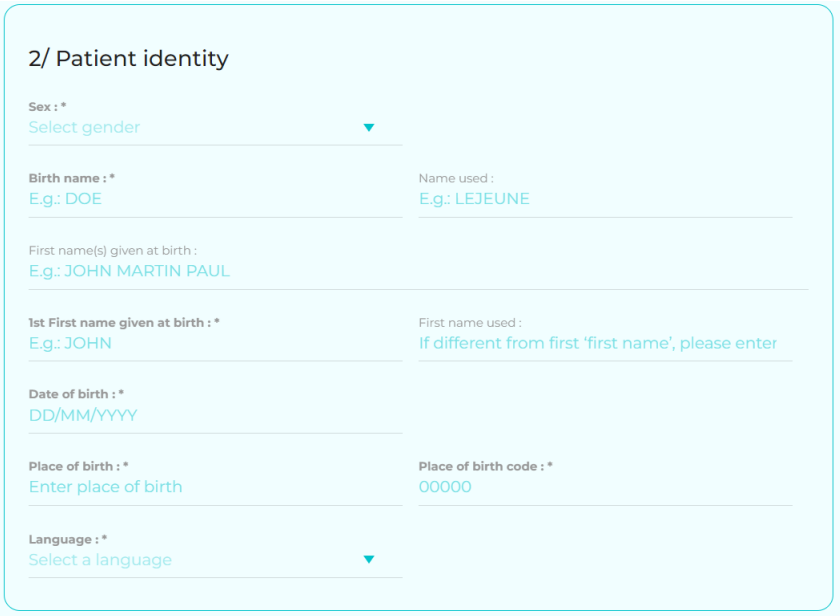
- The device(s) to be linked with the patients:
  - NIV (Ventilation)
  - Bora Band® (connected wristband)
  - If the patient is undergoing oxygen treatment (this information is only optional and does not have an impact on the patient's current care on the platform)

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

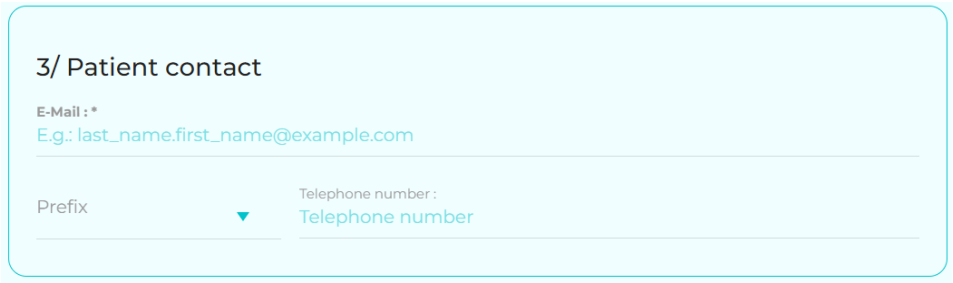


2 Fill in the patient identity file, including all the following information:

- 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)



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



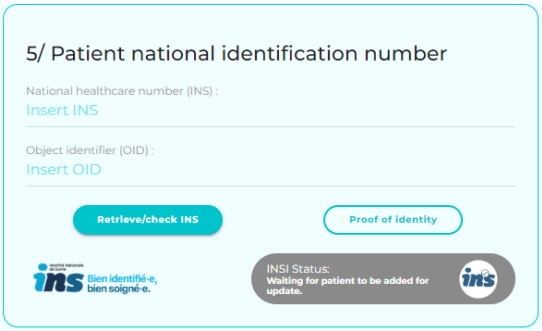
Email address of a trusted third party can be used.

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

To access the INS service, the software must be installed. Refer to annex 1 to follow the installation steps.

5 The "patient national identification" 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".



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

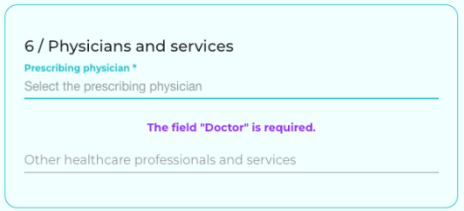
- The INS status is "provisional identity" (default status) when one of the two following cases is true:
  - The "questionable identity", "fictitious identity" or "homonymous identity" attribute was ticked
  - The INS was not recovered and no highly trusted proof of identity was stated as being presented
- 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.

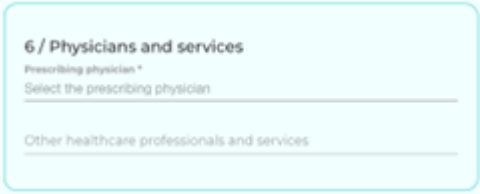
These verifications help qualify the INS and strengthen the patient's identification safety and reliability.

These verifications do not have to be renewed.

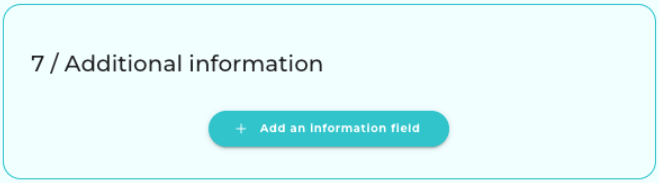
6 Enter the patient's prescribing physician. The service or other physician's associated with the patient's care can also be indicated.



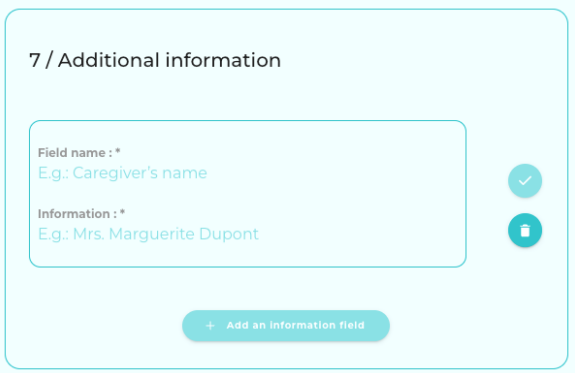
If you are a healthcare professional, you must provide information on your patient's home structure. Your will be automatically added to the "other healthcare professionals and services" category so that you can access the patient's record even if you are not the prescribing physician.



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



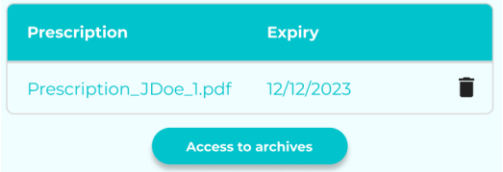
To add a field, you must :
- Give the field a name
- Enter the information you wish to add
- Click on the validate button on the right



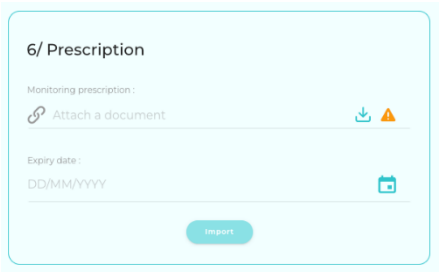
Once a field has been added, you can edit it at any time by clicking on the edit button to the right of the field.

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

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

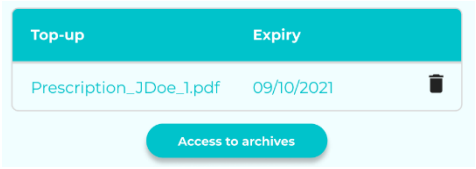


8 Attach the patient's prescription in category "6/ Prescription information" by :
- Selecting the prescription document
- Entering the prescription expiry date
- Clicking on "Import



By entering the expiry date, Bora connect® will notify you
Bora connect® to be notified 15 days before the expiry date, then when the prescription has expired.

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.

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.

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

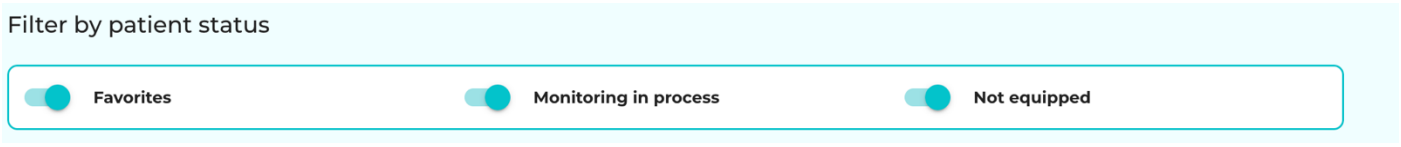
List of patients

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:

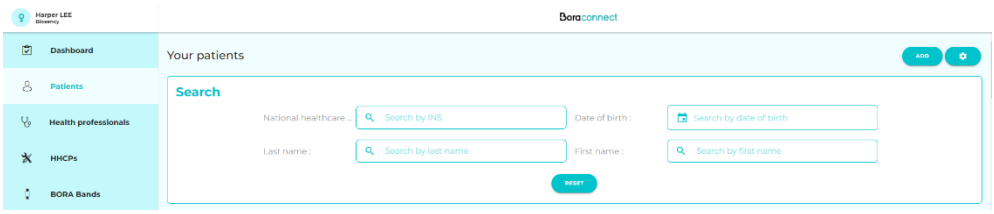
- Favorites
- Monitoring in process
- Not equipped

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.

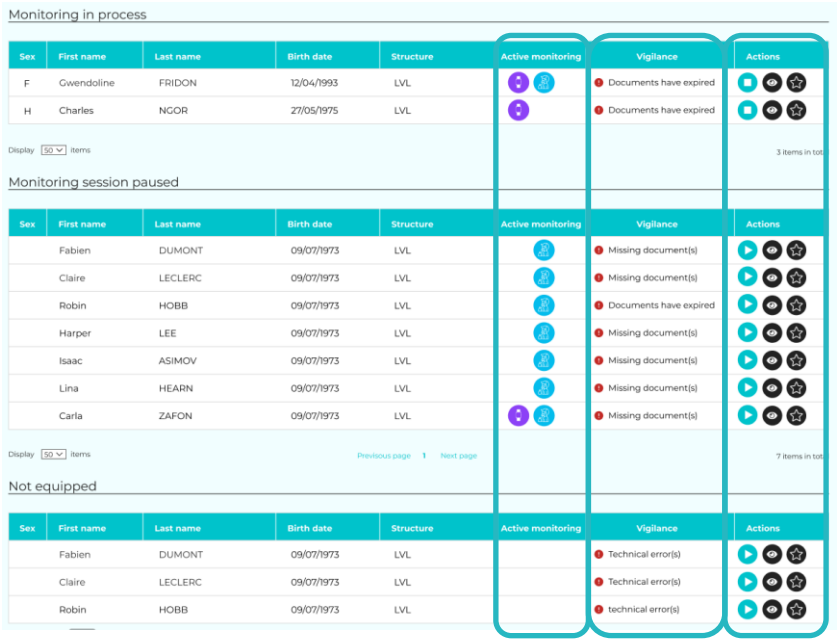


If you are searching for a specific patient, you can use one or more of the following fields in the search box:

- INS
- Last name
- Date of birth
- First name



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



- **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

- **Warning**: displays the warning notifications that the user must review
  - **+ Notification "Document expired/expiring" because :**

    - Case 1: The validity date of the prescription is about to expire (15 days before) or has expired.
    - Case 2: The validity date of the complementary health insurance certificate is coming to an end (15 days before) or has expired.

  - **Missing information"** notification if any important information is missing from the patient file (e-mail address, prescribing doctor, etc.)..
  - **“Missing consent" notification** if the patient's consent to Biosency's data processing is missing. The patient must log in to their account, via the email they have received, to accept it.

You can manage these warning notifications on the page of the patient concerned by resolving the problems mentioned. For example, by updating the documents relating to an “expired document/upcoming expiration” notification.

- **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.

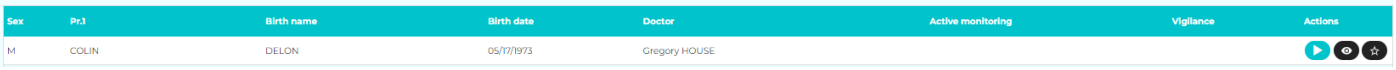
2 Start a remote monitoring session

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



- 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).

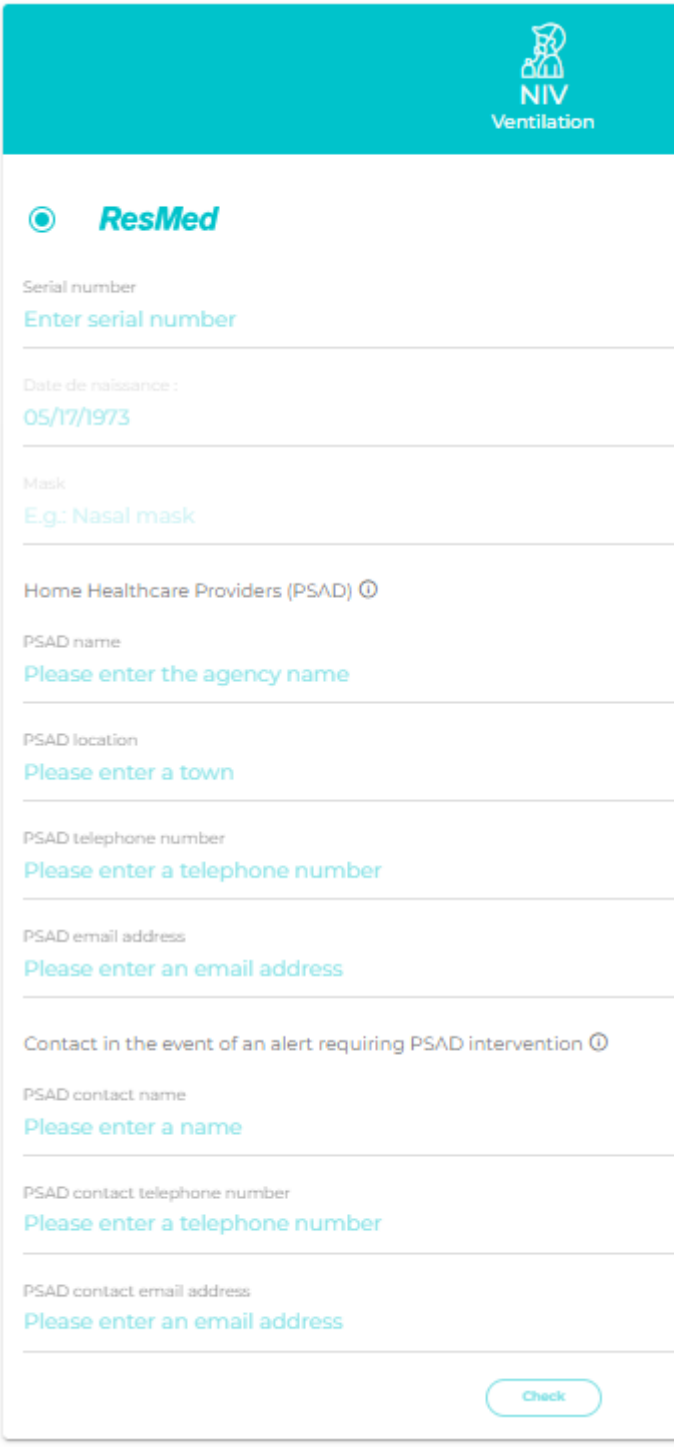
Linking a NIV device

To link a NIV device, click on Link NIV 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.

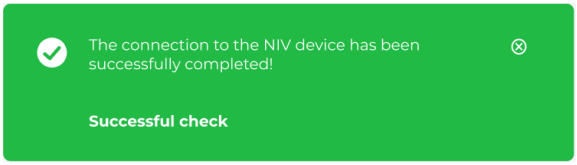
You can then enter the information relating to the healthcare provider agency as well as the point of contact in charge of the installation.
This information is not obligatory to validate the device link-up but it is recommended for having a reference contact in case of any problems.



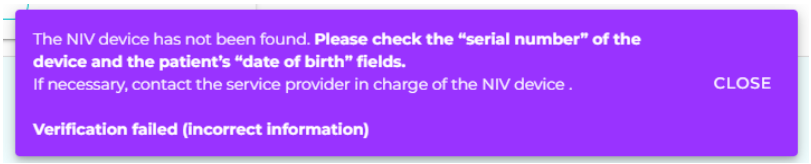
Once all of the information has been entered, click on the Check button to register the device.

Three types of messages can appear:

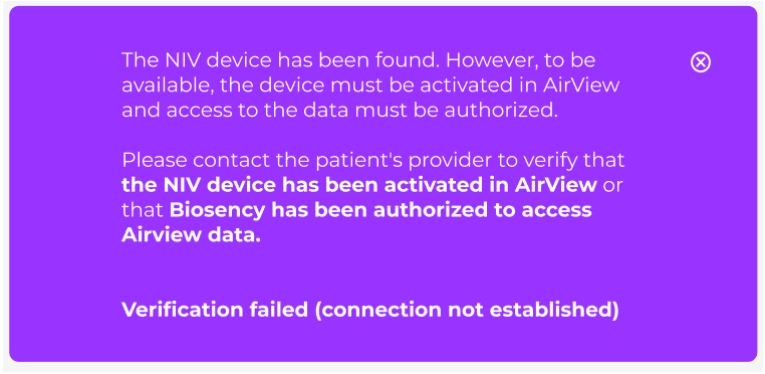
- A message indicating the success of the verification



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



- 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.



Linking a measuring device

To link a measuring device, click on Link Bora band and then:

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

Then click on Check 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 (BVS$^{3®}$ score)
  - The operation and use of NIV devices

Score BVS^3

The Bora Vital Sign Standard Score (BVS$^{3®}$) 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.[1]

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 occur[1].

Interpretation of results

The BVS$^{3®}$ score ranges from 0 σ to 10 σ, with values:

1. Between 0 σ (minimum value) - 3σ 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.
2. Between 3σ - 10σ (maximum value) indicating that the patient's vital signs over the last hour are significantly deviated (≥3σ) from the patient's baseline over the last 15 days.

The alert threshold is set by default in the Bora connect platform at 3.0 σ.

Calculation mode:

The BVS$^{3®}$:

- is not calculated if, over an hour, none of the 3 vital signs (HR / FR / SPo2) is available

- is calculated, and therefore displayed:

o 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

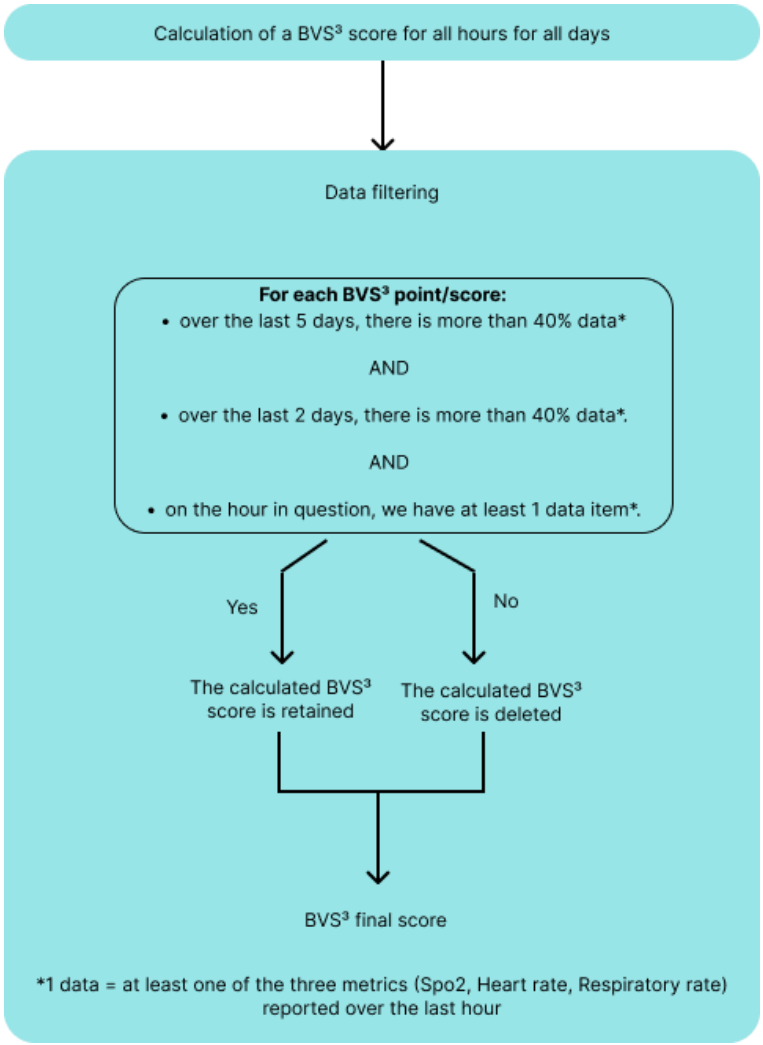
o If, over the last 2 days, at least an average of 40% of one-hour windows (21 out of 48 possible) contain at least 1 vital sign measurement (HR/FR/SpO2).

In practical terms, you need to wait around 3 days for the first BVS$^{3®}$score to be calculated at the start of a telemonitoring session, the number varying according to the number of one-hour windows containing at

[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"*

least 1 vital sign measurement.

The method of calculating the BVS3 score is as follows :



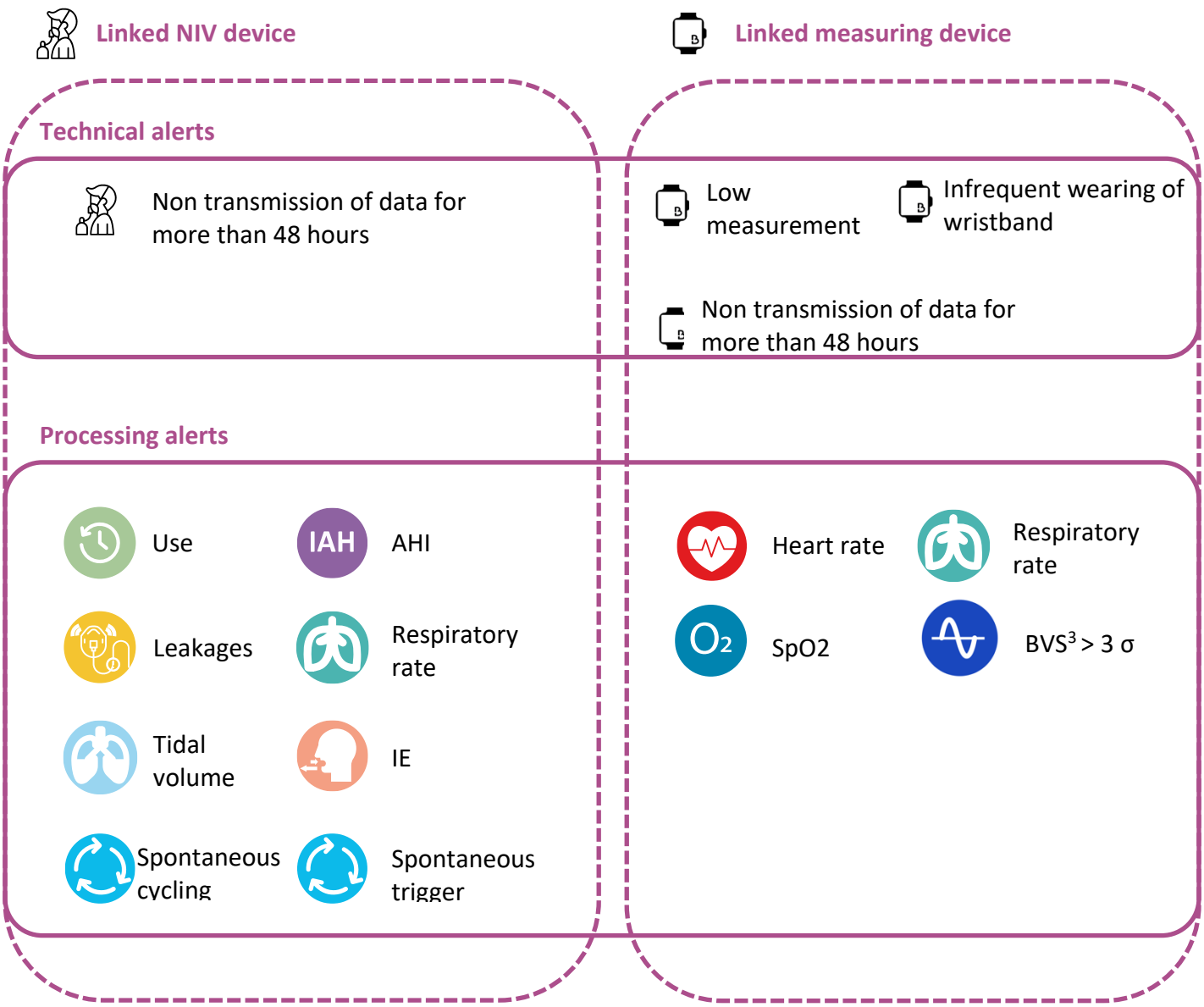
⚠ PRECAUTIONS

1. The BVS$^{3®}$ 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.

2. Failure to calculate BVS3 due to an insufficient number of vital sign measurements may result in a lack of BVS$^{3®}$ alert. Healthcare professional will ensure that this lack of data is compared with other available individual data available (HR, RR, Spo2).

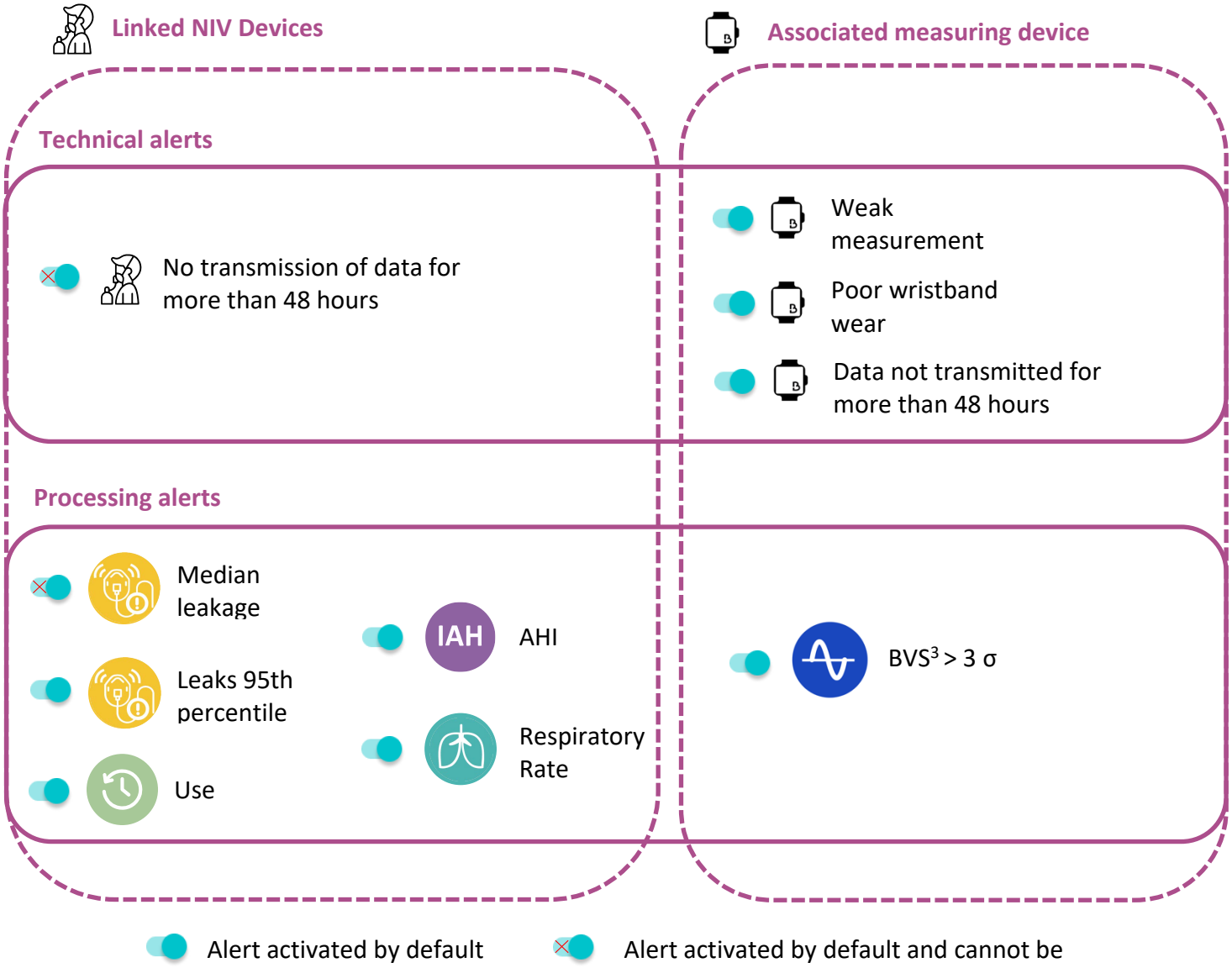
Available Alerts

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



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:



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

1. For alert "BVS3" whose threshold cannot be changed
2. For the "Median Leaks" alert which cannot be deactivated (requirement imposed by the Haute Autorité de Santé)
3. 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.

In addition to the processing alerts already available, new personalised processing alerts can configured by pressing the button + CREATE AN ALERT

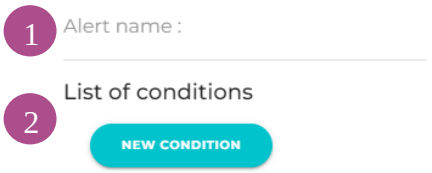
To add a new alert, you need to:

1 Name the alert

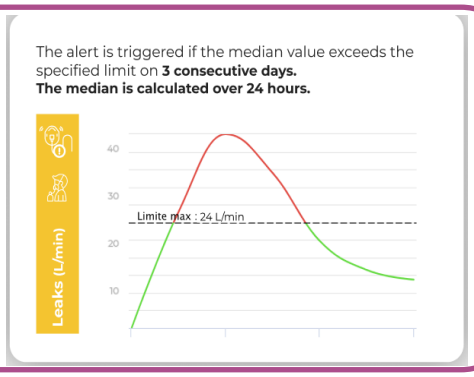
2 Add one or more conditions by selecting for each one:

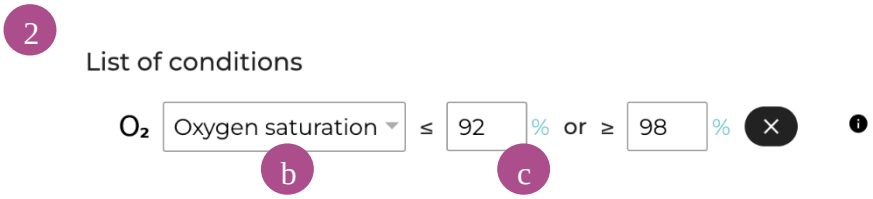
- a the type of condition
- b the vital sign
- c the alert activation threshold

3 Press the CREATE THE ALERT button



An exception is made on the "leak" alert for the NIV devices where the median is calculated over the last 24 hours. The alert will be triggered when the median is greater than 24 L/minute over three consecutive days.

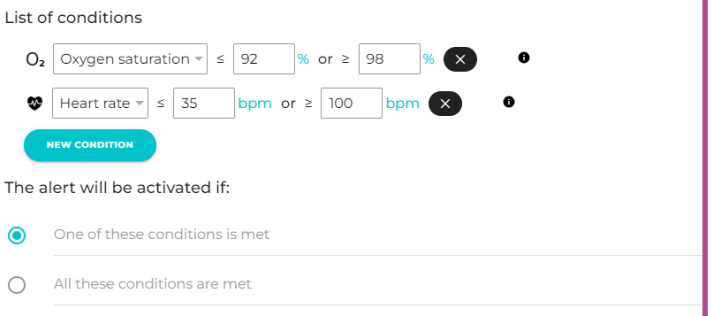




Once this step has been finalised, you can click "Next" to move on to the last step, the start of the remote monitoring session.

It should be noted that in the event that several conditions are created in the same alert, you can choose to have the alert triggered if all the conditions are met or only if one of the conditions is met.

In this 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 conditions attached to different devices cannot be combined.

2 a

A condition based on one or two set limits (e.g., Alert is raised when the saturation is less than 95%).

Note that the median is calculated over 48 hours.

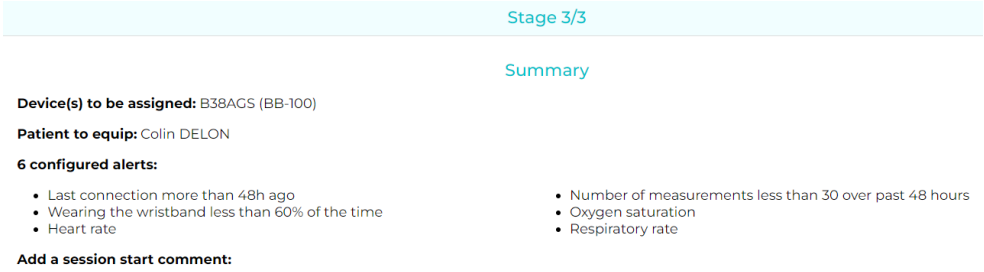
A condition based on one or two limits calculated on a variation from the patient's baseline (e.g., Alert is raised when the heart rate has 20% variation from baseline).

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

Step 3: start the remote monitoring session

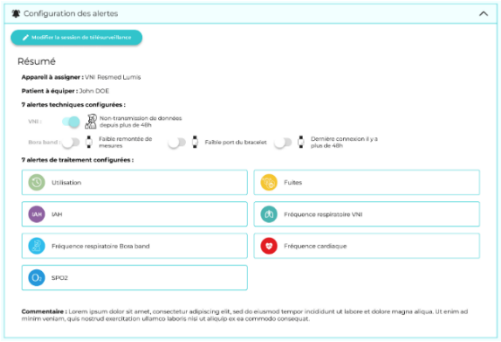
This last step allows you to confirm the summary of the information entered with:

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



A session start comment can be added.

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



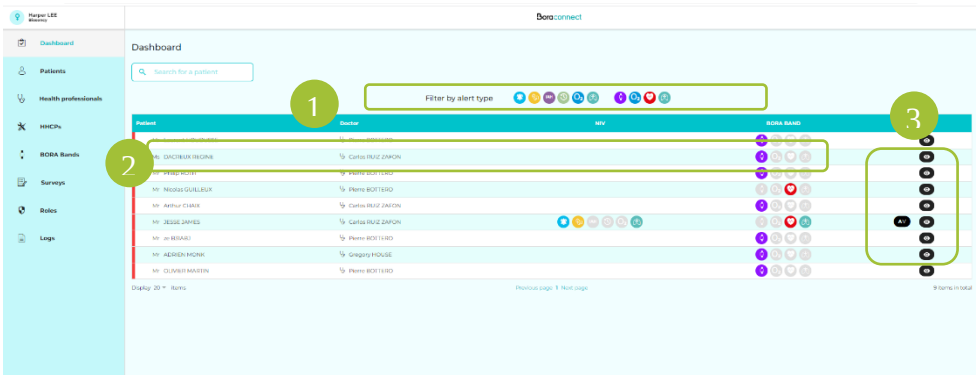
3 Monitor the collected data

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.

M. Isaac ASIMOV

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 alert filter tool bar differs depending on the activated modules (and/or):

Linked NIV device

Alerts related to technical problems

- Technical problem: Non transmission of data for more than 48 hours

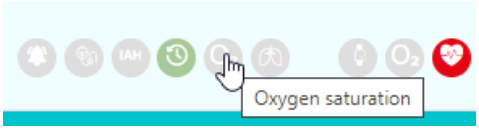
Alerts related to processing

- Excessive unintentional leaks
- AHI
- Use
- Oxygen level of patient
- Respiratory rate

Linked measuring device

- Technical problem:
  - Wearing the wristband < 60% of the time
  - Low data return (< 30 measurements over 48 hours)
  - No connection for 48 hours
- Oxygen level of patient
- Heart rate
- Respiratory rate
- BVS^3 Score > 3 σ

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



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).

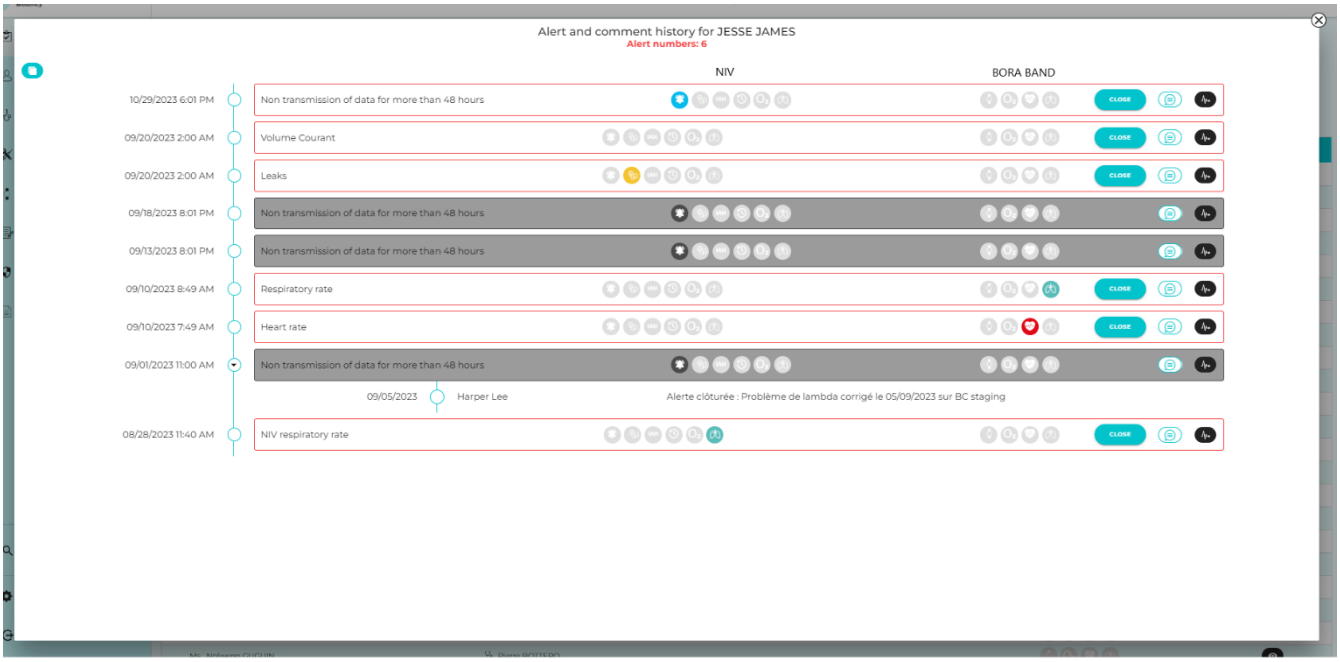
The following information appears for each alert:

- 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 side button. 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 CLOSE 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 CLOSE (1 ALERT).

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 AV 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.

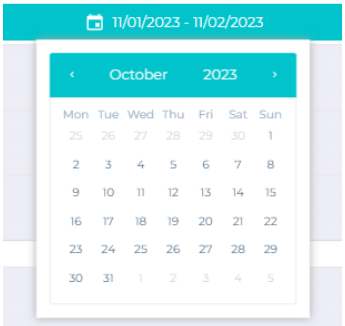
1 Depending on the devices linked to the patients, the graphs that can be displayed differ. Tick the device(s) whose uploaded parameters you want to view.
Click on the buttons AHI/RR/etc. to go directly to the corresponding graph.

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 parameters” for:

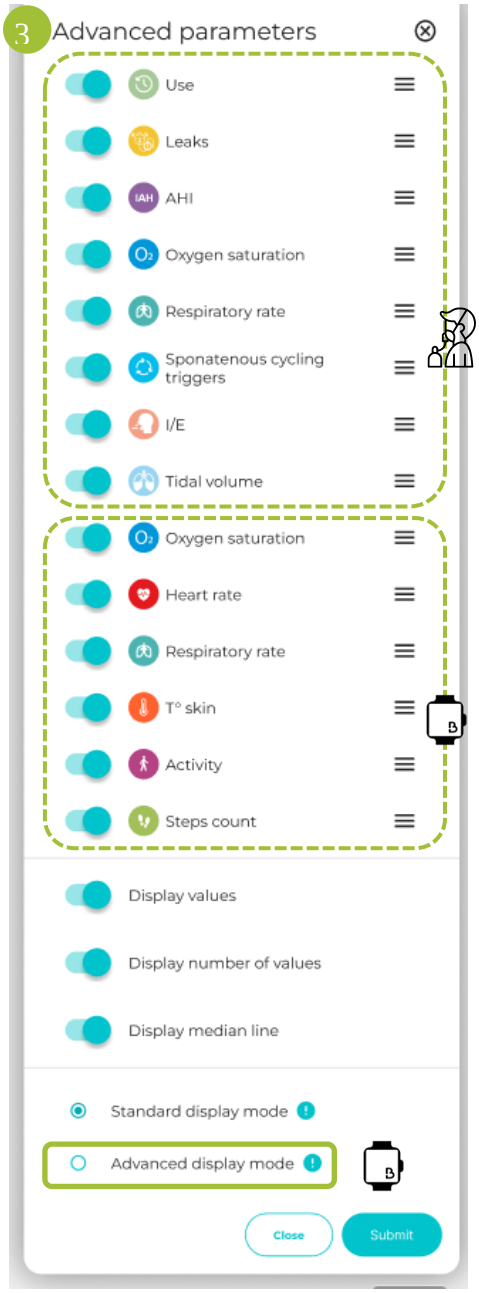
- Manage the display order of the graphs: the graphs are listed in the order of display. To change it, click on the ≡ button of the graph that you want to reposition and press down for the time it takes to move the graph to the right position.
- Select the graphs to display/hide using the button
- Select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

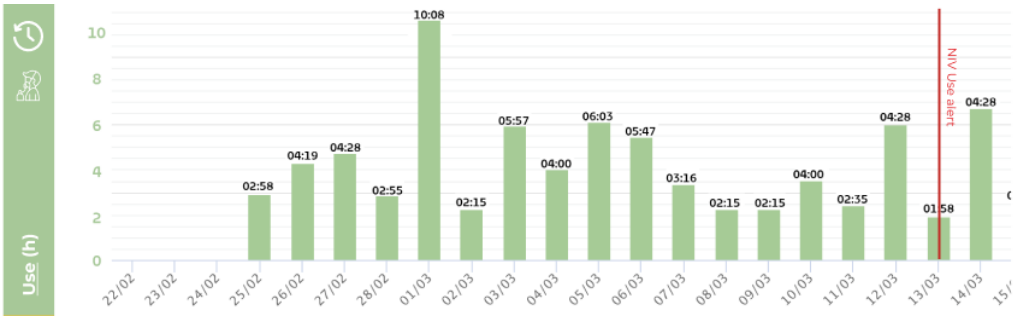
The data are displayed as a histogram or a curve depending on their typology.

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

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

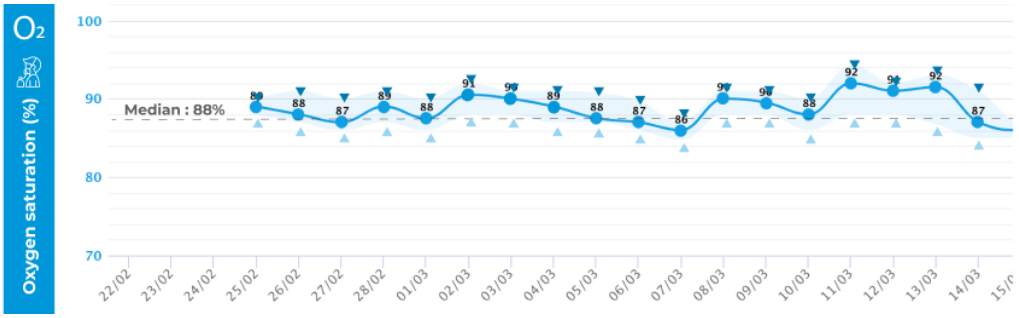
- The number of days with measurements
- The median of values over the selected time period
- The 95th percentile over the selected time period
- The 5th percentile over the selected time period
- A AV button to access the patient's AirView™ account for more details on the daily measurements (valid only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





AV

Measure	30/30 days
Median	8.5 hours



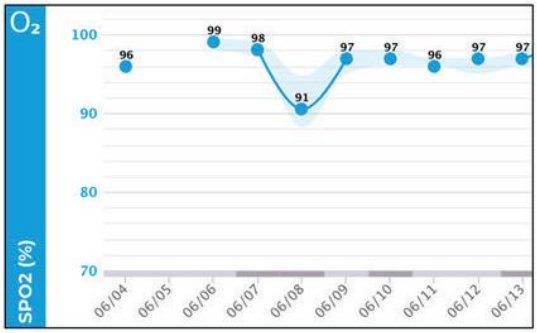
AV

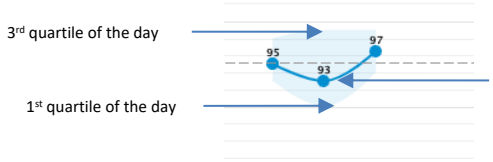
Mesures	30/30 days
95e centile	94%
Médiane	92%

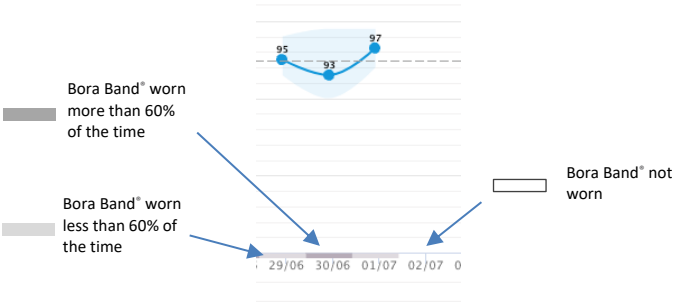
Median ▼95e ▲5e

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

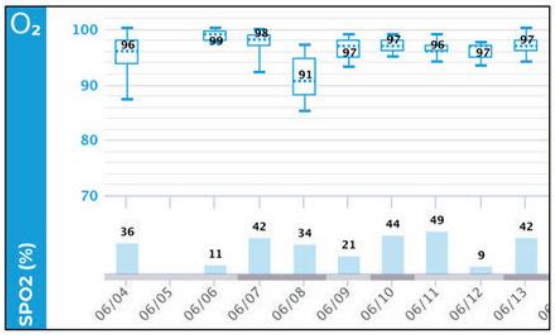
Standard mode

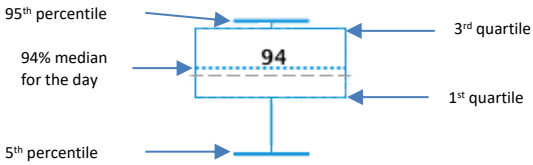


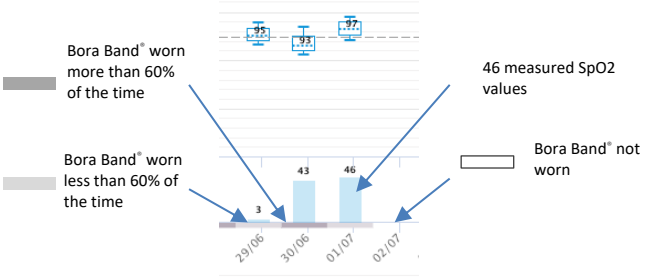




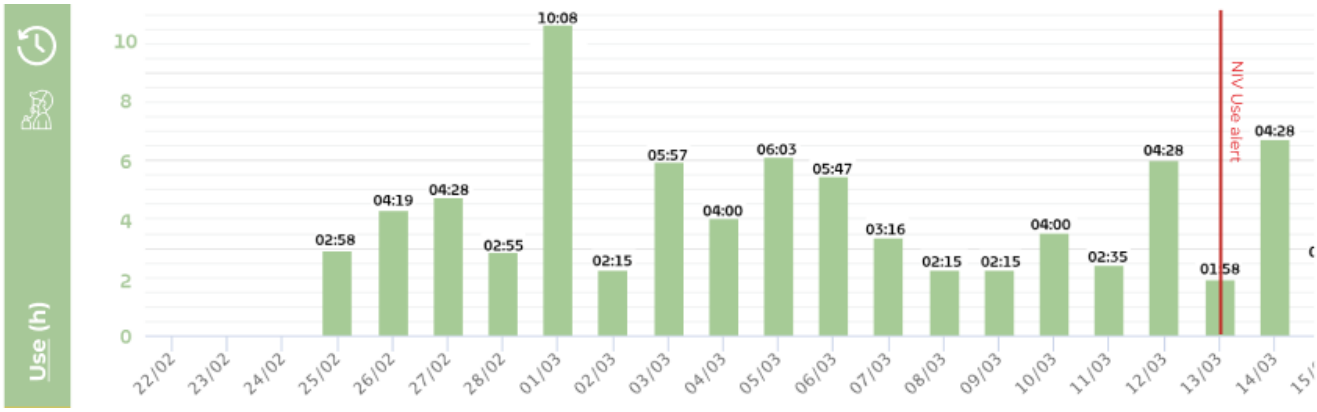
Advanced mode







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**.



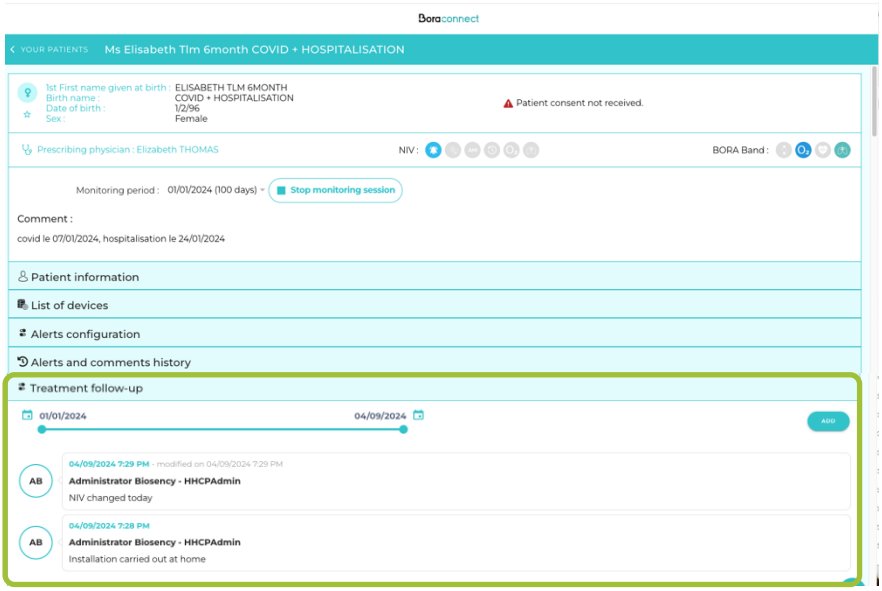
On the histogram measurements for use, the fragmentation of the usage appears when the users go over the graph.

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:

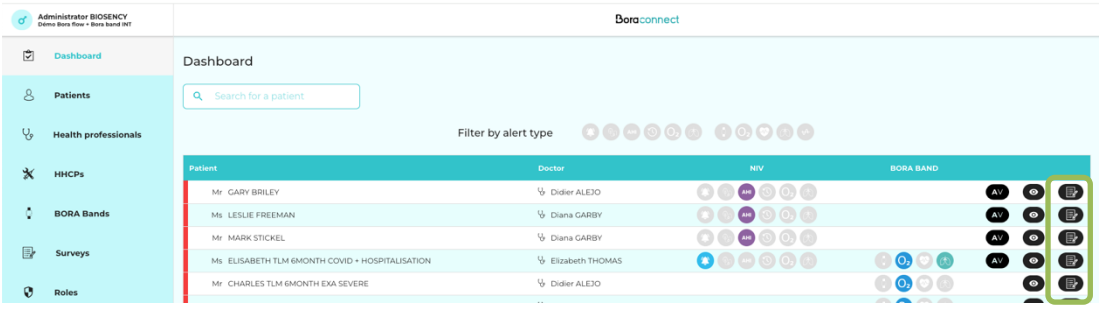
- Arranged in chronological order (from newest to oldest)
- Editable by the author only
- Composed of the following information:
  - Date the note was added (and date of last modification if applicable)
  - First Name Last Name and medical specialty / Role of the author of the note
  - Contents of the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



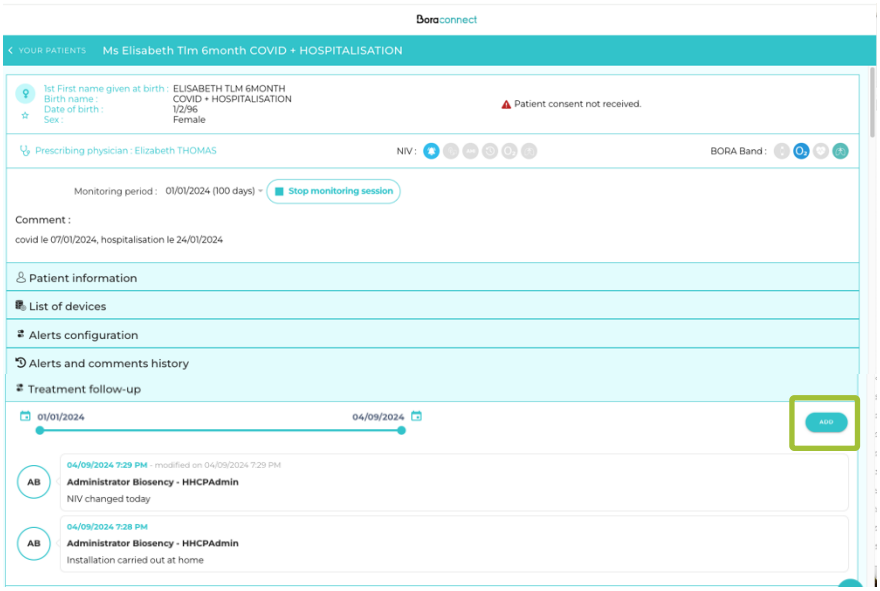
There are three ways to add a briefing note :

- 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.

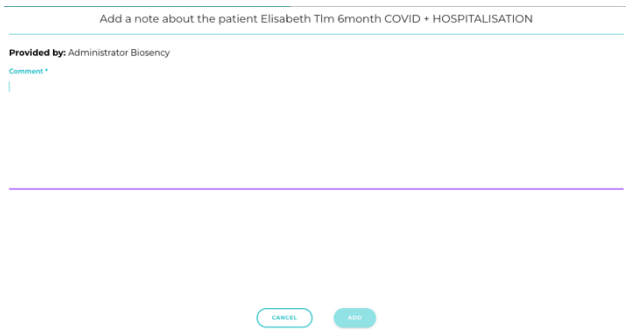


- From the patient file, therapeutic follow-up tab:



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

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

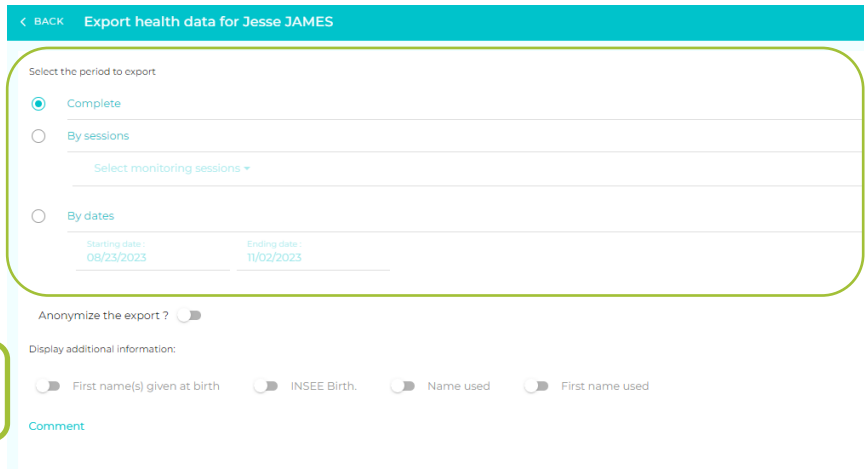


Report export

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

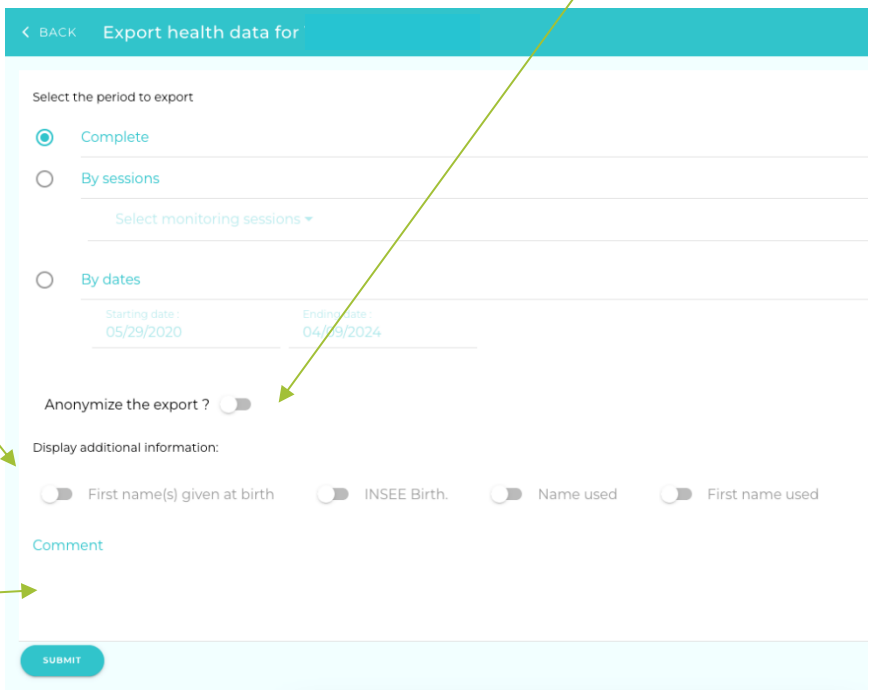


In day mode, you cannot export more than 15 days.

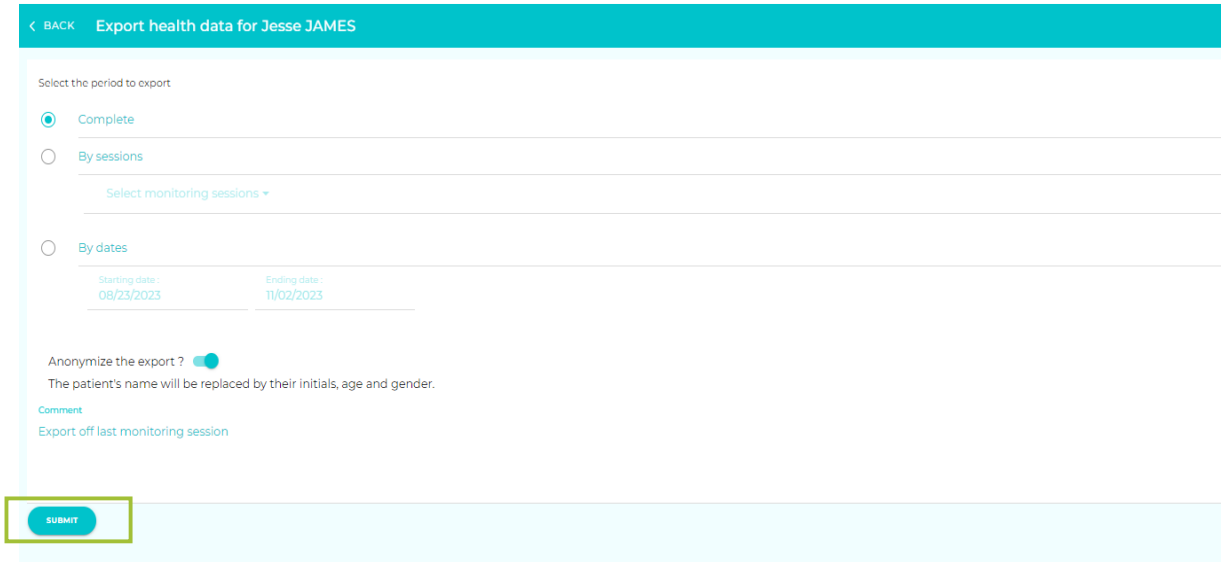
3 You can make the PDF export anonymous. You only need to click on the Anonymize the export ? button. The patient's name will be replaced by their initial, age and sex.

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

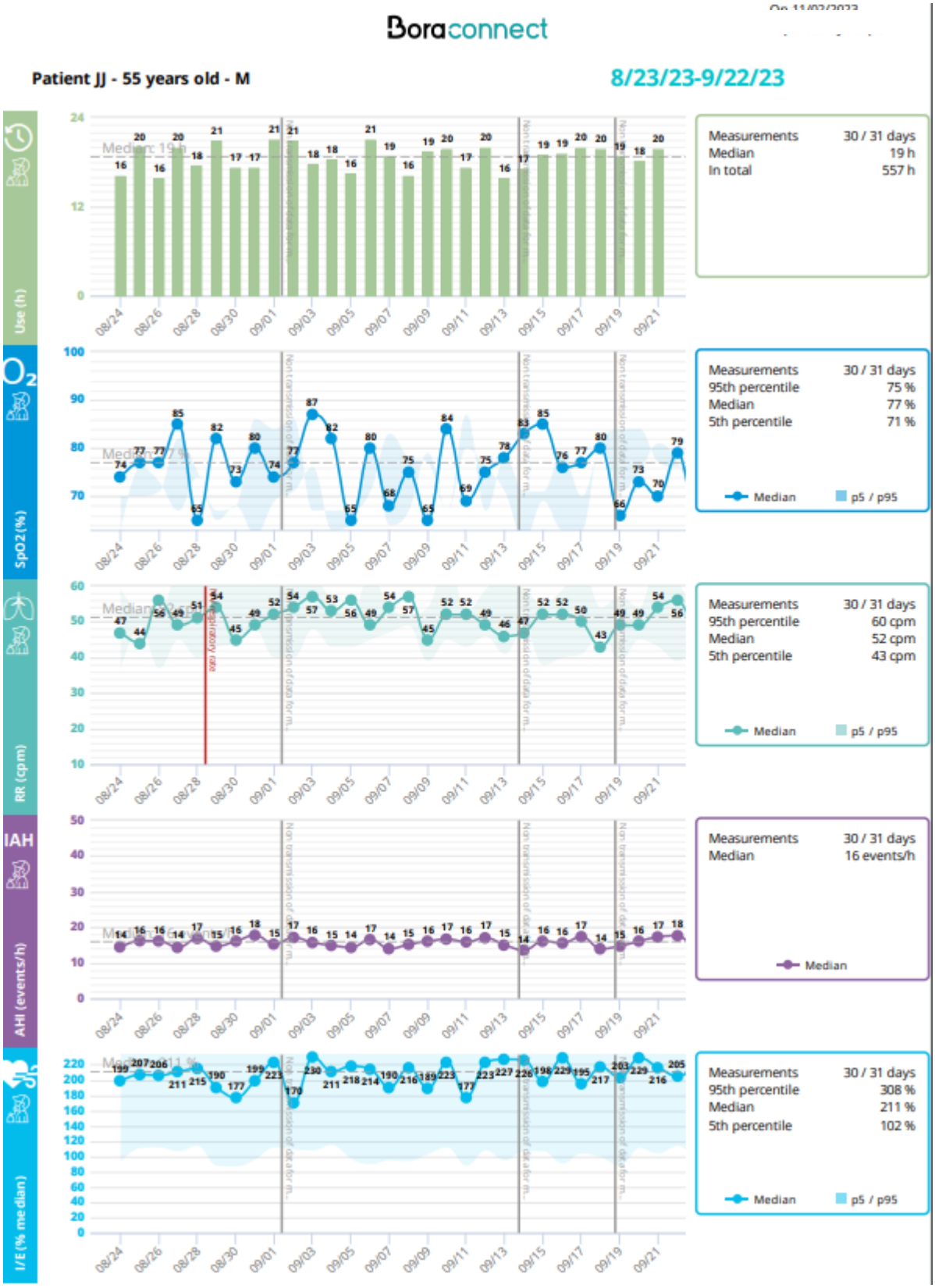
You can enter a specific comment that will be included in the export.



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



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

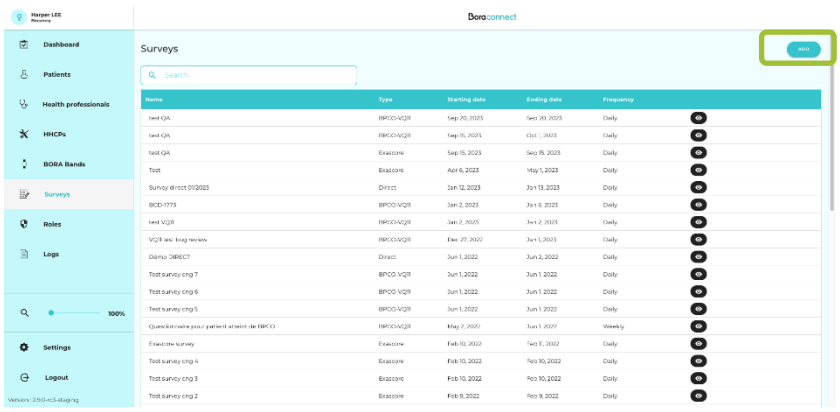


The PDF export will use your current graph parameters for the PDF file. Modify your current display parameters to modify the PDF export.

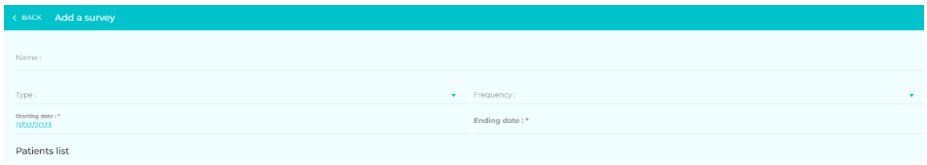
Create a survey

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.**

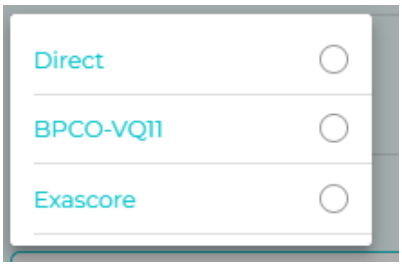
1 Go to the “surveys” tab to create a survey campaign for the patients.
Click on the “add” button.



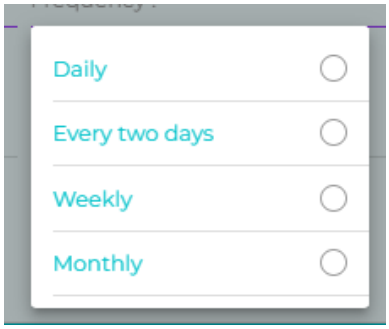
2 Enter a name for the campaign and select the survey type and its frequency. Select a start date and finish date.



3 types of surveys are available:

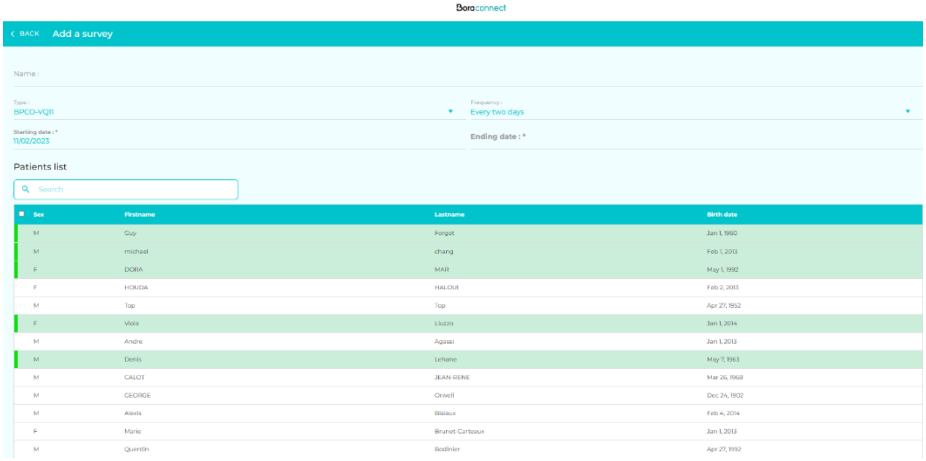


Select the survey's frequency:

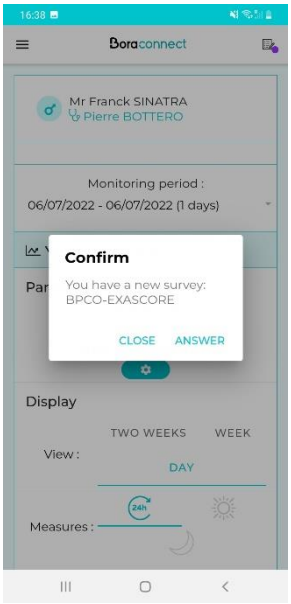


3 Then, select the patients who will receive the survey. Click on the patients on the list.

Click on the ADD button To confirm the creation of the campaign.

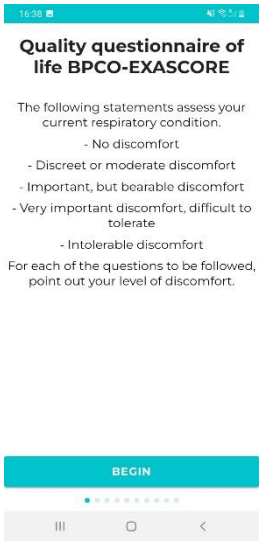


4 The next time that a patient will open the Bora Connect® mobile application, a notification will appear and ask the patient to answer the survey.



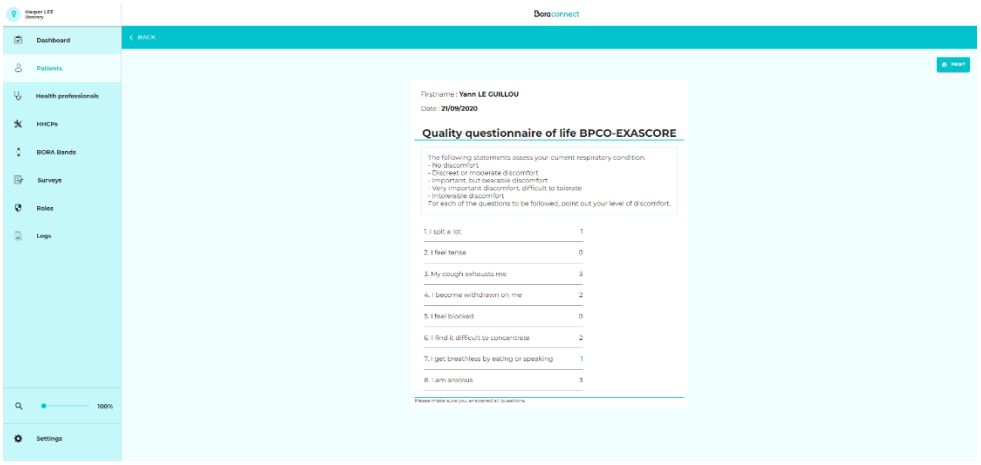
i Patients using a Bora connect for home or Bora connect for study mobile application cannot access the survey feature.

5 Patients can respond on their smartphone:



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

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

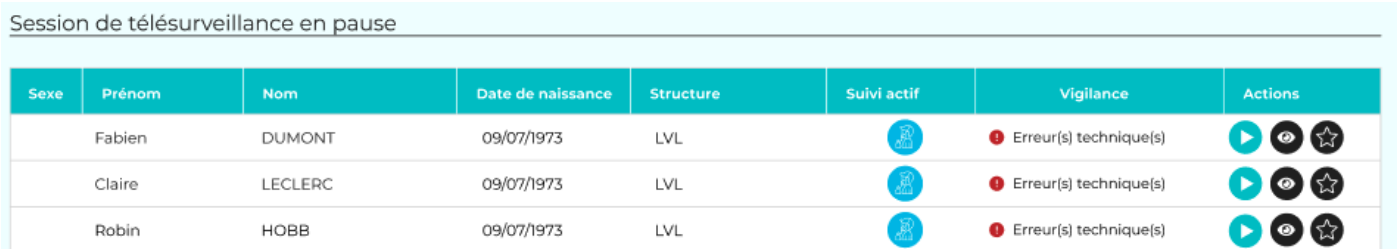


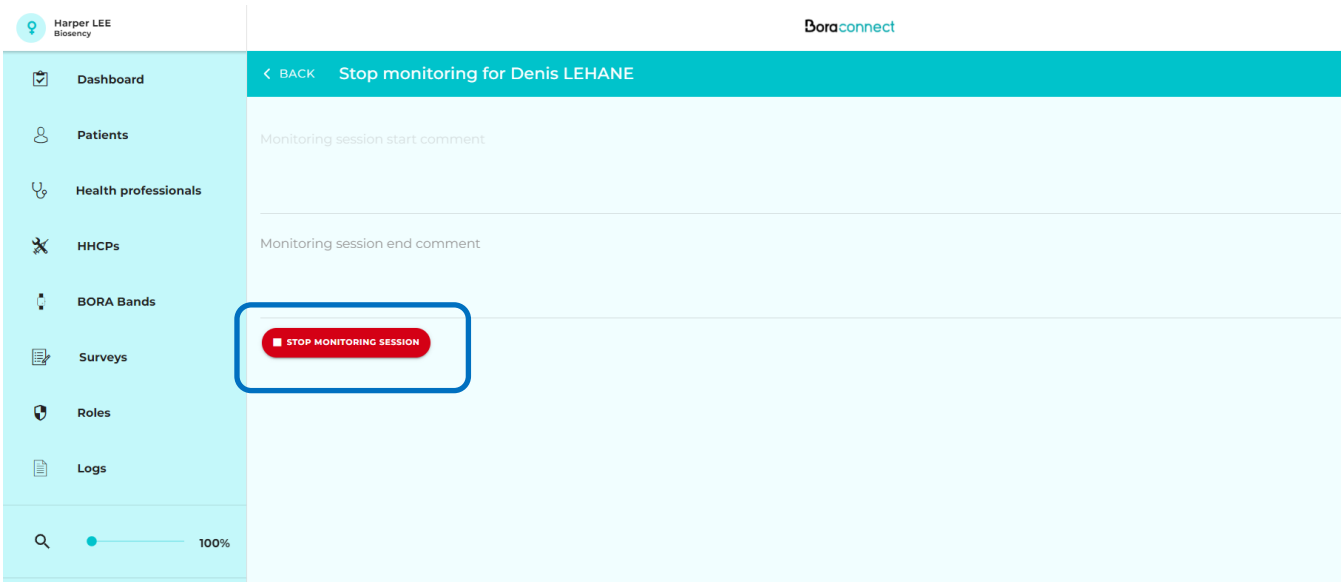
4 Stop a remote monitoring session

A remote monitoring session can be stopped from:

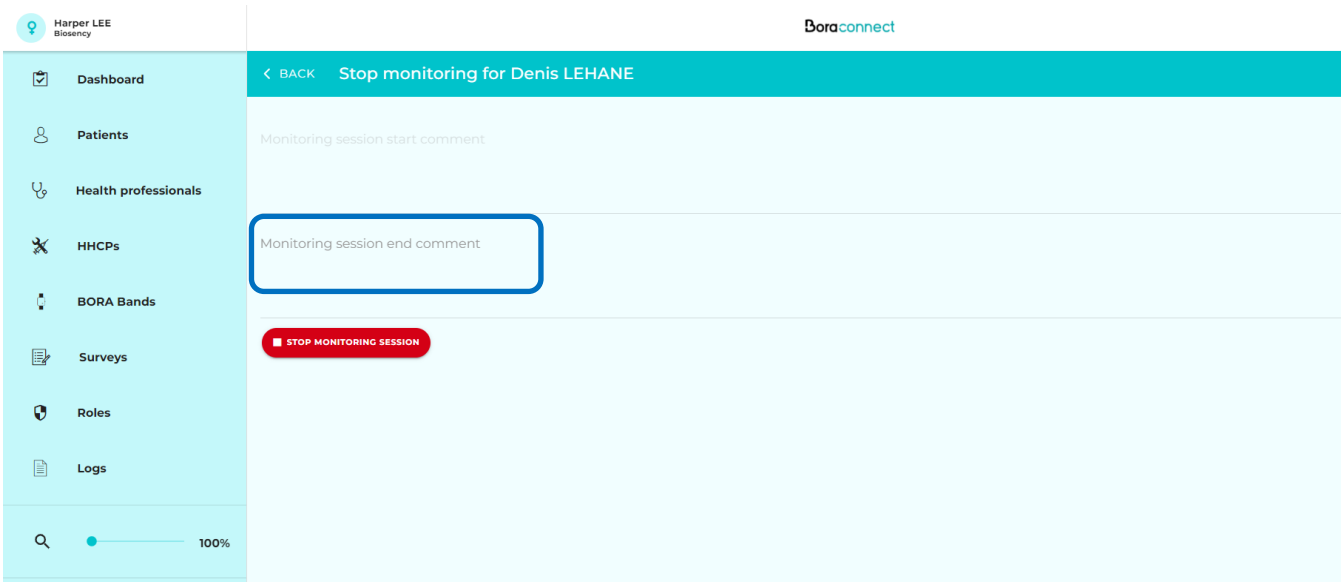
- The list of patients (“Patients” tab) using the "stop” button

- The patient file by clicking on the button 





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



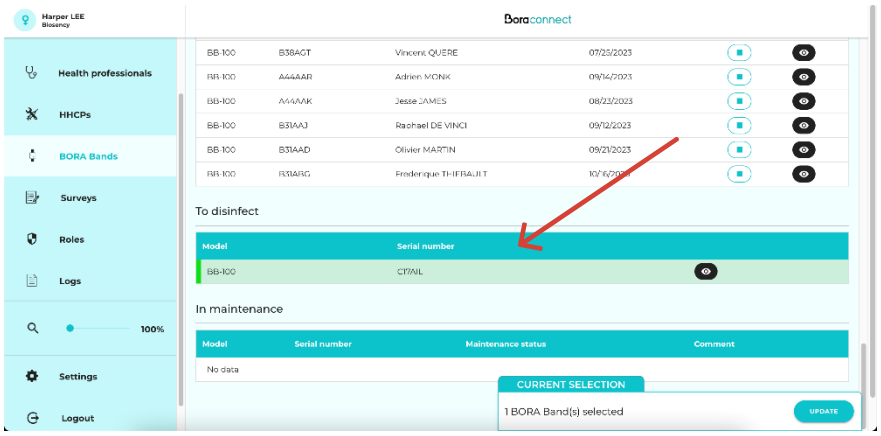
When the session is closed all the devices are automatically disconnected.

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

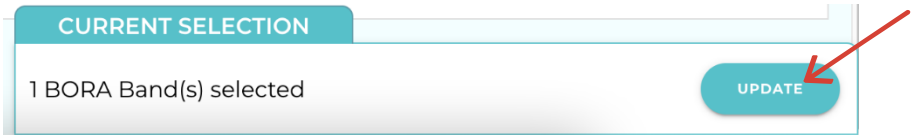
At the end of a remote monitoring session, the Bora band® wristband used for the session will be automatically set to the status "to be disinfected".

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

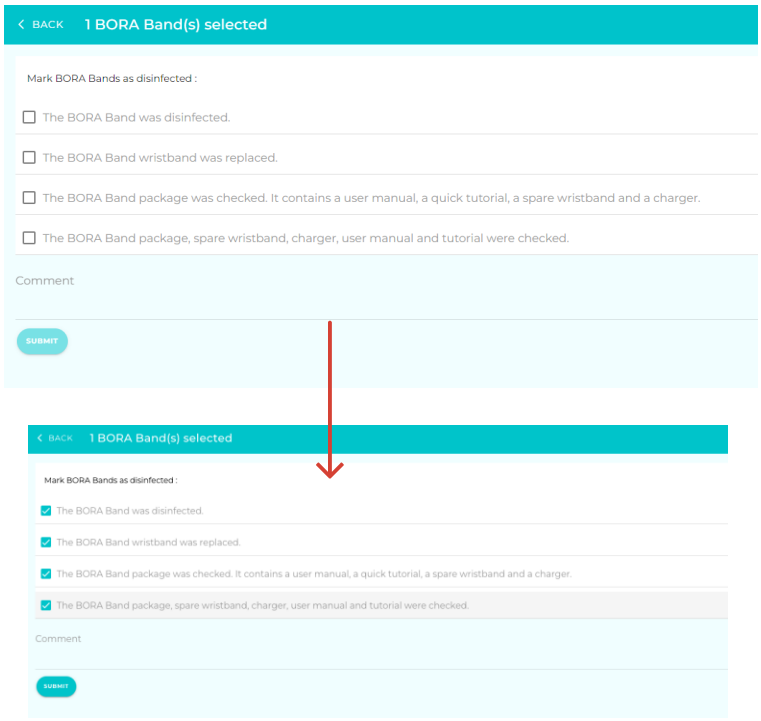
1 Go to the "Bora Band" tab and select the Bora band® wristband(s) to be disinfected on the list.



2 Click on the button to start the disinfection procedure.



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



4 Press on the SUBMIT button to confirm the disinfection.

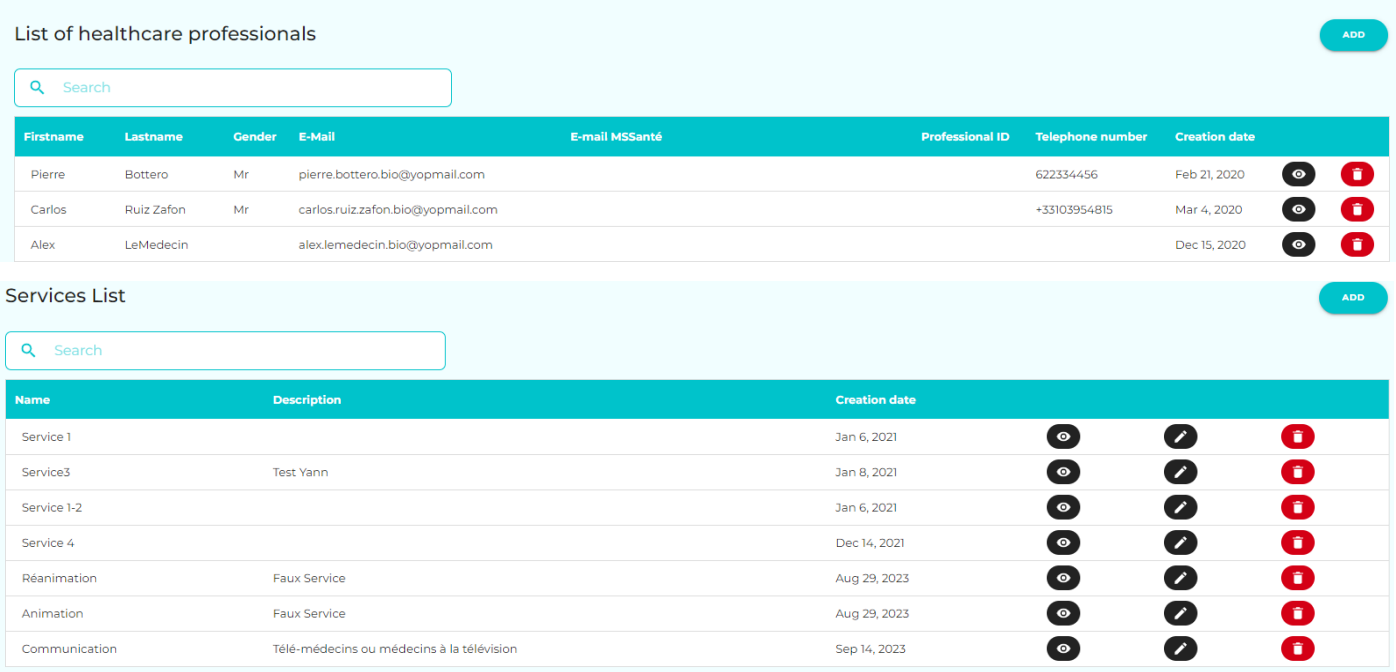
Once you have disinfected your Bora band® wristbands, they are available for the next remote monitoring session.

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

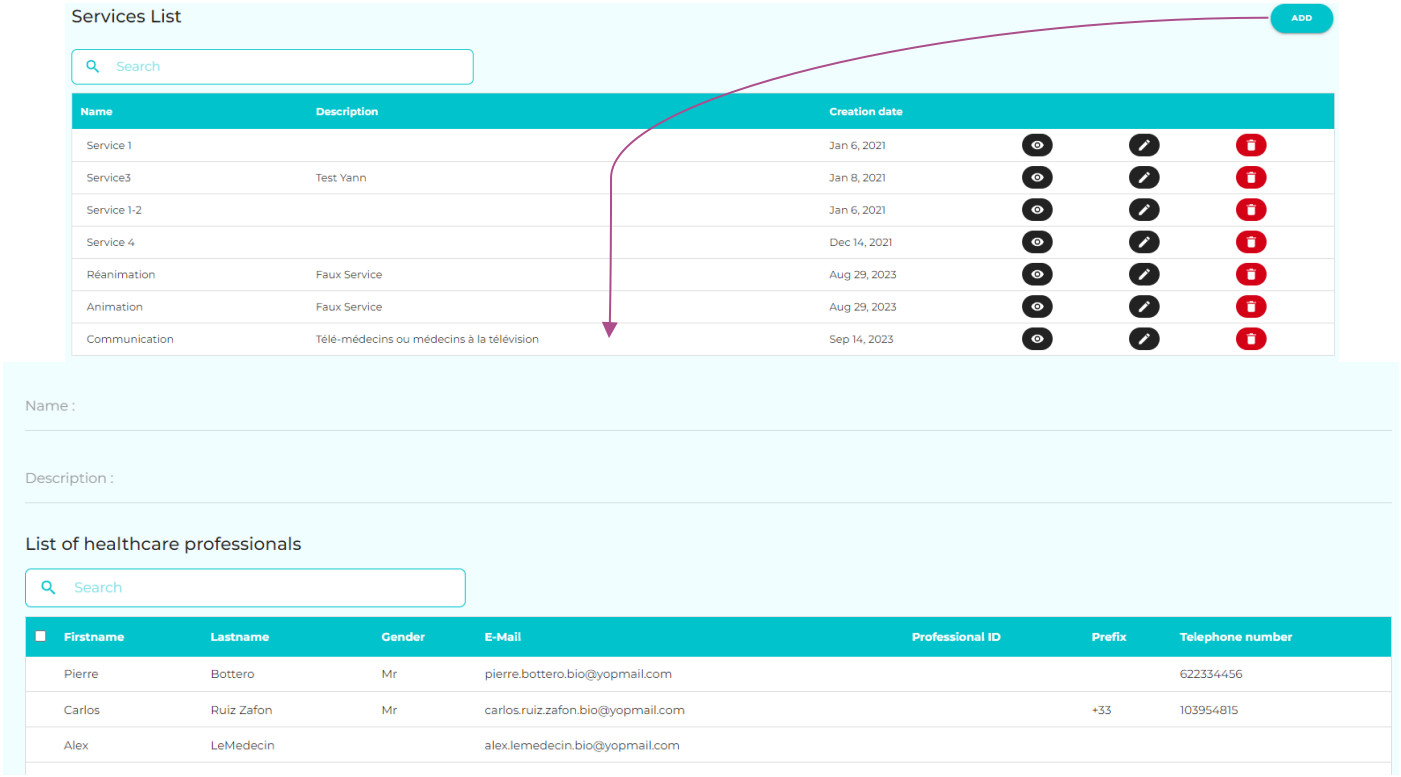
If the module is not activated and you wish to add a healthcare professional, please Biosency customer service.



List of services

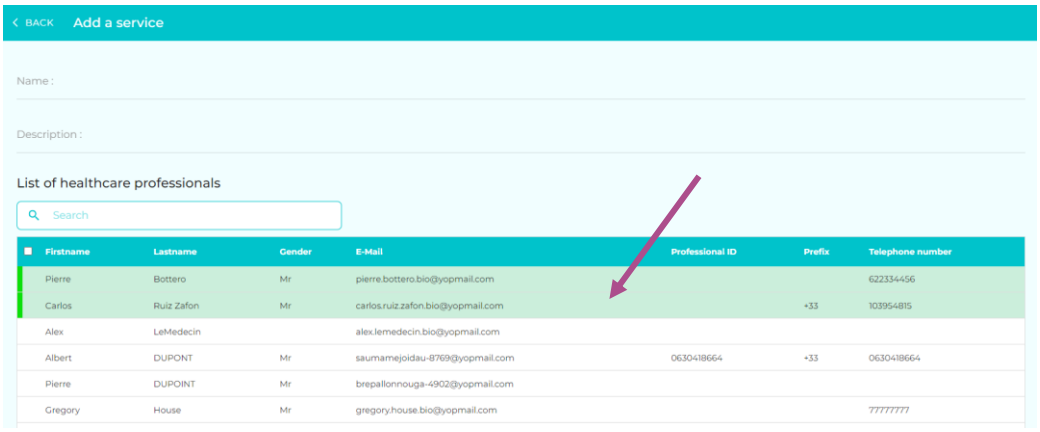
You can create a service that combines several healthcare professionals. A service can then be linked to a patient. All of the service's healthcare professionals can then consult the patient's data.

Click on the button to create a service.



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.

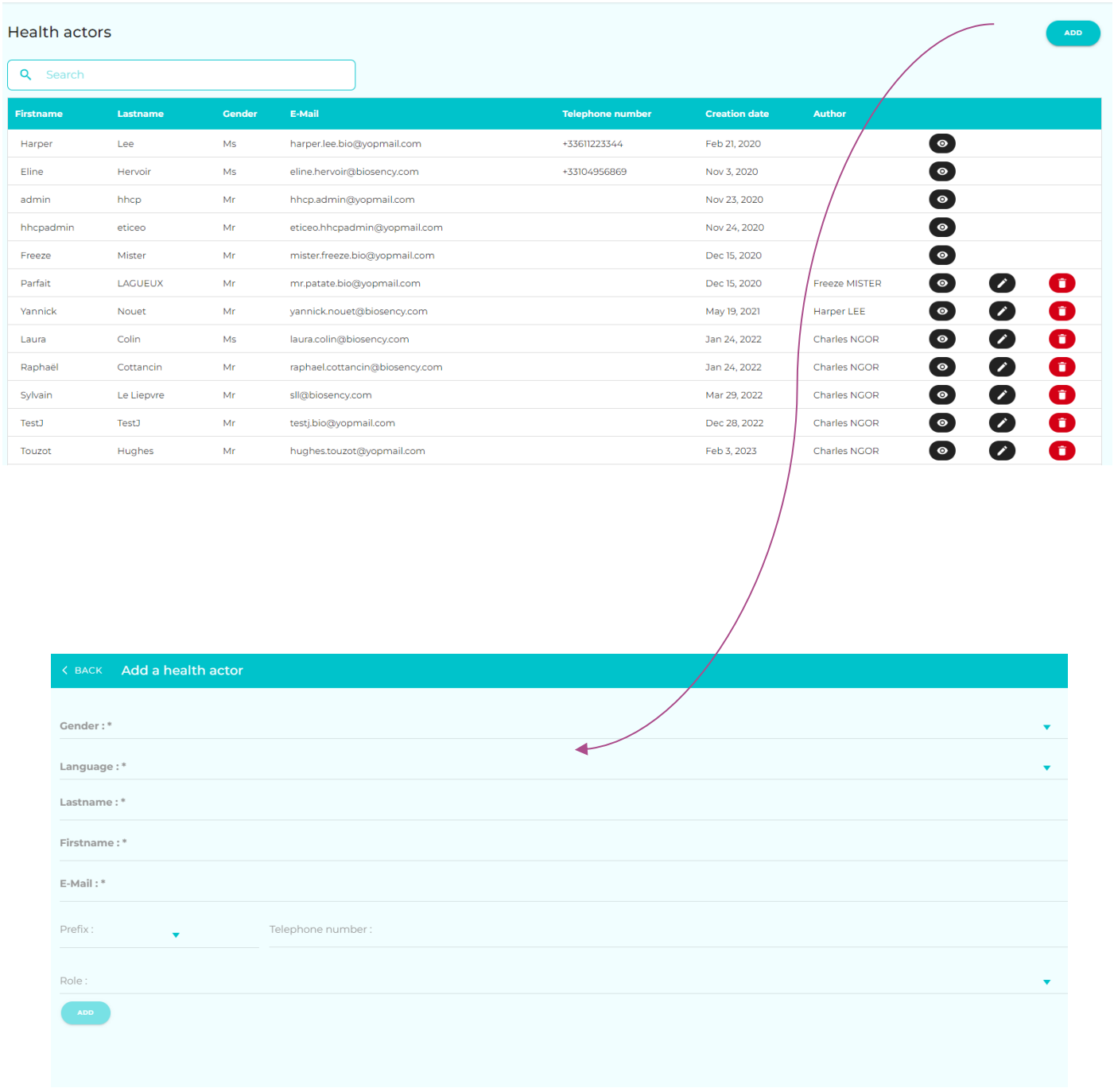


Click on the button to confirm the service's creation.

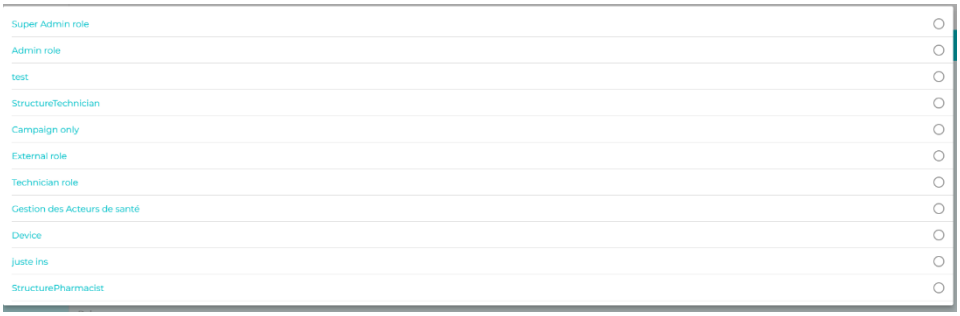
Healthcare stakeholders

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 ADD button to add a new account.



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.

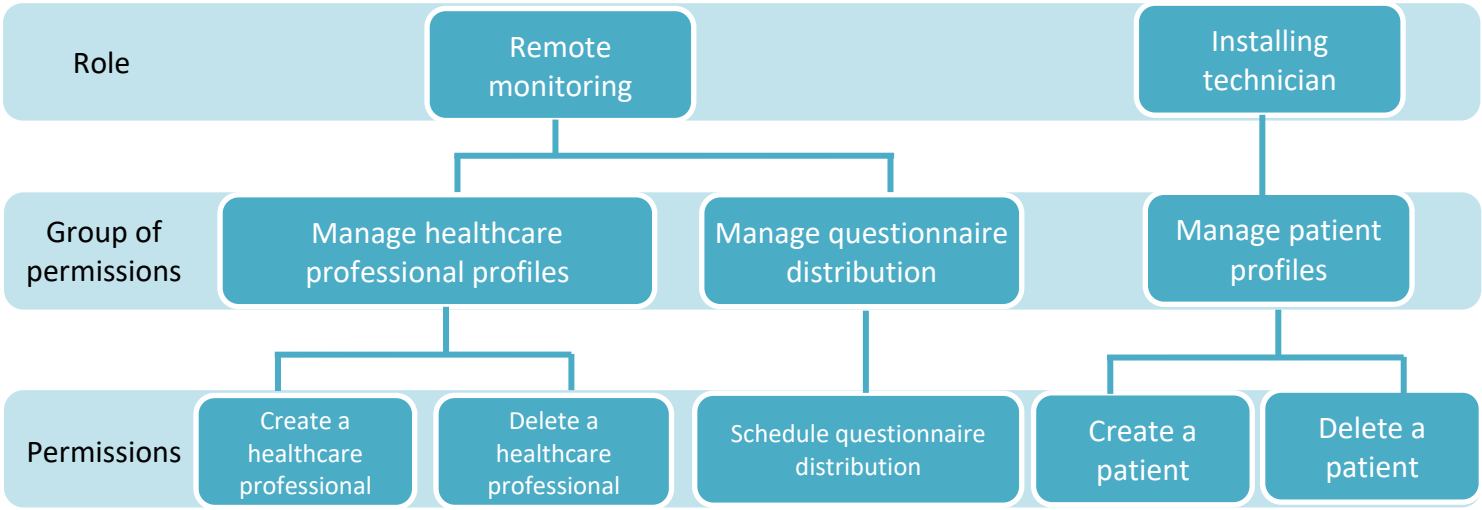
Roles

An organisation is made up of several roles:

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

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:



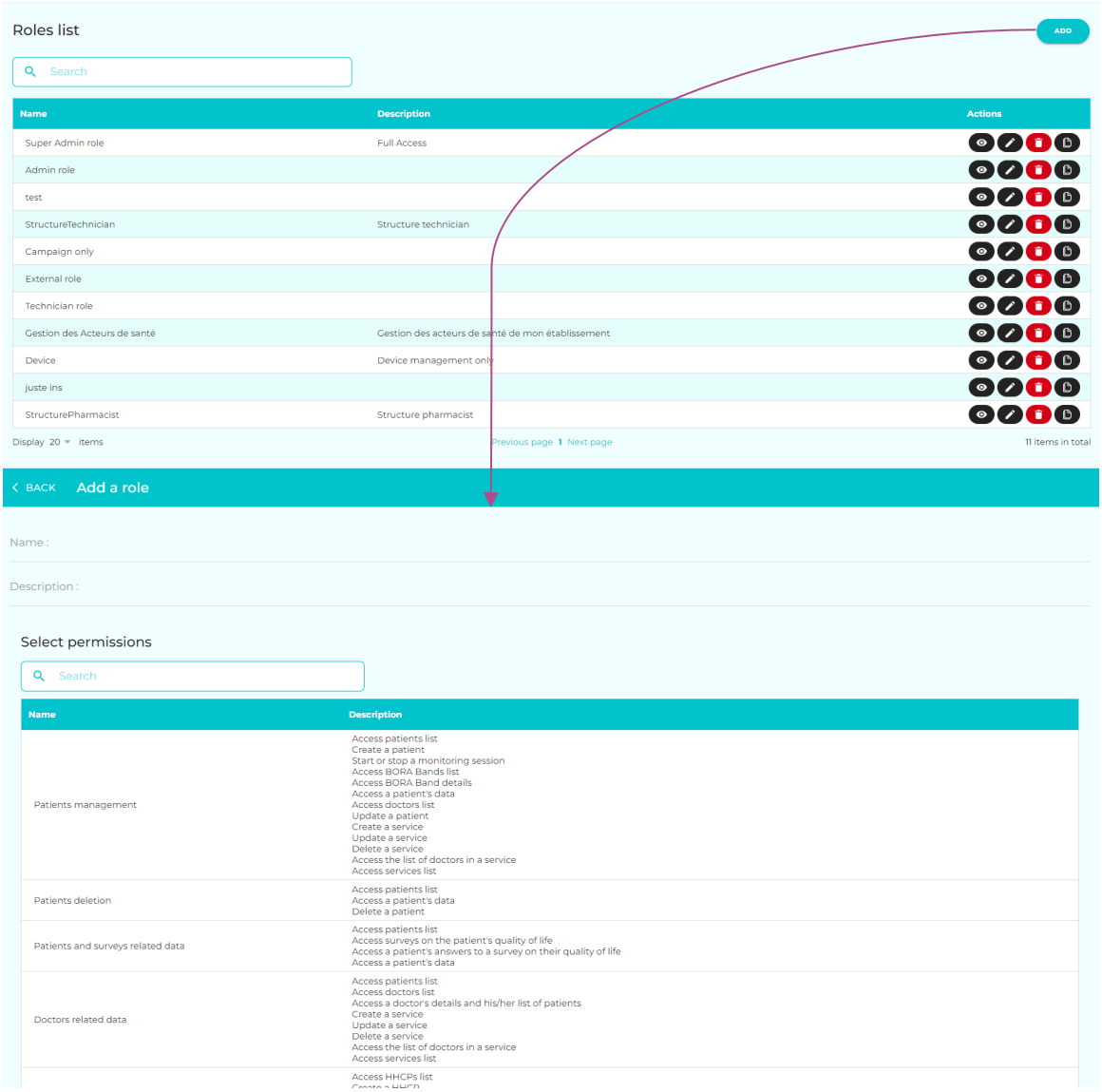
The healthcare administrator is created by a Biosency administrator. They have access to all of the available permissions, in addition to those for managing (creating/deleting) the accounts of healthcare professionals and stakeholders. This role cannot be changed.

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

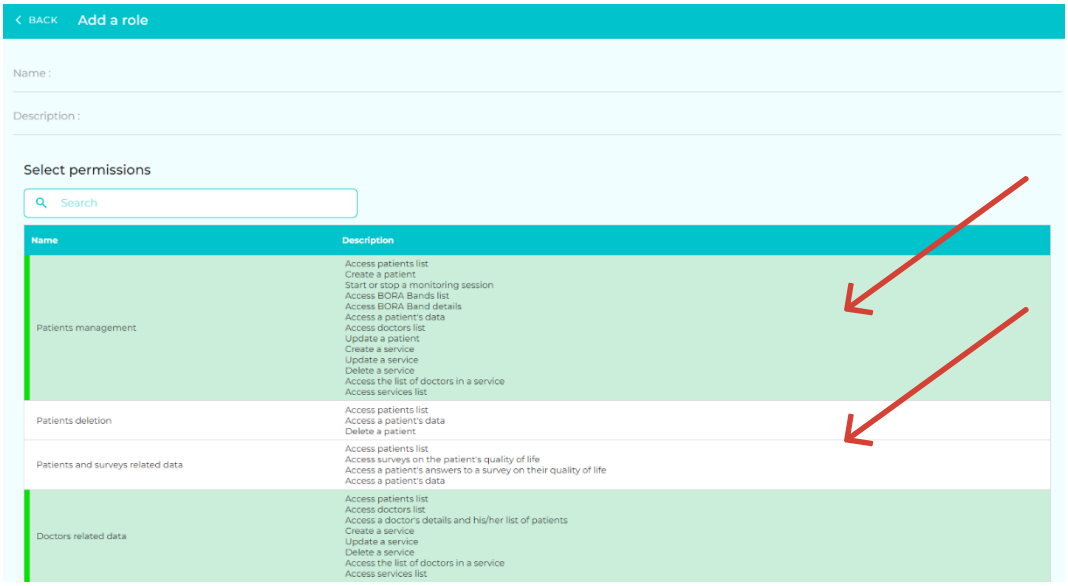
Healthcare stakeholders have a configurable role. This means that a different role can be associated to each healthcare stakeholder profile created,
Default roles are available. These roles are managed in the "Roles" tab.
On this page you can:

- View the available default roles

- Create a new role by clicking on the ADD button



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



Click on the ADD button to confirm the role's creation.

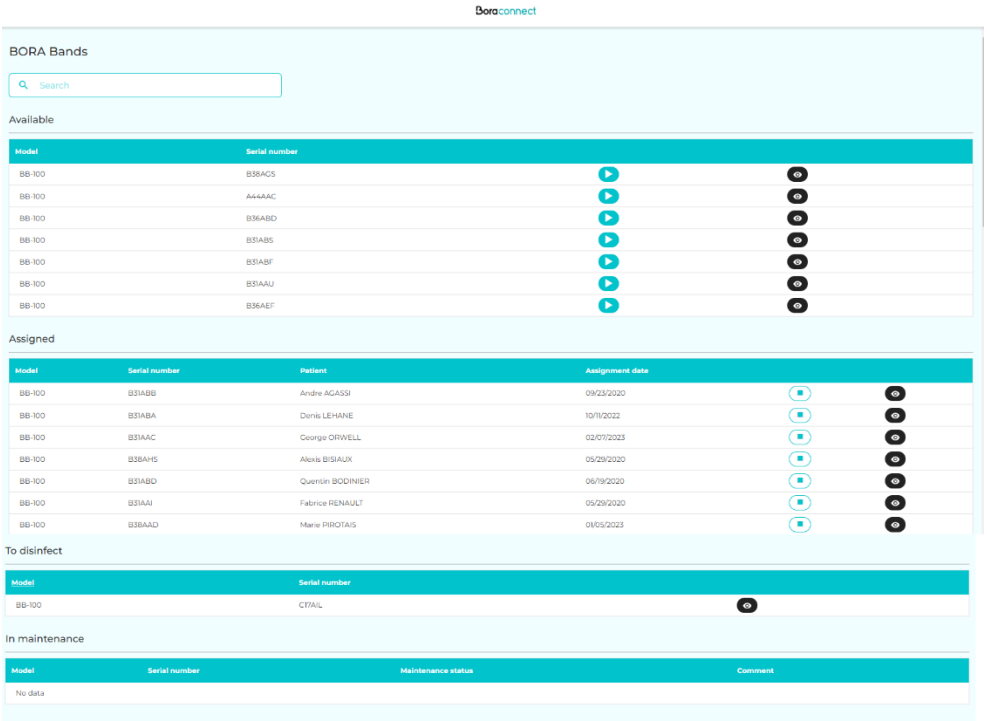
You can from then on use this role for each healthcare stakeholder that is created.

Bora band®

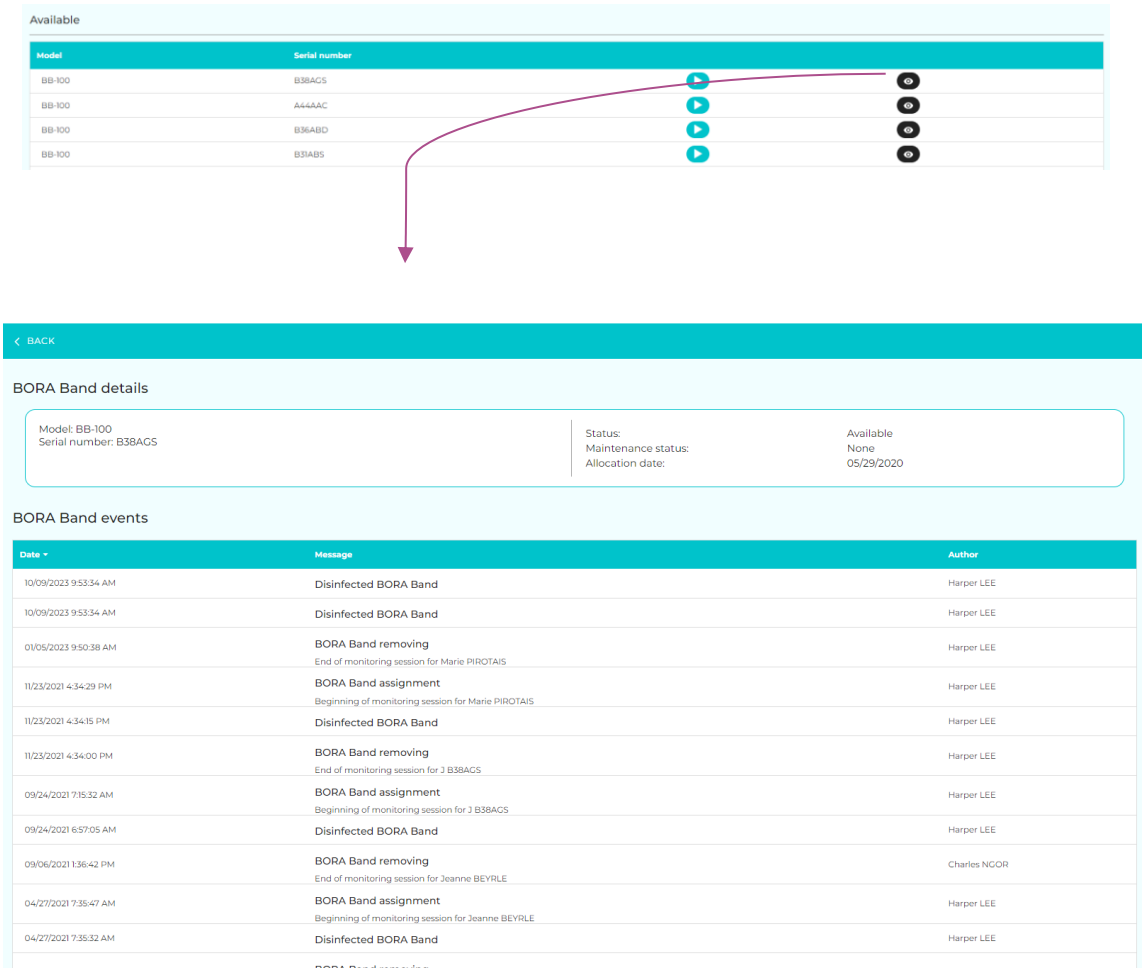
You can use this page to manage your Bora band® fleet in case the module is activated.

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.



Click on the button to assign the wristband to a patient.
Click on the button to consult the details of the Bora band® wristband.

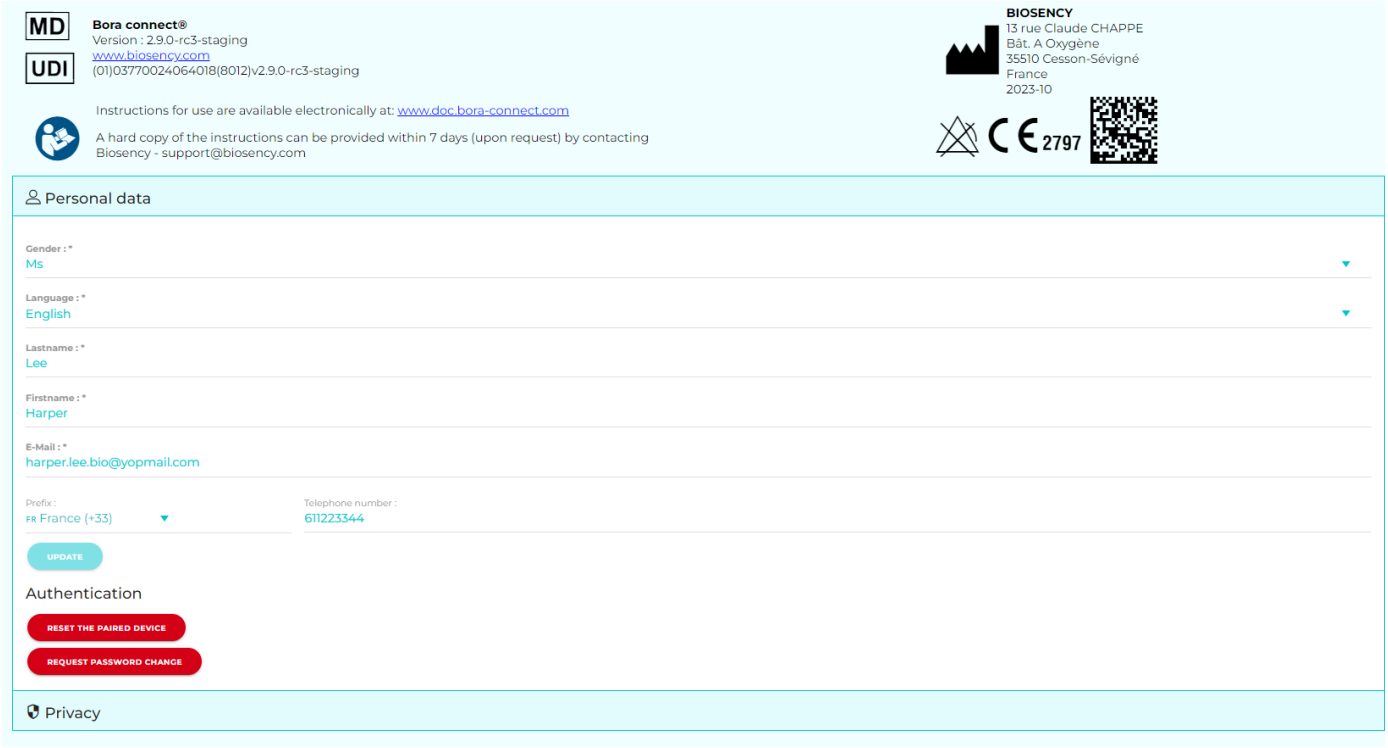


You can consult the details of the Bora band® wristband: model, serial number, status, and date assigned to your organisation.

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.



You can change your identity and email address and change the interface language.
Click on the UPDATE button to confirm the changes.

Multi-factor authentication

Click on the RESET THE PAIRED DEVICE button to reset the telephone number associated with your account (the telephone number that receives a single-use code during the authentication process).

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

Password

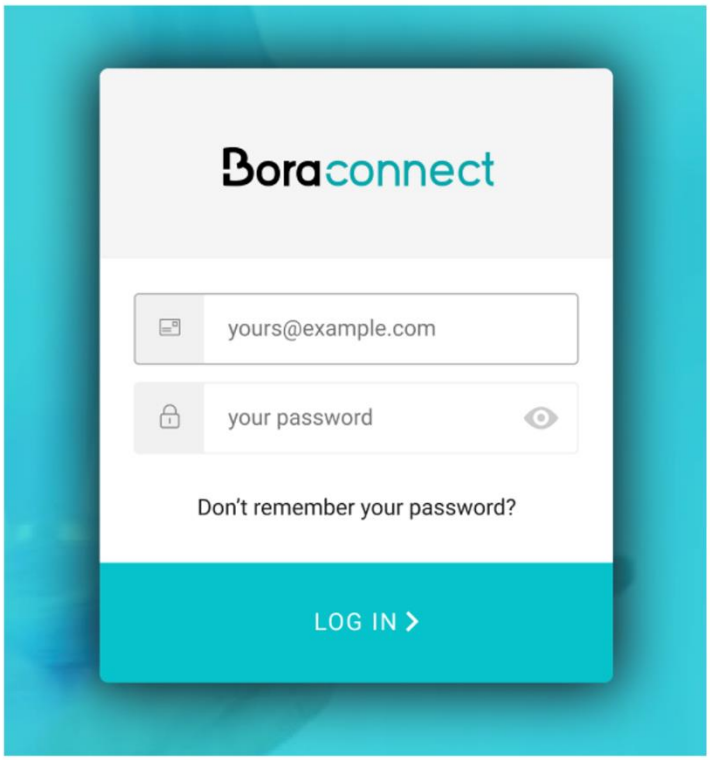
Click on the REQUEST PASSWORD CHANGE button to ask to change your password. You will receive an email that contains a link for resetting your password.

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).

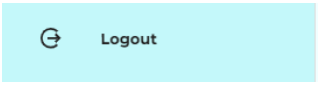


Meaning of figures, symbols and abbreviations

	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 BVS3 > 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. 

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 exclusion, please refer to our general subscription terms and conditions, available on doc.bora-connect.com.

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 Member State where the patient resides.

Assistance

In case of any problems, contact Biosency at support@biosency.com or at 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.

Cyber security

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 a web platform The security options are automatically deployed. There are no specific security options for using Bora connect®. Review the section on security recommendations at https://doc.bora-connect.com

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.	± 1 min
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.	± 1 min
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”.

BVS$^{3®}$

Clinical performances of BVS$^{3®}$ score are the following :

Parameter	Designation	Results
Time	Mean time anticipation before the exacerbation occurs	3 days
Sensitivity	Sensitivity of BVS3 – Probability to detect real exacerbation	85,7%
Specificity	Specificity of BVS3 – Probability to detect false exacerbation	90,9%

Conformity

Standards related to software	IEC 62304 IEC 82304-1

Clinical advantages

Improving the quality of life is a possible clinical benefit of setting up remote monitoring with Bora connect® associated with Bora band®. 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®. 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 associated to Bora band®.

Clinical benefits table

Benefits		Population	Source	Results
Quality of Life improvement	Acceptation of the rehabilitation training	BPCO, OSAS	eMEUSE clinical trial	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
	Patient reassurance	BPCO, OSAS	eMEUSE clinical trial	95% of patients (95% CI : [91% - 99%]) were reassured by the Bora Care® solution
Quality of patient care improvement	Patient compliance	BPCO	DACRE clinical trial 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.	Mean patient compliance of 90% (95% CI : [87% - 92%])
		BPCO, OSAS	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.	Mean patient compliance of 90% (95% CI : [88% - 91%])
		Chronic Respiratory Diseases	APOR clinical study	Mean patient compliance of 90% (95% CI : [82% - 93%])

Quality of patient care improvement	Prevention of (re) hospitalization when associated : - With remote monitoring with Bora Band®	BPCO	DACRE clinical trial 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.	Respiratory rate correlates with readmission (0,607, p-value=0,010) Heart rate correlates with readmission (0,416, p-value=0,097)
	Detection of wrong oxygenotherapy prescription and generation of a new O2 prescription and/or prescribe another exam	Chronic Respiratory Diseases	APOR clinical trial	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%])

Copyrights and Trademarks

Bora band®, Bora connect® and BVS^{3}® are registered trademarks of Biosency in France and Europe.

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 trigger
CE 2797	EC marking that indicates its compliance with the current regulations on medical devices Notified body: BSI NL
DM	Medical device
UDI	Unique device identifier
	Manufacturer and date of manufacture

Manufacturer contact details

Biosency
13 Rue Claude Chappe - Bât A Oxygène,
35510 Cesson-Sévigné
France
support@biosency.com
https://biosency.com/

Annex 1

To be able to use the INS service, you need to:

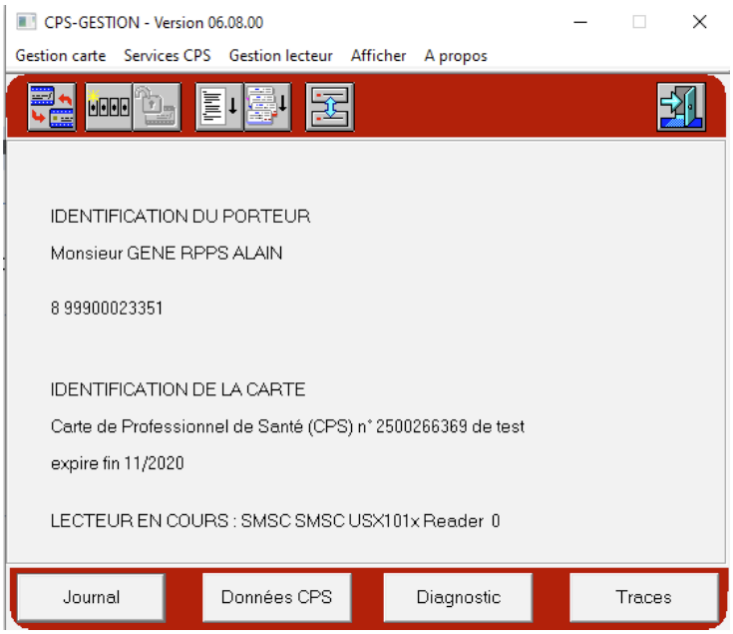
- Install the CPS card reader programme (or open and run it if it is already installed on your computer)
- Install the “Icanopée” software that can access INSi teleservice.

CPS card reader installation

- Install the “Cryptolib” programme:
  - For Windows: https://esante.gouv.fr/services/espace-cps/telechargements-libres/cryptolib-cps-windows
  - For MacOS: https://esante.gouv.fr/services/espace-cps/telechargements-libres/cryptolib-cps-mac-os-x
- Connect your card reader to your computer
- Open the “CPS card management” application
- Insert your card into the reader

If the reader and card are functional, the display must show:

- In Windows: a portion of the card's contents:



- In MacOS: the read card:

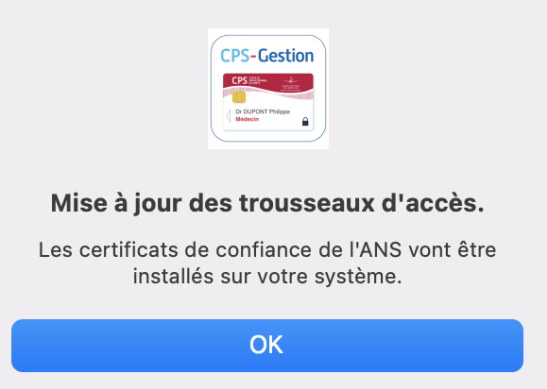
If your card cannot be read and your card reader displays “no PS/SC driver on the computer”, then you need to first install the drivers needed to use your card reader. Refer to the documentation for the model of your card reader.

CPS Gestion application installation

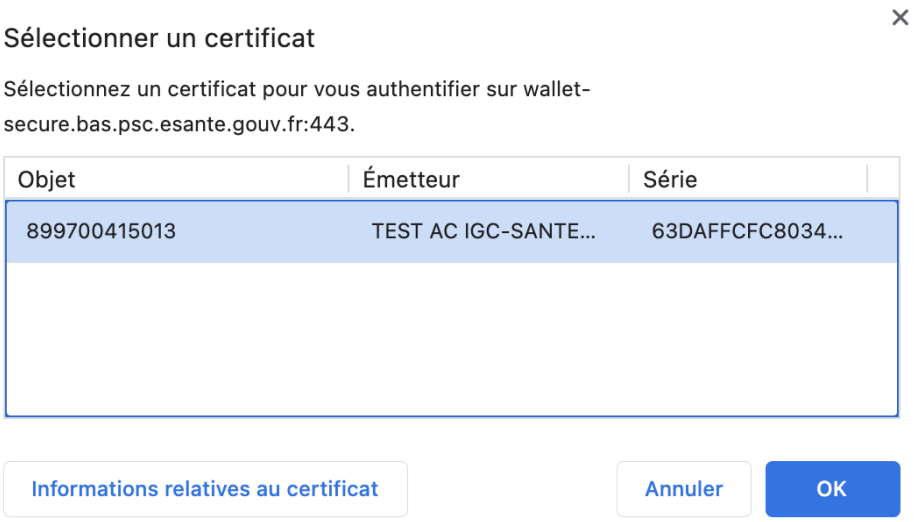
If you want to use Pro Santé Connect to connect to Bora connect®, you need to install the “CPS Gestion” application.

- For MacOS, you'll find the link to the downloadable application here: https://apps.apple.com/fr/app/cps-gestion/id1470411027?mt=12

  This installation will allow you to update the access keychains.



  You can then connect by selecting the appropriate certificate:



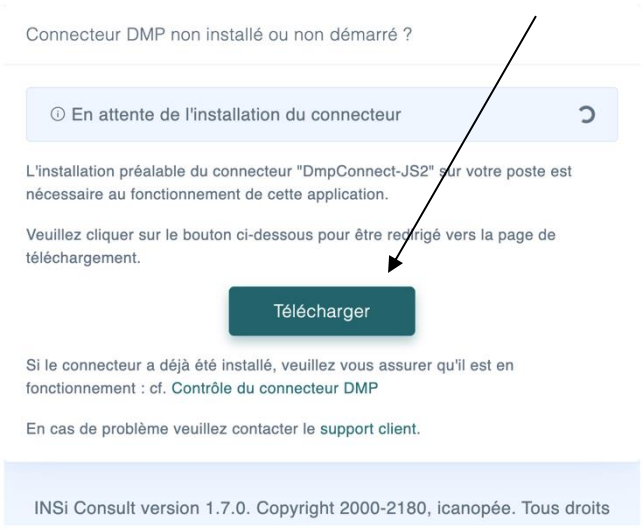
- For Windows, you'll find the link to the downloadable application here: https://apps.microsoft.com/detail/9P2GQM5HLSBS?hl=fr-fr&gl=FR

DmpConnect-JS2 software installation

To access INSi teleservice from Bora connect, you need to install the DmpConnect-JS2 software.

You can access the download link in two ways:

1) By clicking on the “download” button in the dialogue window that opens when you first request to recover INS information.

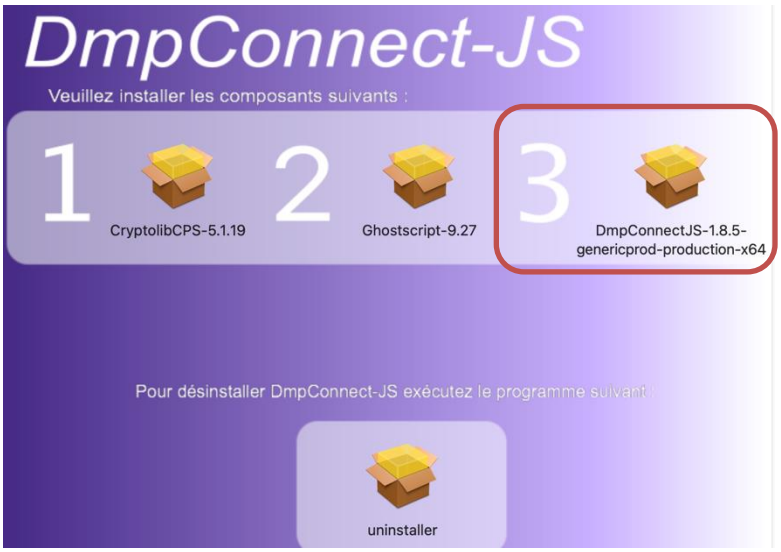


2) By downloading it using this link: https://www.icanopee.fr/telechargement-du-connecteur-dmpconnect-js-insiconsult/.

The first “cryptolibCPS” component is already installed if your card reader is operational (see CPS card reader installation)

Installing the second component is not necessary.

However, you need to install the third component “DmpConnectJS”. Follow the instructions to finalise the installation.


DmpConnect-JS
Veuillez installer les composants suivants :
1
CryptolibCPS-5.1.19
2
Ghostscript-9.27
3
DmpConnectJS-1.8.5-genericprod-production-x64
Pour désinstaller DmpConnect-JS exécutez le programme suivant :
uninstaller

You can test your installation by clicking on "recover/verify INS” on a patient file. The following window should open: