BIOSENCY

Caring anytime, anywhere

Boraconnect®

Web platform & mobile application for healthcare professionals and health actors

User manual

Bora connect® version 3.4
Bora-connect_IFU_3.4_A October 2025

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 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:

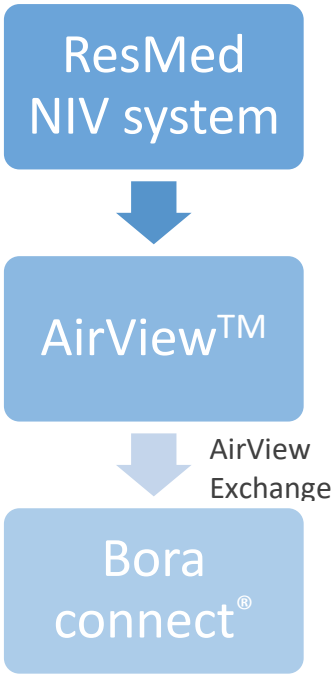
- A mobile application: Bora connect® mobile, Bora connect for Home or Bora connect for Study. Only one of these applications should be installed for patient use. This operation must be carried out by a qualified professional.
- An NGDF data feedback terminal.

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.

⚠ 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://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:

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 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 BVS^{3}® 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 health actors
- configure a patient questionnaire
- manage the fleet of Bora band® devices

Depending on your role, you may not be able to manage the Bora band® fleet or the accounts of patients, healthcare professionals and health actors. 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 (favorites, monitoring in process, not equipped).
- **Healthcare professionals:** a list of all the healthcare professionals and services connect to the organisation.
- **Health actors:** a list of all health actors except for healthcare professionals, involved in the patient's treatment.
-  **Bora band:** a list of all of the Bora band® devices assigned to the organisation.
-  **Models:** a list of all alert models configured by the user or by the membership structure.
- **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 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 and alert models
- Configure questionnaires
- Monitor and export the collected data

These different points are arranged in chapters as shown below:

Start out on Bora connect®

- Connection via email
- Add a patient file
- List of patients

Start a remote monitoring session

- Step 1: Link device(s)
- Step 2: Configure alerts and models for the session
- Step 3: Start the remote monitoring session

Monitor the collected data

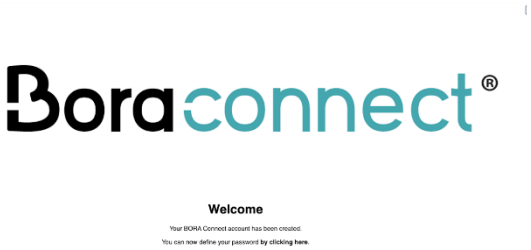
- Use the clinic dashboard and alerts
- Reading and configuring of graphs
- Report export
- Create a survey

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.



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:

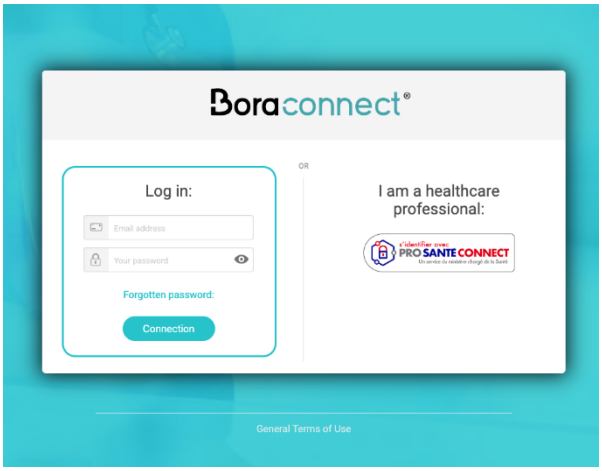
- Lower case letters (a-z)
- Upper case letters (A-Z)
- Numbers (i.e. 0-9)
- Special characters (e.g. !@#$%^&*)

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.

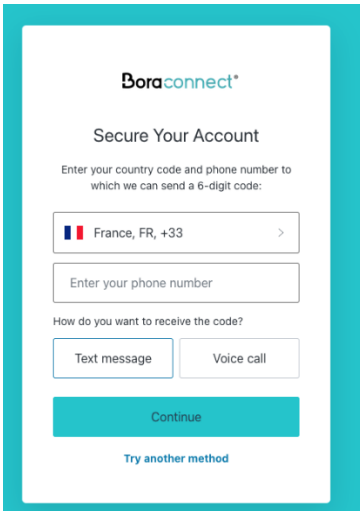
When you connect for the first time, you have to enter a phone number to activate the two-factor authentication.



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

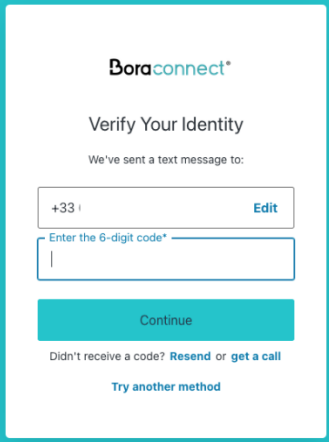
Choose whether you want to receive the code by text message or voice call (the code is given orally).

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



3 **Enter the one-time code received.**

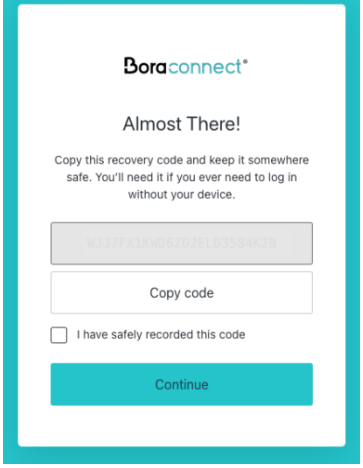
Two-factor authentication will be required at least once every 6 months.



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.

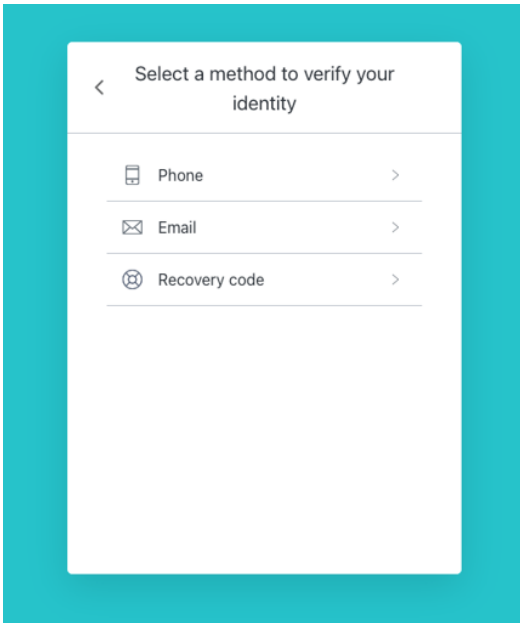
ⓘ This recovery code can only be used once.

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



ⓘ 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

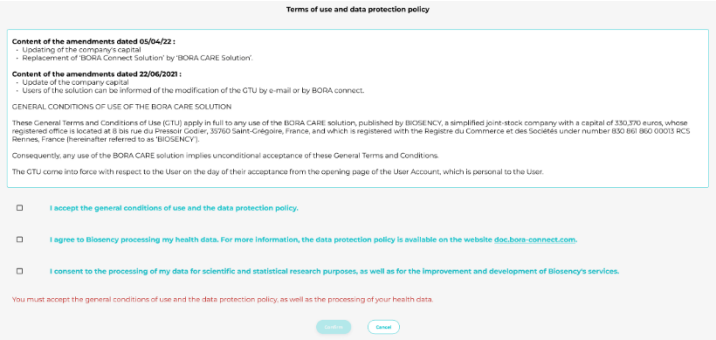


⚠ PRECAUTIONS

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.

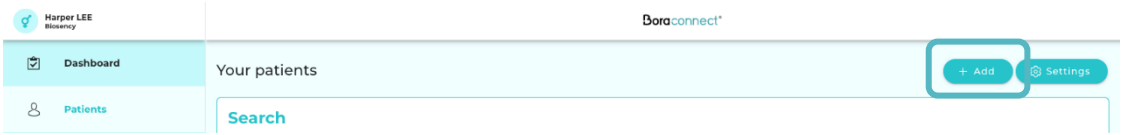
5 For the last step, you will be required to **consent to the processing of your personal data** on the Bora connect® platform.



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

Add a patient file

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

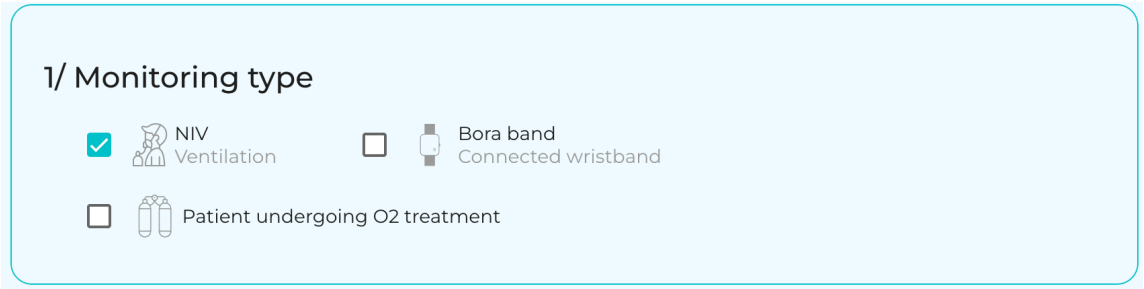


The patient addition file is divided into several categories according to the monitoring type selected. The following categories are shown in all cases:

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

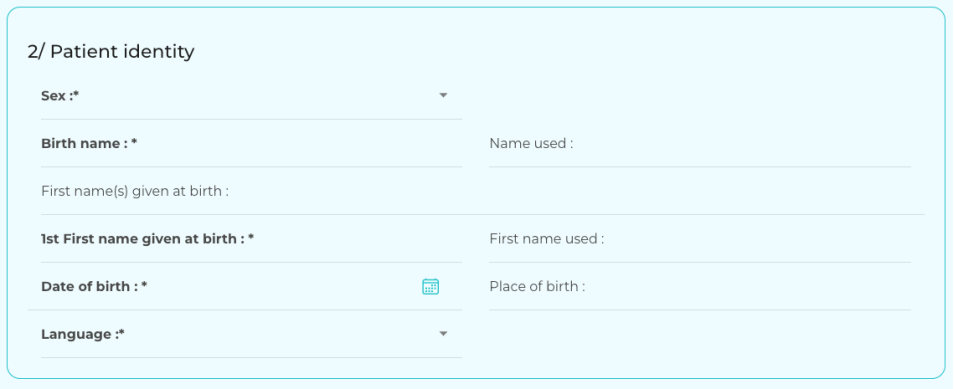
1 The first step in creating a patient file consists of choosing the monitoring type by indicating:

- The device(s) to be linked with the patients:
  - NIV (Ventilation)
  - Bora band® (connected device)
  - 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)



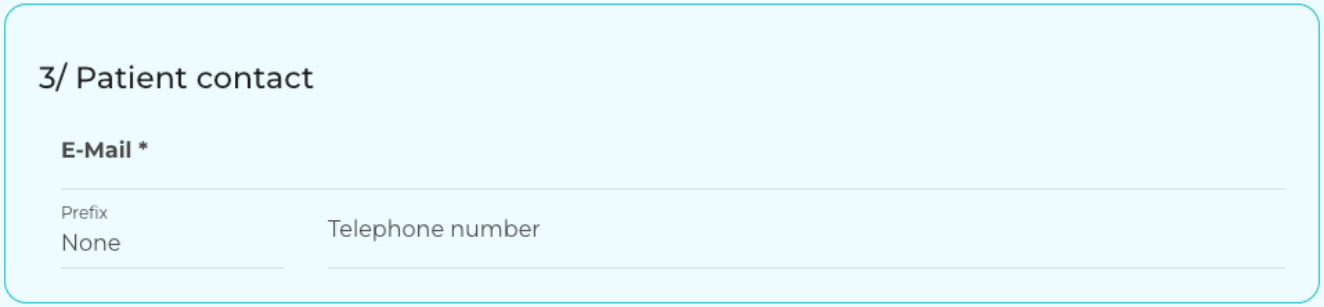
2 Fill in the patient identity file, including all the following information:

- Sex (mandatory)
- Birth name (mandatory)
- Name used
- First name(s) given at birth
- First name given at birth (mandatory)
- First name used
- Date of birth (mandatory)
- Language (mandatory)

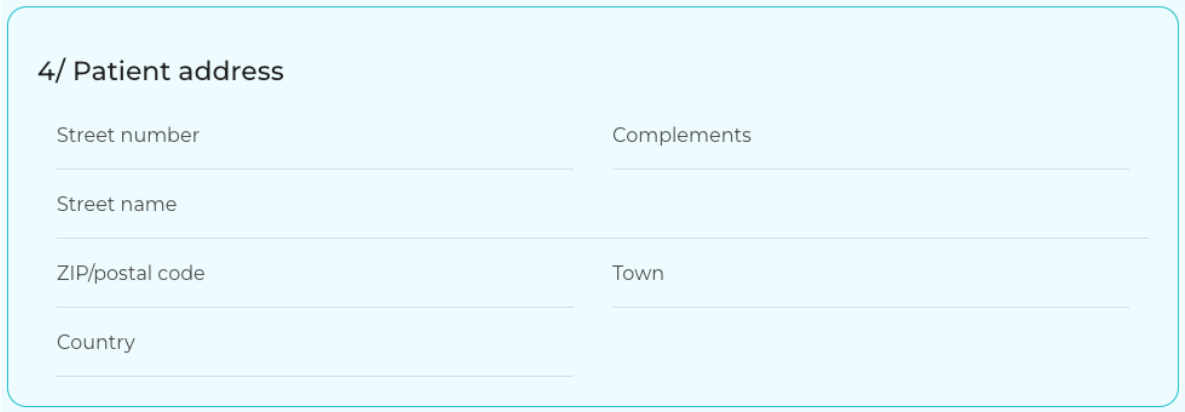


3 Enter the patient contact information: email (mandatory) and telephone number.

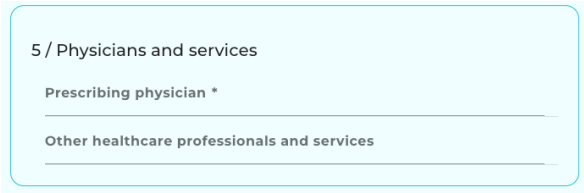
Email address of a trusted third party can be used.



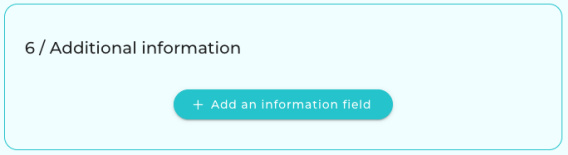
4 Complete the information concerning the patient address.
The "postal code", "town/city" and "country" fields are optional.



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

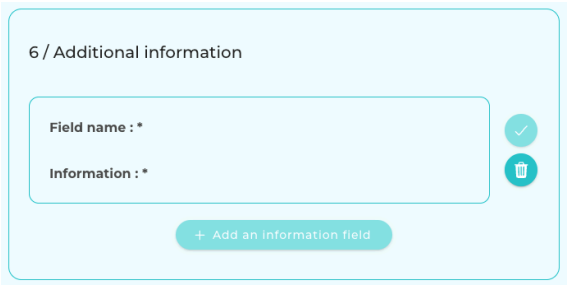


6 If you want, you can add an additional information field to your patient record by clicking on the "Add an information field" button:



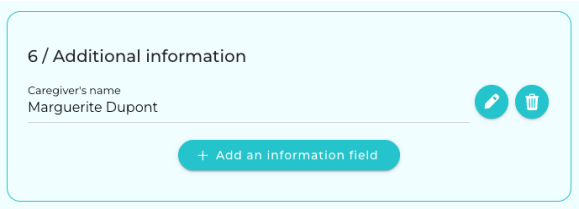
To add a field, you must:

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

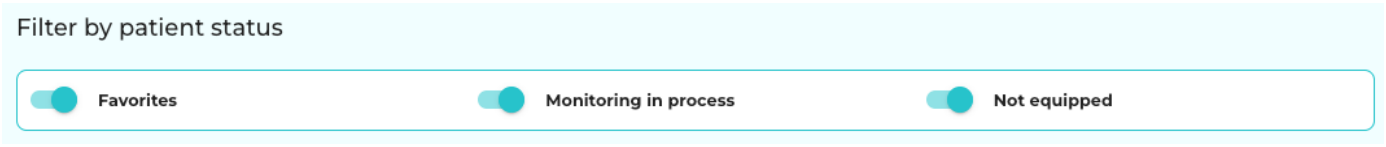
List of patients

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:

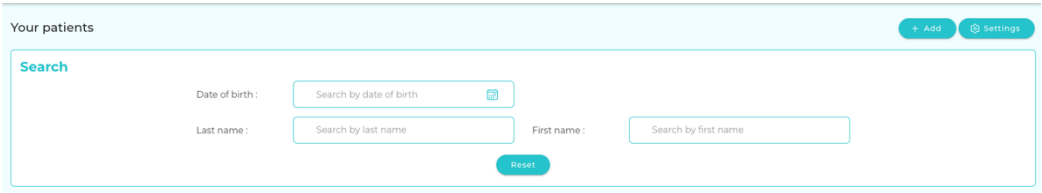
- Favorites
- Monitoring in process
- Not equipped

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.

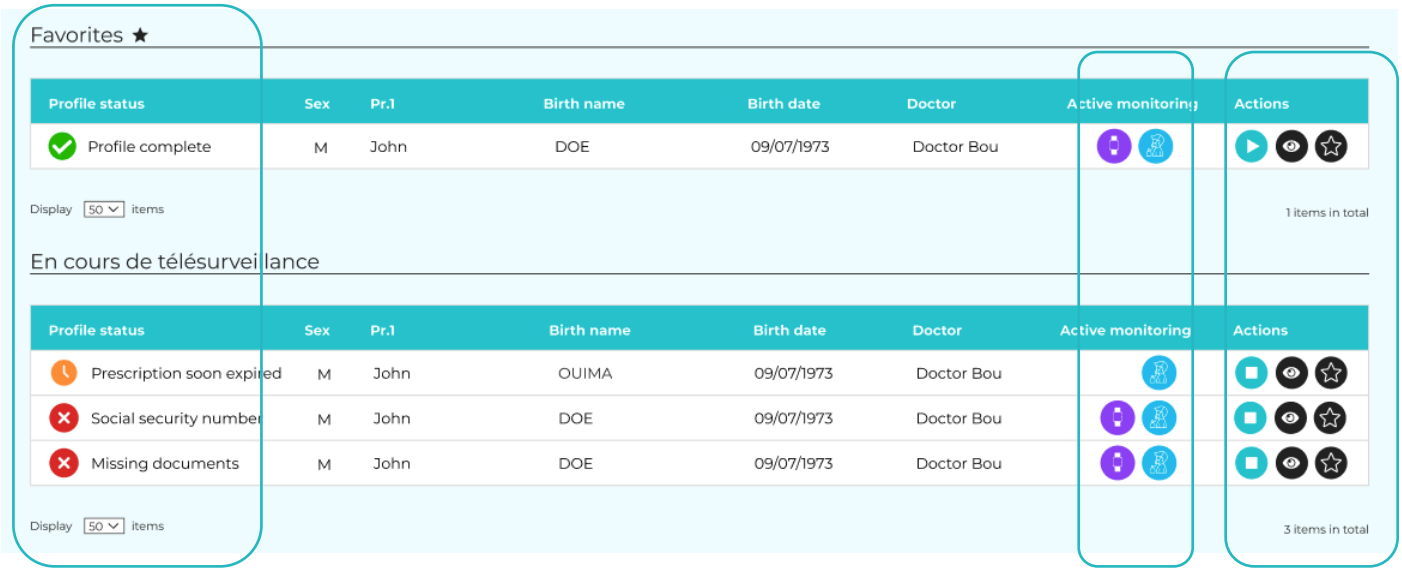


If you are searching for a specific patient, you can use one or more of the following fields in the search box:

- 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

- **Profile status**: displays profile statuses
  - "**Profile complete**": All the necessary fields are completed

- **Actions**: the user can click on different buttons to:
  - Start/Stop the remote monitoring session
  - Be redirected to the patient's detailed file
  - Put the patient among the favorites

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.

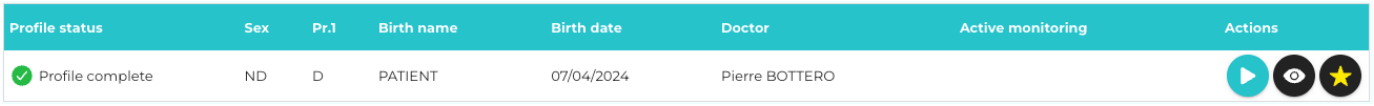
2 Start a remote monitoring session

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.

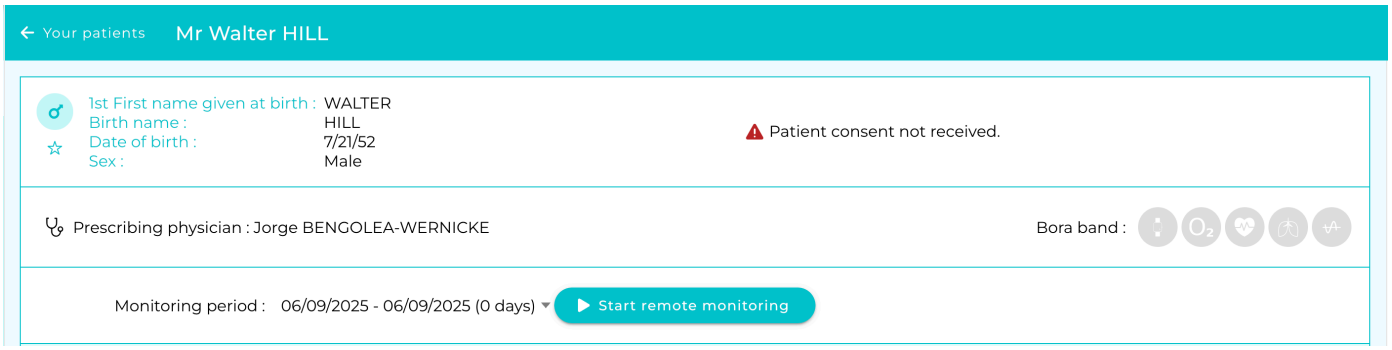
Start a session

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 remote monitoring” button



Three steps 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 device).

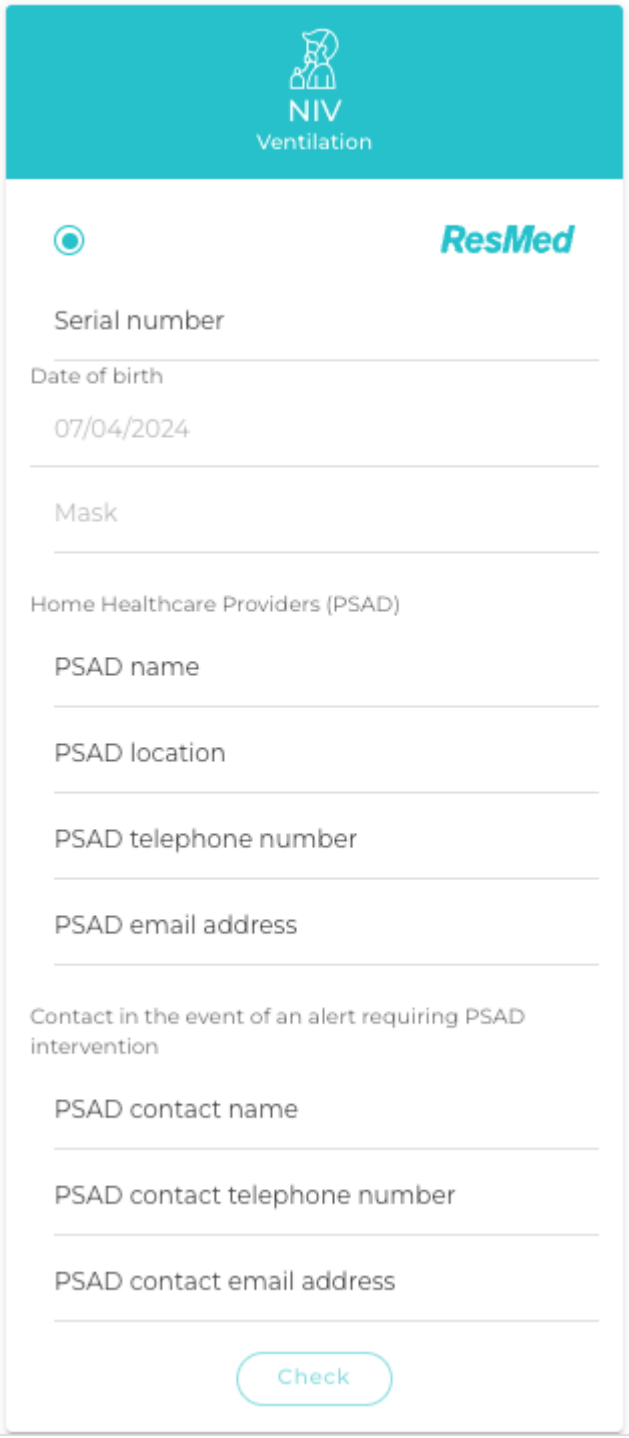
Linking a NIV device

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.

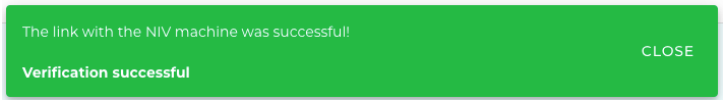
You can then enter the information relating to the healthcare provider agency as well as the point of contact in charge of the installation.
This information is not mandatory to validate the device link-up but it is recommended for having a reference contact in case of any problems.



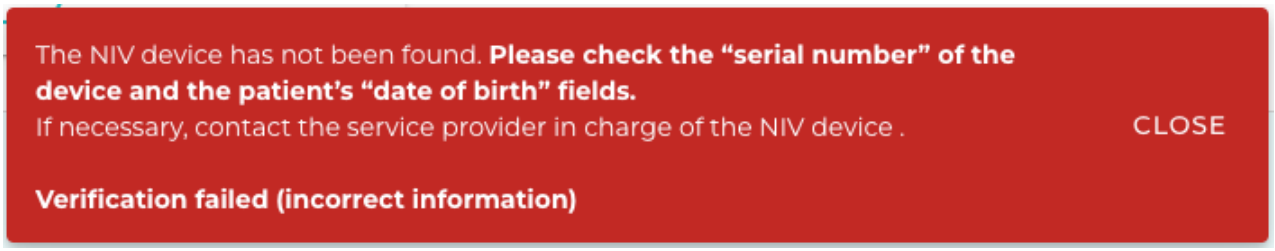
Once all of the information has been entered, click on the button to register the device.

Three types of messages can appear:

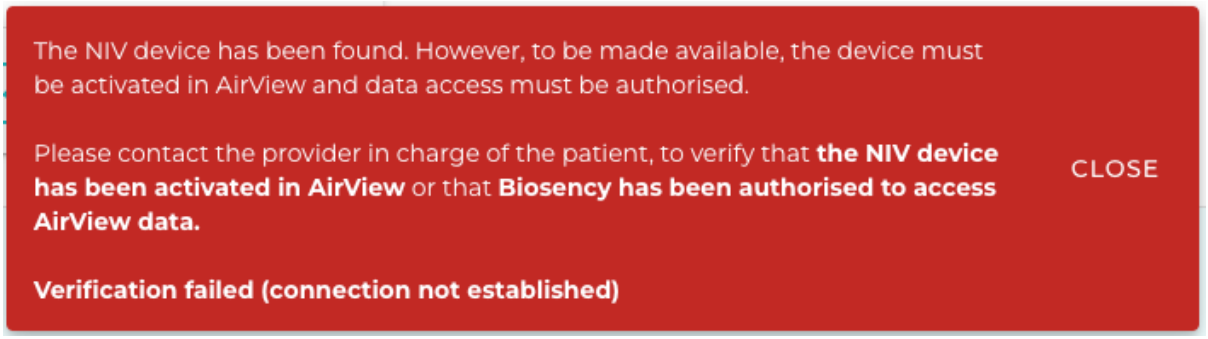
- A message indicating the success of the verification



- 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 and then: 

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

Then click on 

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

BVS$^{3®}$ score

The BVS$^{3®}$ (Bora Vital Sign Standard Score) is an additional tool to assess the vital signs of patients remotely monitored by the Bora Care solution. It is a predictive indicator to help detect COPD exacerbations in patients with respiratory failure.

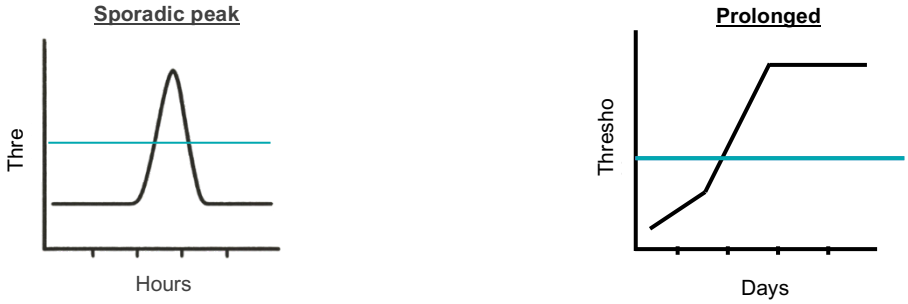
The BVS$^{3®}$ score enables early detection of 86%[1] of COPD exacerbations, an average of 4.4 days before they occur.

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 1 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® device (heart rate, respiratory rate, SpO2) compared to the baseline calculated over the past 15 days.

An alert is triggered as soon as the score exceeds a predetermined and clinically validated threshold of 3σ.

A symptom questionnaire can be configured to be automatically sent to the patient to enable them to confirm the alert. See details in the Questionnaire for BVS^3 alert section.

Interpretation of results



- The higher a score is above the threshold, the greater the number of vital signs that deviate from their baseline and the greater their deviation
- The higher the score, and the longer it remains above the threshold, the greater the variation in vital signs, indicating the need for close patient monitoring.

[1] The performance of the BVS$^{3®}$ score was evaluated during the e-Meuse Santé Study[1] (February 2024)

Calculation mode

The BVS$^{3®}$ score:

- is calculated, and therefore displayed:
    - if, over the last 5 days, at least an average of 25% of one-hour windows (30 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 25% of one-hour windows (12 out of 48 possible) contain at least 1 vital sign measurement (HR/FR/SpO2).

AND

    - if, over the last hour, at least one of the 3 vital signs is available

If the above criteria are followed, the first BVS$^{3®}$ score may appear after 24 hours of monitoring.

How do you best use the score?

- Time trend: The BVS$^{3®}$ score enables you to estimate the risk of exacerbation based on variations in vital signs. Analyse the score's behaviour over several days rather than based on a single measurement.
- Comprehensive view: Integrate all data (vital signs, treatments, habits) into the interpretation.
- Complete clinical assessment: Complement the score analysis with a clinical observation of the patient.
- Patient education about the Bora band®: Insist on regular use of the device at the same measurement site.

PRECAUTIONS

- 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.
- Failure to calculate BVS$^{3®}$ 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:

Linked NIV device

Technical alerts

- No data transmission for more than 48 hours

Treatment alerts

- Use
- AHI
- Leakages
- Respiratory rate
- Tidal volume
- IE
- Spontaneous cycling
- Spontaneous trigger
- SpO2

Linked measuring device

Technical alerts

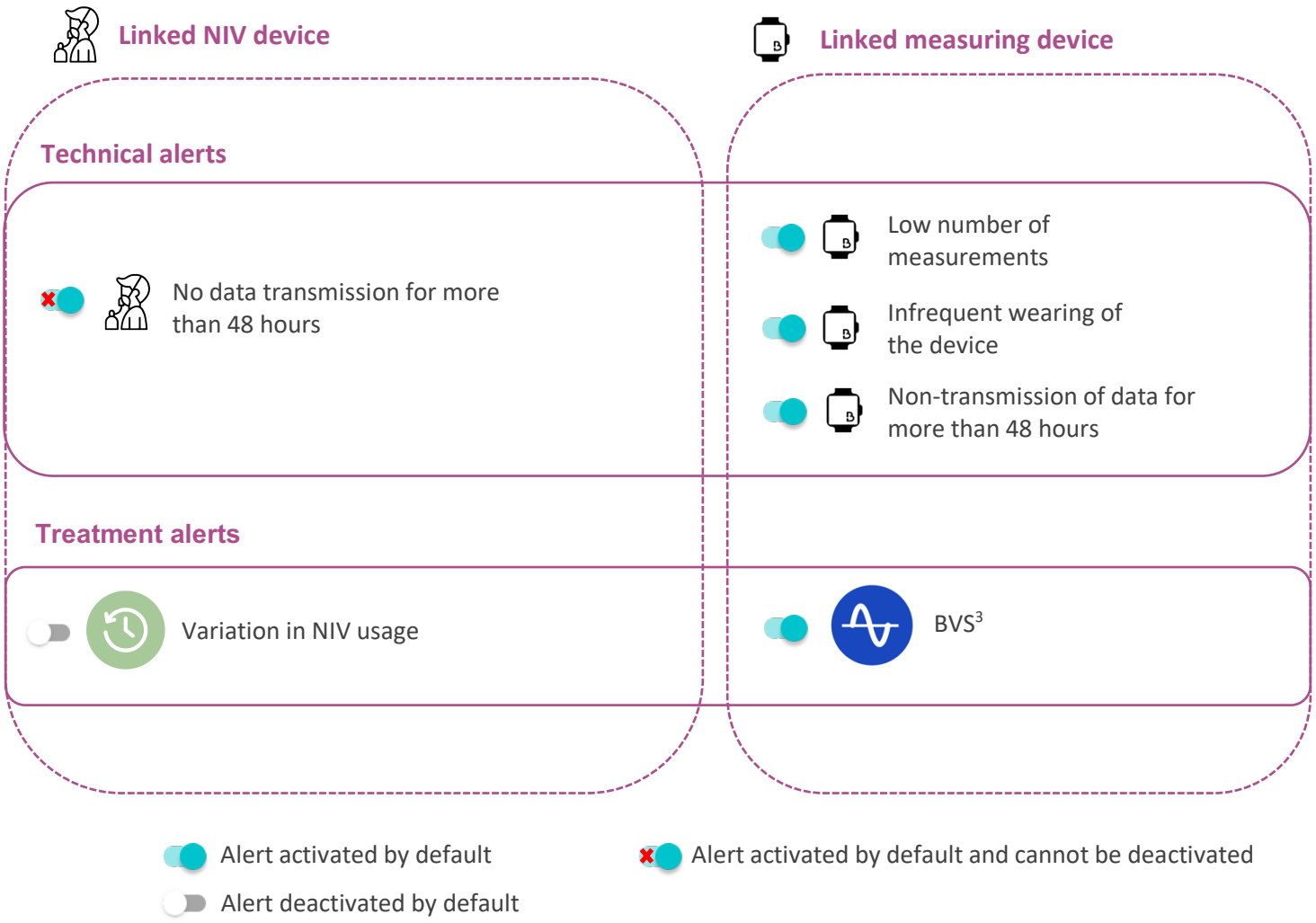
- Low number of measurements
- Infrequent wearing of the device
- Non-transmission of data for more than 48 hours

Treatment alerts

- Heart rate
- Respiratory rate
- SpO2
- BVS$^{3®}$> 3 σ

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:

- For the "BVS$^{3®}$" alert whose threshold cannot be changed
- 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.

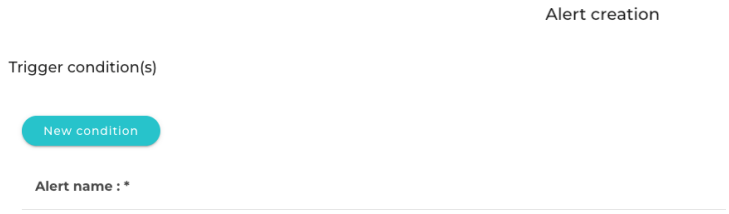
Click on the button to modify an alert.

It is also possible to link a previously-configured alert model when launching a session: refer to the NIV alert models for more details.

Personalised alerts

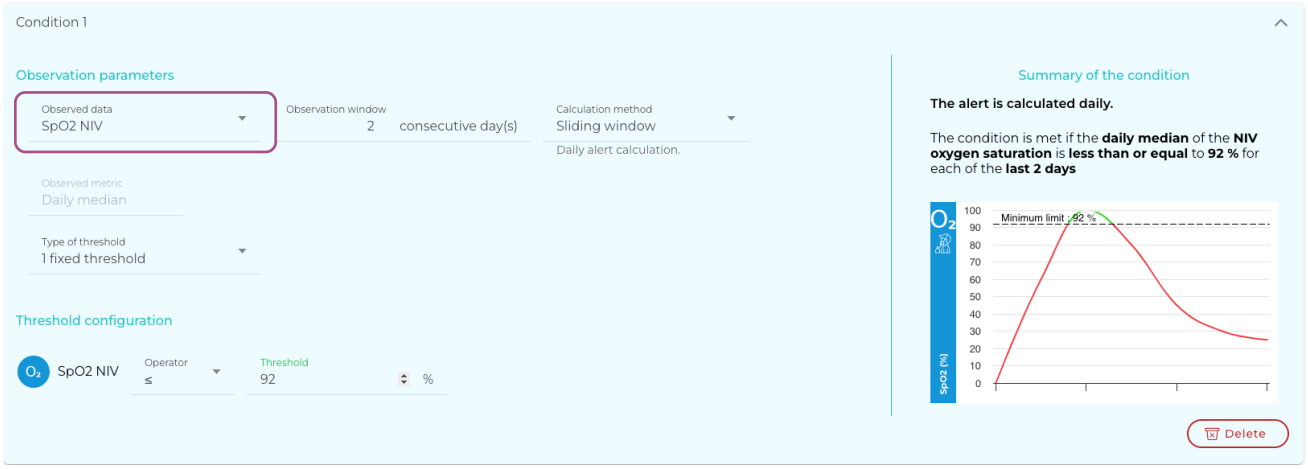
In addition to the treatment alerts already available, new personalised treatment alerts can be configured by pressing the + Create an alert button

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

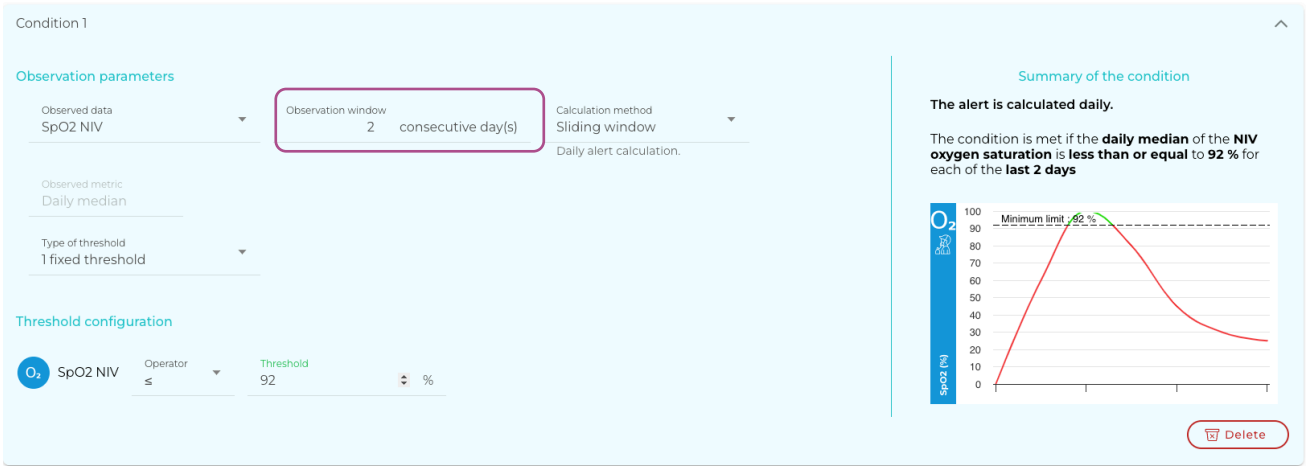


For each of the conditions, you must:

- Choose the observed parameter



- Choose the observation window:



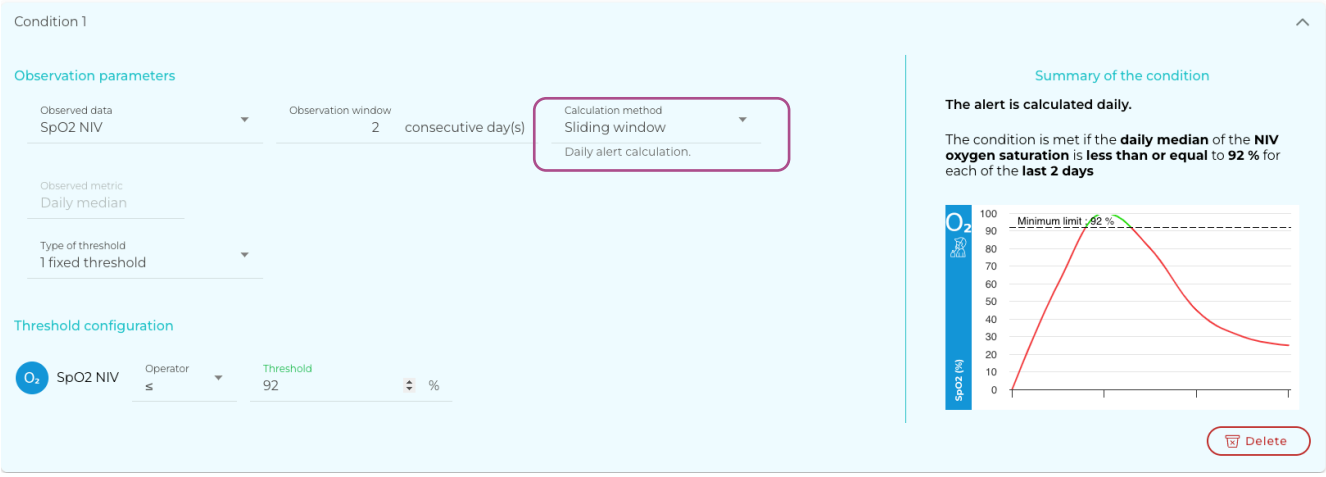
The default observation window value is 2 days, except for the “median leaks” setting where the window is set to 3 days.

The observation window can take a value:

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

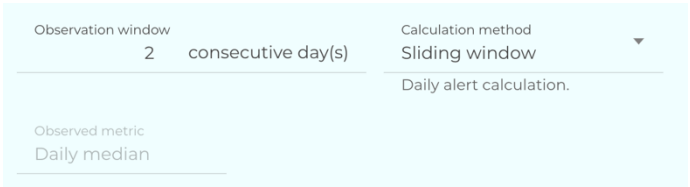
The "NIV median leak" alert is an alert imposed by the HAS reference framework for patients under remote monitoring. The observation window must be between 3 and 7 consecutive days.

- Select the calculation method:

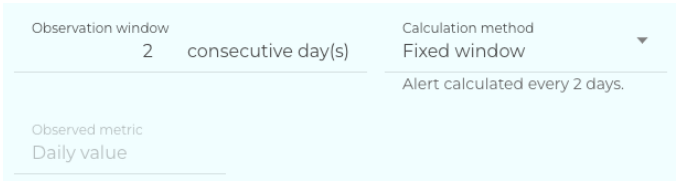


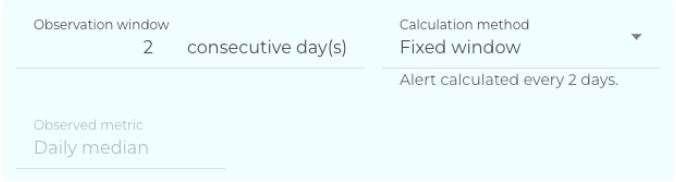
The calculation method enables you to select a fixed or sliding calculation window.

- Sliding window (default): The alert is calculated daily based on the observed data metric. (daily value or daily median)



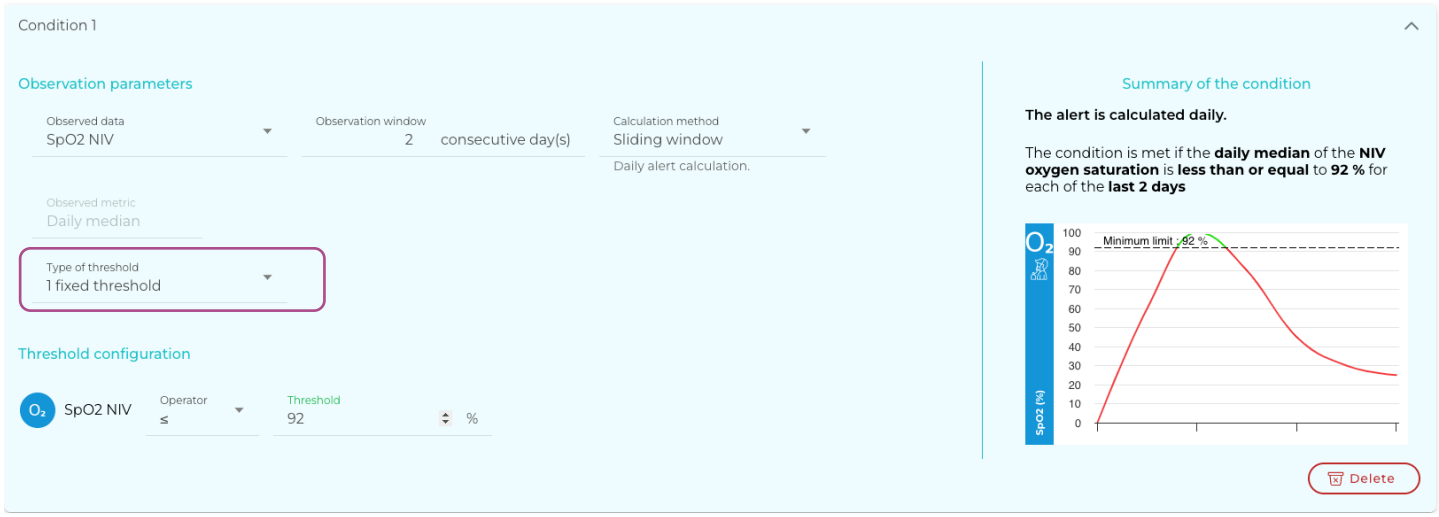
- Fixed window: The alert is calculated every X days (X = number of days selected for the observation window).
  The calculation is based on the average observed data metric over the entire period defined by the observation window.



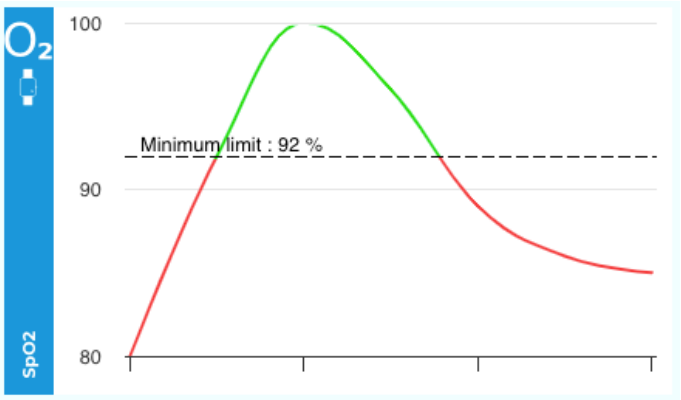


The fixed window can only be used on VNI metrics. It is not applicable to data obtained with the Bora band device.

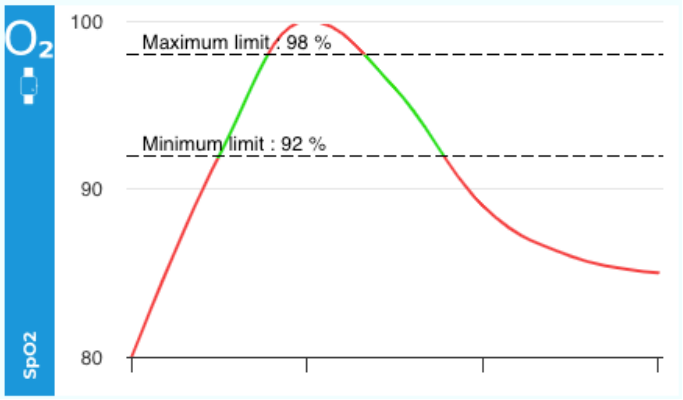
- Select the type of threshold:



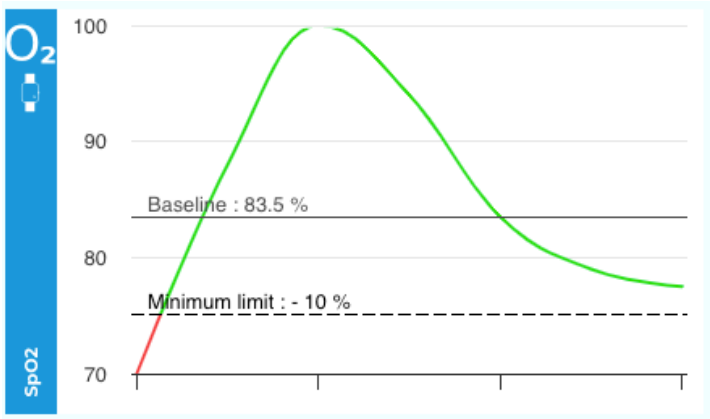
  - 1 fixed threshold: the condition is met if the configured fixed threshold is exceeded (e.g.: Saturation <= 92% SpO2)



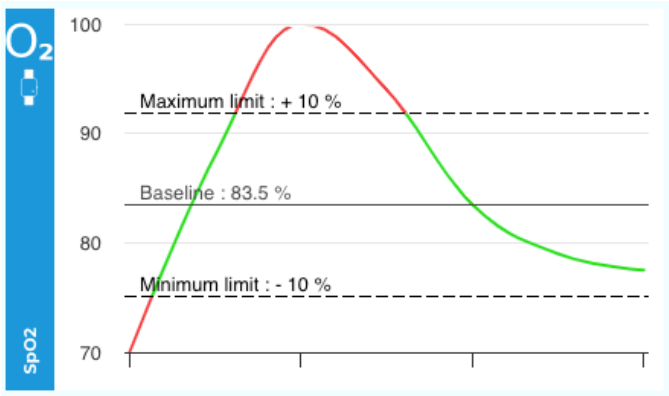
  - 2 fixed thresholds: the condition is met if the observed parameter goes beyond the two set thresholds (e.g.: Saturation is <= 92% OR >= 98%)



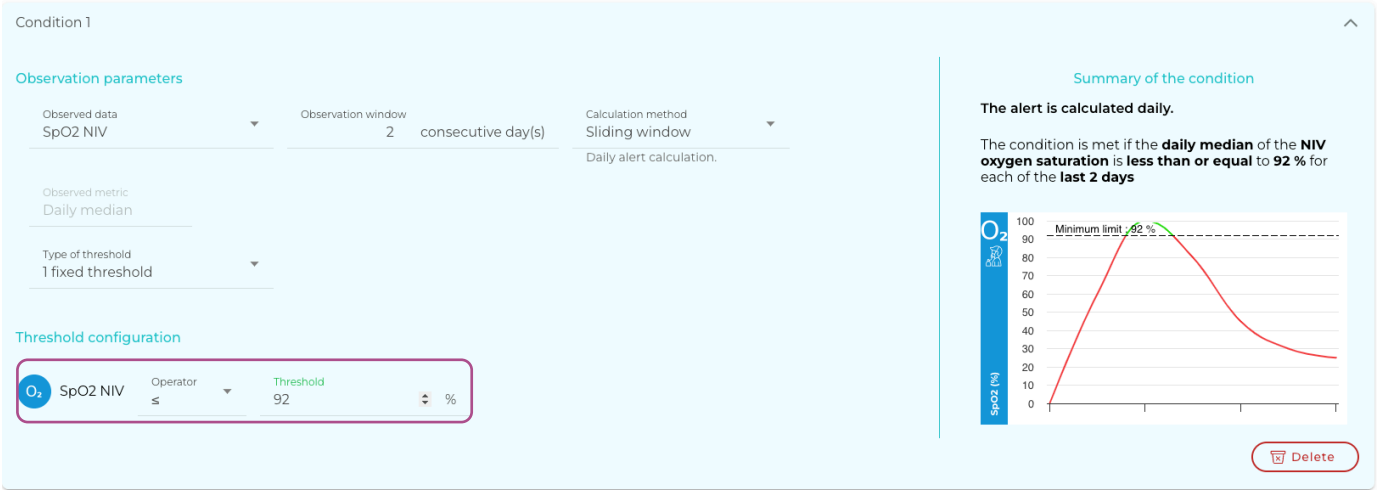
- 1 variable threshold: the condition is met if the observed parameter exceeds the chosen threshold. The threshold value is not fixed. (e.g.: Saturation increases by 10% compared to the baseline corresponding to the median over the last 15 days)



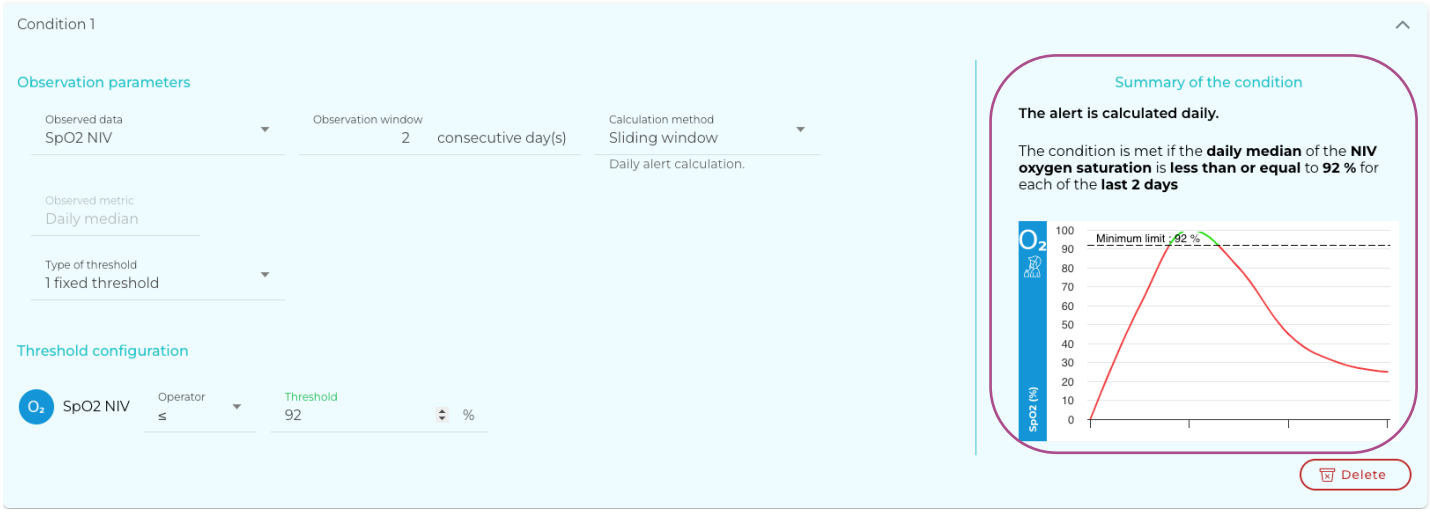
- 2 variable thresholds: the condition is met if the observed parameter exceeds the defined thresholds. The thresholds are not fixed (e.g.: saturation increases by 10% or decreases by 10% compared to the baseline corresponding to the median over the last 15 days)



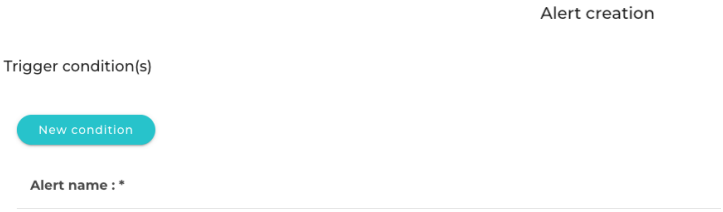
- Configure the thresholds:



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



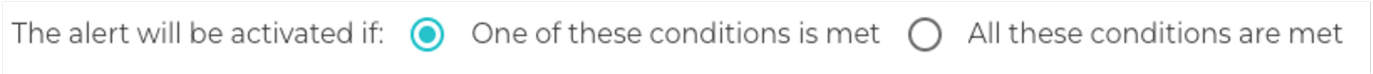
It is possible to set several conditions; By clicking on "New condition" you can add another condition to your alert.



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

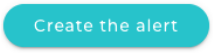
If you create an alert with several conditions, you must choose whether to trigger the alert if all the conditions are met or only if one of the conditions is met.

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 conditions attached to different devices cannot be combined.

⚠ When multiple conditions are added to an alert, they must share the same calculation method (fixed or sliding). This ensures that the calculation method selected for the first condition will automatically be applied to all other alert conditions.

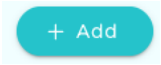
You can confirm the creation of the alert by pressing the 

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.

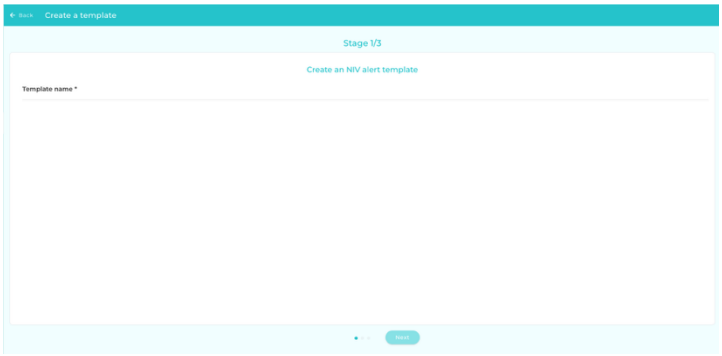
NIV alert models

The “Models” tab, accessible from the side menu, enables you to configure alert models that can be linked to one or more patients.

Clicking the 

button enables you to create a model. This process involves three steps:

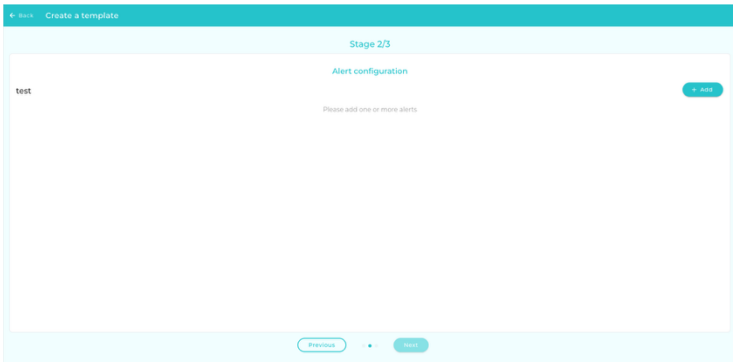
1 Name the model



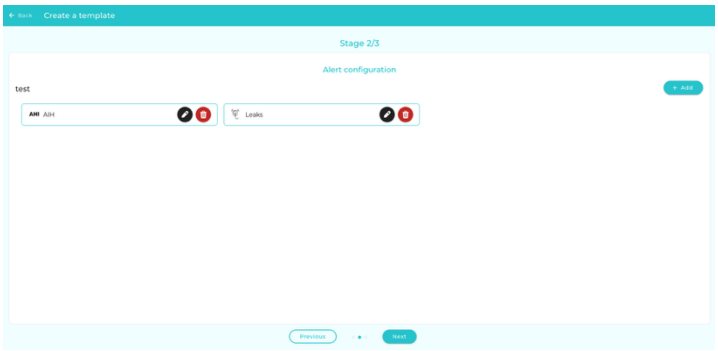
2 Add the alerts

Click “Add” to access the alert configuration page.

Once validated, the alert is added to the model’s alert list. Multiple alerts can be added to the same model.



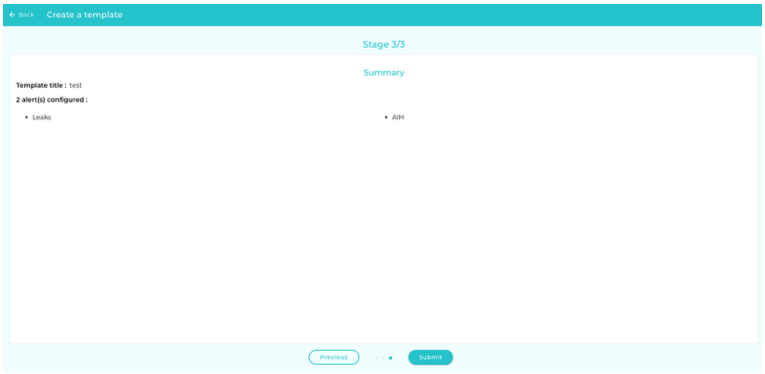
The user can, at any time, **modify** an alert or **delete** it using the relevant icons, before proceeding to the next step.



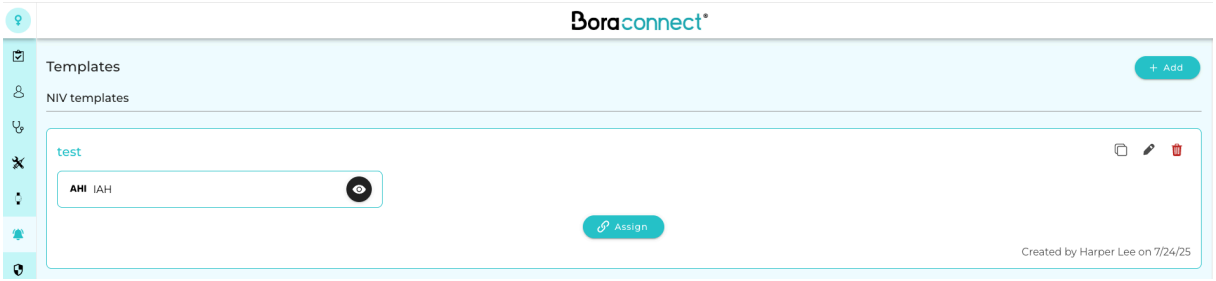
3 Validate the model

The last step provides a summary of the configured alerts.

Once the model is validated, it is added to the list of available models.



Actions available on a model

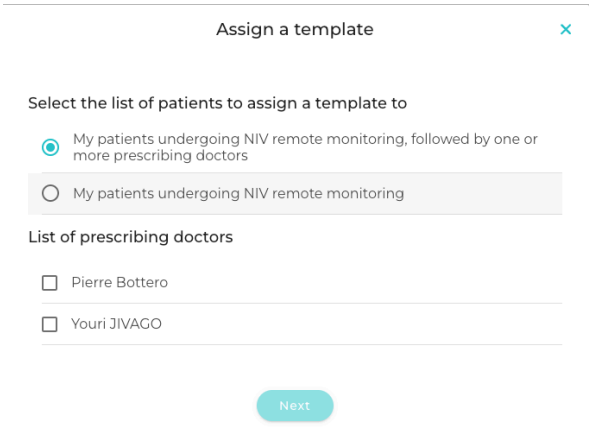


Several actions are possible from the model list:

- **Duplicate**: creates a copy of the model, named “Model name (copy)”. This copy can then be freely modified.
- **Modify**: enables you to modify the model. This returns the user to step 1 of the configuration. After validation, the user’s name and modification date will be displayed at the bottom of the model.
- **Delete**: permanently deletes the model from the list and from all patient records to which it was linked.

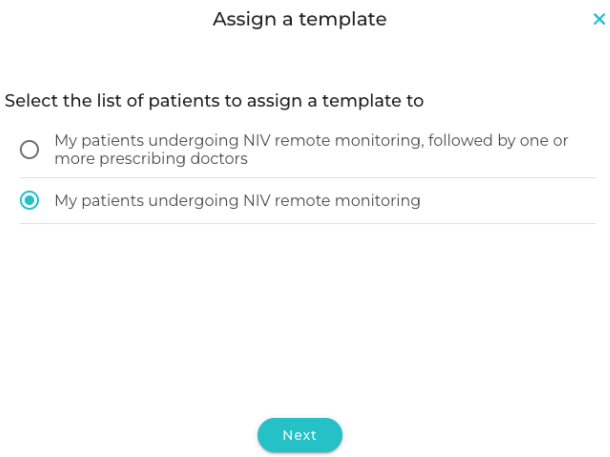
> Warning: Modifying or deleting a model impacts all patients to whom this model is assigned**.**

- Assign **Assign**: enables the model to be linked patients, with two options:
  - **Assign the model to all my patients undergoing NIV remote monitoring, followed by one or more prescribing physicians**.
    The user selects the prescribing physicians whose patients will be assigned the alert model. Only patients visible to the user will be affected.

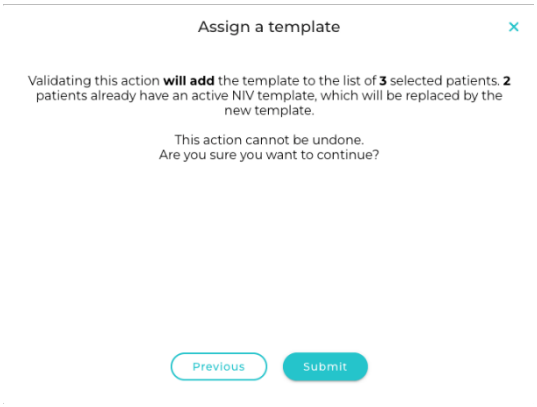


- **Assign the model to all my patients currently receiving NIV remote monitoring.**
  The user selects one or more structures to which they are affiliated, and the model is assigned to all patients belonging to those structures.

  If the user is a healthcare professional and works within multiple structures, the list of structures will be displayed; otherwise, for other users, the list will not be displayed because their account is affiliated with only one structure.

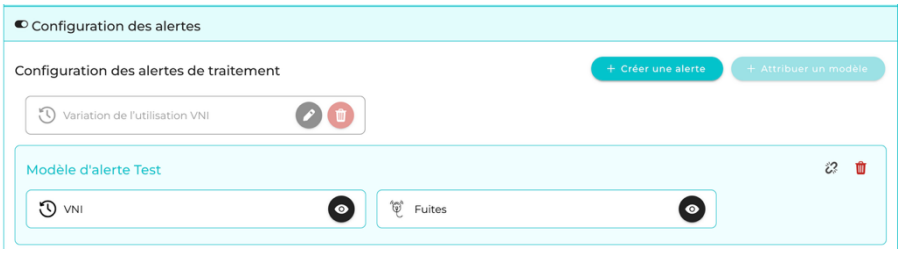


After selection, a confirmation message displays the number of patients affected.



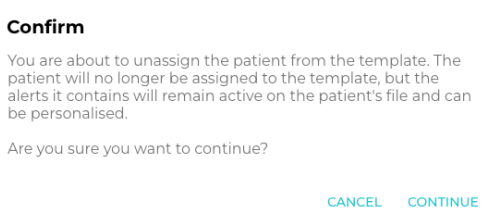
⚠ Warning: If some patients already have a model, it will be replaced by the newly assigned model.
Only one model can be linked to a patient at a time.
Any new assignment replaces the existing model.

Once assigned, the model is displayed in the "Alert Configuration" section of the patient file, in a dedicated box.



Two actions are available here:

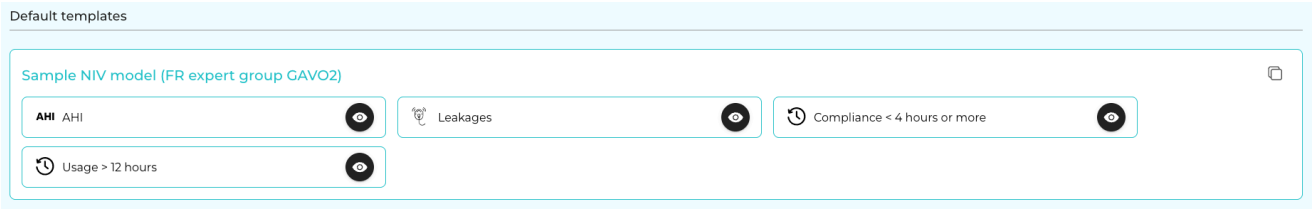
- **Delete**: deletes the model from the patient file, with no impact on the model or other patients.
- **Unassign**: the patient is unassigned from the model; the alerts that were in the model are copied to the patient file. The alerts then become independent of the model and can be modified for the patient.
  An information message notifies of this unassignment.



Default models

A default model is available in the list. It contains alerts based on the recommendations of GavO2 (a French expert group).

This model cannot be modified, assigned or deleted directly. To use it, you must first duplicate it. You can then either assign it as is or customise it before assigning it.
Only one model can be configured per patient.

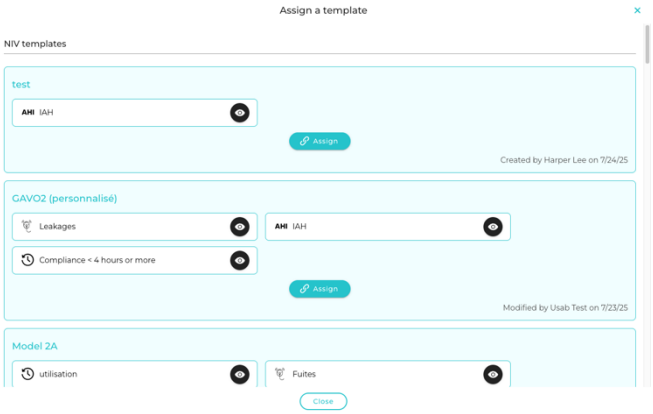


Launching a session with a model

When launching a remote monitoring session, you can link a model to a patient:

The alert configuration step includes the option to add a model.

A list of available models is displayed.

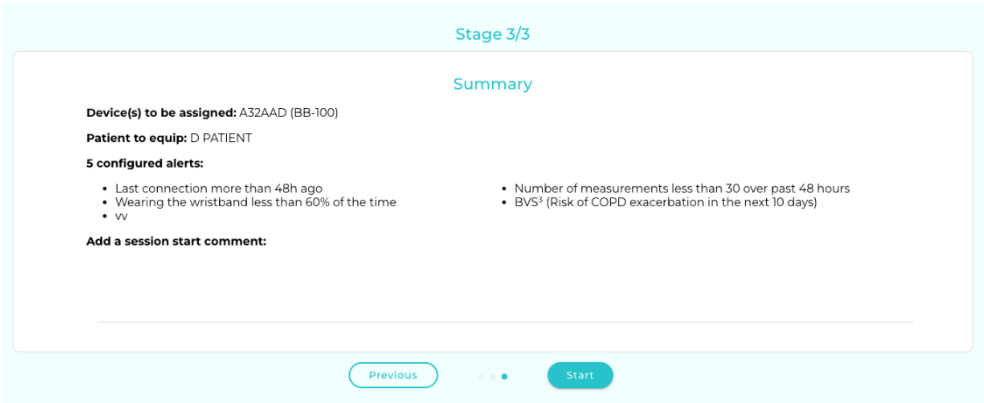


Step 3: Start the remote monitoring session

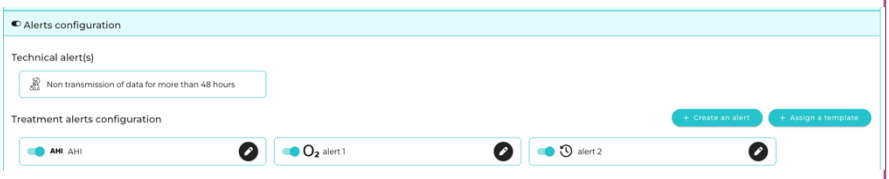
This last step allows you to confirm the summary of the information entered with:

- The assigned devices
- The patient to equip
- The alerts and/or alert models configured

A session start comment can be added.



Note that you can modify these patient alerts later in the "alerts configuration" section on the patient details page. From this section, you can create an alert, enable or disable configured alerts, assign a model or modify any alerts already configured.

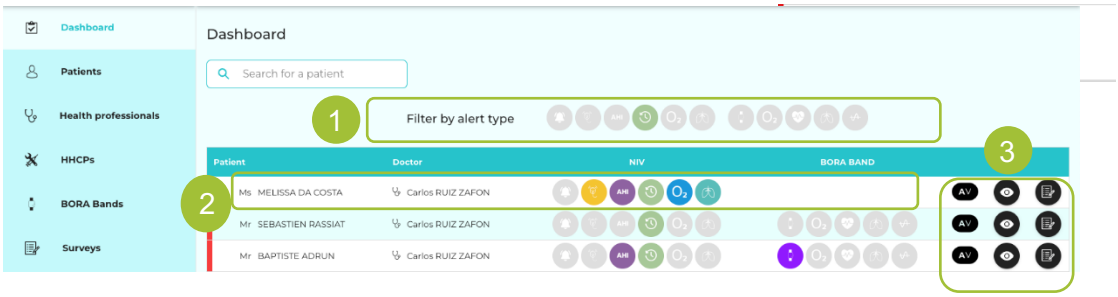


Once the remote monitoring session has started, you can monitor the data uploaded to Bora connect®.

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):

Linked NIV device

Technical alerts

- Technical problem: No data transmission for more than 48 hours

Treatment alerts

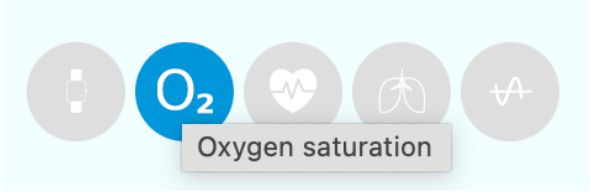
- Excessive unintentional leaks
- AHI
- Use
- Oxygen level of patient
- Patient respiratory rate

Linked measuring device

- Technical problem:
  - Wearing Bora band < 60% of the time
  - Low number of measurements (< 30 measurements over 48 hours)
  - No connection for 48 hours

- Oxygen level of patient
- Heart rate
- Patient respiratory rate
- BVS[3®] Score > 3 σ

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 health actors to help you obtain a record of actions.

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

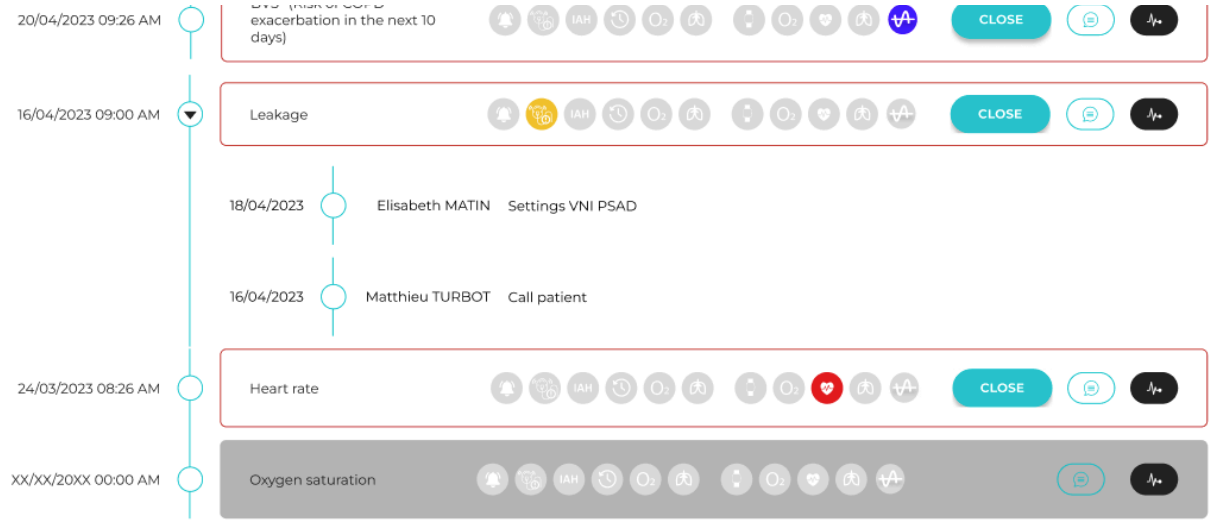
The following information appears for each alert:

- 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 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 (2 alerts) 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.

3 You can view the the patient file by clicking on the button

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

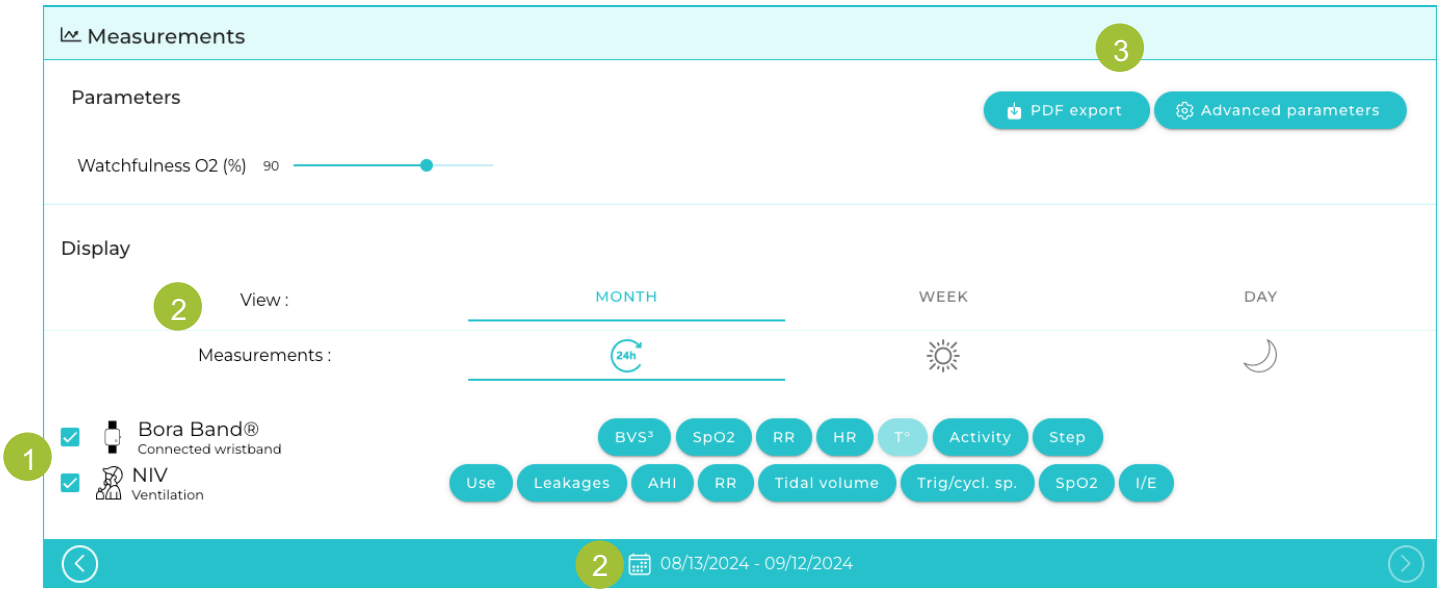
To directly access the patient's therapeutic follow-up, click the button. A notification informs you if a new item has been added to the patient's therapeutic follow-up since your last consultation.

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 or select the button from the dashboard corresponding to the desired patient.

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 (except temperature) 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

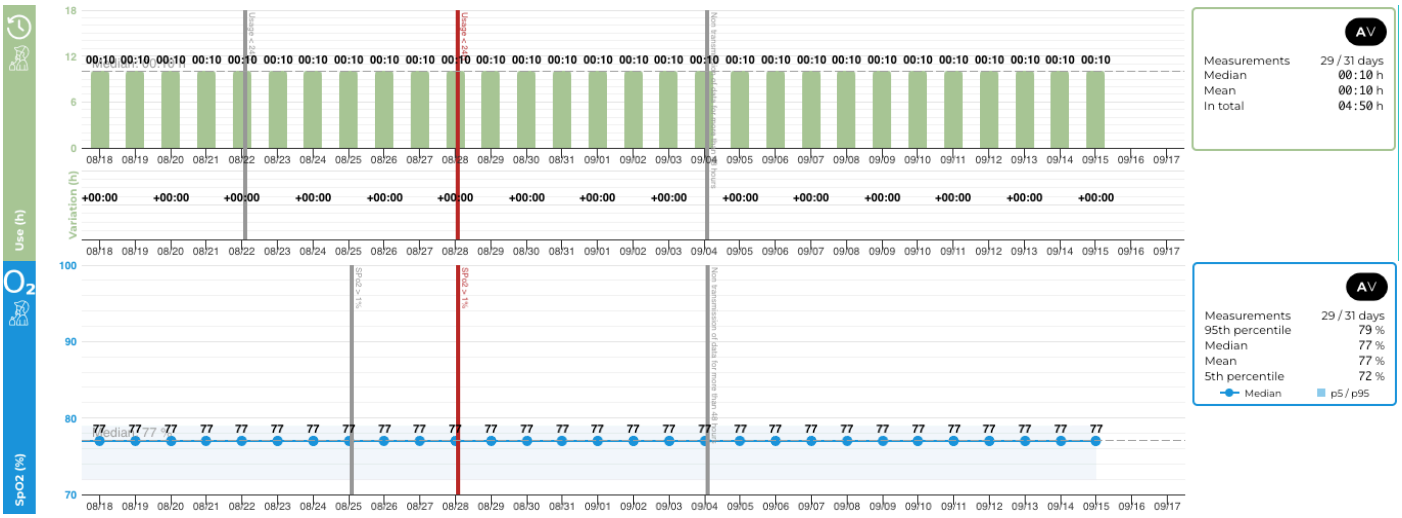
- Select standard or advanced display mode. It should be noted that the advanced mode is only available for the data relating to a Bora Band.

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.

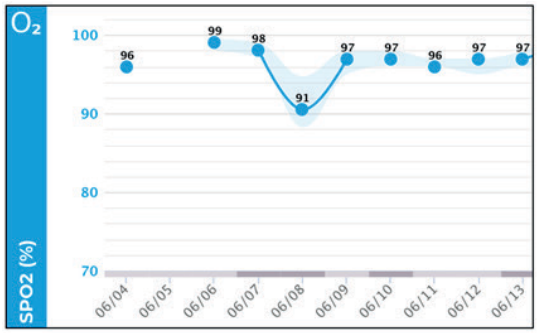
An overview box for graphs, located on the right, display:

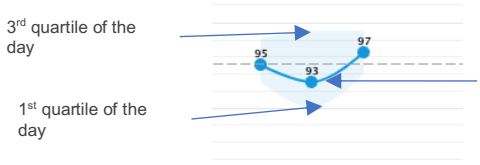
- The number of days with measurements
- The median of values over the selected time period
- The 95th percentile over the selected time period
- The 5th percentile over the selected time period
- A button AV to access the patient’s AirView™ account for more details on the daily measurements (valid only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

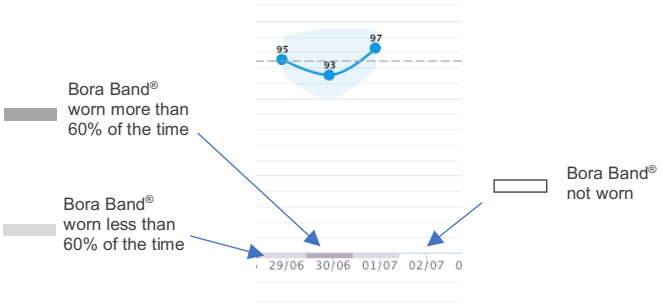


Depending on the mode selected in the advanced settings, the measurements display will be different:

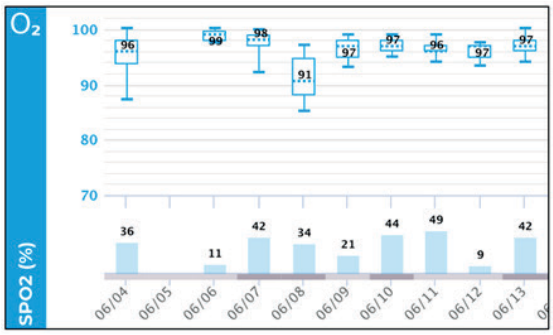
Standard mode

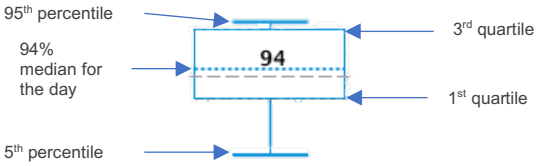


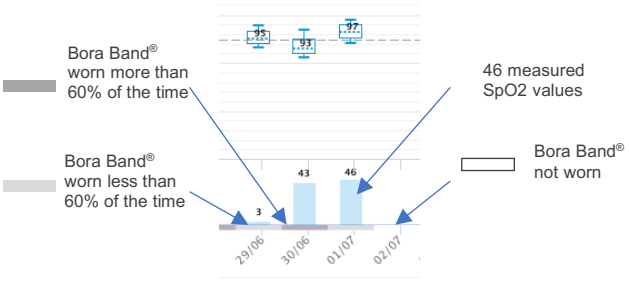




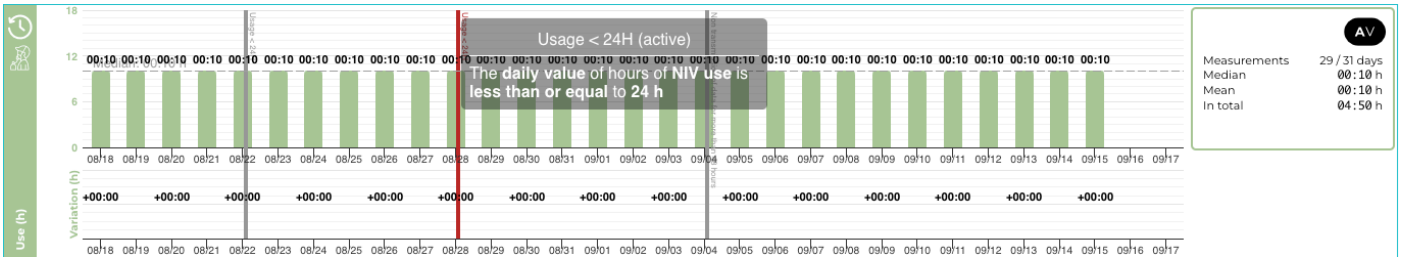
Advanced mode







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.



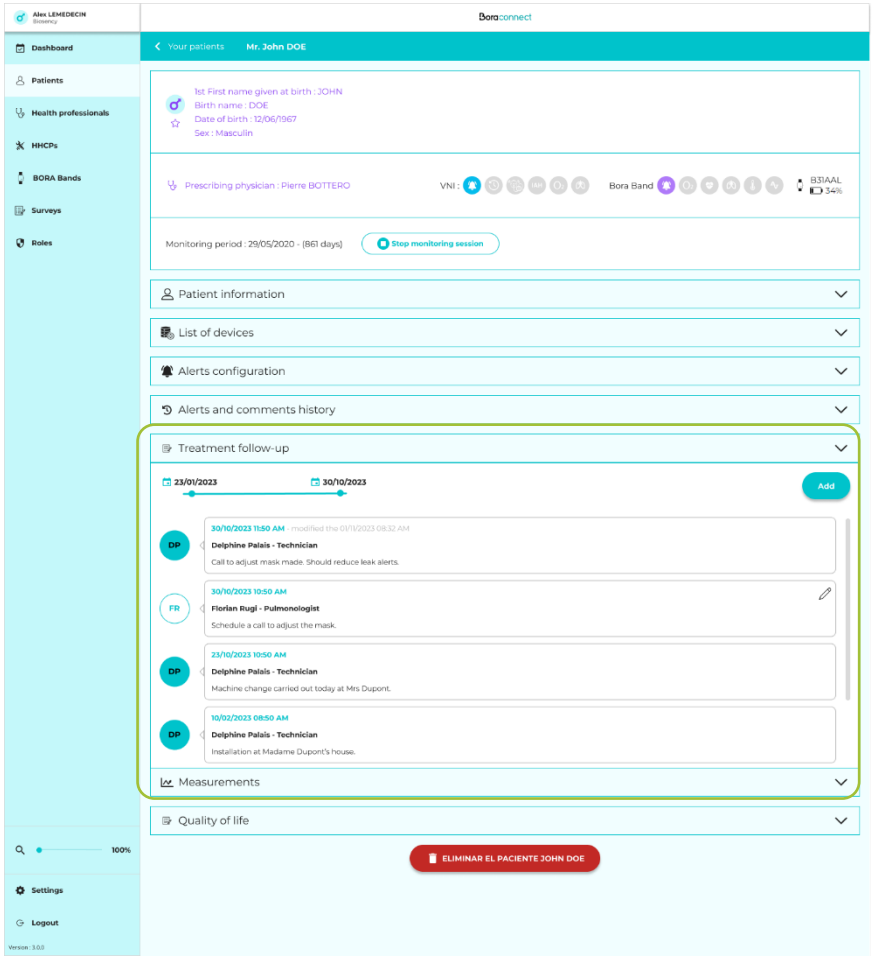
On the histogram measurements for use, the fragmentation of the usage appears when the users go over the graph.

Therapeutic follow-up

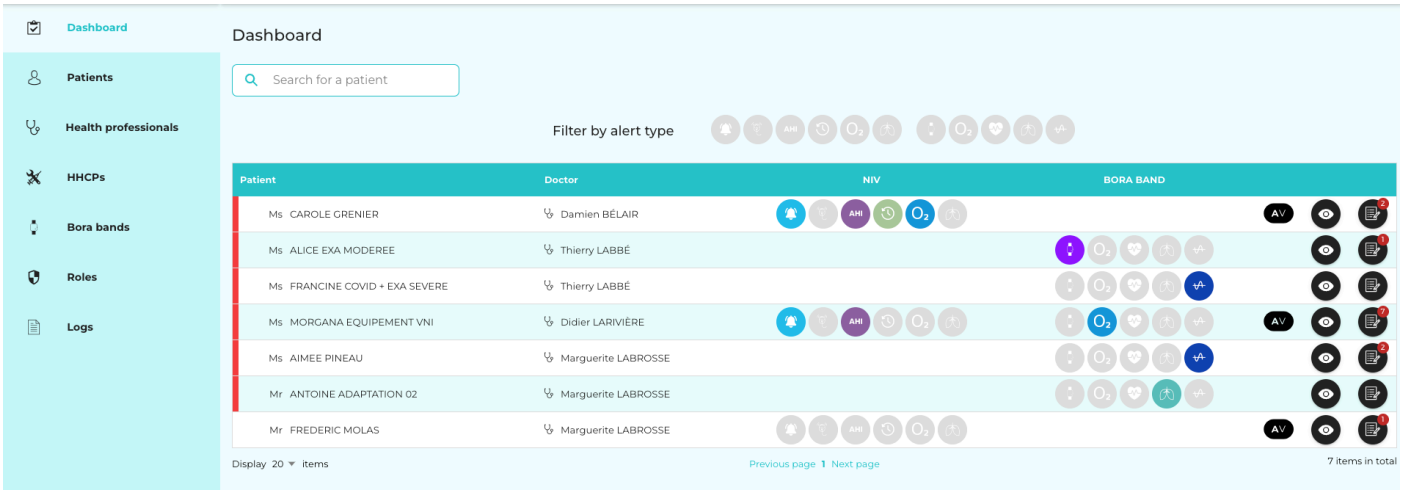
The therapeutic follow-up aims to allow the patient to be monitored through notes filled in by the actors and professionals involved in his or her care pathway.

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



You can also view the therapeutic follow-up directly from the dashboard by clicking the button.



A red notification icon is displayed on the access button  indicating that a new note has been added to the therapeutic follow-up since your last consultation.

The notification is displayed for each user based on their last therapeutic follow-up consultation.

This system enables those health actors involved in the patient's care pathway to be quickly informed when the patient responds to a questionnaire or when a note is added by another healthcare professional or health actor.

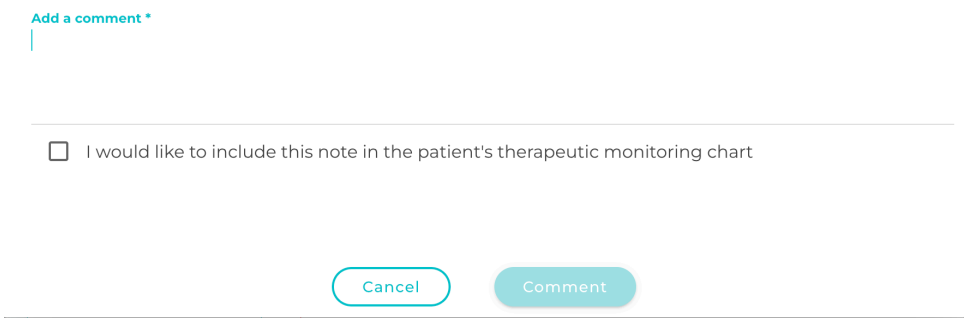
Therapeutic follow-up gathers several pieces of information:

- Briefing notes added manually.

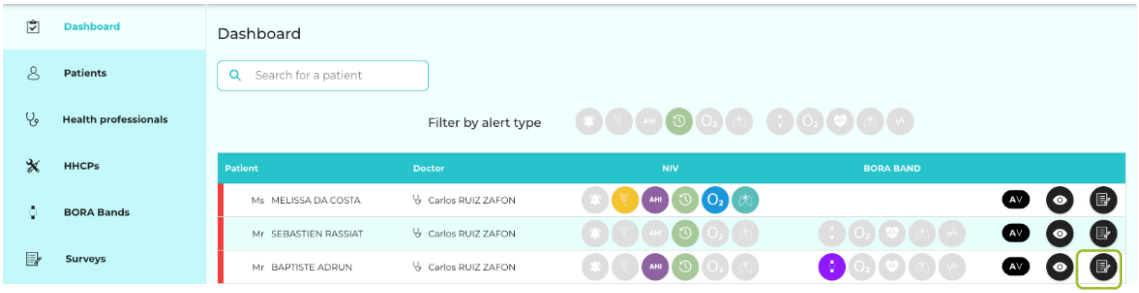
  Actions on questionnaires (add, delete or response) that automatically generate associated notes. These are provided for informational purposes only and cannot be edited

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 monitoring chart".



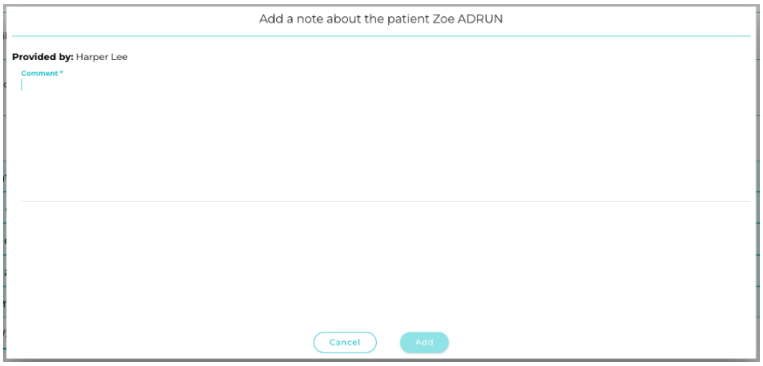
- From the dashboard: you can click on the button to open the therapeutic follow-up  .



- 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)

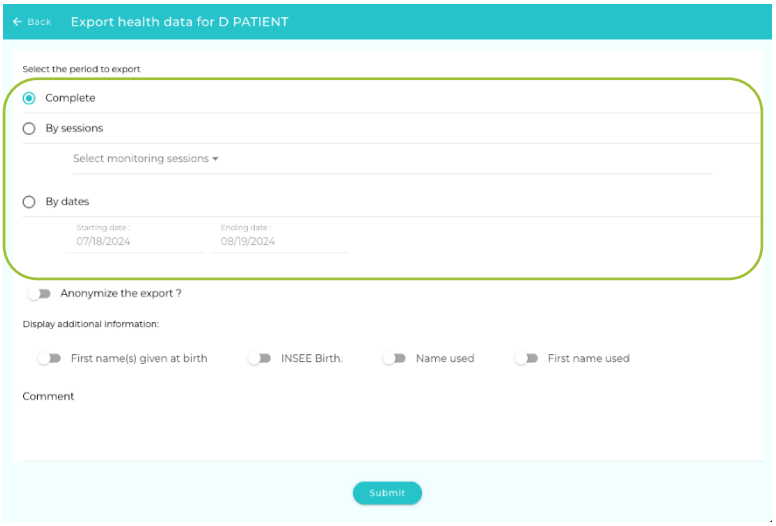


Report export

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

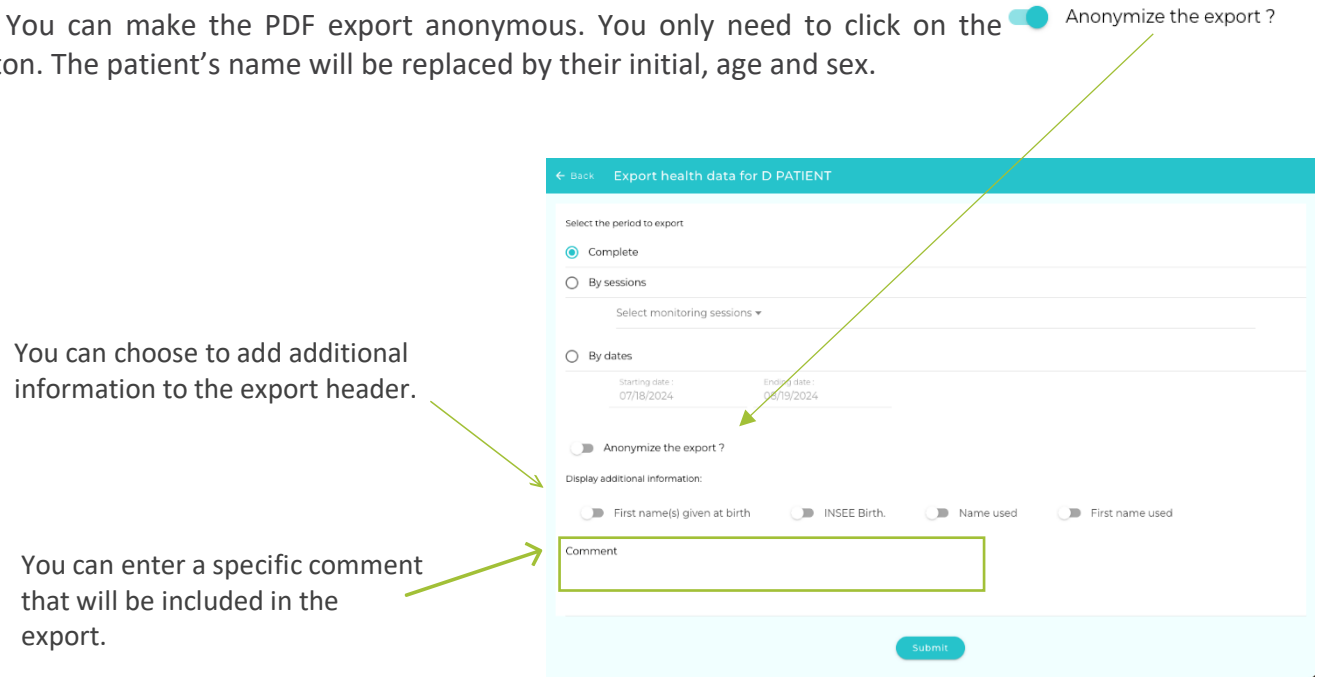
2 Select the measurement period that you want to export:

- 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

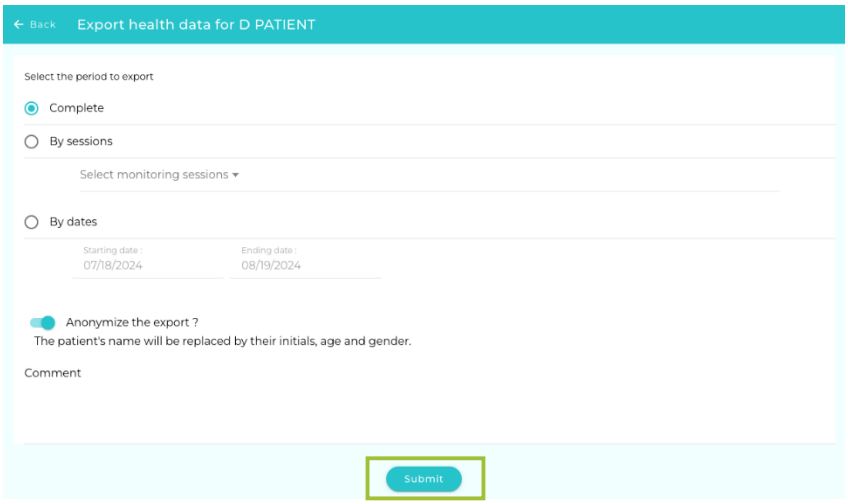


If the measurement graph display is set to day view, you will not be able to export more than 15 days.

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



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:

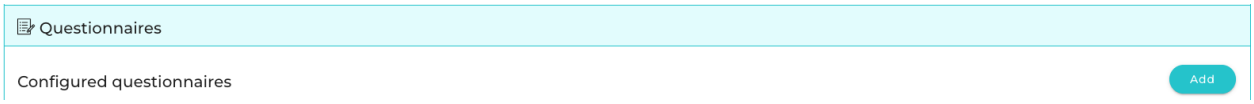
The PDF export will use your current graph parameters for the PDF file. Modify your current display parameters to modify the PDF export.

Configuring a questionnaire

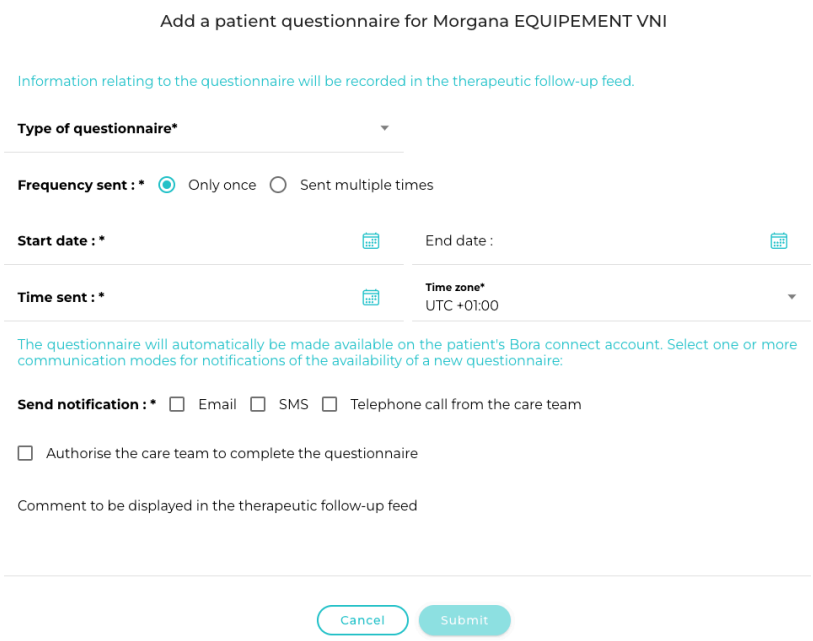
Bora connect® enables you to submit a questionnaire to patients to assess their health or monitor their treatment. Questionnaires are available for all patients, with or without a remote monitoring session in progress.

To configure a questionnaire:

1 In the patient's file go to the "Questionnaire" category at the bottom of the page. Click on the "Add" button.



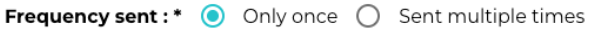
2 Select the type of questionnaire and the frequency at which it is sent. Select a start date, finish date and send time. Mandatory fields are marked with *. The start date is pre-filled with today's date, but it can be changed.



There are several types of questionnaires:

- S3NIV: This questionnaire aims to assess how non-invasive ventilation (NIV) influences the patient's respiratory symptoms, sleep quality and possible side effects.
- SF36: This questionnaire aims to understand how the patient perceives their general state of health and the impact on their daily life.
- VQ11: This questionnaire aims to assess the impact of the patient's state of health on their quality of life.
- O2: This questionnaire aims to gather information about the use of oxygen therapy as part of the patient's remote monitoring.
- BVS³: This questionnaire aims to assess the recent progression of the patient's respiratory symptoms.
- CERT: This questionnaire provides simple visual cues for patients to help them recognize their symptoms and seek medical help if necessary.

Select the questionnaire's frequency.
You can send it once only or send it multiple times.

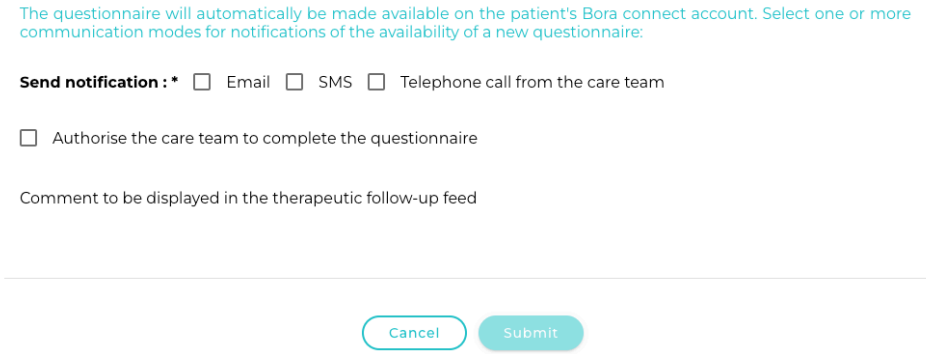


If multiple sending is selected, two fields appear with a drop-down list of choices:

- Recurrence: enter a number to define the interval between each sending (Every...)
- The type of recurrence: days, weeks, months

3 Select the notification delivery method: email, SMS or phone call. A notification is sent to the patient to inform them that a questionnaire is available in their Bora connect® space. If phone call is selected, a member of the healthcare team will contact the patient to inform them of the availability of the questionnaire in their Bora connect® space.

The healthcare team may be authorised to complete the questionnaire by checking the relevant box. In this case, a member of the healthcare team can complete the questionnaire on behalf of the patient by asking them the questions over the phone.



A comment about the addition of the questionnaire can be added to the therapeutic follow-up thread.

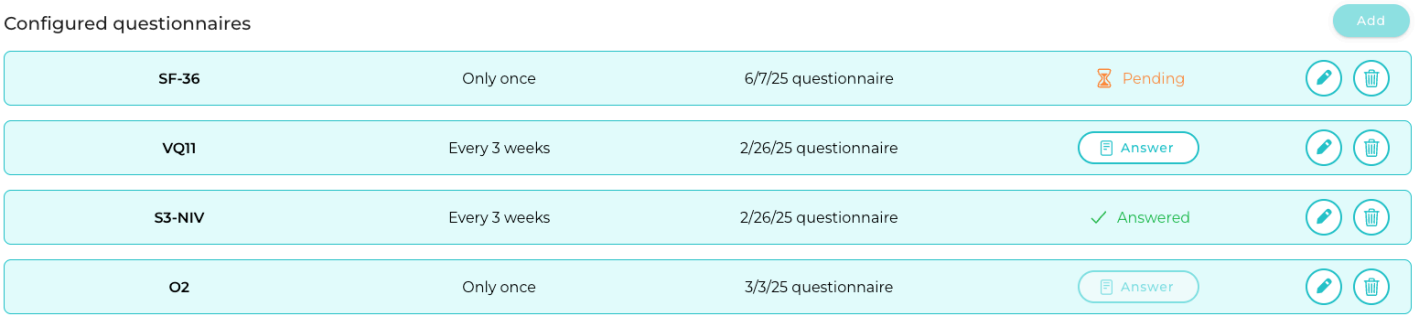
Click on the Submit button to confirm the questionnaire's creation.

4 A notification is sent to the patient via the method chosen when configuring the questionnaire. The notification includes a link to access the Bora connect® account and complete the questionnaire.

The next time that the patient opens Bora connect®, an information window will appear and ask the patient to answer to the questionnaire.

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

5 The configured questionnaires are available in the "Questionnaire" category in the patient file. Here, the patient or members of the healthcare team (if authorised) can answer to questionnaires.

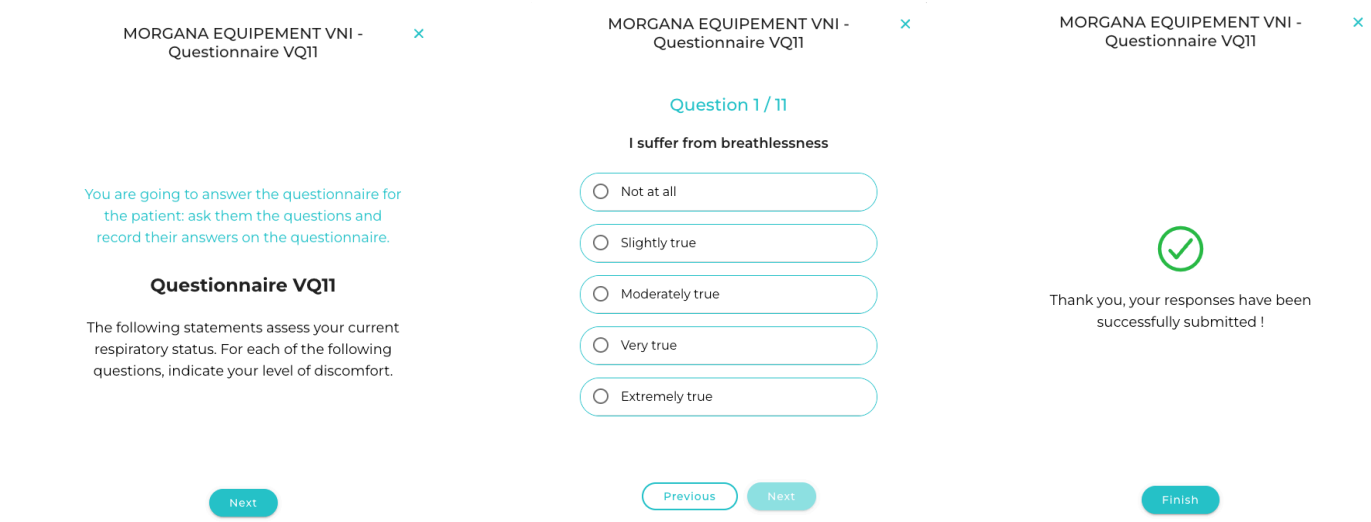


The questionnaire has four statuses:

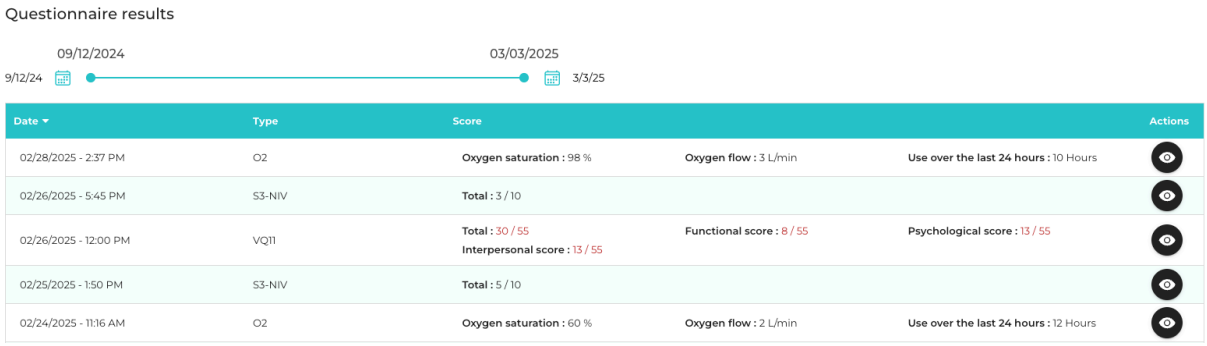
- Answer — The questionnaire is available, and the logged-in user (patient or authorised healthcare team member) can respond to it
- Answer — The questionnaire is available, but the logged-in user is not authorised to respond to it
- Answered — The questionnaire has been completed
- Pending . The questionnaire is not available yet

The patient can answer to the questionnaire on their smartphone.

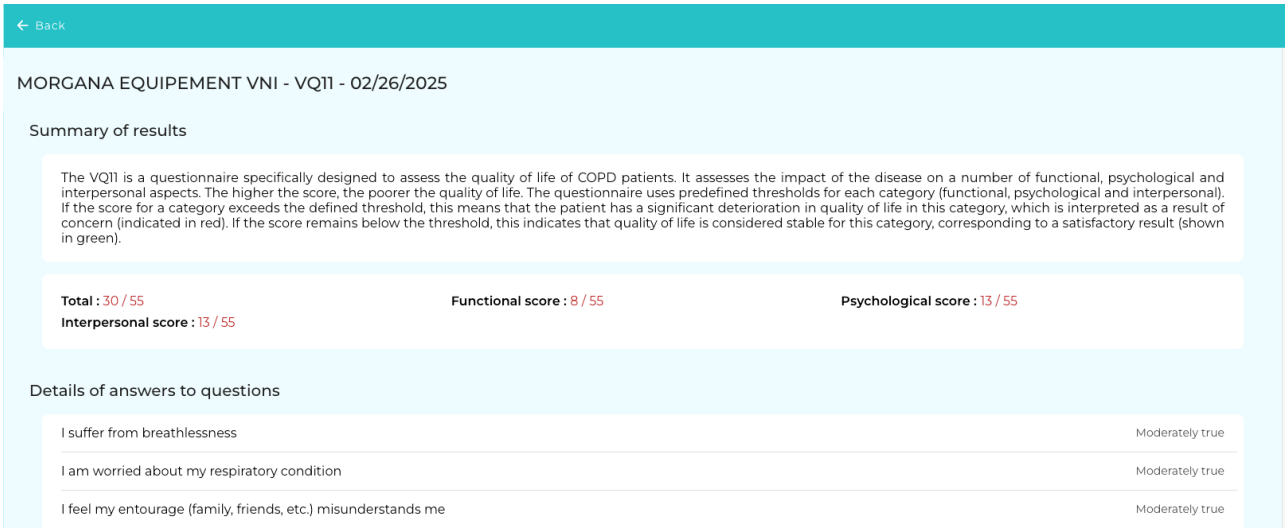
Each questionnaire begins with an introductory screen detailing the purpose of the questionnaire. Various questions are then displayed one by one. On the last page is a “Finish” button to send the questionnaire responses. A final confirmation screen appears to confirm the successful submission of the responses.



6 You can consult the patient's responses in their file in the "Questionnaire" category, "Questionnaire results" section. A chart displays the date and time the questionnaire was completed, the questionnaire type and the score.



7 Click on the button to view the details of the patient's questionnaire responses.



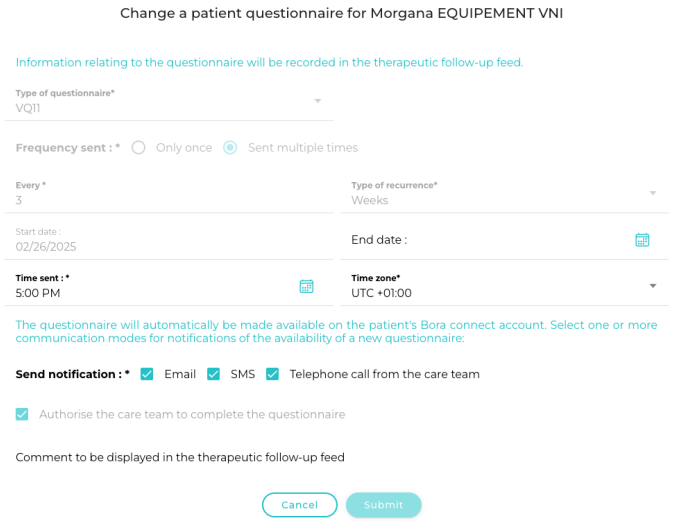
8 You can edit or delete the questionnaire at any time.

Select the button to edit the questionnaire.

The questionnaire edit window opens.

Here you can edit the following fields:

- End date
- Time sent
- Time zone
- Send notification
- Authorise completion by the care team
- Comment

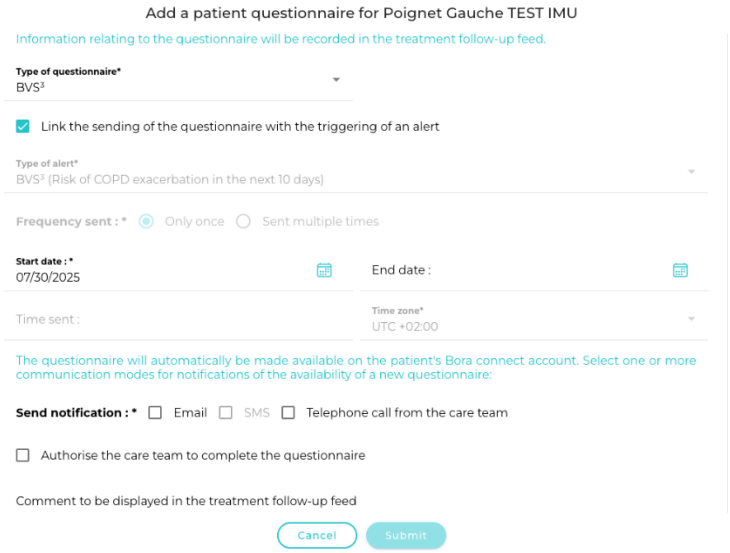


Questionnaire linked to the BVS³ alert

The CERT and BVS³ questionnaires can be configured to be automatically sent when a BVS³ alert is triggered.
There are two configurations to link one of the two questionnaires to the alert:

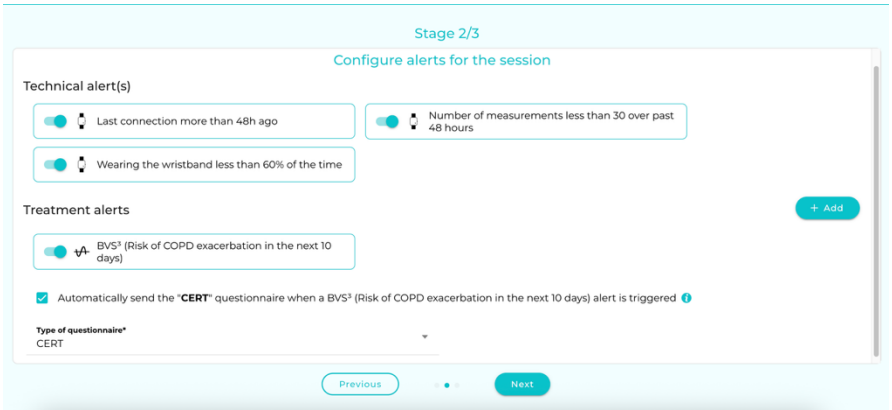
- From the questionnaires tab in the patient file: if the CERT or BVS³ questionnaire is selected, an additional box appears in the questionnaire configuration module.

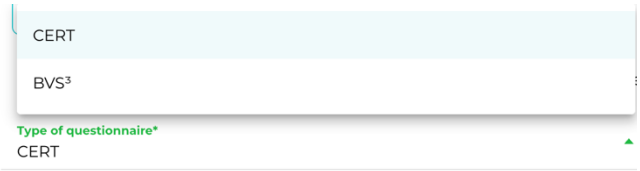
This box enables you to link questionnaire sending with triggering of the BVS³ alert. With this configuration, certain questionnaire parameters cannot be modified and appear greyed out because they are linked to the alert (alert type, sending time, sending frequency)



⚠ Only one questionnaire can be associated with the BVS³ alert

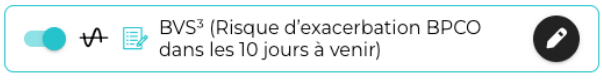
- When launching a remote monitoring session: you can configure alerts in step 2 of launching the session. If a BVS³ alert is present and active, a box enables you to enable or disable automatic sending of the associated questionnaire. The CERT questionnaire is automatically proposed, but the user can choose between CERT and BVS³ in the “type of questionnaire” box. A default configuration for the questionnaire is proposed. To modify these parameters, go to the “Questionnaire” section of the patient file.



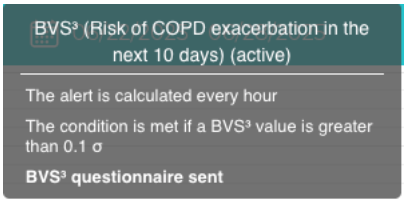


The automatic sending of the questionnaire is indicated in several places:

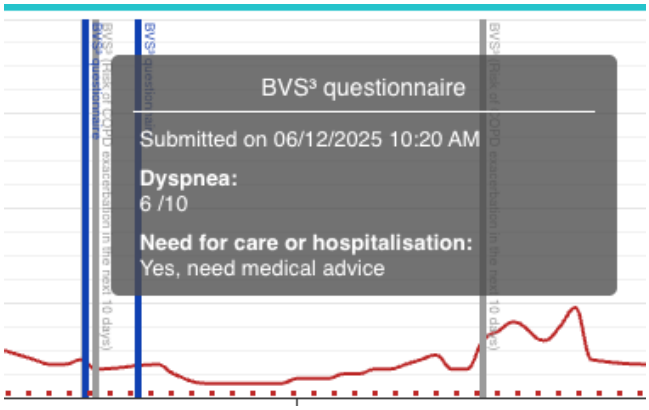
- A “questionnaire” icon appears in the BVS³ alert



- The BVS³ graph displays “BVS³ (or CERT) questionnaire sent” in the alert tooltip

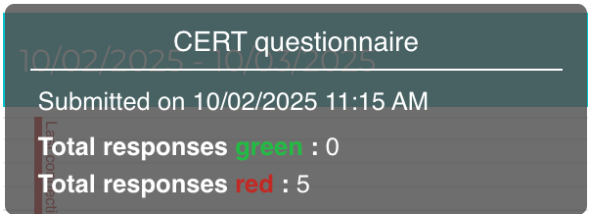


Once the patient completes the questionnaire, a bar is added to the BVS³ graph to mark the time of the response in relation to the progression of the BVS³ score. The associated tooltip indicates:



- For the BVS³ questionnaire:
  - The date and time of the response
  - The level of dyspnea reported by the patient
  - The response regarding the need for medical follow-up or hospitalisation

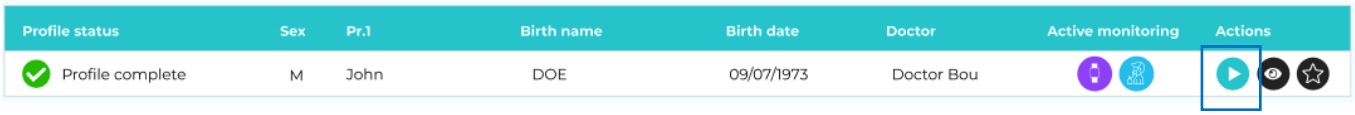
- For the CERT questionnaire:
  - The date and time of the response
  - The number of green responses
  - The number of red responses



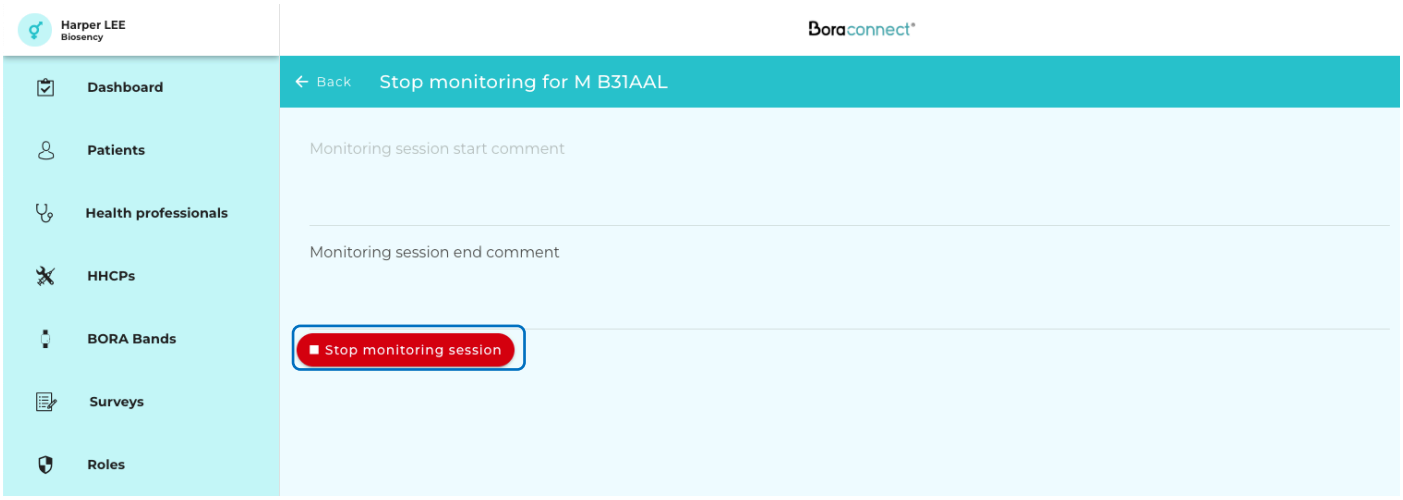
4 Stop a remote monitoring session

A remote monitoring session can be stopped from:

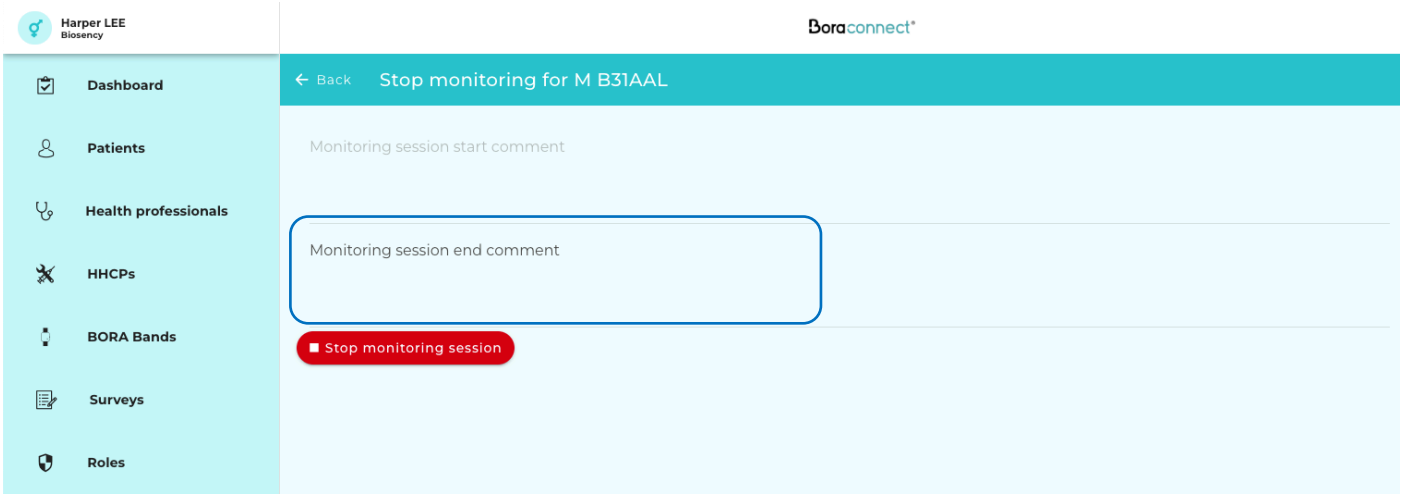
- The list of patients (“Patients” tab) using the "stop” button



- The patient file by clicking on the button 



A comment can be linked to this action.



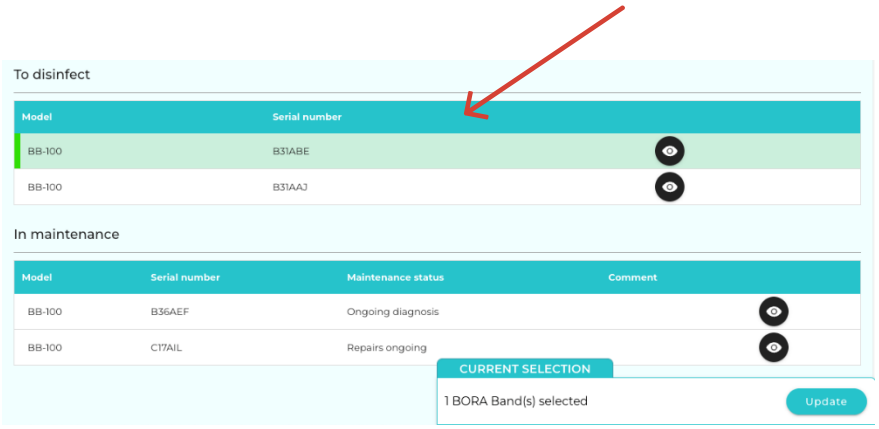
When the session is closed all the devices are automatically disconnected.

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

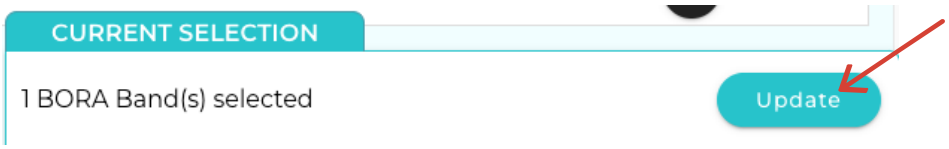
At the end of a remote monitoring session, the Bora band® device used for the session will be automatically set to the status “to be disinfected”.

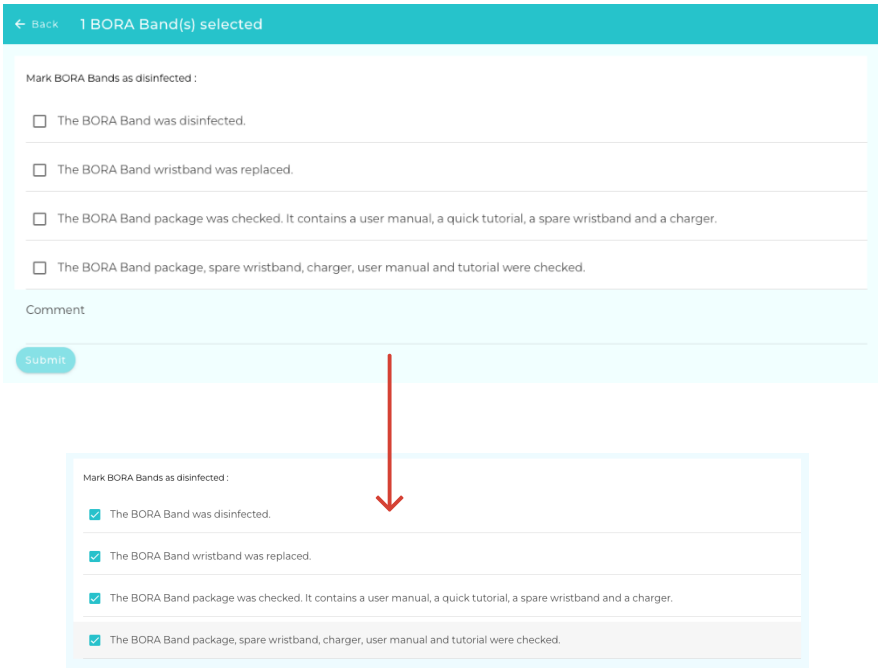
For the Bora band® device to be assigned to a new patient, you need to confirm that the Bora band® device has been disinfected.

1 Go to the “Bora band” tab and select the Bora band® device(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.

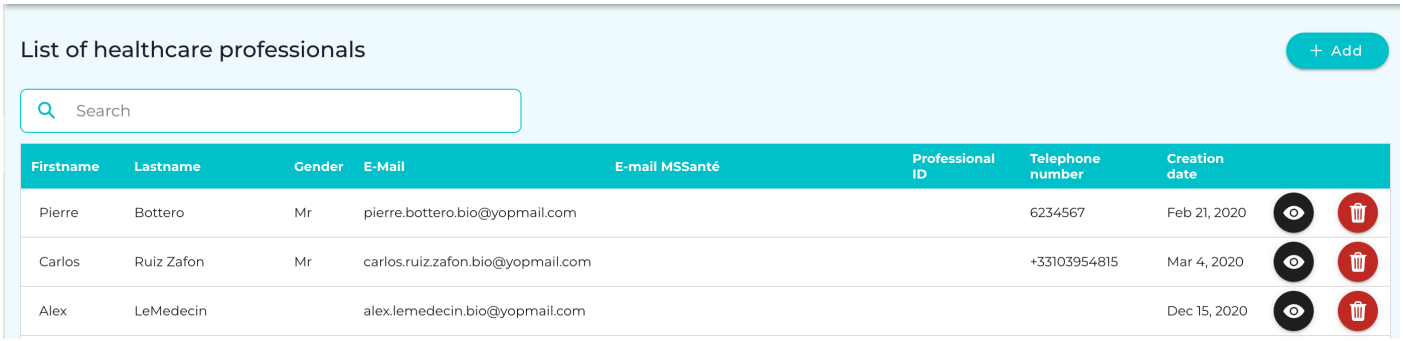
4 Press the button Submit to confirm disinfection.

Once you have disinfected your Bora band® devices, 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.

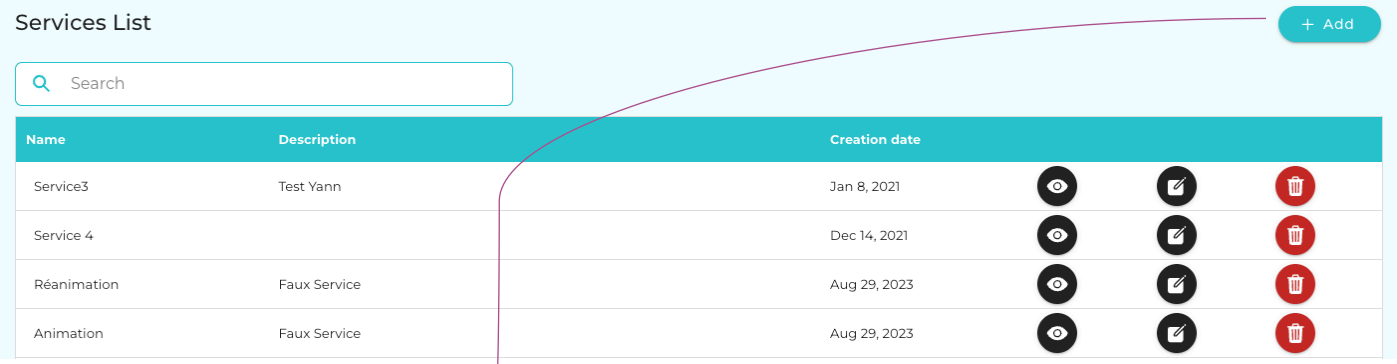
If you wish to add a healthcare professional, please contact Biosency customer service.

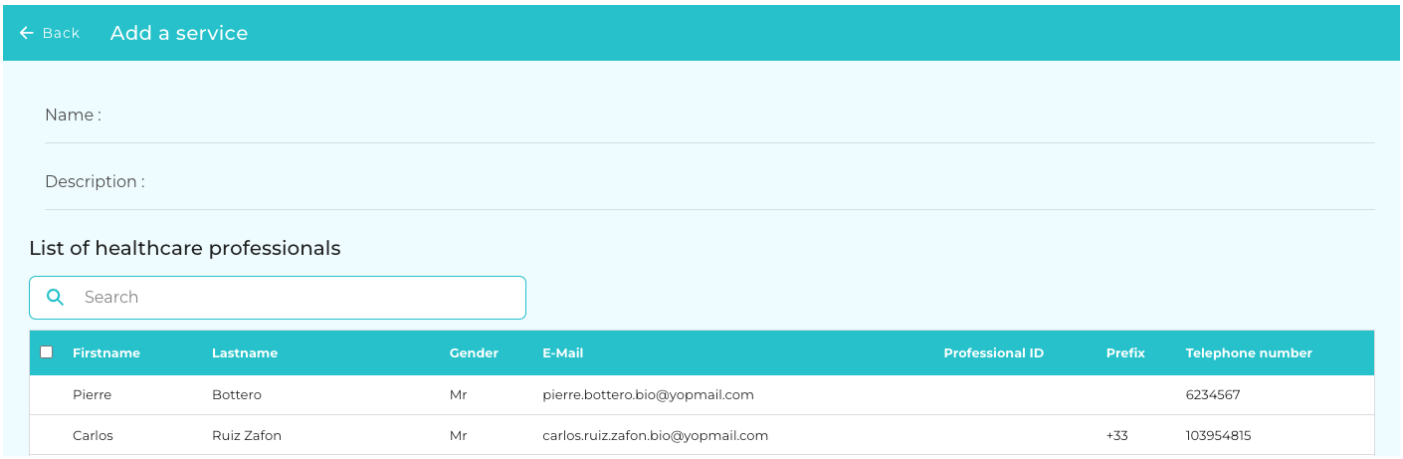


List of services

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.

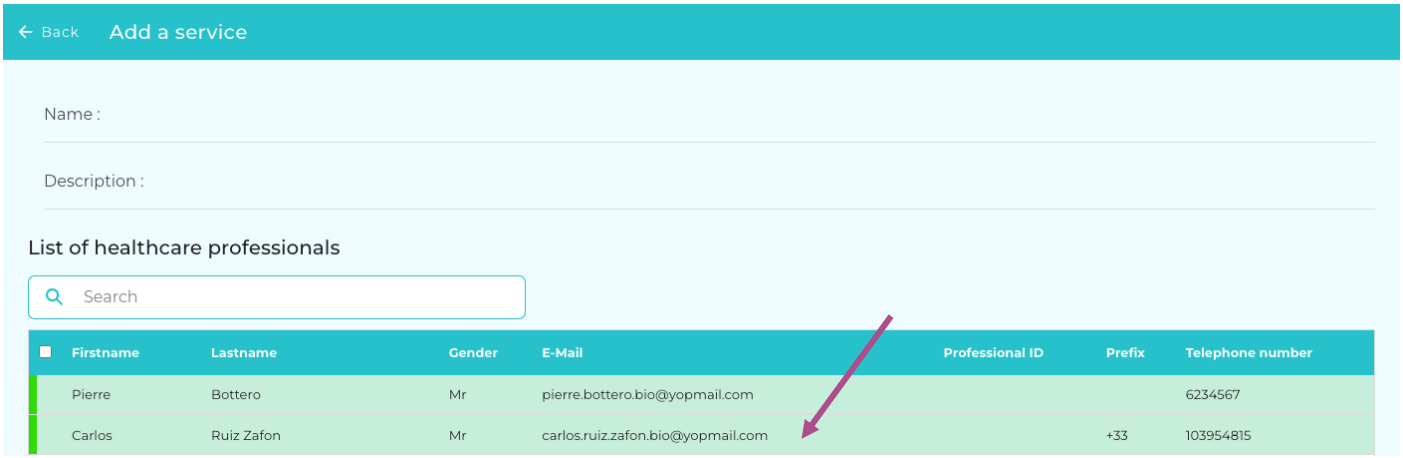
Click on the Add button to create a service.





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.

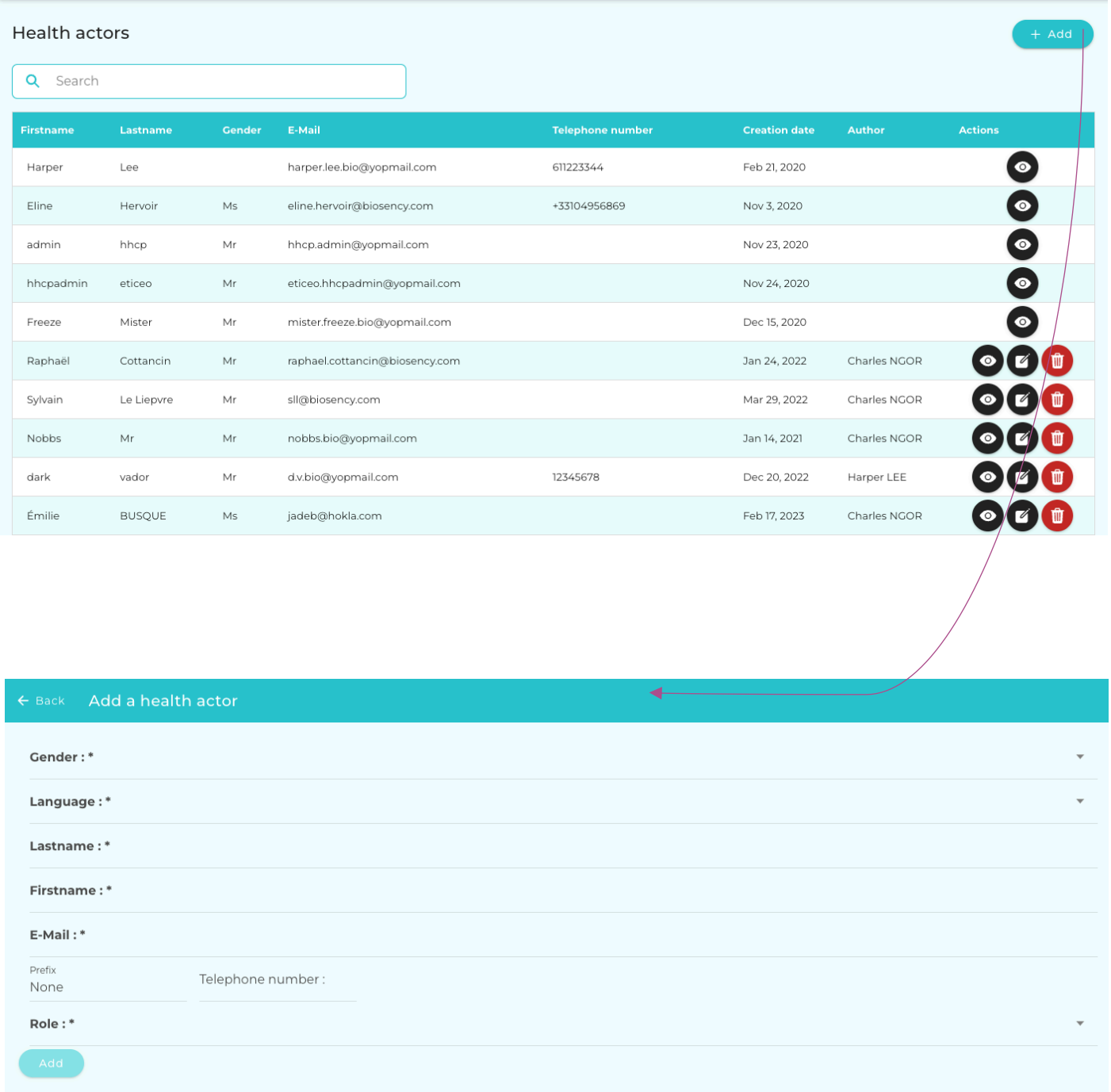


Click on the Add button to confirm the service's creation.

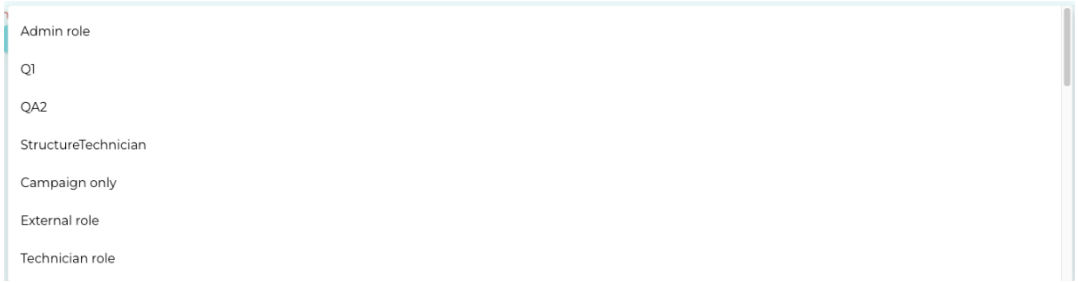
Health actors

You can use this page to manage the account creation of the health actor. Health actors 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 health actor’s account.



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

Click on the button  to add the health actor.

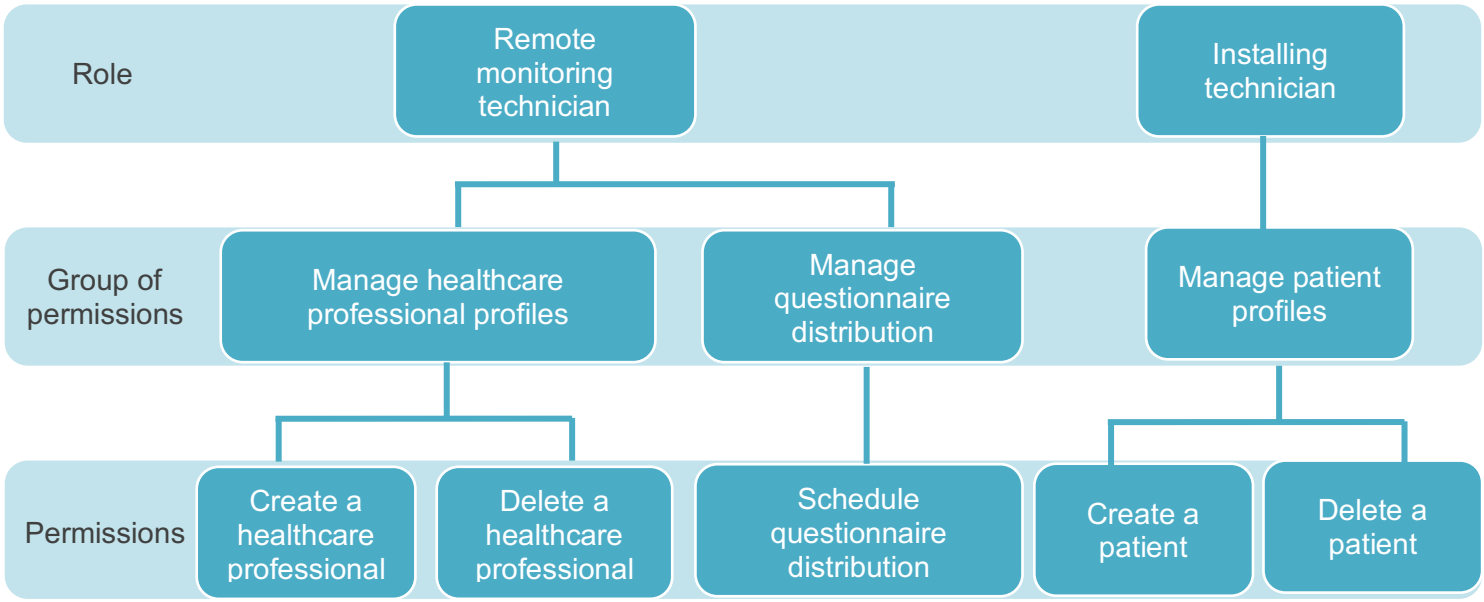
Roles

An organisation is made up of several roles:

- Healthcare administrator
- Health actor
- 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:

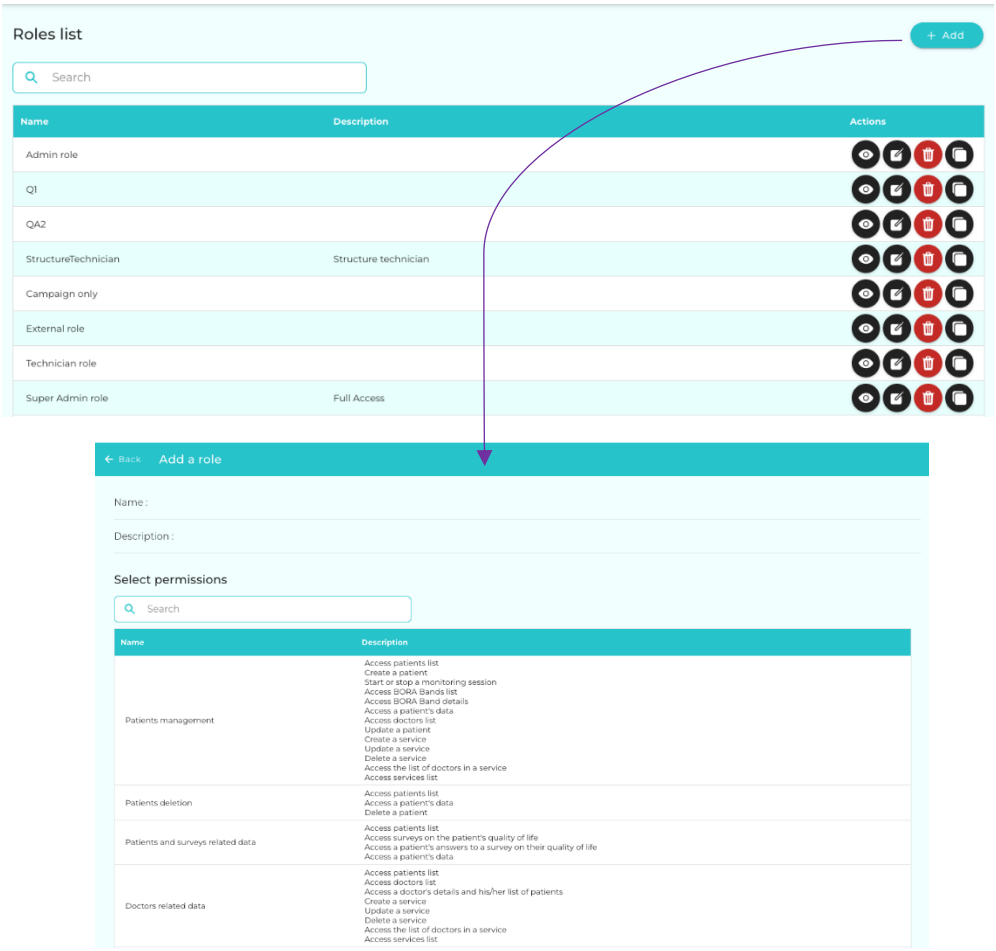


The healthcare administrator is created by a Biosency administrator. They have access to all of the available permissions, in addition to those for managing (creating/deleting) the accounts of healthcare professionals and health actors. This role cannot be changed.

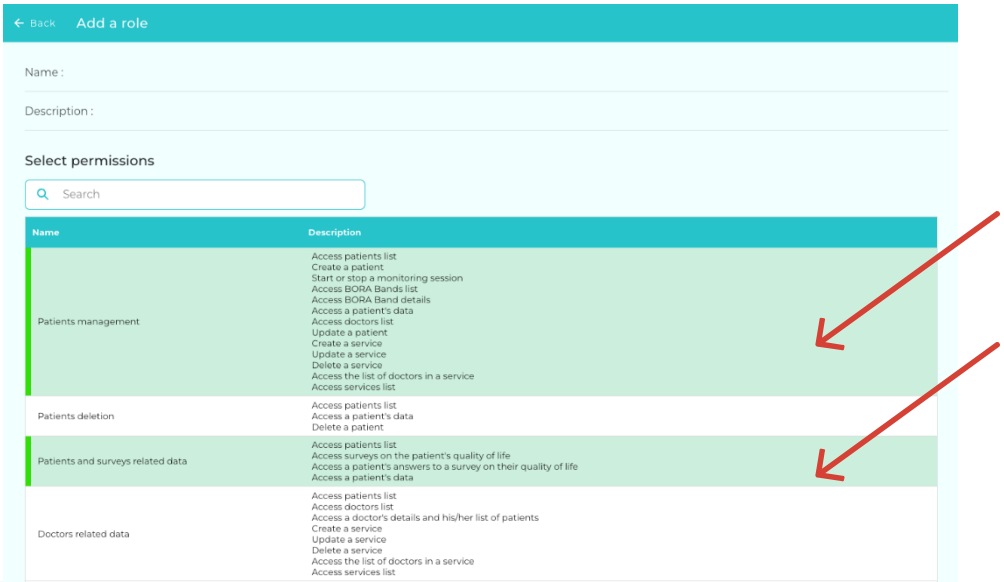
Healthcare professionals only have access to the files of the patients who have been assigned to them. This role cannot be changed.

Health actors have a configurable role. This means that a different role can be assigned to each health actor 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 + 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.

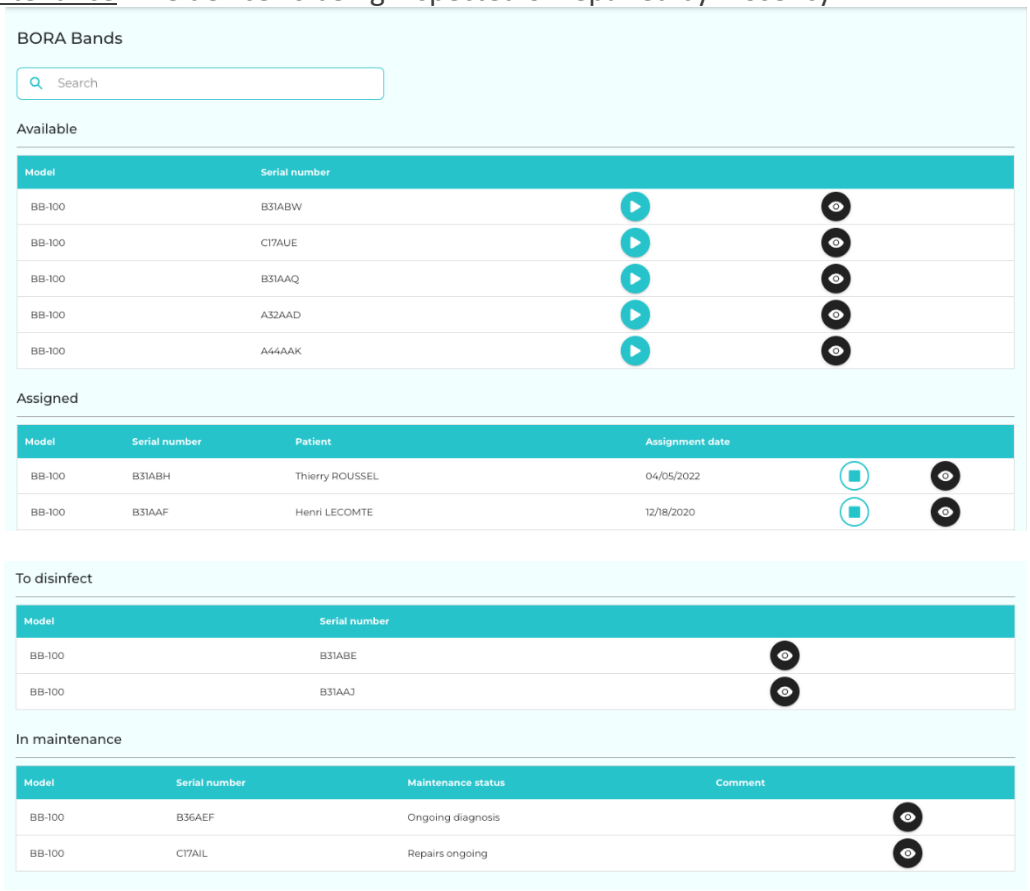
You can from then on use this role for each health actor that is created.

Bora band®

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

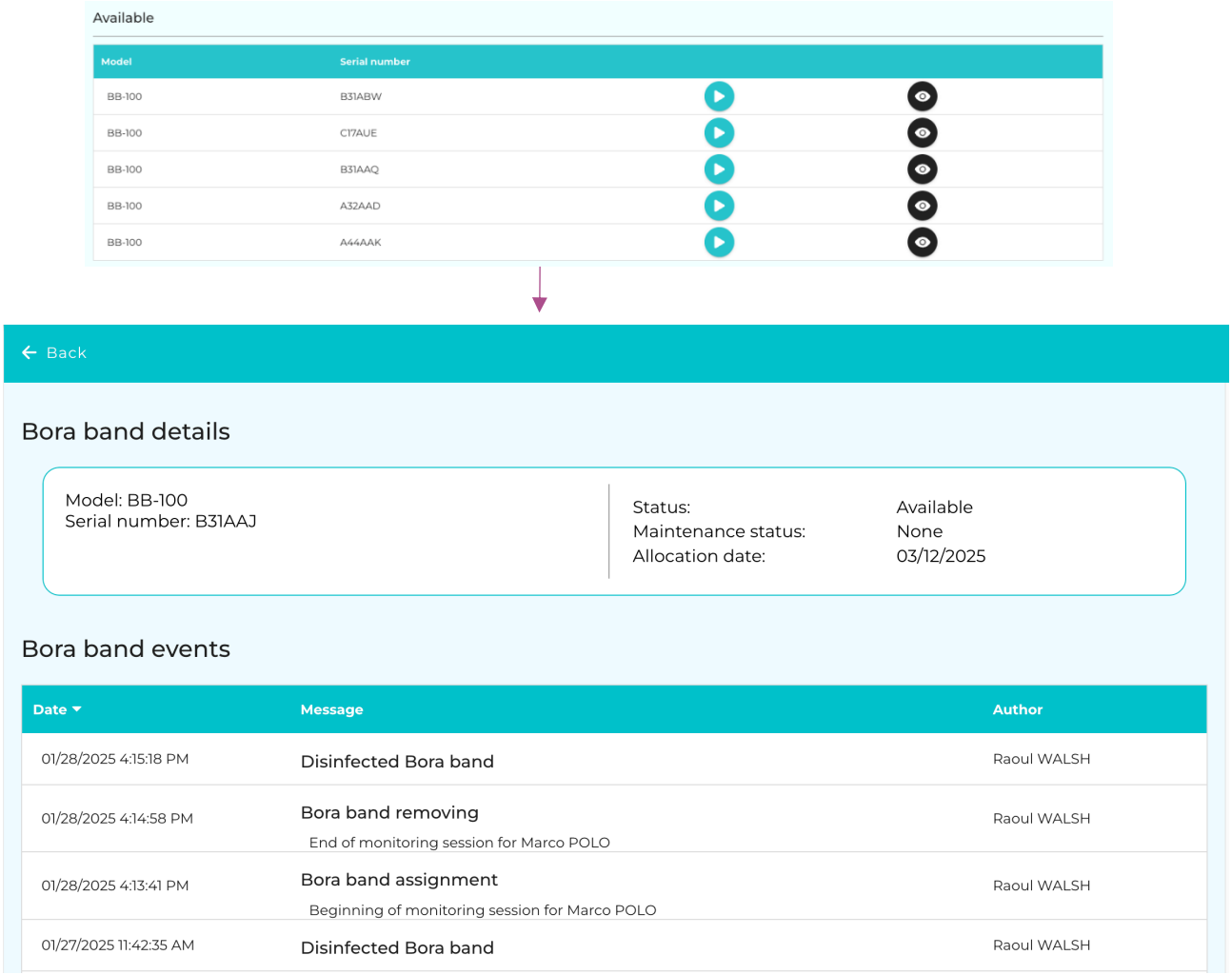
Bora band® devices are given 4 types of status:

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



Click the button to assign the device to a patient.

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

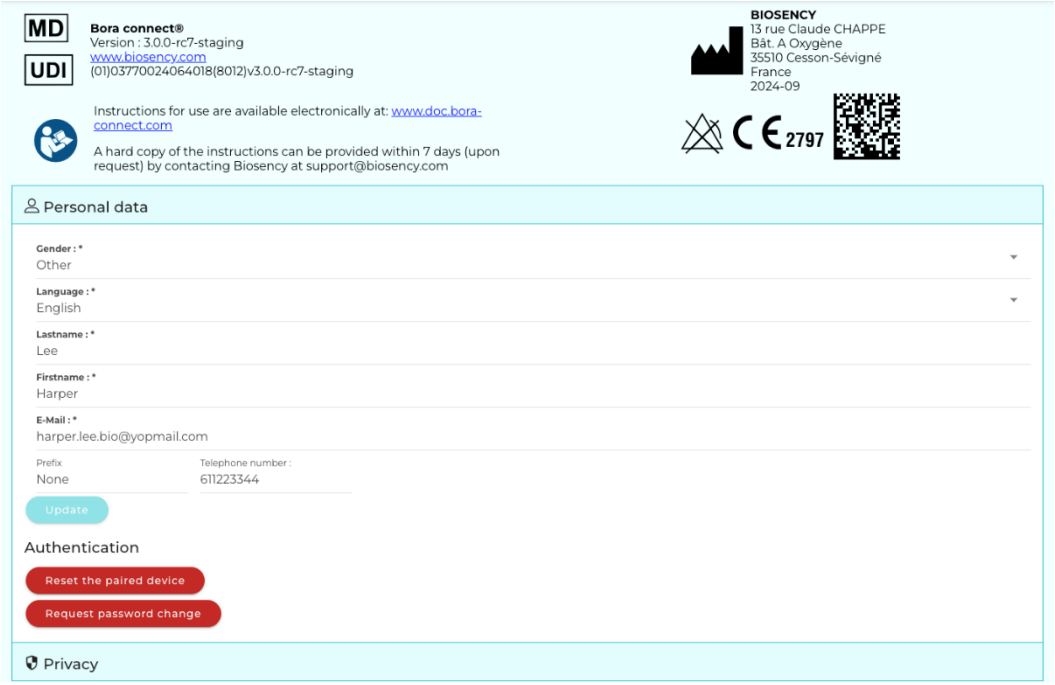


You can consult the details of the Bora band® device: model, serial number, status, and date assigned to your organisation.

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 the Reset the paired device 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

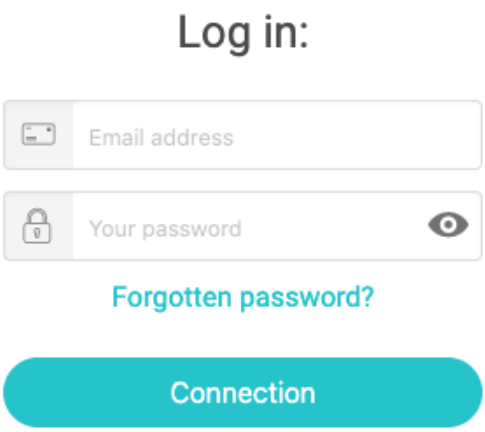
Click on the Request password change button to ask to change your password. You will receive an email that contains a link for resetting your password.

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 or remove as a favorite
	Click to delete
	Click to change
	Click to duplicate
	Click to add a note to the therapeutic follow-up
	Click to unassign the patient from the alert model
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.

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 health actors

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".

The clinical performances of the BVS$^{3®}$ 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

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	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%]).

Copyrights and Trademarks

Bora band®, Bora connect® and BVS3® 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 triggered.
CE 2797	EC marking that indicates its compliance with the current regulations on medical devices. Notified body: BSI NL
MD	Medical device.
UDI	Unique identifier for the device.
	Manufacturer and date of manufacture.
CH REP	Name and address of the registered branch of the Swiss representative.

Manufacturer contact details

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Cesson-Sévigné
France support@biosency.com
https://biosency.com/