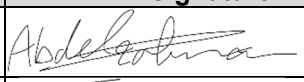
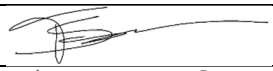
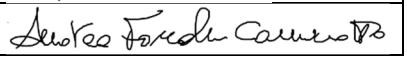
SOFTWARE TEAM A Nihon Kohden Company Version: 04	Technical Documentation **SmartLink** (v3.26) Basic UDI: 805750990SMARTLINK3WM **USER MANUAL**

	Name	Function	Date	Signature
Written by	Abdelrahman Abdellatif	R&D	2025-06-10	
Reviewed by	Thainà Scherer	QARA	2025-06-10	
Approved by	Andrea Forcolin Cominotto	TDIR	2025-06-10	

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1. REGULATORY INFORMATION

SmartLink 3 complies with:

1. the 93/42/CEE Directive.
2. the 60601-1-8:2007 (+ A1:2013 + corrigenda 2010 and 2014) collateral standard, as part of a Distributed Alarm System (DIS - Distributed Information System, DAS – Distributed Alarm System, CDAS – Distributed Alarm System with operator Confirmation).
3. the 80001-2-5:2014 technical report, as part of a Distributed Alarm System (DIS - Distributed Information System, DAS – Distributed Alarm System, CDAS – Distributed Alarm System with operator Confirmation).

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This manual is part of the available SmartLink 3 product documentation.

The product documentation is composed of these documents:

- SmartLink 3 User Manual
- SmartLink 3 Technical Requirements

These documents are available in PDF format and can be downloaded from the Software Team website upon request.

The documents can be saved on offline supports; we recommend using a desktop computer or laptop with Adobe Acrobat Reader DC to view and print them. If another PDF reader is used, please check that all fonts and graphics are correctly displayed.

The documents cannot be disclosed in whole or in part, with any available mean, outside the organization where SmartLink 3 is used and to people different than the ones directly involved in the SmartLink 3 use, configuration, administration and maintenance.

Please note that one or more of the listed manuals might belong to functions not included in your supply, even if the whole manuals set is included in the supplied items.

2. DOCUMENT INTENDED PURPOSE AND READERS

This document gives doctors and nurses instructions for using SmartLink 3 functions.

SmartLink 3 is the Software Team's remote web application for patients monitoring systems.

Other data sources can be connected to SmartLink 3, to manage bedside devices data and alarms:

- Gateways,
- Bed side devices (pumps, ventilators, incubators etc...)

With SmartLink 3 doctors and nurses can review parameters, waveforms and trends, manage alarms notifications and taking-charge, build summary reports and send alarm notifications to SmartPager (the SmartLink component used to send alarm messages to smartphones).

This document contents are for doctors, nurses and health workers that want to use SmartLink 3 functions to improve the patients monitoring adding new useful functions.

2.1. Tasks and Responsibilities

Commissioning and maintenance of SmartLink require activities in charge of different actors.

SmartLink does not require specific product training to be used. The User Manual provides all instructions for correct and safe usage.

The following table lists the tasks and the responsible(s) of each task:

Tasks & Responsibilities			
Task	**Responsible**		
	SWT	**Cust. IT**	**Cust. Aut. User**
CUSTOMER IT INFRASTRUCTURE			
IT infrastructure setup		X	
IT Infrastructure configuration		X	
IT Infrastructure maintenance		X	
SMARTLINK COMMISSIONING AND MAINTENANCE			
SmartLink installation	X		
SmartLink system settings configuration	X		
Explanation to the customer about SmartLink operation	X		

Explanation to the customer about SmartLink settings	X		
Smartlink customer settings decisions			X
SmartLink customer settings implementation	X		
SmartLink settings changes decisions			X
SmartLink settings changes implementation	X		
SmartLink troubleshooting (problem identification)	X	X	X
SmartLink maintenance after troubleshooting (settings or debugging)	X		
SmartLink installation updates	X		

Terms and definitions (Roles & Responsibilities)	
Cust.Aut.User	A User (Nurse, Physician) authorized by the Customer (SmartLink owner)
Cust IT.	A member of the Customer's IT staff designated by the Customer
SWT	A Technician of Software Team

2.2. SAFE AND CORRECT USE CASES

Hereby follow the correct use cases of the SmartLink alarm communicators.

2.2.1. SmartPager

- The Smartphone's screen must be turned on
- The battery must be charged.
- The screensaver must be disabled.
- No lockscreen must be set.
- The sound must not be
  - Disabled
  - Reduced
- The smartphone must not be set to DND (Do not disturbed)
- The Smartphone must not be silenced

2.2.2. Main Alarm Station/Infusion Alarm Station

- The Main Alarm Station (MAS) must not be minimized
- The sound of the MAS must not be disabled
- The sound of the computer must not be disabled

2.2.3. SmartLink adapter list

Refer to 1.09.1b - Tf030 - Supported Connections for the list of devices that can be connected to SmartLink.

2.2.4. SmartLink malfunctioning

In case SmartLink malfunctioning is suspected, refer to the procedures set by your organization to manage this occurrance. Refer also to Support and Contact information to require technical intervention, if the case.

SmartLink forwards Alarm condition within 2 sec from its receival. If you notice a longer forwarding time, refer to Support and Contact information to require technical intervention, if the case.

3. SMARTPAGER APPLICATION

3.1. Connection Status

3.1.1. Connected

When the background of the “Home Screen” is green, the device is connected and able to receive alarms.

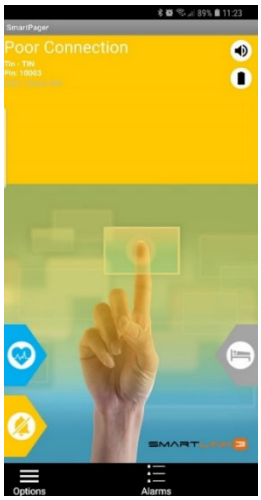
The home screen is composed of:

- “Connected”: indicates that the device is connected and able to receive alarms.
- Hospital name: the name of the hospital and the department to which the pager is associated.
- Sound/Assigned Beds icon: indicates whether the sound of your device is active or set on mute and opens a list of beds assigned to your pager.
- Battery: shows the charge level of the smartphone.
- Options: open the Options Menu.
- Alarms: shows if there are pending alarms and allows to access the alarms list.

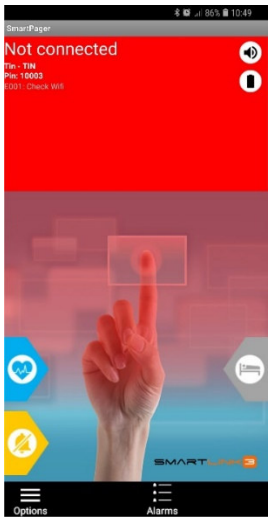


3.1.2. Poor Connection

When the background of the “Home Screen” is yellow, the device’s connection to the server is unstable.



3.1.3. Error – Not Connected



When the background of the “Home Screen” is red, the device is not connected and is not able to receive alarms. In this condition, the device emits a loud and persistent sound and vibrates to alert the user.

NOTE: Administrator privileges are required to access and change the sound options. Three presets are available for the “Not Connected” sound:

Normally the phone will reconnect automatically after a few seconds. If the device does not reconnect automatically, try to:

- Tap “Restart” in the Options Menu
- Check if you are connected to the right Wi-Fi network
- Get closer to the Wi-Fi network (you could be out of range or have a weak signal)

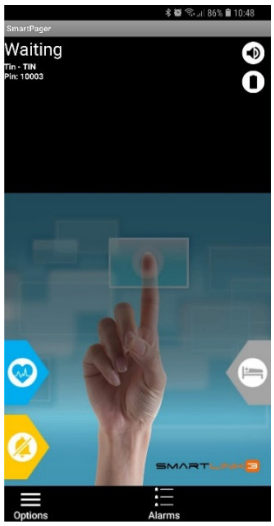
If none of the previous solutions worked, contact your system administrator (see NOTE).

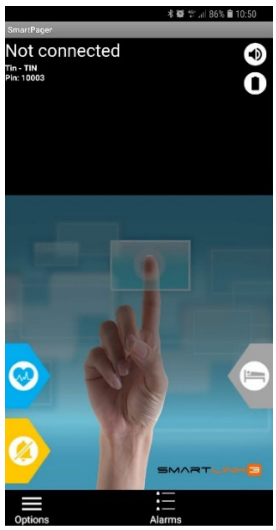
NOTE: In case something if the forwarding chain is not working properly the server may restart; it requires a very short time to be completed and the pager screen could become red. In case of password-protected restart, the password has to be inserted before the system becomes operational again.

3.1.4. Not Connected/Waiting

When the background colour of the Home Screen is black you have 2 conditions:

- “Waiting” → the device is not yet connected and not yet able to receive alarms but is attempting the first connection (normally you see “Waiting” only when you first power on the smartphone).
- “Not Connected” → the SmartPager service is not running and SmartPager will not try to connect to the server until it is manually restarted. The difference between black and red “Not Connected” is that when the background is red SmartPager lost the connection with the SmartLink server, but it is trying to reconnect.

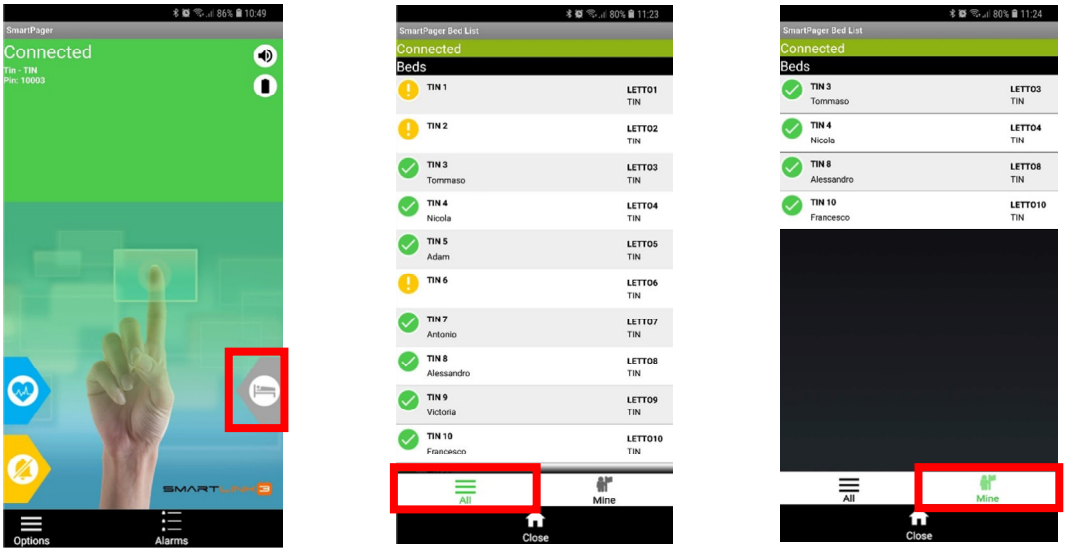




3.2. SmartPager Home Screen Sliders

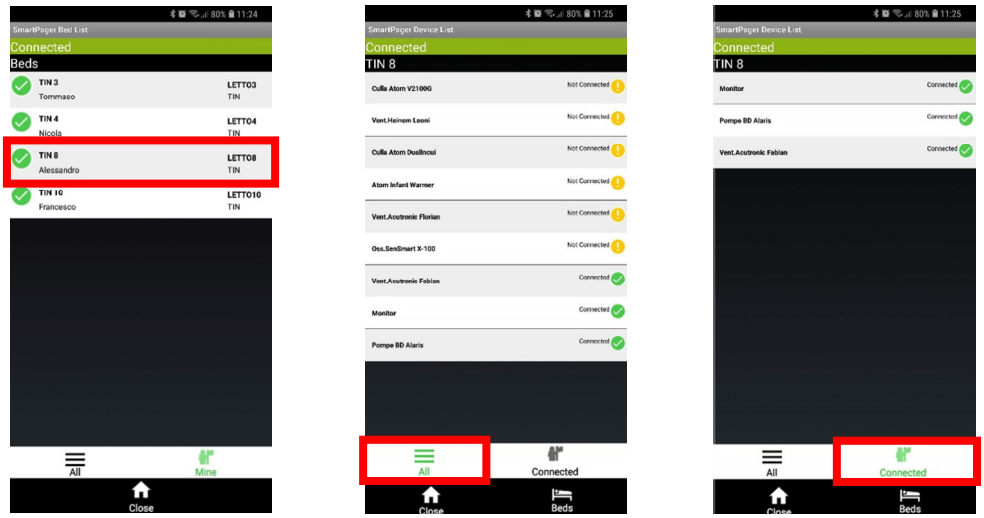
3.2.1. Bed List

The “Bed list” slider shows the list of beds connected to SmartLink.

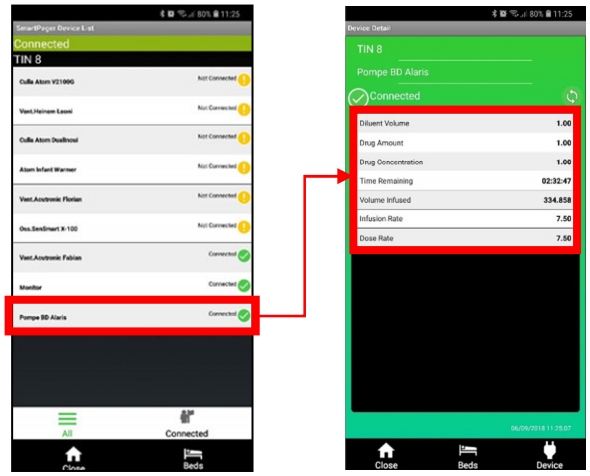


Using the “All/Mine” filter at the bottom you can switch between viewing all the beds of the department or just the beds assigned to you. For each bed, by tapping on the corresponding row you can see the devices in use for that bed.

Using the “All/Connected” filter at the bottom you can switch between viewing all the devices in use for that bed or just the devices that are currently connected to the bed.



Tapping on each device makes it possible to see the parameter it sends in real time.



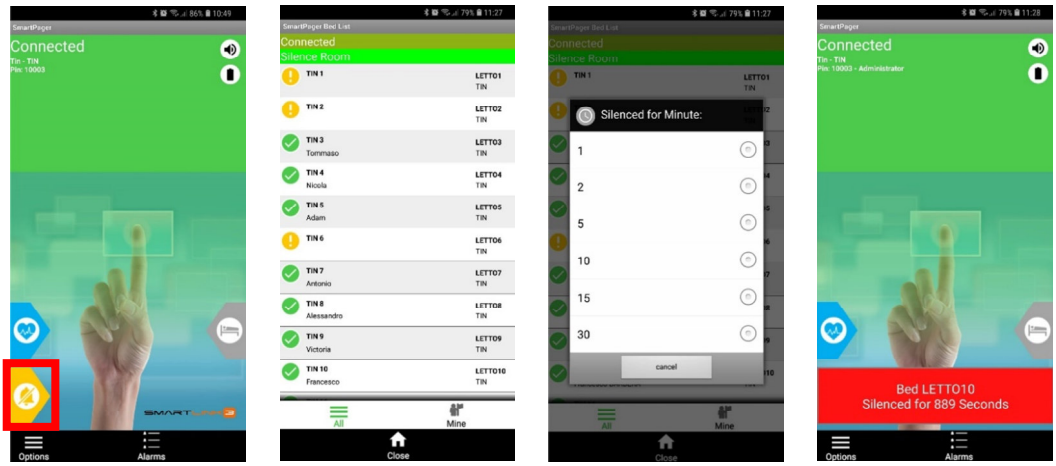
Select the ADT button to insert the patient's information.

3.2.2. Silence Bed

The "Silence Bed" slider allows to select which bed the nurse wants to silence and for how much time. Once the bed is silenced the nurses will not receive the alarms coming from the patient in that bed. All alarms of that bed will be taken in charge automatically by the pager of the nurse that silenced the bed.

This feature is particularly useful when you need to handle the patients (e.g., for cleaning them, adjusting their position, …) as it avoids sending false alarms to all the pagers that have that same bed assigned.

The bed stays silenced for the selected time until the nurse moves the pager or touches the red rectangle.

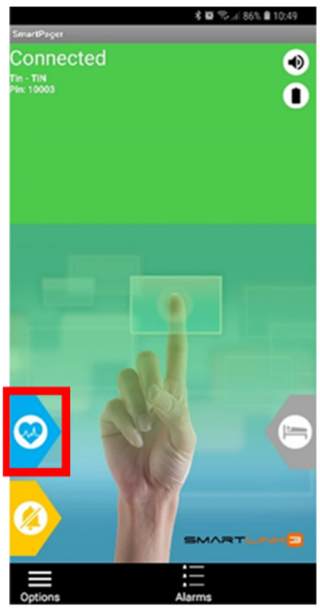


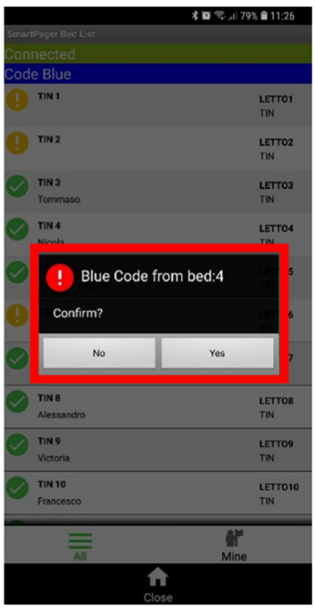
3.2.3. Code Blue

The “Code Blue” slider allows to send a “Code Blue” request for a specific bed in case of an emergency.

Slide the “Code Blue” slider, select the bed where you need help, and then confirm your action.

The Code Blue is managed as an alarm and is sent to all the connected pagers.


Connected
Options
Alarms


Connected
Code Blue
Blue Code from bed:4
Confirm?
No
Yes
All
Mine
Close

3.3. The Alarm Screens

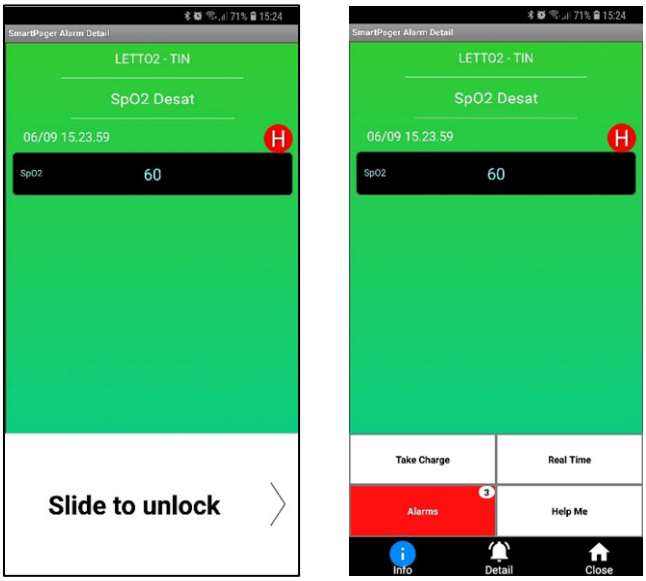
When a new alarm occurs, the device sounds and vibrates and shows the alarm info.

To be able to take in charge the alarm and see more information about it you must slide to unlock the action buttons.

The alarm's information is, from top to bottom: The patient's bed name and department, alarm description, date, and time when the alarm occurred and alarm severity, parameter and parameter value that triggered the alarm.

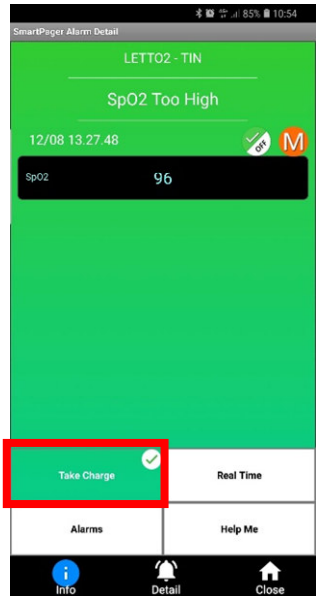
Depending on the type of integration it is also possible to display the alarm trace image.

By unlocking the lower part of the screen, you see four main buttons: Take in Charge, Real Time, Alarms List, Help Me, and three toolbar buttons: Info, and Close.



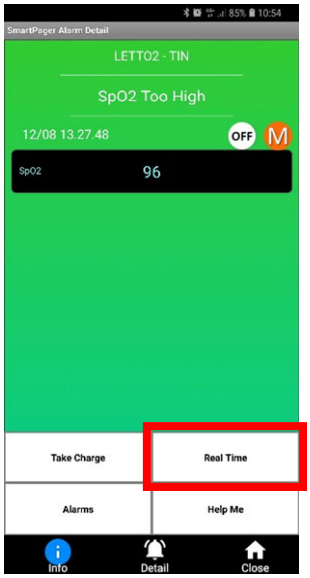
3.3.1. Take Charge

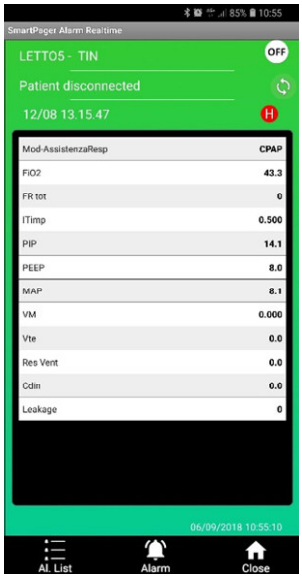
By tapping Take Charge, you take charge of the alarm and automatically notify this action to the other connected pagers. The other users will be able to see when and on which pager the alarm has been taken in charge of.



3.3.2. Real Time

By tapping “Real Time”, you will see, apart from the basic information (patient’s bed name and department, alarm description, date, and time when the alarm occurred and alarm severity), the patient’s measured parameters and their values in real-time, meaning that the values change according to the information sent by the patient monitor you are observing.





The current date and time are shown in the lower-right corner of the screen, indicating that the real-time is functioning.

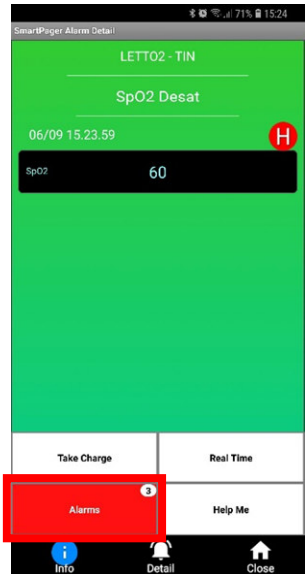
In the “Real Time” screen, you have three toolbar buttons:

- Al. List (Alarms List): goes back to the list of the alarms
- Alarm: goes back to the alarm screen
- Close: rejects the current alarm and goes back to the application Home Screen.

NOTE: if SmartPager has been integrated with the app provided by the monitor manufacturer, Real-Time can show the patient waveforms directly from the manufacturer’s app.

3.3.3. Alarms List

By tapping “Alarms”, you open the alarms list. On the upper-right corner of the button, a dot shows the number of alarms that occurred after the one you are viewing and that are still active or have not been taken in charge yet.

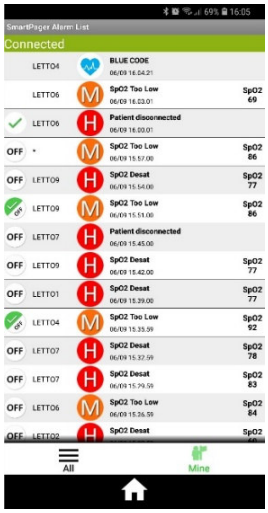


The alarms list contains the list of the last 20 alarms that occurred. In the alarms list screen for every alarm you can see, from left to right:

- The taken in charge status (taken/not taken in charge) indicated by the presence or absence of a green tick, and the “Off” symbol that indicates that the alarm is not active on the monitor
- the patient’s bed name
- the alarm severity
- the alarm description, date and time of when the alarm occurred
- the parameter’s value that triggered the alarm

By tapping on an alarm, you can have more information about it.

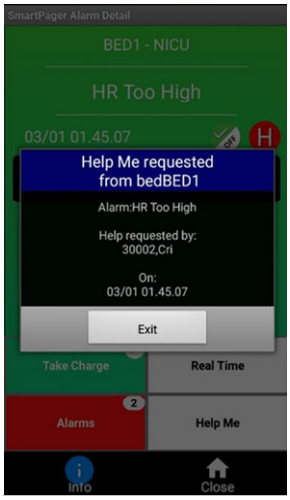
At the bottom of the screen, you can choose between seeing all the alarms that occurred in the department (All) or just the alarms associated with the pager you are holding (Mine).



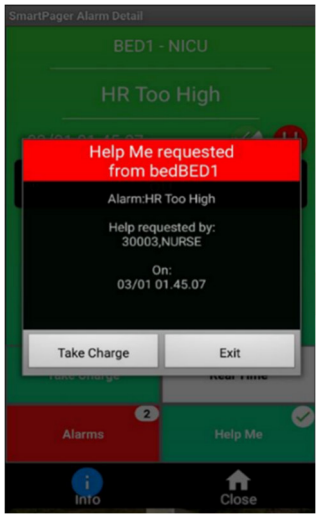
3.3.4. Help Me

By tapping “Help Me”, you send a help request to the other active pagers. The help request notification shows the alarm description and indicates which pager sent the request and when. When receiving a help message notification, the pager sounds and vibrates.

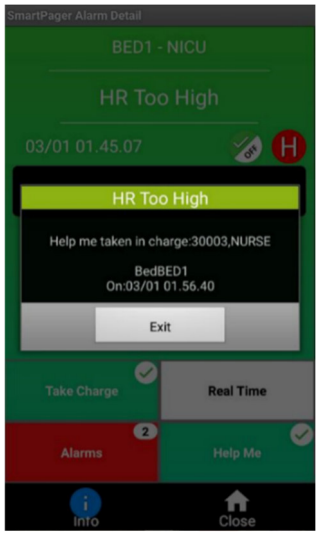




When the help request is sent, this screen appears on the pagers that receive the help request:



Finally, when the help request is taken in charge by someone, this message appears on the pager that sent the help request:



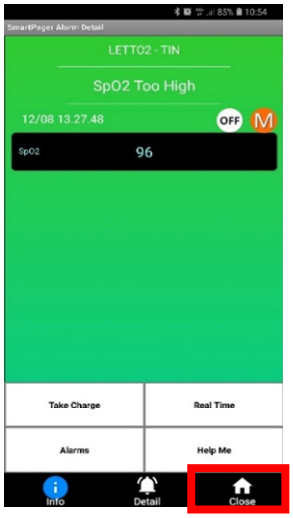
3.3.5. Info

By tapping “Info”, you see if the alarm has been already taken in charge and by whom or if the alarm is still pending.



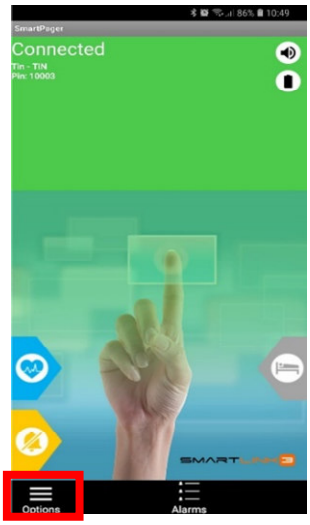
3.3.6. Close

By tapping “Close” you reject the current alarm and go back to the application “Home Screen”.

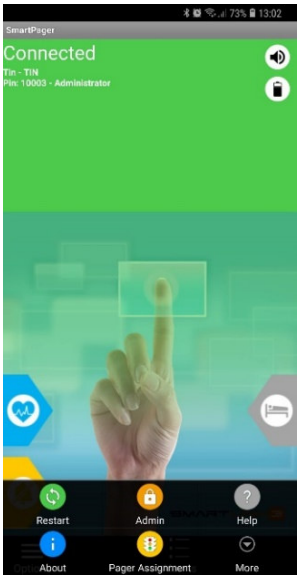


3.4. Options Menu

The Options menu is accessible by tapping “Options” in the lower-left corner of the screen when you are on the application’s home screen.



In the Options Menu six options are available:



3.4.1. Restart

Restarts the application service, meaning that SmartPager will automatically disconnect and reconnect to the SmartLink server. If you notice that the screen frequently changes to Poor Connection (yellow background) you may want to try restarting the service.

3.4.2. Help

Opens the built-in help guide.

3.4.3. About

Shows the product's label.

3.4.4. Pager Assignment

Contains information regarding which beds are assigned to whom.

NOTE: More info on this can be found in chapter *3.5 Pager Assignment on Pager*.

3.4.5. More

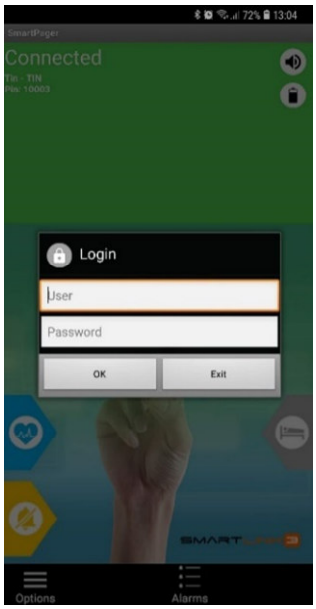
Change department → Allows changing the department from which the pager receives the alarms.

3.5. Pager assignment on the pager

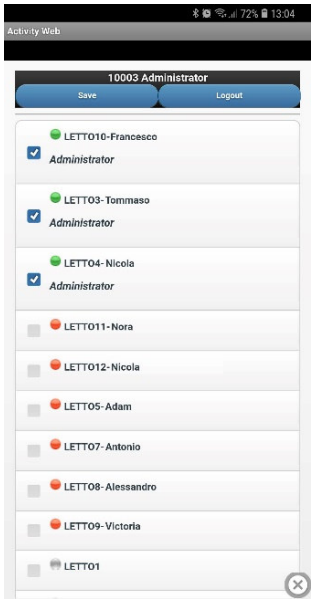
Pager Assignment on Pager allows assigning beds to pagers directly from SmartPager.

To access the Pager Assignment on Pager, open the “Options” menu from the SmartPager home screen, tap “Pager Assignment” and insert your username and password.





The screen that follows shows the list of the beds that you can associate with the pager. Select the beds that you want to associate with the pager and then tap Save.



Through this screen you can quickly identify the beds that are:

- Assigned → Green
- Not assigned → Red
- Assigned to other users → Blue
- Inactive → Grey

From this screen, the nurse selects the beds under their supervision.

The buttons at the bottom allow to:

- Save: confirm the chosen beds assignment and link the pager to the nurse.
- Logout: disassociate the beds assigned to the nurse and disconnect the user.
- My Account: change the user description and password.

NOTE: if you do not have the access credentials to the Pager Assignment, you can still see the general assignment of beds and pagers by leaving the User and Password fields blank and tapping OK.

4. PAGER ASSIGNMENT VIA WEB

The Pager Assignment via web allows authorized users to associate beds with pagers for a selected shift.

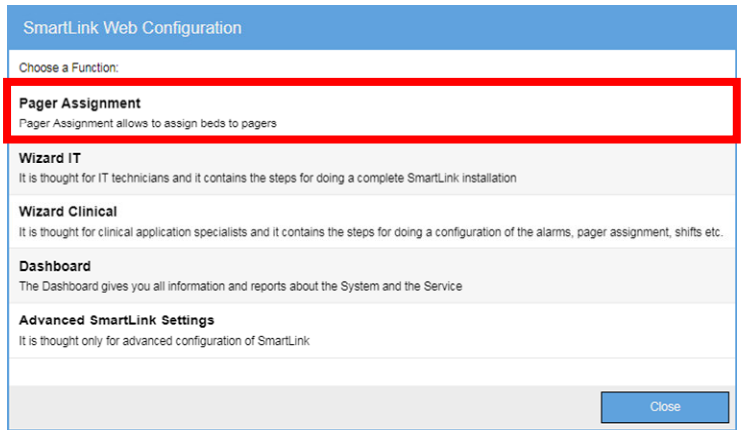
To manage the assignment function open the provided browser and go to:

http://*[ServerIP]**:20010/smartlinkwebapp

* change *[ServerIP]* with the IP address of the SmartLink server (e.g. http://*192.168.1.1*:20010/smartlinkwebapp).

Once on the Login page, insert your Username and Password and select “Pager Assignment”.



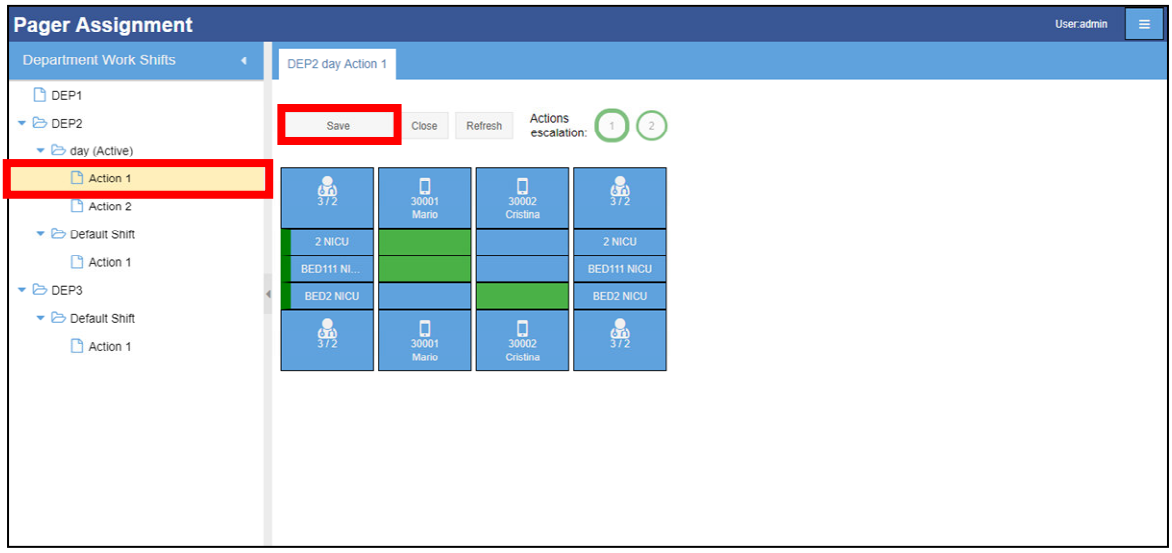


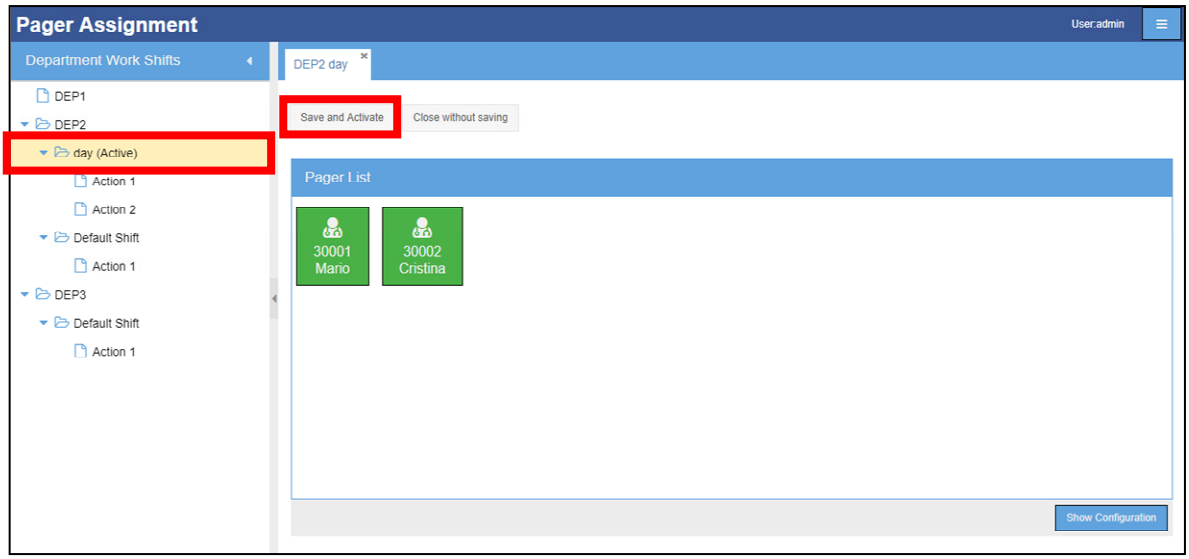
The main screen of the Pager Assignment is divided into two sections:

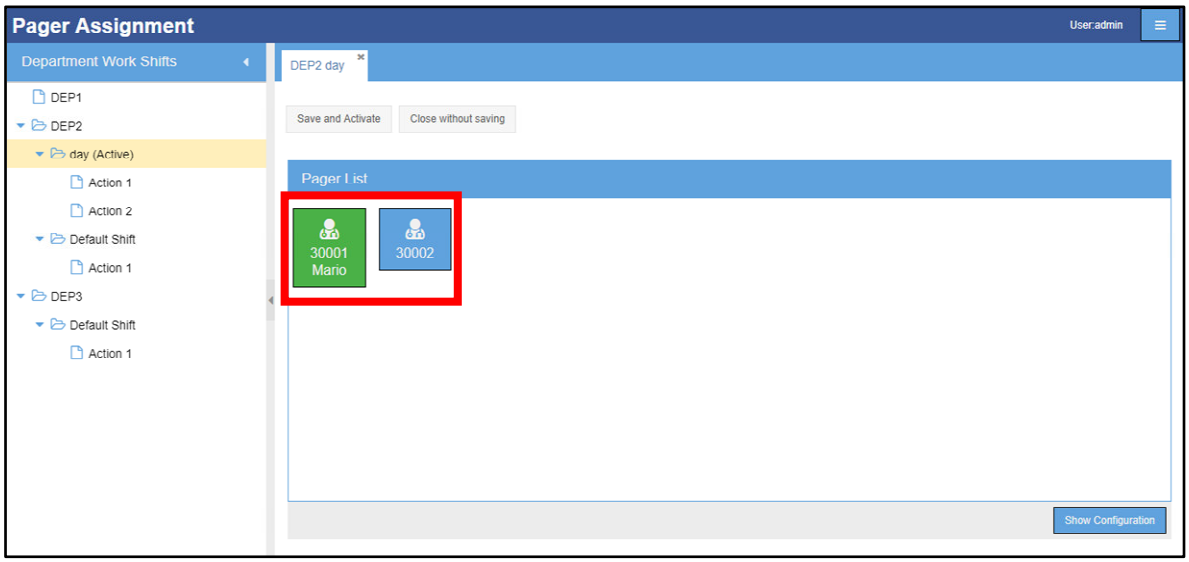
- On the left you can select the department and the action.
- On the right you can select the pagers to be assigned to the department.

For associating the pager to the beds and then to the user:

1) Select the action: select the pager or DECT that will be associated with the beds and will receive the alarms from that group of beds. The associated pagers are highlighted in green. Then click Save.

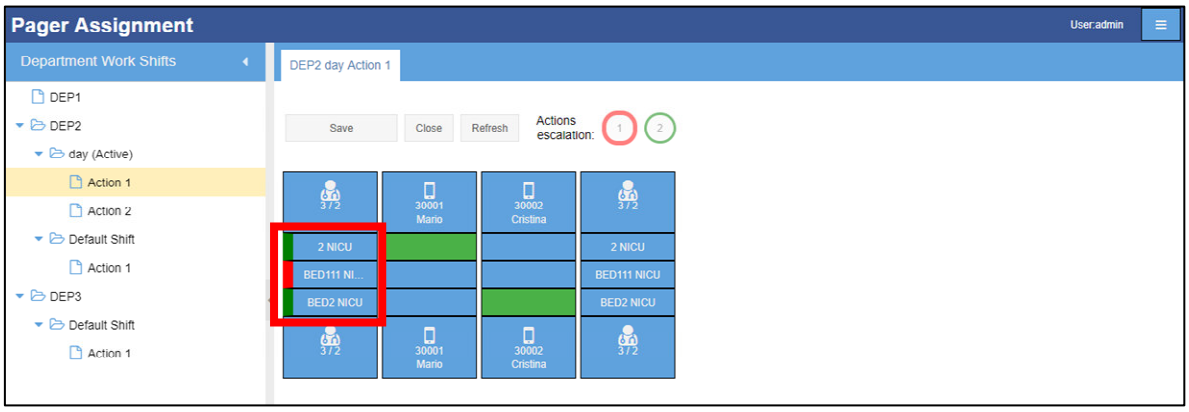






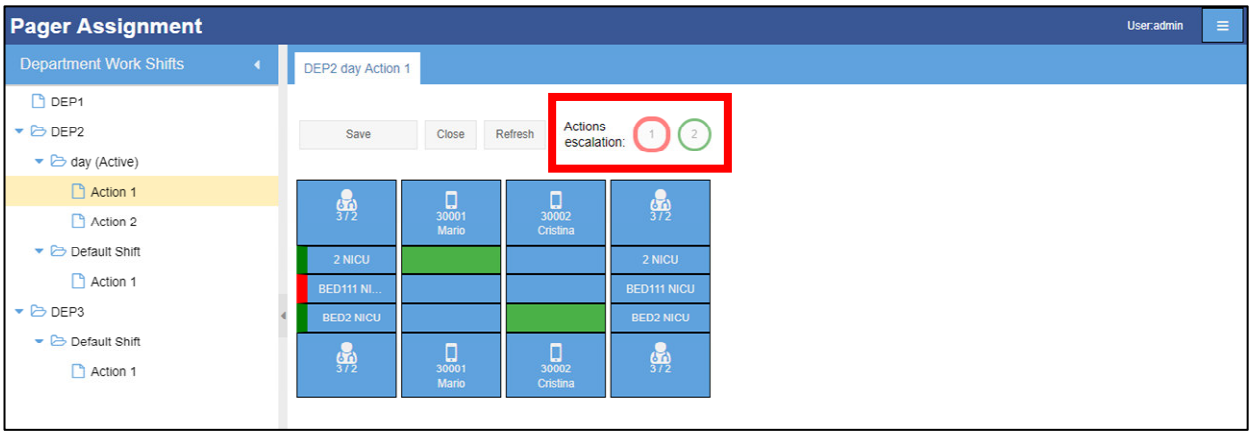
4.1. How to Check if the Assignment is Correct

4.1.1. Check the Beds



If the bed is:

- Red: no pagers are associated with the bed (All pagers will receive alarms from this bed).
- Green: at least one pager is associated with the bed (correct configuration).



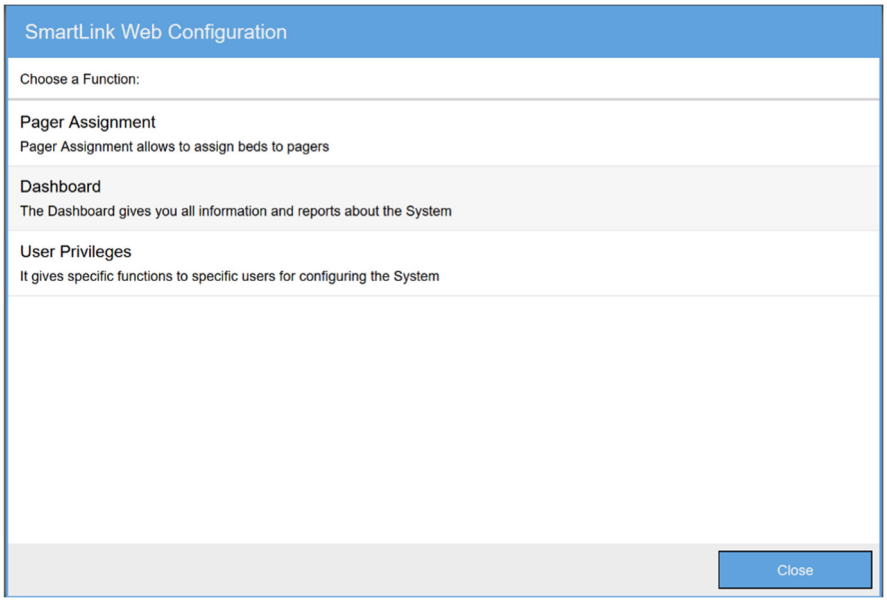
4.1.2. Check the Actions

If the action is:

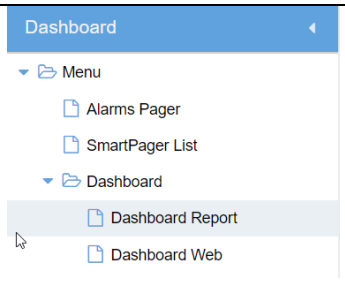
- Red: for at least one bed there is no association. The action must be checked.
- Green: the action configuration is correct.

5. DASHBOARD

Only Physicians and Head nurses can access the Dashboard, to access it they need to login using their user credentials and select “Dashboard”.

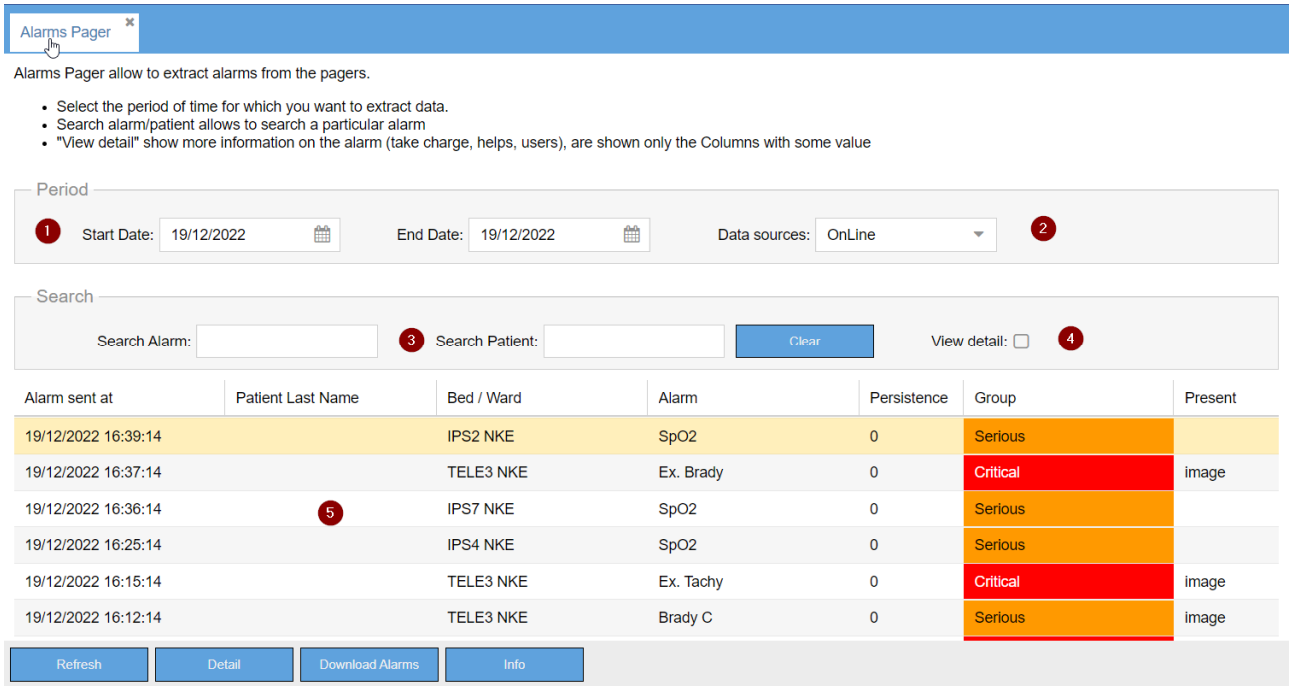


The main items available are:



- Alarms pager: shows the list of alarms received.
- SmartPager List: shows the list of connected/offline pagers to SmartLink
- Dashboard report: provides installation statistics in excel format.
- Display the dashboard on a web page.

5.1. Alarms Pager:



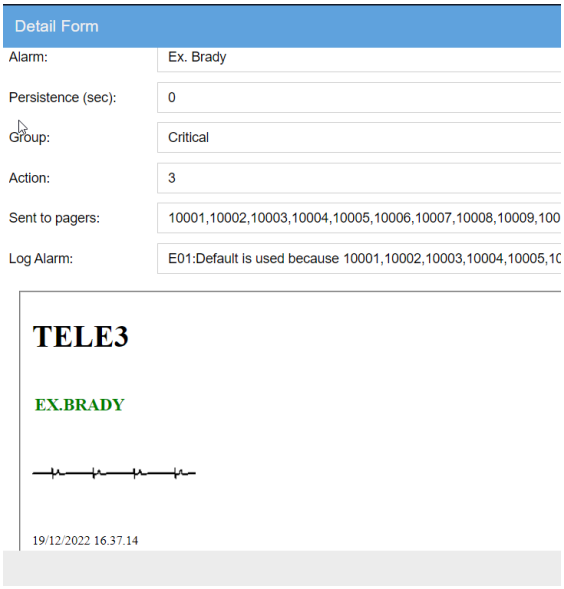
Here are the main functions:

- Extraction of alarms by period
- Possibility of extracting for Online alarms (by default the last 3 days) or from the log
- Search filters for Alarm and Patient
- Possibility to see more information such as: taking charge, help me, etc

- List of alarms with:
  - Alarm date.
  - Patient information.
  - Department and Bed.
  - Alarm description.
  - Persistence.
  - Group (Critical, Serious, etc), displayed in different colours.
  - Image: in case an image is received from the monitor.

5.1.1. Detail

By clicking on the "Detail" button it is possible to see the details of the alarm.



5.1.2. Download Alarms

By clicking on the "Download" button it is possible to see the list of the extracted alarms:

NKE

DashBoard Service: Alarms Details

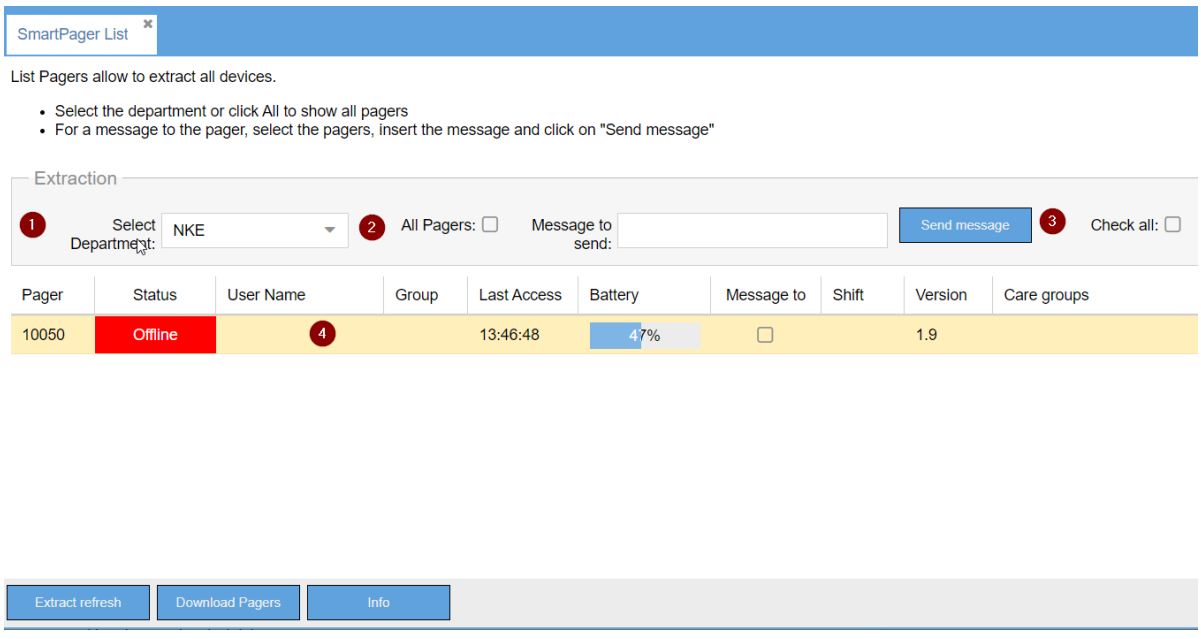
ANALISI STATISTICA dic, 19 2022 dal 2022.12.19-00.00 al 2022.12.19-16.51

Questo report riporta i dettagli della lista allarmi ricevuta in SmartLink

ALLARMI RICEVUTI

Allarme inviato	Letto	Allarme	Ricevuto sul pager	Persistenza	P
19/12 00:04:14	IPS3 NKE	Asystole	19/12 00:04:14	0	
19/12 00:07:14	IPS4 NKE	Apnea	19/12 00:07:14	0	
19/12 00:12:14	TELE3 NKE	Brady C	19/12 00:12:14	0	
19/12 00:15:14	TELE3 NKE	Ex. Tachy	19/12 00:15:14	0	
19/12 00:25:14	IPS4 NKE	SpO2	19/12 00:25:14	0	
19/12 00:36:14	IPS7 NKE	SpO2	19/12 00:36:14	0	
19/12 00:37:14	TELE3 NKE	Ex. Brady	19/12 00:37:14	0	

5.2. SmartPager List:



Here are the main functions:

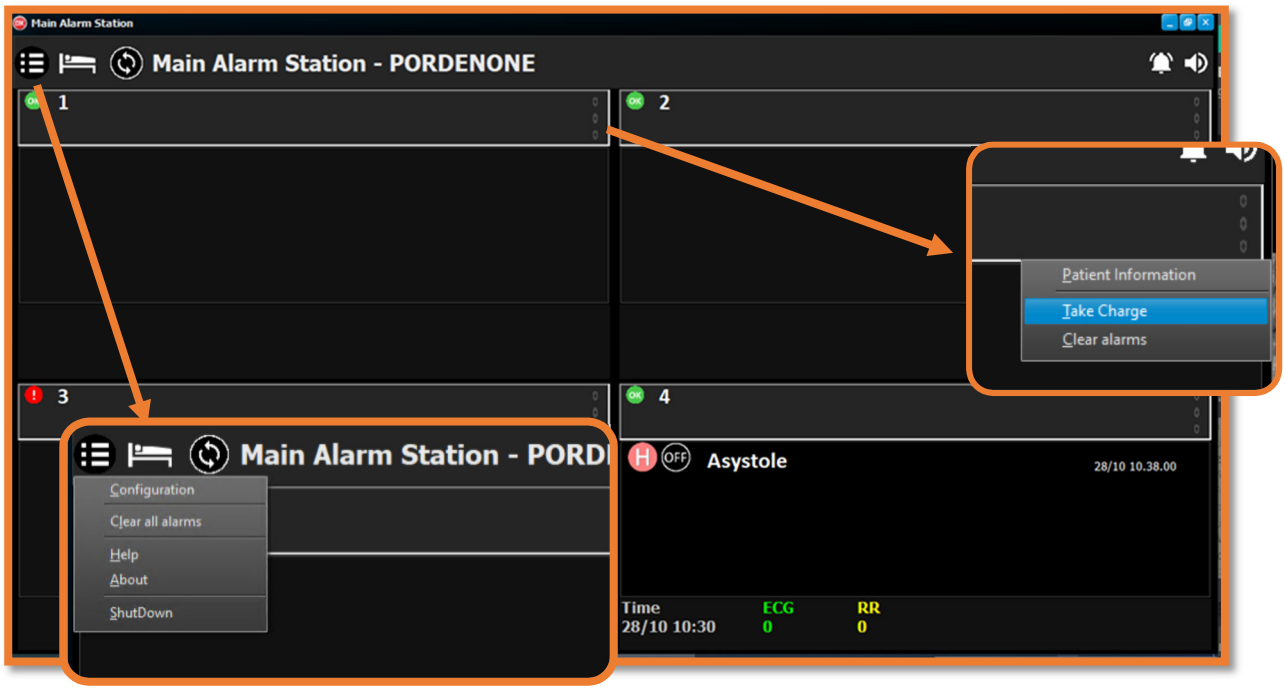
- Visualization of the pagers of the selected Department
- Possibility to see the pagers of all departments.
- Broadcast message: A broadcast message can be sent to one or more pagers (clicking "Check all" sends it to all connected pagers)
- List of pagers connected with the following information:
    - Pin
    - Status: online/offline
    - If the login is active, username.
    - Pager last access.
    - Battery Status: Up-to-date information when connected.
    - Ability to select the pager to send a broadcast message.
    - Version of the SmartPager application installed on the phone (it is important to keep the phones updated to the latest available version)
    - Beds to which it is assigned if pager assignment is active.

5.3. Dashboard Report:

The Report Dashboard provides a variety of reports that are useful for different types of user categories:

- Clinical Staff: is dedicated to the Physician and to those who want to analyse in detail how the system is managed: alarm statistics, classification if physiological or technical alarms, analysis by bed and usage statistics (taking charge, slides, etc.).
- Biomedical Staff: dedicated for the Biomedical team and provides information on infrastructure alarms, use of pagers, battery usage, disconnections, technical alarms.
- IT department: dedicated to the IT team and provides information on the system hardware (server, used space, operating system), alarms on the infrastructure, use of pagers, battery usage, disconnections.
- Alarms details: It provides a detailed analysis of the alarms such as persistence, taking charge, help me, logs. It is also possible to learn about the use of the Code Blue and the Silence bed.
- Pager assignment: Provides detail on pager assignment usage organized by pager, bed, and user.
- Configuration: Provides details on the organization and structure of SmartLink in particular in each tab it is possible to see
    - General: with information on the license and main setting.
    - Alarms: list of alarms divided by category
    - Connectors: list of connected pagers with details
    - Users: list of users
    - Pager assignment: pager assignment configuration detail

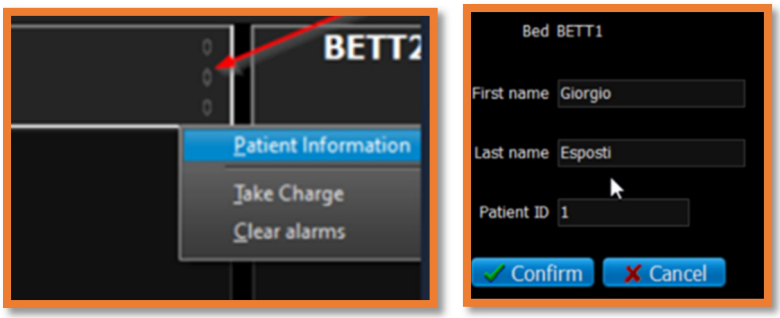
6. MAIN ALARM STATION



- By clicking on:  you can clear the alarms by clicking on the “Clear all alarms” button
- By clicking on  you can deactivate the audio of the alarms received via SmartLink.
- To take in charge of all alarms from a specific bed, click on the three vertical dots next to the bed name and then click “Take in charge”.
- By clicking on  you can see detailed information about each bed.

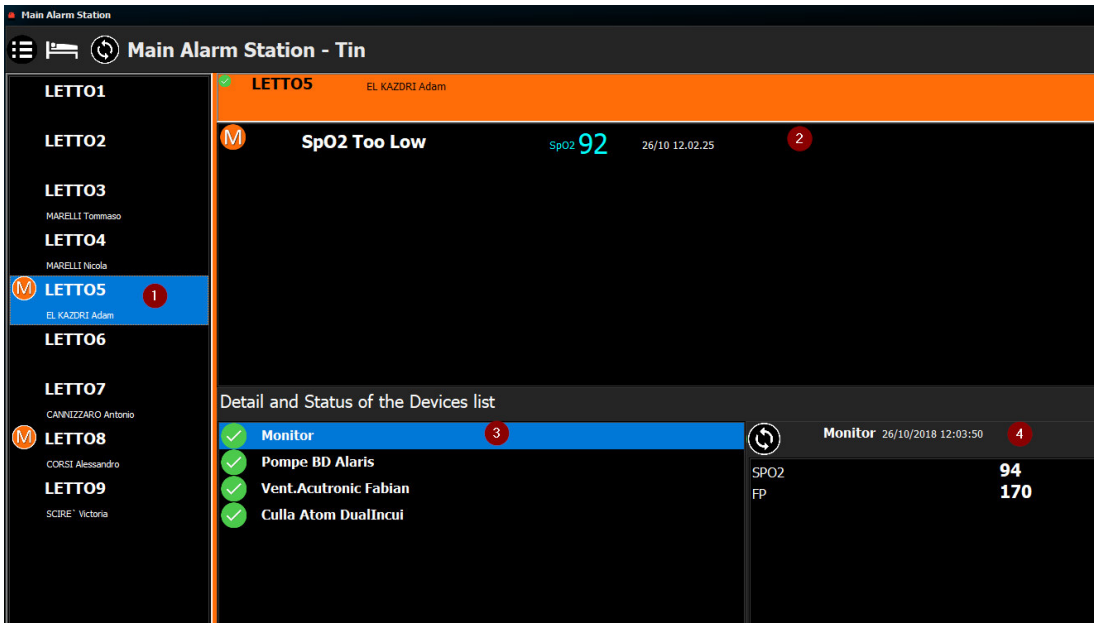
6.1. Patient Information

By clicking on patient information, you can see and set the info of the patient.



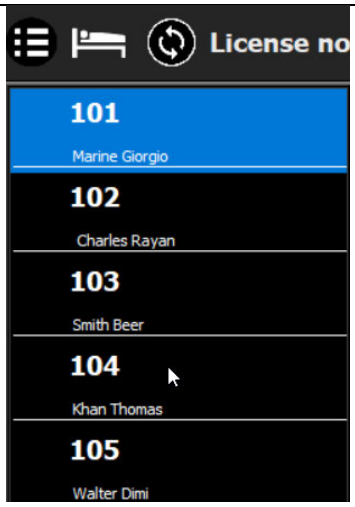
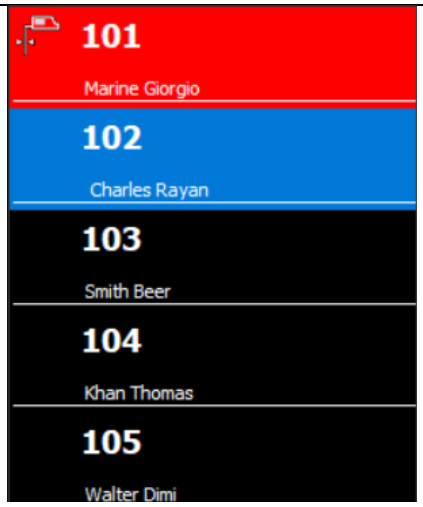
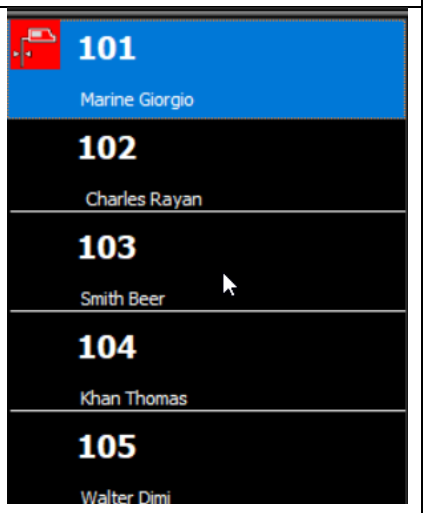
6.2. Beds

6.2.1. Bed list and Bed Details



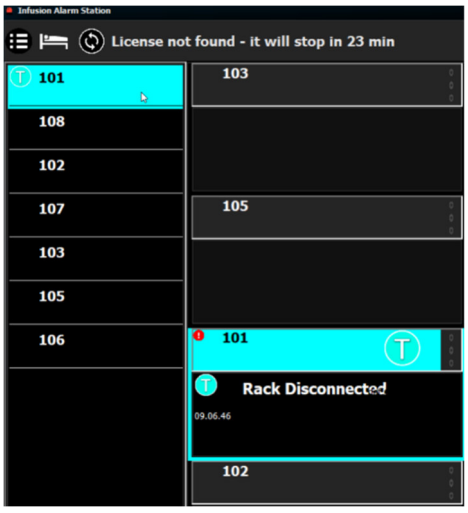
1) Real time bed status.
2) By clicking on the bed, you can see the beds details.
3) Status of connected devices.
4) Connected device parameters.

In addition to the patient's name (optional), the beds are divided by a separator and when an alarm comes, the whole bed is highlighted with colour.

Beds without alarm	We are positioned on bed 102 and an alarm comes in bed 101	There comes an alarm in the bed where we are positioned
		

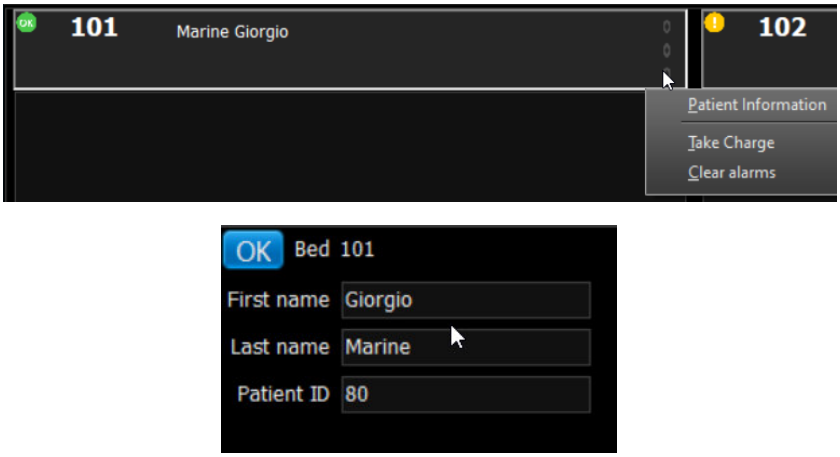
6.3. Alarm

When an alarm arrives, it is automatically placed at the top of the bed list.



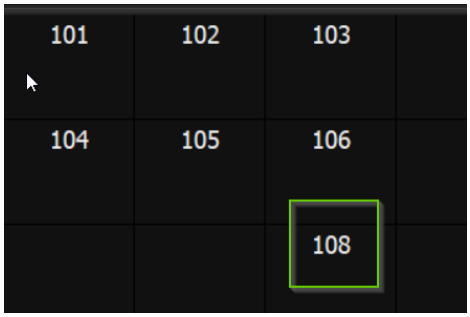
6.4. Patient Information

It is possible to enter the patient's information by clicking on the image on the right: "Patient Information".



6.4.1. Positioning of the Beds at the Customer's Choice

From the configuration is possible to decide the position of the beds and view it in the MAS





6.5. License

6.5.1. Importation

The license can be imported directly from the MAS from the top left menu.

6.5.2. License SmartLink for MAS

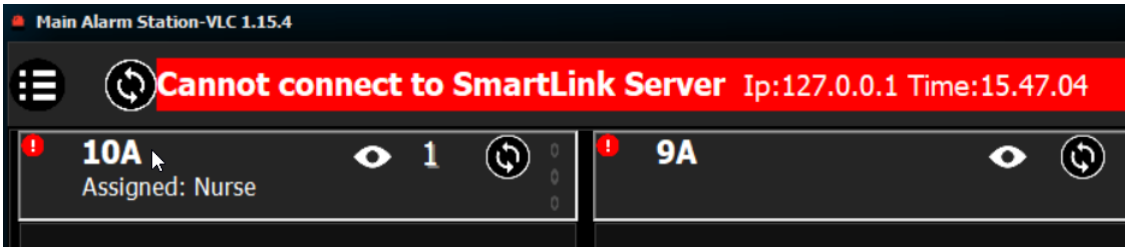
“License SmartLink” give you the possibility to import the License.

6.6. Automatic restart

The MAS always check for a connection to the SmartLink server, if the connection cut out or there are some errors a message “**cannot connect to SmartLink, try again**” will be shown.

6.7. Connection Status

If the MAS loses connection to the SmartLink Server, a red banner is displayed at the top, indicating that the connection to the SmartLink server cannot be established.



Once the connection to the server is reestablished the Main Alarm Station restarts and the message disappears.

6.8. Open External Applications

It is possible to open external applications directly from the Main Alarm Station.

To open the external application, choose the bed and select the three dots on the upper right corner and choose “Open [External Application]”



6.9. Infusion Pump List

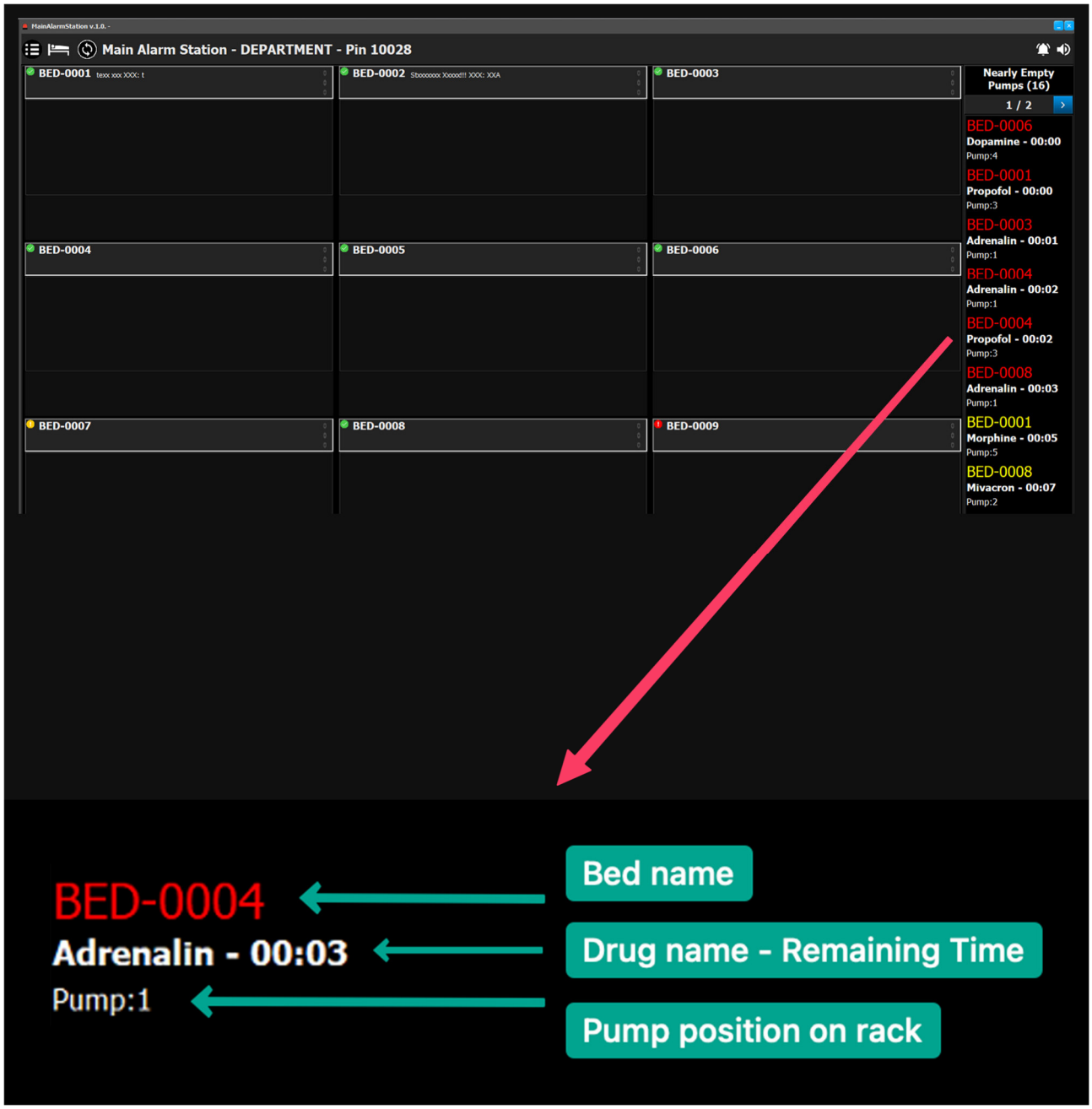
The Infusion Pump List shall be visible on the right side of the MainAlarmStation screen. It shall only contain pumps that are below the 30-minute mark, and they shall be grouped in 3 separate groups:

1. RED
2. YELLOW
3. WHITE

The RED group shall contain pumps that have a remaining infusion time of 5 minutes and below.

The YELLOW group shall contain pumps that have a remaining infusion time that range from 15 to 5 minutes.

The WHITE group shall contain pumps that have a remaining infusion time that ranges from 30 to 15 minutes.

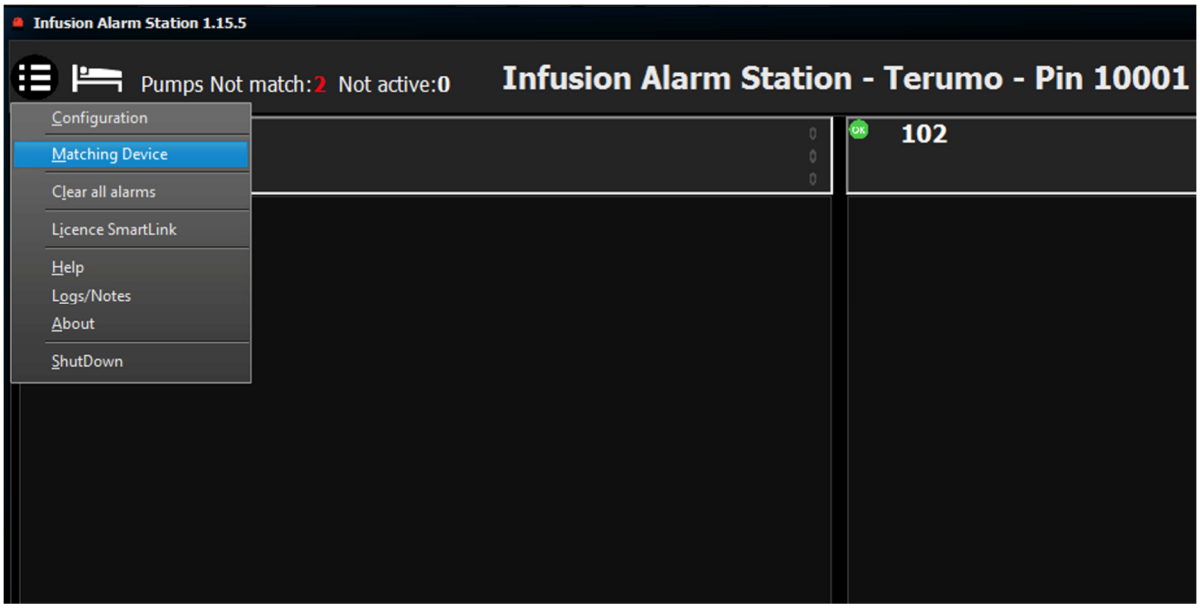


The information regarding the pumps shall refresh automatically every 20 seconds by default.

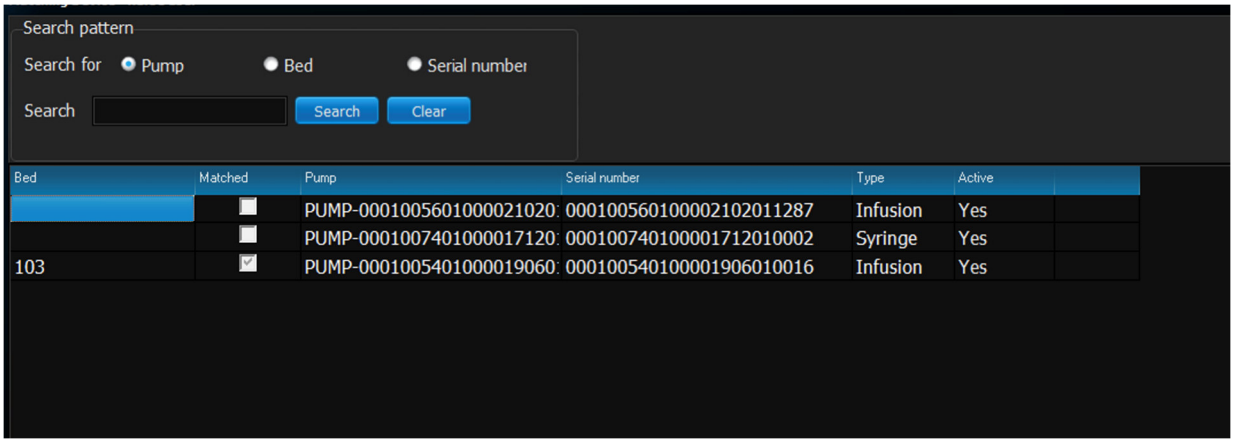
7. Infusion Alarm Station

7.1. Matching Wi-Fi Pumps

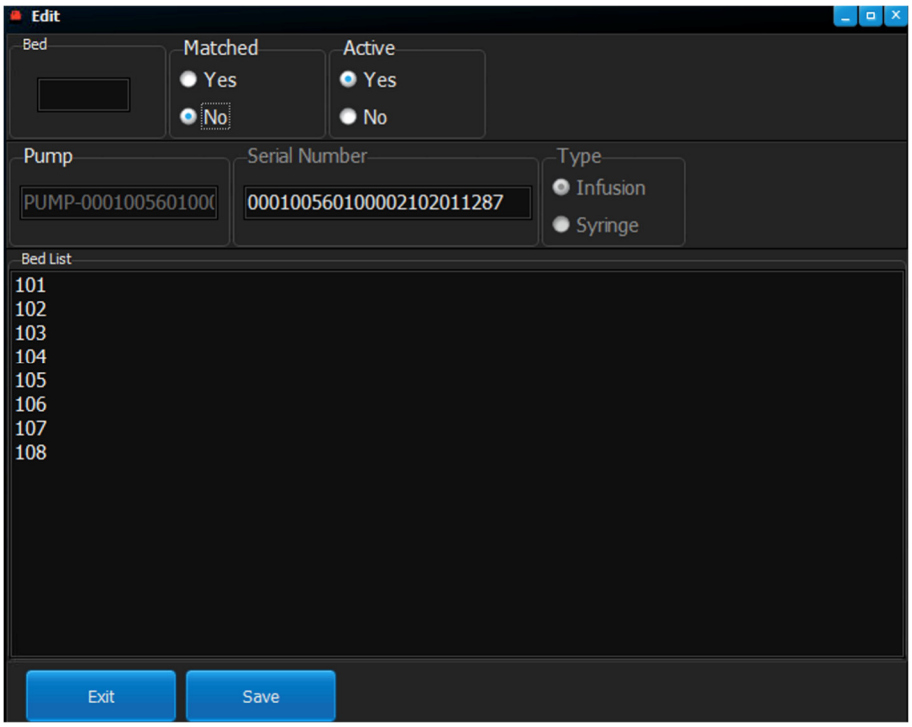
To match WI-FI pumps to the beds, you need to use the “Matching Device” option, accessible from the dropdown menu in the upper left corner of the Infusion Alarm Station (IAS).



Select the pump that you want to match to a bed, by double clicking on it.



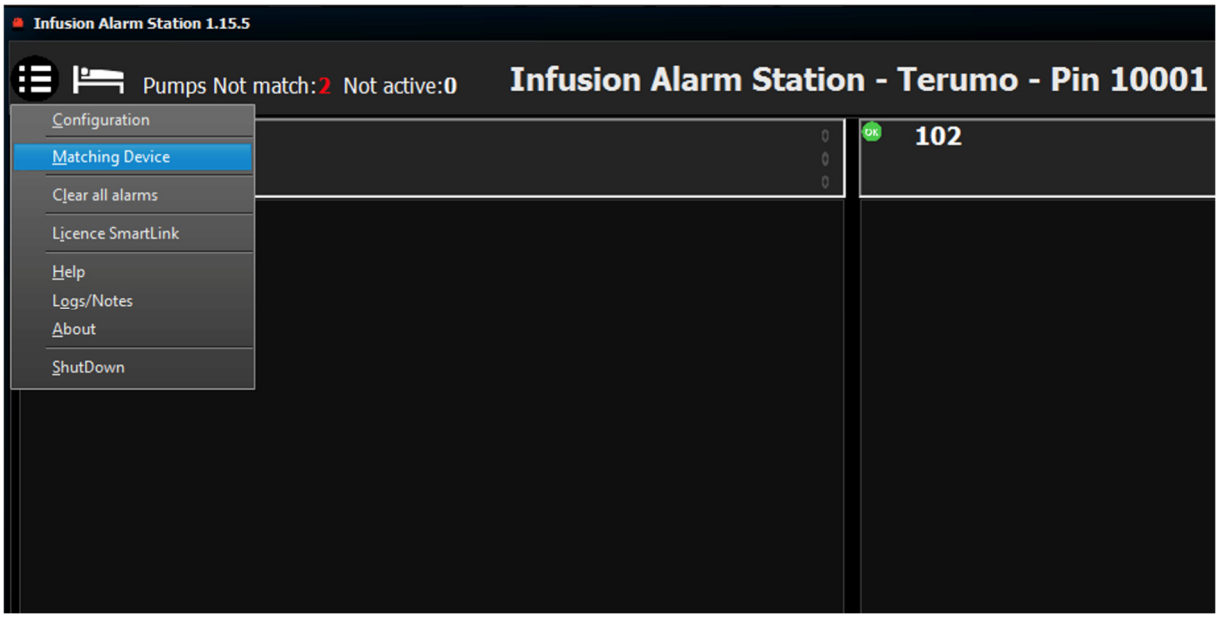
Choose a bed from the available beds list and select save.



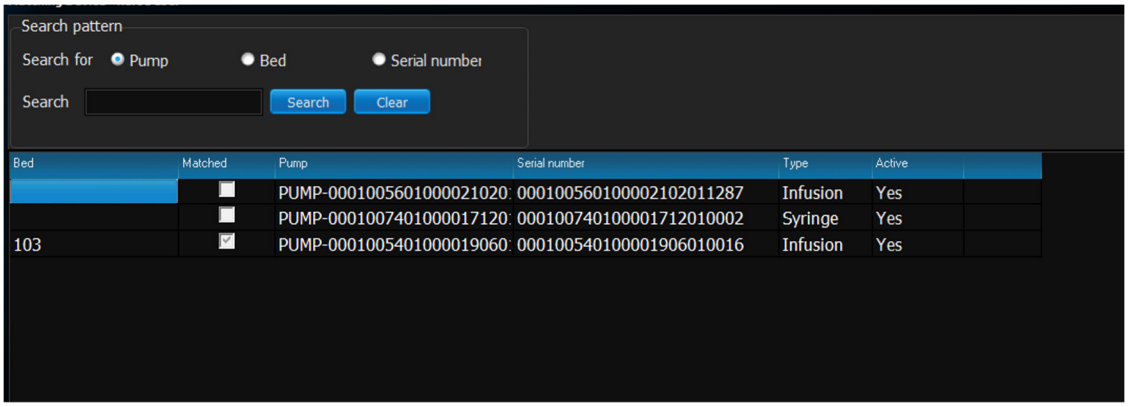
If a Wi-Fi pump is connected to SmartLink but isn't matched to any beds yet, it will be displayed next to the bed list icon in red. The number indicates the amount of pumps that aren't matched.

7.2. Undo Matching Wi-Fi Pumps from Beds

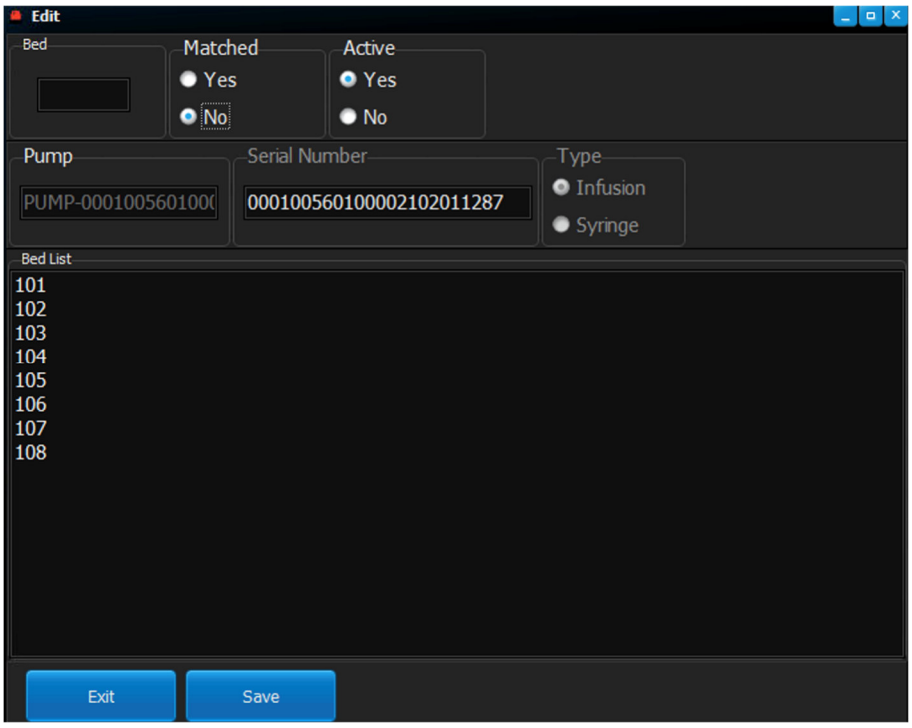
To undo the matching of the WI-FI pumps from a bed, you need to use the "Matching Device" option, accessible from the dropdown menu in the upper left corner of the Infusion Alarm Station (IAS).



Select the pump that you want to be unmatched, by double clicking on it.



And select “No” under the “Matched” section.



If a Wi-Fi pump is connected to SmartLink but isn't matched to any beds yet, it will be displayed next to the bed list icon in red. The number indicates the number of pumps that aren't matched.