SOFTWARE TEAM A Nihon Kohden Company Version: 05	Technical Documentation **SmartLink** (v3.26) Basic UDI: 805750990SMARTLINK3WM **USER MANUAL**

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1 DOCUMENT INTENDED PURPOSE AND READERS

This document is intended to give instructions for safe and correct use of SmartLink to the intended users. It contains important information. Please, read before the use of SmartLink.

1.1 MANUFACTURER CONTACT DETAILS

Legal manufacturer name: Software Team srl Tecnologie Informatiche Avanzate
Address: Via Carducci 39 – 20099 – Sesto San Giovanni (Milano – Italy)
SRN: IT-MF-000024883
e-mail: softwareteam@swt.it
Phone: +39 02 84148166
Fax: +39 02 87183477

1.2 ACCOMPANYING INFORMATION

SmartLink accompanying information consists of the label, marking, User Manual which includes instructions for use and Technical Requirements which includes technical description in accordance with ISO 20417.

Label and marking are displayed on the “about” the software SmartLink.

User Manual and Technical Requirements are provided in electronic form (pdf format) on website https://www.swt.it/customer-area/ in accordance with Commission Implementing Regulation (EU) 2021/2226.

Instructions For Use (IFU) and Technical Requirements are subject to change; the most current version of each document is always available online.

SmartLink User Manual and Technical Requirements in paper form can be requested from the user at any time. The User Manual and the Technical Requirements in paper form will be shipped within 7 calendar days from the user’s request.

1.3 SUPPORT AND CONTACT INFORMATION

If you need help using SmartLink, please contact our technical support group.

Technical support is available by email at the following address: support@swt.it During support session, you may be asked to provide information about SmartLink identifier. The “about” of SmartLink displays the identifier (UDI).

2 MEDICAL DEVICE INFORMATION

2.1 PRODUCT AND TRADE NAME

Product name:	SmartLink
Trade name:	SmartLink
Product type:	Software
EMDN/CND classification:	V92 (MEDICAL DEVICE SOFTWARE - NOT INCLUDED IN OTHER CLASSES)
Basic UDI:	805750990SMARTLINK3WM
MDR version	3.26

2.2 DEVICE DESCRIPTION

SmartLink is a class IIb Medical Device in accordance to the Regulation (EU) 2017/745.

SmartLink is a software with integrator and communicator functions of alarm signals within a Clinical Distributed Alarms Management System with operator Confirmation (CDAS).

It is designed to generate specific alarm signals to notify operators of the existence of an alarm condition and to provide information about alarm conditions received from medical devices. It includes the capability to receive an operator response for delivery of alarm condition with technical confirmation.

2.3 INTENDED PURPOSE

SmartLink is a software intended to forward clinical alarm messages and data to professional health care providers for remotely monitoring of the patient health status.

2.4 INDICATIONS

SmartLink is indicated to allow health care professionals (physicians and/or nurses) remotely receive alarms and remotely review other - near real-time patient data (parameters and physiological values) and alarms and to utilize this information (alarms and data) to improve delivering the patient care in a timely manner. The information provided can reduce the delay of the caregivers in making decisions for diagnostic or therapeutic purposes but does not influence such decisions and cannot cause death or irreversible deterioration of a person's health condition.

SmartLink informs the users of new alarms, and gives the users access to parameters and physiological values received from the connected devices. This information is partial and does not substitute the full information available on the connected devices human interfaces.

2.5 CONTRAINDICATIONS

DO NOT USE SmartLink as the sole communicator for receiving alarm signals (audible and/or visible). In addition to SmartLink another alarm communicator shall be active and operational (e. g. patient monitors and other bedside devices or central stations).

2.6 INTENDED PATIENTS

SmartLink does not directly interact with patients.

SmartLink is not addressed to a specific type of patient or for monitoring a specific disease condition.

The target patient population is the patient population in charge of a ward, or in charge of a healthcare organization.

Patients can be:

- Hospitalized in adult or neonate/pediatric Intensive Care units.
- In stroke units
- In Emergency units
- In Surgery units and in recovery areas after surgery
- Hosted by low acuity units.
- Staying in General medicine units.
- Elsewhere if under control of professional SmartLink users

2.7 MEDICAL CONDITIONS

Medical conditions to be monitored are alarm conditions transmitted by the bedside or other types of medical devices. Alarms conditions based on rules applied to data received from the bedside and other medical devices.

2.8 PATIENT SELECTION CRITERIA

There are no specific patient selection criteria.

Any patient can be controlled using SmartLink functionalities.

All the patients connected to devices that can be interfaced to SmartLink with the purpose of sending to SmartLink data and alarms can be monitored by SmartLink.

2.9 INTENDED USERS

SmartLink can be used by health care professionals as:

- Physicians
- Nurses

2.10 SIDE EFFECTS

There are no known side-effects related to the use of SmartLink.
No side effects have been noticed on the patient population.
No side effects have been noticed on the user population.

2.11 PRECAUTIONS

Users should read this Instruction for correct and safe use.

2.12 DISCLAIMER

The healthcare delivery organization is fully responsible for the settings of the alarm signal originated by sources used in combination with SmartLink.

The healthcare delivery organization is fully responsible for the selection of the alarms that will be managed by SmartLink.

The healthcare delivery organizations should have clinical alarms management policies and protocols.

Nurse and physicians are fully responsible for respond promptly to alarm conditions in a timely manner.

2.13 NOTICE ABOUT SERIOUS INCIDENT

The user is invited to report any serious incident that has occurred in relation to the medical device to the manufacturer and the authority having jurisdiction in their locale.

2.14 SYMBOL LEGEND OF THE LABEL

SmartLink is provided with a label wich gives you information about product and manufacturer. You can see the label in the about information of the software.

This symbol used are explained in the symbol legend.

Symbol	Title	Description
MD	Medical Device	Indicates that the device is a Medical Device
LOT	Batch code	Indicates the lot code of the medical device. For software it corresponds to the Version
	Manufacturer	Indicates the name and address of the medical device manufacturer
	Date of manufacture	Indicates the date on when the medical device was manufactured
	Use-by date	Indicates the date after which the medical device is not to be used
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use and is accompanied by the eIFU website
CE	CE Marking	Indicates conformity to European standards. Includes the reference of the notified body
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information

2.15 EXPECTED LIFETIME

The expected lifetime of SmartLink is 5 (five) years after the software release date (Date of manufacture).

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.

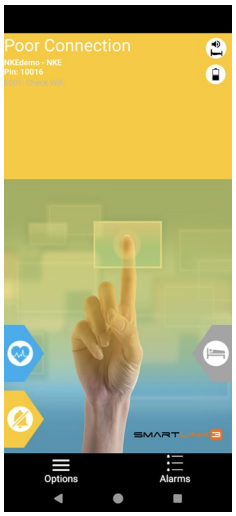
The home screen is composed of:

- "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

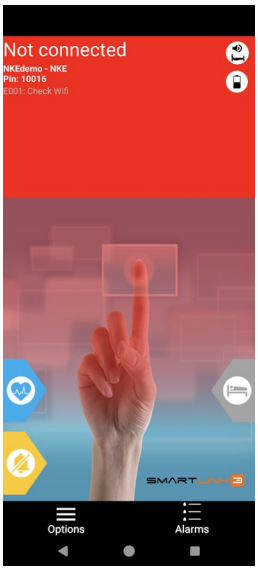


3.1.2 Poor Connection

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:

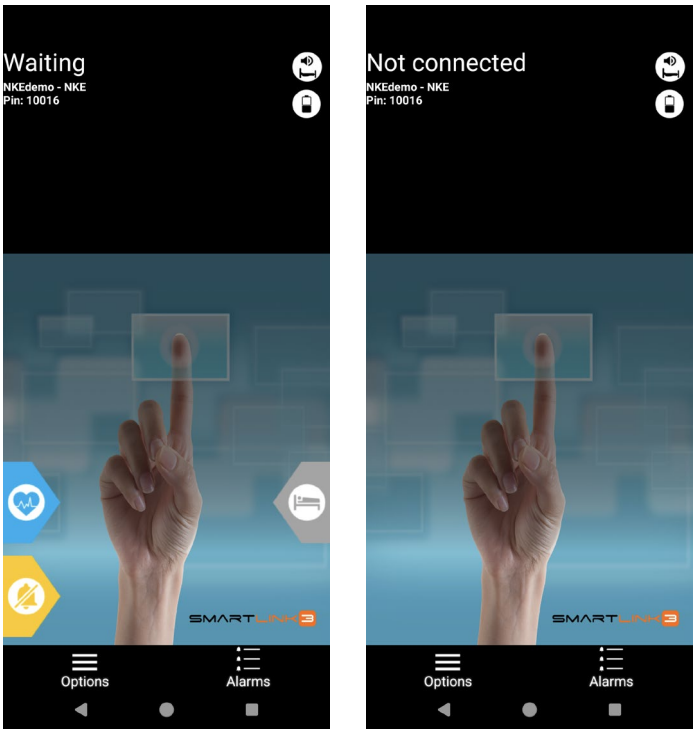
- Tap “Restart” in the Options Menu
- Check if you are connected to the right Wi-Fi network
- Get closer to the Wi-Fi network (you could be out of range or have a weak signal)

If none of the previous solutions worked, contact your system administrator.

3.1.4 Not Connected/Waiting

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

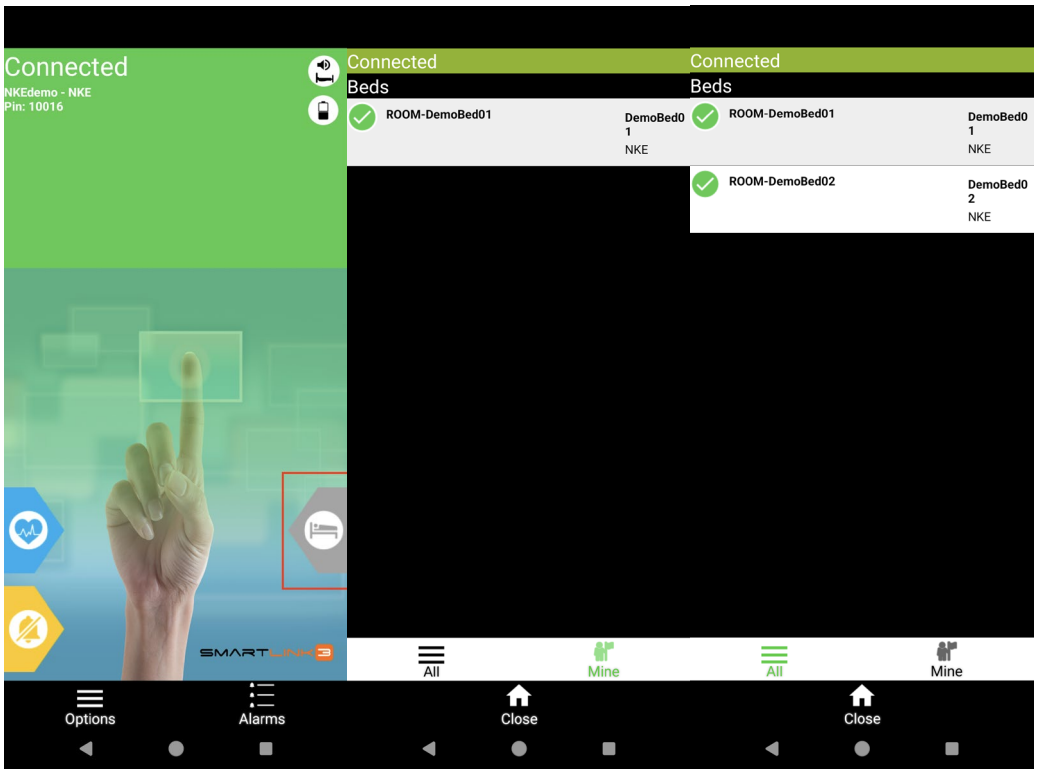
- “Waiting” → the device is not yet connected and not yet able to receive alarms but is attempting the first connection (normally you see “Waiting” only when you first power on the smartphone).
- “Not Connected” → the SmartPager service is not running and SmartPager will not try to connect to the server 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.



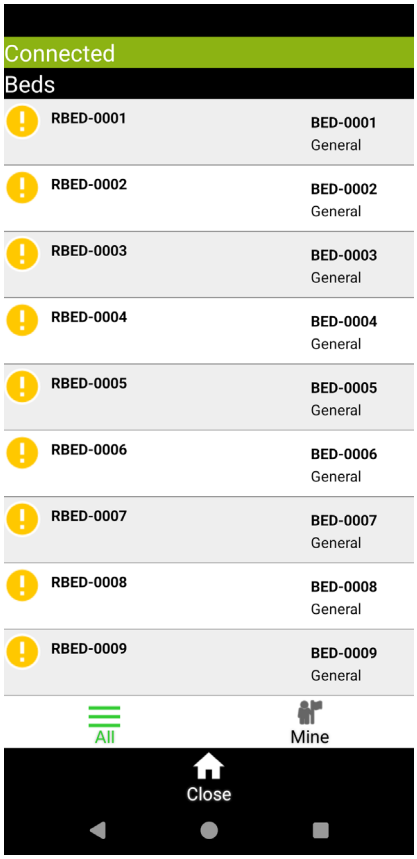
Using the “All/Mine” filter at the bottom you can switch between viewing all the beds of the department or just the beds assigned to you.

For each bed, by tapping on the corresponding row you can see the devices in use for that bed.

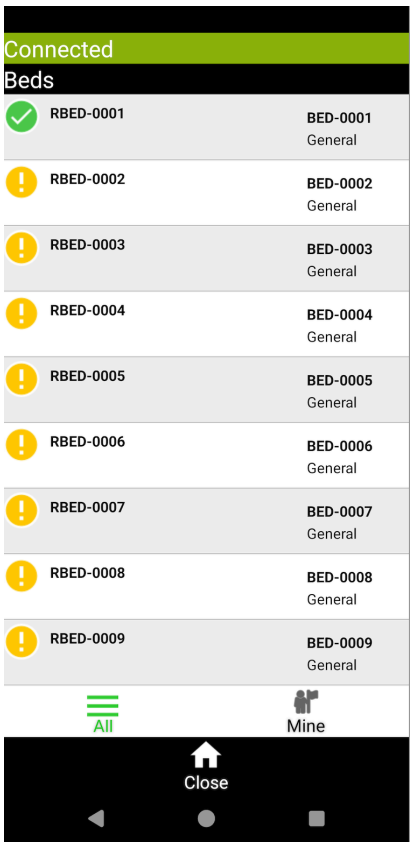
Using the “All/Connected” filter at the bottom you can switch between viewing all the devices in use for that bed or just the devices that are currently connected to the bed.

The connection status of devices is displayed on the left side of the bed name.

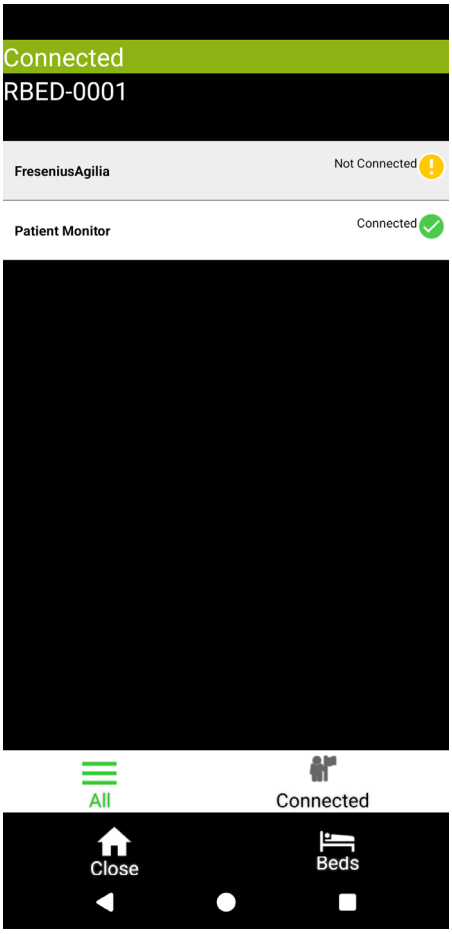
In the bed list, a yellow icon next to the bed indicates that at least one device is disconnected.

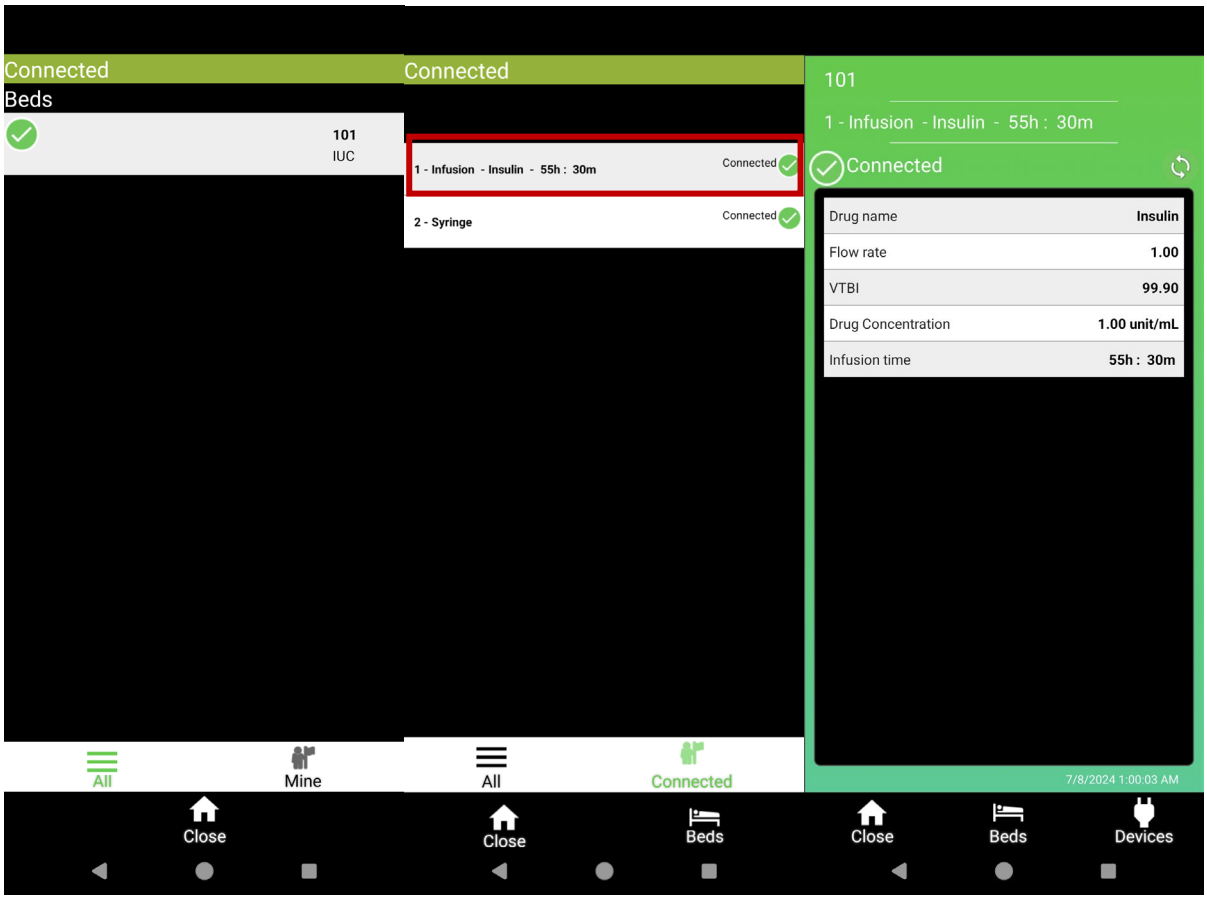


If all devices are connected to the bed, a green checkmark is displayed.

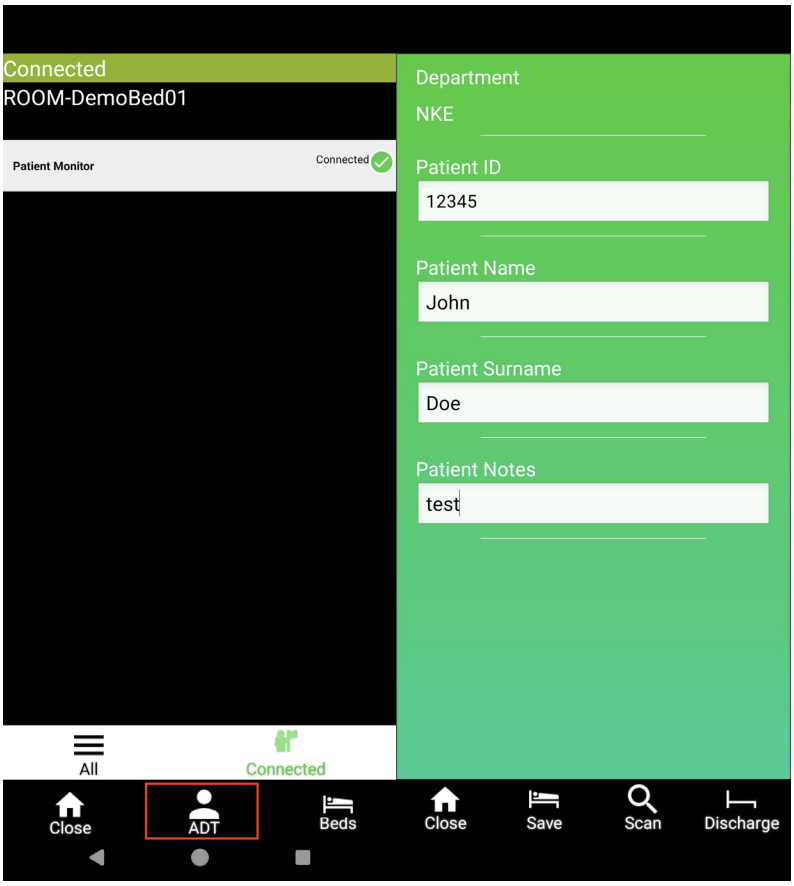


In the device list, the same icons indicate the connection status of each device registered to the bed





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.

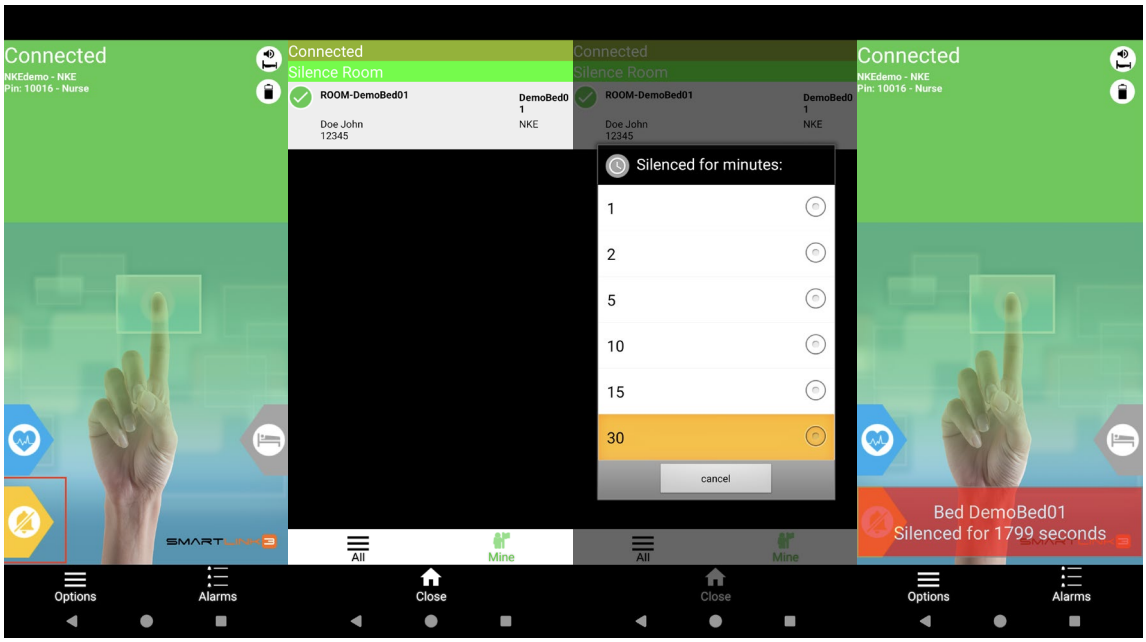
3.2.2 Silence Bed

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.

Software Team Srl - via Carducci 39, 20099 Sesto San Giovanni (Milan, Italy) – (+39) 02 8414 8166 – softwareteam@swt.it – www.swt.it – Capitale Sociale € 46800,00 interamente versato – C.C.I.A.A. Milano n.1301067 Reg. Trib. Milano 289763-7376-B – C.F. e P.IVA 09514120154 – Codice destinatario fatturazione elettronica J6URRTW

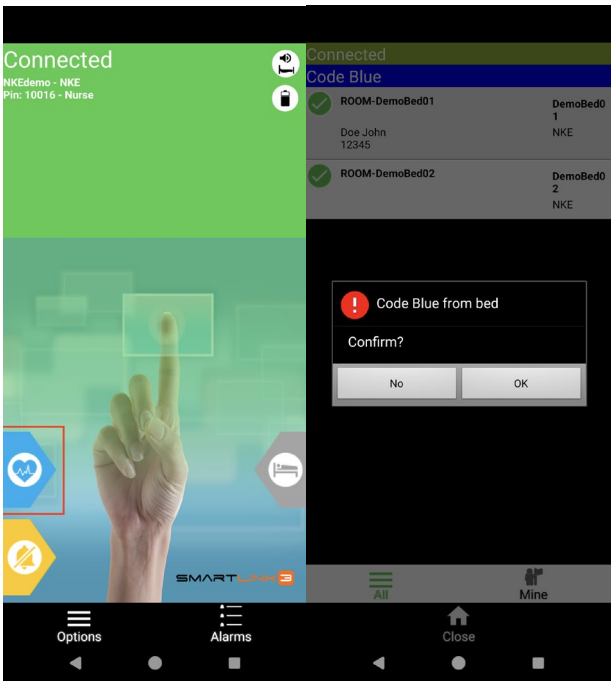


3.2.3 Code Blue

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
NKEdemo - NKE
Pin: 10016 - Nurse
Connected
Code Blue
ROOM-DemoBed01
Doe John
12345
DemoBed01
NKE
ROOM-DemoBed02
DemoBed02
NKE
Code Blue from bed
Confirm?
No
OK
All
Mine
Options
Alarms
Close

3.3 The alarm screens

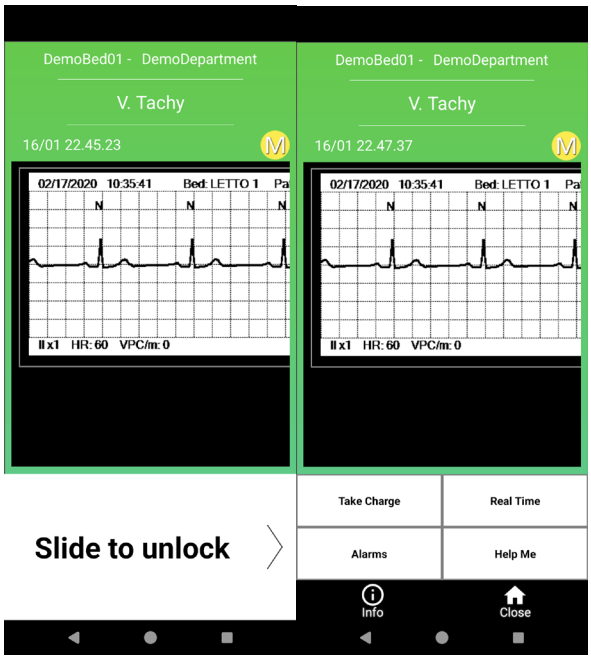
When a new alarm occurs, the device sounds and vibrates and shows the alarm info.

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.

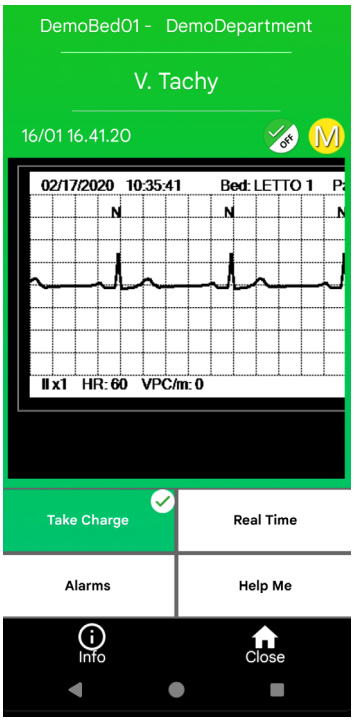
Depending on the type of integration it is also possible to display the alarm trace image.

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.



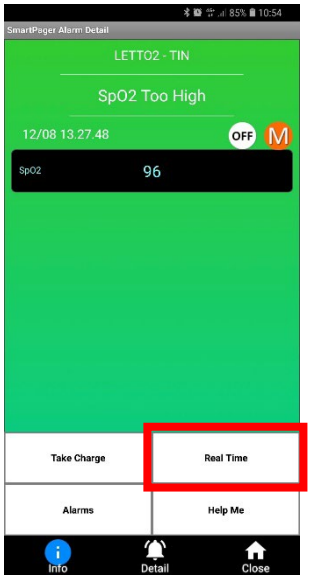
3.3.1 Take Charge

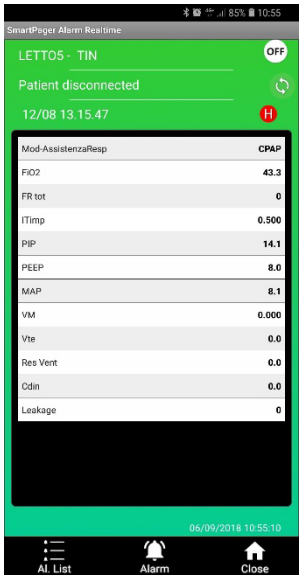
By tapping Take Charge, you take charge of the alarm and automatically notify this action to the other connected pagers. The other users will be able to see when and on which pager the alarm has been taken in charge of.



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.

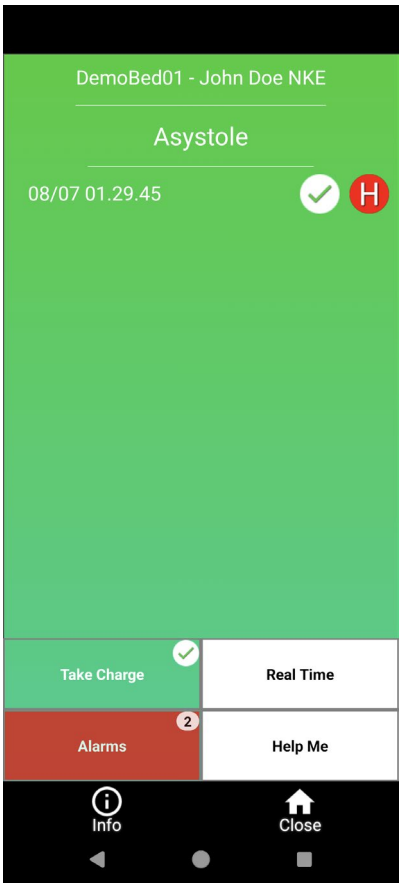
In the “Real Time” screen, you have three toolbar buttons:

- 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.



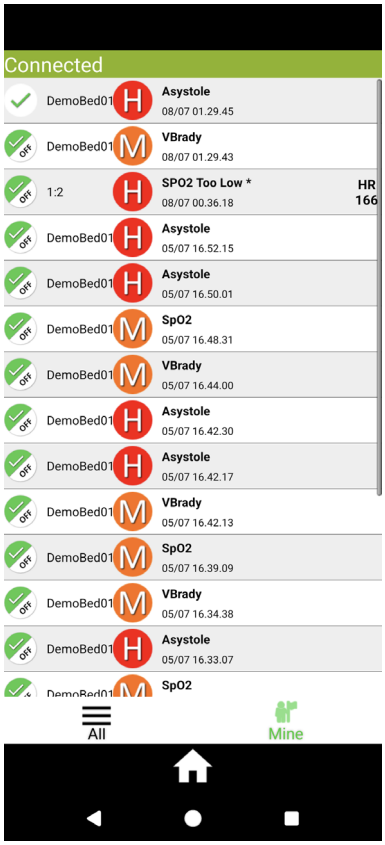
The alarms list contains the list of the last 20 alarms that occurred. In the alarms list screen for every alarm you can see, from left to right:

- 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

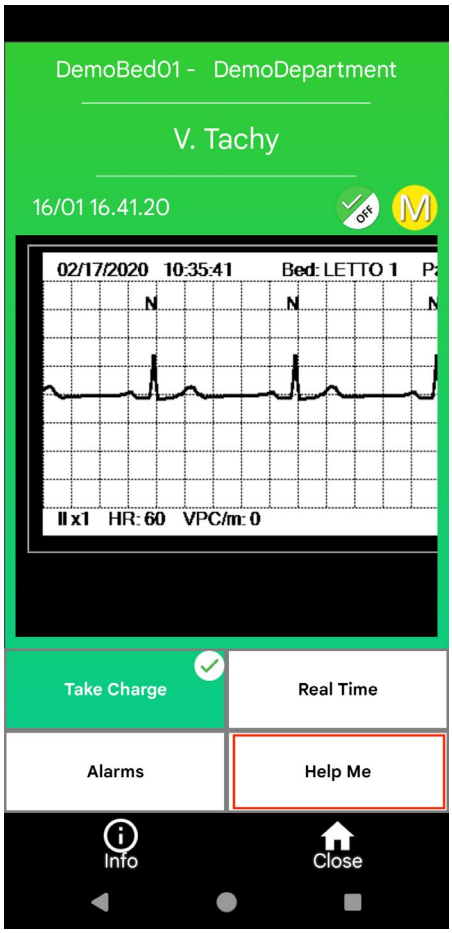
By tapping on an alarm, you can have more information about it.

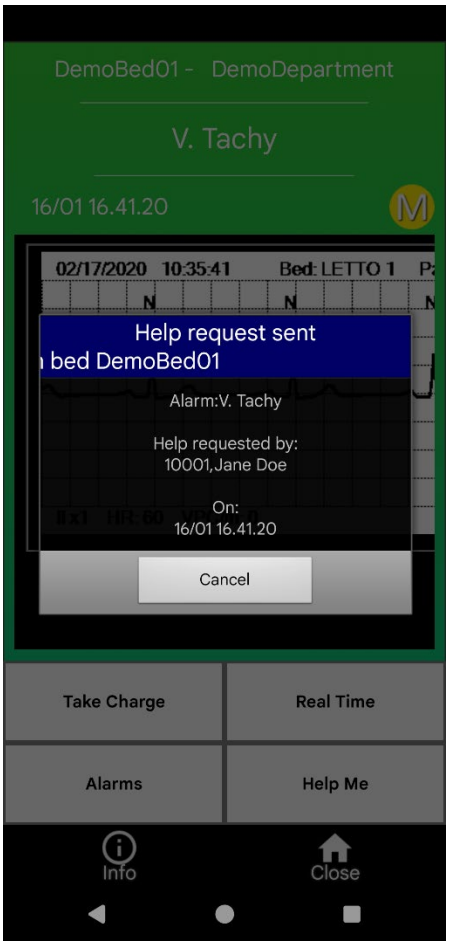
At the bottom of the screen, you can choose between seeing all the alarms that occurred in the department (All) or just the alarms associated with the pager you are holding (Mine).



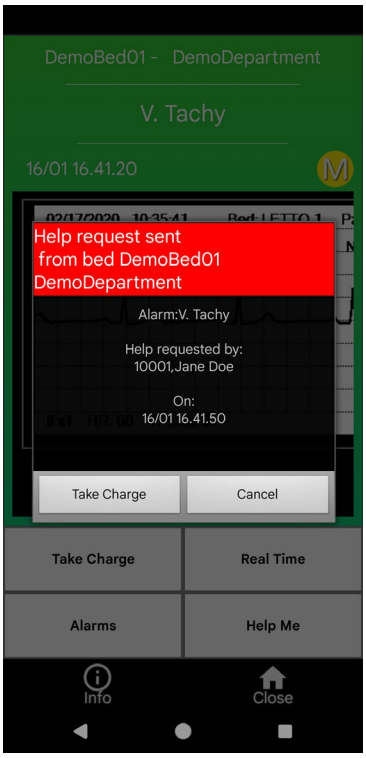
3.3.4 Help Me

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.

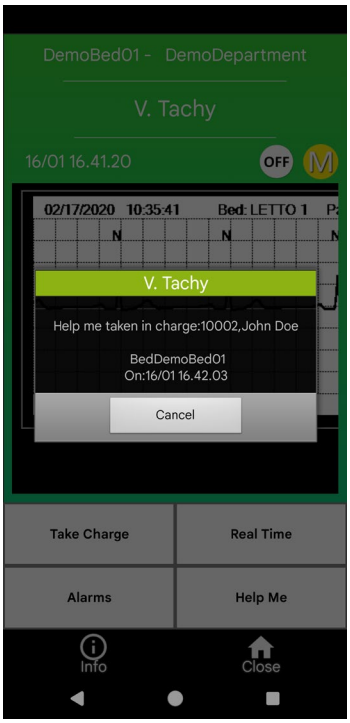




When the help request is sent, this screen appears on the pagers that receive the help request:

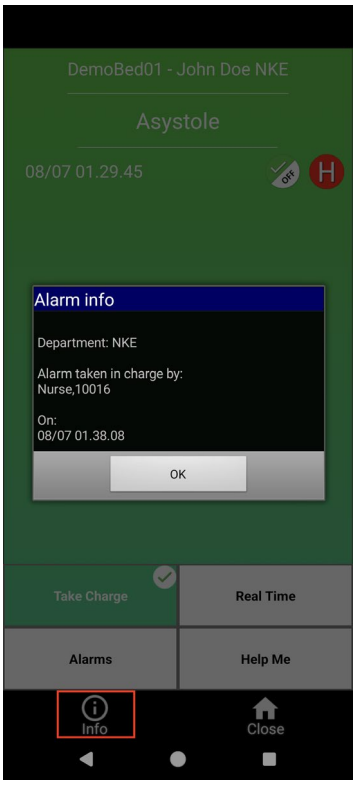


Finally, when the help request is taken in charge by someone, this message appears on the pager that sent the help request:



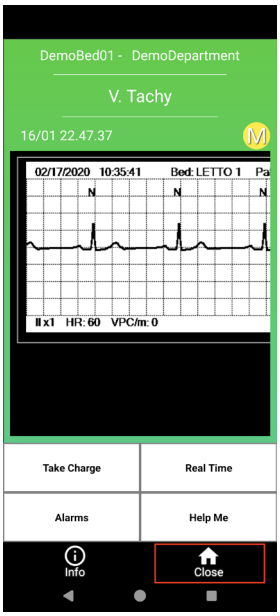
3.3.5 Info

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



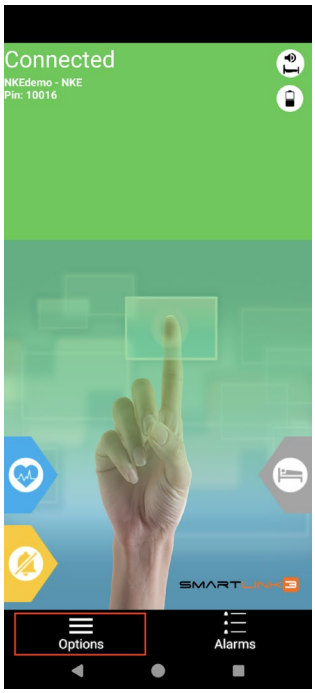
3.3.6 Close

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.

[INSERT IMAGE]

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*.

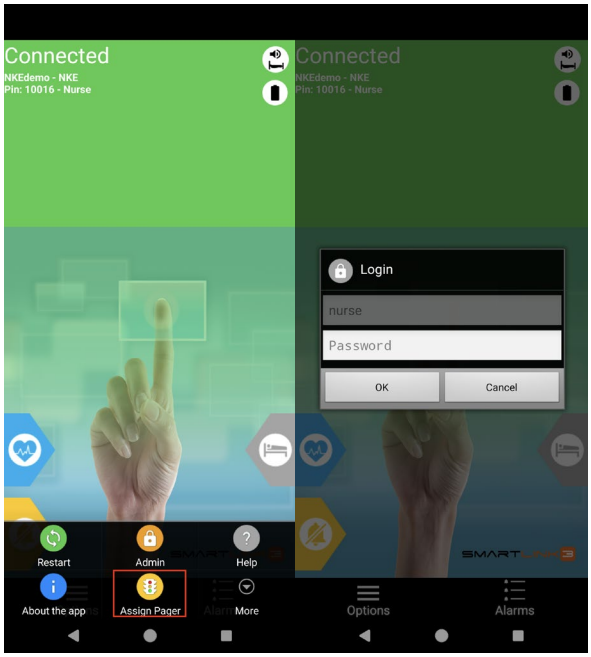
3.4.5 More

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

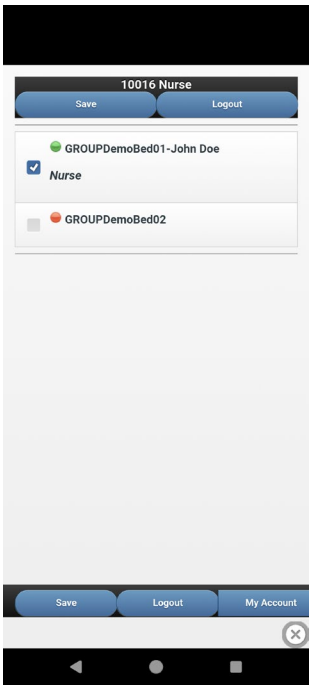
3.5 Pager assignment on the pager

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

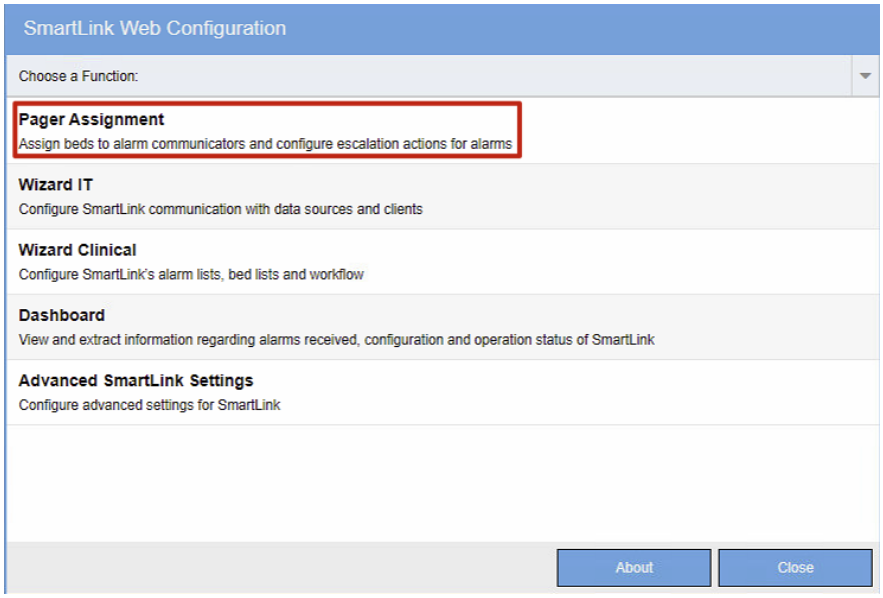
The Pager Assignment via web allows authorized users to associate beds with pagers for a selected shift.

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”.

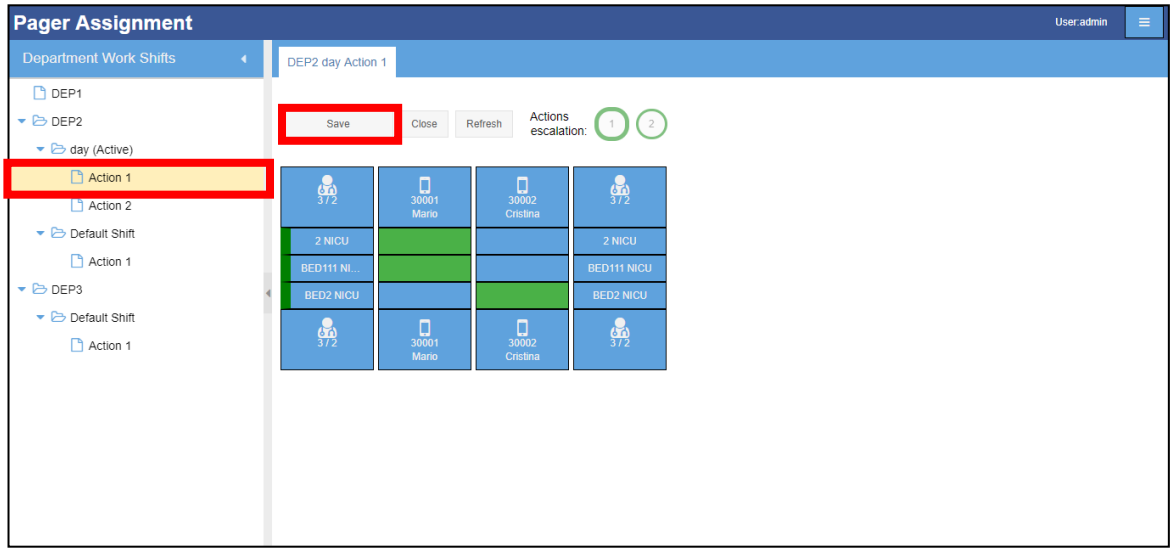


The main screen of the Pager Assignment is divided into two sections:

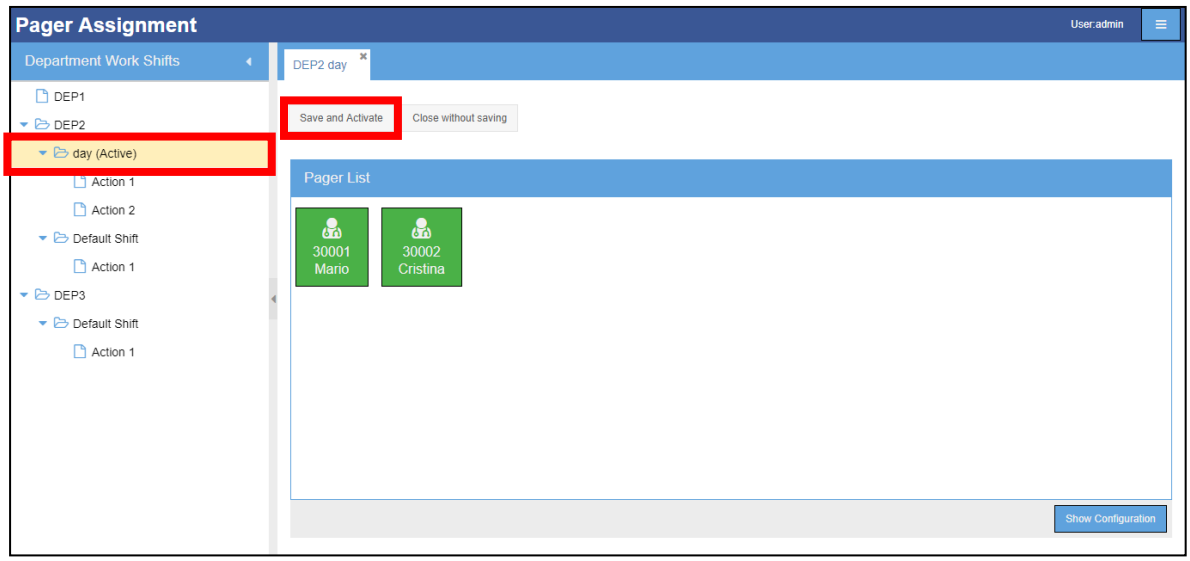
- On the left you can select the department and the action.
- On the right you can select the pagers to be assigned to the department.

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

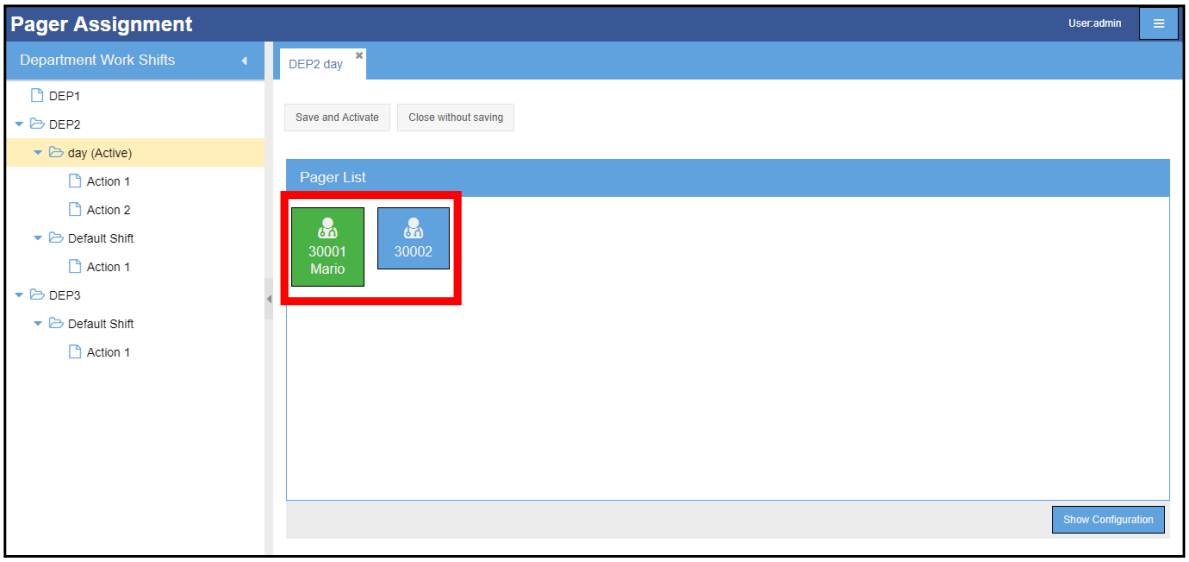
1) Select the action: select the pager or DECT that will be associated with the beds and will receive the alarms from that group of beds. The associated pagers are highlighted in green. Then click Save.



2) Click on the shift (e.g., “day (Active)”) and then click “Save and Activate” to activate the configuration.



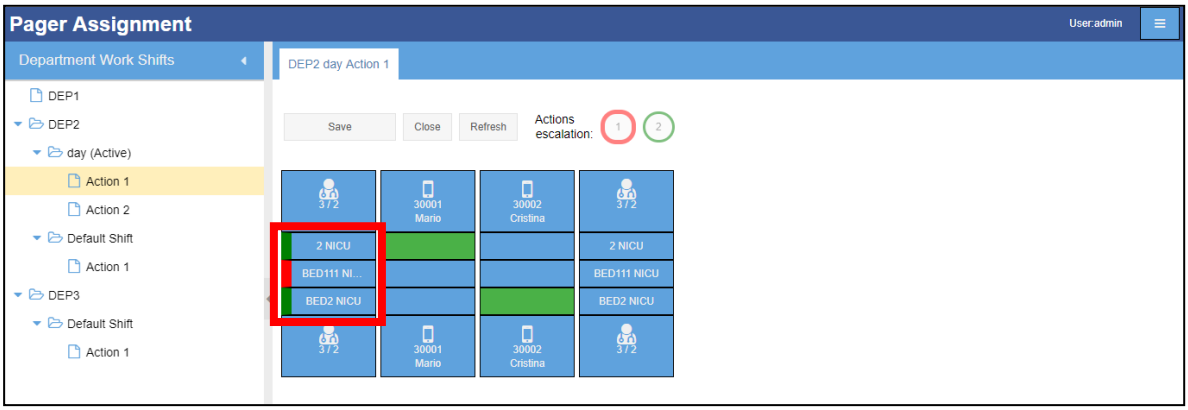
3) Clicking on the shift again you can associate a user to the pager: the associated pagers are highlighted in green.



NOTE: if you want to dissociate a pager from a bed or a user from a pager, re-click the highlighted pager or user and save the configuration.

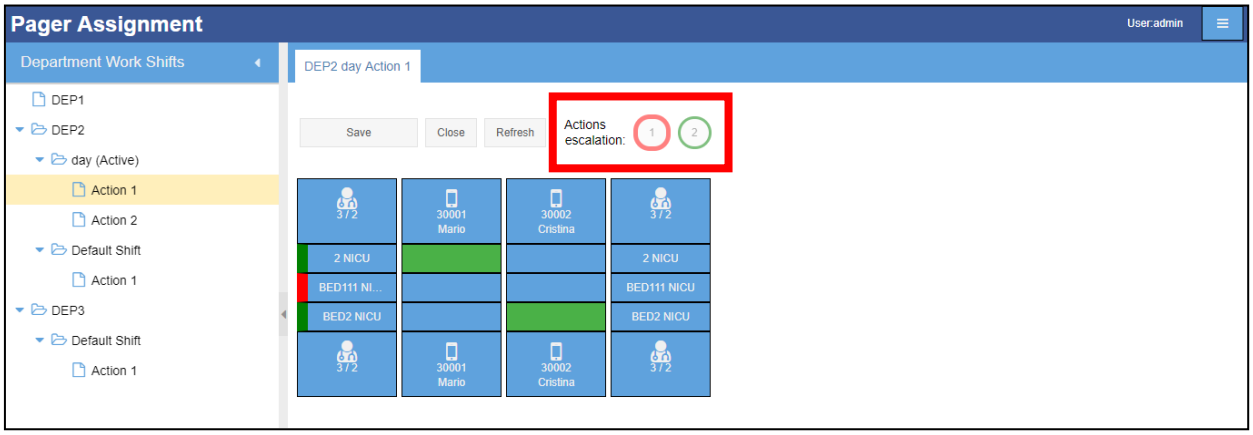
4.1 How to Check if the Assignment is Correct

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).



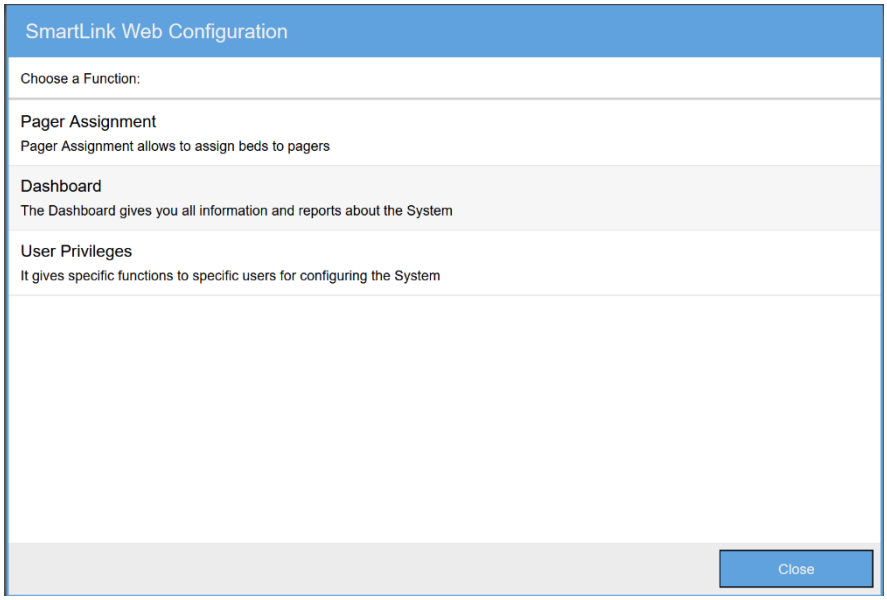
4.1.2 Check the Actions

If the action is:

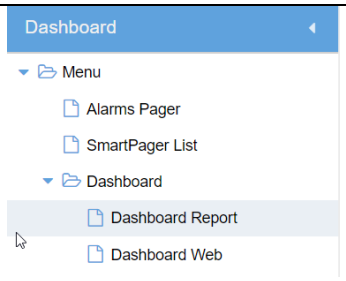
- Red: for at least one bed there is no association. The action must be checked.
- Green: the action configuration is correct.

5 DASHBOARD

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

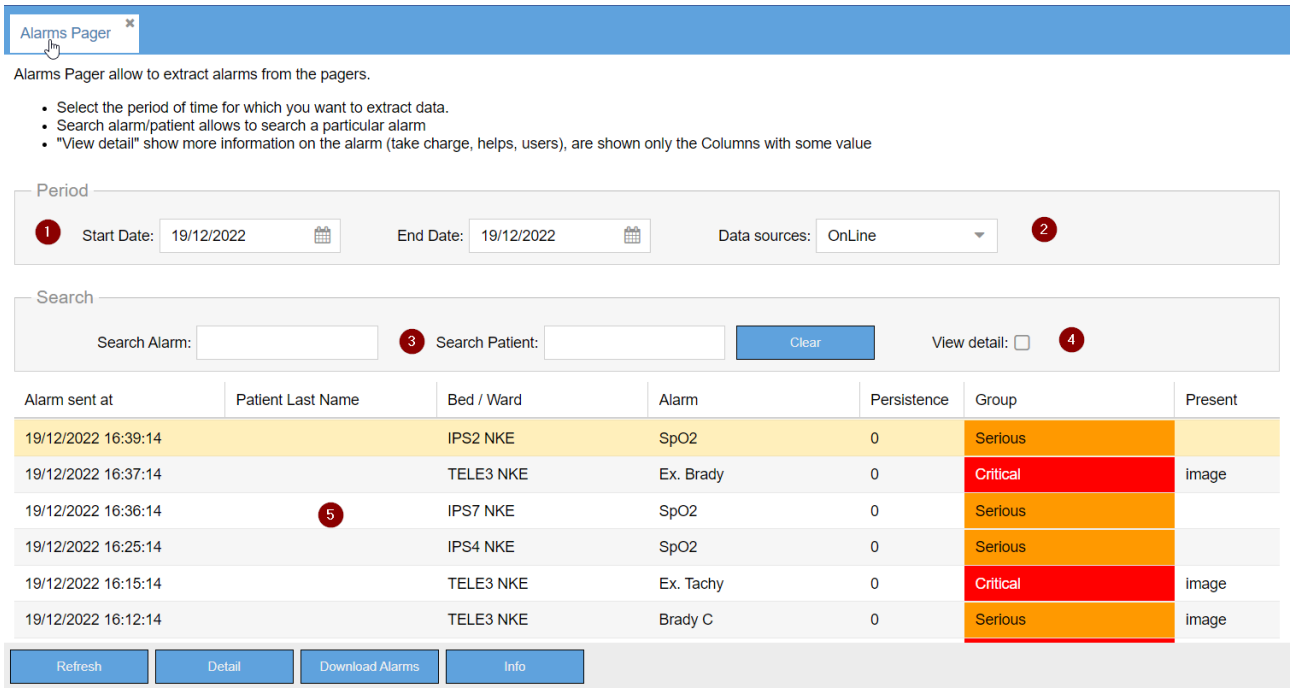


The main items available are:



- 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:



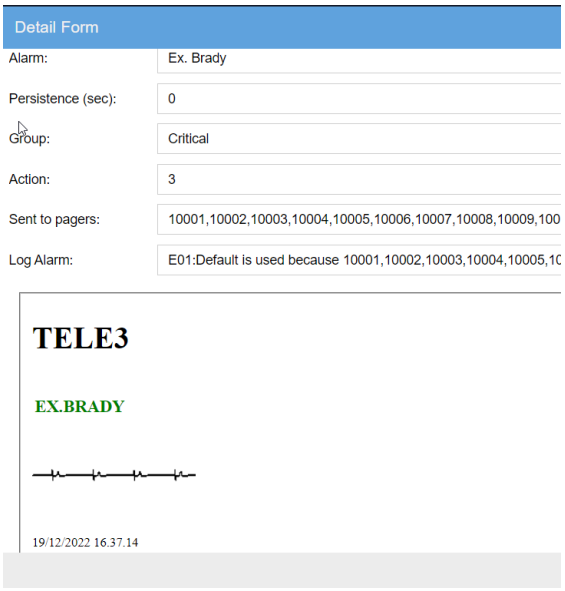
Here are the main functions:

- 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

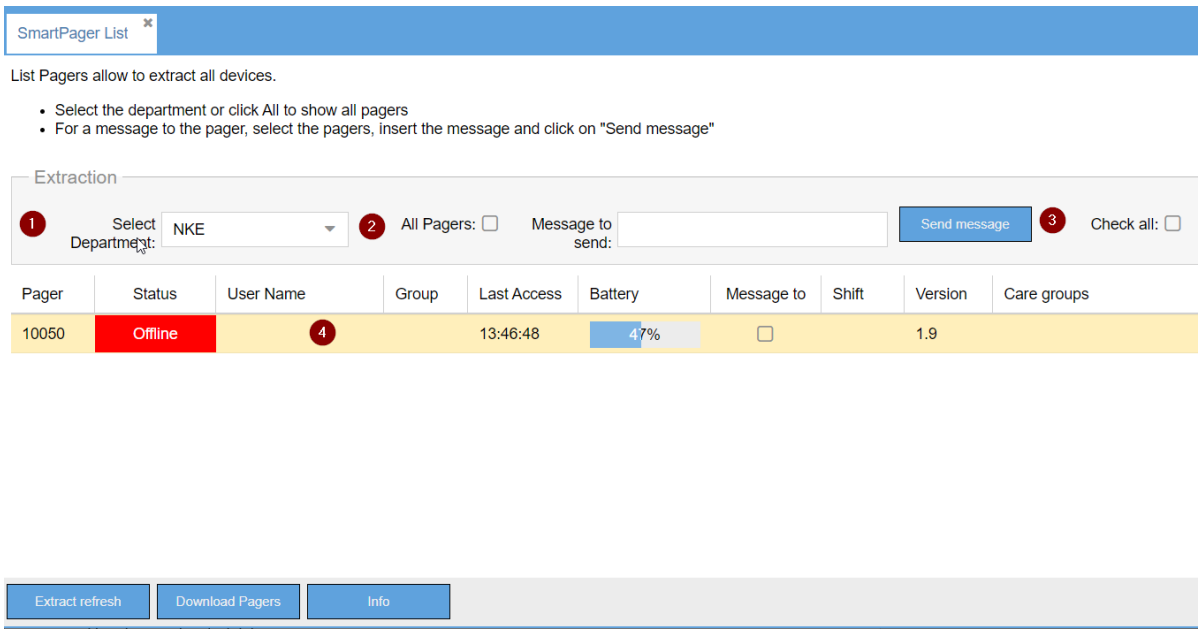
ANALISI STATISTICA dic, 19 2022 dal 2022.12.19-00.00 al 2022.12.19-16.51

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:

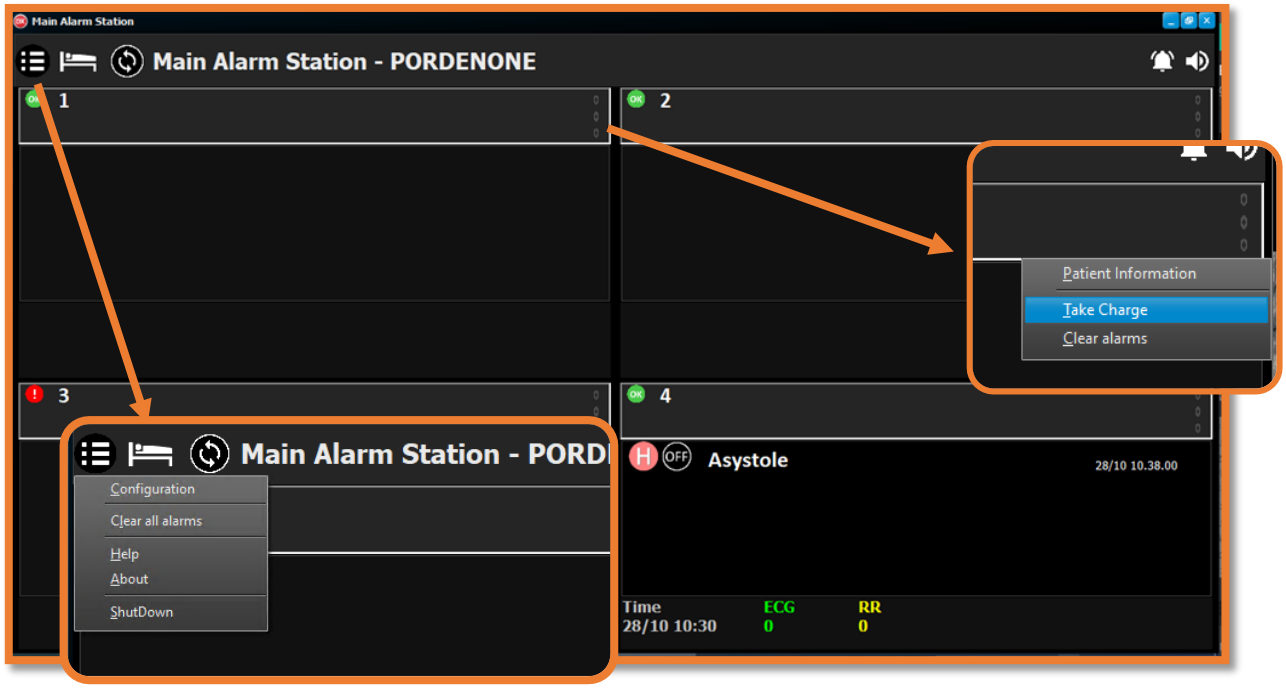
- Visualization of the pagers of the selected Department
- Possibility to see the pagers of all departments.
- Broadcast message: A broadcast message can be sent to one or more pagers (clicking "Check all" sends it to all connected pagers)
- List of pagers connected with the following information:
    - 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 doctor 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

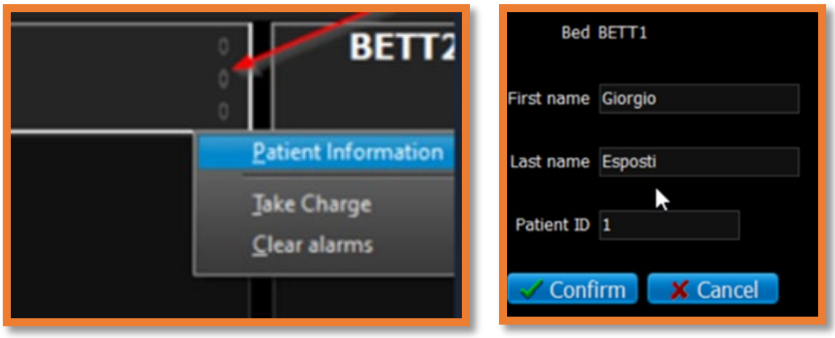
6 MAIN ALARM STATION



- 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.

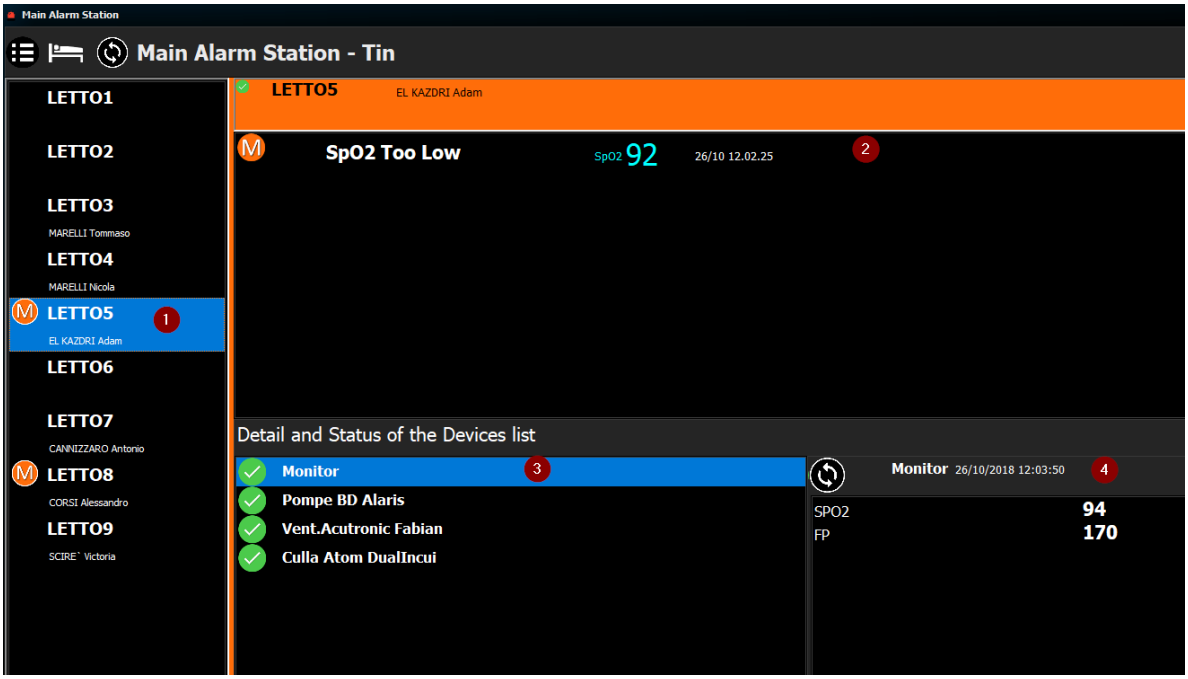
6.1 Patient Information

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



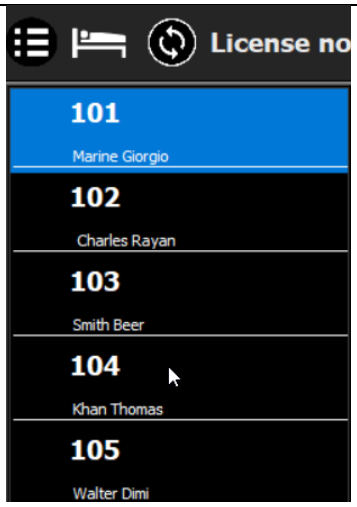
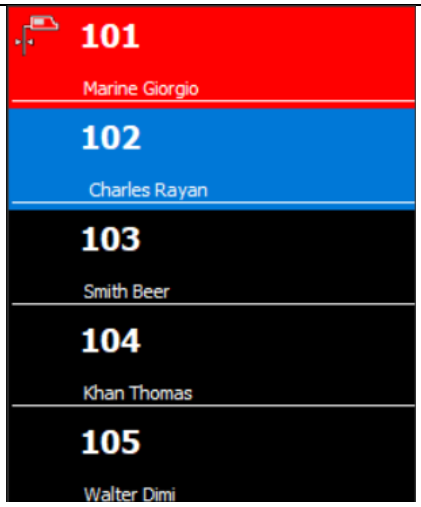
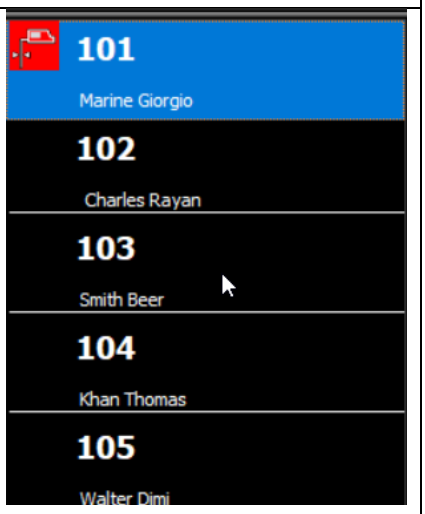
6.2 Beds

6.2.1 Bed list and Bed Details



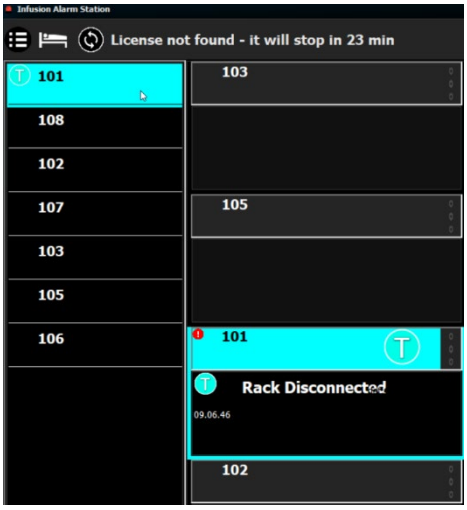
1) Real time bed status.
2) By clicking on the bed, you can see the beds details.
3) Status of connected devices.
4) Connected device parameters.

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
		

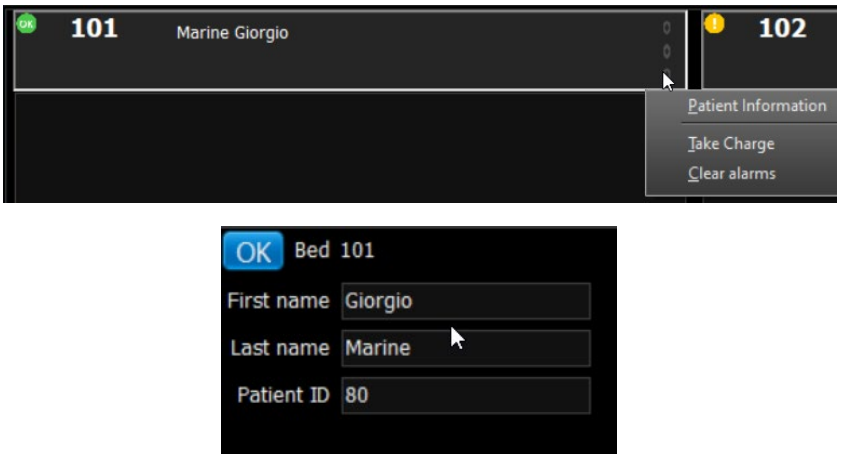
6.3 Alarm

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



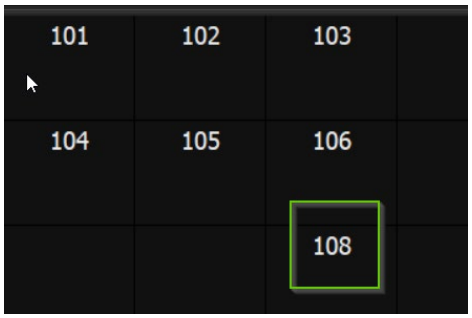
6.4 ADT

It is possible to enter the patient's ADT data 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

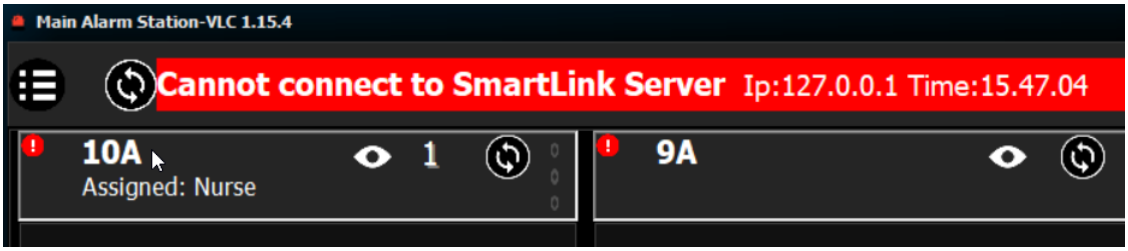
“License SmartLink” give you the possibility to import the License.

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.

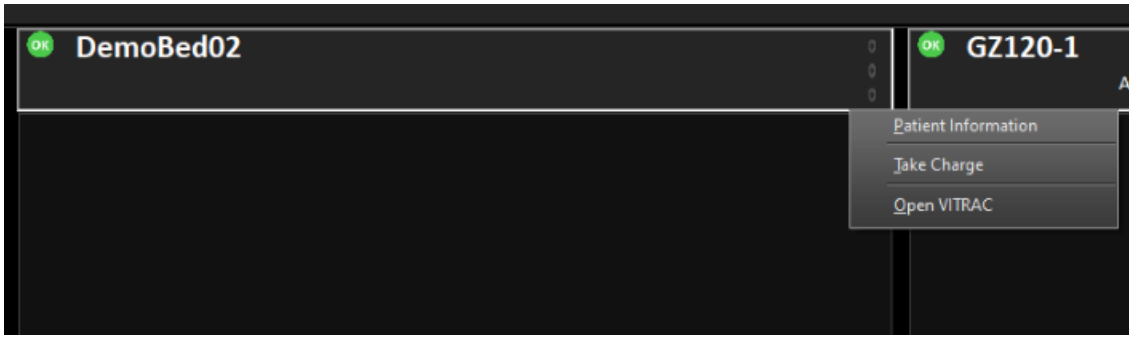


Once the connection to the server is reestablished the Main Alarm Station restarts and the message disappears.

6.8 Open External applications

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

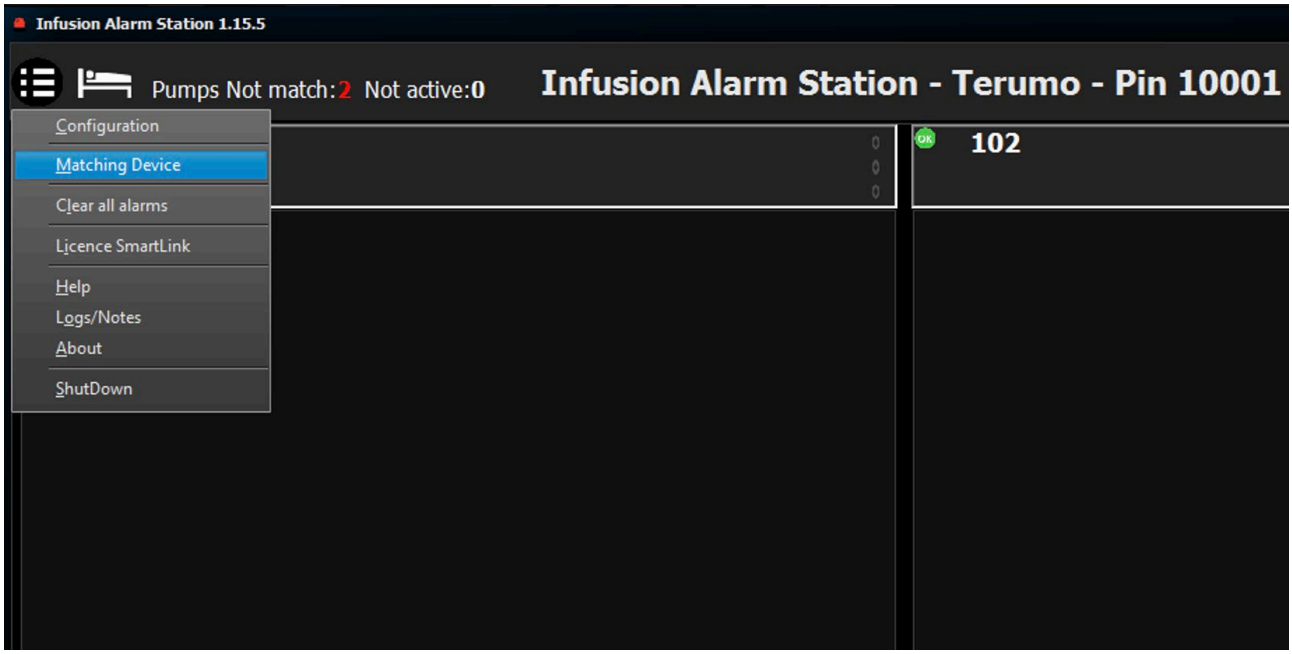
To open the external application, choose the bed and select the three dots on the upper right corner and choose “Open [External Application]”



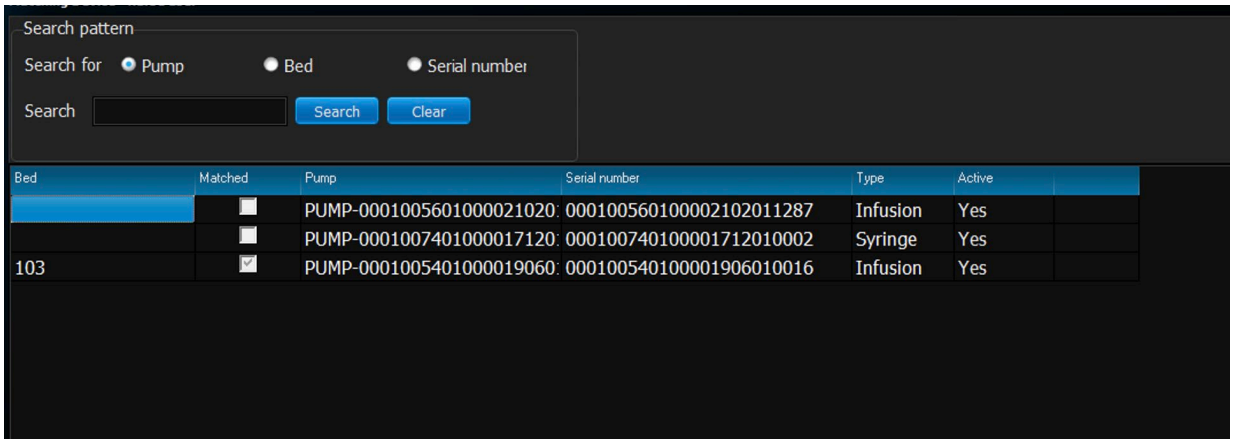
7 Infusion Alarm Station

7.1 Matching Wi-Fi Pumps

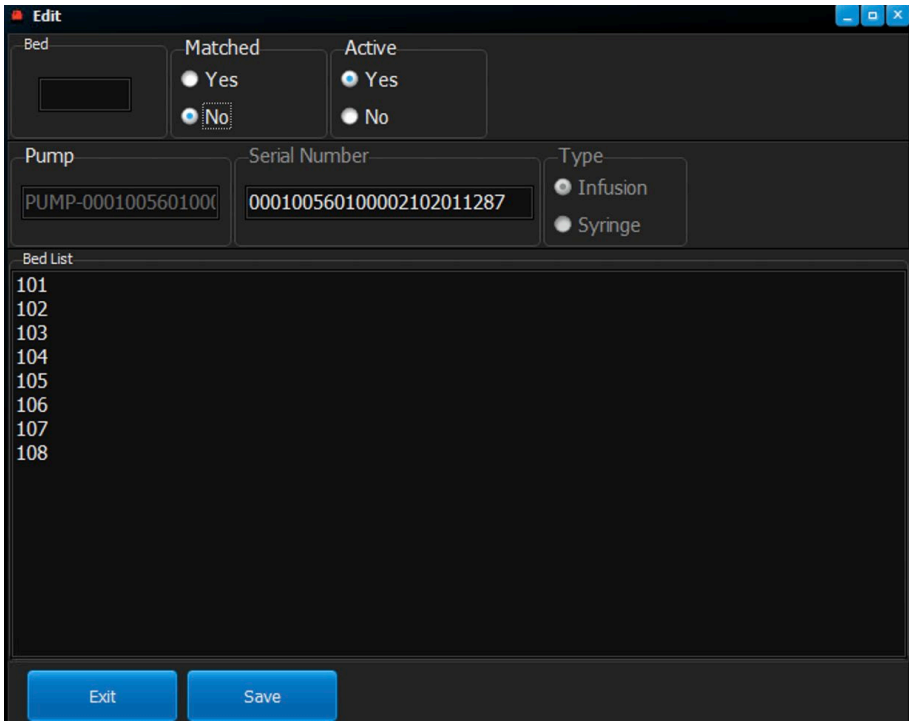
To match WI-FI pumps to the beds, you need to use the “Matching Device” option, accessible from the dropdown menu in the upper left corner of the Infusion Alarm Station (IAS).



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



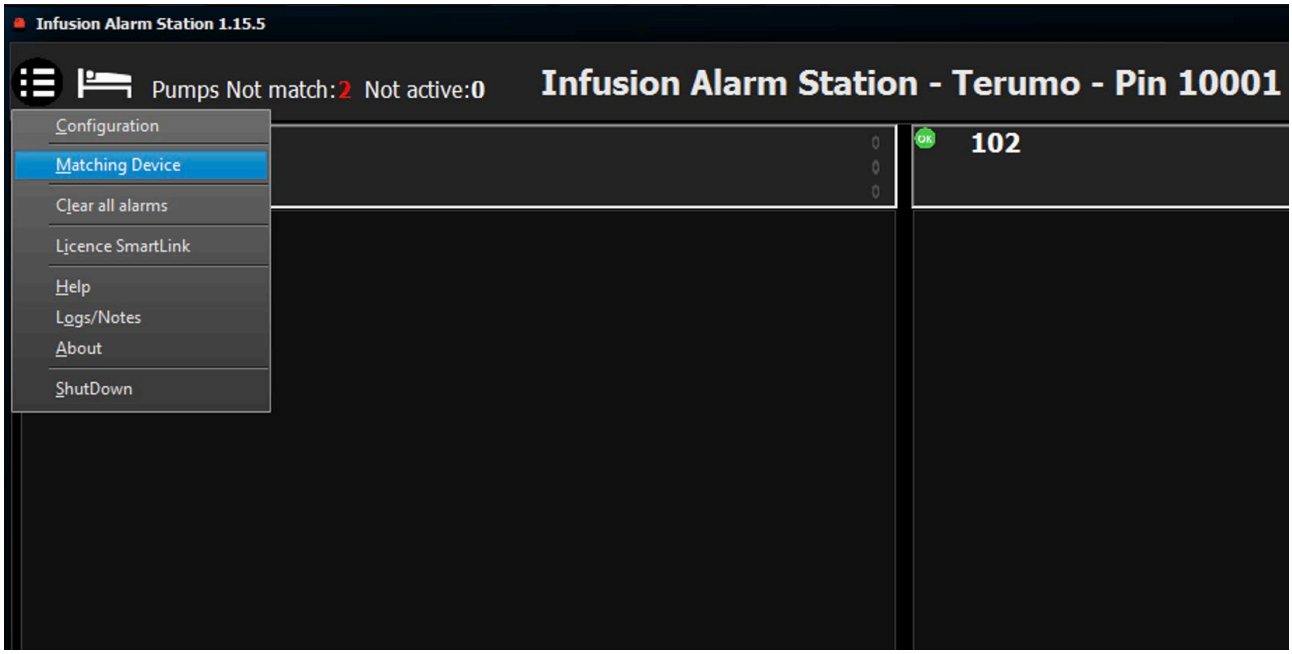
Choose a bed from the available beds list and select save.



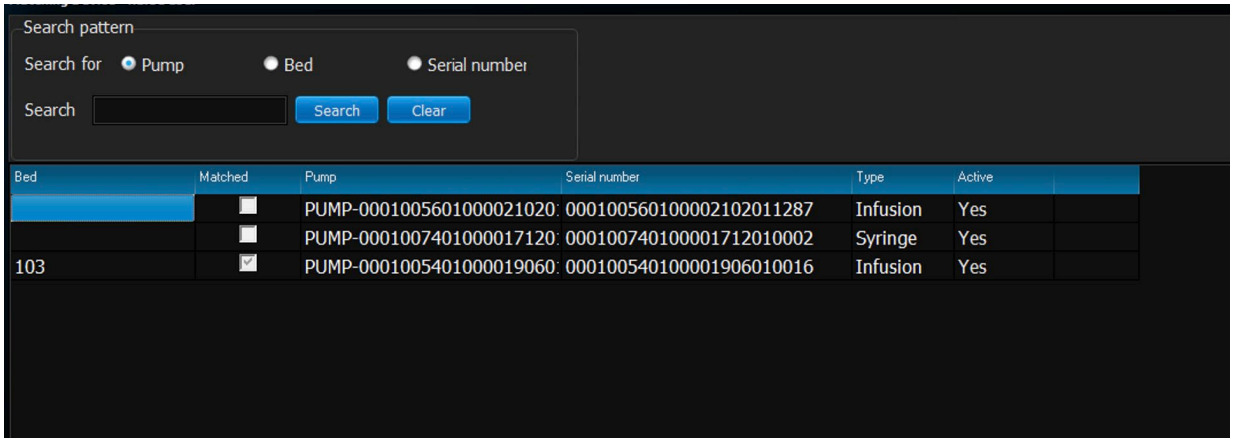
If a Wi-Fi pump is connected to SmartLink but isn't matched to any beds yet, it will be displayed next to the bed list icon in red. The number indicates the amount of pumps that aren't matched.

Undo matching Wi-Fi Pumps from Beds

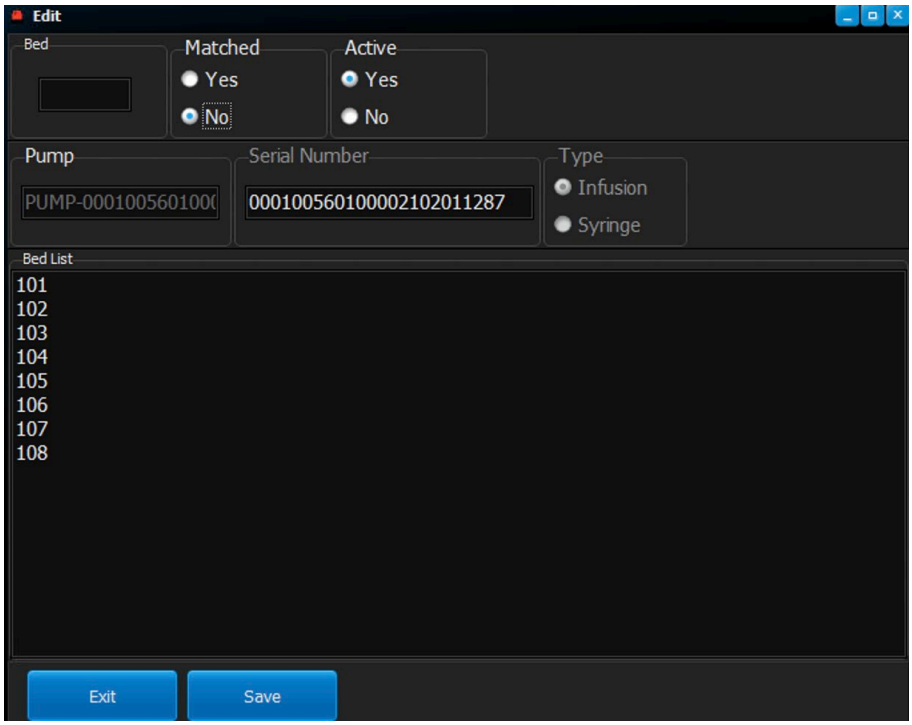
To undo the matching of the WI-FI pumps from a bed, you need to use the "Matching Device" option, accessible from the dropdown menu in the upper left corner of the Infusion Alarm Station (IAS).



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.