TECHNICAL FOLDER

USER MANUAL

SMARTLINK 3

Table of Contents

1. REGULATORY INFORMATION 3
2. DOCUMENT INTENDED PURPOSE AND READERS 4
3. DOCUMENT CHANGE MANAGEMENT 4
4. SMARTPAGER APPLICATION 5
4.1. CONNECTION STATUS 5
4.1.1. Connected 5
4.1.2. Poor Connection 6
4.1.3. Error – Not Connected 7
4.1.4. Not Connected/Waiting 8
4.2. SMARTPAGER HOME SCREEN BUTTONS 9
4.2.1. Bed list 9
4.2.2. Silence Room 11
4.2.3. Blue code 12
4.3. THE ALARM SCREEN 13
4.3.1. Take Charge 14
4.3.2. Real Time 15
4.3.3. Alarms List 16
4.3.4. Help Me 17
4.3.5. Info 19
4.3.6. Detail 19
4.3.6.1. Trend 20

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4.3.6.2. Detail 21
4.3.7. Close 22
4.4. OPTIONS MENU 22
4.4.1. Restart 23
4.4.2. Admin 23
4.4.3. Help 23
4.4.4. About 23
4.4.5. Pager Assignment 24
4.4.6. More 24
4.5. PAGER ASSIGNMENT ON PAGER 25
5. PAGER ASSIGNMENT VIA WEB 27
5.1. HOW TO CHECK IF THE ASSIGNMENT IS CORRECT 29
5.1.1. Check the care groups 29
5.1.2. Check the actions 30
6. SMARTLINK USER INTERFACE SYMBOLS 31
7. SMARTLINK - SMARTWAVES OPERATION 32
7.1. APPS 32
7.2. WAVEFORMS 33
7.3. ALARMS 36
7.4. TRENDS 37
7.5. ADVANCED SEARCH 40
7.6. SUMMARY REPORTS 40

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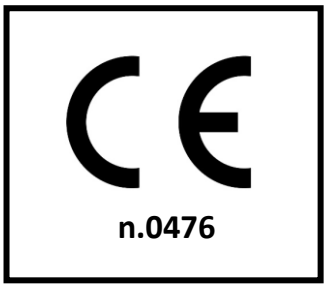
1. REGULATORY INFORMATION

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).



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

The product documentation is composed of these documents:

SmartLink 3 Declaration of Conformity
SmartLink 3 User Manual
SmartLink 3 Administration and Configuration Manual
SmartLink 3 Installation and Update Manual
SmartLink 3 Technical Requirements

These documents are available in PDF format on the desktop of the SmartLink 3 pre-installed virtual machines, are included in the Installer compressed file, and can be downloaded from the reserved area of the Software Team website.

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.

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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) or to third party messaging systems.

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.

3. DOCUMENT CHANGE MANAGEMENT

Revision	Date	Description	Author	Approved
01	13 Mar 2018	First Issue.	TEC – CC	DIG – RM
02	11 May 2018	Contents change	RGQ – MTY	DIG - RM
03	12 Oct 2018	Contents change	RGQ – MTY	TEC - CC

Note on revision 03 – 12 Oct 2018

- ~ Data sources in chapter 2 have been edited
- ~ Former chapters 4 (SmartLink User Interface Symbols) and 5 (SmartLink – SmartWaves Operation) have been moved to the end of the document
- ~ All pictures of chapter 6 have been updated
- ~ Chapter 6.2.2 has been better clarified
- ~ All pictures of chapter 7 have been updated
- ~ Correction of typos and formatting across the document.

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4. SMARTPAGER APPLICATION

4.1. CONNECTION STATUS

4.1.1. 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 ward to which the pager is associated
- Public mode: indicates that you are in Public Mode (when you are in Private Mode there are no writings)
- Sound icon: indicates whether the sound of your device is active or set on mute

  NOTE: the sound options can be accessed and changed only from the SmartLink Server by someone with Administrator rights.
- Battery: shows the charge level of the smartphone
- Options: open the Options Menu
- Alarms: shows if there are pending alarms (the dot in the upper-right corner of the button) and allows to access the alarms list



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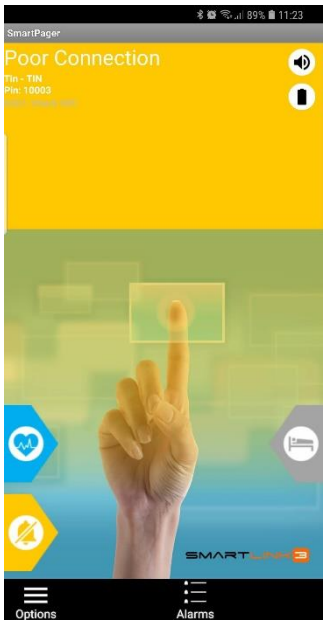
4.1.2. Poor Connection

When the background of the Home Screen is yellow, the device's connection to the server is unstable. In this case you may receive the alarms with some delay.



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4.1.3. Error – Not Connected

When the background of the Home Screen is red, the device is not connected and 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:

- Default ringtone: every 10 seconds the phone gives two “bips” and vibrates;
- Increasing ringtone: the phone sounds and vibrates with the following pattern:
    a) after 10 seconds with 2 “bips”,
    b) after 9 seconds with 3 “bips”,
    c) after 8 seconds with 4 “bips”,
    d) after 7 seconds with 5 “bips”,
    e) after 6 seconds with 6 “bips”.
- Only vibrate: the phone vibrates only.

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

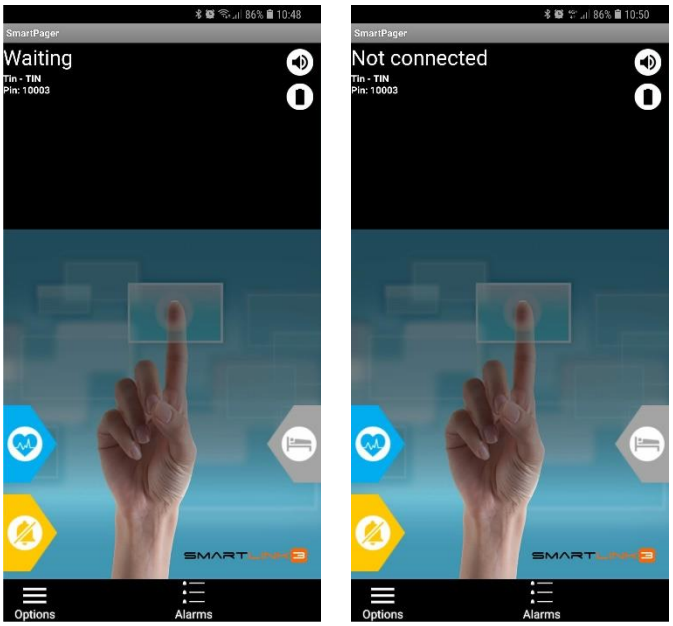
- Tap “Restart” in the Options Menu
- Check if you are connected to the right WiFi network
- Get closer to the WiFi network (you could be out of range or have a weak signal)

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

4.1.4. Not Connected/Waiting

When the background color 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 SmartLink server, but it is trying to reconnect.



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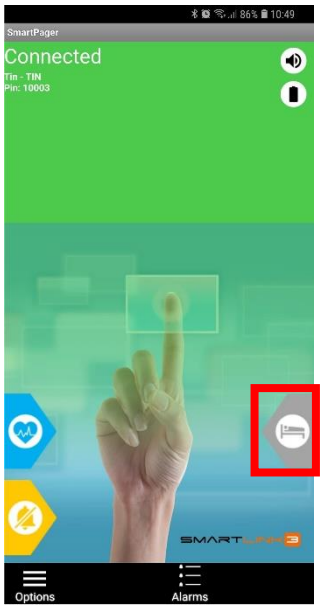
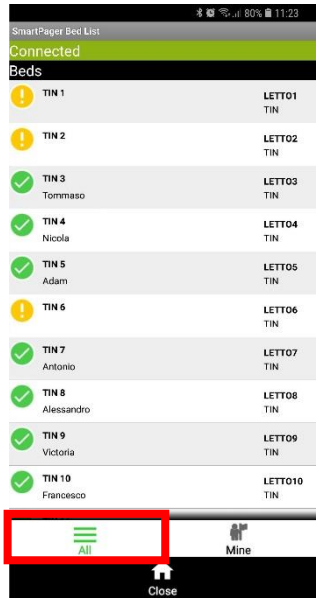
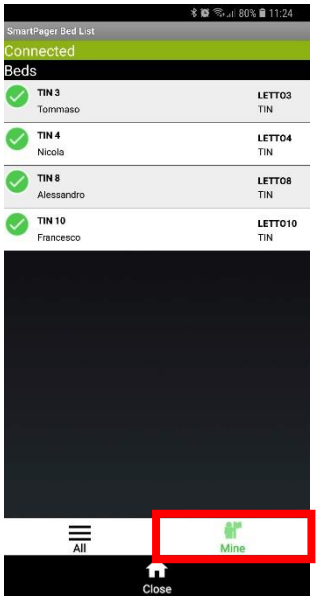
4.2. SMARTPAGER HOME SCREEN BUTTONS

4.2.1. 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 ward or just the beds assigned to you.

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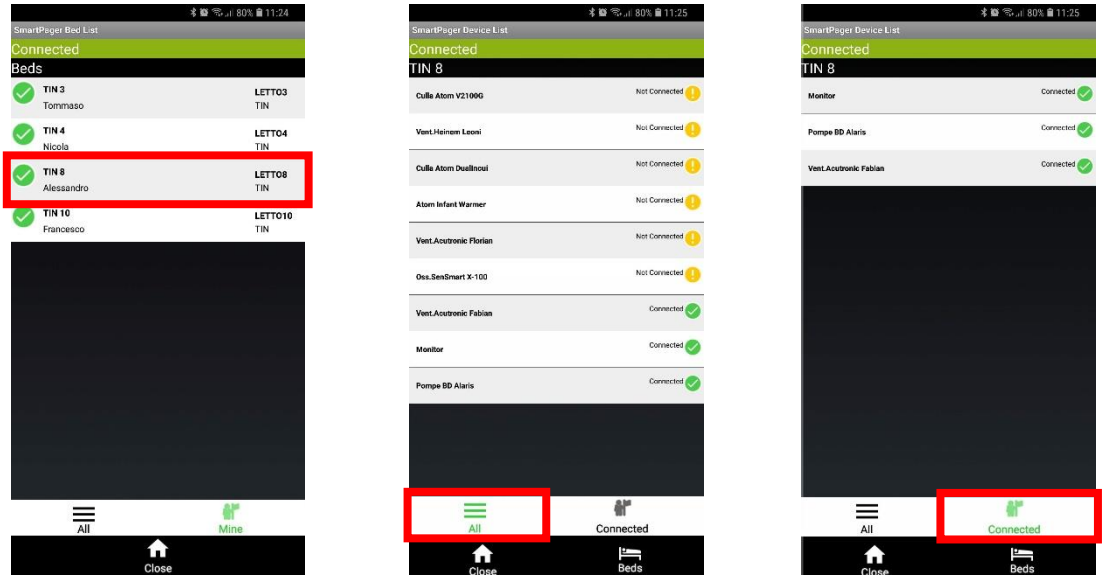
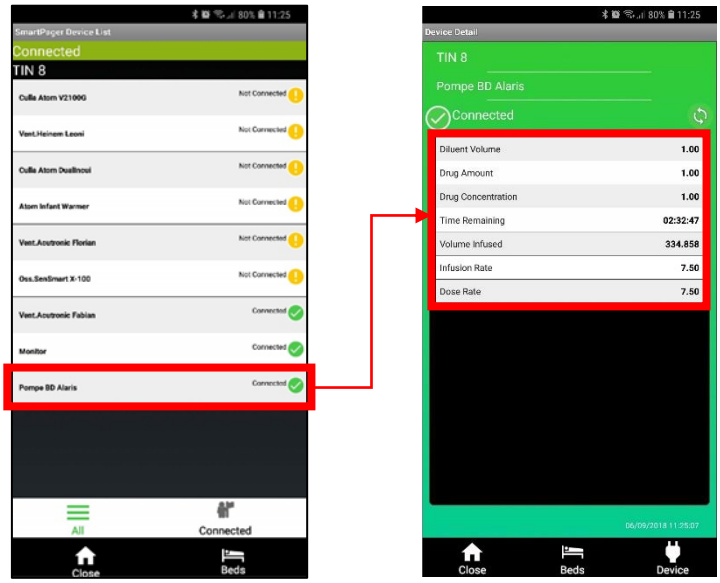
For each bed, by tapping on the corresponding row you can see to see the devices in use for that bed.

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 it is possible to see the parameter that it sends in real time.



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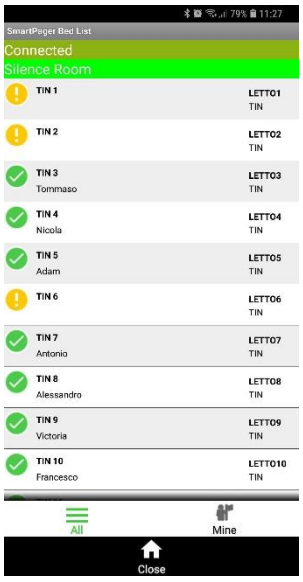
4.2.2. Silence Room

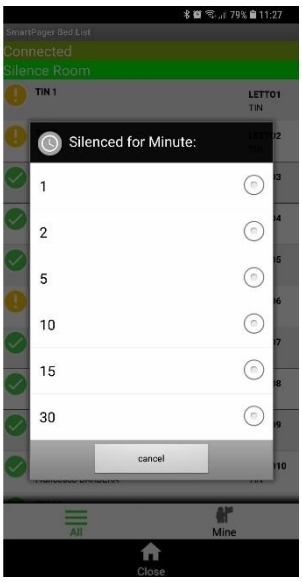
The Silence Room slider allows to select which room the nurse want to silence and for how much time. Once the room is silenced the nurse will not receive the alarms coming from the patient in that room.

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 room assigned.

The room stays silenced for the time selected or until the nurse moves the pager.









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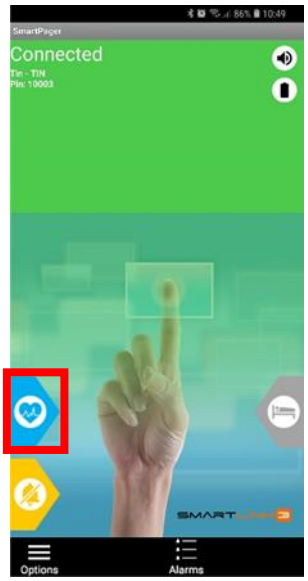
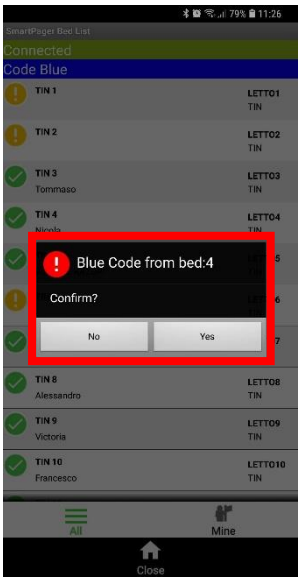
4.2.3. Blue code

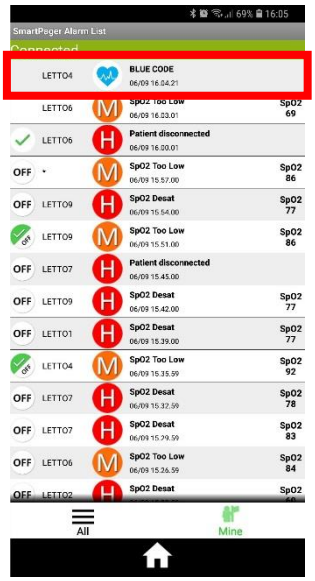
The Blue code slider allows to send a help me request for a specific room in case of emergency.

Slide the blue code and select the room where you need help, then confirm your action.

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







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4.3. THE ALARM SCREEN

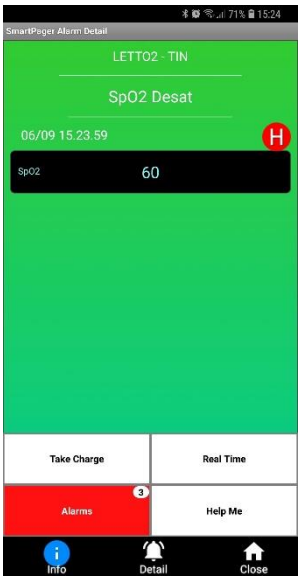
When a new alarm occurs, the device sounds and vibrates and shows the alarm info.

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

The alarm's information are, from top to bottom: Patient's bed number and ward, alarm description, date and time when the alarm occurred and alarm severity, parameter and parameter's value that triggered the alarm.

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, Detail, Close.





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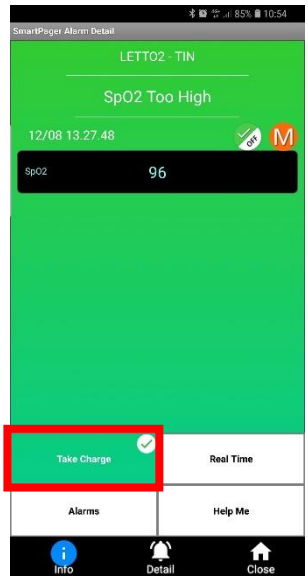
4.3.1. Take Charge

By tapping Take Charge you take in charge 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.



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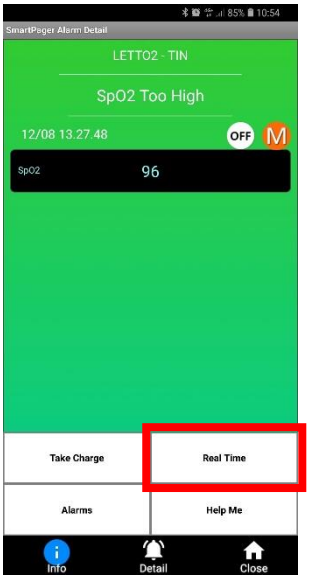
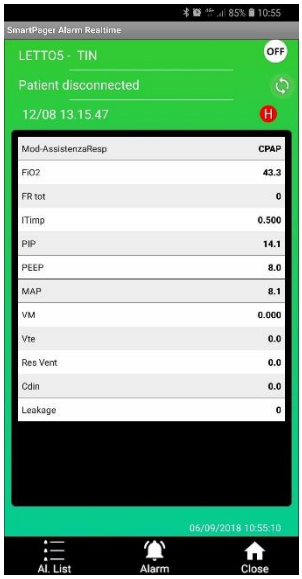
4.3.2. Real Time

By tapping Real Time you will see, apart from the basic information (patient's bed number and ward, 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 actually 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, the Real Time can show the patient waveforms directly from the manufacturer's app.

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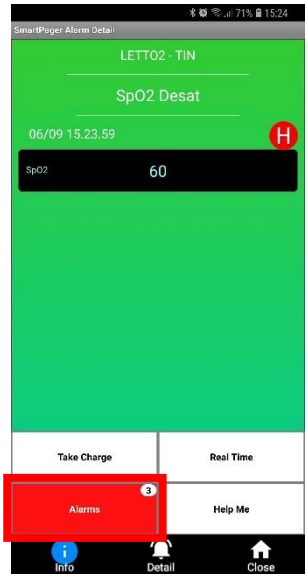
4.3.3. Alarms List

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 all the alarms occurred up to the last one. It is continuously updated by downloading the information directly from the server to let you have all the alarms that occurred, even if the device disconnects from the internet network or if you just turned it on. 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 bed number
- the alarm severity
- the alarm description and the date and time when the alarm occurred
- the parameter’s value that triggered the alarm

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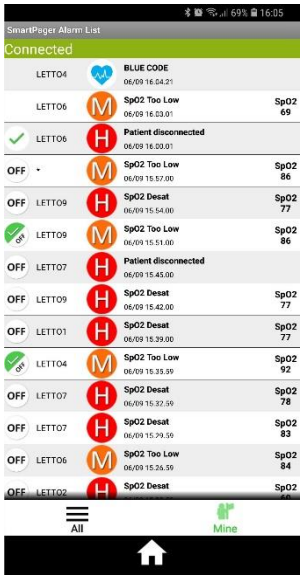
By tapping on an alarm, you can have more information about it.

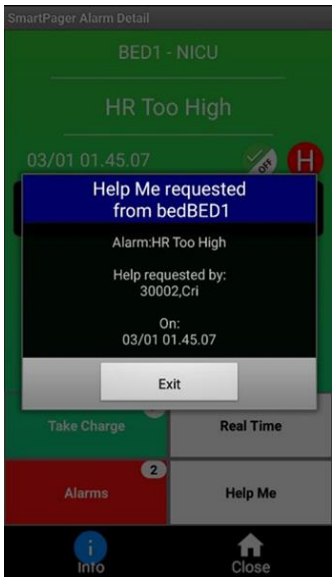
At the bottom of the screen you can choose between seeing all the alarms that occurred in the ward (All) or just the alarms associated with the pager you are holding (Mine).



4.3.4. 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.





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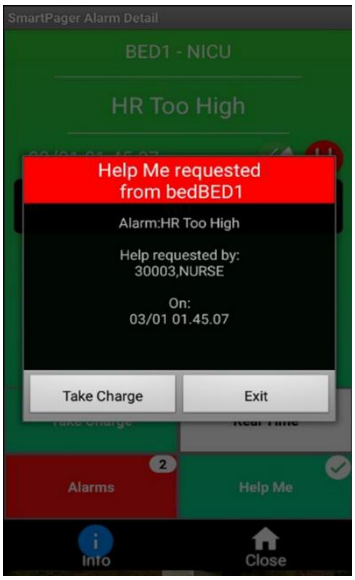
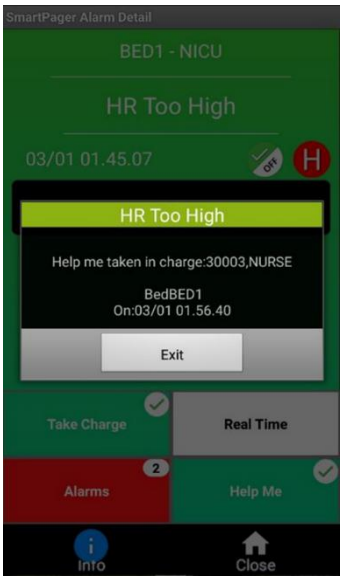
When the help request is sent, this screen appears on the pagers that receive the help request:



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



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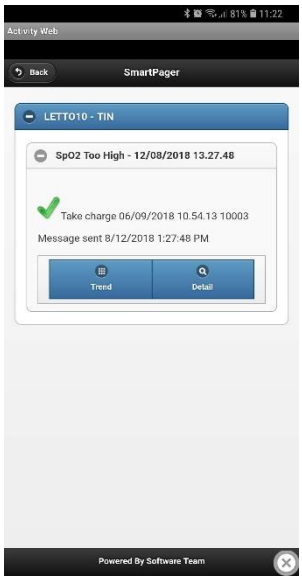
4.3.5. Info

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



4.3.6. Detail

By tapping Detail, you see a screen that allows to see the alarm's trend and the alarm's details. If the alarm has been already taken in charge, you will see the information concerning who took in charge the alarm and when. Otherwise, you will see only when the alarm occurred.



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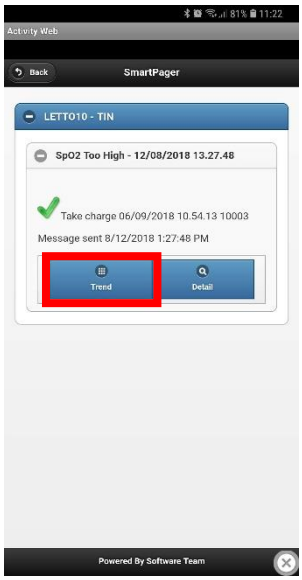
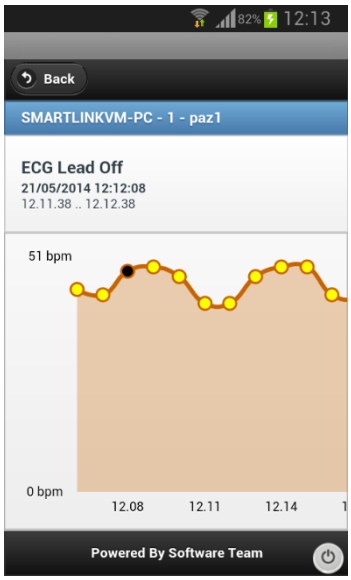
4.3.6.1. Trend

By tapping Trend, you can see a one-minute time span of the alarm's graphic trend; you can move 30 seconds back and forward in the trend each time you tap the dedicated buttons.

Each dot in the trend represents an event that occurred around the alarm, while the black dot represents the alarm you are currently viewing.

By tapping on a dot you can have more information about the event the dot refers to.





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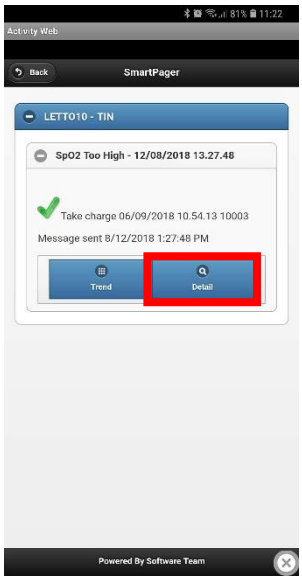
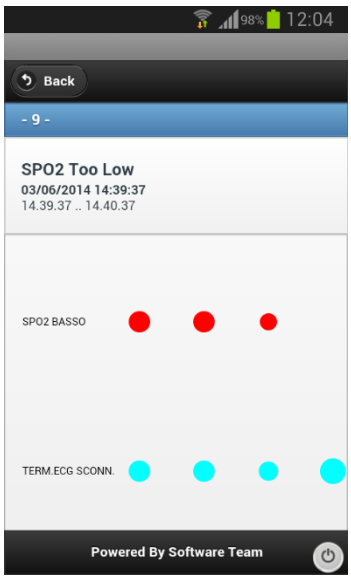
4.3.6.2. Detail

By tapping Detail, the alarm details are shown.

Each dot represents an event, and here are shown all the events that happened in the same minute when the main alarm took place.

The dot's size indicates for how many seconds the event persisted; by tapping on a dot you will see the exact amount of time.





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4.3.7. Close

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



4.4. OPTIONS MENU

The Options Menu is accessible by tapping “Options” in the lower-left corner of the screen, when you are in the application Home Screen.



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In the Options Menu six options are available:



4.4.1. Restart

Reboots 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 rebooting the service.

4.4.2. Admin

SmartPager asks for the password to access the Administrator options. As a user, you don't need to access this section.

4.4.3. Help

Opens the built-in help guide.

4.4.4. About

Gives information about the SmartLink and SmartPager versions and Software Team references (email and website).

By clicking More you can access the Product and Safety information:

- Manufacturer: information about Software Team.
- Product Identification: information about the product and the safety of the product regarding the CE certification.
- Intended Use: information about the clinical purpose of the application and the operational environment.
- Notice: precautions and warnings regarding the product.
- Credits: information about the developers, the testing team and the design team.

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4.4.5. Pager Assignment

Contains information regarding which beds are assigned to whom.

NOTE: More info on this can be found in chapter *6.5 Pager Assignment on Pager*.

4.4.6. More

Beds list → Contains the information about the beds connected to the data source (SmartLink). You can find details regarding the ward where the bed is, the patient name and ID number, the bed status (Online if it is connected, No Data if it is not connected to the data source. NOTE: if the monitor is offline or on standby it doesn't appear in the beds list) and the monitor type (the model of the monitor). The Refresh button allows you to reload the beds list.

Change mode → Switches the application mode between Private and Public. The first one means that the smartphone must be used from inside the hospital, the second one from outside the hospital. "Change mode" is visible only if there is a public IP set in configuration.

NOTE: the application can be used from outside the hospital only if the hospital has a public IP address and the smartphone can connect through a GMS connection.

NOTE: this option may not be active on your pager. For more information ask your system administrator.

Use on background → Allows to use SmartPager in background mode, which means that it is possible to use the phone outside of SmartPager (you can use phone, messages, contacts and settings) while SmartPager is still connected and able to receive alarms in the background. If an alarm occurs, or the pager disconnects (the screen becomes red) SmartPager comes back at the top of the screen.

NOTE: this option may not be active on your pager. For more information ask your system administrator.

Stop Service → Stops the SmartPager service (asks to confirm the action before proceeding). In this case SmartPager cannot receive alarms ("Not Connected" black screen).

NOTE: this option may not be active on your pager. For more information ask your system administrator.

Change department → Allows to change the department from which the pager receives the alarms.

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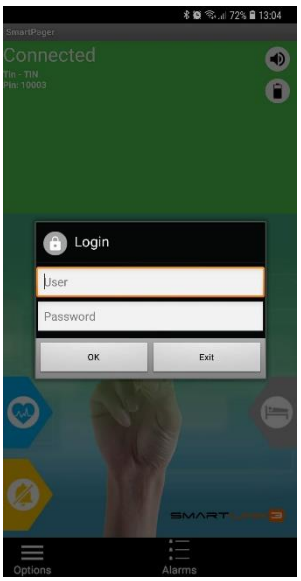
4.5. PAGER ASSIGNMENT ON PAGER

Pager Assignment on Pager allows to assign beds to pagers directly on SmartPager.

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





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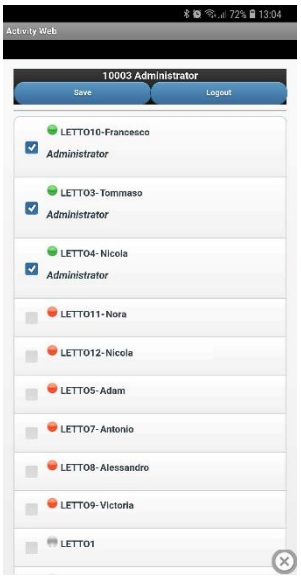
The screen that follows shows the list of the care groups that you can associate to the pager. Select the care groups that you want to associate to the pager and then tap Save.



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

- Assigned → Green
- Not assigned → Red
- Assigned to other users → Blue
- Assigned but with the shift not active → Yellow
- Inactive → Grey

From this screen, the nurse selects the beds under her/his 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.

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5. PAGER ASSIGNMENT VIA WEB

The Pager Assignment web allows authorized users to associate care groups to pagers for a selected shift.

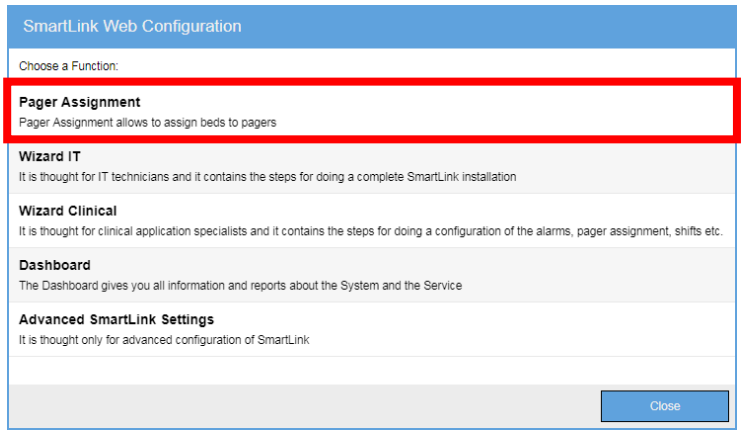
To manage the assignment function open Google Chrome or Mozilla Firefox and go to:

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

* change *[ServerIP]* with the IP address of 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”.





NOTE: each username is associated to a ward, so when you login you will see only the associated ward.

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

- On the left you can select the ward, the shift and the action;
- On the right you can select the pagers to be assigned to the ward and to the shift.

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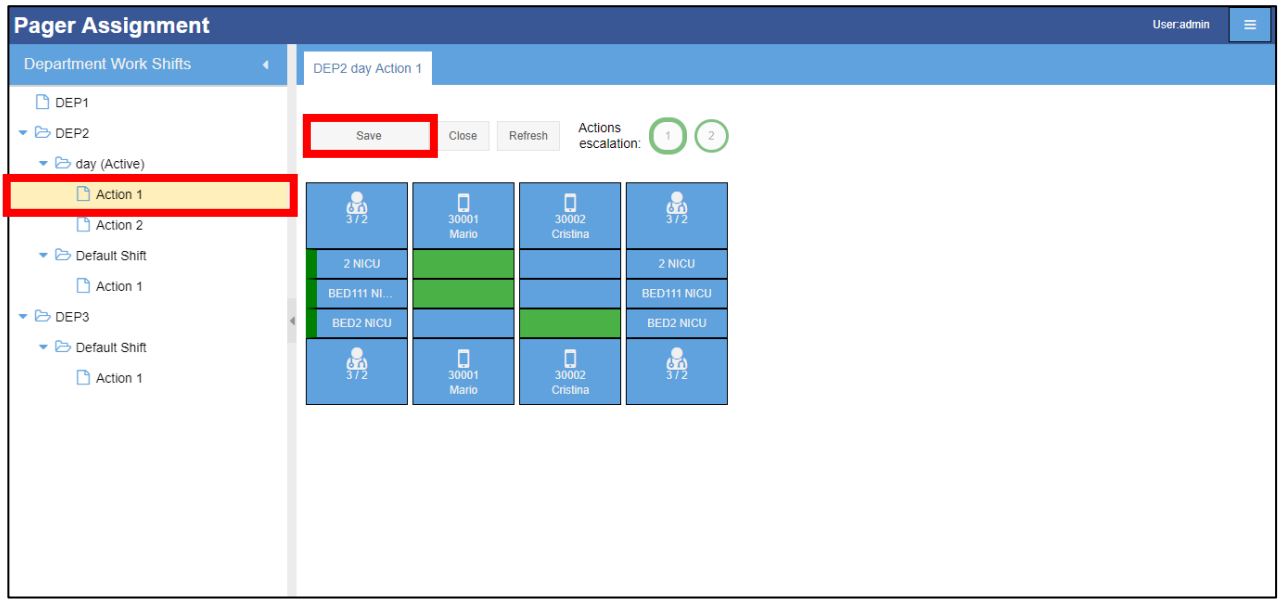
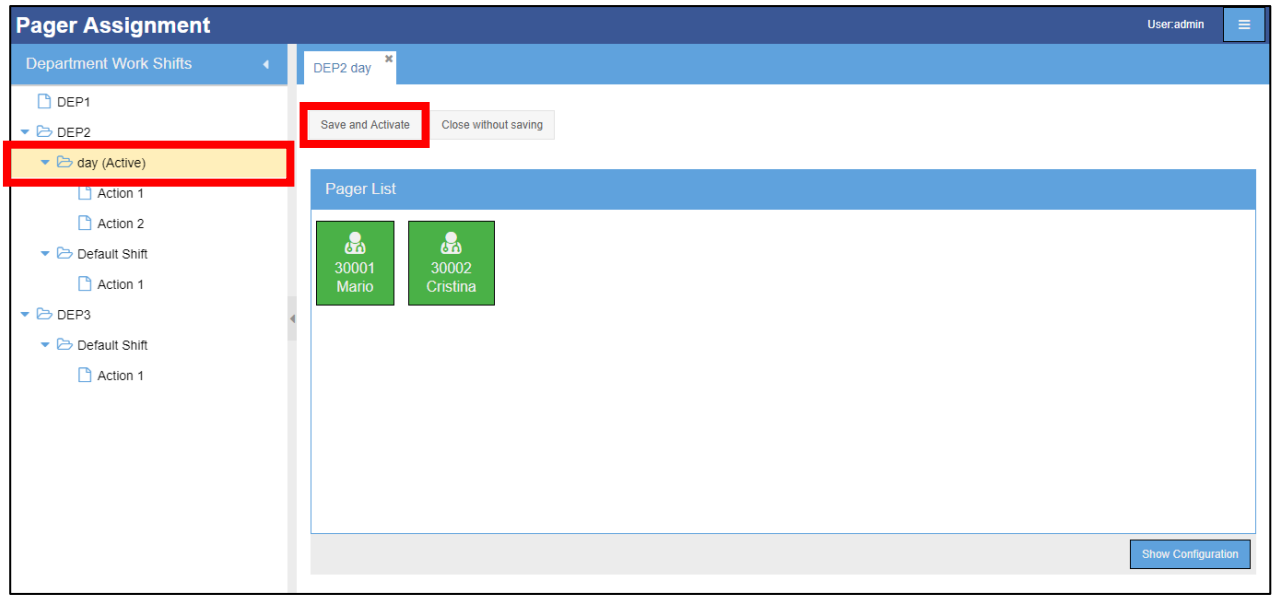
For associating the pager to the care groups and the to the user:

1. Select the action: select the pager or DECT that will be associated to the care groups and will receive the alarms from that groups 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.



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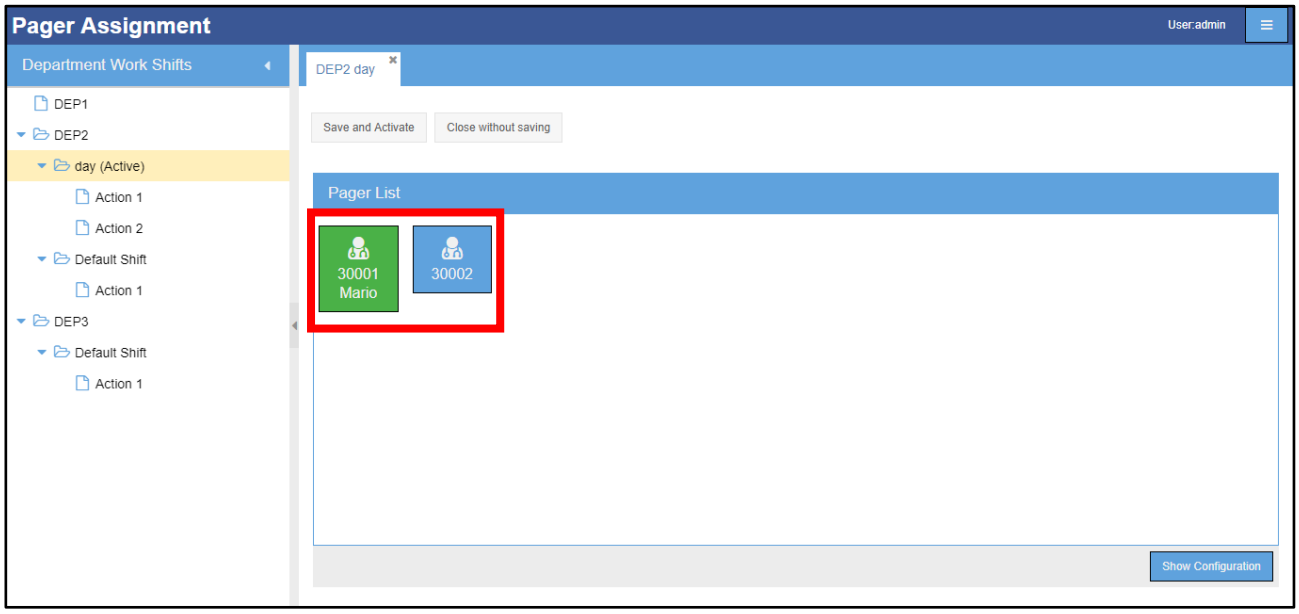
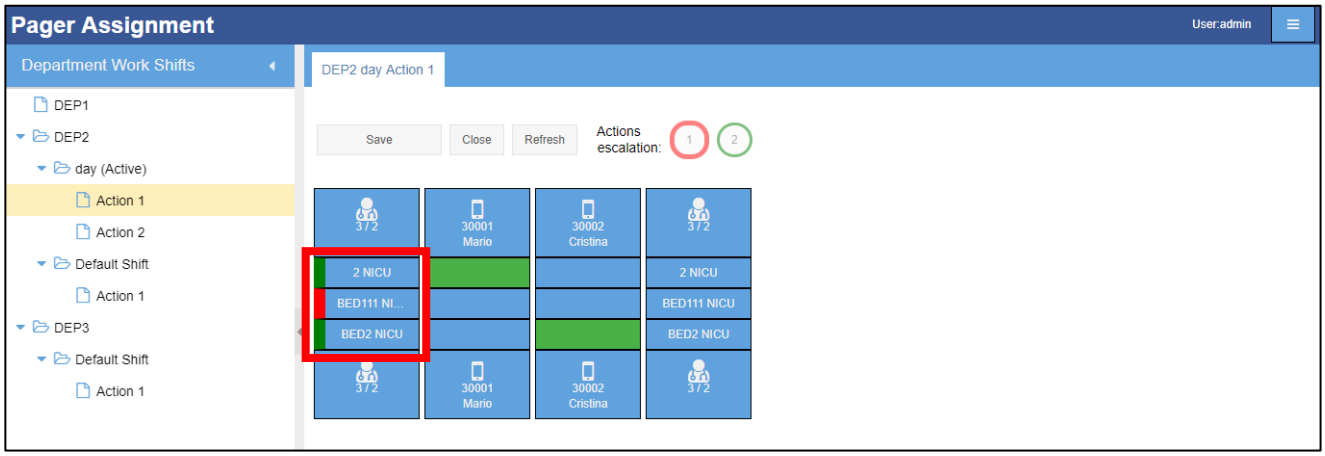
3. Clicking on the shift again you can associate a user to the pager: the associated pagers are highlighted in green.



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

5.1. HOW TO CHECK IF THE ASSIGNMENT IS CORRECT

5.1.1. Check the care groups



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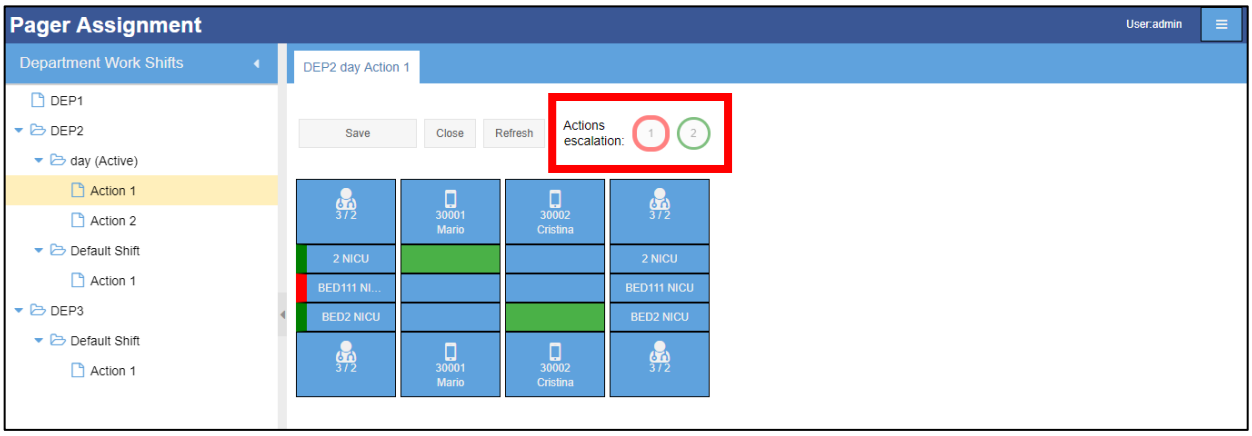
If the care group is:

- ~ Red: no pagers are associated to the care group (no one will receive alarms from this care group);
- ~ Yellow: there are not enough pagers associated to the care group;
- ~ Green: a number of pagers equal or greater than the minimum required is associated to the care group (correct configuration).

5.1.2. Check the actions



If the action is:

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

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6. SMARTLINK USER INTERFACE SYMBOLS

In the main menu of SmartLink 3, the following symbols are used:

	**Apps:** open the applications menu
	**Waveforms:** view real-time waveforms and parameters
	**Alarms:** alarms management and taking-charge
	**Trends:** view graphic and tabular trends
	**Advanced Search:** search archived patients and view trends and replays
	**Summary Reports:** run the summary reports management app
	**Logout:** exit from the application
	**Languages:** change display language
	**Show Guide:** show on-screen hints
	**User Manual:** open SmartLink user manual
	**Power Off:** power off SmartLink

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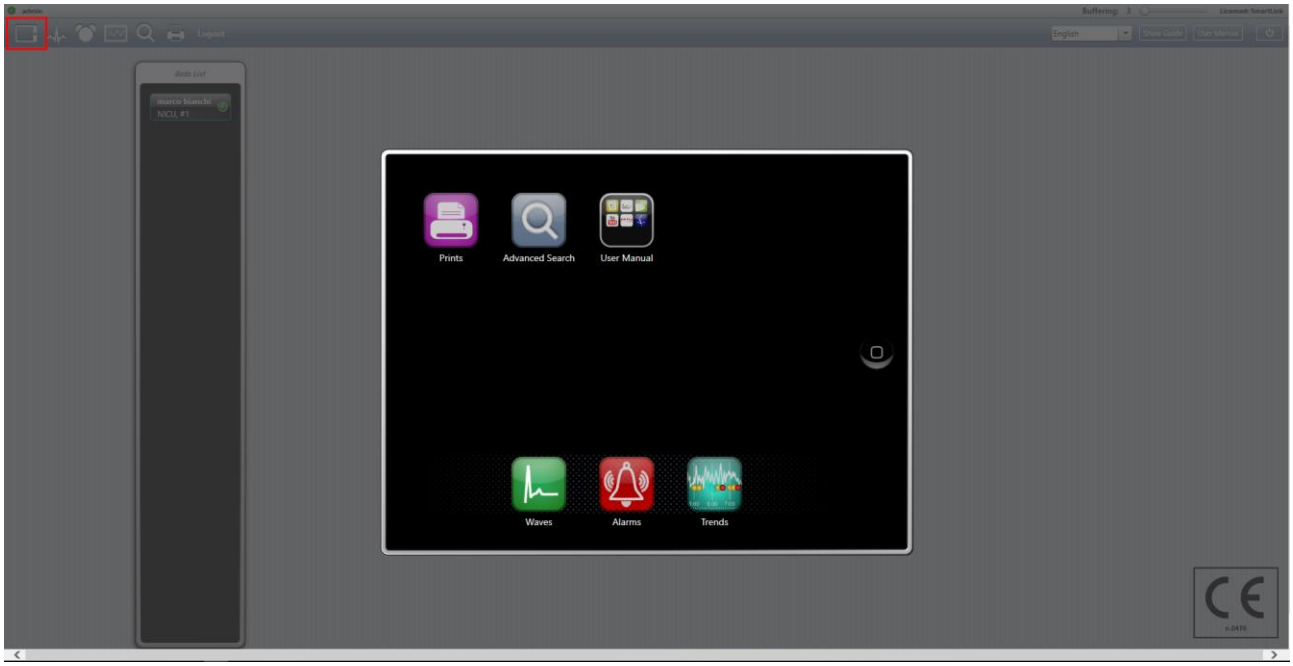
7. SMARTLINK- SMARTWAVES OPERATION

7.1. APPS

The “Apps” icon opens a menu with all the available applications.



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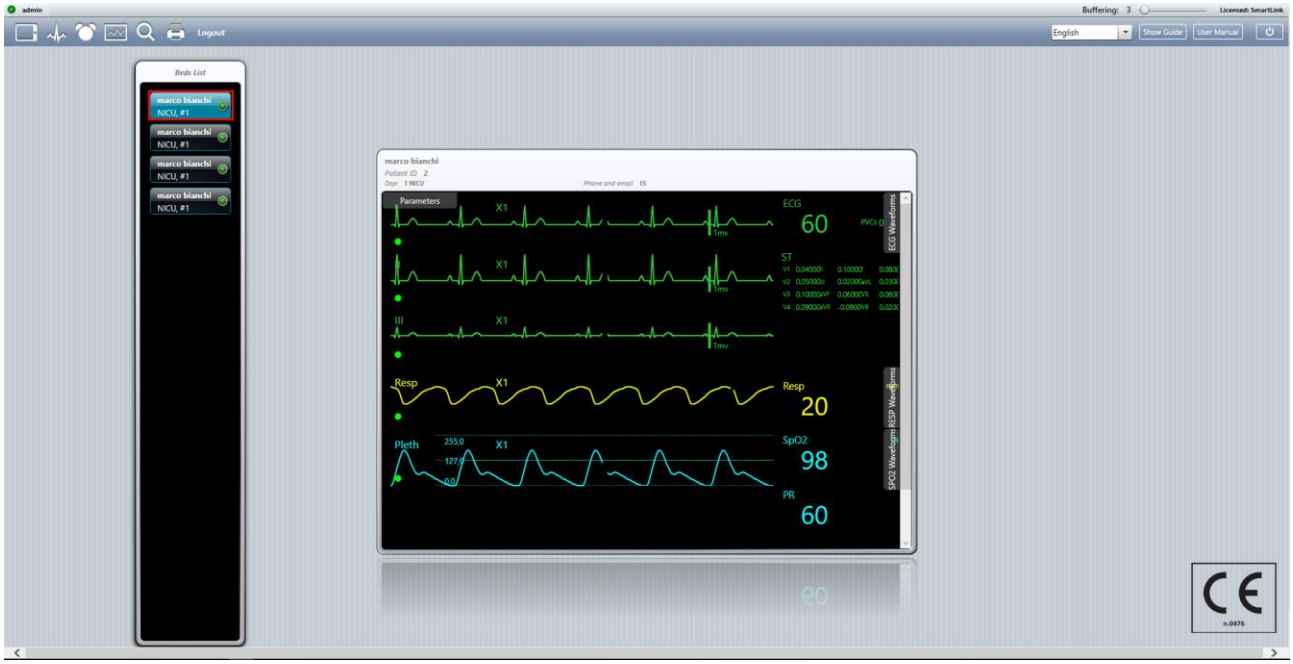
7.2. WAVEFORMS

A few seconds after selecting this option, on the main screen you can see the list of active beds.



By clicking or tapping on one of the available beds, the real-time waveforms display of the selected bed starts.



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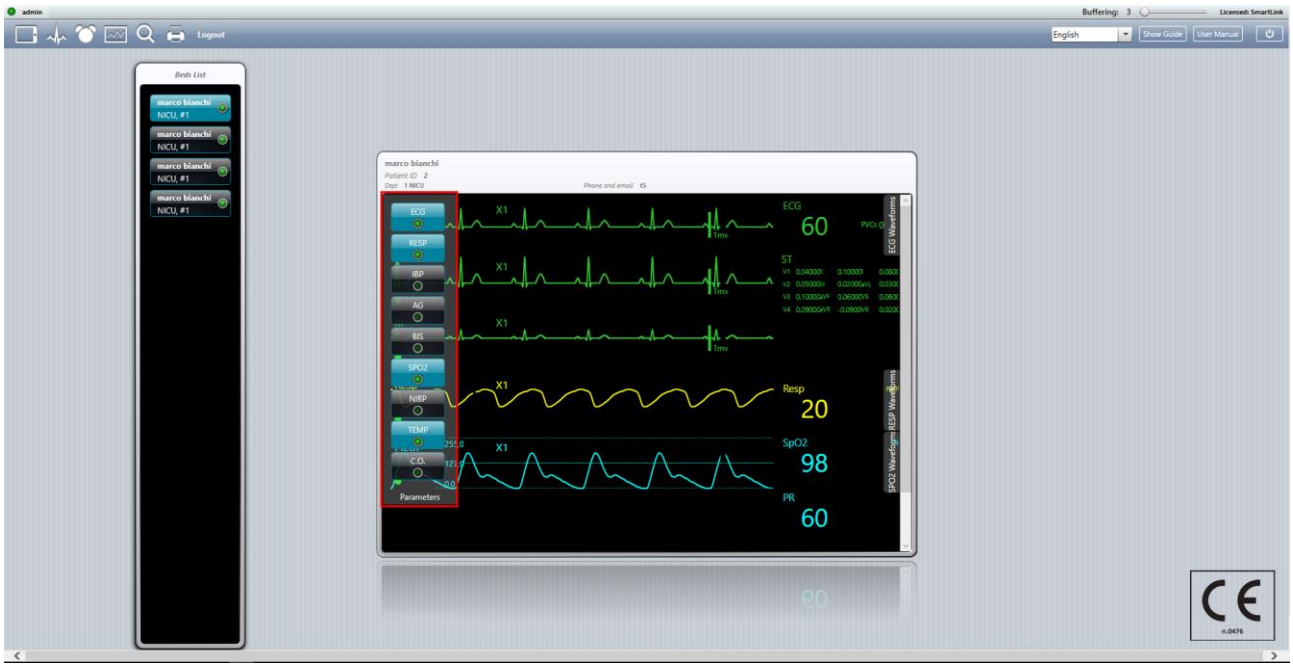
It is possible to choose which parameters to show in the real-time window by opening the “Parameters” label, on the top-left of the real-time window. The parameters highlighted in blue are the active ones.



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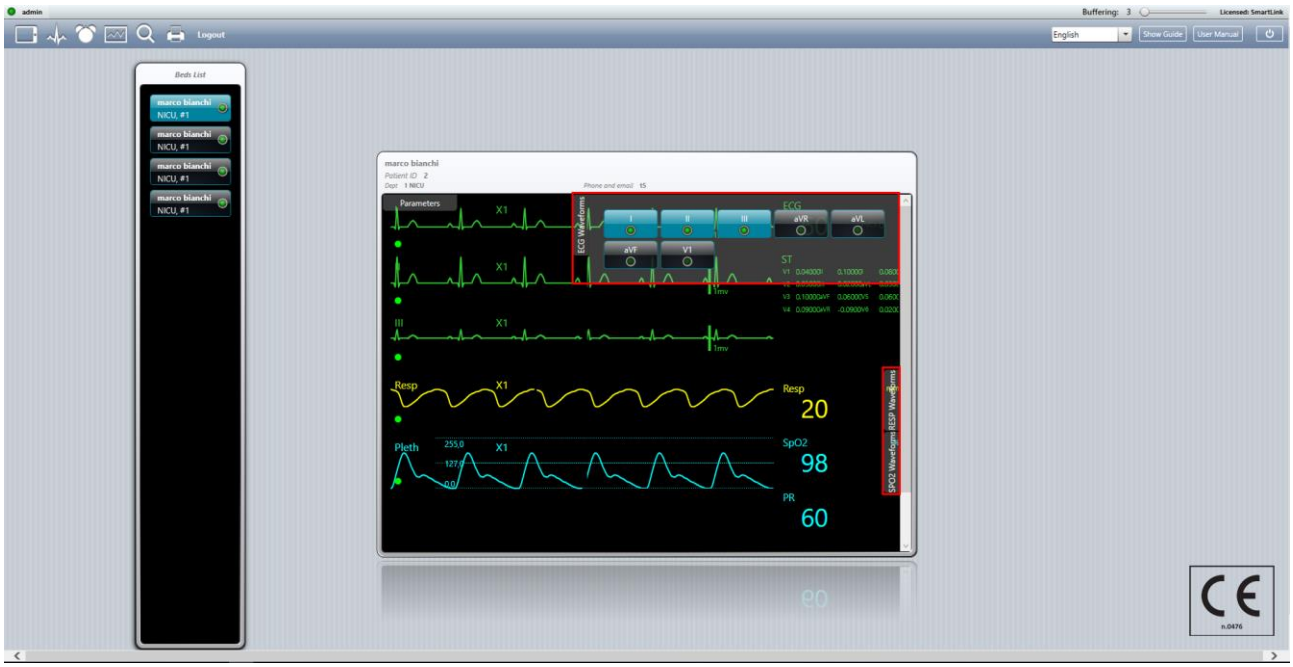
Each parameter has a “Waveforms” label on its right side. By opening the “Waveforms” label you can choose which waveforms you want to display. The waveforms highlighted in blue are the active ones.



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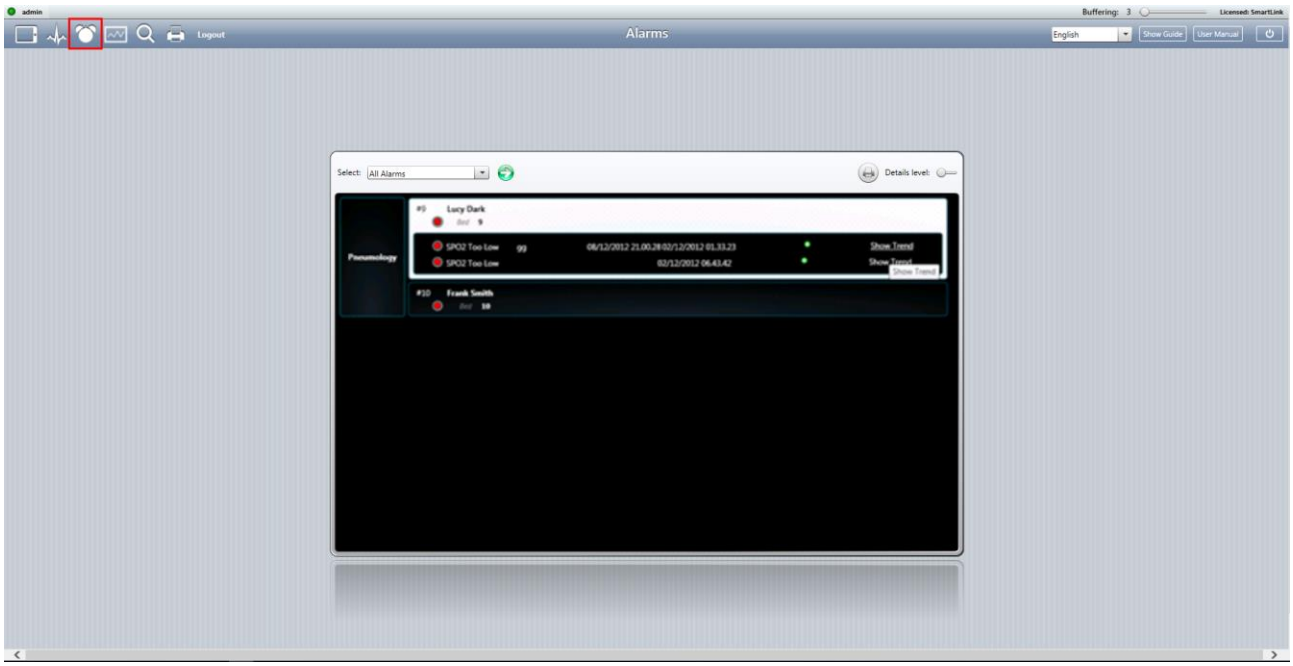
7.3. ALARMS

The “Alarms” icon opens the alarms management function.



The alarm function of SmartLink 3 is a selective tool that, after filtering the alarms using customer-defined rules, sends messages to smartphones or PCs (SMS and emails) using escalation rules.

This screen shows, for each patient having notified alarms, the alarms list and the taking-charge status.

By clicking or tapping on the “Show Trend” link, on the right side of each alarm, the graphic trend of the related parameter is displayed. From this trend a waveforms replay can be run.

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7.4. TRENDS

The “Trends” icon opens the trends management for the selected patient (the one for which the waveforms are currently displayed).



The trends can be zoomed up to a resolution of one pixel per one second. Right-click and, while holding, move the mouse to select and zoom a section of the trend.

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By clicking or tapping “View Table”, in the upper-right corner of the trends window, the system switches to the tabular view. You can toggle between tabular and trend view using the same button.



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From the trend view, the “Replay” label in the upper-left side of the trend window starts the waveforms replay across the position of the timeline in the graphic trend.



During the replay, the waveforms can be stopped/restarted and the replay speed can be adjusted.

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7.5. ADVANCED SEARCH

The “Advanced Search” icon opens the advanced patients search filters.



The advanced search displays all the patients matching the specified search parameters. Double-click on a patient to display the related graphic trends.

7.6. SUMMARY REPORTS

Respiration summary reports have been designed to give doctors and care givers a synthetic and powerful tool to evaluate the patient's respiration parameters during a selected or predefined lapse of time.

For each selected patient, and for a selected lapse of time, SmartLink creates a document of HR and SpO2 graphs, statistic tables, events marks.

The summary reports can be created manually by selecting a specific patient, or automatically by configuring SmartLink for an automatic scheduled reports creation. In this last case patients can be selected by using different criteria (patients list, data available) (e.g. Automatic reports related to a patient's respiration data collected during the night can be planned at 6:00 am).

New reports are listed in the "Planned Reports" section; an orange dot is displayed on the “Print” icon showing the number of the reports available for printing.

Available summary reports need to be confirmed: the doctor must add his comments in the conclusions box, then review and approve the report. After confirmation, reports are printed. A copy of each document is saved into SmartLink database to be available for searching, displaying and re-printing.

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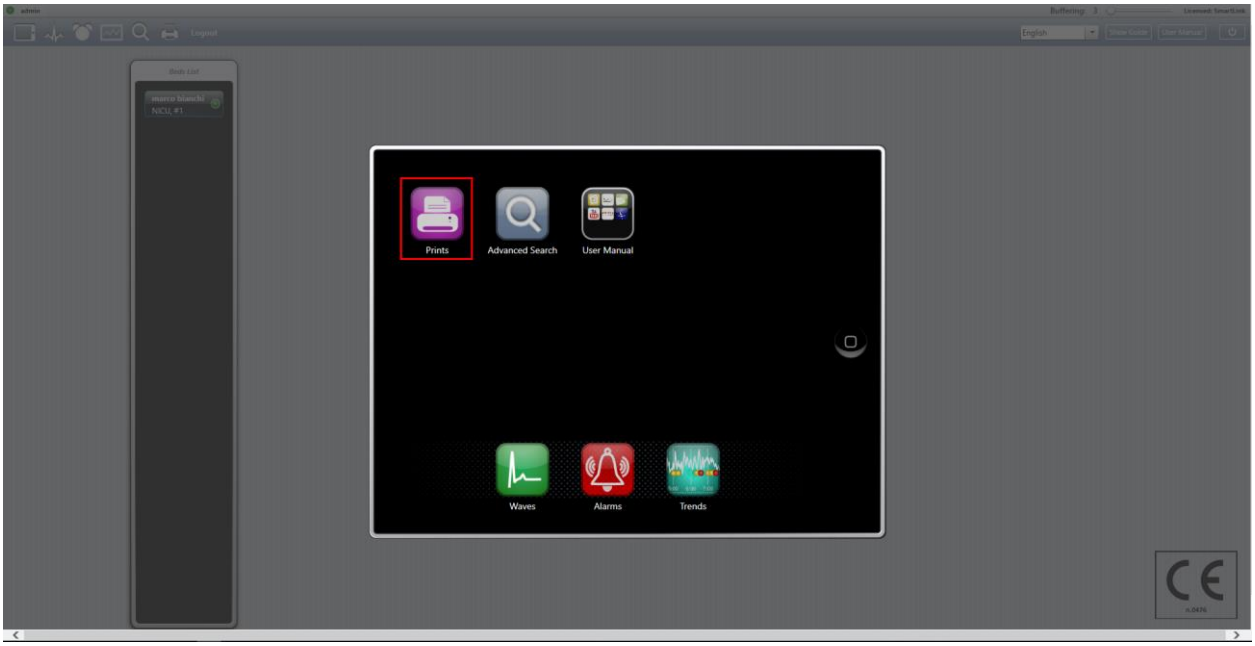
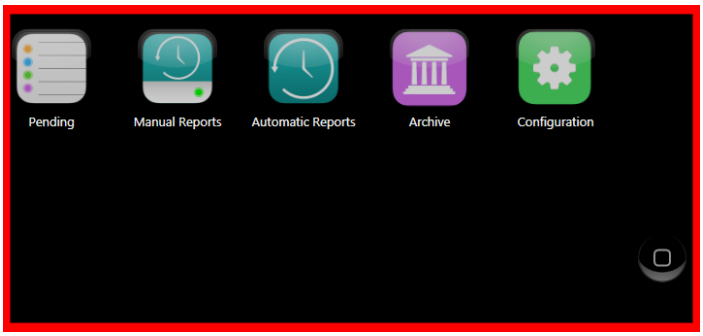
Click or tap the “Apps” icon and choose “Prints”.



From the “Prints” menu you have 5 options: Pending, Manual Reports, Automatic Reports, Archive, Configuration.



~ **PENDING**

The “Pending” function is the first to appear as per default. By using this function the user can view the pending reports available, add comments on them and finalize the process by printing and saving the reports.

The first action is to select a patient from the "Pending" list on the screen: the summary report is displayed in the main window.

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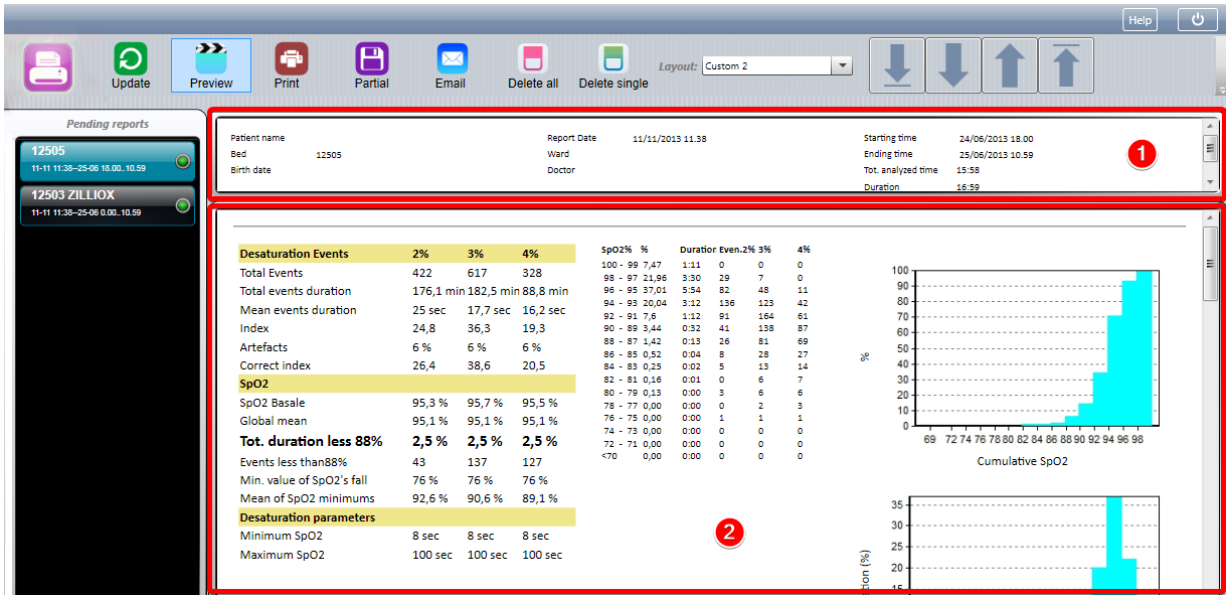
The summary report is composed of three sections:

1. The upper section displays the personal data and the period of time considered.
2. The central section is composed of the main part of the report (graphics, statistics, events list, ...). Use the scroll bar on the right to browse the page or use the shortcut buttons in the upper side of the screen. This part of the report can be configured and customized by selecting/deselecting several elements and/or artefacts.
3. The lower section, the “Conclusions box”, must be used by the doctor to add free text such as clinical comments.



The menu at the top is composed of:

- Update: refresh the list of the pending reports available; new reports are added and confirmed/printed reports are removed.
- Preview: display the print layout of the report.
- Print: finalize and print the report after adding comments.
- Recalculate: recalculate data when elements and/or artefacts are selected or deselected.
- Save: save report changes without confirming and printing or to allow further changes.
- Email: send the report by email.
- Delete all: delete all reports from the list.
- Delete single: delete a single report from the list.

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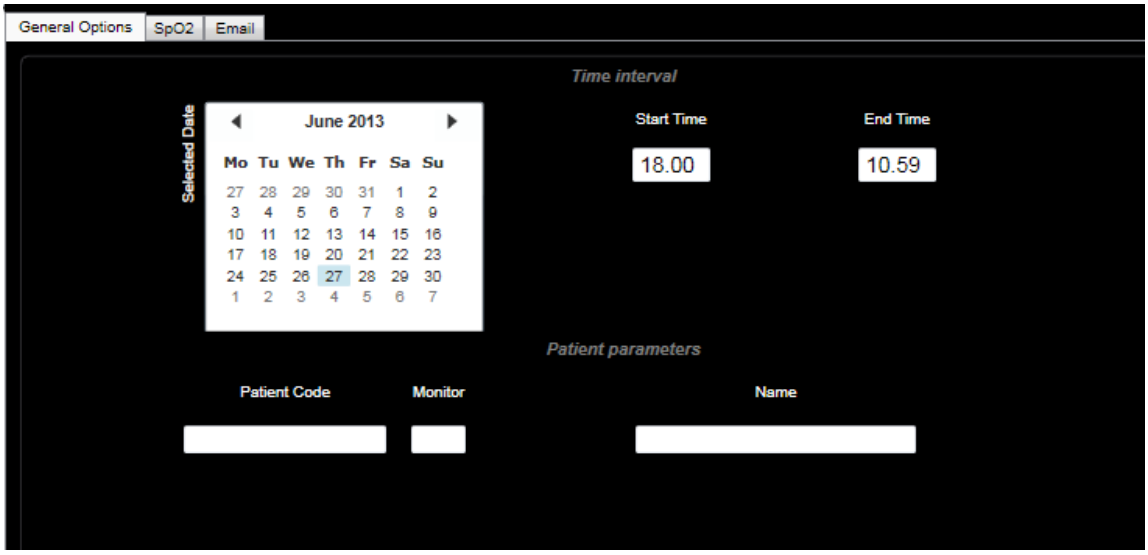
~ **MANUAL REPORTS**

By using this function, the user creates a summary report for a single patient. After choosing the patient, select a day from the calendar and set the time interval needed.



In the main window the user can configure the search parameters:

- Time interval: start/end date and time
- Patient parameters (patient's code, monitor, name)

Note: the end time can be set to include part of the next day (the maximum time interval is 23 hours and 59 minutes).

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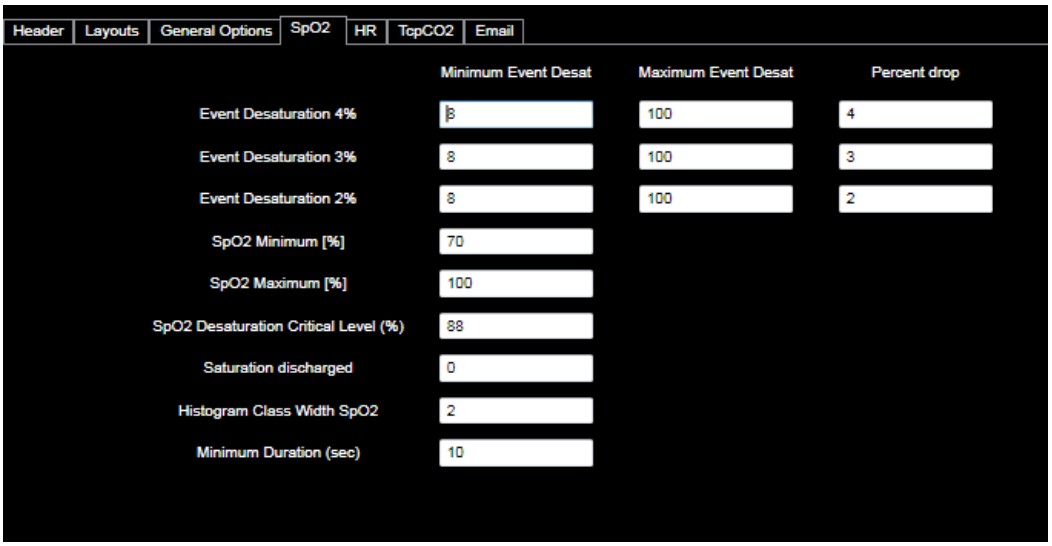
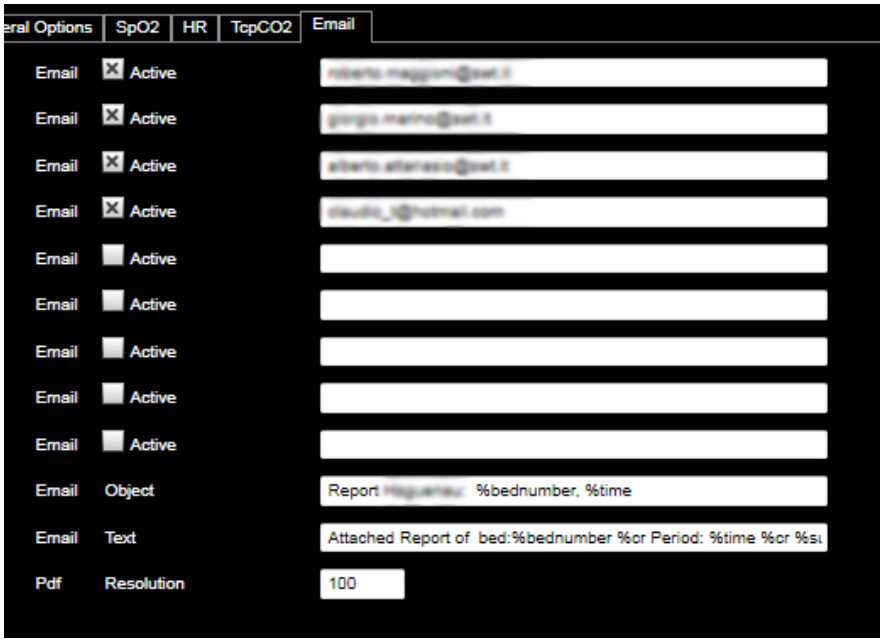
In the SpO2 tab you can change the parameters used for the data processing (e.g. thresholds values to identify an SpO2 desaturation as an event).



In the Email tab you can change the list of recipients that will receive the report.



The bottom menu is composed of:

AUTOMATIC REPORTS GENERATION: reports are processed automatically, and will be put into the “Pendings“ list (only for Report choice).

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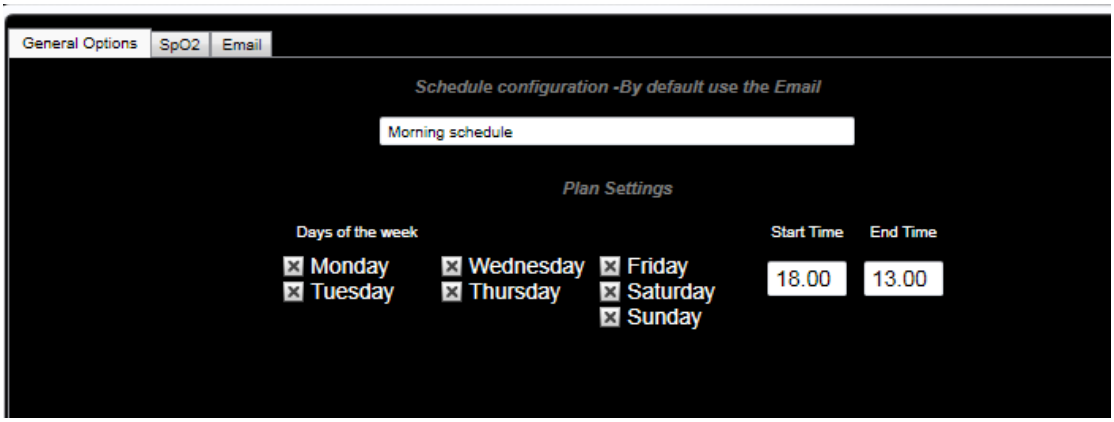
MANUAL REPORTS GENERATION: available patients are listed in the left panel: click on one listed item to select it for reporting. Then type the “Process” button. The reports will be made for the selected patients and the system will switch directly to the “Pendings” function (only for Report choice) for inserting comments and finalize and print the reports.

Clear: to clear the current parameters and start a new search.



~ **AUTOMATIC REPORTS**

By using this function, the user (having the proper rights) plans data processing to automatically have "ready to use" reports at a specific time.



In the configuration window the user can set and save up to five different configurations (displayed on the list on the left).

Configuration parameters:

- File name “provide a name for this schedule”
- Days of the week to be processed
- Time interval: start/end date and time.

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The bottom menu is composed of:

- Refresh: clear the current configuration
- Save: save the current configuration (automatically start 5 minutes after the "end time")
- Run Now: run the current configuration



~ **ARCHIVE**

This tool displays reports that have been already printed and stored.

To run a search, it is necessary to use specific keywords referred to the following criteria:

- Patient's surname
- Date (dd/mm/yyyy)
- Department
- Doctor's surname
- Bed

Conclusions (free text typed in the conclusions box)

The search results are listed in the list on the left.

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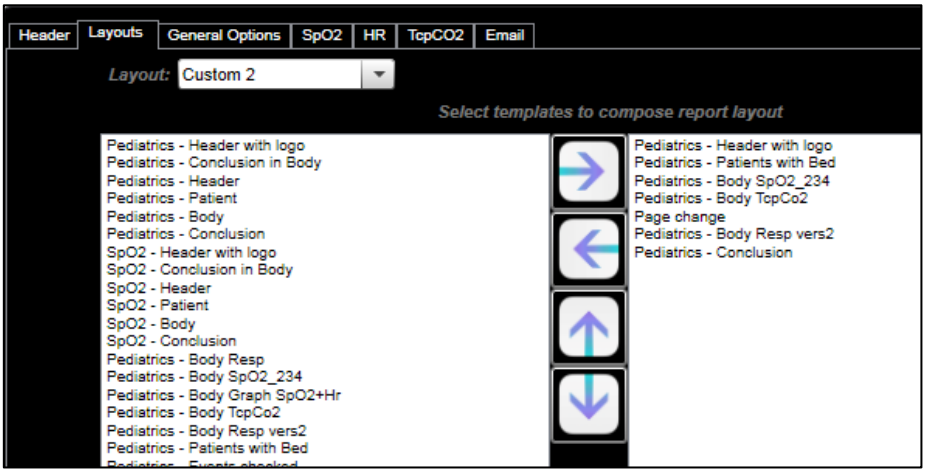
~ CONFIGURATION

The Configuration function allows to customize:

Header → Composed of 4 fields (Facility Name, Name, Address, City). It is possible to use an image in the header: the image must be 90x90 and must be called header.png. Place the image in c:\inetpub\wwwroot\smartlink.



Layouts → Use the layouts screen to select a layout or configure your own: there are up to five layout configurations (e.g. synthetic, extended. with artefacts, ...). On the left side of the screen you have the list of the sections available. On the right side you see the list of the sections selected for the current layout. By clicking the arrows in the center, you can add/remove a section and change the sections order.



General Options → The General Options screen allows to configure other parameters.

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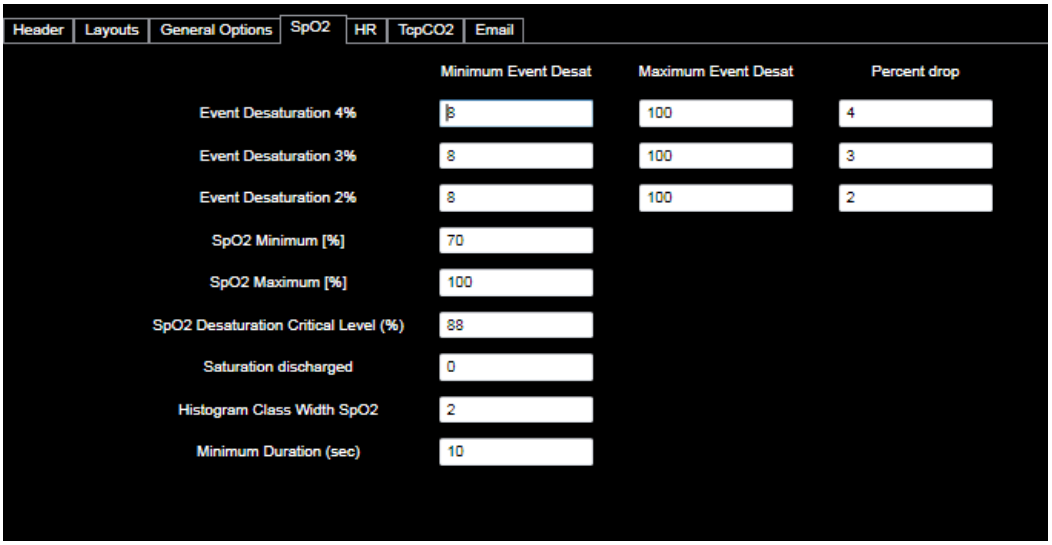
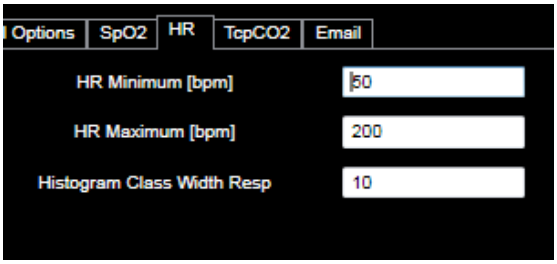
SpO2 → The SpO2 options window is for setting the parameters used for the data processing.



- Event Desaturation: 2-3-4% with Minimum and Maximum Event
- SpO2 Min and Max
- SpO2 Desaturation Critical Level
- SpO2 discharged: Saturation percentage under which the data will be discharged and not used for report computations
- Histogram Class: width
- Minimum duration: seconds

HR → The HR options window is for setting the parameters used for the data processing.



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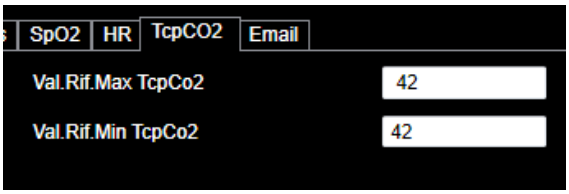
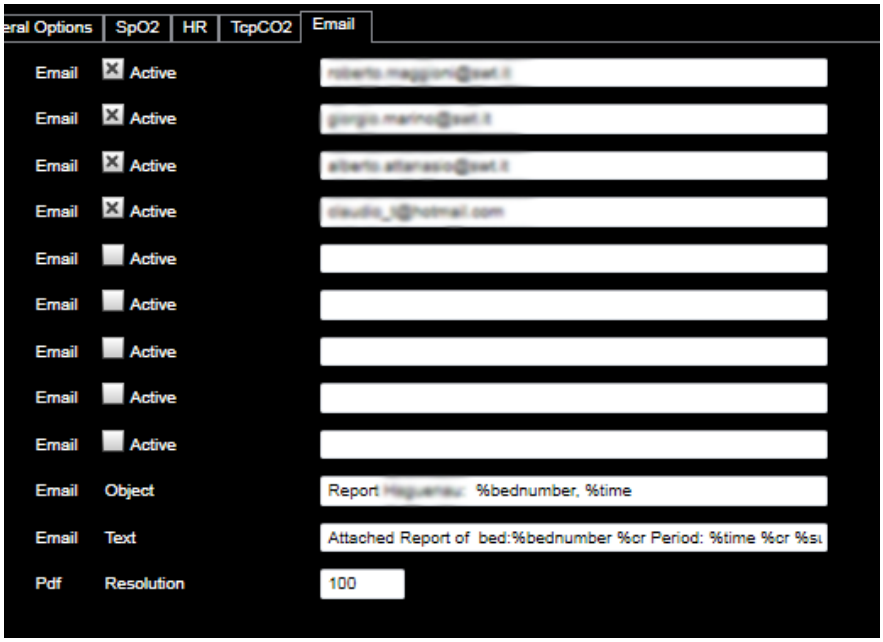
TcpCO2 → The percentage of time under and above two thresholds will be calculated default thresholds: ex % <42% and >= 42%)



Email → Emails can be sent automatically by the scheduler or manually upon user request. The list of recipients is defined here.



- Email Object: the standard subject of the emails.
- Email Text: the standard text (body) of the emails.
- Pdf Resolution = change the quality (and size) of the PDF.

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Using the syntax %field it is possible to insert specific patient's and report's information like bed number, patient name, date of the report:

%bednumber	Bed number
%cr	New blank line (“carriage return”)
%time	Time period
%surname	Surname
%name	Name
%department	Department
%sex	Sex
%doctor	Doctor
%birthdate	Date of birth

SmartReport creates the reports in PDF format. The PDF files are sent as attachments to the selected list of recipients.

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