COGNITO HEALTH®

Prediction is Prevention®

Cognito 3.1A System

User Manual

Cognito Health Incorporation
Cognito 3.1A User Manual
Software Version: 2.0.2
Document Number: MANL-COG005-EN-Vx.xx

The information contained in this manual is subject to change without notice. Cognito Health makes no commitment to update, or keep current, the information contained in this manual.

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Document Symbol Description

⚠ **WARNING**	Remind users of the potential hazards to prevent serious personal injury.
⚠ **CAUTION**	Remind users of the potential hazards to prevent slight or medium personal injury, or equipment damage.

On Product

	Type BF applied part
	Protected from touch by fingers greater than 12 millimeters. Protected from water spray less than 15 degrees from vertical. (For control box)
	The MD symbol indicates the item is a medical device.
	This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Indicates a carrier that contains Unique Device Identifier information.
	取得審驗證明之低功率射頻器材，非經核准，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。低功率射頻器材之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前述合法通信，指依電信管理法規定作業之無線電通信。低功率射頻器材須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

This device complies with FCC Rules Part 15. Operation is subject to the following two conditions:

• This device may not cause harmful interference.

• This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to Part 15 of the Federal Communications Commission (FCC) rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

• Reorient or relocate the receiving antenna.

• Increase the separation between the equipment and receiver.

• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

• Consult the dealer or an experienced radio/TV technician for help.

WARNING! The use of a shielded-type power cord is required in order to meet FCC emission limits and to prevent interference to the nearby radio and television reception. It is essential that only the supplied power cord be used. Use only shielded cables to connect I/O devices to this equipment. You are cautioned that changes or modifications not expressly approved by the

party responsible for compliance could void your authority to operate the equipment.

FCC RF Caution Statement

• **IMPORTANT!** Outdoor operations in the 5.15-5.25 GHz band are prohibited. This device has no ad-hoc capability for 5250-5350 and 5470-5725 MHz.

• **WARNING!** Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

FCC RF Exposure Information

• This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

• This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

No cutting

Do not wash

Do not tumble dry

Do not iron

Do not dry clean

Disinfection under 5000ppm bleach or 3.1% H_2O_2

Refer to instruction manual

On Carton

Fragile

This way up

Keep away from rain

No cutting

The stack limitation is 7 units for control box.

The stack limitation is 2 units for sensor pad.

The MD symbol indicates the item is a medical device.

Corrugated products for recycling

Abbreviation

Cognito 3.1A System	Cognito 3.1A
Heart rate	HR
Respiration rate	RR

About This Manual

This manual is designed to assist you with the safe operation and recommended cleaning of the Cognito 3.1A system. Please read this manual carefully before operating, performing cleaning/disinfection or the regular inspection on this product. If you have any questions about how to use or clean the Cognito 3.1A system, contact your distributor before using the product.

This manual contains instructions for use, troubleshooting and cleaning of the system. Proper tutorials and training are required prior to the use of the system.

Not all features described in this document may be available in all markets. Manufacturer reserves the right to modify, insert, and/or withdraw the information in this manual based on regulations / standards, product enhancements and market needs. Please contact your local distributor to get the latest information.

Intended Use | Indications

The Cognito 3.1A system is intended to provide bed exit and reposition notifications. It is indicated for use with patients in bed throughout the continuum of care. In addition, the system continuously measures respiration rate, heart rate, and motion in a hospital or nursing home in an automated, non-contact manner. This system is suitable for adults. The operation of Cognito 3.1A has been studied in adults during sleep and resting condition.

Cognito 3.1A is designed for use with proprietary components only.

Introduction

The Cognito 3.1A system is designed for continuous and contact-free predictive patient monitoring. The system monitors patient movement/mobility and can notify healthcare professionals and caregivers when a patient attempts to exit the bed or needs repositioning, enabling the caregivers to take timely intervention when patient exits the bed or needs reposition. Heart rate and respiration rate are also provided when the patients are at rest.

The Cognito 3.1A system is used for individual health management. The system is characterized by the features below. The information provided is for administrative purposes only and is not intended as a substitute for medical diagnosis or treatment.

- Tracks events and shows the trends of these events by individual patients on their patient detail page.
- Allows the healthcare professionals to adjust notification settings by individual patient care needs or based on facility protocols.
- Allows healthcare professionals and caregivers to select their unit so that they are notified only when their patients need attention.

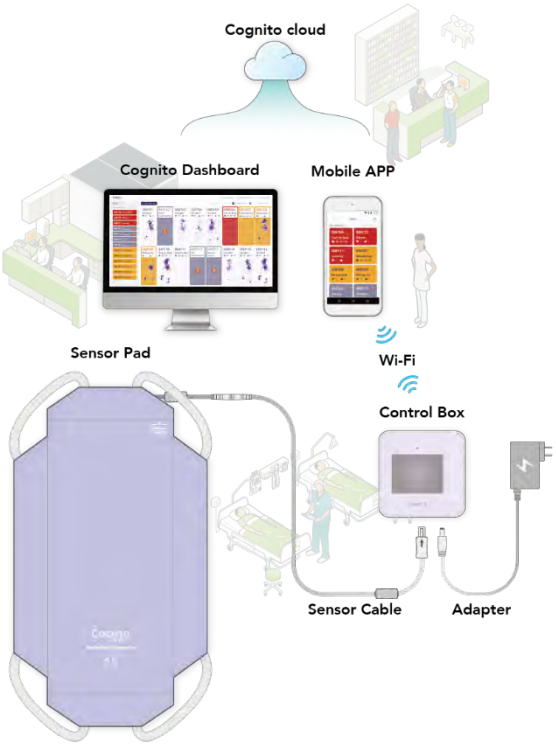
- Includes a “look back” of a patient’s historical time in/out of bed, movement and pressure over time.
- Can be used without Wi-Fi in the event of an internet outage.

The Cognito 3.1A system provides predictive, contact-free monitoring that is virtually invisible to the patient. The system is recommended for use in all care settings. The data collected by the Cognito system is gathered at the bedside and stored in a dedicated, secure Cognito cloud and is HIPAA compliant. The data is time stamped and can be used to document quality of care.

System Components

The Cognito 3.1A system comprises of sensor pad, control box, Cognito dashboard, mobile app and Cognito cloud. It provides bed exit and reposition related notifications for fall prevention and repositioning assistance for healthcare staff and professionals. The system provides personalized settings and healthcare professional or caregiver can select notifications based on individual patient care needs or facility protocols. Heart rate and respiration rate are provided for administrative purposes only and is not intended as a substitute for medical diagnosis or treatment.

The system includes the sensor pad that is placed on the mattress and below the bedding, a mattress cover, and control unit, which collects data and sends it to the cloud. The collected data is displayed on the website user interface and the mobile application, intended to aid in the evaluation of a patient's current status and should be interpreted by a health care practitioner only. For patient data security and privacy, the Cognito cloud stores de-identified patient data. Control box transmission is achieved by using either a Wi-Fi or Ethernet connection.



Cognito 3.1A System Set-up Preparation

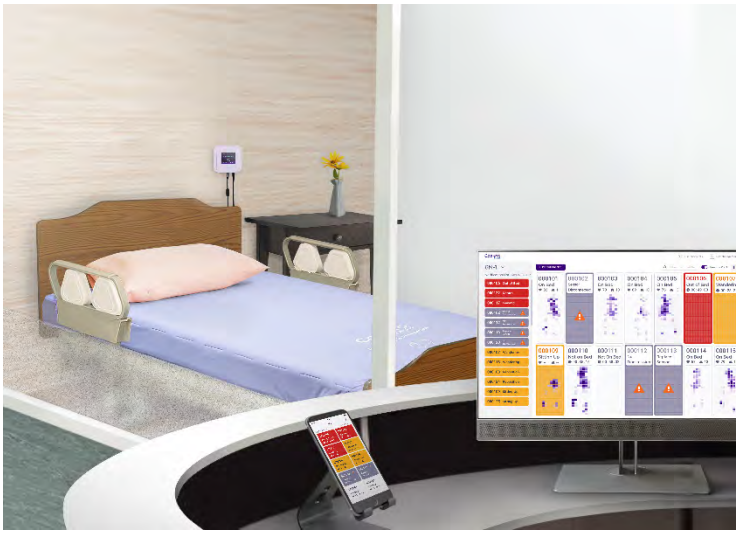
Prior to installation of the Cognito system hardware, the control box is configured and connected to the facility's network. After configuration, the box will be paired with a bed ID. Please see Box Wi-Fi and Box Pairing in *Box Management*. Once this is completed, the Cognito system hardware is set up by placing the sensor pad on top of the mattress and below the bedding. It is then connected to the control box. The control box is plugged into a power outlet and provides power to both the control box and the sensor pad.

After patient check-in, the Cognito system will collect patient movement and position data and transmit it to the cloud and send it to both the nurse dashboard and the mobile application.

In the event of an interruption of Wi-Fi, the Cognito system can be operated without Cognito dashboard and mobile app. In this situation, the system will not keep or store any data in the Cognito cloud or on any device. If you would like to use the system and keep the patient data, please log in Cognito dashboard and follow the instructions of *Box Wi-Fi* to reconnect the Wi-Fi between the control box and Cognito cloud.

The Cognito dashboard is used with a web browser. Supported browsers include Chrome, Edge and Safari. To access the dashboard, use the unique URL assigned to your facility in a browser to login to the Cognito dashboard. The facility may have unique usernames and passwords that were assigned during set-up. Mobile applications can be installed with a file provided by Cognito Health for Android or you can download the mobile app in the App Store for iOS.

The Cognito 3.1A is not a sterile medical device and must be cleaned between patients. When cleaning and disinfecting the product, always make sure to follow the standard sanitation procedure for repetitive use products.



Notifications

Cognito 3.1A provides visual and audible bed exit related and reposition notifications which can help with patient falls and reposition care in pressure injury. Bed exit related notifications include Sitting Up, Leaving, Out of Bed, Wandering and Return. The reposition notification will be provided when the patients need repositioning. Other notifications provide an overview of the patient's current status and system errors.

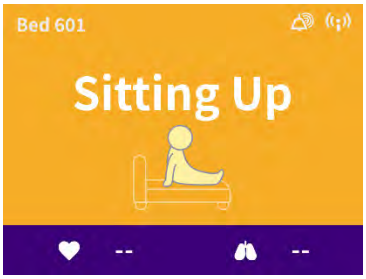
Bed exit related and reposition notifications are displayed in red or yellow, dependent on notification priority, on control box, dashboard and mobile app. The control box also includes a bedside message designed to let the patient know that help is on the way when patients are exiting the bed or out of bed. The bedside message is "Please do not get out of bed. A nurse will come and help you." If the audible bedside message is not desired due to patient tolerance or facility preference, it can be disabled in the patient settings.

Notification settings should be set-up during patient check-in via dashboard based on individual patient health and mobility capabilities. Regular review of these settings is recommended to ensure optimal settings are in place to help with unassisted bed exits and reposition assistance. Settings include: Sitting Up, Leaving, Reposition, Wandering and Return. Notifications will be sent to both the Cognito dashboard and mobile application when a patient movement activates these settings.

Notifications	Bedside Notification	System Notification	To be Deactivated
Leaving / Return	Audible Message	Notification Sound	V
Out of Bed	Audible Message	Notification Sound	X
Wandering	--	Notification Sound	V
Sitting Up	Audible Message	--	V
Reposition	--	Notification Sound	V

Displaying Notifications on the Control Box

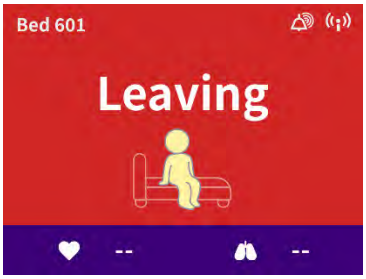
Bed Exit Notifications



Sitting Up

This notification indicates that the patient may be sitting up from lying on the bed. When a patient is sitting up, it may indicate the patient intends to exit the bed, increasing their risk of an unassisted bed exit.

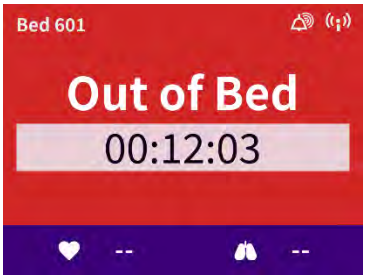
The Sitting Up notification is displayed in yellow on the control box. Bedside message can be turned on from the control box for Sitting Up if it were necessary.



Leaving

This notification indicates the patient may be attempting to leave the bed. Intending to sit at the edge of the bed could precede a fall and immediate assistance is recommended.

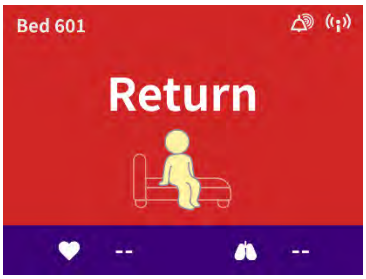
The Leaving notification is displayed in red on the control box and triggers the bedside notification message. The bedside message can be dismissed by tapping “OK” or return button.



Out of Bed

This visual notification indicates the patient has already exited the bed and will include a timer with the length of time the patient has been out of bed.

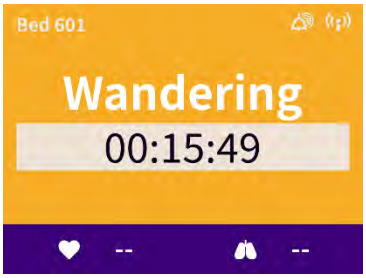
The Out of Bed notification is displayed in red on the control box and alerts the patient with bedside message. The bedside message can be dismissed by tapping “OK” or return button. Press “OK” or return button twice, Not on Bed will be displayed on the screen. Please see Not on Bed in *Additional Notifications*.



Return

This visual notification indicates the patient is back to the bed from out of bed and being at the edge of the bed.

The Return notification is displayed in red on the control box and triggers the bedside notification message. The bedside message can be dismissed by tapping “OK” or return button.

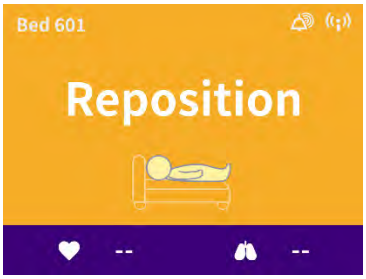


Wandering

During the set-up process with Cognito software, the clinician will determine if the patient is at risk of wandering. If they are, the healthcare professional/ caregiver should set up a wandering alert that will notify them when the patient has exceeded the maximum amount of time the patient is allowed out of bed.

Wandering notification is displayed in yellow on the control box. The default time for triggering wandering notification is 15 minutes after the patient exits the bed. The time setting can be customized to individual patient needs. After the wandering notification is sent, a timer will start to let the healthcare staff and professionals know how much time has elapsed since the patient has exited the bed.

Repositioning Notifications



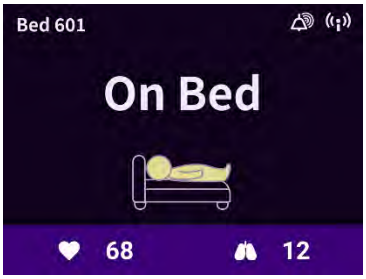
Reposition

When a patient is set-up on the Cognito system, the clinical team will determine how often they need to be repositioned. This can be based on individual patient need or facility protocol. When the pre-set time has elapsed, the Cognito system will give a notification on the control box and system software.

The default time for repositioning notification is every two hours (120 minutes). After repositioning has been completed by either the clinical staff or if the patient has adequately repositioned themselves, the system will automatically dismiss the notification.

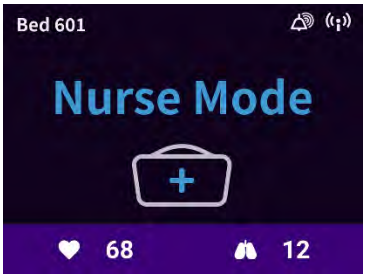
The Reposition is displayed in yellow on the control box.

Additional Notifications



On Bed

This status indicates the patient is on the bed and there is no critical event happening.

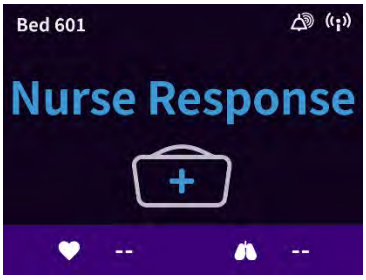


Nurse Mode

Cognito notifications can be temporarily silenced for one minute with nurse mode while the patient status is On Bed to avoid unnecessary notifications.

Nurse mode is displayed with a blue “+” on the control box.

Note: *Please see Operating Instructions of Control Box for further instructions.*

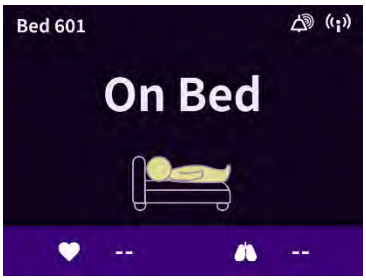


Nurse Response

This notification indicates that the notifications are dismissed and let other healthcare professionals and caregivers know that someone has checked the situation.

Nurse response is displayed with a blue “+” on the control box.

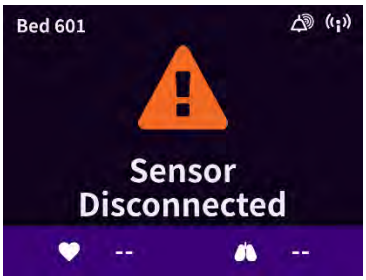
Note: *Please see Operating Instructions of Control Box for further instructions.*



-- indicates that the HR/RR is collected from few cardiac and respiratory cycles. If the system is still detecting the signal and unable to provide a stable HR/RR, no value will be displayed on the screen.

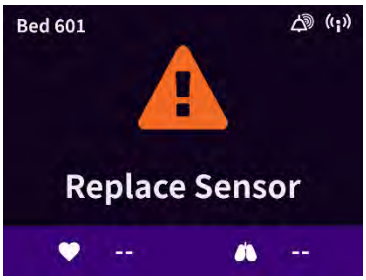
System Error Notifications

The Cognito 3.1A is a self-diagnosing system and guides you to where the problem is occurring. See *Troubleshooting* section for further solutions.



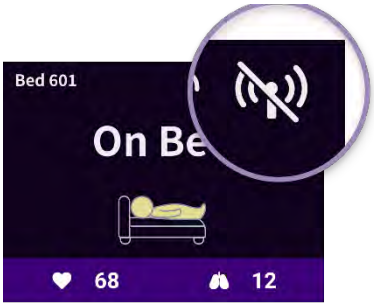
Sensor Disconnected

This status indicates the sensor cable is not connected to the control box or not connected tightly.



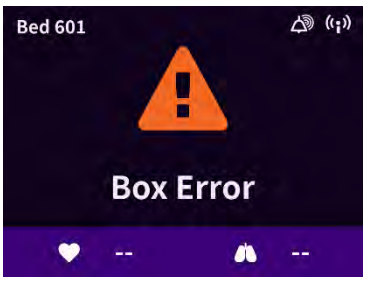
Replace Sensor

This status indicates the sensor pad is not functioning correctly, or the sensor cable is damaged.



No Network Connection

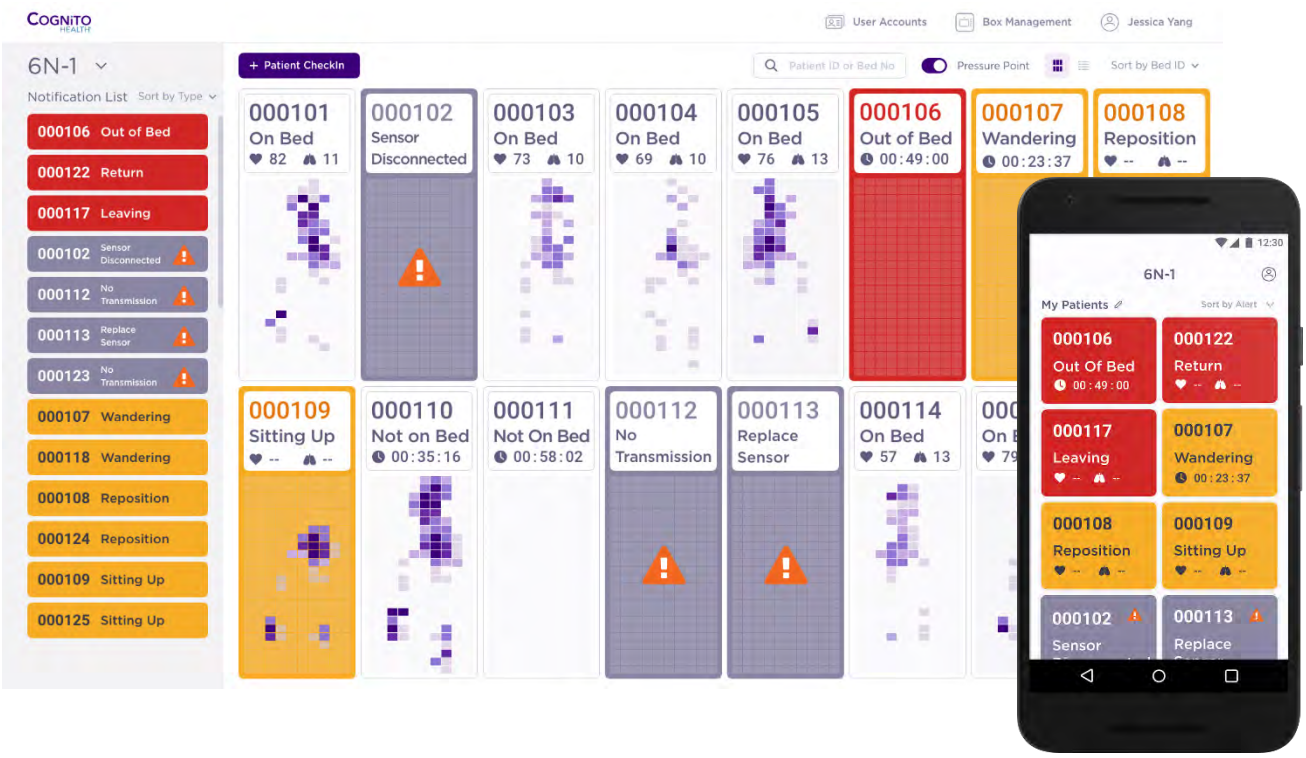
The icon at the top right of the control box indicates the network connectivity. No transmission of the network is the result of disconnection between the control box and the system.



Box Error

This status indicates the control box is not functioning correctly due to an internal software abnormality.

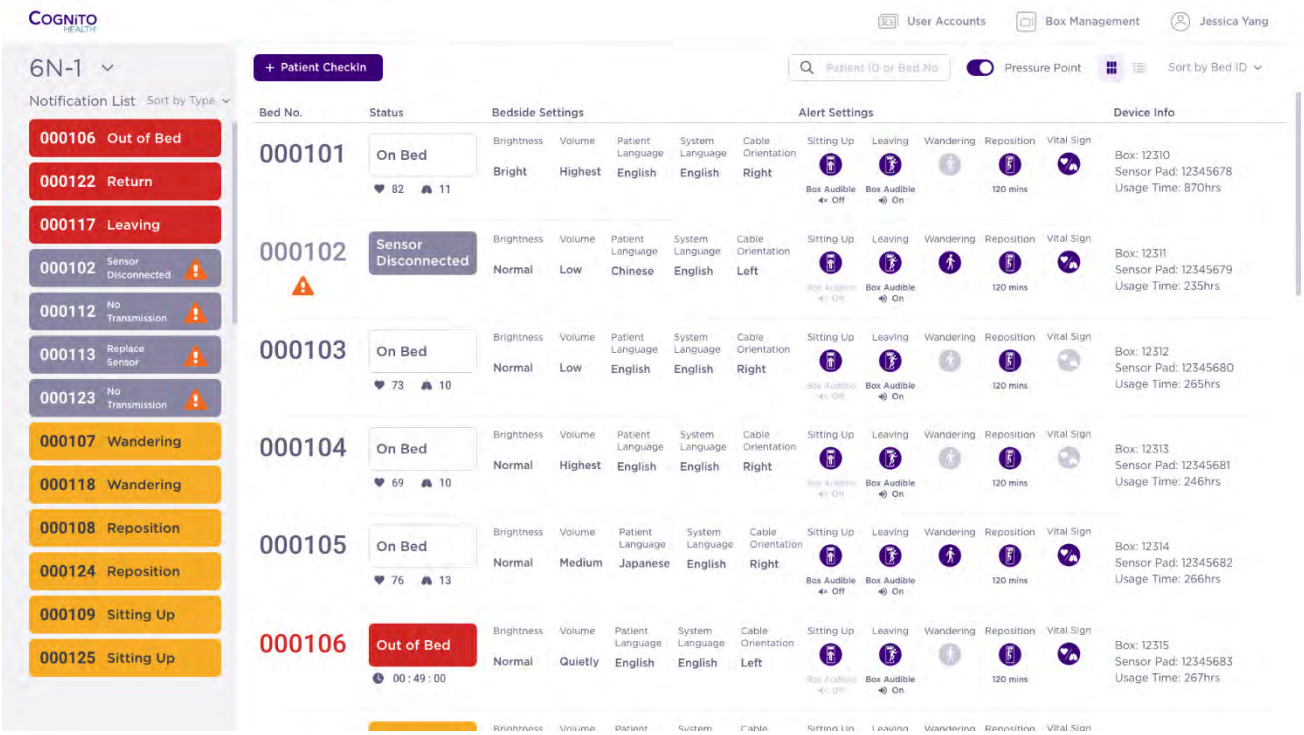
Displaying Notifications on Cognito Dashboard and Mobile App



Cognito dashboard and mobile app provide an overview of the patient in the care unit. A patient card on the dashboard will indicate the status of the patient based on settings selected during patient set-up, and the pressure profile.

The sensors are distributed from shoulder to heel to detect average pressure. The pressure profile on the patient card indicates the pressure distribution and the pressure level, ranging from level 1 to 6. The color of the pressure point will be darker along with the pressure level. Different colors of average pressure help to distinguish which parts of patient's body are with more risk of sustained pressure.

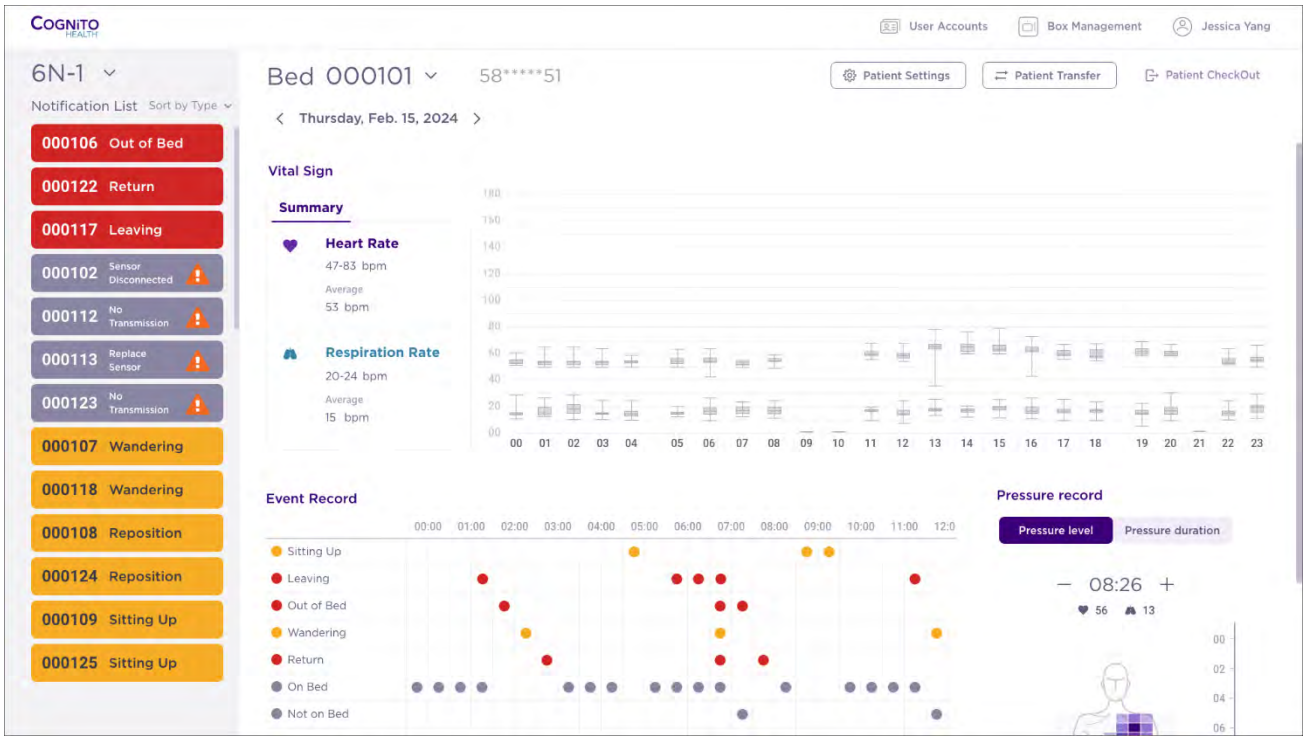
List view is also applicable on Cognito dashboard to see the control box and current notification settings of individual patient.



Tapping a patient card on the dashboard will lead to Patient Detail Page which includes historical Vital Sign, Event Record and Pressure Record. Historical vital sign is sorted with hourly sort and averaged, lowest and highest value are listed for reference. The event record shows the status of the patient when a patient was checked-in, grouped by twenty-minute intervals. Pressure record is tracked minute by minute with pressure level or pressure duration.

Check marks are used to indicate the interaction of a nurse with the system (e.g. Nurse Response or Nurse Mode). Note that multiple events of the same or different types may occur within the same twenty-minute interval. In this situation, one column in the notification record may include multiple events.

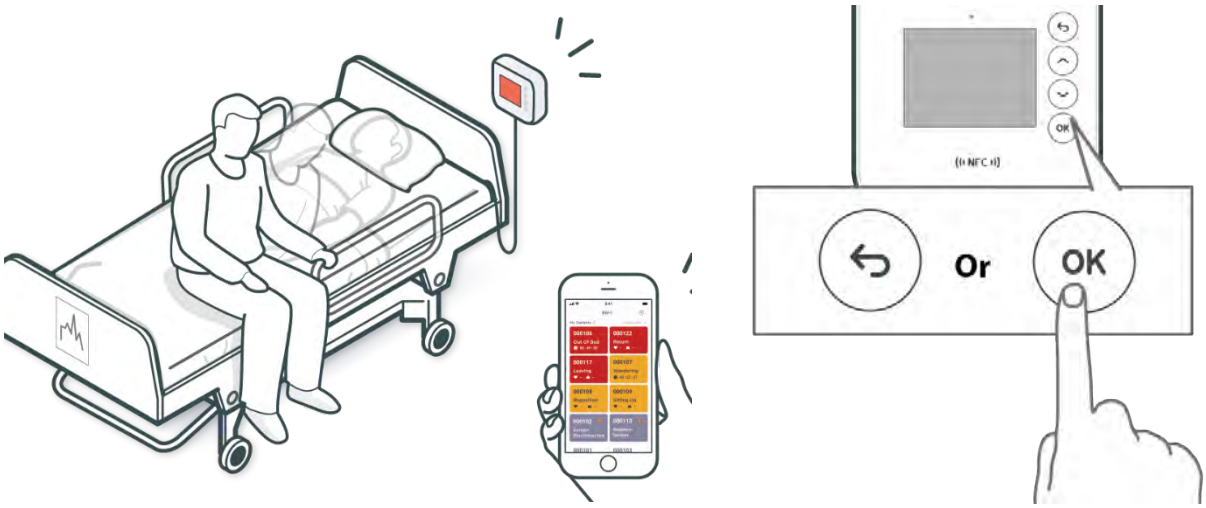
On the mobile app, the patient detail page displays a live pressure profile so that the caregiver or healthcare professional is able to distinguish which part of the body is with greater pressure level while repositioning the patient.



Dismissing Notifications

Dismissing Leaving and Out of Bed Notifications

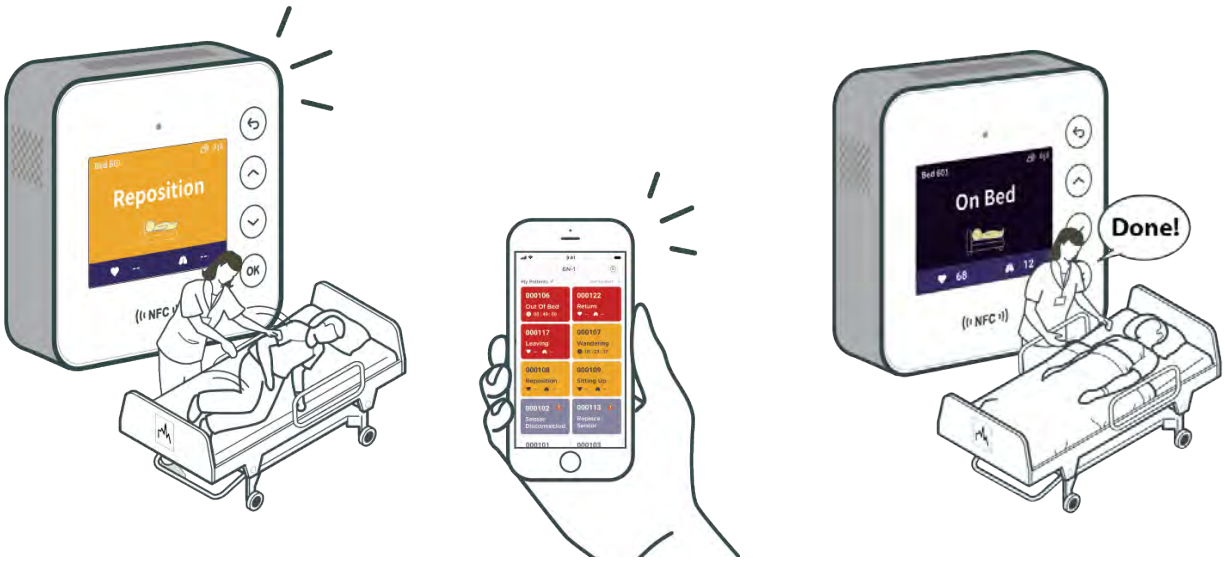
After a Leaving or Out of Bed notification is sent out to the healthcare staff on their mobile app or the Cognito dashboard, the healthcare staff will need to press “OK” or “Return” button on the control box to dismiss the notification and to let others on the care team know they are assisting the patient as “Nurse Response”.



Dismissing Reposition Notification

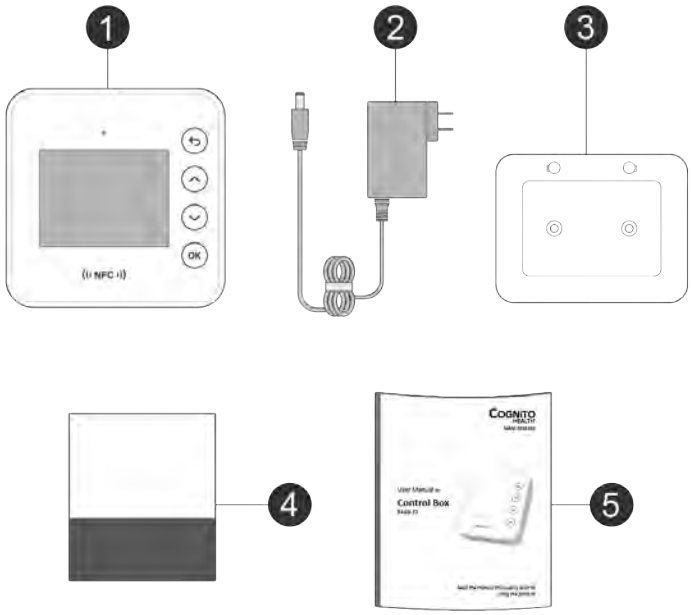
The system notifies the healthcare staff and the professionals when a patient remains on the bed with sustained unrelieved pressure for a pre-determined period of time.

When the patient is sufficiently repositioned, the Reposition notification will be dismissed, and the repositioning timer will automatically reset. The healthcare staff is able to press “OK” or “Return” button on the control box to dismiss the notification and to let others on the care team know they are assisting the patient as “Nurse Response”.
If the patient is sufficiently repositioned by himself/herself, the Reposition notification will also be dismissed, and the system will capture the repositioning in the event record as “Reposition Reset”.

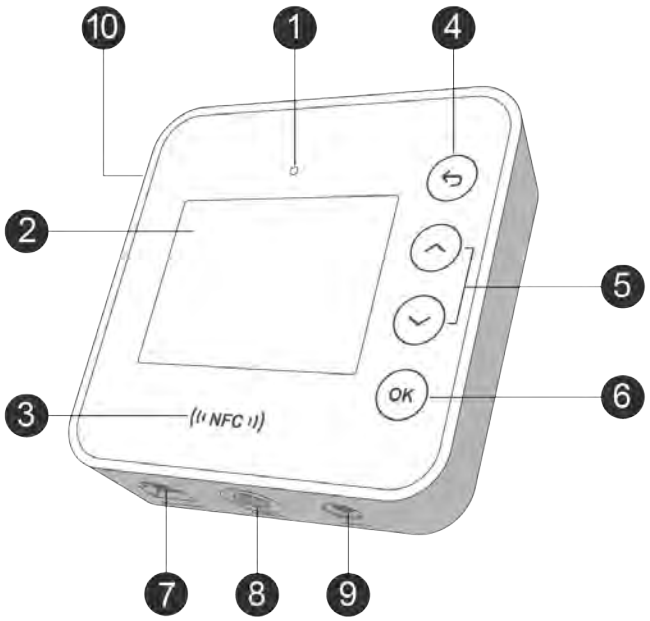


Hardware Introduction

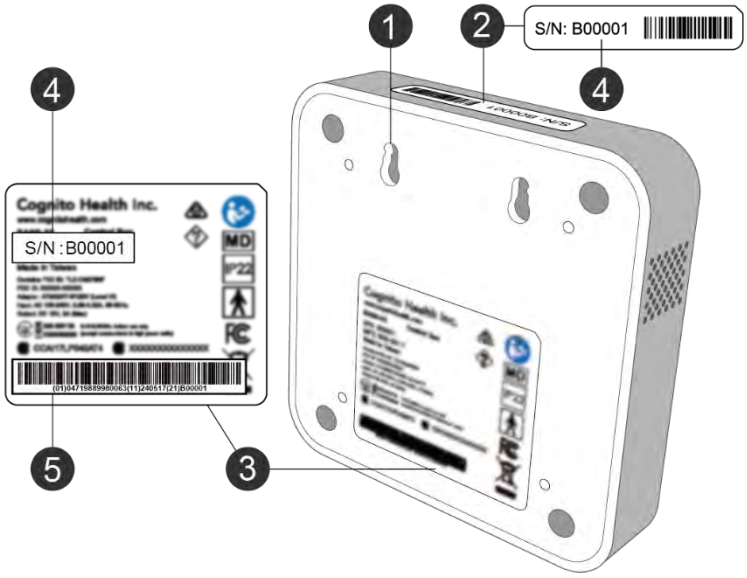
Control Box Exterior



1. Control box (BA6G-32)
2. Power adapter
3. Wall mount plate (ZAC0-A1)
4. Glue tape (ZDB0-A1)
5. User manual

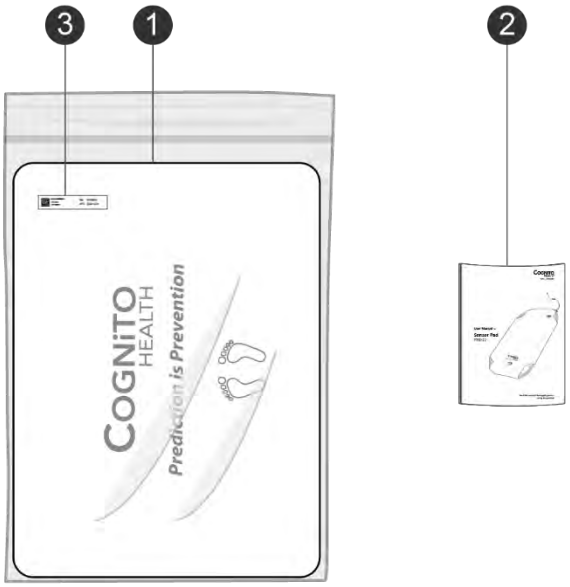


1. Power indication / Connection indicator
2. Screen
3. NFC sensing area
4. Return button
5. Selection buttons
6. OK button
7. Ethernet port
8. Sensor port
9. Power port
10. Speaker

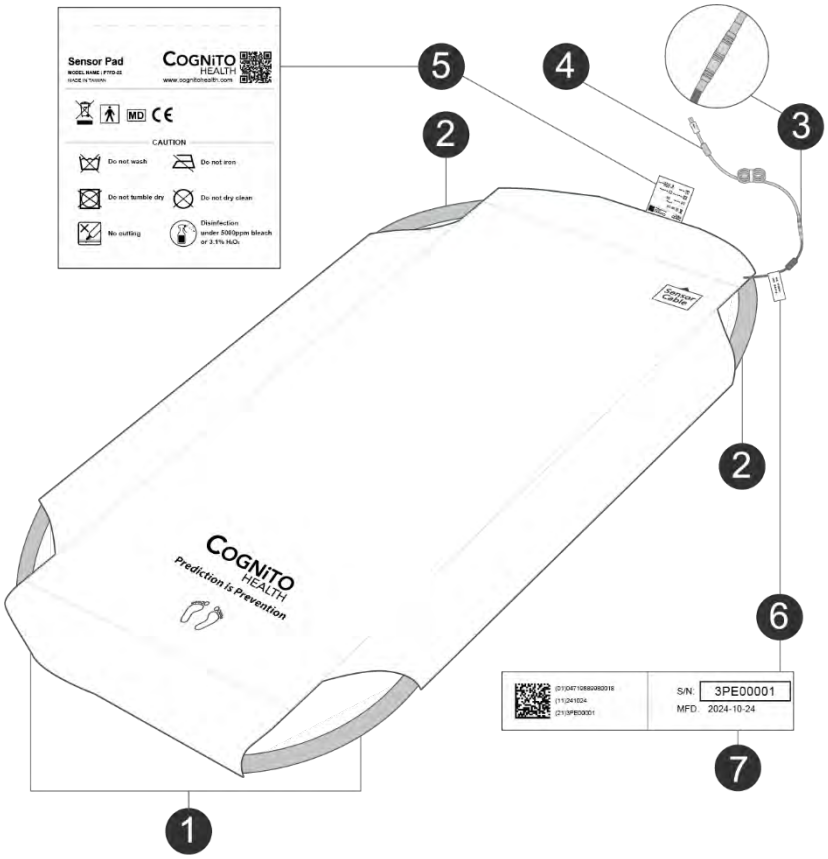


1. Hanger holes
   (for wall mount plate)
2. Serial number label
3. Control box label
4. Control box serial number
5. Control box UDI barcode

Sensor Pad Exterior



1. Sensor pad (P7FD-22)
2. User manual
3. Serial number label



1. Elastic bands
2. Fixed bands
3. Quick release connector for emergency
4. Sensor cable
5. Sensor pad label
6. Serial number label
7. Sensor pad UDI barcode

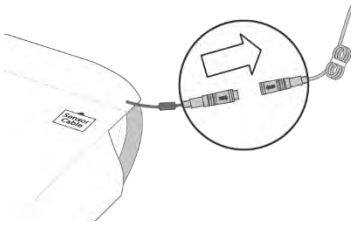
Installation of Control Box and Sensor Pad

⚠ WARNING

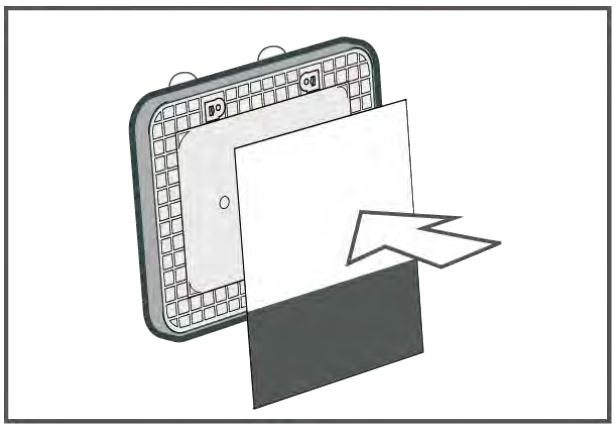
- Confirm that there is no exterior damage after unpacking the Cognito product.
- Operate Cognito products under ambient temperature between 41°F to 104°F (5°C to 40°C) and relative humidity between 15% to 90%.
- ***DO NOT*** use electric heating blankets or other items that will heat up over 113°F (45°C).
- ***DO NOT*** use a damaged sensor cable. Contact your Cognito distributor if a damaged sensor cable is discovered.
- ***DO NOT*** install the control box near patient's head to avoid any safety risk.
- ***Never*** open or modify the control box or the sensor pad. If the system is not functioning, please contact your Cognito distributor.
- If there is any liquid on the surface of the device, dry the device to avoid damaging the control box or the sensor pad.
- Use only detachable parts and accessories approved by Cognito Health.
- Immediately stop using the product if serious contamination or any damage is found.
- ***DO NOT*** put the Cognito product in the place which is difficult to cut off the power.
- The device can be operated immediately after storage.

⚠ CAUTION

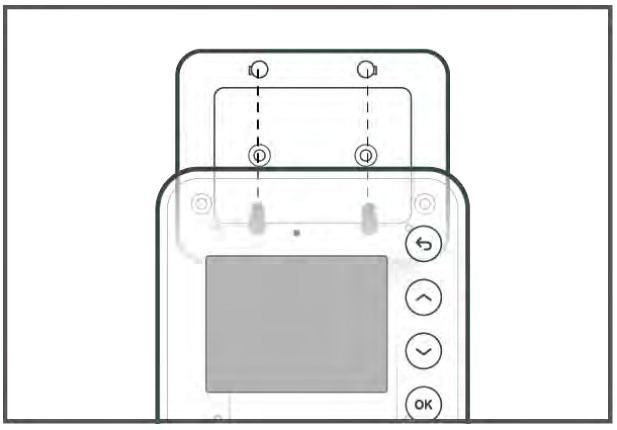
- Unplug the sensor cable from the push-pull connector and the power adapter before cleaning and disinfection, regular inspection or moving the bed to avoid the damage to the products and the accessories.
- Please place the sensor cable in an appropriate location so it will not affect the daily activity of patients or healthcare staff.
- Check that if Leaving/Out of Bed are both properly activated before having the control box into service.
- Use only fingertips to operate the touch screen. Avoid using fingernails, pens or any sharp objects that might damage the screen.
- ***DO NOT*** plug in and out the quick release connector unless it is necessary.
- If the quick release connector is accidentally plugged out, find the arrow marks on the connector and follow the direction of arrow to plug in.



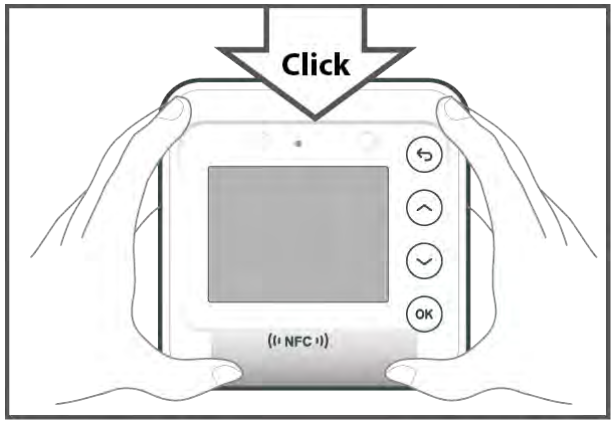
Use Wall Mount Plate with Glue Tape to Install



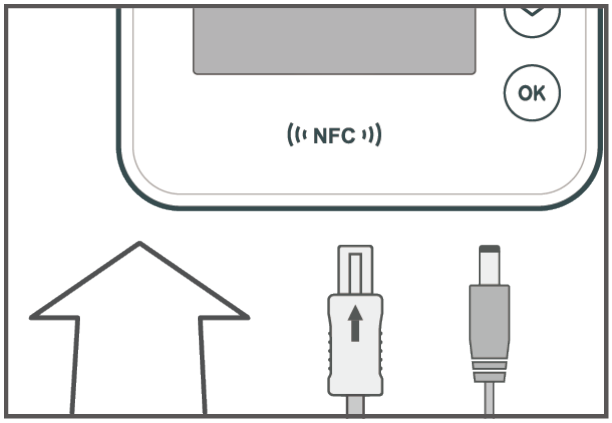
1. Attach the glue tape onto the wall mount plate in rounded square area. Stick and press the wall mount plate to the wall and let it sit for 24 hours.



2. Align the hanger holes of the control box to the hanger buttons of wall mount plate.



3. While holding the control box with both hands, push the control box downwards until it clicks securely into the wall mount plate.



4. Plug in the sensor cable from the push-pull connector and the power adapter to the control box and the control box will automatically be turned on.

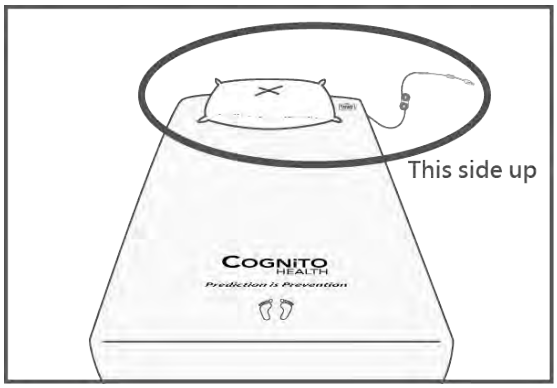
Install the Sensor Pad and Connect to the Control Box

⚠ **WARNING**

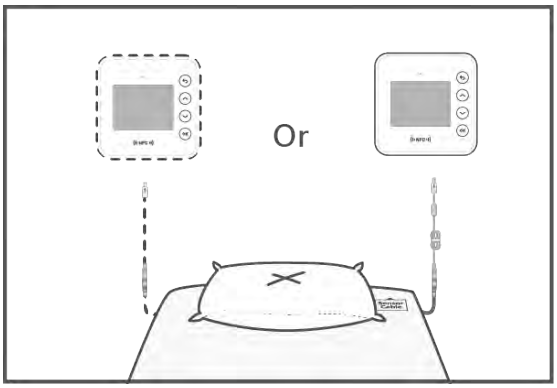
- Unplug the sensor cable from the push-pull connector before cleaning and disinfection, regular inspection or moving the bed to avoid the damage to the products and the accessories.
- Ensure the sensor pad is placed underneath a mattress cover and/or patient bed sheet.
- ***DO NOT*** use damaged sensor cable, contact your Cognito distributor if a damaged sensor cable is discovered.
- ***DO NOT*** pull the sensor cable with force.
- ***DO NOT*** place the sensor cable on or across the mattress surface to prevent ensnaring the patient.
- ***DO NOT*** connect the items that are not sensor cable to the sensor port of control box.
- ***DO NOT*** use electric heating blankets or other items that will heat up over 113°F/45°C.
- For best results, limit the number of items between the sensor pad and the patient. Do not place heavy items, other than patient, on the sensor pad.
- Use of a deep immersion mattress may result in delay/malfunction of bed exit notifications.
- ***Only*** use a sensor pad with one patient at any given time.
- Appropriate routing of the sensor cable is important for the proper function and safety of the Cognito device. Avoid draping or stretching the sensor cable too tightly across the patient's bed.

⚠ **CAUTION**

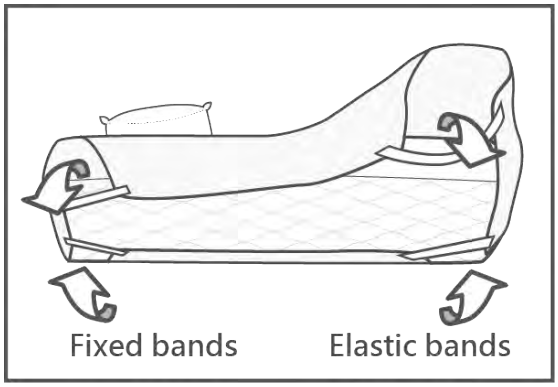
- To safely terminate operation of the system, please disconnect the sensor cable.
- The sensor pad should always be covered with a mattress cover and/or facility bed sheet. Assure the mattress cover and/or facility bed sheet fully covers the sensor.
- Please place sensor cable in an appropriate location so it will not affect the daily activity of patients or healthcare professionals/caregivers.
- Be aware of items that are left on the sensor pad, even when in storage. Heavy, heated, or sharp items could cause damage to the product.
- Set correct cable orientation before use. Incorrect cable orientation setting may cause incorrect detection of patient's position and movement.



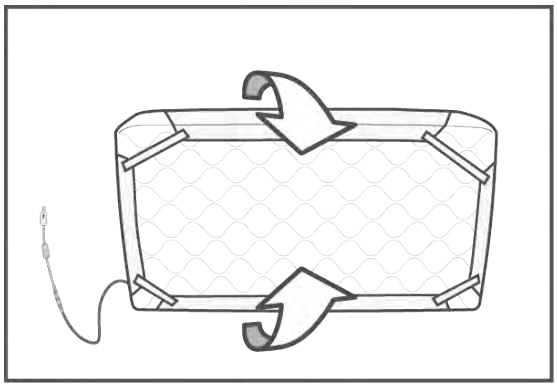
1. Install the sensor pad on the facility's mattress. Make sure the sensor cable is at the head of the patient and Cognito Health logo is at the bottom.



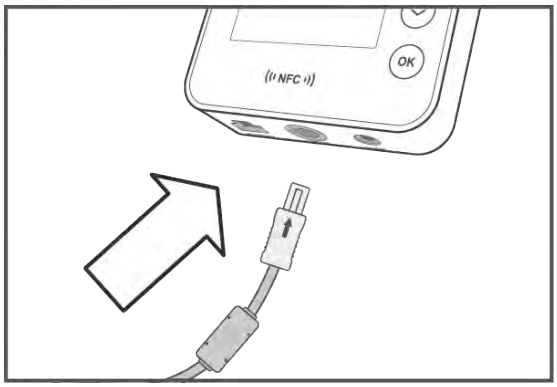
2. Place the sensor pad on bed with the sensor cable at the top right corner or top left corner- whichever is closest to the control box.



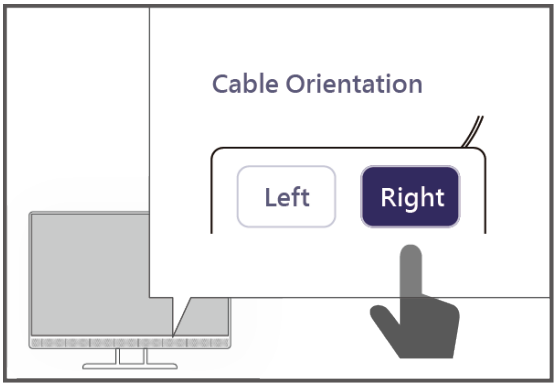
3. Fix the upper fixed bands first and pull the bottom elastic bands downwards to the mattress.



4. Fold the side under the mattress and flatten the sensor pad. Cover the sensor pad with a mattress cover and/or facility bed sheet.



5. Connect the sensor cable from the push-pull connector to the sensor port on the control box and start using Cognito product.



6. Set the cable orientation on the Cognito dashboard to have correct detection and start using Cognito product.

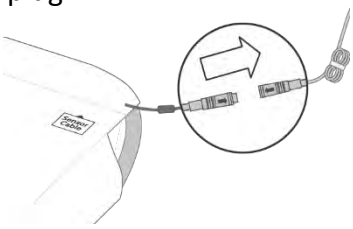
Remove the Control Box

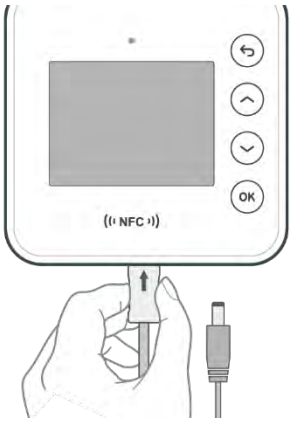
⚠ **WARNING**

- ***DO NOT*** pull the sensor cable with force.
- ***DO NOT*** connect items that are not sensor cable to the sensor port.
- ***DO NOT*** connect cables other than RJ45 type to the Ethernet port.
- ***DO NOT*** put the Cognito product at the place which is difficult to cut off the power.

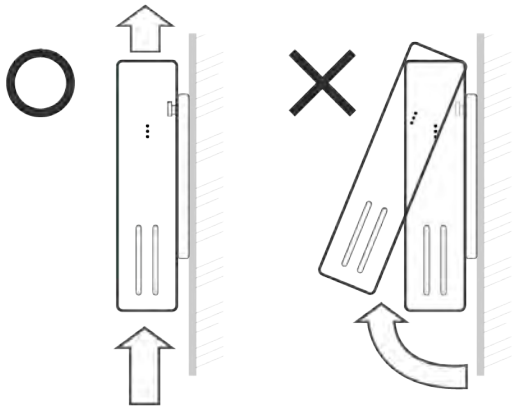
⚠ **CAUTION**

- Removing the control box in an incorrect way may cause damage to the wall mount plate or mounting surface.
- Recommend plugging the power adapter into the UPS (Uninterruptible Power Supply).
- Cognito products and accessories should be kept out of reach of children under 3 years or any individuals who tend to place inedible objects in their mouths.
- ***DO NOT*** plug in and out the quick release connector unless it is necessary.
- If the quick release connector is accidentally plugged out, find the arrow marks on the quick release connector and follow the direction of arrow to plug in





To remove the control box, unplug the sensor cable **ONLY** from the push-pull connector (gray plastic shell) and the power adapter.



Slide the control box upwards, parallel to the wall, from the wall mount plate.

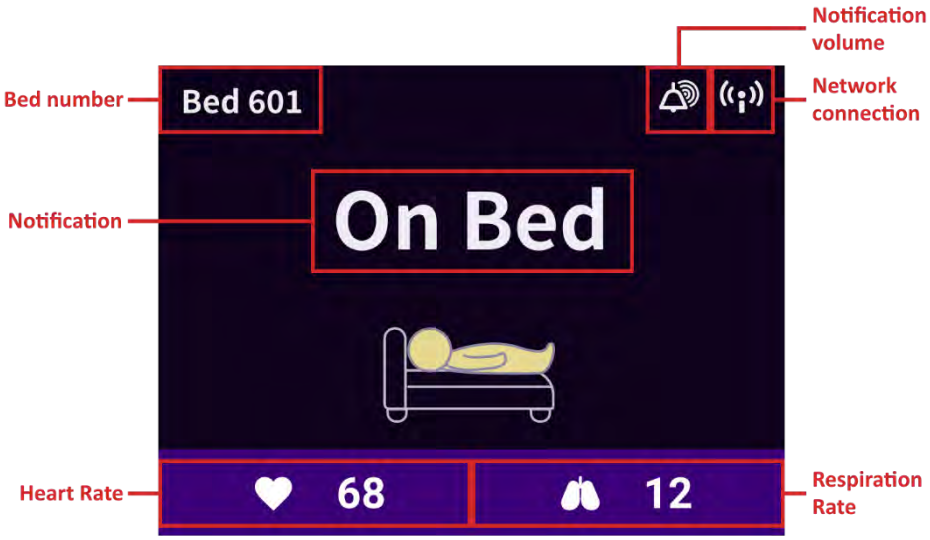
Operating Instructions of Control Box

Power Indicator Light

Event	Connected to the network	Disconnected to the network
Power Connected	Solid light	Blinking
No Power Connected	No light	No light

Note: *If the power indicator is blinking green, please follow instructions or contact the distributor or the manufacture to build the network connection of control box.*

Box User Interface



The control box displays bed ID, notifications/patient status/system status/heart rate and respiration rate, notification volume and network connectivity on the user interface.

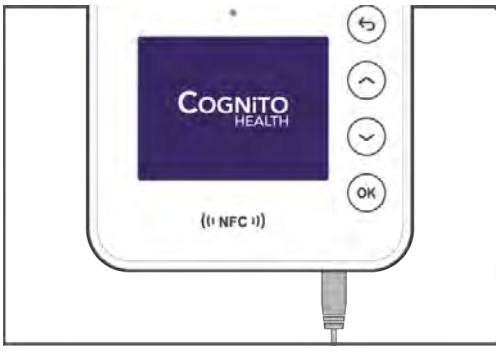
Regular Settings

Control box provides bed exit related and reposition notifications at the bedside. Bedside message from the control box is also provided to alert patients when patients is sitting up, leaving, have been out of bed or returning to the bed. Default settings of the control box are listed below. The settings can be adjusted from either control box or Cognito software.

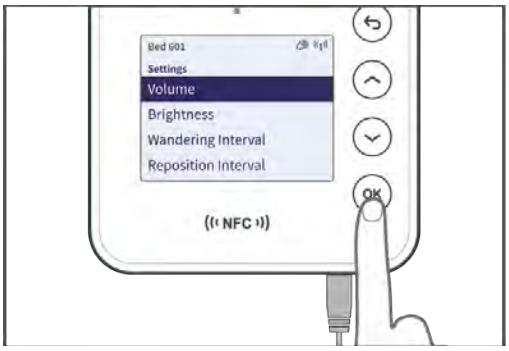
Items	Default Setting
Volume	Mute
Brightness	Dim
Wandering Interval (minute)	15
Reposition Interval (minute)	120
Sitting Up Bedside Message	Off
Leaving/Return Bedside Message	On
Heart Rate/Respiration Rate	On
Patient Language	English
System Language	English

⚠ **CAUTION**

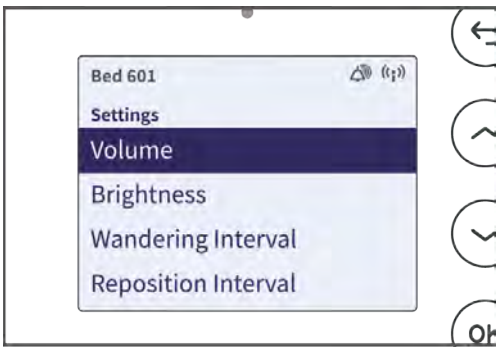
- Connect the sensor pad to the control box. Test getting out of the bed and check that if Leaving/Out of Bed are both properly activated before having the control box and the system into service.
- The control box provides bed exit related and repositioning notifications to support and drive the clinical intervention and decision-making. It is not intended to avoid entire fall incidents and pressure injuries from happening.
- Optimizing fall prevention and pressure injury care is achieved through the utilization of the notification settings together with personal bedside assistance. Notifications or other events can become invalid if the healthcare professional or caregiver does not appear at the bedside.
- Audible alert from the control box has the added advantage of including patients themselves into patient safety protocol. Keeping the sound on benefits all concerned for fall prevention.
- Recommend plugging the power adapter into the UPS (Uninterruptible Power Supply).
- Cognito products and accessories should be kept out of reach of children under 3 years or any individuals who tend to place inedible objects in their mouths.



1. Plug in the power adapter to the control box until the patient or system status is shown. It indicates the control box is ready for settings.



2. Long press “OK” button to get into setting page.



3. Select the setting items you would like to change.

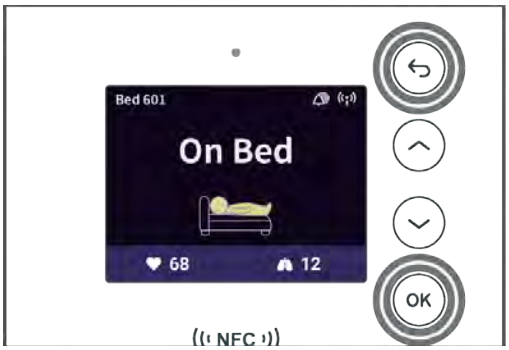
4. Return to notification page to complete the change.

Nurse Mode / Nurse Response

Cognito notifications can be temporarily silenced for one minute with nurse mode to allow for regular nursing care and avoid unnecessary notifications when the patient status in On Bed. Nurse response also silences the notifications for one minute with the same operation. It is displayed when there is a bed exit or reposition notification and to let other staff know that someone has already checked the patients.

Nurse mode/nurse response is displayed with a blue "+" on the control box and is suggested to be activated while the patient is in need of assistance for helping patient get out of the bed or repositioned.

1. Press "OK" or "Return" button to get into nurse mode.



2. To stop nurse mode, press "OK" or "Return" button once again.

3. Or you can wait for one minute, the control box will automatically return to regular use.

Cognito Dashboard

Cognito 3.1A provides various types of notifications on the dashboard program and mobile app. Notifications can be classified into three categories: bed exit, repositioning and product issue related notifications. These notifications enable the healthcare staff and professionals to know when to assist the patients to help with patient falls and reposition care in pressure injury, or when there is a problem with the Cognito system.

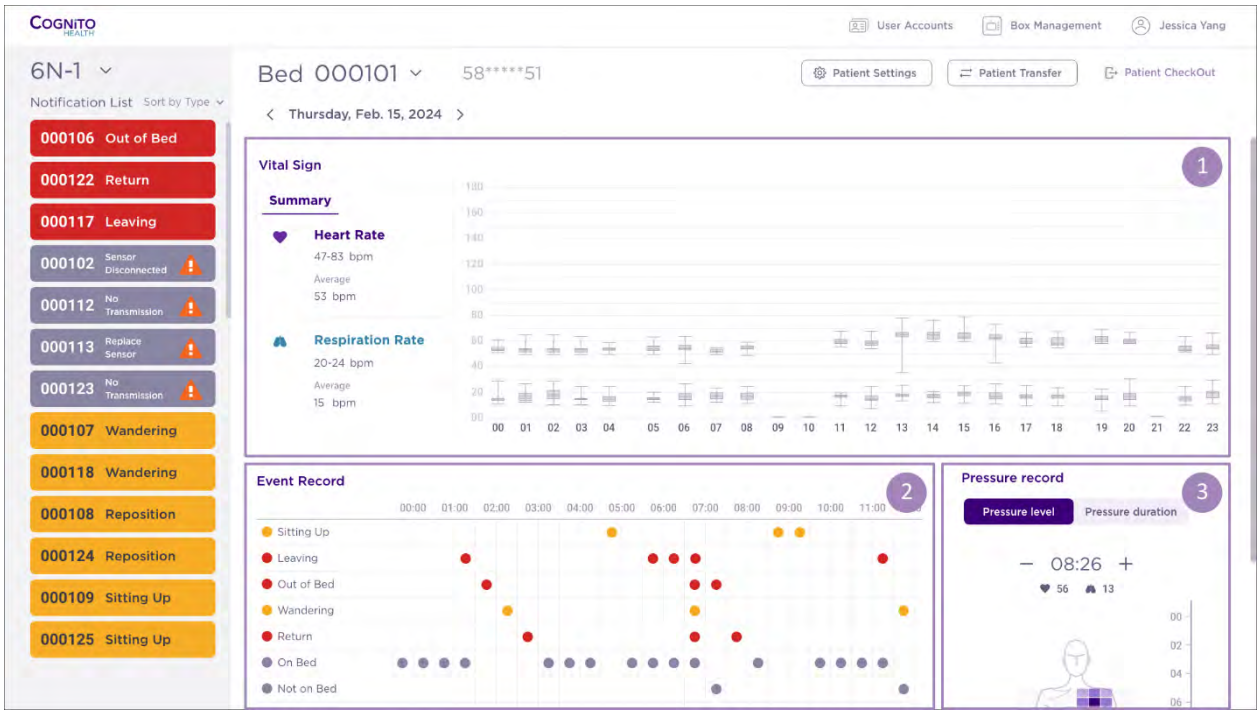
Type in the facility' URL (https://xxxxxxxx.cognitohealth.com.tw) in a browser. Log in to the Cognito dashboard, select a designated care unit (if there are more than one) and start using the Cognito dashboard. To switch to another care unit, please tap the left side drop-down menu to get into another care unit.

Dashboard Interface

Grid View of Main Page

1. ***Cognito logo:*** for going back to the main page
2. ***Care unit drop-down menu*** includes all the care units using Cognito 3.1A in the facility.
3. ***Notification List*** includes all the notifications occurred in the care unit and can be arranged with the order of bed number, notification time or type.
4. ***Search bar:*** to search for the specific patient with bed number or patient ID
5. A patient card represents a bed number. The patient card can be arranged with the order of bed number, notification time or type.
6. ***Management tool bar:*** to arrange control box, user account and the user password
7. ***Toggle*** On/Off the pressure profile within the patient cards displayed on the main page
8. Grid view or list view selection
9. ***Sorting*** of patient cards by bed number, notification time or type

Patient Detail Page

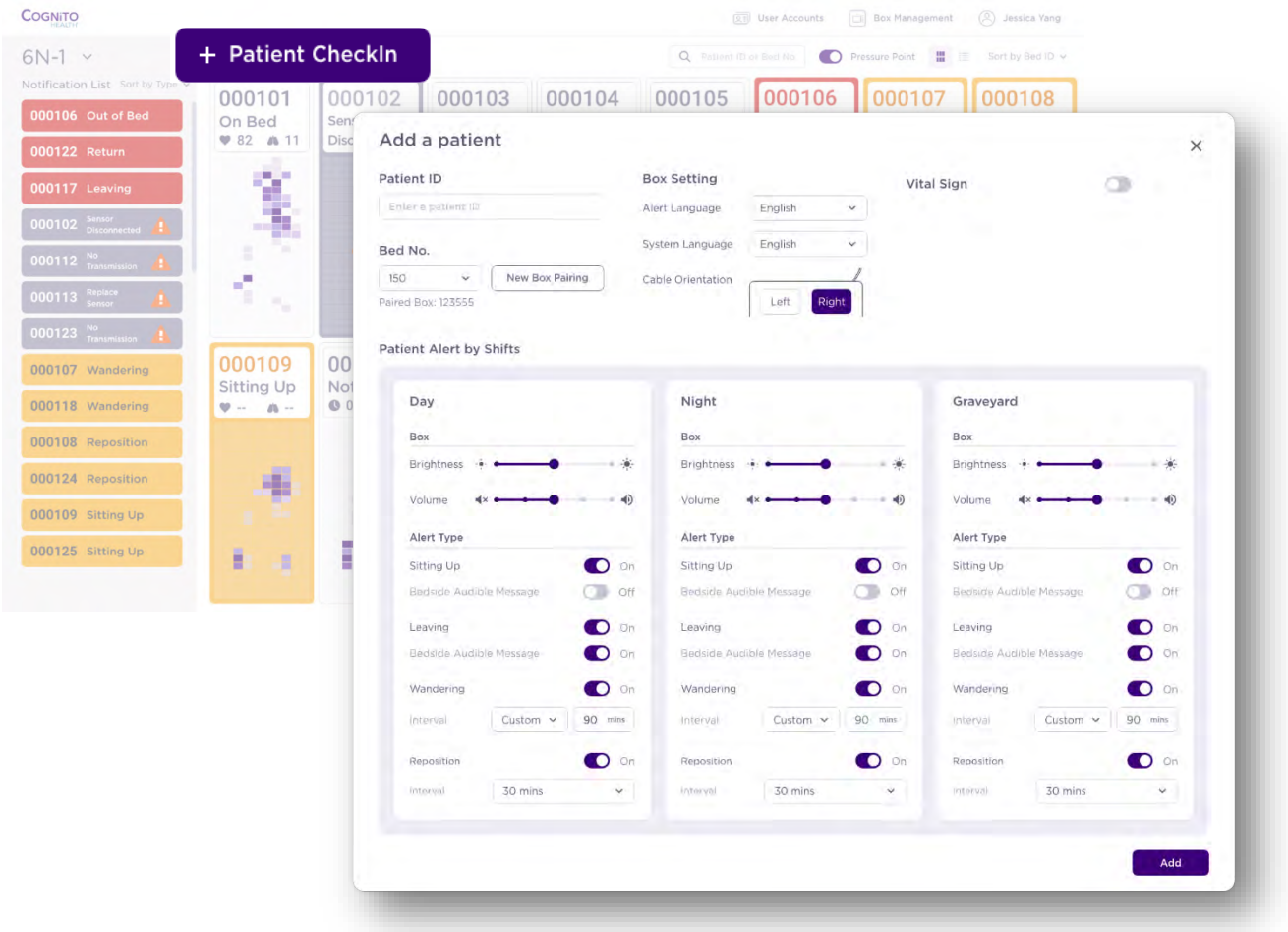


1. ***Vital Sign*** charts the heart rate and respiration rate from the lowest to the highest value by hours and lists averaged value of the day.
2. ***Event Record*** marks each notification with time manner to track patient behavior and protocol adherence. On bed will be listed with patient's posture, including sitting, left lateral, right lateral and supine.
3. ***Pressure Record*** displays the pressure variation with average pressure level or pressure duration over time.

Patient Management

After the control box and the sensor pad are installed in the patient room and paired with a bed ID, users can check-in, check-out, manage and monitor patients.

Add a Patient



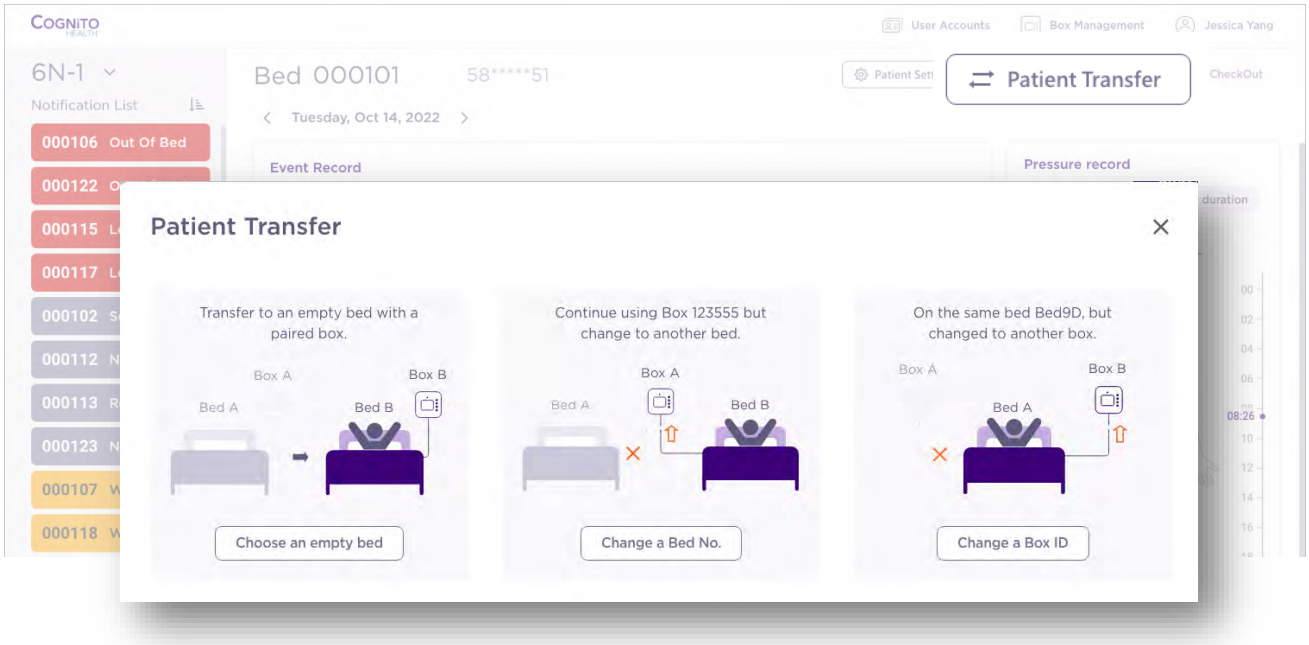
1. Tap 『Patient Check-In』 in the specific care unit. This will open the Patient Check-in window.
2. Type in the patient ID with at least 6 digits and select the bed number of the patient. Adjust the settings of control box and notification settings for bed exit and reposition.
3. Tap 『Add』 to complete.

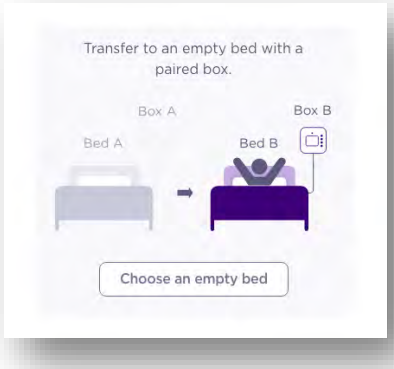
Notice

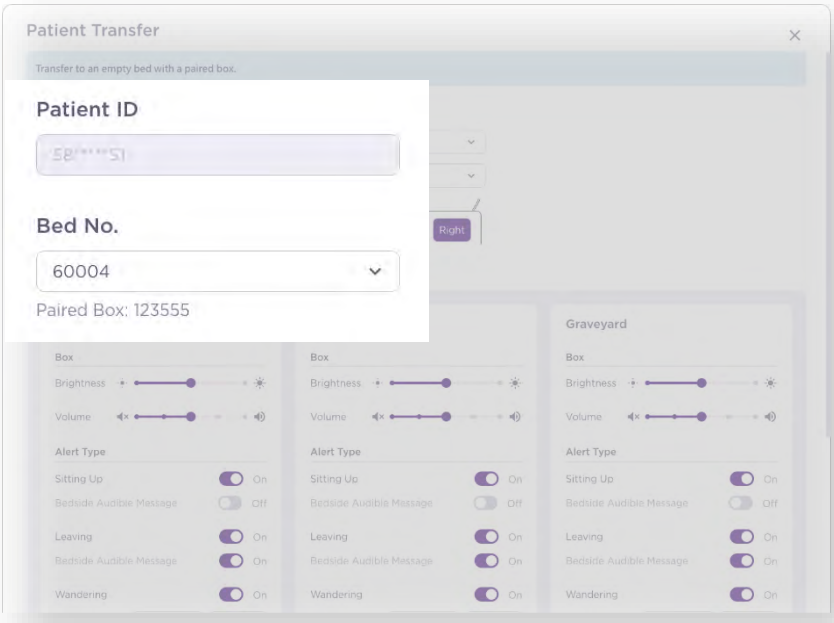
- If the desired bed number is not in the Patient Check-in box, please check if the bed number is in use for another patient and follow instructions to operate *Patient Check-out* first.
- If the bed ID shows No Transmission, follow *Troubleshooting* instructions to connect the control box to the Internet.

Bed Transfer

Transferring a patient to another bed or using a new control box with the same bed number can be done from patient detail page.

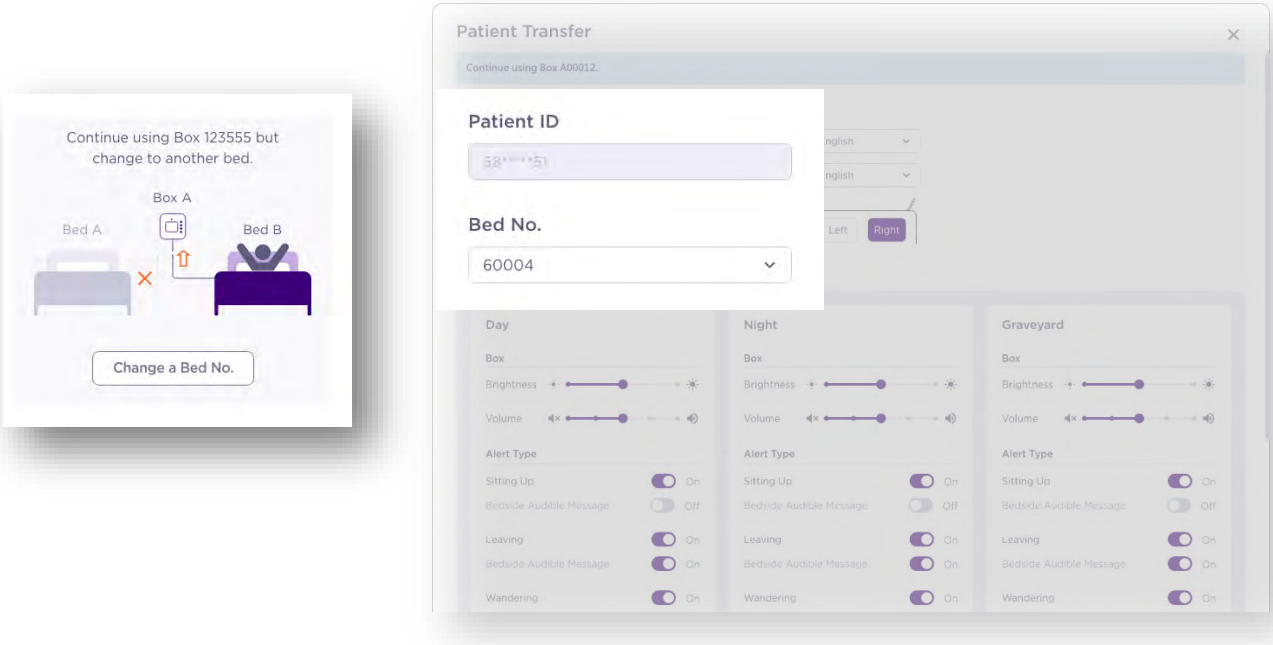




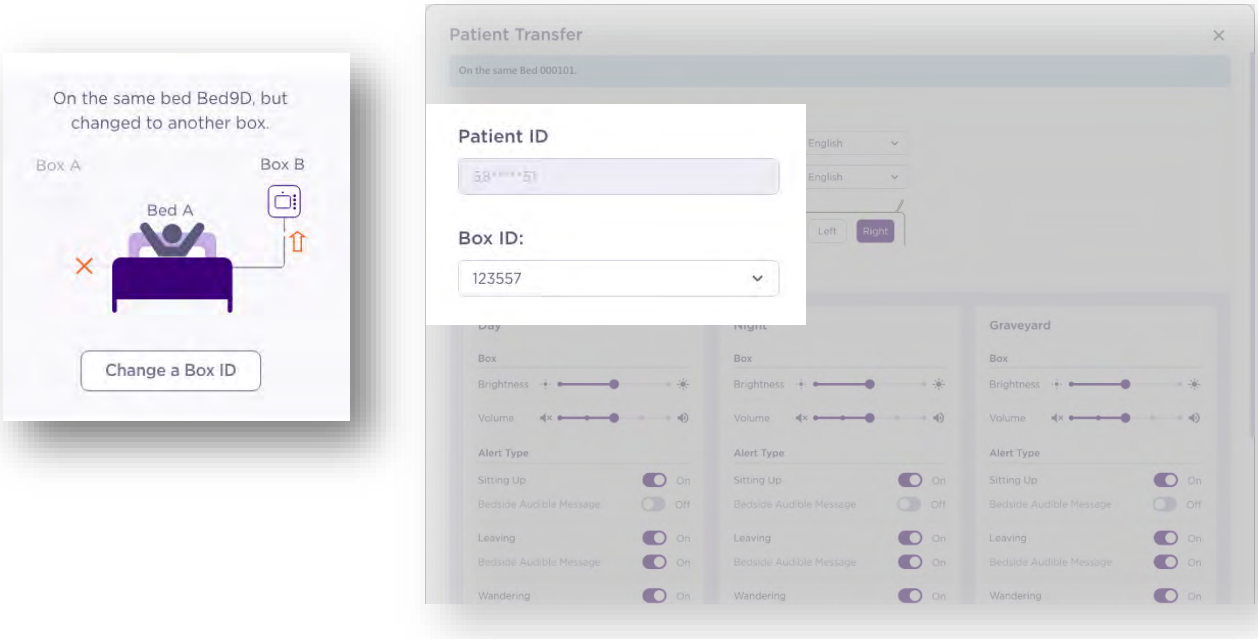


1. Tap a patient card to get into the patient detail page and tap 『Patient Transfer』.
2. Check the hardware of the new bed and see if the control box exists or need to be moved from the original bed.
3. If transferring the patient to an empty bed with a paired box, select the bed number in the drop-down menu which the patient is moving to.

4. If the patient is moving to an empty bed with the original control box, type in the new bed number in Patient Transfer window.



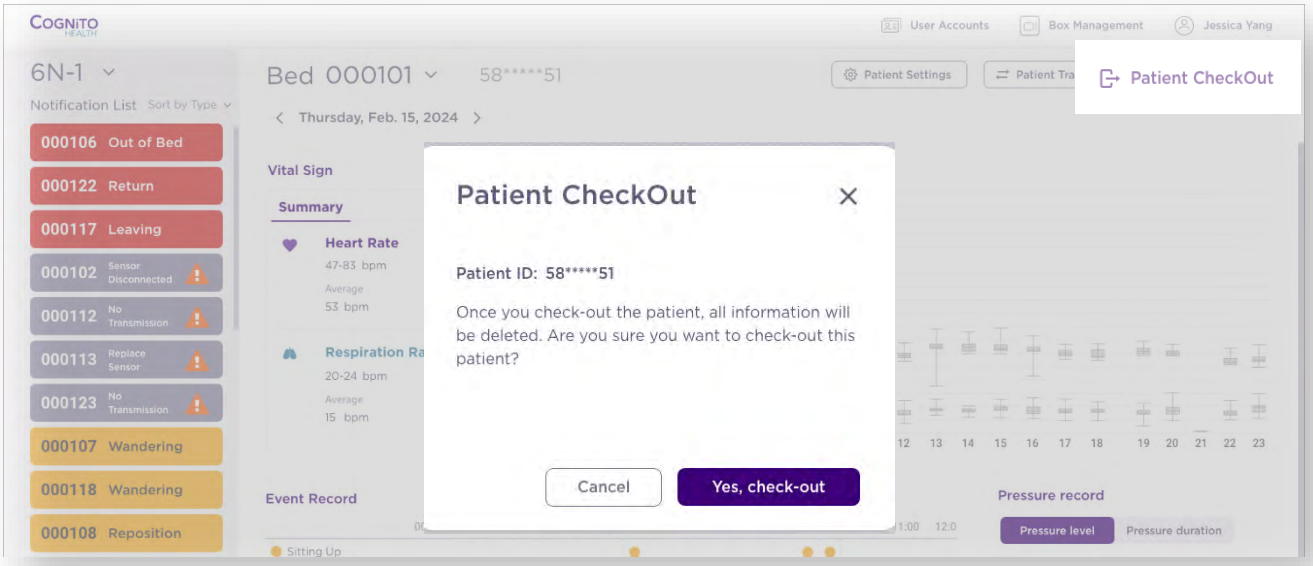
5. If the patient stays in the same bed number but using another control box, select a box ID in the Patient Transfer window.



Note: ensure that the new bed has already been configured and shows in the Box Management list.
CAUTION: *Please ensure that you use the exact same patient ID- if you don't, you will lose visibility to historical patient data.*

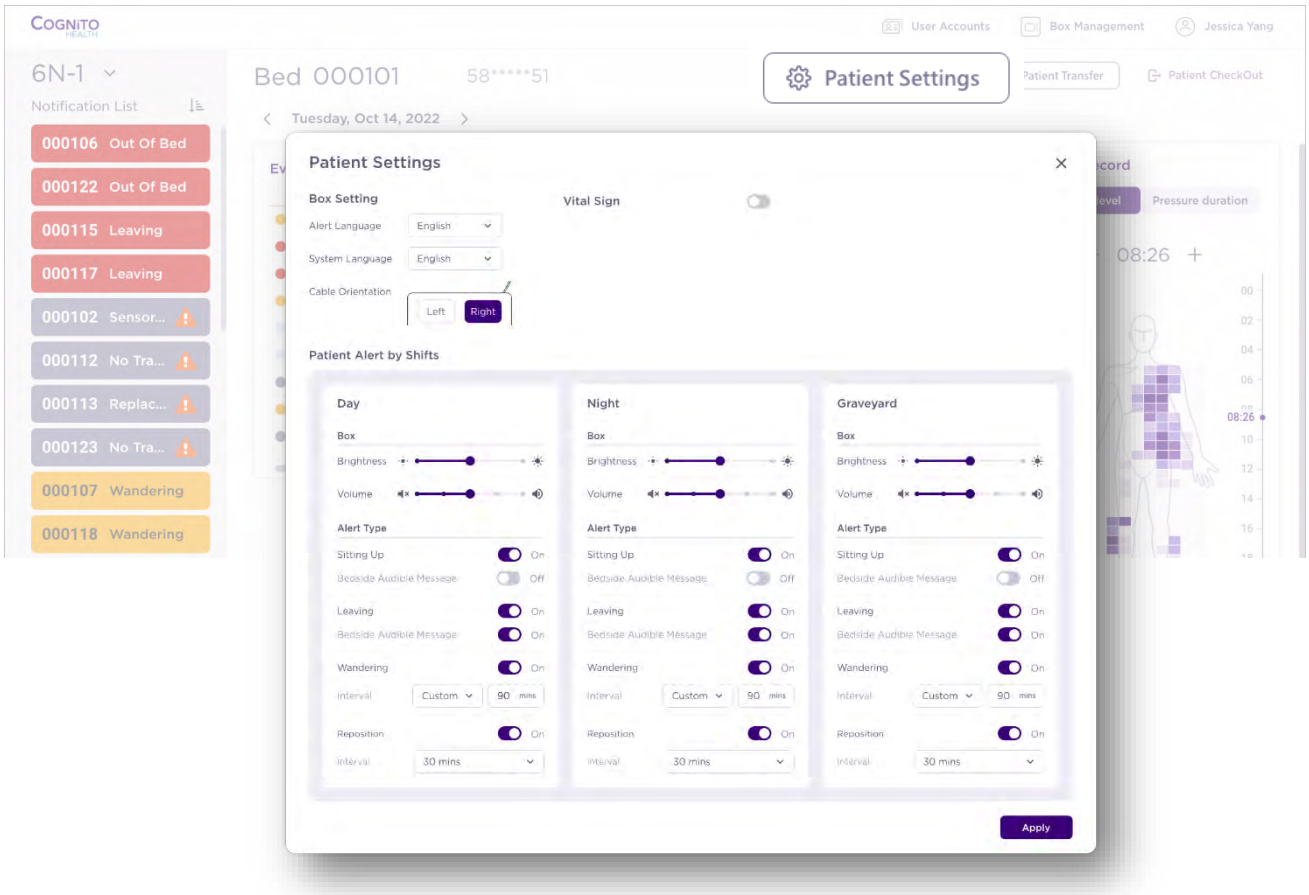
Patient Check-out

If the patient is discharged from the facility, remember to log out the patient to avoid confusion.



1. Tap a patient card to get into the patient detail page.
2. Tap 『Patient CheckOut』 on the tool bar and it will ask you if you are sure to proceed.
3. Click 『Yes』 to complete.

Patient Settings



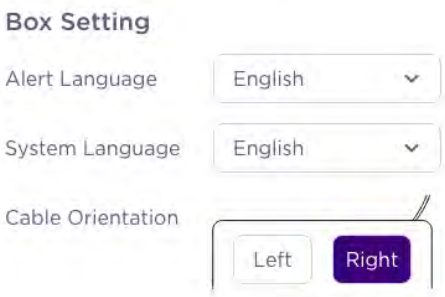
Control box and dashboard notifications settings can be adjusted on patient detail page. An overview of all settings for each patient can be displayed via the Cognito dashboard with list view.

1. Tap a patient card to get into the patient detail page.
2. Tap 『Patient Settings』 on the toolbar.
3. Adjust the dashboard notification and control box settings based on individual patient need or facility protocol.
4. Tap 『Apply』 to complete.

Box Setting

Alert Language

The audible notification from the control box has localized language or music options based on different countries or patient tolerance. The option includes English, Mandarin, Taiwanese, Japanese, Indonesian and music.



System Language

System language indicates the language on the control box interface, including English, Mandarin and Japanese.

Cable Orientation

The sensor pad can be installed with sensor cable either at right or left. Check the cable orientation before use to have proper detection.

Vital Sign

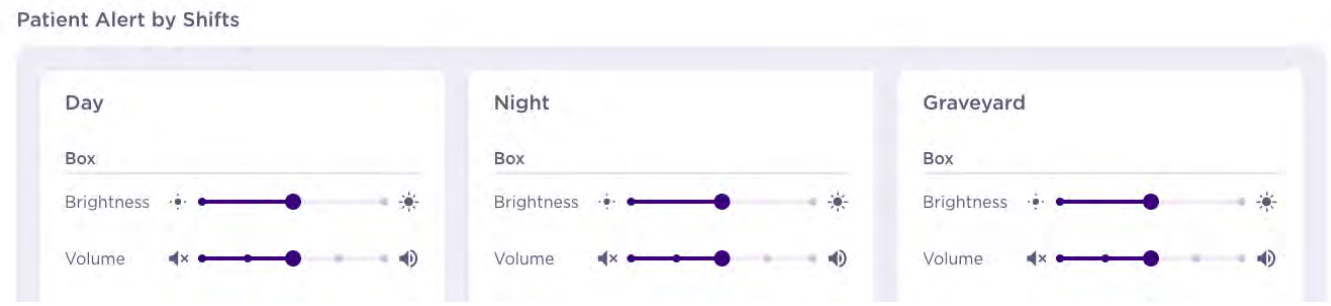
Vital sign can be switched on or off depending on the care needs.

Patient Alert by Shifts

The dashboard notification settings, box brightness and volume can be set by nursing shifts.

Box Brightness and Volume

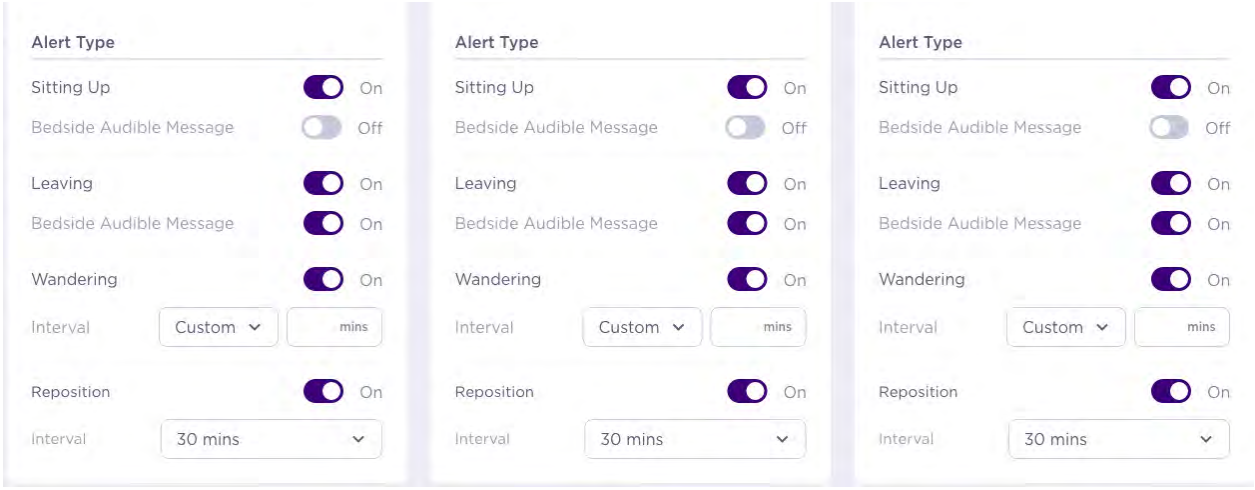
The brightness and volume of control box can be adjusted in three and five levels respectively based on individual patient need and tolerance. Only volume can be set off while the brightness can be set as dim.



Notification Settings

Bed exit and reposition notifications can be turned on or off based on patient's mobility. The default settings are all on for both bed exit and reposition notifications and default time for Wandering and Reposition is 15 minutes and 120 minutes respectively.

The bedside audible message for sitting up and leaving can be activated while these notifications depend on patient's tolerance and clinical needs. Out of bed notification is always on for best interests of patient safety.

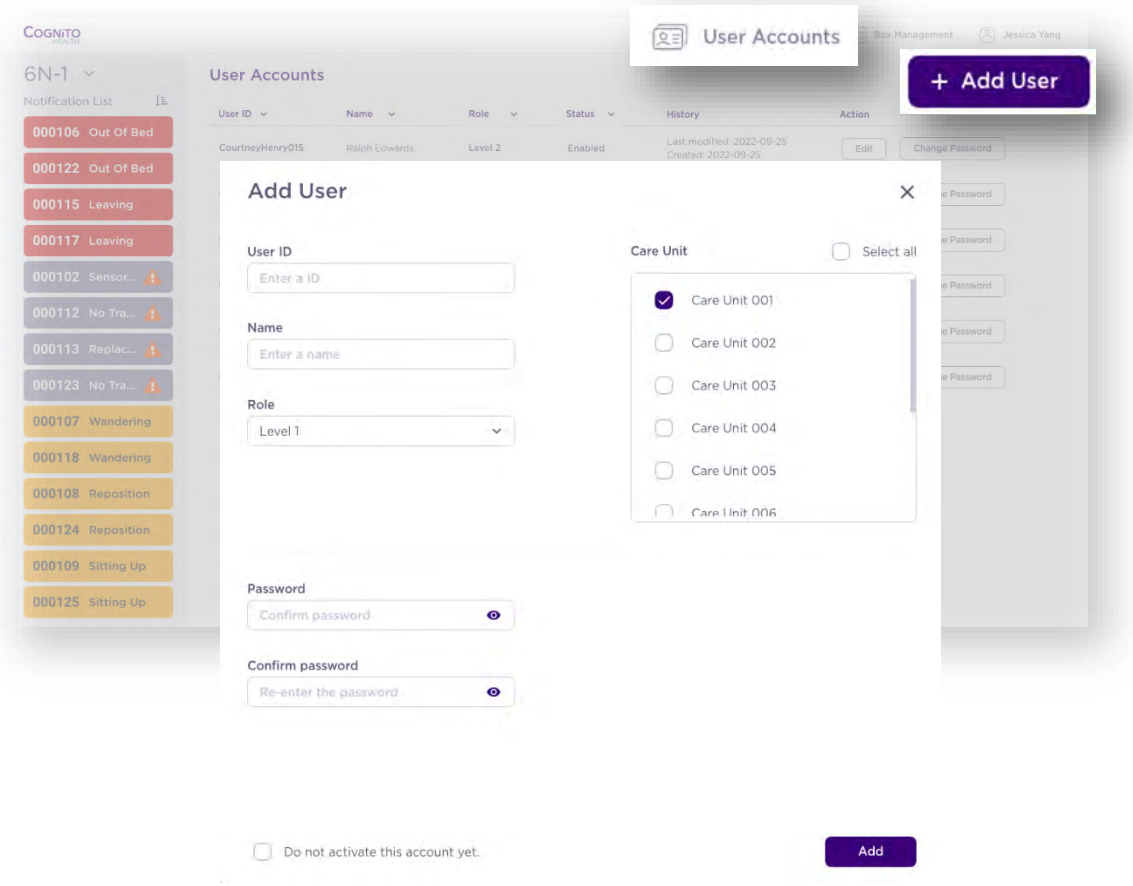


Account Management

The Cognito 3.1A allows healthcare facilities to determine which staff members can access the various features and settings of the Cognito system. The three levels are defined in the table below:

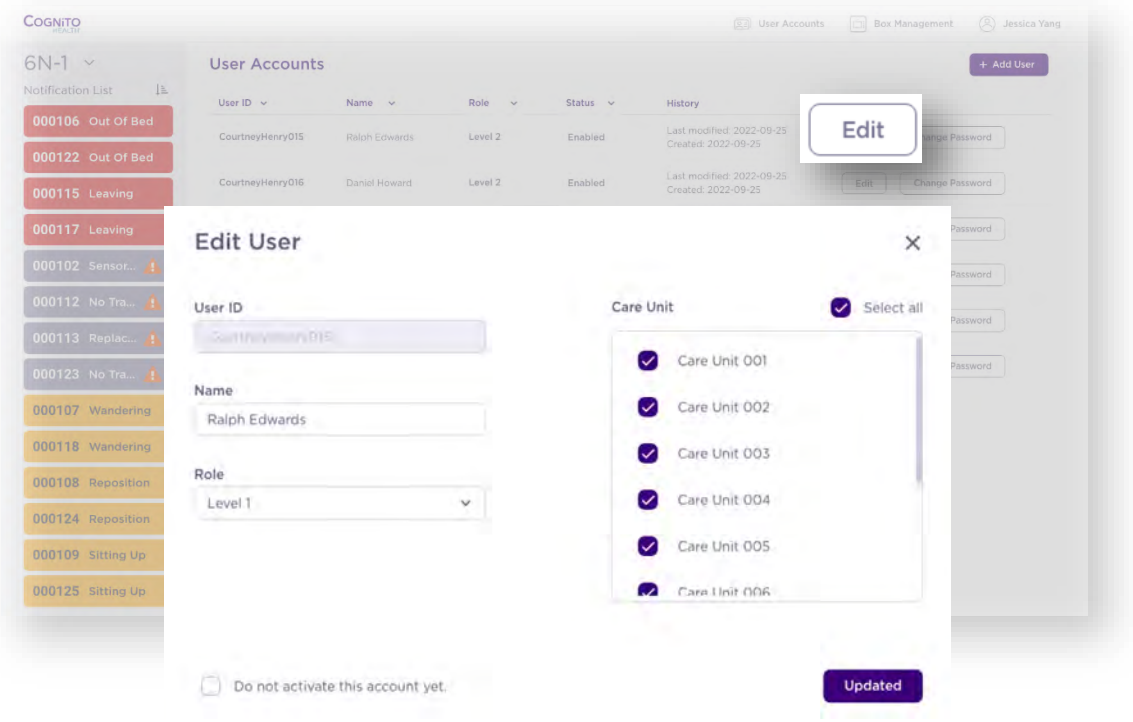
User Level	Level 1	Level 2	Level 3
Access Details	Level 1 has access to all the functions and features, including patient management, control box and account management. This typically includes, but is not limited to: Facility Administration, C-Suite, Clinical Executives, Quality/Safety Manager or Analyst or any "Super User" identified by the facility.	Level 2 has access to the same settings as Level 1 except for box Wi-Fi. This typically includes but is not limited to: Charge Nurse or Nurse Manager, Director of Nursing, or Nursing Staff (RN, LVN, LPN) or any staff member responsible for defining patient care plans.	Level 3 is a limited role, primarily focused on the patients themselves and has access to patient management, monitoring of and responding to patient care notifications. This level is typically recommended for a clinical support team member such as a CNA.

Create a New Account



1. Go to 『User Accounts』 at the top right corner.
2. Tap 『New Account』 to add a new user.
3. Type in the user information, select a user role and the responsible care units of this account.
4. Tap 『Add』 to complete.

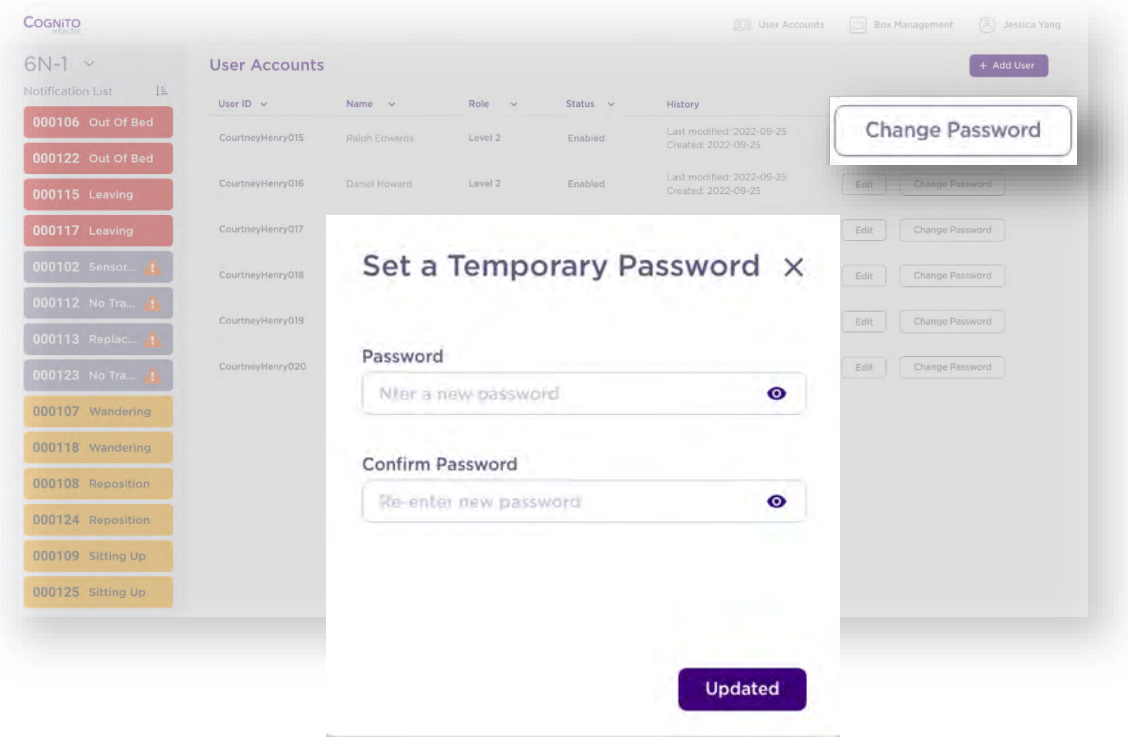
Edit an Account



1. Tap 『Edit』 of the specific user in account list.
2. Modify the information of this account and tap 『Updated』 to complete the editing.

Change Password

If the user forgets the password, level 1 or 2 user is able to set a temporary password for him/her to log in.

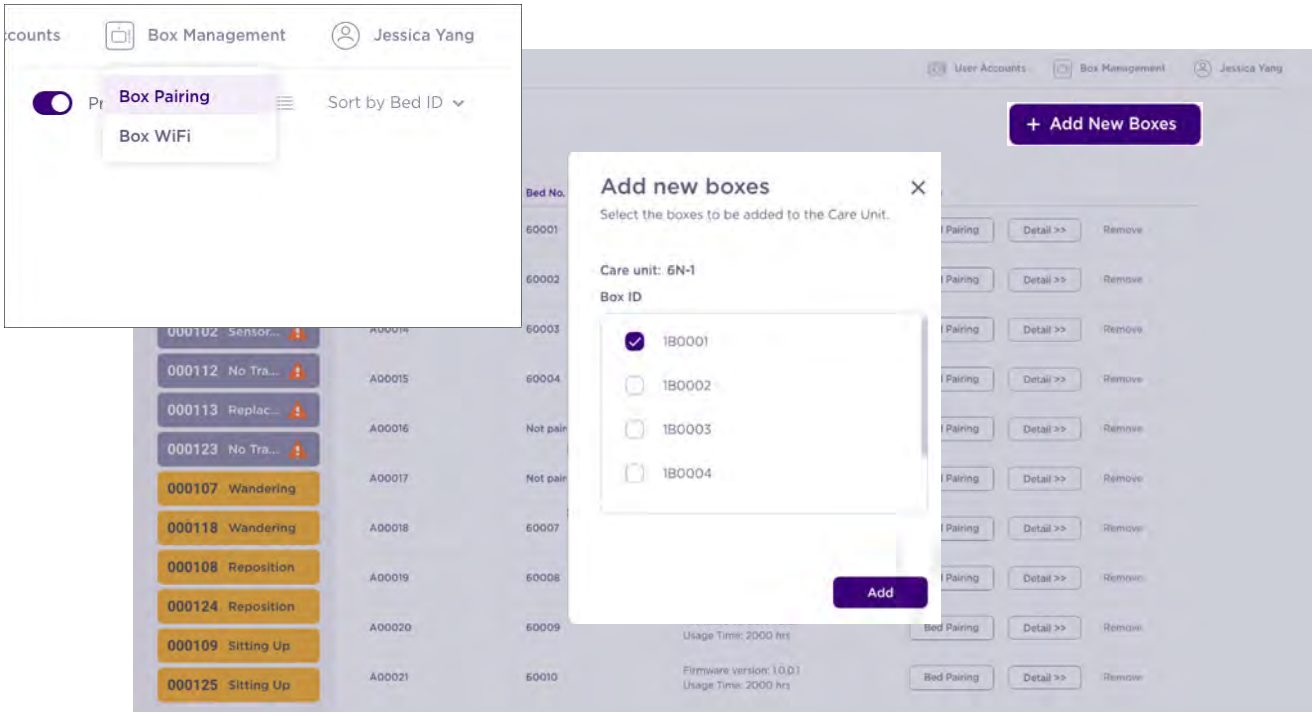


1. Tap 『Change Password』 of the specific user in account list.
2. Set a temporary password for the user and tap 『Updated』.
3. The user is able to log in the system with the temporary password.

Box Management

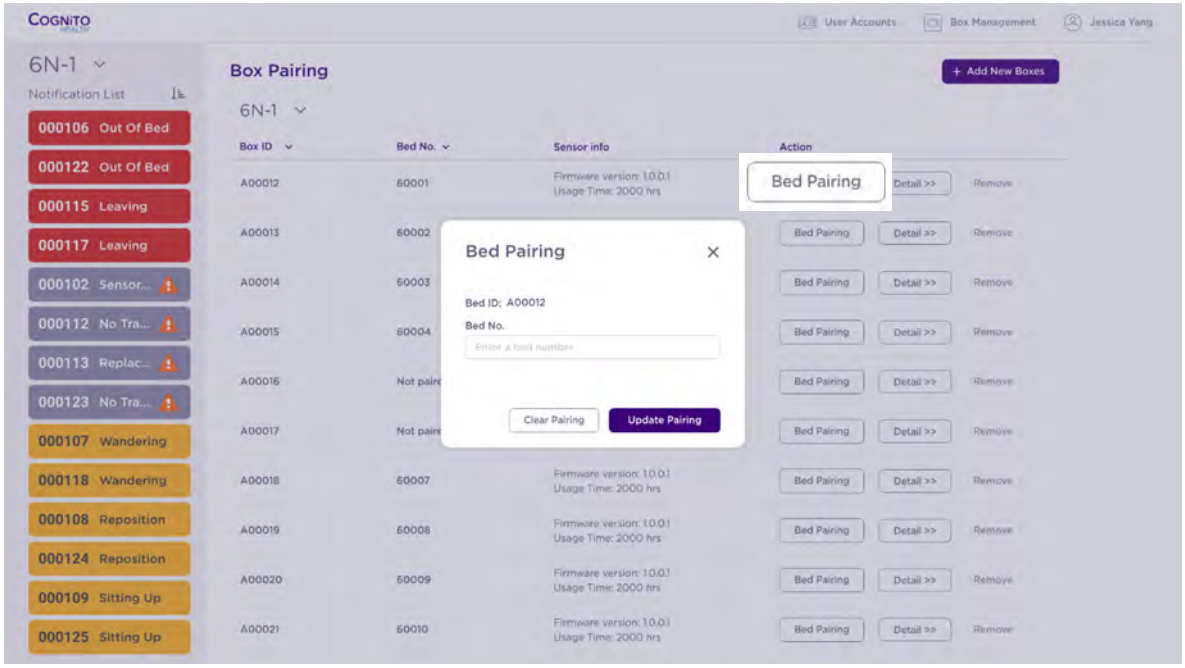
After the installation, control box must be assigned to a care unit and paired with a bed ID which indicates a patient's location in the facility, then patient check-in can be operated afterwards.
Level 1 or 2 user can manage box pairing and box Wi-Fi on the Box Management page while level 3 user can only operate box pairing.
The Box Management page provides the box information list, including serial number, bed ID and firmware version.

Assign a Control Box to a Care Unit



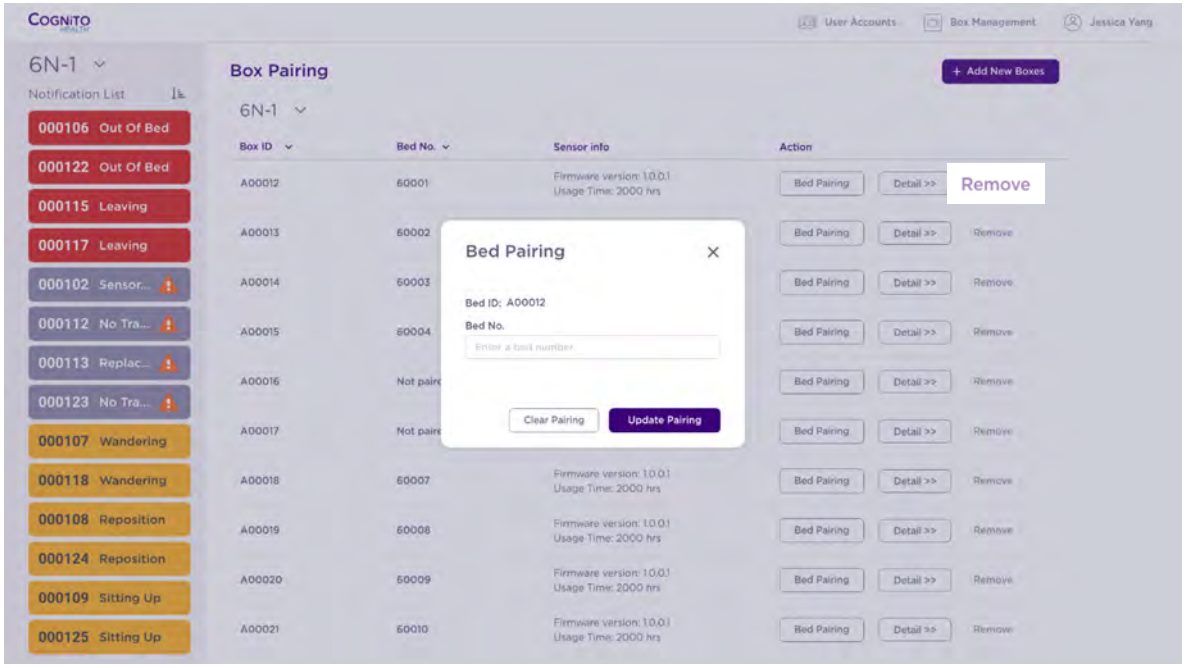
1. Tap Box Management and go to 『Box Pairing』 page to assign the boxes.
2. Select the care unit in the drop-down menu.
3. Tap 『Add New Boxes』 and all the control boxes of the facility are listed in the pop-up window.
4. Select the box IDs and tap 『Add』 to assign.
5. The control boxes are ready to be paired with a bed ID in the care unit and the box information are in 『Details』 page.

Pair a Control Box with a Bed ID



1. Tap 『Bed Pairing』 of the control box list.
2. Type in the bed ID and tap 『Update Pairing』.
3. The bed ID will be ready to check in the patient.

Clear or Remove Pairing of a Control Box

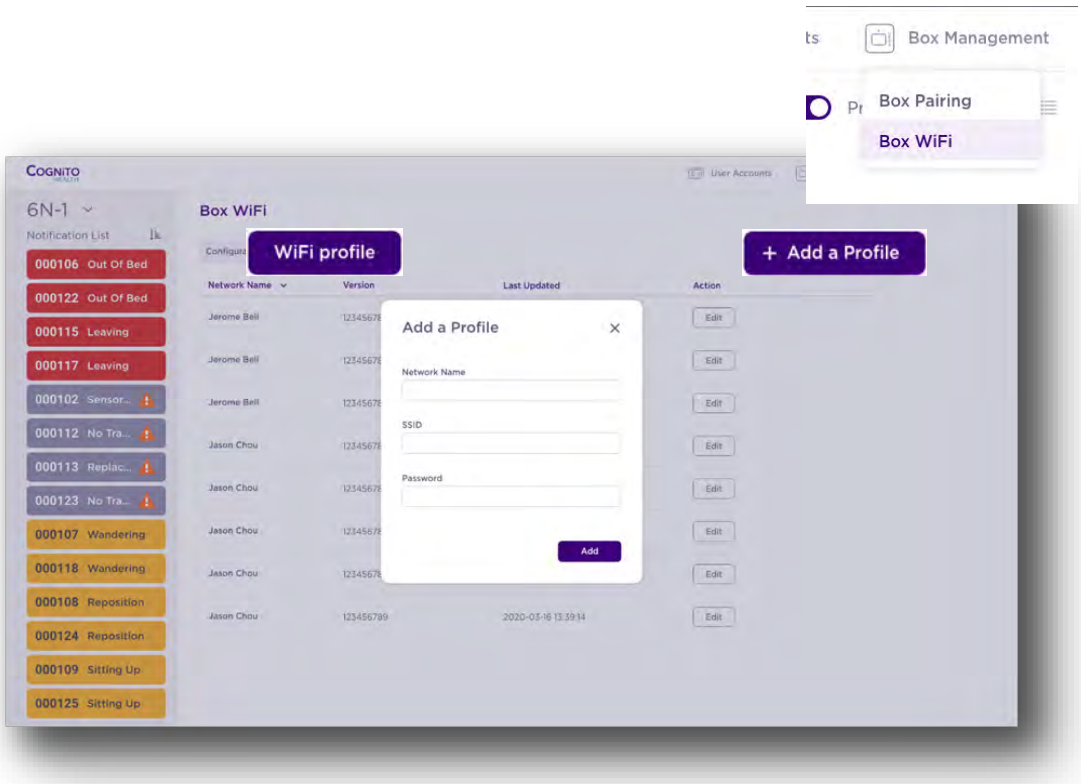


1. If the control box is moved to a different bed for use, tap 『Clear Pairing』 in Bed Pairing window.
2. If the control box is moved to another care unit, tap 『Remove』 to reassign the control box.

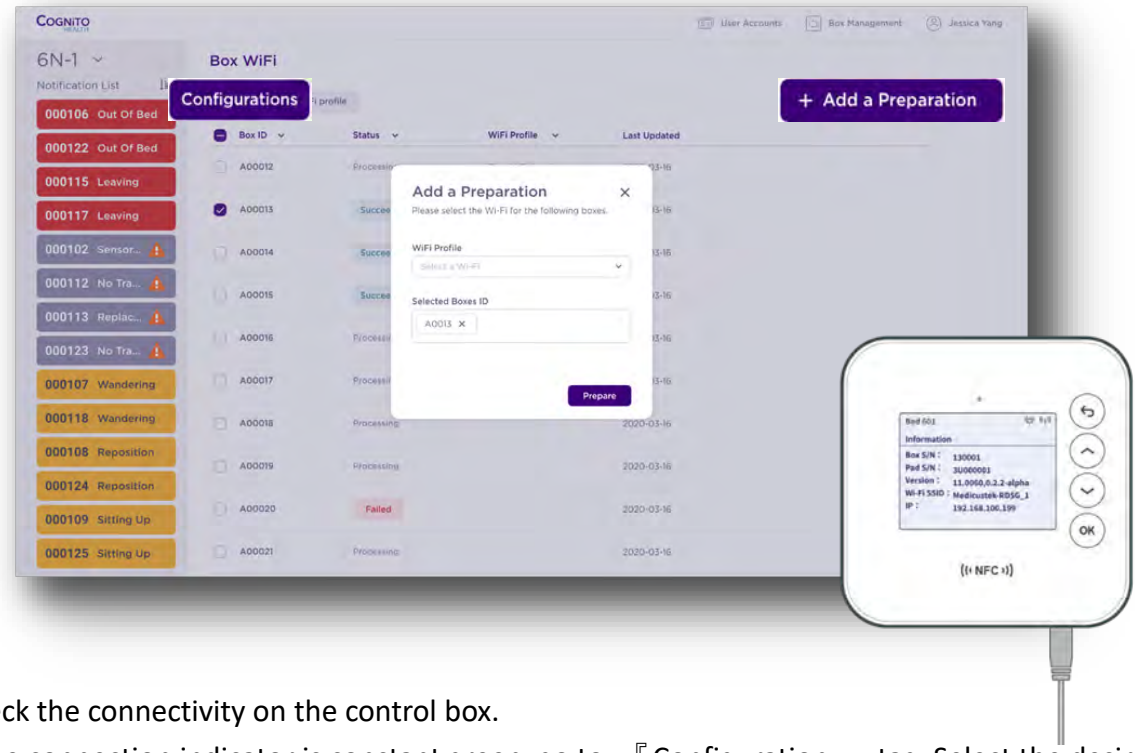
Box Wi-Fi

Box Wi-Fi setting is typically completed by Cognito distribution partner, in order to build connection between the control box and Cognito cloud via facility's network. Only level 1 user have access to Box Wi-Fi.

Create a network profile of the facility in the system first, then prepare control boxes for configuration. Follow the instructions to operate box configuration.



1. Go to the Box Wi-Fi page from the Box Management.
2. Tap 『Add a Profile』 in Wi-Fi profile page.
3. Type in the Network name, SSID and password. Tap 『Add』 to create a Wi-Fi profile.



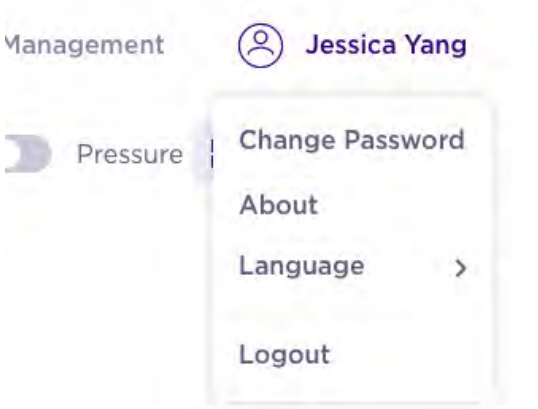
4. Check the connectivity on the control box.
5. If the connection indicator is constant green, go to 『Configuration』 tag. Select the desired control boxes in the tick box.
6. Tap 『Add a Preparation』 and select a Wi-Fi profile in the drop-down menu to connect with.
7. Tap 『Prepare』 to build the Wi-Fi connection between the control box and the cloud.
8. Replug in the power adapter and wait for few minutes to reboot.
9. Long press “OK” button on the control box and get into the Information page. Check if the Wi-Fi SSID is correctly built in.

Note:

1. The Wi-Fi profile is commanded from the cloud to the control box. If the control box is not connected to a network before operating 『Configuration』, plug in a workable Ethernet to process.
2. All the control boxes used in the facility will be listed in the Configuration tag.

Account

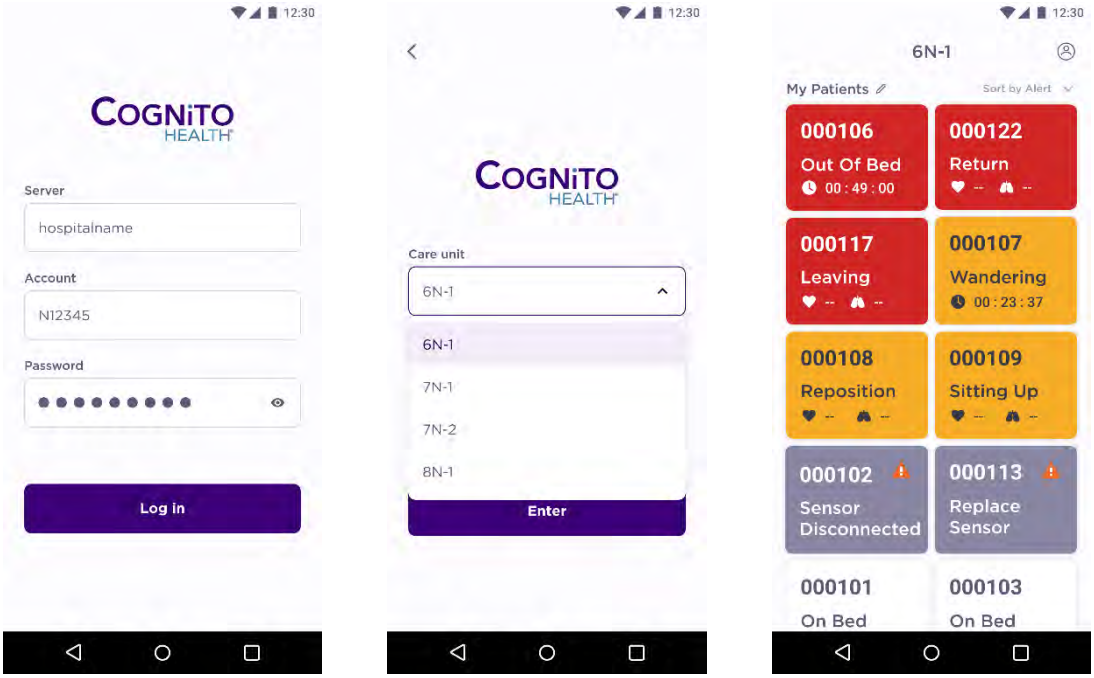
Users can change their password, the dashboard language and log out of the system from User Account menu.



Cognito Mobile App

Mobile app is simply used to notify the healthcare professionals/caregivers and check the live pressure profile, in order to get the notifications and determine for intervention to the patients anytime and anywhere.

Login Mobile App

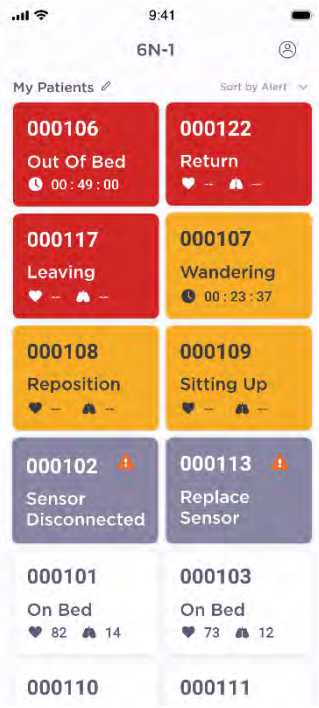


1. Type in server name, user ID and password. Tap 『Login』.
2. Select your responsible care unit and tap 『Enter』.
3. You will get to the main page of the mobile app.

Mobile App Interface

Main Page

All the responsible patients in the care unit will be displayed on the main page. The notifications can be put in order of notification type, time or bed ID.
User is able to log out the system from the portrait icon at the top right corner.



Patient Detail Page

Tap a patient card to get into the patient detail page.
Patient detail page displays the live pressure level with the patient status.

Safety Tips

- Before you start, read this guide to become familiar with all safety requirements and operating procedures.
- No modifications of the Cognito system are allowed. Modifications made to the equipment may pose a potential safety threat to both operators and patients.
- Median/divider placed between the patient and the bed linen that is not provided or recommended by Cognito Health (such as pillow, towel or any kind of pressure distribution aid or for other purposes) might reduce the accuracy of the Cognito system.
- Sterilization by heat, gas, radiation or any harsh materials other than the recommended method can damage the Cognito system.
- The maximum tested patient weight to ensure accurate measurements and the products durability is 226.8 kg. / 500 lbs.
- Remove from service any Cognito system that is defective or damaged. Report immediately to your Cognito distribution partner, including:
  - Torn or damaged sensor pad
  - Broken or damaged sensor cable
  - A ripped or frayed electrical cable
  - A malfunctioning or broken control box
- Control box touch screen- use only fingertips to operate the touch screen. Avoid using fingernails, pens or any sharp objects that might damage the screen.
- Sensor pad
  - Clean the sensor pad according to the instructions provided in this user manual
  - Always wear gloves while cleaning or relocating the sensor pad
  - Ensure power adapter is disconnected from the electrical outlet prior to cleaning the sensor pad
- Place the sensor pad on top of the mattress and under the mattress cover and/or facility bed sheet. Please refer to the installation instructions.
- Ensure a mattress cover and/or a facility bed sheet is placed between the patient and the sensor pad.
- Check that if Leaving/Out of Bed are both properly activated before having the control box and the system into service.
- The system does not contain any self-serviceable parts. Never attempt to open or remove the exterior covers of the hardware components or of the sensor pad. Removal of the covers can create a safety hazard and will void the warranty.
- Once cleaned and removed from a bed, assure the sensor pad is stored in a clean environment.
- Ensure the control box and the sensor pad are adequately protected while not in use.

- If the transmission between the control box and Cognito cloud is interrupted, there will not be a notification from Cognito dashboard and mobile app.
- The Cognito 3.1A provides bed exit related and repositioning notifications to support and drive the clinical intervention and decision-making. It is not intended to avoid entire fall incidents and pressure injuries from happening.
- Fall prevention and pressure injury care get most out of the notification settings with personal bedside assistance. Notifications or other events can go invalid if the nursing staff or healthcare professionals does not appear at the bedside or if the connection between control box and the software is interrupted.
- The information on Cognito 3.1A can only be interpreted by healthcare staff and professionals.
- The Cognito 3.1A system is not intended to substitute ECG or patient monitor.
- Notification settings are patient-oriented features of Cognito 3.1A. It is strongly recommended to adjust the settings before you start monitoring, or have daily adjustment based on patient condition.
- Audible alert from the control box has its advantage to include patients themselves into patient safety protocol. Keeping the sound on benefits all concerned for fall prevention.

Maintenance

Regular Inspection

To prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES, please take the following recommendations:

1. Check that if Leaving/Out of Bed are both properly activated before having the control box and the sensor pad in service.
2. ***DO NOT*** use a damaged sensor cable. Contact the manufacturer or distributor if a damaged sensor cable is discovered.
3. ***DO NOT*** use any other cables or accessories not approved by Cognito Health to avoid negative influence on electromagnetic compatibility.
4. For best results, do not stack or collocate other equipment on the Cognito product. If necessary, please monitor to ensure devices operate normally.
5. Check if there is any damage to the power adapter's power cord and plug.
6. Check the sensor cable and the sensor pad for damage.
7. Promptly remove seriously damaged, soiled, or contaminated Cognito products and notify manufacturer or distributor for pickup.

Note: *Faded color or illegible printing might occur after the sensor pad is used, cleaned, and disinfected.*

⚠ **WARNING**

- Use only detachable parts and accessories approved by Cognito Health.
- ***NEVER*** open or modify the control box or sensor pad. If the system is not functioning, please contact your Cognito distributor.
- ***DO NOT*** install or store products under direct sunlight or a dusty environment.

⚠ **CAUTION**

- To safely terminate operation of the system, perform cleaning/disinfection and regular inspection, please disconnect the sensor cable from the push-pull connector and power adapter.

Storage

After disconnecting the sensor cable, store the sensor pad and the control box under ambient temperature between -13°F to 158°F (-25°C to 70°C) and relative humidity condition between 15% to 90% RH.

⚠ **CAUTION**

- For storage, place the sensor pad on a flat surface. To avoid damage, please do not stack more than three sensor pads in a single stack. ***DO NOT*** stack any other items on the sensor pads.
- Be aware of the temperature and relative humidity of the storage environment; improper conditions may accelerate the aging of the Cognito product.
- The device can be operated immediately after storage.

Cleaning and Disinfection

Sensor Pad

Cleaning and disinfecting the sensor pad is suggested upon patient discharge, bed transfer or body fluid contamination.

1. Wipe the sensor pad with a clean, soft cloth. The cloth is suggested to be damped with bleach under 5000ppm, 75% ethanol or 3.1% hydrogen peroxide.
2. Make sure there are no residues left on the sensor pad.
3. Dry the sensor pad completely before use.

Control Box

Please clean the products regularly. Weekly cleaning is recommended for the control box. Disinfecting the control box is suggested upon patient discharge, bed transfer or body fluid contamination.

1. Wipe the control box with a clean, soft cloth. The cloth should be damped with 200ppm bleach for cleaning and 500ppm bleach for disinfection.
2. Make sure there are no residues left on the control box.
3. Dry the control box completely before use.

⚠ **WARNING**

- ***DO NOT*** disinfect the Cognito products by placing it in any UV light sterilization cabinets.
- ***Only*** use Cognito recommended cleaning agents.
- When Cognito product is used by a patient with scabies, please halt the use for at least 14 days before using it with the next patient.
- ***DO NOT*** soak the device in cleaning solution or disinfectant.
- If there is any liquid on the surface of the device, dry the device to avoid damage to the Cognito product.

⚠ **CAUTION**

- Always disinfect the sensor pad between patients to avoid the risk of cross contamination and infection.

- Make sure the sensor pad is completely dried before fitting the mattress cover and/or facility sheet over the products.
- Frequent or extended use of high-concentration disinfectants will accelerate aging of the cover coat.

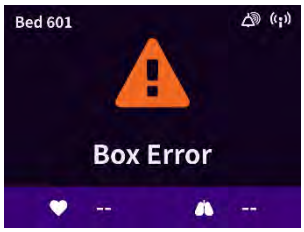
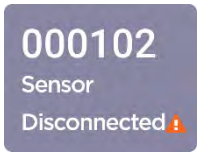
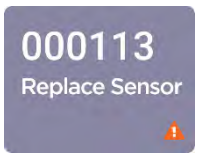
Disposal

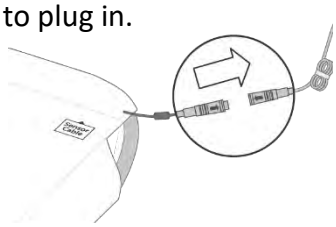
1. The purchaser or user is responsible for rendering the device unusable if it is no longer to be applied (prevention of misuse).
2. The waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately.
3. Please contact your Cognito distributor for information concerning the decommissioning of your equipment.

Troubleshooting

Cognito 3.1A provides several different technical alerts if technical abnormalities are detected. Any other problem, please contact the distributor or the manufacturer for further assistance.

Problem	Troubleshooting
Control box is unresponsive.	1. Make sure the power adapter is connected to the control box and plugged into the power outlet. 2. See *Operating Instructions of Control Box* to observe the power indicator. 3. If the power indicator is unresponsive, please contact the distributor or manufacturer for further assistance.
Patient left the bed, but the Out-of-Bed notification was not triggered.	1. Make sure the power adapter is connected to the control box and plugged into the power outlet. 2. Make sure the sensor is connected and is not damaged. 3. Please flatten the sensor and remove any weight on top of the sensor. Lie on the sensor and get out of bed to ensure Out of Bed notification is sent out. 4. If out-of-bed notification is still not working, please contact your Cognito distributor.
Control box has no sound.	1. Make sure the power adapter is connected to the control box and plugged into the power outlet. 2. Follow *Operating Instructions of Control Box* or *Box Brightness and Volume* in Using the Cognito Dashboard to adjust the volume.
Control box has no light.	1. Make sure the power adapter is connected to the control box and plugged into the power outlet. 2. Follow *Operating Instructions of Control Box* or *Box Brightness and Volume* in Using the Cognito Dashboard to adjust the brightness.
Control box falls off from the hanger of the wall mount plate.	1. Follow *Installation Instructions* to reinstall the control box. 2. Please contact the manufacturer or the distributor if extra accessories were needed.

Button on the control box is unresponsive.	1. Make sure the power adapter is connected to the control box and plugged into the power outlet. 2. If the button were still not working, please contact the manufacturer or the distributor.
Sensor pad is not well-fixed on the facility mattress.	1. Make sure the mattress size conforms to the specification. 2. Make sure the bands of the sensor pad is not damaged or broken off. 3. Follow the instructions and re-install the sensor pad. 4. If the problem is remaining, please contact distributor or manufacturer for further assistance.
Box Error is displayed on the control box user interface. 	1. Control box may return to normal within 1 minute. If not, reconnect the power adapter to the control box. 2. If the error message is remaining, please contact distributor or manufacturer for further assistance.
Sensor Disconnected 	1. Reconnect the sensor cable to the sensor port of the control box. 2. Make sure the push-pull connector cannot be loosened easily. 3. Replace the sensor. 4. If the problem is remaining, please contact the distributor or manufacturer for further assistance.
Replace Sensor 	1. Reconnect the sensor cable of the sensor pad to the sensor port and make sure the gray plastic shell is clockwisely tight. 2. Check if the quick release connector is loosened with uncovered green inner shell. If it is loosened, reconnect the quick release connector. 3. Replace the sensor. 4. If the problem is remaining, please contact the distributor or manufacturer for further assistance.

	NOTE: ***DO NOT*** plug in and out the quick release connector unless it is necessary. If it is accidentally plugged out, find the arrow marks on the quick release connector and follow the direction of arrow to plug in. 
No Transmission 	1. Make sure the power adapter is plugged into the power outlet and the control box. 2. Check the status on the control box. If Box Error is displayed on the control box, please follow the troubleshooting of Box Error. 3. If the network is disconnected on the control box, reconnect the adapter power and contact local IT staff to check the Internet connectivity. 4. If the problem is remaining, please contact distributor or manufacturer to check the system.

Specifications

Sensor Pad

	Sensor Pad
Model Number	P7FD-22
Dimension	1950 (L) x 920 (W) x 10 (T) mm
Weight	7.5 lbs (3.4 kgs)
Weight Capacity	70.5 to 500 lbs (32 to 226.8 kg)
Compatible Mattress Size	188~203 (L) x 84~90 (W) x 9~12 (H) cm
Sensor Cable Length	203cm
Material	Coat: 100% Polyester
Environment *Atmospheric Pressure*	700 hPa to 1060 hPa
Operating Temp.	41°F to 104°F (5°C to 40°C)
Storage and Transportation Temp.	-13°F to 158°F (-25°C to 70°C)
Operating Humidity	15% to 90% RH
Storage and Transportation Humidity	15% to 90% RH

Control Box

		BA6G-32
Dimension	*Length*	4.72 inch (120 mm)
	Width	4.72 inch (120 mm)
	Height	1.1 inch (28 mm)
Weight		0.66 lb (300 g)
Power	*Input Voltage*	12V DC
	Adapter Model	ATM024T-W120V (Adapter Technology)
	Adapter Input	AC 100-240V, 0.58-0.32A, 50-60Hz
	Adapter Output	DC 12V, 2A (Max)
Interface	*to Sensor*	Mini DIN push-pull connector
	Wireless	IEEE 802.11 a/b/g/n/ac Bluetooth 5.0 NFC
	Ethernet	Ethernet 10/100 Mbps
IP Code		IP22
Environment	*Atmospheric pressure*	700 hPa to 1060 hPa
	Operating Temp.	41°F to 104°F (5°C to 40°C)
	Storage and Transportation Temp.	-13°F to 158°F (-25°C to 70°C)
	Operating Humidity	15% to 90% RH
	Storage and Transportation Humidity	15% to 90% RH
Expected Service Life		5 Years

Accessories

		Wall Mount Plate	Glue Tape
Part Number		ZAC0-A1	ZDB0-A1
Dimension	*Length*	3.35 inch (85 mm)	3.78 inch (96 mm)
	Width	4.33 inch (110 mm)	3.31 inch (84 mm)
	Height	0.40 inch (10.25 mm)	0.04 inch (1 mm)

Cognito Dashboard and Mobile App

Browser Requirements	Google Chrome, Microsoft Edge and Safari in current supported version
Recommended Screen Resolution	1920 x 1080
OS Platform	Windows 10 / Mac OS 11 or later version
Mobile Compatibility	Android 10 / iOS 17 or later version
Maximum Monitored Beds	160 beds per facility, 40 beds per care unit
Number of Simultaneous Mobile Device Connections	6 mobile devices per care unit
Data Transport Security	TLS 1.2
Network Ports	Port 443

Contact Information

Please note that any serious incident that has occurred in relation to the device should be reported according to state and federal regulatory guidelines and to the device manufacturer.

Manufacturer / Asia Contact
Cognito Health Inc.
+886-2-2655-8672
No. 3 Yuanqu St., 9F.-1, Nangang Dist,
Taipei 11503,
Taiwan
www.cognitohealth.com

US Local Contact
Cognito Health Corporation
+1-623-224-6400
2755 Canyon Boulevard Boulder
CO 80302
USA
info@cognitohealth.com

EMC Description

<table>
<tr><th colspan="3">Manufacturer’s declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The BA6G-32 is intended for use in the electromagnetic environment (for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT) specified below.
The customer or the user of the BA6G-32 should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance (for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT)</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The BA6G-32 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="5">The BA6G-32 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td rowspan="2">Harmonic emissions
IEC 61000-3-2</td><td>AC 120 V/60 Hz:
Not applicable</td></tr>
<tr><td>AC 230 /50Hz:
Class A</td></tr>
<tr><td rowspan="2">Voltage fluctuations /flicker emissions
IEC 61000-3-3</td><td>AC 120 V/60 Hz:
Not applicable</td></tr>
<tr><td>AC 230 /50Hz:
Compliance</td></tr>
</table>

Manufacturer's declaration-electromagnetic immunity

The BA6G-32 is intended for use in the electromagnetic environment (for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT) specified below.

The customer or the user of the BA6G-32 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,± 15 kV	Contact:±8 kV Air±2 kV,±4 kV,±8 kV,± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical professional healthcare environment or HOME HEALTHCARE ENVIRONMENT.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV,± 2kV line(s) to earth	Mains power quality should be that of a typical professional healthcare environment or HOME HEALTHCARE ENVIRONMENT.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle| 70 % *U*T; 25/30 cycles Voltage interruptions: 0 % *U*T; 250/300 cycle	Voltage dips: 0 % *U*T; 0,5 cycle 0 % *U*T; 1 cycle 70 % *U*T; 25/ 30 cycles Voltage interruptions: 0 % *U*T; 250/ 300 cycle	Mains power quality should be that of a typical professional healthcare environment or HOME HEALTHCARE ENVIRONMENT. If the user of the BA6G-32 requires continued operation during power mains interruptions, it is recommended that the BA6G-32 be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	The BA6G-32 power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment or HOME HEALTHCARE ENVIRONMENT.

NOTE *U*T is the a.c. mains voltage prior to application of the test level.

<table>
<tr><th colspan="4">Manufacturer’s declaration-electromagnetic immunity</th></tr>
<tr><td colspan="4">The BA6G-32 is intended for use in the electromagnetic environment for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT) specified below.
The customer or the user of the BA6G-32 should assure that it is used in such and environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment-guidance
(for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT)</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms:
0,15 MHz – 80 MHz
6 Vrms:
in ISM bands between
0,15 MHz and 80 MHz

80 % AM at 1 kHz</td><td>3 Vrms:
0,15 MHz – 80 MHz
6 Vrms:
in ISM bands between
0,15 MHz and 80 MHz

80 % AM at 1 kHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the BA6G-32 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:
d = 1,2 $\sqrt{P}$
d = 1,2 $\sqrt{P}$ 80MHz to 800 MHz
d = 2,3 $\sqrt{P}$ 800MHz to 2,7 GHz
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>10 V/m
80 MHz – 2,7 GHz
80 % AM at 1 kHz</td><td>3 V/m
80 MHz – 2,7 GHz
80 % AM at 1 kHz</td></tr>
<tr><td colspan="4">NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

Recommended separation distance between portable and mobile RF communications equipment and the BA6G-32

The BA6G-32 is intended for use in an electromagnetic environment (for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT) in which radiated RF disturbances are controlled. The customer or the user of the BA6G-32 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BA6G-32 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The BA6G-32 is intended for use in the electromagnetic environment (for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT) specified below.

The customer or the user of the BA6G-32 should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for professional healthcare and HOME HEALTHCARE ENVIRONMENT)
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450	Pulse modulation [b] 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

The BA6G-32 is intended for use in the electromagnetic environment (for home and professional healthcare) specified below.

The customer or the user of the BA6G-32 should assure that it is used in such an environment.

Frequencies	**Test Level [A/m]**	**Modulation**	**Dwell time [s]**	**Compliance LEVEL [A/m] (for home and professional healthcare)**
30 kHz (a)	8	CW	3	8
134,2 kHz	65	Pulse modulation (b) 2,1 kHz	3	65 (c)
13,56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7,5 (c)

Note:
(a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT.
(b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
(c) r.m.s., before modulation is applied.

THE WARRANTY IS VOID IF THE PRODUCT HAS BEEN OPENED, SUBMERGED, OR MISUSED (E.G., USED CONTRARY TO THE INSTRUCTIONS OR TO THE INTENDED USES OF THE PRODUCT).

THE COMPONENTS OF THE PRODUCTS ARE SUBJECT TO A LIMITED WARRANTY FROM THE DATE OF ORIGINAL PURCHASE.