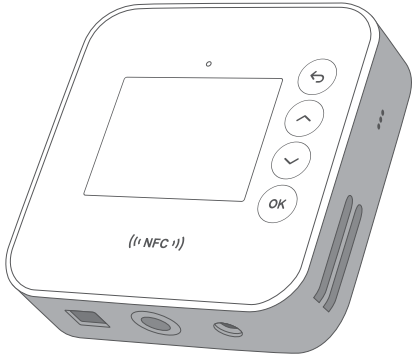
COGNITO HEALTH

MANL-B003-EN-V1.30

User Manual for

Control Box

BA6E-31/BA6E-32



Read the manual thoroughly prior to using the product

About This Manual

This manual is designed to assist you with the safe operation and recommended cleaning of the control box (BA6E-31/BA6E-32). Please read this manual carefully before operating or performing maintenance on this product. If you have any questions about how to use or clean the control box, contact your distributor before using the product.

This manual contains instructions for use, troubleshooting and cleaning of the control box. Proper tutorials and trainings are required prior to the use of control box.

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

Control box (BA6E-31/BA6E-32) is designed for use as part of the Cognito 3.0 system. The Cognito 3.0 system is intended to provide bed exit and reposition notifications. It is indicated for use with patients in bed throughout the continuum of care.

Introduction

The Cognito 3.0 system is designed for continuous and contact-free predictive patient monitoring. The system monitors patient movement/ mobility and can notify caregivers when a patient attempts to exit the bed or needs repositioning.

Cognito 3.0 comprises of sensor pad, control box, Cognito cloud, Cognito dashboard and mobile app, providing bed exit and reposition related notifications for fall prevention and repositioning assistance for healthcare staff and professionals. The system also notifies patients with bedside alert from the control box when patients attempt to exit the bed. Bedside alert has multi-language options for different countries, and mute notification is also available while needed.

The Cognito 3.0 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.

Abbreviation

Sensor Sensor pad

Symbols | Definition

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

IP22

Protected from touch by fingers greater than 12 millimeters
Protected from water spray less than 15 degrees from vertical

CE

The CE Mark signifies the device has met the essential requirements of General Safety and Performance Requirements of European Medical Device Regulation (EU) 2017/745.

MD

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.

Refer to instruction manual

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

· This device may not cause harmful interference, and

· this device must accept any interference received, including interference that may cause undesired operation.

FCC RF Radiation Exposure Statement:

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

· This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

On Carton

Fragile

This way up

Keep away from rain

No cutting

The stack limitation is 3 units

CE The CE Mark signifies the device has met the essential requirements of General Safety and Performance Requirements of European Medical Device Regulation (EU) 2017/745.

MD The MD symbol indicates the item is a medical device.

Corrugated products for recycling

Table of Contents

Ch.1 Exterior Introduction **1**

1.1 Control Box (BA6E-31/BA6E-32) *1*

Ch.2 Operating Instruction **5**

2.1 Installation Instructions *5*

2.1.1 Use Wall Mount Plate with Glue Tape to Install 6

2.1.2 Use Wall Mount Plate with Screws to Install 8

2.1.3 Use VESA Mounts with Screws to Install 12

2.1.4 Remove the Control Box 16

2.2 Operating Instructions *18*

2.2.1 Regular Settings 18

2.2.2 Nurse Mode 21

2.3 Acknowledging and Dismissing Notifications *23*

2.3.1 Bed-Exit Related Notifications 24

2.3.2 Repositioning Related Notifications 29

2.3.3 Dismissing Leaving and Out of Bed Notifications 31

2.3.4 Dismissing Reposition Notifications 33

Ch.3 Control Box Indicator Descriptions 34

3.1 Power Indicator Light 34

Ch.4 Maintenance 35

4.1 Storage 36

4.2 Cleaning 36

4.3 Disinfection 37

4.4 Regular Maintenance 37

4.5 Disposal 38

Ch.5 Troubleshooting 39

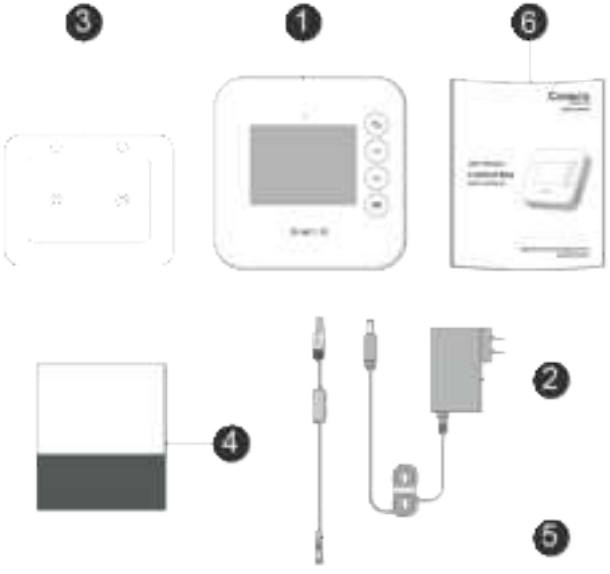
Ch.6 Specifications 44

Ch.7 EMC Description 46

Information of Manufacturer and Contact 54

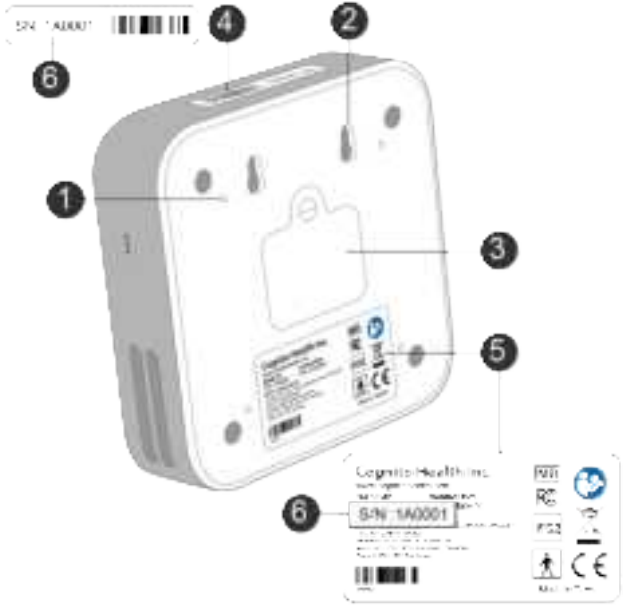
Ch.1 Exterior Introduction

1.1 Control Box (BA6E-31/BA6E-32)



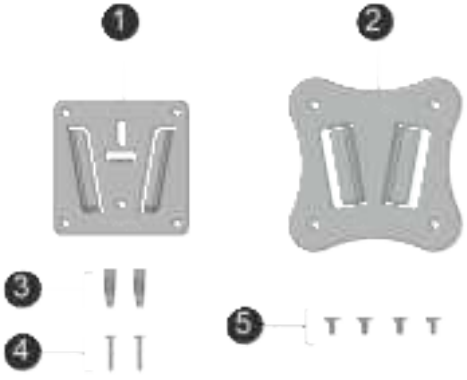
1. Control box (BA6E-31/BA6E-32)
2. Power adapter
3. Wall mount plate (ZAC0-A1)
4. Glue tape (ZDB0-A1)
5. Sensor cable part A (ZNA0-A1)
6. User manual

1. Power indicator/ 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. VESA mount M3 screw holes
2. Hanger holes
   (for wall mount plate)
3. SIM card cover
4. Serial number label
5. Control box label
6. Control box serial number

Note: Control box can be fixed on the wall with either wall mount plate or VESA mounts. Wall mount plate and glue tape are included in the standard package. VESA mounts are optional accessories. Contact the distributor or the manufacturer if VESA mounts set and screws were needed.



1. VESA wall mount
2. VESA box mount
3. Wall mount anchors
4. Wall mount screws 6#
5. Box mount screws M3

Ch.2 Operating Instruction

WARNING

1. Operate the product under ambient temperature between 41˚F/5˚C to 104˚F/40˚C and relative humidity between 15% to 90%.
2. **DO NOT** modify the product.
3. If there is ever liquid on the surface of the device, dry the device immediately.

2.1 Installation Instructions

WARNING

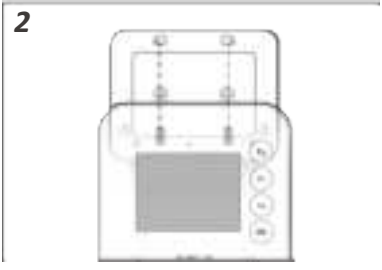
1. Confirm that there is no exterior damage on the product right after unpacking the product.
2. Immediately stop using the product if serious contamination or any damage is discovered.
3. **Only** use accessories, detachable parts, and materials that are approved by the manufacturer.
4. **DO NOT** use a damaged sensor cable. Contact the manufacturer or distributor if a damaged sensor cable is discovered.

CAUTION

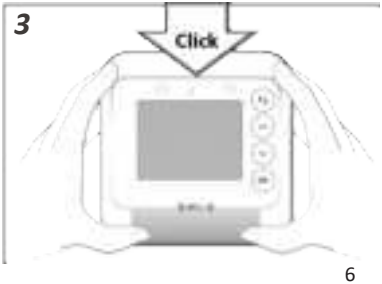
1. Disconnect the power adapter and the sensor cable before performing maintenance.

2.1.1 Use Wall Mount Plate with Glue Tape to Install

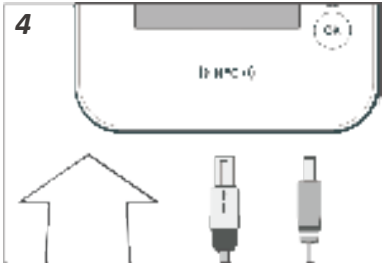
Attach the glue tape onto the wall mount plate in rounded square area. Stick and press the wall mount plate to the wall and let it sit for 24 hours.



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



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



Plug in the sensor cable part A and the power adapter to the control box and the control box will automatically be turned on.

NOTE: Wall mount plate can also be mounted on the wall with anchors and screws. Contact the distributor or the manufacturer for optional accessories.

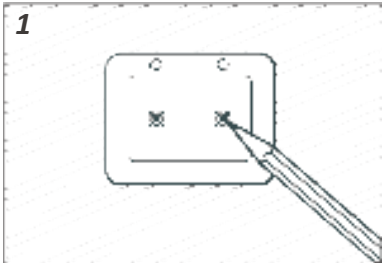
2.1.2 Use Wall Mount Plate with Screws to Install

WARNING

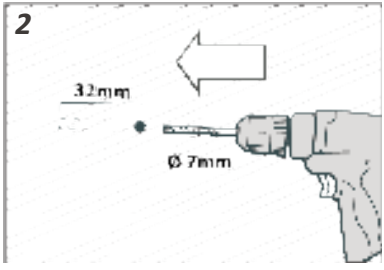
1. **DO NOT** install the device on wood studs, plaster boards or wall made with medium-density fiberboard (MDF).
2. **DO NOT** use your hands directly to install the control box with anchors and screws. Wear work gloves if necessary.

CAUTION

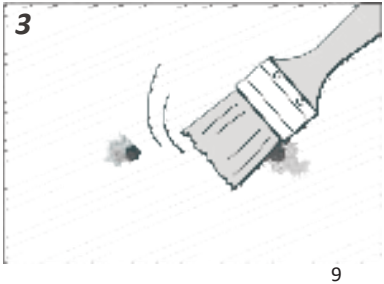
1. Use the anchors and screws on concrete wall.
2. When drilling holes on the walls, make sure you use a drill and drill bit with the specified diameter.
3. Make sure to follow the instructions regarding to the depth of the holes.
4. If other types of anchors and screws were used, make sure the wall mount plate can be well-fixed.



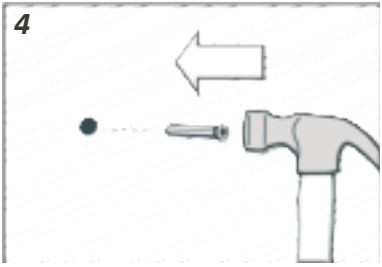
Position and sketch the location of wall mount anchors with wall mount plate.



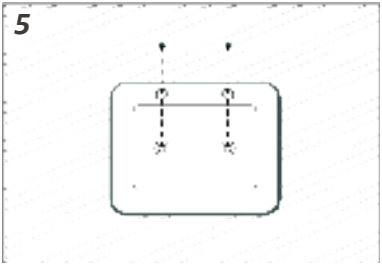
Drill two holes of 32 mm/1.26 inches depth using an Ø 7mm drill bit where the anchor will be fixed.



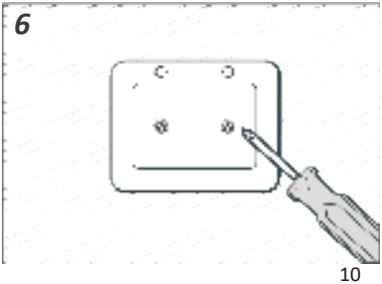
Clean out the drilled holes.



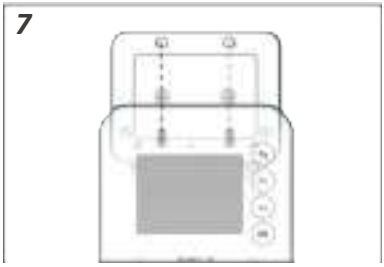
Use a hammer to insert the wall mount anchors into the holes.



Place the wall mount plate and align it with the anchors.

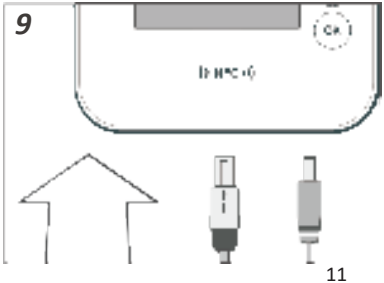


Use a screwdriver to lock and tighten the 6# screws in the anchors.



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

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



Plug in the sensor cable part A and power adapter to the control box and the control box will automatically be turned on.

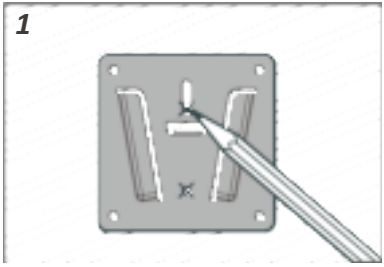
2.1.3 Use VESA Mounts with Screws to Install

WARNING

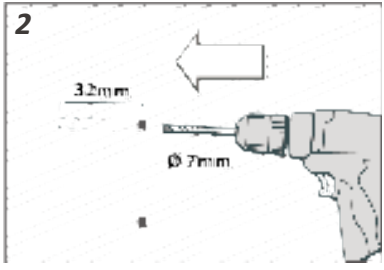
1. **DO NOT** install the device on wood studs, plaster boards or wall made with medium-density fiberboard (MDF).
2. **DO NOT** use your hands directly to install the control box with anchors and screws. Wear work gloves if necessary.

CAUTION

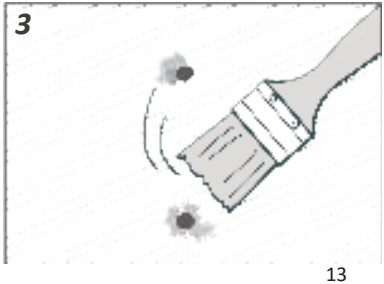
1. Use the anchors and screws on concrete wall.
2. When drilling holes on the walls, make sure you use a drill and drill bit with the specified diameter.
3. Make sure to follow the instructions regarding to the depth of the holes.
4. If other types of anchors and screws were used, make sure the VESA wall mount can be well-fixed.



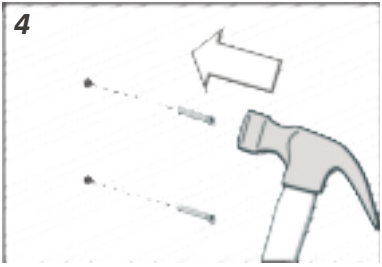
Position and sketch the location of wall mount anchors with VESA wall mount.



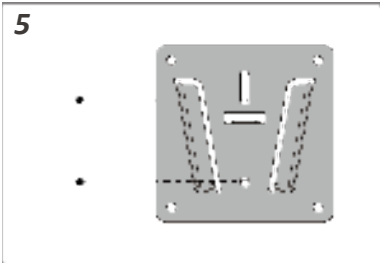
Drill two holes of 32 mm/1.26 inches depth using an Ø 7 mm drill bit where the wall mount anchors will be fixed.



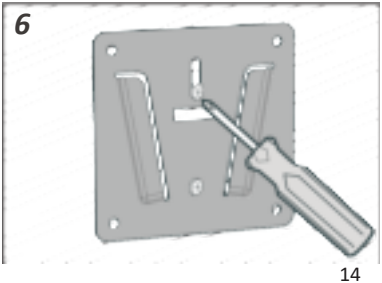
Clean out the drilled holes.



Use a hammer to insert the wall mount anchors into the holes.

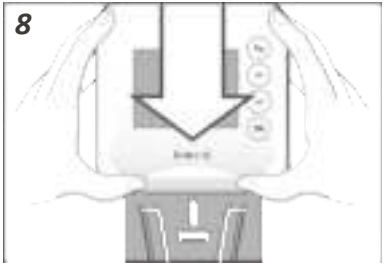


Place the VESA wall mount and align it with the anchors like the image shown.

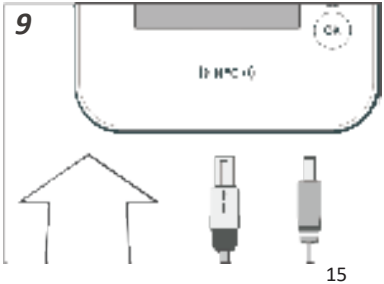


Use a screwdriver to lock and tighten the 6# screws with anchors.

Assemble the control box and VESA box mount with the M3 screws.



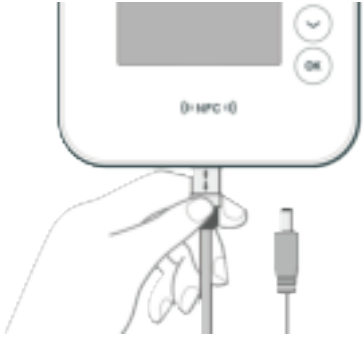
Hold the control box with both hands and slide the VESA box mount into VESA wall mount.



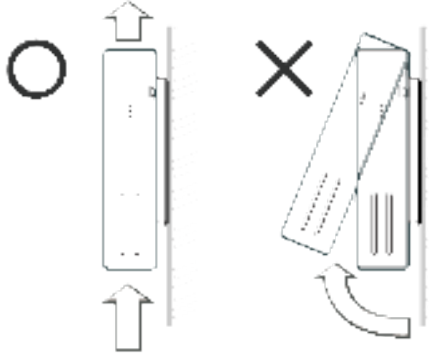
Plug in the sensor cable part A and the power adapter to the control box and the control box will automatically be turned on.

2.1.4 Remove the Control Box

To remove the control box, unplug the sensor cable part A from the gray plastic shell and the power adapter.



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



WARNING

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

CAUTION

1. Removing the control box in an incorrect way may cause damage to the wall mount plate or mounting surface.
2. Remove the power adapter from the control box if it will not be in use for a long time.
3. Recommend plugging the power adapter into the UPS (Uninterruptible Power Supply).
4. Please place the sensor cable in an appropriate location so it will not affect the daily activity of patients or hospital staff.
5. Small parts, e.g. screws, should be kept out of reach of children under 3 years or any individuals who have a tendency to place inedible objects in their mouths.

2.2 Operating Instructions

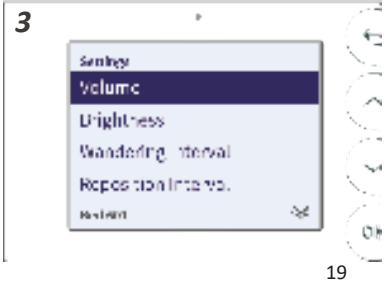
2.2.1 Regular Settings

Control box provides bed exit and reposition related notifications at the bedside. Bedside message from the control box is also provided to alert patients when patients are exiting the bed or have been out of bed. Default settings of control box are listed below. The settings can be adjusted from either control box or Cognito software. Please see Cognito 3.0 User Manual for using Cognito dashboard and mobile app.

Items	Default Setting
Volume	Off
Brightness	Dim
Wandering Interval (minute)	15
Reposition Interval (minute)	120
Sitting Up Bedside Message	Off
Patient Language	English
System Language	English

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.

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



Select the setting items you would like to change.

Return to notification page to complete the change.

2.2.2 Nurse Mode

Cognito notifications can be temporarily silenced for one minute with nurse mode while the patient is still on the bed to allow for regular nursing care and to avoid unnecessary notifications.

Nurse mode is displayed with a blue “+” on the control box and is suggested to be activated while the patient is in bed and assistance is needed for helping patient getting out of the bed or for repositioning.

Press “OK” or “Return” button to get into nurse mode.

To stop nurse mode, press “OK” or “Return” button once again.

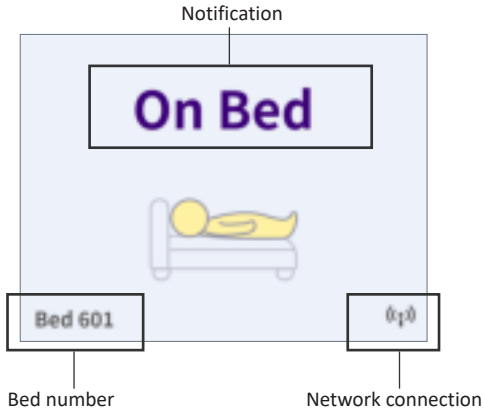
Or you can wait for one minute, the control box will automatically return to regular use.

2.3 Acknowledging and Dismissing Notifications

The control box provides bed exit and repositioning related notifications which can help with fall prevention and pressure injuries. Bed exit notifications include Stirring, Sitting Up, Leaving, Out of Bed and Wandering. Repositioning related notifications include Reposition and Immobile.

Bed exit and repositioning related notifications are displayed on the control box in different colors. 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 have been out of bed.

Other notifications help to know the patient's current status and the system error. Check Troubleshooting for error notifications.



2.3.1 Bed-Exit Related Notifications

Stirring

This notification indicates the patient may be waking up from sleep based on patient activity. Waking up does not necessarily indicate a patient is at risk. However, it indicates that the patient is now more likely to attempt to exit the bed.

The Stirring notification is displayed in green on the control box.

Sitting Up

This notification indicates that the patient is 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 for Sitting Up notification if it were necessary.

Leaving

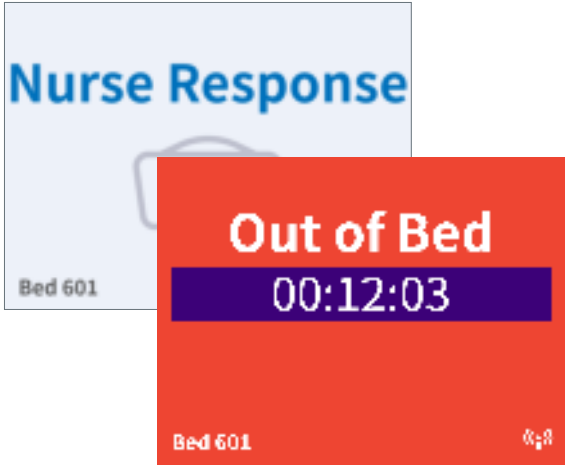
This notification indicates the patient may be attempting to leave the bed. It is also possible that the patient intends to sit at the edge of the bed; nevertheless, this could precede a fall and immediate assistance is recommended.

The Leaving notification is displayed in red on the control box and triggers the bedside message. The bedside message can be dismissed by tapping “OK” or return button and get into the nurse mode, indicating someone is assisting the patient.

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 and the screen will show Nurse Response, indicating someone has checked the situation.



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 staff should set up a wandering alert that will notify caregivers when the patient has exceeded the maximum amount of time the patient is allowed out of bed. When the wandering notification is selected, all other bed exit notifications will be automatically turned off.

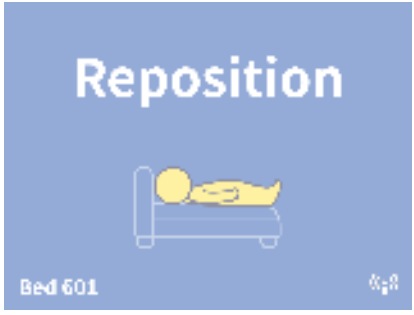
Wandering notification is displayed in red on the control box. The default time for triggering wandering notification is 15 minutes after the patient exits the bed. The time setting can be customized to individual patient needs. After the wandering notification is sent, a timer will start to let the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

2.3.2 Repositioning Related Notifications

Reposition

When a patient is set-up for using Cognito product, the clinical team will determine how often they need to be repositioned. This can be based on individual patient need or facility protocol. 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 notification will automatically be dismissed.

The Reposition notification is displayed in a lighter blue on the control box.



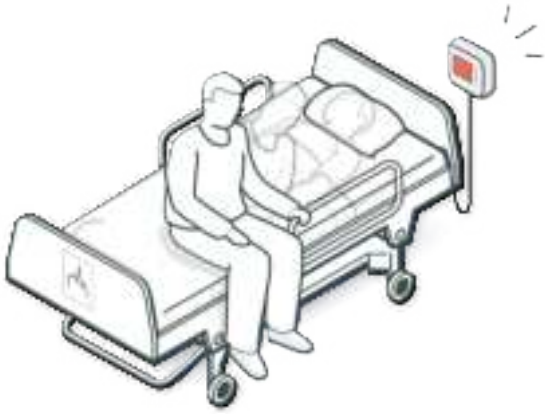
Immobile

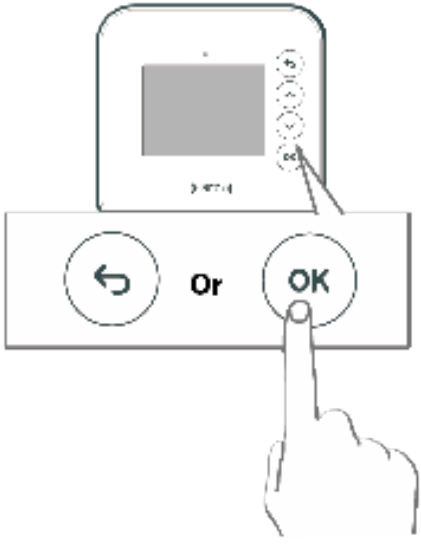
If the sensor pad does not detect patient movement for one hour, the system will send the Immobile notification so that the healthcare staff knows to check on them.

The Immobile notification is displayed in a darker blue on the control box.

2.3.3 Dismissing Leaving and Out of Bed Notifications

After a Leaving or Out of Bed notification is sent out, the healthcare staff will need to press the “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.



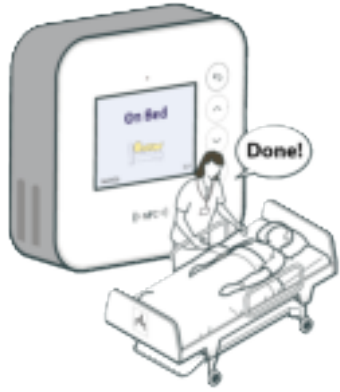


Press “OK” or “Return” button

2.3.4 Dismissing Reposition Notifications

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

There are two ways a patient can be efficiently repositioned, either by a healthcare provider or by repositioning themselves. In both cases, when the patient is efficiently repositioned, the reposition notification will be dismissed and the repositioning timer will automatically reset.



Ch.3 Control Box Indicator Descriptions

3.1 Power Indicator Light

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

NOTE: If the power indicator is blinking green, please follow instructions in Cognito 3.0 System User Manual or contact the distributor or the manufacturer to build the network connection of control box.

Ch.4 Maintenance

WARNING

1. **Only** use accessories, detachable parts, and materials that are approved by Cognito Health.
2. **Only** authorized professionals are permitted to disassemble the device.
3. **DO NOT** modify products.
4. **DO NOT** install or store products under direct sunlight or a dusty environment.

CAUTION

1. To safely terminate operation of the system and perform maintenance, please disconnect the sensor cable and power adapter.

4.1 Storage

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

⚠ **CAUTION**

1. Be aware of the temperature and relative humidity of the storage environment.

4.2 Cleaning

Please clean the products regularly. Weekly cleaning is recommended for the control box.

1. Wipe the control box with a clean, soft cloth. The cloth should be damped with 200ppm bleach.
2. Make sure there are no residues left on the control box.
3. Dry the control box completely before use.
4. Perform the disinfection procedures immediately upon patient discharge, bed transfer or body fluid contamination. See the disinfection procedures under 4.3.

⚠ **WARNING**

1. **DO NOT** soak the device in cleaning solution or disinfectant.
2. If there is ever liquid on the surface of the device, dry the device immediately.

4.3 Disinfection

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 500ppm bleach.
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 control box by placing it in any UV light sterilization cabinets.

CAUTION **DO NOT** disinfect the product with volatile liquids.

4.4 Regular Maintenance

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

1. Maintenance before use is recommended for the control box.
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. Careful consideration and observation are essential when stacking or

collocating Cognito products and when routing cables and accessories.

5. Check if there is any damage to the power adapter's power cord and plug head.

4.5 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 the distributor of the manufacturer for information concerning the decommissioning of your equipment.

Ch.5 Troubleshooting

The control box provides several notifications if technical abnormalities were detected. Any other problem, please contact the distributor or the manufacturer for further assistance.

Problem	Troubleshooting
Control box is unresponsive.	Please refer to chapter 3; observe the power indicator and ensure that the power adapter is connected. Ensure the plug is plugged into the power outlet. Ensure the power adapter is plugged into the control box.

Patient left the bed, but the Out-of-Bed notification was not triggered.	Please refer to chapter 3; observe the power indicator and ensure that the power adapter is connected. Make sure the sensor pad is connected and is not damaged. Please flatten the sensor pad and remove any weight on top of the sensor pad. Lie on the sensor pad and get out of bed to check if Out of Bed notification is sent out. If out-of-bed notification were still not working, please contact the manufacturer or the distributor.
Control box has no sound.	Please ensure the control box is responsive. Follow 2.2 Operating Instructions to adjust the volume.
Control box has no light.	Please ensure the control box is responsive. Follow 2.2 Operating Instructions to adjust the brightness.

Control box falls off from the hanger of the wall mount plate.	Follow 2.1 Installation Instructions to reinstall the control box. Please contact the manufacturer or the distributor if extra accessories were needed.
Button on the control box in unresponsive.	Ensure the power adapter is plugged into the power outlet. Ensure the power adapter is plugged into the control box. If the button were still not working, please contact the manufacturer or the distributor.

Error Messages	Possible Causes	Solutions
 **Replace Sensor**	Sensor pad does not work right, or the sensor cable is damaged.	1. Reconnect the sensor pad to the sensor port of the control box. 2. Reconnect the sensor cable part A and part B. 3. Replace the sensor pad. 4. If the problem is remaining, please contact the distributor or manufacturer for further assistance. NOTE: Sensor cable part B is in the package of the sensor pad (P7FD-21).

 **Sensor Disconnected**	Sensor cable is not connected to the control box or not connected tightly.	1.Reconnect the sensor cable to the sensor port of the control box. 2. Make sure the sensor cable cannot be loosened easily. 3. Replace the sensor pad. 4. If the problem is remaining, please contact the distributor or manufacturer for further assistance.
 **Box Error**	Control box does not work right due to internal software abnormality.	1. Control box may return to normal within 1 minute. If not, replug the power adapter to the control box. 2. If the error message is remaining, please contact distributor or manufacturer for further assistance.

Ch.6 Specifications

Control Box (BA6E-31/BA6E-32)

		BA6E-31	BA6E-32
Dimension	Length	5.12 inch (130 mm)	
	Width	5.12 inch (130 mm)	
	Height	1.38 inch (35 mm)	
Weight		1 lb (450 g)	
Power	Input Voltage	12V DC	
	Adapter Model	MDS-030AAC12 (DELTA)	
	Adapter Input	AC 100-240V, 0.6-0.4A, 50-60Hz	
	Adapter Output	DC 12V, 2A (Max)	
Interface	Sensor Cable (ZNA0-A1)	Mini DIN 7.87 inch (20 cm)	
	to Cognito Dashboard	IEEE 802.11 a/b/g/n/ac Ethernet 10/100 Mbps LTE for 4G SIM card*	
IP Code		IP22	
SIM Card (4G) Supported*		Yes	No
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
Model Name		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)
Compatible Screw		6#	N/A

		VESA Wall Mount	VESA Box Mount
Model Name		ZCB0-A1	
Dimension	Length	3.35 inch (85 mm)	4.33 inch (110 mm)
	Width	3.35 inch (85 mm)	4.33 inch (110 mm)
	Height	0.19 inch (4.7 mm)	0.26 inch (6.5 mm)
Compatible Screw		6#	M3

Ch.7 EMC Description

<table>
<tr><th colspan="3">Manufacturer’s declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The BA6E-31/ BA6E-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 BA6E-31/ BA6E-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 BA6E-31/ BA6E-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 BA6E-31/ BA6E-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 BA6E-31/ BA6E-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 BA6E-31/ BA6E-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 % UT; 0,5 cycle 0 % UT; 1 cycle| 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/ 30 cycles Voltage interruptions: 0 % UT; 250/ 300 cycle	Mains power quality should be that of a typical professional healthcare environment or HOME HEALTHCARE ENVIRONMENT. If the user of the BA6E-31/ BA6E-32 requires continued operation during power mains interruptions, it is recommended that the BA6E-31/ BA6E-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 BA6E-31/ BA6E-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 UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The BA6E-31/ BA6E-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 BA6E-31/ BA6E-32 should assure that it is used in such and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance** **(for the professional healthcare facility environment and HOME HEALTHCARE ENVIRONMENT)**

Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** BA6E-31/ BA6E-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:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

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.

Recommended separation distance between
portable and mobile RF communications equipment and the BA6E-31/ BA6E-32

The BA6E-31/ BA6E-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 BA6E-31/ BA6E-32 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BA6E-31/ BA6E-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 BA6E-31/ BA6E-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 BA6E-31/ BA6E-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)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28	28
1 845							
1 970							

2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/ g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28	28
5 240 5 500 5 785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9	9

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.

Information of Manufacturer and Contact

Please note that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Manufacturer / Asia Contact

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EU Authorised Representative

Joerns Healthcare B.V.

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Zeilschip 26
3991 CT HOUTEN
Nederland

Distributor

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 PRODUCTS).

THE COMPONENTS OF THE PRODUCTS ARE SUBJECT TO THE LIMITED WARRANTY PERIOD(S) AS SET FORTH IN THE PRODUCT AGREEMENT BETWEEN MANUFACTURER AND PARTNER.

MANL-B003-EN-V1.30 Apr., 2022