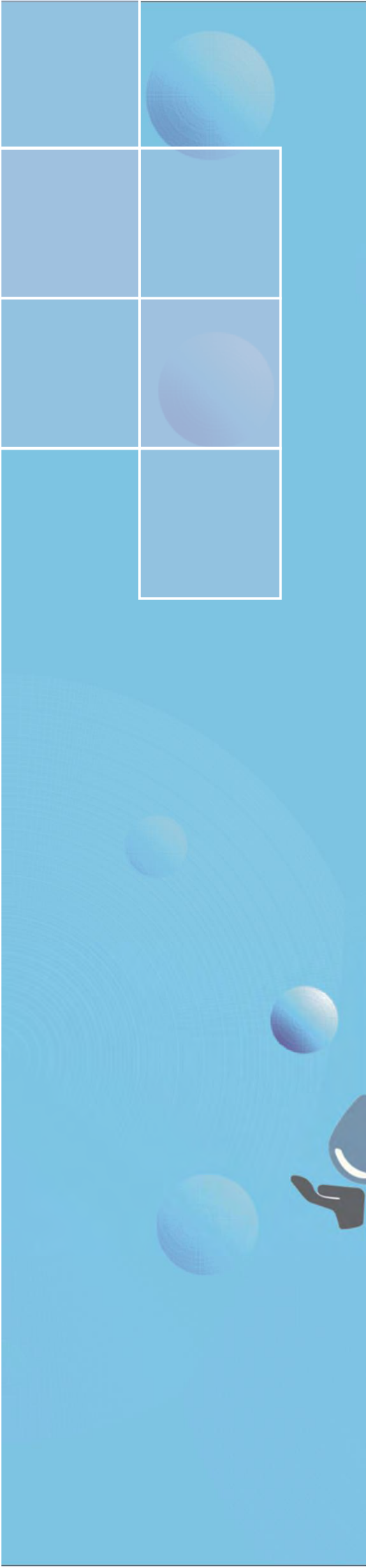




Hyginex

Installation & Maintenance Manual

Version 1.0





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1 Overview

Hyginex hand hygiene control solutions provide a simple and effective solution for monitoring and assisting healthcare workers' hand hygiene compliance in an unobtrusive manner and with almost no management effort. The Hyginex system includes the following components:

Beacon: A battery operated wireless passive radio frequency (RF) transmitter.

Dispenser: A soap and hand sanitizer delivery device that includes sensors and transmitters.

Bracelet: Interacts via wireless connection with beacon and dispenser sensors to detect proper hand washing and hand hygiene habits. It also reminds staff to wash hands according to hospital protocol. And finally, the Bracelet transfers hand hygiene data to the Hyginex server via the Dongle.

Chargers for the bracelets are included with the system purchase.

Dongle: Connects to a hospital ward's computer via USB port. The dongle downloads the data from the various bracelets in the Hyginex system via wireless connection.

Server: Collects the data from the hospital computer and automatically analyzes it.

Report generator: Produces detailed hygiene compliance reports. The scope of a report can cover an individual staff member or all staff members assigned a bracelet. The scope of a report and frequency is determined by the hospital during the purchasing process.





1.1 About this Manual

This manual is for the Hyginex agent. The agent is expected to have knowledge of the Hyginex system operation and basic construction methods.

The manual covers the installation procedure for each hardware component type in the system.

2 Installation

Each component in the system arrives on site preprogrammed. In case custom programming is required, contact Hyginex for programming tools and instructions. This means that the Beacons, dispensers and server are already aware of the bracelets. Each bracelet is assigned to a staff member by the Hyginex agent performing the installation.

The Hyginex system components require the following batteries:

Beacon: Six 1.5V D size alkaline batteries

Dispenser: Three 1.5V AA size alkaline batteries



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Bracelet: One 3.6V Lithium Polymer 120mAh battery (installed during bracelet setup)

Always use new batteries do not mix old and new batteries. This will limit the number of maintenance calls while the system is online.

Each Hyginex agent is supplied with a test bracelet. This bracelet is for testing the installation exclusively. The testing bracelet may be identified by its serial number visible on the face of the bracelet. The serial number is zero.

2.1 Dispenser

The Hyginex Dispenser should be the only type of dispenser on site. All dispensers that are not Hyginex Dispenser should be removed from the ward or area where Hyginex devices will be used. This is necessary because non-logged hand wash events will compromise hygiene data integrity.

2.1.1 Selecting a Mounting Location for a Dispenser

The dispenser can be mounted on a flat wall, next to a sink or entry way. Alternatively, a dispenser can be hung off a bracket from the footboard of a bed or the side of a medication cart.

Note: Avoid mounting sensor devices surrounded/blocked by metallic surfaces. This will prevent RF interference between the Dispenser and the Bracelet.

2.1.2 Installing the Dispenser

➡ To install a Dispenser:

1. Position the Dispenser face down.
2. With a 3 mm Allen wrench, remove the two screws securing the battery cover to the Dispenser.



Note: Do not remove any other screws from the bottom of the Dispenser. This may cause a malfunction of the device.

3. Gently slide the plastic cover off the back of the dispenser. The battery compartment is exposed.

Note: Avoid touching the sensor boards, antenna, or other internal elements in the Dispenser.

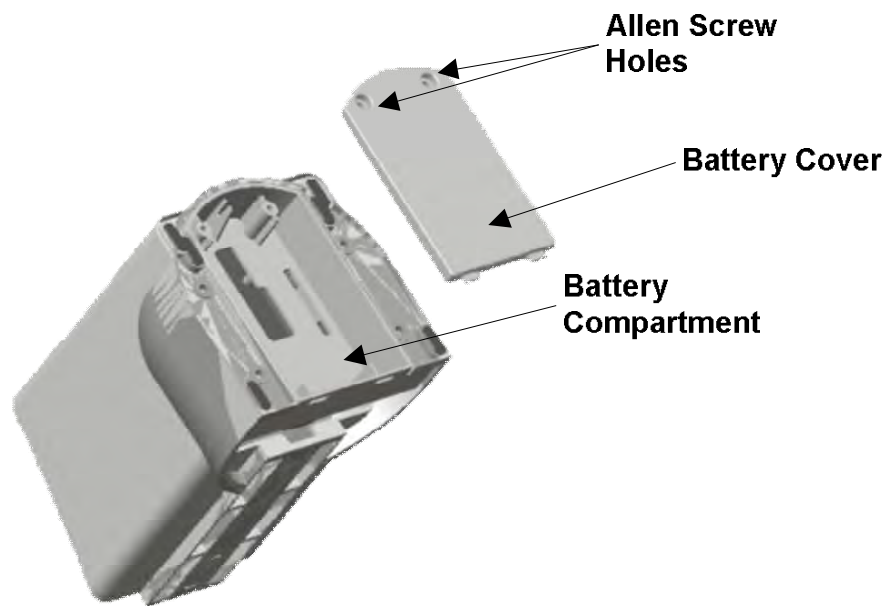


Figure 1: Dispenser Battery Compartment Exposed

4. Insert three AA size alkaline batteries (not supplied) into the Dispenser's battery compartment. Check that the polarity (+, -) is correct.
5. Slide the battery cover back into place; make sure that the battery compartment wiring is not sticking out from the side of the battery cover, and then screw the cover down securely with the Allen screws previously removed in step 2.
6. If it has not already been done, determine a location for the dispenser:
 - ◆ Mounting on a wall
 - a. Position the Dispenser where it will be mounted. In the two oval screw-holes, make a



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mark with a pencil to indicate the location of each mounting screw.

- b. Remove the Dispenser from the wall, and then, with a 3/16-inch (5 mm) drill bit, drill a hole at each of the marks.

To avoid dust from accumulating in the Dispenser, remove the dispenser before drilling.

- c. Attach the Dispenser to the wall using two screws (not included).

Note: The Dispenser must be mounted securely to the wall. Any movement may result in faulty data.

◆ Hanging off a bracket from the footboard of a bed or cart

- a. Line-up the bracket packaged with the dispenser so that the holes on the bracket and Dispenser are aligned.

Note: Before lining up the holes, check that the hook on the bracket faces out towards the back of the Dispenser, see Figure 3.

- b. Thread two cable ties (not included) through the round holes of the bracket and Dispenser, and then secure the ties tightly so there is as little movement as possible between the bracket and Dispenser.
- c. Hang the dispenser off the footboard of the bed.
- d. If practical, secure the bracket to the footboard with cable ties.

Note: Do not mount the device on a sink where it may get wet and damage the device. Instead mount the device on a wall near a sink.



Note: For wall mounting it is recommended to use a minimum of two screws, though three or more may help keep the device strait and fixed in place. The type of screw used for mounting the device depends on the mounting surface. Use your professional judgment or consult an experience contactor to determine the best screw type.



Figure 2: Dispenser with Sink Setup

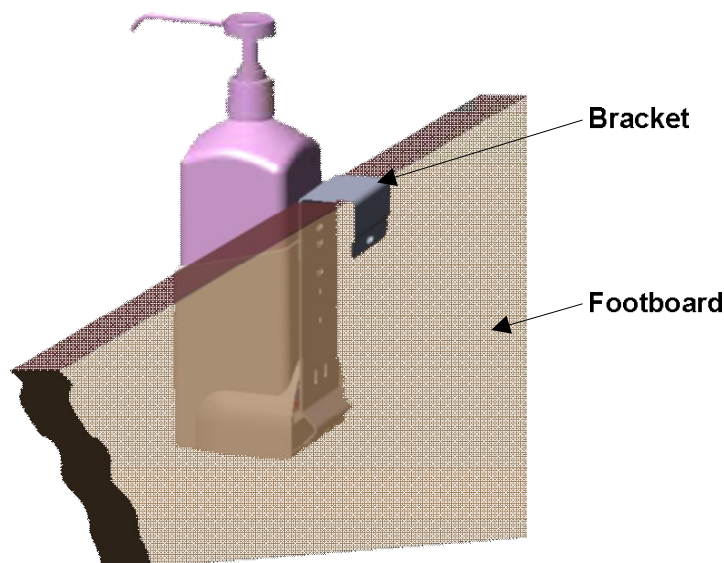


Figure 3: Dispenser with Bracket

Note: The Dispenser must be fixed to the footboard. Any movement may result in faulty data. In addition the Dispenser must be fixed in a vertical position.

2.1.3 Dispenser Recognition Testing

➡ To test a Dispenser:

After installation, insert a sanitizing liquid bottle fitted with a pump into the Dispenser. Wear the Test Bracelet and approach the Dispenser, press the top of the pump lightly and rub your hands. If successful, the LED on the Test Bracelet will blink fast during the hand rubbing, this indicates device recognition.

2.1.4 Documenting a Dispenser installation

Record each successful Dispenser installation in a provided spreadsheet.

Periodically during the system installation, a copy of the spreadsheet should be sent to Hyginex support in case clarification is necessary.



2.2 Charging Station

A fully charged Bracelet is good for approximately 48 hours under normal use.

Each system installation also includes Charging Stations. Each of these devices can charge up to 10 Bracelets at a time. A Charging Stations does not require any special environment, it just has to be close to a power source (i.e. a wall socket) and accessible to the user.

To enhance reliability, a charging station will have a build in sensor to detect a loss of power (the Charging Station no longer has power and is not charging Bracelets). Under these conditions, the system will send a warning SMS to support personnel making them aware of the power situation.

2.2.1 Selecting a Location for a Charge Station

Location criteria for a Charger Station are as follows:

- The power input should be able connect to an appropriate power source.
- The power output connector should be accessible.
- Verify that the Charger Station and cable are located where there is no standing water, dripping water or condensation.

2.2.2 Installing a Charging Station

➡ To install a Charging Station:

1. Position the Charging device in an appropriate and accessible location.
2. Plug the charger cable in to the power source.

2.2.3 Testing a Charge Station

➡ To test a Charge Station:

- Plug the the Test Bracelet in to each one of the charging slots on the charger, make sure that a charging light indicator lights up for every slot. After finalizing the documentation and warning system setup by Hyginex, perform a charger power disconnection warning test. Wear a test bracelet, disconnect the power source from the charging station, wait 5 minutes near the charging station and then wait 5 minutes near an operating dongle. A warning SMS should be sent shortly to the relevant Mobile numbers / pre-defined emails.



Figure 4: Bracelet Charger Station

2.2.4 Documenting a Charging Station Installation

Record each Charging Station installation in a provided spreadsheet.

Periodically during the system installation, a copy of the spreadsheet should be sent to Hyginex support in case clarification is necessary.



2.3 Bracelet

The distribution of the bracelets does not require any special user training.

All Hygiene data is stored on the Bracelet and uploaded to the server when the Bracelet is within range of the dongle.

The Test Bracelet is not for end-users. Its purpose is strictly to test the system.

2.3.1 Wearing a Bracelet

➔ To wear a Bracelet:

1. With the metal straps extended, position the Bracelet on the user's wrist or forearm.
2. Gently begin to fold the straps to the contour of the wrist or forearm. The straps will automatically wrap around the wrist or forearm securing it in place.

➔ To remove a Bracelet:

Extend the metal straps around the wrist or forearm while bending the straps slightly in a curve. The straps will automatically straiten out and remain ridged, thereby releasing it from the wrist or forearm.

2.3.2 Bracelet Recognition Testing

➔ To test a Bracelet:

Wear the bracelet and perform the following tests:

- Approach a Dispenser or Beacon. If successful, the Bracelet will vibrate once, this indicates device recognition and a functional Bracelet.



- Perform a hand wash with a Bracelet, make sure that the LCD/LED is blinking during the hand rub.
- Connect the bracelet to the charger and make sure that the charge indication is on.

2.3.3 Documenting a Bracelet Designation

Record each designation in a provided spreadsheet. This includes information such as the Bracelet serial number and the name of the end-user who will be assigned the Bracelet.

Periodically during the system installation, a copy of the spreadsheet should be sent to Hyginex support in case clarification is necessary.

2.4 Location Beacons

There are two types of Location Beacons:

- Bedside Beacon: This Beacon is located over each bed in a patient room. The objective of this type of Beacon is to detect hand hygiene events of staff as they approach the bed.
- Corridor Beacon: This Beacon is located in the ward corridor(s) out of the line of sight of the Bedside Beacons. The objective of this type of Beacon is to detect staff traffic as they exit patient rooms.

The two Beacon types are physically indistinguishable. The configuration that determines the Beacon type is performed during manufacture.

Initially, Corridor Beacons will be labeled on the casing so the Hyginex agent can quickly identify them.

2.4.1 Selecting a Location for a Bedside/Corridor Beacon

The Hyginex Bedside/Corridor Beacon can be mounted on



a ceiling, or placed on top of a panel in a dropped ceiling. For optimal detection, the following factors must be taken into consideration when selecting a mounting location:

Bedside Beacon

- The Bedside Beacon has a maximum detection angle that covers the patient bed area.
- Where multiple beds are in a patient room, each bed requires its own Beacon. The Beacons must be a minimum of 1.8 meters (5.9 feet) from each other.

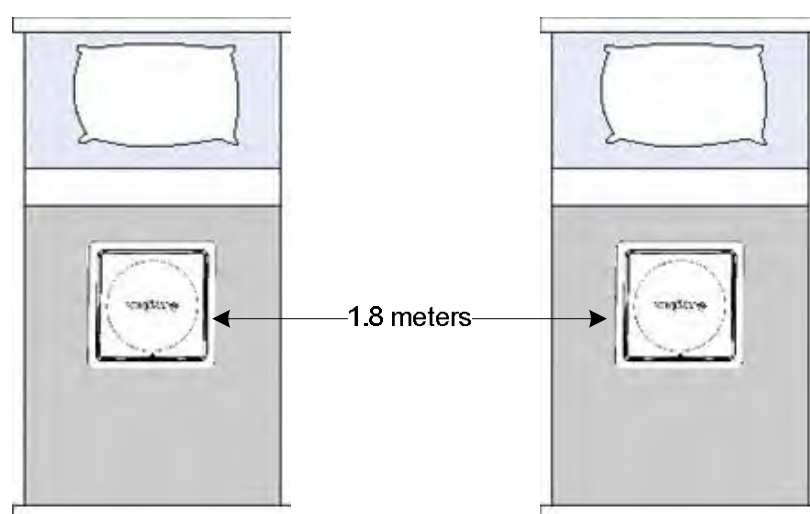


Figure 5: Bird's-eye View of Bedside Beacon Spacing

- In case a patient bed or its surroundings and a Corridor Beacon are within line of sight, the Hyginex Corridor Beacon must be mounted a minimum of 7 meters (16.4 feet) from the patient bed and its surroundings in order to prevent accidental user detection by the Corridor Beacon while a staff member approaches a patient bed.
- The Hyginex bedside Beacon must face the bed. This means the logo on the casing faces the bed, side to side, not head to foot.



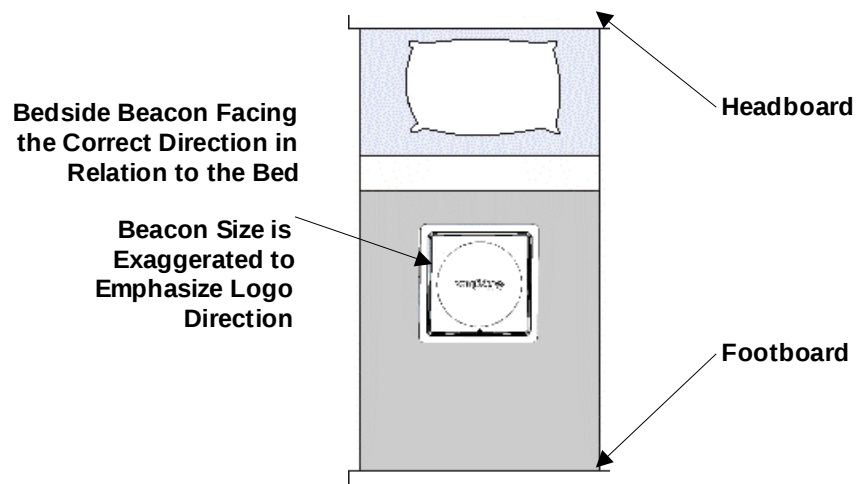


Figure 6: Bird's-eye View of Hyginex Logo Position for Bedside Beacon Placement

Optimal coverage is from the top of the logo to the bottom of the logo. Failure to place the Beacon correctly may result in faulty data.

- The Hyginex Beacon mounting should be above the center of bed.



Figure 7: Hyginex Logo on Beacon with Coverage Indicators

- Verify that the entire coverage area is covered by the Beacon angle and range (see the Hyginex Datasheet or Specifications table). This includes the bedside.



- Installation height must be 2.5 meters (8.2 ft) $\pm$ 0.3 meters (1 ft) in order for a Bracelet to detect the beacon effectively and for the beacon to cover only the relevant area. If the mounting is not at an appropriate height, the detection area might decrease or increase too much.

Note: Avoid mounting the Beacons in front of metallic objects or surfaces that might block the line of sight between a Beacon and the bed or its surrounding. This will prevent RF interference.

Corridor Beacon

- The Corridor Beacon has a maximum detection range of 5 meters (16.4 feet).
- Corridor Beacons are mounted outside a patient room. Where multiple Corridor Beacons exist, each Beacon must be a minimum of 10 meters from each other.
- Corridor Beacons placement must be out of the line of sight of Bedside Beacons, and a minimum of 7 meters away from any Bedside Beacon and its bed's surroundings.
- Corridor Beacons should be placed in high traffic areas (i.e. nurse's stations) in order for the system to collect large amounts of data.

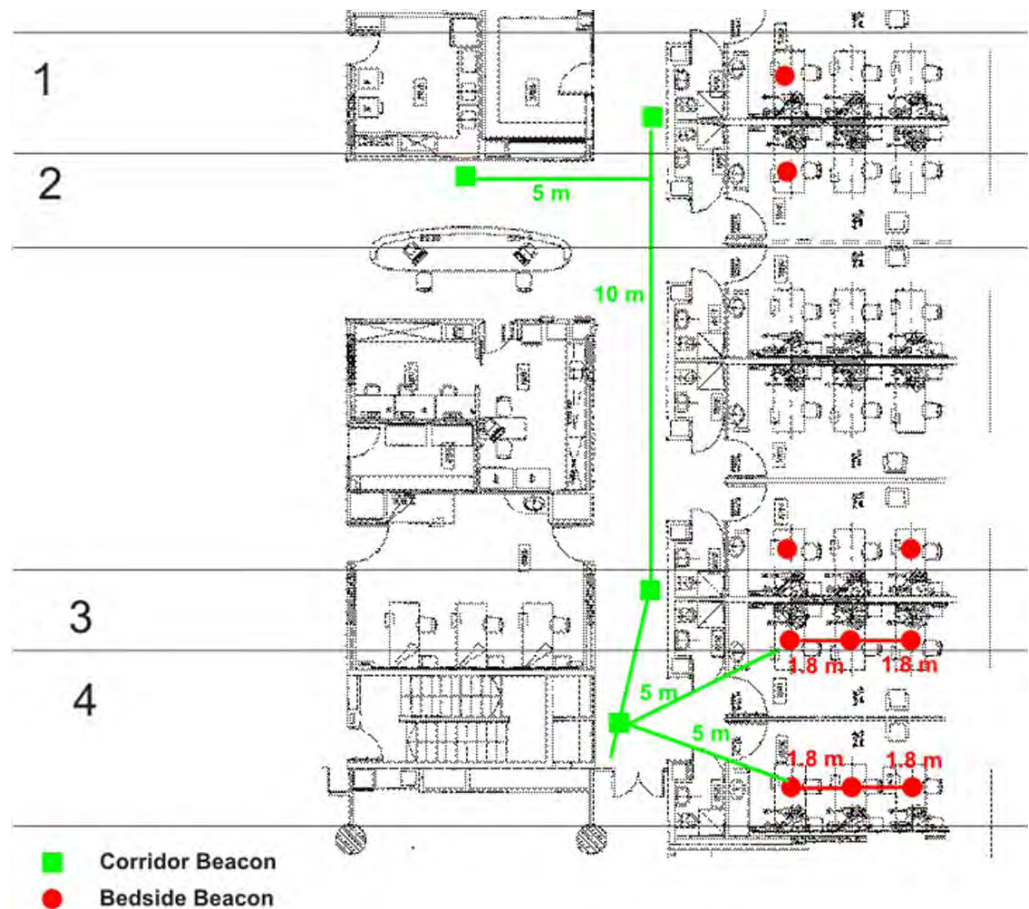


Figure 8: Corridor Beacon Coverage Diagram

In Figure 8 the Corridor Beacon in Area 1 is placed correctly. The Bedside Beacons are blocked by two walls and therefore out of the line of sight of the corridor beacon.

The Corridor Beacon in Area 2 is placed correctly as there is no line of sight to the other Corridor Beacon in area 1.

The Corridor Beacon in Area 3 is placed correctly. Far enough from other Corridor Beacons and not in the line of sight of the Bedside beacons (two walls between the corridor Beacon to the nearest beacon).

The Corridor Beacon in Area 4 is in the line of sight of two Bedside Beacons and less than 7 meters from the Bedside Beacons, therefore it is placed incorrectly.



2.4.2 Installing a Location Beacon

Mounting the Location Beacon requires the following components:

- Drill with a appropriate bit
- Screws and anchors for the ceiling surface
- 3 mm Allen wrench
- Six D size alkaline batteries

If the Location Beacon will be placed on a dropped ceiling panel, you will only need an Allen wrench, batteries and something to secure the device in place.

➔ To install a Bedside/Corridor Beacon on top of a drop ceiling:

Make sure that the drop ceiling does not have a metallic surface, perform an initial installation in one patient room and make sure that all of the beacons are detected properly by the Test Bracelet and there is no attenuation of the RF signal due to the drop ceiling. In case of doubt do not install the beacon on top of the drop ceiling or consult Hyginex technical support regarding the installation.

1. Position the Beacon face up.
2. With the 3 mm Allen wrench, remove the screw securing the back casing to the front casing.
3. Turn the Beacon face down.
4. Push in the plastic clips at the rear of the back casing and gently separate the back casing from the front casing. The battery compartment is exposed (see Figure 10 and Figure 11).

Note: Avoid touching the sensor boards, antenna, or other elements in the front casing.



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5. Insert six D size alkaline batteries (not supplied) into the device's battery compartment. Check that the polarity (+, -) is correct.
6. Line up the slots of the front casing with the mounted back casing. Push the front casing onto the mounted back casing. Listen for the clips to lock in place.
7. With the 3 mm Allen wrench, replace the screw that secures the Front casing to the back casing. This screw is required and may prevent damage to the device and injury to a bystander.
8. Place the Beacon, face down on top of one of the ceiling panels. Ideally directly above the center of a patient bed or in corridor where staff would normally pass through.
9. Secure the Beacon to a support strut in the ceiling as a safety precaution to prevent the Beacon from falling while moving the panel.
10. Place the panel that the Beacon is resting on top of in its original position and mark the panel for easy identification.

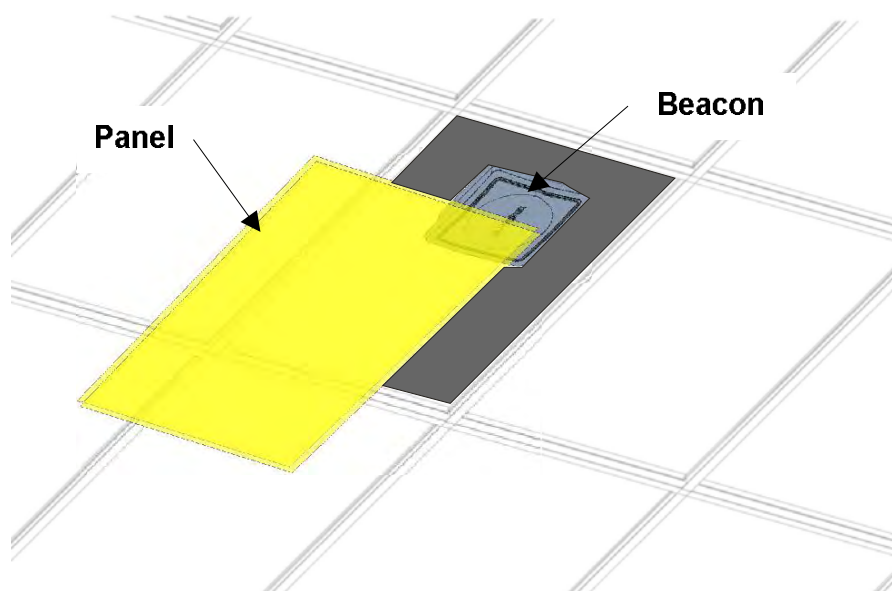


Figure 9: Hyginex Drop Ceiling with Beacon



➡ To install a Bedside / Corridor Beacon (not on top of a drop ceiling):

1. Position the Beacon face up.
2. With the 3 mm Allen wrench, remove the screw securing the back casing to the front casing.
3. Turn the Beacon face down.
4. Push in the plastic clips at the rear of the back casing and gently separate the back casing from the front casing. The battery compartment is exposed.

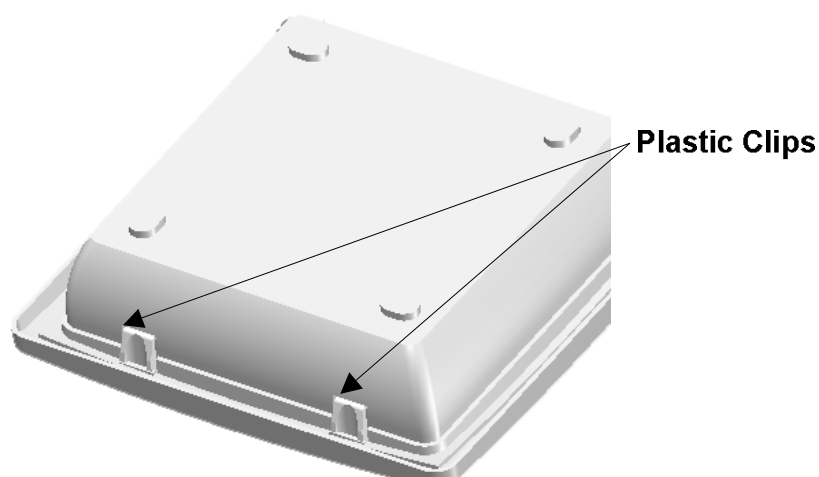


Figure 10: Plastic Clips that Secure Beacon Casing

Note: Avoid touching the sensor boards, antenna, or other elements in the front casing.

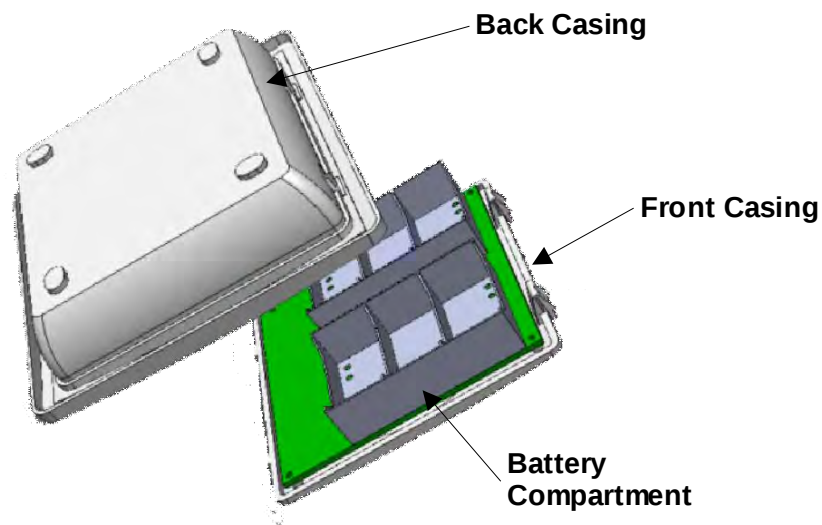


Figure 11: Separating Beacon Casing

5. With a screwdriver, remove the four screw hole punch outs as shown in the Figure 12.

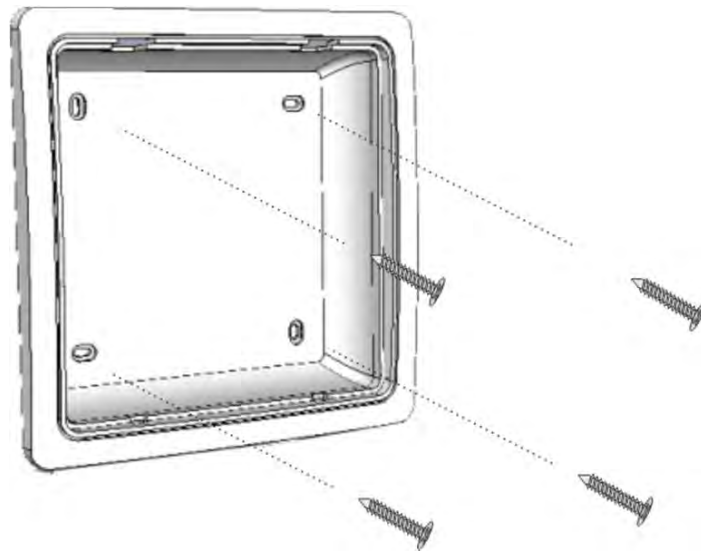


Figure 12: Mounting Screws for Back Casing

6. Place the back casing where you want to mount the device. In each of the four screw-hole slots, make a mark with a pencil to indicate the location of each mounting anchor and screw.
7. Remove the back casing from the ceiling or wall.
8. With a 3/16-inch (5 mm) drill bit, drill a hole at each of the four marks and insert a plastic anchor (not included). Note: To avoid dust from accumulating in



the Beacon, either cover or remove the Beacon front casing before drilling.

Warning: In order to prevent the Beacon from falling off the mounting location, use professional judgment or consult with an experienced contractor about the proper screws and anchors for the mounting surface.

9. Attach the back casing to the ceiling or wall using the four screws (not included).
10. Insert six D size alkaline batteries (not supplied) into the device's battery compartment. Check that the polarity (+, -) is correct.
11. Line up the slots of the front casing with the mounted back casing. Push the front casing onto the mounted back casing. Listen for the clips to lock in place.
12. With the 3 mm Allen wrench, replace the screw that secures the Front casing to the back casing. This screw is required and may prevent damage to the device and injury to a bystander.

Note: Four screws are the minimum number of screws recommended. Use professional judgment to determine if additional screws are necessary. The casing can be mounted with up to eight screws.

When deciding on which screw-holes to use, it is recommended that you set at least one screw on each end of the Beacon.

2.4.3 Testing a Beacon

To test a Beacon:

There are two scenarios for testing Beacons. These scenarios are based on detections between the Beacons.

As a prerequisite, each test requires the tester to wear the Test Bracelet.



Scenario 1: Bedside Beacon test

- a. Enter a patient room *without* disinfection your hands and approach a patient bedside where a Beacon is installed above the bed. After a few seconds, the Test Bracelet vibrates and the red LED glows. This indicates a failure to meet hand hygiene protocol.

Wait 5 minutes and repeat the test, The Test Bracelet will remain asleep.

- b. Enter a patient room and disinfect your hands according to hospital protocol. Approach a patient bedside where a Beacon is installed above the bed and wait 5 minutes. The Test Bracelet will remain asleep. This indicates that you have satisfied hand hygiene protocol.

Make sure that the detection area is limited to the desired area and that the Beacon is not detected from neighboring bedside Beacons or any other area out of the designated area.

Repeat Scenario 1, test a and test b for each bed in a patient room.

Scenario 2: Corridor Beacon test

- a. Leave a patient room, where there is a Bedside Beacon, *without* disinfection your hands. After a few seconds, the Test Bracelet vibrates and the red LED glows. This indicates a failure to meet hand hygiene protocol.

Wait in the corridor for 5 minutes. The alert will not repeat and the Test Bracelet will remain asleep.

- b. Disinfect your hands before leaving a patient room, where there is a Bedside Beacon. Wait about 10 minute, there will be no alert and the Test Bracelet will remain asleep. This indicates that you have satisfied hand hygiene protocol.

After performing the tests in scenario 1 and 2, contact the



monitoring center and verify that the correct results were recorded on the server.

If any of these tests fail:

- Check the batteries in the devices
- Check the positioning of the devices
- Check for RF interference
- Check the dongle, computer, server connection

2.4.4 Documenting a Beacon Installation

Record each Beacon installation in a provided spreadsheet.

Periodically during the system installation, a copy of the spreadsheet should be sent to Hyginex support in case clarification is necessary.

2.5 Hyginex Local Computer

Information about the computer, software and dongle installation is covered in another document. However, it is mention here as part of the general system installation so as not to be over looked when installing the detectors.

3 Test the System - Walk Test

After all of the installations in a room are complete, and the computer and server are online, conduct a Walk Test. A Walk Test is a function/signal verification check. It is also used to determine the detection area of a device.

Contact Hyginex support and let them know that you want to conduct a Walk Test for the devices in a particular room.

While wearing a Hyginex Test Bracelet, go through all of the motions pertaining to hand hygiene as specified by



hospital protocol. Then go through the motions that violate the protocol.

During the Walk Test, examine the LED/LCD on the Bracelet and verify that it glows as required.

Contact Hyginex support and verify that all motions were recorded and that the correct automated actions (i.e. SMSs) performed successfully.

4 Maintenance

4.1 Replacing the Battery

The Hyginex device batteries have a nominal operation life of at least 1 year. Battery status is reported automatically to Hyginex support. The support staff passes this information to the hospital administrator and the local Hyginex agent.

A best practice is to replace the batteries within a week after the battery status indicates that it is low.

To replace the batteries, refer to the installation instruction section for each device.

4.2 Updating the Installation Project Spreadsheet

Any change to the system such as:

- Devices added to the current system
- New Bracelets assigned to staff
- Bracelet reassignment between staff

Requires the Hyginex agent to send an updated spreadsheet to Hyginex support immediately in order to maintain accuracy and accountability.



5 Contact Information

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FCC Statement:

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

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

2. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the 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 FCC Radiation Exposure