SuiteSentry™ Single Screener

Operation and Installation Manual

September 2018

PNPNPNP Rev A


SuiteSentry™
ETS-LINDGREN

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Revision	Date	Author	Primary Reason for Change
A	September 2018	MS	Initial Release

LIST of FIGURES

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Acronyms used in this manual

ACR: .....American College of Radiology
TJC: .....The Joint Commission
Zone II: .....ACR definition of area immediately outside the MRI control room
Zone III: ....ACR definition of area immediately outside the MRI magnet room
Zone IV: ....ACR definition of area inside the MRI magnet room
FMD: .....Ferromagnetic Detector
LED: .....Light Emitting Diode; electronic replacement for lamp
PIR: .....Passive Infra-Red-Detects body heat and motion and
.....enables SuiteSentry Single Screener to go into Active Mode

Symbols and Terms

NOTE: The following Symbols and Terms may be used in this manual:

WARNING!
Warning statements identify conditions or practices that could result in injury or death.

CAUTION!
Caution statements identify conditions or practices that could result in damage to the product or other property.

TIP or HINT:
The following is a recommendation and may help simplfy efforts during the installation.

Damage in Transportation

All packages should be closely examined at time of delivery. If damage to outer package is visible, make certain the notation “damaged in shipment” was written on all copies of the freight or express bill when delivery is accepted by your receiving agent. Whether noted or concealed, **damage must be reported to the carrier** immediately upon discovery, or in any event, within 14 days after receipt, and the contents and containers held for inspection by the carrier. **Transportation company will not pay a claim for damage if an inspection is not requested within this 14 day period**. Transport this product for a period not to exceed 4 weeks. The following environmental conditions must be adhered to in order to avoid damage to the product.

Ambient Temperature: **-34°C (-11°F) to +60°C (+140°F)**
Relative Humidity: **15% TO 95% (Non-Condensing)**
Atmospheric Pressure: **50 kPa (0.5 atm) to 127 kPa (1.25 atm)**

Language Policy – Service Documentation

WARNING

- This Service Manual is available in English only.
- If a customer's service provider requires a language other than English, it is the customer's responsibility to provide translation services.
- Do not attempt to service the equipment unless this service manual has been consulted and is understood.
- Failure to heed this Warning may result in injury to the service provider, operator or patient from electric shock, mechanical or other hazards.

AVERTISSEMENT

- Ce Manuel de maintenance n'est disponible qu'en anglais.
- Si le technicien du client a besoin de ce manuel dans une autre langue que l'anglais, c'est au client qu'il incombe de le faire traduire.
- Ne pas tenter d'intervention sur les équipements tant que le manuel Service n'a pas été consulté et compris.
- Le non–respect de cet avertissement peut entraîner chez le technicien, l'opérateur ou le patient des blessures dues à des dangers électriques, mécaniques ou autres.

WARNUNG

- Dieses Kundendienst-Handbuch existiert nur in englischer Sprache.
- Falls ein fremder Kundendienst eine andere Sprache benötigt, ist es Aufgabe des Kunden für eine entsprechende Übersetzung zu sorgen.
- Versuchen Sie nicht, das Gerät zu reparieren, bevor dieses Kundendienst-Handbuch nicht zu Rate gezogen und verstanden wurde.
- Wird diese Warnung nicht beachtet, so kann es zu Verletzungen des Kundendiensttechnikers, des Bedieners oder des Patienten durch elektrische Schläge, mechanische oder sonstige Gefahren kommen.

AVISO

- Este Manual de Servicio sólo existe en inglés
- Si algún proveedor de servicios ajeno a KDI solicita un idioma que no sea el inglés, es responsabilidad del cliente ofrecer un servicio de traducción.
- No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio.
- La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.

ATENÇÃO

- Este Manual de Assistência Técnica só se encontra disponível em Inglês.
- Se qualquer outro serviço de assistência técnica, que não a KDI, solicitar estes manuais noutro idioma, é da responsabilidade do cliente fornecer os serviços de tradução.
- Não tente reparar o equipamento sem ter consultado e compreendido este Manual de Assistência Técnica.
- O não cumprimento deste aviso pode por em perigo a segurança do técnico, operador ou paciente devido a‘ choques elétricos, mecânicos ou outros.

AVVERTENZA

- Il presente manuale di manutenzione è disponibile soltanto in inglese.
- Se un addetto alla manutenzione esterno alla KDI richiede il manuale in una lingua diversa, il cliente è tenuto a provvedere direttamente alla traduzione.
- Si proceda alla manutenzione dell'apparecchiatura solo dopo aver consultato il presente manuale ed averne compreso il contenuto.
- Non tenere conto della presente avvertenza potrebbe far compiere operazioni da cui derivino lesioni all'addetto alla manutenzione, all'utilizzatore ed al paziente per folgorazione elettrica, per urti meccanici od altri rischi.

1.0 INTRODUCTION & OVERVIEW

SuiteSentry™ Single Screener is a revolutionary patented Ferromagnetic Detector (FMD) system designed to help keep ferromagnetic material from accidentally entering the Magnetic Resonance Imaging magnet room. The system primarily consists of an array of sensors and microprocessors built into a walk-up Sensor Array Column.

This product is intended to reduce the risk from an ordinary object that might suddenly become an unintended projectile due to its attraction to the magnetic field of the MR scanner magnet.

SuiteSentry Single Screener incorporates the following features:

- **Accurately and Rapidly Locates Ferromagnetic Hazards Anywhere on the Body**
- **Uniform Sensitivity with Six (6) Sensor Zones placed equidistant in the Sensor Array Column**
- **No-Touch Activation for the ultimate in convenience and hygiene**
- **Highly Sensitive - Can detect small items down to hairpin size**
- **Used to Self-screen or for Supervised Screening**
- **Variety of Simple Installation Options**

1.1 Background

MR Super-Conducting Scanners generate an enormously strong magnetic field, typically 30,000 to 60,000 times the Earth's magnetic field. Due to the significant technical and economic hurdles in generating the magnetic field, it is never purposely turned off; it is always in the 'ON' condition, 24 hours a day, 7 days a week. This extremely powerful magnetic field, invisible but ever-present, continuously attracts anything which is ferromagnetic (generally containing iron or steel). It can and will attract and pull any ferromagnetic object such as hand tools, oxygen bottles, scissors, chairs, IV stands, and even floor buffers toward the magnet.

1.2 The Current Situation

All personnel who may come in close proximity of the MR scanner, within the four (4) progressively restricted zones of danger, are supposed to receive training about the risks the MRI magnetic field presents, what kind of objects contain ferromagnetic material, and therefore the danger of bringing these materials in close proximity to the magnet. Since the MR static fields is never shut down, this must include maintenance and security personnel who may come in close proximity during non-scanning hours.

The patient procedures adopted in operating these MR devices have evolved into a careful pre-screening of patients to make sure they do not have anything on their person or active/passive implants in their person, which would be attracted by the very strong magnetic field; and, in the case of some heart pacemakers or defibrillators, potentially have their function changed by the scanner's magnetic field.

Even with training and copious use of warning signs, people forget or are unaware that an object may contain ferromagnetic material, thereby increasing the risk of a disaster.

Even small ferrous objects pose a risk of injury. A hairpin, for example, can travel at 40 MPH into a 1.5T magnet. Larger objects have injured and even caused fatalities.

Even if no injury occurs, the financial costs from downtime and re-imaging can be very large.

2.0 PRE-INSTALLATION CHECKLIST

2.1 Product Identification and Shipping List

The SuiteSentry Single Screener hardware is shipped in one corrugated carton. This long carton contains all the items required for assembly and installation of the SuiteSentry Single Screener System. The contents are listed below.

Component	Qty	P/N
SuiteSentry Single Screener - Sensor Array Column Assembly	1	400151
Power Supply - Digital w/ 12' output cable / connector	1	9910-A-01427-C
AC mains power cord – w/ 90° Plug - 3 ft long -- USA	1	6608-A-01497-A
Installation Hardware Kit - SuiteSentry Single Screener	1	9993-A-02760-A
Surface Conduit Accessory Kit – Ivory – SuiteSentry Single Screener	1	9993-A-02041-B
Document Package – SuiteSentry Single Screener	1	0550-A-02016-D
Spacer, Mounting Block Extension	2	2973-A-02778
Mat, Floor, Solo Instructive	1	0540-A-02050
Box, Return Materials, 14" x 8" x 5" (w/ UPS Return Label)	1	2840-A-02838

2.2 Tools Required for Assembly and Installation

1. #2 Phillips screwdriver 6 inches long (15 cm)
2. Box cutting knife with replacement blades
1. Medium duty electric or battery drill with at least 2 spare charged batteries
2. 1/4 inch nut driver/1/4 inch wrench (ratcheting wrench is best)
3. 3/8 inch nut driver/3/8 inch wrench (ratcheting wrench is best)
4. Drill bit index with at least two (2) 1/8 inch drill bits and ½ inch bit for wall togglers
5. Measuring tape up to 12 feet (4 meters)
6. Micro screwdrivers, flat head and Phillips
7. 6 inch (15 cm) bubble level
8. Heavy Duty PVC cutters for wire trim moldings *(Sears 3-1 Accu-Cut Model 37310 recommended)*
9. Painter's tape (for detector) and clear packing tape (for parts return box)

2.3 Summary of Tasks

The following steps are a general guideline and actual workflow may differ depending on the specific site and installation area. This section is provided so the installer has a general outline of the steps in the installation and training process.

TIP! Test SuiteSentry Single Screener in desired installation area prior to permanent mounting to ensure it is viable for that installation location otherwise you may have to relocate due to electromagnetic interference!!!

1. Select and verify the desired mounting location, method of attachment and location of the power outlet. Always Ask!
   (a dedicated outlet might have been put in specifically for the detector)
2. Select method and routing for Power cables to Sensor Column
3. Leave Sensor Column in shipping container for next step!
4. Test Sensor Array Column in desired location before permanent mounting
5. Mount Sensor Array Column
6. Adjust final calibration of Sensor Array Column
7. Mount laminated copy of Short Form Instructions near detector *(SAP)*
   (Only if facility permits, ask first!)
8. Clean area and remove installation debris
9. Train the MRI staff and have them sign provided "Training Record" roster*
10. Take pictures of installed detector*
11. Complete "Quality Assurance Document"*
12. Complete "Installation and Training Acceptance Document"*
13. Have responsible party sign all documents and provide copy to signee*
14. Send all documents and pictures to ETS-Lindgren*
    (Same day preferred, immediately following installation)

* **These items are required for permanent warranty registration file!**
Please make *detailed* *notes* on each document as they will be added to the device

HINT: The installer should request that the SuiteSentry Single Screener be brought to the installation area by the facility staff prior to arrival at the site.

3.0 SITE SELECTION & INSTALLATION GUIDELINES

3.1 Overview

The SuiteSentry Single Screener Ferromagnetic Detector consists of an array of sensors and microprocessors built into a walk-up Sensor Array Column. The detector analyzes objects on patients or personnel passing in front of the Sensor Array Column, screening for the object's potential risk as a ferromagnetic projectile.

If an object made of ferromagnetic material approaches the Sensor Array Column, the system detects the object's ferrous content, analyzes its ferromagnetic mass and threat potential; and, if the mass exceeds the preset sensitivity threshold, an audible alarm is activated and ferrous object indicator lights is illuminated in the vertical sensor array column of the portal.

Since the device detects *only* those materials that will be attracted to the magnet, items made of aluminum, titanium, copper, brass and other non-ferrous materials will not trigger an alarm. Please note, however, that seemingly non-ferrous materials may have enough ferrous properties to activate the audible and visual alarms.

The detector only analyzes moving objects containing ferromagnetic material. Stationary ferromagnetic objects will be ignored.

The SuiteSentry Single Screener is typically installed in Zone 2. The sensitivity should be set to detect objects reliably without exhibiting "false positives". The device is intended to detect and alarm for smaller ferromagnetic objects approximately the size of a typical hair pin or larger when the object is approximately 12 inches from the Sensor Array Column.

SuiteSentry Single Screener has no detection limitations with regard to locating ferromagnetic material inside an object or human body. Therefore, if a ferrous non-superficial or subcutaneous object is detected, further investigation is recommended following your facility's standard practice. Even if our product does NOT react, one should NOT automatically assume that there are no ferromagnetic risks.

WARNING!
This device has not yet been fully evaluated for its efficacy in detection of ferromagnetic objects inside the body, such as IMPLANTS

3.2 Functional Siting Requirements-Location

In order to ensure the system will provide detection and alert for ferromagnetic objects, the unit should be positioned so that all equipment, patients, and personnel entering the magnet room have been screened and can proceed directly to the magnet room. Do not screen patients and then have them sit in waiting area as they may pick up a ferrous object that they did not possess during the screening process. The Sensor Array Column should also be positioned to provide the most useful opportunity for screening patients and staff, if that is your policy or desire.

Summary of Functional Siting Requirements:

- The location should have a measured magnetic fringe field of less than 2 Gauss.
- The preferred location to install SuiteSentry Single Screener is near the Zone 2 patient changing area or another location before entry into Zone 3.
- Keep detector away from magnet room *(**Unit CANNOT be above 2 Gauss**)*
- Locate the detector within the area so as not to interfere with patient transport and to prevent possible damage from patient transport impact.
- If location is on wall with bumper rail guards; modify them to accommodate SOLO installation.

TIP! To ensure the unit is functional in the desired area of operation TEST unit at the desired location PRIOR to permanent mounting!

3.3 Operational Siting Requirements-Performance

Since SuiteSentry Single Screener is designed to detect moving ferrous objects passing near or approaching the Sensor Array Column, the selected site should be away from extraneous moving objects such as printers, office chairs, and file cabinet drawers. Special hardware and software design reduces the sensitivity to moving ferromagnetic objects on the sides and behind the Sensor Array Column, but separation of movable ferromagnetic masses from the sides of the Detector System is also desirable.

Maintain separation from electrical devices, especially those which contain transformers, electrical motors or other moving parts as these devices create magnetic fields which can mimic moving ferromagnetic objects. Distance should be maintained from electrically locked or electrically opening doors. Some doors have magnets mounted on them to activate switches used to indicate that the door is closed. Plan your installation to maintain separation from these doors and devices.

Summary of Operational Siting Requirements:

- Remove electrical devices 9 feet *(3 meters)* away from the installed detector to prevent false positive alarms.
- Ensure area of installation is free from electrical and electromagnetic interference when possible.
- If electronic equipment is within 9 feet *(3 meters)* the detector may very well exhibit false positives. Determine the object/device that causes this condition and remove from immediate vicinity of the detector and allow the detector to stabilize to the environment.

CAUTION!

The SuiteSentry Single Screener detector MUST be placed in area that has LESS than a 2 Gauss field strength. Ensure that it is functionally capable of performing in the preferred area of operation prior to permanent mounting!

3.4 Operational Considerations-Usage

The highest sensitivity to moving objects occurs within 3 inches of the Sensor Array Column. All efforts should be made to minimize traffic in the area of the Sensor Array Column during the screening process as this traffic may have ferromagnetic objects which can cause unintended alarms.

The change from standby to active mode is determined by adjusting the Passive Infrared (PIR) motion sensor located in the Top Control Panel display. Even small ferromagnetic objects on a person or staff member that routinely enter the magnet room may trigger an alarm as these ferrous objects will be magnetized by exposure to the MRI's magnetic field. Once magnetized, some small objects will cause an alarm identical to a larger-in-mass object. To minimize these alarms, staff should be trained to minimize wearing of ferrous objects; such as, underwire bras, shoes with steel shanks or springs, belt buckles, pens, badges, eyeglasses, and hair clips.

Summary of Operational Considerations:

- Staff wearing ferrous material in their clothing will cause the detector to alarm. REMOVE all clothing that exhibits alarms to ensure consistent screening results.
- The detector will alarm for attire such as watches, belts, shoes, and underwire bras. If you feel it pull at or near the bore, the detector will alarm on the object within several feet (5') or more.
- The SuiteSentry Single Screener is to be used only as a prescreening device.
- All staff should acknowledge the detector alarms and not enter zone III if an alarm is displayed until offending ferrous object is removed.

4.0 INSTALLATION, MOUNTING and POWER-UP

4.1 Installation and Mounting of SuiteSentry Single Screener

TIP! Fully read Section 3 & Section 4 prior to starting Installation

Physical installation is simple and only requires a few basic tools. The key to a successful installation is to adhere to the recommendations for installation location as set forth in Section 3.

Once the desired mounting location has been determined, and the SuiteSentry Single Screener prescreening detector has been verified for function in the desired location, the mounting of the detector can commence. Follow the steps below:

CAUTION!

The SuiteSentry Single Screener is sensitive to large dynamic EM pulses as well as strong static gauss fields. If the detector cannot stabilize in the preferred locaiton a secondary location must be found!

Step One: Set Unit in Trial Location: *(Refer to Figures 1, 2 & 3.)*

The SuiteSentry Single Screener comes mounted in rigid foam centered inside the cardboard shipping box. It is meant to remain in the shipping box while still in foam support blocks and can then be placed as a free standing functional detector to ensure functionality in the area where it is to be mounted. This allows the installer to easily place and determine **IF** the detector can be permanently installed in the desired location. It can easily be moved around as needed to ensure the area is compatible with the detector.

The shipping carton and foam blocks are designed to support SuiteSentry Single Screener as a free-standing fixture for initial installation process as well as protect while shipping.

(NOTE: DO NOT LEAVE DETECTOR UNATTENDED – Unit can fall over!)

To prepare SuiteSentry Single Screener from shipping carton, first remove all other equipment placed inside shipping box. With those items out of the box:

- Remove the power supply and power cable from the power supply cover
- Plug in the power supply to the SuiteSentry Single Screener (Bottom Cap-Rear) and the line cord into the outlet -slide SuiteSentry Single Screener away from shipping carton if you need to plug the supply cable in to the bottom cap receptacle. (SEE Fig. 1, 2 and 3 in Sec.4.1)

After the unit automatically sequences through the self-test routine (approx. 35 seconds), it is extremely important to monitor the detector and ensure it is STABLE to the electromagnetic fields in the area. Leave it in this position for at least 5-10 minutes to allow the electronics to normalize to this location**. Very Important: If the blue LED's at top do not stop illuminating, the detector should not be mounted in this location**! Move the detector away from the area incrementally to find a stable location for permanent mounting.

If there are moving objects or other electromagnetic interferences too near which cause the blue bar graph to indicate 1 bar segment or greater, lower the sensitivity or relocate the detector as this location is not suitable. As gauss fields decrease at the cube of the distance, move the detector incrementally away to find a more stable installation location. Sensitivity can be decreased from 1 beep (maximum) to 25 beeps (minimum) (factory setting) incrementally decreased to mid-scale if the location does not allow for maximum sensitivity however the ability to detect smaller objects will be diminished.

The object(s) causing the disturbance should be moved or the SuiteSentry Single Screener should be moved to ensure stability.

If the location is acceptable, continue with the permanent installation steps outlined next.

Installation and Mounting of SuiteSentry Single Screener

(Continued)

Figure 2: Temporary set up in shipping crate

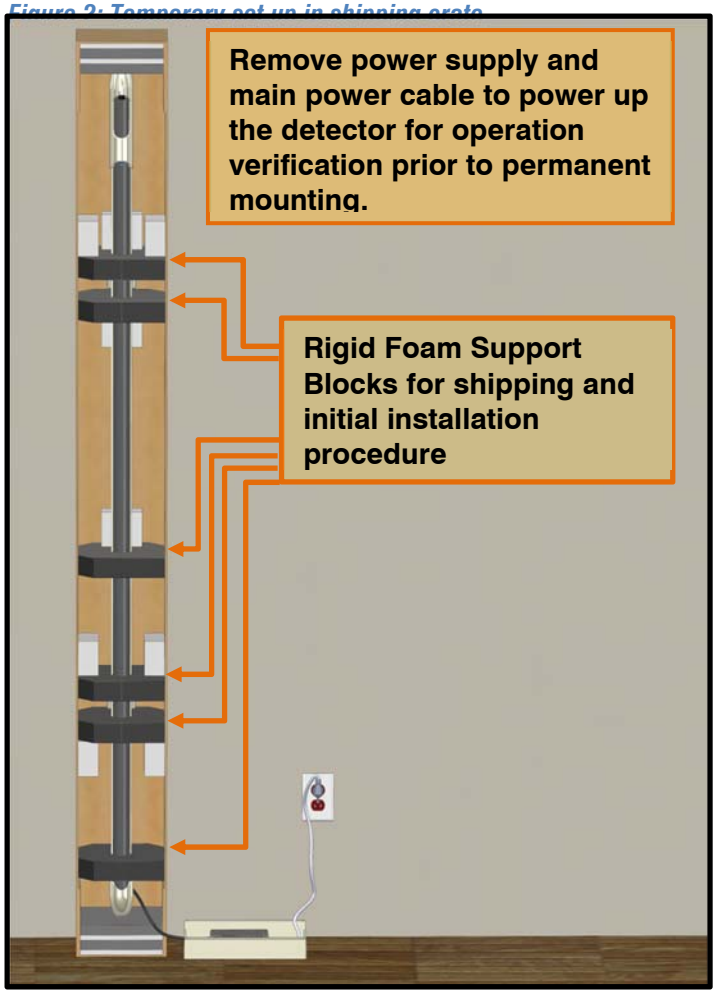


Figure 3: Connect Power Supply to SuiteSentry Single Screener in Shipping Crate

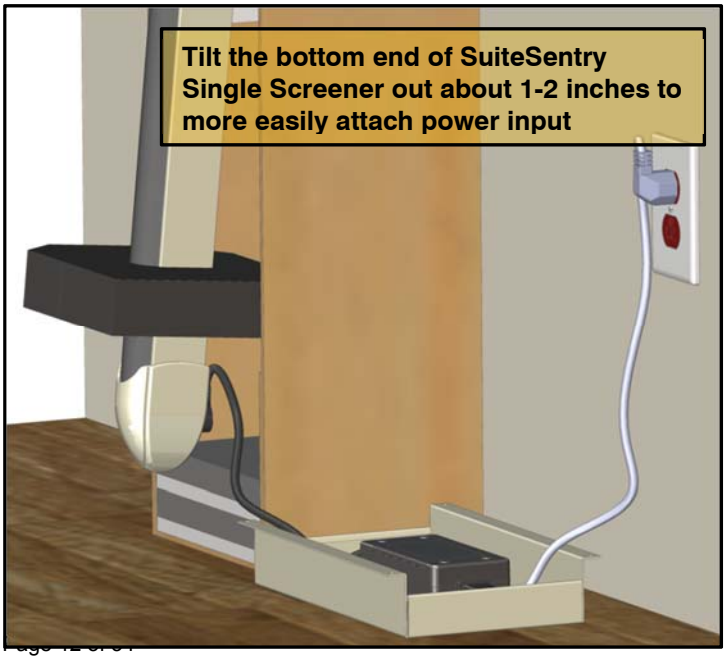


Figure 1: SuiteSentry Single Screener standing – Ready to TEST Location

Step Two: Remove SuiteSentry Single Snanner from the shipping/test carton:

- Remove the SuiteSentry Single Screener and carefully place SuiteSentry Single Screener on floor/horizontal surface out of the way. Carefully remove rigid foam blocks from body of SuiteSentry Single Screener column.

Step Three: Wall Bracket Attachment:

There are two methods to attach the bracket to the wall surface. If not aligned with a stud, the "Wall Toggler" method should be used. One toggle is used with each wall bracket. See method on next two pages. If aligned over a stud, then use wall dog screws to attach bracket to wall.

NOTE: if there is more than 1"/2.5cm railing the mounting extension block kit can be used to bring the detector another 1.5" off of wall face.

1."Wall Toggler" anchor screw method

Be sure you are not over a wall stud !

Note: Pre-drill hole with 1/8" drill bit no more than 1.5" depth, then follow with ½" drill

Mounting Hole measurement and drilling

- Mark the first hole location between studs at **exactly 67 inches from the floor**. Drill a 1/8" hole and the use a ½" drill. The lower mounting hole must be **exactly 41" below** this hole and aligned directly below it to assure the detector will be vertical and not crooked.

TIP! Use the laminated short form instruction sheet to capture the dust from drilling the ½" hole; you will then not make a mess on the floor!

- The strongest attachment to the wall is to use the Wall Toggler". This is a heavy duty toggle bolt kit included in the shipment; Part # 2186 A-02053. It requires a ½" drill bit (not provided) and instructions are included. This is the recommended mounting when locating between wall studs. You use the toggle bolt in the center hole of each wall bracket. See figures 6.1, 6.2, 6.3, 6.4 on Page 15.
- Be precise with your measurements to ensure the brackets will line up with the side mounting holes in SuiteSentry Single Screener column.
- Wall dog(s) maybe used in addition to the togglers on the bracket if needed to ensure a tight fit.

If toggler will not work in this location, as a last resort only, unit may be mounted with 4 wall dog fasteners (included) on each bracket between wall studs.

2."Wall Dog" anchor screw method (ONLY IF TOGGLER WILL NOT WORK!)

Be sure you ar e centered over a wall stud !

- Mark a point at **67 inches** from the floor. Drill into the wall/stud with a 1/8" drill and then attach an anchor screw (Wall Dog) with a #10 flat washer through the bracket hole in the wall bracket. Repeat for all four corners and then repeat for the bottom bracket. The lower mounting hole must be **exactly 41" below** this hole and aligned directly below it to assure the detector will be vertical and not crooked.
- Install second bracket 41" directly below, be sure to stay plumb, and mount bracket same as top.

Reference Documents - Installation Wiring Diagram

Ferromagnetic Detector Mounted to Wall

Figure 4: Drill Locations for Mounting Brackets

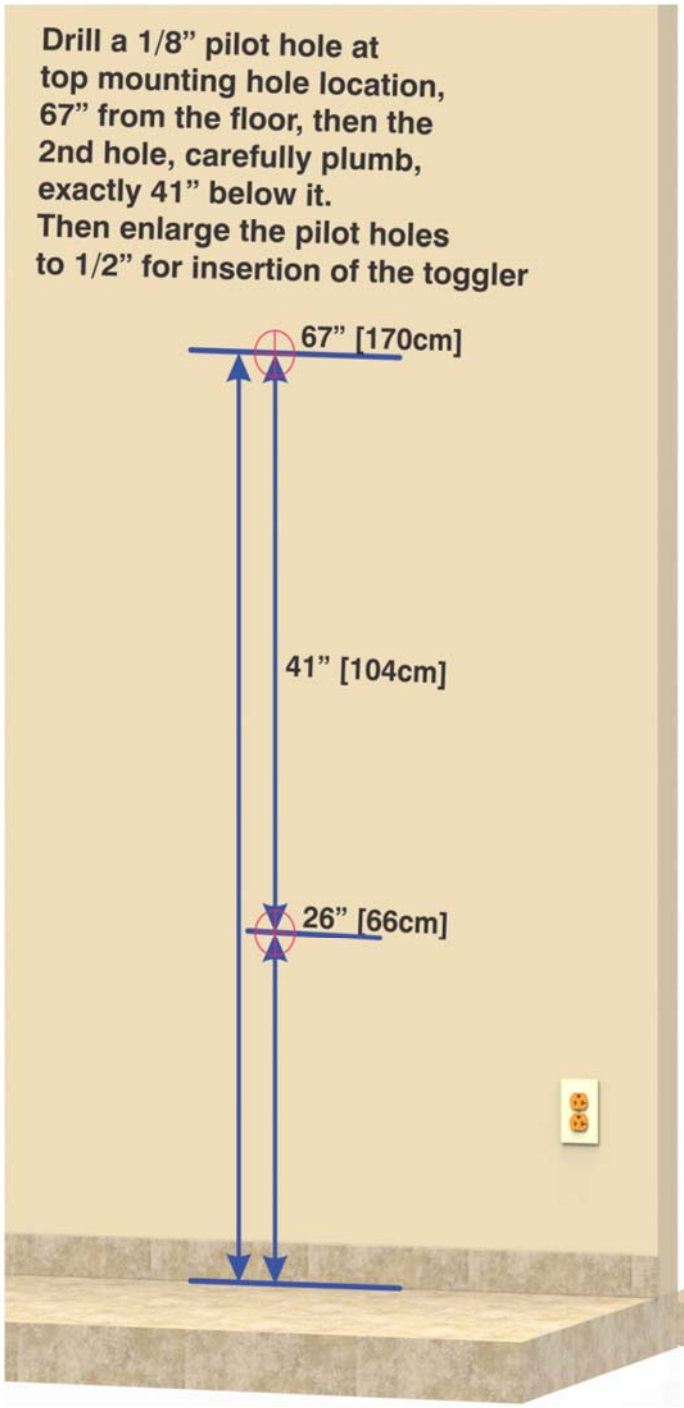
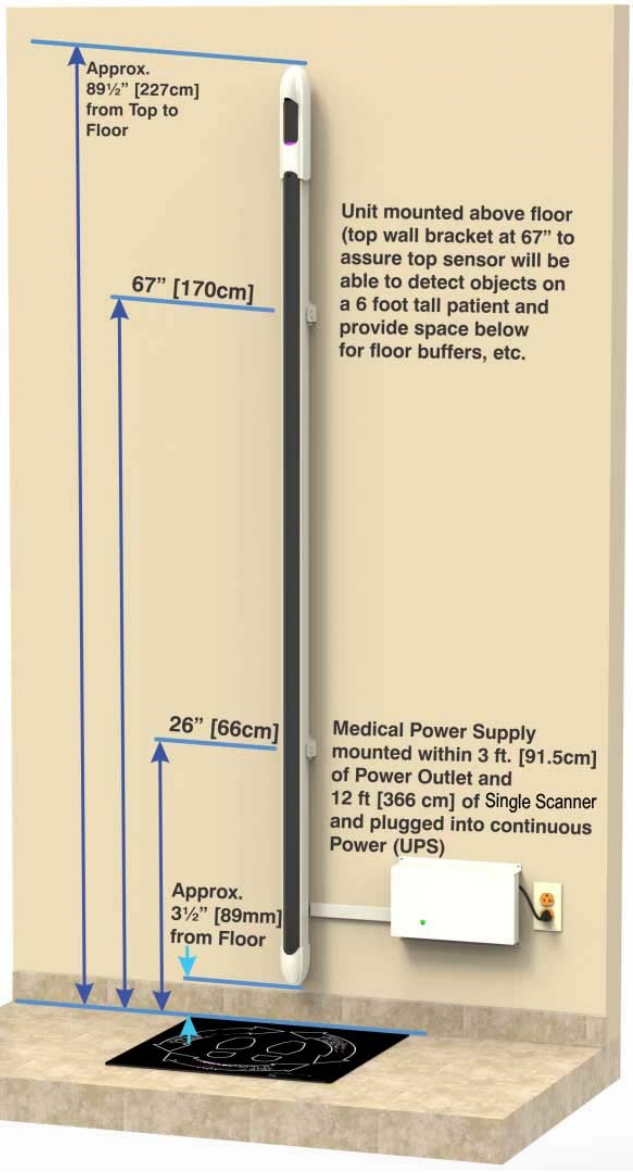


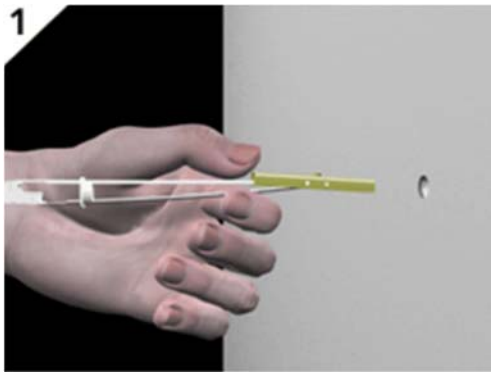
Figure 5: Typical Installation



Wall Bracket Attachment: Wall Toggler Anchor Method (continued)

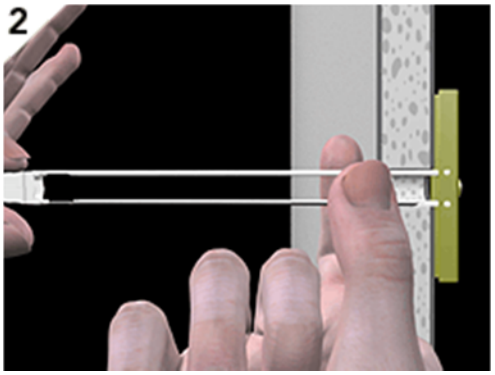
Observe the following steps to install the Togglers into the drywall.

Figure 6.1, 6.2, 6.3, 6.4 Fastening Wall Toggler to Wall

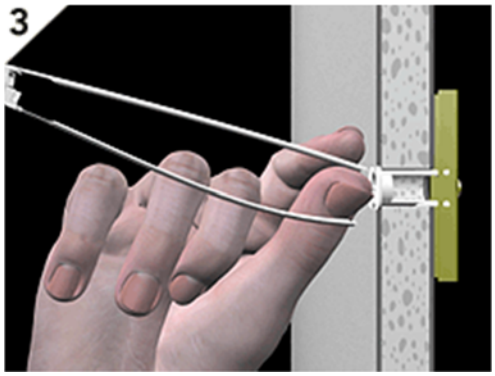


Drill a 1/2" (Ø13mm) hole. Hold metal channel flat alongside plastic straps and slide channel through hole. Minimum clearance behind wall: 1-7/8" (48mm)

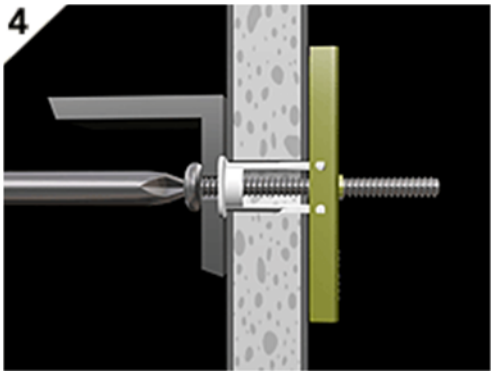
TIP-Use the laminated short form sheet in paperwork packaging to go flush to wall and catch the debris from drilling the large hole!



Hold ends of straps between thumb and forefinger and pull toward you until channel rests flush behind wall. Slide plastic cap along straps with other hand until flange of cap is flush with wall.



Snap straps at wall by pushing side to side, snapping off straps level with flange of cap.

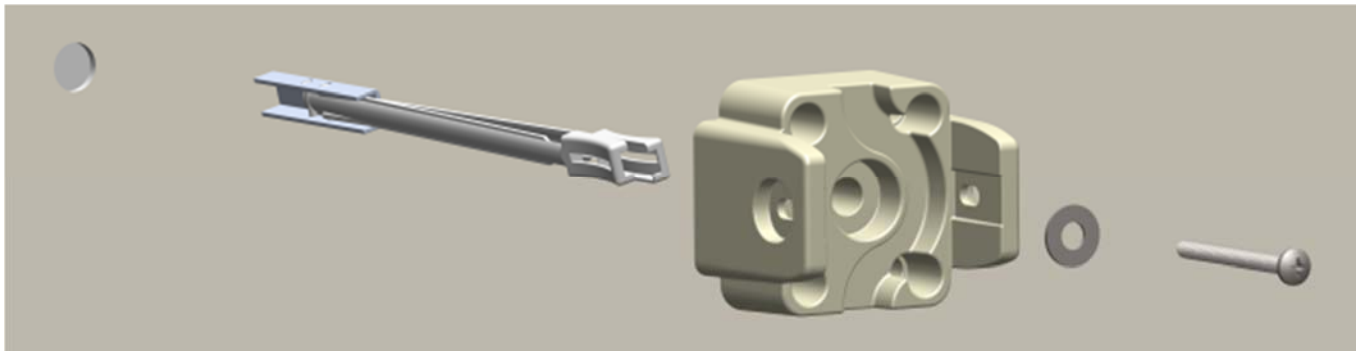


Place item over flange. Insert bolt through item and tighten until flush against item, then stop.

Use the supplied bolt with #10 flat washers in each of the locations.

Wall Bracket Attachment: Wall Toggler Anchor Method (continued)

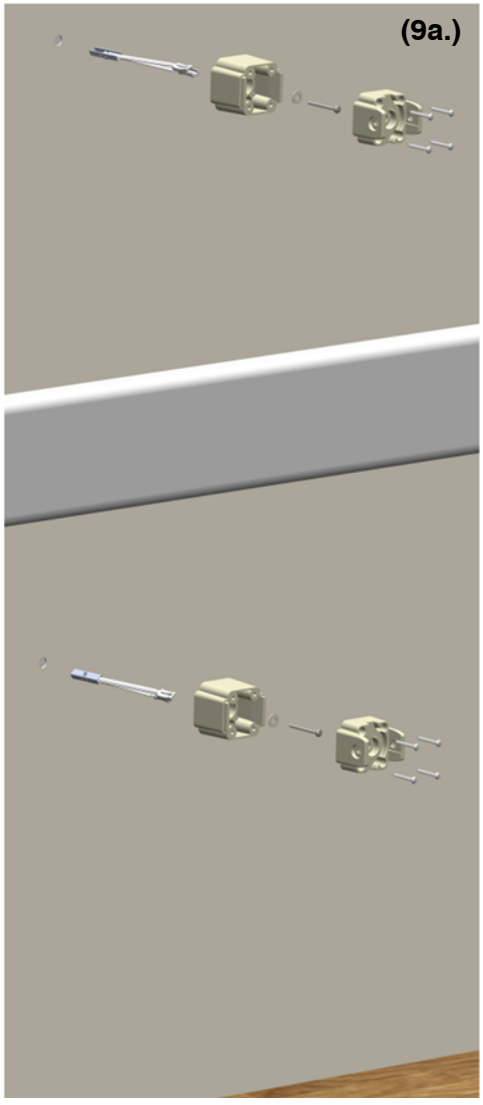
Figure 7: Fastening Wall Toggler through Mounting Block and into wall.

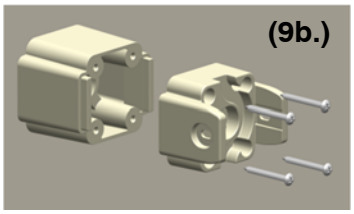


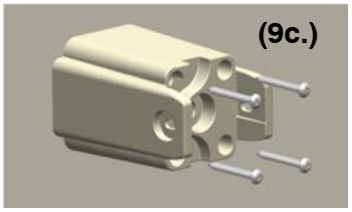
NOTE: The togglers are very strong and **DO** require the use of the included washers to be used.

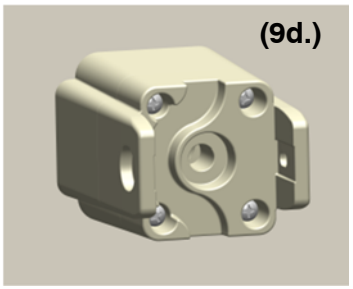
Figure 8: Exploded view of Mounting Block, toggle, screw and washer into wall.

Figure 9 a, b, c, d: Exploded views of Mounting Block+Mtg Block Extension over Rub Rail.









Mounting the SuiteSentry Single Screener Array Column into the Wall Bracket

1. The Sensor Array Column slips inside the mount brackets in a channel. (see Fig. 10)

2. To fasten to the two brackets, insert the side screws through the two brackets and carefully and gently thread into detector column.

   NOTE: Do not use power tools; hand screw only so as not to cross thread!

3. If the distance between the wall and rear bottom cap of the SuiteSentry Single Screener is tight, *before inserting the bottom side screws*, pull the bottom of the SuiteSentry Single Screener forward slightly and insert the Power Cable into the connector at the rear of the SuiteSentry Single Screener.

4. Insert the bottom cross screw in the same manner.

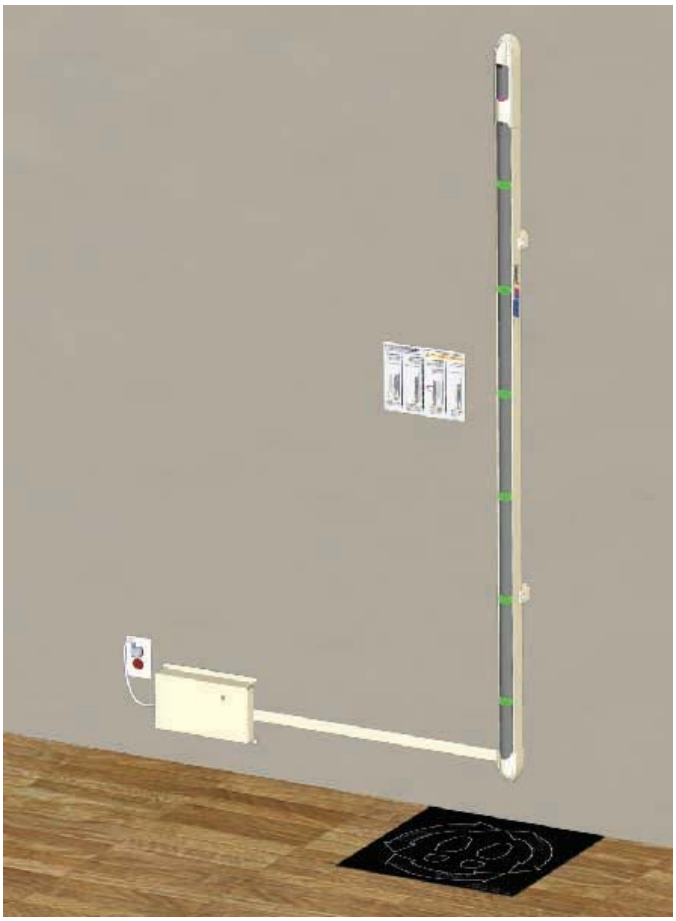
5. Use the Digital Power Supply cover screws (with caps) to mount the Power Supply and Cover to the wall near the power outlet (*but within 6-8 feet of the array).* Module should be mounted so the green ON light is visible through the hole in the Cover using provided double sided tape and leveled/not crooked.

6. Trim all excess cabling NEATLY in wire molding/surface conduit provided in shipping box.

7. Place floor mat and attach short form instructions with permission form the facility management.

Figure 11: Fastening Mounting Block to SuiteSentry Single Screener

Figure 10: Completed Installation



4.2 Power-Up and Diagnostic Instructions

- There is **no** ON/OFF switch.
- Plug in the power supply to the rear bottom connector on the Sensor Array Column and plug the power cord into the wall socket. Verify that the green power indicator on the wall mounted Power Supply is ON *(as it is in Fig. 5)* and the purple power on indicator light in the top display window of the SuiteSentry Single Screener's Sensor Array Column is ON.
- **Note:** To ensure continuous protection, SuiteSentry Single Screener should be powered on at all times. (Emergency Power Outlet is preferred)
- The system will now automatically perform a **Self-Test**. The process takes approx. 35 seconds until the detector is functioning normally. By watching and verifying all 5 conditions outlined below will demonstrate the detector is wired properly and all systems are working correctly and to specification.

1. The Self-Test starts with the audio alarm in the Sensor Array Column beeping (the # of beeps indicates sensitivity setting; the fewer # of beeps the higher the sensitivity setting.)

2. The purple power on LED indicator at top upper bar graph display illuminates.

3. Followed by the 6 green ready-to-scan lights in the vertical section of the Sensor Array Column of the detector illuminating simultaneously for a short period, approximately 1 second.

4. Followed by the upper bar-graph's 8 Red, then 8 Blue, then 8 Green lights.

5. The lights at the top extinguish and each of the 6 groups of 4 amber location lights in the vertical section of the Sensor Array Column flash on briefly, one group at a time, from the bottom to the top of the array and after that solid green LED's come on for approximately 15 seconds.

- The system then changes into **Standby Mode** and is ready for detection of ferrous objects.
- **Remember:** when detector is in standby mode there are **NO** green lights illuminated!
- The Top Cap of the detector will now be displaying a purple power light at the lowest point of the top display window indicating that the detector is powered on and in Standby Mode. See Figure 12 in Section 5.1 for how the lights operate.

5.0 OPERATION PROCEDURES

5.1 General Description of Operation of SuiteSentry Single Screener

When SuiteSentry Single Screener is in operation, the device passively senses the magnet fringe field of the specific environment it is placed in and "normalizes" to it. If an approaching object is made of ferromagnetic material, the sensors in the vertical Sensor Array Column detect the object's ferromagnetic content, analyzes its ferromagnetic mass and threat potential and if it exceeds the preset sensitivity threshold, the detector displays a visual alarm in the approximate area of the offending ferromagnetic object as well as an audible alarm.

SuiteSentry Single Screener series detectors have three (3) distinct modes of operation:

1. **Standby Mode -** Detector is *passively scanning* the ambient environment for threats or ferromagnetic disturbance
2. **Active Mode: Detector is now ready to scan –** *person is near enough to trigger the detector from standby mode and now the Sensor Array Column is showing green LED's*
3. **ALARM & LOCATION Mode –** Detected object is above alarm threshold and is a projectile threat in magnet room– **Visual Location lights *AND* Audio Alarm**

- **STANDBY Mode:** No Green LED's in Sensor Array Column, only the purple POWER ON indicator in the top Display and nothing more. If a ferromagnetic object is brought in proximity to the SuiteSentry Single Screener, an 8 segment blue LED light Ferromagnetic Disturbance Level bar graph in the top display window will indicate the magnitude of the ferromagnetic threat due to the approaching object. The more bar segments that are illuminated, the larger the ferromagnetic disturbance is. The blue lights will indicate ferromagnetic material moving near the detector even if the object or person has not come close enough to trigger the motion detector and put the SuiteSentry Single Screener into the ACTIVE Mode.
- **ACTIVE Mode:** will not be enabled until the object/person is within the adjustable "physical presence" area, approx. 6-10" in front of the detector. As person moves in to the sensing area, the PIR will detect your proximity and cause the system to automatically change into the Ready-to-Scan or ACTIVE Mode and illuminate 6 green indicator lights in the Sensor Array Column as long as motion is detected and for about 3 seconds after motion ceases.
- **ALARM & LOCATION Mode:** If an object on the person is creating a magnetic disturbance **greater than the pre-set threshold**, the system will then automatically change into the **ALARM Mode**. The system will show **the LOCATION** of the offending ferromagnetic object on the Sensor Array Column body through a series of **4 flashing Amber lights** nearest to the detected object. Additionally, the SuiteSentry Single Screener **also displays the location in the top bar graph** with a flashing Amber light at the same relative height, allowing the supervising screener to identify the area while standing back to observe the screening process without causing alarms from the supervising screener's personal attire. Refer to Figure 12 for example.

The detected object(s) should then be removed.

The person should then be rescreened until no ferrous objects are detected by the SuiteSentry Single Screener. Then the patient or staff can safely enter Zone III. Indicating the location of the ferromagnetic object is vital. For example, if the bottom group of amber LEDs is activated, the object is near the floor. There are 6 groups of 4 amber LOCATION indicator lights on the Sensor Array Column with each group representing about 1 foot (30cm) of height. If multiple groups of indicators are illuminated, a number of sensors have been activated, usually indicating a more significant threat.

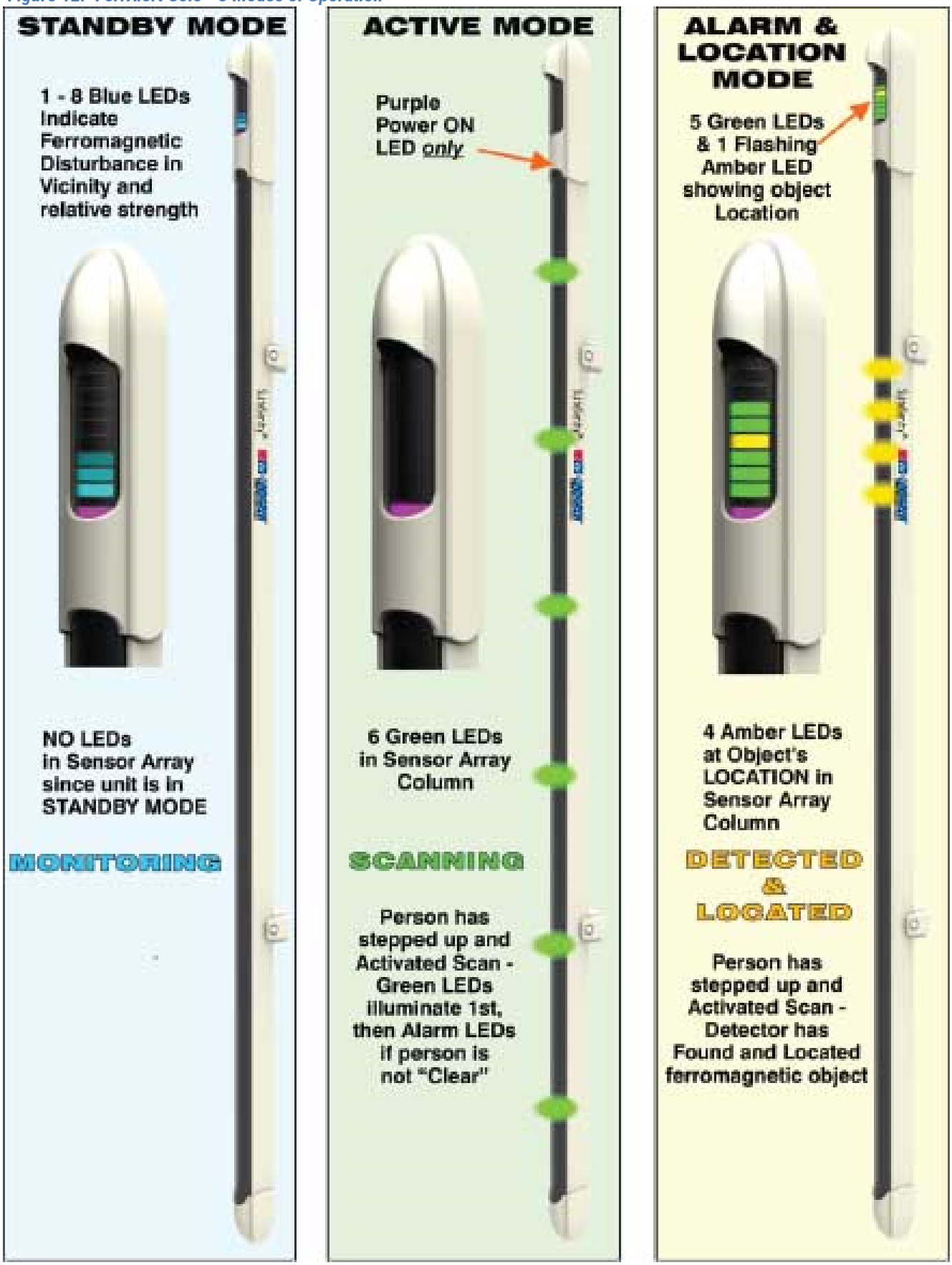
- Nevertheless, if SuiteSentry Single Screener detector does NOT react/alarm, one should **NOT** automatically assume that there are no ferromagnetic risks. **Using this device is a supplement to existing procedures.**

WARNING!

This device has not yet been fully evaluated for its efficacy in detection of ferromagnetic objects inside the body, such as IMPLANTS

SuiteSentry Single Screener - 3 Modes of Operation

Figure 12: FerrAlert Solo - 3 Modes of Operation



5.2 Operation and Usage of SuiteSentry Single Screener

The following steps are recommended for the user to ensure consistent and reliable results while screening themselves, other staff, or patients. Please note there are 2 methods for using the SuiteSentry Single Screener. It is the screener's choice as to which method is best based on possible movement limitations of the person being screened.

APPROACH SuiteSentry Single Screener. Walk in to approximately 4 to 6 inches from the Sensor Array Column. The six (6) green **READY TO SCAN** lights in the Sensor Array Column array will turn on as it sense body heat, the detector is now ready to screen person. *(Figure 13.a*)

METHOD 1:

MAKE A COMPLETE ROTATION, 360 degrees either left or right being careful not to touch or bump the SuiteSentry Single Screener. *(Figure 13.b)*

OR

METHOD 2:

Have patient stand facing the detector either left or right side of the column *(about 4-6 inches away)* and side-step two to three times, going across the SuiteSentry Single Screener sideways, than turn 180° around, facing opposite direction, and side-step **RIGHT**.

- If an offending ferromagnetic hazard is detected, the green READY TO SCAN lights will turn off. An audio alert will sound briefly and amber LOCATION DETECTION lights will flash on the Sensor Array Column at the location *(within a few inches)* of the detected ferromagnetic hazard. Additionally, an indicator at the top of the array aids the supervisor to see the location of the ferromagnetic hazard. *(Figure 13.c*)
- **IF THE ALARM IS TRIGGERED…. IT IS IMPERATIVE TO REMOVE LOCATED OBJECT BEFORE REPEATING PROCESS!**

DO NOT APPROACH THE MAGNET ROOM!
LOCATE the Object, REMOVE the object, REPEAT procedure until CLEAR.

- **IF THE GREEN READY TO SCAN LIGHTS STAY ILLUMINATED, NO FERROMAGNETIC HAZARDS WERE DETECTED**. After moving away, the detector will return to standby mode. The green lights will go out but the purple POWER indicator will be illuminated.
- The detector constantly monitors the ambient magnetic field and the blue bar graph at the top of the array displays the degree of magnetic disturbance being detected1

WARNING!

The SuiteSentry Single Screener is intended to *supplement, not replace* existing screening procedures!

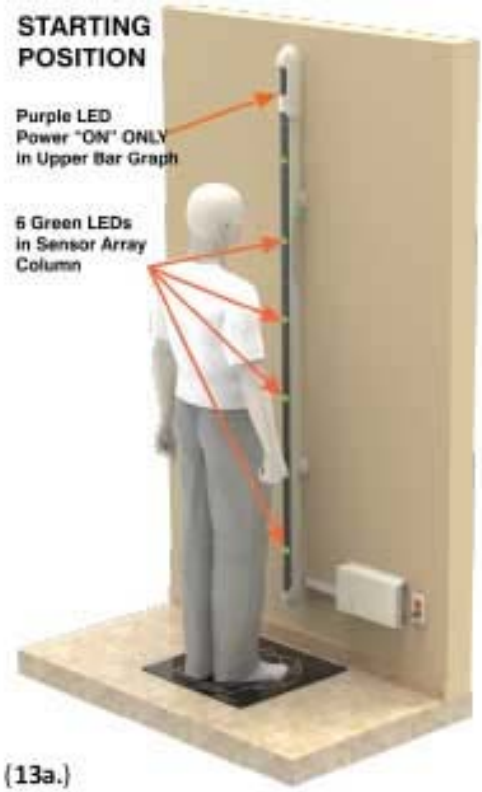
Even the most advanced technology is never 100 % foolproof. Thus, ferromagnetic detectors should not replace current MRI screening procedures. To provide your patients and personnel with the most comprehensive safety we suggest the use of diligent screening protocols together with high quality ferromagnetic detectors.

"..It should be reiterated that their use (Ferromagnetic Detectors) is in no way meant to replace a thorough screening practice, which rather should be supplemented by their usage."

ACR Guidance Document for MR Safe Practices: 2007,

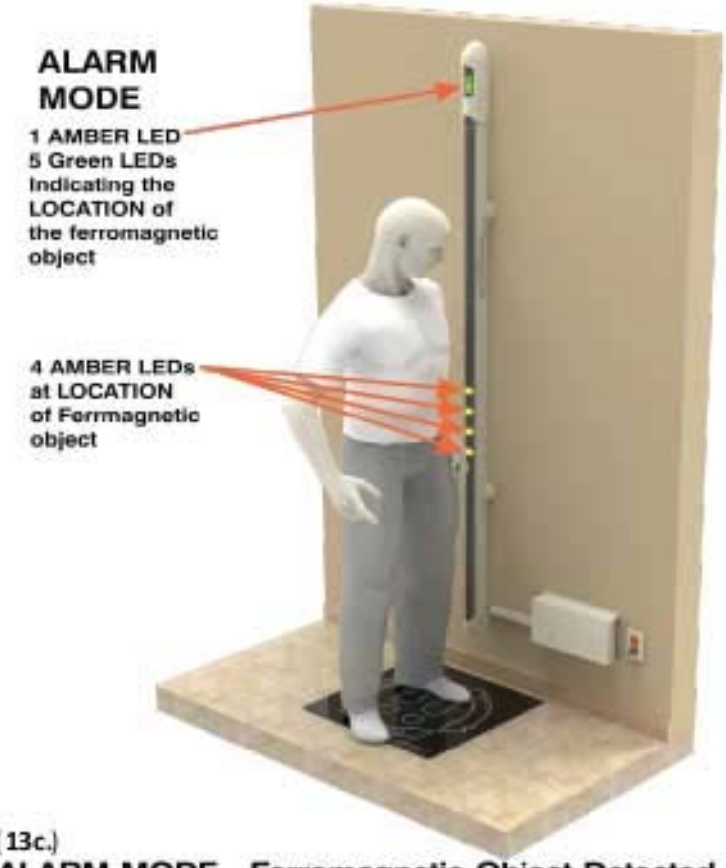
SuiteSentry Single Screener– Operation & Usage

Figures 13 a, b, c: SuiteSentry Single Screener Operation and Usage



(13a.)
ACTIVE Mode--Ready to Scan

(13b.)
NO Ferromagnetic Objects Detected



(13c.)
ALARM MODE - Ferromagnetic Object Detected !

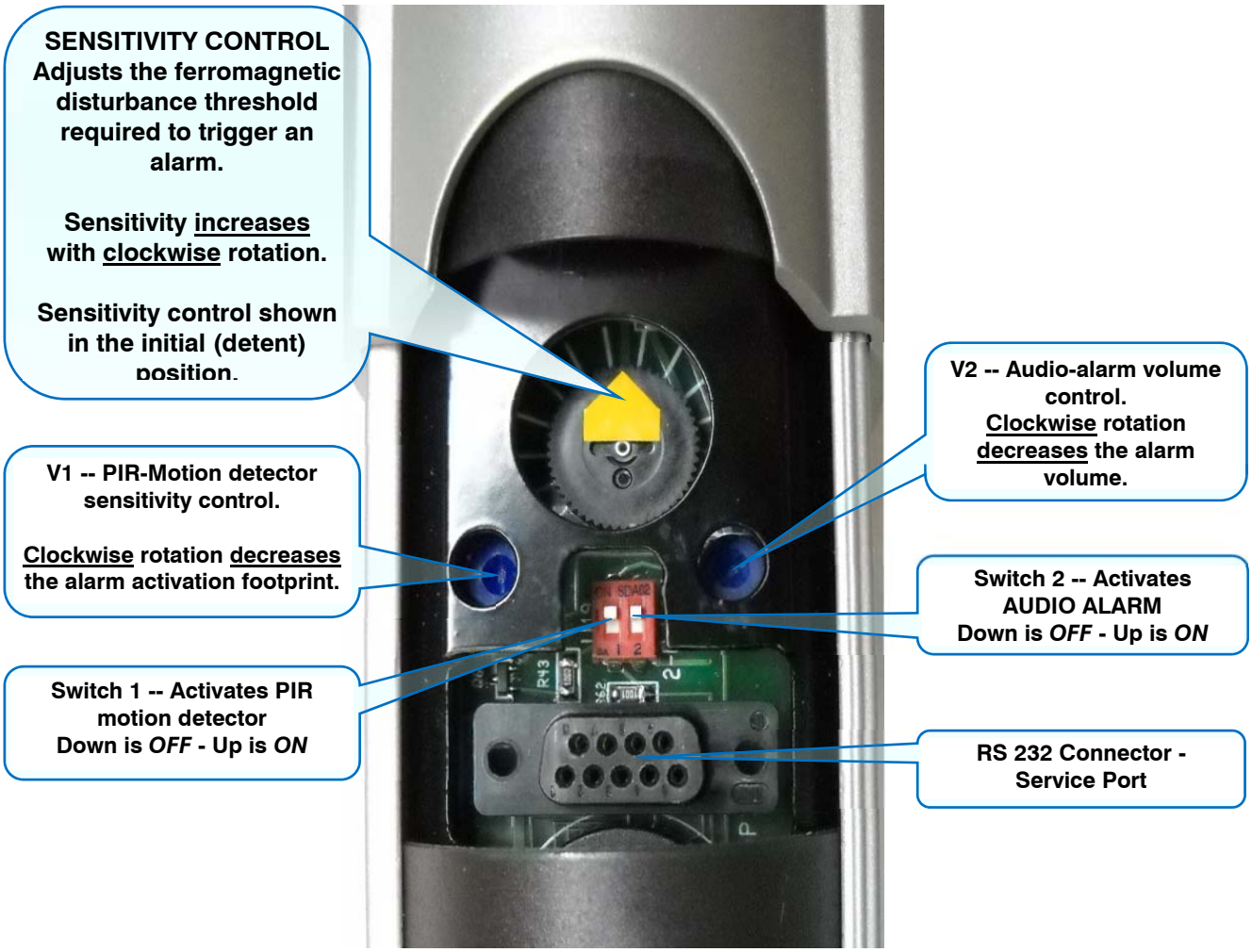
6.0 CALIBRATION & DIAGNOSTIC PROCEDURES

SuiteSentry Single Screener control functions are set at the time of product installation by the installer.

CAUTION! Changing of the control settings should be approached with care as they will alter the behavior of the unit.

Control Functions - Top Control Panel (under slide)

Figure 14: SuiteSentry Single Screener Controls



6.1 Sensitivity Adjustment

SuiteSentry Single Screener produces an audible and visual alarm when detecting ferromagnetic objects. The sensors in the unit are inherently very sensitive and designed for that purpose. Furthermore, the sensors in the SuiteSentry Single Screener are so sensitive that attempting to use them **too** near the MR Scanner or other electronic sources will likely cause inconsistent results and/or reduced sensitivity *(as described in Section 3.3)*.

SuiteSentry Single Screener sensitivity adjustment is set at the time of detector installation by the installer. Changing of the sensitivity control should be approached with care as too high a sensitivity setting may produce undesired alarm activation (False Positives) and too low a sensitivity setting may cause smaller ferromagnetic objects not to trigger the alarm.

Please refer to Figure 14 for the following steps.

1. Access to the **SENSITIVITY** control is located behind the top cover on the Sensor Array Column. Slide the cover up by slightly squeezing and applying steady upward pressure; the cap will slide up approximately 3 inches exposing the controls.
2. Before adjustment is attempted, turn off the motion detector function *Switch 1 in Figure 14* to keep the portal continuously activated allowing determination of the magnetic environment where the portal is located. Make sure that the **ALARM** switch 2 *(DIP switch 2 labeled AUDIO ALARM in figure 14)* is in the ON position during the adjustment to verify alarm is functional. You may shut the alarm off temporarily while adjusting sensitivity.
3. Begin by noting the current setting of the **SENSITIVITY** control as the original setting. To determine exactly where the **SENSITIVITY** control is set, unplug the power cord and plug it back in, counting the number of beeps produced by the audio alarm. The number of beeps indicates the specific sensitivity setting of the **SENSITIVITY** control. One long beep indicates the sensitivity is set to maximum while one shorter beep indicates that the sensitivity has been reduced slightly from maximum. The greater the number of beeps indicates how much the sensitivity has been ***reduced*** by the **SENSITIVITY** control from maximum. Turn the POWER switch OFF and then ON after each adjustment and note the change of the sensitivity setting, as indicated by the number of beeps.
4. If increased sensitivity is desired, rotate the **SENSITIVITY** dial clockwise about ½ of a division at a time and re-evaluate the performance. Do not increase the **SENSITIVITY** dial to the point where <u>any</u> of the blue bars of the bar graph illuminate with ambient conditions. False positive alarms are likely to occur.
5. If decreased sensitivity is desired, rotate the **SENSITIVITY** dial counter-clockwise about ½ of a division at a time and re-evaluate the performance. It is recommended to adjust the sensitivity in one beep increments as described in step 3. The evaluation should include testing the system with objects which are desired to be detected and insuring that the alarm is indeed triggered.
6. When the adjustment is complete, turn on the motion detector using Switch 1, and slide the top cap down.

6.2 Motion Detector Adjustment

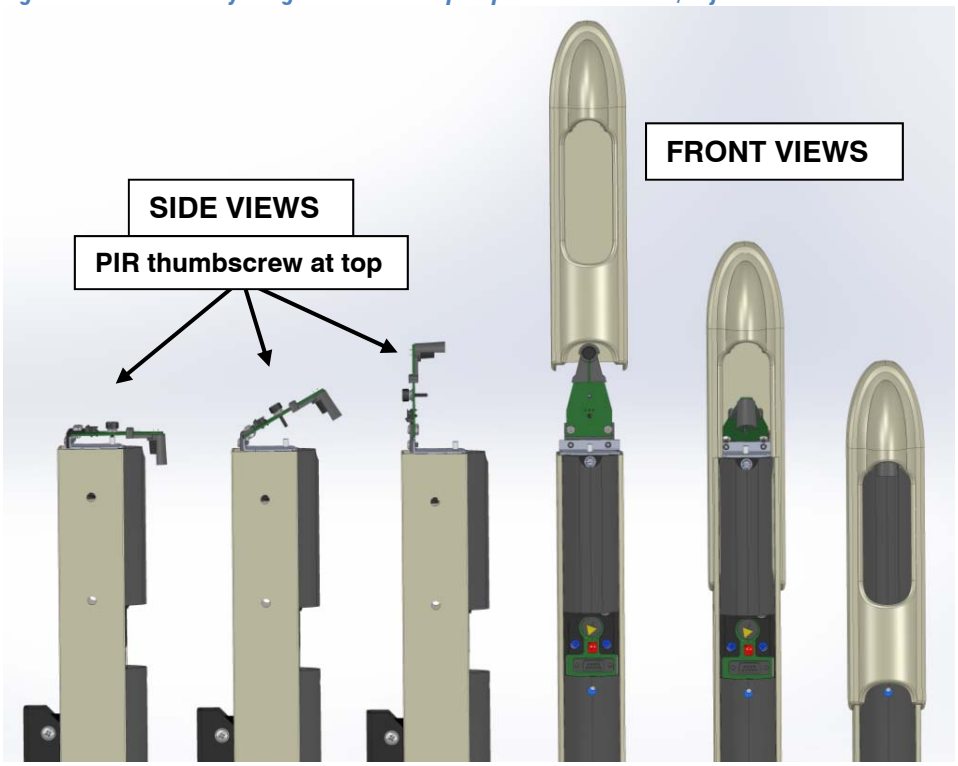
The purpose of the Motion Detector is to control the mode or function of the detector.

Standby Mode: In **Standby Mode** the detector is functioning **ONLY** as an ambient magnetic field display. The detector will NOT display Green LED lights and will NOT register an audible alarm even though it is detecting and displaying disturbances to the local ambient magnetic field through a series of 8 blue LED's at the top cover assembly. See Figure 12.

Active Mode: In **Active Mode** the detector is fully functioning and will display green lights on the vertical column. The detector no longer displays ambient magnetic field as described in Standby Mode. It is while in this Active Mode that the detector shows the location of the offending ferromagnetic object if present in the immediate area. A person should be approximately 8 inches or less for this mode to be used reliably. See Figures 13.a, b and c.

- The Motion Detector is a Passive Infrared Sensor (PIR). It is an electronic device that measures infrared (IR) light radiating from personnel moving in its' field of view. Movement of a person and not an object causes the SuiteSentry Single Screener to change from STANDBY non-alarming mode to ACTIVE ready to alarm mode.
- Access to the various controls is shown in Figure 14. THE TOP CAP WILL NEED TO BE UP
- The audio alarm can be deactivated with Switch 2 in figure 14. The audio is usually left "ON" since this audio provides immediate alarm feedback to the personnel turning in front of the Sensor Array Column. Audio alarm volume can be adjusted by the ALARM control, V2.
- The motion detector can be deactivated with Switch 1. This is useful for setting the system sensitivity and finding sources of stray interference by viewing which sensor(s) are alarming and then determining the cause; such as, a florescent light transformer in the ceiling very near the detector.
- With the motion detector activated, the motion detector sensitivity, V1, can be used to adjust how far away from the Sensor Array Column that the **Active mode** is activated by the Infra-Red sensor (PIR). The control is set at the factory to maximum sensitivity and can be reduced if lower sensitivity is desired. The sensitivity should be set high enough to trigger the alarm mode within 12" or less of the sensor array column.
- To adjust PIR - Use thumb screw to adjust the distance at which the PIR will sense (Fig. 15).

Figure 15: SuiteSentry Single Screener top cap and PIR access/adjustment



7.0 ROUTINE MAINTENANCE and SERVICE

7.1 Cleaning of SuiteSentry Single Screener

Inspect the Sensor Array Column as often as operating conditions require. To the exterior surface, perform the following steps:

1. Ensure that the brackets and mounting assembly is secured to wall; the SuiteSentry Single Screener Sensor Array Column must be securely attached to wall.
2. Remove loose dust on the outside of the sensor arrays with a lint-free fiber cloth. Use care to avoid scratching the Lexan diffuser strip over the LED lights.

Use a soft cloth dampened with water to clean the Sensor Array Portal. You may use an aqueous solution of 75% isopropyl alcohol for more efficient cleaning.

7.2 Periodic Testing of SuiteSentry Single Screener

Perform the SELF TEST routine, detailed in Section 4.2, on a regular basis; quarterly or semi-annually is adequate. *(Page 18)*

This is a "Qualitative Only" method for testing your SuiteSentry Single Screener detector (approx. 3 minutes)

The device you have is our SuiteSentry Single Screener personal screening device. It does not require any maintenance or calibration however this is a field expedient way to test it for functionality.

First unplug and plug in - this will start a hard reboot and watch the lights in top cap and then column for systematic illumination, done sequentially. This takes approx. 45 seconds.

With that established:

The actual sensors are 3" above and 3" below each green led in the column.

- Take a post it/piece of paper and fold it in half to cover sticky side. Put two staples into it side by side or slightly overlapped, does not matter.
- With the detector activated (all green led's are on, this is when it detects the heat from a person through a PIR (Passive infrared) sensor at the very top under the cap) take the stapled post it and at approx. 6" away (left or right) on plane with each sensor, one at a time, move it left to right and towards the column and the sensor will activate at some distance. The action will be as if sweeping across the column from side to side **WITHIN 1 INCH**
- Do this for each of the twelve sensors.
- Each of the sensors will detect the small gauss disturbance and only alarm that specific sensor.

The gauss disturbance from the staple(s) is small enough to not interfere with the sensors 6" Above and below and will test each specific sensor as one can fail and the other work on same board (very rare though!). You can also use a credit card stripe (black ferromagnetic stripe) and we will not erase the data as the sensors are passive and emit no static or dynamic EM/FM fields whatsoever.

8.0 CUSTOMER SERVICE

There are no user serviceable electronic parts in the SuiteSentry Single Screener system.

Please refer all requests for service and/or technical questions to address on the back of this manual.

9.0 SPECIFICATIONS, CLASSIFICATION & REFERENCE DOCUMENTS

9.1 Specifications

NUMBER OF DETECTION ZONES:

Six (6)

HEIGHT OF UNIFORM SENSITIVITY:

Greater than six (6) feet

HAZARD LOCATION INDICATORS:

Four (4) amber flashing lights at height of the hazardous ferrous object and one (1) in the Top Control Panel display.

AMBIENT MAGNETIC DISTURBANCE INDICATOR:

Eight (8) blue LED bars in the top display

FERROMAGNETIC HAZARD SENSITIVITY:

Adjustable

AUDIO INDICATOR:

Selectable, adjustable volume

MOUNTING:

Wall mounted or free-standing with optional Mobile Base using internal battery power while un-plugged and recharges or operates on wall power when plugged in.

POWER REQUIREMENT:

100 to 240 VAC, 47 to 63 Hz, 30 watts

DIMENSIONS:

Height: 86 ¼" (220 cm),
Depth from wall: 3 ¾" (9.525 cm)
Width: 2¼" (5.8 cm)

9.2 Device Classification

This equipment is classified as follows:

- **Safe Extra Low Voltage (SELV)** - exterior case is grounded only for shielding purposes.
- **Ordinary equipment** - exterior case is enclosed but is not water-proof.
- The equipment may be disinfected by denatured alcohol applied ***externally***.
- The equipment is ***not*** **suitable** for use in the presence of flammable anesthetic mixture.

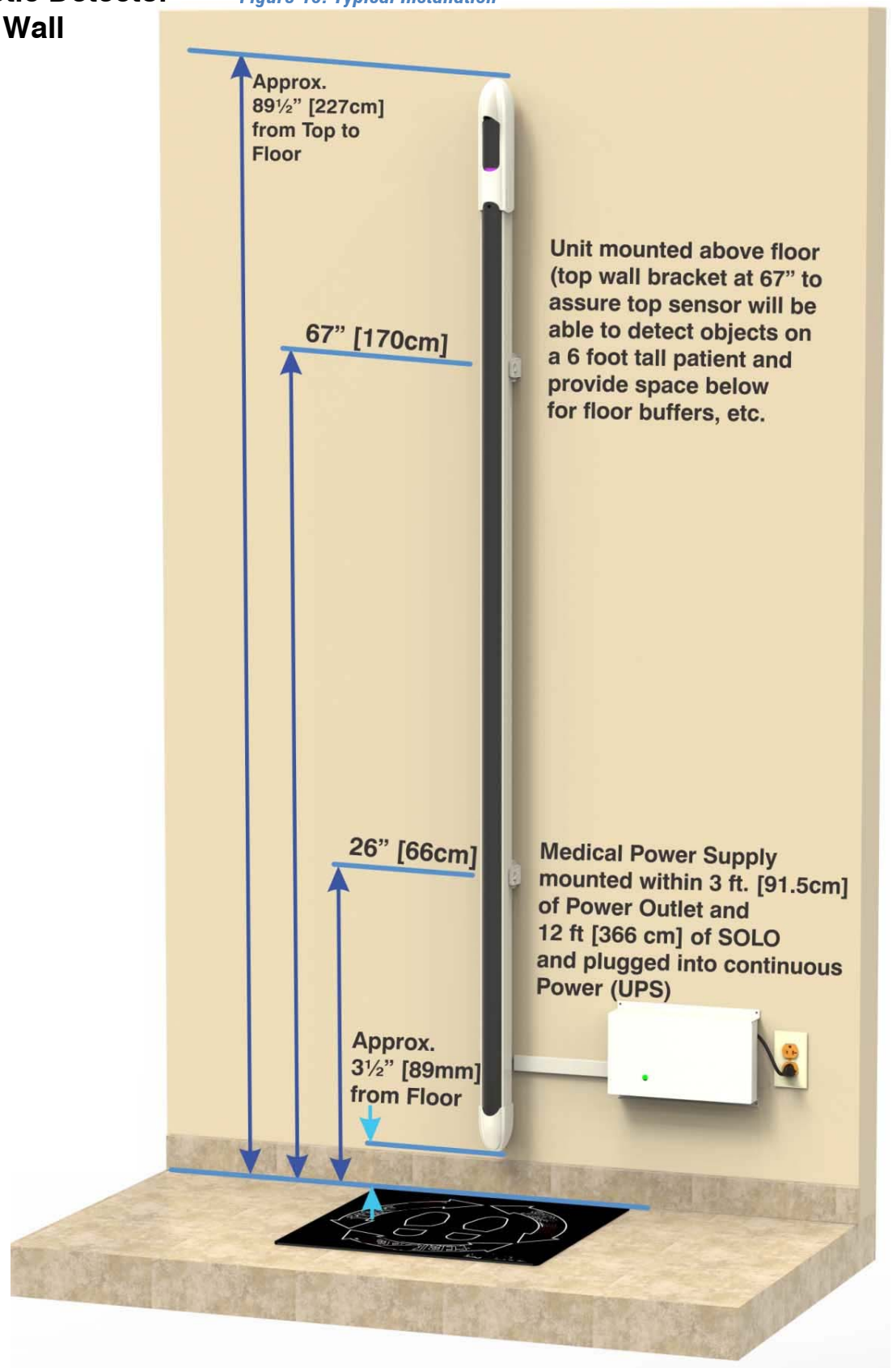
The equipment may be used in continuous operation**.**

9.3 Reference Documents - Installation Wiring Diagram

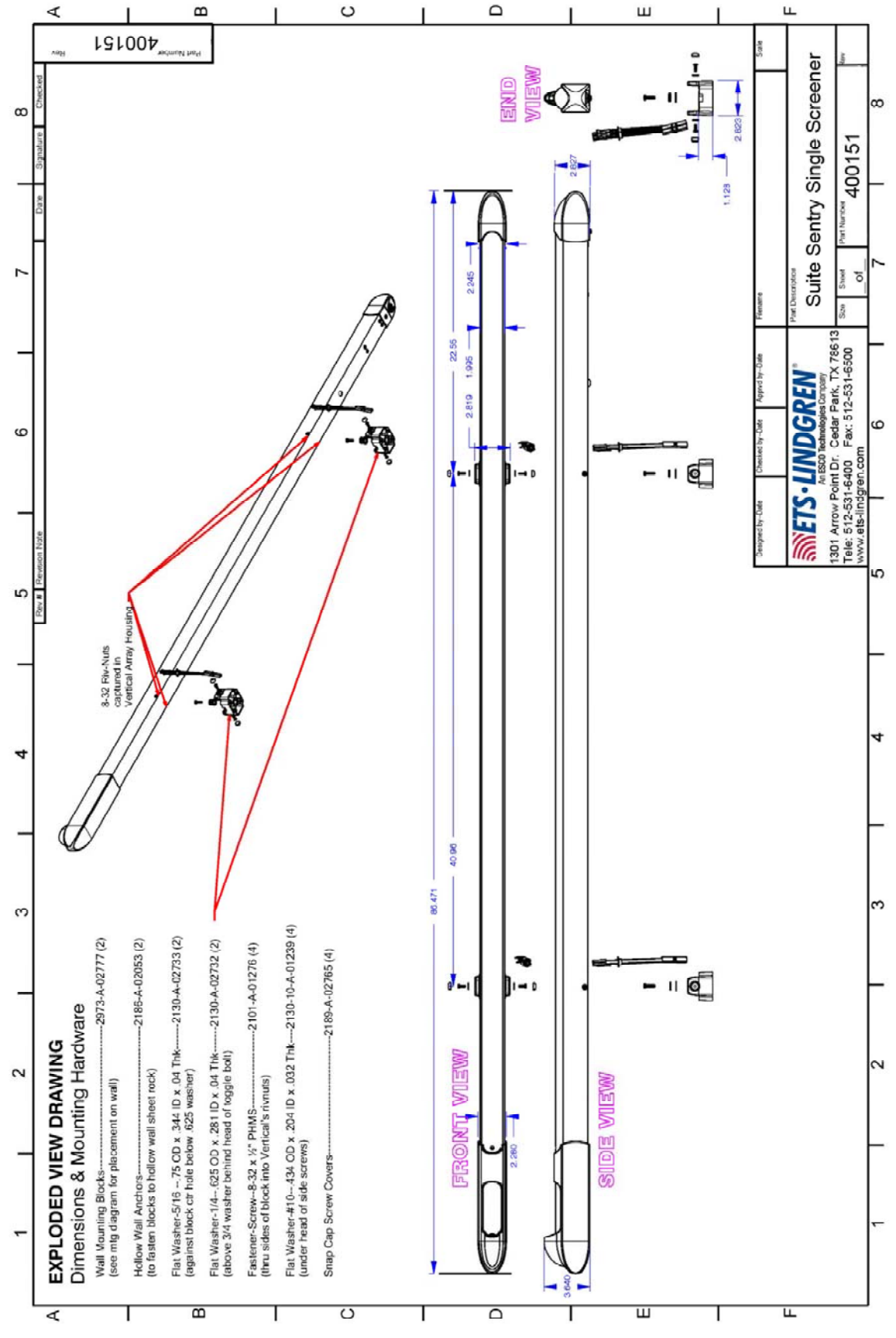
SuiteSentry Single Screener Installation Wiring and

Ferromagnetic Detector Mounted to Wall

Figure 16: Typical Installation



9.4 Mounting Dimensions - SuiteSentry Single Screener



10.0 Typical Installation Pictures

Typical Installation Pictures (continued)

Typical Installation Pictures (continued)

WARRANTY POLICY

ETS-Lindgren, the supplier of SuiteSentry Single Screener Systems, warrants equipment supplied by it to be free from defects in materials and workmanship for the period listed below. If, within such period, any such equipment shall be proven to ETS-Lindgren's satisfaction to be defective, such equipment will be repaired or replaced at ETS-Lindgren's discretion with no charge to the customer.

This warranty shall not apply to equipment not supplied by ETS-Lindgren or to equipment which has been:

a. repaired or modified by others so as, in ETS-Lindgren's sole judgment to affect the same adversely.

b. damaged by accident or impact (Lexan LED light covers are not under warranty).

c. damaged by circumstances beyond ETS-Lindgren's control.

d. damaged by improper operation, maintenance or storage.

e. subjected to other than normal use or service.

WARRANTY PERIOD

Three (3) years from date of installation at the customer's facility or thirty nine (39) months from the factory ship date, whichever date occurs first.

WARRANTY LIMITATIONS

The foregoing Warranties are exclusive and in lieu of all other express and implied warranties except warranties of Title, including, but not limited to implied warranties of merchantability and fitness for a particular purpose.
ETS-Lindgren shall not be subject to any other obligations or liability whatsoever with equipment manufactured by ETS-Lindgren or service rendered by ETS-Lindgren and the foregoing shall not obligate ETS-Lindgren to provide reimbursement for transportation, removal, installation or other expenses which may be incurred in connection with repair or replacement. ETS-Lindgren's sole liability for defects or breach of warranty shall be replacement of the materials involved. Warranty is typically executed through a Return Material Authorization (RMA) and as such it is the responsibility of the facility to remove/replace and make item ready for transportation to KDI facility for repair/replacement.

CONSEQUENTIAL DAMAGES

ETS-Lindgren will not be liable for special, indirect, incidental or consequential damages, and our liability, whether in contract, in tort, under any warranties, or otherwise, cannot exceed the price of the product or part on which such liability is based.

RETURNS

No equipment may be returned without obtaining permission and a Returned Merchandise Authorization (RMA) from ETS-Lindgren. Returned equipment must be packed securely to reach ETS-Lindgren without shipping damages and shipped prepaid by an approved carrier.

Email: technicalsupport@ets-lindgren.com