

PERIOPERATIVE **SPONGE DETECTION**

Situate™ Detection System X
In-service Guide

Medtronic
Further, Together

IN-SERVICE GUIDE OBJECTIVES

When to use this guide

This guide shall be used during in-servicing of groups or individuals at the time of implementation or for supplemental in-service training.

SYSTEM OVERVIEW

The Situate™ detection system X uses a low energy radio-frequency signal to detect Situate™ surgical sponges. It is indicated to detect tagged sponges in the patient and can be used to find missing sponges around the patient and outside of the surgical field.

The role of the Situate™ detection system X is to serve as an adjunct technology. The system **does not** replace manual counts.

The system helps to prevent retained surgical sponges, validate correct counts and rectify miscounts.

Medtronic's recommendation is to scan after the final count and before final closure. Note: Please refer to your hospital's policy.

Additional scanning can be performed any time during the procedure in accordance with the system's Instructions For Use (IFU) and especially when sponge counts are in question.

SYSTEM OVERVIEW

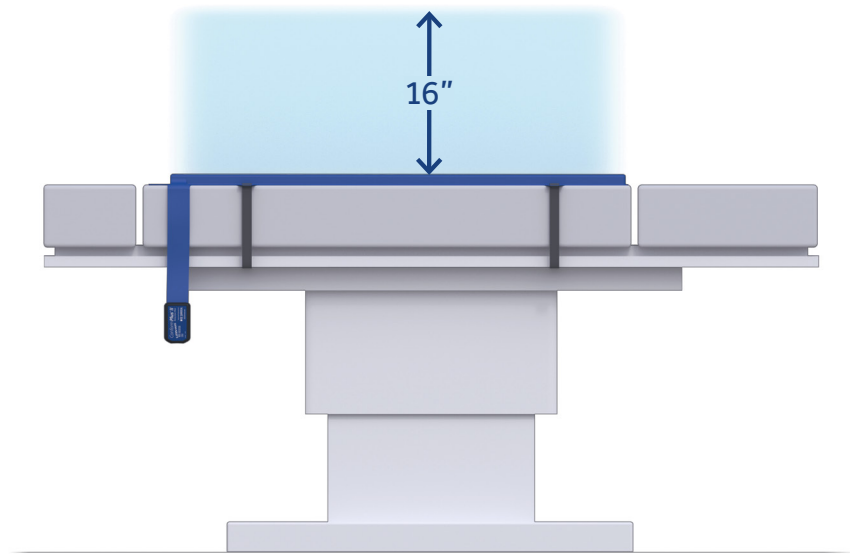
The system has four components:

- Situate™ premium cotton – surgical sponges, towels, gauze, etc., which have an embedded Situate™ tag
- Situate™ detection console 200X – the console contains the electronics that power and operate the scanning devices, as well as the software that provides a graphical user interface (GUI) for user operation and for communication of system status, alarms, and reports
- Situate™ body scanner lite – designed to detect tagged sponges in the surgical site using one-touch automatic scanning technology
- Situate™ room scanner – handheld, motion based, scanning tool used to detect missing tagged sponges in and around the sterile field

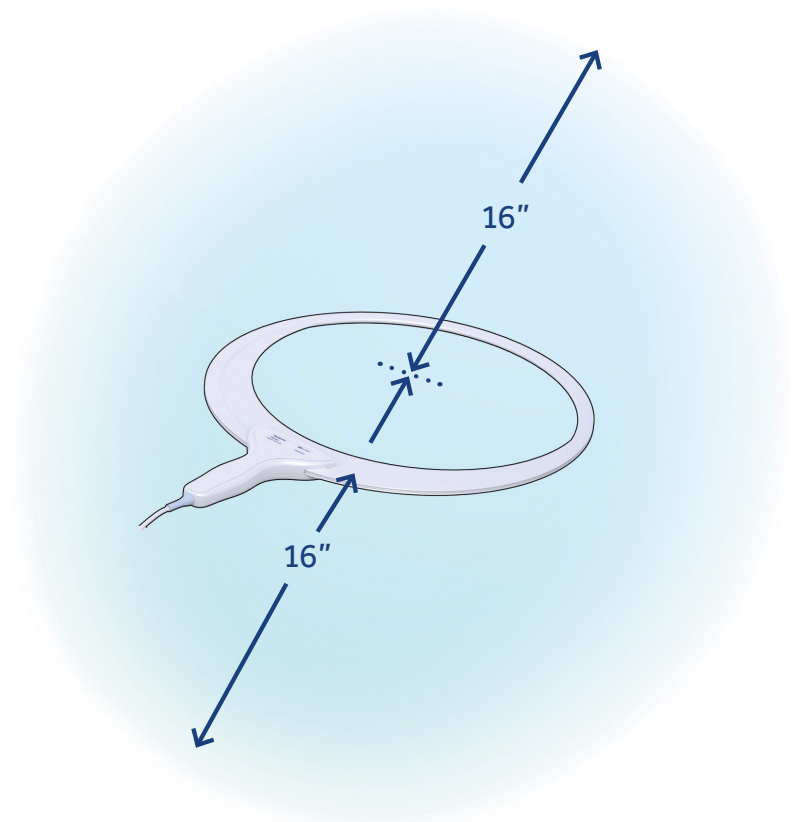


SYSTEM EFFECTIVE RANGES

Situate™ body scanner lite
Depth: 16" (40.64 cm)
Coverage: 42" (106.7 cm)



Situate™ room scanner
16" (40.64 cm)



SITUATE™ PREMIUM COTTON

What it is/how it works

Situate™ premium cotton are single use cotton disposables that must be used with the Situate™ detection system X.

The disposables have an attached RF Tag, which is an electrically passive inductor like device, that is sewn into the green pouch that you will see on all Situate™ premium cotton. When activated by magnetic impulses from the scanning devices, the tag resonates a signal that allows for the detection of these cotton disposables.

How it's used

- You *must* be using Situate™ premium cotton in order for the system to work
Show the green pouch and detect label
- When performing a scan, ensure that all gauze (both used and unused) is at least 36" from the scanning area. Extra sponges in proximity to the scanning area may cause an unwanted detection signal

Caution:

- Gauze sponges that are unfolded or manipulated may release cotton fibers
- Unfolding gauze sponges can expose woven edges and radiopaque marker to damage



SITUATE™ DETECTION CONSOLE 200X

What it is/how it works

The console is the “brains” of the system. It offers instruction and feedback on scanning (i.e. scanning process and result, interference notifications) and is also the storage place of data which can be accessed to evaluate a specific scan result.

How it's used

- The console takes 90 seconds to boot-up. Console self-calibrates every two seconds
Demonstrate how to power on the system
- Connection ports for scanning tools
Demonstrate how to connect the different scanning tools at all connections
- It is important to ensure that the console is secured in its location, to avoid dropping or damaging
Demonstrate how to secure the console using the strap



SITUATE™ BODY SCANNER LITE

What it is/how it works

The Situate™ body scanner lite detects missing tagged sponges in the surgical site using one-touch automatic scanning technology. It contains six (6) radiolucent (X-ray compatible) antennas which transmit magnetic impulses that will stimulate a Situate™ tag, and receive a resonant signal from the tag when it is detected.

Set up

The primary uses of the Situate™ body scanner lite includes surgeries performed in the torso.

- The Situate™ body scanner lite is placed directly on the torso pad of the surgical table, under positioning devices, drapes, and linens
- Ensure the patient is secure and stable in all positions expected to be used in the surgical case. Use straps, heel blocks or other patient securing objects per your hospital's protocol to ensure patient stability.

NOTE: In the event that the body scanner cannot be used, use the appropriate alternative Situate™ scanning device

Demonstrate how to strap the Situate™ body scanner lite properly using the disposable straps.



Note: In gynecological procedures, ensure that the Situate™ body scanner lite is not covering the perineal cutout of the pad.

SITUATE™ BODY SCANNER LITE

Scanning Procedure

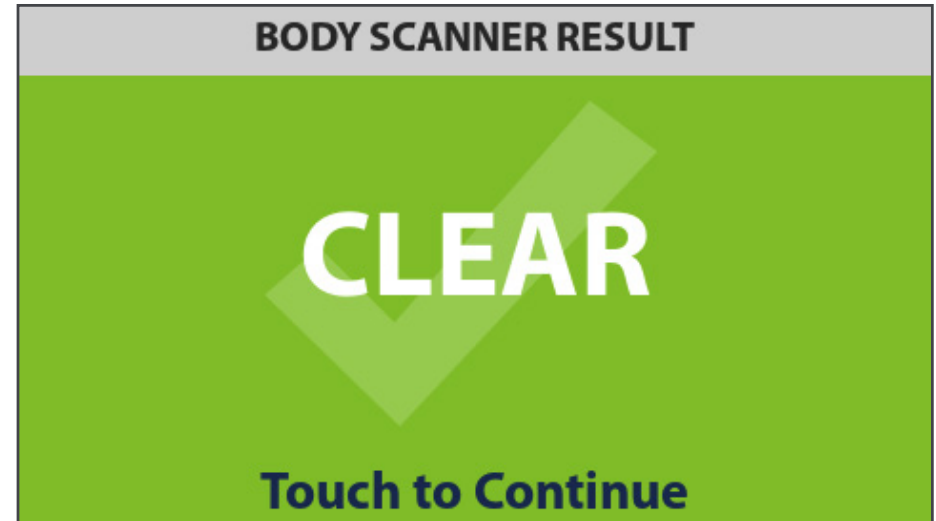
Before starting the scan, ensure that all tagged items (used and unused) are at least 36" from the scanning area.

A scan takes on average 15 seconds.

Demonstrate the following steps:

- **Opening a new case and selecting the device**
- **Initiating the scan**
- **Clear scan result and how to manage**
- **Detection scan result and how to manage**
- **Obtaining a scan confirmation number and when to record it**
- **Closing the case**

Keep in mind that positioning devices can elevate the patient, potentially positioning them outside of the effective range of the Situate™ body scanner lite. If this is the case, consider using the Situate™ room scanner in addition to performing a scan using the body scanner lite.



SITUATE™ ROOM SCANNER

What it is/how it works

The Situate™ room scanner is a handheld, motion-based scanning tool for detecting missing sponges in and around the sterile field (i.e. linens, drapes, trash bins). The wand functions as both an antenna and receiver to look for and detect Situate™ premium cotton. It is also used in conjunction with the Situate™ body scanner lite when the surgical site is beyond the effective range of the Situate™ body scanner lite such as in bariatric cases.

Set up

- Inspect room scanner for cracks and damage both pre and post case
- Drape the wand if using in the sterile field

Demonstrate how to drape the room scanner



SITUATE™ ROOM SCANNER

Scanning Procedure

Before starting the scan, ensure that all tagged items (used and unused) are at least 36" from the scanning area.

The room scanner is a motion based device. When it is moved within range of a tag during scanning, the Console will display a detection screen. When the room scanner is moved out of the tag's range the Console will revert back to displaying the scanning screen.

Demonstrate the following steps:

- Opening new case and selecting the device
- Touch the "start body scanner" button.
- If "detection" is indicated, touch the screen to continue. The scan summary window will display the case confirmation number. Search for and retrieve missing tagged items following hospital protocol.
- Touch "resume case" and repeat the scanning steps until a "clear" scan is reported.
- Once "clear" is indicated, touch the screen to continue and view the scan confirmation number.
- If scanning for the case is complete, record the scan confirmation number in the patient medical record following hospital protocol.
- You may now touch "close case." A prompt will appear to confirm the sponge count was reconciled.
- Select "yes" to confirm and end the scanning case.

SCAN SUMMARY	
Confirmation Code X-15F9B-0013C	
Scan Result: CLEAR Accessory: Body Scanner	
Resume Case	Close Case

SCAN SUMMARY	
Confirmation Code X-15F9B-0013D	
Scan Result: DETECTION Accessory: Body Scanner	
Resume Case	Close Case

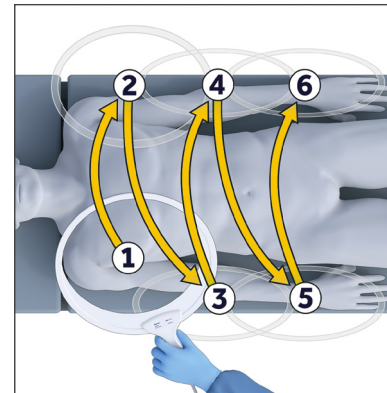
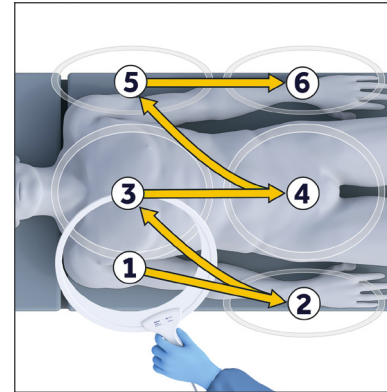
SITUATE™ ROOM SCANNER

Scan Pattern Instructions

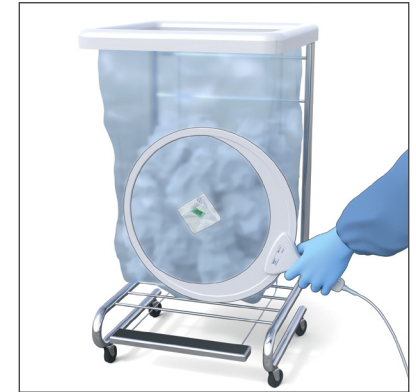
- Each scanning procedure includes a vertical scan pattern as well as a horizontal scan pattern
- Each scan pattern will take between 15-20 seconds at the rate of 3 seconds per pass
- Scan low and slow within 2" of the body, following the contour of the patient's body to ensure thorough scanning for various tag orientations
- The patient scan should be between 30-40 seconds in length. If a scan is stopped in under seven seconds, the console will display "insufficient scan time". A confirmation number will not be provided. Perform an additional scan for more than seven seconds in order to receive a confirmation number

Demonstrate proper wand scan technique:

Torso scan pattern



Scanning the environment

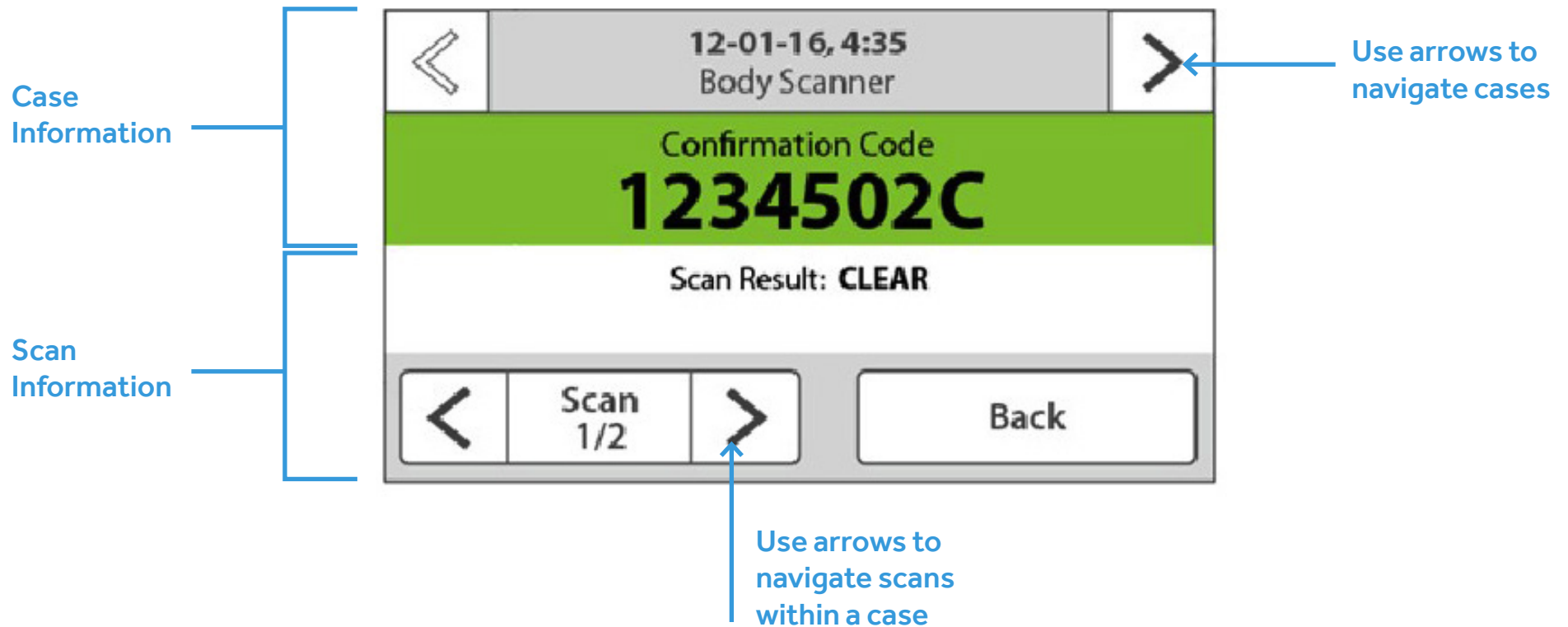


CONSOLE CASE/SCAN RECORDS

What it is/why it is important

The Console stores viewable records of all completed scan records which are grouped by case. Data is stored with a date and time stamp.

Demonstrate how to access and view case/scan records.



TECHNICAL INFORMATION

Pacers/ICDs¹

- Independent laboratory testing and extensive hospitals clinical experience demonstrate the Situate™ detection system X can be compatible with commonly used pacing and defibrillator devices when used in accordance with the manufacturer's direction for use and hospital protocol
- Do not scan while programming pacers or **ICDs**
- Temporary cardiac pacers should be set to a non-sensing, asynchronous mode (**VOO or DOO**) during scanning

Metal/Magnets¹

Metal or magnets within 1 mm of the Situate™ tag will reduce the tag's signal. Avoid direct contact between tag and metal/magnets.

Electrical Equipment¹

Limit the use of electrical equipment such as electrosurgery generators during actual scanning. Power down unused electronic devices and instruments, or move at least 36" away from the scan area.

MRI¹

Independent laboratory testing with regards to translational attraction, migration, and torque, as well as MRI-related heating indicates that Situate™ premium cotton products present no additional risk or hazard to a patient in an MRI environment of up to 3 Tesla, should a sponge/gauze product be present in a post-operative patient.

Radiation¹

The Situate™ detection system X, similar to most medical electronics, emits minor amounts of electrical radiation.

1. Situate™ Detection System [user's guide]. Mansfield, MA: Medtronic; 2016.

HOW TO MAKE A SPONGE STICK

In order to ensure that the tag remains more than 1 mm away from metal, please use the following technique to make a sponge stick:

Step 1



Step 2



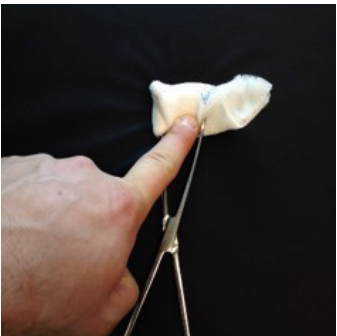
Step 3



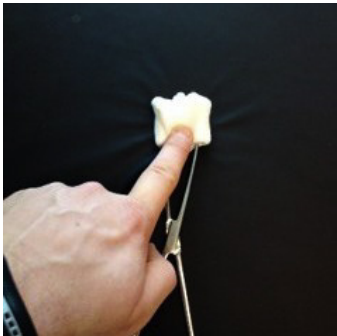
Step 4



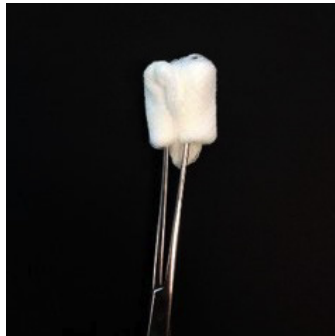
Step 5



Step 6



Step 7



CARE & CLEANING

- Inspect the Situate™ detection system X components for damage, deterioration, abrasion, cracks, splits, punctures, and loose components before and/or after each use. Check cables for kinks or breaks in insulation and connectors for wear or damage that would prevent secure attachment.
- The Situate™ detection system X components are constructed of materials that are resistant to most hospital disinfecting solutions. The recommended cleaning practice is to use isopropyl alcohol-based germicidal wipes.
- Avoid excessive exposure to fluids and cleaning products. Do not submerge. Avoid fluid ingress to any electrical circuitry.

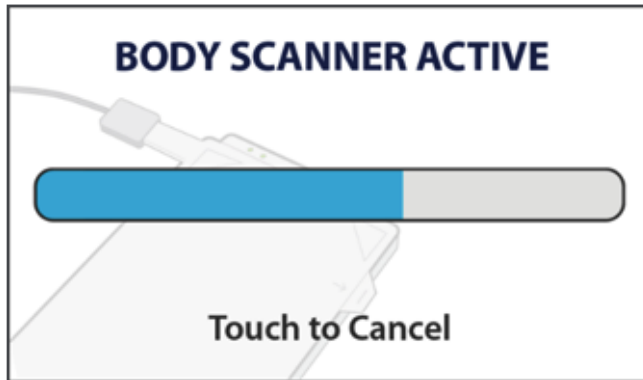
Please only return cleaned or disinfected products to the supplier.

DEVICE NOTIFICATION SCREENS

The Situate™ detection system X is designed with safeguards in place to promote effective scanning. When the System recognizes an interference, the Console will display a notification screen.

Situate™ body scanner lite

Interference detected during scanning will prompt the scan to extend for an additional 20 seconds while the device continues to interrogate the field. This will be seen on the screen when the system is in extended scan mode.



Situate™ room scanner obstruction

Brief exposure to interference causes the console to display a notification screen which can be corrected by moving the scanner away from the noise source. Prolonged exposure to the interference may cause the scan to stop and result in a fault screen.



DEVICE NOTIFICATION SCREENS

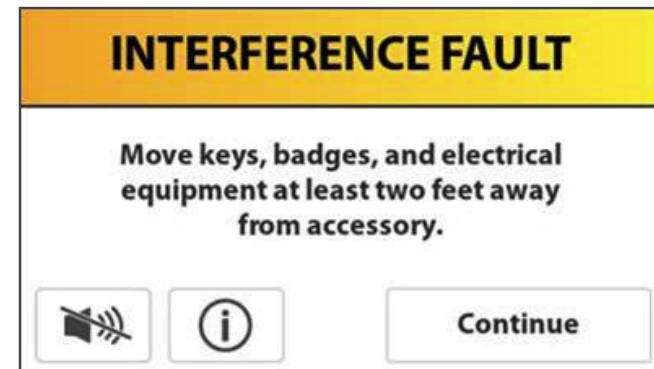
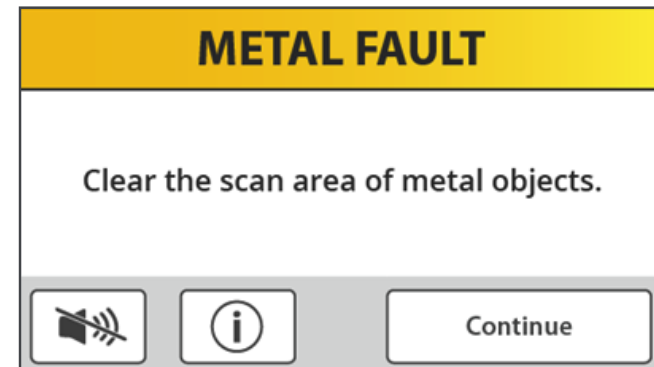
Situat[™] room scanner notifications

Wand Near Metal Screen: Move the scanner away from metal or metal away from the scanner. An accurate scan can still be achieved if the Console returns to the scanning progress screen.

Situat[™] body scanner lite and Situat[™] room scanner notifications

Metal Notification: Follow the prompt, clearing the scan area of metal objects.

Interference Notification: Follow the prompt moving keys, badges, and electrical equipment at least 24" away from scanning device and re-scan the patient.



TROUBLESHOOTING

Console Rebooting

If one of the following situations occurs, you will need to reboot the Console:

- The system stays on a blank white or black screen
- The progress bar freezes during boot-up
- The system freezes on 'Powered by Situate™ detection technology' progress bar screen
- Blue desktop-like screen
- "System Error" is displayed on console

If rebooting the system does not resolve the issue or if error persists, contact Technical Support at Medtronic.

DIRECTIONS FOR USE

For further instructions, refer to the Situate™ detection system X's Instructions For Use (IFU).

Contact Technical Support if need of further assistance, at 1-800-962-9888, Option 2.

© 2020 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.
08/2020 – US-OR-2000027 – [WF# 3792790]

555 Long Wharf Drive
New Haven, CT 06511

800.722.8772
508.261.8000

[medtronic.com/situate](https://www.medtronic.com/situate)

Medtronic