IN-SERVICE GUIDE OBJECTIVES

The purpose of this guide is to serve as a tool to aid in training customers at the time of Situate™ delivery system implementation.

Guide objectives

- To provide information to the customer to promote the successful adoption of our technology
- To ensure that all information conveyed is company approved and consistent with corporate messaging
- To ensure that all items on the Product Training Verification Checklist (07-0071) are covered during in-servicing

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.
SITUATE™ DELIVERY SYSTEM OVERVIEW

22% of all retained sponges are left in the vagina.¹

- The Situate™ delivery system is designed to help clinical staff identify and recover tagged objects in a patient or located in the surrounding areas of a labor and delivery suite.

- The Situate™ delivery system is an adjunct technology and does not replace manual counts. The system helps validate correct counts and rectify miscounts.

- When using the Situate™ delivery system, it is recommended to scan immediately following vaginal delivery. *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.

¹ Gwande et al.
The Situate™ delivery system has four components:

- **Situate™ premium cotton** - all come embedded with a Situate™ RF tag
- **Situate™ delivery console** - the “control box”; scanning is controlled and data is stored here
- **Situate™ delivery scanner** - handheld scanning tool
- **Situate™ delivery stand** - mobile support for the console and Situate™ delivery scanner
SITUATE™ PREMIUM COTTON

What it is/how it works

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

NOTE: Look for the Situate™ green pouch and 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.
SITUATE™ DELIVERY CONSOLE

What it is/how it works

The console is the “brains” of the system and used in conjunction with the Situate™ delivery scanner. It offers instruction and feedback on scanning (i.e. scanning process and result, and interference notifications) and also stores data, which can be accessed to evaluate a specific scan result.

How it’s used

- The console takes 60 seconds to boot-up. The Console self-calibrates every two seconds
  Demonstrate how to power on the system

- Connect the Situate™ delivery scanner (Verisphere) to the console
  Demonstrate how to connect the Situate™ delivery scanner (Verisphere) to the console, showing changes on screen

- It is important to ensure that the console is attached correctly to the Situate™ delivery stand
  Demonstrate how to attach the console to the stand

- The system has two scanning modes: Patient Scan and Room Scan. The console defaults to Patient Scan mode. The user must tap the “Go To” icon to switch between Patient Scan mode and Room Scan mode
  Demonstrate how to switch between scanning modes

The Situate™ delivery system was formerly known as RF Assure.
SITUATE™ DELIVERY SCANNER

What it is/how it works

The Situate™ delivery scanner (Verisphere) is a handheld, motion-free scanning tool. A blinking green LED light will illuminate on the Situate™ delivery scanner (Verisphere) when scanning is in progress.

The Situate™ delivery scanner (Verisphere) has two different scanning modes:

- **Patient Scan**: To be used on patients to detect sponges in vivo. During the motion-free, 3D scan, the user holds the Situate™ delivery scanner in contact or within 1” of the pubic bone. The scan takes approximately 15 seconds to complete

- **Room Scan**: Motion-based scanning used for searching for a missing sponge in the surrounding environment (i.e., trash, linens, etc.). Upon initiating the scan, move the Situate™ delivery scanner at a slow, steady rate. The scan will time out after 2 minutes and 15 seconds, but can be manually stopped at any time

The effective range of the Situate™ delivery scanner is 8”.

Situate™ Delivery Scanner Set Up

Place a sterile drape over the Situate™ delivery scanner. **Show the sterile drape if needed. Demonstrate how to drape the Situate™ delivery scanner**

The Verisphere™ is now the Situate™ delivery scanner

The Situate™ delivery system was formerly known as RF Assure.
PATIENT SCANNING

How to scan with the Situate™ delivery scanner - Patient Scan

- Before starting the scan, ensure that all tagged items (used and unused) are at least 36” from the scanning area.
- Position the draped Situate™ delivery scanner in contact or within 1” of the pubic bone. Once it is properly positioned, tap “Touch to Start” on the Patient Scan screen to begin the scan.
- It is important to hold the Situate™ delivery scanner steady while the scan is in progress.
- The scan will last for approximately 15 seconds. It is important not to stop the scan while it is in progress. Once the scan is complete, it will stop automatically. The console will display either a clear scan in green or a detection in red. Press “continue” to retrieve a scan confirmation number.

- If the scan results in a detection alert, look for the missing sponge following your hospital’s protocol (Refer to the scanning situations and suggested responses section in the Situate™ delivery system’s IFU). Once the sponge has been retrieved, re-scan the patient until a clear scan is obtained. Record the scan confirmation number of the final clear scan in your patient’s medical chart per your hospital’s protocol. All scans are date and time stamped, and stored on the console.

Demonstrate both a detection scan and clear scan using the Situate™ delivery system, while reviewing the points explained previously.

The Situate™ delivery system was formerly known as RF Assure.
PATIENT SCANNING - CONFIRMATIONS

What it is/how it works

- Each scan performed in Patient Scan mode will be assigned a scan confirmation number as a record that a scan was performed

- *Important:* Record the last clear scan confirmation number in the patient’s medical record per your hospital’s policy

![Scan Confirmation Numbers](image)
ROOM SCANNING

How to scan with the Situate™ delivery scanner - Room Scan

- Touch the “Go to” tab on the screen to change the scanning mode to Room Scan mode
  *Reiterate that this is not to be used for Patient Scanning*

- Touch to start scanning and move the Situate™ delivery scanner slow and steady in and around the environment, keeping in mind the 8” effective detection range

- Scanning is concluded either by tapping on “Touch to Stop” or continuing to scan until it times out after 2 minutes and 15 seconds. If the scan needs to continue longer than 2 minutes and 15 seconds, re-initiate scanning by tapping “Touch to Continue” and then “Touch to Start”

- The results of the room scan appear as one of the following screens:

  ![Clear Scan](image1.png)
  ![Detection Scan](image2.png)

Considerations

- Scan confirmation numbers are not given when a room scan is performed

- To stop a “detection” alert, tap the “Touch to Stop” icon

Demonstrate how to use the Situate™ delivery scanner in Room Scan mode, showing both a Clear Scan and a Detection Scan
TECHNICAL INFORMATION

Pacers/ICDs

- Independent laboratory testing and extensive hospital clinical experience demonstrate that the Situate™ delivery system can be compatible with commonly used pacing and defibrillator devices when used in accordance with the manufacturer’s directions and hospital protocol
- Do not scan while programming pacers or ICDs
- Temporary cardiac pacers should be set to non-sensing asynchronous mode (VOO or DOO mode) during scanning

Metal/Magnets

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

MRI

Independent laboratory testing with regards to translational attraction, migrational and torque, as well as MRI-related heating, indicates that Situate™ premium cotton 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.

Radiation

The Situate™ delivery system, similar to most medical electronics, emits minor amounts of electrical radiation. It does not pose a risk to the patient or user.

CARE AND CLEANING

- Before and after use, inspect the delivery scanner for damage and deterioration including abrasion, cracks, splits, punctures, and loose components. Check cables for kinks or breaks in insulation and connectors for wear or damage that would prevent secure attachment
- The System may be cleaned with an isopropyl alcohol based germicidal wipe. Avoid excessive exposure to fluids and cleaning products. Do not submerge. Avoid fluid ingress to any electrical circuitry

The Situate™ delivery system was formerly known as RF Assure.
TROUBLESHOOTING

The Situate™ delivery system is designed with safeguards in place to promote effective scanning. The system is designed to be able to identify environmental factors (i.e., electrical noise) that can impact the accuracy of the scan. When the system recognizes an interference, it will provide feedback on corrective action that needs to be taken in order to obtain an accurate scan.

Interference

Interference is an electronic noise from any electrical device or environmental source that may potentially block or interfere with our signal processing.

When an Interference occurs in “Patient Scan Mode”, resolve by following these steps:

- Touch “Mute” to stop audible alarm
- Follow the directions on the screen and move or power down electrical equipment
- Touch “Continue” and rescan the patient
TROUBLESHOOTING

Scan Obstruction

When a Scan Obstruction occurs in “Room Scan Mode”, resolve by following these steps:

- If the Situate™ delivery scanner is in close proximity to noise, an alarm will sound, followed by an interference screen. Touch “Mute” to stop the audible alarm and follow the screen prompts.

- Move the Situate™ delivery scanner away from the source of the interference (i.e., bed power source, infusion pump, etc.). Once the Situate™ delivery scanner is far enough away from the interference source, it will automatically return to scanning mode and complete the scan.

Electrical interference may be caused by electrical devices in close proximity to the Situate™ delivery scanner.

The Verisphere™ is now the Situate™ delivery scanner.
Rebooting the console

- If display is white, erratic in operation or non-responsive, cycle power to restart console. If issue persists, contact Medtronic

- For further instructions, refer to the Situate™ delivery systems’ Instructions For Use (IFU)