Evaluation: Surgical Sponge Counting and/or Detection Technologies, Focusing on the Medtronic Situate™ Detection System X

A Report Excerpted from Health Devices
July 2018

Also Includes Ratings and Purchasing Advice for:
Stryker SurgiCount Safety-Sponge® System
Charter and General Policy

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Evaluation: Surgical Sponge Counting and/or Detection Technologies, Focusing on the Medtronic Situate™ Detection System X

A Report Excerpted from Health Devices
July 2018

This report focuses on our Evaluation of the Medtronic Situate™ Detection System X. For perspective, it also includes a summary of our findings for the other system we evaluated: the Stryker SurgiCount Safety-Sponge® System sponge counting technology. That summary information is presented below and on the next page. Our detailed Evaluation results for the Situate™ Detection System X begin on page 5.

### RATINGS: SURGICAL SPONGE COUNTING AND/OR DETECTION TECHNOLOGIES

<table>
<thead>
<tr>
<th>Model</th>
<th>Date Last Updated</th>
<th>Rating</th>
<th>Performance</th>
<th>Safety</th>
<th>Workflow</th>
<th>Patient Experience</th>
<th>Interoperability</th>
<th>Maintenance</th>
<th>User Experience</th>
<th>Cost of Ownership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic Situate™ Detection System X</td>
<td>6/2018</td>
<td>Good</td>
<td>Good</td>
<td>Excellent</td>
<td>Not evaluated</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>$53,000 (estimated) over five years</td>
</tr>
<tr>
<td>Stryker SurgiCount Safety-Sponge® System</td>
<td>6/2018</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Not evaluated</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>Good</td>
<td>$53,000 (estimated) over five years</td>
</tr>
</tbody>
</table>
Medtronic Situate™ Detection System X

Our rating is based on the following findings:
Performance—Good
Safety—Good
Workflow—Excellent. The Situate™ can be used to scan the patient at any point (e.g., when closing a cavity within a cavity) during any procedure type, and features automated detection.
Patient Experience—Not evaluated
Interoperability—Good
Maintenance—Good
User Experience—Good
Cost of Ownership—Good; $53,000 (estimated) over five years.

Stryker SurgiCount Safety-Sponge® System

Our rating is based on the following findings:
Performance—Good
Safety—Good
Workflow—Good
Patient Experience—Not evaluated
Interoperability—Good
Maintenance—Good
User Experience—Good
Cost of Ownership—Good; $53,000 (estimated) over five years.
Stryker offers a liability program indemnifying the hospital if a retained sponge event occurs due to nonperformance of the system.
Medtronic Situate™ Detection System X Surgical Sponge Detection Technology

RATING

DEVICE DETAILS

- Name: Situate™ Detection System X (previously known as the RF Assure 200X under RF Surgical)
- Date evaluated: June 2018
- Manufacturer: Medtronic Inc. [101809]
- Software version evaluated: 20150610

DEVICE DESCRIPTION

1. The device is designed for RF detection of surgical soft goods in both the patient and the OR before surgical closure and in the event of a count discrepancy or a misplaced sponge.

2. Major device components and software features:
   a) Situate™ Detection System X Console (previously known as the RF Assure Console 200X)
      (1) Seven-pound console intended for placement on an OR boom or cart. The console features non-interchangeable quick-connect-type outlets for the body scanner and other detection accessories (i.e., room and extremity scanners).
      (a) The console has an Ethernet port and several USB connections for accessing data logs, which can tell interested parties the quantity and results of scans, accessory type, scan duration, and result of all scans from a procedure using that specific console.
      (b) Since these logs are time-stamped, ECRI Institute recommends that your facility’s biomedical engineering department updates the internal clock to account for the start and end of daylight saving time.
   b) Situate™ Body Scanner Lite (previously known as the ConformPlus II Detection Mat)
      (1) Four-pound foam mat intended to lie beneath the draped patient’s abdominal area (dimensions are 42 × 20 × 1 in). The mat has an array of six antennas that successively scan the area encompassing approximately 16 inches above the mat. Users cannot interrupt the mat scan, which requires approximately 17 seconds.
      (2) The console will default to scanning with the detection mat if multiple accessories (i.e., the mat and one of the scanning wands) are plugged into it.
      (3) The detection mat may require annual replacement. If a mat is damaged within a procedure (e.g., bent such that it yields a fault code, or accidentally cut), it should be replaced immediately.
   c) Situate™ RF-tagged surgical soft goods (RFDetect Premium, Situate™ Sponges)

   (2) All scanning is initiated using touchscreen button presses on the console. ECRI Institute recommends that users scan patients before closure regardless of whether a manual count is discrepant, due to the risk of manual counting errors.
      (a) In the event of a detection: The user sees a red screen with an “X,” which continues to a detection code, identifiable as it ends in the letter “D” (e.g., 17905-79D).
      (b) In the event of a clear scan: The user sees a green screen with a check mark, which continues to a clear code, identifiable as it ends in the letter “C” (e.g., 11103-2C). ECRI Institute recommends making entry of this clear code a mandatory field in your patient’s electronic medical record. Closing a cavity prior to receiving a clear code at the console may invite risk of a retained sponge.
1) Medtronic surgical soft goods (laparotomy sponges, gauze, towels, packing, etc.) are available sterile or nonsterile in a variety of dimensions and thicknesses, with a radiopaque element for x-ray detection in the event that an x-ray scan is required. A small, cylindrical, passive RF tag is sewn into the sponge in a corner pocket. Most are available in packs of five or 10 and often purchased as part of a surgical kit.

2) If your facility chooses to employ the Situate™ (or any other technological adjunct to manual counting), ECRI Institute recommends switching all applicable surgical soft goods over to those that are appropriately tagged to reduce the risk of accidentally using a sponge not compatible with the system.

3. Consoles are situated outside the sterile field of ORs. The detection mat is beneath the draped patient, and room and extremity scanners should be covered with a sterile drape for use within the sterile field. The device is typically used for any procedures requiring the use of surgical soft goods, including:
   a) Abdominal surgery
   b) Arthroscopic surgery
   c) Cardiac surgery
   d) Colorectal surgery
   e) Gastrointestinal surgery
   f) General surgery
   g) Neurosurgery
   h) Orthopedic surgery
   i) Pelvic surgery (e.g., OB/GYN) (Note: Medtronic offers a specialty labor and delivery console, the RF Assure Console 200LD-V, for use with its Verisphere scanner; the console and scanner were not examined as part of this Evaluation.)
   j) Plastic/reconstructive surgery
   k) Thoracic surgery
   l) Trauma/emergent surgery
   m) Urologic surgery

4. Optional device components and software features
   a) Situate™ Room Scanner (previously known as the Blair-Port Wand X)
      (1) Eleven-ounce handheld scanning wand with one antenna housed in a plastic, circular frame; this antenna has a scanning radius of 16 in on either side of the device.
      (2) The wand is intended as either of the following:
         a) A room scanner (with a 12 ft cord) to search the OR’s trash, laundry, or other areas
         b) A body scanner, used in conjunction with the detection mat if a patient is particularly large or morbidly obese (i.e., their abdomen lies outside the 16 in range above the detection mat)
      (3) Wanding patterns are recommended in the product’s instructions for use, with the wand approximately two inches above the patient’s body or area of interest, to get an accurate scan. Users can interrupt the room scan as long as it has lasted at least seven seconds; Medtronic estimates that one scan pattern takes between 15 and 20 seconds, and a total wand scan typically lasts approximately 30 to 40 seconds.
      (4) The console will alarm if the user is wanding over a detected RF item and will cease alarming if the user moves the wand too far away from the item.
      (5) The room scanner is not a sterile device, and must be in a sterile drape when present in the sterile field. The room scanner is reusable.
b) Situate™ Extremity Scanner (previously known as the ArQ-Sphere Bi-Nodal Scanner)

(1) Two-pound handheld scanner intended to scan patient extremities or cavities, such as joints, that may be more awkward than the abdomen to navigate with the room scanner.

(2) The scanner is held stationary one inch above, or in contact with a location adjacent to, the surgical site (for example, with the nodes on either side of the shoulder in the case of shoulder arthroplasty), and a scan is initiated. Users cannot interrupt the extremity scan, which requires approximately 16 seconds.

(3) The scanner has a radius of 15 inches outward from the center of the device, and eight inches downward from each of the two nodes.

(4) The extremity scanner requires a sterile drape and is intended as a reusable device.

(5) The extremity scanner may require replacement annually, or if it is physically damaged or is causing unanticipated console faults.

SIGNIFICANT FINDINGS

We performed a variety of tests on this product, including physical tests, a review of product literature/specifications, and inquiries about users’ experience with the device. For more details, see the ECRI Institute’s Testing section of our Evaluation Background on this technology.

Note: Some of the following judgments—such as for performance speed and wand scanning time—are relevant only to detection systems, like the Situate™ Detection System X. Competing systems that count sponges but do not have detection functions will not show advantages in detection-related areas; this does not mean that we find such a system deficient, but only that it does not offer this function, so we cannot provide judgment on it. Other judgments—such as for evidence of reduced occurrence of retained sponges or ability to be used on demand—pertain to both detection and counting systems and can be used to compare both types.

Performance—Good

The device has been evaluated against ECRI Institute’s performance criteria for an adjunct surgical sponge technology and found to meet all required criteria.

Minor Advantages

1. Detection time:
   a) Fast sponge detection can be achieved with both the body and room scanners. In user testing, the average time to detect a single sponge was approximately 30 seconds, with a range of 16 to 60 seconds; longer detection times tended to be associated with room scanning, rather than abdominal scans.
   b) Searching for a missing sponge or retained item can add an average of 18 minutes to a surgical case (Williams et al. 2014). It is important for systems that claim the benefits of sponge detection to do so in a timely manner so as not to prolong the time the patient is under anesthesia or increase the costs associated with OR time, which may be approximately $50 per minute (Macario 2010, Childers and Maggard-Gibbons 2018).

2. Wand-scanning speed:
   a) Fast and consistent detection when using the room scanner.
   (1) Medtronic recommends “low and slow” scanning that follows the contours of a patient’s body at a rate of approximately three seconds per pass, where a pass is a portion of a recommended wand-pattern (for example, shoulder to shoulder or shoulder to hip). The Situate™ console instructs the user on how to perform an effective scan after it has been initiated, though facilities should refer
to the instructions for use for specific wanding patterns.

(2) ECRI Institute found that unless the wand was moved at an unreasonably fast speed or out of the detection range of the instrument, the wand immediately detected a sponge beneath its antenna or hidden under the abdomen of a test subject.

b) It is preferable if sponge detection both is expedient and provides reliable results.

3. Evidence of reduced occurrence of retained sponges:

a) In a study of 2,051 emergent trauma and non-trauma cavitary operations over a five-year period, appropriate use of this system at two facilities allowed the detection of retained surgical sponges in 11 patients before closure. Postoperative x-rays on all patients were negative for retained sponges, indicating that the system found all retained sponges without a need to rely on intraoperative x-rays (Inaba et al. 2016).

b) Medtronic cites this study as evidence of reduced reliance on intraoperative x-ray; there were two facilities involved in this study, one of which elected to drop their requirement for intraoperative x-ray to search for sponges based on these outcomes. Some facilities choose to perform intraoperative x-rays on all procedures, which can be costly and risky in terms of the time the patient spends under anesthesia and receiving potentially unnecessary radiation, the extended OR and procedure time, and the cost and time to use the technology and interpret the result; for example, the cost for the technology and radiologist for one intraoperative x-ray is approximately $290 (Williams et al. 2014) and the cost of OR time is $50 per minute, on average (Macario 2010, Childers and Maggard-Gibbons 2018). If clinicians can rely on detection technology to eliminate retained surgical sponges, there may be significant benefits for the patient and facility. However, ECRI Institute notes that intraoperative x-rays may still be required in order to detect other commonly retained foreign items such as suture needles.

Safety—Good

The device has been evaluated against ECRI Institute’s safety criteria for an adjunct surgical sponge technology and found to meet all required criteria. The device itself is inherently intended to increase patient safety, and as such many safety considerations were included above under the category of Performance.

Notable Findings

1. Users should be aware of the potential for RF and metal interference, for which the system will provide a fault notification, and should be advised that Medtronic recommends the following regarding use of cardiac pacing and defibrillation devices: “Refer to the pacing or defibrillator device manufacturer’s instructions, hospital protocol, and these directions for use to ensure optimal operation of these devices. Do not program pacing or ICD [implantable cardioverter-defibrillator] devices while scanning. Temporary cardiac pacers should be set to non-sensing, asynchronous mode (VOO or DOO mode) during scanning.”

2. Users should be aware of the risk that a sponge may tear upon removal from a patient, leaving a non-tagged portion of the sponge behind; in such an instance, detection technology will not aid in ensuring that all items have been retrieved. Surgical staff should check that sponges are intact when removed from the patient and check the patient for fragments if necessary.

Workflow—Excellent

The device has been evaluated against ECRI Institute’s workflow criteria for an adjunct surgical sponge technology and found to meet all required criteria.
Major Advantage

1. Use on-demand:
   a) Body, room, or extremity scanning is accessible at any point during the procedure, if the console is turned on with the accessories plugged in prior to the start of the procedure. Users should note that depending on the scan, it may take the console seven seconds (minimum time for a room scan) to 17 seconds (required time for a body or extremity scan) to alert users to the presence or absence of a sponge. Users may also use the Situate™ in the event of an emergent or trauma situation when no manual counts can be performed.
   b) Clinicians should be able to utilize the technology at any point during the procedure, such as prior to the closure of smaller cavities or fascia within a procedure or for intermittent counts; counting and detection are performed at many points throughout a procedure, not just at the beginning and the end with a final in-count and out-count.

Minor Advantages

1. Aid in removing intentionally packed sponges:
   a) The system facilitates the management of intentionally retained sponges. Users should run a scan when a patient is brought in for a follow-up procedure, and the system will indicate the presence or absence of a sponge. Presumably, the clinical team would need to note the presence of intentionally packed sponges along with a detection code in the patient’s record.
   b) Clinicians may leave sponges within a patient intentionally as wound-packing material. The system provides a method to notify the user of the presence of an intentionally packed sponge upon follow-up to prevent leaving sponges within a patient for longer than necessary.

2. Automation of manual procedures:
   a) When using the detection mat as the primary scanning tool, users need only push a button on the console to automatically scan the patient. This removes the human, and thus more error-prone, element from the scanning process. After a 17-second scan, the console will inform clinicians whether it detected a sponge within range of the mat’s antennae.
   b) Adjunct sponge counting and detection technologies rely heavily on appropriate use for effective performance. Any features put into place to automate these processes, and thus remove the risk of operator misuse or error, help to reduce the risk of a retained surgical sponge.

Patient Experience—Not Evaluated

Patient experience is not a factor when selecting this device; the patient does not interact with it.

Interoperability—Good

The device has been evaluated against ECRI Institute’s interoperability criteria for an adjunct surgical sponge technology and found to meet all required criteria.

Notable Finding

1. Capacitive pad compatibility:
   a) The Situate™ Body Scanner Lite is not compatible with the newer Megadyne Universal capacitive electrocutaneous return electrode; however, it is compatible with older Mega Soft return electrodes (i.e., those that are 0.6 in thick). In the case of the newer Universal pad, when a patient lies on top of that and the Body Scanner Lite, his or her weight causes mat compression, which brings the metal within the capacitive pad too close to the antenna array of the Body Scanner, possibly resulting in a metal fault.
b) The Situate™ Room Scanner may be used with any version of the Megadyne capacitive pad.

c) Facilities that have elected to use the reusable Megadyne capacitive pad will need to consider which pads and which peripheral scanners to use so as not to hinder the performance of either product.

Maintenance—Good
The device has been evaluated against ECRI Institute’s maintenance criteria for an adjunct surgical sponge technology and found to meet all required criteria.

User Experience—Good
The device has been evaluated against ECRI Institute’s user experience criteria for an adjunct surgical sponge technology and found to meet all required criteria.

Cost of Ownership—Good; $53,000 (Estimated) over Five Years
The device has been evaluated against ECRI Institute’s cost of ownership criteria for an adjunct surgical sponge technology and found to meet all required criteria.

Minor Advantage
1. Existence of a liability program:
   a) Medtronic offers the Situate™ Performance Pledge, which is a risk-share and indemnity agreement. If your facility uses the system appropriately for all your cases, Medtronic will share the risk: In the event of a retained surgical sponge due to system nonperformance, participating customers are eligible for indemnity coverage for unrecovered economic loss, as well as indemnity in the event of a patient lawsuit up to $15 million. Also, customers demonstrating appropriate use get rebate opportunities on measurable reduction of x-ray reliance—specifically:
     1) If a facility that has installed the Situate™ Detection System X does not experience a 50% reduction in the percentage of intraoperative (i.e., prior to closure) x-rays intended to resolve a sponge count discrepancy during a surgical procedure, it is eligible for a one-time rebate on all its sponge purchases per 12-month period. This rebate is subject to further requirements and examination by Medtronic.

b) If appropriate use of an adjunct surgical sponge technology still results in a retained surgical sponge, the manufacturer of that device should aim to relieve hospitals of the burden of the associated patient costs. The National Quality Forum considers retained surgical items a “serious reportable event,” and the U.S. Centers for Medicare & Medicaid Services denies reimbursement to hospitals for any associated costs.

(continued on page 13)
ESTIMATING TYPICAL COST OF OWNERSHIP FOR THE MEDTRONIC SITUATE™ DETECTION SYSTEM X

The costs reported in this table represent typical quotation and purchase costs reported to ECRI Institute’s SELECTplus and PriceGuide databases, respectively. These figures are provided as a guide only and may vary significantly.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Typical Cost</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purchase Costs</strong></td>
<td></td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Capital cost</td>
<td>$8,000</td>
<td>Price of one detection system, based on average quoted price in ECRI Institute’s SELECTplus database. Includes setup, training, and all peripherals/detection accessories.</td>
</tr>
<tr>
<td>Typical accessories</td>
<td>$0</td>
<td>Included in capital cost.</td>
</tr>
<tr>
<td>Warranty</td>
<td>$0</td>
<td>Warranty included in capital cost; covers entire contract term.</td>
</tr>
<tr>
<td>Clinical staff training</td>
<td>$0</td>
<td>Included in capital cost.</td>
</tr>
<tr>
<td>Biomedical staff training</td>
<td>$0</td>
<td>Devices are not typically serviced by biomedical staff.</td>
</tr>
<tr>
<td>Infrastructure modifications</td>
<td>$0</td>
<td>Device setup does not require any infrastructure modifications.</td>
</tr>
<tr>
<td><strong>Total purchase cost</strong></td>
<td><strong>$8,000</strong></td>
<td>—</td>
</tr>
<tr>
<td><strong>Annual Operational Costs</strong></td>
<td></td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Consumables</td>
<td>$9,050/yr</td>
<td>Assumes $0.63 as the average cost of a Medtronic surgical soft good, with 25 surgical soft goods used per procedure, 560 cases per year for that OR, requiring sterile wand drapes ($2.05) for 20% of those cases. Third-party consumables cannot be used.</td>
</tr>
<tr>
<td>Expected part replacement—averaged throughout life of device</td>
<td>$0</td>
<td>Medtronic scanners have an estimated one-year life span with normal, nondestructive use. Annual replacement of peripheral scanning equipment is covered for the duration of the original contract.</td>
</tr>
<tr>
<td>Service</td>
<td>$0</td>
<td>No anticipated service requirements. The system does not require any scheduled or yearly maintenance or calibrations. It performs self-tests at power-up and self-calibrates during active scans.</td>
</tr>
<tr>
<td>Annual license fee</td>
<td>$0</td>
<td>No license required.</td>
</tr>
<tr>
<td><strong>Average annual operational cost outside warranty</strong></td>
<td><strong>$9,000</strong></td>
<td>—</td>
</tr>
<tr>
<td><strong>Estimated Total Cost of Ownership</strong></td>
<td><strong>$53,000</strong></td>
<td>Total purchase cost + (annual operational cost × estimated life)</td>
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</table>

RECALLS AND HAZARDS

The following data is based on Health Devices Alerts records from January 2015 through March 2018.

<table>
<thead>
<tr>
<th>HDA Record</th>
<th>Priority</th>
<th>Date of Last Update</th>
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<tbody>
<tr>
<td>A27967 02: Seneca Medical—Medtronic RF Surgical Systems Sterile Drapes: Sterility May Be Compromised</td>
<td>High</td>
<td>12/6/2017</td>
<td>Packaging</td>
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<tr>
<td>A27967: Medtronic—RF Surgical Systems Sterile Drapes: Sterility May Be Compromised</td>
<td>High</td>
<td>4/17/2017</td>
<td>Packaging</td>
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<td>A27967 01: Cardinal Health—Medtronic RF Surgical Systems Sterile Drapes: Sterility May Be Compromised</td>
<td>High</td>
<td>2/2/2017</td>
<td>Packaging</td>
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### DISCUSSION OF KEY MANUFACTURER CLAIMS

<table>
<thead>
<tr>
<th>Medtronic Claim</th>
<th>Category</th>
<th>ECRI Institute Perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accurately and reliably detects missing tagged sponges in seconds—whether they are in a patient or the OR.</td>
<td>Performance, Workflow</td>
<td><strong>ECRI Institute agrees.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>On average during testing, users were able to locate a single RF-tagged sponge in approximately 27 seconds using the body scanner, in 34 seconds using the room scanner, and in 46 seconds using the room scanner if the sponge was hidden elsewhere in the room.</td>
</tr>
<tr>
<td>Compared to only manual counts, when a miscount occurs, the system lessens patient exposure to anesthesia and shortens procedure time.</td>
<td>Performance</td>
<td><strong>ECRI Institute agrees.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Literature indicates that it can take 18 minutes to reconcile a count discrepancy in an OR (Williams et al. 2014). ECRI Institute believes that use of a detection technology to pinpoint the location of a missing sponge could significantly reduce this time, which in turn would lessen the time the patient is under anesthesia and shorten the overall procedure time.</td>
</tr>
<tr>
<td>Compared to only manual counts, when a miscount occurs, the system decreases the risk of infection.</td>
<td>Performance</td>
<td><strong>Unknown.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>While it is reasonable to theorize that shortening procedure time decreases the amount of time a patient is open during surgery and thus decreases their risk of infection, ECRI Institute is unaware of any clinical data correlating use of the Situate™ system with decreasing hospital infection rates.</td>
</tr>
<tr>
<td>Compared to only manual counts, when a miscount occurs, the system reduces x-ray dependency.</td>
<td>Performance</td>
<td><strong>ECRI Institute agrees.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inaba et al. (2016; not manufacturer-sponsored) used RF-tagged sponge detection in all emergent trauma and nontrauma cavitary operations over a five-year period (2,051 patients), including follow-up x-ray evaluation for all patients. Before closure, the detection system worked as intended and detected retained sponges in 11 patients, which were removed. Postclosure x-rays for all patients were negative for retained sponges (indicating that the system found all retained sponges).</td>
</tr>
<tr>
<td>The Situate™ system has 100% sensitivity and specificity.</td>
<td>Performance</td>
<td><strong>ECRI Institute agrees.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>These claims are based on two studies (Steelman and Cullen 2011, Steelman and Alasagheirin 2012) in which morbidly obese patients were scanned with the body and room scanners. In these patients, the room scanner demonstrated 100% sensitivity and specificity, and the body scanner demonstrated 98.1% sensitivity and 100% specificity. The drop in sensitivity for the body scanner was due to a number of false negatives in super morbidly obese patients, but it is important to note that in these circumstances (in which a patient’s abdomen may be out of the physical scanning range of the body scanning mat), Medtronic recommends the use of the Situate™ Room Scanner.</td>
</tr>
<tr>
<td>Real-time feedback that supports patient safety with unique features that make it a sponge detection solution for the OR: 1. Low energy radio frequency that maintains its signal strength through dense tissue, blood, and bone as well as near metal—making it a solution for in vivo detection. 2. Environmental compatibility as the system filters electrical noise in ORs and meets IEC [International Electrotechnical Commission] medical electrical equipment general requirements. 3. Extended reach that allows for detection outside the patient and across the OR with complementary scanning components.</td>
<td>Performance</td>
<td><strong>ECRI Institute agrees.</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. The system was able to detect through volunteers (to provide the presence of bone and tissue), as well as when sponges were saturated in porcine blood. ECRI Institute notes that the system did appear to work when near metal; however, when a sponge or scanner was directly in contact with metal, a metal fault was indicated on the console. 2. ECRI Institute was unable to cause a system fault when exposing the system to RF interference that may typically exist in an OR (e.g., electrosurgical unit activation, mobile phones, real-time locating systems, proximity access badges); 3. Users were able to locate RF-tagged sponges hidden in the trash and beneath the table of a simulated OR using the Situate™ Room Scanner.</td>
</tr>
<tr>
<td>Medtronic can provide published evidence of cost-effectiveness.</td>
<td>Total Cost of Ownership</td>
<td><strong>ECRI Institute agrees.</strong></td>
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<td>Williams et al. (2014; not manufacturer-sponsored) reasonably estimated implementation costs of $191,000 versus nearly $600,000 in cost savings (intraoperative x-ray and OR time) and costs avoided (assuming two retained sponges for a hospital annually: hospital stay, medical costs, settlement and legal costs). ECRI Institute notes, however, that the figure used to estimate OR costs may vary by study.</td>
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SERVICE AND MAINTENANCE
The following information is provided largely verbatim from the manufacturer.

Warranty
Standard warranty terms: The equipment is warranted for the entire term of the contract.

Inspection and Preventive Maintenance (IPM)
1. IPM frequency: N/A. The system self-calibrates at the start of every use. There is no preventive maintenance needed.
2. Downtime for IPM: N/A

In-House/Third-Party Service
1. Manufacturer supports user repair: No, if the equipment or a component in the system fails to perform, the manufacturer exchanges the device at no cost to the customer as per the contract and warranty terms.
2. Training required and typical cost: Online and on-site training with staff prior to the implementation and on-going as needed. No cost to the customer.
3. Availability of service manual: This is included with the system and also available via PDF for the customer's files.
4. Dedicated test equipment and/or software required: N/A. Software is embedded in the system.
5. Availability of manufacturer assistance: Yes, local sales and clinical representatives are available for in-service and site visits to the customer.

OEM Maintenance
1. Standard OEM service options: N/A. The equipment is warranted for the term of the contract. If the equipment or a component in the system fails to perform, the manufacturer exchanges the device at no cost to the customer.
2. Remote monitoring: N/A
3. Software upgrade and update policy: The manufacturer distinguishes between updates and upgrades. If there is a software flaw, the company will provide an update. For upgrades, the company has options for the customer to upgrade to a newer platform with additional features and benefits.

OTHER PURCHASE OPTIONS
1. Capital Purchase with lower disposables costs
2. Capital Placement with higher disposables costs

BIBLIOGRAPHY