HEALTHCARE SURFACES INSTITUTE™

AHVAP
Association of Healthcare Value Analysis Professionals

Surface disinfection incompatibility with medical devices creates potential patient risks.

Case Study:

September 2021

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ABSTRACT

A large midwestern hospital, with approximately 700 licensed beds and over 1.2 million patient encounters yearly, purchased several hundred state-of-the-art, non-invasive medical device monitoring systems. Within two years, there was visible damage to the monitoring systems, due to chemical exposure during the disinfection process.

Surface disinfectant compatibility is not a new issue to the healthcare industry. The goal of this case study is to find the problem's root causes through deep dive real-world analysis.

Methods

The following investigational methods were used by the authors in this case study:

- Evaluate and understand the selection process used by the hospital for purchasing medical devices.
- Review instructions for use (IFU) and testing data compared to the hospital's cleaning and disinfection process.
- Review test method criteria and disinfectant products used for FDA 510(k) approval and all follow-up testing.
- Calculate costs, both soft and hard costs, incurred by the hospital and the medical device company.

Authors

This case study was a joint educational collaborative effort by Healthcare Surfaces Institute (HSI) and Association of Healthcare Value Analysis Professionals (AHVAP) along with leadership of both organizations highlighted in the case study. The level of detail that we were able to achieve in this case study was due to an agreement of anonymity for both of the organizations.

Keywords

medical device, surface compatibility, infection prevention, surface disinfection compatibility, patient safety, surface validation

ABSTRACT

The hospital's Infection Prevention & Control (IP&C) guidelines to prevent patient risk were not compatible with the only validated cleaning method prescribed by the medical device manufacturer.

Results

Through the deep dive analysis and testing performed, it became evident that the root cause of the damage was chemical exposure to components by the hospital's use of disinfectants known to cause damage. Additionally, there was a complex combination of challenges and gaps, including a lack of understanding about infection prevention products and guidelines used within the hospital by the medical device company and breakdowns in communication within each organization and between both parties. These problems created potential risks to patients and high costs for both the hospital and the medical device company, which could have been avoided.

Another root cause of the problem occurred during the design phase of the monitoring device. Without guidelines or minimum testing standards of all categories of EPA-registered hospital grade disinfectants, the medical company was left to determine which cleaning agents to test for cleanability and compatibility between surface materials and disinfectants when designing their product. As we found in this case study, the hospital's Infection Prevention & Control (IP&C) guidelines to prevent patient risk were not compatible with the only validated cleaning method prescribed by the medical device manufacturer.

Conclusion

Surface disinfection compatibility challenges came to the forefront of the hospital's awareness through the discovery and analysis of damage to the monitoring devices. This case study is an example of how these challenges create risks to patient safety and present significant liability for both the healthcare facility and the manufacturer when not addressed. Due to the complexity of this problem, many facilities pay high costs for repair, replacement, and ongoing maintenance and in many cases the problem is virtually overlooked.

In this case study, the two organizations highlighted worked together to address the gaps and problems that were identified. The hospital then established a single point of contact between the medical device company and the hospital's Value Analysis staff to facilitate more effective communication.

For patient and healthcare worker safety, the hospital ultimately chose to continue using a disinfectant indicated in IP&C guidelines that is not approved for use on the monitoring devices. To address further damage caused by the disinfectant, the hospital and the medical device company collaborated to create and implement an ongoing service program to repair damaged monitor enclosures as necessary.

In early 2017, a midwestern hospital, with approximately 700 licensed beds and over 1.2 million patient encounters yearly, began purchasing monitoring systems from a medical device company. The monitoring system presented an opportunity for increased mitigation of patient risk, in addition to preventative care and on-going training as part of the hospital's safety-centered commitment to patient care and its goal towards becoming a high-reliability organization. The monitoring systems are used on patients throughout the organization, based on current practice guidelines. Each monitoring system is used in the hospital, on average, over one hundred times a year and cleaned multiple times per day.

The medical device company in this case study offering the monitoring system is ten years old with approximately 50 employees located throughout the United States. Their device is currently being used in the United States and abroad.

Disinfection testing during the development of the monitoring system

During the development phase of the monitoring system, the medical device company obtained feedback from several groups, including the hospital's clinical staff. Several successful clinical studies that improved patient outcomes were also completed at the hospital. The studies also played a major factor in the monitoring system's achievement of FDA clearance in December 2016 for use on pediatric patients.

During this time, while the medical device company and the hospital were beginning to form a solid clinical and business relationship, the medical device company did not receive recommendations relating to cleaning and disinfection of their product from additional sources. The medical device company strictly followed FDA guidelines and was not aware of additional guidelines.

The hospital's disinfection guidelines stated that quaternary ammonium-based cleaners should not be used in patient care areas for patient and healthcare worker safety.

The medical device company was not aware of this guideline.

Product approval and implementation at the hospital

There were a few notable gaps we would like to highlight here that are very common. During the product approval process, the hospital did not ask the medical device company about their testing for surface disinfection compatibility before making the purchase of the monitors. Hospital staff did not know what to ask for as it relates to the testing of disinfectants, care and maintenance, and scientific testing data. IP&C approved the use of hydrogen peroxide and bleach-based disinfectant on the device.

IP&C's recommended cleaning products guideline stated that quaternary ammonium-based cleaners should not be used in patient care areas for

patient and healthcare worker safety. The only disinfectant approved for use on the monitor enclosures by the manufacturer, however, was a quaternary ammonium-based cleaning wipe. The hospital guidelines about quaternary ammonium-based disinfectants were not discussed with the medical device company.

The only disinfectant approved for use on the monitor enclosures by the manufacturer was a quaternary ammonium-based cleaning wipe.

The hospital implemented the monitoring devices with a slow-paced, phased approach. The patient care areas with increased risk were selected for implementation first before hospital-wide rollout. The implementation process for the monitors took place from 2017 to 2018. In reviewing the events during this time, communication failures occurred between the hospital and medical device company and internally within each organization. During the analysis, it was discovered that the medical device manufacturer tried to gain access to the list of disinfectants the hospital was currently using but were not successful obtaining the information prior to the devices being implemented.

During implementation, the medical device company did not provide formal training on the cleaning and disinfection protocols for the device. An IFU and user manual for the monitoring system were provided. At one point, the hospital's environmental services team requested separate cleaning instructions with more detail, which the medical device company created for the hospital as a one-page supplemental cleaning instruction sheet.

Investigation of damaged surfaces in the monitoring systems

In early 2019, over two years after implementation of the monitoring systems began, the hospital began to notice cracks within the enclosures of the monitors. The hospital recorded damage to 37 monitors in 2019 and 53 monitors in 2020.

The medical device company was first notified of the enclosure degradation in summer of 2019 through the medical device company's customer communication process. During this time, the medical device company representatives met with the clinical specialty team as the first point of contact. The medical device company went on to meet with Clinical Engineering and Environmental Services managers from the hospital to determine how the devices were becoming damaged.

Assessing cleaning and maintenance procedures of damaged monitors

While viewing how the monitors were being cleaned and disinfected at the hospital, the medical device company representatives observed cleaning

and disinfection methods that did not follow the provided cleaning and disinfection procedure and IFU. The company representatives reviewed the cleaning and disinfection process with Environmental Services staff and management team. The Environmental Services management team said they would review the cleaning and disinfection protocol with their employees.

In addition, a list of the cleaning and disinfection agents being used at the hospital was obtained from Clinical Engineering for further analysis by the medical device company. In the fall of 2019, the medical device company hired a third-party laboratory to test this list of cleaning products on the monitor enclosures to determine the cause of the damage.

Discovery of surface disinfection incompatibility

Several meetings were held from mid-2019 into 2020 to discuss the monitor degradation issues. These meetings included staff from the medical device company and individuals from different departments in the hospital, including Value Analysis, Clinical Engineering, and Purchasing. During this process and upon reviewing the results of the laboratory testing, miscommunications were discovered regarding the cleaning recommendations from the medical device company and the cleaners approved for use in the clinical areas of the hospital.

Miscommunications were discovered regarding the cleaning recommendations from the medical device company and the cleaners approved for use in the clinical areas of the hospital.

IP&C defaulted to the protocol in place and chose to continue using the disinfectant indicated by hospital guidelines to clean the monitoring devices instead of the manufacturer-recommended disinfectant and worked with the medical device company on a program for ongoing service of the monitor systems.

Case Study Timeline of Events

2011- 2016

- Hospital and medical device company start relationship (2011)
- Two clinical studies between hospital and medical device company (2012 & 2016)
- FDA clears monitoring medical device for pediatrics (2016)

2017- 2018

- Phased implementation of monitoring device at hospital
- IFU provided
- Supplemental cleaning instructions provided to hospital environmental services, per their request
- Hospital guideline does not allow quaternary ammonium-based disinfectants to be used in patient care areas; medical device company was not aware of this guideline

2019

- **Summer -** Hospital discovers increased instances of damage to monitors
- **Fall/Winter -** Damaged monitor enclosures replaced by vendor
- Product service program initiated for monitor device
- Data gathered: cleaning agents being used, cleaning process observed
- Vendor hires third party to analyze damaged enclosures

2020

- **Summer -** Hospital designates Value Analyst as new single point of contact with medical device company
- **Fall/Winter -** Third-party surface disinfection compatibility test results provided to hospital
- Past miscommunication in fall 2019 about which cleaning agents were being used on the monitor discovered
- IP&C recommends continued use of disinfectant not approved by the manufacturer on the device, per hospital guidelines

FDA approval

As required by FDA and international regulatory bodies, reusable medical devices should be designed for easy and effective cleaning and disinfection. In the initial 510(k) process, the medical device company's goal was to meet regulatory requirements. The company followed labeling instructions detailing the recommended cleaning and disinfection process. The company also completed regulatory requirements to meet cleaning and disinfection testing requirements following AAMI TIR12 and AAMI TIR30 standards.

After completing requirements for AAMI TIR12 and AAMI TIR30, the medical device company completed the FDA submission in summer 2016. The medical device company received FDA clearance in winter 2016.

Monitoring device disinfection and cleaning instructions

The medical device company submitted the following IFU and user manual to the hospital in spring 2017 during the product implementation phase:

⚠ CAUTION:

Never allow cleaning agents to pool on the equipment as prolonged contact could cause damage.

Not waterproof: The [redacted] monitor, power supply and sensor [redacted] are not certified "water proof". Never immerse in water or other fluids.

Note: For disinfection of the sensor [redacted] make sure to clean the [redacted] thoroughly by wiping from one side to the other and then back again.

Cleaning/disinfection of the Sensor [redacted] was tested as follows:

1. Use two [redacted] Cloths to wipe the Sensor [redacted]. Wipe [redacted] thoroughly and systematically, end to end, making sure all surfaces are wet with disinfectant.
2. Repeat (1) with a second set of two [redacted] Cloths.

Figure 1.

Monitoring system's cleaning and disinfection instructions from 2017 instructions for use (IFU)

The medical device company's 2017 IFU provided the cleaning instructions and specific disinfectant product approved through testing for cleaning and disinfection (Figure 1).

Additional information for cleaning agents that were proven to not damage the product (Figure 2), shown through internal repeated cleanability testing, were provided in the user manual.

Figure 2.

Monitoring system's approved cleaning and disinfection agents from the 2017 user manual

The following agents have been tested and can be used to safely clean the [redacted] monitor, power supply, and sensor [redacted] without damaging the equipment.

Agents	[redacted] Monitor	Power Supply	Sensor [redacted]
1% Sodium hypochlorite bleach	✓*	✓*	✓
70% Isopropyl alcohol solution	✓	✓	✓
1.4% Hydrogen peroxide		✓	✓

* Bleach may cause corrosion of the USB, serial port and power socket of the [redacted] monitor. It may also cause corrosion to the power supply connector, which attaches to the monitor. These components can be cleaned with 70% Isopropyl alcohol solution.

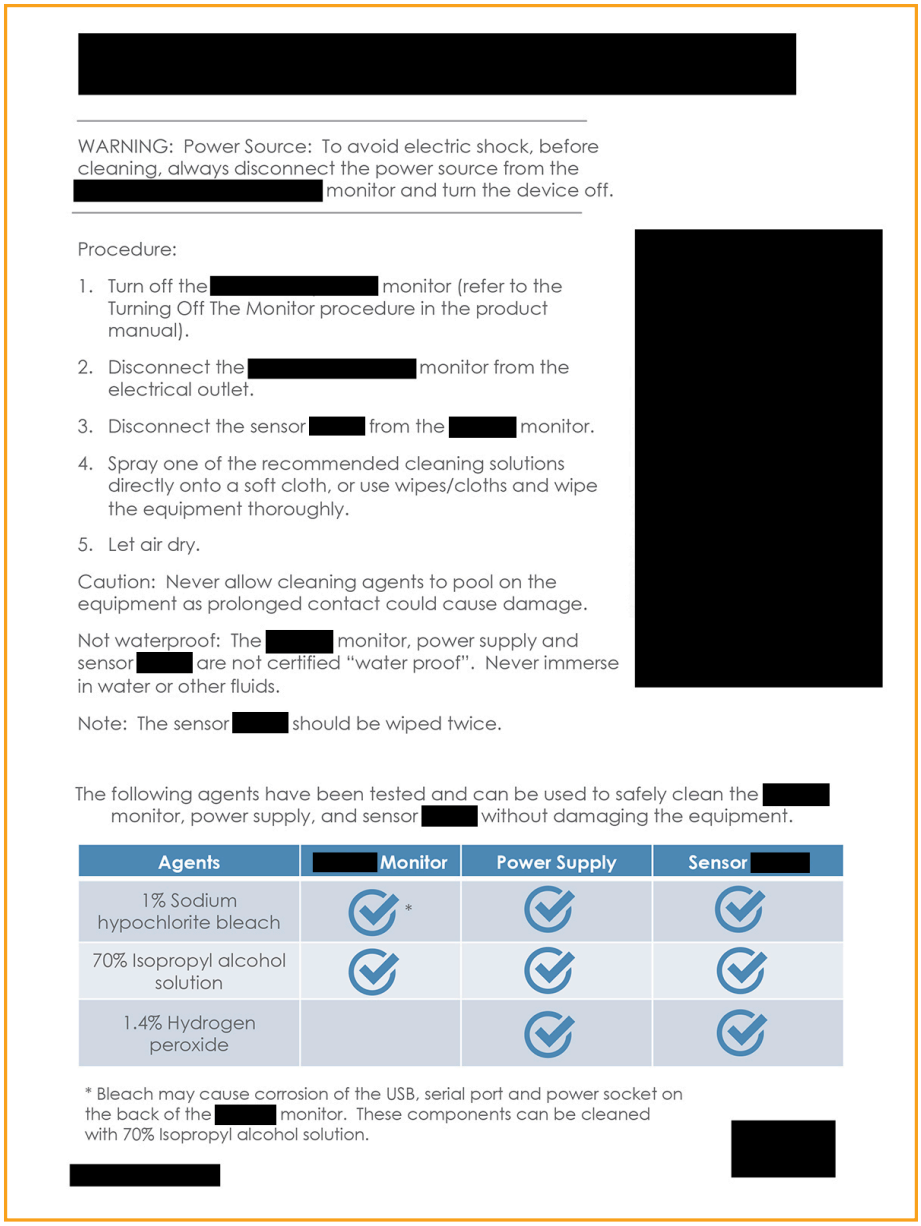
Within the user manual guidelines (Figure 2), an area of confusion was identified. It indicates the use of sodium hypochlorite bleach-based cleaners as approved for all components of the device, but the footnote included indicates that bleach may cause damage to some areas of the monitor.

Disinfection of cables

Another disinfection issue involved a decision by the hospital to use the monitoring system's reusable sensors as a single-patient-use component (used throughout the course of a patient's hospitalization and discarded after). This practice was based upon recommendations from IP&C. The hospital elected to dispose of the cable after a single use in patient care areas due to concerns about their ability to effectively disinfect this component.

Supplemental cleaning instruction page

During implementation of the monitoring systems, Environmental Services requested a supplemental cleaning instructions page and was provided the following by the medical device company.



[redacted]

WARNING: Power Source: To avoid electric shock, before cleaning, always disconnect the power source from the [redacted] monitor and turn the device off.

Procedure:

1. Turn off the [redacted] monitor (refer to the Turning Off The Monitor procedure in the product manual).
2. Disconnect the [redacted] monitor from the electrical outlet.
3. Disconnect the sensor [redacted] from the [redacted] monitor.
4. Spray one of the recommended cleaning solutions directly onto a soft cloth, or use wipes/cloths and wipe the equipment thoroughly.
5. Let air dry.

Caution: Never allow cleaning agents to pool on the equipment as prolonged contact could cause damage.

Not waterproof: The [redacted] monitor, power supply and sensor [redacted] are not certified "water proof". Never immerse in water or other fluids.

Note: The sensor [redacted] should be wiped twice.

[redacted]

The following agents have been tested and can be used to safely clean the [redacted] monitor, power supply, and sensor [redacted] without damaging the equipment.

Agents	[redacted] Monitor	Power Supply	Sensor [redacted]
1% Sodium hypochlorite bleach	✓*	✓	✓
70% Isopropyl alcohol solution	✓	✓	✓
1.4% Hydrogen peroxide		✓	✓

* Bleach may cause corrosion of the USB, serial port and power socket on the back of the [redacted] monitor. These components can be cleaned with 70% Isopropyl alcohol solution.

[redacted]

[redacted]

Figure 3.

Supplemental cleaning instructions

Testing of disinfectants

In the summer of 2019, the hospital began reporting damaged monitor enclosures to the medical device company. After discovery of monitor damage, the medical device company sent broken enclosures to a thirdparty laboratory (third-party laboratory A in this case study) to investigate the damaged enclosures for material failure. Third-party laboratory A also

tested for material failure in accordance with ASTM E573-01 (2013), ASTM E334-01 (2013), ASTM D2240-15e1, ASTM E1356, ASTM D3850, ASTM B748-90 (2016), ASTM E1508-12a.

Results indicated that the degradation of the enclosures was due to chemical composition of cleaners (high levels of potassium and phosphorus) causing brittleness and corrosion and not to manufacturability.

In the fall of 2019, the medical device company representatives were provided with a list of five cleaning and disinfection agents that were currently in use by clinical units and Environmental Services at the hospital. These five cleaning and disinfection agents were tested by third-party laboratory B for chemical analysis per ASTM E 1479-16.

Only one of the five cleaning and disinfecting cloths had been recommended by the medical device company. The other four cloths analyzed were not viable for use on the device due to high levels of potassium and/or phosphorus. Cleaners with high levels of potassium and phosphorus have never been identified as acceptable by the medical device company.

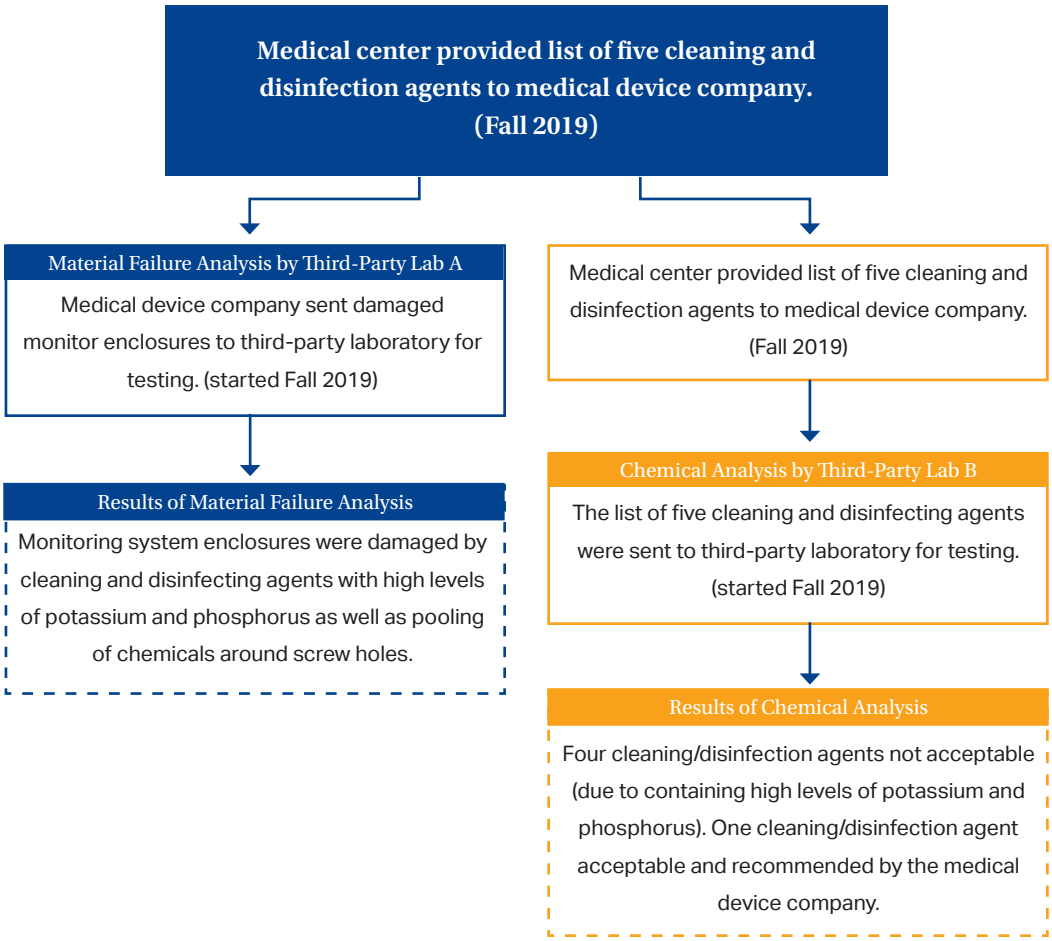


Figure 4.

Timeline of surface disinfection compatibility testing to determine cause of damage to the monitoring system enclosures

In the fall of 2019, while the third-party testing was ongoing, the medical device company employees observed the cleaning and disinfection process at the hospital. It was noticed that the cleaning and disinfection cloths were over-saturated, and the devices were stored face-down post cleaning/ disinfecting, causing fluid to pool around the screw holes when drying, which

is where the cracks in the monitor enclosures were observed. The observed methods were shared immediately with the hospital's Clinical Engineering management.

In February 2020, the medical device company shared the third-party independent testing results with Clinical Engineering and Environmental Services at the hospital.

Updated disinfection and cleaning instructions for monitoring device

The updated 2020 IFU was provided in late summer of 2020 to the hospital:

Cleaning and Disinfection of Reusable Components

Clean and disinfect the [redacted] Sensor [redacted], [redacted] Monitor, and [redacted]:

1. Use two [redacted] Cloths to wipe the component. Visually inspect the component for soil.
2. If no soil is visible, repeat Step 1 with a second set of two [redacted] wipes allowing the disinfectant to sit on the component for 2 minutes, the manufacturer's minimum recommended amount of time.

Figure 5.

Monitoring system's IFU in 2020

The medical device company-approved cleaner is one specific brand of cloth wipes with a quaternary ammonium-based disinfectant (the brand name of the cloth has been redacted in Figure 5 above).

The cloth was not approved for use at the hospital in patient care areas, per IP&C guidelines, due to safety concerns for potential emission of toxic gases if accidentally used in conjunction with other cleaners, such as bleach.

The medical device company's 2020 IFU (Figure 5) continued to recommend the use of a specific brand of quaternary ammonium-based cloth wipes to disinfect and clean the product. The discovery of this information by Value Analysis spurred a deeper discussion on the existing disinfection issues with the monitor device.

Based on the collaboration between the hospital and the medical device company and discovery of the damage of medical device monitor due to surface disinfectant incompatibility, this section discusses the outcomes, related costs, and their impact.

Outcomes

In the fall of 2019, the medical device company replaced, free of charge, all of the damaged monitoring system enclosures. This allowed the medical device company to maintain a good relationship with the hospital. It also allowed the hospital to have enough working product to meet their daily patient needs.

When copies of the third-party laboratory A mechanical failure report and laboratory B chemical analysis report were provided to the Value Analysis team in the fall of 2020, it was discovered that bleach-based cleaning agents were the cause of the damage.

Bleach-based cleaning agents were determined to be the cause of the damage to the monitor enclosures.

After a safety and risk assessment, the hospital continues to use bleach-based disinfection products not approved for use on the device.

It was also discovered that, during a meeting in the fall of 2019, an internal miscommunication at the hospital about the cleaning agents approved for use in their facilities resulted in the confusion between the manufacturer's cleaner recommendations in the IFU and the bleach-based disinfectant that was actually being used at the hospital to clean the monitor devices.

The hospital's discovery that bleach-based cleaners caused damage to the device highlighted the necessity to address the cleaning and disinfection process on the current device. After a risk assessment, the hospital continues to use bleach-based cleaning and disinfection products that are not approved for use on the device due to IP&C guidelines disallowing the use of quaternary ammonium-based cleaners in patient care areas for safety reasons.

To mitigate the damage of the monitors, the medical device company implemented a service program with the hospital beginning in the fall of 2019, which allows the hospital to purchase subassemblies including enclosures as needed from the medical device company. The service program is still in place at the time of this writing. The medical device company trains the hospital's biomedical technicians to troubleshoot, replace subassemblies, and conduct functional testing to ensure the device is working properly after servicing. The hospital reeducated Environmental Services in the proper cleaning procedures to prevent excess bleach-based cleaning product from pooling on the device after cleaning and storage, which helps slow down the damage to the monitor enclosure.

Cost Analysis and Impact

In addressing the issue of the damaged monitor enclosures and the hospital's decision to dispose of reusable sensors, a total of 159.5 hours were spent on problem resolution, with hospital staff accounting for 112.5 hours and 47 hours from the medical device company.

The following costs were incurred during the investigation of damage to the monitors:

Case Study Costs[1] – Medical Device Company	
CATEGORY/SUBCATEGORY	**COSTS**
Testing Costs	
Cleaning/disinfection validation by 3rd party testing lab – one agent[2]	$8,000
Repeated cleanability internal testing lab – one agent	$1,500
Monitors/Enclosures Related Costs	
One-time replacement to hospital due to disinfectant agent damage	$75,000
Third-party testing to determine cause of damage	$5,000
IFU Change – to be based on additional cleaning/disinfectant agent[3]	
Change impact assessment results determine if change in IFU is warranted	$3,000
Administrative labor costs, development of actions for regulatory compliance	$47,500
Estimated total	**$140,000**

1. All work prior to fall of 2019 was associated with normal costs in the process of gaining FDA clearance for a medical device and therefore was not included in this case study
2. Only one agent required testing; all other agents in use by hospital were known not to be compatible
3. IFU change not determined at time of publication due to decrease in wipe availability

Figure 6.

Costs incurred by the medical device company for additional testing, device replacement, and changes to IFU

Case Study Costs – Hospital	
CATEGORY/SUBCATEGORY	**COSTS**
Purchases	
Monitors/enclosures/parts/MC CE time – beyond initial free replacements[1]	$53,504
Reusable cables[2,3]	$4,796,800
Administrative Costs – estimate based on time and type of activities	
Evaluation planning, clinical engineering cable issue review, supply chain logistics, recycling/reprocess space and process planning, report reviews, in-service education	$3,375
Estimated costs beyond expected	**$4,853,679**

1. 5/24/19 to 3/31/21 under maintenance agreement
2. Hospital developed guideline to handle reusable cables as disposable cables
3. 2017–2/29/21 estimated cost difference based on actual use as a disposable cable vs. expected use as reusable cable

Figure 7.

Costs incurred by the hospital due to device damage and cable disposal

Out of the five cleaning agents provided to the medical device company by the hospital, only one cleaning agent was tested for cleaning validation, disinfection validation, and repeated cleanability. Due to the chemical composition of the cleaning agents, the four remaining cloths were not tested since it was known they wouldn't pass initial product durability testing. To complete cleaning and disinfection validation testing and repeated cleanability testing with a third-party laboratory, the total cost for one cleaning agent on one component of the monitoring system (e.g., the monitor in this case study) was $9,500.

It is worthwhile to consider the cost of future testing for the medical device company. Hospitals use a variety of cleaning and disinfection agents and these continue to change over time. Therefore, the overall ongoing cost for testing can become significant for manufacturers, especially for small organizations.

For instance, due to product shortages from the COVID-19 pandemic and updated cleaning and disinfection protocols, the hospital began using three additional cleaning and disinfection cloths and they recommended that the medical device company consider testing these cloths. The additional three cleaning and disinfection cloths in use at the hospital during the pandemic were not included in the original list of five cloths provided by the hospital in 2019.

If a third-party laboratory tests three proprietary cleaning and disinfection agents on both components of the monitoring system, the approximate cost totals $57,000 (based on testing costs outlined in Figure 6).

At the time of this writing, suppliers are limiting the medical device company from obtaining these cleaning and disinfection cloths amidst the COVID-19 pandemic shortages. The medical device company is unable to move forward with additional testing until they can obtain these cleaning and disinfection cloths, perform testing on these cloths, and determine whether these cloths can be approved for use. Without this testing, the hospital must choose to either degrade their product and rely on a service program to maintain safety, or not use the devices that improve patient safety.

The overall ongoing cost for surface disinfection compatibility testing and IFU updates can become significant for manufacturers.

The cost of changing the medical device's IFU is also substantial. The test reports for a cleaning and disinfecting agent that has passed the required testing must be submitted to regulatory bodies to support a device's FDA clearance or approval. If additional cleaning and disinfecting agents are tested and also pass, the medical device company must perform a change impact assessment and may need to notify regulatory agencies of such a change in order to be able to update their IFU, make the applicable change to the IFU, and then notify their customers. All of these additional steps incur costs (see Figure 6 above).

If the additional disinfecting agents eventually pass FDA approval, there are also challenges in notifying the appropriate contact at each hospital to ensure proper communication dissemination. A special 510(k) submission involves up to a 30-day review by the FDA. The user manual change may take 4-5 weeks, which includes the customer ordering and the required shipping time.

CONCLUSIONS

Healthcare facilities are focused on patient safety and mitigating the spread of microbes that cause deadly infections. **A focus on effective cleaning and disinfection strategies can only be successful if surfaces and products are not damaged by the disinfectants that must be used to destroy specific microbes.**

The issues outlined in this case study are not unique to this hospital and medical device company. Surface disinfection compatibility is a critical issue in every healthcare facility, and it is an issue that is virtually overlooked.

In this case study, we saw that:

- The medical device company had no guidance or minimum standards to reference for disinfectant compatibility/durability testing.
- The hospital did not evaluate surface disinfection compatibility/durability as part of their purchasing process because Value Analysis was not part of the review.
- The medical device company lacked a single point of contact to coordinate the product implementation within the hospital.
- No formal training on cleaning and disinfection of the medical device occurred.

This case study illuminates how **gaps in surface disinfection compatibility testing, communication, and collaboration** can result in damaged surfaces that can potentially harbor infectious microbes and can no longer be effectively cleaned and disinfected, thus creating increased risk to patients.

The problem has many aspects, beginning with the selection of surface materials being used in the design of medical devices and ending with testing an assembled product or environment that includes more than one surface material on any one product. To reduce patient risk, the question that must be answered for every surface material present in a healthcare environment is:

"Can this product be cleaned and disinfected with the standard disinfectants being used in this healthcare facility without damaging the surface materials?"

Testing surface disinfection compatibility

There are many different standards organizations and any number of test methods to choose from. However, there are currently no recommendations, minimum standards, or requirements for validating surface disinfection compatibility on surface materials and finished products. In this case study, we learned that only one disinfectant cloth was tested to achieve FDA 510(k) clearance. This does not meet the needs most healthcare facilities have, including the hospital featured in this case study. Several problems were revealed:

1. The cleaning product tested and approved by the manufacturer is not disinfecting agent used by the hospital for patient and healthcare worker safety reasons.

2. In order to address the issue of degradation to the monitoring device, the medical device company had to test their product for compatibility with other disinfectants once they received the list from the hospital.

3. Testing can become cost-prohibitive for product manufacturers.
    a. There are hundreds of proprietary disinfectants and healthcare facilities typically choose one or two disinfectant companies and work with them.

    b. While only one test was initially performed, since the monitoring system has two components (the monitor and a sensor), the cost to test both components for surface disinfectant compatibility of only five cleaning and disinfection agents is almost $100,000 (based on the costs outlined in Figure 6 in the Discussion section of this case study).

Meeting surface disinfection needs within the healthcare environment requires a new approach

Within the hospital setting, there are thousands of medical devices and products installed and used. Currently, manufacturers provide care and maintenance requirements that specify which disinfectants are approved to use. In this case study, the disinfectant specified was one specific brand of disinfectant wipe. This recommendation requires the hospital to purchase this cleaning product and use it for this one device. Now expand this scenario beyond this one device and consider the IFUs for all products used in the hospital and the result is ultimately hundreds of different products required by manufacturers for cleaning and disinfection.

Damaged surfaces develop microbial reservoirs where pathogens can proliferate and avoid disinfection agents, increasing risk to patients and healthcare workers.

This is one of the major gaps – medical device companies are making recommendations without understanding infection prevention policy and the standard disinfection products that are being used within a hospital. In this case study, this is illustrated by the fact that the hospital was not able to disinfect the monitoring device product following its own infection prevention guidelines without dangerously degrading its surface material.

Minimum standards for testing are needed

The design and development of the monitoring device cost tens of millions of dollars and years to launch. Despite this investment, the first major implementation of the device resulted in a situation where additional costs were incurred on both sides and risk to patient and healthcare worker safety increased due to surface disinfection incompatibility. Damage to surfaces creates microbial reservoirs for pathogens to proliferate, increasing risk. Breakdown of surface materials can affect the functionality of medical devices, presenting additional risks to patients. The costs of these risks can be mitigated by ensuring that cleaning and disinfection can be effectively achieved in real-world healthcare scenarios before products are released.

The development of a minimum standard for testing for surface disinfection compatibility should be based on surface material categories using an analog chemistry of categories of disinfectants. Minimum testing requirements that are used consistently provides foundational data and information of the effect each category of disinfectant may have on any given surface. This would allow device manufacturers to comply with testing without serious financial hardship and provide the purchaser with information about all categories of disinfectants that may be used by the medical facility. Most importantly, minimum standards for testing gives the decision-making power regarding which disinfectants a facility uses back to the medical facility, where it should be.

The future cost to maintain and keep medical devices functioning safely could also be greatly reduced if there were a standard cleaning and disinfecting protocol available to medical device manufacturers during the design phase of their devices. It would be beneficial for all parties to come together to develop a standard that balances the needs between infection prevention and device component development.

Communication

Breakdowns in communication were recognized as a primary contributor to the problem discussed in this case study. It is critical to understand the proper communication protocols between hospitals and medical device companies when changes occur that may impact outcomes. Communication challenges between the hospital and medical device company occurred in several areas.

Hospital decisions made in the interest of patient and healthcare worker safety regarding disinfection protocols often conflict with manufacturer IFUs.

Hospital guideline decisions made in the interest of patient and healthcare worker safety regarding disinfection protocols often conflict with manufacturer IFUs. In this case study, hospital guidelines had a direct effect on the issue of degradation of the monitor device that continued for over a year due to a mutual lack of communication about the issue between the hospital and the medical device company.

From 2011 to 2019, the medical device company collaborated with the hospital's clinical specialty team, which took lead for the medical device studies and for product implementation. The company also collaborated with other various clinical units during implementation, and with Clinical Engineering for workflow with returned products as well as cleaning and disinfecting.

In February 2020, the medical device company was asked to work through the Value Analysis program within Supply Chain in an effort to streamline communications. Value Analysis implemented process improvements that over time improved collaboration with clinical staff and Supply Chain. Once the medical device company began communicating through a single point of contact within the hospital, there have been considerable communication improvements, including those regarding cleaning and disinfection processes.

Communication through a single point of contact provides medical suppliers a primary source to help with navigation and information gathering throughout healthcare organizations. This enables clinicians to collaborate and contribute their knowledge to important issues while also decreasing potential for disruptions to their focus on patient care. Most importantly, a single point of contact is beneficial for all parties when enacting changes that would impact processes or devices.

Additionally, there are several communication opportunities for medical device manufacturers to prevent potential surface disinfection compatibility issues. A comprehensive training program for cleaning and disinfection of the devices following purchase and before delivery would provide information to the hospital about the risks associated with using nonapproved or untested disinfectants.

Regarding IFU documentation, hospitals have a need for quick access to cleaning and disinfection information that staff can quickly reference while on the job. This was demonstrated in this case study in the hospital's request to the medical device company for a supplemental cleaning guide for Environmental Services. There is a need to provide comprehensive IFUs using a consistent template with consistent information that healthcare workers can easily reference and use in real-life situations.

Collaboration

We have noted that medical suppliers benefit from having coordinated access to clinical staff for feedback on successes and potential device improvements. If this feedback loop were to be discontinued, the medical device company will be at a disadvantage when developing future product enhancements. This includes the ability to obtain critical information on cleaning and disinfection agents and processes.

Successfully addressing this issue requires more effective collaboration among a diverse group of healthcare professionals, manufacturers, and thought leaders.

As we saw in this case study, the hospital's evaluation and selection process prior to purchasing of the monitoring devices would have benefited from the active participation of a diverse group of healthcare experts who have responsibility for cleaning and disinfection (including, but not limited to, environmental services, infection prevention, biomedical, and nursing professionals). The fact is, often hospital staff do not know what data and information to ask for, particularly information related to the testing of disinfectants and care/maintenance. Without that data from the people who share responsibility for cleaning and disinfecting, healthcare facilities cannot answer critical questions about surface disinfection compatibility.

Successfully addressing this overlooked issue can only be achieved through effective collaboration among a diverse group of healthcare professionals, manufacturers, and thought leaders. Through collaboration, medical device manufacturers will have a greater understanding of what happens in a healthcare setting and therefore begin to address surface disinfection compatibility more thoroughly. This can be accomplished not just through improved testing and communication, but also during product design by selecting materials that support effective cleaning and disinfection. A relationship between infection prevention and control, medical device development teams, and environmental services teams to better understand the obstacles faced in reducing infection rates while developing product is also imperative.

Once all parties understand the challenges that (1) environmental services teams face with cleaning and disinfection challenges, (2) infection preventionists experience working to mitigate the spread of HAIs, (3) hospital operations and biomedical teams undertake in maintaining medical devices and reducing repair and replacement costs, and (4) medical device companies encounter with developing products, true collaboration will occur.

Key Findings and Recommendations

The Healthcare Surfaces Institute has created an effective collaboration platform that brings together a diverse group of healthcare professionals, manufacturers, scientists, academia, and patient advocates specifically to address a foundational issue that is mostly overlooked.

In response to the findings in this case study, we identified the following needs:

- Develop a minimum standard for surface disinfectant compatibility that tests categories of disinfectants instead of proprietary products.
- Designate a single point of contact within a healthcare organization to facilitate collaboration between manufacturers and healthcare professionals, and to communicate important matters to all parties.
- Establish a greater understanding of real-life challenges healthcare professionals face when working to mitigate the spread of infections within the healthcare setting.
- Build an awareness around the selection of surface materials during the design phase by medical device manufacturers based on surface disinfection compatibility. Raw materials must meet minimum standard requirements.
- Create guidelines for product review before purchase and checklists for healthcare selection teams within the healthcare setting that provide them with needed information for product value analysis professionals.
- Medical device suppliers should provide maintenance training and cleaning and disinfection review for healthcare professionals.

The goal of this case study is to shed light on the global healthccare issue of surface disinfection incompatibility. The participants featured in this case study have provided valuable information regarding this problem and we thank them for their transparency about the events that occurred and their commitment to increasing patient and healthcare worker safety.

This case study was a joint educational collaborative effort by Healthcare Surfaces Institute (HSI) and Association of Healthcare Value Analysis Professionals (AHVAP) along with leadership of both organizations highlighted in the case study.

About Healthcare Surfaces Institute

The Healthcare Surfaces Institute (HSI) is the only organization focused on reducing preventable infections and deaths by interrupting the transmission of microbes via contaminated surfaces in the healthcare environment. With a collaboration across healthcare, science, industry, and regulatory agencies, HSI helps increase safety for patients and workers by working to create protocols and develop solutions to bring about the change necessary to address the rampant spread of infection and illness throughout the healthcare system via surfaces.

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About AHVAP

(AHVAP) is an organization of nurses and clinical professionals whose expertise bridges the gap between clinical staff and the supply chain process. Using evidence-based data, professional experience, and an understanding of the cost/quality continuum, these professional Value Analysis facilitators guide the clinical staff in the product selection process and assist with the resolution of quality concerns.

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