Abstract
It is well known that the common goal of all central sterile supply departments (CSSDs) is to prevent healthcare-associated infections. Such infections entail high costs to society, not only economic but also social. Therefore, delivering safe medical devices and guaranteeing a positive contribution to the control of healthcare-associated infections form the main responsibilities of a CSSD. The monitoring of the effectiveness of medical device cleaning processes is highly recommended. However, ensuring a flawless environment for the preparation, assembly, and packaging of medical devices and clean handling of sterilized items is crucial to achieving the goal of safe medical devices. This study analyzed not only the cleanliness of surgical instruments but also two critical aspects of the surrounding environment: the cleanliness of work surfaces and the cleanliness of workers’ hands. To evaluate the cleanliness of surgical instruments, two methods were used: the adenosine triphosphate (ATP) detection method and a residual protein test. It was not the intention of this work to make an exhaustive comparison of these methods. The ATP bioluminescence method was also used for monitoring the cleanliness of work surfaces and workers’ hands. The aims of this study were to establish the most suitable method of evaluating the cleanliness of reusable medical devices in the CSSD and to assess the quality of the environment. Assessing the surgical instruments, work surfaces, and staff hands for cleanliness allowed the identification of possible contamination sources and to correct them by improving cleaning/disinfection protocols. Furthermore, the use of ATP monitoring tests of workers’ hands highlighted the importance of staff compliance with good practice guidelines. Thus, these results have a positive impact on the CSSD quality system and, consequently, on patient safety.

Introduction
Infections associated with healthcare entail high costs to society, not only economic but also social.1–4 Striving for quality improvement in clinical and surgical procedures involves enhancing the quality and safety of medical devices. It is generally known that medical devices cannot be effectively sterilized without full organic matter removal and elimination of microbial load before the sterilization process.5–7 In a central sterile supply department (CSSD), testing medical devices for organic residues after they are cleaned and before they undergo sterilization is highly recommended. Many of the suggested methods for assessing cleaning efficacy are complex and difficult to use in a CSSD. They require chemicals, special equipment, and technical knowledge, and the results are not immediate.8

Taking the above into account, the author decided to determine the efficacy of the cleaning methods for surgical instruments...
using two methods: ATP bioluminescent detection and a commercial residual protein test. Both methods are relatively easy to perform in a CSSD and the test results, after a swab is taken, are available in approximately 10 seconds in the case of the ATP test, and 15 minutes in the case of the commercial residual protein test. Although it is known that the two methods do not detect exactly the same organic residues, both methods can be used as indicators of the cleanliness of the reusable medical devices in the CSSD.\(^9\)\(^{-11}\) The challenge was to establish the most suitable method for evaluating the cleanliness of reusable medical devices.

To evaluate environmental quality, two critical points were assessed: the cleanliness of work surfaces and the cleanliness of workers’ hands. Based on what the author found in the literature, the ATP bioluminescent method was used to monitor both critical points, because it is widely used in food industry hygiene control\(^12\)\(^{-14}\) and lately in the healthcare system.\(^15\)\(^{-18}\)

In addition to the need for clean reusable medical devices, flawless environmental quality in the preparation, assembly, and packaging of medical devices prior to sterilization and clean manipulation of sterilized items is crucial to achieving safe medical devices.\(^19\)\(^{-22}\)

This study aimed to find a quick and easy way to make a precise evaluation of the cleanliness status of a CSSD in terms of medical devices and chosen critical points. Improving environmental quality in the assembly and packaging of medical devices by reducing the detected relative light unit (RLU) levels to an acceptable predefined minimum was also a goal of this study.

**Methods**

**Evaluation of Surgical Instrument Cleaning Effectiveness**

Two methods were used for the evaluation of the effectiveness of cleaning of surgical instruments: a commercial test for testing residual protein and commercial swabs for the ATP detection (see Figure 1). These methods are only two of various possible test methods (e.g., microbial recovery).\(^23\)\(^{-25}\) The protein test was used because it is one of the most frequently used to evaluate surgical instrument cleanliness in our country. The ATP method was used because the author wanted to assess whether this quantitative and easy-to-perform method would be suitable for use in the CSSD. Both methods are described as easy and fast to use, and they were recently proposed as an alternative to microbial methods for monitoring the effectiveness of cleaning of surgical instruments.\(^9\)\(^{,26\)\(^{-29}\) The aim of this study was not to make an exhaustive comparison of the methods. The goal was to establish the best method to use in the CSSD, taking into account the working protocols used, the ease of execution, the speed of obtaining results, and reproducibility.

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**Figure 1.** Monitoring the effectiveness of cleaning: schematic description of the analysis
Eighty surgical instruments from surgical procedure trays usually reprocessed in our service were assessed. In this study, samples of laparoscopic instruments, motors, or other complex surgical instruments were not assessed. The instruments were reprocessed within 6 hours of their use in surgery (but preferably immediately after surgery), in order to avoid biased results because of some limitations of the ATP method,\textsuperscript{30,31} such as the reduction over time of dead cells. The purpose at this stage was to choose which method to use for monitoring instrument cleanliness. Forty instruments were assessed after reprocessing in an automatic washer-disinfector (W-D); the other 40 were assessed after manual cleaning. All of the analyzed instruments looked clean on visual inspection. Swabs were taken from each surgical instrument in the most difficult-to-clean areas. For all 80 instruments, the author also obtained a sample for residual protein testing.

**AATP Bioluminescence Assay**

When ATP is combined with the enzyme luciferase, a reaction takes place resulting in the production of light, which is measured by a luminometer. The readings are expressed in RLU. ATP bioluminescence assays were performed with the Lumitester PD, according to the manufacturer’s instructions. Based on the author’s preliminary experiments and a review of the literature, the following benchmark values for ATP assessment of the surgical instruments were established: ≤15 RLU, pass range; 16 to 30 RLU, caution range; and >30 RLU, fail range.\textsuperscript{26,28,29}

**Residual Protein Test**

Residual protein tests were performed using the Clean-Trace protein test. This is a colorimetric, semiquantitative method based on the Biuret reaction. The manufacturer claims that this test has a sensitivity equivalent to the ninhydrin test specified in EN ISO 15883-1.\textsuperscript{4} It detects as little as 50 µg of protein on surfaces, according to the manufacturer. The test provides an estimate of the surface protein residues by means of a color change. A green result means that the instrument tested is sufficiently clean and ready for the sterilization production.
process. If the color is grey or purple, it means that there is protein remaining on the surgical instrument and recleaning should take place.

**Evaluation of the Cleanliness of Two Critical Points in the CSSD**

For one month in the packaging area and always at the beginning of the working day, two chosen critical points were assessed: work surfaces and workers’ hands.

The ATP bioluminescence assay was used to monitor the cleanliness of the work surfaces. The benchmarks used for this study were the same as those proposed by the manufacturer of the luminometer for the cleanliness of stainless steel surfaces: <200 RLU, pass range; 200 to 400 RLU, caution range; and >400 RLU, fail range.

The same method was used for evaluation of workers’ hands. The benchmarks used were the ones proposed by the luminometer manufacturer: <1,500 RLU, pass range; 1,500 to 3,000 RLU, caution range; and >3,000 RLU, fail range.

**Results and Discussion**

**Evaluation of Surgical Instrument Cleaning Effectiveness**

The ATP bioluminescence detection method indicated that 9.39% of the instruments manually reprocessed and 5.69% of those reprocessed in a W-D were not acceptably cleaned (see Figure 2), whereas 21% and 15% of the manually or W-D reprocessed instruments, respectively, were found to be in the caution zone. The majority of the analyzed instruments were found to be in an acceptable range of RLU values. For those found in the not acceptable range, cleaning was repeated and the cleaning protocol reviewed.

All 80 surgical instruments were also assessed for the presence of residual protein. All surgical instruments that obtained values of ≤30 RLU were also indicated by the readings of protein residues as clean (see Figure 3).

Similar results from both tests were obtained in relation to the possibility of checking the cleanliness of instruments. That is, both methods detected the “not visible to the naked eye” bioburden. However, some instruments that showed ATP values of 30 RLU or greater were indicated as clean by the protein residuals test or, in some cases, it was difficult to determine the precise color of the tests results, green or grey. The subjectivity of the color interpretation might lead one worker to assess an instrument as clean and others to assess it as not clean. The fact is that a color scale is highly subjective.

With the ATP bioluminescent method, numeric values can be obtained and the benchmark values will indicate almost immediately, in an objective way, whether the instrument is clean or needs further treatment. In addition, it is easy to train the staff to take a swab and use the luminometer, rather than take a swab and put it in an incubator for 15 minutes, as is the case with the protein test. Another problem is that the operator often forgets the swab in the incubator for half an hour or more, and the results obtained are not reliable. These observations suggest that the ATP method is more useful in the CSSD because of its practicality.

![Figure 2. Results of ATP monitoring of surgical instrument cleanliness after manual cleaning and after cleaning in a washer-disinfector (W-D)](image_url)
Evaluation of the Cleanliness of Two Critical Points in the CSSD

A clean environment for preparation, assembly, and packaging is essential for delivery of safe medical devices. Thus, it was decided to investigate two critical points: work surfaces and workers’ hands. The goal is to reduce the bioburden on instruments prior to the sterilization process.

Mainly because of the speed of the analysis, the ATP test is currently used in the food industry to monitor environmental cleanliness. In recent years, it has been used in hospital settings to monitor the effectiveness of cleaning practices. In this study, the swabs from the work surfaces were collected after the daily cleaning of work surfaces using the existing institutional protocol for surface cleaning.

Based on the literature, the author decided to use the ATP method to monitor the cleanliness of workers’ hands, mostly due to the speed of the results. ATP is the energy molecule found in all living cells, including bacteria, skin cells, and sebaceous glands. Consequently, ATP testing proved difficult for assessing the state of cleanliness of the hands, because it quantifies both the levels of ATP naturally occurring in the skin and the levels of ATP from other cells. Furthermore, there is no universal baseline for ATP values after handwashing because they vary from individual to individual. Still, it is a good method for evaluating the efficacy of hand hygiene after washing and before starting the daily work, mainly because of the educational effect on employees. When people see high RLU values in the display of the luminometer, they are bewildered and frightened and realize that they have to wash their hands properly.

The author thinks that the educational effect is one of the main advantages of this method over other methods used to test whether workers have washed their hands properly; in addition, there is the ease of execution. That the hands that will manipulate cleaned/disinfected items are clean is critical information for a CSSD. All the staff working at the sterilization service had training in how to wash their hands correctly according to World Health Organization guidelines, and they are instructed to do so every day before starting to work. A correct handwashing procedure should remove any bacteria present, skin cells, sebaceous secretions, sweat, and other organic material present on the hands. The soap provided by the hospital is a basic liquid soap (with a pH value of 5.5), and the hands are dried with a single-use paper towel.

Figure 3. Results of residual protein testing (left) vs. ATP testing (right) of the cleanliness of surgical instruments after manual cleaning and after cleaning in a washer-disinfector (W-D)
The ATP test showed that 95% of the work surfaces were in the *acceptable* range of RLU range values, 5% were in the *tolerable* range, and 0% were *not acceptable* (Figure 4). The average value was 356 RLU.

However, when measuring RLU values for the workers’ hands, we found that 35% showed *acceptable* values, 60% showed *tolerable* RLU levels, and 5% were *not acceptable* (Figure 5). The average value was 5,916 RLU.

The results for work surfaces indicated that they had been satisfactorily cleaned, despite the small percentage of results found in the *tolerable* range. In an attempt to improve the results, the workers were observed for a week to see how they prepared the cleaning/disinfection solutions and how they performed the cleaning/disinfection protocol. The problem was not with the cleaning/disinfection protocol, nor with the preparation of the cleaning/disinfection solutions. The problem was that workers wanted to clean as quickly as possible so that they could start to work as soon as possible, so they were missing some areas. Thus, the answer was to educate the staff by reminding them that, more than speed, we needed the surfaces properly cleaned. After training of the staff (Phase II in Table 1), swabs taken from the surfaces were all in the *acceptable* range, with an average value of 102 RLU.

The results of the Phase I testing of workers’ hands (35% *acceptable* and 5% *not acceptable* values, as shown in Table 1) showed us that there was a problem with handwashing. The strategy used to overcome the problem was the same as that used in the case of work surfaces, which was to educate the staff by retraining in handwashing. However, in this case, the training was not enough, since swabs taken after training showed an average value of 1,950 RLU (Phase II in Table 1). Therefore, it was necessary to raise employee awareness of the need to always wash their hands before starting work. This strategy allowed us to obtain an average value of 671 RLU (Phase III in Table 1).

### Table 1. Evaluation of the cleanliness of workers’ hands and work surfaces using ATP bioluminescence assay

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<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
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<tbody>
<tr>
<td>ATP Detection (Workers hands)</td>
<td>5616 RLU</td>
<td>1950 RLU</td>
<td>671 RLU</td>
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<tr>
<td><em>&lt; 1500 RLU Pass Range; &gt; 3000 Fail Range</em></td>
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<tr>
<td>ATP Detection (Stands)</td>
<td>356 RLU</td>
<td>102 RLU</td>
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<tr>
<td><em>&lt; 200 RLU Pass Range; &gt; 400 Fail Range</em></td>
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<tr>
<td>ATP Detection (Equipment)</td>
<td>6 RLU</td>
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<tr>
<td><em>≤ 15 RLU Pass Range; &gt; 30 RLU Fail Range</em></td>
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**Conclusion**

Using the ATP method is a good way to quickly evaluate the cleaning process in a CSSD. The ATP method is versatile because it allows testing not only of surgical instruments, but also of the surrounding environment of assembly and packaging prior to sterilization.
In particular, we can analyze work surfaces and workers’ hands, two critical points in the CSSD cleaning process. Fast and accurate results are needed in a CSSD, and the possibility of using one single test to analyze key points justifies the use of this method as a good choice. In addition, using a single, easy-to-perform quantitative method streamlines processes and might even reduce costs, which are other important positive aspects of the ATP method.

Moreover, using ATP to monitor hand hygiene serves an educational purpose. When high RLU values were detected, the problem could be immediately solved by repeating the handwashing process. Furthermore, it allows us to change habits of poor hygiene, contributing to the reduction of bioburden in surgical instruments prior to sterilization. In general, the characteristics of the ATP detection method allowed timely assessment of the effectiveness of the cleaning protocol, leading to protocol updates and, thus, to the elimination of potential failures in the cleaning process.

In conclusion, the results obtained using the ATP method for monitoring the effectiveness of cleaning of medical devices, workers’ hands, and work surfaces can be applied to the improvement of cleaning/disinfection protocols. Random cleanliness assessment by the ATP bioluminescence method in a CSSD will increase staff awareness of the importance of compliance with good practice guidelines, thus improving the quality of work done in the department. Hence, such testing has a positive impact on the CSSD quality system and, consequently, on the prevention of healthcare-associated infections and on the enhancement of patient safety.

Further studies should be conducted in the near future to evaluate the need to extend the monitoring of hand hygiene to all workers involved in the reprocessing cycle until the sterilized surgical trays enter the operating room.

References


