

Saving Money and Saving Lives, One Mask at a Time

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In 2014, Don St. Peter was diagnosed with sleep apnea. An apparently healthy and vital man in his early 50s, his only symptom was snoring, and he didn't seem to be at any particular risk of cardiac complications. Like many people, Mr. St. Peter found the prescribed CPAP mask uncomfortable and intrusive, and he abandoned it a few months after he was diagnosed. A year later, Mr. St. Peter had a heart attack and died in his sleep.

Unfortunately, this story is relatively common. What is not common is the impact it had on Mr. St. Peter's daughter, Kristina Weaver. Kristina was a sleep technologist at the time, and she was the one who had performed the sleep study on her dad. Kristina knew she had an ability to change the health trajectory of health for other people's parents. To honor her dad's memory, Kristina spearheaded the Sleep Mask Fit Clinic at the Sleep Lab at Parrish Medical Center in Cocoa, FL, in order to make it easier for patients to comply with wearing their prescribed sleep masks. The Fit Clinic was inaugurated in 2015, shortly after her father's death.

At that time, reusable sleep masks were the default option for patients in many centers, and storing an inventory of multiple sizes, brands and configurations of masks was not unusual. Kristina and her colleagues instituted the daytime Fit Clinic so that patients who had been prescribed a CPAP mask could evaluate as many options as necessary to find one they could wear faithfully. The staff would clean and low level disinfect the masks and accessories after each trial fitting, and re-use them again and again.

Not long before Mr. St. Peter died, the Joint Commission decreed that reusable devices used in sleep centers were semicritical devices and could no longer be cleaned and disinfected with a low-level disinfectant, even if it was EPA approved. Going forward, referencing the Spaulding Classification for risk and level of reprocessing, reusable devices would need to be high-level disinfected as an infection prevention measure. High-level disinfection (HLD) is used for semi-critical devices, those which might touch non-intact skin or mucous

With a clinical background and over 30 years of infection prevention experience in industry, Ann Hewitt has a comprehensive perspective on medical device reprocessing. She has been an invited speaker at national and international meetings on reprocessing, a member of the AAMI ST91 working group and a SME for numerous publications and education programs. Ann is currently the Vice President of Sales & Marketing for Cenorin, LLC.

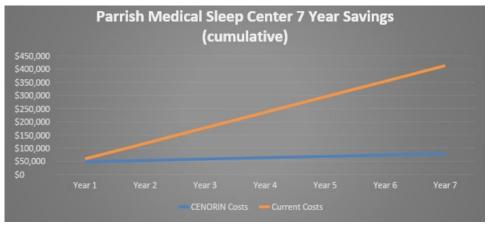
membranes. Semi-critical devices include flexible endoscopes and anesthesia equipment, along with respiratory tubing and face masks. The options for high-level disinfection, or HLD, were historically based on chemicals such as glutaraldehyde or orthophthalaldehyde (OPA).

For many facilities, the burdens to incorporate chemical HLD were unappealing. The chemicals are dangerous to work with. OSHA requires PPE, an eye wash station and a ventilation hood when working with glutaraldehyde. Chemicals need a lot of storage space. State and local regulations on disposal would have to be followed. Most sleep centers, whether hospital based or stand-alone, decided the easiest course of action was to switch to single-use devices, so they could avoid dealing with the consequences of HLD with chemicals.

For Kristina, motivated as she was by her mission to prevent other families from suffering the devastating and preventable loss of a parent at a young age, switching to single use devices (SUDs) wasn't an option. She intuitively recognized that there would be significant ongoing costs to purchasing, storing and disposing single use products in a never-ending cycle. More important, she realized that the success of the Sleep Mask Fit Clinic depended on patients being able to try on as many masks as they needed to find the right fit. If the Sleep Clinic had to discard each single-use mask that was used in the fit clinic, it would quickly go bankrupt.

Kristina and Michele Roberge, the former Sleep Lab Manager at Parrish Medical Center, investigated alternatives, with the goal that their selection must be both cost-effective and completely safe for patients and their staff. They wanted to mitigate the perceived drawbacks of SUDs: the single use devices would be more expensive in the long run, their disposal clogs up the waste stream and is bad for the environment, and managing the logistics of device procurement, storage, opening and disposing was going to require time that they didn't have.

Their research led them to thermal high-level disinfection, a discovery that seemed to check all the boxes they had defined: 1) it was must be non-toxic; 2) must be easy to operate; 3) must be compatible with the materials in their reusable supplies; 4) must meet the expectations of The Joint Commission; and 5) must be so cost-effective that they could continue to run the Fit Clinic at no charge to their patients.



Cumulative savings of over \$300,000 in six years.

"This gives us the ability to help more patients get comfortable on CPAP by offering a variety of different masks."

"I always tell patients, 'There is no reason that you should be uncomfortable on a CPAP mask. We will figure out something that works for you, and we'll keep trialing until we get it right,'" said Michele. "An automated cleaning and high-level disinfection system gives us the ability to help more patients by offering a variety of different masks."

The Parrish Sleep Center initially purchased an Olympic pasteurizer and used it until it wore out a few years later. By that time, Olympic had been purchased by a larger company and was no longer selling or servicing their products, so Parrish had no choice but to purchase from a different company if they wanted to continue offering the Sleep Mask Fit Clinic. The hospital administration was skeptical of their commitment to replacing their old unit with another thermal disinfection system, but Kristina and Michele were confident that chemical-free high-level disinfection was their best option.

They knew they would need to make a persuasive financial case to their administration. With that in mind, they went to Materials Management to get costs on their current inventory of reusable devices. Materials Management was also able to provide the costs of the individual SUDs that were comparable to their reusable devices.

The Sleep Center would pay for their new thermal HLD system in less than a year

The two of them dug into their ongoing purchase history and patient load to do an accurate analysis of their current costs. The Sleep Center was processing each device 15 times before discarding it, so they used 15 as the number of replacement SUDs they would need for each purchase of reusable devices they had been making. The ROI impact stared them right in the face: their anticipated cost savings would be so substantial that the Sleep Center at Parrish Medical Center would pay for a new thermal high-level disinfection system in less than a year, even without including any labor savings or any soft costs. It was an oranges-to-oranges comparison. Their administration agreed with the recommendation to purchase a new system.

Before they could purchase, however, they faced a second obstacle: overcoming the clinical concerns of their Infection Preventionist. Kristina and Michele reviewed manufacturer reprocessing recommendations for every mask they used to ensure they knew how many reprocessing cycles were allowed before discarding. They also had to document that the new system would meet all the manufacturers' guidelines for highlevel disinfection. Once their Infection Preventionist was on board, they were ready to research their options.

Kristina and Michele's research led them to the only system that has received 510(k) clearance from the FDA for thermal high-level disinfection: they selected the 610 Thermal High-Level Disinfection System from CENORIN as their replacement. The entire Sleep Center staff was delighted to realize that the automated cleaning cycle would eliminate the labor they had previously devoted to cleaning their reusable devices before placement in their previous machine.

But labor savings and cost savings weren't the only benefit. Their ability to support the Fit Clinic continued to expand, due to the number of options Parrish could now afford to offer. "We had countless patients coming to us after they'd had a home study and then purchased the first mask they tried when they went to the DME," said Michele Roberge. "It was multiple patients a week, coming in saying, 'This is terrible, it's so uncomfortable.'" Knowing that good fit is critical to compliance, Parrish has placed an intense focus on getting the patient into the right setup. Michelle went on to say, "We earned a reputation among both the primary care doctors and the DMEs in our area for being able to supply patients with the proper fit. The DME tells the patient, 'We'll call Parrish Sleep Center — you can go there to figure out what mask you want, and then we'll do the exchange for you.' Without our thermal high-level disinfection capability, Parrish Sleep Center would not be able to provide this level of service and clinical support. It would just be a testing center."

Kristina expanded on these observations, saying, "When we look at the big picture, daytime fittings create brand awareness and drive volume. We've become a one-stop shop; the word has gotten out that our patients are compliant. For us, these daytime fittings opened up a whole new set of referrals as we became known for providing proper fit. Our compliance levels are above 80%, when the national average is between 50 and 60%." Research backs up the compliance benefits of providing a proper fitting and titration.

Parrish Sleep Center's ability to support this increased volume is entirely based on the cost savings of reprocessing reusable devices instead of using single use devices. Kristina estimates that in the first five years of offering the daytime Fit Clinic, their business increased 540%. She attributes at least half that growth to their ability to offer treatment from beginning to end and supporting compliance with their patients. She celebrates the fact that their fit clinic has created life-long patients because Parrish will offer mask fittings to any patient in their lifetime who want to trial new masks.

Parrish Sleep Center calculated that it took only eight months to hit break-even on its new CENORIN 610 Thermal High-Level Disinfection System. After that, the savings all dropped to the bottom line. Kristina summarized her thoughts: "Our top three benefits are 1) immediate cost savings; 2) better quality patient outcomes from our person-centered care; and 3) brand awareness and increased referrals flowing from that better person-centered care." Eduardo Hernandez, the new Sleep Manager at Parrish Sleep Center, reported that one of the reasons he appreciates the opportunity to be a part of the Parrish Sleep Center team is the capacity to provide education and other support to the community. Without the positive financial impact created by the 610 Thermal High-Level Disinfection System, Eduardo said, "We wouldn't be able to fund activities such as the fit clinic and community education efforts that other facilities might bill for. It is a privilege to work in an environment that consistently puts the patient first."

When asked if she would recommend thermal HLD as a viable option for other sleep centers, Kristina said, "Yes, definitely. We are able to meet the demands of The Joint Commission for infection control while saving a lot of money and being environmentally conscious."

Eduardo added, "We have built-in peace of mind with the 610. On a day when we are fully booked for sleep studies and fittings, we can still get slammed with patients who don't have an appointment. We are able to accommodate them all because we can reprocess our masks and have inventory available no matter how busy we get."

Thermal high-level disinfection is providing improved patient outcomes, improved financial management, and improved staff morale at Parrish Sleep Center. Who would have guessed that "getting into hot water" would be such a profitable thing to do? Kristina summarized their experience by saying, "When we think of the cost of disposable masks and even the impact on our environment, having an option like we have with our thermal high-level disinfection is a game changer." Her dad would be proud of the legacy she's created in his memory.

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