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Pasteurization: Ultimate High-Level Disinfection For Respiratory Therapy Devices

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The topic of cleaning and disinfecting respiratory care devices has not been widely covered in respiratory therapy publications, nor have many clinical studies been completed specifically for this specialty. Yet when RT teams had to face the 2020 coronavirus pandemic, the attention of healthcare providers, government leaders and the media were all placed on therapists and their life-saving ventilators and respiratory care equipment. The crisis also brought to light the supply constraints for this equipment when it was needed in unusually high numbers. Furthermore, the exponential increase in seriously ill patients intensified the need to consider device reuse and reprocessing whenever possible to make up for inadequate supplies in affected geographic areas.

Even in non-pandemic times, however, there are many valid reasons to reprocess and reuse RT medical devices. Healthcare organizations that employ reusable RT components and perform best reprocessing practices consistently stand to gain multiple benefits. These include reducing device supply and per-use costs, reducing infection risk, reducing facility/system costs, improving compliance and regulatory/survey reporting, and reducing the facility and environmental medical waste burden.

Single Use Device		**Reusable Device**
• Anesthesia circuit: $8 • Disposal in hospital: $1 • Storing medical waste in facility: $1 • Picked up by waste management company: $2 • Waste disposed at landfill: $3	**vs**	• Anesthesia circuit: $20 • 10 uses: $2 per use plus $1 to reprocess (washer/HLD-pasteurizer) = $3 per use • 1/10 the waste and disposal costs: 70¢ per use if not recycled
Total: $15 per use		**Total: $3.70 per use**

Figure 1. Cost comparison between Single-use Device and Reusable Device.

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National medical device reprocessing standards

All classified medical devices, including those used in respiratory therapies, are subject to guidance and standards from national regulatory and professional bodies such as FDA, CDC, Joint Commission, ANSI/AAMI, AORN, APIC and IAHCSMM, governing how they must be processed if they are to be reused. These authorities apply the Spaulding Classification to determine the minimum level of disinfection needed to reduce risk to patients and reprocessing technicians. The non-critical, semi-critical and critical classifications are based on the infection risk posed by each device's intended use (whether it touches intact skin, contacts intact mucous membranes or non-intact skin, or is used to enter sterile or vascular areas of the body).

Standards bodies also refer users to the manufacturers' instructions for use for all relevant medical devices, and they recommend strict adherence to these IFU as part of each facility's reprocessing practices. The objectives of standards and manufacturers' IFU are to help reprocessing teams establish consistent practices that optimize reprocessing quality and patient safety. They are based on research, testing and evidence that validate the effectiveness of their recommendations and instructions. Each healthcare facility or system is responsible for documenting its own policies, procedures, training, and continuous quality improvement program in alignment with the national guidelines and manufacturers' IFU.

Guidance for respiratory therapy reprocessing

Respiratory therapy equipment, components and accessories are typically classified as semi-critical devices and are therefore subject to high-level disinfection to render them safe for handling and reuse. HLD is defined as a process for complete elimination of microorganisms on or in a device, except for small numbers of bacterial spores.[6] Guidance for reprocessing devices used in respiratory therapy, anesthesia, sleep labs and pulmonary procedures includes:

- ANSI/AAMI ST58, Chemical sterilization and high-level disinfection in health care facilities
- ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- APIC: Infection Prevention and Control Essentials for Ambulatory Care, 2020
- CDC (APIC): Guideline for Disinfection and Sterilization in Healthcare Facilities 2008

These advisory tools provide evidence-based guidance to help hospital reprocessing departments and ambulatory center teams

establish their protocols for reprocessing respiratory therapy devices. They include recommendations for cleaning and disinfecting devices, training personnel, selecting compatible cleaning methods and products, and following all equipment, device and disinfectant IFU.

Reprocessing challenges RT departments face

Although they must follow the same reprocessing standards as their counterparts, RT technicians face challenges that are different from those of hospital central services technicians. For example, ambulatory care departments, sleep labs and remote facilities often lack specific documented policies and procedures for device reprocessing in their particular environments, which creates the risk of inconsistency and the potential for error. Also, regardless of where they are disinfected, RT components must be reassembled into ventilators and other equipment for the next use, and this is typically the responsibility of trained RT technicians who complete the task in their labs and clinics. They also deal with disinfection workflow challenges such as less counter space, smaller equipment footprints and a lack of defined clean and dirty areas. And finally, they often lack reliable non-manual device tracking, process control and cycle documentation capabilities, which creates more work to assure compliance to device reprocessing limits and regulatory reporting. Proper cleaning and disinfection are still attainable, however, if these constraints are taken into account in location-specific policies and procedures, and if reprocessing equipment is optimized to facilitate the process.

High level disinfection methods

CDC lists the following, among others, as properties of an ideal disinfectant: it should have a wide antimicrobial spectrum; should be nontoxic for users and patients; should be compatible with all device surface materials; should be easy to use; should have a pleasant odor or no odor; should be economical; and should be environmentally friendly.[8] Even though many disinfectants in current use do not meet all these aspirations, healthcare providers must use what is available to them.

Currently marketed high level disinfection methods include automated and manual processes using chemicals such as hydrogen peroxide, peracetic acid and aldehydes. Although they all achieve high level disinfection when used as directed, these chemicals also pose potential risks, including one or more of the following:

- Corrosion, staining and other damage to the processed devices[4]
- Sensitivity and injury to staff during use[7]
- Sensitivity and injury to patients from residues[7]
- Survival of organisms within accumulated biofilms[4]
- Organisms developing reduced susceptibility to the chemical[4]
- Chemical solutions becoming contaminated[4]

These are not the only challenges for users; healthcare providers incur associated ongoing consumable disinfectant supply costs, chemistry monitoring requirements, inventory management responsibilities (to assure expiration dates are coordinated) and waste management costs (for neutralizing chemicals).

Pasteurization raises the bar

In addition to chemical methods, the CDC formally recognizes pasteurization as an effective high-level disinfection method. Studies also confirm its effectiveness even for drug-resistant bacteria.[12] Pasteurization involves the full immersion of devices in heated water at a specific temperature for a specified time period. CDC lists "wet pasteurization at 70°C [158° F] for 30 minutes with detergent cleaning"[3] as a useful method for a variety of devices, and specifically for respiratory therapy and anesthesia equipment and accessories. Global standards (ISO 15883) recommend that to achieve HLD, pasteurization should be performed at a minimum 65° Celsius (149° Fahrenheit). In the United States, pasteurization must achieve a 6-log reduction of the original population of organisms (99.9999%) for HLD.

Table 1. Devices Compatible with a Washer-Pasteurizer/High Level Disinfector*

Healthcare Department	Items
Anesthesiology	• Manual resuscitation bags (auto-inflatable) • Humidifiers • Anesthesia gas machine bag arm rebreathing bags • Laryngoscope blades • Oxygen administration masks and head bands • Non-invasive blood pressure cuffs • Reusable endotracheal tubes • Stylettes • Ventilator breathing circuits • IV arm boards • Pulse oximeter probes • Airways • PEEP valves • Blood pressure cuffs • Ventilator inhalation/exhalation check valve assemblies • End-tidal CO_2 sample line adapter ports • Oxygen sensor circuit "T" • Velcro poseys
Cardiopulmonary Lab	• Pulmonary function testing hoses and pneumo-tachometer • Masks • Mouthpieces • Circuits
Respiratory and Sleep Lab	• CPAP masks, tubing and headgear • Tubing, smooth bore and corrugated • Manual resuscitation bags (auto-inflated) • Hyperinflation bags (Nursery & NICU) • Humidifiers • Ventilator component parts • Laryngoscope blades • Oxygen administration masks and head bands • Blood pressure cuffs • Treatment nebulizers and wall oxygen humidifier bottles • Large bore tubing • Ventilator breathing circuits and water condensation traps • Croup tent components • Airways • PEEP valves • Ventilator inhalation/exhalation check valve assemblies • End-tidal CO2 sample line adapter ports • Oxygen sensor circuit "T" • Velcro poseys • Incentive spirometers • Aero Chambers

*Check each device manufacturer's instructions for use for specific processing instructions.

There are numerous benefits for healthcare facilities that use pasteurization rather than chemical HLD processes. For example, the heated water used in the cycle is ecologically

beneficial since it does not discharge chemical solutions or contamination into drains. Also, the process is economical—it requires fewer chemistries and costs less per cycle (one study estimated annual savings of $30,000 using pasteurization[14]). In addition, pasteurization is compatible with most RT devices (see Table 1). Since the system facilitates a commitment to reusable devices, it helps reduce a facility's single-use inventory, as well as its environmental medical waste footprint and associated costs.

It's important to note, however, that all pasteurizers are not equally effective. CDC noted that "Some data challenge the efficacy of some pasteurization units."[8] However, there is a washer-pasteurizer/high level disinfector available to RT departments that is specifically designed for semi-critical medical device processing. The only such system to be FDA cleared to date, it has undergone extensive testing and provides data to back up its efficacy claims. It meets all HLD standards and offers enhanced patient safety and process control features. The system's full immersion cycle at a temperature of 72° C (161.6° F) for 30 minutes has been shown to achieve a 6-log reduction of all required test organisms for typical medical devices used for anesthesia, pulmonary procedures, sleep labs and respiratory care. It offers accessories and trays to accommodate a wide variety of devices and components.

This particular system also has additional process control and monitoring features and functions to verify effective operation and provide audit records:

- Monitors cycle parameters during cycles to assure thorough cleaning and HLD
- Meters out cleaning agent for consistent dosing during the optional wash cycle
- Documents and prints out verification of each wash/pasteurize cycle step and condition alerts and diagnostics
- Provides condition alerts for insufficient cleaning agent, lid not locked, heat system failure, preventive maintenance, system cleaning, system failure

By performing two automated functions in one, this washer-HLD pasteurizer helps to reduce space and workflow needs while potentially streamlining reprocessing functions. If combined with customized and compliant reprocessing protocols, it can add significant value and time savings to an RT department.

Time to consider safe, economical, ecological options

Pasteurization is a validated method for disinfecting immersible semi-critical medical devices. For specialties like anesthesia, RT and sleep labs, all of which use many semi-critical devices in their therapeutic regimens, a validated automated washing/pasteurization system, when used as part of specific documented high-level disinfection policies and procedures, would help eliminate unnecessary steps and functions, streamline workflows and facilitate audit reporting. When compared to chemical disinfection, the benefits for patients, staff, devices, healthcare budgets and the environment would be significant.

References

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