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New technologies and trends in sterilization and disinfection

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Continued improvements in low-temperature sterilization systems have resulted in reduced processing times and expanded capabilities for instrument reprocessing. As the relationship of environmental surface contamination and health care-associated infections has become more defined, area disinfection systems and antimicrobial surface technologies have emerged as new strategies for disinfection of surfaces.

Recent developments in sterilization technologies that are applicable to health care facilities have followed the trend of the past two-and-a-half decades, a focus on low temperature sterilization systems. The drivers in this market remain unchanged: shorter cycles, improved materials compatibility, expanded instrument capability, environmental friendliness, and reduced costs. Commercially available low-temperature sterilization systems have been enhanced, and at least 2 newer technologies are moving toward commercialization. New biological indicators (BIs) with faster readout times have been developed for the steam sterilization process. Additionally, because of a growing body of evidence suggesting that environmental surface contamination in health care facilities may be directly related to health care-associated infections (HAI), there has been a great deal of technology development in the area of surface disinfection.

Existing technologies for surface disinfection have been improved to address respective limitations and create viable alternatives for decontamination/disinfection of surfaces in room size areas. These "area decontamination systems" are intended to supplement health care facility cleaning and disinfection procedures, which studies have shown to be lacking in effectiveness.[1,2] The use of materials with inherent antimicrobial properties for fabrication of surfaces common to health care facilities has also gained momentum as an alternative means for control of environmental surface contamination. This paper will summarize recent developments in sterilization technology and monitoring as well as provide brief overviews of traditional disinfectants used in health care facilities, area decontamination systems, and environmental surfaces with antimicrobial properties.

STERILIZATION PROCESSES

Vaporized hydrogen peroxide

The Amsco® V-PRO® maX Low Temperature Sterilization System (STERIS Corporation, Mentor, OH) uses vaporized H_2O_2 for terminal sterilization of clean and dry reusable metal and nonmetal medical devices that are used in health care facilities. The V-PRO maX System received Food and Drug Administration (FDA) 510(k) clearance in August 2011. A feature of the system is a conditioning phase that aids in removal of residual moisture in the load to optimize sterilization with the vaporized H_2O_2. The System has a 4.8 ft^3 (136 L) chamber size, an operating temperature of 50°C (122°F), and has 3 preprogrammed cycles:

- Nonlumen cycle: instruments without lumens and instruments with stainless steel (SS) diffusion-restricted areas (w28 minutes).
- Flexible cycle: surgical flexible endoscopes and bronchoscopes with lumens (specified internal diameter [ID] and length) and other nonlumened devices (w35 minutes).
- Lumen cycle: instruments with SS lumens (specified ID and length) and SS diffusion-restricted areas (w55 minutes).

Each of the 3 V-PRO maX cycles is slightly different in regards to the combination of vacuum level depth, conditioning phase, and hold times after injections of vaporized H_2O_2 and air. However, the basic phases of the 3 cycles are similar. After chamber loading, a vacuum pulse is used to remove air and moisture from the chamber. Once the vacuum set point is reached, the load is automatically tested for acceptable moisture content. If the moisture content of the load is determined to be acceptable, the process moves to the H_2O_2 injection phase. If the moisture level of the load is unacceptable, a conditioning phase consisting of an additional vacuum pulse is used to aid in the removal of load moisture.

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Following completion of the moisture check and/or load conditioning, a quantity of H_2O_2 from a 59% H_2O_2 liquid supply is vaporized and injected into the sterilizer chamber. After a hold time, filtered air enters the chamber causing a rise in pressure followed by an additional hold time at the elevated pressure. This sequence of vacuum, H_2O_2 injection/hold time followed by air injection/hold time (referred to as a sterilization pulse) is repeated 3 additional times for a total of 4 pulses in each cycle. Upon completion of the last sterilization pulse, the chamber is evacuated to aerate the load. A catalytic converter decomposes the H_2O_2 sterilant to oxygen (O_2) and water, and no special venting is required. The load can be used immediately or stored for future use.[3,4]

H_2O_2 vapor and gas plasma

The STERRAD® 100NX® Sterilizer (Advanced Sterilization Products, Irvine, CA) uses low-temperature H_2O_2 gas plasma technology for terminal sterilization of heat and moisture sensitive medical instruments and devices. Although this basic technology has been marketed in the United States since 1993, a recent FDA 510(k) clearance in September 2012 has expanded the number of cycle options currently available for the system:

- Express cycle: general medical devices (metal and nonmetal) requiring surface sterilization, mated SS or titanium surfaces, rigid/semirigid endoscopes without lumens and rechargeable batteries (w24 minutes).
- Flex cycle: Single channel flexible endoscopes (2 maximum) with specified ID and length (w42 minutes).
- Standard cycle: general medical instruments (metal and nonmetal) including hinged devices and both single channel SS lumens and polyethylene and/or Teflon® (DuPont™, Wilmington, DE) lumens with specified ID and length (w47 minutes).
- DUO cycle: single channel flexible endoscopes (2 maximum) with specified ID and length, accessory light cords, and cameras (w60 minutes).

The STERRAD 100NX Sterilizer has a 3.3 ft^3 (93.4 L) chamber capacity and operates at 47°C to 56°C (116.6°F-132.8°F). Both the Express and DUO cycles utilize 59% liquid H_2O_2 sterilant. The Standard and Flex cycles use a vaporization system that removes the majority of the water from the 59% liquid H_2O_2 sterilant supply solution resulting in an increased chamber concentration of vapor H_2O_2 and enhanced sterilization capabilities. The sterilizer also has an H_2O_2 monitor for direct measurement of the chamber sterilant concentration, which provides real-time feedback in the event of an overloaded chamber or the presence of absorbent materials.

Despite the differences in cycle times, all of the STERRAD 100NX cycles consist of 2 equal and consecutive phases. After an initial chamber evacuation, the liquid H_2O_2 is vaporized and injected into the chamber with the aid of a deep vacuum. Following a timed exposure of the load to the vaporized H_2O_2, the pressure is increased and subsequently decreased to allow generation of gas plasma. After a short exposure to the free radicals in the gas plasma, the plasma power is terminated and the free radicals recombine to form O_2 and water vapor. This same sequence is then repeated for the second phase of the process. All gases used throughout the cycle are exhausted from the sterilizer into a specially designed filter and are decomposed into O_2 and water vapor. Processed items are ready for immediate use following completion of the process.[5,6]

An additional enhancement to this system is an online tool (STERRAD Sterility Guide) that allows users to look up their medical devices and determine which cycle is appropriate for the device. This guide is maintained in cooperation with most major medical device manufacturers and to date contains ~2,300 devices representing 42 medical device manufacturers for the STERRAD 100NX Sterilization System.[7]

Ozone + H_2O_2 vapor

The STERIZONE® 125L+ Sterilizer (TSO_3, Québec, Canada) combines vapor H_2O_2 and ozone (O_3) in 1 process to create a synergistic effect for enhanced microbial inactivation. (Note: The STERIZONE 125L+ Sterilizer has not been FDA 510(k) cleared for use in health care facilities at this point in time.) The sterilizer is designed for terminal sterilization of heat and moisture sensitive medical and surgical instruments including flexible endoscopes. The sterilizer has a 4.4 ft^3 (125 L) chamber, operates at 40°C to 42°C (104°F-107.5°F) and has 3 preprogrammed cycles (Note: Cycle times based on empty chamber. Actual cycle times may vary depending on load contents and packaging.):

- Cycle 1: general instrumentation and single channel short, flexible endo- Q4 scopes (w46 minutes).
- Cycle 2: rigid channeled instruments and single/multichannel rigid endoscopes (w56 minutes).
- Cycle 3: long single/multichannel flexible endoscopes (w100 minutes).

The STERIZONE 125L+ process begins with a chamber evacuation followed by introduction of vaporized H_2O_2 from a liquid supply. Biologically active free radicals, such as the hydroxyl radical (OH^-), are formed in the chamber and microbial inactivation is initiated. The second phase of the process occurs with the introduction of O_3, which mixes with the H_2O_2 vapor atmosphere. The O_3 is created by an integrated O_3 generator using an external O_2 source (O_2 tank, in-house O_2 supply, or O_2 concentration device). After a short exposure period to the combined H_2O_2 and O_3 sterilants, the chamber is again evacuated, and the sequence of H_2O_2 injection followed by O_3 injection is repeated a specified number of times as determined by the cycle selected. Following completion of the exposure periods, a vacuum followed by O_2 washes are used to remove the sterilant mixture from the chamber. The exhausted H_2O_2 and O_3 sterilants are catalytically converted into O_2 and water, and outside venting is not required. Processed items are available for use immediately following completion of the selected cycle.[8]

It has been demonstrated in liquid systems that combining H_2O_2 and O_3 can increase the concentration of hydroxyl radicals in O_3 thereby increasing the overall oxidation rate of the mixture.[9] The combination of these 2 chemicals is referred to as the *peroxone process* and is an example of an "advanced oxidation process." The O_3 concentration used in the STERIZONE 125L+ process ranges from 2 to 10 mg/L depending on the cycle used, which is much lower than the ~ 85 mg/L O_3 concentration used in the existing STERIZONE 125L O_3 Sterilizer. Based on the high diffusion rate of O_3 and its enhanced oxidation state, penetration into long narrow lumens and subsequent microbial inactivation occur in a relatively short period of time. Packaging requirements for the STERIZONE 125L O_3 process are similar to both existing H_2O_2 and O_3 sterilization systems, ie, nonwoven polypropylene wraps, film/Tyvek® (DuPont, Wilmington, DE) peel pouches, and approved rigid sterilization containers. Paper or other cellulosic materials are contraindicated.

Nitrogen dioxide

Noxilizer Inc (Baltimore, MD) has been developing a room temperature process for sterilization of medical devices using nitrogen dioxide (NO_2) since 2004. Significant advancements

Table 1
HLD/chemical sterilants FDA 510(k) cleared 2002-2012 by type of active agent, based on search of available data bases[15,16]

	Year										
Active agent	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Glutaraldehyde		1		1*	1						
Glutaraldehyde + IPA				1					1		1
OPA		1		1†		1					
H_2O_2							1				
PAA								1†	2†	1†	
H_2O_2/PAA				1					1		
Hypochlorous acid/hypochlorite	1					1					

IPA, isopropyl alcohol; *OPA*, *ortho*-phthalaldehyde; *PAA*, peracetic acid.
*Single use to be used exclusively with the TD-100 Transesophageal Probe Disinfector (CS Medical, LLC, Creedmoor, NC).
†For use in specified automatic endoscope reprocessing system only.

toward commercialization of the technology have been made since that time, especially in industrial "niche-type" applications. (Note: The Noxilizer NO_2 Sterilizer has not been FDA 510(k) cleared for use in health care facilities at this point in time). NO_2 gas has been shown to produce single-strand breaks in microbial DNA thereby disrupting cellular function in a wide range of microorganisms, including bacterial endospores. NO_2 has unique properties including a low boiling point (21°C) and a high vapor pressure (750 mm Hg at 20°C), both of which facilitate effective dispersion of NO_2 gas at low concentrations within a chamber. *Geobacillus stearothermophilus* (*G stearothermophilus*) spores have been documented as the most resistant organism to the Noxilizer process and have demonstrated log-linear inactivation at 3.5 mg/L NO_2 gas concentration and 75% relative humidity (RH).[10] As with all chemical sterilants, there is some degree of toxicity associated with NO_2. The current Occupational Safety and Health Administration permissible exposure limit for NO_2 is 5-ppm, 8-hour time-weighted average. As a reference, Occupational Safety and Health Administration permissible exposure limits (8-hour time-weighted average) for other chemicals commonly used in sterilization processes are 0.1 ppm for O_3 and 1 ppm for H_2O_2 and ethylene oxide.[6]

The Noxilizer process involves an initial evacuation of a "prechamber" followed by introduction of NO_2 gas (evaporated from a liquid supply) until a preset pressure, which controls the NO_2 concentration is reached. The prechamber is then opened to allow the NO_2 gas to enter the evacuated sterilization chamber. After the addition of humidified air to the sterilization chamber, the exposure period begins. This sequence of chamber evacuation and NO_2 gas/humidity introduction may be repeated multiple times during a cycle depending on the sterilization load. The process does not require heat but is impacted by RH. Increasing the RH enhances spore inactivation, which is believed to be related to hydration of the spore coat.[10] Following completion of the final exposure period, the chamber is purged with a series of high-efficiency particulate air-filtered fresh air washes. The exhausted NO_2 gas is passed through a solid chemical scrubber that captures and neutralizes the sterilant. The spent scrubber material can be discarded as nonhazardous solid waste and the scrubbed air vented directly into the sterilizer room. The low boiling point and the low vapor pressure of NO_2 combined with the small amount of gas needed for sterilization result in minimal aeration times.[11]

Although NO_2 is an oxidizer, its oxidizing potential is less than that of H_2O_2 or O_3. This may contribute to the fact that NO_2 is compatible with most polymers used in the fabrication of medical devices as well as with various biomolecules that are not compatible with other existing sterilization methods. Common packaging materials such as nonwoven polypropylene wraps, film/Tyvek (DuPont, Wilmington, DE) peel pouches, and Tyvek/plastic trays can be used in the Noxilizer process, but paper or other cellulosic materials are contraindicated. Noxilizer currently markets the RTS 360 Industrial NO_2 (Noxilizer Inc, Baltimore, MD) sterilizer with a useable chamber volume of 360 L and an 80-minute cycle time for industrial applications. A unit designed for use in health care facilities is in development.[12]

STERILIZATION MONITORING

New rapid readout BI

The Attest™ Super Rapid Readout Biological Indicator System (3M™ Health Care, St. Paul, MN) provides faster readout times for moist heat sterilization processes than currently available BIs. The 1491 BI was FDA 510(k) cleared in April 2011 and is indicated for use in select 132°C (270°F) and 135°C (275°F) gravity displacement cycles. It has a 30-minute incubation time until a negative result can be accepted. The 1492V BI was FDA 510(k) cleared in October 2012 and is indicated for use in select 132°C (270°F) and 135°C (275°F) vacuum-assisted steam sterilization cycles. This BI has a 1-hour incubation time for acceptance of a negative result. The rapid readout of these BIs is based on detection of α-glucosidase enzyme, naturally occurring in the *G stearothermophilus* organism, by measuring the fluorescence produced by the hydrolysis of a nonfluorescent substrate contained in the growth medium. The resultant fluorescent by-product is detected in a specialized incubator/reader, which can be linked with record-keeping software systems using an Ethernet cable. Both of the BIs meet the performance requirements specified in ANSI/AAMI/ISO 11138, parts 1 and 3:2006/(R)2010.[13,14]

CHEMICAL DISINFECTANTS

Although there have not been a large number of novel chemistries and/or product formulations for chemical disinfectants developed in recent years, there are trends that provide some insight into the current and future development of chemical disinfectants. FDA clearances and Environmental Protection Agency (EPA) registrations generate historical databases that can be used for tracking disinfectants by product type and approximate time of introduction into US markets.

High-level disinfectants

High-level disinfectants (HLD)/chemical sterilants are used primarily for processing of medical devices, although a few HLD are indicated for use on environmental surfaces. These products must have FDA 510(k) clearance to be legally marketed in the United States. A listing of 510(k) clearances for HLDs by active agent type and year (2002-2012) is presented in Table 1 above. Eighteen HLD products have been cleared by the FDA in the last 10 years. Whereas glutaraldehyde formulations continue to be developed and

Table 2
EPA-registered tuberculocidal disinfectants effective against *Mycobacterium tuberculosis* 2006-2012 by type of active agent, based on search of available data bases[18-20]

	Year						
Active agent	2006	2007	2008	2009	2010	2011	2012
Quaternary ammonium compounds	6	7	3	3		2	1
Sodium hypochlorite	3	5	6			2	
H_2O_2 or H_2O_2/PAA	3	1	1	2	2	1	
H_2O_2/silver				1		1	
Phenols		1	1				
Sodium chlorite		4	1				
Chlorine dioxide		1	1				
Thymol	1					1	
Citric acid		1					
Nonylphenoxypolyethoxyethanol — iodine complex		1					
Hydrochloric acid	1						
Sodium dichloro-s-triazinetrione	1						

PAA, peracetic acid.

marketed, more oxidizing chemical formulations (H_2O_2 and peracetic acid [PAA]) have been cleared during this time frame than any of the other formulations listed.

Intermediate-level hard surface disinfectants

Intermediate-level hard surface disinfectants are generally used for disinfection of environmental and noncritical medical equipment surfaces and must be registered with the EPA for legal marketing in the United States. The EPA does not have a classification for HLD but does have a designation for a hospital disinfectant. Although there is no explicit requirement, most EPA-registered hospital disinfectants have a tuberculocidal claim and are therefore considered to be intermediate-level disinfectants by the Centers for Disease Control and Prevention and the FDA. EPA-registered surface disinfectants with tuberculocidal claims by active agent type and year 2006 to 2012 are listed in Table 2. Quaternary ammonium chloride disinfectant/cleaners and sodium hypochlorite formulations have the greatest number of registrations during this time period, whereas phenolic-based products have the fewest number of registrations for these traditional disinfectant types. Registrations of oxidizing chemical formulations increased during this time period as compared with prior years, a trend similar to the observation for HLD formulations. This trend for increased regulatory filings of both high-level and intermediate-level disinfectants containing oxidizing chemicals is attributed to enhanced product formulations demonstrating both improved performance and minimal toxicity, thereby addressing many of the problems typically associated with oxidizing based disinfectants.[17]

Additionally, since 2010 there have been at least 15 disinfectants listing sodium hypochlorite as the active agent and 3 disinfectants with H_2O_2/PAA as the active agent that have been registered with EPA for use in health care facilities that *do not* have tuberculocidal claims (and therefore are *not* included in Table 2). However, all 18 of these products do have claims for effectiveness against *Clostridium difficile* (*C difficile)* spores. This would seem to indicate that these products are intended more for use in areas soiled with blood/body fluids and/or for terminal disinfection of isolation rooms rather than for routine applications in general disinfection of environmental surfaces in health care facilities.

New disinfectant formulations

Akwaton (Fosfaton-Akwaton International Ltd, Winnipeg, Manitoba, Canada) is a polyhexamethylene-guanidine hydrochloride-based disinfectant with potential for use in health care settings. This chemical, a biocide of the guanidine family, has recently been reported to demonstrate sporicidal activity at very low concentrations against *Bacillus subtilis* spores inoculated onto hard surfaces: 0.52% (wt/vol) with 1.5 minutes of contact time and 0.36% (wt/vol) with 3 minutes contact time.[21] An earlier study indicated effectiveness of this same compound against a variety of vegetative organisms at concentrations as low as 0.005% (wt/vol) within 1.5 minutes contact time per Association of Official Analytical Chemists use dilution testing.[22] The formulation is claimed to be nontoxic to humans at the concentrations used for disinfection. (Note: This product has not been registered with the EPA at this point in time.)

A newer intermediate-level disinfectant/cleaner formulation that claims a 5-minute kill time for *C difficile* spores and virtually no toxicity was EPA registered in December 2011. The active components of STERIPLEX SD (sBioMed, STERIPLEX® SD, sBioMed® Orem, UT) are listed as 22% H_2O_2, 15% PAA, and 0.015% silver. The product is a 2-part system: part A is a 1-gallon bottle containing 0.015% silver, 10% ethyl alcohol, water, and inert ingredients. Part B (activator) is a 1.3-oz bottle containing 22% H_2O_2, 15% PAA, 15% acetic acid, and water. The activator is added to the gallon container resulting in a 99:1 dilution and a ready-to-use solution with final concentrations of 0.020% H_2O_2, 0.150% PAA, 0.150% acetic acid, and 0.015% silver. The activated product is claimed to be noncorrosive to skin or eyes and has a Hazardous Materials Identification System rating of zero (lowest rating for health, physical, and flammability hazards).[23]

AREA DECONTAMINATION/DISINFECTION: NO-TOUCH ROOM DISINFECTION

The significance of environmental surface disinfection in patient care facilities has emerged as an important component in the overall strategy for prevention of HAI. The focus on disinfection of environmental surfaces has shifted somewhat from traditional surface disinfectants and disinfectant/cleaners to area decontamination/disinfection systems. There are a number of factors that have enhanced this awareness and driven the shift in focus:

A growing body of scientific evidence suggesting that cross contamination of microorganisms from environmental surfaces can be directly related to patient infection

Surfaces such as bed rails, bed surfaces, over-the-bed tables, intravenous fluid poles and pumps, light switches, door knobs, and supply carts are examples of “high-touch” surfaces that have been identified as having the greatest potential for transmission of pathogenic microorganisms.[24] An increasing number of studies now exist indicating that patients occupying a room that was vacated by a patient with a known infection have an increased risk of acquiring an infection from colonization with that same microorganism.[25-29]

Evidence of survival of pathogenic microorganisms on environmental surfaces for long periods of time

Vegetative bacteria such as vancomycin-resistant enterococci (VRE), methicillin-resistant *Staphylococcus aureus*, *Acinetobacter baumannii, Escherichia coli*, and *Pseudomonas aeruginosa* have been shown to persist in the environment for several days to several months depending on environmental conditions such as temperature and humidity.[30,31] Spores of *C difficile* would be expected to survive for significantly longer times because of the inherent nature of bacterial endospores. All of these microorganisms are common sources of HAI.

Inadequacies in cleaning/disinfection using traditional methods and procedures

Inadequacies in cleaning/disinfection using traditional methods and procedures. Studies have demonstrated that less than 50% of environmental surfaces in patient care rooms are being adequately cleaned according to existing hospital policies.[1,2] These findings are likely due at least in part to the minimal time allotted to the housekeeping staff for cleaning and disinfection of each room. A contributing factor to inadequate environmental surface disinfection is that the contact time specified on the disinfectant product label is often too long for practical application. As mentioned previously, most disinfectants used for environmental surface disinfection in health care facilities have a tuberculocidal claim, which typically requires a 5- to 10-minute contact time. Common practice in most health care facilities is to apply a disinfectant and allow it to remain for approximately 1 minute.[32]

Advances in technologies and systems for area decontamination/disinfection

Advances in technologies and systems for area decontamination/disinfection. New systems have been developed and existing systems enhanced for practical decontamination/disinfection of environmental surfaces in room-size areas. It should be noted that these systems are intended for use as an adjunct to routine cleaning and disinfection procedures rather than as an alternative or replacement for traditional cleaning and disinfection methods. These area decontamination/disinfection units are commonly referred to as *no-touch* systems because they are fully automated and therefore generally do not require personnel intervention once the treatment is initiated. Two distinct types of no-touch area decontamination/disinfection systems have been shown to reduce microorganism levels on environmental surfaces: H_2O_2 vapor or mist[33-37] and ultraviolet radiation.[38-42]

In contrast to liquid chemical disinfectants discussed previously, the regulatory framework for these area decontamination/disinfection systems is not well defined. Although some of the chemical vapor systems use an EPA-registered disinfectant or sterilant in their systems, there do not appear to be explicit FDA or EPA requirements for clearance or registration of area decontamination/disinfection systems at this time.

ANTIMICROBIAL SURFACE TECHNOLOGY

Antimicrobial copper surfaces

Copper and copper compounds have been used throughout recorded history to treat infections in humans as well for preservation of various materials. In recent years, there has been increased visibility and promotion of antimicrobial copper touch surfaces for applications in health care facilities. There is considerable scientific evidence indicating that copper alloy surfaces, when maintained and regularly cleaned, exhibit an antimicrobial effect on various microorganisms, particularity those commonly implicated in patient infections.[43-50] Copper is considered a broad-spectrum antimicrobial including activity against bacterial endospores such as *C difficile*.[49,50] Copper surfaces are purported to kill bacterial continuously without the addition of any chemicals and have no harmful effect to the environment or personnel. Additionally, over 350 copper alloys with 65% or more nominal copper are registered with the EPA as solid antimicrobial materials.

Antimicrobial silver surfaces

Silver has been shown to be effective at low concentrations against a broad range of microorganisms. However, data demonstrating antimicrobial activity against bacterial endospores are minimal. Historically, silver has been used in wound treatment and water disinfection, but more recently silver compounds have been incorporated into various medical devices and have also been evaluated for applications on/in environmental surfaces in health care facilities. Incorporation of silver into various materials and surface coatings have been shown to be effective in reducing microbial surface counts.[51-54]

CONCLUSION

Development of improved and new low-temperature sterilization systems has continued. The search for the "ideal sterilant" will likely continue as more sophisticated medical instrumentation and more medical devices with drug or biologic components, ie, combination products, are developed. Faster instrument turnaround times and greater instrument compatibility to the sterilization process are being sought. Improved compatibility of instruments and materials may combine the mutually beneficial effort of both sterilizer manufacturers and device manufacturers. Nonetheless, moist heat sterilization remains as the mainstay for reprocessing of instruments and medical items in health care facilities. In view of the fact that steam sterilization is a fundamentally sound and adaptable technology, enhancements in steam sterilizers have been in the areas of standards compliance; greater flexibility in cycle availability and selection, ergonomic control systems, reduced operational costs, and environmental "friendliness." BIs with shorter readout times will provide a means for faster turnaround times of steam sterilized medical items and will have particular significance relative to the sterility assurance requirements for implantable devices processed in health care facilities.

The need to improve the cleaning and disinfection of environmental surfaces in health care facilities has gained considerable awareness and momentum and is currently an emerging issue in control and prevention of HAI. Whereas it has long been intuitive that disinfection of environmental surfaces was a meaningful practice, the recent scientific evidence suggesting that there may be a direct link between these environmental microorganisms and HAI has created a new awareness of its significance. This awareness along with the associated HAI costs (and possible loss of reimbursement) has driven development and commercialization of area decontamination/disinfection systems as well as promoted applications of antimicrobial surface technologies. The trend toward control of microorganisms in the patient environment is expected to continue and will likely include new materials with inherent antimicrobial properties for environmental surface applications.

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