Infection Prevention Solutions
newsletter

Steam Chemical Indicator Classifications

In 1996, the Association for the Advancement of Medical Instrumentation first published the American National Standards: Sterilization in health care products- Chemical Indicators (ANSI/AAMIST60). In 2005, the standard for ISO 11140-1 was updated and the AAMI organization approved the new standard without US deviation and the new document is now entitled ANSI/AAMI/ISO.

ANSI/AAMI/ISO 11140-1,
"…The chemical indicators described in this part of the ISO 11140 document are classified into six groups. The chemical indicators within each of these classifications are further subdivided by the sterilization process for which they are designed to be used. The classification structure used is solely to denote the characteristics and intended use of each type of indicator as defined by the manufacturer. The classification has no hierarchical significance."

Why is this Valuable to our End-User?

This information is valuable to the end-user as the classifications allow them to understand the performance parameters and tolerances of the various Chemical indicators. When used correctly, the chemical indicator can assist in obtaining the information required to determine the effectiveness of the sterilization process.

(continued on next page)

Steam Chemical Indicator Classes Defined

The ANSI/AAMI/ISO 11140-1:2005 is available from AAM at www.aami.com

Class	ANSI/AAMI/ISO 11140-1: 2005 Definition	Practical Application
Class 1: Process Indicators	"Process indicators are intended for use with individual units, (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designed to react to one or more of the critical process variables."	Indicator tapes, indicator labels, and load cards are examples of externally visible Chemical Indicators that are Process Indicators used for exposure control.
Class 2: Indicators for use in Specific Tests	"Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/ sterilization standards."	Bowie-Dick type tests are specific tests used for equipment control to evaluate the sterilizer performance.
Class 3: Single Variable Indicators	"A single variable indicator shall be designed to react to one of the critical variables and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable."	An example of a Single Variable Indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature. Single variable indicators may be used for pack control monitoring but would not provide as much information as a Class 4 or Class 5 Chemical Indicator. Single Variable Indicators may also be used for exposure control monitoring. This temperature tube would be used to determine that a specific temperature was reached at a specific location in the sterilizer chamber.
Class 4: Multi-variable Indicators	"A multi-variable indicator shall be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variable."	Multi-variable Chemical Indicators are used for pack control. These internal Chemical Indicators are usually paper strips printed with a Chemical Indicator.
Class 5: Integrating Indicators	"Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO 11138 series for BIs."	Integrating Indicators are the most accurate of the internal Chemical Indicators. Integrating Indicators are used for pack control monitoring. They can also be used as an additional monitoring tool to release loads that do not contain implants. For this additional monitoring the Class 5 Integrating Indicator must be used in the appropriate challenge test pack or Process Challenge Device (PCD). These indicators must now have SVs at 121°C/250°F, 135°C/276°F, and at least one more temperature in between. Also, the SV at 121°C MUST be greater than 16.5 minutes to ensure performance is comparable to BIs in saturated steam.
Class 6: Emulating Indicators	"Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process."	Emulating Indicators can be used as internal Chemical Indicators for pack control. Emulating Indicators are specified for specific sterilization cycles which means an end user will need to inventory a different Class 6 Emulating Indicator for each sterilization cycle time and temperature (i.e., 3 min, 5 min, 10 min, 18 min, 40 min, etc.) run in the facility. The response of a Class 6 Emulating Indicator does not necessarily correlate to a Biological Indicator so the indicator cannot be used as an additional monitoring tool to release loads that do not contain implants. (See Class 5 definition) The use of Class 6 Emulating Indicators is presently not covered in any AAMI health-care facilities user documents.

Nowhere to hide

"Every Load Monitoring" gains acceptance in the fight against infection

Disturbing stories of patients contracting deadly infections during hospital stays increasingly fill our newspapers, magazines, television reports and various on-line resources. According to the Association of periOperative Registered Nurses (AORN) Position Statement on Patient Safety, the surgical setting is one of the most potentially hazardous environments for patients. Infection, hemorrhage, and wrong patient / surgery / site are some of the most serious likely complications.[1]

Taking sterilization assurance to the highest level

Working to ensure the highest possible level of sterilization assurance for instruments, implantable devices and other surgical supplies that come in contact with patients' bodies is one of the best ways Sterile Processing Departments (SPD) can do their parts to contribute toward reducing Hospitals Acquired Infections. The question is, what's the best way to ensure that each and every load you send to the operating room has been effectively sterilized?

It is generally accepted that biological indicators (BIs) offer today's surest and most realistic measurement of sterilization cycle lethality. In fact, according to ANSI/AAMI ST79:2006 (10.5.3.1) biological indicators are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process.

Current AAMI guidelines call for the use of BIs under certain situations: to monitor all loads containing implants; for routine sterilizer efficacy monitoring; sterilizer qualification testing; and periodic product quality assurance testing.[2] Today, however, investigating the benefits of using a BI in every load is becoming more common – both as a means of improving patient safety, and to reduce the cost and disruption of potential recalls. "I don't work in a hospital, but as a Consultant I do recommend for hospitals to monitor every load with a BI if they do not quarantine the load before reading the BI, says Colleen Landers, Consultant. "The reason is the risk to the patient and the cost of a recall. If you're releasing prior to reading the BI and only reading the BI once per day (and many people are using a 24-hour BI) you're releasing product for patient use without knowing if your Quality System is totally accurate and thus placing patients at risk."

Another reason more SPDs are turning to Every Load Monitoring with BIs is to reduce the chance of human oversight. "When every load gets a biological indicator, it serves to standardize the process and eliminates any second guessing about whether an implant load was monitored or not. It's one less thing the SPD has to consider or be concerned about. It takes standard practice to best practice, and aggressively pursues the highest standard of care for every patient. At the same time, it makes staff training on the process that much easier," states Martha Young, Senior Technical Service Specialist, 3M Sterilization Products.

Some SPDs have been reluctant to upgrade to every-load monitoring with BIs because of the increased cost. And yet, compared to the potential cost and disruption of multiple load recalls the cost is often insignificant.

What's the real cost?

Consider the breadth and depth of a possible recall:

- Recall, re-pack and re-sterilize all items back to the last negative biological indicator
- Possible delays and rescheduling of surgeries
- Informing surgeons who may have already used a pack item
- Numerous reporting and investigating actions across the facility involving Biomedical Engineering, Infection Control, and Risk Management
- After major repairs are completed, qualification testing per AAMI and department policies
- Concerns over potential litigation should the patient contract an HAI

According to the Center for Disease Control, healthcare associated infections are now the sixth leading cause of death in the U.S., killing almost twice as many people as breast cancer and HIV/AIDS combined.[3] With this in mind, it becomes the healthcare professional's responsibility to utilize the best practices and technology at their disposal, in order to safeguard the patients in their care. Monitoring every load with BIs gives those who are charged with ensuring the sterility of medical instruments and devices one more way to make an important contribution to that fight – and help preserve a hospital's reputation as place of healing.

[1] Association of periOperative Registered Nurses (AORN), "AORN Position Statement, Statement on Patient Safety," www.aorn.org/PracticeResources/AORNPositionStatements/Position_PatientSafety

[2] ANSI/AAMI ST79: 2006 Sections 10.5.3 - 10.7.2

[3] Binder, Leah (The Leapfrog Group), "Infections Caused by Health Care," transcript of congressional testimony to the House Oversight and Government Reform Committee (April 16, 2008)

Post-it® Notes are Going Green: Turning Environmental Policy into Performance

For over a century 3M has been making products that help to make people's lives easier and we've been successful by listening to the needs and interests of our customers. By creating innovative products that address these needs we are able to provide our customers with tangible solutions to their problems. Therefore, when our customers' attention shifted to environmental concerns three decades ago our focus expanded to find new environmentally conscious ways to produce our products.

The 3M Environmental Policy has always been far more than words on a paper for 3M employees. Since the "3P" program (Pollution Prevention Pays) was constructed in 1975 3M has witnessed global environmental results. Such impressive positive results include but are not limited to more than 6,800 employee driven 3P projects and over 1.2 billion kilograms of pollution prevented (aggregate of first year of each project).

One product that 3M has been particularly successful with in respect to environmental concern is Post-it® Notes. Since all Post-it® Notes paper is sourced from paper mills that are certified for sustainable forest management all of Post-it® Notes from the past decade have been recyclable. All Post-it® Notes must contain a minimum of 30 percent postconsumer content. The Post-it® Notes line was first developed to integrate recycled content as a way of creating yet another option to address environmental concerns in the marketplace.

Post-it® Recyclable Notes are not the only environmentally friendly product produced by 3M. Another environmentally friendly product produced by 3M is the Post-it® Super Sticky Recycled Easel. The Post-it® Super Sticky Recycled Easel Pads have bleed through resistant sheets that stick to more surfaces for a longer period of time than other easel pads although they still remove cleanly off of all surfaces. Some of the other features of the Post-it® Super Sticky Recycled Easel pads include but are not limited to: the writing sheets for the easel pads are made from a minimum of 30 percent postconsumer content and 100 percent of the material used to produce the easel storage carton is from recycled materials.

3M's commitment to environmental sustainability over the past three decades has not only served to give customers more environmentally friendly options in the marketplace but rather has further served as a long-term winning business strategy for the company.

Looking forward, 3M is committed to working to reduce our environmental footprint by partnering with our customers to develop innovative solutions to address their environmental challenges. By making a commitment to proactive environmental solutions, 3M is leading the way to corporate environmental responsibility.

Polution
Prevention Pays

Definitions (from PIDAC)

Surgical Hand Antisepsis[1]: The preparation of hands for surgery, using either antimicrobial soap and water or an alcohol-based hand rub, preferably one with residual activity.

Surgical Hand Rub[1]: Surgical hand preparation with an alcohol-based hand rub that has sustained activity.

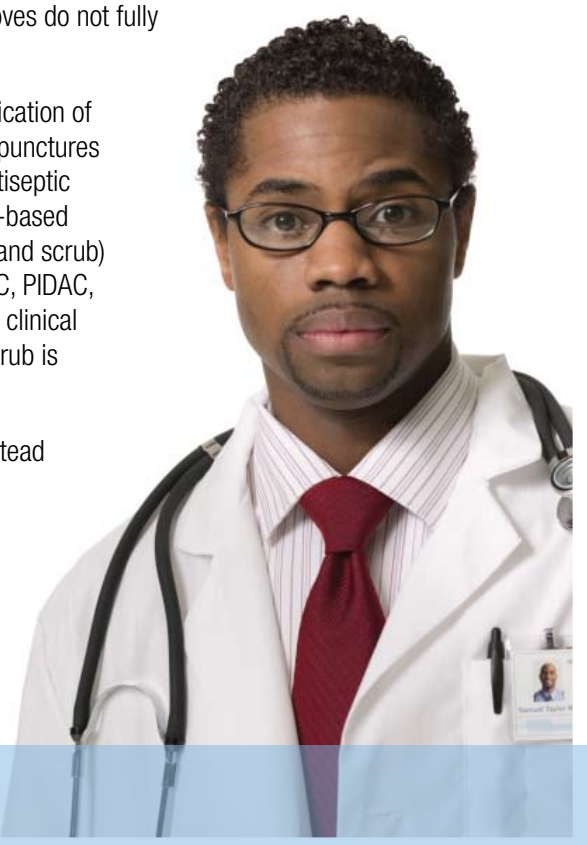
Surgical Hand Scrub[1]: Surgical hand preparation with antimicrobial soap that has sustained activity and water.

With Hand Hygiene becoming the focal point of many patient safety initiatives around the country, it is no wonder all aspects of hand hygiene are getting more attention. Reporting of hand hygiene compliance rates are becoming mandatory in some areas of the country, so we can expect even more attention on this critical aspect of patient care. With this increased focus on general hand antisepsis, also comes an increased focus on surgical hand preparations. The leap has been made that if alcohol is such an effective antimicrobial for hand hygiene, then why would it not be so for surgical hand preparations? As such, many new surgical hand rubs have become available that are much more rapid and effective than traditional soap and water methods[1].

However, is alcohol as a surgical scrubbing product enough? In the same way that additional antimicrobial agents were added to traditional soap and water for surgical scrubbing in the past (i.e. CHG, Iodophores, Tricolsan), the same applies to surgical hand rubs.
Although an excellent rapid antimicrobial, alcohol, simply put, has no persistence. With a significant proportion of surgical procedures lasting over 2 hours, this can create issues and the need for persistency in a surgical procedure is paramount. Microbial growth is generally accelerated due to the moisture and warmth. As such, the environment inside a set of gloves during a long procedure is perfect for microbial growth. According to the WHO, “18% (range: 5–82%) of gloves have tiny punctures after surgery, and more than 80% of such cases go unnoticed by the surgeon. After two hours of surgery, 35% of all gloves demonstrate puncture, thus allowing water (hence also body fluids) to penetrate the gloves without using pressure”[2].
Even if you double glove during a surgical procedure, again according to the WHO “Double gloving decreases the risk of puncture during surgery, but punctures are nevertheless still observed in 4% after the procedure. In addition, even unused gloves do not fully prevent bacterial contamination of hands”

If we look closer to home, PIDAC states “Due to the rapid multiplication of bacteria under surgical gloves and the high percentage of glove punctures found after surgery, a hand hygiene product with a prolonged antiseptic effect on the skin is desirable. In an operative setting, an alcohol-based hand rub (surgical hand rub) or an antimicrobial soap (surgical hand scrub) with persistent activity should be used.”[1] Most bodies (WHO, CDC, PIDAC, AORN) currently agree that due to the strong documentation and clinical support, the need for a persistent agent like CHG in a surgical scrub is important.

Consider the question like this: Would you use a regular soap instead of an antimicrobial one during a surgical scrub? Then why would you use an alcohol only product?



1. Best Practices for Hand Hygiene in all Health Care Settings, Provincial Infectious Diseases Advisory Committee (PIDAC) Ministry of Health and Long-Term Care, May, 2008.
2. WHO Guideline on Hand Hygiene in Health Care (Advanced Draft) 2006

A guide to choosing the right antimicrobial

In the healthcare system, there are various different antimicrobials available. In terms of the most common (in descending order) we have:

Alcohol
Iodohpores
Chlorhexidine Gluconate
Triclosan
Parachlorometaxylenol (PCMX)
Quaternary Ammonium Compounds

Alcohol works through the denaturing of proteins. Alcohol needs water in order to be effective, which is why you will not often see alcohol in concentrations higher than 80 or 90%. Alcohol can also be very drying to the skin, so lower concentrations are often chosen for patient comfort. Iodophores work through free iodine substitution. You will often see the % free iodine listed on the products label. If the % free iodine is too high, this can lead to incidences of irritation or in the extreme chemical burns. Iodine will continue to work as along as it is in contact with the patient's skin. It is highly soluble and can be easily rinsed away. The general rule of thumb for an iodophore is, if you can no longer see it, it is no longer effective. CHG works through the disruption of cellular membrane. CHG's true power is in its ability to bind to the skin surface. This gives it excellent persistent characteristics, but also gives it the ability to accumulate after repeated uses, increasing its effectiveness. It is, however, toxic to the meninges and should be avoided in these cases. Triclosan is a very ubiquitous agent used widely commercially as well as in health care facilities. It is a less effective agent than either iodophores or CHG.[1] PCMX is an alternative option that is used infrequently. Studies are ongoing to determine the efficacy and safety of the product. Quaternary Ammonium Compounds are not commonly used and are formulation and concentration specific.

[1] WHO Guidelines on Hand Hygiene in Health Care (Advanced Draft) 2006

Below is a table from AORN that summarizes some of this info.

Antiseptic Agent	Mechanism of action	Gram + bacteria	Gram – bacteria	Viruses	Rapidity of Action
Alcohol	Denatures Protein	Excellent	Excellent	Good	Excellent
CHG	Disrupts Cell Membrane	Excellent	Good	Good	Moderate
Povidone – Iodine	Oxidation / substitution with free iodine	Excellent	Good	Good	Moderate
CHG with Alcohol	Disrupts Cell Membrane and Denatures Protein	Excellent	Excellent	Good	Excellent
Iodphore with Alcohol	Oxidation / substitution with free iodine and Denatures Protein	Excellent	Excellent	Good	Excellent

(continued on next page)

(continued from previous page)

Antiseptic Agent	Persistent / residual activity	Use on Eye or ear	Use on mucose membrane	Contra-indications	Caution
Alcohol	None	No. Can cause corneal damage or nerve damage	No		Flammable. Does not penetrate organic material. Optimum concentration is 60%to 90%
CHG	Excellent	No. Can cause corneal damage. Can cause deafness if in contact with inner ear.	Use with Caution	Known hypersensitivity to drug or any ingredient. Lumbar puncture and use on meninges	Prolonged skin contact may cause irritation in sensitive individuals. Rare severe hypersensitivity reactions have been reported. Use with caution on mucous membranes.
Povidone – Iodine	Minimal	Yes. Moderate ocular irritant.	Yes	Sensitivity to povidone-iodine. (Shellfish allergies are not a contraindication).	Prolonged skin contact may cause irritation. May cause iodism in susceptible individuals; avoid use in neonates. Inactivated by blood.
CHG with Alcohol	Excellent	No. Can cause corneal damage. Can cause deafness if in contact with inner ear.	No	Known hypersensitivity to drug or any ingredient. Lumbar puncture and use on meninges.	Flammable.
Iodophore with Alcohol	Moderate	No. Can cause corneal damage or nerve damage	No	Sensitivity to povidone-iodine. (Shellfish allergies are not a contraindication.)	Flammable.

Additionally for the lesser used compounds:

Agent	Rapidity of Action	Persistence	Breadth of Spectrum
Parachlorometaxylenol (PCMX)	Intermediate	Low	TBD
Quaternary Ammonium Compounds	Intermediate	TBD	TBD
Triclosan	Intermediate	High	Medium Breadth

page)

You can't argue with the facts.

Using the 3M Clip, Prep, Drape system can help improve patient outcomes

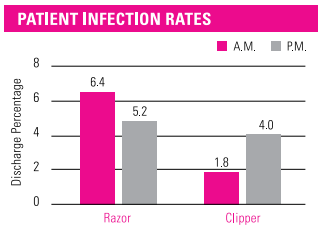
Fact #1: Treating Healthcare Associated Infections

A Canadian study reports that for each case of wound care infection hospitals spend an average of $3937 treating it.[1] (SSI) cost more than preventing them.

Fact #2: Clipping is far superior to shaving.

Clinical evidence proves that as a method of pre-op body hair removal, clipping hair with surgical clippers is far superior to shaving.[2] Shaving can produce cuts, nicks and microscopic epidermal injury which can provide a prime site for bacterial infection.

3M™ Surgical Clippers



Fact #3: One-third of all Healthcare Associated

Infections can be prevented.[3] 3M™ Surgical Clippers, 3M™ DuraPrep™ Surgical Solution and 3M™ Ioban™ Antimicrobial Incise Drapes are all proven to control skin bacteria. And with a strong correlation between bacterial colonization and surgical site infection,[4] controlling skin bacteria becomes of paramount importance.

Fact #4: Skin preps that go on fast and kill fast save you time and money.

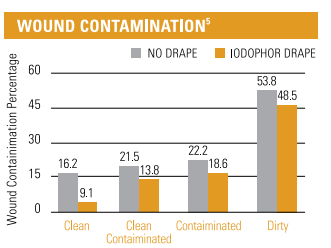
The ORNAC, AORN and CDC recommend preoperative skin preps that are fast-acting, broad spectrum and provide residual action. In addition, 3M™ DuraPrep™ Surgical Solution provides another important difference – it requires less time to apply than traditional scrub and paint. That means with today's high operating costs, less prep time is money saved.

3M™ DuraPrep™ Surgical Solution

Fact #5: Using the right incise drapes makes a clinical difference.

Even with the most careful and rigorous disinfection, bacteria remaining on the skin or regrowth during surgery can still contaminate the surgical site. 3M™ Ioban™ Incise Drapes help to eliminate this problem because they provide continuous antimicrobial activity and a sterile barrier..

3M™ Ioban™ Antimicrobial Incise Drapes



[1] Zoutman, D., McDonald, S., & Vethanayagan, D. (1998) Total and attributable costs of surgical-wound infections at a Canadian tertiary-care centre. Infection Control and Hospital Epidemiology: The Official Journal of the society of Hospital Epidemiologists of America, 19, 254-259. [2]Alexander, J.W., Fischer, J.E., Boyajian, M., et al: The influence of hair-removal methods on wound infections. Archives of Surgery 1983: 118:347-352. [3]Jarvis, W.R. 1996. Selected aspects of the socioeconomic impactof nosocomial infections: morbidity, mortality, cost and prevention. Infection Control and Hospital Epidemiology. 17:552-557.
[4] Garibaldi, R.A., Cushing, D. and Lerer, T. 1991. Risk factors for postoperative infection.American Journal of Medicine,1991, (Suppl 3B): 158S-163S.

Infection Prevention Solutions

Sales Representative Contact List

British Columbia:
Sterilization Specialist
Bruce Billett
778 772 3710

Perioperative Specialist
Anita Veri
800-265-1840 ext 7424

Alberta:
Sterilization Specialist
Tyler Nicholetts
800 265 1840 x7494

Perioperative Specialist
Brent Christensen
800 265 1840 x7457

Manitoba
Infection Prevention Solutions Specialist
Jeffery Palmer
204-250-4004

Ontario:
Toronto West
Infection Prevention Solutions Specialist
Jamie Hollingsworth
800 265 1840 x3805

Downtown Toronto/East Toronto
Preoperative Specialist
Carol Norrish
800 265 1840 x3806

Sterilization Specialist
Chris Collins
800 265 1840 x 3834

Southwestern Ontario
Sterilization Specialist
Christine Broomfield
800 265 1840 x3784

Southwestern Ontario
Perioperative Specialist
Jodie Allen
800 265 1840 x2363

Ottawa/Northern Ontario
Infection Prevention Solutions Specialist
Lyne Taylor
800 265 1840 x3817

Quebec:
Northern Quebec
Infection Prevention Solutions Specialist
Josee Letourneau
800 265 1840 x4757

Montreal/Southern Quebec
Perioperative Specialist
Sylvain Roy
800 265 1840 x4767

Montreal/Southern Quebec
Sterilization Specialist
Christian Gagner
800 265 1840 x4595

Maritimes
Infection Prevention Solutions Specialist
Larry Corscadden
506 459 5550

Your story ideas are always welcome!
Please send your comments, questions and suggestions to: 3MIPSNewsletter@mmm.com