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Monitoring Frequency Guide for Steam Sterilization

Process	Standard Rationale	Standard Frequency	3M Core 4 Product
Equipment Monitoring	10.7.6.1 "*Rationale*: A Bowie-Dick test is conducted every day, before the first processed load, because it is a sensitive and rapid means of detecting air leaks, inadequate air removal, inadequate steam penetration, and noncondensable gases (e.g., air or gas from boiler additives). Insufficient air removal in a dynamic-air-removal sterilizer, particularly a prevacuum cycle, can defeat sterilization and result in nonsterile supplies if undetected. An improperly heated sterilizer could cause false Bowie-Dick test failures. The test is conducted at the same time every day because standardization of the testing procedure reduces the opportunity for error..."[1]	Should be used daily before the first processed load. After installation, relocation, malfunctions and major repairs. After sterilization process failures.	**1 3M™ Comply™ Bowie-Dick Plus Test Pack 00135LF**  Lead Free
Load Monitoring	10.5.3.2 "*Rationale*: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs. In addition, Garner and Favero (1985) and CDC (2003a) recommend routine biological monitoring of sterilizer efficacy. Although the performance of Class 5 integrating CIs has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide additional information about the attainment of the critical parameters of the sterilization process..."[1] 10.6.1 "*Rationale*: ...With respect to implantable devices, biological monitoring is necessary to provide optimal sterility assurance (see also 10.6.3). A Class 5 CI should be included with the BI in the PCD so that if an implant must be released on an emergency basis, additional information about the critical parameters of the sterilization process will be available and documented."[1]	Preferably daily + all loads containing implants which "should be quarantined until the results of the BI testing are available (10.6.3)."[1]	**2 3M™ Attest™ Super Rapid 5 Steam-Plus Challenge Pack 41482V, 41482VF***  **OR** **3M™ Attest™ Rapid 5 Steam-Plus Test Pack 41382, 41382F*** 
Pack Monitoring	10.5.2.1 "Chemical indicators assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile. The use of CIs is part of an effective quality assurance program; they should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process."[1]	Should be used within each pack, tray, rigid container and peel pouch.	**3 3M™ Comply™ (SteriGage™) Chemical Integrator 1243** 
Exposure Monitoring	10.5.2.2.1 "To distinguish between processed and unprocessed items, a process indicator (Class 1 CI), in the form of sterilizer indicator tape, an indicating label, or an indicating printed legend, should be affixed to or printed on each hospital assembled package or rigid sterilization container system intended for sterilization..." "*Rationale*: The purpose of an external CI is to differentiate between processed and unprocessed items, not to establish whether the parameters for adequate sterilization were met."[1]	Should be used on every hospital assembled package or rigid sterilization container system.	**4 3M™ Comply™ Lead Free Steam Indicator Tapes 1322 and 1355 Series**** 

1. All rationale from Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* ANSI/AAMI ST79 A1:2010 & A2:2011 & A3:2012 & A4:2013 (Consolidated text).

* These 3M™ Attest™ pre-assembled packs are equivalent in challenge to the user-assembled biological indicator challenge test pack (16 towel PCD) recommended by AAMI to monitor sterilizers larger than 2 cubic feet.

** Indicator tape is designed to secure wrapped packs.

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