TECHNICAL SERVICES

DELAYED PLANNED MAINTENANCE (PM)

ARE YOU ASSUMING UNNECESSARY RISK?

When you invest in new medical devices or sterilization equipment, it is important that you keep up with the manufacturer's recommended PM schedule to maintain your investment over the life of the equipment. Who is responsible for this? According to various associations and organizations, healthcare facilities are responsible for maintaining, inspecting, and testing all medical equipment critical to patient care.

Best practice is established by quality, standards, and government organizations like the Association for the Advancement of Medical Instruments (AAMI), the Centers for Medicare/Medicaid Services (CMS) and the Food and Drug Administration (FDA); as well as professional associations like the Association for peri-Operative Registered Nurses (AORN), and the International Association of Healthcare Center Service Materials Management (IAHCSMM) that recommend you follow the manufacturer's instructions for use (IFU) for maintenance. The Joint Commission surveys accredited hospitals to determine compliance with many of these organizations' standards, as well as consultation with competency guidelines from professional organizations.

Performing planned maintenance at scheduled intervals

- Reduces costly interruptions to your facility
- Maintains the integrity of your capital equipment warranty
- Regular maintenance helps to extend the life of your equipment
- Helps you meet standards, regulations, and best clinical practice
- Provides the safest environments for both staff and patients

Following the original device manufacturer's recommended PM schedule is critical to ensuring your equipment is functioning properly. A thorough planned maintenance program is essential to safe and proper equipment operation. Comprehensive instructions for planned maintenance can be found in the Maintenance Manuals from ASP.

Only ASP-trained personnel should attempt to perform maintenance on the EVOTECH® ECR and STERRAD® Systems family of low-temperature gas plasma sterilizers. This will avoid personal injury, improper equipment performance, and invalidation of the warranty or other costly damage. Under our service contracts, planned maintenance, adjustments and replacement of worn parts are provided on a scheduled basis. This helps to ensure optimal equipment performance and helps to minimize untimely or costly interruptions for your facility.

ORGANIZATIONAL PM BEST PRACTICES LISTED ON BACK

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Standards and Competency Guidelines include the following:

- **AAMI News: February 2013, Vol. 47, No. 2**
  In the memo distributed to state survey directors, CMS stated that hospitals must follow the manufacturer-recommended planned maintenance (PM) frequencies for any "critical" equipment.
- **AORN 2009 Edition, RP: Sterilization Recommendation VI.a**
  The sterilizer manufacturer's written instructions for use, monitoring, and maintenance should be followed when using a low-temperature hydrogen peroxide gas plasma sterilization system. (PNDS: 175, 198, I122)
- **IAHCSMM Central Service Leadership Manual 2010 (page 419-420)**
  Sterilizer maintenance records in paper or electronic format are required for each sterilizer. The maintenance record should include sufficient information to identify the equipment and to establish a continuous history of all scheduled and unscheduled service.
- **ANSI/AAMI ST58: Chemical sterilization and high-level disinfection in healthcare facilities**
  - **10.4 Implementation of product and process improvements.** The CQI program should assess all components of chemical sterilization and high-level disinfection processes for the ongoing ability to achieve the desired outcome of consistently delivering an efficacious product to the user.
    - Timing and completeness of planned maintenance of gaseous chemical sterilizers and automated processing equipment.
- **ST79: AAMI's Landmark Recommended Practice for Hospital Steam Sterilization**
  - **9.5.2 Scheduled Maintenance** Lubrication of appropriate parts and replacement of expendable parts, such as steam traps, should be performed as needed by qualified personnel. Certain maintenance tasks that require special tools or calibration equipment not available in the healthcare facility should be performed by the manufacturer, the manufacturer's representative, or another qualified service provider. The frequency of maintenance depends on how often the equipment is used and might vary from facility to facility; the manufacturer's written instructions for use (IFU) should be consulted for guidance.
  - **12.3.1 Planned Maintenance** shall be planned and performed in accordance with documented procedures. The procedure for each planned maintenance task and the frequency at which it is to be carried out shall be specified. Records of maintenance shall be retained (see 4.1.2).
  - **Technical Information Report: 6 Sterilization:** 6.1 "Healthcare personnel should follow regular and documented planned maintenance and calibration programs for the equipment used in sterilization.

CMS Office of Clinical Standards and Quality/ Survey & Certification Group
(December 2, 2011, http://ohiocea.files.wordpress.com/2011/12/scletter12_07.pdf)
Manufacturer-recommended maintenance frequency is required for:

1. All equipment critical to patient health and safety; and
2. Any new equipment, until a sufficient amount of maintenance history has been acquired. Alternative equipment maintenance methods are not permitted. Hospitals must continue to follow the manufacturer's recommended techniques for maintaining equipment, even if they alter the frequency of maintenance activities.

ADVANCED STERILIZATION PRODUCTS

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