AEROFLEX™

AUTOMATIC ASSURANCE THROUGH ASP AEROFLEX™ AER WITH AUTOSURE™ MRC MONITOR

ASP AEROFLEX™ Automatic Endoscope Reprocessor (AER) with AUTOSURE™ MRC May Monitor Enhances Compliance and Reduces Patient Risk Associated with Test Strip Errors[2]

Abstract:

Reprocessing flexible endoscopes in today's fast-paced clinical environment demands consistent, effective high-level disinfection (HLD) using automated endoscope reprocessors (AERs). Yet, despite advancements in technology over the last decade, AER operators are still required to manually test biocide minimum recommended concentration (MRC) levels during every cycle using a test strip. With the introduction of the ASP AEROFLEX™ AER with AUTOSURE™ MRC Monitor, automatic MRC testing for every cycle is a standard feature, designed to increase compliance and patient safety and reduce the risk of healthcare-acquired infections during endoscopy procedures. The AUTOSURE™ MRC Monitor is a automated concentration measurement system grounded in mature chemistry and colorimetry; a summary technical explanation is presented in this document.

Endoscopy centers have become laser-focused on keeping procedure rooms fully scheduled to maximize the useof resources and patient throughput. This has a ripple effect throughout the chain of support services which enable supplies, capital equipment and instruments to be ready and available when the patient and physician are scheduled for an endoscopy procedure. This is in no small part due to the rapid rise in endoscopy procedure volumes over the past several years.[3] According to a study published by iData in 2019, there were 31 million GI endoscopy procedures performed in the United States alone in 2018[4], and there is every reason to expect continued procedure growth over the next 2-3 years.

This rise in endoscope use places strain on an already challenged reprocessing environment, where pressure to increase volumes of scopes prepared for the next procedure invites compromises in manual cleaning and disinfection procedures, which has been well documented in recent peer-reviewed research.[5]

To meet the increased procedure demand, endoscopy centers have responded with investment in tools and staff to manage the expanding workload, and the AER is playing a tireless role in ensuring endoscopes are available and properly disinfected as needed.

PROPER BIOCIDE CONCENTRATION IS CRITICAL TO **AER PERFORMANCE & PATIENT SAFETY**

Critical to the effectiveness of AERs is the assurance that the concentration level of the biocide (high-level disinfectant) is adequate to achieve high-level disinfection in every cycle. Many AERs reuse the biocide for multiple cycles and after each cycle, the biocide's effectiveness is reduced to a varying degree, depending in part on microbial and organic matter loads present on the scopes being reprocessed.[17] It is also critical to monitor the biocide concentration for every cycle in AERs using single-use biocides since concentration levels may diminish in these systems as well. As a result, manufacturers' Instructions for Use (IFUs) for single and multiple use biocides recommend MRC testing for every cycle.

"Reprocessing failures can have dire consequences for patients, and infections have been associated with ureteroscopes, cystoscopes, bronchoscopes, colonoscopes, gastroscopes, and duodenoscopes."[2]

- CORI OFSTEAD, MSPH -
AMERICAN JOURNAL OF INFECTION CONTROL

If the biocide concentration level falls below the amount necessary to kill or inactivate microorganisms that are present on the scope, there can be a failure in the AER's high-level disinfecting process. If this occurs, the biocide is said to have fallen below its Minimum Recommended Concentration (MRC). Minimum Effective Concentration (MEC) and MRC are sometimes used interchangeably.

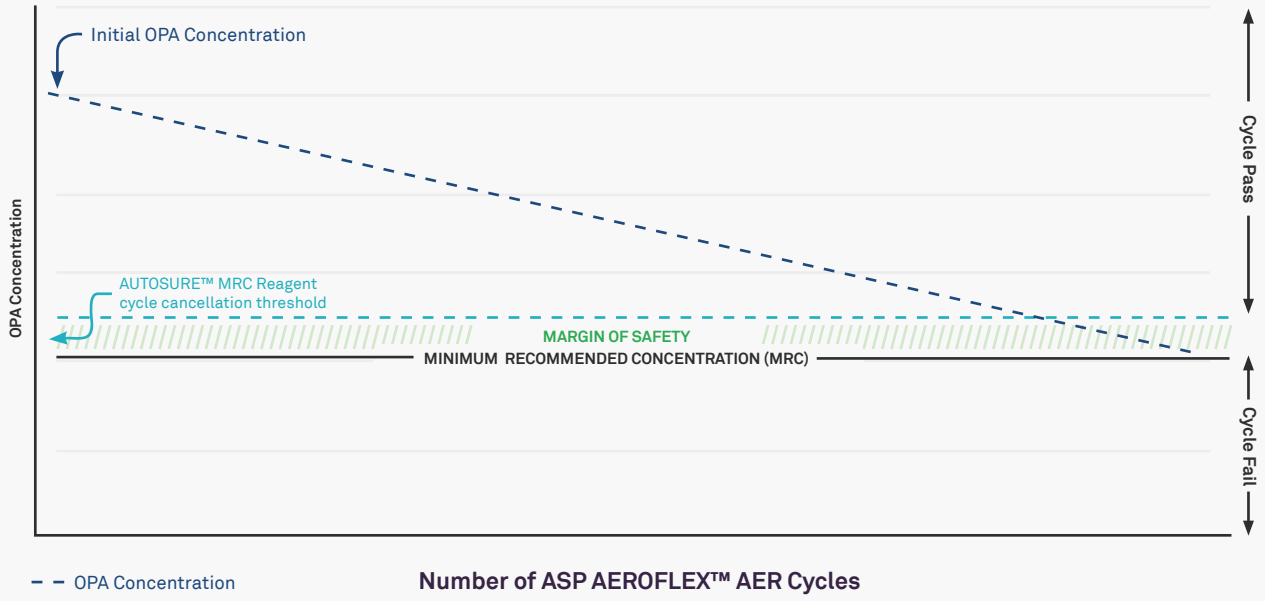
The risks associated with biocide failure in the reprocessing of flexible endoscopes are significant. A review of FDA and CMS reports reveals non-compliance with proper MEC testing protocols have negatively impacted patient outcomes[2], while additional studies have found that GI endoscopy is an important risk factor for the transmission of Carbapenem-resistant Enterobacteriaceae (CRE) and related superbugs.[6,7] Eliminating potential threats to successful flexible endoscope reprocessing remains a top priority.

A WEAK LINK IN AUTOMATIC ENDOSCOPE REPROCESSORS: MANUAL MRC MONITORING WITH TEST STRIPS

While endoscopy procedure volume growth has prompted the purchase and use of more AERs, almost all AERs lack the ability to automatically test and track one of the most important variables in the HLD process: MRC monitoring. Other than the ASP AEROFLEX™ AER, the nearly universal method for MRC monitoring is the test strip, a chemical indicator that changes color in accordance with whether the concentration of biocide has crossed the MRC threshold. Chemical indicator test strips have been in use since the 1950s for a variety of purposes, and in this case, they represent a weak link in the chain of requirements for consistent high-level disinfection of endoscopes. This is because with most AERs, MRC monitoring with a test strip is a step that can be easily missed or done incorrectly. Further, MRC test strips rely on regular staff interaction with the biocide, only deliver a pass/fail result (thus lacking the ability to rate concentration in levels or degrees), are susceptible to subjective interpretation by the AER operator, and provide no record of their correct use.

THE ASP AEROFLEX™ AER ADDED MARGIN OF SAFETY

ASP AERO-OPA™ *ortho*-Phthalaldehyde Solution Concentration VS MRC



NON-ADHERENCE TO MRC TESTING IS WIDESPREAD & PUTS PATIENTS AT RISK[2]

Professional society guidelines for endoscope reprocessing suggest testing biocide MRC during each use (AAMI ST91, AORN 2018), and following HLD manufacturers' IFUs which also recommend testing during each use as referenced above (AAMI ST91, SGNA 2018, AORN 2018)[8,9,10.]

> **"Wherever patient care is provided, strict adherence to evidence-based infection prevention guidelines is essential to ensure that all care is safe care."[16]**
>
> - CORI OFSTEAD, MSPH -
> AMERICAN JOURNAL OF INFECTION CONTROL

Yet, even with clear standards in place, test strip monitoring compliance in the absence of automatic MRC monitoring has been very inconsistent. According to a study commissioned by Advanced Sterilization Products (data collected independently by a 3rd party and blinded with respect to the sponsor) only 47% of US AER operators surveyed indicated they manually check MRC levels before each cycle.[11] A survey of IAHCSMM members in 2019 indicated that 21% did not test MRC every cycle, and that 49% did not document MRC test results.[2]

In their ground-breaking research study published in the American Journal of Infection Control, Ofstead & Associates identified several factors negatively impacting compliance including complex IFUs and inadequate training, time pressure and workflow impact, and occupational health concerns related to interacting with biocides.[2]

Adding to the difficulties associated with manual MRC monitoring is the lack of an electronic record of the task. The MRC test strip yields only a small patch of color change on a piece of paper which must be interpreted by an operator at an exact time interval to ensure an accurate result. Upon this manual reading rests the entire decision to reuse or replace the AER's biocide. And finally, these test results must be recorded manually by the technician to ensure compliance with guidlines.[12]

Table 1 below represents the major steps required for successful use of test strips for MRC monitoring[13].
There are many opportunities to skip steps or perform steps incorrectly, potentially putting patients at risk of infection.

PROCESS STEPS REQUIRED FOR TEST STRIP USE	POTENTIAL CHALLENGES
Use a test strip to measure biocide MRC.	The operator might not perform this step.
Remove one test strip from the bottle and replace the bottle cap immediately.	The operator may not replace the bottle cap immediately.
Use a watch or timer to monitor the following steps.	The operator may not use a watch or timer correctly or monitor the steps closely due to human factors.
Timing control may be critical to accurate reading.	The operator may not read the timer accurately.
Completely submerge, hold for specified period of time and remove.	The operator may not submerge the test strip completely or for the correct amount of time required.
Do not leave the strip in the test solution for longer than the specified time period or "stir" the test strip in the solution.	The operator may leave the test strip in the solution for more than the specified time period or stir the test strip in the solution.
Remove excess solution by standing the strip upright on a paper towel.	The operator may leave excess solution on the test strip.
Do not shake the strip after removal.	The operator may shake the strip after removal.
Read at a specified time period after the test strip is removed from the solution. If less than the specified time, the color change may be incomplete; if more, the color will gradually change to indicate fail.	The operator may not read the test strip at the specified time after removal. The operator must interpret the color change.

According to Rutala and Weber, the margin for error with high-level disinfection is not large enough to tolerate any deviations from optimal practices.[14]

ASP AEROFLEX™

INTRODUCING THE AUTOSURE™ MRC MONITOR: AUTOMATIC MONITORING IS AUTOMATIC PEACE OF MIND

Automated MRC testing is available today through the ASP AEROFLEX™ AER with AUTOSURE™ MRC Monitor. The AUTOSURE™ MRC Monitor is a patent-pending process[15] that is sensitive, accurate and repeatable, delivered through an effective combination of mature chemistry and colorimetry. It provides reliable concentration monitoring of the active ingredient in the biocide, ASP AERO-OPA™ Ortho-Phthalaldehyde Solution, during every cycle.

The AUTOSURE™ MRC Monitor is an effective combination of mature chemistry and colorimetry.

AN INNOVATIVE AUTOMATIC MRC TEST

The test for concentration is a simple, automation-controlled process:

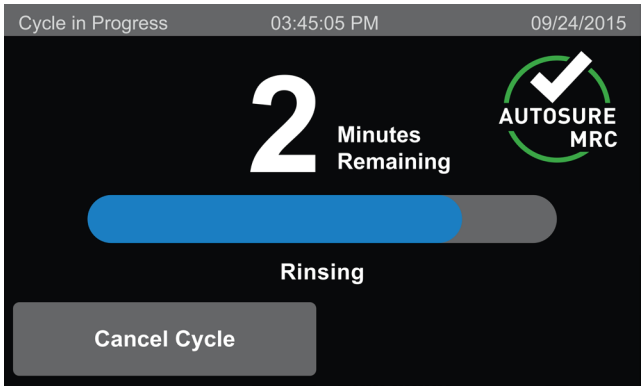
1. A small, specific volume of ASP AERO-OPA™ Ortho Phthalaldehyde Solution is automatically drawn into the AUTOSURE™ MRC Monitor during the disinfection cycle and mixed with a small, exact amount of a specially designed test reagent.

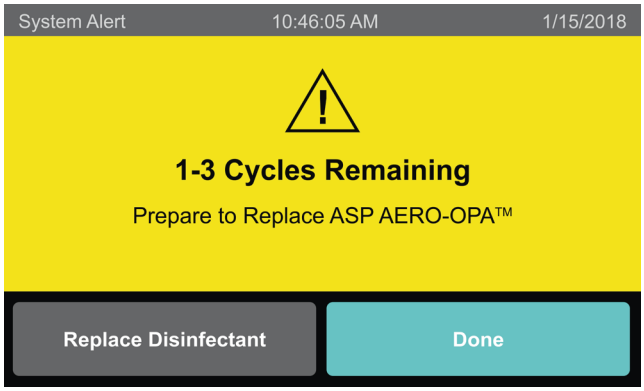
2. The test reagent reacts with the ASP AERO-OPA™ Ortho Phthalaldehyde Solution and creates a color with a darkness (or absorbance) related to the OPA concentration.

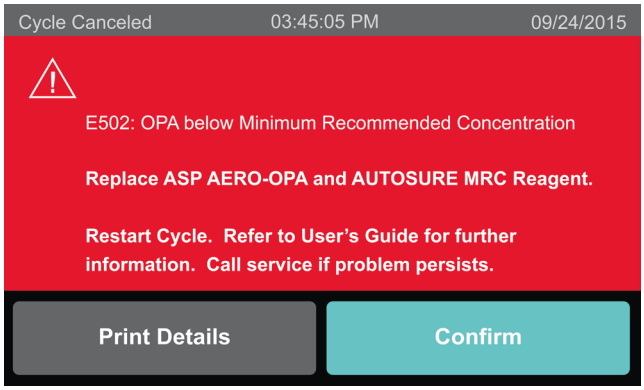
3. The color is quantitatively measured as an absorbance to determine the Ortho-Phthalaldehyde concentration of the sample by shining a light through it and detecting the intensity of light that passes through on the other side. This use of color and light intensity to determine concentration is commonly used by analytical instruments, making this MRC automated test a simple, novel and reliable way to be assured the ASP AEROFLEX™ AER will accurately measure MRC levels for patient-safe endoscopes, every time.

TURNING A COLOR INTO COMPUTER READABLE DATA: COLORIMETRY

Relying on the color of a solution to accurately determine its concentration is a time-tested method of determining the concentration of a chemical in solution. The process of measuring the color is colorimetric, using a simple photodiode. Colorimetry is used in many laboratory instrument applications to sense the depth and presence of color of a solution and convert that information into a signal that can be interpreted by the instrument's logic and software. It is the measurement of color and a resulting value corresponding with the above logic that triggers the display to show the concentration is adequate (pass), should be changed in the next 1-3 cycles (pass with condition), or should be changed immediately (fail).







ASP AEROFLEX™

AUTOSURE™ MRC MONITOR MEANS AUTO-ASSURANCE

The innovative AUTOSURE™ MRC Monitor is available exclusively on the ASP AEROFLEX™ AER and solves two critically-important issues faced by many GI labs; consistent, accurate MRC testing and record keeping which ensures high-level disinfection and documentation compliance for every patient, every cycle.

IN SUMMARY, THE EXCLUSIVE AUTOSURE™ MRC MONITOR REDUCES THE OPPORTUNITY FOR HUMAN ERRORS RELATED TO MANUAL TEST STRIP USE.

- REDUCES PATIENT RISK ASSOCIATED WITH TEST STRIP ERRORS[2]
- MRC TESTING CAN'T BE SKIPPED
- ENSURES BIOCIDE IS ABOVE MRC EVERY CYCLE
- CYCLE WON'T START IF BIOCIDE DOESN'T MEET MRC
- ALWAYS USES VALIDATED CHEMISTRY
- REDUCES STAFF EXPOSURE TO CHEMICALS
- SAVES TIME AND COST ASSOCIATED WITH MANUAL TEST STRIP USE

ENDOSCOPY MANAGERS AND TECHNICIANS CAN NOW CHOOSE THE ASP AEROFLEX™ AER WITH AUTOSURE™ MRC MONITOR AND ENJOY THE PEACE OF MIND THAT COMES WITH KNOWING THAT COMPLIANCE-MANDATED MRC TESTING AND RECORD KEEPING HAVE NOW BEEN SWITCHED FROM MANUAL TO AUTOMATIC.

REFERENCES

1. ASP AEROFLEX™ AER with AUTOSURE MRC™ Monitor may enhance compliance to ASP AERO-OPA™ ortho-Phthalaldehyde and ASP AEROFLEX™ AER instructions for use (IFU), professional society guidelines for endoscope reprocessing, healthcare facility policies and procedures for endoscope reprocessing and government and local environmental regulations for chemical disposal. ASP AEROFLEX™ AER with AUTOSURE MRC™ Monitor may enhance compliance through automated features for HLD minimum recommended concentration (MRC) testing, verified chemistry confirmation, endoscope reprocessing record keeping and neutralization of ASP AERO-OPA™ ortho-Phthalaldehyde before disposal. 2. C.L. Ofstead et al. / American Journal of Infection Control (2019) 1–7, Accessed 12/12/2019 www.ajicjournal.org/article/S0196-6553(19)30849-1/fulltext 3. Everhart JE. The burden of digestive disease in the United States. U.S. Department of Health and Human Services 2008: NIH Publication No. 09-6443. 4. iData Corp., 2019 Gastrointestinal Endoscopic Devices Market Analysis, Size, Trends, United States, 2019-2025, MedSuite 5. Ofstead, Cori L., MSPH, et Al. Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation. Gastroenterology Nursing, Volume 33 | Number 4 | July/August 2010 6. Rutala et al., 2008; ASGE Standards of Practice Committee et al., 2008; AAMI, 2010 7. Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related "superbugs" during gastrointestinal endoscopy. World J Gastrointest Endosc 2014; 6: 457-474 8. Association for the Advancement of Medical Instrumentation (AAMI) ST91 Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities, 2017 9. The Society of Gastrointestinal Nurses and Associates, Inc. (SGNA) Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes, November 2018 10. Association of periOperative Registered Nurses (AORN), Guideline for Processing Flexible Endoscopes, VI.c.1, 2018. 11. Advanced Sterilization Products, ASP™ Endoscope Reprocessing Concept Test Report, April 2018 12. The Joint Commission (TJC) The High-Level Disinfection (HLD) and Sterilization BoosterPak, 2017 13. ASP™ Report Doc. No.: TR-21134 Rev. A (11/18 AEROFLEX™ MRC System. December 14, 2018) 14. Rutala WA, Weber DJ. Reprocessing semicritical items: current issues and new technologies. American Journal of Infection Control 2016;44:e53-62. 15. Yan Fang, Nick N. Nguyen, Kaitao Lu, Inventor; Ethicon, Inc., Assignee; Apparatus and method to measure concentration of disinfectant in medical device reprocessing system, US Patent Pending https://patents.google.com/patent/US20170333584A1/en Accessed 01/28/2020 16. https://disinfectionandsterilization.org/ Accessed 01082020 17. The Society of Gastrointestinal Nurses and Associates, Inc. (SGNA) Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes, 2013

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Protecting patients during their most critical moments

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For further information, please contact your local sales representative or visit asp.com/emea
Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, warnings and precautions.
ASP AEROFLEX™ AER is not available in all EMEA countries.

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