

High-Level Disinfection Chemistry

Single-Use vs Reusable

SINGLE-USE		REUSABLE	
+	No change-out of the bottle after a period of days; 14, 21, 28 or whatever the preferred brand's IFU indicates as the shelf life once opened	-	Requirement to change out the bottle when indicated by the manufacturer's IFU
+	No disposal of HLD at the conclusion of the 14, 21, 28 day shelf life as with single use automated devices the chemical is pumped to waste at the end of each disinfection	-	Varying IFU's by manufacturer and type of chemical that state end of useful life
+	No MRC validation required with a test strip— simply use before expiration date on the bottle	-	Test Strips <ul style="list-style-type: none"> • Does the technician have them and are they the correct brand or type? • Have they been stored properly? • Will the technician use them and if so, correctly per training?
+	No debris or ultrasound gels being returned to the bottle and mixing with the HLD	-	Potential for debris and ultrasound gels to enter into the reuse container—what effect could this have on the MRC, overall chemistry or useful life

FDA observations as reported by healthcare facilities:

The MAUDE (Manufacturer and User Facility Device Experience, www.accessdata.fda.gov) database has numerous instances over the last 24 months in which healthcare workers have used reusable high-level disinfectant beyond the expiration date and have not used test strips properly or at all to validate the MRC. Additionally, if they did use the test strip, they simply continued to perform the high-level disinfection without the correct MRC of the disinfectant.

Potential Causes:

Potential causes include staff turnover, demand on staff to turn dirty instruments quickly, the lack of standardized training on every brand of high-level disinfectant, unclear IFU from manufacturer.

The variety of high-level disinfectant options to the consumer will only lead to continued confusion and mistakes within the central services department at healthcare facilities.



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