



How to correctly select a Cleaning Indicator

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It is vital to control the cleaning processes of medical instruments and materials, since the result influences the success of the subsequent processes for sterilization and/or disinfection. This control is crucial, particularly in automatic washing machines. The process parameters in automatized equipment may deviate from the acceptable limits and alter the cleaning performance.

The cleaning process must be monitored through the use of a cleaning process indicator, which can consist of different kinds of artificial test soils. The international Standards ISO 15883 (part 1 and 5), HTM-01 (part 01 and 05) and ANSI/AAMI (ST79:2017) require the monitoring of this process with a specific regime, through weekly or even daily check-ups.

Standard ISO 15883, in its 5th part, enumerates 19 types of different test soils that can be used in the validation process of thermal washer

disinfectors, but, until now, it has not been possible to establish a unique test soil that complies with the different cleaning requisites from all various medical devices.

The great variety of medical instruments (orthopedic, gynecologic, urologic, dental, neurosurgical, etc.), which vary in both its shape and in the material they are made of, as well as the different types of dirt that contaminate them, force us to use different cleaning procedures and equipment.

Residues such as blood, bone remains, cement and mucosa have different adhesion and composition characteristics. Therefore, they require the use of different cleaning programs and types of detergents for their correct removal. These programs differ, for example, in time and temperature and use different types of detergents, such as enzymatic, alkaline or non-ionic.

There are various «surrogate» cleaning indicators in the market to be used in the routine cleaning control. An optimal cleaning control indicator must be:

FAST | EASY TO USE & INTERPRET | SENSITIVE | ACCURATE | REPRODUCIBLE | ROBUST

Besides, it must have the following characteristics:

1. It should be completely washed if the cleaning process has been satisfactory.
2. It should not be washed in the event that any critical parameter of the cleaning process fails. For example: insufficient exposure time, incorrect detergent doses, low water quality, inappropriate temperature, etc.
3. It should not generate dangerous waste, such as blood derivatives or bacterial inoculum.

In order to select an adequate cleaning indicator that complies with these characteristics, different indicators must be tested, which should have different adhesion characteristics and represent a challenge to simulate the real instruments that will be washed in that reprocessing material center.



Terragene® offers cleaning indicators with two different levels of challenge: Chemdye® Splat CDWA3 and Chemdye® Splat CDWA4, with high and very high levels of challenge, respectively. Splat indicators consist of a synthetic substrate printed with an ink completely made of natural colored substances (proteins, carbohydrates, fatty acids).

In both cases, the indicator's test soil is not toxic, it dissolves easily and is swept along by the washing fluid. The Splat cleaning indicators' formulation allows to monitor all the factors that may affect the result of a cleaning process, both in thermal washer disinfectors and in ultrasonic washing machines.

Chemdye® Splat indicators are used along with

Chemdye® Splat CDWAH holder when used in thermal washer disinfectors, or with CDWAH-U, a special version of holder, for ultrasonic washing machines (Fig. 1). CDWAH holder was designed to simulate the challenges that cleaning has to face with the different types of instruments and medical equipment, and it can be fixed to the tray, allowing a reproducible location of the cleaning indicator inside the washing machine's chamber. When the indicator is placed inside the holder, half of the test soil remains hidden, thus simulating the hinge of an instrument being reached indirectly by the water flow. The other half is covered by a metal mesh, representing in this way an obstacle to the direct access of water, and simulating the surfaces that can be reached by the water spray from the washing machine's sprinkler.

The main objective of the exclusive CDWAH-U design is to keep the indicator in a fixed and reproducible location inside the ultrasonic washing machine's chamber.

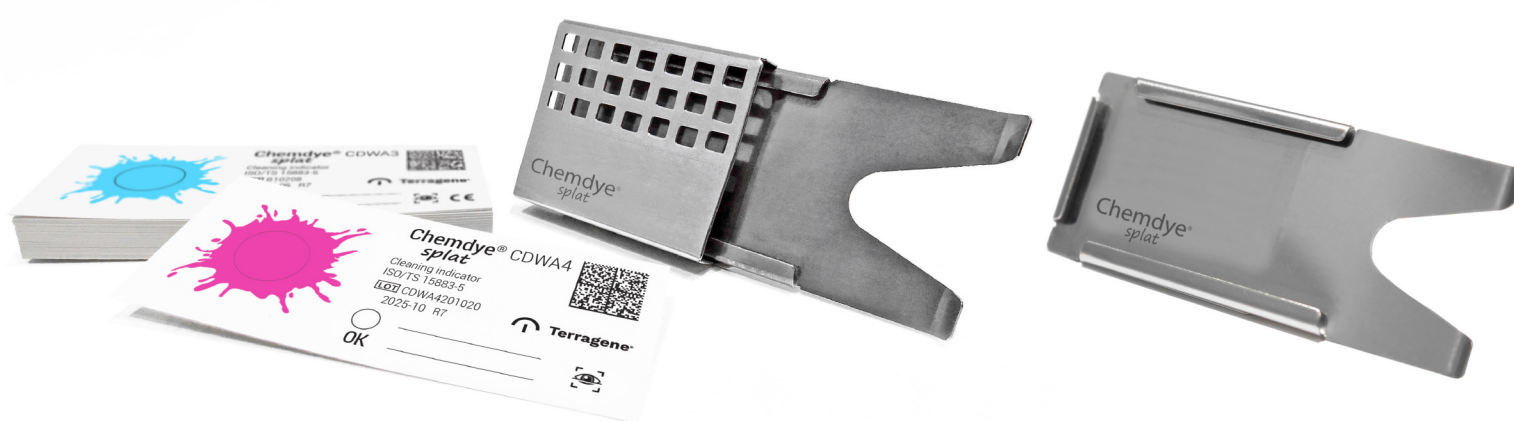


Figure 1. CDWAH and CDWAH-U holders next to CDWA3 and CDWA4 Chemdye® Splat cleaning indicators.



A cleaning performance test must be done as showed in fig. 3 flow chart, in order to determine which indicator should be used in the routine cleaning control. This procedure is performed without distinction of the type of washing machine used (thermal washer disinfectors or ultrasonic washing machines). Below an example for thermal washer disinfectors:

We recommend starting with the most challenging cleaning indicator: Chemdye® Splat CDWA4. Through the use of Chemdye® Splat CDWAH holder, the indicators are fixed to the tray in different positions inside the washing machine’s chamber, and at least, three

for each level or rack. The validated cleaning program is started (only this stage of the cycle should be taken into account and not later stages) and the results are recorded at the end of the cycle. For each indicator, the following information should be stated in the results record: cleaning programs parameters (time and temperature), results obtained for the cleaning indicator, position inside the chamber, kind and doses of detergent and water pressure. The indicator will be the appropriate for the routine control when it is completely cleaned in all positions inside the washing machine (see results guide, fig. 2) and if it is not cleaned when used in failure cycles (Fig. 3).

Results reference guide in
Thermodisinfection washers

✓ OK

✗ FAIL









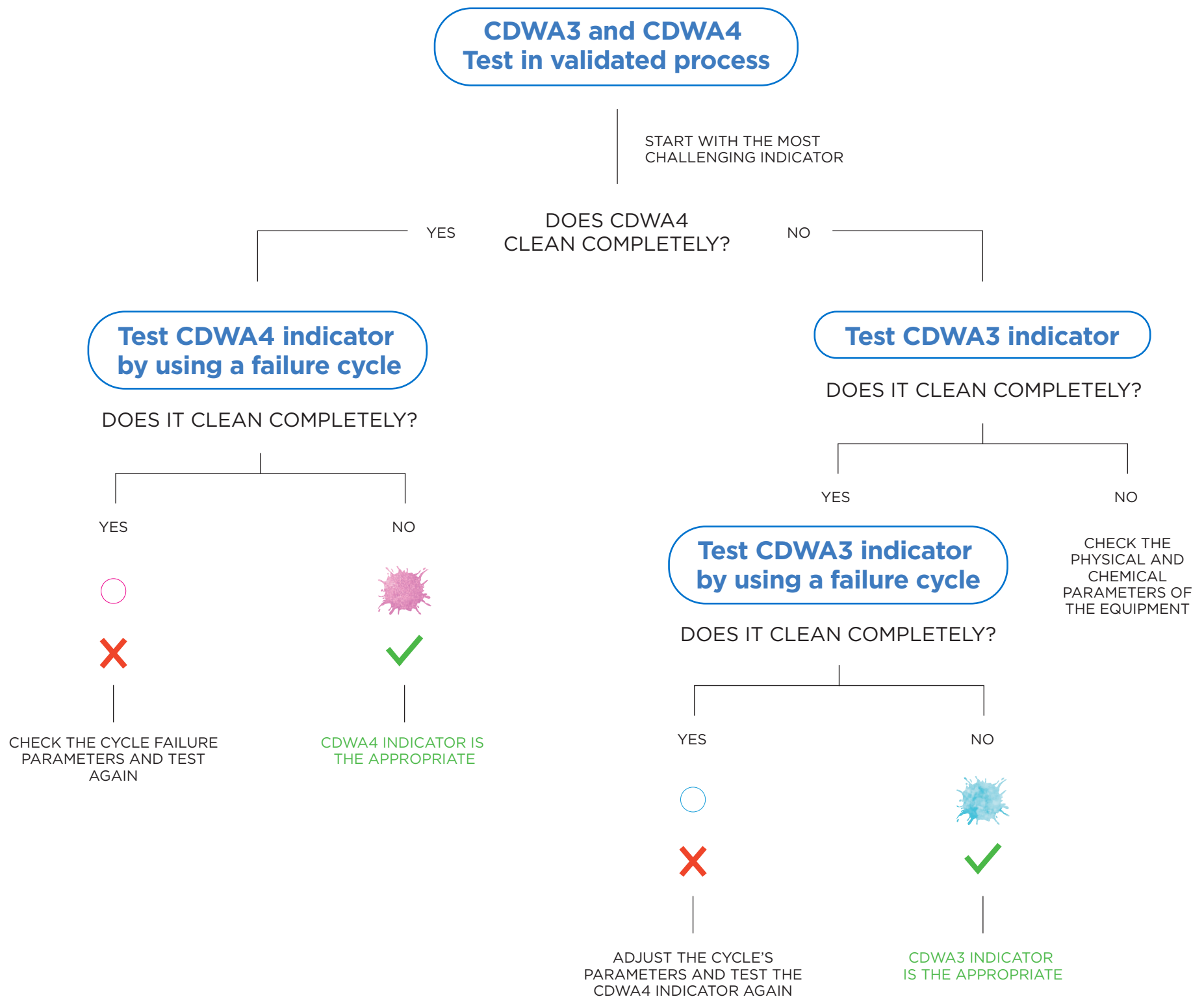
VISUAL RESULTS	BASKET ZONE				COVERED ZONE		
	LOCATION INSIDE WASHER	WATER PRESSURE	MECHANICAL FUNCTIONS (DETERGENT INJECTION PUMP, SPRAY ARMS, ETC.)	TEMPERATURE	EXPOSURE TIME	DETERGENT (TYPE, DOSE)	WATER QUALITY
 PROCESSED AND CORRECT	✓	✓	✓	✓	✓	✓	✓
	✓	✓	✓	✗	✗	✗	✗
	✓	✓	✓	✗✗	✗✗	✗✗	✗✗
	✓	✓	✓	✗✗✗	✗✗✗	✗✗✗	✗✗✗
	✗	✗	✗	✗✗✗	✗✗✗	✗✗✗	✗✗✗
	✗	✗	✗✗✗	✗✗✗	✗✗✗	✗✗✗	✗✗✗
	✗✗✗	✗✗✗	✗✗✗	✗✗✗	✗✗✗	✗✗✗	✗✗✗
 UNPROCESSED	—	—	—	—	—	—	—

Figure 2. CDWA4 results’ guide using CDWAH holder in thermal washer disinfectors.



Figure 3. Selection of the appropriate indicator: use of a failure cycle (sub-optimal conditions) in a validated cycle.



Failure cycle: Cycle modified in at least one of the following conditions: No detergent, room temperature or half of the cleaning cycle's time.

*It is recommended to use purge cycles before this process, since not injecting detergent may not generate failures due to the fact that pipes and pumps might contain detergent.

Once the appropriate cleaning indicator has been selected, it can be used for the routine control of such validated process. Whether the cycle parameters suffer any modification, the kind of load changes or the equipment suffers a revision or repair, a new validation and selection of the appropriate cleaning indicator must be done.

By keeping your cleaning cycle regularly validated through our indicators, you will be complying with the highest international standards. In doing so, you will be ensuring that the first step in the medical material reprocessing cycle was performed successfully, and it will let you start the following step (sterilization/disinfection) with the confidence and satisfaction of a job well done.

