

DIRECTIONS FOR USE

GKE Clean-Record® Cleaning Monitoring Process Indicator

Product | Art.-No.

810-101, 810-102, 810-103, 810-201, 810-202, 810-203, 810-301, 810-302, 810-303, 810-351, 810-352, 810-353, 810-401, 810-402, 810-403, 810-901, 810-902, 810-903, 800-102, 800-111

Application | Indicator selection

For routine monitoring in washer-disinfectors (WDs) and endoscope WD.

Cleaning processes must be adapted to the soiled instruments, are therefore very different and depend on many parameters (cleaning agent, water quality, temperature, spray impulse, etc.).

All indicator versions are tested in a trial run. The indicator with the longest wash-off time, which is just washed off in the validated process, is suitable for routine monitoring. The result can be documented and used as a reference when assessing later test results (see „Handling information“).

For process monitoring, an indicator should be used in the WD and endoscope WD in each batch and program to ensure that no changes have occurred in the process parameters.

Product Description

Indicators (CPI = Cleaning Process Monitoring Indicator):

Five GKE-CPIs identified by colours with different wash-off characteristics are available. Each indicator sheet contains 16 indicator pairs. The additionally available Multi-Colour-Indicator combines three different wash-off properties (red | blue | green) on one indicator.

Plastic holder:

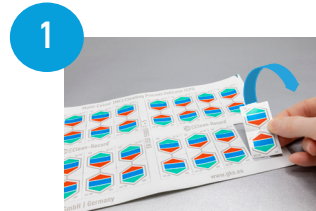
Holder made of durable PVDF plastic for securely holding the indicator with spring-loaded clip to fix to an instrument basket.

Hollow-Flow PCD (PVDC):

During cleaning in the WD and endoscope WD, hollow instruments are connected to adapters. A special Hollow-Flow PCD enables the flow situation to be monitored. It contains two adapters for holding the indicator. The adapter with a gap width of 2 mm produces a higher flow rate and thus stronger cleaning performance. In the adapter with a gap width of 4 mm, the cleaning performance is lower and the test requirement is therefore higher.

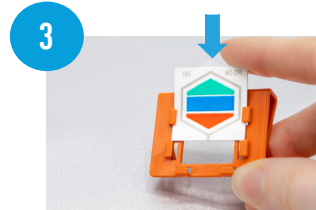
Handling Information

I. Remove the indicator determined during the test run (see „Application | Indicator selection“) from the card (1). Make sure that the indicator substance does not get in contact with hand sanitizer or sweat, as this may affect the indicator properties. Fold indicator pairs back to back so that the indicator surfaces face outwards (2).



a) Placement in the WD chamber with the GKE holder:

Insert the pair of indicators into the holder with the opening facing upwards (3). Fix the holder onto an instrument tray (4).



b) Use of the indicators in the GKE Hollow-Flow PCD

In the adapter with a small gap (2 mm) the indicators are washed off more easily than in the large (4 mm) gap. Select the adapter that just achieves a satisfactory wash result on the inserted indicator in the validated cleaning process. Insert the folded pair of indicators into the adapter so that the water flow hits the folded side during rinsing (5). Close the adapter with the grey lid. A pair of Luerlock (LL) adapters for connection to a flushing nozzle is included.



Connect the silicone hose to a rinsing nozzle that the water flows into the lid of the PCD and out through the adapter, labelled „2 mm“ or „4 mm“ (6).

With the second adapter of attaching a hose to the outlet opening, a hollow instrument can be interposed between the flushing nozzle and the PCD for testing purposes.

II. After completion of the cleaning process remove the indicator and check the result visually if the defined reference wash-off degree is reached. To find the cause of a poorer test result that deviates from the reference, see the section „Troubleshooting“.

III. The responsible person authorized will decide whether to release the batch or re-clean the load.

IV. The indicator is self-adhesive and can be attached onto a documentation sheet with date, WD, program name and batch number and the signature of the person authorized to do so.

Other Application

For monitoring cleaning processes in other cleaning equipment, the CPI can be glued directly to smooth surfaces, e.g. to the chamber wall or to the goods to be cleaned (containers, transport trolleys, bedpans, urine bottles, dishes, etc.).

Performance Characteristics

The 8 test soils described in the EN ISO 15883-5 standard are intended to simulate real soiling, but are not suitable for everyday use because they have to be prepared manually and used immediately. GKE-CPI are specially designed for routine everyday use. They are produced in an automated process, always have the same wash-off properties and serve as a process monitoring indicator for each cleaning cycle.

The indicator substance is non-toxic, is dissolved or dispersed by most cleaning agents and is removed from the RD process with the wash liquor. The indicators can be stuck on after use for documentation.

Troubleshooting

Worse test results, compared to earlier batches, can occur because of different reasons:

Possible reasons	Action
Wrong program	Check documentation! Check if the correct program for the load has been used?
Modified load configuration	Check, if the load configuration complies with the specifications documented in the quality management system and the validation report.
Other location of indicator	Check, if the cleaning process monitoring indicator has been placed at the right location.
Other or expired detergent	Check cleaning detergent container. Did you use the right detergent or is it expired?
Wrong dosage	Check dosage. Mark liquid level in cleaning detergent can, run the program and check if the liquid level or weight differs from standard procedure!
Modified temperature/time cleaning integral	Compare temperature time/integral from current batch with previous ones.
Spray arm not moving	Check, if the spray arm can be turned without resistance. Machine with glass door: Check spray arm during cleaning process. Other machines: Stop program during process and check if spray arm is able to move.
Worse water flow conditions	Check development of foam, pump failure, clogged strainer
Modified water quality	If tap water is used: Check hardness and salt content. Check if values have changed.
	If softened or demineralised water is used: Check water softening or demineralization system by testing pH-value and conductivity.

Storage and Disposal

1. For longer periods store all indicators in the original package.
2. Store indicators always between 5-30°C or 41-86°F with a humidity of 5-80% RH.
3. Do not store indicators together with chemicals, e.g. disinfectants, as this will lead to polymerization of the indicators and may increase the wash-off characteristics. Even if wiping the storage location with disinfectant solution regularly and the indicators are exposed to vapors, the wash-off characteristics may increase as a result.
4. The indicators should not be used after expiry date. They may be disposed with normal waste.

For further technical details please contact your local dealer or GKE directly. We will assist you with any technical questions. Also visit our website www.gke.eu for more information.

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