

gke Clean-Record[®] Cleaning Process Indicators with Hollow-Flow-PCD and Holder

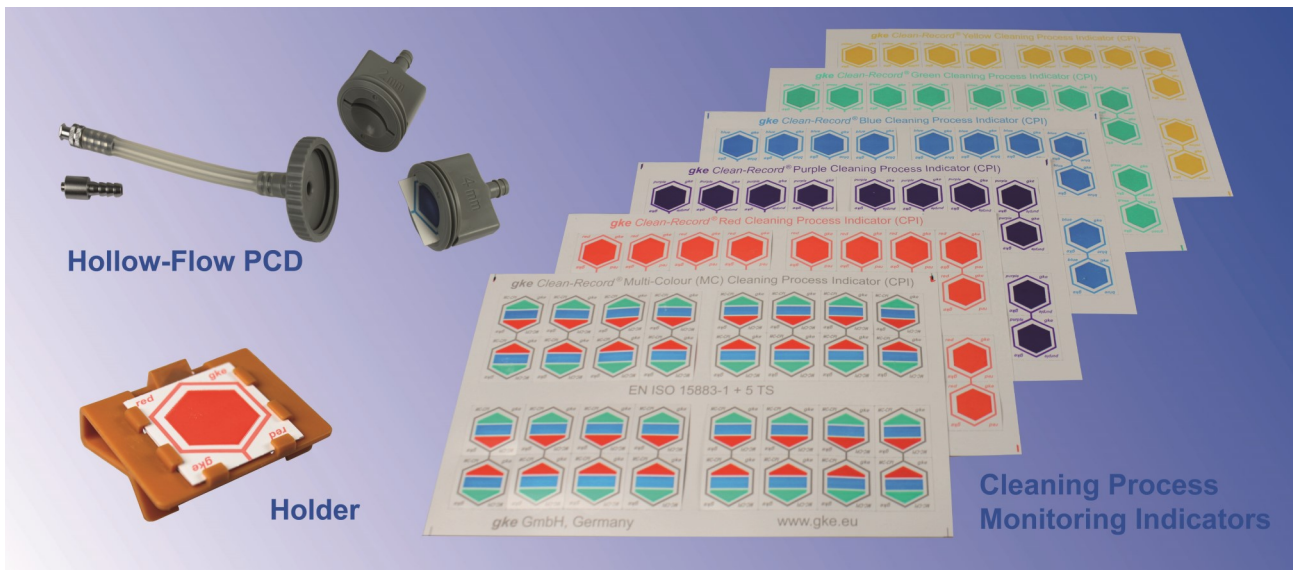


Fig 1: Indicators with holder and Hollow-Flow PCD

General Information

Surgical instruments are contaminated with various soils. Depending on the pre-treatment of instruments the adhesion may be different. Body fluids consist 75-85% of water soluble proteins and can be washed off with cold water. Many disinfectants have the characteristics that they fix soils and then the instruments are more difficult to clean. Instruments should be cleaned with cold water directly after use before the soils can adhere and before disinfectants are used which are fixing soils.

The use of cleaning detergents is very important for the efficacy of cleaning processes if non-water soluble soils are contaminants. Only water-soluble soils can be washed off with water. Fats and other non- water-soluble soils, e.g. lipids or hard baked proteins can only be washed off, if a cleaning detergent is used. Some cleaning detergents are alkaline and hydrolyze the non-water-soluble substances by using a high pH-value making them water-soluble. Other cleaning agents have a neutral pH-value containing enzymes which break up soils and make them water-soluble. Both mechanisms can be combined in one cleaning detergent. Which cleaning detergent suits best, depends on the instruments (e.g. construction, material) and the type of contamination (e.g. fresh blood, dried blood, bone meal, mucus).

Application

The ***gke Clean-Record***[®] cleaning process monitoring indicators are used for routine monitoring of cleaning processes in washer disinfectors (WD). To test hollow instruments, a special hollow flow process challenge device (PCD) can be connected to the hose connection of minimal invasive surgical (MIS) instruments and endoscope carts. In large machines the indicators can also be used and can be adhered directly on metal surfaces.

Firstly, validation of the specified cleaning process must be performed to ensure instrument cleaning under the worst-case conditions without using ***gke*** CPI. For routine monitoring, the CPI is used, which has just been washed-off in the validated process.

In any position within the WD chamber there are completely different spray conditions caused by different reasons:

1. Lower spray conditions can be found in the corners and at the centre of the spray arm axles.
2. Loads create spray shadows.
3. Instruments have areas that are difficult to reach, e.g. splits.
4. Channels which have to be flushed have different flow through characteristics because of their dimensions.

Testing shall be carried out in different locations to demonstrate different spray conditions and the most difficult location should be selected for routine monitoring. It is recommended to test each program daily to ensure that no parameters have changed. If instruments with higher requirements (critical B instruments) have to be cleaned, it is recommended to test each batch to use the result for batch release and for documentation.

Product Description

The self-adhesive indicators have different adhesion characteristics. Therefore, they require different strong mechanical spray force and different detergents to be washed off. It is recommended to test all indicators at the same time together with the most difficult instrument sets as a preliminary test (either using Multi-Colour indicators which contain the three most often used indicators in one indicator).

The indicators are put in a holder which can be fixed on a tray. To monitor the cleaning efficacy of hollow instruments the folded indicator may be placed in a **gke Clean-Record®** Hollow Flow PCD which is supplied with 2 adapters of 2 mm and 4 mm internal split. Small splits at the same flow rate create a higher internal flow through speed and therefore better cleaning efficacy as larger splits will create lower flow through speed and create worse cleaning conditions. At the end of the process the indicators can be adhered for documentation.

Performance Characteristics

The technical specification ISO/TS 15883-5 describes 19 test soils with completely different cleaning properties without making any recommendation, as to which test soil to use. Currently none of the test soils are offered as a reference, because there is no test method defined to compare the soil properties.

The **gke** research center has developed a test equipment (spray rig test) to be able to compare real soils, test soils of the standard and the different **gke Clean-Record®** indicators.

Comparative tests with a normative standard are not possible since currently no standard is available. Still **gke** has already carried out several tests under different cleaning conditions (flow rate, detergents, dosage, temperature etc.) in order to compare the cleaning characteristics of different instruments and **gke** CPI. For the first time it is possible to describe the properties of indicators. Test results are available on request.

The indicator substance is non-toxic and is dissolved and dispersed with most of the cleaning agents and flushed away with the washing fluid.

Benefits

- Use of synthetic test soils on plastic carrier instead of using natural test soils with blood prevent transfer of pathogenic germs and offers long-term stability and long expiry dates.
- Permanent economical batch monitoring is possible for the first time due to cost-effective production of the indicators.
- The five indicator levels require different mechanical force to be washed off and therefore, the use of PCDs is not required.
- Easy documentation because of self-adhesive indicators.
- The indicators are validated against test soils according to ISO/TS 15883-5 with a special spray equipment designed by **gke**.

Order Information

Indicators to monitor the cleaning efficacy in WD and endoscope WD

Art.-No.	Product Code	Quantity	Colour	Application
810-101, -102, -103	W-CPI-Y	160, 480, 960	Yellow	Cleaning process monitoring indicators (CPI) for routine monitoring in WD with different wash-off characteristics
810-201, -202, -203	W-CPI-G	160, 480, 960	Green	
810-301, -302, -303	W-CPI-B	160, 480, 960	Blue	
810-351, -352, -353	W-CPI-P	160, 480, 960	Purple	
810-401, -402, -403	W-CPI-R	160, 480, 960	Red	
810-901, -902, -903	W-MC-CPI	160, 480, 960	Combination Indicator Green, Blue, Red	Special indicators to select and test WD

Holder and Hollow-Flow PCD

Art.-No.	Product Code	Content	Application
800-102	W-PHO	10 plastic holders, colour: orange	for reproducible location of the cleaning indicator on a tray/basket in the WD
800-111	W-HF-PCD	1 Hollow-Flow-PCD with 2 adapters 2 LL-connectors, 2 silicone tubes of 0.3 m lengths	to be connected WD machines to simulate hollow devices

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