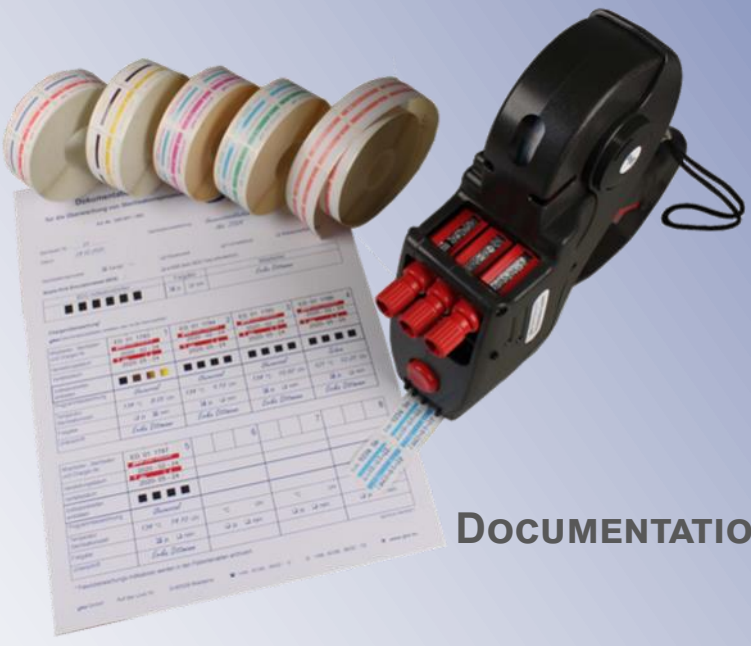
gke

Cleaning and Sterilization Monitoring

Cleaning and sterilization in dental facilities

Sterilization monitoring

Cleaning monitoring



Documentation

gke products for dental practises, clinics and laboratories

Cleaning and Disinfection

Cleaning process monitoring indicators for washer-disinfectors

Pre-cleaning

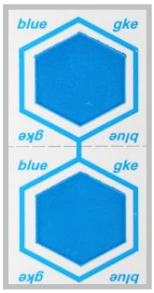
Used contaminated instruments require to be cleaned. For optimal cleaning the instruments are first rinsed off with cold water since 80% of all protein contamination are water-soluble and will be washed off. Pre-cleaning of highly contaminated instruments can be manually carried out with cold tap water with personal protective equipment (PPE), e.g. safety glasses, mask, safety gloves. If instruments with standard contamination can be directly put into a washer-disinfector (WD) and cleaned using a program that starts with pre-cleaning with cold water.

Cleaning

All components of a cleaning process have to be optimized to get a proper cleaning result. WD model, program selection, charging trolley, utilities, load configuration, water quality, detergent, detergent dosage, program runtime, temperature gradation etc. have to be optimized and adjusted to the instruments and its contamination.

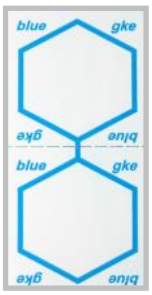
Monitoring of the cleaning process

If a cleaning process has been designed and validated in an optimal way, it has to be assured that it works accordingly during daily routine and does not unnoticeable deviate from the date of validation. Instruments with higher requirements on the cleaning process (critical B-instruments) have basically be cleaned in a washer-disinfector. Cleaning process monitoring indicators can be used in each batch and checked after the cleaning process is completed. ***gke*** offers cleaning process monitoring indicators that are designed with a new technology and simulate different wash-off characteristics. Thereby for each cleaning process an adequate indicator is available. The selection of the appropriate cleaning process monitoring indicator depends on the program used, temperature, time, detergent and other parameters that influence the cleaning process.



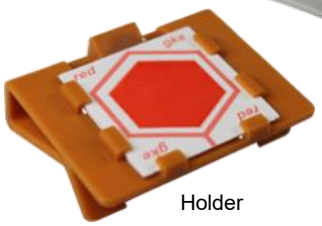
Original indicator

Partly
washed off



Completely
Washed-off

Hollow-Flow-PCD

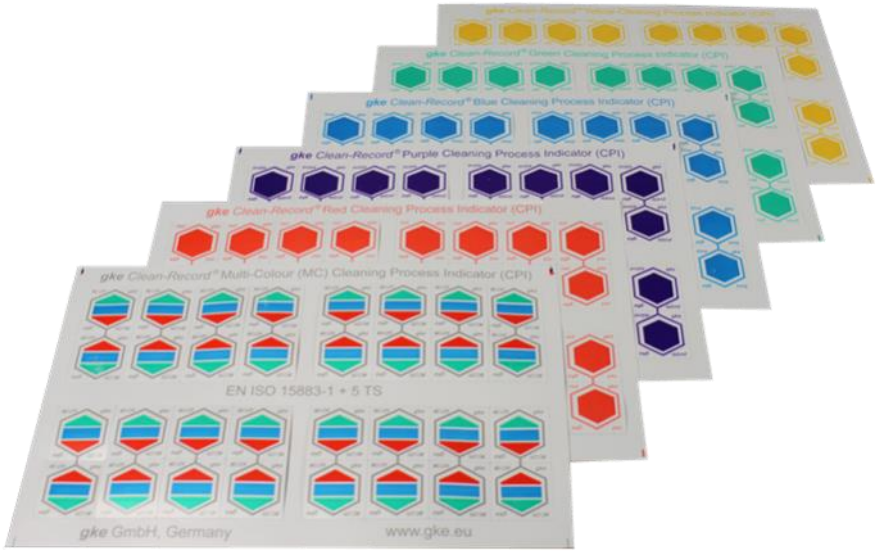


Holder

Art.-No.	Product Code	Quantity
810-101	W-CPI-Y (Cleaning process monitoring indicator, yellow)	160
810-102		480
810-201	W-CPI-G Cleaning process monitoring indicator, green)	160
810-202		480
810-301	W-CPI-B (Cleaning process monitoring indicator, blue)	160
810-302		480
810-351	W-CPI-P (Cleaning process monitoring indicator, purple)	160
810-352		480
810-401	W-CPI-R Cleaning process monitoring indicator, red)	160
810-402		480
810-901	W-MC-CPI Cleaning process monitoring indicators, green, blue, red)	160
810-902		480
800-102	W-PHO (Holder)	10
800-111	W-HF-PCD (Hollow-Flow PCD)	1

Cleaning and Disinfection

Cleaning process monitoring indicators simulating different test soils



Cleaning process monitoring indicators:
W-MC-CPI (green, blue, red), W-CPI-R (red), W-CPI-P (purple), W-CPI-B (blue), W-CPI-G (green), W-CPI-Y (yellow)

Test sheets for ultrasonic cleaning baths

gke offers four different test sheets to check ultrasonic cleaning baths. The test sheet will be immerged in fluids vertically or horizontally to check the different intensity of the mechanical force inside the volume of the liquid.

It is recommended to use the test sheets at least once a day in every program used to ensure that no changes of the process parameter occur. It is also recommended to monitor each batch where loads are difficult to clean.

gke offers different clip-holders of different heights to fix the test sheet inside the ultrasonic cleaning bath at different locations in the volume.

Example of use:
Clip Holder with test sheet in ultrasonic cleaning bath

Art. No.	Product Code	Quantity
810-111	W-U-CPI-Y (Ultrasonic test sheets: yellow)	40
810-112		120
810-211	W-U-CPI-G (Ultrasonic test sheets: green)	40
810-212		120
810-311	W-U-CPI-B (Ultrasonic test sheets: blue)	40
810-312		120
810-411	W-U-CPI-R (Ultrasonic test sheets: red)	40
810-412		120
800-115	W-U-HO-7 (Clip-Holder, 7 cm)	1
800-116	W-U-HO-20 (Clip-Holder, 20 cm)	1

Batch Monitoring System for dental loads - *gke* Dental-BMS

In the past process challenge devices (PCD) were used to check the sterilizer specifications (type test according to EN 285 BD-Test or EN ISO 13060 “Hollow Load Test”) to ensure that the sterilizer is working properly. However, the assurance that a sterilizer is working according to the sterilizer standard specification does not ensure that the load inside the sterilizer is sterilized successfully.

Therefore, the Dental-BMS is not calibrated to the requirements of a sterilizer standard but to the requirements for a typical packaged dental load. This batch monitoring system (BMS) is used for routine monitoring of dental instruments in each cycle. The PCD is designed to prove the steam penetration requirements of each load in order to get a successful test result where hand pieces are the most difficult instruments to sterilize.*

Art.-No.	Product Code	Quantity
211-281	C-S-BMS-Dental-OCPCD-KIT Start-up kit, Compact-PCD, Dental and indicator strips	1+100
200-081	BMS-Dental-OCPCD Compact-PCD, yellow	1
211-252	C-S-PM-SV1 Refill pack indicator strips	250
211-255		500

Process Monitoring System for complex loads with Hollow load test according to EN 867-5*

If more complex instruments are used that are not included in the dental load configuration of the Dental-BMS, it is recommended to use the ***gke*** *Steri-Record*® process monitoring system. It is required that the instruments have been cleaned and disinfected in advance and the design of the instruments is validated so it can be sterilized in steam sterilization processes.

Art.-No.	Product Code	Quantity
211-264	C-S-PM-HL-OCPCD-KIT Start-up kit, Compact-PCD, orange and indicator strips	1+100
200-026	PM-HL-OCPCD PCD, orange, oval	1
211-252	C-S-PM-SV1 Refill pack indicator strips	250
211-255		500

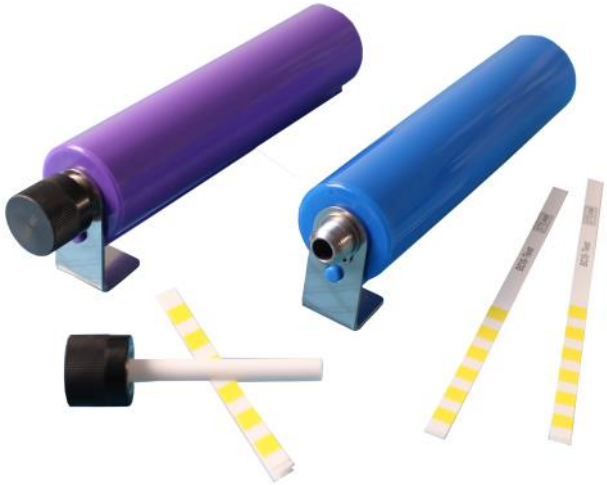
The ***gke*** *Steri-Record*® Compact-PCD® consists of an external plastic casing with an internal stainless steel tube and capsule holding the indicator. All PCDs are re-usable and can be used for a considerable number of sterilization cycles. Only one indicator strips is required for each sterilization process.

* All stated test characteristics were proved in an accredited test laboratory. Test reports are available on request.

Bowie-Dick Test*

The Bowie-Dick Test (type test, no sterility test) is used to check steam sterilizers for air removal and steam penetration after start-up. This test is carried out in an empty chamber and it is mandatory for large sterilizers according to EN 285. However, it is no substitution for routine monitoring. For small type B sterilizers according to EN 13060 a type test is also mandatory after start-up. If a Bowie-Dick-Test, a hollow load test according to EN 867-5 or any other test is used, depends on the type of sterilizer, process validation and specifications of the manufacturer.

gke offers different BDS-Tests. The process challenge device (PCD), ***gke*** Compact-PCD, colour blue, fulfils the requirements of EN ISO 11140-4 and also the hollow load test described in EN 867-5.*



Art.-No.	Product Code	Quantity
211-150	C-S-BDS-EUH-RCPCD-KIT Start-up kit, Compact-PCD, blue and indicator strips (BDS + Hollow Load Test)	1+100
211-120	C-S-BDS-EU-RCPCD-KIT Start-up kit, Compact-PCD, purple and indicator strips (BDS-Test)	1 + 100
211-111	C-S-PM-SV1 Refill pack indicator strips	100
211-112		250
211-115		500

Indicators according to EN ISO 11140 Type 6

For package monitoring

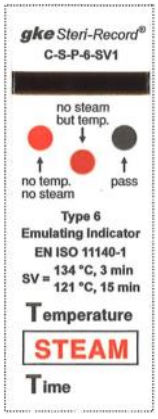
Type 5 and 6 indicators according to EN ISO 11140-1 (former class 5 and 6 until 03/2015) are used to monitor all relevant parameters of a steam sterilization process where they are placed. If indicators are used for routine monitoring they should be placed at the most difficult position to be sterilized, e.g. inside of packaged instruments. Physical data alone such as pressure, temperature etc. do not provide sufficient information to ensure sterility.

For use in special dental cominbation autoclaves

If only cross contamination on surfaces of the instruments should be prevented the instruments are sterilized without being packaged. In special combination autoclaves that clean, lubricate and sterilize dental instruments, the indicator is also placed unpacked into the indicator holder inside the chamber.

Use of a chemical indicator inside the clip of a combination autoclave, e.g. Sirona DAC UNIVERSAL

Art.-No.	Product Code	Quantity
211-243	C-S-P6-SV1 Type 6 Indicators*	250
211-242		500
211-241		2.000
200-001	C-S-Clip (Indicator holder)	1



Indicator after successful colour change

STERILIZATION

Self-contained biological indicators for instant release

The ***gke*** *Steri-Record*® Mini-Bio-Plus self-contained biological indicators (SCBI) are used for validation and routine monitoring inside packs or containers in steam sterilization processes. After sterilization the SCBI can be incubated by the user without a microbiological laboratory. The newly developed Instant-Mini-Bio-Plus SCBI allows an immediate release of the load in sterilization processes without having to wait for the incubation result.

The SCBI consists of a plastic vial with a minimized internal volume containing a biological indicator spore disc and a glass ampoule with growth medium and pH-indicator inside. ***gke*** offers SCBI with different populations. They are designed to be used inside Bio-Compact process challenge devices (Bio-C-PCD®).

The outside label of the SCBI contains a type 1 indicator according to EN ISO 11140-1 to check if the SCBI has been in a sterilization process. The Instant-Mini-Bio-Plus SCBI additionally contains a type 5 indicator inside the vial allowing to instantly evaluate the result of steam sterilization processes at the end of the process.

For incubation of all SCBI incubators are available.

Art.-No.	Product Code	Quantity
324-501	B-S-MBP-10-5	10
324-505		50
324-510		100
324-551	B-S-MBP-I-10-5-SV4	10
324-555		50
324-550		100
300-0xx	B-PM-RCPCD-X Bio-Compact-PCD, round	1
300-0xx	B-PM-OCPCD-X Bio-Compact-PCD, oval	1

Electronic dry bath incubator

The electronic dry bath incubator is used to incubate biological indicators. After the incubation period the colour of the pH-indicator shows the result of the medium. An external microbiological laboratory is not required. Therefore, the results are available much faster.

Art.-No.	Product Code	Quantity
610-120	I-57-AB-MBP Incubator, 57°C	1
610-122	I-V-T-AB-MBP Incubator with variable temperature selection and programming of the incubation time	1

DOCUMENTATION

Manual documentation system

The ***gke*** *Steri-Record*® documentation system is used for batch and patient related traceability after sterilization of medical devices.

By using a ***gke*** labelling device a label of the same content including production and expiry date, batch number and responsible person is adhered on each pack and on the documentation sheet. After opening the sterile pack in the operation room the label can be removed off the package and adhered into the patient file. Thus all information provided on each pack can be traced back from the patient to the processing and approval.

The labels for steam sterilization processes are available in four different colours, optionally with or without indicator.

Art.-No.	Product Code	Quantity
240-820	D-G-NL Labelling device	1
Labels without indicator (750 pcs/roll)		
240-853	D-L-DA-R, red	4
240-861	D-L-DA-G, green	12
240-862	D-L-DA-B, blue	12
240-863	D-L-DA-R, red	12
240-864	D-L-DA-Y, yellow	12
Labels with indicator (750 pcs/roll)		
240-883	C-S-L-1-DA-R, red	4
240-871	C-S-L-1-DA-G, green	12
240-872	C-S-L-1-DA-B, blue	12
240-873	C-S-L-1-DA-R, red	12
240-874	C-S-L-1-DA-Y, yellow	12

Label with indicator (full-scale)

The European Medical Device Directive (MDD) requires for reprocessing of medical devices to use appropriate validated procedures and to document the results of the validation process and routine monitoring. The quality management standard for medical devices (EN ISO 13485) and the validation standards of all sterilization processes (e.g. EN ISO 14937, EN ISO 17665-1 etc.) require monitoring and documentation of all relevant sterilization process parameters. This documentation is required for the production or reprocessing of all medical devices independent of where they are sterilized. For each individual load a batch number is required associated with all relevant parameters used in the sterilization process.

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Designed, developed and made in Germany