

	Technical Information	730-119-EN		V04
	When do Cleaning Process Monitoring Indicators (CPI) have to be used in cleaning processes?	Created	23.01.2014	JM
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The German Robert-Koch Institute (**RKI**)-**KRINKO*** recommendation for monitoring medical devices* covers in annex 3 the topic "commissioning and operation of washer disinfectors (WD) for the reprocessing of medical devices". Daily checkups and batch related checkups, required to release a batch, are listed in the table on page 1269.

In the category "Batch Related Tests" it is quoted "**Visual inspection of goods: cleanliness (if indicated by using a cleaning indicator, e.g. for Critical B Instruments)**"

There are cleaning processes where a cleaning process monitoring indicator (CPI) is not required. If semi critical-A instruments have to be cleaned it is possible to check the cleaning results completely visually with a lighted magnifying glass, as it has only accessible surfaces.

The German **RKI-KRINKO*** recommendation uses the term "if indicated" which means that there are explicit cases where CPI have to be used in each batch. Further down in the text is an example, cleaning critical-B instruments.

If instruments are visibly contaminated after the cleaning process a failure can easily be detected. If the surface of the instruments cannot be visibly checked (= critical-B instruments), it is essential to monitor the process with a CPI, which means using artificial test soils. In this case it is indicated to use a CPI in order to release the batch.

It is important to correct two statements of even trained users like, technicians and consultants:

1. The term "if indicated" is definitely not similar to "optional". This interpretation is not only wrong but also dangerous.
2. It is not only necessary to monitor old washer disinfectors or washer disinfectors of certain manufacturers with CPIs. It is even necessary to monitor a modern washer disinfectant since no machine can detect by itself e.g. if a nozzle has been sealed with a dummy plug or by dirt or if wrong detergents are used etc. (see also TI 730-153).

*Recommendation of the commission for Hospital Hygiene and Infection Prevention (**KRINKO**) at the Robert Koch-Institute (**RKI**) and the German Institute for Pharmaceuticals and Medical Devices (BfArM)