

	Technical Information	730-126-EN		V05
	Best practice to select the correct cleaning process monitoring indicator (CPI)	Created	08.08.2014	JM
		Changed	06.08.2021	KP
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Cleaning processes can be monitored by using a cleaning process monitoring indicator (CPI) made by an artificial test soil. EN ISO 15883-1 requires that a routine monitoring procedure should be used.

It is always a question which CPI or standard test soil should be used locally for routine monitoring.

Different cleaning processes are necessary, since different instruments (orthopaedic, gynaecological, urologic, dental etc.) have to be cleaned with different procedures. Soils such as blood, bone meal, cement, mucus have different wash-off characteristics and require the use of different programs and detergents. Those programs differ e.g. in time and temperature gradient, different detergents with high and low pH value, enzymes, tensides, oxidants, silicates etc.

There is no definition of “clean”. How good to clean an instrument depends on its later use and must be defined by the surgeon in charge, e.g. an implant must be even free of endotoxins.

Different cleaning indicators are available on the market. EN ISO 15883-5 lists different test soils which can be used. A uniform standard test soil is not available. Also, these test soils can't be used for routine monitoring, since they are difficult to produce.

So there are many different cleaning processes, which should be optimized to clean real instruments. Therefore it is unrealistic to just use only one CPI.

An optimal indicator should have two characteristics:

1. It has to be washed off if the cleaning process has been validated correctly before.
2. It shall not be washed off in case of change of any critical parameter in the cleaning process, e.g. wrong detergent, false dosage or expired detergent, etc. making the process less efficient.

Which CPI is suitable for monitoring a cleaning process and fulfils both properties must be determined with test runs. Therefore, GKE offers eight different CPIs with different wash-off characteristics so that a suitable indicator from the GKE range is available for different processes.

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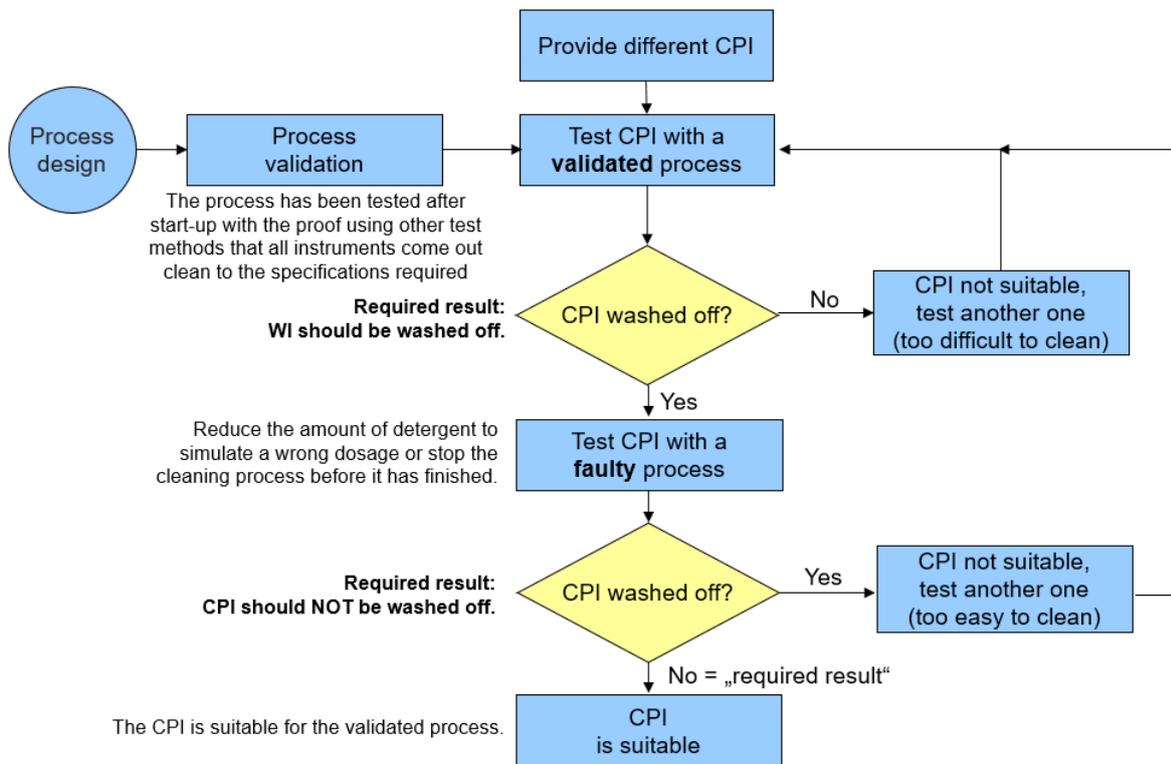
Practical approach:

All indicators are adhered to a plain stainless steel plate of a WD cart or fixed with a GKE holder, so that one side of the indicator can be observed through a glass door, if installed. Also additional indicators of other manufacturers or test soils of the standard EN ISO 15883-5 can be fixed visibly on a basket. Then a validated cleaning program is started and the progress of the indicator wash-off is observed through the window and documented. Some indicators are washed off already with cold water during the pre-cleaning procedure and others are only washed off partly, completely or not at all during main cleaning program. The results, after which time and in which program which indicator has been washed at which extent are documented. A suitable indicator for routine monitoring has just been washed off last.

The best practice to select a CPI can be shown at the following flow-chart:

How to select the correct cleaning process monitoring indicator (CPI)?

After validation this procedure is suitable for all goods incl. hollow devices and instruments with splits.



If the process has changed, the WI-selection has to be repeated.