The Robert-Koch-Institute (RKI) recommendation for reprocessing of medical devices from October 2012 requires a visual inspection of the instruments after each cleaning cycle. It can happen that soils are remaining on the instruments, even if the program has run correctly.

If a contamination is so tiny that it is not visible for the human eye even with additional devices (lighted magnifier glasses, microscope, ...) or the contamination is at a location which is not visible (split, hollow, etc.) the optical test method is limited. In this case a protein test can be used taking a surface swabbing sample from the instrument and chemically analyze it. This way proteins are detected by a chemical reaction which are not seen by visible inspection.

Therefore a protein test can make sense. However, it is not sufficient to release a cleaning process based on a protein test for the following reasons:

1. A protein test can detect proteins only, other soils cannot be observed.

2. The test can only be carried out as a random sample of some instruments. This tested instrument must be cleaned again after the protein test because the used chemicals are toxic. Therefore the instruments which are actually used, are never tested. The protein test is therefore not suitable for routine monitoring.

3. A quantitative protein test is only as good as the protein removal from the instrument. If the removal is not quantitative, the test is not valid.

Taking these reasons into consideration the RKI recommendation recommends to use a cleaning indicator, i.e. an artificial test soil or chemical cleaning indicator, in each batch, especially with critical B instruments, because quite often not all their surfaces are completely visible for inspection.

The following concrete example from a GKE customer illustrates the described situation above:

During the use of GKE cleaning process monitoring indicators (CPI) they noticed that the GKE CPI was not washed off anymore as always before. Water samples taken during the process showed an acceptable pH-value. Also the instruments seemed to be clean and the protein test was negative. However, the different result of the CPI demonstrated that at least one process parameter must have changed.

A detergent, consisting of two liquids coming from two separate canisters had been dosed into the WD. One of the canisters contained an alkaline substance with high pH-value, the other one contained enzymes with neutral pH-value. Both components are mixed shortly before the cleaning step, but supplied and stored separately because the substances are not stable as a mixture.

Both canisters were connected to the WD to dose their content. For further examination of the reason, their filling levels before and after the process have been checked for correct dosage.

After checking the alkaline substance was dosed correctly. However, the liquid of the canister with the enzymatic substance was not dosed at all. This was very difficult to observe because only a minimal amount of this substance is used to avoid foaming. It turned out that the pump supplying the enzymatic component was defect.

So the cleaning cycle contained only the alkaline component of the detergent. Therefore the pH-value measurement as well as the protein test did not show any divergent result, since the alkaline medium hydrolyzes and washes off the proteins, but not necessarily other components which are only dissolved by enzymes.

Because of the defect pump no enzymes were present during the process. This could only be noticed, because the used CPI has been selected that way that it could not be washed off anymore because of the missing enzymes.

This field report allows two important conclusions:

1. A protein test as a control sample is not sufficient because the protein cleaning can be absolutely satisfactory even if the process was faulty.

2. A CPI can show parameter changes in a process. But this is only possible, if the washing-off difficulty level of the indicator is selected that way that it is “just” washed off in a correct process. Therefore a “one universal cleaning process monitoring indicator” does not exist. A CPI rather has to be selected suitable to the process and may only provide a successful test result, if all critical parameters – which have been tested and determined once during a process validation – remain constant.

GKE produces CPIs which are manufactured with different washing-off difficulty levels using a new technology allowing to select a CPI for routine monitoring ideally suitable for the own cleaning process without using a special PCD.