# How to perform cleaning validations of **semi-critical and critical devices** according to ANSI/AAMI ST98

Under AAMI TIR30 no destinction was made between the validation approach for non-critical and semi-critical or critical devices. With AAMI TIR30 now replaced by ANSI/AAMI ST98, additional requirements are specified for the validation of semi-critical and critical devices. An overview of these additional considerations is provided here.

**VALIDATING (SEMI-) CRITICAL DEVICES**

## SIMULATED USE TESTING

- **Full** processing cycles are required prior to the cleaning validation
  - Standard number = **6**
  - More or less may be required depending on the device

## TEST SOIL DETERMINATION

- Relevant processing or procedural contaminants intended to be removed during cleaning have to be included (e.g. lubricants)
  - If not included, a justification is to be provided

## POSITIVE DEVICE CONTROLS

- **Three** are required
- Extraction method should be validated e.g. through exhaustive extraction
- Recovery efficiency should be > **70%**
- **Variability** in recovery efficiency should be addressed (e.g. applying lowest or average recovery efficiency)

## SAMPLE SIZE

- Number of test replicates is **justification based** depending on:
  - Device complexity
  - Data reproducibility
  - Criticality can also be considered
- **Minimum** sample size is **3**
- Three positive device controls
- One negative device control

## VALIDATION OF THE CLEANING PROCESS

- Cleaning process validated separately (additional cycle without disinfection and/or sterilization)
- Process steps which could cause test method interference are to be identified and eliminated if possible (e.g. high temperatures)

## ENDPOINTS AND ACCEPTANCE CRITERIA

- **No visible soil**
- **≥ 2 quantitative**, clinically relevant analytes
  - Protein ≤ 6.4 µg/cm²
  - Carbohydrate ≤ 1.8 µg/cm²
  - Hemoglobin ≤ 2.2 µg/cm²
  - Total organic carbon ≤ 12 µg/cm²

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