IG WiG, Interessengemeinschaft Wiederaufbereitung im Gesundheitswesen

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Recommendation
Validation of da Vinci Instrument Reprocessing Process

Recommendation, Validation of da Vinci Instrument Reprocessing Process

This recommendation was endorsed by the following institutions:

Interessengemeinschaft für die Wiederaufbereitung
im Gesundheitswesen
https://www.igwig.ch/

INTUITIVE https://www.intuitive.com

Foreword

According to SN EN ISO 9001, SN EN ISO 13485 and SN EN 15224 (Quality Management System in Health Care Organizations), "The organization shall implement production and service provision under controlled conditions." This is achieved, inter alia, by validating reprocessing processes in accordance with legal requirements and normative guidelines.

A more general or overriding requirement is that the process owner maintains and actively uses a functioning QM system.

The following recommendation describes what need to be observed in the validation of da Vinci instruments.

For the sake of simplicity, this text only uses the masculine form. Naturally, this use always refers to the feminine form as well.

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List of Abbreviations

°C	Degrees Celsius
AEMP	Reprocessing unit for medical devices
EN	European Norm
IQ	Installation qualification
ISO	International Organization for Standardization
min	Minutes
MP	Medical device
OQ	Operation qualification
PQ	Performance qualification
QM	Quality management
WD	Washer-disinfector
SN	Swiss Norm
SOP	Standard operating procedure
VA	Procedure instruction
e.g.	for example
ZSVA	Central sterile services department (see AEMP)

1 Basis of this Recommendation

- **Swissmedic, Good practice for reprocessing of medical devices**
- **SN EN ISO 15883 "Washer-disinfectors".**
  - Part 1: General requirements, terms and definitions, and tests
  - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
  - Part 5: Test soils and methods for demonstrating cleaning efficacy
- **Swiss Guideline for the Validation and Routine Monitoring of Cleaning and Disinfection Processes for Medical Devices**
  - Part 1: General
  - Part 2: Mechanical washing and thermal disinfection process – washer-disinfectors for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

2 Description and Purpose of this Recommendation

The purpose of this recommendation is to define minimum requirements and a standard PQ process for validating da Vinci instrument washing and disinfection processes. The product design of da Vinci instruments does not allow for visual inspection of their internal areas. This recommendation focuses on analytically controlling cleaning performance by quantitatively determining residual protein (SN ISO 15883-1, Annex C) in order to detect and evaluate residual protein contamination.

Although da Vinci Si and Xi/X instruments differ in the design of their housing, their construction (options for cleaning) and production materials are the same. Since Xi/X instruments have a longer shaft, a PQ which uses Xi/X instruments can be used to confirm the cleaning performance of Si instruments.

A PQ makes it possible to determine the effectiveness of the overall cleaning procedure for the medical devices which are to be prepared for a health care organization. The first step in the PQ is preliminary preparation of the instruments in the operating room, after which the instruments are manually pre-cleaned in the AEMP and processed in a washer-disinfector. The results of the PQ depend on whether AEMP personnel have followed the processing instructions authorized by the manufacturer. Results may also be influenced by the following factors: water quality, effectiveness of the cleaning tools used, contamination originating from the processing environment, effectiveness of the cleaning agent and proper operation of the washer-disinfector. The results of tests to determine residual protein may be influenced by disruptive factors such as cleaning agent residue or lubricant residue on or in the instrument. In general, these disruptive factors result in higher detection results in laboratory analytical evaluations.

Test batches and the number of cleaning tests are specified in accordance with the Swiss Guideline for the Validation and Routine Monitoring of Cleaning and Disinfection Processes for Medical Devices

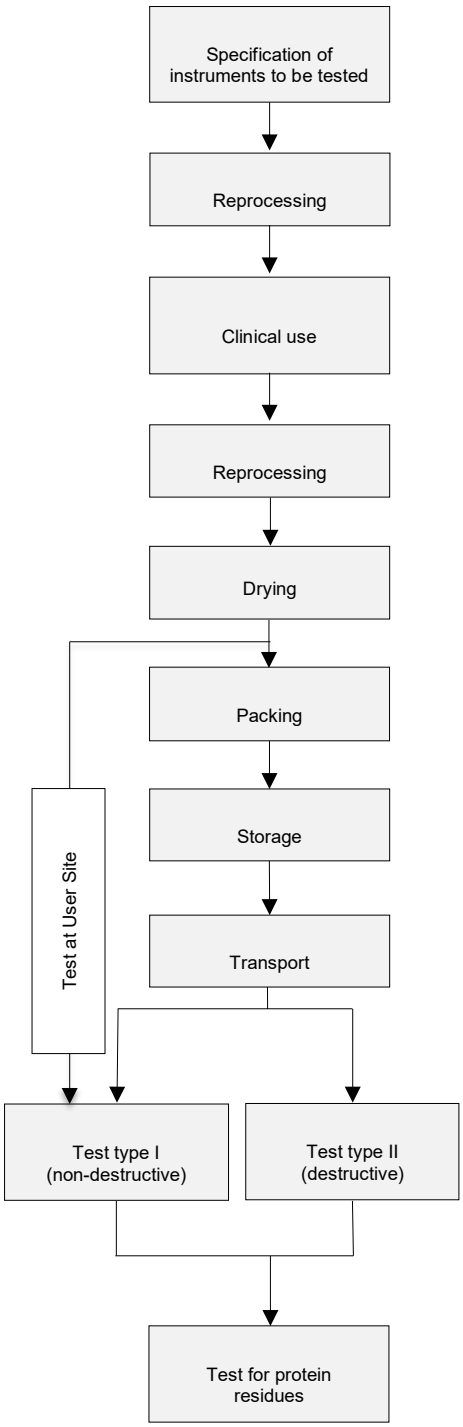
- Part 1: General
- Part 2: Mechanical washing and thermal disinfection process – washer-disinfectors for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

3 Preparatory Measures by the Health Care Organization

- The da Vinci instruments which are to undergo validation should be prepared in accordance with reprocessing instructions before their initial clinical use (1 x manually and 2 x by WD system) in order to remove any contamination which may affect the residual protein test (recommendation by manufacturer Intuitive).
- da Vinci instruments are used for surgical operations.
- Instruments are reprocessed in accordance with reprocessing instructions, whereby the reprocessing process must be stopped before thermal disinfection temperature reaches 60 °C.

4 PQ Flowchart

This flowchart provides an overview of the PQ procedure. Please refer to Intuitive reprocessing instructions for details on specific steps.

Flowchart	Description	User (B) / Validator (V)
	Specification of da Vinci instruments which are to undergo a PQ. Normally three representative instruments (monopolar scissors, bipolar grasper and one additional instrument) are tested in a PQ. This step requires that the IQ and OQ were completed successfully.	B
	Instruments are sterilized in accordance with reprocessing instructions and the corresponding guidelines of the health care organization.	B
	Instruments are used for a surgical procedure.	B
	Instruments are reprocessed in accordance with reprocessing instructions, which specify that the processing process in the washer-disinfector must be stopped before thermal disinfection temperature reaches 60 °C. Instruments must not be sterilized after the cleaning.	B
	Instruments must be carefully dried with clean, oil-free compressed air (e.g. medical compressed air).	B
	Instruments must be packed in such a way that they cannot be re-contaminated. They can therefore be packed in clean, sealable foil pouches. Foil pouches must be sufficiently tear-resistant such that instrument tips cannot penetrate the pouch.	B
	Instruments must be tested for residual contamination as soon as possible; prolonged storage is not recommended. Alternatively, instruments can be stored below 20 °C.	B
	Instruments transported to an external testing lab for examination should be placed in packaging which is sufficiently stable. It is recommended that instruments be shipped by express mail. If instruments show residual moisture, a refrigerated shipment may be required if outside temperatures are high. A batch printout of the washer-disinfector processing procedure must be attached to the PQ documentation.	B
	In the case of non-destructive tests, the tip of the instrument as well as all outer surfaces must be inspected for residual contamination. An extraction of the tip and inner shaft elements must also be carried out for purposes of a subsequent protein test.	V
	A destructive test can be carried out the final time instruments are processed (at their end of life), which will make possible an additional inspection of their inner shaft elements in addition to the extraction.	V
	The protein test should fulfill SN EN ISO 15883-1 guidelines and may be carried out by an external test lab. The test lab should have experience in that area. Alternatively, the test can be carried out in the health care organization itself, by appropriately qualified employees using authorized procedures.	V

5 Washing and Disinfection Process Checklist

Consideration for PQ (*Harmonization with SN EN ISO 15883-1)*

Yes	No	Requirement	Note
☐	☐	Was the pre-cleaning process carried out in accordance with current Intuitive reprocessing instructions?	
☐	☐	Procedural instruction for da Vinci instruments exists and corresponds to current instructions from Intuitive and from the washer-disinfector manufacturer.	
☐	☐	Certification of reprocessing instruction training by Intuitive or of internal organization training	
☐	☐	Is a load carrier specifically adapted to the washer-disinfector available?	
☐	☐	Does the washer-disinfector have a specific program for the process?	
☐	☐	Is the correct process (e.g. automatic program start) being used in the washer-disinfector (cleaning chemicals and parameters)?	
☐	☐	Have da Vinci instruments been adapted to the load carrier (proper loading)?	
☐	☐	Cleaning is evaluated in the washer-disinfector prior to the thermal disinfection phase (note: cleaning chemical residue may cause false-positive results)	
☐	☐	Removal of da Vinci instruments to be tested	
☐	☐	Visual inspection of cleaning results	
☐	☐	Manual drying with clean, oil-free compressed air / lint-free cloth	
☐	☐	Number of da Vinci instruments to be tested must be specified (validation / requalification)	
☐	☐	Disinfection test is carried out thermoelectrically (data logger)	
☐	☐	Recording of A_0 value > 3000 at da Vinci instrument	
☐	☐	Number of test cycles (batches) must be specified – see Part 2 (Swiss Guideline)	
☐	☐	Routine inspection: 1 Instrument per quarter	

6 Validation Procedure

6.1 Preliminary Validation Discussion

- Ensure that IQ/OQ were carried out
- Define instruments (e.g. monopolar scissors, bipolar grasper and one additional instrument)
- Ensure that instruments were properly pre-treated
- Define schedule (date for 1st surgical procedure)
- Basic training was given by Intuitive?
- Procedural instructions in accordance with current reprocessing instructions available?
- Are suitable load carriers available?
- Is an appropriate cleaning program based on Intuitive guidelines available?
- Is a suitable process chemical available?
- Is a suitable transport container and packaging available?
- Is clean, oil-free compressed air available?

6.2 Day of Validation

- Inspection of procedural instructions
- Training certification
- Observation, pre-cleaning (checklist), visual inspection
- At least 1 run-through of entire process using data loggers (thermal disinfection)
- 1 run-through with clinically used da Vinci instruments. Process stopped prior to thermal disinfection
- Drying in order to reduce microbial growth during transport
- Protein analysis extraction on site / send to lab (suitable transport box)
- Residual Protein Extraction on site possible (requires space, training & technical accessories)

6.3 Residual Protein Analysis

- Extraction in accordance with protein extraction description, item 10
- Quantification in accordance with SN EN ISO 15883-1 (BCA / OPA)
- Sending of lab report to validator

6.4 Completion of Validation

- Evaluation of residual protein results in accordance with Swiss Guideline acceptance criteria and measures (item 4.2.1)

- Finalization of validation report
- Optional routine inspection in accordance with Guideline, item 6
- Final discussion between user and validator in order to explain PQ details and results and to determine possible measures

7 Validation Checklist

7.1 General

Yes	No	Requirement	Note
☐	☐	Procedural instructions and work instructions for da Vinci instruments are available and correspond to current instructions from Intuitive and the washer-disinfector manufacturer.	
☐	☐	Certification of reprocessing instruction training by Intuitive available?	

7.2 Infrastructure

Yes	No	Requirement	Note
☐	☐	Washer-disinfector maintained in accordance with manufacturer guidelines?	
☐	☐	Load carrier specifically adapted to washer-disinfector available?	
☐	☐	Washer-disinfector has specific program for process?	
☐	☐	Suitable cleaning chemical?	
☐	☐	Is the correct process (program) being used in the washer-disinfector (e.g. automatic program start)?	

7.3 Day of (initial) surgery:

Yes	No	Requirement	Note
☐	☐	Was the pre-cleaning process carried out in accordance with current manufacturer instructions?	
☐	☐	Have da Vinci instruments been adapted to the load carrier (proper loading)?	
☐	☐	Cleaning evaluated in the washer-disinfector BEFORE thermal disinfection phase (note: cleaning agent residue may cause false-positive results)	
☐	☐	Removal of da Vinci instruments to be tested OK?	
☐	☐	Batch documentation of washer-disinfector process available?	
☐	☐	Visual inspection of cleaning results OK?	
☐	☐	Drying carried out with clean, oil-free compressed air?	
☐	☐	Disinfection test carried out thermo electrically? (data logger)	
☐	☐	Recording of A_0 value > 3000 at da Vinci instrument OK?	
☐	☐	Number of test batches OK?	

7.4 Protein Extraction and Analysis:

- 3 instruments (worst case instruments, e.g. cautery instruments)
- Extraction and analysis in lab
  (suitable transport box available?)
- Extraction on site, analysis in lab
- Extraction and analysis on site

Yes	No	Requirement	Note
☐	☐	*Extraction of residual proteins with SDS in accordance with method description (see section 11.2)*	
☐	☐	Performance of quantitative determination of residual protein from SDS extract *residual protein limit value for each instrument <100* µg	
☐	☐	Number of da Vinci instruments to be tested specified? (validation / requalification)	

7.5 Routine Inspection

1 instrument per quarter → residual protein test (destructive or non-destructive)

8 Preparation of Instruments for Protein Test (Health Care Organization)

8.1 General Preparation:

- Sterile glove or clean disposable glove
- Ensure clean, oil-free compressed air. Recontamination must not occur upon drying.
- Turn on light magnifying glass, 4X zoom as noted in manufacturer instructions
- Place clean surface (e.g. packaging fleece) on side table.
- Seal one side of foil pouch of sufficient size.
- Marker for labeling (markings only on film side of foil pouch)
- Dust protection film for covering packed instruments (additional protection from cross-contamination)
- Express shipment parcel label
- Completed consignment slip from test lab (to the extent possible)
- Have ready appropriately-sized carton for packed da Vinci instruments

Important: The lab or test facility must have experience in residual protein extraction and in residual protein analysis of da Vinci instruments, since a specific process is required. If the analysis is to be carried out by an external body, first get in touch with the lab which will carry out the test for residual contamination to order the test request forms which will need to be completed and to clarify other processing details. Instruments should be sent immediately for the test, so clarify in advance how your health care organization will handle this in terms of mailing. Thursdays and Fridays are not recommended as a surgery day (= shipment day) since the package will be stored over the weekend either in the post office or in a parcel center and will be exposed to influences which cannot be tracked (e.g. heat in the summer). Alternatively, instruments can be stored in cool condition (max. 20 °C) until they are shipped (see section 9 Drying /Transport / Storage)

8.2 Preparation of Instruments for Residual Protein Test

- After use in surgery, reprocess as described in procedural instructions / SOP (pre-cleaning with soaking, flushing, brushing, etc.)
- reprocess in washer-disinfector and stop cycle after final flushing and before disinfection begins (ask technician from manufacturer)
- A printout of the description of the washer-disinfector processing procedure (batch documentation) must be attached.
- Remove instruments using clean disposable gloves and place on a clean surface (fleece), do not touch the tip or hit it in any way. Take each instrument individually from the load carrier one after the other, with no "interim storage".
- **Very thoroughly** dry each instrument using clean, oil-free compressed air (at the tip as well) → residual moisture can cause the SDS solution to become turbid and thus produce incorrect results
- Touch instruments only on their housing
- Carefully inspect the tip of the instrument and the joint under the magnifying lamp for residual contamination (the tip of the instrument must not be touched or come into contact with other objects)
- Using a 2nd person, put each instrument into a separate foil pouch and seal it (take care not to puncture the foil pouch, do **not** use tip protection, put the instrument tip-first in the foil pouch, otherwise there is a risk of contamination through the contacted housing)
- Seal and label the foil bag (date and health care organization → it must be possible for lab to understand from which health care provider these instruments come from)
- Place in carton together with request slip and label again
- Send with requirement sheet to lab immediately (NO interim storage in post office!)
- Clarify return procedure with lab.
- Protein residue extractions and tests may also be carried out in the health care organization itself, by appropriate qualified employees using authorized procedures.

9 Drying /Transport / Storage

9.1 Drying

- Instruments are dried in accordance with manufacturer instructions.

9.2 Transport

- Pack, seal and label dried instruments individually in a foil pouch
- If more than one da Vinci instrument is being transported, each individually packaged instrument should be packed together in one foil pouch. Then use adhesive tape to close or seal the outer packaging.
- Pack instruments in leak-proof, sealable outer packaging and make sure they cannot be shifted during transport
- Notify the lab of the instrument delivery
- Transport should be made promptly, by express mail if possible
- It may be advisable to insure the shipment.

9.3 Storage

- Ideally the protein extraction is carried out immediately after the reprocessing procedure
- If the protein extraction is not carried out immediately after the reprocessing procedure, the instruments must be completely dried

10 Description of Protein Extraction Process

In accordance with SN EN ISO 15883-1, Annex C "Test methods for the detection and assessment of residual proteinaceous contamination"

The description of the extraction process for non-destructive testing is based on the procedure described in the publication "*A method for testing the cleaning of MIS robotic instruments"*. The extraction process for destructive testing which is also described there is not separately described in this recommendation.

10.1 Description of Protein Extraction Process (Non-Destructive)

Important: The protein analysis must be carried out by a lab that has sufficient experience in working with test methods for detecting and assessing residual proteinaceous contamination on da Vinci instruments.

Turbid eluates: The quantification of turbid extracts by means of photometric measuring has proven be difficult. When turbidity occurs, its cause must be determined and stopped as best as possible. A clarifying filtration by means of a syringe filter made of e.g. regenerated cellulose (pore diameter of 0.2 µm, hydrophilic) can remove the turbidity of the extract for a photometric measurement. Nevertheless, it must be ensured that the filter does not have any protein-absorbing properties. The clarifying filtration must be validated just like the other steps in the protein determination process.

10.2 Procedure: Extraction of Protein Residue from 8 mm da Vinci Si/Xi Instruments

To be carried out as part of a PQ for clinically contaminated instruments in accordance with SN EN ISO 15883-1.

10.2.1 Purpose

This procedure uses 1% sodium dodecyl sulfate (SDS) to extract protein residues from areas of 8 mm Si/Xi instruments which have been used clinically and have come into contact with patients. The procedure is part of a PQ for hospitals.

10.2.2 Scope

This extract procedure must be used for bipolar Maryland forceps and monopolar curved scissors in the 8 mm da Vinci product family. The procedure may also be used for other 8 mm instruments if necessary.

10.2.3 Background

The extraction procedure is used as part of type testing of washer-disinfectors in accordance with SN EN ISO 15883-1, which is used to determine the effectiveness of cleaning and restoration through the use of artificial contamination. The procedure has also been evaluated by the da Vinci working group for use as part of a PQ for clinically contaminated instruments. In addition, the procedure was carried out as part of European PQ tests for clinically contaminated instruments.

10.2.4 Test Procedure

10.2.4.1 General Considerations and Preparation

- Disposable gloves must be changed if the distal instrument end to be sampled comes into contact with the hand, in order to avoid transferring the extract from one instrument to another. The holding devices required for the extraction must be clean and dry before use. All syringe and sampling tubes must be clean and free of protein. A syringe must not be used for more than one instrument and must be disposed of after use.
- Extraction sampling tubes must be of the right size. Label the tube for each test instrument and control instrument with the serial number of the instrument, the extraction site (tip or shaft), test date and tester initials.
- Mount the instruments for extraction in a holding device, with the tip pointing to the bottom and the flush ports pointing in the direction of the tester (for Xi instruments).
- Wrap several layers of parafilm or a similar material around the distal openings of the monopolar curved scissors in order to seal them for the extraction process.

10.2.4.2 Extraction

- To extract the distal end of the instrument, the instrument must be fixed in a vertical position using a stand clamp. The working end of the instrument is lowered into a tube (total volume 10–15 ml) which is filled with 6 ml 1% SDS solution (pH = 11).
- A stopwatch is then started. Total extraction time is 30 minutes. The end of the instrument immersed in the SDS solution is taken vertically from the tube for a short time in order to move the branches of the functional part in all directions. To do this, each of the four

control knobs on the back of the housing component are rotated by hand to both the left and the right. After each knob is operated, the process is repeated two more times.

- The end of the instrument is then lowered again in the centrifuge tube and shaken, immersed in SDS solution, on a rotary mixer (vortexer) for 10 seconds.
- 10, 20 and 30 minutes after the start of the extraction process, the four control knobs are again operated three times and the instrument is again mixed on the rotary mixer.
- After the final rotary mixing (after 30 minutes), the extract is brought up from the tube using a disposable syringe (10 ml) and a sterile needle, and the working end is lowered into the emptied tube. Using the syringe (without the needle!) the extract is slowly injected into flush port 1 at the front of the housing component, the syringe remains connected.
- The stopwatch is started again and each of the four control knobs on the back of the housing component are rotated by hand to both the left and the right. After each knob is operated, the process is repeated two more times. The SDS solution is then slowly drawn back into the syringe until air bubbles collect in the syringe. Squeeze the air bubbles from the syringe by holding the syringe upwards. Then inject the extraction solution slowly back into flush port 1.
- This process is repeated at 10, 20 and 30 minutes. If SDS solution collects in the tube, take it up using the syringe and a sterile needle and slowly introduce it again into the shaft (syringe without needle).
- After 30 minutes, seal up the entire extraction solution in the labeled tube.
- Make sure that a separate syringe and needle are used for each instrument in order to avoid cross-contamination.

10.2.4.3 After Extraction

Procedures to be carried out for instruments returned to the health care organization for further clinical use.

- Flush and rinse off instrument with pressurized cold water.
- Process instrument completely, observing Intuitive reprocessing instructions.

10.2.4.4 Quantification of Residual Proteins

Residual protein analysis via OPA / BCA method (depending on analysis laboratory)

11 Possible Sources of Error

- Tests on damaged da Vinci instruments or da Vinci instruments not processed in accordance with manufacturer instructions should be avoided so as to avoid adulterating results.

- A reprocessing procedure carried out as part of a PQ must be stopped before thermal disinfection in accordance with SN EN ISO 15883-1 in order to prevent protein fixation which occurs at temperatures above 60 °C. If no flushing or neutralization is carried out after the cleaning phase, it is possible that da Vinci instruments are not completely flushed. Residue from cleaning chemicals may remain on da Vinci instruments, which may lead to false-positive results in the standard methods for determining residual protein. In such cases, the process should be stopped during the disinfection phase before a temperature of 60 °C is reached.

- After a da Vinci instrument is taken out of the washer-disinfector and before it is transported to the test lab, the tip of the instrument and inner space of the shaft must be dried. The instrument can be dried in accordance with the description in the reprocessing instructions, using clean, oil-free compressed air. If an extraction is performed for an instrument for a residual protein test, just a very small amount of oil in the compressed air may cause turbidity in extracts, which may adulterate test results. Alternatively, the instrument can be dried in a drying chamber, whereby the main flush port on the instrument housing is connected to a Luer connector via an air hose. The temperature in the drying chamber must not exceed 60 °C.

  Note: Other factors may also encourage turbidity of the SDS extract (e.g. cleaning agent residues).

- da Vinci instruments must be protected from environmental contamination, especially after they have been taken from the washer-disinfector and before they are tested for protein residues. Instruments must be handled carefully and handled only on the housing using clean disposable gloves. Contact with the tip of the instrument should be avoided. In addition, da Vinci instruments must be packed and transported in such a way that they cannot be contaminated with protein during transport. They can therefore be transported in clean, sealable foil pouches. Foil pouches must be sufficiently tear-resistant such that instrument tips cannot penetrate the pouch material.

12 References:

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