A method for testing the cleaning of MIS robotic instruments

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The working group DaVinci («AG DaVinci») was founded in order to establish a unified and reproducible test method to quantify the cleaning effect of robotic instruments that had been contaminated by actual use and then reprocessed. Since the instruments have several unique features in terms of their design and the materials used, special elution methods are needed for demonstrable recovery of the residual soils. The group developed a detailed protocol for the method to determine the residual protein content on the instrument type Maryland Bipolar Forceps (MBF; manufacturer: Intuitive Surgical Inc., CA, USA), which is representative for robotic instruments. To establish the method, the participants of the group conducted several round robin tests aimed at, inter alia, determining the recovery rates using different methods of protein quantification. The results of these round robin tests will be published in a subsequent paper.

The group consisted of the following members: Dr. Gabriele Albers (Hybeta GmbH), Dirk Dietrich (Hybeta GmbH), Prof. Dr. Hermann Frister (Hochschule Hannover), Dr. Manuel Heintz (wfk – Institut für Angewandte Forschung GmbH), Henri Hubert (SMP GmbH), Dipl. Umweltwiss. Johanna Köhnlein (HygCen – Centrum für Hygiene und medizinische Produktsicherheit GmbH), Dr. Winfried Michels (c/o Miele & Cie. KG), Dr. Urs Rosenberg (Borer Chemie AG), Klaus Roth (SMP GmbH), Dipl.-Ing. Oliver Schmidt (HygCen – Centrum für Hygiene und medizinische Produktsicherheit GmbH) and Dr. Markus Wehrl (wfk – Cleaning Technology Institute e. V.).
The following guests participated in the working sessions of the AG DaVinci: Klaus Bühler (Intuitive Surgical Sàrl, Aubonne, Schweiz) and Dr. Brian Wallace (Intuitive Surgical, Inc., Sunnyvale, CA, USA). The work of the AG DaVinci was supported by Intuitive Surgical Inc. (USA) by provision of robotic instruments, among other things.

KEY WORDS
- minimally invasive surgery
- robotic instruments
- DaVinci
- cleaning
- residual protein

Introduction

DaVinci instruments

Robot supported minimal invasive operative techniques are being used in more and more hospitals. The most common system is the DaVinci®-System made by the American manufacturer Intuitive Surgical Inc. (Sunnyvale, CA, USA) [1]. The robot system consists essentially of a console to operate the instrument and the operation robot itself, with four arms, via which three surgical instruments (EndoWrist® instruments) as well as the 3D camera system are controlled. Robot-supported surgical procedures are currently used in urology, gynaecology, cardiac surgery, ENT and thoracic surgery.

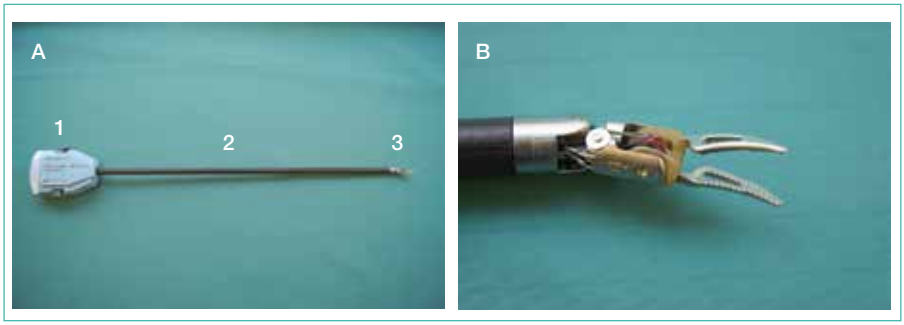

Fig. 1: Maryland Bipolar Forceps (MBF) as an example of a robotic instrument.
1A: Overall view with 1: Housing, 2: Shaft, 3: Distal working end
1B: Detailed shot of the distal end with soil on the pulleys

Considerably more than 90 % of the instruments currently used have a shaft diameter of 8 mm. These instruments are used in DaVinci, DaVinci S and DaVinci Si systems. Moreover, some instrument types for special applications are available, with a diameter of 5 mm. The instruments have a distal working end, which can be fitted with for example tweezers, hooks, scissors, needle-holders, sometimes with coagulating function, depending on the intended use.
One of the most frequently used instruments is the Maryland Bipolar Forceps (MBF; Fig. 1). The distal working end is attached to the shaft, a tube made from a composite material with an external diameter of 8 mm and a length of 43 cm. At the proximal end, the shaft is rotatably mounted in the housing, which is connected to the robotic arm. The distal working end is controlled via Bowden cables installed in the shaft. Their distal and proximal ends are designed as tungsten wires and are controlled by the robot via four rotary knobs on the housing. For cauterising instruments two insulated voltage cables also run through the shaft. The distal

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working end, controlled by the tungsten wires, contains multiple pulleys in all instruments. The Bowden cables run over these to effect the movement of the instrument parts. The interior of the shaft is distally separated from the working end by a septum, through which the cables run in tightly fitting holes.

Reprocessing

The manufacturers of robotic instruments clear each instrument type for a limited number of uses. Regarding classification for reprocessing, these instruments are allocated to the group «critical B» [2, 3]. Because of their geometrical complexity, their soiling with coagulating blood and possibly also intense thermal denaturation of soil (in case of electrocoagulation at the the working end) as well as the deposition of soil into crevice and contact areas during movement, an intense manual pretreatment should be carried out. Due to the slight insufflation overpressure during the operation and the movement of the Bowden cables, small amounts of blood can also enter the interior of the shaft. To flush this out two flushing ports are provided in the housing. Cleaning solution is flushed through Port 1, which is lengthened on the inside with a tube leading up to about 35 mm in front of the septum at the distal end. From there, the cleaning solution instilled into the interior distal area of the shaft flows through the available spaces between the wires, cables and tubes to the rear and exits at the end of the shaft into the housing. Cleaning and flushing within the housing is conducted via Port 2. After manual pre-treatment, automatic cleaning and thermal disinfection is carried out in a WD (washer-disinfector) with a special loading trolley [4, 5]. After visual inspection, functional checks and maintenance, the instruments are packaged and then sterilised with moist heat.

During validation of the reprocessing method used [6], cleaning efficacy has to be evaluated using instruments contaminated by actual use as part of the performance qualification (PQ) [7, 8]. Up to now there were no stringent method descriptions to test robotic instruments for residual protein, so that results from various testing laboratories evaluating efficacy of the cleaning method were hardly reproducible and not comparable [9]. Especially the differences in sampling and the relation of the results to the size of the sampled surface were of particular relevance.

The test method described in the following was developed by participants of the DaVinci AG under communication with the instrument manufacturer and were reviewed in round robin tests. Detailed results of the round robin tests, e. g. the recovery rates of different test soils containing protein and the suitability of protein quantification methods, will be published soon.

Test design

Principles of the tests

Protein was chosen as the main parameter to quantify residual soiling of the instruments. For quantification either the modified ortho-phthaldialdehyde (OPA) method or the bicinchoninic acid (BCA) method can be used.

Before being sampled for the first time, an instrument must have been reprocessed at least three times to minimize possible interfering effects of soils that originate from the manufacturing process and the chosen protein quantification method. Strict compliance with the manufacturer's reprocessing instructions as well as visual inspection of instruments using optical magnification (generally 3 – 5×, e. g. magnifying glass, magnifying lamp) are basic preconditions for elution and determination of the residual protein content. Here, no visually detectable residual soil may be recognised, especially on the wires, pulleys or joints of the functional end.

For visual inspection, the distal working end must be moved manually and the branches opened to the maximum to check hidden areas more thoroughly.

Invisible residual soil, e. g. between the individual wires of the Bowden cables, or at the axis of the pulley can only be assessed by elution and quantification of proteins. Visible residues (precipates) of water constituents have also been identified in isolated cases. For that reason, demineralised water should be used already for the cleaning step. If detergent residues are detected, the duration or number of cleaning steps must be prolonged or increased, respectively.

Sampling sites

Sampling of instruments is targeted, in particular, towards those areas that come into contact with the patient's body fluids and tissues during surgery, and which pose a risk of transmission when the instruments are reused. Such sites include the distal working end and the interior of the distal shaft area. Sampling of the distal working end and shaft is conducted sequentially. The interior of the proximal housing, most distant from the patient, is not sampled since: i) the housing is far away from the patient and can neither directly nor indirectly come into contact with the patient during a procedure; ii) the interior of the housing is covered by a hood and can neither come into contact with the patient nor become contaminated, iii) even in the event of persistence of slight contamination after reprocessing, it is very unlikely that this could be transferred from the housing through the shaft interior to the patient (silicone gasket at the distal working end, insufflation overpressure). The exterior of the shaft and housing is not sampled since this area is composed of geometric, non-critical and exposed surfaces that are easily accessible for manual precleaning and automated reprocessing, and lend themselves to visual inspection.

Removal of instruments

Testing of cleaning efficacy is carried out after interrupting the automatic reprocessing procedure immediately before the start of thermal disinfection stage. The instruments are removed from the WD using gloves and the water is sheaken off. With the distal end held somewhat higher than Port 1, 20 ml of air are injected twice with a disposable syringe to flush out any residual water.

On-site testing

If the instruments are tested on-site, elution should be carried out within one hour after removal from the WD, and protein quantification should be conducted immediately after this. The instruments may however alternatively be packed in plastic bags and stored in a freezer at ≤ –10 °C to await testing.

Shipping of instruments

If testing is not carried out on-site but in an external laboratory, the instruments are packed in a plastic bag or tube and sealed. The instruments are then placed in the original manufacturer's box.

The instruments must be transported under refrigerated conditions and within 24 hours to prevent growth of microorgan-

isms and potential effects on any residual soils present. The instrument boxes are thermally insulated by putting them into polystyrene containers (e. g. as used in the food industry) together with a sufficient number of deep frozen cool packs (≤ –10 °C) and dispatched by mail. To monitor temperature a suitable temperature logger is placed into one instrument box. Upon arrival at the laboratory the logger data are read out and the temperature curve is documented. The temperature should not exceed 20 °C upon arrival at the destination. The instruments are immediately tested or kept in a freezer at ≤ –10 °C until testing is possible.

Testing of instruments stored under frozen conditions

The test instruments are stored in a freezer at temperatures of ≤ –10 °C to prevent microbial metabolism and growth as well as to rule out any effects on the residual soils present. The instruments must be removed from the freezer approximately 2 h before elution to enable them to adapt to room temperature. Only instruments that have reached room temperature should be removed from the packaging (foil packaging, reels/tubular bags etc.) to avoid any effects arising from condensed water deposition.

Setting the type of testing

Type I test: Non-destructive testing

For tests taking place before the end of the instrument's life cycle, i. e. before the number of reprocessing cycles allowed by the manufacturer have been carried out, non-destructive elution of the distal working end and elution of the shaft interior is undertaken, see Fig. 2.

To quantitatively remove any residues from the manufacturing process, new instruments should be subjected to at least two complete automatic reprocessing cycles (cleaning and thermal disinfection) initially. Testing after clinical use is thus carried out after the third cleaning cycle.

Type II test: Destructive test after final use

After the final use the instruments are cleaned. Then a destructive test is carried out in order to quantify any accumulated residual soil occurring at the distal working end and the interior of the shaft, see Fig 2.

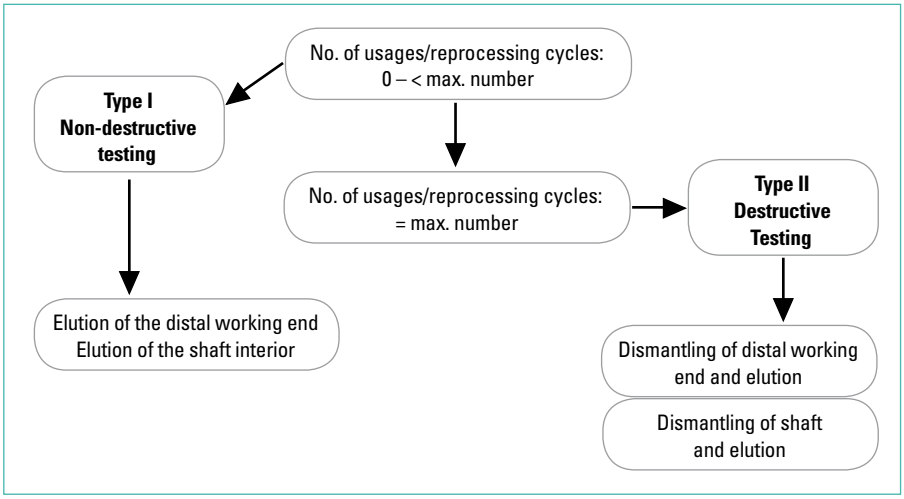

Fig. 2: Selection of test method depending on the number of applications/reprocessing cycles

Materials and methods

Solutions and appliances

- 1% SDS solution (w/w) in H_2O, NaOH solution is used to adjust pH = 11 (Sodium dodecylsulphate, grade for biochemical applications) [e. g. Merck, order number: 1.12533.0050]
- 0.1 M NaOH solution in H_2O
- H_2O, HPLC grade (e. g. Merck, order no.: 1.15333.2500)
- Bovine serum albumin (BSA), Fraction V, purity ≥ 98 % (e. g. Carl Roth, order no.: T844.2)
- Microlitre pipettes, diverse volumes, calibrated
- Pipette tips, diverse sizes
- disposable syringe 10 ml total volume
- Vortex mixer (e. g. Carl Roth, order no.: AH32.1)
- Centrifuge tubes with a total volume of 15 ml (e. g. BD Falcon No. 352099) or 10 ml cryogenic tubes (e. g. Carl Roth, order no. P168.1)
- reaction vessels, diverse
- pH measuring strips e. g. pH = 7, 0 – 14,0 (Carl Roth, order no. C732.2)
- Pieces of silicon tubing, internal diameter 8 mm, external diameter 11 mm, length 8 cm (e. g. Carl Roth, order no.: 9576.1) or various sealing cones suitable for closing shaft ends
- Crile clamps, diverse
- Foil bags, reels, miscellaneous
- Styrofoam boxes (e. g. Overath, Model: K11326 HACCP, order no.: 77335011326)
- Temperature logger (e. g. Ebro, type EBI 300/310)
- Regarding the protein quantification methods (modified OPA method or BCA method), it is referred to EN 15883-1 App. C [10]. Alternatively, modified methods, e. g. [11] or commercial test kits may be used, as long as these are based on the same chemical detection reactions and are equally suitable to quantify protein. Specific detection limits and possible interference factors have to be observed.

Type I test (non-destructive)

Elution of the functional end and of the interior of the shaft

In order to elute the interior of the shaft, the instrument is fixed in a vertical position using tripod clamp. The working end is lowered into a centrifuge tube (total volume 10 – 15 ml) filled with 6 ml 1% SDS solution (pH = 11). Afterwards a stop watch is started. The total elution time is 30 min. The immerged working end is removed from the tube for a short time to enable movement of the parts of the working end into every direction. To effect this, each of the four control knobs on the back of the housing is manually turned to the left and to the right. After turning each knob the procedure is repeated two more times. The working end is then reinserted into the tube, immerged into the SDS solution and is shaken on a vortex mixer for 10 seconds. Ten minutes after starting the elution, three further agitations of the four con-

trol knobs are carried out including mixing on the vortex mixer afterwards. The procedure is repeated after 20 min and after 30 min. After the last vortexing, the eluate is drawn up from the tube using a disposable syringe (10 ml), and the working end is reinserted into the empty tube. The eluate is slowly injected into the flushing port 1 on the front side of the housing, the syringe remains in place. The stopwatch is started again. Each of the four control knobs on the back of the housing is manually turned to the left and to the right. After turning each knob, the procedure is repeated twice.
In the following, the eluate is drawn up three times with the syringe (still in place) and reinjected. The instrument stays until the stopwatch shows 10 minutes. The eluate is then drawn up from the instrument, mixed with the solution discharged into the tube and then completely drawn up again with the syringe. The syringe is again connected to the flushing port 1 and the elution process is repeated. Further repetitions of the whole elution process are performed at 20 and 30 min. Finally, the eluate from the instrument is mixed again with solution discharged into the tube and an aliquot is taken for analysis.

Type II Test (destructive test)

Dismantling of the instruments

The cover of the housing of the instrument being tested is levered off using a screwdriver. The Bowden cables are cut with a fine wire cutter at the control cogs. These then turn freely (Fig. 3). Now the metallic working end can be disconnected from the shaft pipe and the Bowden cables cut with the wire cutter around 8 mm behind the transition of the wire to the metal beam element («hypotube») in the centre of the crimp mark. The insulated electrical cables are cut at the same level.
The shaft is then separated from the housing and pulled off a little, to make the Bowden cables disappear into the shaft pipe at the distal end. On the side leading to the housing end, the Bowden cables are cut, again in the centre of the crimp mark on the «hypotube», as well as the electrical cables and the rinsing tube. Therefore the shaft must be positioned horizontally to ensure that detached components will remain within the shaft.

Elution and testing of the metal working end

The functional end of the metallic working end, and especially the inner cylinder in the area where the Bowden cables pass through to the functional end, is carefully checked with the help of an optical magnifying glass (3 – 5×). Residues must not be visually detectable.
The distal part is now placed in a clean vessel (e. g. 10 – 15 ml centrifuge tubes). 3 ml 1 % SDS solution, pH 11 are added and the tube is closed and a stop watch is started. The tube is shaken for 15 seconds using a vortex mixer and then incubated for 10 minutes. The vortexing and incubation phase are repeated two more times. After 30 minutes the elution ends with a final mixing. After the foam has been allowed to settle somewhat, the tube is opened and the distal end is removed with a pair of tweezers. An aliquot of the solution is removed for analysis.

Elution and testing of the interior of the shaft

A suitable piece of silicon tube (length 8 cm) is pushed halfway onto the end of the shaft, with the Bowden cables, cables and rinsing tube inside. It can be fixed with a clamp if necessary. The loose end of the silicon tube is closed using for example a Crile clamp. The shaft pipe is held upright with the closed end downwards and 4 ml 1% SDS solution, pH = 11 is pipetted into the shaft.
Another piece of silicon tube is now pushed halfway onto the upper end, and closed with a clamp. Alternatively, suitable sealing cones may be used.
The shaft is jolted twice on the table, turned over and jolted twice again, and this is repeated another three times. Each end is thus double jolted four times in total. After 10 minutes incubation the jolting is repeated three times in each direction, and the procedure is again repeated after another 10 minutes soak. The clamp from one end is then removed and the solution is poured into a glass beaker. An aliquot is removed for analysis.

Testing for turbidity

All eluates must be checked for possible turbidity before protein quantification. The eluate in the tube is best inspected against a dark background. If there is visual turbidity, subsequent photometric measurements must not be carried out and the samples are rejected as being unquantifiable. To date, no suitable methods for the removal of these optically interfering substances have been evaluated and verified. In any case, potential causes, such as e. g. the water quality used for the reprocessing steps, must be investigated.

Protein quantification methods

Various established methods can be used to quantify the protein content of the eluate. One example is the modified orthophthaldialdehyde (OPA) method [10, 11]. When using the OPA method it is important to ensure that the capacity of the buffer system used is not exceeded, because the basic mechanism of the method exhibits pH dependency. pH measuring strips can be easily used to check if the pH of the solution varies from pH = 9.3 ± 0.2.
Alternatively, the bicinchoninic acid (BCA) method can be used [7, 10] employing a photometer. The absolute dependency on temperature and time of this method has to be taken into account.
Each method has to be calibrated with a defined protein solution. This must be carried out on every working day. The es-

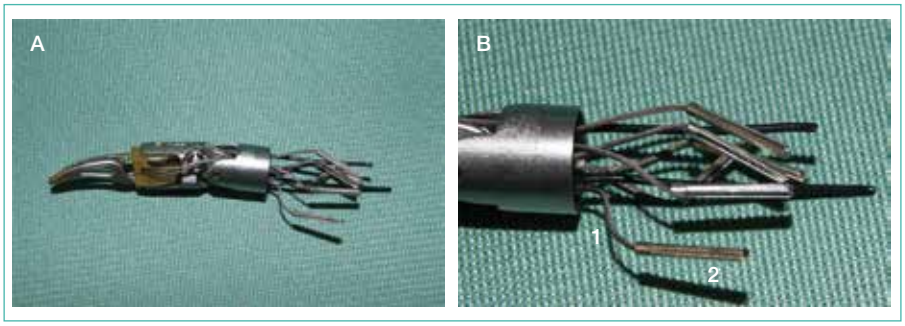

Fig. 3: Dismantled distal working end of a Maryland Bipolar Forceps instrument
3A: Total view of distal working end
3B: Cutting the Bowden cables at the crimp mark on the transition wire (1) – «hypotube» (2)

tablished model protein Bovine serum albumin (BSA, Fraction V) is used for calibration. Laboratories are advised to specify the selected method especially regarding the detection limit.

Calculation of residual protein contents

Robotic instruments are complex composite instruments that consist of a large variety of different materials. In interlaboratory tests conducted by the working group DaVinci, interfering substances – as yet unidentified – have been found to exert considerable interference on protein quantification.

Documentation of results

For documentation of the results, the following information should be listed:

- Type of instruments, number of previous uses/reprocessing cycles
- Transport and/or storage conditions (temperature, period)
- Results of the visual inspection for residual soil
- Information on the visual inspection for turbidity
- Type of test (Type I/II)
- Protein quantification method used, including details about specification
- Results of the protein quantification
  - for Type I tests: total protein content for distal working end plus shaft
  - for Type II tests: protein content for distal working end and shaft

If testing is performed by external laboratories, the operators of the robotic instruments must provide the required information.

Acceptance criteria

To assess the cleaning effect, quantification of residual soils is carried out using the methodology described above. The cleaning effect is assessed by means of acceptance criteria based on the following two parameters:

- Absence of visually detectable residues on all external surfaces, using optical magnification
- Surface-related maximum residual protein content determined on the basis of elution and protein quantification for relevant critical instrument surfaces.

The quantification of residual proteins on robotic instruments is referred to the model protein Bovine Serum Albumin, BSA Fraction V, which is used for calibration of the quantification methods.

For protein quantification of eluates from new robotic instruments, or instruments that had been reprocessed only a few times, interferences were observed for both methods, i.e. the modified OPA and the BCA method (see Section «Principles of the tests»). These interferences caused by hitherto unidentified substances gave rise to false-positive results. Measures to compensate for these variable interfering substances are not available. Hence the true protein content is assumed to range below the measured amount in the eluates from the instruments.

However, the recovery rate for artificially contaminated instruments is usually less than 100 %. Therefore it must be assumed that the residual protein content for real-life instruments is, as a rule, less than the protein amount actually present. A compensation is not possible for non-quantitative recovery, since no specific recovery rate can be ascertained with regard to the contamination of real instruments (variability in the extent of soiling, differences in the storage or reprocessing conditions, effects of chemicals on proteins, etc.).

It can be assumed that overestimation of the residual protein amount due to false-positive results and underestimation of the residual protein amount due to non-quantitative recovery cancel out each other, at least partially. Hence, an undifferentiated inclusion of false-positive results is the best way to get an approximate idea of the actual residual protein content present on robotic instruments.

As acceptance criterion for the cleanliness of robotic instruments, a surface-related maximum residual protein content was specified. That surface-related approach takes account of the widespread variability in terms of size and surface of the medical devices to be reprocessed. At present, working group ISO TC 198 WG13 is discussing setting a maximum protein amount per surface unit between 2 and 6.4 µg/cm^2. The Guideline Groups, composed of members of the DGKH, DGSV and AKI* who are compiling relevant guidelines, aim to find a consensus on an acceptance value of 3 µg/cm^2 for the guidelines on validation of manual as well as automated reprocessing. That aim is based on the evaluation of results obtained for performance qualifications of real-life instruments used in everyday practice, see [12], page 212 of this issue. This surface-related maximum protein content is to be included in the future guideline for manual reprocessing as well as in the revised guideline for automated reprocessing procedures [13, 14]. Both guidelines are to be published in 2013 or 2014. Depending on future technical developments, the acceptance value of 3 µg/cm^2 may be modified or reduced (optimization imperative).

Consequently, in order to be able to specify a surface-related acceptance value for robotic instruments, the relevant instrument surface must be determined. The manufacturer of the robotic instruments has provided the following details, see Table 1.

Table 1: Instrument surfaces of Maryland Bipolar Forceps
Maryland Bipolar Forceps (MBF) (Intuitive Surgical Inc., Sunnyvale, CA, USA)

Instrument site	Surface
Distal working end (external and internal surfaces of the metallic functional end, incl. approx. 2 cm/Bowden cables/cables)	≅ 27 cm^2
Internal surface of shaft (shaft length 42.5 cm, incl. Bowden cables, cables, rinsing tube)	≅ 266 cm^2
Internal shaft surfaces relevant for soiling (6 cm of distal shaft with Bowden cables, cables, 1.5 cm rinsing tube)	≅ 24 cm^2

Acceptance criteria for type I test

For type I testing all external surfaces of the distal working end are eluted. During the ensuing shaft elution, the internal surface areas of the distal functional end are sampled together with the surface of the entire shaft interior. The overall amount of soil in the interior shaft is small and occurs immediately after the functional end (septum with silicone disc) as it is distributed

by approximately only 1 cm by moving the Bowden cables upwards/downwards. For that reason, the critical surface to be assessed is confined to a small section of the entire internal shaft surface area. A consensual decision was taken by the working group to include only 6 cm of the distal shaft area for calculation of the maximum protein content. This avoids inclusion of large surfaces not exposed to soiling, and thus of no relevance, when specifying the acceptance value. Inclusion of unsoiled surfaces would result in the acceptance value being set higher than reasonable.

Maximum residual protein content for type I test

– Distal working end and shaft interior: 155 µg

These values are obtained following elution of critical surfaces: i) distal working end (à 27 cm^2) and ii) 6 cm of distal shaft area (à 24 cm^2); the mathematically calculated value was rounded up by 2 µg.

Acceptance criteria for type II test

Maximum residual protein content for type II test

– Distal working end: 80 µg
– Shaft interior: 75 µg

For this test, in principle the same surfaces are sampled as for type I testing. The only difference is that separate elutions are performed. The acceptance criteria are given separately for both areas sampled to rule out inadmissible accumulation at any particular sampling site. The values are obtained from the surface of the distal functional end (à 27 cm^2) and the relevant shaft area (à 24 cm^2). The acceptance values were rounded down by 1 µg and up by 3 µg, respectively.

Exceeding of acceptance criteria

If the acceptance values are exceeded, the reprocessing process, instruments and sampling technique must be thoroughly analysed. Overshooting of values may be caused by false-positive measurement results. In turn, such results can derive, in particular, from residues or substances persisting after the manufacturing process as well as from maintenance oils that can interfere with photometric measurements. In round robin tests it was noted that eluates could exhibit turbidity levels that made photometric measurements impossible. Methods must be devised to remove interfering substances and/or substances causing turbidity from the eluate; however, at present, no such methods have been developed or established. If necessary, negative controls (instruments to be used only for test purposes) should be used for detailed investigation of the reprocessing processes.

Outliers among the protein values can be expected more often when reprocessing complex instruments compared with their uncomplicated counterparts for which only automated cleaning processes were used. This is because manual pretreatment has a major impact on the results obtained after automated cleaning. Therefore variability of manual pretreatment must be kept to a minimum through strict compliance with the operating procedures.

If the acceptance value is exceeded in individual cases, investigations and corrections should be carried out. Subsequently, another three instruments should be analysed to prove that the questionable result was a genuine outlier. ■

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