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Accredited test authority
pursuant to EN ISO 17025
and accredited inspection
authority pursuant to EN
ISO 17020



St. Johann, 30.10.12

Inspection Report 12793432

W&H Assistina 3x3 (REF19923000)

W&H Assistina 3x2 (REF19922000)

Validation of Cleaning Effectiveness

Lab number
127934001
127934002
127934011

Client designation
W&H Assistina 3x3 Type MB-300 – SN 00502
W&H Assistina 3x2 Type MB-200 – SN 00502
W&H Activefluid MC-1100

Inspection order:	Validation of cleaning effectiveness	Inspector:	Sladana Jusic, Arno Sorger
Inspection date:	18.09.12		
Inspection location:	WHU GmbH, St Johann		
Inspection procedure:	SOP 7030 analogous to ÖNORM EN ISO 15883-1 and ÖNORM CEN ISO/TS 15883-5		
Test order:	Testing of cleaning effectiveness with modified OPA method.		
Receipt of samples:	18.09.12	Samples provided by:	Sladana Jusic
Sampling date:	18.09.12	Sampler:	Sladana Jusic

The inspection was conducted on 18.09.12 and 30.10.12

Only the principal results are summarised in this inspection report.

1.) Test details

The determination of requirements is significant for an evaluation.

Tests of hand and angle pieces and turbines were, on the one hand, conducted under circumstances as close to practical conditions as possible and, on the other, involved worst case scenario testing.

1.1 Testing scope/ method

Testing was based on ÖNORM EN ISO 15883-1 and ÖNORM CEN ISO/TS 15883-5.

1.2 Soiling with blood to evaluate cleaning effectiveness

Heparinized sheep's blood (1 IE/ml blood) is diluted 1:1 with PBS (as a surrogate for rinsing water and saliva) and reactivated with 1.5 IU protamine sulfate /ml blood.

Note: The blood remains on the outside if not diluted, rather than penetrating to the interior of the instrument (as, however, observed under practical conditions). Diluting with PBS does not alter the pH value and ionic strength of the blood. Coagulation properties are also only influenced to a slight degree.

1.3 Soiling the instruments

Soiling was realised with instruments as they are used under practical conditions (clamped drill).

The test instruments were selected according to the difficulty of preparation.



Fig. 1 – Soiling the instrument head

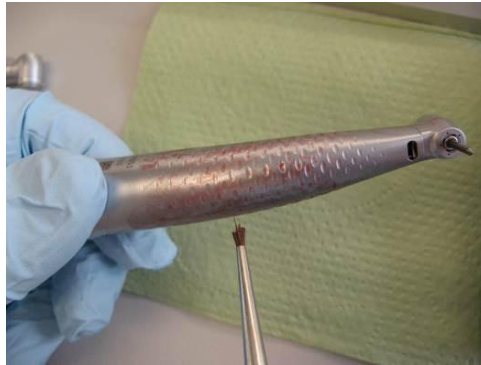


Fig. 2 – Soiling of instrument surface

10 µl of *blood* was pipetted onto the instrument spindle. The exterior of the instruments was soiled with 20µl of *blood* (pipetted initially, subsequently distributed evenly with a hair pencil). The spray channels were each flooded with 5µl of blood. The drying time is 15 minutes.*

*Note: The drying time of 15 minutes was selected to this effect, as immediate preparation following treatment is generally required.

1.4 Recovery of test soiling

Test soiling recovery is realised through elution in 1% SDS

1.5 Protein assay

The protein assay was conducted according to the modified OPA method, enabling determinations to less than 0.3µg blood protein / specimen in this configuration.

2.) Contamination of device through preparation of instruments

Investigations were conducted to ascertain whether the preparation process can pose a hazard to the user through contamination of the device with microorganisms from the instruments.

The investigations with test organisms indicated that no relevant microbiological contamination could be determined in connection with the cleaning fluid, neither in the chamber nor in the emerging air.

3.) Summarised evaluation/findings

The soiling applied corresponds to a protein content of 187µg – 750µg per tested part. The maximum soiling recovered corresponds to a protein content of less than 4µg per tested part.

Assistina 3x3 / Assistina 3x2

The tests conducted with hand and angle pieces and turbines and this documentation indicate that the cleaning effectiveness of the *Assistina 3x3 (REF 19923000) Type MB-300 – SN 00502* and *Assistina 3x2 (REF 19922000) Type MB-200 – SN 00502* in conjunction with the *W&H Activefluid MC-1100* cleaning agent and the process investigated lies at over 99%.

The devices tested are suitable for quality-assured (validated) interior and exterior cleaning of dental instruments.

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Dr. Arno Sorger
Technical Director W.H.U. GmbH
Inspector

To: client