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R E C H E R C H E & D E V E L O P P E M E N T

EVALUATION OF THE EFFICACY OF THE CLEANING STAGE OF THE STANDARD CYCLE OF AN ENDOSCOPE WASHER-DISINFECTOR ACCORDING TO ISO/FDIS 15883-4: 2006 CLAUSES 4.3.5 AND 6.11

(TEST SOIL OF THE ANNEX R OF THE ISO/DTS 15883-5: 2005)

SL-ENT-PAA (SOLSUCOPE SAS)

This document is a translation of the test report edited on April 07th 2007

Test report written by: Dr Lionel PINEAU

Marseilles: April 14th 2011

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I : DESCRIPTION OF THE STUDY :

Title:	Evaluation of the efficacy of the cleaning stage of the standard cycle of an endoscope washer-disinfector according to the ISO/FDIS 15883-4: 2006 (clauses 4.3.5 and 6.11). Test soil of the annex R of the ISO/DTS 15883-5: 2005 SL-ENT-PAA (SOLUSCOPE SAS)
Study n°:	C.002.MED.00.81
Sponsor:	SOLUSCOPE SAS 43, Bd de la Barnière 13010 Marseille <i>Contact: Mr MARTY S.</i>
Test period:	From 24/01/2007 to 31/01/2007
Laboratory manager:	Dr Lionel PINEAU
Test manager:	Audrey BANCOD
Test laboratory:	Laboratoire BIOTECH-GERMANDE Parc Scientifique de Luminy 163 Avenue de Luminy – Case 927 13288 Marseille Cedex 9

II : OBJECTIF OF THE STUDY :

Evaluate according to clauses 4.3.5 and 6.11 of ISO/FDIS 15883-4: 2006⁽¹⁾, the efficacy of the cleaning stage of the standard cycle of the endoscope washer-disinfector SL-ENT-PAA (SOLUSCOPE SAS) against the test soil described in ISO/DTS 15883-5:2005⁽²⁾ annex R.

III : RATIONALE :

Clauses 4.3.5 and 6.11 of the ISO/FDIS 15883-4:2006 specify that for operational qualification, cleaning test (for load, load carrier and chamber walls) shall be performed on a surrogate device using one, or more, of the appropriate test soil by the method given in ISO/TS 15883-5: 2006 for the particular test soil.

In clause 6.11.3 of the ISO/FDIS 15883-4: 2006, the attention of manufacturers is drawn to the fact that test soils(s) and method(s) intended to be used for operational testing is left to user's discretion (see ISO 15883-1:2006 clause 10.t)⁽³⁾ and that this can indicate a need to carry out similar testing before the WD is supplied.

This study is performed to verify, during type testing, the ability of the cleaning phase of the standard cycle of the washer-disinfector to remove one of the tests soil which could be used during operational qualification.

The test soil selected (ISO/TS 15883-5:2006 Annex R) is a complex mixture recommended in ISO/TS 15883-5:2006 and HTM 2030⁽⁴⁾ for the evaluation of the cleaning efficacy of the standard cycle of endoscope washer-disinfector.

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IV : PRINCIPLE :

All external surfaces of a surrogate and the internal surfaces of the chamber walls of the endoscope washer-disinfector are contaminated with the test soil, dried for one hour and then submitted to a standard cleaning-disinfection stage interrupted just prior to the start of the disinfection stage. Seeing that test the washer-disinfector tested is exclusively used for laryngoscope (without internal channel) reprocessing, only the external surfaces of the surrogate device described in the annex R of the ISO/DTS 15883-5:2005 (PTFE tubes with internal diameter of 2 mm and 1 mm) were contaminated.

External surfaces of a surrogate and the internal surfaces of the chamber walls of the endoscope washer-disinfector are visually examined to detect any residual traces of the test soil.

V : MATERIAL:

a) Washer-disinfector:



Photo 1 : SL-ENT-PAA

Name : SL-ENT-PAA
Serial n°: ENT-06001

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R E C H E R C H E & D E V E L O P P E M E N T**Table I :** Characteristics of the SL-ENT-PAA (SOLUSCOPE SAS) standard cleaning/disinfection cycle. Values mentioned in this table do not take into account filling, draining or heating times. Endoscopes are connected according to the washer-disinfector manufacturer recommendations.

PHASES	Nb. of sequences	Time	Chemicals	Temperature
			Nature	
1 Rinsing	1	20 seconds	0.2µm filtered water	28°C to 38°C
2 Cleaning	1	1 minute 40 seconds	Soluscope C - 0.5%	28°C to 38°C
3 Draining	1	30 to 40 seconds		
4 Dynamic rinsing	1	30 seconds	0.2µm filtered water	28°C to 38°C
5 Disinfection	1	5 minutes	Soluscope PA – 2.15% (v/v) [1.07% (v/v) Soluscope P + 1.07% (v/v) Soluscope A]	40°C
6 Draining	1	30 to 40 secondes		
7 Dynamic rinsing	1	30 seconds	0.2µm filtered water	28°C to 38°C
8 Draining	1	1 minute 45 seconds	0.2µm filtered water	28°C to 38°C
9 Blowing	1	30 seconds		28°C to 38°C

b) Soluscope C+ :

Nature:.....Detergent pre-disinfectant.
 Batch n°:.....601261
 Manufacturer:SOLUSCOPE SAS
 Expiration date :.....01/2007
 Internal Reference :.....C.002.MED.00.857
 Actives substances et concentrations :.....Not communicated
 Storage conditions :.....Ambient temperature

c) Soluscope PA :

Nature:.....Peracetic acid-based disinfectant
 + anti-corrosive agent (Soluscope A).
 Batch n° :.....Soluscope P : G353 12
 Soluscope A : H052 13
 Manufacturer:SOLUSCOPE SAS
 Expiration date :.....02/2007 (Soluscope A)
 12/2006 (Soluscope P)
 Internal Reference :.....Soluscope P: C.002.MED.00.792
 Soluscope A: C.002.MED.00.846
 Actives substances et concentrations :.....Peracetic acid 4.6%
 Storage conditions:.....Ambient temperature

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d) Surrogate device :

The surrogate device is constructed from two PTFE tubes of 1.5 m length with a internal diameter of 2 mm and from a PTFE tubes of 1.5 m length with a internal diameter of 1 mm Le dispositif type est construit à partir de deux tubes PTFE de 1,5 m de longueur et de 2 mm de diamètre interne et d'un tube PTFE de 1,5 m de longueur et de 1 mm de diamètre interne. The three tubes are connected to each other each 15 cm using an adhesive tape.

e) Test soil :

Glycerol (Sigma) :..... 30 ml
 Horse serum (Sigma) :..... 30 ml
 Dehydrated hog mucin (Sigma) :..... 5 g
 Unbleached plain flour (Sigma) :..... 2 g
 Safranin(Sigma):..... 1 ml d'une solution aqueuse à 2%
 Water: 50 ml

Internal reference : 1059

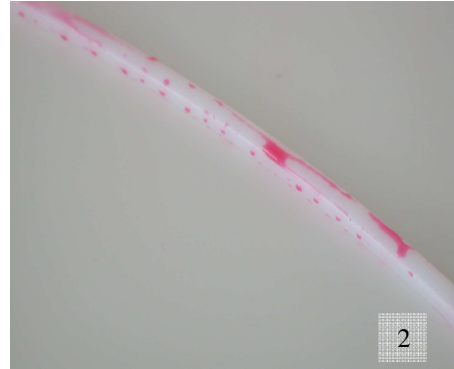
VI : METHOD :**a) Inoculation of the test tubes :**

An even coat of soil is applied to the outer surface of the tubes and on the external surfaces of the chamber walls using a paintbrush.
 Contaminated test surfaces are maintained at room temperature for 1 hour before being used for testing.

b) Assays :

The surrogate device is placed inside the endoscope washer-disinfector according to manufacturer instructions and the standard cleaning/disinfection cycle, as defined in V.b is initiated and interrupted just before the beginning of the disinfection phase (end of phase n°4, see table I).

External surfaces of a surrogate and the internal surfaces of the chamber walls of the endoscope washer-disinfector are visually examined to detect any residual traces of the test soil.

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Photos 1 and 2: Controls: Aspect of internal surfaces of the chamber and of external surfaces of the surrogate device after contamination.



Photos 3 and 4: Assays: Aspect of internal surfaces of the chamber and of external surfaces of the surrogate device after contamination and cleaning by the SL-ENT-APA (SOLUSCOPE SAS) standard cycle (see table I, phases 1 to 4).

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VIII : CONCLUSIONS :

The results of the tests carried out on the cleaning stage of the standard cleaning/disinfection cycle of the SL-ENT-PAA (SOLUSCOPE SAS) endoscope washer-disinfector show no visible traces of residual test soil was detected neither on the surrogate device or on the chamber walls of the washer-disinfector.

Taking into consideration these result, the efficacy of the cleaning stage of the cleaning/disinfection cycle of the SL-ENT-PAA (SOLUSCOPE SAS) endoscope washer-disinfector is consistent with the requirements of ISO/FDIS 15883-4 : 2006 when the test soil is the one described in the annex R of ISO/DTS 15883-5: 2005.

IX : REFERENCES :

- 1 – ISO/FDIS 15883-4:2006: Requirements and tests for washer-disinfectors employing chemical disinfection for thermo-labile endoscopes.
- 2 – ISO/DTS 15883-5:2005: Tests soils and methods for demonstrating cleaning efficacy of washer-disinfectors
- 3 – ISO 15883-1:2006: Washer-disinfectors. General requirements, terms and definitions and tests.
- 4 – HTM 2030 Health Technical Memorandum 2030, Washer-disinfectors – Validation and verification, The stationery Office, London, 1997, ISBN 0-11-322071-5.

X : STATEMENT OF GOOD LABORATORY PRACTICE:

The study was conducted according to NF EN ISO/CEI 17025 (2005) General requirements for the competence of testing and calibration laboratories.

The Quality Assurance Unit (QAU) has reviewed this report and determined it accurately describes the procedures used and that the results and conclusions herein accurately reflect the raw data from the study. Applicable Standard Operating Procedures and Good Laboratory Practice were followed in this study.

The original records of this report, the notebooks, protocol, and final study report are stored in the archives of Biotech-Germande "C.002.MED.00.81".

Lionel PINEAU
Managing director

Signature

Date 14/04/2011

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