Workshop on Endoscope disinfection & sterilization and infection control related to VAP

Endoscope reprocessing: Local challenges

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Contents

- Reprocessing endoscopes
- Pilot validation tests in NTWC
- Tracking and tracing of endoscopes and accessories
- Local Challenges

Spaulding Classification

Device classification	Level of Risk	Definition	Devices (examples)	Spaulding process classification
Critical	High	Entry or penetration into sterile tissue or blood	Implants, scalpels, needles, other surgical instruments, etc.	Sterilization
Semi-critical	Medium	Contact with intact non- sterile mucosa or non-intact skin	Flexible endoscopes, larngoscopes, respiratory and anesthesia equipment	High-level Disinfection
Non critical	Low	Contact with intact skin	Stethoscopes, BP cuffs, bedpans, etc.	Low-level disinfection



Disinfection

- Automatic reprocessor
- Manual disinfection

Automatic Endoscope Reprocessor (AER)

- Double doors (Pass through) concept
- Close system for preparing & draining disinfectant
- Internal water piping disinfection cycle available



safety notice below from HAHO regarding "Possible Anaphylaxes to ASP CIDEX OPA Solution supplied by JnJ"

B. Rinsing Instructions

1. RINSING PROCEDURE

a) Manual Processing:

- Following removal from CIDEXR OPA Solution, thoroughly rinse the medical device by immersing it completely in a large volume (e.g. 8 litres) of water. Use sterile water unless potable water is acceptable. See item 2 or 3 below.
- Keep the device totally immersed for a minimum of 1 minute in duration, unless a longer time is specified by the reusable device manufacturer.
- Manually flush all lumens with large volumes (not less than 100ml) of rinse water unless otherwise noted by the device manufacturer.
- Remove the device and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose.
- Repeat the procedure TWO (2) additional times, for a total of THREE (3) RINSES, with large volumes of fresh water to remove CIDEXR OPA Solution residues. Residues may cause serious side effects. SEE WARNINGS.
 THREE (3) SEPARATE, LARGE VOLUME WATER IMMERSION RINSES ARE REQUIRED.
- Refer to the reusable medical device manufacturer's labelling for additional rinsing instructions.

Drying

- True and pseudo outbreaks of waterborne microorganisms are always associated with wet or inadequately dried lumens of endoscope.
- 70% alcohol flushing is recommended before storage to
 - reduce risk of remaining pathogen
 - Possibility of recontamination of endoscope by waterborne microorganisms.



Storage



- 1. Hang endoscope vertically in a clean, dry and well-ventilated cabinet with all valves & water resistant cap removed.
- 2. Or hold endoscope horizontally on a flat surface with continuous air flow through each channel
- 3. Never store endoscope in the carrying case.







Pilot in NTWC

 Committee of Decontamination and Sterilization – co ordinate

Validation test schedule -

- A. Automated endoscope reprocessor (AER)
- B. Ultrasonic cleaner
- C. Endoscope
- D. Scope cabinet

Validation Test Schedule

ltem	Test Description	Weekly	Monthly	Quarterly	Annually
Α.	Automated Endoscope Repr	oces	sor (A	ER)	
	1. Soil Test for reference load			\checkmark	
	2. Final rinse water for viable count			\checkmark	
	 Final rinse water for organism (Legionellae, Mycobacteria Pseudomonas Aeruginosa) 				\checkmark
	4. Residual proteinaceous contamination test	\checkmark			
	5. Feed water quality test				\checkmark
	6. Inspection and maintainence test				\checkmark

Validation Test Schedule

ltem	Test Description	Weekly	Monthly	Quarterly	Annually
Β.	Ultrasonic Clear	ner			
	1. Soil Test for reference load			\checkmark	
	2. Aluminium foil test		\checkmark		
	3. Sono-test			\checkmark	
	4. Functional checking		\checkmark		
	5. Feed Water quality test				\checkmark
	6. Inspection and maintainence test				\checkmark

Validation Test Schedule

ltem	Test Description	Weekly	Monthly	Quarterly	Annually
C.	Endoscope				
	1. Residual proteinaceous contamination test post manual cleaning				~
	2. Competency audit in reprocessing of endoscope				\checkmark
D.	Scope Cabine	t			
	1. Rinse water for viable count				\checkmark

Validation Test for AER – Soil Test

Validation Test for AER – Soil Test for Reference Load (Quarterly)

- TOSI-Flexi Check
- Monitoring the cleaning efficacy of flexible endoscope washers
- Immediate results
- YES/NO answer for cleaning efficacy
- Additional diagnostic feature in case of cleaning problems

Validation Test for AER – Soil Test for Reference Load

Validation Test for AER – Soil Test for Reference Load

Validation Test for AER – Soil Test for Reference Load

TOSI[®] – FlexiCheck Troubleshooting Guide

Positive result: Both test-soils completely removed.
Result: Polysaccharid-test soil completely removed but visible residue of fibrin left. Indication for: Protein dissolving parameters not optimal Optimisation: Check and/or correct: Cleaning time / temperature / detergent efficiency / dosing
Result: Blood-test soil completely removed but visible residue of Polysaccharide left. Indication for: Polysaccharide dissolving parameters not optimal Optimisation: Check and/or correct: Water quality / detergent efficiency and dosing / Cleaning time and temperature
Result: Polysaccharide-test soil completely removed but red protein residue left. Indication for: Protein denaturating effects (heat or disinfecting agents) Optimisation: Check for high temperature or disinfecting agents during the wash cycle. Run cold pre-rinse if possible.
Result: Both spots of test soil completely left. Indication for: Missing flow / No cleaning efficiency. Optimisation: Check connection of FlexiCheck , machine and cleaning program.

Validation Test for AER – Soil Test for Reference Load

ecord eping for	Autor	matic End	oscopic Re Te Model: O	processo st Freque ER-AW ((r's Cleanin ency: Quart DER 3)	g Efficacy erly Test, S/N: 290	- Soil Test f Annually T 0121 A	or Refere est ID: 60885	nce Load F 5	Record	ť	4
AER	an	Feb	Mar	Apr	May	Jun	lut	Aug	Sep	Oct	Nov	
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\sim							Pass.	Pass		Pass		1
5							NUK MELWAL	KWOK ME	WANG	KWOLD FE W	ANG	
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Validation Test for AER – Final Rinse Water for Viable Count (Quarterly)

Aim: The microbiological quality test of post-disinfection rinse water and determine whether the AER is bacteria free.

Method of sampling

- 1. Ensure sterile sealed bacteria-retentive 0.2 microns filter is use in AER.
- 2. Select the self-disinfection cycle of AER and start the program.
- 3. Run a normal process after performing a self-disinfection procedure.
- 4. Wipe the outlet of the AER where it normally attaches to the endoscope with 70% alcohol and allowing it to air dry.
- 5. Connect the appropriate adaptor with sterile tubing to the disinfected outlet.
- 6. Select the rinse cycle mode, run 50 ml through the tubing and discard.
- 7. Collect a 250ml sample of water in a sterile specimen bottle by using aseptic handling technique.
- 8. Label the specimen and fill in the appropriate specimen request form (HA161) properly.
- 9. Send the obtained specimen to the laboratory as soon as possible.
- 10. Document the result to designated recording book.

Validation Test for AER – Final Rinse Water for Viable Count

Validation Test for AER – Final Rinse Water for Viable Count

Re-sampling is needed if the laboratory result is not acceptable

- 1. Take AER out of service when the laboratory result is failed (Total viable count: >10 C.F.U./100ml).
- 2. Verify the effectiveness of the disinfection process.
- 3. Verify the process parameters that can influence the effectiveness of disinfection process.
- 4. Determine the concentration of the active ingredient in the disinfectant.
- 5. Re-obtain the specimen by excluding the factors that can influence the effectiveness of disinfection process.
- 6. Isolate the involved AER until the laboratory result is acceptable.

Validation Test for AER – Final Rinse Water for Viable Count

	Automatic I	Endoscopic	NTWC Reprocesso	TMH - or's Clean	–E3 Ward ing Efficacy	Combined - Final Rin	l Endoscopy nse Water f	y Centre or Total Vi	able Count	Test Reco	rd	
		· · ·	T Model: (est Freque DER-AW	ency: Quart (OER 3)	erly Test, A S/N: 290	Annually To 0121 A	est ID: 608855				
	Jan 2013	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date	2 1 JAN 2013		n 4 MAR 2013		0.7 MAY 201		8 IIIN 2013		0 9 SEP 201	8		
Test Result	Passo		Pass		Pass		Pass		Pass	Repuir	Requir	Reput
Staff	RN K	C	RN 1eong, Tsz Yil	a C	RN heong XTez Vin	- C	RN RN	Ch	RN Copa Tan Na	· upo	- Cpert	
Date Fest Result	2014 Report	27 FEB 2014 Pays			(4 JUN 2014 Pars	Repair	26/8/2014 Pars			R	ecord
Name & Rank	Cł	eong, Tsz Yin	g		0	heong, Tsz	ng	HO, KAYE			kee	ping i
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	\square	A	
	2015											
Date												
Test Result												
Staff Name & Rank												7

Validation Test for AER – Final Rinse Water for Organism (Anually)

Aim: The microbiological quality test of post-disinfection rinse water and determine whether the AER is free from Legionella, Mycobacteria and Pseudomonas Aeruginosa

Method of sampling

- 1. Ensure sterile sealed bacteria-retentive 0.2 microns filter is use in AER.
- 2. Select the self-disinfection cycle of AER and start the program.
- 3. Run a normal process after performing a self-disinfection procedure.
- 4. Wipe the outlet of the AER where it normally attaches to the endoscope with 70% alcohol and allowing it to air dry.
- 5. Connect the appropriate adaptor with sterile tubing to the disinfected outlet.
- 6. Select the rinse cycle mode, run 50 ml through the tubing and discard.
- 7. Collect a 500ml sample of water in a sterile specimen bottle by using aseptic handling technique.
- 8. Label the specimen and fill in the appropriate specimen request form (HA161) properly.
- 9. Send the obtained specimen to the laboratory as soon as possible.
- 10. Document the result to designated recording book.

Validation Test for AER – Final Rinse Water for Organism

Re-sampling is needed if the laboratory result is not acceptable

	NTWC123110
INSTITUTE OF PATHOLOGY Date: 22 JAN 200 Time: 1 22 FORM MUST BE COMPLETED IN DUPLICATE Clinical disprace	Some Tues Mun Hospital - T6 EDU lor Other Model: OER A I I Adrisu S/N: 2610.170 All:
Specimen & Exam Required: AER Rinsing water for Total viable count (POST-filter Change)	
Date Received	Let. No
	21 01 2013
Date of Report	Pathologist / Medical Microbiologist

Validation Test for AER – Final Rinse Water for Organism

Validation Test for AER – Final Rinse Water for Residual Proteinaceous Contamination Test (Weekly)

Validation Test for AER – Feed Water Quality Test (Annually)

MAL	La 廠商	Doratories i會檢定中心	
		TEST REPORT	
Report No.	:	AS0046348(3)	Date : 05 Aug 2014
Application No	. :-	LS027448(3)	
Applicant	*	ELECTRICAL & MECHANICAL SERVICES DEPT. 3 KAI SHING STREET, KOWLOON, HONG KONG	
Sample Descrip	tion	 Thirteen (13) batches of wastew are sample sample industrial Development Foundation Limited at the fi Samples were refrigerated during delivery. 	d by the staff of CMA following location.
Preservation an	d Storag	: All samples were preserved as APHA 21ed 1060C.	
Sampling Loca	ion	: Washer Disinfector (Endospace) at EDU Tuen Mun	Hospital.
Sampling Date		: 24 Jul 2014.	
Date Received		: 24 Jul 2014.	
Test Period		: 24 Jul 2014 to 04 Aug 2014.	
Test Requested		 Calcium Magnesium Sodium Potassium Fluoride Total Residual Chlorine (on-site measuremen Chloramine Nitrate Nitrogen Sulphate Copper Barium Zinc Aluminium Arsenic Lead Silver Cadmium Selenium Selenium Mercury 	0)
Authorized Sign	ature :	For and on behalf of CMA Industrial Development Foundation Limit Tang Tsz Wang Deputy Manager Environmental Division	Page 1 of

Tel: (852) 2698 8198 Fax: (852) 2695 4177 E-mail: info@cmatcl.com Web Site: http://www.cmatcl.com

Water Quality Test Resference

Department of Health (UK) (2013): Choice Framework for local Policy and Procedures 01-01 – Management and decontamination of surgical instruments (medical devices) used in acute care.

Part D: Washer-disinfectors

Table 6	Requirements for water quality: final rinse and
	process water

Determinant and unit	Maximum pe	rmitted values		
	Final rinse	Other stages		
Appearance	Clear, colourless	-		
Degree of acidity (pH)	5.5 to 8.0	_		
Conductivity at 25°C (uS/ cm)	30	-		
Total dissolved solids (mg/100 mL)	4	-		
Total hardness, CaCO ₃ (mg/L)	50	210		
Chloride, Cl (mg/L)	10	120		
Heavy metals, determined as Lead, Pb (mg/L)	10	-		
Iron, Fe (mg/L)	2	_		
Phosphate, P2O5 (mg/L)	0.2	-		
Silicate, SiO ₂ (mg/L)	0.2	2		
Total viable count (TVC) at 22°C	100	_		
at 37°C (cfu/100 mL)	100			
Bacterial endotoxins (EU/mL)	0.25	-		

Validation Test for AER – Feed Water Quality Test

TEST REPORT Date : 05 Aug 2014 and CMA 要國國南部同日心 _aboratories A Testing Certification

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The 88

LS027448(3)

AS0046348(3)

Test Results

Test Items	Units	nits Results													
		Inlet	OER 3	OER 4	OER 5	OER 6	OER 7	OER 8	OER 9	OER 19	MED 1A	MED 1B	MED 2A	MED 2B	
1. Calcium	mg/L	20	14	13	16	15	10	10	11	10	10	10	10	11	
2. Magnesium	mg/L	2.1	2.4	1.7	1.6	1.8	1.8	1.8	1.6	1.6	1.6	1.7	1.5	1.9	
3. Sodium	mg/L	5.1	6.9	4.8	3.8	3.6	4.9	5.2	4.3	4.0	3.5	4.0	3.7	6.0	
4. Potassium	mg/L	2.0	2.4	2.3	2.2	1.8	2.4	2.3	2.0	2.3	1.8	1.9	2.6	1.8	
Fluoride	mg/L	0.58	0.60	0.64	0.58	0.52	0.61	0.60	0.60	0.62	0.56	0.59	0.58	0.59	
6. Total Residual Chlorine	mg/L	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	< 0.1	< 0.1	<0.1	< 0.1	
7. Chloramine	mg/L	0.2	0.6	1.2	0.9	0.2	<0,1	<0.1	<0.1	0.8	0.4	0.4	1.8	1.1	
Nitrate Nitrogen	mg/L	1000	480	880	460	1000	390	1100	390	710	490	540	600	750	
9. Sulphate	mg/L	8	7	8	8	8	7	8	8	9	8	7	7	7	
10. Copper	mg/L	0.055	0.031	0.33	0.46	0.049	0.029	0.028	0.034	0.030	0.039	0.028	0.035	0.039	
11. Barium	mg/L	0.026	0.015	1.1	0.014	0.019	0.024	0.013	0.016	0.013	0.013	0.014	0.013	0.016	
12. Zinc	mg/L	0.090	0.10	0.13	0.22	0.16	0.063	0.058	0.16	0.092	0.17	0.078	0.14	0.18	
13. Aluminium	mg/L	0.30	0.29	0.56	0.35	0.36	0.48	0.73	1.1	0.45	0.29	0.46	0.43	1.3	
14. Arsenic	mg/L	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	<0.002	<0.002	< 0.002	< 0.002	<0.002	
15. Lead	mg/L	0.004	0.002	0.002	0.003	0.004	0.002	< 0.002	0.004	< 0.002	0.004	0.004	0.004	0.004	
16. Silver	mg/L	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	<0.002	<0.002	< 0.002	< 0.002	<0.00	
17. Cadmium	mg/L	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	0.003	0.044	<0.00	
18. Chromium	mg/L	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	0.092	< 0.002	0.002	0.004	0.002	0.002	
19. Selenium	mg/L	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	<0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.00	
20. Mercury	mg/L	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	< 0.002	<0.002	<0.002	<0.002	< 0.002	< 0.002	<0.00	

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on Services

available

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Validation Test for AER – Inspection and maintainence by Vendor / EMSD (Annually)

-

L43, Offic Tel: (852)	ce Tower, Langham Place, 8 Ar) 2376 1805 Fax: (852) 2376 01	rgyle Street, Mongkok. 30	Kowloon, Hong H	Kang						Date	3	Aug-14	4
Hospit	al	тмн	l	Jnit	EDU	Person Ir	Charge	/ls. Isabe	lla Lee T:	Inspect	tor A	MR Loce	ng
Address		E3 CEC.			Contact F	Phone No	2468	5629	Sales Person				
		DUCTS											
	MODEL	SERIAL NO.	SERVICE CONTRACT	LAMP LIFE		INSPECTIC	ON DETAILS		Earh Leakage check NC < 0.5mA SFC < 1mA	Enclosure leakage check NC < 0.1mA SFC < 0.5mA	Earth bond check < 0.1òhm @ 25A 10s	RESULT	NEED REPAIR
1	OER-AW	2321059	YES / NO		changed	Silencer	function	oK	V	V	V,	OR & NG	YES INO
2	OER-AW J	2321060	YES / NO		4	1	'n	п	V	V	V,	OK/ NG	YES NO
3	OER-AW &	2321061	YES / NO		ч	7	n	2	V	V	V	OK/1 NG	YES /NO
4	OER-AW G	2321062	YES / NO			2	ч	5	V	V	V	OK/ NG	YES / NO
5	OER-AW 10	2321063	YES / NO		PL .	и	~	n	V	V	V	OK/ NG	YES / NO
6	OER-AW	2321069	YES / NO		4	и	n	и	V	V	V	OK/ NG	YES NO
7	OER-AW 4	2321073	YES / NO	1	1 1	n	5	× .	V	V	V	OK/ NG	YES NO
8	OER-AW 2	2900121	YES / NO		~	н	٦.	r	1	V	V	OK/ NG	YES NO
9)		YES / NO									OK / NG	YES / NO
10			YES / NO									OK / NG	YES / NO
11			YES / NO				v					OK / NG	YES / NO
12			YES / NO									OK / NG	YES / NO
C/ INF	FORMATION TO CUSTOME	R											
									Ň				
* C	comprehensive	4			山小	返		×	ACK	NOWLEDGEMEN	⊤: 31 Å	UG 2014	
	DATE OF INSPE	CTION			NAME OF ENG	INEE RUSIGNATU	RE		DAI	E:	PN B1595 Nai Wang		

Validation Test for Ultrasonic Cleaner – Soil Test for Reference Load (Quarterly)

- Aim: To demonstrate the ability of UC to remove soiling and contamination in normal use of re-usable items
- Frequency: Quarterly Test & Yearly Test
- Standard Compliance: ISO 15883-4
- Procedure:
- 1. Prepare the soil test agent by mixing the test agent with warm water filling to "Fill line" marked on the bottle and shake vigorously until even consistency.
- 2. Leave the test agent for at least 10 minutes after mixing.
- 3. Contaminate the test load, chamber wall and load carrier with the test load and leave to dry for 30minutes.
- 4. Operate a normal washing cycle for the load type under testing.
- 5. After completion of the washing cycle, examine the test load, chamber wall and load carrier for the presence of residual test soil by visual inspection.
- 6. The test shall be regarded as satisfactory if it is visually clean.

Validation Test for Ultrasonic Cleaner – Soil Test for Reference Load

Validation Test for Ultrasonic Cleaner – Soil Test for Reference Load

Validation Test for Ultrasonic Cleaner – Soil Test for Reference Load

		Endose	onic Cleane Te Model:	Tu er's Cleani est Freque KM 75006	en Mun Ho ng Efficacy ncy: Quart 20	ospital T6 y <mark>Soil Te</mark> terly Test, S/N: 2817	EDU st for Refere Annually To '390 AID;	ence Load est 609996	Record			
	Jan 2012	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date							A & MOL SOIL			0 - OCT 2012	1	3 DEP 110
Soil Test Result							Pass,		1	Pass		Pass 2012
Inspector 's Name & Rank							WOK METWA		1	RN HEI HAND	K II	PR MEIA
							RN					and have
	Jan 2013	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date												
Soil Test Result												
Inspector 's Name & Rank												
	Jan 2014	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Date												
Soil Test Result												
Inspector 's Name & Rank				ALS THE					1			

Validation Test for Ultrasonic Cleaner – Aluminium Foil Test (Monthly)

- **Aim:** To show the cleaning Test & Yearly Test
- Frequency: Monthly Check, Quarterly Test & Yearly Test
- Standard Compliance: HTM 2030
- Equipment:
- A. Aluminum foil of nominal thickness0.05mm to 0.025mm (Sold as an aluminum foil wrap for cooking);
- B. Tape
- C. Stopwatch

Validation Test for Ultrasonic Cleaner – Aluminium Foil Test

Visual inspection about the erosion on the foil and compare, it with the first test result.

Validation Test for Ultrasonic Cleaner – Sono Test (Quarterly)

- Aim: To test the performance of the ultrasonic cleaner
- Frequency: Monthly Check, Quarterly Test & Yearly Test
- Standard Compliance: Test Indicator Supplier
- Procedure:
- 1. Prepare an empty load.
- 2. Place the Sono Check device into the ultrasonic basket.
- 3. Start operating cycle.
- 4. At the end of cycle, turn the cleaner off and remove the Sono Check device.
- 5. The test would only be considered as satisfactory when the color change from green to yellow. If there is any problem, please inform the supervisors for further action.
- 6. The result of Sono Check should be recorded by photo and kept record.
- 7. This test should be performed monthly or after major repair.

Validation Test for Ultrasonic Cleaner – Sono Test (Quarterly)

Sono Check Record for Endosonic Cleaner

Charles and	(CEU) TM	copy Unit H	Version;	2
- 10 · M.	Monthly Functional (Checking for	Effective Date:	02 Sept 201
	Ultrasonic Clea 起动的神社地东口市	Iner Metalenak	Next Seview:	01 Aug 201
Date 檢測日期:1	JUL 1816			1
Machine Model 超音波清洗機型號:		ОНК	Ultrasonic Cle	aner
Serial Number 機身編號:			21208727	
Preset Temperature 加限温度 37℃-40℃			38 r	
Temperature measured by 重度温度(是否與預設温度	y thermometer 相右)	YES	С и NO 7	Lin .
Water level 水位是否到建水位控制器		YES	。 是 / NO 3	10h
Sufficient amount of dete 清潔劑是否足夠(10ml/L)	rgent	YES		101
The cleanliness of the bas 清洗機是否清潔及沒有沉積	e of tank 毗物	YES	(最 / NO 著	ί.
Aluminum foil test 關紙創試是否合格		Pass B	格 / Fail 不)	支格
此成效檢測紀錄之僅存期限	霧最少五年			
Rank & Signature of Responsi	ble Staff	PCA (\Chan	2 D2481 2 Wine Yi	

Feed water quality test -Annually

CMA Testing and Certification Laboratories 廠商會檢定中心

TEST REPORT

Report No. : AS0046348(3)

Application No. : LS027448(3)

Note : 1. < denotes less than

- 2. mg/L denotes milligram per litre
- APHA denotes American Public Health Association Standard Methods for the Examination of Water and Wastewater 21ed, 2005.

Date : 05 Aug 2014

Health Sector Services 🛃 EMSD ULTRASONIC CLEANER INSPECTION FORM

REG. NO IENTEDU	STATUS : [/] PASS [] SERVICE REQUIRED [] REN	OVED FROM SERVICE				
onic Cleaner	NOTES					
DATE 21/08/2014	TEST EQUIPMENT : 1. ELECTRICAL SAFETY TESTER 2. SOUND LEVEL METER (append other possible test equipment items as appropriate)	Eqpt. ID TMH/SAV/065 TMH/AUD/055				
TEM COMPONENTS	OTHER EQUIPMENT (Please specify):					
DESCRIPTION						
	REG. NO. 728985 IENT EDU onic Chaner	REG. NO728965				

1	PASS	FAIL	NA	QUALITATIVE	DESCRIPTION / COMMENTS
1.1	1	8.8		CHASSIS / HOUSING	
1.2	10			MOUNT/FASTENERS	
1.3	1			AC PLUG/RECEPTACLES	
1.4	4	(-)	-	LINE CORD	
1.5	4	1		STRAIN RELIEFS	
1.6	3			CIRCUIT BREAKER/FUSE	
1.7	. 8			CABLES	
1.8	1	-		FITTINGS/CONNECTORS	
1.9	1			CONTROLS/SWITCHES	
1.10	11	1.11		MOTOR/PUMP/FAN/COMPRESSOR	
1.11			×.	BATTERY/CHARGER	
1.12	1			INDICATORS/DISPLAYS	
1.13	-		18	OTHER EQPT. SPECIFIC PART(S) NOTE 1	
1.14			11	ALARMS/INTERLOCKS	
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(b)		1	$< \delta$	LOW BATTERY	and the second
(0)			1	MECHANICAL INTERLOCK	
(0)		1	ð	OTHER EQPT. SPECIFIC ALARM/INTERLOCK CONDITION #018.2	
1.15			1	AUDIBLE SIGNALS	
1.16			1	LABELING	
1.17		1.0	1	ACCESSORIES	
1.18	1			INTERNAL COMPONENTS	
1.19			1	SELF DIAGNOSTIC	

Inspection & maintainence test -Annually

Validation Test for manual Cleaning of endoscope - Residual Proteinaceous Contamination Test (Annually)

Aim: Half yearly routine checks are designed to test if residual proteinaceous

contamination present on the endoscopes after mechanical cleansing and before disinfection.

Standard compliance: According to unit guideline on reprocessing of endoscope

Procedure:

- 1. Gloves must be worn when utilizing the residual protein test to avoid cross contamination.
- 2. Remove the swab from the pack without touching the bulb.
- If the object to be tested is already wet, swab the object focusing on hinges or cervices which may be contaminated.
- If object to be test is dry, simply wet the swab with sterile water before swabbing areas of interest.
- 3. Unscrew the test reagent cap.
- 4. Swirl the swab in the brown reagent for 10 seconds.
- 5. Inspect the reagent for color change. Protein has been detected if the reagent has turned a shade of blue. The darker the blue intensity and the faster the rate of color change, the more protein detected. Residual protein has not been detected if the reagent remains brown. Color reference is attached for reference.
- 6. Record and sign the record form for Cleaning Efficacy of Endoscopes for Residual Proteinaceous Contamination.
- 7. For any abnormality, inform Supervisor.

Validation Test for Endoscope

Residual proteinaceous contamination test post mechanical cleansing

Mechanical Cleansing>>> Decontaminates up to 99% of the soil

Validation Test for Endoscope Cleaning - Residual Proteinaceous Contamination Test

PCA Reprocessing Endoscope Competency checklist (Annually)							
Mentor:	Mentee	:					
Date (Period):							
Criteria	Date		Ρ	ractic	e		Date
	Ods.	1	2	3	4	5	Asse.
 The endoscope is initially cleaned to remove debris or mucus immediate after removing from patient. 							
2. Leakage test of endoscope is performed under water with all movable parts disassembled.							
3. Suction channel(s) and channel opening(s) are brushed until clean.							
4. The exterior of endoscope and all movable parts are thoroughly cleaned with enzymatic detergent.							
5. The endoscope is disinfected by Automated Endoscope Reproccessor (AER) or manually according to unit guidelines.							
6. Interior and exterior of endoscope are thoroughly rinsed after disinfection.							
7. The exterior of endoscope is wiped and all channels are flushed with 70% alcohol.							
8. The endoscope is dried.							
9. The functions of the endoscope are checked.							
10. The disinfected endoscope is labeled.							
11. The disinfected endoscope is stored in purposely-built cabinet.							
12. Accurate documentation is maintained for tracking and tracing							
Comment:							
Mentor sign:	Mentee	Sign:					

PCA Training Nov 2014	

Validation Test for Scope Cabinet (Annually)

Scope Cabinet

	A Testing d Certifica	tion			
廠	商會檢定中心,	EST REPORT			
	-	EUT KEI OKT			
Report No :	AS0019101(1)			Date: 23.	Apr 2014
Application No :	LS011303(8)				
Applicant :	SCHMIDTBIOM 20/F, CHINACHI 1 HOI WAN STR	EDTECH (HK) LTD. EM EXCHANGE SQUA EET, QUARRY BAY	.RE,		
Sample Description :	Five (5) sample(s Foundation Limit) sampled by the staff of red stated to be :	CMA Industr	ial Development	
	Sample(s)	Name	Mod	lel No.	
Model 1 -	- Endoscope (CF16)	Colonoscope	Olympus C	F Q160L	
Model 2 -	- Endoscope (TJ06)	ERCP scope	Olympus T	JF 160R	
Model 3 -	Endoscope (GF36)	Gastroscope	Olympus C	HF 160	
Model 4 -	- Endoscope (OT 鏡) Cystoscope	Olympus C	YF 5A	
Model 5 -	Endoscope (BF24)	Brochoscope	Olympics D	E E260	
Sampling Location : Sampling Time : Date Received :	ample Status Upon Tuen Mun Hospit Medivators Rotas 13:00 04 Apr 2014; 07 4	Receipt : Refrigerated al, Combined Endoscop cope, Cabinet 2 Apr 2014.	y Centre, Clea	nsing Room, fron	n
Sampling Location : Sampling Time : Date Received : Test Period : Test Requested :	ample Status Upon Tuen Mun Hospit Medivators Rotas 13:00 04 Apr 2014; 07 / 04 Apr 2014 to 15 Total Aerobic Mid	Receipt : Refrigerated al, Combined Endoscop cope, Cabinet 2 Apr 2014. 5 Apr 2014. crobial Count.	y Centre, Clea	nsing Room, from	n
Sampling Location : Sampling Time : Date Received : Test Period : Test Requested : fest Result :	ample Status Upon Tuen Mun Hospit Medivators Rotas 13:00 04 Apr 2014; 07 A 04 Apr 2014 to 15 Total Aerobic Mid	Receipt : Refrigerated al, Combined Endoscop cope, Cabinet 2 Apr 2014. 5 Apr 2014. crobial Count.	y Centre, Clea	Results (n CFU/mL)
Sampling Location : Sampling Time : Date Received : Test Period : Test Requested : Test Result : Sample(s)	ample Status Upon Tuen Mun Hospit Medivators Rotas 13:00 04 Apr 2014; 07 A 04 Apr 2014 to 15 Total Aerobic Mid Name	Receipt : Refrigerated al, Combined Endoscop cope, Cabinet 2 Apr 2014. 6 Apr 2014. crobial Count. Test Item	y Centre, Clea	Results (C Time Point: 0 hour	CFU/mL) Time Point 72 hours
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2. The detection limit of above test is 1.0 x 10° CFU/mL.

***** End of Report *****

Rinse water for viable count

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		fo1793	2468 - 5635	Please indicate the cumulative numbers of PM / C	M and ST performed during the contract.)	
assay technology		Lab Report		The Innovation & Value Le in Occupational Hygiene An	ader	Ref. (Quotation / Invoice No.)
Customer: SMART PRACTICE HEALTH	ICARE LIMITED	Work Order: 20140	80737	Customer No.: 1809		
Attention: PAUL TANG	NIETRAL DI DO			Received Date: August 20, 2014		and and
A007855 UNIT 1513 1514 FUNDA IND 37-39 AU PUI WAN ST FO T NEW TERRITORIES, 652 HONG KONG	TAN SHA TIN			Date Report Revised: August 29, 2014	ESE	
Phone No.: (852) 2156 0905	Project PO I	ID KWC EXPOSURE MO	NITORING EXERCISE 2014	1999 - C.		A. Technician
Fax No.: (852) 2156 0965 Exposure results are the average concentr tested Unless noted below samples we	ration for the period of time monitored. I	RL = Reporting Limit. ND applicable quality control	 None Detected at or above to were within method specification 	the reporting limit. The results relate on ns, lab blanks were subtracted before	ly so the items 4	05/2015
reported, and any customer supplied fiel concentrations reported are based upon file site at http://www.assaytech.com or contact Te	Id blanks were not subtracted from sa eld sampling information provided by the schnical Support at 1-800-833-1258. For deta	mple results. The motar customer. For assistance its of significant method mod	volume at 25 C (24.45 L/mole with the content of this report, ifications go to www.assaytech.com/	 was used to calculate parts per n please visit the Customer Support sect methyloid.html. 	silican, ppm. Air on of our web	
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Annual check

Tracking and Tracing

• No standardization on Tracking and tracing of endoscope and accessories

Take out scope

Print out Traceable labels

To endoscopy room

Tracking labels are generated by SITS Surgical Instrument Tracking System

TMH.T51609.22	TMH.EDU.FB.5.A
COLON BIOPSY FORCEPS-MA	X2(EDU)
Set No.: 26	Max: 99999 Count:93

By scanning the barcode on the plastic tag, a double-adhesive label with instrument particulates, including usage count, will be generated in each reprocessing cycle. Two labels will be supplied by CSSD for patient and ward documentation.

Instrument usage counter

Enhancement after transition to CSSD for reprocessing:

- In the past, counting instrument usage by ward staff.
- Computer system was implemented for instrument counting by CSSD.
- This will save nurse hours from doing admin work.

A process indicator was included on the label. After sterilization, the color will be changed from blue to dark, as stated in <u>NTWC Policy on Decontamination of Reusable Medical Device</u> (Doc. No. NTWC-A-CS-015-V1)

A plastic tag, as individual instrument identifier, was attached at the end of each instrument as liaised with ward staff.

Past practice

New practice

Challenges

- Decontamination room spacing separate clean & dirty : one way direction
- SITS Tracking and tracing of endoscope & accessories
- Listed disinfectant double door AER

Disinfectant Assessment Committee

In use list of antiseptic/ disinfectant/ sterilant (Updated on 21 Jan 2015) For medical devices requiring high-level disinfection

ITEM CODE	DRUG NAME	STRENGTH	TRADE NAME	DSAC SUPPORTED PRACTICES	DATE OF SUPPORT TO USE BY DSAC	Remarks
TRISO3	CHLORINE DIOXIDE	100-125 ppm	Tristel Fuse for Instruments Disinf Soln, 100ml	Flexible Cystoscopes	16.05.2014	
Others						
APER01	APERLAN POKA-YOKE AGENT A (OR EQUIV) DISINF SOLN 5KG	Acetic acid 10-25%, Peracetic acid 5%, Hydrogen peroxide >20%	APERLAN POKA-YOKE AGENT A	For endoscope reporcessing in Getinge POKA- YOKE AER	9.3.15	A grace period of one year for the use of Aperlan for these AER already bought in these 3 hospitals – KWH, QEH and YCH. During this one year period till 9 March 2016, user shall have a
APER02	APERLAN POKA-YOKE AGENT B (OR EQUIV) DISINF SOLN 5KG	Potassium hydroxide 4%	APERLAN POKA-YOKE AGENT B	For endoscope reporcessing in Getinge POKA- YOKE AER	9.3.15	built-in monitoring system to monitor the usage and the monitoring should be reported back to DSAC

CIDEX[®] OPA Solution Is The Standard For Instrument Reprocessing, Cleaning, Disinfecting

As the industry standard for instrument reprocessing, CIDEX® OPA Solution is the time-tested disinfectant you can turn to for rapid, reliable results.

Glutaraldehyde-free (0.55% orthophthalaldehyde) highlevel disinfecting solution. Rapid 5-minute soak time at 25°C in an automated endoscope reprocessor. Twelveminute soak time 20°C for manual reprocessing.

Long-lasting efficacy allows reprocessing of more devices per gallon than with Glutaraldehyde.1,2

https://www.aspjj.com/us/product/high-level-disinfection

Acknowledgement

- All Endoscopy SAG members & co-members
- Ms Alice SHAM, KEC CGM(N) / UCH GM(N) SAG Advisor
- Ms Cecilia YEUNG, CMC DOM(SUR) SAG Convenor
- Ms Salina LO, TMH Deputy GM(N)/DOM(SURG)
- Mr C H KAN, NTWC SNO(ICN)
- Mr Samuel LAW, NTWC COM(CSSD)
- Dr T L QUE Dr, TMH/POH COS(PI)
- Dr K Y YAM Dr, TMH COS(NEURO);

Thank you