Cleaning and disinfection test for reusable medical device

Final Report

Article Name: Vitals360 multi-vitals mobile monitor

Report Number: CSTBB20030092

Method Standard: AAMI TIR30
AAMI TIR12

Sponsor

VoCare Inc

4950 Turkey Foot Road, Zionsville Indiana 46077, USA

Test Facility

CCIC Huatongwei international inspection (Suzhou) Co., Ltd

Room 101, Building G, Ruoshui Road 388, Suzhou, Jiangsu, China

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Abstract

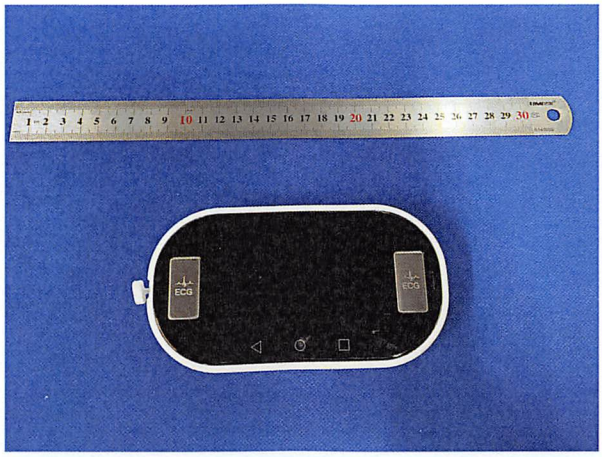
This study validated the effectiveness of defined cleaning and disinfection process according to AAMI TIR30 and AAMI TIR12.

The test article were prepared, contaminated and drying, ready for cleaning and disinfection. After the process, we detected the agent residue and visual inspected the visible dirt on articles. The content of protein and hemoglobin of articles after cleaning processes were determined. After disinfection, the number of log reduction of microorganism for articles were compared against the positive control.

The results showed that after subjecting to challenged cleaning and disinfection procedure, the quantity of protein and haemoglobin residuals were <6.4 μg/cm^2 and <2.2μg/ cm^2 respectively. The number of log reduction of microorganism for Test group was >6.0. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that the cleaning and disinfection process is effective.

Study Verification and Signature



Protocol Number	SST2002001501BB
Protocol Effective Date	2020-03-05
Technical Initiation Date	2020-03-10
Technical Completion Date	2020-03-24
Final Report Completion Date	2020-04-22

Personnel _____ 2020-04-22
Date Completed

Approved _____ 2020-04-22
Study Director — Date Completed

Supervisory _____ _____
Test Facility Manager — Date Completed

Huatongwei international inspection (Suzhou) Co., Ltd.

Quality Assurance Statement and GLP Statement

Quality Assurance Statement

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the HTW's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase Inspected	Date	Study Director	Management
Dosing	2020-03-10	2020-03-10	2020-03-10
Raw Data	2020-03-24	2020-03-24	2020-03-24
Final Report	2020-04-22	2020-04-22	2020-04-22

The findings of these inspections have been reported to Management and the Study Director.

Hui Jiang
Quality Assurance

2020-04-22
Date

GLP Statement

This study was conducted in compliance with current U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58.

The sections of the regulations not performed by or under the direction of HTW, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article and its mixture with carriers, 21 CFR, Part 58.105 and 58.113.

Study Director

2020-04-22
Date

1. Introduction

1.1 Purpose

This protocol is to validate the effectiveness of defined cleaning and disinfection process.

1.2 Reference

This study was conducted based on the following documents:

AAMI TIR12: 2010-designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufactures;

AAMI TIR30: 2011-A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices;

ISO 17664:2017 Processing of health care products-information to be provided by the medical manufacturer for the processing of medical device

2. Material

Test article name:	Vitals360 multi-vitals mobile monitor
Manufacturer:	VoCare Inc, 4950 Turkeyfoot Road Zionsville Indiana 46077 USA
Size:	150x82x30mm
Model:	VC-001
Lot/Batch#:	Solid
Physical State:	Not provided
Color:	Black
Article Material:	ABS, LCD, Metal, PVC
Surface area:	Not provided
Packing Material:	Nylon bag, printed box
Storage Condition:	Room Temperature

The information about the test article was supplied by the sponsor wherever applicable.

3. Instruments and reagents

3.1 Instruments

Autoclave (SHB001), Calibration date(2020-3-16)

Clean Bench (SHB014), Calibration date(2020-3-16)

Biological Safety Cabinet (SHB013), Calibration date(2020-3-16)

3.2 Reagents

0.9% Normal Saline (Sichuan Kelun Pharmaceutical Co., Ltd. B180105051)

Bleach Germicidal Wipes (The Clorox Company, 0619104)

Modified Bradford Protein Assay kit (Sangon Biotech (Shanghai) Co., Ltd. F505DA0001)

Rabbit HB ELISA Kit (Shanghai Jianglai Industrial Limited by Share Ltd. 201906)

TSA medium (Beijing Land Bridge Technology Co., Ltd. 191012)

4. Test of the cleanability

4.1 Cleaning validation

4.1.1 Sample preparation

Three (3) articles used for soiled and cleaned. Positive and negative controls were additionally included in the validation.

4.1.2 Test soil

Artificial Test Soil (ATS): Artificial Test Soil (ATS) prepared by the testing facility.

Composition	Content
Fetal Bovine Serum (FBS)	5 mL
Whole Milk Powder	3 g
Rabbit Whole Blood	2.5 mL
0.9% Normal Saline (NS)	2.5 mL
Escherichia coli	$\geq 10^{10}$CFU/mL

Escherichia coli (CMCC (B) 44102) obtained from CICC (China Center of Industrial Culture Collection), storage Condition: 2-8℃.

The compositions purchase:

Stability:	Stable during the test.
Preparation:	Mix all ingredients together thoroughly in a blender until a liquid uniform mixture is achieved.
Storage Condition:	Room Temperature.

4.1.3 Contamination and drying

Put 0.5 ml ATS in gloves, smearing the whole surface of the test samples. Dry the samples for 60 minutes in the biological safety cabinet (temperature 20-25℃, humidity 40-60%) after contamination. Negative control samples do not perform the operation of contamination.

4.1.4 Cleaning process

Step 1 Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.

Step 2 Clean the monitor with Bleach Germicidal Wipes. Until no visible contaminants remain

Step 3 Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.

Step 4 Wipe off with a dry cloth to remove residual moisture

Step 5 Air dry the monitor thoroughly after cleaning.

After cleaning, wipe the surface with sterile gauze thoroughly 10 times, immerge the gauze into 20 mL normal saline and extract (4oKHZ, 2min). hemoglobin and protein were determined in the extract (15mL).

The protein content of positive controls which are contaminated but not cleaned was analyzed.

4.1.5 Evaluation and statistical analysis

Visible Inspection results shall be presented.

The concentration of the protein and hemoglobin determined in μg/mL will be converted to μg/cm^2, using the device total surface area and the extraction volume.

Recovery efficiency (RE) (%)=The amount of residue of first extraction/ The sum of total four extractions

Note：RE is determined in the validation of extraction method. RE shall no less than 90%

Final Result for Each Device= Residue/ RE× surface area

Note：Surface Area is provided by the sponsor. So the laboratory calculated the surface area of the test article was 385.2 cm^2.

4.1.7 Acceptance criteria

Visual inspection of no visible dirt and take no obvious black to the naked eye as standard.

The content of protein for articles after cleaning processes should be <6.4 μg/cm^2.

Hemoglobin analysis should be <2.2μg/ cm^2.

4.2 Results of the cleaning test

4.2.1 Visual Inspection

Sample No.	Visibly clean	Criteria
Test Group 1	Yes	Pass
Test Group 2	Yes	Pass
Test Group 3	Yes	Pass

4.2.2 Protein and Hemoglobin analysis

Recovery Efficiency Results of Protein (Positive Control)							
	#1(μg)	#2(μg)	#3(μg)	#4(μg)	SUM(μg)	RE%	RE Mean%
Positive Control 1	3321.62	133.25	68.20	23.00	3546.07	93.67	93.03
Positive Control 2	2864.23	156.21	74.23	19.33	3114.00	91.98	
Positive Control 3	2886.65	122.37	66.21	14.56	3089.79	93.43	

Recovery Efficiency Results of Hemoglobin (Positive Control)							
	#1(μg)	#2(μg)	#3(μg)	#4(μg)	SUM(μg)	RE%	RE Mean%
Positive Control 1	1223.10	88.56	19.65	9.87	1341.18	91.20	91.51
Positive Control 2	1356.24	95.32	14.25	8.65	1474.46	91.98	
Positive Control 3	1265.34	88.65	18.55	12.64	1385.18	91.35	

Test Result				
Group	Protein (μg/cm^2)		Haemoglobin (μg/cm^2)	
	Final Result	Conclusion	Final Result	Conclusion
Test Group 1	0.15	＜6.4	0.12	＜2.2
Test Group 2	0.25	＜6.4	0.05	＜2.2
Test Group 3	0.24	＜6.4	0.08	＜2.2
Positive Control Group 1	8.02	/	2.91	/

Positive Control Group 2	6.92	/	3.22	/
Positive Control Group 3	6.97	/	3.01	/
Negative Control Group 1	0.15	/	0.03	/
Negative Control Group 2	0.09	/	0.03	/
Negative Control Group 3	0.12	/	0.06	/
Acceptable Criteria	1. The recovery efficiency should be ≥90%. 2. The content of hemoglobin for test group after cleaning processes should be <2.2 μg/cm^2. 3. The content of protein for test group after cleaning processes should be <6.4 μg/cm^2.			
Conclusion	Acceptable			

5 Test of the disinfect ability

5.1 Disinfection validation

5.1.1 Sample preparation

Three (3) articles used for soiled and disinfected. Positive and negative controls were additionally included in the validation. Positive and negative controls were additionally included in the validation.

5.1.2 Test soil

Artificial Test Soil (ATS): Artificial Test Soil (ATS) prepared by the testing facility.

Composition	Content
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The compositions purchase:

Stability:	Stable during the test.
Preparation:	Mix all ingredients together thoroughly in a blender until a liquid uniform mixture is achieved.
Storage Condition:	Room Temperature.

5.1.3 Contamination and drying

Put 0.5 ml ATS in gloves, smearing the whole surface of the test samples. Dry the samples for 60 minutes in the biological safety cabinet (temperature 20-25℃, humidity 40-60%) after contamination. Negative control samples do not perform the operation of contamination.

5.1.4 Disinfection process

Clean the monitor before disinfection.

Step 1 Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power

line.

Step 2 Disinfect the monitor with enough Bleach Germicidal Wipes for treated surface to remain visibly wet for 30 seconds.

Step 3 Wipe off the disinfection solution with a fresh cloth or towel, dampened with tap water after disinfecting until no visible disinfection agent remains.

Step 4 Wipe off with a dry cloth to remove residual moisture.

Step 5 Air dry the monitor thoroughly after disinfecting.

Flush the inoculation site with 50 ml 0.9% normal saline and wipe the surface with sterile gauze thoroughly 10 times, immerge the gauze into 20 mL normal saline and extract (4oKHZ, 2min).

The number of microorganism was determined by filter membrane (0.45 μm) in the extract (5mL). Prior to the collection, using 100 ml 0.9% normal saline to moisten the membrane, and then filter the collected solution. After filtration, the membrane was placed on the TSA medium and incubated under 37℃ for 7 days.

The CFU of positive controls which are contaminated but not disinfected was analyzed.

5.1.5 Evaluation and statistical analysis

Visible Inspection results shall be presented.

Recovery efficiency (RE) (%)=The number of bacteria of first collection/ The sum of total 4 extractions

Note：RE is determined in the validation of extraction method.

Log Reduction=lg(N)-lg(n), N means average of sum in corresponding positive device control group; n means microorganisms count of corresponding site of each test article.

5.1.6 Acceptance criteria

For recovery efficiency, RE shall no less than 90%.

After disinfection, the number of log reduction of microorganism for test group should be >6.0 compared against the positive device control group.

The microorganism count should $\geq 10^6$ in Positive Device Group.

5.2 Results of the disinfection test

5.2.1 Visual Inspection

Sample No.	Visibly clean	Criteria
Test Group 1	Yes	Pass
Test Group 2	Yes	Pass
Test Group 3	Yes	Pass

5.2.2 Results of the samples elution

Recovery Efficiency Results of Bacteria (Positive Control)							
	#1(CFU)	#2(CFU)	#3(CFU)	#4(CFU)	SUM(CFU)	RE%	RE Mean%
Positive Control 1	115000000	71000	3200	700	115074900	99.93	99.95
Positive Control 2	221000000	83000	4200	400	221087600	99.96	
Positive Control 3	194000000	62000	5100	400	194067500	99.97	

Test Results		
Group	Results (CFU/device)	Average (CFU/device)
Test Group 1	12	12.3
Test Group 2	9	
Test Group 3	16	
Positive Control Group 1	8.2×10^7	9.0×10^7
Positive Control Group 2	9.3×10^7	
Positive Control Group 3	9.4×10^7	
Negative Control Group 1	<1	<1
Negative Control Group 2	<1	
Negative Control Group 3	<1	
Log Reduction of Microorganism	6.86	
Acceptable Criteria	1. Recovery efficiency of positive control should be ≥ 90%. 2. The number of log reduction of microorganism for Test group should be ≥6.0.	

6. Conclusion

Under the conclusion of this study, after subjecting to challenged cleaning and disinfection procedure, the quantity of protein and haemoglobin residuals, the number of log reduce were all less than the acceptance criteria, which validated the cleaning and disinfection process is effective.

7. Compliance

US FDA Good Laboratory Practice Regulations 21 CFR 58, effective June 20, 1979, as amended 52 FR 33780, Sept. 4, 1987, and subsequent amendments

Standard operating procedure of CCIC Huatongwei international inspection (Suzhou) Co., Ltd.

8. Disposal of samples

Destroyed all the remaining samples after the final report has been finished.

9. Record Storage

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Huatongwei.

10. Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.