주식회사 휴먼스캔

HUMANSCAN Co., Ltd.

문서명(Title): 5LI-C00(7L2) Disinfectant Test Report

문서번호(Document #): 502928

개정번호(Revision #): 01

최신 개정 정보(Revision Information)

날짜(Date) yyyy/mm/dd	ECO #	개정번호 (Rev. #)	개정내용 (Description)	작성자 (Written by)
2019/07/19	ECO19-043	01	Initial issued	Deok Young Kang

개정 정보(Revision History); 최신 개정 이전의 개정 정보(들)의 요약

날짜 (Date)	ECO #	개정번호 (Rev. #)	개정내용 (Description)	작성자 (Written by)
N/A	N/A	N/A	N/A	N/A

내 용 (Contents)

1.0 목적 (Purpose)

This document summarizes the test result for compatible disinfectants to 5LI-C00(7L2) medical ultrasound transducer. HUMANSCAN provide the compatible disinfectants list to customer based on this test result.

2.0 적용 범위 (Scope)

Medical Ultrasound Transducers made by HUMANSCAN and the transducers has RTV 664 and Radel R-51000 as housing material of 5LI-C00(7L2) ultrasound transducer.

3.0 용어 정의 (Terms & Definitions): N/A

4.0 책임 및 권한(Roles & Responsibility)

4.1 Tested and Reported by
- 4.1.1 Name: Deok Young Kang
- 4.1.2 Job title: Production Technical Engineer
- 4.1.3 Major: Medical Engineering
- 4.1.4 School Graduate: College graduate

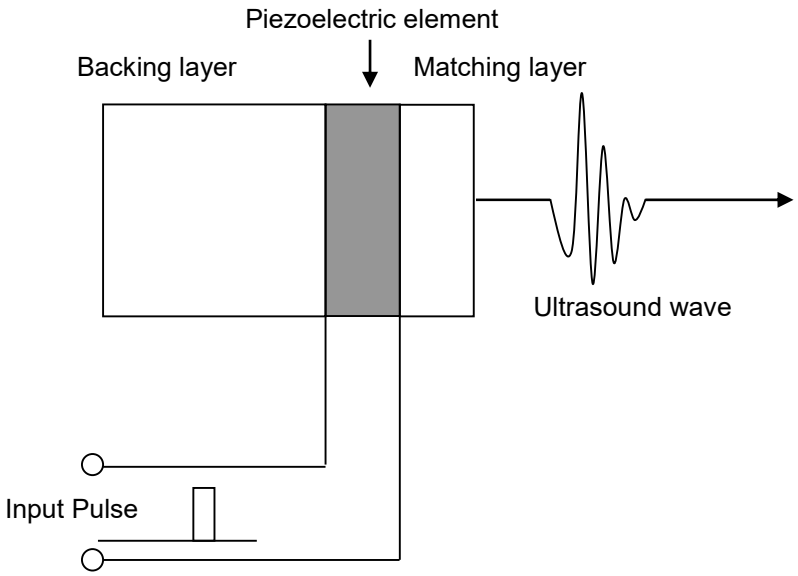
4.2 Reviewed by
- 4.2.1 Name: Ho Jung
- 4.2.2 Job title: Director (Production Department)
- 4.2.3 Major: Physics (Study on the Piezoelectric Properties of PMN-PT Single Crystal and It's Application)
- 4.2.4 School Graduate: Master of Science

4.3 Approved by
- 4.3.1 Name: Won Seop Park
- 4.3.2 Job title: Quality Manager / Quality Management Representative
- 4.3.3 Major: Physics (Development of backing for medical ultrasonic probe applications)
- 4.3.4 School Graduate: Master of Science

5.0 대상 제품 기본 원리 (Description of the Device)

5.1 Product Description: The device is a medical ultrasound transducer having several elements for ultrasound diagnostic imaging system.

5.2 Basic principle



A ultrasound transducer emits a pulse into the human body. The ultrasound wave propagates through the tissue and part of it will be reflected and scattered. Echoes due to reflection and scattering can be received by the same transducer some time later. This wave signal is converted into electrical signal and transfer to ultrasound diagnostic imaging system. And the electrical signal is processed and the image on a display screen.

*** Non-sterile, no software, no medicinal substance, no tissues and blood of human and anima*

6.0 시험 구성 (Test Configuration)

6.1 Environmental Condition

6.1.1 Temperature: Room temperature

6.1.2 Humidity: 40% ~ 90%

7.0 시험 대상 (Testing Items)

Category	Disinfectant	Manufacturer	Type	Usage Time(m)	Testing Time(W)
HLD	STERANIOS 2% (same as ANIOXYDE 1000)	ANIOS	Solution	5	1
HLD	CIDEX OPA	ASP	Solution	5	1
HLD	Gigasept FF	Schülke & Mayr	Solution	15	1
HLD	Oxivir Tb Wipes	Diversey	Wipe	10	1
HLD	Protex Ultra	PARKER	Wipe	4	1
HLD	Sekusept easy	ECOLAB	Solution	15	1
HLD	Tristel Trio Wipes System	Tristel	Wipes	0.5	1
LLD	CaviWipes and Cavicide	Metrex	Wipe/Spray	3	1
LLD	CLEANISEPT WIPES	Dr. Schumacher	Wipe	Unknown	2
LLD	CLEANISEPT WIPES forte	Dr. Schumacher	Wipe	2	1
LLD	Clinell Universe wipes	GAMA	Wipe	5	1
LLD	Enzol	WPI	Solution	10	1

LLD	Protex Spray and Wipes	PARKER	Wipe/Spray	10	1
LLD	Protex ULTRA Wipes	PARKER	Wipe	1	1
LLD	Sani-Cloth AF3	PDI	Wipe	3	1
LLD	SONO Ultrasound Wipes	SONO	Wipe	10	1
LLD	Super Sani-Cloth	PDI	Wipe	2	1
LLD	Transeptic	PARKER	Spray	10	1
LLD	Sani-Cloth Bleach	PDI	Wipe	3	1

*** Total 19 disinfectants*

8.0 시험 절차 (Test Procedures)

8.1 시험 준비 (Preparation)

8.1.1 Sample: Full assembly ultrasound transducer with RTV 664 and RTP RADEL-5100

8.1.2 Testing container

8.1.2.1 Nalgene bottle (1L): for assembled sample

** Top of bottle shield by para-film

8.2 초기 확인 (Initial checking)

8.2.1 Tester should check the appearance of testing samples and pulse-echo test result before starting the test.

8.3 시험 진행 – 조립 샘플 (Testing – Assembled sample)

8.3.1 Prepare each disinfectants according to each manual of disinfectants.

8.3.2 If the chemical is type of solution or spray, gel, the disinfectant should be filled over the bonding line of nosepiece and handle case. And soak the sample in the prepared Nalgene bottle.

8.3.3 If wipe, the disinfectant should wrap on the sample directly and tighten by para-film or rubber band.

8.3.4 Sealed up to top of Nalgene bottle by para-film.

8.4 확인 (Checking)

8.4.1 Tester should check the appearance of assembled sample and record the result of checking after 3 or 1 week(s).

8.4.2 Tester should progress the pulse-echo test of each sample after 3 or 1 week(s).

9.0 적합성 판정 (Criteria of Compatibility)

9.1 Appearance: No visual defects (e.g. discoloration, deformation, permanent contamination, crack, etc,.)

9.2 Sensitivity: The standard deviation of relative sensitivity should be lower than 2dB

9.3 Electrical safety: The result of Hipot or leakage current test should be passed.

10.0 시험 결과 (Test Result)

Sample		Chemical	Manufacturer	Type	Result		
No.	ID				Visual	Sens.	Safety
1	CI-190522-01	STERANIOS 2% (same as ANIOXYDE 1000)	ANIOS	Solution	Pass	Pass	Pass
2	CI-190522-01	Super Sani-Cloth	PDI	Wipe	Pass	Pass	Pass

3	CI-190511-01	SONO Ultrasound Wipes	SONO	Wipe	Pass	Pass	Pass
4	CI-190515-01	CIDEX OPA	ASP	Solution	Pass	Pass	Pass
5	CI-190511-01	Transeptic	PARKER	Spray	Pass	Pass	Pass
6	CI-190511-01	Protex Spray and Wipes	PARKER	Wipe/Spray	Pass	Pass	Pass
7	CI-190507-01	Gigasept FF	Schülke & Mayr	Solution	Pass	Pass	Pass
8	CI-190512-01	Oxivir Tb Wipes	Diversey	Wipe	Pass	Pass	Pass
9	CI-190415-01	Clinell Universe wipes	GAMA	Wipe	Pass	Pass	Pass
10	CI-190511-01	Sekusept easy	ECOLAB	Solution	Pass	Pass	Pass
11	CI-190411-01	Tristel Trio Wipes System	Tristel	Wipes	Pass	Pass	Pass
12	CI-190415-01	Sani-Cloth AF3	PDI	Wipe	Pass	Pass	Pass
13	CI-190515-01	CaviWipes and Cavicide	Metrex	Wipe/Spray	Pass	Pass	Pass
14	CI-190515-01	CLEANISEPT WIPES forte	Dr. Schumacher	Wipe	Pass	Pass	Pass
15	CI-190411-01	Protex ULTRA Wipes	PARKER	Wipe	Pass	Pass	Pass
16	CI-190411-01	CLEANISEPT WIPES	Dr. Schumacher	Wipe	Pass	Pass	Pass
17	CI-190415-01	Enzol	WPI	Solution	Pass	Pass	Pass
18	CI-190522-01	Protex Ultra	PARKER	Wipe	Pass	Pass	Pass
19	CI-190507-01	Sani-Cloth Beach	PDI	Wipe	Pass	Pass	Pass

11.0 첨부 자료 (Appendix)

11.1 Appendix1 : Test Result _ STERANIOS 2%(same as ANIOXYDE 1000)
11.2 Appendix2 : Test Result _ Super SANI-Cloth
11.3 Appendix3 : Test Result _SONO ULTRASOUND WIPES
11.4 Appendix4 : Test Result _ CIDEX OPA
11.5 Appendix5 : Test Result _Trnasepic spray
11.6 Appendix6 : Test Result _ Protex Spray and Wipes
11.7 Appendix7 : Test Result_Gigasept FF
11.8 Appendix8 : Test Result _OXIVIR TB WIPES
11.9 Appendix9 : Test Result _Clinell Universe wipes
11.10 Appendix10 : Test Result _ Sekusept easy
11.11 Appendix11 : Test Result _ Tristel Trio Wipes System
11.12 Appendix12 : Test Result _Sani-Cloth AF3
11.13 Appendix13 : Test Result _ CaviWipes and Cavicide
11.14 Appendix14 : Test Result _ CLEANISEPT WIPES forte
11.15 Appendix15: Test Result _ Protex ULTRA Wipes
11.16 Appendix16 : Test Result _CLEANISEPT WIPES
11.17 Appendix17 : Test Result _Enzol
11.18 Appendix18 : Test Result _ Phrotex ultra
11.19 Appendix19 : Test Result_ Sani-Cloth Bleach

12.0 관련 문서 (Related Documents)

12.1 Disinfectant Test Guidance for Medical Ultrasound Transducer (DoC.#: 100162)

13.0 추가 정보 (Additional Information): N/A

14.0 최종 결론 (Conclusion)

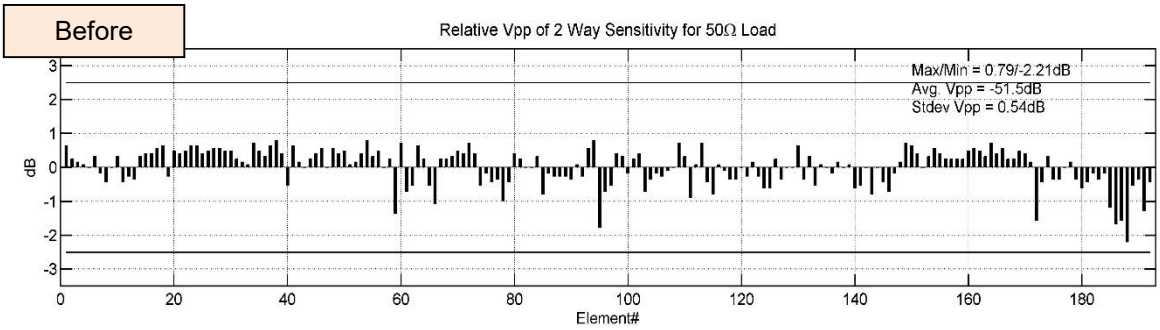
14.1 Compatibility of each disinfectant for 5LI-C00(7L2) medical ultrasound transducer is in below table.

Sample #	Chemical	Manufacturer	Type	Result
1	STERANIOS 2% (same as ANIOXYDE 1000)	ANIOS	Solution	Pass
2	Super Sani-Cloth	PDI	Wipe	Pass
3	SONO Ultrasound Wipes	SONO	Wipe	Pass
4	CIDEX OPA	ASP	Solution	Pass
5	Transeptic	PARKER	Spray	Pass
6	Protex Spray and Wipes	PARKER	Wipe/Spray	Pass
7	Gigasept FF	Schülke & Mayr	Solution	Pass
8	Oxivir Tb Wipes	Diversey	Wipe	Pass
9	Clinell Universe wipes	GAMA	Wipe	Pass
10	Sekusept easy	ECOLAB	Solution	Pass
11	Tristel Trio Wipes System	Tristel	Wipes	Pass
12	Sani-Cloth AF3	PDI	Wipe	Pass
13	CaviWipes and Cavicide	Metrex	Wipe/Spray	Pass
14	CLEANISEPT WIPES forte	Dr. Schumacher	Wipe	Pass
15	Protex ULTRA Wipes	PARKER	Wipe	Pass
16	CLEANISEPT WIPES	Dr. Schumacher	Wipe	Pass
17	Enzol	WPI	Solution	Pass
18	Protex Ultra	PARKER	Wipe	Pass
19	Sani-Cloth Bleach	PDI	Wipe	Pass

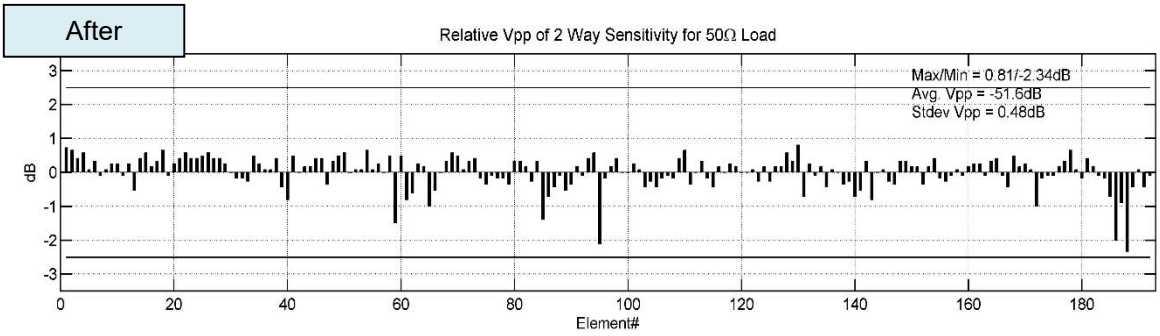
[Appendix 1: Test Result _ STERANIOS 2%(same as ANOXIDE 1000)]

- Pulse echo – Pass (Deviation: -0.06dB, Before: 0.54dB / After: 0.48dB)

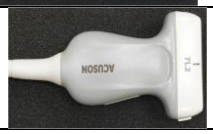
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

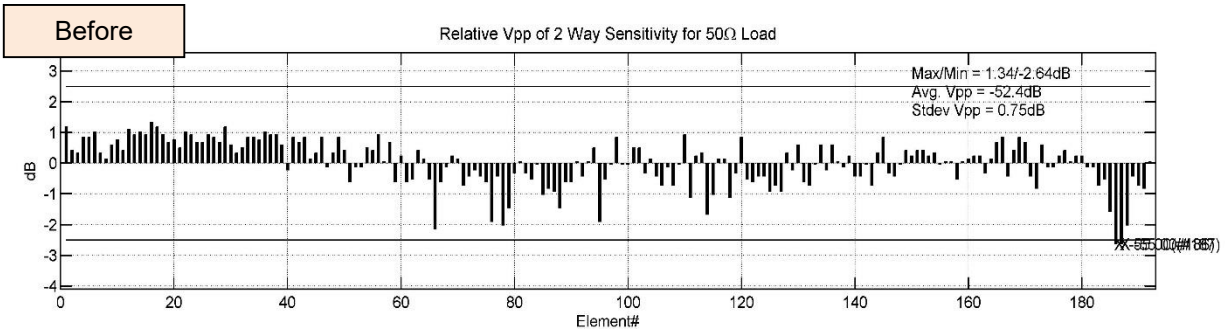
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

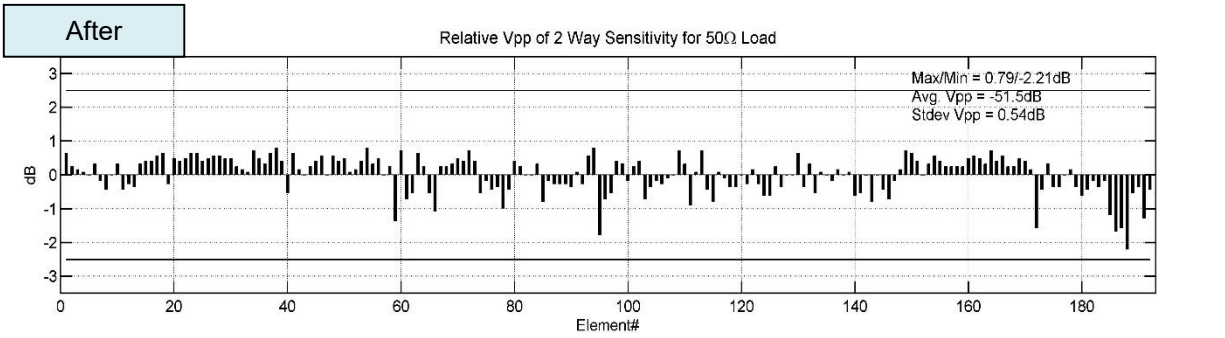
[Appendix 2: Test Result _ Super SANI-Cloth]

- Pulse echo – Pass (Deviation: -0.21dB, Before: 0.75dB / After: 0.54dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

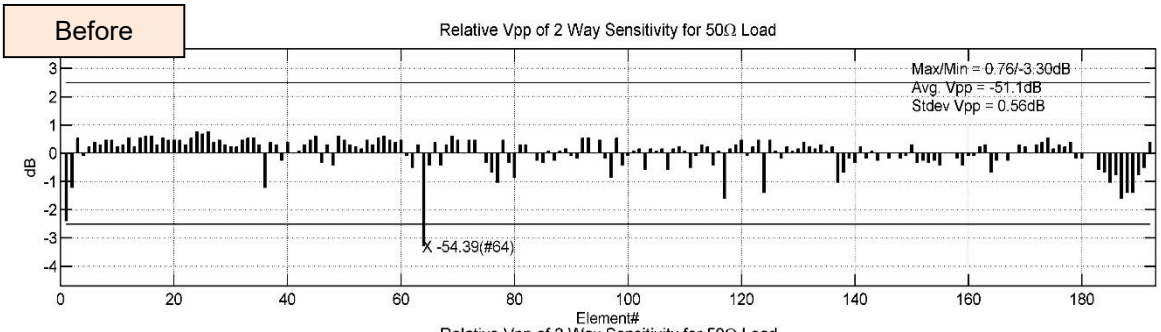
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

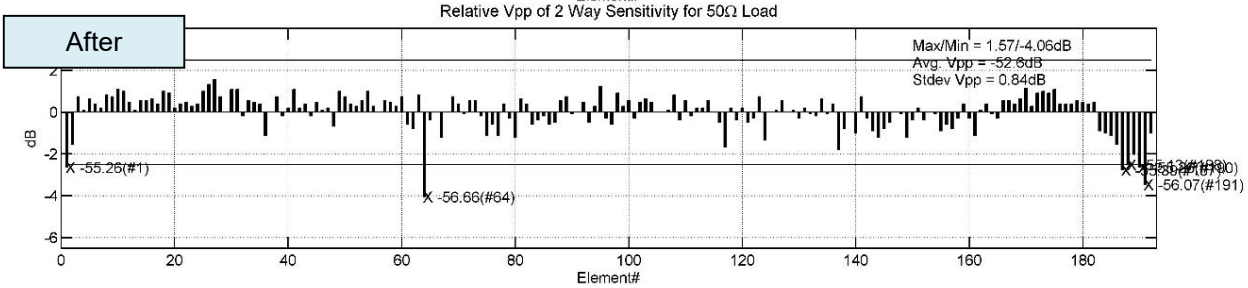
[Appendix 3: Test Result _SONO ULTRASOUND WIPES]

- Pulse echo – Pass (Deviation: 0.28dB , Before: 0.56dB / After: 0.84dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

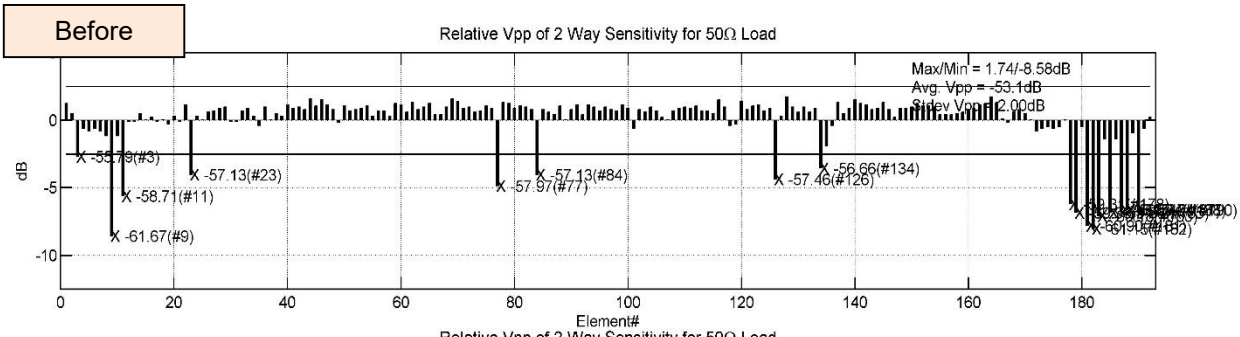
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

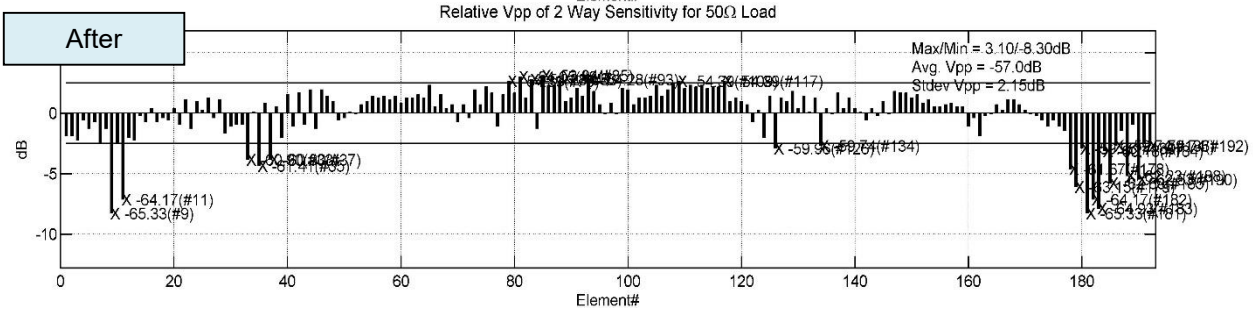
[Appendix 4: Test Result _ CIDEX OPA]

- Pulse echo – Pass (Deviation: 0.15dB, Before: 2.00dB / After: 2.15dB)

Before



After



- Visual: Pass

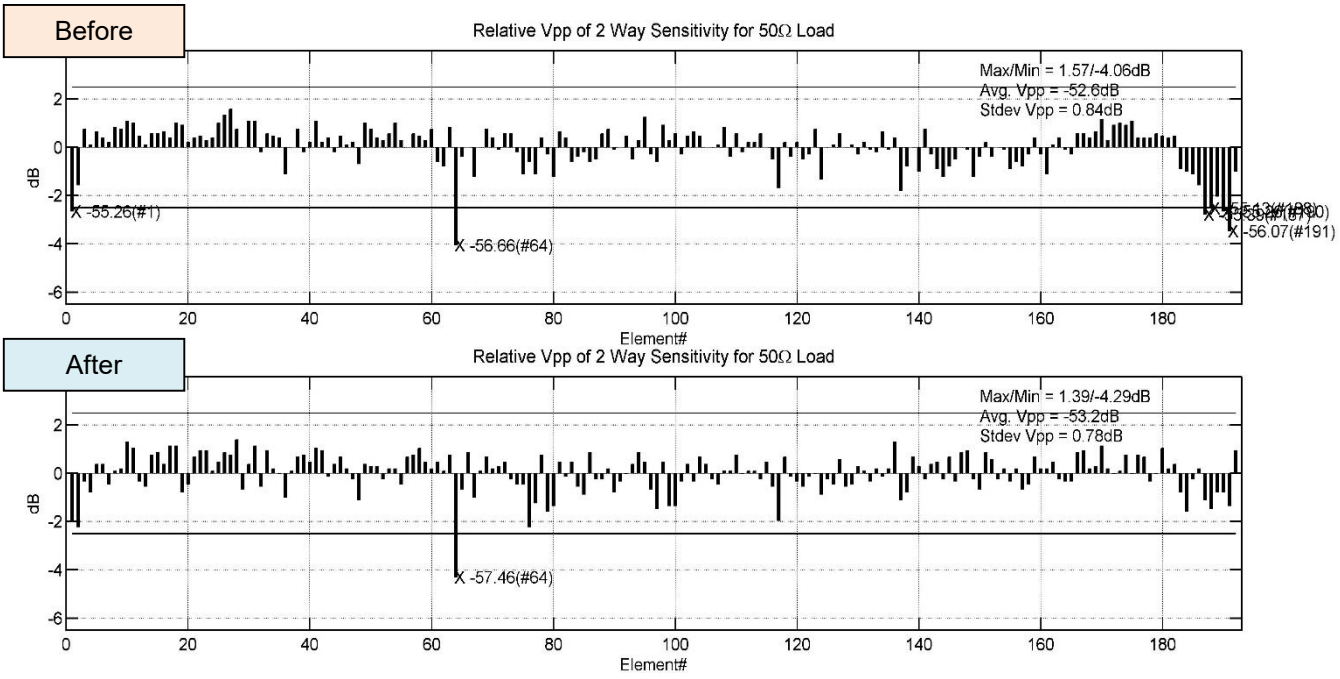
	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

[Appendix 5: Test Result _Trnasepic spray]

- Pulse echo – Pass (Deviation: -0.06dB, Before: 0.84dB / After: 0.78dB)



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

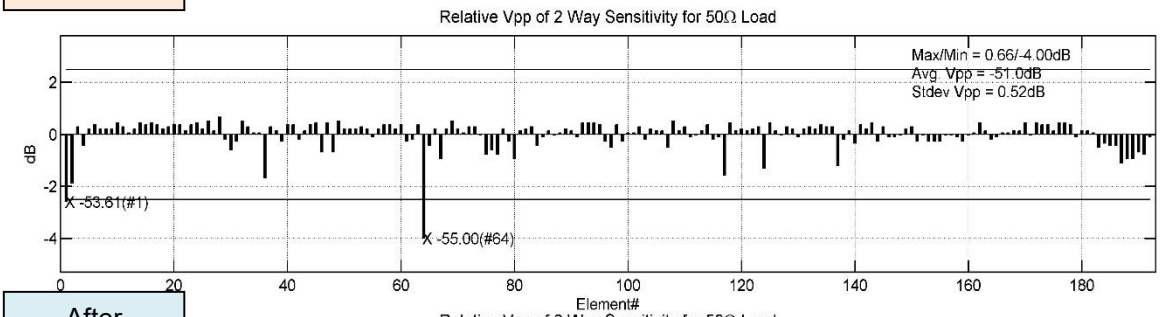
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

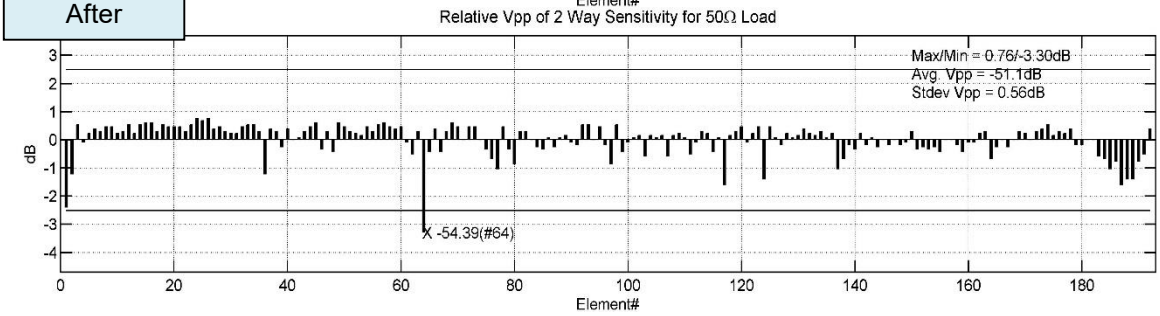
[Appendix 6: Test Result _ Protex Spray and Wipes]

- Pulse echo – Pass (Deviation:0.04dB , Before: 0.52dB / After: 0.56dB)

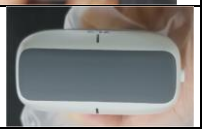
Before



After



- Visual: Pass

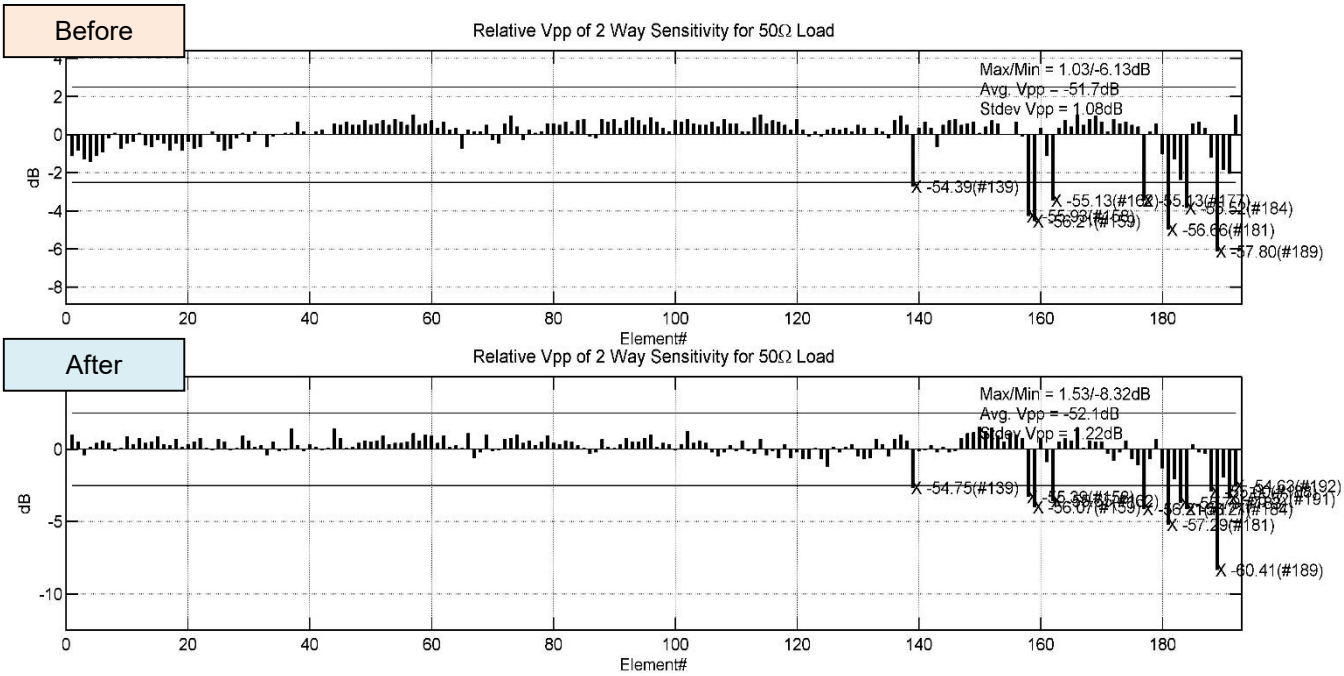
	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

[Appendix 7: Test Result _Gigasept FF]

- Pulse echo – Pass (Deviation: -0.14dB, Before: 1.08dB / After: 1.22dB)



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

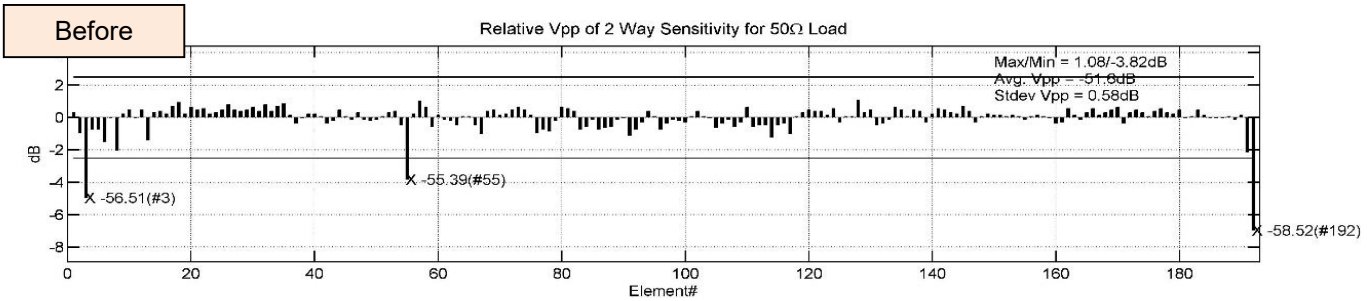
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

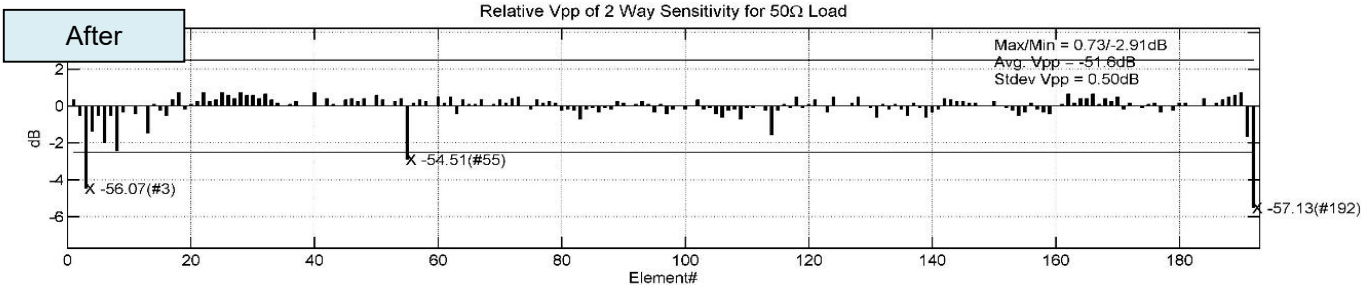
[Appendix 8: Test Result _OXIVIR TB WIPES]

- Pulse echo – Pass (Deviation: -0.08dB, Before: 0.58dB / After:0.50dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

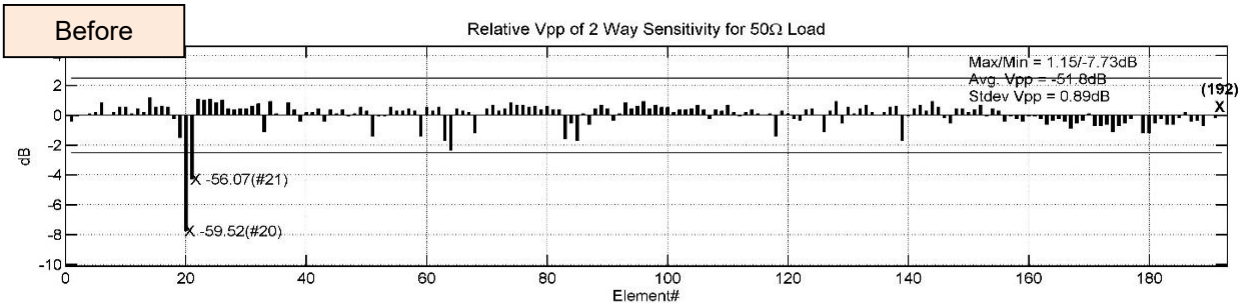
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

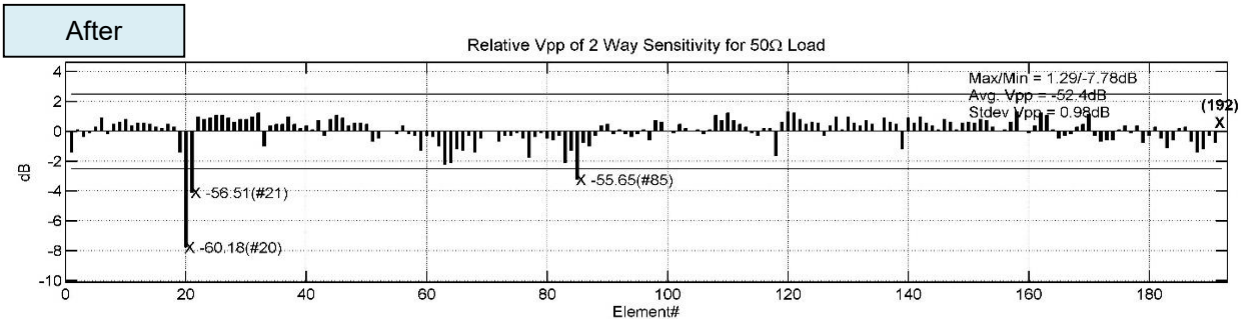
[Appendix 9: Test Result _Clinell Universe wipes]

- Pulse echo – Pass (Deviation: 0.09dB, Before: 0.89dB / After: 0.98dB)

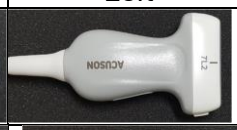
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

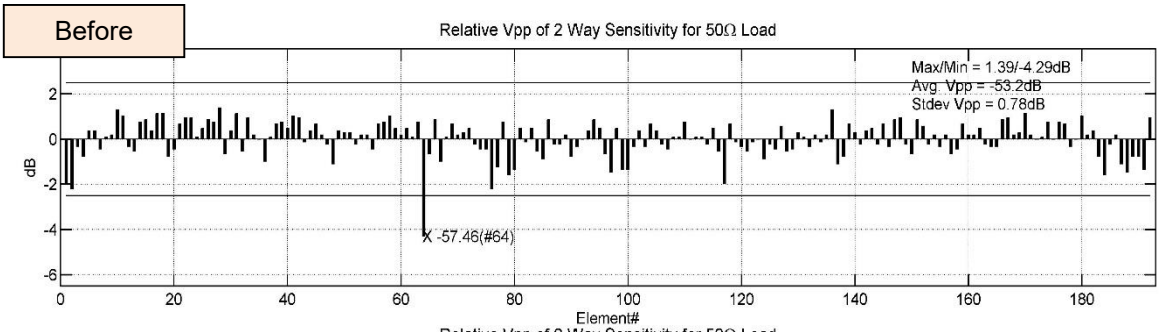
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.002
After	Pass	0.003

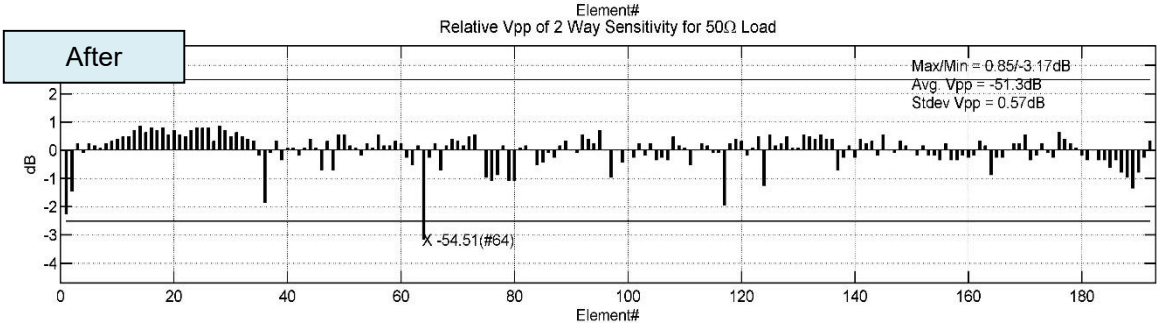
[Appendix 10: Test Result _ Sekusept easy]

- Pulse echo – Pass (Deviation: -0.21dB, Before: 0.78dB / After: 0.57dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

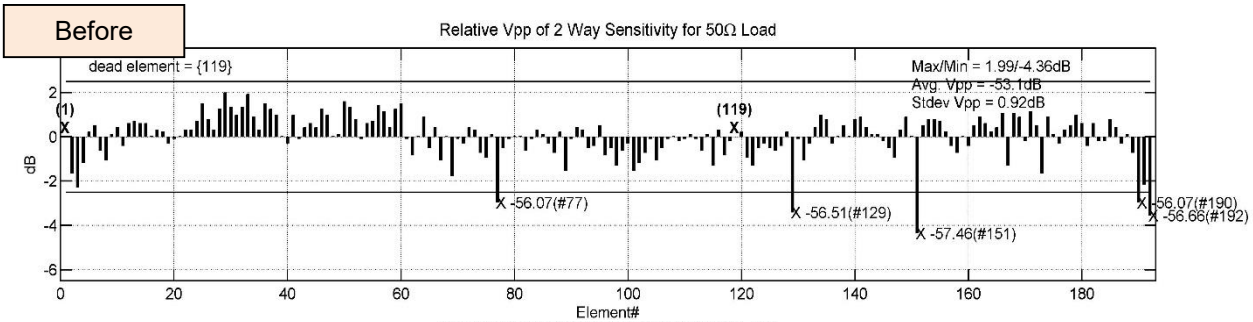
- Electrical Safety:

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

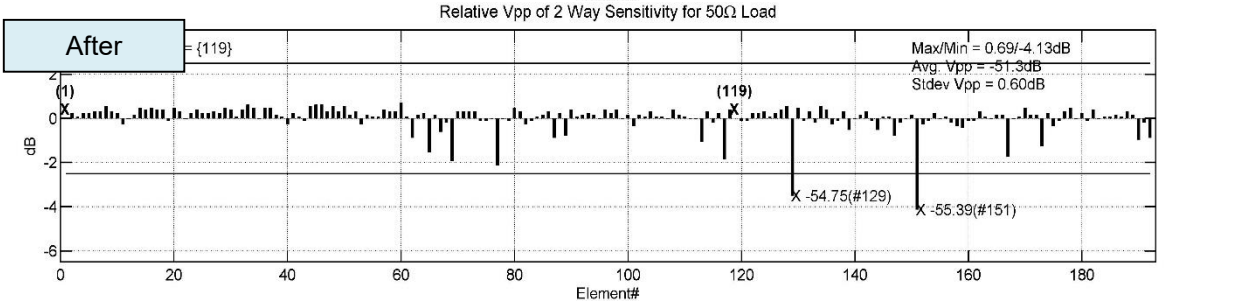
[Appendix 11: Test Result _ Tristel Trio Wipes System]

- Pulse echo – Pass (Deviation: -0.32dB, Before: 0.92dB / After: 0.60dB)

Before



After



- Visual: Pass : Pass

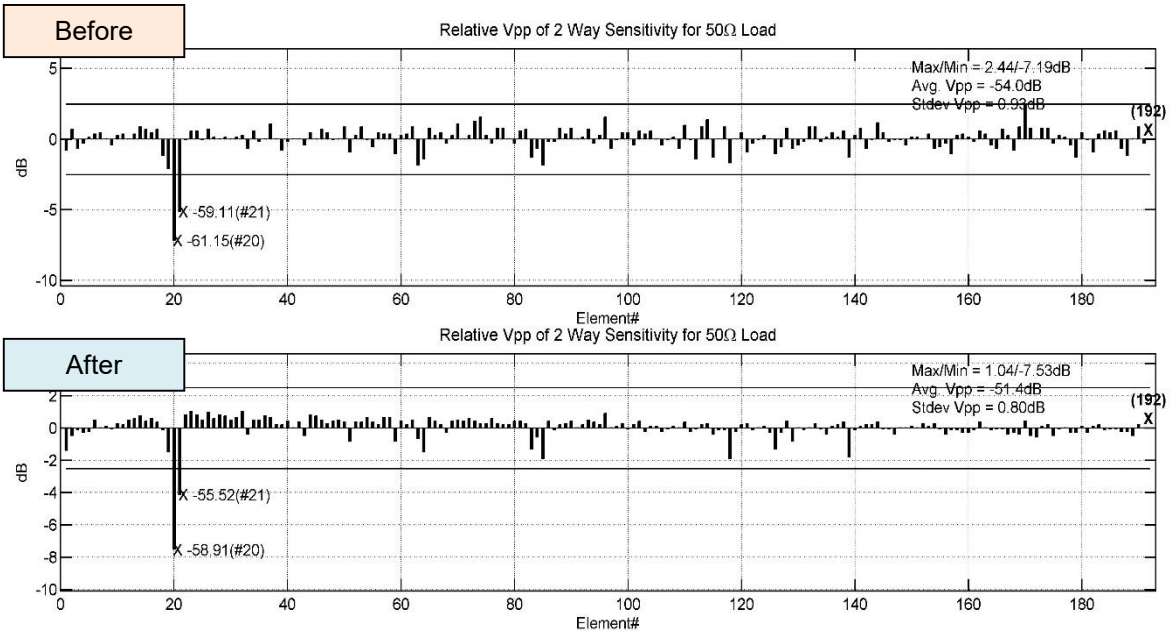
	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

[Appendix 12: Test Result _Sani-Cloth AF3]

- Pulse echo – Pass (Deviation: -0.13dB, Before: 0.93dB / After: 0.80dB)



- Visual: Pass

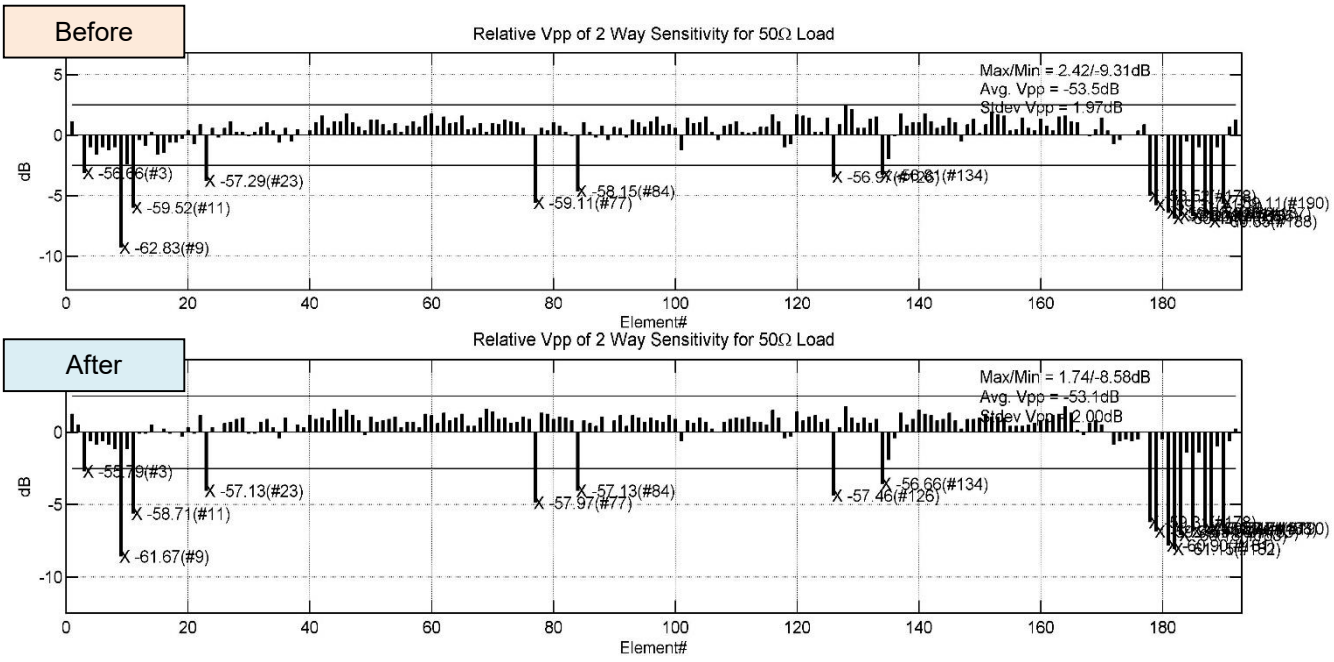
	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.002
After	Pass	0.003

[Appendix 13: Test Result _ CaviWipes and Cavicide]

- Pulse echo –Pass (Deviation: -0.03dB, Before: 1.97dB / After: 2.00dB)



- Visual: Pass : Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

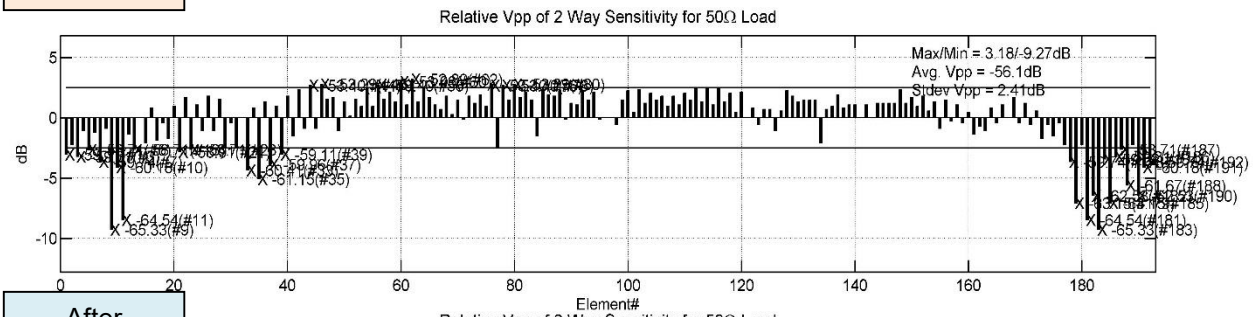
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

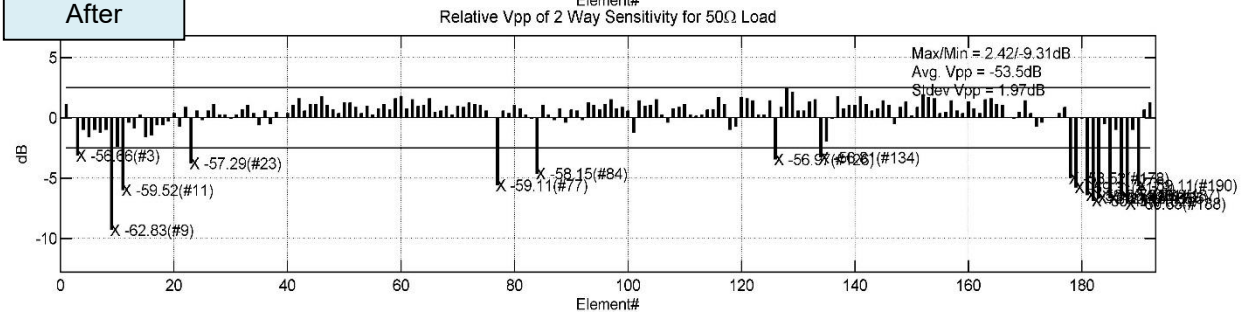
[Appendix 14: Test Result _ CLEANISEPT WIPES forte]

- Pulse echo – Pass (Deviation: 0.44dB, Before: 2.41dB / After: 1.97dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

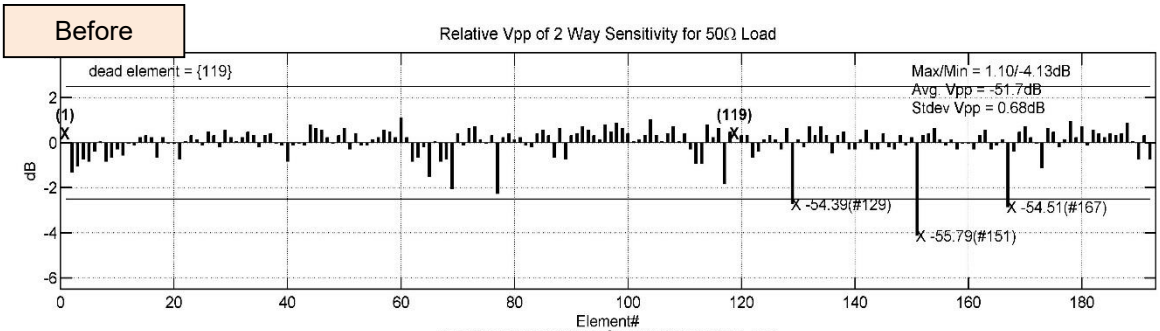
- Electrical Safety:

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

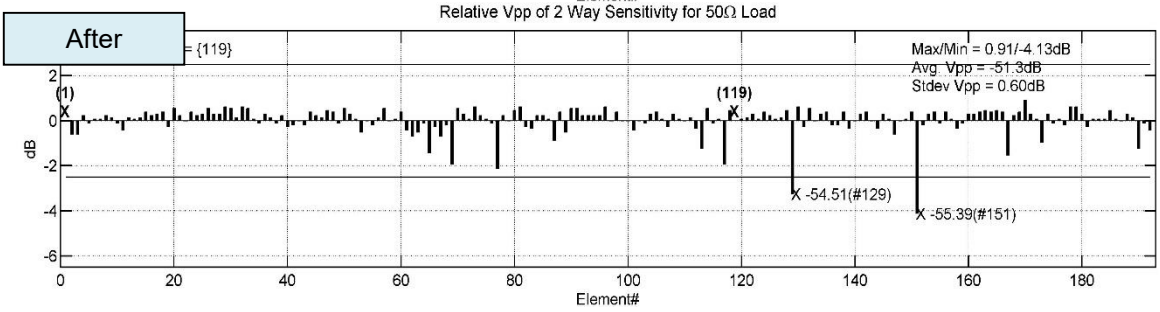
[Appendix 15: Test Result _ Protex ULTRA Wipes]

- Pulse echo – Pass (Deviation: -0.08dB, Before: 0.68dB / After: 0.60dB)

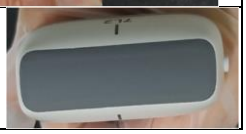
Before



After



- Visual: Pass

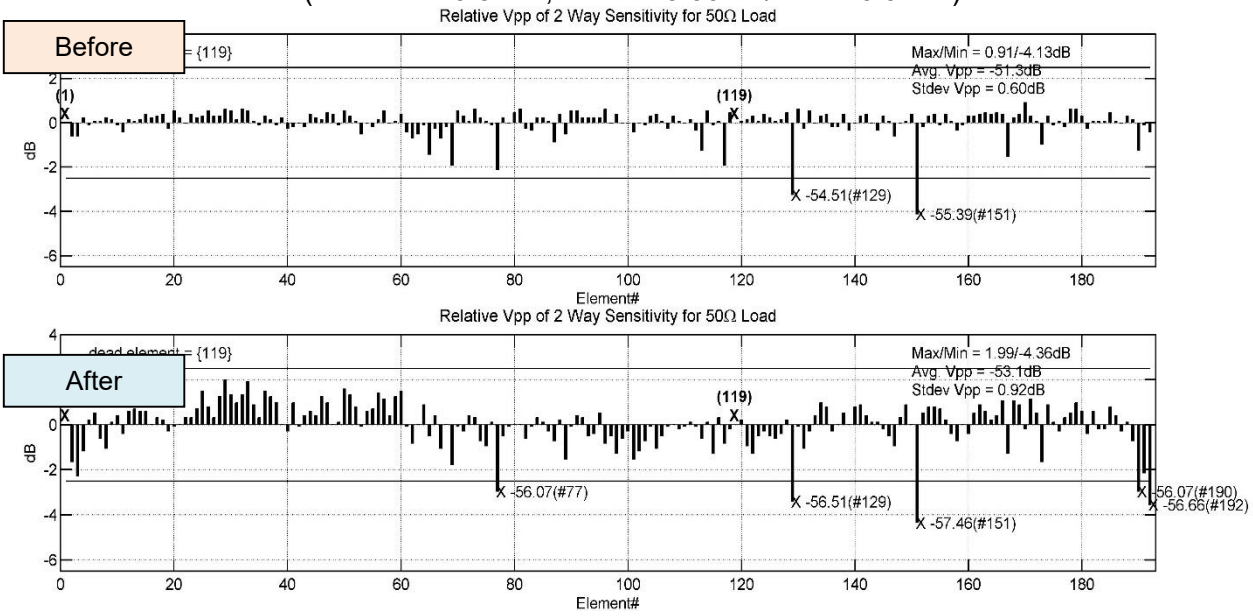
	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

[Appendix 16: Test Result _CLEANISEPT WIPES]

- Pulse echo – Pass (Deviation: 0.32dB, Before: 0.60dB / After: 0.92dB)



- Visual: Pass

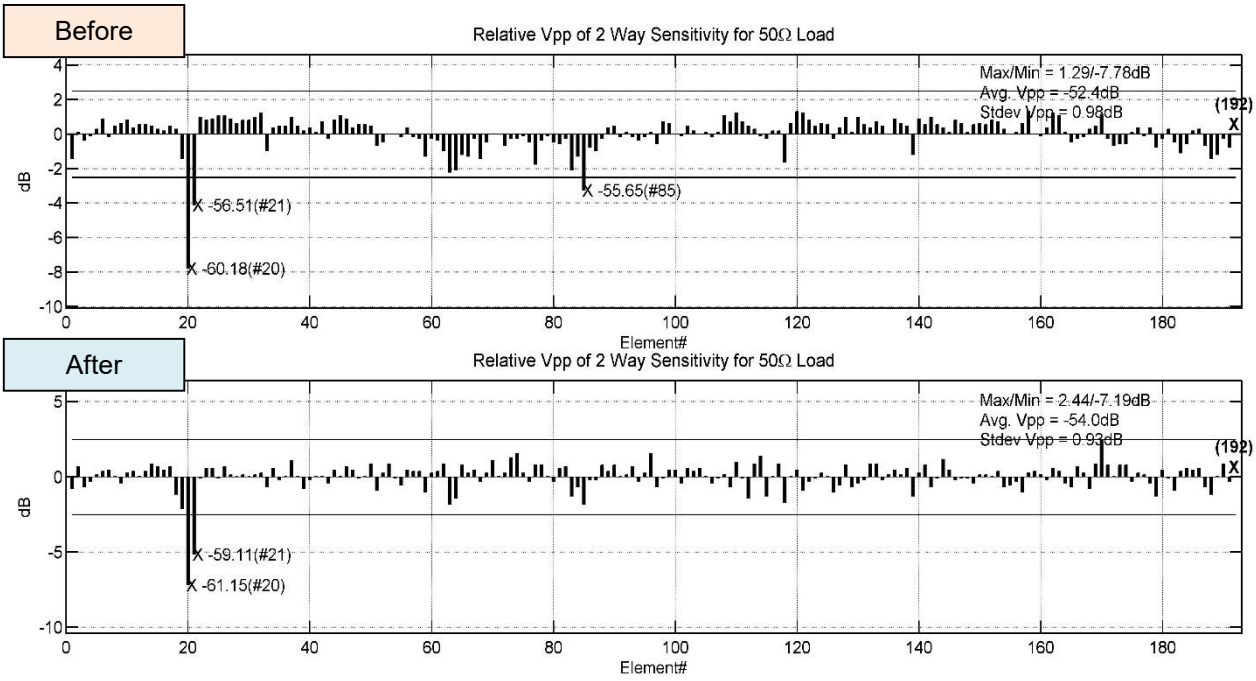
	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

[Appendix 17: Test Result _Enzol]

- Pulse echo – Pass (Deviation: -0.05dB, Before: 0.98dB / After: 0.93dB)



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

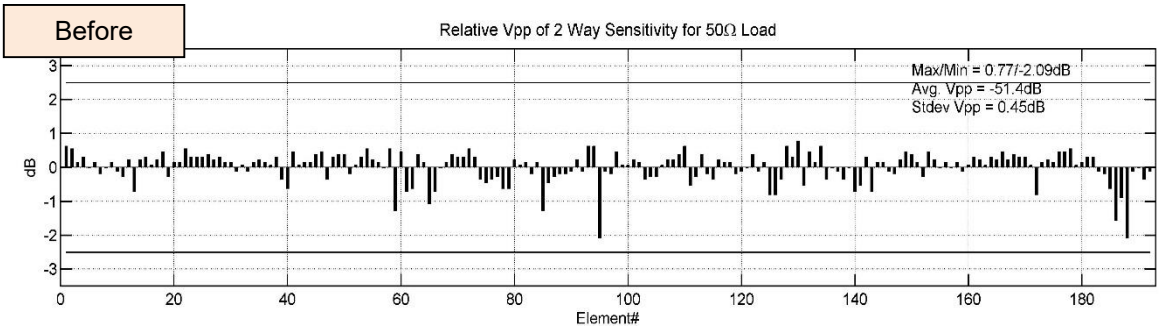
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.002

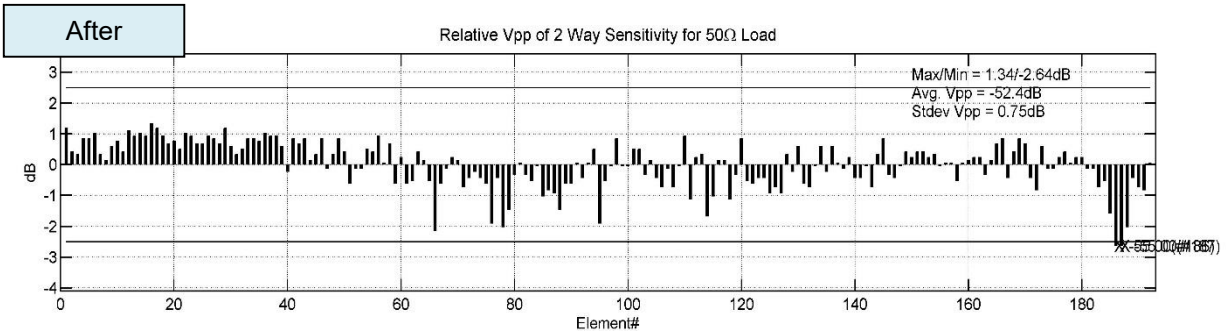
[Appendix 18: Test Result _ Phrotex ultra]

- Pulse echo – Pass (Deviation: 0.30dB, Before: 0.45dB / After: 0.75dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

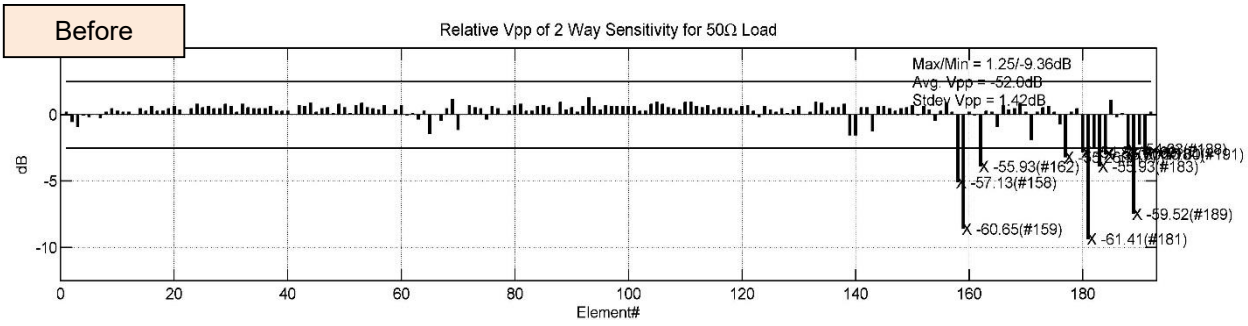
- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

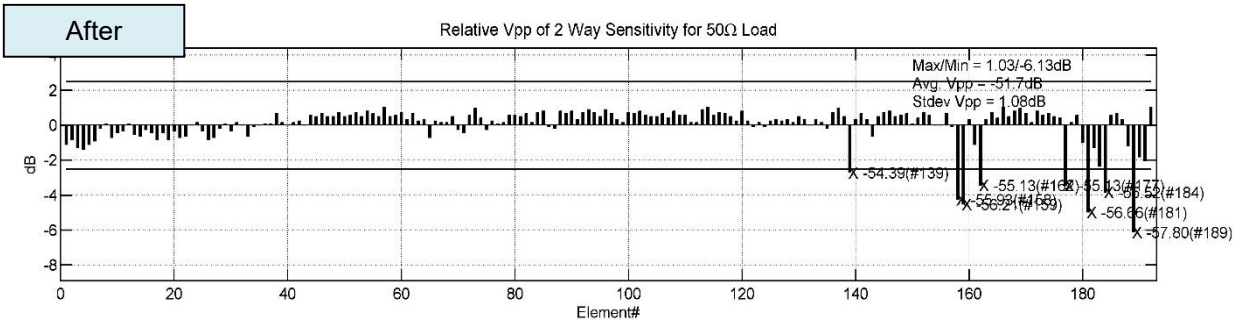
[Appendix 19: Test Result_ SaniCloth Bleach]

- Pulse echo – Pass (Deviation: -0.34dB, Before: 1.42dB / After: 1.08dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety: Pass

	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003