주식회사 휴먼스캔

HUMANSCAN Co., Ltd.

문서명(Title): 5LI-C00(7L2) Disinfectant Test Report_2nd

문서번호(Document #): 5503467

개정번호(Revision #): 01

최신 개정 정보(Revision Information)

날짜 (Date)	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 2nd 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

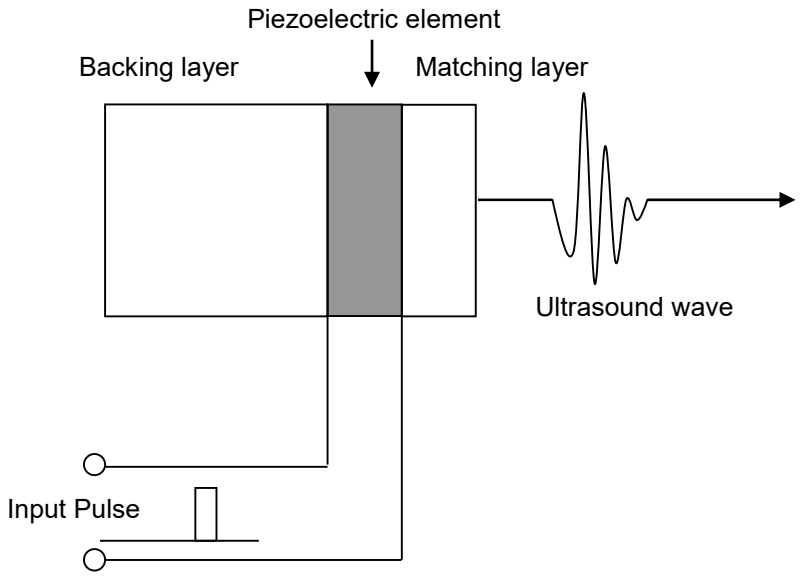
4.2 Reviewed by
- 4.2.1 Name: Ho Jung
- 4.2.2 Job title: Director (Production Department)
- 4.2.3 Major: Physics (Study on the Piezoelectric Properties of PMN-PT Single Crystal and It's Application)
- 4.2.4 School Graduate: Master of Science

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	CIDEX	ASP	Solution	5	1
LLD	Clorox Healthcare Bleach Germicidal Wipes	CloroxPro	Wipe	3	1
LLD	Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant	CloroxPro	Wipe	1	1
HLD	MetricCide OPA Plus	Metrex	Solution	12	2
HLD	Metricide Plus 30	Metrex	Solution	15	2
HLD	Rapicide OPA/28	CANTEL	Solution	10	2
HLD	Rely+On Perasafe	LANXESS	Solution	10	2
HLD	Revital-Ox RESERT HLD	STERIS	Solution	8	2
LLD	Matrix Wipes	Whiteley	Wipe	3	1
LLD	Sani-Cloth HB	PDI	Wipe	10	2
HLD	Metrizyme	Metrex	Solution	3	1

*** Total 11 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-190507-07	CIDEX	ASP	Solution	Pass	Pass	Pass
2	CI-190507-07	Clorox Healthcare Bleach Germicidal Wipes	CloroxPro	Wipe	Pass	Pass	Pass
3	CI-191109-01	Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant	CloroxPro	Wipe	Pass	Pass	Pass
4	CI-190507-07	MetricCide OPA Plus	Metrex	Solution	Pass	Pass	Pass
5	CI-191109-01	Metricide Plus 30	Metrex	Solution	Pass	Pass	Pass
6	CI-200108-01	Rapicide OPA/28	CANTEL	Solution	Pass	Pass	Pass

7	CI-200108-01	Rely+On Perasafe	LANXESS	Solution	Pass	Pass	Pass
8	CI-191109-01	Revital-Ox RESERT HLD	STERIS	Solution	Pass	Pass	Pass
9	CI-190507-07	Matrix Wipes	Whiteley	Wipe	Pass	Pass	Pass
10	CI-200108-01	Sani-Cloth HB	PDI	Wipe	Pass	Pass	Pass
11	CI-190507-07	Metrizyme	Metrex	Solution	Pass	Pass	Pass

11.0 첨부 자료 [Appendix]

11.1 Appendix1 : Test Result_CIDEX
11.2 Appendix2 : Test Result_Clorox Healthcare Bleach Germicidal Wipes
11.3 Appendix3 : Test Result_Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant
11.4 Appendix4 : Test Result_Metricide OPA Plus
11.5 Appendix5 : Test Result_Metricde Pluse 30
11.6 Appendix6 : Test Result_Rapicide OPA/28
11.7 Appendix7 : Test Result_Rely+On Perasafe
11.8 Appendix8 : Test Result_Revital-Ox RESERT HLD
11.9 Appendix9 : Test Result_Matrix Wipes
11.10 Appendix10 : Test Result_Sani-Cloth HB
11.11 Appendix11 : Test Result_Metrizyme

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]

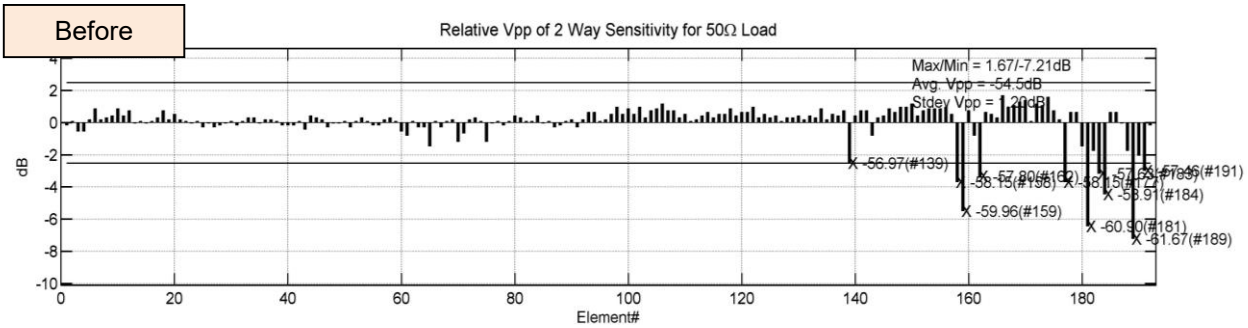
14.1 Compatibility of each disinfectant for 5LI-C00(7L2) medical ultrasound transducer is in below table.

Sample #	Chemical	Manufacturer	Type	Result
1	CIDEX	ASP	Solution	Pass
2	Clorox Healthcare Bleach Germicidal Wipes	CloroxPro	Wipe	Pass
3	Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant	CloroxPro	Wipe	Pass
4	MetricCide OPA Plus	Metrex	Solution	Pass
5	Metricide Plus 30	Metrex	Solution	Pass
6	Rapicide OPA/28	CANTEL	Solution	Pass
7	Rely+On Perasafe	LANXESS	Solution	Pass
8	Revital-Ox RESERT HLD	STERIS	Solution	Pass
9	Matrix Wipes	Whiteley	Wipe	Pass
10	Sani-Cloth HB	PDI	Wipe	Pass
11	Metrizyme	Metrex	Solution	Pass

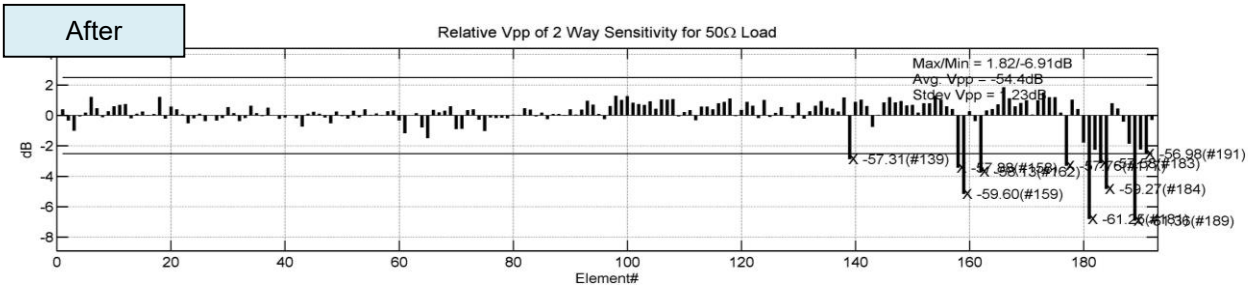
[Appendix 1: Test Result _ CIDEX]

- Pulse echo – Pass (Deviation: 0.03dB, Before: 1.20dB / After: 1.23dB)

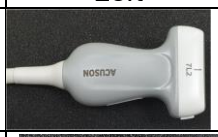
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

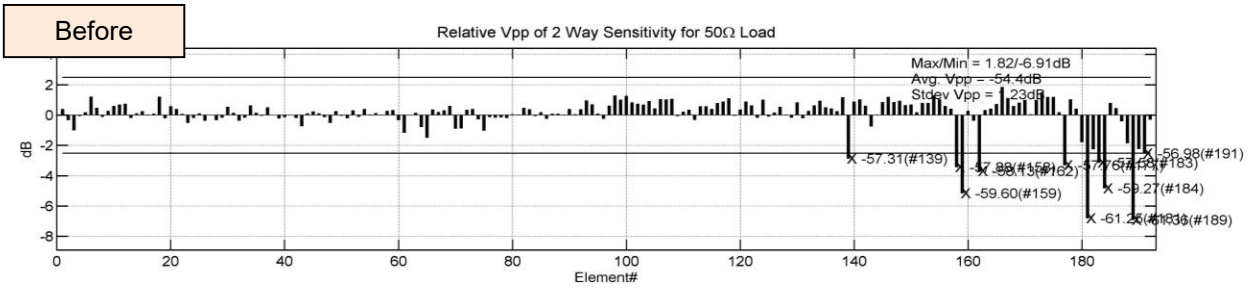
- Electrical Safety: Pass

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

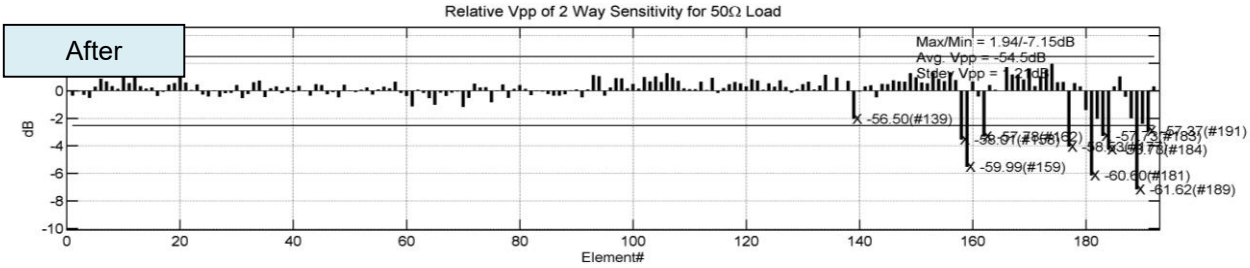
[Appendix 2: Test Result _ Clorox Healthcare Bleach Germicidal Wipes]

- Pulse echo – Pass (Deviation: -0.02dB, Before: 1.23dB / After: 1.21dB)

Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

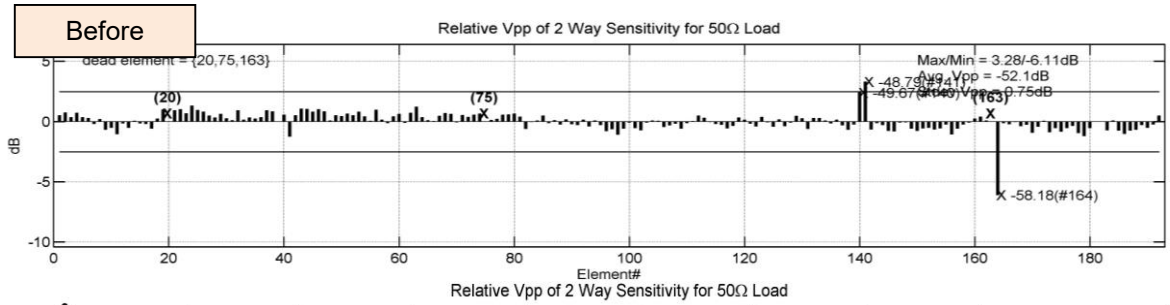
- Electrical Safety: Pass

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

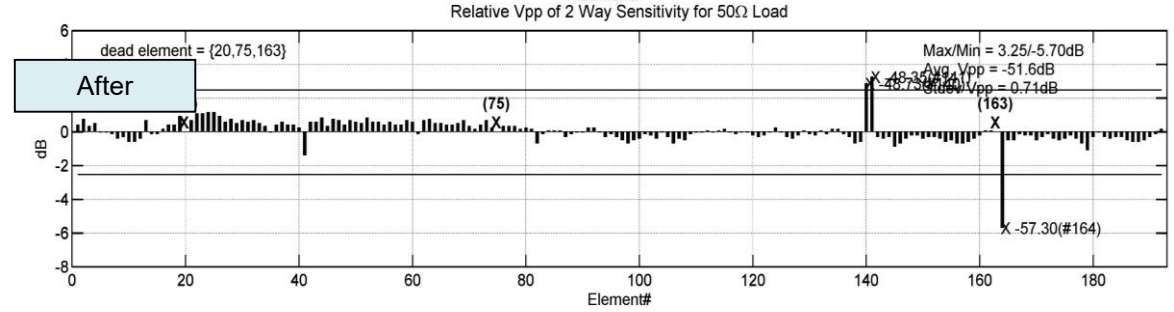
[Appendix 3: Test Result _ Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant]

- Pulse echo – Pass (Deviation: -0.04dB , Before: 0.75dB / After: 0.71dB)

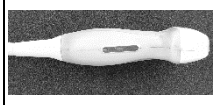
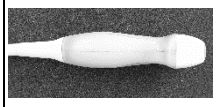
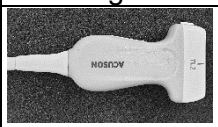
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

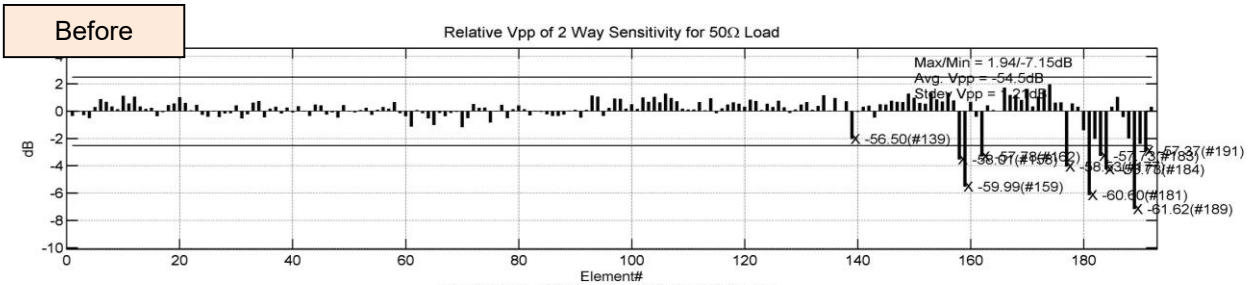
- Electrical Safety: Pass

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

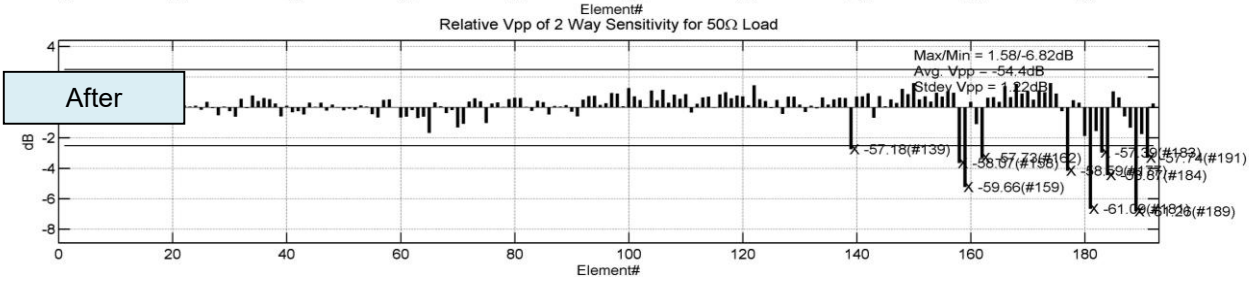
[Appendix 4: Test Result _ MetriCide OPA Plus]

- Pulse echo – Pass (Deviation: 0.01dB, Before: 1.21dB / After: 1.22dB)

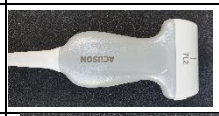
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

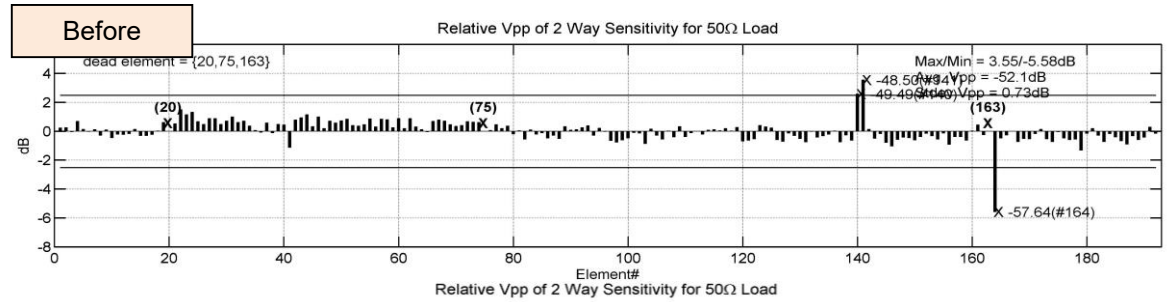
- Electrical Safety: Pass

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

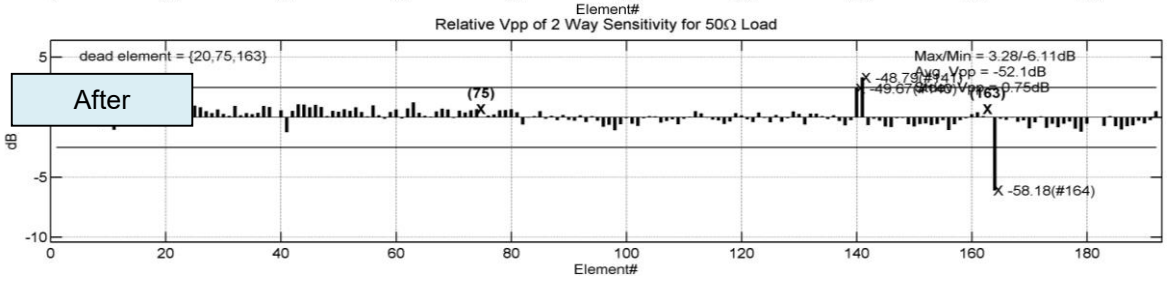
[Appendix 5: Test Result _ Metricide Plus 30]

- Pulse echo – Pass (Deviation: 0.02dB, Before: 0.73dB / After: 0.75dB)

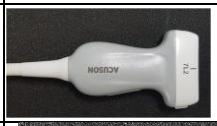
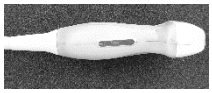
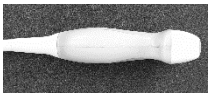
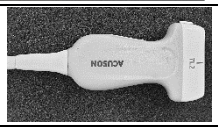
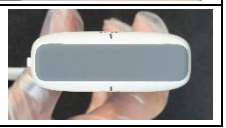
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

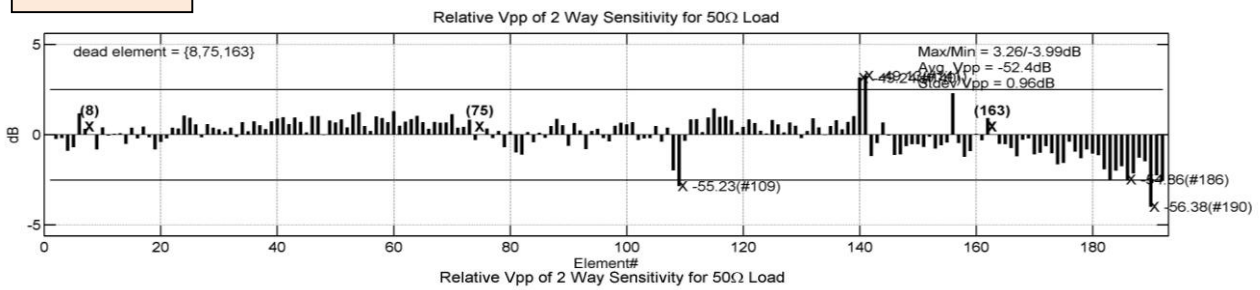
- Electrical Safety: Pass

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

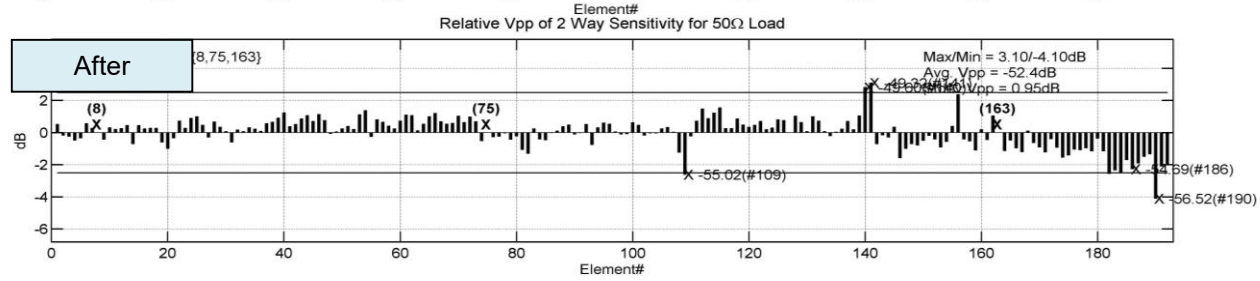
[Appendix 6: Test Result _ Rapicide OPA/28]

- Pulse echo – Pass (Deviation: -0.01dB , Before: 0.96dB / After: 0.95dB)

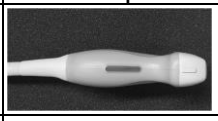
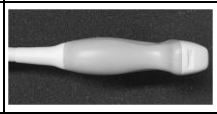
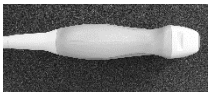
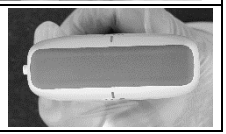
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

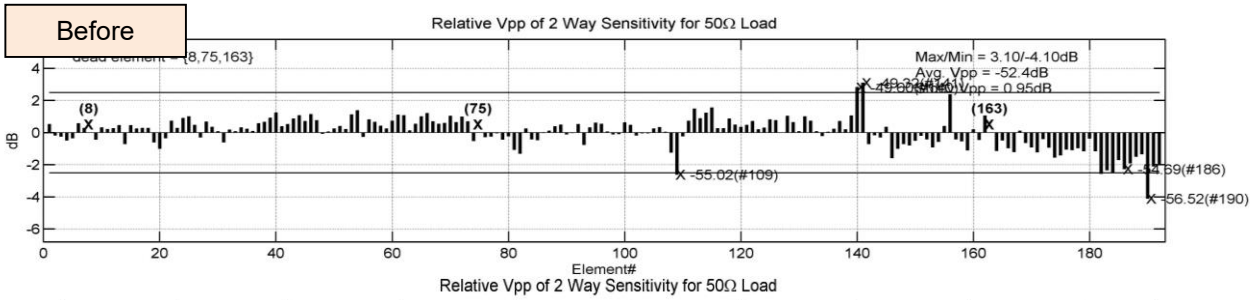
- Electrical Safety: Pass

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

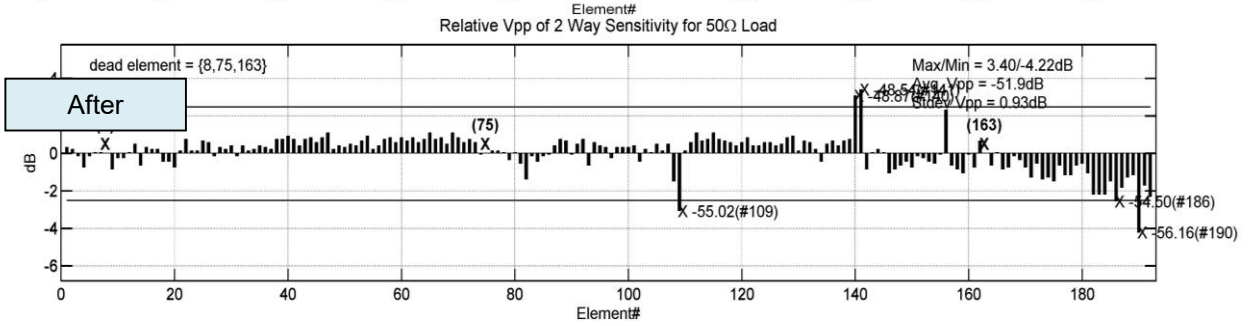
[Appendix 7: Test Result _ Rely+On Perasafe]

- Pulse echo – Pass (Deviation: -0.02dB, Before: 0.95dB / After: 0.93dB)

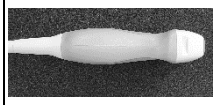
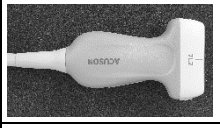
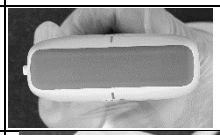
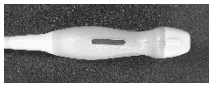
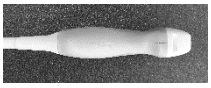
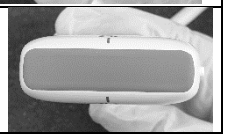
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

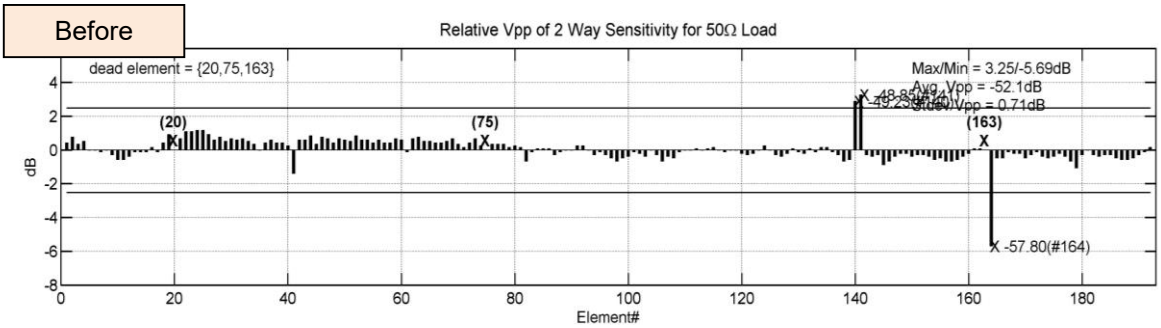
- Electrical Safety: Pass

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

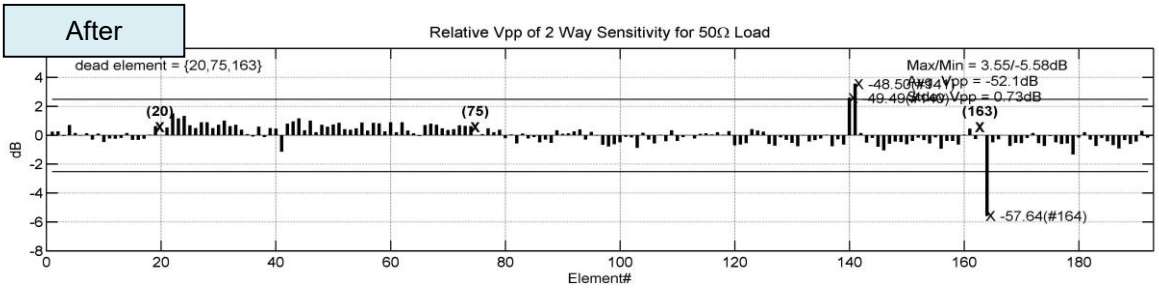
[Appendix 8: Test Result _Revital-Ox RESERT HLD]

- Pulse echo – Pass (Deviation: 0.02dB, Before: 0.71dB / After:0.73dB)

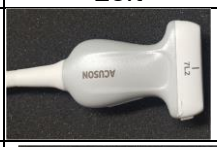
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

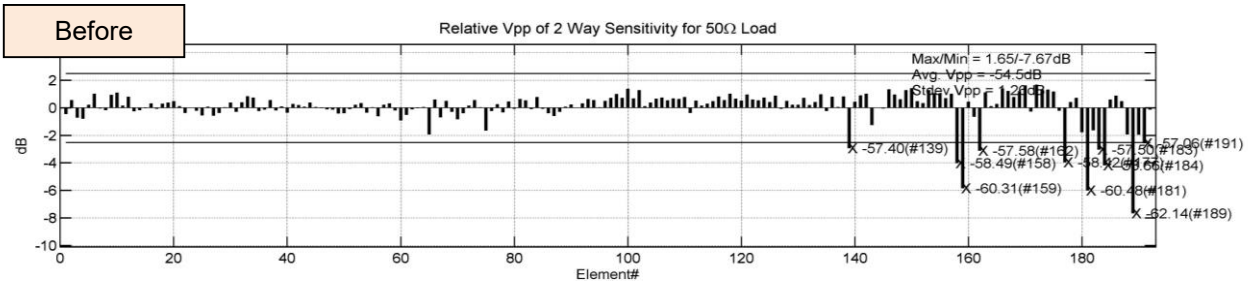
- Electrical Safety: Pass

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

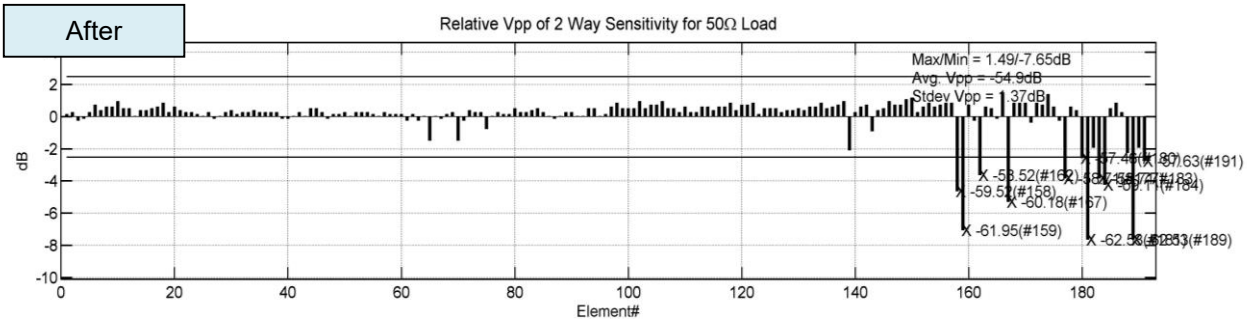
[Appendix 9: Test Result _ Matrix Wipes]

- Pulse echo – Pass (Deviation: 0.14dB, Before: 1.23dB / After: 1.37dB)

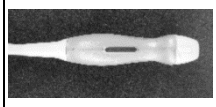
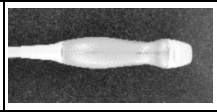
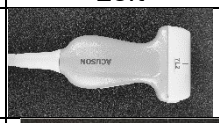
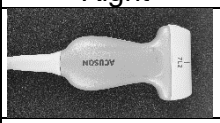
Before



After



- Visual: Pass

	Top	Bottom	Left	Right	Lens
Before					
After					

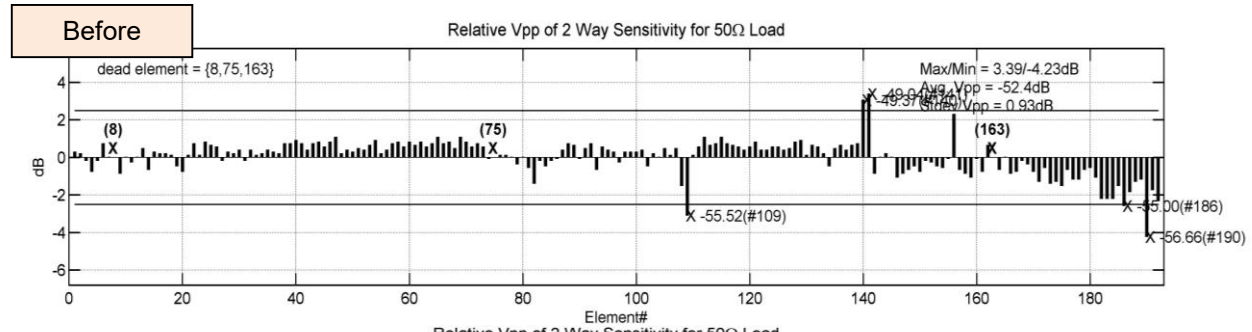
- Electrical Safety: Pass

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

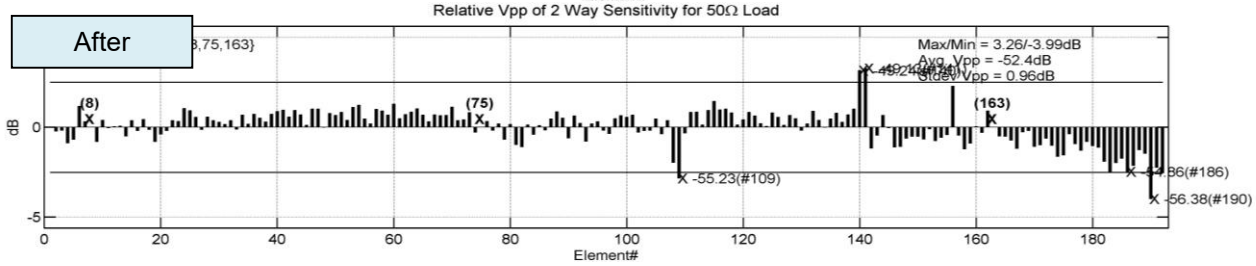
[Appendix 10: Test Result _ Sani-Cloth HB]

- Pulse echo – Pass (Deviation: 0.03dB, Before: 0.93dB / After: 0.96dB)

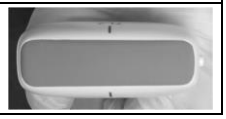
Before



After



- Visual: Pass

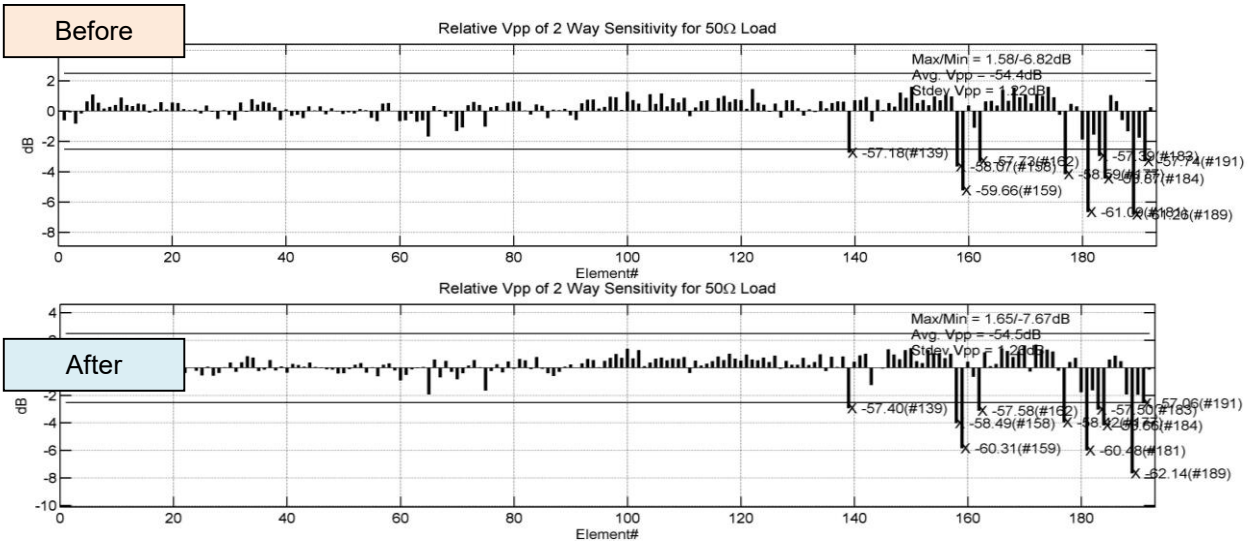
	Top	Bottom	Left	Right	Lens
Before					
After					

- Electrical Safety:

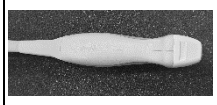
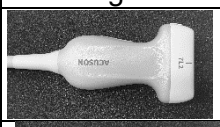
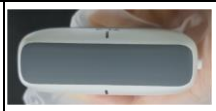
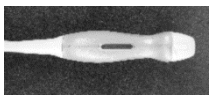
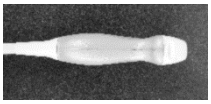
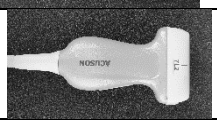
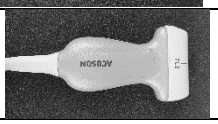
	Hi-pot	Leakage current(mA)
Before	Pass	0.003
After	Pass	0.003

[Appendix 11: Test Result _ Metrizyme]

- Pulse echo – Pass (Deviation: 0.01dB, Before: 1.22dB / After: 1.23dB)



- 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