

Technical Report

To : To Whom it may concern

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Date : Apr 11th, 2023

Title : Technical report_CW2 transducer disinfection compatibility test

■ Executive Summary:

CW2 transducer material compatibility testing demonstrated that there are no deleterious effects on CW2 transducer with gigasept FF (new), CIDEZYME. Testing was performed with extended exposure testing protocol and showed that two disinfectants did not harm the CW2 transducer, and it is compatible with reprocessing process using them. CIDEZYME and ENZOL are chemically identical and for more information, please see appendix 1).

This report will be a justification to update compatible disinfectants in the Transducer Disinfectant Compatibility Matrix (P/N 11335653).

■ Scope :

- Test protocol: Transducer Disinfectant Qualification Process (P/N 5931980)
5.2.1 Liquid Extended Exposure / 5.2.2 Spray/wipes Extended Exposure Protocol
- Pass/Fail Criteria: Transducer Disinfectant Qualification Process (P/N 5931980)
- Transducers and the results

No	Transducer	P/N	S/N	Tested disinfectants	Type	Test results
1	CW2	10789380	21101376	gigasept FF (new)	Liquid	Pass
2	CW2	10789380	21101380	CIDEZYME	Liquid	Pass

Two CW2 transducers were tested, and all of them passed imaging testing and hipot & leakage testing. We can confirm that all outer materials are compatible with them.

- List of Disinfectants

Product name	Reprocessing level	Cas No	Active ingredient	Concentration
gigasept FF (new)	High level disinfectant	638-37-9	Succindialdehyde (11.9%),	11.9%
		696-59-3	Dimethozytetrahydrofuran(3.2%)	3.2%
CIDEZYME	Cleaner	9014-01-01	Subtilisins(proteolytic enzymes)	<5%
ENZOL	Cleaner	9014-01-01	Subtilisins(proteolytic enzymes)	<5%

CIDEZYME and ENZOL are chemically identical and CIDEZYME was tested as a representative. For more information, please see appendix 1).

■ Transducer & disinfectant family:

● Disinfectant family

Disinfectants and cleaners can be grouped by the concentration of active ingredients based on the Cleaner and Disinfectant family classification document (P/N 11508294). five disinfectants used in these testing are the representatives of each ingredient groups. So other disinfectants and cleaners can be covered by these testing results.

● Transducer family

Transducers can be also grouped by construction and similar outer materials. following table shows that CW2 and CW5 transducer have the same outer materials, except T-bar. But it's also made of ULTEM HU 1000 the same as handle & Head assembly parts, so it will not affect the testing results.

Product name	Head Assembly	Handle	Strain relief	Cable	Cable sleeve	Connector	T-bar
CW2 transducer	ULTEM HU 1000	ULTEM HU 1000	Polyurethane Elastomer	PVC	ULTEM HU 1000	Nickel Plated Zinc Alloy	ULTEM HU 1000
CW5 transducer	ULTEM HU 1000	ULTEM HU 1000	Polyurethane Elastomer	PVC	ULTEM HU 1000	Nickel Plated Zinc Alloy	N/A



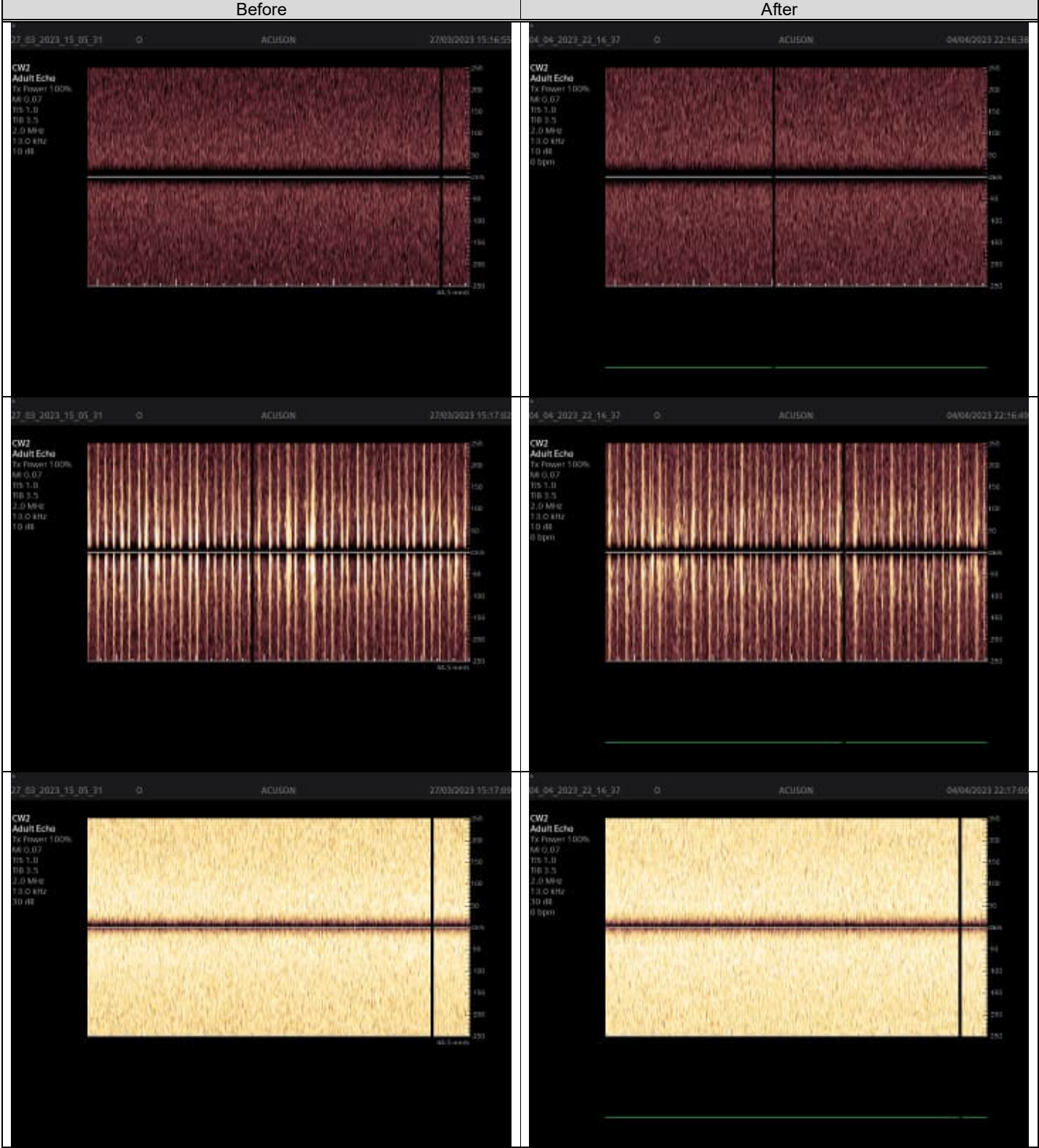
Picture 1. CW2 and CW5 transducer



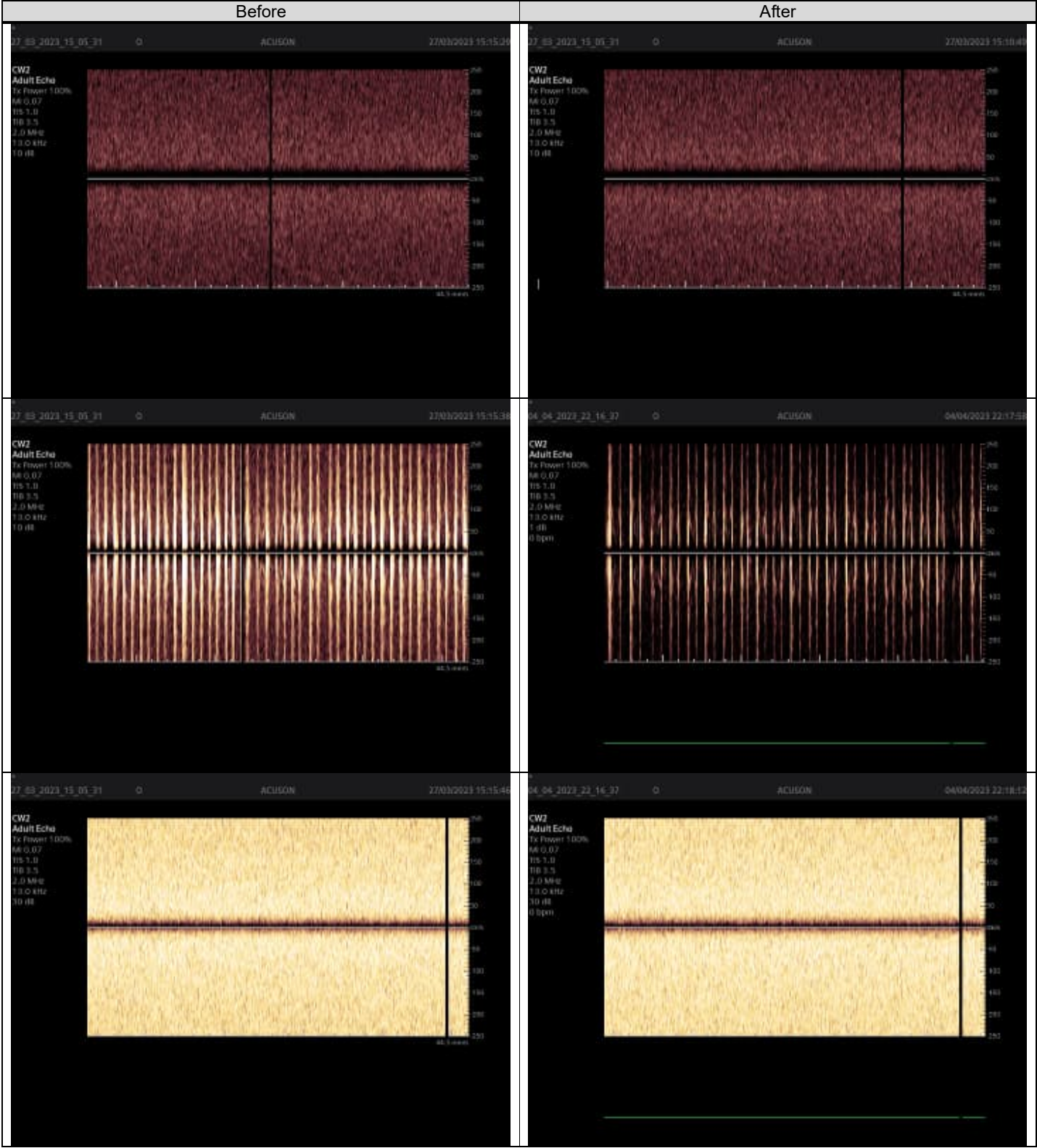
■ Summary of the imaging test result

- It's confirmed that all of samples have the same imaging performance as before exposure to disinfectants.

1) SN 2101376 (CIDEZYME)















2) SN 21101380 (gigasept FF (new))



■ Visual inspection

- No visual defects were found in all samples.

XDCR	S/N	Test	Head assembly	Handle & Strain relief	Cable	Judge
CW2	2110 1376	Before				No defect
		After				

XDCR	S/N	Test	Head assembly	Handle & Strain relief	Cable	Judge
CW2	2110 1380	Before				No defect
		After				

■ Conclusion:

Based on these test results, CW2 and CW5 transducer are compatible with gigasept FF (new), CIDEZMYE and ENZOL. This Results will be updated in Transducer Disinfectant Compatibility Matrix (P/N 11335653).

■ Related Document

Transducer Cleaner Disinfectant Qualification Process, P/N 5931980
The Transducer Disinfectant Compatibility Matrix, P/N 11335653
Cleaner & Disinfectant Family Classification, P/N 11508294
Transducer Family Classification for Reprocessing, P/N 11508925

■ Appendix





1) SDS documents of disinfectants



CIDEZYME_SDS_2 MSDS-gigasept_ff
0210222.pdf _new_.pdf

2) Test results

3)

XDCR	S/N	Test	Hipot & Leakage Test
CW2	21101376	Before	 230328.PLM_Hipot .10789380.2110137
		After	 230405.PLM_Hipot .10789380.2110137
CW2	21101380	Before	 230328.PLM_Hipot .10789380.2110138
		After	 230405.PLM_Hipot .10789380.2110138