SIEMENS Healthineers

21.03.26 SoYun, Park

Technical Report

To : **To Whom it may concern**

CC : **Kang SungYoul(Danny) (US XDCR CD-TRE TDS MPE), Rumwell, Reginald (SHS US XDCR DC-TRE), Kim, GiSeok (US XDCR CD-TRE TDS MPE)**

From : **Park, SoYun(US XDCR CD-TRE TDS MPE)**

Date : **Mar 15th , 2021**

Title : materials compatibility test with Perform.

■ Executive Summary:

This report is to qualify the material compatibility of 4V1c, 5C1, 10L4, 14L5, 18L6, 4Z1c, 8C3HD, 14L5SP, 10MC3, EC9-4, V5Ms and Z6Ms transducers with Perform. All transducers have been tested and determined to be compatible with this disinfectant except for 10L4, 4Z1c and Z6Ms. These three transducers are not compatible with this disinfectant. 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 Protocol (soak transducers for 168 hours at 30℃)
- Pass/Fail Criteria: Transducer Disinfectant Qualification Process (P/N 5931980)

- Disinfectant

Perform used in the testing is a powder type, the disinfection powder is diluted with water to the desired concentration for use. The manufacture which called Schulke confirmed that the spectrum of efficacy / reprocessing level depends on the concentration of the use solution. Please refer to the Attachment 1.

The material compatibility test was carried out at 2% solution. For this reason, Perform is classified as HLD in this report. Please see below for detailed ingredient information.

Use solution of Perform	Reprocessing Level
0.5%	LLD
1%	LLD
2%	HLD

- Ingredient information

Disinfectants	Reprocessing level	Active ingredient	CAS No	Concentration
Perform	HLD	Pentapotassium bis(peroxymonosulphate) bis(sulphate)	70693-62-8	45%
		Anionic surfactants	-	5-15%
		Non-ionic surfactants	-	<5%

- Tested transducers and the results

Transducers	P/N	S/N	Transducers family	Test results
4V1c MP2	07695724	20160450	A2	PASS
5C1 TC-ZIF	11268278	20220296	A3	PASS
10L4 MP456	10787114	20210535	A4	Fail
14L5 MP456	11254090	21010221	A5	PASS
18L6 MP456	10787113	21080257	A6	PASS
4Z1c MP2	10789391	20130044	A7	Fail

SIEMENS Healthineers

8C3HD MP2	10135943	21070497	A9	PASS
14L5SP MP2	10041226	21080039	S1	PASS
10MC3 DL260 & TC-ZIF	11268679	20060694	E1	PASS
EC9-4 DL260 & TC-ZIF	10789383	20220122	E2	PASS
V5Ms	11013704	21060007	T3	PASS
Z6Ms	10436113	83534016	T5	Fail

These transducers are the representative of each transducer family group. Therefore, the group members can be covered by results of representatives. Following table shows the transducer family as Transducer Family Classification for Reprocessing (P/N 11508294).

Transducers	P/N	Family
4V1c MP2 (representative)	**07695724**	A2
8V3 MP1.5	10789382	
8V3 MP456	11014578	
5C1 MP456 (representative)	**11291794**	A3
4V1 MP456	11014576	
CH5-2 DL260	08648086/ 10789386	
CH5-2 TC-ZIF	10136141	
5C1 TC-ZIF	11268278	
7C2 TC-ZIF	11268277	
16L4 TC-ZIF	11284846	
8V4 TC-ZIF	11284847	
5P1 TC-ZIF	11014154	
P8-4 DL260 & TC-ZIF	10030615/ 10789389 & 11014543	
P4-2 DL260 & TC-ZIF	08648045/ 10789385 & 10136143	
13L4 TC-ZIF	11361589	
DAX MP456	10787116	
5V1 MP456	11291796	
VF16-5 DL260	10785041	
VF16-5 TC-ZIF	11014552	
10L4 MP456 (representative)	**10787114**	A4
VF10-5 DL260 & TC-ZIF	08648110/ 10789387 & 10136142	
11L4 DL260 & TC-ZIF	11361584 & 11284844	
9L4 MP2	10035946 / 10789393	
14L5 MP456 (representative)	**11254090**	A5
10V4 MP1 & TC-ZIF & MP456	08266709 &11319697 & 11014579	
4P1 MP2	10041224/ 10789398	
VF13-5 TC-ZIF	10789372	
14L5 MP2.0	10041221/ 10789396	
18L6 MP456 (representative)	**10787113**	A6
VF12-4 DL260	10136922	
12L4 MP2	10786035	
6C1HD MP2	10135941	
12L3 TC-ZIF	11268279	
18L6HD MP2	10041227/ 10789400	
9C3 MP456	10787112	
4Z1c MP2 (representative)	**10033682/ 10789391**	A7
8C3HD MP2 (representative)	**10135943**	A9
18L6HD MP2	10041227/ 10789400	
6C1HD MP2	10135941	
14L5SP MP2 (representative)	**10041226**	S1
VF13-5 SP DL 360	08266907	

SIEMENS Healthineers

10MC3 (representative)	**11284842 & 11268679**	E1
EC9-4 (representative)	**8648029/ 10789383 & 10136144**	E2
V5Ms (representative) 5VT TC-ZIF	**11013704** 11370949	T3
Z6Ms (representative)	**10436113**	T5

■ Summary of the test result

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
4V1c	20160450	Hipot test		0.207 mA	0.177 mA	-	Pass
		Leakage test		12.794 uA	11.510 uA	-	Pass
		Probe element test	Sens.std at 4.0MHz	0.42 dB	0.43 dB	0.01 dB	Pass
			Sens.std at 3.0MHz	0.29 dB	0.3 dB	0.01 dB	Pass
			Sens.std at 1.5MHz	0.45 dB	0.48 dB	0.03 dB	Pass
			TOF	7.65 ns	5.2 ns	2.45 ns	Pass
			Dead element	0	0	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
5C1	20220296	Hipot test		0.242 mA	0.216 mA	-	Pass
		Leakage test		15.395 uA	14.060 uA	-	Pass
		Probe element test	Sens.std at 4.0MHz	0.81 dB	0.75 dB	0.06 dB	Pass
			Sens.std at 3.0MHz	0.55 dB	0.49 dB	0.06 dB	Pass
			Sens.std at 1.8MHz	0.41 dB	0.32 dB	0.09 dB	Pass
			TOF	6.4 ns	4.8 ns	1.6 ns	Pass
			Dead element	0	1	1	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass
		Final decision		Pass, there was a single dead element. But it is considered that the dead element was not caused by disinfectant. Because there was no sensitivity degradation.			

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
10L4	20210535	Hipot test		0.250 mA	0.213 mA	-	Pass
		Leakage test		14.855 uA	13.928 uA	-	Pass
		Probe element test	Sens.std at 6.0MHz	0.53 dB	0.66 dB	0.13 dB	Pass
			Sens.std at 8.0MHz	0.63 dB	0.63 dB	0 dB	Pass
			Sens.std at 4.0MHz	0.37 dB	0.43 dB	0.06 dB	Pass
			TOF	3.75 ns	5.31 ns	1.56 ns	Pass
			Dead element	0	0	0	Pass
		Cosmetic Inspection		No defect	bubbles on the lens surface	-	Fail
		Final decision		Fail			

SIEMENS Healthineers

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
14L5	21010221	Hipot test		0.152 mA	0.175 mA	-	Pass
		Leakage test		10.272 uA	10.885 uA	-	Pass
		Probe element test	Sens.std at 8.5MHz	0.44 dB	1.1 dB	0.66 dB	Pass
			Sens.std at 10.5MHz	0.54 dB	1.15 dB	0.61 dB	Pass
			Sens.std at 6.0MHz	0.49 dB	0.55 dB	0.06 dB	Pass
			TOF	2.88 ns	5.63 ns	2.75 ns	Pass
			Dead element	0	0	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
18L6	21080257	Hipot test		0.213 mA	0.248 mA	-	Pass
		Leakage test		13.114 uA	15.001 uA	-	Pass
		Probe element test	Sens.std at 10.0MHz	0.64 dB	0.64 dB	0 dB	Pass
			Sens.std at 12.0MHz	0.63 dB	0.66 dB	0.03 dB	Pass
			Sens.std at 8.0MHz	0.59 dB	0.66 dB	0.07 dB	Pass
			TOF	3.31 ns	6.79 ns	3.48 ns	Pass
			Dead element	1	1	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
4Z1c	20130044	Hipot test		0.363 mA	0.385 mA	-	Pass
		Leakage test		24.854 uA	26.332 uA	-	Fail
		Probe element test	Sens.std at 1.2MHz	0.19 V/V	0.22 V/V	1.273381597 dB	Pass
			Sens.std at 3.0MHz	0.15 V/V	0.17 V/V	1.087153246 dB	Pass
			TOF	9.7 ns	9.5 ns	0.2 ns	Pass
			Dead element	20	20	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass
		Final decision		Fail, 4Z1c failed the leakage test, but this sample already had a high result of leakage test before test. So we have to do retest with good condition sample.			

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
8C3HD	21070497	Hipot test		0.253 mA	0.313 mA	-	Pass
		Leakage test		15.898 uA	18.920 uA	-	Pass
		Probe element test	Sens.std at 6.0MHz	0.58 dB	0.59 dB	0.01 dB	Pass
			Sens.std at 3.5MHz	0.41 dB	0.44 dB	0.03 dB	Pass
			Sens.std at 8.0MHz	0.59 dB	0.6 dB	0.01 dB	Pass
			TOF	4.55 ns	3.97 ns	0.58 ns	Pass
			Dead element	0	0	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass

SIEMENS Healthineers

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
14L5SP	21080039	Hipot test		0.142 mA	0.172 mA	-	Pass
		Leakage test		8.759 uA	9.874 uA	-	Pass
		Probe element test	Sens.std at 8.5MHz	0.45 dB	0.59 dB	0.14 dB	Pass
			Sens.std at 10.5MHz	0.56 dB	0.73 dB	0.17 dB	Pass
			Sens.std at 6.0MHz	0.46 dB	0.51 dB	0.05 dB	Pass
			TOF	7.01 ns	3.77 ns	3.24 ns	Pass
			Dead element	0	0	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass

XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
10MC3	20060694	Hipot test		0.227 mA	0.208 mA	-	Pass
		Leakage test		14.126 uA	13.753 uA	-	Pass
		Probe element test	Sens.std at 6.5MHz	0.4 dB	0.59 dB	0.19 dB	Pass
			Sens.std at 5.0MHz	0.4 dB	0.7 dB	0.3 dB	Pass
			Sens.std at 8.0MHz	0.68 dB	1.34 dB	0.66 dB	Pass
			TOF	6.4 ns	8.77 ns	2.37 ns	Pass
			Dead element	0	0	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass

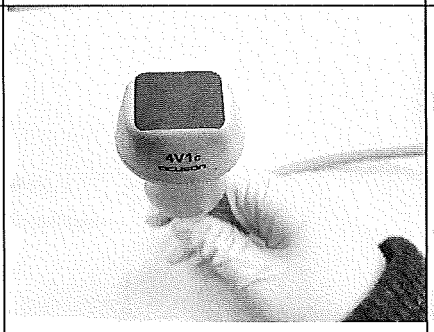
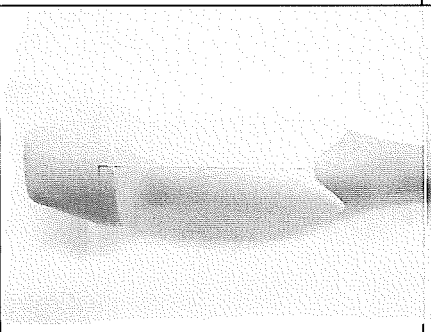
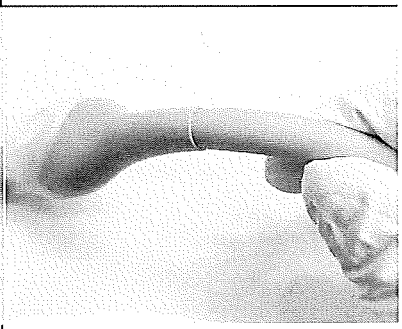
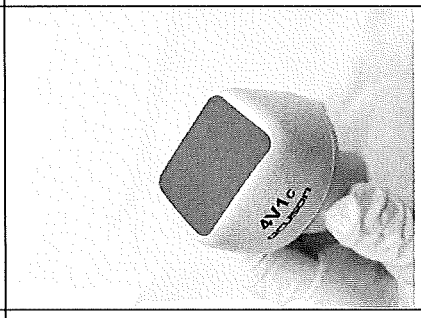
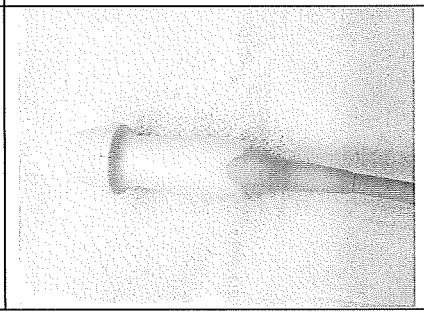
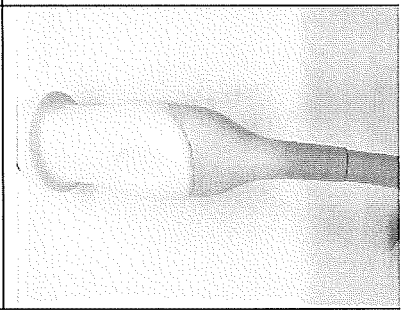
XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
EC9-4	20220122	Hipot test		0.233 mA	0.222 mA	-	Pass
		Leakage test		14.420 uA	14.013 uA	-	Pass
		Probe element test	Sens.std at 6.5MHz	0.73 dB	0.49 dB	0.24 dB	Pass
			Sens.std at 4.0MHz	0.66 dB	0.54 dB	0.12 dB	Pass
			Sens.std at 8.0MHz	0.9 dB	0.59 dB	0.31 dB	Pass
			TOF	5.87 ns	5.43 ns	0.44 ns	Pass
			Dead element	0	0	0	Pass
		Cosmetic Inspection		No defect	No defect	-	Pass

XDCR name	XDCR S/N	Section			Before soaking	After soaking	Diff(After-Before)	Result
V5Ms	21060007	Hipot test			3.97 mA	4.96 mA	-	Pass
		Leakage test			247.362 uA	298.852 uA	-	Pass
		Probe element test	Sens Stdev at 0 deg	at 7MHz	1 dB	0.8 dB	0.2 dB	Pass
				at 5MHz	0.97 dB	0.9 dB	0.07 dB	Pass
				at 3.5MHz	1.44 dB	1.2 dB	0.24 dB	Pass
			TOF		3.6 nS	3.6 nS	0.0 ns	Pass
			Dead element		0	0	0	Pass
		Cosmetic Inspection			No defect	No defect	-	Pass

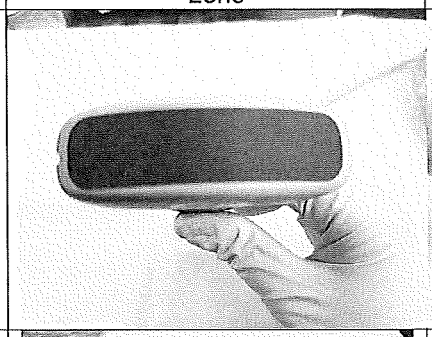
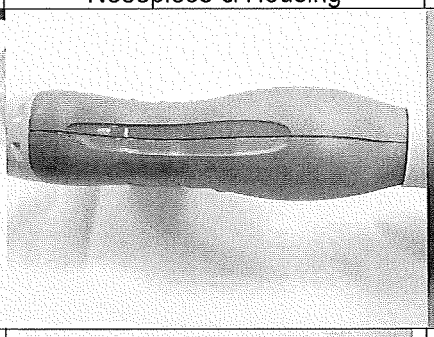
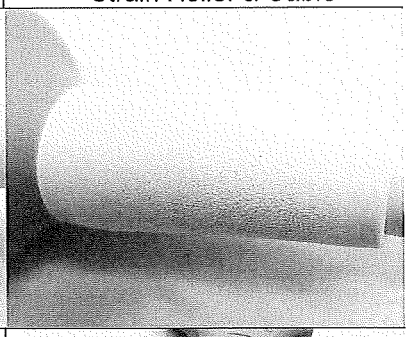
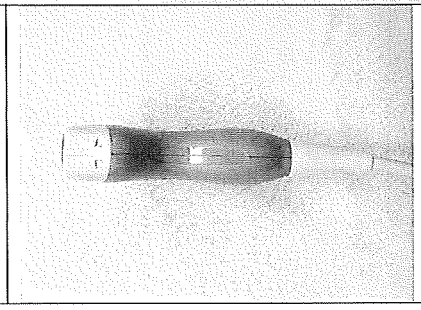
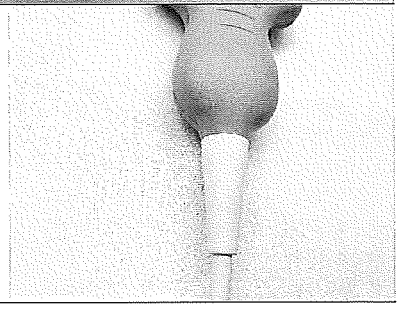
SIEMENS Healthineers

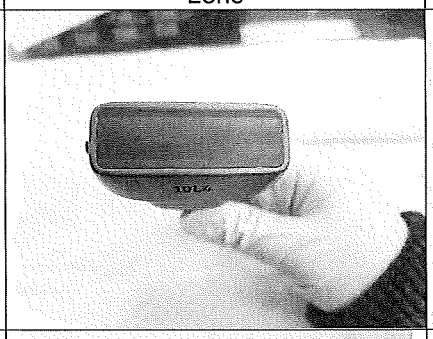
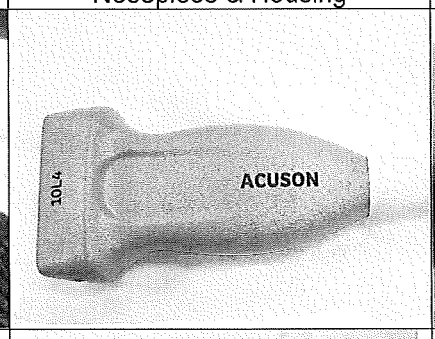
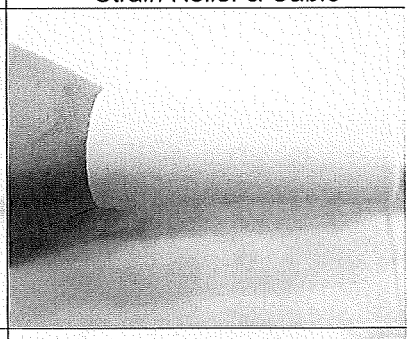
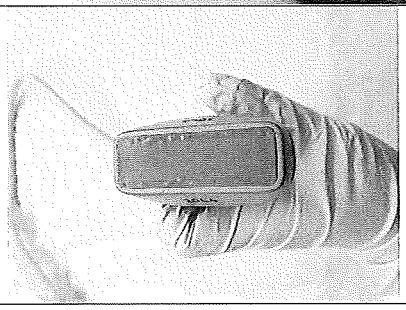
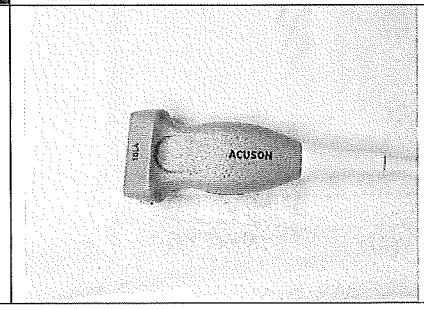
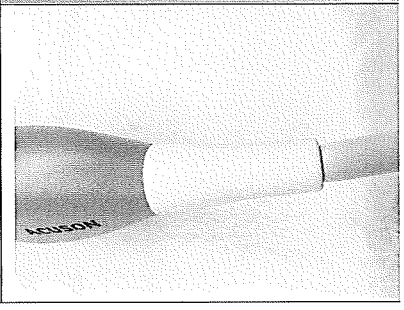
XDCR name	XDCR S/N	Section		Before soaking	After soaking	Diff(After-Before)	Result
Z6Ms	83534016	Hipot test		4.49 mA	4.5 mA	-	Pass
		Leakage test		276.431 uA	274.966 uA	-	Pass
		Probe element test	Sensitivity Stdevat 3MHz	0.17 V/V	0.18 V/V	0.496471675 dB	Pass
			Sensitivity Stdevat 5MHz	0.15 V/V	0.16 V/V	0.560574472 dB	Pass
			Sensitivity Stdevat 6MHz	0.11 V/V	0.12 V/V	0.755771218 dB	Pass
			TOF	8.6 ns	8.2 ns	0.4 ns	Pass
			Dead element	6	40	34	Fail
		Cosmetic Inspection		No defect	No defect	-	Pass
		Final decision		Fail			

■ Cosmetic inspection

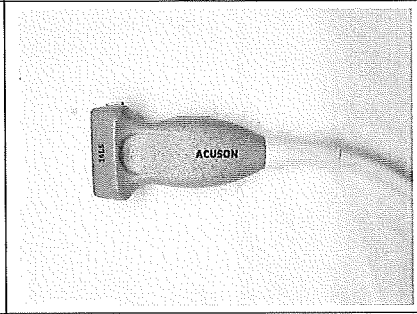
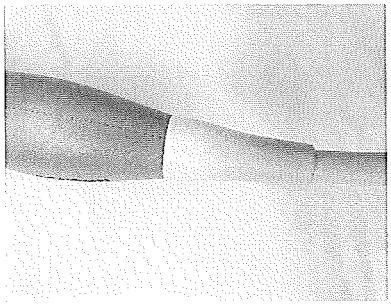
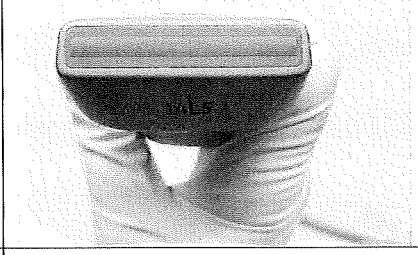
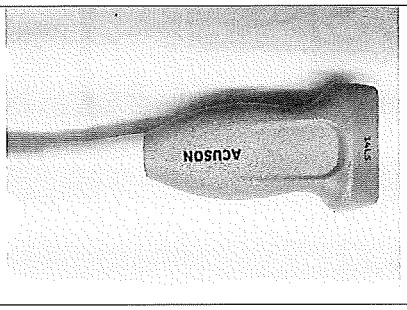
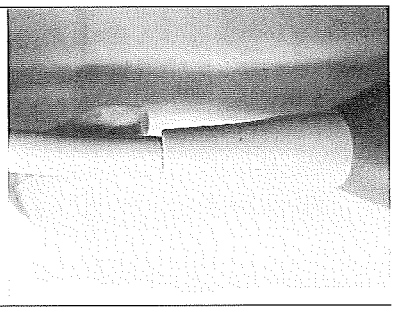
XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
4V1c	Before			
	After			
Result		No defect		

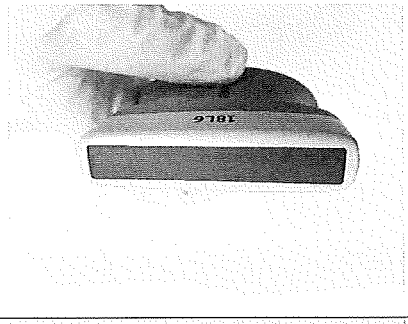
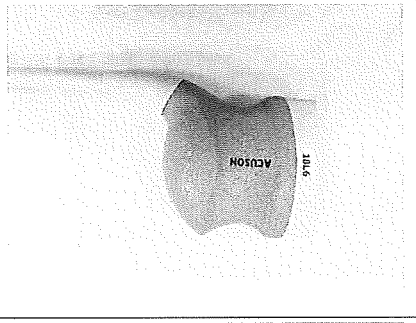
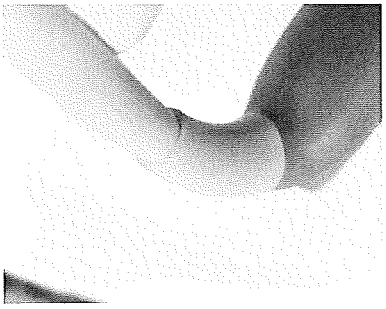
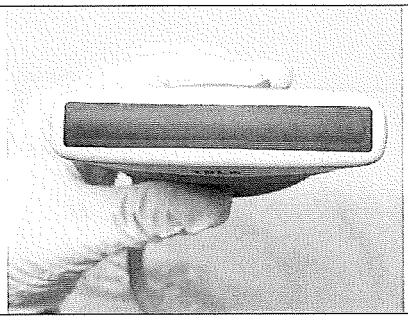
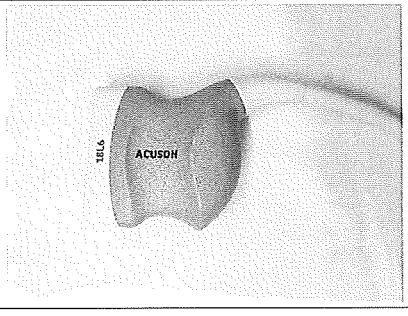
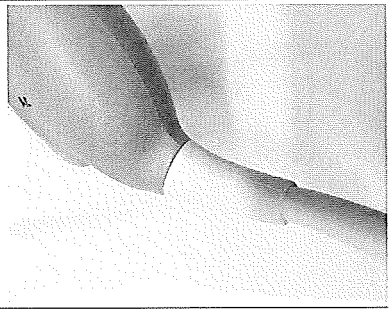
SIEMENS Healthineers

XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
5C1	Before			
	After			
Result		No defect		

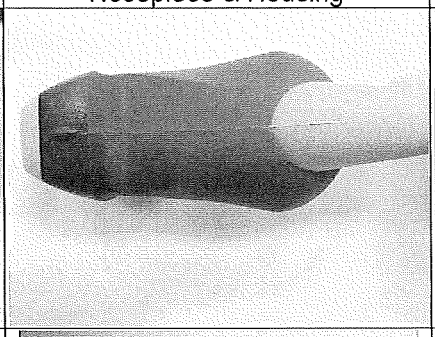
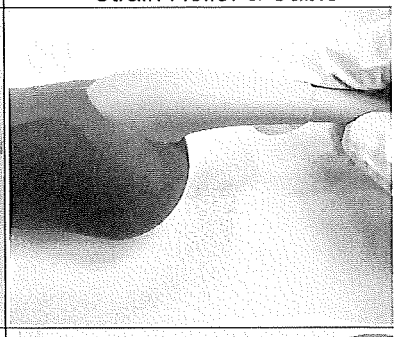
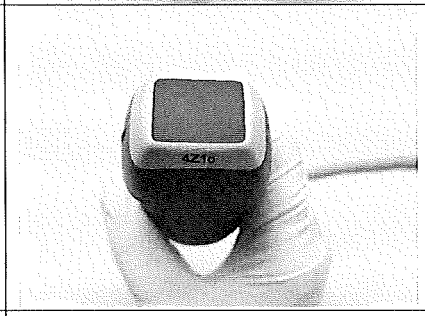
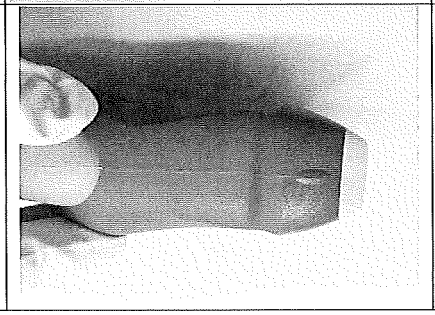
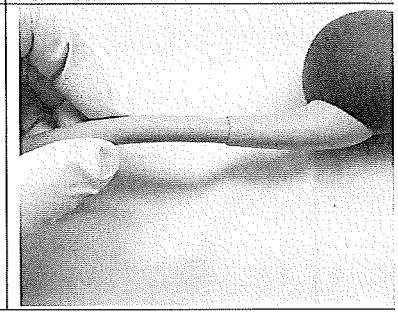
XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
10L4	Before			
	After			
Result		Some bubbles come up on the lens surface.		

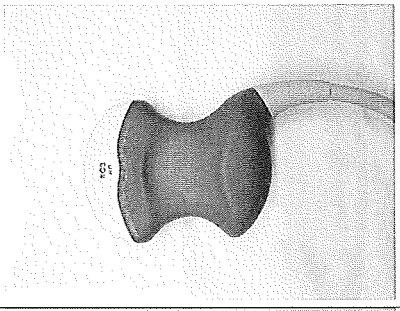
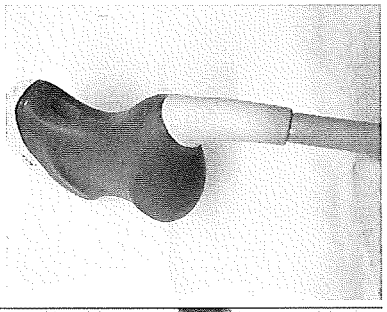
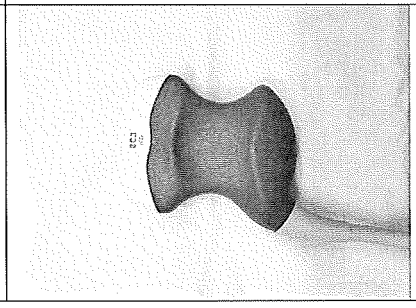
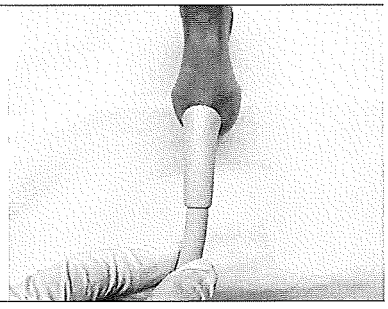
SIEMENS Healthineers

XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
14L5	Before			
	After			
Result		No defect		

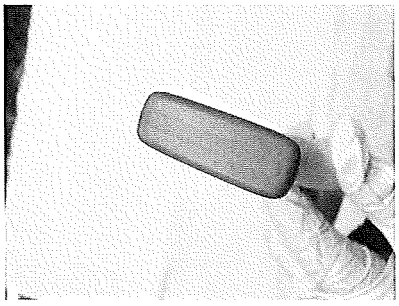
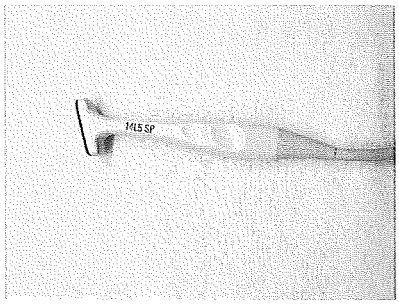
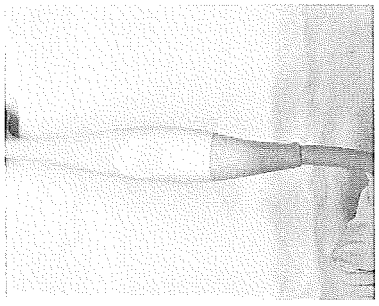
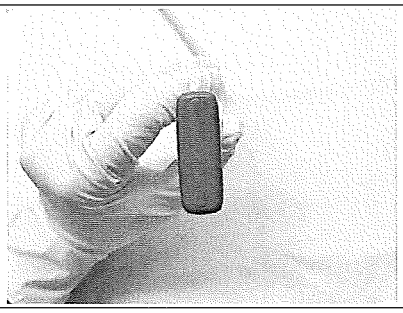
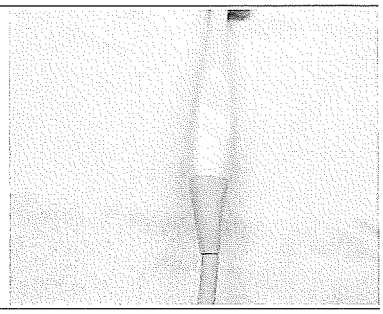
XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
18L6	Before			
	After			
Result		No defect		

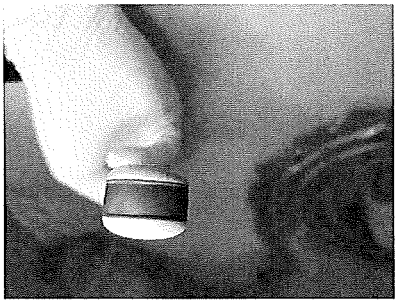
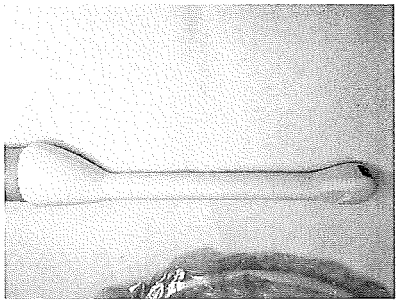
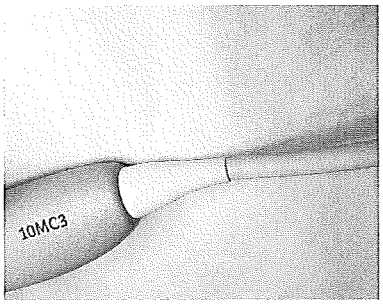
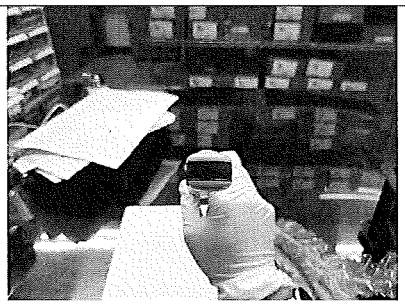
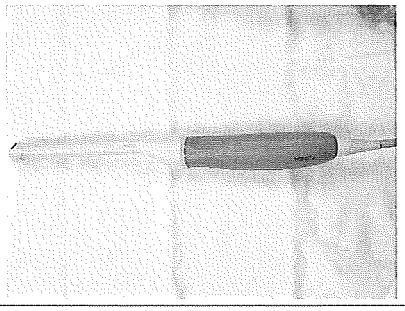
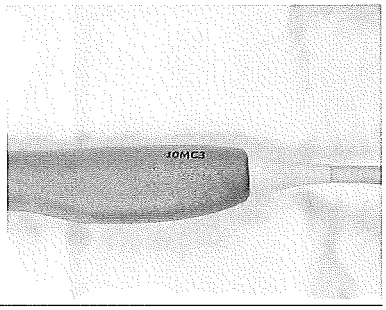
SIEMENS Healthineers

XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
4Z1c	Before			
	After			
Result		No defect		

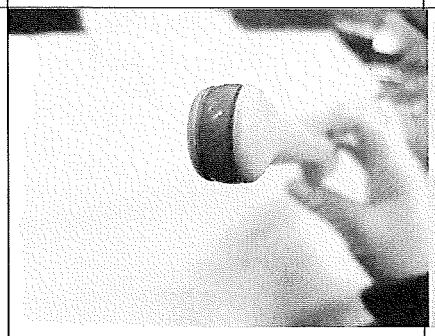
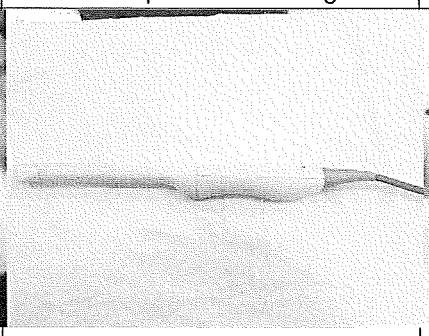
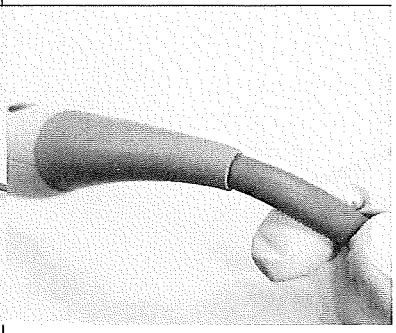
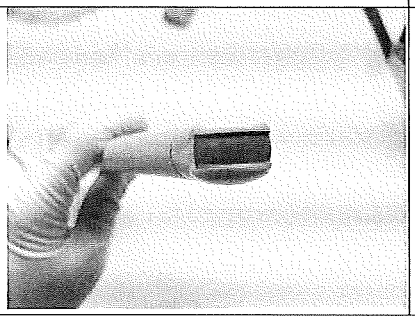
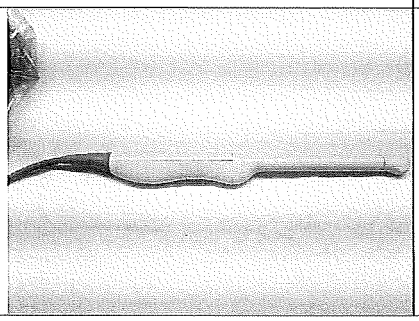
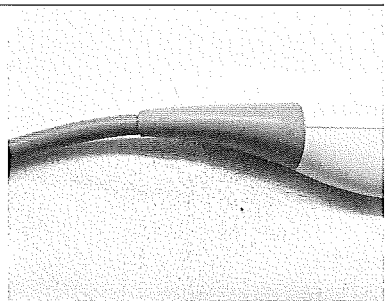
XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
8C3HD	Before			
	After			
Result		No defect		

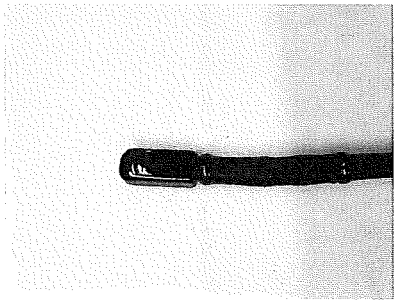
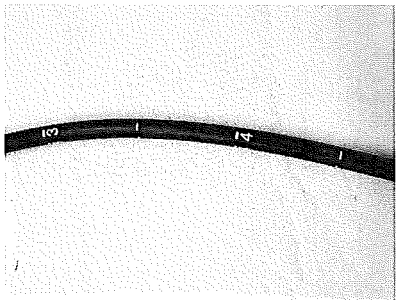
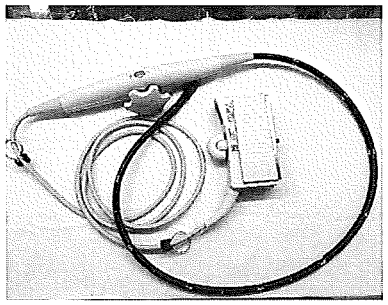
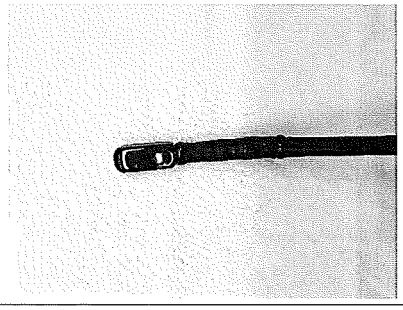
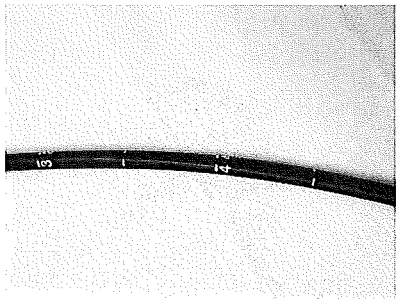
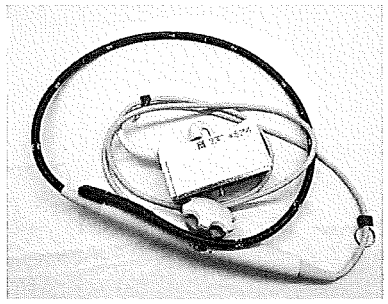
SIEMENS Healthineers

XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
14L5SP	Before			
	After			
Result		No defect		

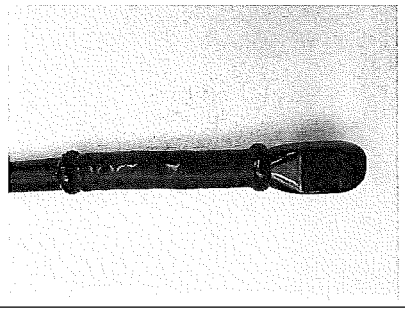
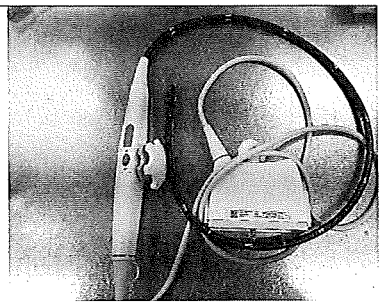
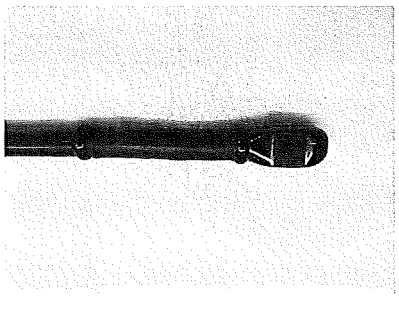
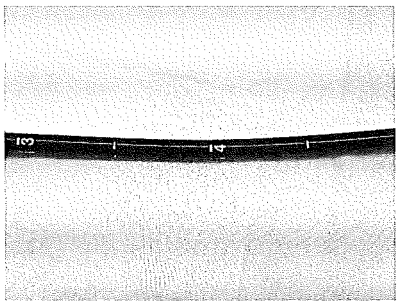
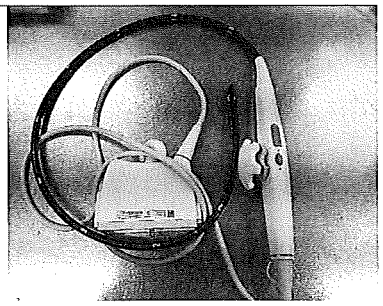
XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
10MC3	Before			
	After			
Result		No defect		

SIEMENS Healthineers

XDCR	Test	Lens	Nosepiece & Housing	Strain Relief & Cable
EC9-4	Before			
	After			
Result		No defect		

XDCR	Test	Lens & Articulation	Guide tube	Overall
V5Ms	Before			
	After			
Result		No defect		

SIEMENS Healthineers

XDCR	Test	Lens & Articulation	Guide tube	Overall
Z6MS	Before			
	After			
Result		No defect		

■ Conclusion:

As this result, Perform is approved to use on 4V1c, 5C1, 14L5, 18L6, 8C3HD, 14L5SP, EC9-4, 10MC3 and V5Ms. Moreover, Each transducers in transducer groups of A2, A3, A5, A6, A9, S1, E1, E2 and T3 can also be used in this disinfectant wipes. 10L4, 4Z1c and Z6Ms are not compatible with these disinfectants. These results will be updated in Transducer Disinfectant Compatibility Matrix (P/N 11335653).

■ Test Procedure

1) Test protocol: Transducer Disinfectant Qualification Process (P/N 5931980)

5.2.1 Liquid Extended Exposure Protocol (soak transducers for 168 hours at 30℃)

2) Pass/Fail Criteria: Transducer Disinfectant Qualification Process (P/N 5931980)

In order for a disinfectant to be qualified for use with a particular transducer group, the long-term soak and cyclic disinfection exposures:

1) Must not cause the test transducer to fail hipot or leakage current tests.

2) Must not cause the relative sensitivity standard deviation to increase by more than 2 dB (array transducers only).

3) Must not cause the time of flight (TOF) standard deviation to increase by more than 5nS (array transducers only).

4) Must not cause a significant increase in the number of dead elements, as judged by engineering (single or small groups of dead elements may be due to other causes).

5) Must not cause mechanical degradation related to transducer performance in the form of cracking, micro-crazing, swelling, corrosion, separation on all the surfaces that cleaner/disinfectant

SIEMENS Healthineers

contacted.

6) May occur discoloration of acoustic lens or other materials as this is not related to transducer performance.

Since only safety tests and visual inspection are performed on mechanical and CW transducers, these must be inspected with particular care for signs of physical deterioration.

If a transducer fails any of the above criteria, it will be inspected by Engineering to determine the cause of failure. If the failure appears to be related to a manufacturing defect, or other issue not caused by the disinfection exposure, a second transducer of the same type will be tested to confirm the result.

■ 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

■ Attachment

1) Technical data sheet of Perform


2020.08.14 MSDS perform.pdf


Perform Info.pdf


AW_ Introductions and more help ne

2) Test results

XDCR name	XDCR S/N	Test	Probe acoustic Test	Hipot & Leakage Test
4V1c	20160450	Pre-test	x2ng4.impulse.analysis.production.pol x2ng4.impulse.evaluation.production.post_c	SCM FAO-01 Station.Engineerin
		Post-test	x2ng4.impulse.analysis.development.pl x2ng4.impulse.evaluation.development.post	SCM FAO-01 Station.Engineerin
5C1	20220296	Pre-test	x2ng4.impulse.analysis.production.pol x2ng4.impulse.evaluation.production.post_c	SCM FAO-01 Station.Engineerin
		Post-test	x2ng4.impulse.analysis.development.pl x2ng4.impulse.evaluation.development.post	SCM FAO-01 Station.Engineerin
10L4	20210535	Pre-test	x2ng5.impulse.analysis.development.pl x2ng5.impulse.evaluation.development.post	SCM FAO-01 Station.Engineerin

SIEMENS Healthineers

		Post-test	x2ng5.impulse.ana lysis.development.pl.development.post x2ng5.impulse.eva	SCM FAO-01 Station.Engineerin
14L5	21010221	Pre-test	x2ng5.impulse.ana lysis.production.pol.production.post_c x2ng5.impulse.eva	SCM FAO-01 Station.Production
		Post-test	x2ng5.impulse.ana lysis.development.pl.development.post x2ng5.impulse.eva	SCM FAO-01 Station.Engineerin
18L6	21080257	Pre-test	x2ng5.impulse.ana lysis.production.pol.production.post_c x2ng5.impulse.eva	SCM FAO-01 Station.Production
		Post-test	x2ng5.impulse.ana lysis.development.pl.development.post x2ng5.impulse.eva	SCM FAO-01 Station.Production
4Z1c	20130044	Pre-test	PE test_4Z1c Perform Before_21	Hipot&Leakage test_4Z1c Perform
		Post-test	PE test_4Z1c Perform After_210	SCM FAO-01 Station.Production
8C3HD	21070497	Pre-test	x2ng5.impulse.ana lysis.production.pol.production.post_c x2ng5.impulse.eva	SCM FAO-01 Station.Production
		Post-test	x2ng5.impulse.ana lysis.development.pl.development.post x2ng5.impulse.eva	SCM FAO-01 Station.Production
14L5SP	21080039	Pre-test	x2ng5.impulse.ana lysis.production.pol.production.post_c x2ng5.impulse.eva	SCM FAO-01 Station.Production
		Post-test	x2ng5.impulse.ana lysis.development.pl.development.post x2ng5.impulse.eva	SCM FAO-01 Station.Production
10MC3	20060694	Pre-test	x2ng4.impulse.analysi s.production.post_cab x2ng4.impulse.eval.pr oduction.post_cable.1	SCM FAO-01 Station.Production.FA

SIEMENS Healthineers

		Post-test	x2ng4.impulse.analysis.development.post_c x2ng4.impulse.eval.development.post_cabl	SCM FAO-01 Station.Engineering.FA
EC9-4	20220122	Pre-test	x2ng4.impulse.analysis.production.pol x2ng4.impulse.evaluation.production.post_c	SCM FAO-01 Station.Engineerin
		Post-test	x2ng4.impulse.analysis.development.pl x2ng4.impulse.evaluation.development.post	SCM FAO-01 Station.Engineerin
V5Ms	21060007	Pre-test	xdcrii2.impulse.analysis.production.pl xdcrii2.impulse.evaluation.production.pre_ca	SCM TEE-01 Station.Production
		Post-test	xdcrii2 V5Ms 210308 SN2106007	SCM TEE-01 Station.Engineerin
Z6Ms	83534016	Pre-test	PE test_Z6Ms (SN 83534016).pdf	Hipot&leakage test_Z6Ms (SN 865
		Post-test	sc2000.trb200.mix=1.prod.pn=10436	SCM TEE-01 Station.Production