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Test Report

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Date : **Nov 24th, 2016**

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Title: Probes update including Humanscan C5-2v and L10-5 on NX2 & NX2 Elite system

■ Executive Summary:

NX2 system and NX2 Elite system has been launched and supports existing transducers such as P4-2, CH5-2, VF10-5, EC9-4, CW2, CW5 and C8F3 and also new transducers such as C5-2v and L10-5v. All these transducers will be listed in the Transducer Disinfectant Compatibility Matrix. As adding new transducers, C5-2v and L10-5v, compatibility testing has been performed by Humanscan with some field-most-popular cleaners & disinfectants.

This memo will be a justification to update compatible disinfectants in the Transducer Disinfectant Compatibility Matrix.

■ Probe and compatible disinfectants information:

1. Probes available to use on NX2/ NX2 Elite

XDCR	Manufacturer	P/N	System	
P4-2	Siemens	10789385	NX2 Elite	NX2
CH5-2	Siemens	10789386	NX2 Elite	NX2
VF10-5	Siemens	10789387	NX2 Elite	NX2
EC9-4	Siemens	10789383	NX2 Elite	NX2
CW2	STI	10789380	NX2 Elite	-
CW5	STI	10789381	NX2 Elite	-
C8F3	STI	10786652	NX2 Elite	NX2
C5-2v	Humanscan	11284925	NX2 Elite	NX2
L10-5v	Humanscan	11284926	NX2 Elite	NX2

NX2	Pricebook P/N[1]	PROBE MODEL
X	11284925	C5-2v
X	10786652	C8F3
X	8648086/ 10789386	CH5-2
X	8648029/ 10030334/ 10789383	EC9-4
X	11284926	L10-5v
X	8648045/ 10033670/ 10789385	P4-2
X	8648110/ 10789387	VF10-5

NX2 Elite	Pricebook P/N[1]	PROBE MODEL
X	11284925	C5-2v
X	10786652	C8F3
X	8648086/ 10789386	CH5-2
X	7472744 / 10041655/ 10789380	CW2
X	7472777 / 10041656/ 10789381	CW5
X	8648029 / 10030334/ 10789383	EC9-4
X	11284926	L10-5v
X	8648045 / 10033670/ 10789385	P4-2
X	8648110/ 10789387	VF10-5

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2. Approved Lists of Cleaners/ Disinfectants

Approved disinfectants for each transducer on NX2/ NX2 Elite system.

Approved List of Cleaners

Note: Gigasept FF may discolor the transducer. There is no associated degradation of imaging performance or transducer reliability. You can use Gigasept FF as a cleaner and a disinfectant.

	ENZOL	Gigasept FF	Transeptic
C5-2v	✓~~NA~~	NA	✓
CH5-2	✓	✓	✓
C8F3	NA	NA	NA
L10-5v	✓~~NA~~	NA	✓
VF10-5	✓	NA	✓
EC9-4	NA	✓	✓
P4-2	✓	✓	✓
CW2	✓	✓	✓
CW5	✓	✓	✓

✓ = compatible
NC = not compatible
NA = not applicable (not tested)

Approved List of Disinfectants

Note: Cidex OPA and Gigasept FF may discolor the transducer. There is no associated degradation of imaging performance or transducer reliability. You can use Gigasept FF as a cleaner and a disinfectant.

	CIDEX	CIDEX PLUS	CIDEX OPA	Gigasept FF	Milton	PI-Spray II	Rely+On Virkon	Revital-Ox RESERT HLD	Super Sani-Cloth
C5-2v	✓~~NA~~	✓~~NA~~	✓~~NA~~	NA	NA	✓	✓~~NA~~	✓~~NA~~	✓
CH5-2	✓	✓	✓	✓	✓	✓	✓	✓	✓
C8F3	✓	✓	✓	NA	NA	✓	NA	NA	NA
L10-5v	✓~~NA~~	✓~~NA~~	✓~~NA~~	NA	NA	✓	✓~~NA~~	✓~~NA~~	✓
VF10-5	✓	✓	✓	NA	NA	✓	NA	NA~~✓~~	✓
EC9-4	✓	✓	✓	✓	✓	✓	✓	✓	✓
P4-2	✓	✓	✓	✓	✓	✓	✓	✓	✓
CW2	✓	✓	✓	✓	✓	✓	✓	NA	✓
CW5	✓	✓	✓	✓	✓	✓	✓	NA	✓

✓ = compatible
NC = not compatible
NA = not applicable (not tested)

Figure 6. Approved List of Disinfectants.

■ Humanscan C5-2v, L10-5v compatibility test

1) Material Matrix

C5-2v and L10-5v use the same material on transducer outer components. Compatibility test results with disinfectants will be the same each other. In this test,

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[3CE-C00(C5-2v) Probe MATERIAL MATRIX]

	Probe Module				Cable Assembly					
Object/part or Description	Transducer Nosepiece Plastic (*)	Lens Material (*)	Transducer Housing Adhesive	Cable Jacket to strain relief Adhesive scanhead and pod	Transducer case (Housing)	Strain Relief, Transducer	Cable Jacket	Strain Relief, Pod	Pod Knob	Pod Housing
Technical Data	Poly Phenylsulfone , Min 1.20mm thick	RTV Silicone , Min 0.390mm thick	EPOXY , Min 0.02mm thick	Cyclohexanone	Poly Phenylsulfone , Min 0.75mm thick	PVC , Min 1.44mm thick	PVC , Min 0.8mm thick	PVC , Min 0.75mm thick	ABS/PC , Min 1.2mm thick	Die Cast Aluminum Alloy , Min 1.2mm thick
Manufacturer	LG Chem	MOMENTIVE	3M	Junsei	LG Chem	TSC	SUMITOMO	TSC	SABIC	Custom Alloy Sales/Light Metals, Inc
Part Number (type/model)	ABS LG704W	RTV 664, A and B	DP420	020116	ABS LG704W	TWS-8050	TYPE4	TWS-8050	CYCOLOY C1110HF	A380
Flammability	UL94	N/A	N/A	N/A	UL94	N/A	N/A	N/A	N/A	N/A
UL File Number	E67171v	N/A	N/A	N/A	E67171v	N/A	N/A	N/A	N/A	N/A

*** "(*)" is patient or operator contact materials*

[8LE-C00(L10-5v) Probe MATERIAL MATRIX]

	Probe Module				Cable Assembly					
Object/part or Description	Transducer Nosepiece Plastic (*)	Lens Material (*)	Transducer Housing Adhesive	Cable Jacket to strain relief Adhesive scanhead and pod	Transducer case (Housing)	Strain Relief, Transducer	Cable Jacket	Strain Relief, Pod	Pod Knob	Pod Housing
Technical Data	Poly Phenylsulfone , Min 1.20mm thick	RTV Silicone , Min 0.380mm thick	EPOXY , Min 0.02mm thick	Cyclohexanone	Poly Phenylsulfone , Min 0.75mm thick	PVC , Min 1.44mm thick	PVC , Min 0.8mm thick	PVC , Min 0.75mm thick	ABS/PC , Min 1.2mm thick	Die Cast Aluminum Alloy , Min 1.2mm thick
Manufacturer	LG Chem	MOMENTIVE	3M	Junsei	LG Chem	TSC	SUMITOMO	TSC	SABIC	Custom Alloy Sales/Light Metals, Inc
Part Number (type/model)	ABS LG704W	RTV 664, A and B	DP420	020116	ABS LG704W	TWS-8050	TYPE4	TWS-8050	CYCOLOY C1110HF	A380
Flammability	UL94	N/A	N/A	N/A	UL94	N/A	N/A	N/A	N/A	N/A
UL File Number	E67171v	N/A	N/A	N/A	E67171v	N/A	N/A	N/A	N/A	N/A

*** "(*)" is patient or operator contact materials*

2) Disinfectant

Below disinfectants were tested with each transducer.

P/N	S/N	Chemical
C5-2v	EC8-015003	Super Sani Cloth
L10-5v	EL15-015002	Sani Cloth HB
L10-5v	EL15-015011	Transeptic
L10-5v	EL15-015014	PI Spray II
C5-2v	EC8-016018	Cidex OPA
C5-2v	EC8-015017	Virkon
C5-2v	EC8-015013	Revital-Ox Resert XL HLD
C5-2v	EC8-015003	Anioxyde 1000
L10-5v	EL15-015002	Enzol
C5-2v	EC8-016015	Cidex
L10-5v	EL15-016009	Cidex Plus

3) Scope

- Verification test criteria : Materials Requirement of GTRS (P/N 7297265)
- Test procedure : Transducer Disinfectant Qualification Protocol (P/N 5931980)

- Pass/Fail Criteria: Followed Transducer Disinfectant Qualification Protocol (P/N 5931980) except TOF deviation check.

4) Test Result

Refer to the attached test report from Humanscan Co., Ltd. All tested cleaners and disinfectants on C5-2v and L10-5v are compatible.

■ Test Procedure

: refer to the Transducer Disinfectant Qualification Protocol (P/N 5931980)

Long-Term disinfectant test can be divided into two kinds of soaking test. One is a High-level disinfectant soaking for 500 hours at room temperature in each High-Level disinfectant. The other is a Pre-cleaner soaking for 7 days at room temperature in a relevant Pre-Cleaner. Finally, the probe would be inspected by test criteria, and then compared with pre and post-test result.

1) Long-Term Soak Test Procedure :

Please refer to the long-term soaking test procedure in the Long Term Soak Protocol of Transducer Disinfectant Qualification Protocol (P/N 5931980) for specific procedure.

- High-level disinfectants

Pre test before soaking (Acoustic, Hipot/Leakage, Cosmetic inspection) → soak or wrap or spray the the transducer into relevant High-Level disinfectant → leave it at room temperature for 500hours → after soaking, then rinse and Post test

- Pre-Cleaners

Pre test before soaking (Acoustic, Hipot/Leakage, Cosmetic inspection) → soak or wrap or spray the transducer into the relevant Pre-Cleaner → leave it at room temperature for one day and clean it and dry→ Repeat it for 7days → Post test

2) Pass/Fail Criteria from Transducer Disinfectant Qualification Protocol (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:

- ☞ Must not cause the test transducer to fail Hipot or leakage current tests.
- ☞ Must not cause the relative sensitivity standard deviation to increase by more than 2 dB (array transducers only).
- ☞ Must not cause the time of flight (TOF) standard deviation to increase by more than 5nS (array transducers only).
- ☞ 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).
- ☞ Must not cause mechanical degradation in the form of cracking, micro-crazing, swelling, change of lens color or significant fading of printing on the housing.
- ☞ Must not cause separation of the acoustic lens from the housing.

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 at any of the post-soak tests, it will be inspected by Engineering to determine the cause of failure. If considered necessary, a second transducer of the same type will be tested to confirm the result.

■ Conclusion:

NX2 system and NX2 Elite system will be updated with P4-2, CH5-2, VF10-5, EC9-4,

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CW2, CW5, C8F3, C5-2v and L10-5v.

- **Attachment:**
  Verification report for disinfectants with C5-2v and L10-5v by Humanscan

502160_R01_Verifi
cation Report for d