Siemens Healthineers Ltd.

Confidential

No. ZT07S-S1059
Jul.20, 2022
NIHON DEMPA KOGYO CO.,LTD.
PRODUCTION DEPT. 3
ULTRASONIC PROBE DEVELOPMENT SECT.
MANAGER Yasunobu Hasegawa
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Report on business requirements

Your Spec No. 11575443
NDK Model No. T01771
NDK Spec No. ZT07S-012

1 Objective
Verify business requirements.

2 Verification details

TVP Tag	TPRS Tag	Specification	Test Definition	Sample Size	Verification Method	Criterion
11.0.1	3.9.1.1-1	Sani-Cloth AF3	Duration: 168 hours at 20 ºC (At room temperature)	n=1	Safety Appearance	1)Transducer shall pass safety testing of Hipot and Leakage Current Tests. Hipot (4 000 V [AC rms] / 50 Hz 60 seconds) : ≤ 2 mA Leakage Current (264 V [AC rms] / 60 Hz) : ≤ 0.05 mA 2)Mechanical damage to the plastic housing such as cracking etc.
	3.9.1.1-2	Super-Cloth HB	Duration: 168 hours at 20 ºC	n=1		
	3.9.1.1-3	Super Sani-Cloth	Duration: 168 hours at 20 ºC (At room temperature)	n=1		
	3.9.1.1-4	Enzol	Duration: 168 hours at 20 ºC (At room temperature)	n=1		
	3.9.1.1-5	Transeptic	Duration: 168 hours at 20 ºC (At room temperature)	n=1		
	3.9.1.1-6	Metrricide	Duration: 500 hours at 20 ºC (At room temperature)	n=1		
	3.9.1.1-7	Dis OPA	Duration: 500 hours at 20 ºC (At room temperature)	n=1		
	3.9.1.1-8	Gigasept FF (new)	Duration: 500 hours at 20 ºC or 336 hours at 31 ºC Submersion Level : Past the strain relief	n=1		
	3.9.1.1-9	Disinfectant : Trophon EPR	Total Cycle: 4,000 cycles	n=1		
	3.9.1.1-10	RESERT OX HLD	Duration: 168 hours at 30 ºC (At room temperature)	n=1		
	3.9.1.1-11	Metrricide	Temperature : Room temperature (approx. 20 ºC) Total Cycle : 20 cycles Soaking Time : 1 hour per one cycle	n=1		
	3.9.1.1-12	Dis OPA	Temperature : Room temperature (approx. 20 ºC) Total Cycle : 20 cycles Soaking Time : 1 hour per one cycle	n=1		
	3.9.1.1-13	Gigasept FF (new)	Temperature : Room temperature (approx. 20 ºC) Total Cycle : 20 cycles Soaking Time : 1 hour per one cycle	n=1		
	3.9.1.1-14	RESERT OX HLD	Temperature : Room temperature (approx. 20 ºC) Total Cycle : 20 cycles Soaking Time : 1 hour per one cycle	n=1		
	3.9.2.1	Temperature Cycle	Temperature : -10 ~ 60℃ Humidity : - Cycle : 20 Cycle Dwell time : 1 hour Ramp up time : - Ramp down Time : - Package : - Operation : -	n=3	Electrical characteristics Safety Appearance	1)No mechanical damage to the plastic housing such as cracking etc. 2)Average value of sensitivity :difference before and after the test ±30%(＋2.27dB/-3.09dB) 3)Hipot (4 000 V [AC rms] / 50 Hz 60 seconds) : ≤ 2 mA
	3.9.2.2	WHTOL (Wet High Temperature Operating life Test)	Temperature : 60℃ Humidity : 90%RH Cycle : N/A Dwell time : 168 hour Ramp up time : 50 min Ramp down Time : 50min Package : Unpacked Operation : Operation	n=3		
	3.9.2.3	ISTA 2A	Test Sequence 1) Pre-Humidity 2) Compression 3) 1st Vibration 4) Drop 5) 2nd Vibration Package : Packed Operation : non-Operation	n=3		

2 Verification details

TVP Tag	TPRS Tag	Specification	Test Definition	Sample Size	Verification Method	Criterion
11.0.1	3.9.2.4	RDT (Reliability Demonstration Test)	The Transducer population shall have a Reliability of at least 80% @ 80% Confidence Interval over 1,200 hours of operation @ 25 °C ambient	n=1	Electrical characteristics Safety Appearance	1)No mechanical damage to the plastic housing such as cracking etc. 2)Average value of sensitivity :difference before and after the test ±30%(＋2.27dB/-3.09dB) 3)Hipot (4 000 V [AC rms] / 50 Hz 60 seconds) : ≤ 2 mA
	3.9.2.5	4HT (High Heat High Humidity Test)	Temperature : 60℃ Humidity : 95%RH Cycle : N/A Dwell time : 250 hour Ramp up time : 50 min Ramp down Time : 50min Package : Unpacked Operation : Non-Operation	n=3		
	3.9.2.6	OTHC (Operating Temperature & Humidity Cycle)	Temperature : +20 ~ +40℃ Humidity : 15 ～ 80% RH Cycle : 10 cycle Dwell time : 1 hour Ramp up time : 50 min Ramp down time : 50 min Package : Unpacked Operation : Operation	n=3		
	3.9.2.7	STHC (Storage Temperature & Humidity Cycle)	Temperature: -40 ~ +60°C and then +10 to +60°C →-10 ~ +60°C and then +10 to +60°C Humidity: 10 % RH / 95 % RH Number of Cycles: Minimum of 4 cycles at each set of below Conditions* Dwell time: 1 hour Ramp up time: 50 min Ramp down time: 50 min Packaged: Packed Operation: Non-operating * conditions: (A) 10°C to 60°C at 95% RH & (B) -40°C to 60°C at 10% RH	n=3		
	3.9.2.8	Atmospheric Pressure	Up to 10,000 ft : Operating 10,000~36,000 ft : Non-Operating Package : Unpacked Operation : Operation and Non-Operation	n=3	Safety Appearance	No mechanical damage to the plastic housing such as cracking etc. Hipot (4 000 V [AC rms] / 50 Hz 60 seconds) : ≤ 2 mA
	3.9.2.9	Drop Test	Height : 1.22 m Drop : 9 drops(3 drops on of 3 main orientations) Package : Unpacked Operation : Non-Operation	n=3	Safety	Hipot (4 000 V [AC rms] / 50 Hz 60 seconds) : ≤ 2 mA
	3.9.2.10	Vibration	Vibration : Random 5 Hz 0.012 G^2/Hz 50 Hz 0.012 G^2/Hz 100 Hz 0.0006 G^2/Hz Horizontal : 27 minutes, Vertical : 54 minutes	n=3	Safety Appearance	No mechanical damage to the plastic housing such as cracking etc. Average value of sensitivity :difference before and after the test ±30%(＋2.27dB/-3.09dB) Hipot (4 000 V [AC rms] / 50 Hz 60 seconds) : ≤ 2 mA
	3.9.2.11	Transducer Assembly Reliability and Noise Test (Cable Bending)	Sample level : Transducer Angle : 90° in the initial direction, then 180° in the opposite direction, and then returning 90° to the starting position.(Clockwise and counterclockwise) Centerline of the transducer : 75mm from the point where the transducer strain relief ends on the cable Cycle rate : 20cycles / min. Weight load : 450g Weight location : weight shall be applied the end of the transducer Dwell cycle : 250 k cycles Package : Unpacked Operation : Non-operation Sample size : 3ea	n=3	Image	Evaluation with ultrasonic diagnostic system : There should be no missing images like black lines in the image in the air.

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3 Criterion

Items		Measurement Condition	specification	Criterion
Electrical characteristics	Sensitivity	All elements	Average : -60.0±2.5dB Deviation : (max-min)5.6dB Max.	Average value of sensitivity :difference before and after the test ±30%(＋2.2dB/-3.0dB)
Safety	Hipot	All channels	AC4KV,cutoff current 2mA,1minite	≦2mA
	Leakage Current	All channels	264V(AC)/60Hz≦50μA	≦50μA
Appearance	Appearance	Appearance	Window,Housing, bush,Cable	Mechanical damage to the plastic housing such as cracking etc. No oil leaks.

4 Result

TVP Tag	TPRS Tag	Sample name	Verification Date	Used Equipment	Test Engineer	Result
11.0.1	3.9.1.1-1	ES1-07	Feb.25, 2022	Withstanding voltage tester : KIKUSUI TOS8650 Tester : sanwa PC7000/PC720M	K.Misuo	Pass
	3.9.1.1-2					Test omitted because it has the same composition as 3.9.1.1-1
	3.9.1.1-3	ES1-08	Feb.25, 2022		K.Misuo	Pass
	3.9.1.1-4	ES1-09	Feb.25, 2022		K.Misuo	Pass
	3.9.1.1-5	ES1-07	Mar.8, 2022		K.Misuo	Pass
	3.9.1.1-6	ES1-08	Mar.25, 2022		K.Misuo	Pass
	3.9.1.1-7	ES1-09	Mar.25, 2022		K.Misuo	Pass
	3.9.1.1-8	21-002	Jun.23, 2022	According to Siemens Report Technical report_NDK 9VC2, 9VE4 Transducer disinfection compatibility test.		Pass
	3.9.1.1-9	ES1-15	-	UnderTest		-
	3.9.1.1-10	ES1-07	Mar.16, 2022	Withstanding voltage tester : KIKUSUI TOS8650 Tester : sanwa PC7000/PC720M	K.Misuo	Pass
	3.9.1.1-11	ES1-07	Mar.31, 2022		K.Misuo	Pass
	3.9.1.1-12	ES1-08	Mar.31, 2022		K.Misuo	Pass
	3.9.1.1-13	ES1-14	-	Testing at Siemens		-
	3.9.1.1-14	ES1-09	Mar.31, 2022	Withstanding voltage tester : KIKUSUI TOS8650 Tester : sanwa PC7000/PC720M	K.Misuo	Pass
	3.9.2.1	ES1-01 ES1-02 ES1-03	Feb.21, 2022	Temperature Cycle chamber : ESPEC TSE-11-A Chamber : ESPEC SH-641 Pulsar : OLYMPUS 5800PR Digital oscilloscope : Tektoronix DPO3032 Withstanding voltage tester : KIKUSUI TOS8650 Tester : sanwa PC7000/PC720M	K.Misuo	Pass
	3.9.2.2	ES1-04 ES1-05 ES1-06	Apr.7, 2022		K.Misuo	Pass
	3.9.2.3	ES1-01 ES1-02 ES1-03	Apr.2, 2022		K.Misuo	Pass
	3.9.2.4	ES1-10	-	Testing at Siemens		-
	3.9.2.5	ES1-01 ES1-02 ES1-03	Apr.22, 2022	Temperature Cycle chamber : ESPEC TSE-11-A Chamber : ESPEC SH-641 Pulsar : OLYMPUS 5800PR Digital oscilloscope : Tektoronix DPO3032 Withstanding voltage tester : KIKUSUI TOS8650 Tester : sanwa PC7000/PC720M	K.Misuo	Pass
	3.9.2.6	ES1-04 ES1-05 ES1-06	Apr.15, 2022		K.Misuo	Pass
	3.9.2.7	ES1-07 ES1-08 ES1-09	May.23, 2022		K.Misuo	Pass
	3.9.2.8	22-002 22-007	Apr.28, 2022	According to Siemens Report SGS-R22-0871-EN00		Pass
	3.9.2.9	ES1-01 ES1-02 ES1-03	May.18.2022	Withstanding voltage tester : KIKUSUI TOS8650	K.Misuo	Pass
	3.9.2.10			Accoding to the result of 3.9.2.3		Pass
	3.9.2.11	ES1-11	-	Testing at Siemens		-

No abnormality under the above conditions for the items for which the test was completed.

4 Conclusion

Items that have completed the test have passed the criteria.
Items under test will be repoted after the test is completed.

separate sheet1. 3.9.1.1-1 Sani-Cloth AF3
separate sheet2. 3.9.1.1-3 SuperSani-Cloth
separate sheet3. 3.9.1.1-4 Enzol
separate sheet4. 3.9.1.1-5 Transeptic
separate sheet5. 3.9.1.1-6 Metrricide
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separate sheet11. 3.9.2.1 Temperature Cycle
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separate sheet17. 3.9.2.9 Drop Test

TVP Tag 11.0.1
TPRS Tag 3.9.1.1-1

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Separate sheet 1

Specification Sani-Cloth AF3

Method Wrap the Sani-Cloth AF3 around the probe and leave it for 168 hours.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment
Hipot	Pass
Leakage Current	15.70 μA Pass
Appearance	Pass

Appearance

TVP Tag 11.0.1
TPRS Tag 3.9.1.1-3

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Separate sheet 2

Specification Super Sani-Cloth

Method Wrap the Super Sani-Cloth around the probe and leave it for 168 hours.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment
Hipot	Pass
Leakage Current	15.10 μA Pass
Appearance	Pass

Appearance

TVP Tag 11.0.1
TPRS Tag 3.9.1.1-4
Specification Enzol

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Separate sheet 3

Method Immerse the probe in Enzol and leave it for 168 hours,
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment
Hipot	Pass
Leakage Current	16.00 μ A Pass
Appearance	Pass

Appearance

Confidential

Specification Transeptic

Method Immerse the probe in Transeptic and leave it for 168 hours.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment
Hipot	Pass
Leakage Current	15.80 μ A Pass
Appearance	Pass

Appearance

TVP Tag 11.0.1
TPRS Tag 3.9.1.1-6

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Separate sheet 5

Specification Metrricide

Method Immerse the probe in Metrricide and leave it for 336 hours.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment
Hipot	Pass
Leakage Current	16.30 μ A Pass
Appearance	Pass

Appearance

Specification Dis OPA

Method Immerse the probe in Dis OPA and leave it for 500 hours.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

結果

Items	Results and judgment
Hipot	Pass
Leakage Current	16.90 μA Pass
Appearance	Pass

Appearance

TVP Tag 11.0.1
TPRS Tag 3.9.1.1-10

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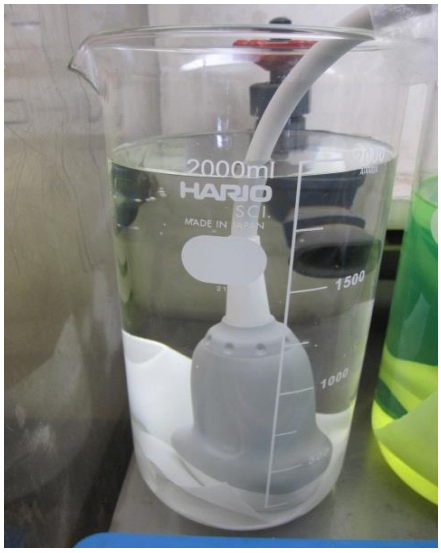
Specification RESERT OX HLD

Method Immerse the probe in RESERT OX HLD and leave it for 168 hours.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023



Result

Items	Results and judgment
Hipot	Pass
Leakage Current	16.30 μ A Pass
Appearance	Pass

Appearance

TVP Tag 11.0.1
TPRS Tag 3.9.1.1-11
Specification Metrricide

Confidential

Method Immerse the probe in Metrricide and perform immersion 1h-5min / 20 cycles.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment
Hipot	Pass
Leakage Current	16.40 μ A Pass
Appearance	Pass

Appearance

TVP Tag 11.0.1
TPRS Tag 3.9.1.1-12
Specification Dis OPA

Confidential

Separate sheet 9

Method Immerse the probe in Dis OPA and perform immersion 1h-5min / 20cycles.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment
Hipot	Pass
Leakage Current	14.90 μ A Pass
Appearance	Pass

Appearance

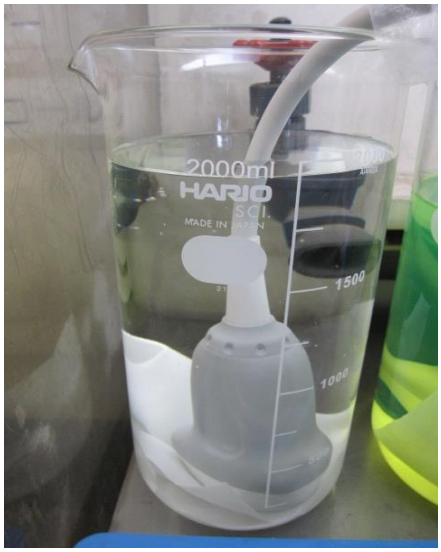
TVP Tag 11.0.1
TPRS Tag 3.9.1.1-14
Specification RESERT OX HLD

Confidential

Separate sheet 10

Method Immerse the probe in RESERT OX HLD and perform immesion 1h-5min / 20cycles.
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023



Result

Items	Results and judgment
Hipot	Pass
Leakage Current	15.70 μ A Pass
Appearance	Pass

Appearance

TVP Tag 11.0.1
TPRS Tag 3.9.2.1

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Separate sheet 11

Specification Temperature Cycle

Method　−10℃/60℃、1h each、40cycles

After that, check the Electrical characteristics, Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TSE-11-A	161000912	Nov.2022
5800PR	40081305	Jun.2022
DPO3032	C010119	Mar.2023
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment		
	ES1-01	ES1-02	ES1-03
Electrical characteristics	Pass	Pass	Pass
Hipot	Pass	Pass	Pass
Leakage Current	15.00 μA Pass	15.10 μA Pass	15.70 μA Pass
Appearance	Pass	Pass	Pass

Appearance

ES1-01	ES1-02	ES1-03
		

TVP Tag 11.0.1
TPRS Tag 3.9.2.2

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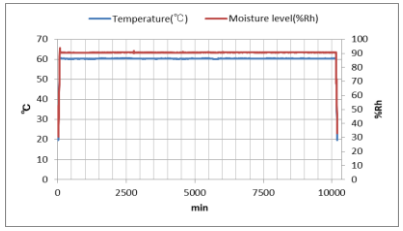
Separate sheet 12

Specification WHTOL(Wet High Temperature Operating life Test)

Method Temperature：＋60℃
Humidity：90%
Cycle：－
Dwell time ：168 hours (10080min)
Ramp up time：50min
Ramp down Time：50min
Package ： Unpacked、Operation : Operation
After that, check the Electrical characteristics, Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
SH-641	92014497	Jun.2022
5800PR	40081305	Jun.2022
DPO3032	C010119	Mar.2023
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023



Result

Items	Results and judgment		
	ES1-04	ES1-05	ES1-06
Electrical characteristics	Pass	Pass	Pass
Hipot	Pass	Pass	Pass
Leakage Current	14.30μA Pass	16.10μA Pass	15.50μA Pass
Appearance	Pass	Pass	Pass

Appearance

ES1-04	ES1-05	ES1-06
		

TVP Tag 11.0.1
TPRS Tag 3.9.2.3
Specification ISTA 2A

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Separate sheet 13

Method 1)Pre-Humidity
2)Compression
3)1st Vibration
4)Drop
5)2nd Vibration
Package : Packed、Operation : non-Operation
After that, check the Electrical characteristics, Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
5800PR	40081305	Jun.2022
DPO3032	C010119	Mar.2023
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Result

Items	Results and judgment		
	ES1-01	ES1-02	ES1-03
Electrical characteristics	Pass	Pass	Pass
Hipot	Pass	Pass	Pass
Leakage Current	15.30μA Pass	15.30μA Pass	15.40μA Pass
Appearance	Pass	Pass	Pass

Appearance

ES1-01	ES1-02	ES1-03
		

TVP Tag 11.0.1
TPRS Tag 3.9.2.5

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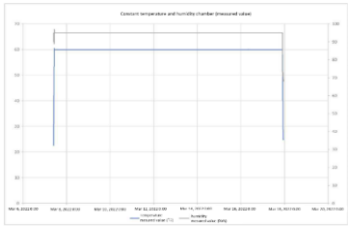
Separate sheet 14

Specification 4HT(High Heat High Humidity Test)

Method Temperature : ＋60℃
Humidity : 95%
Cycle : －
Dwell time : 250h
Ramp up time : 50min
Ramp down Time : 50min
Package : Unpacked、Operation : Non-Operation
After that, check the Electrical characteristics, Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
5800PR	40081305	Jun.2022
DPO3032	C010119	Mar.2023
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023



Result

Items	Results and judgment		
	ES1-01	ES1-02	ES1-03
Electrical characteristics	Pass	Pass	Pass
Hipot	Pass	Pass	Pass
Leakage Current	15.10 μA Pass	15.40 μA Pass	15.40 μA Pass
Appearance	Pass	Pass	Pass

Appearance

ES1-01	ES1-02	ES1-03
		

TVP Tag 11.0.1
TPRS Tag 3.9.2.6

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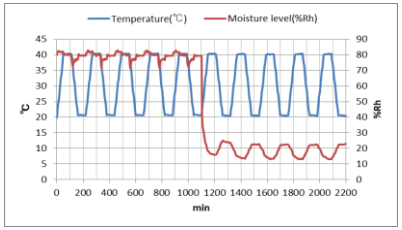
Separate sheet 15

Specification OTHC(Operating Temperature & Humidity Cycle)

Method Temperature：＋20～＋40℃
Humidity ：10～80%
Cycle：10 cycle
Dwell time：1h
Ramp up time：50min
Ramp down time：50min
Package : Unpacked、Operation : Operation
After that, check the Electrical characteristics, Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
SH-641	92014497	Jun.2022
5800PR	40081305	Jun.2022
DPO3032	C010119	Mar.2023
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023



Result

Items	Results and judgment		
	ES1-04	ES1-05	ES1-06
Electrical characteristics	Pass	Pass	Pass
Hipot	Pass	Pass	Pass
Leakage Current	14.10 μA Pass	15.00 μA Pass	15.10 μA Pass
Appearance	Pass	Pass	Pass

Appearance

ES1-04	ES1-05	ES1-06
		

TVP Tag 11.0.1
TPRS Tag 3.9.2.7

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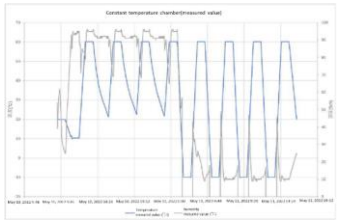
Separate sheet 16

Specification STHC(Storage Temperature & Humidity Cycle)

Method Temperature：−10～+60℃ and then +10～＋60℃
Humidity：10%/95%
Number of Cycles: Minimum of 4 cycles at each set of below Conditions
(A) +10° C to +60° C at 95% RH &
(B) −10° C to +60° C at 10% RH
Dwell time：1h
Ramp up time：50min,Ramp down time：50min
Packaged: Packed、Operation: Non-operating
After that, check the Electrical characteristics, Hipot, Leakage current, Appearance.

Used Equipment	Serial No.	Calibration Period
5800PR	40081305	Jun.2022
DPO3032	C010119	Mar.2023
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023



Result

Items	Results and judgment		
	ES1−07	ES1−08	ES1−09
Electrical characteristics	Pass	Pass	Pass
Hipot	Pass	Pass	Pass
Leakage Current	16.60μA Pass	15.10μA Pass	15.10μA Pass
Appearance	Pass	Pass	Pass

Appearance

ES1−07	ES1−08	ES1−09
		

TVP Tag 11.0.1
Verification Tag 3.9.2.9
Specification Drop Test

Confidential

Separate sheet 17

Method Height : 1.22 m
Drop : 9 drops(3 drops on of 3 main orientations)
Package : Unpacked
Operation : Non-Operation
After that, check the Hipot, Leakage current and Appearance.

Used Equipment	Serial No.	Calibration Period
TOS8650	12262118	Dec.2022
PC7000/PC720M	20025100350	Mar.2023

Temperature and humidity at the time of test

Temperature	Humidity
25.1℃	38.4%

Drop direction1

Drop direction2

Drop direction3

Result

Items	Result and judgement		
	ES1-01	ES1-02	ES1-03
Hipot	Pass	Pass	Pass
Leakage Current	15.30 μA Pass	15.10 μA Pass	15.70 μA Pass
Appearance	Pass	Pass	Pass

Appearance

ES1-01	ES1-02	ES1-03