



**DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION
FACILITIES DEVELOPMENT DIVISION**

**APPLICATION FOR HCAI SPECIAL SEISMIC
CERTIFICATION PREAPPROVAL (OSP)**

OFFICE USE ONLY

APPLICATION #: OSP-0752

HCAI Special Seismic Certification Preapproval (OSP)

Type: New Renewal

Manufacturer Information

Manufacturer: GE Healthcare

Manufacturer's Technical Representative: Du Pengfei

Mailing Address: 3000 N. Grandview Blvd., Waukesha, WI 53188

Telephone: +86 1891-1901406

Email: Pengfei.du@gehealthcare.com

Product Information

Product Name: Fluoroscopy and Radiography Systems

Product Type: NA

Product Model Number: Definium Tempo / Definium Tempo Pro

General Description: System components of multiple-component medical diagnostic radiography imaging system.

Mounting Description: See Certified Product Tables, See Certified Product Tables

Tested Seismic Enhancements: None

Applicant Information

Applicant Company Name: TRU Compliance, by Structural Integrity Associates

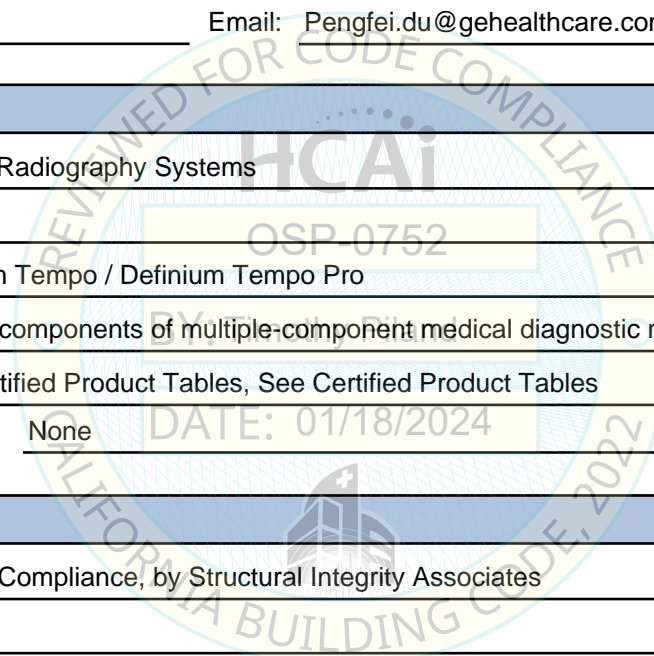
Contact Person: Daniel Zentner

Mailing Address: 233 SW Wilson Ave, Suite 101, Bend, OR 97702

Telephone: (541) 292-5839

Email: dzentner@structint.com

Title: Program Manager





**DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION
FACILITIES DEVELOPMENT DIVISION**

California Licensed Structural Engineer Responsible for the Engineering and Test Report(s)

Company Name: STRUCTURAL INTEGRITY ASSOCIATES, INC.

Name: LACHEZAR HANDZHIYSKI California License Number: S6515

Mailing Address: 5215 Hellyer Avenue, Suite 210, San Jose, CA 95138

Telephone: (669) 437-0200 Email: Lhandzhiyski@StructInt.com

Certification Method

GR-63-Core ICC-ES AC156 IEEE 344 IEEE 693 NEBS 3

Other (Please Specify): _____

Testing Laboratory

Company Name: CHINA TELECOMMUNICATION TECHNOLOGY LABS (CTTL)

Contact Person: Lanfang Cui

Mailing Address: No. 299, Tengfei Road, Industrial Park, Lianchi District, Baoding, Hebei, China

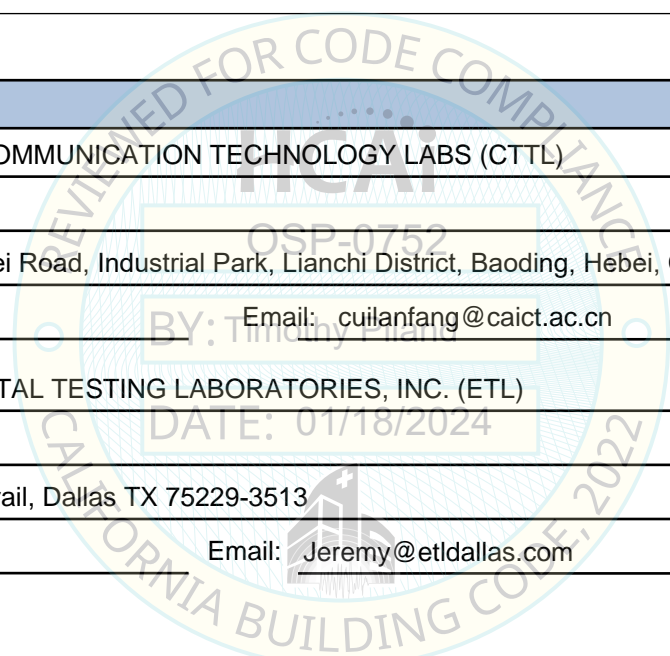
Telephone: +86 0312-6798950 Email: cuilanfang@caict.ac.cn

Company Name: ENVIRONMENTAL TESTING LABORATORIES, INC. (ETL)

Contact Person: Jeremy Lange

Mailing Address: 11034 Indian Trail, Dallas TX 75229-3513

Telephone: (972) 247-9657 Email: Jeremy@etldallas.com





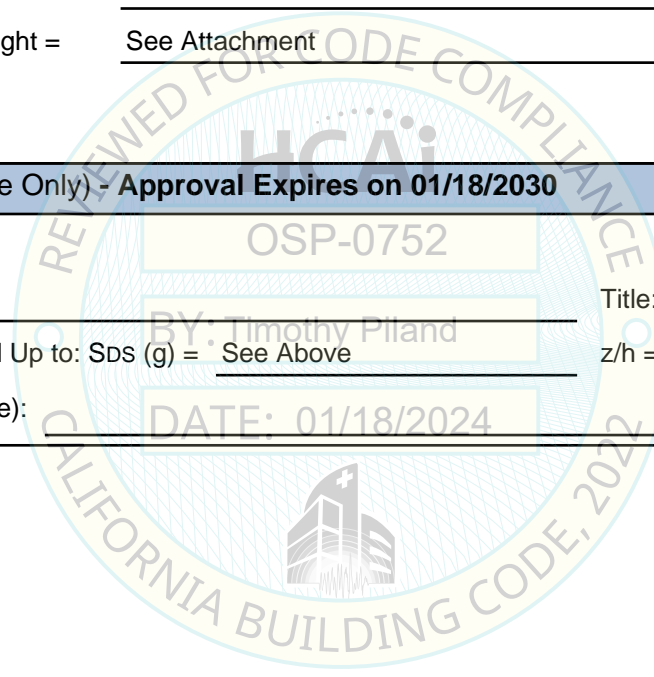
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Seismic Parameters

Design Basis of Equipment or Components (F_p/W_p) =	<u>See Attached Table 4</u>
SDS (Design spectral response acceleration at short period, g) =	<u>See Attached Table 4</u>
a_p (Amplification factor) =	<u>See Attached Table 4</u>
R_p (Response modification factor) =	<u>See Attached Table 4</u>
Ω_0 (System overstrength factor) =	<u>2.0</u>
I_p (Importance factor) =	<u>1.5</u>
z/h (Height ratio factor) =	<u>1 and 0</u>
Natural frequencies (Hz) =	<u>See Attachment</u>
Overall dimensions and weight =	<u>See Attachment</u>

HCAI Approval (For Office Use Only) - Approval Expires on 01/18/2030

Date:	<u>1/18/2024</u>	OSP-0752	
Name:	<u>Timothy Piland</u>	BY: Timothy Piland	Title: <u>Senior Structural Engineer</u>
Special Seismic Certification Valid Up to: SDS (g) =	<u>See Above</u>	DATE: 01/18/2024	z/h = <u>See Above</u>
Condition of Approval (if applicable):	<u></u>		



SPECIAL SEISMIC CERTIFICATION CERTIFIED COMPONENT MATRIX

2200668-CR-002-R4



Manufacturer: GE Healthcare	TABLE 1
Model Line: Definium Tempo / Definium Tempo Pro	

Certified Product Construction Summary:
Constructed of carbon steel, aluminum, and plastic components

Certified Options Summary:
2 or 3 Meter Bridge
134" to 228" and 12m Longitudinal Rails

Mounting Configuration:
Ceiling mounted - rigid
Note: Installed mounting must be of similar configuration and equivalent strength and stiffness to those tested.

Building Code: CBC 2022 **Seismic Certification Limits:** $S_{DS} = 2.0g$ $z/h = 1.0$ $I_p = 1.5$
 $S_{DS} = 2.5g$ $z/h = 0.0$

Assembly (Components)	Subcomponents	Model Number	Dimension (in)			Weight (lbs.)	Notes	UUT
			Depth	Width	Height ¹			
Overhead Tube Suspension (2 meter bridge)	2 Meter Bridge	5823488	90.9	228.0	41.1 - 104.1	1,065	UUT: 228" Longitudinal Rails	7
	Tube Support ²	5822306						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
Overhead Tube Suspension (2 meter bridge)	2 Meter Bridge	5823488	90.9	472.0	41.1 - 104.1	1,213		Interp.
	Tube Support ²	5822306						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
	Longitudinal Rails (12m)	5492991						

Notes:
1. Range of outer height from top of longitudinal rail to the lowest point **2.** China made **3.** Mexico made **4.** Design, construction, materials and grades, quality control and quality assurance methods used in manufacturing for products in Mexico and China are identical. Manufacturing process at both locations are ISO 13485 certified.

TRU Compliance, by Structural Integrity Associates, Inc.

844-TRU-0200 | info@trucompliance.com

SPECIAL SEISMIC CERTIFICATION CERTIFIED COMPONENT MATRIX

2200668-CR-002-R4



Manufacturer: GE Healthcare	TABLE 1
Model Line: Definium Tempo / Definium Tempo Pro	

Certified Product Construction Summary:
Constructed of carbon steel, aluminum, and plastic components

Certified Options Summary:
2 or 3 Meter Bridge
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Mounting Configuration:
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Note: Installed mounting must be of similar configuration and equivalent strength and stiffness to those tested.

Building Code: CBC 2022
Seismic Certification Limits: $S_{DS} = 2.0g$ $z/h = 1.0$ $I_p = 1.5$
 $S_{DS} = 2.5g$ $z/h = 0.0$

Assembly (Components)	Subcomponents	Model Number	Dimension (in)			Weight (lbs.)	Notes	UUT
			Depth	Width	Height ¹			
Overhead Tube Suspension (2 meter bridge)	2 Meter Bridge	5823488	90.9	228.0	41.1 - 104.1	1,065	UUT: 228" Longitudinal Rails	Same ⁴
	Tube Support ³	5822306-1						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
Overhead Tube Suspension (2 meter bridge)	2 Meter Bridge	5823488	90.9	472.0	41.1 - 104.1	1,213		Interp.
	Tube Support ³	5822306-1						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
	Longitudinal Rails (12m)	5492991						

Notes:
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SPECIAL SEISMIC CERTIFICATION CERTIFIED COMPONENT MATRIX

2200668-CR-002-R4



Manufacturer: GE Healthcare	TABLE 1
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Certified Options Summary:
2 or 3 Meter Bridge
134" to 228" and 12m Longitudinal Rails

Mounting Configuration:
Ceiling mounted - rigid
Note: Installed mounting must be of similar configuration and equivalent strength and stiffness to those tested.

Building Code: CBC 2022 **Seismic Certification Limits:** $S_{DS} = 2.0g$ $z/h = 1.0$ $I_p = 1.5$
 $S_{DS} = 2.5g$ $z/h = 0.0$

Assembly (Components)	Subcomponents	Model Number	Dimension (in)			Weight (lbs.)	Notes	UUT
			Depth	Width	Height ¹			
Overhead Tube Suspension (3 meter bridge)	3 Meter Bridge	5823489	128.9	228.0	41.1 - 104.1	1,111	UUT: 228" Longitudinal Rails	8
	Tube Support ²	5822306						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
Overhead Tube Suspension (3 meter bridge)	3 Meter Bridge	5823489	128.9	472.0	41.1 - 104.1	1,259		Interp.
	Tube Support ²	5822306						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
	Longitudinal Rails (12m)	5492991						

Notes:
1. Range of outer height from top of longitudinal rail to the lowest point **2.** China made **3.** Mexico made **4.** Design, construction, materials and grades, quality control and quality assurance methods used in manufacturing for products in Mexico and China are identical. Manufacturing process at both locations are ISO 13485 certified.

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SPECIAL SEISMIC CERTIFICATION CERTIFIED COMPONENT MATRIX

2200668-CR-002-R4



Manufacturer: GE Healthcare	TABLE 1
Model Line: Definium Tempo / Definium Tempo Pro	

Certified Product Construction Summary:
Constructed of carbon steel, aluminum, and plastic components

Certified Options Summary:
2 or 3 Meter Bridge
134" to 228" and 12m Longitudinal Rails

Mounting Configuration:
Ceiling mounted - rigid
Note: Installed mounting must be of similar configuration and equivalent strength and stiffness to those tested.

Building Code: CBC 2022 **Seismic Certification Limits:** $S_{DS} = 2.0g$ $z/h = 1.0$ $I_p = 1.5$
 $S_{DS} = 2.5g$ $z/h = 0.0$

Assembly (Components)	Subcomponents	Model Number	Dimension (in)			Weight (lbs.)	Notes	UUT
			Depth	Width	Height ¹			
Overhead Tube Suspension (3 meter bridge)	3 Meter Bridge	5823489	128.9	228.0	41.1 - 104.1	1,111	UUT: 228" Longitudinal Rails	Same ⁴
	Tube Support ³	5822306-1						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
Overhead Tube Suspension (3 meter bridge)	3 Meter Bridge	5823489	128.9	472.0	41.1 - 104.1	1,259		Interp.
	Tube Support ³	5822306-1						
	X-Ray Tube	46-155400G284						
	Collimator (AL01C II eL)	5730663						
	Longitudinal Rails (134" to 228")	46-316480G1 to 46-316480G24						
	Longitudinal Rails (12m)	5492991						

Notes:
1. Range of outer height from top of longitudinal rail to the lowest point **2.** China made **3.** Mexico made **4.** Design, construction, materials and grades, quality control and quality assurance methods used in manufacturing for products in Mexico and China are identical. Manufacturing process at both locations are ISO 13485 certified.

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SPECIAL SEISMIC CERTIFICATION CERTIFIED COMPONENT MATRIX

2200668-CR-002-R4



Manufacturer: GE Healthcare	TABLE 2
Model Line: Definium Tempo / Definium Tempo Pro	

Certified Product Construction Summary:
Constructed of carbon steel, aluminum, and plastic components

Certified Options Summary:
14x17 or 17x17 FlashPad

Mounting Configuration:
Base mounted - rigid
Note: Installed mounting must be of similar configuration and equivalent strength and stiffness to those tested.

Building Code: CBC 2022
Seismic Certification Limits: $S_{DS} = 2.0g$ $z/h = 1.0$ $I_p = 1.5$
 $S_{DS} = 2.5g$ $z/h = 0.0$

Assembly (Components)	Subcomponents	Model Number	Dimension (in)			Weight (lbs.)	Notes	UUT
			Depth	Width	Height			
Radiographic Table	Table ¹	GCTBL-C4	33.6	93.7	23.0 - 35.4	852		9
System Cabinets	System Cabinet	GCC-C4	23.6	35.4	36.7	459.0		3
	System Cabinet (Mexico)	GCC-C44	23.6	35.4	36.7	459.0	Same as GCC-C4	Same ⁴
Workstation	HP Z4G4 Workstation ³	8780000-W27	9.6	22.6	20.1	23.0		4
Wallstands	Motorized Extended	GCEWS-C3	65.7	27.0	103.5	642		1a, 1b
	Motorized	GCWS-C3	52.9	27.0	103.5	624		Interp.
	Non-tilting	GCWS-C5	40.4	27.0	108.3	554		Interp.
	Manual	GCMWS-C5	40.1	27.0	103.4	537	XR646 system only	2
FlashPad HD (Subcomponents)	FlashPad HD 14 x 17 ²	5771417	15.0	18.0	0.6	7.2		2
	FlashPad HD 17 x 17	5771717	18.0	18.0	0.6	8.4		9

Notes:
1. Table weight does not include 617 lbs. simulated patient load present during testing. **2.** Seismically certified units shall have the detector retention bracket present when used with 14 x 17 detector. **3.** Monitor is not included, the monitor is portable. **4.** Design, construction, materials and grades, quality control and quality assurance methods used in manufacturing for products in Mexico and China are identical. Manufacturing process at both locations are ISO 13485 certified.

UNIT UNDER TEST (UUT) SUMMARY SHEET

2200668-CR-002-R4



Manufacturer: GE Healthcare Model Line: Definium Tempo / Definium Tempo Pro								
UUT	Unit Description (Mounting)	Report Number (UUT #)	Testing Lab	Year Tested	ISO 17025 Accredited?	S _{DS}	z/h	I _p
1a	Motorized Extended Wall (GCEWS-C3) w/ FlashPad HD 17x17 with Detector Tray (Base mounted - rigid)	SQ12-1812-01 r2 (UUT8)	Environmental Tesing Lab (ETL)	2018	Yes	2.0 2.5	1.0 0.0	1.5
1b	Motorized Extended Wall (GCEWS-C3) w/ FlashPad HD 17x17 W/O Detector Tray (Base mounted - rigid)	SQ12-1812-01 r2 (UUT8A)	Environmental Tesing Lab (ETL)	2018	Yes	2.0 2.5	1.0 0.0	1.5
2	Manual Extended Wall (GCMWS-C5) w/ FlashPad HD 14x17 (Base mounted - rigid)	SQ12-1812-01 r2 (UUT9)	Environmental Tesing Lab (ETL)	2018	Yes	2.0 2.5	1.0 0.0	1.5
3	System Cabinet (GCC-C4) (Base mounted - rigid)	No. B22X80804 Rev.1 (UUT3)	China Telecommunication Technology (CTTL)	2022	Yes	2.0 2.5	1.0 0.0	1.5
4	HP Z4G4 Workstation (8780000-W27) (Base mounted - rigid)	No. B22X80804 Rev.1 (UUT4)	China Telecommunication Technology (CTTL)	2022	Yes	2.0 2.5	1.0 0.0	1.5
5	AP Assembly (5845913) w/ Mounting Bracket (Wall mounted - rigid)	No. B22X80804 Rev.1 (UUT5)	China Telecommunication Technology (CTTL)	2022	Yes	2.0 2.5	1.0 0.0	1.5
6	Tether Interface Box, TIB (5876669) (Wall mounted - rigid)	No. B22X80804 Rev.1 (UUT6)	China Telecommunication Technology (CTTL)	2022	Yes	2.0 2.5	1.0 0.0	1.5
7	Overhead Tube Suspension (2 meter bridge) (Ceiling mounted - rigid)	No. B22X80805 Rev.1 (UUT3)	China Telecommunication Technology (CTTL)	2022	Yes	2.0 2.5	1.0 0.0	1.5
8	Overhead Tube Suspension (3 meter bridge) (Ceiling mounted - rigid)	No. B22X80805 Rev.1 (UUT1)	China Telecommunication Technology (CTTL)	2022	Yes	2.0 2.5	1.0 0.0	1.5
9	Radiographic Table (GCTBL-C4) w/ FlashPad HD 17x17 (Base mounted - rigid)	No. B22X80805 Rev.1 (UUT2)	China Telecommunication Technology (CTTL)	2022	Yes	2.0 2.5	1.0 0.0	1.5
Notes:								

UNIT UNDER TEST (UUT) SUMMARY SHEET


2200668-CR-002-R4



Manufacturer:	GE Hualun Medical Systems, Co. Ltd	UUT 2
Model Line:	Definium Tempo / Definium Tempo Pro	
Model Number:	Manual Extended Wall (GCMWS-C5) w/ FlashPad HD 14x17	
Serial Number:	N/A	
Test Report:		SQ12-1812-01 r2 (UUT9)

UUT Properties						
Weight (lbs.)	Dimension (in)			Lowest Natural Frequency (Hz)		
	Depth	Width	Height	Front-Back	Side-Side	Vertical
537	40.4	27.0	103.5	9.72	9.49	>33.33

UUT Highest Passed Seismic Run Information									
Building Code	Test Criteria	S _{DS} (g)	z/h	I _p	A _{FLX-H} (g)	A _{RIG-H} (g)	A _{FLX-V} (g)	A _{RIG-V} (g)	
CBC 2022	ICC-ES AC156	2.0	1.0	1.5	3.20	2.40	1.67	0.67	
		2.5	0.0						

Product Construction Summary:	Test Mounting Details:
Constructed of carbon steel, aluminum, and plastic components	

Options/Subcomponent Summary:	
Description	Part Number
Detector: GE FlashPad HD 3543 wireless, removable detector	Model No. 5771417
X-Ray Grid (Anti-Scatter Grid): 120cm by Mitaya Mfg. Co. Ltd.	GE P/N 46-286129P74
*Grid holder tray included a supplemental latching mechanism, which is not part of the standard mfd product, to secure grid within tray during test	

UUT2 was base mounted - rigid using four (4) 5/8" SAE J429 Grade 8 bolts to tapped holes in aluminum plate.
 Detector tray included a retention bracket which GE states is part of the standard mfd product, to secure 14x17 detector to the tray during test. Bracket must be removed to exchange detectors and re-installed when 14x17 is used.
 Unit maintained structural integrity and remained functional per manufacturer requirement after shake table test. Contents were included in testing per operating conditions.

UNIT UNDER TEST (UUT) SUMMARY SHEET

2200668-CR-002-R4



Manufacturer:	GE Hualun Medical Systems, Co. Ltd	UUT 7
Model Line:	Definium Tempo / Definium Tempo Pro	
Model Number:	Overhead Tube Suspension (2 meter bridge)	
Serial Number:	N/A	
Test Report:		No.B22X80805 Rev.1 (UUT3)

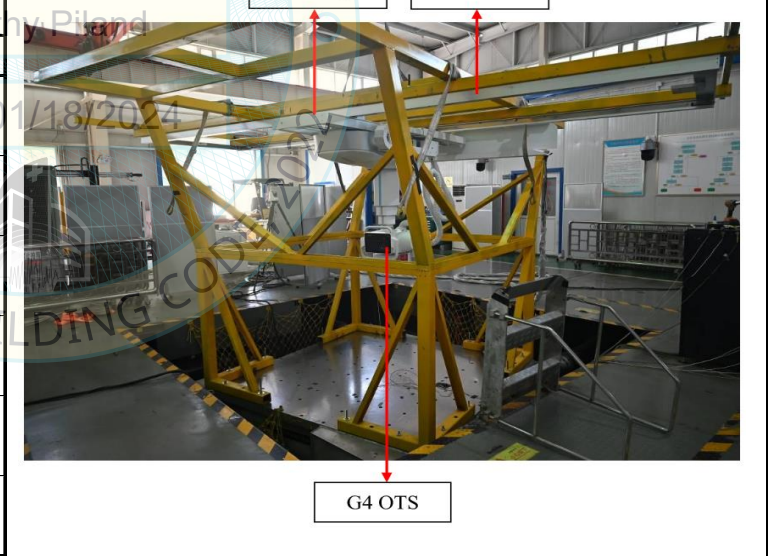
UUT Properties						
Weight (lbs.)	Dimension (in)			Lowest Natural Frequency (Hz)		
	Depth	Width	Tested Height ¹	Front-Back	Side-Side	Vertical
1,065	90.9	228.0	72.0	N/A	N/A	N/A

UUT Highest Passed Seismic Run Information									
Building Code	Test Criteria	S _{DS} (g)	z/h	I _p	A _{FLX-H} (g)	A _{RIG-H} (g)	A _{FLX-V} (g)	A _{RIG-V} (g)	
CBC 2022	ICC-ES AC156	2.0	1.0	1.5	3.20	2.40	1.67	0.67	
		2.5	0.0						

Product Construction Summary:
Constructed of carbon steel, aluminum, and plastic components

Test Mounting Details:

Options/Subcomponent Summary:	
Description	Part Number
Collimator (AL01C II eL) (GE Healthcare)	5730663
G4 OTS (GE Healthcare)	5822306
Longitudinal Rails (228") (GE Healthcare)	46-316480G24
OTS 2M Bridge (GE Healthcare)	5823488
Tube Support (GE Healthcare)	5822306
X-Ray Tube (GE Healthcare)	46-155400G284



Test Mounting Details:

¹ Outer height from top of longitudinal rail to the lowest point

Min Height: 41.1"
Max Height: 104.1"

UUT7 was ceiling mounted - rigid. The 6-meter Rail and 2-meter Bridge were connected to the fixture using twenty-four (24) M12 screws. The fixture was connected to the table using sixteen (16) M16 screws. The bridge of both systems are powered on and locked by an electromagnetic brake when testing as same as normal use. Unit maintained structural integrity and remained functional per manufacturer requirement after shake table test. Contents were included in testing per operating conditions.

UNIT UNDER TEST (UUT) SUMMARY SHEET

2200668-CR-002-R4



Manufacturer:	GE Hualun Medical Systems, Co. Ltd	UUT 8
Model Line:	Definium Tempo / Definium Tempo Pro	
Model Number:	Overhead Tube Suspension (3 meter bridge)	
Serial Number:	N/A	
Test Report:		No.B22X80805 Rev.1 (UUT1)

UUT Properties						
Weight (lbs.)	Dimension (in)			Lowest Natural Frequency (Hz)		
	Depth	Width	Tested Height ¹	Front-Back	Side-Side	Vertical
1,111	128.9	228.0	72.0	N/A	N/A	N/A

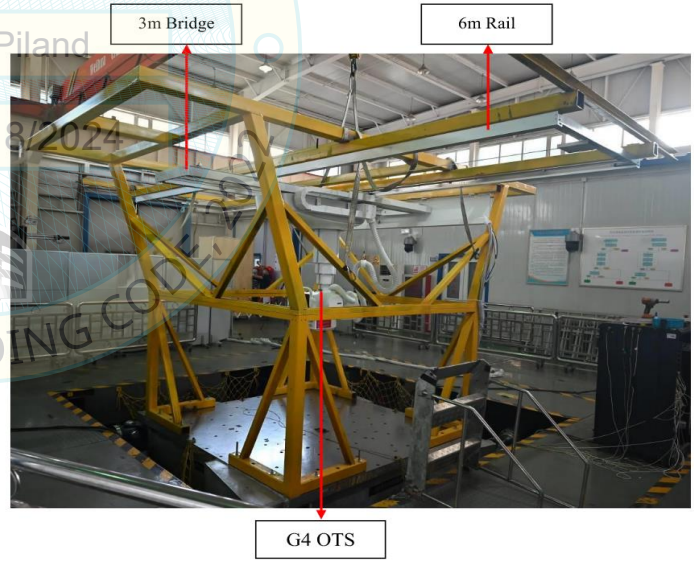
UUT Highest Passed Seismic Run Information									
Building Code	Test Criteria	S _{Ds} (g)	z/h	I _p	A _{FLX-H} (g)	A _{RIG-H} (g)	A _{FLX-V} (g)	A _{RIG-V} (g)	
CBC 2022	ICC-ES AC156	2.0	1.0	1.5	3.20	2.40	1.67	0.67	
		2.5	0.0						

Product Construction Summary:
Constructed of carbon steel, aluminum, and plastic components

Test Mounting Details:

Options/Subcomponent Summary:

Description	Part Number
Collimator (AL01C II eL) (GE Healthcare)	5730663
Longitudinal Rails (228") (GE Healthcare)	46-316480G24
OTS 3M Bridge (GE Healthcare)	5823489
Tube Support (GE Healthcare)	5822306
X-Ray Tube (GE Healthcare)	46-155400G284



Test Mounting Details:

¹ Outer height from top of longitudinal rail to the lowest point

Min Height: 41.1"
Max Height: 104.1"

UUT8 was ceiling mounted - rigid. The 6-meter Rail and 3-meter Bridge were connected to the fixture using twenty-four (24) M12 screws. The fixture was connected to the table using sixteen (16) M16 screws. The bridge of both systems are powered on and locked by an electromagnetic brake when testing as same as normal use. Unit maintained structural integrity and remained functional per manufacturer requirement after shake table test. Contents were included in testing per operating conditions.

