



DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION
FACILITIES DEVELOPMENT DIVISION

APPLICATION FOR HCAI SPECIAL SEISMIC
CERTIFICATION PREAPPROVAL (OSP)

OFFICE USE ONLY

APPLICATION #: OSP-0753

HCAI Special Seismic Certification Preapproval (OSP)

Type: [X] New [] Renewal

Manufacturer Information

Manufacturer: GE Healthcare

Manufacturer's Technical Representative: Tom Farnow

Mailing Address: 3000 N. Grandview Blvd., Waukesha, WI 53188-1696

Telephone: (888) 406-1101

Email: Tom.Farnow@geh seismic.com

Product Information

Product Name: CT Systems

Product Type: NA

Product Model Number: Omni Legend PET-CT System

General Description: System components of a multiple-component medical imaging system. Special Seismic Certification is limited to functions related to Computed Tomography (CT) medical imaging services.

Mounting Description: See Certified Product Tables

Tested Seismic Enhancements: Seismic enhancements made to the test units and/or modifications required to address anomalies during the tests shall be incorporated into the production units.

Applicant Information

Applicant Company Name: EASE LLC

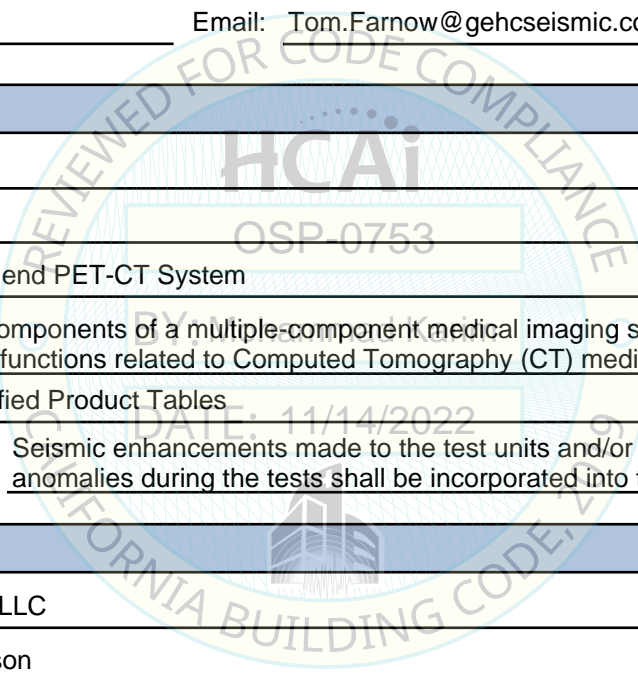
Contact Person: Jonathan Roberson

Mailing Address: 5877 Pine Ave. Suite 210, Chino Hills, CA 91709

Telephone: (909) 606-7622

Email: jon@easeco.com

Title: Principal Structural Engineer





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

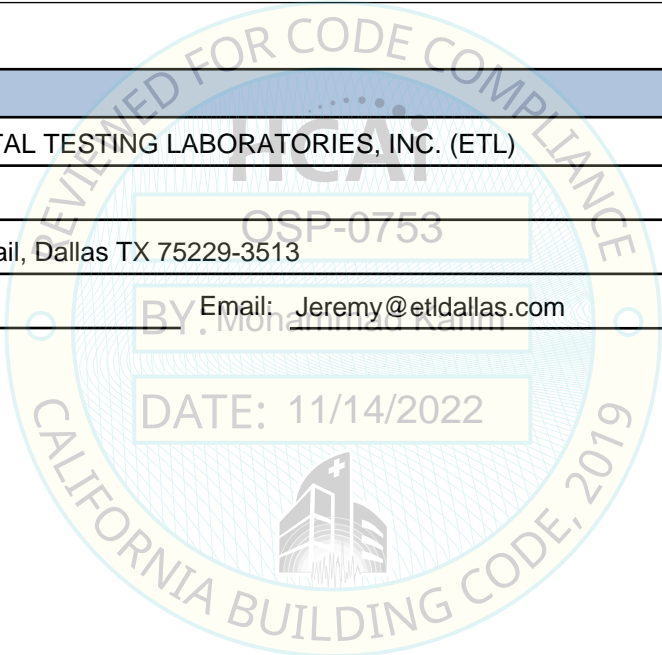
Company Name: EASE LLC
Name: Jonathan Roberson California License Number: S4197
Mailing Address: 5877 Pine Ave., Suite 210, Chino Hills, CA 91709
Telephone: (951) 295-1892 Email: jon@EASECo.com

Certification Method

GR-63-Core ICC-ES AC156 IEEE 344 IEEE 693 NEBS 3
 Other (Please Specify): _____

Testing Laboratory

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) = See Attachment

SDS (Design spectral response acceleration at short period, g) = 1.52

a_p (Amplification factor) = See Attachment

R_p (Response modification factor) = See Attachment

Ω_0 (System overstrength factor) = 2.0

I_p (Importance factor) = 1.5

z/h (Height ratio factor) = 1

Natural frequencies (Hz) = See Attachment

Overall dimensions and weight = See Attachment

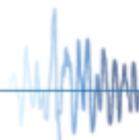
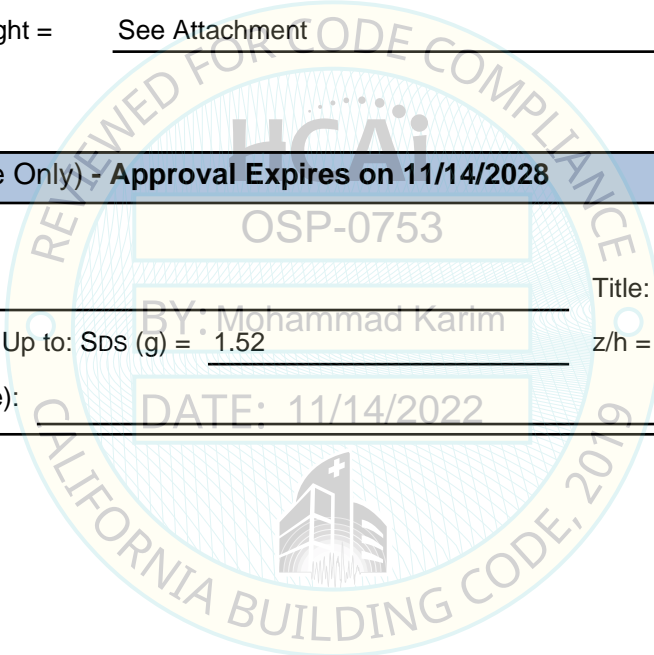
HCAI Approval (For Office Use Only) - Approval Expires on 11/14/2028

Date: 11/14/2022

Name: Mohammad Karim Title: Supervisor, Health Facilities

Special Seismic Certification Valid Up to: SDS (g) = 1.52 z/h = 1

Condition of Approval (if applicable): DATE: 11/14/2022



ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS

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TABLE 1:

Manufacturer		GE HEALTHCARE							S _{Ds} = 1.52 at z/h = 1			
System		OMNI LEGEND PET-CT System [2]										
COMPONENT	MODEL NUMBER	APPROX. DIMENSIONS [IN]			MAX. WT. [LB]	MOUNT	BASIS [1]	F _P /W _P	a _P	R _P	Ω ₀	
		W	D	H								
GANTRIES [2]												
Omni Legend PET-CT Gantry												
32 cm Omni PET Gantry	6890030-2	92	67	76	3638	Rigid Base	UUT-2212-1	1.82	1	1 ½	2	
CT Gantry (TaiX), PET Specific	6670000-21				3434							
Omni Legend PET-CT Gantry												
32 cm Omni PET Gantry	6890030	92	67	76	3638	Rigid Base	SAME	1.82	1	1 ½	2	
CT Gantry (TaiX), PET Specific	6670000-21				3434							
Omni Legend PET-CT Gantry												
16 cm Omni PET Gantry	6890015	92	67	76	3606	Rigid Base	INT	1.82	1	1 ½	2	
CT Gantry (TaiX), PET Specific	6670000-21				3434							
Omni Legend PET-CT Gantry												
16 cm Omni PET Gantry	6890015-2	92	67	76	3606	Rigid Base	INT	1.82	1	1 ½	2	
CT Gantry (TaiX), PET Specific	6670000-21				3434							
<i>Discovery MI PET-CT Gantry</i>												
25cm Columbia PET Gantry, Weldment	5990025-22	77.4	93.6	76	2443	Rigid Base	UUT-1901-1	1.82	1	1 ½	2	
Revolution EVO CT Gantry, PET Specific	5454001-170				3940							
PATIENT TABLES												
PROSCAN Patient Table	5101900	26	136	22 / 42	1808 [3]	Rigid Base	UUT-10390-3	1.82	1	1 ½	2	
Mobile Ready Global PET-CT Table Ed3	5101900-20	26	136	22 / 42	1808	Rigid Base	SAME	1.82	1	1 ½	2	
CONSOLES												
Open Console (HP Z8G4)	5946404-15	15.8	26.4	22.7	142 [4]	Rigid Base	UUT-1914-2	1.10	1	2 ½	2	

Table continues next page

ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS

ATTACHMENT PAGE | 2 OF 2

TABLE 1:

<i>Manufacturer</i>	GE HEALTHCARE										S_{Ds} = 1.52 at z/h = 1		
<i>System</i>	OMNI LEGEND PET-CT System [2]												
COMPONENT	MODEL NUMBER	APPROX. DIMENSIONS [IN]			MAX. WT. [LB]	MOUNT	BASIS [1]	F _P /W _P	a _P	R _P	Ω ₀		
		W	D	H									
POWER DISTRIBUTION													
NGPDU-61	2326492-61	27.6	21.7	41.8	818	Rigid Base	UUT-1313-2	1.10	1	2 ½	2		
Power Distribution Box (PDB)	5627940	19.7	9.5	24.8	68	Wall	UUT-1901-3	1.10	1	2 ½	2		
<i>Mount</i>	<p>RIGID BASE: free-standing, base-mounted configuration with the component rigidly attached to a supporting structure and no lateral support above the base.</p> <p>WALL: refers to condition where the unit is fully supported, both vertically and laterally, by a building wall or partition.</p>												
<i>Notes</i>	<p>1. BASIS:</p> <ul style="list-style-type: none"> • UUT-####-#: Indicates that a test specimen matching these characteristics was tested as part of this testing program. • INT (Interpolate or extrapolate): Indicates model that was not specifically tested, and for which seismic qualification was established through evaluation of testing of similar models in the product line. • SAME: Indicates model is physically, mechanically & electrically the same as test specimen. Differences are limited to color, software, and/or identification number. <p>2. System (including Gantries) requires the use of Omni Seismic Collector Kit 5919418.</p> <p>3. <i>Patient Table weight does not include the 300 lb. simulated patient load present during testing.</i></p> <p>4. Weight includes mounting bracket hardware.</p> <p>5. Seismic certification is limited to functions related to Computed Tomography (CT) for diagnostic assessment of trauma.</p> <p>6. <i>Gray italic formatting indicates unit is not a component of system and used as basis for seismic qualification only.</i></p>												

ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT-1313-2 NGPDU-61						
<i>Manufacturer:</i>		GE Hangwei Medical Systems CO., LTD				
<i>Identification:</i>		Model No.: 2326492-61				
		Serial No.: 322132HM2				
<i>Description:</i>		System component of several GEHC CT systems. Tested as component of Optima CT580 System.				
<i>Mounting:</i>		<u>Rigid Base (Floor) mounted using:</u> (2) – 3/8" dia. ASTM A574 Socket Head Cap Screws w/ washer through GE mounting brackets to floor plate. <u>GE mounting assembly including:</u> (2) – Seismic Bracket, System Cabinet (P/N 2354563-2) Each bracket mounted to cabinet w/ (2) – M10-1.5 X25mm Class 12.9 Socket Head Cap Screw, Black Oxide (Torque= 38.4 N-m) (2) – M10 Lock Washer (P/N 2203-M10-07) (2) – M10 Flat Washer (P/N 2000-M10-03)				
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Side-Axis	Front-Axis	Vert-Axis
27.6	21.7	41.8	796 + 22 brackets = 818	15.7	19.9	45
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						
S _{DS} (G)	z/h	I _p	A _{FLX-H} (G)	A _{RIG-H} (G)	A _{FLX-V} (G)	A _{RIG-V} (G)
2.0	1.0	1.5	3.20	2.40	1.74	0.70
2.6	0.0					
Unit maintained structural integrity and remained functional per manufacturer requirement						



UUT-1901-3 Power Distribution Box						
<i>Manufacturer:</i>		CETC ECRIEEEPOWER (ANHUI) CO., LTD				
<i>Identification:</i>		Model No. 5627940				
		Serial No.: 56200000003				
<i>Description:</i>		System component of several GEHC CT systems. CT/PET Panel Door secured closed with M8-8.8 SHCS at two locations.				
<i>Mounting:</i>		Rigid wall mounted using: (4) - 1/4" dia. Hex Washer Head, self-tapping, self-threading sheet metal (TEK) screws w/ - (2) - 1.25" O.D. x 5/16" I.D. fender washers at top and - (2) - standard washers at bottom to 16ga. backing plate.				
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Side-Axis	Front-Axis	Vert-Axis
19.7	9.5	24.8	66	---	---	---
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						
S _{DS} (G)	z/h	I _p	A _{FLX-H} (G)	A _{RIG-H} (G)	A _{FLX-V} (G)	A _{RIG-V} (G)
2.0	1	1.5	3.2	2.4	1.68	0.68
2.5	0					
Unit maintained structural integrity and remained functional per manufacturer requirement						



ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT 1914-2 Open Console w/ Z8G4						
<i>Manufacturer:</i>		GE Hangwei Medical Systems Co., LTD.				
<i>Identification:</i>		Model No.: 5946404-15 Serial No.: 000000HM1				
<i>Description:</i>		System component of several GEHC CT systems. - HP Z8G4 Computer - Open style console - Configuration controlled verification unit that is equivalent to standard production.				
<i>Mounting:</i>		Rigid Base (Floor) mounted using: GE Console Anchor Kit 5812703-2 (3) – 3/8" dia. SAE J429 Grade 8 bolts to test fixture. NOTE: Console Anchor Kit 5812703-2 is included standard w/ console.				
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Side-Axis	Front-Axis	Vertical-Axis
15.8	26.4	22.7	141.5 w/ brackets	14.6	30.1	26.2
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						
S _{DS} (G)	z/h	I _p	A _{FLX-H} (G)	A _{RIG-H} (G)	A _{FLX-V} (G)	A _{RIG-V} (G)
2.0 2.5	1 0	1.5	3.2	2.4	1.68	0.68
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.						



UUT-2212-1 Omni Legend PET-CT Gantry						
<i>Manufacturer:</i>		GE Healthcare				
<i>Identification:</i>		CT Gantry	PET Gantry			
Model No.		6670000-21	6890030-2			
Serial No.		688078HM5	None			
<i>Description:</i>		Component of Omni Legend PET/CT System Production equivalent unit CT Gantry Weight: 3434 lb PET Gantry Weight: 3638 lb Gantry requires the use of Omni Seismic Kit 5919418.				
<i>Mounting:</i>		Rigid Base (Floor) mounted using: (8) – 5/8" dia. SAE J429 Grade 8 bolts.				
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Side-Axis	Front-Axis	Vert-Axis
92	67	76	7072	11.45	7.43	15.42
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						
S _{DS} (G)	z/h	I _p	A _{FLX-H} (G)	A _{RIG-H} (G)	A _{FLX-V} (G)	A _{RIG-V} (G)
2.0 2.5	1.0 0.0	1.5	3.20	2.40	1.68	0.68
Unit maintained structural integrity and satisfied manufacturer requirement for CT diagnostic imaging.						



ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT-10390-3 PROSCAN Patient Table						
<i>Manufacturer:</i>		GE Healthcare				
<i>Identification:</i>		P/N: 5101900				
		S/N: 176453HM9				
<i>Description:</i>		System component of several GEHC PET/CT systems. Tested as component of Discovery PET/CT 690 System				
<i>Mounting:</i>		Rigid Base (Floor) Mounted using (4) - 5/8" diameter SAE J429 Grade 8 bolts to interface plate.				
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Side-Axis	Front-Axis	Vert-Axis
25.6	135.8	22/ 42	1808	---	5.3	>33
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						
S _{DS} (G)	z/h	I _p	A _{FLX-H} (G)	A _{RIG-H} (G)	A _{FLX-V} (G)	A _{RIG-V} (G)
1.52	1	1.5	2.43	1.82	1.02	0.41
Unit maintained structural integrity and remained functional per manufacturer requirement						



UUT-1901-1 Discovery MI PET-CT Gantry						
<i>Manufacturer:</i>		GE Healthcare				
<i>Identification:</i>		CT Gantry	PET Gantry			
Model No.		5454001-170	5990025-22			
Serial No.		CJRPX16000014CN	CL251900001PT			
<i>Description:</i>		System component of the Discovery MI PET-CT System. <ul style="list-style-type: none"> • Revolution EVO CT Gantry, PET Specific • 25cm Columbia PET Gantry (Weldment) The tested configuration included both a PET gantry and a CT gantry in a complete PET-CT assembly. Seismic Kit (P3000BK) installed. Unit included enhancements to construction not found on then-standard production units. These enhancements subsequently include in revision of Seismic Kit (P3000BK).				
<i>Mounting:</i>		Rigid Base (Floor) mounted using: (8) – 5/8" dia. SAE J429 Grade 8 bolts.				
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Side-Axis	Front-Axis	Vert-Axis
77.4	93.59	76	6383 (reported) 6206 (measured)	7.4	5.9	10.7
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						
S _{DS} (G)	z/h	I _p	A _{FLX-H} (G)	A _{RIG-H} (G)	A _{FLX-V} (G)	A _{RIG-V} (G)
2.0	1.0	1.5	3.20	2.40	1.68	0.68
2.5	0.0					
Unit maintained structural integrity and satisfied manufacturer requirement for CT diagnostic imaging.						

