DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION
FACILITIES DEVELOPMENT DIVISION

APPLICATION FOR HCAI SPECIAL SEISMIC CERTIFICATION PREAPPROVAL (OSP)

OFFICE USE ONLY

APPLICATION #: OSP-0735

HCAI Special Seismic Certification Preapproval (OSP)

Type: ☐ 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@gehcseismic.com

Product Information

Product Name: CT Systems

Product Type: NA

Product Model Number: Revolution Ascend

General Description: Multiple-component medical diagnostic imaging system. Special Seismic Certification is limited to components of the systems identified in Attachment 1 for functions related to Computed Tomography (CT) diagnostic imaging services.

Mounting Description: Rigid, Floor Mounted

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 Engineer

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

Seismic Parameters

Design Basis of Equipment or Components (F_p/W_p) = See Attachment

S_{DS} (Design spectral response acceleration at short period, g) = 2.0 at z/h = 1; 2.5 at z/h = 0

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 and 0

Natural frequencies (Hz) = See Attachment

Overall dimensions and weight = See Attachment

HCAI Approval (For Office Use Only) - Approval Expires on 12/06/2029

Date: 12/6/2023

Name: Mohammad Karim Title: Supervisor, Health Facilities

Special Seismic Certification Valid Up to: S_{DS} (g) = See Above z/h = See Above

Condition of Approval (if applicable):

ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS

TABLE 1:

Manufacturer	**GE HEALTHCARE**	**S_{DS} = 2.0 at z/h = 1** **S_{DS} = 2.5 at z/h = 0**
System	**Revolution Ascend; Revolution Ascend Elite; Revolution Ascend Plus; Revolution Ascend Select** [2]	

COMPONENT	MODEL NUMBER	APPROX. DIMENSIONS [IN] W	D	H	MAX. WT. [LB]	MOUNT	BASIS [1]	F_P/W_P	a_P	R_P	Ω_0
GANTRIES [3]											
Revolution Ascend Gantry	6969000-300	84.6	40.8	75.8	3979	Rigid Base	UUT-2201-1	2.40	1	1 ½	2
Revolution Ascend Gantry	6969000-200	84.6	40.8	75.8	3979	Rigid Base	SAME	2.40	1	1 ½	2
Revolution Ascend Gantry	6969000-100	84.6	40.8	75.8	3979	Rigid Base	SAME	2.40	1	1 ½	2
Revolution Ascend Elite Gantry	6967000-100	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Elite Gantry	6967000-200	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Elite Gantry	6967000-300	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Plus Gantry	6966000-100	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Plus Gantry	6966000-200	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Plus Gantry	6966000-300	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Select Gantry	6965000-100	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Select Gantry	6965000-200	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution Ascend Select Gantry	6965000-300	84.6	40.8	75.8	3979	Rigid Base	INT	2.40	1	1 ½	2
Revolution EVO Gantry	*5454001-60*	*80.7*	*40.9*	*76.3*	*4012*	*Rigid Base*	*UUT-1433-1*	*2.40*	*1*	*1 ½*	*2*
PATIENT TABLES [4]											
GT1700V	*5122080-11*	*25.6*	*93.3*	*19.2 - 41.2*	*1059* [5]	*Rigid Base*	*UUT-1126-2*	*2.40*	*1*	*1 ½*	*2*
GT1700V	5122080-12	25.6	93.3	19.2 - 41.2	1059	Rigid Base	SAME	2.40	1	1 ½	2
GT2000X	5380966	25.6	114.5	18.3 - 41.3	1258	Rigid Base	INT	2.40	1	1 ½	2
GT2000	*5121647-3*	*25.6*	*114.5*	*18.3 - 41.3*	*1146* [6]	*Rigid Base*	*UUT-1408-4*	*2.40*	*1*	*1 ½*	*2*
GT2000	5121647-4	25.6	114.5	18.3 - 41.3	1146	Rigid Base	SAME	2.40	1	1 ½	2
NG1700 Elite Standard Table	5989000	25.6	118.3-179.7	19.5 - 41.2	1209 [9]	Rigid Base	UUT-2309-1A	2.40	1	1 ½	2
NG2000 Elite Heavy Table	5979000	25.6	135.1-210.2	19.5 - 41.2	1315 [10]	Rigid Base	UUT-2309-2	2.40	1	1 ½	2

Table continues next page.

TABLE 1:

CONSOLES [7]											
Operator Console - Standalone	5940104-31	23.6	25.6	21.0	132	Rigid Base	UUT-2201-2	1.44	1	2 ½	2
Operator Console - Standalone	5940104-21	23.6	25.6	21.0	132	Rigid Base	SAME	1.44	1	2 ½	2
Operator Console - Standalone	5940104-11	23.6	25.6	21.0	132	Rigid Base	SAME	1.44	1	2 ½	2
POWER DISTRIBUTION (PDU) [8]											
Power Distribution Unit	*2326492-80*	*27.6*	*21.7*	*41.8*	*841*	*Rigid Base*	*UUT-1126-3*	*1.44*	*1*	*2 ½*	*2*
Power Distribution Unit	2326492-81	27.6	21.7	41.8	841	Rigid Base	SAME	1.44	1	2 ½	2
Power Distribution Unit	2326492-31	27.6	21.7	41.8	816	Rigid Base	UUT-2309-3	1.44	1	2 ½	2

Mount	RIGID BASE: free-standing, base-mounted configuration with the component rigidly attached to a supporting structure and no lateral support above the base.
Notes	1. BASIS: • 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. 2. All listed systems require system seismic kit 5881922 (also referenced as B77162RE). 3. Gantries are qualified with 4 or 8 anchors and require the use of seismic kit 5881922. 4. Patient Tables require the use of seismic kit 5881922. 5. *Patient Table (GT1700V) weight does not include 350 LB patient load present during testing.* 6. *Patient Table (GT2000) weight does not include 550 LB patient load present during testing.* 7. Operator consoles require the use of seismic kit 5881922. 8. Power Distribution Units require the use of seismic mounting bracket P/N 2354563-2. 9. Patient Table (NG1700 Elite) weight includes footswitch but excludes 500 lb. patient load present during test. 10. Patient Table (NG2000 Elite) weight includes footswitch but excludes 544 lb. patient load present during test 11. *Gray italic formatting indicates unit is not a component of system and used as basis for seismic qualification only.*

UUT-1126-2 GT1700V Patient Table

MANUFACTURER:	GE Hangwei Medical Systems Co., LTD
IDENTIFICATION:	Model No.: 5122080-11
DESCRIPTION:	Component of the Optima CT660 System included as basis for components of Revolution Ascend CT System 350 lb. simulated patient load (not included in tabulated weight). Unit requires the use of Seismic Kit 5881922 which contains mounting hardware assemblies.
MOUNTING:	Rigid Base: mounted using (4) – 5/8" dia. hex head bolts to interface plate.

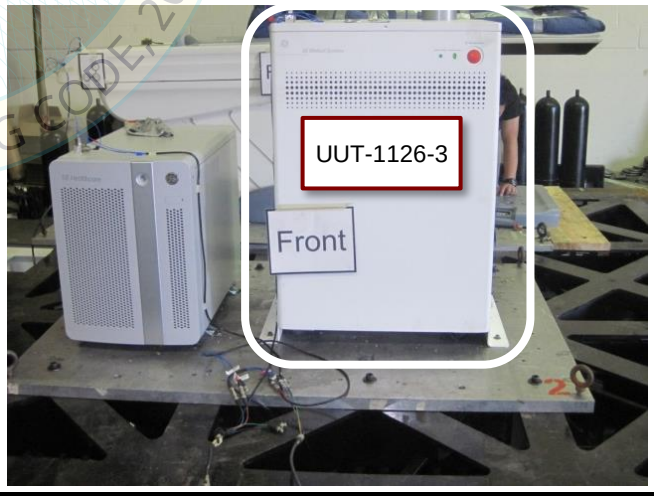
DIMENSIONS [in]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight [lb]	Transverse-Axis	Longitudinal-Axis	Vertical-Axis
25.6	93.3	36	1059	3.9	15.2	14.2

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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 2.6	1.0 0.0	1.5	3.20	2.40	1.74	0.70

Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-1126-3 Power Distribution Unit (PDU)

MANUFACTURER:	GE Hangwei Medical Systems Co., LTD
IDENTIFICATION:	Model No.: 2326492-80 Serial No.: 270337HM9
DESCRIPTION:	Component of the Optima CT660 System included as basis for component of Revolution Ascend CT System
MOUNTING:	Rigid Base (Floor) mounted using: (2) – 3/8" dia. ASTM A574 Socket Head Cap Screws w/ washer through each GE mounting bracket to floor plate. (4 anchors total) GE mounting assembly including: (2) – Seismic Bracket (P/N 2354563-2) Each bracket mounted to cabinet w/: (2) – M10 x 25mm Class 12.9 bolt (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]	F/B (X) - Axis	S/S (Y) - Axis	Vert (Z) - Axis
27.6	21.7	41.8	841	20.4	20.6	13.8

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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 satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-1408-4 GT2000 Patient Table

MANUFACTURER:	GE Hangwei Medical Systems CO. LTD.
IDENTIFICATION:	Model No.: 5121647-3
DESCRIPTION:	Component of the LightSpeed VCT System included as basis for components of Revolution Ascend CT System 550 lb. simulated patient load (not included in tabulated weight). Unit requires the use of Seismic Kit 5881922 which contains mounting hardware assemblies.
MOUNTING:	Rigid Base: (4) – 5/8" dia GR 8 hex head bolts w/ GEHC supplied patient table foot assembly.

DIMENSIONS [in]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight [lb]	Transverse-Axis	Longitudinal-Axis	Vertical-Axis
25.6	114.5	35.5	1146	2.7	7.1	5.7

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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	3.20	2.40	1.68	0.68

Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-2201-1 Revolution Ascend Gantry

MANUFACTURER:	GE Healthcare Japan Corporation
IDENTIFICATION:	Model No.: 6969000-300 Serial No.: NG004
DESCRIPTION:	Component of Revolution Ascend CT System Contains modification that will be included in standard production units. Unit requires the use of Seismic Kit 5881922 which contains mounting hardware assemblies.
MOUNTING:	Rigid Base: mounted using (4) or (8) – 5/8" dia GR 8 hex head bolts w/ GEHC supplied mounting hardware assemblies.

DIMENSIONS [in]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight [lb]	S/S (X) - Axis	F/B (Y) - Axis	Vert (Z) - Axis
84.6	40.8	75.8	3979	9.00	6.22	8.99

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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	3.20	2.40	1.68	0.68

Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-2201-2 Operator Console - Standalone

MANUFACTURER:	GE Healthcare Japan Corporation
IDENTIFICATION:	Model No.: 5940104-31 Serial No.: SACENG002
DESCRIPTION:	Component of Revolution Ascend CT System Includes: HP Z8 G4 Workstation (ID No.: 5809620-7 Serial No.: 4CV907WMT2) GE Healthcare Power Box (ID No.: 5808401-2 Serial No.: DW2003029) Unit requires the use of Seismic Kit 5881922 which contains mounting bracket hardware.
MOUNTING:	Rigid Base: mounted using (3) – 3/8" dia. hex head bolts to interface plate.

DIMENSIONS [in]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight [lb]	S/S (X) - Axis	F/B (Y) - Axis	Vert (Z) - Axis
23.6	25.6	21.0	132	24.62	31.57	20.89

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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	3.20	2.40	1.68	0.68

Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-2309-1A NG1700 Elite Standard Table

MANUFACTURER:	GE Hangwei Medical Systems CO. LTD.
IDENTIFICATION:	Model No.: 5989000 Serial No.: 755251HM6
DESCRIPTION:	Component of Revolution Ascend CT System. Unit modified at lab prior to test. Modification shall become part of standard manufactured product. Requires use of system seismic kit B77162RE (5881922) which contains mounting hardware assemblies for table. 500 lb. simulated patient load (not included in tabulated weight).
MOUNTING:	Rigid Base: (6) – 5/8" dia SAE J429 Grade 5 bolts w/ GE supplied patient table foot assembly.

DIMENSIONS [in]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight [lb]	Longit. (X) - Axis	Transv. (Y) - Axis	Vert (Z) - Axis
25.6	147.5	32.7	1209	11.0	3.5	5.7

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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	3.20	2.40	1.68	0.68

Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-2309-2 NG2000 Elite Heavy Table

MANUFACTURER:	GE Hangwei Medical Systems CO. LTD.
IDENTIFICATION:	Model No.: 5979000 Serial No.: 755250HM8
DESCRIPTION:	Component of Revolution Ascend CT System. Unit modified at lab prior to test. Modification shall become part of standard manufactured product. Requires use of system seismic kit B77162RE (5881922) which contains mounting hardware assemblies for table. 544 lb. simulated patient load (not included in tabulated weight).
MOUNTING:	Rigid Base: (6) – 5/8" dia SAE J429 Grade 5 bolts w/ GE supplied patient table foot assembly.

DIMENSIONS [in]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight [lb]	Longit. (X) - Axis	Transv. (Y) - Axis	Vert (Z) - Axis
25.6	164.3	32.7	1315	10.2	3.3	6.5

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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	3.20	2.40	1.68	0.68

Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-2309-3 Power Distribution Unit (PDU)

MANUFACTURER:	GE Hangwei Medical Systems Co., LTD
IDENTIFICATION:	Model No.: 2326492-31 Serial No.: ENG prototype 006
DESCRIPTION:	Component of Revolution Ascend CT System * Weight includes 22 lb mounting brackets.
MOUNTING:	Rigid Base (Floor) mounted using: (2) – 1/2" dia. SAE J429 Grade 5 bolts w/ washer through each GE mounting bracket to floor plate. (4 anchors total) GE mounting assembly including: (2) – Seismic Bracket (P/N 2354563-2) Each bracket mounted to cabinet w/: (2) – M10 x 25mm Class 12.9 bolt (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]	F/B (X) - Axis	S/S (Y) - Axis	Vert (Z) - Axis
27.6	21.7	41.8	816 *	19.1	15.1	27.5

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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 satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.

UUT-1433-1 REVOLUTION EVO GANTRY

MANUFACTURER:	GE Healthcare
IDENTIFICATION:	Model No. 5454001-60
DESCRIPTION:	System component of the Discovery 610 PET/CT System Larger variant of the Freedom Workspace table w/ (2)-EIZO LCD Monitors mounted to articulated arms Requires Seismic Kit B7660MY
MOUNTING:	Rigid Base (Floor) mounted using (4) – 5/8" DIA GR 8 bolts w/ GEHC supplied foot assembly to HSS interface frame.

DIMENSIONS [in]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight [lb]	F/B (X) - Axis	S/S (Y) - Axis	Vert (Z) - Axis
80.7	40.9	76.3	4178	5.5	5.5	7.4

ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2022 CBC
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 remained functional per manufacturer requirement