APPLICATION FOR HCAI SPECIAL SEISMIC CERTIFICATION PREAPPROVAL (OSP)

OFFICE USE ONLY

APPLICATION #: OSP-0628

HCAI Special Seismic Certification Preapproval (OSP)

Type: ☐ New ☒ Renewal

Manufacturer Information

Manufacturer: GE Healthcare

Manufacturer's Technical Representative: Tom Farrow

Mailing Address: 3000 N. Grandview Blvd., Waukesha, WI 531881696

Telephone: (888) 406-1101 Email: Tom.Farnow@gehcseismic.com

Product Information

Product Name: CT Systems

Product Type: NA

Product Model Number: See Attachment 1

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

Mounting Description: Rigid Base mount

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

Contact Person: Jonathan Roberson

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

Telephone: (909) 606-7622 Email: j.roberson@easeco.com

Title: SE

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 1

S_{DS} (Design spectral response acceleration at short period, g) = 2.00 (z/h = 1); 2.50 (z/h = 0)

a_p (Amplification factor) = See Attachment 1

R_p (Response modification factor) = See Attachment 1

Ω_0 (System overstrength factor) = See Attachment

I_p (Importance factor) = 1.5

z/h (Height ratio factor) = 1 and 0

Natural frequencies (Hz) = See Attachment 2

Overall dimensions and weight = See Attachment 1

HCAI Approval (For Office Use Only) - Approval Expires on 07/10/2029

Date: 7/10/2023

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:

SYSTEM MFR.	**GE Healthcare**
SYSTEM	**Revolution Maxima / Revolution Ace**

COMPONENT	MODEL NUMBER	APPROX. DIMENSIONS (IN.) W	D	H	MAX. WT. (LB.)	MOUNT [6]	BASIS [1]	F_P/W_P	S_{DS}	z/h	a_P	R_P	Ω_0
GANTRIES [5]													
Revolution Maxima Gantry	6670000-2	80.4	40.2	76.3	3434	Floor	UUT1914-1	2.40 1.13	2.0 2.5	1 0	1	1 ½	1 ½
Revolution Maxima Gantry	6670000-4	80.4	40.2	76.3	3434	Floor	SAME						
Revolution Maxima Gantry	6670000-200	80.4	40.2	76.3	3434	Floor	SAME						
Revolution Maxima Gantry	6670000-400	80.4	40.2	76.3	3434	Floor	SAME						
Revolution Ace Gantry	6670000-3	80.4	40.2	76.3	3434	Floor	SAME						
Revolution Ace Gantry	6670000-5	80.4	40.2	76.3	3434	Floor	SAME						
PATIENT TABLES [5]													
GT1700V Table	5122080-11 [4]	25.6	93.3	19.2 / 41.2	1059 [2]	Floor	UUT1126-2	2.40 1.13	2.0 2.5	1 0	1	1 ½	1 ½
GT1700V Table	5122080-12	25.6	93.3	19.2 / 41.2	1059	Floor	SAME						
CONSOLES													
Open Console w/ Z8G4	5946404-15	15.8	26.4	22.7	142 [3]	Floor	UUT1914-2	1.44 1.13	2.0 2.5	1 0	1	2 ½	2
Open Console w/ Z8G4	5946404-25	15.8	26.4	22.7	142 [3]	Floor	SAME						
POWER DISTRIBUTION													
Power Distribution Unit	2326492-80 [4]	27.6	21.7	41.8	841 [3]	Floor	UUT1126-3	1.44 1.13	2.0 2.5	1 0	1	2 ½	2
Power Distribution Unit	2326492-81	27.6	21.7	41.8	841 [3]	Floor	SAME						

MOUNT	Floor (Rigid Base): free-standing, base-mounted tower 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. • SAME: Model is physically, mechanically & electrically identical to a tested unit, except for possible variations in model number, color and/or software. 2. 1700V Patient Table weight does not include the 350 lb. simulated patient load present during testing. 3. Weight includes mounting bracket hardware. 4. Model is not used with the system(s) identified in this table; it is included only to establish basis for seismic qualification. 5. Requires use of additional GE bushing kit B76632DA (P/N 5841169). 6. See Attachment 2 for additional mounting information.

ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT 1914-1 Revolution Maxima CT Gantry

Manufacturer:	GE Hangwei Medical Systems Co., LTD.
Identification:	Model No.: 6670000-2 Serial No.: 000000HM11
Description:	Component of Revolution Maxima - Non-tilt Gantry - Touchscreen display on front (x2) - Configuration controlled verification unit that is equivalent to standard production.
Mounting:	Rigid Base (Floor) mounted using: (4) – 5/8" dia. SAE J429 Grade 8 bolts to test fixture. GE Bushing Kit P/N 5841169.

Dimensions (in.)				Lowest Resonant Frequency (Hz.)		
Width	Depth	Height	Weight (lb.)	Front-Axis	Side-Axis	Vertical-Axis
80.4	40.2	76.3	3434	9.9	11.6	14.0

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	3.2	2.4	1.68	0.68

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

UUT 1914-2 Open Console w/ Z8G4

Manufacturer:	GE Hangwei Medical Systems Co., LTD.
Identification:	Model No.: 5946404-15 Serial No.: 000000HM1
Description:	Component of the Revolution Maxima / Revolution Ace CT Systems - HP Z8G4 Computer - Open style console - Configuration controlled verification unit that is equivalent to standard production.
Mounting:	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						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	3.2	2.4	1.68	0.68

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

ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT 1126-2 GT1700V Table

Manufacturer:	GE Hangwei Medical Systems Co., LTD
Identification:	Model No.: 5122080-11
Description:	System component of the **Optima CT660 System.** Also used with other CT systems. Test specimen included a simulated patient load of 350 lb. Requires additional kit as follows: • B7660MY (Optima CT660 system) • B76632DA (Revolution Maxima / Revolution Ace)
Mounting:	Rigid Base (Floor) mounted using (4) – 5/8" dia. hex head bolts to test fixture.

Dimensions (in.)				Lowest Resonant Frequency (Hz.)		
Width	Depth	Height	Weight (lb.)	Transverse-Axis	Longitudinal-Axis	Vertical-Axis
25.6	93.3	19.2 / 41.2	1059+ 350 Patient	3.9	15.2	14.2

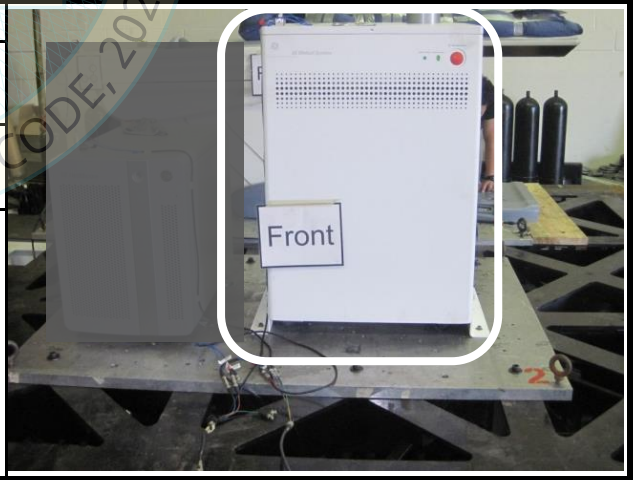
ICC-ES AC156 Shake Table Test Parameters **Code: 2022 CBC**

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	1.5	3.2	2.4	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:	System component of the **Optima CT660 System.** Also used with other CT systems.
Mounting:	Rigid Base (Floor) mounted using: (4) – 3/8" dia. ASTM A574 Socket Head Cap Screws w/ washer through GE mounting brackets to floor plate. (2 anchors ea. bracket) GE mounting assembly including: (2) – Seismic Bracket, System Cabinet (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.)	Front-Axis	Side-Axis	Vertical-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 2.6	1 0	1.5	3.2	2.4	1.74	0.70

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