



DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION
FACILITIES DEVELOPMENT DIVISION

APPLICATION FOR HCAI SPECIAL SEISMIC
CERTIFICATION PREAPPROVAL (OSP)

OFFICE USE ONLY

APPLICATION #: OSP-0812

HCAI Special Seismic Certification Preapproval (OSP)

Type: [X] New [] Renewal

Manufacturer Information

Manufacturer: Canon Medical Systems Corporation

Manufacturer's Technical Representative: Krystal Ouren

Mailing Address: 2441 Michelle Drive, Tustin, CA 92780

Telephone: (949) 540-5781

Email: kouren@us.medical.canon

Product Information

Product Name: CT Systems

Product Type: NA

Product Model Number: Aquilion ONE / INSIGHT Edition (See Attachment 1)

General Description: Multiple component system for the provision of Computed Tomography (CT) medical imaging. Seismic Certification is limited to the systems & components identified in Attachment 1.

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)

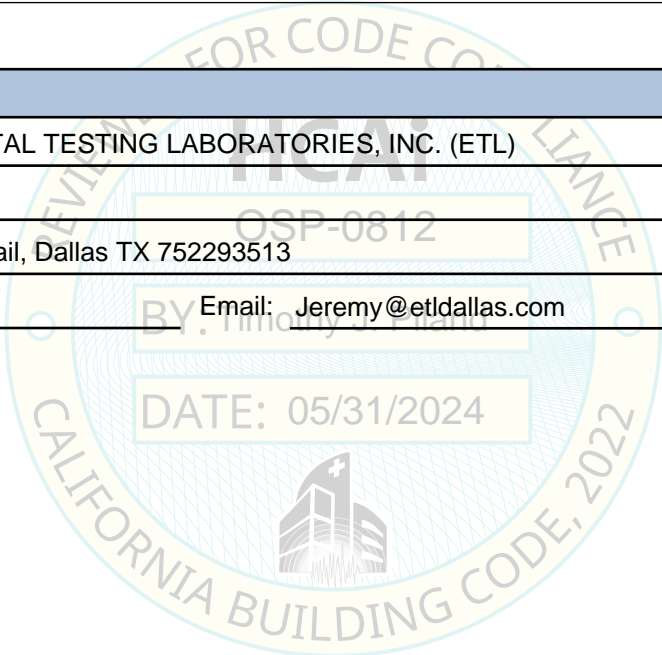
Company Name: EASE LLC
Name: Jonathan Roberson California License Number: S4197
Mailing Address: 5877 Pine Ave., Suite 210, Chino Hills, CA 91709
Telephone: (951) 295-1892 Email: jon@EASECo.com

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 752293513
Telephone: (972) 247-9657 Email: Jeremy@etldallas.com



"A healthier California where all receive equitable, affordable, and quality health care"



STATE OF CALIFORNIA – HEALTH AND HUMAN SERVICES AGENCY



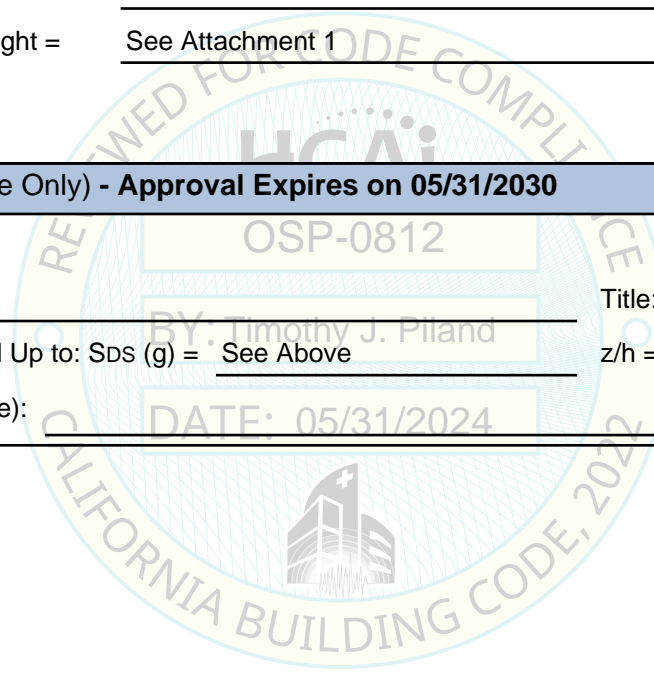
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Seismic Parameters

Design Basis of Equipment or Components (F_p/W_p) =	See Attachment 1
SDS (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 1
R_p (Response modification factor) =	See Attachment 1
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 2
Overall dimensions and weight =	See Attachment 1

HCAI Approval (For Office Use Only) - Approval Expires on 05/31/2030

Date:	5/31/2024		
Name:	Timothy Piland	Title:	Senior Structural Engineer
Special Seismic Certification Valid Up to: SDS (g) =	See Above	z/h =	See Above
Condition of Approval (if applicable):			



ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS

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TABLE 1:

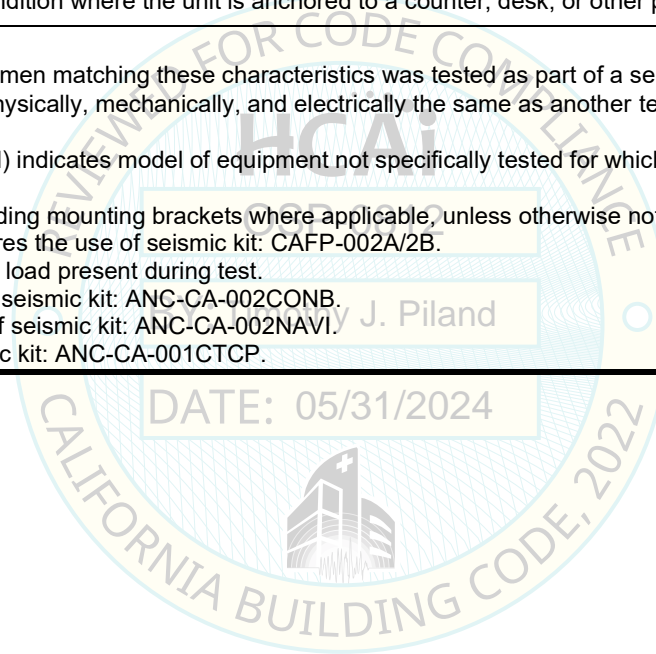
Manufacturer		CANON MEDICAL SYSTEMS CORPORATION							S _{DS} = 2.0 at z/h = 1		
System		Aquilion ONE / INSIGHT Edition (TSX-308A/3)							S _{DS} = 2.5 at z/h = 0		
Component	Identification No.	Approx. Dimensions [in.]			Wt. [lb] ^[2]	Mount	Basis ^[1]	F _P /W _P	a _P	R _P	Ω ₀
		W	D	H							
CT GANTRIES											
Aquilion CT Scanner Gantry – Type H	CGGT-046A/1A	91.73	37.8	78.54	5340	Rigid Base	UUT-2301-1	2.40 1.13	1	1 ½	2
w/ Gantry Rear Panel Kit Option	CAGP-008A/1B										
w/ Gantry Illumination Kit Option	CGLT-002A/1B										
PATIENT COUCHES											
Patient Couch ^[4]	CBTB-041A/1A	27.2	113 – 197	21.7 – 41.7	1595	Rigid Base	UUT-2301-3	2.40 1.13	1	1 ½	2
w/ CT Fluoro Option ^[3] (For Couch Operating Panel)	TSXF-008A/1B										
POWER DISTRIBUTION											
Power Distributor (Type G)	CETF-010B/2A	32.3	26.77	51.77	1434	Rigid Base	UUT-2301-7	1.44 1.13	1	2 ½	2
Power Distributor – Type G	CETF-010B/2A	33.5	26.8	51.8	1433	Rigid Base	UUT-1906-6	1.44 1.13	1	2 ½	2
w/ UPS Kit for Power Distributor	CEUC-001A/6B										
Power Distributor – Type G	CETF-010B/2A	33.5	26.8	51.8	1433	Rigid Base	SAME AS UUT-1906-6	1.44 1.13	1	2 ½	2
w/ UPS Kit for Power Distributor	CEUC-002A/6B										
CONSOLE COMPONENTS											
Con Box – Type G ^[5]	CKCN-021A/1B	23.23	38.0	66.1	865	Rigid Base	UUT-2301-4	1.44 1.13	1	2 ½	2
w/ Display Console Option	CGS-93A/1B										
w/ Reconstruction Processing Option	CCRS-003A/1C										
NAVI Box – Type A ^[6]	CKCN-021A/1B	7.8	12.1	13.7	27	Rigid Base	UUT-2301-6	1.44 1.13	1	2 ½	2
USER INTERFACE											
Control Pad ^[7]	BSX74-3199*B	11.7	3.6	2.4	1.9	CTA	UUT-2202-3	1.44 1.13	1	2 ½	2
Monitor 27" LCD on Standard Mount (Shenzhen Beacon Display Technology Co., Ltd.)	BSX75-0608E*A	25.4	9.9	18.3 – 21.4	26.5	CTA	UUT-2202-4	1.44 1.13	1	2 ½	2
Monitor 27" LCD (Shenzhen Beacon Display Technology Co., Ltd.)	BSX75-0608E*A	25.4	8	19	21.5	CTA	UUT-2202-5	1.44 1.13	1	2 ½	2
w/ Optional Peerless-AV Mount	LCT100S										

Table continues next page


ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS


TABLE 1:

<i>Manufacturer</i>	CANON MEDICAL SYSTEMS CORPORATION										$S_{DS} = 2.0$ at $z/h = 1$	
<i>System</i>	Aquilion ONE / INSIGHT Edition (TSX-308A/3)										$S_{DS} = 2.5$ at $z/h = 0$	
Component	Identification No.	Approx. Dimensions [in.]			Wt. [lb] ^[2]	Mount	Basis ^[1]	F _P /W _P	a _P	R _P	Ω ₀	
		W	D	H								
<i>Mount</i>	<p><u>Rigid Base</u>: free-standing, base-mounted configuration with the component rigidly attached to a supporting structure and no lateral support above the base.</p> <p><u>CTA (Countertop Anchored)</u>: refers to a condition where the unit is anchored to a counter, desk, or other piece of rigid fixed furniture.</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 a seismic test program. • "SAME" indicates component is physically, mechanically, and electrically the same as another test specimen with differences limited to model number, color, and/or software. • "INT" (Interpolated or Extrapolated) indicates model of equipment not specifically tested for which seismic qualification is established through testing of similar models in the product line. <p>2. Tabulated weights are as tested, including mounting brackets where applicable, unless otherwise noted.</p> <p>3. CT Fluoro Rail Holder Assembly requires the use of seismic kit: CAFP-002A/2B.</p> <p>4. Patient Couch weight excludes patient load present during test.</p> <p>5. Con Box – Type G requires the use of seismic kit: ANC-CA-002CONB.</p> <p>6. NAVI Box – Type A requires the use of seismic kit: ANC-CA-002NAVI.</p> <p>7. Control Pad requires the use of seismic kit: ANC-CA-001CTCP.</p>											




ATTACHMENT 2: TEST SPECIMEN SUMMARY


UUT-2301-1 Aquilion CT Scanner Gantry – Type H						
MANUFACTURER: Canon Medical Systems Corporation						
IDENTIFICATION: ID No.: CGGT-046A/1A Serial No.: 1AA2352002						
DESCRIPTION: Component of Aquilion ONE / INSIGHT Edition System (as tested) <u>Includes Gantry Rear Panel Kit option</u> ID No.: CAGP-008A/1B <u>Includes Gantry Illumination Kit Option</u> ID No.: CGLT-002A/1B						
MOUNTING: Rigid Base (Floor) mounted using (8) – 3/4" diameter SAE J429 Grade 8 bolts.						
DIMENSIONS [in.]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight (lb.)	Side Axis	Front Axis	Vertical Axis
91.73	37.8	78.54	5340	8.15	7.18	7.68
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	3.20	2.40	1.68	0.68
2.5	0					
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.						

UUT-2301-3 Patient Couch						
MANUFACTURER: Canon Medical Systems Corporation						
IDENTIFICATION: ID No.: CBTB-041A/1A Serial No.: 1AA2352002						
DESCRIPTION: Component of Aquilion ONE / INSIGHT Edition System (as tested) <u>Included options:</u> CT Fluoro TSXF-008A/1B (for Couch Operating Panel) Requires use of Seismic Kit CAFP-002A/2B (for Fluoro Option) *Test Patient Load of 562 lb not included in component weight Test in clinical position: Depth = 149" / Height = 38.2"						
MOUNTING: <u>Rigid Base (Floor) Mounted:</u> (6) – 5/8" dia. SAE J429 Grade 5 Hex Head Bolts to aluminum interface plate.						
PROPERTIES:						
DIMENSIONS [in.]				LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Weight (lb.)	Transverse Axis	Longitudinal Axis	Vertical Axis
27.2	113 – 197	21.7 – 41.7	1595*	3.79	7.18	7.91
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	3.20	2.40	1.68	0.68
2.5	0					
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.						


ATTACHMENT 2: TEST SPECIMEN SUMMARY


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UUT-2301-4 CON Box – Type G with Options							
MANUFACTURER: Canon Medical Systems Corporation							
IDENTIFICATION: ID No.: CKCN-021A/1B Serial No.: 1BB2352002							
DESCRIPTION: Component of Aquilion ONE / INSIGHT Edition System (as tested) <u>Included options:</u> (1) Display Console Kit ID No.: CGS-93A/1B Serial No.: 1BA2357002 (2) Reconstruction. Processing Kit ID No.: CCRS-003A/1C Serial No.: CCRS-003A/1C Requires use of Seismic Kit: ANC-CA-002CONB.							
MOUNTING: Rigid Base (Floor) Mounted: (6) – 1/2" dia. SAE J429 Grade 5 Hex Head Bolts to aluminum interface plate.							
PROPERTIES:							
DIMENSIONS [in.]				Weight (lb.)	LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height			Side Axis	Front Axis	Vertical Axis
23.2	38.0	66.1	865 (as tested)	13.61	11.74	12.71	
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	3.20	2.40	1.68	0.68	
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.							

UUT-2301-6 NAVI Box – Type A							
MANUFACTURER: Canon Medical Systems Corporation							
IDENTIFICATION: ID No.: CKCN-021A/1B Serial No.: 1BB2352002							
DESCRIPTION: Component of Aquilion ONE/ INSIGHT Edition (as tested) Requires use of Seismic Kit: ANC-CA-002NAVI							
MOUNTING: Countertop Anchored (CTA) mounted using (4) #10 x 3/4" Flat Head Wood Screws through external brackets included in seismic kit into 1-1/8" thick Plywood							
PROPERTIES:							
DIMENSIONS [in.]				Weight (lb.)	LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height			Front Axis	Side Axis	Vertical Axis
13.7	12.1	7.8	26 w/o brackets 27 w/ brackets	48.94	>50	48.65	
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	3.20	2.40	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-2301-7 Power Distributor – Type G							
MANUFACTURER: Canon Medical Systems Corporation							
IDENTIFICATION: ID No.: CETF-010B/2A Serial No.: 2AA2352413							
DESCRIPTION: Component of Aquilion ONE/ INSIGHT Edition (as tested)							
MOUNTING: <u>Rigid Base (Floor) Mounted:</u> (6) – 1/2" dia. SAE J429 Grade 8 Hex Head Bolts to aluminum interface plate.							
PROPERTIES:							
DIMENSIONS [in.]				LOWEST RESONANT FREQUENCY [Hz]			
Width	Depth	Height	Weight (lb.)	Side Axis	Front Axis	Vertical Axis	
32.3	26.13	51.25	1434 (as tested)	12.46	11.82	12.48	
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	3.20	2.40	1.68	0.68	
2.5	0						
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.							

UUT-1906-6 Power Distributor – Type G with UPS Kit							
MANUFACTURER: Canon Medical Systems Corporation							
IDENTIFICATION: ID No.: CETF-010B/2A Serial No.: 2AA1967001							
DESCRIPTION: Component of Aquilion ONE / PRISM Edition CT System (TSX-306A/3) (as tested) <u>Includes UPS Kit for Power Distributor</u> ID No.: CEUC-001A/6B Serial No.: 6BB1967002							
MOUNTING: <u>Rigid Base (Floor) Mounted:</u> (6) – 1/2" dia. SAE J429 Grade 8 Hex Head Bolts to aluminum interface plate.							
PROPERTIES:							
DIMENSIONS [in.]				LOWEST RESONANT FREQUENCY [Hz]			
Width	Depth	Height	Weight (lb.)	Side Axis	Front Axis	Vertical Axis	
33.5	26.8	51.8	1433	9.91	9.93	16.65	
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	3.20	2.40	1.68	0.68	
2.5	0						
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.							

ATTACHMENT 2: TEST SPECIMEN SUMMARY

UUT-2202-3 Control Pad	
MANUFACTURER:	Canon Medical Systems Corporation
IDENTIFICATION:	ID No.: BSX74-3199*B Serial No.: 2250037
DESCRIPTION:	Component of Aquilion ONE / PRISM Edition CT System (TSX-306A/3) (as tested) Requires use of Seismic Kit: ANC-CA-001CTCP
MOUNTING:	Countertop Anchored (CTA) mounted using (1) 1/2" x 7.5" strip and (2) 1/2" x 2.5" strips 3M Dual Lock (SJ3540 to SJ3540) on 1-1/8" thick Plywood with control pad case feet removed



PROPERTIES:							
DIMENSIONS [in.]				Weight (lb.)	LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Side Axis		Front Axis	Vertical Axis	
11.7	3.6	2.4	1.9	29.25	27.91	28.24	
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	3.20	2.40	1.68	0.68	
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.							

UUT-2202-4 Monitor 27" LCD on Standard Mount	
MANUFACTURER:	Shenzhen Beacon Display Technology Co., Ltd.
IDENTIFICATION:	Part No.: BSX75-0608E*A Serial No.: CL2713*A22150014
DESCRIPTION:	Component of Aquilion ONE / PRISM Edition CT System (TSX-306A/3) (as tested) 27" LCD Monitor including standard mount *Tested at 21" height
MOUNTING:	Countertop Anchored (CTA) mounted using (4) #10 x 1-3/4" Flat Head Wood Screws into 1-1/8" thick Plywood



PROPERTIES:							
DIMENSIONS [in.]				Weight (lb.)	LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Side Axis		Front Axis	Vertical Axis	
25.4	9.9	18.3 – 21.4*	26.5	4.56	4.04	4.12	
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	3.20	2.40	1.68	0.68	
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.							

ATTACHMENT 2: TEST SPECIMEN SUMMARY

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UUT-2202-5 Monitor 27" LCD with Optional Peerless-AV Mount							
MANUFACTURER:		Shenzhen Beacon Display Technology Co., Ltd.					
IDENTIFICATION:		Part No.: BSX75-0608E*A					
		Serial No.: CL2713*A21150006					
DESCRIPTION:		Component of Aquilion ONE / PRISM Edition CT System (TSX-306A/3) (as tested)					
		27" LCD Monitor w/ Optional Peerless-AV LCT100S Desktop Mount					
MOUNTING:		Countertop Anchored (CTA) mounted using (1) M10 Bolt w/ nut and grommet included in LCT100S Desktop Mount through 1-1/8" thick Plywood					
PROPERTIES:							
DIMENSIONS [in.]				Weight (lb.)	LOWEST RESONANT FREQUENCY [Hz]		
Width	Depth	Height	Side Axis		Front Axis	Vertical Axis	
25.4	8	19	21.5	5.21	9.46	9.33	
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)	
2.0	1	1.5	3.20	2.40	1.68	0.68	
2.5	0						
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.							

