



**OFFICE OF STATEWIDE HEALTH PLANNING AND DEVELOPMENT
FACILITIES DEVELOPMENT DIVISION**

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

OFFICE USE ONLY

APPLICATION #: OSP-0710

OSHPD Special Seismic Certification Preapproval (OSP)

Type: New Renewal

Manufacturer Information

Manufacturer: GENERAL MEDICAL MERATE SpA Manufacturer's

Technical Representative: Francesca Colamonaco

Mailing Address: Via Partigiani 25, Seriate, BG 24068

Telephone: On File

Email: On File

Product Information

Product Name: Fluoroscopy and Radiography Systems

Product Type: NA

Product Model Number: CLISIS Systems (Seismic Version)

General Description: The CLISIS Systems (Seismic Version) is a multiple component medical imaging system which consists of a table unit, system digital cabinet, generator, and a user interface comprised of a monitor, control console, and extender box for keyboard and mouse input. Additionally, the system may be configured to include an optional non-tilting manually positioned wallstand unit, and/or optional manually positioned Overhead Tube Suspension (OTS). Evaluation for seismic qualification is limited to basic r

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





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

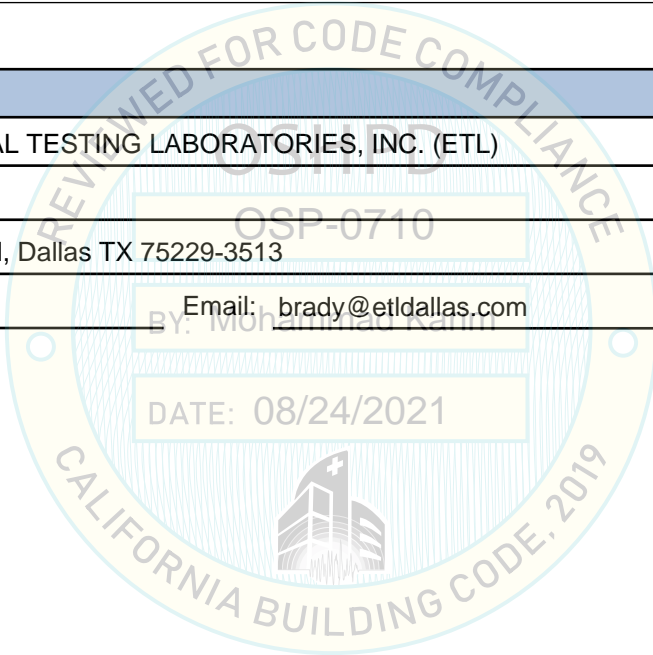
Company Name: EASE
Name: Jonathan Roberson California License Number: S4197
Mailing Address: 5877 Pine Ave., Suite 210, Chino Hills, CA 91709
Telephone: (951) 295-1892 Email: jon@EASECo.com

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: Brady Richard
Mailing Address: 11034 Indian Trail, Dallas TX 75229-3513
Telephone: (972) 247-9657 Email: brady@etldallas.com





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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 (z/h = 1); 2.5 (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

Overall dimensions and weight = See Attachment

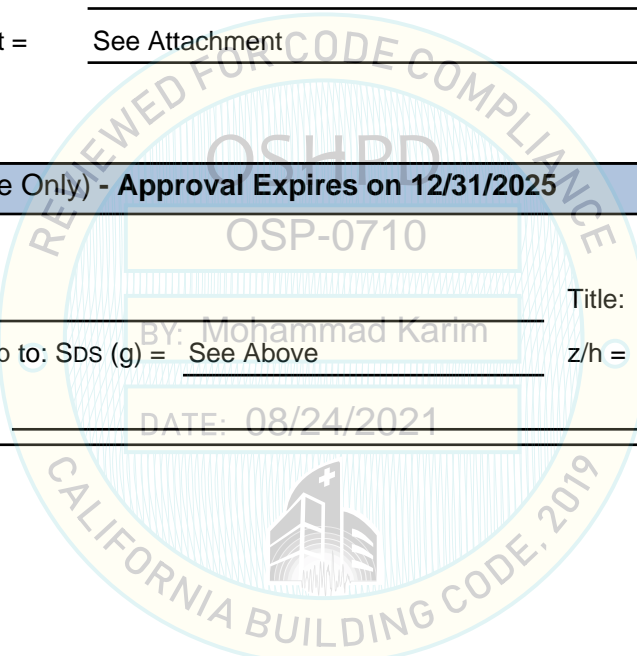
OSHPD Approval (For Office Use Only) - Approval Expires on 12/31/2025

Date: 8/24/2021

Name: Mohammad Karim Title: Supervisor, Health Facilities

Special Seismic Certification Valid Up to: SDS (g) = See Above z/h = See Above

Condition of Approval (if applicable): DATE: 08/24/2021



ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS

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TABLE 1:


Manufacturer		GENERAL MEDICAL MERATE SpA (GMM)							S _{DS} = 2.0 at z/h = 1			
System		CLISIS SYSTEMS (Seismic Version) ^[2]							S _{DS} = 2.5 at z/h = 0			
COMPONENT	IDENTIFICATION NUMBER	APPROX. DIMENSIONS [IN]			MAX. WT. [LB]	MOUNT	BASIS ^[1]	F _p /W _p	a _p	R _p	Ω ₀	
		W	D	H								
PATIENT TABLE												
CLISIS EXEL DRF Tilting Table	CS006/G (Model No.) ^[3]	96.85 – 163	79.13 – 87	69.69 – 116.14	3241	Rigid Base	SAME AS UUT-2005-1	2.40 1.13	1	1 ½	2	
SYSTEM CABINET												
System Digital Cabinet	O-D4000RF-PDT (Type No.) ^[4]	22.36	29.02	35.47	243	Wall/Floor	SAME AS UUT-2005-2	1.50 1.13	2 ½	6	2	
GENERATOR												
Generator 80kW (H.V. Indico IQ Generator) Series: Opera G800IQ	VZW2558FD822-10 (Part No.) ^[5]	20.08	16.14	41.73	201	Rigid Base	SAME AS UUT-2005-3	1.50 1.13	2 ½	6	2	
OVERHEAD TUBE SUSPENSION												
Manual Overhead Tube Suspension (OTS)	PN002/G (Type No.)	118.5	173.6	49.2 – 116.1	735	Ceiling	SAME AS UUT-2005-4	3.60 1.50	2 ½	2 ½	2	
WALLSTANDS												
Vertical non-tilting wall stand, RIGHT opening w/ Thales Wireless detector Pixium 3543 EZ - Option CMEDB	O-RS10-DX (Type No.) Pixium 3543 EZ (Model No.)	24.41 14.96	16.75 0.59	88.58 18.11	377 6.6	Wall/Floor	SAME AS UUT-2005-5	2.40 1.13	1	1 ½	2	
Vertical non-tilting wall stand, RIGHT opening w/ Thales Wireless detector Pixium 2430 EZ - Option CMND	O-RS10-DX (Type No.) Pixium 2430 EZ (Model No.)	24.41 10.43	16.75 0.59	88.58 12.8	377 4.4	Wall/Floor	INT	2.40 1.13	1	1 ½	2	
Vertical non-tilting wall stand, LEFT opening w/ Thales Wireless detector Pixium 3543 EZ – Option CMEDB	O-RS10-SX (Type No.) Pixium 3543 EZ (Model No.)	24.41 14.96	16.75 0.59	88.58 18.11	377 6.6	Wall/Floor	INT	2.40 1.13	1	1 ½	2	
Vertical non-tilting wall stand, LEFT opening w/ Thales Wireless detector Pixium 2430 EZ – Option CMND	O-RS10-SX (Type No.) Pixium 2430 EZ (Model No.)	24.41 10.43	16.75 0.59	88.58 12.8	377 4.4	Wall/Floor	SAME AS UUT-2005-6	2.40 1.13	1	1 ½	2	


Table continues on next page


ATTACHMENT 1: SEISMIC CERTIFIED COMPONENTS


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<i>Manufacturer</i>	GENERAL MEDICAL MERATE SpA (GMM)										$S_{DS} = 2.0$ at $z/h = 1$	
<i>System</i>	CLISIS SYSTEMS (Seismic Version) ^[2]										$S_{DS} = 2.5$ at $z/h = 0$	
COMPONENT	IDENTIFICATION NUMBER	APPROX. DIMENSIONS [IN]			MAX. WT. [LB]	MOUNT	BASIS ^[1]	F _P /W _P	a _P	R _P	Ω ₀	
		W	D	H								
USER INTERFACE												
Control Console (CLISIS EXEL DRF)	Host Controller XSNA (Type No.) ^[6]	17.32	10.63	7.48	18	CTA	SAME AS UUT-2005-7	1.44 1.13	1	2 ½	2	
RadiForce (23.0") Multitouch Color LCD Monitor w/ Desk mount kit (GMM)	MS236WT (Model No.) 162396 (Part No.)	21.93	9.75	21.0	22.5	CTA	SAME AS UUT-2005-8	1.44 1.13	1	2 ½	2	
Monitor Extender Box	O-D4000RF-PDT (EXT Box) (Type No.)	8.25	9.75	5.5	3.5	CTA	SAME AS UUT-2005-9	1.44 1.13	1	2 ½	2	
<i>Mount</i>	<p>RIGID BASE (FLOOR) MOUNT: free-standing, base-mounted tower configuration with the component rigidly attached to a supporting structure and no lateral support above the base.</p> <p>WALL/FLOOR MOUNT: combined rigid base and rigid wall mount configuration; base of unit bears on and anchored to rigid base (floor) and is attached to a supporting structure with lateral support above the base at a wall.</p> <p>CEILING: equipment is anchored to, and suspended from, a rigid framing system at or slightly above the ceiling line of the room.</p> <p>COUNTERTOP ATTACHED (CTA): equipment is base mount anchored to a built-in countertop or similar horizontal surface providing a fixed, rigid support.</p>											
<i>Notes</i>	<ol style="list-style-type: none"> BASIS <ul style="list-style-type: none"> SAME indicates component is physically, mechanically, and electrically the same as another test specimen with differences limited to identification number, color, and/or software. INT (Interpolated): Indicates model of equipment not specifically tested for which seismic qualification is established through testing of similar models in the product line. CLISIS Systems (Seismic Version) is the unique configuration of the CLISIS Systems line of R/F systems as defined in this table. It requires the use of GMM Seismic Kit P/N 162435 which contains seismic kits for individual components. Tilting Table requires use of GMM Seismic Kit P/N 162436. System Digital Cabinet requires use of GMM Seismic Kit P/N 162393. Generator requires use of GMM Seismic Kit P/N 162321. Control Console requires use of GMM Seismic Kit P/N 162395. 											


UUT-2005-1 CLISIS EXEL DRF Tilting Table						
MANUFACTURER: GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Model No.: CS006/G S/N: 01280						
DESCRIPTION: Component of CLISIS Systems (Seismic Version)						
<p>Production equivalent prototype unit that includes enhancements relative to then-current standard production.</p> <p>Horizontal Configuration (0°) w/ Patient Load of 502.5 lb</p> <p>Included modifications to address anomalies observed in testing. These modifications will be included in future production units and in GMM System Seismic Kit P/N 162435.</p> <p>*Unit tested in configuration offering least seismic withstand capacity.</p>						
MOUNTING: Rigid Base (Floor) mounted using (15) – 1/2" dia. SAE J429 GR 5 hex head bolts to interface.						
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
96.85 – 163*	79.13 – 87*	69.69 – 116.14*	3241	3.29	3.96	3.11
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2019 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-2005-2 System Digital Cabinet						
MANUFACTURER: GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Type No.: O-D4000RF-PDT S/N: 38737						
DESCRIPTION: Component of CLISIS Systems (Seismic Version)						
Mounting Brackets included in GMM Seismic Kit P/N 162393.						
MOUNTING: <u>Wall/Floor mounted:</u> Wall mount with bracket by GMM with (2) – 1/4" DIA HWH TEK SCREWS w/ 1" x 9/16" washers to 5/8" Gyp Board over 16 GA steel track backing plate. Floor mount with bracket by GMM with (2) – 3/8" DIA SAE J429 Grade 5 Bolts to interface frame.						
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
22.36	29.02	35.47	243	11.25	21.18	20.24
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2019 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-2005-3 Generator 80kW (H.V. Indico IQ Generator) Series: Opera G800IQ						
MANUFACTURER: Communications & Power Industries Canada, Inc. (CPI) & GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Part No.: VZW2558FD822-10 S/N: AMQ01955A20						
DESCRIPTION: Component of CLISIS Systems (Seismic Version) Mounting Plate is included in GMM Seismic Kit P/N 162321.						
MOUNTING: Rigid Base (Floor) mounted using (4) – M12 CLASS 8.8 bolts to interface frame.						
DIMENSIONS (in.)			Weight (lb.)	LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height		Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
20.08	16.14	41.73	201	11.57	17.69	9.57
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2019 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	1	1.5	3.2	2.4	1.68	0.68
2.5	0					
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.						

UUT-2005-4 Manual Overhead Tube Suspension (OTS)						
MANUFACTURER: GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Type No.: 5769324 (Same as PN002/G) S/N: 37500						
DESCRIPTION: Component of CLISIS Systems (Seismic Version)						
MOUNTING: Ceiling mounted with (2) – 3/8" DIA SAE J429 GRADE 5 Hex Bolts w/ Unistrut P1008 channel nuts through a GMM mounting bracket to Unistrut P1001 support. Connection to Longitudinal Rail at mounting bracket made with (1) – M10x30 Class 8.8, screw cage, plain washer, and M10 nut. Typical each intersection of (2) Longitudinal rails spaced approx. 76.8" apart (out-to-out) and (6) – Unistrut P1001 supports spaced 27.6" apart. Each Unistrut P1001 supports spans perpendicular to longitudinal rails and is attached to HSS frame members spaced 40" max o.c. w/ (2) – 1/2" DIA SAE J429 Grade 8 bolts and Unistrut P1010 channel nuts.						
DIMENSIONS (in.)			Weight (lb.)	LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height		Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
118.5	173.6	49.2 – 116.1	735	N/A	N/A	N/A
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2019 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	1	1.5	3.2	2.4	1.68	0.68
2.5	0					
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.						


UUT-2005-5 Vertical Non-tilting Wall Stand, RIGHT opening w/ 3543 EZ DETECTOR						
MANUFACTURER: GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Type No.: 5805017 (Same as O-RS10-DX) S/N: 37569						
DESCRIPTION: Component of CLISIS Systems (Seismic Version) <u>Includes detector:</u> Thales Wireless detector Pixium 3543 EZ - Option CMEDB 14.96" x 0.59" x 18.11", 6.6 [lb] Part No.: 63124836						
MOUNTING: <u>Wall/Floor mounted:</u> Wall attachment: GMM bracket at top with (2) – M6 Class 8.8 bolts to holes tapped in 3/8" THK x 6.3" W x 4" H steel plate welded to test frame. Floor Attachment: (4) – 1/2" DIA SAE J429 Grade 5 Bolts to interface.						
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
24.41	16.75	88.58	377	N/A	N/A	N/A
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2019 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	1	1.5	3.2	2.4	1.68	0.68
2.5	0					
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.						

UUT-2005-6 Vertical Non-tilting Wall Stand, LEFT opening w/ 2430 EZ DETECTOR						
MANUFACTURER: GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Type No.: 5805016 (Same as O-RS10-SX) S/N: 37569						
DESCRIPTION: Component of CLISIS Systems (Seismic Version) <u>Includes detector:</u> Thales Wireless detector Pixium 2430 EZ - Option CMND 10.43" x 0.59" x 12.8", 4.4 [lb] Part No.: 63125597						
MOUNTING: <u>Wall/Floor mounted:</u> Wall attachment: GMM bracket at top with (2) – M6 Class 8.8 bolts to holes tapped in 3/8" THK x 6.3" W x 4" H steel plate welded to test frame. Floor Attachment: (4) – 1/2" DIA SAE J429 Grade 5 Bolts to interface.						
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
24.41	16.75	88.58	377	N/A	N/A	N/A
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS						CODE: 2019 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	1	1.5	3.2	2.4	1.68	0.68
2.5	0					
Unit satisfied AC156 requirements for structural integrity and manufacturer requirements for functionality after AC156 test.						

UUT-2005-7 Control Console (CLISIS EXEL DRF)						
MANUFACTURER: GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Type No.: 5786779 (Same as Host Controller XSNA) S/N: 37384						
DESCRIPTION: Component of CLISIS Systems (Seismic Version) - Requires use of GMM Seismic Kit 162395.						
MOUNTING: Rigid Base (Countertop Attached) with (4) – #10 x 3/4" SMS to 3/4" plywood.						
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
17.32	10.63	7.48	18	>50	>50	48.08
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS				CODE: 2019 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-2005-8 RadiForce (23.0") Multitouch Color LCD Monitor w/ GMM Desk Mount Kit						
MANUFACTURER: EIZO / GMM						
IDENTIFICATION: Model No.: MS236WT S/N: 24244099						
DESCRIPTION: Component of CLISIS Systems (Seismic Version) <u>Includes Desk Mount Kit:</u> GMM Desk Mount Kit Part No.: 162396						
MOUNTING: Rigid Base (Countertop Attached) with (4) – #10 x 3/4" SMS to 3/4" plywood.						
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
21.93	9.75	21.0	22.5	4.32	7.45	11.75
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS				CODE: 2019 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-2005-9 Monitor Extender Box						
MANUFACTURER GENERAL MEDICAL MERATE SpA (GMM)						
IDENTIFICATION: Type No.: O-D4000RF-PDT (EXT Box) S/N: N/A						
DESCRIPTION: Component of CLISIS Systems (Seismic Version)						
MOUNTING: Rigid Base (Countertop Attached) with (2) – #10 x 3/4" SMS to 3/4" plywood.						
DIMENSIONS (in.)				LOWEST RESONANT FREQUENCY (Hz.)		
Width	Depth	Height	Weight (lb.)	Longit. (X)-Axis	Transv. (Y)-Axis	Vert. (Z)-Axis
8.25	9.75	5.5	3.5	>50	>50	14.86
ICC-ES AC156 SHAKE TABLE TEST PARAMETERS				CODE: 2019 CBC		
S _{DS} (G)	z/h	I _p	A _{FLEX-H} (G)	A _{RIG-H} (G)	A _{FLEX-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.						

DATE: 08/24/2021

