Wismar, November 23, 2010

Test Report #409.212.6
Mechanical Strength Tests
on

CapnoTrue ASP

Equipment under Test (EuT):

Description: multifunction patient monitor (SpO2, CO2)
Model: CapnoTrue ASP

Manufacturer: **bluepoint medical GmbH & Co. KG**
An der Trave 15
23923 Selmsdorf, Germany

Test Laboratory: CEcert GmbH
Alter Holzhafen 19
D 23966 Wismar, Germany

Purpose of test: Conformity qualification

Applied Standards: **ISO 21647:2004, ISO 9919:2005**

Classification met: **To be used during patient transport outside healthcare facility portable**

Detailed Test Specification:

Tests:	Test specification: [1]	Result:
Shock (Test Ea / Eb)	**1000 m/s^2 / 6 ms half sine** **3** shocks in each perpendicular axis	**PASS**
Broad band random (Test Fh)	**10 – 100 Hz: 5,0 (m/s^2)^2/Hz** Test time on each axis: **30 min** **100 – 200 Hz: -7dB/octave** **200 – 2000 Hz: 1,0 (m/s^2)^2/Hz**	**PASS**
Free Fall (Test Ed)	**250 mm** 1 time from each attitude	**PASS**

Comment:
PASS - EuT meets the requirements **FAIL** - EuT does not meet the requirements **NA** - requirements are not applicable
1) For detailed specification and results see appended test report.

Evaluation :

The Equipment under Test (EuT) meets the mechanical strength requirements in accordance with Intended application and classification as listed above.

Period of test: 22.04.2009 - 05.11.2010

This test report with appendix consists of **16** pages.

1 General information

Product description:

Description:	multifunction patient monitor (SpO2, CO2)
Model:	CapnoTrue ASP
Manufacturer:	bluepoint medical GmbH & Co. KG
Contact person:	Mrs. Heidi Fröhlich

Brief description/Introduction:

Product description: Non-invasive pulse oximeter and sidestream capnograph (with Nomo technology.

The product tested consists of the following main components:
multifunction patient monitor, ISA Module, SpO_2 sensor

Intended Application: The CapnoTrue CO2/SpO2 Monitor is intended to provide continuous monitoring of end-tidal CO2 concentration (EtCO2), inspired CO2 concentration (FiCO2), functional arterial oxygen saturation (SpO2), respiration rate (RR) and pulse rate (PR) of adult, pediatric infant and neonatal patients.

Participant in the tests: none

List of documents providing further information on the EuT:

- Instructions for use and technical description --
- Circuit diagrams, Component part list, etc. --
- Description of safety systems (specifying for example safety circuits, redundant circuits etc.) --

Responsible for the technical content of the test report:

	Name:	Signature:
Examiner	Kerstin Katzmann	
Head of Test Laboratory	Bernd Schmidt	

Note:

The CEcert GmbH assures the applicant that the tests are carried out within the scope of the tests outlined under point 2 and in accordance with the test specifications outlined under point 3. Any exceptions or deviations will be clearly indicated.

The results contained in this test report are relevant exclusively to the item(s) submitted for testing. The CEcert GmbH is not liable for any conclusions and generalizations which may be drawn from the test results and applied to further samples and examples of the type of device represented by the item submitted for testing.

This report may only be reproduced or published in its entirety. Written permission must be obtained from the CEcert GmbH prior to the reproduction or publishing of extracts.

2 Test Specification

2.1 General

The purpose of these tests is to certify the conformity of the Equipment under Test (EuT) with the applied standards.

2.2 Applied standards

ISO 21647:2004, ISO 9919:2005

2.3 Classification

- to be used during patient transport outside healthcare facility
- portable

2.4 Exceptions and deviations from requirements

none

2.5 Applied test methods

Part of applied standard	Basic standard for test procedure	Chapter
clause 21.102	**IEC 60068-2-27:1987** Electrical engineering; Basic environmental testing procedures: Test Ea: Shock	**4.1.**
clause 21.102	**IEC 60068-2-64:2008** Electrical engineering; Basic environmental testing procedures: Test Fh: Vibration, broad band random (digital control)	**4.2.**
clause 21.102	**IEC 60068-2-31:2008** Environmental testing - Part 2-31: Test Ec: Rough handling shocks	**4.3.**

2.6 Applied non-standard methods

none

2.7 Test sequence

If not otherwise stated in this report, test performed in sequence as listed under section 2.5 with the specimen listed in section 3.1

3 Specification of the Device/Equipment under Test (EuT)

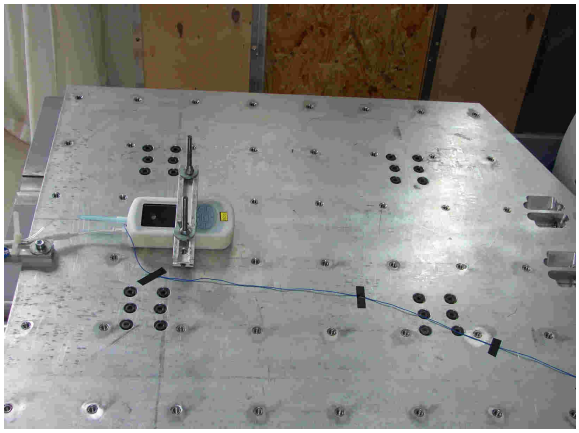
3.1 Product configuration tested

Description:	Model:	Type No.:	Manufacturer:	Notes:
Equipment under Test:				
multifunction patient monitor (SpO2, CO2)	CapnoTrue ASP	SN: 40420182 REF: 4090112002-D	bluepoint medical GmbH & Co. KG	
Components:				
DC power supply	FW 7660M/06	--	FRIWO	
Mainboard	V1.9	--	bluepoint medical GmbH & Co. KG	20091026
Powerboard	V1.1	--	bluepoint medical GmbH & Co. KG	20091026
ChipOx	--	--	bluepoint medical GmbH & Co. KG	
ISA Module	700101	100177	phasein	
Rechargeable Li-ion Battery	CT-2500	3095522111	bluepoint medical GmbH & Co. KG	3090122005
Silicon cover	--	--	bluepoint medical GmbH & Co. KG	
Accessories/peripherals:				
SpO_2 Sensor	SC6500	EWK02106	bluepoint medical GmbH & Co. KG	
Nomo Adapter	--	REF: 3090122009	bluepoint medical GmbH & Co. KG	
Disposable sampling line	--	REF: 3090121014	bluepoint medical GmbH & Co. KG	
Sidestream airway adapter	Adult / paediatric	REF: 3090121002	bluepoint medical GmbH & Co. KG	
Simulators: none **Software:** Device – V4.1; PC – V1.1				

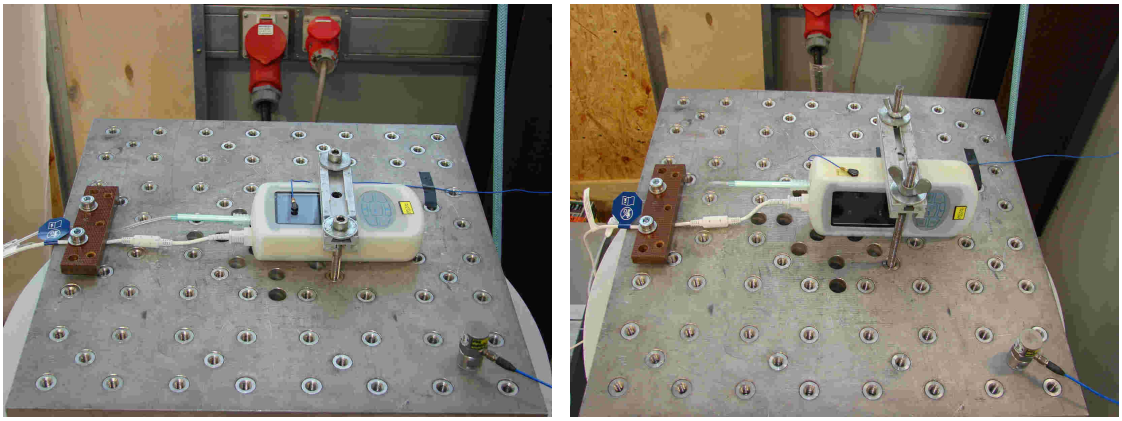
3.2 Cables and Lines

Interface:	Type/model/plug:	Length:	Shielding:	Comments:
mains (extension line)	2 wire	0,5m	no	not attached during test
DC supply line	Round plug 3-pin	2m	no	from mains adapter, not attached during test
SpO_2 Sensorcable	Minimed_plug 6-pin	1,5m	no	attached during test

3.3 Notes and/or Sketches



Equipment under Test (EuT) and assigned test axis Z



Equipment under Test in direction of the x-axis and in direction of the y-axis

Dimension of EuT: 150 mm x 80 mm x 40 mm
Mass of EuT: < 400 g

3.4 Operating Condition of the Specimen

The status of the test object during the tests represented its normal area of deployment.

Operating condition during test: During the test, the device was switched off.

Functional Test: The sensor was connected to the patient monitor. The monitor operating condition was measuring ON. While testing, the values were observed.

Power supply: internal battery powered

Climatic conditions during the tests:

Ambient temperature: 23 °C ± 3 °C
Relatively air humidity: 30 % - 55 %
Air pressure: 86 kPa - 106 kPa (860 mbar - 1060 mbar)

3.5 Mounting Conditions and absorbing means of EuT

The specimen was mounted on a rigid fixture as described in IEC 60068-2-47. The fixing points were chosen under consideration of all absorbing means and isolators.

3.6 Acceptance criteria

The Equipment or System shall be able to provide the Essential Performance and remain safe after each test. Particular the following degradations shall not be allowed during and after test:

- component failures;
- loosening of components (internal/external) which can cause hazardous situation and unintended malfunctions;
- cracks in the exterior;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an alarm;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- noise on a waveform in which the noise is indistinguishable from physiologically-produced signals or the noise interferes with interpretation of physiologically-produced signals;
- artefact or distortion in an image in which the artefact is indistinguishable from physiologically-produced signals or the distortion interferes with interpretation of physiologically-produced signals;

and shall not degraded below the following requirements after each environmental test procedure is completed (functional test):

- comply with the intended functions and rated data;
- no changes in intended function and programmable parameters;

Additional specifications (influencing functions): none

3.7 Sampling particulars

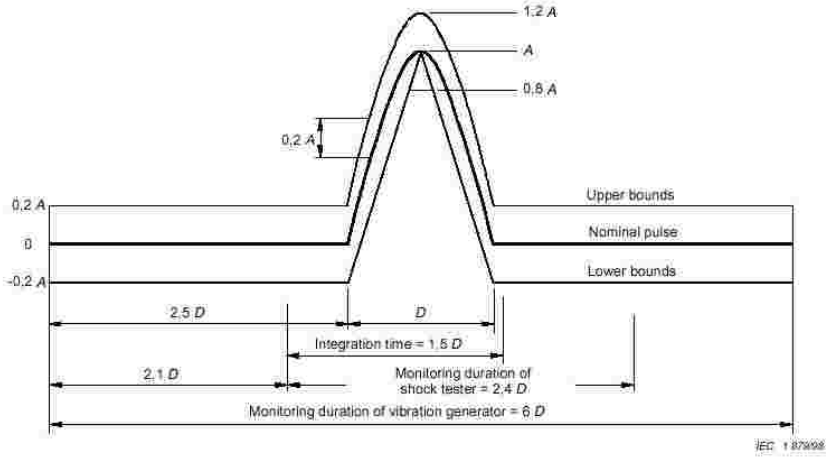
The product was tested as a single device.

4 Measurement and test results

4.1 Test Ea: Shock

Test set-up: IEC 60068-2-27 (not tested in its packing and transport case)

Test process:
The shocks applied to the EuT have the shape of a half-sine pulse.
Reference point: fixing point (see picture in section 3.3) – single point control on this pint
Measuring point: enclosure of EuT (see picture in section 3.3)
Shock repetition: 1 / sec.
The degree of severity of the test is characterised by the following parameters.



Initial measurement:

Functional test:		**PASS**
Electrical and mechanical check:		**PASS**
Visual inspection:		**PASS**

Conditioning:

EuT	Test axis	Test condition / severity	Notes/observation	Compliance Pass/ Fail/ NA
Operation : off				
CapnoTrue ASP	X – Axis (X+) and (X-)	A = **1000 m/s²** (102 G)	none	**PASS**
CapnoTrue ASP	Y – Axis (Y+) and (Y-)	D = **6 ms**	none	**PASS**
CapnoTrue ASP	Z – Axis (Z+) and (Z-)		none	**PASS**
While tests the EuT was not powered on and no functional test was performed.				

Number of shocks: 3 shocks in each perpendicular axis (18 in total)

Final measurement:

Functional test:		**PASS**
Electrical and mechanical check:		**PASS**
Visual inspection:		**PASS**

Test evaluation:
No relevant influencing functions of the equipment could be observed during the tests. There was no function failure nor loss of data, neither was there any change in the operating conditions. No mechanical degradation or cracks in the exterior could be observed.

According to the above test set-up the equipment under test specified in chapter 3 meets the mechanical shock requirements.

4.2 Test Fh: Vibration broad band random (digital control)

Test set-up: IEC 60068-2-64 (not tested in his packing and transport case)

Test process:
At broad-band random vibration test the excitement of test device is applied by a function of GAUSSian white noise with a restricted frequency band. The acceleration spectral density is constant in the nominal frequency range. At the margins this spectrum is falling down with determined slopes. Here the spectrum is controlled at the single control and reference point at the mounting plate of the generator. The random vibration is applied on the test device for a determined time. The degree of severity of the test is characterized by the following parameters.

Reference point:	fixing point (see picture in section 3.3) – single point control on this pint
Measuring point:	enclosure of EuT (see picture in section 3.3)
Cross-axis motion:	The cross-axis motion at the measuring points in both axes perpendicular to the test axis is less than – 3dB of the specified ASD level. The total r.m.s value of this cross-axis motion does not exceed 50 % of the severity level.

Initial measurement:

Functional test:	**PASS**
Electrical and mechanical check:	**PASS**
Visual inspection:	**PASS**

Conditioning:

EuT	Severity level (ASD)	Test axis	Test condition / duration	Notes/observation	Compliance Pass/ Fail/ NA
Operation: off					
CapnoTrue ASP	10 - 100Hz / 5,0(m/s²)²/Hz	X – Axis	30 min	none	**PASS**
CapnoTrue ASP	100 - 200 Hz / - 7dB/octave	Y – Axis	30 min	none	**PASS**
CapnoTrue ASP	200 – 2000 Hz / 1,0(m/s²)²/Hz	Z – Axis	30 min	none	**PASS**

Crest factor:	at least 2,5
Sample rate (f_{high}):	5425,34 Hz
Frequency resolution (B_e):	10 Hz
Statistical degree of freedom:	200 DoF
Shape of ASD level:	as described above

Final measurement:

Functional test:	**PASS**
Electrical and mechanical check:	**PASS**
Visual inspection:	**PASS**

Final response investigation:
Final vibration response investigation shows no significant mechanical failures and changes in the dynamic behavior (resonance peak level).

Test evaluation:
No relevant influencing functions of the equipment could be observed during the tests. There was no function failure nor loss of data, neither was there any change in the working conditions. No mechanical degradation or cracks in the exterior could be observed.

According to the above test set-up the equipment under test specified in chapter 3 meets the mechanical vibration (broad band random) requirements.

4.3 Test Ed: Free fall

Test set-up: IEC 60068-2-32 (not tested in his packing and transport case)

Test process:

Procedure 1 as described in IEC 68-2-32: The EuT was released to allow free fall from the severity level by the examiner with a minimum of disruptance at the moment of release. The test surface was a smooth, hard, rigid surface of concrete. The high of fall was measured from the part of specimen nearest to the test surface.

Initial measurement:

Functional test:	**PASS**
Electrical and mechanical check:	**PASS**
Visual inspection:	**PASS**

Conditioning:

EuT	Severity level / High of fall	Test axis / attitude from which the EuT was dropped	Number of falls	Notes/observation	Compliance Pass/ Fail/ NA
CapnoTrue ASP	250 mm	(+X) – Axis	1 from each attitude	none	**PASS**
CapnoTrue ASP		(+Y) – Axis		none	**PASS**
CapnoTrue ASP		(+Z) – Axis		none	**PASS**
CapnoTrue ASP		(-X) – Axis		none	**PASS**
CapnoTrue ASP		(-Y) – Axis		none	**PASS**
CapnoTrue ASP		(-Z) – Axis		none	**PASS**

While test was applied the specimen was in operation (functional test).

Final measurement:

Functional test:	**PASS**
Electrical and mechanical check:	**PASS**
Visual inspection:	**PASS**

Test evaluation:

No relevant influencing functions of the equipment could be observed during the tests. There was no function failure nor loss of data, neither was there any change in the working conditions. No mechanical degradation or cracks in the exterior could be observed.

According to the above test set-up the equipment under test specified in chapter 3 meets the free fall requirements in accordance with applied standard.

5 Uncertainty of the measuring system

Overall uncertainty (K=2): 5.1 %
(estimation/calculation performed in PA_Umwelt_Shock&Vibration_1)

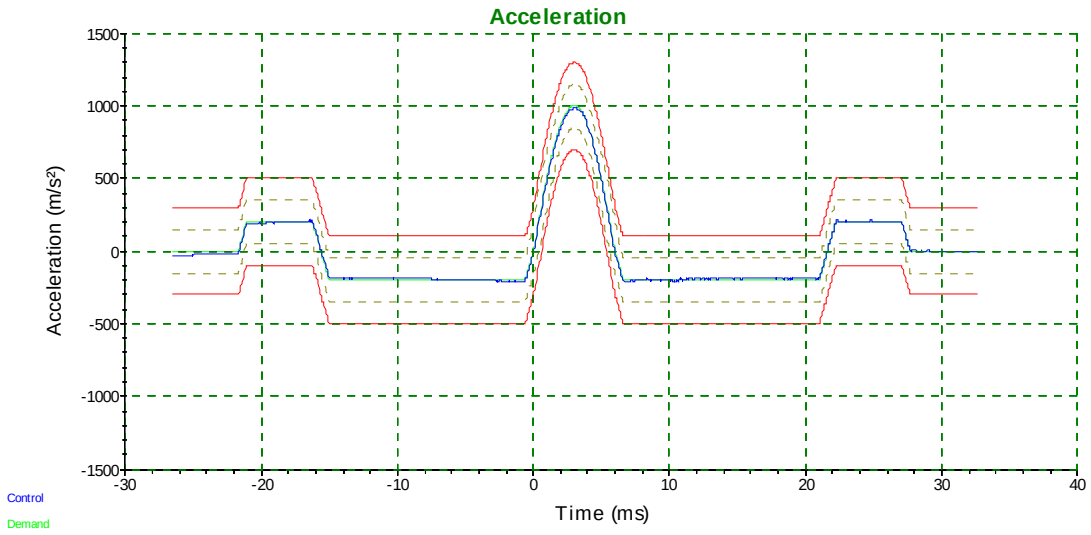
6 Information about the Test Equipment

Description	Model/type	Manufacturer	Serial no.	Last Cal	Cal. due
Shake Table	TIRA-Vib 5142	TIRA	nn	2009,10	2010,09
Vibration Controller	VR-8500	Vibration Research	0e0053	2009,10	2010,09
Software Vibration View	Vibration View	Vibration Research	Ver. 5.0.4.	nn	Nn
ICP Accelerometer	353B31	PCB	1034707	2009,10	2010,09
Amplifier	840.02/52	TIRA	nn	2009,10	2010,09
ICP Accelerometer	352C22	PCB	81653	2009,10	2010,09
Shake table and climatic chamber combination	TIRA-Vib 5142 + C-40/350	TIRA / CTS	nn	2009,10	2010,09
Shake Table and Degauss unit	TV 56280/LS	TIRA	216/07	2009,10	2010,09
Amplifier	A52318	TIRA	216/07	2009,10	2010,09
Test jig 400 x 400	THS 40-180	TIRA	216/07	nn	nn

Annex List:

Title **Page**

Test Data Ea/Eb: Shock acceleration x Axis + (1000 m/s^2 / 6 ms half sine)



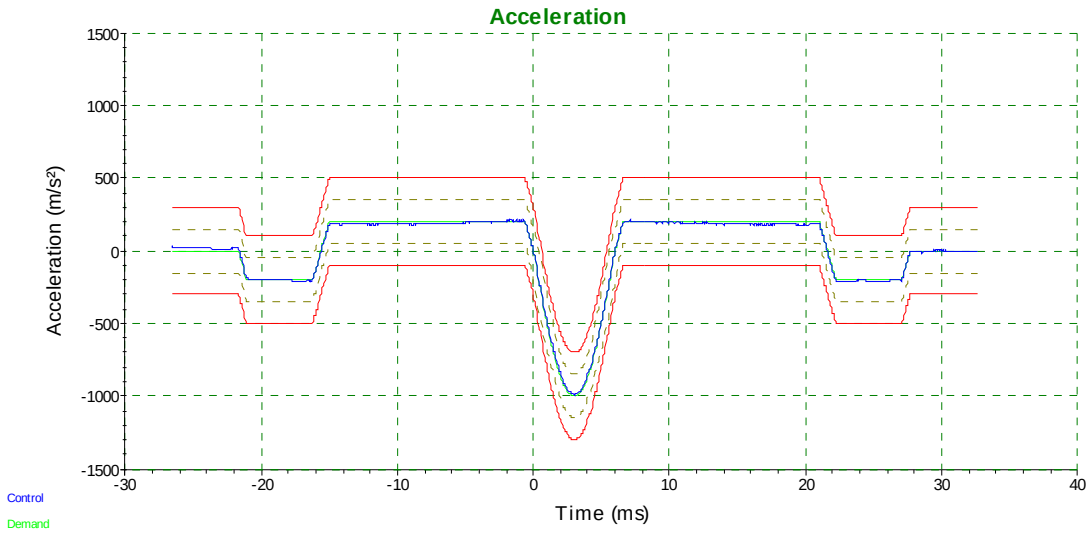
Current Measurements:

Control amplitude: 989.6 m/s²
Output voltage: 4.566 Volts peak

Channel Measurements:

	Acceleration
353B31	1002 m/s²
352C22	2125 m/s²

Test Data Ea/Eb: Shock acceleration x Axis (-) (1000 m/s^2 / 6 ms half sine)



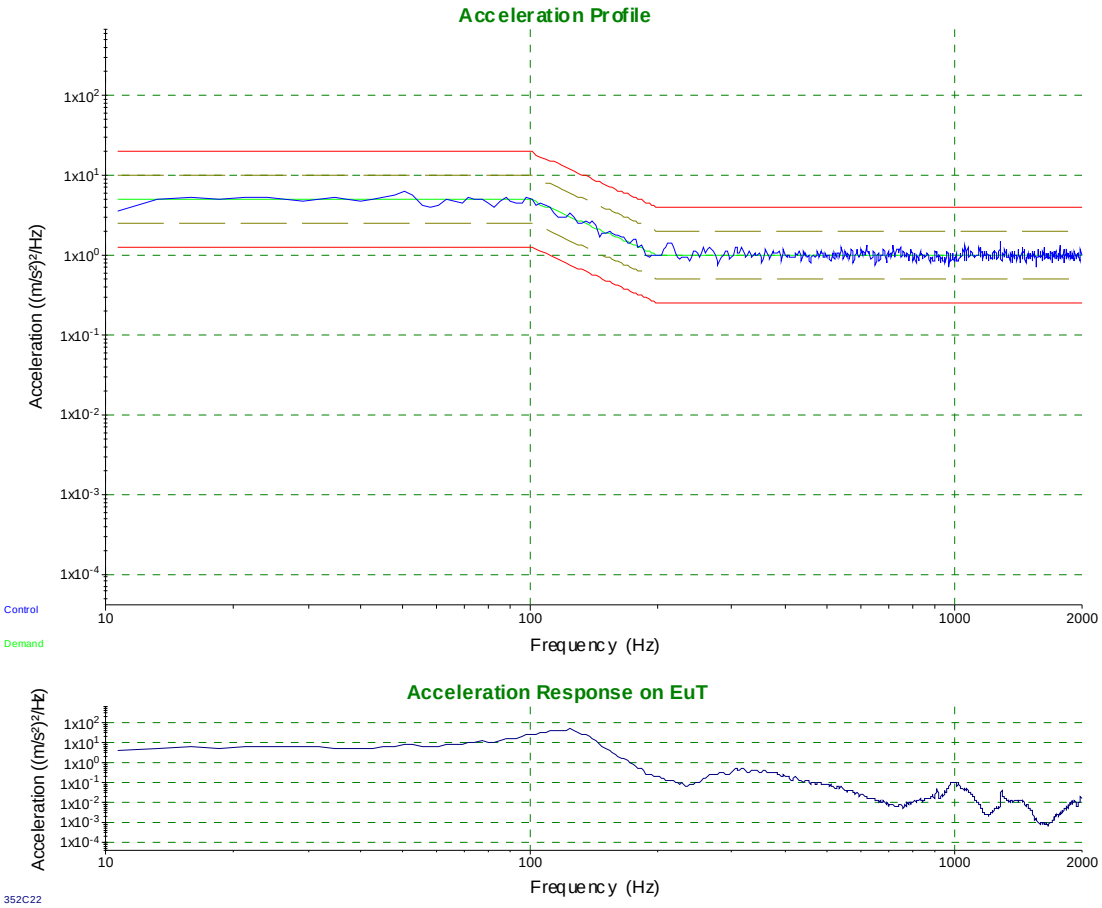
Current Measurements:

Control amplitude: 992.5 m/s²
Output voltage: 4.628 Volts peak

Channel Measurements:

	Acceleration
353B31	1010 m/s²
352C22	1982 m/s²

Test Data Fh: Vibration, broad band random in direction of x-axis



Breakpoint table

Frequency	**(m/s²)²/Hz**	**dB/Octave**
10 Hz	5	0
100 Hz	5	-6.99
200 Hz	1	0
2000 Hz	1	

Measurements:

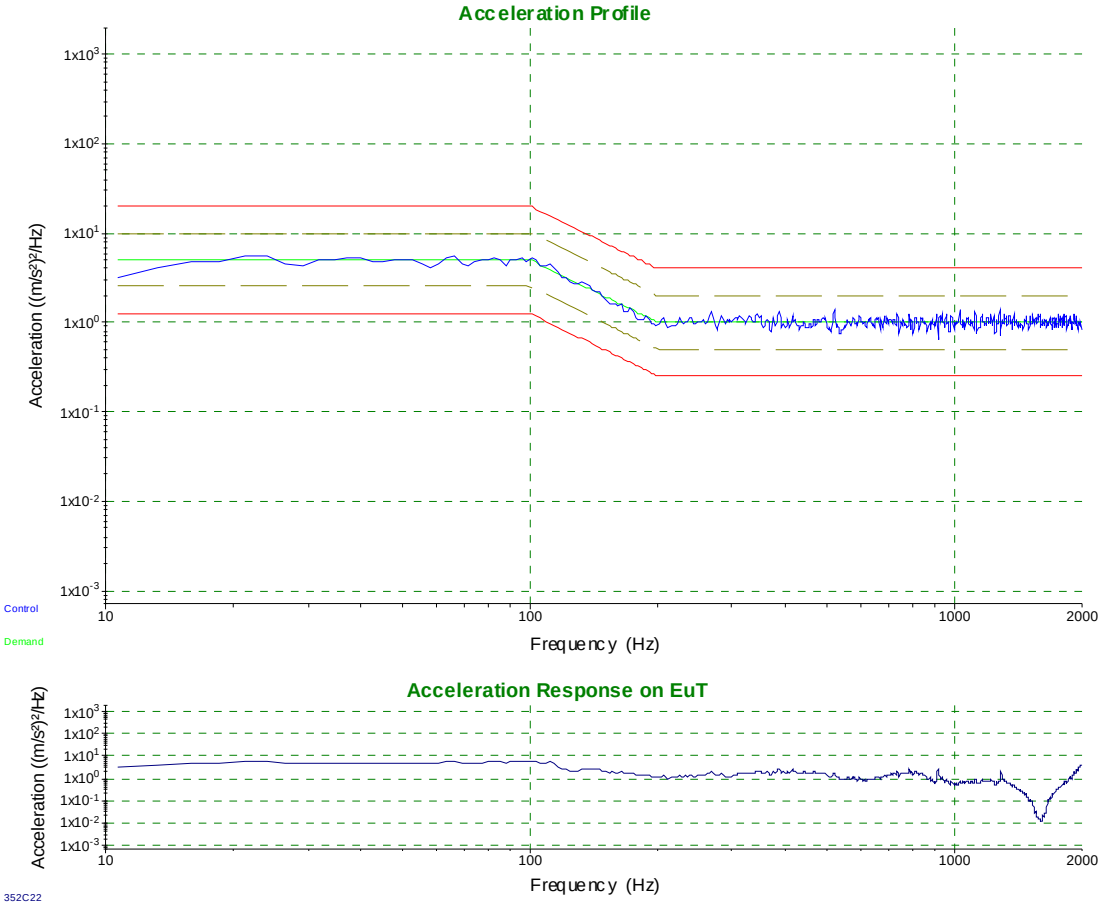
Demand: 49.82 m/s² RMS	6.815 mm pk-pk
Control: 49.92 m/s² RMS	7.768 mm pk-pk

Channel Measurements:

Ch1: 49.91 m/s² RMS	Ch1 in-band: 49.87 m/s² RMS
Ch2: 50.31 m/s² RMS	Ch2 in-band: 49.34 m/s² RMS
Drive voltage: 0.4489 Vrms	

System gain is 0.008991 Volts/m/s² (Max system gain limit = 10.2)

Test Data Fh: Vibration, broad band random in direction of y-axis



Breakpoint table

Frequency	(m/s²)²/Hz	dB/Octave
10 Hz	5	0
100 Hz	5	-6.99
200 Hz	1	0
2000 Hz	1	

Measurements:

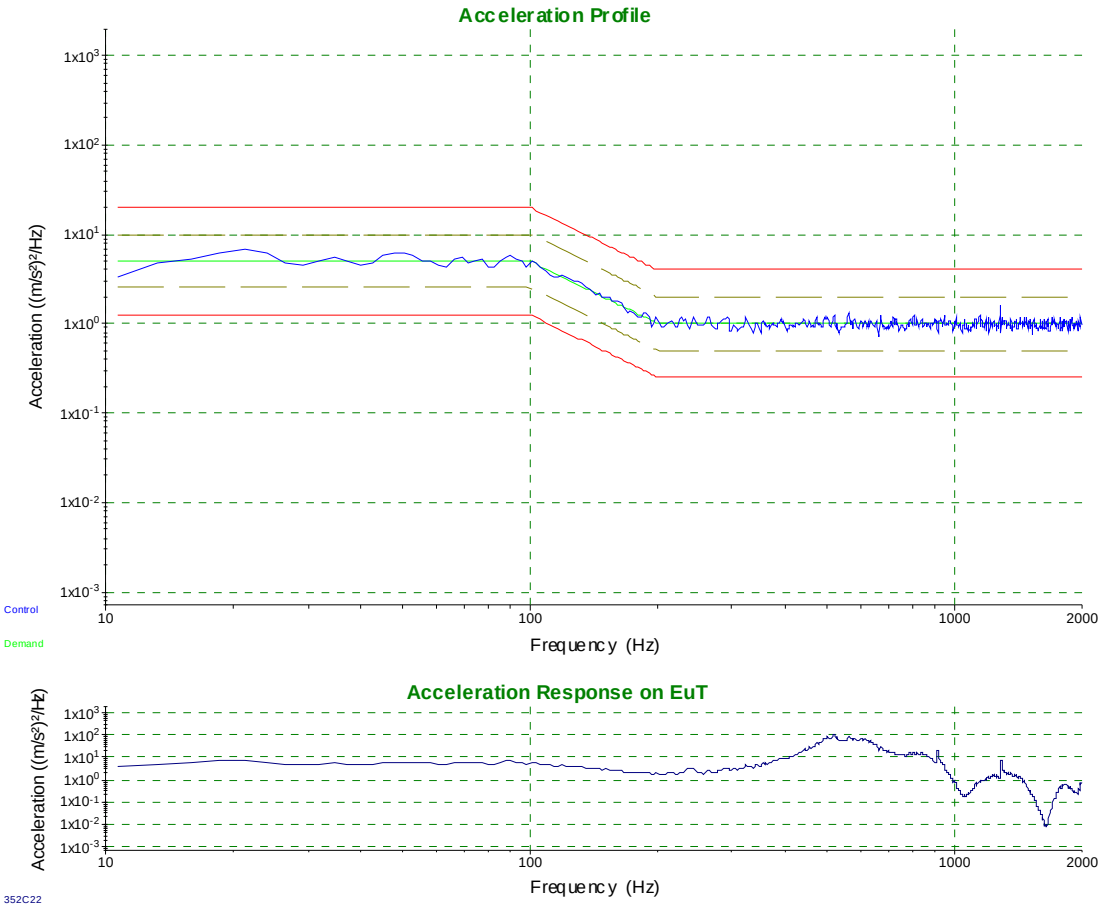
Demand: 49.82 m/s² RMS	6.815 mm pk-pk
Control: 49.78 m/s² RMS	7.404 mm pk-pk

Channel Measurements:

Ch1: 49.52 m/s² RMS	Ch1 in-band: 49.73 m/s² RMS
Ch2: 49.42 m/s² RMS	Ch2 in-band: 49.29 m/s² RMS
Drive voltage: 0.4458 Vrms	

System gain is 0.008956 Volts/m/s² (Max system gain limit = 10.2)

Test Data Fh: Vibration, broad band random in direction of z-axis



Breakpoint table

Frequency	(m/s²)²/Hz	dB/Octave
10 Hz	5	0
100 Hz	5	-6.99
200 Hz	1	0
2000 Hz	1	

Measurements:

Demand: 49.82 m/s² RMS	6.815 mm pk-pk
Control: 49.76 m/s² RMS	7.707 mm pk-pk

Channel Measurements:

Ch1: 49.93 m/s² RMS	Ch1 in-band: 49.7 m/s² RMS
Ch2: 137.8 m/s² RMS	Ch2 in-band: 137.5 m/s² RMS
Drive voltage: 0.4395 Vrms	

System gain is 0.008833 Volts/m/s² (Max system gain limit = 10.2)

Additional Photo Documentation: