

Protocol

Medical Device Testing, Inc.

In-Vitro Simulated Gait Motion for Intravascular Devices Protocol

Rev. 1.0

IN-VITRO ACCELERATED FATIGUE TESTING PROTOCOL

THIS IS A TEST PLAN FOR ACCELERATED, AXIAL/TORSIONAL/BENDING FATIGUE TESTING OF DEVICES.

AUTHOR:

DOCUMENT ID:

APPROVED BY:

DATE

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1.0 OBJECTIVE

The testing objective is to meet the requirements for *in vitro* mechanical fatigue testing. The test will demonstrate the integrity of the device under mechanical fatigue for a minimum of 10 years post-implantation. The testing is performed on the test specimen deployed inside a mock vessel. The mock vessel will be exposed to mechanical stimulation to simulate the physiologic motion experienced *in-vivo*. Mechanical stimulation can include axial compression, axial rotation, and bending. The test is accelerated to obtain results in a shorter time period than physiological rates would allow and is conducted under simulated physiological conditions with saline at 37°C +/- 2°. A device failure is defined as any broken or cracked strut visible at 30x magnification during or at the end of the test. The device manufacturer will also examine the devices post-testing and provide acceptance and/or failure criteria.

Testing will be conducted at Medical Device Testing Services Facilities, in Minnetonka, Minnesota, under the direction of trained Medical Device Testing Services personnel.

2.0 SCOPE

This document will describe the protocol used to test the device durability during cyclic testing using simulated *in-vivo* conditions. This document will provide instruction for test set-up, data collection, and test completion.

3.0 SAMPLE SIZE AND IDENTIFICATION

Samples will be representative of devices prepared for commercial distribution. The table below may be used for identification.

FIXTURE POSITION	POSITION/CONFIGURATION	LOT OR ID#
1	TBD	
2		
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4.0 EQUIPMENT

- a) Bose Model 3300-AT Bose Test System – (ELF3300AT-001)
- b) Bose WinTest® Controls and Software
- c) Computer, ≥ 400MHz CPU
- d) Required number of devices – 2 to 16
- e) Multi Station Axial/torsional/bending test fixture provided by Medical Device Testing Service (ISN#,) with 26 mm bending mandrels.
- f) Saline solution:
- g) Recirculating water bath
- h) Associated Paper Work
 - (1) ELF Test Set Up Checklist
 - (2) Test Deployment Form
 - (3) Daily Data Sheets (Template 99127)

6.0 INSTALLATION

- a) Install the fixturing on Bose ELF test system.



← Top Platen: Axial Displacement

← Middle Platen: Bending

← Bottom Platen: Torsional Displacement

- a. The top shaft of the ELF 3300 AT connects to the top platen which provides axial displacement.
- b. The bottom torsional actuator of the ELF 3300 AT connects to the lead screw in the center of the fixture, which provides torsional displacement and bending.

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- i. Torsional displacement signal is translated through a series of gears and shafts (timing belt and pulleys), with a terminal fixture shaft connecting with the sample.
- ii. The bending of the sample is accomplished with a cam. The cam rises through the center of the fixture pushing rods out toward the samples. The rods push a mandrel into contact with the tube, bending the tube to the required angle.



- b) Align the bending mandrels with yoke.
 - a. Loosen the yoke using the two screws underneath the middle platen.
 - b. Manually move mandrel forward until it makes contact with the yoke.
 - c. Tighten yoke to ensure proper alignment.

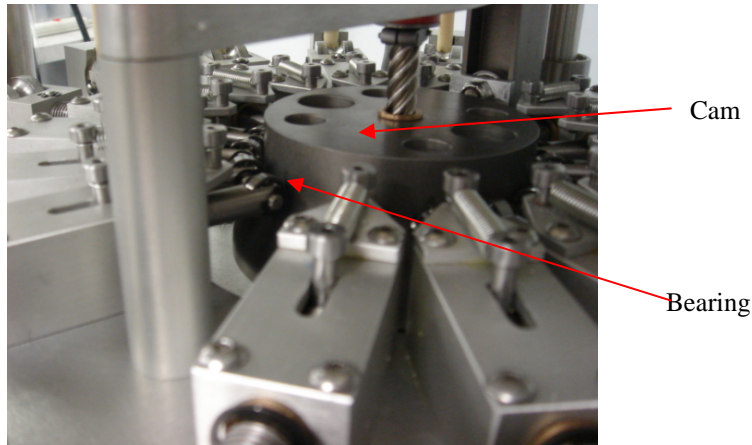


- c) Align the zero point of the rotation.

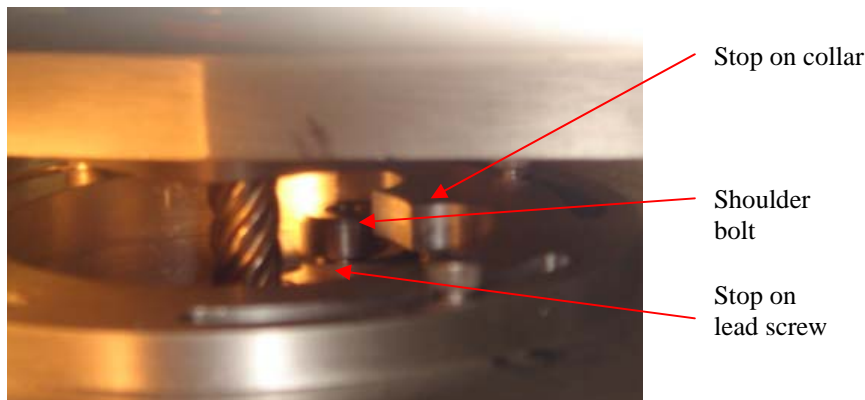
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- a. The cam should be lifted until the bearings on the bending shaft just contacts the angled portion of the cam.



- b. Set the zero at this point.
- c. Adjust the mechanical stop for the rotation at the zero point. The collar needs to be rotated until the shoulder bolt on the gear, the stop on the collar, and the stop on the lead screw all line up.



- d) Attach mock arteries.
 - a. Mock arteries should be attached when fixture has zero rotation (-65 degrees from the zero point) and the axial movement and the lowest point.
 - b. Attach mock arteries to the top and bottom attach tubes.
 - c. Apply zip-ties to reduce leaks.

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- e) Plumb the fixture for saline flow loop.
 - a. Saline should flow in the top of the mock arteries and down through the bottom.
 - b. Use manifold on the top and bottom to direct flow to each station.



Bottom manifold



Top Manifold

- f) Start the tester at the 2 Hz test frequency and adjust the fixturing and PID terms to achieve a stable sine wave for each axis of stimulation.
 - a. Program the rotational controller:
 - i. Synchronize for 2 movers
 - ii. Half sine 0 5 hz
 - iii. Dwell 0.05 sec
 - iv. Half sine TBD 6 hz
 - v. Half sine 0 6 hz
 - vi. Dwell 0.05
 - vii. Synchronize for 2 movers
 - viii. Half sine TBD 5 hz
 - ix. Repeat
 - b. Program the axial controller
 - i. Synchronize for 2 movers

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- ii. Half sine TBD mm 5 hz
- iii. Synchronize for 2 movers
- iv. Half sine TBD 5 hz
- v. Repeat

7.0 ACCELERATED TEST DEVICE DEPLOYMENT

- a) Visually inspect the synthetic arteries prior to deployment and remove any unsuitable samples.
- b) Flush the synthetic arteries with saline water and install on the tester.
- c) Deploy the devices.

8.0 ACCELERATED FATIGUE TEST START UP

- a) Determine the test command parameters to obtain the appropriate axial tension strain level, TBD at time of test.

9.0 MONITORING

- a) Set and apply the appropriate limits to prevent damage to the tester due to fluctuations.
- b) Create a new job folder on the server. C/Data Files/ WinTest Data/ JOB#. All data concerning the current test should be stored here.
- c) Set up data acquisition to electronically capture displacement max/min, rotation max/min, torque max/min, and cycle count approximately every four hours.
- d) Manually record displacement max/min, rotation max/min, torque max/min, cycle count and temperature. Document the information on the Daily Data Sheet.
- e) Daily Monitoring
 - i) Record pre-determined parameters on the Daily Data Sheet
 - ii) Observe devices for migration.
 - iii) Observe devices for failure.
 - iv) If an abnormal observation occurs, contact the Operations Manager or Director of testing.

10.0 TEST SHUTDOWN: PROTECTIVE LIMITS OR MALFUNCTIONS

- a) Retrieve the history from the show menu, record notes regarding shut down and contact the Operations Manager or senior lab personnel.
- b) The operations manager or lab personnel may resume the test and/or contact the customer at their discretion, based on the shut down specifications.

11.0 TEST COMPLETION

- a) Document the date of test cycle completion.
- b) Inspect the devices while still on the instrument.

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- c) Inform the customer of the test completion and inspection results.
- d) Remove the test samples from the fixture by sliding the ends of the samples off the fittings and put them back into the original container with solution.
- e) Return the test samples, physiological samples, and any remaining samples to customer.
- f) If no report was requested, send an electronic version or a cd containing all of the customer's raw data within 2 days of test completion.

12.0 PROJECTED SCHEDULE FOR TESTING.

SAMPLE NUMBER 16 CYCLES TBD FREQUENCY TBD

CYCLE START DATE: TBD

PREDICTED CYCLE END DATE:

These times reflect an estimate for the time to complete the various stages of the testing. As the test proceeds, more definitive dates may be established to account for set up, artery adjustments, data acquisition, problems, etc.

Revision History:

Version	Change	Date