

Protocol

Medical Device Testing, Inc.

Company Axial/Torsional ELF Protocol

Rev. 1.0

***IN-VITRO* ACCELERATED FATIGUE TESTING PROTOCOL**

THIS IS A TEST PLAN FOR ACCELERATED, TORSIONAL FATIGUE TESTING OF **COMPANY** DEVICES. THE DURATION OF THIS TEST SIMULATES **10** YEARS OF IMPLANTATION LIFE.

AUTHOR: **COMPANY**

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APPROVED BY:

DATE

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1.0 OBJECTIVE

The testing objective is to meet the requirements for *in vitro* mechanical. The test will demonstrate the integrity of the device under mechanical fatigue. The testing is performed on the test specimen deployed inside a mock vessel. The target strain is determined based upon the physiologic motion of the *in-vivo* deployment site. 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°. The device manufacturer will also examine the devices post-testing and provide acceptance and/or failure criteria.

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 determining the target strain, validating the test, 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		
2		
3		
4		
5		
6		
7		
8		
9		

4.0 EQUIPMENT

- a) Bose Model 3300-AT Bose Test System – (CC – ELF)
- b) Bose WinTest® Controls and Software
- c) Computer, ≥ 400MHz CPU
- d) Required number of devices – 2
- e) Multi Station Axial/torsional test fixture provided by Medical Device Testing Service (ISN# 00679, PN55050)
- f) Torque cell -(ISN 00674).
- g) Sub-Assembly Tool
- h) Sample Sub-Assembly Pieces
 - (1) Saline Chamber n=12
 - (2) Chamber caps top (n=12) bottom (n=12)

- (3) Sample Shaft n=12
- i) Distilled Water:
 - (1) Bath Clear
- j) 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: Torsional Displacement

Bottom Platen: Axial Displacement

- b)
 - a. The top shaft of the ELF 3300 AT connects to the bottom platen which provides axial displacement.
 - b. The bottom torsional actuator of the ELF 3300 AT connects to the belt drive on the top platen, which provides torsional displacement.
 - 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.
- c) Start the tester at the 6 Hz test frequency and adjust the fixturing and PID terms to achieve a stable sine wave for each axis of stimulation.

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) Customer representative deploys the devices in the MDTS lab.
- d) **Assemble the Sample Sub-Assemblies**
 - a. Position lock collar on the sub-assembly tool rod at pre-determined assembly length.
 - b. Screw sample shaft on to the assembly tool.
 - c. Screw bottom chamber cap on to the assembly tool. *Note* only the bottom chamber cap has the appropriate screw holes for this position.*
 - d. Place the top chamber cap in place over the chamber. Slide the chamber on to the



Company Axial/Torsional ELF Protocol

Rev. 1.0

sample shaft until the chamber meets the assembly tool end.

- e. Push the assembly tool rod down until the lock collar is flush against the tool.
- f. Lock the set screw.



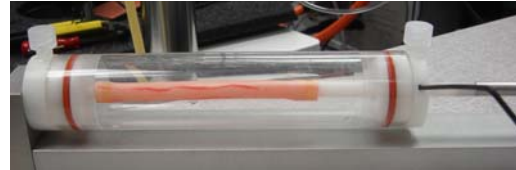
- g. Install sample on the sample shaft. Ensure that any latex artery, if used, DOES NOT interfere with the saline inlets/outlets on the shaft.



- h. Release the set screw and adjust the assembly tool pull rod and sample shaft to provide adequate room to install the sample on the bottom chamber cap. Again, ensure that the latex artery DOES NOT interfere with the saline inlets/outlets on the shaft.
- i. Place the assembly tool rod in the original position (lock collar flush against the tool). Check that the sample is not being compressed or pulled on.



- j. Slide the chamber down, fitting it onto the bottom chamber cap.
- k. Lock the sample shaft in place (preventing unwanted torsion) via the 3 screws around the circumference of the top chamber cap.
- l. Loosen the assembly tool set screw.
- m. Unscrew the assembly tool rod from the sample shaft.
- n. Release the chamber from the assembly tool via the screws on the bottom chamber cap.
- o. The sample sub-assembly is now complete.



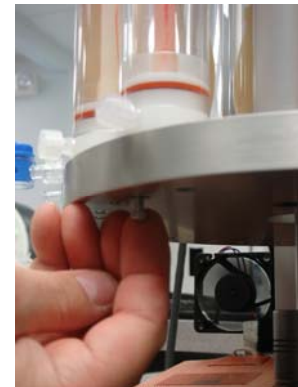
e) Install the Sample Sub-Assembly on the ELF 3300 AT Fixture

- a. Position the lock collar of the top platen flush with the platen face



- b. Position the chamber on the bottom platen.

- c. Screw in the 2 bottom platen screws, fixing the chamber to the platen.



- d. Slide the fixture lock collar down over the sample shaft (~ 1/2 way) and lock the collar in place.

- e. Release the top chamber cap set screws, allowing the sample shaft to rotate freely.



Company Axial/Torsional ELF Protocol

Rev. 1.0

- f. Fill the chamber with saline.
- g. Turn on the heater.

- f) Record the device deployment configuration on the Device Deployment Form.

- g) Mark the ends of tubes and/or fittings to allow traceability of sample ID and orientation during testing. Also mark an angular orientation to provide a reference point for migration monitoring.

- h) If test warrants, additional accessories may be utilized to achieve and maintain the test target parameters. These accessories include throttles, clamps, and devices approved by the Operations Manager.

8.0 ACCELERATED FATIGUE TEST START UP

- a) Determine the test command parameters to obtain the appropriate axial tension strain level (7%), compression strain level 3% and torsional strain level (+/-12.5 degrees), test frequency (6 Hz), and test duration (10,000,000 cycles).

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.

- 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 9 CYCLES_10 MILLION FREQUENCY 6HZ

CYCLE START DATE: 5/7/2007

PREDICTED CYCLE END DATE: 5/27/2007

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