

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

THIS IS A TEST PLAN FOR ACCELERATED FATIGUE TESTING OF CUSTOMERS DEVICES. THE DURATION OF THIS TEST SIMULATES X YEARS OF IMPLANTATION LIFE.

**AUTHOR:** CUSTOMER

**DOCUMENT ID:**

**APPROVED BY:**

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**Title: Standard ELF Protocol** \* Highlighted areas require Customer input

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- f) ELF fixture provided by MDTS or Customer
- g) Associated Paper Work
  - (1) Test Deployment Form
  - (2) Daily Data Sheets (Template 99127)

**5.0 FIXTURING**

- a) Choose, design, and implement the proper fixturing for the current test.
- b) Visually inspect the fixturing for uniformity and consistency. Verify that the fixturing meets the specifications for the current test.

**6.0 INSTALLATION**

- a) Install the fixturing on the EnduraTec ELF test system per the customer's protocol.
- b) Start the tester at the projected test frequency and adjust the fixturing and PID terms to achieve a stable sine wave.

**7.0 ACCELERATED TEST DEVICE DEPLOYMENT**

- a) Deploy the test devices according to the customer's protocol.
- b) Record the device deployment configuration on the Device Deployment Form.
- c) If appropriate mark the left and right ends of the device on the fixturing, providing a reference point for migration monitoring.

**8.0 ACCELERATED FATIGUE TEST START UP**

- a) Determine the test command parameters to obtain the protocol dictated conditions.
- b) If test warrants, additional accessories may be utilized to achieve and maintain the test target conditions. These accessories include throttles, clamps, and devices approved by the Operations Manager.

**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#. This data is backed up on the server. All data concerning the current test should be stored here.
- c) Set up data acquisition.
- d) Determine what parameters need daily monitoring per the customers protocol. 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.

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iii) If an abnormal data point is observed continue with the list below until the situation has been addressed:

- (1) Check that the laser micrometer is positioned correctly, re-measure the data point.
- (2) Purge the system and re-measure the data point.
- (3) Notify a senior lab technician or Operations Manager to assess the situation:
  - (a) Analyze the trend in data
  - (b) If necessary inspect the device endoscopically
  - (c) If there is a suspected failure the Lab Technician, Operations Manager or Director of Testing will contact the customer.

- f) **Inspect visually/endoscopically per Operation Managers discretion or customers protocol.**  
 Document inspection on the Inspection Data Sheet.
- g) Prepare a weekly Customer Update including observed parameters to be emailed once a week, or per customer's protocol.

**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 arteries from the instrument per customer's protocol.**
- e) Return the test samples, physiological samples, and any remaining samples to the **customer**.
- f) **If requested complete a test report within 2 weeks of test completion.** Send the report for revisions. Once the report has been finalized send a signed cover sheet along with a CD containing all of the customer's raw data.
- g) If no report was requested, send the CD containing all of the customer's raw data within 2 days of test completion.

**12.0 PROJECTED SCHEDULE FOR TESTING.**

**SAMPLE NUMBER** \_\_\_\_\_ **CYCLES** \_\_\_\_\_ **FREQUENCY** \_\_\_\_\_

**CYCLE START DATE:** \_\_\_\_\_

**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