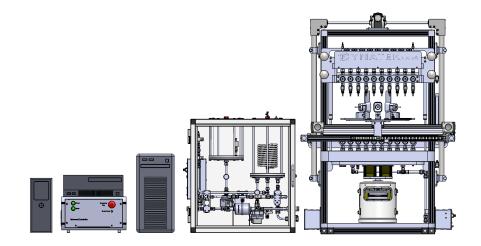
# FtF Fatigue to Fracture Tester



#### Why Fatigue to Fracture is needed

Current regulatory standards require testing to success for the intended lifetime of the device. In addition to this requirement, device manufacturers have long sought to bolster their safety data by exploring the endurance limit of their products. Properly executed FtF testing can predict the lifetime of your product. It can also identify locations of future failure and verify Finite Element Analysis (FEA) predictions.

#### Dynatek Labs offers a real solution

This instrument is the latest in a series of historic contributions that Dynatek Labs has been responsible for over the past 40 years. Building on the well-established fundamentals of fatigue to failure, Dynatek's patented<sup>1</sup> FtF tester is a unique and effective solution to evaluate predictory Fatigue to Fracture (FtF) testing of vascular stents, endovascular prothesis, and other tubular elements. Leveraging our decades-long expertise developing radial fatigue testers, Dynatek has further enhanced the experience by offering a robust instrument capable of delivering hyper-physiological pressure excursions, paired with visual monitoring of samples to pinpoint the precise moment and location of fractures.

1 US Patents # 10,627,315 B2; # 10,605,700 B2

#### **Testing Advantage**

A properly designed and executed FtF evaluation can predict:

- 1. Endurance limits by varying the load, frequency of test, temperature, or pH
- 2. Predict potential failure locations of the device
- 3. Verify the validity of a Finite Element Analysis









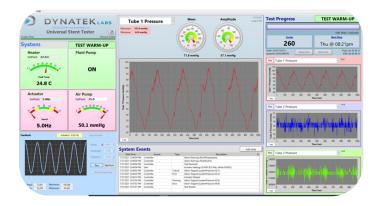
#### **FtF Features**

- Extremely strong stainless manifold capable of 2000 mmHg cyclic loading
- Unique bellows design with up to 1 billion cycle lifetime
- Components capable of withstanding up to 60 °C temperature and pH 12.0
- Custom designed electromagnetic motor that delivers years of continuous service
- Specialized mock vessel envelopes to facilitate realistic response at hyper-physiological pressures
- Continuous monitoring of temperature, cycle, frequency, and relevant pressures
- 360-degree visual monitoring across all samples for precise identification of fractures

"Engineers know that this kind of tester is absolutely vital to developing a longlife implantable device."

#### Software

DynUC Universal software controls and monitors all experimental parameters and records them as frequently as once per minute. All parameters are automatically written to a secure datafile. Tandem camera software provides visual verification of fractures with precise time-stamps to correlate cycle count.



## **Dynatek Labs FtF Product Specifications**

#### Description

Number of samples Sample diameter Sample length (straight) Sample configuration Manifolds Temperature range pH range Systemic pressure Control system Variables controlled and/or monitored

Certification Data poll interval Power requirement Test samples of various dimensions Unattended operation

#### Specification

 $\leq 10$ 1-10 mm ID ≤ 250 mm linear for easy visualization stainless steel, proximal and distal room temp to 60 °C 5.0 to 12.0 up to 28 psi Dynatek's Universal Controller temperature, cycle rate and count, systemic pressure, sample pressure(s), visual fracture detection CE mark ≥ 1 min 120/240 V 50/60 Hz yes yes



Specifications are subject to change without notice.

PJLA Testing

Accreditation# 102435

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To receive a customized proposal, contact us today at:

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