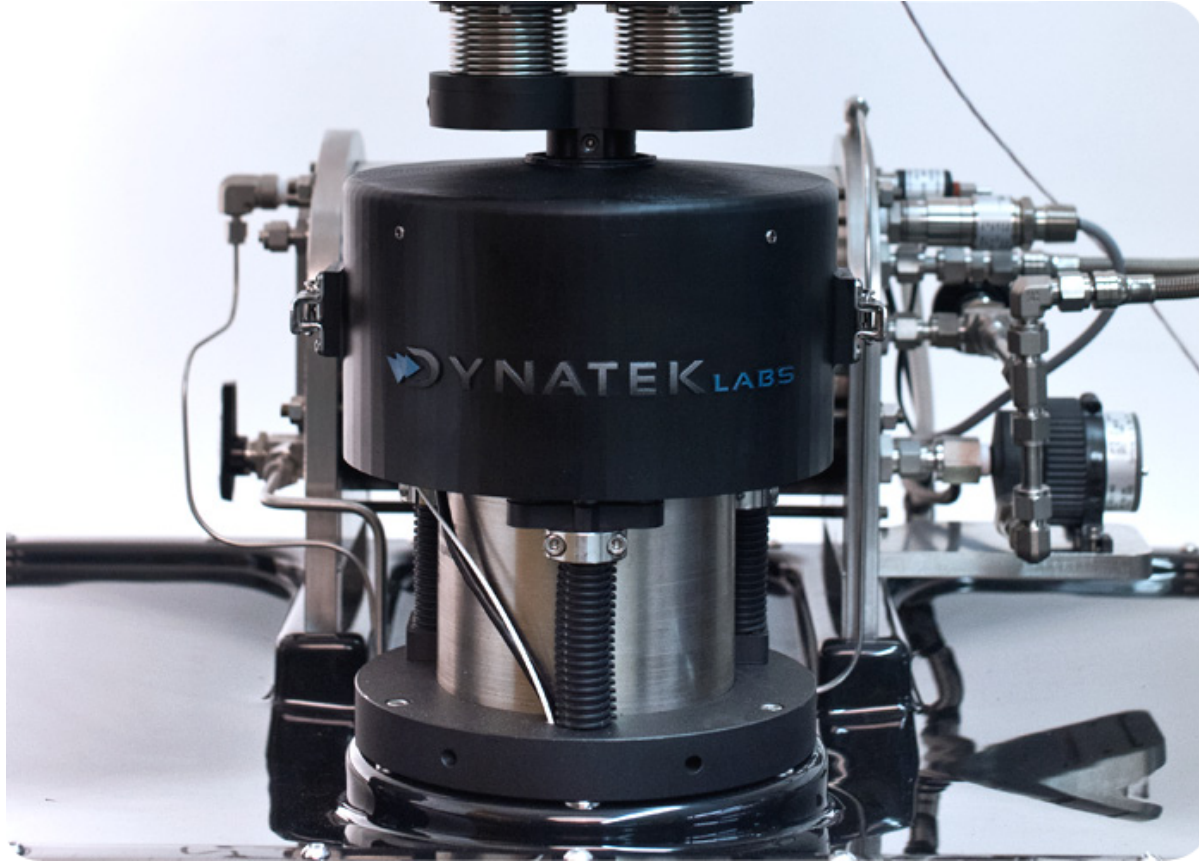


FtF Fatigue to Fracture Tester (pat. pend.)



Why Fatigue to Fracture is needed

Although most new medical device standards and regulatory guidelines require Fatigue to Fracture (FtF) testing, the most important reason to develop a Fatigue to Fracture program is to ensure that your new product lifetime enhances the company's reputation and financial success. 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

Dynatek Labs has always cast an eye forward to the needs of the future. Although the fundamentals of FtF are well established, the real innovations center on experimental protocols that result in successful predictions of endurance limits and sites of future failures. Dynatek has developed an instrument, testing protocols, and testing envelopes that address properties of all implantable tubular elements such as stents and endovascular prostheses.

Dynatek Labs radial FtF device tester can, along with novel mock arteries, deliver cyclic pressures up to 50 psi (2500 mmHg).

Testing Advantage

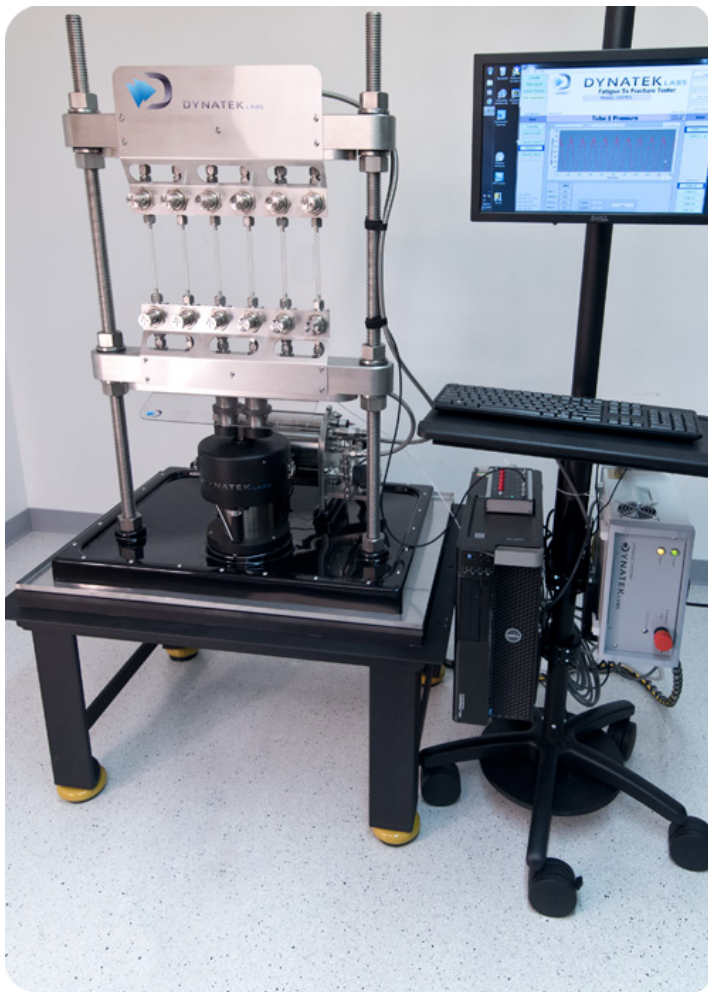
A properly designed and executed FtF evaluation can predict:

1. Endurance limits by varying the load, frequency of test, temperature or pH
2. Predict potential failure locations of the device
3. Verify (or not) the validity of a Finite Element Analysis

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DYNATEK LABS
Leading the world in medical device testing



Complete FtF tester.

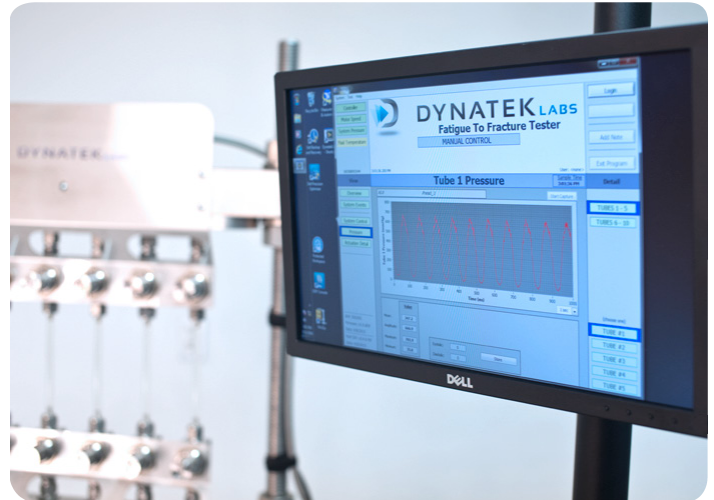
FtF has

- Extremely strong stainless manifold capable of 2000 psi loading
- Unique bellows design allowing lifetimes of up to 1 billion cycles before failure
- Components that can withstand up to 60 °C temperature and pH 12.0
- High pressure capacitance tank with a view window and electronic fluid level monitor
- Custom designed electromagnetic motor that delivers years of service
- State of the art explosion proof case (optional), that cannot be tampered with, to maximize the safety of the operators or observers
- Handy computer and controller cart that lets the user choose options for comfort and useability

Software

Perhaps the most impressive component of the FtF instrument is our Universal Software that controls and monitors all experimental parameters and records them as frequently as once per minute. LabView-based programming coupled to a powerful SBRIO and FPGA has extraordinary capabilities to control, monitor and record each moment of an experiment.

“Engineers know that this kind of tester is absolutely vital to developing a long life implantable device.”

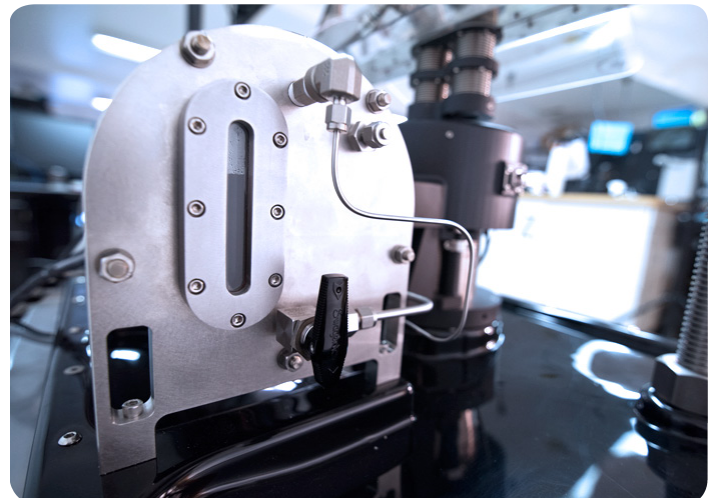


Proprietary LabView-based controller software.

As you can see in the photos, the Dynatek FtF tester is an impressive, strong and powerful instrument. Not just built for endurance testing, it includes a safety enclosure that ensures operator safety.

The second part of the story is focused on the unique mock artery system that we have developed. By using a combination of outer and/or inner mock vessel you can:

1. Produce aggressive contraction only loading
2. Produce aggressive expansion only loading
3. Produce aggressive expansion and contraction loading



High-pressure capacitance tank with observation window and float switch.



The FtF tester supports up to six samples.



Optional safety enclosure.

The Dynatek FtF tester is a unique and effective way to carry out predatory FtF testing on vascular stents, endovascular prothesis (or other tubular elements that may not be a medical device). This instrument is the latest in a series of historic contributions that Dynatek Labs has been responsible for over the past 30 years.

Dynatek personnel will custom design any protocol or instrument to meet your needs.

Dynatek Labs FtF Product Specifications

Description

of samples
Sample diameter
Sample length (straight)
Sample configuration
Manifolds
Capacitance tank
Pressure transducer
Temperature range
pH range
Sample temperature control
Systemic pressure
Control system
Variables controlled and/or monitored
Certification
Safety enclosure
Cleaning
Freq. of pertinent data stored
Test samples of various dimension
Power required
Unattended operation
Ionic solution restriction
Testing modes
Sound

Specification

≤ 6
1-8 mm ID
≤ 250 mm
linear for easy photography
stainless steel, proximal and distal
reinforced stainless steel with observation window and float switch
high pressure / high resolution
room temp to 60 °C
5.0 to 12.0
24v circulatory pump
up to 28 psi
Dynatek's Universal Controller
temp, cycle rate, cycle count, systemic pressure, sample pressure
CE mark
Optional
Alcoholic cleaner and sterilant
≥ 1 min
yes
120/240 V 60/50 Hz
yes
chloride levels < 0.2 M
sample deflection or pressure ¹
< 60 dBA

1 Sample deflection monitoring requires optional high speed camera.

Specifications are subject to change without notice.

To receive a customized proposal, contact us today at:



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