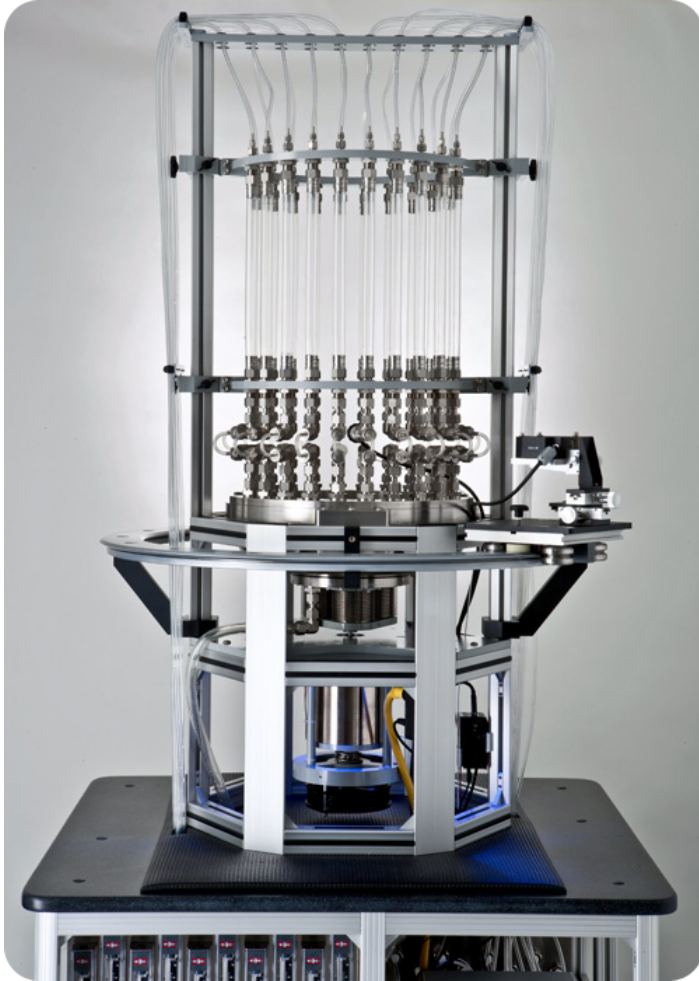


CDT-20 Stent Tester



CDT-20 Particle Counting Stent Tester

Dynatek's patented¹ Coating Durability Tester utilizes a Hyper Drive linear motor to produce an adjustable bellows compression which allows for physiologically relevant stent loading conditions for up to 20 test samples from physiological to accelerated testing rates of up to 150Hz.

Dynatek's laser particle detection system allows accurate real-time counting, sizing, and data logging of shed particles from each drug-eluting stent during testing, giving a time course of shed particulates from each sample.

The large number of samples greatly benefits manufacturing QA when ongoing testing of approved stents is required.

- FDA accepted with appropriate documentation.
- A master file on the machine is located at the USFDA.
- Compact integrated mounting stand or benchtop configurations available.
- Ability to test up to 20 samples simultaneously under precisely controlled test parameters.²
- Ability to test samples of slightly varying sizes of the same design at the same precisely controlled test parameters.
- Patented¹ system used to detect and identify, in real time, the number and size of shed particles from each sample.
- Integrated system has a smaller footprint than previous systems.
- Advanced universal controller with unmatched data collection ability.
- Data logging to a TDMS file which can be accessed by Excel or other software such as DIAdem and Matlab, for managing, analyzing, and reporting the test data collected.
- Unique redundant filtration system that allows for filter changes without test interruption.
- Frequency, temperature, and pressure controls give the user the ability to establish, maintain, and recall required test parameters.
- Ability to monitor sample tube pressures at all test frequencies.
- Closed loop laser micrometer feedback allows for automatic control and monitoring of mock artery distension.
- Long life electromagnetic Hyper Drive linear motor.
- Design allows for easy access to test samples.
- Universal controller allows for future expansion of the CDT-20 system to accommodate future host computer technology.
- Future upgrades with advance SCADA technology allow complete lab monitoring of all machines from a single host computer.

¹ US Patent # 7,621,192 B2

² Number of test samples dependent on diameter and compliance of sample tubes.

SD 511
050620



DYNATEK LABS
Leading the world in medical device testing



Lower section of the CDT-20 showing flow meters, controller, and particle counters.

Available Add-ons

- Individual filters for each test sample.
- Various diameters of graft tube adapters for different test sample sizes.
- Custom modifications for the rack mount system.
- Valves to allow individual samples to be removed or replaced without interrupting the test.
- Very large diameter test samples possible with custom hardware.
- Alternative cap tanks and fluid heaters for higher test temperatures.
- UPS (Uninterruptable Power Supply) system.
- Adapters for catheter deployment of stents on the tester.
- Custom particle counter calibration for atypical particle size ranges.
- Custom collection filters available to aid in chemical analysis of particles.
- Other custom modifications at customer request.

High-throughput testing speeds you to regulatory approval

The CDT-20 features Dynatek's Hyper Drive linear motor to produce an adjustable bellows compression which allows for physiological to accelerated loading conditions for up to 20 stent samples simultaneously. Unrivaled flexibility allows you to test straight, curved or bifurcated tube configurations under precisely controlled test parameters, while tube deflection is monitored by a laser micrometer. The CDT-20 is available in two configurations: benchtop or with an integrated mounting stand.



Dynatek's CDT-20 benchtop Coating Durability Tester

"...if you're not counting particles in real time, you're not getting the full picture..."

Particle counts track shedding behavior of stents

Particle shedding by coated and bare metal stents is a regulatory concern, but it doesn't need to be yours – with the CDT-20. With cutting-edge patented technology, the CDT-20 features 20 custom-designed laser particle counters that detect, in real time, the number and size of particles greater than 5 microns shed by each individual stent during pulsatile durability testing. Once these particles are detected, they are categorized into between 2-6 configurable size ranges or virtual 'bins.'

Real time counts offer powerful insight into potential disease state formation

Instead of a single count of all shed particles after a test run is completed, the CDT-20 allows you to count particles as they are being shed. As particles pass through the particle counter, they are detected and logged by particle size and quantity. Real time counts let you visualize when and how much your stent is shedding particles at every stage of testing, helping you understand your stent's potential for promoting a pathological condition *in vivo*.

Deflection monitoring that exceeds current regulatory standards

The CDT-20 can monitor the tube deflection of up to 20 stents serially with a laser micrometer that actively measures the real-time outer diameter of the selected mock artery as it undergoes deflection. For the most accurate picture of stent deflection, however, we recommend the optional high-speed camera. The high-speed camera tracks two digital points on the stent and the relative distance between the markings will change as the mock vessel hosting the stent expands and contracts, providing critical stent deflection data. With the CDT-20, you will be compliant with the requirement of upcoming regulations that mandate observation of actual stent deflection.



Newly designed UC Controller

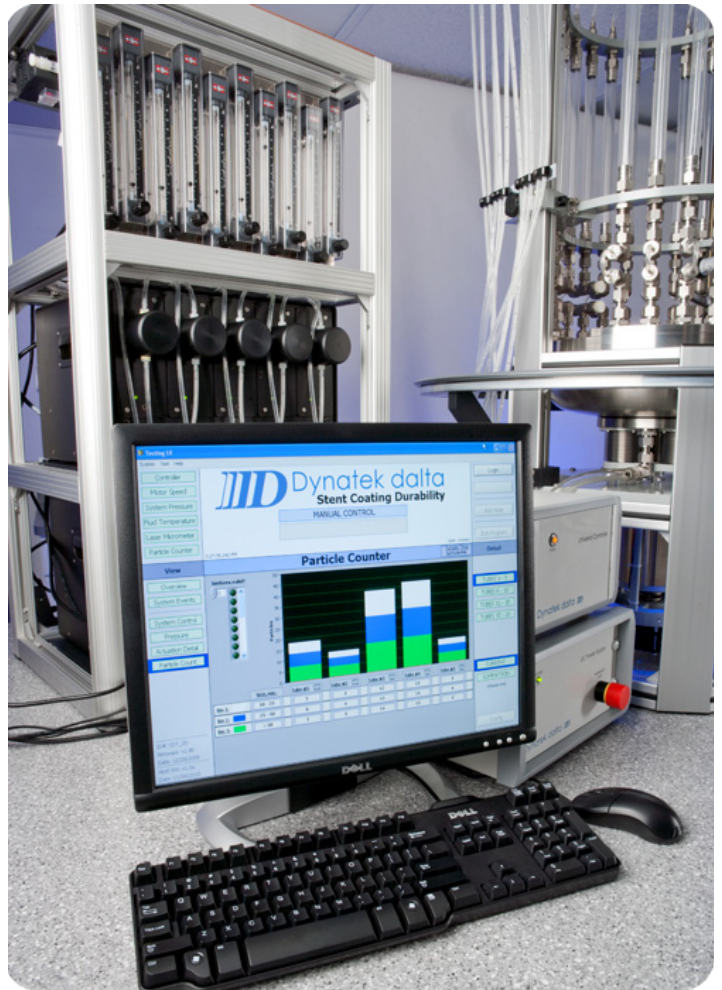


Newly designed 5 Sensor Particle Counter

"...the CDT-20 takes us beyond compliance to true patient safety by allowing us to address standards passed or being drafted by the ASTM and AAMI/ISO committees that focus on the release of particulates from stents..."

Particle characterization drives stent design

An optional filtration system for the CDT-20 is available, featuring a separate filter for each stent sample. The particles shed by each stent are captured by individual downstream filters, allowing you to chemically characterize them. Chemical characterization of particles sheds light on potential toxicity and provides vital information that affects coating and stent design.



"You guys are always easy to contact and provide the best customer support ever; truly appreciate it!"

Dynatek Labs Model CDT-20 Product Specifications

Description	Specifications	Additional Information
Number of test samples	20 test samples	20 test samples standard
Mock vessel configuration	Straight, curved, or bifurcated	Additional special configurations upon request
Mock vessel length (straight)	Adjustable to ≤ 254 mm	
Mock vessel inner diameter	≈ 1.5 mm to ≤ 10 mm	
Typical mock vessel compliance	5% to 7% per 100 mmHg	Other specifications available upon request
Testing rate	1.2 to 150 Hz	
Testing fluid	PBS or distilled water	Other testing solutions possible
Fluid temperature	Ambient to $\leq 45^{\circ}\text{C}$	
Flow rate	100 mL/min per sample	Per Lane
Test control parameters	Stent deflection (with high speed camera), Tube deflection (with laser micrometer), Tube pressure (with pressure transducer)	
Laser micrometer	Solid-state laser diode (optional; 780 nm)	
Pressure transducer range	0-10 psig	
System fluid filter	0.2 micron	
Particle capture filters	20 (optional)	1 common or up to 20 individual
Particle capture pore size	5 micron (optional)	Other pore sizes available
Controller	Universal Controller, featuring the NI™ Single-Board RIO platform	
Software	Dynatek DAQ software based on LabVIEW architecture	
Capacitance tank	1.5 gal	

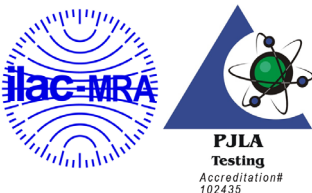
Dynatek Labs Particle Counter Product Specifications

Description	Specifications	Additional Information
Number of particle counter modules	20	Individual modules for each sample lane
Particle size range	5-900 micron	Size and count up to 100 micron Count up to 900 micron
Particle count range	15,000 p/mL @ 10 micron	
Particle bin range	2-6 bins	5 bins of 5-100 micron 1 bin for 100-900 micron
Particle counter calibration standard	USP <788>, ASTM F658	
Sizing resolution	5-50 micron: +/- 1 micron 50-100 micron: +/- 5 micron	

Module	Dimensions	Power	Weight
CDT-20 Integrated system	38"W x 40"D x 94"H	120 VAC 12 A	745 lbs. (complete system)
CDT-20 Bench Top system	60"W x 72"D x 53"H	120 VAC 12 A	600 lbs. (complete system)

*Specifications are subject to change without notice.

To receive a customized proposal, contact us today at:



Dynatek Labs, Inc.
 105 East 4th Street
 Galena, MO 65656
 800.325.8252
 1.417.357.6155
 www.dynateklabs.com
 salesdd@dynateklabs.com

