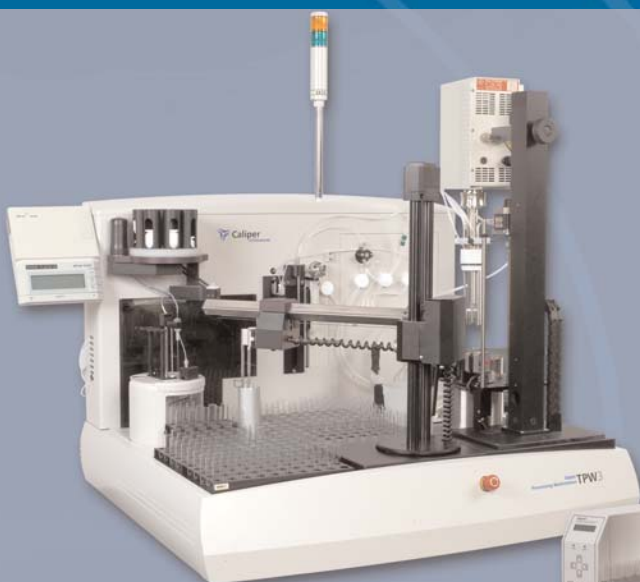


Available in
April 2006!

Tablet and Active Ingredient Processing Workstations



*Local Solutions
for the Global
Pharmaceutical
Industry*

 **Caliper**
LifeSciences

Local Solutions for the Global Pharmaceutical Industry

TPW3 and APW3 perform fully automated sample preparation and analysis for the most common pharmaceutical tests in the Development and Quality Assurance functions. Starting as early as Phase 1 Development, all the way through to Manufacturing Quality Assurance, Caliper's Assay Workstations will increase laboratory productivity and analytical quality. TPW3 and APW3 are compatible with SQL Server Enterprise Edition. This allows electronically approved methods to be made available for the local use in:

- Method Development
- Material Characterization
- Formulation Development
- Process Validation
- Product Transfer
- Equipment Cleaning Validation
- Raw Material Testing
- QA Release Testing
- On Going Stability



Workstation methods are electronically available throughout the global corporation

Customer Collaboration

Caliper Life Sciences has worked with the pharmaceutical industry's expert automation chemists to design and test these products. This three year long collaboration has resulted in products that maintain the basic functionality of the well-known TPW II and Prelude products while increasing:

- Method flexibility
- Analytical quality
- Capacity
- Reliability
- Productivity



TPW3 and APW3 are third generation products that have improved productivity for over 15 years.

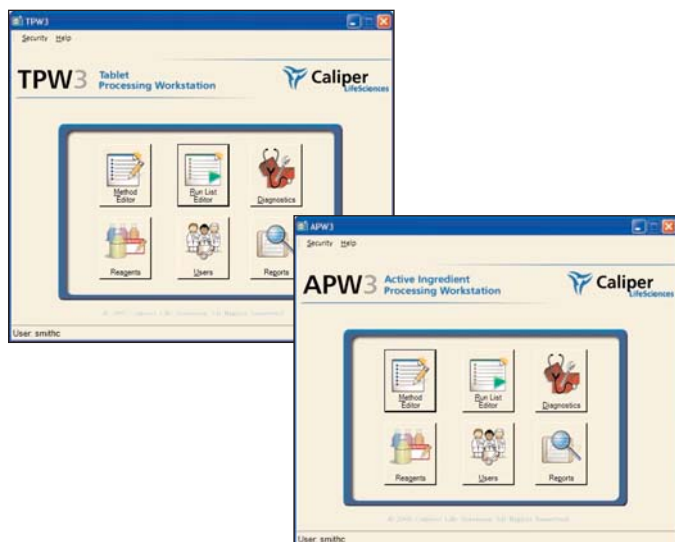
They perform fully automated sample preparation and analysis for the most common pharmaceutical tests in the Development and Quality Assurance laboratories.



Tablet Processing Workstation **TPW3**

The TPW3 is specifically designed to prepare and analyze pharmaceutical solid dosage forms and intermediate granulations. The TPW3 uses a high shear homogenizer to disperse samples in a vessel containing 50-500 mL of solvent. This makes TPW ideal to efficiently extract analyte for:

- Tablet and Capsule Content Uniformity
- Tablet and Capsule Assay
- Tablet and Capsule Stability and Other Impurities
- Blend and Granulation Uniformity



Active Ingredient Processing Workstation **APW3**

The APW3 is intended for use testing pure Active Pharmaceutical Ingredients (APIs). It may be used in other situations where smaller solvent volume is required. The APW3 processes samples in 16mm X 100mm tubes. The APW3 may be used for diverse applications, including:

- API assay
- API stability and other impurities
- Residual components
- Cleaning validation
- Creams and semi-solid dosage forms
- Drug loaded medical devices
- Other extractions for assay



Improved Quality of Analysis

The TPW3 and APW3 improve the quality for every day laboratory tasks as well as more complicated sample preparations. For walk-up use of just a few samples, or extended runs of many samples, you can be confident in the quality of your analytical results.

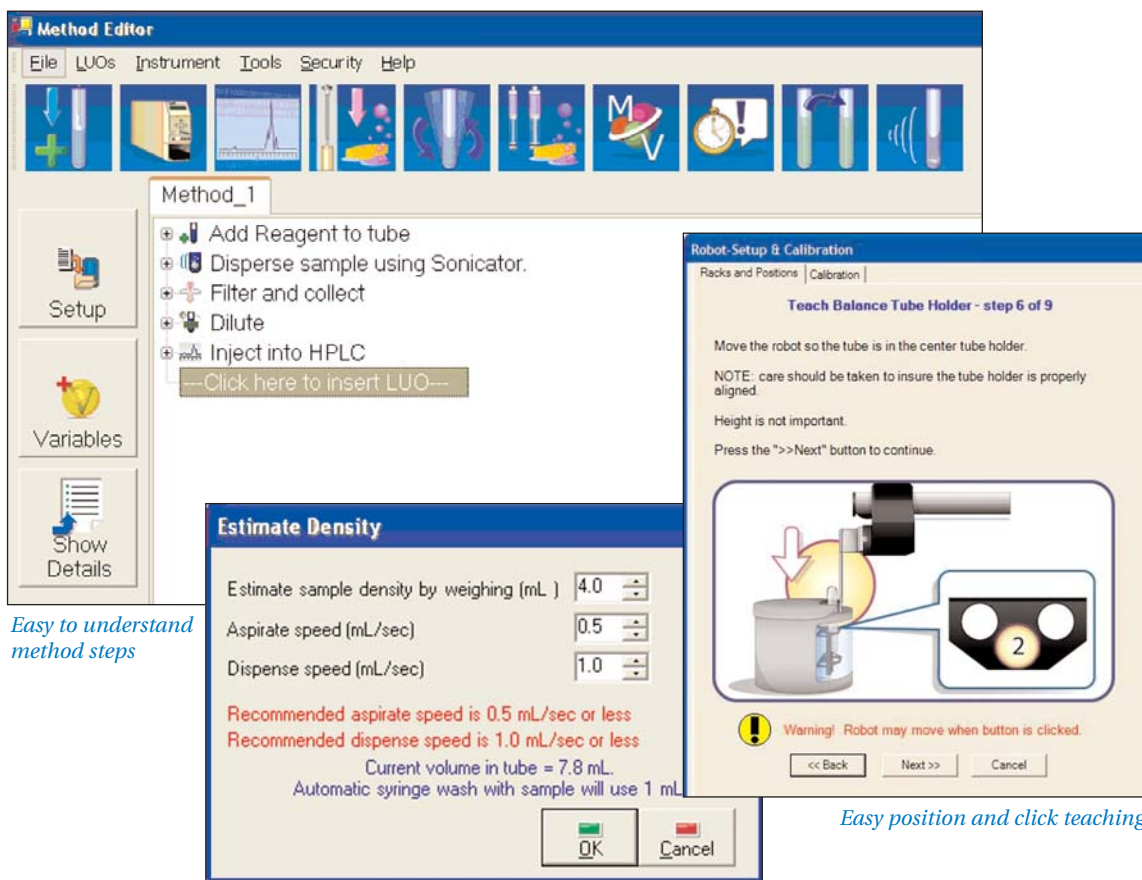
- Gravimetric confirmation assures liquid dispense accuracy and precision.
- Complies with ASTM requirements for volumetric delivery precision and accuracy.
- Eliminates analyst technique as a source of variability.
- Serial processing assures the timing of method steps and wait time for injection are identical from sample to sample.
- Assays unstable drugs and degradents immediately after preparation.
- Provides a level of precision that is difficult to achieve in a batch mode of operation.
- Technique dependent steps such as dispersing or extracting are precisely defined and controlled to be reproducible.
- In most cases, optimized methods will meet or exceed manually obtained analyte recovery.
- Correlation coefficients are expected to meet or exceed manual results.



Ease of Use

Methods are easily written by selecting icons that represent various method steps. Each step includes commonly used default values with easy "fill in the blank" operation for each parameter:

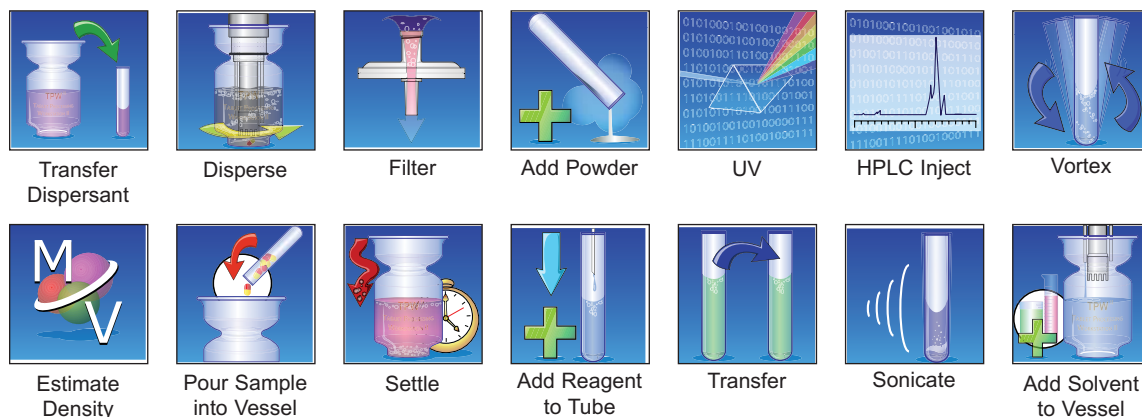
- Software recommends settings for dilutions and other parameters.
- Key method variables can be applied at run time to evaluate their impact in method development.
- Database sharing makes it easy to use the exact same method throughout the global organization.



Easy to understand method steps

Easy position and click teaching

Easy to use software provides complete control, volume status and recommendations



Increased Productivity

Productivity brought by the TPW3 and APW3 Workstation transcends typical cost of labor considerations.

- The saved labor allows more time for other, more critical, challenges.
- Typically a TPW3 can do the work of two analysts.
- When applied early in development, benefits will compound throughout the product's life cycle.
- APW3 and TPW3 have been designed with reliability in mind.
- Easy to teach positioning requires less time for support.
- The secure audit trail provides a faster and more accurate investigation of Out Of Specification (OOS) events.
- Increased productivity allows more samples to be run, which translates to a more robust process validation design.

Fully Compliant

The TPW3 and APW3 are primarily intended for use within the regulated pharmaceutical industry around the world. Compliance has been taken into consideration in all aspects of use.

- The FDA and other regulatory agencies around the world routinely accept Caliper's Assay Workstations.
- The TPW3 and APW3 Workstations use the same chemistry that has already been validated using standard laboratory techniques.
- Revalidation of the original chemistry is typically not required.
- The FDA has accepted submissions originally developed on the Processing Workstations.
- Comprehensive and secure documentation provides 21CFR Part 11 compliance.
- Electronic signatures serve to record the approval status of methods and test results.
- Adapted methods are usually filed as an Alternate Method in annual NDA and ANDA updates.
- Dispensed volumes comply with USP requirements for volumetric delivery.
- TPW3 and APW3 do not use unproven, inferential, chemo-metric approaches.
- Demonstration of equivalent recovery and minimal carry over is typically used to demonstrate suitability.
- A full line of validation services are available from Caliper Life Sciences.

Increase Capabilities with Optional Accessories

Options expand the basic capability to meet individual customer needs.

- EasyFill sample collection stores samples in septum-capped vials and 96 well plates.
- Sonicating probe and wash station facilitates preparing solutions. It automatically reads preparation temperature.
- Bar code reader supports common industry formats.
- Automation Certified Filters are available from Pall.
- Acid resistant versions of the TPW3 and APW3
- Rack adapter for Caliper's TurboVap LV allows convenient transport for rapid evaporation.
- Large tube adapter provides utility for 20 X 150mm sample tubes for TPW3.
- Rack adapter for AutoDose PowderNium allows convenient transport of automatically dispensed powdered samples.
- Evaporation resistant caps.



TurboVap® LV Concentration Workstation



ATTRIBUTES

Caliper's TPW3 and APW3 include unique features and capabilities that provide precise and productive unattended sample preparation.

CAPACITY AND FLEXIBILITY	APW3	TPW3
* Up to 300 samples can run unattended using single tube methods	X	
* 150 single step dilutions can be performed	X	
Up to 100 samples can run unattended using a single step dilution		X
* Depending upon method settings, a very large number of methods may be linked together	X	X
* Depending upon method settings, a very large number of methods may be overlapped	X	X
Up to nine solvents or reagents are available	X	
Up to five solvents or reagents are available		X
* Abbreviated methods may be used to evaluate functionality	X	X
* Variables can be easily modified for method developers	X	X
DISPERSIONS AND EXTRACTION		
Disperses samples in vessel with volumes from 50-500mL		X
High shear homogenizer for fast dispersion and extraction		X
Disperses samples in test tubes with volumes from 1-8 mL in 16X100 mm tubes	X	
* Redesigned optional sonicating probe to facilitate rapid solubility or extraction	X	
* Infrared temperature measurement for optional sonicating probe	X	
Filter dispersion with a wide variety of Pall Automation Certified filters	X	X
Mixing with reciprocating vortexer	X	X
WEIGHING		
Gravimetric confirmation assures dispenses meet USP and ASTM requirements for volumetric measurement	X	X
Utilizes a dual range four to five-place balance to weigh samples, add reagents and carry out dilutions	X	X
Uses a three place balance to weigh dispersant solvent for high shear mixing		X
* Gravimetric assist dispensing may be de-selected to allow for faster operation when accuracy is less critical	X	X
Gravimetric traceability throughout the sample prep provides a record for OOS investigations and assurance of sample integrity	X	X
DILUTION		
Dilutions ratios as high as 1:10,000 can be performed	X	X
Dilution step details are automatically suggested	X	X
* Two single-step dilutions can be performed within a method	X	X
* Overlapping methods allows serial dilutions to be performed	X	X
FINISH		
HPLC injection is enabled with an on board Rheodyne injector	X	X
* Integrated interface for Waters Empower	X	X
* Versatile control of standards for bracketing	X	X
* Multiple injections may be performed within a method	X	X
On-line UV/VIS detection via contact closure	X	X
Samples may be collected in a variety of formats for off line analysis	X	X
Flexible cleaning capabilities	X	X
SOFTWARE		
* Provided with SQL Server Developer Edition		
* SQL Enterprise Edition Database compatible	X	X
21CFR11 Compliant	X	X
Easy to use step by step LUO (Laboratory Unit Operation)	X	X
* Software makes all variables available for each LUO for complete control	X	X
* Security is customer IT configurable to meet your corporate policy	X	X
* Customer IT configurable for LIMS		
* XML, Excel, PDF output supported	X	X
* Diagnostics are captured in the compliant database	X	X
* Fault tolerant networking to shared SQL database	X	X
HARDWARE		
* All new control architecture for supportability and reliability	X	X
* Positive encoder feedback for precise device control	X	X
* Multipoint position referencing	X	X
* Position and click teaching	X	X
* Indicates a NEW feature		

Powder Transfer and Filter Station



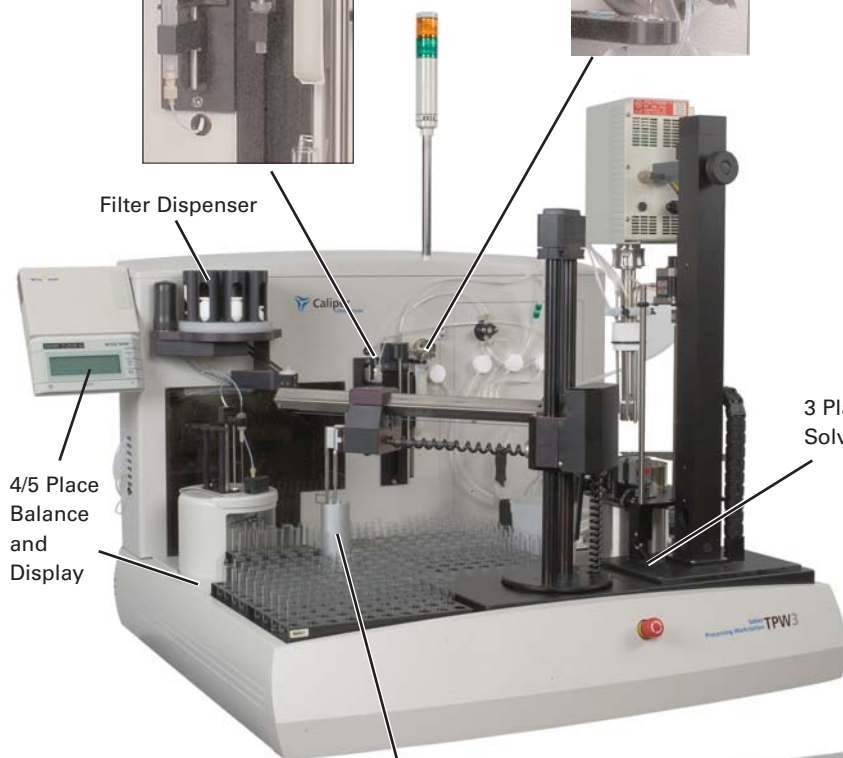
Rheodyne HPLC Injector



Dispersing Homogenizer



Filter Dispenser



4/5 Place Balance and Display

3 Place Extraction Solvent Balance

Vortex Mixer

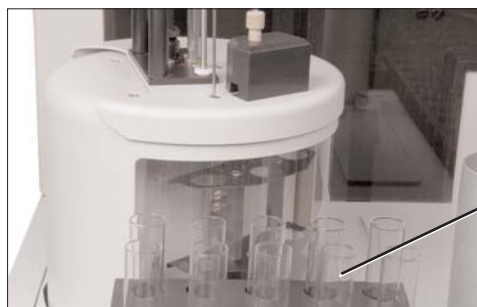
EasyFill Sample Collection

Emergency Stop

Status Light



Tablet for Content Uniformity



Weighing for Samples and Reagent Dispense

Standards Rack

Optional Sonicating Probe



Customer**FIRST** Services & Support

The Caliper Life Sciences' Customer First Service & Support Organization is equipped to provide our TPW3 and APW3 customers with a variety of support options:

- Flexible service plans to keep your equipment running trouble-free.
- Technical Support via phone, fax or email.
- Introductory, advanced and troubleshooting Training Courses to enhance your product experience.
- Application Services to maximize the return on your automation investment.
- Validation Services including a Standard Validation option, Re-Validation Package, 21 CFR Part II Validation, and Fast Val option.

To request more information on our services and support, or to speak to a member of our Customer First team, please contact us at 508-435-9761 or tech.support@caliperLS.com.

To learn more about either the TPW3 or APW3, please contact us at 508-435-9500 or cust.support@caliperLS.com



Caliper Life Sciences
Corporate Headquarters
68 Elm Street
Hopkinton, MA 01748-1668
1-508-435-9500
www.caliperLS.com
Fax: (508) 435-3439
Email cust.support@caliperLS.com

Worldwide Offices

Benelux
Caliper Life Sciences N.V.
Klapstraat 13
B-1790 Tervuren
Belgium
Telephone: +32-53-66-26-70
Fax: +32-53-66-27-32

France
Caliper Life Sciences S.A.
ZAC PARIS-NORD II
13 rue de la Perdrix
BP 48016 Tremblay en France
95911 Roissy CDG Cedex
France
Telephone: +33-1-48-63-71-35
Fax: +33-1-48-63-71-53

Germany
Caliper Life Sciences GmbH
Eisenstrasse 9c
DE-65428 Rüsselsheim
Germany
Telephone: +49-6142-834-93-0
Fax: +49-6142-162-821

Japan
Caliper Life Sciences Japan
Saito-Bldg. 2F
Yushima 2-17-15, Bunkyo-ku
Tokyo 113-0034
Japan
Telephone: +81-3-5840-6551
Fax: +81-3-5840-6554

Switzerland
Caliper Life Sciences AG
Nordstrasse 17
CH-4665 Oftringen
Switzerland
Telephone: +41-62-788-7000
Fax: +41-62-788-7017

United Kingdom
Caliper Life Sciences Ltd.
1 Wellfield
Preston Brook
Runcorn, Cheshire WA7 3AZ
United Kingdom
Telephone: +44-1928-711448
Fax: +44-1928-791228

Caliper Life Sciences has representative offices worldwide. Please visit www.caliperLS.com for locations and contact information.

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