



REGULATORY POSITION

TA INSTRUMENTS
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I. BUSINESS

1. What products and services does TA Instruments provide?

TA Instruments designs, manufactures, sells and services scientific test equipment known as thermal analyzers and rheometers. Scientific equipment of this type includes differential scanning calorimeters, thermogravimetric analyzers, thermomechanical analyzers, dynamic mechanical analyzers, rheometers and others. This series of apparatus measures one or more physical properties of materials as a function of temperature. The temperature range of interest is from -180 to 1500 °C (-540 to 2730 °F). This is from approximately liquid air to white hot temperature. Products consist of a personal computer based controller, a measurement module, data acquisition and analysis software, and accessories.

2. How long has TA Instruments been in business?

Founded: 1963

TA Instruments was found as the Instrument Products Division of the DuPont Company in 1963. In 1990, the business was divested from DuPont into a stand-alone business. In 1996 the Waters Corporation purchased it. In 1993, TA Instruments acquired Carri-Med, Plc., a UK company, and in 2003 Rheometrics Scientific.

3. What are the annual gross sales of TA Instruments?

1999 Sales : \$65,000,000

4. **How many people are currently employed by TA Instruments?**

Employment:	ca. 300	Worldwide
	ca. 199	USA
	ca. 160	New Castle, DE

5. **How many and in which countries does TA Instruments have distribution/sales/service offices?**

TA Instruments operates sales offices, customer service, and support facilities in the USA and in 11 other countries. We also operate through agents and distributors in 43 other countries. A list of sales offices, customer service, and support facilities is available upon request.

6. **To what general markets does TA Instruments provide products and services?**

TA Instruments markets primarily to industrial (67 %), academic (25 %) and government (8 %) accounts. Primary application areas include polymer (55 %), chemicals (19 %) and pharmaceuticals (16 %).

7. **How long has TA Instruments been a supplier to the pharmaceutical industry?**

Since 1963

8. **What portion of TA Instruments business is in the Pharmaceutical sector?**

Approximately 16 % of our business is in the Pharmaceutical sector.

9. **How many systems are in place in the pharmaceutical industry?**

Estimated number of TA Instruments system installations in the pharmaceutical industry was 100 in 2002.

10. **Does TA Instruments have certification to any recognized international standards?**

TA Instruments has been ISO 9002 Certified since 1994 and was the first supplier of thermal analysis to be so certified. TA Instruments currently holds ISO 9001:2000 Certification.

TA Instruments services and calibrates only the apparatus that it manufactures. It is not a third party calibration or service organization. It is exempt from Guide 25 requirements under section 4.11.2.b.1 of the QS 9000 standard.

11. **How long have TA Instruments hardware products been available? What is the model history of the products?**

DSC Model -----	Introduced -----	Discontinued -----
900	1968	1971
CB II, 10, 910, 912	1971	1993
2010, 2910, 2920	1988	2001
Q10, Q100, Q1000	2001	present

TGA Model -----		
950	1963	1971
50, 951	1971	1993
2050, 2950	1989	2001
Q50, Q500	2001	present

Controller/Software Models -----		
900	1963	1971
990	1971	1978
1090	1978	1984
9000 – RMX	1984	1989
2000 – RMX	1989	1997
OS2 – DOS	1995	1998
Thermal Solutions	1998	1999
Thermal Advantage	1999	present

12. **How long have TA Instruments software products been available? What is the version history of the product and number of releases per year?**

Thermal Advantage (Q Series)	2001
Universal Analysis (Windows®)	2000
Advantage Integrity for Thermal Analysis	2002
Rheology Advantage	2000
Rheology Analysis	2000
Advantage Integrity for Rheology	2003

13. **Does TA Instruments have a stated Corporate Quality Policy?**

Yes. Policy attached as Appendix B

14. **Does TA Instruments have a separate Quality Assurance Organization?**

Yes. The Quality Assurance Manager leads the Quality Assurance Organization.

15. **Does TA Instruments have a Quality Audit Program?**

TA Instruments regularly participates in within laboratory repeatability and between laboratory reproducibility programs (*i.e.*, interlaboratory tests) sponsored by the American Society for Testing and Materials (ASTM International).

16. **What training do staff members undergo when joining the company?**

Initial employee training is conducted by Human Resources and includes company policies and procedures, time keeping requirements, EEO and Affirmative Action, Sexual Harassment, code of Conduct and General Safety, Right-to-Know with regard to Material Safety Data Sheets and Chemical handling.

This is followed by job and safety training by the respective departments according to ISO guidelines.

Training is documented in the individual employees training records and is updated during the annual review of performance.

17. **Are written records of training maintained for each staff member?**

Yes.

18. **Is TA Instruments considered a large business by governmental law or regulation?**

Yes. TA Instruments is not considered a small business.

19. **What is TA Instruments Data Universal Numbering System (DUNS) number?**

61-5257847

20. **Does TA Instruments provide validated products and services?**

TA Instruments provides, upon request, Certificates of Software Validation.

Upon completion of a confidentiality agreement, TA Instruments will make the following documents available to an authorized representative of the government, your company or a regulatory agency for inspection at TA Instruments, New Castle, Delaware:

- o Manufacturing Requirements Definitions (i.e. new product proposal)
- o Function Specifications (*i.e.*, engineering specifications)
- o Software Quality Plan?
- o Test Program?
- o Test Summary Reports (*i.e.*, approval for shipment)
- o Defect Status Reports?
- o Source Code Documentation
- o Hardware Testing Configuration
- o Revision Status Information, and
- o Release Notes.

The accessory kit provided with each instrument contains an end-use material that may be used for calibration of the major signals from that module in conjunction with ASTM International standards.

In some cases, certified reference materials, traceable to one or more national reference laboratories, are available as extra cost options.

II. Software Quality Assurance

1. What is the current version of the software?

Thermal Advantage (Q Series)	2.0
Universal Analysis (2000)	3.9
Specialty Library	1.4
Rheology Advantage (AR Control)	5.0
Rheology Advantage (CP Control)	5.0
Rheology Advantage	5.0
Rheology Advantage with Enhanced Polymer Library	5.0
Rheology Navigator™	5.0
Advantage Integrity™ for Thermal Analysis	2.0 Included in Thermal Advantage
Advantage Integrity™ for Rheology	2.0

2. Are previous versions of the software, source code and associated documentation available?

TA Instrument's general policy is to support the current and one previous release of software. Source code and associated documentation is available for review at the New Castle, DE facility upon execution of a Confidentiality Agreement.

3. Is the development process such that custom modifications to the software can be completed in a timely fashion? How are custom changes integrated into the development process?

TA Instruments does not perform custom modification to applications software.

4. What is the operating system (OS)?

Thermal Advantage (Q Series)

Microsoft Windows® NT 4.0 Professional with Service Pack 3
Microsoft Windows® 2000 Professional with Service Pack 2 or higher
Microsoft Windows® XP

Advantage Integrity

Microsoft Windows® 2000
Microsoft Windows® XP Professional

Advantage Integrity Server

Microsoft Windows® 2000 Server Software

5. **Has TA Instruments undergone previous pharmaceutical industry audits?**

Yes - Pfizer, Inc. 2004 Fully Acceptable

6. **How does TA Instruments assure that the software programmers and evaluators are qualified?**

Most of TA Instruments software programmers and evaluators have been with the Company for 10 years. Job descriptions are available, and training records are available for each programmer and evaluator.

7. **Does TA Instruments have a formal complaint handling system?**

Yes. A formal documented complaint handling (corrective action reporting) system is handled in the Quality Management System.

8. **Are Escrow Accounts available?**

Yes. Escrow Accounts are available through Data Security International, Inc. that provides the third party vault storage vault.

9. **Does TA Instruments use a formal change control procedure to change existing procedures and functionalities?**

Yes. A formal documented change control procedures exists.

10. **Is system documentation available for customers or third party auditors?**

Yes. Information is available at the New Castle, DE facility following the executing of a Confidentiality agreement.

11. **What is TA Instruments warrantee/guarantee?**

TA Instruments warrants its instruments for defects in workmanship or materials for 12 months after installation or 15 month after shipment, whichever is less. Consumable items (such as glassware, heating elements, etc.), where the lifetime depends upon use, have shorter warrantee periods.

Warrantee replacement, including software, is on a no charge basis except in cases where the replacement item has expanded capabilities not present in the original.

III. Instruments and Systems Quality

1. Does TA Instruments manufacture its own electronic circuit boards?

No. TA Instruments designs its own circuit boards but third party vendors manufacture the boards.

2. How does TA Instrument control engineering changes to its circuit boards?

Circuit boards are built to TA instruments designs using TA Instruments drawings. Changes to the drawings are documented through Engineering Drawing Change Orders (ECOs).

3. Does TA Instruments test components, sub-systems and the complete system?

Printed circuit boards are tested for minor functionality at our suppliers. In some cases, sub-systems are check for functionality as part of the instrument assembly process. Major testing is performed at the complete system level.

4. How is instrument calibration performed or demonstrated?

Calibrations performed during manufacturing are largely electronic in nature. At installation, our service engineer performs on-site calibration using reference materials traceable to a national reference laboratory, if applicable. A certificate of calibration is then issued to this effect.

5. Are traceable reference materials included with the instruments?

The TA Instruments Service Engineer using traceable reference materials and ASTM International standards demonstrates performance of the instrument. The instrument accessory kit includes high purity materials that may be used by the user for performance verification on an on-going basis. Additionally, traceable reference materials are available from TA Instruments as an extra cost option.

IV. Instrument and System Safety, Electromagnetic Certification

1. To what safety standards does TA Instruments products comply?

Canada

CAN/CSA-22 No. 1010-92 Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1: General Requirements and Amendments.

Europe

(In accordance with Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.)

EN61010-1: 1993 Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1: General Requirements and Amendments.

United States

UL3101-1 Electrical Equipment for Laboratory Use; Part 1: General Requirements

2. To what electromagnetic standards does TA Instruments products comply?

Australia and New Zealand

AS/NZS 2064: 1997 Limits and methods of measurement of electronic disturbance characteristics of industrial, scientific and medical (ISM) radio frequency equipment.

Canada

ICES-001 Issue 3 March 7, 1998 Interference - Causing Equipment Standard: Industrial, Scientific, and Medical Radio Frequency Generators.

Europe

(In accordance with Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility.)

EN61326-1: 1997 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General Requirements and Amendments (for class A equipment).

United States

CFR Title 47 Telecommunications Chapter I Federal Communications Commission, Part 15 Radio frequency devices (FCC regulation pertaining to radio frequency emissions).

V. END USER SUPPORT

1. **Are there peer-reviewed publication by non-vendor affiliated groups (preferably industrial) demonstrating successful applications of the system?**

Not available.

2. **Is formal user training available?**

A tiered training approach is used. The Service Engineer provides introductory training to the user at the time of installation. This is followed by a more in depth applications oriented training by the Technical Representative at the users site. Formal “getting started” information is available through the Internet. Each instrument purchase includes Internet training and one day training at an off-site location.

3. **Is the cost for training included in the purchase price?**

Both no-charge and for-fee training is available.

4. **Is there a help-line/e-mail (internet) address to assist in the timely resolution of problems?**

Telephone and Internet help desk service are available from 8:00 am to 4:00 pm ET, Monday through Friday.

5. **Are there complete manuals available?**

Getting Started Guides are available as on-line help documents associated with each instrument module and major software products. The user may print out this manual for hard copy needs.

Additionally, an on-line help system is available. On-line documentation includes detailed operational, setup and troubleshooting information.

6. **Are there systems available for at-user evaluations?**

Demonstration or evaluation systems are available through the local Technical Representative in the United States, Canada, Europe and Japan.

7. **What is the approximate turnaround time for repairs, availability of spare parts?**

Repair is usually completed within 3 working days in the United States Canada, Western Europe and Japan.

8. **Are service contracts available?**

Yes. Service contracts are available in the United States, Canada, Western Europe and Japan.

9. **Does the equipment have to be returned to the manufacturer for service or repair?**

No. On-Site repair and service is provided in the United States, Canada, Western Europe and Japan.

10. **If an instrument in warranty has to be returned to a location in or outside its country of use during warranty, will TA Instruments meet the cost of shipping?**

Under TA Instruments' terms-of-sale, the user is required to meet the cost of shipping for equipment returned for warranty service. As a matter of practice, however, the user meets the cost of shipping to TA Instruments and TA Instruments meets the cost of repair and return shipping to the user.

11. **If service support is provided, will TA Instruments provide and meet service engineer travel costs while the instrument is in warranty?**

Yes. There is no charge for Service Engineers travel expenses for warranty service in the United States, Canada, Western Europe and Japan.

12. **Is validation support for customers available (i.e., test cases, validation plans, IQ/OQ/PQ documents, and examples as scripts)? Is there an additional charge for these items?**

IQ/OQ documents are available as an extra cost option. TA Instruments does not currently supply performance qualification (PQ), test cases, validation plans or scripts.

VI. ENVIRONMENTAL PRACTICES

1. What is TA Instruments position on toxic chemical use?

TA Instruments has filed and continues to file the Toxic Chemical Release Inventory Form (Form r) as described in sections 313(a) and (g) of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11023) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13106).

2. What is TA Instruments environmental position?

TA Instruments certifies that none of its facilities are listed on the Environmental Protection Agency (EPA) List of Violating Facilities.

VII. BUSINESS PRACTICES

1. **Does TA Instruments provide any segregated facilities for its employees or guests?**

No. TA Instruments is an Equal Opportunity Employer.

2. **Does TA Instruments Meeting Affirmative Action Requirements?**

TA Instruments has developed and has on file affirmative action programs required by the rules of the Secretary of Labor (41 CFR 60-1 and 60-2).

3. **Does TA Instruments maintain a formal Safety Manual?**

Yes.

4. **Does TA Instruments have a dress code?**

Yes. Business casual except in warehouse where shorts are permitted. Warehouse workers require safety shoes.

TA Instruments

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To contact your local TA Instruments representative visit our website at www.tainst.com