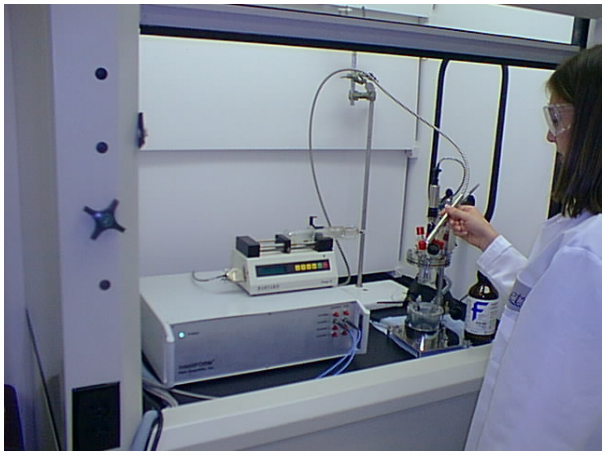
IntelliFORM®

Intelligent Fiber Optic Reaction Monitoring

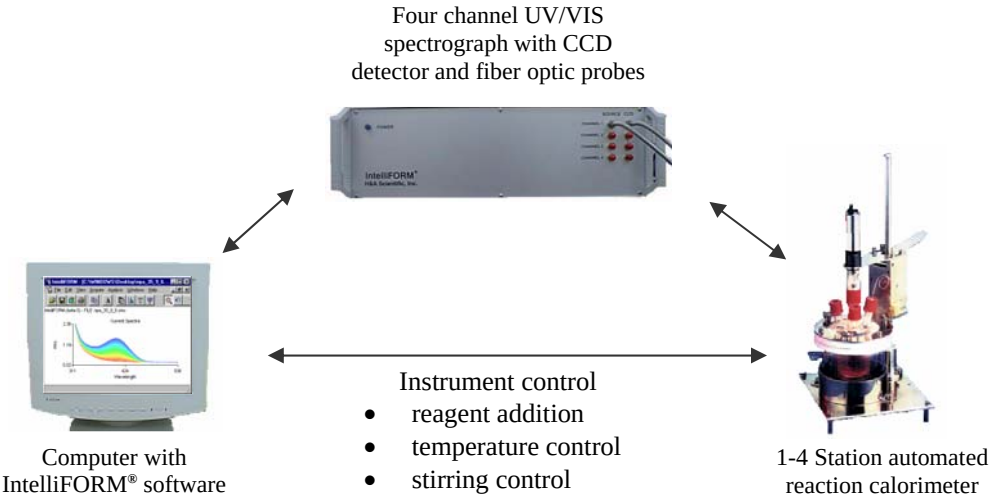


Did the reaction under test produce more or less product?
Did the reaction under test produce the product faster or slower?

Here is our solution to your problem!

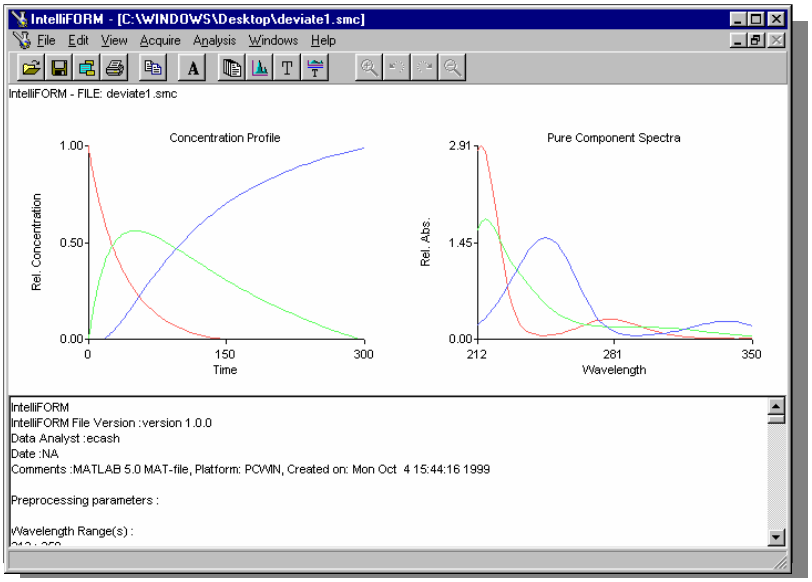
H&A Scientific Incorporated

IntelliFORM® is a Microsoft Windows® application that analyzes batch reactions to determine which reactions produce more product and have faster reaction rates. IntelliFORM®, when coupled with a laboratory scale automated reaction calorimeter and UV/visible fiber-optic spectrograph, forms a complete reaction station capable of fully characterizing batch chemical reactions. IntelliFORM® makes use of self-modeling curve resolution (SMCR) to estimate composition profiles of reactants, intermediates, and products for single batches as well as multiple batches. Without the aid of referee (standard) measurements, IntelliFORM® can characterize batch processes and give development scientists valuable information about the progress of batch reactions.



IntelliFORM® Overview

H&A Scientific, Inc., teamed with East Carolina University and Glaxo Wellcome, designed the IntelliFORM® project from the "ground up" to build a state-of-the-art system for characterizing batch chemical reactions. It is an integrated package for instrument control, data acquisition, and data analysis. IntelliFORM® is capable of analyzing the UV/Vis mixture spectra collected during data acquisition to estimate reaction profiles.



General Features

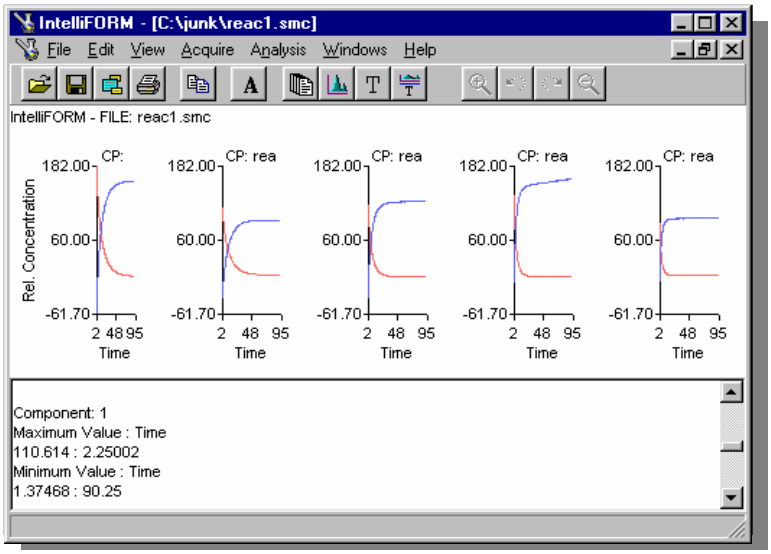
- IntelliFORM® uses different curve resolution algorithms to estimated concentration profiles and pure component spectra.
- The user is able to view the estimated composition profiles and pure component spectra.
- Spectroscopic data can be loaded and analyzed from IntelliFORM® generated files, MATLAB® files, or tab separated data in a defined text format.

IntelliFORM® uses principle component analysis (PCA) to determine the number of independent spectroscopically identifiable components. The PCA model is then mathematically resolved through an iterative process to estimate reaction profiles. Most importantly, IntelliFORM® uses a self-modeling process that requires no information about

peak shapes, locations, or identities. Constraints are utilized to produce composition profiles that are non-negative. Similarly, pure component spectra are required to be non-negative. With these two general, physically meaningful constraints, useful estimates of composition profiles of starting materials, intermediates, and products can often be estimated. When this is carried to a multi-way approach, several batches can be analyzed at once and comparisons between the composition profiles can be made to determine which batches produced more product and which batches reacted faster. These algorithms are all well documented in the scientific literature [1,2].

Batch Analysis Features

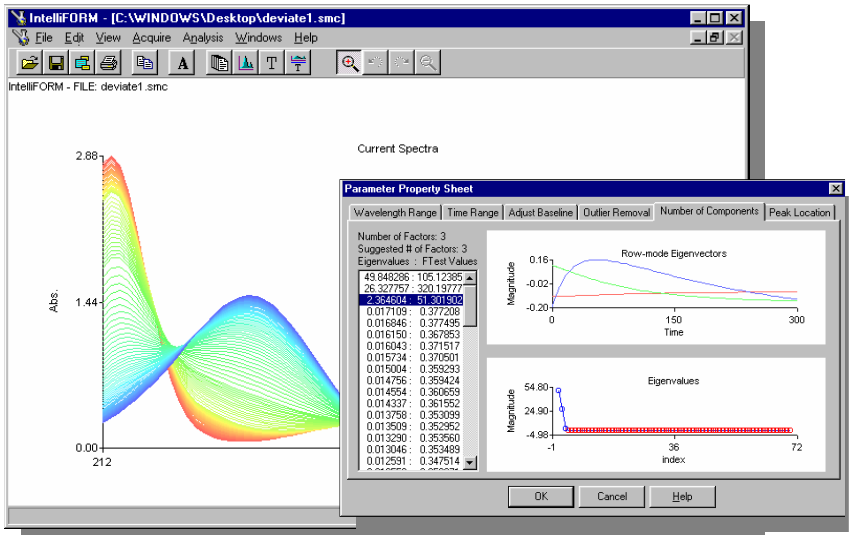
- IntelliFORM estimates concentration profiles and provides plots for the user.
- IntelliFORM provides sequentially plotted multi-way results of concentration profiles that can be used to determine relative concentration differences.
- Summary information, which includes maxima and minima of concentration profiles for each component, is provided in the text report.



Supported Algorithms

After IntelliFORM® preprocesses the data, three algorithms are available to calculate concentration profiles and pure component spectra:

- Autowin – Automatic Window Factor Analysis [1].
- ITTFA – Iterative Target Transformation Factor Analysis [2].
- Multi-way ITTFA – Iterative Target Transformation Factor Analysis for multiple batches [2].

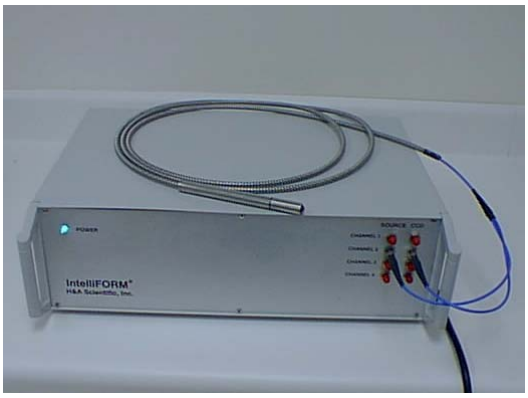


Innovative Accomplishments

- IntelliFORM® offers a complete package for preparing data for analysis that gives the user freedom to explore different data parameters and see how they effect the curve resolution results.
- Multiple wavelength and time segments are supported in IntelliFORM®.
- Eigenvectors from a principle component analysis are viewable and the number of significant components can be automatically determined from an F-test.
- A needle search algorithm as well as Evolving Factor Analysis (EFA) is available for manual or automatic initialization of SMCR calculations.

1. A. Quin, P. Gemperline, B. Baker, M. Zhu, D. Walker. Fiber-optic UV/visible composition monitoring for process control of batch reactions, Chemom. Intell. Lab. Systems., 45 (1999) 199-214
2. P. Gemperline, M. Zhu, E. Cash, D. Walker. Chemometric characterization of batch reactions, ISA Transactions., 38 (1999) 211-216

Options



1. IntelliFORM® Software

Free 30-day support
Maintenance Agreement (Optional)

2. IntelliFORM® Spectrograph and Software

Free 30-day support
Maintenance Agreement (Optional)
Installation (Optional)
Software Training (Optional)

3. IntelliFORM® Spectrograph and Software with Reaction Station

Free 30-day support
Maintenance Agreement (Optional)
Two days of installation (including execution of IQ protocols)
Software, spectrophotometer, and calorimetry training

Support and Training

We supply Validation Certificates, Manuals, and Installation Qualification (IQ) documents with all options. We also offer additional consulting services in the form of User Acceptance validation documents and software testing.

H&A Scientific, Inc. develops, manufactures, and markets quality computing systems for scientific data acquisition, processing, and management.

The H&A Scientific, Inc. Quality Statement is:

H&A Scientific, Inc. is continually maintaining and improving its established Quality Assurance Program which is designed to maintain compliance with requirements of FDA's Good Manufacturing Practices (GMPs). Where applicable, GLP procedures are also followed.

IntelliFORM® has been developed according to our Quality Assurance Program. The Quality Assurance Program, supported by everyone at H&A Scientific, Inc., addresses the following areas:

- Production, control, and issue of SOPs and General Documents
- Quality and Project Plans
- Complete Functional Specifications and Design Documents
- Configuration Management
- Documented Software Testing
- Change Control
- Maintenance Plans
- Monitoring adherence to SOPs through internal auditing procedures
- Compliance with current regulatory requirements

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