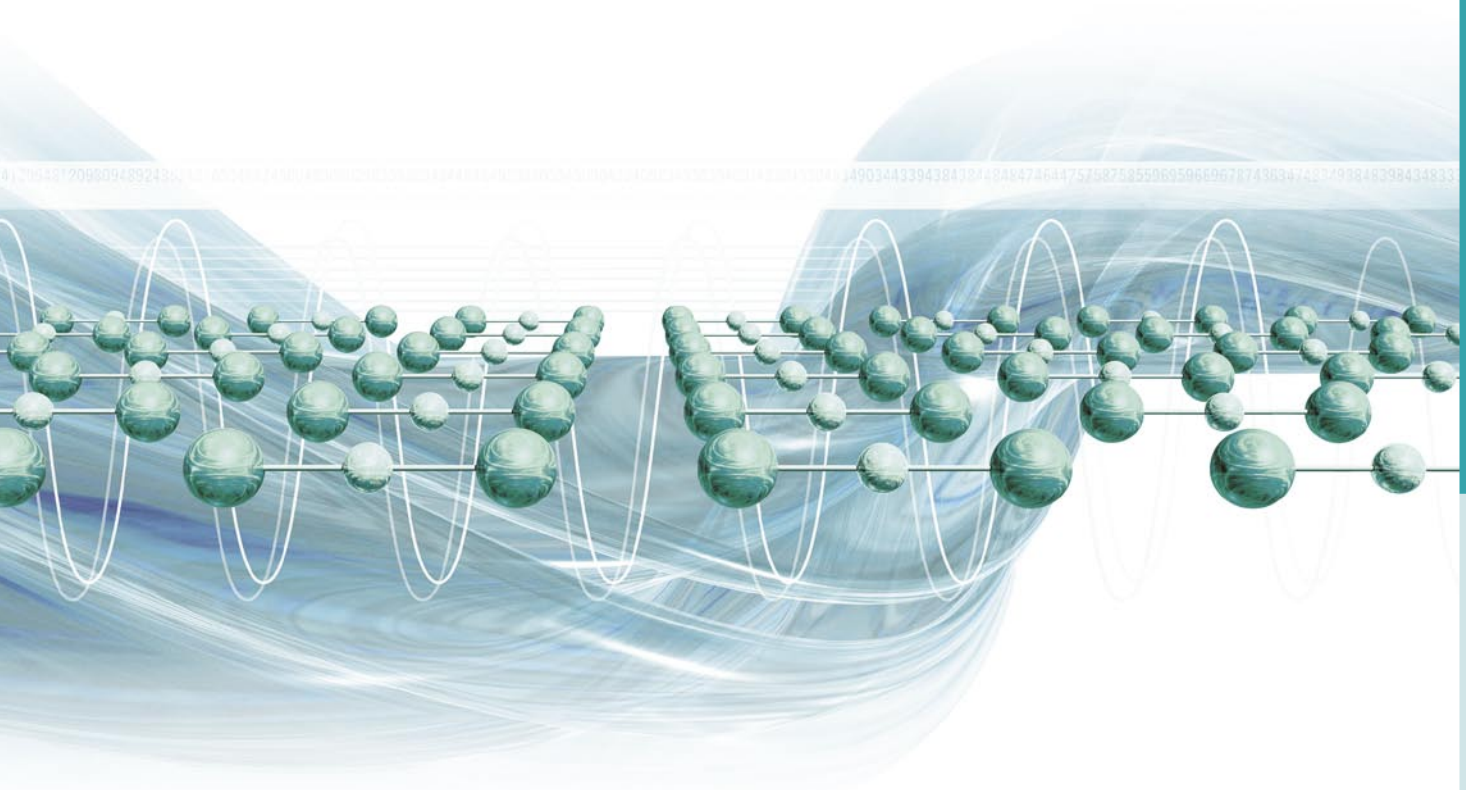
Clarity SST Extension

Software module for System Suitability Test

The System Suitability Test (SST) is an integrated module designed to validate a chromatography system based on the evaluation of chromatograms that have been acquired from the Clarity station.

SST Extension controls whether the individual values of selected parameters fall inside specified limits. Alternatively it can control the mean value of all controlled chromatograms against those limits.

SST Extension is an optional addition to Clarity software, it cannot be used as a standalone program.



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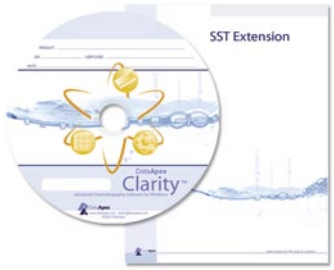


The SST Extension is an optional, fully integrated addition to Clarity software. It can be ordered as a part of new software or as an extension to existing software.

The Clarity Chromatography Software is designed to acquire and evaluate data from up to four multidetector chromatographs at a time (four independent timebases).

The SST Extension is accessible in all Instruments within a station. The SST Extension is also compatible with Clarity Offline software.

Features

Performance Qualification: *is a procedure confirming that the analytical system is fit for a given type of analysis. Usually the overall system performance is tested by this procedure with respect to the requirements of the desired application.*

Operational Qualification: *is a procedure confirming that the data station is performing according to the manufacturer's specification. This feature also requires the Validation kit, which can be ordered separately (p/n CVK).*

SST Report: *The overall results of the validation as well as a detailed description of the validation method can be included in printouts or saved to a PDF file.*

Summary table: *All validated chromatograms are displayed with the validation parameters. Results can be:*
✓ - Validation was successful
✖ - Validation failed
? - Validation cannot be performed (e.g. missing limits).

Validation parameters: *Retention Time, Area, Height, Amount, Amount %, Width at half height, Asymmetry, Symmetry/Tailing, Capacity, Efficiency, Efficiency/Length, HETP, Resolution.*

Validation limits: *The SST validates results against upper and lower limits and RSD. Optionally it can control the limits for each chromatogram or for mean of all validated chromatograms.*

Online validation: *Chromatograms can be validated as they are measured in a sequence. Consequently, automatic actions can be triggered based on the result of the validation.*

Offline validation: *Validation can be performed manually or automatically using batch process.*

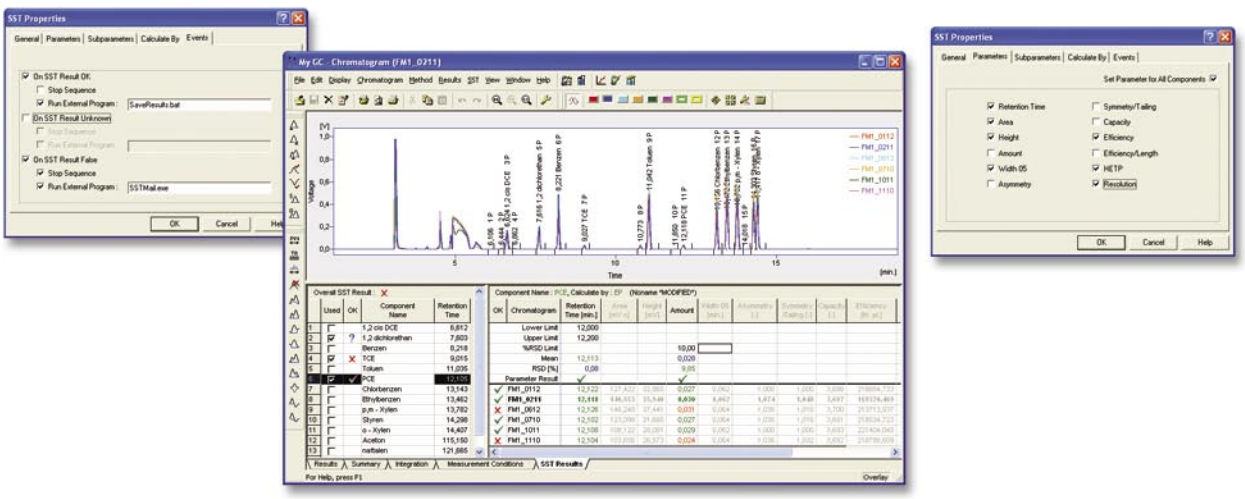
LIMS: *SST Results can be automatically exported to database.*

Pharmacopoeia: *Calculations according to European (EP, and DAB, BP, ASTM), United States (USP) or Japanese (JP) pharmacopoeia are available.*

SST Events: *The SST result can trigger specific actions such as pausing the running sequence or starting an external program. This allows for the automation of most common actions.*

Specification

Part No.:	A22
Related Products:	Clarity (p/n C50) - required
	Clarity offline (p/n C59)
	Validation Kit (p/n - CVK)



EXTENSIONS