

Enhanced Synergy 2000 SE Architecture Enforces Integrity of Electronic Quality Records

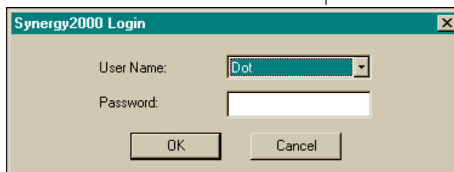
SPC Software Features Additional Layer of Security, Support for 21 CFR Part 11

Replacing paper documents with electronic production records and digital signatures requires a technology that ensures the authenticity, integrity and confidentiality of the electronic data. Synergy 2000 SE has been designed to address the highest security concerns of today's data-driven businesses.

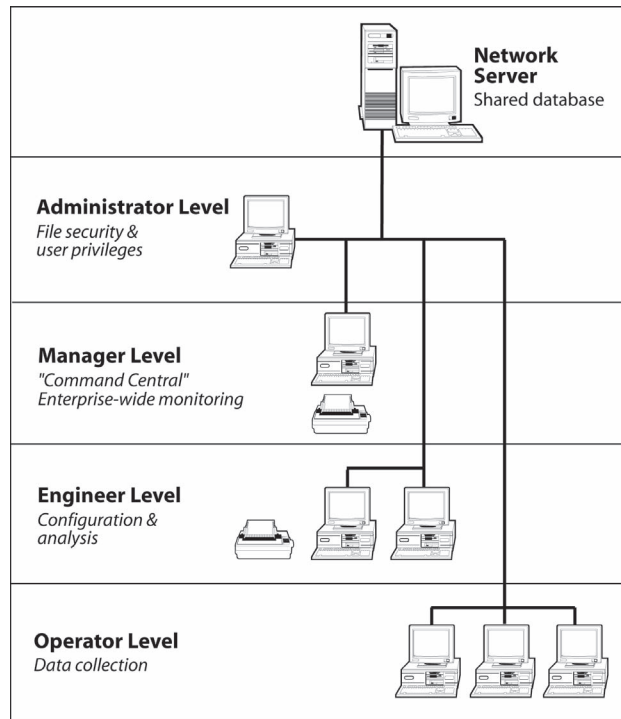
Synergy 2000 SE is for companies who want to:

- Implement a *closed security system* where a dedicated individual controls system access, data security, user privileges, data change logs, audit trails and password aging
- Migrate to a paperless environment
- Respond rapidly and more comprehensively to product quality and safety issues
- Improve upon expensive and tedious "hard copy" document storage methods
- Reduce data entry errors
- Take advantage of the ultimate in data traceability and data tracking
- Meet reporting deadlines more efficiently than ever before

For industries regulated by the U.S. Food & Drug Administration (FDA), Title 21 Code of Federal Regulations (CFR) Part 11, establishes the criteria under which the FDA equates electronic records with paper documents and electronic signatures with their handwritten facsimiles. Synergy 2000 SE fully complies with all aspects of 21 CFR Part 11.

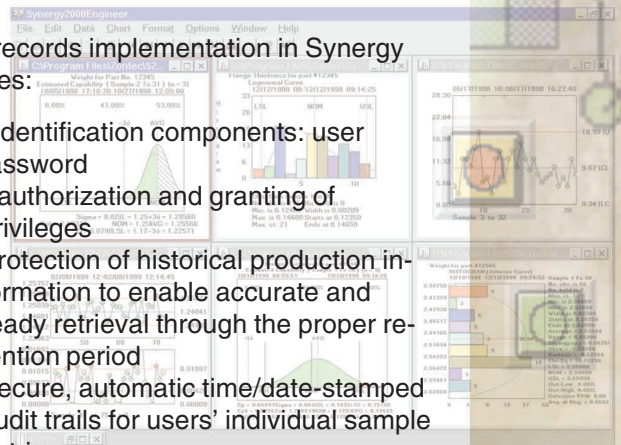


Synergy 2000 provides the two distinct identification components—user name and password—as specified by 21 CFR Part 11



The electronic records implementation in Synergy 2000 SE includes:

- Two distinct identification components: user name and password
- Easy-to-use authorization and granting of privileges
- Protection of historical production information to enable accurate and ready retrieval through the proper retention period
- Secure, automatic time/date-stamped audit trails for users' individual sample entries
- Data change management facilities that document the editing of records without obscuring original data



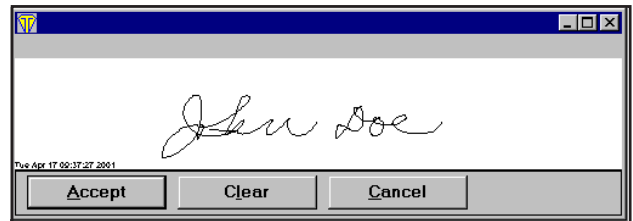
	ID1	ID2	ID3	Changes	E Signature	Obs.1	Obs.2	Obs.3	Obs.4	Obs.5	Note1	Average	Range	
18	Lot # 78	M1/KTR				0.749	0.754	0.749	0.753	0.755		0.752	0.006	12/1/2
19	Lot # 78	M1/KTR				0.744	0.756	0.760	0.751	0.754		0.753	0.016	12/1/2
20	Lot # 78	M1/KTR				0.755	0.754	0.749	0.745	0.751		0.751	0.010	12/1/2
21	Lot # 78	M1/KTR			<i>John Doe</i>	0.757	0.754	0.753	0.749	0.741		0.751	0.016	06/2/2
22	Lot # 78	M1/KTR			<i>John Doe</i>	0.753	0.751	0.750	0.749	0.744		0.749	0.009	12/1/2
23	Lot # 78	M1/KTR			<i>John Doe</i>	0.748	0.750	0.753	0.748	0.755		0.751	0.007	06/2/2
24	Lot # 78	M1/KTR			<i>John Doe</i>	0.743	0.752	0.747	0.757	0.750		0.750	0.014	06/2/2
25	Lot # 78	M1/KTR			<i>John Doe</i>	0.756	0.751	0.748	0.752	0.745		0.750	0.011	06/2/2

Synergy 2000 SE users can view comprehensive audit trails including signatures, date and time stamps alongside the SPC data itself

- Ability to capture handwritten signatures via an optional digital signature pad
- Instantaneous tracking of part/lot/batch numbers, machine/cell/department numbers, measurement devices, assignable cause and corrective action for every data point
- Robust real-time statistical process control capabilities that stand up to enterprise-wide mission-critical operations

Technical Requirements for Synergy 2000 SE Version 5.0

- Personal computer/server with Celeron®, AMD®, Pentium® II, III or 4 processor (or better)
- Super VGA (or better) video graphics adapter and monitor
- CD-ROM drive
- 128MB extended memory
- Microsoft® Windows® 9x/NT/ME/2000/XP
- Recommended local area networks: Windows NT Server, Windows 2000 Server or Novell Netware
- Any printer supported by the Windows Operating System
- *Optional:* Automatic data collection devices
- *Optional:* Stylus-controlled LCD signature pad with capture software



You can choose to incorporate handwritten signatures into your records with an electronic signature pad

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