

We offer three different 21CFR Compliant Software Packages:



1295 Morningside Avenue, Unit 16-18
Scarborough, ON M1B 4Z4 Canada
Phone: 416-261-4865 Fax: 416-261-7879
www.scigiene.com

<i>MAIN SOFTWARE FEATURES</i>	<i>21CFR DB Full Database</i>	<i>21CFR LE Limited Edition</i>	<i>21CFR VIEWER Read Only</i>
21 CFR- Part 11 compliant	♦	♦	♦
Secure database	♦	♦	♦
Electronic signatures	♦	♦	♦
Levels of access permission, privileges, and authorization to customize what the users can do	♦	♦	♦
Audit trails	♦	♦	♦
User names, login names & passwords	♦	♦	♦
Password minimum number of characters and expire interval	♦	♦	♦
Record statistics & details	♦	♦	♦
Customized data entries & queries	♦	♦	♦
Microsoft Access database	♦	♦	♦
Intelligent handling of time zones	♦	♦	♦
Mean Kinetic Temperature	♦	♦	♦
Export data to other 21CFR DB databases	♦	♦	♦
Read logger	♦	♦	♦
Logger initialization	♦	♦	
Import record	♦		
Record search filter	♦		
Customized filter attributes	♦		
Record summary	♦		

<i>MAIN SOFTWARE FEATURES</i>	<i>21CFR DB Full Database</i>	<i>21CFR LE Limited Edition</i>	<i>21CFR VIEWER Read Only</i>
Real time display	♦		
Number of users	5 users plus administrator	2 users plus administrator	2 users plus administrator
Number of locations	1	1	1
Multiple tracing option	Up to 120 traces in one graph	1 trace by graph only	1 trace by graph only
21 CFR-Part 11 Compliance Report	A document reports how the 21CFR DB software addresses the 21 CFR part 11 Requirements	A document reports how the 21CFR LE software addresses the 21 CFR part 11 Requirements	A document reports how the 21CFR LE software addresses the 21 CFR part 11 Requirements
Recommendations	<ul style="list-style-type: none"> • Companies with one or multiple locations • Manage more than 100 records a year • Require more than 2 users • Require software validation documents in place for FDA inspections • Use programmable as well as single use units. 	<ul style="list-style-type: none"> • Companies with only one location • Manage less than 100 records a year • Require no more than 2 users • Write their own validation manual • Use programmable as well as single use units. 	<ul style="list-style-type: none"> • Locations that only receive units. • Read-only version. It cannot program loggers
Customer support & upgrades	2 years of customer support, service packs and version upgrades (including enhancements). 90 day warranted satisfaction or full refund	1 year of customer support, service packs and version upgrades (including enhancements) 90 day warranted satisfaction or full refund	1 year of customer support, service packs and version upgrades (including enhancements) 90 day warranted satisfaction or full refund

This is not a web-based program so you do not have to conduct an extensive QA Audit to find out if the program is truly 21 CFR Part 11 compliant.



1295 Morningside Avenue, Unit 16-18
 Scarborough, ON M1B 4Z4 Canada
 Phone: 416-261-4865 Fax: 416-261-7879
www.scigiene.com