HPLC and UPLC Chromatography Systems

Simulation Resource Capacity Model User Guide

Release 1.2

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Business Resource Modeling

Documentation Example

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Table of Contents

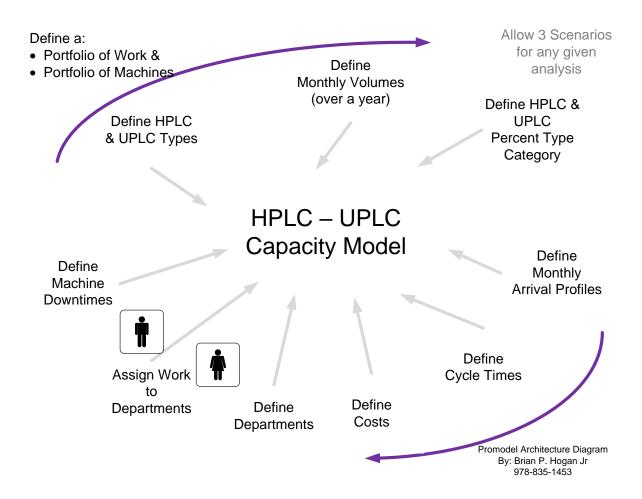
1	Overview	pg 3
2	Model Installation	pg 4
3	Excel Control Panel	pg 5
4	Model Parameters	pg 13
5	Create & Run a Scenario	pg 15
6	Model Report Variables	pg 16
7	Working with Output Reports	pg 18
8	Excel Output Reports	pg 20

1 Overview

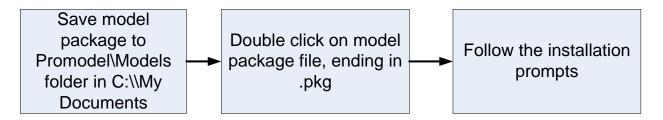
ABC H-UPLC Simulation Model developed a resource modeling solution in 4Q2010 that predicts the number of PRA manager staff required to process a portfolio of assays, aka test-type-types, based on a profile developed by the ABC team for GMP, Research, and Development Analytical labs.

The profile creates a dynamic test-type portfolio of work and generates a range of HPLC-UPLC machines required to process the workload. Configure the solution to test multiple scenarios of high-medium-low test-type-type volumes to help provide management with information on the number of machines required to support production.

The following is a high-level view of the model's data collection architecture. The following sections will detail how to run the model, update the data collection spreadsheet, and analyze reports in the simulator.



2 Model Installation



When MyModel_Inc provides model updates typically we will send you a model "package" file via email. This file installs and updates all the files needed to work with the resource model automatically.

Included in this file will be the model's Excel control panel. The Excel control panel contains all the worksheets used to profile test-types, aka pieces, or regulatory pieces.

Detailed instructions to install a model package:

- 1.1 Start by saving the attached (.pkg) file from email to: Program Files \ MyModel_Inc \ Models
- 1.2 Open MyModel_Inc
- 1.3 Select File \ Install Model Package
- 1.4 In the "Package File" section browse the model's location from 1.1 and highlight.
- 1.5 The "Destination" location automatically populates, select "OK."
- 1.6 Y ou will be asked if you want to load the model package now and select "yes"
- 1.7 The completes the installation of the simulation model
- 1.8 FYI simulation model files have ".mod " as their extension

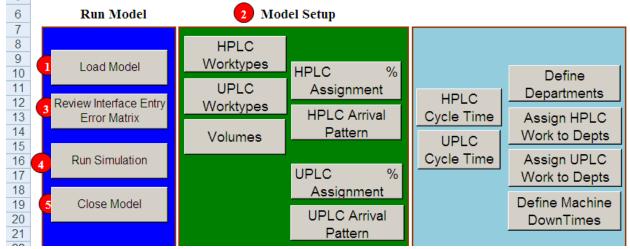
Note: steps 1.2 forward can be skipped by double clicking on the package file and performing the same series of steps

ABC has a global license arrangement with MyModel_Inc and all ABC team members are strongly encouraged to get the software installed and work with the simulation model. Please download the software from the following link:

ABC IT can install this software remotely. It must be licensed and the key can be obtained by contacting MyModel_Inc Support at 888-776-6633 or emailing at support@MyModel_Inc.com

3 Excel Control Panel

The following section details each of the components seen below.



3.1 Load & Run Model

The model is being configured for loading and running inside the MyModel_Inc application. This functionality may be turned on in the future.

	3.2 HPLC & UPLC Worktypes										
	A	С	D								
1	Define HPLC Demand in Simulation										
3	This table is cross-referenced throughout the interface.										
4	Enter the demand work name and activity	code	the entire inter	fac							
5	The "On" "Off" switch is a master switch. If any work type is set t										
6				_							
			On (1) or Off								
7	HPLC Work Defintion	ID	(0) in Model								
8	Impurity	1	1								
9	Disso	2	1								
10	Potency	3	1								
11	Method Devlelopemtn	4	1								
12	Validation > Phase 1 Phase 2	5	1								
13	Reagction Completion	6	1								
14	PGI Methods> Lowlevel	7	1								
15	Clean by Test Methods	8	1								
16	ID Tests	9	1								

Update column A with all the available test-type types available to the simulation model. The names in column A will appear through the entire Excel interface.

The ID is a unique numeric ID for each test-type. Please don't change these values but keep them in mind as there are custom Excel "output reports" detailing test-type-type throughput by ID.

Since the model generates work "dynamically" if there are test-type-types a user would like to not generate work for in an experiment they can enter "0" in column D next to the test-type and it will not be created in the simulation run.

3.3 Volumes

,				
6		Enter T	otal HPLC and UP	LC Monthly V
7	Table 1	Baseline Profile	Scenario 2	Scenario 3
8	Mth_1	100	T(917,1113,1113)	
9	Mth_2	100	T(917,1113,100)	
10	Mth_3	100	T(1091,1325,100)	
11	Mth_4	100	T(1017,1235,100)	
12	Mth_5	100	T(979,1189,100)	
13	Mth_6	100	T(1067,1296,100)	
14	Mth_7	100	T(950,1153,100)	
15	Mth_8	100	T(1052,1277,100)	
16	Mth_9	100	T(936,1137,100)	
17	Mth_10	100	T(854,1037,100)	
18	Mth_11	100	T(792,962,100)	
19	Mth_12	100	T(796,966,100)	
20	Year Total	1200	0	0
21	Table 2	Enter % work that	is HPLC; REMAIN	IDER IS UPLC
22	Table 2	Baseline Profile	Scenario 2	Scenario 3
	Mth 1	60		
23				
23	Mth_2	60		
	Mth_2 Mth_3	60		
24 25 26	Mth_2 Mth_3 Mth_4	60 60		
24 25	Mth_2 Mth_3 Mth_4 Mth_5	60 60 60		
24 25 26 27 28	Mth 2 Mth 3 Mth 4 Mth 5 Mth 6	60 60 60		
24 25 26 27 28 29	Mth 2 Mth 3 Mth 4 Mth 5 Mth 6 Mth 7	60 60 60 60		
24 25 26 27 28	Mth 2 Mth 3 Mth 4 Mth 5 Mth 6	60 60 60		

In any given model, users can create 3 profiles to represent different scenarios of work volume flowing into the labs.

For every month enter the test-type "volume" coming into the simulation model. Triangular distributions can be entered T(Minimum, average, Maximum) if one wants to the simulator to vary the amount of work arriving in any given month. Other statistical distributions, eg Lognormal(mean, st. dev), can also be entered.

Users can use the following table located to the right of the table above to help with the creation of the Triangular distributions.

ikery, wax)										
stribution	Create a T-Di									
	0%		17.64%							
Paste In	Max	Mode	Min							
T(917,1113,1113)	1113	1113	917							
T(917,1113,200)	200	1113	917							
T(1091,1325,300)	300	1325	1091							
T(1017,1235,400)	400	1017 1235								
T(979,1189,500)	500	1189	979							

3.4 H-UPLC Assignment %

	1	HPLC Dynamic Profile Gener	ator			Home			
	3	Input Percent mix of demand work for dynamic profiling; input whole #s instead of							
	4								
	5	Whole # only - no distributions		HF	PLC Generator Profi	le			
	6	HPLC Defintion	On / Off	Baseline Profile	Scenario 2	Scenario 3			
	7	Impurity	1	11	100.00				
	8	Disso	1	11					
	9	Potency	1	11					
	10	Method Devlelopemtn	1	11					
	11	Validation > Phase 1 Phase 2	1	11					
	12	Reaqction Completion	1	11					
	13	PGI Methods> Lowlevel	1	11					
	14	Clean by Test Methods	1	11					
	15	ID Tests	1	12					
	16		1						
+	32		1						
+	126								
	127	END	Ĭ	1.0000	1.0000	0.0000			

The generation of a dynamic test-type profile will use this percent table to assign a test-type to each piece of work entering the model. Users perform an analysis of existing test-type transaction data, or input their gut profiles, via percent. The model uses a random number generate to assign a test-type to each piece of work.

In the "Baseline Profile" above, if 100 test-types were coming in about 11% of them would be an "impurity" and the remaining 89% is split into the other categories as seen.

Ensure that each profile equals 100%. As such, MyModel_Inc recommends that only "whole" percentages are entered as decimal values wouldn't have any material impact on the test-type type being randomly assigned.

Users are welcome to change the names in the "green" boxes to the scenario name. However, please keep in the mind the simulator refers to the yellows columns numerically from left to right as values of 1 to 3 when making scenarios in the simulator.

3.5 H-UPLC Arrival Pattern

							_		ot percer	~ .	•			
3	It level to	el loading, go with 27 days as model rounds thus, 3.4 is 3%, while 3.6 is 4% of total coming in based on monthly arrival quantity												
5								Annual Ar	rival Profi	ile				
6	Profile 1 >	Day	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
7		1	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
8		2	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
9		3												
10		4												
11		5	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
12		6	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
13	1	7	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
14	1	8												
15	1	9												
16	1	10	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
17	1	11	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
18	1	12												
19	1	13	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
20	1	14	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0

The submission patterns informs the model "when" during a month test-types are going to come into the model to be worked on. Users enter whole percentage values for every day of the month for every month of the year. Days can be skipped as long as the sum of all the days is 100.

Submission arrival patterns will hopefully be generated from the DIM data system. It is as simple as getting the count of total pieces arriving per day and then dividing this count by the total pieces arriving in a given month. If data is only available weekly, then put the percentages in Day 1 for week_1, Day_8 for week_2, etc.

If there is any seasonality in the data, the monthly profiles can be changed to illustrate more work coming in the start, middle, or end of month across multiple months.

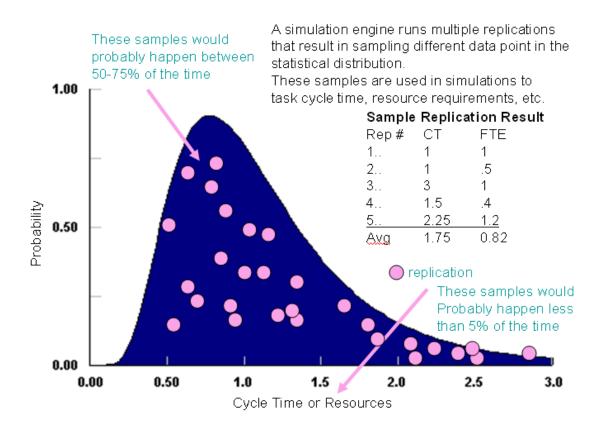
Users are able to create profiles either by month or quarter. Users can create a total of 4 profiles and then select which one to run in any given scenario.

3.6 H-UPLCTest-type Cycle Time

		HOURS	HOURS	HOURS	HOURS	HOURS	HOURS	HOURS	HOURS	HOURS
	HPLC Setup CT			HPLO	HPLC Run Production CT			Post-Processi	ng CT	
		Baseline Profile	Scenario 2	Scenario 3	Baseline Profile	Scenario 2	Scenario 3	Baseline Profile	Scenario 2	Scenario 3
Demand Vork Defintion	n/ Of	Notes	Notes	Notes	Notes	Notes	Notes	Notes	Notes	Notes
Impurity	1	T(2,4,8)			L(19,6)			L(19,6)		
Disso	1	T(2,4,8)			L(10,3)			L(10,3)		
Potency	1	T(2,4,8)			L(16,5)			L(16,5)		
Method Devlelopemtn	1	T(2,4,8)			L(20,7)			L(20,7)		
Validation > Phase 1 Phase 2	1	T(2,4,8)			L(38,13)			L(38,13)		
Reagction Completion	1	T(2,4,8)			L(63,21)			L(63,21)		
PGI Methods> Lowlevel	1	T(2,4,8)			L(18,6)			L(18,6)		
Clean by Test Methods	1	T(2,4,8)			L(7,2)			L(7,2)		
ID Tests	1	T(2,4,8)			L(10,3)			L(10,3)		
END		END	END	END	N END	END	END	N END	END	END

All test-types have a Setup, Run, and Post-Processing time. Time entered can be either a constant or statistical distribution. A total of 3 profiles has been provided for each test-type type thus users are able to make scenarios. All data is in hours unless otherwise requested.

Statistical distributions: the Lognormal L(mean, standard deviation) is a distribution where 80% of the time cycle time is around the mean and the other 20% has it varying to the far right in tail. Please consult MyModel_Inc if this may be appropriate.



3.7 Define Departments

1 2 3	- 4	AB	C	E	F (I N	0 P
	1	Dep	artment Assignment Tables				
	2	Only	"Cost" and "Efficiency" are used in the mod	del	_	•	
	3	Whole	#s only				
	4		Internal Departments	Other Factor	rs		
	5		Department Name	# of Machines	Cost per Run	Efficiency Matrix	
	6	-	GMP-HPLC	3	0	1.00	П
	7		GMP-UPLC	4	0	1.00	П
	8		Research Analytics-HPLC	5	0	1.00	
	9		Research Analytics-UPLC	6	0	1.00	
	10		Development Analytics-HPLC	7	0	1.00	
	11		Development Analytics-UPLC	8	0		
	12			0	0		
	13			0	0		
	14			0	0		П
	15	1		0	0		П
Γ٠	16			0	0		П
	17			0	0		П
	18	1		0	0		П
	40	1		0	0		

Machines are currently defined in the model by a total for each department. The model supports 20 different internal and outsource departments. ABC could use this feature for comparing internal vs. outsource machine requirements and cost.

1	HPLC Work Departm			nt Profile								ı		
2	Input whole #s only - no distr	ributio	ns										Ho	ome
4					Only whole	numbers ar	e brought into	the model						
6	LIDIO 1 4 LID 4 AA							nt Assignm	ent					
7	Demand Work Defintion	On / Off	GMP-HPLC	GMP-UPLC	Research Analytics- HPLC	Research Analytics- UPLC	Development Analytics- HPLC	Development Analytics- UPLC	0	0	0	0	0	% table 1
8	Impurity	1	20		20		10							0.50
9	Disso	- 1	20		20		10							0.50
10	Potency	1	20		20		10							0.50
11	Method Devlelopemtn	1	20		20		10							0.50
12	Validation > Phase 1 Phase	1	20		20		10			Т				0.50
13	Reaqction Completion	1	20		20		10			Т				0.50
14	PGI Methods> Lowlevel	1	20		20		10							0.50
15	Clean by Test Methods	1	20		20		10			Т				0.50
16	ID Tests	1	20		20		10							0.50
47		- 4						,				Г		0.00

The model provides the capability to select via percent "what department's machines will do the work." The model and output reports will be configured to illustrate total work being done by department and all the departments collectively.

The data to support the generation of this table will be either from the DIM or business intelligence. If total counts of work done by each department by each test-type this table will be very easy to generate.

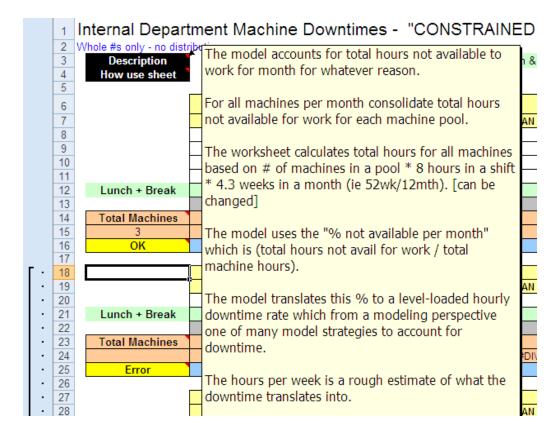
If this data is not available then the team will have to use broader percentages to assign how work will "flow" by percent to each of the departments entered.

3.9 Define Machine Downtime

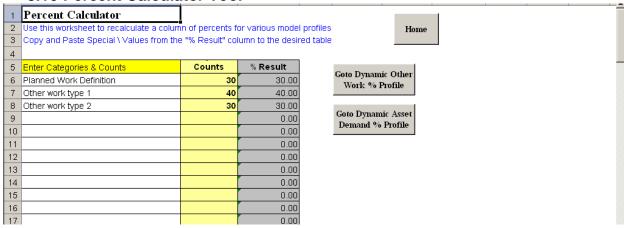
Internal Depart	mont Machine Downtimes "CONSTRA	INED MOE	\ <u>_</u> "	
		INED MOL) <u>_</u>	
		Lunch & Break H	lours Per month	
How use sheet				
	GMP-HPLC			
		JAN Hrs	FEB Hrs	MAR Hrs
	machines_1			
	machines_2			
	machines_3			
Lunch + Break				
	Total Hours not available for work/Mth			
Total Machines	Total Days= 5days/wk*8hr/dy*4.3wk/mth*# of machines	516.00	516.00	516.00
3	% of Month Not Available (used in model)			
OK	Hours per Week in Downtime			
	GMP-UPLC			
		JAN Hrs	FEB Hrs	MAR Hrs
	Whole #s only - no distr Description How use sheet Lunch + Break Total Machines	Whole #s only - no distributions Description How use sheet GMP-HPLC machines 1 machines 2 machines 3 Lunch + Break Total Hours not available for work/Mth Total Machines Total Days= 5days/wk*8hr/dy*4.3wk/mth*# of machines 3 % of Month Not Available (used in model) OK Hours per Week in Downtime	Whole #s only - no distributions Description How use sheet GMP-HPLC JAN Hrs machines 1 machines 2 machines 3 Lunch + Break Total Hours not available for work/Mth Total Machines Total Days= 5days/wk*8hr/dy*4.3wk/mth*# of machines 3 % of Month Not Available (used in model) OK GMP-UPLC	CMP-HPLC GMP-HPLC JAN Hrs FEB Hrs

The model is designed to run both resource "constrained" and "unconstrained." In the constrained mode work is only performed if and when machines are not working on another test-type. In the unconstrained mode the model generates as many machines as necessary to perform work.

If running constrained they would populate this table with the number of hours a month a machine, or group of machines, is not available due to downtime, etc.



3.10 Percent Calculator Tool

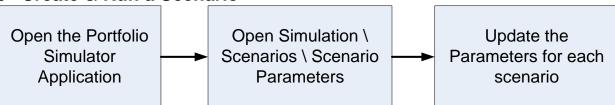


To help analysts develop percent tables utilize this spreadsheet to enter in counts of data and it will generate a % table that can be copied and pasted anywhere in the workbook.

4 Model Parameters

The following parameters are updated for every scenario. They have been organized by into the following categories to help with training.

Category	Parameter Name	Description
Model Setu	лр	
	Animation On	Enter "Yes" to run with model animation and "No" to run without.
	Backup Hours Interval	Enter the denominator of # of periods that completed backlog hours work is recorded in backlog hr statistics. The higher the number the larger of chunk of hours is reported. The lower the number the more frequent hours completed are reported.
	# of Simulation Days	# of days to run the simulation for.
	# Replications	Enter # of times to run model and generate multiple replication data set. Generally a min of 30 is required when getting serious about analyzing machines.
Pending		
_		
Excel Cont	trol Panel Table Selection	
	Volume Profile #	Enter profile (1 to 3) to select which monthly dynamic food profile to run from the "Dyn_Food_Volume" worksheet.
	Test-type Assignment Profile #	Select which profile (1 to 3) will be used to dynamically profile demand work.
	Arrival Profile #	Enter 1 for mth top grid, 2 for mth bottom grid, 3 for top Q profile or 4 for bottom from the arrivals wkst.
	Cycle Time - Profile #	Enter which Planner/Scheduler cycle time profile to use for Test-type Demand work from the "Demand _Work_CT" wkst.
Machines		
	Machines - Internal or Outsource	Enter 1 for internal or 2 for outsource. 1Q2010 - model reports not setup for outsource.
Custom Re	eport Warnings	
	Max Days Test-type in Model Warning	Enter the max number of days an test-type can be in the system before being flagged as exceeding a mgmt benchmark



Any simulation model is designed to model up to 3 scenarios for any model run. The analyst is responsible for profiling all the scenarios in the Excel Control Panel and then they use the Simulation \ Scenarios Menu to tell the model which brands to run.

Perform the following:

- a) for each product double click or hit "edit" to update the parameters. Typically most users will only have to update the "model setup" category for the length of the simulation that they want to run. Users should also keep in mind that for "quick and dirty" experiments about 10 replications are run but for full resource analysis anywhere from "30 to 70" replications are required.
- b) Change the "scenario name" to match the product being modeled so it can be viewed as such in the output reports.
 - a. FOR THE FIRST MODEL RUNS LEAVE THE NAMES THE SAME SO AS TO NOT HAVE TO RECREATE THE REPORTS.
- c) "disable" any products not being run
- d) Hit "run scenarios" to run the model.

6 Model Report Variables

	Report Variables	
Category	Variable Name	Description
Machine Pe	rformance	A
	Avg_Machine_CT_in_Days	Across all test-type types illustrates average time a manager performs a consult.
Backlog		
	Backlog_Hours_Average	Illustrates the total average amount of work "to be done" over the course of a week \ month.
	Backlog_Hours_Total	Illustrates total backlog hours of work to be processed by machines.
	Backlog_Piece_Count_Machines	Count of # of pieces being processed in model for all machines
	Demand_Exceed_User_Defined_Timeframe	This variable can be used go gauge model performance. Currently set for 2 week intervals, it will illustrate when any test-type took longer than 2 weeks to complete. This is a user defined period set in the "User Defined Test-type Process Time" model parameter.
III a sama A mala		
Hours Anal	ysis Hours_Cumulative_for_all_Test-type	Illustrates total hours of work generated for all test-types over time.
	Hours_Daily_Before_Machines_Assigned	Illustrates total work arriving in the model before assigned to machines for processing.
	Hours_Daily_Processed_by_Machines	Average daily hours of work performed by the machines
	Hours_Monthly_Processed_by_Machines	Average monthly hours of work performed by the machines.
Lagation		
Location	Location: Setup Process Contents	Illustrates the amount of pieces coming into the model for consult then flowing on to machines for processing. Good model visual of test-type arrival patterns.
	Location: Run Q Contents	When running resource constrained, will illustrate the number of pieces waiting for a resource.
	Location: Run Process Contents	Illustrates the total average amount of work being done by the machines
	Location: Run Q Contents	If running constrained, illustrates the total test-types waiting for a manager to become available.
		When running constrained, illustrates the
Machine s	Machines_Constrained_Machines_Get	average cycle time they are performing work, i.e. the time from when they are gotten to work on a piece until they finish working on a piece.

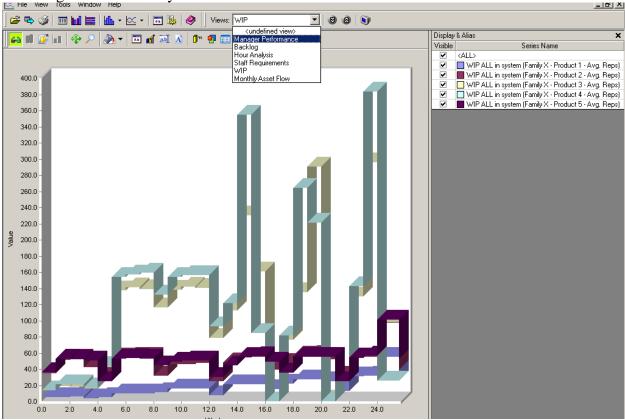
	Machines_Available	Average # of machines available to perform work. Ex: if there are 10 staff and this graph illustrate an average of 5 available, then the machines are performing at least 5 FTEs worth of work.
	Machines_Required	Average # of machines required to process test-types. It is important to display the data averaged by week of month to get number of machines needed. If averaging data by 24 hour period the results will be less meaningful.
	Machines_Utilization_Constrained	When running resource constrained, i.e. model only processes work based on available machines, this statistic illustrates the utilization rate for all the machines in the resource pool. 100% = 100% utilized, thus if "flat lined" at 100% then machines are not able to keep up with all possible work in model.
	Total_Cumulative_Pieces_Processed_by_Machines	Summary statistic of total test-type volumes processed in model.
	Total_Month_Pieces_Processed_by_Machines	Illustrates total test-types processed over the course of a month. Useful in seeing test-type workflow.
WIP = Work in process		
	WIP All in System	Shows all test-types flowing through model over time.
	WIP Consult an Pieces pend FTE Assignment	When running constrained, illustrates test- type buildup and flow while waiting for a consult manager to become available.
	WIP Machines Assigned Pieces Work Rate	When test-types are assigned, illustrates how fast they are being worked on.
	WIP Machines Pieces Wait for Available Staff	When running constrained, illustrates test- type buildup and flow while waiting for a manager to become available.
	WIP_Tot_Hrs_Processed_Machines	Illustrates total hours of work being processed by machines over time
Monthly Test-type Flow		
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Work_Test-type_Flow_Mth_1	Increment and decrement of test-types done month 1
	Work_Test-type_Flow_Mth_2	Increment and decrement of test-types done month 2
	Work_Test-type_Flow_Mth_3	Increment and decrement of test-types done month 3
	Work_Test-type_Flow_Mth_4	Increment and decrement of test-types done month 4
	Work_Test-type_Flow_Mth_5	Increment and decrement of test-types done month 5
	Work_Test-type_Flow_Mth_6	Increment and decrement of test-types done month 6
	Work_Test-type_Flow_Mth_7	Increment and decrement of test-types done month 7
	Work_Test-type_Flow_Mth_8	Increment and decrement of test-types done month 8

7 Working with Output Reports

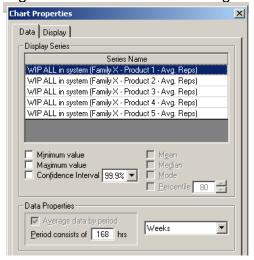
The 3DR output viewer has 6 report categories that analysts can select to break down how model family performed. The "views" come as a default in the model package installation but users can also make any report that they like from the available variables.

The report sections are: Monthly Performance, Backlog, Hours Analysis, Staff Requirements, WIP (work in process)., and Monthly Test-type Flow. Please note that these sections were defined by MyModel_Inc

and can be changed or added to by ABC.

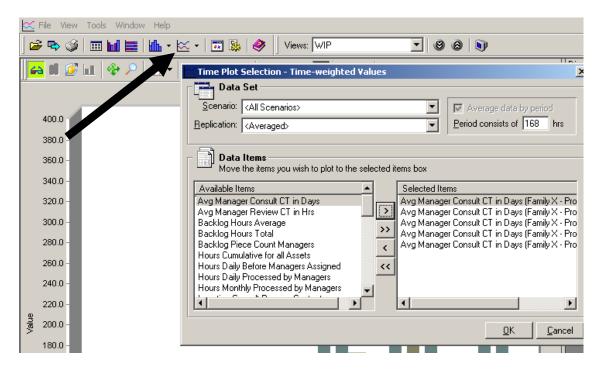


Right click on the chart to change a variety of features as follows:



Creating a Report:

- a) select the "time series" box to open the report variable selection window
- b) select the desired variable and hit the right arrow
- c) check the "average data by period" window. For this model data is either averaged by day (24 hour), week, (168 hour), or month, (731 hour). Users will have to experiment with all three to achieve the desired resolution level. Most resource graphs are done either weekly or monthly.



There are a number of other graphing options that users can play with to manipulate the color and style of the graphs. Please feel free to either contact the project's consultant or MyModel_Inc's Support group for immediate help if the consultant is not available.

MyModel_Inc Support support@MyModel_Inc.com 888-776-6633

8 Excel Output Reports

A variety of custom Excel reports can also be created. The model has been configured with the following 2 that generate every run. Please use them as proxy for further report creation that will suit ABC's analysis needs.

The following generates a simple summary of monthly work performed. OUTPUT_Monthly_Arrivals_Completions.xls

The following is a summary of "all" work processed by the model.

