

ML CathCAD® User Guide

**CathCAD®: The Software for Developing Your Next MicroCatheter
Roth Technologies, LLC**

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I. Introduction

Welcome to the MultiLumen (ML) CathCAD® Software User Guide. This manual will provide basic instructions on how to use the SOFTWARE.

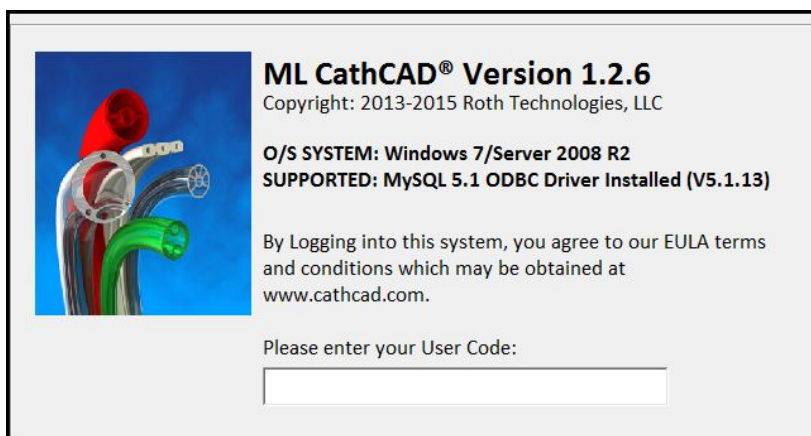
Modeling systems that depart from the SOFTWARE base assumptions may and will result in numerical results that are "different" from reality. It is important to understand that the SOFTWARE model outputs should be validated by or in conjunction with building and testing the actual device.

II. Reference Documents

- **CathCAD® End User License Agreement (EULA)**, Roth Technologies
- **Fundamentals of CathCAD®**, Roth Technologies (PowerPoint Presentation)
- **Introduction to Composite Tubing Design**, Roth Technologies
- **CathCAD® Installation Guide**, Roth Technologies
- *Design Considerations in Small Diameter Tubing*, Roth, **MDDI**, January, 2001

III. Running the Program

After the SOFTWARE is installed, the User may double click the SOFTWARE Program Icon to execute it. A splash screen similar to the one shown appears when the program is run. The SOFTWARE will run on Windows XP, Windows 7, Windows 8, and Windows 10. Previous versions of the Windows Operating System are NOT supported.



The SOFTWARE login screen indicates what version of the Windows operating system you are utilizing as well as the MySQL ODBC driver that is loaded on your computer.

Your company has been provided a ten to twelve character length passcode for logging into the SOFTWARE.

You may submit a request to sales@cathcad.com to change your passcode character string. This character string identifies your company within the **CathCAD®** system. The EULA prohibits you from sharing this character string to any unauthorized users. If you happen to lose control of your passcode, contact sales@cathcad.com and we will change your login passcode.

IV. Using the ML CathCAD® System

The SOFTWARE was developed and compiled to run under Microsoft Windows Operating System. Its use and execution should be easily understood by an individual who is familiar with the design and construction of layered composite tubing.

The following section provides basic instructions on how to use the SOFTWARE. This guide assumes that the User is familiar with specifying a composite tubing layered design. If you are not familiar with designing composite tubing, the reader is referred to the document, ***Introduction to Composite Tubing Design***, which is available for download from our website.

The SOFTWARE'S analytical engine that is utilized to compute the properties of composite tubing in ML CathCAD® is IDENTICAL to that of CathCAD® Standard and CathCAD® Advanced. However, the front end program interface was developed and optimized for entering and computing the required parameters for multilumen tubing.

The data entry process for the SOFTWARE consists of the following sequential steps:

- Enter the Number of Layers
- Select the appropriate MultiLumen configuration via the MultiLumen Designer Button
- Enter the dimensional parameters for the MultiLumen Design (and save the results). This step computes the inertial properties of the design (effective area, I_{xx} , I_{yy} , and J_{zz}).
- Select the MultiLumen material
- Enter the outer layer(s) construction (if applicable)
- Select the COMPUTE button
- Select the EXPORT TO EXCEL button to export the results to Excel if you so desire

The following DIFFERENCES are apparent when comparing the required/necessary parameters between single and multilumen tubing.

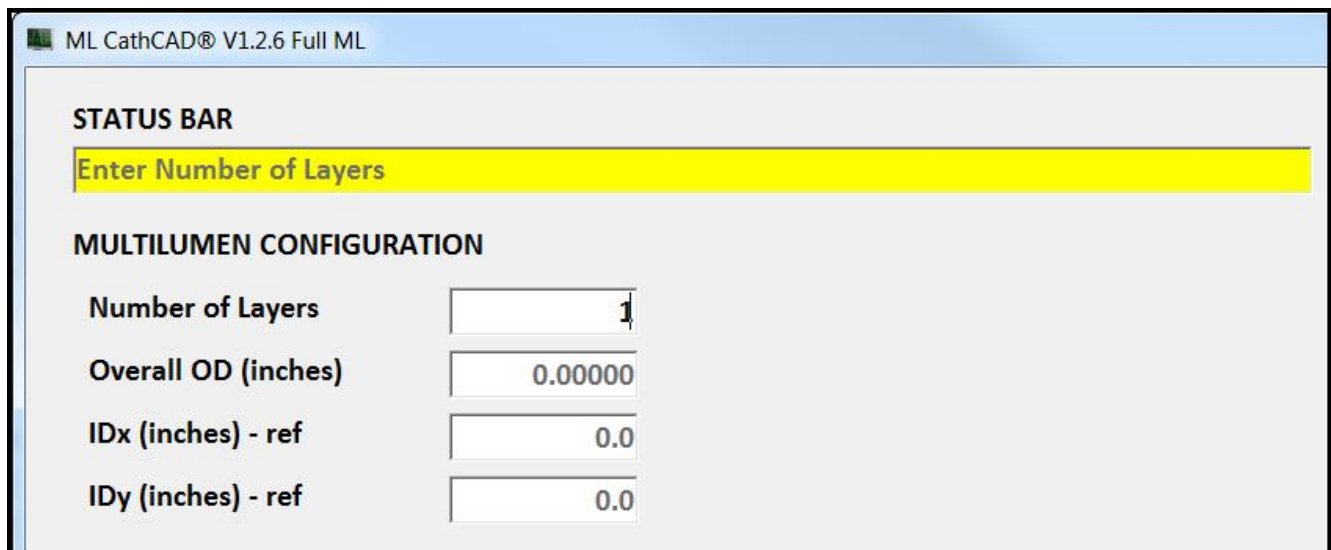
- Typically, the concept of a global inner diameter (i.e. ID) does not exist for a multilumen tube
- The flexural rigidity of the design may VARY as a function of the tube angle. As a result, the SOFTWARE computes both EI_{xx} and EI_{yy} (i.e. the flexural rigidity about both the x-axis and y-axis).
- The kink radius of the design may also VARY as a function of the tube angle. As a result, the SOFTWARE computes the kink radius of the design about the x-axis AND the y-axis.
- There exists some tube rotational angle at which the flexural rigidity will be at a MAXIMUM as well as an angle (rotated by 90 degrees) at which it will be at a MINIMUM. This angle may be computed using Mohr's Circle.

Number of Layers

This field is used to enter the number of layers in the MultiLumen tubing design.

- For Licensed Users of CathCAD® Complete, the minimum number of layers in a design is one (1) and the maximum number of layers in a design is three (3).
- For Licensed Users of ML CathCAD® Limited, the number of layers in the design is set to one (1) and cannot be changed.
- In the SOFTWARE, Layer 1 is defined as the extruded multilumen design itself.

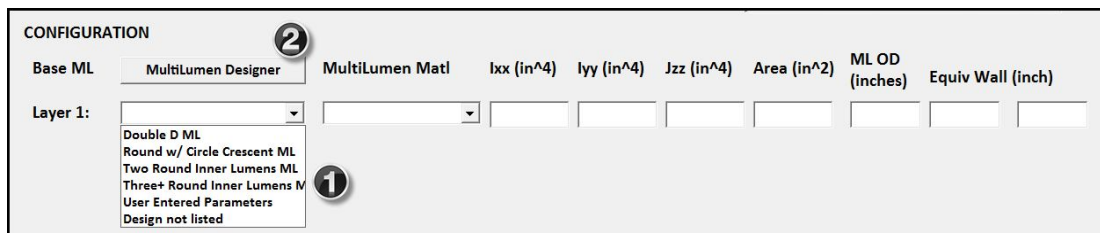
After the Number of Layers has been defined, the SOFTWARE will update the screen to show the data entry fields required to completely define the design so that its mechanical properties may be computed..



MultiLumen Designer

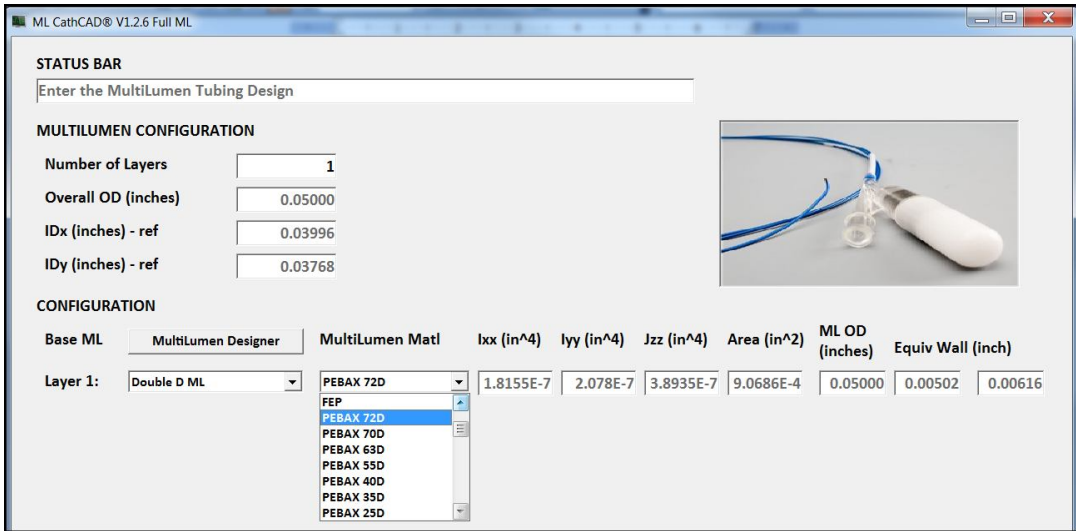
After entering the Number of Layers in the design:

- The User should select the MultiLumen Design (1) from the drop down box as shown.
- Then select the MultiLumen Designer command button (2) to enter the multilumen design. More specific instructions are provided on the MultiLumen Designer in the Section VII of this document.

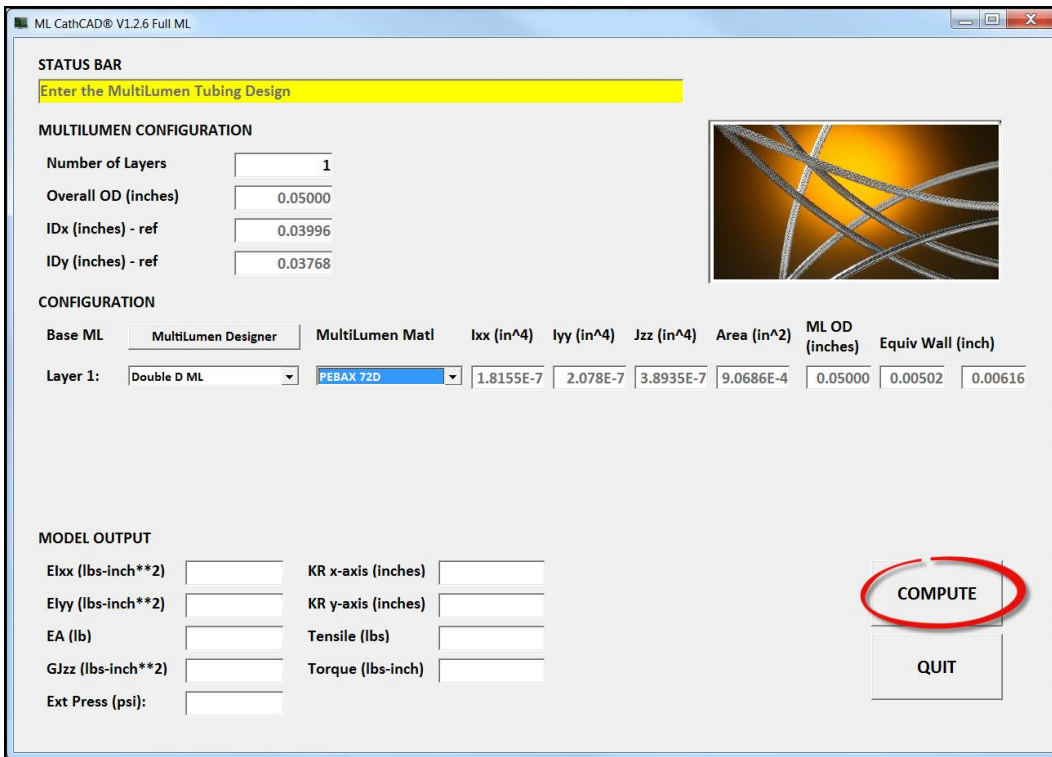


MultiLumen Material

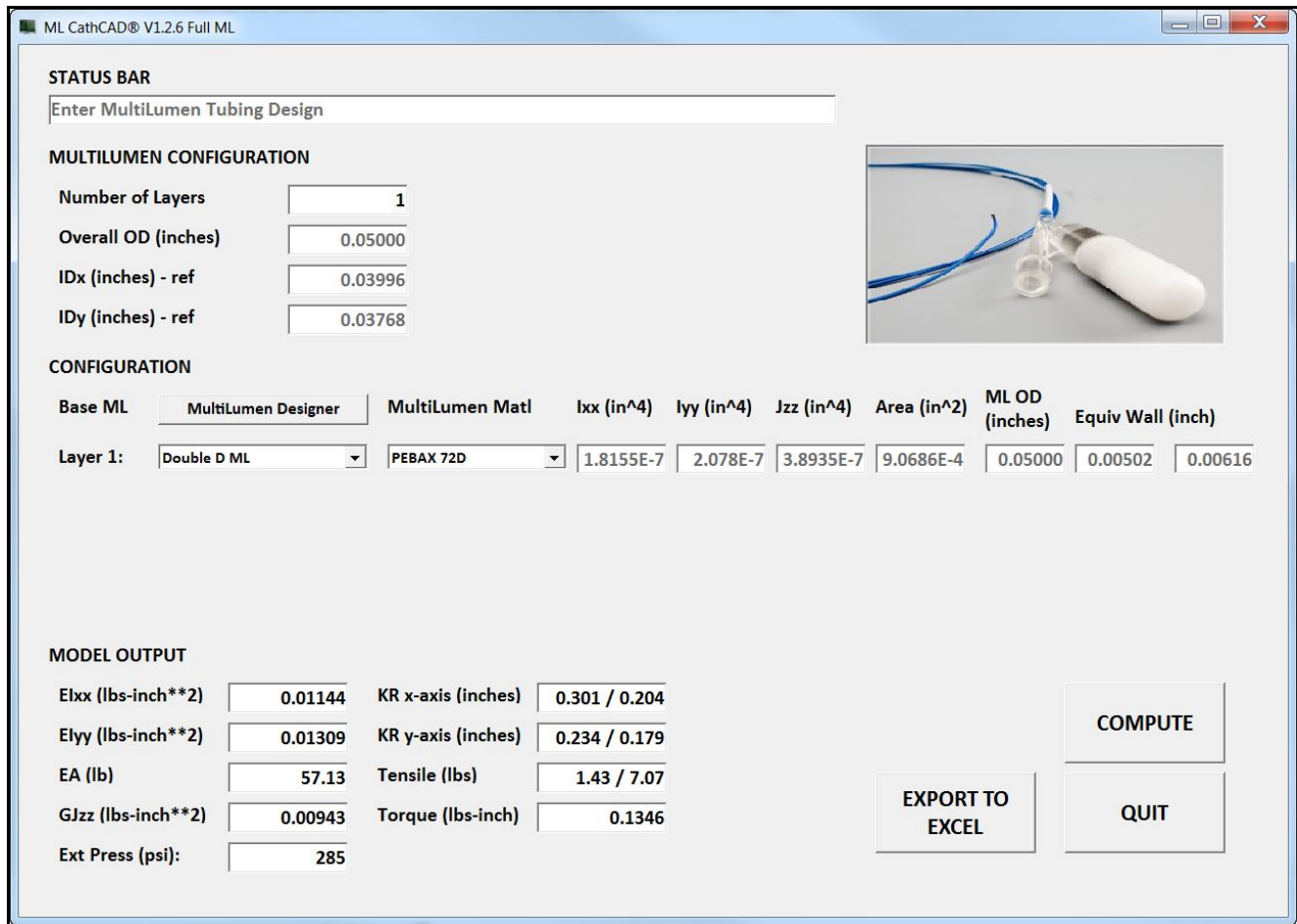
After entering/saving your design from the MultiLumen Designer function, the computed inertial properties of your design are transferred into the SOFTWARE and are shown on the screen. The next step is to select the multilumen material from the drop down box as shown.



At this point, your design is completed (for a one layer design). Select the COMPUTE button.



The model output fields are calculated and displayed on the Main Screen as shown. The **EXPORT TO EXCEL** function becomes active at this point as well.



MultiLayered Construction (Layers 2 and 3)

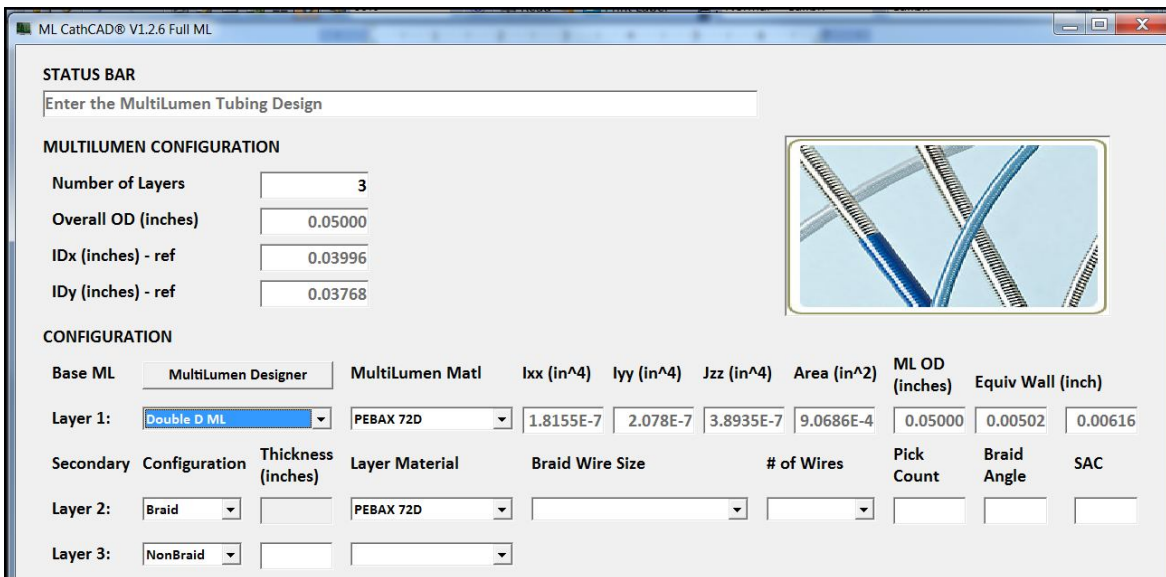
If the number of Layers in your design are greater than one, the associated fields for these layers become active. These fields are defined as the Layer Configuration, Wall Thickness (in inches), and the Layer (Matrix) Material. If the Layer Configuration is defined as a BRAID layer, then the additional fields of Braid Wire Size, total number of CW/CCW Braid Wires, and Pick Count become visible and need to be defined by the User as well.

In the example shown below:

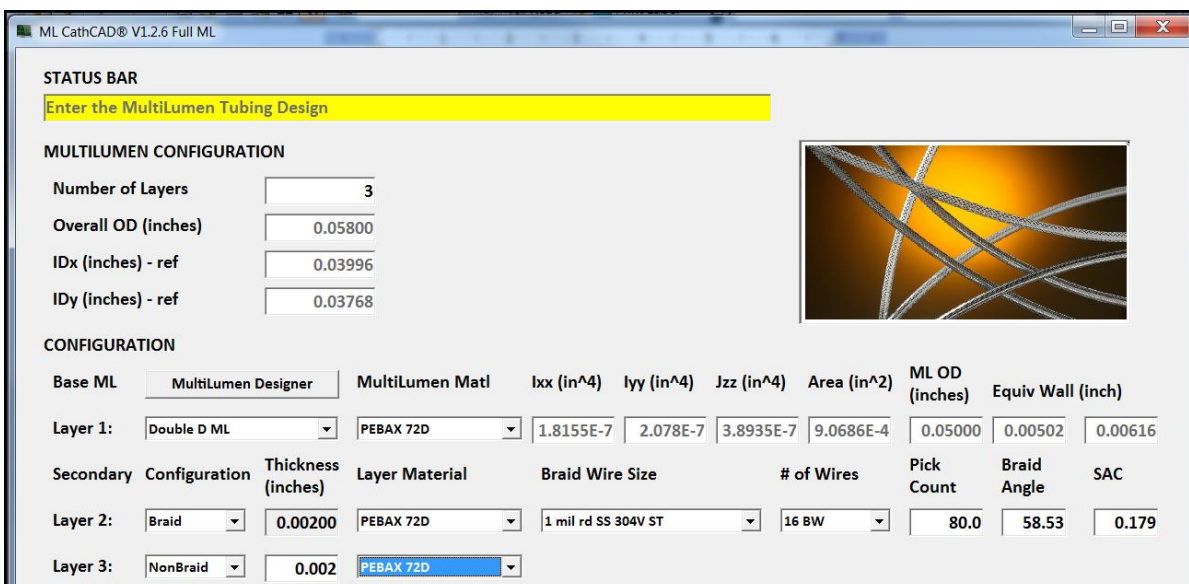
1. Layer 1 is defined as the MultiLumen design itself (previously developed)
2. Layer 2 is defined to be a Braided Layer.

- a. The expected inputs are the layer (matrix) material, the Braid Wire Size, the total number of Braid Wires, and the Pick Count.
- b. The thickness of the layer is computed by the SOFTWARE based on the braid wire size chosen.
- c. The braid angle and surface area coverage (SAC) of the braid layer are computed values.

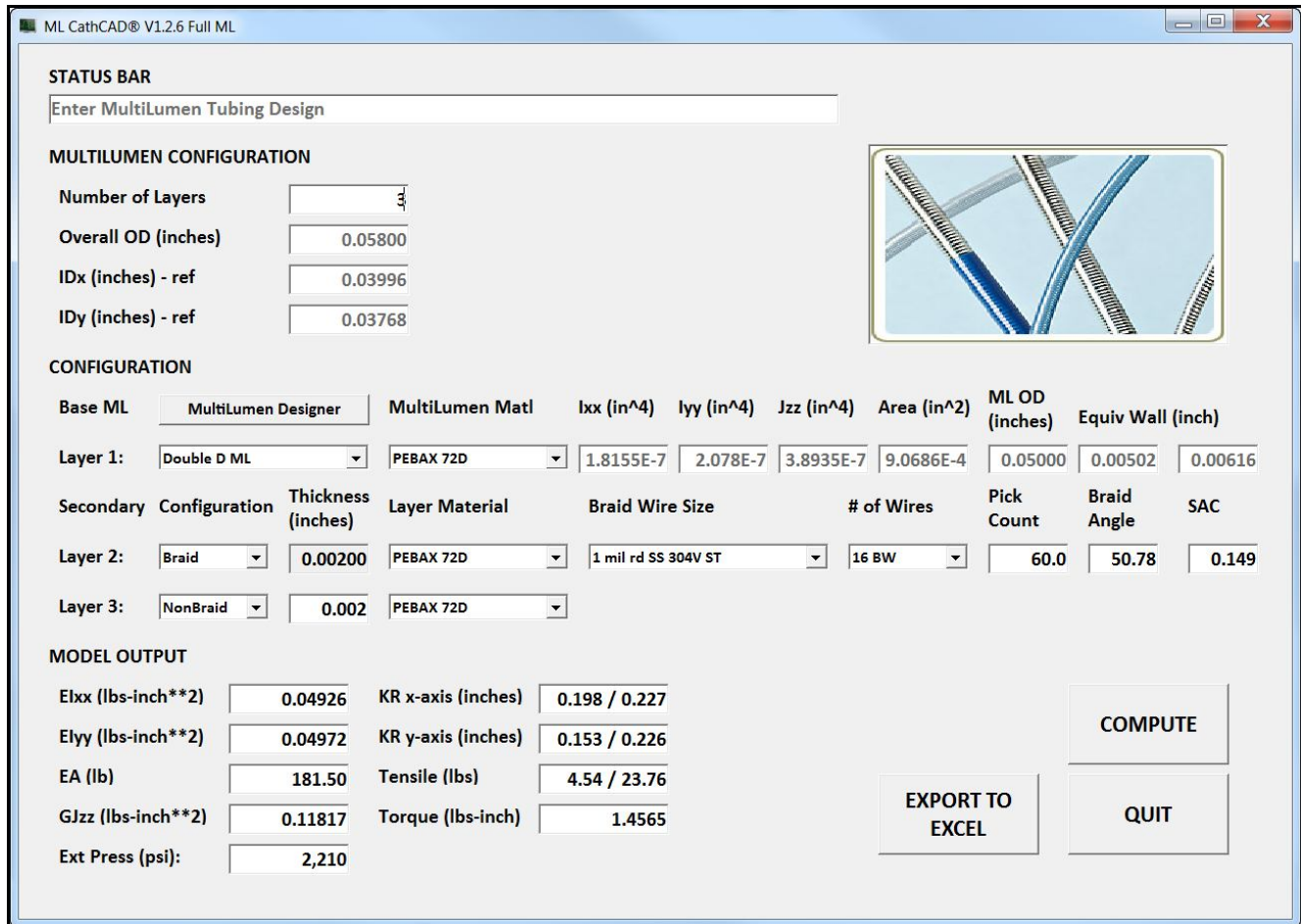
3. Layer 3 is set to a configuration as a NonBraid. As a result, the expected inputs to define a NonBraid layer is the thickness of the layer and the layer material. The outer layer of a design CANNOT be a braid reinforced layer. The screen shot below shows a layered configuration that has NOT been filled out.



The screen shot below shows the layered configuration after being completed by the User.



If the braid angle of the design is known but not the Pick Count, you can enter trial values of the pick count into the SOFTWARE until your desired braid angle shows up on the screen. The computation from Braid Angle to Pick Count is nearly instantaneous. After the required values have been entered, the User can select the **COMPUTE** button to generate the model outputs. The screen shot below shows the results obtained after pressing the **COMPUTE** button.



Error Correction

If the User enters incorrect values into a field, the SOFTWARE will automatically update the value as applicable. Examples of the system performing error corrections on User entered data are as follows:

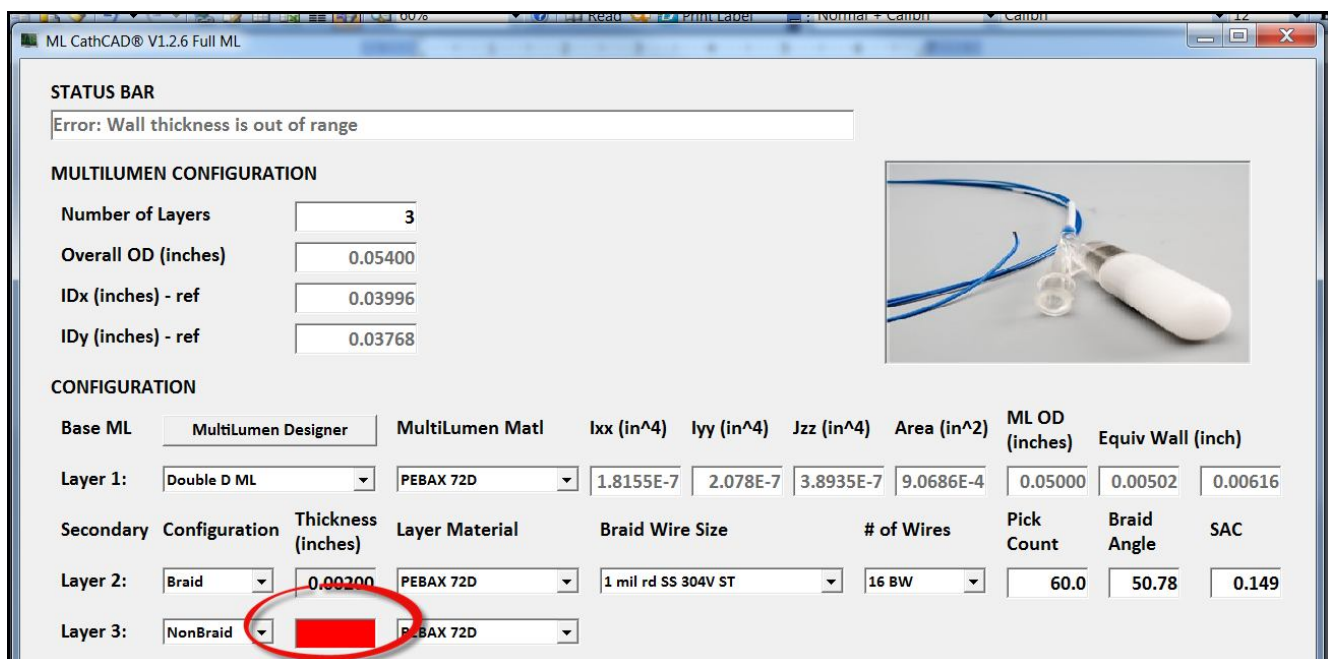
1. Entering nonnumeric data into data entry fields. An example of this would be for the User to enter the letter "A" into the tubing OD field.
2. Entering negative numbers
3. Entering large number into applicable fields
4. Entering a braid size/# of wires/pick count which results in a SAC (braid surface area coverage) that exceeds a maximum limit (set to approximately 80 percent as a default)

In these cases, the SOFTWARE intelligently intercepts the data being entered into the field, reviews it for applicability, and adjusts the values as applicable. In most cases, the SOFTWARE deletes the information being entered if it thinks it is incorrect, thus forcing the User to reenter/correct the data.

If you select the **COMPUTE** button before all the fields have been properly entered, the SOFTWARE will identify only the FIRST field that it finds that is incorrect/empty and will highlight it in RED for two to three seconds. Correct your mistake(s) and then select with the **COMPUTE** button.

In the example below, the Layer 3 thickness field was left blank. The SOFTWARE has highlighted this field to bring it to the operator’s attention.

The STATUS BAR also displays an error message indicating that the Wall Thickness was out of range.



ML CathCAD® Model Outputs

The SOFTWARE computes the following outputs:

- Elxx is an estimate of the catheter flexural rigidity about the x-axis
- Elyy is an estimate of the catheter flexural rigidity about the y-axis
- EA is an estimate of the catheter longitudinal rigidity
- GJ is an estimate of the catheter torsional rigidity

- The Kink radius is an estimate of the smallest radius the catheter will make in an UNLOADED (no axial force applied or internal pressure applied) condition. This computation assumes a perfectly manufacturer catheter (i.e. perfect concentricity and manufactured to nominal dimensions). Two values are provided
 - The first value is the estimated kink radius due to buckling
 - The second value is the estimated kink radius due to material failure
 - The kink radius about the x-axis AND the y-axis are provided
- Failure mode computations:
 - Tensile strength (yield and ultimate)
 - Maximum torque
 - External pressure failure ("crush")

All of these values are exported to Excel as part of the EXPORT TO EXCEL function.

V. Material and Braid Wire Data

The SOFTWARE allows for changes to the material inputs (i.e. matrix materials, braid wire sizes, # of braid wires) to be configured without recompiling the SOFTWARE. The materials and braid wire sizes are stored on a MySQL server running on our LINUX Server that is connected to the Internet. Connection between your computer and our Server is completed over Port 3306.

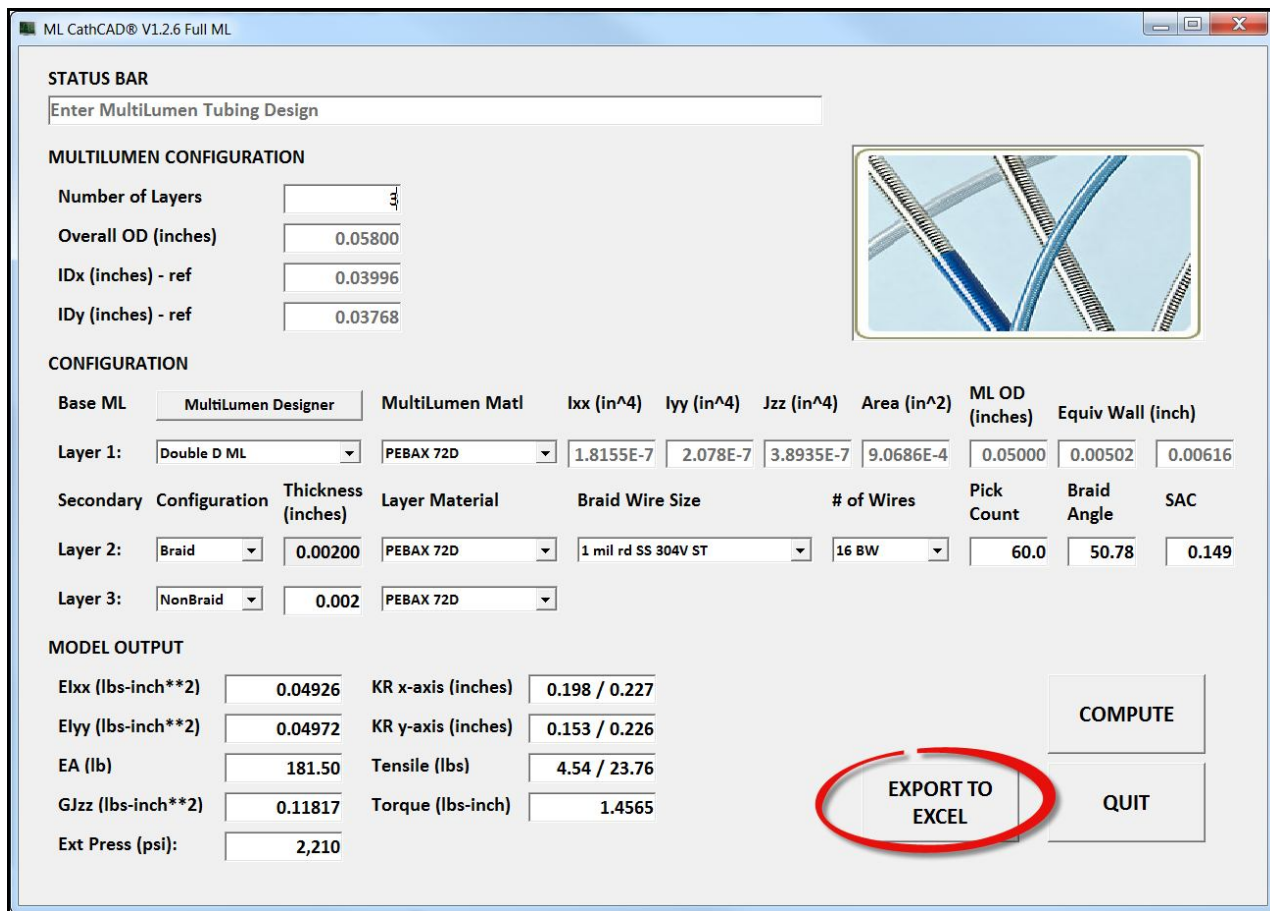
If you have a requirement to add a new material, braid wire size, and/or # of braid wires, contact us at sales@cathcad.com and we will add your new item for you. After we load the data, the next time you run the SOFTWARE, the new item will appear automatically.

A base database of materials and braid wires has been loaded into the database for your company. The list of available materials, braid wires, etc can be customized at no charge for your company. This customization also includes the order that the materials appear on your drop down boxes. Note that any customization of materials, braid wires, etc is specific for your company.

VI. Exporting Modeling Results to Microsoft Excel

The SOFTWARE integrates directly with Microsoft Excel if this program is loaded on your computer. The combination of the SOFTWARE and Excel eliminates the requirement to write your results down on paper. Instead, the SOFTWARE directly exports the SOFTWARE results directly to Excel in a standard output format. This section explains step by step on how to export your results to Excel.

1. When a complete design is entered and computed, the **EXPORT TO EXCEL** button will become visible. This is your indication that the SOFTWARE has loaded the results into memory and is ready to export the results to Excel.



2. Select the **EXPORT TO EXCEL** button.

a. The **EXPORT TO EXCEL** will become faded.

b. Within a brief period of time (depending on your computer speed this may be as long as five to ten seconds) the **VIEW EXCEL** button will become active.

c. An instance of Excel has become active but is currently **HIDDEN** from your view. This instance of Excel contains your computed model data.

3. This process of entering models into the SOFTWARE, Computing, and Exporting to Excel can be repeated over and over. With time the User will gain confidence in this Excel export capability.

4. Viewing and working with your exported model results in Microsoft Excel is accomplished by the **VIEW EXCEL** and **HIDE EXCEL** button on the Main Menu.

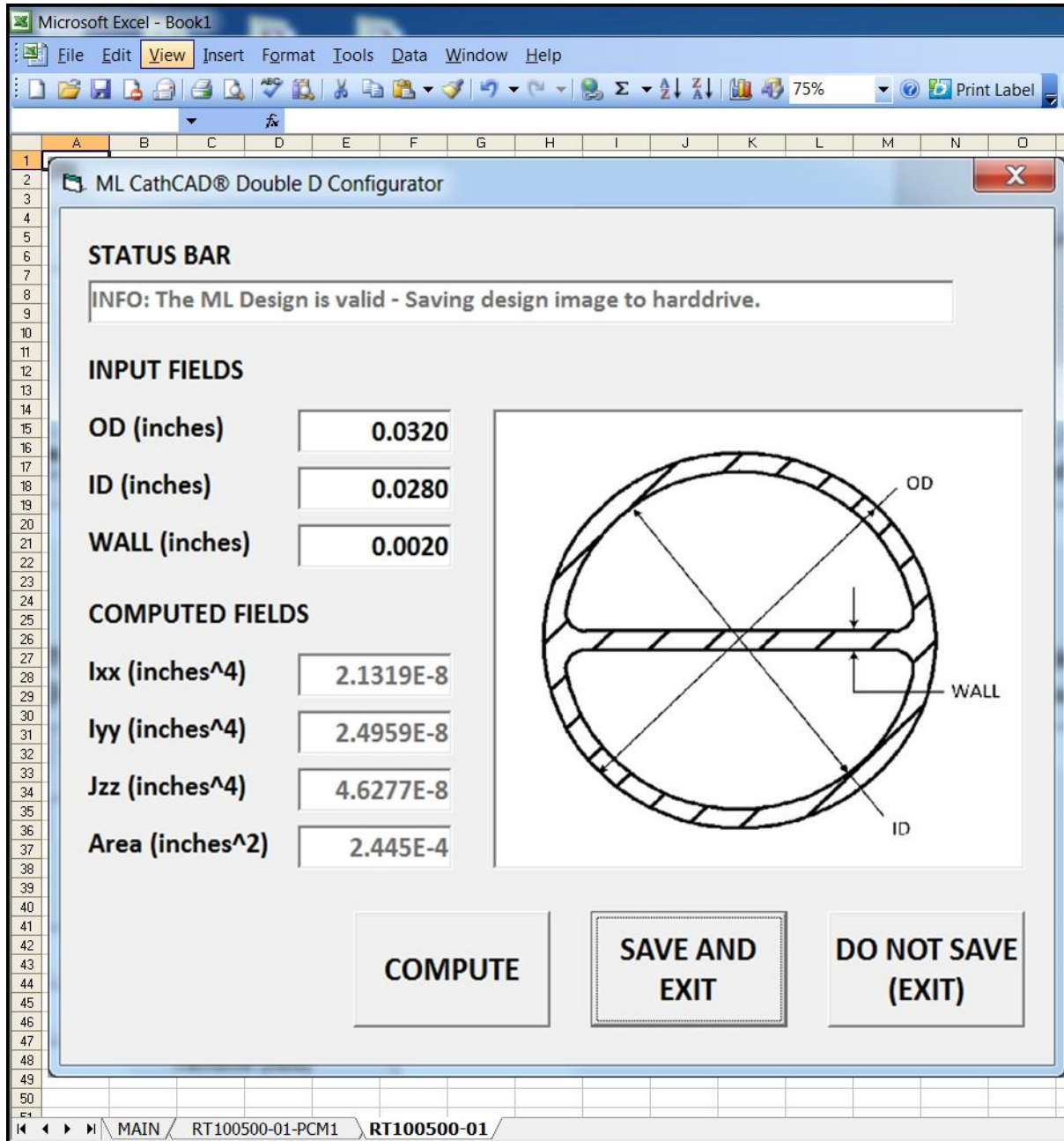
- a. When Excel is hidden but contains data, the **VIEW EXCEL** button becomes active. Simply select this button and Excel will become VISIBLE (on the task bar) allowing you to access your data directly in Excel. Likewise when the SOFTWARE is running and Excel is visible, the **HIDE EXCEL** button becomes active. This button allows you to have Excel active but not visible on your desktop.
- b. When you exit or quit the SOFTWARE, the Excel worksheet will become visible with your data.
- c. Your model results, as stored and formatted in Excel, is ready for immediate printing if you export five or less model runs. If you export more than six or more model runs to the same Excel spreadsheet, the printed results may be too small to read. As a result, the User may need to manually format the Excel spreadsheet to improve its printability.
- d. It is the User's responsibility to SAVE the results within Excel.
- e. A Project Number is automatically generated by the SOFTWARE for each model that is exported to Excel. This allows the User to identify a particular model run by a unique identifier. An example of the complete project number for an exported model run would be RT100000-01. The project number format is described as follows:
- Project numbers are configured to start with the account User's initials (e.g. RT)
 - Project numbers (by default) start at 100000.
 - Individual exported model runs begin with 01 and increment by one. If four models were exported to the same Excel spreadsheet, they would be identified as RT100000-01, RT100000-02, RT100000-03, and RT100000-04.
 - An example of the exported SOFTWARE generated format to Excel is provided on the next page which clearly illustrates the project number.
- f. The SOFTWARE makes its best efforts to interface to Excel properly. The User should not perform the following operations:
- Close Excel if the SOFTWARE has opened it. The SOFTWARE expects Excel to be available once it has launched it. If you do mistakenly close Excel, the SOFTWARE does its best to reopen Excel for export purposes in a graceful manner.
 - Delete rows and/or columns in Excel while the SOFTWARE is working with Excel.
- NOTE: It is the User's responsibility to SAVE and store the resulting Excel file. While the SOFTWARE will export the model results to Excel, the SOFTWARE does not SAVE the results to a file.
- g. The example below shows the results for four model runs that were generated from the SOFTWARE and exported to Excel using the **EXPORT TO EXCEL** button.

EXPORT TO EXCEL FORMAT

	A	B	C	D	E	F
2	MultiLumen Design	N/A	Double D ML	Round w/ Circle Crescent ML	Two Round Inner Lumens ML	Three+ Round Inner Lumens ML
3	MultiLumen Material	N/A	PEBAX 7233 SA01	PEBAX 7233 SA01	PEBAX 7233 SA01	PEBAX 7233 SA01
4	Number of Lumens	unity	2	2	2	2
5	MultiLumen OD	inches	0.0330	0.2000	0.2000	0.2000
6	MultiLumen Design Parameters	See Applicable ML Design Drawing	ID: 0.0300 inches	ID1: 0.1200 inches	ID1: 0.0500 inches	ID1: 0.1200 inches R1: 0.0300 inches THETA1: 270.0 degs
7			Wall: 0.0015 inches	L1: 0.0300 inches	ID2: 0.1200 inches	ID2: 0.0500 inches R2: 0.0650 inches THETA2: 90.0 degs
8			N/A	R1: 0.0750 inches	L1: 0.0650 inches	N/A
9			N/A	R2: 0.0900 inches	L2: 0.0300 inches	N/A
10			N/A	THETA: 180.0 deg	N/A	N/A
11	BA = Braid Angle	Layer 2	N/A	N/A	N/A	N/A
12	SAC = Surface Area Coverage	Layer 3	N/A	N/A	N/A	N/A
13	BM = Braid Matrix Material					
13	OVERALL OD	inches	0.0330	0.2000	0.2000	0.2000
14	ML CathCAD® OUTPUTS					
15	E _{lxx} (x-axis) FLEXURAL RIGIDITY	lbs-inch**2	0.0014	2.5579	3.6674	3.6674
16	E _{lyy} (y-axis) FLEXURAL RIGIDITY	lbs-inch**2	0.0016	3.4941	5.0339	5.0339
17	E _A LONGITUDINAL RIGIDITY	lbs	14.31	876.24	1342.02	1342.02
18	G _{Jzz} TORSIONAL RIGIDITY	lbs-inch**2	0.0011	2.3277	3.3465	3.3465
19	KINK/MATL FAILURE RADIUS (x-axis)	inches	0.417 / 0.151	1.638 / 0.919	0.920 / 0.923	0.920 / 0.923
20	KINK/MATL FAILURE RADIUS (y-axis)	inches	0.336 / 0.128	1.005 / 0.675	0.420 / 0.678	0.420 / 0.678
21	TENSILE STRENGTH	lbs	0.358 / 1.567	21.906 / 95.953	33.550 / 146.958	33.550 / 146.958
22	MAXIMUM TORQUE	lbs-inch	0.0052	1.7937	2.7101	2.7101
23	EXT COLLAPSE PRESSURE	psi	25	148	1219	1219

If you have a particular format that you wish to use for your purposes -- please contact us.

With the release of ML CathCAD® V1.4.0 the Export to Excel function also includes a screen shot of the ML Design Configurator Screenshot. The Excel Sheet name for this exported image will include the project number.



VII. MultiLumen Designer

The beauty of the ML CathCAD® Software is the MultiLumen Designer function. The following multilumen designs have been preprogrammed into the SOFTWARE:

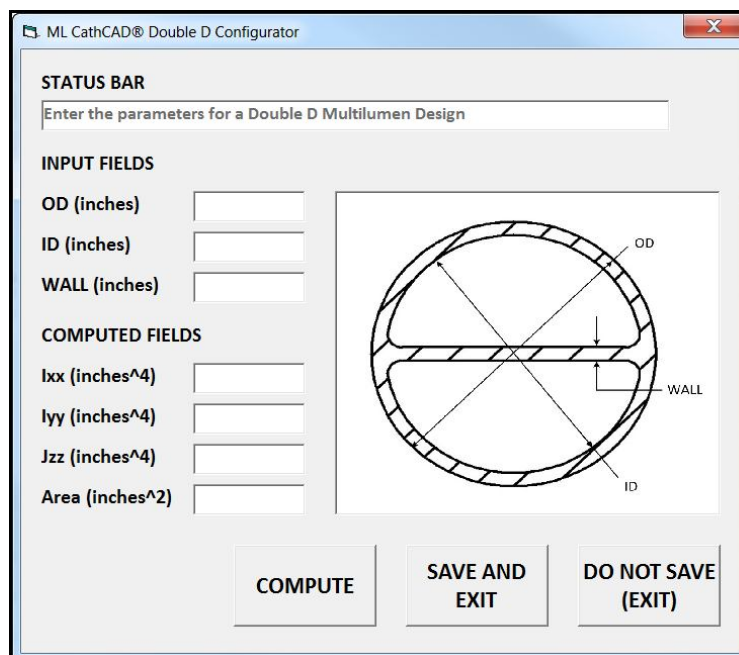
- Double D
- Multiple Round Inner Lumens (two, three, four, or five)
- Circle Crescent w/ one round lumen
- Steerable Catheter

If the configuration you are designing does NOT fall into any one of these categories, the SOFTWARE allows the User to enter the necessary parameters into the system as computed from a design program such as Solidworks® or AutoCAD®

The following steps are to be followed to enter the parameters for a Double D multilumen design:

- Select the Double D ML from the drop down menu
- Select the MultiLumen Designer command button. The designer for this multilumen design will appear on the screen
- Based on the figure notation, enter the ID, OD, and WALL
- Select the COMPUTE button. If the design is valid, the results of the design will appear on the screen.
- To save the design, select the SAVE AND EXIT button.

The other multilumen designs can be completed similar to this procedure.

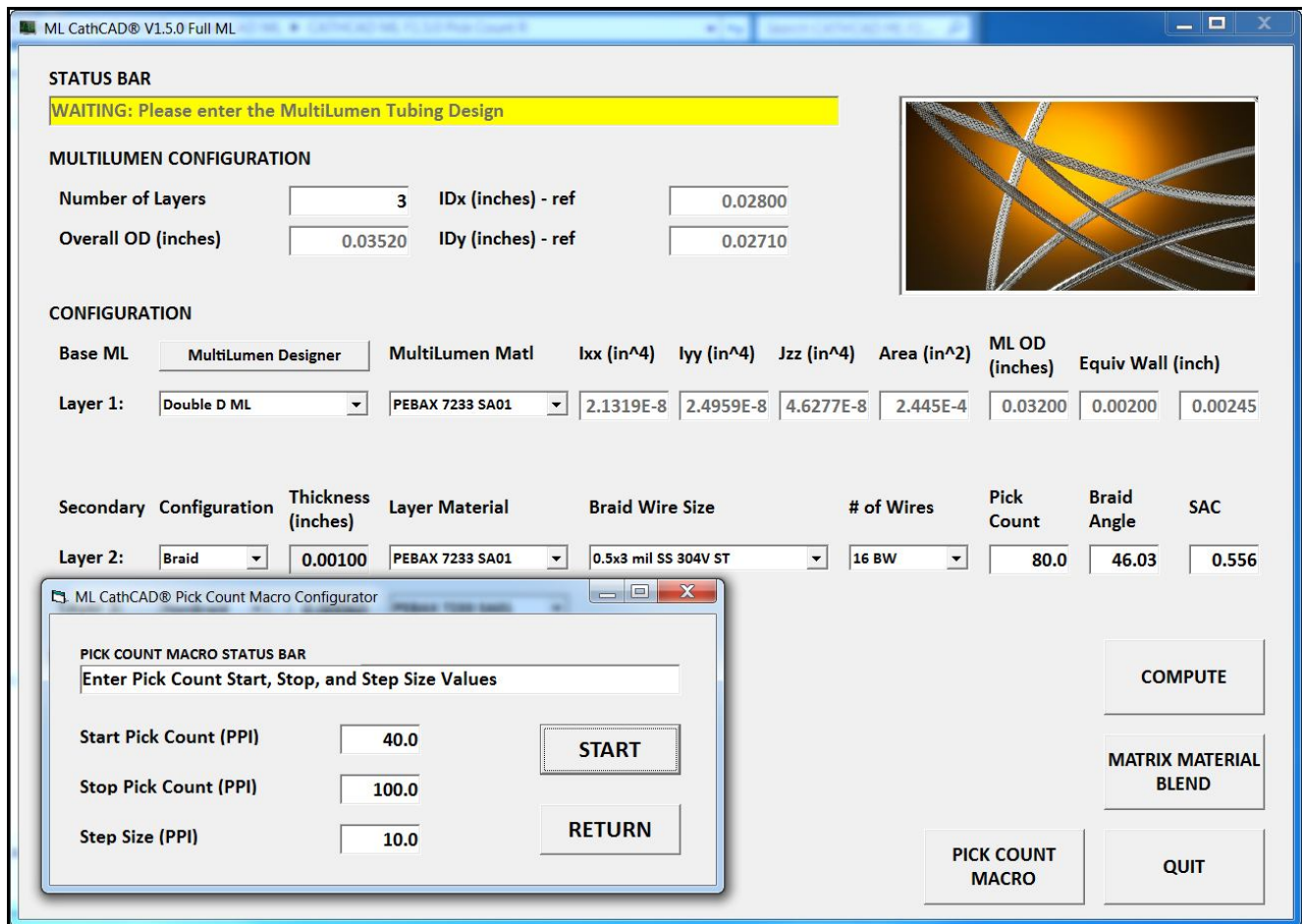


VIII. Pick Count Macro and Graphing

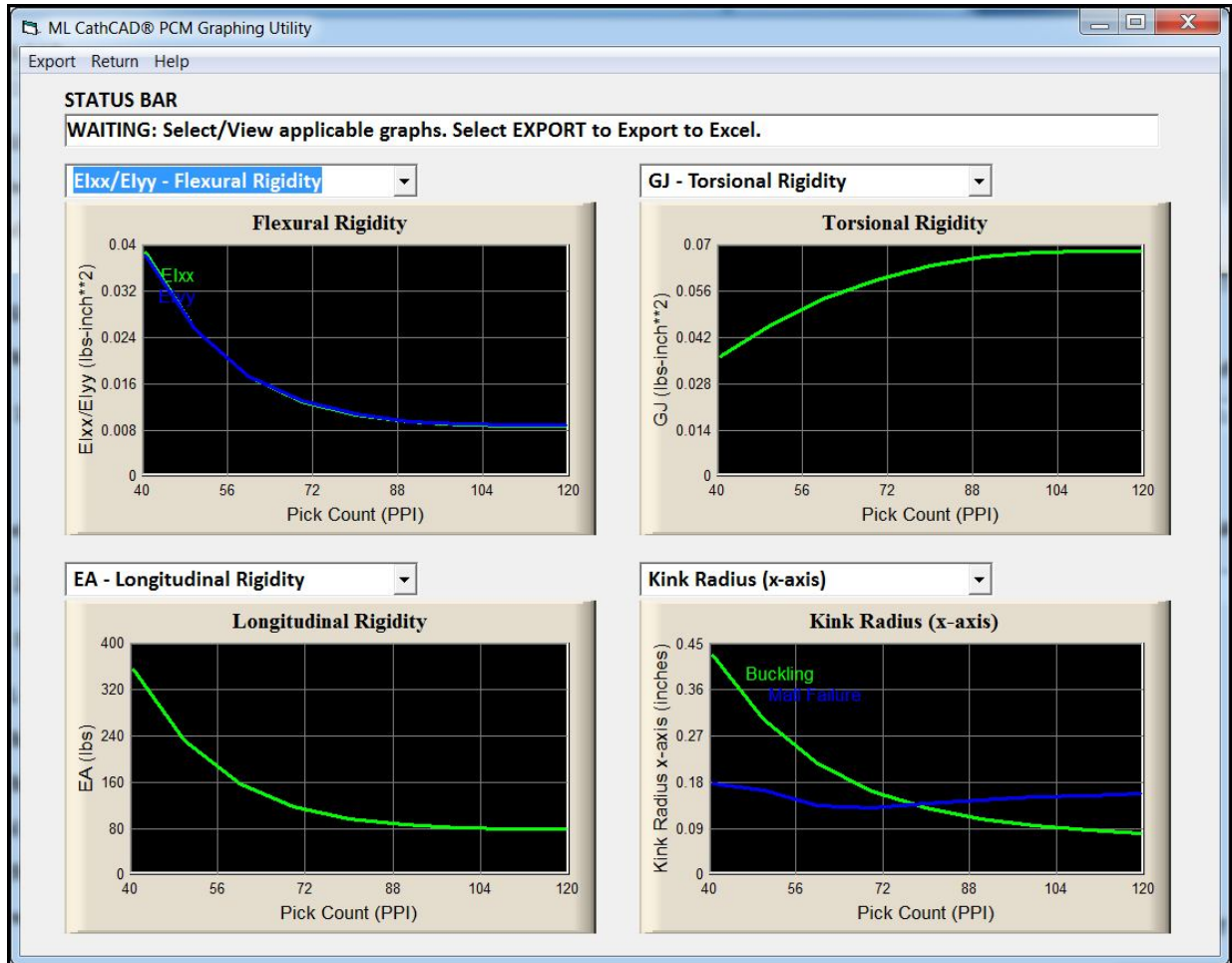
In order to simplify the modeling of composite tubing, the SOFTWARE was updated to include the Pick Count Macro feature. This function allows for varying the pick count for braided ML composite tubing.

To proceed with the Pick Count Macro function, complete the following steps:

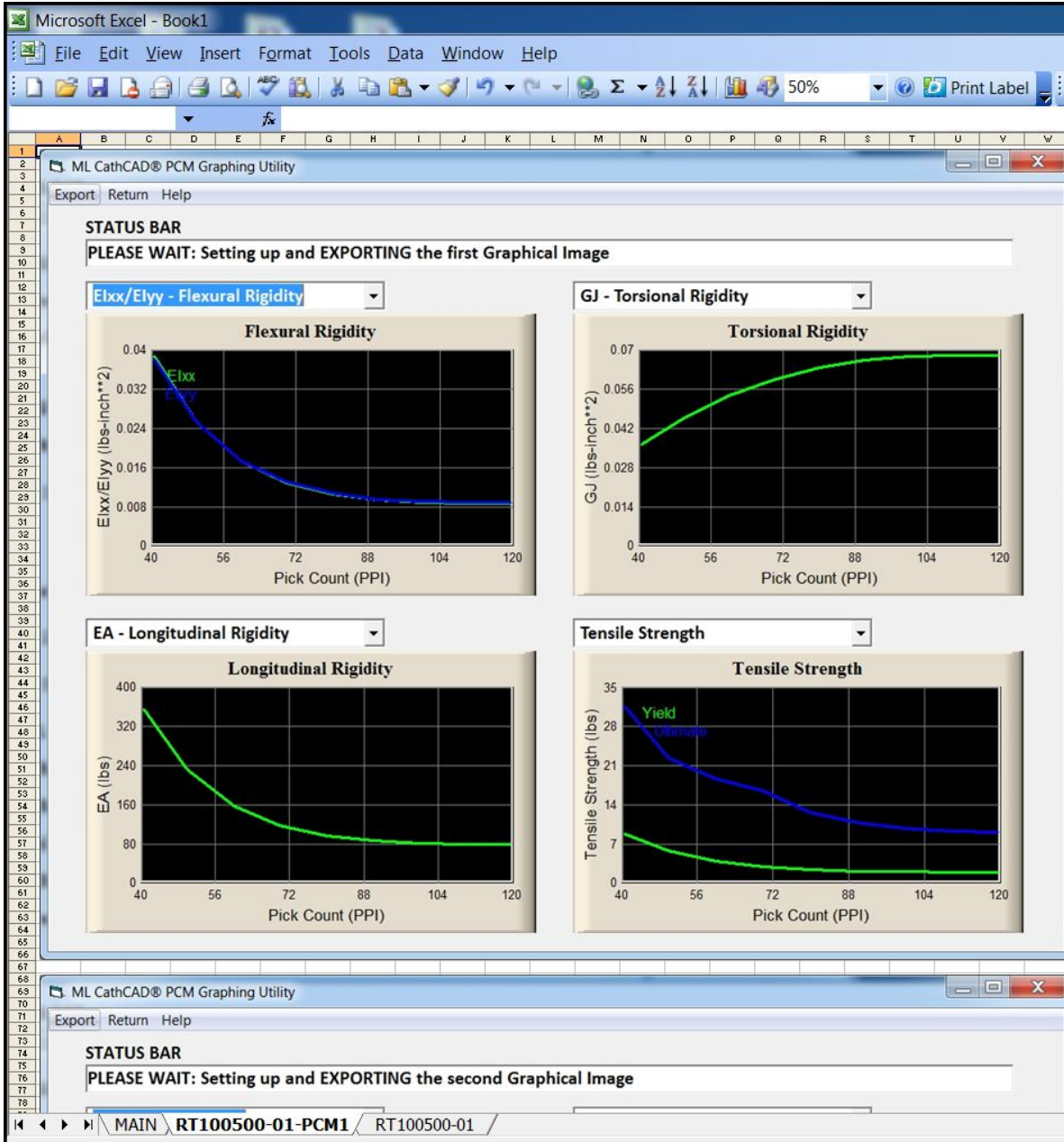
- Enter a valid design into the SOFTWARE. The design MUST include BRAID reinforcement. Select the Pick Count Macro button.
- The SOFTWARE will review your design. If it is proper, the Pick Count Macro designer will appear on the screen. Enter the start, end, and pick count step sizes). Select the START button to proceed or RETURN to cancel the operation



- The SOFTWARE will loop through the pick count limits automatically. When it is completed, the GRAPHING utility will appear on the screen allowing the User to review the SOFTWARE outputs as a function of pick count.



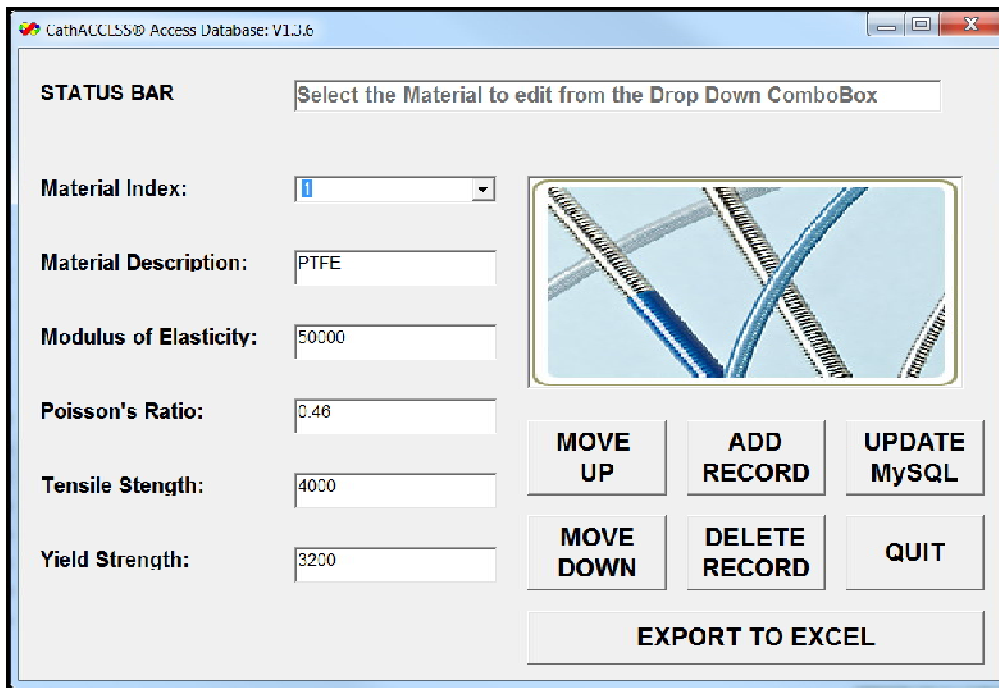
- To EXPORT the graphical results to Microsoft Excel select the EXPORT menu item at the top of the screen. This function will export two screens with all relevant graphs directly to Microsoft Excel.



When you are completed reviewing the results, select the RETURN menu item. The results of the computation will also be exported (automatically) to Microsoft Excel as well. This process can generate a lot of data quickly so don't be surprised if there are many columns of data in Excel for you to review and look at as well.

IX. CathACCESS®

For our sophisticated Users of the SOFTWARE, we offer the ability to directly interface to the MySQL Materials Database with our utility program, CathACCESS®. Contact us via email at sales@cathcad.com in order to be configured for use of this program.



CathACCESS® allows you to do the following:

- **UPDATED RECORD:** Update a Material record including Material Description, Modulus of Elasticity, Poisson's Ratio, Tensile Strength, and Yield Strength
- **ADD RECORD:** Add a New Material
- **DELETE RECORD:** Delete a Record from the Materials Database
- **EXPORT TO EXCEL:** This exports all records from the Database to Excel.

X. Reporting Errors or to Request Feature Updates

Report system crashes or situations where the SOFTWARE generates incorrect results via email to sales@cathcad.com. Please provide as much information as possible with regards to the setup of the program when the error occurred.

We also encourage and accept feature requests from our Users. Please email these requests to sales@cathcad.com as well.