

CathSOLVER™ User Guide

Included as part of the CathCAD® Software

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

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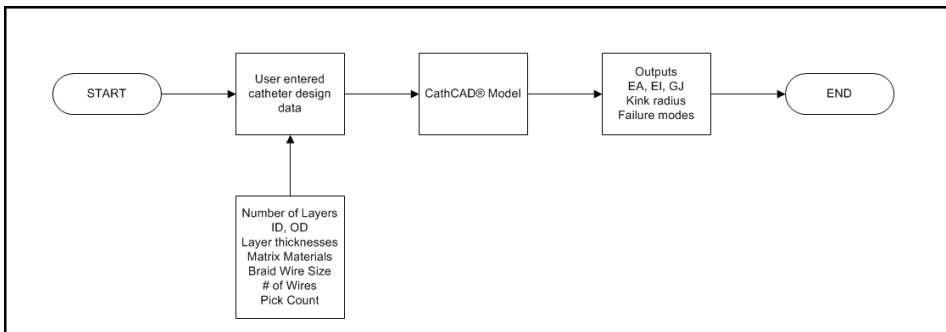
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I. Introduction

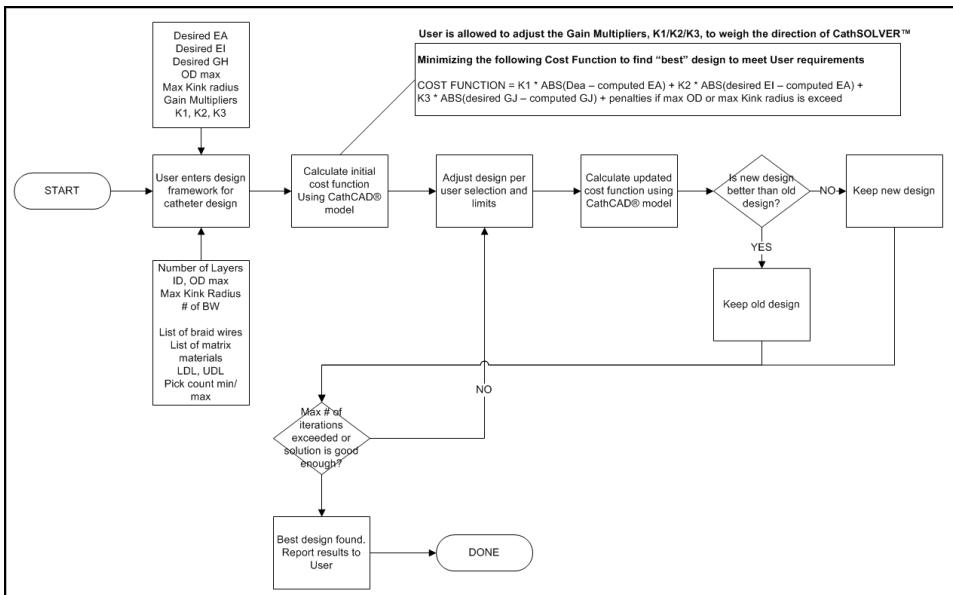
This document summarizes the CathSOLVER™ module that was incorporated into CathCAD® Standard V3.9.0 and higher.

I. Background Information

The CathCAD® software provides and executes the Forward Direction when designing a catheter design, that is, given the design ID/OD, Number of Layers, and the required inputs for each layer (material, thickness, etc) – the Software computes and provides the mechanical characteristics of the design including but not limited to EA, EI, GJ, Kink radius, and the various failure mode limits.



The CathSOLVER™ function was integrated into CathCAD® Standard V3.9.0 and higher to simplify the catheter design process. The CathSOLVER™ function provides and executes the Reverse Direction of the catheter design problem. Given a design framework, ID, OD maximum, number of layers, and desired EA, desired EI, GJ, and maximum kink radius - the Solver will find the “best” design that meets the User’s requirements.



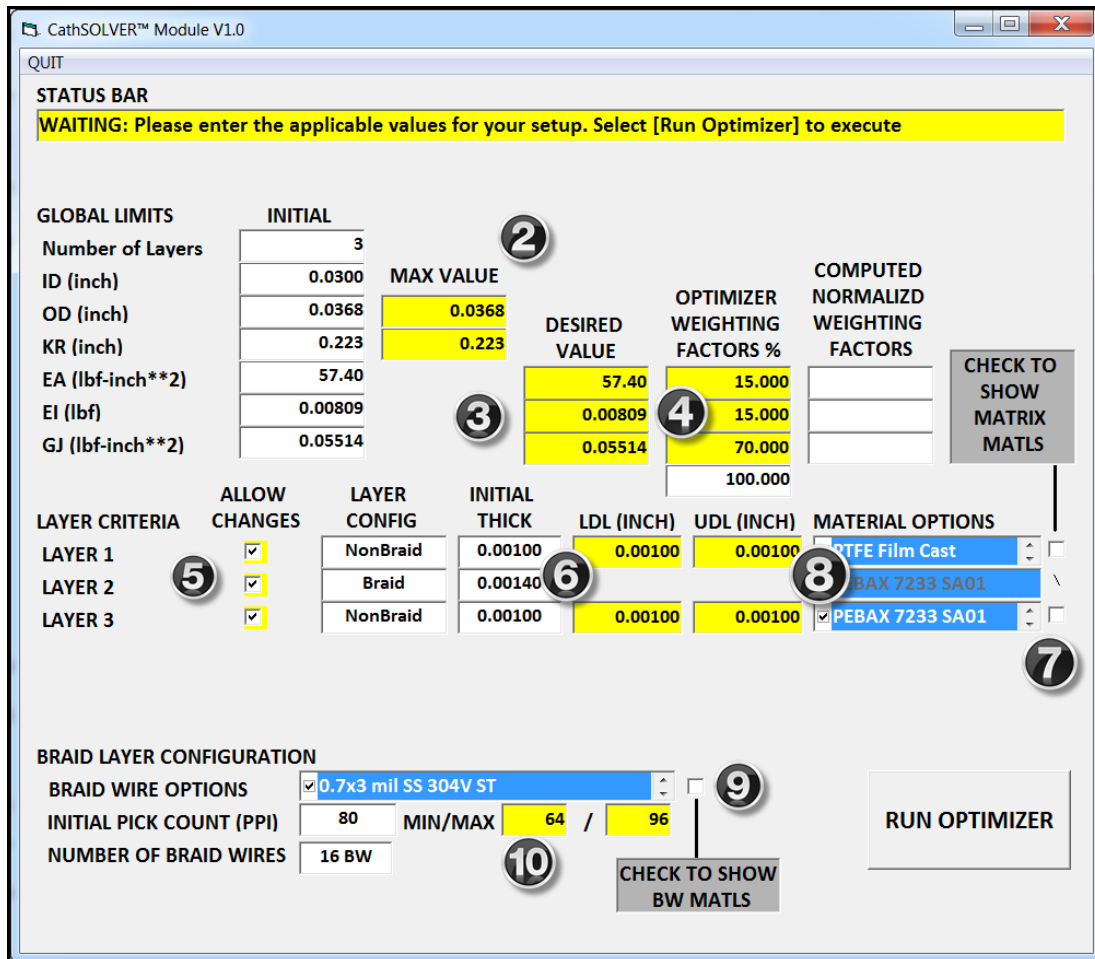
CathSOLVER™ is able to execute the catheter design process by finding a design that meets the Users goals by executing literally hundreds of designs in a very short time period as no human entry of each model is required.

III. Executing the CathSOLVER™ Function

This section provides step by step instructions on executing the CathSOLVER™ module in order to optimize a design.

Step 1: Execute the framework for your design by entering a valid design and selecting the COMPUTE button. When this is complete, the CathSOLVER™ button will appear.

Action: Select the CathSOLVER™ button to enter the CathSOLVER™ module. Refer to the following figure as Steps 2-10 are summarized.



Step 2: Enter the upper (maximum) values allowed for the OD and Kink Radius. For best performance – these values should be larger than the entry values

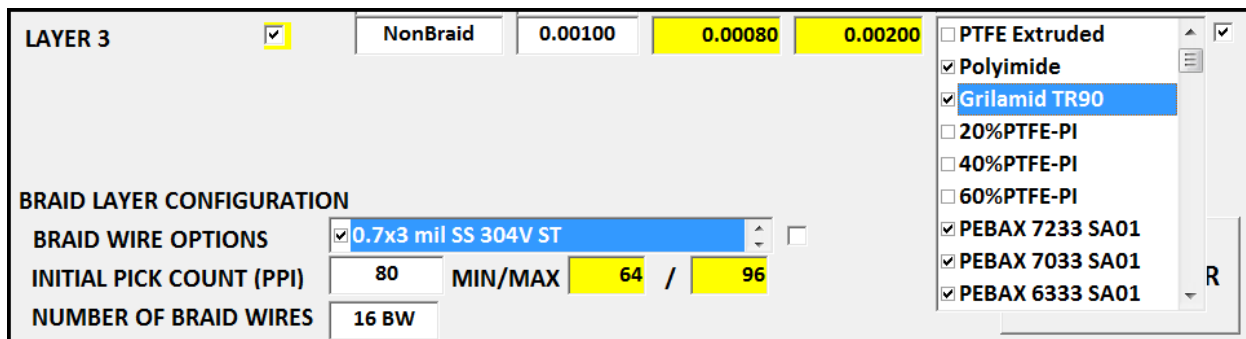
Step 3: Enter the desired values of EA, EI, and GJ in the units as shown.

Step 4: Enter the desired weighting factors used by CathSOLVER™. These values should approximately add up to the value of 100, however, the system will automatically normalize these values.

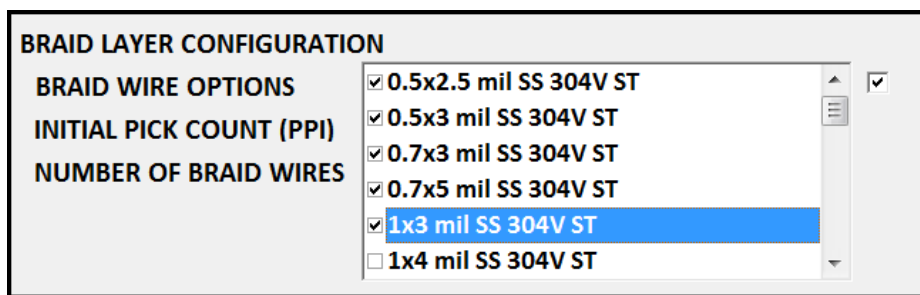
Step 5: Select or unselect the Layers that you wish to be modified (updatable) by CathSOLVER™. As an example – you may wish to have a Layer to be unchangable such as a base layer of PTFE (inner liner) where the material and dimensions of the layer are known and will not change in the design.

Step 6: Enter the LDL (lower dimensional limit) and UDL (upper dimensional limit) for the nonbraid layers. This allows CathSOLVER™ to adjust and optimize the layer thickness.

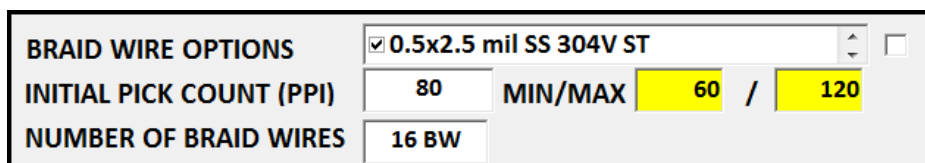
Step 7: Select the materials you wish to be evaluated for each nonbraid layer. This is done by (a) selecting the “show the matrix materials” checkbox, (Step 8) selecting the materials, and then unchecking the “show the matrix materials” checkbox. The number of materials that may be evaluated is limited to twenty (20) but less is better. The screenshot below shows that Layer 3 is enabled, the LDL/UDL wall thickness limits are 0.8 to 2 mils, and a number of matrix materials have been selected by the user (Polyimide, Grilamid, PeBax 72D, etc).



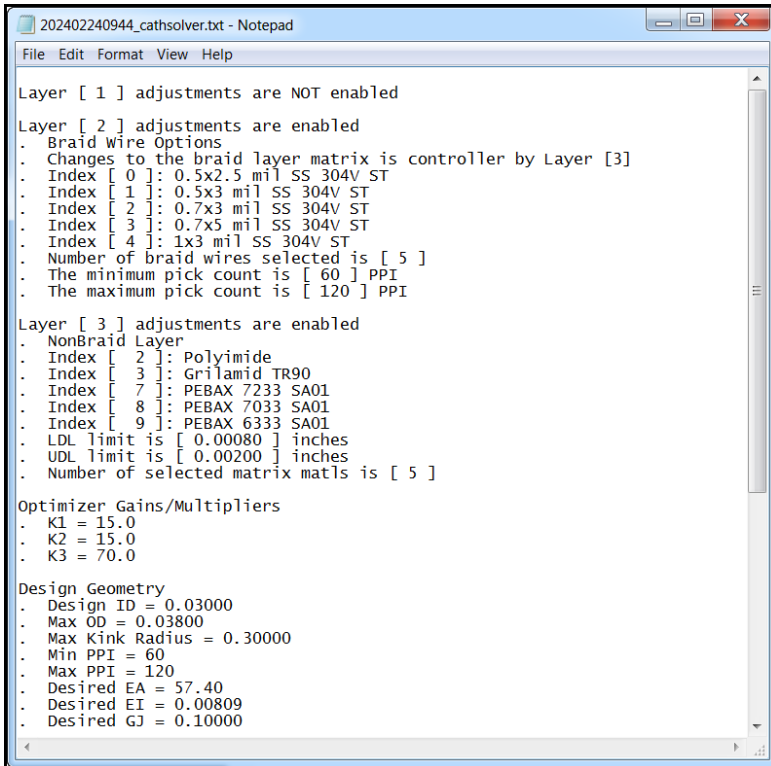
Step 9: Select the braid wires that you wish to be evaluated for each braid layer design. This is done by (a) select the “show the braid wire materials” checkbox, selecting the appropriate braid wires, and then unchecking the “show the braid wire materials” checkbox. The screenshot belows shows that the User has selected at least five braid wires including 0.5x2.5, 0.5x3, 0.7x3 mil SS 304, etc.



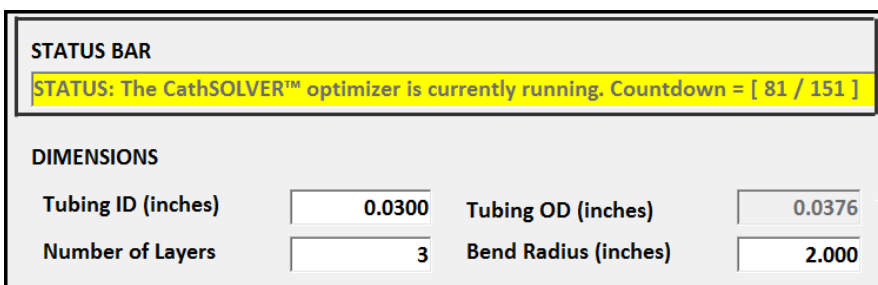
Step 10: Enter the pick count min value and pick count max value. The screenshot below shows a min and max pick count of 60 and 120 PPI.



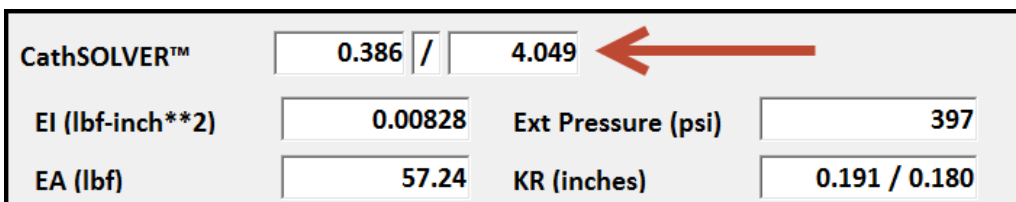
When all the applicable information is entered, select the [RUN OPTIMIZER] button. The Software will evaluate the entries and provide a text document that summarizes the entries. This document will clearly identify any issues with the solver entries. If the design is valid, the CathSOLVER™ will execute automatically.



The CathSOLVER™ module will then drive the CathCAD® software to find the “best” design based on the Users inputs. When the solver is running – the Status Bar will show the countdown summary (number of models executed versus the expected max number of models to be executed).



A numerical status of the best versus starting cost function value(s) are also shown on the screen.



Each model run that results in an improved (reduced) cost function is automatically exported to Microsoft Excel (if the software is installed on your computer). Typically ten to twenty plus models will be exported for a given design optimization that is well (properly) defined and a solution to the problem is physically possible.

The screenshot shows the case where the cost function of the design decreased from 4.049 (initial) to the best value of 0.393 (best) which is a decrease of over 90 percent.

MODEL RUN ID	UNITS	RT100785-01	RT100785-13	RT100785-14	RT100785-15
ID	inches	0.0300	0.0300	0.0300	0.0300
OD	inches	0.0368	0.0376	0.0376	0.0376
WALL	N/A	3.40 mils	3.80 mils	3.80 mils	3.80 mils
COMPOSITE LAYERED DESIGN Layer 1 = Inside Layer BA = Braid Angle SAC = Surface Area Coverage BM = Braid Matrix Material	Layer 1	1.0 mils PTFE Film Cast	1.0 mils PTFE Film Cast	1.0 mils PTFE Film Cast	1.0 mils PTFE Film Cast
	Layer 2	0.7x3 mil SS 304V ST, 16 BW, 80 PPI, BA=46.4 DEG, SAC=55.3%, BM = PEBAX 7233 SA01	0.7x5 mil SS 304V ST, 16 BW, 100 PPI, BA=52.7 DEG, SAC=86.2%, BM = PEBAX 7033 SA01	0.7x5 mil SS 304V ST, 16 BW, 98 PPI, BA=52.1 DEG, SAC=85.6%, BM = PEBAX 7033 SA01	0.7x5 mil SS 304V ST, 16 BW, 97 PPI, BA=51.8 DEG, SAC=85.3%, BM = PEBAX 7033 SA01
	Layer 3	1.0 mils PEBAX 7233 SA01	1.4 mils PEBAX 7033 SA01	1.4 mils PEBAX 7033 SA01	1.4 mils PEBAX 7033 SA01
	Layer 4	N/A	N/A	N/A	N/A
	Layer 5	N/A	N/A	N/A	N/A
	Layer 6	N/A	N/A	N/A	N/A
CathCAD® Outputs		CF = 4.049	CF = 0.500	CF = 0.424	CF = 0.393
E COMPOSITE MODULUS OF ELASTICITY	PSI	160,891	146,381	143,926	142,830
G COMPOSITE SHEAR MODULUS	PSI	548,551	833,603	830,851	829,283
EI FLEXURAL RIGIDITY	lbf-inch**2	0.00809	0.00854	0.00840	0.00833

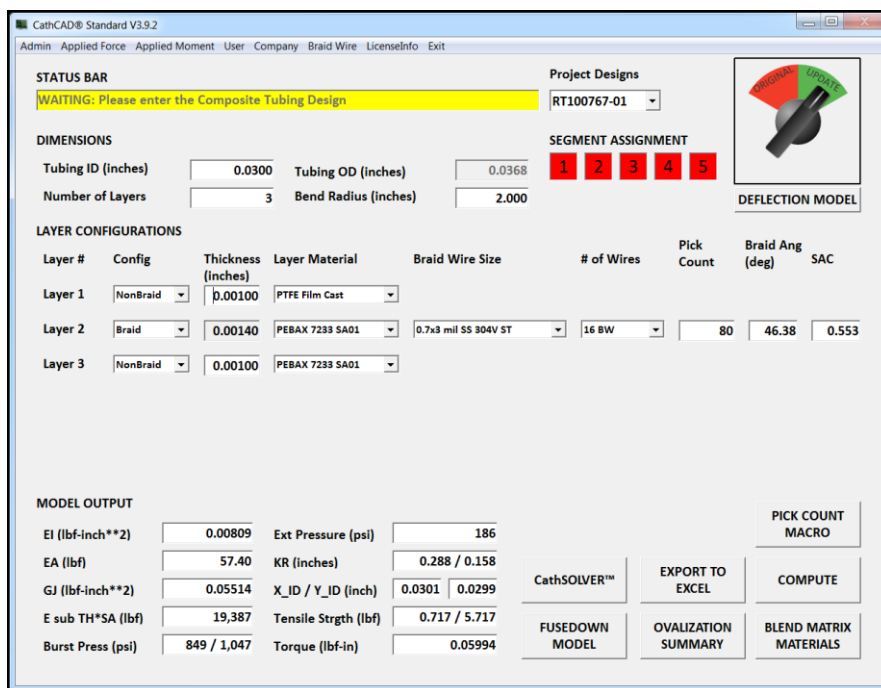
IV. Illustrated Example (step by step)

This section provides a step by step illustration of optimizing the torque output for a simple braided composite design. The values from the Software may vary from the illustration as the material properties in the User databases may have been updated at the time this guide was generated.

Step 1: Enter the following design into the Software

MODEL RUN ID	UNITS	RT100801-01
ID	inches	0.0300
OD	inches	0.0368
WALL	N/A	3.40 mils
COMPOSITE LAYERED DESIGN Layer 1 = Inside Layer BA = Braid Angle SAC = Surface Area Coverage BM = Braid Matrix Material	Layer 1	1.0 mils PTFE Film Cast
	Layer 2	0.7x3 mil SS 304V ST, 16 BW, 80 PPI, BA=46.4 DEG, SAC=55.3%, BM = PEBAX 7233 SA01
	Layer 3	1.0 mils PEBAX 7233 SA01
	Layer 4	N/A
	Layer 5	N/A
	Layer 6	N/A

The results from the Software are illustrated below. At this point – select the CathSOLVER™ function.



In the CathSOLVER™ module – set the following parameters as follows:

- OD max to 0.0390 inches
- Kink radius max to 0.300 inches
- Desired GJ to 0.10000 lbf-inch**2
- Deselect Layer 1 (no changes allowed)
- Set Layer 3 UDL to 0.002 inches
- Select the four materials for Layer 3 as shown (PeBax 55D, 63D, 70D, and 72D)
- Select the four braid wires as shown (0.7x3, 0.7x5, 1x3, and 1x4 SS 304)
- Set the pick count range min/max values from 50 min/120 PPI max (not shown)

All other values remain unchanged. When completed – select the [Run Optimizer] button.

The screenshot shows the CathSOLVER™ Module V1.0 interface. At the top, there is a 'QUIT' button and a 'STATUS BAR' with a message: 'WAITING: Please enter the applicable values for your setup. Select [Run Optimizer] to execute'. Below this is a table for 'GLOBAL LIMITS' with columns for 'INITIAL', 'MAX VALUE', 'DESIRED VALUE', 'OPTIMIZER WEIGHTING FACTORS %', and 'COMPUTED NORMALIZED WEIGHTING FACTORS'. The parameters listed are Number of Layers, ID (inch), OD (inch), KR (inch), EA (lbf-inch**2), EI (lbf), and GJ (lbf-inch**2). The OD (inch) and KR (inch) rows have their 'MAX VALUE' cells highlighted in yellow. Below the global limits is a table for 'LAYER CRITERIA' with columns for 'ALLOW CHANGES', 'LAYER CONFIG', 'INITIAL THICK', 'LDL (INCH)', and 'UDL (INCH)'. The rows are for LAYER 1, LAYER 2, and LAYER 3. The 'ALLOW CHANGES' column has checkboxes, and the 'LDL (INCH)' and 'UDL (INCH)' columns have yellow highlights. To the right of the layer criteria is a 'MATERIAL OPTIONS' list with checkboxes for various materials, including PTFE Film Cast, PEBAX 7233 SA01, PEBAX 7033 SA01, PEBAX 6333 SA01, PEBAX 5533 SA01, PEBAX 4533 SA01, PEBAX 4033 SA01, PEBAX 3533 SA01, and PEBAX 2533 SA01. At the bottom left is a 'BRAID LAYER CONFIGURATION' section with 'BRAID WIRE OPTIONS' and 'NUMBER OF BRAID WIRES' lists, both with checkboxes and a scrollable list of options.

GLOBAL LIMITS	INITIAL	MAX VALUE	DESIRED VALUE	OPTIMIZER WEIGHTING FACTORS %	COMPUTED NORMALIZED WEIGHTING FACTORS
Number of Layers	3				
ID (inch)	0.0300				
OD (inch)	0.0368	0.03900			
KR (inch)	0.223	0.300			
EA (lbf-inch**2)	57.40		57.40	15.000	0.03
EI (lbf)	0.00809		0.00809	15.000	
GJ (lbf-inch**2)	0.05514		0.10000	70.000	
				100.000	

LAYER CRITERIA	ALLOW CHANGES	LAYER CONFIG	INITIAL THICK	LDL (INCH)	UDL (INCH)
LAYER 1	<input type="checkbox"/>	NonBraid	0.00100	0.00100	0.00100
LAYER 2	<input checked="" type="checkbox"/>	Braid	0.00140		
LAYER 3	<input checked="" type="checkbox"/>	NonBraid	0.00100	0.00100	0.00200

MATERIAL OPTIONS

- PTFE Film Cast
- PEBAX 7233 SA01
- 60%PTFE-PI
- PEBAX 7233 SA01
- PEBAX 7033 SA01
- PEBAX 6333 SA01
- PEBAX 5533 SA01
- PEBAX 4533 SA01
- PEBAX 4033 SA01
- PEBAX 3533 SA01
- PEBAX 2533 SA01

BRAID LAYER CONFIGURATION

BRAID WIRE OPTIONS

- 0.7x3 mil SS 304V ST
- 0.7x5 mil SS 304V ST
- 1x3 mil SS 304V ST
- 1x4 mil SS 304V ST
- 1x5 mil SS 304V ST
- 1x7 mil SS 304V ST

NUMBER OF BRAID WIRES

The optimizer report will be generated – a screenshot of this summary is provided below.

```

Layer [1] adjustments are NOT enabled

Layer [2] adjustments are enabled
- Braid Wire Options
- Changes to the braid layer matrix is controller by Layer [3]
- Index [1]: 0.7x3 mil SS 304V ST
- Index [2]: 0.7x5 mil SS 304V ST
- Index [3]: 1x3 mil SS 304V ST
- Index [4]: 1x4 mil SS 304V ST
- Number of braid wires selected is [4]
- The minimum pick count is [20] PPI
- The maximum pick count is [120] PPI

Layer [3] adjustments are enabled
- NonBraid Layer
- Index [1]: PEBAX 7233 SA01
- Index [2]: PEBAX 7033 SA01
- Index [3]: PEBAX 6333 SA01
- Index [4]: PEBAX 5533 SA01
- LDL limit is [0.00100] inches
- UDL limit is [0.00200] inches
- Number of selected matrix mats is [4]

Optimizer Gains/Multipliers
- K1 = 15.0
- K2 = 15.0
- K3 = 70.0

Design Geometry
- Design ID = 0.03000
- Max OD = 0.03800
- Max Kink Radius = 0.30000
- Min PPI = 50
- Max PPI = 120
- Desired EA = 37.40
- Desired EI = 0.00809
- Desired GJ = 0.10000

Evaluating EA/EI/GJ
The original and desired values of EA/EI/GJ were good

LDL/UDL Limits
- Layer [1]: LDL = 0.00100
- Layer [2]: LDL = 0.00100
- Layer [4]: UDL = 0.00100
- Layer [3]: UDL = 0.00200

Braid Wire Dimensional Check
- Wall thickness = 0.00450
- Wall allocated to braid layer = 0.00230
- Started with [4] braid wires selected
- Ended up with [4] braid wire selected

NonBraid UDL Thickness Dimensional Check
- Wall thickness = 0.00395
- Layer [3] allocated wall thickness was 0.001350 inches
- UDL value of 0.002000 inches will not fit into the design
- The UDL value for this layer was adjusted

Variation Metric
Braid Layer [4]: Number of items change = 27
NonBraid Layer [3]: Number of items change = 33
Variation Metric = 33
    
```

The CathSOLVER™ will now execute the design problem. In this cases – the solver function will execute only 99 modeling runs automatically. The built in optimizer function has some randomness built into it so the results obtained for the same design problem may vary from run to run (which is to be expected).

When the CathSOLVER™ function is completed – a summary report will be generated and displayed to the User. The results of each improved modeling run will also be exported directly to Microsoft Excel.

The Solver report screenshot for the example is provided below. The user input weightings of 15/15/70 percent were normalized to values of 0.026/185.45/90.238 to account for the differences in the relative values of the computed values of EA/EI/GJ automatically by the Software.

CATHSOLVER™ SUMMARY

OBJECTIVE FUNCTION =

Norm Gains	Final	Desired
0.026 * ABS (53.94 -	57.40) + <= EA
185.45 * ABS (0.0082 -	0.0081) + <= EI
90.238 * ABS (0.0927 -	0.1000) <= GJ

MODEL RUN	INITIAL DESIGN	FINAL CathSOLVER™ DESIGN
Inner Diameter	0.0300 inches	0.0300 inches
Outer Diameter	0.0368 inches	0.0390 inches
DESIGN	1.0 mils PTFE Film Cast/ 0.7x3 mil SS 304V ST, 16 BW, 80 PPI, BA=46.4 DEG, SAC=55.3%, BM = PEBAX 7233 SA01/ 1.0 mils PEBAX 7233 SA01	1.0 mils PTFE Film Cast/ 1x4 mil SS 304V ST, 16 BW, 64 PPI, BA=40.5 DEG, SAC=63.3%, BM = PEBAX 5533 SA01/ 1.5 mils PEBAX 5533 SA01
OBJ FUNCTION	4.048	0.767
EI = Flexural Ridigity	0.00809 lbf-inch**2	0.00816 lbf-inch**2
EA = Long Ridigity	57.40 lbf	53.94 lbf
GJ=Torsional Ridigity	0.05514 lbf-inch**2	0.09265 lbf-inch**2
Kink Radius	0.223 inches	0.219 inches

As the reader may observe – the output torsional rigidity goal was nearly obtained while still maintaining the original flexural and longitudinal rigidity.

The exported Microsoft Excel modeling runs is provided below as well (this guide only shows the first and last modeling runs for brevity). The outputs obtained depend greatly on the weighting function applied.

MODEL RUN ID	UNITS	RT100801-01	RT100801-14
ID	inches	0.0300	0.0300
OD	inches	0.0368	0.0390
WALL	N/A	3.40 mils	4.50 mils
COMPOSITE LAYERED DESIGN Layer 1 = Inside Layer BA = Braid Angle SAC = Surface Area Coverage BM = Braid Matrix Material	Layer 1	1.0 mils PTFE Film Cast	1.0 mils PTFE Film Cast
	Layer 2	0.7x3 mil SS 304V ST, 16 BW, 80 PPI, BA=46.4 DEG, SAC=55.3%, BM = PEBAX 7233 SA01	1x4 mil SS 304V ST, 16 BW, 64 PPI, BA=40.5 DEG, SAC=63.3%, BM = PEBAX 5533 SA01
	Layer 3	1.0 mils PEBAX 7233 SA01	1.5 mils PEBAX 5533 SA01
	Layer 4	N/A	N/A
	Layer 5	N/A	N/A
	Layer 6	N/A	N/A
	CathCAD® Outputs		CF = 4.048

V. 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.