

CathRAD® User Guide

The Marker Band Design and Visibility Optimization Software

Roth Technologies, LLC

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I. Introduction

Welcome to the **CathRAD®** Marker Band and Visibility Optimization Software User's Guide. This guide will provide you basic instructions on how to implement and use the software. Use of this software is subject to the End Users License Agreement (EULA) which is located at www.cathrad.com.

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

II. Reference Documents

- **End User License Agreement (EULA)**, Roth Technologies
- **Installing MySQL ODBC Driver**, Roth Technologies

III. Implementation

Three components are necessary in order to run the CathRAD® software:

1. The software, identified as CATHRAD.EXE, which may be obtained from our website.
2. The MySQL ODBC driver must be loaded on your computer.
 - If you are running Windows XP, you must load the MySQL 3.5.1 Driver, 32 bit driver
 - If you are running Windows 7, you must load the MySQL 5.1 Driver, 32 bit driver
 - Note that in both cases, you **MUST** load the 32 bit driver MySQL driver even if your operating system is 64 bit.
 - Other operation systems are **NOT** supported
3. The computer that is used to run the software **MUST** be connected to the Internet. There is an interchange of material data between the computer and an External Database Server. If the interchange of data is slow and/or interrupted, the program may not run correctly or timeout.

The network connection may be hardwired (preferred) to your network. You may also connect the computer to your Network via a Wireless connection.

IV. Running the Program

In order to run the program, it must be copied from the media that it was provided to you on (i.e. on a CD-ROM, USB Flash Drive, or downloaded from our website directly) to the Desktop of the computer you intend to run it on.

Warning: The program WILL NOT execute if you try to run it directly from the CD-ROM drive.

It is recommended that you save the program on your computer Desktop.

Once the program is on the computer Desktop, you can double click the CathRAD® Program Icon to execute it. A splash screen similar to the one shown appears when the program is run. The current software will only run on Windows XP and Windows 7. Previous versions of the Windows Operating System are NOT supported.



V. Logging into the CathRAD® program

Your company has been provided a ten to twelve character length passcode for logging into the **CathRAD®** system. You may submit a request to sales@cathrad.com to change your passcode character string. This character string identifies your company within the **CathRAD®** 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@cathrad.com and we will change your login passcode.

By logging into the system, you agree to the terms listed on the End User License Agreement (EULA). The current version of the EULA is located at www.cathrad.com.

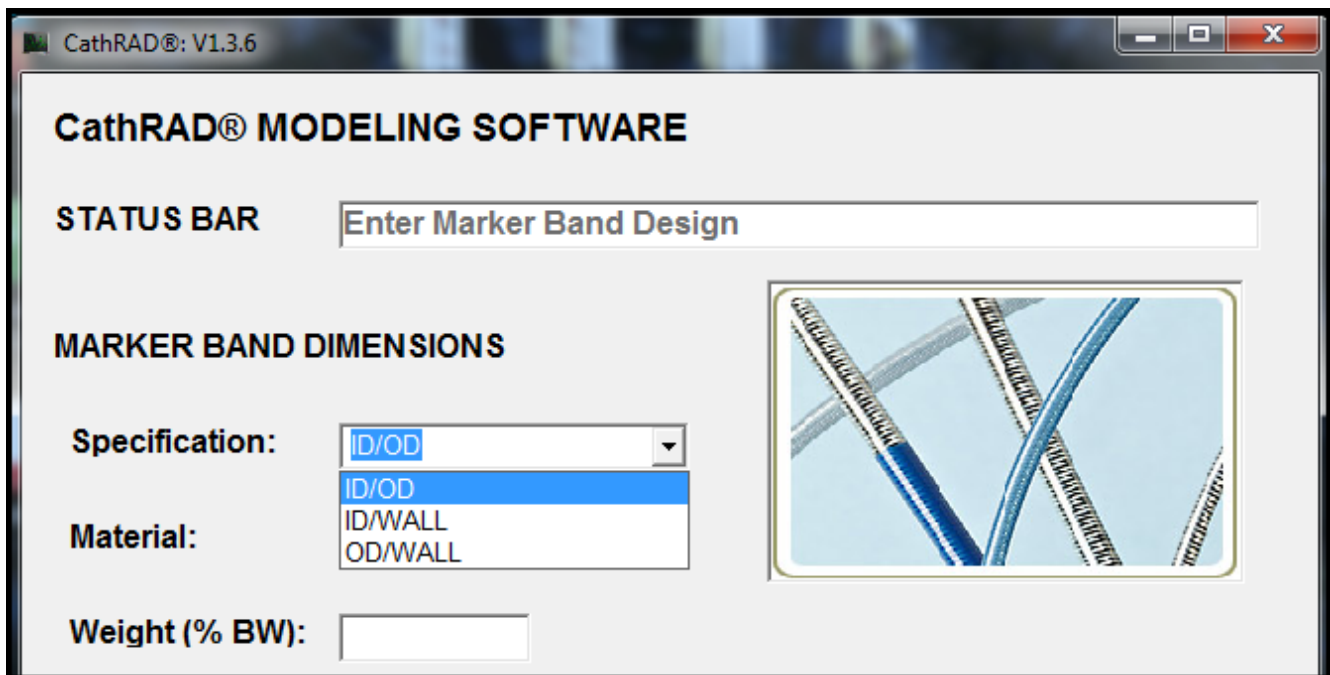
VI. Using the CathRAD® System

The **CathRAD®** software was designed to run under Microsoft Windows. Its use and execution should be easily understood by an individual who is familiar with the design of catheter marker bands. The software may also be used to model radiopaque polymer formulations.

Specification

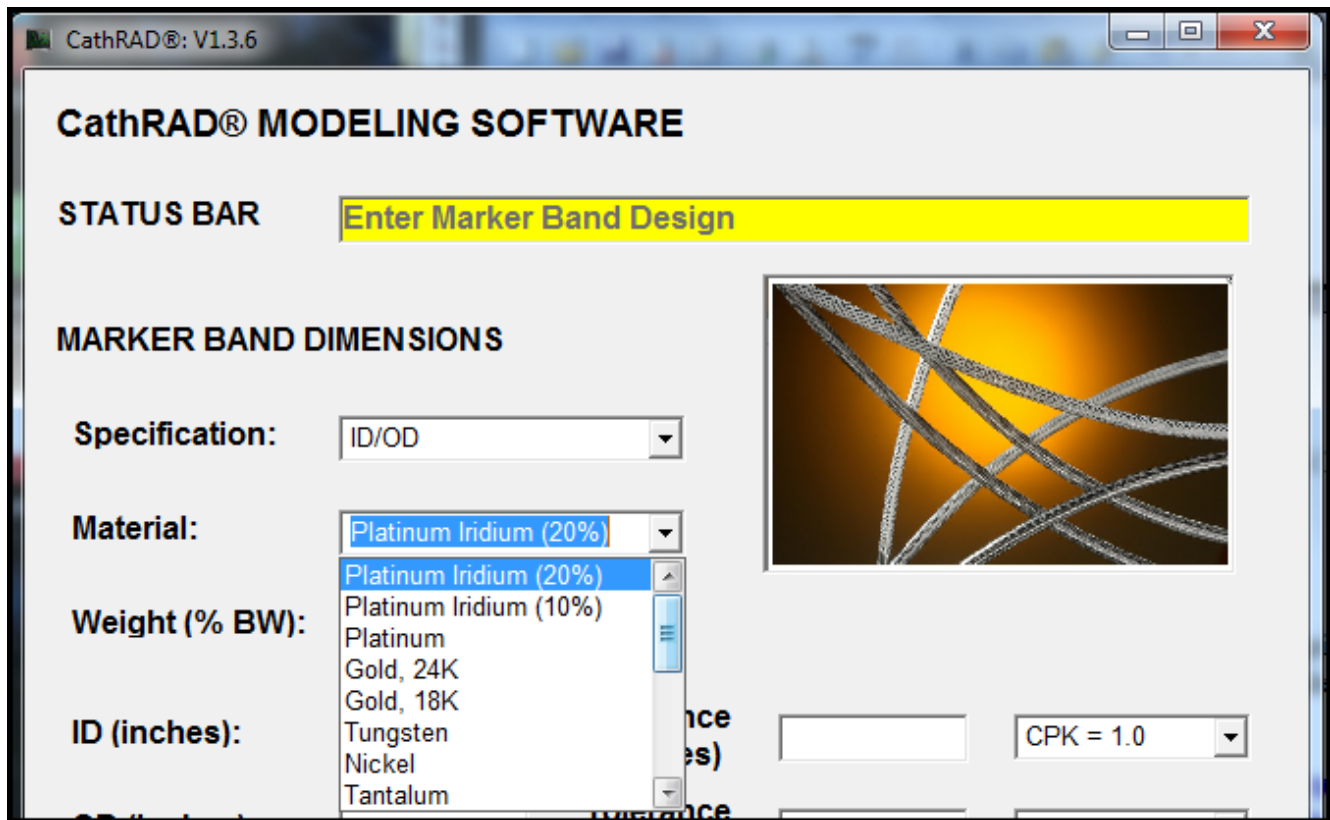
Select the marker band specification in this field. The following options apply:

- ID and OD specified, Wall is reference only
- ID and Wall specified, OD is reference only
- OD and Wall specified, ID is reference only



Material

Select the marker band material from the list of materials provided. The list includes the normal materials that are used in marker band designs such as Platinum, Platinum Iridium, Gold, and Tungsten.



Material Weighting

Certain materials that have been loaded into the CathRAD® software allow for a weight percentage. This allows designs and manufacturing processes where material is loaded/mixed into plastics which then are subsequently extruded. Examples of these materials include Tungsten, BaSO₄, Bi₂O₃, BiOCl, and Bi₂O₂CO₃.

- If the material is a non-loading material, the default percentage of 100% is implemented by the software and may not be modified.
- If the material may be used in a mixture, the user may enter a percentage between 0 and 100 percent.


This software capability may be modified and updated for your specific company's requirements. The example shown below illustrates where Tungsten has been selected as the material at a 50 percent loading.

MARKER BAND DIMENSIONS

Specification:

Material:

Weight (% BW):



Marker Band ID (units of inches)

This section becomes available under the ID/OD and ID/Wall Specification methods. Enter the marker band ID, tolerance, and statistical tolerance assumption in these three fields.

MARKER BAND DIMENSIONS

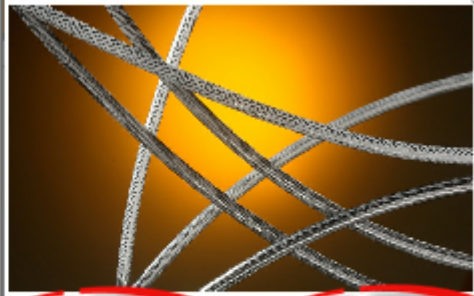
Specification:

Material:

ID (inches):

Tolerance (inches):

CPK = 1.0



Marker Band OD (units of inches)

This section becomes available under the ID/OD and OD/Wall Specification methods. Enter the marker band OD, tolerance, and statistical tolerance assumption in these three fields.


MARKER BAND DIMENSIONS

Specification:

Material:

ID (inches): Tolerance (inches): CPK = 1.0

OD (inches): Tolerance (inches): CPK = 1.0



Marker Band Wall (units of inches)

This section becomes available under the ID/Wall and OD/Wall specification methods. Enter the marker band wall, tolerance, and statistical tolerance assumption in these three fields.

MARKER BAND DIMENSIONS

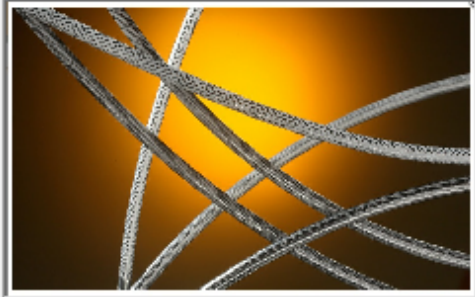
Specification:

Material:

Weight (% BW):

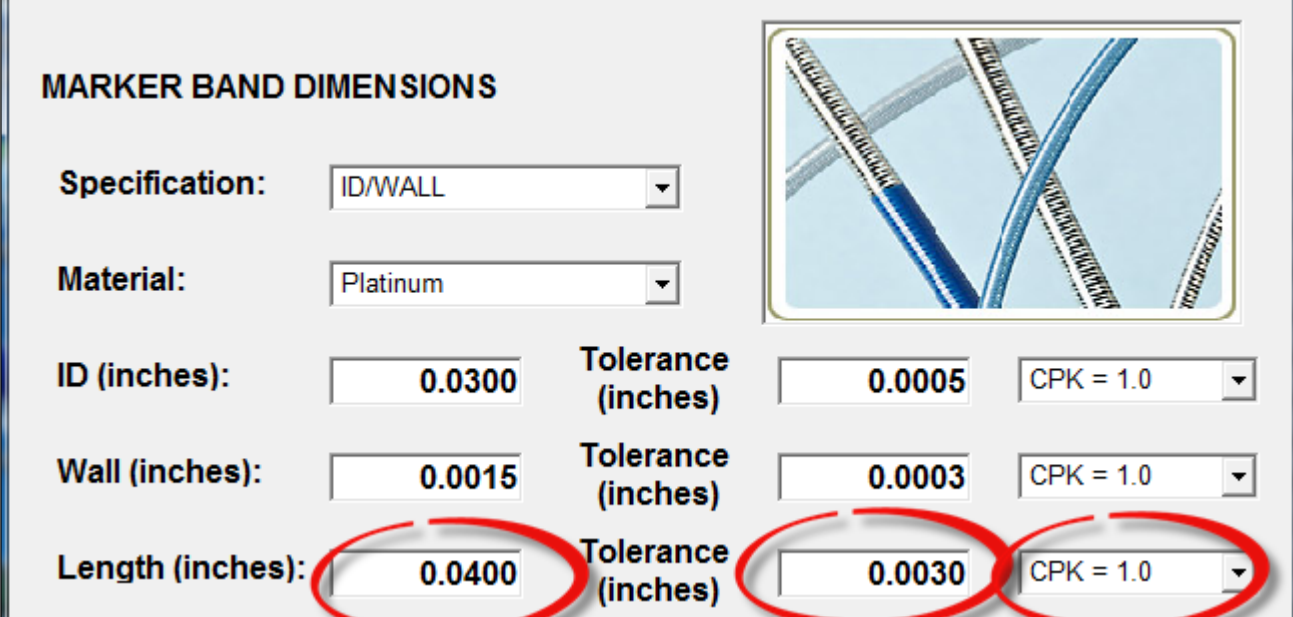
ID (inches): Tolerance (inches): CPK = 1.0

Wall (inches): Tolerance (inches): CPK = 1.0



Marker Band Length (units of inches)

Enter the marker band length, tolerance, and statistical tolerance assumption in these three fields.



MARKER BAND DIMENSIONS

Specification: ID/WALL

Material: Platinum

ID (inches): 0.0300 Tolerance (inches): 0.0005 CPK = 1.0

Wall (inches): 0.0015 Tolerance (inches): 0.0003 CPK = 1.0

Length (inches): 0.0400 Tolerance (inches): 0.0030 CPK = 1.0

Tolerance (CPK)

As noted in the prior sections, the CathRAD® design inputs (ID, OD, Wall, and Length) includes a process capability/CPK field. The following section details how the process capability fields are used in the software's computations.

- The manufactured process is governed by a Normal (Gaussian) Distribution.
- The mean of the manufacturing process is the nominal dimension.
- The tolerance field is utilized to compute the standard deviation of the process depending on the CPK field

The software has three process capabilities built into it:

- CPK = 1.0 which means that that the defect rate is 2,700 parts per million (ppm)
- CPK = 1.33 which means the defect rate is 64 ppm
- CPK = 2.0 which means the defect rate is 0.002 ppm

Many of the manufacturers of marker bands use statistical tolerance methodologies. This data can be obtained from the supplier(s) and used in the CathRAD® software.

Error Correction

If you enter what the system thinks is incorrect values, **CathRAD®** will automatically update the value as applicable. Examples of this update is as follows:

1. Entering nonnumeric data into applicable fields (for example: entering the letter “A” into the marker band ID field)
2. Entering negative numbers
3. Entering unusually large number into applicable fields
4. Entering design configurations which results in physical designs that are impossible (e.g. entering an ID/OD design such that the wall thickness is negative)
5. Hitting the COMPUTE button with not all of the required fields completed

In these cases, the software intercepts the data being entered into the field, reviews it for applicability, and adjusts the values as applicable. In most cases, the software simply deletes the information being entered if it thinks it is incorrect, thus forcing the operator to reenter/correct the data. If you select the **COMPUTE** button before all the fields have been properly entered, the software will identify the **FIRST** field that it finds that is incorrect/empty and will highlight it in RED for approximately three seconds. Correct your mistake(s) and then select with the **COMPUTE** button.

VII. CathRAD® Software Outputs

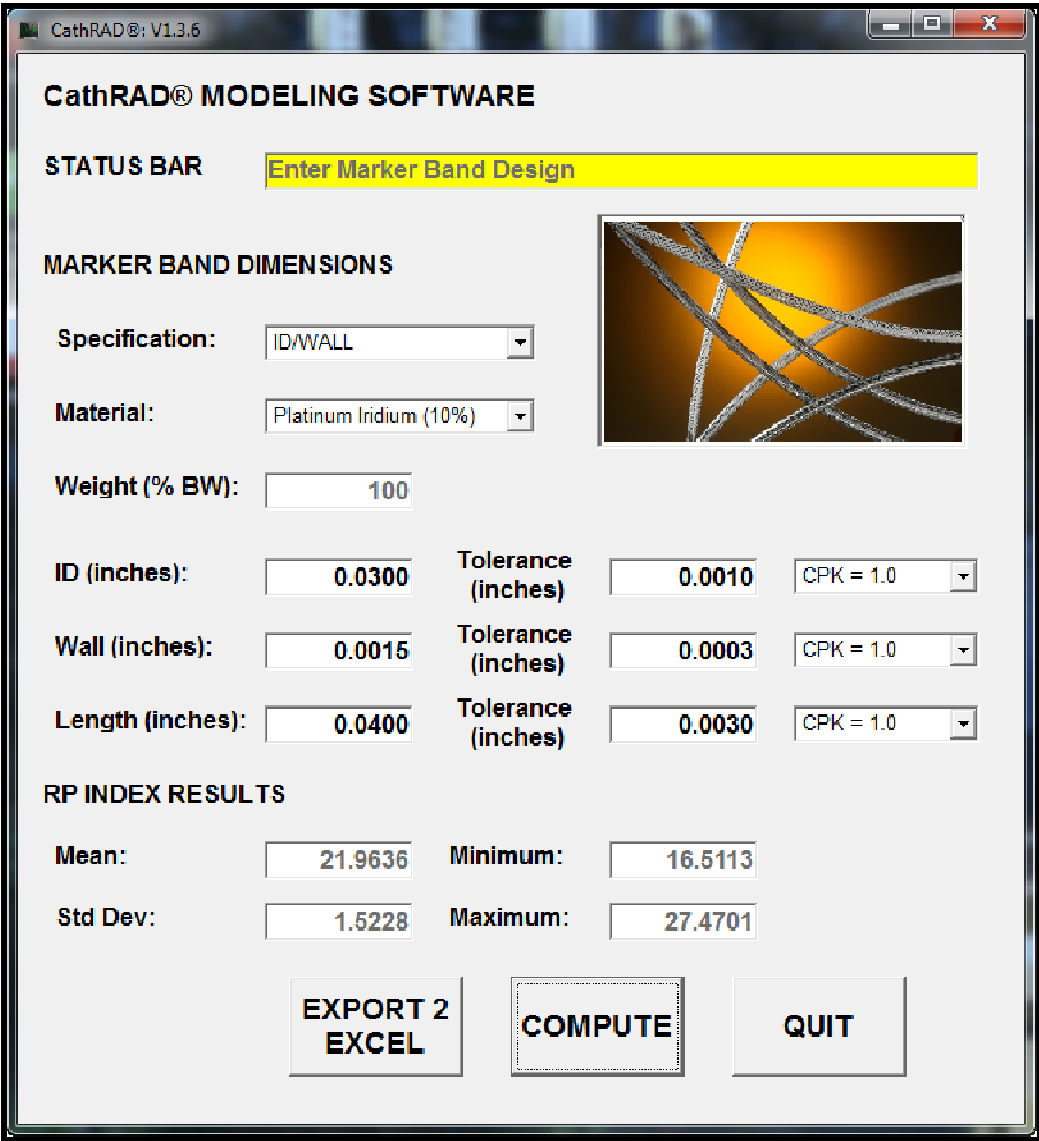
The **CathRAD®** Software computes the following RP Index outputs:

- Mean
- Standard Deviation
- Minimum
- Maximum

These outputs are based on a Monte Carlo simulation that is generated from the user's inputs. The Monte Carlo simulation algorithm built into the software works as follows:

- A domain is defined from the marker band design inputs (ID, OD, Wall, Length, and Material)
- The inputs for a specific marker band design "modeling run" are generated randomly assuming a Normal Distribution for each of the inputs based on the nominal dimension, tolerance, and the process capability.
- The software computes the RP Index (i.e. the marker band visibility) for each modeling run
- When all the "modeling runs" are completed, the results are compiled and the mean, standard deviation, min/max are computed.

The use of the Monte Carlo algorithm in the software allows the user to understand the expected marker band visibility variation due to tolerances. An example of the RP Index Result summary provided by the software is shown in the following screen shot.



These outputs appear at the bottom of the screen. The output values are computed when all the Input fields (as previously discussed) are entered and the Operator selects the **COMPUTE** button. Once a particular design is setup, multiple model runs can be completed very quickly by changing the applicable field values and reselecting the **COMPUTE** button.

VIII. Material Data

The **CathRAD®** allows for dynamic changes to the marker band material inputs to be configured without recompiling. The marker band material information are stored on a MySQL server running on a Virtual Domain Server connected to the Internet.

If you have the requirement to add a new material, contact us at sales@cathrad.com and we will add your new configuration for you. After we load the data, the next time you run **CathRAD®**, the new item will appear automatically.

A base configuration of materials has been preloaded for your company. The list of available materials can be customized at no charge for your company. This includes order that the materials appear on your drop down boxes. Note that any customization is proprietary for your company and will only appear for you.

IX. Exporting Modeling Results to Microsoft Excel

The **CathRAD®** software integrates with Microsoft Excel if this software is loaded on your computer. The combination of **CathRAD®** software and Excel eliminates the requirement to write your results down on paper. Instead, **CathRAD®** directly exports the results directly to a standard model output format. This section explains step by step on how to accomplish this integration.

1. When a particular design is entered and modeled in the software, the **EXPORT 2 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 2 EXCEL** button on the Main Menu.
 - a. The **EXPORT 2 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.

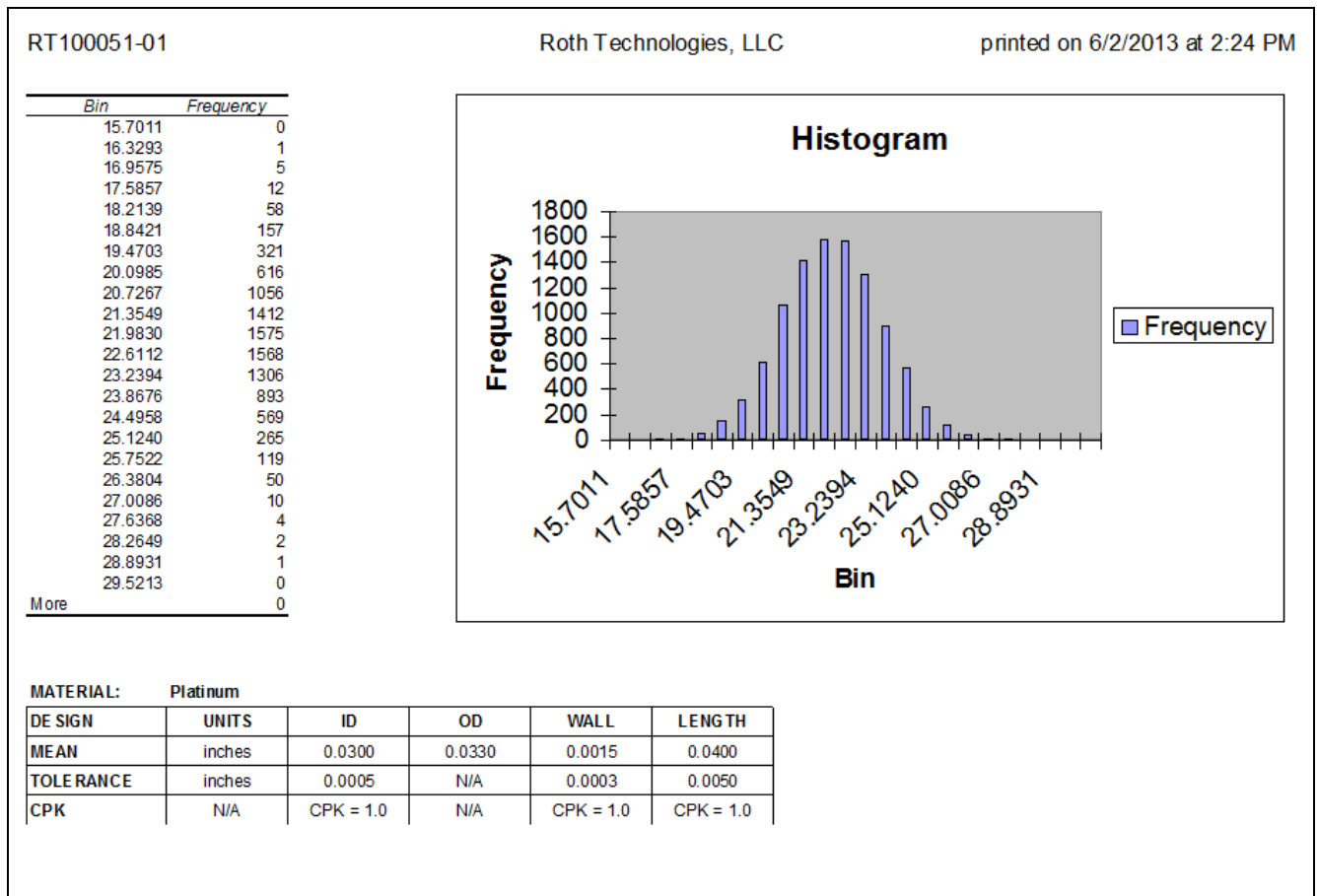
- a. When Excel is hidden but contains data, the **VIEW EXCEL** button becomes active. Simply select this button and Excel will become **VISIBLE** allowing you to access your data directly. Likewise when the software is running and Excel is visible, the **HIDE EXCEL** button becomes active. This button allows you to have Excel active but not visible on your desktop.
 - b. When you exit or quit **CathRAD®**, the software will automatically make Excel visible before terminating.
 - 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 **CathRAD®** for each model that is exported to Excel. This allows the user to identify a particular model run by a unique identifier.
 - f. The software makes its best efforts to interface to Excel properly. The user should not perform the following operations:
 - Close Excel if **CathRAD®** has opened it. **CathRAD®** expects Excel to be available once it has launched it. If you do mistakenly close Excel, **CathRAD®** does try to reopen Excel for export purposes.
 - Delete rows and/or columns in Excel while **CathRAD®** is working with Excel.
- NOTE: It is the user's responsibility to **SAVE** and store the resulting Excel file. While **CathRAD®** will export the model results to Excel, the software does not **SAVE** the results to file.
- g. The example below shows model runs that were generated from the software and exported to Excel using the **EXPORT 2 EXCEL** button.

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	A	B	C	D	E	F
1	MODEL RUN ID	UNITS	RT100051-01	RT100051-02	RT100051-03	RT100051-04
2	MATERIAL	N/A	Platinum	Platinum Iridium (20%)	Platinum Iridium (20%)	Gold, 24K
3	ID	inches	0.0300	0.0300	0.0300	0.0300
4	Tolerance (+/-)	inches	0.0005	0.0005	0.0005	0.0005
5	Statistical Limits	N/A	CPK = 1.0	CPK = 1.0	CPK = 1.0	CPK = 1.0
6	OD	inches	0.0330	0.0324	0.0320	0.0320
7	Tolerance (+/-)	inches	N/A	N/A	N/A	N/A
8	Statistical Limits	N/A	N/A	N/A	N/A	N/A
9	WALL	inches	0.0015	0.0012	0.0010	0.0010
10	Tolerance (+/-)	inches	0.0003	0.0003	0.0003	0.0003
11	Statistical Limits	N/A	CPK = 1.0	CPK = 1.0	CPK = 1.0	CPK = 1.0
12	LENGTH	inches	0.0400	0.0400	0.0400	0.0400
13	Tolerance (+/-)	inches	0.0050	0.0050	0.0050	0.0050
14	Statistical Limits	N/A	CPK = 1.0	CPK = 1.0	CPK = 1.0	CPK = 1.0
15	CathRAD(TM) OUTPUTS (MONTE CARLO SIMULATION)					
16	RP INDEX	MEAN	21.9038	17.5229	14.5937	13.9197
17		STD DEV	1.5341	1.5178	1.5033	1.4271
18		MIN	16.3293	12.1083	8.7850	8.4928
19		MAX	28.8931	23.8818	20.3193	19.4067

The Excel output file is preformatted and ready to print.

The software also generates a Histogram within Excel as well. Each Histogram is generated and stored in a separate Excel worksheet. The following shows an example:



X. Reporting Errors

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

XI. Success Stories

We would gladly welcome your personal success stories using our software. Please submit (via email) your catheter design project designs and how CathRAD® contributed to your success.