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Hellenic Complex Systems Laboratory

Tool for quality control design and evaluation

Technical Report VIII

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WOLFRAM Demonstrations Project

Tool for Quality Control Design and Evaluation

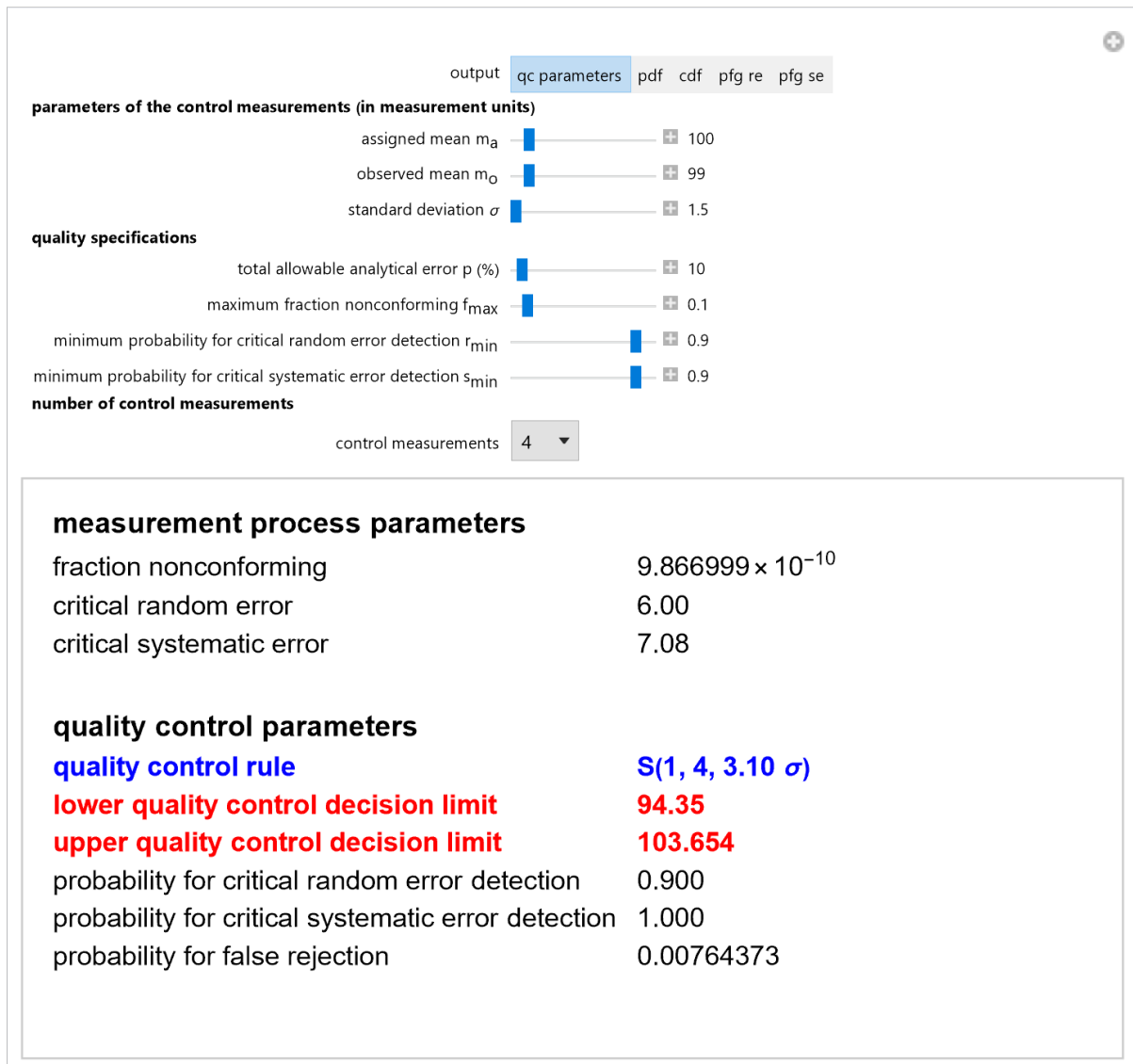**Aristides T. Hatjimihail** [a]

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Search Terms: quality control, quality control design, measurement, random error, systematic error, total allowable analytical error, fraction nonconforming, critical random error, critical systematic error, decision limits, probability for random error detection, probability for systematic error detection, probability for false rejection, power function graph

Short Description of the Demonstration

This Demonstration can be used to estimate various parameters of a measurement process and to design the quality control rule to be applied. You define the parameters of the control measurements that are the assigned mean, the observed mean, and the standard deviation, in arbitrary measurement units. In addition, you define the quality specifications of the measurement process, that is, the total allowable analytical error (as a percentage of the assigned mean), the maximum acceptable fraction of measurements nonconforming to the specifications, and the minimum acceptable probabilities for random and systematic error detection. Finally, you choose the number n of control measurements.

$S(1, n, d\ \sigma)$ is a quality control rule that rejects the analytical run if at least one of the c control measurements is less than $m_o - d\ \sigma$ or greater than $m_o + d\ \sigma$, where d is a positive real number and mo and σ are the mean and the standard deviation of the control measurements. The quantities $m_o - d\ \sigma$ and $m_o + d\ \sigma$ are the lower and the upper quality control decision limits. Then the fraction nonconforming f, the critical random and systematic errors of the measurement process, as well as the quality control decision limits and the respective probabilities for critical random and systematic error detection and for false rejection are estimated. Finally, by choosing the type of output, you can see the estimated quality control (qc) parameters or plot the probability density function (pdf), the cumulative density function (cdf) of the control measurements, or the power function graphs for the random error (pfg re) and systematic error (pfg se).
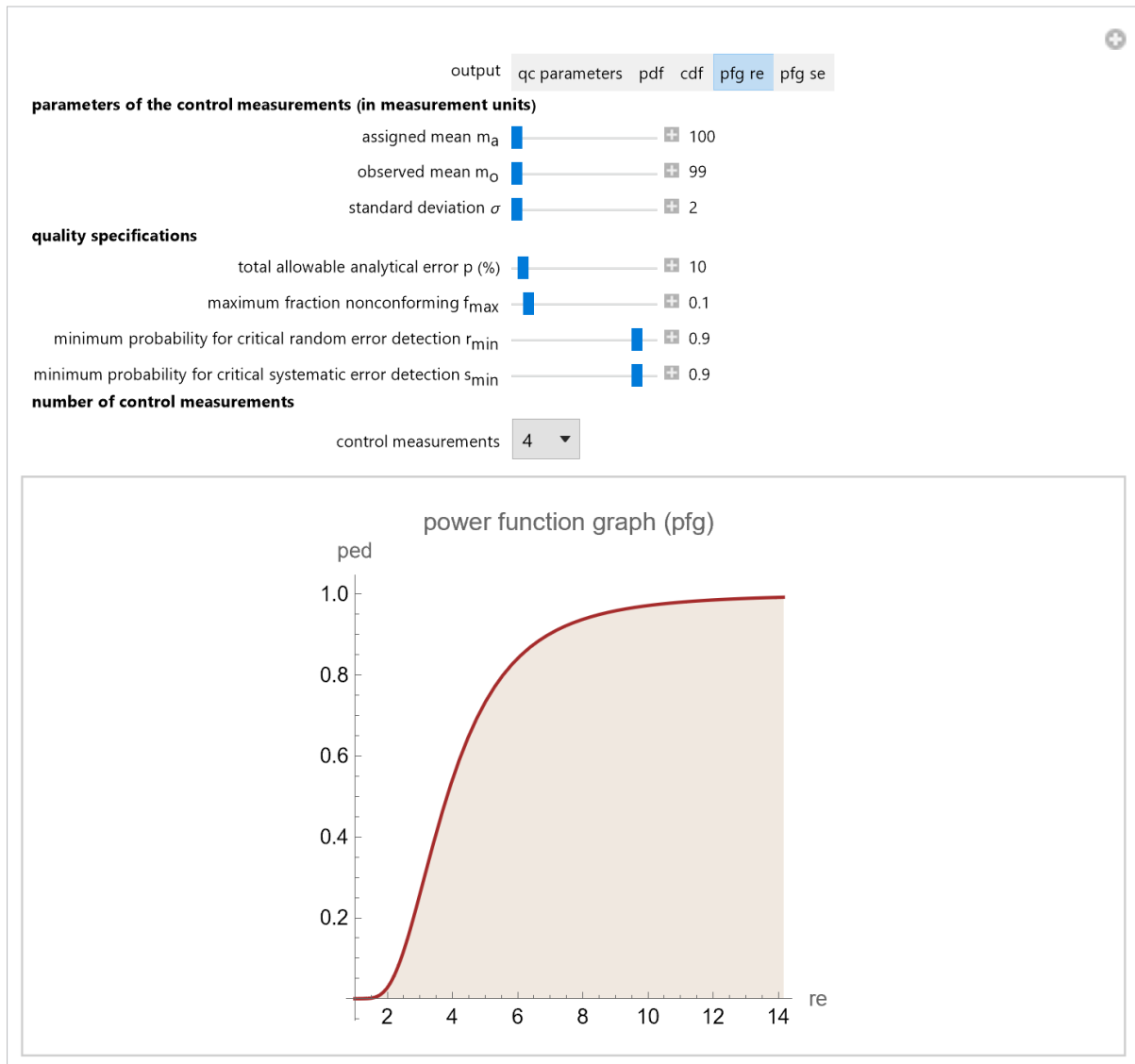
The parameters are estimated and the functions are plotted if $10^{-100} \leq f \leq f_{max}$, where f is the fraction nonconforming and f_{max} is the maximum acceptable fraction nonconforming.

output | qc parameters | pdf | cdf | pfg re | pfg se

parameters of the control measurements (in measurement units)

assigned mean m_a	▣	100
observed mean m_o	▣	99
standard deviation σ	▣	1.5

quality specifications

total allowable analytical error p (%)	▣	10
maximum fraction nonconforming f_{max}	▣	0.1
minimum probability for critical random error detection r_{min}	▣	0.9
minimum probability for critical systematic error detection s_{min}	▣	0.9

number of control measurements

control measurements | 4 ▼

measurement process parameters

fraction nonconforming	9.866999×10^{-10}
critical random error	6.00
critical systematic error	7.08

quality control parameters

quality control rule	**S(1, 4, 3.10 σ)**
lower quality control decision limit	**94.35**
upper quality control decision limit	**103.654**
probability for critical random error detection	0.900
probability for critical systematic error detection	1.000
probability for false rejection	0.00764373

Figure 1: *The measurement process parameters and the quality control parameters of a measurement process, with the settings shown at the top.*
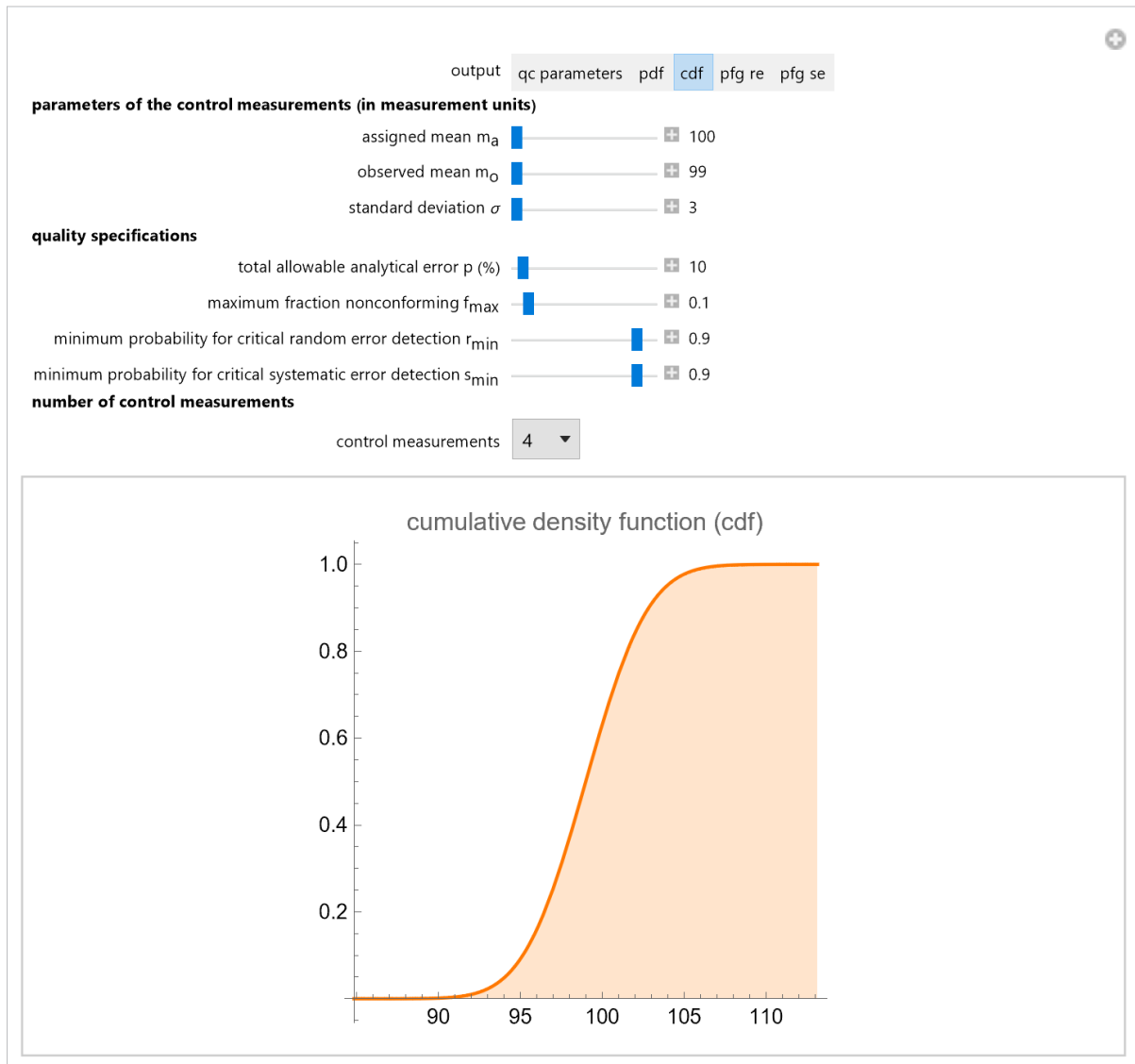
Figure 2: *The cumulative density function of the measurement error of a measurement process, with the settings shown at the top.*

output qc parameters pdf cdf **pfg re** pfg se

parameters of the control measurements (in measurement units)

assigned mean m_a ▮——————— ⊞ 100

observed mean m_o ▮——————— ⊞ 99

standard deviation σ ▮——————— ⊞ 2

quality specifications

total allowable analytical error p (%) ▮——————— ⊞ 10

maximum fraction nonconforming f_{max} ▮——————— ⊞ 0.1

minimum probability for critical random error detection r_{min} ———————▮ ⊞ 0.9

minimum probability for critical systematic error detection s_{min} ———————▮ ⊞ 0.9

number of control measurements

control measurements 4 ▾

power function graph (pfg)

ped

1.0

0.8

0.6

0.4

0.2

2   4   6   8   10   12   14   re

Figure 3: *The power function graph for the random error of the quality control rule S(1, 4, 3.10 σ) applied upon a measurement process, with the settings shown at the top.*
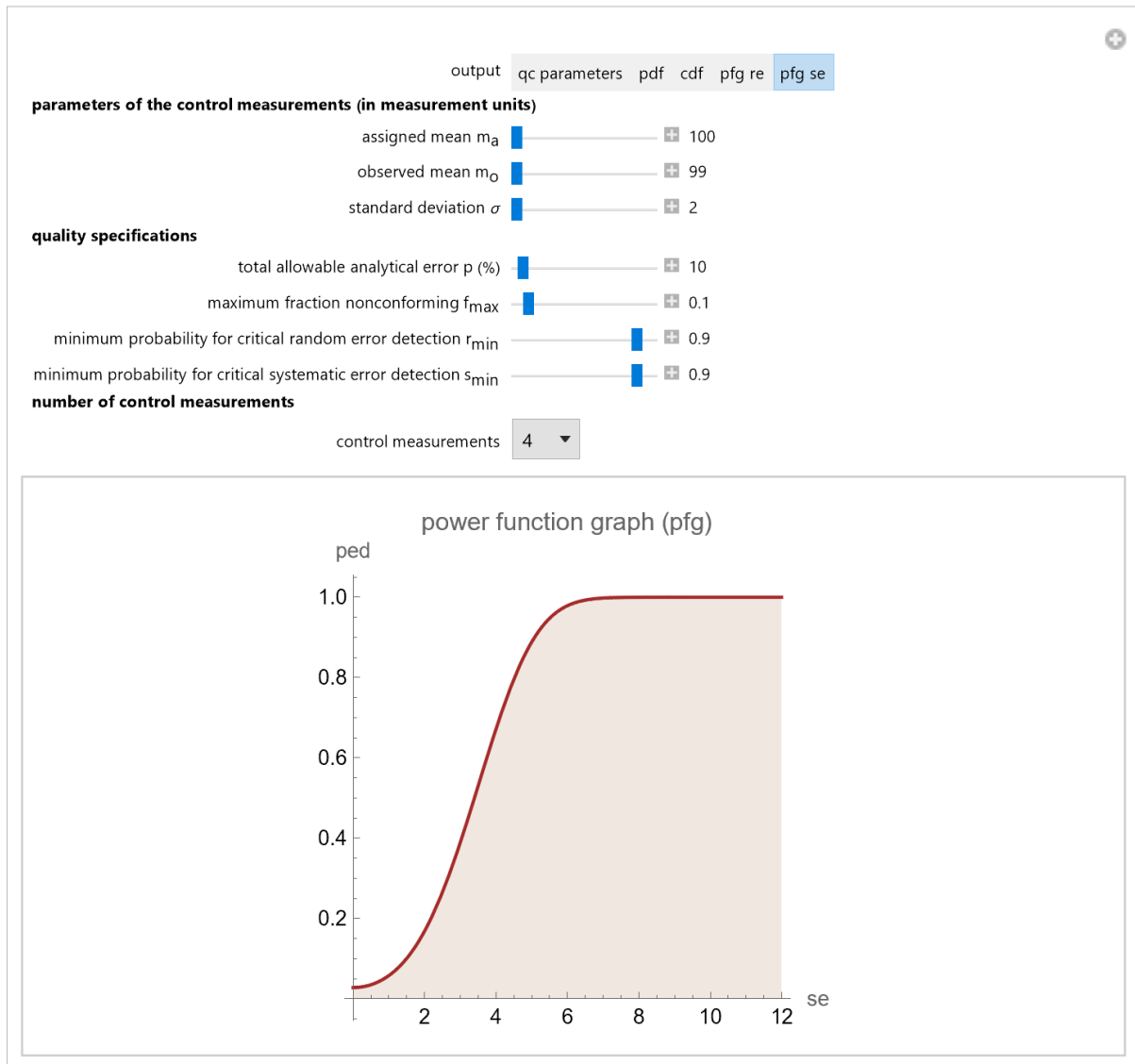
Figure 4: *The power function graph for the systematic error of the quality control rule S(1, 4, 3.10 σ) applied upon a measurement process, with the settings shown at the top.*

Details

Let m_a, m_o, and σ be the assigned mean, the observed mean, and the standard deviation of the control measurements. Let $p/100$ be the total allowable analytical error (expressed as a fraction), f_{max} the maximum (acceptable) fraction nonconforming, and r_{min} and s_{min} the minimum (acceptable) probabilities for critical random and systematic error detection. Then the following equations are used to estimate the parameters [1, 2]:

(a) the fraction nonconforming: $f = 1 - \int_{m_a\left(1-\frac{p}{100}\right)}^{m_a\left(1+\frac{p}{100}\right)} \left(\frac{e^{\frac{(-m_o+x)^2}{2\sigma^2}}}{\sigma\sqrt{2\pi}} \right) dx$

(b) the critical random error r_c: $1 - \int_{m_o\left(1-\frac{p}{100}\right)}^{m_o\left(1+\frac{p}{100}\right)} \left(\frac{e^{\frac{(-m_o+x)^2}{2r_c^2}}}{r_c\sqrt{2\pi}} \right) dx = f_{max}$

(c) the critical systematic error s_c: $\int_{m_o\left(1-\frac{p}{100}\right)}^{m_o\left(1+\frac{p}{100}\right)} \left(\frac{e^{\frac{(\epsilon\, s_c-m_o+x)^2}{2s_c^2}}}{s_c\sqrt{2\pi}} \right) dx = f_{max}$, where $\epsilon = 1$ if $m_o < m_a$ and

$\epsilon = -1$ otherwise,

(d) the factor d of the decision limits $m_o \pm d\,\sigma$ of the quality control rule $S(1, n, d\,\sigma)$ is the minimum solution of both of the following two equations for the variable d:

(1) $\left(\int_{m_o-d\,\sigma}^{m_o+d\,\sigma} \left(\frac{e^{\frac{(-m_o+x)^2}{2r_c^2}}}{r_c\sqrt{2\pi}} \right) dx \right)^n = r_{min}$

(2) $\left(\int_{m_o-d\,\sigma}^{m_o+d\,\sigma} \left(\frac{e^{\frac{(\epsilon\, s_c-m_o+x)^2}{2\sigma^2}}}{\sigma\sqrt{2\pi}} \right) dx \right)^n = s_{min}$, with ϵ as before in (c),

(e) the probability for false rejection p_f of the quality control rule $S(1, n, d\,\sigma)$:

$p_f = 1 - \left(\int_{m_o-d\,\sigma}^{m_o+d\,\sigma} \left(\frac{e^{\frac{(-m_o+x)^2}{2\sigma^2}}}{\sigma\sqrt{2\pi}} \right) dx \right)^n$

(f) the probability for error detection p_e of the random error e_r and the systematic error e_s of the quality control rule $S(1, n, d\,\sigma)$: $p_e = 1 - \left(\int_{m_o-d\,\sigma}^{m_o+d\,\sigma} \left(\frac{e^{\frac{(e_s-m_o+x)^2}{2e_r^2}}}{e_r\sqrt{2\pi}} \right) dx \right)^n$

The power function graphs ("pfg") are the plots of the probabilities for error detection versus the size of the error.

This Demonstration can be used as a tool for the design and evaluation of alternative quality control rules for a measurement process.

References

[1] A. T. Hatjimihail, "A Tool for the Design and Evaluation of Alternative Quality Control Procedures," Clinical Chemistry 38, 1992 pp. 204–210.

[2] A. T. Hatjimihail, "Estimation of the Optimal Statistical Quality Control Sampling Time Intervals Using a Residual Risk Measure," PLoS ONE 4(6), 2009 p. e5770.

Source Code

Programming language: Wolfram Language

Availability: The updated source code is available at:

https://www.hcsl.com/Tools/Demonstrations/ToolForQualityControlDesignAndEvaluation.nb

Software Requirements

Operating systems: Microsoft Windows, Linux, Apple iOS

Other software requirements: Wolfram Player®, freely available at: https://www.wolfram.com/player/ or Wolfram Mathematica®.

System Requirements

Processor: x86-64 compatible CPU.

System memory (RAM): 4GB+ recommended.

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https://demonstrations.wolfram.com/ToolForQualityControlDesignAndEvaluation/

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