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The Analysis of Different Approaches Related to the Measurement Uncertainty in Biomedical Calibration

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ABSTRACT

As a result of the calculation of expanded uncertainty, the measurement uncertainty defines an interval within which the measurand lies. Expanded uncertainty is generally calculated by using z-distribution in conjunction with coverage factor k . But, by using z-distribution, correctly finding the interval which the measurand lies within, with a specified confidence level, requires too many measurements which must be done repeatedly. In an ideal case, the number of measurements must approach infinity. Since this is not the case in practice, if the number of measurements is small, using Student's factor $t_{v,p}$ instead of coverage factor k results in the definition of a relatively wider interval and more accurate results. This situation is shown, as a result of an analysis done on a biomedical system, by calculating the measurement uncertainty and the interval within which the measurand lies in a confidence level of 95%, comparing two different approaches.

Key Words: Biomedical calibration, Measurement uncertainty, t-distribution, z-distribution

1. INRODUCTION

Total Quality Management (TQM), which is a management model of an establishment, focuses on the quality that is maintained by the attendance of all employees and aims at customer satisfaction for a long period of time. Furthermore, TQM takes a long period of time as a basis for a continuous improvement. By this approach, TQM clarifies the understanding of process in service [1, 2].

The quality system arranged by ISO 9001, is used for appreciation of an establishment by other national and international establishments in terms of quality assurance [3]. These standards, which have also been accepted and arranged according to certain conditions by "Turkish Standards Institution" and can be provided if needed, constitutes an assurance model for quality systems' design, development, production, installation and service quality [4]. Due to this fact, health care organizations, which are aware of the importance of TQM, document the usage of some standards, such as ISO 9001, in their organizations.

In the last 10 years, impressive developments have been achieved in the health care sector. Because of the developments in measurement capacity, an appreciable development has been achieved, and in the end, the successful treatment ratio has increased dramatically.

For an increase in service quality, for increased successful treatment ratio and for development in accurate diagnosis, according to TQM, high-tech medical devices must perform optimally. Due to this reason, documentation and determination of the accurate operation of medical devices in a tolerance limit prescribed by international standards becomes an important issue. For TQM, the continuity of calibration is an obligation [5, 6].

Calibration is a series of measurements. It is a process of measuring and documenting the accuracy of test and measuring devices and determining the deviation of these devices by using a measurement standard or system that is known to be accurate [1].

Like the "National Institute of Standards and Technology", NIST, which provides the traceability of measurement and calibration laboratories located in the United States of America and works in cooperation with the United States Medical Community, there are institutes such as the "Turkish Standards Institution", and the "Turkish Accreditation Agency", which provides the accreditation between national and international institutions and works in a similar field to NIST. These institutes have the functions of giving accreditation certificates to provide the worldwide comparability, reliability and standardization of measurement results, and by this way improving the

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health care, establishing a national and international reference laboratory network, etc [7].

The most important issue in calibration is the confidential and accurate calculation of measurement uncertainty and specifying these data on a calibration certificate. The aim of this work is to present an optimum way of representing measurement uncertainty and by this way minimize the diagnostic errors.

2. MEASUREMENT UNCERTAINTY

In general, the result of a measurement is obtained only by an approximation or an estimation of the value of the specific quantity subject to measurement called measurand. Due to this reason, in order for the result to be complete, a quantitative statement of measurement uncertainty must be included in the result. According to Comité International des Poids et Mesures's (CIPM's) approach, these components can be grouped into two categories. These categories differ from each other according to the method they use to estimate the numerical values of components of uncertainty [7]:

A. Uncertainty components, evaluated by statistical methods
B. Uncertainty components, evaluated by other means

It is not always so simple to decide in which category to include the uncertainty component. Thus, generally uncertainty components are classified as "random" or "systematic". But, sometimes the terms random and systematic cause misunderstanding. Hence, more obvious explanation can be used for classifying the components of uncertainty; these are "component of uncertainty arising from a random effect" and "component of uncertainty arising from a systematic effect" [7].

The evaluation of uncertainty by statistical analysis of a series of observations is termed a Type-A evaluation of uncertainty. The evaluation of uncertainty by methods other than the statistical analysis is called Type-B evaluation of uncertainty. For Type-B evaluation all available information is considered to evaluate standard deviation and variance. So called available information can be data obtained from former measurements, data and experience about the equipment used, devices' specifications supplied by the manufacturer, data found on calibration and other certificates, uncertainty components related with the reference data that is obtained from hand-books, etc. [8].

2.1 Evaluation of Type-A Standard Uncertainty

Symbols that are used for evaluation of Type-A uncertainty are given as follows:

u_i : i^{th} standard uncertainty component

u_i^2 : i^{th} estimated variance

s_i : i^{th} statistically estimated standard deviation

s_i^2 : i^{th} statistically estimated variance

Here, i, represents the component number. For Type-A evaluation, standard deviation of a component is equal to the statistically estimated standard deviation, that is $u_i = s_i$, where $u_i = \left|\sqrt{u_i^2}\right|$.

Evaluation of Type-A standard uncertainty may be based on any valid statistical method for treating data. In this case, generally the best estimate, without a change in observation conditions, is the sample mean of n independent observations [7].

$$x_i = \overline{X_i} = \frac{1}{n}\sum_{k=1}^{n} X_{i,k} \qquad (1)$$

$x_i = \overline{X_i}$: Input estimate

X_i : Input quantity ($i = 1,2,\ldots,N$)

N : Number of input quantities

$$Y = f(X_1, X_2, \ldots, X_N) \qquad (2)$$

$$y = f(x_1, x_2, \ldots, x_N) \qquad (3)$$

Y : Output quantity (observed)

y : Output estimate

The standard uncertainty, $u(x_i)$ associated with x_i is the estimated standard deviation of the mean [7].

$$u(x_i) = S(\overline{X_i}) = \left[\frac{1}{n(n-1)}\sum_{k=1}^{n}(X_{i,k} - \overline{X_i})^2\right]^{1/2} \qquad (4)$$

$u^2(x_i) = s^2(\overline{X_i})$: variance

Estimated variance is;

$$s^2(\overline{X_i}) = \frac{1}{n(n-1)}\sum_{k=1}^{n}(X_{i,k} - \overline{X_i})^2 \qquad (5)$$

In order for the estimate, obtained at the end of n independent observations, to be reliable, the number of independent observations must be larger.

2.2 Evaluation of Type-B Standard Uncertainty

The uncertainty component u_i specified at any source can be associated with different confidence levels. For example, coverage factors of 1.64, 1.960, 2.576 are associated with confidence levels of 90%, 95%, 99%, respectively. When evaluating standard deviation, if there is no contradictory information, normal (Gaussian) distribution is assumed and given uncertainty is divided by the appropriate coverage factor at the given confidence level [7, 8].

In some cases with a presumed normal distribution, input quantity is assumed to be at the center of limits,

a_- and a_+, with 50% probability, that is, $a = \frac{a_- + a_+}{2}$. In this case uncertainty is given as,

$$u(x_i) = 1.48a \tag{6}$$

where 1.48 is the coverage factor at a confidence level of 50%.

If the quantity in question is modeled by normal distribution and estimation of lower and upper limits are a_- and a_+ such that the best estimated value of the quantity is $a = \frac{a_- + a_+}{2}$ and there is a 67% probability that the value of the quantity lies in the interval a_- to a_+, the uncertainty $u(x_i)$ is approximately equal to a, i.e. $u(x_i) \cong a$, since $\mu \pm \sigma$ covers 68.3% of normal distribution, where μ is the expected value and σ is the standard deviation.

When the probability of the value of quantity in question to lie in the interval a_- to a_+ is 100%; and the value of the quantity to lie anywhere within the interval is equally probable, it can be modeled by uniform or rectangular probability distribution. The best estimate of the value of the quantity with $u_i = \frac{a}{\sqrt{3}}$ is then:

$$x_i = \frac{a_- + a_+}{2} \tag{7}$$

Where,

$$a = \frac{a_+ - a_-}{2} \tag{8}$$

If the quantity is modeled by normal distribution, the uncertainty component is found by dividing the given expanded uncertainty by the coverage factor associated with the specified level of confidence [10]. That is,

$$u_i(x_i) = \frac{U}{k} \tag{9}$$

where U is the expanded uncertainty. If this uncertainty component is calculated with the help of the tolerance limit specified by the manufacturer at a specified level of confidence, equation (9) takes the form as equation (10) [10]. That is;

$$u_i(x_i) = \frac{ToleranceLimit}{k} \tag{10}$$

If there is not enough information about the appropriate distribution [4], the variance associated with x_i can be calculated as:

$$u_i^2(x_i) = \frac{(a_+ - a_-)^2}{12} \tag{11}$$

If the distribution is triangular rather than rectangular, then $u_i(x_i)$ can be calculated as:

$$u_i(x_i) = \frac{a}{\sqrt{6}} \tag{12}$$

2.3 Evaluation of Combined Uncertainty

The combined standard uncertainty of the measurement result y, designated by $u_c(y)$ and taken to represent the estimated standard deviation of the result, is the positive square root of the estimated variance $u_c^2(y)$ obtained from the equation below,

$$u_c^2(y) = \sum_{i=1}^{N} \left[\frac{\partial f}{\partial x_i}\right]^2 u^2(x_i) + 2\sum_{i=1}^{N-1}\sum_{j=i+1}^{N} \frac{\partial f}{\partial x_i}\frac{\partial f}{\partial x_j} u(x_i, x_j) \tag{13}$$

Equation (13) is based on a first-order Taylor series approximation of $Y = f(x_1, x_2, ..., x_N)$ and is conveniently called the propagation of uncertainty.

$$\frac{\partial f}{\partial x_i} = \frac{\partial f}{\partial X_i}; X_i = x_i \tag{14}$$

The partial derivatives above are often called as sensitivity coefficients. $u(x_i)$ is the input estimate associated with x_i, and $u(x_i, x_j)$ is the estimated covariance associated with x_i and x_j [8].

If all the input values are independent of each other, then the variance of $u(x_i, x_j)$ would be zero; therefore, Equation (13) takes the form

$$u_c^2(y) = \sum_{i=1}^{N} \left[\frac{\partial f}{\partial x_i}\right]^2 u^2(x_i) \tag{15}$$

2.4 Evaluation of Expanded Uncertainty

Although the combined standard uncertainty u_c is used to express the uncertainty of many measurement results, when health and safety are concerned it is often required that a measure of uncertainty that defines an interval about the measurement result y within which the value of the measurand Y is confidently believed to lie. The measure of uncertainty intended to meet this requirement is called expanded uncertainty. Expanded uncertainty, denoted by U, is obtained by multiplying $u_c(y)$ by a coverage factor (k).

$$U = ku_c(y) \tag{16}$$

In this case, the measurement result is denoted by $Y = y \pm U$. It is confidently believed that the measurand Y lies within this interval. That is

$$y-U \le Y \le y+U \tag{17}$$

In general, the value of the coverage factor k is chosen on the basis of the desired level of confidence to be associated with the interval defined by $U = ku_c(y)$. Typically, k varies from 2 to 3. When the normal distribution applies and u_c has negligible uncertainty, $U = 2u_c$ (i.e., k =2) defines an interval having a level of confidence of approximately 95% and $U = 3u_c$ (i.e., k =3) defines an interval having a level of confidence greater than 99% [7, 8].

2.5 Important Issues of Measurement Process and Information Reported on Measurement Report

Avoiding some serious mistakes in health care applications requires appropriate and accurate measurement, examining the proper operation of devices that are used in the measurement process and a high quality service. Due to these reasons, some issues must be handled particularly and carefully. Determining the measurement points carefully, properly selecting the measurement devices, examining measurement conditions and educating relevant staff are some of these issues. In addition to these, definition of the reference device, instruction of calibration, reference values, measured values, measurement error and measurement uncertainty must be included in the measurement report [2, 8].

3.APPLICATION OF DIFFERENT APPROACHES USED IN MEASUREMENT UNCERTAINTY ON A BIOMEDICAL SYSTEM

On Table 1 below, values taken from a patient monitoring system during the calibration process are given. Measurement uncertainty, associated with the values, is calculated by the use of t-distribution and z-distribution. Finally, the results are compared.

Firstly, uncertainty will be calculated step by step by using z-distribution at a 95% level of confidence and the interval in which the measurand lies will be shown.

First of all, the uncertainty for systolic blood pressure is calculated as follows:

Table1. Blood pressure and heart beat rate values taken from a patient monitoring system during calibration process.

Value applied by blood pressure monitor analyzer	**Sys./Dia. (mmHg)** 60/30	**Heart beat rate (BPM)** 40
Value measured by patient monitoring system	1. 58/28 mmHg	39
	2. 61/28 mmHg	39
	3. 59/28 mmHg	39
	4. 59/28 mmHg	39
	5. 59/28 mmHg	39
	6. 60/27 mmHg	39
	7. 59/28 mmHg	39
	8. 59/28 mmHg	40
	9. 60/28 mmHg	40
	10.60/27 mmHg	39

1. Equation (1) is applied by taking, n =10

$$\bar{x} = \frac{1}{10}(58+61+59+59+59+60+59+59+60+60) = 59.4 \tag{18}$$

From Equation (4) $C_1 = (58-59.4)^2 + (61-59.4)^2 + 5.(59-59.4)^2 + 3.(60-59.4)^2$

$$u(x_i) = \sqrt{\frac{1}{10.9}[C_1]} \cong 0.267 \tag{19}$$

2. The uncertainty given on the certificate of calibrator, modeled by normal distribution, is $\pm\%0.5 \pm 1mmHg$ at a %95 level of confidence for the range of 0-300 mmHg. In this case, for systolic pressure, the value applied by the calibrator is 60 mmHg. Therefore, a change of $\pm\%0.5$ in pressure corresponds to $60.(5/1000) = 0.3mmHg$. When $\pm 1mmHg$ is added, the tolerance limit becomes 1.3 mmHg. Since the coverage factor at a %95 level of confidence is 1.960, from equation (10), the uncertainty component is calculated as:

$$U_{ser} = \frac{1.3}{1.960} \cong 0.663 \tag{20}$$

3. The uncertainty component arising from reading depends on the least significant digit that can be read from the display of the patient monitoring system. In this application, it is 1.0 mmHg. Half scale is 0.5 mmHg. The uncertainty arising from truncation or rounding of the half scale is modeled by rectangular distribution [9].

$$U_{okuma} = \frac{1}{2\sqrt{3}} \cong 0.289 \tag{21}$$

4. In addition to these, some uncertainty components arise due to various parameters of the observation environment, such as heat, humidity, air pressure or due to observer's reading. Since these observations are done under the same conditions and the effects of these uncertainty components are known to be small compared to the other uncertainty components, they are neglected.

5. Combined uncertainty is obtained from the calculated uncertainty components as follows

$$U_c = \sqrt{(0.267)^2 + (0.289)^2 + (0.663)^2} \cong 0.771 \qquad (22)$$

The unit of combined uncertainty is the same as that of measurand (mmHg).

6. Expanded uncertainty is calculated using normal distribution at a 95% level of confidence as follows

$$U = 2.U_c = 2x0.771 = 1.542 \qquad (23)$$

Finally, the interval that the measurand lies within is expressed with a 95% level of confidence as

$$59.4 \pm 1.542 \text{ mmHg} \qquad (24)$$

By the way shown below, the interval for the diastolic blood pressure is calculated:

1. The uncertainty component arising from repeated observations is found by using equation (1) with n =10.

$$\bar{x} = \frac{1}{10}(28+28+28+28+28+27+28+28+28+27) = 27.8 \qquad (25)$$

$$C_2 = 8.(28-27.8)^2 + 2.(27-27.8)^2$$

$$u(x_i) = \sqrt{\frac{1}{10.9}[C_2]} \cong 0.133 \qquad (26)$$

2. The uncertainty given on the certificate of the calibrator, modeled by normal distribution, is $\pm\%0.5 \pm 1mmHg$ at a %95 level of confidence for the range of 0-300 mmHg. For diastolic pressure, the value applied by the calibrator is 30 mmHg. Therefore, a change of $\pm\%0.5$ at pressure corresponds to $30.(5/1000) = 0.15mmHg$, so, the tolerance limit becomes 1.15 mmHg. Since the coverage factor at a %95 level of confidence is 1.960, from equation (10), the uncertainty component is calculated as:

$$U_{ser} = \frac{1.15}{1.960} \cong 0.587 \qquad (27)$$

3. The uncertainty component arising from reading (modeled by rectangular distribution [9]) becomes

$$U_{okuma} = \frac{1}{2\sqrt{3}} \cong 0.289 \qquad (28)$$

4. Uncertainty components arising from observation environment are neglected.

5. Combined uncertainty is calculated from square root of sum of squares of calculated uncertainty components. That is,

$$U_c = \sqrt{0.133^2 + 0.587^2 + 0.289^2} \cong 0.668 \qquad (29)$$

6. Expanded uncertainty is found as

$$U = 2.U_c = 1.336 \qquad (30)$$

By the use of expanded uncertainty obtained by using z-distribution, the interval where the measurand is believed to lie within with 95% level of confidence can be written as

$$27.8 \pm 1.336 \qquad (31)$$

Finally, the interval for heart beat rate is calculated by using z-distribution.

1. The uncertainty component specified by standard deviation and arising from repeated observations is calculated by applying Equation (4).

$$\bar{x} = \frac{1}{10}(39+39+39+39+39+39+39+40+40+39) = 39.2 \qquad (32)$$

$$u(x_i) = \sqrt{\frac{1}{10.9}\left[8.(39-39.2)^2 + 2.(40-39.2)^2\right]} \cong 0.133 \qquad (33)$$

2. The uncertainty component given on the certificate of the calibrator and modeled by normal distribution is 1%. For 40 BPM, this indicates ± 0.4 tolerance limit at a 95% level of confidence. Since the coverage factor at a 95% level of confidence is 1.960, the uncertainty component arising from the calibrator is found as

$$U_{ser} = \frac{0.4}{1.96} = 0.204 \qquad (34)$$

3. The uncertainty component arising from reading (modeled by rectangular distribution [9]) becomes

$$U_{okuma} = \frac{1}{2\sqrt{3}} \cong 0.289 \qquad (35)$$

4. Uncertainty components arising from observation environment are neglected.

5. Combined uncertainty is calculated from square root of sum of squares of calculated uncertainty components. That is,

$$U_c = \sqrt{0.133^2 + 0.204^2 + 0.289^2} \cong 0.378 \qquad (36)$$

6. Expanded uncertainty is found as

$$U = 2.U_c \cong 0.756 \qquad (37)$$

By the use of expanded uncertainty obtained by using z-distribution, the interval where the measurand is believed to lie within with 95% level of confidence can be written as

$$39.2 \pm 0.756 \qquad (38)$$

In the calculations above, especially in the expanded uncertainty calculations, the last two digits could be neglected; but since the aim of this analysis is different, these values have been left as they are and the later calculations will be done in the same way. In fact, when z-distribution is used for calculating the uncertainty, the number of observations should approach infinity. When expanded uncertainty is to be calculated, if the number of observations is less than 30, then instead of using z-distribution and coverage factor k, t-distribution and t-factor (Student's constant) $t_{\nu,p}$ should be preferred when calculating the expanded uncertainty.

$$U = t_{\nu,p} U_c \tag{39}$$

Equation (16) takes the form of equation (39), where ν is the degree of freedom, p is the level of confidence and $t_{\nu,p}$ is the Student's constant at the given level of confidence [7, 8]. (the values of $t_{\nu,p}$ are given on Table E1.)

Degree of freedom, ν, for single parameter and single series of independent input values can be calculated as follows

$$\nu = N - 1 \tag{40}$$

Systolic diastolic blood pressure and heart beat rate values are recalculated below, using t-distribution. For all measurements $N = 10$, $\nu = 9$ and by the use of Table E1 $t_{9,\%95} = 2.262$ values are used.

1. $U = 2.262 \times U_c = 2.262 \times 0.847 \cong 1.744$ (41)

For systolic blood pressure, when t-distribution is used, the interval that the measurand lies within with a 95% level of confidence is found to be

59.4 ± 1.744 mmHg (42)

2. $U = 2.262 \times U_c = 2.262 \times 0.736 \cong 1.511$ (43)

For diastolic blood pressure, by the use of t-distribution, the interval is found to be

27.8 ± 1.511 mmHg (44)

3. $U = 2.262 \times U_c = 2.262 \times 0.393 \cong 0.855$ (45)

Finally the interval for beat rate is found as:

39.2 ± 0.855 BPM (46)

4. DISCUSSION

When it is kept in mind that calibration, which is a series of measurements, is used for finding a relation between the exact value of the measurand and the value measured by the device subject to calibration, the importance of the calculation of external effects becomes clearer. Due to this reason, measurement uncertainty must be specified on the certificates of the devices subject to calibration.

In this paper, the importance of TQM in health care applications, issues that should be handled carefully during the measurement process and information that must be specified on the measurement report are mentioned; specifically, comparison of different approaches (namely z-distribution and t-distribution for evaluating measurement uncertainty) is made. Finally, by an analysis of the data taken from a patient monitoring system for systolic/diastolic blood pressure and heart beat rate during calibration, it is shown that using t-distribution provides more convenient results and a wider interval which the measurand lies within. In this work since, in practice, the usage of t-distribution is not widespread information about t-distribution is given only in section 3 and associated Student's constant is given in Table E1 [7, 8].

5. RESULTS

When the data taken from a patient monitoring system is considered, it is seen that the interval obtained by using z-distribution is covered by 80% of the measured values for heart beat rate, and by 90% of that of systolic blood pressure values. On the other hand, the interval defined by measurement uncertainty evaluated using t-distribution is covered by all measured values, i.e. systolic/diastolic blood pressure and heart beat rate. Since the number of measurements is small, the interval defined by measurement uncertainty evaluated using t-distribution is wider then the interval defined by measurement uncertainty evaluated using z-distribution, at the same level of confidence. This can be seen clearly from Table E1. Due to ease of calculations, and for standardization, evaluating the measurement uncertainty using z-distribution is widely used. But, if number of measurements is small, i.e. ≤ 30, Student's constant, t, is much larger than coverage factor, k, at the same level of confidence. In this case, using t-distribution proposes a more accurate approach for evaluating the measurement uncertainty, since evaluating the measurement uncertainty using z-distribution requires the number of measurements to approach infinity.

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APPENDIX

E1. For t-distribution, Student's constant, $t_{\nu,p}$, with normal distribution, where ν is the degree of freedom at the associated level of confidence, p.

Degree of Freedom $\nu = N-1$	$t_{\%90}$	$t_{\%95}$	$t_{\%99}$
1	6.314	12.706	63.657
2	2.920	4.303	9.925
3	2.353	3.182	5.841
4	2.132	2.776	4.604
5	2.015	2.551	4.032
6	1.943	2.447	3.707
7	1.895	2.365	3.499
8	1.860	2.306	3.355
9	1.833	2.262	3.25
10	1.812	2.228	3.169
11	1.796	2.201	3.106
12	1.782	2.179	3.055
13	1.771	2.16	3.012
14	1.761	2.145	2.977
15	1.753	2.131	2.947
16	1.746	2.120	2.921
17	1.740	2.110	2.898
18	1.734	2.101	2.878

Degree of Freedom $\nu = N-1$	$t_{\%90}$	$t_{\%95}$	$t_{\%99}$
19	1.729	2.093	2.861
20	1.725	2.086	2.845
21	1.721	2.080	2.831
22	1.717	2.074	2.819
23	1.714	2.069	2.807
24	1.711	2.064	2.797
25	1.708	2.06	2.787
26	1.706	2.056	2.779
27	1.703	2.052	2.771
28	1.701	2.048	2.763
29	1.699	2.045	2.756
30	1.697	2.042	2.75
40	1.684	2.021	2.704
45	1.68	2.01	2.69
100	1.66	1.984	2.626
120	1.658	1.98	2.617
∞	1.645	1.960	2.576