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BUDGED OF UNCERTAINTIES IN MEDICAL MEASUREMENTS

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Abstract - The report presents the sources of uncertainties, met during medical measurements. They are the results of using measuring method, electromedical instrument measuring features and the form of biomedical standard (predicted value). Biological changeability of biomedical object plays the main role

Keywords: measuring uncertainties, medical instrumentation.

1. THE BIOMEDICAL OBJECT CHARACTERISTIC

Here, tested object this is biomedical object which means:

1. the PATIENT, like **real existing material object**,
2. PHENOMENA COMPLEX bounded with its existence.

The biomedical value is the measurable value. This is only one characteristic feature or complex of features. Sometimes they are important (measured values) for the object in measuring point of view, the other time - conditioning the state of measured value (i.e. influencing values).

Their identification is a natural goal of cognitive process necessary for its full knowledge and plays fundamental role in its diagnosis and therapy. In this article a man is the biomedical object. It is characterised by many phenomenae and wide range of different parameters and considerably differs from technical objects [1], [2], [3]:

1. it is the system compound of many subsystems closely connected, where every steady-state disorder is compensated by other subsystem and for this reason it is inadmissible to disturb one subsystem functioning when the second is tested,
2. such complicated system makes which it is impossible to isolate anyone's subsystem and testing it separately,
3. there exist many physical, chemical etc. features, which characterise every subsystem functioning which means that such an object is multiparameter,
4. it is impossible arbitrarily to make many tests during a very long time, because organism strongly changes its parameters and its features, depending on the measurable surrounding conditions and other unmeasurable influences (e.g. patient' disposition),
5. all biomedical signals are of low energy and their values are comparable to surrounding noises and disturbances, with almost the same frequency range. For this reason the object absolutely must be tested in isolation from such influences,
6. the time-constant component of a biomedical signal is very big, comparing to a very low level of the variable component, that gives the most substantial diagnostic information,
7. the man - the tested biomedical object - has a very important feature - intelligence, and for this reason he can generate himself a special state, where we can notice:
   – repeatable results,
   – special state of biological system, disclosing characteristic states of his organism and surprising organism changeability,
8. the natural biological changeability is characteristic of human organism,
9. during an object testing special requirements of electric safety must be strongly fulfilled.

Generally such object characterises the wide spectrum of features (see Tab. 1)

TABLE 1. Processes and phenomena accompanying of human organism [4].

Processes and phenomena	The character of value	Examples
Biological	Genetic	Disease susceptibility inheritance
	Morphological	Erythrocytes form and structure
	Anatomical	Brain structure
	Physiological	Kidney working pathology
	Psychological	Mental unrest
Chemical	Composition	Acetone in urine
	Concentration	Carbon dioxide in blood
	Oxygenation	Oxyhaemoglobin in blood
	Accidity	Stomach content accidity
Physical	Mechanical	Blood flow velocity in artery
	Electrical	Brain electropotential
	Acoustic	Respiratory sounds in lungs
	Thermal	Body temperature
	Optical	Visual acuity
	Magnetic	Heart magnetic field
	Radiant	Isotope (testing) in organ

Most of them change in time and are registered in a form of signals, important for medical diagnosis. These signals are of four types (Fig. 1):

1. spontaneous, existing independently of patient's will (e.g. ECG signal),
2. specially modified by the patient (e.g. forced expiration),
3. modified by observer (ed. evoked brain potentials),
4. caused by an artificial factor (e.g. rentgenographic signal in densitometry).

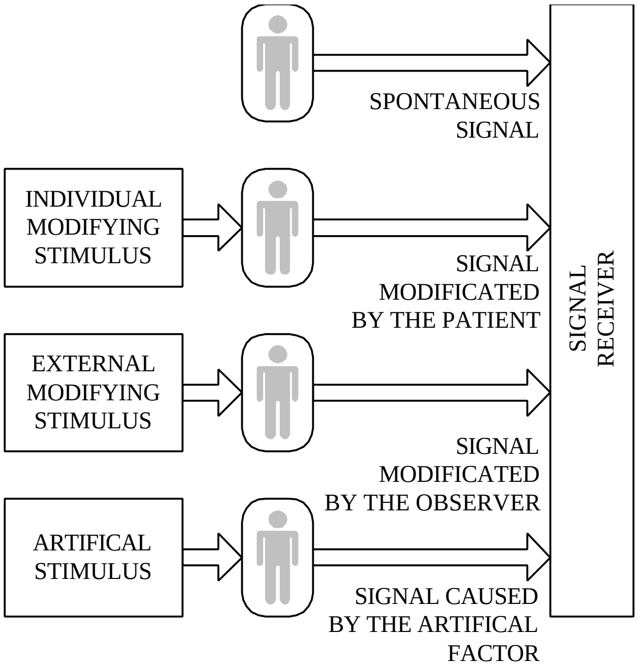

Fig. 1. The fundamental way of diagnostic signals generation in human organism.

The signal, that is the answer of the object' properties changes and for this reason the measuring results interpretation is sometimes very difficult. The standardisation of this signal is possible only in some cases (see point ***3*** and ***4***, above).

A good example is the respiratory system testing during forced expiration (see above, point ***2***). The purpose of it, is to disclose the mechanical properties of the lungs (flow resistance, tissue compliance) which is possible only while special testing signal (Fig. 2).

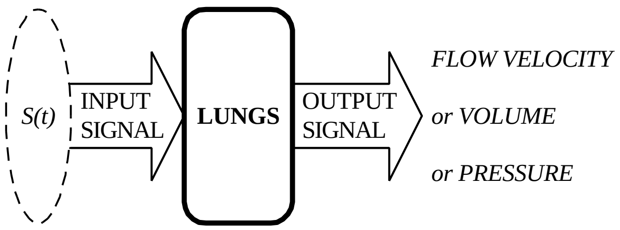

Fig. 2. Block diagram of lung testing.

ATS organisation (American Thoracic Society) has presented the conditions, which must be fulfilled for the test acceptance in signal testing point if view: acceptability (satisfactory start of test, adequate exhalation time, fulfilled of end criterion) and repeatability of forced expiratory manoeuvre [5], [6].

2. THE STRUCTURE OF THE COGNITIVE PROCESS OF A BIOMEDICAL OBJECT

The diagnostic medical instrument must compare the unknown measured value with a standard value. This operation is performed two times (Fig. 3).

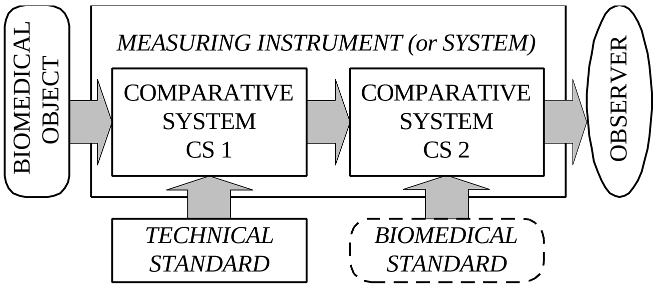

Fig. 3. Measuring structure for a biomedical object.

The first time using a technical (reference) standard (e.g. of voltage, pressure) and the second - with a biological standard existing as a predicted value (e.g. predicted ECG signal parameters (Δt, ΔV)).

The quality of technical standard is usually known with high precision. The definition of biomedical standard causes many problems (Tab. 2).

TABLE 2. The way of identification the best measures of the spirometric parameters. The basic parameters are P_1, P_2 or P_3 [7].

No.	The proper test selection	The measure of representation the parameter's value	Remarks
1.	2 tests	Maximum P_1	Preceding 1 or 2 tests
2.		P_1 mean value	When only the differences are not more then 10 %
3.	3 tests	Maximum P_1	Sometimes 2 preceding tests
4.		Maximum P_1 and P_2	Even though from different tests
5.		Mean P_1 of two tests	
6.		Mean P_1 of 3 tests	Preceding 1 or 2 tests
7.	4 tests	Mean P_1 of 3 last tests	
8.	5 tests	Maximum P_1	
9.		Mean P_1 of 2 or 3 maximal or last 3	
10.	6 tests	Mean P_1 of last 2 tests	
11.	3 ÷ 8 tests	Maximum P_1 or P_2 or P_3	
12.		Maximum $P_1 + P_2$ or $P_2 + P_3$ or $P_1 + P_2 + P_3/2$	
13.		Mean of three maximal P_1 or P_2 or of all	

Finally, calculated medical standards are presented with different reliability (Tab. 3). This causes that the diagnosis differs depending of the predicted value which was used (Fig. 4).

3. BIOMEDICAL STANDARD DEFINITION

The biomedical standard exists in two forms. The first, in general, is used for a great population of people. It has usually constant or almost constant character (e.g. body temperature) (Fig. 5).

TABLE 3. Statistical parameters of predicted values in spirometry (two examples: *FVC* and *FEV*$_1$ parameters) [8].

No.	Source	*FVC*				*FEV*$_1$			
		Female		Male		Female		Male	
		r	*RSD*	*r*	*RSD*	*r*	*RSD*	*r*	*RSD*
1.	K'83*	0.85	0.64	0.70	0.48	0.86	0.52	0.86	0.52
2.	R'86*	0.72	0.53	0.75	0.40	0.75	0.45	0.82	0.32
3.	P'86*	0.69	0.58	0.62	0.39	0.59	0.48	0.69	0.29
4.	C'81*	0.73	0.64	0.86	0.39	0.80	0.49	0.89	0.33
5.	E'93*	-	0.61	-	0.43	-	0.51	-	0.38
*author: Knudson'83, Roca'86, Paoletti'86, Crapo'81, ECSC'93									
r - linear correlation coefficient, *RSD* - residual standard deviation									

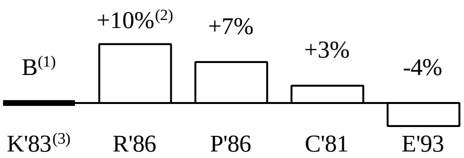

Fig. 4. Relative differences [(2)] of predicted values for *FVC* parameter: [(1)] for the best formula (the biggest correlation coefficient) and for the others. The basis - different propositions [(3)], compare Tab. 3 [2].

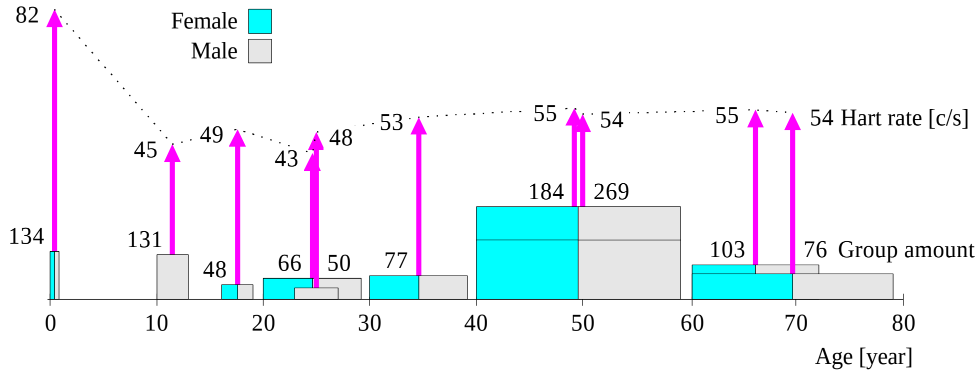

Fig. 5. Minimal twenty-four hours heart rate for healthy patients. This value was calculated as mean in interval: $(x_{min} + x_{max})/2$ [9]. Every „rectangle" (defined for male or male/female) presents another sourec of measuring information. Sometimes they complete each other, sometimes they overlap. Their likelihood differs as a result of different amount of samples (patients).

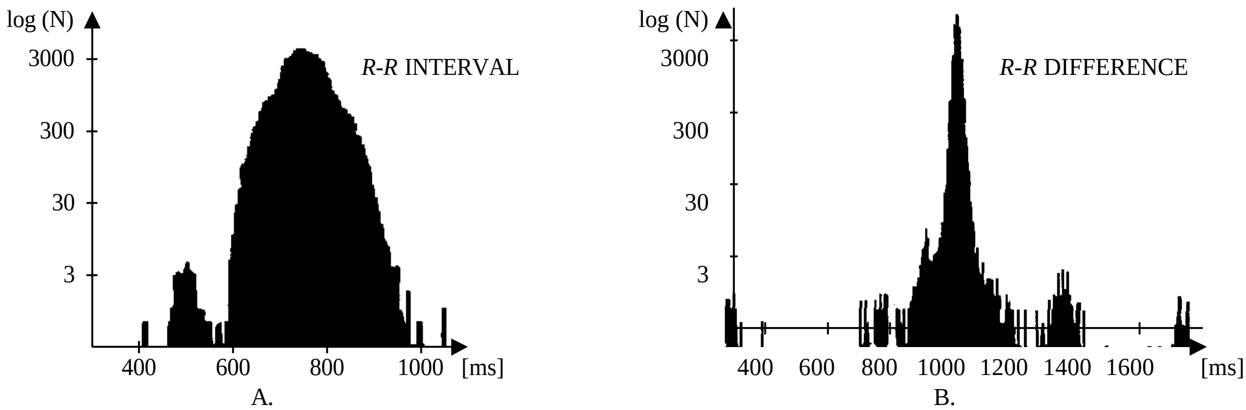

Fig. 6. Histogram of *R-R*-interval (A) and *R-R*-Difference (B) in holter electrocardiography (24 h registered) for an ill patient [9].

The second - is the individual one, having sometimes „walking" character with steady change in value (e.g. ECG parameters in holter electrocardiography). These two standards are characterised by high step of uncertainty resulting from biological changeability (see Tab. 4 and Fig. 6).

TABLE 4. Estimates of proportion of intersubject variation in some respiratory parameter [10].

Factor	Proportion in [%]
Sex	30
Age	8
Height	20
Weight	2
Race	10
Technical errors	***3***
Unexplained	27

4. EXPANSION COEFFICIENT

During calculations of expansion coefficient for uncertainty level definition usually the statistical distribution of measured value or measuring instrument feature are normal (Gaussian) [10]. But in medicine many parameters have neither normal nor rectangular distribution. Where it is normal, cut left or right its statistical parameters are defined in a special way. If x_1, x_2, ... x_n - measured values, x^* - cut value, new variable r_i is:

$$r_i = \frac{x_i - x^*}{a} \quad (1)$$

where $a \neq 0$, a - constant. For the normal distribution one side cut, mean value x_{cm} and standard deviation s_c can be calculated as:

$$x_{usr} = a \cdot r_{sr} + x^* \quad (2)$$

$$s_u = a \cdot s_r \quad (3)$$

where:

$$s_r = \frac{\sum_i r_i}{n} \cdot g(z) \quad (4)$$

$$r_{sr} = z \cdot s_r \quad (5)$$

$$z = f(y) \quad (6)$$

$$y = \frac{n \cdot \sum_i r_i^2}{2 \cdot \left(\sum_i x_i \right)^2} \quad (7)$$

$g(z)$, $f(y)$ - special functions [11].

5. THE SOURCES OF UNCERTAINTIES IN BIOMEDICAL MEASUREMENTS

Many sources of uncertainties existing in biomedical engineering are as follows [12]:

1. **unrepresentative sampling**, i.e. measured sample sometimes do not represent the measured phenomenon (e.g. cholesterol level, measured in different time of day),
2. **not complete information about surrounding influences or not perfect measurement of the parameters of surrounding environmental conditions** (e.g. heart rate in unknown physical effort or in mental excitation),
3. **nonaccurate value concerning standards and standard materials** (e.g. pattern recognition of biological structure during X-ray or USG- diagnose),
4. **nonaccurate values of constants and the parameters, which are external** (not always concerning a biomedical object), but are used in data processing (e.g. residual volume of lungs, calculated in nitrogen dilution method, when it is known that the patient produces nitrogen in his organism and exhales it),
5. **approximations and simplifying assumptions sticking in the method or measuring procedure** (e.g. rheography, in which the tested object the blood flow velocity is defined basing on assumption of electrical structure),
6. **changes in repeated observations that are made in apparently identical conditions** (e.g. forced expiration, when the patient tries to make the same expiration many times, but despite this the results differ).

6. RESULTS

All sources of uncertainties that exist during the process of measurement of a biomedical object can be divided into two parts: disclosed and undisclosed.

The disclosed are: **1-** model of measured object, **2-** measuring method, **3-** measuring instrument, **4-** influences of surrounding environmental conditions, **5-** biological changeability of a tested object. The first four are the same like for tested technical objects.

The undisclosed are: **1-** the method or instrument influences the measuring object (or biomedical phenomenon), **2-** conscious or unconscious patient's activity, **3-** natural biological changeability. Although the instrument influence is met in technics and can be anticipated, during biomedical object testing it is very complicated to estimate it because it depends on many object's features.

One must notice that biological changeability appears two times: as disclosed and undisclosed. The undisclosed depends largely on the investigator' experience.

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