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ANALYSIS OF THE OXYGEN MEASUREMENT SYSTEM CAPABILITY IN THE BREATHING GAS FOR DIVERS

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ABSTRACT

Maintaining a stable oxygen content during the hyperbaric exposure process with breathing air is important for the safety of divers and for diving equipment. This paper presents an analysis of the ability of a measurement system selected for testing[1] to control the oxygen content in the breathing atmosphere of a hyperbaric facility. The measurement system was qualified according to the requirements of the supervised process. The evaluation of the measuring system selected for tests, designed to control the oxygen content with the use of MSA procedures[2] was carried out in KTPP AMW[3] for the DKGN-120 complex[4].
Keywords: measurement system analysis, diving breathing air quality, diving gases, measurement system, process variation.

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INTRODUCTION

The quality of the breathing agent is of fundamental importance to maintain the safety of underwater diving operations and the operation of diving technology. It also significantly affects the development of technologies for the distribution, production and quality control of breathing air in the processes of supplying hyperbaric facilities. The need to maintain the high quality of breathing air used in the diving activities of the Polish Armed Forces results from the provisions of the applicable national normative requirements: NO-07-A005:2010, NO-52-A201:2012 [1,2], safety regulations in force in the Polish Armed Forces [3] and standardisation documents of the NATO[5], AdivP-04 [4,5]. The need to ensure proper breathing air quality for hyperbaric exposures requires proper qualification and metrological supervision of the measuring systems in use. In order to measure the composition of the breathing air, portable and bench mounted measuring devices, as well as different types of automatic indicator systems, are used. This paper presents an attempt to qualify the selected system for measuring oxygen content in breathing air and to assess its capacity[6] to supervise the process of hyperbaric exposures in the Experimental Deep-water Diving Complex (DGKN-120) of the Department of Underwater Works Technology (KTPP AMW). The usability and reliability of the measurement system for the purpose of inference are considered to be the main criteria for the evaluation of a measurement system planned to be used for process monitoring. Usability is understood as the ability of the system to measure data within the defined tolerance limits of the process while maintaining the required stability over time. Reliability of a measuring system on the other hand should be considered as the degree of accuracy with which the approximate value measured by the system represents the real value.

From a toxicological and technical risk point of view, the safe and effective implementation of hyperbaric exposure is determined by the control of numerous dynamically changing parameters, including the measurement and control of atmospheric constituents and the proportion of harmful pollutants [6]. Therefore, the implementation of online measurement of some values for process monitoring purposes reduces the risk of potential hazards of the hyperbaric environment. Thus, in order to ensure correct inferences regarding changes in the composition of the atmosphere, it is necessary to use an appropriate supervision tool understood as a measurement system with confirmed metrological properties. The need for metrological testing and validation of measurement systems is a critical factor in the assessment of the capability and functional correctness of measurement systems used in hyperbaric technology. This paper describes a method for the qualification and evaluation of a selected system for measuring oxygen content and supervising the process of hyperbaric exposure using breathing air in DGKN-120.

PROBLEM SITUATION

Oxygen present in the atmospheric air is a component necessary for the functioning of the human body. However, under hyperbaric conditions, it becomes a source of potential safety hazards for divers and for the diving technology used. The monitoring of oxygen content in the atmosphere of a hyperbaric facility is carried out by means of systems designed to control it. Currently available measurement systems allow the identification of potential toxicological and technical risks occurring during hyperbaric exposures.

These risks will not be repeated as they have already been discussed [6,7,8]. The use of a reliable measurement system is intended to minimise the risk of these hazards. Achieving a quality level critical to the proper functioning of a measurement system requires that the system meets a number of metrological requirements. The measurement system has to be assessed in relation to the supervised process. The task of the analysed system is the supervision of the hyperbaric exposure process by controlling the oxygen content in the breathing air. According to the adopted assumptions, each system should be used in a way which ensures that the measuring capacity is adequate to the metrological requirements. Inferring the course of a process requires correct analysis and interpretation of the measurements made by means of capable measurement systems. Guided by the requirements [9] of PN-EN ISO 10012, an effective measurement management system ensures its adaptation to the intended use and the achievement of product[7] and process[8] quality objectives. This system must be reliable and usable and therefore should carry out measurements under operating conditions with an accuracy close to the requirements set out in NO-07-A005:2019, NO-52-A201:2012 [1,2].

Ensuring correctness and precision of measuring systems determines the need to carry out periodic capability assessments of qualified systems using certified reference material (working measurement standards)[9]. For the validation of a measurement system, the precision (reproducibility and repeatability) of measurement should be taken into account, including variability from the measurement system and operators, linearity, accuracy, limit of detection and quantification, and the range of the chosen method [10].

WORK OBJECTIVE

The aim of this study is to assess the capability of the oxygen percentage measurement system in the breathing medium for divers. The tested measuring system is an element of a measuring station dedicated to measuring the oxygen content in breathing air. The system was assessed in terms of its qualification to supervise the process of hyperbaric exposure using breathing air in the DGKN-120 complex. The validation of the measurement system was conducted on the basis of tests of the declared metrological quality characteristics and evaluation of the possibility of making measurements in a hyperbaric environment[10] taking into account the required legal and normative conditions applicable in the Polish Armed Forces [1,3]. The reliability of the system was examined by analysing experimental empirical data obtained during measurements. The measurement material was obtained by performing multiple measurements of the certified reference material.

MATERIAL AND METHODS

For the purposes of the conducted analysis, the components of precision of the measurement system

were verified in terms of the evaluation of repeatability without the participation of reproducibility due to the use of an automated system (measurements are made without the influence of the operator). The following were also examined: accuracy, uncertainty against the tolerance range of the supervised process and resolution, as components of the correctness of the measurement system. Identification of outliers in a series of n=180 measurements was carried out by means of tests: Q-Dixon and Grubbs. The null hypothesisH_0 – there are no outliers in the sample, was verified against the alternative hypothesis H_1 there is at least one outlier in the sample. The obtained values of test functions were compared with critical values. Based on the results of the analysis, it was decided to reject measurement no. 37 $x_{37} = 20{,}82\%(v/v)$ from the analysed series of empirical data. Table 1 shows the basic descriptive statistics of the distribution of empirical measurement data after outlier elimination.

Tab. 1

Tabulation of descriptive statistics of the data for n=179[11] working standard measurements x_wz=21,200±0,212%(v/v) as of 15.01.2020.

Statistics	Measurement value	Unit
Number of valid measurements	179	-
Mean	20,88	$\%(v/v)$
Standard error of mean	0,0008	$\%(v/v)$
Standard deviation	0,01	$\%(v/v)$
Modal value	20,88	$\%(v/v)$
Minimum	20,85	$\%(v/v)$
Maximum	20,91	$\%(v/v)$
Median	20,88	$\%(v/v)$
Skewness	0,52	-
Kurtosis	0,69	-
First quartile Q1	20,87	$\%(v/v)$
Third quartile Q3	20,89	$\%(v/v)$
Coefficient of variation	0,05	%

After the exclusion of outliers for the distribution of 15.01.2020 the mean value of the measurement was obtained $\bar{x}_{O_2} = 20{,}88\%(v/v)$, lower than the reference value of the standard $x_{wz} = 21{,}2\%(v/v)$ O_2. The difference shown is $\Delta_{O_2} = \bar{x}_{O_2} - x_{wz} = 0{,}32\%\left(\frac{v}{v}\right)$ and suggests the presence of a statistical error. Modal value is equal to $20{,}88\ \%(v/v)$ and correspondes to the calculated mean value $\bar{x}_{O_2}$. The skewness value amounts to $SK = 0{,}52 > 0$ and kurtosis $KU = 0{,}69$ indicate that there is a minimal right deviation and that the measurements are clustered close to the mean value but do not indicate significant departures from a normal distribution. The empirical distribution of the analyte measurement series and the confidence intervals for the mean value $\bar{x}_{O_2}$ and the median (Me) are presented in Fig. 1.

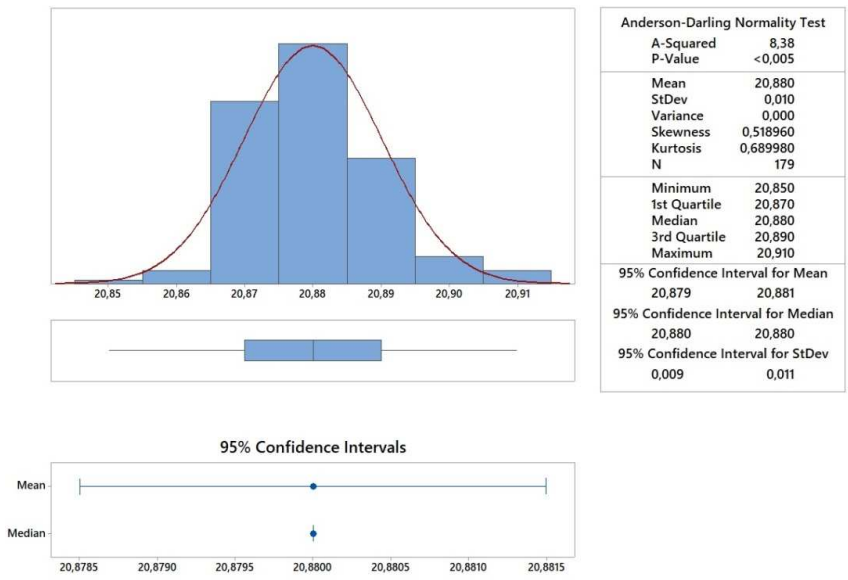


Fig. 1. Histogram of the empirical distribution of $\mathbf{n = 179}$ etalon measurements $\mathbf{x_{wz} = 21{,}200 \pm 0{,}212\%(v/v)}$ along with the confidence interval[12] for the mean $(\mathbf{1 - \alpha = 0{,}95})$. Source – own study.

The conducted graphical test of normality of the empirical distribution, presented in Fig. 2, confirms compliance with the normal distribution. The distribution of points is characteristic for measuring systems, it results from the resolution of the measuring instrument [11]. Consequently, leading to an interpretation discrepancy, the p[13] $-$ $value$ < 0,005 for the A $-$ D test ($Anderson-Darling\ test$).

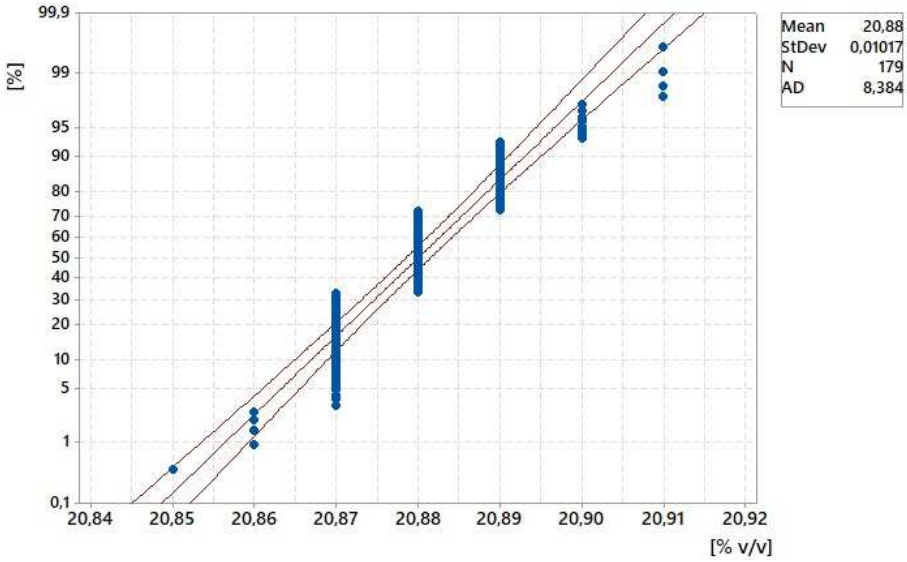


Fig. 2. Graphical test of normality for the results of measurement of the oxygen etalon $x_{wz} = 21{,}2\ \%(v/v)$ as of 15.01.2020. Source – own study.

1 MSA PROCEDURE

For an initial analysis of the capability and stability of the measurement system, the first MSA procedure was applied, whereby based on the obtained series of empirical measurement data against the nominal value x_wz, the measurement uncertainty was determined, as was the capability of the the measurement system indices C_g[14] and C_{gk}[15] and the systematic error including standard determination uncertainty, identified [10,12]. Based on the applicable requirements for the controlled process, the oxygen content tolerance limits were determined $C_{O_2} \in [18 \div 25\%](v/v)$ in the atmosphere of the hyperbaric facility. DWG[16] $= 18\%(v/v)$ is related to the risk of hypoxia, whereas $GWG = 25\%(v/v)$ is related to the materialisation of fire hazard [6] [13]. Fig.3. shows a plot of the measurement process[17] against the analyte reference value $x_{wz} = 21{,}200 \pm 0{,}212\%(v/v)$.

Evaluation of measuring process capability was carried out based on the determined measuring device capability indicators C_g and C_{gk}. The capability indices of the measurement system allows for the making of a preliminary assessment of the measurement system for application to the monitoring of the hyperbaric exposure process and will enable the identification of potentially deterministic disturbances of the process. In a process capable of meeting the critical quality requirements of CTQ, the indicators should take values of $C_g, C_{gk} > 1{,}33$[18] [10]. The spread factor C_g, which indicates the potential capability of the measuring device, was calculated from the relation: $C_g = \frac{2 \cdot k/100 \cdot T}{6 S_g}$ where: $k \in [10 \div 20]$, $S_g -$ standard deviation of measurement results, $T -$ tolerance range.

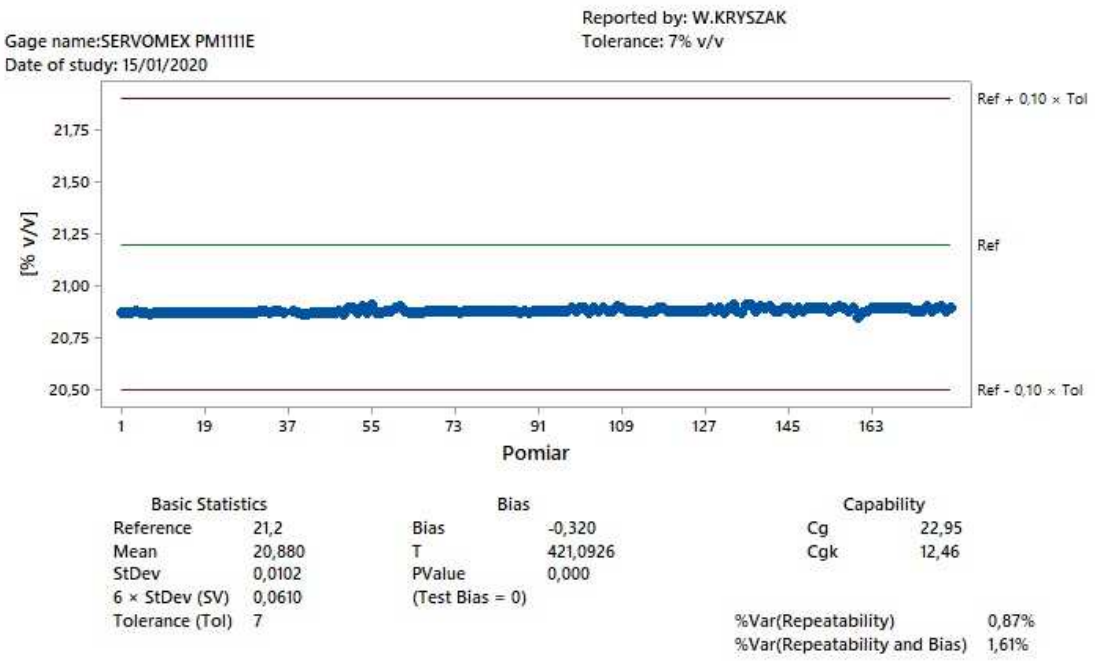


Fig. 3. Procedure 1 for evaluating the measurement system ability (MSA) against the etalon $x_{wz} = 21{,}2\%\left(\frac{v}{v}\right)$ and control lines $DWG = 20{,}5\%\left(\frac{v}{v}\right)$ and $GWG = 21{,}9\%\left(\frac{v}{v}\right)$ of the process tolerance $(0{,}1T)$[19]. Source – own study.

The centering index C_{gk} expressing the real capacity of the process taking into account its current centering and spreading was determined from the relation: $C_{gk} = \frac{k/100 \cdot T - |\bar{x} - x_{wz}|}{3S_g}$, where $\bar{x}$ – mean value of the process, x_{wz} – reference value for the standard. The indices are related to the process tolerance limits $k = 0{,}1 \div 0{,}2T = 0{,}1 \div 0{,}2(GWG - DWG)$. Due to the validity of the characteristics $k = 0{,}1$ was adopted for the calculations. The determined $C_g = 22{,}95$ and $C_{gk} = 12{,}46$ indicate that the critical quality requirements CTQ of the analysed measurement process are met. Its variability is small in relation to the adopted tolerance field, and the high value of C_g determining the potential capability of the process means that the total variability of the measuring system is as high as 22,95 times within $\pm 0{,}1T$ of the tolerance field.

There is a noticeable shift in the distribution from its nominal value, and the difference in the values C_g, C_{gk} indicates the possibility of identifying deterministic disturbances causing process instability.

The observed difference between the mean value of the measurement series and the nominal value indicates the occurrence of a systematic error as a component of system correctness. The identification of the error was performed using Student's t-test. The determined average value $\bar{x}_{O_2} = 20{,}88\%(v/v)$ was compared with the reference value[20] $x_{wz_{O_2}} = 21{,}2\%(v/v)$ and hypothesis $H_0: bias = 0$ was verified against the alternative $H_1: bias \neq 0$. The calculated value of the test statistic $t = 421{,}09$ is greater than the critical value $t_{kr} = 1{,}96$ for the significance level of $\alpha = 0{,}05$, $p - value = 0$, therefore the hypothesis H_0 was rejected in favour of the alternative H_1 assuming that the measurement is affected by the presence of a statistically significant error $bias = 0{,}32\%(v/v)$. In this case, it should be compensated by making adjustments and/or adjustments to the measuring system. To assess the significance of the bias, the effect of uncertainty of the standard setting should also be considered.

Therefore, the result $\bar{x}_{O_2} = 20{,}88\%(v/v)$ of the measurement series was compared with the value of the etalon $x_{wz} = 21{,}2\%(v/v)$ taking into account, respectively, the uncertainty values[21]: of the measurement series $u_{\bar{x}} = 0{,}002$ and of the standard $u_{x_{wz}} = 0{,}212$ (for $k = 2$)[22] and $(1 - \alpha = 0{,}95)$. Calculations were performed using the relation: $|\bar{x}_{O_2} - x_{wz}| < 2\sqrt{u_{\bar{x}}^2 + u_{x_{wz}}^2} = 0{,}320 > 0{,}207$ [12] thus confirming that the value of the calculated bias has a statistically significant effect on the measured value.

Using the value of the calculated C_g coefficient, the value of the variation resulting from variability was determined: *%Var(Rep)*[23]=0,87% fig. 4 as were the percentage value from repeatability and bias *%Var(Rep and Bias)*[24] = 1,61% depending on C_{gk}. Both of the determined values should not exceed $> 15\%$[25]. The values obtained are less than the critical value. This confirms that the observed variability of the measurement system is very low, as confirmed by the position of the distribution of the measurement data in relation to the nominal value including the tolerance limits T fig. 4.

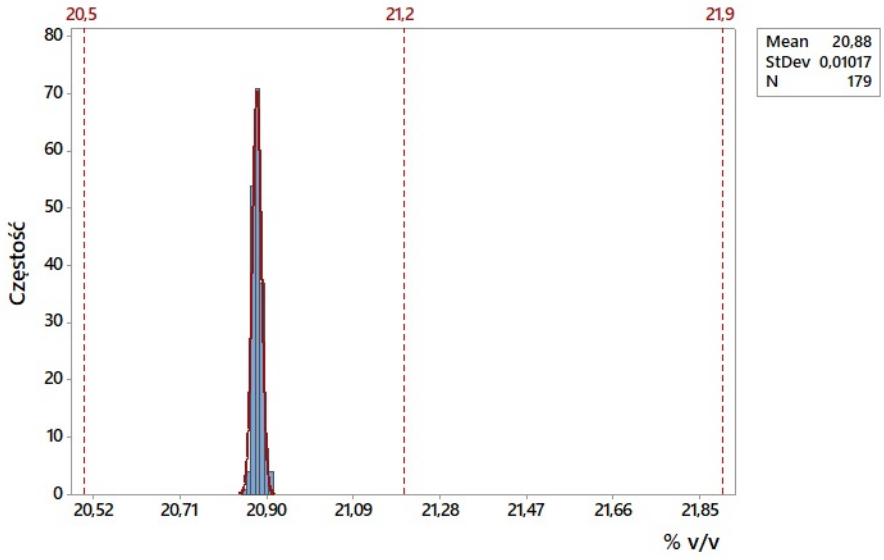


Fig. 4 Measurement system variability against $(\pm 0{,}1 \cdot T)$ process tolerance range $DWG = 20{,}5\%(v/v)$; $GWG = 21{,}9\%(v/v)$; $x_{wz} = 21{,}2\%(v/v)$; $\bar{x}_{O_2} = 20{,}88\%(v/v)$. Source – own study.

In the conducted research, a series of single measurements were made, and the obtained data were continuous, therefore it was decided to use these data sets in the developed project[26] control chart[27] [10] single observations and I-MR[28] – fig. 5. This type of control charts is quite sensitive to random disturbances and is used to assess the spread and stability of the process [14].

A number of points present outside the established DWG and GWG control lines were observed on the individual values chart. There are nine such points on the MR moving chart. The trends indicate a permanent shift of the process position with respect to the centre line ($\bar{x}$ corresponds to position LC). These facts signal a disruption and insufficient stability of the process. The exceeding of the control limits and the permanent shift with respect to the centre line determine the need to improve stability by changing the position of the measurement data distribution with respect to the nominal value x_{wz}, and thus to the centre line LC.

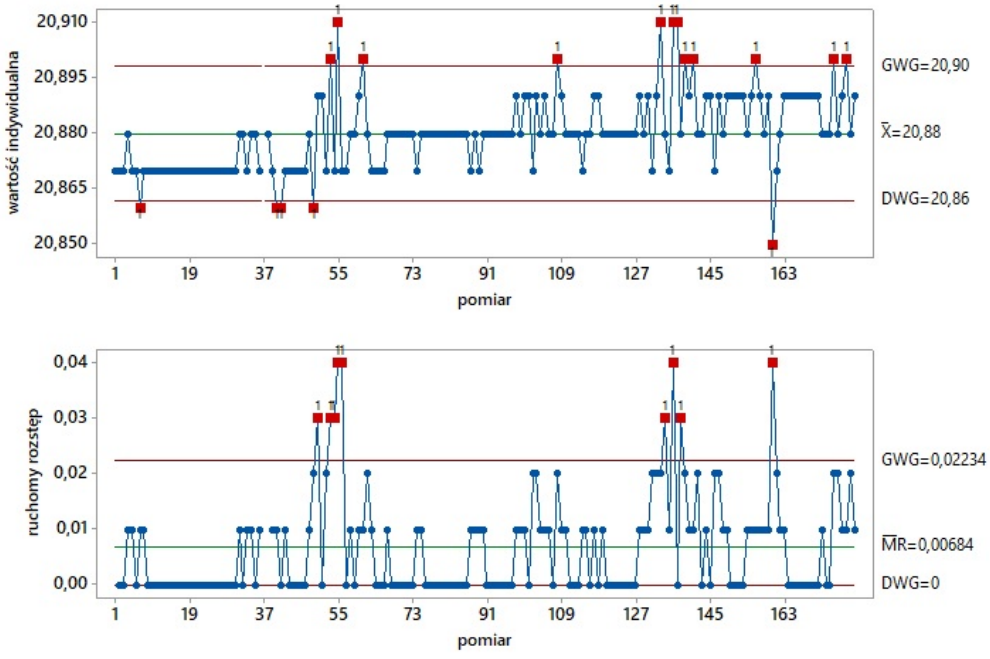


Fig. 5 I-MR control chart for monitoring the stability of a measuring system. Source: own study.

LINEARITY ASSESSMENT

Verification of linearity and estimation of mean systematic error, within the specified variation range[29] of the process was carried out by verifying data distribution with respect to the reference material for measurement series $n = 180$ and standards: $x_{wz1} = 6{,}8\%(v/v)$, $x_{wz2} = 21{,}2\%(v/v)$, $x_{wz3} = 40\%(v/v)$. Mean values $\bar{x}_{O_2}$ of individual measurement series were compared with reference values $x_{wz\,1..3}$ of etalons. The analysis of linearity of the measuring system and the estimation of the systematic error are presented in Fig. 6.

The systematic error in the studied concentration range of the measured values of etalons ranges from $-0{,}43$ to $-0{,}09\%(v/v)$, while the average error $\overline{bias} = -0{,}27\%(v/v)$.

For the range (from 18% to 25%) most significant from the process point of view, a relatively high value of $bias = -0{,}32\%(v/v)$ was identified. The determined mean bias value indicates a significant deviation of the reference mean, which represents 464.8% of the total process variability. Such a large proportion of the error is not acceptable and requires compensation. The percentage of linearity[30] of the measurement system indicates that the influence of the linearity of the measurement system represents 1% ($a = 0{,}010 \cdot 100\% = 1\%$) of the total process variation.

The performed analysis, despite demonstrating statistically significant linearity, also confirmed the previous assumptions regarding the occurrence of a significant influence of the constant and variable (mean) bias on the measurement value of the analysed measuring system. The system can be considered capable only after recalibration and bias compensation.

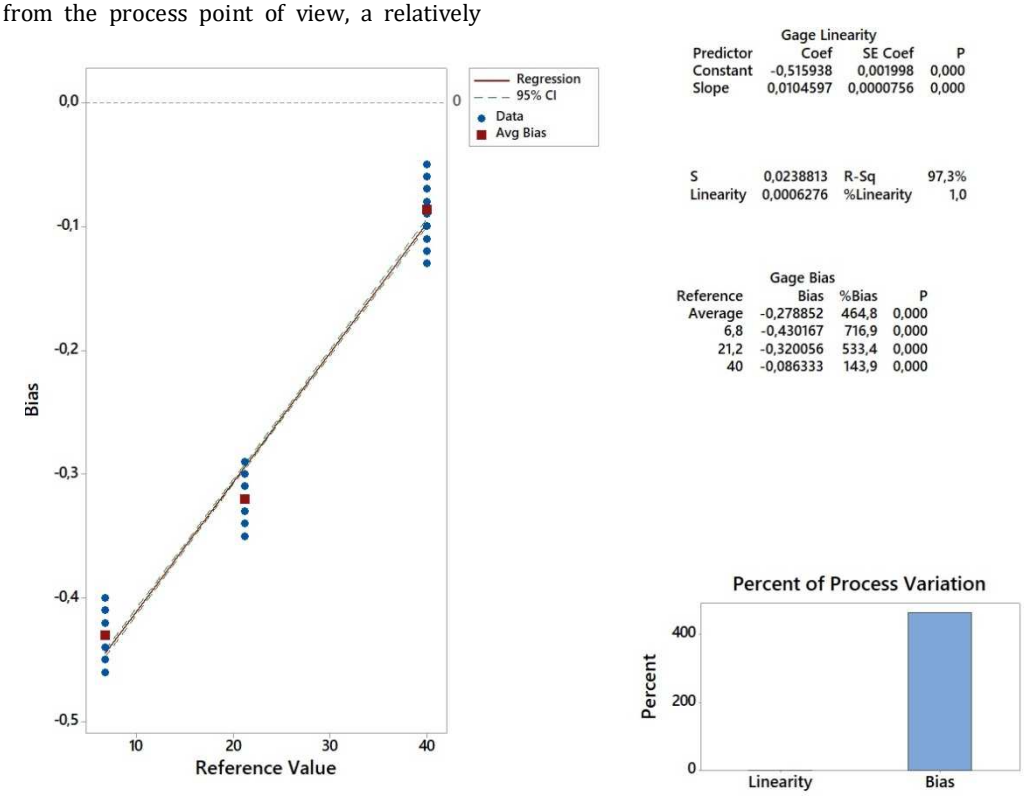


Fig. 6 Linearity and systematic error analysis of the measurement system based on measurement series of oxygen etalons: $\mathbf{x_{wz1} = 6{,}8\%(v/v)}$, $\mathbf{x_{wz2} = 21{,}2\%(v/v)}$, $\mathbf{x_{wz3} = 40\%(v/v)}$ as of 15.01.2020. Source – own study.

REPEATABILITY ASSESSMENT

After evaluation of the measurement system in terms of correctness by verifying the presence of bias and testing linearity, the variability of the measurement system %GRR[31] and its precision without reproducibility was determined. For this purpose, repeatability was evaluated using one-way ANOVA crossed variance analysis. The qualification of the measurement system was carried out in terms of the adopted specification limits. The repeatability analysis[32] of the measurement system was performed in relation to reference values[33] for the adopted specification range monitored by the process measurement system ($T = 7\%v/v$). Total variation is the sum of: TV[34]$= PV$[35] $+ GRR = 100{,}831$, where: PV – process variability; GRR – variability originating in the measurement system. Due to the use of an automated system, hypothesis H_0 – meaning there is no difference between operators – what was not considered (in the system studied), was the potential for the operator's to influence the results, therefore, the accepted hypothesis was: H_0 – there is no difference between parts[36], against the alternative: H_1 – against the variability of the analysed measurement system the variability of the process is visible. Fig. 7 shows the results of one-way ANOVA variance.

One-Way ANOVA Table

Source	DF	SS	MS	F	P
part	2	101669	50834,3	531147286	0,000
Repeatability	537	0	0,0		
Total	539	101669			

α to remove interaction term = 0,05

Gage R&R

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	0,000	0,00
Repeatability	0,000	0,00
Part-To-Part	282,413	100,00
Total Variation	282,413	100,00

Process tolerance = 0,7

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)	%Tolerance (SV/Toler)
Total Gage R&R	0,0098	0,059	0,06	8,39
Repeatability	0,0098	0,059	0,06	8,39
Part-To-Part	16,8051	100,831	100,00	14404,41
Total Variation	16,8051	100,831	100,00	14404,41

Number of Distinct Categories = 2422

Fig. 7 Results of ANOVA variance analysis of the measurement process variation against the tolerance interval $T = 7\%(v/v)$ of the controlled process $n = 180$ measurements and 3 parts without operator participation. Source – own study.

For the adopted significance level $\alpha = 0{,}05$ the analysis indicates, that due to the obtained value $p - value = 0 < 0{,}05$ the tested hypothesis H_0 should be rejected and the alternative hypothesis should be adopted – against the background of the variability of the analysed measurement system the variability of the process within a specific specification range is visible (i.e. there is a significant difference between the parts). It follows that due to the repeatability, with the help of the measurement system, it is possible to identify the variability of the monitored process. Consideration of the percentage contribution of the individual variations to the total variation[37] from the ANOVA table obtained, fig. 7, showed that the total contribution of the observed variation comes from the differences between the parts[38], and not from the measurement system. The source of the determined variability of the tested measuring system $GRR = 0{,}059$ is exclusively the repeatability component.

The variability of the measuring system GRR equated to the total variability $TV = 100{,}831$ fulfils the adequacy condition for a measuring system capable of monitoring the $\frac{GRR}{TV}$ process without limitations, the $\%SV(\%GRR)$ calculated below is equal to: $\%SV(\%GRR) = \frac{GRR}{TV} \cdot 100\% = \frac{0{,}059}{100{,}831} \cdot 100\% = 0{,}059\% < 10\%$. It follows that, due to its repeatability, the system is suitable without restriction for the monitoring of the process carried out. The measuring system also meets the criterion for product monitoring: $\%SV(\%GRR) = \frac{GRR}{T} \cdot 100\% = 0{,}84\% < 10\%$. In the analysis performed, an assessment was also made of the distinctness of the measurement system, perceived as the number of distinct categories NDC[39]$= \sqrt{2 \cdot \left[\left(\frac{100}{\%GRR}\right)^2 - 1\right]} \approx 2422 \gg 14$. The measurement system meets the adequacy condition[40]. The system, due to its repeatability criterion, is fit without constraint to supervise this hyperbaric exposure process.

The precision of a measurement system can be expressed in terms of a coefficient of variation CV, which enables a relative comparison between different techniques, e.g. instrumental ones, used to analyse the same factor (oxygen content in the breathing air). The value CV[41] is determined on the basis of the relative standard deviation RSD[42] obtained from the relation [12]: $RSD = \frac{S}{\bar{x}} = 0{,}0000478$. For the determined deviation, the value of the variation coefficient assumes the value $CV = RSD \cdot 100\% = 0{,}048\%$ and proves low variability of the measurements, which indicates high precision of the measuring system.

ASSESSMENT OF STABILITY OVER TIME

The evaluation of the stability of the system Fig. 8 for maintaining metrological characteristics constant in time was performed on the basis of periodic measurements of the reference value. The stability of the measurement system is the difference between the average value of the results of identical measurement series $\bar{x}_{O_2}$ to the etalon nominal value x_{wz}. Measurements were taken at specific time intervals. The system will achieve a higher degree of stability the smaller the differences identified over time $\Delta x_{wz} = \Delta x_{wz} - \bar{x}_{O_2}$. The system was tested by periodically measuring the etalon $x_{wz} = 21{,}2 \pm 0{,}212\%(v/v)$.



Fig. 8 Stability over time $\bar{x} \pm \Delta x(1-\alpha = 0{,}95)$ for oxygen etalon measurements $x_{wz} = 21{,}2 \pm 0{,}212\%(v/v)$. Source – own study.

The minimum sensor stability declared over a period of 1 month is $\Delta = 0{,}2\%(v/v)$[43]. For the purposes of the supervised process $x_{wz} \pm 0{,}7\%(v/v)$ corresponding to 0,1T was taken as the limit value. In the course of the conducted tests no exceeding of the specification limits was observed, fig. 9. The system met the requirements specified by the manufacturer, nevertheless, the variability of the measured value is visible. According to the presented distribution, the largest difference between the average values of the series of observed measurements was: $\Delta_{\bar{x}} = \bar{x}_1 - \bar{x}_2 = 21{,}085 - 20{,}760 = 0{,}325\%(v/v)$[44].

CONCLUSIONS

The identified difference between the average value and the nominal value has a significant impact on the evaluation and conclusion of the controlled process. The current capability of the measurement system cannot be accepted for measurements in responsible hyperbaric systems. Despite the lack of qualification of the system, the test results confirmed many of its advantages indicating its potential capability. Notwithstanding the insufficient accuracy, in some cases the system exceeded the defined requirements of the individual components of correctness and precision[45]. The advantage of the system is a very high level of measurement precision and a large number of distinguishable categories. Correctness correction[46] will allow the system to be qualified to supervise the hyperbaric exposure process with breathing air. The developed test results demonstrate the possibility of using the sensor of the analysed system also for other purposes, e.g. for monitoring the composition of the atmosphere or for continuous verification of the declared operational parameters of breathing air treatment systems in other hyperbaric facilities and indicator systems, etc. The advantages of the system allow its prospective use in newly developed or upgraded atmospheric control systems of hyperbaric facilities[47].

In the qualification of systems for reasons of safety of hyperbaric exposures, the verification of the metrological quality characteristics of the systems in operation plays a key role. This determines the necessity of using in operational tests, only qualified, reliable and useful analytical systems of confirmed effectiveness for taking measurements. Taking into consideration the results obtained, the implementation of new systems should be preceded by verification tests[48] of the measurement systems in terms of the declared metrological parameters. The dynamically developing technology of analytical systems suggests that it will soon be possible to use more accurate, stable, robust and less costly measuring systems. As it is well known that besides the reliability of measuring systems in the construction of new hyperbaric facilities, their selection is also influenced by the economic conditions related to their acquisition and lifecycle costs.

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[1] an appropriately organised set of elements constituting an organisational whole and under common control, designed to extract measurement information from a test item and transfer it to an observer in a usable form,
[2] measurement System Analysis - is a method of analysis of capacity and stability of measurement instruments and systems used in quality engineering,
[3] department of Underwater Works Technology of the Naval Academy (AMW),
[4] experimental deep-water hyperbaric system,
[5] North Atlantic Treaty Organization,
[6] this capacity means not only functional correctness but above all conformity of the measuring system with its declared quality characteristics: resolution, uncertainty, accuracy, repeatability, reproducibility, and stability over time,
[7] measurement processes must be metrologically validated,
[8] this should be regulated, i.e. stable, centred and under control if the critical quality requirements of CTQ according to NO-07-A005:2010 are met,
[9] working standard – a measurement standard which is used permanently for calibration or verification of measuring instruments or measuring systems. Working measurement standards should be subjected to metrological control in accredited Military Metrology Laboratories and calibration laboratories operating on the basis of the current edition of the international standard PN-EN IEC 17025 or in justified cases in NMI (National Metrology Institutes),
[10] control sample decompressed to normobaric conditions,
[11] following outlier elimination,
[12] the probable interval within which the mean of a given normal distribution lies,
[13] *p-value* – the p-value of a hypothesis test is the smallest value of the significance level α which leads to the rejection of the zero hypothesis H_0,
[14] C_g – measuring system spread factor,
[15] C_{gk} – measuring system position indicator,
[16] DWG –lower limit GWG – upper limit,
[17] run chart,
[18] in processes it is recommended, where possible, that the value of the index is $C_{gk} > 1{,}33$. Alternatively at a level of at least $C_g, C_{gk} > 1{,}67$. C_gk>1,33,
[19] the required condition for the suitability of the system to measure a characteristic with tolerance T is that $u \leq (0{,}1 \cdot T)$ [10],
[20] certified reference material,
[21] for the calculation, the uncertainty of the reference value is equal to the expanded uncertainty divided by the spread factor $\frac{U}{k} = \frac{0{,}212}{2} = 0{,}106\%(v/v)$,
[22] from standard certificate no. 1495569 dated 27.09.2017 issued by Linde gaz Polska,
[23] %Var(Repeatabilty),
[24] %Var(Repeatabilty and Bias),
[25] $\%Var(Rep), \%Var(Rep\ and\ Bias) = 15\%$ corresponds to the value of the capacity factors for the measurement system C_g, C_{gk} =1,33,
[26] a set target value for the process and a known standard deviation,
[27] the chart can be developed by a project or stabilisation method, based on a series of at least n>30 measurements before the control limits and the centre line are calculated and plotted. After elimination of the deterministic causes of the disruption signals and stabilisation of the process, the control limits should be recalculated,
[28] Individual Value − Moving Range,
[29] in general the concentration range for linearity analysis covers values between 50 and 150% of the expected value of the analysis results, for economic reasons it was decided to use available standards slightly exceeding these values,
[30] $\%Linearity = 1{,}0\%$,
[31] ang. Gauge Repeatability and Reproducibility,
[32] conditions of normality of distribution, equality of variances, homogeneity and randomisation of data are met,
[33] covering the range of variation of the controlled process,
[34] Total Variation,
[35] process variation,
[36] the expected result does not depend on the part (the variation from the device does not show the variation of the process),
[37] total gage R&R,
[38] part to part,
[39] Number of distinct categories,
[40] $ndc \geq 14$ capable system, $ndc = 4 - 13$ conditionally capable system, $ndc \leq 3$ incapable,

[41] Coefficient of Variation,
[42] Relative Standard Deviation,
[43] therefore, changes in the limit values were expected $\Delta x_{wz} \pm 0{,}8\%(v/v)$,
[44] between trials from 23.10 and 26.11.2019,
[45] except for reproducibility due to an automated system without operator involvement,
[46] centering after alignment,
[47] if economically justified,
[48] e.g. system validation through laboratory and in-service testing of individual units in a specialised laboratory,
[49] such as optical sensors, ultrasound sensors, etc.