POLISH HYPERBARIC RESEARCH 1(62)2018
Journal of Polish Hyperbaric Medicine and Technology Society
Faculty of Mechanical and Electrical Engineering of the Polish Naval Academy

ANALYSIS OF THE BREATHING AIR PRODUCTION PROCESS FOR HYPERBARIC PURPOSES

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ABSTRACT

The quality of breathing air plays a key role in the safety of divers and hyperbaric facilities. Paradoxically, the change of regulations concerning quality requirements for breathing mixes has imposed the need for verification of the technical and laboratory bases used in their production and control. This article presents the results of research related to the rationalisation of the process of production and supply of breathing air for the purposes of hyperbaric oxygenation. The work was carried out using the SixSigma method.
Keywords: underwater works technology, diving gases, capability, process, control charts.

ARTICLE INFO

PolHypRes 2018 Vol. 62 Issue 1 pp. 7 - 32
ISSN: 1734-7009 **eISSN:** 2084-0535
DOI: 10.2478/phr-2018-0001
Pages: 26, figures: 23, tables: 7
page www of the periodical: www.phr.net.pl

Publisher
Polish Hyperbaric Medicine and Technology Society

Original article

Submission date: 13.08.2017
Acceptance for print: 29.09.2017

INTRODUCTION

The changes related to Poland's accession to the North Atlantic Treaty Organisation (NATO) necessitated the need for modernisation of the *Polish Armed Forces* to ensure the interoperability. The implementation of *STANAG* standardisation documents[1] in the *Polish Armed Forces* required undertaking many organisational measures aimed at solving the emerging problems. One of them was the insufficient quality of the breathing air used for hyperbaric purposes. Poland's unconditional acceptance of the provisions of *STANAG* 1458[2] and *AdivP*-01[3] without the proper preparation of the *Polish Armed Forces* significantly limited the capacity to carry out underwater activities, thus reducing the use of domestic equipment in the production of breathing air.

PROBLEM

As shown by the context analysis[4] of the problem connected with ensuring the necessary quality in the process of supplying the *Polish Armed Forces* with breathing air that was carried out at the turn of the century, there was a need to undertake staged systemic actions. In this context, in a sudden encounter with *NATO* requirements related to breathing air supply systems, a potential threat occurred of a significant reduction of the operational capacity of the *Polish Armed Forces* due to the inability to use the existing equipment.

Targeted actions were to ensure the removal of a high failure level of breathing air supply sources in a given time perspective. As recently as in 2002, after the initiation of changes in the breathing air supply system, the scale of prohibition of operation reached nearly 80–90% [1] of the air supply sources used by the *Polish Armed Forces*. The necessary changes required significant expenditures on the modernisation of breathing air production systems and distribution operated in the *Polish Armed Forces*, as well as gradual replacement of the old systems with new ones. The article presents the counterbalancing of the two processes: modernisation and successive replacement of old systems with new ones.

With regard to the normative content [2] of breathing air pollutants, an analysis was carried out with regard to their toxic effect. It was based on previously published research results, which despite the significant passage of time are still valid [3], as they were supplemented with newer results in later publications [4].

Based on the diagnosis of the situation, it appeared that in order to ensure the provision of the *Polish Armed Forces* with appropriate systems for the production, storage and distribution of breathing air, it is not sufficient to replace the compressor, filtration and distribution systems with newer ones. There was also a need to modernise the laboratory base and build an air purification facility adjusted to the technical conditions of the systems used for the production, storage and distribution of breathing air.

OBJECTIVE OF THE WORK

The objective of the work consisted in the rationalisation of the process of production, storage and distribution of breathing air for hyperbaric purposes with consideration of the need to fulfil the assumed critical quality requirements *CTQ*5[5]. It was assumed that the project's goal was possible to accomplish by use of the *SixSigma* approach, consisting in the determination and implementation of the necessary scope of modernisation of systems used thus far to obtain, store and distribute breathing air for hyperbaric purposes.

METHOD

The work was carried out using the recognised scientific methods of the *SixSigma* approach, which is one of many pro-quality systems used. This method is oriented towards implementation of a long-term quality improvement strategy involving the elimination of process variability at all stages of its realisation through successive implementation of improvement projects. The *SixSigma* approach combines well-known quality control techniques (*SPC*[6]) with other statistical methods. The basis of this method is the improvement and continuous development of new solutions as part of a streamlined process. The improvement of capability of an extremely inefficient process was based on the application of a recognised method of product improvement. The aim was to successively reduce system variability.

The advantage of this method is its focus on maximising the reduction of defects in the process, leading to the improvement of quality at a reasonable and acceptable cost. The consistent application of the established *DMAIC*[7] algorithm based on the implementation of a set of activities or tasks in a methodical manner leads to the development of the desired solution. Most quality improvement systems are based on simple organisational and motivational actions, as is for instance *Lean Management*.

The comprehensive *SixSigma* approach does not eliminate these methods, it simply extends them. As soon as all the obvious, deterministic causes disturbing the process under consideration are eliminated with the use of simple methods, other mathematical methods can be used to diagnose the extent to which the process deviates from its natural variability. The low popularity of the *SixSigma* approach results, among other things, from the necessity of incurring significant expenditures on software and the employment of a team of trained specialists who can use scientific methods to implement industrial processes and laboratory activities.

The use of this approach requires special tools and statistical techniques, which results in a relatively high cost of their implementation. The greatest problem also lies in the necessity to change the approach of those involved in the production process resulting from changes in the organisational culture of the process. This involves a constant requirement for employee training within the observance of *SOP*[8].

Despite these difficulties, an informed decision was taken to implement the project on the basis of the *SixSigma* strategy.

Due to limited resources and possibilities, only selected methods of the $SixSigma$ approach were used. The work objectives were defined with the use of a context analysis based on the $SWOT$[9] method. Rationalised processes were defined with the use of the QFD[10] diagram, whilst the risk analysis was based in accordance with the $FMEA$[11] approach. The base of responses from a tested system was analysed in terms of explorable determinism using *Data Mining* methods. The exploration of the collected base of observational data sets of control samples was conducted towards the identification of an occurrence of unexpected relationships and special disruptions. The stability of rationalised processes was tested using SPC[12] [13] statistical control methods.

The conclusions were drawn using statistical inference methods based on practical distribution of a random variable. During the experiments, typical methods of deterministic design of experiments[14] were used, as well as the rules of uncertainty of measurement results using statistical analysis methods of a series of observations – the *type A* method [5].

RESEARCH

The process subject to rationalisation was defined in the definition phase[15]. Its place in the system was indicated as was its closest environment[16]. The main stakeholders of an improved process were defined and their CTQ requirements were specified as being critical from the point of view of product quality [6]. The client's requirements were translated into critical quality requirements CTQ[17]. A high-level process map was defined encompassing the context and the system connected with the process under improvement, and other processes operating in the said system. Products have been hierarchised in relation to their links to quality requirements CTQ. Next, in the measurement phase, using the QFD[18] method the CTQ were diagnosed[19] for the rationalised process. A preliminary risk analysis was performed for the process of supply of air for hyperbaric purposes with the $FMEA$[20] methods. This allowed to establish the methods to improve process stability with regard to compliance with CTQ. The analysis showed that many product characteristics are interdependent[21]. The processes of quality control, filtration and training were recognised as the three most important processes of breathing air production for hyperbaric purposes.

It was assumed that the main indicator of achievement of the objective would be a reduction in critical impurities found in 90% of analysed samples. Next, the process map was analysed once again and supplemented with a physico-chemical analysis system. The said supplementation is important as the results of the physico-chemical air tests constituted system response confirming the fulfilment or non-fulfilment of requirements regarding process limitations – fig. 1. The analyses of the measurement system were omitted, as they were carried out in earlier studies [7].

In the analysis phase, the current level of contamination in the obtained breathing air was determined on the basis of systemic and deliberately collected, stored and processed data. A technical experiment was carried out allowing selection of filtration kits which were either available on the market or possible to design, implement and produce ourselves. The fulfilment of critical quality requirements CTQ was verified on the basis of the responses from the breathing air production systems. The level of compliance with the quality requirements CTQ with the achievements of leading countries of $NATO$ was compared. The level of process variability was diagnosed as well as the directions for its improvement.

Fig. 1 Improved general map of the process of production, storage and distribution of air approved for use in hyperbaric oxygen conditions presented in the form of a $SIPOC$ diagram.

SELECTION OF A FILTRATION AND COMPRESSION SYSTEM

Proper selection of air treatment systems was a significant problem when conducting effective modernisation of breathing air supply systems for hyperbaric purposes. During the research it was necessary to determine the possibility of meeting the critical quality requirements CTQ. In the selection of the compression system for testing it is reasonable to use the worst-case scenario method, taking into account the purposefulness of maintaining these installations in further operation. In the capitalisation of knowledge, the existing types of construction solutions were analysed. Despite the reduction in the number of offshore military units and vessels of the $Polish\ Navy$, between 100 and 150 different air supply systems were used in hyperbaric conditions. This includes approximately 26–30 high-performance compressors, 30–40 marine compressors on vessels and 45–50 portable systems powered by electricity or a diesel motor [8].

According to the results of quarterly measurements of various types of air supply sources it was found that the system installed on the ship proj. 570 equipped with a compressor $EK\,7.5-3M$ and $P140\,BAUER$ filtration system met the quality requirements CTQ in contrast to the remaining breathing air supply systems intended for hyperbaric purposes.

Market study showed that domestic producers are not able to quickly offer a ready-made range of filter cartridges that meet the minimum quality requirements CTQ. Based on the conducted analysis tab. 1 presents the ranking of the considered filtration systems [9]. Theoretically, a filtration system series should ensure fulfilment of critical quality requirements CTQ in the process. Tests of the $P61$ filtration system series manufactured by $BAUER$ were carried out in relation to the most popular compressors in the Polish Armed Forces $EK2-150$ and $A3HW1\ GERA-32/70$[22].

Bench tests performed on a model system based on a selected physical model allowed the obtainment of

measured results for breathing air samples, which are presented in tab. 2. The collected measurement results initially confirmed the possibility of satisfying the critical quality requirements CTQ for the production of breathing air for hyperbaric purposes by the proposed sets of filters [10]. The use of a set of filters in combination with a water-oil separator and automatic condensate discharge caused a multiple reduction in the content of CO, CO_2, H_2O, CH_4 in the product.

Tab. 1

Ranking of filtration system following the evaluation of technical and quality parameters in terms of meeting quality requirements CTQ for the process of supply of breathing air for hyperbaric purposes.

Filter type	Comparative ranking – *benchmarking*
$P140\ BAUER$	1
$P120\ BAUER$	2
$L\&W\ COMPRESORS\ FP - 2/10 - 1/2{,}3$	3
$FWD - 200\ ZSRR + GP - 200\ ZSRR$	4

Tab. 2

The comparison of analyses of control samples from breathing air supply sources before and after modernisation.

Mix under measurement	Measuremet unit	Compressors			
		Before modernisation		After modernisation	
		No. 2727	No.12833	No. 2727	No.12833
Oxygen	%	20.77	20.92	20.93	21
Carbon dioxide CO_2	%	0.0468	0.0317	0.0	0.0101
Carbon monoxide, CO	ppm	0.69	0.62	0.41	0.32
Nitrogen oxides NO_x	ppm	0.111	0.255	0.196	0.082
$C_nH_m$vapours calculated into CH_4	$mg \cdot m^{-3}$	3.93	1	0.5	0.4
Steam H_2O	$mg \cdot m^{-3}$	111	56.98	10.95	9.55

The assessment of the possibility of dissemination of the proposed filters together with the diagnostic indicator[23] may enable the fulfilment of critical quality requirements CTQ. The elimination of the impact of the occurring hazards of failure to meet critical quality requirements CTQ will be achieved through modification of certain subprocesses in a way that ensures obtaining products that meet the requirements for a rationalised process. The tests were carried out on three specified control groups, whose division is presented in tab. 3-4.

Tab. 3

General division into control groups with regard to the applied air treatment solution.

The type of applied compression and filtration system	Control group
classic filter cartridge + classic supply source	1
new filter cartridge + classic supply source	2
new filter cartridge + new supply source	3

Observations were conducted in order to evaluate changes in the target function during configuration changes using the statistical methods of process control SPC[24]. This made it possible to determine the scale of responses to the changes introduced. An efficient process was such that was considered to be stable, effective and aligned [11].

Tab. 4

General division into control groups with regard to the applied air treatment solution in accordance with tab. 3.

Compressor type	Serial no.	Control group
BAUER VERTICUS 150 – 15 – 05	5108-1183	3
BAUER MARINER 320*D*	5208-3667	3
BAUER MARINER 320*E*	5208-3666	3
BAUER MARINER 320*E*	5104-1720	3
BAUER MARINER 250*E*	5101-0345	3
Sauer & Sohn WP 5000	442	3
EK – 7.5 – 3*M*	342	2
*EK*2 – 150	183	1
*EK*2 – 150*M*	2727	2
*EK*2 – 150*M*	12833	2
*A3HW*1*M*	4278/1035	1

RESEARCH RESULTS

The decision regarding the level of investment related to the successive modernisation or replacement of air supply sources was based on research results. At the initial stage of the research, the authors referred to the results obtained in the years 2002–2006.

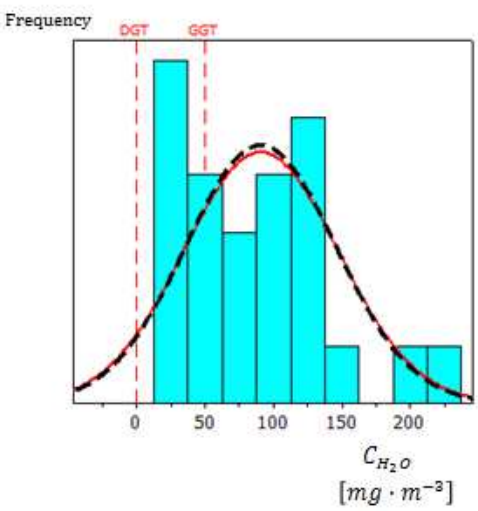

Fig. 2 The histogram of empirical distribution of measurement data with control limits ($\bar{x} = 90.6\, mg \cdot m^{-3}$, $n = 25$, $DGT^{25} = 0$, $GGT^{26} = 50\, mg \cdot m^{-3}$) for compressor $EK2 - 150$.

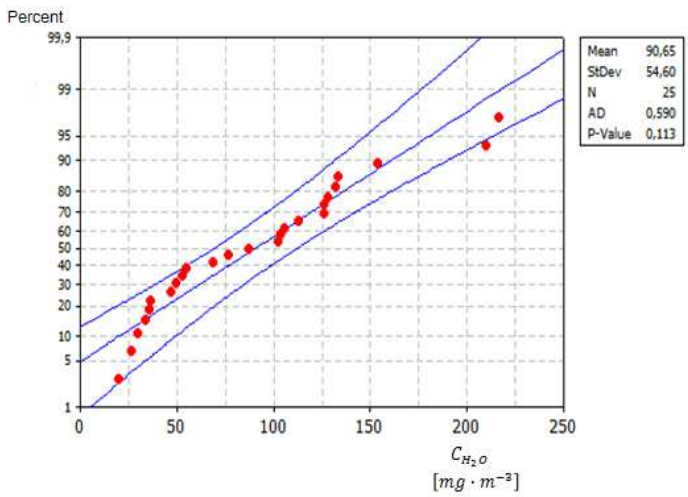

Fig. 3 The graphic test of normality of distribution of empirical data.

Fig. 2 presents the distribution of measurements of H_2O content performed for the system equipped with an $EK2 - 150$ compressor prior to modernisation, in concord with tab. 4. The results of C_{H_2O} measurements are above the upper tolerance limit $C_{H_2O}^{max}$, thus failing to meet one of the critical quality requirements CTQ. The presented example illustrates an extremely inefficient production process. The histogram presents the process course referenced to the defined limits of CTQ specification. In cases when the possibility for improvement is limited or impossible, further actions should involve a technological leap usually associated with the use of a new type of machinery, technologies,changes in *SOP, etc.* The above measures may in consequence lead to a reduction in process variability. Testing of the normality of distribution[27] of empirical data can be carried out using for instance the AD[28] – fig. 3.

Theoretically, for a normal distribution the standard deviation for the σ population consisting of n measurements gives a standard distribution $\sigma_{\bar{x}}$ of the mean value $\bar{x}$ amounting to $\sigma_{\bar{x}} = \frac{\sigma}{\sqrt{n}}$ [12]. It is assumed that for a stabilised process under statistical control, the distribution of mean values $\bar{x}_i$ for individual measurement series should not exceed the control limits located within the distance $\pm 3 \cdot \sigma_{\bar{x}}$ from the designated central line constituting the global mean $\bar{\bar{x}} = \frac{1}{m} \cdot \sum_i^m \bar{x}_i$ [11]. The thus established control limits of the variability range contain approximately 99.73% of all values for the normal distribution. The analysed process is not under statistical control, as the spread of results is greater and well beyond the set tolerance limits. This suggests that the process is influenced by a deterministic phenomenon causing an increase in process variability deviating from

natural. This gives the field for process improvement by introducing changes in some of its parameters.

Fig. 4 presents a comparison of compressors with respect to the maximum content of H_2O in the case of breathing air for hyperbaric conditions amounting to $C_{H_2O}^{max} = 5.0 \cdot 10^{-2} g \cdot m^{-3}$ [10] As expected, the measurement results presented in fig. 5 show that the most effective solution consists in the use of the $MARINER\ 250E$ system, however modernisation of the $EK - 7.5 - 3\ M$ compressors is also acceptable. The measurement results obtained for the $A3HW1M$ compressor depart significantly from those obtained both for the $MARINER\ 250E$ and $EK - 7.5 - 3M$.

As part of the control of the breathing air production process, each type of air supply source was considered separately. The control was performed using the statistical quality management method SPC implemented with the use of control charts [12,11]. The control charts were used to monitor process quality through the control of location and variability of measurement results in relation to the defined tolerance limits. Fig. 6 presents the obtained H_2O measurement results recorded on a control chart[29] $IX - MR$[30]. The control charts were used to monitor the quality of particular quarterly H_2O content measurements collected in chart IX – upper graph in fig. 5.

Upon the summation of each point, the global mean value $\bar{x}$ and the upper and lower limit is referenced to the three values of the mean standard deviation $\bar{s}$ from measurements $\pm 3 \cdot \bar{s}$, with the exception of outliers. Outliers are marked in red and are located outside the accepted limits. The movable range chart MR is located below the individual observations chart IX – bottom graph in fig. 6. Due to the method used there is no fixed value for the first measurement. Successive mean values of the movable range $\overline{MR}$ are used to calculate the approximate value of mean standard deviation $\bar{s}$ for each portion of collected measurements used to calculate the limits for individual measurements IX. The calculations were performed using standard statistical software – $MINITAB$.

The distribution of measurements shown in control charts $IX - MR$ in fig. 6 indicates that the air quality is compliant with the specification.

All measurements are below the upper tolerance limit GGT_2. Beyond the control line UCL[31] distortions occur both on chart IX and the moving range chart $\overline{MR}$. When the control charts did not show irregularities understood as the exceedance of the tolerance limits or constant trends, it could be assumed that the process is under the statistical contro[32].

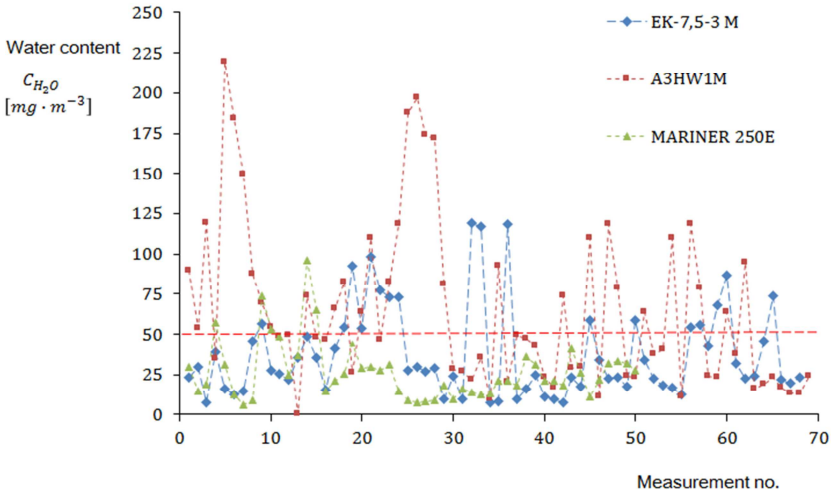

Fig. 4 Consecutive C_{H_2O} concentration measurement results in the breathing air for various compressors in the years 2002–2013.

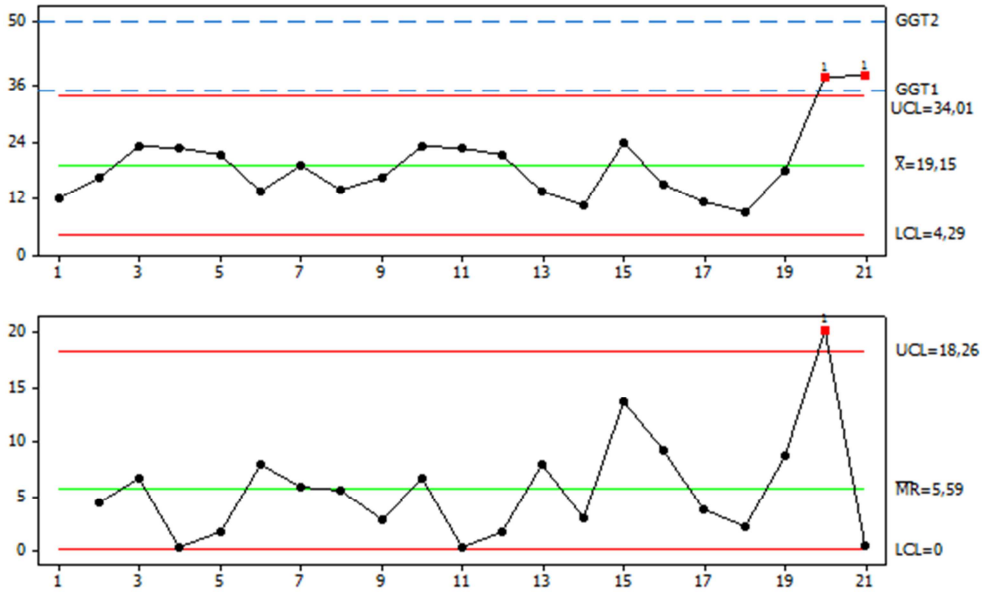

Fig. 5 The distribution of H_2O measurement results in control chart $IX - MR$ obtained for $MARINER\ 320D$ compressor.

Fig. 6 presents an empirical data distribution histogram for the $MARINER\ 320D$ compressor. The considered distribution falls within the specification limits. The distribution under consideration is within the specification limits, although there are measurements in the GGO[33] zone and outside the UCL that indicate poor alignment.

To assess the process capability, point measures C_p and C_{pk} are used. The dispersion index C_p[34] expresses the potential capacity of the process to meet critical quality requirements CTQ, if a monitored process parameter oscillates within the specification limits $[USL; LSL]$. This index constitutes the reference range of the $USL - LSL$ specification limits to sixtuple standard deviation value s of the process: $C_p = \frac{USL-LSL}{6 \cdot s}$. Its value should be greater than unity $C_p > 1$. Process alignment index C_{pk} shows real potential process capability taking into account its current alignment and spread. The assumed C_{pk} index is a smaller value from the distance of the global correct value commonly calculated as the global mean $\bar{\bar{x}}$ for the monitored parameter within the defined time from specification limits $C_{pk} = \min\left\{\frac{USL-\bar{\bar{x}}}{3 \cdot s}; \frac{\bar{\bar{x}}-LSL}{3 \cdot s}\right\}$.

In the case of process capability assessment regarding the fulfilment of quality requirements CTQ the real process capability index C_{pk}[35] should be at least greater than unity $C_{pk} > 1$[36]. The analysis of the above indexes gives us the opportunity to identify an occurrence of deterministic disturbances that lead to process instability. If the value of both indicators is the same, it can be concluded that the process is stable from the point of view of its alignment. Depending on the needs the indices can be calculated at the stage of machine qualification[37] and its short-[38] or long-term assessment with regard to capability. In this case the indices are marked respectively as C_m, C_{mk} and P_p, P_{pk}.

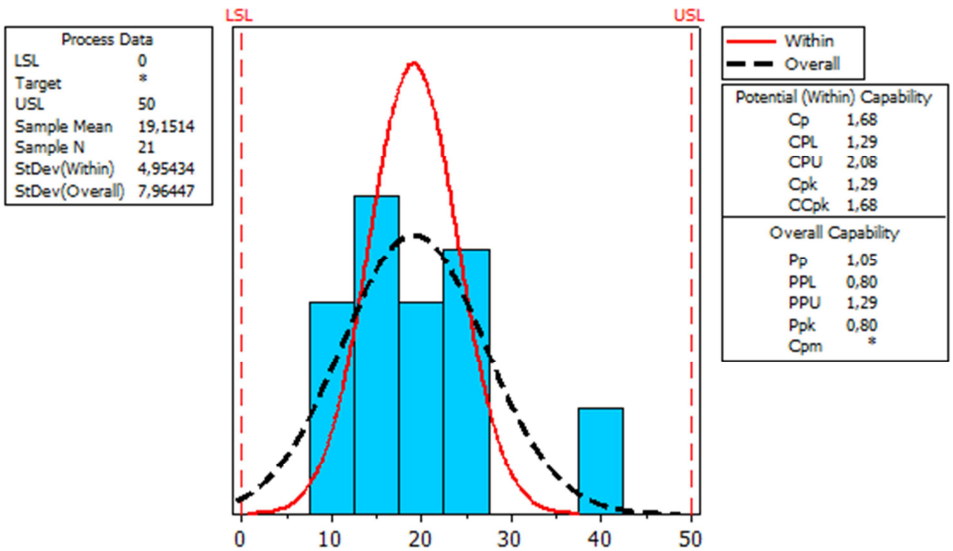

Fig. 6 The histogram of empirical distribution of measurement data with the control limits ($\bar{x} = 19.15mg \cdot m^{-3}$, $n = 21$, $DGT = 0$, $GGT = 50mg \cdot m^{-3}$) for the *MARINER* 320*D* compressor.

The share of results exceeding the upper limit of CO_2 and H_2O contents in control groups of the tested systems in accordance with tab. 3–4. is collectively presented in tab. 5.

Tab. 5

The share of results exceeding the upper limit of CO_2 and H_2O contents in control groups in accordance with tab. 3–4 in the years 2002–2013.

Compressor type	Control group	Frequency of non-compliances with quality requirements CTQ in cl. II breathing air [%]	
		CO_2	H_2O
*EK*2 – 150	1	20	66.60
A3HW1M	2	8.69	44.92
*EK*2 – 150*M*	2	14.81	44.23
EK 7.5 – 3*M*	2	16.17	23.52
Sauer & Sohn WP 5000	3	10.91	12.72
BAUER MARINER 250*E*	3	10	4,00
BAUER MARINER 320*E*	3	4.54	4.54
BAUER VERTICUS 180 – 15 – 5	3	25	3.57
BAUER MARINER 320*D*	3	9.52	0

The greatest share of non-compliant CO_2 results obtained for the new system is odd. The same filtration systems is used in the $BAUER\ VERTICUS$ $180-15-5$ and in other compression systems of the third group, yet it indicated narrower non-compliance levels of $5-10\%$ with regard to the required limit of $C_{CO_2}^{max} = 0.05\%_v$. This shows that even the most modern filtration systems are not resistant to the operator's non-compliance with the SOP in the area of equipment inspection and in the process of taking control samples.

In the case of the modernised systems of group 2, in accordance with tab. 3–4. Measured results exceeding the content $C_{CO_2}^{max} = 0.05\%_v$ oscillate within a range of between 8.69%–16.17%. The non-modernised systems of group 1, as shown by tab. 5. indicated approximately 20% of limit exceedances $C_{CO_2}^{max} = 0.05\%_v$.

With regard to H_2O content reduction the most efficient solution is that applied for group 3, where the share of non-compliances falls between 3.57% and 4.54% – tab. 5. In the case of group 2, depending on the compression system and the use of the same filtration the share of non-compliances oscillates within the range between 23.52% and 44.92% % – tab. 5. Most non-compliances are observed in group 1, i.e. approximately 66.6% – tab. 5. The use of modern filtration systems does not meet the quality requirements of CTQ at a satisfactory level due to the use of exhausted compression systems. The same filtration systems used with new compression systems are by many times more effective and lead to a reduction in the number of inconsistencies for H_2O: up to 4% in the case of the $MARINER$ $250E$ and up to 3.57% for the $VERTICUS$ $180-15-05$.

The poor modernisation opportunities of the air supply systems are mainly due to the older systems being more prone to operator error. Such hazards have caused a significant reduction in the service life of filter cartridges, thus increasing operating costs and not ensuring sufficient system stability.

Tab. 5 collectively presents mean values $\bar{x}$ calculated for the tested systems and the error value $\Delta\bar{x}$ for the inference significance at the technical level of $\alpha = 0.05$. The results are presented in fig. 7. The differences between mean values $\bar{x}$ obtained by new and legacy systems are significant.

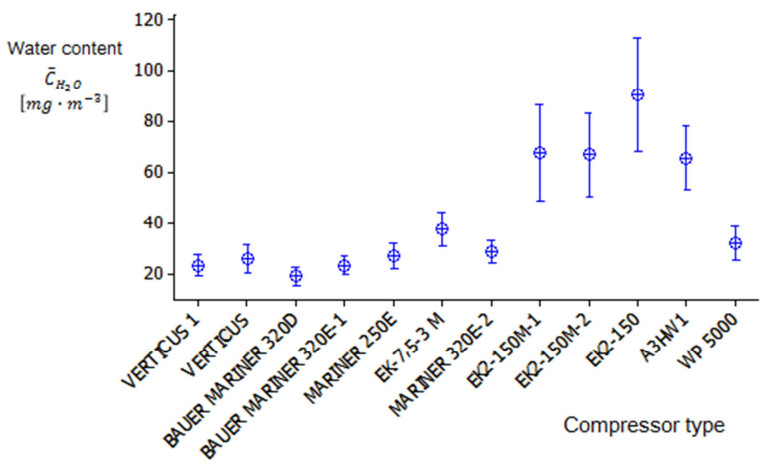

Fig. 7 Mean values $\bar{x} \pm \Delta x(P = 0.95)$ for H_2O content measurements in various compression systems in the years 2002–2013.

Tab. 6

A summary of process capability indicators in relation to ensuring H_2O content within the specification limits of $C_{H_2O} \in [LSL = 0;\ USL = 5.0 \cdot 10^{-2} g \cdot m^{-3}]$.

Hierarchy	Control group	Compressor type	C_p	C_{pK}
Operative systems				
1	3	*MARINER* 320*D*	1.68	1.29
2	3	*MARINER* 320*E*-1	1.14	1.06
3	3	*VERTICUS* 1[39]	1.13	1.09
Periodically inoperative systems				
4	3	*VERTICUS*	0.93	0.89
5	3	*MARINER* 320*E* – 2	0.91	0.77
6	3	*MARINER* 250*E*	0.76	0.69
7	3	*Sauer & Sohn WP* 5000	0.5	0.36
8	2	*EK* – 7.5 – 3*M*	0.43	0.21
Completely inoperative systems				
9	2	*A3HW1M*	0.25	–0.16
10	2	*EK*2 – 150*M* – 2	0.25	–0.17
11	1	*EK*2 – 150	0.17	–0.28

Calculated process capability indicators for the analysed systems as listed in tab. 5 with regard to the fulfilment of critical quality requirements CTQ in relation to H_2O content with reference to the requirements for class II breathing air at the level of $C_{H_2O} \in [LSL = 0;\ USL = 5.0 \cdot 10^{-2} g \cdot m^{-3}]$ are collectively presented in tab. 6. The completely inoperative systems require rotation.

ARCHIVE DATA ANALYSIS

In concord with the adopted procedure, all records of critical measurements for compression and filtration systems made in the years 2002-2006 were collected in the laboratory measurement database. It provided the basis for analysing the effects of introduced changes in the process improvement phase. The results of the measurements obtained in 2002 are presented in Fig. 8. Two groups of outliers were determined, which were marked with a red line. After identifying the reasons and the lack of economic, organisational or technical justification, the least efficient systems were eliminated and replaced with more modern ones.

Fig. 9 presents the distribution of H_2O content measurement results in 2003, whereas Fig.10 in 2004, the circled areas present laboratory measurement results showing the identified incorrect indications[40] of the $OEM - 7$ laboratory electrolyte moisture meter. The same distribution is presented on the control chart – Fig. 11. Fig. 12 indicates the measurements that were made for naval hyperbaric systems, and then incorrectly included in the measurement database of compression and filtration systems.

The results of measurements of hyperbaric systems showed contamination of storage and distribution systems. Fig. 14–15 present a summary of the value of measurements carried out in the years 2002-2006 before and after the elimination of outliers or incorrectly qualified values. From the initial number of 861 measurements of H_2O content, after an elimination for further analysis and statistical inference at the stage of process improvement, 817 measurements were left. Fig. 13 presents a summary of measurement data obtained in the years 2002-2006. The measurements are presented chronologically in the order of their observations.

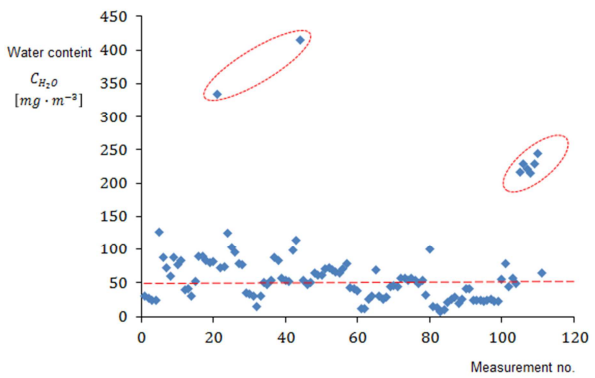

Fig. 8 Scatter diagram of H_2O content measurement results in 2002: $\bar{x} = 6.27 \cdot 10^{-2} g \cdot m^{-3}$, $n = 111$, $LSL = 0$, $USL = 5.0 \cdot 10^{-2} g \cdot m^{-3}$.

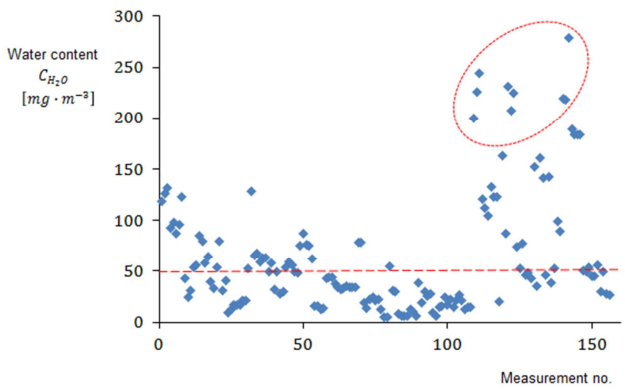

Fig. 9 Scatter diagram of H_2O content measurement results in 2003 after the elimination of $ST - 1 - 125$ compressor: $\bar{x} = 6.4 \cdot 10^{-2} g \cdot m^{-3}$, $n = 156$, $LSL = 0$, $USL = 5.0 \cdot 10^{-2} g \cdot m^{-3}$.

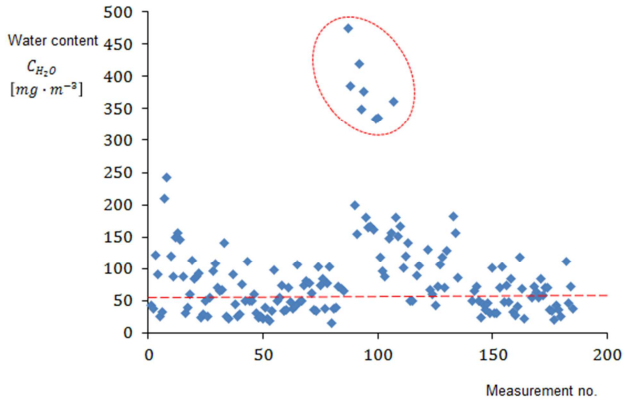

Fig. 10 Scatter diagram for H_2O content measurements in 2004 r.: $\bar{x} = 8.94 \cdot 10^{-2} g \cdot m^{-3}$, $n = 166$, $LSL = 0$, $USL = 5.0 \cdot 10^{-2} g \cdot m^{-3}$.

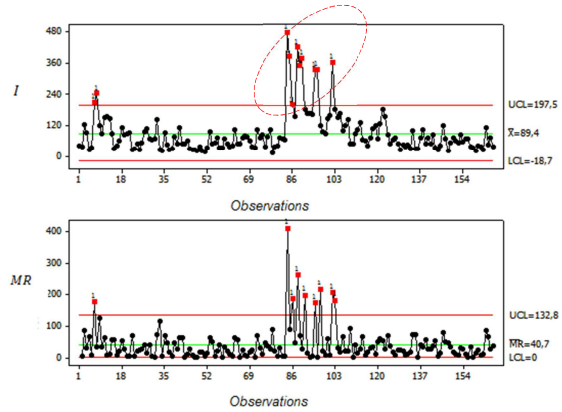

Fig. 11 Control chart $IX - MR$ for H_2O measurement contents in 2004 with the erroneous measurements $OEM - 7$ in the circle.

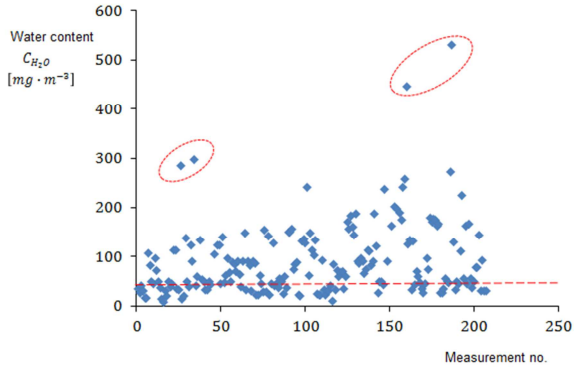

Fig. 12 Scatter diagram for H_2O content measurements in 2005: $\bar{x} = 8.84 \cdot 10^{-2} g \cdot m^{-3}$, $n = 200$, $LSL = 0$, $USL = 5.0 \cdot 10^{-2} g \cdot m^{-3}$.

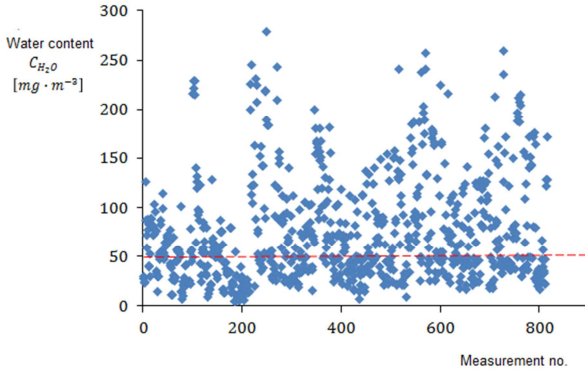

Fig. 13 Chronological summary of H_2O content results in the years 2002–2006 constituting a comparative distribution for the inference regarding future changes in technology.

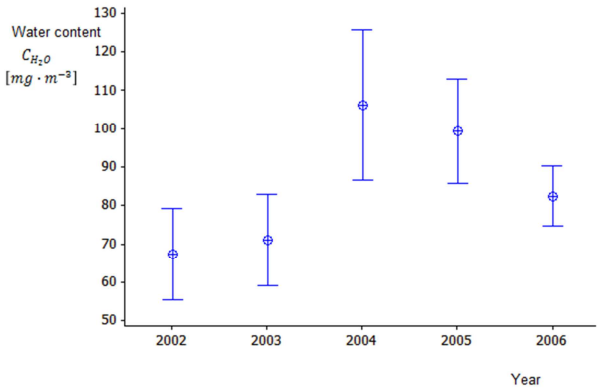

Fig. 14 Mean values diagram with the absolute error $\bar{x} \pm \Delta x(P = 0.95)$ for H_2O content measurements in particular years in the period between 2002–2006.

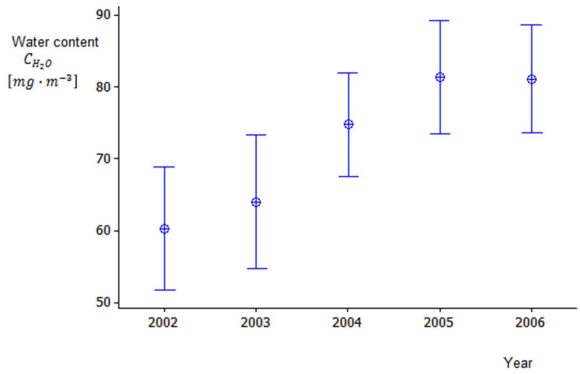

Fig. 15 Mean values along with the absolute error $\bar{x} \pm \Delta x(P = 0.95)$ for H_2O content measurements in the years 2002–2006 after the elimination of outliers.

Most H_2O measurements performed in 2002-2006 are above the required upper specification limit, and their distribution after removing the outliers for which a deterministic cause has been found, can be considered as stochastic and accepted as a practical distribution for statistical inference.

Such an inference is extremely rarely applied due to the lack of data allowing to build reliable stochastic practical distributions. By conducting systemic observations for about fifteen years, it was possible to collect a rich enough experimental material enabling this type of inference[41].

PROCESS YIELD

The average occurrence of non-compliances with regard to H_2O in the years 2002–2004 was below 10%, which corresponds to ca $2{,}78\sigma$[42],i.e. process yield Y_{FT}[43] defined as a product approved in the first attempt is approximately $Y_{FT} \gtrsim 90\%$. This is an unsatisfactory level that requires changes, because, as can be assumed on the basis of analysis, it is already practically under statistical

control and apart from the change in technology, there is no other method of increasing the process's capability. The solution to the problem consisting in the possibility of making a technological leap thanks to the application of newer compression and filtration systems was hindered by the financial and time-related barriers.

Due to the lack of funds, it was necessary to focus on process rationalisation consisting in a systematic implementation of group 2 modernisation solutions and, to a limited extent, the provision of new compression and filtration systems from group 3 in order to improve the quality of the process of supply of breathing air for hyperbaric conditions. Modernisation solutions give the possibility of a partial improvement of the process until the financial barrier allowing for the technological leap is overcome. The use of new compression systems may bring us closer towards the fulfilment of quality requirements in the minimum range of $4.5 \cdot \sigma$, which according to tab. 7 corresponds to the process yield at the level of $Y_{Tp} > 99.87\%$ and the number of defects per one million performed analyzes[44] of $DPMO < 1350$.

The Y_{Tp} value is referred to as production cycle yield[45] and constitutes the probability p of an occurrence of an event consisting in the absence of defects $k = 0$ in a considered period of time. To estimate this probability, *Poisson's theoretical distribution* is used, as incidents involving an occurrence of non-compliances are relatively rare and hence considered to be mutually independent.

The *Poisson distribution* is a limit binomial distribution for rare events and takes the form of a formula: $(k, \lambda) = \frac{\lambda^k \cdot e^{-\lambda}}{k!}$, where λ is the expected number of incidents involving a non-compliance, which can be calculated as a frequency probability of $\lambda = 1 - \frac{DPMO}{10^6}$.

In the considered case $\lambda = 0.00135$, and the probability formula can be reduced as follows: $p(k = 0, \lambda) = \frac{\lambda^k \cdot e^{-\lambda}}{k!}\Big|_{k=0} = e^{-\lambda}$.

Such yield $Y_{Tp} \equiv p(k = 0, \lambda)$ will in this case amount to $Y_{Tp} = e^{-0.0013} \cong 0.998$. Quality measurements for the *Six Sigma* method are presented in tab.7

Tab. 7

The share of non-compliances as percentages and parts per million ppm in the function of multiplied factor of normal standard deviations σ.

Standard deviation factor	$DPMO$ non-compliances	Y_{FT} non-compliances
1σ	691462 ppm	31%
2σ	308538 ppm	69.2%
2.5σ	158655 ppm	84.2%
2.8σ	96800 ppm	90.3%
3σ	66807 ppm	93.3%
4σ	6210 ppm	99.4%
4.5σ	1350 ppm	99.87%
5σ	233 ppm	99.977%
6σ	3.4 ppm	99.99966%

RESULTS

The following is a summary of the results of tests on breathing air for hyperbaric purposes carried out in the years 2002-2007. At that time, the breathing air intended for hyperbaric purposes was still different from the established CTQ quality requirements, although as a consequence of the implemented modernisation works a marked improvement was achieved. In fig. 17, the inference based on the standard uncertainty $k = 1$ ($p \cong 0.68$) was assumed, in contrast to fig. 16, where the statistical inference based on the expanded uncertainty $k = 2$ ($p \cong 0.95$) was applied.

The comparison between fig. 16 and fig. 17 shows that the inference based on theoretical normal distribution does not allow to indisputably state that the result from 2007 differs from earlier measurements, as the significance α_0 for this inference is included in the range of $\alpha_0 \in [0.05; 0.32]$ and is too high in relation to the commonly accepted critical value $\alpha_0(kr) < 0.05$.

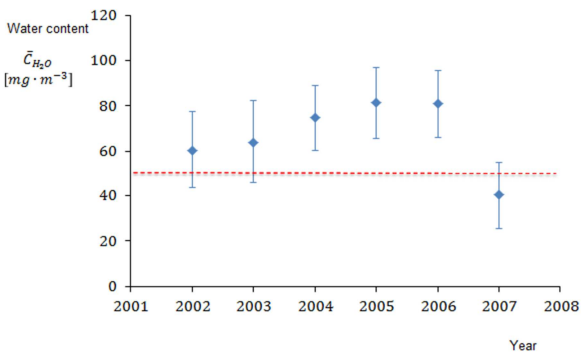

Fig. 16 The diagram of mean values of H_2O content measurements with expanded uncertainty $\bar{C}_{H_2O} \pm \Delta\bar{C}_{H_2O}(k = 2)$ for normal distribution.

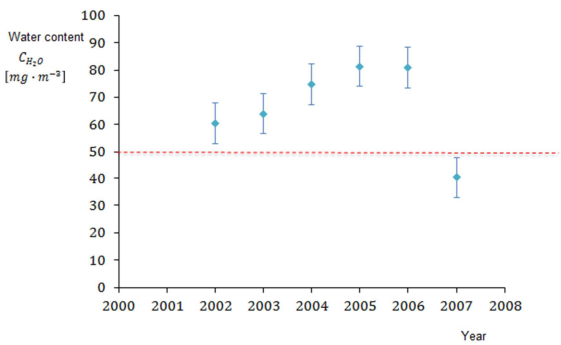

Fig. 17 The diagram of mean values of H_2O content measurements with standard uncertainty $\bar{C}_{H_2O} \pm \Delta\bar{C}_{H_2O}(k = 1)$ for normal distribution..

This is due to the degeneration of data containing a comparable level of random and systematic errors. Systematic variability is related to the different configuration of systems for which the measurement results are averaged. A typical statistical inference for a large sample of $N > 30$ is usually based on a normal distribution. The assumption of normality of distribution comes from the adopted minimisation of systematic variability to at least a lesser order than that of accidental variation, which can be treated as "white noise" with a normal distribution. The proposed inference in the area of a comparable level of an accidental and systematic error can only be carried out if there is enough historical data available making up the practical distribution of the random variable analysed.

INFERENCE

Sets of test results for the content of H_2O in the breathing air until 2006 can be used to create a practical distribution model. The $N = 818$ base of measurement results was collected with regard to the used systems to provide the breathing air for hyperbaric conditions from the years 2002 to 2006. In the inference for the year 2007, in which $n = 119$ measurements were made, for the purposes of the base of historical measurements it is required to select consecutive measurements and calculate their average value.

Then, moving by one measurement, another average value should be calculated. This way we will obtain the following empirical distribution of mean values: $m = N - n - 1 = 698$ – fig. 18. Next, the question was posed how often in the past the mean $\bar{x}_{2007}$ $(n = 119) \cong 0.403\ g \cdot m^{-3}$ occurred that was obtained in 2007 or a lower value. It is possible to observe that it had not occurred at all. Thus, it results that the intuitively observed clear change in 2007 is fully confirmed by the inference based on empirical distribution.

Conducting the above inference did not allow to determine its significance on the basis of the frequency probability p , because the number of cases n of an occurrence of the observed difference in 2007 amounted to $n = 0$. For this reason, the inference was repeated for subsequent quarters of 2007, following the same procedure as before.

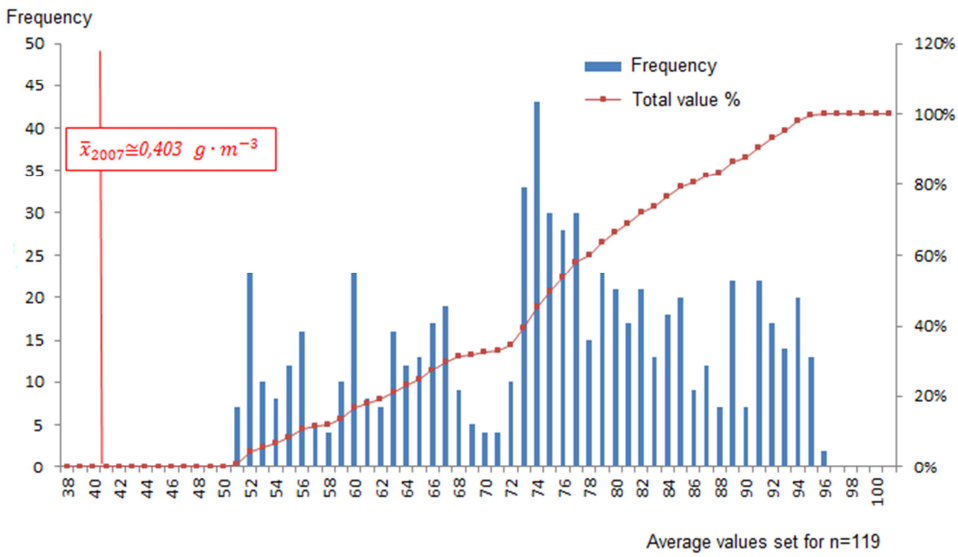

Fig. 18 Histogram of frequency of occurrence of average H_2O measurement values in the years 2002–2006 and the average value in 2007 for $n = 119$ and the average $\bar{x}_{2007}(l = 119) \cong 0.403\ g \cdot m^{-3}$.

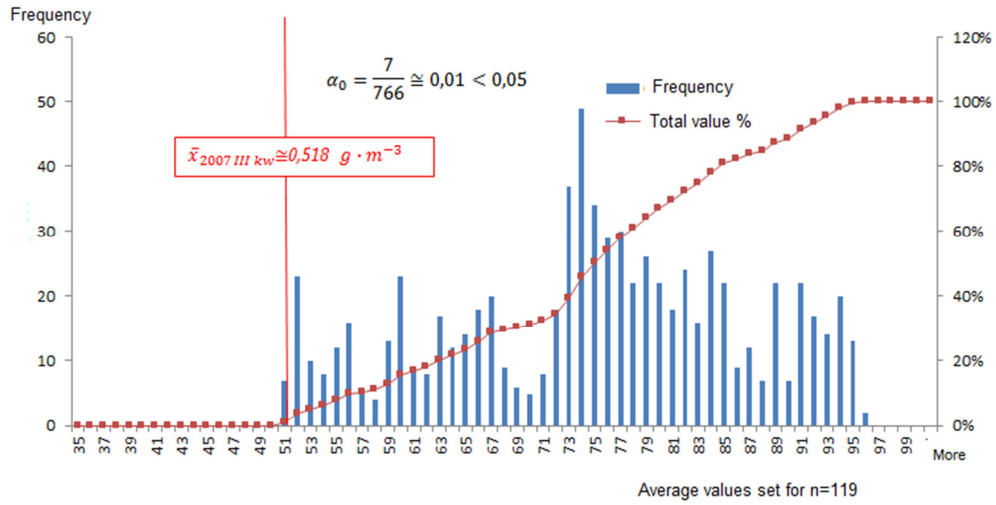

Fig. 19 The histogram of frequency of occurrence of average H_2O measurement values in the years 2002–2006 and for the 3rd quarter of 2017 for n = 27 and the average $\bar{x}_{III\ 2007}(l = 27) \cong 0.518\ g \cdot m^{-3}$

In the 3rd quarter of 2007 the average value $\bar{x}_{III\ 2007}(l = 27) = 0.5183\ g \cdot m^{-3}$ was obtained for the sample with $l = 27$. In the case of a practical distribution with the size of $k = 766$ the result was the same or smaller by $o = 7$ times – fig. 19.

Hence the frequency probability p of an occurrence of the value $\bar{x}_{III\ 2007}(l = 27) = 0.5183\ g \cdot m^{-3}$ amounts to $p = \frac{o}{k} = \frac{7}{766} \cong 0.01$. Assuming that the probability p is statistically average, it is possible to adopt the significance level of the conducted statistical inference of $\alpha_0 \leq 0.01$. Based on a practical distribution for 2007, at the confidence level $\bar{P} > 99\%$, the differentiating effect was observed of actions undertaken in relation to changes in technology towards a clear improvement in meeting the quality requirements CTQ with regard to H_2O content in the breathing air. A similar analysis was carried out in relation to CO_2 content.

The inference based on a practical distribution, as in the case of H_2O content, used the conducted CO_2 measurements. The base of $N = 871$ average measurement results was collected for the operated systems of supply of breathing air for hyperbaric conditions in the years 2002–2006. While performing the inference for 2007 $n = 119$ measurements on CO_2 content were made and an empirical distribution was created with the count of $m = N - n - 1 = 751$ – fig. 20. The frequency of an occurrence of the average value $\bar{x}_{2007}(l = 119) = 0.03\%_v$ or a smaller value was checked in the empirical distribution, from $k = 751$ average values from the practical distribution for a simple sample with the count of $l = 119$. The obtained average value $\bar{x}_{2007}(l = 119) \cong 0.03\%_v$ for 2007 was previously obtained $o = 259$ times – fig. 20. Therefore, the frequency probability p of an occurrence of value $\bar{x}_{2007}(l = 119) = 0.03\%_{v/v}$ is $p = \frac{o}{k} = \frac{259}{751} \cong 0.34$.

Assuming that the probability p is statistically average, it is possible to adopt the significance level of the conducted statistical inference of $\alpha_0 \leq 0.34$. This means that from the statistical point of view there is no reason to believe that in 2007 a statistically significant change was observed with the possibility of making an I error of α_0 type consisting in the rejection of the true zero hypothesis H_0 of the lack of an occurrence of a difference in a simple sample in 2007 in relation to years 2002–2006 at the level $\alpha_0 \leq 0.34$.

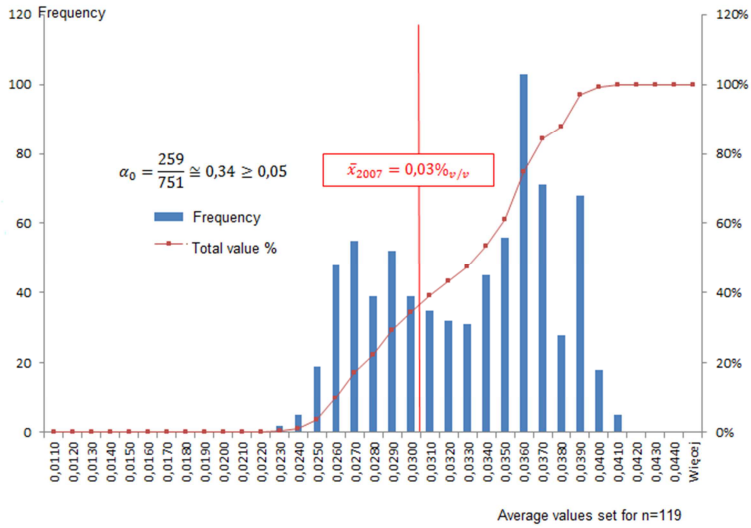

Fig. 20 The histogram of average values of CO_2 measurement values in the years 2002–2006 and the average $\bar{x}_{2007}$ $(l = 119) = 0.03\%_v$.

Based on the practical distribution for 2007, no differentiating effect was noted in relation to the actions undertaken with regard to the changes in technology towards a clear improvement in the fulfilment of quality requirements CTQ regarding CO_2 content in the breathing air approved for hyperbaric conditions, contrary to the content of H_2O.

The conducted statistical inferences for other years and other pollutants did not show a significant change towards ensuring the conditions to meet the quality requirements CTQ at a higher level than in the comparative period. It is only possible to notice a slow, successive improvement towards a better fulfilment of the quality requirements CTQ.

PROCESS CONTROL

The validation process verified the process efficiency and the level of fulfilment of quality requirements CTQ by the product. Fig. 21 presents the distribution of mean values $\bar{x}_{2006-2013}$ of process control measurements with regard to H_2O content in relation to normal distribution with the coverage factor $k = 2$. The reduction of $\bar{C}_{H_2O}$ content in the monitoring phase is of permanent character and the obtained responses of a modernised systems are qualitatively better than in the years 2002–2006. Based on the distribution of mean values $\bar{x}_{2002-2013}$ of measurements two groups of measurements were obtained: group I for years $l \in (2002 - 2006)$ and group II for $l \in (2007 - 2013)$.

As a result of the conducted statistical inference it was previously possible to indicate qualitative changes in H_2O content measurements which occurred in the years 2006–2007. In subsequent years further system improvements took place, which is confirmed by the differences between the observations from years $l \in (2007 - 2008)$ and 2009. Since 2009, the obtained measurement results in the majority of new and modernised systems remain within the limits set by the quality requirements CTQ.

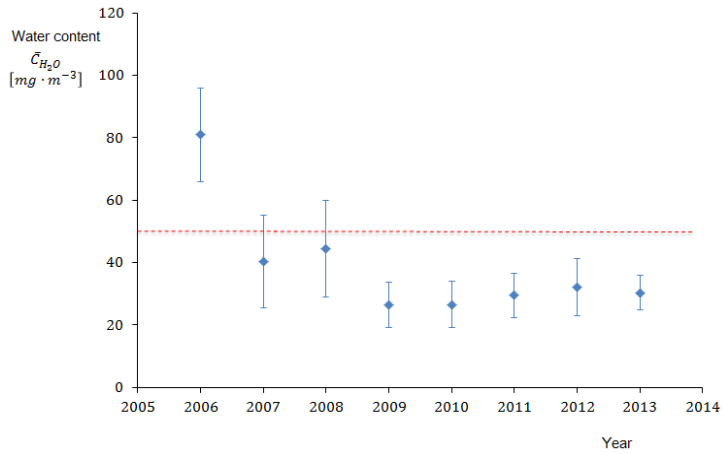

Fig. 21 The diagram of average values of H_2O content measurements with extended uncertainty $\bar{C}_{H_2O} \pm \Delta\bar{C}_{H_2O}(k = 2)$, for the inference based on a normal distribution.

It was assumed that at the current technological level it would be satisfactory to meet the critical quality requirements CTQ in the first attempt Y_{FT}, i.e. with the process yield level of $Y_{FT} \geq 90\%$, which corresponds to approximately $\sigma \cong 2.8$. This level was periodically achieved: $Y_{FT} = 100 - 8.84 \geq 91.16\%$ – fig. 22.

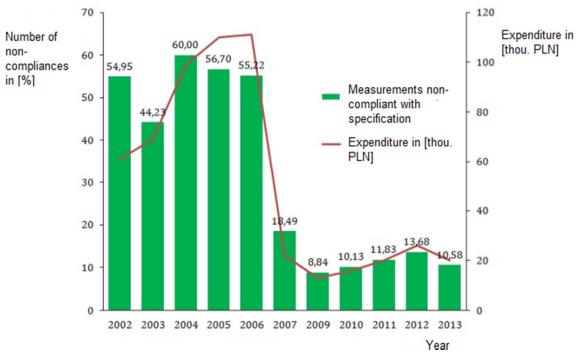

Fig. 22 Number of non-compliances and resources allocated due to the necessity of carrying out a repeated air analysis in the years 2002–2013.

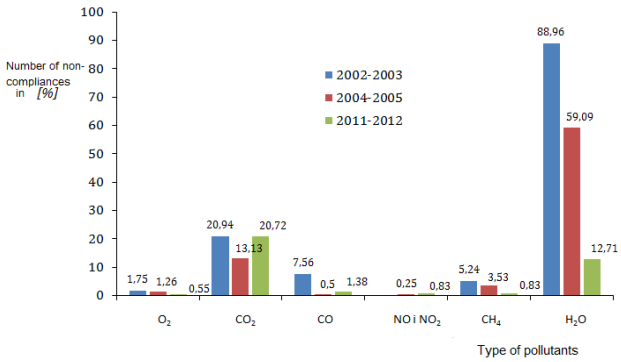

Fig. 23 Changes in the number of non-compliances for particular groups of pollutants with the division into selected periods in the years 2002–2012.

In 2009-2013, the share of non-compliant samples was below $Y_{FT} < 14\%$. The decreasing number of non-compliances resulted in measurable financial savings resulting from the lack of necessity to perform laboratory re-analyses[46] of products. Fig. 23 shows the number of non-compliances regarding the content of particular breathing air pollutants obtained in the years 2002-2013.

The reduction of the number of non-compliances in the content of H_2O was not accompanied by a proportional reduction in the number of defects in CO_2content. This indicates limitations of the currently used technology. Further improvement can only be achieved by its modification.

SUMMARY

In the course of the research and implementation carried out in the years 2002–2017, the achieved capability of the process of production, storage and distribution of breathing air approved for use in hyperbaric conditions in the *Polish Armed Forces* was between $2.5\sigma - 3.0\sigma$ – tab. 7.

It was demonstrated that the implementation of the work objective can be accomplished in an effective way using the methods of the $SixSigma$ approach, with the purpose of diagnosis of the scope of the necessary modernisation at each stage of the works as the basic project task. In the rationalisation of production processes it is assumed to strive towards permanent exceedance of the level of 6σ.

While conducting observations of the process of production, storage and distribution of the breathing air approved for use in hyperbaric conditions in the *Polish Armed Forces*, one can safely conclude that with the current state of the available technology, it is not possible to achieve such a level of process capability for the whole system.

On the other hand, when looking at the technical solutions and descriptions of the technology available on the market, it seems that achieving the process capability of 4.5σ should be within reach provided that sufficient investment funds are available.

FINAL CONCLUSIONS

As a result of the project, important conclusions have been drawn that stand in opposition to the widely accepted beliefs:

1. The current technique and operating conditions do not allow to achieve the capability for production, storage and distribution of the breathing air intended for hyperbaric oxygen conditions higher than 3σ. The history of compression devices, drive motors and typical installations of chemical engineering is long and abounds in revolutionary changes in technology. When looking at systems for the production, storage and distribution of the breathing air for hyperbaric conditions, it is difficult to resist the impression that these devices represent the mainstream of the technical progress. If we were to ask engineers to vote on the level of capability of this process on the basis of an overview of the available technique, a small percentage of them would be sceptical with regard to the thesis that they do not guarantee the capability level of 4.5σ. However, it appears that this is not possible when it comes to the fulfilment of critical quality requirements CTQ or $NATO$ standards. It seems that these requirements have been adopted without sufficient knowledge of the needs and state of technology. It can be safely said that the standards that were in force in Poland before joining $NATO$ were more pragmatic, excluding the fire safety issues.
2. Due to the relatively low capability of the process of production, storage and distribution of breathing air for hyperbaric conditions it is not possible to resign from laboratory quality control.
3. Investing in the modernisation and rotation of obsolete technology does not currently lead to an increase in the capability of the process of production, storage and distribution of

breathing air intended for hyperbaric oxygen conditions.

It seems quite unbelievable that the current stage of equipment rotation and replacement with newer systems does not bring a rapid quality improvement from the point of view of the process of production, storage and distribution of breathing air for hyperbaric purposes in the Polish Armed Forces. Presumably, this is an effect of the scale factor as today's investments constitute a small fraction in relation to the number of devices used.

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[1] Standardisation Agreement – an agreement defining the processes, provisions, conditions concerning common military/technical procedures and equipment,
[2] STANAG 1458 Diving Gas Quality,
[3] STANAG 1372 ADivP-01(B) Allied Guide to Diving Operations,
[4] The context is understood as the systemic environment, i.e. the suprasystem to the system ensuring adequate quality of breathing air,
[5] Critical to Quality,
[6] Statistical Process Control,
[7] D-Define, M-Measure, A-Analyse, I-Improve, C-Control,
[8] Standard Operational Procedures,
[9] S-Strengths/W-Weakness, O-Opportunities, T-Threats,
[10] Quality Function Deployment,
[11] Failure Mode and Effects Analysis,
[12] Statistical Process Control,
[13] Utilisation of selected process control charts and estimation of process capability indicators,
[14] It was decided to refrain from using statistical experiment design methods due to relatively well-known mechanisms and models of changes occurring during the experiments,
[15] Procedure algorithm phase,
[16] Suprasystem,
[17] i.e. the following ten basic conditions: precision, currency, adequacy, compatibility, maintenance-freeness, efficiency, reliability, mobility, experience/SOP, redundancy,
[18] Quality Function Deployment,
[19] Diagnosis is understood as a formulation of conclusions regarding system condition on the basis of examination of processes occurring in it or only of their effects, usually allowing the formulation of prospective recommendations,
[20] Failure Mode and Effects Analysis,
[21] Numerous interactions are expected,
[22] Which in the past posed the majority of problems in the process of ensuring quality of hyperbaric air due to the greatest number of exceedances of CO_2 and H_2O levels in laboratory periodic tests,
[23] SECURUS Bauer System,
[24] Statistical Process Control,
[25] DGT (LCL) – lower tolerance limit. – LCL stands for Lower Control Limit,
[26] GGT (UCL) – upper tolerance limit. – UCL stands for Upper Control Limit,
[27] When the measurement data do not fall within the normal distribution it is required to match them with a different distribution or perform their transformations, e.g. Johnson's, Box-Cox's,
[28] Anderson-Darling test,
[29] Control Chart,
[30] Moving Range – a chart where the range is an absolute value of the difference between two consecutive measurements in neighbouring samples,
[31] Upper control line,
[32] It should be understood that systematic errors have been compensated for, and in the process, it is possible to observe only incidental errors in relation to the applied accuracies of the conducted observations,

[33] Upper warning limit $\geq 2 \cdot \bar{s}$,
[34] If in extremely inefficient processes, the improvement of the C_p index is impossible, actions should be taken to completely change the process, e.g. by replacing the machine,
[35] An improvement of C_{pk} index is usually possible to achieve by operator,
[36] If possible, it is recommended that the value of the C_{pk} index is equal to $C_{pk} > 1.33$. In companies for which product quality is a priority, such as $\mathrm{GM\ lub\ Ford}$, the value of capability indicators should at least be equal to $C_p, C_{pk} > 1.67$,
[37] E.g. after the purchase and installation,
[38] E.g. before the commencement of serial production,
[39] Control indicators after the rejection of two erroneous measurements (operator's mistakes),
[40] Equipment failure,
[41] This does not eliminate the possibility to conduct inference based on theoretical distributions.
[42] Quality measurement in 6σ, i.e. Sigma quality level,
[43] Final Yield,
[44] Defects per million opportunities,
[45] Throughput Yield,
[46] The share of non-compliances may can be considered in the context of over-estimated funds related to the required performance of a re-analysis following system correction.