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Research Article

Evaluation Of The Uncertainty In Determining The Compression Class Of A Compression Knitted Garment

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Abstract

Accurate determination of the compression class is a key factor in ensuring the therapeutic effectiveness and quality of medical-purpose compression knitted garments. However, the reliability of compression class assessment is strongly influenced by measurement errors and uncertainties associated with testing procedures and data processing. This article addresses the problem of evaluating the measurement uncertainty in determining the compression class of compression knitwear. A systematic approach to uncertainty evaluation is proposed in accordance with international metrological requirements. The study is based on experimentally obtained parameters, including extensibility, working extensibility, residual deformation, surface density, and breaking load, which are used to classify compression garments according to standardized criteria. The developed uncertainty evaluation program allows for a comprehensive assessment of the accuracy of test results and enhances the objectivity and reliability of compression class determination. The findings of this study contribute to improving quality control procedures and ensuring compliance of medical compression garments with regulatory and performance standards.

Keywords

Testing, methods, result processing, product, compression class, knitwear, extensibility, breaking load, surface density, uncertainty.

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OCLC – 1368736135

Introduction

Relevance of the study

Studies devoted to the evaluation of the uncertainty of research results concerning the compression class of medical-purpose compression knitted garments are practically absent; therefore, this research topic is relevant.

Purpose of the study

The purpose of this study is to develop a program for evaluating the uncertainty of the results of determining the compression class of medical-purpose compression knitted garments in accordance with international requirements.

Presentation of the main material

The compression class (CC) of highly elastic therapeutic and preventive hosiery products and sleeves is determined based on experimentally obtained values of extensibility, working extensibility, residual deformation, surface density, breaking load, and the requirements specified in the standard [1, Table 6].

The extensibility L_p of a test strip at a gauge length L_0 equal to (100 ± 1)mm, obtained from the elongation scale in millimeters, corresponds to its extensibility expressed as a percentage [1, Clause 6.5.5.1].

At a gauge length equal to (50 ± 1)mm, the extensibility L_p, %, of the test strip is determined by the formula

$$L_p = L_0 C \quad (1)$$

where C is the conversion coefficient for recalculating the gauge length to 100 mm, equal to 2.

The calculation error is $\pm 0.1\%$. The obtained value is rounded to the nearest integer. The actual value of extensibility of elastic products under stretching is taken as the arithmetic mean of the test results of five test strips.

To determine the working extensibility of hosiery products and sleeves, it is necessary to directly measure on the product the length (width) of each of the three controlled sections l_i [1, Figure 2 (a, b)] and, using the size chart provided by the manufacturer, find the corresponding body circumference $(l_{o.t})$. Then, the working extensibility of the product $L_{p.p}$, %, for each of the three controlled sections is calculated by the formula

$$L_{p.p} = \frac{l_{o.t} - l_i}{l_i} \cdot 100 \quad (2)$$

where $l_{o.t}$ is the body circumference, mm; l_i is the corresponding length of the controlled section on the product, mm.

The determination of residual deformation during stretching before and after washing is carried out in accordance with the standard [1, Clauses 6.7.4.1 and 6.7.5.1].

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The load scale of the tensile testing machine is selected so that the breaking strength value of the tested strip falls within the range of 20%–80% of the maximum value of the scale.

The distance between the grips of the tensile testing machine is set to (100 ± 1)mm. For high-extensibility bandages, joint fixation bandages, hosiery products, and sleeves, a distance between the grips of the tensile testing machine of (50 ± 1)mm is allowed, and for fixing tubular mesh bandages—(25 ± 1)mm.

During testing, the lowering speed of the lower grip of the tensile testing machine is set to be constant and equal to 100 mm/min.

The residual deformation L_d, %, is calculated by the formula

$$L_d = \frac{L_2 - L_0}{L_0} \cdot 100 \qquad (3)$$

where L_0 is the gauge length of the test strip, equal to 100 mm; L_2 is the length of the test strip after a 30-minute holding period under load followed by a subsequent 30-minute holding period without load, mm.

The calculation error is ± 0.1 %, and the value is rounded to the nearest integer.

The surface density is determined in accordance with [1, Clauses 6.2.4 and 6.2.5] by weighing each test strip with an error of ± 0.01 g.

The actual surface density PP, g/m^2, is calculated by the formula

$$PP = \frac{m}{lb} \cdot C \qquad (4)$$

where m is the mass of the test strip, g; l is the length of the test strip, mm; b is the width of the test strip, mm; C is the conversion coefficient, equal to 10^6.

The final result is taken as the arithmetic mean of the results of five measurements. The calculation error is ± 0.1 g/m^2. The obtained value is rounded to the nearest integer.

It is advisable to determine the compression class (CC) of the product using a software tool. The simplest implementation of such a program is the one developed by the authors in the Excel environment (Table 1).

Table 1. Program for determining the compression class of the product and their uncertainties

	A	B	C	D	E	F	G	H
1	n = 1	m_i, g	l_i, mm	b_i, mm	PP, g/m^2	x_1, %	x_2, N	x_3, %
2		3,5	101	101	343,1	35	198	133

3	n = 2	3,6	101	102	349,4	38,9	195	130
4	n = 3	3,4	101	100	336,6	42	197	131
5	n = 4	3,6	100	99	363,6	45	196	132
6	n = 5	3,7	102	101	359,2	47,6	195	133
7	x_{cp}	3,56	101,0	100,6	350,4	42	196	132
8	CC =	III	<30 %	<49,0 N	<120 %	$<40 g/m^2$		
9	$a_{1j}=\delta x_{1j}/2$	0,01	1	1	C=10^6	1	1	1
10	$a_{2j}=\delta x_{2j}/2$	0,1	0,1	0,1		0,1	0,1	0,1
11	δx_{3j}	1	1	1		1	1	1
12	$u_A(x_j)$	0,05	0,3	0,5	5	2,2	0,6	0,6
13	$u_B(x_j)$	0,3	0,6	0,6	1,0	0,8	0,8	0,8
14	$u(x_j)$	0,3	0,7	0,8	1,1	2,4	1,0	1,0
15	$c_j=\partial f/\partial x_j$	98,426	3,469	3,483		3,161	0,672	1,000
16	$c_j \cdot u_A(x_j)$	5,019	1,097	1,776		7,015	0,392	0,583
17	$c_j \cdot u_B(x_j)$	0,294	0,648	0,648		0,819	0,819	0,819
18	$r(m, l)=$	0,310	$r(l, b)=$	0,620	$r(m, b)=$	0,231	$r(x_1,x_2)=$	-0,626
19	k=	2,776	$r(m, l)=$	0,565	$r(l, b)=$	1,369	$r(x_2,x_3)=$	0,324

20	r(m, b)=	0,411	$u_{cA}(y_1)$=	5	$u_{cB}(y_1)$=	1,0	r(x_1,x_3)=	0,174
21	$u_s(y_1)$=	6	υ_{eff}=	4	$t_p(\upsilon_{eff})$=	2,776	P=	0,95
22	t(x_1,x_2)=	1,390	t(x_2,x_3)=	0,592	t(x_1,x_3)=	0,306	U(PP)=	15
23		0		0		0	U =	25
24	$u_{sA}(y_1)$=	0	9	$u_{sB}(y_1)$=	0	1,7		
25	$u_s(y_1)$=	0	9	υ_{eff}=	4			
26	Recording of the measurement result, g/m^2			350	±	25	P=	0,95

Depending on the results of comparing the values obtained experimentally with the requirements of the standard [1], a Roman numeral corresponding to the compression class (CC) of the product appears in cell B8 (**Table 1**) in the case of positive comparison results; otherwise, information about the non-compliance of the product with the requirements of standard [1] may appear in cells C8:F8 in the form “<30 %”, “<49.0 N”, “<120 %”, “<40 g/m^2”.

The estimates (arithmetic mean values) of the input quantity, with the number of observations $n_j > 3$, are determined by a well-known formula and are displayed in cells B7:H7.

The program developed by us also makes it possible to automate the process of evaluating accuracy characteristics, in particular, the uncertainty of the measurement results of the mass m, length l, and width b of the strip, the initial length L_0, extensibility, working extensibility L_p, mm, and breaking load, surface density, and ultimately the uncertainty in determining the compression class of the tested product.

The evaluation of the uncertainty of product test results, especially for medical products, is a requirement of the international standard ISO/IEC 17025 [2] and the identical state standard of the Republic of Uzbekistan O‘z DSt ISO/IEC 17025 [3].

The implementation of the listed standard requirements is carried out based on the use of the “Guide to the Expression of Uncertainty in Measurement” (GUM: 1993) [4]. As a rule, these

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requirements cause certain difficulties for laboratory personnel.

Taking these circumstances into account, we developed a program [5–7] for determining the compression class of medical-purpose compression knitted garments and for evaluating the uncertainty of measurement and test results. As a result of further studies of this program, we identified some shortcomings, which mainly consist in certain specified accuracy characteristics and the arrangement of program elements in specific Excel cells.

In order to eliminate these shortcomings, we developed a program that determines the standard uncertainties (SU) of the measurement results m_i, l_i, b_i, working extensibility x_1, breaking load x_2, and extensibility x_3 according to types A and B.

Type B uncertainties were evaluated taking into account: weighing errors (± 0.01 g), measurement errors (± 1%), calculation errors (± 0.1), rounding, as well as errors related to the scale division value of measuring instruments and setups, and the setting of the distance between the grips [1].

The program then calculates the sensitivity coefficients $\partial f/\partial x_j$ and $\partial f/\partial x_L$ (SC) of the output estimate to changes in the input estimates and x_L, the contribution of the standard uncertainties (SU) of the input estimates to the combined standard uncertainties (CSU) of type A and type B, the correlation coefficients (CC) between the input estimates, and evaluates their significance using Student's criteria,

$$t_p\left(\bar{x}_j, \bar{x}_L\right) = \left| \frac{r\left(\bar{x}_j, \bar{x}_L\right)}{\sqrt{1 - r^2\left(\bar{x}_j, \bar{x}_L\right)}} \right| > t_p\left(n-2\right) \quad (5)$$

where $t_p(\bar{x}_j, \bar{x}_L) = t_p(n-2)$ is the quantile of the Student's t-distribution with $(n-2)$ degrees of freedom.

After determining all components of the measurement uncertainty, their combined standard uncertainty $u_s(y)$ is evaluated in accordance with the law of propagation of uncertainty [4].

Next, the coverage factor k (cell B19) and the expanded uncertainties of the measurement results (cell H23) are calculated as

$$U = k \cdot u_s\left(y\right) \quad (6)$$

The coverage factor k is determined as the Student's coefficient for the effective number of degrees of freedom ν_{eff}, calculated using the Welch–Satterthwaite formula,

$$\nu_{\text{eff}} = \left(n-1\right)\left(1 + \frac{u_B^2\left(y\right)}{u_A^2\left(y\right)}\right)^2 \quad (7)$$

Compilation of the uncertainty budget.

For the analysis of the obtained results, they are presented in the form of an uncertainty budget (Table 2), which includes a list of all input quantities, their estimates together with the assigned standard measurement uncertainties,

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sensitivity coefficients and degrees of freedom, the measurement result, the combined standard uncertainty, the effective number of degrees of freedom, the coverage factor, and the expanded uncertainty.

Table 2. Uncertainty budget

Uncertainty Budget								
Quantity (X_i) and its unit	Estimate, x_i	Type of uncer-tainty	Probability distribution	Standard uncertainty (SU, CSU) $u(x_i)$	Degrees of freedom (υ)	Sensitivity coefficient (c_i)	Contribution to uncertainty	
							Abso-lute	%
Input quantity, X_i								
m, g	3,56	Type A	normal	0,05	n-1	98,426	5,019	85
		Type B	uniform	0,3	∞	1	0,294	9
		SU	uniform	0,3			5,027	83
l, mm	101,0	Type A	normal	0,3	n-1	3,469	1,097	4
		Type B	uniform	0,6	∞	1	0,648	45
		SU	normal	0,7			1,274	5
b, mm	100,6	Type A	normal	0,5	n-1	3,483	1,776	11
		Type B	uniform	0,6	∞	1	0,648	45
		SU	normal	0,8			1,891	12
x_1, %	42	Type A	normal	2	n-1	3,161	7,015	62
		Type B	uniform	0,8	∞	1	0,819	23
		SU	normal	2,4			7,063	61
x_2, *N*	196,2	Type A	normal	0,6	n-1	0,672	0,672	1
		Type B	uniform	0,8	∞	1	0,819	23
		SU	normal	1,0			1,059	1
x_3, %	131,8	Type A	normal	0,6	n-1	1	0,583	0,4
		Type B	uniform	0,8	∞	1	0,819	23
		SU	normal	1,0			1,005	1

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Output quantity, Y								
y_1, g/m²	350	Type A	normal	5	4	1	5	37
		Type B	uniform	1,0			1,0	32
		CSU		6			2,776	9
Compression class	III	Type A	normal	9	4		Coverage factor	U
		Type B	uniform	1,7				
		CSU		9			2,776	25

From the analysis of the uncertainty budget, it follows that the combined standard uncertainty in evaluating the compression class and the surface density of the product is mainly (83%) due to the standard uncertainty of measuring the mass of the tested strip.

Conclusion

1. Testing laboratories are recommended to use the program that allows automating the process of quality assessment of medical-purpose compression knitted garments—namely, the determination of their compression class and the uncertainty of test results.
2. In order to improve the quality of compression class determination and reduce the uncertainty of test results, priority should be given to increasing the accuracy of measuring the mass of the tested strip.
3. In accordance with the requirements of standards [2, 3] and the GUM Guide [4], the uncertainty estimates of tests must be indicated in test certificates.

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