MEDICAL TEXTILE EQUIPMENTS FOR CLASS ONE WITH A NON-INVASIVE CHARACTER

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Abstract: *The research work is focused on the CLASS 1 medical textiles like clothes, linen, towel and other medical items for professionals and patients. These medical items are defined by the relevant technical standards and EU requirements. The requirements for the textile fabrics in the healthcare sector are determined in terms of the end use according to its purpose and usage. Basic requirements for medical items are specified in Government Regulation of the Czech Republic no. 268/2014 Coll. [1], which determines technical requirements for medical items in accordance with European Directive 93/42/EEC. This directive specifies the basic parameters of these products from the point of view of their safety and lays down classification of medical devices into classes' I-III according to the risk of use. The theme of this research is to show the characteristics of medical textiles products under Class I. Products in this class present a low risk of use from the point of view of the user's health. These are mostly non-sterile, non-invasive products that are not subject to the pre-market approval process. On the basis of a survey of the Czech market, these products are used as textile products in healthcare, rehabilitation, spa and after-care and long-term care facilities. Based on the findings and information, it is apparent from the point of view of the material composition what kind of the fabrics is commonly used in these facilities. The material composition of 36.9% of the total products consumed consist of 100% Cotton (CO) in mercerized treatment, 24.1% of the material was made of 100% Polyester (PES), material composition 65% PES / 35% CO is represented by 20.2% of products, material composition 50% PES / 50% CO is represented by 16.7% of products from offered assortment, other types of material composition and use of special fibers is represented in the assortment of medical products of Czech suppliers only Marginal 2.1% of products. It is clear that there is a need for research and development of new types of textiles in mixtures with new, functional fibers in order to achieve the special utility properties of the products. One of the key objectives was to find a suitable solution for achieving the special utility properties of the fabrics for the manufacture of medical items according to their purpose and usage. The utility value of these items are then defined in terms of the useful properties like vapour resistance, antibacterial treatment, active protection of the health of workers in the environment affected by infectious and toxic influences, better user comfort of employees and clients in terms of improvement of personal feelings and work performance, and economic product relations and easy maintenance of products with respect to environmental protection. In the field of health care, the thermo-physiological properties of clothing and the characteristics of air transport, water vapour and moisture are an essential component of comfort. Secondly, the feeling of comfort is influenced by a good make of clothing, a practical and aesthetic design. Requirements for properties are governed by ČSN P ENV 14 237 "Textiles in Health Care". This standard defines the basic properties and methods of textile testing for health care to ensure the suitability of the product for the intended use. It sets minimum requirements to meet acceptable usability.*

Keywords: *medical textiles, utility properties, comfort.*

1 HEALTHCARE TEXTILES

On the basis of a survey of the Czech market, information was obtained on the textile products used in health care, rehabilitation, spa and after-care and long-term care facilities [2]. Each of these environments has its own specifics that govern the use of personal and patient clothing, bedding and medical devices with an emphasis on minimizing health security risks.

From a view of material composition, it has been found that, in these facilities are used fabrics where:

- The material composition of 100% CO in sanforized or mercerized treatment is represented by 36.9% of products from the offered assortment of Czech manufacturers.
- The material composition of 100% PES is represented in 24.1% of the products from the offer of Czech manufacturers.
- The material composition 65% PES / 35% CO represents 20.2% of products from the offered range of Czech suppliers,

- The material composition of 50% PES / 50% CO represents 16.7% of the products from the offered assortment.
- Other types of material composition and use of special fibers are only 2.1% of products in the range of Czech products [2].

From the above, there is a need for application research and development of new types of textiles in mixtures with new, functional fibers in order to achieve the special utility properties of the products. The object of the invention is therefore the textile fabrics for the production of professional and patient clothes, bed linen, towels, drapes and other textile medical devices whose requirements for utility properties are defined by legislation and other technical standards. The aim of the solution is to achieve the special utility properties of the fabrics for the production of medical devices according to their purpose and use.

1.1 Basic requirements for medical textiles and devices

The basic requirements for medical devices are laid down in Government Decree No. 268/2014 Coll., laying down technical requirements for medical devices in accordance with Directive 93/42/EEC [1]. It specifies the basic parameters of these products from the point of view of their safety and lists the classification rules for the inclusion of medical devices in classes according to the risk of use. Class I presents a low risk of use from the point of view of the user's health safety. These products are mostly non-sterile, non-invasive, not subject to the pre-market approval process. For Class I medical devices (sterile) and for all Class IIa, IIb, III devices, the Authorized Person is required to participate in the conformity assessment. For the class I medical devices (non-sterile), the manufacturer carries out the conformity assessment itself without the participation of an authorized person.

The aim of the solution is to achieve the special utility properties of the textile fabrics for the manufacture of medical devices according to the purpose and the method of use by using:

- sophisticated intelligent fiber blends,
- special yarns,
- improved textile and clothing technology.

2 TEXTILES FABRIC IN HEALTHCARE

The requirements for the textile fabrics in the health sector are determined with regard to the end use of the product according to the:

- purpose of use,
- type of usage.

The purpose of the application characterizes the function of the product in the set of medical devices used in terms of its determination due to its interaction with the human organism and the environment (first layer, second layer of clothing). Method of use is defined by the terms of use due to the characteristics of the user's working environment and separated products at once and repeatedly used [3].

The set of utility properties of the fabric is divided according to the following scheme into properties characterizing the user's requirements in terms of

- clothing comfort,
- the appearance,
- durability,
- functional protection.

The set of these requirements is a criterion of quality of a product that is controlled by both the manufacturer and the customer by measuring output properties according to the valid standards.

3 COMFORT FEATURES

Comfort is defined as the state of the organism where all physiological functions are optimal [4]. In the field of health care, the thermos-physiological properties of clothing and the characteristics of air permeability, water vapor and moisture transports are an essential component of comfort. If these properties are not consistent, there is a disturbing perception of clothing comfort. For a feeling of comfort are also important others utility properties as of the hand touch of fabric from the mechanical-comfort viewpoint the THV (Total Hand Value) and heat capacity and thermal conductivity of fabrics represented by the effusivity.

Many factors influence the comfort of clothing from yarn properties to structure of fabric and there are multiple methods how to measure the comfort objectively [5-8]. Last but not least, the feeling of comfort is influenced by the good fitting of garments and a practical and aesthetic design [9]. The medical environment places specific requirements on clothing and textiles. Apparel must be suitable in a relatively warm environment, but at the same time it must cover the skin and avoid contamination of the clean, sterile environment with the human organism, through skin bacterial flora, skin and hair scalp.

3.1 Selected utility properties and other specification

Clothes and generally textiles for use in healthcare are tested for user comfort using the methods they list see Table 1.

Table 1 Selected methods for determining the functional properties of garment comfort [9]

FUNCTIONAL PROPERTIES OF CLOTHING COMFORT	
Utility property	**Air permeability**
Method of determination	ČSN EN ISO 9237- Determination of the permeability of fabrics to air
Measuring equipment	SDL M021S
Result	Speed of air flow
Physical unit	$mm.s^{-1}$
Utility property	**Thermal resistance**
Method of determination	ISO 11092:2014 Physiological effects - Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test)
Measuring equipment	SGHP 8.2 Skin Model
Result	Thermal resistance - Rct
Physical unit	$m^2.K.W^{-1}$
Utility property	**Resistance to water vapour**
Method of determination	ISO 11092:2014 Physiological effects - Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hotplate test)
Measuring equipment	SGHP 8.2 Skin Model
Result	Resistance to water vapour - Ret
Physical unit	$m^2.Pa.W^{-1}$
Utility property	**Thermal conductivity, thermal effusivity**
Method of determination	ASTM D7984 - 16 Standard Test Method for Measurement of Thermal Effusivity of Fabrics Using a Modified Transient Plane Source (MTPS) Instrument
Measuring equipment	FOX 314, TCi
Result	Coefficient of thermal conductivity, thermal effusivity
Physical unit	$W.m^{-1}.K^{-1}$, $W^2.s.m^{-4}K^{-2}$
Utility property	**THV-Total Hand Value**
Method of determination	Internal regulation IP KOD 01-2004
Measuring equipment	Kawabata system
Result	HV, THV
Physical unit	Degree [-]
Utility property	**Integral transport of moisture**
Method of determination	AATCC 195-2011 Liquid Moisture Management Properties of Textile Fabrics
Measuring equipment	MMT - Moisture management tester
Result	Wetting time [s], Absorption [%/s], Maximum wetting radius [mm],Textile solution spreading rate [mm/s], OWTC [%] - The cumulative unidirectional fluid transmission index, OMMC -Index overall indicator of moisture management fabric

3.2 Functional characteristics of medical protective clothing and equipment

The functional and protective properties of medical clothing include the bacteriostatic efficacy of clothing and reduced flammability. Both protective properties can be achieved by:

- special treatments applied,
- addition of fibers with a special function to the material composition.

3.3 Lifetime of medical clothing and equipment

The lifespan of the garment is characterized by the use time which has not resulted in any limitations on the durability of the wear properties. In the case of textile products in the health sector, the lifetime is measured by the number of washing maintenance cycles which are usually performed after one-day use. In Czech health care, the use time of 100 to 150 maintenance cycles is generally recognized until the removal of work clothes. This represents approximately 800 to 1200 hours of wearing [10].

On the basis of a current statistical data and a survey of the needs of the health sector, a consumption of textile fabrics of Class I (non-sterile) in the following years was estimated (see Table 2) [9].

Table 2 Estimation of the volume of textiles for healthcare in the Czech Republic, assuming the durability of 150 washing cycles and daily change of laundry [9]

VOLUMES OF FLAT TEXTILES FOR HEALTH CARE AND AFTER-CARE		
User	**Assortment Kind**	**Estimation of the volume of textiles [m^2/year]**
Patients	Beddings	2 072 596
	Apparel for patient examination	212 130
	Garments for a patients	20 039 010
Dressed for a medical professionals	Clothes	2 229 776
	Other garments	1 114 888
Total together		25 668 400

3.4 Durability properties of medical clothing

Durability properties include tensile strength, seam strength, abrasion resistance, but also a change in dimensions after washing and ironing. The Table 3 presents an overview of evaluation methods and their characteristics.

3.5 Selected utility properties for health protection

Table 4 provides an overview of laboratory methods by which healthcare products can be tested for flame retardancy and bacteriostatic effectiveness.

Table 3 Methods of determination of selected durable utility properties [9]

DURABILITY	
Utility property	**Determination of tensile strength and elongation**
Method of determination	ČSN EN 29073-3
Measuring equipment	Dynamometer LabTest 2.050
Result	Maximum force and elongation
Physical unit	N, %
Utility property	**Seam tensile properties of fabrics**
Method of determination	ČSN EN ISO 13935-1,2
Measuring equipment	Dynamometr LabTest 2.050
Result	Maximum force and elongation
Physical unit	N, %
Utility property	**Determination of the abrasion resistance of fabrics by the Martindale method**
Method of determination	ČSN EN ISO 12947
Measuring equipment	SDL M235 Martindale
Result	Number of cycles to abrasion
Physical unit	Number of cycles
Utility property	**Determination of dimensional change in washing and drying**
Method of determination	ČSN EN ISO 5077
Measuring equipment	Laboratory washing machine
Result	Dimensional change in the longitudinal and transverse directions
Physical unit	%

Table 4 Methods of determination of selected protective utility properties [9]

PROTECTIVE PROPERTIES	
Utility property	**Burning behavior of textile fabrics**
Method of determination	ČSN EN ISO 6940 - Burning behaviour - Determination of ease of ignition of vertically oriented specimens
Measuring equipment	SDL Atlas M233M
Result	Length, firing rate
Physical unit	s, $mm.s^{-1}$
Utility property	**Inflammability - ignition source by the smouldering cigarette**
Method of determination	ČSN EN 1021-1, 2 Furniture. Assessment of the ignitability of upholstered furniture. Ignition source smouldering cigarette
Measuring equipment	SDL Atlas M233P1
Result	Ignition time
Physical unit	s
Utility property	**Antimicrobial efficacy**
Method of determination	ČSN EN ISO 20645 - Textile fabrics - Determination of antibacterial activity - Agar diffusion plate test
Measuring equipment	Petri dish, climatic chamber
Result	Number of bacteria colonies
Physical unit	Verbal description, number
Utility property	**Antimicrobial efficacy**
Method of determination	AATCC Test Method: 147-2004 - Antibacterial Activity Assessment of Textile materials: Parallel Streak Method
Measuring equipment	Petri dish, climatic chamber
Result	Number of bacteria colonies
Physical unit	Verbal description, number
Utility property	**Antimicrobial efficacy**
Method of determination	AATCC Test Method: 100-2004 - Antibacterial Finishes on Textile Materials: Assessment of
Measuring equipment	Petri dish, climatic chamber
Result	Reduction of bacteria
Physical unit	%
Utility property	**Antimicrobial efficacy**
Method of determination	ČSN EN ISO 20743 - Textiles - Determination of antibacterial activity of textile products
Measuring equipment	Petri dish, climatic chamber
Result	Antimicrobial efficacy
Physical unit	Number of CFU bacteria
Utility property	**Antimicrobial efficacy**
Method of determination	ASTM E 2149 – Standard Test Method for Determining the Antimicrobial Activity of Immobilized Antimicrobial Agents Under Dynamic Contact Condition
Measuring equipment	Laboratory shaker
Result	Bacterial reduction
Physical unit	%

4 MATERIALS, METHODS AND ANALYSIS

Standard ČSN P CEN/TS 14 237 "Textiles for healthcare and social services facilities" distinguishes the requirements in terms of described utility properties for two-use textile fabrics [11].

- Bedding
- Clothes

Based on those requirements, a selection was recommended for the design of the final product.

- Fibers and mixtures
- Mixed yarns
- Production textile technology
- Special finishing

4.1 Advised methods for evaluation comfort

Some of basic advised methods for an evaluation of comfort of garments, which are connected to a physiological comfort, are listed up in the Table 1. All of these properties and methods for their evaluation have a direct connection to a comfort of garments. Some of selected of them which are the most important were chosen (see list below).

- MMT - Moisture Management Tester. A method to characterize fabric properties in multi-dimensions liquid transfer.
- Thermography - for a tracking and recording of speed and an area of a liquid spreading in the textile surface can be used the thermal imaging techniques.
- SGHP - Skin model - for an evaluation a heat and water vapour resistance.
- Kawabata system KES – for an objective measurements of hand properties.
- C-Therm Tci – for an objective evaluation of thermal effusivity.

Other advised method for determine an important property of textile material used in medical textiles is 3D scan of porosity of textile materials by using a μCT system like is device SkyScan 1174.

Porosity represents one of the basic parameters of textile fabrics, which significantly affects air permeability and thus the overall physiological comfort of garment [12].

Table 5 Suggested threads, yarns, finishes and properties for a medical textiles used as a beddings [9]

Bedding			Utility properties
Component	**Commercial name**	**Default polymer, reagent**	**Comfort / Health / Safety / Durability**
Threads	Trevon	PP	thermo/ antimicrobial/ reduced flammability / excellent
	Lenzing FR	regenerated cellulose	touch feeling / - / reduced flammability / good
	Dante	regenerated cellulose	touch feeling / - / reduced flammability / good
Yarn	Tepar	PP	thermos / - / reduced flammability / excellent
Finish	Proban	crosslinking agents on the basis of phosphorus compounds using the synergism of nitrogen	- / non-toxic / reduced flammability / good
	Spolapret OS	crosslinking agents on the basis of phosphorus compounds using the synergism of nitrogen	- / non-toxic / reduced flammability / good

Table 6 Suggested threads, yarns, finishes and properties for a medical textiles used as a garments [9]

Garments			Utility properties
Component	**Commercial name**	**Default polymer, reagent**	**Comfort/Health/Safety/Durability**
Threads	Tencel C	regenerated cellulose	touch felling, hydrophilic / hemostatic support healing / antimicrobial / good
	Tencel	regenerated cellulose	touch felling, low friction coefficient, hydrophilic / healing support / - / good
	Sea-Cell	regenerated cellulose	touch felling, hydrophilic / healing support / - / good
	Trevira Bioactive	man-made, PES	- / - / antimicrobial / excellent
	Prolen	man-made , PP	- / - / antimicrobial / excellent
	Siltex	man-made, PP	- / - / antimicrobial / excellent
	Trevon	man-made, PP	- / - / antimicrobial / excellent
Yarn	Coolmax fresh FX	man-made, PES	thermal insulation / - / antimicrobial / excellent
	Tepar	man-made, PES	thermal insulation / - / antimicrobial, flame-retardant / excellent
	Climawell	man-made, PP	thermal insulation / - / antimicrobial / excellent
	Bio Silver	man-made, PP	thermal insulation / - / antimicrobial / excellent
	Multitech	man-made, PA	touch felling, softness / - / antimicrobial / excellent
	Lenzing Modal	regenerated cellulose	touch felling / hemostatic / antibacterial hemostatic / good
	Lenzing Promodal	regenerated cellulose	touch / support healing / - / good
Finish	SANITIZED® SILVER	ionty Ag	- / support healing / antibacterial / good
	NBK SANLIC		- / support healing / antibacterial / good

4.2 Required utility properties of medical textiles

From the point of view of the use value of the bedding, the components according to Table 5 can be considered as an optimal option for ensuring protection, comfort and durability.

From the point of view of utility value of the healthcare clothing, the components according to Table 6 can be considered as an optimal variant for ensuring protection, comfort and durability.

As is shown in the tables above, the recommended bedding properties include the protective function of reduced flammability, comfort, durability and health promotion. Recommended utility properties for a patients and medical workwear which are preferred for them is a protective function antimicrobial and bacteriostatic and also a comfort and durability properties of clothing.

5 CONCLUSION

The design of textile fabrics for healthcare according to purpose and usage is based on the legal requirements for application in terms of their protective, comfortable and durable function. The estimated consumption of different types of medical textiles in the next years in the Czech Republic at the level of 25 million m^2 of a textile per year clearly demonstrates the importance and necessity of research in this area of the textile industry.

Work activities in the health sector have a risk character. There are many biological, chemical, cytostatic and other factors that can negatively affect employee health and cause occupational disease.

To ensure better properties of medical devices and to achieve antibacterial, anti-inflammatory, thermoregulatory and other active functions, new fibers have been identified. These new fibers and yarns made are the main bearers of the desired functions in designing fabrics with a prognosis of expected utility properties. The resulting mixed functional yarns are thus output from the first phase of the fiber processing into the fabric. Depending on the type of yarn used and the yarn construction, special functional properties of the sheet can be achieved, which are then evaluated according to selected methods for assessing the physiological comfort during their use, especially the most important utility properties - the evaporation resistance *Ret*. The required bedding properties are defined by ČSN P CEN/TS 14 237 "Textiles for healthcare and social services facilities", where the resistance value for water vapor $Ret \leq 6$ [m^2.Pa.W^{-1}] is also recommended. Therefore, the result from the evaluation of the vapour resistance is strongly recommended to carry out by a various methods which are advised in this paper. Suggested threads, yarns, finishes and properties for used as medical textiles for garments and also for beddings are a part of results of this article. Water vapour resistance depends mainly on the structure of the fabric influenced by the yarn construction and the technology used by in a fabric production. The result also affects the finishing of the fabric, which can significantly change this utility property.

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