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IMPROVING THE QUALITY OF NONWOVEN MATERIALS MANUFACTURING BASED ON ANALYSIS OF ITS WATER PERMEABILITY

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Abstract: Composite nonwoven materials such as polypropylene are widely used for medical purposes due to their unique properties. During the production process, polymer fibers are created using multiple extruders; the material is formed from a web of polypropylene fibers bonded together by cooling and rolling out between cylinders. The production process is often unreliable; hence properties such as water resistance vary across the length of the composite. The nonwovens are often used to manufacture medical attire, which further needs to be sterilized, and in order to choose the optimal method, one needs to know the cloth's water resistance. The aim of the study was to investigate the statistical distribution of permeability in composite nonwovens and its relevance to business decisions. Investigation was performed on multiple samples at different stages of production. It was found that water resistance is strictly correlated with the quality of the material and is increased in the sterilization process. The statistical analysis of water resistance in nonwoven material, both raw and processed, can be used by medical manufacturers in order to optimize costs in the production process.

Keywords: composite nonwoven materials, water resistance distribution, spunbonded–meltblown technology.

1 Introduction

Composite nonwoven materials such as polypropylene are widely used for medical purposes due to their unique properties. The materials are manufactured in large quantities; technological lines are automated and produce thousands of meters of material per minute. When production lines are not managed properly, the quality of material suffers. During the production process, polymer fibers are created using multiple extruders; the material is formed from a web of polypropylene fibers bonded together by cooling and rolling out between cylinders.

The production process is often unreliable; hence, properties such as water resistance vary across the length of the composite. The nonwovens are often used to manufacture medical attire, which further needs to be sterilized, and in order to choose the optimal method, one needs to know the cloth's water resistance. The biggest nonwovens manufacturer used to have a 55% market share. Due to bad quality monitoring procedures, the company did not know the exact quality of the material. The production lines were poorly adjusted, but the quality control conducted by the company did not show any problems. The customers, manufacturers of medical attire, found out on their own that the material did not meet the required standards, and because of that, in a span of three years, the company's market share went down to 30%.

The aim of the study was to investigate the statistical distribution of permeability in composite nonwovens and its relevance to business decisions. Investigation was performed on multiple samples at different stages of production. It was found that water resistance is strictly correlated with the quality of the material and is increased in the sterilization process.

The statistical analysis of water resistance in nonwoven material, both raw and processed, can be used by medical manufacturers in order to optimize costs in the production process.

2 Literature analysis

Composite nonwovens have received much attention in recent years due to their characteristics, like absorbency, elasticity, durability, protection, permeability, and ability to create multifunctional products.

Due to their low production costs and easy production process, they have become important for many industries. Among other things, they can be used in medicine to protect medical personnel from exposure to biological hazards and shield different products from contamination by humans.

Medical products, such as operating room gowns, aprons, surgical masks, head covers, shoe covers and such like, protect doctors and patients from infections. They provide a barrier that transmits water vapor and, at the same time, is fluid impermeable, which should not be underestimated during medical procedures [3].

Nonwoven materials are produced by combining different types of materials such as polymers, glass fibers, wood, paper and cotton. Materials for surgical purposes are made in spunbonded-meltblown processes where polyethylene or polypropylene is melted and formed into yarns. In the spunbond process, relatively thick and long spun yarns are produced from granulated polyethylene. In the meltblown process, the polymer is melted into very thin short fibers, which are blown against the moving surface (collector screen) and create a web. The spunbond-meltblown-spunbown (SMS) is a composite material, which is bonded together and sealed by callenders. Spun fibers are evenly distributed in the material, which accounts for its strength.

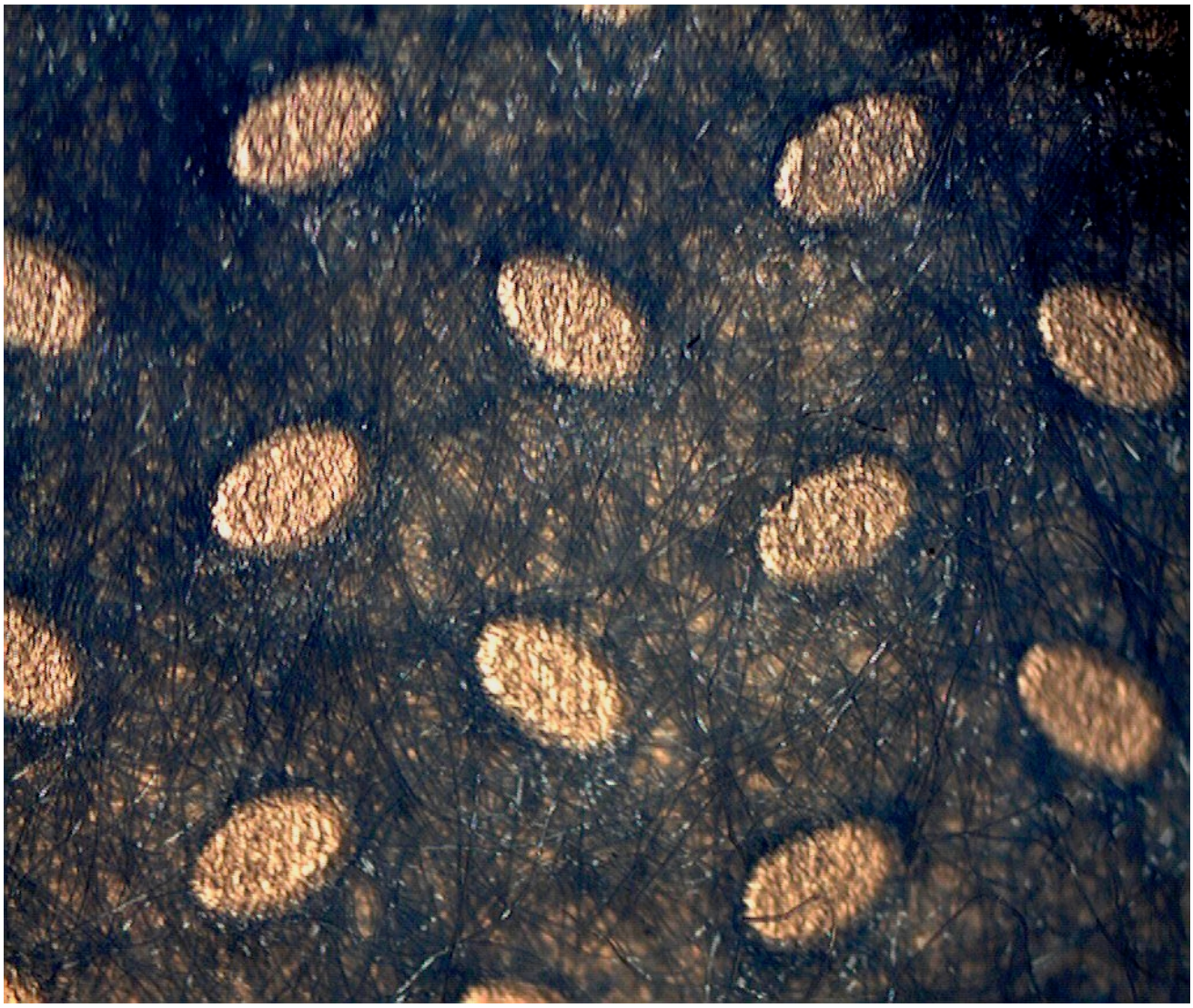

Figure 1. Surface view of nonwoven polypropylene material
(*source:* Authors' own research. Lens: Z20 x 100. Photograph taken by Sławomir Pilarczyk)

Through using thin melted fibers, a material gains good absorption, filtration efficiency, water resistance, and thermal insulation. Such a material varies significantly in its thickness because the fibers are distributed unevenly [8].

In Fig. 1, in the foreground, thick spun fibers can be observed. In the background, thin melted fibers create a thick web. Both materials are heat-sealed in the oval dots. The material density affects many nonwoven properties like water permeability, which is the most important feature that allows the possibility of nonwovens' medical use.

According to the mathematical models, the water permeability in nonwoven materials is strictly dependent on fiber density and orientation [4, 5, 6 and 7]. In industrial practice, the European standard EN 13795 [2] defines requirements for medical products. In accordance with this standard, water permeability must be tested according to the EN 20811 standard [1], which specifies a hydrostatic pressure method for determining the resistance of fabrics to penetration by water. During the test, water pressure is increased over the fabric specimen at the rate of 6 m H_2O/h (100 mm H_2O/min) until water leaks through the material in three places.

The water height (an estimator of pressure) at which the third water drop appears determines the water resistance of nonwoven material. Water pressure tests are applied both to raw material and to ready-made, sterilized products. Nonwoven raw materials manufacturers determine the water resistance of their products so that customers can compare materials' properties. Medical products manufacturers are obliged to perform water permeability tests before introducing their products to the market. According to the EN 13795 [2], non-invasive products classified as "Class I", like surgical gowns, drapes and clean air suits, must meet strict requirements; the fabric after sterilization must withstand water pressure of more than 0.002 MPa (200 mm H2O).

According to the EN 20811 standard [1], water permeability test reports must include, among other things, individual results and their mean. However, although the aforementioned standard permits using the mean value of water permeability to assess the nonwoven material, it was found that, due to the thickness irregularity, the water resistance could not be accepted for the sterilized medical products.

The EN 13795 standard [2] defines areas of varying validity; the chest and sleeves are considered critical, while the other parts are considered less important. If the thinner part of the material appears in the critical area, it might threaten the safety of patients and healthcare professionals.

The paper presents a method of evaluation of nonwoven materials, taking into account its statistical significance. The aim of the study was to investigate the statistical distribution of permeability in composite nonwovens and its relevance to business decisions. Investigation was performed on multiple samples at different stages of production. It was found that water resistance is strictly correlated with the quality of the material and is increased in the sterilization process. The statistical analysis of water resistance in nonwoven material, both raw and processed, can be used by medical manufacturers in order to optimize costs in the production process.

3 Methodology

Nonwovens production lines produce from 10,000 to 20,000 Mg of material per year (9 – 21 Mg/production shift). The output varies depending on the fabric weight, thickness, and width (from 3.2 m to 5.4 m). Depending on the type of the material (spunbond, meltblown, or SMS), the production speed varies from 38,000 to 86,000 m^2/h (200 to 450 m^2/min). This implies, during the analysis of data describing the characteristics of the raw material and finished products, the possibility and necessity of applying the law of large numbers and using simulation statistics methods. Of great importance, taking into account the production speed, is maintaining a stable production process and obtaining a product of reproducible quality.

The raw material coming from the production process, an SMS nonwoven fabric, is quasi-uniform, reproducible, and continuous; however, it may be thinner or thicker, sparser or more compact. Its weight may be easily checked, so manufacturers keep a tight grip on it; however, they claim that the weight may vary by ±5%.

Material density strictly depends on the production process and affects water permeability, and its assessment is more difficult. Taking into account the weight variability, the other physical properties may also vary. Water permeability may be used as an indicator of production process and material quality.

The raw nonwoven material from which the surgical gowns are sewn are delivered with required certificates issued by a certified laboratory. The water permeability reported by the laboratory is an average value of tested material samples.

Nevertheless, the surgical gown manufacturers decided to test the material on their own. The aim of these tests was to confirm whether the material really meets the EN 20811 standard requirements [1].

In Fig. 2, the water permeability of a piece (1.6 m x 4.3 m) of raw nonwoven material is presented. The sample was cut into 90 equal pieces of 0.26 m x 0.29 m. Each piece of the material was tested according to EN 20811 standard; samples marked in red are below the requirements [1].

When the machines are worn out, one side of the material may be worse; also, due to the production line characteristics, the fiber properties are different along the material.

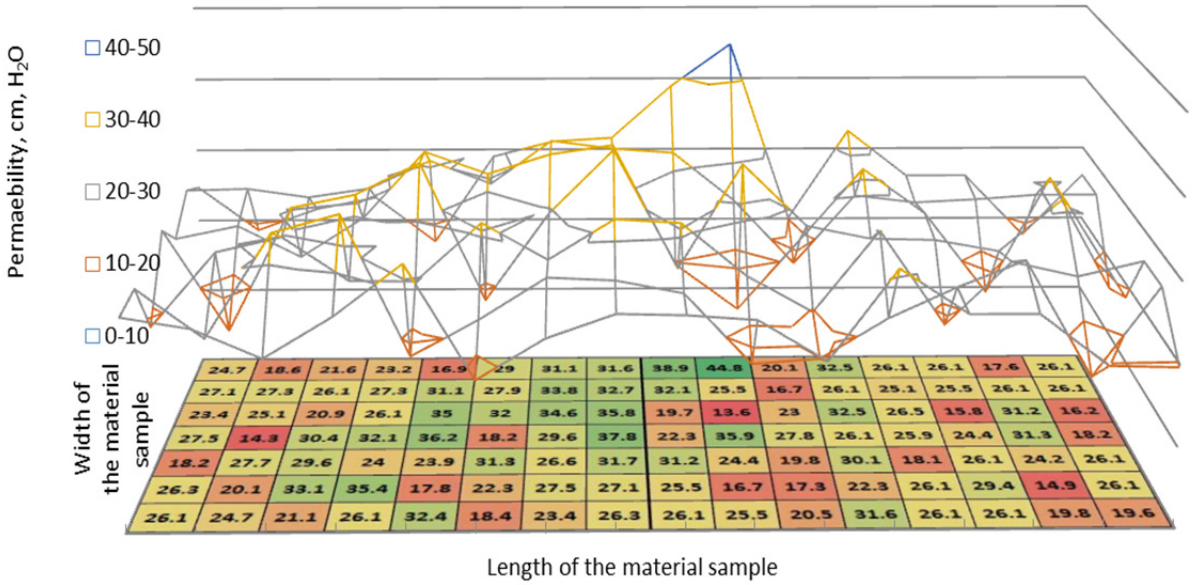

Figure 2. Water permeability of raw nonwoven material
(*source:* Authors' own research)

Nonwoven attire customers are interested in hermetic clothes, especially taking into account the critical areas. Each specific surgical gown must meet the hermeticity requirements, a feature that is very important for them. One surgical gown is made from 4 m^2 of raw material, that is, from 0.0002% to 0.0004% of one production shift. The water permeability of ready-made nonwoven products may also be tested.

The tests are performed with non-sterilized and sterilized products. In this connection, a few problems may be introduced:

- How many material samples should be taken to ensure the representativeness of the measurement?
- How should the stability of the production process where the water permeability is both a critical parameter and an unobserved variable be assessed? It is impossible to test all the material be-

cause, during water permeability tests, the samples are damaged?

- How should the water permeability fluctuations recorded during the tests of the material samples be described and interpreted?
- How should the water permeability risk level that permits manufacturers to bring the nonwoven material to the market be evaluated and determined?
- How should the impact of the sterilization process on the water permeability be evaluated?

For ready-made products the minimum effective measuring unit is one product; for instance, one surgical gown, which, from the customers' point of view, is the minimal testing unit. Each product has a strictly defined critical area (acc. to EN 13795 [2]), which corresponds to the potential risk of a lack of hermeticity. The tested specimens are derived from that area.

The number of samples taken from the minimal effective measuring unit is a maximum effective number of units. The critical area of the surgical gown allows one to take 24 material samples with dimensions of about 0.2 x 0.3 m. The minimal risk level corresponds to one testing sample that does not meet the EN 13795 standard requirements [2]; 1 out of 24 specimens implies a 4.2% risk of permeability loss.

4 Results

To build the water permeability distribution, it is required to take at least three minimum effective units. That means 72 samples. When needed, the number of samples may be increased by more units (with 24 samples per unit). Sampling must allow identification of the places from where the specimens were taken; the aim is to evaluate the fluctuations of the production process.

The distribution range must be wide enough to ensure its continuity. At least one observation must fall into one interval. In the lower part of the distribution, the number of observations must allow the efficient identification of the risk of water permeability loss. If the distribution intervals are too wide, they will cover too many water permeability results and identification may be impossible. Similarly, too wide intervals imply distribution gaps, which make it impossible to evaluate the risk.

Construction of the distribution requires the preparation of a simulation algorithm based on a simulation starting point and a measurement step that determines interval width and uniquely assigns individual test results to the relevant permeability intervals. Using the algorithm, the distributions for non-sterilized and sterilized material were prepared. Fig. 3, presents the proper data aggregation, whereas Fig. 4 presents wrong distributions.

In Fig. 5, three water permeability distributions are presented. Water permeability distributions should be performed for different steps-ranges which should group individual results. This allows one to evaluate the sensitivity of the loss of the distribution's continuity, depending on the level of aggregation of results. The assumed risk level (16.6%) regards three tested surgical gowns with one sample per gown that does not meet permeability requirements.

The samples of water permeability below 200 mm should exceed the design risk level, but neither raw nor steam sterilized materials meet the standards. Sterilization with Ethylene Oxide (EO) improves water permeability over the risk threshold, so manufacturers using that kind of sterilization method may expect good products.

Table 1 shows the results of the simulation; permeability decreased the most in raw materials that were the most permeable before EO sterilization. It is shown that the average expected decrease was about 100 mm H_2O, which means that the raw material should withstand water pressure of at least 100 mm H_2O.

Above simulation enables to assess the quality of nonwoven material based on the samples taken from the lot. It is not enough to prepare the distribution with random number of intervals because information required for material evaluation will not be visible; however properly prepared distribution might help making right business decisions.

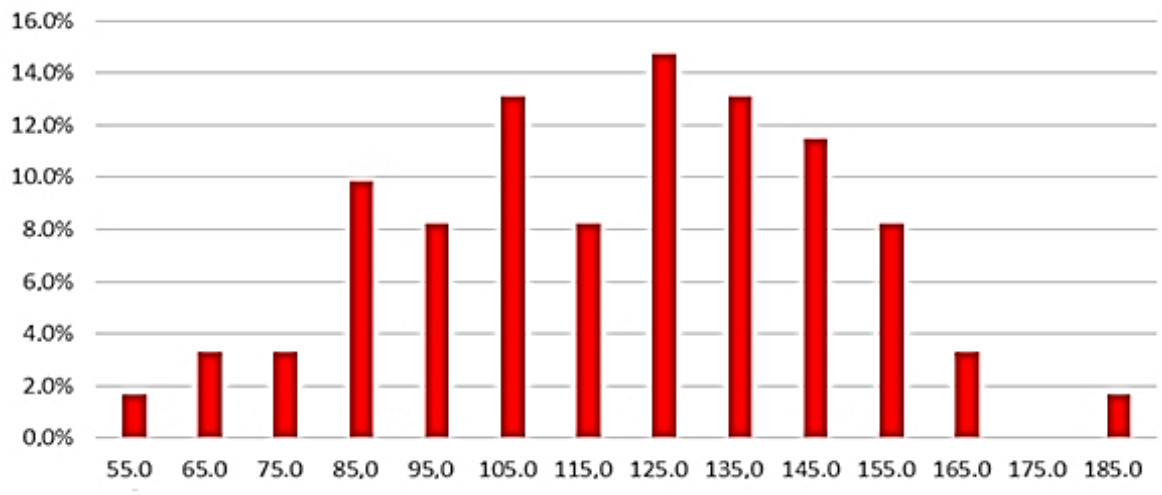

Figure 3. Correct water permeability distribution
(*source:* authors' own research)

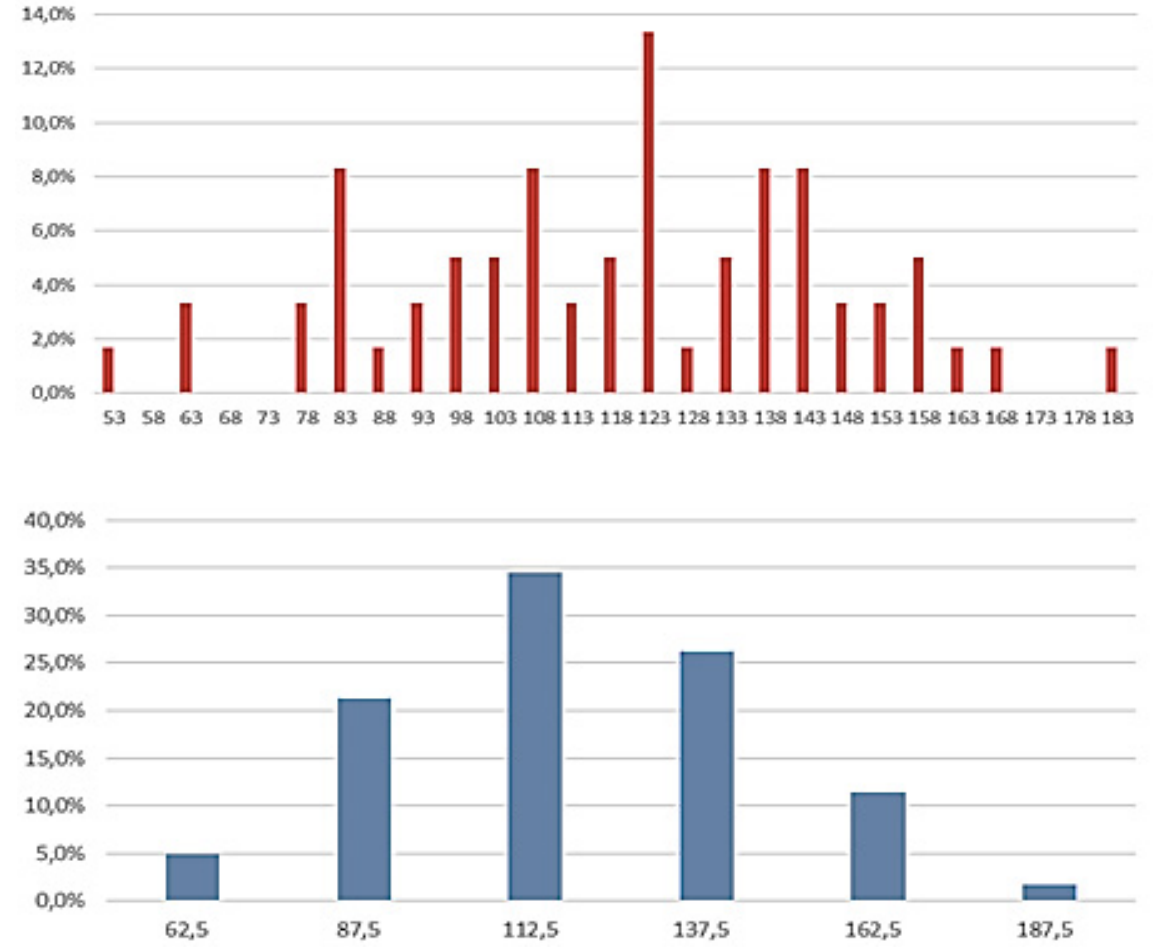

Figure 4. Probability distribution of a nonwoven material; in the upper chart too many intervals imply discontinuity in the distribution; in the lower chart the samples are grouped into too large sets, and determination of confidence intervals is impossible
(*source:* authors' own research)

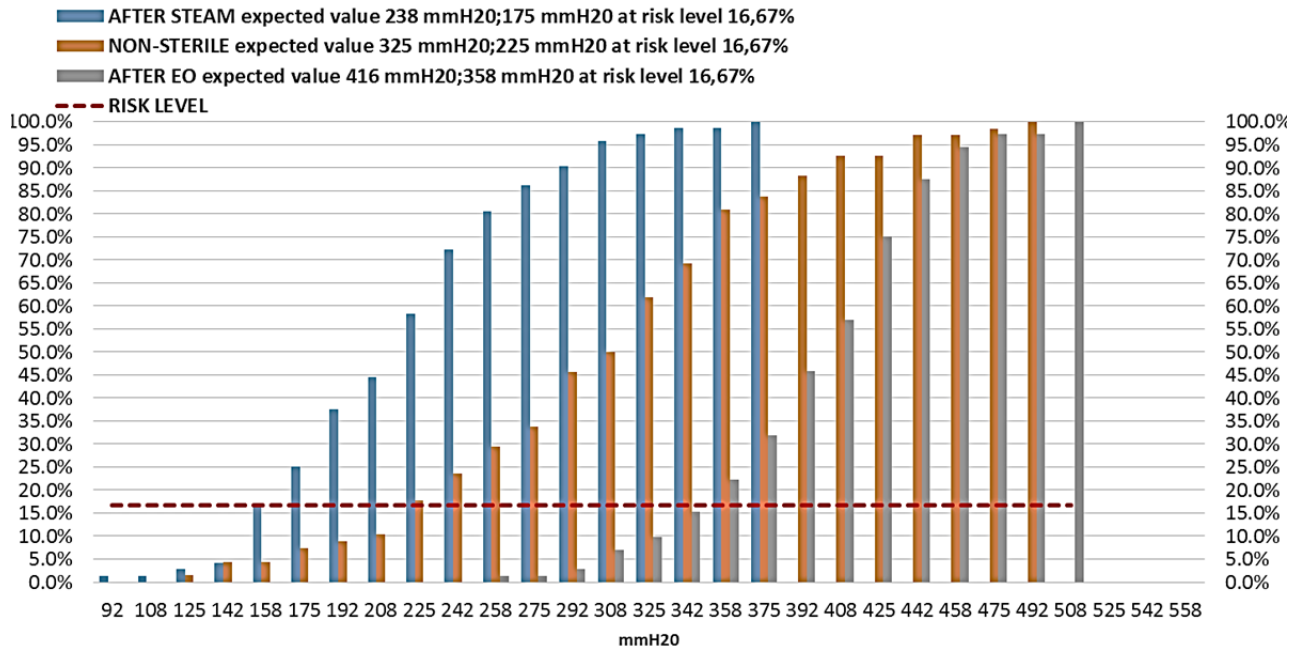

Figure 5. Distribution of water permeability expected value of raw and sterilized nonwoven material (*source:* authors' own research)

Table 1. Results of the simulation (*source:* authors' own research)

Main statistical parameters, mm H_2O	**Non-sterile**	**After Steam**	**After EO**		**Non-sterile**	**After Steam**	**After EO**
	Expected value for the samples above the threshold				**The threshold at a given level of risk (16,67%)**		
max	370	292	444		221	200	321
min	202	196	343		100	58	196
middle value in the range	286	244	394		161	129	259
Difference relative to non-sterile							
max		-78	74			-21	100
min		-6	141			-42	96
middle value in the range		-42	108			-32	98

5 Conclusion

The method described in the article allows one to:

- objectively select a representative number of samples to be examined (standard does not define how to ensure the selection of representative samples),
- determine the acceptable risk of not fulfilling quality requirements,
- determine the effect of the type of sterilization on the level of permeability, and
- determine the stability of the process of production of nonwovens and, consequently, the ability to compare the quality of nonwovens, both from the same manufacturer and from different manufacturers.

Before the implementation of new procedures in nonwoven manufacturing plants, about 20% of material had not met the strict medical requirements and had to besold as defective commodity with a 70% discount.

As a result of the analysis presented above, new procedures of quality control were introduced in the company.

Each batch of material is produced to customers' orders, and the production lines can be properly configured and fine-tuned for each recipient to allow for higher quality. The product now retains consistent parameters, has appropriate thickness, is well formed and each lot is identifiable.

To further ensure that quality is up to standards, a specified amount of product samples must be tested in the customer's own certified laboratory.

Since the production is adjusted for each customer, the minimum order size had to be increased from one shipping container to two intermodal containers that allowed the production process to remain profitable and allowed the unit material price to decrease by 6%.

Due to better product characteristics, the medical gown manufacturers were able to adjust the cutting, sealing, stitching and ultrasonic welding processes in order to increase their own production capacity by 15%.

Now, all medical attire sewn from nonwoven materials fulfills all rules and regulations, so the medical gown manufacturers are no longer forced to use the Ethylene Oxide sterilization and are free to use whichever sterilization method they see fit – most often the choice is steam sterilization, which is less expensive and much faster than the Ethylene Oxide one.

Presently, the nonwoven materials manufacturer, due to the consistently good quality of their product, is able to participate in large bids in the hope of restoring their market share.

The application of statistical methods for nonwoven material evaluation allows for correct assessment of its quality, conducting informed price negotiations, and achieving greater profits.

6 References

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