Medical textiles testing and quality assurance

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6.1 Introduction

The world textile industry is moving rapidly toward the manufacture of high-added value fiber products (Czajka, 2005; Anand, 2001; Rajendran and Anand, 2002a). This is happening in the healthcare and well-being sectors. Medical textiles are known as healthcare textiles. Medical textiles are the products and constructions used for medical and biological applications and are used primarily for first aid, clinical, and hygienic purposes. They consist of all textile materials used in health and hygienic applications, eg, gauze or bandage materials to scaffolds and a large variety of prostheses or implants in both consumer and medical markets (Islam Kiron, 2015).

The textile sector is one of the most rapidly expanding sectors in the technical textile market. Medical textiles are widely used nowadays in medical and healthcare applications such as surgical applications, wound dressing, orthopedic splints, and cardiovascular grafts as medical devices (Walker, 1999; Rajendran and Anand, 2012). The increasing demand for functional textiles for healthcare applications has changed the conventional purpose of clothing as solely for covering and protecting the body. Therefore, there is a growing interest in production of specific textiles for the top niche markets. Fibers or fabrics can be treated to have a specific function, eg, high water or moisture absorbency, thermal comfort, antimicrobial properties, or UV resistance. The growing interest in production of disposable medical textiles for better healthcare and low cost production leads to the development of new materials with improved clinical hygiene. In this way, the demand for more innovative products also leads to the development of traditional or topical wound management products, eg, swabs, gauzes, and bandage. Additionally, the fast improvement in the field of surgery and medical implants leads to the development of new products for new applications, eg, sutures, cardiovascular devices, and so on.

6.2 Types of medical textiles

Medical textiles can be divided into five categories according to their fiber sources (natural or synthetic) and applications as shown in Scheme 6.1.

Implantable materials include molecularly engineered or bioengineered textiles that react with biological media and are aimed at assisting in tissue healing and repairing

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processes, for example, wound closure, cardiovascular grafts, artificial tendons, ligaments, cartilage, etc. (Anand, 2001; Buschmann et al., 2015).

Various biodegradable and nonbiodegradable materials are currently used for the medical implants. Though more biodegradable materials have already been developed and made available in the market to replace nonbiodegradable textiles, some material properties (eg, durability and mechanical) need to improve to ensure successful use as implantable medical textiles or devices. On the other hand, conventional metallic implants are slowly losing their market-leading role because of their potential drawbacks, such as the risk of infections, mechanical failure, lack of biocompatibility, and the probable need for a second surgery to remove the device after the fracture heals (Anand et al., 2005). Hence, biodegradable polymers with reinforced composite materials are under evaluation for prosthetic implants. These implants have been used in cardiovascular (eg, stent) to bone and skin regeneration, and helping host cells adhere to the implants and repair or reconstruct the injured and damage tissues (Rajendran and Anand, 2002b). Various knitted, woven, and nonwoven textiles, nano-fibrous matrices, and composites may be used in the production of different medical implants for replacement of damaged tissue, including blood vessels, segments arteries, ligaments, and wound closures (eg, sutures). The implants should perform aptly for the purpose. Therefore, implant performance testing methods have to meet certain criteria to satisfy the desired application requirements. The textile implants should demonstrate satisfactory performance, for example, be biocompatible, have certain porosity to provide the required space, and facilitate blood circulation for human tissue growth and regeneration. Furthermore, in some cases they should be biodegradable or bioabsorbable, but not be toxic and contaminated.

6.2.1 Nonimplantable materials

All types of fiber or textile materials have been developed along and/or with incorporating functional materials (eg, hydrogel, bioactive, silver nanoparticles) for external applications. These medical textiles are largely used for external healthcare applications, which are mainly aimed at protecting and enhancing healing through providing protection against infection, for example, gauzes, bandages, pressure garments, etc. (Rajendran and Anand, 2002a, 2012; Walker, 1999; Islam Kiron, 2015; Buschmann et al., 2015). There are different types of surgical wound dressings or devices, depending on their intended applications. For example, primary wound dressings are placed next to a wound surface and are mainly made of cellulose fibers (Meena et al., 2013). Protective and supporting dressings, bandages, and adhesive tapes are also used for wound administration. However, all dressing products should have some required properties. Materials should decrease the surface of adherence, and not have any loose fibers that may be caught in the wound, causing further injury. Therefore, the dressing has to be stable with spatial structure and easily adsorb wound secretions, and moreover, the process of changing the dressing should be painless.

6.2.2 Healthcare/hygiene products

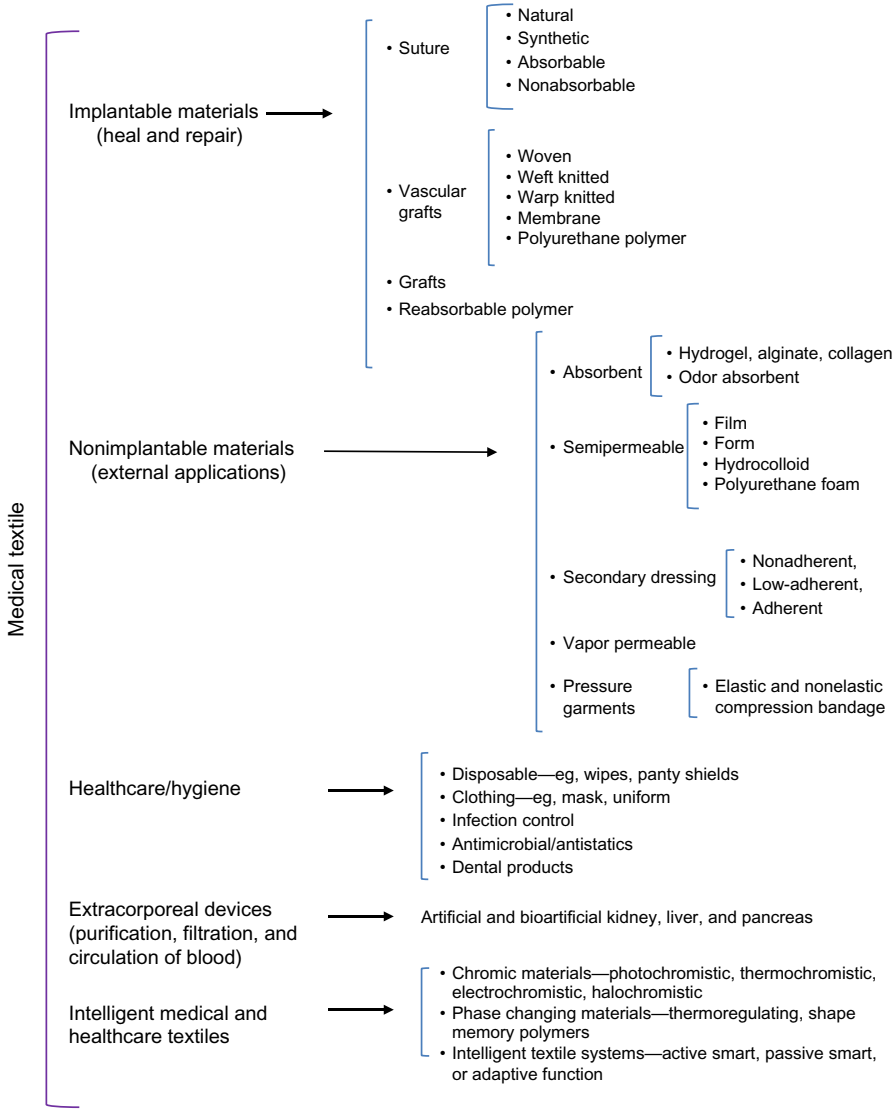
Healthcare/hygiene products are usually available over the counter and normally used for hygienic purposes to prevent infection and transmission of diseases, provide hygiene, and enhance care in the hospital ward and operating room (Rajendran and Anand, 2012). It is important to keep the operating theater clean and free from infection. Surgical gowns and masks are a possible carrier of bacterial infection to the patients. Hence, gowns and masks should be infection free and also act as a barrier to minimize the release of pollutant particles into the air. Conventionally, the gowns and masks are made from woven materials, largely cotton, that are both a source of dust, and, can easily release contaminated particles (Hutmacher, 2001). These textiles are lightweight, nonallergic, and have a high level of air permeability.

6.2.3 Extracorporeal devices

Fibers and textile technology is used in mechanical devices for purification, filtration, and circulation of blood from, for example, artificial livers or kidneys, or for artificial respiration. These devices provide support for vital organs through mechanical assistance. Artificial organs such as kidneys, livers, hearts, and lungs are made largely from cellulose, polyester, polypropylene fibers, or silicon membranes to mimic the natural function of the organ (Meena et al., 2013). Some intelligent textiles are used as mechanical devices that are designed to monitor body parameters and analyze the physiology of the human body. The majority of current smart textiles use physical sensors to monitor parameters such as movement (accelerometers), foot pressure, and breathing movement temperature (thermistors), and electric field and electric signals from heart and skeletal muscles (electrocardiography and electromyography respectively). Chemical sensor-based textiles are relatively new devices with emerging potential to monitor the health and well-being of the consumer through simultaneous interactions with body fluids or odors (Lay-Ekuakille, 2010).

6.3 Medical textile performance testing

Medical textiles are classified in Scheme 6.1. This scheme detailing constituents of various polymeric substances (eg, natural or synthetic) and their construction processes as outlined in the previous section is important in defining medical textiles aptly. Similarly, testing the properties and performance of medical textiles with suitable methods under accredited standards is essential. Thus, it is worthwhile to adequately describe all test methods, performance testing features, results analysis, and presentation guidelines of test results prior to marketing and commercialization of a device or product. This is done so that care and quality assurance of medical textiles will be documented appropriately, which benefits users.



Scheme 6.1 Classification of various medical textiles (Rajendran and Anand, 2002b, 2012; Islam Kiron, 2015; Buschmann et al., 2015; Anand et al., 2005; Meena et al., 2013).

6.4 Methods, standards and validation

In response to ever-increasing innovation and development of medical textiles, medical textile performance testing is required during the manufacturing process. The test requirements developed by the European Medical Devices Directive are presented in this section. There are different classes of test methods and standards. However, the conformity with each test standard depends on the types and classes of the medical

textiles. Moreover, the devices or products should satisfy and/or be capable of adhering to the rules and regulations of the European Union (EU). In 1993, the European Council Directive 93/42/EEC was published to establish requirements for all medical devices. It is often referred to as the Medical Device Directive (MDD), and is mandatory in the EU. This standard covers all medical device performance testing, including medical textiles, which describe the test requirements that need to be considered in a broad range of applications. However, in 1998, the European committee mandated the 'European committee for standardization (CEN)' to establish a European standard (EN 13795), more specifically for medical textiles, eg, surgical gowns, drapes, and clean air suits. This standard fills the missing technical part of the MDD. The EN 13795 demonstrates vital progress for better safety and provides better protection for people. The EN 13795 covers different aspects of the product from design, development, and production to their safe use condition, storage, and packaging, including transportation, labeling, and other physicochemical and microbial properties of the medical device. The product application considers the related risks, and each device is typically classified into Class I, Class II, or Class III. Class I covers low-risk devices, such as medical textiles that are used in operation theaters, which include gowns, drapes, and clean air suits. This standard has been written with a test method purpose, and aims to prevent the transmission of infection and contamination between medical staff and patients during surgical operations, and other potential hospital-related infections. The devices that possess a higher-risk potential for consumers, patients, and healthcare staff are classified under Class II or Class III. For example, medical textiles used for wound dressing are noninvasive devices, and typically fall in Class I, unless they are intended for wounds that breach the dermis. Wound dressings that manage the microenvironment of the wound, or are used for healing or repairing damaged skin tissues, fall in Class II (IIa and IIb). Similarly, medical textiles which are used either as nonimplantable devices (eg, antimicrobial agents consisting of dressings or patches produced from fibers or fabrics) or implantable devices (eg, cardiovascular grafts) are categorized in Class II. This is because when antimicrobial agents are applied on a fiber or fabric (textile), they are considered a drug, and the resulting device that includes the antimicrobial drug will be considered a combination product as defined in 21 CFR 3.29(e) in the EN 13795. In addition to monitoring and controlling health risks, this standard aims to provide a performance and safely level for the products during its entire lifecycle. The EN 13795 specifically focused on woven and nonwoven medical textiles and provides instruction for the test method required for the products. To date, the EN 13795 has been modified five times, the latest in 2013, and includes: BS EN 13795-2:2004+A1:2009, BS EN 13795-3:2006+A1:2009, BS EN 13795-1:2002+A1:2009. The latest version sets the minimum requirement for a product to be in compliance with the standard. The minimum value sets in the standard describe and distinguish the requirement for products for standard (less critical) and higher (critical) performance. The products within the critical zone are more involved with the chance of transferring the infection in the operation room, eg, the pieces of the surgical gowns which are in front and in the immediate zone of the operation site. On the other hand, products within a less critical zone are used, for example, to apply pressure during the surgical process or to be in contact with biological fluids.

6.4.1 Medical textiles performance testing (EN 13795)

The EN 13795 generally consists of three parts. The first part (EN 13795-1) consists of general requirements for production, and defines the design, processing, and assessment requirements of the products. This part aims to provide the same level of safety for the product through its entire lifecycle. In part 2 (EN 13795-2), the test method for assessing the characteristics of the product indicated in part 1 is described. The performance requirements of the products are described in part 3 (EN 13795-3) and are subdivided into critical and less critical zones for the products. High-risk products are more likely to be involved in infection transfer, and therefore, there should be clear labeling on the product to indicate the product's use in either the critical zone or less critical areas. The EN 13795 does not present specific suggestions for specific products that need to be used for surgical operation. However, risk assessment needs to be performed by the healthcare service provider, after asking the supplier of the product for information. For products intended to be sterilized or reused, the manufacturer should be able to provide enough information, eg, cleaning, packaging, and sterilization protocols, and product reuse techniques. Additionally, the product needs to have a clear label to show the intended application of the product zone area (high risk or low risk). The manufacturer should also provide test results and the rationale used for the differentiation and classification of the product as low or high risk. Moreover, before commercialization of the product, the manufacturer should test the finished product according to the guidelines provided by the standardization (validation) authorities such as the European Standards (EN), British Standards (BS), American Society for Testing and Materials (ASTM), International Organization for Standardization (ISO), and United States Food and Drug Administration (FDA).

Hence this chapter mainly explains the medical textiles performance testing methods recommended in part 2 of EN 13795 e.g.

6.4.2 Resistance to microbial penetration in dry (ISO 22612) or wet conditions (ISO 22610)

The resistance to microorganism penetration test quantifies the total microorganism counts that passed through a fabric when the fabric is in dry or wet condition. For example, contaminated talcum powders are poured and then plunged onto the fabric surface by using a metal plunger (Fig. 6.1). The results are reported as the number of colony-forming unit bacteria counted on an agar plate. The spores of *Bacillus subtilis* are normally used for this test. In the wet condition of this test (Fig. 6.2), the fabric is placed on a plate of agar, and the contaminated liquid (instead of talcum powder) is poured on the fabric. Typically, the test material is covered by a polyethylene film (10 μm thickness) then the contaminated fluid is subjected to a rotational mechanical abrasion stress using a mechanical finger under defined pressure (20 kPa, kilopascal) and time (15 min) so that the fabric is in contact with liquid and agar. The test is repeated five times in total for 15 min each. Then the CFU (colony-forming units) are observed after incubation at 35°C for 24 h, and results are reported as the BI (barrier index) in Table 6.1.

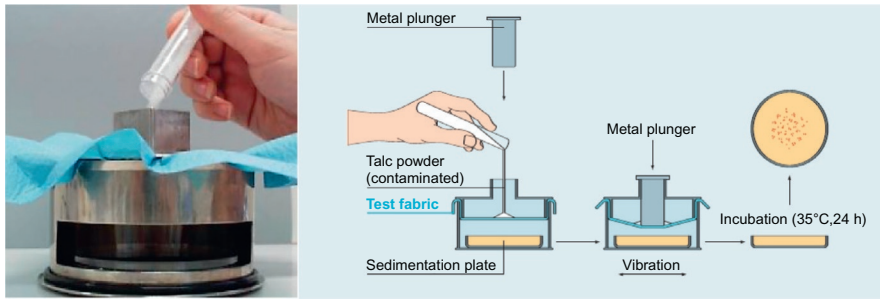


Fig. 6.1 Test device to evaluate resistance to microbial penetration in dry conditions.

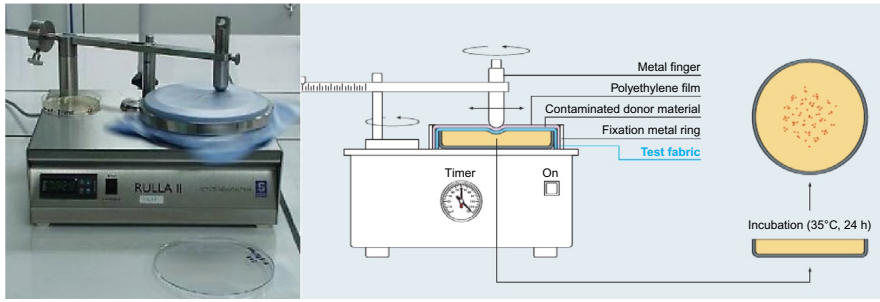


Fig. 6.2 Test device to evaluate resistance to microbial penetration in wet conditions.

Table 6.1 Summary of the performance requirement for textiles to microbial penetration

Unit	Standard performance		High performance	
	Critical area	Less critical area	Critical area	Less critical area
Surgical gowns and drapes				
Dry (Log_{10} (CFU))	N/A	≤300 CFU[a]	N/A	≤300 CFU[a]
Wet (BI)	≥2.8[b]	N/A	6.0[c]	N/A

[a]Test concentration: 10^8 CFU/g of talcum powder and vibration time of 30 min.
[b]The least significant differences for barrier index was found to be 0.98 at 95% confidence interval, therefore, materials varying by less than 0.98 BI are not different while materials varying by more than 0.98 are probably different.
[c]BI = 6.0 is the maximum achievable value and means no penetration for the purpose of this standard.

There are many ways textiles can be contaminated, due to their uses and/or through their environment. Potential threats include germs and fungi. However, there are a number of antimicrobial and antifungal medical textiles available nowadays. Antimicrobial performance testing using appropriate standard methods, test results, validation, and documentation is important. These tests are described in the following section.

6.4.3 Test method for evaluation of cleanliness—microbial contamination (EN 1174, replaced by EN ISO 11737)

This test is especially important when a product is not sold as sterile. The test determines the potential of the product for microbial contamination. When the product is aimed to be sold as sterile, this test is necessary to achieve the assurance level for sterilization (CFU:10^{-6}), allowing it to be labeled as sterile. The test results reported as CFU/100 cm^2. This test standard does not provide a fixed test procedure, but the requirement for the test method and the mechanism of test specified.

6.4.4 Test method for evaluation of cleanliness—particulate matter (ISO 9073-10)

Medical staff are generally very concerned about the protection and comfort of the patient and the surgical team. Because routes of infection are contact or airborne, dispersion of human skin particles are often the carrier of infection. A healthy individual can disperse into the air ~5000 bacteria-carrying skin particles per minute during walking, and males disperse more than females (Abreu, 2014). The particles are 5–60 μm in size and the average number of aerobic and anaerobic bacteria carried is estimated to be about 5 per skin particle (Abreu, 2014). For the determination of cleanliness—particular matter particle counts should be in the range of 3–25 μm, as particles in this size range carry microorganisms. The particle count result is reported as a particulate matter index (IPM) in Log(10) of particulate matter: IPM = Log(10)PM.

6.4.5 Test method for assessment of resistance to liquid penetration (EN 20811)

The ability of medical textiles to withstand the penetration of liquid contaminants is important for the health and safety of the healthcare staff and the patient (Behera and Arora, 2009; Kramar, 1998). Water spray impact tests evaluate the splash resistance of a fabric to liquid penetration. This test, also known as the hydrostatic test, evaluates the liquid penetration property of the fabric under hydrostatic pressure, and helps predict how the fabric will perform against fluid penetration. Considering that many procedures deal with the irrigation of tissue fluid, a fabric with high fluid resistance can be a great help by providing the required barrier against fluid penetration under applied pressure, for example, when a patient's arm comes in contact with contaminated fluid. For this test, the area of the test specimen should be 100 cm^2 with a water pressure increase rate of 10 ± 05 cm/min. Results expressed in a water column (cm) with higher values indicate better resistance of the tested fabric (Table 6.2). According to ASTM F1670 and ASTM F1671, body fluid or blood-borne pathogen stimulants should be used to perform the test while in AATCC 42 and 127; water is recommended for both spray and hydrostatic liquid penetration tests.

Table 6.2 Summary of the performance requirement for textiles to liquid penetration

Unit	Standard performance		High performance	
	Critical area	Less critical area	Critical area	Less critical area
Surgical gowns				
cm (H_2O)	≥20	≥10	≥100	≥10
Surgical drapes				
cm (H_2O)	≥30	≥10	≥100	≥10

6.4.6 Test method for measuring the linting of textile materials in the dry state (ISO 9073-10)

For this test, the fabric is subjected to cyclic torsion and axial efforts, similar to what is routinely practiced by healthcare staff (Fig. 6.3). The number of particles released from the fabric are measured in the same manner as the cleanliness test. However, a linting test measures the particle reserve in the product for a longer term. The result typically reports as the coefficient of linting in Log(10) values and calculates for the particle sizes of 3–25 µm.

Unit	Standard performance		High performance	
	Critical area	Less critical area	Critical area	Less critical area
Surgical gowns and drapes				
IPM	≤3.5	≤3.5	≤3.5	≤3.5
Log_{10} (lint count)	≤4.0	≤4.0	≤4.0	≤4.0

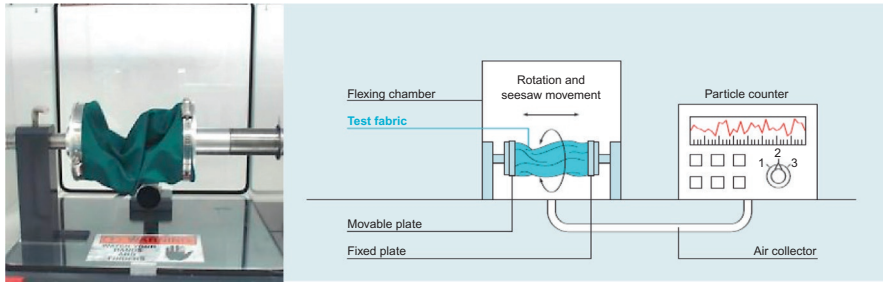


Fig. 6.3 Test device for measuring the linting of textile materials in the dry state.

6.4.7 Dry and wet burst strength (EN 13938-1)

The resistance of medical textiles to puncture or bursting is tested using the same method in dry and wet conditions (Fig. 6.4). This test is recommended because some area of the fabric is subject to bursting, or to puncture stress during use in the operating

theater. The fabric can be damaged by the surgeon's elbow during an operation (DuPont Medical Fabrics, 2014). This damage can happen anytime, but it typically appears by exerting pressure on small areas of the fabric. A specifically designed apparatus is typically used to execute the test, which is capable of producing a various constant rate of increase in volume per unit time between 100 and 500 cm^3/min to within ±10% of the indicated value, or the apparatus with a testing time to burst of (20 ± 5) sec may be applied. The results of this test are expressed and reported in kPa and a higher reading indicates higher resistance of the fabric.

Unit	Standard performance		High performance	
	Critical area	Less critical area	Critical area	Less critical area
Surgical gowns and drapes				
Dry (kPa)	≥40	≥40	≥40	≥40
Wet (kPa)	≥40	N/A	≥40	N/A

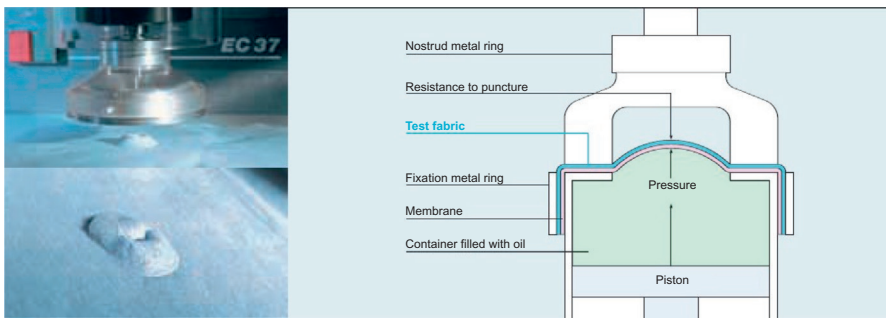


Fig. 6.4 |Test device for examining the bursting strength of textile materials.

6.4.8 Tensile strength of medical textiles in dry and wet condition (EN 29073-3:1992)

The ability of medical textiles to withstand tensile strength is evaluated using this test. Normal wear of the garment imposes a natural stress on the fabric. This test is usually conducted to measure tensile strength for test samples in dry and wet environments (Fig. 6.5). This test standard recommends that the dry test specimens should be conditioned in the standard temperate atmosphere of a relative humidity of (65 ± 2)% and a temperature of (20 ± 2)°C for at least 24 h. The dimensions of test specimens are (50 ± 0.5) mm wide and of sufficient length to allow a jaw separation of 200 mm. Adequate length is required to avoid any risk due to heterogeneity of test specimen. At least five test specimens are required for dry testing, and another five test specimens are required for wet testing. To create the recommended condition for wet testing, the test specimens should be soaked with distilled water or fully deionised water for at least 1 h at (20 ± 2)°C. Then, the specimen is removed from the water, shaken off

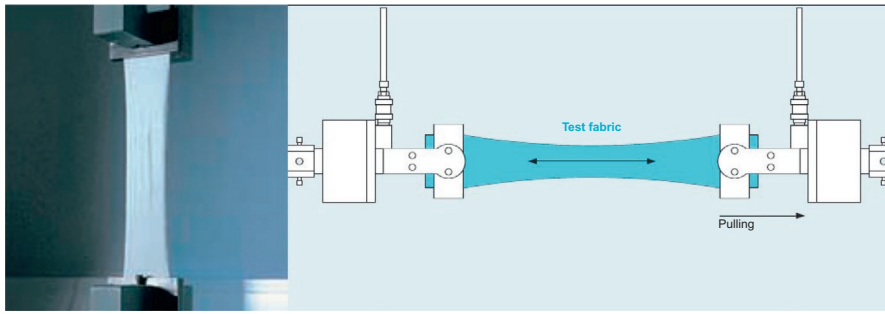


Fig. 6.5 Test device for examining the tensile strength of textile materials.

Table 6.3 Summary of the tensile strength performance requirement for textiles in dry and wet condition

Unit	Standard performance		High performance	
	Critical area	Less critical area	Critical area	Less critical area
Surgical gowns				
Dry (N)	≥20	≥20	≥20	≥20
Wet (N)	≥20	N/A	≥20	N/A
Surgical drapes				
Dry (N)	≥15	≥15	≥20	≥20
Wet (N)	≥15	N/A	≥20	N/A

excess water, and tested immediately. The results (Table 6.3) are reported in Newton (N), and higher numbers indicate better strength of the fabric.

6.4.9 The requirement and importance of medical textiles performance testing for the healthcare staff and the medical textile industry

The EN 13795 requirements implemented important modifications for better practices in the medical industry, which has led to highly sophisticated materials and processing systems and a higher degree of safety for patients and healthcare staff. Sophisticated guidance is provided for hospitals, fabric manufacturers, scientists, and purchasing organizations that are active in the medical textile industry. Generally, this standard provides better safety and protection for patients, nurses, surgeons, and other healthcare staff, and protects them against infections that could result from post-operation processes. Furthermore, this standard provides quality assurance and regulations for hospitals purchasing the products. The regulations in the standard set higher goals for manufacturers with specific and desirable criteria for improving devices and product quality, and also provide guidance for innovation. The textile industry, in particular

the manufacturers involved in producing raw or finished materials that are used in manufacturing medical textiles (devices), is also required to set new quality control techniques to be consistent with the standard. For example, a reusable medical textile product manufacturer should specify the lifetime of the product, and the suitability of the product for reuse.

6.4.10 Tests for surgical masks

One in twenty hospitalized patients experience healthcare associated infections, which is approximately equal to 4 million infections and 37,000 deaths a year in the EU. Pathogen transfer normally occurs during the surgical procedure in operating rooms and other medical installments. The noses and mouths of the healthcare professionals on the operating teams are one of the main important sources of spreading and transferring the pathogens. Breathing, coughing, speaking, or sneezing can release different amounts of droplets from mucous membranes of nose and the mouth. These released droplets are dried, and the nuclei are suspended in the air, which can be transmitted to a susceptible site such as an open wound or sterile equipment. A surgical mask is the main barrier against this infection. The mask covers the nose, mouth, and chin, and provides a barrier for transmittance of the infections. Therefore, it is important to evaluate the performance efficiency of the mask for the protection against pathogen transfer. In the EU, the surgical mask should comply with the EN 14683 standard and have a CE label. This standard provides a requirement for design, construction, and testing methods for evaluation of the surgical masks.

Masks are classified into four types (see the following table) based on their performance efficiency, and, according to this standard, three tests are recommended as follows:

Types	Particulate respirator high fluid resistance (mmHg)	Particle filtration efficiency	Breathability—delta *P* (mm H_2O/cm^2)
Level 1	80	≥95%	<4.0
Level 2	120	98% at 0.1 μm	<5.0
Level 3	160	98% at 0.1 μm	<5.0
Level 4	160	99.9% at 0.1 μm	>5.0

6.4.10.1 Bacterial filtration efficiency

This test's objective and scope are to measure the amount of pathogens released through the mask in the air by measuring the amount of retained infection agents in the mask. According to the product's (mask) efficiency, the product is classified in Type 1 (95%) and Type 2 (98%). Over several years, the bacterial filtration efficiency (BFE) has had different requirements as established by the European committee, which were used to amend EN 14683 and ASTM F2101 (in the case of the United States). Therefore, manufacturers have to comply with both requirements by performing two separate tests. This was due to differences in the preconditioning requirement by each test as outlined in Table 6.4. However, in the latest revision of the EN 14683, the preconditioning

Table 6.4 Preconditioning requirements

	After EN 14683
Standard	Preconditioning requirement: EN 14683:2014
EN 14683	21 ± 5°C and 85 ± 5% relative humidity prior to testing
ASTM F2100	21 ± 5°C and 85 ± 5% relative humidity prior to testing

requirement of both tests aligned and the manufacturer needed to only use one test. ASTM 2101 does not define the acceptable level for bacterial deficiency, and therefore, is required to report the specific condition under which the test is conducted. For this test the *Staphylococcus aureus* is used as the challenging microorganism to evaluate the filtration efficiency. The mask is challenged by subjecting it to bacterial aerosol at a flow rate of 28.3 L/mm (1 ft^3/min) inside the medical face mask (Fig. 6.6). The test can be performed using both sides of the mask (face side and liner side) to evaluate the filtration efficiency of the mask related to aerosol generated from both the patient and the wearer of the mask. Testing the mask without considering the parameters such as physiochemical degradation, thermal stress, or wetting contaminant might lead to an inaccurate result, and consequently a false sense of security; therefore, masks need to be tested after suitable pretreatment if the stress conditions are of concern. The test method is quantitative and the maximum filtration efficiency that can be determined using this method is 99.9%. The ASTM 1201 does not measure the breathability of the mask or any other items related to ease of breathing using the medical face mask.

Fig. 6.6 Test instrument and set-up of measuring of BFE.

Also, it needs to be considered that this test only evaluates the filtration efficiency of the material used for construction of the mask and does not evaluate design, fit or facial sealing abilities of the medical face mask. Similarly, other medical textiles (garments), eg, surgical gowns, surgical drapes, and sterile barrier systems, can also be tested for BFE using this test.

Typically the resistance of mask to airflow is determined in this test as:

Type 1 and 2 (nonsplash resistant) $\leq$29.4 Pa/cm^2
Type IR and IIR (splash resistant) $\leq$49.0 Pa/cm^2

6.4.10.2 Splash resistance (synthetic blood)

Blood vessels can be punctured or damaged during medical procedures, which results in a blood splash that requires a face mask to resist this impact. Several parameters are involved in the splash of blood from the punctured vessel, including the size of the puncture and the distance from the puncture. Medical face masks should be able to resist liquid penetration (eg, blood splash, body fluids). Parameters such as viscosity, polarity, and surface tension of the fluid are important factors affecting the splash resistance of the mask. On the other hand, the structure, hydrophilicity, and hydrophobicity of the material and the design of the mask also are crucial parameters affecting the resistance of the mask. For this test, the synthetic blood is prepared with a red dye and surface tension of the synthetic blood is adjusted 0.042 ± 0.002 N/m. However, this blood will not always duplicate the polarity and wetting behavior of the real blood. This test assumes that the medical face mask will be in a close distance of ~300 mm to the splash area, and a blood stream with velocities of 80, 120, and 160 mmHg are used for this test (Fig. 6.7). These blood velocities cover the mean human blood pressure of 80–120 mmHg. The maximum value is 120 mmHg, which corresponds to average systolic blood pressure. The mask is intended to protect against small splashes of blood from the rupture of small arterials. In addition to the three preceding tests, the FDA (Food and Drug Administration) also prescribes the measurement of filtration efficiency regarding inert particles (latex), fire tests, and tests to measure biocompatibility. Therefore, the manufacturer should be able to test and classify their surgical masks in type, for the European market (EN 14683) and for the American one (ASTM F2101). The precondition requirements for the test are described in Table 6.4.

While the preconditioning requirements aligned, the required tests for both standards and the performance results are different between two standards, which typically depend on the claimed properties of the mask (Table 6.5).

In addition to standard EN 13795, there are a number of other standards for medical textiles and surgical masks proposed and described in the EN standard, ASTM, and also in international standards, including standards for testing of water vapor permeability (breathability) of the fabric in EN 31092 and ISO 11092, thermal insulation testing of the fabric in EN 15831 and ASTM F2370, air permeability of the fabric in ISO 9237, water penetration resistance in ISO 811, nontoxicity of the medical device in ISO 10993, measurement of the electrical risk in ISO 2878 (BS2050) and EN 1149, protection against laser beams, primary ignition, and penetration in ISO 11810-1 and

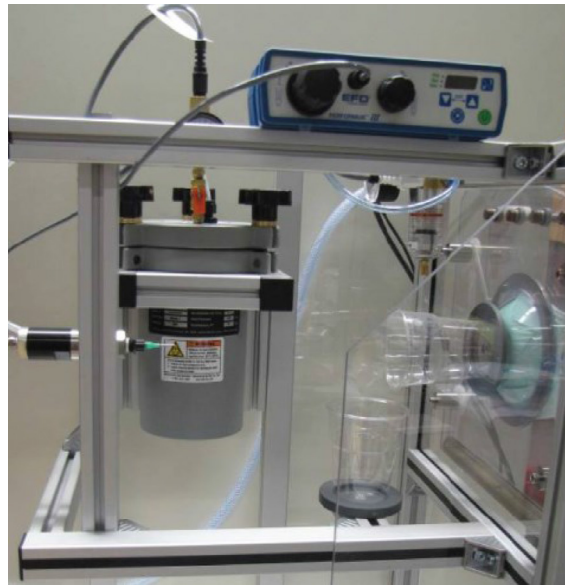


Fig. 6.7 Test instrument and set-up of measuring splash resistance.

secondary ignition in ISO 11810-2. These test standards are important and required to validate the performance efficiency of the medical textiles.

Water penetration resistance (ISO 811)

Breathability is the ability of the fabric to permit water vapor to pass through and to prevent the entry of water (Behera and Arora, 2009). The comfort properties of a fabric depend on its ability to transmit water and vapor from the body to prevent accumulation of liquid on the skin. In this way, thermal energy generated by the body will be transmitted, and vapor moisture will be diffused, resulting in a comfortable condition (McCann and Bryson, 2014). The value of breathability is calculated by measuring the quantity of moisture vapor through a fabric during a specified time period and reported as the moisture vapor transmission rate (MVTR) (Gokarneshan et al., 2015). Higher values indicate better removal of vapor and moisture, and prevention of the accumulation of gas and vapor. The MVTR is reported as grams per square meter (g/m^2) under defined temperature and humidity (Gokarneshan et al., 2015). Air permeability is another factor that affects the comfort property of the fabric and has a close relation to water vapor permeation. The ability of the fabric to permeate air or water might change due to changes in the different temperature and humidity conditions, eg, the fabrics made of cotton and wool might experience resistance to air or water permeation due to swelling and closeness of the pores in the fabric. A surgical gown needs to be completely waterproof, and considering a moderate working speed of 20°C, the gown needs to provide the air permeability of 100 $L/m^2/min$ and the water vapor permeability of 400 $g/m^2/24$ h. The resistance of the fabric to pass the water is measured by subjecting materials (100 cm^2) to a steadily increasing pressure of water

Table 6.5 Test requirements and performance requirements by Type, in EN 14683:2014 and level barrier in ASTM F2100-11

	Characteristic					
Test	Type I	Type II	Type IIR	Level 1	Level 2	Level 2
21 ± 5°C and 85 ± 5% relative humidity prior to testing	≥95	≥98	≥98	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2						
H_2O/cm^2	<3.0	<3.0	<5.0	<4.0	<5.0	<5.0
Pa/cm^2	<29.4	<29.4	<49.0	<39.2	<49.0	<49.0
Submicron particulate filtration efficiency at 0.1 micron (%)	Not required	Not required	Not required	≥95	≥98	≥98
Splash resistance/synthetic blood resistance (mmHg)	Not required	Not required	120 (16.0 kPa)	80	120	160
Pass result						
Flame spread	Not required	Not required	Not required	Class 1	Class 1	Class 1
Microbial cleanliness (CFU/g)	≤30	≤30	≤30	Not required	Not required	Not required

on one face until water passes. The pressure at which penetration occurred is noted. The material should be clamped during the test period without slipping, and no tendency should occur at the clamped zone. For this test, only distilled water at $20 \pm 2°C$ should be used, and the pressure should increase 10 ± 0.5 cmHg or 60 ± 3 cm H_2O/min and the results obtained by both rates should be reported, and the pressure should be read at 0.5 accuracy cm H_2O.

Thermal manikin (EN ISO 15831—ASTM F2370)

This test is used to measure the thermal insulation of the fabric. It is possible to measure the breathability and define the range of the fabric utility when the test is combined with Skin Model (Huang and Qian, 2008). The evaporation resistance of different clothing systems can be quantified using this test under isothermal conditions. The test is performed using a manikin, which is dressed completely; then the manikin is placed into a chamber with an adjustable climate condition, different temperature, and variable humidity and wind speed. The obtained data then can be used to model and predict the physiological response of the wearer in different climate conditions (OECD, 2009a). Considering that there are many parameters involved in this test, the measurement of evaporation resistance is a complex phenomenon. The measurement includes heated body parts such as feet (EN 345), hands (EN 511), gloves to protect against the cold, and whole body manikins (ASTM F1291). The standard for measuring the thermal insulation of clothing uses a heated thermal manikin (ASTM F2370-05) and determines water vapor resistance using a sweated thermal manikin (ASTM F1291-05). Furthermore, ISO 15831 provides methods for determining clothing insulation using a heated thermal manikin.

Cytotoxicity and nontoxicity performance testing (ISO 10993)

When the medical textile or part of it is considered as the medical device, then its toxicity performance testing requires validating under the ISO 10993 test standard. The fabric or parts of it are put in either direct or indirect contact with the cell culture system (eg, L929 cell line), and then the cell viability results determine the release of toxic materials from the tested fabric or device.

The in vitro tests for cytotoxicity assess the response of cells in culture to direct contact with devices or to their extracts. The ISO 10993-5 (1999): "Tests for In Vitro Cytotoxicity" specifies procedures for testing devices by direct or indirect contact, extracts of devices, and filter diffusion. The test should be performed on: (a) an extract of the test sample, (b) the test sample itself. Extracts of test devices and materials (eg, medical textiles) are tested by exposure to the cell culture system (eg, L929 mouse fibroblast cell line). The presence of cytotoxic leachates is indicated by loss of cell viability. In the direct method, the test device or a part of it is directly exposed on a mammalian cell layer which is protected by an agar layer. In this way, the cytotoxic leachate diffuses through the cell layer through agar, and the loss of viable cells indicates the toxicity of the tested material. In the direct contact method, the test material is directly put on the cell culture system, and no protective agar layer is used. About a half million to one million of cells are used for each test, and cytotoxicity of the material is measured after 24–72 h of cell exposure to the extract or the material. A useful way to grade test samples is given in Tables 6.6 and 6.7.

Table 6.6 Grading recommended for in vitro cytotoxicity test results

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable
2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules, no extensive cell lysis; not more than 50% growth inhibition observable
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable
4	Severe	Nearly complete or complete destruction of the cell layers

Table 6.7 Cytotoxic test procedure recommended by ISO 10993-5

ISO 10993-5
0.5–1 million of cells per dish
Extract ratio:
If the thickness $\geq$1.0 mm
25 cm^2 per 20 mL
If thickness $\geq$0.5 mm
60 cm^2 per 20 mL
If thickness $\leq$0.5 mm
120 cm^2 per 20 mL
24–72 h of exposure period
Toxicity determination: quantification of the survived colonies
Positive controls: materials that provide a reproducible cytotoxic response

Furthermore, some materials, including medical textiles, have the potential to cause allergy or irritation. The sensitization potential of the material is therefore required to be tested. The ISO 10993-10 assesses the possible contact hazards from chemicals released from the devices, which may produce skin, mucosal, or eye irritation and skin sensitization. Currently, there has been no satisfactory in vitro test to eliminate the requirement for in vivo testing to evaluate irritation. However, the rat skin Transcutaneous Electrical Resistance (TER) test and the human skin model test have been internationally validated and accepted as alternative tests to assess the skin corrosion with chemicals (OECD, 2009a,b). To perform the test, an animal (rabbit) with the healthy intact skin needs to be used and the fur on the back of animal is clipped 24–4 h of testing with approximate size of 10 cm × 15 cm and then 0.5 g or 0.5 mL of materials apply to the site and then the application site is covered with

Table 6.8 Scoring system for skin reaction

Reaction	Irritation score
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised ~1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the injection sites shall be recorded and reported	

Table 6.9 Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0–0.4	negligible
0.5–1.9	slight
2–4.9	moderate
5–8	severe

2.5 cm × 2.5 cm nonocclusive dressings (such as a gauze patch). The chemical characterization of the test materials is the prerequisite for this test. The irritation scores of all animals are the main measuring technique that are added together and divided by the total number of animals and reported as the cumulative irritation index (eg, Tables 6.8 and 6.9).

Human skin irritation test

According to ISO 10993-10, two of the most commonly used methods of testing for skin sensitization or irritation are the Guinea pig maximization test (GPMT) and the Buehler closed-patch test. Of these, the maximization test is the most sensitive method. The Buehler closed-patch test and the Magnusson–Kligman GPMT allow the expression of such allergic materials by an initial stimulation. Both tests can be used for the performance testing of medical textiles. However, the maximization test is recommended when the test material is manageable for intradermal injection. The

Table 6.10 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

sensitization is highly dependent on the applied dose, and if the irritation threshold is not reached, then the highest possible concentration might apply. However, the health of the animal should be considered, therefore, the induction dose is normally selected through preliminary tests. For the GPMT, a healthy young animal should be used, and in the case of powder or liquid materials, a minimum of ten animals should be treated with the test sample, and five animals should be used as the control group. For testing the extract of the material, again ten animals should be treated with the sample, and five should be used as the control group. The sample material is applied in the form of a patch 4–8 cm^2 and after 24 h the application site is assessed for erythema and odema using the Magnusson and Kligman grading system, which is shown in Table 6.10.

6.5 Care and quality assurances

Medical textiles in the healthcare or hospital care sectors play many important roles nowadays (Anand, 2001; Rajendran and Anand, 2012; Meena et al., 2013). As research has progressed, fibers and textile materials have found their way into a variety of healthcare and medical applications; as a result, medical textiles sectors are growing enormously. In medical and healthcare (hospital care) sectors, medical textiles and related products are used in the operating theater of the hospital ward for the hygiene, care, and safety of staff and patients (Rajendran and Anand, 2012; Meena et al., 2013). In many cases, these textiles are not yet defined aptly or well-known as medical textiles, but are used as hospital garments. However, at present, manufacturers, producers, and users are not getting enough information about the suitability of the textile materials (garments) used in hospital care and/or in surgery applications. Medical textiles as disposable products have been proposed for operating room garments and drapes with the objective of reducing microbial contamination of the incision and of protecting the operating room staff from infection. But the real practices are different, where reusable materials have been often used in surgery. This situation is reversed nowadays due to the spread of Ebola, the HIV virus, Hepatitis B infection, and other viruses. So the need to protect healthcare workers from the patient has become a major concern, which creates research opportunities and market demands for the development of more effective protective medical textiles. Furthermore, manufacturers or producers, retailers, and the services industry also need to consider the environmentally conscious population when deciding between recycling potentially contaminated products and/or disposing of the products in landfills.

By reviewing literature, market research reports, and accounting for recent advancements in medical procedures and textile engineering, the use of textile materials as medical textiles in the healthcare or hospital care industry is growing immensely (Marketsandmarkets, 2015). Hence, care and quality assurance of medical textiles are critically important to consider. Adequate actions have not yet been taken in ensuring quality and performance of medical textiles. At the same time, enough actions have not yet been taken to provide information associated with product performance testing standards to manufacturers or producers for ensuring product care and quality assurances. Thus, it appears that the product performance test results, validation, and correct documentation are important, and useful for everyone from manufacturers to end-users. With this information, manufacturers and retailers can demonstrate due diligence to authorities within the target markets through the certification of suppliers. Furthermore, the care and quality assurance documentation will allow the entire industry to gain consumers' trust through product safety reliance.

6.6 Medical textiles and its future trends

Medical textiles are one of the most important, and fastest-growing sectors of the textile industry. The medical textiles industry has been enhanced with existing products, and also creating new ones with new materials and innovative designs. Some of these new products are being designed for accelerating healing, infection control, and noninvasive surgical procedures. At present, the global market for medical textiles is worth hundreds of billions of dollars (Eriksson and Sandsjo, 2015; Robert and Rachel, 2015). The world demand for disposable medical supplies is forecasted to expand 6.2% annually to $198 billion in 2016 (Robert and Rachel, 2015). Increased enforcement of infection prevention standards, together with a growing number of hospital, surgical, and outpatient procedures, will enhance overall advances (Marketsandmarkets, 2015; Textile World, 2015; Shishoo, 2011; Eriksson and Sandsjo, 2015; Robert and Rachel, 2015). Population growth, aging populations, and the construction of new medical facilities are a driving force for this industry. Hence its importance will increase even more in the future. Medical textile products cover a wide range of uses, which include surgical gowns, operating room drapes, face masks, staff uniforms, hospital bedding and curtains, hygienic wipes and bandages, cardiovascular grafts, and also a variety of other unique applications. Medical textiles are increasingly used for hygienic purposes, and for first aid and clinical purposes, in addition to wound care practice such as protection from infection, bandaging, and applying pressure on wounds (Textile World, 2015; Shishoo, 2011). However, it appears that high energy costs, lack of raw materials, transportation costs, and unawareness in developing countries of hygienic practices might slow developments in the medical textile industry, and/or hinder the advancement of technology. The invention and development of new fibers and fabrics allow combining several functionalities such as breathability, temperature control, shock proofing, resistance to fluids, and a lot more in one material. However, the growth of care for the aging population

has been broadening the market for new products. Treatment and management of diabetic wounds is a good example. Nevertheless, the incorporation of healing substances shifts medical textiles to innovative medical products (Rajendran and Anand, 2002a). Also, future research should be focused on development of suitable technology and standards to better meet the growing demand for health and safety products. Thus, the existing performance testing standards need to be refined and modified further through more experiments and data collection processes. In this way, some parameters such as breathability and water vapor transmission need to be determined objectively to obtain and specify the minimum comfortable limits. To achieve this, research and development is required to design and develop medical textiles with different levels of permeation, porosity, gas permeability, etc., through application of new raw materials and optimizing current techniques of material construction and coating (Gokarneshan et al., 2015). The biopolymer and genetically modified microorganism will be developed for production on new fibers as well. An example is polyhydroxybutyrate (PHB), developed by Zeneca Bio products. High molecular weight polyester with a bacterial source, which is biocompatible and biodegradable with suitable thermoplastic properties, can melt into fibers that are knitted into manufactured medical textiles (Plackett, 2011). Production and development of new fibers expands the range of applications of medical textiles even more, and therefore, the utilization of textiles for medical use becomes more challenging. However, the need to improve and understand the performance of these new materials is inevitable to target specific applications. Environmentally friendly processes such as enzymatic processes need to be applied more often and replace the chemical treatments of textiles, so that enzymes with low energy requirements and higher yields can be developed (Plackett, 2011). The quality control system and standards, therefore, need refinement to meet new waste management criteria and programs deemed to be essential. Nevertheless, the future of the medical textile market is more dependent on the development of innovative products with improved comfort, higher performance, and lower cost. Table 6.11 summarizes a developing stage of technical textiles, including medical and smart textiles.

6.7 Conclusion

Several pieces of literature and reports documented that the use of medical textiles in healthcare and hospital care sectors is growing significantly. This is largely due to the care for the quickly rising aging population, and the need to prevent the spread of various infectious diseases. Hence, the performance testing and care and quality assurance of medical textiles are critically important at the present time and in the future as well. In this chapter, some performance testing methods and standards for the evaluation of medical textiles are reviewed and discussed. In many cases, there is a consensus between the defined requirement by different organizations, including EN, ISO, and ASTM. However, medical textiles manufacturers are still required to meet performance testing requirements to be able to present their products in markets that

Table 6.11 Development stages of technical textiles

Time horizon (Years)	Barrier	Early warning	Sustainability	Functionality
0–3	Barrier maintained with lower basis weights at lower cost • Fully impervious to bacteria, virus, prions and fluids • Simpler material structures	None at present	Incorporation of some biopolymers at low additive levels • Down gaging and light weighting • Reduction of medical waste costs	• Water vapor transmission rate and breathability of fabric influenced by body temperature • Connectivity—gowns and gloves • Cooling or heating apparel and surgical drapes
3–5	Odor elimination • Smoke elimination • Tear-proof and puncture-proof drapes, gowns and gloves	Detection and disclosure of a break in barrier	Biobased polymers becoming economically justifiable • Move to green materials via current or green manufacturing technologies, reducing energy usage	• Monitoring capabilities—temperature, blood pressure, breathing, oxygen—through embedded sensors • Conformable materials for comfort, ease of donning and doffing apparel • Integrated radio-frequency identification tracking for compliance
5+	Active enhancement of the environment around the drape to promote bacterial and viral barrier	• Sensors fine-tuned to detect patient distress, providing feedback and alerts • Self-healing/repairing of breached materials	Self-cleaning surfaces in hospitals—operating room tables, curtains and cubicles • Reusable and disposable products • Resterilizable and reusable products	• Encapsulated solidifying technology that provides instant rendering of bodily fluids noncontaminating, both in mobility and potency

requires either of the test standards endorsed. Also, these performance testing methods (standards) that are required to ensure care and quality assurance, including reuse and resterilization, should be checked regularly, accounted for, and described.

6.8 Sources of further information and advice

Test methods or standards, images, and websites:

EN	European standards (European Committee for Standardization, CEN, Comite' Europee'n de Normalisation); http://www.cencenelec.eu/standards
BS	British Standards Institution; https://www.standardsuk.com
ASTM	American Society for Testing and Materials; http://www.astm.org/
ISO	International Organization for Standardization; http://www.iso.org/
FDA	United States Food and Drug Administration; http://www.fda.gov/

Textile world; http://www.textileworld.com
Centexbel, Textile Competence Centre; http://www.centexbel.be
NIOSH's Skin Exposures and Effects at http://www.cdc.gov/niosh/topics/skin
Quick Selection Guide to Chemical Protective Clothing, Fourth Edition, at http://www.cdc.gov/niosh/ncpc1.html
Council Directive 93/42/EEC of Jun. 14, 1993 concerning medical devices; http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1459226038342&uri=CELEX:31993L0042
OSHA Dermal Exposure Topic Page at https://www.osha.gov/SLTC/dermalexposure/index.html
http://www.fibre2fashion.com/industry-article/technology-industry-article/biotech-textiles/biotech-textiles4.asp
http://www.textileworld.com/Issues/2012/November-December/Nonwovens-Technical_Textiles/Medical_Textiles-How_Smart_Do_They_Have_To_Be
http://www.marketsandmarkets.com

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Various standard test methods and associated test device (set-up) images are stated in this chapter. The authors are gratefully acknowledge the European standard authority, British standard authority, and American standard and testing authority.

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