

IDENTIFICATION OF THE BRAZILIAN DEMAND FOR ACCREDITED ASSAYS FOR INTELLIGENT TEXTILES APPLIED TO HEALTH THROUGH PATENT ANALYSIS

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ABSTRACT

The market for wearable technologies generated around R\$350 billion in revenue in 2019, including several applications. Among these, those related to health care have been standing out, allowing diagnoses to be facilitated and lives to be saved. However, the existence of accredited testing laboratories is one of the challenges to be faced by the national industry to expand its participation in the smart textiles market. This study aims to identify the Brazilian demand for accredited assays focused on intelligent textiles applied to the healthcare area. To this end, an analysis of patent data from this area was performed in order to determine the current coverage of these tests and the respective existing gaps. It was concluded that most of the technologies developed in smart textiles applied to health require electrical, magnetic, and software testing. Among these, the greatest demand for software testing in smart textiles was found.

Keywords: Accredited Testing Laboratories; Smart Textiles; Patent Analysis.

1. INTRODUCTION

The textile industry has been developing products with technical functionalities and active, responsive, interactive, and intelligent structures (De Lima, 2016). These specific functions given to textiles can be called “smart properties” according to Almeida (2006). The so-called smart textiles, on the other hand, are those capable of interpreting and responding appropriately to changes in the environment, that is, the properties of these materials change due to the influence of the external environment. There is significant progress in the smart textiles industry in the US and the European Union (Valdes, 2018). Amidst the various applications provided to smart textiles, those focused on medicine and personal safety have stood out for their importance, since they can directly save lives. This gives them a higher added value and profit for their investors (Black, 2007).

Thanks to smart textiles used in healthcare, patients can be discharged from hospital to continue recovering at home more quickly because they can be monitored at home. The transdisciplinary nature of smart textiles alone is unquestionable, and when they are applied to medicine and medical care, this feature is intensified (Langenhove, 2007).

On the other hand, there are also concerns regarding certain risks that patients run with the use of these smart textile technologies, such as: possible damage caused by nanoparticles used in the composition or generated during the handling of the smart textiles; presence of metals necessary for electrical conduction; allergic reactions caused by electrochemical components of the clothing; generation of electromagnetic fields that may cause problems in hypersensitive patients; lack of regulation for maximum levels of magnetic fields to which a patient can be exposed; possibility of contact between the skin and an uninsulated conductive wire, which may cause discomfort or wounds; and other aspects related to information security, since medical information or data related to geolocation must be confidential; it is therefore necessary to provide cybersecurity both for patients and for those who have access to this data (Dolez *et al.*, 2018).

In relation to smart textiles, however, the lack of normalization and standardization hinders the development of the production chain of these materials in Brazil. Without norms and regulations, it becomes unfeasible to evaluate whether the quality standards required by the societies of consumer countries are being met. For example, it is not known what are the aging effects of the batteries needed to run some smart textiles, or how to maintain them, or what would be the consequences, especially for

human health, of defective products (Dolez *et al.*, 2018).

New textile materials have intrinsic and functional properties; their standardization is not simple, because it involves an overlap between the standardization of the “traditional” textile product and the standardization of the additional intrinsic and functional properties of the product, which makes it “smart” (Coyle, Diamond, 2016). In this sense, it is important to highlight that the European Community has commissioned the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI) to establish a standardization program for smart textiles to meet the European Regulations for these products (Decision M/553, 2017). The International Organization for Standardization (ISO) has in its structure a technical committee (TC38) on textile standardization that has been working on creating standards for smart textiles.

Standards and regulations, along with metrology, conformity assessment (testing, certification, inspection, etc.), and accreditation, activities that are carried out by specific technological institutions in the countries of the world, constitute the country’s quality infrastructure, defined as:

“(…) the totality of the institutional framework (public or private) necessary to establish and implement standardization, metrology (scientific, industrial, and legal), accreditation, and conformity assessment services (product and system inspection, testing and certification), necessary to provide acceptable evidence that products and services meet defined requirements, whether these are required by regulatory authorities (technical regulation) or by the market (contractually or inferred)” (Ruso, Filipović, Pejović, 2017).

The integral element of such infrastructure that confers reliability to it through the attestation of technical competence in conformity assessment is the accreditation, as understood from the international definition of the term. In Brazil, the only body responsible for accrediting companies that provides services in the area of conformity assessment (certifiers, inspection firms, and laboratories, among others), recognized by the Brazilian Government, is the National Institute of Metrology, Quality, and Technology (Inmetro). At Inmetro, the activity is the responsibility of the General Accreditation Coordination (Cgcre). It was historically agreed to call the set of test laboratories accredited by Inmetro for the various tests, sectors, and products as the Brazilian Network of Test Laboratories (RBLE).

With this, based on the accreditation, consumers and governmental bodies can be sure that the products tested in Brazil or abroad, whether imported, exported, or commercialized nationally, meet the required quality standards, having this evaluation been done in technically competent laboratories. Currently, the RBLE has 1,235 accredited laboratories (INMETRO, 2021) for the most diverse products and tests, whether physical, chemical, or biological. However, there are to date no laboratories accredited to perform tests on smart textile products. One possible cause is the extensive range of components that make up these products.

For Brazil, there are numerous challenges to be faced by the domestic industry to expand participation in the smart textiles market, so that these products become, in fact, similar to ordinary clothing in terms of comfort. One of them is the need for a laboratory network of tests related to smart textiles applied to the health area, also known as “medical textiles”, which enables the demonstration of conformity of this product and its components to ensure that the quality standards are met. Thus, the following questions arise: is the current Brazilian network of testing laboratories compatible with the technological trends of intelligent textiles for health care? Are the tests required for medical textiles available? This paper aims to answer these questions, using patent analysis as a tool to identify the types of tests applicable to smart textiles.

Smart Textiles Applied to Healthcare: Medical Textiles.

Smart textiles derive from the translation of the original term “smart textiles”, which in turn are found within smart materials. In the current context, “smart behavior” is defined by a material’s ability to “sense” a stimulus, interact with it passively or actively, and change its mechanical, electrical, or thermal properties according to the stimulus (FERREIRA, 2015).

Considering that clothing, in a way, is a second skin, we infer that there is a wide possibility of the emergence of new intelligent textiles, which, despite having emerged in Japan in the 1990s, are still considered incipient developments. Intelligent behavior is thus defined by the ability to react in a useful, reliable, reproducible, and generally reversible way. The absence of reversibility does not disqualify smart behavior, but it is highly undesirable in the case of smart textiles, as it makes them disposable after a single use. In this sense, smart textiles must have the ability to make changes in a controlled and predictable way, detecting and acting with appropriate responses to certain stimuli (piezoelectric, electric, magnetic, etc.) (Ferreira *et al.*, 2014).

Sanchez (2006) states that smart textiles are divided into three classes: microencapsulated, electronic, or nanotechnological. This microencapsulation allows isolating the active compounds by means of a biopolymer membrane, enabling the release of the active ingredient by diffusion, rupture, dissolution of the biopolymer, friction, or biodegradation. In addition to the sensing capability, a minimum characteristic of a smart textile, it must have at least one of the following properties: data processing, actuation, storage, and communication. Thus, one can understand why the creation of intelligent textiles that are also water-wash resistant is the great challenge of this technological segment, since such characteristics depend on miniaturized electronic components (Ferreira *et al.*, 2014).

Intelligent health-related textiles, or medical textiles, are products used for medical and biological purposes, mainly in first aid, clinical, and hygiene-related areas, such as gauze or bandaging materials and a wide variety of prosthetics or implants in the consumer and medical markets (Ali; Shavandi, 2016). According to Bartheis (2011), medical textiles have a relationship with the technical area and the life sciences, contemplating both knowledge of textile engineering, chemistry, testing, and certifications, and by the life sciences area, such as medicine, microbiology, and comfort. The predominant function performed by an intelligent textile applied to medical care is the measuring of biosignals, the most mentioned in the literature being: temperature; cardiogram; myography; acoustic recordings of heart, lung, digestion, and joints; ultrasound of blood flow, movement, breathing, humidity; blood pressure, and sweat (Das; Chowdhury, 2014).

Smart clothes that monitor patients are largely smart textiles developed by biomedical engineering that allow the entire clinical picture of the patient’s well-being inside their home to be recorded, allowing a much more complete visualization of the patient’s condition than with sporadic visits. Biomedical engineering aims to improve human well-being and promote health by creating devices for diagnosing, treating, and curing medical conditions (Coyle, Diamond, 2016).

Wearables can have great market acceptance because of their life-saving capability, as these smart textiles enable much faster clinical intervention due to the immediate availability of information on patients’ clinical status (PARK; JAYARAMAN, 2010).

A recent example of using smart clothing for accident prevention is reported by Chico-Morales *et al.* (2018), in which smart clothing fitted with an “armor”, knee pads,

control board, magnetic sensors, magnetic straps, Wi-Fi module, and system power platform can help minimize the risk of accidents to crawling babies. This system detects magnetic safety tapes placed by parents in dangerous places. When the baby goes beyond these zones, an alarm is triggered, causing the parents to intervene immediately. If the connection to the Wi-Fi network is interrupted, the system triggers a warning horn. The main types of materials and technologies used in the development of smart textiles applied to health are: phase change materials; thermochromic materials; conductive fibers and wires; quantum tunneling composites for computers; piezoelectric resistance; organic electronics or plastics; biomaterials; light emitting polymers; light emitting diodes; optical fibers; solar cells and photovoltaics; photoluminescence; photochromic materials; holography; plasma technologies; nanotechnology for coating fibers and fabrics; microencapsulation for gradual release of therapeutic substances; global positioning system; radio frequency identification (RFID) tags; and microelectronic mechanical systems (MEMS) (Van Langenhove, 2007).

These types of technology are combined to form systems capable of giving rise to different medical smart textiles, whose main purposes are divided into: wound care materials (which in turn are divided into materials for fluid control, odor control, bacterial control, physical barriers, space filling, debridement, homeostatic effect, low adherence, reducing bedsores, ion metal metabolism, and accelerating wound regeneration); wearable assistance for mobile health monitoring; materials for monitoring patients with heart disease; and textiles for monitoring physiological signals (LINTU, 2007).

For making sensors in smart clothing, the following materials are used, among others: metallic silk, organza, stainless steel filament, metal-coated aramid, conductive polymer fiber, conductive polymer coating, and carbon fiber. These materials are used because of their sensitivity, electricity conduction, and data transmission capability (Syduzzaman *et al.*, 2015).

The benefits of smart textiles applied to medicine and health care that stand out are: integration of functionality into textile interfaces; flexible materials that mold to the body; wearable materials suitable for clothing and accessories; versatility of structure, reduction of invasive procedures; inclusive design solutions for all patients; remote or home monitoring of activities; low power requirements for connection to the communication network; cost-effective solutions for disposable uses and the integration of response to therapy in the monitoring (Cattrysse, 2007).

2. METHODOLOGY

The QuestelOrbit software (a platform that searches and analyzes information contained in patent applications, whose differential is in the grouping by patent family) was used to survey and analyze the intelligent textile technologies. The data mining made use of the combination of two groups of keywords that proceeded in 884 families of patents. The aim was to retrieve from this result: the main classifications determined by the International Patent Classification (IPC), and the main filing countries.

After this survey, it was possible to understand which were the main classifications associated with smart textiles related to health, according to the IPC. A new cut and analysis was then performed using the QuestelOrbit software, restricting the search to classification A61 medical or veterinary science, which resulted in 323 families of patents. From the perspective of the availability of the national infrastructure of accredited testing laboratories, an analysis was made, according to the research objective, through a survey on Inmetro's website "Sistema de Consulta aos Escopes de Acreditação dos Laboratórios de Análises Clínicas (System for Consulting the Accreditation Scopes of Clinical Analysis Laboratories - ISO 15189) and Accredited Testing Laboratories (ISO/IEC 17025) (Rede Brasileira de Laboratórios de Ensaio - RBLE)", searching for all the accredited laboratories belonging to RBLE. The laboratories sought gathered technical competencies and capabilities linked to industries, universities, and technological institutes, and were qualified to perform testing services, ensuring the ability to obtain results according to nationally and internationally recognized methods and techniques.

The number of patent applications was then correlated to the testing classes, as established by the General Accreditation Coordination of Inmetro (Cgcre). The material collected in the patent application survey was analyzed and classified according to the testing classes, as shown in **Figure 1**, extracted from Annex I of NIT-DICLA-016-09 (Cgcre, 2020). These classes, defined by Cgcre, are sets of tests related to one or more quantities (physical, chemical, biological, or software), established based on the classification made by the various global accreditors, signatories of the International Laboratory Accreditation Cooperation (ILAC) agreement, subscribed by Cgcre. In accrediting a test laboratory, Cgcre classifies the tests according to these classes, since the testing is the most important factor in laboratory accreditation (Cgcre, 2011).

The 323 patents of intelligent textiles applied to health were analyzed in order to understand the objective of the invention, and how this would be achieved in regards to

the physical, chemical, or biological phenomena responsible for the functionality of the inventive act contained in the patent. The claims made by the patent's author were analyzed in parallel, so that some functioning mechanisms could be clarified. Many patents had inventive acts that would need more than one type of analysis (electrical, mechanical, software, etc.). Since software testing was required for most patents, they were assigned only the type of testing that would determine the efficiency of their main purpose.

3. RESULTS AND DISCUSSION

In the QuestelOrbit software, it was used the combination of the keywords ((smart or intelligent or IoT) w (textile or textiles or fabric)) and (e-textiles or smart garments or smart clothing or smart shirt or electronic textiles) in the title, abstract, and claims. The combination resulted in 902 patent families. We identified 18 families

in common in the two searches, which totaled 884 patent families. The evolution of patent publications, with search criteria in titles, abstracts, and claims, without a time frame, can be seen in **Figure 2**.

The first publication occurred in 2001. In 2005, there were 11 publications, more than double that of 2004. The study showed an average annual growth of approximately 35%, with a small drop in 2012. From 2014 to 2018 a growth of 218% was recorded, a high increase over previous years. It is highlighted in **Figure 3** the amount of patent documents published in the applicant countries. National deposits are market indicators that need to be protected.

The predominance of China is observed, as the country with the largest number of patent documents referring to smart textiles, with 506 publications, followed by the United States with 198 publications and South Korea with 171 publications. This result demonstrates an intensity

TEST CLASSES	
A. CLINICAL AND PATHOLOGICAL ANALYSIS	G. ACOUSTIC, VIBRATION, AND SHOCK TESTING
B. MECHANICAL TESTING	H. OPTICAL TESTING
B. ELECTRIC AND MAGNETIC TESTING	I. IONIZING RADIATION TESTING
C. CHEMICAL TESTING	K. SOFTWARE TESTING
D. THERMAL TESTING	G. ACOUSTIC, VIBRATION, AND SHOCK TESTING
E. NON-DESTRUCTIVE TESTING	

Figure 1: Classes of Tests

Source: extracted from CGCRE_NIT-DICLA-016-09 (2020)

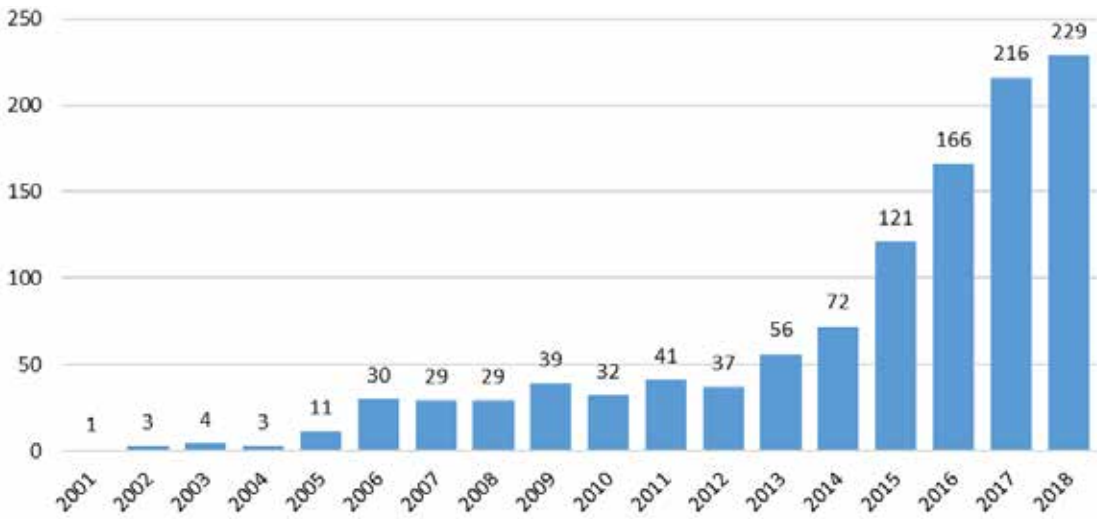


Figure 2. Annual Evolution of Patent Publications on Smart Textiles

Source: own elaboration (2020)

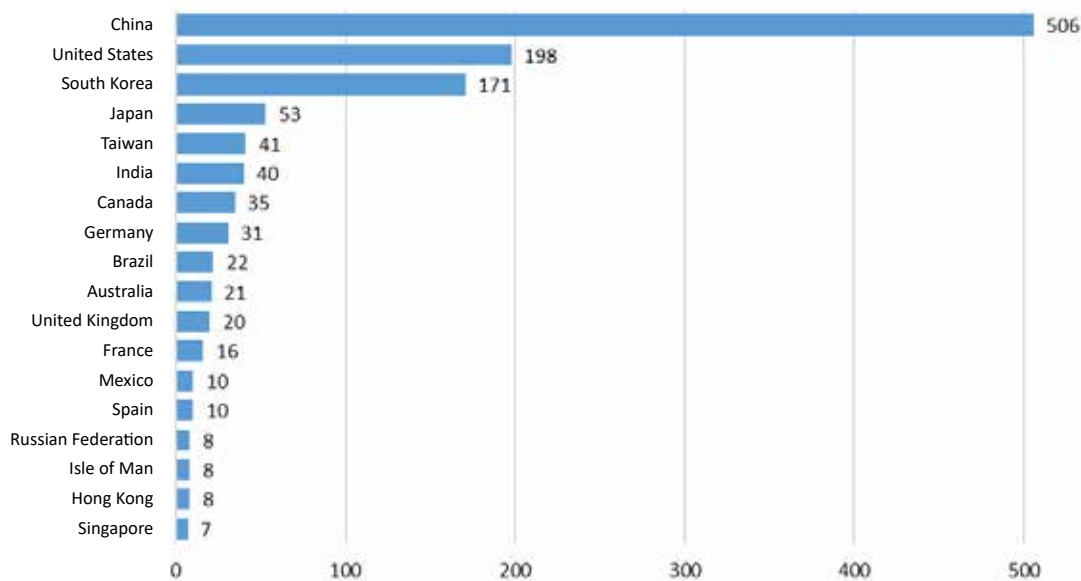


Figure 3. Patent families by country of publication

Source: own elaboration (2020)

of scientific research and technological production in the area by that country, in which the majority of patents are issued by Chinese universities.

According to the International Patent Classification, patents related to textiles belong to section D, as described in Espacenet. However, the absolute majority of patents resulting from the research were classified in the following order: sections A (Human Needs), G (Physics), and lastly D (Textiles, Paper). Thus, **Figure 4** presents the first 30 subclasses, according to the International Patent

Classification (IPC) related to smart textiles. There is a great variability in the subclasses used for patent classification.

The largest number of deposits is found in classification A41D, with 162 deposits, referring to outerwear, protective clothing, and accessories, followed by classification G06F (Electrical Digital Data Processing - computer systems based on specific computer models), and A61B (Diagnosis; Surgery; Identification), with 104 and 103 deposits, respectively. The superiority of A41D is probably

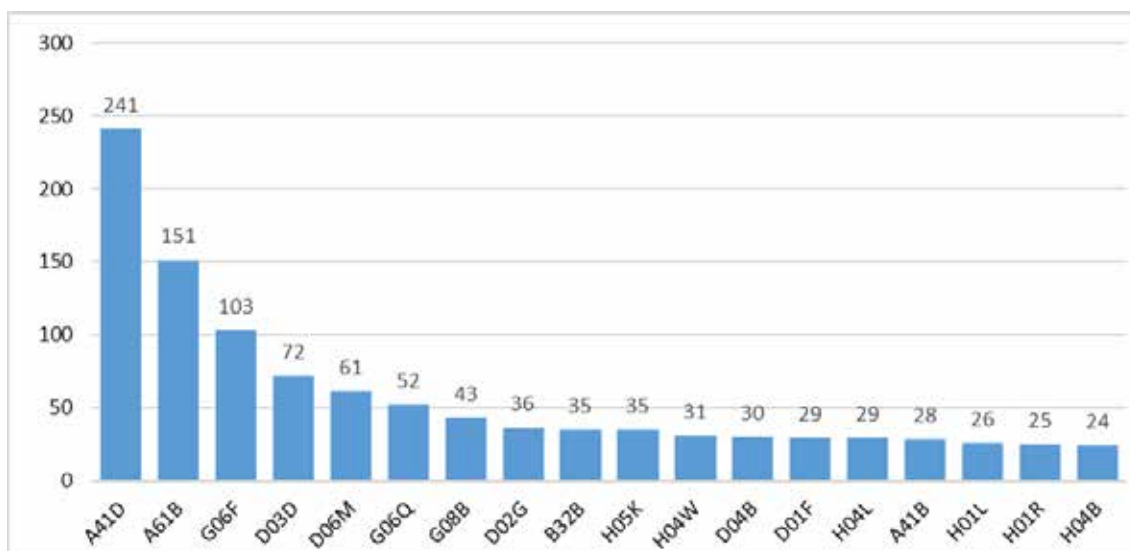


Figure 4. Number of patent families by IPC subclass

Source: own elaboration (2020)

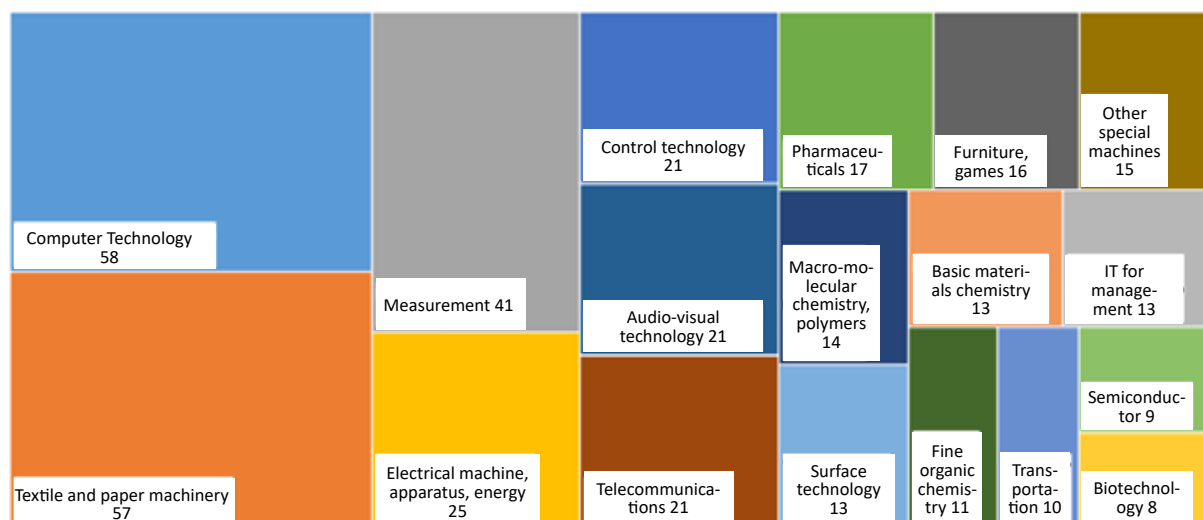


Figure 5. Dominant Technologies

Source: own elaboration (2020)

due to the lower complexity required for making accessories, while the superiority of the codes A61B and G06F corroborates the results to be presented by the present work. Based on this study, a new analysis was performed in the QuestelOrbit software, narrowing the search with the combination of the keywords ((SMART OR INTELLIGENT) W (TEXTILE# OR GARMENTS)) / CLMS / AB / DESC / ODES AND (A61#)/IPC which resulted in 284 patent families.

Figure 5 is based on the codes of the International Patent Classification (IPC), identified in the set of patents analyzed. It is possible to identify the technological domain and the main technology related to smart textiles for healthcare. The number in each quadrant represents the number of patent families that were identified in the technology described.

The main technologies related to smart textiles with medical application have properties originating in the electronic sphere, such as the ability to respond to stimuli from the environment, which can be realized through coating, graphic arts, and other technical sciences that ensure additional functions to the materials.

It is important to note that Brazil does not appear as a filing country, but as a publishing country. In 2004, there was the first request for protection of a family of smart textiles patents in Brazil. In the two following years, there was a considerable evolution, with the largest registrations occurring in 2014 and 2015.

4. TESTING LABORATORIES FOR TEXTILE PRODUCTS

Through the survey of information contained in the Inmetro website "Consultation System for Accreditation Scopes of the Test Laboratories (ISO/IEC 17025)", laboratories were identified in the Activity area: Textile, Clothing, and Related Articles. In the Inmetro website, there are laboratories of all classes of tests: mechanical tests, electrical and magnetic tests, chemical tests, thermal tests, vibration and shock tests, optical tests, biological tests, ionizing radiation tests, and software tests.

Only laboratories in the Activity Area: Textiles, Clothing, and Related Articles were identified by testing class. Of the total tests offered in the São Paulo region, 21% are mechanical tests, 12% electrical and magnetic tests, 21% chemical tests, 14% thermal tests, 12% vibration and shock tests, 8% optical tests, 8% biological tests, and 4% ionizing radiation tests. In Rio de Janeiro, there is only one laboratory responsible for offering mechanical, chemical, and thermal tests. In Paraná, there is an offer of mechanical, chemical, and biological testing classes, and in Santa Catarina, mechanical, electrical, and magnetic tests are offered. This survey found 14 laboratories for mechanical tests, six for electrical and magnetic tests, 14 for chemical tests, eight for thermal tests, six for vibration and shock tests, four for optical tests, five for biological tests, two for ionizing radiation tests, and no laboratory in the activity area "Textile, Clothing, and Related Articles - software tests".

Regarding the need for test development, **Figure 6** shows a parallel between the respective percentages of

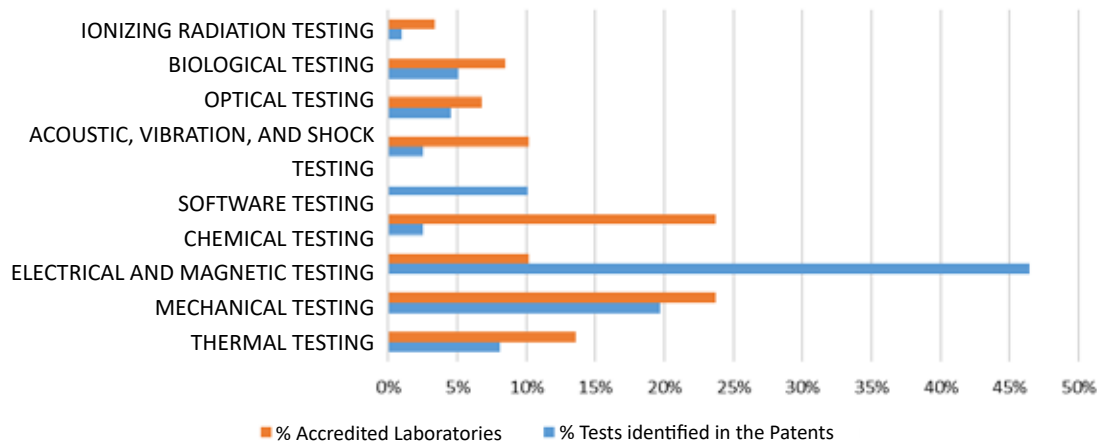


Figure 6. Tests (%) X Accredited Laboratories (%)
Source: own elaboration (2020)

test needs in relation to the total and the percentage of accredited laboratories in relation to the total number of laboratories:

- Of the 284 patent families analyzed, 20% needed mechanical tests, and among the Brazilian accredited laboratories, 24% perform mechanical tests on traditional textiles;
- 46% of the analyzed patent families need electrical and magnetic tests and only 10% of the accredited laboratories perform this type of test on traditional textiles;
- 3% of the patent families analyzed need chemical tests and 24% of the accredited laboratories in Brazil perform this type of test on traditional textiles;
- 8% need thermal tests and we have 14% of accredited laboratories performing this type of test on traditional textiles;
- 10% of the analyzed patents need software testing, and the figure reveals that there is no accredited laboratory that performs this type of testing on textile materials.

5. FINAL CONSIDERATIONS

This article has made it possible to understand the concept and meaning of the term “smart textiles”, as well as the main bottlenecks and barriers to its market expansion. It was possible to identify the main families of patents related to smart textiles, as well as to identify and

analyze the priority areas for its development. Another contribution was the identification of the main technological characteristics present in smart tissues applied to health, as well as the main demands of accredited laboratories for tests related to quality and safety verification for this type of product.

The RBLE emphasis on traditional textile products stands out, indicating a lag in relation to the theme of intelligent textiles applied to health. The Brazilian accredited laboratories are not yet prepared to meet the demand for all classes of smart textiles applied to health; therefore, it would be important to prioritize strategies that will allow a more comprehensive performance in relation to this segment in the short and medium term. It is suggested that the network of accredited laboratories be expanded through public-private funding, prioritizing the main classes of testing identified in this study for intelligent textiles for health, equipping the country with this important element of quality infrastructure.

As mentioned, most health-related smart textiles require electrical, magnetic, software, and mechanical testing to ensure their quality and function. A considerable proportion of these materials transmit measurement data via Wi-Fi to devices controlled by doctors, nurses, parents, caregivers, etc.; hence, software testing deserves more attention. It is important to keep in mind that software testing can be applied to many different types of products. There are currently eight accredited laboratories that perform Software Testing on other types of materials.

In parallel to the strengthening of the accredited laboratory infrastructure, necessary for the development of the production of intelligent health-related textiles in

Brazil, it is important that this production be stimulated by the business sector. It must be aware of the importance of the technology and innovation sectors for the establishment of its company in the market, which can occur through the articulation between the public and private sectors – as for example with the incubation of technological projects to develop these technologies, with the help of accredited laboratories – or can also occur through partnerships between Inmetro and Universities and Federal Institutes.

This type of correct action, if taken into account, can put the country at a great marketing advantage in relation to others, since this activity can stimulate investments to meet demands in advance, increasing the competitiveness of its products in the international market, which will have more quality and especially safety.

Methods of innovation development based on the articulation between the consumer market and the producer can prove to be an effective mode of innovation. In the particular case of smart textiles applied to medicine, direct contact through periodic meetings with the National Cancer Institute (INCA), the Brazilian Society of Cardiology (SBC), and the Brazilian Society of Diabetes (SBD), besides other sectors linked to the care of people who will consume smart textiles applied to health, would be essential to the perception of innovation/market improvement demands.

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