The Science of Safety: Personal Protection Equipment (PPE) that saves lives

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Narrative Review

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Abstract

Background

Health, as a human fundamental right, implies not only guaranteeing access to attention but to create the ideal conditions for the interaction between healthcare providers and patients. Within this context, the sanitary environments play a key role to ensure quality and efficacy in healthcare services which represents an ongoing challenge when it comes to controlling the risks to which healthcare providers and patients are exposed plus preventing nosocomial infections and cross-contamination among different areas. Hence, the Personal Protection Equipment is essential to comply with the occupational safety norms and the patient's safety.

Objective: To highlight the importance of accurate selection and usage of PPE considering the standards' framework and the applicable quality tests to promote their efficient use within healthcare environments.

Method: Analytical methods based on the specific international standards for each product including sampling methods established within the ISO 2859-1:1999, about the PPE with greater demand during the COVID-19 pandemic for which the Sanitary Regulatory Superintendency (SRS) has an installed capacity to make quality and performance analysis.

Results: The research results highlight the importance of selecting the adequate PPE considering the risk exposure, applicable international standards for each product and the need to comprehend the information that stems from the quality evaluations for an appropriate decision making.

Conclusion: The events during the COVID-19 pandemic denoted the several vulnerabilities in developing countries within the healthcare system, the access to it, and the challenges related to the healthcare technology such as drugs, medical devices (without the PPE) among others. This situation poses some questions about how prepared we are to confront future pandemics, how much the identified gaps have changed within the last few years and which is our capacity to respond and adapt to change from the regulatory perspective. Clearly, these topics have an important place in many international organizations, governments and regulatory authorities.

Keywords: : Personal Protection Equipment. International Standards, Occupational Safety, Medical Devices, Quality Verification and Performance

Introduction

Historically, the Personal Protection Equipment has been used in various fields and has evolved to address the challenges of public health, occupational safety, and advancements in science and technology, to fulfill its purpose more efficiently.

According to the International Labour Organization (OIT, 2024), ''PPE is equipment that will protect the user against the risk of accidents or of adverse effects on health. It can include items such as safety helmets, gloves, eye protection, high-visibility clothing, safety footwear, safety harnesses and respiratory protective equipment (RPE).''In healthcare settings, the main PPE include, but not limited to, gloves for medical examinations and surgery, medical masks, respirators, surgical gowns and biosecurity suits. PPE is also used in other fields, such as the industrial sector.

In healthcare environments, PPE serves a dual purpose: to protect both the healthcare personnel and patients. Despite its importance, there is a remarkable gap between the production of and the access to these products, especially in developing countries.

This inequality is influenced by other factors such as the geographical location, countries' purchasing power, local production capacity, and centralized manufacturing. The matter has been exposed during the recent pandemic of COVID-19, developing into many risks, for instance:

- World shortage.
- Centralized manufacturing.
- Marketing of substandard products at an international level.
- Limited access to laboratory trials to verify the products' quality.
- Lack of technical information to guide users.
- Linguistic barriers hinder comprehension of technical information on product use.

Even though the COVID-19 pandemic has been controlled, the aforementioned issues persist, despite the efforts of local governments and international organizations such as the Pan American Health Organization (PAHO) and the World Health Organization (WHO). These organizations played a key role by providing updated technical information and promoting equal access to overcome the production barriers. In the PPE and occupational safety market, it is essential the compliance with

In the market for PPE and occupational safety, compliance with regulations that ensure products provide an adequate level of protection and satisfactory performance against the risks users face is essential. For this reason, the present study also addresses the applicable international reference standards for these products, as well as the standards used in quality evaluations conducted by the Quality Control Laboratory of the Sanitary Regulatory Superintendency (SRS).

Considering the aforementioned points, it is crucial to seek solutions that address current challenges in the best possible way. Providing clear information to users is essential so they can select the appropriate PPE for their tasks, understand the importance of usage and handling instructions, and become familiar with the applicable standards and key performance tests that demonstrate the quality of these products.

Materials and methods

The study was carried out considering the main PPE used in sanitary settings, for which the PAHO issued requirements during the COVID-19 pandemic (WHO, 2020). Additionally, products installed at the SRS for quality and performance analysis were included. These products are:

- Medical gloves (both for clinical examination and surgical use)
- Medical masks
- Respirators
- Surgical gowns
- Biosafety suits

The information collection methods used were:

a. Literature Reference

The literature review includes international standards applied to the quality analysis for the aforementioned PPE, which are listed below:

- EN 149:2001+A1 Respiratory protective devices
- Filtering half masks to protect against – Requirements, testing, marking.
- NIOSH 42 CFR PART 84 – Approval of respiratory protective devices.
- EN 13795-1:2019 Surgical clothing and drapes – Requirements and test methods.
- ISO 13938-1:2019 Textiles – Bursting properties of fabrics.

• ISO 9073-3 Textiles – Test methods for nonwovens.
• EN 14683:2019 Medical face masks – Requirements and test methods.
• ISO 11193-1:2020 Single-use medical examination gloves.
• ASTM D3578-19 Standard specification for rubber examination gloves.
• ASTM D6319-19 Standard specification for nitrile examination gloves for medical application.
• ASTM D6977-19 Standard specification for polychloroprene examination gloves for medical application.
• ASTM D5250 Standard specification for poly (vinyl chloride) gloves for medical application.
• ASTM D3577-19 Standard specification for rubber surgical gloves.
• RTS 11.03.01:21 Dispositivos médicos. Mascarillas de uso médico. Especificaciones técnicas y métodos de ensayo.

On the other hand, the WHO published the document titled "Technical specifications of personal protective equipment for COVID-19", that includes the recommendations and criteria for the decision-making that PPE must comply with in healthcare environments during the pandemic. In relation to the PPE subjected to this study the WHO detailed the information shown in Table 1.

Table 1. WHO recommendations for PPE technical specific recommendations

Item	Characteristics	Performance standards (or alternative equivalent standard)
Gloves, medical examination (non-sterile)	Gloves, examination, nitrile (preferable), latex, polychloroprene or PVC, powder-free, non-sterile (e.g. minimum 230 mm total length). Minimum thickness 0.05 mm. Sizes S, M, L.	EN 455 ASTM D6319, D3578, D5250, or D6977 EN 374, optional additional Or alternative equivalent set of standards.
Gloves, surgical (sterile)	Gloves, surgical, nitrile (preferable), latex, polyisoprene or polychloroprene, sterile, powder-free, single use. Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Minimum thickness 0.10 mm. Sizes ranging 5.0–9.0.	N 455 ASTM D3577 Sterility: United States Pharmacopeia EN ISO 11607 Or alternative equivalent set of standards
Particulate respirator	Good particle filtration (minimum 94% or 95%), good breathability with design that does not collapse against the mouth (e.g. duckbill, cup-shaped). May be tested for fluid resistance (NIOSH/FDA surgical N95, EN 149 FFP2+Type IIR, GB 19083 Grade/Level 1).	Fluid resistant respirator: • Minimum NIOSH approved (42 CFR Part 84) and FDA cleared "surgical N95" • EN 149, minimum "FFP2" and EN 14683 Type IIR • GB 19083, minimum "Grade/Level 1" • Or alternative equivalent standard Non-fluid resistant respirator: • Minimum NIOSH approved "N95" according to 42 CFR Part 84 • EN 149, minimum "FFP2" • GB 2626, minimum "KN95" • Or alternative equivalent standard

Item	Characteristics	Performance standards (or alternative equivalent standard)
Mask, medical for health care worker	Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance.	Fluid resistant masks (surgical masks): • EN 14683 Type IIR • ASTM F2100 Level 1, 2 or 3 • YY 0469, with at least 98% bacterial droplet filtration • Or alternative equivalent standard Non-fluid resistant mask: • EN 14683 Type II • YY/T 0969, with at least 98% bacterial droplet filtration • Or alternative equivalent standard
Gown, surgical	Single use, disposable, non-woven material, length mid calf, sterile or non-sterile. Critical zones may be more fluid resistant than non-critical zones. Or Single use, woven material, length mid-calf, sterilizable. Critical zones may be more fluid resistant than non-critical zones. Reusable gowns should meet the minimum performance requirements after maximum suggested laundering cycles.	AAMI PB70 and ASTM F2407 EN 13795 EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cmH2 O YY/T 0506 or alternative equivalent set of standards EN 556, if sterile, or alternative equivalent set of standards .

Source: World Health Organization. (2020, p. 4–6). Technical specifications of personal protective equipment for COVID-19. Interim Guidance. Acronyms, PVC: Polyvinyl chloride. EN: European Standards. ASTM: American Society for Testing and Materials. ISO: International Organization for Standardization. NIOSH: National Institute for Occupational Safety and Health. FDA: Food and Drug Administration. FFP: Filtering Face Pieces. GB: Guobiao, Chinese for "National Standard", mandatory. EEUU: Estados Unidos de América. CFR: The Code of Federal Regulations. YY: Chinese word for medicine, "industry standard". YY/T: Chinese word for medicine, "industry standard"/ Recommended. AAMI: Association for the Advancement of Medical Instrumentation.

b.Sampling Method

The medical devices sampling analyzed in the Quality Control Laboratory is made in accordance with the standard ISO 2859-1:1999 Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection, considering an inspection level, lot size, sampling size, and the AQL. Following, in Table 2, it is detailed the amount of samples required according to the lot size.

Table 2. Sampling plan for PPE analysis

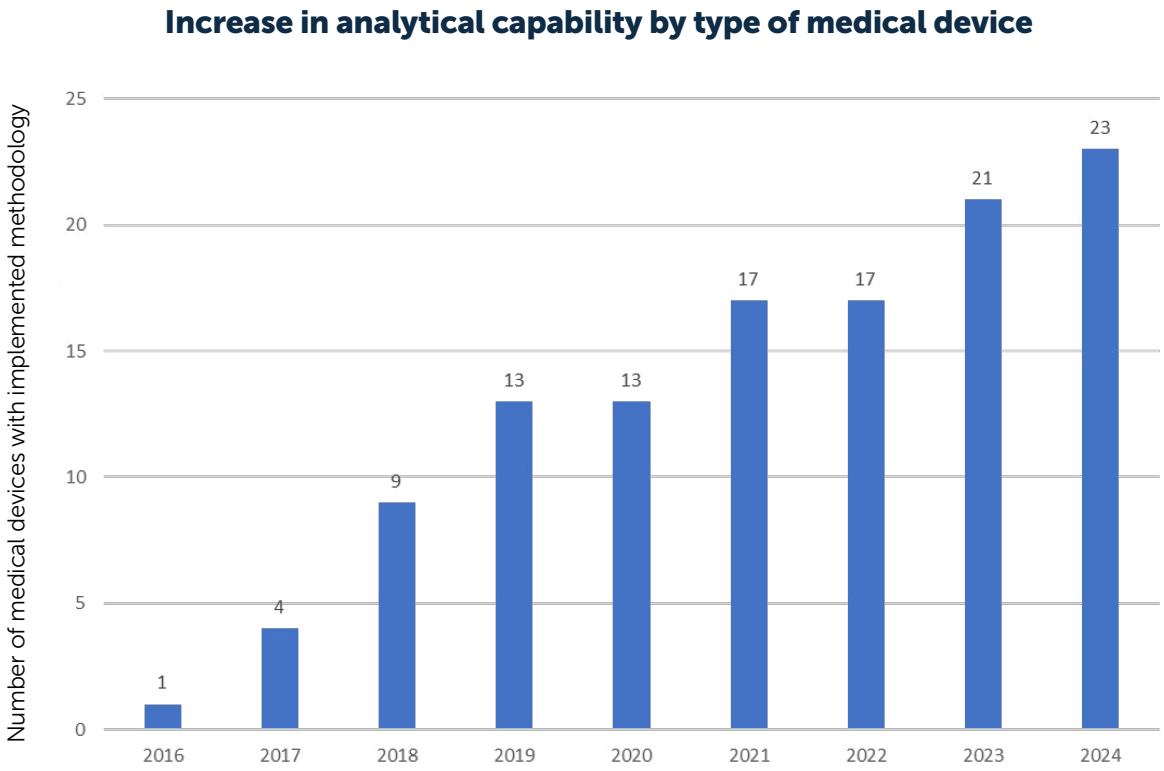
Batch size	Surgical gloves	Surgical gowns and drapes	Biosecurity suit	Medical use masks	Particle respirators	Examination gloves
281 to 500	108	167	49	69	65	76
501 to 1200	108	187	59	69	65	93
1201 to 3200	184	187	68	83	65	170
3201 to 10000	219	207	78	83	65	205
10001 to 35000	279	207	78	83	65	265
35001 to 150000	369	252	93	83	65	355
150001 to 500000	519	252	93	83	65	505
500001 to more	744	252	93	83	65	730

Source: self made

c. Quality control and applied performance

The Quality Control Laboratory has the installed capacity to make quality and performance evaluations on a diverse type of medical devices. In the graph, it can be observed an annual increase in the analysis capacity among different products which reflects that, up to date, the methodologies implemented have a scope up to 23 products 5 of which belong to PPE being the subject studied.

Graph 1. Graph that details the increase in analytical capacity in the SRS Quality Control Laboratory.



Source: self made

In table 3, are represented the implemented tests for the PPE evaluation showing the product type, analytical method, test and applicable standards.

Table 3. Description of analytical tests for PPE

Nª	Medical devices	Analytical method	Test	Applicable standards
1	Respirators	Qualitative	Visual inspection	ISO 20417:2021, EN 149:2001 + A1: 2010
		Physical mechanical	Filter efficiency	NIOSH 42 CFR part 84
			Breathing resistance	EN 149:2001 + A1:2010
2	Surgical gowns and drapes	Qualitative	Visual inspection	ISO 20417:2021, BS EN ISO 13688:2013
		Physical mechanical	Liquid penetrant inspection	EN 13795-1:2019, ISO 811:2018, ISO 139:2005
			Bursting test	EN 13795:2019, ISO 139:2005, ISO 13938-1:2019

Nª	Medical devices	Analytical method	Test	Applicable standards
			Hydraulic bursting test	EN 13795:2019, ISO 139:2005, ISO 13938-1:2019
			Tensile strength in a dry state	EN 13795:2019, ISO 9073-3:1989, ISO 186:2002, ISO 139:2005
			Tensile strength in a wet state	EN 13795:2019, ISO 9073-3:1989, ISO 186:2002, ISO 139:2005
3	Clean Air Suits	Qualitative	Visual inspection	ISO 20417:2021, BS EN ISO 13688:2013
		Physical mechanical	Liquid penetrant testing	ISO 9073-16:2007
			Tensile strength in a dry state	EN 13795:2019, ISO 139:2005, ISO 139381:2019
			Tensile and elongation strength	ISO 9073-3:1989
4	Masks	Qualitative	Visual inspection	EN 14683:2019 + AC, RTS 11.03.01:2021, ISO 20417:2021
		Physical mechanical	Differential pressure	EN 14683:2019, RTS 11.03.01:2021
			Splash test	ISO 22609:2004, RTS 11.03.01:2021
5	Medical use gloves (examination and surgical)	Qualitative	Visual inspection	ISO 11193-1:2020, ASTM D3578-19, ASTM D6319-19, ASTM D6977-19, ASTM D5250-19, NTS 11.37.01:13, ISO 10282:2023, ASTM D3577-19
		Physical mechanical	Width	ASTM D3578-19, ASTM D6319-19, ASTM D6977-19, ASTM D5250-19, ASTM D3577-19
			Length	ASTM D3578-19, ASTM D6319-19, ASTM D6977-19, ASTM D5250-19, ASTM D3577-19
			Thickness	ASTM D3578-19, ASTM D6319-19, ASTM D6977-19, ASTM D5250-19, ASTM D3577-19, ASTM D3767-03
		Physical mechanical	Air tightness	ASTM D3578-19, ASTM D6319-19, ASTM D6977-19, ASTM D5250-19, ASTM D3577-19, ASTM D5151-06, ASTM D5151-19
			Physical properties before and after aging	ASTM D412-16 (2021)

Source: self made. Acronyms, ISO: International Organization for Standardization. EN: Euronorm. NIOSH: National Institute for Occupational Safety and Health. CFR: The Code of Federal Regulations. RTS: Reglamento Técnico Salvadoreño (Salvadoran Technical Guidelines). NTS: Norma Técnica Salvadoreña (Salvadoran Technical Standards). ASTM: American Society for Testing and Materials.

Results

In January 2024, the International Labour Organization published a set of recommendations about the PPE (ILO, 2024), highlighting its importance and the need to guarantee workplaces are safe environments. This includes providing users technical information, clear instructions, training in the adequate use of PPE, and ensuring the supervision to guarantee their correct use.

The same publication suggests guidelines to appropriately select the PPE suggesting it is essential to answer at least three key questions: Who is exposed to a risk and which risk? How long does this exposure last? and How exposed are they? Once these questions are answered a suitable PPE can be chosen in function to the residual risks in compliance with the applicable international standards. Besides, the PPE must adapt the user's anatomy considering aspects such as size, complexion and ergonomy including the equipment's weight and the possibility of wearing multiple PPE simultaneously.

Up to now, the compliance with standards becomes especially relevant since the PPE design can vary according to the geographical region and the physical characteristics in their population. For instance, during the pandemic, it was common to find breathers that did not adjust to the salvadoran population's anatomy due to the difference between complexion and size which made fitting difficult.

Then again, the evaluations performed in the Quality Control Laboratory, based on their installed capacity, have allowed the verification of the main performance characteristics according to the applied standards. These evaluations included the following analytical tests:

1. Particle breathers

a. Filter efficacy

This test determined the filter's efficiency level in particle breathers type N, for this the equipment shown in Figure 1 is used. This injects a spray based on a 2% sodium chlorine solution in such a way that particles are vertically directed through a controlled air flow in L/min from the breather's external to internal side, which is in contact with the user's face. This way, particle penetration is measured through the filter and determines its efficacy in percentile terms from 0 to 100%. The results are compared with the manufacturer's standards to verify its conformity.

Figure 1. Equipment images to determine the filter's efficacy

Figure 1a) Particulate Filter Efficiency Tester

Figure 1b) Sample holder

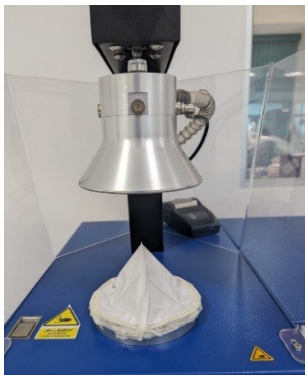
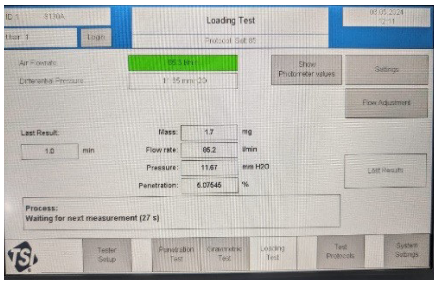


Figure 1c) Equipment screen menu



Note: equipment and premises from the Quality Control Laboratory at SRS

It is worth mentioning a relevant aspect within the science applied on the development of this test. Firstly, it must be considered that the breather's design is made to cover the upper-respiratory tract on the user, these being, the mouth, and nose. Hence, the test focuses on evaluating the filter's capacity to retain the particles suspended in the external environment, preventing contact with the respiratory tract. This is crucial in situations where there is exposure to pathogens and harmful particles, and an effective barrier is required to minimize risk of inhalation.

The barrier's efficacy will depend on the appropriate PPE selection. Namely, it will be more effective as long as a hermetic seal between the breather and the user's face is guaranteed, which is related to fitting. Moreover, it is fundamental to pay attention to the particles users are exposed to as solid particles, vapors, gasses, or particles with oil, among others. These factors are key to favor the most adequate breather.

b. Breathing resistance

This test's goal is to measure the resistance to breathing, expressed in units of pressure, during the inhaling and exhaling process and through a mannequin equipped with a flow sensor. For this, the breather is evaluated by sending airflow while the mannequin is placed into five different positions, as shown in Figure 2. The exhaling measures are taken first and secondly the inhaling measures.

Figure 2. Equipment to determine the resistance to breathing.

Figure 2a) Breathing resistance tester

Figure 2b) Mannequin placement during the test

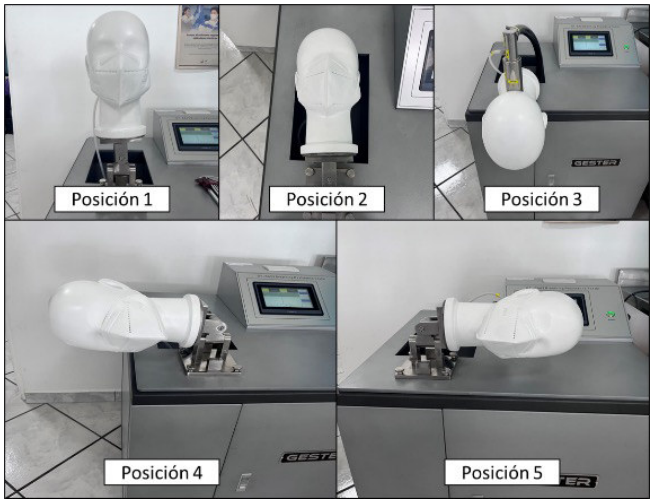
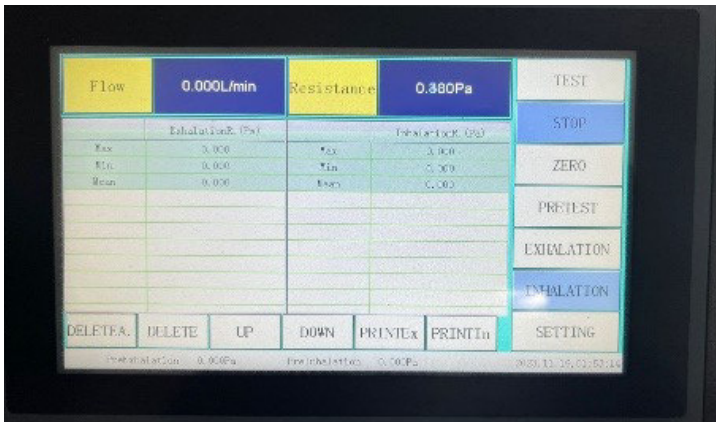


Figure 2c) Menu options on screen



Note: equipment and premises from the Quality Control laboratory at SRS.

Remember breathing involves two processes: inhaling, through which air is taken from the environment and oxygen is transported from the lungs to all body cells, and exhaling which eliminates carbon dioxide. Consequently, this test allows to correlate the different anatomical placings the human body can adopt during the PPE usage safely simulating inhaling and exhaling.

If the test's results exceed the acceptable limits, a major breathing difficulty through the breather is evident which would be unsuitable for use since there must be a balance between the protection offered by the barrier and a safe and efficient breathing.

2. Surgical gowns and drapes

a. Liquid penetrant testing

The test aims to determine the tensile strength of the material when subjected to maximum tension without compromising its barrier properties. To achieve this, the specimens are evaluated in two orientations: one cut in the longitudinal direction and the other in the transverse direction relative to the material. The specimen is held at both ends, maintaining a distance of 200 mm between the clamps, and a longitudinal force is applied at a constant speed until rupture occurs. From the force-elongation curve, the tensile strength and elongation are determined. Figure 6 shows an image of the equipment used in the test.

Figure 3. Image of the equipment for determination of liquid penetration resistance

Figura 3a) Hydrostatic Head Tester

Figure 3b) Sample holder

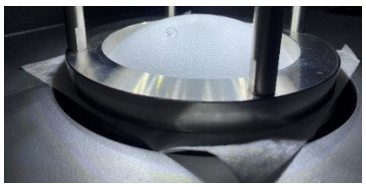
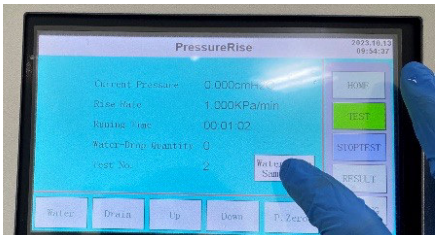


Figure 3c) Menu options displayed on the equipment screen



Note: equipment and premises from the Quality Control laboratory at SRS.

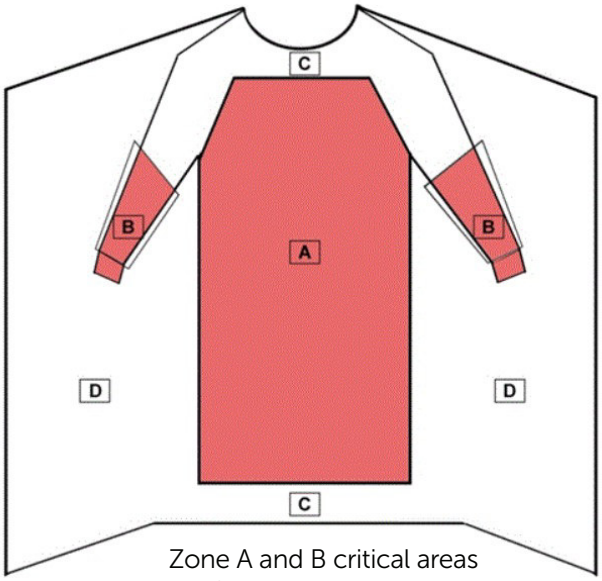
It is essential to recognize the importance of having an effective barrier before exposure to fluids in clinical and hospital environments, where fluids may be present either by gravity or under pressure. Proper risk identification is directly linked to the correct selection of the type of barrier. Accordingly, the standards establish at least two levels of barrier performance: standard and high-performance.

Standard performance is associated with less stringent requirements in terms of the hydrostatic pressure to which the material is subjected, although it is still effective against the risk of exposure. High performance, on the other hand, requires greater ability to protect against fluids under higher pressure, such as in surgical procedures.

Another variable to be taken into account is the criticality of the barrier according to the exposure zone. Figure 4 shows the distribution of critical and less critical areas according to the area to be protected. Areas A and B are classified as critical, since in a clinical or surgical procedure they are the most prone to exposure to body fluids, such as blood. In contrast, areas C and D are considered less critical to such exposure.

In conclusion, the requirements for the product's quality are determined by two key factors: the performance level (high or standard) and the zone type (critical or less critical). It is essential that the manufacturers include both features on the product label to allow a proper and informed selection of the PPE. According to the performance evaluation, unless otherwise specified by the manufacturer, the gowns must be evaluated under the performance criteria for critical areas.

Figure 4. Image that describes the distribution of critical areas and less critical on surgical gowns.



Zone A and B critical areas
Zone C and D less critical areas

Note: adapted from Medical Gowns, por U. S. Food & Drug Administration, 2024. https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns#g5

b. Burst Resistance in Dry and Wet Conditions Using the Hydraulic Method
The test involves evaluating the material's ability to withstand a specific pressure without compromising its barrier properties before bursting occurs. A specimen is taken and placed on an expandable membrane using a support with a test area of 50 cm^2 and a diameter of 79.8 mm. Hydraulic pressure is then applied to the diaphragm, causing it to expand along with the material until the specimen ruptures. Figure 5 shows an image of the equipment used for the test.

Figure 5. Image of the equipment for determining burst resistance using the hydraulic method

Figure 5a) Burst Resistance in Dry and Wet Conditions Using the Hydraulic Method analyzer

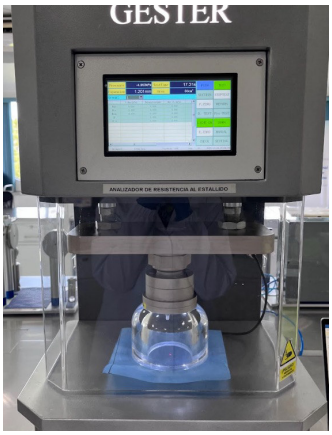
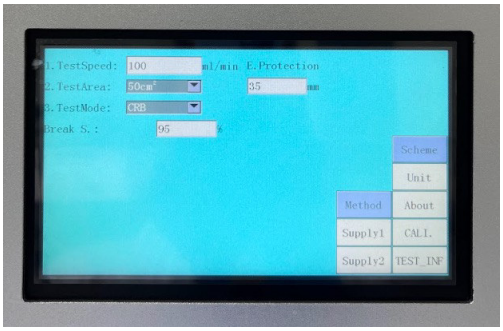


Figure 5b) Menu options displayed on the equipment screen



Note: equipment and premises from the Quality Control laboratory at SRS.

This test is designed to evaluate the mechanical resistance of the material when subjected to expansion rupture. As in the Hydrostatic Head Tester, the product quality is linked to two key factors: the performance type (standard or high) and the zone classification (critical or non-critical). It is important to highlight that, in a dry state, the quality requirements are the same for both performance types and barrier areas. However, the test in a humid state is required only for critical zones, regardless of the performance type. This ensures uniformity in the requirements associated with the material's mechanical resistance, providing an effective barrier.

c. Tensile strength in dry and wet condition

The purpose of the test is to determine the tensile strength of the material when subjected to maximum stress without compromising its barrier properties. For this purpose, specimens are evaluated in two orientations: one cut in longitudinal direction and the other in transverse direction with respect to the material. The specimen is clamped at both ends, maintaining a distance of 200 mm between the jaws, and a longitudinal force is applied at a constant speed until rupture occurs. From the force-elongation curve, the breaking strength and elongation are determined. A picture of the equipment used in the test is shown in Figure 6

Figure 6. Image of the equipment for determining the tensile strength in dry and wet condition.

Figure 6a) Universal Testing Machine

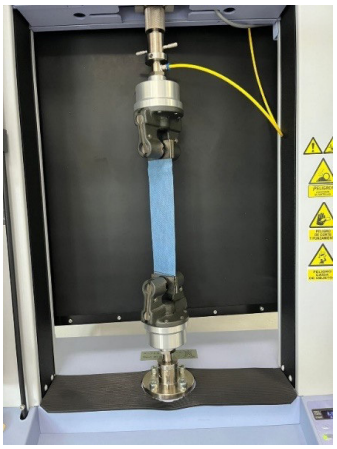
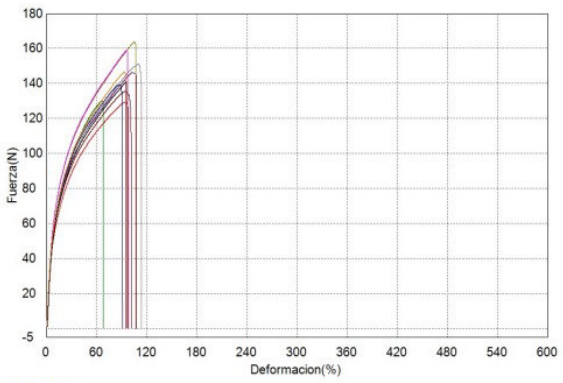


Figure 6b) Force vrs deformation of the material under tensile stress Graph



Note: equipment and premises from the Quality Control laboratory at SRS.

The results indicate that the material maintains its resistance when subjected to tensile stress during use. Furthermore, it is observed that two factors are linked to product quality: performance type (standard or high performance) and exposure zone (critical or less critical). It is important to highlight that the requirements the material must fulfill to guarantee an effective barrier are consistent, regardless of the performance type or exposure zone.

3. Clean Air Suits

For Clean Air Suits, tests for liquid penetration resistance, dry burst resistance, and tensile strength and elongation are applied. These tests are conducted similarly to those performed on surgical clothing; obtaining as a result, the same concepts regarding the interpretation of the results.

4. Masks

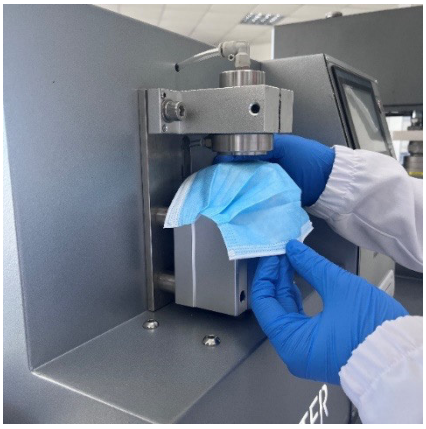
a. Differential pressure

The test consists of measuring the pressure required to allow a continuous airflow of 8 L/min to pass from the inner side to the outer side of the mask through a circular test area with a diameter of 25 mm. Thus, the face mask differential pressure tester shown in Figure 7 is used.

Figure 7. Image of the equipment for determining the differential pressure

Figure 7a) Face Mask Differential Pressure Tester

Figure 7b) Sample holder



Note: equipment and facilities from the Quality Control laboratory at SRS.

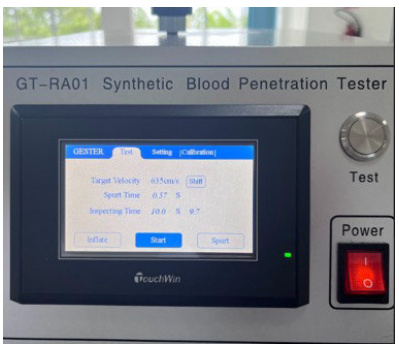
Medical masks are designed to cover the user's airway, including the mouth and nose, without affecting the natural breathing process, which consists of inhalation and exhalation. In the differential pressure test, the maximum resistance of the material is measured in Pascals, ensuring that the user's ability to breathe safely through the filter is maintained, while also keeping a barrier mechanism that prevents the flow of pathogens or particles into both airways. Any result that exceeds the acceptance limits indicates that the filter media may hinder the breathing process and put the user at risk.

b. Test method for resistance against penetration by synthetic blood
This test consists of injecting a quantity of synthetic blood over a mask horizontally to simulate a situation in which this could be splashed by a blood vessel perforation. The test is carried out under different pressure conditions (10.6 kPa, 16.0 kPa, and 21.3 kPa) and injection speeds (450 cm/s, 550 cm/s, and 635 cm/s) to determine the pressure and speed at which the sample resists the penetration of synthetic blood. Figure 8 shows a photograph of the equipment used for the test.

Figure 8. Image of the equipment for determining the splash resistance

Figura 8a) Analizador de resistencia a salpicaduras

Figura 8b) Opciones de menú en pantalla del equipo



Note: equipment and facilities from the Quality Control laboratory at SRS.

5. Surgical and examination gloves

a. Dimensions: width, length and thickness

Dimensional testing for surgical and examination gloves, no matter the material, are focused on verifying the width, length and thickness according to the glove size. These measures are made by using the digital equipment shown in figure 9, which allow obtaining accurate results automatically.

Figure 9. Dimensional testing equipment for surgical and examination exams.

Figure 9a) Automated width tester for gloves

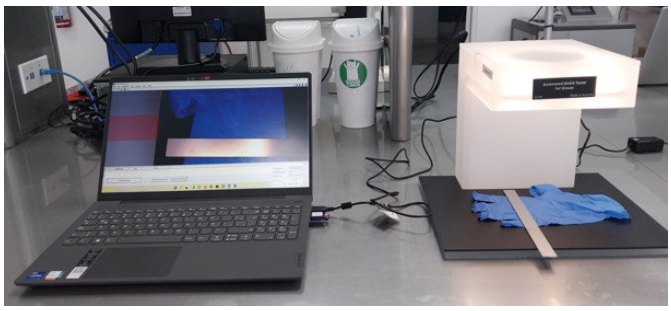


Figura 9b) Automatic length tester for gloves

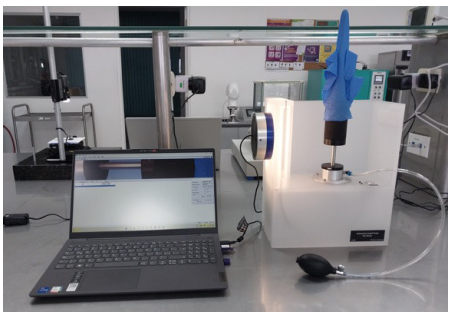
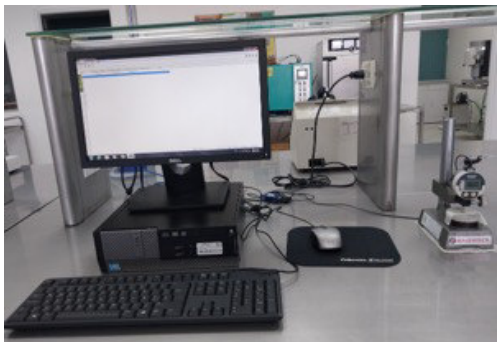


Figure 9c) Thickness tester



Note: equipment and facilities from the Quality Control Laboratory at SRS

Examination and surgical gloves offer a protective barrier for the healthcare providers and patients. Examination gloves are not usually sold sterile, whereas surgical gloves are since they are destined for invasive procedures where the skin's natural barriers have been compromised. This difference is key between both products meaning the PPE election must be based on whether the procedure is invasive or not. Afterwards, it is important to consider the dimensions corresponding to each size to select the most suitable choice.

b. Air tightness

This is a qualitative integrity test consisting in filling the glove with a liter of water to detect possible leaks through perforations in the material. It is made in surgical and examination gloves regardless of the material. The results allow evaluating the protection barrier faced during habitual use and exposure to bodily fluids.

c. Physical properties before and after aging.

The performance test for physical properties, before and after aging, are made in examination and surgical gloves, regardless of the material. The running of these tests depends on the shelf life for the lot. According to international standards, if it has been six months or more, it is only necessary to evaluate the physical properties before aging. However, if the time has gone on for fewer than six months, after aging properties must be evaluated as well which consists in applying controlled temperature conditions and air flow within a determined time frame, using the aging oven that is shown in Figure 10.

Figure 10. Picture of equipment to determine the physical properties before and after aging.

Figure 10a) Universal Testing Machine

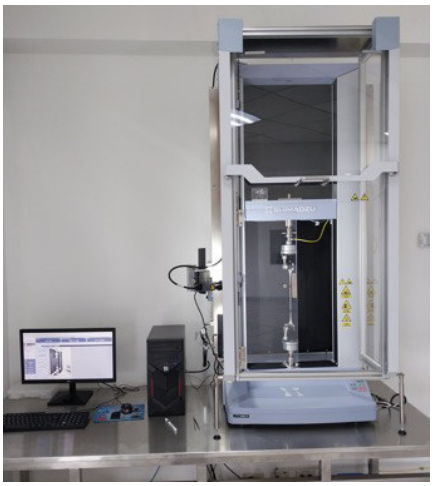


Figure 10b) Four cell aging oven

Note: Equipment and facilities from the Quality Control Laboratory at SRS.

The material's evaluation can determine three key characteristics:

• **Minimum Tensile Strength** (applicable before and after aging): measures the material's capacity to endure tensile strength without breaking. The minimum strength required varies according to the material and its habitual use (medical or surgical).

• **Maximum Tensile Strength at 500% elongation** (applicable only before aging): it evaluates the maximum strength when it is stretched to the 500% of its original size.

• **Minimum breaking elongation** (applicable before and after aging): measure the minimum elongation the material must reach before breaking.

These parameters allow the evaluation of the material's resistance, its capacity to stretch and adaptability to the wearer as well as its performance in the habitual use.

Discusion

The information collected in this study, in accordance with the understanding of concepts and quality attributes associated with the performance requirements for the PPE, is of utmost importance for an accurate selection based on the risks to which the healthcare professional is exposed.

Currently, high quality technical information is available allowing an informed decision about the PPE suitable for the healthcare environment. Also, within the Central American region the facilities count with the installed capacity to evaluate the quality among these products which places us in a privileged position to face the challenges that come with the substandard and falsified products. While the implementation of analytical tests is not simple and requires a considerable investment, it is the only way to evaluate the quality and performance of products in the market.

Despite the advances, gaps remain at a regional and international level, which relegates developing countries in a disadvantageous position. An example of this is the manufacturing centralization within certain regions or countries. Along these lines, it is fundamental to keep constant support from all productive sectors in society to be able to increase responsiveness and be better prepared before a new healthcare crisis.

Conclusion

The events that occurred during the COVID-19 pandemic revealed weaknesses among the regulators and healthcare systems at a global level, especially the ones intertwined with medical devices. Years after this earthshaking event, we can identify a positive worldwide impact: the importance of medical devices regulation has come into play, initiatives have come under way to harmonize regulation, access policies have been implemented, and post-market surveillance among other relevant aspects.

Solving the identified gaps during the pandemic is not an easy task and it is still a discussion topic in many forums. The scope in this challenge involves economy, politics, and healthcare which frequently exceeds the regulating authorities capacity and even healthcare systems as a whole. This position brings us to some queries: How prepared are we to face future pandemics? How much have the identified gaps changed in the last few years? What is our capacity and adaptation to change from the regulators' perspective?

Unquestionably, these matters become top priority in many international organizations' agendas as well as governments and regulators globally. We have significantly moved forward in singling out issues and lessons learned, acknowledging the importance of regulatory harmonization and convergence as well as the need of flexible dynamic regulating bodies to strengthen our responsiveness. Thus, it can be assured we are on the right track, and, undoubtedly, better prepared compared to some years ago.

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