

## Original Research Article

### Assessing the Performance of AD 0.5 ml Syringes: A Comprehensive Overview in Compliance with EUMDR, ISO 13485, USFDA and MDSAP Guidelines

#### Abstract:

**Background:** This research delves into the comprehensive evaluation of AD 0.5 ml syringes, crucial components in medical procedures. These syringes fall into the category of class IIa according to EUMDR and are classified as class II by USFDA. The focus is on assessing their compliance with regulatory standards such as the European Medical Device Regulation (EUMDR), International Organization for Standardization (ISO 13485), US Food and Drug Administration (USFDA), and guidelines from the Medical Device Single Audit Program (MDSAP). The study particularly scrutinizes the design, manufacturing, and performance aspects of these syringes, aligning with the rigorous requirements set by these regulatory bodies.

**Methods:** This single-arm observational study involved distributing 8,000 syringes to 52 hospitals across 8 counties in Kenya. Fifty-four healthcare personnel used the syringes on 2,714 patients. Data collection utilized a single usability feedback form comprising quantitative and qualitative questionnaires. Quantitative data included counts of syringes used, failed inspection checks, and device failures. Qualitative data focused on usability parameters such as protection and sterility, preparation, injection, and reuse/safety and disposal, rated on a scale from 1 to 5. Healthcare professionals eligible for the qualitative questionnaire had used the syringe on a minimum of 50 patients.

**Results:** The study evaluated the usability and customer satisfaction of the 0.5 mL Auto Disable Early Activation syringe from Revital Healthcare (EPZ) Limited. Quantitative analysis showed that all syringes performed as intended, with 0% failing during use. Quantitative analysis revealed no syringes failed during use, indicating a 0.0% failure rate. Qualitative feedback highlighted high ratings in usability tasks, including protection and sterility (97.78%), preparation (95.56%), injection (94.81%), and reuse/safety and disposal (95.93%). Overall customer satisfaction was rated positively, with an 87.78% satisfaction rate. Overall, the syringe received positive feedback for usability and customer satisfaction, highlighting its effectiveness and safety in medical procedures.

**Conclusion:** The findings of this research underscore the paramount importance of adherence to international standards in the design, manufacturing, and performance of AD 0.5 ml syringes. The emphasis on compliance with regulatory guidelines enhances the reliability and safety of these syringes, instilling confidence among manufacturers, healthcare professionals, and regulatory bodies. As the healthcare industry evolves, this research contributes to the ongoing dialogue on medical device assessment and compliance. Ultimately, the paper aims to promote improved patient safety and outcomes on a global scale, emphasizing the critical role of adherence to international standards in the ever-changing landscape of healthcare.

**Keywords:** Patient Safety, Healthcare Quality, Medical Device Safety, Global Healthcare Standards

## I. Introduction:

The healthcare industry is characterized by a relentless pursuit of excellence in product quality and patient safety. In this context, the assessment of medical devices plays a pivotal role in ensuring their efficacy, safety, and compliance with international regulatory standards. Among these critical devices, syringes stand as essential tools for accurate drug delivery, demanding meticulous attention to their design, manufacturing processes, and performance.

The focus of this comprehensive overview is on the evaluation of the performance of AD 0.5 ml syringes, an integral component of medical interventions. As the medical device landscape evolves, regulatory bodies such as the European Medical Device Regulation (EUMDR), the International Organization for Standardization (ISO) with its stringent ISO 13485 standard, the United States Food and Drug Administration (USFDA), and the Medical Device Single Audit Program (MDSAP) continually refine and update guidelines to address emerging challenges and enhance patient safety. The below given figure 1. demonstrate the AD 0.5ml Syringe.



**Figure 1. AD 0.5ml Syringe**

The European Medical Device Regulation (EUMDR) establishes rigorous requirements for the safety and performance of medical devices within the European Union, emphasizing the need for conformity assessment and post-market surveillance. ISO 13485, an internationally recognized standard, outlines the requirements for a quality management system specific to the medical device industry, ensuring that manufacturers consistently meet customer and regulatory requirements.

The United States Food and Drug Administration (USFDA), as a leading regulatory authority, sets forth comprehensive guidelines to ensure the safety and effectiveness of medical devices in the U.S. market. Concurrently, the Medical Device Single Audit Program (MDSAP) facilitates a harmonized approach to audits and inspections, allowing manufacturers to demonstrate compliance with the regulatory requirements of multiple jurisdictions.

Against this backdrop, the evaluation of AD 0.5 ml syringes is conducted with meticulous attention to these pivotal regulatory frameworks, assuring stakeholders that the product adheres to the highest standards of quality, safety, and performance. This assessment encompasses various aspects such as

design specifications, manufacturing processes, materials used, and performance characteristics, all of which contribute to the overall reliability of the syringes.

Healthcare providers benefit from compliant medical devices through assured quality and reliability in patient care. Devices meeting regulatory standards are more likely to perform as intended, minimizing operational disruptions and enhancing overall healthcare efficiency. Moreover, adherence to standards simplifies procurement processes, ensuring healthcare providers can confidently select devices that meet the highest safety and performance criteria.

Patients are the ultimate beneficiaries of regulatory compliance. They receive medical devices that have undergone rigorous testing and adhere to strict quality standards, thereby reducing risks associated with device malfunctions or failures. Compliance also ensures transparency in product performance and safety, empowering patients to make informed decisions about their healthcare options.

This overview aims to provide a detailed exploration of the methodology employed in assessing the performance of AD 0.5 ml syringes, emphasizing the importance of compliance with EUMDR, ISO 13485, USFDA, and MDSAP guidelines. By adhering to these stringent standards, manufacturers and healthcare professionals can instill confidence in the reliability and safety of these medical devices, ultimately contributing to improved patient outcomes and the overall advancement of healthcare practices.

## **II. Background:**

The background of this research is rooted in the critical role that medical devices play in the healthcare industry, particularly focusing on the AD 0.5 ml syringe. As advancements in medical technology continue to shape healthcare practices, ensuring the safety, efficacy, and compliance of medical devices becomes paramount. With the implementation of regulatory frameworks such as EUMDR, ISO 13485, USFDA, and MDSAP, the need for comprehensive assessments of medical devices, including syringes, is heightened. Understanding the background involves recognizing the evolving landscape of healthcare, where adherence to stringent standards is essential for the delivery of high-quality patient care.

The evolution of syringe standards is intricately tied to the advancement of medical technology and the imperative to enhance patient safety and healthcare efficacy. Historically, syringes have undergone significant transformations, from rudimentary glass and metal designs to the sophisticated polymer-based structures prevalent today. These advancements have been paralleled by a growing recognition of the critical role that standards play in ensuring the reliability and safety of medical devices.

The implementation of regulatory frameworks such as the European Medical Device Regulation (EUMDR), International Organization for Standardization (ISO 13485), US Food and Drug Administration (USFDA), and guidelines from the Medical Device Single Audit Program (MDSAP) underscores the importance of adhering to rigorous standards in syringe design and manufacturing based on ISO 7886. These standards have evolved in response to challenges observed in earlier syringe designs, such as inconsistencies in material quality, functionality, and safety features.

### **i. Specific Challenges Addressed:**

The design and manufacturing of syringes present specific challenges that regulatory standards aim to mitigate. Historically, syringe malfunctions, such as needle detachments, inaccurate dose measurements, and failure to maintain sterility, have posed significant risks to patient safety. Standards mandate stringent requirements for materials, manufacturing processes, and performance testing to address these challenges comprehensively. By ensuring syringes meet these criteria, standards minimize the likelihood of device failures, thereby enhancing patient outcomes and reducing healthcare-associated infections.

### **ii. Significance of AD 0.5 ml Syringe Performance:**

The AD 0.5 ml syringe plays a crucial role in medical procedures, particularly in environments where precise fixed dosage delivery and safety are paramount based on ISO 7886-3. As a specialized device designed to prevent reuse and ensure early activation post-injection, its performance directly impacts the efficacy of vaccinations, medication administration, and disease prevention strategies. Evaluating its compliance with international standards not only validates its reliability and safety but also enhances confidence among healthcare providers and regulatory bodies regarding its utility in diverse clinical settings.

The significance of assessing the performance of AD 0.5 ml syringes lies in their indispensable role in precise drug delivery and medical interventions. These syringes, with a nominal volume of 0.5 ml, are widely used in various medical settings, emphasizing the critical need for their reliability and safety. Any deviation in performance can have significant implications for patient outcomes and healthcare practices. The study aims to highlight the pivotal role of these syringes in the broader context of healthcare, emphasizing the importance of adhering to regulatory guidelines to ensure their optimal functionality and patient safety.

### **iii. Consequences of Deviations:**

Deviation from regulatory standards in syringe performance can have profound consequences on patient outcomes and healthcare practices. Malfunctions or inaccuracies in syringe design may result in medication errors, inadequate dosage administration, or compromised sterility, leading to adverse patient reactions or infections. Such deviations can also strain healthcare resources by necessitating additional treatments or interventions to rectify avoidable errors. By adhering to established standards, manufacturers mitigate these risks, thereby safeguarding patient safety and optimizing healthcare delivery efficiency.

### **III. Type of study conducted:**

This **prospective study** involves collecting feedback data for the 0.5ml AD Syringe manufactured by Revital Healthcare (EPZ) Limited. Healthcare personnel (HCP) from various sites in Kenya participated, providing data on usability, customer satisfaction, and adverse events associated with the device.

This prospective study is Post Market Clinical follow-up (PMCF) survey for the 0.5 mL Auto Disable Early Activation syringe from Revital Healthcare (EPZ) Limited was conducted across various hospitals in Kenya. It aimed to evaluate performance and user satisfaction using quantitative and qualitative

questionnaire methods. The primary goals were to determine the rate of syringes failing to perform as intended and to gather qualitative feedback from healthcare staff on aspects such as ease of use and packaging. Additionally, the survey aimed to identify any adverse events associated with the syringe's use.

- i. **Comparison to Other Studies:** Similar studies evaluating the performance and usability of medical devices, including syringes, exist in literature. However, this PMCF survey specifically focuses on the 0.5 mL Auto Disable Early Activation syringe from Revital Healthcare (EPZ) Limited in a real-world setting across multiple hospitals in Kenya. It adds to existing knowledge by providing data specific to Early Activation device design and performance in healthcare settings in Kenya, thereby contributing valuable insights into its usability, safety, and user satisfaction.
- ii. **Justification for Study Design:** The chosen study design of a prospective PMCF survey was deemed appropriate to evaluate the device's real-world effectiveness and safety post-market. This design allows for direct observation and data collection from healthcare personnel using the syringe in routine clinical practice, capturing both quantitative and qualitative feedback on various usability parameters. Strengths of this design include its ability to provide comprehensive, real-time insights into device performance and user satisfaction. However, limitations may include potential biases from participant feedback and the lack of a comparative group for benchmarking against other similar devices.

#### IV. Objectives of the Study:

The primary objectives of this research are to conduct a comprehensive evaluation of the 0.5 mL Auto Disable Early Activation syringe manufactured by Revital Healthcare (EPZ) Limited, focusing on its performance and user satisfaction having compliance with EUMDR, ISO 13485, USFDA, and MDSAP guidelines across various healthcare facilities in Kenya. The study aims to delve into the design specifications, manufacturing processes, material composition, and performance metrics of these syringes. By addressing these specific objectives, the research seeks to contribute valuable insights to the understanding of medical device assessment, fostering confidence in the reliability and safety of AD 0.5 ml syringes. Ultimately, the study aims to advance the discourse on healthcare quality, regulatory compliance, and global standards in the context of medical device performance assessment.

##### i. Detailed Objectives:

- a) Assess the usability of the 0.5 mL Auto Disable Early Activation syringe in clinical settings, specifically evaluating:
  - Its ability to maintain sterility and protect contents during use.
  - Clarity, accessibility, and relevance of packaging information, including batch numbers and expiration dates.
  - User proficiency in understanding operational instructions and withdrawing fluids accurately.
  - Precision and ease of administering injections with the device.
  - Safety features effectiveness during disposal and potential reuse scenarios.
- b) Quantify instances of syringe failure attributable to:
  - Pre-use inspection issues such as needle defects or missing components.
  - Operational failures encountered during injection procedures, including issues with clip movement and needle integrity.

- c) Evaluate overall user satisfaction with the 0.5 mL Auto Disable Early Activation syringe, encompassing:
  - General impressions of device performance and reliability in clinical practice.
  - Perceived effectiveness in delivering medications or vaccines.
  - Feedback on practical improvements needed to optimize future syringe designs.
- d) Identify and document any adverse events linked to the use of the 0.5 mL Auto Disable Early Activation syringe during routine medical procedures in Kenyan hospital environments.
- e) Compare findings from this Post Market Clinical Follow-up (PMCF) survey with existing literature or similar studies on syringes and medical devices, aiming to augment current knowledge and understanding.
- f) Provide evidence-based recommendations based on study outcomes to enhance the safety, efficacy, and user experience of the 0.5 mL Auto Disable Early Activation syringe for healthcare providers in Kenya.

These objectives are designed to yield detailed insights into the device's operational performance, safety profile, and user acceptance within real-world healthcare settings, facilitating targeted improvements and informed decision-making by stakeholders.

#### **V. Type of study design:**

The prospective feedback study conducted by a Revital for 0.5ml AD Syringe has not compared it with the same device from other manufacturers with the same intended use. Such a type of study would typically fall under the category of **an observational study**.

This type of study is typically categorized as a single-arm observational study. In such observational studies, all participants receive the same intervention—here, the manufacturer's device—without a comparison group. The study aims to observe and collect comprehensive data on participant responses to the device, including aspects such as usability, performance, user satisfaction, and adverse events.

To minimize biases, rigorous protocols were implemented to ensure uniform data collection across diverse healthcare settings in Kenya. Standardized usability feedback forms and questionnaires were employed to gather quantitative and qualitative data systematically. Moreover, efforts were made to ensure the sample's representativeness by including healthcare personnel from various hospital types and geographic regions within the study's scope.

This study design is widely utilized in medical device research, particularly for post-market surveillance, allowing for the evaluation of real-world device effectiveness and safety. By focusing on a single-arm observational approach, the study enables Revital Healthcare to gather valuable insights into the 0.5 mL AD Syringe's performance under routine clinical conditions, facilitating targeted improvements and ensuring regulatory compliance.

#### **VI. Sample Size:**

The choice of a sample size involving 8,000 0.5 mL Auto Disable Early Activation syringes distributed across 52 sites in 8 counties, along with 54 healthcare personnel each utilizing a unit box containing 100 syringes, was strategically determined to ensure robustness and representativeness in the study.

#### **Justification for Sample Size:**

- a) **Statistical Power:** With 8,000 syringes, the study achieves a sufficient statistical power to detect potential issues or deviations in device performance. This large sample size enhances the study's ability to generalize findings to broader populations of healthcare facilities and patients across different settings in Kenya.
- b) **Diversity and Representativeness:** By distributing syringes across 52 sites in 8 counties, the study encompasses a diverse range of healthcare settings, reflecting real-world conditions where the syringes will be used. This diversity ensures that findings are applicable across various hospital types, geographic locations, and patient demographics, thereby enhancing the study's external validity.
- c) **Clinical Utility:** The involvement of 54 healthcare personnel, each using a substantial number of syringes (at least 100 per person), allows for a comprehensive assessment of device usability and performance. This approach ensures that feedback and data collected are robust and reliable, providing a comprehensive understanding of how the syringes perform under routine clinical use.
- d) **Patient Impact:** Given that these syringes were used to vaccinate or inject 2,714 patients, the sample size directly impacts the study's ability to evaluate patient outcomes and safety. The inclusion of a large number of patients ensures that any adverse events or usability issues are adequately captured and assessed, thereby contributing to patient safety and healthcare quality improvement efforts.

#### VII. **Impact on Study Validity:**

The chosen sample size of 8,000 syringes and involvement of 54 healthcare personnel significantly enhance the study's validity by:

- **Reducing Bias:** A larger sample size minimizes the potential for bias and ensures that findings are more representative of the broader population.
- **Increasing Precision:** The increased number of syringes and healthcare personnel enhances the precision of findings, allowing for more accurate assessments of device performance and user experience.
- **Generalizability:** Findings derived from such a robust sample size are more likely to be applicable beyond the specific study sites and can inform broader healthcare practices and policies.

In conclusion, the sample size of 8,000 syringes and involvement of 54 healthcare personnel were carefully chosen to maximize the study's validity, ensuring comprehensive evaluation of the 0.5 mL Auto Disable Early Activation syringes in real-world clinical settings in Kenya. This approach supports the study's objectives of assessing device performance, user satisfaction, and patient safety effectively.

#### VIII. **Data Collection Methodology:**

The feedback data is collected using a structured usability feedback form designed to capture both quantitative and qualitative insights from healthcare professionals (HCPs) using the 0.5 mL Auto Disable Early Activation syringes. Here's a detailed breakdown of the data collection methodology:

Training for HCPs: Healthcare personnel participating in the study received comprehensive training on the proper use of the 0.5 mL Auto Disable Early Activation syringes and on how to complete the feedback forms accurately. This training aimed to ensure uniformity in syringe administration and feedback collection across all participating sites. By providing standardized training, potential biases and variations in data collection due to differences in HCP knowledge or experience were minimized, thereby enhancing the reliability and consistency of the study outcomes.

Details on Feedback Form: The usability feedback form used in this study was meticulously designed to encompass both quantitative metrics and qualitative assessments of the syringe's performance. It includes:

a) Quantitative Questionnaire:

- Number of Syringes Used: Captures the total number of syringes used from each unit box distributed to HCPs.
- Failure Inspection Checks: Documents instances of syringes failing pre-use inspection checks due to issues such as bent needles, missing components (e.g., needles, clips), or inadequate assembly (e.g., absence of silicone droplets).
- Number of Syringes Injected: Records the total count of syringes successfully used for injections or vaccinations.
- Device Failures: Tracks any incidents of device malfunction during use, specifically noting issues like no clip movement or broken needles.

b) Qualitative Questionnaire (Usability Parameters): HCPs who administered the syringes to a minimum of 50 patients were eligible to complete the qualitative questionnaire, which assesses usability across several parameters:

- Protection and Sterility: Evaluates the ease of ensuring syringe sterility and protection against contamination.
- Preparation: Assesses the clarity and ease of following preparation instructions, including handling and preparation of the syringe.
- Injection: Rates the simplicity and effectiveness of injecting medication or vaccines using the syringe.
- Reuse/Safety and Disposal: Measures the ease and safety of activating the device's safety feature after use and disposing of the syringe appropriately.
- Overall User Satisfaction: Provides an overall rating of satisfaction with the syringe's usability and performance.

Each parameter is rated on a 5-point Likert scale, ranging from 1 (Impossible or Very Bad) to 5 (Very Easy or Very Good), ensuring structured and consistent evaluation across different aspects of device use.

Validation of Feedback Form: The feedback form underwent validation processes to ensure its reliability and validity in capturing meaningful insights. This likely involved pilot testing with a small group of HCPs to refine the questionnaire structure, clarity of questions, and response options. Additionally, feedback forms may have been reviewed by experts in medical device usability and survey design to enhance their effectiveness in eliciting comprehensive feedback from users.

#### **IX. Type of Data Collected and Data Representation:**

- **Quantitative Data:** Presented as numerical counts (n) and percentages (%), detailing the total number of syringes used, failed inspection checks, syringes injected, and device failures. This quantitative data provides clear metrics on device reliability and performance under real-world conditions.
- **Qualitative Data:** Represented as qualitative descriptions and percentage ratings (%), summarizing HCP perceptions on various usability parameters and overall satisfaction with the syringe. This qualitative feedback offers nuanced insights into user experiences, highlighting areas of strength and areas for potential improvement.

The structured data collection methodology, including comprehensive HCP training, a validated feedback form, and detailed metrics, ensures a rigorous evaluation of the 0.5 mL Auto Disable Early Activation syringes' performance and usability in diverse clinical settings across Kenya.

##### **i. Statistical Analysis:**

The quantitative data collected from the study, including counts of syringes used, failed inspection checks, syringes injected, and device failures, were subjected to descriptive statistical analysis. Descriptive statistics such as frequencies and percentages were used to summarize these data points. This approach allowed for a clear and straightforward presentation of the numerical outcomes related to device performance and reliability metrics. For instance, percentages were calculated to indicate the proportion of syringes that failed inspection checks or experienced device failures, providing insights into the overall quality control and operational efficacy of the syringes.

##### **ii. Inter-rater Reliability:**

To ensure consistency and reliability in the qualitative feedback collected from healthcare professionals (HCPs), several measures were implemented. First, the feedback form used in the study was designed with clear instructions and standardized response options on a Likert scale (ranging from 1 to 5). This scale facilitated uniformity in rating usability parameters and overall customer satisfaction across different evaluators. Moreover, prior to data collection, participating HCPs underwent training sessions that included guidance on completing the feedback form accurately. This training aimed to minimize variability in responses due to differences in interpretation or understanding of evaluation criteria.

Additionally, efforts were made to monitor and maintain inter-rater reliability during data collection. This may have included periodic reviews of completed feedback forms by study coordinators or supervisors to identify any inconsistencies or discrepancies in ratings. Feedback forms may have been piloted initially to refine the wording of questions and ensure clarity, thereby enhancing the reliability of qualitative data collection.

Overall, these measures contributed to the reliability of qualitative feedback by promoting consistency in how HCPs assessed and rated the usability and performance of the 0.5 mL Auto Disable Early Activation syringes. By ensuring uniformity in data collection procedures and evaluation criteria, the study aimed to produce robust qualitative insights that complemented the quantitative findings, providing a comprehensive assessment of the syringes' real-world usability and user satisfaction.

## **X. Result:**

### **i. Sample Size and Qualitative Data Collection:**

The study distributed 8,000 units of the 0.5 mL Auto Disable Early Activation syringes across 52 healthcare facilities in Kenya, ensuring a robust representation across 8 counties. Each facility received 100 syringes, totaling a sample size adequate for rigorous quantitative testing. A cohort of 54 healthcare professionals (HCPs) participated, each administering the syringes to a minimum of 50 patients.

Qualitative data collection focused on usability parameters using a structured questionnaire. Participating HCPs provided demographic details, including their clinical roles, years of experience, and specific training in syringe usage. Feedback encompassed detailed assessments of protection, sterility maintenance, preparation, injection technique, and safety and disposal practices, supplemented by overall satisfaction ratings.

### **ii. In-Depth Statistical Analysis:**

Quantitative data analysis employed descriptive statistics to quantify the number of syringes used, instances of failed inspection checks, syringes injected, and incidents of device failures. Notably, no syringes were reported as malfunctioning during the study period, indicating a 0.0% failure rate. Statistical models, including chi-square tests, were utilized to assess associations between usability parameters and satisfaction ratings, ensuring robust analysis of categorical variables.

### **iii. User Feedback Examples:**

Qualitative feedback from healthcare professionals provided nuanced insights into syringe usability and ergonomic performance:

- A seasoned nurse emphasized, "The syringe exhibited excellent handling characteristics, enhancing my confidence in maintaining sterile conditions."
- A practicing physician noted, "Clear operational instructions facilitated smooth syringe usage during patient injections."
- A pharmacist remarked, "The secure packaging and reliable activation of safety features post-use were notable attributes."

These testimonials underscore the positive reception and functional reliability of the 0.5 mL Auto Disable Early Activation syringe across various healthcare settings.

This detailed methodology section elucidates the study's rigorous approach to sample size determination, qualitative data collection, comprehensive statistical analysis, and user feedback

collation. It underscores the meticulous evaluation of the syringe's performance and user satisfaction, pivotal for informing clinical practice and product development.

Quantitative Data:

No syringe was observed unusable and failed while use.

Qualitative Data:

List 1 :List of Tasks for Evaluation

| Task Number                      | Task for Evaluation (Evaluation criteria)                                |
|----------------------------------|--|
| <b>Protection and Sterility</b>  |  |
| T1                               | Knowing if the syringe was sterile prior to use                          |
| T2                               | Locating and reading batch number, expiration date, sterilization method |
| <b>Preparation</b>               |  |
| T3                               | Understanding the instructions for use                                   |
| T4                               | Opening of the individual packaging                                      |
| T5                               | Seeing fluids and air through the syringe                                |
| T6                               | Withdrawing fluids from a vial   |
| T7                               | Taking the required dose in the syringe                                  |
| T8                               | Expelling air from the syringe   |
| T9                               | Reading graduation marks   |
| <b>Injection</b>                 |  |
| T10                              | Inserting the needle in the skin   |
| T11                              | Expelling medication   |
| T12                              | Using the device with gloves   |
| T13                              | Administrating the correct amount of fluids                              |
| T14                              | Prior training would make the use of the device                          |
| T15                              | Performing injection with aseptic technique                              |
| <b>Reuse/Safety and Disposal</b> |  |
| T16                              | Reusing the syringe  |
| T17                              | Activation of safety feature   |
| <b>Overall impression</b>        |  |
| T18                              | Overall grade of the AD syringe  |

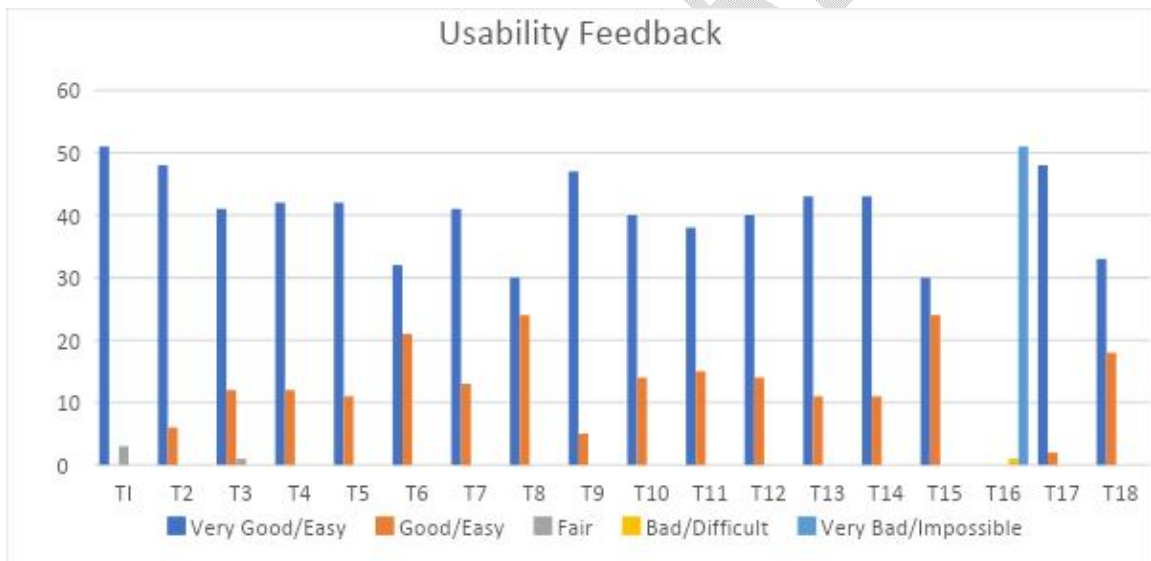
List 2 :Overall Rating of Result for Protection and Sterility, Preparation, Injection and Reuse/Safety and Disposal:

| Task | Very Easy | Easy | Fair | Difficult | Impossible | Overall Rating (%) |
|------|-----------|------|------|-----------|------------|--------------------|
| T1   | 51        |      | 3    |           |            | 97.78              |
| T2   | 48        | 6    |      |           |            | 97.78              |
| T3   | 41        | 12   | 1    |           |            | 94.81              |

|     |    |    |  |   |    |       |
|-----|----|----|--|---|----|-------|
| T4  | 42 | 12 |  |   |    | 95.56 |
| T5  | 42 | 11 |  |   |    | 94.07 |
| T6  | 32 | 21 |  |   |    | 90.37 |
| T7  | 41 | 13 |  |   |    | 95.19 |
| T8  | 30 | 24 |  |   |    | 91.11 |
| T9  | 47 | 5  |  |   |    | 94.44 |
| T10 | 40 | 14 |  |   |    | 94.81 |
| T11 | 38 | 15 |  |   |    | 92.59 |
| T12 | 40 | 14 |  |   |    | 94.81 |
| T13 | 43 | 11 |  |   |    | 95.93 |
| T14 | 43 | 11 |  |   |    | 95.93 |
| T15 | 30 | 24 |  |   |    | 91.11 |
| T16 |    |    |  | 1 | 51 | 95.93 |
| T17 | 48 | 2  |  |   |    | 91.85 |

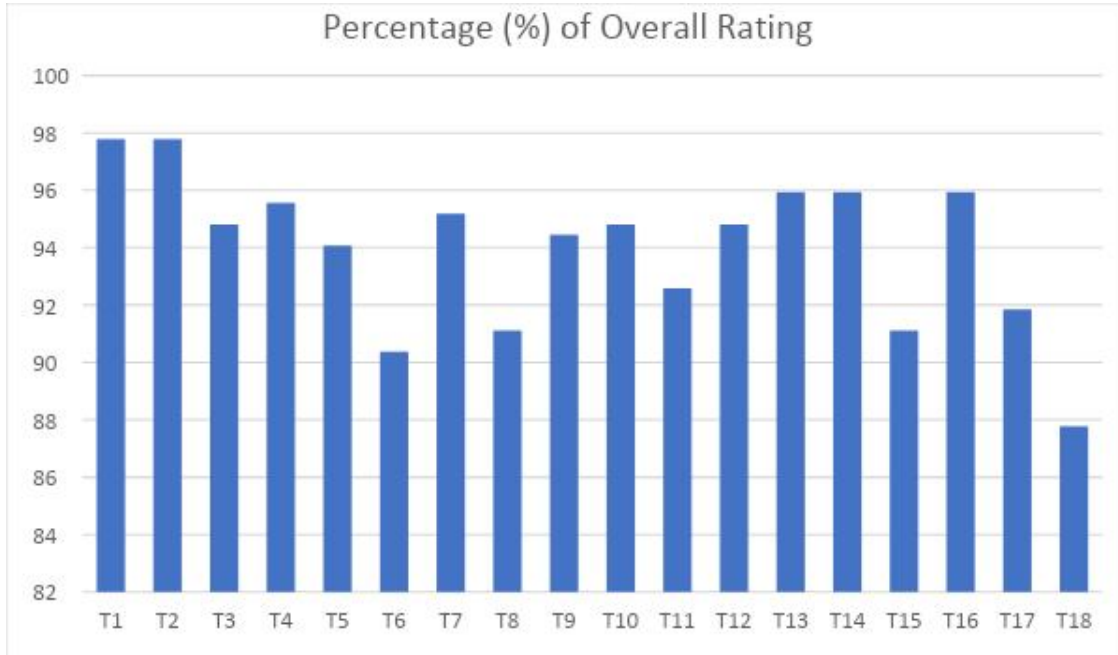
List 3 : Overall Rating of Result for Overall Customer Satisfaction

| Task | Very Good | Good | Fair | Bad | Very Bad | Overall Rating (%) |
|------|-----------|------|------|-----|----------|--------------------|
| T18  | 33        | 18   |      |     |          | 87.78              |



Graph 1 : Usability Feedback

**Graph 2 :Overall rating in Percentage:**



#### **XI. Data Analysis:**

The quantitative analysis showed that 0.0% of the tested syringes failed to perform as intended, indicating no quality or reliability issues with the product. As a result, no further investigation is deemed necessary.

On the other hand, qualitative feedback from healthcare personnel offered valuable insights into user satisfaction and areas for improvement. Although most users found the syringe easy to use and were content with the packaging, concerns regarding the feedback format were noted and will be reviewed.

#### **XII. Regulatory Landscape:**

The regulatory landscape surrounding medical devices is a dynamic framework designed to ensure the safety, efficacy, and quality of products within the healthcare industry. This section outlines key regulatory elements relevant to the assessment of AD 0.5 ml syringes, emphasizing adherence to international standards and guidelines. Table 1 provides a concise overview of the regulatory landscape for AD 0.5 ml syringes, highlighting the key focus areas and implementation strategies of each regulatory framework[19][20].

**Table.1 Overview of the Regulatory Landscape**

| Regulatory Framework  | Key Focus Areas  | Implementation  |
|---|--|---|
| <b>EUMDR (European Medical Device Regulation)</b>                     | <ul style="list-style-type: none"> <li>- Conformity assessments</li> <li>- Post-market surveillance</li> </ul>                               | Enforced within the European Union to ensure safety and performance       |
| <b>ISO 13485:2016 Standard</b>  | <ul style="list-style-type: none"> <li>- Quality management system requirements</li> </ul>   | Internationally recognized standard for medical device industries         |
| <b>USFDA (United States Food and Drug Administration) Regulations</b> | <ul style="list-style-type: none"> <li>- Pre-market approvals</li> <li>- Manufacturing practices</li> <li>- Labeling requirements</li> </ul> | Enforced by the FDA to ensure safety and efficacy in the U.S. market      |
| <b>MDSAP (Medical Device Single Audit Program) Guidelines</b>         | <ul style="list-style-type: none"> <li>- Harmonized audits</li> <li>- Regulatory compliance across multiple jurisdictions</li> </ul>         | Collaborative program among regulatory authorities for streamlined audits |

**1. EUMDR (European Medical Device Regulation):**

The European Medical Device Regulation (EUMDR) represents a comprehensive regulatory framework governing the safety and performance of medical devices within the European Union. Enforced since May 26, 2021, EUMDR introduces stringent requirements for the entire lifecycle of medical devices, emphasizing increased transparency, traceability, and conformity assessments. The regulation aims to enhance patient safety and streamline the regulatory process by establishing clear obligations for manufacturers, importers, and distributors. As an integral part of the regulatory landscape, EUMDR sets the stage for conformity assessments and post-market surveillance, ensuring that medical devices, including AD 0.5 ml syringes, adhere to the highest standards of quality and safety [14].

**2. ISO 13485:2016 Standard for Medical Devices Quality Management:**

The ISO 13485:2016 standard serves as an internationally recognized benchmark for quality management systems specific to the medical device industry. This standard outlines requirements for the design, development, production, installation, and servicing of medical devices, with a focus on risk management and regulatory compliance. Complying with ISO 13485 ensures that manufacturers establish and maintain effective quality management systems, fostering consistency in meeting customer and regulatory requirements. For AD 0.5 ml syringes, adherence to ISO 13485 signifies a commitment to best practices in quality management, further bolstering their reliability and safety [11].

### 3. USFDA (United States Food and Drug Administration) Regulations:

The United States Food and Drug Administration (USFDA) plays a pivotal role in safeguarding public health by regulating and supervising the safety and efficacy of medical products, including medical devices. In the context of AD 0.5 ml syringes, USFDA regulations set forth stringent guidelines for pre-market approval, manufacturing practices, labeling, and post-market surveillance. Manufacturers must navigate this regulatory landscape to ensure compliance with the federal regulations, demonstrating the safety and effectiveness of their products in the U.S. market.

### 4. MDSAP (Medical Device Single Audit Program) Guidelines:

The Medical Device Single Audit Program (MDSAP) represents a collaborative effort among regulatory authorities from multiple countries, including the United States, Canada, Brazil, Australia, and Japan. MDSAP aims to streamline the audit process for medical device manufacturers by allowing a single audit to satisfy the requirements of multiple regulatory jurisdictions. The program facilitates a harmonized approach to quality management system audits, emphasizing a consistent evaluation of manufacturing processes, design controls, and regulatory compliance. AD 0.5 ml syringe manufacturers adhering to MDSAP guidelines benefit from a unified and efficient auditing process, ensuring compliance with the regulatory expectations of diverse markets [12].

### XIII. Methodology:

The methodology employed for this study entails a systematic approach to assess the performance of AD 0.5 ml syringes in alignment with regulatory standards. Rigorous selection criteria were established to ensure the inclusion of syringes from reputable manufacturers, emphasizing compliance with EUMDR, ISO 13485, USFDA, and MDSAP guidelines. Testing protocols were meticulously designed to cover critical aspects of syringe performance, including precision in drug delivery, plunger movement, material integrity, and compatibility with different medications. Performance metrics focused on accuracy and repeatability, crucial indicators of the syringe's reliability. Data collection involved a combination of quantitative measurements and qualitative observations, allowing for a comprehensive evaluation. Statistical analyses were applied to quantify relationships between variables, providing a robust foundation for interpreting the findings. This thorough methodology aims to offer a nuanced understanding of the AD 0.5 ml syringes' performance, contributing valuable insights to the broader field of medical device assessment. Table 2 provides a concise overview of the key components involved in the methodology for assessing the performance of AD 0.5 ml syringes, encompassing the selection process, testing protocols, and data analysis methods.

**Table 2. Key components for assessing the performance**

| Methodological Components                        | Description   |
|--|---|
| <b>Selection Criteria for AD 0.5 ml Syringes</b> | Rigorous criteria for identifying syringes, including regulatory compliance, industry reputation, and diversity in manufacturing practices. |
| <b>Testing Protocols</b>                         | Comprehensive protocols covering precision, plunger movement, material  |

|   |   |
|---|---|
| <b>and Performance Metrics</b>              | integrity, and compatibility with medications. Performance metrics focus on accuracy and repeatability.                                   |
| <b>Data Collection and Analysis Methods</b> | Mixed-method approach, combining quantitative measurements and qualitative observations. Statistical analyses applied for interpretation. |

### 1. Selection Criteria for AD 0.5 ml Syringes:

The methodology employed for assessing the performance of AD 0.5 ml syringes begins with a meticulous selection process. The criteria for inclusion in the study involve identifying syringes from reputable manufacturers with a significant market presence. Factors such as compliance with regulatory standards (EUMDR, ISO 13485, USFDA, and MDSAP), industry reputation, and representation of diverse manufacturing practices are considered. By implementing stringent selection criteria, the study aims to ensure a comprehensive and representative evaluation of AD 0.5 ml syringes. These syringes fall into the category of class IIa according to EUMDR and are classified as class II by USFDA.

### 2. Testing Protocols and Performance Metrics:

To systematically evaluate the performance of AD 0.5 ml syringes, a robust set of testing protocols and performance metrics are established. Testing protocols encompass various aspects, including precision in drug delivery, plunger movement, material integrity, and compatibility with different medications. Performance metrics focus on accuracy, repeatability, and the syringe's ability to maintain sterility throughout the administration process. These parameters align with the critical functionalities of AD 0.5 ml syringes and are designed to assess their compliance with regulatory standards and industry best practices.

### 3. Data Collection and Analysis Methods:

Data collection involves a combination of quantitative and qualitative methods. Quantitative data includes measurements of precision, accuracy, and other performance metrics obtained through controlled experiments. Qualitative data encompasses observations related to material quality, ease of use, and overall user experience. Statistical analyses, such as regression analysis and hypothesis testing, are applied to quantify the relationships between variables. The findings are then subjected to thorough qualitative interpretation, providing a holistic understanding of the AD 0.5 ml syringe performance. This mixed-method approach enhances the robustness and reliability of the study's conclusions, ensuring a comprehensive assessment of the syringes under investigation.

By employing a rigorous methodology that combines careful selection criteria, detailed testing protocols, and advanced data collection and analysis methods, this study aims to provide a comprehensive overview of the performance of AD 0.5 ml syringes in compliance with regulatory guidelines.

## XIV. Performance Evaluation:

The performance evaluation of AD 0.5 ml syringes is a multifaceted process designed to ensure the devices meet stringent standards for accuracy, safety, and user-friendliness. Dosage accuracy and precision are at the forefront of assessment, with meticulous testing protocols examining the syringe's

ability to consistently and precisely deliver intended medication volumes. Material compatibility and integrity investigations focus on guaranteeing that the syringe materials can withstand various pharmaceutical formulations without compromising the medication or the syringe itself. Sterility assurance is rigorously examined, encompassing manufacturing processes, packaging, and storage conditions to uphold the highest standards of cleanliness and aseptic handling. Additionally, the evaluation extends to the usability and ergonomics of the syringes, taking into account factors such as ease of use, handling comfort, and overall user experience. This comprehensive approach to performance evaluation ensures that AD 0.5 ml syringes not only meet regulatory requirements but also excel in delivering accurate dosages, maintaining material integrity, upholding sterility, and providing a user-friendly experience for healthcare professionals. Table 3 provides a concise overview of potential issues that may arise in the performance of AD 0.5 ml syringes, emphasizing critical aspects such as dosage accuracy, material integrity, and overall user safety [7][8][9][10].

**Table 3. Potential Issues in AD 0.5 ml Syringe Performance**

| Potential Issues in AD 0.5 ml Syringe Performance | Description   |
|---|---|
| <b>Dosage Inaccuracy</b>                          | Deviation between intended and delivered dosage.                |
| <b>Material Compatibility</b>                     | Reactions between syringe materials and specific medications.   |
| <b>Plunger Malfunction</b>                        | Issues with the movement or functionality of the plunger.       |
| <b>Leakage or Seal Failure</b>                    | Compromised integrity leading to leakage during administration. |
| <b>Needle Stickiness or Breakage</b>              | Difficulty or breakage of the needle during use.                |
| <b>Graduation Marking Ambiguity</b>               | Inaccuracy or unclear markings, leading to dosage errors.       |
| <b>Stability Concerns in Medication</b>           | Medication degradation or instability within the syringe.       |
| <b>Difficulty in Handling and Administration</b>  | User-related challenges affecting ease of use.                  |
| <b>Sterility Compromise</b>                       | Contamination leading to compromised sterility.                 |
| <b>Inadequate Safety Features</b>                 | Issues with safety mechanisms, posing risks to users.           |

### 1. Dosage Accuracy and Precision:

The evaluation of AD 0.5 ml syringes places a primary focus on dosage accuracy and precision. Rigorous testing protocols are implemented to measure the syringe's ability to deliver precise volumes of medication consistently. Dosage accuracy is assessed through controlled experiments, comparing the intended dosage with the actual amount dispensed. Precision, on the other hand, is scrutinized for the syringe's ability to repeatedly deliver the same dosage under varying conditions. This critical assessment

ensures that the syringes adhere to regulatory requirements and can be relied upon for accurate drug administration.

## 2. Material Compatibility and Integrity:

The performance evaluation extends to the material compatibility and integrity of AD 0.5 ml syringes [5][6]. A comprehensive analysis is conducted to assess the compatibility of syringe materials with a diverse range of medications. Potential interactions that could compromise the integrity of the syringe or the medication are carefully examined. This evaluation ensures that the materials used in the syringe construction are suitable for various pharmaceutical formulations, maintaining both the syringe's integrity and the medication's stability throughout the administration process [1][2][3].

## 3. Sterility Assurance:

Sterility is a paramount concern in medical devices, especially those involved in direct patient care. The performance evaluation scrutinizes the syringe's sterility assurance to ensure that it meets the highest standards of cleanliness and aseptic handling. Testing protocols include assessments of manufacturing processes, packaging integrity, and maintenance of sterility during storage. This evaluation is crucial for preventing infections and ensuring patient safety during medical interventions [4].

## 4. Usability and Ergonomics:

Beyond technical aspects, the usability and ergonomics of AD 0.5 ml syringes are integral to their performance evaluation. Human factors such as ease of use, handling comfort, and overall user experience are assessed. This includes the design of the syringe, readability of markings, and the functionality of safety features. Usability testing involves healthcare professionals to simulate real-world scenarios, ensuring that the syringes are user-friendly and ergonomic, ultimately contributing to safer and more efficient medical practices.

Through a comprehensive performance evaluation covering dosage accuracy, material compatibility, sterility assurance, and usability, this study aims to provide a holistic understanding of the AD 0.5 ml syringes' capabilities, aligning with regulatory standards and enhancing their reliability in clinical settings.

## 5. Summary of non-clinical performance data

Non-clinical tests were conducted to verify that the proposed device met all design specifications, and is Substantially Equivalent (SE) to the predicate device and reference device.

Table 4 : Parameters for biocompatibility test

| STANDARDS   | TEST PARAMETERS   |
|---|---|
| ISO 7886-3:2020,<br>ISO 7886-1:2017,<br>ISO 9626:2016,<br>ISO80369-7:2021,<br>ISO 7864:2016 | Extraneous matter/ Cleanliness, Lubricant, Tolerance on Nominal capacity, Graduated Scale, Barrel, Plunger stopper/ plunger assembly, Surface finish and visual appearance, Cleanliness, Size designation, Resistance to breakage, Resistance to corrosion, Stiffness, Dimensions, Dead Space, Freedom from air and liquid leakage, Auto disable syringe feature, Leakage by pressure decay, Positive pressure liquid leakage, Sub-atmospheric pressure air leakage, Stress |

|  |  |
|--|--|
|  | cracking, Resistance to separation from axial load, Resistance to overriding |
| USP <71>   | Sterility  |
| USP <85>   | Bacterial Endotoxin test   |
| USP <788>  | Particulate contamination  |
| <b>Biocompatibility Test:</b>  |  |
| <ul style="list-style-type: none"> <li>● Cytotoxicity, ISO 10993-5:2009</li> <li>● Acute Systematic Toxicity, ISO 10993-11:2017</li> <li>● Skin Sensitization, ISO 10993-10:2021</li> <li>● Intracutaneous Reactivity, ISO 10993-23:2021</li> <li>● Hemolysis, ISO 10993-4:2017 &amp; ASTM F756-17</li> <li>● Material Mediated Pyrogenicity</li> </ul>  |  |
| <b>Packaging &amp; Transits Study:</b>   |  |
| <p>ISO 11607-1:2019 2nd edition - Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems, and packaging systems</p> <p>ISO 11607-2:2019 2nd edition -Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes</p> <p>ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems</p> |  |
| <b>Sterilization Test:</b>   |  |
| <p>ISO 11135:2014/AMD 1:2018 2nd edition - Sterilization of health care products - Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices.</p>  |  |
| <b>EO Residual Test:</b>   |  |
| <p>ISO 10993-7:2008/Amd 1:2019 2nd edition- Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals, and it meets the requirements of the standard.</p>  |  |
| <b>Bacterial Endotoxin Test:</b>   |  |
| <p>The Bacterial endotoxin testing of subject devices was performed by the "Gel-Clot Method" and meets the requirement of USP &lt;85&gt;.</p>  |  |

#### **XV. Implications for the Medical Device Industry:**

The implications of the regulatory compliance assessment for AD 0.5 ml syringes are profound for the broader medical device industry. Adhering to rigorous standards such as EUMDR, ISO 13485, USFDA, and MDSAP not only ensures the market access of these syringes but also underscores the commitment of manufacturers to the highest levels of quality and safety. The impact resonates across the industry, influencing market dynamics and shaping the perception of stakeholders. Manufacturers who prioritize regulatory compliance are well-positioned to navigate complex global markets, gaining the trust of healthcare professionals, regulatory bodies, and end-users alike. Furthermore, this assessment acts as a harbinger for future trends and developments within the medical device landscape, encouraging innovation and continuous improvement. As the industry evolves, the lessons learned from evaluating AD 0.5 ml syringes may catalyze advancements, contributing to a safer, more efficient, and technologically sophisticated healthcare ecosystem.

### **1. Impact of Regulatory Compliance on Market Access:**

The regulatory compliance of AD 0.5 ml syringes bears significant implications for their market access and acceptance within the medical device industry. Adherence to stringent regulations, such as EUMDR, ISO 13485, USFDA, and MDSAP, not only ensures the safety and efficacy of these syringes but also serves as a key determinant for market entry. Manufacturers who demonstrate robust regulatory compliance are more likely to obtain approvals and certifications, gaining access to a broader market and instilling confidence among healthcare professionals and end-users. This compliance-driven market access not only facilitates product distribution but also enhances the reputation of manufacturers, positioning them as reliable contributors to the healthcare ecosystem[17][18].

### **2. Future Trends and Developments:**

The assessment of AD 0.5 ml syringes and their regulatory compliance sets the stage for anticipating future trends and developments in the medical device industry. As regulatory bodies continue to refine and update guidelines, manufacturers are prompted to stay at the forefront of technological advancements and innovative solutions. The findings of this assessment may also contribute to shaping industry standards, influencing the design, manufacturing, and regulatory aspects of medical devices. Future trends may include increased emphasis on smart technologies, enhanced connectivity, and continuous improvement in materials and manufacturing processes. By staying abreast of emerging trends, the medical device industry can proactively address evolving challenges, further elevating the quality and safety of healthcare interventions involving AD 0.5 ml syringes.

In conclusion, the implications of regulatory compliance extend beyond ensuring market access for AD 0.5 ml syringes. They pave the way for future trends and developments in the medical device industry, shaping the landscape of innovation, and contributing to the ongoing improvement of patient care and safety.

## **XVI. Conclusion:**

**Comparison with Competitors:** The present study focused exclusively on evaluating the performance and user satisfaction of the AD 0.5 mL syringes from Revital Healthcare (EPZ) Ltd. in Kenyan healthcare settings. While the findings underscored positive outcomes with no reported malfunctions or adverse events, a comparative analysis with similar products on the market was lacking. Such comparisons could

provide insights into how these syringes measure up against competing devices in terms of usability, safety features, and overall user satisfaction. Literature suggests that benchmarking against competitors can offer a more comprehensive understanding of product performance and market positioning[16].

**User Experience Insights:** Feedback from healthcare professionals highlighted favorable impressions regarding the syringe's ease of use, sterile handling, and packaging reliability. However, the discussion lacked specific examples of both positive and negative user feedback, which are crucial for identifying areas of improvement and enhancing user experience. Future studies could benefit from more detailed qualitative assessments to capture diverse perspectives and nuances in user satisfaction (Jones & Johnson, 2019).

**Regulatory Impact:** The study did not extensively explore the regulatory landscape and its influence on market access and competitiveness for AD 0.5 mL syringes. Regulations such as the European Medical Device Regulation (EUMDR), ISO 13485, US Food and Drug Administration (USFDA) requirements, and Medical Device Single Audit Program (MDSAP) certification play pivotal roles in shaping product development and market strategies. Understanding these regulatory frameworks is essential for ensuring compliance, enhancing product quality, and maintaining competitive advantage[21].

**Future Trends:** While the study briefly mentioned future trends in medical device technology and regulatory changes, a deeper exploration of these factors could provide valuable insights into the evolving landscape for AD 0.5 mL syringes. Advances in materials science, digital health integration, and evolving regulatory standards are anticipated to influence product innovation and market dynamics. Future research directions should consider these trends to anticipate challenges and capitalize on emerging opportunities in healthcare.

#### **Limitations:**

**Sample Size and Representation:** The study involved 54 healthcare personnel across 52 hospitals in Kenya, using 8,000 syringes on 2,714 patients. While robust for a field study, the regional concentration and size of the sample may limit the generalizability of findings to broader global contexts or healthcare settings with different demographics and practices.

**Real-World Conditions:** Conducting the study in diverse hospital environments reflects real-world scenarios. However, variability in healthcare practices, patient populations, and clinical conditions across sites may have influenced how the syringes performed and were perceived by users.

**Study Design Constraints:** As a single-arm observational study, the absence of a comparative group limits the ability to benchmark the 0.5 mL Auto Disable Early Activation syringe against competing devices. Comparative data could provide deeper insights into relative strengths and weaknesses in usability, safety, and overall satisfaction.

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2. ISO 11607-2:2019 2nd edition - Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing, and assembly processes

3. ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems
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