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Failure Causes and Risk Analysis of Syringe Pumps (Infusion Pumps) Based on Real-World Data

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Abstract: ***This paper introduces the operating principles and structures of syringe pumps and infusion pumps. It analyzes 340 repair records of syringe pumps (infusion pumps) used in the emergency and ICU departments of Longwan Campus of the Second Affiliated Hospital of Wenzhou Medical University from January 1, 2021 to July 1, 2024, to find out the causes of failures and conduct a brief risk analysis of the failures. It is hoped that these risks can be avoided in future clinical use to ensure the safety and effectiveness of the machine.***

Keywords: Syringe Pumps; Infusion pumps; Failure Causes; Risk Analysis.

1. INTRODUCTION

In modern medical practice, syringe pumps (infusion pumps) are key tools for precise control of drug infusion. Their stability and accuracy are crucial for patient treatment. This device uses sophisticated mechanical and electronic systems to strictly control the infusion rate, total amount and time, and is widely used in medical fields such as intensive care, anesthesia, pain treatment and chronic disease management [1-3]. However, the failure problems that syringe pumps (infusion pumps) may encounter during use cannot be ignored [4]. These failures may be caused by wear and tear of the device hardware, errors in the software program, improper operation or interference from environmental factors. Specifically, hardware failures may involve damage or failure of components such as the pump structure, sensors, and motors; software failures may manifest as program errors, algorithm defects or system compatibility issues; improper operation may include medical staff's unfamiliarity with the equipment, misoperation or lack of necessary training; and environmental factors may include power fluctuations, electromagnetic interference, temperature and humidity changes, etc. Given the importance of syringe pumps (infusion pumps) in medical care and their potential failure risks, this article will conduct an in-depth analysis of the causes of failures that occur during the use of syringe pumps (infusion pumps) and evaluate the resulting risks. We will start from multiple aspects such as equipment structure, working principle, software design, operating specifications, environmental adaptability, etc., and combine clinical actual cases and data analysis to accurately locate the root cause of the failure. Through this in-depth research, we hope to provide clinical medical staff with more specific and practical fault prevention and response strategies, help them better master the use of syringe pumps (infusion pumps), and reduce the occurrence of failures. At the same time, we also hope to provide valuable feedback and suggestions to medical device manufacturers, and promote their continuous improvement and optimization in various aspects such as product design, production, and maintenance, so as to comprehensively improve the safety, reliability and user experience of syringe pumps.

2. MATERIALS AND METHODS

2.1 Current Utilization Status of Syringe Pumps (Infusion Pumps)

Currently, the total number of syringe pumps and infusion pumps in our hospital adds up to 1,158, and the brands are SINOMDT (601 units) and SMITHS MEDICAL (557 units). There are very few other brands, which will not be discussed in this article. Among SINOMDT, the model of syringe pump is SN-A1, and infusion pump is SN-1A; Among SMITHS MEDICAL, the model of syringe pump are GRASEBY C9, GRASEBY F6 and WZ/WZS series, and the infusion pumps is GRASEBY 1200 (Figure 1). This article focuses on the syringe pumps and infusion pumps used in the emergency and ICU departments of the Longwan Campus of our hospital. Through in-depth analysis of the working principle, structural characteristics and actual failure statistics of the equipment, it aims to provide clinical medical staff with scientific failure prevention and response strategies, and provide improvement suggestions for medical equipment management departments, so as to jointly improve the medical safety and quality of the emergency and ICU departments.

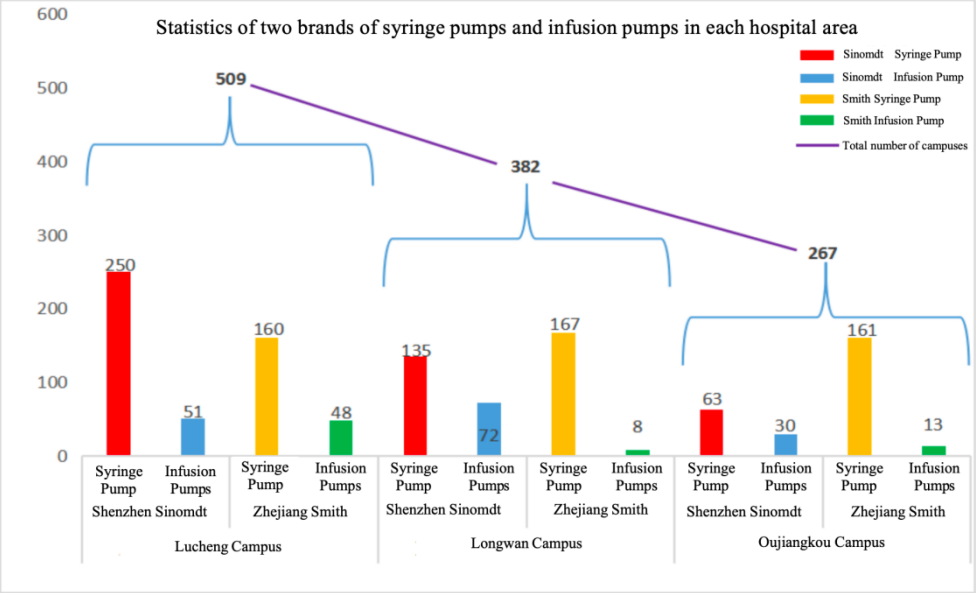

Figure 1: Statistics of two brands of syringe pumps (infusion pumps) in each hospital area

2.2 Basic Structure and Principle of Pumps of SINOMDT

The SN-A series syringe pump is a constant-volume micro-injection pump. It employs a dual-processor structure to precisely control the motor [5]. The motor drives a mechanical transmission device to push the syringe for injection. Meanwhile, it monitors various sensors and the injection process in real time, providing corresponding sound and light alarm signals when abnormalities occur. System status parameters can be displayed on the a liquid crystal display (LCD) touch screen. Users can preset and modify system configuration parameters directly by touching the screen or by using the buttons for setup and modification. The SN-A series syringe pump comprises a pump housing, a power supply system, a motor drive system, an input system, a storage system, a control system, a display system, a sensor monitoring system, and an alarm system. Additionally, it includes a communication module (optional), a handle (optional), and an infusion stand fixing clamp (optional) (Figure 2).

The SN-S series infusion pump utilizes a dual-microprocessor structure to precisely control the motor. System status parameters are displayed on the LCD touch screen. Users can preset and modify system configuration parameters directly on the touch screen or through key settings [6]. The motor drives a mechanical transmission device, which in turn moves the pump plate of the finger - pressure peristaltic pump to squeeze the liquid medicine in the infusion tube. This ensures that the medicine enters the patient's body at a uniform speed, with an accurate dosage, and in a safe manner. The infusion pump also monitors various sensors and the infusion process in real time, providing corresponding sound and light alarm signals when abnormalities occur. In addition to the aforementioned structure, the SN - S series infusion pump is equipped with a tube peristaltic module and a drip sensor (optional).

On this basis, the system of syringe pump and infusion pump also allows for convenient multi-channel liquid filling and data transmission during its use (Figure 3).

Figure 2: SN-A series syringe pumps and SN- S series infusion pumps

Figure 3: Multi-channel infusion workstation

2.3 Basic Structure and Principle of Pumps of SMITHS MEDICAL

The GRASEBY C9 syringe pump is a flat-design micro-injection pump that employs a three-processor architecture, comprising a user interaction processor, a drive processor, and a safety processor. When used in conjunction with a syringe, it regulates the flow rate of the liquid injected into the patient's body [7]. The pump offers four infusion modes: rate mode, time mode, weight mode, and multi-rate mode. It can accommodate syringes of various specifications, such as 5ml, 10ml, 20ml, 30ml, and 50/60ml. Additionally, it has functions for automatic syringe calibration and dynamic pressure display. The GRASEBY C9 syringe pump consists of a housing, a motor drive system, an input system, a storage system, a control system, a display system, a sensor monitoring system, and an alarm system. Due to its lightweight and compact design, it enables multi - channel superposition and simultaneous operation (Figure 4).

The GRASEBY 1200 infusion pump is a volumetric infusion pump designed to be used in conjunction with a matching infusion set. The positive pressure generated by this infusion pump controls the flow rate of the liquid (such as medicine, nutrient solution, etc.) injected into the patient's body [8]. It comprises two major components: a finger-pressure peristaltic mechanism and a control and display system. The finger-pressure peristaltic mechanism consists of a stepper motor, a gear transmission mechanism, a crankshaft, pressure tablet, a power box, and a pressure plate. When in operation, the stepper motor rotates and drives the twelve tablets installed in the power box to move back and forth regularly through the gear transmission mechanism. These tablets alternately squeeze the infusion tube placed between the pressure plate and themselves, pumping out the medicine. The operation control system is responsible for operating and controlling the various output functions of the pump and monitoring the pump system through the dual single - chip microcomputers. During infusion, the disposable infusion set is installed in the pump, forming an infusion system together with the medicine bottle (Figure 5).

Figure 4: GRASEBY C9 and its multi-channel infusion workstation

Figure 5: GRASEBY 1200 infusion pump

2.4 Failure Statistics

The author extracted 340 repair reports concerning syringe pump (infusion pump) failures from the emergency and ICU departments of the Longwan Campus between January 1, 2021, and July 1, 2024, from the hospital's asset management system and then categorized the failure types and counted the number of repair reports for each type (Table 1 and Figure 6).

Table 1: Statistics of Fault Types and the Number of Repair Requests

Fault types	**Human Factors**		**Non-human factors**				
	The panel or buckle is broken	Other improper operations	Power-related issues	Software alarm error	Rate No	Screen display problems	Other hardware accessories failure
Number of repair requests	42	15	40	78	27	94	44

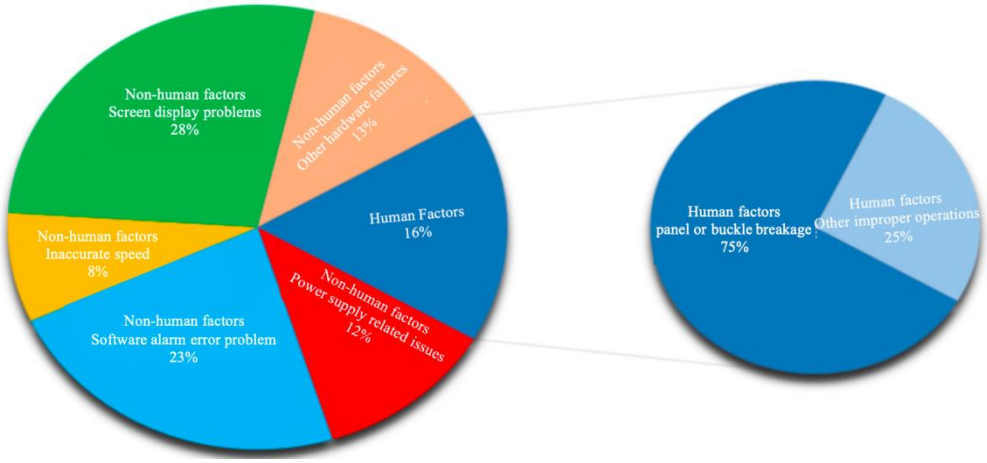

Figure 6: Percentage of each failure type

2.5 Risk Analysis

According to the data in the chart, the faults can be roughly categorized into two types: human factors and non-human factors. Regarding the human factors, all the reports related to panel or buckle breakage were for SN-A1 syringe pumps; other faults caused by improper operation by the operator mostly occurred during the using new and old machines of SMITHS MEDICAL.

Among non - human factors, power - related problems involve the machine's inability to charge or the adapter burning out. By the way, there is a case where the adapter of a machine burns out repeatedly. The machine in question is GRASEBY C9 syringe pump (Figure 7); Regarding the recurring issue of the GRASEBY C9 syringe pump's adapter burning out, we also visited the department. According to the department, even after the machine is repaired and there is no impact, the adapter can suddenly burn out and emit a burning smell. This greatly affects the patient's mood, poses a high risk of use, and impacts patient and family satisfaction with the entire department and even the hospital. Moreover, GRASEBY C9 syringe pump may also experience a back-suction phenomenon during use, causing the patient to have a blood return, which further increases the risk of use. Therefore, there is reason to question whether the adapter of this device truly meets the safety standards and whether its design complies with electrical specifications.

Figure 7: fault diagram of the Adapter of GRASEBY C9

Software alarm error problems include random alarms or the absence of alarms, key errors, motor errors, system errors, sensor errors, and various ERR code alarms (Figure 8). Both brands and models may experience inaccurate rates, screen display problems, and damage to other internal and external parts of the machine. However, the issue of unsmooth screen operation or screen display problems is specific to the SN-A1 syringe pumps and SN-1A infusion pumps (Figure 9).

Figure 8: System error

Figure 9: White screen

Among the human factors, almost all the pumps with broken buckles or panels are from SINOMDT (Figure 10). To address this problem, we have gained a deep understanding of the department's usage habits. Combining the design and appearance of the new machine, we preliminarily concluded that the frequent panel breakage is caused by the unreasonable design of the machine appearance. In order to facilitate the simultaneous use of multiple channels and integrate charging and data transmission, the research and development personnel sacrificed the handle. During the machine- picking process, the nurse has to turn the knob behind the charging frame with one hand to release the machine and take the device with the other hand. The palm of an adult woman is not large enough to fully grasp the machine of this thickness, making it easy for the machine to slip and cause the panel to break. In addition, residual liquid is likely to remain during use. After drying, the machine and the charging frame may stick together, preventing the machine from being taken out and increasing the risk of panel breakage. Moreover, the data cable of the device screen is exposed. When the panel is broken, it is easy to pull out the cable.

Even when the panel is intact, the cable is prone to breaking (Figure 11). At the same time, the machine is very susceptible to liquid contamination during use, which poses a high medical risk and is highly inconvenient for the department staff. Therefore, we can consider this cause of failure as a non - human failure cause resulting from the machine itself. In this way, the proportion of failures caused by non - human factors will increase accordingly, which is an aspect worthy of attention.

Figure 10: Fault diagram of the panel

Figure 11: Wiring diagram

3. DISCUSSION ON RISK MONITORING AND IMPROVEMENT

3.1 Standardized Operation and Training

In fact, a certain proportion of failures are caused by the clinical department's lack of familiarity with operations. This is a situation that both the clinical department and the Medical Engineering Department must pay attention to. The clinical department must strengthen self - inspection, regularly organize internal learning, training, and assessment sessions for syringe pumps (infusion pumps), and promptly address the issue of users' lack of familiarity with operations. Meanwhile, the Medical Engineering Department must also enhance inspections and supervision. According to the department's training needs, it should promptly arrange relevant usage training as well as legal and regulatory training, which will facilitate subsequent equipment management work.

3.2 Equipment Maintenance and Quality Control

Standards and specifications are formulated to ensure the safety, accuracy and reliability of syringe pumps (infusion pumps) during use. This not only guarantees the safety of patient monitoring but also enhances the quality of hospital services and medical safety [9-11]. The content of quality control comprises five parts: inspection, preventive maintenance, performance testing, fault repair, and adverse event monitoring and reporting [12-18]. The scope of an engineer's responsibility is to regularly implement the above five aspects for syringe pumps (infusion pumps). For example, inspections are conducted every two months to ensure the basic functions and safety of syringe pumps. Preventive maintenance is carried out at least once a year to check whether the functions of the syringe pumps are normal and whether the casing is damaged, cracked, or stained. Performance testing is also conducted at least once a year, and the testing content includes the calibration of infusion accuracy, the accuracy of flow control, the sensitivity of pressure monitoring, the reliability of the alarm function, etc. In

addition, electrical safety tests are performed. During fault repairs, detailed records should be made of the cause of the fault, the maintenance measures taken, the replaced parts, the results of re - testing, etc. For adverse event reporting, detailed records should be made of the time, location, personnel involved, the project, the results, the problems found, and the solutions, etc. Finally, a database for adverse events of syringe pumps (infusion pumps) was established to analyze the fault types, occurrence times, and related factors, providing a basis for equipment selection and process optimization [17, 18]. Additionally, dynamic tracking can be carried out through the PDCA method [19].

4. SUMMARY

Although the failure rate of a machine's hardware and related accessories may experience an outbreak period after a certain number of years in the machine's life cycle, it is unreasonable for equipment with a service life of less than two or three years, even if it is not brand - new, to have such a high failure rate. Although a machine may have multiple types of failures and causes, after excluding duplicate data, failures caused by the equipment itself still account for a large proportion. Therefore, these failures need to be addressed by reporting adverse events. The purpose is also to call on manufacturers of syringe pumps (infusion pumps) not only to pay more attention to ergonomic design in appearance but also to make breakthroughs and focus more on product quality, striving to achieve a balance. In addition to the aforementioned treatment methods, when facing clinical pain points, engineers from the Medical Engineering Department can also approach the problem from the perspective of their own work and solve clinical inconveniences through detailed improvements. For example, in response to the problem of the easy slippage of the syringe pumps of SINOMDT mentioned above, two improvement plans can be considered. One is to install a push - pull chassis inside the charging frame and matching buckles at the bottom of each machine. In this way, after the machine is pulled out of the charging frame, the operating space above the machine becomes larger. The nurse can loosen the bottom buckle of the machine with both hands to take the device away. It will not slip because the bottom is suspended in the air when the device is pulled out. At the same time, this device will not affect the normal operation of the injection pump or the infusion tube at the front panel. The second is to establish a new workstation mode, using an automatic pop-up method to take the syringe pump (infusion pump). This not only retains the original charging frame that is convenient for charging and data transmission but also frees both hands and makes the operation more advanced.

The author is merely offering this as a starting point for discussion and also hopes that more engineers will pay attention and expand their thinking to avoid similar risks, thus ensuring the safety and effectiveness of the machine.

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