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To cite this article: Chang Jun Wen *et al* 2019 *IOP Conf. Ser.: Mater. Sci. Eng.* **569** 042028

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Reliability Analysis of Aseptic Connection Instrument Connection Based on Fuzzy FTA

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Abstract. The reliability of the aseptic feeder in small-scale production is unstable. This paper proposes a triangular fuzzy evaluation method, which can derive the probability of occurrence of basic events in the FTA model. Sensitivity analysis is used to identify the largest source of risk for a fault and is verified by ANSYS simulation. Studies have shown that the reliability of a sterile docking instrument is 72.98%. Considering that the instrument is still in the research and development stage, it is necessary to further optimize the temperature field of the heating piece to provide construction for the reliability growth of the aseptic feeder instrument. Sexual opinion.

1. Introduction

A sterile docking device is a high frequency docking device that functions by allowing two standard sterile medical PVC tubing to be connected in a closed sterile environment [1]. In order to make the instrument work in a sterile environment and successfully complete the high-frequency connection task, first squeeze the pipe before work, then use the heating plate and high temperature principle to ensure the pipe is sterile. And it will ensure that no particles and chemical residues are produced. At present, CompoDock automatic aseptic bonding machine provides a large number of aseptic technical quality control in the domestic medical field heat sealing process, and is widely used in blood and its component preservation and white blood cell separation and filtration technology [2]. With the rapid growth of demand for networked instruments abroad, it has gradually exposed the loopholes in instrument security technology research, and the problems and management in the assembly inspection process are not perfect, especially the lack of systematic security analysis research and management. Therefore, on the basis of considering various aspects of the actual project, the operation process of the connected instrument is analyzed. This paper establishes a safety accident analysis model, combines FTA method and triangular fuzzy theory to quantitatively and qualitatively analyze the safety of connected instruments, and then performs ANSYS simulation verification on key fault parts. In this case, we must take risk management of the medical device and take effective measures to control the risk to an acceptable level to avoid unacceptable risks to the medical device, thereby reducing the occurrence of similar problems and reducing the company's losses. In this way, Chinese products can be exported to foreign countries better.

2. Connection instrument fuzzy FTA analysis

2.1. FTA model establishment and analysis method



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The equipment connected to the instrument is in a high temperature operating environment for a long time. Due to improper operation management, improper technology, equipment defects and other factors, it is easy to cause various accidents [5]. Combined with the actual situation in the operation of the connection instrument, considering the main influencing factors causing the connection failure accident, the tree diagram of the failure of the instrument connection failure is compiled, as shown in Figure 1.

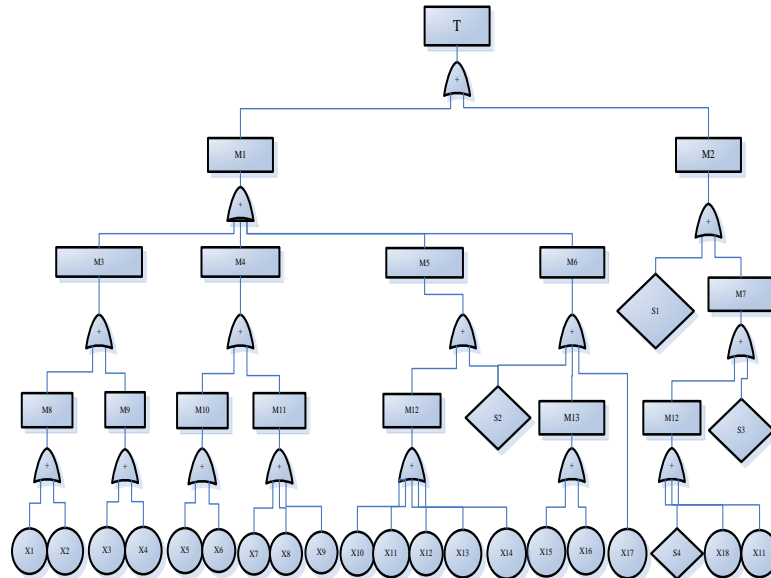


Figure 1. Instrument connection failure accident tree diagram.

Through the factors listed in the above-mentioned free trade agreement, the causes of various upper-level events affecting the highest events can be identified, and corresponding preventive measures can be developed based on these reasons to optimize the design, manufacture and connection of instruments. Operation and maintenance provide an important reference. The event name is shown in Table 1.

Table 1. Event name table.

Code	Event	Code	Event
T	Connection failed	X1	Left shift motor output out of control
M1	Leakage	X2	PLC control instruction error
M2	Unable to conduct	X3	Excessive spring travel
M3	Insufficient axial clamping force	X4	Gearbox gear loose
M4	Left tube right tube misaligned	X5	Fixture positioning deviation is too large
M5	Fusing temperature not reached	X6	Reference plate thermal expansion
M6	Poor connection to the pipe surface	X7	Upshift motor has failed
M7	Connection tube over-melting	X8	Gearbox gears with clearance
M8	Insufficient motor output	X9	The stability of the stabilizer is not equal
M9	Pipe clamp is not compacted	X10	Insufficient heating time
M10	Horizontal baseline change	X11	Heating distance is too long
M11	Left and right benchmarks are not at the same level	X12	Heating time is too long
M12	Heating unit failure	X13	The cutting wire does not reach the specified temperature
M13	Poor connection pipe material	X14	Heating sheet preheating time is too short
S1	Software control system failure	X15	Bubbles in the pipe joint
S2	The tissue inside the tube adheres to the welded surface	X16	Impurities at the connection
S3	Fan failure	X17	Tube material is different from slot

The risk of connection failure is small, defined by the minimum set of paths, and there is only one control scheme, which requires more prevention and improvement. Change the incident tree to use Boolean operations to get instrument connection failure events. There is a minimum cut set that contains 22 basic content that reflects the instrument's success tree and uses Boolean operations to find the smallest path to the incident tree that the instrument cannot connect to. Set as:

$$\{X1X2X3X4X5X6X7X8X9X10X11X12X13X14X15X16X17S1S2S3S4\}$$

2.2. Triangular fuzzy number quantitative calculation top event probability

The basic event occurrence probability value P can be directly obtained by using the failure mode and occurrence probability of the company's connected instrument components, and the normalization of the triangular fuzzy number is performed and characterized as: $q = (P, P, P)$. For basic events without statistical data, or through accurate data statistics, it is impossible or difficult to obtain the probability of occurrence. The fuzzy comprehensive evaluation method (FCE) is introduced, and the 3σ method is used to characterize the fuzzy probability of the occurrence of basic bottom events [2].

Let the weighted mean of the estimated probability of each evaluation be m and the variance be σ . Assuming that the probability value obeys a normal distribution, according to rule 3σ , the probability that the probability actual value is included in the interval $[u-3\sigma, u+3\sigma]$ is 99.7%. The probability value of each basic bottom event is vaguely characterized as $[m-3\sigma, m+3\sigma]$. This characterization method is called 3σ characterization. By determining the linguistic value, the relevant staff member evaluates the basic event language description whose fault probability is not clear based on experience, and then estimates the scores of the basic events and unexpanded events by five experts who are engaged in the field research.

Table 2. Language values and corresponding probabilities.

Language description	Very low	Lower	medium	Higher	Very high
Probability	Below 0.005	0.005—0.01	0.01—0.05	0.05—0.1	0.1-1

Table 3. Basic event fuzzy probability table.

Event	Fuzzy probability value	Event	Fuzzy probability value	Event	Fuzzy probability value
S1	(0.002,0.003,0.004)	X6	(0.001,0.002,0.003)	X15	(0.0001,0.001,0.0019)
S2	(0.0006,0.001,0.0012)	X7	(0.004,0.005,0.006)	X16	(0.0005,0.001,0.0015)
S3	(0.002,0.004,0.006)	X8	(0.0084,0.01,0.0116)	X17	(0.001,0.002,0.003)
S4	(0.001,0.0002,0.003)	X9	(0.0008,0.001,0.0012)	X18	(0.02,0.05,0.1)
X1	(0.002,0.004,0.006)	X10	(0.028,0.04,0.062)		
X2	(0.0005,0.001,0.0015)	X11	(0.04,0.05,0.08)		
X3	(0.0007,0.001,0.0013)	X12	(0.01,0.04,0.07)		
X4	(0.0018,0.003,0.0042)	X13	(0.05,0.05,0.054)		
X5	(0.0009,0.001,0.0011)	X14	(0.001,0.01,0.0011)		

Suppose that the group FCE is performed on the probability of occurrence of a basic event, and the set of estimated probability values is obtained as 3σ , The mathematical expectation of discrete random variables as its mean, that is *Formula (1)*, among them $i=1,2,\dots,n$. Calculate the standard deviation of discrete random variables *Formula (2)*. In the middle X_k Corresponding to k The probability value of the item event. According to the discrete probability theory: *Formula (3)*.

$$m = E_{(x)} = \frac{1}{n} \cdot \sum_j a_{ij} \quad (1)$$

$$\sigma = \sqrt{D_{(x)}} = \sqrt{\sum_k [x_k - E_{(x)}]^2 P_k} \quad (2)$$

$$P_k = P[X = x_k], \quad k=1,2,\dots,n \quad (3)$$

The basic event is represented by a triangular fuzzy number as $[m-3\sigma, m+3\sigma]$, m Represents the most probable probability

estimate for a basic event, $m+3\sigma$ The most probable probability estimate for the basic event, the fuzzy probability values for all basic events are shown in the table.

The magnitude of the instrument's risk can be measured by the probability of the highest event occurring. There are many ways to solve the fuzzy probability of top events. Since the fault tree of the instrument connection failure has only one minimum path set, it is more suitable to use the minimum path set method to solve the fuzzy probability of the top event. The top event fuzzy probability is calculated as follows:

$$P(T) = \prod_{r=1}^k \left\{ \left[1 - \prod_{x_i \in p_r} (1 - a_i) \right] \left[1 - \prod_{x_i \in p_r} (1 - m_i) \right] \left[1 - \prod_{x_i \in p_r} [1 - b_i] \right] \right\} \quad (4)$$

In the middle: k is the number of minimum path sets; r is the ordinal number of the minimum path set; $x_i \in p_r$ represents the r basic event of the i minimum path set; (a, m, b) are the lower bounds of the probability of occurrence of the basic event, most likely And the upper limit.

According to the calculation formula of the top event fuzzy probability, the triangular fuzzy probability distribution (0.1763, 0.2802, 0.4236) of the instrument connection fault accident can be obtained. The results show that the probability of top events is between 17.63% and 42.36%, and the probability of occurrence of top events is most likely to be 28.02%. In other words, the reliability of the system is about 72.98%. The ambiguity of the probability of occurrence of top events is determined by the ambiguity of the basic events, and the basic analysis of risk analysis can be described in the form of triangular ambiguities.

2.3. Sensitivity analysis

The sensitivity analysis calculates the degree of influence of the probability of occurrence of the basic event on the probability of occurrence of the highest event, in order to find the basic event that has a greater impact on the highest event, and takes effective measures to reduce the more sensitive basic events of probability. . Commonly used sensitivity assessment indicators include fuzzy probability importance index, critical fuzzy importance index and key importance index.

Based on the type of fuzzy number used in this paper, the sensitivity assessment indicator is defined as:

$$C_i = \frac{[P(T) - P(T_i)]}{P(T)} \quad (5)$$

In the formula: The C_i sensitivity evaluation indicator for the i basic event; $P(T)$ The probability of occurrence of a fault tree top event; $P(T_i)$ The probability of occurrence of a top event when the i basic event does not occur.

In order to better reduce the probability of failure of the top event, by finding larger sensitivity indicators C_i In turn, the probability of occurrence of the i basic event is reduced. Through the sensitivity analysis of the connection failure accident of medical devices, the sensitivity index C_i of each basic event is greater than 0.1:

$C_{10}=0.1428, C_{11}=0.3568, C_{12}=0.1428, C_{13}=0.1478, C_{18}=0.1784$. So X_{10} 、 X_{11} 、 X_{12} 、 X_{13} 、 X_{18} . there is a great influence on the probability of occurrence of the top event. The five basic events of heating film length and distance, as well as the cutting line that does not reach the specified temperature, are the greatest source of risk, that is, the temperature field analysis of the heating element should be taken, and appropriate measures should be taken to reduce the occurrence of the above basic events of the heating element. Probability can quickly reduce the probability of an accident associated with an instrument failure.

3. Simulation verification

3.1. Simulation experiment

We used ANSYS14.0 software to perform ANSYS simulation experiments on silicon carbide heaters, the key components of the instrument. First, a thermal conduction simulation analysis of the heating

assembly during connection is performed, which includes a power distribution of the heating sheet and a schematic diagram of the heat conduction region.

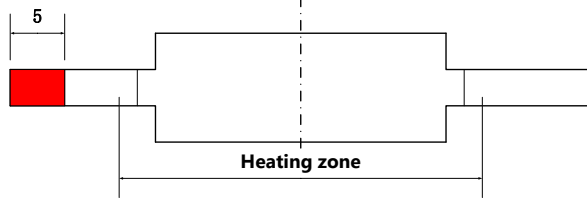


Figure 2. Thermal power distribution of the heater chip.

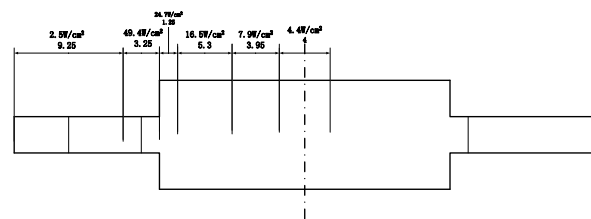


Figure 3. Schematic diagram of the heat transfer zone.

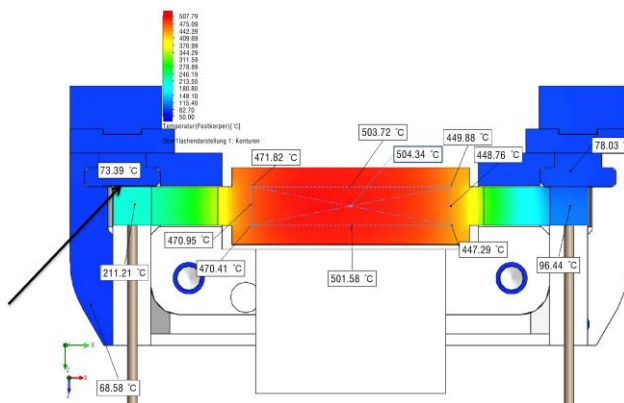


Figure 4. Analysis of the temperature field of the heater after 100 connections.

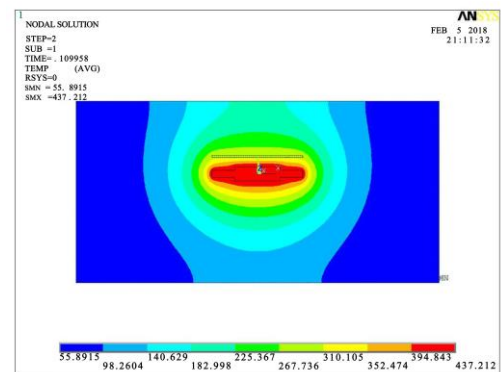


Figure 5. Temperature field distribution of the heating device.

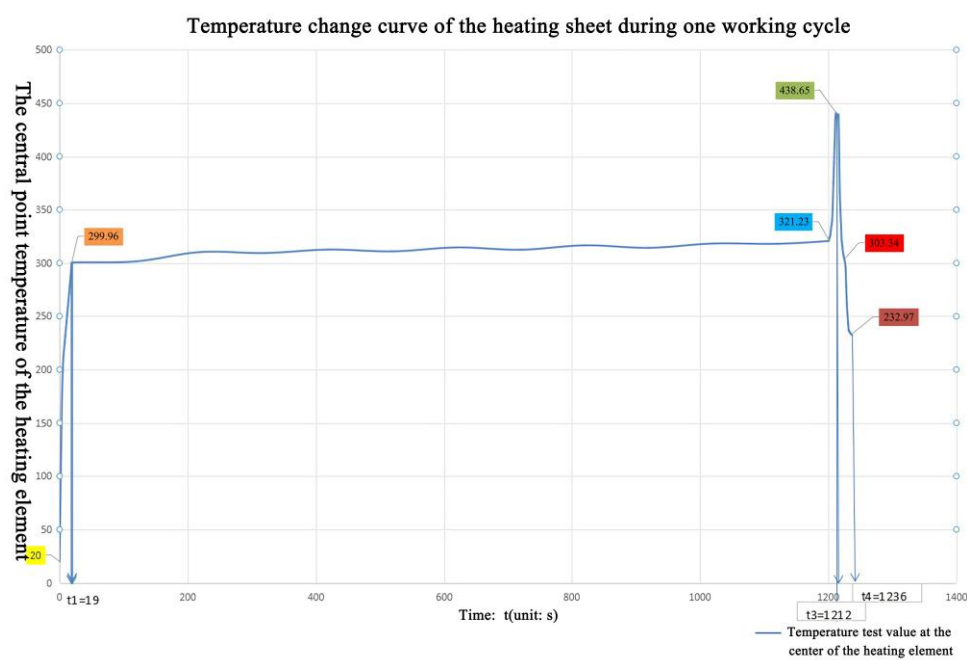


Figure 6. Temperature field diagram of the heater chip during one duty cycle.

3.2. Analysis of test results

According to the analysis of the experimental results, the temperature field temperature of the heating plate after the multiple processing was too high, and the core temperature exceeded the expected

design of 440 °C. Therefore, it is necessary to optimize the heating distance and heating time of the heater chip.

4. Conclusion

According to the identification and analysis of risk factors, the fault tree of the instrument connection fault is established, and the fault tree is qualitatively analyzed to obtain the minimum cut set, indicating that the basic event combination that can lead to the highest event is unique, and the probability of each basic event directly affects the instrument. Safety and reliability. Using the triangular fuzzy theory, the fuzzy probability distribution of event probability is calculated as (0.1763, 0.2802, 0.4236), and the reliability of the system is about 72.98%. Sensitivity analysis results show that the heating time length and distance, the five basic events and the top event with the cutting wire not reaching the specified temperature have the highest probability of occurrence. The control measures should be taken first. Through ANSYS simulation analysis, it is necessary to focus on the temperature field analysis as the feeder instrument. The design approach to reliability growth provides valuable guidance.

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