

Research in Design of ENT Treatment Unit based on AHP-QFD-FBS

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Abstract. To obtain the demands of doctors and patients, the analysis of user behavior and interviews on the users of the ENT treatment unit are conducted in this paper. Then, the weight of the demands is calculated by using the Analytic Hierarchy Process. We combine the quality function deployment to construct the relationship matrix of the user requirements-functional requirements and rank the importance of functional requirements. Finally, the FBS mapping relationship and functional importance to design the ENT treatment unit are combined. It makes the design process of ENT treatment unit more scientific and provides new ideas to design medical devices.

Keywords: AHP; QFD; FBS; ENT Treatment Unit; Product Design.

1. Introduction

According to relevant data from the National Bureau of Statistics of China, the number of general hospitals, the number of practicing doctors, and the number of patients in medical and health institutions are increasing year by year, which reflects the increasing demand for medical devices from hospitals and patients. In terms of the supervision of medical devices, the relevant regulations on the supervision and management of medical devices have undergone several revisions, and it is becoming more and more perfect. Due to the continuous increase in demands, improvement of management, and development of technology, the higher requirements are put forward for the design and production of medical devices. The major medical device in the ENT department is the comprehensive ENT treatment unit. It is a complex system with many demands and functions of users. A design process to guide the design of users is building using AHP, QFD and FBS, which makes the design more scientific and reasonable.

2. Product Design Process Based on AHP, QFD and FBS

Quality function deployment (QFD) is a better method to improve the quality of product design in the user-needs-oriented product design method [1]. One of the important bases for quality function deployment in making design decisions is the weight of user needs, and its accuracy directly affects the quality of product design [2]. Analytic hierarchy process (AHP) is a multi-objective decision-making analysis method combining qualitative and quantitative analysis. The accuracy of user demand weight determination in quality function deployment can be effectively solved by AHP [3]. Function-Behavior-Structure (FBS) is a design model, which is proposed by Professor Gero to express the early process of product concept design. Function refers to product technical functions that can meet user needs. Behavior refers to the way product functions interact with users, and Structure refers to the structural form that realizes functions and the combination and positional relationship between them. This model starts from the product function, and achieves the transformation from function to structure through the layer-by-layer mapping between FBS, and finally achieving innovative product design. Su Jianing and others combined AHP, QFD and TRIZ to design the rosebud picking machine [4]. Combining AHP and QFD, Wang Zhen et al. proposed an evaluation method for automatic sorting devices, and improved the automatic sorting devices [5]. Tang Lin et al. combined AHP and QFD to design the shape of the abdominal exercise device for the

elderly [6]. Zhou Shengxiang et al. combined AHP, QFD and AD to design the chestnut harvester [7]. Chen Yuan et al. combined AHP, QFD and TRIZ to design bathroom-related products [8]. The house of quality is the core of quality function deployment [9], the structure of the house of quality is shown in Figure 1 [10].

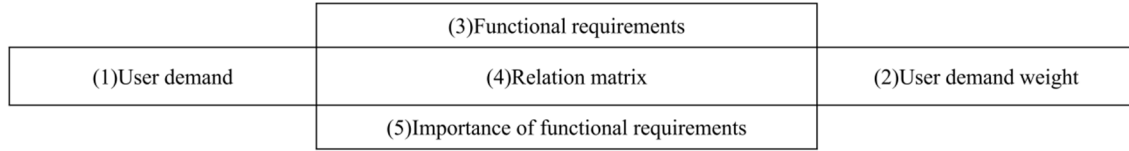


Fig 1. House of quality model

The steps of combining AHP, QFD and FBS model construction are as follows:

(1) First, it is necessary to determine the needs of users, and then use the analytic hierarchy process to determine the relative weight of each user's needs;

(2) Then, transform the user's needs to functional requirements. Study the correlation between needs and requirements and record them with scores, and calculate the importance score of each functional requirement;

(3) Finally, guide the final design according to the function-behavior-structure mapping.

The detailed process of step (1) is as follows: Organize and classify the user needs obtained in the previous research, construct a hierarchical structure for these user needs, and then use several importance levels to compare and evaluate each user demand at the same level. The importance level scale is shown in Table 1. Afterwards, the comparison results of user needs at the same level constitute a judgment matrix, and the characteristic equation corresponding to the judgment matrix is: $AW = \lambda_{\max}W$. To avoid inconsistencies in relative weight evaluation, consistency testing is required: $CI = (\lambda_{\max} - n) / (n - 1)$ and $CR = CI / RI$ [11]. When $RI < 0.1$, it means that the result meets the consistency test, otherwise the judgment matrix needs to be corrected [12].

Table 1. Importance level scale

Scale	Meaning
1	Both factors are of equal importance
3	Compared to two factors, the former is slightly more important than the latter
5	Compared to two factors, the former is significantly more important than the latter
7	Comparing to two factors, the former is strongly more important than the latter
9	Compared with two factors, the former is extremely important than the latter
2,4,6,8	The median value of the above two adjacent judgments
Reciprocal	If the scale of comparison between factor i and j is 4, then the scale of comparison between factor j and i is 1/4

Table 2. Average random consensus index

n	1	2	3	4	5	6	7	8	9
RI	0.00	0.00	0.58	0.90	1.12	1.24	1.32	1.41	1.45

3. Constructing the Matrix of ENT Treatment Unit

3.1 Obtaining User Needs

3.1.1 Experimental Design

(1) Basic Information: We Conducted a 2-week natural observation at the otolaryngology department of Xuzhou First People's Hospital. The observed equipment is the ENT treatment unit of MG-ET100.

(2) Recording equipment: A total of two machine positions are arranged to record the process of users using the ENT treatment unit at the same time. The No. 1 machine is facing the ENT treatment

unit, mainly recording the doctor's operation behavior in the preparation stage and maintenance stage. The No. 2 camera is obliquely facing the seat to shoot, mainly recording the doctor's operation behavior and the patient's behavior during the use phase. Simultaneously record the voice information of doctors and patients.

(3) Determination of target users: Otolaryngology doctors and patients. Because the age of doctors is mainly distributed between 25-55 years old. In order to avoid the influence of age difference, a doctor aged 25-30, 30-35, 35-40, 40-45, and 50-55 was selected for key observation.

(4) Purpose of observation: Obtain information on the behavior of otolaryngology doctor during the use of the ENT treatment unit, the behavior of the patient, and language information.

(5) Observation process: After being approved by the observed person, the two devices are placed in the designated location, and the observer exits the consultation room after the recording is turned on, observes outside the clinic, and records the behavior of the observed person in real time. After the end, express your gratitude to the observed person, and pack up the items and equipment you brought and take them away.

3.1.2 Experimental Results

Observation and analysis of the behavior of doctors and patients during the use of the ENT treatment unit can obtain the following records. During the preparation phase: (1) The patient mainly waits on the seat. If there is an item in his hand, the patient will look left and right to see if there is a place to put it. It is inferred that the patient has a need to place the item at this time. (2) The doctor mainly sterilizes the instrument on the table of the ENT treatment unit. It can be observed that the doctor will hesitate to choose a rigid endoscope, and sometimes look for tweezers and alcohol cans. Not only that, when alcohol cotton balls are used to wipe the front end of the rigid endoscope, it is often not completely wiped. After disinfection, the gauze used to wipe the front end of the rigid endoscope may be placed on the countertop and used after the rigid endoscope is used. It can be seen that the labels on the rigid endoscope did not effectively help the doctor, and the position of the tweezers jar and the alcohol jar was not fixed, which made it difficult to find it. According to the follow-up interview, the reason why the doctor did not discard the gauze here was: after use, the instrument needs to be wiped. Since it will be disinfected before use, it is not necessary to perform aseptic treatment at this time.

In use phase: (3) The patient maintains a fixed posture at this time, observes his expression, and finds that he does not see pain, but when checking children, he will wave his hand to stop the doctor from operating it, accompanied by yelling. Since children have a more direct expression of pain, it is speculated that there will be some pain during the examination. (4) At this time, the doctor holds the patient's head with one hand, and the other hand holds the rigid endoscope and moves slowly, with the head facing the monitor. When checking different positions, you can see: sometimes the head needs to be at a 45-degree angle, and the line of sight will repeatedly move from the monitor to the patient's examination site.

During the maintenance phase: (5) The patient will leave the seat and wait for the doctor. At this time, most patients will ask the doctor for the result, and the doctor is disinfecting the instrument at this time. The doctor also forgets to turn off the power supply of the endoscope camera and lighting at this time, and also directly places the rigid endoscope on the ENT treatment unit. Not only that, but sometimes rigid endoscopes are not sterilized. After the interview with the doctor later, we can know the reason: too many patients are seen in a day, and it is too time-consuming to put the rigid endoscope back in place, turn off the power and disinfect it.

3.2 Determine the Level and Weight of Each Need

Organize and classify the collected user needs, and divide the user needs into three categories: comfort needs, easy-to-use needs, and aesthetic needs, forming a clear hierarchical relationship between needs and establishing a hierarchical structure, as shown in Figure 2.

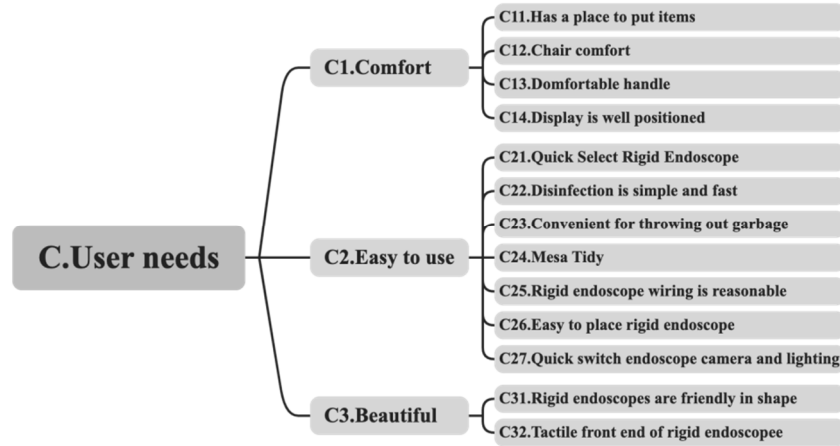


Fig 2. A hierarchical model of user needs for ENT treatment unit

Solve the largest eigenvalues and eigenvectors according to the above, and normalize the eigenvectors to obtain the weight values of various user requirements, see Tables 3, 4, 5, and 6. Among them, the RI values were all less than 0.1, which met the consistency inspection standard.

Table 3. User needs judgment matrix and weight

	C1	C2	C3	Weights	Consistency result
C1	1	1/3	4	0.280	0.074
C2	3	1	5	0.627	
C3	1/4	1/5	1	0.094	

Table 4. Comfort judgment matrix and weight

	C11	C12	C13	C14	Weights	Consistency result
C11	1	3	1/3	1/2	0.179	0.048
C12	1/3	1	1/4	1/2	0.096	
C13	3	4	1	2	0.471	
C14	2	2	1/2	1	0.253	

Table 5. Useful aspect judgment matrix and weights

	C21	C22	C23	C24	C25	C26	C27	Weights	Consistency result
C21	1	1/5	1/4	1/2	2	1/3	1/2	0.056	0.021
C22	5	1	2	4	6	3	4	0.345	
C23	4	1/2	1	3	5	2	3	0.233	
C24	2	1/4	1/3	1	2	1/2	1/2	0.078	
C25	1/2	1/6	1/5	1/2	1	1/4	1/3	0.039	
C26	3	1/3	1/2	2	4	1	2	0.149	
C27	2	1/4	1/3	2	3	1/2	1	0.100	

Table 6. Judgment matrix and weights for aesthetics

	C31	C32	Weights	Consistency result
C31	1	1/3	0.250	0
C32	3	1	0.750	

The weight values of each user demand and category are synthesized, and the specific results are shown in Table 7.

3.3 Conversion of User Needs to Functional Requirements

Determining functional requirements is one of the necessary links in the practice of optimal design of ENT treatment unit. Use affinity graph method to classify user needs, and convert them into specific functional requirements, as shown in Table 8.

Table 7. User demand level and secondary demand weight

Use stage	Secondary user needs	Secondary user demand weight
C1.Comfort	C11. Has a place to put items	0.050
	C12. Chair comfort	0.027
	C13. Domfortable handle	0.132
	C14. Display is well positioned	0.071
C2.Easy to use	C21. Quick Select Rigid Endoscope	0.035
	C22. Disinfection is simple and fast	0.216
	C23. Convenient for throwing out garbage	0.146
	C24. Mesa Tidy	0.049
	C25. Rigid endoscope wiring is reasonable	0.024
	C26. Easy to place rigid endoscope	0.093
	C27. Quick switch endoscope camera and lighting	0.063
C3.Beautiful	C31. Rigid endoscopes are friendly in shape	0.024
	C32. Tactile front end of rigid endoscopee	0.071

Table 8. Level 1 and Level 2 functional requirements

Functional Requirements	Secondary Functional Requirements
F1 Personalization Features	F11. Handle grip function
	F12. Display adjustable function
	F13. Storage function
	F14. Chair custom adjustment function
F2 Practical function	F21. Disinfection Intensive Treatment Function
	F22. Disposal function of medical waste
	F23. Rigid endoscope placement function
	F24. Endoscope and lighting switch function
	F25. Countertop function partition function
	F26. Handle indication function
	F27. Wire configuration function
F3 Visualization function	F31. Rigid Endoscope Front Affinity
	F32. Rigid endoscope is friendly in appearance

3.4 Ranking of the Importance of Each Functional Requirement

In the "user needs - functional requirements" relationship matrix of the ENT treatment unit, the left wall is the user needs; the right wall is the relative weight of each requirement; the ceiling is the functional requirements. The middle room needs to be filled with specific symbols to represent the relationship between each user's needs and each functional requirement. The corresponding symbols are defined in Table 9 [13]. These relationships are determined by the doctors and patients of the ENT treatment unit. Finally, the value of the ground is obtained according to the left wall, right wall, ceiling and room of the matrix, that is, the importance of each functional requirement.

Table 9. Symbol definition table

The symbol	Definition	Strength
●	Indicates a strong relationship, or very important	9
○	Indicates a certain degree of relationship, or is more important	5
△	Indicates a certain degree of relationship, or is more important	1
Empty	It doesn't matter	0

According to the research case of this paper, the relationship matrix of "User requirements - Functional requirements" of the ENT treatment unit is constructed, as shown in Figure 3.

Perform function-behavior-structure mapping on the corresponding functions, and rank the importance of the functional requirements, the results are shown in Figure 4.

	F11	F12	F13	F14	F21	F22	F23	F24	F25	F26	F27	F31	F32	User demand weight
C11			●	○							△			0.050
C12			○	●										0.027
C13	●				○		○		△	△	△	△	○	0.132
C14		●		○				△	△					0.071
C21	○				△		○		○	●		△	○	0.035
C22	○				●	○	△		●	△	△		○	0.216
C23					○	●			○		△			0.146
C24					△	△	○	△	●	△	△		△	0.049
C25					△		○	○	○		●		△	0.024
C26	●				○		●		△	○	○		●	0.093
C27								●	△		△			0.063
C31	○						△	△		△	△	△	●	0.024
C32												●	△	0.071
Importance	3.400	0.639	0.585	0.848	3.907	2.443	2.277	0.831	3.769	1.201	1.361	0.830	3.112	

Fig 3. "User needs - functional requirements" relationship matrix

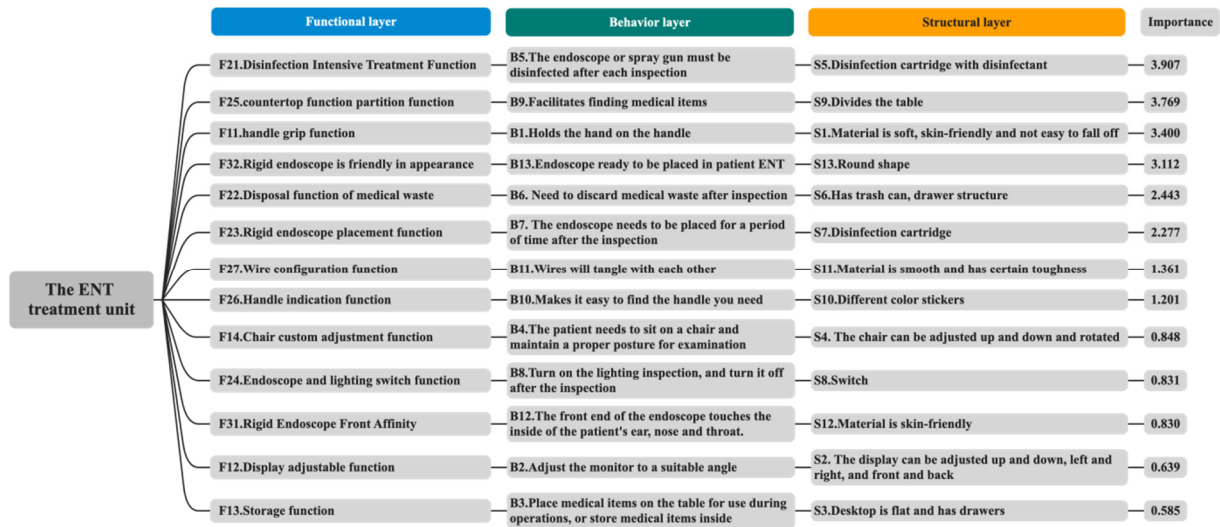


Fig 4. Ranking of the importance of functional requirements of ENT treatment unit

4. Design Description of ENT Treatment Unit

From the above, it can be seen that the ENT treatment unit is the most important in the F21 disinfection and intensive treatment function, the F25 countertop function partition function, the F11 handle holding function, and the F22 medical waste disposal function. Therefore, we will focus on the design practice of this part next.

4.1 Analysis of Existing ENT Treatment Unit

The ENT treatment unit belongs to the second category of medical devices, and it implements product registration management. Therefore, the companies that sell the ENT treatment unit in China's mainland and the corresponding product models can be queried on the State Drug Administration. According to the imported medical device products registered on the State Drug Administration, the ENT treatment units imported from abroad in my country are mainly produced by three companies: Dantschke medizintechnik gmbh & co. kg in Germany, Yongdao Medical Instrument Co., Ltd. in Japan, and South Korea's Chammed Co., Ltd.. According to the research on the products of these companies, it can be concluded that in terms of structure, the ENT treatment unit is based on a rectangular parallelepiped cabinet, on which equipment such as inspection lights, brackets, and monitors are added. Some will also be equipped with smart seats. The ENT treatment unit is mainly composed of cabinets, examination lights, brackets, monitors, lights and smart seats.

(1) Cabinet. The whole is rectangular. The countertops are flat, some are at a certain angle and even have grooves to place corresponding items, and their edges have a certain degree of arc chamfering. There are drawers or slots and holes on the cabinet body to place corresponding items.

The turning points are generally arc chamfered. The back of the cabinet body has a structure that supports inspection lights and brackets.

(2) Check lights. The inspection lights are generally fixed on the back of the cabinet, and some are also fixed on the countertop. The connection between the inspection lights and the cabinet is composed of cylinders or cuboids connected to each other, generally in a three-stage structure. The structure of the first segment is responsible for the overall horizontal movement. The structure of the second segment is responsible for the overall vertical movement. The structure of the third section is responsible for the adjustment of the 360-degree direction of the inspection lamp body.

(3) Brackets. The brackets are generally fixed on the back of the cabinet, and some are also fixed on the countertop, and can also be integrated on the inspection light. Due to different requirements, multi-layer structures can be arranged. The bracket can generally be divided into a cylinder and a flat plate. The cylinder is responsible for fixing, and several flat plates form a plane to place items. The placed items mainly include: endoscope camera, endoscope light source, display, and film viewing light.

(4) Display. It can be integrated into the examination light or placed on a stand.

(5) Film viewing lamp. It can be integrated on the examination light or on the stand.

(6) Smart seats. The common seat shape, the lower part is usually cylindrical, which is convenient for rotation and up and down adjustment. The upper seat surface is in the shape of a cube, the back of the chair fits the back in a trapezoidal shape, and is equipped with cuboid-shaped armrests and head cushions.

In terms of color, the main color of each component of the existing ENT treatment unit is white, and the bright and clean white gives people a simple, pure, sacred and refreshing feeling. Supplemented with silver white, black, gray and corporate colors, it has the emotional attributes of seriousness, stability and strength.

In terms of material, the materials of the various parts of the existing ENT treatment unit are mainly stainless steel, plastic and metal, giving people a cold, professional and clean emotional feeling. Part of the material is glass and rubber, giving people a warm and friendly feeling.

4.2 Analysis of Disinfection Methods of ENT Treatment Unit

According to relevant national standards and literature, common disinfection and sterilization methods for endoscopes are as follows:

(1) Chemical immersion disinfection method. In clinical practice, commonly used endoscope disinfectants include o-phthalaldehyde, glutaraldehyde, acid oxidation potential water, peracetic acid and chlorine-containing disinfectants. Compared with glutaraldehyde and acidic oxidation potential water, o-phthalaldehyde (OPA) has the advantages of stable performance, short disinfection time, low concentration and strong killing ability [14]. Compared with peracetic acid and chlorine-containing disinfectants, OPA has the advantages of no irritating odor, less harmful volatile substances, and less irritation to the skin and mucous membranes. Therefore, OPA is more suitable for the needs of rapid turnover of clinical diagnosis and treatment [15].

(2) Low temperature sterilization method. There are mainly hydrogen peroxide plasma and ethylene oxide sterilization methods, which are not suitable for disinfection and sterilization of long and narrow lumen-shaped objects.

(3) Boiling sterilization method. It uses high temperature to kill bacteria and viruses on the surface of medical devices. Usually, the boiling time should be 20 minutes or more.

According to Chinese standards, for rigid endoscopes that need to be repeatedly disinfected or sterilized, the disinfection or sterilization methods cannot cause damage or corrosion to them. The external material of common rigid endoscopes is mainly stainless steel, and its internal structure includes eyepieces, spacer tubes, rod mirrors, objective lenses, and lighting fibers. Due to its good internal sealing, the part of the internal structure that is in contact with the outside is mainly the objective lens. The surface of the objective lens is mainly made of glass, so it has certain corrosion resistance. Since the disinfection method needs to be simple, fast, easy to operate, and the cost should

not be too high, considering the disinfection method comprehensively, the soaking method should be selected, and the soaking liquid should be OPA.

4.3 Design and Description

In order to fully understand the design scheme of the ENT treatment unit, the details are now drawn and explained, as shown in Figures 5 and 6.

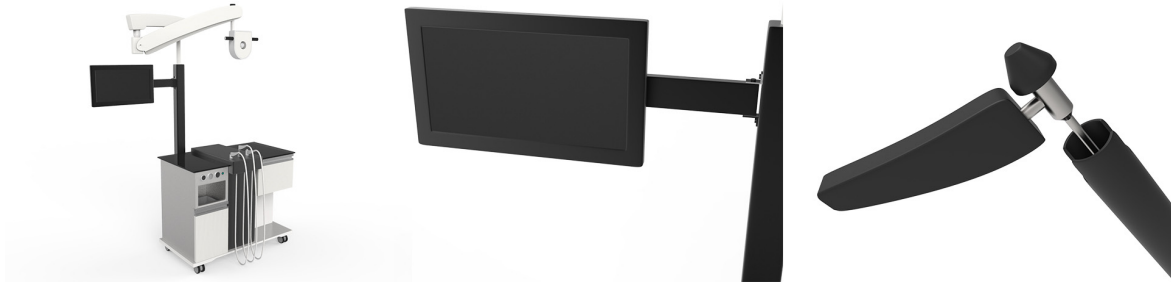


Fig 5. Main body of the ENT treatment unit



Fig 6. Details of the ENT treatment unit

(1) Display. Since the height of each person is inconsistent, although most people use a certain height, there will still be a certain angle between the human line of sight and the plane of the display. In order to make the angle as vertical as possible. The display can not only rotate horizontally, but also can rotate up and down.

(2) Drawers. Because the ENT endoscope needs to be loaded with the built-in camera module and lighting module in the rigid endoscope, and these modules are usually produced or purchased separately from the manufacturer. Due to different manufacturers, the size will vary, and sometimes it is necessary to adjust camera and lighting related parameters, then put it into the ENT treatment unit in the form of a drawer, and only need to open the drawer when adjustment is required.

(3) Trash can. Since the trash can needs to be replaced frequently, it is designed to be pullable, similar to a drawer, and the trash bag can be replaced and cleaned by pulling it out.

(4) Spray guns, suction guns, and rigid endoscopes. They have similar structures, so the comfort of the handle is mainly considered, so the shape of the handle is mainly curved, and the material is soft. In addition, the design of the spray gun can disassemble the structure, and the spray gun can be disassembled into the handle part and the medicine bottle part, which is convenient for the replacement of different medicines.

(5) Spray suction gun and rigid endoscope disinfection device. Since the disinfection method of the spray, suction gun and the front end of the rigid endoscope is the soaking method, the disinfectant is put into a cylinder of corrosion-resistant material, and the cylinder can be rotated and disassembled, which is convenient for disassembly, cleaning and dressing change.

5. Summary

With the continuous improvement of economic level and quality of life, otolaryngologist and patients pay more and more attention to the quality of ENT disease inspection equipment. However,

with the continuous development of technology and the continuous improvement of supervision, hospitals, doctors and patients have put forward higher requirements for the ENT treatment unit. In this context, combined with the requirements obtained from the previous user research, the paper uses the analytic hierarchy process to calculate its weight, and then combines the quality function expansion to construct the "user requirements - functional requirements" relationship matrix of the ENT treatment unit, and obtained the importance of each functional requirement, and then completed the design of the ENT treatment unit according to the guidance of function-behavior-structure mapping. While improving the efficiency and scientificity of the design process, it also improves the consultation efficiency and user experience of the ENT treatment unit.

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