Study on the Instrument for Testing Radiofrequency Ablation Catheter

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Abstract: Objective — To design a detection instrument for detecting the quality of radiofrequency ablation electrode, which can quickly detect the physical properties of radiofrequency ablation electrode. Methods — The DC constant current source is introduced to measure the small resistance, test whether the thermocouple is well connected, and measure the resistance between the positive and negative wires of the thermocouple at the plug (1-core and 2-core) to determine whether the thermocouple is well connected. The resistance of the good product is about 40Ω. Detect whether the inner tube and outer tube of RF ablation are in good physical contact through resistance, and judge whether there is physical contact between the inner tube and outer tube by detecting the resistance between the positive conductor of thermocouple (2 cores) and RF connecting wire (3 cores). When in good contact, the resistance is about 0.5 Ω; Measure the short circuit between 4~8 cores of the plug and judge whether the code is correct. The measurement method of pipeline absolute tightness is adopted to detect the change of pipeline pressure. Results — The developed radiofrequency ablation electrode detector can accurately measure the resistance, circuit and pipeline tightness of radiofrequency ablation, and can meet the requirements of detection accuracy. Conclusion — The quality of the prototype is stable and can meet the needs of users.

***Keywords*:** radiofrequency ablation, electrode detection, thermocouple, tightness

1. Introduction

Radiofrequency ablation (RFA) is a minimally invasive technique that has been used in clinical practice in recent years [1-3]. It is widely used in the treatment of liver tumors, fibroids, thyroid tumors, disc herniation, trigeminal neuralgia and other diseases [4-7]. RFA involves the electrode inside the tumour, and the high-frequency alternating current flowing through the electrode causes ionic stirring which triggers frictional heat and thermal damage, resulting in coagulative necrosis of the tissue instantaneously. RFA is great effective in the treatment of tumours smaller than 3 cm and the greatest advantages of RFA are no operation, small damage to patients and quickly recovery after procedure, thus RFA gaining popularity among doctors and patients. Wu [8] improved the effectiveness and safety of radiofrequency ablation of brain lesions by designing a radiofrequency ablation system for brain lesions. The system can be used to plan the parameters of radiofrequency ablation of brain lesions, which has certain clinical application value. Eliel et al. [9] prospectively characterized and optimized radiofrequency energy deposition to determine ideal parameters for achieving large ablation zones. And founded that RF ablation may have important clinical relevance in regards to the clinical utility compared to other competitive forms of thermal tumor ablation. Belghazi [10] introduced the operating principle of radiofrequency ablation devices, pointing out the differences of radiofrequency ablation devices among gynecology, liver and heart according to different operating sites, and explained the texting methods and matters needing attention of each performance according to the requirements of test in the standard.

In this paper, according to the current research status, we design a reliable, stable and portable liver radiofrequency ablation electrode detector system, which can quickly test the physical performance of liver radiofrequency ablation electrodes. It can provide a technical reference for the quality control analysis of liver radiofrequency ablation devices.

2. Structural analysis of live radiofrequency ablation apparatus

The basic structure of the liver radiofrequency ablation instrument is shown in Figure.1 and consists of a mainframe, radiofrequency ablation electrodes, cooling water tubing, neutral electrode and foot switch. The treatment principle is: the radiofrequency current generated by the mainframe is inserted into the patient's diseased tumor tissue through the radiofrequency ablation electrode needle [11], and the heat generated by the alternating current (350-500kHz) is used to achieve in situ inactivation of liver cancer cells [12] [13], and the radiofrequency current is returned to the mainframe through the neutral electrode. Doctors control the host by a foot switch to deliver the radiofrequency current on time. The heating target of the radiofrequency ablation instrument is 60°C~100°C, which can lead to irreversible damage to the tumour tissue. When the temperature exceeded 100°C to 110°C will result in charring and vaporisation of the tissue.

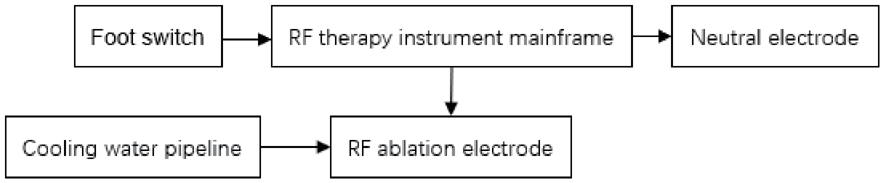


Figure 1. Structure of RF Ablation Therapeutic Apparatus

The neutral electrode is generally fixed in the patient's thigh and other places with rich blood vessels. The neutral electrode has a large area, small current density and does not generate heat concentration. During the treatment, the radiofrequency ablation electrode is directly inserted into the middle of the tumor (the site needs to be ablated). Due to the small surface area of the radiofrequency electrode and the high current density, a large amount of heat is generated in the tissue touching with the radiofrequency ablation electrode, which causes the tumour (local tissue) to coagulate and necrosis, thus achieving the purpose of ablation treatment.

The radiofrequency ablation electrode is needle-shaped, and its internal structure is shown in Figure 2, consisting of an outer tube, an inner tube and a negative electrode. The end connection between the inner tube and the negative electrode forms the thermocouple temperature sensor. The outer tube is connected to the radio frequency connection line, and the 15mm ~ 25mm tip of the outer tube is bare. The current is applied to the tumor site, and the other parts are coated with an insulating layer. The inner tube is the positive side of the thermocouple and is connected to the positive thermocouple lead. The negative electrode is connected to the negative thermocouple lead. The space between the inner tube and the negative electrode is the inlet cavity, and the space between the inner tube and the outer tube is the backwater cavity. The temperature of the radiofrequency ablation electrode can be accurately controlled by the water flowing in the inlet cavity and the backwater cavity taking away part of the heat. In order to accurately control the temperature of the RF electrode needle, the end of the inner tube must be in close contact with the outer tube and keep the same temperature with the outer tube.

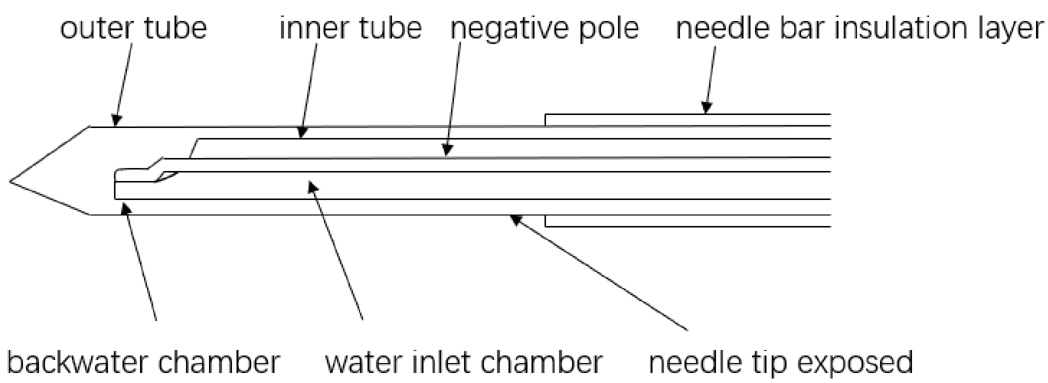
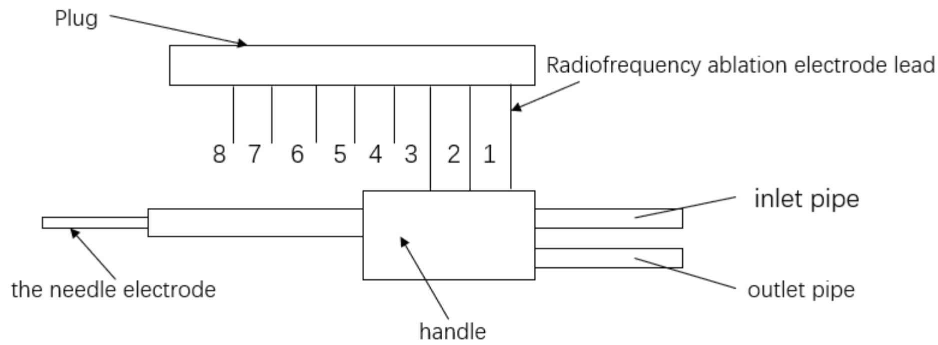


Figure 2. Internal Structure of the Radiofrequency Ablation Electrode

3. Principles of radiofrequency ablation electrode performance testing

Radiofrequency ablation electrodes are disposable, high-value consumable, and it is necessary to strictly control its quality. We proposed and designed the radiofrequency ablation electrode detector (Hereinafter referred to as the detector) according to the requirements of the industry standard "YY0776 Liver Radiofrequency Ablation Treatment Equipment" and our actual needs for producing radiofrequency ablation electrodes [14][15]. The inspection structure of the radiofrequency ablation electrode is shown in Figure 3. The plug is connected with the main engine of the radiofrequency ablation therapy instrument, and the water inlet and outlet pipes are connected with the corresponding water tank respectively.



(1 — Thermocouple negative wire; 2 — Thermocouple positive wire; 3 — RF connecting cable; Code line: 4, 5, 6, 7, 8)

Figure 3. Structure of radiofrequency ablation electrode detector

The plug of the radiofrequency ablation electrode detector is 8-core, with 1-core connected to the negative pole of the thermocouple, 2-core connected to the positive pole of the thermocouple (inner tube), 3-core (RF current output wire) connected to the outer tube. In addition, 4 to 8 cores are coded for connection (for example: 4, 5, 6, 7 cores short-connected for specification A, 4, 5, 6, 8 cores short-connected for specification B, and so on), so that the host can easily distinguish the specifications of the electrodes and apply different strengths of RF current to the electrodes of different specifications. In addition, the completed RF ablation electrode must to be connected between inner and outer tube in physical in order to promise the temperature is same.

To promise the quality of product to meet the requirements of industry standards, the following performance testing should be done.

(1) Whether the thermocouple is well connected;

(2) Whether inner and outer tube are well connected;

(3) Whether the plug coding line is connected correctly;

(4) Whether the cooling water channel is well sealed;

In order to meet the above requirements, after texting the qualified products repeatedly, the following measures are accepted to testing.

(1) Measure the resistance of the wire between the positive and negative electrodes of the thermocouple at the plug (1-core, 2-core) to determine whether the thermocouple connection is good. The resistance of a good product is about 40Ω;

(2) According to test the resistance between the positive wire of thermocouple (2-core) and RF connecting wire (3-core) to determine whether the inner and outer tube is in physical contact. When physical contact is good, the resistance is about 0.5Ω;

(3) Measure the short circuit between 4-8 cores of the plug to determine whether the coding is correct;

(4) Use compressed air to replace water because after water goes into the pipeline, it is not easy to clean. Compressed air is used instead of water to test the sealing of the cooling water circuit.

4. Design a solution for the system

4.1 Electrical system design

The circuit of detector is divided into five parts: power supply, resistance RX testing circuit, plug code reading, significant shown and key input, single-chip computer control system, pressure signal amplification circuit. The diagram of the circuit structure is shown in Figure 4. ATmega16 single-chip computer is used as the main controller. The control system of single-chip computer is composed with ATmega16 and TLV2548 analog-to-digital converter and other chips. ATmega16 is a high-performance, low-power 8-bit CMOS micro controller based on an augmented AVR RISC. ATmega16 has the following features: 16K bytes of programmable Flash memory in the system, 512 bytes of EEPROM, 1000 bytes of SRAM, 32 universal I/O port lines and it can meet all the needs of detector. TLV2548 is a high performance and lower-power 12 bits CMOS analog to digital converter with 8 8 channels data conversion capability, with sample retention and SPI serial output function. Pressure signal amplifying circuit is composed of TL062CP with low bias voltage and high stability, which amplifies voltage signal outputted by the pressure sensor and convert it into a digital signal by TLV2548.

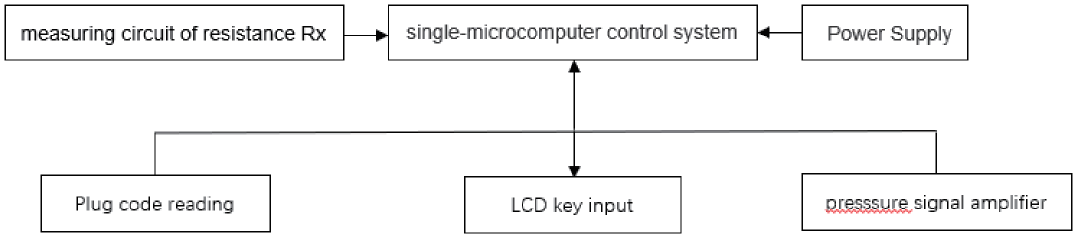


Figure 4. Electrical System Diagram

4.2 Design of resistance testing

Use the method of measuring resistance to test whether thermocouple is in good connection and whether the inner and outer tube are in good physically connection [16]. The measuring circuit is shown in Figure 5.

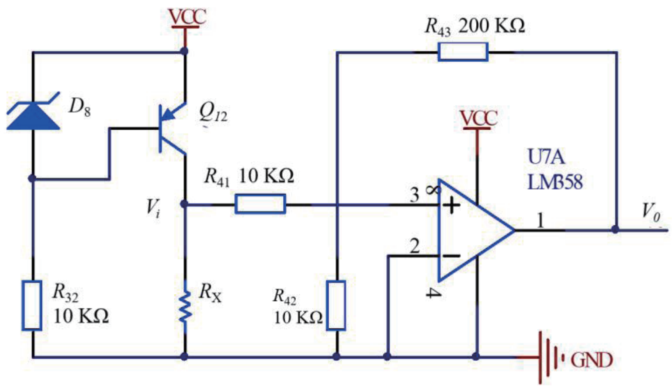


Figure 5. Circuit for measuring resistance RX

R_x is resistance to be measured in the picture and constant current source is composed with D_8, Q_{12}, R_{32} for R_x. Use the amplifier LM358 to amplify the voltage on R_x.

$$V_0 = \frac{R_{43}}{R_{42}} V_i \tag{1}$$

$$V_i = I_i \times R_x = \frac{V_z \text{-} V_{be}}{R_{32}} R_x \tag{2}$$

From Formula (1) and (2):

$$R_x = \frac{VR_{42} \times R_{32}}{R_{43}(V_z \text{-} V_{be})} V_0 \tag{3}$$

Where: V_Z — reverse voltage of Zener diode D_8; V_{be} — base input voltage of triode Q_{12}.

Analog switch circuit MAX4581 is used to connect 4~8 core plug and measure the five cores shorting condition. The circuit is shown in Figure 6. MAX4581 is a multiplexer switch with signal input and eight output. Its truth table is shown in Table 1. H stands for high level and L stands for low level. X is the input terminal, X0~X7 are the output terminal with eight road. It is determined by three alternative outputs, C, B and A, that one of the output is short circuited to the X-terminus and the others are open.

In Figure 6, if a high level H is added to X0, then the 4-core of plug is high level and the others connected with 4-core are also high level. In this way, the short-connection condition between 4-core and the others can be judged according to the level states of P10-P14. Add a high level to X0~X4 successively and read the level states of P10~P14 respectively, then the short-connection condition of 4 to 8 core wire can be judged.

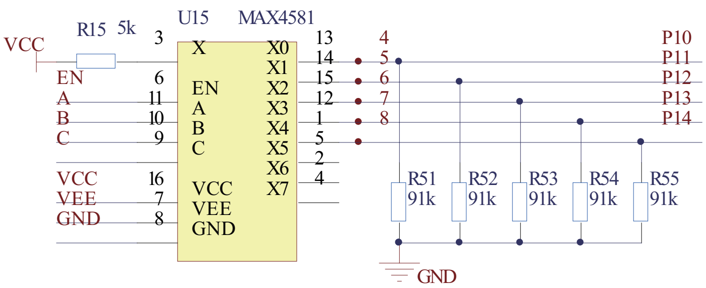


Figure 6. Plug code read circuit diagram

Table 1. MAX4581 multi-channel switch information

EN	Selection end			Output
	C	B	A	
H	×	×	×	X0 ~ X7 Open circuit
L	L	L	L	X0=X
L	L	L	H	X1=X
L	L	H	L	X2=X
L	L	H	H	X3=X
L	H	L	L	X4=X
L	H	L	H	X5=X
L	H	H	L	X6=X
L	H	H	H	X7=X

4.3 Design of pipeline sealing test

Highly stable pressure sensors are used to detect the sealing of the piping [17]. The structure of the gas circuit as shown in Figure 7. The air source inflates the pressure sensor and the measured pipeline through the solenoid valve, after inflation, close the solenoid valve to stop inflation. After waiting for a stable time and the pressure in the pressure sensor and the measured pipeline is stabilized, the pressure sensor can detect the stability of pressure in the measured pipeline for a period of time to determine whether the measured pipeline is leak.

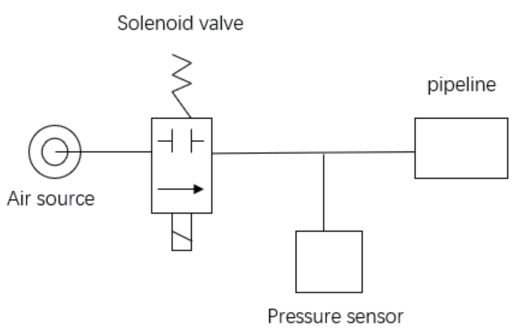


Figure 7. Testing Gas Circuit of Sealing

4.4 Design of system software

The system software includes the main program, data conversion program, coding judgment program, gas leakage judgment program [18] and other parts. The main program receives key input, starts data conversion, controls the LCD display related parameters and data results.

The gas leakage judgment procedure starts the solenoid valve (Figure 7) to inflate the pipeline and sensor. After the air pressure is stable, the solenoid valve on the pipe wall will delay for 30 seconds. During the delay time, read the air pressure once every 10 milliseconds. By detecting the change of air pressure in the pipeline within 30 seconds, it can be determined that the sealing performance of the pipeline is whether the requirements meets the requirement.

The coding judgment program controls MAX4581 to add the high level to 4, 5, 6, 7 and 8 core in turn, as shown in Figure 6. After each core is powered on, TLV2548 successively converts the output voltage values of P10 to P14 and judges the voltage range. After a power on, the voltage of the cores connected together is the same, which can determine which cores are connected together. According to this, the specification of the radiofrequency ablation electrode can be determined.

5. Conclusion

This design provides a measure to testing the physical performances of the radiofrequency ablation electrode, which can detect the connection performance of the thermocouple inside the radiofrequency ablation electrode. The resistance of a good product is 40Ω. The resistance is about 0.5Ω, testing whether the connection between inner and outer tube is good. The high stability pressure sensor is used to test the sealing of the pipeline, and the resistance between the thermocouple positive wire (2 cores) and the radio frequency connection wire (3 cores) is detected to determine the short-connection between the 4 ~ 8 cores. This method can realize the identification of the target of the radiofrequency ablation electrode. After three months of trial in a company which products “radiofrequency ablation electrode” in Rizhao, Shandong Province, the performances of the detectors is basic in line and can meet the needs of the production and inspection of the enterprise. In the subsequent research, the identification structure of the instrument and equipment will be optimized to further improve the efficiency of target detection.

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