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Development of Portable Micro Medical Negative Pressure Therapy Instrument

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Abstract:

Vacuum sealing drainage (VSD) and vacuum-assisted closure (VAC) are two critical technologies that have been widely used in recent years to treat severe soft tissue injury, osteomyelitis, acute severe pancreatitis, severe abdominal trauma, intra-abdominal infection, body surface abscess, old hematomas, skin ulcers, pressure sores, among other conditions. At the moment, clinical applications of negative pressure therapy instruments have a large volume, an unstable negative pressure, high power consumption, noise, cumbersome operation, and a single mode of operation. The portable micro medical negative pressure therapy instrument studied in this article has been improved based on the conventional negative pressure therapy instrument, and has a simple operation, stable negative pressure, a variety of working modes, adjustable pressure, good safety performance, high intelligence, light weight, small volume and portability.

Keywords: *Portable negative pressure therapeutic instrument, Single chip microcomputer, Sensor*

I. INTRODUCTION

Negative pressure therapy is a cutting-edge technique that has been developed and applied in clinical practice in recent years to promote wound healing. The therapy is effective at preventing contamination and cross-infection, improving local blood supply, reducing tissue edema, reducing bacteria, promoting granulation tissue growth, alleviating pain, and lowering treatment costs [1]. In 1993, German surgeons Dr. Fleischmann et al. [2] proposed vacuum sealing drainage (VSD) for the treatment of infected extremity wounds. In 1997, Argenta [3] and Morykwas [4] pioneered negative vacuum-assisted closure (VAC) to increase local blood supply and promote granulation growth of the wound, which has significant efficacy in wound recovery [5]. VSD and VAC are two critical technologies that have been widely used in recent years to treat severe soft tissue injury, osteomyelitis, acute severe pancreatitis, severe abdominal trauma, intra-abdominal infection, body surface abscess, old hematomas, skin ulcers, pressure sores, among other conditions. VSD is usually used to drain body cavities and body surface wounds, which require continuous suction at low pressure; whereas VAC is used to drain body surface wounds, particularly chronic wounds, which require a period of continuous suction followed by intermittent cyclic suction [6].

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Current medical negative pressure therapy instruments are inconvenient for patients, restrict their daily activities, produce unstable negative pressure, consume a lot of power, generate much noise, and operate in a single mode. To advance negative pressure wound treatment technology, this article examines the conventional negative pressure therapy instrument and focuses on realizing simple operation, negative pressure stability, a variety of operating modes, adjustable pressure, high safety performance, high intelligence, and light quality in a portable micro medical negative pressure therapy instrument. Additionally, the instrument is appropriate for burn skin surface drainage, chronic diseases, and patients who require prolonged wound treatment. Patients with the machine can leave the bed or go outside at will, uninhibited by daily behavioral activities. This increases the patient's level of comfort during treatment. Patients can transport the machine to the hospital, thereby shortening the length of stay and lowering hospital costs.

II. MATERIALS AND METHODS

2.1 Circuit Design

The portable micro medical negative pressure therapy instrument, as illustrated in Figure 1, is composed of the following modules: a power supply module, a central control module, a negative pressure driving module, a drainage bottle module, an alarm module, a display module, and a negative pressure sensing module. Different treatment modes are chosen based on the patient's current state of trauma [7], and the dressing is applied to the trauma area and connected to the drainage bottle module. Two components make up the hardware framework: the host computer and the drainage bottle. The host computer is comprised of a power supply system, a control and execution module, a microcontroller [8] (model STM32F103VET6), a sensor [9] (model MPXV5050V), a circuit alarm module, an LCD display, based on an MPXV5050V sensor module, a microcontroller (STM32F103VET6), a control module, a sensor module, and an alarm module. The system microprocessor is a 32-bit STM32F103VET6 ARM microcontroller that acts as the control core for the entire instrument. The STM32F103VET6 microcontroller features a 72 MHz CPU, up to 1 MB of flash memory, motor control peripherals, and full-speed CAN and USB interfaces, combining excellent performance with real-time functionality and increased coding density for faster interrupt response. The microcontroller also includes 64 kSRAM, 512 kflash, three digital-to-analog converters (ADCs), a maximum power dissipation of 434 mW, four general-purpose timers, two advanced timers, and two basic timers, 80 general-purpose input/output (GPIO) pins, and 12-bit DACs with two channels. It operates between 2.0 and 3.6 V.

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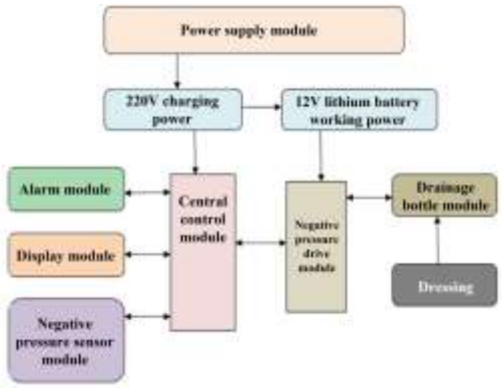

Fig.1 Diagram of structure composition of portable micro medical Negative pressure therapeutic instrument

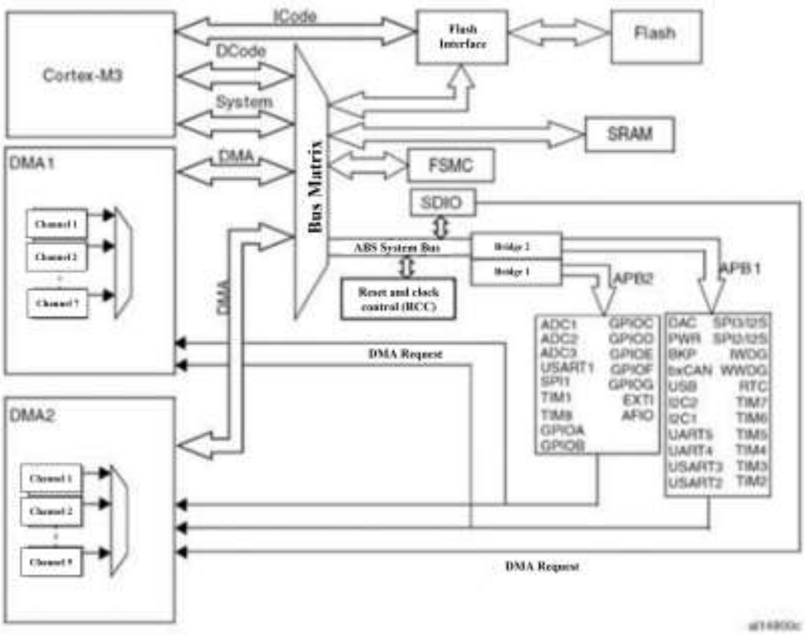

Fig.2 Diagram of circuit composition of portable micro medical Negative pressure therapeutic instrument

The microcontroller's ADCs are 12-bit successive approximation ADCs [10] with 18 channels capable of measuring 16 external and two internal signals. The A/D conversion of each channel can be performed in single, continuous scan, or intermittent mode. The ADC's output can be stored in a 16-bit data register in either left- or right-aligned mode. The analog watchdog [11] feature enables the application to determine if the input voltage exceeds or falls below a user-defined high/low threshold. The maximum ADC conversion rate is 1 MHZ, which corresponds to a conversion time of 1 us (at ADCCLK = 14M and 1.5 ADC clocks sampling period). The circuit structure of the system is shown in Figure 2. The negative pressure sensor serves as the instrument's operational and feedback link; it collects negative pressure values from the vacuum pump output, converts them to a specific current output to the filter circuit, and then outputs to the microcontroller via the AD sampling circuit's output. The sensor is based on the MPXV5050V integrated silicon pressure sensor with high-temperature resistance, temperature compensation, and calibration

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on-chip. Between 0°C and 85°C, it has a 2.5 percent error rate and a temperature compensation range of -40°C to +125°C.

2.2 Form and Structural Design

The portable micro medical negative pressure therapy instrument weighs less than 1kg and is powered by a rechargeable battery. The design incorporates an external collection bottle snap; and the weight and volume are always comfortable for health care workers or patients to carry with one hand. The designed product is 16 cm * 8 cm * 8 cm in size, with a tolerance of 1 cm on all dimensions. The product shell is made of an ABS material with a suitable hardness [12], which cannot be bent or deformed with one hand. To ensure the drainage bottle is airtight, it should be made of rigid PVC with a rubber cap; the stopper's edge should be smooth. The collection bottle has a capacity of 500 mL and a card position identical to that of the negative pressure machine shell, thereby increasing the capacity of the collection bottle clasp, which can also be used to hang a larger collection bottle, i.e., when in use, the bottle body is directly fixed horizontally on the back of the negative pressure machine shell (the display side is the front). Drainage connection tube [13] is made of medical silicone tubes with a diameter of 3 mm* 5 mm, tubes that are highly transparent, non-toxic, tasteless, and do not irritate human tissues. Additionally, it is resistant to shrinkage and has a high degree of resilience, withstanding pressures of up to 60 KPa without deforming after repeated tests to ensure effective attraction transmission. Figure 3 depicts three perspectives on the design of a portable miniature medical negative pressure therapy instrument.

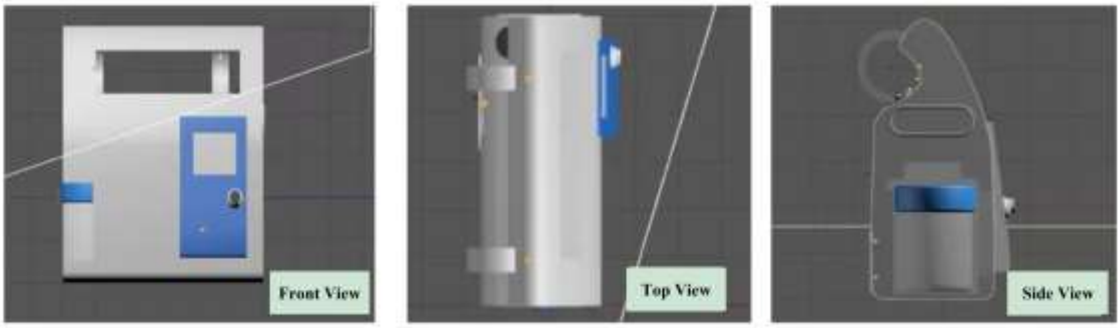

Fig.3 Diagram of the front view, top view and side view of the instrument in CAD design

2.3 System Design

The instrument works by forcing the diaphragm inside the pump to reciprocate, compressing and stretching the air inside the fixed volume of the pump cavity to create a vacuum (negative pressure), and creating a pressure difference between the pumping port and the external atmospheric pressure. The pressure difference forces the gas into the pump cavity, where it is compressed and then discharged. In the main panel of the product, the treatment parameters can be set to allow the microcontroller to control the pulse wave shaping circuit, which produces a duty cycle-adjustable waveform. This pulse sequence is output by the microcontroller's PWM [14] port, via the drive gate U9, and finally via the photoelectric

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coupling, causing the field effect tube to conduct, the current to be shaped and amplified in order to control the vacuum pump motor's speed, and finally the size of the air pressure generated by the vacuum pump. The schematic diagram of the system is shown in Figure 4. The vacuum pump detection and protection circuit is illustrated in Figure 5, the power supply circuit in Figure 6, and the charging indication circuit in Figure 7. Other charging protection circuits, time control circuits, sound and light alarm circuits, and so forth are not illustrated due to the space constraint.

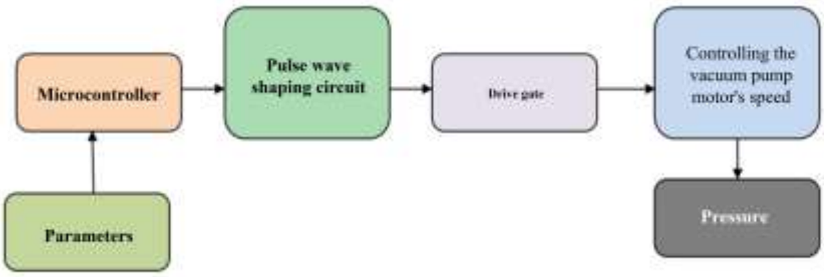

Fig.4 Diagram of negative pressure control system of portable micro medical Negative pressure therapeutic instrument

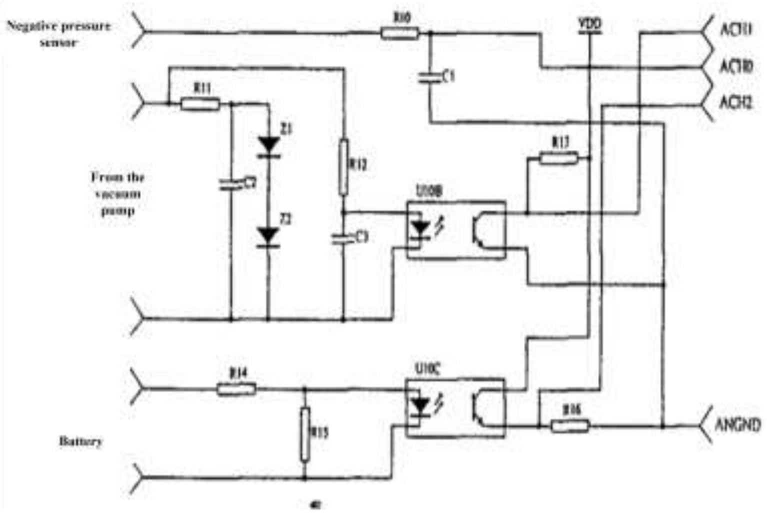

Fig.5 Diagram of detection and protection circuit schematic of Vacuum pump

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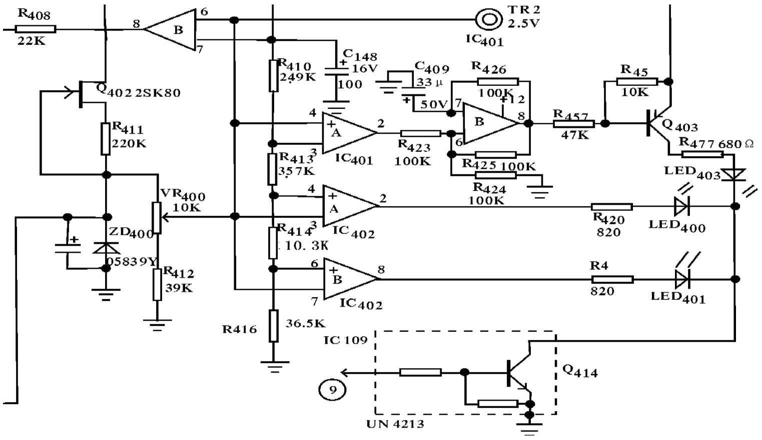

Fig.6 Diagram of charging indicator

2.4 Software Design

When the system is powered on, the microcontroller initializes the system's internal registers, timers, and other soft components; the operator configures the system's running parameters according to demand, including the running time and mode (e.g., default parameters). The system starts and begins to run when the touch screen start button is pressed. The system can also continue operating in the mode it was in prior to suspension; the framework diagram is shown in Figure 7.

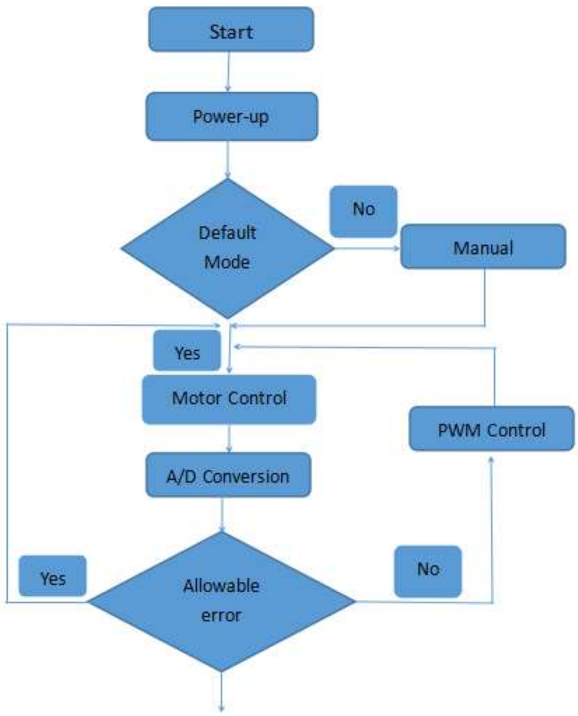

Fig.7 Diagram of negative pressure control system

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Fig.8 Diagram of the layout of the main interface

Fig.9 Diagram of working mode setup interface

The system is controlled via a powerful and intuitive EView MT506L touch screen. In addition to the standard HMI functions such as indicators, switches, data display and input, and abnormal alarms, the system includes several unique features [15]. The control interface, which was created using the configuration software EasyBuilder 500 [16], is divided into four sections: parameter setting, parameter display, system control, and alarm. The interface is simple to use and easily expands upon the original system. The main interface's layout is shown in Figure 8, including a power display, a time display, a number display, a negative pressure value display, a working mode display, a set working time, a remaining working time, a system setting, a negative pressure value setting, a working mode setting, an increase and decrease mode, and a data review module. The interface for setting the negative pressure value may include an input box and numeric keyboard for manually entering the corresponding value. After entering the interface is entered, as illustrated in Figure 9, the appropriate mode can be chosen. After logging into the interface, the user may click the dialog box to begin entering the required data. After logging in, the user can view the data in numerical order and then click to exit.

III. Results

3.1 Functionality Testing

Following the system prototype design, the functional test experiments, test content and test results are shown in Table I.

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TABLE I. Functional tests and results of portable micro medical Negative pressure therapeutic instrument

SERIAL NO.	FUNCTION	TEST RESULTS
1	Power display	The charge level in a battery pattern was displayed, as well as the percentage of charge remaining.
2	Time display	The current date and time could be displayed.
3	No.	There was a corresponding number for each treatment record in the historical data after each run.
4	Vacuum value display	The current vacuum value was displayed in real-time, with font size larger than others.
5	Operating mode display	The working mode of current setting was displayed.
6	Working time setting	The working time set by the system was displayed.
7	Remaining working time	The remaining working time was calculated according to the set working time.
8	System setting	The user could enter the setting interface by pressing on the right part of the screen, which included date and time setting, respectively. After setting, the user could resume the main interface by clicking OK. The date and time generally changed automatically with the system settings. Generally, it is not recommended for the user to set the date and time, and password management should be performed.
9	Vacuum value setting	The user could enter the setting interface by pressing on the right part of the screen, where an input box and a number keyboard was displayed. After setting, the user could resume the main interface by clicking OK.
10	Operating mode setting	The user could enter the setting interface by pressing on the right part of the screen, which included intermittent mode, continuous mode, increment/decrement mode, respectively. After setting, the user could resume the main interface by clicking OK.
11	Intermittent mode	After the intermittent mode was selected, an intermittent timer was created and the system automatically started and stopped according to the time setting until the set working time was reached, and displayed the equipment's remaining operating time.
12	Continuous mode	After the system was started, the vacuum value was increased at a constant rate from 0 to the set value, and the system operates until the set value was reached.
13	Increment/decrement mode	After the system was started, the subatmospheric pressure value increased from the minimum to the set value and then decreased from the set to the minimum value at a constant rate, repeating the process until the system stops working.
14	Data Review	Set as click button, click the screen in the right half to enter the interface of this setting, the data for each use can be displayed, the device can be set as a product with storage function, at least 1000 data can be recorded, and the cycle can be overwritten.

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3.2 Performance Test

The instrument's performance indicators were evaluated, and the results are shown in Table II.

TABLE II. The results of the experiment of portable micro medical Negative pressure therapeutic instrument

SERIAL NUMBER	FUNCTION	**TEST RESULTS**
1	Pumping flow	The maximum pumping flow shall not be less than 2 L/min, and the pumping rate is 1875 mL/min.
2	Maximum vacuum value	60kPa ± 3kPa
3	Operating noise	Normal operating noise ≤ 46 dB. Foam is used to wrap the negative pressure pump design to further reduce equipment noise.
4	Maximum negative pressure (drainage bottle)	The maximum negative pressure value endured by the drainage bottle: -60kPa ± 3kPa. A high-quality material is used to avoid the bottle body collapsing under suction when the maximum negative pressure is applied.
5	Maximum negative pressure (connecting tube)	The connecting tube has not collapsed under the maximum negative pressure.
6	Fluid full alarm	The system emitted a warning tone when the liquid level in the collection bottle reached the warning line. The alarm was weight-sensitive. The system activated the alarm when the liquid reached the predetermined weight.
7	Fault alarm	When the product was not operating normally, the system prompted for an alarm, a low-pressure alarm, and a tilt alarm.
8	Low battery prompt	When the battery capacity display fell below 20%, the system prompted the user to charge and set the charging indicator. When the battery capacity was less than 20%, the device continued to function normally.
9	Air leak alarm	When air leakage occurred because of inadequate air sealing, an air leakage prompt and alarm were triggered. When the negative pressure failed to reach the set negative pressure value during the liquid suction process, a back pressure alarm was triggered.

IV. CONCLUSION

The negative pressure therapy technology effectively prevents contamination and cross-infection, improves local blood supply, decreases tissue edema, reduces bacteria, promotes granulation tissue growth, alleviates pain, and lowers treatment costs, and is therefore valued in clinical applications. The portable micro medical negative pressure therapy instrument developed by the authors of this paper features a hardware design with strong functions and anti-interference ability, with STM32F103VET6 microcontroller as the core, ensuring high precision and safety in system control. After performance monitoring, the equipment operates steadily, with excellent control performance and practicality, meeting the requirements for simple operation, negative pressure stability, various operating modes, pressure regulation, good safety, high intelligence, light quality, and small size.

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