An Improved Device for the Calibration of Nerve and Muscle Stimulator

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Keywords: Nerve and Muscles Stimulator, RMS Value of Output Current, Stimulating Signal Frequency, DC Component, RMS Value of Interference Current, Pulse Duration, Channel Stability, Treatment Time Error, Calibration Device.

Abstract: Nerve and muscle stimulator is widely used in medical institutions for the diagnosis and/or therapy of neuromuscular disorders. This article presents a novel design of calibration test device for the calibration of nerve and muscle stimulator, and studies the essential parameters of the equipment such as "RMS value of output current", "stimulating signal frequency", " DC component ", "RMS value of interference current", "pulse duration", "channel stability" and “treatment time error” in order to present a feasible procedure for the periodic calibration of nerve and muscle stimulator and to establish the metrological traceability system of the instrument. The calibration result shows that the calibration test device and the calibration procedure presented in this article can ensure the metrological traceability of nerve and muscle stimulator.

1 INTRODUCTION

Nerve and muscles stimulator is medical electrical equipment for the application of electric currents via electrodes in direct contact with patient for the diagnosis and/or therapy of neuromuscular disorders. It can provide low and/or intermediate frequency pulse electrical stimulation for the treatment of headache, paralysis, renal calculus, sciatica and angina pectoris. Its working principle is to generate a variety of different output signals according to the needs of diagnosis and treatment purposes. The electrodes are patched to the patient’s skin to stimulate the rhythmic contraction of nerves and muscles, so as to delay the atrophy of diseased muscles and help the compensatory proliferation of muscle fibers, which will promote the function recovery of nerve excitation and conduction. Nerve and muscle stimulator is wildly used in China, however, applicable national metrological verification regulation of which has not been issued so far, and the corresponding traceability system of which has not been established yet.

The purpose of this paper is to study the influencing factors on essential technical parameter such as "RMS value of output current", "stimulating signal frequency", " DC component ", "RMS value of interference current", "pulse duration", "channel stability" and “treatment time error” of nerve and muscle stimulator, so as to design a novel calibration device and to establish an applicable calibration procedure, in order to improve medical treatment quality, which will ultimately benefit the patients’ health and guard their safety.

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2 DESIGN OF CALIBRATION DEVICE FOR NERVE AND MUSCLE STIMULATOR

The calibration device for nerve and muscle stimulator is mainly composed of channel selection part, signal conditioning part, high-speed AD sampling analysis part, power management part and operating system. The channel selection part selects one or more different channels to be tested through CPU control, and adjusts the signal through the resistance attenuation network and PGA (digital controllable gain amplifier) of the signal conditioning part to adapt to AD sampling. The CPU collects the measured signal through its own high speed signal sampling channel, obtains the amplitude frequency parameters of the signal through FFT (fast Fourier transform), and ultimately gets all the parameters needed through other algorithms, which will all be displayed on TFT LCD for reading. The power management section manages all power supplies of the device. The system diagram of the calibration device is demonstrated in Figure 1:

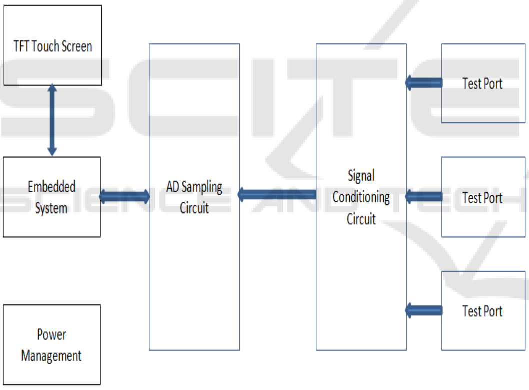

Figure 1: System Diagram of the Calibration Device for nerve and Muscle Stimulator.

2.1 Channel Selection Part

The device can test three input channels respectively, and can also test two or three superimposed signals at the same time, which is realized by CPU controlling relay network. The relay network is composed of self-locking relays, and the advantage of which is low power consumption for the control current only needs to be applied when the switch pulls in the channel and there is no need to maintain the current after, which reduces the power consumption of the whole device. After channels are determined, channel impedance can be selected according to the test requirements.

2.2 Signal Conditioning Part

Since the test range of the designed input signal is up to ± 700V, the input signal must be attenuated to meet the maximum input range of the system circuit elements. The attenuation network adopts resistance attenuation, which attenuates the signal about 148 times.

In order to ensure the measurement accuracy of the small signal, the system uses PGA (digital controllable gain amplifier) 280 to amplify the small signal and improve the accuracy of AD sampling. PGA280 is a zero drift, HV programmable gain amplifier. Its excellent electrical characteristics ensure the stability of the signal measured by the system.

2.3 High Speed AD Sampling Analysis

The main control unit and high-speed AD sampling of the system adopt SMT32F407VET6. SMT32F407VET6 is a microprocessor with ARMCortex-M4 core specially designed by ST Microelectronics based on embedded applications requiring high performance, low cost and low power consumption. The core contains ARM® 32-bit cortex ®- M4CPU of FPU, adaptive real-time accelerator (ART accelerator ™) for realizing no-wait state operation performance, and MPU with DPS instruction set for realizing the performance of 210 DMIPS/1.25DMIPS/MHz (Dhrystone 2.1). The memory is consisted of Flash of up to 1MB and SRAM of up to 192 + 4 KB including 64-KB CCM (kernel coupled memory) data RAM and flexible external storage controllers with up to 32-bit data bus: SRAM, PSRAM, NOR / NAND memory.

2.4 Power Management Part

The device adopts a single lithium-ion battery to provide power supply. The power supply voltage of the digital part of the system is 3.3V, the power supply voltage of the LCD backlight and relay is 5V, and the voltage of the analog (PGA) part is ± 5V.

Power supply circuit of digital part: the power supply of digital part is generated by step-down DC / DC chip TPS62260 manufactured by TI. This chip is an efficient DC / DC step-down chip with output current up to 600mA, switching frequency up to 2.25MHz, input voltage of (2-6)V, and static power consumption as low as 15μA. Its 100% duty cycle can provide electricity when the battery voltage is low to the output voltage, further improving the utilization of the battery.

LCD backlight and relay power supply circuit: the power supply of this part is generated by step-up DC / DC chip TPS61040 manufactured by TI. This chip is an efficient DC / DC step-up chip with an output current of 400mA, a switching frequency of 1MHz, an input voltage of (2-6) V, an output voltage of up to 28V and a static power consumption of 28μA.

Analog (PGA) power supply circuit: the power supply of this part provides analog voltage for PGA, and its power performance directly affects the performance index of the whole system, therefore, higher requirements of this part is necessary. The power supply of this part is generated by dual output DC / DC chip TPS65133 manufactured by TI. The output voltage of the chip is fixed at ± 5V, with the accuracy of 1%. The output current of the chip from positive to negative direction is up to 250mA, with excellent line and load transient response. The power supply circuit operates in continuous conduction mode (CCM) to supply noise-free output voltage.

2.5 Operating System

μC / OS II (Micro Control Operation System Two) is a scalable, preemptive, real-time multitasking kernel that can run based on ROM. it has high portability, especially suitable for microprocessors and controllers. It is a real-time operating system (RTOS) with the same performance as many business operating systems. μC / OS II can be roughly divided into five parts: core, task processing, time processing, task synchronization & communication, and CPU transplantation.

1) Core (OSCore. c) is the processing core of the operating system, including operating system initialization, operating system operation, leading in and out of interrupts, clock beat, task scheduling, event processing and so on. It’s the part that maintains the basic work of the whole system.

2) Task Processing (OSTask. c) is closely related to the operation of the task, including task creation, deletion, suspension, recovery, etc. μC / OS II dispatches basic unit of task, therefore, this part is also very important.

c) Clock (OSTime. C) μ The minimum clock unit in μC / OS II is timetick. Task delay and other operations are completed here.

d) Task synchronization & communication part is the event processing part, including semaphore, mailbox, message queue, event flag, etc. It is mainly used for the interconnection between tasks and access to critical resources.

e) The interface with CPU refers to the porting part of used CPU of μC / OS-II. As a universal operating system, implementation of key issues still needs to be transplanted into μC / OS-II according to the specific contents and requirements of specific CPU. This part is usually written in assembly language because it involves system pointers such as SP. It mainly includes the bottom implementation of interrupt level task switching, the bottom implementation of task level task switching, the generation and processing of clock beat, the related processing of interrupt and so on.

3 CALIBRATION PROCEDURE

Connect the calibration device presented in Chapter 2 with a nerve and muscle stimulator according to Figure 2:

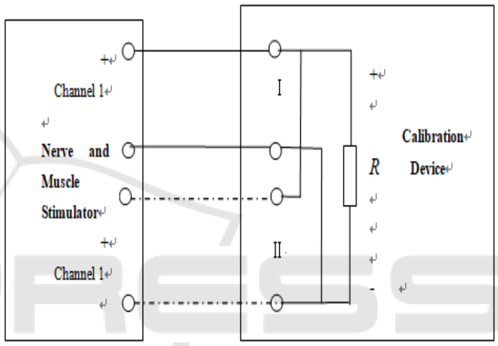

Figure 2: Schematic Diagram of Calibration for Nerve and Muscle Stimulator.

3.1 Error of Output Current RMS Value

Set the impedance of the calibration device to 500 Ω and the voltage to 700V, select a channel of the stimulator, adjust the output power of the stimulator to the maximum value, observe the output signal waveform, and record the maximum current RMS value measured by the calibration device after the signal waveform is stable. The error of output current RMS value of the stimulator is calculated according to equation (1):

$$\triangle I = \frac{I - I_0}{I_0} \times 100\% \qquad (1)$$

I——Maximum nominal RMS current of nerve and muscle stimulator, mA;

$\triangle I$——Error of Maximum nominal RMS current;

I_0——Maximum nominal RMS current measured by calibration device, mA.

3.2 Stimulating Signal Frequency Error

Set the impedance of the calibration device to 500 Ω and the voltage to 700V, adjust the output power of the stimulator to the half of the maximum value, observe the output signal waveform, and record the frequency measured by the calibration device after the signal waveform is stable. The error of stimulating signal frequency of the stimulator is calculated according to equation (2):

$$\triangle f = \frac{f - f_0}{f_0} \times 100\% \qquad (2)$$

f——Nominal stimulating signal frequency of nerve and muscle stimulator, Hz;

$\triangle f$——Stimulating signal frequency error;

f_0——Stimulating signal frequency value measured by calibration device, Hz.

3.3 DC Component Error

Set the impedance of the calibration device to 500 Ω (or 2000Ω when the calibrated nerve and muscle stimulator is applied in Ophthalmic or dental diagnosis) and the voltage to 700V, adjust the output power of the stimulator to the maximum value, observe the output signal waveform, and record the DC component measured by the calibration device after the signal waveform is stable. The DC component error of the stimulator is calculated according to equation (3):

$$\triangle I_D = \frac{I_D - I_{D0}}{I_{D0}} \times 100\% \qquad (3)$$

I_D ——Nominal DC component of nerve and muscle stimulator, mA;

$\triangle I_D$——DC component error;

I_{D0} ——DC component value measured by calibration device, mA.

3.4 Pulse Duration Error

Set the impedance of the calibration device to 1000 Ω and the voltage to 700V, select the commonly used output signal of the nerve and muscle stimulator, and the electrical stimulation mode channel of the calibration device, adjust the output power of the stimulator to the half of the maximum value, observe the output signal waveform, and record the pulse duration measured by the calibration device after the signal waveform is stable. The pulse duration error of the stimulator is calculated according to equation (4):

$$\triangle T = \frac{T - T_0}{T_0} \times 100\% \qquad (4)$$

T ——Nominal pulse duration of nerve and muscle stimulator, μs;

△T——Pulse duration error;

T_0 ——Pulse duration value measured by calibration device, μs.

3.5 Treatment Time Error

Select the nominal timing value (5min or 10min) of the nerve and muscle stimulator, and measure the actual stimulation treatment time with a stopwatch. The time error is calculated according to equation (5):

$$\triangle t = \frac{t - t_0}{t_0} \times 100\% \qquad (5)$$

t ——Nominal treatment time of nerve and muscle stimulator, min;

$\triangle t$——Treatment time error;

t_0 ——Treatment time measured by calibration device, min.

3.6 RMS Value of Interference Current

For stimulators with two or more stimulation channels, it is necessary to measure the interference current of the stimulator. Select two or three measured signals with similar frequencies of the nerve and muscle stimulator, set the impedance of the calibration device to 500 Ω and the voltage to 700V, adjust the power output of the stimulator to the maximum value, observe the output signal waveform, and record the RMS value of the interference current measured by the calibration device after the signal waveform is stable.

3.7 Channel Stability

Set the impedance of the calibration device to 1000 Ω and the voltage to 700V, select the commonly used output signal of the nerve and muscle stimulator, and the electrical stimulation mode channel of the calibration device, adjust the output power of the stimulator to the half of the maximum value, observe the output signal waveform, and record the maximum and minimum RMS current values under the same frequency measured by the calibration device within

30min after the signal waveform is stable. The pulse duration error of the stimulator is calculated according to equation (6):

$$\gamma = \frac{I_{\max} - I_{\min}}{2\bar{I}} \times 100\% \tag{6}$$

$I_{\max}$ ——Maximum RMS value of output current, mA;

$I_{\min}$ ——Minimum RMS value of output current, mA;

$\bar{I}$ ——Average RMS value of output current, mA;

γ ——Channel stability

4 CALIBRATION RESULT

Select several typical types of nerve and muscle stimulators as the calibrated subjects. The experimental result is demonstrated in Table 1:

Table 1: Calibration Results.

Type	Parameter	Result
XY-K-SISS-K	Error of Output Current RMS Value	3.9%
	Stimulating Signal Frequency Error	8.7%
	DC Component Error	2.8%
	Pulse Duration Error	3.1%
	Treatment Time Error	1.3%
	RMS Value of Interference Current	70mA
	Channel Stability	2.0%
KT-90A	Error of Output Current RMS Value	9.9%
	Stimulating Signal Frequency Error	4.2%
	DC Component Error	6.8%
	Pulse Duration Error	1.0%
	Treatment Time Error	1.3%
	RMS Value of Interference Current	64mA
	Channel Stability	1.9%
PHENIXUSB4	Error of Output Current RMS Value	6.4%
	Stimulating Signal Frequency Error	0.0%
	DC Component Error	5.9%
	Pulse Duration Error	-2.0%
	Treatment Time Error	-5.3%
	RMS Value of Interference Current	5.0mA
	Channel Stability	1.7%
KWD-808I	Error of Output Current RMS Value	3.1%
	Stimulating Signal Frequency Error	0.0%
	DC Component Error	6.8%
	Pulse Duration Error	1.0%
	Treatment Time Error	-3.3%
	RMS Value of Interference Current	4.5mA
	Channel Stability	0.4%

The calibration results have met the metrological criterion set by YY 9706.210-2021 *Test method for measuring output characteristics of nerve and muscle stimulators* and the enterprise standards of the calibrated subjects.

5 CONCLUSIONS

The article studies the key technical parameters such as "RMS value of output current", "stimulating signal frequency", " DC component ", "RMS value of interference current", "pulse duration", "channel stability" and “treatment time error” of nerve and muscle stimulator, designs the appropriate calibration device for the measurement of the parameters, and presents the novel calibration procedure for the equipment, and the feasibility of which has been proved by the calibration results.

Therefore, the article presents a feasible procedure for the periodic calibration of nerve and muscle stimulator in order to establish the metrological traceability system of the instrument. Further work is worth to be done to improve the calibration method of infant phototherapy incubator.

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