

# Establishment of calibration equipment for defibrillator analyzer and evaluation of measurement uncertainty

Yunling Wang<sup>1,2</sup>, Zhiqiang Zhan<sup>1,2,\*</sup>, and Lei Yu<sup>1,2</sup>

<sup>1</sup>Shanghai Institute of Measurement and Testing Technology, Shanghai, China

<sup>2</sup>Shanghai Key Laboratory of On-line Testing and Control Technology, Shanghai, China

**Abstract.** A cardiac defibrillator is a medical electrical device used to defibrillate the heart of patients. In JJF1149-2014, defibrillator analyzers are used to measure the output energy of cardiac defibrillators, whose energy accuracy is an important parameter. This manuscript describes establishment of calibration equipment for defibrillator analyzer, including voltage divider module, sampling module and data processing module. Measurement uncertainty is evaluated for measurement results at last.

## 1 Introduction

A cardiac defibrillator is a medical electrical device used to defibrillate the heart by applying electrical pulses to the patient's skin (external electrodes) or exposed heart (internal electrodes) through electrodes. The width of the instantaneous high-energy pulse is (4-10) ms, and the output energy is (40-400) J. The output energy of the cardiac defibrillator is very important. It may not reach the effect if too small, or the patient may be injured if too large.

In *JJF1149-2014 Calibration Specification for Cardiac Defibrillators* [1], defibrillator analyzers are used to measure the output energy of cardiac defibrillators. Therefore, the energy accuracy of the defibrillator analyzer is an important parameter.

By querying related literature, and combining years of experience, we summarized two methods, comparison method [2,3] and power integration method [4-8].

a) comparison method

This method requires a defibrillator and a standard defibrillator analyzer as a standard device. Firstly, use the standard defibrillator analyzer to calibrate the energy value of the defibrillator, denoted as  $E_0$ . Then use the calibrated defibrillator analyzer to measure the energy value of the defibrillator, denoted as  $E_1$ . Set  $\Delta E$  the error of energy value, then

$$\Delta E = E_1 - E_0 \tag{1}$$

This method is simple to operate. However, the output energy of the cardiac defibrillator is unstable with poor repeatability. When energy value is 300J, the maximum deviation of the output energy may reach  $\pm 10$ J. When this method is used for calibration, the measurement uncertainty is relatively large, about 4.6% ( $k=2$ ).

---

\* Corresponding author: [zhanzq@simt.com.cn](mailto:zhanzq@simt.com.cn)

b)power integration method  
 According to the energy formula

$$E = \int_0^T P(t)dt = \frac{\int_0^T V(t)^2 dt}{R} = \int_0^T I(t)^2 R dt = \int_0^T V(t)I(t)dt \quad (2)$$

where  $E$  is the energy,  $P$  is the power,  $V$  is voltage,  $I$  is electricity, and  $R$  is resistance.

This method needs to design an energy test system with high requirements for the standard device. This method solves the problems of poor repeatability of the cardiac defibrillator and traceability of energy value.

We choose this method for measurement.

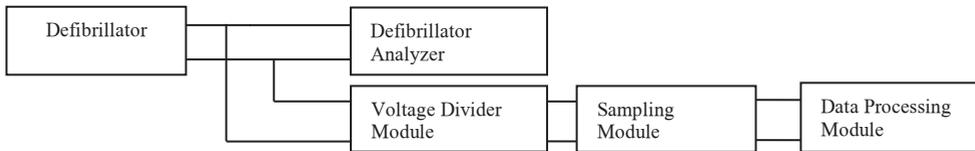
## 2 Establishment of calibration equipment

If the sampling time  $T$  of the device is short enough (less than  $0.1\mu s$ ), then

$$E = \sum_1^n V(n)^2 \times \frac{T}{R} \quad (3)$$

The schematic diagram of the equipment is shown in Fig. 1. The voltage divider module uses a voltage divider, and divider ratio  $r$  is a fixed value, such as 1000:1. The sampling module uses an oscilloscope, whose voltage is donated as  $V_o(n)$ . The defibrillator analyzer has a fixed resistance, usually  $50\Omega$ , which can be calibrated by a digital multimeter. Then

$$E = \sum_1^n (V_o(n) \times r)^2 \times \frac{T}{R} \quad (4)$$



**Fig. 1.** The schematic diagram of the equipment

### 2.1 Analysis of pulse waveform of cardiac defibrillator

We need to analyze the pulse waveform generated by the defibrillator.

The energy of the cardiac defibrillator is 360J, measured by an oscilloscope with a voltage probe shown in Fig. 2.a. The waveform has a width of 5ms and a peak value of 3.16kV.

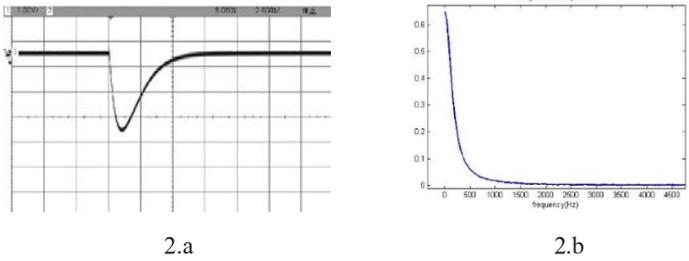
The Fourier transform of the non-periodic continuous-time signal  $x(t)$  can be expressed as

$$X(\omega) = \int_{-\infty}^{\infty} x(t)e^{-j\omega t} dt \quad (5)$$

The discrete Fourier transform (DFT) of a finite-length discrete signal  $x(n)$  is defined as

$$X(k) = \sum_{n=0}^{N-1} x(n)W_N^{kn}, k = 0,1, \dots, N - 1, W_N = e^{-j\frac{2\pi}{N}} \quad (6)$$

Fig. 2.b shows the curve of the pulse signal in the frequency domain by MATLAB. The energy of the signal is mainly concentrated in the low frequency part, that is, the part from DC to 1kHz. Therefore, the defibrillation analyzer calibration system needs to meet requirements of the AC voltage peak value greater than 3.16kV, DC to 1kHz with high accuracy.



**Fig. 2.a** Waveform generated by the defibrillator **2.b** curve in frequency domain.

### 2.2 Voltage divider module

After investigating voltage dividers on the market, we found many manufacturers with different performance. Finally, we customized the VD5 voltage divider by ROSS company.

The specifications of the instrument are as follows

**Table 1.** DC voltage and AC voltage (60Hz)

DC voltage			AC voltage(60Hz)		
Applied voltage kV	As left output V	Deviation	Applied voltage kV	As left output V	Deviation
0.5000	0.49995	-0.01%	0.35000	0.35056	0.16%
1.0000	0.99993	-0.01%	1.0000	0.99974	-0.03%
2.0000	1.99990	0.00%	1.5000	1.49886	-0.08%
3.5000	3.49998	0.00%	2.5000	2.49701	-0.12%
5.0000	5.00007	0.00%	3.5000	3.49621	-0.11%

It can be seen from table that the error of the voltage divider ratio at DC is much less than  $\pm 0.1\%$ , and the error of voltage divider ratio at 60Hz is less than  $\pm 0.2\%$ .

According to specification, the error is about  $\pm 3\%$  at 1MHz, and the 3dB bandwidth point is about 7.1MHz. The frequency response curve is relatively flat below 1kHz. The instrument meets the requirements of the equipment.

### 2.3 Sampling module

We need a high-precision real-time sampling oscilloscope, which can be used to process the results in real time. We chose the 14-bit PXI-5122 oscilloscope produced by NI, which has a bandwidth of 100MHz and a sampling rate of 100MS/s.

Our institute is authorized for calibration of NI instruments. We can use the calibration program Calibration Executive to adjust the accuracy of the PXI-5122. After adjustment, its AC accuracy can reach 0.37%, which greatly improves the accuracy of the oscilloscope.

To use PXI-5122, we need a NI PXI-1050 chassis, a PC with PCI slots, and PCI-8336 and PXI-8336 for communication.

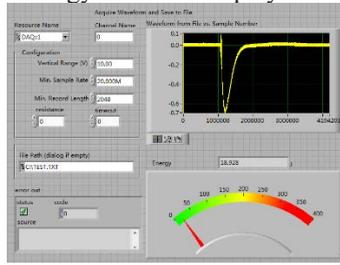
### 2.4 Data processing module

When using a traditional oscilloscope for measurement, we must save data into a csv file, then copy the file to a computer for data processing. Thus, the results cannot be displayed in real time.

We write LabVIEW programs for NI oscilloscope, and the program can display result in real time.

The front panel of the energy test program is as follows. Resistance is used to set the

resistance value, that is, the internal resistance value of the defibrillation analyzer measured by the 3458A multimeter. The Energy indicator displays the calculated energy value.



**Fig. 3.** Front panel of program.

## 2.5 Measurement results

Set the defibrillator in six energy levels. The test results are as follows.

**Table 2.** Results

Level	Indication value of defibrillator analyzer	Measured value of calibration equipment	Error
30 J	29.4 J	29.51 J	-0.1 J
50 J	47.7 J	47.87 J	-0.2 J
100 J	96.4 J	96.57 J	-0.2 J
200 J	200.3 J	200.50 J	-0.2 J
300 J	300.2 J	301.05 J	-0.9 J
360 J	354.4 J	354.70 J	-0.3 J

## 3 Evaluation of measurement uncertainty

### 3.1 Evaluation of standard uncertainty

Evaluations of standard uncertainty are as follows.

1) The measurement uncertainty component  $u_1$  introduced by ac accuracy of the high voltage divider

According to the specification, the voltage divider VD5 is generally better than  $\pm 0.1\%$  DC,  $\pm 0.2\%$  50/60 Hz. Take the ac accuracy as the maximum permissible error for calculation. Assuming it is uniformly distributed, we take  $k_1 = \sqrt{3}$ , thus  $u_{1rel} = 0.2\% / \sqrt{3} = 0.115\%$ .

2) The measurement uncertainty component  $u_2$  introduced by resistance accuracy of the digital multimeter

According to the specification of the digital multimeter 3458A, the resistance accuracy is  $(12 \times 10^{-6} \times \text{reading} + 5 \times 10^{-6} \times \text{range})$  when range is 100Ω. Assuming it is uniformly distributed,  $k_2 = \sqrt{3}$ , and reading is 50Ω, thus  $u_{2rel} = (12 \times 50 + 5 \times 100) / 10^6 / 50 / \sqrt{3} = 1.27 \times 10^{-5}$ .

3) The measurement uncertainty component  $u_3$  introduced by frequency accuracy of the oscilloscope

According to calibration performance test data of PXI-5122, maximum permissible error of timing is  $\pm 5.3 \times 10^{-6}$  after calibration. Assuming it is uniformly distributed, we take  $k_3 = \sqrt{3}$ , thus  $u_{3rel} = (12 \times 50 + 5 \times 100) / 10^6 / 50 / \sqrt{3} = 1.27 \times 10^{-5}$ .

4) The measurement uncertainty component  $u_4$  introduced by ac amplitude accuracy of the oscilloscope

According to the specification of PXI-5122, maximum permissible error of DC is  $\pm 0.65\%$ .

Assuming it is uniformly distributed, we take  $k_4=\sqrt{3}$ , thus  $u_{4rel}=0.65\%/\sqrt{3}=0.375\%$ .

5) The measurement uncertainty component  $u_5$  introduced by the resolution of the calibrated defibrillator analyzer

The resolution of the defibrillator analyzer is 0.1J, then  $a_5=0.05J$ . Assuming it is uniformly distributed, we take  $k_5=\sqrt{3}$ , then  $u_5=a_5/k_5=0.03J$ .

6) The measurement uncertainty component  $u_6$  introduced by the measurement repeatability of the calibrated defibrillator analyzer

Set the defibrillator in six energy levels, 30J, 50J, 100J, 200J, 300J, 360J, and test each energy level for 10 times. The test standard deviation of a single measurement result is

$$s(x) = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{n-1}} \tag{7}$$

Standard uncertainty is expressed by test standard deviation, so  $u_6=s$ .

**Table 3.** Measurement repeatability.

Energy level	30J	50J	100J	200J	300J	360J
$u_6$	0.048J	0.052 J	0.048 J	0.053 J	0.097 J	0.084 J

### 3.2 Standard uncertainty subscale

**Table 4.** Standard uncertainty subscale.

No.	Relative uncertainty component					
	Sources of uncertainty	Type	Measurement error or accuracy	Distribution type	Inclusion factor	Standard uncertainty
1	Ac accuracy of the high voltage divider	B	0.2%	Uniformly distribution	$\sqrt{3}$	0.115%
2	Resistance accuracy of the digital multimeter	B	$2.2 \times 10^{-5}$	Uniformly distribution	$\sqrt{3}$	$1.27 \times 10^{-5}$
3	Frequency accuracy of the oscilloscope	B	$5.3 \times 10^{-6}$	Uniformly distribution	$\sqrt{3}$	$3.06 \times 10^{-6}$
4	Ac amplitude accuracy of the oscilloscope	B	0.65%	Uniformly distribution	$\sqrt{3}$	0.375%
5	The resolution of the calibrated defibrillator analyzer	B	0.05J	Uniformly distribution	$\sqrt{3}$	0.03J
6	Measurement repeatability of the calibrated defibrillator analyzer	A	$s$	/	/	$u_6$

### 3.3 Uncertainty synthesis

The uncertainty components  $u_{1rel}, u_{2rel}, u_{3rel}, u_{4rel}$  are independent of each other. According to the formula

$$E = \sum_1^n (V_o(n) \times r)^2 \times \frac{T}{R} \tag{8}$$

$$\frac{u(E)}{E} = \sqrt{4 \times \left[\frac{u(V_o)}{V_o}\right]^2 + 4 \times \left[\frac{u(r)}{r}\right]^2 + \left[\frac{u(T)}{T}\right]^2 + \left[\frac{u(R)}{R}\right]^2} \tag{9}$$

Which is  $u_{Erel} = \sqrt{4 \times u_{4rel}^2 + 4 \times u_{1rel}^2 + u_{2rel}^2 + u_{3rel}^2} = 0.787\%$ .

The uncertainty components  $u_5$  and  $u_6$  are positively correlated, and the larger one among them is chosen to be participated in the synthesis.

In summary, there are two main sources of uncertainty. One is  $u_{Erel}$ , and one is  $u_{6rel}$ . These two components are independent of each other.

$$u_{crel} = \sqrt{u_{Erel}^2 + u_{6rel}^2} \tag{10}$$

Calculate the relative combined standard uncertainty at different energy level respectively.

**Table 5.** Relative combined standard uncertainty

Energy level	30J	50J	100J	200J	300J	360J
$u_{crel}$	0.808%	0.797%	0.792%	0.790%	0.790%	0.790%

### 3.4 Extended uncertainty

The inclusion factor is 2. The expanded uncertainty is expressed separated.

$$U=1.6J(k=2) \text{ (20J~100J)}$$

$$U_{rel}=1.6\%(k=2) \text{ (100J~360J)}$$

## 4 Results

We firstly analyzed the defibrillation signal generated by a defibrillator, then designed the measurement equipment, including voltage divider module, sampling module, and data processing module. With LabView program, the equipment can measure the energy value in real time. At last, the uncertainty evaluation results are given.

## Acknowledgments

This work is supported by Shanghai Municipal Bureau of Quality and Technical Supervision 2018-24, and Shanghai Institute of Measurement and Technology F00RY1611.

## References

1. JJF1149-2014 Calibration Specification for Cardiac Defibrillators, GAQSIQ, (2014).
2. QED-6 user’s guide, BIO-TEK, (2002).
3. Cui Li. Analysis and evaluation of the uncertainty of the defibrillation analyzer verification results. *Chinese Medical Equipment*, 36-38, **11**, 12(2014).
4. Zhang Huanghui. Development of calibration system for defibrillator analyzers[J]. *Electrical Instrument & Measurement*. **56**, 11(2019).
5. Zhang Yadong, Li Yanfeng, et al. Research on defibrillation pulse energy measurement system based on STM32. *Medical and Medical Equipment*, 8-10, **36**, 1(2015).
6. Yao Guohong, Zhang Yadong, Li Yanfeng, et al. Development of defibrillation energy standard source. *Medical and Medical Equipment*, 10-13, **36**, 9(2015).
7. Su Yanping, Yao Nianling, Cui Li. Analysis and research on quality verification methods of cardiac defibrillators. *China Medical Equipment*, 22-24, **11**,3 (2014).
8. Wei Chuan, Wang Lin, Yan Ling. Research on Traceability Method of Cardiac Defibrillator Testing and Calibration Equipment. *China Test*, 34-36, **37**, 5(2011).