Implementation of Defibrillator Calibrator for Working Standard

Nuntachai Thongpance[1], **Thawat Kaewgun**[1], **Anatasak Wongkamhang**[1], **Kittipan Roongprasert** [1], **Yutthana Pititeeraphab**[1], **Anuchit Nirapai**[1], and **Phichitphon Chotikunnan**[1],

ABSTRACT

The Calibration Laboratory of Faculty of Biomedical Engineering, Rangsit University, Thailand (BMERSU) has set up a calibration facility for defibrillators. Defibrillators are medical devices designed to resume the normal heart pulse of a patient by discharging energy pulses to a person who is suffering from an emergency cardiac attack. They are commonly used in hospitals and medical institutes. In the past at the BMERSU, the working standard for calibration of defibrillator was a standard commercial defibrillator analyzer imported from foreign country with high cost, more complexity, and difficult to repair and maintenance. In addition, if we use a technology imported from abroad without researching and developing the technology for own use. We cannot be self - reliant and cannot compete with other countries in the field of technology development. Currently, we adopted the principle of the sampling method to develop a defibrillator calibrator for using in our calibration laboratory. The implementation of the defibrillator calibrator was composed of 3 main parts: 1) the input part consisting of the paddle electrodes receptacle, 2) the signal conditioner and processing part including voltage attenuator circuit , surge protection circuit, and microcontroller ARM Cortex M3 ,STM32F107VCT 6 for processing of energy, peak voltage, peak current, pulse period and plotting the both monophasic and biphasic waveforms and 3) the display part consisting of LCD touch screen display for displaying the energy value in Joule unit , peak voltage in Volt unit, peak current in Ampere unit , period in millisecond unit and the waveforms of the unit under test. It is calibrated for accuracy of the load resistance and energy measuring by the standard defibrillator analyzer Fluke Model Impulse 6000D and the Laboratory of Calibration Services and Environmental Analysis, Department Technology Promotion Association (Thailand – Japan). The results shown that the average percentage uncertainties (k=2) are ± 0.01% and ± 1.1% respectively.

Keywords: Defibrillator Calibrator, Sampling Method

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[1]Faculty of Biomedical Engineering, Rangsit University, Phathumthani, THAILAND E-mail: nthongpance@hotmail.com

1. INTRODUCTION

Nowadays, Thailand has a policy to be the Medical Hub of Asia. For the purpose that can be supported as the policy above, the establishment where is related to the health care has to be certified by the organization standards in the national level and /or international level. One of the important elements that is certified as stated acceptance is to make an accurate medical equipment in use at all times by giving priority to the maintenance of proper medical facilities. One factor which is the main component in the maintenance of medical instrument is testing and calibration of medical devices for ensuring that the accuracy and precision are standard in the measurement at all time. [1]

A defibrillator is an electronic device that was designed to restore the normal heart rhythm of a patient during Sudden Cardiac Arrest (SCA) by applying an energy pulse. It is commonly available in hospitals, ambulances and medical institutes. Conventional defibrillators can only be used by medical professionals, who were trained to determine whether or not a patient shall be defibrillated. Some modern type automatic external defibrillators (AED) were designed to be used by non-trained personnel. AED could automatically analyze the heart rhythm of the patient, and provide visual or voice prompts to the operator. Due to the effectiveness of the device and the increase in public awareness, the numbers of AEDs available in public area have increased dramatically. Conventional defibrillators generate monophasic waveforms and allow electric current to only flow in one direction. Modern defibrillators generate biphasic pulse to a patient with an energy level in the range from 50 J to 360 J. For biphasic defibrillation, current flows in two directions. It has the capability of detecting the impedance of the patient, and adjusting the output energy level accordingly. An example of a biphasic pulse is illustrated in Fig. 1. The pulse width of a biphasic waveform is usually between 8 ms and 13 ms. Depending on the energy setting and the impedance of the patient, the peak output voltage from a defibrillator could be more than 1500 V. There are also different proprietary biphasic waveforms used by specific manufacturers, and some waveforms are designed to work at different energy and impedance levels. [4,5]

In order to ensure the effectiveness and safety of

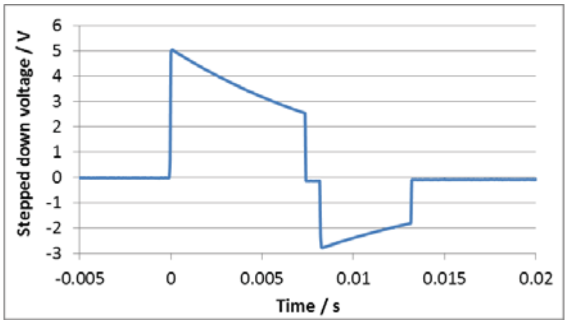

Fig.1:: Wave shape of a stepped down biphasic pulse.[7]

defibrillators, their output energy level should be calibrated regularly. International standards specify the accuracy requirements of the energy function of a defibrillator. If the amount of energy applied to the patient is lower than the pre-set value, it will not be enough to restore normal heart rhythm. Alternatively, if the amount of energy applied to the patient is higher than the pre-set value, hazardous effects may result.

Defibrillator calibrators are used to measure the energy delivered by defibrillators. The important properties of them are including higher accuracy than unit of defibrillators under calibration least 3 times. Their working ranges cover area of usage and devices to be calibrated. In addition, adopted standards can be traced back to national primary standards. [2,3]

The AAMI DF80 standard the verification test protocol of defibrillator allows a ±15% tolerance in testing the measured delivered energy against the specified selected energy. However, the international standards of acceptable deviations for the calibration of defibrillator output energy are ±4 J at the energy below 25J and ±15% of reading at higher energy. [2,3]

Many hospitals, medical institutes, and testing laboratories in Thailand are equipped with defibrillator calibrators for routine calibration of defibrillators. Due to increasing requests for the calibration of defibrillator calibrators, BMERSU has developed calibration laboratory for defibrillators. This paper will present a method developed at BMERSU for developing the Defibrillator Calibrator.

2. PRINCIPLE OF DEFIBRILLATOR CALIBRATOR

Normally there are two basic methods of measuring the energy in a defibrillator pulse. The first method is the calorimetric method. The electrical pulse discharged into a coil of copper wire immersed in a water tank is determined by observing the temperature changes of the coil as a function of time. The second method is the sampling method. An ordinary load and measuring the voltage and current applied as functions of time from which the energy delivered could be calculated from these sampled signals. [2]

For the sampling method, the defibrillator calibrator is designed to measure the energy of the discharge pulse delivered by a defibrillator. The energy contained in a pulse of arbitrary wave shape, such as the biphasic waveform shown in Fig. 1, can be calculated by

$$E = \int_0^T v(t) \cdot i(t) dt, \tag{1}$$

where
E is the energy of the discharge pulse,
$v(t)$ is the voltage as a function of time,
$i(t)$ is the current as a function of time, and
T = time duration of the pulse.

According to Ohm's law, when the voltage is applied across a fixed resistance, the energy dissipated in the resistance is described by

$$E = \frac{\int_0^T [v(t)]^2 dt}{R}, \tag{2}$$

Where R is the resistance of the load.

When the energy reached to the patient, it will be reduced by the equation (3)

$$E_{delivered} = E \left\{ \frac{R_{patient}}{R_{patient} + R_{inductor}} \right\} \tag{3}$$

E is the energy that has stored in the capacitor which has a measure in joule.

$E_{delivered}$ is the energy that comes to the patient which has a measure in joule.

$R_{patient}$ is the patient's chest resistance (RL) which has a measure in ohm.

$R_{inductor}$ is the induction coil resistance (L) which has a measure in ohm. [1]

The output pulse of a defibrillator is applied across two paddles of the calibrator, with an internal load R (usually 50 Ω). The voltage developed across the load is given to a squaring circuit and an integrator circuit. The pulse integrator circuit integrates the squared pulses. The integrated value divided by the resistance of the load is the energy of the pulse. From Equation (2), it shows that the power supplied by the defibrillator is proportional to the square of the potential difference across the resistor with a constant value. In this case, the graph of the relationship between energy and electrical voltage will look like a parabolic graph.

We have researched and developed the defibrillator calibrator using the principle of calorimetric method and the sampling method. After the research was completed, it was found that the calibrator developed using principle of sampling method are suitable for using as working standard for our calibration laboratories. This article is intended to provide a brief overview of how this calibrator is developed. [1]

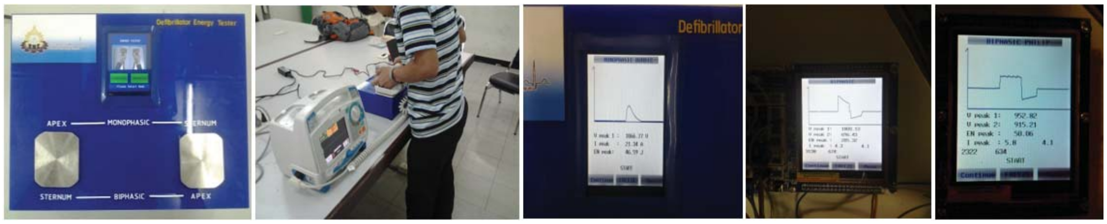

Fig.2:: Data table and graph relationship between standard energy and output voltage across resistor.

3. MATERIALS AND METHOD

The implementation of defibrillator calibrator can be described by a block diagram as shown in Figure 3, 4 and 5. The main principle of this research is to reduce the several hundred Joules , many thousand volts and high electric current of a generated pulse from a defibrillator by using paddle electrodes receptacle. It composes of stainless steel which does not affect to the loss of energy. It's including the size that can support to all defibrillator's paddle. After that the signal was sent to the analog signal conditioner circuits which consisting of the voltage attenuator and non-inverting summing amplifier circuit to make all pulses signal are in the positive side and sent to the ARM Cortex M3 microcontroller for converting to digital signal and signal processing.[1]

In terms of processing the researcher used C language to program the polynomial equation of relationship between standard energy, standard maximum voltage and standard maximum electric current and their digital output, including plot graphs the relationship between the voltage versus time of the signal measured both biphasic and monophasic waveforms in the microcontroller.[6] When the processing is completed, it will send the data to display on touch screen graphic LCD color by connecting through the ADS7846 chip. For the processing signals of this research can be described as follows the flow chart shown in Figure 5. [1]

For the display part, this research has used the touch screen graphic LCD color module provides peak voltage, peak current, pulse period, and the amount of energy delivered during a defibrillator discharge. This LCD is configured to work in 10-bit mode. The graphic LCD module has a resolution of 320 x 240 pixels and displays both monophasic and biphasic delivered current wave forms. This LCD module communicates with the ARM Cortex M3 STM32 F107VCT6 microcontroller via a 10-bit data bus. [1]

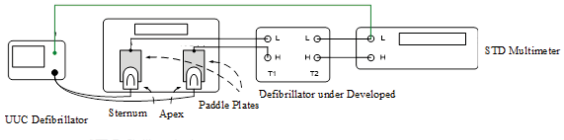

Fig.3:: Schematic of measurement of the relationship between the energy from the standard defibrillator analyzer and the voltage across the paddle measured by the defibrillator calibrator to be developed.

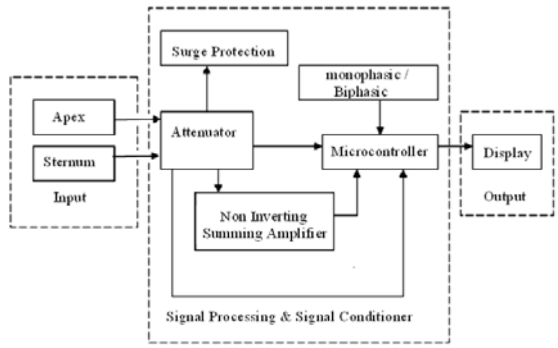

Fig.4:: This block diagram show design and construction of the research [1]

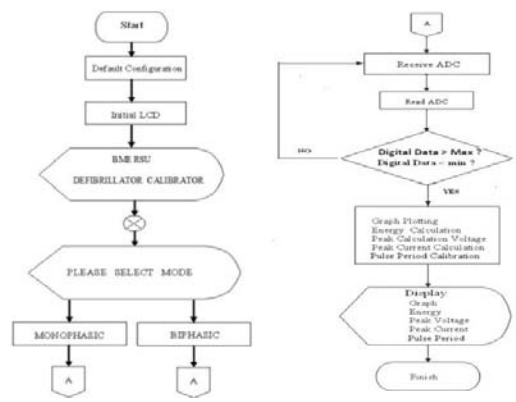

Fig.5:: Shows the flow chart of signal processing part

4. RESULTS

A) Accuracy of the Load Resistance

Based on Eq. (2), the energy dissipated in the resistor is related to the resistance value of the load. In this procedure, the internal resistance across the two paddles of the calibrator under developed is used as a common load. Therefore, it is essential to calibrate the internal resistance of it. The internal resistance is obtained by calibrated with the Laboratory of Calibration Services and Environmental Analysis, Department Technology Promotion Association (Thailand – Japan).The results of calibration are shown in Table I.

Table 1:: The results of internal resistance calibration.

Load resistance (Calibration step)	UUC Nominal Value (Ohm)	%Error (%)	% Uncertainty (±%) (k=2)
Defib.Load	50	0.89	0.01

Energy(J)	AverageVoltage (V)
5	0.43
10	0.58
20	0.82
30	0.99
50	1.26
100	1.8
150	2.02
200	2.54
300	3.1
360	3.48

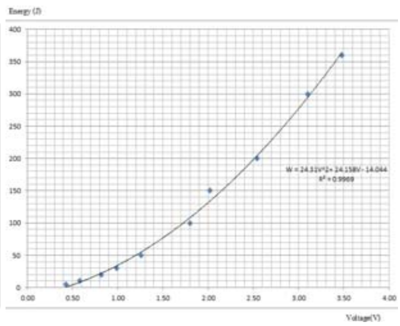

Fig.6:: Data table and Graph relationship between standard energy and output voltage across resistor

B) Features of the prototype defibrillator calibrator

Figure 2 shows the completed of the prototype defibrillator calibrator has the capability to calibrate the energy supply of the monophonic and biphasic defibrillator. Furthermore, it can display the value of energy, maximum voltage, maximum current and period of waveforms of unit under calibration.

C) Accuracy of Energy measurement

After the calibration of the internal resistance of the prototype, the accuracy of energy measurement of it is finally determined. The accuracy of energy measurement of the prototype was obtained by comparing with the defibrillator analyzer FLUKE Model Impulse 6000D and calibration with the Laboratory of Calibration Services and Environmental Analysis, Department Technology Promotion Association (Thailand – Japan). The results are is shown in Table 2.

D) Accuracy of Vp,Ip, and period of wave pulse for biphasic defibrillator

Based on the testing of accuracy for measuring of Vp,Ip, and period of wave pulse, the 10 of biphasic defibrillators under test were measured the maximum voltage, peak current and phase of the signal at phase 1 and phase 2 using this prototype. The measured value was tested with 5 times. Shown in Table 3.

Table 2:: The results of internal resistance calibration.

Applied Energy (Joules)	Average % Error (%)	Average %Uncertainty (%) (k=2)
50	0.6	1.3
100	1.2	1.4
200	1.9	1.3
360	0.5	0.3
average	1.1	1.1

Table 3:: The results of function testing of Vp, Ip, and period of wave for biphasic defibrillator

Average % Error of Vpeak at Phase1 (%)	Average % Error of Vpeak at Phase2 (%)	Average % Error of Ipeak at Phase1 (%)	Average % Error of Ipeak at Phase2 (%)	Average % Error of Period	
				T_1 (%)	T_2 (%)
0.05	0.65	0.27	0.54	4.0	4.0

5. DISCUSSION

This paper introduced and discussed the implementation of the energy function of defibrillator at BMERSU laboratory for energy level up to 360 J. The proposed technique has a number of advantages. The internal resistance of the prototype is used as the load in the energy calculation. This could minimize the additional uncertainty resulting from using an external load. This method can also be used to plot the waveform of the delivered pulse of a defibrillator. In order to evaluate the characteristics of the pulse, the short biphasic pulse is analyzed in the frequency domain by a Fourier transform in the processing part.

The processing part of this research is developed by inputting variant standard energy values into constant load resistors and measuring output voltages. Then, relationship data between standard energy and the output voltages will be recorded. Relationship equation between standard energy and the output voltage of will be derived by applying calibration graph with the polynomial method for further data processing [5]. From this research, the coefficient of determination; R2 of the relationship between standard energy and the output voltage is 0.99. Therefore, it is accurate to use the output voltage of instead of standard energy and applied to the load resistors.

Table 1, Table 2, and Table 3 show the standard calibration results for energy measurements of the calibrator by the standard defibrillator and standard calibration laboratories for traceable calibrations of the defibrillator. These tables correspond to the condition of 3 sets of energy waveforms that are monophasic waveform in range of 10 J- 360J, biphasic waveform in range of 10 J-200J and rectilinear waveform in range of 10 J -200 J. The average percentage error and measurement uncertainty are about 1.1 %. Furthermore the results of functional testing of Vp,Ip and period of waves showed a very small percentage of discrepancies. According to the accuracy criteria of standard calibration device must more accurate than defibrillator under test at least 3 times, the deviation of standard device must be less than 5J at the energy below 50 J and less than 15 % of reading at the higher energy under test. Therefore, The prototype can be used to be the working standard of BMERSU Calibration Laboratory for testing and/or calibration of defibrillators.

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Nuntachai Thongpance is currently associate professor and dean of Faculty of Biomedical Engineering, Rangsit University.He established undergraduate and graduate course in medical instrumentation and biomedical engineering at Rangsit University. Nuntachai received his Master of Engineering in nuclear technology from Chulalongkorn University in 1987, and his Bachelor of Science in physics with the second-class honours from Prince of Songkla University in 1984. His research interests include medical device,biomedical engineering and healthcare management engineering.

Thawat Kaewgun received Bachelor of Engineering in electrical engineering from Rangsit University and Master of Science in biomedical instrumentation from King Mongkut’s University of Technology Northbangkok, Bangkok, Thailand in 2003 and 2012, respectively. He is currently a lecturer in Faculty of Biomedical Engineering, Rangsit University. He teaches the biomedical electronics and medical instrumentation course. His researches focus on biomedical electronics.

Anatasak Wongkamhang is currently associate dean, Faculty of Biomedical Engineering, Rangsit University. He received Bachelor of Science in biomedical instrumentation, from Rangsit University and Master of Engineering in biomedical engineering from King Mongkut’s Institute of Technology, Ladkrabang, Bangkok, Thailand in 2010 and 2015, respectively. He is currently a lecturer in clinical engineering. He teaches the medical device management. He is a co-founder of the clinical engineering research lab, Faculty of Biomedical Engineering, Rangsit University. His researches focus on clinical engineering.

Kittipan Roongprasert is currently lecturer, Faculty of Biomedical Engineering, Rangsit University.He received Bachelor of Science in biomedical instrumentation,from Rangsit University and Master of Engineering in biomedical engineering from King Mongkut’s Institute of Technology, Ladkrabang, Bangkok, Thailand in 2006 and 2016, respectively. He teaches the maintenance engineering in medical instrumentation. His researches focus on clinical engineering.

Yutthana Pititeeraphab received Bachelor of Industrial Technology in telecommunication technology, and Master of Engineering in biomedical electronics from King Mongkut’s Institute of Technology, Ladkrabang, Bangkok, Thailand in 2002 and 2007, respectively. He is currently an assistant professor in biomedical engineering. He teaches the product design engineering and microcontroller programming with its applications. He is a co-founder of the Rehab and Robotics Lab, Faculty of Biomedical Engineering, Rangsit University. His researches focus on robotic arm, haptic device, microcontroller and control system.

Anuchit Nirapai received his Bachelor of communication engineering from Srinakharinwirot University and Master of Science in communication engineering from King Mongkut’s University of Technology North Bangkok, Thailand in 2008 and 2015, respectively. He is currently a lecturer in Faculty of Biomedical Engineering,Rangsit University. He teaches the the software design, health information technology and Internet of

Medical Things (IoMT). He is a co-founder of the internet of medical things Lab, Faculty of Biomedical Engineering, Rangsit University. His researches focus on health information technology and Internet of Medical Things (IoMT).

Phichitphon Chotikunnan received Bachelor of Engineering in Mechatronics Engineering from Pathumwan Institute of Technology in 2011 and Master of Engineering in Electrical Engineering at King Mongkut's University of Technology Thonburi in 2015. He is currently the lecturer in Faculty of Biomedical Engineering,Rangsit University. He teaches the medical robotic and microcontroller programming with its applications. His research interrests are fuzzy logic control (FLC), iterative learning control (ILC) and robotics.