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EVALUATION OF THE ENERGY RELEASED BY A DEFIBRILLATOR FROM THE PERSPECTIVE OF CLINICAL ENGINEERING

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ABSTRACT
Electro-Medical Equipment's (EMEs) are an important instrument for intervention in medical institutions of Brazil. This article aims to estimate the level of reliability in the operation of certain defibrillation equipment used in Hospital das Forças Armadas (HFA), located in Brasília (Brasil), specially regarding the energy released, and also, to evaluate measurement uncertainty. The equipment used for the tests was the Defibrillator Analyzer DNI Nevada, Impulse 3000 model and serial number 3347, and it was used for collecting data of released energy. The collected data were organized into spreadsheets and processed graphically, the selected pattern energy were of 10, 100 and 200 Joules (J), namely, five repetitions for each chosen energy. The measuring uncertainty analysis of the defibrillators were done by means of a normative metrological test that uses statistic results and which certifies the adequacy of EEMs to security and ABNT and manufacturer standards. By quality standards, both compliance and prospect of Clinical Engineering (CE). The results found the average, standard deviation, accuracy uncertainty, measurement uncertainty and combined standard uncertainty, among others, which served to review and completion of uncertainty and measurement.

INTRODUCTION
A The Clinical Engineering (CE) to appear in the 40s and it had the aim of guaranteed effectiveness of technological park associated to health and to make the EEMs reliable on the management of operators and users. These preoccupation of CE extended to the 60s and the technology evolution to carry the increment of demanded for activities of management of EEMs, with a searched of solutions for problems in electrical safety in relation to Health Care Clinic Establishment (HCE)[1].

The CE also encompass the mensuration of aspects of quality of Technologies in health. Therefore in function of complexity and technology magnitude of EMEs, present in EAS, to appear to need of management a perfect functionality of these hospital instruments. The CE response by use of EME without risk, because orient programs of inspection and prevent maintenance[2].

The defibrillators are equipment's that attended to emergency cases in Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). Their use consists in apply a electric shock of intensive pulse and fast in the cardiac muscle. The aim is revert arrhythmias, by contractions of cardiac fiber s and therefore of normal rhythm. The Sudden Cardiac Death (SCD), caused by VF, also use the intervention of desfibrillators[3,4].

Many papers in specialized literature describe the investigation of operational capacity of EEMs, such as their prevent and corrective maintenance. The most important works for present study are: Oliveira5, Oliveira6, Foiatto7, Duarte8, Souza1. In this publication is proposed frequently measurements of defibrillator and cardioverter, by energy measurement, voltage and peak current for to evaluate the performance of these hospital equipments. Between the prescribe tests by standard, to stand out the ABNT NBR IEC 60601-2-4:2005, that describe the correct operation of EMEs, and determine that the amount released energy is a determination factor for safety of equipments reliability[9]. The Oliveira's[6] , Souza's[1] works the evaluation of energy mensuration, with base in degree of uncertainty present for a defibrillator analyzer and cardioverters, besides of measurement of released energy by EMEs, based in metrology process.

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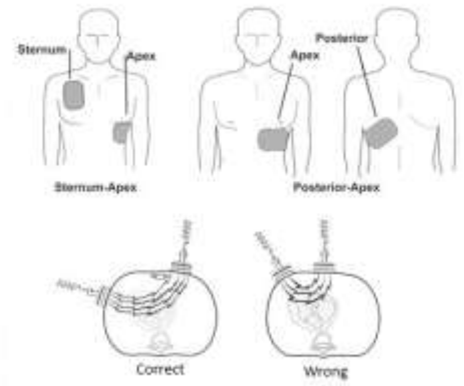
In the defibrillation process is important the adequacy of released electric current, that depend of selected energy and thoracic impedance. Other important factors are the size and distance between pads, the applied force on These, the use of gel or saline solution and breathing situation (inspiration or expiration). Based in repetition shocks decrement of impedance effects[10].

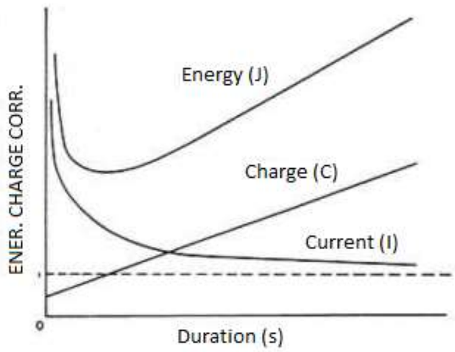
The amount of energy released by defibrillator associated to energy that flow normally of cardiac muscle, this mean understand that the defibrillators a natural pacemaker and long scale, more that can´t danger the heart. Thus, the density of electrical current implies in the correct position of electrodes (pads) (Figure 1)[11, 12,13].

Figure 1: Application of electric current to thorax (Source: TACKER[13]).



In accordance with ABNT NBR IEC 60601-2-4:2005 the thoracic impedance should be measured. In adults the impedance fluctuates typically between 25 and 175 Ω, whereas the standard reference is 50 Ω[1]. In the same direction, They have been identified in studies of Tacker[13] some implicates related to intensity of shock in defibrillation process. One of the points highlighted is that long duration shock require minus current that shock more short. Those factors generate intensive curve vs duration. A important aspect of Tacker´s[13] work is that for majority of wave forms, exists a insensitive of minimal energy able to do break off the fibrillation, normally each pulse have a duration of 3 to 8 ms.

Figure 2: Function that describes intensity and duration of current defibrillation (Source: Adapted from Tacker[13]).



DOSDALL *et al*[14] investigated the answers of all heart to shocks of defibrillation and verify that, given the complexity understanding this mechanism, the advanced in technical of computational modeling, electric mapping and optical process of cardiac excitation and its response to defibrillation shocks It facilitates understanding.

Exist innovations related to typologies of defibrillators, in function of enhanced wave form of discharge, such as: alternating current, sinusoidal pulse, capacitive discharge and control current. Therefore, the actual defibrillators can be monitored through physiological parameters, event log, internal and external defibrillation, external pacemaker, synchronization with the QRS peak[1].

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The automatic external defibrillation (DEA) and, therefore cardioverters provide monitoring circuit for detect the electrical activity of heart and synchronize the application of electric pulse defibrillator, on QRS peak of ECG, in cases that is possible detect and recognize the signal of electrical activity[13,10,12].

The standard ABNT NBR IEC 60601-2-4 talk about the pulse application should occur up to 60 ms of QRS peak of Electrocardiogram (ECG), In typical synchronization of cardioverters and in case of signal synchronization obtained of a input of external signal, the example of output synchronization of multipara meter monitor, the pulse is up to 25 ms of QRS peak. Such measurement of time promotes the state of fiber relax[10].

The intensity of energy used in shock given to the patient is calculated for defibrillator, because exists difficult in measurement the electric current through thorax patient, seen that from individual for other the flow varies. Consequently, the quantity of energy used in defibrillation is resultant of relation of transthoracic impedance of patient and internal resistance of defibrillator. This relation can be understood with this equation:

$$E_{provided} = E_{stored} \cdot \left[\frac{R_{patient}}{(R_{patient} + R_{defibrillator})}\right]$$

The vulnerabilities of EEMs have been target of recurrent inquietude by CE, for example: functional danger on patient; danger of organs or adjacent tissue and others. A defibrillation or cardioverter inappropriate can initiate VF, reconstruction or dangerous arrhythmias. For example, without located the electrodes correctly or gel electrolytes of pads, exist the danger of don´t produce desired effect or promotes burns, principally when necessary apply many shocks[11].

This paper present a evaluation of collect data of defibrillations used in HFA, by means of curve fitting, moreover the research and effectiveness of discharge response for evaluation the effectiveness related to release energy.

METHODS

For implement the routines of standardization of defibrillators of HFA, attending the perspectives of EC, in other words, promotes efficient preventive maintenance, and was necessary to choose the equipment more important for hospital. It is prioritized for those equipments with malfunction and risky for patients or operators, or still, the paralyzation unfeasible economic and sociably the service to users. Between the equipments with this characteristic is defibrillator Zoll M Series, this research was done in data bank of CE of HFA.

So, they were selected 9 analog model equipments, manufactured between 1998 and 2011. The defibrillator Zoll M Series (Figure 3) has capable of providing up to 200 J of energy, transform the alternating electric current in direct and applied energy (charge) to patient, through electrodes (pads). Couple a system of ECG, and it´s synchronized, this mean that should recognize the wave R (or S) of ECG, prevent the discharge of energy when the ventricle is wakened10. The table 1 present the minimum parameters necessary for estimate the uncertain of measurement, the same indicate a charge, the video resolution and precision of released energy (High or Low)**.**

Figure 3: Defibrillator ZOLL M Series (Source: Manual Service of Manufacturer)

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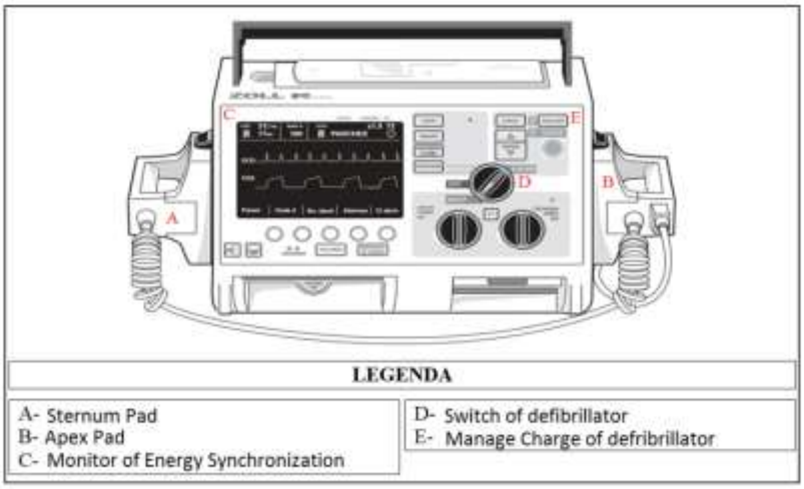

Table 1. Parameters of Cardioverter Zoll M Series (Source: Adapted of Manual Service of Manufacturer)

PARAMETERS USED IN CALCULATED OF UNCERTAIN - CARDIOVERSOR ZOLL M SERIES

Charge	50 Ω +/- 1%	
Video Resolution	0.1 J	
	HIGH-END	LOW-END
Precision	+/- 2% readings for 100-360 J	+/- 2% readings for 20-50 J
	+/- 2.0 J for <100 J	+/- 0.4 J for <20 J
	Note: Precision specified for levels of energy <360 J	

The evaluation of compliance of selected equipments was done based to Brasil Standard ABNT NBR IEC 60601-24:2005, related to description on table 2.

Table 2: Principal parameters established by ABNT NBR IEC 60601-2-4:2005 (Source: Adapted of ABNT NBR IEC 60601-2-4:2005).

Parameters of operation		**ABNT NBR IEC 60601-2-4:2005**
Environment operating conditions	Temperature	0 a 40°C
	Relative Humidity relative to air (without condensation)	30 a 95%
Maximum energy selected	External Defibrillation	360 J
	Internal Defibrillation	50 J
	Accuracy	± 15% of energy selected or ± 3J (Higher)
Peak Voltage		5000 V (resistance of charge of 175 Ω)
Peak Current		uninformed
Charge Time	Frequent Use	15 s
		20 s
	Don´t frequent	25 s (battery depreciated for 15 discharges of maximum energy)

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The method of measurement parameters of delivered energy consist in turn on the Analyzer of Defibrillator and select a desired energy in the equipment in study, of 10, 100 e 200 J, according to options of selection of energy and, thus, a discharge of energy applied in Analyzer of Defibrillator on resistive charge of 50 ohms, such as establish in proper manual.

Five repetitions were applied of test for each energy, increment and decrement including the effect of hysteresis in measurements. So, It avoided the committal of useful life of equipment's as a result of large charge of energy. The reduced number repetitions don´t cause damage in performed calculations, maintaining the necessary mathematical considerations of data reliability, because some arrange was considered for reliability of statistics calculate, the example of t-coefficient Student for probabilities distributed[15].

Moreover, as the analyzer of defibrillator was tracked, some data in its certificate was used for the calculate measurement uncertainty.

The parameters were interpreted of visual form and manual, in one only phase and, the released energy was observed in a general template for each defibrillator and shoot. This procedure was repeated for 5 times according to scale selected. Next, it was elaborate a template abstract for analysis of data and uncertainty of measurement for to show in the results.

The procedure of preventive and corrective maintenance don´t include the periodic evaluation of measurement uncertainty of its equipment's, due to scope of contract, however it is realized each month by CE one inspection and each year a test of verification of operation for all defibrillator as prevention. The annual test, in ruler, verify the released energy by defibrillator, using a analyzer of tracking defibrillator.

CALCULATE OF RESULTS OF MEASUREMENT WITH SOURCES OF UNCERTAINTY

In process of evaluation, it was implement analysis of uncertainty measurement of defibrillators, using limits establish for ABNT and manufacturers. For the results of measurement are used two parameters: the average value of indicators and uncertainty of measurement, based to orientation of Guide for the expression of measurement uncertainty (INMETRO[17)] and publication of Brasil version of EA-4/02 – (INMETRO[16]).

In process for measurement the sources of uncertainty should be estimated, for conformation of measurement system. The evaluation methods of Type A or Type B contribute for calculate of uncertainty. In relation of method Type A to show that the uncertainty of result expression for average in function of probably density with a observation of frequency distribution. In method type B to predominate scientific knowledge: i) data of previous measurement, ii) specification of manufacturers, iii) data originate of calibrations, iv) Standards and reports, v) theory research, of response of chain measurement, vi) knowledge of behavior and properties of instruments, vii) Environment conditions and other important information for analyze[17].

For calculate the RM was implement the analysis of measurement process, a identification of uncertainty sources, a estimative of standard uncertainty, the calculate of sensibility coefficients, a evaluation of possible correlations, calculate of combined standard uncertainty, calculate of expanded uncertainty, round of uncertainty and result of measurement[1].

PROCESS OF MEASUREMENT

The released energy was reading by instrument of measure with the associated uncertainty, without operator influence, because the indicator of analyzer is digital. In this context, it was used the defibrillator analyzer, mark DNI Nevada, model Impulse 3000 and serial number 3347. The certification of analyzer is according to uncertainty Standards for contribution of present analyze. The equations were grouped in incremental order:

1) Result of Measurement

$$Y = \bar{X} + IM$$

2) Average

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$$\bar{X} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

3) Standard Deviation

$$Re = \sigma(x_i) = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{n-1}}$$

4) Experimental Standard Deviation of Average

$$\mu(\sigma) = \frac{\sigma(x_i)}{\sqrt{n}}$$

5) Uncertainty of Accuracy of Analyzer

$$\mu(\Delta_{exa}) = \frac{\Delta_{exa}}{\sqrt{3}}$$

6) Uncertainty of Resolution of Analyzer

$$\mu(\Delta_{res}) = \frac{\Delta_{res}}{2\sqrt{3}}$$

7) Combined Standard Uncertainty

$$\mu_c(y) = \sqrt{\left(\frac{\sigma}{\sqrt{N}}\right)^2 + \left(\frac{\Delta exa}{\sqrt{3}}\right)^2 + \left(\frac{\Delta res}{2\sqrt{3}}\right)^2}$$

8) Expanded Uncertainty

$$U = k \cdot \mu_c(y)$$

9) Effective Liberty degree

$$v_{ef} = \frac{u_c^4(y)}{\frac{u^4(\sigma)}{4}}$$

10) Round of Uncertainty

RM = Y ± U

RESULTS

The estimative of errors and uncertainty, of released energy delivery by defibrillators are demonstrate in Table 3, where it show identify compliances according to maximum errors described in technical standard ABNT NBR IEC 60601-2-4:2005 and by manufacturer. In this case only equipment 8 overtake limits of tolerance, based to manufacturer standard, in other words, the released energy of 200 J obtain sum total of error more the uncertainty of 21,2 J, wherein the establish limit by manufacturer is until 20 J. This small difference of 1,2 J can be justified for defibrillator doesn´t have operational system upgrade, because based to manufacturer this case to give maximum performance and flexibility into the equipment.

In the perspective of EC, verify that the equipment in study were in good conditions of operation, the operation manual were present in local, they are provided of register in ANVISA (Brasil agency of equipments), the data difference of manufacturers between them are small and in terms of technological advanced they are to able monitoring anything rhythms of shocks, such as assisted defibrillation. Moreover, some equipments were indicated for change or charge of battery, the problem was to solve by CE.

Studies realized between 2010 and 2012 present compliances of released energy by defibrillators and the importance of contribution in uncertainty process of measurement, based to establish metrology. According to

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previous studies, the uncertainty type A and B more limits of standards, they are essentials for conclusion the compliance of equipment.

In last years, we observe that biggest target of studies of EC it´s in sense of intensify the metrological process as guaranty of operation and improvement of management of EMEs and despite of increment in invest of EC service, it is poor the application of associated test to uncertainty measurement of EMEs, mainly in the supported equipment of life.

Table 3. Template of Results

Equip.	*Choose Energy (J)*	*Result*		*Error + Uncertainty*	*Tolerance*		*Conforme (C) Não Conforme (NC)*	
		Average	+/- Uncertainty		ABNT	Manuf.	ABNT	Manuf.
1	10	9,8	0,5	0,7	3	1	C	C
	100	98,0	2,3	4,4	15	10	C	C
	200	209,7	5,0	14,8	30	20	C	C
2	10	10,3	0,5	0,8	3	1	C	C
	100	100,3	2,7	3,0	15	10	C	C
	200	212,6	5,3	17,9	30	20	C	C
3	10	10,2	0,5	0,7	3	1	C	C
	100	98,4	2,6	4,1	15	10	C	C
	200	207,2	5,0	12,2	30	20	C	C
4	10	10,1	0,5	0,6	3	1	C	C
	100	97,3	2,4	5,1	15	10	C	C
	200	207,9	4,9	12,8	30	20	C	C
5	10	10,0	0,5	0,5	3	1	C	C
	100	98,7	2,5	3,8	15	10	C	C
	200	210,5	5,1	15,5	30	20	C	C
6	10	10,2	0,5	0,7	3	1	C	C
	100	98,0	2,3	4,4	15	10	C	C
	200	207,7	4,8	12,6	30	20	C	C
7	10	10,1	0,5	0,6	3	1	C	C
	100	98,3	2,4	4,1	15	10	C	C
	200	210,3	5,0	15,2	30	20	C	C
8	10	10,3	0,5	0,8	3	1	C	C
	100	100,7	2,5	3,2	15	10	C	C
	200	216,1	5,1	21,2	30	20	C	NC
9	10	10,0	0,5	0,6	3	1	C	C
	100	97,3	2,3	5,0	15	10	C	C
	200	206,2	4,8	11,0	30	20	C	C

The Graphic 1 present of results of uncertainty in relation to released Energy applied (Eaplicado) and the measurement energy (Emedido), to show that in choose of values highest of energy exist a gradual increment of uncertainty of energy measure.

Graphic 1. Applied Energy x Measure Energy x Uncertainty

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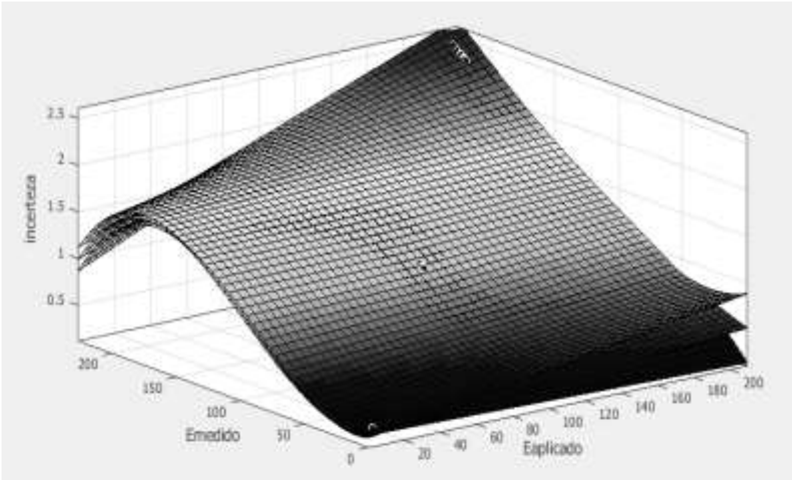

Exist a direct relation between human health and security to supply of parameters of equipment, it's not enough only equipment in operation, it has to able for supply establish in actual standards.

DISCUSSION

Dichotomy risk-benefit in use of EMEs, to carry more actions of maintenance and training in the correct use, by service part of EC. The technological metrologies in health to show as essential tools, because it guaranty the reliability in performance, by criteria normative. This interest is evident in research of Souza1, Medeiros[18], Moraes e Oliveira[19], Alexandrino[20], Florence[3], Foiato[7], Oliveira[5], Taghipour[2], because the element study are the metrological performance of medical technology, as fundamental required for hospital accreditation.

The technology used in health and its management can to improve maintenance of human health, and the other hand expose users, operators and environment to risk factors, such as related in works of Alexandrino[20], the measurement process of EMEs applied in current study, can be easily assimilated by service of CE of EAS, in function of added value to quality of evaluation performance of equipment's. Moreover, the routine of measurement uncertainty (calibration) of these equipment's assistant in consensus of world cardiologic community, around of values of energy, voltage, current and waveform more effective in reversion process of arrithm[1].

Several studies, confirm the importance of metrological evaluation, as synonym of good performance and security of health equipments[3,5,6,7]. The analysis of performance of operation of equipment's reaffirms attention in management, from the point of view of EC. Metrological Bases certain and well defined and the correct treatment of mathematical model of uncertainty guarantee a correct evaluation of equipment parameters. And the most important is that from uncertainty calculates, verify unexpected events, for example voltage drop of source, clamping of defibrillator, flexibility and measurement of uncertainties. All these considerations satisfy the requirement in research reason and consequences of waveform of defibrillation applied to patient, while assumptions of increment of safety and reliability of equipment in study.

The evaluation of defibrillators was oriented by compliance in relation to allowable maximum errors for current regulations and specify by manufacturer.

CONCLUSION

It was estimated by mean of analyze, calculates, templates and graphics the compliance level in operation of some equipment's used in defibrillation in HFA and the uncertainty measurement of released energy. The data collect was organized in templates and processed by graphical form, with metrological test that certify the compliance of equipment used in HFA.
So, this work contribute for uncertainty analyze of measurement released energy related to EMEs and allow consider the dispositions of security establish by standards of quality, such as compliance and perspective of CE. The incremental use of CE service is a important factor for dissemination of measurement uncertainty of EMEs,

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exist the necessary de best orientation in relation to technological park of EAS, and common contribution of EC service.

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