

Testing of anesthesia machines and defibrillators in healthcare institutions

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Abstract

Objective. To improve the quality of patient treatment by improving the functionality of medical devices in healthcare institutions. To present the results of the safety and performance inspection of patient-relevant output parameters of anesthesia machines and defibrillators defined by legal metrology.

Design and Setting. This study covered 130 anesthesia machines and 161 defibrillators used in public and private healthcare institutions, during a period of two years. Testing procedures were carried out according to international standards and legal metrology legislative procedures in Bosnia and Herzegovina.

Results. The results show that in 13.84% of tested anesthesia machine and 14.91% of defibrillators device performance is not in accordance with requirements and should either have its results be verified, or the device removed from use or scheduled for corrective maintenance.

Conclusions. Research emphasizes importance of independent safety and performance inspections, and gives recommendations for the frequency of inspection based on measurements. Results offer implications for adequacy of preventive and corrective maintenance performed in healthcare institutions. Based on collected data, the first digital electrical database of anesthesia machines and defibrillators used in healthcare institutions in Bosnia and Herzegovina is created. This database is a useful tool for tracking each device's performance over time.

Keywords – *inspection, anesthesia machine, defibrillator, safety, clinical engineering*

Conflict of interests

The authors hereby declare that they have no conflicts of interest.

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Introduction

Discoveries and technological developments during 19th and 20th centuries led to the development of medical devices (MDs) that revolutionized the way medical care is provided, especially in critical situations, such as surgical procedures, when medical professionals have only minutes to diagnose and/or to perform invasive medical treatments. There are multiple safety and conformity requirements on operational rooms. These requirements are codified in form of standards, guidelines, normative documents, and checklists. In 2007 to 2008 World Health Assembly set safety during surgeries as the second most prominent safety challenge and reported that in low and middle-income countries problems associated with surgical safety are due to poor state of infrastructure and equipment, unreliable supplies and quality of medications, shortcomings in organizational management and infection control, and difficulties in supply and training of personnel. This research resulted in World Health Organization (WHO) guidelines in 2009 [1] which define requirements on environment, facilities, and personnel to ensure a safe surgical process. Similar to WHO requirements, national agencies and governmental bodies define minimum requirements for operating rooms [2,3].

Statistics show that number of surgeries is rising which means that greater number of patient is affected by risk of surgery and depending on accuracy of MDs [4,5]. During surgery, patient is unconscious and anesthesia machine (AM) measures and controls his vital parameters, thus any device whose performance is out of specified parameters poses a risk to patient's life. In critical situations, patient resuscitation may be needed and a defibrillator needs to work properly and effectively each time. Even though MD management strategies have been adopted, [6-8] numerous incidents involving AMs and defibrillators have been reported [9-11].

According to French health ministry's register, 1004 reports of incidents including AMs were reported in 1998, with 2% of cases resulting in death and 11% resulting in serious injuries [9]. Medication error during anesthesia is a common type of error that is usually caused by faulty components of the machine, such as vaporizer or the circles for mixing anesthetic gases with fresh air [10]. Food and Drug Administration Defibrillator Working Group reviewed data from MD Reporting System and a five-state survey and concluded that the frequency of defibrillator failures during clinical use was unacceptably high. These data include 156 reports of defibrillator problems reported in emergency centers, 676 reports of defibrillator failures, 594 inspections of in-service defibrillators, and site visits to 212 emergency care facilities [11,12]. Consequences of these incidents vary from minor injuries to

life threatening situations, as well as unfortunately fatal outcomes. For these reasons, both devices were tested in this research.

Safety and performance of MDs is defined by international standards issued by prominent worldwide organizations [13-15] and national regulatory bodies. The Association of Anesthetists recommended procedure for pre-operative checking of aesthetic machines by incorporating usage of calibrated oxygen analyzer [16]. In spite of these regulations, rate of incidents including AMs and defibrillators show that current MD management practices don't ensure reliability [9-11]. This suggests that additional, objective evidence-based methods should be adopted to ensure MDs safety and performance reliability. Technology assessments by independent organizations are a part of the solution to the challenge and motivated research focused on patient outcomes [17]. Assuming that MD measurements affect human health and are traceable to S.I. units (International System of Units), MDs can be introduced into legal metrology system [18-21]. European Association of National Metrology Institutes and National Institute of Standards and Technology have recognized this as priority in ensuring patient safety, so traceability of medical measurements is main topic for planned and ongoing projects [22, 23]. These projects aim to establish practices to increase accuracy, precision, and reliability of medical measurements in order to increase quality of life. In accordance with this, MDs have already been introduced into legal metrology system in some European countries, including Bosnia and Herzegovina (BH) and Turkey [24-32]. In this way, MD is recognized as measuring device that needs to comply with periodic inspections in order to improve patient safety. These inspections are a set of processes that show whether a MD meets requirements set forth in the standards related to its device type.

This study aimed to investigate the electrical safety of AMs and defibrillators, and to perform independent inspection of efficiency of preventive and corrective maintenance performed either by the healthcare institution's technical division or official distributor of MDs. Additionally, the purpose of this study was to define the traceability chain of device output parameters to increase the quality and safety of care.

Methods

The inspection of AMs and defibrillators was conducted according to the legislated parameters of the legal metrology system in BH - Rules on metrological and technical requirements for these MDs published in the

Official Gazette of BH no. 75/14 [33, 34]. Technical requirements are in accordance with international standard IEC 60601, as well as other international standards and manufacturers' recommendations.

Performance of AM is tested at four points, and performance of defibrillators is tested at eight points in measuring range. Defibrillators were evaluated by their output energy, and AMs according to volume of gases (air/oxygen/N₂O) and concentration of the anesthetic gases (Sevoflurane). Parameter volume was chosen since volume control ventilation (VCV) is the most used mode that applies to most of the medical ventilators/anesthesia machines available on market today [35]. The ranges of output parameters and maximum permissible errors for devices are given in Table 1.

Performance testing procedures included (1) visual inspection of MD and (2) measurement of output parameters to determine its error. Prior to performance inspection, all tested devices were subject to electrical safety inspection conforming to IEC 60601 [14]. All devices that passed the safety inspection were subject to performance inspection, while those that failed were labeled as faulty and sent for corrective maintenance.

A. Testing procedure

The electrical safety test was conducted using a standard Fluke Biomedical ESA 620 [36] that performs automated electrical safety inspections according to IEC 60601 [14] and IEC 62353 [14] electrical safety standards. For measurement of AMs output volume and other respiratory parameters, standard IMT Flow Analyzer was used [37]. This device measures gas volume flowing from the machine to the artificial lungs provided with the standard. The accuracy of device is $\pm 2\%$. Massimo Corporation sensor of anesthesia gases was used measurement of concentration of anesthesia gases. For measuring the output parameters of defibrillators, a Fluke Biomedical Impulse 7000 DP standard was used [38]. The range of devices is 0.1 to 600 J with an accuracy of $\pm 1\%$ of reading + 0.1 J. All measurements were saved and stored on a PC for subsequent analysis. All etalons were previously calibrated in ISO 17025 accredited laboratory to obtain measurement traceability [39-41].

Inspection of all devices was conducted by institution authorized by Institute of Metrology of BH by procedures in accordance with prescribed by state bylaws and quality system set up by ISO 17020 [13]. This study was approved by Management Board of the inspection institution (Approval no. 157/16 from 25.07.2016.).

Visual inspection was conducted in order to make sure that the medical equipment in use still conforms to the specifications released by the manufacturer, and has not suffered from any external damage and/or contamination.

During the visual inspection, AMs and defibrillators were checked for cracks on casings, control panels, switches, doors, cables, probes, batteries and other constitutive parts.

Measurement of output parameters was performed in order to determine whether a MD fulfils prescribed requirements of measurement error. Performance testing procedure for AMs is defined as follows:

- Prepare standard for measurement;
- Conduct AM self-test if applicable;
- Use hoses to connect output of AM to input of standard;
- Choose volume control operating mode on AM;
- Adjust volume and concentration of anesthetic gases to the first measuring point;
- Take measurement at a set measuring point;
- Set volume and concentration of anesthesia gases to the next measuring point;
- Take measurement at a set measuring point;
- Repeat steps 7 and 8 until measurements at all measuring points are taken.
- After all measurements are taken, turn off AM, close the air and other gases, and leave the machine in standby mode.

Performance testing procedure for defibrillators consists of the following steps:

- Prepare standard for measurement;
- Place both standard and assessed devices on a clean, flat surface;
- Select manual defibrillation mode on device under inspection;
- Select energy on assessed device to first measuring point;
- Charge tested device;
- Place electrodes on standard and discharge tested device;
- Save measurement results;
- Repeat steps 5 – 7 until all measurements are taken;
- After all measurements were taken, errors were calculated and stated in terms of absolute or relative error depending on requirements.

B. Tested medical devices

Study covers 130 AMs and 161 defibrillators tested in period from January 2015 to January 2017 in public and private healthcare institutions in BH. The main criteria for choosing institutions in this study was that they had an operating room with AMs and one or more corresponding defibrillators. For all of these institutions, periodical inspections are mandatory according to the legal metrology framework in BH.

Each device was twice subjected to safety and performance testing, first time in 2015 and second time in 2016. When testing AMs corresponding defibrillators in operational units were tested as well. Some operational units had more than one defibrillator and that is the reason why the number of tested defibrillators exceeds the number of tested AMs. The type of defibrillator covered in this study is an external manual defibrillator. MDs of various manufacturers and types were included in the study. Detailed overview of manufacturers and types of tested devices is presented in Table 2.

The tested devices were divided into two groups based on measurement results:

- Accurate (A) –measured output was within maximum permissible error for all measurement points;
- Faulty (F) - measured output was not within maximum permissible error for at least one measurement point;

All measured data were analyzed using the Mann-Whitney non-parametric test [42]. Calculated p-value represents probability that the discrepancies found between the samples are due to chance.

Results

According to analyzed data, 23.71% of devices were marked as faulty. Additionally, 37.5% of tested devices marked as accurate (A) have output errors larger than 5%. 36 of 103 accurate anesthesia devices have output error larger than 5%. As for defibrillators, 54 out of 137 accurate devices have an output error larger than 5%.

A. Anesthesia machines

Out of 130 tested AMs 20.77% of them had output parameter values that were not in accordance with maximum permissible error, as shown in Table 3. It has been noticed that one device can yield accurate results for its first two measuring points yet then break out of the limits at higher volumes.

Analysis of output volume for AMs shows a statistical difference between accurate and faulty devices, stating that in the case of faulty devices, measured output values are higher or lower than the reference value. Measurement results of output volume for accurate devices are presented in Fig. 1. Measurements for all tested devices are in stated limits and it should be noted that, for accurate devices outputs tend to have values lower than reference. Median values of measurements for each measuring point are lower than corresponding reference value.

Distributions of volume measurements for faulty AMs are given in Fig. 2. Median values for each measurement point are out of the range specified with maximum permissible error. For each measurement point the median value of measurement is lower than the reference value. Also, extreme maximum values were detected, which pose great risk to patient health and can potentially lead to operative or post-operative complications.

Graphic representation of measurement results for concentration of anesthetic gases is given in Fig. 3. Fig. 4 represents results for the measurement of anesthetic gas concentration in faulty devices. Median of measured values is below the corresponding reference value, stating that in most cases the AM is not inserting enough anesthetic gas into the system.

Measured volumes and gas concentration of accurate and faulty devices were statistically different ($p < 0.05$), except for the concentration of 1%.

B. Defibrillators

Out of 161 tested defibrillators, around 15% of them had the output energy discharge that was not within the stated maximum permissible error, as shown in Table 3.

Fig. 5 shows the boxplot diagrams for reference energies for all three groups of tested defibrillators labeled as accurate devices. Fig. 6 shows the boxplot diagrams for reference energies for all three groups of tested defibrillators labeled as faulty devices.

The analysis of the energy measured in defibrillators shows statistical differences in the values of accurate and faulty defibrillators.

Limitations

This study includes a limited number of devices that were available for testing during the study. However, the variety of types of devices was sufficient to derive general conclusions on the device performance and the significance of performance.

Discussion

As technology improves, main focus of researchers and scientists is to improve the quality of patient treatment improving the functionality of MDs. Modern AMs are equipped with sensors, safety features, and improved graphical user interface, but the patient relevant parameters remained the same (volume and flow of air/anesthesia gases). Also, modern defibrillators are equipped with features for patient monitoring and automated synchronization, but the most important relevant parameter for the patient remains output energy. Increased sophistication of MDs makes them faster, accurate and easier to use, but also increases the risk of incident, since there are more factors that can lead to this situation [12]. Also, due to this sophistication of MDs, at some point medical professionals become dependent on these technological advancements, such as device results and automated analysis reports. Usage of these devices requires understanding of which electrical, mechanical and software components in devices could be malfunctioning and lead to complications or injuries.

High-income, developed countries developed mechanisms for solving problems regarding MDs. Regulatory agencies or nongovernment bodies established databases of incidents regarding MDs. Analysis of these databases yields improvement of safety procedures during the manufacturing or usage of MDs. Inspection of performance of AMs and defibrillators in operating rooms in these countries is part of daily safety checks and periodical maintenance performed by clinical engineering department. Despite of the above, incidents are not rare and unfortunately, they result in injuries and deaths of patients. Literature overview suggests that in ensuring MD safety, more attention should be paid to device output parameters that directly affect the patients [2, 8, 22, 23].

Introducing MDs into legal metrology system in BH was a way of adopting safety procedures in healthcare institutions in BH. Analysis of performance inspections has revealed that AMs are often poorly maintained, with lack of automation and modern safety features such as alarms of oxygen valves. Due to lack of procedures in operating rooms, defibrillators are often neglected and placed in unreachable places. Also, the safety and performance of these devices was not maintained according to international recommendations and standards.

Numerous studies show that insufficient respiration during anesthesia is the one of major causes of postoperative complications [43-45]. Given the significant percentage of faulty AMs in this study, the importance of establishing a unique database of incidents involving AMs in BH is emphasized. The results of this study follow trends of previous studies of anesthesia failures conducted in other European countries and in the USA [43-45]. Adopted testing method has proven to be useful in situations when device output parameters were out of specification and the device seemed to be functioning properly. This behavior was detected in more than 5% of measurements. In these cases, preventive maintenance methods were not sufficient to detect such a device performance. In approximately 7% of faulty devices, the vaporizer or circle for mixing air was the cause of faulty performance. The majority of problems though were associated with regulating volume at the device output. In these cases, leaks in the device were detected or device filters were clogged.

Given aforementioned faulty devices rates, it's obvious that a basic understanding of metrology is essential for the daily practice of medicine. In intensive care, clinical decision-making is often determined by measurements of physiological and other variables to an extent unrivalled by most other medical specialties. Therapeutic success and ultimately outcomes in the critically ill depend on the correct interpretation of such measurements. Therefore, physicians should be aware of metrological concepts and understand the limitations and constraints. Since international consensus definitions exist, it is necessary to use them and promote them in the medical research and literature [46].

Results of this research are in agreement with previous reports on rates of defibrillator failure showing that one type of defibrillator proved to have the worst performance of all tested manufacturers and device types. The most usual failure was connected to a device capacitor, resulting in the device being unable to charge to reference value. As results in Table 4 show, the trend of reducing faulty rate of device performance was detected. The faulty rate in AMs in 2016 was 3.24% lower and 4.71% for defibrillators. These results suggest that periodic safety and performance testing increase the reliability of devices used in public and private healthcare institutions.

Conclusion

Results of study offer implication of adequacy for preventive and corrective maintenances performed in healthcare institutions. Based on the statistical results, it can be concluded that with good preventive maintenance, all used devices can be held at an appropriate level of accuracy to provide patients with quality treatment. It is possible to suggest improvement of preventive maintenance procedures as well as training programs for technicians who will be able to adequately recognize possible problems in system functionality during preventive maintenance. Furthermore, healthcare institutions should develop mandatory policies to perform self-testing of AMs prior to their usage, and also for defibrillators with frequency of at least once a week.

Based on collected data the first digital database of AMs and defibrillators used in healthcare institutions in BH was created, consisting of information on the manufacturer, type, serial number of device, as well as measuring results. This database is a useful tool for tracking each device's performance over time.

Implications

Inspections enable establishing MDs traceability chain so standard relative/absolute error for MD is known and kept in permissible limits so transfer of visiting anesthesiologist and medical professionals is easier and risk of complications due to MDs is lowered.

Adopted inspection procedures could be implemented in other Balkan countries to investigate the state of MDs in healthcare institutions, since most of these devices were donated by high-income European countries in 1990s. For most of these devices authorized services don't exist and spare parts are difficult to find. Thus, their maintenance is difficult and it's not known if device performance in terms of patient relevant parameters is inspected. Benefit of suggested inspection procedures is simplicity and evidence based decision derived on sight by trained professional.

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Tables

TABLE 1. Output parameters, specified measurement ranges and error ranges for anesthesia machines and defibrillators according to Rules on metrological and technical requirements for anesthesia machines and defibrillators

Anesthesia machine	Measurement range	Error range
Volume	100 – 400 [ml]	± 10% of reading
Anesthesia gas	1 – 8 [%]	± 1% of reading
Defibrillator	Measurement range	Error range
Energy	2- 70 [J]	± 1 [J]
	70 – 200 [J]	± 5 [J]
	200 do 360 [J]	± 10 [%] of reading

TABLE 2. Manufacturer specifications and models of tested anesthesia machines and defibrillators

Anesthesia machine			Defibrillator	
	Manufacturer	Type	Manufacturer	Type
1	GE	AESPIRE S5	NIHON KOHDEN	CARDIOLIFE TEC 5521K
2		AVANCE PRO	GE	CARDIOSERV
3	DRAGER	FABIUS		RESPONDER 2000

4		FABIUS MRI	PHYSIOCONTROL	LIFEPAK 11
5		JULIUS		LIFEPAK 12
6		TIBERIUS		LIFEPAK 15
7		PRIMUS	SCHILLER	DEFIGARD 3002
8		SULA 808	MARQUETTE	CARDIOSERV
9	ACOMA	PH-3F	METRAX	PRIMEDIC DEFIMONITOR
10	MINDRAY	WATO EX-55	CARDIOLINE	DELTA LIFE 550
11	MARQUETTE	FLOW I	BURDICK	MEDIC 5
	SMS COMPANY	ANESTHESIA MACHINE	GIMA	RESCUE LIFE

TABLE 3. Tested medical devices

	Anesthesia machine	Defibrillator
Accurate	103	137
Faulty	27	24
TOTAL	130	161

TABLE 4. Tested medical devices by year

Anesthesia machine	Accurate (A)	Faulty (F)
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2015	84.54%	15.46%
2016	87.78%	12.22%
Defibrillator		
2015	82.66%	17.34%
2016	87.37%	12.63%

Figures

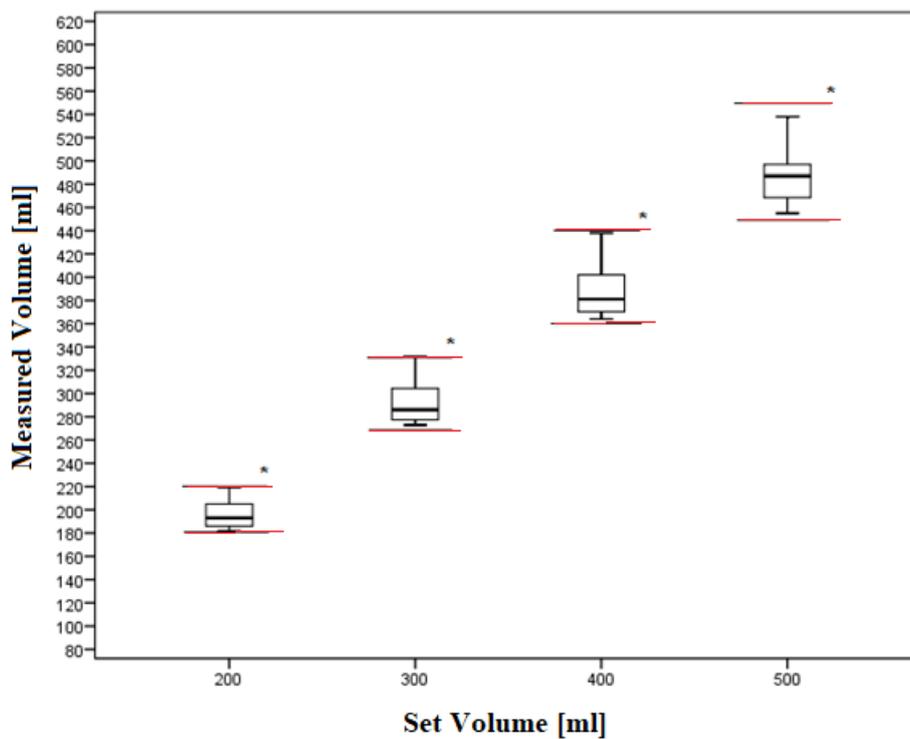


Fig. 1 Boxplot representation of the results of statistical tests performed on volume measurements for accurate (A) anesthesia machines

Note: x axis represents measurement points and y axis represents values of volume achieved at each measurement point. Lines represented with * are maximum permissible values of volume on each

measurement point. Boxplots represent distribution of measurement values at each measurement point (lower, upper quartile and median value)

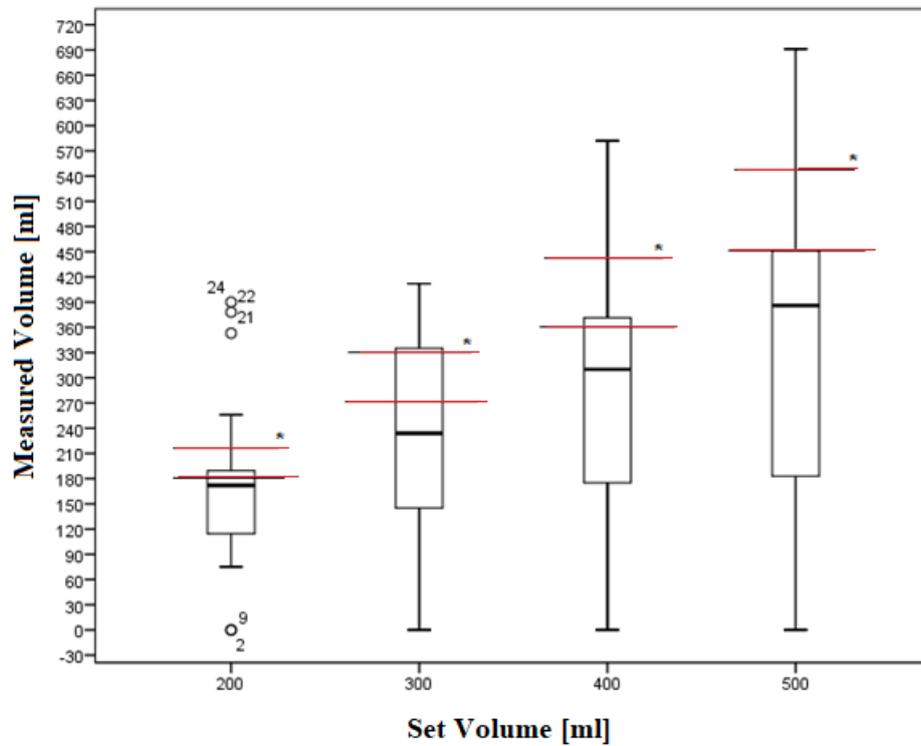


Fig. 2 Boxplot representation of the results of statistical tests performed on volume measurements for faulty (F) anesthesia machines Note: x axis represents measurement points and y axis represents values of volume achieved at each measurement point. Lines represented with * are maximum permissible values of volume at each measurement point. Boxplots represent distribution of measurement values at each measurement point (lower, upper quartile and median value). o represents measurement outliers – single extreme high or low measurement values; The numbers by the o mark represent the number of samples

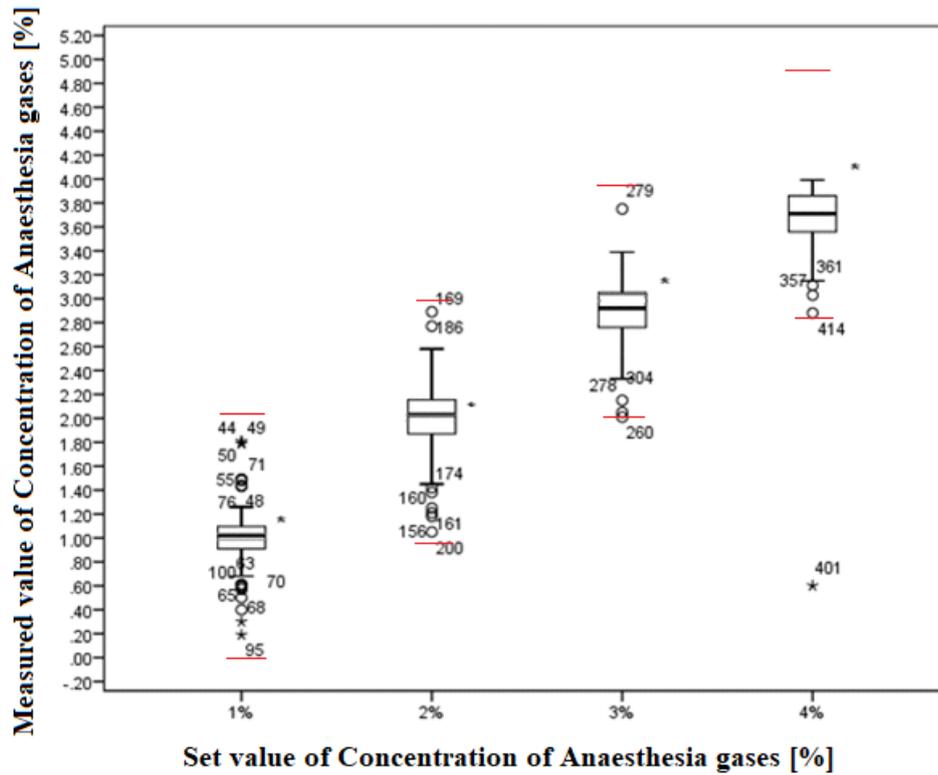


Fig. 3 Boxplot representation of the results of statistical tests performed on accurate (A) anesthesia machines for concentration of anesthesia gases Note: x axis represents measurement points and y axis represents values of concentration of anesthetic gases (Sevoflurane) achieved at each measurement point. Lines represented with * are maximum permissible values of volume at each measurement point. Boxplots represent distribution of measurement values at each measurement point (lower, upper quartile and median value)

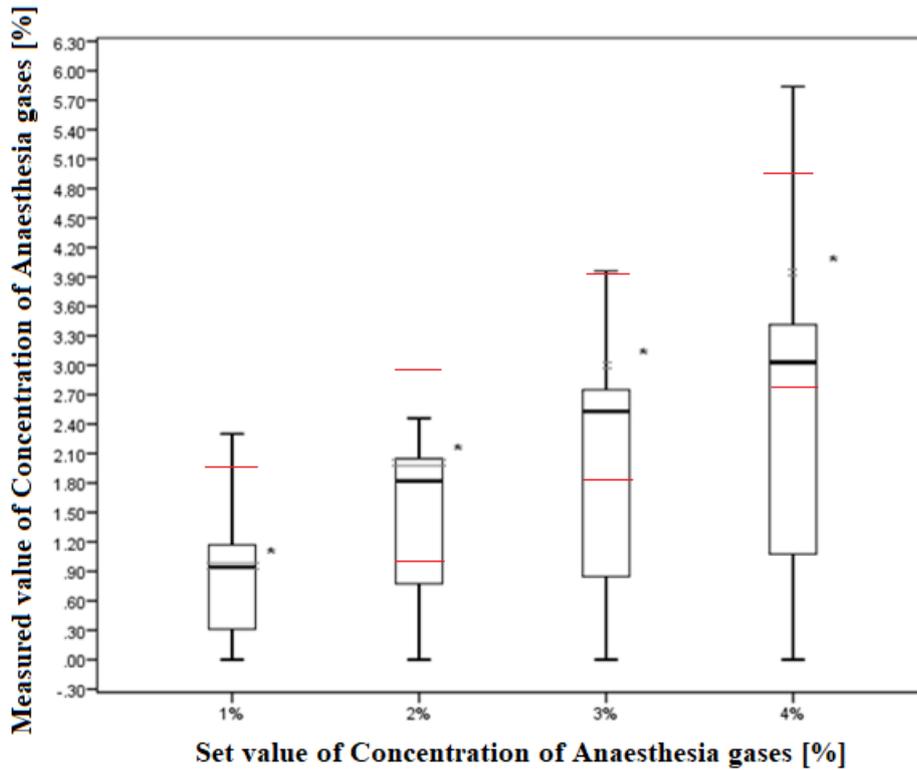
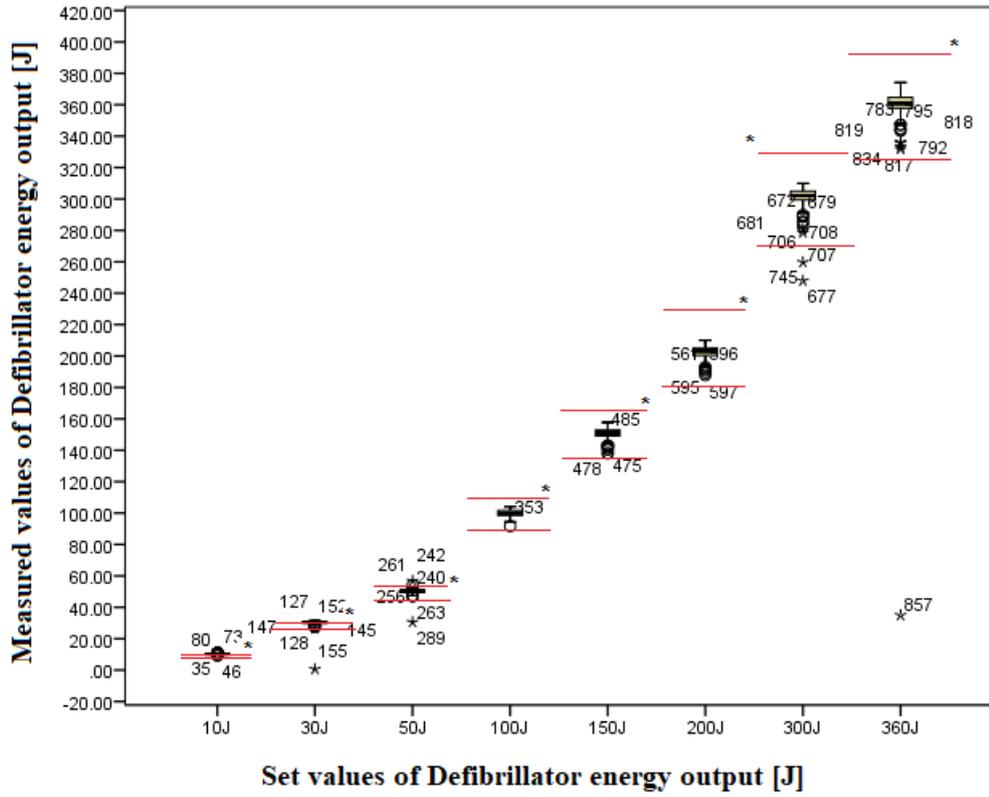
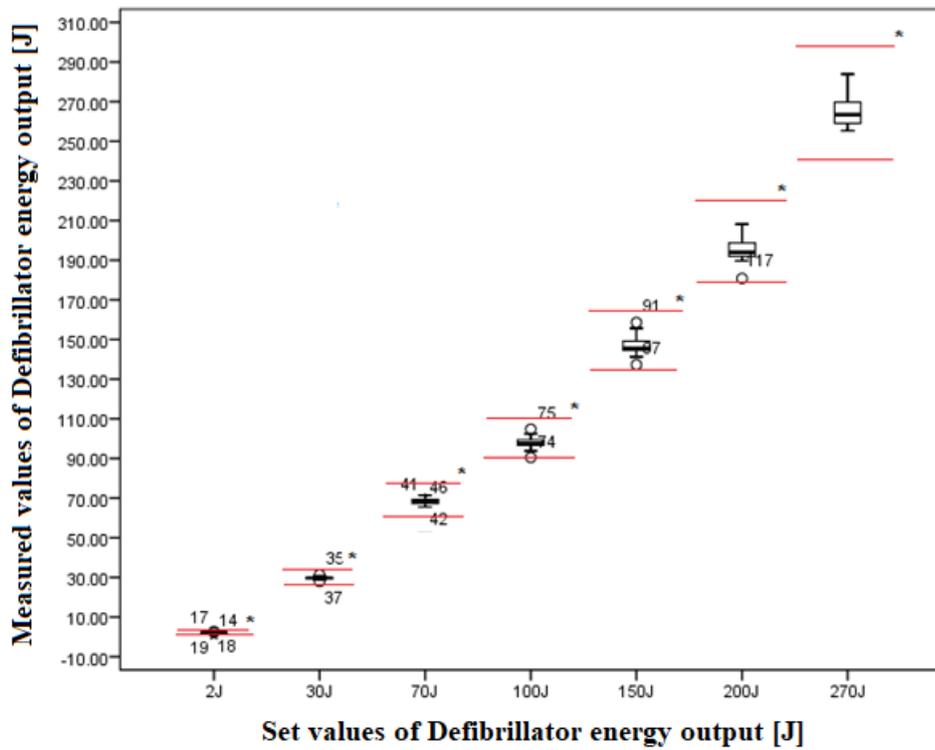


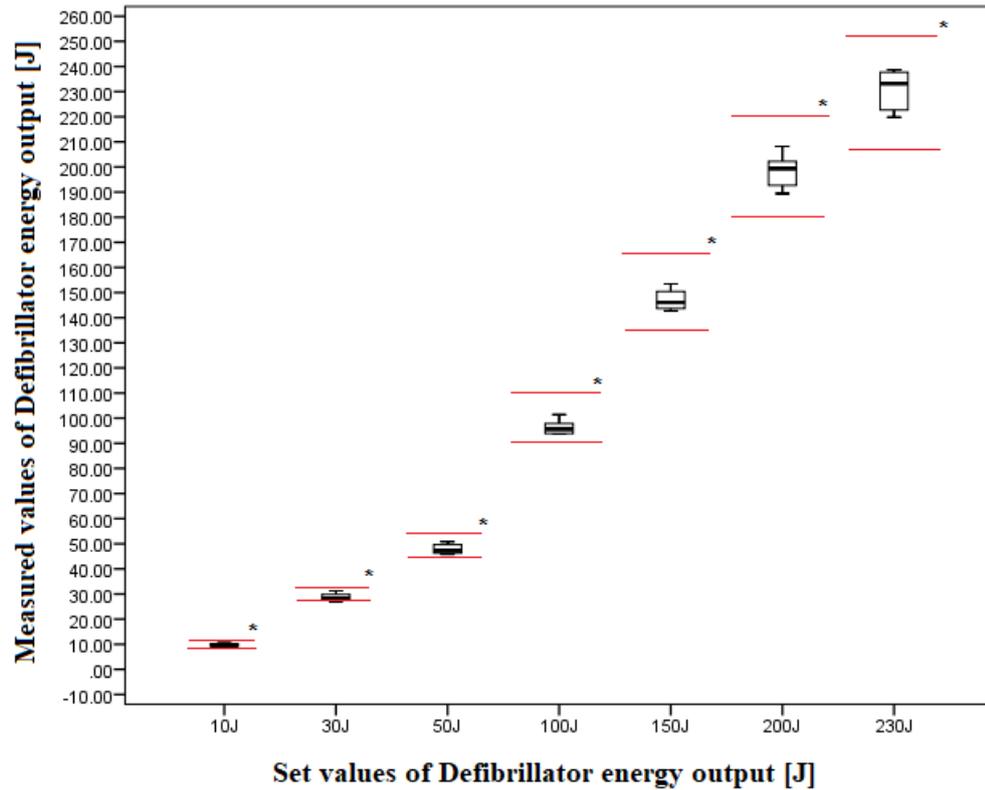
Fig. 4 Boxplot representation of the results of statistical tests performed on faulty (F) anesthesia machines for concentration of anesthesia gases. Note: x axis represents measurement points and y axis represents values of concentration of anesthetic gases (Sevoflurane) achieved at each measurement point. Lines represented with * are maximum permissible values of volume at each measurement point. Boxplots represent distribution of measurement values at each measurement point (lower, upper quartile and median value). o represents measurement outliers – single extreme high or low measurement values; The numbers by the o mark represent the number of samples



a. Defibrillators with maximum output energy 360 J



b. Defibrillators with maximum output energy 270 J



c. Defibrillators with maximum output energy 230 J

Fig. 5 Boxplot representation of the results of statistical tests performed on energy measurements for accurate (A) defibrillators. Note: x axis represents measurement points and y axis represents values of energy achieved at each measurement point. Lines represented with * are maximum permissible values of volume at each measurement point. Boxplots represent distribution of measurement values at each measurement point (lower, upper quartile and median value).

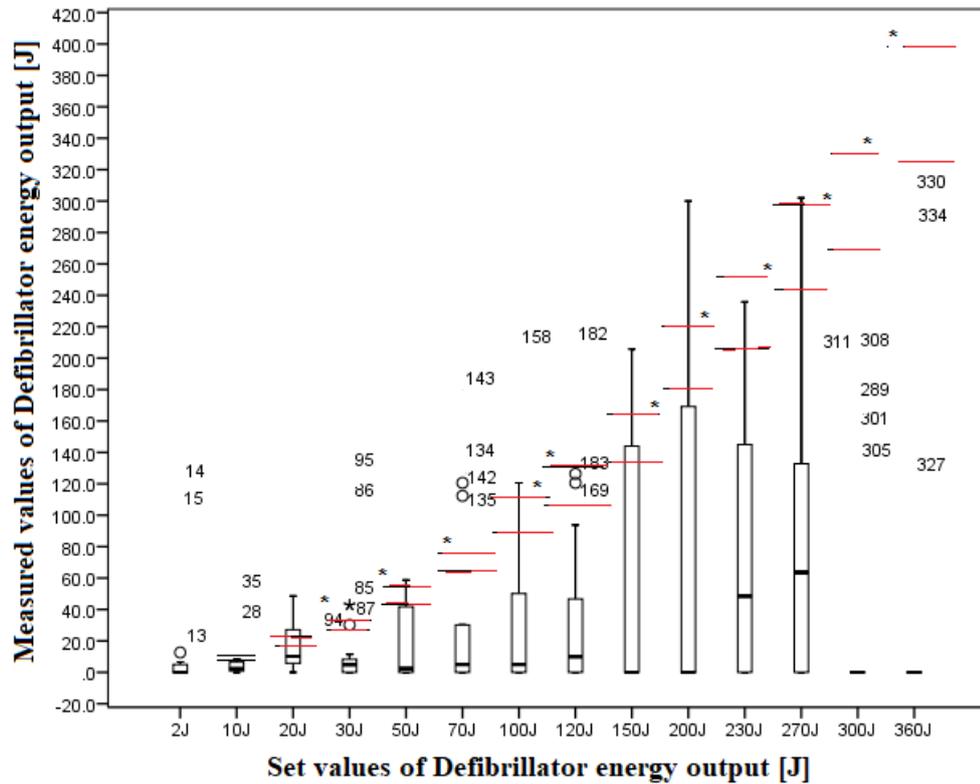


Fig. 6 Boxplot representation of the results of statistical tests performed on energy measurements for faulty (F) defibrillators. Note: x axis represents measurement points and y axis represents values of energy achieved at each measurement point. Lines represented with * are maximum permissible values of volume at each measurement point. Boxplots represent distribution of measurement values at each measurement point (lower, upper quartile and median value). o represents measurement outliers – single extreme high or low measurement values; The numbers by the o mark represent the number of samples