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Protocols for Performance Evaluation in Medical Equipment

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***Abstract* —** Healthcare service providers must count on the availability of quality control for their medical equipment which will assure total reliability in its operation, as well as results, thus complying with technical specifications and standards. Within this study, a medical equipment evaluation protocol is developed to quantify said equipment performance. In this context, performance tests in biomedical equipment assess the performance, operation, and compliance of biomedical equipment specifications to provide reliable information on its performance. This paper develops a protocol of evaluation for medical equipment that enables the quantification of its performance. To achieve this, it takes into account the general information of the equipment, its condition, as well as, manufacturer recommendations, among others, obtaining a protocol that can be applied to different types of equipment and that provides reliable and objective information, in terms of all the aspects that involve its operation.

***Keywords* —** Biomedical equipment, performance test, calibration, clinical engineering.

Protocolos para evaluación de desempeño en equipos médicos

Resumen — Las instituciones prestadoras de servicios de salud deben disponer de un control de calidad para los equipos médicos que garantice total confiabilidad en su funcionamiento y resultados, logrando el cumplimiento de los requisitos establecidos por las especificaciones técnicas y normas. En este contexto, las pruebas de desempeño en equipos biomédicos evalúan el desempeño, funcionamiento y cumplimiento de especificaciones de estos para brindar información confiable sobre su funcionamiento. En este trabajo se desarrolla un protocolo de evaluación de equipos médicos que permite cuantificar su desempeño, para esto se tiene en cuenta la información general del equipo, su estado y recomendaciones del fabricante entre otros; obteniendo un protocolo que pueda ser aplicado a diferentes tipos de equipos y que brinde información confiable y objetiva, en función de todos los aspectos que involucran su funcionamiento.

Palabras clave — Equipo biomédico, pruebas de desempeño, calibración, ingeniería clínica.

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Protocolos para avaliação de desempenho em equipamentos médicos

Resumo — As instituições prestadoras de serviços de saúde devem dispor de um controle de qualidade para as equipas médicas que garanta total fiabilidade em seu funcionamento e resultados, conseguindo o cumprimento dos requisitos estabelecidos pelas especificações técnicas e normas. Neste contexto, as provas de desempenho em equipas biomédicos avaliam o desempenho, funcionamento e cumprimento de especificações destes para brindar informação confiável sobre seu funcionamento. Neste trabalho desenvolve-se um protocolo de avaliação de equipamentos médicos que permite quantificar seu desempenho, para isto se tem em conta a informação geral do equipamento, seu estado e recomendações do fabricante entre outros; obtendo um protocolo que possa ser aplicado a diferentes tipos de equipamentos e que brinde informação confiável e objetiva, em função de todos os aspectos que envolvem seu funcionamento.

Palavras-chave — Equipamento biomédico, provas de desempenho, calibração, engenharia clínica.

I. Introduction

A performance test is regarded as a set of activities that can include measurements and that contributes evidence to assess performance of biomedical equipment. Since technology is an essential part in the provision of healthcare, its accurate evaluation and performance make assessment crucial for contributing to the achievement of efficiency in medical attention and effective access to quality healthcare services. Parallel to this, there are national and international regulations and standards which govern and orient the evaluation of medical devices, making it necessary to unify criteria for the implementation of a practical evaluation system for this type of technology.

Statistics from developed countries assure that 21% of hospital accidents are caused by medical technology [1]. Likewise, a study carried out at a Healthcare Provider (*IPS*, in Spanish) and published in the *American Journal of Preventive Medicine* [2] shows that adverse events associated to medical technology more often occur due to device failures than errors in its use. This is why the accurate evaluation of these technologies is of the utmost importance. The performance of biomedical equipment can be evaluated from diverse viewpoints, technical, clinical and financial aspects being of special interest. It is important for healthcare institutions to know the physical and operating conditions of their equipment in relation to their capacity to satisfy the clinical needs for which the equipment was purchased, as well as, the financial convenience of its operation.

The Ministry of Health and Social Protection in Colombia, specifically the Department of Medication and Health Technologies, works to define minimum requirements for these activities. These can include metrological procedures and can be performed within technical support service provision, maintenance, or at any other time in the biomedical equipment's life cycle, duly labeled as performance evaluations [3].

This is why evaluating the performance of biomedical equipment in use contributes to patient safety and should be considered a surveillance tool. However, in the field of clinical engineering, there are only a few centers for technology evaluation which allow for the necessary evidence for a report of the equipment's operation, according to existing standards and regulations, as well as, for any decision making, which influences adverse effects on patients.

This paper's objective is the development and application of a biomedical equipment evaluation plan to quantify its performance according to standards, offering objective and accurate information in terms of determining parameters of performance.

The study begins with an extensive review of applicable standards and tests [4, 5, 6]. This is followed by the design of tests and register formats. After that is the application of tests, to conclude with the design corresponding reports.

II. Methodology

As a major step for the development of performance evaluation protocols, common requirements were established. These requirements include the general information that must be taken into account, such as, minimum tests, standards implementation [7], equipment parts' conditions and manufacturer recommendations, among others. Non-equipment specific tests were designed for their application on different equipment types, guaranteeing good performance of said equipment.

General characteristics of the equipment were grouped together and applicable tests for evaluations were proposed. These tests were defined according to the equipment and its features. Additionally, the equipment was evaluated under its operating conditions and manufacturer specifications, for which specific tests had to be defined according

to model and ranges of operation, based on technical specifications [8, 9], as shown on Fig. 1.

Specific tests for each piece of equipment were defined according to the following selected items: 1. equipment measurement variable, 2. measurement and operation variables, and 3. number of values to measure and number of repetitions.

After implementing the medical equipment's protocol, as well as, the general and specific tests to be applied, its condition and performance was analyzed in order to finally generate a report which shows results obtained, information about who performed the tests and who carried out their respective reviews. This reports gives out information on quantity and quality of the equipment analyzed and whether it conforms, or not, to the standards and operating specifications of the manufacturer [10].

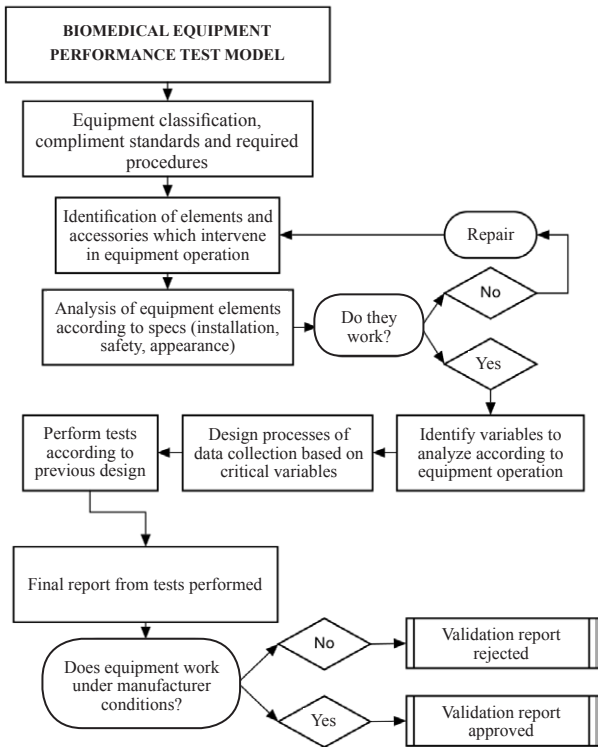

Fig 1. Scheme of implemented methodology. Own source

The analysis of the condition of the parts linked to the equipment was done by means of general tests, which include visual inspection evaluations, as well as, electrical safety tests. Stemming from these, the operation of the parts and accessories was evaluated according to manufacturer specification and stipulated standards. Once the adequate performance was confirmed for all applicable elements, the variables related to the medical equipment and its features were defined. These were evaluated by means of specific tests and metrological procedures to compare values obtained against the respective regulation and manufacturer standards. The resulting data was registered in the protocol in order to obtain a report that enables the analysis of the equipment's performance.

Lastly, in order to fully carry out the verification of the evaluation process, the signatures of both the evaluator and the reviewer were registered. The reviewer is the last person to approve or reject the continuation of the evaluated equipment under the previously stated conditions.

III. Results

A. General Format

A form was designed for the implementation of different medical equipment, including identification, branch location, necessary equipment on which to perform tests (patterns, inputs, forms, manuals) and safety recommendations. The second part (Table 1) refers to the general tests according to the type of equipment, as is the visual inspection test, condition and operation tests. Only some of the items are shown on the table. Subsequently, we can see specific equipment and technical characteristics tests required by the manufacturer. Lastly, we see the part in which to include the results and the final equipment report.

Table 1. Performance evaluation, general tests. Own source

GENERAL TESTS				
Characteristic	**Complies with specs**	**Yes**	**No**	**Value/ Observations**
Electric safety				
Visual inspection	The device is clean	X		
	No damage on case, monitor, knobs or switches	X		
	No physical damage of EKG, electrodes, skin temperature line, SpO2 sensor	X		Oximetry cable not found

B. Vital Signs Monitor

The choice of equipment tested (i.e., vital signs monitor) was mainly based on its constant use at healthcare centers, as well as, the importance of its good operation. Also, the choice was based on the different tasks it performs, all of which result in the appropriate focus for the study.

The generic characteristics of a DRAGUER INFINITY DELTA XL vital signs monitor were analyzed and the

general tests to be carried out, according to its properties, were established. Said tests include electrical safety, visual inspection, operation and condition of parts. In order to evaluate the medical equipment under manufacturer's conditions it was necessary to have the equipment's technical specifications. These were used to design specific tests, such as, biological signals monitoring, sound and visual alarms, and battery tests closely related to the operation and model of the specific vital signs monitor (Table 2).

For this protocol, 37 tests were carried out, only two of which are included for each item as an example. The other tests are related to measurements and evaluation of implied variables in the operation of the equipment and its accepted values, respectively.

Through these specific tests unique features of the equipment are evaluated, such as, alarms and their respective available modifications, battery function and variables that lead to measurement taking. Some of the described tests are presented as follows.

Table 2. Performance evaluation, specific tests. Own source

SPECIFIC TESTS		
Characteristics	**Complies with specs**	**Value/ observations**
Battery	Correct battery and duration charge	No charger
	Message of state of battery operation charge	No charger
Alarms	Modification of upper and lower alarm levels of all measurable parameters	
	Alarm silencing option	
EKG monitoring	Simultaneous display per derivations	
	Channel and functional derivations modifications	
SpO2 monitoring	Consistent plestimograph curve	
	Measured values*	
Respiration monitoring	Consistent respiration curve	
	Size and signal position modification	
Temperature monitoring	Consistent temperature channels	
	Numeric temperature display	
Monitoring non-invasive pressure	Numeric pressure display (Systolic, diastolic, and medium)	
State messages and indicators	Volume modification of operation of voice messages	
	Visual indicators of state of operation	

Variables such as oxygen saturation, temperature, beats per minute and systolic, diastolic and mean pressure were measured, from which measurements are obtained to continue the evaluation. Upon the application of tests designed and using biological signs simulators, the respective values for each evaluated variable were obtained for each critical point, as well as normal patient values. Upon analysis of these results and taking into account if they are within their range of operation and error limits accepted according to the manufacturer, we can conclude whether or not the vital signs monitor is apt to continue operating.

Some of the measurements made for each variable and its respective acceptable values, as well as, errors recommended by the manufacturer are presented below. It must be noted that said values are taken from manufacturer specifications and these can vary for each equipment type. As shown in Table 3, four pieces of data for each assessed value were taken, allowing for an error of ± 1 °C.

Table 3. Temperature measurements and values. Own source

Temp (°Celsius) Pattern	**DUT (°C)**	**Specs and averages obtained**		**According to Specs**
20	21	Error: ± °C	1	
	20.9	Min. value accepted	19	Complies
	20.6	Max. value accepted	21	Complies
	20.9	Average	20.85	
23	22.9	Error: ± °C	1	
	23.8	Min. value accepted	22	Complies
	23.8	Max. value accepted	24	Complies
	23.7	Average	23.55	

Table 4 shows the measurements taken for pressure, of which three pieces of data for the assessed value were taken. Also, tests are analyzed with an accepted error of ± 3 mmHg.

Table 4. Pressure measurements and values. Own source

Pressure (mmHg) Pattern	Pressure (mmHg) EBP	Specs & averages obtained		According to specs
100	100	Error: ± mmHg	3	
	101	Min. avg. value	97	Complies
	102	Max. avg. value	103	Complies
		Average	101	
80	83	Error: ± mmHg	3	
	83	Min. avg. value	77	Complies
	83	Max. avg. value	83	Complies
		Average	83	
120	124	Error: ± mmHg	3	
	122	Min. avg. value	117	Complies
	123	Max. avg. value	123	Complies
		Average	123	
150	148	Error: ± mmHg	3	
	148	Min. avg. value	147	Complies
	149	Max. avg. value	153	Complies
		Average	148,3	

Table 5. EKG measurements and values. Own source

Bpm pattern	Read	Specs & averages obtained		According to specs
30	30	Error: ±	2	
	30	Min. avg. value	28	Complies
	30	Max. avg. value	32	Complies
		Average	30	
80	80	Error: ±	2	
	80	Min. avg. value	78	Complies
	80	Max. avg. value	82	Complies
		Average	80	
120	120	Error: ±	2	
	120	Min. avg. value	118	Complies
	120	Max. avg. value	122	Complies
		Average	120	

The values above show the results of the tests of electrocardiograph signs, which correspond to three measurements for each value proposed in the ECG simulator. It also shows an error on the value measured of ±2 bpm, given the technical specifications of the tested equipment.

In order to easily analyze the previous results, a graph is made which enables the confirmation of whether or not the values obtained are within the error range proposed by the manufacturer. The graphic representation below shows only the ECG variable.

Fig. 2 shows that the three measurements for each value coincide and are found within the accepted limits stipulated by the manufacturer.

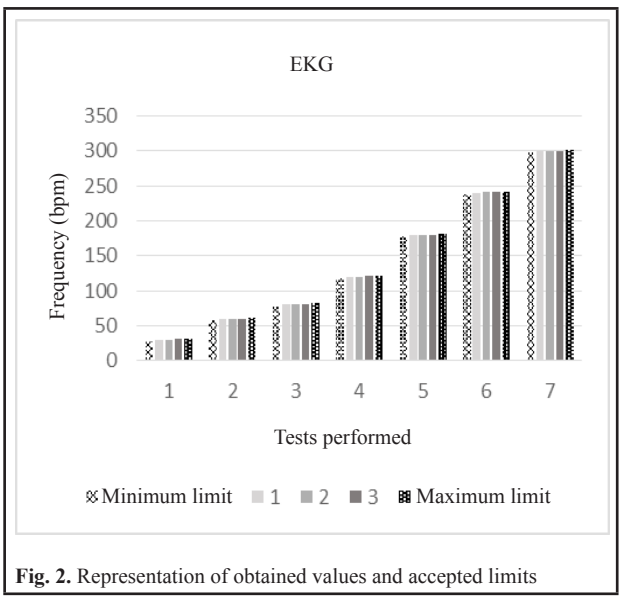

Fig. 2. Representation of obtained values and accepted limits

We can get enough bases to make a decision as to equipment performance, thanks to the evaluation protocols designed and tests applied. Results shown are a summary of what has been carried out, which is why a complete evaluation report is not presented nor is the final decision of validity of the evaluated equipment made.

IV. Discussion

The measurement ranges for the application of tests notably contribute to the performance evaluation of the equipment. It is considered necessary to establish these ranges taking into account values that are generally used and critical in diagnosis, since these are the one which influence the valuation or procedure while the medical equipment is in operation.

We must consider the observations that result from the tests to determine if the equipment should continue operating, if it is necessary to establish conditions of use, and if so, their justification. This is necessary because the medical equipment can present minimal failures that do not generate adverse effects in the patient nor hinder his/her safety.

The constant search for improvement in standardization in favor of patient safety has led to the adjustment of previous maintenance and calibration processes resulting

in new ones which aid the assurance of the correct medical equipment operation. All this is achieved through the redefinition of concepts, such as the way we choose the equipment for calibration and metrological control or the application of tests to confirm said equipment's operation. The application of performance tests is necessary for any piece of medical equipment and is an additional tool to aid in the assurance of its good condition and operation according to its specifications. It contributes in decision making during the stages of pre and post market, as well as in aiding future acquisition processes.

The protocols proposed for the performance evaluation of technology aim toward a change in the paradigm with relation to procedures and instructions for the validation of these technologies. They make possible the quality certification of products guaranteeing their conformity to safety and accuracy, corresponding to the values specified by the manufacturer.

These protocols enable the extrapolation of a great amount of equipment of different brands, models, measurement variables and unique needs of each institution, since they enable the application of tests tailored to each type of technology. They also enable groupings by variable, for example the design of performance tests for electrocardiographs, non-invasive blood pressure monitors and oximeters, which can later jointly point toward a test for a vital signs monitor, with minimal changes needed to the protocols.

V. Conclusion

The protocols proposed during the study constitute a base on which to carry out a performance evaluation of the equipment specified, enabling its application on technological equipment of different brands and models, provided an adequate selection of characteristics is made.

The primary input for the creation of these protocols are manufacturer instructions, since measurement ranges, physiological magnitudes, resolution and accuracy, among others, vary from one piece of equipment to another, or even from one model to another of the same brand.

Designing a protocol to cover all points, from the most general to the most specific per equipment, offers a guide which makes it possible to generate similar protocols for many types of technological equipment without requiring significant changes. This enables the quick amplification of a test protocol bank, while said tests are subject to changes and improvements themselves. At the same time, this enables achieving a stable protocol in a short amount of time that will show evidence of future evaluation processes of technology acquisition processes.

A medical device's operation validation is important so that its merchandising and use do not generate adverse events on the patient. Thus, the creation of these types of protocols is essential for the acceptance of new or existing technologies. However, we recommend implementing improvements in the design of the tests and standardizing protocols created so that they can be applicable to any type of medical equipment.

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Conflicts of Interest

The authors state they have no conflict of interests.

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