CONSIDERATION ON THE MAINTENANCE EQUIPMENT IN A MOBILE HEALTH UNIT

IONICI CRISTINA, *University "Constantin Brâncuşi , Tg-Jiu, Romania*
feliciaionici@gmail.com

Abstract: In order to ensure the level of maintenance and performance appropriate to the purpose for which the medical devices are made and to avoid the generation of incidents, users have the obligation: to ensure that they only use medical devices when, within the framework of professional activities, they use equipment for the purpose of diagnosing, preventing, monitoring, predicting, prognosticating, treating or ameliorating a disease, as defined in art. 2 point 1 of Regulation (EU) 2017/745.

KEY WORDS: *mobile health unit, medical equipment, biomedical. maintenance, biomedical engineer.*

1. INTRODUCTION

Preventive maintenance, periodic inspection, is carried out at the level of the equipment operator and by the biomedical engineer, it is usually planned, established in such a way as to ensure that the medical equipment does not present defects, so that major problems are detected early. The schedule of technical revisions in the USM, preventive maintenance, is according to **table 1**.The acquisition of medical equipment is an important activity of the engineer in the technical support service, who establishes the sufficient number of medical devices needed, their technical characteristics and quality.[1.2.3.4.6.7.8.9.]

Table 1. Technical characteristics

Crt	Name/ standardized by MS	Model	Manufacturer	Year of manufacturer	alendar month											
					1	2	3	4	5	6	7	8	9	10	11	12
1	Vital functions monitor	USM	DE 6228262		*	*	*	*	*	*	*	*	*	*	*	*
2	EKG/EGG	USM	404395		*	*	*	*	*	*	*	*	*	*	*	*
3	Defibrillator	USM	404395		*	*	*	*	*	*	*	*	*	*	*	*
4	Ventilator Mecanichal	USM			*	*	*	*	*	*	*	*	*	*	*	*
5	Surgical aspirator	USM			*	*	*	*	*	*	*	*	*	*	*	*

6	**Oxygen cylinders**	**USM**			*	*	*	*	*	*	*	*	*	*	*	*
7	**Hydraulic ambulance strecher**	**USM**			*		*		*		*		*		*	

2. EXPERIMENTAL - Monitoring and maintenance of equipment in the USM

The Corrective maintenance or repair is a procedure for identifying and resolving malfunctions of medical devices, so that they are restored to normal functional condition and within the appropriate limits of the parameters established by the manufacturer, involving the replacement of certain spare parts and/or consumables. The results of the repair operation must also be recorded to serve as basic information, the technical support device, to be subsequently used with the aim of improving the functionality of the device. x this point.

Medical technologies are developing very rapidly, which implies a greater difficulty for technical support staff, biomedical engineers, for maintaining the equipment, requiring a specialization to keep up with the technology, and the budget of health institutions does not allow it. This is why it is highly recommended that the maintenance of very sophisticated medical devices be externalized. Recommendations for the maintenance style applied depending on the type of medical device are presented in Table 2

Tabelu 2. Inventory of medical equipment

Crt.	Medical Device	Device	Recommendation
1	**Sophisticated Technologies**	Computed tomography (CT) scanner, angiography machine, automated laboratory analyzer	Outsourced maintenance contracts with the medical device manufacturer or its authorized representative.
2	**Advanced Technologies**	General X-ray machine, fluoroscope, mobile X-ray machine, patient monitor, electrosurgery unit, artificial ventilation machine	Internal maintenance, if human and technical resources are sufficient.
3	**Simple Technologies**	Surgical suction pump, surgical lamp	Internal maintenance.

The certainty that the medical devices used during the medical act are at the functional and professional parameters, they must be checked periodically. At the same time, it was found that the metrological verification does not provide for checks of general safety, electrical safety, functionality and alarm control, and most importantly - of performance, which does not guarantee the safety and quality of the medical act.

The procedure for cyclical verification of a benchmark, through laboratory tests, provides for the following actions:

- Notation of the defining performance parameters through examination and testing;

- Fulfillment of the set of acceptable criteria for the medical device (imposed values, specified limits, accessories, etc.);
- Test report containing the results obtained from the examinations and tests, if the medical device does not meet the acceptability criteria and if at least one of the measured values of the essential safety or performance requirements is close to the specific permitted limits;
- Periodic approval, periodic verification, based on which the medical device can be used

To confirm the safety of medical devices, some developed countries, including some EU member states, have implemented another procedure, namely periodic verification through laboratory tests (public or private). There are also medical institutions that practice the same type of verification with testing equipment within their own laboratories due to the fact that these institutions have the financial and human resources to equip these laboratories and the appropriate skills to carry out the necessary procedures.condition is monitored by both the medical staff and the biomedical engineers of the Department of Biomedical,table 3.

Table 3.

AUTHORIZAȚION NR.B/CR4/K,L/15/2354/0/ VALIDITY 12 month

VERIFICATION BULLETIN
OPENING-CLOSING
NO. from date

In accordance with the legal provisions regarding the responsibility assumed for checking the safety valve type manufacturing series/beneficiary lot USM, the safety valve was checked from at least 3/5 successive openings, and the measured values are within the deviations mentioned in the technical prescription PT C7. This bulletin guarantees the repair/check/adjustment and sealing with the following parameters :

p_1 = L_1/l_1= G_1 =

p_2 = L_2/l_2= G_2 =

a = b_1= b_2 = d_0=

Responsible for supervising the work

For the spring valve, the setting pressure is completed:
a- deviation of the setting pressure.
b1- increase in pressure when opening
b2- decrease in pressure when closing
- For the lever and counterweight valve, the following is completed: :
p_1 = bar L_1/l_1= mm G_1 = kg
p_2 = bar L_2/l_2= mm G_2 = kg

Inspections and maintenance are vital for the safe operation of medical equipment, sufficient technical and medical knowledge is also required to ensure adequate maintenance of medical devices, we can say that maintenance of medical equipment must be ensured by technical support personnel. Maintenance of medical devices includes: preventive maintenance and corrective maintenance

The responsibility for reporting incidents with medical devices lies primarily with medical personnel, medical and healthcare institutions, other users, the manufacturer or its authorized representative. Incidents are reported, in accordance with the legislation in force, to the responsible authority in this field, namely the Agency for Medicines and Medical Devices.

3.CONCLUSION

- Keeping a medical device in circuit with a large number of operating hours leads to a waste of the financial resources of the medical institution, to avoid this phenomenon, the biomedical engineer recommends purchasing new and more efficient devices, with innovative technologies. To comply with the provisions for medical devices put into operation according to Government Ordinance no. 37/2022 amending Law no. 95/2006.
- We can certify that the activities related to medical devices are the responsibility of specialized personnel, technical support personnel, therefore they must govern the adequate management of medical devices, which includes the accumulation, implementation and modification of all data that influence the operation of the equipment in the USM.
- We can certify that activities related to medical devices are the responsibility of specialized personnel, technical support personne.

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