Medical Technology Management at Medpark International Hospital

Biomedical Engineer **Chiriac Elena**

Presentation

Medpark International Hospital opened its doors in February 2011 and is located near the city center, facilitating thus rapid access of the patients to health services from any sector of the city.

The modern building of hospital 6 floors includes:

* Polyclinic
* Operating Bock
* Intensive Care
* Maternity
* Stationary
* Department of diagnostic services (radiology, laboratory).

Hospital includes a variety of the newest and most modern medical devices:

1. Philips Ultrasound Systems
2. Schiller ECG, Holter Monitors and Defibrillator
3. Argus infusion and injection pumps
4. Mobile Rontgen
5. Philips Allura angiography and others

Devices are subject to monitoring, recording, maintenance process, repair and modernization under Medical Device Management Plan approved in the hospital.

Medical Device Management Plan at Medpark International Hospital

Medical Device Management Plan is developed jointly by different hospital departments because its execution implies involvement of several units: Administration, Technical Department, Quality Management Department, Accounting, etc.

Structure of the Plan:

1. **Purpose**
2. **Content**
3. **Responsible Persons**
4. **Definitions**
5. **Stages of Implementation**
6. **Related Documents**

1. PURPOSE: The purpose of the plan is to establish a standard method for inventory of medical devices, performing their calibration and maintenance activities as well as following their repair.

2. CONTENTS: The plan includes activities on supervising breakdowns and performing calibration and maintenance works as well as inventory of the medical devices.

3. Responsible Persons: Biomedical Unit staff and persons who have been given the custody of medical devices are responsible for the implementation of the plan.

4. DEFINITIONS:

Custody implies free usage of the medical devices provided to the hospital by the producer/distributor company in return for purchasing medical consumables, kits and reagents, etc. from the supplier by the hospital (client).

5. Stages of Implementation

5.1. Purchasing and Receiving Medical Devices: For the purchase of a medical device all the requests on its acquisition are communicated under the **“Procurement Process".**

5.2. Inventory of Medical Devices and Custody: Inventory of medical devices is carried out according to the **"fixed asset records."** Inventory is prepared by the responsible person from Biomedical Department and is recorded into the **“Medical Device Inventory List".**

5.3. Training for Users:

User training for the newly acquired devices is performed in accordance with “Employee Training" and under the supervision of Biomedical Department. It implies contacting the company which is to perform and is obliged to ensure performing the biomedical training. If the user staff changes and user errors resulting in subsequent breakdowns appear, the training is to be repeated.

5.4. Periodical Maintenance:

Preparation of calibration and maintenance plan

Maintenance of medical devices that have service contracts;

Maintenance of medical devices that do not have contracted service;

Maintenance of medical devices within the warranty period;

Maintenance works are carried out by completing **“Control and Periodical Maintenance Form “** prepared for the medical devices and are recorded into **“Device Registration Card.“**

Report on maintenance and/or servicing submitted by the related companies to Biomedical Department is included into folders whereas the maintenance work performed is recorded into **"Device Registration Card“**

Calibration works

Preparation of Calibration and Maintenance Plan:
Medical devices that require calibration are provided with labels whereon you can find the calibration period and date when the last calibration was performed.

Calibration Performance:
Calibration work is done in the area the devices are located, Biomedical Department workspaces or at related outsourced company. Upon completing the calibration works Biomedical Department receives **Calibration certificates** provided by the given institutions.

Calibration work performed by Biomedical Department corresponds to " **Medical Device Calibration Instruction**" and "**Calibration Device Operating Instruction**".

Evaluation of the calibration certificates is performed by the responsible person from Biomedical Department. Calibration certificates are archived and calibration is recorded into "**Calibration and Maintenance Plan**" and "**Device Registration Card**"

Breakdowns of Medical Devices

Breakdowns of medical devices are communicated by means of **"Repair Form"** filled in and submitted to Biomedical Department. If the breakdown is eliminated by an outsourced company, it should complete a report on the performed activity, approved afterwards by the hospital staff of Biomedical Department.
The report is included into the folder and the repair work performed is recorded into **"Device Registration Card "**

Repair Work Classification:

- Repairing damages of the devices which possess service contracts within the warranty and custody periods
- Repairing damages of the devices which possess service
- Repairing damages of the devices under warranty
- Repairing damages of the devices which do not have any service contract and are outside the warranty period

Providing Spare Parts for Maintenance and Troubleshooting:

If maintenance and troubleshooting activity requires spare parts, Biomedical Department performs researching of the related commercial offers .

Reccall : If the devices are withdrawn from the use by the manufacturer, the respective device is returned to the producer with the related report.

6. RELATED DOCUMENTS

- Procurement Process
- Medical Device Inventory List
- Calibration and Maintenance Plan
- Form on Medical Device Transfer to Another Institution
- Repair Form
- Device Registration Card
- Medical Device User Manual
- Control and Periodical Maintenance Form

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LISTA DE INVENTARIERE A DISPOZITIVELOR MEDICALE

NUMARUL DE SERIE	NUMAR DE INVENTAR	COD BIOMEDICAL	NUME DISPOZITIV	MARCA	MODEL	LOCAŢIE	PLANUL DE MENTENANTA		PLANUL DE CALIBRARE	
							INCLUS	NEINCLUS	INCLUS	NEINCLUS

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PLANUL DE CALIBRARE ŞI MENTENANŢÂ

Anul :

Mentenanta Planificata: ◇ | Calibrarea Planificata: △

Mentenanta Curenta : ◆ | Calibrare Curenta: ▲

Mentenanta Aminată : ◆ | Calibrare Aminata : ▲

Numar de Inventar	Numele Dispozitivului , Utilajului , Echipamentului	Compania (Institutia) ce efectueaza mentenanta	Dispozitivul de calibrare		Garanţie - Contract (de întreţinere şi de calibrare)			Ianuarie				Februarie				Martie				Aprilie				Mai				Iunie				Iulie				August				Septembrie				Octombrie				Noiembrie				Decembrie	
			Da	Nu	Nu este	Este	Data de completare	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2

Elaborat de: Elena Chiriac, Bioinginer medical

Aprobat de:

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FORMULAR DE TRANSFER A DISPOZITIVULUI MEDICAL ÎN ALTĂ INSTITUȚIE

Informatia despre Dispozitiv	
Termenul de livrare a dispozitivului	
Pentru Sectia	
Numele Dispozitivului	
Producator (Brand)	
Modelul	
Nr de Serie	
Starea Dispozitivului	
Furnizat de catre:	
Accesorii: (Cablu, electrozi, accesorii , etc) Mentionati tipul si numarul.	

Informatie despre compania ce livreaza dispozitivul	
Numele Companiei	
Adresa	
Telefon	
Fax	
Oficiul fiscal	
Numărul de înregistrare fiscală	

Informatiile de mai sus scrise de pe dispozitiv. Informatiile sunt specificate de catre companie sa de spital .

Termeni de livrare

1. Firma va livra dispozitivul X spitalului , data ----- ora ----- anul -----
2. Firma livra dispozitivul cu conditia ca toate optiunile sa fie in deplina functionare (se va verifica).
3. raspunderea asupra transportul dispozitivului de la spital la firma si de la firma la spital se asigura de catre
4. Innainte de exploatare se face calibrarea dispozitivului din partea personalului biomedical
5. Dispozitivul ce nu trece calibreaza , nu se va permite exploatarea si se va intoarce la firma

Daca firma nu respecta punctele de mai sus pierderile suportate de catre spital sunt achitate de catre firma.

Spitalul predat

Semnatura

Firma primit

Semnatura

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FORMULAR PENTRU REPARAŢII

Se completează de către persoana care a depistat defectul

Secţia unde se afla Dispozitivul:	Data:
Dispozitivul defect:	Ora:
Numar de Inventar * :	
Descrierea problemei:	
* Numărul de pe eticheta dispozitivului	
Persoana care a depistat defectul:	Semnătura:

Se completează de către serviciul tehnic

Numele comercial al Dispozitivului:		Inceputul reparatiei: Data _____ Ora:_____
Modelul Dispozitivului:		Finalizarea reparatiei: Data _____ Ora_____
Dispozitiv:	☐ In Garanţie	☐ In afara garanţiei
Defectiune	☐ Reparatia efectuata de catre Serviciul Tehnic	☐ Reparatie efectuata de catre Companiile exterioare
Procesul de reparatie		
Piese de schimb		
Cauza defectiunii	☐ Eroarea Utilizatorului	☐ Termen de exploatare depasit
	☐ Abuz la exploatare	☐ Alte
Rezultat	☐ Defectiune inlaturata	☐ Neexploatabil (nu se mai poate folosi) ☐ Este intors la companie
	☐ Asigurare cu alt dispozitiv	☐ Altele
Explicaţie		

REPARATIA EFECTUATA	PREDARE EFECTUATA
Nume şi prenume	Nume şi prenume
Semnătura	Semnătura

Informatii despre dispozitiv			
Brand(Marca):		Model:	
Data primirii:		Numar de Inventar:	
Locul amplasarii dispozitivului:			
Garantie nu exista		Inceputul garantiei:	Data expirarii garantiei
Caracteristici ale dispozitivului			
NOTA: partea de jos trebuie creata conform fiecarui dispozitiv in parte .			
Capacitate		Puterea:	
Numarul de cilindri:		Repartizarea:	
Acumulator:		Fregventa:	
Tipul de ulei:		Cos :	
Filtru de aer:		Avertisment de volaj:	
Filtru de combustibil:		Izolarea:	
Filtru de ulei:			
Informatii despre intretinere (mentenanta)			
Planul de Mentenanta	Neincluse	Incluse	Perioada de Mentenanta (Intretinere) :
Contract de Mentenanta	Nu	Da	
In cazul cind mentenanta (intretinerea) se face de companiile externe;			
Data Inceperii Contractului de Mentenanta :		Data expirarii contractului de Mentenanta:	
Informatii de contact al centrului de service autorizat:			
In cazul cind mentenanta se face de catre serviciul tehnic;			
Procedurile de mentenanta urmate: NOTA: Este necesar de clasificat Procedurile indeplinite in cadrul mentenantei in concordanta cu perioadele de mentenanta (lunare , semestriale, anuale , etc) Ca urmare aceste liste vor fi folosite la alcatuirea instructiunilor de exploatare sau la intocmirea tabelelor de control pentru mentenanta .			
Dispozitivele(instrumentele) utilizate pentru mentenanta:			
Informatii despre calibrare			
Planul de calibrare Inclus	Neinclus	Perioada de calibrare (perioade):	
Calibrarea se efectueaza de companile externe			
Acordul (contractul) de calibrare cu compania:			
Informatii de contact			
Data Inceputului contractului de calibrare		Data expirarii contractului de calibrare	
calibrarea se face de catre departamentul tehnic biomedical			
Proceduri de calibrare NOTA: procedurile de calibrare vor fi enumerate .Ca urmare aceste liste vor fi folosite la alcatuirea instructiunilor de calibrare.			
Dispozitive utilizate pentru calibrare:			
Mentenanta / Calibrare / Inregistrarea defectelor			

Daca exista un registru de evidenta a procedurilor (lista de control , mentenanta, etc) de indicat in formular data si denumirea .

Data	Descrierea procesului	Persoana ce efectueaza
	-	-
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FORMULAR DE CONTROL SI MENTENANȚĂ PERIODICĂ

Numar de Inventar:

Numele Dispozitivului:

Localizarea Dispozitivului:

DESCRIEREA PROCEDURII	Efectuat	Neefectuat	DESCRIERE
Persoana ce efectueaza mentenanta			
Data efectuarii mentenantei			
Semnatura			

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MULȚUMIM PENTRU ATENȚIE