Institution Name: Directorate General of Specialized Medical Care, MOH

Document Title: Rehabilitation Medical Equipment & Devices Procedure

Approval Process

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Contents Table:

Acknowledgement

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Acronyms:

MOH	Ministry of Health
IRLS	Incident Reporting and Learning System

1. Introduction

An increasing number of medical equipment and devices are being used to support the delivery of care in both hospitals and primary care settings. The availability of such devices assists greatly in the ability of healthcare organizations to effectively monitor, treat and support the care of service users in the management of their medical conditions. It also allows for the management of care in a community setting and facilitates self-care for patients. Moreover, it is a requirement that all rehabilitation departments have in place a procedure on the deployment, monitoring and control of medical devices.

2. Scope

This procedure applies to all Medical rehabilitation services in the governmental institutions and private sectors. It also applies to companies who are contracted by the MOH to provide services in relation to any aspect of the management of medical equipment and devices.

3. Purpose

The purpose of this document is to outline a systematic approach to the management of medical devices and equipment across ministry of health.

4. Definitions

Medical equipment/devices: means any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose.

5. Procedure

5.1 Procurement

5.1.1 Any member of staff wishing to procure an item that is defined as a medical device or piece of equipment used for patient care' should seek advice from the head of the rehabilitation department who will then liaise with Biomedical Engineering Department to ensure that the device is being purchased from an MOH approved supplier.

5.2 Device Deployment

5.2.1 When equipment is allocated to a department, therapists have primary responsibility for the way they treat the equipment and the state in which it is left. These responsibilities can also include performance checks before use and routine maintenance, such as charging batteries.

5.3 Maintenance and Repair

5.3.1 All devices should be maintained and repaired in accordance with the manufacturer's instructions which should be helped locally for reference.

5.3.2 All electrical equipment should have an in date test safety certificate.

6. Responsibilities

6.1 Head of Rehabilitation Department is responsible for:

6.1.1 Written procedures on proper maintenance and cleaning of all equipment. A routine preventive maintenance schedule, semi-annual, is strictly adhered to for personnel and patient safety.

6.1.2 Records of maintenance and cleaning should be kept within the department.

6.2 All staff is responsible for:

6.2.1 Ensure that they are conversant with the content of this procedure and are appropriately trained and competent to use the medical/equipment devices which they are required to use as part of their duties.

6.2.2 Incident reporting and should follow the Policy and Procedure of Incident Reporting and Learning System (IRLS) in respect of incidents involving medical devices.

6.2.3 Their own health and safety and also other people who may be affected by their acts or omissions.

6.2.4 Report any problem relating to use, maintenance, and servicing or decontamination.

6.3 Biomedical Engineering Department is responsible for:

6.3.1 Provide expert advice on all aspects of the management of medical devices/equipment.

6.3.2 Develop and maintain the systems required to effectively and safely manage medical devices/equipment.

6.3.3 Carry out an ongoing program of monitoring to provide assurance in relation to the effectiveness of the systems in place for the safe management of medical devices/equipment.

6.3.4 Procurement of medical technologies

6.3.5 Evaluation of new medical technologies

6.3.6 Maintenance and service of medical technologies

6.3.7 Advise on the compliance requirements of relevant legislation

7. Document History and Version Control

Document History and Version Control			
Version	**Description of Amendment**	**Author**	**Review Date**
01	Initial Release	Nayfeen Al-Kharusi Grases Barrion	October / 2023
02			
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Nayfeen Al_Kharusi Grases Barrion	National Rehabilitation Services Taskforce For Polceis & Guidelines devlopment	Dr.Kadhim Jaffar Sulaiman	

8. Related Documents:

Policy and Procedure of Incident Reporting and Learning System (IRLS) (MOH/ DGQAC/ P&P/ 002/ vers.01) (found in Shifa)

9. References:

Title of book/ journal/ articles/ Website	Author	Year of publication	Page
Health & Safety Handbook: Safety Representatives Information Manual,	Chartered Society of Physiotherapy, London.	(1994)	
htt://www.hse.Ie/eng/Publications/services/Hospital		2014	
Provision and Use of working Equipment Regulations		1998	
Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'. Date:	Study Group 1 of the Global Harmonization Task Force	2012	

Appendix 1: Electrically Energized Equipment

The following electrotherapy items will be checked prior to use as per the following paragraph below:

- Ultrasound units
- Transcutaneous Electrical Nerve Stimulation **(**Tens)
- Interferential therapy
- Electrical stimulators
- Paraffin wax bath
- Moist heat packs
- Exercise equipment such as Treadmill, Bicycle and Stairmaster, Wall bars
- Electrical powered mobilization or treatment tables.

Prior to the operation of electrically energized equipment, the therapist will comply with the following:

- Know correct operation and application of equipment.
- Visually inspect equipment prior to use for damage to power cord, plug, equipment dials and meters, and treatment accessories prior to use.
- Any equipment failing the visual inspection will be considered unsafe for use and should be tagged "unsafe, do not use" before being set aside.
- Report unsafe equipment to the head of rehabilitation department.