

Institutional Handbook of Operating Procedures
Policy 09.13.22

Section: Clinical Policies	Responsible Vice President: EVP and CEO Health System
Subject: General Procedures	Responsible Entity: Business Operations and Facilities

I. Title

Handling of Malfunctioning or Defective Equipment, Devices, and Supplies

II. Policy

To ensure the safety of patients and others, all UTMB employees are expected to identify, remove, repair, or replace items that have caused or could cause harm to patients, employees, and others.

III. Removal of Device

If equipment, devices, or supplies appear to be defective, or are believed to have malfunctioned, the items shall be removed from service and tagged. Tags are available from Clinical Equipment Services.

IV. Removal of Tag from Device

Tags identifying the item as defective or malfunctioning shall not be removed by personnel other than the designated repair department or contracting agency.

V. Inspection

Department directors or their designees shall assure that the item is inspected and repaired as needed by the appropriate department/ technician.

VI. Incidents Caused by Equipment Malfunctions

If there is reasonable probability to suspect that the item may have caused an incident which contributed to the serious illness, serious injury, or death of a patient of the facility, the attending physician, and the Risk Management Department shall be notified immediately by telephone. If the item malfunctioned while in use it should not be repaired or disposed of until an investigation is complete and such action is authorized by the Risk Management Department.

Additionally, the incident should be documented using the incident reporting tool as outlined in [IHOP Policy 9.13.13, Unusual Event Reporting](#).

VII. Medical Recall Report

When UTMB is notified by a manufacturer or other entity of a medical recall or “alert” status, this information shall be handled per [IHOP Policy 9.13.11, Medical Device/Supply Recall Follow-up and Reporting](#).

VIII. Related UTMB Policies and Procedures

[UTMB Clinical Equipment Master Plan](#) (section from the EOC Master Plan)

IX. Dates Approved or Amended

<i>Originated: 04/01/1994</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>
10/03/2013	09/10/2009
	10/31/2019

X. Contact Information

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