Handling of Malfunctioning or Defective Equipment Devices and Supplies

Audience All employees in the Pulmonary Function Laboratory.

Policy To ensure the safety of patients, employees and others. Employees are expected to identify, remove, repair, or replace items that pose potential safety hazards.

Removal of Device

If equipment, devices, or supplies appear to be defective, or are believed to have malfunctioned, the item shall be removed for service and tagged. Staff will contact CES (Clinical Equipment Services) for malfunctioning or defective devices. If contaminated with blood or body fluids, clean and decontaminate it and attach completed Laboratory Equipment Decontamination Form (obtained from EH&S online form). The tag should indicate the name, model, serial number of the item and the reason for the repair or removal. Contracted Sodexo (CES contractor) will manage filing of an FDA Medical Device Report (MDR), if necessary.

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.

Inspection & Repair

The Manager or designee shall assure that the equipment is inspected, repaired, and certified for return to service by the appropriate service technician.

Incident Management

If there is reasonable probability to suspect that the item may have caused an incident that contributed to the serious illness, serious injury or death of a patient of the facility or an employee, notify the Program Manager immediately by telephone. Call Quality and Healthcare Safety (Galveston Campus) immediately. (Refer to IHOP 9.13.16 Sentinel Events).

If the item malfunctioned while in use it should not be repaired or Disposed of until an investigation is completed and Risk Management Authorizes such action. Additionally, the incident should be documented The Patient Event Reporting System (RL Datix) on the iUTMB website as outlined in IHOP Policy 9.13.13 Unusual Event Reporting.

Recalls and Alerts

Any recalls and alerts sent directly to the department should by copied to Quality and Healthcare Safety. Investigation and follow-up should begin immediately at the department level. Refer to IHOP Policy 9.13.11 Medical Device/Supply Recall Follow-up and Reporting for additional guidelines in responding to recalls.

References UTMB IHOP Policy 9.13.22
FDA Medical Device Regulations
http://fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm

This form documents the approval and history of the policies and procedures for the Pulmonary Function Laboratory. The Medical Director signs all policies verifying initial approval. Annually thereafter, the Director and/or designee may approve reviews and revisions.

Date	Approved by:	Signature
11/08	V. Cardenas, MD Medical Director Pulmonary Laboratory	
6/09	V. Cardenas, MD No changes to the policy	
7/10	V. Cardenas, MD No changes to the policy	
2/12	A. Duarte, MD Medical Director Pulmonary Function Laboratory No changes to the policy	
5/14	A. Duarte, MD Medical Director Pulmonary Function Laboratory No changes to the policy	
8/16	A. Duarte, MD Medical Director Pulmonary Function Laboratory No changes to the policy	
11/17	A. Duarte, MD Medical Director Pulmonary Function Laboratory No changes to the policy	
9/19	A. Duarte, MD Medical Director Pulmonary Function Laboratory No changes to the policy	
2/22	A. Duarte, MD Medical Director Pulmonary Function Laboratory Changes to the policy	
8/23	A. Duarte, MD Medical Director Pulmonary Function Laboratory No changes to the policy	