

University of Texas Medical Branch	Effective Date:	Sept 09
Pulmonary Function Clinic	Revised Date:	Jul 23
Policy 1-11 Medical Device/Supply Recall: Follow-up and Reporting	Review Date:	Jul 23

Medical Device/Supply Recall: Follow-up and Reporting

Audience All Pulmonary Function Laboratory Staff

Policy The PFT Laboratory adheres to IHOP 09.13.11 regarding medical device/supply recalls. The Program Manager is responsible for ensuring the department's compliance with this policy.

Alert Notification & Response

UTMB subscribes to the ECRI Alerts Tracker Hazard and Recall System for management of medical equipment and device recalls. Every Friday, ECRI sends an email notification of hazards and recalls to the Program Manager. The Program Manager is expected to review each recall in the Notice and submit a response within the specified timeframe based on the alert classification. (See ERCI Documentation Instructions). The response should include a summary of actions taken, to Include:

- Quantity of affected product;
 - Actions taken to identify and, if applicable, recall/remove/replace product;
 - Final disposition of product, including # dispositioned.
- The Program Manager or designee will submit the response in the online ECRI tracking system.

Any notices sent by manufacturers directly to PFT Laboratory will be sent to Manager, Technical Consultant and/or Medical Director immediately. Additional information for ABL 90 analyzer is in policy 01-07.

Document Maintenance

Notices sent by manufacturers will be kept on file in the Managers office.

References UTMB IHOP Policy 9.13.11 Medical Device/Supply Recall:
Follow-up and Reporting
ERCI Documentation Instructions

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
9/09	V. Cardenas, MD Medical Director Pulmonary Laboratory No changes to the policy	
7/10	V. Cardenas, MD	

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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
8/21	A. Duarte, MD Medical Director Pulmonary Function Laboratory No changes to the policy
7/23	A. Duarte, MD Medical Director Pulmonary Function Laboratory Changes to the policy