

(717) 783-1379

April 26, 2010

[REDACTED]  
[REDACTED]  
Allentown Women's Center  
1409 Union Boulevard Rear  
Allentown, Pennsylvania 18109

Dear [REDACTED]

On March 31, 2010, an onsite investigation was conducted at Allentown Women's Center as follow up to the Department of Health's receipt of two serious event reports. The survey findings revealed that the clinic failed to provide services in accordance with 28 Pa. Code Chapter 29, Subchapter D, Ambulatory Gynecological Surgery in Hospitals and Clinics. Specifically, the clinic did not meet the following requirements:

29.33 (1) Each medical facility shall have readily available equipment and drugs necessary for resuscitation. If local anesthesia is utilized to perform an abortion in a medical facility during the first trimester, then the following equipment shall be ready to use for resuscitation purposes:.....(iii) Assorted size airways and endotracheal tubes ....(vi) Intravenous fluids including blood volume expander)

The onsite investigation found that resuscitative equipment was not readily available. Findings include:

Procedure room #1: one (1) endotracheal tube expired 8/2008, one (1) endotracheal tube expired 11/09, one laryngeal mask expired 10/2008 and one (1) laryngeal mask expired 12/2204. Procedure room #2: one (1) 500cc bag of 0.9% Na Chloride expired 8/08, Epinephrine 1 vial expired 6/09, Atropine 0.4mg/ml expired 2/10, one (1) vial Flumazenil expired 1/10, one (1) laryngeal mask expired 12/04, one (1) laryngeal mask expired 7/07, one (1) laryngeal mask expired 8/08, one (1) endotracheal tube expired 6/08 and one (1) endotracheal tube expired 8/08.

Expired items were found mixed with current items with no assurance that at the time of an emergency an appropriate current item, and not an expired item, would be used. Upon questioning, the Director of Nursing acknowledged there was no way for staff to distinguish whether using a current or expired item. The Director of the facility acknowledged that the facility had neither developed nor was following any procedures to ensure that when resuscitation of an abortion patient was required current, not expired, drugs and equipment





1998

*Allentown  
Women's  
Center®*

June 10, 2010

Division of Home Health  
Pennsylvania Department of Health  
Harrisburg, PA 17104

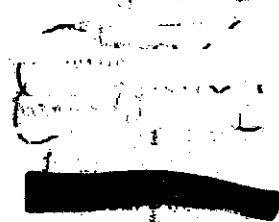
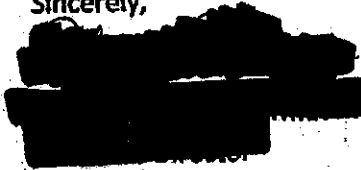
In response to your letter dated April 26, 2010 outlining the findings of the onsite investigation that was conducted on March 31, 2010, we are submitting a written plan of correction for your review.

In addition to the written plan of correction, we are providing the following:

1. Job descriptions for the new positions of Nursing Coordinator and Risk Manager to replace the Director of Nursing position;
2. A copy of Allentown Women's Center's revised monthly equipment check policy and log forms;
3. A copy of an equipment inspection report, which includes inspections of blood pressure cuffs, performed by Muhlenberg Medical Repair on May 12, 2010;
4. A copy of Allentown Women's Center Surgical Abortion Protocols, Page 3, Section III, Detection of Pregnancy policy;
5. Copies of inspection certificates on all of our ultrasound equipment, dated May 26, 2010; and
6. A copy of Allentown Women's Center's last Patient Safety Meeting minutes dated April 6, 2010 and an email to committee members specifying dates for the next three meetings.

Please contact me at (610) 770-9077 ext. 11 with any questions about this plan of correction as well as to inform us if the Pennsylvania Department of Health is satisfied with this plan of correction. We appreciate your feedback and look forward to hearing back from you.

Sincerely,



*"All Women Count at AWC"*

1409 Union Blvd., Rear, Allentown, PA 18109  
(610) 770-9077 (877) DLAC AWC  
Fax: (610) 770-9220

[www.allentownwomenscenter.com](http://www.allentownwomenscenter.com)  
[www.myspace.com/allentownwomenscenter](http://www.myspace.com/allentownwomenscenter)  
[contact@allentownwomenscenter.com](mailto:contact@allentownwomenscenter.com)

**PENNSYLVANIA DEPARTMENT OF HEALTH ONSITE INVESTIGATION**  
**MARCH 31, 2010**  
**ALLENTOWN WOMEN'S CENTER PLAN OF CORRECTION**

**Staffing Changes:** Effective April 1, 2010, the Director of Nursing was terminated from her employment at the Allentown Women's Center. Her responsibilities have been replaced by the Nursing Coordinator and the Risk Manager. Job descriptions are attached.

**Requirement: 29.33 (1)** Each medical facility shall have readily available equipment and drugs necessary for resuscitation. If local anesthesia is utilized to perform an abortion in a medical facility during the first trimester, then the following equipment shall be ready to use for resuscitation purposes:....(iii) Assorted size airways and endotracheal tubes...(vi) Intravenous fluids including blood volume expanders.

**Findings:** Expired items were mixed with current items [in procedure rooms] with no assurance that at the time of an emergency an appropriate current item, and not an expired item, would be used.

**Plan of Correction:** All expired medications and stock in procedure rooms was immediately replaced. Immediate feedback was given to medical staff about checking medications and supplies for expiration on a daily basis. A policy was implemented to ensure that employees who are restocking procedure rooms are rotating older stock to the front and putting newer stock in the back to ensure that older supplies and medications do not remain on the shelves. In addition, expiration dates have been marked boldly in dark permanent marker when medications and supplies are received so that they are clearly labeled on each item. Each month medical staff will complete a monthly checklist that will verify that supplies and medications have been rotated and ensure that any supplies or medications which are about to expire are removed and discarded appropriately. The Nursing Coordinator will ensure that the medical staff are completing their responsibilities each month and participate in the monthly rotation. A copy of the revised checklist / policy is attached.

**Findings:** There was no evidence that automatic blood pressure cuffs were inspected to ensure they were in proper working order.

**Plan of Correction:** All blood pressure cuffs will be calibrated and inspected annually. The automatic blood pressure cuffs that the Allentown Women's Center was using at the time of inspection have been discarded and are no longer being used. If AWC decides to replace the automatic blood pressure cuffs, they will be serviced and inspected annually and also tested monthly for accuracy against manual cuffs and batteries will be changed at least monthly. The 2010 calibration/inspection report for the manual blood pressure cuffs is attached. The operational and performance check for the Critikon / Dinamap used in the recovery room is attached.

**Requirement: 29.33 (5)** Prior to the performance of any abortion, appropriate methods shall be used to determine positive evidence of pregnancy by test result, history, and physical exam, or other reliable means; and such findings shall be entered in the medical record of the patient.

**Findings:** 1) There was no assurance that pregnancy tests performed at the facility were accurate, or that results secured through the ultrasounds were supported by histories, physical examinations or other reliable means. 2) The ultrasound machines had not had maintenance performed on them annual per manufacturer guidelines.

**Disputed Finding and Explanation:** The Allentown Women's Center disputes the first finding that there was no assurance that pregnancy tests were accurate or that results secured through ultrasounds were supported by histories, physical examinations or other reliable means. Investigators reviewed medical records showing that every patient completes medical history information about her last menstrual period and that the physician performs a manual pelvic exam prior to the start of every abortion procedure. These results support the findings of the ultrasound exam. In addition, investigators were given a copy of Allentown Women's Center Surgical Abortion Protocols, where it clearly states on page 3, Section III. Detection of Pregnancy, that in the event that an ultrasound is negative, a urine pregnancy test will be performed. If positive, the patient is counseled regarding ectopic pregnancy, referred for additional tests as needed, and/or rescheduled for a repeat ultrasound at a later date to confirm an intrauterine pregnancy prior to abortion. If the pregnancy test result is negative, the patient is counseled that she is not pregnant and given referrals for continued care as needed. Investigators were provided with documentation of daily laboratory control tests assuring the accuracy of urine pregnancy tests.

**Plan of Correction:** The Allentown Women's Center will complete annual maintenance on ultrasound machines per manufacturer guidelines. Certificates of maintenance inspections on all ultrasound equipment are attached.

**Requirement: Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. 1303.310 (a) (2)** (relating to the patient safety committee) requires that the patient safety committee shall meet at least quarterly.

**Finding:** Documentation showed that the safety committee only met three (3) times a year; not quarterly as required.

**Plan of Correction:** The Patient Safety Officer at the time of the site review has since been terminated and replaced by the Nursing Coordinator, [redacted]. The Risk Manager, F. [redacted], has been delegated to schedule meetings, keep minutes, and issue reminders to committee members. A PSC meeting was conducted on April 6, 2010, and the next three meetings have already been scheduled according to the requirements outlined in the Allentown Women's Center Patient Safety Plan. The next three meetings are scheduled for July 13 at 3pm, October 12<sup>th</sup> at 3pm, and January 11<sup>th</sup> at 3pm. The Executive Director will sign off on all

meeting minutes and confirm with the Patient Safety Officer that the meetings have been conducted as scheduled on a quarterly basis. Minutes of the most recent meeting and an email discussing scheduling of future meetings are attached.

Respectfully Submitted,

[REDACTED]

[REDACTED]

Allentown Women's Center  
1409 Union Blvd., Rear  
Allentown, PA 18109

[REDACTED]

Allentown Women's Center  
1409 Union Blvd., Rear  
Allentown, PA 18109

## **JOB DESCRIPTION: Nursing Coordinator**

**Responsible to: Medical Director, Executive Director, Assistant Director**

### **Primary Duties:**

- I. Administration**
  - a. Participate in weekly management meetings to discuss staffing, training, services, and supplies;
  - b. Participate in biannual medical committee dinners;
  - c. Be available to staff to answer questions and provide guidance as needed. Seek input from supervisors as appropriate.
  - d. Train new medical staff on equipment checks, daily checklists, and other daily and monthly responsibilities. Oversee training checklists for new medical employees and coordinate with staff doing hands-on training.
  - e. Train new ultrasound staff and assure they have completed both hands-on and didactic training (textbook and CD-Rom).
  - f. Maintain adequate medical inventory, including supplies, equipment, and pharmaceuticals; find lowest prices, place orders, and complete monthly inventory checks. Teach staff the First-In First-Out (FIFO) system so that all staff uses the oldest supplies first.
  - g. Maintain a calendar that lists medication expiration dates and be prepared to replace expired medications on or before their expiration dates.
  - h. Maintain relationships with vendors we order from.
  - i. Coordinate with Risk Manager or other administrative staff to ensure that medical equipment maintenance and repairs and other small repairs are completed in a timely manner.
  - j. Maintain relationship with University of Washington stem cell research program and coordinate with them regarding sending of specimens and supplies.
  - k. Schedule and facilitate medical staff meetings as needed;
  - l. Professionally and sensitively triage patient, clinic, and employee problems as they arise and coordinate with appropriate staff.
  
- II. Patient Services**
  - a. Assist in line-jobs and cover lunch breaks as needed; primary float/traffic person in the medical area.
  - b. Train and work in line jobs as scheduled including, but not limited to, counseling, telephone counseling, check-in, recovery room, ultrasound, laboratory, gyn assisting, procedure assisting, traffic, back float, and autoclave.
  - c. Assist physician conduct telephone consults with patients complying with 24-hour waiting period law as needed;
  - d. Set up procedure room for Essure patients and assist in Essure procedures. Assure that Essure adequate inventory of Essure supplies.
  
- III. Risk Management**
  - a. Oversee adherence to medical protocols during clinic and that no one changes protocol without approval of both the Medical Director and the Executive Director;
  - b. Oversee general cleanliness of exam rooms, autoclave, and recovery and delegate duties prn;
  - c. Monitor the Mifeprex follow-up log each week and contact patients who do not show for follow-up. Assure that all patients have been logged and coordinate with Risk Manager to send certified letters to patients who do not show by phone. Document and keep copies of all attempts to contact patient in the patient record.
  - d. Coordinate with Risk Manager to review records for patients who had complications and were treated elsewhere and contact patient by phone to follow-up. Review with patient's physician and Medical Director. Review with Executive Director at weekly meetings.
  - e. Coordinate with Risk Manager to keep track of patients needing medical clearance prior to surgery and follow-up with patients if needed.



- f. Maintain adequate drug inventory and follow DEA regulations for medication purchase and storage. Ensure that accurate logs are kept for narcotics and other drugs.
- g. Enter Essure patients in Essure follow-up log, schedule Essure follow-up appointment and coordinate with Risk Manager to schedule HSG appointment.
- h. Make sure all tissue specimens sent out to local labs and UW are logged in post-ab book on the date they are sent and that the pathology report results are logged in on the date received. Review pathology reports with Medical Director and have him sign off. Log any patients needing further follow-up in the post-ab book and contact patients to review results as needed.
- i. Coordinate with Risk Manager on reporting to the Department of Health any post-abortion pathology reports that shows evidence of absence of pregnancy, live birth, or viability within 15 days of the date of the report.
- j. Fill the role of Patient Safety Officer and manage and comply with all of the guidelines outlined in the Allentown Women's Center Patient Safety Plan. Assure that all incidents, infrastructure failures, and serious events are reported within 24 hours to the Patient Safety Authority through the PA-PSRS system.
- k. Conduct quarterly Patient Safety Committee meetings on or about the 2<sup>nd</sup> week of January, April, July, and October. Review Patient Safety Authority publications and newsletters and share at the PSC meetings. Review minutes of PSC meetings at staff meetings. Attend state PSA trainings.
- l. Assure that Executive Director and Medical Director are alerted to all safety incidents involving patients and staff within a few hours of the incident occurring. Make arrangements for another person to monitor patient safety activity and file reports when you are not in the office.
- m. Inform Risk Manager of all staff medical incidents including falls, needle sticks, etc. and coordinate with Risk Manager and Assistant Director as appropriate to triage incident management and follow-up.
- n. Organize and implement a chart audit system for both gyn and abortion services to track and correct errors made in charting. Pull 20 random abortion charts and 10 gyn charts from the previous month and review for errors. Provide a list of errors for staff to correct and return when completed. Report about chart audits at quarterly staff meetings and discuss ways to prevent charting errors.
- o. Coordinate with the Gyn Services Coordinator to log all ab patients needing further gyn follow-up for non-ab related issues (IUD preps, cysts, etc.).
- p. Collaborate with the Medical Director and Risk Manager to implement quarterly medical emergency drills
- q. Coordinate with Risk Manager about updating medical forms and training materials as changes occur.
- r. Rotate in monthly equipment checks with other medical staff and follow-up with those doing checks each month for reports and to ensure adequacy of crash cart.

#### IV. Other

- a. Keep up to date on all regulations and follow Department of Health and NAF regulations at all times.
- b. Be alert to security issues and report concerns and incidents promptly to the Executive Director
- c. Set morale and tone of the medical area, including "care and feeding" of physicians and CRNAs

#### V. Provide other functions as requested by the Executive Director or Medical Director.

**JOB DESCRIPTION: Risk Manager**

Responsible to: Executive Director, Medical Director, Assistant Director

Collaborates with: Nursing Coordinator

Primary Duties:

- I. Administration**
- a. Participate in weekly management committee meetings to discuss patient complications and other risk management issues that arise week to week;
  - b. Participate with the Medical Committee dinner meetings biannually and keep minutes
  - c. Fill the role of On-Call Coordinator and set the on-call phone schedule and train new on-call staff;
  - d. Assist in line-jobs as needed; provide staff with coverage over lunch breaks, etc.;
  - e. Coordinate with Nursing Coordinator to assure that medical equipment repairs, maintenance and other small repairs are completed in a timely manner;
  - f. Attend and take minutes at medical staff meetings scheduled by Nursing Coordinator.
  - g. Be alert to security issues and report incidents promptly to Executive Director;
  - h. Facilitates regular trainings and inservices led by appropriate personnel to educate staff in best practices in the following areas: OSHA / Bloodborne pathogens, CPR and emergency equipment use, appropriate medical documentation, medical emergencies, security and disaster scenarios.
  - i. Conduct OSHA / Bloodborne Pathogen orientation, HIPAA training, review medical and emergency protocols, and Patient Safety Plan orientation for new staff and keep records of all trainings. Update Bloodborne Pathogen Exposure Control Plan annually and as changes occur.
  - j. Keep records of annual PPD testing and coordinate with RN to administer tests. Keep logs of Hep B vaccinations and remind staff when next vaccination is due.
  - k. Assist with new physician, resident, and medical student/intern orientations and obtain paperwork on all visiting residents and students.
  - l. Schedule annual CPR training for all medical staff; obtain CPR certification from independent contractors
  - m. Maintain copies of current licenses, CPR certifications, malpractice insurance coverage, CVs, etc. for all MDs, CRNPs, RNs, and CRNAs and update personnel information in the Department of Health notebook quarterly and when changes occur
  - n. Obtain a list of board certified pathologists from laboratories we send specimens to at least once per year and as lab personnel changes. Keep copies of pathologist CVs on file.
- II. Risk Management**
- a. Review reports received from on-call staff and coordinate with Nursing Coordinator to follow-up on patient calls and obtain medical records.
  - b. Review all patient complications with Medical Director and Executive Director.
  - c. Check the Mifeprex log each month to assure that all Mifeprex patients were logged, and follow-up calls and letters have been sent to patients who did not show. Report all Mifeprex failures to Danco (in addition to the state and NAF). Assist Nursing Coordinator with patient follow-up as requested.
  - d. Submit complication reports to the State within 30 days of patient's first visit and submit NAF complication reports once per month. Review all reports with Executive Director prior to sending and keep copies in Risk Management notebook.
  - e. Report all medical abortion failures to DANCO in addition to the state and NAF
  - f. Follow-up with all Essure sterilization patients, schedule HSG appointments, send patients reminder letters and give patients confirmation calls prior to HSG appointments.
  - g. Collaborate with Nursing Coordinator and GYN Services Coordinator to oversee adherence to medical protocols; update written abortion protocols and gyn practice guidelines as changes occur;
  - h. Update patient education materials and consent forms as changes in protocol and patient education information occur. Collaborate with other administrative staff as needed.

Revised 6/10/10

- i. Function as the HIPAA and OSHA compliance officer - assure and oversee compliance with OSHA, Department of Health, and HIPAA regulations;
- j. Update Department of Health Manual quarterly and keep a list of when documents in the manual need renewal; those expiring in the next quarter should be renewed in the current quarter;
- k. Prepare for and help conduct inspections from HIPAA, OSHA, Department of Health, and third party payors; Conduct mock inspections at least once annually
- l. Serve on the Patient Safety Committee, schedule quarterly meetings and keep minutes. Assist PSO with filing reports and attend state training meetings.
- m. Review requests for records and coordinate with Administrative Assistant to copy records and obtain necessary fees; review all records requests with Executive Director prior to sending
- n. Assign and oversee equipment checks and assure they are completed each month; participate in monthly equipment check rotation.
- o. Review crash cart checklists and medical end of day checklists each month for completeness. Collaborate with Nursing Coordinator to address any issues that arise.
- p. Ensure that MSDS log is current and any new products are listed within.
- q. Collaborate with the Nursing Coordinator and Medical Director to implement quarterly medical emergency drills
- r. Collaborate with the Escort and Security Coordinator to implement quarterly security emergency drills and test alarm system with altronics.
- s. Coordinate with Nursing Coordinator to keep track of patients needing medical clearance prior to surgery and follow-up with the patients if necessary;
- t. Coordinate with Nursing Coordinator to check the post-abortion book and the Recovery Room follow-up log each day for follow-up calls that need to be made to patients with post-op medical problems.
- u. Monitors sterilization logs each month for completeness.
- v. Assist Nursing Coordinator with chart review as needed.
- w. Continually monitors regulatory policies for ambulatory surgical centers and abortion clinics from agencies within the abortion care field (NAF, ACN) and federal, state, county, city laws, and responds to any changes by reviewing with the Board of Directors, updating internal policies and informing staff.
- x. Schedule and oversee shredding for documents older than 7 years.
- y. Complete a monthly back-up of the Allentown Women's Center website.

### III. Other

- a. Train and work line jobs as requested. It is expected that administrative work for this position will be reviewed daily, but completed primarily during non-clinic days and secondarily during downtime when working line jobs. Risk Manager is expected to work an average of 8 hours per day, 40 hours per week including line jobs.
- b. Be alert to security issues and report concerns and incidents promptly to the Executive Director
- c. Set morale and tone of the medical area, including "care and feeding" of physicians and CRNAs

### IV. Provide other functions as requested by the Executive Director or Medical Director.

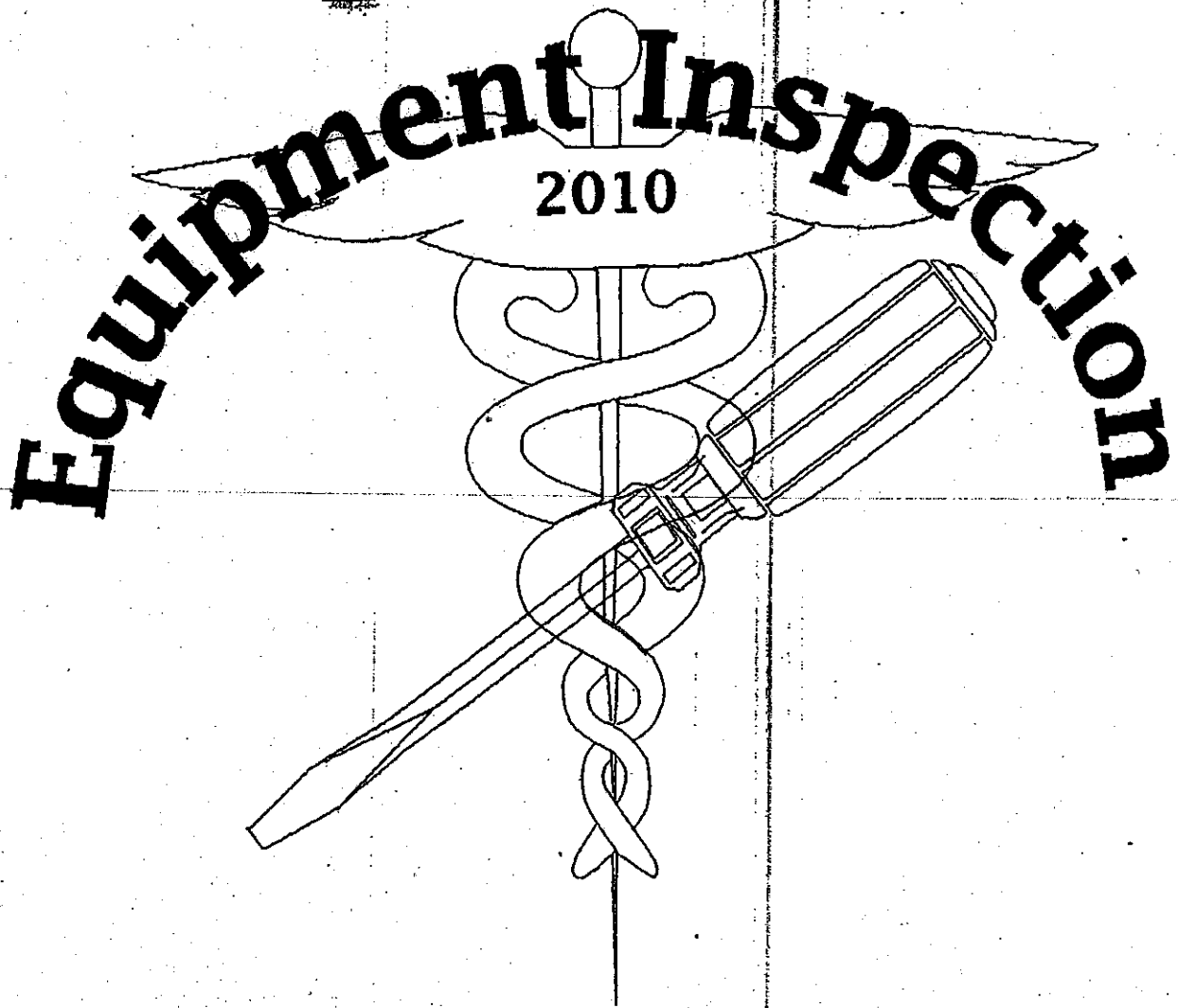
Monthly Equipment, Medication Supply Checklist

Policy: All medical staff are required to rotate monthly to complete this checklist to ensure that a) all machines are working properly; b) rotate stock so that the oldest stock (meds and supplies) is used first and dispose of any expired stock; c) make sure there are clearly marked expiration dates on all medications and supplies; d) set aside / discard any medication or supplies that are about to expire; and e) add anything we need to order on the supply list.

My initials in each box indicate that I have done or have assured that the following have been done:

2010 STAFF ASSIGNED TO COMPLETE:	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEPT	OCT	NOV	DEC
RR-Check exp on all meds and supplies. Check meds in nurse station cabinet, rotate control pill cabinets, and refrigerator. Rotate stock so that oldest stock is used first. Check manual cuff for accuracy.												
Check oxygen tanks in procedure rooms and recovery rooms. Dust hanging mobiles in procedure rooms.												
Check all drawers and cabinets in all procedure rooms and set aside expired instruments (re-autoclave), gloves, and medication (and those about to expire). Rotate stock so that oldest stock is used first. Assure expiration dates are clearly marked.												
Check refrigerators in recovery room, lab, and freezer pm. Sterilization, Defrost as needed, Defrost.												
Assure that all supplies and medications in the crash cart and hemorrhage kit are not expired and replace any that are about to expire. Assure that no meds or supplies are missing.												
Autoclave - Check all cabinets for instruments needing re-sterilizing. Check expiration dates of all stock and meds and rotate stock so that order sheet is used first. Complete inventory order sheet for Nursing Coordinator.												
Check the canulas in each procedure room and over the freezer for expiration dates. Rotate older stock to procedure rooms and set aside supplies that are about to expire.												
If applicable: Replace batteries of automatic blood pressure cuffs. Check readings of cuffs and set aside cuffs with any discrepancies for service.												
Traffic Station / Supply room - check exp dates and clearly mark on all meds, needles, and supplies. Rotate older stock forward.												

# Muhlenberg Medical Repair, Inc.





## Muhlenberg Medical Repair, Inc.

P.O. Box 39  
Mohnton, PA 19540-0039

Telephone (610) 777-9693  
Fax (610) 777-0897

Equipment tested has been checked for excessive electrical chassis leakage and proper earth bond resistance.

Test equipment complies with the standards set forth by the following:

IEC 60601, IEC 60601-1, AAMI, NFPA 99, and the newly published standard for in-service and after repair testing of medical electronic devices, the IEC 62353.

**Muhlenberg Medical Repair, Inc.**

**We Service:**  
EKG's, Sterilizers, BP Units, Centrifuges,  
Suction Pumps,  
Exam Tables and Much More

**We Provide:**  
Electrical Safety Inspections, Replacement Parts, Quick Response

Ext. 203  
Phone: 610 777-9693 Fax: 610 777-0897

Medical Equipment Repair Service  
Since 1983



# Muhlenberg Medical Repair, Inc.

## Concise Latest Test Results

From: 5/12/2010 To: 5/12/2010

Client: \_\_\_\_\_ Company: Allegheny Women's Center Address: 1469 Union Blvd

MMR009853	Sterilizer	5/12/2010	Regular	Pass	DML
MMR009854	Sterilizer	5/12/2010	Regular	Pass	DML
MMR009855	Defibrillator	5/12/2010	Regular	Pass	DML
MMR009856	Diagnostic Ultrasound	5/12/2010	Regular	Pass	DML
MMR009857	Diagnostic Ultrasound	5/12/2010	Regular	Pass	DML
MMR009858	Diagnostic Ultrasound	5/12/2010	Regular	Pass	DML
MMR009859	LCD Monitor	5/12/2010	Regular	Pass	DML
MMR009860	Hystoscope	5/12/2010	Regular	Pass	DML
MMR009861	Light Source	5/12/2010	Regular	Pass	DML
MMR009862	Centrifuge	5/12/2010	Regular	Pass	DML
MMR009863	Hemopoint H2	5/12/2010	Regular	Pass	DML
MMR009864	Card Test Rotator	5/12/2010	Regular	Pass	DML
MMR009865	Patient Monitor	5/12/2010	Regular	Pass	DML
MMR009866	Colposcope	5/12/2010	Regular	Pass	DML
MMR009867	Microscope	5/12/2010	Regular	Pass	DML
MMR009868	Office Kart	5/12/2010	Regular	Pass	DML
MMR009869	Patient Monitor	5/12/2010	Regular	Pass	DML



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P.O. Box 39  
Mohnton, PA 19540-0039

Telephone (610) 777-9693  
Fax (610) 777-0897

Allentown Women's Center  
1409 Union Blvd.  
Allentown, PA 18109

Hello [REDACTED]

Here is the list of Blood Pressure Units that were calibrated/inspected on 5/12/2010.

<u>Manufacturer</u>	<u>Model</u>	<u>Serial Number</u>
Tycos	Pocket Aneroid	0506204213
Tycos	Pocket Aneroid	0505173108
Tycos	Pocket Aneroid	0406253105
Tycos	Pocket Aneroid	0201083645
PSS	Pocket Aneroid	053970
PSS	Pocket Aneroid	125115

Gauges were calibrated, cuffs, bladders, bulbs, valves were checked for proper operation.

Muhlenberg Medical Repair, Inc.

Medical Equipment Repair Service  
Since 1983





# Muhlenberg Medical Repair, Inc.

P.O. Box 39  
Mohnton, PA 19540-0039

Telephone (610) 777-9693  
Fax (610) 777-0897

## Patient Monitor Performance Results

Account Name: Allegheny Women's Center

Account Location: Allegheny PA Room \_\_\_\_\_

Date: 5 / 6 / 10 Next Due: 5 / 30 / 11

Manufacture: Critikon Model: DINAMAP 845XT

Unit Sn.: 43739

IC #: \_\_\_\_\_ Technician: SJU

Visual Inspection: Power Cord to Chassis OK  
 Line Cord OK  
 Power Cord Plug OK

Battery Display	Pass <u>—</u> Fail <u>—</u>	<u>N/A</u>
Switches	Pass <u>✓</u> Fail <u>—</u>	
Chassis	Pass <u>✓</u> Fail <u>—</u>	
Receptacles	Pass <u>✓</u> Fail <u>—</u>	
Patient Cable	Pass <u>✓</u> Fail <u>—</u>	
Lamps	Pass <u>✓</u> Fail <u>—</u>	
Alarms	Pass <u>✓</u> Fail <u>—</u>	
Display Reading 1	<u>168</u> Actual	<u>168.5</u>
Display Reading 2	<u>119</u> Actual	<u>118.0</u>
Display Reading 3	<u>53</u> Actual	<u>54.0</u>
Results: Report Only	Acceptable <u>✓</u> Unacceptable <u>—</u> Action Required <u>—</u>	

Comments \_\_\_\_\_

**Invoice**

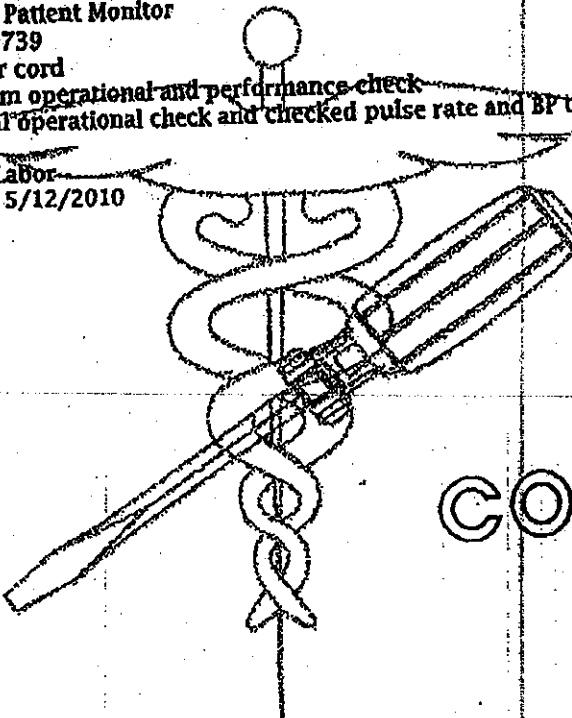
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 Mohnton, PA 19540-0039  
 (610) 777-9693 Fax (610) 777-0897

5/19/2010 20322

Allentown Women's Center  
 1409 Union Blvd  
 Attn: Accounts Payable  
 Allentown, PA 18109

Allentown Women's Center  
 1409 Union Blvd  
 Allentown, PA 18109

Jen Net 15 6/3/2010 SJV 5/18/2010 MMR

1	<p>Critikon/Dinamap Patient Monitor          MD. 845XT SN. 43739          1 cuff and 1 power cord          (Request to perform operational and performance check          (Performed general operational check and checked pulse rate and BP on parameter          checker.)          Hr. Tech. Service Labor          Returned to client 5/12/2010</p> 	110.00	110.00T
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COPY

\* Accounts not paying invoices by set terms may require payment by credit card on future service calls. Thank you for your prompt payment.

We accept Master Card, VISA & American Express.  
 Please call (610) 777-9693 ext. 202 to make payment.

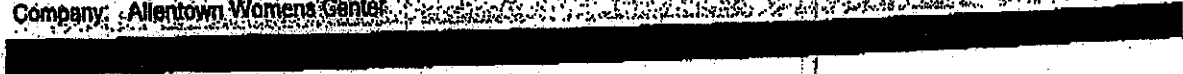
Subtotal	\$110.00
Sales Tax (6.0%)	\$6.60
<b>Total</b>	<b>\$116.60</b>
Payments/Credits	\$0.00
<b>Balance Due</b>	<b>\$116.60</b>



# Muhlenberg Medical Repair, Inc.

## Test Certificate

Company: Allentown Womens Center



Asset: MMR009856      Description: Diagnostic Ultrasound      Model: 2205675      Serial No: 237051  
 Applied Parts: < None >      Manufacturer: GE

Test	Mains	SFC	AP	Type	Limit	Result	Unit	Status
Earth Continuity +200mA DC	---	---			0.30	0.188	Ohm	Pass
Earth Continuity -200mA DC	---	---			0.30	0.188	Ohm	Pass
L-PE Voltage	---	---				122	V	Informati
L-NE Voltage	---	---				2	V	Informati
EUT Line Current	---	---				0.8	A	Informati
Load	---	---				0.1	KVA	Informati
Equipment Leakage	Normal	Normal			500	19	µA	Pass
Equipment Leakage	Reversed	Normal			500	79	µA	Pass
AP Leakage	Normal	Normal	1	CF	50	< 26	µA	Pass
AP Leakage	Reversed	Normal	1	CF	50	< 25	µA	Pass

Comments:

Overall Status: Pass

Date Of Test: 6/12/2010

Tested By:



# Muhlenberg Medical Repair, Inc.

## Test Certificate

Company: Allentown Womens Center

Asset: MMR009857

Description: Diagnostic Ultrasound

Applied Parts: < None >

Manufacturer: GE

Model: 46-285213G2

Serial No: 53706

Test	Main	SFC	AP	Type	Limit	Result	Unit	Status
Earth Continuity +200mA DC	---	---			0.30	0.136	Ohm	Pass
Earth Continuity -200mA DC	---	---			0.30	0.138	Ohm	Pass
L-PE Voltage	---	---				120	V	Informati
L-NE Voltage	---	---				2	V	Informati
EUT Line Current	---	---				1.7	A	Informati
Load	---	---				0.2	kVA	Informati
Equipment Leakage	Normal	Normal			500	51	µA	Pass
Equipment Leakage	Reversed	Normal			500	79	µA	Pass
AP Leakage	Normal	Normal	1	CF	50	< 25	µA	Pass
AP Leakage	Reversed	Normal	1	CF	50	< 26	µA	Pass

Comments:

Overall Status: Pass

Date Of Test: 5/12/2010

Tested By: [Redacted]



# Muhlenberg Medical Repair, Inc.

## Test Certificate

Company: Allentown Womens Center

Asset: MMR009858  
Applied Parts: < None >

Description: Diagnostic Ultrasound  
Manufacturer: Advanced Technology Model: UM4A

Serial No: U25556

Test	Mains	SFC	AP	Type	Limit	Result	Unit	Status
Earth Continuity +200mA DC	---	---			0.30	0.148	Ohm	Pass
Earth Continuity -200mA DC	---	---			0.30	0.148	Ohm	Pass
L-PE Voltage	---	---				122	V	Informati
L-NE Voltage	---	---				2	V	Informati
EUT Line Current	---	---				4.8	A	Informati
Load	---	---				0.8	KVA	Informati
Equipment Leakage	Normal	Normal			500	29	µA	Pass
Equipment Leakage	Reversed	Normal			500	78	µA	Pass
AP Leakage	Normal	Normal	1	CF	50	< 25	µA	Pass
AP Leakage	Reversed	Normal	1	CF	50	< 25	µA	Pass

Comments:

Overall Status: Pass

Date Of Test: 5/12/2010

Tested By:

**III. Detection of Pregnancy**

- A) **Ultrasound Exam**  
An abdominal or vaginal ultrasound will be performed on all women prior to the abortion procedure to determine the gestational size. This will be recorded on the patient chart. If a pregnancy cannot be seen on ultrasound, a sensitive urine pregnancy test will be run. If this is negative, it will be assumed that the patient is not pregnant. If this is positive, ectopic precautions will be reviewed and the patient will be rescheduled for another ultrasound at a later date. If there is any suspicion of an ectopic pregnancy, the patient will be referred to a hospital or her own gynecologist immediately.
- B) **Pelvic Exam**  
The procedure physician will perform a bi-manual examination of the patient prior to the procedure to determine uterine size, position adnexal masses, or any other abnormal pathology. This will be noted on the chart.

**IV. Ineligible Patients and Referrals to Other Agencies**

- A) **Indications**
  1. Medical condition warrants a procedure in a hospital setting
    - This is determined through consultation with the Medical Director, the Executive Director, the physician performing the procedure, AWC support staff, and the patient's own private physicians.
  2. Gestational age is beyond the limits of the Allentown Women's Center.
    - Patients being referred to a second trimester facility may require a copy of the ultrasound picture to take to the agency and the patient's counselor may give her a copy. A copy of the signed ACA consent form will also be given to the patient.
  3. Ambivalence, which is not overcome with counseling assistance.
    - The patient will be given the option to reschedule to a later date if she is still within AWC's gestational limits. The counselor will provide decision-making materials and referrals and resource information that will aid her in making a decision.
  4. Inability or refusal to sign an informed consent.

**V. Guidelines for History and Physical Findings**

It is the physician's responsibility to review each patient's chart. Counseling and nursing staff also review the chart, as well as the ultrasound technician who will review the chart when the ultrasound is done.

- A) Blood pressure, pulse, temperature, history, hemoglobin, blood type, urinalysis for sugar and protein, height and weight, must be recorded on the patient chart prior to the procedure.
- B). Any abnormal findings should be brought to the physician's attention (in addition to those listed in section I - Eligibility):
  1. Disease or surgery of the uterus, ovaries, or tubes
  2. Epilepsy or seizures
  3. Heart disease or murmur
  4. Anemia (hematocrit of  $\leq 28$ )
  5. Fainting, dizzy spells
  6. History of bleeding problems / bleeding tendency
    - a) Need medical clearance from patient's physician and AWC physician
    - b) Coumadin / Heparin must be discontinued 4 days prior to surgery
    - c) Lovenox can be started, but must be discontinued 18-24 hours pre-surgery
    - d) PT, PTT, and INR will be ordered at physician's discretion
    - e) AWC physician with assistance from Director of Nursing or Assistant Director will coordinate with patient's physician / hematologist for patient follow-up

# Sentinel IMAGING

THE SENTINEL IMAGING GROUP, INC.

1170 Winola Road Ste 1A  
Clarks Summit, PA 18411  
888 838 7488 570 587 0161  
570 587 0710 Fax

SYSTEM GE RT 3200S

SERIAL # 53706 YMF

LOCATION ALLEGHENY WOMEN'S CENTER

PITTSBURGH PA

## CERTIFICATE OF

# PREVENTIVE MAINTENANCE INSPECTION

This document was issued on MAY 26 2010 to confirm that a Preventive Maintenance Inspection was completed on this date on the Ultrasound System listed above. After thorough cleaning and inspection, the system was found to meet the following criteria for functionality and performance:

- Verification of integrity and functionality of all electrical and electronic components, including A/C power cable and power distribution devices, control panels, keyboards, and trackballs, scanheads and scanhead cables, ECG cables, monitors, peripherals, and all associated video, power, and control cables, and all circuit boards and sub-assemblies. All cooling fans checked and all filters cleaned. All voltages checked.
- Verification of integrity and functionality of all mechanical components and devices, including system cart, panels, and closures, wheels, casters, and brakes, keyboard and monitor positioning and securing hardware, and cable management systems.
- Comprehensive evaluation of all elements of system performance and functionality, including bootstrap, scanhead switching and initialization, selection and verification of 2-D, 3-D, M-Mode, Color, Doppler, ECG, Image Management, and all other included modalities or features with appropriate video switching and system response, image quality and functionality verified for monitors, vcrs, and system peripherals. 2-D image quality on all scanheads verified with ATS model 539-5 tissue equivalent phantom.

# Sentinel IMAGING

THE SENTINEL IMAGING GROUP INC.

1170 Windle Road Ste 1A  
Clarks Summit, PA 18411  
888 638 7488 570 587 0161  
570 587 0710 Fax

SYSTEM GE LOGIQ ZVO ALPHA  
SERIAL # L223705  
LOCATION ALLEGANY WOMEN'S CENTER  
AVENUE PA

## CERTIFICATE OF

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# Sentinel IMAGING

THE SENTINEL IMAGING GROUP INC.

1170 Winola Road Ste 1A  
Clarks Summit, PA 18411  
888 838 7488 570 587 0161  
570 587 0710 Fax

SYSTEM ATL UIM 4 PWS  
SERIAL # 425355  
LOCATION AMERICAN WOMEN'S CENTER  
ALLENTOWN PA

## CERTIFICATE OF

# PREVENTIVE MAINTENANCE INSPECTION

This document was issued on MAY 26 2010 to confirm that a Preventive Maintenance Inspection was completed on this date on the Ultrasound System listed above. After thorough cleaning and inspection, the system was found to meet the following criteria for functionality and performance:

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- Verification of integrity and functionality of all mechanical components and devices, including system cart, panels, and closures, wheels, casters, and brakes, keyboard and monitor positioning and securing hardware, and cable management systems.
- Comprehensive evaluation of all elements of system performance and functionality, including bootup, scanhead switching and initialization, selection and verification of 2-D, 3-D, M-Mode, Color, Doppler, ECG, Image Management, and all other included modalities or features with appropriate video switching and system response, image quality and functionality verified for monitors, vcrs, and system peripherals. 2-D image quality on all scanheads verified with ATS model 539-5 tissue equivalent phantom.

# Patient Safety Committee Meeting

4/6/10

Attending: \_\_\_\_\_

Minutes: P \_\_\_\_\_ 10

**Last Meeting:** The 12/29/09. We discussed non-blaming environments in an office setting and manufacturer vs. human error. We discussed outside influences to a healthy work space and being up to date on new and changing protocols. Kate Wilgruber was added as the newest member to the Patient Safety Committee

**Committee Change:** L \_\_\_\_\_, GYN Coordinator, will now be attending all meetings. \_\_\_\_\_ is the new Patient Safety Officer at AWC.

**Incidents:** There have been several incidents since the last meeting:

1. A patient came in for a routine 2<sup>nd</sup> trimester surgical abortion with IV sedation. The procedure was successful with moderate cervical bleeding and no perforations. The patient's vitals allowed her to be released. The patient called AWC approximately ½ hour later stating that she was hemorrhaging (bleeding through two regular pads within one hour). Patient was told to return to AWC for further evaluation. Upon entering the AWC parking lot the patient had an episode of syncope and collapsed. Two medical staff members rushed to the parking lot with a wheel chair to help the patients and she was taken immediately to a procedure room where her bleeding was temporized. Her hemoglobin was checked as well as other vitals. Patient was sent to the hospital by ambulance for a blood transfusion. The hospital did a D&C claiming that their ultrasound showed retained fetal parts. \_\_\_\_\_ n did not feel that this was accurate. Hospital procedure resulted in a perforation and belly bleed. Patient had to have a hysterectomy and remained in the hospital for 4-5 days.

**Corrective Action:** Although the outcome of this incident shows that the hospital was at fault, we discussed procedure for further evaluating patients with the need for hospital care. Make sure that the patient is going to a reliable hospital (we discussed anti-choice doctors). This incident was also not reported in a timely fashion (the required 24 hours) so the committee discussed the need to be prompt with reports as well as informing other staff members who can do PSA reports if the patient safety officer is not available. We also discussed the possibility of meeting patients outside who are having complications, in case they need medical attention upon arrival. The committee felt that this may be difficult in some cases as there are often protesters present in the morning.

2. A patient came in that was approximately 16 weeks of gestation. Upon inserting laminaria, the patient began hemorrhaging. Patient's ultrasound showed placenta previa. Her procedure was done immediately to slow the bleeding, but she continued to bleed from the cervix. Physician packed the uterus to stop bleeding and patient was given 4 liters of fluids, her hemoglobin was re-checked and her blood pressure was monitored. Patient's hemoglobin dropped from an initial 10g to 6g. The patient was also anemic. The patient was told to remain on bed rest. Status follow up calls were made over the weekend and AWC physician receive no response. The patient called the following Monday complaining of cramping and was told to return to AWC for further evaluation. Her hemoglobin had dropped to 2g, re-ultrasound was normal. The patient was taken by medical staff to the hospital for a blood transfusion. Her hemoglobin did return to a normal 12g after hospital treatment. Patient is now doing well.

**Corrective Action:** Committee discussed the possibility of doing re-ultrasounds on all laminaria patients before Dilapan insertion. Also discussed more strongly considering hospital evaluation and observation for patients who have an unstable blood pressure reading and their hemoglobin drops 4g below their original Hgb.

3. A patient was given Misoprostol before her procedure, as is protocol with patients. However, the patient was doing a non-surgical procedure not requiring pre-operative misoprostol. As such she was given twice the amount of Misoprostol needed, No sequellae. It came to the attention of staff that the patient was administered medication before her chart was received by the person administering the medications.

**Corrective Action:** No meds or treatment to be given to patients before a medical staff receives her chart with proper documentation.

**Discussion:** Ultrasound quality assurance: it was recommended that medical staff receive a refresher course on ultrasound training and make sure all new staff complete the training video. We discussed the possibility of an ultrasonographer coming in to conduct a training session. Medical staff who feel they did not get an accurate reading must always seek a second opinion.

The committee discussed the need to keep up with checking expired medications, supplies, and equipment. We will develop a new end-of-day checklist for making sure rooms are clean and organized. We also discussed the need to rotate stock.

The Committee discussed some position changes, i.e. being appointed the new Patient Safety Officer and what that entails as well as the need for scheduled meetings.

**Suggestions:** presented a periodical on Patient Safety with a quiz that Committee Members may be interested in reading!

**Next Meeting:** Tuesday, July 13<sup>th</sup>, 2010 at 3pm

[Redacted signature block] 4/7/10

**From:**  
**Sent:**  
**To:**

Monday, May 10, 2010 1:14 PM

**Subject:**

Patient Safety Meetings

Hi all,

I have scheduled the next few Patient Safety Authority Meetings for the year. Granted these are tentative dates, but we would like to try to stay as close to these dates as possible and not have to reschedule. It is imperative that these meetings be held as needed since the Dept of Health dictates that this must be done. As per our last meeting, we scheduled our next for July 13th, 2010 at 3pm.

I have scheduled the next few meetings following July's for the following dates:

Tuesday, October 12th at 3pm  
and Tuesday January 11th, 2011 at 3pm

I know some of you have school and that this may not work with your schedule, so please let me know.

Thanks!

PS. If you read or hear anything in the media or in journals, etc, that you think may benefit the Patient Safety Committee, please feel free to bring this up at meetings for discussion. Input is always welcome!

Allentown Women's Center

well behaved women rarely make history"