

**TRI-CITY HEALTHCARE DISTRICT
 AGENDA FOR A REGULAR MEETING
 OF THE PROFESSIONAL AFFAIRS COMMITTEE
 OF THE BOARD OF DIRECTORS
 May 10, 2018, Thursday
 12:00 Noon– Assembly Room 1
 Tri-City Medical Center, 4002 Vista Way, Oceanside, CA 92056**

The Committee may make recommendations
 to the Board on any of the items listed below,
 unless the item is specifically labeled "Informational Only"

	Agenda Item	Page Nos.	Time Allotted	Requestor/ Presenter
1.	Call To Order/Opening Remarks		2 min.	Chair
2.	Approval of Agenda	1-2	2 min.	Chair
3.	Public Comments NOTE: During the Committee's consideration of any Agenda item, members of the public also have the right to address the Committee at that time regarding that item.		5 min.	Standard
4.	Ratification of Minutes of the April 2018 Meeting	3-10	2 min.	Committee
5.	New Business			
a.	Consideration and Possible Approval of Policies and Procedures	11		Committee
	Patient Care Services			
	1. Activated Clotting Time Testing by Medtronic ACT Plus Procedure	12-16		
	2. Amnisure Placental Alpha- 1 Microglobulin (PAMG 1) Test for Rupture of Fetal Membranes (ROM) Procedure	17-20		
	3. Code Blue and Emergency Care Standardized Procedure	21-25		
	4. Glucose Point of Care Testing Using the Nova Stat Strip Blood Glucose Meter Procedure	26-35		
	5. Hemoglobin using the HemoCue HB 201 Analyzer Procedure	26-43		
	6. HMS Plus Homestasis Management System Procedure	44-48		
	7. Medication Recall Policy	49		
	8. Urine PH	50-51		
	9. Whole Blood PT INR Using the Roche Coaguchek XS Plus Meter Procedure	52-57		
	Unit Specific			
	Behavioral Health Services			
	1. Treatment Planning	58-59		
	2. Washer Dryer Use	60-61		
	Rehabilitation			
	1. Disaster Plan – Outpatient	62-63		
	2. Fire Plan - Inpatient Rehab	64		
	3. Fire Plan - Outpatient Rehab Services	65-66		
	4. Fire & Internal Disaster Drill, Outpatient	67		
	5. Fire Plan –Outpatient Rehab Services	68-69		

	6. Staff Rotations 7. Supervision of Patient, OP 1106 Surgical Services 1. Staff Based Committee Meetings Policy Formulary Requests <ul style="list-style-type: none"> • Albuterol MDI – P & T 	70 71 72-82 83		
6.	Motion to go into Closed Session		2 min.	Committee
7.	CLOSED SESSION a. Minutes Approval b. Medical Audit and/or Quality Assurance 1. Chief of Staff Report 2. Quality Assurance Committees Reports (Committee (Health & Safety Code Section 32155) c. Conference with Legal Counsel – Significant exposure to litigation (Government Code Section 54956.9(b))		30 min.	Chair
8.	Reports from the Committee Chairperson of any Action Taken in Closed Session (Government Code, Section 54957.1)		10 min.	Chair
9.	Comments from Members of the Committee		5 min.	Committee
10.	The next meeting of the Professional Affairs Committee of the Board is on May 10, 2018 .		1 min.	Chair
11.	Adjournment		1 min.	Chair

DRAFT

Tri-City Medical Center Professional Affairs Committee Meeting Open Session Minutes April 12, 2018

Members Present: Director Leigh Anne Grass, Director Laura Mitchell, Director Larry Schallock, Dr. Contardo, Dr. Souza, Dr. Johnson and Dr. Ma.

Non-Voting Members Present: Steve Dietlin, CEO, Scott Livingstone, COO , Sharon Schultz, CNE/ Sr. VP, Susan Bond, general legal Counsel and Marcia Cavanaugh, Sr. Director for Risk Management.

Others Present: Oska Lawrence, Merebeth Richins, Candice Parras, Eva Froyd, Joy Melhado, Lisa Mattia, Patricia Guerra and Karren Hertz.

Members Absent: Carlos Cruz, Chief Compliance Officer.

Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
1. Call To Order	Director Grass called the meeting to order at 12:07 PM in Assembly Room 1.		Director Grass
2. Approval of Agenda	The committee reviewed the agenda; there were no additions or modifications.	Motion to approve the agenda was made by Director Schallock and seconded by Dr. Souza	Director Grass
3. Comments by members of the public on any item of interest to the public before committee's consideration of the item.	Director Grass read the paragraph regarding comments from members of the public.		Director Grass

Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
4. Ratification of minutes of March 2018.	Director Grass called for a motion to approve the minutes from March 8, 2018.	Director Schallock approved and Dr. Souza seconded the motion to approve the minutes from March 2018.	Karren Hertz
<p>5. New Business</p> <p>a. Consideration and Possible Approval of Policies and Procedures</p> <p>Patient Care Services</p> <p>1. Abbreviations, Use of</p> <p>2. Automatic Stop Orders Policy</p> <p>3. Continuous Ambulatory Peritoneal Dialysis Procedure – tracked changes Continuous Ambulatory Peritoneal Dialysis Procedure – clean copy</p> <p>4. Emergency Department Standardized Procedure</p>	<p>There was a question on the use of abbreviation “qhs”. Patricia Guerra will check and review into how this word is being used in CERNER.</p> <p>Dr. Johnson made a small clarification on the automatic stop orders policy; it was noted that this policy provide the guidelines for discontinuing narcotics, antibiotics, chemotherapeutic agents and all other agents.</p> <p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p>	<p>ACTION: The Patient Care policies and procedures were approved. Dr. Souza moved and Director Schallock seconded the motion to approve the policies moving forward for Board approval.</p>	<p>Patricia Guerra</p>

Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
<p>5. Fall Risk Procedure and Score Tool Procedure</p> <p>6. Infusion Pump Syringe or PCA Module System with Guardrails Procedure</p> <p>7. Infusion Pumps, Intravenous Therapy Policy</p> <p>8. Point of Care Testing Competency Assessment Procedure</p> <p>9. Power Injection with Peripherally Inserted Central Catheter (PICC) Procedure</p>	<p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p> <p>It was noted that the power injection is still being in use mostly in IR in conjunction with a special PICC line.</p>		
<p>Administrative</p> <p>1. Non-Beneficial Treatment 399</p>	<p>Director Schallock asked the committee if the situation of providing non-beneficial treatment happens frequently in the hospital. Currently, Tri-City still deals with this kind of scenario. Unrepresented seeks hospital treatment; some cases are brought out for discussion and review in the Bioethics Committee . And then, the Interdisciplinary areas meet to make sure that patient is discharged with a sustainable treatment plan.</p>	<p>ACTION: The Administrative policy was approved. Director Schallock moved and Director Mitchell seconded the motion to approve this policy moving forward for Board approval.</p>	<p>Patricia Guerra</p>

Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
Unit Specific Behavioral Health Services <ol style="list-style-type: none"> 1. AMA Discharges 2. Managing the Medical Record for ED visits 3. Notification of MediCal Beneficiary of Denial of Benefits 4. Notification of Responsible Persons 5. One to One Observation of Patients 6. One to One Patient Supervision 7. Orientation of New Patients 8. Pastoral Care 9. Patient Belongings 10. Patient Discharge Types 	<p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p> <p>This policy is being pulled out as it needs further review and clarification.</p> <p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p> <p>There was no discussion on this policy.</p> <p>There was a brief discussion the volunteer chaplains. Since BHU is a special unit with a specific population, chaplains needs to be oriented thoroughly giving special attention to safety issues.</p> <p>There was no discussion on this policy.</p> <p>This policy addresses patients who want to leave the hospital without having completed their treatment.</p>	<p>ACTION: The Behavioral Health policies were approved. Director Mitchell moved and Dr. Souza seconded the motion to approve the policy moving forward for Board approval.</p>	<p>Patricia Guerra</p>

Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
11. Patient Responsibilities	Joy stated that for the most part, BHU patients comply with the rules in the unit such as participating in groups and other activities requiring patient participation.		
12. Patient Satisfaction Surveys	There was no discussion on this policy.		
13. Psychiatric Advanced Directive	There was no discussion on this policy.		
14. Release of Information	There was no discussion on this policy.		
15. Role of Medical Staff Leadership in Behavioral Health Services	There was no discussion on this policy.		
16. Scabies Lice Fleas in the BHU	There was no discussion on this policy.		
17. Scope of Service - Behavioral Health Unit	There was no discussion on this policy.		
18. Smoking Guidelines for Behavioral Health Unit	There was no discussion on this policy.		
19. Solicitation of Patients/Referrals to Self	There was no discussion on this policy.		
20. Telephone Use	It was noted that there are no cell phones allowed in the Behavioral Health unit.		
21. Treatment of Patients	There was no discussion on this policy.		

Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
22. Unit Staff Meetings	The minutes for the staff meetings are distributed to the people who were not able to attend to make sure they are all aware of the changes and other important things pertaining to the department.		
23. Utilization Management	There was no discussion on this policy.		
24. Visiting in Behavioral Health Unit	Joy stated that BHU patients get mail and they do have the ability to write somebody if they want to.		
25. Vital Signs	There is no discussion on this policy.		
26. Washer Dryer Use	This policy is being pulled out for further review and clarification.		
Infection Control 1. Department Specific Infection Control Behavioral Health Services - IC 7	There is no discussion on this policy.	ACTION: The Infection Control policy was approved. Director Mitchell moved and Director Schallock seconded the motion to approve the policy moving forward for Board approval.	Patricia Guerra
Women & Newborn Services 1. Breast Milk, Pumping, Handling and Storage of 2. Formula Feeding Procedure 3. Infant Feedings – tracked changes	It was clarified to the committee that the hospital continues to participate in the	ACTION: The WNS policies were approved. Director Mitchell moved and Director Schallock seconded the motion to approve the policy moving forward for Board approval.	Patricia Guerra


Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
<p>Infant Feedings – clean copy</p> <p>Formulary Requests</p> <ul style="list-style-type: none"> • Albuterol/Ipratropium inhaler • Bupropion • Combivir • Darunavir • Droperidol • Exparel • Fluticasone inhaler • Fluticasone/Salmeterol inhaler • Genvoya • Ipratropium inhaler • Lansoprazole solu-tabs • Medium chain triglycerides • Mepivacaine • Nitroglycerin 0.3 mg and 0.6 mg sublingual tablets • Nitroglycerin 0.4 mg spray • Raltegravir • Salmeterol inhale • Tivicay • Verapamil SR 	<p>program to have exclusive breastfeeding for newborns. Currently, we are at 54.5 % percentile for infant feedings and in Path 2 Category for being baby-friendly hospital in the county.</p> <p>*It was noted that patients can bring in their Albuterol from home. In addition, the inhaler and nebulizer are placed in the patient's bedside because the RT/ RP are the ones taking care of these medications thus reducing the inventory for the Pharmacy.</p> <p>*Droperidol manufacturer has no plans to resume production in the future.</p> <p>*The drug Exparel is the medication that is given to Peri-op patients at the beginning of the case.</p> <p>*Fluticasone is being changed to Symbicort while admitted as inpatient at the hospital since it does the same job.</p> <p>*Oska had reported that there is a fair amount of HIV patients that come to the hospital so the drug Tivicay has been added to the formulary.</p>	<p>ACTION: The formulary requests changes were approved. Director Mitchell moved and Director Schallock seconded the motion to approve the policy moving forward for Board approval.</p>	<p>Patricia Guerra</p>
<p>7. Closed Session</p>	<p>Director Mitchell asked for a motion to go into Closed Session.</p>	<p>Director Schallock moved, Dr. Souza seconded and it was</p>	<p>Director Grass</p>

Topic	Discussion	Follow-Up Action/ Recommendations	Person(s) Responsible
		unanimously approved to go into closed session at 12:40 PM.	
8. Return to Open Session	The Committee return to Open Session at 1:45 PM.		Director Grass
9. Reports of the Chairperson of Any Action Taken in Closed Session	There were no actions taken.		Director Grass
10. Comments from Members of the Committee	No comments.		Director Grass
11. Adjournment	Meeting adjourned at 1:48PM.		Director Grass

**PROFESSIONAL AFFAIRS COMMITTEE
May 10, 2018**

CONTACT: Sharon Schultz, CNE

Policies and Procedures	Reason	Recommendations
<u>Patient Care Services Policies & Procedures</u>		
1. Activated Clotting Time Testing by Medtronic ACT Plus Procedure	3 Year Review, Practice Change	
2. Amnisure Placental Alpha - 1 Microglobulin (PAMG1) Test for Rupture of Fetal Membranes (ROM) - Procedure	3 Year Review	
3. Code Blue and Emergency Care Standardized Procedure	3 Year Review, Practice Change	
4. Glucose Point of Care Testing using the Nova Stat Strip Blood Glucose Meter Procedure	3 Year Review, Practice Change	
5. Hemoglobin using the HemoCue HB 201 Analyzer Procedure	3 Year Review, Practice Change	
6. HMS Plus Hemostasis Management System Procedure	3 Year Review, Practice Change	
7. Medication Recall Policy	3 Year Review, Practice Change	
8. Urine PH	3 Year Review, Practice Change	
9. Whole Blood PT INR Using the Roche CoaguChek XS Plus Meter Procedure	3 Year Review, Practice Change	
<u>Unit Specific</u>		
<u>Behavioral Health Services</u>		
1. Treatment Planning	Practice Change	
2. Washer Dryer Use	Practice Change	
<u>Rehabilitation</u>		
1. Disaster Plan - Outpatient 1502	3 Year Review, Practice Change	
2. Fire Plan - Inpatient Rehab 1508	DELETE	
3. Fire Plan - Outpatient & Wound Care Center 1509	DELETE	
4. Fire-Internal Disaster Drill, 161 - 1506	DELETE	
5. Fire-Internal Disaster Drill, Wellness Center 1507	3 Year Review, Practice Change	
6. Staff Rotations - 615	3 Year Review	
7. Supervision of Patient, OP 1106	3 Year Review, Practice Change	
<u>Surgical Services</u>		
1. Staff Based Committee Meetings Policy	DELETE	
<u>Formulary Requests</u>		
1. Albuterol MDI P&T	Remove from Formulary	

 Tri-City Medical Center		Patient Care Services
PROCEDURE:	ACTIVATED CLOTTING TIME TESTING BY MEDTRONIC ACT PLUS	
Purpose:	To accurately measure the clotting time of heparinized patients.	
Supportive Data:	Authorized to perform procedure: RN, LVN, Perfusionist, CV tech with appropriate orientation, training, and competency validation. ACT testing is under the direction, authority, jurisdiction and responsibility of the Laboratory Director.	
Equipment:	1. Medtronic ACT Plus 2. Medtronic ACTtrac (electronic QC) 3. Temperature Verification Cartridge 4. CLOTtrac HR controls	5. Syringes, no larger than 10 mL 6. 19 gauge blunt tip needle or other blood collection needle 7. HR-ACT cartridges

A. SPECIMEN:

1. Fresh whole blood collected during angiogram or operative procedure, **four-hundred (400)** microliters per cartridge channel.
2. Fresh whole blood specimens should be tested as quickly as possible following sample collection. Test within **sixty (60)** seconds when there is no anticoagulant on board. Test within **two (2)** minutes when the sample is heparinized.

B. PROCEDURE:

1. HR-ACT Patient Test:
 - a. From the Main Menu, select HR-ACT as the cartridge type.
 - a.i. Note: Lot numbers and expiration dates for cartridges and controls must be entered prior to running a test (see below).
 - b. Verify the correct Patient ID in the upper right hand corner of the screen. If the ID is not correct, from the Main Menu enter the Patient ID (10-digit financial number / i.e. 600 #) and User ID (employee ID) numbers.
 - c. Pre-warm the cartridge for at least **three (3) to five (5)** minutes (up to **twelve (12)** hours).
 - d. Tap or shake the HR-ACT cartridge to re-suspend the kaolin activator.
 - e. Using a syringe and blunt tip needle, fill each cartridge chamber with the appropriate patient sample to the level between the fill lines (400 microliters per channel).
 - f. Insert the cartridge into the ACT Plus, and close the actuator heat block to initiate the test.
 - g. Clot formation is signaled by an audible tone, the actuator heat block opens and the results are displayed.
 - h. **Manually Transmit Patient Tests**~~MANUALLY TRANSMIT PATIENT TESTS~~ to the lab data manager and the patient's electronic chart: From the main menu, select Transmit Test Results. Select Transmit Patient Tests. Exit to the main menu.
2. To Remove and Add a New Cartridge Lot/ Exp Date:
 - a. From the Main Menu select Cartridge Lot.
 - b. Use the Up/Down arrows to select HR-ACT.
 - c. Press Remove Lot.
 - d. Use the Up/Down arrows to select and highlight the lot to be removed.
 - e. Press Remove Selected Lot to delete the selected cartridge lot number.
 - f. Press Add Lot Number and enter the lot number with the barcode scanner. The lot number and expiration date will populate their respective fields.
3. To Remove and Add a New Control Lot/ Exp Date:
 - a. From the Quality Control Menu select Control Lot.
 - b. Use the Up/Down arrows to select the control type.
 - c. Press Remove Lot.

Department Review	Clinical Policies & Procedures	Nursing Executive Committee	Department of Pathology	Medical Executive Committee	Professional Affairs Committee	Board of Directors
01/07, 10/10,01/14, 11/15	11/10, 02/14, 12/15	11/10, 02/14, 01/16	04/18	03/14, 04/18	01/11, 04/14	01/11, 04/14

- d. Use the Up/Down arrows to select and highlight the lot to be removed.
- e. Press Remove Selected Lot to delete the selected lot number.
- f. Press Add Lot Number and enter the lot number with the barcode scanner. The lot number and expiration date will populate their respective fields.
- g. Press Set Range and enter the control range.
- h. Press Enter to confirm the range.

C. **PRINCIPLE:**

1. The ACT Plus is a coagulation instrument intended for determining coagulation endpoints in fresh whole blood; the endpoint is formation of fibrin. The clotting times are performed in duplicate and the results for each channel, the average of the two channels and the difference are displayed.
2. High Range ACT (HR-ACT): The HR-ACT is a kaolin activated clotting time test performed on fresh whole blood where the heparin concentration is **one (1) unit/ mL** or higher.

~~D. **CALIBRATION:**~~

- ~~1. ~~Not applicable.~~~~

E.D. **QUALITY CONTROL (QC):**

1. If proper QC is not performed or is out of range, the QC lockout feature will be engaged preventing patient testing until QC status is acceptable.
2. Quality Control testing for the ACT Plus is performed using a combination of liquid controls and electronic (ACTtrac) controls. According to **Clinical Laboratory Improvement Amendments (CLIA)** guidelines, two **(2)** levels of control for coagulation procedures should be performed every eight hours of patient testing.
3. Electronic Control: The ACTtrac is a battery-powered software used to identify instruments that no longer fall within mechanical calibration specifications.
 - a. To perform an ACTtrac test:
 - i. From the Main Menu, select ACTtrac as the cartridge type.
 - ii. Enter **zero (0)** as the Patient ID and the appropriate User ID. (The system will not accept user ID's that have not been entered into the data management program).
 - iii. Select the Quality Control menu. Select Control Type, press key until the same control range as selected on the ACTtrac is displayed. Verify the control lot #. Press Enter to confirm.
 - iv. Place ACTtrac into the heat block and close to start the test. The test is complete upon hearing an audible tone with the results displayed.
 - v. Push the Quality Control button again and select the second range to be tested by ~~p~~pressing the Control Type key until the same range to be tested on the ACTtrac is displayed. Press Enter to confirm.
 - vi. Place ACTtrac into the heat block and close to start the test. The test is complete upon hearing an audible tone with the results displayed.
 - vii. The ACT Plus will indicate if the QC passed or failed. This will complete the level one and level two electronic controls required every eight hours when the ACT Plus is in use.
4. Liquid Controls: Two **(2)** levels of liquid control are performed for the HR-ACT (CLOTtrac HR normal and abnormal). Used in conjunction with the ACTtrac electronic control, liquid controls are performed every seven days and with a change in cartridge lot number **or new Shipment**.
 - a. Control storage and stability: Store controls in the refrigerator, between 2° and 10°C.
 - b. Controls are stable until the expiration date on the package when stored at refrigeration temperatures. CLOTtrac controls are stable for **two (2)** hours following reconstitution.
 - c. Preparation: Follow instructions on current package insert of controls if different than below.

- i. Remove controls and deionized water diluent from the refrigerator and bring to room temperature for approximately **ten (10)** minutes.
 - ii. Add 1.8 mL of deionized water to the lyophilized sheep blood.
 - iii. Allow at least **ten (10)** minutes for adequate rehydration of the normal control and **twenty-five (25)** minutes for rehydration of the abnormal control. **Do not agitate or mix until completely rehydrated**~~DO NOT AGITATE OR MIX UNTIL COMPLETELY REHYDRATED.~~
 - iv. Shake the control vigorously to mix until the red blood cells are uniformly dispersed and the control is completely reconstituted.
 - d. Performance:
 - i. Select HR-ACT as the cartridge type.
 - ii. Enter **zero (0)** as the Patient ID and the appropriate User ID.
 - iii. Select Quality Control. Select Control Type, press key until the correct control HR-NM or HR-AB is displayed. Press Enter to confirm. The current control lot number will be displayed.
 - iii-1) Note: Lot numbers and expiration dates for cartridges and controls must be entered prior to running a test (see below).
 - iv. Pre-warm the cartridge for at least **three (3) to five (5)** minutes (up to **twelve [12]** hours).
 - v. Tap or shake the HR-ACT cartridge to re-suspend the kaolin activator.
 - vi. Using a syringe and blunt tip needle, fill each cartridge chamber with the appropriate control to the level between the fill lines (**four-hundred (400)** microliters per channel).
 - vii. Insert the cartridge into the ACT Plus and close the actuator heat block to initiate the test.
 - viii. The ACT Plus will incubate the control sample for **three-hundred (300)** seconds and then begin the clot detection cycle.
 - ix. Clot formation is signaled by an audible tone, the actuator heat block opens and the results are displayed. The ACT Plus will indicate if the QC passed or failed.
5. Transmit Data: Quality Control Data must be manually transmitted to the laboratory data manager (via network connection). Each week, after performing liquid controls, transmit data.
 - a. From the Main Menu, select Transmit Test Results.
 - b. Press Transmit Unsent QC tests.
 - c. Press Transmit Unsent Patient tests.
 - d. Exit to the Main Menu.

E. CALCULATIONS:

- A-1. The ACT Plus calculates the mean or average clotting time for the duplicate channels and the difference in seconds between channels when a High Range ACT test is performed.

F. REFERENCE RANGE:

- B-1. Duplicate clotting times for the HR-ACT should fall within 10% of each other for baseline or normal samples and 12% of each other for prolonged or heparinized samples. The operable range of the Instrument is 25 – 999 seconds.
- 4-a. Normal Un-Heparinized Range: 96 – 172 sec
 - b. Therapeutic Range:
 - i. OR **greater than or equal to (\geq) 480 sec**
 - ii. Cath Lab **greater than or equal to (\geq) 200 sec; based on clinical judgment**
 - e-iii. IR **greater than or equal to (\geq) 200 sec; based on clinical judgment**

F.G. NOTES AND LIMITATIONS:

1. The HR-ACT is intended for use with fresh whole blood where the heparin concentration is **one (1) units/mL** or greater. During cardiopulmonary bypass the HR-ACT may be affected by the

following: dilution of plasma coagulation factors, the use of citrated blood products, use of anti-platelet agents, hypothermia, change in platelet number or function.

2. Interfering Substances: Activated blood specimens, either in-vivo (patient's coagulation mechanism activated) or in-vitro, due to improper sample collection and handling may cause erroneous results. Sample collection and testing should be repeated if improper collection is suspected or if test results are questionable.

G.H. MAINTENANCE:

1. Record Maintenance on the Instrument Maintenance Log.
2. Routine Cleaning: Clean the exposed surfaces of the actuator and dispenser and the instrument case using a hospital approved disinfectant **between patients' testing-**
3. **Discard of all of the completed testing materials and controls in the provided and approved waste containers.**
- 3-4. Temperature Verification: Verification of the ACT Plus heat block should be performed once a month and may be done with a Temperature Verification Cartridge that is supplied with the instrument or with calibrated thermometer and water-filled cartridge.
 - a. Using the Temperature Verification Cartridge:
 - i. From the Quality Control menu enter User ID.
 - ii. Select Temperature Adjustment.
 - iii. Insert the Temperature Verification Cartridge into the actuator heat block.
 - iv. Wait 10 minutes for temperature equilibration to occur.
 - v. Press the button on the Temperature Verification Cartridge for temperature reading.
 - vi. Enter the reading from the Temperature Verification Cartridge using the numeric keypad. The entered value will appear highlighted in the Thermometer Reading on the display.
 - vii. Press Enter to confirm.
 - viii. Select Repeat Adjustment variable function key to repeat the temperature adjustment if necessary.
 - b. Using a Thermometer:
 - i. From the Quality Control menu enter User ID.
 - ii. Remove the plunger assembly from a cartridge and fill with 0.2 to 0.3 mL of water.
 - iii. Insert the cartridge into the actuator heat block.
 - iv. Select Temperature Adjustment.
 - v. Place a calibrated thermometer in one of the cartridge reaction chambers.
 - vi. After about 5 minutes check the thermometer reading.
 - vii. Enter the reading from the thermometer using the numeric keypad. The entered value will appear highlighted in the Thermometer Reading on the display.
 - viii. Press Enter to confirm.
 - ix. Select Repeat Adjustment variable function key to repeat the temperature adjustment if necessary.
 - c. Notes:
 - i. The instrument displayed temperature and thermometer measured temperature should read between 36.5° to 37.5° C.
 - ii. The thermometer temperature should be within $\pm 0.5^\circ$ C of the instrument displayed temperature.
 - iii. The time, date and temperatures of the thermometer and the display will be logged in the instruments temperature log.
 - iv. Wait a minimum of 10 minutes before repeat adjustments are performed.
 - v. Values must be between 35 °C and 39 °C.
- 4-5. Actuator Assembly Cleaning:
 - a. The Actuator Assembly should be cleaned monthly or as soon as possible after contamination with blood. The exposed surfaces of the actuator assembly (with the

actuator heat block in the open position) should be cleaned with one of following cleaning detergents: isopropyl alcohol, methanol, propyl alcohol, glutaraldehyde, bleach, ethanol, Liqui-Nox®, parachlorometaxlenol, hydrogen peroxide, or mild detergent.


- a.i. Dip a swab in cleaning solution.
- b.ii. Swab the flag lift wire, removing all blood.
- c.iii. Swab inside the actuator assembly cover, especially the detector and emitter areas of the photo-optical sensor. Remove any excess cleaning solution with a dry swab. If blood should get into the detector of the lamp area and cannot be removed with a swab, Error Code "4" may be displayed.

I. **TROUBLESHOOTING:**

G.1. Refer to the ACT Plus Operator's Manual for Cause and Resolution for System Messages.

H.J. **REFERENCE(S):**

1. Medtronic ACT Plus Automated Coagulation Timer Operators Manual. Rev. 1.0, 4/04.
2. **ACT Plus Individualized Quality Control Plan (IQCP) in Point of Care/ Lab binder.**

 Tri-City Medical Center	Patient Care Services
PROCEDURE:	AMNISURE PLACENTAL ALPHA-1 MICROGLOBULIN (PAMG1) TEST FOR RUPTURE OF FETAL MEMBRANES (ROM)
Purpose:	To assist in the evaluation of vaginal fluid for the presence of amniotic fluid.
Supportive Data:	The AmniSure ROM test detects ruptured membranes by detecting placental alpha-1 microglobulin (PAMG-1), a protein marker in the amniotic fluid in vaginal secretions of pregnant women. This test is used for definitive purposes. CLIA classified as Moderately Complex.
Equipment:	1. Test kit (with sterile swab, solution vial, test strip) 2. Timer (with attached vial holder)

A. PRINCIPLE:

1. AmniSure ROM test is a rapid, non-instrumented, qualitative test for the detection of amniotic fluid in vaginal discharge of pregnant patients who report signs, symptoms, or complaints suggestive of rupture of membranes. Premature Rupture of Membranes (PROM) prior to 37 weeks' gestation complicates up to 12% of all pregnancies.
2. AmniSure uses the principle of immunochromatography to detect human PAMG-1 (placental alpha-1 microglobulin) protein present in amniotic fluid of pregnant women. Placental Microglobulin was selected as a marker of fetal membrane rupture due to its unique characteristics (i.e. high level in amniotic fluid, low level in blood, and extremely low background level in cervico-vaginal discharge when the membranes are intact).

B. PROCEDURE:

1. Store the kit in a dry place at 4 to 24C (40 to 75F). DO NOT FREEZE. When stored as recommended the test is stable until the "use by" date on the foil pouch. Use within 6 hours after removing from foil pouch. **Check integrity of package prior to use, and ensure that no excessive moisture is noted and no mechanical damage to the test strip is seen.**
2. Open the test kit and remove contents.
3. Shake the solvent vial to make sure that all the liquid in the vial settles to the bottom.
4. Open the solvent vial and place into vertical position. The metal loop on the side of the timer is the vial holder. You may place the solvent vial in this holder.
5. Specimen Collection and patient Identification:
 - a. **Identify patient per Patient Care Services Policy – Identification, Patient**
 - b. Speculum examination is not required.
 - c. Position patient lying flat on back.
 - e-d. **Wear gloves for infection prevention.** Collect sample of vaginal discharge using sterile vaginal swab provided in kit.
 - i. Remove swab from packaging using care not to touch anything prior to insertion into vagina.
 - ii. Holding swab in the middle of the stick carefully insert the polyester tip of the swab into the vagina until fingers contact the skin no more than 2-3 inches (5-7 cm) deep.
 - iii. Withdraw swab after one minute has elapsed.
6. Place the swab into the vial.
7. Rinse the swab by rotating for one minute.
8. Tear open the foil pouch at the test notches and remove the AmniSure test strip.
9. Dip the white end of the strip (marked with arrows) into the solvent.
10. Allow the strip to remain in solvent for 10 minutes, unless two lines are clearly visible.
 - a. Note: a strong leakage will make results visible within minutes, while a small leak may take the full time. A negative result must not be read until the full 10 minutes has elapsed.

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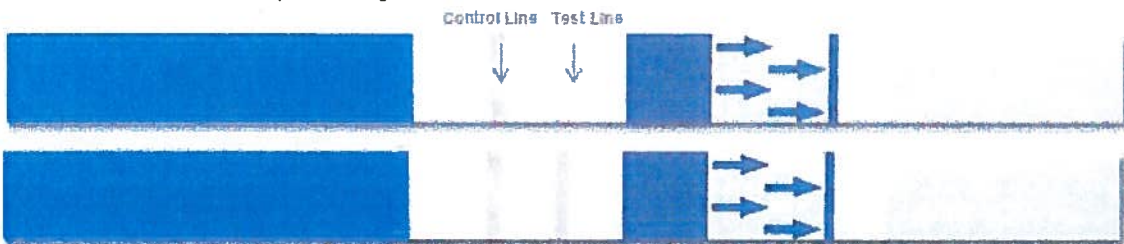
11. Read the results by placing the strip on a clean, dry flat surface.
12. Do not read or interpret after 15 minutes have passed since placing the strip into the vial (or after 5 minutes from removing from vial).
13. **Discard the testing and sampling materials into the waste management container.**

C. **REPORTING RESULTS:** There are three possible result interpretations:

1. No membrane rupture (control line present)



2. There is a rupture (control line and test line present) [Test line may be very faint and/or broken. This is still considered positive.]



3. Test invalid (control line not present)



4. Notes:

- a. The darkness of the lines may vary—do not try to interpret the test result based on the darkness of the line.
- b. The test is valid even if the lines are faint or uneven.

5. For each test the following must be documented:

- a. Date and time of testing
- b. Operator's identification
- c. Internal QC
- d. Patient result

D. **DOCUMENTATION:**

1. Document according to current departmental procedures.
2. In I-View, first document the internal controls (internal qc, daily qc)
 - a. Pass = control line in the control region and background clears. Ok to report patient test.
 - b. Fail = control line absent and/or the background does not clear. Repeat patient with new test kit.
3. Once the internal QC is documented as "Pass", document the results as Positive or Negative.

E. **QUALITY CONTROL:**

1. Initial validation of internal control by demonstration of concordance with external controls was performed by the lab prior to test implementation.
2. External controls (positive and negative) must be performed upon every new lot, and shipment, and monthly on every box currently in use and if there is suspicion that the product performance is compromised.
- a-3. **Perform positive and negative QC procedure.**
 - b-a. Positive control: use commercial stabilized positive control purchased through manufacturer, or use known Amniotic Fluid.
 - e-b. Negative control: use saline solution.
- 2-4. Daily (or day-of-testing) controls may be limited to the internal procedural control. Internal

controls validate that adequate sample volume was present and adequate capillary migration of the sample has occurred.

- 3-5. To interpret internal controls:
 - a. Positive control: a colored line appearing on the control region
 - b. Negative control: a clear background on the control region.
 - c. Patient tests where the control line is not present or the background has not cleared must not be reported. Repeat testing with a new Amnisure test strip.
- 4-6. Procedure for Liquid External Controls:
 - a. Obtain liquid external controls (quality controls, QC, controls) from the lab's **temperature controlled freezer and keep in a temperature controlled refrigerator in the unit prior to testing.**
 - b. PAMG-1 is present (positive) or absent (negative) from the vials. SKIP the swab collection steps.
 - c. Use the solvent vials provided by the laboratory. Save the unused solvent vials from the test kits and return to the lab with results.
 - d. Open the vial provided by the lab, place in the vial holder
 - e. Tear open the foil pouch at the test notches and remove the AmniSure test strip.
 - f. Dip the white end of the strip (marked with arrows) into the solvent.
 - g. Allow the strip to remain in solvent for 10 minutes, unless two lines are clearly visible.
 - h. Read the results by placing the strip on a clean, dry flat surface.
 - i. Do not read or interpret after 15 minutes have passed since placing the strip into the vial (or after 5 minutes from removing from vial).
- 5-7. To interpret external liquid controls:
 - a. Positive control = Positive, line in control region and line in test region (2 lines).
 - b. Negative control = Negative, line in control region and NO line in the test region (1 line).
 - c. Controls PASS if the positive control is positive and the negative control is negative. Test kits are ok to use for patient testing.
 - d. Controls FAIL if the positive control is not positive, the negative control is not negative and/or the control line does not appear. DO NOT use test kits for patient testing. Contact the Laboratory.

F. **LIMITATIONS:**

1. Expect discrepant results from other methods used to test for ruptured membranes (Nitrazine, Ferning, and Pooling). AmniSure is more accurate and more sensitive than the other methods, and except in rare cases (with interfering substances or deviated procedure), should be considered correct.
- 4-2. Test strip must be used within 6 hours from removing from foil pouch.
- 2-3. A significant presence of blood on the swab can cause the test to malfunction. Do not report results. The test still functions properly with only a trace amount of blood on the swab.
- 3-4. Do not interpret results greater than 15 minutes after placing the test strip into the vial.
- 4-5. False negative results may occur when the sample is taken more than 12 hours after the fetal membrane rupture has occurred.
- 5-6. Test should not be performed within 6 hours after the removal of disinfectant solutions or medications from the vagina.
7. **Test should be run immediately after sample is obtained. If sample can not be processed immediately for testing, it must be run within 30 minutes from collection time.**

G. **INTERFERING SUBSTANCES:**

1. Vaginal infections, urine and sperm do not interfere with results.
2. The performance of AmniSure has not been established in the presence of the following contaminants; meconium, anti-fungal creams or suppositories, KY Jelly, baby powder (starch and talc), Replens, and baby oil.

H. **RELATED DOCUMENTS:**

1. **Patient Care Services Policy – Identification, Patient**

I. **REFERENCES:**

1. AminSure International US package insert. ASP 1100-US0002. 8/10/2010
2. **AmniSure Individualized Quality Control Plan (IQCP) in Point of Care/Lab binder**

PATIENT CARE SERVICES

STANDARDIZED PROCEDURE: CODE BLUE AND EMERGENCY CARE

I. POLICY:

- A. Function: Management of Code Blue and emergency care in the adult (14 years or older) patient including cardiopulmonary arrest (CPA), cardiac dysrhythmias, acute respiratory compromise (ARC), and hypotension associated with volume deficit.
 - A-1. **Special considerations shall be observed in the management of cardiac arrest, bradycardia, asystole, and pulseless electrical activity (PEA) in the post-sternotomy patient following cardiac surgery.**
- B. Circumstances:
 - 1. Setting: Tri-City Medical Center
 - 2. Supervision: None required. However, upon arrival of a physician or Code Blue Registered Nurse (RN), nursing staff will follow orders of the Code Blue RN and ultimately orders from physician.
 - 3. Patient contraindications – Patients with written orders contrary of the Standardized Procedure. Patients with Special Considerations:
 - a. No Code – A no-code is synonymous with “no resuscitation” or “do not resuscitate” and allow a natural death
- C. Definitions:
 - 1. Cardiopulmonary Arrest (CPA)- any pulseless cardiac arrests requiring chest compressions and or defibrillation, or cardiac events with pulse requiring chest compression for poor perfusion
 - 2. Cardiac Dysrhythmias – Any sustained tachy or brady dysrhythmias requiring immediate intervention due to life threatening potential or that may result in the patient becoming symptomatic.
 - 3. Acute respiratory compromise (ARC) – Any decrease in respiratory rate, depth, and/or decrease in oxygenation requiring immediate intervention due to life threatening potential or that may result in a patient becoming symptomatic.
 - 4. Hypotension associated with volume deficit – Any decrease in blood pressure of 30 - 40 mmHg or more from pre-operative/pre-procedural levels or less than 80 mmHg systolic associated with signs of absolute or relative fluid loss.
 - 5. **Emergent Resternotomy – A re-opening of a surgically-closed sternum to resuscitate a patient experiencing a life-threatening arrest following cardiac surgery to reverse cardiac tamponade and/or to provide internal cardiac massage.**
- D. Data Base:
 - 1. Subjective – Patient complains of dizziness, lightheadedness, chest pains, shortness of breath, or confusion.
 - 2. Objective – Decreased level of consciousness or unresponsive, respirations labored or absent and/or pulse absent, rhythm disturbances (if patient is monitored), low or absent blood pressure.
 - 3. Diagnosis -- Life threatening emergency.
 - 4. Plan:
 - a. Initiate Standardized Procedure as appropriate and notify attending physician
 - a.i. **Notify cardiothoracic surgeon if patient is a post-sternotomy cardiac surgery patient.**
 - a.ii. **Notify anesthesiologist in Post-Anesthesia Care Unit (PACU)**

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- b. Initiate standardized procedure/advanced life support as appropriate and call Code Blue by dialing 66 on the telephone request a "Code Blue" announcement and provide patient location.
5. Assessment -- Patient will be reassessed after each intervention.
6. Record Keeping -- Events are to be recorded in the electronic health record (EHR) (in the emergency event record) and the Cardiopulmonary Arrest Record. White copy to remain on chart.

II. **PROCEDURE:**

A. **CARDIAC DYSRHYTHMIAS**

1. Continuous cardiac monitoring.
2. Administer oxygen to maintain SpO₂ greater than or equal to 95%
3. Establish IV access with normal saline (NS) solution.
4. Notify attending physician/anesthesiologist in PACU prior to initiation of treatment if situation permits. Otherwise, contact appropriate physician after therapy is started.

B. **ASYSTOLE OR PULSELESS ELECTRICAL ACTIVITY (PEA)**

1. Initiate CPR at a rate of at least 100-120/minute ratio 30:2 and call Code Blue.
 - a. **Special Considerations for Post-Sternotomy patients experiencing asystole: Before initiating CPR, if epicardial pacing wires are present, first connect pacing wires to external pacemaker and initiate emergency pacing (DOO mode at 80 beats per minute at the maximum atrial and/or ventricular output voltages).**
 - i. In the absence of epicardial pacing wires, initiate external pacing.
 - ii. If there is a delay in obtaining pacing equipment beyond one minute, begin CPR.
 - b. If attempts to pace fail to restore cardiac output, begin CPR.
 - c. Prepare for emergent resternotomy within five minutes of onset of event.
 - d. **Special Considerations for Post-Sternotomy patients experiencing PEA: If a pacemaker is attached and functioning, briefly turn off the pacemaker to exclude underlying ventricular fibrillation (VF).**
- 1-2. Establish IV access with NS.
- 2-3. Confirm asystole in more than one lead.
4. Administer Epinephrine 4:10,000 (0.1 mg/mL) 1 mg IV, repeat every 3-5 minutes.
 - 3-a. **Use Epinephrine cautiously in the post-sternotomy patient by administering in increments of 0.5 mg IV.**
- 4-5. Obtain ABGs.

C. **VENTRICULAR FIBRILLATION AND PULSELESS VENTRICULAR TACHYCARDIA**

1. Initiate CPR at a rate of at least 100-120/minute ratio 30:2 and call Code Blue.
 - a. **Special Considerations for Post-Sternotomy patients: Before initiating CPR, administer three consecutive defibrillation shocks with 200 joules each.**
 - b. **External cardiac massage may be delayed up to one minute while providing defibrillation attempts.**
 - c. **After three failed attempts to defibrillate, begin CPR.**
 - d. **Prepare for emergent resternotomy within five minutes of event.**
 - e. **Administer Amiodarone 300 mg IVP via a central line.**
 - 1-f. **Continue CPR with single defibrillation with 200 joules every two minutes until resternotomy.**
2. Defibrillate with 200 joules. Resume CPR immediately after shock for 5 cycles or 2 minutes.
3. Establish IV access with NS.
4. Administer all medications during CPR or before or after defibrillation.
5. Epinephrine: 4:10,000 (0.1 mg/mL) 1 mg IV, repeat every 3 - 5 minutes.

- 5.a. **Use Epinephrine cautiously in the post-sternotomy patient by administering in increments of 0.5 mg IV.**
 6. Pause CPR briefly (less than 10 seconds) to check rhythm after 5 cycles or 2 minutes of CPR.
 7. Defibrillate with 200 joules and resume CPR for 5 cycles (2 minutes)
 8. Consider antiarrhythmic:
 - a. Amiodarone 300 mg IVP once.
 - b. In 3 – 5 minutes, consider,
 - i. Additional 150 mg of Amiodarone IV **push**
 - ii. Lidocaine 1.5 mg/kg IV push first dose, then 0.5 mg/kg, repeats in 5 minutes up to a total of 3 doses or total dose of 3 mg/kg.
 9. Defibrillate with 200 joules and resume CPR for 5 cycles or 2 minutes
 10. Consider Magnesium sulfate 2 grams in ~~100 mL D5W administered over 2 minutes~~ **(4 mL of a 50% solution diluted in 10 mL D5W or normal saline) IVP or intraosseous (IO)** for torsades de pointes. Identify and treat cause.
 11. After return of spontaneous circulation (ROSC), begin continuous infusion of medication effective in dysrhythmia suppression as recommended below:
 - a. Amiodarone 1 mg/min x 6 hours, then 0.5 mg/min maintenance drip
 - b. Lidocaine drip (2 gm in 500 mL D5W) at 1mg/min
- D. **BRADYCARDIA:**
SYMPTOMATIC: Serious signs and symptoms such as chest pain, shortness of breath, decreased level of consciousness, or hypotension are present and believed to be related to a slow heart rate.
1. Administer oxygen to maintain SpO₂ greater than or equal to 95%
 2. Establish IV access with NS.
 3. **Special Considerations for Post-Sternotomy patients experiencing severe bradycardiabradycardia: If epicardial pacing wires are present, connect pacing wires to external pacemaker and initiate emergency pacing (DOO mode at 80 beats per minute at the maximum atrial and/or ventricular output voltages).**
 - 2-a. **In the absence of epicardial pacing wires, initiate external pacing.**
 4. Atropine 0.5 mg IV push, repeat every 3 - 5 minutes up to a total of 3 mg.
 - 3-a. **Atropine is not recommended for the post-sternotomy patient.**
 - 4-5. Initiate transcutaneous pacing (TCP) at rate of 80 and mA of 80.
 - a. Ensure 1:1 capture is obtained
 - b. Set safety margin 10 mA above initial capture
 - 5-6. Consider dopamine 5 mcg/kg/min. The Code Blue RN may titrate in increments of 2 mcg/kg/min every 5 minutes to maintain heart rate greater than 60bpm up to 20 mcg/kg/min as Blood Pressure tolerates. Or start Epinephrine 2 mcg/min. The Code Blue RN may titrate in increments of 2 mcg/min every 5 minutes to maintain heart rate greater than 60bpm up to 20 mcg/min as BP tolerates.
- E. **TACHYCARDIA – UNSTABLE PULSE PRESENT:**
UNSTABLE: Heart rate is greater than 150 bpm and serious signs and symptoms such as chest pain, shortness of breath, decreased level of consciousness, altered mental status, hypotension, or acute heart failure are present and believed to be related to rapid rate. Prepare to perform immediate synchronized cardioversion.
1. Institute oxygen therapy to maintain SpO₂ greater than or equal to 95%.
 2. Establish IV access with NS.
 3. Notify Respiratory Care Practitioner (RCP)
 4. Consider sedation if the patient is conscious, but do not delay cardioversion
 5. Ensure the defibrillator pads and monitor leads are attached to the patient and the defibrillator is in synchronization mode
 6. Synchronized cardioversion with the following initial dose. Select synchronization mode with each increase in joules.
 - a. **Narrow Regular QRS Complex: Cardiovert with 50 – 100 joules**

- b. Narrow Irregular QRS Complex: Cardiovert with 120 – 200 joules
 - c. Wide Regular QRS Complex: Cardiovert with 100 – 200 joules
 - d. Wide Irregular QRS Complex. Do not use synchronized function. Defibrillate with 200 joules.
 7. Call Code Blue, if appropriate
 - F. TACHYCARDIAS STABLE (Regular QRS Complex Pulse Present):
 1. Narrow Regular QRS Complex:
 - a. Attempt Vagal maneuvers (bear down, cough)
 - b. Adenosine 6 mg rapid IV push repeat in 1 - 2 minutes with 12 mg IV push if needed.
 2. Undifferentiated Regular Monomorphic Wide QRS Complex
 - a. Adenosine 6 mg rapid IV push, repeat in 1 – 2 minutes with 12 mg IV push if needed
 - b. Amiodarone 150 mg IVPB over 10 minutes seek expert consultation for maintenance infusion
 - G. TACHYCARDIA (Stable Irregular QRS Complex Pulse Present)
 1. Identify rhythm as atrial fibrillation or atrial flutter or multifocal atrial tachycardia
 - a. Narrow Irregular QRS Complex
 - i. Seek expert consultation to control rate with diltiazem or beta blockers
 - b. Wide Irregular QRS Complex
 - i. Amiodarone 150 mg IVPB over 10 minutes
 - ii. Seek expert consultation to control rate
 - H. CHEST PAIN (Related to coronary artery occlusion or spasm)
 1. Assess pain quantity, quality, location, radiation, time of onset and precipitating factors.
 2. Apply oxygen at 4 L/min via nasal cannula.
 - a. Supplemental oxygen is not needed for patients without evidence of respiratory distress if the SpO₂ is greater than or equal to 95%
 3. Administer Nitroglycerin 0.4 mg sublingual every 5 minutes PRN for chest pain up to 3 doses. Hold if SBP is less than 90 mmHg.
 - a. If Nitroglycerin is ineffective in relieving chest pain and patient has no contraindications, administer Morphine 1 mg IV push times 1.
 - i. Use with caution in unstable angina/non-STEMI.
 4. Obtain STAT 12-lead ECG and review for ischemic changes.
 - I. ACUTE RESPIRATORY COMPROMISE(With pulse)
 1. Open patient's airway and administer one breath approximately every 6 seconds via bag mask.
 2. Administer oxygen to maintain SpO₂ greater than or equal to 95%
 3. Call Code Blue if appropriate.
 4. Establish IV.
 5. Administer Naloxone (Narcan) 0.4 mg IV if patient has a patient controlled analgesia (PCA) or receiving narcotics.
 6. Obtain STAT ABGs and chest x-ray as indicated.
 7. Assist with intubation as appropriate.
 - J. HYPOTENSION ASSOCIATED WITH VOLUME DEFICIT
 1. Administer oxygen to maintain SpO₂ greater than or equal to 95%
 2. Establish large bore IV access with normal saline solution.
 3. Infuse 250 mL normal saline or lactated ringers; repeat every 10 minutes up to a total of 1000 mL.
 4. After fluid bolus, consider vasopressors to maintain systolic blood pressure greater than 90 mmHg
 - a. Dopamine 5 mcg/kg/min. The Code Blue RN may titrate in increments of 2 mcg/kg/min every 5 minutes for SBP > 90mmHg or MAP >65mmHg up to 20 mcg/kg/min

- b. Norepinephrine 2 mcg/min. The Code Blue RN may titrate in increments of 2 mcg/min every 5 minutes for SBP >90mmHg or MAP > 65mmHg up to 30 mcg/min.

III. **DEVELOPMENT AND APPROVAL OF THE STANDARDIZED PROCEDURE:**

- A. Method: This Standardized Procedure was developed through collaboration with Nursing, Medicine, and Administration.
- B. Review: Every two (2) years.
- C. Standardized Procedure follows American Heart Association (~~2010~~ 2015) Advanced Cardiac Life Support Guidelines.

IV. **CLINICIANS AUTHORIZED TO PERFORM THIS STANDARDIZED PROCEDURE:**

- A. All ACLS-certified Registered Nurses from the following clinical areas:
 1. Intensive Care Unit
 2. Telemetry
 3. Post Anesthesia Care Unit
 4. Endoscopy, Cardiac Cath Lab and Interventional Radiology who have successfully completed requirements as outlined below are authorized to direct and perform the Code Blue and Emergency Care (Cardiopulmonary Arrest) Standardized Procedure.
 5. Emergency Department

V. **REQUIREMENTS FOR RNs INITIATING INTERVENTIONS:**

- A. Current California RN license.
- B. Education: Successful completion of Basic ECG course, ACLS course (with a current course completion card).
- C. Experience: Initial job requirement.
- D. Initial Evaluation: During initial Critical Care Skills Lab or in Department Orientation.
- E. Ongoing Evaluation: Annually during Skills Validations with standardized procedure test.

VI. **REFERENCES:**

- A. American Heart Association (AHA): Advanced Cardiovascular Life Support (ACLS)
- B. Dunning et al. (2017) The society of thoracic surgeons expert consensus for the resuscitation of patients who arrest after cardiac surgery. *The Annals of Thoracic Surgery* 103(3), 1005-1020.
- E.C. Ley, S. J. (2015) Standards for resuscitation after cardiac surgery. *Critical Care Nurse*, 35(2), 30-38.



PROCEDURE: GLUCOSE POINT OF CARE TESTING USING THE NOVA STATSTRIP BLOOD GLUCOSE METER

Purpose: To accurately determine blood glucose levels at the patient's bedside.

Supportive Data: The Nova StatStrip Meter is used to monitor blood glucose in patients who have been diagnosed by conventional means. The meter is not to be used for screening or diagnosis of diabetes. Personnel trained and assessed through the Point of Care program may perform this procedure. Testing is under the supervision of the Laboratory Point of Care Coordinator and under the jurisdiction of the Laboratory Medical Director.

- Equipment:**
1. Alcohol Swab
 2. Docking Station
 3. Gauze
 4. Gloves
 5. **Luer lock needleless blood sampling access device**
 6. **Needleless cannula**
 - 5-7. Nova StatStrip Meter
 - 6-8. Single-use Lancet
 - 7-9. StatStrip cleaning strips
 - 8-10. StatStrip control solutions level 1 low (green bottle) & level 3 high (red bottle)
 - 9-11. StatStrip test strips

A. DEFINITION(S):

1. **Critically ill adult:** any patient receiving intensive medical intervention/therapy with decreased peripheral blood flow, as evidenced by one or more of the following:
 - a. Severe hypotension requiring the administration of two or more intravenous vasopressors;
 - b. Any patient with a core body temperature equal or less than (\leq) 35°C;
 - c. Any patient with Emergency Severity Index (ESI) of one.
2. **Critically ill neonate:** all neonates in the Neonatal Intensive Care Unit (NICU) are defined as critically ill.

B. PREPARE THE METER:

1. Touch the screen to activate the meter.
 - a. Note: the meter is designed such that the operator uses his or her finger when dealing with the touch screen. Any sharp or abrasive material may damage the meter.
 - b. Blue bar with screen title at the top of the meter will prompt next step.
2. From the Welcome screen, Press OK/Login to begin.
 - a. For troubleshooting hints see the StatStrip Troubleshooting Guide on the Tri-City Medical Center Healthcare District (TCHDMG) Intranet under **Departments>Clinical>Clinical Products**.
3. Perform Quality Control (QC) if indicated by meter. Meter is configured to require a QC both high and low every 24 hours. Meter will lock out at 24 hours and screen will display QC Lockout L1/L3 QC required if QC not performed. See QC and Calibration section for instructions on completing the QC.
4. At the Enter Operator ID Screen, scan or manually enter your Operator **Identification (ID)**. ID must be 5 digits long; use zeroes to precede a 3- or 4-digit Employee ID Number (**EID**). Press Ok/Accept.
5. At Patient Test screen press accept or select QC.
6. At the Enter Strip Lot screen, scan the strip lot from the bottle matches the number displayed on the screen.
7. At the Enter Patient ID screen, **scan/verify** the AZTEC symbol from the Patient's armband or manually enter Patient 10 digit Financial Identification Number (FIN#), Press Accept.

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- a. Non-Registered Patients in emergent situations.
 - i. Emergent patients should be issued a John/Jane Doe packet. Scan the AZTEC symbol from the packet.
 - ii. If packet not available, enter an invalid Patient ID to get to the downtime override key (use the following 10 digit FIN# 1 2 3 4 5 6 7 8 9 0)
 - iii. Fill out the Point of Care Testing Correction Form
 - iii.iv. ~~a~~Available on TCMC Intranet), **click on Forms Icon>Electronic Forms>Patient Care Services Forms**
8. At the Confirm Patient ID screen
 - a. Valid Patient ID: Verify the FIN# (Account Number) and Patient Name are correct. Press Ok/Accept.
 - b. Invalid Patient ID: The Admission/Discharge/Transfer (ADT) feature was unable to pull Patient Name. This will occur if the meter has not been recently downloaded and does not have current ADT information, if the scanned encounter has been discharged, or if the patient is not yet registered and a John/Jane Doe ID was scanned.
 - i. Verify the Patient ID. If the correct number was scanned, and the encounter is current press Ok/Accept to Override. The Patient ID will be recognized by the data manager, the error resolved, and the result will chart.
 - ii. If the encounter is not current, obtain an armband for the current encounter and continue testing. If ~~staff~~~~you~~ press OK/Accept and Override a discharged encounter, the result will not chart. ~~Staff~~~~You~~ must fill out the Point of Care Testing Correction Form and send it to the lab for error resolution.
 - iii. If the patient a John/Jane Doe and is not yet registered, press OK/Accept to Override. When the patient is registered, complete the Point of Care Testing Correction Form.
9. At the Insert Strip screen, insert a test strip into the strip port at the top of the meter. The print should face up and the gold contacts enter the meter.

C. **PATIENT PREPARATION:**

1. **Critically ill adult:**
 - a. **Only arterial or venous whole blood may be used. Do not use serum, plasma, or capillary blood.**
 - i. **To obtain whole blood from an arterial catheter, follow procedure for blood sample collection in Online Clinical Skills Arterial Catheter: Blood Sampling.**
 - ii. **To obtain whole blood from a central venous access device, follow procedure for blood sample collection in Patient Care Services (PCS) Procedure: Central Venous Access Devices, Adults.**
 - iii. **To obtain whole blood by venipuncture, follow procedure for blood sample collection in PCS Venipuncture for Specimen Collection.**
 - 1) **Only fresh whole blood or whole blood collected in lithium heparin collection device should be used for arterial and venous specimens. Test within 30 minutes when not sampling directly from a lancing device**
 - 2) **Fluoride, EDTA, Sodium and Ammonium blood collection devices should not be used.**
 - iii.iv. **To obtain whole blood from a midline catheter, follow procedure for blood sample collection in PCS Midline Catheter, Adults.**
2. **Critically ill neonates:**
 - a. **Collect neonatal arterial or neonatal heel stick samples. The system has not been evaluated for use with neonate venous blood,**
 - b. **The system is not intended for use with neonate Cord blood samplespecimens.**
- 2-3. **Non-critically ill adult**

- a. Capillary, Arterial, or Venous whole blood may be used. Do not use serum or plasma.
 - b. **Only fresh whole blood or whole blood collected in lithium heparin collection devices should be used for arterial and venous specimens.** ~~Sodium, Lithium, and Ammonium heparin are acceptable anticoagulants for syringes or vacutainer tubes.~~ Test within 30 minutes when not sampling directly from a lancing device.
 - c. Sample size is 1.2 uL.
- 3-4. Obtain single-use lancet
- 4-5. Select puncture site – see Patient Care Service (PCS) Collection of Blood Specimen by Skin Puncture.
- a. Adult/child - finger puncture
 - b. Newborn – heel stick
- 5-6. Use the lancet to puncture the appropriate site - see PCS Collection of Blood Specimen by Skin Puncture.

D. **SPECIMEN COLLECTION AND PATIENT TEST :**

1. At the Apply Sample screen, obtain blood sample and touch the test strip to ~~the~~ a drop of blood. Hold the test strip to the blood until the meter begins the 6 second count-down.
 - a. If the strip is not filled completely in the first attempt, you must repeat the test with a new puncture and a new test strip.
 - i. Repeated squeezing of the puncture site may dilute the specimen with tissue fluid
 - b. Criteria for rejection: If you receive a strip error for insufficient sample application or any other **error code reason**, you must repeat the test with a new finger puncture and a new test strip.
 - i. Repeated squeezing of the puncture site may dilute the specimen with tissue fluid
 - c. When collecting the sample: keep the meter level, or pointed **slightly downward** while wet test strip is in the meter. Do not tilt the meter up while there is any chance that blood can drip down into the meter. If liquid gets into meter, use the cleaning strips to wick the extra fluid as soon as possible.
 - d. Results will display in 6 seconds.
2. At the Patient Test screen
 - a. Review results:
 - i. Results may be read directly from the meter.
 - ii. Results in the normal range display in Blue.
 - iii. Results outside the normal range display in Red.
 - iv. ↑ One arrow up indicates the result is high, but not critical.
 - v. ↑↑ Double up arrows indicate the result is critical high.
 - 1) Follow PCS Critical Results and Critical Tests/Diagnostic procedure.
 - vi. ↓ One arrow down indicates the result is low, but not critical.
 - vii. ↓↓ Double down arrows indicate the result is critical low.
 - 1) Follow PCS Standardized Procedure Hypoglycemia Management in the Adult Patient
 - 2) Follow PCS Standardized Procedure Newborn Hypoglycemia During Transition to Extrauterine Life
 - 3) Follow PCS Critical Results and Critical Tests/Diagnostic procedure.
 - viii. LO indicates the result is below the readable range of the meter, or <10.
 - 1) <10 meter reads LO. Continue with treatment and retest according to standardized procedure for hypoglycemia
 - ix. HI indicates the result is above the readable range of the meter, or >600.
 - 1) Results >600 mg/dL: obtain an order for a STAT lab glucose for a valid result for treatment (Confirmatory Testing).

- 2) Results that do not correlate with prior treatment: obtain an order for a STAT lab glucose to verify result.
- b. Enter Comments: After the result displays, you must enter a comment to describe the ~~reason~~ **sample source** for testing. Once the comment is selected verify the comments display correctly on the screen. If you fail to select a comment the result will not automatically be charted after you accept ~~and~~ download the meter.
 - i. **Arterial**
 - ii. **Finger stick**
 - iii. **Heel stick**
 - iv. **Venous**

~~Routine~~
~~Post Tx recheck~~
~~s/s of hypOGlycemia~~
~~s/s of hyperGlycemia~~
~~Insulin drip~~
- c. Accept or Reject:
 - i. You must ACCEPT the result at the meter for it to be automatically charted.
 - ii. If, for any reason you do not want the result to be charted, select REJECT.
 - iii. If you select neither and the meter turns off, the result will sit in a queue in the lab awaiting resolution.
 - iv. Fill out and submit the Point of Care Testing Correction Form to the LAB.
3. Clean and disinfect the meter after each patient. See cleaning under Maintenance section.
- 3.4. Log off meter by selecting logout on Patient Test Screen, ~~touching blue bar at top of meter or~~ docking the meter when you are finished testing. Store the meter in the docking cradle and not in the tote. Battery must charge and data must transmit.
 - a. The Left light is Green when the meter is connected to the network.
 - b. The Center light is Green when data is transmitting
 - c. The Right light is Green when the battery is fully charged and Amber when the battery is charging.
 - d. Auto log off will occur after 6 ½ minutes of inactivity.

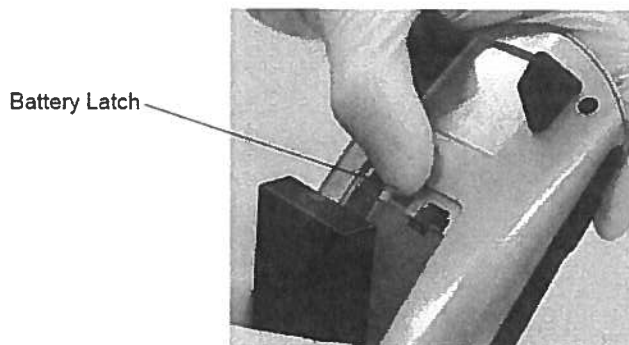
E. **DOCUMENTING RESULTS:**

1. Patients must be identified with the Financial/ Account Number (FIN). Only results identified with **the** FIN will be charted in CERNER. The FIN number should be scanned from the AZTEC (2D) barcode on the ARMBAND. Linear Barcodes must not be scanned or the results will not transmit to Cerner.
2. Dock the meter in the cradle. Results and comments will automatically post to the chart.
3. If the result does not immediately chart,
 - a. Verify the meter is properly docked and connected.
 - b. The INTERFACE may be temporarily down; the results will transmit and post when the interface is again functional.
4. Result was not ACCEPTED in the meter. Complete the Point of Care Testing Correction Form and send to the lab. The lab will resolve the error and process the result to the chart.
 - a. Patient ID was not recognized. (John/Jane Doe). **Use downtime procedure. Select Override button on the meter, continue testing, accept the result and dock the meter. Manually enter the result on the patient's chart for immediate documentation.** Complete the Point of Care Testing Correction Form and send the lab. The lab will resolve the error and process the result to the chart **at a later time whenever possible.**

F. **MAINTENANCE:**

1. Charging the Meter:

- a. When the battery Low symbol displays on the screen, place the meter into the docking station. If you have a spare battery that is fully charged, you can change the battery.
 - b. The meter should always be left in the docking station when not in use.
2. Cleaning the Meter:
- a. Never immerse the meter in any cleaning agent or water.
 - b. Never spray the meter with a disinfectant solution
 - c. Do not get excess liquid into the strip port or docking port or under the touch screen. This will damage the meter.
 - d. Clean daily and when visibly soiled
 - e. Disinfect the meter after each patient.
 - f. Using a hospital-approved disinfectant wipe, remove the wipe and wring out excess liquid, thoroughly clean the outside of the meter, avoiding the bar code scanner and electrical connector. Gently wipe the surface area of the test strip port making sure no fluid enters the port. Allow the meter to dry before docking.
 - f.i. **Hospital approved bleach wipes may be used if required by patient diagnosis (for example clostridium difficile).**
 - g. If the screen is 'cloudy' from a buildup of cleaning solution, wipe the screen with a water dampened gauze or alcohol pad then dry with clean gauze.
 - h. If Strip port well is filled with, QC solution, blood or other liquid, **dry the Strip port** ~~use the cleaning strips to wick the extra fluid (see StatStrip Troubleshooting Guide).~~
 - i. **If unable to remove liquid or the liquid dries and cannot be removed, send the meter to the Lab.**
3. Changing the Battery:
- a. If the meter is left out of the docking station for more than 8 hours or 40 tests, the battery will need to be recharged. If the meter is needed for immediate use, change the battery.
 - b. Touch the screen or the Sleep Mode Button to wake the meter up. This will allow the operator approximately 2 minutes to change the battery and not lose date/time settings.
 - c. If it takes longer than 2 minutes to change the battery. Dock the meter to reset the date and time.
 - d. Push down on the cover latch to release the cover. Take the battery cover off the back of the meter.
 - e. Push up on the battery latch. Remove the drained battery.



- f. Replace with a fully charged battery. (The battery is keyed to allow only insertion from bottom first then push in the top.)
 - g. Replace the battery cover.
 - h. Place the drained battery into the docking station to recharge. Be sure the light to the left comes on signifying the correct positioning of the battery.
4. Supplies and Storage :
- a. Nova Stat Strip Glucose Meter (Operates 15 to 40C; 59 to 104F)
 - b. Stat Strip Glucose Test Strips (Store in original bottle 15 to 30C)
 - i. When opened mark each bottle with the expiration date (180 days / 6 months)

- ii. Once opened, both Stat Strip bottles in the single package must be labeled because there is no safety seal on the individual bottle.
- iii. Stable when stored as indicated for 180 days or until the printed expiration date (whichever comes first).
- c. Stat Strip Glucose Control Solutions, level 1 low and level 3 high (Store 15 to 30C)
 - i. When opened, mark the bottle with the expiration date (90 days/ 3 months).
 - ii. Once opened, stable for 90 days or until the printed expiration date (whichever comes first).
- d. Do not use strips or controls past their expiration date.
- e. Remove the test strip from the vial only when ready to test and recap vial.

G. QUALITY CONTROL AND CALIBRATION:

1. Quality Controls (QC) are used to confirm that the meter and test strips are working correctly.
2. Control Frequency:
 - a. Meter is configured to require a QC with both Level 1 low and Level 3 High every 24 hours. Meter will lock out at 24 hours and screen will display QC Lockout.
 - b. Perform a QC if a patient test has been repeated and the blood glucose results are still lower or higher than expected
 - c. Perform a QC any time you have a concern about the function of the meter, i.e it is dropped or problems are identified (storage, operator, instrument)
 - d. Performing a QC with both Level 1 low and Level 3 high solution is required for Alere / Freedom to recognize new operators in the system. This shall be done upon initial and annual competency.
3. Perform QC with both Level 1 low and Level 3 high QC solutions to unlock meter: If one QC level fails, repeat the test only for the level that failed.
4. Procedure:
 - a. From the Welcome Screen press Login.
 - b. Manually Enter or Scan your Operator ID and press OK/Accept.
 - c. From the Patient Test Screen, press QC.
 - d. At the Enter Strip Lot screen, ~~scan~~**verify** the strip lot from the bottles. **Verify the strip lot number** matches the number displayed on the screen.
 - e. At the Enter QC Lot screen, scan the QC lot
 - f. At the Insert Strip screen, insert the test strip into the meter.
 - g. Mix the control well by rolling the vial, do not shake.
 - h. At the Apply Sample screen, touch the tip of the test strip to the drop of control and the strip will fill by capillary action. Keep contact with the drop of control until the meter beeps, indicating sufficient sample was obtained.
 - i. The test strip must fill completely on the first attempt. If insufficient sample is obtained, repeat with a new test strip.
 - ii. **HOLD THE METER LEVEL** or downward **WHILE TESTING**. This prevents any excess liquid from seeping down the strip and into the meter, causing damage.
 - iii. If liquid gets into meter, ~~dry~~**perform** strip port ~~cleaning by inserting cleaning strips immediately to wick liquid.~~
 - 1) **If unable to remove liquid or the liquid dries and cannot be removed send the meter to the lab.**
 - i. The QC Result screen will show with a PASS or FAIL Press Ok/Accept.
 - j. If QC fails select comment and, perform corrective action:
 - i. Verify the correct level of control was scanned and tested.
 - ii. Verify the test strips and control solutions are not expired. If expired, open new strips or controls.
 - iii. Mix the control thoroughly. Repeat the test with a new strip. If the second test fails, contact the lab.
 - k. Log off meter when you are finished testing. Auto log off will occur after inactivity.

- I. The meter does not require calibration.

H. **PRINCIPLE/CLINICAL SIGNIFICANCE:**

1. This test is CLIA WAIVED for capillary, venous, and arterial whole blood and neonatal capillary whole blood.
2. Glucose is measured amperometrically, using an enzyme based test strip.
3. The meter is plasma calibrated to allow easy comparison of results with laboratory methods.
4. The measurement of glucose is used in the monitoring of carbohydrate metabolism disturbances including diabetes mellitus, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
5. Testing by this method is not for diagnosis of or screening for diabetes.
6. Limitations
 - a. Capillary blood glucose testing ~~may is not be~~ appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. ~~Examples include, but are not limited to, severe hypotension, shock, hyperosmolar hyperglycemia (with or without ketosis) and severe dehydration.~~ Venous and arterial **whole blood is the only more accurate sample that shall be used for any patient receiving intensive medical/interventional therapy with decreased peripheral blood flow, as evidenced by one or more of the following:**
 - i. **Severe hypotension requiring the administration of two or more intravenous vasopressors**
 - ii. **Any patient with a core body temperature equal or less than (\leq) 35°C**
 - iii. **Any patient with ESI of one**
 - b. When performing frequent testing in a patient, try to use the same blood ~~source~~type as consistently as possible.
 - i. Rationale: Venous and capillary blood may differ in glucose concentration by as much as 70 mg/dL, depending on the time of blood collection after food intake. Draw lab serum glucose for the most accurate glucose value.
7. A test within 20% of laboratory results is considered accurate.
8. Interfering Substances
 - a. The StatStrip Glucose meter exhibits no interference from the following substances at known therapeutic levels: Acetaminophen, Ascorbic acid, Dopamine, Ephedra, D+ Galactose, Ibuprofen, L-Dopa, Methyl-Dopa, Salicylate, Tetracycline, Tolazamide, and Tobutamide.
 - b. The StatStrip Glucose meter exhibits no interference from the following substances at or above the upper clinical normal range concentrations: Bilirubin, Cholesterol, Creatinine, Triglycerides, and Uric Acid.
 - c. The StatStrip Glucose meter exhibits no interference from the following substances at the normal therapeutic levels found in renal dialysis: D(+) Maltose monohydrate, D(+) Maltotetraose, and D(+) Maltotriose.
 - d. The StatStrip Glucose meter exhibits no interference in blood specimens with hematocrits from 20% to 65% or with varying oxygen content.

I. **REFERENCE INTERVALS:**

1. Meter range 10-600 mg/dL
 - a. <10 meter reads LO. Continue with treatment and retest according to standardized procedure for hypoglycemia.
 - b. >600 meter reads HI. Order lab glucose to obtain a valid number for treatment.
2. Reference Range (all in mg/dL)

	NORMAL	CRITICAL LOW	CRITICAL HIGH
a. Adults	70 – 110	\leq 40	\geq 450
b. Neonates	45 – 120	\leq 30	none established

3. Critical Results must have follow up documentation of physician notification and any interventions.
4. Any result that is questionable or does not correlate with patient symptoms or treatment history should be repeated with a new finger puncture to rule out operator, strip, or meter error. If repeat meter value does not 'make sense', order a lab glucose.

J. **REFERENCE(S):**

1. Nova Biomedical. StatStrip Glucose Test Strips Package Insert. Ref 42214. 20162-03.
2. Nova Biomedical. StatStrip Glucose Control Solution Package Insert. Ref 41741 & 41743. 201707-0340.
3. Nova Biomedical. StatStrip Glucose Hospital Meter IFU. Ref 5584741853 H. 201542-06.
4. Nova Biomedical. CIB 04-11SS Rev. B. Cleaning and Disinfection Procedure. 2015-0642-04-2042.

K. **FORM(S):**

1. Point of Care Testing Correction Form

L. **RELATED DOCUMENT(S):**

1. **Online Clinical Skills Arterial Catheter: Blood Sampling**
2. **PCS Procedure: Central Venous Access Devices, Adults**
- 1-3. **PCS Procedure: Collection of Blood Specimen by Skin Puncture**
- 2-4. **PCS Procedure: Critical Results and Critical Tests/Diagnostic procedure**
5. **PCS Procedure: Midline Catheter, Adults**
- 3-6. **PCS Standardized Procedure Hypoglycemia Management in the Adult Patient**
- 4-7. **PCS Standardized Procedure Newborn Hypoglycemia During Transition to Extruterine Life**
- 5-8. **PCS Procedure: Venipuncture for Specimen Collection**
9. **Point of Care Correction Form**
- 6-10. **StatStrip Troubleshooting Guide**

Point of Care Testing Correction Form

NURSING Complete this form when 1. Valid Result was not "Accepted" at meter. 2. Any ID other than the current FIN # (account) was used to identify the patient in the meter/instrument. Complete in full and return to Lab. Result will be charted after the lab resolves the error.	
POC Test: <input checked="" type="checkbox"/> <input type="checkbox"/> Glucose (Nova Statstrip) <input type="checkbox"/> Hemoglobin (Hemocue 201DM) <input type="checkbox"/> Urine Dipstick (Siemens Clinitek) <input type="checkbox"/> ACT (Medtronic ACT Plus)	Reason for Exception: <input checked="" type="checkbox"/> <input type="checkbox"/> Result not ACCEPTED at meter <input type="checkbox"/> Unregistered Patient (scan John/Jane Doe armband) <input type="checkbox"/> Scanned Armband of old encounter, bypassed warning <input type="checkbox"/> Scanned wrong barcode, did not confirm <input type="checkbox"/> Downtime override used <input type="checkbox"/> Scanning function not working <input type="checkbox"/> Manual entry of Patient FIN # not accepted
Date of Test:	Comments: Unit: <input type="checkbox"/> Other <input type="checkbox"/>
Time of Test:	Operator Name/ID: (Performed Test)
Result:	Correct Patient ID: (fill out or attach chart label) Name: _____
Correct Patient ID Verified by:	MRN: _____ FIN: _____
Send to Lab via pneumatic tube or Fax to x4048	
LAB USE ONLY	
Corrected by:	Date/Time:
Comments:	

If the meter is not behaving like expected, remove the battery and reinsert to reset.

Stat Strip™ Troubleshooting Guide

1 Low Battery



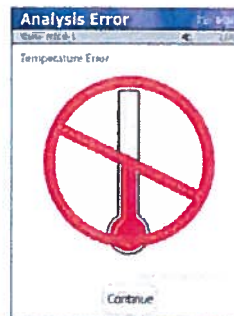
Charge battery by placing into docking station. Takes 2 hours to fully charge battery. Or change battery. Extra battery is stored in docking station.

2 Test Strip Removed



Test has been cancelled. Insert new strip and repeat the test.

3 Temperature



Meter will only work in a temperature range of 59 -104°F (15 -40°C). Home Care Nurses – meter may overheat in car.

4 QC or Blood in Strip well



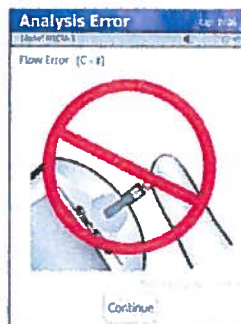
Insert Cleaning Strip *immediately* to absorb liquid before it dries. If meter will not turn on and replacing battery does not restore function, return to lab.

5 Strip Rejected



Occurs after test strip insertion or during analysis. Insert new strip and repeat the test. Strips can be damaged if they drop out of container or are contaminated with cleaning solution or wipes.

6 Flow Error

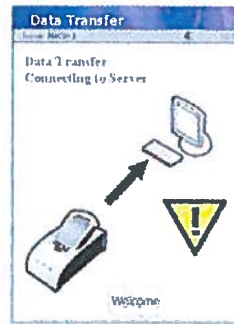


Analysis Error/A flow error occurs when the strip is not filled on the first attempt. You cannot overfill the strip.

Technique Tips:

1. Touch edge of strip while in the meter to blood droplet and do not pull back until strip fills completely.
2. Place patient's hand on a flat surface so the hand does not shake causing strip to lift off finger tip before meter fills completely.
3. Operator should stabilize the meter so the strip itself is not shaking as the patient's finger is touched.

7 Transfer Failed



Docking stations are universal: Any meter can be docked in any docking station.

DATA TRANSFER FROM METER TO CERNER

- ~Verify black power cord is plugged into docking station and electrical outlet
 - ~Verify all 3 lights on docking station are on:
 - Left = power cord in docking station to electrical outlet plug
 - Middle = connection to Ethernet (data uploading and downloading)
 - Right = battery charging (amber), fully charged (yellow)
 - ~Verify blue or yellow internet cable is clicked in docking station and data jack port
- NOTE:** The meter and docking station will still work if CERNER is down. Information from the meter will not chart to Cerner until CERNER is back up. Follow PCS CERNER Downtime Policy.
- ~If all 3 lights are on in docking station but meter is frozen or screen is dark, replace battery with new battery. If still not working **Call POC Coordinator in the Lab x 7974.**
 - ~If power cord and battery lights are on but the middle Ethernet light is off, go to TCMC intranet, click on support, then click on Information Technology and enter a work order to IT. Include the meter Identification Information written on the label.
 - ~Call **IT Help Desk x7370**. IT can check the internal server and Rals Freedom server.
- 24 hour customer support 1-855-676-7536**

nova
 biomedical
 Nova Biomedical
 200 Prospect Street
 Waltham, MA 02454 Tel:
 800-545-6682 •
 www.novabiomedical.com



PROCEDURE: HEMOGLOBIN USING THE HEMOCUE 201 DM ANALYZER

Purpose: To accurately determine hemoglobin levels at the patient's bedside.

Supportive Data: Hemoglobin testing using the HemoCue meter is classified as waived testing under federal law.
Authorized to perform the procedure: RN, LVN
Testing is under the direction, jurisdiction, and responsibility of the Laboratory Director

- Equipment:
1. 1 Lancing Device
 2. 1 Alcohol pad
 3. HemoCue HB 201 Microcuvettes
 4. HemoCue Hb 201 DM Analyzer
 5. Protective Gloves

A. ANALYZER OVERVIEW:

1. Always slide the analyzer into and out of the docking station by means of the tracks. Never try to lift the analyzer out of or press the analyzer downwards into the docking station. This will damage the casing and power outlets.
2. The analyzer is powered by a rechargeable battery. When un-docked, the battery can be recharged via the AC adaptor. When docked, the battery is charged via the USB inlet.
3. A green light from the LED on the docking station indicates that the station is receiving power and the battery is fully charged. A flashing green light indicates the battery is charging.
4. A steady red light indicated an internal communication error within the docking station. A flashing red light indicates an external communication error. Contact the Laboratory for troubleshooting.
5. Use only fingertips for pressing the display buttons. Sharp-edged objects can damage the display. Screen responds to the LIFT of the finger.
6. Refer to Attachment 1 for guide to Display and Function buttons.
7. When using the barcode scanner, *hold* the barcode scanner button down until the numerical information registers.




B. QUALITY CONTROL PROCEDURE:


1. The QC Reminder feature will indicate the time when the next QC is due.
2. Perform two levels of liquid QC each day of testing and upon opening a new vial of microcuvettes. If QC is unsuccessful, QC lockout will be engaged, and the meter will not allow patient testing.
3. Verify that the control vials are clearly marked with an expiration date and are not expired. Controls are good for 30 days after opening. The laboratory supplies controls. Verify the cuvettes are marked with an open and expiration date and are not expired. **Cuvettes are stored at room temperature in a dry place with an operating temperature 15° C to 30° C and relative humidity up to 90%.** Cuvettes are good for 3 months after opening. The department orders cuvettes.
4. Fill the cuvette:
 - a. Mix the control solution gently until there is no longer a "ring" on the bottom of the vial when inverted. Do not roll the vial between the palms of your hands. Vials must be mixed properly to assure successful subsequent QC results.
 - b. Fill the cuvette directly from the vial or by wicking up a drop from a piece of scotch tape. Wipe the rim and cap with a clean tissue before re-capping.
 - c. Wipe excess control from the outer surface of the cuvette. Look for air bubbles in the field of the cuvette. If any air bubbles are present, fill a new cuvette. Small bubbles around the edge can be ignored.
5. Turn the meter on and enter your User ID (5-digit employee ID number.)

Department Review	Clinical Policies & Procedures	Nursing Executive Council	Division of Pathology	Medical Executive Committee	Professional Affairs Committee	Board of Directors
10/12, 12/15	10/12, 01/16	10/12, 01/16	04/18	11/12, 04/18	01/13	01/13

6. Select QC. Select Level 1.
7. Place the cuvette into the holder and slide the holder into the analyzer.
8. Scan the cuvette batch number.
9. Scan the control lot number (If entered manually, must be 8 digits; i.e. lot GH1161 is entered 00001161.)
10. The result will display along with an interpretation:
 - a. Pass: result falls within acceptable limits.
 - b. Pass, with warning: result falls within acceptable limits but outside 2SD.
 - c. Fail: result falls outside acceptable limits.
11. Enter a comment if necessary (notepad lower left corner).
 - a. Opened New Vial (of cuvettes)
 - b. Wrong Level; Repeat
 - c. Out; Repeat
12. Accept or Reject the measurement.
13. Run the second level: Select QC. Select Level 3.
14. QC must Pass (or Pass, with warning) before continuing with Patient testing. If QC Fails:
 - a. Verify the Cuvettes and Control are not expired.
 - b. Remove the Cuvette holder and see if there is blood inside the meter (the optics).
 - c. Clean the meter if necessary.
 - d. Re-mix the control vial and test again.
 - e. If controls are still out, contact the Laboratory.

C. PATIENT TESTING PROCEDURE:

1. Specimen Collection:
 - a. Identify the patient.
 - b. Perform a skin puncture.
 - c. Wipe away the first 2 or 3 drops of blood with a lint-free wipe (do not use cotton balls). Reapply light pressure towards the fingertip until another drop of blood appears.
 - d. When the drop is large enough, fill the Cuvette in one continuous process. Do not refill.
 - e. Wipe off excess blood from the outer surface of the Cuvette with lint-free tissue. Be careful not to touch the open end of the cuvette.
 - f. Look for air bubbles in the filled Cuvette. If any air bubbles are present, fill a new cuvette. Small bubbles around the edge can be ignored.
 - g. NOTE: If a second sample is to be taken from the same finger stick, wipe away the remains of the initial sample and fill a second Cuvette from a new drop of blood.
 - h. Testing should be completed within 10 minutes of filling the Cuvette.
2. Using the Meter:
 - a. Power on the meter and enter your Operator ID with the touch-screen or the barcode scanner.
 - b. Select the Patient Test button .
 - c. Place the cuvette into the holder and slide the holder into the analyzer.
 - d. Enter the required information:
 - i. Cuvette batch number (scan the vial)
 - ii. Patient ID (manually enter the 8-digit MRN, or scan the FIN from the patient's armband)
 - e. Verify the entered information.
 - f. Results will be displayed in 15-45 seconds. You may:
 - i. Add a comment  (to reject the result, add a comment, then select reject)
 - ii. Verify the result with another cuvette . Both results will be displayed along with the mean.

- iii. Confirm the result —the result will remain displayed until the “confirm” button is selected. You may pull out the cuvette holder and inspect the cuvette while the results are still displayed. Accept or reject the result.

D. **REPORTING RESULTS:**

1. Document results on the 24-hour patient flow record.
2. A history of results is stored in the meter and downloaded to the Lab Data Management System for review.

E. **REFERENCE RANGE:**

1. Expected range for hemoglobin:
Infant: 15.5 – 24.5 g/dL
Adult: 12.0 – 16.0 g/dL
2. Critical Range
Infant: ≤ 7.0 g/dL
Adult: ≤ 7.0 g/dL or ≥ 20.0 g/dL
3. Results above 25.6 g/dL will be displayed as over-range.
4. Results above 20.0 g/dL must be confirmed with a laboratory test.
5. Repeat unexpected results with a new skin puncture or with a lab draw.

F. **PROFICIENCY TESTING PROCEDURE:**

1. Proficiency testing is conducted three times a year. The Laboratory (and Point of Care Program) subscribes to Proficiency Surveys through the College of American Pathologists.
2. Proficiency test samples are to be run in the same manner as patient samples and by personnel who routinely perform patient testing.
3. Select QC.
4. Select Proficiency Test. Fill a cuvette with proficiency testing sample, place it into the cuvette holder, and slide the holder in.
5. Enter the specimen ID.
6. Record the results on the Result sheet provided by the lab.

G. **METER MAINTENANCE:**

1. The Analyzer will perform a Self-Test and Calibration each time it is powered ON.
2. Performed Daily:
 - a. Cleaning the Cuvette Holder:
 - i. Pull the cuvette holder out to the Loading position.
 - ii. Carefully press the small catch positioned in the upper right corner of the Cuvette holder.
 - iii. While pressing the catch, carefully rotate the Cuvette holder sideways as far as possible to the left.
 - iv. Remove the Cuvette holder from the Analyzer (the holder should slide out easily; if there is some resistance, pull at a different angle) and clean with an alcohol wipe or Sanicloth.
 - v. Once the Cuvette holder is completely dry it may be reinserted into the Analyzer.
3. Performed As Needed:
 - a. Cleaning the Display:
 - i. Make sure that the Analyzer is turned off. The display should be blank.
 - ii. Use an alcohol wipe to clean the outer case and glass screen. Wring any excess liquid from wipe before using. Excess liquid may damage the internal workings of the meter and the touch screen. DO NOT use any cleaner other than alcohol on the glass screen.
 - b. Cleaning the Optics:
 - i. Remove the Cuvette holder.




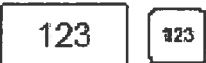




- ii. Use a cotton-tip swab moistened with alcohol or water. Place inside the opening of the optronic unit and swab side to side 5-10 times. If the swab is dirty, repeat with a new swab until cleaning removes no more blood. Wait 15 minutes before replacing the Cuvette holder (the optics must dry).
4. If the meter is not working or displays an error code, contact the Laboratory for troubleshooting and Maintenance.

H. **Resources on Intranet – Clinical Products :**



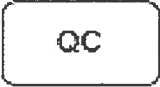





1. HemoCue Hb 201 DM Analyzer Reference Manual. 901111 040309.
2. HemoCue Hb 201 DM Analyzer Instructions for Use. 901114 070323-140726.
3. HemoCue Hb 201 Microcuvettes Package Insert. Art nr 151705-050527-12140726.
4. **HemoCue Hb 201 Technical letter No 21, June 2012 , GPM287INT_130718**
5. **HemoCue Hb 201 Performance _ Report, GPM342INT_140415**

ATTACHMENT 1

NAVIGATION BUTTONS:




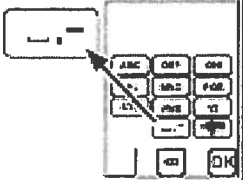




Button	Designation	Function
	Erase button	Erases the last input
	Previous image button	Returns to the previous image NOTE: Inputs/changes made in the current image will not be saved
	Text mode button	Switches to text input mode
	Numeric mode button	Switches to the numeric input mode
	Barcode Scanner button	Switches to the Barcode Scanner mode
	Scroll bar arrow (Up)	Scrolls upwards in a list of different options or in a text
	Scroll bar arrow (Down)	Scrolls downwards in a list of different options or in a text
	Next image button	Continues to the next image in the Help sequence

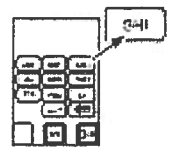
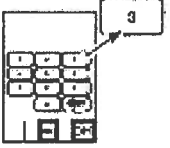




PROCEDURE BUTTONS:

Button	Designation	Function
	Patient test button	Activates the Patient Test procedure
	STAT test button	Activates the STAT (Short Turn Around Time) Test procedure
	QC test button	Activates the QC (Quality Control) Test procedure
	Stored data button	Activates the Stored Data function
	Settings button	Activates the Settings menu
	Verify button	Allows for the performance of a second test, on the same patient, using a new Cuvette, without the need for re-entering the Patient ID and other information
	Comment input button	Allows a comment to be added to the current result
	Comment input button (dotted)	Button appearance confirms that comments have been added to the result

ATTACHMENT 1


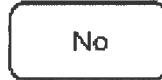
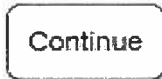




OTHER DISPLAY BUTTONS:

Button	Designation	Function
	Help button	Displays on-line help regarding other buttons, procedures, etc.
	Confirm button	Saves text or numbers and/or displays the next screen image NOTE: All inputs/changes will be saved
	Log Out button	Logs out the operator NOTE: The Log Out button is only displayed if the Operator ID is required.
	Special Character button	Enters a special character (see explanations below) NOTE: Other special characters can only be loaded into the Analyzer by means of the Barcode Scanner.
	See above	Space – press once
	See above	Period – press twice
	See above	Hyphen – press three times
	View button	Provides a more detailed description of the highlighted item.






Button	Designation	Function
	Letter buttons	Allows input of a text Example: To enter a "G" – press once To enter an "H" – press twice To enter an "I" – press three times NOTE: Only capital letters will be entered. Lower-case letters can be entered into the Analyzer by means of the Barcode Scanner.
	Digit buttons	Allows input of a digit
	Add button	Allows addition of a comment to a result, an item to a list, etc.
	Delete button	Allows deletion of a comment from a result, an item from a list, etc.
	Accept button	Accepts a measurement
	Reject button	Rejects a result A rejected result will be saved and flagged as rejected.

ATTACHMENT 4

OTHER DISPLAY BUTTONS (CONT.):




Button	Designation	Function
	Save button	Stores the entered information
	No button	The entered information will not be stored.
	Continue button	Continues the current operation
	Statistics button	Displays statistics on the chosen subject
	Date format button	Switches between the following date formats: <ul style="list-style-type: none"> • YYMMDD • DD.MM.YY • MM/DDYY
	Time format button	Switches between the following time formats: <ul style="list-style-type: none"> • 12 hours • 24 hours
	AM/PM button	Enables adding "AM/PM" (only 12-hour format)

DISPLAY SYMBOLS:

Symbol	Designation	Function
	Battery	Indicates the voltage status of the Battery in four levels. The furthest to the left is fully charged, the one to the right is almost empty.
03/03/04	Date	Indicates the Date format chosen (from three possibilities) in the Settings Menu
	Big Hourglass	The big hourglass is displayed when the Analyzer is in the measuring or selftesting state
	(rotating)	NOTE: The big hourglass is rotating when displayed
	Small hourglass	When the small hourglass is displayed, the instrument is in a measuring or blanking state NOTE: When displayed in the Main Menu, only Settings and Stored Data functions are available. It is also possible to log out
	Waste bin	Indicates that a result has been rejected. The result is stored in the Analyzer.

ATTACHMENT 1

DISPLAY SYMBOLS (CONT.):

Symbol	Designation	Function
	QC Reminder	Reminder that a QC Test will be required within stated time or number of measurements
	QC Lockout	QC Lockout, i.e. no more Patient Test measurements can be made The required QC Test has not been performed.
	Lockout	Supervisory Lockout The Analyzer has been locked by the Supervisor. A text that indicates this will be displayed.



PROCEDURE: HMS Plus Hemostasis Management System:
Activated Clotting Time, Heparin Assay, Heparin Dose Response

Purpose: To monitor heparin management during cardiopulmonary bypass.

Supportive Data: POC Quality Management Manual (Vol. I)

Authorized to Perform Procedure: Perfusionist

A. DEFINITION:

1. The Medtronic HMS Plus Hemostasis Management System Operator's Manual has been reviewed and found acceptable to NCCLS standards. Testing should follow manufacturer instructions and recommendations as indicated in the user manual and package inserts. Exceptions or clarifications specific to Tri-City Medical Center are listed in this procedure.

B. TITLE:

1. HMS Plus Hemostasis Management System

C.B. INTRODUCTION/ PRINCIPLE:

1. The HMS Plus instrument is an integrated system consisting of a component for tracking clot detection and computing results, a component for sample delivery, and the single use test cartridges for actual performance of the tests.
2. The detection process uses the plunger assembly within the cartridge. This assembly is lifted and dropped through the sample/reagent mixture by a lifting mechanism in the HMS Plus actuator. As the sample clots, a fibrin web forms around the daisy, located on the bottom of the plunger assembly, and impedes the rate of decent of the assembly. A photo optical system located in the actuator assembly of the instrument detects this change in fall rate. The end point of the test is the time at which clot formation is detected; from these clotting times, derived results are calculated for all tests.

D.C. SPECIMEN:

1. Fresh whole blood, collected in a 3 mL Monoject syringe that is supplied with the cartridges. Blood may be obtained either by venipuncture or from arterial or venous access lines. See instructions below.
 - a. Venipuncture Collection: The venipuncture must be fast, non-traumatic, and the first 2 to 3 ml of blood collected and discarded in a separate syringe in order to prevent contamination of the test sample with tissue activator (thromboplastin) and the potential for erroneous results. Blood should flow quickly into the syringe.
 - b. Indwelling Catheter Collection: Flush the line with 5 ml saline, and using separate, single use syringes, collect at least 5 ml or 6 dead space volumes of blood and discard prior to collection of the test sample in order to eliminate the risk of excess dilution and contamination of the sample with heparin from the catheter or line.
2. Minimum sample volumes:
 - a. HDR 3.0 mL
 - HPT (4 channel) 1.5 mL
 - HPT (6 channel) 2.5 mL
 - HPT and HR-ACT 2.5 mL
3. Handling Conditions:
 - a. Specimens should be tested as quickly as possible following sample collection.
 - i. HDR: within 60 seconds, since the specimen is Unheparinized.
 - ii. HPT and HR-ACT: within 60 seconds when there is no anticoagulant on board. Within 2 minutes when sample is heparinized.
4. Reagents/Supplies:

Department Review	Clinical Policies & Procedures	Nurse Executive Council	Department of Pathology	Medical Executive Committee	Professional Affairs Committee	Board of Directors
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- a. Refer to HMS Plus Operator's manual, section 4-2: Cartridge Design.
 - b. Refer to HMS Plus Operator's manual, section 4-3: Types of Test Cartridges.
 - i. HMS Plus Instrument
 - ii. Test cartridges
 - iii. 3- mL syringes
 - iv. 19-gauge 1 7/16-inch blunt needles
5. Types of Cartridges
- a. Heparin Dose Response (HDR): The HDR is a modified HR-ACT, which measures the *in vitro* anticoagulant response to a known concentration of heparin. This response can be used to evaluate a patient's resistance or sensitivity to heparin. It can also be used to estimate a minimum heparin dose required to achieve a desired target clotting time (HR-ACT).
 - b. Heparin Assay (HPT): The Heparin Assay test uses the principle of heparin/protamine titration to quantitatively determine the concentration of heparin in the sample. The heparin concentration determined by the HPT test is used to calculate any additional heparin required to maintain the patient at the [Protocol Hep Conc] entered into the system.
 - c. Activated Clotting Time (HR-ACT): The HR-ACT is a functional evaluation of the intrinsic coagulation system. It evaluates heparin anticoagulation as well as numerous factors affecting intrinsic clotting.
6. Cartridge Preparation:
- a. HDR: Cartridges should be gently shaken or tapped to re-suspend the kaolin and pre-warmed in the heat block of the HMS Plus for at least 3 minutes prior to using.
 - b. HPT: Gently shake or tap the cartridge before use. Pre-warming of the HPT cartridge is not required.
 - c. HR-ACT: Cartridges should be gently shaken or tapped to re-suspend the kaolin and pre-warmed for at least 3 minutes in the heat block of the HMS Plus.
7. Precautions:
- a. HPT: If the heparin concentration is measured at Channel 1 in a Heparin Assay cartridge that does not have a zero (protamine) in Channel 1, the actual heparin may be lower than the measured value. Similarly, if it is measured in Channel 4 of a four-channel cartridge or Channel 6 of a six-channel cartridge, the actual heparin value may be higher than the measured value. In these cases, another test with a different cartridge (lower or higher as needed) should be run to confirm the result.
 - b. Regarding Heparin Concentration: see HMS Plus Operators manual 2-5.
 - c. Regarding Heparin Dose Response: see HMS Plus Operators Manual 2-6.
8. Instrumentation/Calibration:
- a. Refer to HMS Plus Operator's Manual, section 1: Product Description: Application and Use. Refer to HMS Plus Operator's manual, section 3: Installation and Setup. No user Calibration.
9. Quality Control:
- a. Refer to HMS Plus Operator's manual, section 7: Maintenance and Quality control.
 - a-b. Refer to Control material Package Insert.
 - c. Refer to the Lab generated form: HMS Plus Maintenance Log for current QC requirements.
 - b-d. Indicate completed QC on log.
 - e-e. Liquid quality control must be run:
 - i. On each new lot/shipment of test cartridges (Refer to Note: New Reagent Lot Validation) ~~b-}~~
 - i-ii. Once per week
 - d-f. Electronic quality control must be run each 8 hours of use (once per shift)
10. New Reagent Lot Validation.
- a. For ACT and HPT cartridges, test liquid controls on new lots/shipments of cartridges before use.

- i. If controls fall within the Manufacturer established ranges, or "pass", the new lot/shipment of cartridges is considered acceptable for use.
 - ii.b. For HDR cartridges, run a patient on the old and new lots concurrently.
 - 4)i. For the new lot of reagent to be considered acceptable for use, the difference in results must be clinically insignificant, as determined by the Perefusionist.
 - iii.c. Indicate on the "New Reagent Lot Validation Log" that the lot number has been tested and is acceptable for patient use.
 - iv.d. The laboratory will review control data to ensure that control and patient ranges are similar across different lots of cartridges.
11. Notes:
- b.a. Before performing a quality control test, valid lot numbers and expiration dates for both cartridges and controls must be entered. In the case of the HR-ACT controls the ranges for the controls must also be entered.
 - e.b. **Note:** Because controls are produced using prior USP heparin formulation, the heparin type should be set to [Porcine] to run liquid controls. Attempts to run the controls while in the [IU] heparin type setting will result in longer than expected run times for the control test and may produce a failed control result—run times exceeding 249 seconds. (Notice dated 3/8/10).
- d-12. Instructions for performing Heparin Assay CONTROLS:
- i.a. Set heparin type:
 - 4)i. from main menu, select "instrument parameters"
 - 2)ii. select "heparin type"
 - 3)iii. toggle to [Porcine]
 - 4)iv. press "enter" to confirm selection
 - 5)v. perform QC testing
 - ii.b. Quality control records are maintained in the instrument and periodically downloaded and reviewed by the Laboratory designee.

E.D. QC RANGES HEPARIN ASSAY:

Four-Channel			
HPT Control	Cartridge Type (mg/kg)	Required Channel Detection	Required Clotting Time
Red/Yellow	0.0 – 0.9 RED	4	< 249 sec
Red/Yellow	0.0 – 1.5 YELLOW	3 or 4	< 249 sec
Tan/Silver	1.5 – 3.0 TAN	4	< 249 sec
Tan/Silver	2.0 – 3.5 SILVER	3 or 4	< 249 sec
Blue/Gold	2.5 – 4.0 BLUE	3 or 4	< 249 sec
Green/White	3.5 – 5.0 GREEN	3 or 4	< 249 sec
Purple/Black	4.5 – 6.0 PURPLE	3 or 4	< 249 sec

Six-Channel			
HPT Control	Cartridge Type (mg/kg)	Required Channel Detection	Required Clotting Time
Orange	0.0 – 2.5 ORANGE	5 or 6	< 249 sec
Blue/Gold	1.5 – 4.0 GOLD	5 or 6	< 249 sec
Green/White	2.5 – 5.0 WHITE	5 or 6	< 249 sec
Purple/Black	3.5 – 6.0 BLACK	5 or 6	< 249 sec

F.E. HR-Act

Ranges will change lot to lot—refer to the package insert.	
CLOTtrac HR Normal	75 – 115
CLOTtrac HR Abnormal	270 – 710

G.F. MAINTENANCE:

1. Refer to HMS Plus Operator's manual, section 7: Maintenance and Quality control.

- a. To be completed monthly:
 - i. Verify dispenser volume delivery
 - ii. Verify heat block temperature
- b. To be completed routinely:
 - i. Clean the instrument case and exposed surfaces of the actuator and dispenser of dust and dried blood
 - ii. Clean/ Replace salvage reservoir (located under the dispenser).
- c. Maintenance is recorded on the Lab generated form: HMS Plus Maintenance Log.
- d. **Discard of all the completed testing materials and controls in the provided and appropriate waste containers.**

H.G. PROCEDURE:

1. Refer to HMS Plus Operator's manual, section 5: Operating Instructions.
 - a. Note: Users of the HMS Plus must be aware of which type of heparin is being administered and configure the HMS Plus appropriately. Due to the change in potency, when NEW USP heparin is used, the HMS instrument "heparin type" must be set to "IU" to ensure correct blood dispensing and calculations of results. (Notice dated 12/19/09)
 - b. Instructions for performing HPT and HDR PATIENT tests with new USP Heparin:
 - c. Set heparin type:
 - i. from main menu, select "instrument parameters"
 - ii. select "heparin type"
 - iii. toggle to [IU]
 - iv. press "enter" to confirm selection
 - v. perform QC testing

I.H. CALCULATIONS:

1. Refer to HMS Plus Operator's manual, section 4-11: Calculations.
 - a. Blood Volume Calculations
 - b. Heparin Dose Response Calculations
 - c. Heparin Bolus Dose Calculations
 - d. Heparin Assay Calculations

J. EXPECTED VALUES/ REFERENCE RANGE/ CRITICAL VALUES:

- ~~1. Expected values/ reference range/ critical values~~

K.I. TECHNICAL NOTES:

1. Refer to HMS Plus Operator's manual section 2: Warnings and Operational Precautions.

L.J. LIMITATIONS:

1. Refer to HMS Plus Operator's manual, section 2: Warnings and Operational Precautions.
2. **Difficulty in collection of the sample for testing may result in activation and erroneous results. If the test results do not correlate with the patient's clinical picture the test should be repeated on a new sample.**

M.K. REPORTING RESULTS:

1. Results are recorded in the patient medical record.
2. **POCC evaluates held up patients' results that are pending to post on patients' charts whenever needed.**

N.L. REFERENCE(S):

1. Medtronic. *HMS Plus Version 4.0 Hemostasis Management System Operator's Manual*. 2005
2. Medtronic. HEPtrac™ Electronic Quality Control Operator's Manual, 1998.
3. Medtronic. Heparin Assay Cartridges. Package Insert. 2004. A10740001-02.
4. Medtronic. Heparin Assay Controls. Package Insert. 2004. A08717001-01.
5. Medtronic. HR-ACT Cartridges. Package Insert. 2003. UC200402200ML.

6. Medtronic. HR-ACT Controls. Package Insert. 2004. A08718003-01.
7. Medtronic. Heparin Dose Response Cartridges. Package Insert.
8. NCCLS Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline, AST2-A, Volume 19, Number 9, June 1999.
9. **HMS Plus Individualized Quality Control Plan (IQCP) in Point of Care/Lab binder.**

O.M. ATTACHMENTSRELATED DOCUMENT(S):

1. Log_ACT HMS Plus Troubleshooting (Rev.1_042010)
2. Log_HMS maintenance (Rev. 2_072010)
3. Log_ACT HMS Plus New Lot Acceptability Testing log (Rev.1_102010)
4. Log_ACT/HMS New Reagent Lot Validation Log (Rev.1_102010)



**Tri-City Medical Center
Oceanside, California**

PATIENT CARE SERVICES Pharmacy Manual

ISSUE DATE: 02/03 **SUBJECT:** Medication Recall

REVISION DATE: 06/03, 08/05, 01/06, 03/08, 02/09 **POLICY NUMBER:** ~~IV.1.9~~
07/11, 11/14


Department Approval:	10/1601/18
Clinical Policies & Procedures Committee Approval:	11/1602/18
Nurse Executive Council Approval:	01/1703/18
Medical Staff Department/Division Approval:	n/a
Pharmacy and Therapeutics Committee Approval:	02/1703/18
Medical Executive Committee Approval:	03/1704/18
Professional Affairs Committee Approval:	04/17
Board of Directors Approval:	04/17

A. POLICY:

1. The Pharmacy Department shall maintain a system whereby drugs subject to recall are immediately identified, removed from active inventory, and sequestered.
2. The Pharmacy Department is notified of manufacturer's or Food and Drug Administration (FDA's) recall or medication discontinuation proceedings through direct mail, wholesaler's notification, written or electronic FDA Safety Alert or Recall Notification.
 - a. Chronological files of such notifications, alerts, and recall notices shall be maintained for at least one (1) year.

B. PROCEDURE:

1. When the Pharmacy Department receives information about a medication recall or discontinuation by the manufacturer or the FDA for safety reasons, **affected providers and/or patients will be notified of the recall or discontinuation if required by law or regulation.**
 - a. ~~All individuals ordering, dispensing, and/or administering recalled or discontinued medications are notified.~~
 - b.a. ~~Affected providers and/or patients will be notified of the recall or discontinuation if required by law or regulation.~~
2. The pharmaceutical buyer or designee shall remove all lots of a recalled drug if found in inventory. Recalled medications are replaced with an unaffected lot number of the same medications or generic equivalent, when available.
 - a. A record of actions taken shall be written on the recall notice; including none found in inventory and the date the action was taken.
 - a.b. **If affected lots of recalled drugs were identified in inventory, the Pharmacy Director or designee will be notified of all actions taken by the buyer or designee.**
 - b. ~~The notice is forwarded to the Director of Pharmacy or designee upon completion of the recall action.~~
3. All drug storage areas of the hospital shall be inspected, including satellite pharmacies, surgery and other floor stock areas if applicable.
4. Recalled medications are quarantined in a designated area separate from active stock. This area is clearly identified.
5. Recalled medications are returned in accordance with manufacturers/recall notice specifications.
6. Medications recalled for safety reasons are reported to the Pharmacy and Therapeutics Committee.

 Tri-City Medical Center	Patient Care Services
PROCEDURE: URINE PH	
Purpose:	To provide an accurate and reliable method for reading urine pH.
Supportive Data:	An RN may perform this procedure. Testing is under the direction, authority, jurisdiction, and responsibility of the Laboratory Medical Director.
Equipment:	1. pH paper or strips, approved by laboratory 2. Two (2) Levels Quality Control (current manufacturer provided by lab)

A. PRINCIPLE:

1. Urine pH can be affected by several internal and external causes. Diet is the main, non- medical determinant of urine pH. A high protein diet will produce acid urine (pH below 7.0). A vegetarian diet will produce alkaline urine (pH above 7.0). Medical factors to consider are respiratory or metabolic acidosis or alkalosis, renal function, crystal or calculi formation, urinary tract status, and medications.

B. SPECIMEN:

1. **All specimens should be handled using the principles of Universal Precautions due to the potential presence of pathogenic material.**
- 1-2. **Collect freshly clean catch (voided) urine, catheterized (cath) or suprapubic urine.**
3. **Collect in a clean dry container. Label with patient identification.**
- 2-4. **If you do not perform the urine pH testing in the presence of the patient, you must label the urine container.**
- 3-5. **Because of certain rapid chemical changes and the rapid proliferation of bacteria, test the urine within 2 hours. Reject and re-collect any urine sitting at room temperature greater than two (2) hours as pH will falsely increase with time. Mix well before testing.**

C. ~~Reagents and Supplies~~ REAGENTS AND SUPPLIES:

1. pH indicator test Strips.
2. Two levels of urine quality control (QC).
 - a. Request test strips and controls from the lab.

D. ~~Quality Control~~ QUALITY CONTROL:

1. Two levels of quality control (QC) must be tested daily before performing patient tests and when opening a new vial of strips.
2. Record results on Point of Care Quality Control log. Verify results are within acceptable ranges.

C.E. PROCEDURE:

- ~~SUPPLIES: Request test strips and controls from the lab.~~
2. ~~QUALITY CONTROL: Two levels of quality control (QC) must be tested daily before performing patient tests and when opening a new vial of strips.~~
- a-1. Verify strips are not expired. Strips expire on the date listed on the container. If no expiration date is listed by the manufacturer, assign an expiration date 12 months after open the date. Mark this date on the container.
 - b-2. Use current manufacturer and lot of controls as supplied by the lab. Verify expiration is clearly marked and that the controls are not expired.
 - e-3. Open-vial stability may change with a change in the Control Manufacturer, but in general, expiration date is 30-days after opening.
 - d. ~~Record results on Point of Care Quality Control log. Verify results are within acceptable ranges.~~


Department Review	Clinical Policies & Procedures	Nurse Executive Council	Department of Pathology	Medical Executive Committee	Professional Affairs Committee	Board of Directors
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3. PATIENT:

- a-4. Mix urine sample well **before testing**.
- b-5. Dip pH indicator strip into urine. Leave test strip in urine until color no longer changes **and is stable**. Remove. Draw the edge of the strip along the rim of the container to remove excess urine.
- c-6. **Read pH by cComparing**- the color change of the strip to color chart on package and select the value of the closest match.
- d-7. Record Results in the medical record.

D. REFERENCES:

- 1. No normal range established

 Tri-City Medical Center		Patient Care Services										
PROCEDURE:	WHOLE BLOOD PT/INR USING THE ROCHE COAGUCHEK XS PLUS METER											
Purpose:	To provide an accurate and reliable method to monitor oral anticoagulant therapy in the point of care setting.											
Supportive Data:	Point of Care The CoaguChek XS Plus is a CLIA waived system. Roche Technical Support: 1-800-428-4674. www.coaguchek.com											
Equipment:	<table border="0"> <tr> <td>1. CoaguChek XS Plus meter</td> <td>6. Lancet (at least 1.8mm depth)</td> </tr> <tr> <td>2. CoaguChek XS PT test strips</td> <td>7. Alcohol wipe or soap and water</td> </tr> <tr> <td>3. CoaguChek XS PT test strip code chip (from same box as test strip)</td> <td>8. Gauze or tissue</td> </tr> <tr> <td>4. CoaguChek XS Plus Liquid Controls</td> <td>2-9. Bandages</td> </tr> <tr> <td>4-5. CoaguChek XS Plus Liquid Control code chip</td> <td></td> </tr> </table>		1. CoaguChek XS Plus meter	6. Lancet (at least 1.8mm depth)	2. CoaguChek XS PT test strips	7. Alcohol wipe or soap and water	3. CoaguChek XS PT test strip code chip (from same box as test strip)	8. Gauze or tissue	4. CoaguChek XS Plus Liquid Controls	2-9. Bandages	4-5. CoaguChek XS Plus Liquid Control code chip	
1. CoaguChek XS Plus meter	6. Lancet (at least 1.8mm depth)											
2. CoaguChek XS PT test strips	7. Alcohol wipe or soap and water											
3. CoaguChek XS PT test strip code chip (from same box as test strip)	8. Gauze or tissue											
4. CoaguChek XS Plus Liquid Controls	2-9. Bandages											
4-5. CoaguChek XS Plus Liquid Control code chip												
Authorized to Perform Procedure:	Registered Nurse (RN), License Vocational Nurse (LVN), Medical Assistant (MA)											

A. INTRODUCTION/PRINCIPLE:

1. Prothrombin Time (PT) is a test of the blood's ability to clot. Blood clots form in response to vessel injury to prevent excessive loss of blood. If blood clots form inappropriately and lodge in the vascular system of important organs, serious consequences such as stroke can result. In certain medical conditions (i.e. atrial fibrillation or mechanical heart valves) blood clots are more likely to form, and there is increased risk of stroke. Oral anticoagulants are used to prevent clots in these conditions.
2. Oral anticoagulants have a narrow therapeutic range and the response to a standard dose varies widely both between patients and within a patient over time. Patients undergoing oral anticoagulant therapy must have their level of anticoagulation monitored often. Dosage adjustments should be made as needed to ensure maximum safety and efficacy.
3. The Prothrombin Time (PT) test is the principle assay used to monitor oral anticoagulant therapy. The dosage of oral anticoagulant is adjusted based on the PT test results to recommended therapeutic ranges. The PT can be reported in seconds or as an International Normalized Ratio (INR). The INR is a mathematical conversion that compensates for differences between PT methods.
4. The CoaguChek XS Plus test strip and meter will provide an electrochemical measurement of Prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood works with the chemicals in the test strip to make a small electric current in the test strip that measures blood-clotting time.

B. SPECIMEN:

1. Requirements:
 - a. Fresh capillary whole blood or fresh venous whole blood drawn in an anticoagulant-free plastic syringe.
 - b. The blood sample must be applied to the test strip within 10 minutes of removing the strip from its container.
 - c. Capillary sample must be applied to the strip within 15 seconds of the fingerstick.
 - d. Minimum sample size is 10 uL of blood.
2. Criteria for rejecting specimens:
 - a. Plasma or serum cannot be used.
 - b. Sample size cannot be less than 10 uL.

Department Review	Clinical Policies & Procedures	Nurse Executive Council/Committee	Department of Pathology	Pharmacy and Therapeutics Committee	Medical Executive Committee	Professional Affairs Committee	Board of Directors
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- c. Additional blood sample must not be added to the test strip once testing has begun.
 - d. Meter will beep to indicate that sufficient blood has been applied and that testing has begun.
 - e. Venous sample cannot be collected in a syringe containing anticoagulant, or into a glass tube or syringe.
 - f. Sample must be used immediately after collection.
 - g. Do not collect from an arm receiving an infusion line for **intravenous (IV)** therapy.
3. Collecting a Fingertick Sample:
- a. Prepare lancet device according to manufacturer's instructions. Set it aside until finger puncture is needed.
 - b. Warm the hand by having the patient hold it under their arm, using a hand warmer, or washing with warm water.
 - c. If possible, have the patient hold his or her arm down to the side, so the hand is below the waist, for about 30 seconds to increase blood flow.
 - d. Massage the finger from its base.
 - e. Clean the selected finger with alcohol wipe or use soap and warm water. Allow to air dry completely.
 - f. Prepare the meter.
 - g. When the meter displays the flashing test strip and blood drop symbols, with the hand still down, stick the side of the finger with a lancet. Do not wipe away the first drop of blood. Do not puncture the finger until the flashing test strip and blood drop symbol appears on the meter screen.
 - h. Gently squeeze and release the finger from the base to develop a hanging drop of blood.
 - i. Blood should be applied within 15 seconds of the puncture. Do not touch the strip with the finger. Do not apply a second drop or disturb the strip while testing.
 - j. While the flashing test strip and drop of blood symbols are flashing on the display, apply the first drop of blood as outlined in ~~V.I.B PROCEDURE~~-Performing a Test **Procedure**.

~~C.~~ **REAGENTS/SUPPLIES:**

1. ~~CoaguChek XS Plus meter~~
2. ~~CoaguChek XS PT test strips~~
3. ~~CoaguChek XS PT test strip code chip (from same box as test strip)~~
4. ~~CoaguChek XS Plus Liquid Controls~~
5. ~~CoaguChek XS Plus Liquid Control code chip~~
6. ~~Lancet (at least 1.8mm depth)~~
7. ~~Alcohol wipe or soap and water~~
8. ~~Gauze or tissue~~
9. ~~Bandages~~

~~D.C.~~ **STORAGE AND STABILITY:**

1. Store test strips in their container, with the cap closed.
2. Store test strips at room temperature or in the refrigerator (2-30 °C or 36-86 °F).
3. When stored properly, the test strips can be used until the expiration date printed on the test strip container.
4. Store test strips in a cooler with an ice pack when transporting in a car.
5. Dispose of strips past their "use by" date.
6. Use the test strip within 10-minutes after removing it from the container.
7. Do not open a vial of test strips or touch a test strip with wet hands or gloves. This may damage the test strips.
8. Close the container tightly.
9. A blue color on the back of the test strip indicated storage conditions have been maintained. A lavender or purple color indicates that storage conditions have been exceeded. Do not use and dispose of any test strips with a lavender or purple color on the back.

E.D. OPERATING CONDITIONS

1. Temperature: Use between 59F and 90F. Humidity: Use between 10-85%.
2. Use only fingertips on touchscreen.
3. Place on level, vibration-free surface while testing.
4. Do not use near strong magnetic fields.

F.E. METER SET-UP (CHANGES FROM DEFAULT SETTINGS)

1. Lockouts > QC > New Code > YES

G. ~~INTRUMENTATION/CALIBRATION:~~

1. ~~The CoaguChek XS System has quality control functions integrated into the meter and test strips; two levels of QC are automatically run with every patient test. If the QC results are acceptable, the patient results will display.~~
2. ~~Liquid controls must be performed on each new shipment and lot of test strips. Record results on the Quality Control Log.~~

H.F. QUALITY CONTROL:

1. The CoaguChek XS System has quality control functions integrated into the meter and test strips; two levels of QC are automatically run with every patient test. If the QC results are acceptable, the patient results will display.
2. Liquid controls must be performed on each new shipment and lot of test strips. Record results on the Quality Control Log.

I.G. PROCEDURE:

1. Before Testing:
 - a. A code chip is required for each lot of test strips. The XS Plus meter will store data from 60 code chips.
 - b. Leave the code chip in the meter to protect the electrical contacts.
 - c. Inserting the Code Chip:
 - i. Be certain the meter is Off.
 - ii. Remove the old code chip and throw it away.
 - iii. Make sure the 3-number code on the new test strip container matches the 3-number code on the new code chip.
 - iv. Insert the code chip into the code chip slot on the meter with the printed side facing up it snaps into place.
2. Performing a test:
 - a. Use hand hygiene.
 - b. Prepare the lancet device according to manufacturer's instructions.
 - c. Place meter on a flat surface, free of vibrations, or hold it so it is roughly horizontal.
 - d. Turn the meter on using the power button.
 - e. The main menu will be displayed. Check the battery level (if there are no bars left in the battery symbol, ~~you cannot~~ **it is not possible to perform any more tests**). Check that the date and time are correct.
 - f. Select 'Patient Test'.
 - g. Enter the patient ID, then press OK. Select the patient from the list, or select 'New Patient' and enter a patient ID.
 - h. The test strip symbol prompts ~~staff~~ you to enter a test strip. Remove a test strip from the container and close the container tightly. Hold the strip so the print is facing upward. Slide the strip into the test strip guide in the direction indicated by the arrows. Slide it in as far as it will go. A beep tone indicates the meter has detected the strip.
 - i. If this is a new lot of test strip, ~~you will be~~ **it is necessary** required to run liquid QC **first**. Refer to ~~V.I.C PROCEDURE~~ Performing Liquid Quality Control **procedure**.
 - i. An hourglass symbol shows that the meter is warming (approximately 30 seconds).
 - j. When the meter is ready, the flashing test strip and blood drop symbols appear. ~~and~~

- ~~t~~The meter begins a countdown, ~~staff~~**You** have 120 seconds to apply blood to the test strip. Do not obtain sample until the flashing test strip and drop of blood appear on the display. Strip must be used within 10 minutes of removing it from the container.
- k. Identify the sample target area on the test strip.
 - l. Collect the fingerstick blood sample as outlined in "Specimen":
 - m. Do not wipe away the first drop of blood.
 - n. Apply the first drop of blood to the top or side of the target area within 15 seconds of puncture. Do not touch the strip with the finger.
 - i. ~~Note: you can~~ dose the target area by bringing the patient's finger to the top of the test strip, or keeping the meter level, by bringing the meter to the patient's finger so that the side of the test strip touches the blood drop. Do not apply a second drop. Do not touch strip while a test is in progress.
 - ii. Be certain that blood covers the sample target area completely.
 - iii. The meter beeps when it detects the drop. The flashing blood drop symbol disappears. Do not add more sample. Do not touch the test strip or move the meter until the result is displayed.
 - o. ~~You must~~ Wait for results—this takes about one minute.
 - p. ~~If you must~~ **retest is necessary**, use a new fingerstick from the opposite hand and a new test strip.
 - q. Read and record results. Remove the test strip.
 - r. Turn the meter Off.
 - s. Dispose of materials in biohazard or sharps container.
3. Performing Liquid Quality Control:
- a. Remove control vials from the fridge.
 - b. Open the lid of the control bottle and remove the rubber cap.
 - c. Hold the dropper with the sealed dropper neck pointing upward, then cut off the end of the cap with scissors. **Ensure dropper is away from face to prevent contamination**~~Do not hold the dropper close to your face~~. Do not squeeze the bulb of the dropper while cutting the tip.
 - d. Apply gentle pressure to the reservoir to transfer the entire contents of the dropper to the bottle. Make sure the dropper does not come in contact with the dried control plasma.
 - e. Close the bottle. Keep the dropper at hand.
 - f. Swirl the bottle using a circular motion to completely dissolve all the control plasma inside. Do not shake the bottle or turn it on its side. The solution is not ready to be applied to the test strip. (Controls may be used up to 30 minutes after reconstitution.)
 - g. Turn the meter on. Check the battery level, date, and time.
 - h. Select QC Test.
 - i. Remove a test strip from the container, close the container, and insert the test strip into the meter.
 - i. ~~If you are~~ using a new test strip lot and have not inserted the test strip code chip, ~~you must~~ do so now.
 - ii. ~~If you are~~ using a new control lot, ~~you must~~ insert the code chip that came with the control solution.
 - j. Select the code already stored for ~~your~~ control or select New Code to use a new control solution.
 - k. Select the level for this measurement.
 - l. The hourglass will appear while the strip is warming.
 - m. When the strip and dropper symbol display, ~~you may~~ apply the sample. **Staff**~~You~~ have 120 seconds to complete this step.
 - i. Using the dropper, draw up the dissolved contents of the vial.
 - ii. Apply a single drop of solution to the test strip. Enough sample is applied when the meter beeps.
 - n. The result will be displayed and saved to memory.
 - o. If liquid QC test fails, an arrow will be displayed and flash. Repeat first with the same

- control and a new test strip. If the control still fails, repeat with a new vial of control. If control continues to fail, contact the laboratory.
- p. Remove the test strip and turn the meter off.
4. Recalling Results:
 - a. From the main menu, select 'Memory'.
 - b. Select 'Patient Result' or 'QC Result'.
 - c. Scroll through the data using the up and down arrows. The most recent test is listed at the top.
 - d. Select a result. The patient ID, test result, date and time of test, and strip code is displayed.
 - e. ~~If you select~~ the 'individual' symbol **is selected**, only results for this patient will be displayed.
 5. Cleaning the Meter:
 - a. Use only 70% isopropyl alcohol or 10% bleach to clean the meter housing:
 - i. With the meter turned OFF, ensure the blue test strip guide cover remains tightly closed while cleaning the housing.
 - ii. Make sure no liquid enters the meter or accumulates near any opening.
 - iii. Let the disinfectant sit on the meter for at least ~~one~~**two minutes for alcohol wipes and five minutes for bleach wipes.**
 - iv. Wipe away residual moisture and fluids after cleaning the housing.
 - v. Allow wiped areas to dry for at least 15 minutes before performing a test.
 - b. Use only 70% isopropyl alcohol or 10% **bleach** to clean the test strip guide upon opening a new bottle of test strips. Use of any other cleaning solutions can result in damage to the meter or incorrect patient results.
 - c. With the meter turned off, ~~use your thumbnail to~~ open the cover of the test strip guide by pressing its front edge upward.
 - d. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean.
 - e. Hold the meter upright with the test strip guide facing down. (This will help prevent fluid from entering the meter.) Clean the easily accessible areas of the test strip guide with a cotton-tipped swab. Ensure the swab is only damp, not wet. Caution: do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide. Wipe the test strip guide area. Let the cleaning solution sit for at least one minute.
 - f. Wipe away any residual moisture and fluids. Let the inside of the test strip guide dry for at least 15 minutes with the cover off.
 - g. Close the cover. Make sure it snaps into place.
 6. Troubleshooting:
 - a. If the meter displays a message other than a result, refer to the Error Messages section of the CoaguChek XS Plus System User Manual.
 7. Calculations: n/a
 8. Expected values/reference range/critical values:
 - a. Normal Range:
 - i. The CoaguChek XS meter displays results in units equivalent to those used for the laboratory plasma measurements.
 - ii. Normal, healthy, warfarin free individuals: 0.9 – 1.0 INR
 - b. Therapeutic Range: must be determined by the physician/**Allied Health Professional (AHP)** for each patient based on the reason for anticoagulation therapy and how each patient responds to treatment.
 - i. Less intense 2.0-3.0 INR
 - ii. More intense 2.5-3.5 INR (mechanical heart valves, etc)
 - c. Reportable range:
 - i. The meter will display results 0.8 – 8.0 INR.
 - ii. Any INR greater than or equal to 3.1 must be verified by the laboratory.

- d. Unexpected results:
 - i. If the meter displays an unusual test result, check the strip code, date, and time programmed into the meter.
 - ii. Repeat the test with a new fingerstick and test strip. If the result is still unexpected, draw a sample for the laboratory.
- e. Limitations:
 - i. This method should not be used for patients being treated with Hirudin.
 - ii. Hematocrit ranges between 25-55% do not significantly affect test results.
 - iii. The presence of anti-phospholipid antibodies (such as lupus Ab) can lead to prolonged clotting times. Test using a lab APA-insensitive method.
 - iv. Do not use the meter near strong electromagnetic fields.
 - v. Results are unaffected by heparin levels up to 0.8U/mL and low molecular weight heparin levels up to 2 IU anti-factor Xa activity/mL.
 - vi. Failure to follow cleaning procedures correctly can lead to a falsely elevated result.
- f. Reporting results:
 - i. Record the result in the patient's chart.
 - ii. Record the result on the XS Plus Patient Test Log (for regulatory requirements).

J.H. REFERENCE(S):

1. Roche Diagnostics. CoaguChek XS PT Test Product Insert. 7/2010. 05967716001 (02).
2. Roche Diagnostics. CoaguChek XS Plus System Policies and Procedures. 2007. 05021499001-00-0807.
3. Roche Diagnostics. CoaguChek XS Plus System User Manual. 05021464001 (02) 2009-11 USA.
4. **Roche Diagnostics. CoaguChek XS Plus System Policy and Procedure manual CD 2012.**

~~K. ATTACHMENTS):~~

- ~~1. Logs_xs plus (Rev.4_052012)~~
- ~~2. XS Plus Instrument Log~~
- ~~3. XS Plus Reagent Log~~
- ~~4. XS Plus Patient Test Log~~
- ~~5. XS Plus Troubleshooting Log~~
- ~~6. XS Plus Equipment Issue Log~~
- ~~7. XS Plus Quality Control Log and New Lot Acceptability Log~~
- ~~8. Logs_High Confirmation (Rev.1_042012)~~

Behavioral Health Services
Inpatient Behavioral Health Unit

SUBJECT: Treatment Planning
POLICY NUMBER: 722

ISSUE DATE: 03/08
REVISION DATE(S): 08/09, 03/13, 06/16

Department Approval: 09/17
Division of Psychiatry Approval: n/a
Pharmacy and Therapeutics Approval: n/a
Medical Executive Committee Approval: n/a
Professional Affairs Committee Approval:
Board of Directors Approval:

A. **PURPOSE:**

1. To establish the requirements for interdisciplinary treatment and to develop appropriate treatment plans that address patients' identified problems.

B. **POLICY:**

1. A patient's treatment on the Inpatient Behavioral Health Unit (**BHU**) will be guided by a written, individualized interdisciplinary, medically approved plan of care that meets all regulatory requirements.

C. **PROCEDURE:**

1. Treatment planning will begin with the initial treatment plan that is developed by the Registered Nurse (**RN**) at the time of the patient's admission.
 - a. The RN will synthesis assessment data gathered from the psychiatric liaison assessment, the attending psychiatrist, and the initial nursing assessment to identify at least one and up to several presenting patient problems.
 - b. The RN will establish the plan by completing a problem sheet for each identified problem and recording short term goals and interventions that address that problem.
2. Pursuant to written clinical assessments the treatment team will meet to develop the interdisciplinary treatment plan.
3. The treatment plan will be patient centered and will be based upon biopsychosocial assessment data that includes, at minimum, the patients strengths and limitations, present concerns, presenting symptoms and problems, medical co-morbidities, physical health needs, risks, psychiatric history, allergies, substance abuse co-morbidities, preferences for de-escalation techniques, support systems, and current housing situation.
4. High value is placed upon maximum patient participation in treatment planning.
5. Following each discipline's presentation of pertinent assessment data the team, led by the psychiatrist, will identify the core problems that will be addressed during the hospitalization.
6. Problems will include any significant medical or substance abuse co-morbidities in addition to those related to the present psychiatric symptomatology.
7. If psychotropic medication has been prescribed for the patient fall risk will be identified as a problem to be addressed.
8. Long term, and short term treatment goals and interventions will be developed for each identified problem and the clinical discipline best credentialed to provide the interventions will be assigned.

9. Expected time for goal achievement will be identified as well.
10. Treatment interventions should be complete and should include the groups the patient will be attending, as well as individual therapy that is assigned.
11. All core clinical assessments will be completed before the treatment planning conference is held. It is expected that the treatment plan will be developed 72 hours after the patient's admission.
12. At the conclusion of the treatment planning meeting each clinical staff that participated will sign the treatment plan.
13. A recorder will document the identified problems **and treatment goals**, in language the patient can understand, ~~and treatment goals~~ and will review the plan with the patient.
14. The patient will be given an opportunity to add to the plan, or to comment on it, in writing, and will be asked to sign the plan to acknowledge that it has been discussed.
15. The patient will be given a copy of the treatment plan upon his or her request.
16. At least every seven (7) days after the treatment plan has been developed the team will meet to review the patient's progress toward established treatment goals and to modify the plan to increase its effectiveness. Patient input will be sought for treatment plan reviews.
17. Documentation in clinical notes in the patient's medical record will be based upon the problems, goals, and interventions identified in the treatment plan.
18. If additional problems are identified after the treatment plan has been written and before the treatment plan review, an additional problem sheet will be added to the plan. The clinical staff who identifies the problem will be responsible for informing the team of its addition.
19. Each clinical staff will review the patient's treatment plan for assigned patients after receiving report and before planning interventions for that patient every day on each shift. This will ensure consistency in approach and will maximize achievement of the identified treatment goals.

D. RELATED DOCUMENT(S):

1. **Behavioral Health Services Policy: Clinical Assessment**
2. **Behavioral Health Services Policy: Suicide Risk Assessment and Management**
3. **Behavioral Health Services Policy: Treatment of Psychiatric Patients in Psychiatric Assessment Area**
- 20-4. **Patient Care Services Procedure: Fall Risk Procedure and Score Tool**

Behavioral Health Services
Inpatient Behavioral Health Unit
Crisis Stabilization Unit

SUBJECT: Washer/Dryer Use
POLICY NUMBER: 405

ISSUE DATE: 04/05
REVISION DATE(S): 04/10, 03/13, 06/16

Department Approval: 09/17
Division of Psychiatry Approval: n/a
Pharmacy and Therapeutics Approval: n/a
Medical Executive Committee Approval: n/a
Professional Affairs Committee Approval:
Board of Directors Approval:

A. **PURPOSE:**

1. To establish guidelines for safe usage of washer and dryer in the Behavioral Health Unit (BHU) and Crisis Stabilization Unit (CSU).

B. **POLICY:**

1. Any wet or soiled clothing or linen is considered to be potentially infectious. Therefore, Standard Precautions are always used in handling of these items.
 - a. Contain patient's clothing at source of used in moisture proof bag.
 - b. Carry bagged laundry to the laundry room for washing/drying.
 - c. Launder one patient's clothing at a time. Do not mix clothing with other patient's clothing.
2. The laundry room will remain locked at all times for safety and protection of patient property. Staff will **launder patient clothes** ~~facilitate use of laundry room~~. **Patients are not permitted in the laundry room.**

C. **PROCEDURE:**

1. Routine washing and drying of patient's clothing:
 - a. Don gloves prior to handling patient's clothing.
 - b. Place clothing into washer.
 - c. Select load size, i.e., small, medium, large.
 - d. Set water temperature. Hot water should be used for heavily soiled clothing.
 - e. Sort clothing accordingly.
 - f. Measure detergent (30 cc medium load, 60 cc large load).
 - g. Turn control knob to desired wash cycle.
 - h. Push appropriate button to start machine.
 - i. Check inside washer for cleanliness, and if necessary, wipe with Super Sani-Cloth, Germicidal Disinfectant Wipes (purple top container); hospital approved disinfectant.
 - j. After wash cycle has finished, place laundered clothing into dryer.
2. Operation of dryer:
 - a. Clean lint filter before **and after each use of the** ~~starting dryer for each use~~.
 - b. Select desired temperature.
 - c. Turn control knob clockwise to desired drying cycle.
 - d. Turn control knob clockwise to desired time of automatic shutoff.

e. Remove clothing promptly and return to patient promptly (use patient labels as appropriate).

3. Washing and Drying of heavily soiled or stained clothing:

a. Disinfection of washing and drying machines in health-care facilities is not needed as long as gross soil (e.g., feces) is removed before washing and proper washing and drying procedures are used.

b. The physical removal of bulk solids before the wash/dry cycle, proper temperature, and detergent shall be used for heavily soiled clothing items.

| D. **REFERENCE(S):**

1. Guidelines for Environmental Infection Control in Health-Care Facilities: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, 2003.

REHABILITATION SERVICES POLICY MANUAL
~~TRI-CITY MEDICAL CENTER~~
4002 Vista Way, Oceanside, California

**SUBJECT: OUTPATIENT DISASTER PLAN-
2124 EL CAMINO REAL**

POLICY NUMBER: 1502

ISSUE DATE: 7/91

REVISION DATE(S): 10/93, 9/97, 12/99, 11/02, 2/03, 1/06, 1/09, 5/12

Department Approval Date(s): 03/18

Department of Medicine Approval Date(s): n/a

Medical Executive Committee Approval Date(s): n/a

Professional Affairs Committee Approval Date(s):

Board of Directors Approval Date(s):

~~ISSUE DATE: 7/91~~

~~SUBJECT: OUTPATIENT DISASTER PLAN 2124 El
Camino Real Oceanside~~

~~REVISION DATE: 10/93, 9/97, 12/99, 11/02,
2/03, 1/06, 1/09, 5/12~~

~~STANDARD NUMBER: 1502~~

~~REVIEW DATE:~~

~~CROSS REFERENCE:~~

~~APPROVAL:~~

This Policy / Procedure applies to the following Rehabilitation Services' locations:

~~F~~ 4002 Vista Way, Oceanside, CA

~~F~~ 161 Thunder Drive, Suite 112, Vista, CA

~~F~~ 6250 El Camino Real, Carlsbad CA ~~3861 Mission Ave B25, Oceanside, CA~~
~~510 Hacienda Drive 108A, Vista, CA~~

A. PURPOSE:

1. To ensure the appropriate response and safety of the Outpatient Rehabilitation Services personnel in the event of a major disaster.

B. PERSONNEL:

1. ~~The Orthopedic Service Line Rehab Leadership Staff Administrator~~
~~Supervisors and Seniors~~
2. Department Staff

C. PROCEDURE:

1. In the event of a Disaster Alert Phase:
 - ~~1.a.~~ **Rehab Services Leadership In Charge** or their designee will be notified by Administration and advised of the circumstances.
2. The ~~Orthopedic Service Line Administrator~~ **Rehab Leadership**/Designees will then:
 - a. Notify the Outpatient clinic by phone if possible, two-way radio, or by messenger in the event the phone/radio is not working.
 - b. Review the Department's Disaster Plan and call-back protocol.
 - c. Inventory equipment and supplies.
 - d. **Emergency evacuation/area of refuge will be located at the South East corner of the parking lot.**

3. In the event of a Disaster Activation Phase:
 - a. Employees in the outpatient clinic, located at ~~161 Thunder Drive~~ **2124 El Camino Real**, will immediately cancel all therapies, lock/~~secure the area~~**building**, and return to the main hospital Rehabilitation Services Department or other assigned area.
 - b. Activate the call-back protocol.
 - c. In the event that the disaster is in the clinic, dial 911 and report the disaster to the ~~Orthopedic Service Line Administrator~~ **Rehab Services Leadership In Charge** and the main hospital's Emergency Department by phone, if workable, two-way radio, or by messenger if phone/radio contact is impossible. Outpatient employees ~~should~~ **shall** remove any patients from danger. They should then wait for assistance from **EMS** or the Medical Center in a safe area, such as outside in the back parking lot.
 - d. The ~~Orthopedic Service Line Administrator~~ **Rehab Services Leadership In Charge** will notify the Disaster **Incident command (ICC)** ~~Control Center~~ and Emergency Department of the Department's readiness.
 - e. The ~~Orthopedic Service Line Administrator~~ **Rehab Services Leadership In Charge** will submit periodic reports to the ~~Disaster Control Center~~ **ICC**.
 - f. The Department will be expected to assist in the management of disaster victims. Personnel will be requested to respond to triage areas.
4. Ongoing Review:
 - a. This Policy/Procedure will be reviewed and updated as needed.
 - b. It is ~~the responsibility~~ **the responsibility** of the Department ~~Managers and Supervisors~~ **Leadership** to orient and educate the staff to the plan, including periodic drills, to maintain an -updated version of the plan and update ~~the call-back roster~~ **br**.

~~Delete next page.~~

PROCEDURE: FIRE PLAN INPATIENT REHABILITATION SERVICES 1508

Purpose: Staff members are responsible for removing patients from designated areas within the rehabilitation unit.

DELETE: Follow hospital wide Environment of Care: Fire Plan Code Red Policy.

A. POLICY:
~~Staff members are responsible for removing patients from designated areas within the rehabilitation unit.~~

PROCEDURE:

~~Rescue:~~

- ~~1. Patients should be escorted from the danger area to the parking area behind the Behavioral Health Sciences/Rehab Unit. Routes to be followed, depending on the danger, are: exit through the O.T. kitchen area to the parking area or exit through the gymnasium via 1 North to the emergency exit door (next to Room 104) and to the parking area. Refer to Rehabilitation Services evacuation plan.~~

~~Alarm:~~

- ~~2. Turn on the alarm.~~
 - ~~a. Notify the PBX operator by dialing 66. State the location of the fire, indicating, if possible, its severity.~~
 - ~~b. Pull the nearest fire alarm.~~

~~Contain~~

- ~~3. **Extinguish:** Close all doors, windows, and use fire extinguisher to confine the area of the fire, if appropriate, until help arrives.~~

~~Extinguish~~

- ~~a. To operate the extinguisher, twist out the safety pin, direct the horn at the base of the fire, and then press the valve lever.~~
- ~~b. Do not use water pressure extinguisher or fire hose on any electrical apparatus, oil or grease fire. CO₂ extinguishers are provided in areas where this type of fire is likely to occur.~~
- ~~c. Use wet blankets or spreads, if necessary, to help control the blaze.~~

~~**Volunteers & Non Staff Personnel**~~

~~Tri-City Healthcare District believes strongly in the principle of life safety. The organization recognizes as a practical matter that members of the medical staff/Allied Health Professionals and many volunteers and students are not present much of the time and are not likely to be a reliable resource during a fire response. Therefore, the medical staff, volunteers, and students do not have a specific defined role in the fire response plan. They are instructed to remain in the area they are located at the time an alarm sounds and to render assistance under the direction of the manager or employees of the area as needs arise.~~

- ~~4. Remove all valuable records if possible.~~
- ~~5. Responsibility for reporting a fire:~~
 - ~~a. During business hours, the Director of Rehabilitation Services should report any fire and fill out a Quality Review report.~~

Department Review	Department of Medicine	Pharmacy and Therapeutics	Medical Executive Committee	Administration
12/15, 03/18	n/a	n/a	n/a	07/91, 02/94, 03/97, 10/00, 11/02, 01/09, 05/12



REHABILITATION SERVICES-POLICY-MANUAL

SUBJECT: FIRE PLAN - OUTPATIENT REHAB SERVICES- POLICY NUMBER: 1509

ISSUE DATE: 07/91

REVISION DATE(S): 02/94, 08/97, 10/99, 11/02, 02/03, 01/06, 05/08, 01/09

Department Approval: 12/15,03/18
 Department of Medicine Approval: n/a
 Pharmacy and Therapeutics Approval: n/a
 Medical Executive Committee Approval: n/a
 Professional Affairs Committee Approval:
 Board of Directors Approval:

~~ISSUE DATE: 7/91~~

~~SUBJECT: FIRE PLAN FOR OP REHAB SERVICES & WOUND CARE CENTER at 161 Thunder Drive, Vista~~

~~REVISION DATE: 2/94, 8/97, 10/99, 11/02, 2/03, 1/06, 5/08, 1/09~~

~~STANDARD NUMBER: 1509~~

~~REVIEW DATE: 5/12~~

~~CROSS-REFERENCE:
APPROVAL:~~

~~A. PURPOSE~~

- ~~1. To remove patients from danger area in the event of a fire.~~

~~B. POLICY~~

~~**POLICY:**~~

- ~~1. Staff members are divided into 2 teams that are responsible for removing patients from designated areas within the clinic. **Outpatient Clinic.** Areas/teams will be updated on an annual basis or as needed (team assignment is on Page 2 of this policy).~~
- ~~1. Team Areas:~~
- ~~a. = Front lobby, OT room, chart room, lobby restroom, Medical Director and Wound Care Center Director offices, Wound Care Center treatment rooms 1-4, hyperbaric chamber room, hall restroom~~
- ~~B = Rehab gym, rooms 5-9, staff restroom, lunch room, Private treatment rooms, central therapy treatment area, staff office, and two restrooms consist of OT staff, PT staff, and Rehab Aides.~~
- ~~Front office and waiting area consists of Office staff.~~

~~**PROCEDURE:**~~

~~Rescue:~~

- ~~2. The individual who sees the fire will remove rescue anyone in immediate danger from the area. Front office staff will notify the emergency medical system by dialing 911, giving the exact location of the building, the fire, and, if possible, the severity of the fire.~~

~~Alarm:~~

~~Dial "911"~~

- ~~3. Code Red, with the location, will be announced 3 times over the loudspeaker.~~

~~EXTINGUISH/Contain:~~

4. Staff members in the vicinity of the fire will contain the fire ~~if safe to do so by closing, close all doors and windows,~~ place a wet towel at the base of door, and, if possible, use a fire extinguisher to confine the area of the fire until help arrives.

~~CONTAIN~~Extinguish:

1. Staff members in the vicinity of the fire will contain the fire, close all doors, place a wet towel at the base of the door, and, if possible ~~if safe to do so,~~ use a fire extinguisher to confine the area of ~~extinguish~~ the fire until help arrives. **To operate the extinguisher: Supervisors are responsible for showing new employees the location of extinguishers and alarm pull stations during department orientation. Remember the acronym PASS for extinguisher use:**

~~— Pull safety pin from extinguisher on/off lever~~

~~— P: PULL the pin~~

~~— Aim nozzle at the base of the fire~~

~~— A: AIM the nozzle at the base of the fire~~

~~— Squeeze the trigger~~

~~— S: SQUEEZE the handle~~

~~— Sweep the base of the fire~~

~~— S: SWEEP back and forth across the base of the fire~~

~~Evacuation Plan: In the event of a fire or disaster requiring Outpatient Clinic evacuation, follow these steps:~~

~~— Sound the alarm: "Evacuate the Building."~~

~~— All staff members will ensure that all of our patients are safely removed from designated areas within the Outpatient Clinic.~~

2. All staff members will evacuate patients with whom they are in immediate contact.

~~— Team A exits with patients through front via the Clinic's side doors and will exit door. the building and wait in the designated congregation point.~~

~~— Team B exits with patients through the Clinic's front door and waits in the designated congregation point.~~

~~— Volunteers & Non Staff Personnel:~~

~~— Tri-City Healthcare District believes strongly in the principle of life safety. The organization recognizes as a practical matter that members exit through the back door in the gym. Close doors of the medical staff/Allied Health Professionals and many volunteers and students are not present much of the time and flip tags in assigned areas before exiting. All staff are not likely to be a reliable resource during a fire response. Therefore, the medical staff, volunteers, and patients/students do not have a specific defined role in the fire response plan. They are instructed to remain in the area they are located at the time an alarm sounds and to render assistance under the direction of the manager or employees of the area as needs arise.~~

- a. **Designated Congregation Point:** In the event of an emergency requiring evacuation of patients and staff, all personnel and patients will evacuate the Outpatient Clinic and congregate to the back outside the building's side entrance in the east parking lot of the facility. area. An alternative location may be determined if the original designated congregation point is found to be unsafe during the event.

REHABILITATION SERVICES

SUBJECT: Fire and Internal Disaster Drill - Outpatient-Wellness **POLICY NUMBER:** 1507

ISSUE DATE: 01/09
REVISION DATE(S): 05/12

Department Approval: 08/15003/18
Department of Medicine Approval: n/a
Pharmacy and Therapeutics Approval: n/a
Medical Executive Committee Approval: n/a
Professional Affairs Committee Approval:
Board of Directors Approval:

~~ISSUE DATE: 1/09~~ ~~SUBJECT: FIRE & INTERNAL DISASTER DRILL - WELLNESS CENTER~~
~~REVISION DATE: 5/12~~ ~~STANDARD NUMBER: 1507~~
~~REVIEW DATE:~~ ~~CROSS REFERENCE:~~
~~APPROVAL:~~

~~A. PURPOSE~~

~~B. To ensure a complete understanding of proper response to a fire or internal disaster in the Wellness Center located at 6250 El Camino Real, Carlsbad, CA 92009~~

A. POLICY:

1. Mock fire and internal disaster drills will be held on a minimum of once every twelve months.

B. PROCEDURE:

- ~~1.~~ 1. The Director of **Safety**/Environment of Care and/or ~~Senior Leadership designee~~ **Therapist** will be responsible for the coordination and implementation of mock fire and internal disaster drills at the Wellness Center.
- ~~1.2.~~ 1.2. The Director of **Safety**/Environment of Care and/or ~~Leadership designee~~ **Senior Therapist** will inform a Rehab Services staff member that a mock drill is starting and exactly what and where the mock fire or disaster is.
- ~~2.3.~~ 2.3. The staff will respond according to the Rehabilitation Services Department's fire or disaster plan.
- ~~1.4.~~ 1.4. The Director of **Safety**/Environment of Care and/or ~~Leadership designee~~ **Senior Therapist** will observe and take notes. Any problems or questions will be addressed at the time of the drill. The summary of result will be shared with the Wellness Center Rehab Services staff at the subsequent staff meeting, and any resulting questions will be addressed in that forum.
5. Results of the drill will be sent to Director of **Safety**/Environment of Care.



DELETE – no longer use this location

REHABILITATION SERVICES

SUBJECT: FIRE PLAN - OUTPATIENT REHAB SERVICES POLICY NUMBER: 15091506

ISSUE DATE: 07/91

REVISION DATE(S): 02/94, 08/97, 10/99, 11/02, 02/03, 01/06, 05/08, 01/09

Department Approval:	08/1503/18
Department of Medicine Approval:	n/a
Pharmacy and Therapeutics Approval:	n/a
Medical Executive Committee Approval:	n/a
Professional Affairs Committee Approval:	
Board of Directors Approval:	

ISSUE DATE: 7/91

SUBJECT: FIRE PLAN FOR OP REHAB SERVICES & WOUND CARE CENTER at 161 Thunder Drive, Vista

REVISION DATE: 2/94, 8/97, 10/99, 11/02, 2/03, 1/06, 5/08, 1/09

STANDARD NUMBER: 1509

REVIEW DATE: 5/12

CROSS REFERENCE:
APPROVAL:

A. PURPOSE

1. To remove patients from danger area in the event of a fire.

B. POLICY:

2. Staff members are divided into 2 teams that are responsible for removing patients from designated areas within the clinic. **Outpatient Clinic.** Areas/teams will be updated on an annual basis or as needed (team assignment is on Page 2 of this policy).
3. Team Areas:
 - Front lobby, OT room, chart room, lobby restroom, Medical Director and Wound Care Center Director offices, Wound Care Center **Private** treatment rooms 1-4, hyperbaric chamber room, hall restroom, **central therapy treatment area, staff office, and 2 restrooms, consists of OT staff, PT staff, and Rehab Aides.**
 - Rehab gym, rooms 5-9, staff restroom, lunch room **Front office and waiting area consists of Office staff**

PROCEDURE:

1. TEAM AREAS:

- a. **TEAM A:** Front lobby, OT room, chart room, lobby restroom, Medical Director and Wound Care Center Director offices, Wound Care Center treatment rooms 1-4, hyperbaric chamber room
- i. **Consists of:** Office staff, Hand Therapy staff, Wound Care nurses, medical assistants and hyperbaric technicians, Wound Care Center Physician, Program Director
- b. **TEAM B:** Rehab gym, rooms 1-5, staff restroom, lunchroom, staff office
- c. **Consists of:** OT/PT staff, Rehab Aides

2. RESPONSIBILITIES:

4. **Rescue:** The individual who sees the fire will remove anyone in immediate danger from the area.
- B. Front office staff will notify the emergency medical system by dialing 911, giving the exact location of the building, the fire, and, if possible, the severity of the fire.

1. ~~Alarm: Code Red, with the location, will be announced 3 times over the loudspeaker.~~
2. ~~Contain, EXTINGUISH: Staff members in the vicinity of the fire will contain the fire, close all doors and windows, place a wet towel at the base of door, and, if possible, use a fire extinguisher to confine the area of the fire until help arrives.~~
 - a. ~~To operate the extinguisher, twist out the safety pin, direct the horn at the base of the fire, and then press the valve lever.~~
1. ~~CONTAIN, Extinguish: Staff members in the vicinity of the fire will contain the fire, close all doors, place a wet towel at the base of the door, and, if possible **safe to do so**, use a fire extinguisher to confine the area of ~~extinguish~~ the fire until help arrives. **To operate the extinguisher:**~~
 - ~~**Pull safety pin from extinguisher on/off lever**~~
 - ~~**Aim nozzle at the base of the fire**~~
 - ~~**Squeeze the trigger**~~
 - ~~**Sweep the base of the fire**~~
- ~~Evacuation Plan: In the event of a fire or disaster requiring Outpatient Clinic evacuation, follow these steps:~~
 - ~~Sound the alarm: "Evacuate the Building."~~
 - ~~All staff members will ensure that all of our patients are safely removed from designated areas within the Outpatient Clinic.~~
2. ~~All staff members will evacuate patients with whom they are in immediate contact.~~
 - ~~Team A exits with patients through front **via the Clinic's side doors and will exit door, the building and wait in the designated congregation point.**~~
 - ~~Team B exits with patients through the Clinic's front door and waits in the designated congregation point.~~
- ~~Volunteers and Non-Staff Personnel:~~
 - ~~Tri-City Healthcare District believes strongly in the principle of life safety. The organization recognizes as a practical matter that members exit through the back door in the gym. Close doors of the medical staff/Allied Health Professionals and many volunteers and students are not present much of the time and flip tags in assigned areas before exiting. All staff are not likely to be a reliable resource during a fire response. Therefore, the medical staff, volunteers, and patients/students do not have a specific defined role in the fire response plan. They are instructed to remain in the area they are located at the time an alarm sounds and to render assistance under the direction of the manager or employees of the area as needs arise.~~
- a. ~~Designated Congregation Point: In the event of an emergency requiring evacuation of patients and staff, all personnel and patients will evacuate the Outpatient Clinic and congregate to the back ~~outside the building's side entrance in the east parking lot of the facility.~~ area.~~

REHABILITATION SERVICES POLICY MANUAL

SUBJECT: Staff Rotations

ISSUE DATE: 11/88

REVISION DATE(S): 1/91, 11/94, 5/97, 1/00, 1/06, 1/09, 4/12

Department Approval Date(s): ~~07/15~~03/18

Department of Medicine Approval Date(s): n/a

Pharmacy and Therapeutics Approval Date(s): n/a

Medical Executive Committee Approval Date(s): n/a

Professional Affairs Committee Approval Date(s): 09/15

Board of Directors Approval Date(s): 09/15

A. POLICY:

1. Occupational Therapy, Physical Therapy and Speech Language Pathology is accountable through Leadership Structure of Rehabilitation Services to promote a varied clinical experience, through the change in their primary work area, while maintaining a system of continuity of care in each work area.

B. PROCEDURE:

1. A minimum of one therapy staff member will be the primary therapy provider in each designated area which includes but is not limited to:
 - a. Outpatient services
 - i. Orthopedics
 - ii. Neurologic
 - iii. Lymphedema
 - iv. Hands
 - v. Aquatics
 - vi. Swallow Studies
 - vii. Pediatrics
 - viii. Other Specialties based on current practice
 - b. Inpatient services
 - i. Medical/Surgical
 - ii. Acute Rehabilitation
 - iii. Orthopedics
2. Upon request, the staff may be given the option of rotating to another primary work area, or as deemed appropriate by the Leadership Structure of Rehabilitation Services.
3. Rotations will proceed with the following considerations:
 - a. Each area must maintain a minimum of one staff member or as indicated based on patient care needs
 - b. Staff will orient to the work area
 - c. Staff will be notified of upcoming rotations as appropriate/applicable

REHABILITATION SERVICES

SUBJECT: Supervision of Patients - Outpatient
POLICY NUMBER: 1106

ISSUE DATE: NEW
REVISION DATE(S):

Department Approval: 09/15
Department of Medicine Approval: n/a
Pharmacy and Therapeutics Approval: n/a
Medical Executive Committee Approval: 02/18
Professional Affairs Committee Approval:
Board of Directors Approval:

ISSUE DATE:	SUBJECT: SUPERVISION OF PATIENTS OP
REVISION DATE:	STANDARD NUMBER: 1106
REVIEW DATE:	CROSS REFERENCE:
	APPROVAL:

A. ~~PURPOSE~~

- ~~1. To follow the state and discipline specific guidelines necessary for Patient Supervision during Physical, Occupational, Speech and Language Pathology sessions provided by TCMC Rehabilitation Services Staff.~~

B.A. POLICY/PROCEDURE:

1. All physical, occupational and speech and language pathology evaluations and treatments will be ~~conducted~~ **directed** and supervised by discipline specific licensed **clinical** staff.

B. PROCEDURE:

1. Licensed clinical staff includes: Physical Therapists (**PT**), Occupational Therapist, Speech and Language Pathologists **&and** Physical/Occupational Therapy Assistants.
2. Support Staff may include PT Aides **&and** Rehabilitation Aides.
3. Support staff ~~will~~ **may** carry out tasks under the guidance of the Licensed Physical/Occupational Therapists in supporting patient therapy sessions as per the guidelines established by the state and discipline specific regulatory body.

C. REFERENCE(S) LIST:

1. California Physical Therapy State Practice Act. (n.d.). Physical Therapy Board of California. Retrieved July 7, 2015, from Physical Therapy Board of California Website: <http://leginfo.ca.gov/cgi-bin/displaycode?section=bpc&group=02001-03000&file=2620-2634>
2. California Board Of Occupational Therapy Regulations. (2015). *Title 16, Division 39 California Code of Regulations-*.

TRI-CITY MEDICAL CENTER
Oceanside, California

SURGICAL SERVICES POLICY MANUAL

DELETE

No longer have these committees.
Surgery representatives (staff RN's) participate in TCMC Shared Decision Making councils.

SUBJECT: STAFF BASED COMMITTEES/MEETINGS

ISSUE DATE: 04/94

REVISION DATE(S): 01/05; 05/09; 10/12; 01/13

Department Approval Date(s): 03/18

Operating Room Committee Approval Date(s):

Board of Directors Approval Date(s):

A. ~~STAFF BASED UNIT COMMITTEES:~~

~~1. EXISTENCE / PURPOSE~~

~~Unit based nursing committees are organized to accomplish the business of managing the unit and participatively involve the nursing staff in decision making in clinical and managerial issues.~~

~~2. CURRENT UNIT NURSING COMMITTEES~~

~~Current Operating Room staff committees consist of a Coordinator Committee and the following Shared Decision Making Committees: Professional Development Council, Performance Improvement/Quality Council, Practice Council and Nursing Leadership Council. The function of each staff group is detailed below.~~

B. ~~COORDINATOR COMMITTEE:~~

~~1. PURPOSE~~

~~The committee meets to review budgetary/capital issues, preference card, inventory, and equipment/instrumentation issues. It provides a forum for identifying issues and decisions regarding supplies, instrumentation, computer records, capital equipment and cost containment.~~

~~2. FUNCTION~~

~~The committee will plan for standardization of supplies and instrumentation in the OR. It will discuss capital equipment requests from the surgical division. The committee will develop processes for the procurement of special equipment and implants.~~

~~3. SCOPE OF AUTHORITY~~

~~The OR Coordinators Committee is accountable to the Director of Surgical Services.~~

~~4. MEMBERSHIP~~

~~The unit based OR Coordinators Committee shall consist of RN coordinators representing the surgical service department, the Director, Perioperative Manager, OR Educator, OR Materials Manager, and OR Informatics Specialist.~~

~~5. OFFICERS~~

~~The committee will be chaired by the Perioperative Manager and the minutes shall be taken by an appointed committee member.~~

~~6. AGENDA~~

~~Agenda ideas should be submitted to the Chairperson at least one week prior to the meetings. Additional items may be added as necessary. An agenda will accompany the minutes of each meeting.~~

~~7. RECORD KEEPING~~

~~Minutes shall be recorded at each meeting the recorder shall place a copy of the minutes in the Nurse Coordinator Meeting Minutes Binder, which will be maintained in the OR staff lounge.~~

~~8. ATTENDANCE~~

~~Members are expected to attend the scheduled meetings. Members must notify the Chairperson if unable to attend. The Chairperson will appoint a temporary Chairperson to perform the functions of the position in his/her absence.~~

~~9. MEETING DAY AND TIME~~

~~The unit based Nurse Coordinator Committee shall meet the first Monday of every month from 1300-1430, or more frequently as deemed necessary by the Chairperson.~~

C. NURSING PROFESSIONAL DEVELOPMENT COUNCIL:

~~1. NAME~~

~~The name of the council shall be called the nursing professional development (NPDC) council.~~

~~2. MISSION STATEMENT~~

~~The NPDC council defines and maintains educational standards that promote professional development and ongoing clinical competency and quality in all practice settings for nurses, technicians and surgical support staff at all levels through: (1) professional engagement; (2) commitment to professional development; (3) teaching and role development utilizing EBP; and (4) commitment to community involvement through structural empowerment.~~

~~3. PURPOSES~~

~~The purposes of the NPDC council are to:~~

- ~~a. Support of all nursing, technicians and support staff employees to promote professional growth and competency~~
- ~~b. Provide a structure and process to enable all levels of nurses, technicians and support staff to actively participate in organizational decision-making groups~~
- ~~c. Establish and promote relationships and partnerships among all types of community organizations~~
- ~~d. Help nurses, technicians and support staff extend their influence to professional and community groups~~
- ~~e. Encourage educational advancement~~
- ~~f. Provide for the sharing of educational information and resources~~
- ~~g. Encourage communication of best practices~~
- ~~h. Act as a resource in continuous development, improvement, and evidence-based practice~~
- ~~i. Provide and promote continuing education~~
- ~~j. Act as a resource for other communities of practice~~
- ~~k. To promote the development of nursing as a profession~~
- ~~l. Networking~~
- ~~m. Support and encourage preceptorships and mentoring in all practice settings~~

~~4. OBJECTIVES~~

~~The objectives of the NPDC council shall be to:~~

- ~~a. Use multiple strategies to establish and support lifelong professional learning, role development, and career advancement~~
- ~~b. Achieve improvements because of nurse and technician involvement~~
- ~~c. Identify improvements due to involvement in professional organization(s)~~

- d. Summarize changes over time showing the organization met goals for improvement:
 - i. in formal education
 - ii. in professional certification
 - iii. in participation of nurses and technicians in all specialties and subspecialties
 - e. Evaluate effectiveness of structures and processes used to develop and provide continuing education programs for nurses and technicians at all levels, including onsite internal electronic and classroom methods, not including orientation
 - f. Support nurses involved in community educational activities
 - g. Engage non-nurse employees and community members interested in becoming nurses through career development opportunities
 - h. Promote the teaching role of nurses, technicians and support staff at all levels
 - i. Facilitate effective transition of new graduate nurses into the work environment
 - j. Support academic practicum experiences and nurses and technicians serving as preceptors, instructors, and adjunct/faculty
 - k. Identify and allocate resources for affiliations
 - l. Facilitate participation of nurses and technicians at all levels in service to the community.
5. RESPONSIBILITIES
- a. Educational and competency needs of staff related to practice, quality, and competency
 - b. Staff education through in-services, staff development programs, and continuing education (contact hours)
 - c. Resources to meet staff education needs
 - d. Certification and academic advancement
 - e. Educational programs that reflect evidence-based nursing practice
 - f. Outcomes of educational programs (i.e., mentorship, preceptor, recognition, unlicensed assistive personnel [UAP], and academics)
6. ACCOUNTABILITIES
- The NPDC council is accountable for the following, which must be carried out where designated and cannot shift elsewhere in the Tri-City Medical Center:
- a. Learning activities (i.e., conferences, workshops, educational fairs, and in-service trainings)
 - b. Professional and specialty certifications
 - c. Unit education activities (i.e., mandatory training/education and documentation, in-services, competency verifications, unit specific training)
 - d. Academic affiliations (i.e., student nurses)
 - e. Transition programs (i.e., preceptors, mentors, graduate nurses, and leadership [e.g., charge nurse programs])
 - f. Orientation
 - g. Staff development for career advancement (i.e., RNs, APNs, LPNs, and UAP)
 - h. External education funding opportunities (i.e., partnerships, grants, scholarships, community fund sources [e.g., through partnerships with academic affiliates])
 - i. Recruitment and recognition programs
 - j. Communication of activities as appropriate
7. MEMBERSHIP
- a. Membership on the unit-based NPDC shall be open to voluntary representatives from each shift, each specialty, and all job categories.

- b. The Perioperative Clinical Educator shall serve as facilitator.
 - c. Membership is a one-year commitment.
8. OFFICERS
- a. The committee shall elect a Chair, Co-Chair and Secretary.
 - b. Each position shall serve a term of 1 year; the Co-Chair shall become the chairperson after one year.
 - c. See "Committee Officers" responsibilities in TCMC Shared Decision Making By-laws.
 - d. The Chair shall represent the Surgery NPDC at the TCMC Shared Decision Making council on the first Tuesday of the month at 0800-1000.
 - e. The Chair shall present the committee report monthly to the Perioperative Leadership Meeting, the second Tuesday of each month at 1300.
9. DECISION MAKING MECHANISM
- a. Decisions will be made by a majority vote of the members present.
 - b. Whenever possible, a round table discussion and vote will be utilized so each member has opportunity to voice their concerns/vote.
10. AGENDA
- a. Agenda items shall be submitted at least one week prior to the meeting, by completing a Shared Decision Making Action Request Form (located in the Coordinator's Office) and submitting to the chair.
 - b. The Chair shall formulate and print the agenda for each meeting.
11. RECORD KEEPING
- a. Minutes shall be recorded at each meeting by the Secretary/designee.
 - b. Minutes shall be electronically saved in the designated folder on the Surgery Shared Drive, printed and posted in the NPDC binder in the staff lounge, and posted on the NPDC bulletin board by the Surgery front desk.
 - c. Minutes shall be printed for each meeting for member review and approval.
 - d. All meeting handouts, forms and records shall be maintained in the NPDC binder in the staff lounge.
 - e. Records shall be maintained for 3 years.
12. MEETING SCHEDULE AND ATTENDANCE
- a. Meetings are scheduled the 3rd Monday of each month at 1200-1300. If the regularly scheduled meeting falls on a holiday, the meeting will be rescheduled to a different Monday.
 - b. Members are expected to attend the scheduled meetings. Members shall notify the chair if unable to attend the meeting.
 - c. Four or more unexcused absences per year will result in members forfeiting their membership on the committee.

D. PERFORMANCE IMPROVEMENT/QUALITY COUNCIL:

- 1. NAME
The name of the council shall be called the NPIQC.
- 2. MISSION STATEMENT
The mission of the NPIQC is the empirical measurement of quality outcomes related to nursing leadership and clinical practice for Tri-City Medical Center, demonstrating how nurses, technicians and support staff make an essential contribution to patient, the workforce, organizational, and consumer outcomes.
- 3. PURPOSES
The purposes of the NPIQC are to:

- a. Promote continuous improvement in the quality of patient care, EBP, and clinical research, measuring and reporting compliance with established standards of care and practice
- b. Establish baselines for measures and track progress over time compared to baseline and national benchmarks (i.e., NDNQI) in defining areas of improved performance and those needing further effort to improve
- c. Mentor and lead in providing quality patient care and creating practice environments that contribute to the well-being of the workforce and the community

4. OBJECTIVES

The objectives of the NPIQC shall be:

- a. Establish monitors and ensure compliance for identified patient care and practice standards
- b. Monitor structures and processes that involve direct care in tracking and analyzing staff satisfaction and/or engagement data
- c. Continually assess and monitor relationships among structures and processes of care and associated outcomes,
 - i. Empirical quality outcome, (e.g., patient outcomes, risk-adjusted mortality index, healthcare-acquired infections, falls and injuries associated with falls, hospital-acquired pressure ulcer occurrence/prevalence, patient overall satisfaction, patient satisfaction with nursing care/educational information/pain management, patient perception of safety, and specialty population-specific outcomes)
 - ii. Staff outcomes (e.g., levels of staff engagement and satisfaction, perception of nurse autonomy, turnover and vacancy rates, percentages of direct care registered nurses, nurse leaders and technicians with certification, educational preparation of staff, rates and types of staff injuries, and staff perceptions of safe culture and work environment and orientation and/or effectiveness of continuing education programs)
 - iii. Organizational outcomes (e.g., efficiency and/or elimination of waste, CNE impact on system-level change, consumer outcomes, impact of community outreach programs, and community health and welfare)
- d. Partner with all nursing governance and unit-level councils and nurses to evaluate and track changes in practice and outcomes related to these changes
- e. Collaborate with the CQC to ensure dissemination of comprehensive quality data to direct care staff
- f. Benchmark, summarize, and report nursing-sensitive indicator data (i.e., NDNQI) aggregated at unit and organization levels to change and/or improve practice at the point of care: patient falls, nosocomial pressure ulcer prevalence and/or incidence, blood stream infections, urinary tract infections, ventilator-associated pneumonia, restraint use, IV infiltrations, and other specialty-specific nationally benchmarked indicators
- g. Mentor and guide staff in making essential contributions to patient, nursing workforce, organizational, and consumer outcomes through the empirical measurement of quality outcomes

5. RESPONSIBILITIES

- a. Establish monitors for identified patient care and nursing practice standards to ensure compliance

- b. Evaluate monitors which remain out of compliance for more than one quarter
- c. Act as a resource and provide education for unit-level quality improvement functions
- d. Monitor root cause analysis for all sentinel events
- e. Review sentinel events and adverse events to initiate change in practice
- f. Assist with regulatory compliance (e.g., The Joint Commission)
- g. Oversee unit-level quality projects and changes in practice related to performance measures outcomes data

6. ACCOUNTABILITIES

The NPIQC is accountable for the following, which must be carried out where designated and cannot shift elsewhere in the Tri-City Medical Center:

- a. Performance measures
- b. Performance improvement activities
- c. Support Tri-City Medical Center mission, vision, values, and annual performance improvement plan using an interdisciplinary team approach
- d. Collaborate with NDNQI site coordinator, quality systems representative(s), and unit councils to monitor and educate staff about performance measures and how they impact quality patient care (i.e., NDNQI reports)
- e. Audit and manage data
- f. Safe practice
- g. Incident reports and root cause analyses for performance and safety improvement
- h. Product and service evaluations
- i. Patient and staff satisfaction scores
- j. Effectiveness of performance improvements
- k. Quality assurance—monitor standards; quality/performance improvement—monitor and improve
- l. Celebrations for quality/performance improvements (e.g., National Healthcare Quality Week)

E. PRACTICE COUNCIL:

1. NAME

The name of the council shall be called the nursing practice council (NPC).

2. MISSION STATEMENT

The mission of the NPC is to model and guide exemplary professional nursing and technician practice in the following areas: (1) professional practice models (PPM); (2) care delivery systems; (3) interdisciplinary care; (4) accountability, competence, and autonomy; (5) ethics, privacy, security, and confidentiality; (6) diversity and workplace advocacy; (7) a culture of safety; and (8) quality care monitoring and improvement to provide the highest quality care for those served by the organization (e.g., patients, families, community).

3. PURPOSES

The purposes of the NPC are to:

- a. Develop a PPM, the overarching conceptual framework for nursing care
- b. Integrate care delivery systems within the PPM to promote delivery of nursing care
- c. Cultivate interdisciplinary and interprofessional collaboration to achieve high-quality patient outcomes through comprehensive care plans and collegiality

- d. Review available resources—the basis of care delivery systems, competency assessments, and evaluations—necessary for staff to practice autonomously
- e. Facilitate equity with workplace advocacy addressing ethical issues and privacy, security, and confidentiality
- f. Ground professional practice in a culture of safety, quality monitoring, and quality improvement with outcome measures in patient and quality indicators

4. OBJECTIVES

The objectives of the NPC shall be:

- a. Develop, apply, evaluate, adapt, and modify the PPM and care delivery systems as appropriate
- b. Incorporate regulatory and professional standards into the care delivery systems
- c. Facilitate investigation, development, implementation, and systematic evaluation of standards of practice and standards of care
- d. Collaborate with the clinical quality council (CQC) to involve direct care nurses in tracking and analyzing staff satisfaction and engagement data
- e. Engage internal experts and external consultants to improve care in the practice setting
- f. Trend data to formulate staffing plans and acquire necessary resources to provide consistent application of care delivery systems and monitor how direct care staff participate in staffing and scheduling activities
- g. Incorporate guidelines (i.e., *ANA Principles of Nurse Staffing* [American Nurses Association (ANA), 2001b]) from nursing specialty organizations and federal and state mandated requirements into staffing and scheduling processes
- h. Guide decisions on unit and nursing service data used in budget formulation, implementation, monitoring, and evaluation
- i. Facilitate leadership roles and participation in collaboration to ensure:
 - i. An interprofessional and interdisciplinary continuum of care across multiple settings using continuous quality and process improvement
 - ii. Development of policies and standards of care
 - iii. Integration and evaluation of information systems and technology used for clinical care monitoring, documentation, and communication
 - iv. Comprehensive patient education programs and resources
- j. Assure ready access to, and routine use of, current literature, professional standards, and other data sources to support autonomous practice
- k. Assess use of self-appraisal performance review and evaluations
- l. Assist in development and management of structures and processes supporting shared leadership (outcome), participatory decision-making, participatory/self-scheduling, and staff autonomy
- m. Facilitate staff accountability to resolve issues related to patient care practice, competency, quality, and/or operational issues
- n. Evaluate how staff resolve issues related to patient privacy, security, and confidentiality and how they use available resources (i.e., *ANA Code of Ethics for Nurses* [American Nurses Association, 2001b]) to address complex ethical issues
- o. Guide staff in identifying and addressing disparities in managing care of diverse patient in:
 - i. Using resources to meet unique and individual needs of patients and families
 - ii. Promoting a nondiscriminatory climate for patients

- iii. Resolving problems related to incompetent, unsafe, or unprofessional conduct
 - iv. Implementing workplace advocacy initiatives for caregiver stress, diversity, rights, and confidentiality
 - p. Monitor structures and processes used to improve workplace safety for nurses, based on standards by The Joint Commission, the Institute of Medicine, ANA's *Safe Patient Handling and Movement* (www.nursingworld.org/MainMenuCategories/ANAPoliticalPower/Federal/Issues/SPHM.aspx), Patient Safety Center guidelines (www.patientsafetycenter.org), etc., that support a culture of patient safety
 - q. Communicate the facility wide approach for proactive risk assessment and error management across disciplines and the roles of staff at all levels in that approach
 - r. Monitor resources used to monitor and improve the quality of patient care and coordinate and evaluate care among other disciplines and support staff
 - s. Communicate structures and processes used to identify significant findings and trends in overall patient satisfaction with nursing as compared to benchmarked sources
 - t. Monitor and disseminate patient satisfaction data showing how Tri-City Medical Center outperforms the mean of the national databases used (i.e., NDNQI) and resultant action plans: pain, education, courtesy and respect from nurses, careful listening by nurses, response time, and other nurse-related national survey questions
5. RESPONSIBILITIES
- a. Standards of care and practice
 - b. Clinical excellence (critical thinking and clinical judgment)
 - c. Care delivery
 - d. Resource utilization
 - e. Information systems
6. ACCOUNTABILITIES
- The NPC is accountable for the following, which must be carried out where designated and cannot shift elsewhere in the Tri-City Medical Center:
- a. Standards of practice
 - b. Safe patient handling and movement
 - c. Nursing service excellence
 - d. Employee satisfaction scores
 - e. Patient satisfaction scores
 - f. In services and adherence to hospital policy and procedure
 - g. Competency assessment
 - h. Patient care delivery model(s)
 - i. Overarching professional practice model(s)
 - j. Patient acuity
 - k. Collegial and collaborative relationships among interprofessional partners and interdisciplinary team members

F. NURSING LEADERSHIP COUNCIL:

1. NAME

The name of the council shall be called the nursing leadership council (NLC).

2. MISSION STATEMENT

The mission of the NLC is to encourage the professional development of nurses, technicians and support staff at all levels to empower them to contribute to the decision-making process related to practice and to provide quality care in a safe environment through transformational leadership.

3. PURPOSE

The purpose of the NLC is to facilitate excellence and promote positive patient outcomes in an environment that supports autonomous professional practice in (1) strategic planning, (2) advocacy and influence, and (3) visibility, accessibility, and communication.

4. OBJECTIVES

The objectives of the NLC shall be to:

- a. Continuously assess, describe, and demonstrate how the department's mission, vision, values, and strategic and quality plans reflect the organization's current and anticipated strategic priorities
- b. Advocate for resources (i.e., fiscal, technology, material, and human) to support unit/service goals
- c. Improve the Tri-City Medical Center's effectiveness and efficiency through strategic planning structure(s), process(es), and outcome(s) at point of care
- d. Guide transition during planned/unplanned change through advocacy and influence
- e. Support and guide leadership development, performance management, mentoring activities, and succession planning
- f. Support and guide leaders as they value, encourage, recognize/reward, and implement innovation
- g. Establish and maintain strong visibility, easy accessibility, and effective communication to improve work environments and patient care
- h. Support and guide changes in the work environment and patient care based on input and collaboration with staff at every level

5. RESPONSIBILITIES

- a. Department policies, procedures, standards of care, guidelines, and protocols to meet regulatory guidelines and leadership when procedures are developed, reviewed, and revised in an evidence-based process, using current research, standards of care, and best practice findings:
 - i. Existing procedures according to regulatory and Tri-City Medical Center standards and policies
 - ii. NLC collaborates with the standards of care (policies and procedures) committee and EBP committee representatives to provide input and leadership as needed
 - iii. Specialty-specific procedures at unit level
- b. Practices that ensure fiscal viability
- c. Cost accounting systems to achieve cost reductions
- d. Activities to facilitate practice
- e. Staffing patterns to meet the needs of defined patient populations
- f. Nursing representative(s) to participate in councils, committees, and/or champions
- g. Input and leadership in:
 - i. Clinical advancement and peer review processes
 - ii. Evaluation and modification of care delivery systems

- iii. Selection and implementation of nursing information systems
 - iv. Development of the department and Tri-City Medical Center strategic plans
 - h. Program and service development
 - i. Annual department goals
 - j. Collaborate on recruitment and retention activities
6. ACCOUNTABILITIES
- The NLC is accountable for the following, which must be carried out where designated and cannot shift elsewhere in the Tri-City Medical Center:
- a. Mission, vision, and values of Tri-City Medical Center
 - a. Philosophy of professional nursing and professional practice
 - b. Parameters for clinical practice
 - c. Primary decision-making related to management and clinical practice
7. MEMBERSHIP
- a. Membership on the unit based NLC shall be open to voluntary representatives from each shift, each specialty, and all job categories.
 - b. The Perioperative Manager shall serve as facilitator.
 - c. Membership is a one-year commitment.
8. OFFICERS
- a. The committee shall elect a Chair, Co-Chair and Secretary.
 - b. Each position shall serve a term of 1 year; the Co-Chair shall become the chairperson after one year.
 - c. See "Committee Officers" responsibilities in TCMC Shared Decision Making By-laws.
 - d. The Chair shall represent the Surgery NPDC at the TCMC Shared Decision Making council on the first Tuesday of the month at 0800-1000.
 - e. The Chair shall present the committee report monthly to the Perioperative Leadership Meeting, the second Tuesday of each month at 1300.
9. DECISION MAKING MECHANISM
- a. Decisions will be made by a majority vote of the members present.
 - b. Whenever possible, a round-table discussion and vote will be utilized so each member has opportunity to voice their concerns/vote.
10. AGENDA
- a. Agenda items shall be submitted at least one week prior to the meeting, by completing a Shared Decision Making Action Request Form (located in the Coordinator's Office) and submitting to the chair.
 - b. The Chair shall formulate and print the agenda for each meeting.
11. RECORD KEEPING
- a. Minutes shall be recorded at each meeting by the Secretary/designee.
 - b. Minutes shall be electronically saved in the designated folder on the Surgery Shared Drive, printed and posted in the NPDC binder in the staff lounge, and posted on the NPDC bulletin board by the Surgery front desk.
 - c. Minutes shall be printed for each meeting for member review and approval.
 - d. All meeting handouts, forms and records shall be maintained in the NPDC binder in the staff lounge.
 - e. Records shall be maintained for 3 years.
12. MEETING SCHEDULE AND ATTENDANCE

- a. ~~Meetings are scheduled the 3rd Monday of each month at 1300-1400. If the regularly scheduled meeting falls on a holiday, the meeting will be rescheduled to a different Monday.~~
- b. ~~Members are expected to attend the scheduled meetings. Members shall notify the chair if unable to attend the meeting.~~
- c. ~~Four or more unexcused absences per year will result in members forfeiting their membership on the committee.~~

Albuterol Metered Dose Inhaler (Ventolin): Recommendation for formulary removal

Requestor: Oska Lawrence, PharmD

Declared conflicts of interest: None

Situation: Albuterol is a short-acting beta-agonist used for the management of asthma exacerbations

Background: Albuterol is offered as a metered dose inhaler (MDI) device which administers a fine mist that is inhaled. The medication may not be shared between patients nor can it be sent home with the patient upon discharge.

Assessment:

- Each albuterol MDI costs \$19
- A therapeutically equivalent medication, albuterol 0.83 mg/mL nebulized solution costs \$0.11 per dose
- The Pharmacy Service has recommended a revision to the Automatic Therapeutic Interchange policy to permit the conversion of albuterol MDI to an equipotent dose of albuterol 0.83 mg/mL nebulized solution
- A conversion from albuterol MDI to albuterol nebulized solution would save TCMC approximately \$7,800 annually

Recommendation(s):

- The P&T Committee approved the Pharmacy Service recommendation that albuterol MDI be removed from the TCMC formulary at this time (applies only to inpatient supply. **Does not include unique Albuterol MDI products stocked in ED or Surgery**)
- All future inpatient orders for albuterol MDI will be converted to an equivalent dose of ipratropium nebulized solution as per the Automatic Therapeutic Interchange Policy
- This proposed change would not alter practice in the ED (provide discharge inhaler with teaching) nor in Surgery
- All recommendations were reviewed and agreed upon by Dr. Yamanaka (Pulmonary) and Amy Waldrop (Manager, Respiratory Therapy)