CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
DEPARTMENT OF PUBLIC HEALTH

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda University Medical Center - Murrieta	25862 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	The following reflects the findings of the Department of Public Health during an inspection visit: Complaint Intake Number: CA00397790 - Substantiated Representing the Department of Public Health: Surveyor ID # 2487, HFENS The inspection was limited to the specific facility event investigated and does not represent the findings of a full inspection of the facility. Health and Safety Code Section 1280.3(g): For purposes of this section "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Health and Safety Code section 1280.1 (d): This section shall apply only to incidents occurring on or after January 1, 2007. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties assessed under subdivision (a) shall be up to one hundred thousand dollars ($100,000) per violation. With respect to incidents occurring on or after January 1, 2009, the amount of the administrative penalties assessed under subdivision (a) shall be up to fifty thousand dollars ($50,000) for the first administrative penalty, up to seventy-five thousand dollars ($75,000) for the second subsequent administrative penalty, and up to one hundred thousand dollars ($100,000) for the third and every		Preparation and execution of this plan of correction does not constitute an admission or agreement of the facts alleged or conclusions set forth on the Statement of Deficiencies. This plan of correction is prepared and executed solely because it is required by the Federal/State Law. The following represents Loma Linda University Medical Center Murrieta's plan of correction. APC 3/13/17 ESB	

Event ID:BLFL11 2/27/2017 2:51:52PM

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Eric A Dietz, Director Patient Safety TITLE (X6) DATE: 3/9/17

By signing this document, I am acknowledging receipt of the entire citation packet. Page(s) 1 thru 8

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda University Medical Center - Murrieta	28062 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	subsequent violation. An administrative penalty issued after three years from the date of the last issued immediate jeopardy violation shall be considered a first administrative penalty so long as the facility has not received additional immediate jeopardy violations and is found by the department to be in substantial compliance with all state and federal licensing laws and regulations. The department shall have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section Title 22, California Code of Regulations, Division 5, Chapter 1, Article 3, Section 70223 (b)(2), Surgical Service General Requirements: (b) A committee of the medical staff shall be assigned responsibility for: (2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. Based on interview and record review, the facility failed to: 1. Implement their policy and procedure regarding safety in the operating room; 2. Develop and implement a policy and procedure regarding the use of a surgical device (Aquamantys Bi-polar hand piece).		Loma Linda University Medical Center Murrieta's Surgical Service and Medical Staff has developed, maintained and implemented written policies and procedures in consultation with other appropriate health professionals and administration. Policies were approved by the governing body. Specifically a policies and procedure regarding safety in the operating room and policy and procedure regarding the use of surgical device [Aquamantys Bi-Polar hand piece] Corrective action taken include:	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda Univeralty Medical Center - Murrieta	28062 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	These failures resulted in: 1. A full thickness thermal burn injury to Patient A's left calf; and 2. The surgical staff to be unaware of what precautions and safeguards were needed for use of a surgical device. These failures caused Patient A to sustain a full thickness thermal burn injury that required extensive wound treatments (to include a surgical procedure), placed the patient at risk for increased health deterioration, harm, including death, and had the potential to place all patients undergoing the same surgical procedure at risk for health deterioration, harm, and death. "Thermal burns are burns to the skin caused by an external heat source. A full thickness burn is the most severe burn involving all layers of skin. Nerve endings, small blood vessels, hair follicles, sweat glands are all destroyed. Subcutaneous fat tissue, muscle and bone may also be involved." (Referenced from Derm Net NZ (December 29, 2013)-a resource for general practioners and dermalogists). Findings: The clinical record for Patient A was reviewed. Patient A was admitted on April 29, 2014, with the diagnosis of osteoarthritis of both knees		A root cause analysis was conducted and opportunities for improvement were identified. • The aquamantys System [AM] was immediately removed from service and evaluated by the Clinical Engineering Department and found to be in good working order. • The AM representative provided re-training to the Operating Room staff on the proper use of the machine. Training included the proper placement of the want when not in use and maintaining the alarm volume at an audible setting. • Staff were required to complete a quiz to assure competency on the use of the AM. Retaining was completed for staff not meeting 95% • It was identified that the AM does not have an attachment holder for the wand and the company has no alternate. The facility has designed a mechanism for placement of the want when not in use.	5/10/2014 5/6/2014 5/9/2014 5/9/2014 5/9/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda University Medical Center - Murrieta	28062 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	(inflammation of the joint cartilage of the knees). The document entitled "Perioperative Report" dated April 29, 2014, indicated Patient A had knee replacement surgery for both knees. The report further indicated the surgeon used an "Aquamantys System" during Patient A's surgery on April 29, 2014. According to the manufacture's insert, the "Aquamantys System" is a surgical (cautery) device that includes a hand piece called the Aquamantys Bi-polar piece which has an electric current that generates heat to seal tissues in order to help prevent blood loss. The physician "Progress Notes" dated May 1, 2014, at 9:48 p.m., indicated "Bilateral knee hemovacs (drains) removed without any difficulty. The dressings are dry and intact. Diffuse tenderness with palpation. Mild diffuse swelling. Calves are soft. Left calf with blistering." There was no documentation of physician orders that addressed the left calf blistering. The nursing "Progress Notes" dated May 6, 2014, at 2:26 p.m., indicated "Dr...(physician's name) rounded this am and looked at what she referred to as an open blister on patients leg, around calf area. She said she saw it yesterday when she rounded. Order was given to primary (physician) to apply santyl ung (wound treatment) and wound nurse consult. Photo taken."		• The policy "Fire Prevention in the OR' was reviewed revised. • Physician practice was reviewed by the Surgical Quality Review Committee and appropriate actions have been taken. Audits will be completed for each use of the AM to assure that the machine has been safely used before, during and after the surgical procedure. To date 100% has been achieved for the past 3 months. Results of the audit were incorporated in the OR Quality Dashboard and reported in accordance with the established reporting calendar Reports are forward to appropriate committees in accordance with the Quality oversight Structure. Person Responsible: Director, Perioperative Services	8/20/2014 6/26/2014 8/15/2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda University Medical Center - Murrieta	28062 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	The order to treat Patient A's left calf blister was written five days after the physician documented discovery of the blistering. The document entitled, "Initial Inpatient Wound Care Consult," dated May 9, 2014, was reviewed. The document indicated: "On POD #7 (Patient Observation Day), nurse noted a large L (left) posterior calf wound post op (after surgery)...Large Left posterior calf full thickness wound...presumably caused by thermal burn injury from OR (Operating Room) Aquamantys hemostasis sealer." During an interview with the Operating Room Director (ORD), on June 9, 2014, at 1:45 p.m., the ORD stated some surgeons use the Aquamantys Bi-polar hand piece during procedures requiring cautery (in order to help prevent blood loss). The ORD also stated the device was used by surgeons when an incision (cut) was made into the skin. She stated when a surgeon was not using the device, the device was removed from the operating table. The ORD stated she was informed by the Wound Care Nurse, on May 6, 2014, that Patient A sustained a burn injury to the left calf during a surgical procedure that included the use of the Aquamantys System. The ORD stated her investigation included an interview with Operating Room Technician (ORT) 1 who was present during Patient A's surgical procedure. She stated ORT 1 stated when he entered the OR room, he "Saw more steam than usual", saw the device (Aquamantys) under the patient's leg, yelled			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda University Medical Center - Murrieta	28062 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	"Stop", and removed the device. She stated, "All staff know to report incident's like seeing more steam than usual from a device, and to check the patient. No one (of the OR team) reported the incident. The policy is to tell the Charge Nurse as soon as possible when an incident happens and generate an incident report." The ORD stated the facility policy and procedure regarding the safe use of a cautery device during a surgical procedure was not followed. The surgeon who performed the procedure was not available to interview per ORD as she was on vacation. During a follow up visit, conducted on July 30, 2014, the clinical records for Patient A were reviewed. The clinical records indicated Patient A received extensive wound treatments to the left calf following discharge from the facility on May 9, 2014. The records further indicated Patient A was readmitted on June 6, 2014, for a surgical procedure to remove large areas of necrosis (dead tissue) from the burn injury site. On July 30, 2014, at 9:40 a.m., an interview was conducted with the Process Integrity Manager (PIM). The PIM stated the facility's investigation of the incident was completed on June 11, 2014. The PIM stated the surgeon who performed the surgery did not attend the facility's review of the incident, but the assistant surgeon was present. The PIM stated the facility's review concluded "it was human			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda University Medical Center - Murrieta	28062 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	error" that caused Patient A to sustain a full thickness thermal burn to the left calf, from the Aquamantys device during Patient A's surgery on April 29, 2014. The PIM stated the surgeon who performed the procedure was unavailable for interview because she was, "Still on vacation." She stated when a new device is adopted for use by the facility, the manufacturer of the device has a technician come to the facility to provide an in-service training to staff regarding safety and the use of the device. She stated the facility did not require documentation that indicated what staff had received the training for the Aquamantys device. The PIM stated the facility did not require physicians to attend the in-service training, and instructions for the use of the device were located on the top of the device. The PIM further stated the operating room (OR) staff did not follow the facility's policy and procedures regarding safety during Patient A's surgical procedure by not ensuring the cautery device (Aquamantys) was protected when not in use. The facility policy and procedure entitled, "Fire Prevention in the Operating Room," dated, November 12, 2013, indicated, "All staff entering the Perioperative, Procedural/Invasive areas will demonstrate knowledge of safety and prevention. B. Nurse Manager/Charge Nurse/Clinical Educator Responsibilities: 1.Education and direction of the operating staff. 2. Enforcement of the department's fire safety procedure."			

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050770	A. BUILDING _____ B. WING _____	08/06/2014

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
Loma Linda University Medical Center - Murrieta	28062 Baxter Road, Murrieta, CA 92563 RIVERSIDE COUNTY

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
	The policy further indicated, "Controlling Heat Sources 1. Cautery. A. Never place the cautery pencil on the patient. Place the cautery pencil in the protective holster to prevent accidental activation of cautery." A review of the manual instructions entitled, "Aquamantys System and Bipolar Sealers," dated January 9, 2013, indicated, "Precautions. Surgery should be performed by persons with adequate training and preparation. Personnel should fully understand the nature and use of RF (radio frequency-electrical current) before performing electrosurgical procedures to avoid the risks of shock and burn hazards to both patient and operator..." The facility failed to implement their policy and procedure regarding safety in the operating room, and failed to develop and implement a policy and procedure regarding the use of a surgical device which was the direct cause of Patient A sustaining a full thickness thermal burn to his left calf. This facility failed to prevent the deficiency(ies) as described above that caused, or is likely to cause, serious injury or death to the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code Section 1280.3(g).			