

6/21/10

California Department of Public Health

POC accepted
Nanette [Signature]

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA070000139	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 02/18/2010
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CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

JUN 17 2010

NAME OF PROVIDER OR SUPPLIER DOMINICAN HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 1555 SOQUEL DRIVE SANTA CRUZ, CA 95065
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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED 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
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E 000 Initial Comments

The following reflects the findings of the California Department of Public Health during investigation of a complaint and an entity reported incident conducted on 1/27/10 through 2/18/10.

For entity reported incident CA00211822, regarding unanticipated patient death, State deficiencies were issued under the California Code of Regulations, Title 22, Sections 70203(a)(2) and 70215(a)(2).

For complaint CA00192889, regarding physician services, the allegation was not substantiated.

Inspection was limited to the specific complaint and entity reported incident investigated and does not represent the findings of a full inspection of the hospital.

Representing the California Department of Public Health: [Redacted], Health Facilities Evaluator Nurse.

E 000

E242 T22 DIV5 CH1 ART3-70203(a)(2) Medical Service General Requirements (2) Corrective Actions

Deficiency: The hospital failed to ensure a respiratory care practitioner provided care in accordance with hospital policy when initiating BiPap.

Discussion of Findings: At the time of this event, Respiratory Care Policy #354-70 - BiPap - NPPV Non-Invasive Positive Pressure Ventilation was in place. This approved policy (2/08) explicitly stated that a patient on BiPap may be cared for on 2NE, a medical-surgical unit. Additionally, it stated under Procedure, #2, on page 2 of 3 (attached) that ABGs were to be done 30 minutes before, and 30 minutes after initiation of BiPap *if indicated and ordered* by the physician. In the case of Patient 1, at 12:45 a.m. he exhibited signs of air hunger which was assessed by the Respiratory Therapist and considered to need urgent intervention. Delaying care to perform ABGs was not assessed to be in the best interest of quality patient care and therefore was *not indicated*. Instead, the Respiratory Therapist alerted the RN in charge of the patient to immediately contact the physician for an order for BiPap while he secured the necessary machine. At 12:50 a.m. the order for BiPap was received and the patient was placed on the intervention at 30% O2.

E 242 T22 DIV5 CH1 ART3-70203(a)(2) Medical Service General Requirements

(2) Developing, maintaining and implementing 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.

This Statute is not met as evidenced by: Based on staff interview and record review, the hospital failed to ensure a respiratory care practitioner provided care in accordance with

E 242

Licensing and Certification Division

Nanette [Signature]
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE President CEO

(X6) DATE

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E 242	<p>Continued From page 1</p> <p>hospital policy when initiating BiPAP (method of respiratory ventilation with use of a machine) therapy to a sampled patient (1). Findings:</p> <p>Patient 1 was admitted to the hospital with diagnoses including chronic obstructive pulmonary disease exacerbation (an increase in the severity of a disease or in any of its signs or symptoms).</p> <p>A nurse's note on 12/3/09 at 12:45 a.m. documented a physician was called because Patient 1 was "air hungry despite" his oxygen saturation (level of oxygen saturation in blood) was 100% on two liters of oxygen by nasal cannula (tubing inserted into nostrils to deliver oxygen).</p> <p>A physician's order was obtained, and at 12:50 a.m., Patient 1 was started on BiPAP with 30% oxygen. The patient's heart rate was 120 beats per minute and respiratory rate was 34 breaths per minute. The late entry nurse's note on 12/3/09 at 7:59 a.m. indicated Patient 1 was pulseless and breathless at 2:30 a.m. Patient 1 was pronounced dead at 3:10 a.m.</p> <p>The hospital's policy, "Respiratory Care Services," revised on 02/08, outlined procedures that included staff was to remain with the patient until stable on BiPAP unit and to obtain arterial blood gases (ABG, test to measure amount of oxygen and carbon dioxide from the blood) 30 minutes before, and 30 minutes after, initiation of BiPAP.</p> <p>During an interview on 1/27/10 at 12 noon, the respiratory care practitioner manager stated respiratory care practitioners were to obtain ABGs 30 minutes before, and 30 minutes after,</p>	E 242	<p>At the time of on-site investigation by the surveyor, the Respiratory Therapist who cared for this patient was on a Family Medical LOA and was not available for interview. Instead the Manager of Respiratory Therapy was interviewed by the Evaluator RN. Unfortunately, this individual could not speak to the rationale for the primary therapist's judgment in not delaying care to obtain pre-therapy ABGs. And may not have been able to properly articulate the immediate reassessment and treatment plan taken by the primary therapist. Subsequent to the on-site survey, upon return from his FMLA, the primary therapist was interviewed by internal staff. This was completed on 6/1/10.</p> <p>The hospital feels that had the RN evaluator had the benefit of the facts from the primary therapist, no deficiency would have been identified relative to pre-therapy ABGs.</p> <p>The Statement of Deficiency also discusses concern by the HFEN that the Respiratory Therapist failed to stay with the patient to assess effectiveness of the intervention and clinical stability, according to current policy. The patient's medical record clearly identifies under the section for Respiratory Therapy that the primary therapist stayed with this patient from the time the intervention was initiated at 12:50 a.m. until 1:05 a.m., a period of 15 minutes, during which time the patient was assessed to be stabilizing. This assessment was based on vital sign improvement (heart</p>	6/1/10

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E 242	Continued From page 2 initiation of BiPAP. He acknowledged it was reasonable to check on the patient 30 minutes after initiation of BiPap, given the patient's heart rate was elevated. There was no reassessment of Patient 1's condition after he was placed on BiPAP, and the record lacked documentation an ABG was drawn. During this investigation, an administrative staff was asked to arrange an interview with the respiratory care practitioner who set up Patient 1's BiPAP. The administrative staff stated the respiratory care practitioner was on leave and was unavailable for interview.	E 242	rate went from 120 beats per minute to 100 beats per minute and the respiratory rate went from 34 per minute to 20 per minute; and the patient was assessed as less anxious and resting more comfortably. The hospital feels that the primary therapist was compliant with the policy at the time and his duty to stay with the patient until stabilized. The patient's primary RN was also at the patient's bedside during this period of time. Taken as an opportunity to further improve patient care based on events that occur, it was discussed and determined that an increase in the frequency of respiratory therapy assessment following initiation of BiPap would benefit future patients.	
E 292	T22 DIV5 CH1 ART3-70215(a)(2) Planning and Implementing Patient Care (a) A registered nurse shall directly provide: (2) The planning, supervision, implementation, and evaluation of the nursing care provided to each patient. The implementation of nursing care may be delegated by the registered nurse responsible for the patient to other licensed nursing staff, or may be assigned to unlicensed staff, subject to any limitations of their licensure, certification, level of validated competency, and/or regulation. This Statute is not met as evidenced by: Based on staff interview and record review, the hospital failed to ensure a registered nurse provided ongoing assessment when initiating BiPAP therapy (method of respiratory ventilation by machine) to a sampled patient (1). Health & Safety Code Section 1280.1(c): For purposes of this section "immediate Jeopardy" means a situation in which the licensee's	E 292	The Statement of Deficiencies also noted that the 30 minute post-therapy ABGs were not performed as required by policy secondary to the fact that the primary respiratory therapist was busy attending to another patient (NICU). The primary therapist's intention, after a full assessment of Patient 1, was to return and draw an ABG. Based on his anticipated ability to return, the respiratory therapist did not request additional assistance. During the internal interview of this primary respiratory therapist, he indicated that he was on his way back to obtain the ABGs when the Code Blue was paged.	

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E 292	<p>Continued From page 4</p> <p>RN 1 stated the patient's isolation room was hard to hear and see, the negative airflow system was very loud, and the disconnect alarm on the BiPAP was hard to hear. RN 1 also stated usually, when a patient was on BiPAP they were placed in a room where the patient could be seen from outside the room. RN 1 had to walk into the room to see Patient 1.</p> <p>On 2/18/10, administrative staff (ADM 1) stated there was no nursing policy available addressing the management of patients placed on BiPAP. ADM 1 stated the BiPAP was started for Patient 1, "obviously", to treat the patient's change in respiratory condition. ADM 1 also stated the hospital had a new process after this incident including transfer of the patient to a monitored bed when placed on BiPAP.</p> <p>The hospital's policy, "Respiratory Care Services," revised on 02/08, outlined procedures that included staff was to remain with the patient until stable on BiPAP unit and to obtain arterial blood gases (ABG, test to measure amount of oxygen and carbon dioxide from the blood) 30 minutes before, and 30 minutes after initiation of BiPAP. There were no ABG's obtained for Patient 1 before, or after, he was placed on BiPAP.</p> <p>There was no ongoing nursing assessment after initiation of BiPAP therapy on 12/3/09 to determine whether Patient 1's condition improved.</p> <p>The hospital's failure to provide ongoing assessment of the patient's condition is a deficiency that has caused, or is likely to have caused, serious injury or death for the patient, and therefore constitutes an immediate jeopardy</p>	E 292	<p>3. The Respiratory Services policy and procedure# 354-70 <u>BiPap – NPPV Non Invasive Positive Pressure Ventilation</u> has also been revised as it relates to the obtaining of pre-BiPap ABGs and reassessment frequency of patients placed on BiPap. The policy now states that pre-therapy ABGs will be obtained, unless the patient's condition is emergent. After initiation of BiPAP, patient assessment will occur within 30 minutes. The physician will be called with the assessment findings for further orders. Additionally the policy changes the requirement of reassessment after BiPAP initiation from a minimum of every 6 hours to every 4 hours.</p> <p>Date of Corrective Action: 6/8/10 Responsible Person: Director of Respiratory Services with approval of Medical Director of Respiratory Services. Monitoring: Random monitoring of completion of pre-therapy ABGs and reassessment frequency of all patients on BiPap has been implemented and will continue for a period of 90 days, or longer if less than 95% performance is observed.</p> <p>4. Respiratory Services Staff education related to the revisions in the BiPap policy has been initiated. At the time of this POC, 75% of staff has been educated. Date of Corrective Action: Education completion date: 6/30/10 Responsible Person: Director of Respiratory Services</p>	<p>6/8/10</p> <p>6/30/10</p>

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E 292	Continued From page 5 within the meaning of Health and Safety Code, Section 1280.1.	E 292	<p>Monitoring: Random monitoring of completion of pre-therapy ABGs and reassessment frequency of all patients on BiPap has been implemented and will continue for a period of 90 days, or longer if less than 95% performance is observed.</p> <p>Tag E 292 T22 DIV5 CH1 ART3-70215(a)(2) Planning and Implementing Patient Care</p> <p><u>Deficiency:</u> The hospital failed to ensure a registered nurse provided ongoing assessment when initiating BiPaP therapy to patient. The hospital's failure to provide ongoing assessment of the patient's condition is a deficiency that has caused, or is likely to have caused, serious injury or death for the patient, and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code, Section 1280.1.</p> <p><u>Discussion of Findings:</u> 1. At the time of this event the hospital had an approved nursing services policy and procedure, #8610pc-114 Assessment of Patients. This approved nursing policy (2/07), Attachment 1, indicates that nursing shall reassess a patient when there is a significant change in condition, but at a minimum of every shift (8 hours) for patients being cared for on the Medical – Surgical Unit. Immediately following this event, the hospital initiated a Root Cause Analysis to investigate the facts of the case. From this</p>	

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within the meaning of Health and Safety Code, Section 1280.1.

E 292

RCA, the following timeline was made:
 23:20 – Report from evening RN
 23:30 – Respiratory Therapist (RT) came to nursing station and informed RN that patient was “air hungry”, suggesting the patient be placed on BiPap.
 23:40 – RN assessed patient and noted patient as having difficulty breathing. Vital signs were BP – 139/91, heart rate – 139, Respiratory Rate – 24. O2 saturation was 100% on 2L O2 by nasal cannula. The electronic medical record shows that this set of vital signs was documented at 24:00.
 23:45 – Discussion between RT and RN. RT felt patient could benefit from BiPap and RN placed call to physician with change of condition status.
 24:00 – Rapid Response Team (RRT) was already on the unit attending to another patient. Consultation between primary RN and RRT RN occurred regarding criteria for BiPap.
 00:50 – Patient was placed on BiPap by RT
 01:00 – RN reassessment of vital signs indicates heart rate now 91 and respiratory rate is 24.
 01:11 – Patient was medicated with Ativan by RN
 01:15 – RN and RT are in the patient room monitoring patient. At this time the patient was assessed as tolerating BiPap satisfactorily, vital sign improvement: (heart rate went from 120 beats per minute to 100 beats per minute and the respiratory rate went from 34 per minute to 20 per minute).
 02:30 – RN in to see patient and found pulseless and breathless.

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within the meaning of Health and Safety Code, Section 1280.1.

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The hospital feels that it is clear from this timeline that the patient's primary nurse was aware of the patient's overall condition from the beginning of her shift at 23:00. It is also clear that when the RT assessed the patient as "air hungry", the RN proceeded to complete a reassessment. She collaborated with the RRT RN, which is the standard of care, and was in close collaboration with the RT during this time. Per physician's order the patient was expeditiously placed on BiPap and given the ordered anti-anxiety medication. Both the RT and the primary RN stayed with the patient for a period of 15 minutes, performing continuous assessment after which time the patient was noted to be stabilizing. The primary RN was interviewed at the time of the RCA. She noted that at this time, the patient appeared "more relaxed, his eyes were closed, the head of the bed was up and he was resting". She also stated the call light was placed on the patient's lap and that the patient was instructed to notify the RN if he began to have more difficulty. Based on current hospital policy and approved Standards of Nursing Care, the standard of nursing care in terms of assessment, reassessment and care planning was met.

Following this event, the hospital, based on its philosophy of continuous quality improvement, took key factors in this event as an opportunity to improve the Standard of Care related to BiPap patients to a higher level. The following actions

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within the meaning of Health and Safety Code, Section 1280.1.

E 292

Monitoring: A random review of BiPap patients are being monitored to ensure the appropriate level of care placement and the appropriate frequency of reassessment is performed. A minimum of 10% of BiPap patients for a period of 60 days or longer if performance is not observed at least 95%.

3. Nursing staff education related to the revisions in the BiPAP policy will be conducted on the units which have monitored beds (TCU/ICU).
Date of Corrective Action: Education completion date: 7/30/10
Responsible Person: Chief Nursing Executive
Monitoring: Audit of completion to be conducted for 100% compliance.

Discussion of Findings Related to Assessment of Immediate Jeopardy:

The Standards of Nursing Care for this patient were met as they relate to assessment, reassessment and care interventions. The facts of the case may not have been totally appreciated by the HFEN as the timeline of nursing assessment was not called for, nor discussed during CDPH's on site investigation. The hospital's internal Root Cause Analysis of this event did not reveal that any deficiency in nursing assessment, reassessment or care interventions took place. In addition to meeting the elements of the hospital's approved Nursing policies

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within the meaning of Health and Safety Code, Section 1280.1.

E 292

related to assessment and reassessment and standards of care for a patient on a medical surgical unit, the primary RN consulted with the RRT RN for the patient's criteria for BiPap, notified the patient's physician in a timely manner, performed the ordered interventions in a timely manner and stayed with the patient until his condition was assessed as improved and the patient stated he was more comfortable. Proper patient education related to calling the RN immediately should he begin to feel worse.

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Dominican Hospital

A member of CHW

Respiratory Care Policy 354-70

RESPIRATORY CARE SERVICES	<u> X </u> POLICY <u> X </u> PROCEDURE <u> </u> STANDARD
Noninvasive Positive Pressure Ventilation (NPPV) Bilevel Positive Airway Pressure (BiPAP) Philips V60 Ventilator	Prepared by: <u>Respiratory Care Services</u> Approved by: _____ Michael Ellison, MD, Medical Director

PERSONNEL: RT X RN LVN NA OTHER _____

Purpose

NPPV and/or BiPAP may be used in the treatment of acute respiratory failure, chronic obstructive pulmonary disease, restrictive thoracic disease, neuromuscular disease, and hypoventilation syndromes. The goals of NPPV are to reduce the work of breathing and restore adequate gas exchange by improving alveolar ventilation and correcting hypoxemia.

The following policy and procedure applies only to the use of the Philips V60 ventilator. For the use of CPAP and BiPAP as applied to other chronic conditions, see Respiratory Care Policy 354-80.

Indications

NPPV and/or BiPAP provided with the Philips V60 ventilator is indicated for spontaneously breathing patients greater than 20 kg. The ventilator may also be used with an artificial airway (endotracheal tube or tracheostomy tube) with patients meeting the same criteria for noninvasive support.¹

Indications and Inclusion Criteria

- Acute respiratory failure
- Chronic respiratory insufficiency
- Sleep apnea
- Dyspnea
- Accessory muscle use
- Paradoxical breathing
- Tachypnea
- Clinical impression of impending intubation
- SpO2 <90%
- Arterial blood gas analysis: pH less than 7.35; PaCO2 greater than 45 mmHg, PaO2 <60mmHg

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Contraindications and Relative Exclusion Criteria

- Severe respiratory failure without spontaneous respiratory drive
- Respiratory arrest; need for immediate intubation
- Untreated pneumothorax , pneumomediastinum, or pneumopericardium
- Airway obstruction
- Inability to maintain patent airway or clear secretions
- Impaired swallowing with chronic aspiration
- Severe aspiration risk
- Excessive pulmonary secretions
- Nose bleed
- Uncontrolled arrhythmias
- Severe hemodynamic or cardiac instability
- Recent facial, esophageal, or gastric surgery
- Facial trauma
- Esophageal tear
- Hypersensitivity to mask material

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Inform the physician and consider intubation if the patient meets any of the relative exclusion criteria.

Location

The Philips V60 ventilator may only be used on patient care units with telemetry monitoring of both heart rhythm and pulse oximetry.

Equipment and Setup

The following equipment is required for the setup and assembly of the Philips V60 ventilator:

- Philips V60 noninvasive ventilator
- Test lung
- Oxygen analyzer
- Noninvasive breathing circuit
- Bacterial filter
- Complete Philips V60 operational verification form (see attached)

Initiating BIPAP

- Obtain or follow written physician order for “BIPAP Protocol” or specific BIPAP settings.
- Gather and prepare equipment.
- Introduce yourself and explain procedure to patient.
- Following standard precautions, size patient for nasal or full-face mask.
- Power on the V60 noninvasive ventilator and setup with initial settings
- Attach mask to circuit and place over patient’s nose and mouth if using a full-face mask.
- Adjust headgear to properly seat the mask, avoid over-tightening.

Initial Settings:

- Mode: Spontaneous/ timed (S/T)
- IPAP: 12 cmH2O
- EPAP: 5 cmH2O
- Set rate: 4-8 breaths/ minute
- FiO2: Titrate FiO2 to maintain SpO2 \geq 92%

Alarm Guidelines

The following alarm guidelines are appropriate for initial adult settings.²

- Hi rate (5- 90 breaths/min): 5- 10 breaths above observed frequency
- Lo rate (1- 89 breaths/min): 1 breath above set frequency**
- Hi V_t (200- 2500 ml): 200 – 300 ml above observed tidal volume
- Lo V_t (OFF, 5 -1500ml): 100 ml or 10-15% below set or observed tidal volume
- HIP (5-50 cmH₂O): 10 – 20 cmH₂O above set or observed PIP
- LIP (OFF, 1-40 cmH₂O): 3-5 cmH₂O below set or observed PIP
- Low V_e (OFF, 1-99 L/min): 2-5 L/min or 10-15% below observed minute volume
- LIP T (Low insp pressure delay): 20 seconds

The **low respiratory rate alarm of the Philips V60 noninvasive ventilator does NOT distinguish between spontaneous breaths and ventilator breaths. The alarm is active when set 1 breath above the set ventilator frequency.

Assessment and Monitoring Guidelines

Assess and monitor the following parameters upon initiation of the Philips V60 ventilator:

- Patient comfort
- Level of dyspnea
- Respiratory rate
- Heart rate
- Blood pressure
- Pulse oximetry
- Accessory muscle use
- Patient-ventilator synchrony
- Mask fit
- Skin Integrity

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Perform an assessment of patient's skin integrity twice per shift and obtain a consult from a wound care nurse if any skin breakdown signs are noted. Protective dressing may be necessary for patients with delicate skin or those at risk for skin breakdown.

Titrate NPPV Settings

Inspiratory positive airway pressure (IPAP), expiratory positive airway pressure (EPAP), FiO₂, inspiratory rise, and ramp adjustments may be titrated to minimize respiratory distress, optimize ventilation and oxygenation, and maintain patient comfort. A humidifier may be added to the circuit if the patient is on NPPV for >24 hours.

Guidelines for the Evaluation of Effectiveness of NPPV

- In most cases a blood gas will be obtained prior to initiation of NPPV. However, if NPPV is applied emergently, a blood gas may be deferred.
- To evaluate the effectiveness of NPPV, patient assessment will occur within 30 minutes or sooner if condition warrants. The physician will be called with the assessment finding for further treatment orders.

- Patient assessment will occur 30 minutes following initiation of NPPV; documentation of settings or changes will occur at this interval.
- Patients requiring greater than 2 hours of continuous NPPV for ventilation or oxygenation failure should be reassessed by a physician and monitored closely for signs of failure.
- Routine assessment and documentation of ventilator settings shall occur every 4 hours.

Signs of Failure

The following assessment items may be signs of failure or intolerance to NPPV therapy and require emergent intervention:

- Hemodynamic instability
- Decreased mental status
- Respiratory rate >35
- Worsening respiratory acidosis or oxygenation by arterial blood gas analysis
- Inability to maintain SpO₂ >92%
- Inability to tolerate mask
- Inability to manage pulmonary secretions or inadequate cough
- Patient refuses therapy

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Weaning Criteria

The patient may be weaned from NPPV support when they predominately meet the following criteria:

- Clinically Stable
- RR <24 breaths/min
- HR < 110 beats/min
- pH >7.35
- SpO₂ ≥92% on ≤ 40% FiO₂

Titrate PS to 5 cmH₂O or Trial off NPPV on O₂ per protocol to maintain SpO₂ ≥92%.

Repeat patient assessment during trial off NPPV and monitor patient for signs of failure.

If patient fails weaning, reinstitute NPPV at previous settings.

Reassess weaning readiness Q4 hours.

Patient assessment will occur once per shift during the first 24 hours following discontinuance of NPPV.

Documentation

1. Documentation shall be completed on the Respiratory Care Ventilator flowsheet every 4 hours and with any change in settings.
2. BIPAP will be documented in Clinvision under BIPAP-NPPV every 4 hours.

References

1. Philips Respironics V60 Ventilator User Manual. 2009
2. Wilkins, R.L., et. al. Egan's Fundamentals of Respiratory Care. Pp. 1068-69. 2009.
3. Hess, D. How to Initiate a Noninvasive Ventilation Program: Bringing the Evidence to the Bedside. Respir Care 2009;54(2)232-243

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