MODERATE SEDATION

BAYLOR University Medical Center at Dallas

Policy Name:
Moderate Sedation/Analgesia for Non-Anesthesia Providers

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Anesthesiology & Pain Mgmt

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Michael A. E. Ramsay, MD, FRCA
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SCOPE

This policy applies to BUMC physicians and Registered Nurses who are caring for inpatients or outpatients that require medications for sedation/analgesia, prior to undergoing therapeutic or diagnostic procedures. Sedation/analgesia lies on a dose and response dependent continuum leading from minimal sedation to general anesthesia (see Table 1). This policy is specifically intended for patients who are over 12 y/o and 80 lbs. or greater. Patients not meeting both requirements need sedation/analgesia administered by an anesthesia provider or credentialed Emergency physician as governed by the standards of care established by the Department of Anesthesiology.

This sedation policy does not apply to the following cases:

A. Patients who have an anesthesia provider administering the sedation.
B. Patients in critical care units receiving sedation and / or analgesia not related to a procedure
C. Patients who are mechanically ventilated and whose cardiovascular/ respiratory status is continuously monitored by the same monitoring devices as specified by this policy.
D. Patients in neonatal intensive care unit (NICU) in which there is a specific NICU sedation policy approved by the Director of Anesthesia.
E. Patients in which the administration of deep sedation is ordered.

Table 1 – Definition of General Anesthesia and Levels of Sedation/Analgesia

"Sedation and analgesia" comprise a continuum of states ranging from minimal sedation (anxiolysis) through general anesthesia.

	Minimal Sedation (Anxiolysis)	Sedation/ Analgesia	Deep Sedation/ Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response* to verbal or tactile stimulation	Purposeful response* after repeated or painful stimulation	Unarousable, even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular function	Unaffected	Usually maintained	Usually maintained	May be impaired

* Reflex withdrawal from a painful stimulus is not considered a purposeful response.

Developed by the American Society of Anesthesiologists; approved by the ASA House of Delegates October 13, 1999

PURPOSE

A. To enact a uniform standard of care at Baylor University Medical Center (BUMC) facilities for patients receiving medications administered by non-anesthesia providers for moderate sedation/analgesia during diagnostic or therapeutic procedures.

B. To provide guidelines for credentialed physicians and qualified RN's employing moderate sedation/analgesia to afford their patients comfort during diagnostic or therapeutic interventional procedures while minimizing the associated risks and focusing on patient safety.

POLICY

A. Specific medications may be administered to patients during diagnostic or therapeutic procedures that produce sufficient sedation/analgesia to require special monitoring and clinical expertise to recognize and rescue patients that become over sedated in order to minimize the associated risks.

B. A physician credentialed in moderate sedation/analgesia determines that the patient is an appropriate candidate for sedation/analgesia.

C. Informed consent for moderate sedation will be obtained by the physician prior to the procedure in accordance with the Informed Consent Policy.

D. Medications administered for sedation/analgesia will be administered after the patient arrives in the location in which the procedure will be performed and will not be initiated on the nursing unit prior to transport of the patient to another location.

E. The same moderate sedation/analgesia procedures will be followed regardless of the technique and route of medication administration (e.g., oral, nasal, parenteral, rectal).

F. Emergency equipment will be present at the bedside during sedation until the patient has regained their pre-sedation status.

G. Personnel necessary for provision of sedation/analgesia are:

1. A designated individual, other than the practitioner performing the diagnostic or therapeutic procedure, to monitor the patient throughout the period of sedation. This individual may assist with minor, interruptible tasks once the patient's level of sedation and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.
2. An individual physically present and capable of establishing a patent airway and providing positive pressure ventilation with a means of summoning additional assistance.
3. An individual with current Advanced Cardiac Life Support (ACLS), or Advanced Trauma Life Support (ATLS), immediately available within 5 minutes, such as a code team.

H. Intravenous access will be maintained throughout sedation/analgesia and during the recovery phase until the patient is no longer at risk for cardio-respiratory depression.

I. Supplemental oxygen will be present and considered during sedation/analgesia unless specifically contraindicated for a particular patient or procedure.

J. Transfer of Care/Condition: If a physician transfers sedation/anesthesia care to an anesthesiologist or CRNA, then the responsibility for further documentation and monitoring becomes the responsibility of the anesthesia provider.

K. Sedation regimens that require the routine use of reversal agents are discouraged.

L. An anesthesia provider will be consulted when in the judgment of the practitioner it would optimize care of the patient.

M. Each patient's pre-sedation assessment is documented by the physician indicating that the patient is an appropriate candidate for sedation/analgesia. The physician prescribing the sedation/ analgesia documents immediately prior to sedation the following:

1. Age
2. Abnormalities of the major organ systems
3. History of sleep apnea or Gastro-esophageal Reflux Disease (GERD)

4. Personal and family history of previous adverse experiences with sedation/analgesia as well as regional and general anesthesia.
5. Drug allergies, current medications, herbal supplements
6. Time and nature of most recent oral intake
7. History of tobacco, alcohol, substance use, and abuse
8. Pregnancy
9. Pertinent laboratory, radiological, and functional studies
10. Mental status, level of consciousness,
11. Examination of heart and lungs,
12. American Society of Anesthesiologist (ASA) Class, sedation/anesthesia risks (Table 2).
13. Airway assessment, (Table 3)
14. Risks and benefits and anesthesia plan.
15. Alternatives will be discussed with patient prior to procedure.

Table 2 – American Society of Anesthesiologists Physical Status Classification

Class	**I**	Normal healthy patient
Class	**II**	Mild systemic disease
Class	**III**	Severe systemic disease
Class	**IV**	Severe systemic disease/constant threat to life
Class	**V**	Not expected to survive without operation

Table 3 – Airway Assessment Procedures for Sedation and Analgesia

Positive pressure ventilation, with or without tracheal incubation, may be necessary if respiratory compromise develops during sedation-analgesia. This may be more difficult in patients with atypical airway anatomy. In addition, some airway abnormalities may increase the likelihood of airway obstruction during spontaneous ventilation. Some factors that may be associated with difficulty in airway management are:

History	Previous problems with anesthesia or sedation Stridor, snoring, or sleep apnea Advanced rheumatoid arthritis Chromosomal abnormality (e.g., trisomy 21)
Physical Examination	
Habitus	Significant obesity (especially involving the neck and facial structures)
Head & Neck	Short neck, limited neck extension, cervical spine disease or trauma, neck mass, decreased hyoid-mental distance (< 3cm in an adult), Tracheal deviation, dysmorphic facial features (e.g., Pierre-Robin syndrome)
Mouth	Small opening (< 3 cm in an adult), edentulous, protruding incisors, Loose or capped teeth, dental appliances, high arched palate, macroglossia, tonsilar hypertrophy, nonvisible uvula
Jaw	Micrognathia, retrognathia, trismus, significant malocclusion

N. Patients will be fully monitored for at least two hours after administration of an opioid or benzodiazepine reversal agent unless the credentialed physician writes an order to reduce this period of monitoring.

O. The duration and frequency of monitoring during the recovery phase will be individualized depending on the level of sedation achieved; the overall condition of the patient and the nature of the intervention for which the sedation/analgesia was administered.

P. Each area providing moderate sedation will conduct a random sample (minimum 15/month) of audits using the MIDAS (Moderate Sedation – 2008 forward) module. In addition to the random sample, an audit will be completed on every patient who experiences an adverse outcome (an RRT or Code Blue, any patient requiring a reversal agent or an admission or transfer to a higher level of care).

Health Care Improvement will monitor the data base and report all adverse outcomes including the use of reversal agents to the appropriate Peer Review Committee or Nurse Manager whichever is most appropriate. An aggregate report will be sent to the Chief of the Anesthesia Department with a narrative of issues addressed during the reporting period.

Q. A Midas risk event will be completed in the event of an adverse drug reaction.

RESPONSIBILITIES

Director of Anesthesiology:

Development of standards of practice and guidelines for sedation/analgesia in collaboration with other departments that provide the service.

Medical Director of Department where procedure is planned:

A. Ensures that physicians and Registered Nurses performing sedation/ analgesia have appropriate credentials.

B. Ensures that quality improvement data is reviewed and appropriate actions taken.

Credentialed Physician (***MD/DO***):

A. Completion of a pre-sedation evaluation and assessment prior to preceding with sedation/analgesia to determine that the patient is an appropriate candidate for sedation/analgesia.

B. Consults the appropriate medical specialist before sedation/analgesia is initiated in patients with significant underlying conditions in the setting of a planned procedure. For emergency diagnostic and therapeutic procedures, the clinical judgment of the provider must weigh the risk and benefits of going ahead with procedural sedation.

C. Completes physician portion of Sedation Record or similar form.

D. Prescribes medications and is physically present during the procedure.

E. Ensures patient has completed the recommended minimum fasting period prior to initiating the sedation.

F. Initiation of "TIME OUT" prior to the administration of sedation.

G. Medical supervision of recovery and discharge after sedation.

H. Rescue of the patient when indicated.

I. Ensure that the patient is provided with written post-sedation instructions and warnings.

Qualified Registered Nurse (***RN***):

A. Validation of physician credentials in moderate sedation through on-line privilege viewer.

B. Assuring emergency equipment is present at the bedside.

C. Proper identification of the patient using two forms of identification

D. Verification of informed consent

E. Review of the physician's documentation concerning patient pre-sedation status

F. Monitoring of the patient during sedation until the patient's pre-sedation status has returned.

G. Documentation of patient monitoring parameters on Sedation Record or similar form.

H. Assisting with rescue of the patient when necessary according to established Basic Life Support (BLS) procedures and in keeping with the scope of practice for Registered Nurses.

DEFINITIONS

When used in this Policy these terms have the following meaning:

A. Moderate sedation/analgesia: A drug induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway and/or adequate spontaneous ventilation. Cardiovascular function is usually maintained.

1. Medications that can be used for sedation are: lorazepam (Ativan); diazepam (Valium); morphine sulfate; fentanyl; diphenhydramine (Benadryl); midazolam (Versed) (Table 4).

2. The use of minimal sedation such as topical, local, and oral analgesic agents can be given in accordance with the scope of practice of each licensed health care provider.

Table 4 – Guidelines for Use of Moderate Sedation Agents

OPIOID NARCOTICS		
Morphine Sulfate	**Fentanyl**	**Meperidine *(Demerol)***
Classification: Opiate Agonist	**Classification:** Opiate Agonist	**Classification:** Opiate Agonist
Indications: Management of moderate to severe pain, sedation	**Indications:** Pain relief, sedation	**Indications:** Management of moderate to severe pain
Side Effects: Respiratory depression, nausea, vomiting, bradycardia, hypotension, peripheral vasodilatation, histamine release, pruritis, increased ICP	**Side Effects:** Respiratory depression, nausea, vomiting, bradycardia, hypotension, skeletal and thoracic muscle rigidity especially following rapid IV administration.	**Side Effects:** Respiratory depression, nausea, vomiting, bradycardia, hypotension, peripheral vasodilatation, histamine release, pruritis, increased ICP
Contraindications: Increased ICP, severe respiratory depression, and hypersensitivity to opiates.	**Contraindications:** Increased ICP, severe respiratory depression, and hypersensitivity to opiates.	**Contraindications:** Increased ICP, severe respiratory depression, patients receiving MAO inhibitors, use with caution in patients with seizure disorders, patients with tachyarrythmias, patients ≥65 years, and hypersensitivity to opiates.
Peak Effect: IV: 20 minutes Oral: 60 minutes Suppository: 20-60 minutes Subcutaneous: 50-90 minutes IM: 30-60 minutes	**Peak Effect:** IV: 3-15 minutes IM: 15 minutes Oral: 20-30 minutes	**Peak Effect:** IV. 5-20 minutes IM: 30-50 minutes Oral: 60 minutes
Duration: 3-5 hours	**Duration:** 30 minutes-1 hour; respiratory depression may last longer than analgesia	**Duration:** IV, SC, IM: 2-4 hours
Dose, Infants & Children: IV: 0.05-0.1 mg/kg/dose up to 2 mg Oral: 0.3-0.6 mg/kg **Dose, Adults:** IV: Initial dose 1-5 mg. (maximum recommended initial dose of 10mg) May repeat in 1-2 mg increments to a maximum recommended total dose of 20 mg **Concomitant sedatives, debilitated or patients ≥65 years:** Initial dose IV: 1 mg	**Dose, Infants & Children:** IV: 1-2 mcg/kg **Dose, Adults:** IV: 0.5-1 mcg/kg/dose (50-100 mcgs) **Concomitant sedatives, debilitated or patients ≥65 years:** Initial dose IV: 12.5-25 mcg/dose	**Dose, Children:** IV: 0.05-1.5 mg/kg/dose **Dose, Adults:** IV: 25-50 mg/dose **Concomitant sedatives, debilitated or patients ≥65 years:** Initial dose IV: 12.5 mg/dose
Drug interactions: Phenothiazines may antagonize the analgesic effect of opiates. CNS depressants, MAO inhibitors, tricyclic antidepressants may potentiate morphine's adverse effects. Reduce doses in patients ≥65 years, hypovolemic, or high risk patients and with concomitant use of sedatives and other narcotics.	**Drug interactions:** CNS depressants, MAO inhibitors, tricyclic antidepressants may potentiate fentanyl's adverse effects. Reduce doses in patients ≥65 years, hypovolemic, or high risk patients and with concomitant use of sedatives and other narcotics.	**Drug interactions:** MAO inhibitors greatly potentiate the effects of meperidine. CNS depressants, tricyclic antidepressants, phenothiazines may potentiate the effects of meperidine. Reduce doses in patients ≥65 years, hypovolemic, or high risk patients and with concomitant use of sedatives and other narcotics.
Antagonist: *Narcan*	**Antagonist:** *Narcan*	**Antagonist:** *Narcan*
Considerations: Administer IV drug over a minimum of 5 minutes	**Considerations:** Administer IV drug over 3-5 minutes Apnea may precede sedation	**Considerations:** Administer IV drug over a minimum of 5 minutes

Table 4 – Guidelines for Use of Moderate Sedation Agents
(continued)

SEDATIVES	
Midazolam *(Versed)*	**Diazepam (*Valium*)**
Classification: Benzodiazepine	**Classification:** Benzodiazepine
Indications: Sedation, amnesia	**Indications:** Sedation, amnesia
Side Effects: Bradycardia, hypotension, respiratory depression, apnea, cardiac arrest, laryngospasm.	**Side Effects:** Bradycardia, hypotension, respiratory depression, apnea, cardiac arrest, laryngospasm, phlebitis, pain with injection
Contraindications: CNS depression, respiratory depression, severe uncontrolled pain, severe hypotension	**Contraindications:** CNS depression, respiratory depression, severe uncontrolled pain, severe hypotension
Peak Effect: IV: 5-7 minutes IM 15-30 minutes Oral: 30 minutes	**Peak Effect:** IV: 5-15 minutes Oral: 45 minutes-1 hour
Duration: 1-2 hours	**Duration:** 2-6 hours
Dose, Children: IV: 0.05 mg/kg/dose Maximum recommended initial dose: 2 mg May repeat after peak effect to recommended total dose of 5 mg Oral: 0 5-0.75 mg/kg Maximum recommended oral dosages: 6 months to 5 years: 6 mg and ≥6 years: 10 mg	**Dose, Children:** IV. Initial dose 0.05 mg/kg/dose (maximum recommended initial dose of 5 mg) May repeat after peak effect with incremental doses of 0.05 mg/kg (maximum recommended incremental dose of 1 mg) to a maximum recommended total dose of 10 mg Oral: 0.2-0.3 mg/kg Maximum recommended dose: 10 mg
Dose, Adults: IV: 0.5-2 mg slow push over at least 2 minutes May repeat dose after peak effect as needed to a maximum recommended total dose of 2.5-5 mg	**Dose, Adults:** IV: Initial dose 5 mg. May repeat after peak effect with 2.5 mg doses as needed to a maximum recommended total dose of 10 mg Oral: 10 mg **Concomitant opioids, debilitated or patients ≥65 years:** IV, PO: 2.5 mg/dose
Drug Interactions: Reduce doses in patients ≥65 years, hypovolemic, or high risk patients and with concomitant use of sedatives and other narcotics. **If opioids (narcotics) or other CNS depressants are administered concomitantly, the midazolam dose should be reduced by 30%, if <65 years of age or by at least 50%, if >65 years of age.** Because of the potential for serious and/or life-threatening prolonged sedation that can occur with increased plasma concentrations of midazolam, the concurrent use of protease inhibitors and midazolam is contraindicated.	**Drug Interactions:** Opioids (narcotics) or other CNS depressants may enhance sedation and respiratory depression. Reduce doses in patients ≥65 years, hypovolemic, or high risk patients and with concomitant use of sedatives and other narcotics. Caution should be exercised if diazepam and protease inhibitors are administered concurrently. The patient should be monitored for excessive benzodiazepine adverse effects, such as confusion, excessive sedation, and respiratory depression.
Antagonist: *Flumazenil*	**Antagonist:** *Flumazenil*
Considerations: IV form of Midazolam may be given PO. Mix in coke or fruit juice. Do not use Sprite or 7•Up. Do not administer undiluted. The drug is bitter and requires flavor to mask the taste. Administer IV doses slowly over 2-5 minutes Administer oral dose 15-30 minutes prior to the procedure	**Considerations:** Flush IV before and after with normal saline. Administer IV doses slowly, not to exceed 1 mg/minute Do not dilute Return of drowsiness may occur 6-8 hours later because of enterohepatic recirculation. Administer oral dose 15-30 minutes prior to the procedure

Table 4 – Guidelines for Use of Moderate Sedation Agents

(continued)

SEDATIVES (continued)	
Lorazepam (Ativan)	**Pentobarbital Sodium (Nembutal)**
Classification: Benzodiazepine	**Classification:** Barbiturate
Indications: Management of anxiety, sedation, amnesia	**Indications:** Sedation
Side Effects: Bradycardia, hypotension, respiratory depression, apnea, cardiac arrest, laryngospasm	**Side Effects:** Respiratory depression, hypotension, bradycardia, apnea (with rapid IV administration), laryngospasm, nausea, vomiting, hypothermia
Contraindications: CNS depression, respiratory depression, severe uncontrolled pain, severe hypotension	**Contraindications:** Liver impairment, chronic or acute pain, porphyria
Peak Effect: IV: 15-60 minutes Oral: 60 minutes	**Onset of Action:** Oral: 15-60 minutes IV: within 1 minute
Duration: IV, Oral: 30 minutes-3 hours	**Duration:** Oral, rectal: 1-4 hours IV: initial sedative effect lasts 15 minutes
Dose, Infants &Children: Oral, IV. 0.05 mg/kg/dose Maximum recommended dose of 2 mg	**Dose, Children >6 months:** Oral, IM, rectal: 2-6 mg/kg Maximum recommended dose of 100 mg IV. Initial dose 1-3 mg/kg/dose Maximum recommended initial dose of 100 mg May repeat 1 mg/kg/dose every 5 to 10 minutes up to a maximum recommended total dose of 6 mg/kg. Do not exceed 200 mg maximum recommended total dose.
Dose, Adults: Oral, IV, IM: 0.05 mg/kg/dose Usual dose 2 mg, maximum recommended total dose of 4 mg **Concomitant opioids, debilitated or patients ≥65 years:** IV, PO: dose should not exceed 2 mg.	**Dose, Adults:** Oral: 100 mg IM: 150-200 mg IV: 100 mg initial dose may repeat incremental doses up to recommended maximum total dose of 200 mg
Drug Interactions: Opioids (narcotics) or other CNS depressants may enhance sedation and respiratory depression.	**Drug Interactions:** Opioids (narcotics) or other CNS depressants may enhance adverse effects.
Antagonist: Flumazenil	
Considerations: Although maximal CNS effects may last only up to 3 hours, lorazepam remains in the circulatory system up to 12 hours and may result in significant accumulation with repeated doses Administer IV doses slowly over 2-3 minutes Administer oral dose 15 to 30 minutes prior to the procedure	**Considerations:** Highly alkaline, MUST be diluted. Dilute in Normal Saline to a maximum concentration of 10 mg/ml. Avoid extravasation or rapid IV administration. Administer IV doses @ 2 mg/kg/min (max. 50 mg/min) **Rapidly moves from brain to plasma so although maximal CNS effects may last only 15 minutes, pentobarbital remains in the circulatory system for over 24 hours, and there may be significant accumulation with repeated doses*

Table 4 – Guidelines for Use of Moderate Sedation Agents
(continued)

SEDATIVES (continued)	
Chloral Hydrate	**Diphenhydramine (Benadryl)**
Classification: Sedative, hypnotic	**Classification:** Antihistamine
Indications: Sedation for non-painful procedures	**Indications:** Mild sedation, antiemetic
Side Effects: GI upset, paradoxical excitement	
Contraindications: Hepatic or renal impairment, gastritis or ulcers, severe cardiac disease	**Contraindications:** Acute asthma attacks, angle-closure glaucoma, peptic ulcer, urinary tract obstruction, hyperthyroidism. Can worsen CNS and respiratory depression when used with CNS depressants
Peak Effect: 30 minutes-1 hour	**Peak Effect:** 2-4 hours
Duration: 4-8 hours	**Duration:** 4-7 hours
Dose, Infants & Children: Oral, rectal: 25-50mg/kg/dose up to 1.5 gm 60 minutes prior to procedure May repeat 60 minutes after initial dose as needed to a total maximum recommended total dose of 125 mg/kg or 2 grams	**Dose, Children:** IV/PO: 1-1.25 mg/kg (Maximum recommended dose of 50 mg) *Maximum recommended daily dose = 5 mg/kg or 300 mg* **** May cause excitation especially in young children.***
Dose, Adults: Oral, rectal: 1-2 grams	**Dose, Adults:** IV;IM: 6.25-50 mg PO: 25-50 mg **Patients ≥65 years:** not recommended
Drug Interactions: May potentiate effects of CNS depressants	**Drug Interactions:** Additive sedation when given with other CNS depressants

Table 4 – Guidelines for Use of Moderate Sedation Agents
(continued)

REVERSAL AGENTS	
Naloxone (*Narcan*)	**Flumazenil (*Romazicon*)**
Classification: Opiate antagonist	**Classification:** Benzodiazepine antagonist
Indications: Reverse respiratory and CNS depression secondary to receiving a narcotic	**Indications:** Reverse sedative effect of Benzodiazepines
Side Effects: Nausea, vomiting, hypertension, hypotension, tachycardia, ventricular arrhythmias, sweating	**Side Effects:** Arrhythmias, nausea, vomiting, pain at injection site, blurred vision, seizures
Contraindications: Use with caution in patients with cardiovascular disease	**Contraindications:** Benzodiazepine dependence, benzodiazepines used for the treatment of seizures and tricyclic antidepressant over dose
Onset of Action: IV. within 2 minutes ETT. within 2-5 minutes	**Peak Effect:** 6-10 minutes
Duration: 20-60 minutes – this is shorter than that of most opioids, therefore repeated doses may be needed	**Duration:** 1-2 hours – this is shorter than that of most benzodiazepines, therefore repeated doses may be needed
Dose, Infants and Children: IV: 0.005-0.01 mg/kg/dose every 2-3 minutes up to 3 doses to reverse respiratory depression **Reversal of narcotic overdose may require doses of 0.1 mg/kg** *(max: 2 mg)*	**Dose, Children <20 kg:** *initial* - 0.01 mg/kg IV over 15 seconds (max 0.2 mg) *repeat* - 0.01 mg/kg IV repeat after 1 minute **Dose, Children 20-40 kg:** *initial* – 0.2 mg IV over 15 seconds *repeat* – 0.2 mg IV, repeat after 1 minute
Dose, Adults: IV: 0.4-2 mg every 2-3 minutes until desired effect is attained	**Dose, Adults:** *initial* – 0.2 mg IV over 15 seconds *repeat* – 0.2 mg IV at 1 minute intervals **Total maximum recommended cumulative dose =* 1 mg
	Drug Interactions: Use with caution in overdosage involving mixed drug overdosage. Toxic effects may emerge (especially with tricyclic antidepressants) with the reversal of the benzodiazepine effect by flumazenil.
Considerations: Administer IV over 30 seconds, undiluted	**Considerations:** Give through a large vein to minimize pain at injection site *Do not use to reverse sedation from Benzodiazepines given for seizures.*

Table 4 – Guidelines for Use of Moderate Sedation Agents
(continued)

LOCAL ANESTHETICS		
Lidocaine 2.5% and Prilocaine 2.5% (*EMLA Cream*)	**Lidocaine Hydrochloride (*Xylocaine*)**	**Lidocaine Hydrochloride with Epinephrine**
Classification: Local Anesthetic	**Classification:** Local Anesthetic	Epinephrine increases the duration of action of Lidocaine by causing vasoconstriction which slows the vascular absorption of Lidocaine Do not use in distal portions of the body such as digits, nose, ears, penis
Indications: Topical anesthesia for use on normal intact skin	**Indications:** Production of local infiltration anesthesia or topical anesthesia of mucous membranes	
Side Effects: Local pallor or blanching, erythema, alterations in temperature sensation, edema, itching	**Side Effects:** Bradycardia, hypotension, cardiovascular collapse, agitation, anxiety, nausea, vomiting, respiratory depression or arrest, blurred vision **Side effects are generally dose related and may result from high plasma levels related to excessive dosage, rapid absorption or inadvertent IV infection*	
Contraindications: Patients less than twelve months of age who are receiving treatment with methemoglobin-inducing agents, patients with a known history of sensitivity to local anesthetics of the amide type	**Contraindications:** Known history of hypersensitivity to local anesthetics of the amide type	**Dose:** **Children & Adults:** Injection: Maximum of 4.5 mg/kg/dose. Do not repeat within 2 hours Route: percutaneous 0.5% with 1:200,000 epinephrine 1% with 1:100,000 epinephrine 1% with 1:200,000 epinephrine
Onset of Action: 1 hour for dermal analgesia 2 hours for muscular analgesia	**Onset of Action:** Within 5 minutes	**Buffered Lidocaine** Numerous studies have shown that Lidocaine can be effectively buffered with Sodium Bicarbonate. This can decrease the local pain associated with the injection of Lidocaine. Combining 9 ml of Lidocaine with 1 ml of Sodium Bicarbonate in the same syringe has been shown to be an effective buffer.
Peak Effect: 2-3 hours		
Duration: 1-2 hours after removal of cream	**Duration:** 1-2 hours	
Dose: 0.5 to 2 grams under occlusive dressing	**Dose, Children & Adults:** Injection: Maximum of 4.5 mg/kg/dose. Do not repeat within 2 hours. Route: Percutaneous: 0.5% to 1% solution Topical: Liquid viscous (2%)	
Administration: Apply a thick layer of EMLA Cream to site and cover with an occlusive dressing such as *Tegaderm* Cream may be left on for 2-3 hours without loss of efficacy		

B. Credentialed Physician: A physician who meets the educational requirements established by the Director of Anesthesia for administration of moderate sedation. This includes:

   1. Review of sedation material provided by Anesthesia Department and successful completion of the Knowledge Assessment Test.
   2. Demonstrated competency by fulfilling one of the following requirements:

a. Residency training in moderate sedation in an ACGME-approved program, or

b. ATLS, ACLS, or PALS provider card, or

c. A record of being proctored on at least 10 sedation cases.

C. Qualified Registered Nurse: A Registered Nurse who has completed additional training in which competencies in sedation have been documented and patient monitoring skills are validated initially and annually. This includes a minimum requirement of current certification in Advanced Cardiac Life Support (ACLS).

D. Non-Anesthesia Provider: A physician who is not an anesthesiologist or a Registered Nurse who is not a current CRNA.

E. Pre-sedation status: The documented physical status of the patient prior to the administration of sedation/analgesia.

F. Emergency equipment: This includes emergency medications—cardiac monitoring, pulse oximetry, and a defibrillator (see Table 5).

Table 5 – Emergency Equipment for Sedation and Analgesia

Appropriate emergency equipment should be available whenever sedative or analgesic drugs capable of causing cardiorespiratory depression are administered. The lists in Table 5 should be used as a guide, which should be modified depending on the individual practice circumstances. Items in brackets are recommended when infants or children are sedated utilizing intravenous medications/agents.

Intravenous equipment	• Gloves, tourniquets, alcohol wipes, sterile gauze pads, tape • Intravenous fluid, Intravenous catheters (24-22 gauge), Intravenous tubing (pediatric "microdrip" (60 drops/ml)) • Assorted needles for drug aspiration, intramuscular injection (intraosseous bone marrow needle) • Appropriately sized syringes (1-ml syringes)
Basic airway management equipment	• Source of compressed oxygen (tank with regulator or pipeline with flowmeter • Source of suction, suction catheters (pediatric suction catheters) • Yankauer-type suction • Face masks (infant/child), self-inflating breathing bag-valve set • Oral and nasal airways (infant/child-sized), lubricant • Stethoscope and pre-cordial stethoscope
Advanced airway management equipment	• Laryngeal mask airways (pediatric) • Laryngoscope handles (tested), laryngoscope blades (pediatric) • Endotracheal tubes: Cuffed 6.0-8.0 mm ID; uncuffed 2.5-6.0 mm ID) • Intubating stylets (appropriately sized for endotracheal tubes)
Pharmacologic Antagonists	• Naloxone, Flumazenil
Emergency Medications	• Epinephrine, ephedrine, vasopressin, atropine, amiodarone, nitroglycerin (tablets or spray), lidocaine, diphenhydramine, Glucose 50% (10 or 25%), diazepam, or midazolam, hydrocortisone, methylprednisolone, or dexamethasone

PROCEDURES

These procedures are to be followed; however, they are not meant to be a substitute for professional judgment when assessing and treating patients.

MD/DO A. Credentialed physicians administering moderate sedation/analgesia will confirm the sedation-oriented aspects of the patient's medical history and how these might alter the patient's response to sedation/analgesia immediately before the initiation of sedation.

MD/DO B. Develops a sedation plan through performing and documenting a pre-sedation assessment.

MD/DO C. Writes medical order for procedure and indicates medication to be used for moderate sedation/analgesia.

MD/DO D. Validates that patient has been compliant with required fasting guidelines in Table 6. If the procedure is emergent, then the physician must make a risk/benefit assessment on proceeding without the NPO requirements being met.

Table 6 – Summary of American Society of Anesthesiologists Pre-procedure Fasting Guidelines *

* These recommendations apply to healthy patients who are undergoing elective procedures. They are not intended for women in labor. Following the Guidelines does not guarantee that complete gastric emptying has occurred.

Ingested Material	Minimum Fasting Period ‡
Clear Liquids Examples of clear liquids include water, fruit juices without pulp, carbonated beverages, clear tea, and black coffee.	2 hours
Non-human Milk Since non-human milk is similar to solids in gastric emptying time, the amount ingested must be considered when determining an appropriate fasting period.	6 hours
Light Meal A light meal typically consists of toast and clear liquids. Meals that include fried or fatty foods or meat may prolong gastric emptying time. Both the amount and type of food ingested must be considered when determining an appropriate fasting period.	6 hours

Comments :

Patients with specific problems such as hypoglycemia, hepatic disease, gastroesophageal reflux, or conditions associated with delayed gastric emptying will need individualized NPO orders and/or IV fluid after being made NPO.

Milk is not a clear liquid.

‡ The fasting periods apply to all ages.

RN E. Hands off the care of other assigned patients to another RN

RN F. Confirms presence of emergency equipment and medications at bedside as listed in Table 5.

RN G. Identifies the patient using two forms of identification.

RN H. Begins monitoring of patient and documents the following patient parameters prior to the administration of sedation:

1. anesthesia consent completed

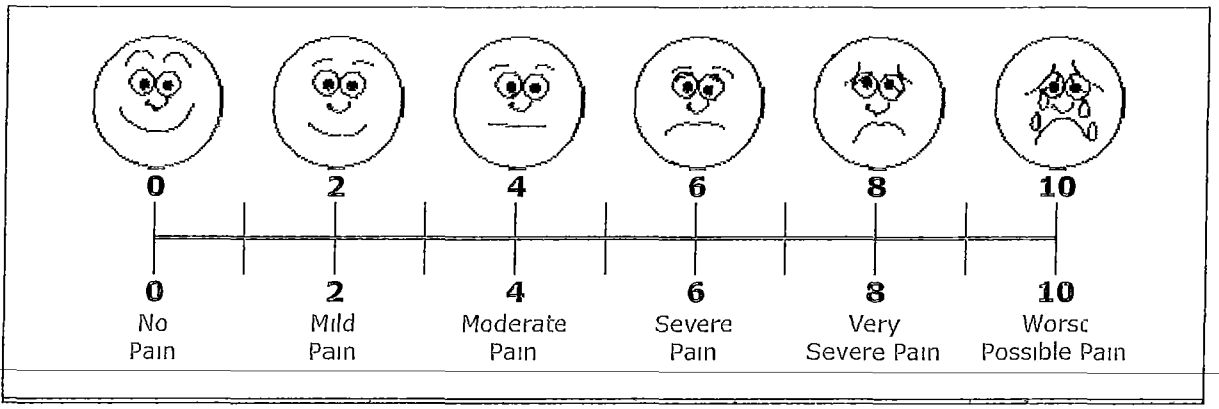
2. medication(s) given prior to sedation that may affect patient's level of consciousness
3. known allergies
4. NPO timeframe
5. patient weight
6. level of consciousness and Ramsay Sedation Scale (Table 7)
7. neurological status, pain assessment, pain score (see Table 8)
8. Blood pressure, pulse rate
9. respiratory rate and quality
10. oxygen in use; percent oxygen saturation
11. cardiac rhythm
12. intravenous (IV) site, needle gauge, type of fluid
13. completion of official TIME OUT process

Table 7 – Ramsay Sedation Scale
A measurement of patient sedation

Level 1	Anxious and agitated or restless
Level 2	Cooperative, oriented, tranquil
Level 3	Responds to commands only
Level 4	Asleep, but has brisk response to glabellar tap* or loud auditory stimulus
Level 5	Asleep, but has sluggish response to glabellar tap* or loud auditory stimulus
Level 6	No response

* Glabellar tap is a tap between the eyebrows.

Table 8 – Zero-to-10 Numeric Pain Intensity Scale



MD/DO I. Initiates official TIME OUTprior to sedation being given.

RN J. Documents the time and dosage of all medications administered.

RN K. Documents respiratory rate and quality, percent oxygen saturation, blood pressure, heart rate, pain scale scores (Table 8) and cardiac rhythm in the following intervals until the conclusion of the recovery phase:

1. at least every five minutes during the procedure, and
2. at the beginning and conclusion of the recovery phase, and
3. at least every 15 minutes during the recovery phase unless the patient's condition warrants more frequent measurements.

RN L. Continuously monitors patient's level of consciousness and records the Ramsay Sedation Scale (Table 7):

1. after the administration of each sedation agent, and
2. at least every 15 minute during the procedure and recovery phase.

RN M. Monitors patient's oxygenation until the patient is no longer at risk for respiratory depression.

MD/DO N. Documents any complications occurring during the period from initiation of sedation/analgesia until discharge of the patient from the sedation recovery area.

RN O. Monitors patient until the following discharge criteria are met:

1. Patient has returned to their pre-sedation mental status.
2. Aldrete Score (Table 9) of 8 or higher (or patient's pre-sedation baseline score), and
3. Ramsay Sedation Scale score of 2 (or the patient's pre-sedation baseline score).

4. Vital signs, respiratory pattern and oxygenation are stable and within acceptable limits.
5. In an outpatient setting:
   a. A responsible adult is willing to accompany the patient to their home and are able to report any post-procedure complications.
   b. Written instructions regarding post-procedure diet, medications, activities and a telephone number to be called in case of an emergency are provided.
6. At least two hours have elapsed since the administration of any opioid or benzodiazepine reversal agent.

Table 9 – Aldrete Scoring System
A measurement of patient recovery after anesthesia

ACTIVITY	
Score of 2	Moves 4 extremities voluntarily or to command (except surgical limitations)
Score of 1	Moves 2 extremities voluntarily or to command (except surgical limitations)
Score of 0	Moves 0 extremities voluntarily or to command
RESPIRATION	
Score of 2	Spontaneous unlabored respiration (deep breath, cough freely)
Score of 1	Dyspnea (limited breathing)
Score of 0	Apnea (assisted breathing)
CIRCULATION	
Score of 2	Blood Pressure plus or minus 20% of preanesthetic level, stable pulse
Score of 1	Blood Pressure plus or minus 20-50% of preanesthetic level, variable pulse
Score of 0	Blood Pressure plus or minus 50% of preanesthetic level, variable pulse
CONSCIOUSNESS	
Score of 2	Awake – oriented × 3 (fully awake)
Score of 1	Arousable on calling
Score of 0	Not responding, or responding only to pain
OXYGEN LEVEL	
Score of 2	Able to maintain oxygen saturation greater that 92% on room air
Score of 1	Needs oxygen inhalation to maintain oxygen saturation greater than 90%
Score of 0	Oxygen saturation less than 90% even with oxygen supplementation

A total Aldrete score is 10; a score of 9 or 10 is usually required for transfer of patient.

MD/DO P. Ensures the following procedures are enacted in the event of a patient becoming obtunded and/or loss of a patent airway:

1. Basic Life Support (BLS)
2. Reversing opioids and/or benzodiazepines
3. Issue appropriate consults such as Code Team and/or anesthesia provider as indicated.

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Yaney, LL. 1998. Intravenous Conscious Sedation. *Journal of Intravenous Nursing* 1:9-19.

RELATED INTERNAL DOCUMENTS

Document Number	Document Name
BHCS.CEPC.8.P	Informed Consent
	BUMC Crash Cart, Checking

ATTACHMENTS

Attachment Number	Attachment Name
BUMC.ANES.CARE.05.A1	BUMC Sedation Record
BUMC.ANES.CARE.05.A2	Discharge Instructions for Moderate Sedation and Deep Sedation

Baylor University Medical Center at Dallas

Attachment Name:
BUMC Sedation Record

Attachment Number:
BUMC.ANES.CARE.05.A1

Date of Last Review:
09/30/2013

☐ MODERATE SEDATION
☐ DEEP SEDATION

SEDATION RECORD

DATE	PHYSICIAN	PROCEDURE	DEPT	PATIENT WEIGHT

M.D. TO FILL OUT | Pt assessed immediately pre sedation ☐ YES | ASA CLASS | PERTINENT HISTORY & PHYSICAL/LAB ON CHART ☐ YES ☐ NO | ANESTHESIA CONSENT SIGNED ☐ YES | NPO SINCE ____ | PAIN ACCEPTABLE Y N

SEDATION/ANESTHESIA RISKS, BENEFITS, ALTERNATIVES DISCUSSED WITH PT PRIOR TO PROCEDURE ☐ YES | CURRENT MEDICATION ON CHART ☐ YES ☐ NO | PRE-PROCEDURE VITAL SIGNS | O2 ☐ ROOM AIR ☐ ___ L/min | SAO2 | B/P | P | R | T | PAIN

ANESTHESIA PLAN | Airway Assessment | M.D. Exam | PREMEDICATION | EFFECT

PRIOR ANESTHETIC PROBLEMS ☐ YES ☐ NO | PRE PROCEDURE EKG RHYTHM ________ RESPIRATORY PATTERN ________ NEURO ASSESSED ☐ RESP. ASSESSED ☐

ALLERGIES | MONITORS. B/P ☐ ausc ☐ auto ☐ art. ☐ EKG ☐ OXIMETER ☐ OTHER ________

O2
Liters/min. ________
% ________
☐ Face mask
☐ Nasal cannula

IV SITE	NEEDLE GAUGE	TYPE FLUID

COMMENTS

TIME OUT INITIATED: ________

Assess every 5 minutes

INTRAPROCEDURE

TIME	B/P	P	EKG	R	PATTERN	SAO2	PAIN	RAMSAY SCALE	ALDRETE SCALE	MEDICATION (Dose & Route)	Initials	COMMENTS

PROCEDURE TIME START ____ STOP ____ | INITIALS | SIGNATURE | INITIALS | SIGNATURE

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SEDATION RECORD PAGE 1 OF 2

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DATE:_____

SEDATION RECORD PART 2

TIME	B/P	P	EKG	R	PATTERN	SAO2	PAIN	RAMSAY SCALE	ALDRETE SCALE	MEDICATION (Dose & Route)	Initials	COMMENTS

POST-PROCEDURE EKG RHYTHM_____	INTAKE_____ OUTPUT_____	INITIALS	SIGNATURE
POST PROCEDURE RESPIRATORY PATTERN -_____	☐ SEE ADDITIONAL PAGE	INITIALS	SIGNATURE

Assess every 5-15 minutes

RECOVERY

ADMIT TO RECOVERY: EKG RHYTHM _____ RESPIRATORY PATTERN -_____

TIME	B/P	P	EKG	R	PATTERN	SAO2	PAIN	RAMSAY SCALE	ALDRETE SCALE	MEDICATION (Dose & Route)	Initials	COMMENTS ☐ See Post Invasive Flowsheet

POST RECOVERY EKG RHYTHM_____ RESPIRATORY PATTERN_____

MEDICATION VERBAL ORDERS: DICTATION NUMBER
GIVEN BY_____ M.D._____ INTAKE_____ OUTPUT_____

PATIENT DISCHARGED. ☐ HOME ☐ ROOM ☐ WHEELCHAIR ☐ STRETCHER ☐ WITH O2 ☐ WITHOUT O2

INITIALS | SIGNATURE | INITIALS | SIGNATURE

INSTRUCTIONS TO OUTPATIENTS: WRITTEN INSTRUCTIONS GIVEN? ☐ YES

DISCHARGE TIME | SIGNATURE

☐ PATIENT/SIGNIFICANT VERBALIZED UNDERSTANDING OF INSTRUCTIONS

PAIN ACCEPTABLE AT DISCHARGE. Y N

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SEDATION RECORD PAGE 2 OF 2

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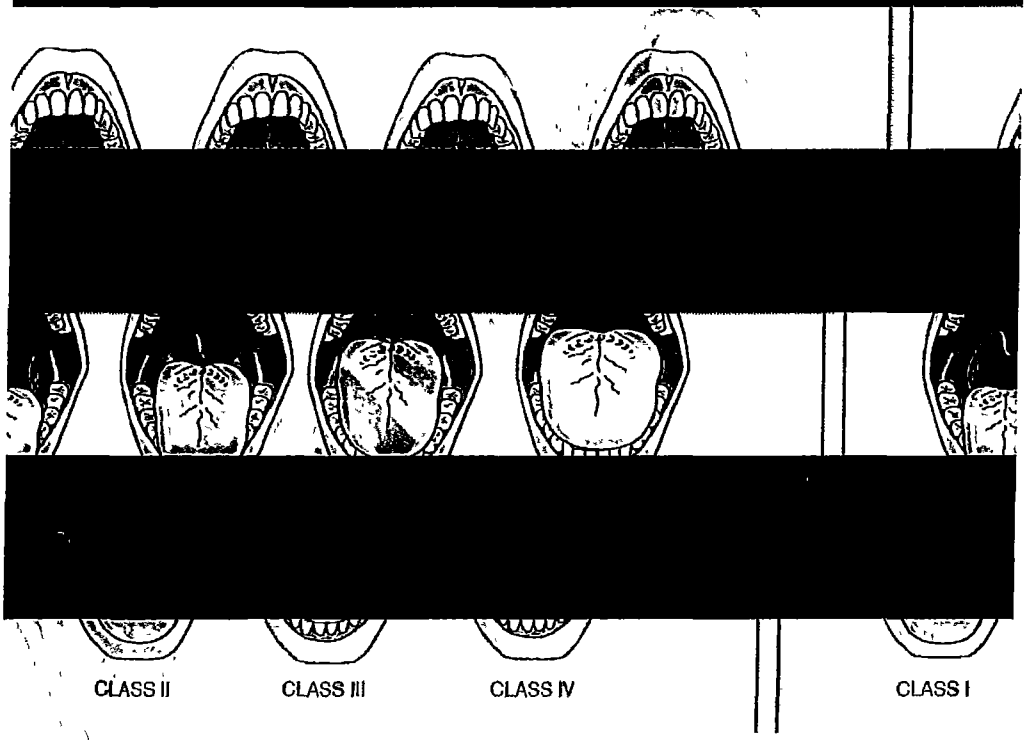
MALLAMPATI CLASSIFICATION SCALE: (AIRWAY ASSESSMENT)

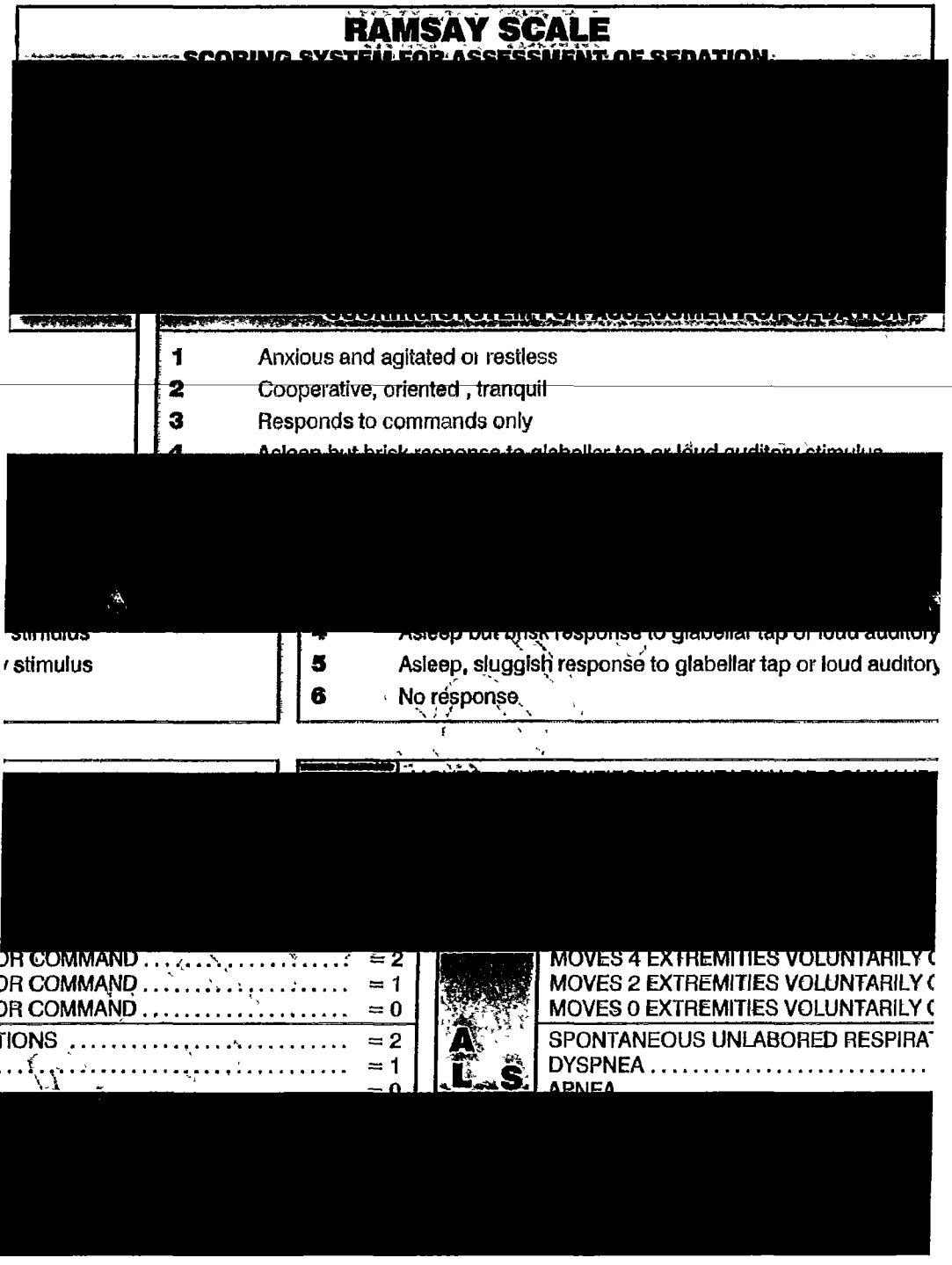
[redacted]

CLASS I = visualization of the soft palate, fauces, uvula, anterior and posterior pillar.
CLASS II = visualization of the soft palate, fauces, uvula.
CLASS III = visualization of the soft palate and the base of the uvula.
CLASS IV = soft palate is not visible at all

[redacted]



CLASS II CLASS III CLASS IV CLASS I



RAMSAY SCALE

SCORING SYSTEM FOR ASSESSMENT OF SEDATION

[redacted]

1	Anxious and agitated or restless
2	Cooperative, oriented , tranquil
3	Responds to commands only
4	Asleep but brisk response to glabellar tap or loud auditory stimulus
5	Asleep, sluggish response to glabellar tap or loud auditory
6	No response

[redacted]

OR COMMAND	= 2		MOVES 4 EXTREMITIES VOLUNTARILY
OR COMMAND	= 1		MOVES 2 EXTREMITIES VOLUNTARILY
OR COMMAND	= 0		MOVES 0 EXTREMITIES VOLUNTARILY
TIONS	= 2	A	SPONTANEOUS UNLABORED RESPIRA
	= 1	L	DYSPNEA
	= 0	S	APNEA

[redacted]

DISCHARGE INSTRUCTIONS FOR MODERATE SEDATION AND DEEP SEDATION

You have been given medication to sedate you during your procedure today. This may have included both a pain medicine and sleeping medicine. You may continue to have some drowsiness for the next 6-8 hours after discharge. Please observe the following instructions over the next 24 hours following discharge from hospital.

HOME CARE

1. For at least the next EIGHT HOURS, you should be watched by a responsible adult to look for any worsening of your condition. Have this person read these sedation instructions.
2. DO NOT TAKE ANY OVER THE COUNTER MEDICATIONS that your doctor has not instructed you to take for the next FOUR HOURS. Non-prescribed medications might react with the medicines you were given in the hospital causing a much stronger response than usual. Continue any regularly prescribed medications as instructed by your doctor.
3. DO NOT DRINK any ALCOHOL for the next 24 HOURS
4. **DO NOT DRIVE** or operate dangerous machinery during the next 24 HOURS
5. Resume your diet as instructed by your doctor
6. If sent home with any medical equipment, use the equipment as instructed by your doctor.

Special Instructions _____

_____

FOLLOW UP with your doctor if you are not alert and back to your usual level of activity within TWELVE hours.

YOUR DOCTOR IS: _____ Telephone # _____

Contact your doctor immediately if any of the following occur:

- Increased drowsiness
- Increased weakness or dizziness
- Having difficulty breathing

Name of responsible adult accompanying you home: _____

X _____
Patient / Significant Other Signature

X _____
Nurse Signature Date / Time

Form 043024

MED REC NO _____
PATIENT _____
PHYSICIAN _____
BILLING NO. _____

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43624 (Rev 7-04)
DISCHARGE INSTRUCTIONS
MODERATE SEDATION AND DEEP SEDATION I-275

The following chart is a patient you cared for in the ED who was given Moderate Sedation for a procedure. Please review the Moderate Sedation quality form below, sign your name and date on the specified lines. Please make any comments or give feedback in the area provided. Thank you!

Baylor Emergency Department Physician QA Review: Moderate Sedation

Patient Name _____ **Occurrence Date**_____ **Procedure**_____

ID/Billing #_____ **Physician** _____ **Nurse** _____

Did the physician complete the required pre-sedation assessment check list? ❒ Yes ❒ No

Was the physician credentialed for Moderate Sedation? ❒ Yes ❒ No

"Time Out" time noted? ❒ Yes ❒ No

Documented that patient/family received IV sedation discharge instructions? ❒ Yes ❒ No ❒N/A (Admitted)

(Patients, who undergo moderate conscious sedation and are discharged, must also be given the IV sedation discharge instructions...in addition to their other discharge instructions.)

Mallampati Score ❒Class I ❒Class II ❒Class III ❒Class IV ❒Not Doc

ASA Score ❒ASA 1 ❒ASA 2 ❒ASA 3 ❒ASA 4 ❒ASA 5 ❒Not Doc

Any adverse outcome? ❒ Yes ❒ No

If yes, explain:_____

_____

_____

Comments:

_____

_____

_____

_____

Physician Signature: _____ **Date:** _____

QA RN Signature: _____ **Date:** _____

Revised 2014.04_DP