STANDARDIZE 4 SAFETY INITIATIVE

Standardize 4 Safety is the first national, interprofessional effort to standardize medication concentrations to reduce errors, especially during transitions of care.

These national standards will cover:

- Concentrations and dosing units for intravenous continuous medications for adult patients.
- Concentrations for compounded oral liquid medications.
- Concentrations and dosing units for intravenous continuous medications for pediatric patients.
- Doses for oral liquid medications.
- Concentrations for intravenous intermittent medications.
- Concentrations for PCA and epidural medications.

The Standardize 4 Safety initiative began in 2008 when a multi-stakeholder IV summit was held to address preventing patient harm and death from intravenous (IV) medication errors. Among the recommendations made by the participants was to establish national standards for IV medications in hospitals including standardized concentrations and dosing. In addition, it was recommended that the national standards be created in collaboration with the Food and Drug Administration (FDA), the pharmaceutical industry, and other stakeholders. Since the summit, establishing standardized concentrations has garnered strong support from ASHP members, the Joint Commission, the Institute for Safe Medical Practices (ISMP), and others. 1 2 3 4

In 2015 the FDA, through its Safe Use Initiative, awarded ASHP a grant to develop and implement national standardized concentrations for IV and oral liquid medications. The aims of the grant were to: (1) identify a nationwide expert interprofessional panel consisting of physicians, nurses, and pharmacists; (2) create standards for adult continuous IV infusions, compounded oral liquid medications, pediatric continuous IV infusions, doses for liquid medications, intravenous intermittent infusions, and PCA and epidural medications; (3) disseminate the standards and assess their adoption.

WHY STANDARDIZE

*To Err is Human* was published in 1999 and highlighted the harm to patients from healthcare error. In that report, medication errors were stated to be responsible for one of 131 outpatient and one of 854 inpatient deaths. Healthcare continues to struggle to eliminate harm to patients. A systematic review and meta-analysis in 2019 estimated one in 20 patients are exposed to preventable medical harm with the highest incidence of events due to medications. Compounded medications, especially those given intravenously, are known to be high risk for error due to added complexity and multiple steps required for determining dosing when ordering, concentrations for preparation, and rates of infusion for administering. Using standardization as a quality improvement tool decreases variation, improves safety, and is the foundation for using clinical pathways and evidence-based guidelines. Standardization allows providers to manage excessive and unintended variation as they customize care for patients.

PRINCIPLES FOR PEDIATRIC CONTINUOUS INFUSION STANDARDS

- Safety first — use commercial when possible
- Try to limit to one concentration when possible
- Consider concentration relative to fluid status.
- Use more concentrated when possible
- Consider operational dispensing aspects and steps including waste
- Patient/ Clinical Needs

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HOW THE NATIONAL MEDICATION CONCENTRATION STANDARDS WERE DEVELOPED

A comprehensive environmental scan was conducted to identify the appropriate medications to be addressed in the respective standard concentrations. A multi-disciplinary expert panel was convened for each standard concentration category. Members were selected based on their expertise in the subject matter and identified with assistance from organizations such as The American Society of Anesthesiologists, Society of Critical Care Medicine, and American Association of Critical-Care Nurses. Each expert panel was charged to establish standard principles to guide their decisions in creating the respective standard concentration recommendations. Once a draft of standards was established, it was released for public comment and review by ASHP staff and ISMP. The expert panel subsequently met to address all comments and generate the National Medication Concentration Standards.

PRINCIPLES FOR EXPERT PANEL DELIBERATIONS

- Operational considerations (costs and waste)
- Use more concentrated when possible
- Limit to one concentration when possible
- FDA-approved commercial products
- Patient clinical needs
EXPERT PANEL

PHYSICIANS

Mitchell Goldstein
Loma Linda University Health

Randi Trope
Cohen Children’s Northwell Health

Vinay Vaidya
Phoenix Children’s Hospital

NURSES

Wendy Cross
American Association of Critical-Care Nurses

Rebecca Isbell

Rachel Joseph

Kimberly Whalen
Massachusetts General Hospital

Lori Williams
University of Wisconsin Health

PHARMACISTS

Jared Cash
Primary Children’s Hospital

Regine Cauthers White
Wolters Kluwer

Brandon Clubb
Riley Hospital for Children

Kim Jeong-eun
New York Presbyterian Hospital

Jake Luke
Primary Children’s Hospital

Rachel Meyers
Rutgers

Shelly Morvay
Nationwide Children’s Hospital
DISCLAIMERS

• Suggested concentrations may differ from the package insert (PI) information for a drug. This is due to clinical needs that may have transpired postmarket. When this is the case, studies are available to support the use of a concentration different than what the parent company originally pursued through the new drug application (NDA) process.

• Please use the utmost caution when using a concentration different than the PI, especially if rate information is used from the PI.

• Dosing units were derived from PI information, commonly used drug-reference guides, and clinical practice guidelines.

• Of special note, the expert panel is recommending that weight-based dosing be used for vasopressors (i.e., per kg, per minute), which may differ from institution specific guidelines. We strongly encourage that drug libraries and electronic health records (EHRs), including the electronic medication administration record, make distinct differences for weight-based vs. non-weight-based dosing so nurses can easily distinguish what pump programming is needed.

• These concentrations are guidelines only and are not mandatory. It is our hope that organizations will voluntarily adopt these concentrations and join a national movement to use standardization across the care continuum as an error-prevention strategy for patient safety.

• The information contained in this table is subject to the professional judgment and interpretation of the practitioner. ASHP has made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, any reader of this information is advised that ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information in the self-assessment tool. Any user of the table is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in it, and will bear no responsibility or liability for the results or consequences of its use.

CONSIDERATIONS IN USING THE PEDIATRIC CONTINUOUS INFUSION STANDARDS

The 80/20 rule was applied by the expert panel to determine recommended standard concentrations. The concentrations listed reflect those applicable to most patient care circumstances. The panel recognizes situations occur where the most appropriate concentration for a patient may not be the recommended standard.

Whenever possible one standard infusion concentration is the recommendation. When more than one standard concentration was recommended it was to accommodate patient care needs for extremely small neonates, fluid restrictions, differences required for peripheral versus central lines, to simplify calculations and accommodate limitations of pump infusion rates.

Medications with more than one recommended concentration are listed from lowest to highest concentration, with the numbering corresponding to the respective stability reference(s).

The concept of bracketing was employed for references for stability. For more information review: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q1d-bracketing-and-matrixing-designs-stability-testing-new-drug-substances-and-products.

The Pediatric Continuous Infusion Standards are intended for children less than 50 kg.
### PEDIATRIC CONTINUOUS INFUSION STANDARDS

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<tr>
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</table>
| Alprostadil | 1. 5 mcg/mL             | mcg/kg/min   | No                     | Possibly depending on vial      | 1. Pharmacia & Upjohn Company. Prostin VR Pediatric® (alprostadil sterile solution) injection prescribing information. Kalamazoo, MI; 2013 April. AHFS  
|           | 2. 10 mcg/mL            |              |                        |                                 | 1a. Pharmacia & Upjohn Company. Prostin VR Pediatric® (alprostadil sterile solution) injection prescribing information. Kalamazoo, MI; 2013 April. AHFS  
1b. Product Information: Activase(R) intravenous injection, alteplase intravenous injection. Genentech, Inc.(per Manufacturer), South San Francisco, CA, 2015- Micromedix |
| Amiodarone | 1. 1.8 mg/mL            | mcg/kg/min*  | Yes - 1.8 mg/mL         | Yes                             | 1a. Campbell S, Nolan PE, Bliss M et al. Stability of amiodarone hydrochloride in admixtures with other injectable drugs. *Am J Hosp Pharm*. 1986; 43:917–21.  
1b. Product Information: amiodarone HCl intravenous injection, amiodarone HCl intravenous injection. Teva Canada Limited (per Health Canada), Toronto, ON, Canada, 2016. - Micromedix  
2. Product Information: amiodarone HCl intravenous injection, amiodarone HCl intravenous injection. Teva Canada Limited (per Health Canada), Toronto, ON, Canada, 2016. - Micromedix |
|           | 2. 3.6 mg/mL            |              |                        |                                 | 1a. Pharmacia & Upjohn Company. Prostin VR Pediatric® (alprostadil sterile solution) injection prescribing information. Kalamazoo, MI; 2013 April. AHFS  
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</table>
| Argatroban | 1 mg/mL                | mcg/kg/min*  | Yes                    | Yes                             | 1a. Product Information: argatroban injection, argatroban injection. GlaxoSmithKline, Research Triangle Park, NC, 2009.  
| Bumetanide | 1. 0.04 mg/mL          | mcg/kg/hour* | Yes - 0.25 mg/mL undiluted drug from the vial | Yes                             | 1. Cornish LA, Montgomery PA, Johnson CE. Stability of Bemetanide in 5% dextrose injection. AJHP 1997;54:422-3  
|           | 2. 0.25 mg/mL          |              |                        |                                 |             |
| Cisatracurium | 1. 1 mg/mL            | mg/kg/hour   | Yes, undiluted from the 2 mg/mL vial | Yes                             | 1. Pignard J. Physiochemical stability study of injectable solutions of cisatracurium besilate in clinical conditions. Ann Fr Anesth Reanim. 2014; 33:304-9.  
|           | 2. 2 mg/mL             |              |                        |                                 |             |
| Dexmedetomidine | 4 mcg/mL       | mcg/kg/hour  | Yes                    |                                 | 1. Hospira. Precedex® (dexmedetomidine) injection prescribing information. Lake Forest, IL; 2016 Apr. |
| DOBUTamine | 1. 1000 mcg/mL        | mcg/kg/min   | Yes                    | Possibly, depending on pharmacy or outsourcing facility lab | 1. Hospira. Dobutamine in 5% dextrose injection prescribing information. Lake Forest, IL; 2006 June.  
<p>|           | 2. 2000 mcg/mL        |              |                        |                                 |             |
|           | 3. 4000 mcg/mL        |              |                        |                                 |             |</p>
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</table>
| **DOPamine** | 1. 800 mcg/mL           | mcg/kg/min    | Yes                    | Possibly, depending on pharmacy or outsourcing facility label         | 1. Hospira. Dopamine hydrochloride and 5% dextrose injection prescribing information. Lake Forest, IL; 2014 May.  
2. Hospira. Dopamine hydrochloride and 5% dextrose injection prescribing information. Lake Forest, IL; 2014 May.  
3. Hospira. Dopamine hydrochloride and 5% dextrose injection prescribing information. Lake Forest, IL; 2014 May. |
|              | 2. 1600 mcg/mL          |              |                        |                                                                        |                                                                             |
|              | 3. 3200 mcg/mL          |              |                        |                                                                        |                                                                             |
| **EPINEPHrine** | 1. 10 mcg/mL²          | mcg/kg/min    | No                     | Possibly, depending on pharmacy or outsourcing facility label         | 1. Hook R, Neault A, Scharrer, et.al. Chemical stability of epinephrine 10 mcg/mL diluted in 0.9% sodium chloride and stored in polypropylene syringes at 4 degrees and 25 degrees C. Int J Pharm Compd. 2023;27:347-351.  
<p>|              | 2. 20 mcg/mL            |              |                        |                                                                        |                                                                             |
|              | 3. 40 mcg/mL            |              |                        |                                                                        |                                                                             |</p>
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<td></td>
<td>2. 20 mg/mL</td>
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</table>
| Fentanyl (NYL)     | 1. 10 mcg/mL           | mcg/kg/hour  | Yes, as undiluted from 50 mcg/mL vial | Possibly depending on pharmacy or oursourcing facility label | 1. Extedned Stability for Parenteral Drugs 6th Edition, 2017. Ed. Bing, CD et. al. ASHP, 4500 East-West Highway, Suite 900, Bethesda, MD 20814  
|                    | 2. 50 mcg/mL           |              |                        |                                 |                                                                                                                                         |
| Furosemide         | 1. 2 mg/mL             | mg/kg/hour   | Yes, as undiluted from 10 mg/mL vial | No                              | 1. Negro S, Rendon AL, Azuara M, et.al. Compatibility and Stability of Furosemide and Dexamethasone Comined in Infusion Solutions. Arzneimittelforschung. 2006;56:714-20.  
|                    | 2. 10 mg/mL            |              |                        |                                 |                                                                                                                                         |
| Heparin (anticoagulation therapy) | 1. 50 units/mL | units/kg/hour | Yes                    | No                              | 1. B.Braun Medical Inc. Heparin Sodium in Dextrose Injection prescribing information. Bethlehem, PA. 2018. April  
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<tbody>
<tr>
<td>HYDROMORPHINE</td>
<td>1. 0.2 mg/mL</td>
<td>mg/kg/hr</td>
<td>No, but many pharmacies purchase from outsourcing facilities</td>
<td>Possibly depending on pharmacy label or outsourcing facility label</td>
<td>1. Ensom MHH, DeCarie D, Leung K, et al. Stability of hydromorphone-ketamine solutions in glass bottles, plastic syringes, and IV bags for pediatric use. <em>Can J Hosp Pharm</em>. 2009; 62(2):112b.</td>
</tr>
<tr>
<td>INSULIN (regular)</td>
<td>1. 0.2 units/mL</td>
<td>units/kg/hour</td>
<td>Yes</td>
<td>Possibly depending on pharmacy label or outsourcing facility label</td>
<td>1. Product Information: HUMULIN(R) R subcutaneous injection, intravenous injection, insulin human subcutaneous injection, intravenous injection. Lilly USA LLC (per FDA), Indianapolis, IN, 2018. Micromedex</td>
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<td></td>
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<td>2b. Product Information: HUMULIN(R) R subcutaneous injection, intravenous injection, insulin human subcutaneous injection, intravenous injection. Lilly USA LLC (per FDA), Indianapolis, IN, 2018. Micromedex</td>
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| Isoproterenol | 1. 20 mcg/mL  
2. 64 mcg/mL | mcg/kg/min   | No                     | Possibly depending on pharmacy label or oursourcing facility label                             | 1. Isuprel (isoproterenol hydrochloride injection, USP) [prescribing information]. Lake Forest, IL: Hospira Inc; March 2013. Pediatric Injectable drugs 11th edition  
| Ketamine   | 1. 2 mg/mL  
2. 10 mg/mL | mg/kg/hour   | Yes, undiluted drug from the vial of 10 mg/mL | Possibly depending on pharmacy label or oursourcing facility label                             | 1. Product Information: KETALAR intravenous injection, intramuscular injection, ketamine HCl intravenous injection, intramuscular injection. Par Pharmaceutical (per FDA), Chestnut Ridge, NY, 2017.  
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| Labetalol | 1. 1 mg/mL  
2. 5 mg/mL | mg/kg/hour   | Yes, undiluted drug from the vial of 5 mg/mL | Possibly depending on pharmacy label or oursourcing facility label | 1. Product Information: labetalol HCl intravenous injection, labetalol HCl intravenous injection. Hospira, Inc. (per DailyMed), Lake Forest, IL, 2015.  
| Lidocaine$^4$ | 1. 4 mg/mL  
<table>
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</table>
| Midazolam | 1. 0.3 mg/mL (easier pump programming than 0.35 mg/mL less decimal) | mg/kg/hour   | Yes, undiluted drug from the vial of 1 mg/mL vial and 5 mg/mL vial | Possibly, depending on pharmacy or outsourcing facility label | 1. Good PD, Schneider JJ, Ravenscroft PJ. The compatibility and stability of midazolam and dexamethasone in infusion solutions. J Pain Sympt Manag. 2004;27: 471-5.  
# Pediatric Continuous Infusion Standards

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2a. Wilson TD, Forde MD, Crain AVR, Dombrowski LJ, Joyce MA. Stability of milrinone in 0.45% sodium chloride, 0.9% sodium chloride, or 5% dextrose injections. *Am J Hosp Pharm*. 1986;43(9):2218-2220.  
2b. Wong F, Gill MA. Stability of milrinone lactate 200 mcg/mL in 5% dextrose injection and 0.9% sodium chloride injection. *Int J Pharm Compound*. 1998; 2(2):168b |
|            | 2. 200 mcg/mL           |              |                        |                                 |            |
| Morphine   | 1. 0.2 mg/mL            | mg/kg/hour   | Yes, undiluted drug from the vial of 1 mg/mL vial or ready-to-use products or premix products available | Possibly depending on pharmacy label or oursourcing facility label | 1. Veechio M, Walker SE, Iazzetta J et al. The stability of morphine intravenous infusion solutions. *Can J Hosp Pharm*. 1988; 41:5–9.  
|            | 2. 0.5 mg/mL            |              |                        |                                 |            |
|            | 3. 1 mg/mL              |              |                        |                                 |            |
## PEDIATRIC CONTINUOUS INFUSION STANDARDS

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</table>
| Naloxone     | 1. 16 mcg/mL            | mcg/kg/hour  | Yes, 0.4 mg/mL vials, however will most likely compound from 1 mg/mL vials | Yes                            | 1a. Product Information Naloxone Hydrochloride Injection, solution. Hospira Inc. Lake Forest, IL. 9/2019. 4 mcg/mL.  
|              | 2. 40 mcg/mL            |              |                        |                                |                                               |
|              | 3. 400 mcg/mL           |              |                        |                                |                                               |
| Nicardipine  | 1. 0.1 mg/mL            | mcg/kg/min*  | Yes - 0.1 mg/mL        | Yes                            | 1. Product Information: CARDENE(R) IV solution for IV infusion, nicardipine HCL solution for IV infusion. EKR Therapeutics, Inc, Bedminster, NJ, 2014.  
|              | 2. 0.2 mg/mL            |              |                        |                                |                                               |
|              | 3. 0.5 mg/mL            |              |                        |                                |                                               |
| Nitroglycerin| 1. 200 mcg/mL           | mcg/kg/min   | Yes                    | No, product does have concentration in mcg/mL | 1. Product Information: Nitroglycerin Injection. Abbott Laboratories, North Chicago, IL, October 2014  
<p>|              | 2. 400 mcg/mL           |              |                        |                                |                                               |</p>
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<tbody>
<tr>
<td>Nitroprusside</td>
<td>1. 200 mcg/mL 2. 500 mcg/mL</td>
<td>mcg/kg/min</td>
<td>Yes</td>
<td>Possibly depending on pharmacy label or oursourcing facility label</td>
<td>1. Product Information: NIPRIDE RTU intravenous injection, sodium nitroprusside intravenous injection. Exela Pharma Sciences, LLC (per FDA), Lenoir, NC, 2017.</td>
</tr>
<tr>
<td>Octreotide</td>
<td>1. 2.5 mcg/mL 2. 10 mcg/mL 3. 50 mcg/mL</td>
<td>mcg/kg/hour</td>
<td>No, however the 50 mcg/ml concentration may be used undiluted from the available vial/ampule.</td>
<td>Possibly depending on pharmacy label or oursourcing facility label</td>
<td>1. Novartis Pharmaceuticals. Sandostatin® (octreotide acetate) injection prescribing information. East Hanover, NJ; 2012 March.</td>
</tr>
<tr>
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</table>
| Pantoprazole | 0.8 mg/mL               | mg/kg/hour   | No                     | No                            | 1a. Donnelly RF. Stability of pantoprazole sodium in glass vials, polyvinyl chloride minibags, and polypropylene syringes. *Can J Hosp Pharm.* 2011; 64:192-8.  
| Phenylephrine| 1. 80 mcg/mL            | mcg/kg/min   | No                     | Possibly depending on pharmacy label or outsourcing facility label | 1a. West-Ward Pharmaceuticals. Phenylephrine hydrochloride injection prescribing information. Eatontown, NJ; 2012 Dec.  
1b. Éclat Pharmaceuticals. Vazculep® (phenylephrine hydrochloride) injection prescribing information. Chesterfield, MO; 2014  
<p>| Propofol     | 10 mg/mL                | mcg/kg/min*  | Yes                    | Yes                           | 1. Fresenius Kabi USA, LLC. Diprivan® (propofol) injectable emulsion prescribing information. Lake Zurich, IL; 2017 Nov. |</p>
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</table>
| Remifentanil | 1. 50 mcg/mL (non-recon vial straight drug)  
2. 250 mcg/mL | mcg/kg/min                    | No                     | Possibly depending on pharmacy label or oursourcing facility label                              | 1. Mylan Institutional LLC. Ultiva® (remifentanil hydrochloride) prescribing information. Rockford, IL; 2017 Dec.  
| Rocuronium   | 10 mg/mL                | mcg/kg/min*                   | Yes, undiluted drug from the vial of 10 mg/mL | Possibly depending on pharmacy label or oursourcing facility label | 1. Hospira. Rocuronium bromide injection prescribing information. Lake Forest, IL: 2014 Feb. |
| Sodium Bicarbonate | 1. 0.5 mEq/mL  
2. 1 mEq/mL | mEq/kg/hour                   | Yes, undiluted if using the prefilled 0.5 mEq/mL syringes and as undiluted drug from the 1 mEq/mL vial | No | 1. Hospira. Sodium Bicarbonate Injection, USP Vial dosage and administration. Lake Forest, IL. 1/2018.  
<p>| Sodium Chloride | 0.5 mEq/mL (3%) | mL/kg/hour vs. mEq/kg/hour, depending on institution protocols | Yes, as 500 mL bags | Yes, based on dosing units used | 1. Product information: sodium chloride 3% 5% intravenous injection, Baxter Healthcare Corporation (per DailyMed) Deerfield, IL, 20014. |
| Tacrolimus   | 0.02 mg/mL              | mg/kg/day                     | No                     | Possibly depending on pharmacy label or oursourcing facility label                              | 1. Astellas Pharma US, Inc. Prograf® (tacrolimus) capsules and injection prescribing information. Northbrook, IL; 2015 May. |</p>
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<td>Terbutaline</td>
<td>1 mg/mL</td>
<td>mcg/kg/min*</td>
<td>Yes, undiluted from the 1 mg/mL vial</td>
<td>Possibly depending on pharmacy label or oursourcing facility label</td>
<td>1. Glascock JC, DiPiro JT, Cadwallader DE et al. Stability of terbutaline sulfate repackaged in disposable plastic syringes. <em>Am J Hosp Pharm</em>. 1987;44:2291–3.</td>
</tr>
<tr>
<td>Tranexamic Acid</td>
<td>100 mg/mL (straight drug)</td>
<td>mg/kg/hour</td>
<td>Yes, undiluted from the 100 mg/mL vial</td>
<td>No</td>
<td>1. Pfizer Injectables. Cyklokapron* (tranexamic acid) injection prescribing information. New York, NY; 2013 May.</td>
</tr>
<tr>
<td>Vecuronium</td>
<td>1 mg/mL²</td>
<td>mcg/kg/min*</td>
<td>No, but when the vial is diluted then no further dilution is needed</td>
<td>Yes</td>
<td>1. Product InformationL Vecuronium bromide intravenous injection lyophilized powder for solution. Fresenius Kabi USA, LLC (per DailyMed) Lake Zurich, IL. 2016</td>
</tr>
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*BOLD - dosing units differ from concentration units

*Updated: March 2024*

**NOTES**

1 The expert panel and ISMP recommend different concentrations of epinephrine vs. norepinephrine given different indications despite same dosing units.
2 Babies under 500 gms may require a lower concentration.
3 The hydromorphone standard concentrations are intended for continuous infusion devices and NOT via PCA.
4 The recommended concentrations are intended for cardiac indications only.
5 The panel recognizes these two concentrations are 10x differences, however these are the only two concentrations studied for stability.