# ESETT USE NEXT BOX

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### Use Next Box – Study Drug Strata

Use Next Box color will correlate to study drug strata

<18 years	children = purple	
	young adults = yellow	
>65 years	older adults = gray	



### Contents

- Protocol Assist Device iPod
- Study Drug Vial
- Broselow-like tape
- Dosing Chart
- Inclusion/Exclusion Criteria
- Instruction Card
- iPod charger





# Study Drug Vial





# Study Drug Vial 4504 ESETT Study Drug

fosphenytoin 16.66 mg PE/ML, valproate 33.33

mg/ml, or levetiracetam 50mg/ml.

PE= phenytoin equivalent.

I.V. Solution in 0.9% sodium chloride injection.

Caution: New Drug - Limited by Federal Law to Investigational Use Manufactured by University of California, Davis

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This vial contains 100 mL.

IND Number: 119756

### Length Based Weight Estimation

Colors match Broselow

### Use only for Children



### Length Based Weight Estimation





# Pocket Card





#### -Inclusion Criteria-

- Seizing for >5 minutes
- Continued/recurring now despite adequate benzo
- Last dose of benzos given >5 minutes ago
- Last dose of benzos given <30 minutes ago
- Age  $\geq$  2 years (and  $\geq$  7.5kg)

#### -Exclusion Criteria-

- Known pregnancy, sever	e metabolic/liver/	renal disease
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- Known allergy or contraindication to:

phenytoin (Dilantin), fosphenytoin (Cerebyx), levetiracetam (Keppra), or valproic acid (Depakote)

- For this episode of status epilepticus already...

given intravenous 2nd line anticonvulsant or

non-benzo sedatives with anticonvulsant properties (propofol, etomidate, ketamine, etc) or

endotracheally intubated

 Status epilepticus thought to be caused by: hypoglycemia < 50 mg/dL hyperglycemia > 400 mg/dL acute traumatic brain injury cardiac arrest/post anoxia

- Prisoner

- Opt-out identification declining ESETT

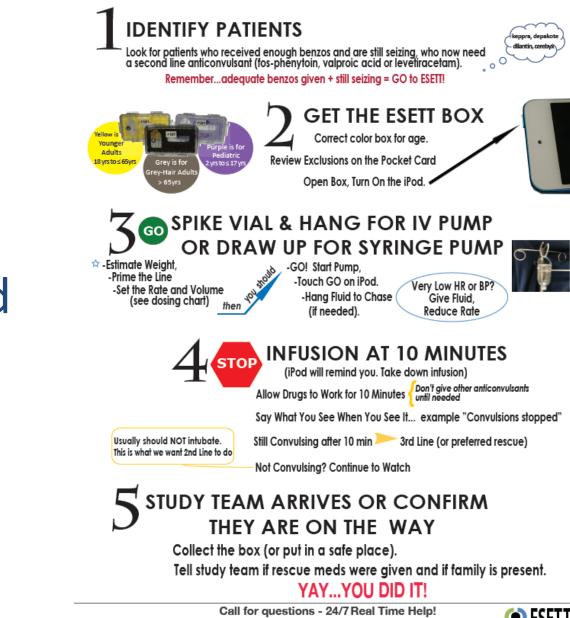


#### DOSE ADMINISTRATION CHART

Estimated Weight (Kg)	Infusion Volume (total mL)	Rate (mL/min over 10 min)	length based color (peds only)
0 - 7.4	Do Not Enroll		Grey
			Pink
7.5 - 9.9	9	0.9	Red
10 - 12.4	12	1.2	Purple
12.5 - 14.9	15	1.5	Yellow
15 - 19.9	18	1.8	White
20 - 24.9	24	2.4	Blue
25 - 29.9	30	3.0	Orange
30 - 34.9	36	3.6	Green
35 - 39.9	42	4.2	
40 - 49.9	48	4.8	
50 - 59.9	60	6.0	
60 - 69.9	72	7.2	
70 - 74.9	84	8.4	
≥75	90	9.0	

Established Status Epilepticus Treatment Trial

#### Patient still seizing? Go to ESETT



1-855-ESETT-PI (373-8874)

### Instruction Card

# iPod Charger and Tether







### Loading the Use Next Box

- WebDCU<sup>™</sup> will specify which study drug vial should be placed in each box
- Once loaded in designated Use Next Box, confirmation will be required in WebDCU<sup>™</sup>





### Storage

- Secured area
- Temperature controlled:
  2-8 degrees C
- Easily accessible by clinical team
- Ongoing reminders to clinical team
- Back-up study drug vial stored in pharmacy





Established Status Epilepticus Treatment Trial

## Subject Enrollment

- Treating team will use the matching Use Next Box based on the subject's estimated weight
- Length based weight estimation tool





# Restocking

- Enter randomization CRF in WebDCU<sup>™</sup> within 8 hours
- Restock with back up vial\*
- Charge iPod
- Reload length based weight estimation tool
- Reload iPod charger

\*Nothing is entered into WebDCU<sup>™</sup> for the back-up vial



### Study Drug Replacement

- Enter randomization information into WebDCU<sup>™</sup>
- Next treatment assignment will be shipped
- Restock Use Next Box with back-up study drug vial
- New vial arrives, exchange with back-up vial
- Return back-up vial to pharmacy







# **Supplies and Contacts**

Need more boxes? Supplies?
 <u>ESETT-Supplies@umich.edu</u>

• ESETT Site Managers

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