PROTOCOL ASSIST DEVICE

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Key Features

• Option to unblind when clinically necessary
• Infusion timing
• Prompts at 20 and 60 minutes
• Notification of study team member
• Audio recording and back-up source documentation
Infusion Timing

ESETT Drug Code 1234

Press immediately when study drug infusion starts

Start Protocol

Elapsed Time:

10:03

Please Stop Infusion
It has been 10 minutes from the infusion start.

OK
Assessments – 20 and 60 Minutes

20 Minutes
Please answer the following questions at 20 minutes from the infusion start. Were there clinically apparent seizures?

Yes | No | Unknown

Was responsiveness to verbal commands or noxious stimuli improved?

Yes | No | Unknown

Submit Answers

60 Minutes
Please answer the following questions at 60 minutes from the infusion start. Were there clinically apparent seizures?

Yes | No | Unknown

Was responsiveness to verbal commands or noxious stimuli improved?

Yes | No | Unknown

Submit Answers and Finalize
Routine Unblinding

ESETT Drug Code 1234

Please return device to use next box and give to ESETT study team

Complete Protocol

Please only unblind when there is an immediate clinical need. Do not share with study team.

Unblind

ESETT Drug Code 1234

Please return device to use next box and give to ESETT study team

Unblind

Unblind

Please confirm that there is an immediate clinical need to unblind

No
Yes

Please only unblind when there is an immediate clinical need. Do not share with study team.
DEVICE SET UP
Protocol Assist Device Set-Up

- Confirm device is fully charged
- Select Set Up
- Scan barcode on vial and in WebDCU™
# Protocol Assist Device Set-Up

<table>
<thead>
<tr>
<th>Pediatric</th>
<th>Younger Adults</th>
<th>Older Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>2yr to &lt;17</td>
<td>18yr to &lt;65yr</td>
<td>65yr or older</td>
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</tbody>
</table>

- **Confirm color coding** (WebDCU, vial, device)
- **Add study team member contact info**
- **Power down device** and place with instructions in use next box
Other Device-Related Considerations

• Data transfer and reset
• What happens when it doesn’t work?
• Routine checks and updates
• How will sites receive?