Sleep SMART
Sleep SMART KOEO Process Flow

Helgi G. Helgason, MS, RPSGT, RST
Project Manager, FusionHealth
hgh@fusionhealth.com
Overview

Process Flow
Tasks
T3
Run-In Night
Randomization
Care Management
Sleep SMART broad overview

1. **Day 1**: Subject recruitment
2. **Night 1**: T3 test (deployed on site as HSAT plus ECG)
3. **Day 2**: Upload on site via KOEO; auto-score with data oversight
   a. AHI ≥ 10/hr & CAI < 50% of the AHI (meets criteria)
   b. Fitted for aCPAP mask
4. **Night 2**: aCPAP Run-In Night
   a. Intolerant (excluded)
   b. Tolerant (included) > 4hrs & CAI < 10/hr, and subject agrees to continue
5. **Treatment assignment**:
   a. Intervention group - aCPAP with Sleep SMART Care Management
   b. Control group - standard of care for OSA
6. **Care Management**:
   a. 6 months in study
Login and Process Launch

Chrome Browser
Enter: app.koeo.com
Login with User E-mail and password
Create Subject

Sleep SMART
Subject ID
DOB: 1/1/1900
Identification
Mini USB cable connected from computer to T3 device

This task must be handled in the KOEO Interactive Tool (KIT).

Please follow these steps if you have NOT installed the KIT yet:
- Download the KIT from the download page.
- Install the KIT by running the installer.
- Start the KIT to make sure it starts correctly.
- Finally, connect the Nox T3 device to the computer USB port, then click on T3 Setup.

Please follow these steps if you have installed the KIT already:
- Run the KIT to make sure it starts correctly.
- Connect the Nox T3 device to the computer USB port, then click on T3 Setup.
KOEO Interactive Tool (KIT)

Open KOEO Interactive Tool?
- Always open these types of links in the associated app

[ ] Cancel  [ ] Open KOEO Interactive Tool

KOEO USA
Username *
User2@gmail.com

Password *
[ ]

Login

<table>
<thead>
<tr>
<th>T3 Device</th>
<th>Available Setup Tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>T3 Setup</td>
<td>T3 Setup (Available since Tuesday, February 19, 2019 11:19 AM)</td>
</tr>
<tr>
<td>T3 Upload</td>
<td>MR043526</td>
</tr>
</tbody>
</table>

FusionHealth
T3 Setup - Timezone and Prepare

After this task is complete the device is configured.

You insert a new AA battery into the T3 device.

Verify battery status of AAA batteries in oximeter.

Apply the device and sensors to the subject.

Start the T3 test.
Upload T3 Data Task

This task will also link to the KOEO Interactive Tool (KIT) as before. T3 device connected to mini USB cable and computer.
Login to KIT
Select Upload T3 Data
Data will be analyzed at FusionHealth

Monday - Friday
5am, 11am, 5pm, 10pm EST
Saturday and Sunday
10am and 4-6pm EST
Possible Outcomes from T3 Test

<table>
<thead>
<tr>
<th>Task Name</th>
<th>Patient ID</th>
<th>Patient Name</th>
<th>Status</th>
<th>Best Time To Call</th>
<th>Created On</th>
<th>Tenant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redo Upload T3 Data</td>
<td>MR043526</td>
<td>202, Sleep SMART</td>
<td></td>
<td></td>
<td>2019-02-19</td>
<td>SleepSMART</td>
</tr>
<tr>
<td>T3 Setup</td>
<td>MR043526</td>
<td>202, Sleep SMART</td>
<td></td>
<td></td>
<td>2019-02-19</td>
<td>SleepSMART</td>
</tr>
<tr>
<td>Excluded - No Valid Data</td>
<td>MR043526</td>
<td>202, Sleep SMART</td>
<td></td>
<td></td>
<td>2019-02-19</td>
<td>SleepSMART</td>
</tr>
<tr>
<td>Mask Questions</td>
<td>MR043526</td>
<td>202, Sleep SMART</td>
<td></td>
<td></td>
<td>2019-02-19</td>
<td>SleepSMART</td>
</tr>
</tbody>
</table>
Mask Questions - 1st task of Run-In Night
APAP Night 1 Task

### Task Details

<table>
<thead>
<tr>
<th>Task Name</th>
<th>Patient MR</th>
<th>Patient Name</th>
<th>Substatus</th>
<th>Best Time To Call</th>
<th>Created On</th>
<th>Tenant</th>
</tr>
</thead>
<tbody>
<tr>
<td>APAP Night 1</td>
<td>MR043526</td>
<td>202, Sleep SMART</td>
<td></td>
<td></td>
<td>2019-02-19</td>
<td>SleepSMART</td>
</tr>
</tbody>
</table>

### Task: APAP Night 1

**75% Complete**

#### Retry Run-In Night?

Can only be performed if the Run-In Night is unsuccessful due to EXTERNAL CIRCUMSTANCES - defined as the PAP study had to be stopped if, for example, a nurse comes in and stops the study because the patient needs to be moved. The subject cannot fail PAP on Night one and then ask to give it another try.

- **Yes**
- **No**

#### Indicate subject’s run-in night outcome

Subjects “pass” the run-in night if: (1) usage hours are ≥ 4.0, AND (2) the aCPAP derived CAI is ≤ 10. Subjects who pass the run-in night and agree to continue with Sleep SMART are eligible for randomization.

- **Eligible for randomization**
- **Not eligible for randomization**

**Submit**

---

*FusionHealth*
Repeating Run-In Night

Can only be performed if the Run-In Night is unsuccessful due to EXTERNAL CIRCUMSTANCES - defined as the PAP study had to be stopped if, for example, a nurse comes in and stops the study because the patient needs to be moved. The subject cannot fail PAP on Night one and then ask to give it another try.
Successful Run-In Night

75% Complete

Retry Run-In Night?
Can only be performed if the Run-In Night is unsuccessful due to EXTERNAL CIRCUMSTANCES - defined as the PAP study had to be stopped if, for example, a nurse comes in and stops the study because the patient needs to be moved. The subject cannot fail PAP on Night one and then ask to give it another try.

Yes

No

Indicate subject’s run-in night outcome
Subjects “pass” the run-in night if: (1) usage hours are ≥ 4.0, AND (2) the aCPAP derived CAI is <10. Subjects who pass the run-in night and agree to continue with Sleep SMART are eligible for randomization.

Eligible for randomization

Not eligible for randomization

Definition of Success:
Usage ≥ 4 hours
CAI remain < 10 on aCPAP machine-generated data
No Interruptions or Run-In Night or Limitations due to Clinical Care

Submit ✓
Treatment Assignment Task

Indicate subject's treatment assignment

| Intervention group (CPAP) | Control group (No CPAP) |

This is based upon randomization from WebDCU.

If No CPAP - select Control Group (No CPAP) and click Submit. No more tasks and the process is complete.

If CPAP - select Intervention group (CPAP) and click Submit. Next Task will be Enter Patient Info.
Enter Patient Info Task

Very important for successful Care Management.

Data entry must be valid information and accurately entered.
Dispensing Questions Task

The last task in the Process.
Successful hand-off to the Sleep SMART Care Team.
Data Entry must be exact.
Two (2) best masks to be dispensed - may be the same mask.
No more tasks in KOEO for the sites.
Support

KOEO Support Phone Number
888-505-0280 extension 4006

KOEO Support E-mail
support@koeo.com

Helgi Gunnar Helgason, MS, RPSGT, RST
hgh@fusionhealth.com
Questions?