









Overview

Process Flow

Tasks

T3

Run-In Night

Randomization

Care Management



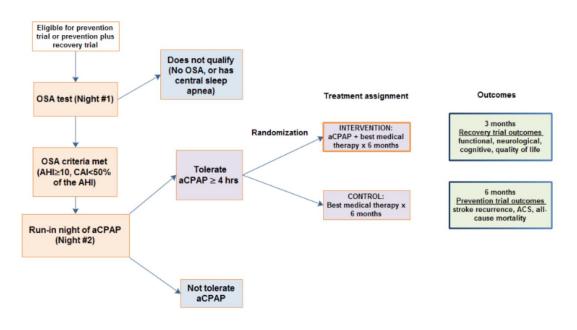
Sleep SMART broad overview

- 1. <u>Day 1</u>: Subject recruitment
- 2. Night 1: T3 test (deployed on site as HSAT plus ECG)
- 3. <u>Day 2</u>: Upload on site via KOEO; auto-score with data oversight
 - a. AHI \geq 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. <u>Treatment assignment</u>:
 - a. Intervention group aCPAP with Sleep SMART Care Management
 - b. Control group standard of care for OSA
- 6. <u>Care Management</u>:
 - a. 6 months in study



Sleep SMART Flow

Sleep SMART flow



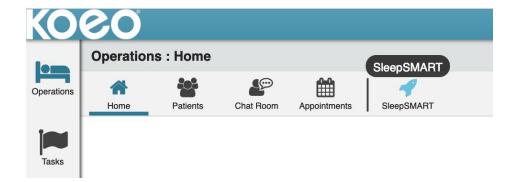


Login and Process Launch



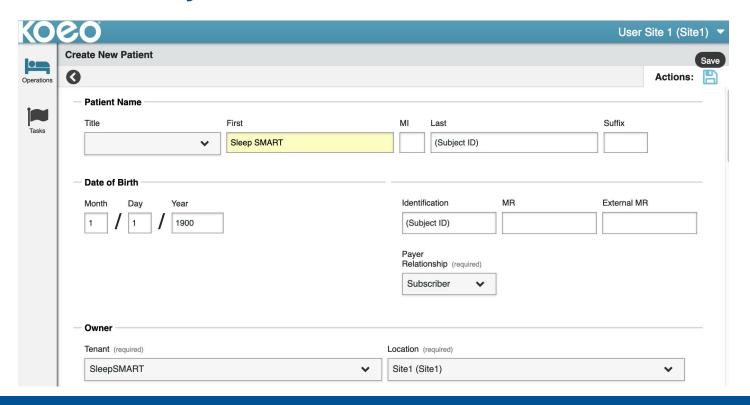
Chrome Browser Enter: app.koeo.com

Login with User E-mail and password





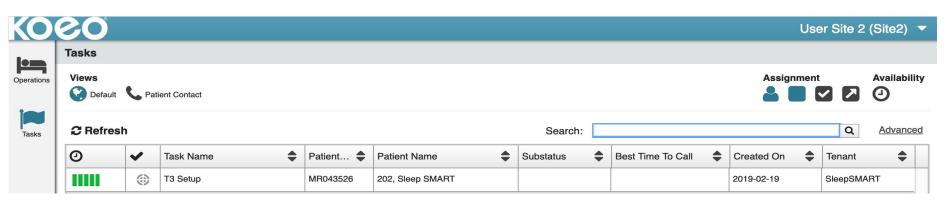
Create Subject



Sleep SMART Subject ID DOB: 1/1/1900 Identification



T3 Setup Task

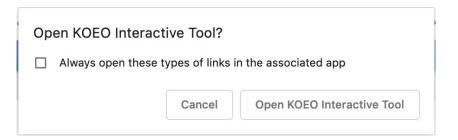


Mini USB cable connected from computer to T3 device

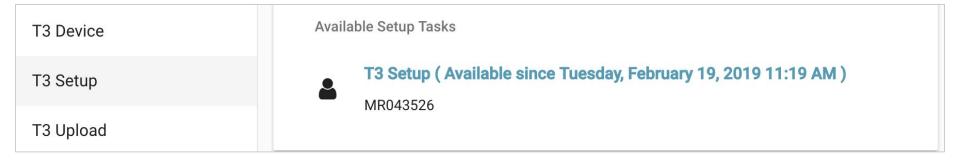




KOEO Interactive Tool (KIT)

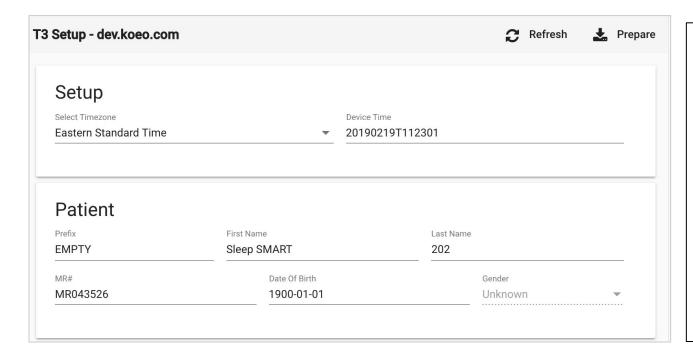








T3 Setup - Timezone and Prepare



After this task is complete the device is configured.

You insert a new AA battery into the T3 device.

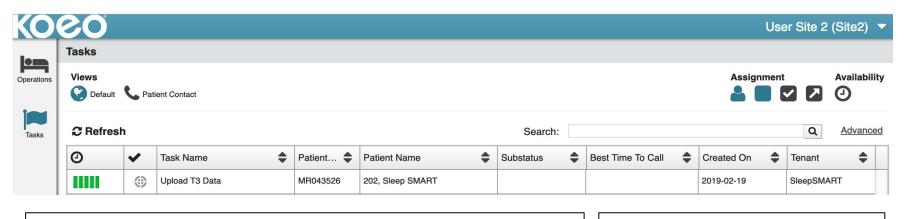
Verify battery status of AAA batteries in oximeter.

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

7 days per week 10am and 2pm ET

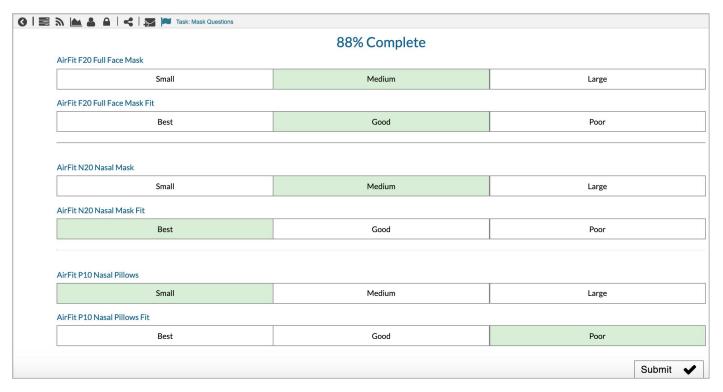


Possible Outcomes from T3 Test

0	~	Task Name	Patie 💠	Patient Name	Substatus 💠	Best Time To Call \$	Created On 🜲	Tenant 💠
	0	Redo Upload T3 Data	MR043526	202, Sleep SMART			2019-02-19	SleepSMART
0	~	Task Name	Patient 💠	Patient Name	Substatus 💠	Best Time To Call 🔷	Created On 🔷	Tenant \$
	(1)	T3 Setup	MR043526	202, Sleep SMART			2019-02-19	SleepSMART
0	~	Task Name	Patient \$	Patient Name	Substatus	Best Time To Call \$	Created On 🔷	Tenant 💠
0	•	Task Name Excluded - No Valid Data	Patient •	Patient Name 202, Sleep SMART	Substatus 💠	Best Time To Call 💠	Created On	Tenant \$
					Substatus	Best Time To Call		
1.14 - 4.14			MR043526		Substatus \$	Best Time To Call Best Time To Call		



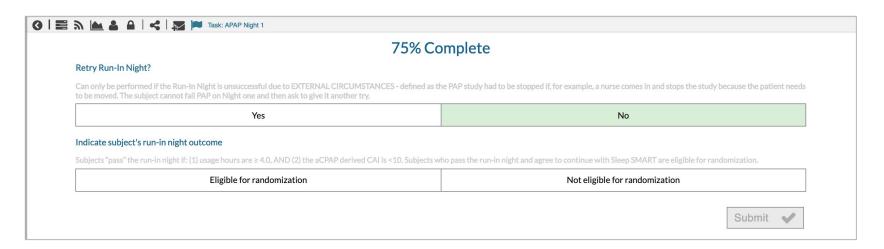
Mask Questions - 1st task of Run-In Night





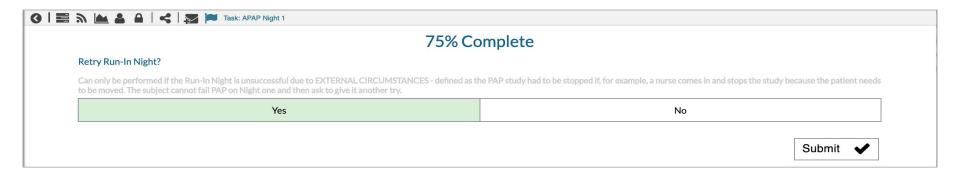
APAP Night 1 Task

0	~	Task Name \$	Patient MR 💠	Patient Name \$	Substatus	Best Time To Call \$	Created On \$	Tenant \$
IIIII	•	APAP Night 1	MR043526	202, Sleep SMART			2019-02-19	SleepSMART





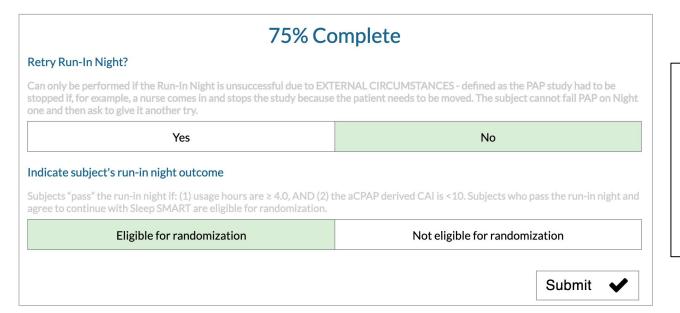
Repeating Run-In Night



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



Definition of Success: Usage ≥4 hours

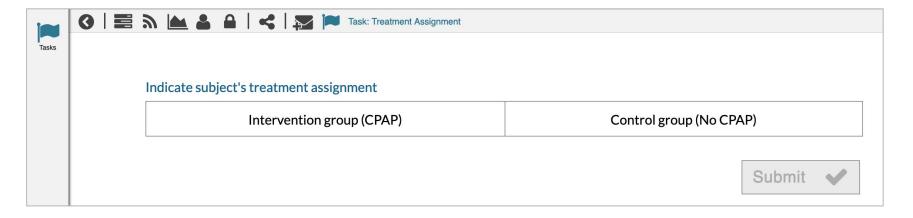
CAI remain < 10 on aCPAP machine-generated data

No Interruptions or Run-In Night or Limitations due to Clinical Care





Treatment Assignment Task



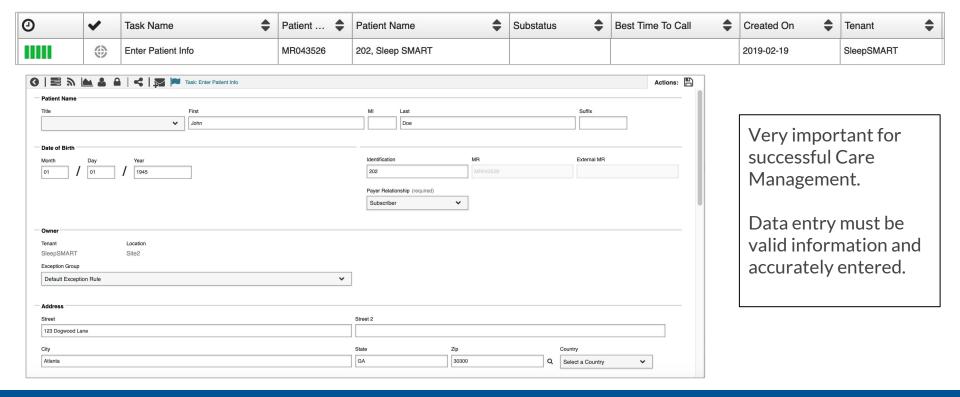
This is based upon randomization from WebDCU.

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.

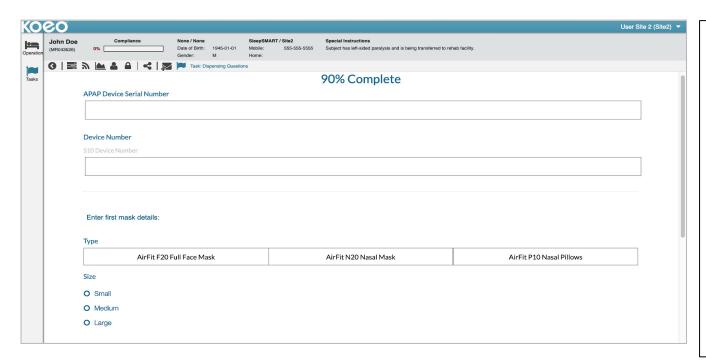


Enter Patient Info Task





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

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KOEO Support E-mail

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Questions?

