



CYCLE RCT Cycling Refresher Meeting

Thursday, Jan 13, 2022 @ 12:00 -1:00 pm

Hosted by: Julie Reid, Geoff Strong & Alex Molloy






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Agenda

Pre-Meeting tasks:

- Watch tablet training video
- Hands-on training with bike


Print paper copies and bring to meeting

- Case report forms (S, 5R, 5C, 5S)
- Quiz answer sheets (completed prior to meeting)


Time	Activity
60 mins	Cycling Refresher Meeting
5 mins	Welcome and introductions
15 mins	Overview of CYCLE RCT <ul style="list-style-type: none"> • Protocol, study schema, timepoints • Lessons learned from interim analysis
25 mins	Scenarios, case report forms, and troubleshooting
10 mins	Quiz review
5 mins	Questions and next steps

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Overview of CYCLE RCT






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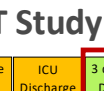
CYCLE: Critical Care Cycling to Improve Lower Extremity Strength

Research Question:
In medical-surgical ICU patients, does 30 minutes of in-bed cycling and routine PT started within the first 4 days of mechanical ventilation, compared to routine PT improve patient function at 3 days post-ICU?

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CYCLE



- **Design:** 360 patient, multicenter, international open-label randomized trial
- **Population:** Medical-surgical adults within the first 4 days of mechanical ventilation
- **Intervention:** 30 minutes/ day of in-bed cycling + routine physiotherapy
 - Until ICU discharge, 28 days, or able to march on the spot for 2 consecutive days, whichever comes first
- **Comparison:** Routine physiotherapy
- **Primary Outcome:** Physical Function ICU Test @ 3 days post-ICU discharge by blinded outcomes assessors

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Inclusion Criteria

- Adults ≥ 18 years old
- Mechanically ventilated ≤ 4 days
- Expected additional 2-day ICU stay
- ICU LOS ≤ 7 days
- Ambulated independently (with or without gait aid) pre-hospital admission

Exclusion Criteria

- Acute condition impairing ability to cycle (e.g., leg fracture)
- Body habitus unable to fit bike
- Proven/suspected neuromuscular weakness of the legs (e.g., stroke, Guillain Barre)
- Inability to follow commands in local language pre-ICU
- Severe cognitive impairment pre-ICU
- Temporary pacemaker
- Pregnancy
- Expected hospital mortality $>90\%$
- Palliative goals of care
- Persistent exemptions (see next pg)
- Able to march on spot at time of screening

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RCT Daily cycling exemptions

Cardiovascular

1. Any increase in vasopressor/ inotrope within last 2 hours
2. Active MI, or unstable/ uncontrolled arrhythmia per ICU team
3. MAP <60 or >110 mmHg within the last 2 hours or per ICU team limits
4. HR <40 or >140 bpm within the last 2 hours

Respiratory

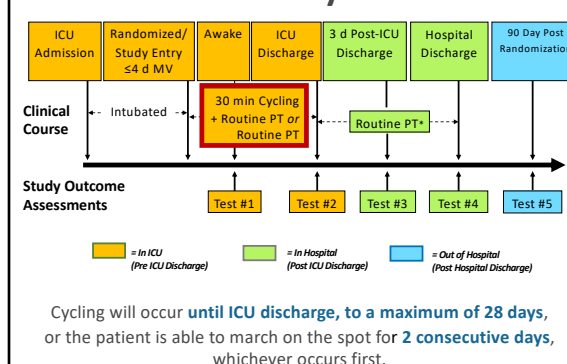
1. Persistent SpO₂ <88% within the last 2 hours or out of range per ICU team
2. Neuromuscular blocker within last 4 hours

Other

1. Severe agitation (RASS >2 [or equivalent]) within last 2 hours
2. Uncontrolled pain
3. Change in goals to palliative care
4. Team perception that in-bed cycling is not appropriate despite absence of above criteria

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CYCLE RCT Study Schema



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Overview of Cycling Protocol

- **30 minutes/day** of in-bed cycling plus routine PT, **5 days/week**, during their ICU stay
- Cycling occurs **until ICU discharge, to a maximum of 28 days**, or the patient is **able to march on the spot for 2 consecutive days**, whichever occurs first.
- **Start with passive cycling at 5 RPM with 0.6 Nm of resistance**
- Complete **as much active cycling as possible** during each session at a **self-selected RPM**
 - Speed can be adjusted to +/- 5rpm of patient's self-selected pace
 - Please **do not** adjust the resistance

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Recognizing Active Cycling



- Power is greater than zero
- Cogwheel is grey (blue if motor is on)
- Numbers appear for percentage of right and left leg contribution

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Key Responsibilities- ICU PT

- Assist RC when screening patients for study eligibility
- Screen patients for exemptions and deliver cycling and/or routine PT as appropriate
- Determine patient eligibility and complete ICU awakening and discharge strength and function assessments as appropriate
- Complete therapy session and assessment paperwork
- Maintain and clean equipment and report any issues to Research Coordinator
- Communicate with the Research Coordinator on:
 - ***All safety events**
 - *** Bike issues** (lasting > 5mins)
 - **Delivery of intervention**
 - **Assessment progress and completion**
 - **Patient status and location**
 - **Deviations in protocol**
 - **Staffing issues**

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Screening Considerations

Considerations when screening ICU patients for study eligibility

- RC and ICU PT discuss patient eligibility + workload/capacity, prior to approaching the SDM/patient for consent

Cycling protocol targets

- When screening patients consider whether the patient will be in the ICU long enough to receive at least 2 cycling sessions
- 1st cycling session delivered within first 4 days of mechanical ventilation

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Marching on the spot



- Ensure patient receives at least 2 cycling sessions before selecting this reason
- **Reason is reversible and not permanent**
- If a patient was marching on the spot and their medical condition deteriorates, assess to restart cycling if within 28 days of randomization

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Safety Events



- **Serious Adverse Events (SAEs): Cardiac arrest or unplanned extubation**
 - ICU PT to notify RC immediately
 - RC to follow-up with site PI
 - RC to communicate with Methods Centre (MC)
 - MC must communicate all SAEs to Data Monitoring Committee (DMC) within 24 hours
- **Adverse Events (AEs)**
 - Please communicate AE with RC so data entry can be prioritized
 - MC must communicate AEs to DMC every 6 months
 - Next AE submission to DMC in September 2021

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Bike Issues



Bike issues lasting > 5 minutes?

- Contact Methods Centre/Restorative Therapies immediately (call or FaceTime)
 - Please try to provide us with photos and/or video of the issue

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Scenarios



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Scenario 1



For the next scenarios, please record your responses on the following case report forms:

- PT Therapy: Worksheet (Form 5)
- PT Therapy: Routine PT/Rehab (Form 5R)
- PT Therapy: Cycling (Form 5C)
- Safety Events (Form 5S)

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Scenario 1



- Screening for temporary exemptions on PT Worksheet (5)
 - Routine PT
 - Cycling
- Complete Cycling form (5C)
- Complete Routine PT form (5R)
- Complete Safety Events (5S) (if applicable)
- Complete PT Worksheet (5), including Cognitive Screening

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Example 1:

Does this patient have any routine PT temporary exemptions?

Vitals:	8:00	9:00	10:00
HR	122	125	119
BP (MAP)	115/46 (66)	118/55 (71)	114/49 (61)
SPO2	95%	93%	94%
RR	22	25	23
Ventilation:	8:00	9:00	10:00
Mode	PCV	PSV	PSV
Pressure	12	12	10
PEEP	10	10	10
FIO2	0.35	0.35	0.35
Medication:	8:00	9:00	10:00
Norepinephrine	10mL/hr	5mL/hr	0mL/hr
Neuro	8:00	9:00	10:00
RASS	-3	-2	-1

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PT Worksheet (Form 5)

1. Was routine PT/ rehab done today?

- ☒ Yes (submit Form 5R)
☐ No (check one of a, b, c, or d and specify where necessary)
- a) ☐ Patient discharged from ICU before 1200pm
b) ☐ Temporary exemption criteria met (check ALL; if #10 specify)
- ☐ 1. Increase in inotropes/vasopressors (2h)
 - ☐ 2. Active MI, or unstable/uncontrolled arrhythmia per ICU team
 - ☐ 3. MAP <60 or >110 (2h) or out of range for this patient per ICU team
 - ☐ 4. HR <40 or >140 (2h)
 - ☐ 5. SpO₂ <88% (2h) or out of range for this patient per ICU team
 - ☐ 6. Neuromuscular blocker (4h)
 - ☐ 7. Severe agitation RASS >2 or SAS >6 or equivalent (2h)
 - ☐ 8. Uncontrolled pain
 - ☐ 9. Changes in goals to palliative care
 - ☐ 10. Other concern [e.g., active haemorrhage, acute peritonitis, new pelvic, groin, or extremity wound precluding routine PT/ rehab, new known or suspected muscle inflammation (specify below)]

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Example 2:

Does this patient have any cycling temporary exemptions?

Vitals:	12:00	13:00	14:00
HR	127	125	120
BP (MAP)	93/62 (72)	91/63 (70)	90/55 (62)
SPO2	93%	94%	96%
RR	22	25	23
Ventilation:	12:00	13:00	14:00
Mode	PSV	PSV	PSV
Pressure	12	14	14
PEEP	10	10	10
FIO2	0.40	0.45	0.45
Medication:	12:00	13:00	14:00
Norepinephrine	5mL/hr	10mL/hr	15mL/hr
Neuro	12:00	13:00	14:00
RASS	-2	-3	-4

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PT Worksheet (Form 5)

2. Was cycling done today? | week M Tu W Th F Sa Su |

- ☐ N/A, patient not randomized to cycling
☒ Yes (submit Form 5C)
☒ No (check one of a, b, c, d, or e and specify where necessary)
- a) ☐ Patient discharged from ICU before 1200pm
b) ☐ Patient marched on the spot for 2 consecutive days
c) ☒ Temporary exemption criteria met (check ALL; if #10 specify)
- ☒ 1. Increase in inotropes/vasopressors (2h)
 - ☐ 2. Active MI, or unstable/uncontrolled arrhythmia per ICU team
 - ☐ 3. MAP <60 or >110 (2h) or out of range for this patient per ICU team
 - ☐ 4. HR <40 or >140 (2h)
 - ☐ 5. SpO₂ <88% (2h) or out of range for this patient per ICU team
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Documenting a cycling session on Cycling Therapy (Form 5C)

- You enter the room and begin bike setup @ 14:51. Cycling session starts @ ~15:00
- Prior to reaching 30 minutes, patient requests to end the session due to fatigue
- Biking is complete (session stopped) @ 15:21.
- You exit the room with the bike 15:30

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The image shows two screenshots of the Cycling Therapy software. The top screenshot, labeled 'Tablet @ 5 minutes', displays a virtual cycling environment with a target speed of 10 and a power output of 1.3. The bottom screenshot, labeled 'Tablet @ 10 + 20 minutes', shows the same environment with a target speed of 5 and a power output of 0.0. To the right of the screenshots is a 'Tablet @ Session End' summary window showing the following data:

Distance Travelled:	1.92 km
Energy Expended:	0.2 kCal
Energy per Hour:	0.7 kCal/hour
Average Power:	0.8 W
Average Asymmetry:	0%
Total therapy time:	0:20:49
Time active (off motor):	0:09:48
Time passive (on motor):	0:11:01

- You enter the room and begin bike setup @ 14:51. Cycling session start @ ~15:00
- Prior to reaching 30 minutes, patient requests to end the session due to fatigue.
- Biking is complete (session stopped) @ 15:21.
- You exit the room with the bike 15:30.

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Cycling (Form 5C)

1. Cycling session start time (equipment prepped and enter room)
 14:51 (24-hr:min)

5. CYCLING THERAPY
 (AMN, leave check at end of session)

Session Duration	Mode (Active, Passive)	Power (Watts)	Any active cycling (Distance traveled, Time taken)	Time taken (min:sec)	Time taken (hr:min:sec)
5 min	Active	20	1	3	1:03
10 min	Active	4	0	0	0:00
20 min	Active	4	0	0	0:00

6. Did cycling finish before 30 minutes? ☐ No ☒ Yes (check ALL that apply)
 Patient's request ☒ Tired ☐ Other (specify) _____
 Therapist stopped session ☐ Agitation ☐ Cardiovascular (specify) _____ ☐ Respiratory (specify) _____ ☐ Other (specify) _____
 Physician stopped session ☐ (specify) _____
 Other ☐ (specify) _____

7. Any safety events during cycling therapy?
 *Any session in any of these events occur: suspected new unstable uncontrolled arrhythmia, concern for MI, cardiac arrest, unplanned extubation
☒ No ☐ Yes (complete Safety Events Form 5D)

8. Cycling session end time (take down complete and end of cycling therapy portion of therapy session)
 14:51:30 (24-hr:min:sec)

Comments: _____

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Cycling (Form 5C)

RT 300 ID: _____ RT 300 PIN: _____ PT THERAPY: CYCLING (Form 5C)

Day of week: ☐ M ☐ Tu ☐ W ☐ Th ☐ F ☐ Sa ☐ Su

1. Cycling session start time (equipment prepped and enter room)
 14:51 (24-hr:min)

2. Pre-cycling therapy assessments

RASS	SAS / VAMASS	RASS Conversion Chart	CAM-ICU
1. RASS: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9	SAS: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9	RASS Conversion Chart: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9	2. CAM-ICU: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9

3. Vitals: Highest O₂ % received (24-hr:min:sec) _____

4. ALL advanced life support strategies received DURING CYCLING today (check ALL that apply)

1. Airway Access: ☐ No ☐ Yes → ☐ ETT ☐ Tracheostomy
2. Mechanical Ventilation (MV): ☐ No ☐ Yes → ☐ None/Spontaneous (e.g. mask, vent/mask, nasal prongs) ☐ Invasive MV (e.g. pressure assist control, volume assist control, pressure support) ☐ Non-invasive MV (e.g. BiPAP, CPAP by mask not ETT or trach, e.g. nocturnal)
3. Other Ventilation Strategy: ☐ No ☐ Yes → ☐ ECMO/ECLS ☐ Nitric oxide ☐ High-flow nasal cannula (e.g. AIRVO, Optiflow)
4. Vasopressor / Inotropic: ☐ No ☐ Yes → ☐ Vasopressin, norepinephrine, phenylephrine, epinephrine, milrinone, vasopressin
5. Dialysis: ☐ No ☐ Yes → ☐ Intermittent (ICD) ☐ Continuous (CRRT) ☐ Peritoneal ☐ Sustained low efficiency (SLED) ☐ Other (specify) _____
6. Femoral Catheter in Situ: ☐ No ☐ Yes → ☐ Venous ☐ Arterial ☐ Other (specify) _____

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Completing the Routine PT/rehab (Form 5R)

Objective:

- Pt received supine in bed, awake, but drowsy. Orally Intubated, PSV 10/10, FiO₂ 0.35

Vitals Pre-session:
 HR 118, BP: 115/60, SpO₂: 92%, RR: 23

- RASS: -2, CAM ICU positive
- Auscultation on arrival:
- Coarse crackles right upper lobe, decreased air entry right lower lobe, left side clear
- The patient is not on dialysis, and does not have a femoral catheter.
- Pt is not on any vasopressors/inotropes
- Session duration = 20 minutes

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Summary of routine PT/rehabilitation

Treatment:

- Active assisted range of motion exercises in bed:
- Pt instructed on shoulder flexion, elbow flexion, wrist flexion/extension, finger flexion/extension, hip and knee flexion, hip adduction/abduction, ankle dorsiflexion/plantarflexion. Moderate verbal cues required
- 10 repetitions of each bilaterally.

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Summary of routine PT/rehabilitation

Chest Physiotherapy:

- Pt assisted into left side lying (2-person moderate assist) for percussions to right LL x 45 seconds
- SpO₂ suddenly dropped to 83%, with RR increase to 40. Pt placed on 100% O₂, returned to semi fowlers and suctioned. Pt was encouraged to cough 5 times
- Suctioned 3 passes (inline suction) for mucous plug and moderate secretions
- Pt continued to require higher FiO₂ during recovery (FiO₂ 0.5 for 15 minutes), then able to wean down to 0.4 to maintain SpO₂ 93%

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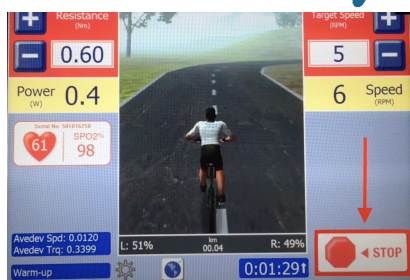
Summary of routine PT/rehabilitation

Vitals Post-Session:
 HR: 127, BP: 125/66, SpO₂: 93% (FiO₂ 0.4), RR: 27

- Auscultation: Clear air entry to right UL and ML. Persistent diminished breath sounds RLL. Left Clear

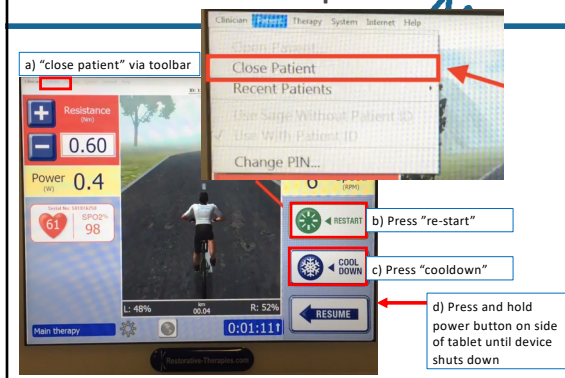
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Scenario 2 – pause session



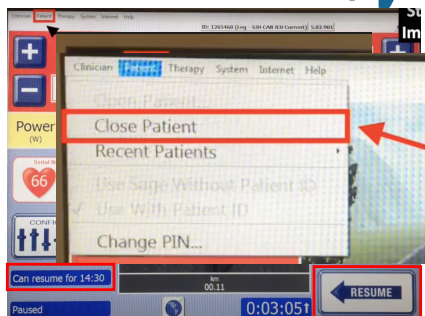
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Scenario 2 – end session options



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Scenario 2 – end session + save data



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Scenarios

During the cycling therapy session...

- The patient is complaining of discomfort in his knee. You pause the session and attempt to reposition the patient however he continues to complain, and tells you that the pain is too much, and he cannot do any more cycling today. How do you complete the session without losing the patient's cycling data?
- The patient accidentally self-extubates. How do you stop the session?

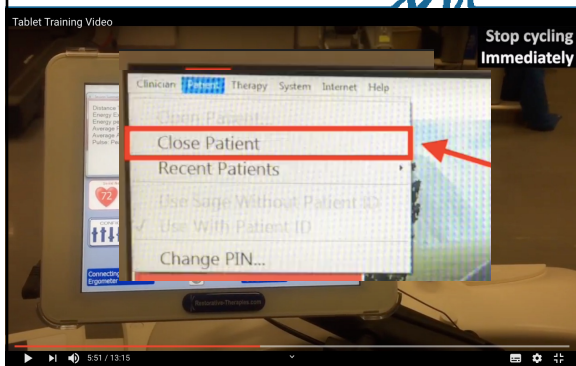
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Scenario 3



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Scenario 3 – close session + save data



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Scenario 4

You are ready to start a cycling session.

You press “go” and the following message appears:

“Ergometer Communications Error”



What does this error message mean?

What could cause this issue and what checks can you do to fix this issue and start the session?

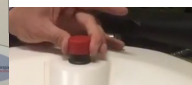
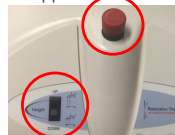
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Scenario 4

Check the the following power-related sections:

- AC power cord inserted into wall outlet
- AC power cord inserted into bike AC inlet
- Bike “system power” switch in “on” position (beside AC inlet)
- Emergency stop button is off (“raised” position). Rotate clockwise until button elevates (hear a popping noise)

Toggle “height” switch up/down. If bike elevates/lowers, bike is receiving power and “ergometer communications error” will disappear



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Questions?

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Next Steps – Practice!

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Cycling Competency Checklist

COMPETENCY
Cycling
<ul style="list-style-type: none"> • Understands components of bike including items found in cubby hole (pulse oximeter, batteries, etc.) • Demonstrates appropriate patient setup including: <ul style="list-style-type: none"> - Calf straps and pedal straps secured properly - Proper leg and body alignment (<90° at knee and hip, no knee hyperextension, lower leg parallel with floor when pedal in 12 o'clock position, heels remain on pedals, bike aligned over middle of patient's body) - All 4 brakes locked - Q/straps secured safely • Applies pulse oximeter to patient and ensures connection to tablet • Able to switch out calf supports and lower leg bars for different sizes (if appropriate) • Provides appropriate explanation and instructions to patient/family for cycling session and cues patient appropriately throughout session • Understands where to find and when to use study vs. clinical cycling patient IDs
Tablet
<ul style="list-style-type: none"> • Logs in as a clinician • Opens a patient on SAGE • Revises a patient PIN • Demonstrates knowledge of how and when to change control speed (± 5 RPM of active speed) • Able to identify active vs. passive cycling by observing tablet screen (cogwheel colour, contribution percentages, power) • Demonstrates knowledge of how and when to stop a cycling session and save data to tablet • Able to enable and disable internet connection within SAGE • Troubleshoots ergometer communications error • “Resumes” cycling session after pausing (does not “Restart”)

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