Agilik Clinician Tuning Guide

This quick reference guide is intended to support certified orthotists already trained in the use of the Agilik system and Test Drive during clinical assessments. It serves as a checklist for the basic tuning of the device. *This quick start guide does not replace the full instructions for use. Refer to IFU for complete safety, operation and maintenance information.*

The guide focuses on tuning the Test Drive using the Agilik Care software. For instructions on fitting the device to the patient's size, please refer to the Agilik Test Drive Instructions for Use (IFU).

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1. Test Drive: Optimal Fitting Checklist

Prior to appointment:

- ❑ Agilik Care app and firmware are up to date.
- ❑ If patient's measurements are known in advance, change cuffs, carbon tubes and footplates appropriately to reflect patient size.
- ❑ Battery is charged.

Foot Sensor:

- ❑ Ensure the ankle bone is adjacent to the ankle hinge, the foot is properly centered over the foot sensor, and straps are not overly tight.
- ❑ During trials, straps may loosen — check and maintain strap tension throughout the duration.
- ❑ If the foot sensor has been optimized, select 'Reset to defaults' then 'Write changes.'

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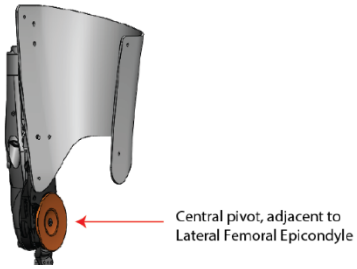
Assistive Devices:

- ❑ **AFO:** The free pivot ankle hinge may not suit all users – have them bring their own AFO or use an off-the-shelf option if needed.
- ❑ **Walking Aids:** Recommend starting in the parallel bars and transitioning to their typical mobility aids such as a walker, forearm crutch or cane.
- ❑ **Knee Center:** Confirm the carbon bars are adjusted so that the central pivot is correctly aligned.



Shell Fitting:

- ❑ Address poor shell fitting by inserting foam between the shell and the patient's limb (if needed).
- ❑ Ensure all straps are securely tightened.

Setup:

- ❑ Power up the device by pressing the button located on the holster. LED should turn green.
    - Battery level can be seen once strap is undone and top part of battery is exposed.
- ❑ Reference Angle:
    - On the test drive the Reference Angle will be set manually on each power up. Extend the patient's leg one at a time to their end range of movement without hyperextension and click the button located on the actuator for a quick button press. This will change the USER LED to solid orange.
- ❑ Have the patient first stand to assess fit and alignment and then walk with their walking aides (e.g., crutches/walker/cane) or in parallel bars with the power turned off.
    - ***Note:*** We should know at this point if the patient can walk unassisted or uses walking aides — we are assessing fit and alignment at this stage.

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2. Agilik Foot Sensor Tuning

For more in-depth instructions please refer to Agilik Care App User Manual starting at page 38.

- ❑ **Step 1:** Open the Foot Sensor Optimizer found under the "Gait" → "Swing/Stance" tab. Make sure to 'reset' the sensors to defaults and enable all zones before capturing data.
  - ***Note:*** We do not want to add any torque without the foot sensor being optimized first.
- ❑ **Step 2:** Click "Start Capture" once the user has started walking.
- ❑ **Step 3:** Have the user walk 6-10 steps.
- ❑ **Step 4:** Click "Stop Capture," or allow the Window Length time to elapse, and view non-optimized data plots. Ensure that there is a distinguishable difference between foot contact (stance) and no contact (swing).
- ❑ **Step 5 (if needed):** Click "Optimize"
  - Determine if the signal is improved and usable.
    - If yes, click "Write Changes".
    - If no, click "Optimize" again.
      - Repeat until the desired signal reading is achieved.
- ❑ **Step 6:** Once the desired signal is achieved, save the new foot sensor parameters to the device by clicking "Write Changes."

3. Agilik Tuning Checklist

- ❑ **Step 1: No torque**
  - For Test Drive tuning: Determine the biomechanical goals for this patient. Consider their current ROM when setting up the Starting Point Parameters. If possible, select 'Start Stream' and have the patient walk for a few steps to ensure all the phases of gait are being recognized.
- ❑ **Step 2: Starting Torque Parameters for a Test Drive Trial**
  - Start with low torque settings according to the following table. Once the setting has been written, either click 'Enable Torque' on the app or have the patient quick press on one of the buttons on the Agilik.

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Starting Torque Values for Users (Test Drive)				
	With Contractures		Without Contractures	
	Pediatric	Adult	Pediatric	Adult
Early Stance	-3	-5	-2	-4
Mid-Stance	-3	-5	-2	-4
Late Stance	0	0	0	0
Early Swing	1	2	1	2
Late Swing	-2	-2	-1	-1

- ❑ **Step 3: Optimize Torque Parameters**
  - Incrementally increase torque parameters until you reach optimal settings.
  - Examples include:
    - Increasing extension torque in Early and Mid-stance for weight acceptance/improved stability/reduce knee buckling in stance.
    - Applying flexion torque in Late stance for push off before swing.
    - Increase Early swing flexion torque for toe clearance and increase extension torque in Late swing for increase step length.
- ❑ **Step 4: Modes**
  - **Standing:** Confirm the Standing Mode Torque is adequately set at the equivalent of 'Early Stance Torque.'
  - **Stair Descent:** Confirm the Stair Descent Torque is set at the equivalent of 'Early Stance Torque.'

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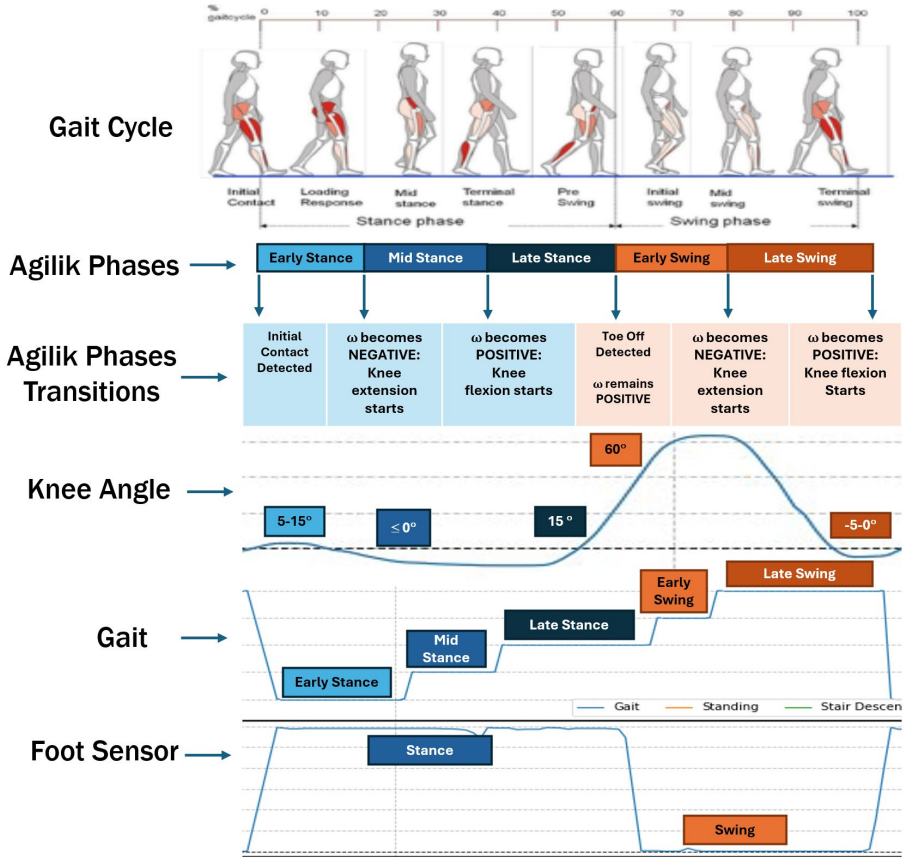
Understanding Agilik Gait Phases



The Agilik divides gait into five simplified phases using nomenclature that does not exactly match that traditionally used in gait analysis. The Agilik recognizes the phase of gait based on information received by two sensors: Foot Sensor (foot sensor: on during stance, off during swing) and ω (knee angular velocity: negative in knee extension, positive in knee flexion).

INFO

Create a final configuration/recording with optimal settings which can be referred to for definitive device fitting and save this on the PC.

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4. Agilik KAFO: Optimal Fitting/Tuning Checklist

Before Fitting – Without the Patient:

- ❑ If it is your first time delivering an Agilik, reach out to BPI and SPS to coordinate a call after receiving the KAFO and before the patient trial.
- ❑ Ensure the Reference Angle has been set correctly and that foot sensors are working properly.
- ❑ Ensure both the Agilik app and Firmware are up to date.

Fitting – With the Patient:

- ❑ Ensure time is allocated prior to tuning, for fitting and mechanical KAFO changes.
- ❑ Use the last saved configuration from the patient's test drive trial. Upload this file directly on the Agilik Care app once connected to the Agilik Device(s). Select 'Load configuration from file' then 'Write Changes'.
- ❑ On first power up, ensure the patient passes through their set reference angle. If the do successfully, this will be indicated by a solid orange LED.
- ❑ Ensure the FSR has not been optimized, if so 'Reset it to defaults'.

Refer to Agilik Foot Sensor Tuning (page 2) for this step for more in-depth instructions.

Tuning

- ❑ Once torque has been enabled, ensure all the settings for Stair Decent Mode and Standing are adjusted for the patient.
- ❑ The patient can download the Agilik Connect App from either Google Play Store or the App store. The app manual is available on bionic-power.com.

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