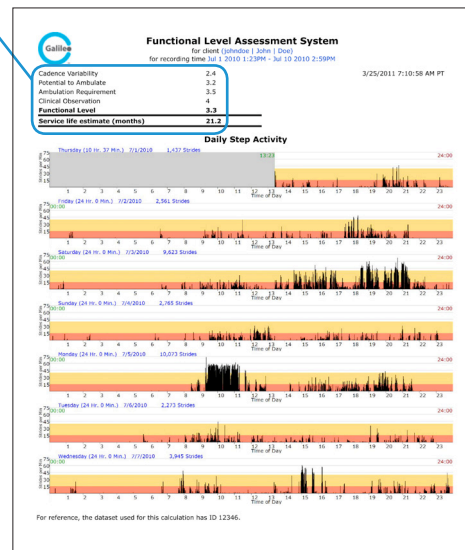


# Lesson 1

## Understanding the Functional Level Indexes

This lesson explains the meaning of the Functional Level Indexes that appear at the top of Galileo Functional Level Report.

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A typical Functional Level Report

### The Functional Level Indexes

The Functional Level Indexes that appear at the top left corner of the Galileo Functional Level Report are calculated based on comparisons to thousands of previous patient records. They provide a Functional Level, equivalent to K-level with an additional decimal point of gradation, for each of three measures that the Centers for Medicare and Medicaid Services (CMS) deems relevant to establishing K-level. Combined with the clinician’s own observation of the patient’s functional ability (Clinical Observation), they provide a Functional Level score that is equivalent to overall K-level and is applicable to both prosthetic and orthotic patients.

### Cadence Variability

This rating quantifies the patient’s ability to transition among various gait cadences. It is calculated based on the amount of time

the patient spends within the various gait ranges that are indicated by the colored bars on the ambulation report (orange bar=0–15 steps per minute, yellow bar=16–40 steps, and white bar=41 or more steps).

### Potential to Ambulate

This rating quantifies the patient’s current maximum ability to ambulate. It is calculated based on intense activity recorded during the Galileo test period.

## Ambulation Requirement

This rating quantifies the amount of ambulation the patient requires to carry out daily activities. It is based partly on the total number of steps the patient has taken and partly on the number of steps taken in a row, signifying endurance. For example, a postal carrier will have a higher ambulation requirement than will an auto mechanic, who will in turn have a higher requirement than the typical office worker.

## Clinical Observation

This rating is provided by the clinician. It signifies the clinician's observation of the patient's K-level (for amputees) or functional abilities (for orthotics patients). It should be based on the following criteria as set forth by CMS:

- **K0 (Level 0)** Does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance the quality of life or mobility.
- **K1 (Level 1)** Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence—typical of the limited and unlimited household walker.
- **K2 (Level 2)** Has the ability or potential for ambulation with the ability to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces—typical of the limited community walker.
- **K3 (Level 3)** Has the ability or potential for walking with variable cadence—typical of the community walker who is able to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple walking.

- **K4 (Level 4)** Has the ability or potential for prosthetic use that exceeds basic walking skills, exhibiting high impact, stress, or energy levels—typical of the prosthetic demands of the child, active adult, or athlete.

## Functional Level

Functional Level is calculated from the average of the four indexes described above, rounded to the nearest tenth. It is compatible with the current K-level system for amputees and provides a quantified outcomes measure for orthotics patients. The additional digit documents the patient's proximity to the nearest full K-level and empowers the clinician to document subtle pre- and post-treatment effects.

## Service Life Estimate

This number documents the number of months it will take the patient to take 3 million strides, based on the activity level he or she demonstrated during the Galileo test. Prosthetic components are typically tested to 3 million load cycles to pass ISO testing for the durability and strength of prosthetic components. A Galileo test performed when the patient receives a new device can predict when the device should be replaced, based on this criterion.