

Stepping Beyond K-Levels: The Functional Level Assessment System



INTRODUCTION



Introducing an Objective Measure of Amputee Activity Levels

In this paper, Orthocare Innovations introduces the Functional Level Assessment System, the first in a range of evidence based practice measures that will be available to clinicians via Orthocare's Galileo outcomes platform. This new classification technology for lower-limb amputees' activity levels combines clinician insight with the collection, analysis, and documentation of objective data to justify reimbursement and improve outcomes. Unlike the current approach to assigning K-levels, which is often based on imprecise, subjective, and insufficient data and documentation, the Functional Level Assessment System is simple to use and requires minimal clinician effort but yields nuanced, accurate, and quantified data that are acceptable to payers.

CURRENT SYSTEM



The Current System: K-Levels Fall Short

The current approach for classifying amputee activity levels is the Medicare Functional Classification Level (MFCL), otherwise known as the K-levels. K-levels were developed by the Centers for Medicare & Medicaid Services in response to the availability of increasingly advanced, expensive prosthetic components. CMS intended to give payers the information they need to determine which devices are medically necessary for each patient. Unfortunately, the K-levels as currently applied have the following serious limitations:

- **K-levels are usually assigned based on subjective classification methods.**

CMS did not delineate any objective measures that clinicians should use to assess amputee activity levels and thereby assign K-levels. Many outcomes measures for lower-limb prosthesis users are available, but each has a specific problem that limits its validity and reliability. For example, patient-reported outcomes questionnaires such as the PEQ, AAS, and AMPPro are susceptible to subject interpretation (bias), coaching, answer inflation, and sensitivity. Timed walking tests such as the “get-up-and-go” test, 10-meter walk time, and “L” test are objective and easy to administer in clinical settings but may not be specific to the typical and challenging walking tasks of everyday life. Observational scales such as Russek’s Code are designed to rate prosthesis users on a series of functional tasks in the clinical setting, but these scales measure capacity and may not translate well to typical performance on real-world ADL.¹ While some prosthetists do obtain relevant, accurate, and objective data on their lower-limb patients, the process of collecting, analyzing, and reporting it can be expensive and time-consuming.

At the end of this intensive data collection and reporting process, payers may or may not accept the resulting information. Clearly, there is an unmet need for relevant, reliable, quantified data that is easily retrieved and documented and is readily accepted by payers.

- **K-levels classify only the patient’s current state and do not address his or her potential to undergo functional shifts.**

One of the ironies of the current approach is that some amputees who are classified within it are subjected to unnecessary mobility limitations because their “K-level appropriate” prosthetic components do not support the higher-level functioning of which they are capable. This happens partly because the current categories do not recognize the functional ranges between the K-levels, where individuals who potentially could break through their ambulatory ceilings get stuck.² This is particularly relevant to patients between the K2 and K3 levels. A better approach to classification would solve this dilemma by offering more nuanced levels that reveal patients’ clinical potential and trajectory.

¹ Stepien JM, Cavenett S, Taylor L, Crotty M. Activity levels among lower-limb amputees: self-report versus step activity monitor. *Arch Phys Med Rehabil.* Jul 2007;88(7):896–.

² Kahle JT, Highsmith MJ, Hubbard SL. Comparison of non-microprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference. *J Rehabil Res Dev.* 2008;45(1):1–14.

- **K-levels are highly vulnerable to intentional misuse and fraud.**

Because the K-levels are not yet assigned based on objective, reliable measures, the payer system is highly vulnerable to exaggeration and outright fraud. Fraudsters deplete the reimbursement pool and fuel dramatic increases in government regulation and payer audits. To stop abuses and ensure that each prosthesis user is equipped with the right technology, activity levels should be assessed and documented using a validated, objective method.

- **K-levels no longer satisfy some payers' reporting and documentation requirements.**

Perhaps the most urgent reason to improve upon current measurements and technologies is that public and private payers nationwide are increasingly demanding objective, quantitative data to justify claims. This is particularly true for claims for advanced prostheses. Already, some private payers require data beyond clinician opinion and patient self-report instruments. National health care reform policies will only accelerate this trend because as coverage is mandated, payers will cut costs by denying suspect claims. The key to claims approval is ironclad documentation.

We do not mean to suggest that quantitative data will—or should—ever replace clinical judgment. However, in the current political and economic climate, even the most expert clinicians will still need to provide extensive documentation to satisfy reimbursement requirements. Clinicians need new technology to help fulfill this task. For any technology to meet clinicians' basic needs in this arena, it must support their clinical judgment with objective data to yield detailed documentation that payers will actually accept. For the technology to prove better than merely adequate, it must do all of this smoothly while reducing clinicians' and administrators' workloads.

In short, there is currently no gold standard for establishing K-levels, and the K-level system as currently implemented is inadequate to the demands of modern clinical practice. It is based on unreliable estimates, leaves the profession vulnerable to fraud, and increasingly fails to satisfy documentation requirements.

The Functional Level Assessment System is designed to solve these problems. It is based on both clinical judgment and an objective, quantified functional activity measure that payers accept. It is extremely easy to use, is based on research-validated technology, and provides access to many other business and clinical benefits of the StepWatch™ and Galileo™ systems.

FUNCTION



Why the Functional Level Assessment System Works

Orthocare Innovations built on years of experience and thousands of prosthetics patient records to develop the Functional Level Assessment System. It serves the prosthetics profession by enhancing clinical judgment with objective data, improving clinical outcomes, and streamlining the reimbursement process. It guides the clinician through a simple, user-friendly, and objective approach to assessing and documenting patient mobility. Additionally, it protects the profession from fraud and helps clinics operate at maximum efficiency. Finally, its use can help clinicians improve their relationships with payers, referral sources, and patients.

Under the Functional Level Assessment System, a precise evaluation of patient mobility is completed and documented through the following steps:

1. The patient wears Orthocare's unobtrusive StepWatch™ Activity Monitor to collect one week's worth of functional-activity data.
2. The clinician electronically transmits the patient activity data to Orthocare, where it is analyzed using proprietary algorithms that are part of the Galileo™ Clinical Outcomes Assessment System.
3. Orthocare transmits a report back to the clinician for use in clinical assessment and claims. The report includes the patient's Functional Level Assessment System K-level, which includes

one decimal place worth of gradation—K0.0 to K4.9—and an analysis of patient mobility patterns.



The accuracy of the StepWatch Activity Monitor has been validated in more than 80 published, peer-reviewed papers.

The Functional Level Assessment System is fully compatible with the current K-level modifiers and offers these significant improvements over current approaches while requiring little, if any, additional effort on the part of clinicians or support staff:

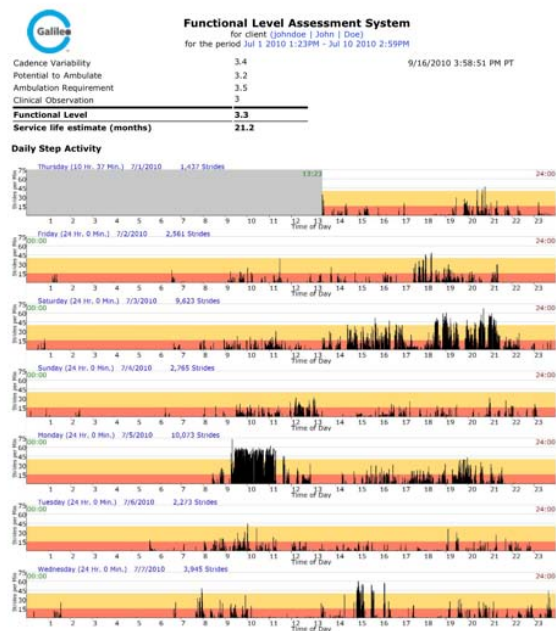
- The Functional Level Assessment System is based on objective, quantified, and documented data that is clinically comprehensive and meaningful.
- The Functional Level Assessment System utilizes Orthocare’s extensively validated, easy-to-use StepWatch™ technology and the Galileo™ Clinical Outcomes Assessment System.
- The Functional Level Assessment System helps protect the profession’s interests from fraud and differentiates the system’s users from suspected fraudsters.
- The Functional Level Assessment System radically reduces the time and resources needed to meet payer requirements for outcomes data and documentation.

WHY GALILEO WORKS



The Power of Numbers

Under the current system, patients are classified as K0, K1, K2, K3, or K4 using self-reports, clinical observation, and perhaps a few minutes' worth of quantitative data collection. By contrast, Functional Level Assessment System classifications integrate clinical observation with objective, quantified data that the StepWatch™ collects over a full week of patient activity. The StepWatch™ monitors and continuously records the wearer's number of steps per selected time interval (adjustable from a few seconds to a few minutes). The data collected by StepWatch™ can finally bring quantified, documented meaning to patient-selection terms such as "baseline and faster than baseline rate of walking," "long distance," and "variable cadences." The data also allow clinicians to report all the complexities of the patient's real-life mobility patterns in detail and to identify patterns that require specialized components or supplies. For example, the data may show that a self-identified athlete is



Galileo reports are easy to use and understand. Payers, patients, and referral sources can all use these reports to validate treatment efficacy.

almost entirely sedentary outside of her weekly soccer game, while a self-identified couch potato walks his dog several miles a day and performs manual labor for extra income.

In the Functional Level Assessment System, the complexities of patients' mobility are reflected in classifications that include an additional decimal point worth of gradations per K-level and extend from K0.0 to K4.9. These modified K-levels describe not only the patient's current condition, but also his or her proximity to either the next higher or lower full K-level. Such information can help clinicians track subtle declines and improvements and can anticipate patients' clinical trajectory. Using this information, the clinician might help a patient who

has improved from K2.6 status to K2.8 to transition toward more advanced components, and encourage a patient who has declined from K2.5 to K2.2 to have a general health assessment. The clinician also may communicate this valuable information to the patient's referring physician or use it to help develop in-house care protocols.

ACCURACY



The **StepWatch™** monitor is an unobtrusive, wearable device that incorporates sensors, data storage, and a permanent battery that is designed to last for many years. It automatically collects and retains data without any effort by the wearer, and can be adjusted in various ways by the clinician.

Developed through a grant from the National Institutes of Health, the StepWatch™'s accuracy has been validated in more than 80 peer-reviewed papers. It is the gold standard for activity monitoring across numerous health care fields and is the activity-monitoring system of choice at more than 140 research institutions worldwide, including the Mayo Clinic, Cornell University, and select U.S. Department of Veterans Affairs (VA) facilities.

The **Galileo™ Clinical Outcomes Assessment** technology accepts patient activity data from the StepWatch™, transmits and stores it through a HIPAA-compliant Web-based interface, and analyzes it using Orthocare proprietary algorithms. From this analysis, it generates a simple, easy-to-read report known as the Evidence-Based Performance Analysis for K-Level Determination. This report shows the patients' Cadence Variability Index, Peak Performance Index, and Ambulation Energy Index, with a K-level graded to a tenth of a point assigned to each index. The indexes are balanced with the practitioner's stated clinical observation, which is weighted equally to the calculations. The indexes and clinical-observation score are then combined to assign a definitive Functional Level Assessment System K-level. This K-level classifies a fair, accurate, and validated assessment of the patient's current condition and also his or her proximity to either the next higher or lower full K-level. In Orthocare's

developmental testing, this system has proven to be more than 98% accurate at assigning K-levels when compared to the clinical observations of highly qualified prosthetists.

OBJECTIVITY



The Functional Level Assessment System is based on sensor-collected data, making fraudulent claims more difficult to generate. This helps defend against increased regulation of the profession and protects the reimbursement pool. Just as importantly, clinicians who utilize the Functional Level Assessment System are immediately differentiated from suspected fraudsters in the eyes of payers, referral sources, and patients who understand the classification system. The Functional Level Assessment System demonstrates that clinicians who use it base their claims on real, objective data. It also helps ensure that patients benefit from using a limb system that is optimally crafted to their personal functional performance level, enabling better real-world mobility and activity.

ACCEPTED BY PAYERS



The Galileo™ system automatically quantifies and documents both K-level and specific patient-selection criteria for even the most advanced lower-limb prostheses. This information appears on read-at-a-glance reports that payers accept and which Orthocare will update as reporting requirements inevitably expand. This automated process improves clinical and administrative efficiency by saving the time and resources that would otherwise be spent on testing, data analysis, developing documentation packets, and resubmitting denied claims.

CONCLUSION



Using objective, quantified data from proven Orthocare technology, the Functional Level Assessment System positions clinicians to improve clinical care, streamline business practices, protect the profession, and meet or exceed documentation requirements. Never has the profession needed such a system more, and never before has an activity measurement technology offered such promise. Outcomes measures should not be underestimated; if generated under the Functional Level Assessment System, however, they can be better understood. We hope this white paper advances this important objective.

SUPPORTIVE LITERATURE



The following peer-reviewed articles reference the accuracy of the StepWatch™ technology and its application in assessing the function of prosthesis users:

Berlin JE, Storti KL, Brach JS. Using activity monitors to measure physical activity in free-living conditions, *Physical Therapy*, 86(8):1137-1145, August 2006.

Cavanaugh JT, Coleman KL, Gaines JM, Laing L, Morey MC. Using step activity monitoring to characterize ambulatory activity in community-dwelling older adults. *Journal of the American Geriatrics Society*, 55(1):120-4, January 2007.

Coleman KL, Smith DG, Boone DA, Joseph AW, del Aguila MA. Step Activity Monitor: long-term continuous recording of ambulatory function, *Journal of Rehabilitation Research and Development*, 36(1): 8-18, 1999.

Coleman KL, Boone DA, Laing LS, Mathews DE, Smith DG. Quantification of prosthetic outcomes: elastomeric gel liner with locking pin suspension versus polyethylene foam liner with neoprene sleeve suspension, *Journal of Rehabilitation Research and Development*, 41(4), 591-602, 2004. [full text online: <http://www.rehab.research.va.gov/jour/99/36/1/contents.html>].

Foster RC, Lanningham-Foster LM, Manohar C, McCrady SK, Nysse LJ, Kaufman KK, Padgett DJ, Levine JA. Precision and accuracy of an ankle-worn accelerometer-based pedometer in step counting and energy expenditure, *Preventive Medicine*, 41(3-4): 778-783, Sep-Oct 2005.

Franklin PD, McLaughlin J, Boisvert CB, Wenjun L, Ayers DC. Pilot study to document quantity and variation of independent patient exercise and activity after total knee arthroplasty. *J Arthroplasty*, 21(6 Supp 2):157-63, September 2006.

Gardner AW, Montgomery PS, Scott KJ, Blevins SM, Afaq A, Nael R. Association between daily ambulatory activity patterns and exercise performance in patients with intermittent claudication. *Journal of Vascular Surgery*, 48(5): 1238-1244, 2008.

Klute GK, Berge JS, Orendurff MS, Williams RM, Czerniecki JM. Prosthetic intervention effects on activity of lower-limb amputees, *Archives of Physical Medicine and Rehabilitation*, 87(5):717-722, May 2006.

Mudge S, Stott NS, Walt SE. Criterion validity of the StepWatch Activity Monitor as a measure of walking activity in patients after stroke. *Arch Phys Med Rehabil*, 88(12):1710-5, Dec 2007.

Hafner BJ, Willingham LL, Buell NC, Allyn KJ, Smith DG. Evaluation of function, performance, and preference as transfemoral amputees transition from mechanical to microprocessor control of the prosthetic knee. *Archives of Physical Medicine and Rehabilitation*, 88(2):207-217, February 2007.

Shepherd EF, Toloza E, McClung CD, Schmalzried TP. Step Activity Monitor: Increased accuracy in quantifying ambulatory activity, *Journal of Orthopaedic Research*, 17(5):703-708, 1999. [Study conducted with recipients of total hip replacement.]

Smith DG, Domholdt E, Coleman KL, del Aguila MA, Boone DA. Ambulatory activity in men with diabetes: relationship between self-reported and real-world performance-based measures, *Journal of Rehabilitation Research and Development*, 41(4), 571-580, 2004. [full text online <http://www.vard.org/jour/04/41/4/smith.html>].

Song KM, X KF, Capello T, Coleman K. Use of the StepWatch Activity Monitor for characterization of normal activity levels of children, *Journal of Pediatric Orthopedics*, 26(2):245-249, Mar-Apr 2006.

Stepien JM, Cavenett S, Taylor L, Crotty M. Activity levels among lower-limb amputees: self-report versus step activity monitor. *Arch Phys Med Rehabil.* 88(7):896-900, Jul 2007.

REPRESENTATIVE USERS



The following is a representative list of StepWatch™ Users:

Mayo Clinic

Johns Hopkins University

Columbia University

Weil Cornell Medical Center

Duke University

University of Miami

U.S. Department of Defense

Mount Sinai School of Medicine

University of Pittsburgh Medical Center

Massachusetts General Hospital

University of Michigan

Washington University

University of Washington

National Institutes of Health

Hong Kong Polytechnic University

U.S. Department of Veterans Affairs

Seattle Children's Hospital

Albert Einstein Medical Center

University of Florida

University of Iowa

Georgia Institute of Technology

Rehabilitation Institute of Chicago

University of California, Davis

Magee Rehabilitation Hospital

Texas Scottish Rite Hospital



DEALING WITH FRAUD AND ABUSE IN THE PAYMENT SYSTEM FOR LOWER-LIMB PROSTHESES CALLS FOR NEW POLICIES AND NEW TECHNOLOGIES

By: Kenneth M. Nelson, MD

Over the past decade, increased attention has been paid to Medicare fraud associated with lower limb prostheses. Cases of microprocessor-controlled prosthetic devices billed to non-amputee beneficiaries have been featured by the media in spectacular fashion. Adoption of new policies by payers and utilization of newly available technologies, could contribute significantly to preventing such abuses.

HOW FRAUD OCCURS

The lack of objective standards, and the failure to require documentation of compliance with such standards to support payment, allows fraud and abuse to occur. This situation is further complicated by lack of familiarity with prostheses on the part of the payer's review staffs. Nurses, physicians and payers rarely have a good working knowledge of artificial limbs. Prosthetics claims are relatively uncommon and, despite their high cost, are not a high priority item. This empowers fraudsters to submit claims that would be questioned or rejected by knowledgeable reviewers or better review systems. Direct fraud operates in several different ways:

SIMPLE FALSE CLAIM, PROSTHESIS WITHOUT AMPUTATION

This is the most blatant, and in some ways, the simplest type of fraud: submission of claims for a subscriber who does not need a prosthesis. The subscriber may never have undergone amputation, or may even be dead. One significant step in reducing this fraud would be to ensure that payments only go to licensed and/or accredited orthotics and prosthetics providers. Requiring this level of qualification would immediately eliminate numerous bad actors, and protect legitimate businesses and organizations that represent highly qualified and skilled providers. This policy change was issued by Medicare, but never implemented.

Implementation would prevent random entities from applying for and receiving a Medicare provider number for their operations where no medical devices or supplies may ever be provided. AOPA has estimated that such a step could save \$100 million in the Medicare system alone.

UPCODING

A more subtle fraud may be perpetrated through falsification of the grading of an amputee's activity to justify a more expensive prosthesis. Patient activity levels are graded from K-0 through K-4. Each level from 1 through 4 is associated with a more complex prosthesis to allow for the full potential to ambulate further, over increasingly difficult terrain. The definitions of increasing potential to ambulate and the documentation of such actual or potential activity level have not been outlined by payers in a manner that can be quantified and documented. This situation allows fraud by upcoding (knowingly claiming a more complex and expensive prosthesis than the patient was furnished or needs), for financial gain by the provider.

UTILIZING NEW TECHNOLOGY TO MEASURE, DOCUMENT AND JUSTIFY NEED

Current medical policy utilizes definitions of K-levels that are too vague to support good patient care and appropriate payment. Terms such as "baseline and faster than baseline rate of walking," "long distance," and "variable rates" are subjective. Self-report questionnaires can be influenced by coaching. And even prosthetists who are genuinely trying to provide appropriate care for their patients may understand these terms differently, producing significantly different approaches to treating similarly situated patients.

Now, Orthocare Innovations has developed a new technology to provide objective, quantitative analysis of cadence and gait. The Galileo system provides a functional level of assessment as an objective measure of amputee subscriber activity levels. It will establish a consistent, generally accepted standard of the activity level to be assigned to each K-Level, and simplify K-Level assignment. With this technology, it is now possible to identify objectively and document which patients can utilize increasingly sophisticated prostheses. The Galileo system will facilitate provision of the appropriate prosthesis for the patient, and also protect payer funds from improper payments.

Delivering Medicare payments only to qualified orthotic and prosthetic providers would be a significant step in reducing fraud and abuse in the Medicare system. In the meantime, through the use of independently derived, objective, quantitative measurement of activity in lower limb prostheses, it is possible for all payers—government and private alike—to move from “pay and chase” to “review and approve” or “review and deny.” The current, cumbersome prior approval system might not be necessary if claims submissions were supportable by independent analysis of the amputee’s functional level assessment through Galileo technology, and correct payment could be based on such documentation. All responsible providers of orthotic and prosthetic devices—and all taxpayers—should welcome such changes.

Kenneth M. Nelson, MD, MPH, CFE, has over 30 years of experience in healthcare, including 20 years as Medical Advisor, Office of Inspector General, U.S. Department of Health and Human Services and ten years in leadership positions at government contractor Palmetto Government Benefits Administrators, where he served as Medical Director for the Medicare Durable Medical Equipment national contractor (SADMERC) and at TriCenturion, where he focused on program integrity and compliance issues. At the SADMERC, he was intimately involved in the coding, coverage, and pricing of Durable Medical Equipment. He has served as an Associate Division Director for the National Cancer Institute and as a Health Fellow in the U.S. Senate. He is the author of over a dozen publications in healthcare management and clinical and basic research. Dr. Nelson also serves on the Orthocare Innovations Medical Advisory Board.



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