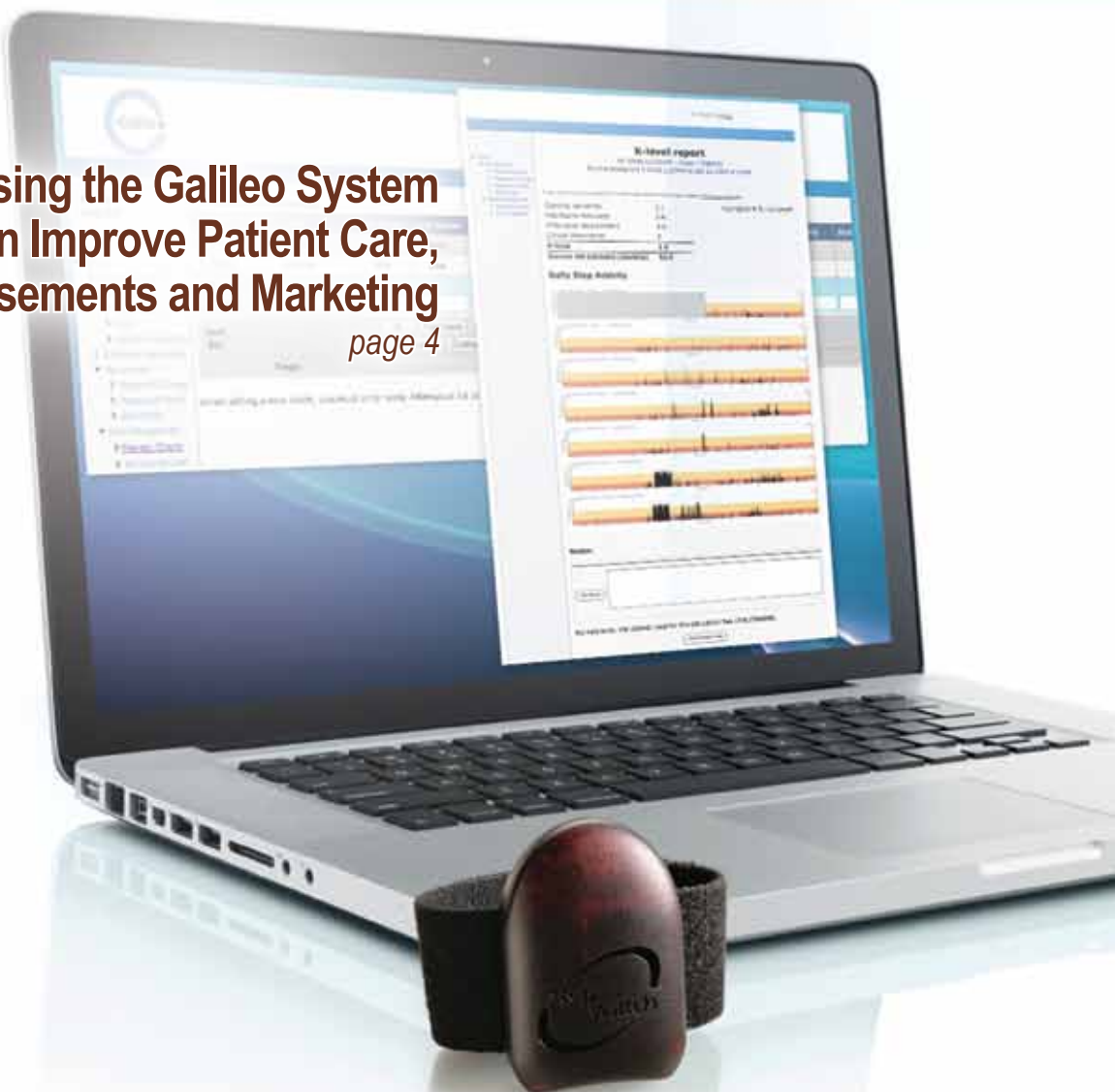


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OPGA Member Magazine

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It All Gets Better

How Using the Galileo System Can Improve Patient Care, Reimbursements, and Business Marketing

One of the most challenging realities of O&P is that the rules of clinical care and business practice are always changing. It's one thing to practice and study for long years to enter a life-changing profession, but it's another to bring your education and dedication to bear for a decade, then suddenly find that you can't get paid for working the way you always have. These are the days when relying on your own best judgment and patient self-reports to justify providing a quality leg can mean losing \$30,000 in a RAC audit, and when replacing even broken components oftentimes requires a pitched battle through pre-authorization. We also now know that old standards of clinical care are less certain than they used to be—for example, research now shows that patient self-reports of activity tend to be highly inaccurate, and patients are just as likely to under-report their activity as exaggerate it. Customers, both patients and referral sources, are mercurial as well. Many physicians now want to see from their O&P partners the same metrics of success they are forced to provide in their own profession, while patients themselves increasingly want to really understand why you provide certain devices.

The key to surviving (and thriving) in the face of these challenges is to meet these demands with as little change to your business model as possible—you have enough to do without rethinking every aspect of your business and clinical practice. Orthocare Innovations has invented a system that enables you to do exactly that: improve reimbursements, safeguard claims, enhance clinical care, and step up your relationships with customers, all while putting out little, if any, additional effort. This system is the Galileo Functional Level Assessment System, the first in a series of evidence-based-practice technologies that Orthocare is making available within the Galileo outcomes-data platform.

Lower-Limb Justifications are Hamstrung

Among the most frustrating uncertainties in modern O&P practice are the ambiguities surrounding justification of devices for lower-limb patients. Orthotists have no standard functional classification for lower-limb patients, and prosthetists are forced to lump patients into K-Levels. The K-levels—officially known as the Medicare Functional Classification Level (MFCL)—were designed by the Centers for Medicare and Medicaid Services (CMS) to help payers determine what patients should receive from the range of increasingly expensive prosthetic components. Unfortunately, the K-levels as currently applied and the methods orthotists are forced to rely on have the following serious limitations:

¹Stepien 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.

Subjectivity

CMS never delineated objective criteria for assigning K-levels to amputees or assigning functional levels to orthosis wearers. According to David Boone, CP, MPH, PhD, only a very, very small number of O&P clinicians regularly collect outcomes measures when assigning K-level or choosing an orthosis, simply because most clinicians believe that in-clinic tests take far too much time to conduct, document, and report, and their outcomes aren't sure to be accepted by payers. Of the in-clinic measures that a few clinicians use, such as timed walking tests, the "get-up-and-go" test and Russek's Code, they simply don't reflect patients' abilities in real-life settings over a useful scale of time. This causes unnecessary difficulty in justifying treatments and K-level assignments and makes it harder than it should be to feel completely confident in choosing componentry. Clearly, there is an unmet need for relevant, reliable, quantified data that is easily retrieved and documented and is readily accepted by payers.

Classifying current states without tracking change and potential

One of the ironies of the current approach is that some patients are unnecessarily held back because their currently justifiable or "K-level appropriate" components do not support the higher-level functioning they are actually capable of. This happens partly because the current categories fail to recognize the functional ranges (especially those between the K-levels) where individuals who potentially could break through their ambulatory ceiling get stuck. This is particularly relevant to patients who fall between K2 and K3. A better approach to classification would offer a nuanced indicator of functional ability that reveals patients' clinical potential. Such an indicator would not only help clinicians and payers predict which patients can do more, it would also provide a longitudinal health history that would red-flag major changes.

Vulnerability to fraud and abuse

Clinicians who think fraud isn't their concern probably have never suffered through an audit. The reality is that fraud is a crushing burden on the profession because it fuels dramatic increases in audits, regulations, and documentation requirements. For a fraudster, changing a non-ambulatory granny into a bounding K3 is as simple as the stroke of a pen. Payers, knowing this, consider even the most circumspect clinicians suspect. Because of this, activity levels should be assessed and documented using a validated, objective method that is as near to irrefutable as possible.

Inadequacy for payers

Perhaps the most urgent problem with the current system is that public and private payers nationwide are increasingly demanding objective, quantitative data to justify claims. This is particularly true for claims for advanced orthoses and prostheses, and is becoming more urgent under health care reform laws, which spur payers to cut costs.

Quantitative data will never replace clinical judgment, nor should it. However, in the developing political and economic climate, even the most expert clinicians will still need to provide extensive documentation to be reimbursed.

Galileo's Functional Level Assessment System is designed to solve these problems. It enhances clinical judgment with objective data, improves clinical outcomes, and streamlines the reimbursement process. It guides the clinician through a simple, user-friendly, and objective approach to assessing and documenting patient mobility for both prosthetics and orthotics. 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. It is based on both the clinician's own judgment and an objective, quantified functional activity measure designed to appeal to payers. It is extremely easy to use, is based on research-validated technology and provides access to many other business and clinical benefits of the Galileo™ system.

How Galileo's Functional Level Assessment System Works

Orthocare Innovations built on years of experience and thousands of O&P patient records to develop the Galileo technology and its Functional Level Assessment System.

Here's how it works:

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 through Orthocare's HIPAA-compliant Web server, where it is analyzed using proprietary algorithms.
3. Orthocare instantly transmits the Galileo Functional Level Report back to the clinician. The report includes the patient's

Functional Level, which is equivalent to K-level but includes one decimal place worth of gradation—0.0 to 4.9 vs. K0 to K4—and an analysis of patient mobility patterns.

Galileo's Functional Levels are fully compatible with orthotic practice and the current K-level modifiers, and they offer these significant improvements with little, if any, additional effort from clinicians or support staff:

- Galileo's Functional Levels are based on real scientific data—objective, quantified, and documented—that reflects real-world activity in real-world environments.
- Galileo produces a read-at-a-glance one-page report that can be submitted with claims, radically

reducing the time and resources needed to meet payer requirements for outcomes data and documentation.

- Galileo's Functional Levels utilize what is perhaps the most accurate and highly validated activity monitoring technology on the market (the StepWatch™) along with the O&P-specialized, easy-to-use Galileo™ software and Web server.
- Galileo's Functional Levels help protect the profession's interests from fraud and show payers and referral sources that the clinicians who use it are not fraudsters. This makes it a powerful business marketing tool while providing protection during audits and claims review.

Three Ways Clinicians Use Galileo™

Before-and-After Proof

Apply the StepWatch during the initial patient evaluation or after casting to collect the patient's pre-treatment mobility levels. Then, apply StepWatch again after the treatment has been delivered and the patient has had time to heal any co-morbidities. Include both Galileo Functional Level Reports in the claim to help definitively prove treatment outcomes.

Pre-Authorizations

Apply the StepWatch during the initial evaluation, then include the Galileo Functional Level Report in your pre-authorization to prove that the patient is active enough to justify use of a certain device. Or, allow the patient to use a loaner version of the device and provide before-and-after reports that demonstrate any improvements in functioning due to the device change.

Audit Protection

Collect Galileo data as appropriate when providing any significant treatment that requires reimbursement, then include the Functional Level Reports in the patient's records. During audits, every record will be backed up by ironclad, scientific data.

Sensor Power

Under the current system, clinicians generally justify treatments based solely on patient self-reports, in-clinic observation, and in rare cases, a few minutes' worth of quantitative data collection. In contrast, clinicians who use Galileo Functional Level classifications also integrate their professional judgment with sensor-collected functional data that the StepWatch gathers over a full week of patient activity. The StepWatch monitors and continuously records the wearer's number of steps per minute (or other time interval the clinician selects), recording intensity of activity, persistence, bursts of speed, and other key mobility factors. This data finally brings scientific, 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 understand and report all the complexities of the lower-limb prosthetic or orthotic patient's real-life mobility patterns in detail and to identify patterns that require specialized components or supplies.

It's All in the Nuances

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 0.0 to 4.9. These modified K-levels, suitable for both prosthetics and orthotics, describe not only the patient's current condition, but also his or her proximity to either the next higher or lower full K-level. This information empowers clinicians to track subtle declines and improvements and anticipate patients' clinical trajectory. This is powerful information when reporting treatment outcomes and medical necessity to payers. With Galileo, clinicians can irrefutably prove that a patient became more active after receiving a new brace or knee, or that a patient who has transitioned from Functional Level 2.3 to 2.6 to 2.8 in a year is likely to soon need more durable, dynamic components. Clinicians who can show referral sources these powerful metrics may also become far more appealing as contractors, because they can both prove treatment outcomes and augment the physicians' own information. These reports are also valuable as bridges to better communication with patients; patients who can "see" evidence of their health and activity feel more engaged in their care.

Genuine Data

Galileo's Functional Level Assessment System is based on sensor-collected data, making fraudulent claims more difficult to generate. This means that clinicians and businesses that demonstrate their use of Galileo are immediately elevated above suspected fraudsters in the eyes of payers, referral sources, and info-centric patients. Galileo-using clinicians also help defend against increased regulation of the profession and protect the reimbursement pool. Just as importantly, clinicians who use Galileo can feel more confident that the treatments and devices they provide are optimally crafted to their patients' personal functional performance, enabling better real-world mobility and activity.

Anticipating Payer Requirements

Galileo's Functional Level Reports are designed for payers to accept, and Orthocare will update them as reporting requirements inevitably expand. Galileo's automated process improves clinical and administrative efficiency by saving time and

resources otherwise spent on testing, data analysis, developing documentation packets, and resubmitting denied claims.

All Together Now

Using objective, quantified data from proven Orthocare Innovations technology, Galileo's 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. Though still badly underutilized in O&P, outcomes measures should no longer be underestimated; if generated under the Functional Level Assessment System, however, they can improve all O&P practice.

StepWatch + Galileo™ = Accuracy

The StepWatch monitor is an unobtrusive, wearable device that incorporates sensors, data storage, and a permanent battery that is designed to last for about seven 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 Functional Level Report. This report shows the patients' Cadence Variability Index, Ambulation Potential Index, and Ambulation Requirement Index, with a Functional Level—equivalent to K-level—that is graded to a tenth of a point for each index. The indexes are balanced with the practitioner's own clinical observation, which is weighted equally to the calculations. The indexes and clinical-observation score are then combined to assign a definitive Functional Level. This Functional Level provides 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. Research has also shown these calculations to be highly consistent with K-level evaluations by expert prosthetists.