CASE STUDY:
MEDICAL DEVICES

Improving Physical Therapy Outcomes and Reducing the Risk of Injury

How do you make a gait training rehabilitation system carry more weight with more control while increasing safety for both therapist and patient?

When patients have endured a long period of inactivity, the number-one priority for physical therapists is to get them up and walking again. A category of medical devices known as body weight support (BWS) systems – motorized, ceiling-mounted machines for patients relearning to walk – has evolved to assist therapists in gait training.

Bioness, a BWS manufacturer, saw market opportunities in three areas:

- Patient throughput – Bioness wanted a BWS that could help reduce the cost of rehabilitation and health care. It envisioned a system that could handle up to three patients at a time.
- Safety – In manually assisting patients and keeping them from falling, physical therapists often sustain injuries of their own, especially to the back and wrist. Bioness saw that the market would reward a device that reduced the risk of those injuries.
- Weight limits – To balance market requirements for both capacity and safety, Bioness specified that the BWS should accommodate patients weighing up to 400 pounds/180 kilograms.

In theory, Bioness could have met those requirements by simply upgrading its existing products with a heavier overhead track, a stronger motor and thicker rope. But it saw that the real opportunity for improving patient outcomes lay in a BWS that offered therapists precise control and responsiveness, which are harder to achieve as the machine gets heavier. Bioness wanted a product that would let therapists closely regulate patient movement horizontally and vertically, and offload) up to 200 pounds/90 kilograms of the patient's body weight during rehabilitation exercises.

Bioness engaged D&K Engineering to design and manufacture its next-generation BWS, the Vector Gait and Safety System.

"Aha!" moments in the design partnership

The companies started with multiple information-gathering sessions and in-service demonstrations of Bioness' existing BWS to flesh out the improvements Vector would include. The back-and-forth between D&K and Bioness yielded several "Aha!" moments early in the project:

- The existing BWS was powered and controlled through a thick wire tether from the trolley on the ceiling-mounted track, which D&K believed added to the load on the trolley and impaired the system's responsiveness. D&K suggested getting eliminating the long, heavy tether to afford therapists better control and to allow patients to move more easily along a closed loop instead of back and forth.
- That improvement prompted the question of how to power the trolley. D&K came up with the idea of adding a power rail alongside the overhead track to

carry electricity to the trolley. For control, D&K suggested Wi-Fi-enabled controllers in the trolley communicating with a mobile app that the therapist would run on a specially configured smartphone and on a PC.

- The closed-loop configuration improved space utilization and made it possible to exercise as many as three patients at a time, but it also raised the potential for trolleys to collide. D&K added a spring that allowed trolleys to come in contact without causing damage or injuring patients. Like two cars with very long bumpers, colliding trolleys stop, letting therapists intervene manually.

Most important, D&K's questions and observations brought clarity to the issue of what Bioness would consider a successful project.

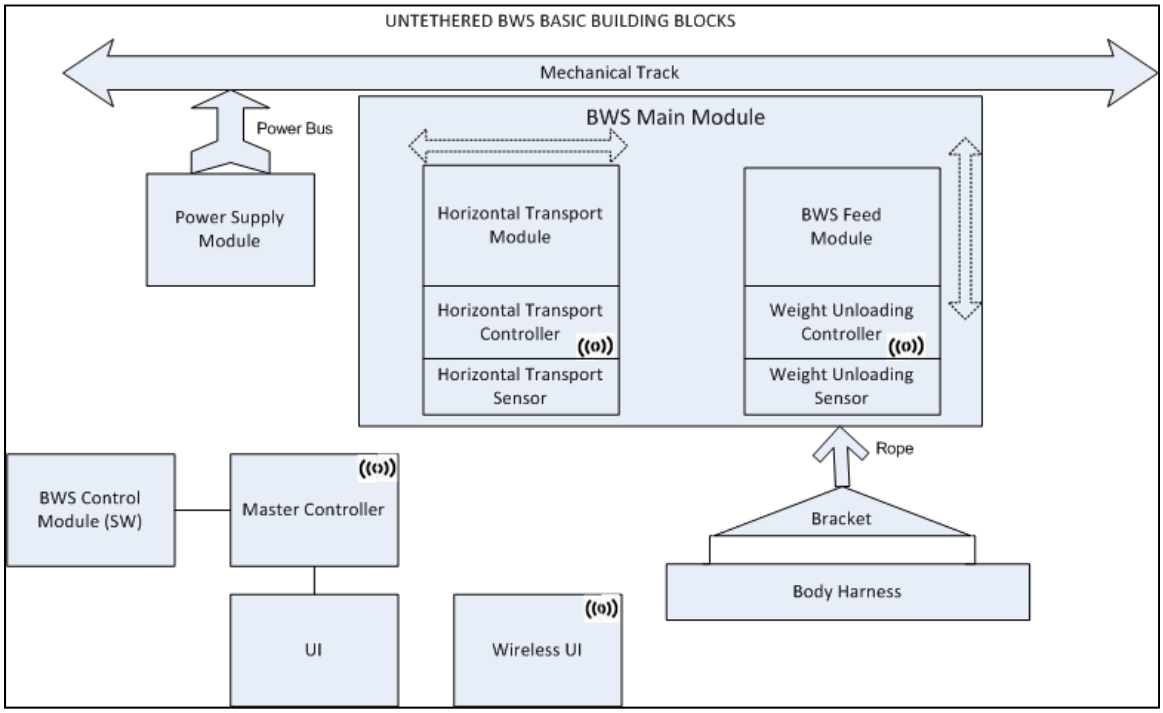
Applying 4 Phases of Product Development

With high-level agreement on how Vector would look and function, D&K kicked off the four phases that govern all its electromechanical design work.

Phase 1: Program Planning, Functional Decomposition and Architecture

The essence of phase 1 is to make decisions and reduce risk before building any hardware. The companies collaborated on the transition from Bioness' business-facing market requirements document to D&K's first deliverable: an architecture document from which phase 2 design work could begin.

The system architecture included a block diagram of the main mechanical components:



Block diagram, untethered body weight support system (Vector)

- Mechanical Track – Ceiling-mounted, with a power rail.
- BWS Main Module – Robotic trolley comprising:

  - Horizontal Transport Module – Maintains a position either directly above or at a controlled angle relative to the patient.
  - Horizontal Transport Controller – Powers and controls the motion of the Horizontal Transport Module along the Mechanical Track, communicating with the Master Controller wirelessly.
  - BWS Feed Module – As required by the Weight Unloading Controller, offloads some of the patient's weight by applying a precisely measured amount of tension to the rope, which is attached to the patient's harness.
  - Weight Unloading Controller – Sets rope tension and rope length according to predetermined values from the therapist's Master Controller, and detects/communicates the patient's fall to the Master Controller.
- Main User Interface (UI) – Allows the therapist to enter commands and create/modify/execute exercise recipes. Provides the therapist with data about the exercise session.
- Wireless User Interface (WL-UI) – Runs on a mobile device (e.g., Samsung Galaxy S III) and has some of the functionality of the Main User Interface (UI).
- BWS Control Module – Software module that translates the exercise recipe and commands entered by the therapist into signals communicated to the Horizontal Transport Controller and the Weight Unloading Controller. Also responds to signals received from controllers and sensors.
- Master Controller – Windows-based PC that hosts the UI and communicates wirelessly with the Wireless UI and BWS Control Module. Connected to trolley via Wi-Fi.
- Power Supply Module – Provides all the power required by the trolley through the power rail.
- Rope, Bracket, and Body Harness – Connect the patient to the BWS Main Module.

Since Vector qualified as a medical device, risk management was a large part of phase 1 activity. D&K involved UL early on – before making significant decisions – to assess risk in test configurations, manufacturing processes and certification schedule, and in the design of the power rail and wireless control.

Next, Bioness requested an accelerated schedule so that it could demonstrate a working prototype of Vector at an upcoming trade show. D&K accommodated the request by adding resources to the project who worked in parallel to traditional phase 1 activities. As a result, Bioness was able to demonstrate basic functionality long before Vector was commercially available.

Once the architecture was on paper, D&K conducted its phase 1 gate review involving all Bioness decision makers. D&K proposed three different architectural options and meticulously laid out the pros, cons and risks of each option. At the end of the review, Bioness selected the architecture that best suited its business goals and understanding of what its customers wanted.

Phase 2: Development – Design and Engineering Prototypes

With sign-off on the architecture, D&K's engineers began designing Vector with computerized modeling work of basic physics phenomena and the details of the control algorithms they planned to implement. Then they turned to procuring hardware components and getting them to work together.

D&K devoted long hours of computational modeling to the mechanical engineering needed to optimize the BWS for size and weight. It was necessary for Vector to bear up to 400 pounds of patient weight and lift that weight after a fall, but Bioness did not want an over-built product. The companies arrived at important trade-offs to support the right weight with all FDA-mandated safety factors while keeping the system as small, light and responsive as possible.

Bioness gave D&K the latitude to choose hardware components based on reliability and pedigree in medical devices. D&K also sought to future-proof Vector by specifying a qualification process for components subject to obsolescence, like the PC and the mobile device. For basic safety components like motors and control modules, D&K chose stable, long-life parts from well-known suppliers like National Instruments to shorten the development cycle and ensure that Bioness would not soon find itself back at square one in a regulatory certification process.

Phase 3: Design Verification

In this phase, D&K followed its signature processes for design and manufacturing: from computer into machine shop, from machine shop onto manufacturing floor. It began building Vector according to the approved design and rapidly iterating on the design based on interim test results.

Starting UL early in the project paid off in prompt certification. By phase 3, UL had followed Vector through months of design and phase gate reviews – asking questions, pointing out things to consider – and had come to understand how the device would be used. The UL engineer selected only relevant certification tests, which helped keep the project on schedule and within budget.

At UL's test facility, once Vector was configured and tested as designed, UL declared it compliant with IEC 60601-1 (3rd edition), a series of rigorous technical standards for the safety and effectiveness of medical electrical equipment. UL also certified D&K's manufacturing process for the product.

Phase 4: Product and Manufacturing Process Validation

Following design verification, D&K started work on Vector's transition to manufacturing in the same facility in which it was designed.

Selecting and working with suppliers involved having the QA team ensure that the entire supply chain was in place: providing correct specifications, documenting requirements rigorously and imposing quality control measures on incoming materials.

D&K also builds manufacturing training into its engineers' core duties. That meant that the employees who designed Vector could walk to the other side of the building, work with the employees who manufactured the critical first few units and refine manufacturing processes instantly.

Benefits of Vector

With a product that raises the bar for capacity, safety and weight limits, Bioness and its customers cite several important benefits of the Vector Gait and Safety System:

- Therapist workflow – Traditionally, patients coming in for gait training have required considerable physical assistance from one or more therapists who get them out of a wheelchair, walk them and catch them in case of a fall. Vector removes much of the hands-on, manual work of gait training. Fewer, less-muscular therapists can now work with a single patient with less risk of injury, and more therapists can exercise more patients simultaneously.
- System control – Existing body weight systems included a software component, but D&K improved it with a GUI-based PC application and mobile app designed for usability and a therapist's common tasks.
- Analytics and patient measurement – Several times per second, the PC captures and logs data over Wi-Fi, including speed and direction of the trolley, tension on the rope, amount of offload force, walking speed, gait details, number of falls and total distance/time walked. The therapist can view

the data in near-real time on the PC and export it. Physicians can use the data to gauge patient progress and modify the exercise recipe accordingly.

- Therapeutic value – Vector outstrips the weight limitations of previous and competing systems, yet it introduces finer control over patient movement with greater responsiveness. By ensuring that the offloading force remains constant and that the trolley is not tugging the patient forward or backward, Vector embodies D&K's expertise in motion control.

"We were very pleasantly surprised by our productive partnership with D&K Engineering. They took Vector from our market requirements document through design and manufacture, including UL certification. Their early suggestion that we switch from tethered control and power to wireless control and a ceiling-mounted power rail was a paradigm shift that told me we were working with the right people. They showed flexibility in accelerating delivery of a prototype we could demonstrate at a trade show, which gave us a huge competitive advantage." – Russell Bediyoskin, VP Products, Bioness Inc.