

iTrac Product Guide for Clinicians

- **Dr. Jarrod Nichols, DC, CSCS – Bio**

- Dr. Jarrod Nichols was born and raised in rural Kansas. After completing undergraduate studies in kinesiology at Kansas State University he received his Doctor of Chiropractic degree from Palmer College of Chiropractic in Davenport, Iowa where he graduated Magna Cum Laude in 2004. Dr. Nichols is a Certified Strength and Conditioning Specialist and a Certified Fellow of Chiropractic Biophysics. In 2005 he opened Nichols Chiropractic, PA in Manhattan, Kansas where he lives with his wife Dr. Shawn Nichols, DDS and their two sons Mason and Sutton.



While receiving his training in structural spinal correction, Dr. Nichols observed a troubling chasm between the abundant peer reviewed research supporting that therapy and the lack of sophisticated therapy equipment available to apply the therapeutic protocol in clinical practice. It was his desire to create a modern extension traction therapy system utilizing advanced technology to provide doctors and patients with effective and comfortable structural correction solutions. In 2005 Nichols Therapy Systems, LLC was formed to research & develop the iTrac® Extension Traction Therapy System. iTrac® utilizes computer controlled pneumatics to achieve measurable, consistent structural spinal correction.

Dr. Nichols is pleased to work with Pivotal Health Solutions to offer clinical support to doctors world-wide as they advance the level of care offered to their patients through the utilization of iTrac® Therapy.

- **Introduction**

- This product guide provides information to help chiropractors and physical therapists understand the features and benefits of the iTrac® Therapy System.

- **For clinical questions, email Dr. Nichols at: drnichols@nicholschiropractic.com**

- **Target Audience**

- The target audience is progressive doctors and therapists that have a desire to be on the cutting edge of physical medicine and rehabilitation. The clinician purchasing an iTrac® system will be the professional committed to providing patients the highest level of structural spinal correction available.

- **Safety**

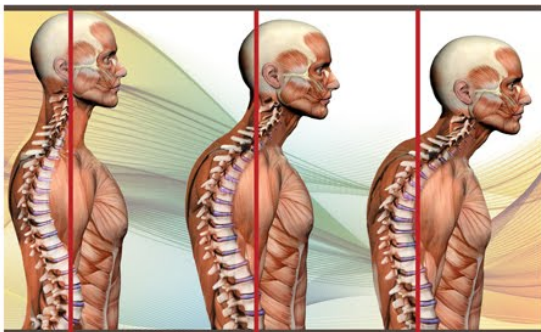
- The iTrac® Cervical Traction System is cleared by the U.S. Food and Drug Administration (K131983)

- **Specifications**

- General
 - Dimensions: 42" L x 30" W x 52" H
- Technical
 - Rated Voltage: 120 V or 230 V
 - Rated Frequency: 60 Hz
 - Current: 10 A
 - Electrical Class: Type 1 Class B
 - Duty Cycle: 1 min. On 9 min. Off

- **The Need for iTrac® Therapy**

- Most chiropractors and physical therapists provide manipulation, mobilization, manual therapy, massage and active muscular rehabilitation to address cervicogenic conditions such as neck pain, headaches, migraines, TMJ disorders, upper back pain, etc. These treatments are beneficial for improving the function of the neck but research has shown they do nothing for improving its structure. Recognizing that the majority of chronic cervicogenic conditions are caused by underlying structural abnormalities in the neck, it can be deduced that structural correction of these abnormalities, utilizing cervical extension traction therapy, is vital to the successful long-term resolution of these conditions. Physical medicine specialists have not had modern treatment technology available to effectively and comfortably deliver cervical extension traction therapy to their patients, until now. iTrac® Therapy comfortably and effectively delivers structural correction of abnormal neck curve and Forward Head Posture (FHP) to patients, which in turn, enhances the effectiveness of the functional therapies currently be utilized by chiropractors and physical therapists. By combining structural therapy with functional therapy, practitioners are now able to consistently and confidently offer patients long-term solutions for their cervicogenic conditions.
- Patients not only want to feel better fast, but they want to feel better for many years to come. By incorporating iTrac® Therapy into any existing functional treatment protocol, clinicians can expect improved healing, long-lasting symptomatic relief and superior quality of life improvement for their patients.



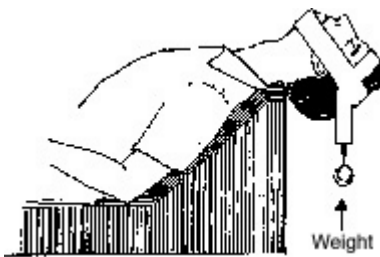
- **More About Forward Head Posture (FHP)**

- Forward Head Posture is an epidemic that is becoming more prevalent across all age demographics in modern times due in large part to our increasing use of hand-held digital devices, laptops, etc. that force us to maintain a "head-forward" or "flexed-head" posture for extended periods of time.
- FHP is one of the most common abnormal postures in our society. It is estimated that ninety percent of the U.S. population has a diagnosable degree of forward head posture.
- Using the simplest definition, FHP is described as carrying the head forward of the center of the shoulder. As the head moves forward, the body's center of gravity shifts and causes the upper body to drift backward which in turn causes the shoulders to slump forward.
- The head should be positioned over the body in such a way that from the side, the ear lobe is centered directly above the center of the shoulder.
- With FHP, posterior neck muscles have to work much harder to keep the head (chin) from dropping forward onto the chest.
- For every inch the head moves "forward", the resultant force exerted on the muscles of the neck, shoulders and upper back is equivalent an additional 10 lbs. In other words, the muscles of a patient who exhibits 2 inches of FHP must support a load of 20 lbs in addition to the normal weight of the head. This forces those muscles to remain in constant contraction which leads to a chain reaction of: chronically tight neck and shoulder muscles » muscular trigger points » increased pressure on the nerves, discs and joints of the spine » cervicogenic conditions.
- *FHP cannot be corrected by simply "standing up straight".
- *FHP cannot be corrected long-term by exercise alone.

- Common causes of FHP
 - Looking down while working on a computer, texting, or reading
 - Laying on back with an overly-large pillow under the head
 - Carrying a backpack or heavy purse slung over the shoulder
 - Driving with the head more than 2 inches away from the headrest
 - Sitting improperly with shoulders rounded and back hunched

- **A Review of the Predicate Equipment & Methodology**

- Historically, most professional therapy intended to correct abnormal neck curve and forward head posture has been provided by chiropractors and physical therapists via commercially available equipment that utilized suspended lead or iron weights to exert traction forces on the patient's cervical spine (example shown is typical). While the science supporting cervical curve restoration refers to incrementally adding small amounts of weight throughout the treatment to maximize the therapeutic benefit, that same research notes that such effort was impractical in a real-life office setting due to the high demand this placed on busy chiropractic/therapy assistants. Therefore, patients were routinely subjected to fast traction load application which resulted in muscle guarding and discomfort, both of which are counterproductive to the therapeutic goals of extension traction.



- **Features, Benefits and Limitations of Rope, Pulley and Weight Machines**

- Features
 - Simple in design
 - Low price
 - Low tech
- Benefits
 - Capable of delivering traction force to the cervical spine
- Esthetic Limitations
 - Visually intimidating
 - Visually antiquated in appearance
 - Unacceptable to many younger clinicians wanting to bring a fresh look and feel to chiropractic and physical therapy
- Functional Limitations
 - Immediate application of full traction weight often results in muscle guarding, limiting effectiveness of the therapy
 - Inability to effectively regulate, measure and monitor traction angle and force application due to a lack of standardization among these traction devices

- **Features and Benefits of the iTrac® Therapy System**

- iTrac® delivers proven extension traction therapy protocols to doctors and their patients in a technologically advanced manner. Features and benefits of the system are listed below.

- Features

- Variable Rate Progressive Traction™

- Computerized progressive application of traction forces

- Reduces/Eliminates “muscle guarding”
 - Improves comfort
 - Increases patient compliance
 - Maximizes therapeutic benefit
 - Eliminates human error in force application

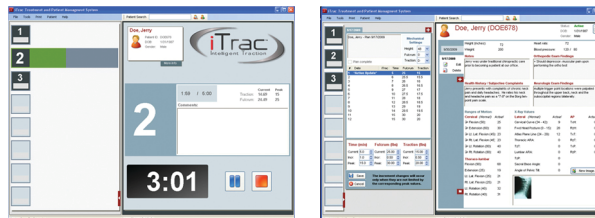
- Modern presentation of state-of-the-art technology

- Clean, ergonomic design results in greatly improved office space efficiency
 - High-tech system is very appealing to doctors of every age demographic
 - Self-contained – requires only standard 110V electrical power

- Versatility

- The iTrac® Therapy System offers 60 unique combinations of traction angle settings allowing the physician to create treatment plans that precisely match each patient’s unique needs
 - The system’s computer controlled pneumatics provide infinite traction force and time combinations and enable virtually effortless modification of treatment plans
 - Once a treatment plan is created by the physician, an employee/assistant can easily and accurately administer the treatments with minimal training required

- Software Features



- **Patient Exam Tool** with specific fields for diagnostic findings, comment(s), history, notes and all pertinent Range-of-Motion values.
 - The exam tool also provides dynamic image management allowing x-rays and other images or documents to be automatically thumbnailed and linked to the patient file for full viewing at any time
 - **Patient Education Tool** automatically generates a refined animation comparing the patient’s exam range-of-motion values to the ideal range-of-motion values they might achieve following successful therapy
 - **Treatment Plan Tool** allows the clinician to quickly and easily create an initial 12-visit treatment plan that corresponds with the unique needs of the patient. The system automatically delivers the next successive treatment to the patient, then records that specific treatment data in the patient file.

- Following the successful completion of the initial 12-visit treatment plan the clinician can choose to either extend the current plan to 24-visits or create an entirely new 12-visit plan.

- **Treatment Recommendation Report Tool**



- lets clinicians compile exam, x-ray and treatment recommendation information into an easy to read document that can be presented to the patient during a report of findings to objectively validate the need for care.
 - This report can also be sent to referring physicians to effectively communicate exam findings and treatment recommendations.
- **Progress Report Tool** quickly harvests and assembles pre- and post-treatment exam and x-ray information into a professional document that displays the patient's progress following a series of iTrac® treatments.
 - This report can also be sent to referring physicians to objectively demonstrate the patient's improvement following the successful completion of his/her treatment plan.

- **Benefits**

- Precise computer control results in consistent, repeatable treatments and reduces the risk of human error
- State-of-the-art, ergonomic design enhances a modern office environment and improves patient compliance and comfort. Compact footprint allows maximum utilization of valuable office space
- Digital data processing and file storage allows instant development, administration and viewing of patient treatment plans. This feature allows the doctor to easily and quickly modify and edit an existing treatment plan
- Variable Rate Progressive Traction™ specifically designed to match the viscoelastic property of soft tissues maximizes patient comfort and effectiveness of traction treatment by dramatically reducing the amount of stress-relaxation exhibited by the soft-tissues being treated
- Effective patient management software allows the doctor to record and monitor patient progress and easily enter and retrieve exam and x-ray information
- Valuable Report Tool allows doctors to print professional treatment recommendation reports and progress reports at the touch of a button to effectively communicate with patients and referring physicians.

- **How iTrac® Extension Traction Therapy Works**

- iTrac® extension traction therapy primarily targets the large ligament (anterior longitudinal ligament) that supports the front of the spine by exerting precisely directed counterbalancing forces into the cervical region of the spine.
- The viscoelastic nature of ligaments allows them to change shape/length when a series of sustained loads are applied in a manner that stretches them beyond their normal functional limit.

- This is the same principle utilized by orthodontists to change the position and alignment of teeth.
 - Changing the shape/length of the anterior longitudinal ligament allows the neck curve to be restored to its normal shape and in the process reduces forward head posture.
 - **Who Is A Candidate For iTrac® Extension Traction Therapy?**
 - **Patients with Forward Head Posture (FHP)**
 - Forward Head Posture is a key indicator that iTrac® Therapy is warranted.
 - A simple posture analysis can determine whether or not a patient exhibits FHP.
 - Posture analysis is a particularly valuable tool for clinicians who don't offer x-ray services in his/her clinic.
 - FHP, in and of itself, is enough to validate the need for iTrac® Therapy.
 - It is estimated that 90% of the U.S. population has a diagnosable degree of Forward Head Posture (FHP) leading to common cervicogenic conditions such as:
 - Headaches
 - Migraines
 - Neck pain
 - TMJ disorders
 - Upper back pain
 - Shoulder pain
 - Carpal tunnel
 - Arm/Hand pain and numbness
 - Therefore, 90% of patients walking through the door of any clinic may be suitable candidates for iTrac® Therapy based on posture alone.
 - **Patients with Abnormal Neck Curve**
 - FHP is often accompanied by an abnormal cervical curve.
 - Abnormal cervical curve (cervical hypolordosis or kyphosis) is another significant factor that establishes the need for iTrac® Therapy.
 - A standing neutral lateral (side-view) cervical x-ray is necessary to determine the true structural alignment of the cervical spine.
 - X-ray analysis is a particularly valuable tool for clinicians who want to offer his/her patients the most objective exam data supporting the need for iTrac® Therapy.
- **Practice Management**
 - **What CPT code is used for iTrac® Therapy**
 - 97012 – Mechanical Traction
 - **How many treatments are required?**
 - The frequency of iTrac® Therapy treatments in the “corrective” phase of care is generally most effective when utilized at a frequency of 3x/week for 4-12 weeks. However, it is up to the physician to determine what best suits his/her patient based the clinical presentation of the patient.
 - An average treatment lasts 12 minutes.
 - Progress exams can be performed at the conclusion of each 12 visit series or at a frequency consistent with the clinician's standard re-exam protocol.
 - Once the desired neck curve and posture changes are achieved, the patient may be progressed to a “maintenance/supportive” phase of care which entails periodic

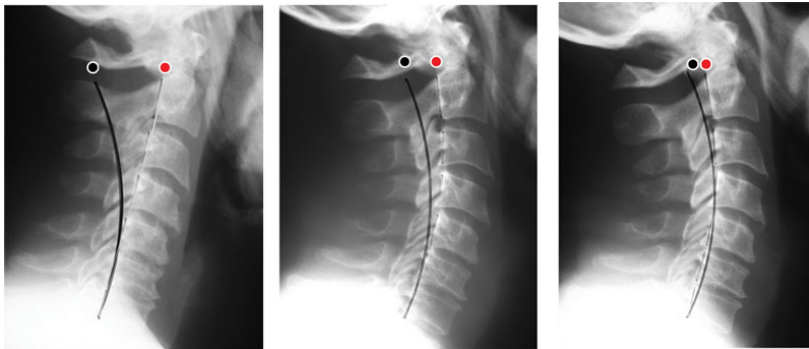
iTrac® Therapy treatments ranging from 1x/week to 1x/month depending on what the clinician determines to be most suitable for the patient.

- An average supportive iTrac® treatment is 8 minutes.
- iTrac® provides clinicians an objective purpose for recommending ongoing supportive care to his/her patients.
- Once patients experience iTrac® Therapy they understand the benefit of ongoing supportive care to eliminate the opportunity for his/her condition to relapse and for symptoms to return.

○ **Integrating iTrac® Therapy into an existing practice**

- iTrac® is not intended to replace existing clinical treatment protocols. Rather, it is designed to be an adjunct therapy to existing treatment protocols in chiropractic and physical therapy clinics to maximize therapeutic benefit to the patient.
- iTrac® is a passive therapy designed to reduce Forward Head Posture and restore the cervical curve. When combined with a traditional protocol of manipulation, mobilization, muscular strengthening, and massage (or any combination of these) the therapeutic outcomes are maximized.
- iTrac® offers existing clinics an opportunity to diversify their service offering and enhance their ability to effectively treat chronic, posture-related cervicogenic conditions.
- iTrac® creates an opportunity for clinics to maximize patient volume and revenue without requiring additional doctor time with the patient.
- The user-friendly iTrac® software interface allows clinicians to quickly create unique treatment plans that are easily administered by clinical assistants. No extensive training is required. Therefore, very little time is required of the doctor and staff to successfully add iTrac® Therapy to his/her existing treatment protocol.
- High volume clinics can operate up to eight iTrac® devices simultaneously from a single iTrac® computer.
- iTrac® requires no change in a clinic's external marketing plan to attract a new patient demographic because the patients who need it already exist within the practice's patient base.

○ **What will iTrac® Therapy do for your patients?**



- Deliver effective posture correction and improved functional outcomes
- Provide significant symptomatic relief and enhanced quality of life

