Quantifying pain to lead the path to wellness
BioTraceIT™ values the capacity to improve medical care and interventions by quantifying pain ultimately impacting quality of life and wellness. BioTraceIT™ focuses on novel technologies at the cutting edge of wearable health care. We deem new solutions as paramount to new paradigms.

Back up and running.

By measuring pain, we quantify wellness.
BioTraceIT™ is patented technology that quantifies, tracks and assesses pain. We’re revolutionizing pain management for people and animals.

BioTraceIT™ offers a wearable monitor that quantifies pain using skin-mounted sensors that measure processing of pain signals by the nervous system – much like an ECG. Research in canine, equine, and human patients has proven the ability of PainTrace® to quantify pain.

At present, there is no device or method available which can measure a patient’s level of pain. The exception to this statement is BioTraceIT™’s patented technology behind the PainTrace® device, which has been independently proven to effectively quantify pain via measurement of central nervous system (CNS) activity. PainTrace® can provide both real-time instantaneous pain measurements and pain monitoring over longer periods, such as months or years.

PainTrace® is a hand-held device which utilizes disposable ECG-like sensors to obtain a real-time numerical pain reading. General veterinary visits, osteoarthritis exams, surgical interventions, and preventative measures will all benefit from PainTrace®’s novel, disruptive technology.

There is currently no pain measurement device for veterinarians to evaluate patient health, recovery, and monitor wellness over time. For animals, without the ability to verbalize pain, veterinarians must rely upon observation and known indicators of pain. However, animals often instinctively mask pain which increases the difficulty of evaluating pain levels, and the associated questions related to drug dosage, patient recovery, and effectiveness of treatments. The use of PainTrace® can not only quantify pain but improve early diagnosis and aid in guiding preventative measures and early interventions to promote wellness.
PRODUCT CAPABILITIES

PainTrace® provides a quantitative measure of pain via non-invasive, simple, fast application of disposable sensors to the skin. Product application entails shaving of excessive hair if required; adhesion of sensors; and a minute to calibrate. Bluetooth technology combined with data acquisition software allows veterinarians to monitor pain levels real-time. Apps are in development for smartphones and tablets.

PainTrace® delivers an instantaneous pain measurement. Using the PainTrace® scale:

- More Pain Equals A More Negative Number
- A Positive Number Equates To No Pain (or increasing levels of wellness).

EXAMPLE DATA

The following examples, in both canine and equine patients, represent data during clinic visits or over a 6 month post-surgical follow-up.

PAIN MONITORING DURING EXAM

CANINE

Greyhound presented with inflamed digit of left forelimb. The dog did not respond to the veterinary exam, and appeared to be masking pain. PainTrace® was utilized and it became evident pain was experienced upon weight bearing on the affected left foot and ambulation demonstrated shoulder involvement. The following describes the PainTrace® data below and the associated exam:

- Minor discomfort during right forelimb exam
- Pain (based on negative deflection) during left forelimb exam
- Noted pain when dog weight bearing on left forefoot; generally was “guarding” foot
- Shifted weight to forelimbs to increase weight bearing on left forelimb; observed broadening of “pain peaks”
- Walked dog and noted increased pain during left forelimb weight bearing and suspected foot and shoulder
- Pain (based on negative deflection) upon left shoulder exam. No pain during right shoulder exam.
- Pain (based on negative deflection) during walk back to exam room.
ZOOM-VIEW OF NAIL CLIPPING, TO QUICK, UNDER ANESTHESIA

We were surprised that pain would breakthrough the anesthesia during nail clipping, and further surprised when every digit on every paw elicited pain. Although cutting to the quick would affect the nerve and cause high pain levels.

PAIN DURING DENTAL CLEANING AND NAIL CLIPPING, TO QUICK, UNDER ANESTHESIA

CANINE

Dog was placed under anesthesia for dental cleaning and removal of growth on the lower eyelid. During anesthesia an aggressive nail clipping was also undertaken due to the dog’s resistance to nail clipping while awake.

The following describes the PainTrace® data below and the associated procedure under anesthesia:

- Nail clipping on all four paws; pain experienced based on negative deflection (zoom-view of all four paws in second data set to the right)
- Dental cleaning; pain experienced based on negative deflection – Dental pain rivals intense neuralgia due to high density of nerves
- Removal of growth from lower lid from incision to sutured closure; no pain detected
- Veterinary checked dental probing gums, scalpel irritation at end of check detected

POST-SURGICAL PAIN MONITORING OVER MONTHS

EQUINE

The following data represents a 15 year old horse with laminitis. To alleviate pain the nerves were cut to the affected foot. Pre-surgically pain was measured and the pain levels were monitored post-surgically for six months.

- You can see pre-op pain levels were -22 this was on a bad day
- 2 days post-op a -45 pain level reflects more pain from the chronic pain plus surgical pain
- 10 days post-op the horse is recovering at a -5 reflecting less pain than the pre-operative levels
- 18 days post-op no pain at +9. Any positive number reflects the absence of pain. The more positive the number the greater the level of wellness
- 25 days post-op +4 at the end of the first day out of the stall; some fatigue is registered
- 6 months post-op +9. A PainTrace® reading of +9 was the average reading for this horse post-surgically
BioTraceIT™ has developed a technology for non-invasive and continuous pain monitoring. PainTrace® products comprise a compact medical device, consumable sensors and wearables, and software. BioTraceIT™’s PainTrace® medical device measures pain through the acquisition of direct biosignals that quantify the nervous system’s response to pain. The device provides an instantaneous, real time, numeric readout indicating a level of pain (or the absence of pain).

A PainTrace® reading from start to finish takes less than 5 minutes; training for use is less than an hour; and the cost of the device and consumables has been deemed reasonable based on veterinarian feedback. PainTrace® delivers a compelling value proposition for veterinarians with annual profits to the veterinarian upwards of $20,000 from a single PainTrace® device implemented into patient visits.

Disposable sensors provide continuing revenues to both the Company and the practicing veterinarian. Although financial projections are synopsized below, detailed cash flow sheets for BioTraceIT™ and the positive economic impact for a veterinarian are available, and may be shared upon request.

More recent studies further support the customer’s interest in their pet’s wellness and their willingness to pay for services. The total number of veterinary visits increased 4.9 percent (during a recession) from 193.0 million in 2006 to 202.4 million in 2011. Total veterinary visits for dogs increased over 9 percent. Total veterinary expenditures for all pets increased 14.3 percent from $24.5 billion in 2006 to $28 billion in 2011. The CPI increased 11.6 percent. The mean expenditure per dog increased from $200 to $227 and the mean veterinary expenditure per cat increased from $81 to $90. All of these factors plus an increasing incidence of diseases, e.g. zoonotic diseases, support the adoption of PainTrace®, AAHA accredited hospitals must evaluate pain at every patient visit. The AAHA/AAPF Pain Management Task Force stated, “Pain should be thought of as the fourth vital sign – after temperature, pulse, and respiration – and integrated into all patient evaluations.” Without the ability to verbalize a condition, the assessment of pain is much more difficult.

PainTrace® will also provide a significant revenue stream for veterinary offices. Using conservative assumptions and regular usage, PainTrace® annual revenues and costs can generate a significant profit to the veterinarian. A full breakdown of the projected revenues and operational expenses is available upon request.

In 39 years of training thoroughbreds this is the only thing I have seen that can accurately detect both pain and pain relief in a horse. I do not like to race any horse in pain and it is often hard to tell with minor injuries. BioTraceIT™’s device removes the guesswork and even lets you follow the animal’s recovery with a simple, inexpensive procedure that anyone can administer in a few minutes.

Don Combs
Kentucky Derby winning trainer
Market / Sales and Distribution

In the U.S. animal market, veterinary market sales will be implemented by a direct sales force along with the appropriate internal support teams. Additionally, several distributors have been identified to complement BioTraceIT™’s sales team and leverage existing relationships. Discussions with major veterinary diagnostic and pharmaceutical companies are also in progress for proposed partnerships. The animal market sales force will first target larger animal hospitals. Initial market entry will focus on two major applications: surgical interventions and osteoarthritis exams and treatment, which will aid in appropriate pharmaceutical usage and support preventative diagnostics of chronic disease such as OA.

Several studies supporting use of PainTrace® are initiated. Application of PainTrace’s real-time pain monitoring will support physical exams to evaluate diseases such as osteoarthritis and preventative evaluate joint health. Currently, veterinarians rely upon reaction of the patient to manipulation without a distinct and quantifiable measure. As the BioTraceIT™ sales force expands, thought leaders and increasing studies communicate the value of the PainTrace® pain monitoring system. Increasing data will transform PainTrace® from a quantitative measure to a completely objective measure of pain via the analysis of collected pain measures and patient demographics. The equine market is an additional source of sales. Wireless technology will allow for pain levels to be measured before, during and after exercise to determine when the horse is fit to resume training or has undetected pain. Case studies have demonstrated PainTrace® can additionally provide earlier detection of labor pains as well as early diagnosis of heaves and colic.

Production

The company has third party contractors to manufacture the PainTrace® device, and consumables - sensors and the wearable enclosures.

Competition

As referenced earlier, PainTrace® acquires a direct biosignal from the nervous system and converts that signal into a quantitative measurement of pain. No other product, in either the animal or human market, either currently for sale or currently being developed is known to utilize technology similar to BioTraceIT™. We have dedicated a significant amount of research to evaluating potentially competitive technologies. All current approaches appear to lack the capacity to detect the absence of pain.

Current claims to objective pain measurement in the veterinary diagnostic market include “Voyce Pro” dog collar from i4C Innovations and PetPace collar for cats and dogs. Both devices use sensors in the collar to measure readily available vital signs including: temperature, pulse, respiratory rate, activity level, and body position. By evaluating activity levels, information is extrapolated to relate to pain measurement. Other technologies that also extrapolate data to provide an objective pain measurement include gait analysis; where the amount of weight bearing correlates to pain levels. Gait analysis requires larger equipment and is predominantly appropriate for laboratory research not typical veterinary practice diagnostics or at-home monitoring. No one, in either the animal or human market, is measuring the distinct pain biosignal which is the core of the PainTrace® technology.

Competitive Advantages

PainTrace® provides real-time pain measurement and monitoring:
- PainTrace® provides superior sensitivity and specificity. Potential competition demonstrated poor specificity which evidences limited ability to detect the absence of pain.
- Data demonstrates capacity to monitor pain over extended periods.
- Inexpensive, quick, easy to use solution for both point of care and telemedicine.
- Electronic Health Record compatibility and Apps in next-generation device.
- PainTrace® provides an excellent value proposition for veterinarians.
Deborah Dullen
PRESIDENT AND COO
Deborah is the co-founder of the BioTraceIT™ team, formed in 2014. She brings over twenty years of experience in both the biotech and medical device fields with expertise in business development, sales, research and development, and global market entry. Deborah has worked for J&J DePuy-Synthes and Eli Lilly in both market development and clinical research roles. She has worked with thousands of medical device sales representatives resulting in a broad global business network. She has also founded other successful startups, including Imtakt Corporation, which continues to thrive. Her skills are key in transforming the company from an R&D entity into a marketed medical device company offering valuable tools to the medical community. Prior to forming BioTraceIT™, Deborah’s consulting group worked with Cardinal Health.

Leonard J. Shore
VICE PRESIDENT AND GENERAL COUNSEL
Leonard Shore is an attorney with over 30 years of experience in the private sector and was involved with the predecessor company. After issuance of the patent in October, 2013, Leonard and Deborah teamed to form BioTraceIT™, which acquired the assets of the predecessor company. Mr. Shore has acted as general counsel (and investor) to several high-tech startups. He has been general counsel to four companies which became publicly traded (OTC) entities, including Nastech Pharmaceutical, one of the first companies to seek FDA approval to utilize nasal delivery of recognized pharmaceuticals.

John J. Picchiottino
DIRECTOR OF ENGINEERING (MSEE)
Mr. Picchiottino has been an electrical engineer associated with the development and manufacturing of biofeedback devices since 1969. He worked closely on PainTrace® for many years. In his FDA registered manufacturing facility, designed and constructed the current PainTrace® device. Mr. Picchiottino has agreed to re-join the company and collaborate with current engineering staff in the development of the next generation device.

PARTNERSHIPS WITH ANIMAL HEALTH COMPANIES SOUGHT
BioTraceIT™ is seeking strategic partnerships to support product manufacture and entry into the market.

Management Team

Deborah Dullen
PRESIDENT AND COO

Leonard J. Shore
VICE PRESIDENT AND GENERAL COUNSEL

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