Compremium

# A New Standard for Soft-Tissue Assessment: Objective | Non-Invasive | Reproducible

**CPMX1 closes the gap in soft-tissue evaluation, giving clinicians reliable data to support critical decisions.**


White Paper

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# Introduction:
# The Need for Better Soft Tissue Assessment in Musculoskeletal Care

Soft tissue health is crucial to recovery after musculoskeletal injury or surgery, as factors like swelling, blood flow, or delayed healing can mean the difference between a smooth recovery and long-term complications. Yet clinicians currently lack a reliable, non-invasive way to monitor it. CPMX1 fills this gap by providing a non-invasive, objective, real-time data on soft tissue status, enabling earlier intervention and reducing procedural risks. This technology enhances clinical decision-making and supports value-based care by improving outcomes, efficiency, and safety for patients.

Clinical decisions in musculoskeletal trauma often hinge on the condition of soft tissue. The current standard relies heavily on subjective palpation or invasive pressure measurements: approaches that can be limited in reliability, reproducibility, and patient comfort, with outcomes frequently affected by the level of clinical experience. In many acute settings, clinical assessments are commonly performed by less experienced healthcare providers such as residents. The gap in today's routine care leads to uncertainty regarding surgical timing, inconsistent management strategies, and an increased risk that interventions may occur too early, resulting in unnecessary procedures like premature fasciotomies, or too late, potentially allowing complications to progress and compromise patient outcomes.

Effective soft tissue management is essential in perioperative care, where tissue condition guides surgical readiness and shapes postoperative outcomes. Injuries such as high-energy tibial plateau fractures often result in significant swelling, blistering, or compromised skin integrity, making temporizing stabilization necessary until tissues improve. The AO Foundation, recognized globally as an authority in orthopedic trauma, emphasizes that "every fracture treatment starts with soft tissue management." This principle reflects their position that careful assessment and care of soft tissue are critical determinants of patient outcomes following musculoskeletal injury. Prioritizing soft tissue management helps reduce infection

risk, supports optimal healing, and improves surgical results, setting the foundation for best practices in fracture care (1). Supporting this perspective, Borrelli concluded in his study that “significant soft tissue injuries generally accompany high-energy tibial plateau fractures. The successful management of the soft tissues surrounding the proximal tibia in the pre-, intra-, and postoperative periods is nearly as important as the accurate and thoughtful treatment of the displaced fracture.” Operating before adequate tissue recovery raises the risk of complications, infection, and poor healing, while unnecessary delays can prolong recovery and increase costs (2).

Regulatory and clinical experts agree that accurate and timely assessment of compartment pressures is crucial for patient safety and optimal outcomes in limb compartment conditions. The FDA‘s Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee met on September 9, 2020, to evaluate the regulatory classification and safety standards for intracompartmental pressure monitor devices. The panel emphasized the value of monitoring approaches that minimize procedural risks, reflecting a general trend toward non-invasive solutions in clinical practice. The panel recognized the important role these devices play in helping clinicians detect and manage compartment pressure-related complications in a timely and effective manner, especially among patients with co-morbid conditions and those unable to reliably communicate symptoms (3).

The CPMX1 System (Compremium AG, Switzerland) was developed by doctors, for doctors, to provide a non-invasive, quantitative method for assessing soft tissue compressibility across diverse clinical settings. In this white paper, acute compartment syndrome (ACS) is highlighted as a high-stakes reference condition because it is well-studied and underscores the importance of timely, accurate soft tissue evaluation. While ACS serves as a case example, CPMX1’s clinical utility extends to a wide range of perioperative and acute care scenarios where objective assessment of soft tissue compressibility can support earlier recognition of complications, guide intervention timing, and improve patient management.

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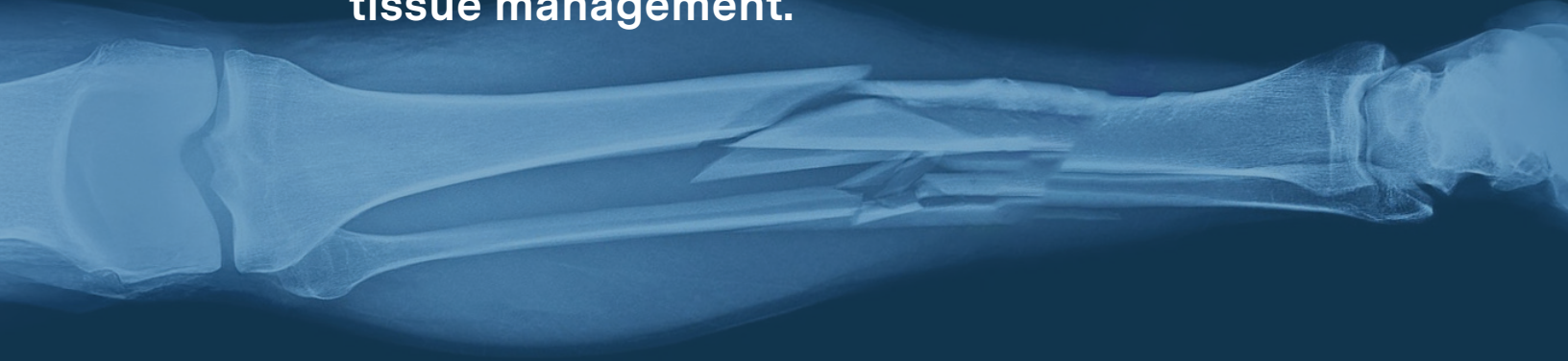

# From Research to Real-World Impact

A decade of rigorous research has laid the foundation to transform a scientific concept into a validated, FDA-cleared solution that delivers objective, non-invasive soft tissue monitoring for clinical use.

The scientific journey began with the recognition that invasive methods for measuring compartment pressures presented limitations, including variability, invasiveness, and patient discomfort. Early work by Large et al. in 2015 highlighted these challenges, noting significant interobserver variability in needle-based techniques (4). This prompted efforts to develop a non-invasive, objective alternative, ultimately leading to CPMX1.

Based on a clinical study using Compremium's prototype, Sellei et al. (2015) introduced the concept of soft tissue compressibility as a surrogate marker for pressure. This concept was subsequently validated in a series of follow-up studies, further supporting its reliability and clinical relevance. In cadaveric and in vitro models, they demonstrated a strong inverse correlation between elasticity and pressure, validating reproducibility with excellent intra- and inter-observer reliability (5, 6). These studies provided key building blocks to the body of knowledge that further informed the development of CPMX1. With this evidence as a foundation, Bloch et al. extended the research to animal models and confirmed that compressibility ratios accurately reflect changes in compartment pressure (7), further supporting the technology's clinical relevance. Human studies by Herring et al. demonstrated the feasibility of using dual-sensor probes for non-invasive pressure assessment in controlled environments (8). Marmor et al. built upon this work in a 2021 prospective clinical study involving 52 patients under general anesthesia before surgery. Their research established strong correlations between CPMX1 measurements and direct intra-compartmental pressures, with high intra- and inter-observer reliability (9, 10).

Since 2014

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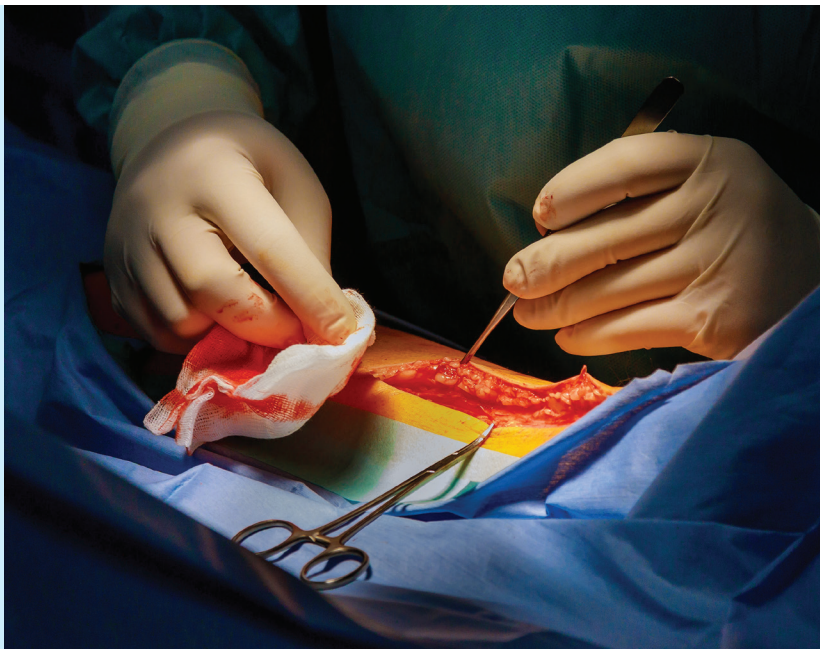
clinical studies support the reliability and utility of the CPMX1 System in musculoskeletal and trauma care.



Further studies extended these findings into trauma settings. Sellei et al. demonstrated that non-invasive compressibility measurements could reliably distinguish affected from unaffected compartments with high sensitivity and specificity. In their study, compressibility was significantly reduced in affected limbs compared to contralateral healthy limbs, showing a strong correlation with elevated invasive compartment pressures, both in clinically suspected ACS and high-pressure states without confirmed ACS. A relative compressibility value below 10.5% indicated a compartment at risk, while values near 5% signified confirmed ACS, with 95.8% sensitivity and 87.5% specificity (11, 12). The method also demonstrated high intra- and inter-observer consistency. Likewise, Anwander et al. validated the reproducibility of CPMX1 measurements in 60 volunteers, confirming strong agreement between experienced and less experienced observers (13).

In the prospective observational study Evaluation of Soft Tissue Compressibility for Assessment of Acute Compartment Syndrome (14), conducted at the University Hospital of Berne, Switzerland, 504 measurements were performed by four independent investigators to validate the inter-rater reliability of the novel, non-invasive compressibility method. The study yielded an **intraclass correlation coefficient (ICC) of 0.911**— demonstrating **excellent reproducibility**, confirming the previous scientific studies and the method's robustness for clinical application. The strength of these results was so compelling that they served as the scientific foundation for FDA approval, which was granted in just 82 days after submission.

In a 2023 prospective study, Sellei et al. used pressure-related ultrasound to evaluate muscle compressibility in 25 pediatric patients with forearm fractures. The study found that even subtle differences in muscle swelling, undetectable by palpation, could be captured using this non-invasive method (15). This work supported the CPMX1 measurement principles applied in trauma and recovery monitoring in pediatrics. This work helps illustrate CPMX1's potential to be used across the full range of age groups.

Reviews by Novak et al. recognized the potential of non-invasive ultrasound-based methods as objective tools for assessing compartment-related conditions, identifying CPMX1 as the most promising technique currently available (16, 17). These reviews synthesized evidence supporting the measurement principles underlying CPMX1. Van Heeswijk et al. further demonstrated the relevance of ultrasound-guided compressibility techniques in sports medicine by evaluating 35 healthy volunteers, providing additional support for the scientific foundation of CPMX1's technology (18).

# Objective Metrics at the Core: CP-Value and CP-Quotient Fueling CPMX1

CP-Value and CP-Quotient provide objective, real-time measurements of soft tissue compressibility. These parameters are intended to assist clinicians in real-time informed decision-making and monitoring changes over time.

In daily clinical practice, decisions regarding soft tissue management, such as timing of surgery, monitoring post-injury recovery, and identifying complications, are often made without objective data. This is where CP-Value and CP-Quotient provide a critical advantage. These proprietary parameters form the foundation of the CPMX1 system and are designed to give clinicians real-time, quantitative insights into soft tissue compressibility that cannot be obtained through palpation or current device solutions (Figure 1 and Figure 2).

## THE CP-VALUE - OR COMPARTMENT COMPRESSIBILITY VALUE

The CP-Value quantifies how much tissue compresses under controlled pressure, providing a standardized and repeatable measurement to guide decision-making. It is a numerical representation of the compressibility of soft tissue, calculated by measuring how much a compartment deforms under a defined external pressure. Using a combination of ultrasound imaging and precision pressure sensors, CPMX1 captures parameters to inform deformation response. A lower CP-Value indicates stiffer tissue with reduced compressibility, which may be associated with swelling, edema, or elevated compartment pressures. Conversely, a higher CP-Value reflects more elastic and compliant tissue with normal or recovering soft tissue status. This metric serves as an early indicator for changes in tissue condition, helping clinicians to track progression or improvement over time and to make informed, risk-based decisions regarding intervention, surgical timing, and ongoing patient management.

## THE CP-QUOTIENT - OR COMPARTMENT COMPRESSIBILITY QUOTIENT

The CP-Quotient standardizes assessment by comparing the CP-Value of the affected limb with that of the contralateral, uninjured limb. It is calculated as: CP-Quotient = CP-Value (uninjured limb) ÷ CP-Value (injured limb). This ratio offers a personalized, patient-specific reference, enabling clinicians to account for individual variability in tissue properties. In acute situations with one-sided soft tissue injuries, a significantly lower CP-Quotient may indicate increased compartment stiffness and a heightened risk for complications such as compartment syndrome.

Together, the CP-Value and CP-Quotient provide a robust, objective framework for assessing soft tissue health, enhancing the precision of diagnosis, monitoring, and surgical planning throughout the patient care continuum.

While the scientific foundation of CP-Value and CP-Quotient is strong, their clinical relevance is even more compelling. In a prospective study involving 16 patients at risk for acute compartment syndrome (ACS) (19), the CP-Quotient identified one patient who required fasciotomy and flagged two others as at risk. In one of those cases, the CP-Quotient normalized without intervention, helping avoid unnecessary surgery. This kind of personalized, real-time monitoring would not be possible without objective data. Usability and workflow integration were also evaluated. All clinicians in the study reported confidence using the system, describing it as intuitive and safe. No device-related adverse events or technical issues were observed. For clinicians, this translates into a tool that fits seamlessly into workflow, enhances interdisciplinary communication, and improves documentation quality.

CPMX1 provides objective measurements to accompany soft tissue assessment. These results are intended to complement other clinical parameters and patient context for comprehensive risk evaluation.

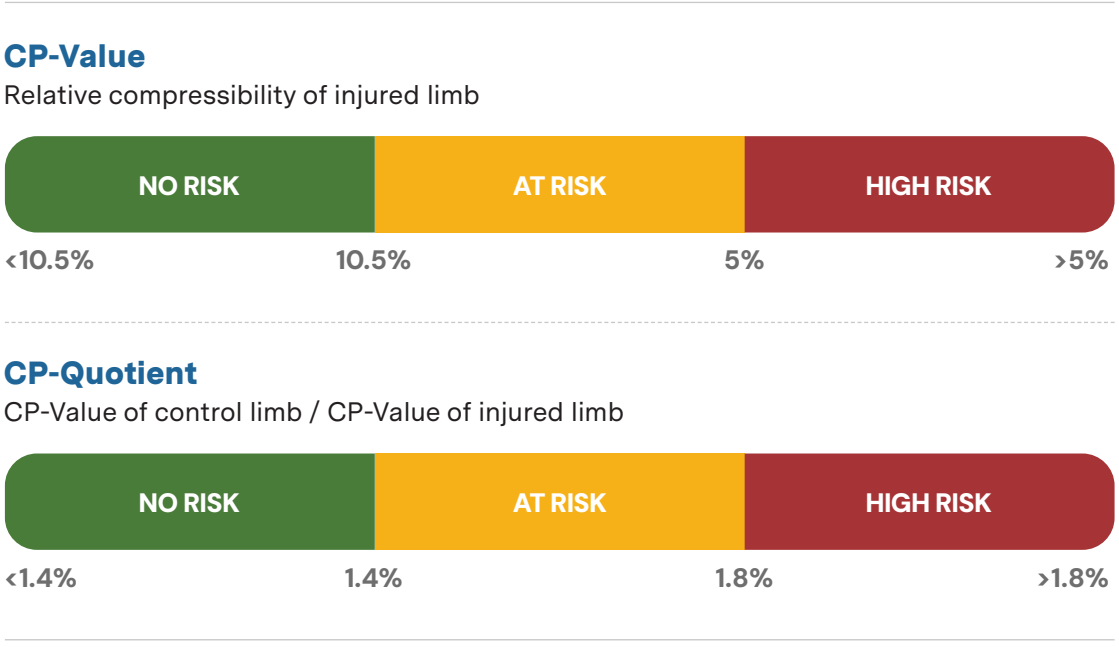



**Figure 1. CP-Value and CP-Quotient as Quantitative Indicators of Soft Tissue Compressibility and Risk Stratification.**

CP-Value provides a real-time measurement of tissue compressibility, while CP-Quotient compares readings from the injured and uninjured limbs to establish a personalized baseline. These measurements can be tracked over time to support more informed clinical decisions.

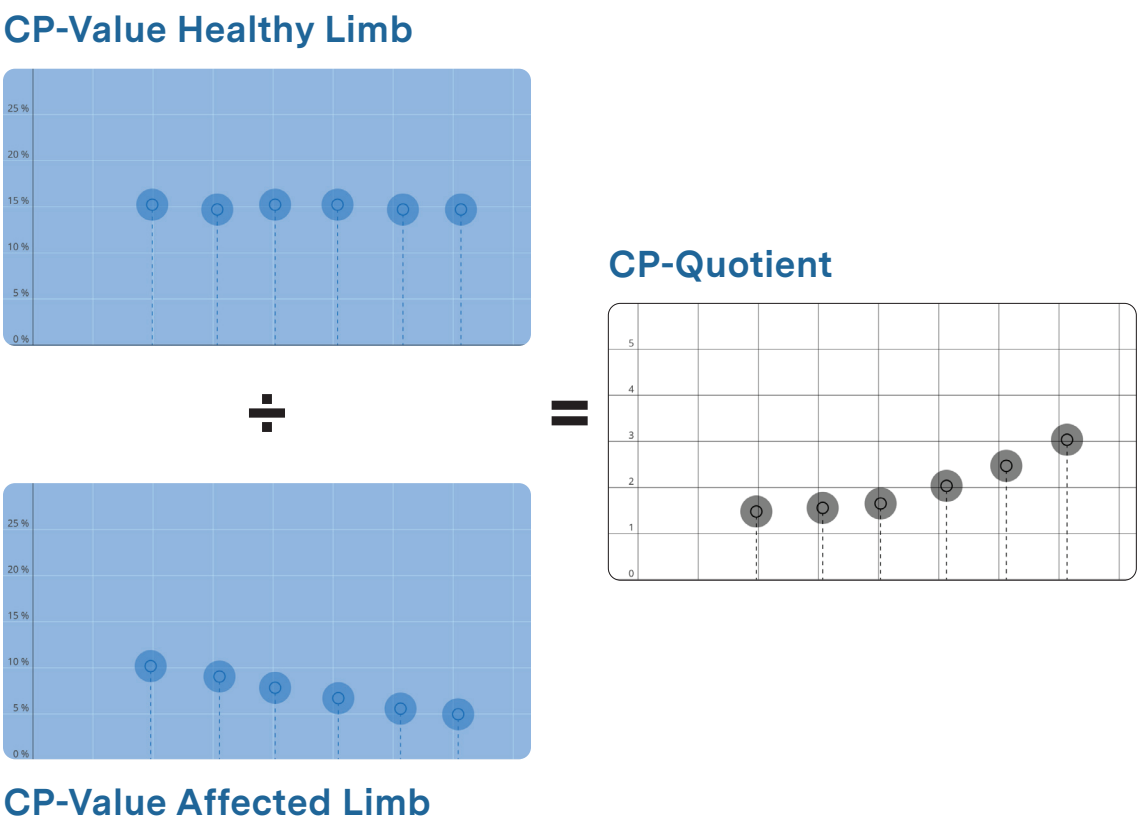
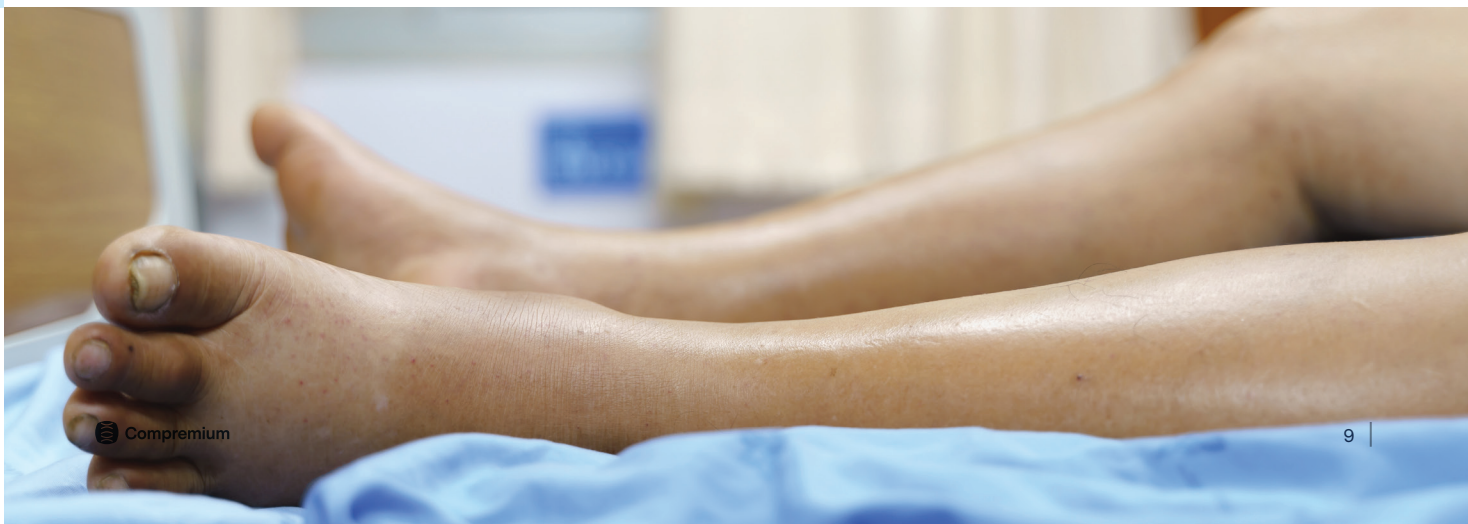



**Figure 2. CP-Quotient: A Bilateral Comparison to Support Clinical Decisions.**

Left Panels: Matched CP-Value measurements from the healthy and affected limbs at the same time points. Right Panel: CP-Quotient values (healthy ÷ affected) computed from each paired measurement and displayed in measurement order; the dashed line is a visual reference. Values closer to 1 indicate similar compressibility between limbs, while larger deviations from 1 indicate greater asymmetry.



# Economic Impact of Advanced Soft Tissue Monitoring

In value-based care models, hospitals are increasingly accountable for outcomes tied to complications, delayed diagnoses, and prolonged hospitalizations. Poorly managed soft tissue injuries, particularly those involving swelling and elevated compartment pressures, contribute to increased resource utilization, extended lengths of stay, medico-legal exposure, and higher costs for both providers and payers.

Evidence from literature shows that delays in timely intervention led to longer hospital stays, increased use of healthcare resources, and greater risk of complications. Technologies that enable earlier, objective assessment of soft tissue health, such as CPMX1, align with healthcare priorities to reduce avoidable complications, enhance clinical efficiency, and improve both patient outcomes and resource utilization. Soft tissue injuries, especially when complicated by elevated compartment pressures, impose a significant economic burden. Particularly, injuries leading to acute compartment syndrome (ACS) substantially increase hospital costs, length of stay, and the likelihood of additional surgical procedures. Avoidable complications, including medico-legal exposure from delayed or missed ACS recognition, add to direct hospital costs and extended care needs. Objective measurements may help support earlier recognition documentation.

Kantor et al. reported that tibial plateau fractures complicated by ACS were associated with a 2.85-fold increase in total treatment costs compared to fractures without ACS ($P < 0.001$), with ACS emerging as the single largest contributor to increased costs after adjusting for confounding factors ($r^2 = 0.57$) (20). Similarly, Schmidt et al. demonstrated that patients with tibial fractures and ACS had hospital stays three times longer and incurred more than double the charges compared to patients without ACS ($P < 0.005$ and $P < 0.00004$, respectively) (21).

Further economic modeling by Boyers et al. illustrated that missed or delayed diagnoses of ACS, leading to limb salvage procedures or amputations, can cost upwards of USD 53,736 per patient, while prompt diagnosis and intervention average just USD 6,313 (22). These data emphasize the critical financial consequences of delayed recognition and the value of early detection.

# Supporting Decision-Making and Team Coordination

By introducing objective compressibility measurements, CPMX1 equips clinical teams with a common reference point that improves confidence, communication, and continuity of care.

Beyond cost considerations, CPMX1 supports rapid decision-making in the time-critical setting of soft tissue injuries, including suspected acute compartment syndrome. In training environments where assessments may be performed by residents with varying experience, objective compressibility measurements provide reproducible data that reduce reliance on subjective palpation. This is especially valuable during night shifts or weekends when more experienced staff may not be available. By enabling on-duty teams to detect early changes, perform intermittent measurements as indicated, and escalate care using objective data, CPMX1 promotes timely, confident decisions and ensures continuity of care around the clock.

The CPMX1 solution also fosters interdisciplinary trust by introducing a shared, objective framework that enhances collaboration across emergency departments, trauma teams, orthopedic services, and perioperative care. Quantitative compressibility data supports more consistent communication and joint decision-making, breaking down silos and enabling aligned action across specialties.

# Conclusion: Raising Standards in Soft Tissue Assessment

CPMX1 redefines the standard for soft tissue assessment by delivering precision, speed, and confidence. With its objective and non-invasive technology, CPMX1 transforms clinical decision-making, giving healthcare teams the power to identify risk early, intervene effectively, and protect patient outcomes from uncertainty and complications.

FDA-cleared and already being integrated into US hospitals, CPMX1 is proving its value in real-world practice. It empowers clinicians with actionable data when timing is critical, shifting soft tissue evaluation from subjective judgment to objective measurement.

CPMX1 does not replace clinical judgment; it amplifies it, providing robust, quantitative insights to every bedside, every team, and every clinical decision.

For healthcare providers committed to delivering outcome-driven, value-based care, CPMX1 is the missing link. It closes the diagnostic gap and delivers what medicine demands: reliable answers, timely action, and better patient results. The future of soft tissue assessment is here. Bring CPMX1 to your practice and experience the transformation in patient care.

# Testimonials

*The CPMX1 System is able to monitor precisely, non-invasively muscle compressibility and tissue pressure. These reliable data are a big step forward in providing the best care for our patients in an urgent medical need.*

### Prof. Dr. med. Ulrich Stöckle

Executive Director Center of Muskulo-skelatal Surgery, Charité. President of German Society for Trauma Surgery.

*The concept of relative compartment compressibility is intuitively appealing, as it allows us to objectify and quantify what has traditionally been a manual, subjective examination.*

### Prof. Dr. med. Richard Sellei

Prof. Dr. med. Richard Sellei, Chief Physician in the Department of Orthopedics and Trauma Surgery at Sana Klinikum Offenbach. Since 2014, Dr. Sellei and his team have conducted extensive published studies in the field of Acute Compartment Syndrome that validate CPMX1's potential.

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# About Compremium

Compremium is a Swiss medical device company based in Bern, specializing in the non-invasive diagnosis of pressure-related conditions in the human body. Its proprietary measurement technology, which combines ultrasound imaging with pressure sensing, was originally developed by Dr. Ulrich Baumann. The company was founded in 2020 by Vincent Baumann and private investors to bring this innovation to market. The technology has been validated in more than 40 clinical studies and shows promise across over 30 medical indications.
Compremium received FDA 510(k) clearance for its lead tissue-assessment application CPMX1 for the following indication for use: “The Compartmental Compressibility Monitoring System (CPM#1) is intended for real-time and intermittent monitoring of relative compartment compressibility. The relative compartment compressibility (CP Value) is not meant for trend analysis.” 510(k) Number: K223509. Compremium plans further FDA and CE submissions in 2025. A prototype of the device has been in use aboard the International Space Station for eight years through a collaboration with NASA.

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