



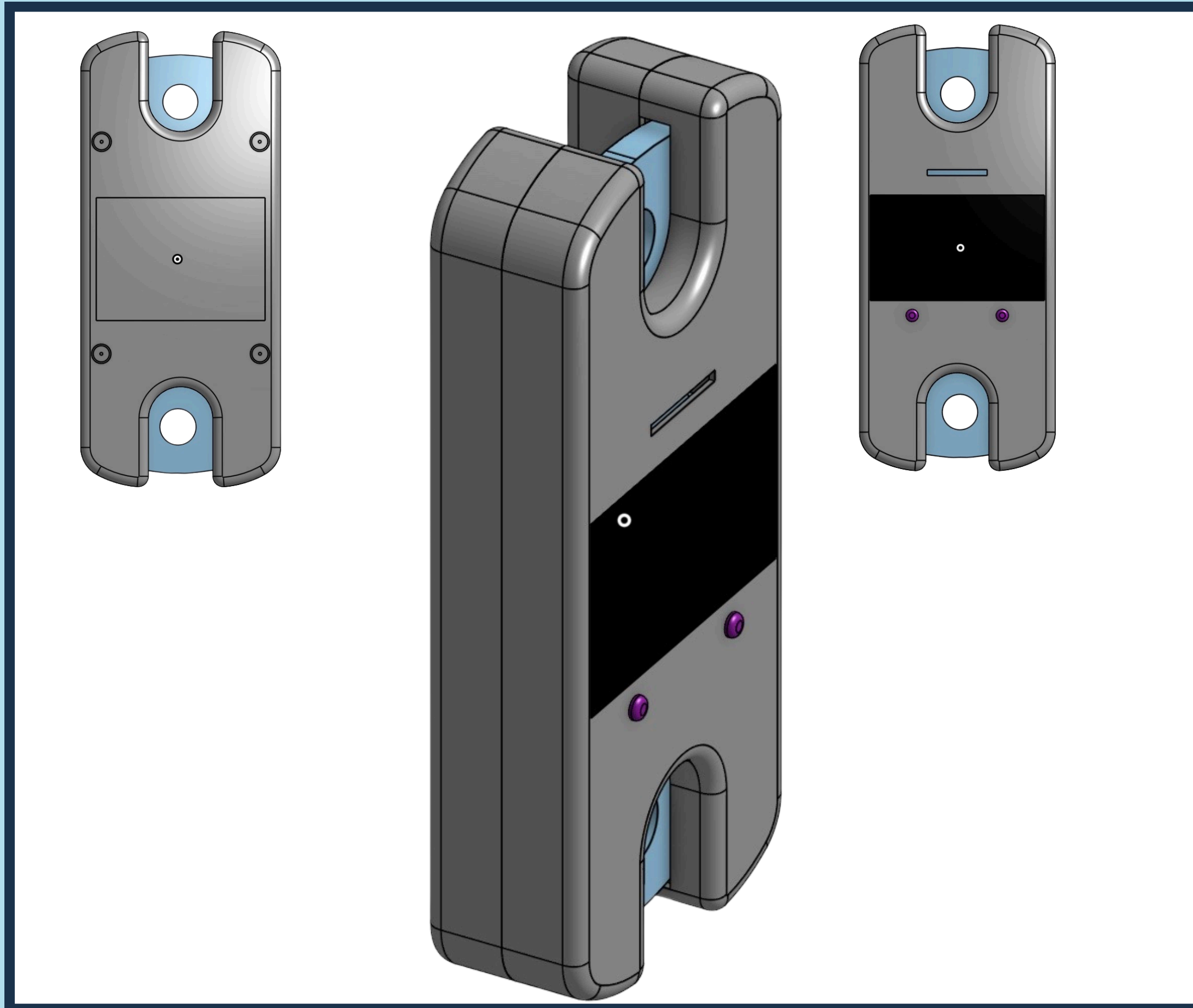
Scoliosis

- Scoliosis is a condition where the spine curves sideways, typically in an "S" or "C" shape.
- Affects about 2–3% of the population, most commonly adolescents.
- Severe scoliosis is usually defined as a spinal curve greater than 40–50 degrees.
- Can cause visible deformity, back pain, limited mobility, and in some cases, breathing or cardiac issues.
- Severe scoliosis often requires preoperative treatment, such as halo gravity traction, to gradually reduce spinal curvature and improve surgical outcomes.



SPINEALIGN  
Real-Time Monitoring  
Device for Halo Gravity  
Traction

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Halo Gravity Traction

- Halo Gravity Traction (HGT) is a preoperative treatment used to gradually straighten the spine in patients with severe scoliosis before surgery.
- It involves a halo ring fixed to the skull and connected to weights via a pulley system, applying gentle, continuous traction over time.
- Patients typically use HGT for several weeks to a few months, depending on the severity of the curve and how they respond.
- Doctors usually check in weekly to monitor progress, adjust the load, and make sure the spine is responding appropriately.
- If patients remove weight or don't apply the full prescribed load—often due to discomfort, limited mobility, or lack of supervision—the treatment may appear less effective.
- As a result, doctors might increase the load unnecessarily, thinking the traction isn't working, when in reality the issue is inconsistent use rather than inadequate force.

Our Solution

- Our device continuously monitors and records traction load in real time during halo gravity traction therapy.
- It stores up to a week's worth of data on an SD card, allowing doctors to review usage patterns on a computer during check-ins.
- Equipped with long-lasting batteries, the device is designed to last the entire treatment period without frequent recharging.
- It easily attaches between the halo ring and the traction cable, with quick reattachment to different setups like the walker, wheelchair, or bed.
- A built-in LCD screen displays the real-time load, allowing doctors and caregivers to verify that the correct weight is being applied.
- By providing accurate usage data, the device helps doctors avoid overcorrecting or prolonging treatment due to unrecognized underuse.



THERE IS A NEED FOR A HALO GRAVITY TRACTION SYSTEM WITH INTEGRATED REAL-TIME, CONTINUOUS LOAD MONITORING TO ENSURE PRECISE TREATMENT ADJUSTMENTS BASED ON APPLIED FORCES AND USAGE DURATION.

Testing

- Drop tests verified the durability of the device casing.
- Electrical and communication checks ensured stable power, wiring, and data flow between components.
- Calibration tests confirmed accurate zeroing
- Noise and environmental testing assessed signal stability under vibration
- SD card validation ensured reliable data storage and retrieval.
- Tested across a range of loads, with system output matching applied weight within 95% accuracy.

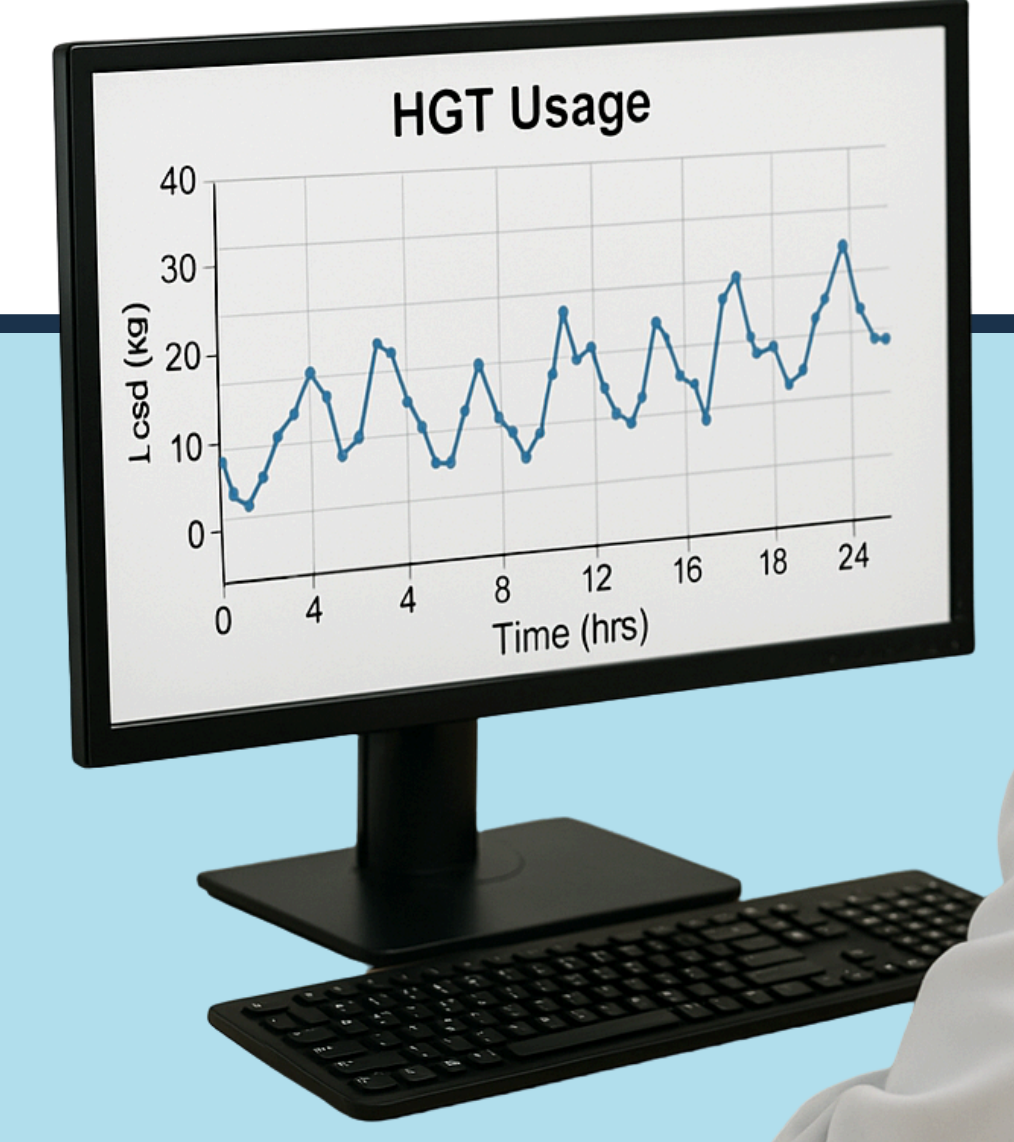


Market/Reimbursement/Regulation

- Target users include pediatric spine centers, orthopedic surgeons, caregivers of the patient, and hospital staff managing halo traction.
- Fills a market gap by tracking real-time traction load and usage outside the clinic.
- Helps reduce complications and treatment time by enabling data-driven traction adjustments.
- Likely qualifies as a Class I or II device under FDA guidelines; potential for 510(k) exemption or clearance.
- May not have direct CPT reimbursement but supports bundled care models and improves outcomes in reimbursed procedures.
- Designed for easy integration with existing traction setups across hospital environments.

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