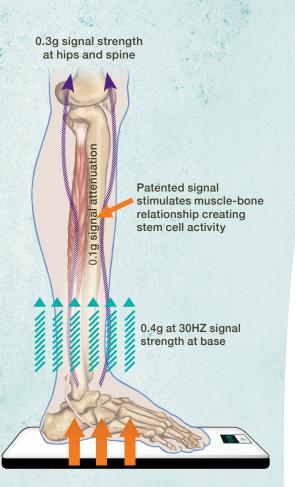
# a new Sensation in vibration

LivMD is a safe<sup>\*</sup> scientific solution for treating bone, joint and muscle conditions.

\* As determined by International Organization for Standardization (ISO) and Occupational Safety and Health Administration (OSHA).

LivMD



## How LivMD works

- Users stand on LivMD for 10 minute sessions
- Patented technology transmits compact rapid vibrations throughout the lower limbs and torso
- Vibrations stimulate muscle-bone relationship
- LivMD influences stem cell activity and differentiation

## **Device specifications**

Weight: 9 kg Height: 6 cm Length: 45 cm Width: 35 cm User weight range: 23-125kg

As determined by International Organization for Standardization (ISO) and Occupational Safety and Health Administration (OSHA).

# LivMD is a safe<sup>\*</sup>, scientific-based solution

## with these approved indications:

#### **Physical Therapy & Rehab**

- Redevelops muscles
- Restores motion to joints
- Relieves minor muscle aches and pains
- Restores fast twitch action of Type IIA muscle fibers in lower legs
- Restores dynamic action of calf muscle fibers

#### **Bone & Muscle Health**

- Safe & effective treatment for osteoporosis/penia
- Maintaining and/or increasing bone density
- Strengthens and increases muscle mass
- Stimulates blood & lymphatic flow
- For use as an adjunct treatment for obesity

# The research behind IOW-intensity vibration

Bones and muscles respond to dynamic loading and forces. Apply them or take them away and the tissue will respond accordingly.<sup>1</sup> Musculoskeletal deconditioning, that can occur through aging or disability, increases the risk of fractures. Exercise, such as walking and running is known to help maintain a good muscle and bone health. But these strategies may not be possible for frail, disabled or more elderly people. Low-intensity vibration, an acceleration of less than 1 gravity (g=acceleration of 9.81m/s2 and frequency greater than 30Hz) is a safe approach to this problem.<sup>2</sup>

Bones respond to both large low frequency and small high-frequency forces and grow more bone as a result. Taking away such forces increases the resorption of bone.<sup>3</sup> Muscle is similarly affected. As we age the faster contracting muscle fibers (10-50Hz) decline proportionately.<sup>4</sup> This can lead to greater musculoskeletal instability and poorer quality. LIV acts as an alternative to these high frequency small sized forces.<sup>5</sup> In scientific studies at a cellular level, LIV has been shown to stimulate bone formation cells (osteoblasts), while reducing production of fat cells.<sup>6</sup> It also reduces the activity of bone resorption cells (osteoclasts).

## LIV and Musculoskeletal conditioning

There are a number of human trials that evaluate the use of LIV as we age. In a placebo controlled trial in post-menopausal women LIV was shown in the women with high compliance to reduce loss of bone mineral (BMD) in the femoral neck, (Rubin 2004). In pre-menopausal women using LIV over 12 months, bones (hip and spine) and muscle in the lower back showed increases using LIV, (Gilsanz 2006). A more recent trial in post-menopausal women showed no significant difference with LIV compared to control, (Slatskova 2011). The placebo group in that study did not lose significant bone density over study period. In adults with Thalassemia six months of LIV use showed significant increases in whole body bone mineral content (BMC) and BMD, (Fung 2012).

> A large study in 710 women over 60 years using LIV for 18 months, showed reductions in falls and fractures in the group using LIV compared to controls,

(Leung 2014). There were significant benefits in muscle strength and balance and some bone benefit using LIV. The study concluded that LIV is effective in reducing falls and associated injuries.

## **Bone loss in Children**

LIV provides a safe non-pharmacological intervention for children and young people with osteoporosis. Children with disabling conditions, including cerebral palsy used LIV for six months and showed 18% benefit in tibial bone quality compared to control (Ward 2004). A second study showed increases in cortical bone strength after six months of LIV use, (Wren 2010). This is important to reducing fracture risk. In a more recent placebo controlled study in boys with Duchenne muscular dystrophy very significant bone improvements were seen from LIV use over 12 months, (Bianchi 2013). In girls with adolescent idiopathic scoliosis LIV was used for 12 months and significant BMD increases were shown in the femoral neck as well as increase in lumbar spine bone

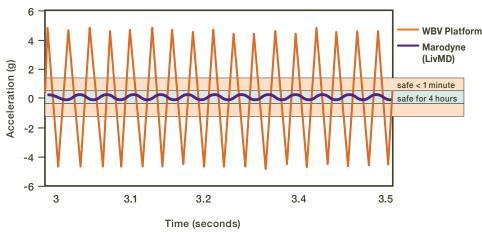
FOCUS	STUDY	INDICATION	DEVICE USE	PATIENTS & RESULTS
Bone and Muscle	Gilsanz et al., JBMR Vol 21, No.9, 2006	Musculoskeletal enhancement in young women with low BMD	30Hz, 0.3g 10 min's 7/7 12 months	48 females 15-20 yrs
				2.0% cortical bone, 2.3% cancellous bone, 4.9% paraspinous muscle benefit
Muscle Postural Stability and Mobility	Muir et al., Gait & Posture 33 (2011). 429-435	Reduce risk factors for fracture during long-term bed rest	30Hz, 0.3g 10 min's 7/7 3 months	29 adult volunteers
				Postural stability & flexion strength retained to baseline
Bone, Muscle Postural Stability and Mobility	Leung et al., Osteoporosis Int. 2014 Jun; 25(6):1785- 95.	Long-term effects of LIV on fall, fracture rates, muscle performance and bone quality	35Hz, 0.3g 20 min's 5/7 18 months	710 female +60 yrs
				18.6% active group compared to 28.7% control group fall/ fractures rate
				Significant stability compared to controls
				BMD non significant difference
Bone	Rubin et al., JBMR Vol 19, No.3, 2004	Prevention on bone loss in post menopausal women	30Hz and 90Hz 0.3g 20 min's 7/7 12 months	70 post-menopausal females
				2.7% relative benefit in BMD
Bone	Slatskova et al., Ann Intern Med. 2011,155:668-679)	To determine if WBV improves bone density and structure	30Hz, 0.3g 20 min's 7/7 6 months	202 post-menopausal females
				12 month change in Vol TBMD mg/cm3 90HZ +0.4, 30Hz (0.1) control (0.2) compared baseline
				Calcium and Vitamin D used by all subjects
Bone	Fung et al., Published online 28 June 2012 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/ajh.23305	Pilot study on effect of WBV on Bone density in patients with thalassemia	30Hz, 0.2g 20 min's 7/7 6 months	18 subjects (10 male, 9 adults)
				2.6% increase whole body BMC, 2.6% BMC/ht, 1.3% aBMD in adults
Bone	Ward et al., JBMR Vol 19, No.3, 2004	Osteogenesis in Children with disabling conditions (cerebral palsy)	90Hz, 0.3g 10 min's 7/7 6 months	20 children 4 -19 yrs
				18% relative benefit in Vol TBMD
Bone	Wren et al., J Pediatr Orthop 2010;30:732–738	Effect of LIV on bone and muscle in children with cerebral palsy	30Hz, 0.3g 10 min's 7/7 6 months	31 children 6 – 12 yrs
				Increased cortical bone area and moment of inertia
Bone	Lam et al., Osteoporosis Int (2013) 24:1623-1636	Effect of LIV on osteopenia in children with adolescent idiopathic scoliosis	32-37Hz, 0.3g 10 min's 7/7 6 months	149 women 15 – 25 yrs
				2.15% femoral neck BMD 1.17g absolute increase lumbar spine BMC
Bone	Bianchi et al., 2013	Impact of LIV on muscle strength and BMD in boys with Duchenne muscular dystrophy	30Hz, 0.3g 10 min's 7/7 12 months	21 males 6 – 13 yrs
				Benefit: spine BMAD 7.9%, TB 6.8%, Femoral neck 9.8%
Bone, Bone Healing after fracture	Leung et al., Paper No. 30 • ORS 2011 Annual Meeting	Use of LIV within post-operative rehabilitation of unilateral trochanteric fractures	35Hz, 0.3g 20 min's 7/7 Post op day 4 to 6 months concurrently with standard fracture rehabilitation	40 adults +65 yrs
				Device users: enhanced QoL
				and function, Hip BMD 1.5% benefit, 1.7% less loss in femoral neck, earlier fracture healing.

## Is it safe?

The low-intensity vibration signal delivered by LivMD is considered safe<sup>\*</sup> for up to 4 hours of exposure per day according to the International Safety Organization (ISO) threshold for human tolerance of vibration, ISO-2631.

OSHA (The Occupational Safety and Health Administration) and the ISO have come out with specific advisories on duration thresholds for human tolerance, which is dependent on both frequency and duration. In the figure from ISO-2631, it shows time (horizontal), and acceleration (vertical), with the dark "hockey-sticks" indicating how much time you can safely be exposed to these signals.

# Safety: Exposure limits for humans



- Plot of plate surface accelerations of WBV Platform (orange) and Marodyne LivMD (purple)
- Threshold lines for 1 hour and 1 minute are drawn onto the chart for reference
- Exposures greater than 1 minute must have accelerations inside the 1 minute band

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