Osteoboost®

User Manual

 Please read carefully.

This manual covers the function and proper use of Osteoboost with provided accessories.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Do not use or operate Osteoboost until you have read and understood this manual.

Protected by Patent osteoboost.com/patents
Additional patents may be pending in the U.S. and elsewhere.

Bone Health Technologies, Inc.

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osteoboost.com

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User Manual's Scope

This manual covers the function and proper use of Osteoboost with provided accessories.

Definitions

Osteoboost
Wearable belt with an internal pack that delivers mechanical stimulation to the lower spine and hips.

Osteoboost Charger
5V charger which plugs into a standard wall outlet.

Refer to Instruction Manual
Indicates a requirement to read and understand the User Manual and other accompanying instructions before use of the device.

Rx Only

Prescription Only
Osteoboost is to be sold only to or on the prescription or other order of a practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

SN

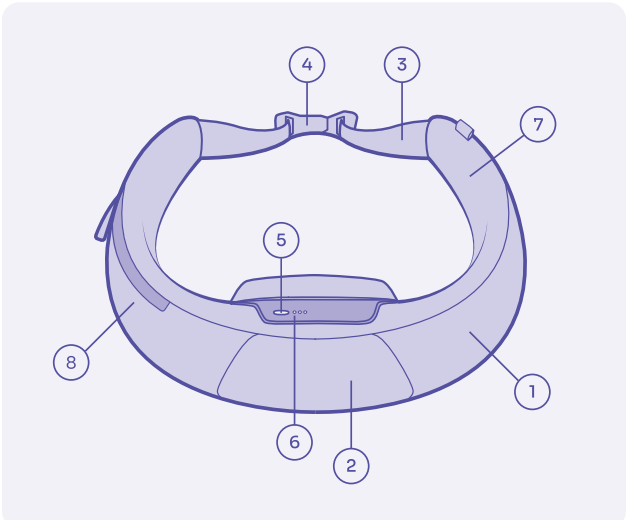
Serial Number
Indicates serial number of the device

REF

Catalog Number
Indicates the model number of the device system/kit

Manufacturer
Indicates the manufacturer of the device

Figure 1. Osteoboost



1. nylon belt
2. vibration pack (located within the nylon belt)
3. straps
4. clasp
5. power button
6. status lights
7. hip accelerometer (located within the nylon belt)
8. zippered storage pocket

Instructions

1. Download the Osteoboost App (Optional)

Scan the QR code or visit **osteoboost.com/app** to download the Osteoboost app for easy setup and session tracking.

2. Watch How-To Video

Scan the QR code or visit **osteoboost.com/video** to watch a step-by-step video on how to put on Osteoboost and start your first treatment session.

3. Get Set Up

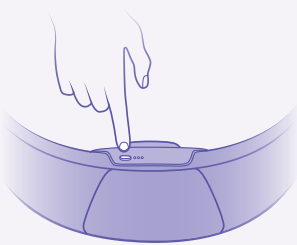
Before putting on Osteoboost, remember to use the restroom or complete any activities that Osteoboost may interfere with.

Wear a thin layer of clothing under Osteoboost for maximum comfort. Bulky items or jackets can be worn over the belt if needed. Remove any items around your waist, such as belts, to ensure a proper fit.

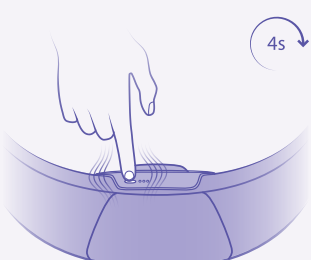
You are limited to 30 minutes of treatment per day, which resets each new calendar day.

4. Turn on Osteoboost

Press the power button once. The lights will illuminate green and white, and the device will beep to indicate it is powered on. You will hear a dull double-tone every 20 seconds until Osteoboost is placed correctly on your body.

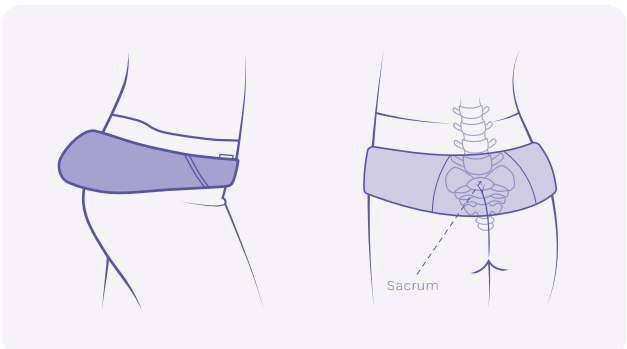


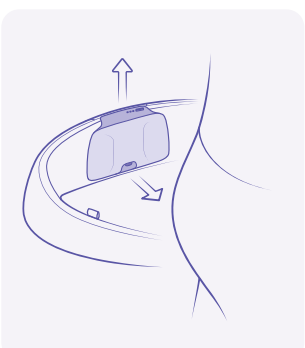
To turn off your device, hold the power button for 4 seconds.



5. Put on Osteoboost

Wrap the device low around the widest part of your hips (not waist), ensuring the foam pad on the back rests against your sacrum (top of your buttocks). The belt should sit low on your hips, not your waist.

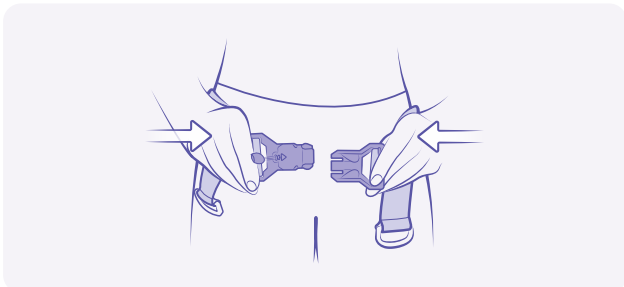




Make sure the orientation is correct:

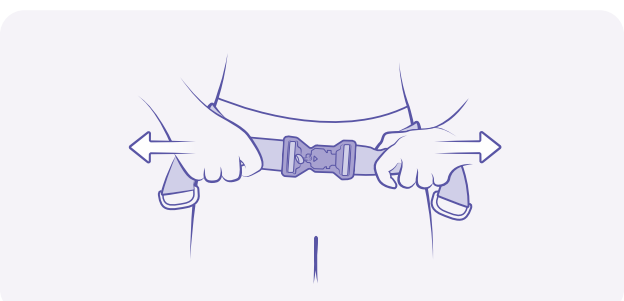
- The power button and light indicators should be facing up.
- The small Osteoboost tag should be on your right side.

Secure the magnetic clasps by bringing the ends together until they snap into place.



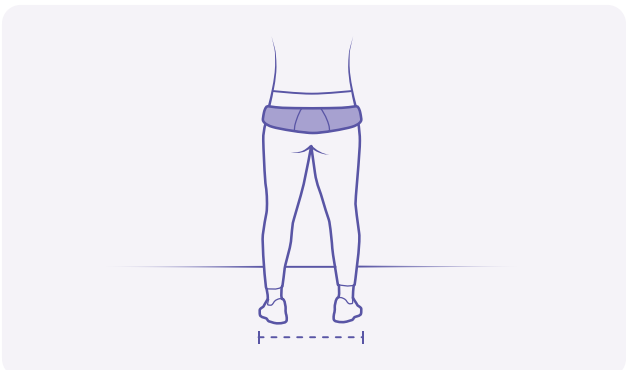
6. Tighten the Straps

Pull both straps to adjust the belt snugly around the widest part of your hips. The fit should be snug and secure, but still comfortable, to ensure the pack provides optimal pressure to your sacrum for effective treatment.



7. Stand Still for Pressure Check

After securing Osteoboost snugly around your hips, the device will perform a pressure check to ensure proper positioning and contact. **Stand upright and completely still** during this step, as any movement or fidgeting may interfere with the process. The pressure check typically takes a few seconds to complete.



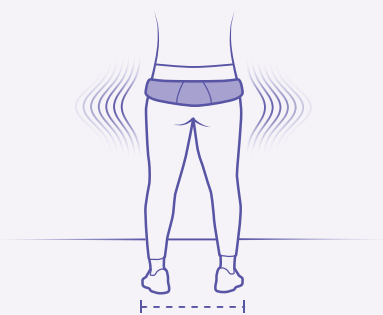
If the pressure is sufficient, you will hear an ascending tone, and the device will automatically proceed to the calibration step, where it will begin pulsing.

If the pressure is insufficient, Osteoboost will emit a dull double-tone every 20 seconds. Tighten the straps to improve the fit. If the tone continues, loosen the straps slightly, lower the belt to sit more securely on your hips, and tighten it again. Repeat these adjustments until you hear the ascending tone and the device begins pulsing, indicating that the pressure check is complete and calibration is starting.

8. Stand Still for Calibration

After the pressure check is complete, Osteoboost will automatically begin the calibration process. This step typically takes 5-20 seconds. During calibration, the device will pulse intermittently. **Stand upright and completely still** with your feet shoulder-width apart to allow the device to calibrate properly. Avoid bending your knees, swaying, or standing near external vibration sources (e.g., washing machines).

Once calibration is successful, the device will switch from pulsing to continuous vibration, signaling the start of the treatment session. If the device stops vibrating during calibration, reposition Osteoboost, press the power button once, and repeat the pressure check and calibration steps.



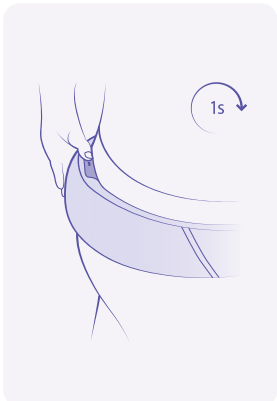
If repeated calibration attempts fail, please contact Bone Health Technologies at support@osteoboost.com or (833)-GO-OSTEO / (833)-466-7836 (toll-free) for technical assistance.

9. During the Session

Once calibration is complete, Osteoboost will vibrate continuously for the 30-minute treatment session. You should remain upright while wearing Osteoboost, but you may walk around or perform light work or chores during the treatment session. Osteoboost will automatically stop vibrating after the 30-minute session is complete, and you will hear a celebratory tone. The device will turn off automatically.

If you attempt to use the device again the same day after completing the 30-minute treatment, all three LEDs will blink red and white, indicating that the daily treatment limit has been reached.

If problems occur:
If the device detects any problems, it will alert you. Refer to the Troubleshooting section or Appendix A in the User Manual to resolve the issue.

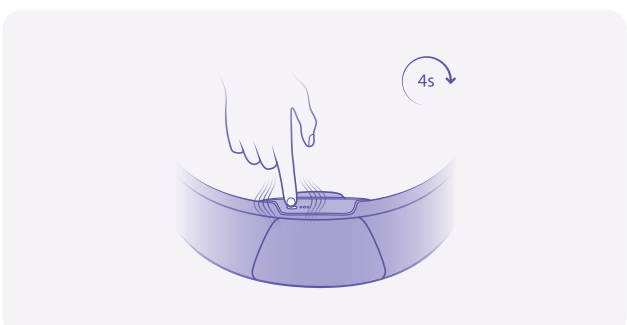


Pausing and resuming:
You can pause the session at any time by pressing the power button.

While paused, you must keep Osteoboost on your body. If you remove the device, you will need to restart the pressure check and calibration process. Press the power button again to resume treatment.

If the device is paused for more than 10 minutes, it will automatically turn off.

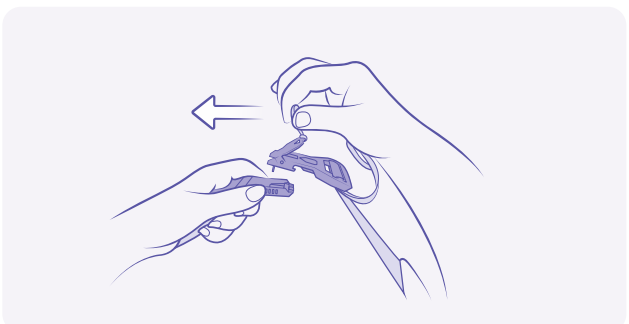
Stopping early:
If needed, you can power down the device manually by holding the power button for 4 seconds. If you stop early, you can complete the remaining time later in the day, but you are limited to 30 minutes of treatment per calendar day.



10. Taking Off Osteoboost

At the end of the 30-minute treatment session, Osteoboost will play a celebratory tone and automatically turn off.

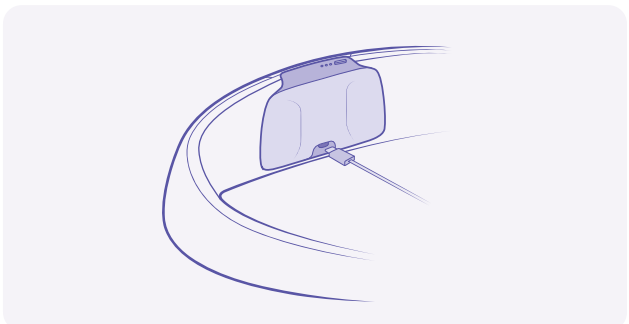
To remove the device, release the magnetic clasp by pulling the tab firmly to the left while holding the device firmly with your other hand to prevent it from dropping.



If the device plays a dull tone instead of a celebratory one, it may need to be charged before your next session. If the device's LEDs show a low battery level (amber) or a critically low battery level (flashing red light), it will need to be charged before your next session.

11. Charging Osteoboost

To charge Osteoboost, plug the supplied charger into a wall outlet, and insert the other end into the charging port of Osteoboost. Push with firm pressure until the plug is fully inserted.



Note: The lights will not turn on automatically during charging. To check the charging status, press the power button:

- A flashing white LED indicates charging is in progress.
- All three battery lights will appear solid when the device is fully charged.

The battery may take up to 4 hours to charge fully. It's recommended to charge Osteoboost weekly.

If the device's LEDs show a low battery level (amber) or a critically low battery level (flashing red light), it will need to be charged before use.

Indications for Use

Osteoboost is indicated to reduce the decline in bone strength and volumetric bone density, as assessed via CT (computed tomography) scans that were analyzed using the O.N. Diagnostics VirtuOst estimate of vertebral bone strength and density in postmenopausal women with osteopenia of the lumbar vertebrae or total hip as diagnosed via dual x-ray absorptiometry with a bone mineral density T-score between -1.0 and -2.49.

- The clinical effects have only been observed for the duration of the clinical study performed to support the indications for use (1 year).
- Fracture risk was not evaluated in the clinical study to support the indications for use, so it is not known how the treatment effects correlate with fracture risk.
- The clinical effects have been demonstrated only for those who used the device as indicated.

Device Description

Osteoboost is a wearable belt with an incorporated motor that is designed to transmit low-amplitude, high-frequency (20-40 Hz) mechanical stimulation, also called vibration therapy, to the spine and hips. In this context, vibration therapy refers to the application of mechanical stimulation calibrated to promote bone health. Osteoboost's vibration therapy is not the same as massage vibration. Osteoboost delivers calibrated vibration that provides medically targeted forces designed to stimulate bone tissue.

Osteoboost consists of a vibration pack mounted inside a nylon belt (Figure 1). The device is secured tightly against the lower back with a nylon strap that is buckled in the front and pulled tight by the patient. The device is intended to be worn on top of a thin layer of clothing and positioned such that the vibration pack sits tightly over the sacrum (Figure 2).

A thin piece of foam padding is attached to the belt at the interface between the patient's clothing and the vibration pack to improve comfort and facilitate consistent energy transfer to the patient's spine and hips. After belt placement and before the beginning of each treatment session, Osteoboost performs a pressure check and a calibration step to ensure that a safe and therapeutic dose is delivered to the patient. The calibration step typically takes 5-20 seconds.

The device is available in three sizes and each size adjusts in belt length of up to approximately 5-10 inches. The size range will accommodate a hip circumference from 32 to 56 inches.

The device is intended to be worn and used to administer treatment during normal daily activities that involve an upright patient body position. Specifically, patients are instructed to administer treatment during activities that involve standing and walking, such as getting ready in the morning, cooking, doing the dishes, other light household chores, going for a walk, and walking the dog.

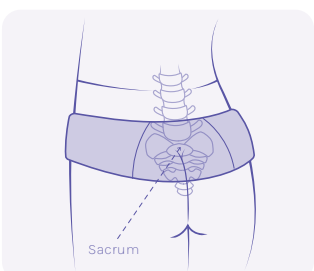


Figure 2.
Back view of Osteoboost, depicting correct positioning on the body when the vibration pack (hard pack mounted on the back of the belt) is placed over the sacrum.

Frequency of Use

The daily Osteoboost treatment session is 30 minutes. The minimum frequency of use is 30 minutes of treatment per day, at least 5 days per week. For best results, Osteoboost should be used on a daily basis.

Clinical Trial Description & Results

Summary

In a 12-month triple-blinded, randomized, sham-controlled clinical trial of postmenopausal women with osteopenia, Osteoboost demonstrated a 2.36% relative benefit vs. sham (or placebo) for change in vertebral bone strength at 12 months.

For the active Osteoboost device, there was a 0.48% reduction in vertebral bone strength for patients who used the device per the protocol, a statistically significant difference compared to the 2.84% reduction in vertebral bone strength for patients who used a sham, non-therapeutic (i.e. placebo) version of the device per the protocol. The protocol required treatment a minimum of 3 days per week consistently throughout the year.

Osteoboost also reduced loss of vertebral bone density as measured by CT scan, demonstrating a 0.29% reduction in patients who used the active device, a statistically significant difference compared to the 1.97% reduction for patients who used the sham device.

Study Design

The primary effectiveness endpoint was a comparison of the percentage change in vertebral bone strength between the active treatment and sham control groups, as calculated at 12 months (vs. baseline).

Vertebral bone strength was calculated using VirtuOst, a software-only medical device that analyzes data in computed tomography (CT) scans to estimate bone mineral density and bone strength. A CT scan of the first lumbar vertebra (L1) was taken at baseline and at 12 months, from which finite element analysis was used to estimate vertebral bone strength. Safety was evaluated by adverse events. The enrolled subjects were followed for 12 months.

Subject Population and Baseline Demographics

The study enrolled postmenopausal female subjects aged 52-82 diagnosed with low bone mass (osteopenia) defined by a DXA T-score between -1.0 and -2.49. The majority of the subject population was Caucasian women (120/126; 95%), with only 6/126 (5%) non-Caucasian subjects.

A candidate was excluded from the study if she met ANY of the following conditions:

- Had osteoporosis, as defined by a bone mineral density (BMD) at the femoral neck total femur, or lumbar spine of T score ≤ -2.5 (defined by DXA)
- Had a 10-year probability of major fracture >20% or hip fracture >3% based on results of the Fracture Risk Assessment (FRAX) Tool
- Was currently taking or had taken bisphosphonates or other prescription osteoporosis medications in the past 24 months, or estrogen replacement therapy, glucocorticosteroids, or other drugs affecting bone in the past 3 months
- Had at least one fracture or at least one major surgery within the past 6 months
- Smoked >10 cigarettes per day over the past 6 months
- Had an average of 14 alcoholic drinks per week over the past 6 months
- Had type I diabetes
- Had a history of severe renal disease or kidney failure
- Had gastric bypass surgery
- Had been diagnosed with chronic renal disease, cirrhosis, multiple myeloma, neuromuscular disease, osteomalacia, Paget's disease, osteogenesis imperfecta, severe osteoarthritis, rheumatoid arthritis, severe peripheral neuropathy, gastrointestinal malabsorption or sprue, an eating disorder (e.g., anorexia nervosa, bulimia),

uncontrolled hypertension, or chronic diseases known to affect the musculoskeletal system (e.g., muscular dystrophy)

- Had been diagnosed with an endocrine disorder known to adversely affect bone density, such as hyperparathyroidism, hyperthyroidism, or Cushing's syndrome
- Had cancer and/or was being treated for cancer
- Had a bilateral oophorectomy
- Was being treated for a herniated disc
- Had any prolonged immobilization (i.e., bedrest) for over one week or non-weight bearing for greater than one month of the axial or lower appendicular skeleton within the last 3 years
- Was engaged in high-impact activity at least three times per week (including but not limited to tennis, aerobics, running, weight-bearing activity, or exercise more intense than fast walking).
- Had a known allergy to neoprene
- Had a hip circumference >56 inches
- Had a Body Mass Index (BMI) > 35
- Had abnormal results for the following laboratory tests:
  - Serum 25(OH)D outside of the range: 10-100 ng/mL
  - Serum calcium outside of the range: 8.9-10.4 mg/dL
  - Serum parathyroid hormone (PTH) outside of the range: 12-88 pg/mL
  - Thyroid-stimulating hormone (TSH) outside of the range: 0.4 – 5.0 mIU/L
  - Follicle-stimulating hormone (FSH) less than 40 (mIU/L)
- Had joint replacement implants in the ankle, knee, or hip
- Had a spinal fusion procedure
- Had an active implant (e.g., implanted neurostimulator) in the areas of the lumbar or thoracic spine, pelvis, or buttocks
- Had a major change in high-impact physical activity level (increase or decrease) in the past 3 months

- Had undergone or was undergoing transgender hormone therapy
- Was deemed unsuitable for enrollment in the study by the Principal Investigator.

Subject Accountability

Of the 265 women who were screened, 126 women were enrolled in the study. All 126 subjects were randomized to either the Active Treatment or Sham Control Treatment and were included in the intent to treat (ITT) population. Of the 126 subjects that were enrolled, 64 subjects in the Active Treatment group and 61 subjects in the Sham group met the full eligibility criteria and received the allocated intervention, so these 125 subjects were included in the modified Intent to Treat (mITT) population.

Of the 125 subjects in the mITT population, 60 subjects in the Active Treatment group and 50 subjects in the Sham group completed a CT scan at 12 months and were included in the Complete Cases (CC) population.

Because treatment effectiveness requires a degree of compliance with the treatment regimen, analyses on the mITT population and a Per Protocol (PP) population were conducted for all endpoints. The PP population included all mITT subjects who completed an average of at least 3 sessions per week of at least 24 minutes of total device use per day over the 12-month study. The number of subjects included in the PP analysis was 73/126, with 39/73 subjects in the Active treatment group and 34/73 in the Sham Control group.

Subject Disposition			
		Treatment Group	
Disposition	All Subjects (n = 265), n (%)	Active (n = 64), n (%)	Sham (n = 62), n (%)
Screened	265 (100.0%)	/	/
Enrolled [1]	126 (47.5%)	/	/
Intention-to-Treat (ITT) [2]	126 (47.5%)	64 (100.0%)	62 (100.0%)
Modified Intention-to-Treat (mITT) [3]	125 (47.2%)	64 (100.0%)	61 (98.4%)
Complete Cases (CC) [4]	110 (41.5%)	60 (93.8%)	50 (80.6%)
Per-Protocol (PP) [5]	73 (27.5%)	39 (60.9%)	34 (54.8%)
Early Terminations	15 (5.7%)	4 (6.3%)	11 (17.7%)
Reasons for Early Termination			
Osteoporosis	2 (0.8%)	0 (0.0%)	2 (3.2%)
Started ERT	1 (0.4%)	1 (1.6%)	0 (0.0%)
Lost to follow-up	4 (1.5%)	3 (4.7%)	1 (1.6%)
Other	8 (3.0%)	0 (0.0%)	8 (12.9%)

(1) All subjects who, during screening, satisfied all of the eligibility criteria and signed the Informed Consent Form.

(2) All enrolled subjects who were randomized to either the Active Treatment or Sham Treatment group.

(3) All ITT subjects who initiated at least one treatment session (i.e., device touched the subject's body) and met all eligibility criteria.

Primary Endpoints

There were no statistically significant differences between the treatment groups of the primary analysis population (mITT).

However, additional analysis on the PP population demonstrated a 0.48% reduction in bone strength for subjects who used the active device (which provided vibration therapy) versus a 2.84% reduction in bone strength for subjects who used the sham, non-therapeutic version of the device. This reflects a modest, yet statistically significant 2.36% difference (p-value = 0.028, two-sided t-test) between the active treatment group and the control group for the PP population who used the device for at least 3 weekly sessions consisting of at least 24 minutes each.

In the PP population, the treatment group lost 0.29% of their volumetric BMD (vBMD) as compared to the sham control group which lost 1.97% of their vBMD reflecting a statistically significant 1.68% difference (p-value = 0.016, two-sided t-test) in vBMD loss between the study groups. There was also a statistically significant 1.34% difference (p-value = 0.026. two-sided t-test) in vBMD loss observed between the active treatment group and the sham control group in the complete cases (CC) population.

The clinical relevance of these statistical differences has not been correlated with fracture risk and bone fragility.

(4) All mITT subjects who completed at least one study effectiveness endpoint assessment (CT, DXA, and/or SF-12) at Month 12.

(5) All CC subjects with no major protocol deviations who completed an average of at least three sessions per week during each 3-month period of the study (i.e., an average of at least three sessions per week in each quarter: Months 1-3, Months 4-6, Months 7-9, and Months 10-12).

Primary Endpoint: Percentage Change (%) in Vertebral Bone Strength at Month 12 vs. Baseline

Analysis Population	Active Group	Sham Group	Difference (Active - Sham)	P-value[1]
Modified Intention-to-Treat (mITT) [2]				
N	64 [3]	61	125	0.17
Mean (SE)	-1.40% (0.67%)	-2.74% (0.66%)	1.33% (0.97%)	
95% CI for Mean	(-2.73%, -0.08%)	(-4.04%, -1.43%)	(-0.57%, 3.24%)	
Complete Cases (CC)				
N	59 [3]	50	109	0.068
Mean (SE)	-1.25% (0.69%)	-2.92% (0.59%)	1.67% (0.91%)	
95% CI for Mean	(-2.62%, 0.13%)	(-4.11%, -1.73%)	(-0.13%, 3.47%)	
Per Protocol (PP)				
N	39	34	73	0.028*
Mean (SE)	-0.48% (0.81%)	-2.84% (0.67%)	2.36% (1.06%)	
95% CI for Mean	(-2.12%, 1.17%)	(-4.21%, -1.47%)	(0.26%, 4.47%)	

(1) P-value is from a two-sided two-sample t-test. (*) indicates that there is a statistically significantly difference in the mean percentage change in vertebral bone strength at Month 12 between the Active group and Sham group at significance level of 0.04356.

(2) Multiple imputation of missing vertebral bone strength data was performed using race, age category (50-60, 60+), BMI category (normal, overweight, obese), non-missing vertebral bone strength at Baseline and Month 12, and non-missing lumbar spine areal BMD at Baseline, Month 6, and Month 12.

(3) CT scans at Baseline and Month 12 for one subject were obtained but were not analyzed due to unusual morphology at all levels.

Limitations of the Clinical Significance of the Study Data

- The clinical effects have only been observed for the duration of the clinical study performed to support the indications for use (1 year).
- Fracture risk was not evaluated in the clinical study to support the indications for use, so it is not known how the treatment effects correlate with fracture risk.
- The clinical effects have been demonstrated only for those who used the device as indicated.
- In the clinical study of the device, a very high majority of Caucasian patients were evaluated (under-represented non-Caucasian population). Therefore, the effect of using the device in non-Caucasian population is not clearly demonstrated.
- The safety and effectiveness of the device has not been evaluated in patient populations with high-risk factors for developing bone fragility or fractures, such as heavy smoking, Type I diabetes, history of fractures, renal disease, and BMI > 35.
- Clinically relevant adverse events include back pain, dizziness and muscle weakness.

Warnings

Please read all instructions carefully before use. Observe all warnings and precautions in this manual.

Let your doctor know before use of Osteoboost if you have any of the following conditions: 1) are allergic to neoprene, 2) are being treated for a herniated disc, 3) have had a spinal fusion procedure, 4) have a joint replacement implant in the ankle, knee, or hip, or 5) have an active implant (e.g. implanted neurostimulator) in the areas of the lumbar or thoracic spine, pelvis, or buttocks.

This device has been evaluated in a clinical study with a high majority of Caucasian women without high-risk factors for developing bone fragility, such as heavy smoking, type I diabetes, renal disease, or a history of fractures. The safety and effectiveness of the device has not been evaluated in a significant number of non-Caucasian women, in subjects with high-risk factors for developing bone fragility, or in subjects with a BMI > 35. This device is indicated for postmenopausal women with osteopenia and has not been studied in people with osteoporosis.

Do not attempt to open, repair, or modify the unit or replace parts. Attempting to do so could result in bodily injury or harm. If the unit or any parts are not working, please contact Bone Health Technologies at support@osteoboost.com or (833)-GO-OSTEO / (833)-466-7836 (toll-free). Repairs should only be made by Bone Health Technologies authorized personnel.

Do not use Osteoboost near external sources of vibration such as, but not limited to, washing machines.

Do not apply Osteoboost directly to the skin. Wear a thin layer of clothing between the device and the skin.

Do not attempt to insert any objects (other than the supplied charger), including bodily parts into any ports. Doing so could result in bodily injury or harm.

Do not clean Osteoboost. If there is a minor spill on Osteoboost, dab the area with a dry cloth. If a larger spill has occurred, dab the area with a dry cloth and contact Bone Health Technologies at support@osteoboost.com or (833)-GO-OSTEO / (833)-466-7836 (toll-free).

Avoid contact between Osteoboost and water and/or fluids. Do not immerse or submerge Osteoboost in water and/or fluids. If Osteoboost gets wet, please discontinue use and notify Bone Health Technologies.

Do not use Osteoboost if it shows obvious signs of damage. If damage occurs, please contact Bone Health Technologies at support@osteoboost.com or (833)-GO-OSTEO / (833)-466-7836 (toll-free).

Discontinue use and notify Bone Health Technologies if any of the following device problems occur:

- Device runs longer than 30 minutes
- Device is dropped and damage to belt or plastic enclosure occurs
- Abnormal noise or rattling is heard
- Device cannot be powered down manually (holding down power button)
- Device status is unclear: device shuts down randomly, “freezes”, etc.
- Device vibrations cause aches, pain, tenderness, or bruising at site of application
- Device vibrations cause dizziness/vertigo/motion sickness/headache
- Device material causes adverse skin reaction

Precautions

Handle Osteoboost carefully. Do not drop.

Use Osteoboost only as instructed by this manual.

Ensure that Osteoboost is worn as directed by this manual. Osteoboost should be tight, yet comfortable, on the body when worn. Osteoboost will notify you when it is too loose.

Only charge Osteoboost with the supplied charger.

Use caution when undoing the strap. Hold both ends of the device firmly when releasing the clasp to prevent dropping Osteoboost.

When using Osteoboost in an environment at the upper operating temperature limit of 40°C (104°F), the temperature of the nylon cover over the vibration pack of the Osteoboost may reach 41.1°C (106°F) during use. This portion of the cover does not touch your body during normal use, but may feel warm if held for extended periods. Set Osteoboost down or hold Osteoboost by the straps if the temperature is uncomfortable.

Risks and Side Effects

Consult your doctor if you experience pain during or after use of Osteoboost. Potential risks of therapeutic vibration include:

- Lower or upper back pain
- Leg or pelvic pain
- Aches, tenderness, or bruising at site of application
- Adverse skin reactions

Discontinue use and consult your doctor if you experience temporary side effects during or after use of Osteoboost. Temporary side effects of therapeutic vibration with Osteoboost include:

- Muscle weakness
- Digestive or gastrointestinal issues
- Dizziness, loss of balance, vertigo, or motion sickness
- Blurred vision
- Headaches

Use and Storage Environment

Osteoboost is intended to be used and stored in a home environment between 50°F and 104°F (10°C to 40°C).

Cleaning

Osteoboost does not require cleaning. Please do not attempt to wash the device. Only dab with a dry cloth if any liquids spill on the device.

Disposal and Repairs

All repairs are to be completed by Bone Health Technologies personnel only.

All disposals are to be completed by Bone Health Technologies personnel only.

Troubleshooting

A list of common problems and solutions is below. Please contact Bone Health Technologies at support@osteoboost.com or (833)-GO-OSTEO / (833)-466-7836 (toll-free) if the problem cannot be resolved after referring to the list below or if your issue is not listed here. In addition, a comprehensive list of device errors and explanations can be found in Appendix A.

Problem	Indicators	Potential Solution
Session not starting or session pauses	Dull Tone (every 20 seconds) 	Unsuccessful Calibration: If Amber and White LEDs are blinking, ensure the belt is on your hips (not waist) and you are standing still during calibration.
Session not starting or session pauses	Dull Tone (every 20 seconds) 	Low Pressure: If Amber LED is blinking, ensure the belt is tightly wrapped around your hips (not waist) and the foam pad is resting against your sacrum.
Device indicates an error and shuts down	Alert Sound 	If Red and White LEDs are blinking, the session has been completed for the day. The device will be ready to run a new session the next day.
Device indicates an error and shuts down	Alert Sound 	If Red LED is blinking, the battery is extremely low. Charge the device prior to running a session.
Device indicates an error and shuts down	Alert Sound 	If Red LED is solid, there may be a hardware issue. Restart the device. If the problem persists, contact Bone Health Technologies.

Legend:

Power Button (for LED location reference)


represents flashing

indicates no light

solid white, amber, red, or green light

Technical Support

For technical support, please contact Bone Health Technologies at support@osteoboost.com or (833)-GO-OSTEO / (833)-466-7836 (toll-free).

Bluetooth

Bluetooth wireless communication is enabled on your device for optional communication with Osteoboost's companion mobile app. For more information on connecting, configuration, and use of Bluetooth, contact Bone Health Technologies at support@osteoboost.com or (833)-GO-OSTEO / (833)-466-7836 (toll-free).

Warranty

For warranty information, please visit osteoboost.com/legal/limited-warranty.

Appendix A: Alarms and Alerts

Visual/Audible Status Updates

The status of Osteoboost is provided by three LEDs on top of the vibration pack, an internal speaker, and vibration.

Battery Charge Levels			
Full		Medium	
Low		Critically Low	

Operating Osteoboost			
Status	**LEDs**	**Sounds**	**Vibration**
Transitioning to Next Step		Happy Tone	
Fit Check Unsuccessful, Waiting for Belt to Be Tightened	Battery Level	Dull Tone (every 20 seconds)	No
In Therapy Session		None	Yes
Therapy Paused		None	No
Therapy Complete	Battery Level	Celebration Tone (Dull Tone if battery needs to be charged before next use)	No
Finished Daily Session		Alert	No
Device Off		None	No

Appendix B: Technical Specifications

Electromagnetic Compatibility

Osteoboost is intended to be used in or around the home. The device is safe in a normal electromagnetic interference environment. Osteoboost complies with the International Standard IEC 60601-1-2: 2014 + AMD1:2020 for Electromagnetic Compatibility (EMC). The equipment requires compliance with EMC precautions for installation and commissioning according to EMC guidelines listed below.

Guidelines and Manufacturer's Declaration-Electromagnetic Emissions

Osteoboost is intended for use in the electromagnetic environment specified below. The user of the Osteoboost device should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidelines
Radiated Emissions – CISPR 11	Class B	Osteoboost is suitable in all home-use locations, including those directly connected to the public low-voltage power grid.
Conducted Emissions – CISPR 11	Class B	
Harmonic Emissions – IEC 61000-3-2	Class A	
Flicker – IEC 61000-3-3	All parameters	

Osteoboost is a battery-powered, portable device. The device is not operable for therapy while the device is connected to AC Mains via the provided charging cable.

While operating Osteoboost, Osteoboost may stop vibrating due to electromagnetic interference. Move to another location and attempt to turn on Osteoboost. If Osteoboost does not turn on or vibrate, contact Bone Health Technologies.

While charging Osteoboost, Osteoboost may stop charging due to electromagnetic interference. Move to another location and attempt to charge Osteoboost. If Osteoboost does not charge, contact Bone Health Technologies.

Guidelines and Manufacturer's Declaration- Electromagnetic Immunity

Osteoboost is intended for use in the electromagnetic environment specified below. The user of the Osteoboost device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Level of Compliance	Electromagnetic Environment – Guidelines
Electro-Static Discharge Immunity – IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	It is not recommended to use Osteoboost when the Relative Humidity is less than 10%
Electrical Fast Transient/ Burst Immunity – IEC 61000-4-4	± 2.0 kV	AC Mains (L-N-GND) Not applicable for DC Power Ports and Signal Lines	
Immunity to Surges – IEC 61000-4-5	± 1.0 (line to line) ± 2.0 kV (line to earth)	AC Line to Line (Differential mode Not applicable for DC Line to Ground, DC Line to Line, or Signal to Ground	
Voltage Dips/ Interruptions Immunity – IEC 61000-4-11	>95% for 0.5 periods >95% for 1 period 30% for 25/30 periods >95% for 250/300 periods	100% for 0.5 periods 100% for 1 period 30% for 25/30 periods 100% for 250/300 periods	

Guidelines and Manufacturer's Declaration- Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Level of Compliance	Electromagnetic Environment – Guidelines
Power Frequency Magnetic Field Immunity – IEC 61000-4-8	30 A/m	30 A/m	
Conducted RF, EM Field Immunity – IEC 61000-4-6	3 Vrms (0.15 – 80 MHz) 6 Vrms (ISM Bands) 6 Vrms (Amateur Radio Bands)	3 Vrms (0.15 – 80 MHz) 6 Vrms (ISM Bands) 6 Vrms (Amateur Radio Bands)	Portable and mobile RF communications equipment should be used no less than the recommended minimum separation distance from Osteoboost.
Radiated, RF, EM Field Immunity – IEC 61000-4-3	10 V/m (80-2700 MHz) 80% AM at 1kHz	10 V/m (80-2700 MHz) 80% AM at 1kHz	Recommended Separation Distance $d = 0.6\sqrt{P}$ 80-2700 MHz where P is the maximum output power rating of the transmitter in watts (W), and d is the minimum separation distance in meters (m)
Proximity Magnetic Field Immunity – IEC 61000-4-39	8A/m, CW, 30kHz; 65A/m (rms), PM at 2.1 kHz, 50% duty cycle, 134.2kHz; 7.5A/m (rms), PM at 50 kHz, 50% duty cycle, 13.56MHz	8A/m, CW, 30kHz; 65A/m (rms), PM at 2.1 kHz, 50% duty cycle, 134.2kHz; 7.5A/m (rms), PM at 50 kHz, 50% duty cycle, 13.56MHz	Close proximity to strong magnetic field not recommended

Portable and mobile RF communications equipment can affect Osteoboost. It is recommended to use the following separation distance. These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection characteristics of structures, objects, and people.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and Osteoboost

Osteoboost is intended for use in the home environment, where radiated RF disturbances are controlled. The user of Osteoboost can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Osteoboost as recommended below and in accordance with the maximum output power of the communications equipment.

Frequency Band (MHz)	Service Type	Maximum Power (W)	Minimum Separation Distance (m)
380-390	TETRA 400	1.8	0.3
430-470	GMRS 460, FRS 460	2.0	0.3
704-787	LTE Band 13, 17	0.2	0.3
800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	2.0	0.3
1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	2.0	0.3
2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	2.0	0.3
5100-5800	WLAN 802.11 a/n	0.2	0.3

FCC Interference Statement

FCC ID: 2BMSV-2007A This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications to this product may negate your authority to operate the product.

Performance Specifications

Component	Specification
Battery	3500mAh Li-ion battery
Power Supply	USB-C: 5V, 2A max.
Run-time between charges	Minimum 5 hours (~10 sessions)
Service Life to 80% capacity	Minimum 2 years (~300 charges)

General Characteristics

Parameter	Specification
Dimensions	Approximately 42” W x 5”H x 3”D
Weight	Approx. 3 lbs.
Mobility	Portable
Ingress Protection	IP22
Environmental Use Conditions	Ambient temperature: 50°F to 104°F (10°C to 40°C) Ambient relative humidity: 15% to 90% (non-condensing) Atmospheric pressure: 700 hPa to 1060 hPa
Data Storage	Data written to internal flash chip
Data Recording	Motor speed, motor current, battery capacity, pressure, acceleration summary: every 1 s Detailed acceleration: 400Hz for 0.5 s, every 15 min

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