



VPro+ Vibration Device

INDICATION FOR USE

The VPro+ Vibration Device is intended to be used by the orthodontic patient to aid with seating of removable aligners during orthodontic treatment.

DEVICE DESCRIPTION

The VPro+ Vibration Device can be used as a portable vibration device. When wearing removable aligners, the device can be applied to the portion of the aligners overlying the occlusal surface of the teeth. The device is a rechargeable portable battery powered device. The device consists of the following components: a vibration unit, mouthpiece adapter, charging cradle, charging cable, and wall charging adapter. Once the vibration unit and mouthpiece are coupled together the device can be used orally to apply vibration to removable aligners overlying the occlusal surfaces of the teeth.

PREPARATION AND USE OF VPro+ VIBRATION DEVICE

1. The VPro+ Vibration Device is packaged ready for use.
2. Inspect and clean prior to use. Rinse mouthpiece under water prior to first use. Mouthpiece is an attachable and detachable accessory which cannot cause harm.
3. Charge the device fully prior to first use. (Refer to charging section)
4. Device is assigned with a specific patient ID using the Propel VPro+ Mobile App. Once assigned, the device is ready for use.
5. Connect the VPro+ Mouthpiece to the Vibration Device. Confirm that the device feels secure and stable before inserting the mouthpiece end into the patient's mouth.
6. Depress the on-switch to activate the device.
7. Patients will apply vibrational forces from the device to areas of the occlusal surface of the teeth when wearing removable aligners
8. The device will function for 5 minutes per use and will automatically shut-off after the duration of treatment.
9. Clean after use and charge the unit if necessary. Refer to "Charging" and "Cleaning" section. Store used device at room temperature.
10. Physicians can view usage summaries and stored records on the Propel mobile application once the device has been assigned/used.
11. The VPro+ Vibration Device should be used for a total of 5 minutes per day in a single session.

MOBILE APPLICATION

1. Download "Propel VPro+" App from Apple App Store or Google Play.
2. Ensure mobile device's Bluetooth is on.
3. Follow onscreen instruction to locate and pair device.
4. Click on 'Enter Your Name' and type your name
5. Click on the 'SELECT DEVICE' option. It will display your Device ID similar to 'VPLUS_000B57A933E5'
6. Click on the Device ID and the Device will flash a green light
7. Click on the 'SELECT VPro+ DEVICE' button at the bottom which will direct you to the previous screen
8. Click on 'GET STARTED' to start using the device
9. Upon successful pairing, a Yellow LED will blink twice.
10. Device can be located after pairing using the Locate function in the settings tab.
11. Mobile app will monitor use and time for all sessions.

PRECAUTIONS

- It is important to read the VPro+ Vibration Device Instructions for Use prior to operation for proper use, maintenance and care.
- The device is intended to be re-used.
- Before use, inspect the device and packaging to verify that no damage has occurred as a result of shipping and handling. Do not use damaged products.

- Always recharge the device in accordance with the Instructions for Use prior to use. Refer to "CHARGING" section.
- Never use any other alternative power sources or instruments in conjunction with the Device.
- Do not use the device to clean or brush teeth.
- Use the VPro+ Vibration Device only as instructed by the physician.
- Not recommended for patients with Vertigo or Temporomandibular Joint (TMJ) Syndrome
- Device should not be modified. Any modification will impair functionality.

HOW SUPPLIED

The VPro+ Vibration Device is supplied with the portable vibrating device, mouthpiece adapter, charging cradle, charging cord, wall charging adapter.

CHARGING

Charge the device by placing the vibration device in the charging cradle while the cradle is connected to a power source. A red light will illuminate from the back of the device to indicate that the device is charging. If the device is fully charged, the device will not charge and instead will blink green. The device will not vibrate while it is charging. Recommended charging time is once a week. The device is internally powered (3.7 VDC) by a rechargeable lithium-ion polymer battery pack. The wall charging adapter operates within the range of 100-240V. The device is inoperable while charging is occurring.

DEVICE NOTIFICATIONS

Green LED (1 Blink)	App has connected
Yellow LED (2 Blinks)	Successful Pairing
Blue (Slowing Blinking)	Charging in progress
Green (Slowing Blinking)	Charging complete
Blue (3 Blinks)	Session Start
Green (3 Blinks)	Session End
Green Blinks and Vibration	Device Locate
Red (1 Blink)	Critical Battery
Redlight backside	Firmware update or charging
Red (2 Blinks)	Device Reset/Reboot

STORAGE

The device should be stored in the original packaging. Proper care should be taken to ensure that the devices are not damaged. Used devices should be stored at room temperature.
Storage Temperature: -30°C to 60°C
Storage Humidity: 15 to 90%
Atmospheric Conditions: 700 kPa to 1060 kPa

CLEANING

The device should be cleaned after each treatment use. Detach the mouthpiece from the Vibration Device. Rinse the Mouthpiece and the vibration device under water and let dry.

EXPOSURE and INTERFERENCE

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy




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and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures: Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help.

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment
- 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
- In order to comply with FCC/ RF Exposure requirements, this device must be installed to provide at least 20 cm separation from the human body at all times

TECHNICAL SPECIFICATIONS AND SYMBOLS

Warning: No modification of this equipment is allowed

Power supply	3.7 Volt Battery, Internally Powered
Equipment Type	 Type B Applied Part
Ingress Protection Rating: IP X7	Protected when device is submerged in water up to 1 meter

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The VPro+ Vibration Device is intended to be used by the orthodontic patient to aid with the seating of removable aligners during orthodontic treatment.		
Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Propel VPro+ Vibration Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class B	The Propel VPro+ Vibration Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	N/A	
Voltage fluctuations/flicker emissions EN 61000-3-3	N/A	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The VPro+ Vibration Device is intended to be used by the orthodontic patient to aid with seating of removable aligners during orthodontic treatment

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	N/A ±8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated Immunity EM 61000-4-3	80-1000 MHz V/H 1000-2500 MHz V/H	N/A	N/A
Electrical fast transient/burst EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

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<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>EN 61000-4-11</p>	<p><5 % U_T (>95 % dip in U_T) for 0,5 cycle</p> <p>40 % U_T (60 % dip in U_T) for 5 cycles</p> <p>70 % U_T (30 % dip in U_T) for 25 cycles</p> <p><5 % U_T (>95 % dip in U_T) for 5 s</p>	<p>0% U_t (100% dip in U_t) for 0,5 cycle</p> <p>0% U_t (100% dip in U_t) for 1 cycle</p> <p>70% U_t (30% dip in U_t) for 25 cycles</p> <p>0% U_t (100% dip in U_t) for 250 cycles</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Propel VPro+ Vibration Device requires continued operation during power mains interruptions, it is recommended that the Propel VPro+ Vibration Device be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field</p> <p>EN 61000-4-8</p>	<p>3 A/m</p>	<p>30 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE</p>	<p>U_T is the a.c. mains voltage prior to application of the test level.</p>		

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<p>Guidance and Manufacturer's Declaration – Electromagnetic Immunity</p>			
<p>The VPro+ Vibration Device is intended to be used by the orthodontic patient to aid with seating removable aligners during orthodontic treatment.</p>			
<p>Immunity Test</p>	<p>EN 60601 Test Level</p>	<p>Compliance Level</p>	<p>Electromagnetic Environment - Guidance</p>

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<p>Conducted RF EN 61000-4-6</p> <p>Radiated RF EN 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>The portable and mobile RF communications equipment should not be used close to any part of the Propel VPro+ Vibration Device than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = \left(\frac{35}{V} \right) \sqrt{P}$ $d = \left(\frac{35}{E} \right) \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left(\frac{2}{E} \right) \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Interference may occur in the vicinity of equipment marked with the following symbol:</p>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

	Non-sterile
	Manufacturer
	Authorized Representative, EU
	Use By
	Caution, consult accompanying documents
	Follow Instructions for Use
	Type B Applied Part
	Prescription
Australian Sponsor	Authorized Representative Australia

For:
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European Authorized Representative:
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The Netherlands

Australian Sponsor
Emergo Australia
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Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia



	Catalog Number
	Lot Number