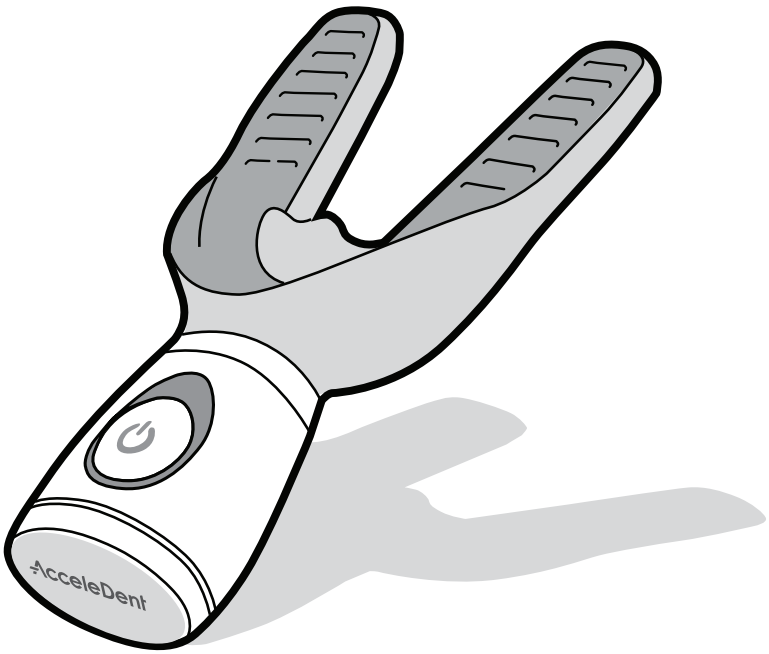
DIRECTIONS FOR USE



AcceleDent®

OPTIMA™

REF 405-1307-001 Rev D

CE 0086

Rx only

-20°C 50°C

RoHS

30% RH 93% RH

700 hPa 1060 hPa

Contents

1.0 Introduction

Thank you for choosing AcceleDent® Optima™ which works with your current orthodontic treatment to deliver a better experience from start to finish. *AcceleDent Optima* uses SoftPulse Technology® to help your current orthodontic treatment work faster. It does this by generating small vibrations called micropulses to gently accelerate the movement of your teeth as they are guided by your orthodontics.

2.0 About the Manufacturer

Contact the manufacturer, OrthoAccel®, about any questions or concerns that are specifically related to *AcceleDent Optima* and its components.

Customer Service Center:

North America: 1-866-866-4919
Spain: +34900839096
United Kingdom: +448000988430
France: + 33805080086
Italy: +39800596833
Germany: +49032221096268
Outside North America: +442033181915

EMERGO EUROPE: +31703458570
Email: customerservice@orthoaccel.com
Online: www.acceledent.com

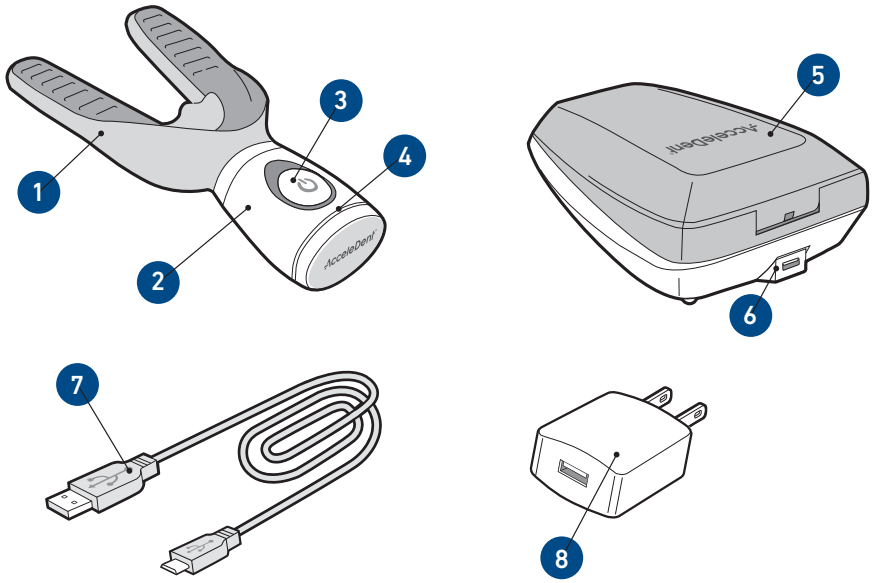
3.0 Intended Use/Indications for Use and Contraindication

AcceleDent Optima is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and aligners to help facilitate minor anterior tooth movement.

Contraindications for Use

- Use of osteoporosis drugs
- Poor oral hygiene
- Periodontal disease that is not under full control for at least 3-4 months prior to the start of treatment.

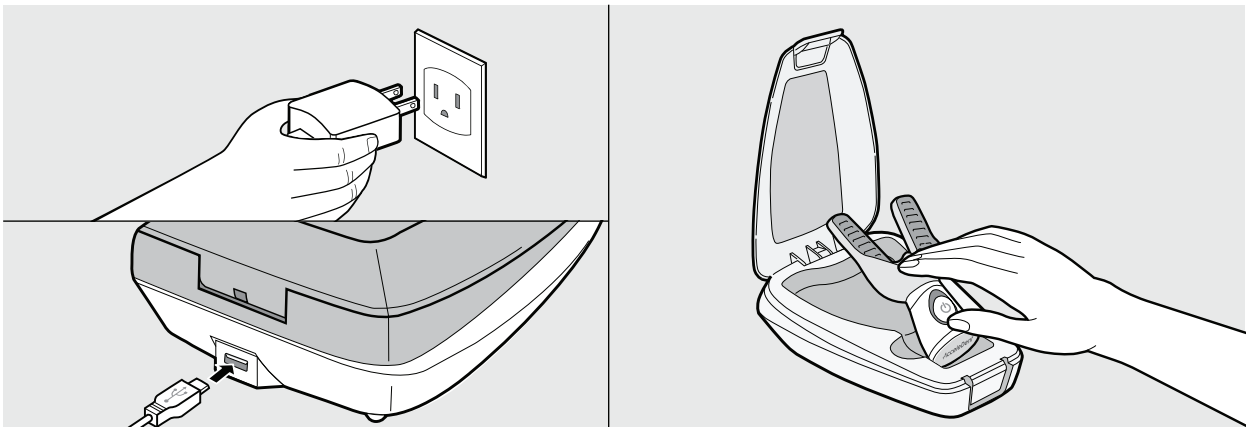
4.0 AcceleDent Optima Component Summary with Images



1. MOUTHPIECE
2. ACTIVATOR
3. ON/OFF BUTTON (STAND-BY)
4. STATUS INDICATOR
5. CHARGING CASE
6. USB CHARGING PORT
7. USB CHARGING CABLE
8. POWER ADAPTER

5.0 Use

5.1. Set-Up and Charging

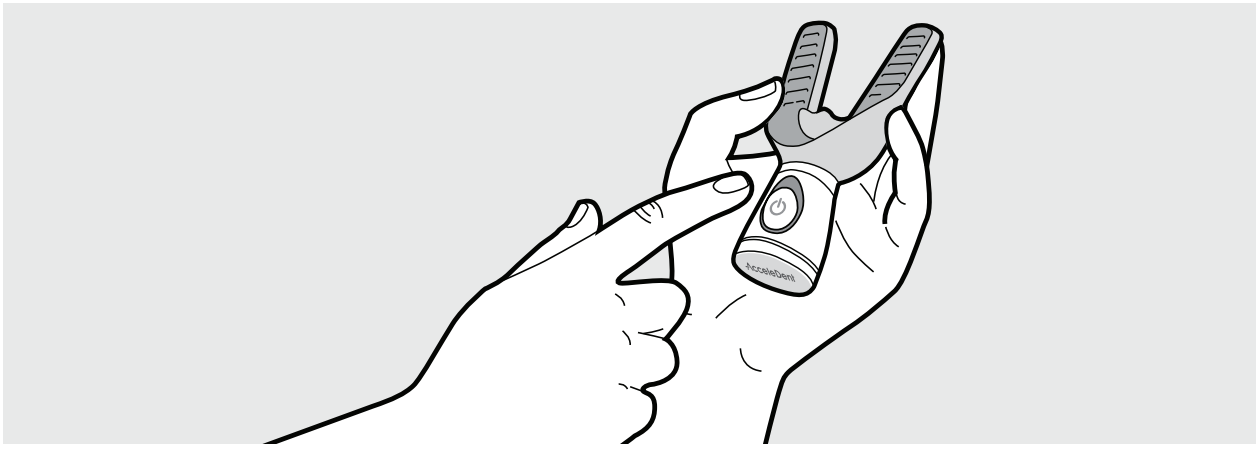


5.1.1. Power the Charging Case by connecting the USB Charging Cable to an electrical source.

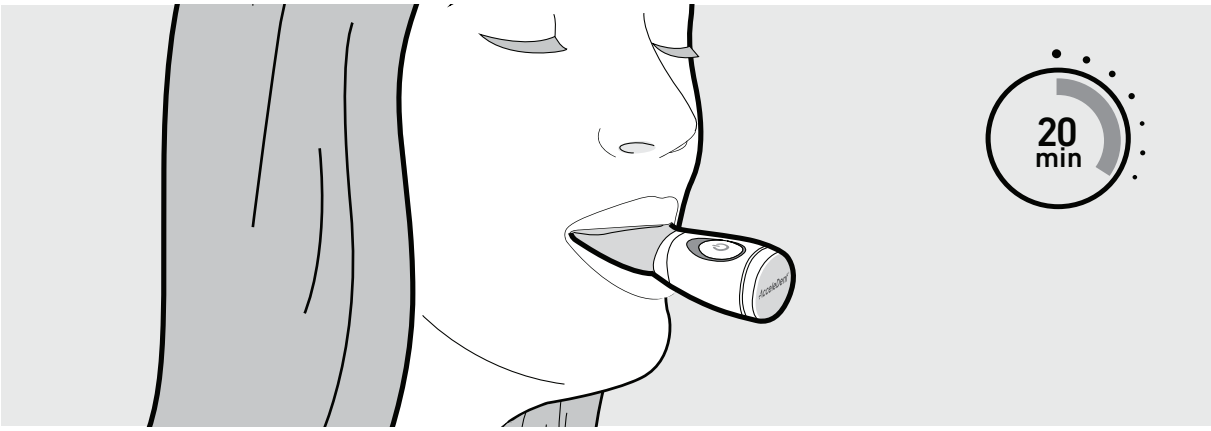
5.1.2. Open Charging Case by pushing down on the top of the latch (Unlock symbol). Check to make sure the *AcceleDent Optima* Activator is secure in the Charging Case for proper charging. To close the lid securely, push down on the front of the latch (Lock symbol).
Note: The lid does not need to be closed for proper charging.

5.1.3. The Status Indicator on the *AcceleDent Optima* Activator will be solid orange while charging and turn off when fully charged.

5.1.4. Prior to first use, charge for at least 8 hours.

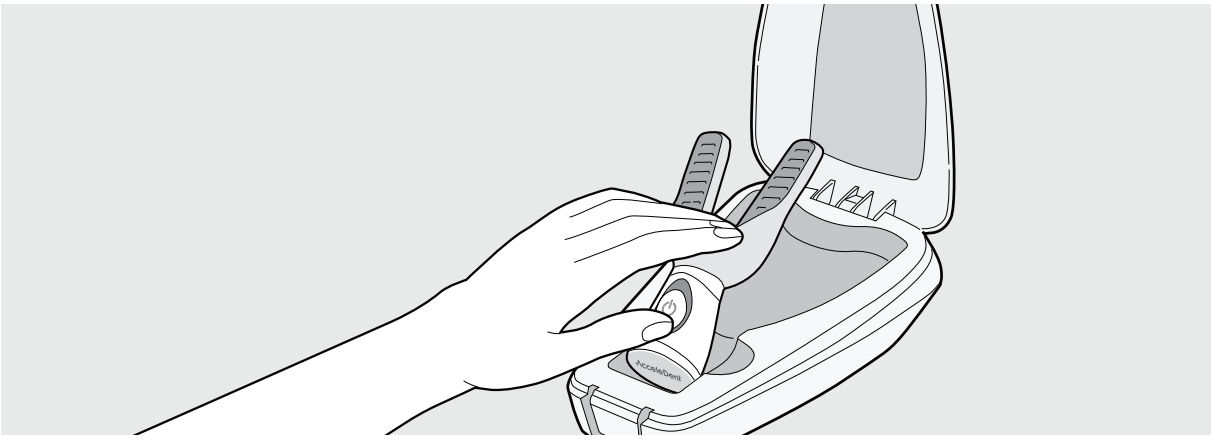


5.1.5. To begin your treatment session, press the on/off button. The Activator will vibrate, and the Status Indicator will be solid blue. The device will automatically turn off after 20 minutes of treatment.



5.1.6. Place the Mouthpiece in your mouth and bite down gently. *AcceleDent Optima* features a half-time indicator, which will pulse 2 times at the 10-minute mark. After 20 minutes of treatment, the Activator and Status Indicator light will automatically turn off.

5.1.7. To pause your treatment session for up to 5 minutes, press the on/off button once. During the pause, the Status Indicator will pulse blue slowly. When you are ready to resume, press the on/off button again to resume treatment. *AcceleDent Optima* will remember how long you used it as long as the interruption does not exceed 5 minutes. After 5 minutes of being paused, *AcceleDent Optima* will operate for a full session of 20 minutes at its next use.



5.1.8. Recharge the Activator after each treatment by returning it to the powered Charging Case. Place the *AcceleDent Optima* Activator securely in the Charging Case to ensure proper charging.

5.1.9. The Status Indicator will blink orange when the battery is low.

5.2. Indicators for the AcceleDent Optima Device

Solid orange	Charging battery
Blinking orange	Low battery
Solid blue	Active treatment
Solid blue and pulsing vibration	Mid-point treatment
Slow pulsing blue	Paused treatment
Fading blue to none	End of treatment
Alternating orange and blue blinking	End of device life

5.3. Use Schedule

5.3.1. By using AcceleDent Optima for 20 minutes per day, the small vibrations, or micropulses will help your teeth respond to orthodontic treatment more quickly.

5.3.2. Select a consistent time for use each day. This way using *AcceleDent Optima* becomes a routine, and you may be less likely to forget a daily session.

5.3.2.1. Some patients prefer using *AcceleDent Optima* just after they wake up and brush their teeth in the morning. Others use the appliance while engaged in a consistent daily activity, such as reading, watching TV, or using a computer/mobile device. Try several approaches and decide on the approach that works best for you.

5.3.2.2. You may find that occasionally using *AcceleDent Optima* right after you receive a wire change or switch to a new aligner tray is a good time to help reduce pain.

5.3.3. Try to find a time that you can use *AcceleDent Optima* without interruption as it is best not to stop use in the middle of a session.

5.3.4. You may easily pause and resume use if you are interrupted during a session. To pause, press the power button on the Activator. Refer to 5.1.7 for further information.

5.4. AcceleDent App Use

5.4.1. The *AcceleDent* App was developed to provide doctors and patients an easy way to track usage and provide motivation during your orthodontic treatment. It is not mandatory for *AcceleDent Optima* treatment, but your Orthodontist may recommend its use so that they can easily see if you will be experiencing the intended faster tooth movement, by using your *AcceleDent* for the recommended 20 minutes every day. The app is also a great motivational tool, an easy way to register your warranty, and connect with your practice through the app's messaging feature.

5.4.2. *AcceleDent* App is compatible with mobile devices with Android 6.0 or iOS 9.0 or later versions.

5.4.3. Install the Free *AcceleDent* App:

5.4.3.1. Android™ Device: Search in Android Market or Google Play™ Store for the *AcceleDent* App. Apple® Device: Search in Apple App Store® for the *AcceleDent* App.

5.4.3.2. Follow specific steps recommended by your device manufacturer for downloading the app.

5.4.4. Complete Registration:

5.4.4.1. Open the app and begin registration by tapping on Register.

5.4.4.2. Enter your name and email address, read and accept the Terms of Use.

5.4.4.3. Enter profile information including email address.

5.4.4.4. When you receive your confirmation email, confirm your registration and then log back in.

5.4.5. Pair Your Activator with Your Mobile Device:

5.4.5.1. Follow prompts given in the app during registration as a patient to complete pairing, including allowing the app to use your device's camera to scan the larger 2D barcode on the *AcceleDent* packaging. If you do not have your packaging, use the barcode located on the bottom of your Charging Case.

5.4.5.2. If you did not pair your Activator during registration of the app, you may pair later by accessing the Support tab located at the bottom of the main Menu (the three horizontal bars in the top left corner) and then tap on My Activator. You will then receive prompts given in the app to complete pairing.

5.4.6. Use Your Timer:

5.4.6.1. Go to Main Menu and tap My AcceleDent. The Timer starts automatically once you have paired your activator and press the on/off button on your Activator to start treatment.

5.4.6.2. If you pause your treatment session, a unique Pause Timer will be automatically visible on your app screen. When you resume treatment by pressing the button on the activator, the Timer will pick up where you left off.

5.4.7. View Your Dashboard:

5.4.7.1. From Usage History on the Main Menu, you will be able to see your overall usage percentage, which is your own achievement progress towards the goal of daily 20 minute sessions, your global ranking compared to all the other *AcceleDent* patients and more.

5.4.8. See Your Achievements:

5.4.8.1. On the Achievements Screen, you will see awards you have earned and awards that are still waiting for you to unlock.

5.4.9. Set Your Reminder:

5.4.9.1. To set up a daily reminder in your *AcceleDent* App, navigate to the Support tab and tap on Notifications. Make sure your notifications are on and select your preferred treatment time. You will then receive a push notification every day at this time, even if your app is closed.

5.4.10. Connect to Your Community:

5.4.10.1. Within Community, you can receive messages and keep track of friends. Positive reinforcement from your support network can be motivating to achieve excellent usage goals.

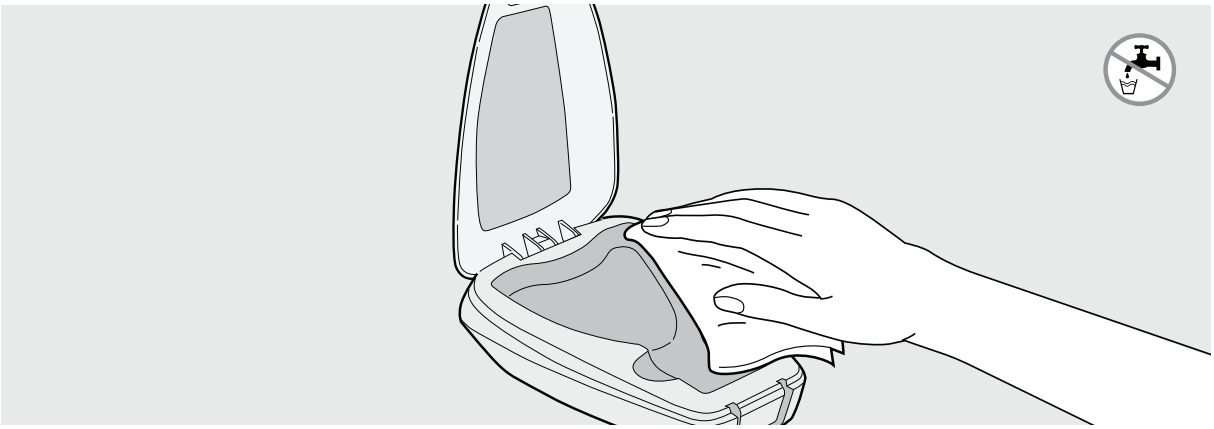
5.4.10.2. Family and friends can also use the *AcceleDent* App and register to become Observers, you may then grant them permission to view your dashboard reports, achievements, and send words of encouragement from within the messaging feature.

5.4.11. The information that is wirelessly transmitted via the Bluetooth communication link between the *AcceleDent Optima* Activator and the paired mobile device is the Activators motor performance information, battery status, and use data such as length of use and time of use. No patient identifying information is communicated through the wireless connection between your Activator and the app. Firmware updates, if needed, may also be wirelessly communicated from the *AcceleDent* App through the Bluetooth connection back into the Activator. Before any firmware updates are made, you will receive a notification so that you can choose a convenient time for the update to occur. For any questions about the firmware update, please contact customer service.

6.0 Care

6.1. Cleaning

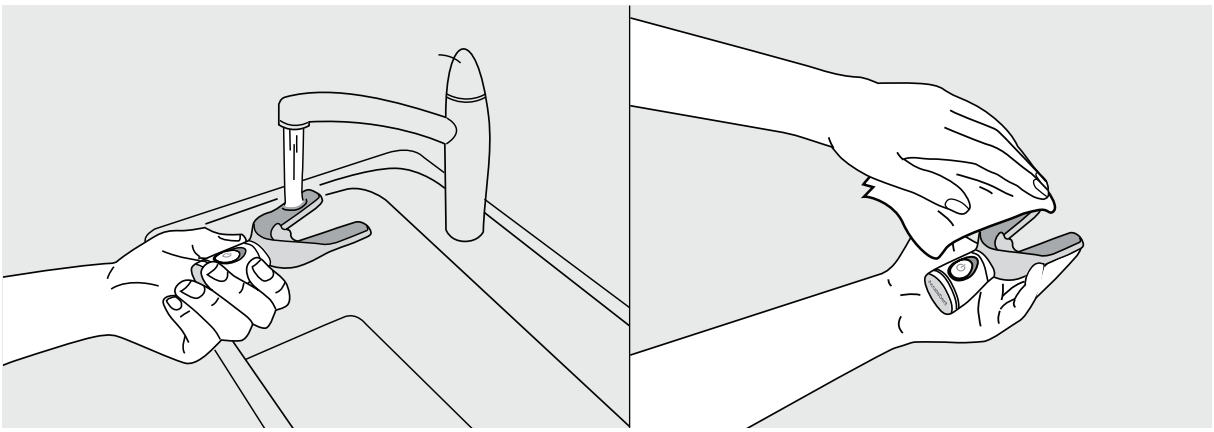
6.1.1. Simple hand cleaning is sufficient to remove accumulation of dirt or other build-up on the Activator and Charging Case.



6.1.2. For the Charging Case:

6.1.2.1. **DO NOT** rinse or submerge the Charging Case in water.

6.1.2.2. As needed, unplug from power source and wipe external and internal surfaces using a soft moist cloth. Dry with a soft cloth before reconnecting to power source.



6.1.3. For the Mouthpiece:

6.1.3.1. After each use, rinse the Mouthpiece with warm running water and wipe with a dry cloth prior to storage or charging.

6.1.3.2. Activator is waterproof, but it is recommended that the Activator is not submerged in water or cleaning solutions for an extended period of time.

6.1.3.3. Occasional cleaning with dish soap, dental cleaning solutions, and/ or brushing with toothpaste is acceptable.

6.2. Storage

6.2.1. Store *AcceleDent Optima* and Accessories away from pets, pests, and children to avoid inadvertent damage.

6.2.2. Activator should be stored in the Charging Case when not in use.

6.2.3. When not charging, unplug the Charging Case from the USB Cable and wall mount power supply.

6.2.4. Clean and store all components in a cool, dry place.

6.3. Disposal

6.3.1. The rechargeable battery inside of your Activator cannot be replaced.

6.3.2. In order to protect and preserve our environment, the Activator Assembly, Charging Case, USB Cable and Power Adapter should be disposed of at a designated collection facility for batteries and other electrical devices like cell phones, computers, video games and electronic tools.

6.3.3. These designated collection facilities are free of charge to the consumer because *OrthoAccel* and its distributors have acquired the appropriate registrations. The separated collection of electronic equipment waste allows for proper recycling, saves energy and resources and prevents hazardous material from going to a landfill. The internet can be a helpful tool to locate the nearest recycling center for batteries and electrical devices, or contact *OrthoAccel* Technologies, Inc. at 1-866-866-4919 (North America) or +44 (0) 203-318-1915 (outside of North America) or customerservice@orthoaccel.com for assistance.

7.0 Warranty

7.1. Express Limited Warranty

7.1.1. *OrthoAccel* Technologies, Inc. (*"OrthoAccel"*) warrants that the product packaged with this warranty (the "Product") will be free from significant defects

in materials and workmanship under normal use and service for a period of one year from the date of purchase (the "Warranty Period"). This limited warranty is non-transferable and applies only to the original purchaser and the initial orthodontic patient using the Product. This limited warranty also applies only when the Product is used in accordance with the Product manual and directions for use found on the Product website.

7.1.2. This limited warranty covers all defects encountered in normal use and service but does not apply if: (1) the Product is modified or tampered with or disassembled, (2) the Product is damaged by an act of God, misuse, abuse, neglect, accident, or mishandling, (3) the Product is not used or maintained in accordance with the accompanying user documents, or (4) the serial number on the Product is defaced, altered or removed. In addition, this limited warranty does not cover normal wear such as discoloration or fading, and normal wear that does not compromise use of the appliance such as chips, scratches, and abrasions. Your exclusive remedy for breach of this limited warranty during the Warranty Period shall be, at the option of *OrthoAccel*, the replacement of the Product with a new Product, as determined by the *OrthoAccel* Warranty. Replacement shall not extend the original Warranty Period.

7.1.3. All returns for warranty service will require an RMA (Return Merchandise Authorization). To receive an RMA for obtaining warranty services, you must call 1-866-866-4919 in North America or +44 (0) 203-318-1915 if outside of North America. In addition, if your product has not been registered you must submit proof of the date of original purchase such as a copy of your dated invoice and must insure, pack and ship the Product to an authorized service center in accordance with *OrthoAccel's* instructions within 7 days after your receipt of an RMA. The package must include your RMA. RMA's will not be extended or reissued.

7.1.4. No Implied Warranties: Limitations on Damages

7.1.5. The Express Limited Warranty provided above is the only expressed warranty made to you and is in lieu of all other warranties, whether express or implied. Without limiting the generality of the foregoing, *OrthoAccel* disclaims any and all other warranties, express or implied. With respect to the product including its condition, the existence of any latent or patent defects, its non-infringement of third party rights and its merchantability or fitness for any particular use. In no event shall *OrthoAccel* or any of its affiliated or subsidiary companies be liable for any special, incidental, or consequential damages based upon breach of warranty, breach of contract, negligence, tort, or any other legal theory. Such damages include, without limitation, loss of savings or revenue; loss of profit; loss of use; the claims of third parties including, without limitation, dental professionals; and cost of any substitute equipment or services.

7.2. Legal Limitations

7.2.1. Some jurisdictions do not permit or allow limitations on how long implied warranties last or the exclusion or limitation of incidental or consequential damages. If any terms of this limited warranty, including, without limitation, the exclusion of damages, are limited or prohibited by your jurisdiction, the prohibited provision shall not apply but the remainder of this limited warranty shall remain in full force and effect. You may have rights in addition to this limited warranty under the laws of your jurisdiction, which may vary from jurisdiction to jurisdiction.

7.3. Customer Service and Replacement

7.3.1. For additional support during use, please reference the Frequently Asked Questions (FAQ) and Troubleshooting Guide located at acceledent.com/FAQ.

7.3.2. If you have any questions or comments after reading the provided materials, please contact the *OrthoAccel* Customer Service:

North America: 1-866-866-4919
Outside North America: +44 (0) 203-318-1915
Email: customerservice@orthoaccel.com
Online: www.acceledent.com
EMERGO EUROPE: +31-70-345-8570

8.0 Safety

8.1. Patients undergoing orthodontic treatment under the supervision of an orthodontist or dental professional are the intended operators of this product. While not exclusive, the intended user profile primarily comes from the following demographics: male and female teens (13 - 17 years old with adult consent or supervision, as required), and male and female adults (18 - 65 years old). No age or eduction level restrictions.

8.2. This product is designed to enhance your orthodontic treatment only. Use this product only for its intended use as described in this manual.

8.3. (For healthcare professionals): Please instruct patients to read these Directions For Use for precautions to be taken in the event of changes in the performance of the device and precautions to be taken regarding the exposure of the device to reasonably foreseeable environmental conditions.

8.4. Contact your physician, orthodontist or dentist if you have any medical concerns about *AcceleDent Optima*. Discontinue use of this product and immediately contact your orthodontist if any discomfort or pain is experienced.

8.5. *AcceleDent Optima* has been tested and is in compliance with safety standards for electromechanical devices. *AcceleDent Optima* meets the required electrical safety and emissions standards; however, the appliance has not been tested for effects on any other specific medical devices (such as pacemakers, cochlear implants, and/or nerve stimulators). Please contact the other device manufacturers with any questions or concerns about effects on their devices.

8.6. This appliance is not intended for use by persons (including children) with reduced physical, sensory, or mental capabilities unless they have been given supervision or instruction concerning use by a person responsible for their safety, or unless otherwise indicated by an orthodontist or dentist.

8.5. Warnings

8.5.1. WARNING: DO NOT plug the Power Adapter into an outlet with a voltage other than that specified on the Power Adapter as it may cause electric shock and permanent damage to your device. This product is designed to operate within a range of 100 – 240 volts. Voltage converters DO NOT guarantee voltage compatibility.

8.5.2. WARNING: NEVER force the Power Adapter into an outlet; if it does not easily fit into the outlet, discontinue attempts as it may cause electric shock and permanent damage to your device.

8.5.3. WARNING: NEVER charge your device using a Power Adapter that does not meet specifications as listed in the Technical Description of this manual as it may cause electric shock and permanent damage to your device.

8.5.4. WARNING: *AcceleDent Optima* should not be stacked or located on or around other equipment that may create electromagnetic interferences.

8.5.5. WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of *AcceleDent Optima*, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

8.5.6. WARNING: NEVER use a damaged Activator, Charging Case, USB Charging Cable, or Power Adapter as it may cause electric shock and/or further damage to your device. Refer to the section in this manual titled "Customer Service and Replacement" if your *AcceleDent Optima* or any of its components no longer work properly.

8.5.7. WARNING: DO NOT place or store the device or accessories near any heated surfaces, as it could cause fire or permanent damage to your device.

8.5.8. WARNING: DO NOT place or store the Power Adapter or Charging Case where it will sit in a pool of water or where it can fall or be pulled into a bathtub, sink, or toilet. DO NOT reach for a Charging Case that has fallen into water. Unplug immediately.

8.5.9. WARNING: DO NOT use accessories and cables other than those specified or provided by the manufacturer of this equipment. This could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

8.5.10. WARNING: DO NOT interconnect the Charging Case USB connector to equipment not specified in this manual.

8.5.11. WARNING: The Federal Communications Commission does not allow any modifications or changes to the unit EXCEPT those specified in this manual. Failure to comply with this government regulation could void your right to operate this equipment.

8.5.11.1. No modification of the equipment is allowed.

8.5.11.2. DO NOT attempt to replace the battery.

8.6. Precautions

8.6.1. DO NOT use *AcceleDent Optima* without it being prescribed by an orthodontist or dentist. This is a prescription device which must be prescribed by an orthodontist or dentist. As with many medical devices, use by an individual without the proper issuance from an orthodontist or dentist can result in unintended consequences.

8.6.2. CONSULT your orthodontist or dentist prior to use of this product if you have had any recent craniofacial surgery (above the neck).

8.6.3. DO NOT share your *AcceleDent Optima* device. *AcceleDent Optima* is a single patient device (one patient to one device). Use of the device by more than one person may result in the transmission of viral and bacterial infective agents, even if an effort has been made to sanitize it.

8.6.4. DO NOT use a Mouthpiece that is damaged. Consult your orthodontist or dentist if the Mouthpiece no longer fits comfortably for any reason. Inappropriate cleaning may also cause damage to the Mouthpiece (see “Care” section).

8.6.5. DO NOT use *AcceleDent Optima* outside of the environmental conditions specified in the Technical Description of this manual.

8.6.6. DO NOT use *AcceleDent Optima* outside of the electromagnetic environment specified in the Technical Description of this manual.

8.6.7. DO NOT clean any components or accessories in the dishwasher or microwave.

8.6.8. DO NOT boil, steam or dry heat sterilize any components or accessories.

8.6.9. DO NOT rinse or submerge the Charging Case or accessories in water.

8.6.10. DO NOT attempt to service or perform maintenance on the device. This product contains no serviceable parts.

8.6.11. DO NOT attempt to charge the Activator with a Qi charger or any other wireless charger than the one supplied by OATI.

8.6.12. DO NOT expose Activator or Charging Case to UV light for an extended period of time as it may discolor.

9.0 Help

9.1. If you have any questions, concerns, or to report an unexpected operation or events regarding your *AcceleDent Optima* product, please contact the Customer Care Center for your country (visit www.acceledent.com for contact information). If you need immediate assistance, please contact the *OrthoAccel* Customer Service.

10.0 Technical Description

10.1. *AcceleDent Optima* complies with IEC 60601-1 and 3rd Edition Amendment 1; IEC 60601-1-11; IEC 60601-1-2 and 4th Edition; IEC 60601-1-6/62366; IEC 60601-1 2nd Edition Amendment 1 and 2. This information is intended to provide environmental operating conditions, transport/storage conditions, as well as IEC 60601 equipment ratings, electrical safety classification for the included equipment. Conditions should fall between the ranges detailed below.

10.2. The expected service life of *AcceleDent Optima* is two years.

10.3. **Environmental Operating Conditions**

Ambient Temperature Range: 5-35°C
Maximum temperature of any external component at maximum ambient

temperature: 50°C
Relative Humidity Range: 15-90%
Atmospheric Pressure Range: 700-1060 hPa

10.4. Transport and Storage Conditions

Ambient Temperature Range: -20 to 50°C
Relative Humidity Range: 30 - 93% RH

10.4.1. If *AcceleDent Optima* has been transported or stored at its maximum or minimum transport or storage conditions, the product shall be allowed to cool or warm for at least two hours within the environmental operating conditions before use.

10.5. The Activator is a Type BF Applied Part, meaning this medical device has direct contact with the patient. Such devices shall be marked with  symbol.

10.6. A Power Adapter intended for connection to the USB port of the Charging Case shall comply with the relevant product standard e.g. IEC 60950-1 or IEC 62368-1 for IT-equipment and the IEC 60601-series for Medical Electrical Equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated in the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents.

10.7. Use the provided Power Adapter or one that is certified as Class II adapter with double or reinforced insulation. Such Power Adapter shall be marked with  symbol or labeled Class II. The specifications of an appropriate Power Adapter are detailed below:

10.7.1. Certification: Class II, IEC 60950
Output Voltage: 5 V
Output Current Limit: 1 A
AC Input Voltage Range: 100-240 V
AC Input Current: 0.2 A
AC Input Frequency: 50/60 Hz

10.8. Any person who connects external equipment to the USB connector has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact a qualified medical technician or your local representative.

10.9. The USB port located on the back of the Charging Case is for battery charging purposes only. The Charging Case has no data communication ability. The Charging Case shall have two means of protection, as Class II equipment, in order to prevent the parts from exceeding voltage, current, or energy limits defined by IEC 60601-1. As a precaution, the USB connector should not be touched or manipulated when connected to the Power Adapter and when the Power Adapter is connected to the supply mains. The Power Adapter can be isolated from the supply mains by unplugging the device. Do not position the charging case to make it difficult to operate the disconnection device (USB cable).

10.10. Ingress Protection Class

10.10.1. The Charging Case is rated IP32; it is protected from intrusion of solid foreign objects greater than 2.5 millimeters, except dust or lint, and against vertically falling water drops when enclosure is tilted up to 15°.

10.10.2. The Activator is rated IP67; it is protected from total dust ingress and from immersion between 15 centimeters and 1 meter in depth.

10.11. FCC Compliance Statement

10.11.1. 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.

10.11.1.1. 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 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 particular installation. If this equipment does cause harmful interference to radio or television reception, which can be recognized by turning the equipment off and on, the user is encouraged to troubleshoot to correct and reduce the interference by one or more 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.

- Please contact the OrthoAccel Customer Service.

10.11.2. Recommended separation distances:

10.11.2.1. *AcceleDent Optima* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of *AcceleDent Optima* can help prevent, reduce or correct electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *AcceleDent Optima* device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitted m**		
	1150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	.23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

10.12. CAN ICES -3 (B)/NMB-3(B)

10.12.1. This device complies with Industry Canada's licence -exempt RSSs. Operation is subject to the following two conditions:
(1) This device may not cause interference; and
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

10.13. Environmental Specifications

10.13.1. Electromagnetic Requirements:

10.13.1.1. *AcceleDent Optima* complies with all applicable and required standards for electromagnetic compatibility.
AcceleDent Optima is suitable for the home healthcare environment meaning all environments except for near active HF SURGICAL EQUIPMENT and areas of high intensity of EM DISTURBANCE.

10.13.1.2. *AcceleDent Optima* transmits and receives electromagnetic

energy at 288 kHz +/- 10 kHz for the purposes of wireless charging.

AcceleDent Optima complies with the Bluetooth Low Energy (BLE) standard; it transmits and receives electromagnetic energy through at 2.4 to 2.4835 GHz. The band is split into 40 2 MHz channels. The maximum transmit power is less than 1 mW.

10.13.1.3. See IEC 60601-1-11 clause 4.2.3.1 for applicable conditions. This device has been tested and found to comply with requirements for CISPR 11 Class B digital devices, which is designed to provide reasonable protection against interference in a residential setting. However, there is no guarantee that interference will not occur in a particular installation.

10.14. Electromagnetic Emissions

10.14.1. The Activator is intended for use in the electromagnetic environment specified below. The customer or the user of the unit should assure that it is used in such an environment.

10.14.2. In accordance with Clause 4.3 of IEC 60601-1, *AcceleDent Optima* does not have Essential Performance.

Emissions Test	**Compliance**	The *AcceleDent Optima* uses RF energy for internal function and low power communication; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Group 1	
RF Emissions CISPR 11	Class B	The system 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 IEC61000-3-2	N/A	
Voltage fluctuations / Flicker emissions IEC61000-3-3	N/A	

10.14.3. Bluetooth Low Energy:

10.14.3.1. Bluetooth, Bluetooth Low Energy, Bluetooth Smart and the Bluetooth logo are registered trademarks of Bluetooth SIG.

10.15. Electromagnetic Immunity

10.15.1. Electromagnetic Immunity Part 1

10.15.1.1. The Activator is intended for use in the electromagnetic environment specific below. The customer or the user of the Activator

should assure that it is used in such an environment.

IMMUNITY Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical domestic environment.
Surge IEC 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 domestic environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% drop, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods Voltage Interruptions (all input current)	100% drop, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods 100% drop, 5 seconds	Mains power quality should be that of a typical domestic environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical domestic environment. Tested in X, Y, and Z axes. Can be waived due to a justification that there are no magnetic components. Assumes a minimum distance of 15 cm to magnetic source in actual usage
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

10.15.2. Electromagnetic Immunity Part 2

10.15.2.1. The Activator is intended for use in the electromagnetic environment specific below. The customer or the user of the Activator should assure that it is used in such an environment.

IMMUNITY Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6V Amateur 0,15 MHz – 80 MHz Enclosure 10V/m 80% AM at 1 kHz or risk frequency 80 MHz – 2700 MHz	6 V Enclosure 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of *AcceleDent Optima*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2,5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a) should be less than the compliance level in each frequency range. b) Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *AcceleDent Optima* is used exceeds the applicable RF compliance level above, the *AcceleDent Optima* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating *AcceleDent Optima*. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

10.16 Material:

10.16.1. *AcceleDent Optima* is made of biocompatible materials. The *AcceleDent Optima* Activator has been tested and verified to have less than 0.01% by mass of Latex proteins. The *AcceleDent Optima* Activator has been tested and verified to have less than 0.01% by mass of DEHP.

11.0 Symbols and Definitions

Symbol	Description
LOT	Lot number or batch code
REF	Reference or Catalog number
S/N	Serial Number
P/N	Part Number, Model Number or Reference
	Date of manufacture
	Manufacturer
	Use by date
	Follow Instructions for use
	Refer to instruction manual
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Certification that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
	Class II Equipment
	Type BF Applied Part: Devices that have direct contact with the patient, or parts that have long term contact with the patient.
	Interference may occur in the vicinity of equipment marked with the following symbol.
	Bluetooth enabled
EC REP	Authorized representative in the European Community
CE 0086	European Conformity (CE) Mark, with notified body number

	Temperature limitation
	Separate collection for electric and electrical equipment
	Keep Dry
	Fragile
	Stand-by
	20 minutes for treatment
	Open Charging Case by pushing down on this part of the latch
	Close Charging Case by pushing down on this part of the latch
	Humidity limitation
	Atmospheric pressure limitation
	Not waterproof
IP32	Is protected from intrusion of solid foreign objects greater than 2.5 millimeters, except dust or lint, and against vertically falling water drops when enclosure is tilted up to 15°.
IP67	Is protected from total dust ingress and from immersion between 15 centimeters and 1 meter in depth.

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