

Directions for Use

AcceleDent[™]

THE **FAST** TRACK
TO STRAIGHT TEETH



OrthoAccel® is a registered trademark of OrthoAccel Technologies, Inc.®

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AcceleDent is covered by one or more of the following US patents: 6648639, 6832912, 7029276, and others pending.

Rx only
For orthodontic applications

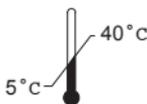
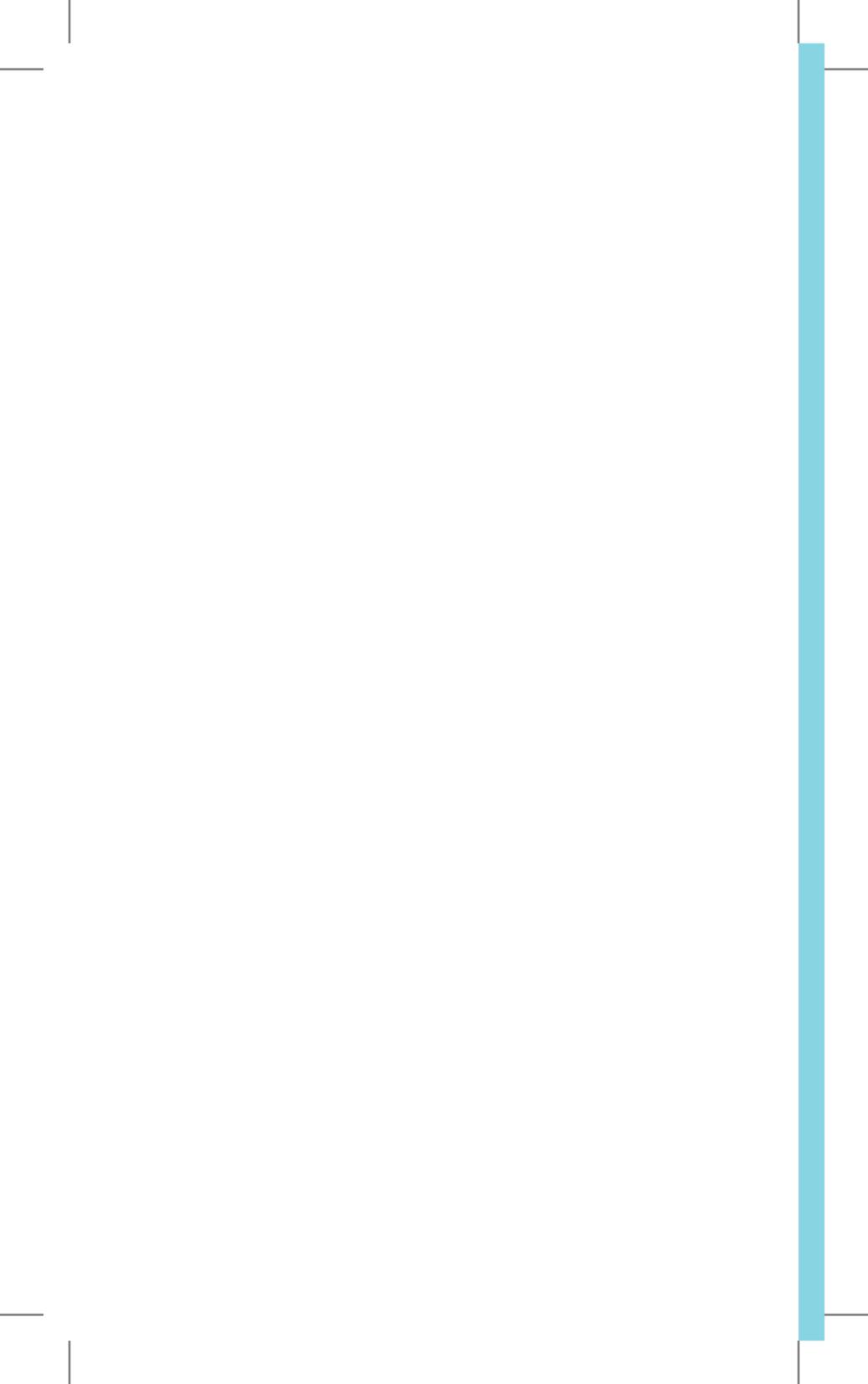


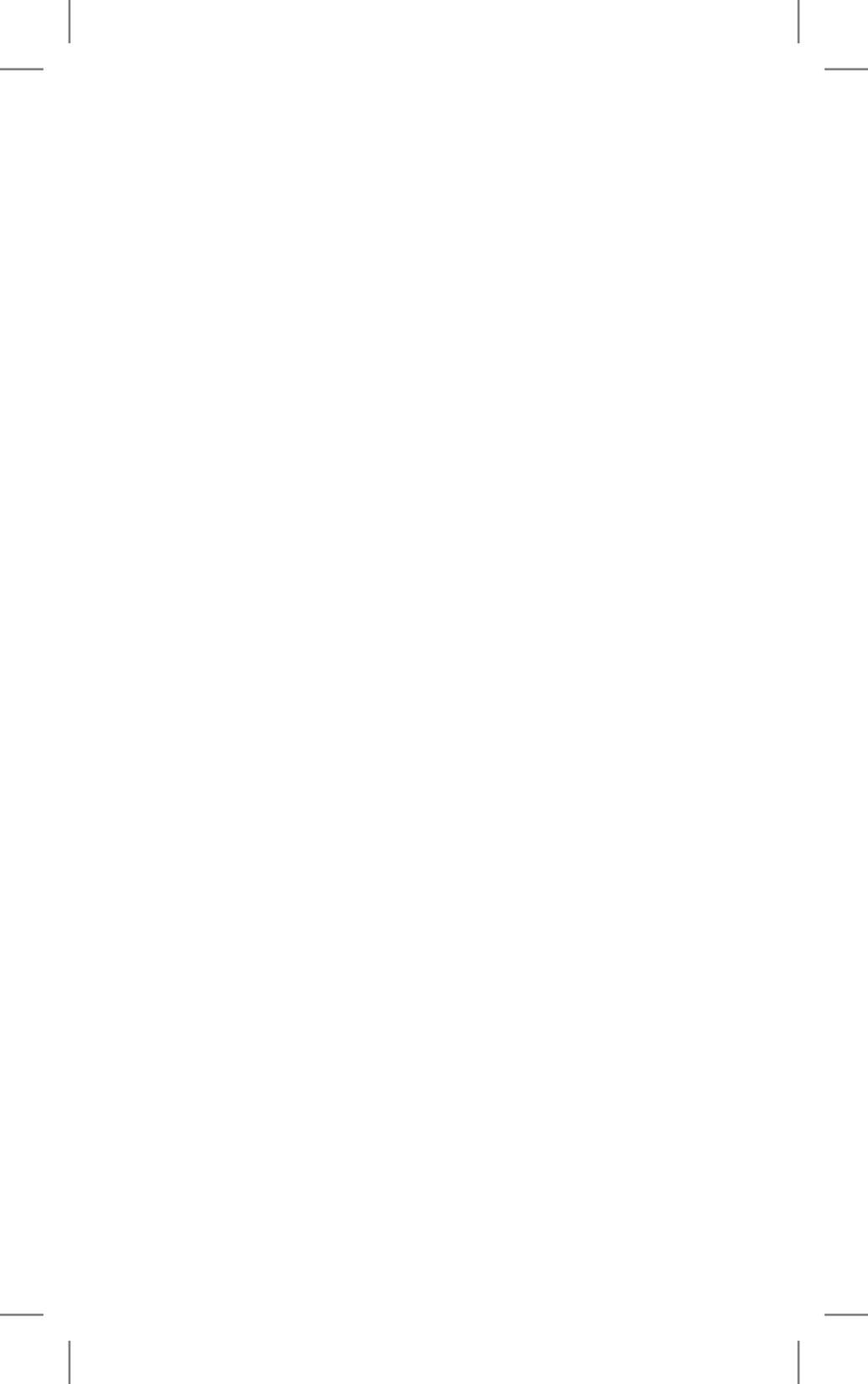
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1.0 Introduction

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Talk with Your Orthodontist

Your orthodontist is your best resource for information about your care and AcceleDent. If you need assistance with any aspect of your orthodontic care, ask your orthodontist. OrthoAccel is not authorized to make any representations related to your specific treatment, or to provide any form of orthodontic treatment advice or consultation.

Use this handy reference guide to keep track of your information:

Office Name: _____

Orthodontist: _____

Address: _____

City, State, Postal Code: _____

Telephone Number: _____

Emergency Tel. Number: _____

Treatment Start Date (Yr/Mo): _____

About the Manufacturer

Talk with the manufacturer – OrthoAccel Technologies, Inc. - about any questions or concerns that are specifically related to AcceleDent and its components.

Customer Service Information

For assistance, contact the OrthoAccel Customer Service Center:

North America: +1 832.631.1660

Outside North America: +44 (0) 203.318.1915

Email: customerservice@acceleddent.com

Online: www.acceleddent.com

Intended Use/Indications for Use

AcceleDent is an orthodontic accessory intended for use during orthodontic treatment. It is used in conjunction with orthodontic appliances such as braces and helps 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

AcceleDent Components

1 Activator

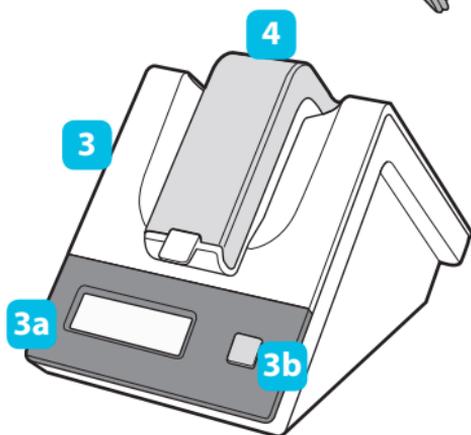
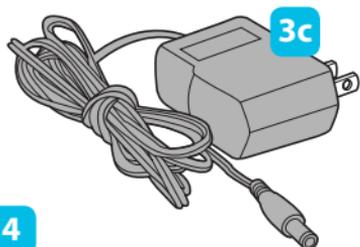
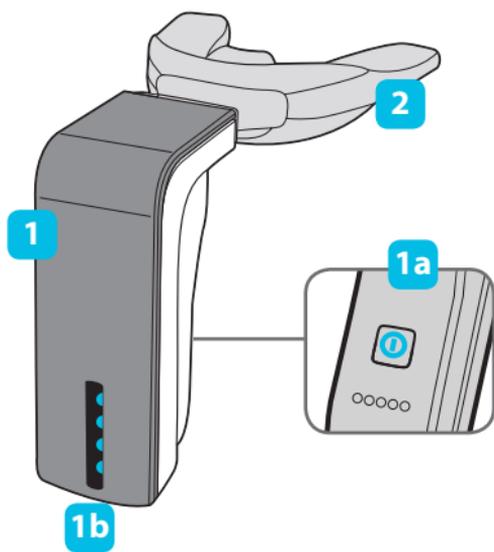
- 1a Power Button
- 1b Battery Gauge

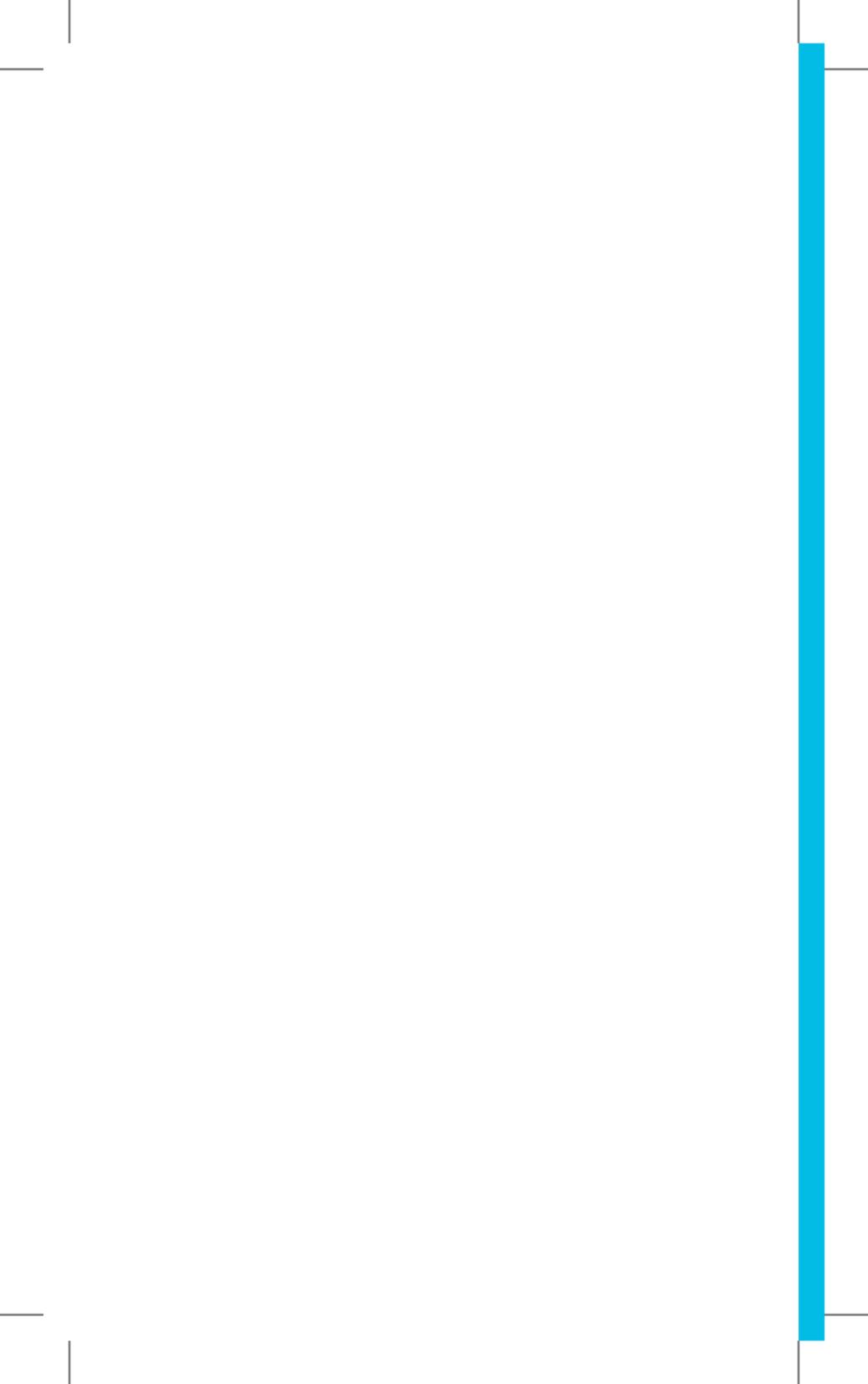
2 Mouthpiece

3 Charging Port

- 3a SmartDisplay
(See Charging Port section for
complete display information)
- 3b Display Button
- 3c Power Source

4 Travel Shell





2.0 Use

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Set-up and Charging the Unit

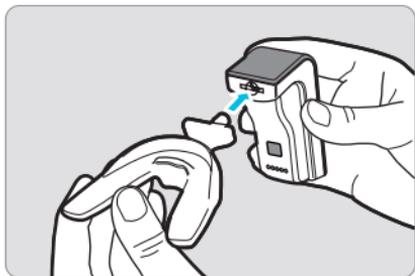
Fully charge the Activator prior to initial use. Do not leave the Activator docked on an unpowered Charging Port as this will drain the Activator battery.

The Activator must be enclosed within the Travel Shell in order to dock on the Charging Port. **To properly dock the Travel Shell for charging, engage the Mouthpiece end into the Charging Port and then gently push downward until the front end clicks into place.** The Activator is properly docked to the Charging Port if the LED lights on the Activator cycle from dark to light and the SmartDisplay LCD viewing screen on the Charging Port can be advanced to the various information windows.

To maximize the time between charges, the Activator should be recharged every 3 to 5 days or when no lights are visible on the Battery Gauge. Although it takes several hours to fully charge a discharged Activator, most of the charge occurs within the first hour. The battery life is approximately 2.5 years.

If you have any questions about beginning your use of AcceleDent, ask your orthodontist.

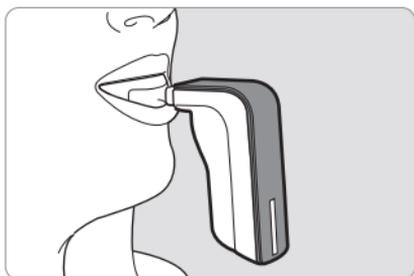
Steps for Use



1. Insert Mouthpiece into Activator. Make sure these two components are properly attached. Two small recessed slots on the end of the Mouthpiece guide the connection with the correct side of the Mouthpiece facing up. A very light tug on the Mouthpiece should not cause disconnection from the Activator.



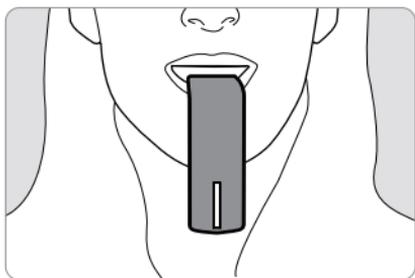
2. Turn the Activator "ON." Press and hold the power button down until the Activator begins gentle pulsing.



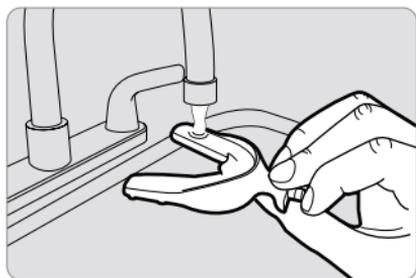
3. Place appliance in mouth and bite down. Biting lightly, with just enough force to hold the appliance in place, is ideal. It is not necessary to bite with excessive pressure. The appliance does not need to be held by hand once placed inside the mouth and held by the bite, although the hands can be used to adjust the position throughout the session as needed. You will be more comfortable if you relax the jaw and facial muscles, while maintaining enough force to stabilize the Mouthpiece.

(continued on next page)

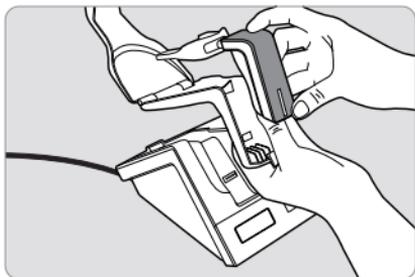
Steps for Use (cont'd)



4. Complete 20-minute session. Simply keep the appliance in place while it is pulsing. The HalfTime indicator will “stutter” at the 10-minute mark. If the appliance needs to be shut off or paused during use, simply press the button on the Activator in the same manner used when turning the appliance on.



5. Remove and rinse Mouthpiece. The recommended method for cleaning is to rinse with lukewarm water. See the “Care” section for further details.



6. Dock Activator. When a session is complete, the Activator can be re-docked on the Charging Port. Please note that the Activator must be enclosed within the Travel Shell in order to dock on the Charging Port. To properly dock the Travel Shell for charging, engage the Mouthpiece end into the Charging Port and then gently push downward. A click indicates that the appliance has been properly situated. The appliance can remain on the Charging Port at all times while not in use; it is not harmful to the battery. However, it is only necessary to dock the appliance on the Charging Port when it is running low on charge, so check the Battery gauge.

Do not leave the Activator docked on an unpowered Charging Port as this will drain the Activator battery.

The Activator is properly docked to the Charging Port if the LED lights on the Activator cycle from dark to light and the SmartDisplay LCD viewing screen on the Charging Port

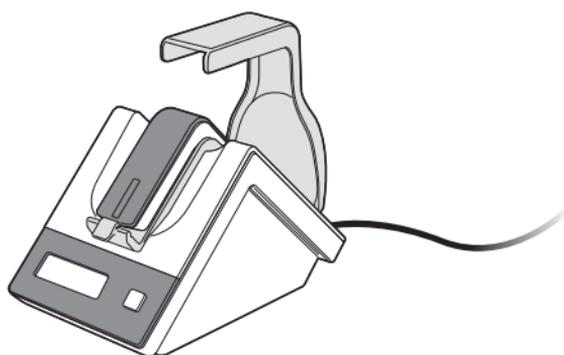
can be advanced to the various information windows.

Note: OrthoAccel recommends bringing your AcceleDent to each orthodontist appointment so that your appliance and usage can be checked.

Use Schedule

Use AcceleDent for twenty minutes per day and experience gentle pulsing to the teeth that will help your teeth respond to orthodontic treatment more quickly.

Select a consistent time for use each day. This way, it becomes a routine and you are less likely to forget. Try to find a time that you can use AcceleDent uninterrupted – it is best not to stop use in the middle of a session. It is fine to adjust the external unit with your hand occasionally. Some patients prefer using AcceleDent 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 or watching TV. Try several approaches and decide on the approach that works best for you. Dock the Activator, enclosed within the Travel Shell, in order to upload and view the SmartDisplay data on compliance and usage. See the “Charging Port” section of this guide for further details.



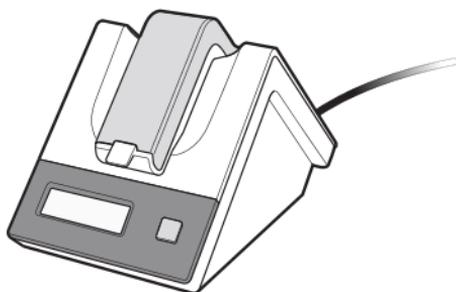
You may easily pause and resume use if you must be interrupted during a session. To pause, press the power button on the Activator and hold it down for about one second. When you are ready to resume, press it again to unpaue. The appliance will maintain memory toward the twenty-minute total use duration as long as the interruption does not exceed five minutes. After five minutes, re-starting AcceleDent will result in a new twenty-minute session.

AcceleDent features a HalfTime Indicator, during which the gentle pulsing goes on and off for a few seconds, to signal that ten minutes has elapsed.

The Mouthpiece is waterproof and may be cleaned under running water. The Activator is not water resistant and should not be exposed to running water or submerged under water. No component of the appliance is dishwasher-safe. Hand-clean only.

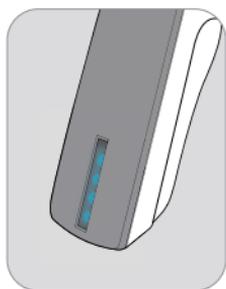
Charging Port

Use the Charging Port for best results from AcceleDent. Each time you dock your Activator, usage information is loaded to the Charging Port. This may be recorded and provided to your orthodontist. Your orthodontist may ask you to provide information about duration of use or number of uses, and all is readily available from your SmartDisplay.



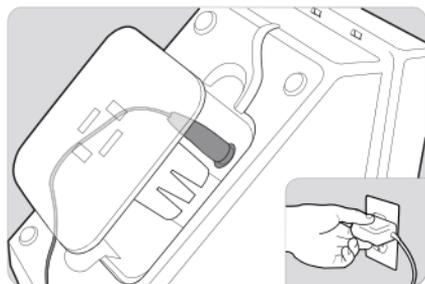
Position the Charging Port in a convenient location near an electrical outlet. **Fully charge the Activator prior to initial use.** The Battery Gauge lights on the Activator will cycle from dark to light while charging and the SmartDisplay LCD viewing screen on the Charging Port can be advanced to the various information windows. When fully charged the cycling from dark to light will stop and all four Battery Gauge lights will be illuminated solid. It takes several hours for a fully discharged Activator to fully charge. The battery charge level can be monitored on the Activator's Battery Gauge, similar to a mobile phone, by quickly pushing and

releasing the power button. Once fully charged the appliance will continue to work without further recharging for approximately five days.



It is not necessary to attach the Mouthpiece in order to dock the Activator, but the Activator must be enclosed in the Travel Shell to properly dock the Activator. The Travel Shell itself is what actually docks to the Charging Port.

The Charging Port, featuring a convenient cord wrap, is designed to last for the entire duration of your orthodontic treatment and has a two-year limited warranty.



Charging Port (cont'd)

The Travel Shell and Mouthpiece are both waterproof. None of the system components are dishwasher-safe. See related details in the warranty.

There are no self-service parts in the Charging Port. Removing the cover will void the warranty and presents an electrical shock hazard. For more information on servicing the Charging Port see the warranty outlined in the Directions for Use. Do not return any part of a used AccelDent to your orthodontist for repair.

SmartDisplay

The SmartDisplay LCD viewing screen is located on the lower left side of the Docking Station. The Display Button is located to the right of the viewing screen.

There are five separate information windows available on the single SmartDisplay Screen. Scan each window by pressing the Display Button to view each information window.

The first information window, the Welcome Screen, is displayed when the Charging Port is turned on. You will see “Visit www.aceledent.com”



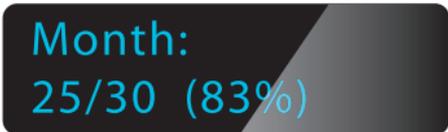
Visit
www.aceledent.c

The second window is the “Last Week” data area. This area indicates the number of days that AcceleDent was used during the last 7 days.



Week:
6/7 (86%)

The third window is the “Last Month” data area. This area indicates the number of days that AcceleDent was used during the last 30 days.



Month:
25/30 (83%)

Charging Port (cont'd)

The fourth window is the "Total" data area. This area indicates the total number of uses for the AcceleDent.



Total:
145 uses

Note: For all information windows related to use, a standard treatment session involves using AcceleDent for the full intended twenty minutes. Therefore, when counting daily use sessions, if the appliance is used for less than ten minutes, no treatment usage is registered. If the appliance is used for at least ten minutes, but less than a full session of twenty minutes, a half-treatment usage is registered. If the appliance is used for a full twenty minutes, a full treatment usage is registered.

The fifth window shows the software version.

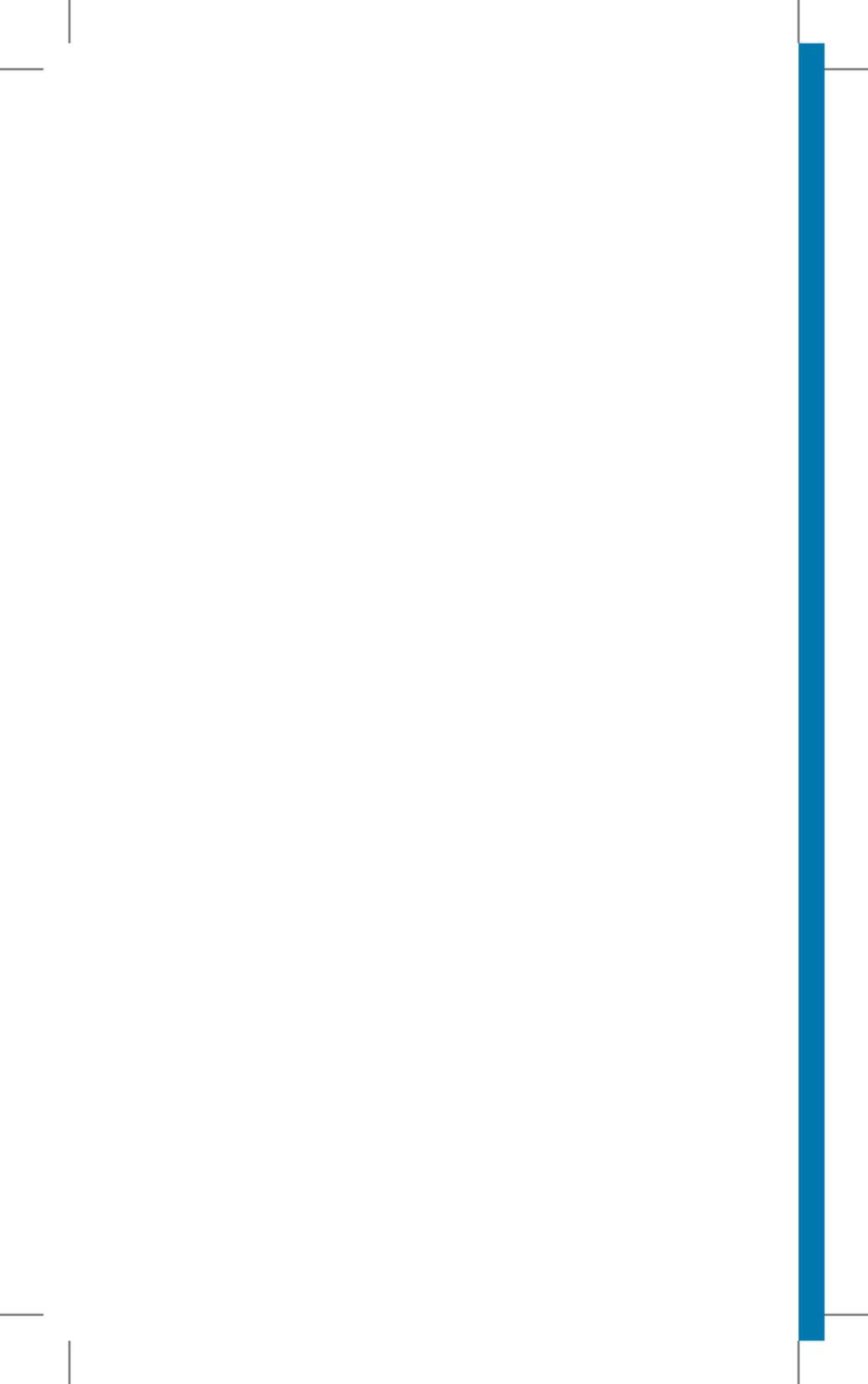
Travel Shell

The Travel Shell serves two purposes.

First, it is a convenient carrying case for patients who use AcceleDent daily in locations away from home.

Second, it serves as an enclosure for docking the Activator on the Charging Port.

To order an extra Travel Shell, contact your orthodontist.



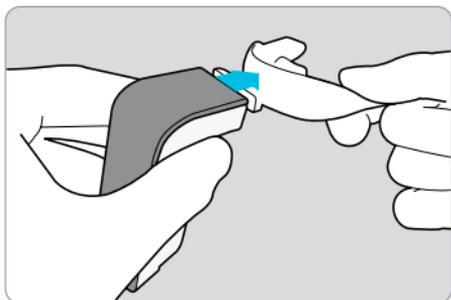
3.0 Care

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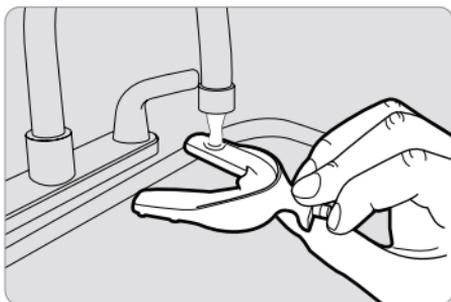


Cleaning

Remove the Mouthpiece from the Activator by gently pulling the two components away from one another to disconnect. This should not require significant force.



Use a damp cloth to wipe down all surfaces of the Activator. Avoid inserting anything into the recess that receives the Mouthpiece. The metal contacts of the Activator must be free of any dirt or residue and may be cleaned with a Q-tip® as needed.



The Mouthpiece should be rinsed after each use. Rinsing with warm water and gently wiping with a damp cloth or toothbrush should be

Cleaning (cont'd)

sufficient for regular, everyday cleaning.

Periodically, the Mouthpiece can be further cleaned with a toothbrush and toothpaste.

Always unplug the Charging Port before cleaning. Use a damp cloth to wipe the external surfaces of the unit.

Note: Do not clean any of the appliance components or accessories in a dishwasher. Simple hand-cleaning is sufficient to remove and prevent accumulation of dirt or other build-up.

Storage

The Activator and attached Mouthpiece can be housed on the Charging Port at all times, but the Charging Port can also be stored when not in use. Unplug, clean and store it in a cool, dry place away from direct sunlight. The convenient cord wrap underneath the Charging Port is helpful.

Note: Leaving the Activator housed on the Charging Port will drain the battery requiring the battery to be fully charged prior to the next use.

Avoid storing the Activator and Mouthpiece in extreme temperatures. They can be stored with or without the Travel Shell, although the Travel Shell is designed to allow for safe and sanitary storage in a broader range of situations.

Replacement

The Mouthpiece is the only component of AcceleDent that is intended for replacement during the course of your treatment. Periodically, the Mouthpiece may become worn or torn from routine daily use. If you have any questions about whether or not a replacement Mouthpiece needs to be issued, ask your orthodontist. Generally, evidence of bite marks does not indicate that the Mouthpiece needs to be replaced, although it may indicate that too much bite force is being exerted during use. If any surface of the hard inner core of the Mouthpiece is exposed it should not be used and should be replaced immediately.

As your orthodontic treatment progresses, your orthodontist may issue you a new Mouthpiece based on the progress of your tooth realignment. Different Mouthpiece forms exist for different and specific stages of your treatment. You may be periodically refitted and issued a new Mouthpiece even if your current one does not appear to be damaged in any way.

Disposal

The Mouthpiece and Travel Shell can be disposed of with normal household waste. The rechargeable battery inside of your Activator cannot be replaced. In order to protect and preserve our environment the Activator and Charging Port should be disposed of at a designated collection facility for batteries and other electrical devices like cell phones, computers, video games and electronic tools. The crossed out wheeled bin symbol, which appears on the product packaging and labeling, indicates that separated collection is required for the recycling of electrical and electronic equipment. These designated collection facilities are free of charge to the consumer because OrthoAccel and its distributors have acquired 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 +1 832.631.1660 (North America) or +44 (0) 203.318.1915 (outside North America) or *customerservice@acceledent.com* for assistance.



4.0 Safety

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Voltage

Caution, to reduce the risk of electrocution or fire, DO NOT plug the Charging Port into an outlet with a voltage other than that specified on the AC adapter plug. This product is designed to operate within a range of 100 – 240 volts. Voltage converters DO NOT guarantee voltage compatibility. Never force the plug into an outlet; if it does not easily fit into the outlet, discontinue attempts to force the plug.

Water

Caution, do not place or store the Charging Port where it can fall or be pulled into a bathtub, sink, or toilet. DO NOT reach for a Charging Port that has fallen into water. Unplug immediately. Unplug the Charging Port before cleaning and determine that it is dry before plugging into an electrical outlet.

Warnings

To reduce the risk of burns, electrocution, fire, or injury:

Discontinue use if this product appears damaged in any way (Activator, Mouthpiece, or Charging Port). This product contains no serviceable parts. Refer to the section in this manual titled "Customer Service" if your AcceleDent or any of its components no longer works properly or needs repair.

Never use the Charging Port if it has a damaged cord or plug. Keep away from heated surfaces. Do not use the Charging Port outdoors.

Avoid using a Mouthpiece that is damaged, particularly if it is crushed or bent. Torn edges may break off while in use. Consult your orthodontist if the Mouthpiece no longer fits comfortably for any reason. Inappropriate cleaning may also cause damage to the Mouthpiece (see "Care" section).

This product is designed to enhance your orthodontic treatment only. Use this product only for its intended use as described in this manual. Discontinue use of this product and immediately contact your orthodontist if any discomfort or pain is experienced.

AcceleDent is a prescription appliance for a

single patient. Sharing the appliance and/or Mouthpiece is not recommended. The appliance has been fitted for your use and based on your orthodontic case and treatment. As with many medical devices, use by an individual without the proper issuance from an orthodontist can result in unintended consequences. In addition, use of the appliance 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.

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.

Do not use the appliance while performing tasks that require full attention, such as driving or operating heavy machinery.

Do not play with the appliance or use it for any purpose aside from its intended use as described in this manual.

AcceleDent is a treatment-specific appliance and none of its components or accessories, alone or in combination, is intended for use by

Warnings (cont'd)

more than a single patient in any setting.

Do not use components, accessories, or attachments other than those recommended by the manufacturer.

Never incinerate the Activator, as its battery may explode.

DO NOT clean any component or accessory of AcceleDent in the dishwasher.

Precautions

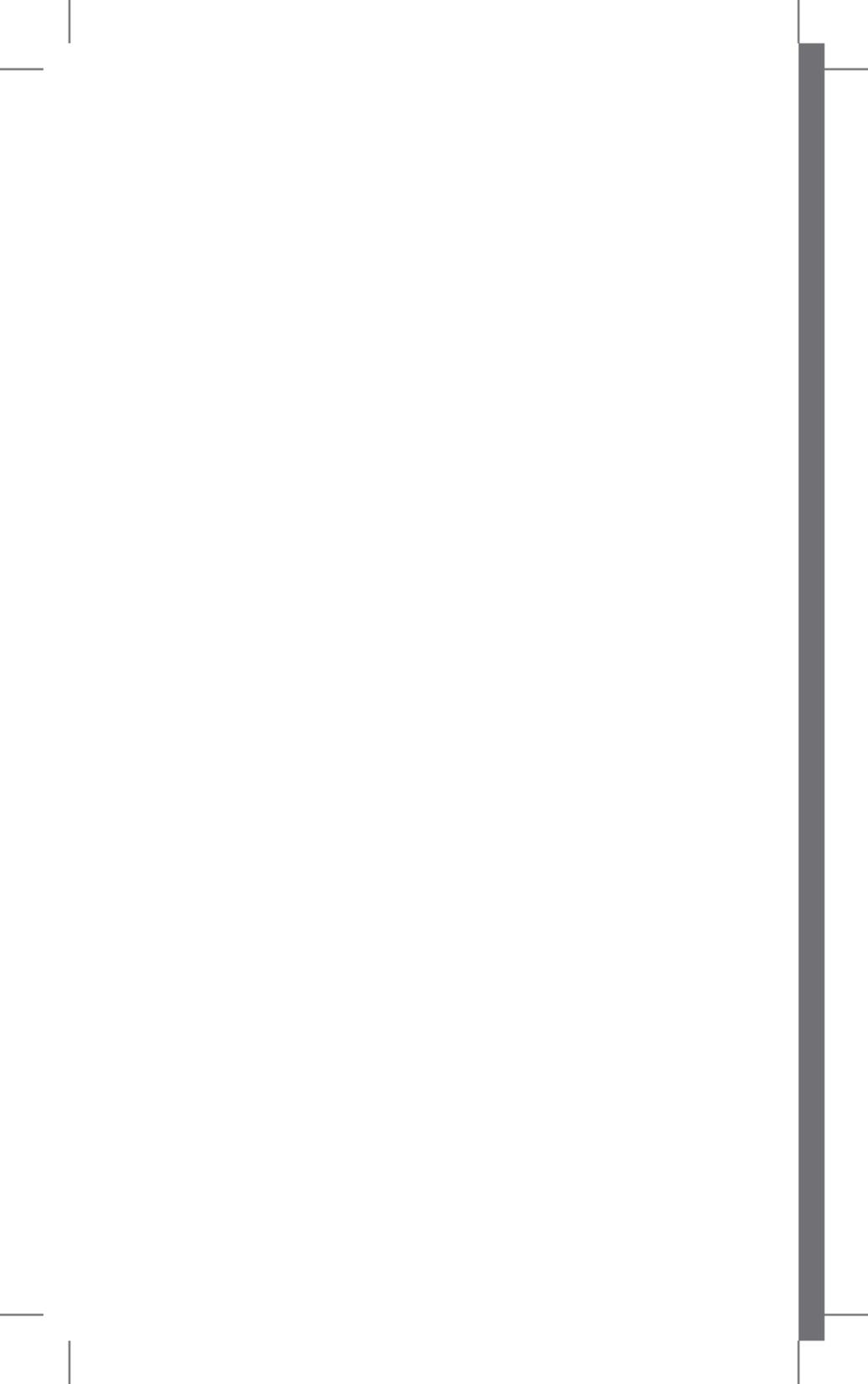
Consult your orthodontist prior to use of this product if you have had any recent craniofacial surgery (above the neck).

Contact your orthodontist if any bleeding, discomfort, or pain occurs after the initial use of AcceleDent.

AcceleDent 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, nerve stimulators). Please contact the other device manufacturers with any questions or concerns about effects on their devices.

AcceleDent has been tested and is in compliance with safety standards for electromechanical devices.

Call your physician or orthodontist if you have any medical concerns about AcceleDent.



5.0 Help

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Customer Service

If you have any questions or comments after reading the enclosed materials (this Directions for Use manual and the Quick-Start Reference Guide), please contact the OrthoAccel Technologies Customer Service Center:

North America: +1 832.631.1660

Outside North America: +44 (0) 203.318.1915

Email: customerservice@accedent.com

Online: www.accedent.com

Troubleshooting

This section lists several of the more commonly observed troubleshooting situations. If you cannot find the answer to your question here, or if the situation you are experiencing is not addressed here, please contact the Customer Care Center in your country (visit www.acceleident.com for contact information). If you need immediate assistance, contact OrthoAccel Technologies, Inc. via telephone at +1 832.631.1660 (North America) or +44 (0) 203.318.1915 (outside North America) or customerservice@acceleident.com.

Why doesn't the Activator work?

You may need to charge AcceleDent. Charge the Activator overnight by docking it on the Charging Port. Also confirm that the Mouthpiece is inserted correctly into the Activator.

I charged my Activator according to the instructions and the appliance is still not working.

Check to confirm that the Charging Port is plugged correctly into an electrical outlet. The electrical outlet must be live and not controlled by a light switch. The Activator must be enclosed within the Travel Shell in order to dock on the Charging Port. The Activator is properly

docked to the Charging Port if the LED lights on the Activator cycle from dark to light and the SmartDisplay LCD viewing screen on the Charging Port can be advanced to the various information windows.

Why does my appliance seem less powerful when I use it?

You may get used to the pulsation and therefore notice the vibration less over time.

My appliance would not charge while I was traveling, but it charges just fine when I am at home.

The Charging Port can be used with common worldwide voltages between 100 – 240V AC, at either 50 or 60 Hz. A simple plug adapter is all that is required.

EXPRESS LIMITED WARRANTY

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 two years from the date of purchase (the "Warranty Period"). This limited warranty is non-transferrable and applies only to the original purchaser and his or her initial dental 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 packaged with this Product.

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, (4) the Product is repaired by someone other than authorized service center, or (5) 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 tear 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 repair or replacement of the Product (with new or comparable rebuilt parts) or a new or refurbished Product, as determined by OrthoAccel. Warranty repair or replacement shall not extend the original Warranty Period.

All returns for warranty service will require an RMA (Return Merchandise Authorization). To receive an RMA for obtaining warranty services, you must call +1 832.631.1660 if 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 packing must include your RMA. RMA's will not be extended or reissued.

NO IMPLIED WARRANTIES; LIMITATIONS ON DAMAGES

THE EXPRESS LIMITED WARRANTY PROVIDED ABOVE IS THE ONLY EXPRESS 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.

LEGAL LIMITATIONS

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.

FAQ

1. Is there any clinical trial information available?

Yes. Data from a randomized and controlled clinical trial on 45 patients is available. In general, patients were young, with an average age of 21.5 years (median 18.8, range 12.4 to 40.6). Seventeen males and 28 females were enrolled in the study with the following ethnic origins: 26 Hispanic, 14 Caucasian, 4 African American and 1 Asian. Twenty-three patients received treatment with a functioning AcceleDent appliance (treatment group) and 22 patients with a non-functioning AcceleDent appliance (sham control group). Mini implants provided posterior anchorage and a fixed reference point for measurements during space closure. The reported adverse events were similar between the treatment and control groups and there were no reports of unintended adverse device effects. A safety review of panoramic x-rays showed no indication of increased root resorption due to AcceleDent use and the number of patients with loose mini implants was equally distributed between the treatment and control groups. Note that root resorption is possible with any orthodontic case - talk to your orthodontist about this unintended treatment consequence. AcceleDent was well tolerated and did not increase the level of discomfort associated with orthodontic treatment. Most patients found AcceleDent easy-to-use, reliable and easy-to-clean.

Overall satisfaction for AcceleDent was high and increased with time. Several patients did report some drooling associated with AcceleDent use; this experience typically lessened over time. During space closure, patients' teeth moved an average 38% to 50% faster in the group treated with AcceleDent.

Additionally, surveys asked patients at each visit about the most common activities engaged during appliance use and what one word they would use to describe their experience. The most common activities during use were watching television, reading, using the computer, listening to music and doing homework. The most frequently used words to describe AcceleDent were easy, effortless, good and simple.

2. How does AcceleDent work?

The appliance uses patented technology to gently pulse the teeth and surrounding structures such as the alveolar bone and the periodontal ligament (which serves to "attach" the teeth and bone).

3. Who can benefit from using AcceleDent?

The AcceleDent System is designed to increase the rate of tooth movement in patients undergoing treatment with a conventional fixed orthodontic appliance, which may reduce treatment time. The use of AcceleDent with other types of orthodontic appliances has not been studied.

FAQ (cont'd)

4. How can I determine whether or not AcceleDent is working for me?

Your orthodontist has the ability to measure the amount of tooth movement that has taken place while using AcceleDent. You should contact your orthodontist to help you understand how much you are benefiting from AcceleDent.

5. Is AcceleDent safe?

AcceleDent has a good safety profile, as indicated by a university study in humans and several animal studies. AcceleDent is considered safe under normal conditions of use with a conventional fixed orthodontic appliance.

6. How often should I see my orthodontist?

Your orthodontist will help you determine how often you should be seen for orthodontic appointments.

7. Does AcceleDent hurt while being used?

In clinical trials, AcceleDent was well tolerated and did not increase the level of discomfort associated with orthodontic treatment.

8. How can I get further information regarding AcceleDent?

You may contact your orthodontist regarding the proper use of your appliance. You may also visit the following website: www.acceledent.com

9. What if the appliance is just turned “on” and then set down on the countertop for the required twenty minutes?

The compliance information will be transferred to the Charging Port and it will appear that the appliance was used for a full session. However, there will be no clinical benefit and so it is likely that an orthodontist will be able to determine non-compliance clinically.

10. If I absolutely have to interrupt the twenty-minute session for a few minutes, when I turn it back on, does it have memory toward the twenty minutes or does it reset?

The appliance will maintain memory toward the twenty-minute total use duration as long as the interruption does not exceed five minutes. After five minutes of being turned off, the appliance will work (pulse) for a full session of twenty minutes at its next use.

11. How do I know if I am biting into the Mouthpiece correctly and with the right amount of force?

Bite pressure on the Mouthpiece should be just firm enough to hold the appliance in place without the use of the hands. It is not necessary to bite forcefully into the Mouthpiece. Doing so will cause the Mouthpiece to wear out more quickly and may require it to be replaced.

FAQ (cont'd)

12. If I use the appliance for more than the recommended duration, does it add incremental benefit?

No. The appliance initiates a biological change in the bone surrounding the roots of your teeth. Additional daily use greater than the prescribed twenty-minute duration has not been evaluated and thus is not recommended.

13. What is the best way to clean AcceleDent?

The Mouthpiece should be rinsed well with lukewarm water after each use. You may occasionally use a soft liquid dishwashing detergent, or a mild soap or toothpaste to gently brush the Mouthpiece. The Activator can be wiped with a damp cloth as necessary. The metal contacts of the Activator must be free of any dirt or residue and may be cleaned with a Q-Tip® as needed. It is recommended that the appliance air dry before being stored in the Travel Shell. Do not use a dishwasher as this will void the warranty and could cause damage to the product.

14. Can I use my AcceleDent in the shower?

No, the appliance is not water-resistant and should not be used in the shower.

15. Can I sanitize my AcceleDent and share it with a friend who also has braces?

AcceleDent is a prescription appliance for a single patient. Sharing the appliance and/or

Mouthpiece is not recommended. The appliance has been fitted for your use and based on your orthodontic case and treatment. As with many medical devices, use by an individual without the proper issuance from an orthodontist can result in unintended consequences. In addition, use of the appliance 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.

16. Can I try to wear AcceleDent while I am sleeping?

It is not recommended that the appliance be used while sleeping.

17. Is there some way that AcceleDent can “track” my usage?

Yes. Docking the Activator (which requires enclosing it within the Travel Shell) on the Charging Port also allows the usage history and details to be registered. The amount of usage can then be observed on the SmartDisplay.

18. Is there some way that AcceleDent can remind me to use it on a daily basis?

The appliance is not designed to provide reminders. It is recommended that AcceleDent be worked into some part of your daily routine in order to maximize compliance.

FAQ (cont'd)

19. It feels powerful - is there a lower-intensity setting?

The intensity cannot be reduced. The settings for the appliance have been preset and cannot be adjusted.

20. How often does the appliance need to be recharged?

It is recommended that the appliance be placed on the Charging Port only when it needs to be recharged as indicated by the Battery Gauge on the Activator (approximately every five days). Recharging the Activator more often will ultimately reduce the battery life.

21. How long does a charge last?

Once fully charged, the appliance will hold enough charge to last for approximately five days, based on recommended usage duration.

22. What type of battery does the appliance contain?

The rechargeable battery in the appliance is a medical grade Lithium ion battery.

23. When my treatment is complete, what should I do with the appliance?

Reference the "Disposal" section of this manual for further details.

24. Why do I experience a tingling sensation when I use the appliance? Is this normal?

You may experience a tingling sensation, similar to a vibrating toothbrush, when using AcceleDent for the first several times. This sensation will diminish as you become more accustomed to using the appliance.

25. Is the product under warranty?

Yes, the details of the warranty can be found in this manual.

Symbols



Do not reuse



Batch code



Date of manufacture



Caution, consult accompanying documents



Manufacturer



Lower limit of temperature



Consult instructions for use

Rx only

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



Use by YYYY-MM-DD or YYYY-MM



Serial number



Authorized representative in the European Community



Upper limit of temperature



Temperature limitation



Negative control



Separated collection for electrical and electronic equipment



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