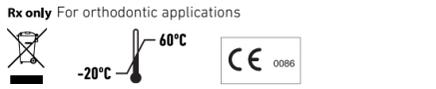
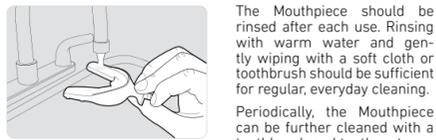


AcceleDent® Direction for Use

OrthoAccel® is a registered trademark of OrthoAccel Technologies, Inc.® AcceleDent is a registered trademark of OrthoAccel Technologies, Inc.® AcceleDent Aura is covered by one or more of the following US patents: 6648639, 6832912, 7029276, and others pending.



| | |
|-------------------------|--|
| 1.0 Introduction | Thank you for choosing AcceleDent Aura. Talking with your Orthodontist About the Manufacturer Intended Use/Indications for Use and Contraindications Technical Description Aura Components |
| 2.0 Use | Set-Up and Charging the Unit Steps for Use and Use Schedule FastTrac – Usage Report Travel Case |
| 3.0 Care | Cleaning Storage Replacement Disposal |
| 4.0 Safety | Voltage Water Warnings Precautions |
| 5.0 Help | Customer Service Troubleshooting Warranties FAQs |



Use a soft cloth to wipe the external and internal surfaces of the travel case.

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

Storage

Unplug the Activator from the USB extension cable or wall mount power supply, clean and store it in a cool, dry place away from direct sunlight. The Activator and attached Mouthpiece can also be stored in the Travel Case which designed to allow for safe and hygienic storage. The Travel Case contains storage cavities for the Activator and Mouthpiece, USB Extension Cord, and Power Adapter. Avoid storing the Activator and Mouthpiece in areas where they may be exposed to extreme temperatures.

Replacement

The Mouthpiece is the only component of AcceleDent Aura that may require replacement during the course of your treatment. Periodically, the Mouthpiece may become worn or torn from routine daily use. Throughout the course of your treatment, your bite pattern may change and an alternate sized mouthpiece may be required. 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 refitted and issued a new Mouthpiece even if your current one does not appear to be damaged in any way.

1.0 Introduction

Thank you for choosing AcceleDent Aura

Thank you for choosing AcceleDent Aura which works with your current orthodontic treatment to deliver a better experience from start to finish. AcceleDent Aura 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.

Talk with your Orthodontist

Your orthodontist is your best resource for information about your care and AcceleDent Aura. 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

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

Customer Service Information

For assistance, contact the OrthoAccel Customer Service Center:
 North America: +1 866.866.4919
 Outside North America: +44 (0) 203.318.1915
 Email: customerservice@orthoaccel.com
 Online: www.acceledent.com

Disposal

The Mouthpiece and Travel Case 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 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 trash can 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 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 North America) or customerservice@acceledent.com for assistance.

4.0 Safety

Voltage

Caution, to reduce the risk of electrocution or fire, DO NOT plug the power adapter 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 Power Adapter or Activator where it can fall or be pulled into a bathtub, sink, or toilet. DO NOT reach for an Activator that has fallen into water. Unplug immediately.

Warnings

To reduce the risk of burns, electrocution, fire, or injury: Discontinue use if this product appears damaged in any way (Activator, Mouthpiece, Power Adapter, USB Extension Cord). This product contains no serviceable parts. Refer to the section in this

Intended Use/Indications for Use

AcceleDent Aura 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.

Technical Description

The following is a technical description for the AcceleDent Aura. This information is intended to provide environmental operating conditions, transport/storage conditions, as well as IEC 60601 equipment ratings, and electrical safety classification for the included equipment. Conditions should fall between the ranges detailed below.

Warning: No modification of this equipment is allowed.
 Environmental operating conditions:
 Ambient temperature range 5° C - 40° C
 Maximum temperature of any external component at maximum ambient temperature: 44°C
 Relative humidity range 15% - 93%
 Atmospheric pressure range 700 hPa – 1060 hPa
 Transport and Storage Conditions:
 Minimum Ambient Temperature: - 20° C
 Maximum Ambient Temperature: 60° C
 Maximum Humidity: 93%

The AcceleDent Aura Activator is an applied part according to IEC 60601 3rd Edition and is classified to be a part BF applied part. Type BF Applied Part

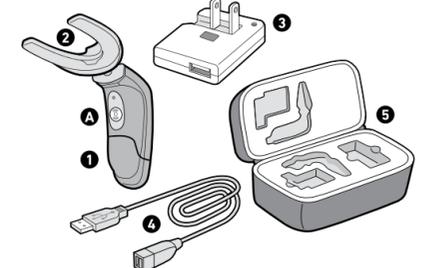
The power adapter technical information is detailed below.
 Part Number: P5A05F-050Q
 Output Voltage: 5V
 Current Limit: 1 A
 AC Input Voltage Range: 100-240 V
 AC Input Frequency: 50 - 60 Hz

Protection Class: Class II Equipment

- 1 Activator "ON/OFF" button is a push-push button to turn activator on and off.

AcceleDent Aura Features and Components

- 1 Activator
- 2 Mouthpiece
- 3 Power Adapter
- 4 USB Extension Cable
- 5 Travel Case



2.0 USE

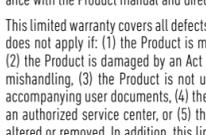
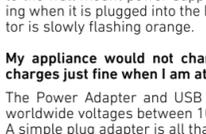
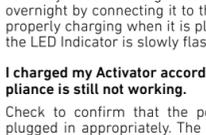
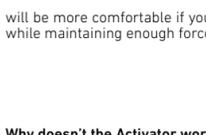
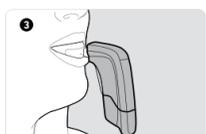
Set Up and Charging the Unit

Fully charge the Activator prior to initial use by charging it overnight. The Activator is properly charging when it is plugged into the Power Adapter and the LED Indicator is slowly flashing orange. To maximize the time between charges, the Activator should be recharged every 3 to 5 days or when the LED Indicator is quickly flashing orange when the Activator is powered on but not charging. Do not let the battery completely discharge as this may affect the data reporting of the FastTrac Usage Report.

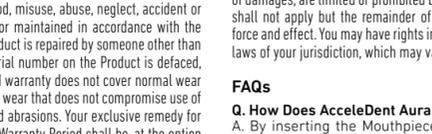
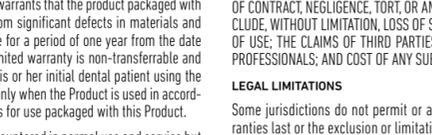
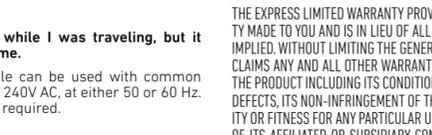
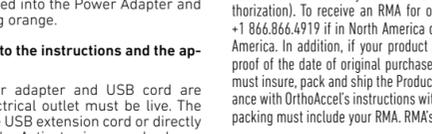
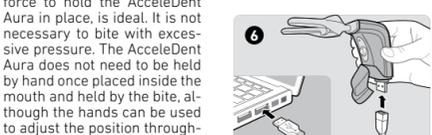
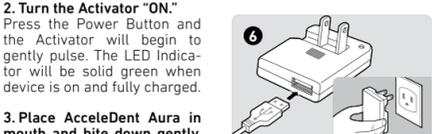
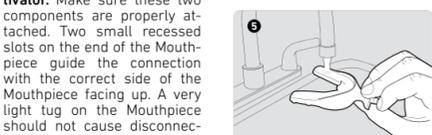
The battery life is approximately 2 years. DO NOT USE THE ACCELEDENT AURA WHEN THE ACTIVATOR IS CHARGING OR WHEN IT IS CONNECTED TO A COMPUTER.

If you have any questions before using AcceleDent Aura, please consult your orthodontist.

Steps for Use



will be more comfortable if you relax the jaw and facial muscles, while maintaining enough force to stabilize the Mouthpiece.



will be more comfortable if you relax the jaw and facial muscles, while maintaining enough force to stabilize the Mouthpiece.

4. Complete 20-minute session. Simply keep the AcceleDent Aura in place while it is powered on. The Half-Time indicator will pulse 3 times at the 10-minute mark. If the appliance needs to be shut off or paused during use, simply press the Power Button on the Activator.

5. Remove and rinse Mouthpiece. The recommended method for cleaning is to rinse with lukewarm water. ONLY RINSE THE MOUTHPIECE WHEN IT IS DETACHED FROM THE ACTIVATOR. The Activator is **not water resistant** and should not be exposed to running water or submerged under water. See the "Care" section for further details.

6. Charging the Activator. When a session is complete or when the LED Indicator is quickly flashing orange indicating a low battery, the Activator can be recharged. The Activator is properly charging when it is plugged into the Power Adapter and the LED Indicator is slowly flashing orange. The Activator may also be charged by plugging the USB Extension Cable into a computer's USB port.

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

Use Schedule

Use AcceleDent Aura for twenty minutes per day hands-free and the small vibrations, or micropulses 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 Aura 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 Aura 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. Plug the USB into the computer to upload and view the FastTrac.htm usage report. Refer to the "FastTrac" section for further details.

You may easily pause and resume use if you are interrupted during a session. To pause, press the Power Button on the Activator. When you are ready to resume, press it again to unpause. AcceleDent Aura will remember how long you used it as long as the interruption does not exceed 5 minutes. After 5 minutes of being turned off, AcceleDent Aura will operate for a full session of 20 minutes at its next use.

AcceleDent Aura features a Half-Time Indicator, which will pulse 3 times at the 10-minute mark to signal that ten minutes has elapsed. The Activator is **not water resistant** and should not be exposed to running water or submerged under water. The Mouthpiece is waterproof and may be cleaned under running water after first being disconnected from the Activator.

No component of AcceleDent Aura is dishwasher safe. Hand-clean only.

FastTrac Usage Report

To view the FastTrac Usage Report, insert the AcceleDent Aura into a USB port on the host computer. The AcceleDent Aura will register as if it were a FLASH drive. The user will need to navigate to that drive as they would for any other FLASH drive.

SoftPulse Technology™. Faster tooth movement may decrease the duration of your orthodontic treatment – and can even help to make your orthodontics more comfortable.

Q. Is AcceleDent Aura safe?
 A. Yes. AcceleDent with SoftPulse Technology™ has been proven safe in several clinical trials.

Q. How is the orthodontic treatment accelerated?
 A. Your braces work on their own by moving your teeth in specific directions. AcceleDent Aura uses SoftPulse Technology™ to generate small vibrations – micropulses – enhancing the movements directed by your braces allowing for faster overall treatment.

Q. How do I know if I am biting into the Mouthpiece correctly and with the right amount of force?
 A. Bite pressure on the Mouthpiece should be just firm enough to hold your AcceleDent Aura in place without using your hands. Avoid biting forcibly into the Mouthpiece as that may cause excessive wear.

Q. Can I try to wear AcceleDent Aura while I am sleeping?
 A. No. It is not recommended that AcceleDent Aura be used while sleeping.

Q. Can I wear my AcceleDent Aura when it is charging or connected to a computer?
 A. No, do not wear your AcceleDent Aura when it is charging or connected to a computer.

Q. Do I have to do the full 20 minute treatment at one time?
 A. Yes. It is recommended that you use your AcceleDent Aura for a continuous 20 minute period each day.

Q. If I absolutely have to interrupt the 20 minute session for a few minutes, when I turn my AcceleDent Aura back on, does it remember how long I used it?
 A. Yes. AcceleDent Aura will remember how long you used it as long as the interruption does not exceed 5 minutes. After 5 minutes of being turned off, AcceleDent Aura will work for a full session of 20 minutes at its next use.

Q. If I use AcceleDent Aura for more than the recommended 20 minute treatment time, does it add incremental benefit?
 A. No. Additional daily use greater than the prescribed 20 minutes duration is not recommended.

Q. How often does AcceleDent Aura need to be recharged?
 A. To maximize the time between charges, the Activator should be recharged every 3 to 5 days.

Q. What is the best way to clean AcceleDent Aura?

For Windows

The default Windows configuration will ask how the drive is to be opened. Open it as a folder. If the folder does not open, go to My Computer and select ACCELEDENT drive.

For Mac
 Mac OS will put a drive icon on the screen. The user should double click the ACCELEDENT drive icon.

When the files on the ACCELEDENT drive are displayed, double click on the FastTrac.htm file. The file will open in the default browser. This is the usage report. For Internet Explorer only, accept "Enable ActiveX controls. The data table is always displayed.

The three sections of the FastTrac report can be reviewed by using the scroll down applications. The three sections of the FastTrac report consist of:

- (1) The AcceleDent Usage Summary
- (2) The AcceleDent Daily Usage Graph
- (3) The AcceleDent Daily Usage Table

The AcceleDent Usage Summary summarizes the Total Number of Days in Treatment, Total Minutes Used, Average Use (Minutes/Day), Overall Usage, Device Time, and Battery Depletion Count. When the battery had been fully depleted, the overall usage percentage may be inaccurate. If this occurs, please reset the device time and date.

The AcceleDent Daily Usage Graph shows the usage percentage vs. the date. Drag the cursor over the graph to view Daily %, Prior 30 Day %, Total Number of Sessions, and Total Number of Minutes for any specific treatment date.

The AcceleDent Daily Usage Table details Daily %, Prior 30 Day %, Total Number of Sessions, and Total Number of Minutes of use per a session. This area of the report indicates the summary of each session by date.

You must use the "Safely Remove Hardware" feature in Windows or the "Eject Drive" feature in MAC OS before removing the device from the Host PC; otherwise error messages may appear on the host PC. This is standard operation for any FLASH drive.

Note: The AcceleDent Aura will not be damaged if it is not removed from the host PC properly.

As a result of full battery depletion, the overall usage percentage may be inaccurate and this requires that the device date is reset. To reset the device date:

A. The Mouthpiece should first be disconnected from the Activator and then rinsed well with lukewarm water after each use. You may occasionally use a soft liquid dishwashing detergent, a mild soap, or toothpaste to gently brush the Mouthpiece. The Activator can be wiped with a soft cloth as necessary. It is recommended that you allow your AcceleDent Aura to air dry before being stored in the Travel Case. **Do not place the Mouthpiece or the Activator in a dishwasher as this will void the warranty and could cause damage to the product.**

Q. Can I use my AcceleDent Aura in the shower?
 A. No. AcceleDent Aura is not water-resistant and should not be used in the shower.

Q. Can I sanitize my AcceleDent Aura and share it with a friend or family member who also has braces?
 A. No. AcceleDent Aura is an FDA cleared, single-use prescription device. Sharing the AcceleDent Aura and/or the Mouthpiece is prohibited. Your orthodontist prescribed AcceleDent Aura for your use only based upon your unique orthodontic treatment plan. Use of AcceleDent Aura without the supervision and direction of an orthodontist may result in adverse unintended consequences.

Q. What type of battery does AcceleDent Aura contain?
 A. The rechargeable battery in AcceleDent Aura is a medical grade Lithium ion battery.

Q. What shall I do with my AcceleDent Aura once treatment is finished?
 A. You should dispose of your AcceleDent Aura as you would with any other device with a rechargeable battery. Reference the "Disposal" section of the Directions for Use manual for further details.

Q. What does it mean if my Activator stops working and the LED Indicator is flashing alternating green and orange?
 A. The Activator will deactivate after completing the equivalent of 18 months of 20 minute daily sessions. If you are in the middle of a treatment plan please contact your orthodontist.

Q. Why did the date change on my FastTrac Usage Report?
 A. If your Activator battery is fully drained and the activator shuts down (no flashing LED Indicator or vibrations), the date on the Usage report will reset to January 1, 2012. The battery has to be charged when the LED indicates a low battery (when the LED Indicator is quickly flashing orange when the Activator is powered on but not charging). Refer to the FastTrac Usage Report section to reset date.

| For all browsers except Safari | For Safari |
|--|--|
| Open the report in the browser. Select the "File" menu and select: | Open the report in the Safari browser. |
| "Save page as..." for Google Chrome and Firefox | Open the "File" menu and select "Save As..." |
| "Save As..." for Internet Explorer | Verify the ACCELEDENT device is selected. |
| Verify "Save In" location is AcceleDent drive. | Verify the format selected is "Page Source." |
| Verify the "Save as type:" is Text File | Save the file as file name "SETLOCK.htm" |
| Save the file as the file name "SETLOCK.txt" | Select the Save button. |
| Close FastTrac Report and safely remove Activator from the host computer. | Close FastTrac Report and safely remove Activator from the host computer. |
| Plug USB back into host computer and open the usage report. The time and date will be updated as this point. | Plug Activator back into host computer and open the usage report. The time and date will be updated as this point. |

The AcceleDent Aura will read the date and time from the time stamp provided by the host PC operating system. No files will be saved on the device.

Travel Case

- The Travel Case serves two purposes:
- 1) As a convenient carrying case for patients who use AcceleDent Aura daily in locations away from home.
 - 2) To hygienically and securely store the Activator, Mouthpiece, Power Adapter, and USB Extension Cord.

3.0 Care

Cleaning

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

Use a soft cloth to wipe down all surfaces of the Activator. Avoid inserting anything into the recess that receives the Mouthpiece.



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| | | | |
|-----------------------------|-----------------------------|----------------------------|--|
| LOT | Batch code | Class II Equipment | Separated collection for electrical and electronic equipment |
| Use by | Date of manufacture | Use by YYYY-MM-DD | Keep dry |
| Manufacturer | Lower limit of temperature | Upper limit of temperature | Type BF Applied Part |
| SN | Serial number | Temperature limitation | Fragile |
| Follow Instructions for Use | Refer to Instruction Manual | CONTROL | "ON"/"OFF" (Push-Push) |

SN 405-0409-001A, L67000

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

Authorized representative in the European Community
 CE Mark