

ORTHO GUIDE



AcceleDent[®]
aura

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. AcceleDent Aura should be used a total of 20 minutes per day in a single session.

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

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 Aura. AcceleDent Aura 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 Aura 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 Aura.

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 manual titled "Customer Service" if your AcceleDent Aura or any of its components no longer works properly or needs repair. NEVER charge your device using an unauthorized AC adapter plug as it may cause permanent damage to your device.

Never use the USB Extension Cord if it has a damaged cord or plug. Keep away from heated surfaces. 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 Aura is a prescription device for a single patient. Sharing the appliance and/or Mouthpiece is prohibited. 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 or-

thodontist. 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 Aura is a treatment-specific appliance, and none of its components or accessories, alone or in combination, is intended for use by 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 Aura in the dishwasher.

Radiofrequency energy (RF) from cell phones and other sources of electromagnetic energy such as hand held radio transceivers can interfere with normal operation of the Activator. If the Activator exhibits erratic operation make sure it is not in close proximity to a cell phone or any other device suspected of emitting radiofrequency energy.

Never use the Power Adapter and USB Extension Cord if it has a damaged cord or plug. Keep away from heated surfaces. Do not use the Power Adapter and USB Extension Cord outdoors.

Never use your AcceleDent Aura while it is plugged into a powered outlet or computer.

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

DO NOT operate the device in the shower, or other situations exposing the AcceleDent to water.

Warning: No modification of this equipment is allowed.

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

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Rx Only For orthodontic applications



Congratulations on making the decision to implement AcceleDent Aura as a part of your patients' care. OrthoAccel Technologies, Inc. is committed to improving orthodontic treatment through the development and commercialization of innovative science and technologies.

COMPONENTS

» **Activator** - Small extraoral component that generates the vibrational force of approximately 0.25N (25 g) at 30 Hz.



» **Mouthpiece** - Connects to Activator; patient occludes on the Mouthpiece to transfer vibrational force from the Activator to the dentition.



» **Power Adapter, USB Extension Cord** - For recharging the appliance and providing usage information via the FastTrac Usage Report.



» **Travel Case** - Allows the appliance to be easily and safely carried while "on the go".



PACKAGING

The Activator, Travel Case, USB Extension Cord and Power Adapter are packaged together. The Mouthpiece is packaged separately and, at the orthodontist office, is added to the AcceleDent Aura once the optimal size and profile have been determined for the individual patient by the orthodontist.

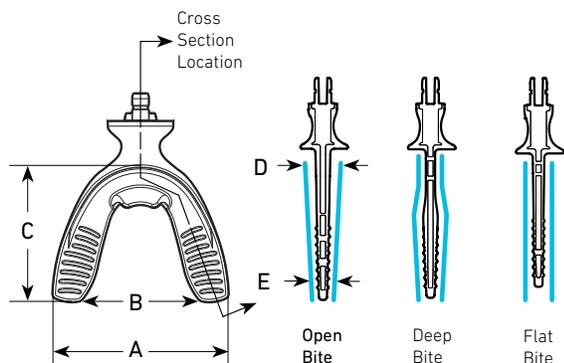
Additionally, each AcceleDent Aura includes a complete Directions for Use booklet for easy reference and a Quick Reference Guide for convenient initial use.



OVERVIEW OF MOUTHPIECES

AcceleDent Aura Mouthpieces are available in two sizes (small and large) based primarily on the anatomical dimensions of the patient's dental arches. Each size is available in three profiles based primarily on the type of malocclusion (anterior open bite, anterior deep bite and normal flat plane occlusion).

The sizes and profiles have been developed based on a statistical analysis of a sample population and are intended to allow for a maximum contact of teeth with the Mouthpiece in a high percentage of patients and case types.



	Small			Large		
	Open Bite	Deep Bite	Flat Bite	Open Bite	Deep Bite	Flat Bite
A	62.6	62.6	62.7	69.9	69.9	70.0
B	31.9	31.9	31.8	37.8	37.8	37.8
C	52.1	52.4	52.1	51.9	51.9	51.5
D	5.3	3.5	4.4	5.3	3.5	4.3
E	3.1	3.1	3.1	3.1	3.1	3.0

All Dimensions in mm

FITTING YOUR PATIENTS WITH THE MOUTHPIECE

A sterilization tray with Trial Mouthpieces is provided in the AcceleDent Aura Starter Kit.

Select the size of Trial Mouthpiece that best fits the patient's upper arch in terms of width and anterior-posterior dimension. Optimize occlusal contact by evaluating the three profile options for the selected size.

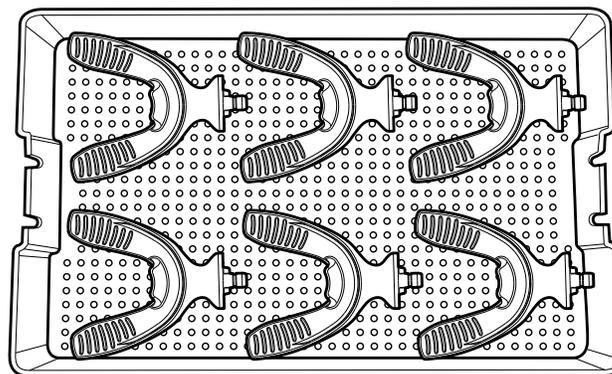
The Trial Mouthpiece must be sterilized prior to use as follows:

- Steam Sterilization with pre-vacuum: 3 - 4 minutes at 270°F (132°C) and 28-30 psi (193 - 207 kpa), double wrapped, 30 minute dry time
- Steam Sterilization with gravity displacement: 15 minutes at 270°F (132°C) and 15 -17 psi (104 - 117 kpa), double wrapped, 30 minute dry time

The sterilization instructions have been validated to a Sterility Assurance Level (SAL) of 10⁻⁶ in accordance with USFDA (21 CFR Part 58) Regulations, ISO 17664 and ISO 17665-1 using the biologics indicator overkill method.

In general, the Mouthpiece selected should be the smallest size possible for patient comfort without impinging on the cheeks and tongue.

During the course of orthodontic care, the patient may require additional Mouthpieces due to wear, change in overbite, or continued growth. Therefore, the fit of the Mouthpiece should be reevaluated at adjustment visits, particularly if the patient complains of poor fit or discomfort.



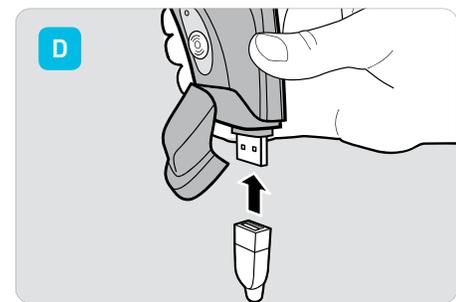
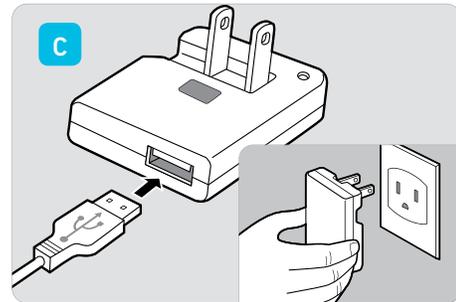
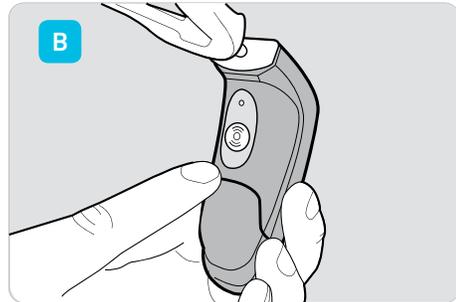
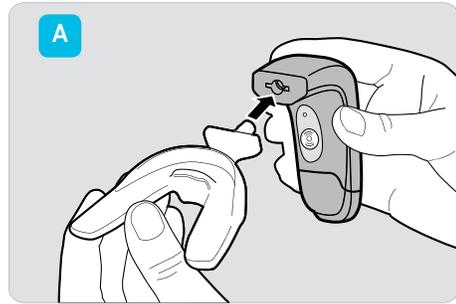
FIRST USE

It is highly recommended that the patient quickly tests the appliance in the "on" position while in the office. For Mouthpiece size selection purposes, the sensation of the vibratory force may allow patients to better report the feeling of fit and comfort.

Ask the patient to attach the selected Mouthpiece to the Activator **(A)**. It is advised to either observe the patient attaching these components or to demonstrate the process to ensure correct usage. Turn the Activator on by pressing the Power Button until it begins gentle pulsing and place the Mouthpiece inside the mouth **(B)**. Biting down 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 biting, although the hands can be used to adjust its position throughout the session as needed. Educate the patient that relaxing the jaw and facial muscles, while maintaining enough force to stabilize the Mouthpiece, will improve comfort. Once the patient has experienced the appliance in use for a short period of time (approximately one minute) it should be turned off by depressing the Power Button so that an evaluation for fit and comfort of the Mouthpiece can be made. Although some people experience drooling due to the Mouthpiece, people typically accommodate and have less drooling over time.

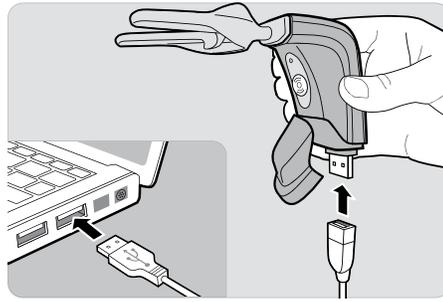
At home and prior to the first use, the patient should charge the system overnight by plugging the Power Adapter into a powered electrical outlet and connecting the Activator using the USB extension cord **(C)**. The Activator is properly charging when it is plugged into the Power Adapter and the LED Indicator is slowly flashing orange. The Activator is fully charged when the LED Indicator is solid green. **(D)**. A full charge will allow three to five complete treatments. The battery life is approximately 2 years. To maximize the time between charges, the Activator should be fully recharged every three to five days or when the battery is low, which is indicated by the LED Indicator quickly flashing orange when Activator powered on but not charging. Do not let the battery completely discharge as this may cause the date to reset in the FastTrac Usage Report.

Encourage your patients to review the Directions for Use, which can be found with the AcceleDent Aura packaging.



FASTTRAC USAGE REPORT OVERVIEW

The USB has the capability to “read” data stored within the Activator and provide both the patient and office staff with information about compliance and appliance usage patterns. Therefore, the patient should be instructed to bring his or her Activator to each follow-up visit.



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.

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.

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 “SETCLOCK.htm”
Save the file as the file name “SET-CLOCK.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.

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:

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.

Note: A standard treatment session involves using AcceleDent Aura for a full 20 minutes. AcceleDent Aura features a Half-Time Indicator, which will pulse 3 times at the 10-minute mark to signal that ten minutes has elapsed. If the appliance is used for less than 10 minutes, no session will be registered. One treatment session will be registered if AcceleDent Aura is used for a minimum of 10 minutes.

CUSTOMER SERVICE INFORMATION

For assistance, contact the OrthoAccel Technologies, Inc. Customer Service Center at +1 866.866.4919 (North America) or + 44 (0) 203.318.1915 (Outside North America) or customerservice@orthoaccel.com or on the internet at www.aceledent.com.

For further information including troubleshooting, frequently asked questions, cleaning, warnings and hazards, and warranty, please also refer to the Patient Directions for Use booklet included in the AceleDent Aura packaging or visit www.aceledent.com.

SYMBOLS



Batch code



Keep dry



0086 CE Mark



Date of manufacture



Fragile



Use by
YYYY-MM-DD



Manufacturer



Follow operating
instructions OR Follow
Instructions for Use



Authorized representative
in the European
Community



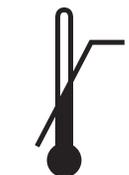
Lower limit of
temperature



Refer to Instruction
Manual/Booklet



Serial number



Upper limit of
temperature



Temperature
limitation



Negative control



Separated collection
for electrical and
electronic equipment

Rx only

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

405-0411-001A, L77000



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