

Regulatory Information, Specifications, and Warranty

Introduction

This document contains information and specifications for A-dec products. The information here and in the A-dec Resource Center at www.a-dec.com, supersedes information included in any other document that came with your A-dec product. Additional local regulatory requirements may apply to use or install certain products. You are responsible for understanding and complying with all applicable legal and regulatory requirements and safety recommendations prior to purchase, installation, and use of A-dec products.



NOTE For information concerning non-A-dec products, consult the Instructions for Use (IFU) provided with the product or contact the manufacturer.

Universal and Instrument Cautions

The following list is not a complete list of all "Cautions" that apply to each A-dec product. Users are responsible for reviewing all Instructions for Use, including product-specific Instructions for Use, and installation guides provided with A-dec products.



CAUTION Local regulation requires licensed plumbers and electricians to install utilities. All plumbing and utilities must conform to prevailing local codes.



CAUTION The manner and method for accessing utilities within the wall is the responsibility of the dental dealer, architectural services, and/or contractors. Utilities must be accessible without the use of tools.



CAUTION To avoid the risk of electrical shock or burns, do not perform service or maintenance on the equipment while it is in use with a patient.



CAUTION The ultrasonic scaler tip can reach 144.5°F (62.5°C) when used without water coolant. The warm water syringe handle and output water can reach 133°F (56°C) when set to the highest output water temperature. The intraoral camera LEDs can reach 120°F (49°C). The electric motor and attachment can reach 114°F (46°C). The curing light tip can reach 114°F (46°C). To reduce the risk of burns or thermal injury to skin or tissue, care should be taken to minimize contact with skin and tissue.



CAUTION When removing or replacing covers, take care not to damage any wiring or tubing. Verify that the covers are secure after replacing them.



CAUTION To prevent injury and/or product damage, use care when moving other equipment into the range of motion of the dental unit and/or the dental chair.

Equipment Alterations Policy/Disclaimer

Modifications or alterations of A-dec equipment that expand the use of A-dec equipment beyond its design and intent, or override any safety feature may jeopardize doctor, patient, or staff safety. Modifications that alter the electrical or mechanical safety of A-dec dental equipment are in conflict with Underwriters Laboratory (UL) construction file requirements and are not sanctioned by A-dec. Examples of modifications that diminish safety design include, but are not limited to: rendering access to the line voltage without the use of tools, modification of supporting elements that increase or shift loading characteristics, and the addition of any powered device that exceeds the design limits of the dental system.

Equipment Alterations Policy/Disclaimer (continued)

The use of accessory equipment that does not comply with the safety requirements of A-dec dental equipment may lead to a reduced level of safety of the resulting system. It is the responsibility of the equipment distributor and the installer, not A-dec, to comply with all building code requirements in the installation of equipment. It is the responsibility of the person(s) who requests, approves, or performs any equipment modification or alteration to comply with all safety requirements and recommendations. A-dec will not respond to inquiries on an individual basis. Modifications or alterations of A-dec dental equipment are at your own risk. You will indemnify and defend A-dec from any resulting claims, including product liability claims, that may arise from any alterations, modifications, or installation contrary to this policy. Additionally, such modification or alteration voids A-dec's applicable product warranty and may invalidate UL or other regulatory agency approvals.

Safety Considerations for Accessory Equipment



WARNING The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system, including potential for serious injury or death from electrical shock, burns, or interference with patient medical device function. Caution must be used when connecting medical products to a multiple socket outlet due to the combination of leakage currents between products when the ground connection to the building is broken or disconnected.

Consideration relating to the use of accessory equipment shall include evidence that safety certification of the accessory equipment has been performed in accordance to the IEC 60601-1 standard along with any national deviations.

Low voltage communication cables (USB, Ethernet, etc.), either supplied by A-dec or installed in the field, shall be routed away from single insulated or non-insulated mains voltage (100 - 240 VAC). Electrical connections to A-dec equipment are not permitted unless the combination of the accessory and the A-dec equipment has been evaluated to the IEC 60601-1 standard along with any national deviations.

Anyone connecting equipment to the signal input or signal output part is configuring a medical system and is, therefore, responsible for ensuring that the system complies with the requirements of IEC 60601-1. Do not connect non-medical equipment directly to mains power if the non-medical equipment is intended to be isolated from medical equipment using a medical grade isolation transformer.

If you have general questions regarding A-dec equipment, please contact A-dec Customer Service or your local authorized A-dec dealer or distributor.

Preventive Inspection of A-dec Dental Equipment

Over time, normal wear and tear may affect the performance of the equipment. You should periodically inspect the water and air lines for any visible cracks or cuts in the tubing, which may lead to leaks; inspect O-rings for damage; and inspect the entire equipment for any loose fittings or screws. To prevent problems from occurring, you should replace the tubing and O-rings and tighten the screws and fittings as necessary.

Expected Service Life

"Service Life" is the maximum length of time that an A-dec or A-dec | W&H product may remain functional under normal use (which is based on approximately 50 patients per week), with proper care, maintenance, and service. Service Life does not include normal service "wear and tear" components that are intended to be replaced from time to time, nor are products guaranteed to last for the expected Service Life:

Product Category	Service Life (years)
All A-dec Dental Chairs, Operator and Assistant Stools, Dental Lights, Delivery Systems, Support Systems, Monitor Mounts, Dental Furniture, and related components except components listed separately below	20
A-dec Heated Syringes	10
A-dec Electric Motors, Motor Tubing, and Control Modules	7
A-dec W&H Synea®, Proxeo®, Endea®, Alegra®, Air Motors, and Assistina Products	7

The actual Service Life of A-dec and A-dec | W&H products may be less, based on a number of factors, including environment, manner and frequency of use, cleaning and maintenance frequency, and preventive maintenance frequency. All products should be regularly inspected by a trained service technician.

Additional information on cleaning, asepsis, maintenance, and preventive maintenance of A-dec and A-dec | W&H products is available in the Resource Center at www.a-dec.com.

^{*}Service Life information is provided for general planning purposes only and should not be relied upon for any reason. Service Life does not include normal service "wear and tear" components and is separate from the warranty period. There are no implied or explicit extensions of the warranty period. For complete details, see "Limited Warranty" on page 3.

Limited Warranty

Scope

A-dec warrants all goods listed below against defects in material or workmanship under normal intended use when purchased from A-dec or an authorized A-dec dealer. A-dec's sole obligation under the warranty is to provide parts for the repair, or replacement of any defective component with one that is equivalent to the original in performance. This warranty is in lieu of all other warranties or obligations express or implied. A-dec expressly disclaims all implied warranties of merchantability or fitness for a particular purpose. In no event will A-dec be liable for indirect, special, incidental, exemplary, or consequential damages of any kind.

The repair or replacement of components is contingent upon A-dec's styles and color options available at the time of the warranty claim. If a warranty claim is filed after a product or color has been discontinued, A-dec reserves the right to honor the warranty in one of the following ways:

- 1. Replace the affected component with a new component in the same style and/or color.
- 2. Replace the affected component, and other product components in the operatory with a product style and/or color similar to the originally purchased style and/or color.

The buyer will have no other remedy. The warranties set forth herein provide specific legal rights. Additional rights may exist, based on the jurisdiction of purchase and use of the product to the extent that those rights apply to this agreement. Warranty exclusions are identified in the following sections. Written notice of product failure must be given to A-dec within the warranty period.

Period

The warranty period, measured from the date of delivery, is as follows:

Goods	Warranty
Hydraulic Dental Chair Cylinder (tilt and lift)	10 years
All Dental Chairs, Operator and Assistant Stools, Dental Lights, Delivery Systems, Sterilizers, Monitor Mounts, Dental Furniture, and related components	5 years
A-dec EA-53 Electric Motor, Tubing, and Control Modules; A-dec W&H Synea,® Proxeo,® Endea,® W&H Primea™*, Air Motors, and Assistina Products (warranted per item V. in Exclusions)	2 years

Goods	Warranty
A-dec W&H Alegra® Products (warranted per item V. in Exclusions)	1 year
A-dec NLX and NLZ Electric Motors and Control Modules (warranted per item V. in Exclusions)	1 year

*In International markets outside of US and CAN, the Primea RG series handpiece has a warranty of 1 year.

Components replaced under warranty or purchased retain the balance of the original product warranty or are warranted for 1 year after delivery (whichever is greater).

Exclusions

The warranty does not cover:

- I. Damage resulting from improper installation or maintenance, accident, misuse, abuse, neglect, alterations, freight damage, or natural disaster.
- II. Damage resulting from the use of chemicals and process for cleaning, disinfecting, or sterilization.
- III. Normal service items such as (but not limited to): light shields, light bulbs, filters, O-rings, handpiece tubing, water bottles, and water cartridges. Also, normal wear and tear is not covered.
- IV. Consumable products held beyond the expiration date shown on the packaging.
- V. All other products, not manufactured by A-dec, including OEM, follow the original manufacturer's warranty, and are not covered by A-dec's warranty. Examples include, but not limited to: sterilizers, maintenance equipment, cameras, curing lights, ultrasonics, control modules, electric motors, attachments, handpieces, and turbines. Please contact A-dec Customer Service for specific warranty information.
- VI. Failure to follow A-dec Instructions for Use (operation and maintenance instructions) and/or modification or alteration of A-dec's product will void the warranty.

Product Identifiers

When you inquire about service, please provide the relevant product identifier. For most A-dec equipment, this is the serial number (S/N), which is on the product serial tag. The S/N code may appear in three different formats:

Model and Version

S/N: <u>15A</u>311-B<u>12345</u>

Year/Month Unique Number

S/N: 11H12345

Month/Year Unique Number

S/N: L3 12345

For newer products, the first three characters of the serial number indicate the year and month the product was manufactured.

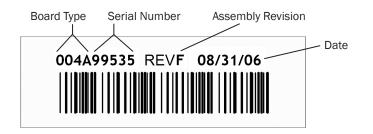
For older products, the first two characters indicate the month and year the product was manufactured (e.g., L3=December 2003).

Letter	Month	Letter	Month
Α	January	G	July
В	February	Н	August
С	March	I	September
D	April	J	October
Е	May	K	November
F	June	L	December

For other A-dec products, the relevant product identifier may be a lot number. The number format may vary, but indicates what batch the product was manufactured in.

Circuit Board Assembly Revision

When calling A-dec Customer Service about a circuit board issue, please have the assembly revision available. The assembly revision is located on the barcode label on each circuit board that contains software.



Product Versions

Specifications for different versions of a product model are the same unless otherwise noted.

Software Revisions

Contact A-dec for information about compatibility, upgradability, or software revision (which is derived from the assembly revision shown on the barcode label). See the following list for software revisions:

Part Number	Board Name	Software Revision
43.0000.XX	Standard Touchpad	1.XXXX
43.0001.XX	A-dec Relay Module	1.XXXX
43.0003.XX	A-dec 511 Chair (Version A)	1.XXXX
43.0043.XX	Dental Light Relay	1.XXXX
43.0084.XX	Vacuum Flush Control	1.XXXX
43.0085.XX	Water Heater Controller	1.XXXX
43.0105.XX	Preference ICC® /A-dec Inspire® Dryer Control	1.XXXX
43.0107.XX	A-dec 500 Deluxe Touchpad	1.XXXX
43.0114.XX	A-dec 300 Deluxe Touchpad	1.XXXX
43.0137.XX	Cuspidor	1.XXXX
43.0200.XX	57XL LED Dental Light	1.XXXX
43.0213.XX	Capacitive Deluxe Touchpad	1.XXXX
43.0253.XX	QVIOLS	1.XXXX
43.0254.XX	Control Head (Version F)	1.XXXX
43.0363.XX	A-dec 311 and A-dec 411 Chair	1.XXXX
43.0390.XX	A-dec 511 (Version B)	1.XXXX
43.0399.XX	37XL LED Dental Light	1.XXXX
43.0490.XX	DCAP, Cap Sense	1.XXXX
61.3771.XX	A-dec 200, Performer® 8000, Decade® Plus 1221, Cascade® 1040 Chair	1.XXXX



NOTE The format of the software revision number is Y.XXXX where Y denotes a major revision and XXXX denotes a minor revision.

Deluxe Touchpad Messages

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Item #	Screen Message	Conditions to Generate Message	A-dec 300 Touchpad	A-dec 500 Touchpad
1	Power loss during use. Settings may have changed. Press a button to continue.	The touchpad powered-on and found that the touchpad powered-off with a handpiece out of a holder. This message alerts the doctor that any changes made to the handpiece setup before the outage may not have been saved and the current settings may not be what is expected.	X	X
2	This touchpad is not calibrated. Call for service. Press any button.	The air pressure sensor in the touchpad is not calibrated. This appears only when the user enters the Air Pressure display screen. The touchpad will still function, but the handpiece speed may not function correctly.	Х	
3	This button is disabled.	The user pressed a button that was disabled using the EN/DIS jumper on the chair circuit board.	Х	Х
4	Too many handpieces in use: — Control Head — Assistant's	Too many handpieces are withdrawn or are not fully seated in the control head or assistant's holders.	X	
5	Too many handpieces in use: - Control Head 12345 - Assistant's 123	Too many handpieces are withdrawn or are not fully seated in the control head or assistant's holders. The numbers correspond to the specific holder positions that are withdrawn.		Х
6	Chair will not move while Foot Control is in use.	The foot control disc is pressed and the user tried to move the chair or the user is moving the chair and the foot control gets pressed.	Х	Х
7	Chair in Factory Default mode.	This appears while the jumper on the chair circuit board is in the factory default position, whether the routine is running or not.	Х	Х
8	Chair in Factory Default mode — RUNNING.	This appears when the factory default routine is running.	Х	Х
9	Chair in Factory Default mode — PASSED.	This appears when the factory default routine is successfully completed.	Х	Х

Item #	Screen Message	Conditions to Generate Message	A-dec 300 Touchpad	A-dec 500 Touchpad
10	Chair in Factory Default mode — FAILED.	Factory default mode did not complete successfully. Troubleshoot as needed.	Х	Х
11	Chair in Enable/ Disable mode.	This appears when the jumper on the chair circuit board is in the enable/disable position.	X	Х
12	Chair disabled by a chair stop switch.	A chair stop switch is activated and the chair is not allowed to move in the direction selected.		Х
13	Chair disabled by cuspidor stop function.	A cuspidor stop switch is activated and the chair is not allowed to move in the direction selected.		Х
14	Chair is already at that position.	The chair was already at Position X and the user pressed the Position X button.	Х	Х
15	Function halted by additional button press.	The chair was in the process of moving to Position X and the user pressed a chair motion button, which causes the chair movement to stop.	Х	X
16	Chair back reached time limit. Please wait.	The A-dec 311 and A-dec 411 chair back duty cycle is limited to 50 percent. The user has been moving the chair back too often and needs to wait before trying again.	Х	
17	Advanced Air Controller is not functioning.	The Advanced Air controller has detected an Advanced Air system error.		Х
18	Advanced Air handpiece not detected. Only basic air operation is available.	The user withdrew a handpiece from the Advanced Air holder position, but an Advanced Air handpiece wasn't detected. Press any button to use an installed handpiece in basic air mode.		X
19	No data communication with Advanced Air Controller.	The Deluxe Plus Touchpad does not receive periodic status reports from the Advanced Air Controller.		Х

Application Specification

Intended Patient Population

There are no restrictions on patient population that may be treated by A-dec equipment. The patient is not intended to be the user of A-dec equipment.

Intended Part of the Body or Type of Tissue Applied to or Interacted With

A-dec equipment may come into contact with human tissue for transient periods during dental procedures. Most often, the intended patient contact location is incidental contact with exterior skin surfaces, though some specific devices may also contact the oral cavity. (See Cautions above regarding risk of electrical shock and burns.)

Intended User Profile

A-dec equipment is intended for use only by properly trained and licensed dental or medical practitioners for the purposes listed under the Indications for Use and in accordance with the equipment's Instructions for Use document and applicable health and safety regulations and recommendations.

Intended Application and Use Statements

Air/Water Syringes — An air/water syringe is intended to deliver compressed air, water, or a spray (air and water together) to the oral structures and operating areas of dental patients during diagnostic and therapeutic treatment by licensed health care professionals.

Assistant's Instrumentation — Assistant's instrumentation is intended to provide a mounting location in addition to providing air, water, vacuum, and electrical power to dental devices for use during diagnostic and therapeutic treatment by licensed health care professionals. Assistant's instrumentation may be mounted to dental chairs, dental carts, dental cabinets, and walls.

Clinical Devices — Clinical devices (handpieces, scalers, curing lights, intraoral cameras, etc.) are intended to be used on dental patients during diagnostic and therapeutic treatment by licensed health care professionals.

Cuspidors — A dental cuspidor is intended to provide a chair-side location for dental patients to rinse their mouths during diagnostic and therapeutic treatment by licensed health care professionals.

Delivery Systems — A delivery system is intended to provide a mounting location in addition to providing air, water, vacuum, and electrical power to dental devices for use during diagnostic and therapeutic treatment by licensed health care professionals. Delivery systems may be mounted to dental chairs, dental carts, dental cabinets, and walls.

Dental Cabinets — A dental cabinet is intended to provide a storage location for dental equipment and supplies and to provide a mounting location for dental products used during diagnostic and therapeutic treatment of dental patients by

licensed health care professionals.

Dental Chairs — A dental chair is intended to support the patient during diagnostic and therapeutic treatment by licensed health care professionals.

Dental Lights — A dental operating light is intended to illuminate the oral structures and operating areas of dental patients during diagnostic and therapeutic treatment by licensed health care professionals.

Dental Stools — A dental stool is intended to provide seated support for members of the dental team during diagnostic and therapeutic treatment of dental patients by licensed health care professionals.

Floor Boxes — A floor box is intended to provide a storage location for air and water manual shutoff valves, filters, pressure pre-regulators, vacuum or gravity drains, electrical outlets, and medical grade power supplies.

High Volume Evacuators (HVEs) — A high volume evacuator is intended to evacuate fluids and debris from the oral cavity during diagnostic and therapeutic treatment by licensed health care professionals.

 ${\bf ICV}^{\otimes}$ — An ICV is intended to facilitate the cleaning of vacuum instruments used on dental patients during diagnostic and therapeutic treatment by licensed health care professionals.

ICX® — A-dec ICX tablets are specially formulated to maintain dental unit waterlines by preventing the accumulation of bacteria.

Monitor Mounts — A monitor mount is intended to support and position a medical grade or equivalent flat-panel monitor.

Saliva Ejectors (SEs) — A saliva ejector is intended to evacuate fluids and debris from the oral cavity during diagnostic and therapeutic treatment by licensed health care professionals.

Simulators — A dental simulator is intended for instructional use in a laboratory setting.

Sterilization Centers — A sterilization center is intended to provide a storage location for cleaning and sterilization equipment and supplies used to clean and sterilize medical products.

Support Systems — A support system is intended to provide a storage location for clinical products and to provide a connection location for air, water, and electricity to the clinical devices during diagnostic and therapeutic treatment by licensed health care professionals.

Tooth Dryers — A tooth dryer is intended to provide warm, dry air to the oral cavity during diagnostic and therapeutic treatment by licensed health care professionals.

Identification of Symbols

These symbols appear on the actual product or are used in documentation to alert the user about cautions, warnings, hazards, or tips.

Symbol	Description
c All °us	Recognized by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, and Amendment 1.
CUL US 12CJ Dental Equipment	Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, Amendment 1, and 80601-2-60.
C UL US	A-dec Inspire: UL Listed to ANSI/AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1, ANSI/NFPA 70, "National Electrical Code", and Canadian Electrical Code C22.1-09. ICV & Preference ICC: UL listed to UL 61010A-1 and Canadian CAN/CSA C22.2, No.1010.1-92 safety standards. Simulator: UL listed to UL 61010-1 (3rd Edition), BS EN 61010-1 (3rd Edition) and Canadian CAN/CSA C22.2, No. 61010-1 (3rd Edition) safety standards.
C€	Conforms to applicable European Directives/Regulations (refer to Declaration of Conformity).
EC REP	EU Authorized Representative.
(Protective earth (ground).
-	Functional earth (ground).
†	Type B applied part.
<u></u>	Caution: Hot surface.
Z	Electrical and electronic waste. Do not dispose of with domestic waste.
M	Date of manufacture.
***	Manufacturer of equipment.
135° C	Sterilizable up to the stated temperature.
~ ~	VAC symbol. VAC/VDC symbol.
	Contains hazardous substances.

Symbol	Description					
REF	Model Num (Catalog Nu		SN	Serial number.	PN	Part Number.
	Refer to accompanying documents for additional information. e.g., IMPORTANT: For more information, see the A-dec Equipment Asepsis Guide (p/n 85.0696.00).					
0	instructions	s. ·	ction sign. Not parts as show	a caution. Take note n.	e of addition	al important
\triangle				ns may result in produce adjustment screw	_	• •
*	_ ·	N. To avoi	d eye and skir	ı damage due to exp e gloves when opera		raviolet radiation, wea g light.
Danger	Warning. Bi e.g., WARNI cross conta	NG: Infecti		y be present. Follow	asepsis pro	otocol to prevent
<u>F</u>	Warning. Dangerous voltage. e.g., WARNING: Disconnect the main power or shut off the main power before servicing. Failure to turn off the power before you begin this procedure can lead to electrical shock.					
<u> </u>	Warning. Failure to follow instructions may result in product damage or serious injury or death. e.g., WARNING: Turn off the power before removing the pump cover. Failure to turn off the power before you begin this procedure can lead to product damage and result in serious injury or death.					
	Attention. Failure to follow instructions may result in product damage. e.g., ATTENTION: Circuit boards are sensitive to static electricity. Electrostatic Discharge (ESD) precautions are required when touching a circuit board or making connections to or from the circuit board. Circuit boards should be installed only by an electrician or qualified service person.					
STOP	Read This. Indicates that a decision must be made about which directions to follow. e.g., READ THIS! If you are installing an LED light, follow the instructions that are shipped with the LED light instead of the following section.					
(2)	Do not re-use. e.g., CAUTION: Disposable HVE and saliva ejector tips are not sterilizable and should not be reused.					
-29°C (122°F)	Temperature shipping and storage limits. Relative humidity shipping and storage limits.					
11	This way up.	Ţ	Fragile.	Ke	ep dry.	Use by date.

Environmental Specifications

Temperature/Humidity	Specification
Storage/Transportation Temperature	-20°F to 122°F (-29°C to 50°C) - Relative humidity: 10 – 95%.
Operating Temperature	50° F to 104° F (10° C to 40° C) - Relative humidity: 10 – 95% .
Indoor Use	Altitude up to 2,000 m (6,563'), installation category II, pollution degree 2.

Classification of Equipment (IEC-60601-1)

Type/Mode	Classification
Types of Shock Protection	CLASS I EQUIPMENT: All A-dec products with mains voltage.
Degree of Shock Protection	TYPE B APPLIED PART: All A-dec products with Applied Parts. Note: For clinical devices, refer to the Instructions for Use that came with the product.
Degree of Protection Against Water Ingress	Footswitch: IPX1 All other products: IPX0
Mode of Operation	CONTINUOUS OPERATION: All models except dental chairs. CONTINUOUS OPERATION WITH INTERMITTENT LOADING: A-dec dental chairs - 5% duty cycle (maximum ON time is 20 seconds). Note: For clinical devices, refer to the Instructions for Use that comes with the product.
Flammable Gasses	Not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide, where such gasses may accumulate in concentration (closed space).

Classification of Equipment (IEC-61010-1)

Type/Mode	Classification
Types of Shock Protection	CLASS I EQUIPMENT: (Earthed) Simulator, Preference ICC, and ICV.

Electrical Rating

A-dec Product	Frequency (Hz)	Voltage Range (VAC)	Maximum Current (Amps)		
Dental Chairs					
A-dec 200 and Performer 8000	50-60	100/110-120/220-240	Input = 10/10/10 Duplex output = 10 Amps max. Chair circuit board output = 2 Amps max. Chair pump typical = 4/4/2		
A-dec 311, A-dec 411, and A-dec 511 (chair rating includes optional chair- powered modules)	50-60	100/110-120/220-240	Input = 10/10/10 Duplex output = 10 Amps max. 511 Chair power supply = 4 Amps max. Chair pump typical = 4/4/2		
Delivery Systems, Assista	nt's Instrume	ntation, and Cuspidors			
Systems with 300W Power Supply, including: A-dec 200, Performer 8100/8200/8500, 2671/2615, 2561/2562, 4631/4635, 3072, 7004, and A-dec 342.	50-60	100/110-120/220-240	Input = 3.1/2.8/1.4 Output with optional duplex on 2671/2615, 2561/2562 = 7 Amps max.		
3420 Pac 1 Field and Institutional Units, N57D Bench Control, N74 M.O.M.	50-60	100-240	1.6		
Halogen Dental Light (Low Voltage)					
A-dec 200 Chair-Mount	50-60	12.1/17	5.5		



NOTE Allowable mains voltage fluctuations $\pm 10\%$ of rated voltage.

Electrical Rating (continued)

A-dec Product	Frequency (Hz)	Voltage Range (VAC)	Maximum Current (Amps)			
LED Dental Lights (Mains Voltage)						
A-dec 573L Post-Mount, A-dec 374L, 574L Cabinet-Mount, A-dec 375L, 575L Wall-Mount, A-dec 376L, 576L Ceiling- Mount, and A-dec 377L, 577L Track- Mount; A-dec 378L, 578L Universal Single	50-60	100-240	1.25			
A-dec 578L Universal Dual	50-60	100-240	2.5			
LED Dental Lights (Low Voltage)						
A-dec 570L Retrofit Head, A-dec 371L/372L/571L/572L Chair-Mount, A-dec 378L, 578L Stationary/In-Bench Simulator	50-60	16-24 (AC or DC)	1.5			
Power Supplies						
24 VDC Power Supply/LED light	50-60	100-240	1.25			
24 VDC Power Supply (small)/cabinets	50-60	100-240	1.6			
24 VDC Power Supply (large)/cabinets	50-60	100-240	2.5			
24 VDC Power Supply (60W)/carts	50-60	100-240	1.6			
25W Power Supply	50-60	100/110-120/220-240	0.3/0.3/0.15			
80W Power Supply	50-60	100/110-120/220-240	0.9/0.8/0.4			
300W Power Supply	50-60	100/110-120/220-240	3.1/2.8/1.4			
Dental Furniture						
Preference Collection®	60	120	20			
Preference ICC®	50-60	100-120	15			
ICV	50-60	110-120/220-240	0.5/0.5			
A-dec Inspire Cabinet Models 591, 592, 593, 594, and 595	50-60	100-120	20			
A-dec Inspire Distribution Box	50-60	100-240	10 Duplex output = 7 Amps max.			
A-dec Inspire Power Box	50-60	100-240	10			

A-dec Product	Frequency (Hz)	Voltage Range (VAC)	Maximum Current (Amps)
Miscellaneous			
Simulator 41L and 42L	50-60	100/110-120/220-240	10/10/5 Duplex output = 7 Amps max.
Bitewing X-Ray Viewer	50-60	24	0.5
Monitor Mounts Performer 880X,381, 382, 482, 581, 584, 585, 586, and 587	50-60	100-240	10



WARNING To avoid risk of electrical shock, which could lead to serious injury or death, this equipment must only be connected to a supply mains with a protective earth (ground). Connection of extension cords or multiple socket outlets to the dental system may reduce the overall safety of the dental system and is not allowed.



NOTE For products that are permanently connected to fixed wiring (no power cord plug), a switch or circuit breaker shall be used to disconnect the product from mains power.

Mains connections shall be made by qualified personnel in compliance with local building and electrical codes.



NOTE Countries using a mains plug other than the North American plug (such as Australia, Denmark, Switzerland, etc.) shall use a plug that is rated appropriately for the voltage and current of the product.

For products that use the mains plug for mains disconnection (products without a mains on/off switch), position the equipment so that the mains plug is easily accessible.

Electromagnetic Compatibility

This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation but cannot anticipate or guard against every potential installation scenario. In the event of interference with medical deliveries or medical devices, to avoid risk of serious injury or death, turn off A-dec products and reconfigure to power the devices from separate mains supplies and/or increase the physical distance between devices.

Electromagnetic Immunity

Immunity Test	IEC 60601-1-2 Test Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 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%.
Radiated RF Immunity IEC 61000-4-3	10 V/m 80% AM at 1 kHz 80 MHz - 2700 MHz	
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF Immunity IEC 61000-4-6	6 V 80% AM at 1 kHz 150 kHz - 80 MHz	
Power Frequency (50-60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	100% dip for 0.5 cycle 100% dip for 1 cycle 30% dip for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the dental equipment requires continued operation during power mains
	100% drop for 250 cycles (5 seconds)	interruptions, it is recommended that the dental equipment be powered from an uninterruptable power supply or a battery.

Electromagnetic Emissions

Emissions Test	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	A-dec dental equipment is suitable for use in all locations.
Harmonic emissions IEC 61000-3-2	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	

Maximum Chair Capacity

Chair	Patient Load	Chair Mount Accessory Load (offset)	Chair Mount Applied Moment	
A-dec 511, Version B w/front mount w/back mount	500 lb (227 kg)	63 lb (29 kg) @ 23" (58.4 cm)	121lb-ft (164 N • m)	
	500 lb (227 kg)	169 lb (77 kg) @ 44" (11.5 cm)	619lb-ft (839 N • m)	
A-dec 511, Version A A-dec 411	400 lb (181 kg)	250 lb (113 kg)	n/a	
w/post mount w/Radius® mount w/support link mount	400 lb (181 kg)	170 lb (77 kg) @ 41.5" (105 cm)	588 ft-lb (797 N • m)	
	400 lb (181 kg)	115 lb (52 kg) @ 45.5" (116 cm)	433 ft-lb (587 N • m)	
	400 lb (181 kg)	70 lb (31 kg) @ 23" (58.4 cm)	125 ft-lb (169 N • m)	
A-dec 311, Version B w/post mount w/Radius mount w/pedestal mount w/support link mount	400 lb (181 kg)	170 lb (77 kg) @ 41.5" (105 cm)	588 ft-lb (797 N • m)	
	400 lb (181 kg)	115 lb (52 kg) @ 45.5" (116 cm)	433 ft-lb (587 N • m)	
	400 lb (181 kg)	149 lb (67 kg) @ 28" (71 cm)	347 ft-lb (470 N • m)	
	400 lb (181 kg)	70 lb (31 kg) @ 23" (58.4 cm)	125 ft-lb (169 N • m)	
A-dec 311, Version A w/base mount w/Radius mount	400 lb (181 kg)	160 lb (72 kg) @ 24" (61 cm)	320 ft-lb (434 N • m)	
	400 lb (181 kg)	75 lb (24 kg) @ 24" (61 cm)	150 ft-lb (203 N • m)	
A-dec 200	400 lb (181 kg)	184 lb (83 kg) @ 16" (40.6 cm)	245 ft-lb (332 N • m)	
Performer 8000, Version B		61 lb (28 kg) @ 28.5" (72 cm) 83 lb (38 kg) 11.6 lb (5.26 kg) @ 14.4" (36.6 cm)	145 ft-lb (197 N • m) 130 ft-lb (176 N • m) 14 ft-lb (19 N • m	
Performer 8000, Version A w/Radius front or back mount	400 lb (181 kg)	40 lb (18 kg) @ 28.5" (72 cm)	95 ft-lb (129 N • m)	
w/ post mount	400 lb (181 kg)	83 lb (38 kg)	130 ft-lb (176 N • m)	
w/ rear mount	400 lb (181 kg)	11.6 lb (5.26 kg) @ 14.4" (36.6 cm)	14 ft-lb (19 N • m)	

Monitor Mount Maximum Loads

Monitor Mount Type	Maximum Monitor Weight
A-dec 581	20 lb (9 kg)
Performer 8800	20 lb (9 kg)
584 (central console) , 585 (wall), 586 (ceiling)	20 lb (9 kg)
587 (track)	20 lb (9 kg)
A-dec 381, 382, 482	20 lb (9 kg)

Note: Monitors at 19 inches (483 mm) diagonal and smaller have been determined to not interfere with the intended motion of other moving parts of the dental system or dental cabinet. For monitors larger than 19 inches (483 mm) diagonal, verify the monitor will not interfere with other moving parts of the dental system or dental cabinet.

Delivery System Rated Loads

Devices located inside the Control Head: 5 lb (2.3 kg)

Tray load: 4 lb (1.8 kg)

Utility Specifications and Requirements

	Pressure/Vacuum	Flow	Other Requirements
Air	80 - 125 psi (550 - 860 kPa)	2.5 scfm (71 SL/min) minimum during normal use 7.5 scfm (210 SL/min) peak intermittent flow	 air quality to conform to ANSI/ADA specification #94 humidity limit: dew point ≤ -20°C (at atmospheric pressure) oil contamination limit: ≤ 0.5 mg/m³ particulate contamination limit: ≤ 100 particles per cubic meter for 1 - 5 µm particle size 90 psi (621 kPa) (minimum unregulated) is recommended for delivery systems with Advanced Air air filter effective mesh size is 50 microns
Water	60 ± 20 psi (410±140 kPa)	1.5 gpm (5.7 L/min) minimum, not to exceed 40°C (104°F)	water to meet World Health Organization Guidelines for Drinking-Water Quality water supply to meet local plumbing codes, including backflow prevention pH limits between 6.5 and 8.5 maximum particle size <100 µm water hardness limit is less than 2.14 mmol/l (<12°dH) water filter effective mesh size is 50 microns
Vacuum	wet: 10 ± 2 inches of Hg (34 \pm 7 kPa) dry/semidry: 4.5 ± 1 inches of Hg (16 \pm 3.5 kPa)	9 scfm (255 SL/min) minimum 12 scfm (340 SL/min) minimum	• solids filter maximum mesh opening size: $0.043"~(1.080~\text{mm})\cong 1080\mu\text{m}~\text{A-dec }200, \text{Performer }8000/8200/8500, 2671/2615, 4631/4635)} \\ 0.047"~(1.194~\text{mm})\cong 1200~\mu\text{m}~\text{A-dec }351/361/362/363, 551/561$

Note: For additional utility specifications required prior to installation, see the Pre-Installation Guide associated with your product.

High Volume Evacuator (HVE) and Saliva Ejector (SE) Head Loss with Respect to Flow of 551 Assistant's Instrumentation on 511B Chair

Tubing and HVE/SE	90 NL/min	150 NL/min	200 NL/min	250 NL/min	300 NL/min	350 NL/min	*400 NL/min
	(3.18 SCFM)	(5.30 SCFM)	(7.06 SCFM)	(8.83 SCFM)	(10.59 SCFM)	(12.36 SCFM)	(14.13 SCFM)
11 mm HVE (standard bore) valve with 13 mm Easy Flex Tubing (p/n 11.1357.00)	0.33 in-Hg	1.09 in-Hg	1.88 in-Hg	2.97 in-Hg	4.51 in-Hg	6.65 in-Hg	9.54 in-Hg
	1.12 kPa	3.69 kPa	6.37 kPa	10.06 kPa	15.27 kPa	22.52 kPa	32.31 kPa
15 mm HVE (large bore) valve with 16 mm Easy Flex Tubing (p/n 11.1287.01)	0.11 in-Hg	0.32 in-Hg	0.54 in-Hg	0.82 in-Hg	1.17 in-Hg	1.62 in-Hg	2.16 in-Hg
	0.37 kPa	1.08 kPa	1.83 kPa	2.78 kPa	3.96 kPa	5.49 kPa	7.31 kPa
11 mm HVE (standard bore) valve with 16 mm Easy Flex Tubing (p/n 11.1288.01)	0.20 in-Hg	0.54 in-Hg	0.91 in-Hg	1.41 in-Hg	2.07 in-Hg	2.93 in-Hg	4.03 in-Hg
	0.68 kPa	1.83 kPa	3.08 kPa	4.77 kPa	7.01 kPa	9.92 kPa	13.65 kPa
11 mm HVE (standard bore) valve with 13 mm PVC Tubing (p/n 11.1286.01)	0.38 in-Hg	1.03 in-Hg	1.70 in-Hg	2.57 in-Hg	3.72 in-Hg	5.22 in-Hg	7.14 in-Hg
	1.29 kPa	3.49 kPa	5.76 kPa	8.70 kPa	12.60 kPa	17.68 kPa	24.18 kPa
SE (standard bore) valve with 10 mm Easy Flex Tubing (p/n 12.1228.01)	5.03 in-Hg 17.03 kPa	Exceeds 12 in-Hg (40.64 kPa) at flow rates above ~125 NL/min.					
SE (standard bore) valve with 6 mm PVC Tubing (p/n 11.1227.01)	8.89 in-Hg 30.10 kPa	Exceeds 12 in-Hg (40.64 kPa) at flow rates ~100 NL/min.					

^{*}Note: 400 NL/min values are calculated extrapolations from previously measured data points.



CAUTION U.S. Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of this device.

Applied Parts

The following devices are considered to be "applied parts" as defined in IEC 60601-1: air handpiece, electric handpiece, scaler, curing light, air/water syringe, tooth dryer, High Volume Evacuators (HVE), Saliva Ejector (SE), and intraoralcamera.

Transporting the Dental System

When transporting the dental system:

- Place the chair base fully-down, and the chair back fully-up.
- Empty the self-contained water bottle and tubing.
- Depressurize air tubing.
- Secure the chair body to the chair baseplate.
- Place the delivery system over the seat.
- Detach the upholstery, and center and secure the light and upholstery above the chair.
- Secure the delivery system and light to prevent movement.
- Secure the dental system to the transporting vehicle.

Decommissioning and Disposal of A-dec Equipment

A-dec dental equipment removed from service should be decommissioned in accordance with local regulatory requirements. Circuit boards and electrical cabling should be recycled as electrical salvage. Aluminum, brass, iron, and steel components should be recycled as metal salvage. Molded plastic components include mold marks indicating the type of plastic and should be recycled accordingly. The cuspidor, waste lines from the cuspidor, and extraction lines should be treated as biologically contaminated materials and handled with appropriate precautions during dismantling. Any material unsuitable for recycling should be disposed of appropriately. For information regarding material type of A-dec equipment, please contact A-dec Customer Service.

RoHS/REACH

A-dec products and processes comply with the following regulations related to Materials Declarations and Substance Restrictions:

- RoHS 2 (2011/65/EU)
- REACH (Regulation [EC] No. 1907/2006), Regulation (EC) No. 765/2008

A-dec does not intentionally include in its products any of the Substances of Very High Concern (SVHCs) identified in the REACH Regulation. Under Article 33 of REACH, A-dec is required to notify its customers of the following SVHCs that exist in A-dec products in concentrations greater than 0.1% of gross weight:

- bis(2-ethylhexyl) phthalate, CAS # 117-81-7 (DEHP); present in certain hoses and gaskets.
- 1,3,5-tris(oxiranylmethyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione, CAS # 2451-62-9 (TGIC); present in select coatings.
- Diboron Trioxide, CAS # 1303-86-2; present in select electrical components.

California Proposition 65



WARNING Cancer and reproductive harm. www.P65Warnings.ca.gov.

Regulatory Information, Specifications, and Warranty Instructions for Use

Contact Information

If you have a question that is not addressed in this document, please contact A-dec Customer Service at one of the following phone numbers:

- 1.800.547.1883 (within USA and Canada)
- +1.503.538.7478 (outside USA and Canada)

Customer service is available Monday through Friday, from 5 a.m. to 5 p.m. Pacific Standard Time (PST).

Report all serious incidents involving A-dec equipment to A-dec Inc. If the incident occurs in the EU, also report to A-dec's EU Authorized Representative and the competent authority of the EU Member State in which the user/patient is established.

Serious incidents may result in:

- Life threatening illness or injury
- Permanent impairment of a body function or body structure
- Medical or surgical intervention to prevent life threatening illness or injury or permanent impairment of a body function or body structure

Product Documentation

This Instructions for Use document and other product documentation is available for download in the Resource Center at www.a-dec.com.

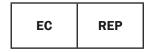




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