Instructions for Use

A-dec® 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.**

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.

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

Disclosure of Residual Risk

This product complies with relevant safety and performance standards and has been designed with state-of-the-art design mitigations. Nonetheless, mitigations cannot eliminate all risk of potential harm to the patient and user when operating our products or any products available. Residual risks exist from the following:

- Device functional failures or misuse
- Electro-magnetic and electrical hazards
- Mechanical and slip hazards
- Biocompatibility hazards
- Cleaning and cross-infection hazards

Incident Reporting

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.

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 Prevent water leaks or electrical issues to avoid damaging equipment, furniture, and floors, as well as potential for fire or smoke. Local regulation may require 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.

WARNING Shock or burn hazard. Do not perform service or maintenance on equipment while in use.

Universal and Instrument Cautions (*continued*)

CAUTION Low voltage shocks are possible when removing service covers over internal circuits. Only work on internal circuits when powered if you are certain that they do not carry facility power.

WARNING Shock hazard. Take care not to damage any wiring or tubing when removing or replacing covers. 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.

CAUTION You can be burned by hot components. Minimize contact with skin and tissue. Be aware that:

- 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).

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.

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 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

The actual Service Life of A-dec 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 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. or complete details, see "A-dec, Inc. Express Limited Warranty" on page 3.*

A-dec, Inc. Express Limited Warranty

The A-dec, Inc. Express Limited Warranty is available at www.a-dec.com/legal/warranty.

For quick access, scan, tap, or click this QR code.

If you would like to receive a physical copy of the A-dec, Inc. Express Limited Warranty or if you have any questions, please contact A-dec Customer Service at:

- 1.800.547.1883 or customer.service@a-dec.com (within the USA and Canada)
- +1.503.538.7478 or a-decglobal@a-dec.com (outside the USA and Canada)

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

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: 15A311-B12345

Year/Month Unique Number

S/N: 11H12345

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

Month/Year Unique Number

S/N: L312345

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
A	January	G	July
B	February	H	August
C	March	I	September
D	April	J	October
E	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.

Unique Device Identifier (UDI)

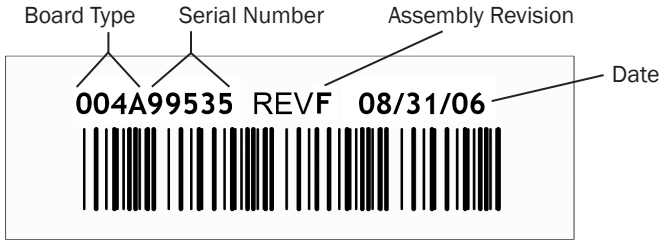
The Unique Device Identifier (UDI) contains both machine readable and human readable formats. For descriptions of the GS1 Application Identifiers (AI), see the table below.

UDI GS1

AI	Data Content
01	Global Trade Item Number (GTIN)
10	Batch or lot number
11	Production date (YYMMDD or YYYY-MM-DD)
21	Serial number

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.



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 table for software revisions.

The software version numbers for DS7, CP5i, and CP5 are managed digitally in the user interfaces of the touch controls.

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/B)	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	Deluxe Plus Touchpad Driver	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
43.0399.XX	37XL LED Dental Light	1.XXXX
43.0490.XX	Deluxe Plus Touchpad 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

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.	X	
3	This button is disabled.	The user pressed a button that was disabled using the EN/DIS jumper on the chair circuit board.	X	X
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 1 2 3 4 5 — Assistant's 1 2 3	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.		X
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.	X	X
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.	X	X
8	Chair in Factory Default mode — RUNNING.	This appears when the factory default routine is running.	X	X
9	Chair in Factory Default mode — PASSED.	This appears when the factory default routine is successfully completed.	X	X
10	Chair in Factory Default mode — FAILED.	Factory default mode did not complete successfully. Troubleshoot as needed.	X	X
11	Chair in Enable/ Disable mode.	This appears when the jumper on the chair circuit board is in the enable/ disable position.	X	X
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.		X
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.		X
14	Chair is already at that position.	The chair was already at Position X and the user pressed the Position X button.	X	X
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.	X	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.	X	

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 Operational Security Profile

A-dec equipment is intended for use within dental office operatories or mechanical rooms in the case of compressors and vacuums. No special physical access restrictions beyond typical dental practice restrictions to only clinicians or qualified service technicians.

Dental office networked product security is a joint responsibility between stakeholders, such as device manufacturers like A-dec, suppliers, healthcare providers, integrators, operators, regulators and, in some cases, patients.

Dental offices using A-dec connected equipment should also incorporate best practice, state-of-the-art security practices. These office security prevention and maintenance practices are necessary to protect your patient records and your practice financial data from loss of data confidentiality, data integrity, or device or data availability.

Security best practice may include network firewalls, on-board malware detection and prevention on patient record systems, staff security awareness training, software updates as requested by software vendors, network access controls such as segmentation, user authentication, least privilege, and privilege separation, among others.

Effective office security hygiene for a dental office is not typically any different than for any other medical office or financial institution. Nonetheless, cybersecurity awareness may not be within the expertise of a private dental practice. If so, then consider employing the services of a licensed or certified medical device product security specialist to assist in specifying appropriate off-the-shelf standard security tools and assisting with set-up, configuration, and ongoing maintenance.

Product Cybersecurity Protections

Some A-dec devices have remote connectivity capability to enable remote software status and version polling, software updates, or maintenance monitoring. Any device connected to the network in your dental office should have state-of-the-art security controls to protect patient data and your practice financial data. You should also control physical access to your touchpads and other user interfaces, and USB drives to prevent unauthorized attempts to access device configuration or sensitive data.

The following are security controls included in A-dec devices:

- Patient and financial data: No patient data or practice financial data are stored or passed through any A-dec device.
- External USB Port: Some A-dec devices have external USB ports. These ports are pass-through USB that enable connection to powered accessories such as intraoral cameras. These ports do not connect to A-dec equipment.
- Internal USB ports: When available, internal USB ports will only recognize and connect to A-dec authorized devices.
- Wireless: Wireless capability is disabled until enabled at the device user interface and then disables again automatically after a time out for chairs and delivery systems. Standard network protocols and data encryption help prevent cyber attacks and information disclosure.
- Ethernet: Similarly, any connection through Ethernet includes state-of-the-art protections such as standard network protocols and data encryption that help prevent cyber attacks and information disclosure.

Intended Application and Use Statements

Air/Water Syringes — An air/water syringe (and tip) 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.

Air Vacuum System (AVS) — An air vacuum system is intended to provide suction to evacuate fluids and debris from the oral cavity during diagnostic and therapeutic treatment by licensed health care professionals.

Clinical Devices — Clinical devices (handpieces, scalers, curing lights, intraoral cameras, scanner, 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 spit out particles and liquids that have accumulated in 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 Face Shields — A dental face shield protects the wearer from droplets and spray directly from the oral cavity of the patient during diagnostic and therapeutic treatment.

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.

Evacuation System Cleaner — The A-dec Evacuation System Cleaner is formulated to remove build-up of organic and inorganic materials in dental vacuum lines.

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.

ICV® — 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.

ICX Renew® — Fast-acting ICX Renew shock treatment is intended to lower bacterial contamination in effluent and remove buildup of non-pathogenic microbial contamination from dental unit waterlines.

ICX Restore™ — Fast-acting ICX Restore shock treatment is intended to remove buildup of contamination from dental unit waterlines.

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 Centers — A support center 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

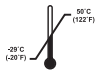
These symbols appear on the actual product or are used in documentation to alert the user about cautions, warnings, hazards, or tips.

Symbol	Description
c UL 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.
CLASSIFIED c UL 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 LISTED	**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.
UL CERTIFIED SAFETY US-CA E340465	Certified 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.
CE	Conforms to applicable European Directives/Regulations (refer to Declaration of Conformity).
EC REP	EU Authorized Representative.
	Regulatory compliance mark for Australia and New Zealand.
UDI	UDI—Identifies the carrier that contains unique device identifier information.
GS1	GS1—Identifies the carrier that contains unique device identifier information.
	Protective earth (ground) (ISO 60417-5019).
	Functional earth (ground) (ISO 60417-5017).
	Type B applied part (ISO 60417-5840).
	Caution: Hot surface (ISO 60417-5041).

Symbol	Description
	Electrical and electronic waste. Do not dispose of with domestic waste (ISO 60417-6414).
	Date of manufacture (ISO 7000-2497).
	Manufacturer of equipment (ISO 7000-3082).
135° C	Sterilizable up to the stated temperature (ISO 7000-1844).
135°C	Steam sterilizable up to the stated temperature (ISO 7000-2868).
	VAC symbol (ISO 60417-5032). VDC symbol (ISO 60417-5031). VAC/VDC symbol (ISO 60417-5033).
	Contains hazardous substances (ISO 7000-3723).
REF	Model Number (Catalog Number) (ISO 7000-2493).
SN	Serial number (ISO 7000-2498).
PN	Part Number.
MD	Medical Device.
LOT	Lot Code (ISO 7000-2492).
	Use by date (ISO 7000-2607).
Rx Only	Caution. U.S. Federal law restricts this device to sale by or on the order of a licensed physician.
	Data Matrix—Two-dimensional code that encodes text or numeric data related to device identification.
	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) (ISO 7000-1641)

Identification of Symbols (*continued*)

Symbol	Description
	General mandatory action sign. Not a caution. Take note of additional important instructions. e.g., NOTE: Assemble parts as shown (ISO 7000-M001).
	Caution. Failure to follow instructions may result in product damage or minor injury. e.g., CAUTION: Do not overtighten the adjustment screw. Overtightening could break the screw (ISO 1000-0434B).
	Caution. Optical radiation. e.g., CAUTION. To avoid eye and skin damage due to exposure to ultraviolet radiation, wear Class II safety glasses and protective gloves when operating a curing light (ISO 7010-W027).
	Warning. Biological hazard. e.g., WARNING: Infectious waste may be present. Follow asepsis protocol to prevent cross contamination (ISO 7010-W009).
	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 (ISO 7010-W012).
	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 (ISO 7010-W001).
	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 (ISO 60417-5134).
	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 (ISO 7000-3308).
	Product information is available electronically.
	Do not re-use. e.g., CAUTION: Disposable HVE and saliva ejector tips are not sterilizable and should not be reused (ISO 7000-1051)..

Shipping Symbol	Description
	For indoor use only.
	Temperature shipping and storage limits (ISO 7000-0632).
	Relative humidity shipping and storage limits (ISO 7000-2620).
	Atmospheric pressure shipping and storage limits (ISO 7000-2621).
	This way up (ISO 7000-0623).
	Fragile (ISO 7000-0621).
	Keep dry (ISO 7000-0626).
	Do not stack (ISO 7000-2402).

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 311/311flt, A-dec 411, and A-dec 511/511flt (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, Assistant's Instrumentation, and Cuspidors			
Systems with 300W Power Supply, including: A-dec 200, A-dec 332/332flt/332pro, 333/333pro, 334/334pro, 335/335pro, 336/336pro, A-dec 532/532pro, 533/533pro, A-dec 341sp, A-dec 342/342pro, Performer 8100/8200/8500, 2671/2615, 2561/2562, 4631/4635, 3072, and 7004.	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
LED Dental Lights *(Mains Voltage)*			
A-dec LED Dental Light Models, 374L, 375L, 376L, 377L, 378L, 573L, 574L, 575L, 576L, 577L, and 578L	50-60	100-240	1.25
A-dec 578L Universal Dual	50-60	100-240	2.5

A-dec Product	**Frequency** (Hz)	**Voltage Range** (VAC)	**Maximum Current** (Amps)
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 392, 393, 394, 395, 397, 591, 592, 593, 594, and 595	50-60	100-120	20
A-dec Inspire Cabinet Model 391	47-63	100-240	0.45
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

Electrical Rating (*continued*)

A-dec Product	Frequency (Hz)	Voltage Range (VAC)	Maximum Current (Amps)
Miscellaneous			
Simulator 41L/41pro/42L/42pro	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
Dental Cart 343pro	50-60	100/110-120/220-240	Input=3.1/2.8/1.4 Output with optional duplex= 10 Amps max
Dry Vacuums)			
DV5/DV5plus	50-60	220-240	16.5
DV7/DV7plus	50-60	220-240	16.5
DV10/DV10plus	50-60	220-240	24
DV12/DV12plus	50-60	220-240	24
Oil-Free Compressors)			
SC3 (120 V)	50-60	110-220	11.5
SC5 (120 V)	50-60	110-220	16.5
SC3 (240 V)	50-60	220-240	7
SC5 (240 V	50-60	220-240	9
SC7	50-60	220-240	12
SC10	50-60	220-240	15
SC12	50-60	220-240	16.5

NOTE Allowable mains voltage fluctuations ± 10% of rated voltage.

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 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	

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	3V/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	3VRMS 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 100% drop for 250 cycles (5 seconds)	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 interruptions, it is recommended that the dental equipment be powered from an uninterruptable power supply or a battery.
Magnetic Field Immunity - Proximity Fields	8A/m CW at 30kHZ 65A/m 2.1kHz PM at 134.2kHz 7.5A/m 50kHz PM at 13.56MHz	N/A

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.

Maximum Chair Capacity

Chair	Patient Load	Chair Mount Accessory Load *(offset)*	Chair Mount Applied Moment
A-dec 511, Version B and 511flt			
w/front mount	500 lb (227 kg)	63 lb (29 kg) @ 23" (58.4 cm)	121 ft-lb (164 N • m)
w/back mount	500 lb (227 kg)	169 lb (77 kg) @ 44" (11.5 cm)	619 ft-lb (839 N • m)
A-dec 511, Version A	400 lb (181 kg)	250 lb (113 kg)	n/a
A-dec 411			
w/post mount	400 lb (181 kg)	170 lb (77 kg) @ 41.5" (105 cm)	588 ft-lb (797 N • m)
w/Radius® mount	400 lb (181 kg)	115 lb (52 kg) @ 45.5" (116 cm)	433 ft-lb (587 N • m)
w/support link mount	400 lb (181 kg)	70 lb (31 kg) @ 23" (58.4 cm)	125 ft-lb (169 N • m)
A-dec 311, Version B and 311flt			
w/post mount	400 lb (181 kg)	170 lb (77 kg) @ 41.5" (105 cm)	588 ft-lb (797 N • m)
w/Radius mount	400 lb (181 kg)	115 lb (52 kg) @ 45.5" (116 cm)	433 ft-lb (587 N • m)
w/pedestal mount	400 lb (181 kg)	149 lb (67 kg) @ 28" (71 cm)	347 ft-lb (470 N • m)
w/support link mount	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	400 lb (181 kg)	160 lb (72 kg) @ 24" (61 cm)	320 ft-lb (434 N • m)
w/Radius mount	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			
w/Radius front or back mount	400 lb (181 kg)	61 lb (28 kg) @ 28.5" (72 cm)	145 ft-lb (197 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
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" (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" (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 class 4: The pressure dewpoint is <=+ 37 °F (3 °C) medium temperature and at 0.7 MPa constant system pressure. This is equivalent to an atmospheric dewpoint of <= -6 °F (-21 °C). • oil contamination limit: ≤ 0.5 mg/m^3 • Particle class 2: The maximum number of particles per cubic metre as a function of particle size in the dental air are as follows: Particle size maximum number of particles per cubic meter: • 0,1 µm < d ≤ 0,5 µm ≤ 400 000 • 0,5 µm < d ≤ 1,0 µm ≤ 6 000 • 1,0 µm < d ≤ 5,0 µm ≤ 100 • 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 ± 7 kPa) dry/semi-dry: 4.5 ± 1 inch of Hg (16 ± 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 mm) ≅ 1080µm A-dec 200, Performer 8000/8200/8500, 2671/2615, 4631/4635) 0.047" (1.194 mm) ≅ 1200 µm A-dec 351/361/362/363, 545/551/561

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

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 intraoral camera.

Transporting the Dental System or Cart

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.

When transporting the dental furniture cart:

- Secure the drawers before transport (closed with straps or tape).
- Do not roll the cart over thresholds or other obstacles. Lift it high enough for the casters to move over any floor obstacles.
- Secure the top and bottom of the cart 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 (2015/863/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:

- Lead, CAS # 7439-92-1, used in various brass and electrical components.
- Octamethylcyclotetrasiloxane CAS 556-67-2 present in Simulator valves.
- Dodecamethylcyclohexasiloxane CAS 540-97-6 present in Simulator valves.
- Decamethylcyclopentasiloxane 541-02-6 present in Simulator valves.
- Bis(2-(2- methoxyethoxy)ethyl)ether CAS: 143-24-8 present in soldered components.

California Proposition 65

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

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).

Product Documentation

This Instructions for Use document and other support documents are available for download in the Resource Center at www.a-dec.com.

For quick access to this document online, scan, tap, or click this QR code, which points to: a-dec.com/resource-center.

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