Regulatory Information and Specifications

Introduction

This document contains the required regulatory information and specifications for A-dec products.

Products Requiring Agency Information

Specific regulatory product information must accompany some products. The types of equipment that require this information include:

- Dental chair
- Delivery system and assistant's instrumentation
- Cuspidor
- Dental light
- Lab equipment
- Monitor Mounts

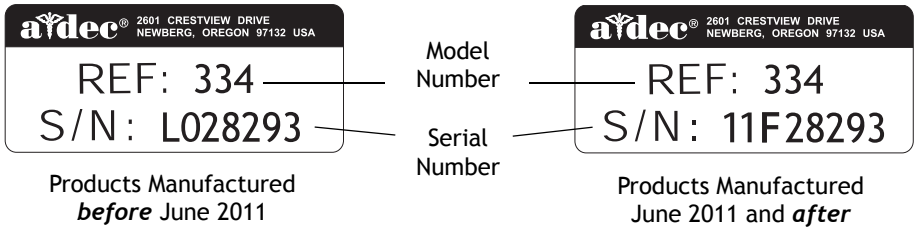
Equipment Alterations Policy

Certain modifications or alterations of A-dec equipment which expand the use of A-dec equipment beyond its design and intent, or which override any safety features of A-dec equipment may jeopardize doctor, patient, or staff safety. Field modifications that alter the electrical and/or mechanical safety of A-dec dental devices are in conflict with Underwriters Laboratory (UL) construction file requirements and are not sanctioned by A-dec. Examples of field 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 not complying with the equivalent safety requirements of A-dec equipment may lead to a reduced level of safety of the resulting system. It is the responsibility of the equipment distributor and the installer to assure that the installation complies with all building code requirements. The responsibility to determine whether a modification or alteration of A-dec equipment falls within these constraints is with the person(s) who initiates, approves and/or performs such modification or alteration. A-dec will not respond to inquiries on an individual basis. This person(s) will be deemed to have assumed all associated risks with such alteration or modification and will hold A-dec harmless from resulting claims, including product liability claims. Additionally, such modification or alteration voids A-dec's warranty and may invalidate UL or other regulatory agency approval.

Serial Number

When you inquire about service, please provide the serial number, which is the S/N code on the product serial tag.

Figure 1. Serial Number Label Examples



The first letter of the serial number indicates the month the product was manufactured. For products manufactured ***before*** June 2011, the first digit of the serial number indicates the year of manufacture (for example, L0 = December 2010). For products manufactured June 2011 and ***after***, the first two digits indicate the year of manufacture (for example, 11F = June 2011).

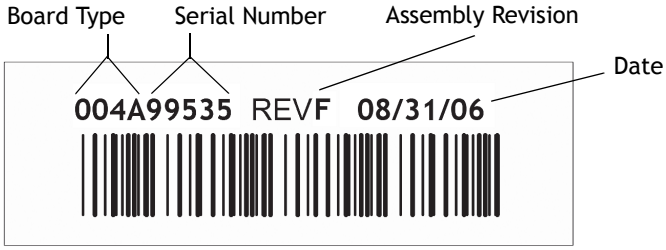
Table 1. Key to Month of Manufacture

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

Barcode and Software

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.

Figure 2. Example of Circuit Board Barcode Label



Software is not field upgradeable. Consult A-dec for questions about compatibility, upgradability, or software revision (which is derived from the assembly revision shown on the barcode label).

NOTE The software revision of the A-dec 311 chair circuit board is 1.nnnn where "nnnn" denotes the number (0000 through 9999).

Safety Considerations for Accessory Equipment

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.

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 the A-dec Dental System are not permitted unless the combination of the accessory and the A-dec Dental System has been evaluated to the IEC 60601-1 standard along with any national deviations.

All configurations shall comply with the system standard IEC 60601-1-1 or IEC 60601-1:2005. Anyone connecting additional equipment to the signal input part or signal output part is configuring a medical system, and is, therefore, responsible to ensure that the system complies with the requirements of the Medical Electrical Systems standard IEC 60601-1-1 or IEC 60601-1:2005. If you have questions or concerns, contact A-dec Customer Service or your local authorized A-dec dealer or distributor.

Universal Cautions

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.

Preventative Inspection

Over time, wear and tear can affect the performance of the equipment. Periodically inspect the water and air lines for any visible cracking or cuts in the tubing which can lead to leaks. Inspect the fittings and check for any loose screws. To prevent problems from occurring, replace the tubing and tighten the screws and fittings as necessary.

Transporting the Dental System

When transporting the dental system:

- Chair base should be fully down, and the chair back should be fully up.
- Chair body should be secured to the chair baseplate.
- Delivery system should be over the seat.
- Upholstery should be detached, and the light and the upholstery should be centered and secured above the chair.
- Delivery system and light should be secured to prevent movement.
- Dental system should be secured to the transporting vehicle.

Identification of Symbols

These symbols appear on the actual product where appropriate. These same symbols are used in documentation to alert the user/reader of cautions, warnings, hazards, or tips.

Symbol	Description
	Recognized by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1 (2601-1) and CAN/CSA C22.2, No. 601.1 and/or ANSI/AAMI ES60601-1 and CAN/CSA C22.2 No. 60601-1.
	Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1 (2601-1) and CAN/CSA C22.2, No. 601.1 and/or ANSI/AAMI ES60601-1 and CAN/CSA C22.2 No. 60601-1.
	UL listed to UL 61010A-1, BS EN 61010-2-010 and Canadian (CAN/CSA C22.2, No. 1010.1-92) safety standards.
	Refer to accompanying documents.
	Conforms to applicable European Directives (refer to Declaration of Conformity).
	Conforms to MDD 93/42/EEC for Class IIa devices.
	Protective earth (ground).
	Functional earth (ground).
	Type B applied part.
	Class II equipment.
	Caution: Metal surfaces can be hot during and following the dry cycle.
	General mandatory action sign. Important to follow instructions. Not a caution. i.e., NOTE: Assemble parts as shown.
	Caution. Failure to follow instructions could result in damage to product or minor injury. i.e., CAUTION: Do not over tighten the adjustment screw. Over tightening could break the screw.
	Biohazard. Potential infection if instructions are not properly followed. i.e., BIOHAZARD: Biohazard from dental equipment can result in life-threatening diseases or infection.
	DANGER. Failure to turn off the power before you begin this procedure can lead to electrical shock. i.e., DANGER: 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. DANGER: Line voltage. Only a licensed electrician should remove the cover.
	WARNING. Failure to turn off the power before you begin this procedure can lead to product damage and result in serious injury or death. i.e., 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.

Environmental Specifications

Temperature/Humidity	Specification
Storage/Transportation Temperature	-29°C to 50°C (-20°F to 122°F) - Relative humidity: 80% for up to 31°C, decreasing linearly to 50% at 40°C.
Operating Temperature	10°C to 40°C (40°F to 104°F) - Relative humidity: 80% for up to 31°C, decreasing linearly to 50% at 40°C.
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: Dental chairs, dental lights, power supplies, and monitor mounts. CLASS II EQUIPMENT: Chair, wall, and cart-mounted delivery systems.
Degree of Shock Protection	TYPE B APPLIED PART: Delivery systems only.
Degree of Protection Against Water Ingress	ORDINARY EQUIPMENT: All products.
Mode of Operation	CONTINUOUS OPERATION: All models except dental chairs. CONTINUOUS OPERATION WITH INTERMITTENT LOADING: Dental chairs - 5% duty cycle.
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, ICV, lab control.

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

Electrical Rating

A-dec Product	Frequency (Hz)	Voltage Range (VAC)	Maximum Current (Amps)
Dental Chairs			
A-dec 200, A-dec 311, A-dec 511, 1040, 1221, & 8000	50-60	100/110-120/220-240	10/10/10
Delivery Systems, Assistant's Instrumentation, and Cuspidors			
Systems with 300W Power Supply	50-60	100/110-120/220-240	3.1/2.8/1.4
Dental Lights (Mains Voltage)			
Ceiling, Post, Wall, Single Track, & Preference Mount Lights	50-60	100/110-120/220-240	3.1/2.8/1.4
Dual Track Light	50-60	110-120/220-240	5.6/2.8

Electrical Rating (continued)

A-dec Product	Frequency (Hz)	Voltage Range (VAC)	Maximum Current (Amps)
Dental Lights (Chair-Mounted)			
Performer® 8000	50-60	10.8/12.1	4.4
Cascade® 6300	50-60	12.1/16/17	5.5
A-dec 571/572	50-60	12.1/16/17	5.5
A-dec 371/372	50-60	12.1/17	5.5
A-dec 200	50/60	12.1/17	5.5
Power Supplies			
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®	50-60	110-120	20
Preference ICC®	50-60	110-120	20
ICV®	50-60	110-120/220-240	0.5/0.5
Miscellaneous			
Simulator 41L, 42L, 4810, 4820, M66AA	50-60	100/110-120/220-240	10/10/5
Lab Control with 300W Power Supply	50-60	100/110-120/220-240	3.1/2.8/1.4
Bitewing X-Ray Viewer	50-60	24	0.5
International Junction Box	50-60	100-240	15
Monitor Mounts	50-60	100-240	10

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, etc.) shall use a plug that is rated appropriately for the voltage and current of the product.

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. In the event of interference, power devices from separate mains supplies and/or increase physical distance between devices. Contact A-dec Customer Service if you have any questions.

Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Class A	The dental equipment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following caution is heeded (see CAUTION below).
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

CAUTION This equipment/system is intended for use by health care professionals only. The equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the dental equipment or shielding the location.

Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	B	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	B	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	B	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	B B B C	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.
Power Frequency (50-60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	A	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

NOTE U_T is the AC mains voltage prior to application of the test level.

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 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 specific questions regarding material type, please contact A-dec Customer Service. For decommissioning information on associated equipment from other manufacturers, refer to the documentation from the manufacturer.

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).

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