Instructions for Use

# 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 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. For complete details, see "A-dec, Inc. Express Limited Warranty" on page 3.*

## A-dec, Inc. Express Limited Warranty

### Scope

A-dec, Inc. warrants the products described in the table below against defects in material or workmanship under normal intended use when purchased from A-dec or an authorized A-dec dealer. The warranty period is measured from the date of A-dec's invoice. If you have questions about when your warranty coverage begins, please contact A-dec Customer Service.

| Product | Warranty Period |
|---|---|
| Hydraulic Dental Chair Cylinder (tilt and lift) | 10 years |
| All Dental Chairs; Operator and Assistant Stools; Dental Lights, Delivery Systems; Monitor Mounts; Dental Furniture; Mechanical Room Compressors and Vacuums; and original components | 5 years |
| Mechanical Room Add-On Accessories and Control Modules | 1 year |
| Electric Motors, Handpieces, Tubing, and Control Modules | 1 year |
| Replacement components and parts | Remainder of original product warranty period or 1 year (whichever is greater) |
| Repairs performed by A-dec, including associated parts, service and clinical components | 6 months |

Products (including accessories, components, and replacement parts) not manufactured by A-dec are covered by the original manufacturer's warranty and are not covered by A-dec's warranty. Examples include, but are 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 of the original manufacturer, or you may contact the original manufacturer directly.

### Exclusions

A-dec's Limited Warranty does not cover:

i. A-dec products that have been used in direct or indirect combination with unapproved third party products, including third party parts (i.e., products not authorized or manufactured by A-dec).

ii. Representations and warranties made by any person or entity other than A-dec.

iii. Damage caused by normal wear and tear or the natural breakdown of materials over time.

iv. Damage caused by improper installation, care, or maintenance, accident, misuse, abuse, neglect, negligence, tampering, failure to seek and obtain repair or replacement in a timely manner, alterations, freight damage, natural disaster, or any other cause or force majeure beyond A-dec's control (**failure to follow A-dec's Instructions for Use and applicable product operation and maintenance instructions, including installation instructions, will void the warranty**).

v. Damage caused by routine maintenance or in connection with the use of chemicals and processes for cleaning, disinfecting, or sterilizing.

vi. Changes in color caused by natural or artificial light.

vii. Normal service items, including, but not limited to: light shields, light bulbs, filters, O-rings, tubing, water bottles, diaphragms, and water cartridges.

viii. Products that have been altered or modified.

ix. Certain types of upholstery and countertop finishes (e.g., certain special orders).

Consumable products are not covered by this Limited Warranty. Contact A-dec Customer Service with questions about warranty or returns for these items. Any returned consumable product must be in its original, unopened packaging.

### Warranty Assistance and Contact Information

If you purchased your product from an A-dec dealer, for warranty assistance, please contact your authorized A-dec dealer during the warranty period. The dealer will discuss with you arrangements for the product(s) to be delivered to them for inspection or for inspection to occur on site.

If A-dec determines that the product has a defect that is covered under this Limited Warranty, the product will be repaired or replaced with a product that is comparable to the original in performance. If the product is covered under A-dec's Limited Warranty, you will not be charged for parts, but the A-dec dealer performing the repair(s) will charge you a call out fee (if applicable) and any applicable repair service fees. In certain circumstances, you may be responsible for promptly shipping the product to A-dec and associated transport/shipping costs; A-dec is not responsible for packages lost or damaged in transit, and you are responsible for purchasing insurance. Please note that styles and color options available at the time of service may vary. If a product or color has been discontinued, a replacement in the product style or color that is the most similar to the original will be provided.

**Warranty Assistance and Contact Information** *(continued)*

If you have a question that is not addressed in this Limited Warranty or if you purchased your product directly from A-dec and need warranty assistance, 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).

**Warranty Limitations; Exclusive Remedy; Damages Disclaimer**

A-dec's sole obligation and your exclusive remedy under this Limited Warranty is the repair or replacement of defective products or components. A-dec's Limited Warranty is in lieu of all other warranties and obligations, express or implied. A-dec expressly disclaims all implied warranties, including but not limited to implied warranties of merchantability, durability, or fitness for a particular purpose or use.

A-DEC SHALL NOT BE LIABLE FOR AND EXPRESSLY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, SPECIAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OR DELAYS, HOWEVER CAUSED, WHETHER FOR BREACH OF WARRANTY, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, PROPERTY DAMAGE, OR PERSONAL INJURY, HOWEVER CAUSED, WHETHER FOR BREACH OF WARRANTY, BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE.

**Limitation of Liability**

WITHOUT LIMITING THE DAMAGES DISCLAIMER ABOVE, THE MAXIMUM LIABILITY OF A-DEC AND ITS SUPPLIERS, AFFILIATES, DEALERS, RESELLERS, AND AGENTS, AND EACH OF THEIR EMPLOYEES, DIRECTORS, AND CONTRACTORS TO YOU IS LIMITED TO THE PURCHASE PRICE YOU PAID FOR THE PRODUCT. SOME JURISDICTIONS DO NOT ALLOW THE LIMITATION OR EXCLUSION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATIONS OR EXCLUSIONS MAY NOT APPLY TO YOU IN WHOLE OR IN PART.

**Governing Law and Venue; Severability**

To the full extent permitted under applicable law, this Limited Warranty and any disputes arising out of or in connection with A-dec products ("Disputes") shall be governed by the laws of the State of Oregon, USA, excluding conflicts of law principles and excluding the Convention for the International Sale of Goods. The courts located in Multnomah County, Oregon, USA shall have exclusive jurisdiction over any Disputes. Disputes must be resolved individually, without resort to any form of class action. If any provision of this Limited Warranty is unlawful, void or unenforceable, the meaning of such provision will be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it will be severed from the remainder of this Limited Warranty, which will remain in full force and effect. If there is any inconsistency between the English and other versions of this Limited Warranty, the English version shall prevail.

This Limited Warranty gives you specific legal rights, and you may also have other rights that vary by jurisdiction.

**Modification or Withdrawal of the Warranty**

A-dec reserves the right in its discretion to modify or withdraw this Limited Warranty at any time without notice. Any modification or withdrawal will not affect products already installed and fully paid for prior to the date of such modification or withdrawal. No A-dec dealer, reseller, service provider, agent, or employee is authorized to make any modification, extension or addition to this warranty.

This Limited Warranty is valid as of February 4, 2021.

**For UK Customers**

In the United Kingdom and the Republic of Ireland, this Limited Warranty is provided by A-dec Dental UK, Ltd. of Austin House, 11 Liberty Way, Nuneaton, Warwickshire. CV11 6RZ, telephone 0800.ADEC.UK (2332.85), fax 024 7634 5106, email info@a-dec.co.uk and applies to products sold to customers located in the United Kingdom and the Republic of Ireland.

**For Australia Customers**

**Warranty Provider and Warranty Period**

In Australia, this Limited Warranty is provided by A-dec Trading Company, Inc. trading as A-dec Australia (A-dec) (ARBN 002 806 117) of Unit 8, 5-9 Ricketty Street, Mascot NSW 2020, telephone 02 8332 4000, email a-dec@a-dec.com.au and applies to products sold to customers located in Australia. In Australia the warranty period is calculated from the date of supply to the customer.

**IMPORTANT NOTICE REGARDING YOUR CONSUMER RIGHTS**

The benefits given to you under this warranty are additional to other rights and remedies that you may have in relation to your purchase and use of the goods to which this warranty relates. Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure. As our goods are not of a kind ordinarily acquired for personal, domestic or household use or consumption, we are permitted to limit our liability under the Australian Consumer Law for failure to comply with certain guarantees, where it is fair and reasonable to do so, to one or more of the following: (i) the replacement of the goods or supply of equivalent goods, (ii) the repair of the goods, (iii) the payment of the cost of replacing the goods or of acquiring equivalent goods, or (iv) the payment of the cost of having the goods repaired. A-dec Australia provides no warranty against defects beyond the rights and remedies given under this express limited warranty and those which are available under the Australian Consumer Law.

## 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: 15A 311-B 12345

Year/Month Unique Number

S/N: 11H 12345

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: L3 12345

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)

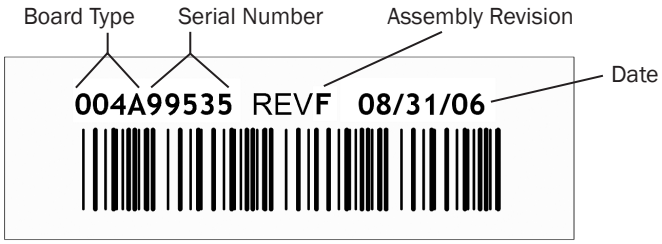
The Unique Device Identifier (UDI) contains both machine readable and human readable formats. For descriptions of the GS1 Application Identifiers (AI), see the table below.

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.




## 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 table 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/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 | 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 |
| 43.0399.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

| 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:<br>— Control Head<br>— 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:<br>— Control Head<br>1 2 3 4 5<br>— Assistant's<br>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 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 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 —** 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.

## Intended Application and Use Statements (*continued*)

**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 |
|---|---|
|  | 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 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. |
|  | **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. |
|  | 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. |
|  | Conforms to applicable European Directives/Regulations (refer to Declaration of Conformity). |
|  | EU Authorized Representative. |
|  | Protective earth (ground). |
|  | Functional earth (ground). |
|  | Type B applied part. |
|  | Caution: Hot surface. |

| Symbol | Description |
|---|---|
|  | Electrical and electronic waste. Do not dispose of with domestic waste. |
|  | Date of manufacture. |
|  | Manufacturer of equipment. |
|  | Sterilizable up to the stated temperature. |
|  | Steam sterilizable up to the stated temperature. |
|  | VAC symbol.<br>VDC symbol.<br>VAC/VDC symbol. |
|  | Contains hazardous substances. |
| REF | Model Number (Catalog Number). |
| SN | Serial number. |
| PN | Part Number. |
| MD | Medical Device. |
| LOT | Lot Code. |
|  | Use by date. |
| Rx Only | Caution. U.S. Federal law restricts this device to sale by or on the order of a licensed physician. |
|  | GS1 DataMatrix for Unique Device Identifier. |
|  | Refer to accompanying documents for additional information.<br>e.g., IMPORTANT: For more information, see the A-dec Equipment Asepsis Guide (p/n 85.0696.00). |
|  | General mandatory action sign. Not a caution. Take note of additional important instructions.<br>e.g., NOTE: Assemble parts as shown. |
|  | Caution. Failure to follow instructions may result in product damage or minor injury.<br>e.g., CAUTION: Do not overtighten the adjustment screw. Overtightening could break the screw. |
|  | Caution. Optical radiation.<br>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. |

## Identification of Symbols (*continued*)

| Symbol | Description |
|---|---|
|  | Warning. Biological hazard.<br>e.g., WARNING: Infectious waste may be present. Follow asepsis protocol to prevent cross contamination. |
|  | Warning. Dangerous voltage.<br>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. |
|  | Warning. Failure to follow instructions may result in product damage or serious injury or death.<br>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.<br>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. |
|  | Read This. Indicates that a decision must be made about which directions to follow.<br>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. |
|  | Do not re-use.<br>e.g., CAUTION: Disposable HVE and saliva ejector tips are not sterilizable and should not be reused. |
|  | Temperature shipping and storage limits. |
|  | Relative humidity shipping and storage limits. |
|  | Atmospheric pressure shipping and storage limits. |
|  | This way up. |
|  | Fragile. |
|  | Keep dry. |
|  | Do not stack. |

## 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.<br>Note: For clinical devices, refer to the Instructions for Use that came with the product. |
| Degree of Protection Against Water Ingress | Footswitch: IPX1<br>All other products: IPX0 |
| Mode of Operation | CONTINUOUS OPERATION: All models except dental chairs.<br>CONTINUOUS OPERATION WITH INTERMITTENT LOADING: A-dec dental chairs - 5% duty cycle (maximum ON time is 20 seconds).<br>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<br>Duplex output = 10 Amps max.<br>Chair circuit board output = 2 Amps max.<br>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<br>Duplex output = 10 Amps max.<br>511 Chair power supply = 4 Amps max.<br>Chair pump typical = 4/4/2 |
| **Delivery Systems, Assistant's Instrumentation, 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<br>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 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 |

| A-dec Product | Frequency (Hz) | Voltage Range (VAC) | Maximum Current (Amps) |
|---|---|---|---|
| **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<br>Duplex output = 7 Amps max. |
| A-dec Inspire Power Box | 50-60 | 100-240 | 10 |
| **Miscellaneous** | | | |
| Simulator 41L and 42L | 50-60 | 100/110-120/220-240 | 10/10/5<br>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 |

**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<br>CISPR 11 | A-dec dental equipment is suitable for use in all locations. |
| Harmonic emissions<br>IEC 61000-3-2 | |
| Voltage Fluctuations/Flicker Emissions<br>IEC 61000-3-3 | |

## 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<br>Test Level | Electromagnetic Environment<br>Guidance |
|---|---|---|
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact<br>±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<br>IEC 61000-4-3 | 10 V/m<br>80% AM at 1 kHz<br>80 MHz - 2700 MHz | |
| Electrical Fast Transient/Burst<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Conducted RF Immunity<br>IEC 61000-4-6 | 6 V<br>80% AM at 1 kHz<br>150 kHz - 80 MHz | |
| Power Frequency (50-60 Hz)<br>Magnetic Field<br>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,<br>Short Interruptions, and<br>Voltage Variations on<br>Power Supply Input Lines<br>IEC 61000-4-11 | 100% dip for 0.5 cycle<br><br>100% dip for 1 cycle<br><br>30% dip for 25 cycles<br><br>100% drop for 250 cycles<br>(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. |

## Maximum Chair Capacity

| Chair | Patient Load | Chair Mount Accessory Load *(offset)* | Chair Mount Applied Moment |
|---|---|---|---|
| **A-dec 511, Version B** | | | |
| *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** | | | |
| *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<br>• humidity limit: dew point ≤ −20 °C (at atmospheric pressure)<br>• oil contamination limit: ≤ 0.5 mg/$m^3$<br>• particulate contamination limit: ≤ 100 particles per cubic meter for 1 - 5 µm particle size<br>• 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<br>• water supply to meet local plumbing codes, including backflow prevention<br>• pH limits between 6.5 and 8.5<br>• maximum particle size <100 µm<br>• water hardness limit is less than 2.14 mmol/l (<12 °dH)<br>• water filter effective mesh size is 50 microns |
| **Vacuum** | wet:<br>10 ± 2 inches of Hg (34 ± 7 kPa)<br>dry/semi-dry:<br>4.5 ± 1 inches of Hg (16 ± 3.5 kPa) | 9 scfm (255 SL/min) minimum<br><br>12 scfm (340 SL/min) minimum | • solids filter maximum mesh opening size:<br>0.043" (1.080 mm) ≅ 1080µm A-dec 200, Performer 8000/8200/8500, 2671/2615, 4631/4635)<br>0.047" (1.194 mm) ≅ 1200 µm 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.*

**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 intraoral camera.

## 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 (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:

- 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.
- Lead , Diboron Trioxide, CAS # 1303-86-2; present in select electrical components.
- 2-(2H-benzotriazol-2-yl)-4,6 ditertpentylphenol (UV-328), CAS # 25973-55-1 used in certain fiberglass junction boxes
- N,N-dimethylformamide, CAS # 68-12-2, used in certain electrical components
- Lead monoxide (lead oxide), CAS # 1314-41-6, used in certain electrical components
- Lead, CAS # 7439-92-1, used in various brass and electrical 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).

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 are available for download in the Resource Center at www.a-dec.com.

a-dec®
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