Regulatory Information, Specifications, and Warranty

A-dec® S76

SURGICAL LIGHT

INTRODUCTION

Local regulatory requirements may apply to use or install the 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 this 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 consult the Instructions for Use (IFU) provided with the product or contact the manufacturer

APPLICATION SPECIFICATION

Intended Use

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

Intended Patient Population

There are no restrictions on patient population that may be treated by dental light. The patient is not intended to be the user of dental light.

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

Most often, the patient contact location is incidental contact with exterior skin surfaces.

Intended User Profile

Dental Light 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

Dental Surgical Light is intended for use within dental office operatories. 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, suppliers, healthcare providers, integrators, operators, regulators and, in some cases, patients.

Dental offices using 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.

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
- Electromagnetic and electrical hazards
- Mechanical hazards (suspended masses, moving parts)
- Cleaning and cross-infection hazards
- Photobiological hazard

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

CAUTION Some technical documents, such as pre-installation guides, kit installation guides, and service documents, may only be available in English. Do not perform the activities outlined in these documents unless the content is understood and followed.

CAUTION Prevent electrical issues to avoid damaging equipment, furniture, and floors, as well as potential for fire or smoke. Local regulation may require licensed electricians to install utilities. All 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 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.

CAUTION Replacement of batteries by unauthorized personnel or with non-approved batteries may result in electrical shock, fire hazard, device malfunction, or injury to patients and users. Use only manufacturer-specified replacement batteries and follow the instructions in the user manual. After replacement, verify proper function

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.

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

CAUTION To prevent injury and/or product damage, use care when moving the product into the range of motion and cleaning. Do not exceed the prescribed maximum loads during operation. Do not overload the mechanical limit switches of the arms and head. When installing, always maintain the correct distance between the patient and the lamp in all positions.

CAUTION To prevent injury from falling masses do not use detergents or disinfectants that are abrasive, corrosives or acids
Do not use detergents or disinfectants containing ammonium hydroxide, hydrogen peroxide, ammonium chloride, methylene chloride, methyl alcohol, chloride or chloride ions, phosphorous ions, cleaners based on trilene, petroleum, white spirit or similar.
Do not spray chemical agents directly onto the lamp.
Do not use wet wipes without squeezing them to remove excess liquid.

WARNING The user is required to use disposable covers on the handles of the lamps or to disinfect them after each patient.
For surface disinfection, use appropriate disinfection procedures as defined into Instructions for Use.

WARNING this product emits potential hazardous optical radiation. Do not stare at the light emitted from the surgical light. Eye injury may occur.
Do not point light beam directly into the patient's eyes, especially for patients with an increased risk of eye damage (e.g., children, elderly patients with eye diseases). In this case, always use appropriate protection and precautions.
It cannot be excluded that patients who are particularly photosensitive or who have taken photosensitizing medication may experience erythema or allergic reactions to light. In this case, discontinue the treatment and use very low levels of illumination.

Incident Reporting

Report all serious incidents involving this equipment to the Manufacturer. 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.

Equipment Alterations Policy/Disclaimer

It is forbidden any modification or alteration of the device.
Modifications or alterations of the device that expand the use beyond its design and intended use, or override any safety feature may jeopardize doctor, patient, or staff safety. Modifications that alter the electrical or mechanical safety of dental equipment are in conflict with Underwriters Laboratory (UL) construction file requirements and are not sanctioned by the Manufacturer. Examples of modifications that diminish safety design include, but are not limited to:

- Alteration with equipment that is not from or sanctioned by the Manufacturer.
- Rendering access to the line voltage without the use of tools. Modification of supporting elements that increase or shift loading characteristics.
- 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 this device may lead to a reduced level of safety of the resulting system.

It is the responsibility of the equipment distributor and the installer, not of the Manufacturer, 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.
The Manufacturer will not respond to inquiries on an individual basis.
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 alterations of the device are at your own risk. You will indemnify and defend the Manufacturer from any resulting claims, including product liability claims, that 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. Electrical connections to the device are not permitted unless the combination of the accessory and the device 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 or power supply compatible with the input data of the device.

Preventive Inspection

Over time, normal wear and tear may affect the performance of the equipment. You should periodically inspect the moving parts of the device to ensure that plays and corrosion are not present.

Maintenance

Maintenance must be carried out only by specialized technicians approved by the Manufacturer or by A-dec.

Expected Service Life

Service Life* is the maximum length of time that the device 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 Service Life is separate from the warranty period. There are no implied or explicit extensions of the warranty period.

Product Category	Service Life (Years)
Surgical Lights	10

The actual Service Life of the device 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 the device is available in the Resource Center at www.a-dec.com. If you have general questions regarding the device, please contact A-dec Customer Service or your local authorized A-dec dealer or distributor.
* Service Life information is provided for general planning purposes only and should not be relied

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/Canada)
- +1.503.538.7478 or a-decglobal@a-dec.com (outside the USA/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 This is the serial number (S/N), which is on the product serial tag. The S/N code may appear in the following format:

S/N: 25LC012345
Year Progressive Univoqual Number

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.

AI	Data Content
01	Global Trade Item Number (GTIN)
21	Serial number
11	Production date (YYMMDD)
90	Model
241	Customer Part Numbers

Product Cybersecurity Protections

Some A-dec devices connected to the dental light 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:

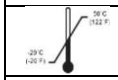
- Patient and financial data: No patient data or practice financial data are stored or passed through any A-dec device.
- External USB Port: the devices has an external USB ports. This port enable connection to USB keys for software updates and log downloads only.
- Internal USB ports: When available, internal USB ports will only recognize and connect to A-dec authorized devices.

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
	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)
	Refer to instruction manual/booklet Note: on Medical Equipment "Follow Instructions for use" ISO 7010-M002
	General mandatory action sign. Not a caution. Take note of additional important instructions. e.g., NOTE: Assemble parts as shown (ISO 7000-M001).
	Caution or Warning. Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	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).
	Certified by UL with respect to electric shock, fire and mechanical hazards only in accordancewith ANSI/AAMIES60601-1, CAN/CSAC22.2 No. 60601-1, and Amendment 1.
	Conforms to applicable European Directives/Regulations (refer to Declaration of Conformity), (Medical Device Regulation [EU] 2017/745 Annex V).
	EU Authorized Representative (ISO 15223-1, Clause 5.1.2).
	Swiss Authorized Representative (MU600_00_016).
	Regulatory compliance mark for Australia and New Zealand (AS/NZS 4417.1).
	UDI—Identifies the carrier that contains unique device identifier information (ISO 15223-1, Clause 5.7.10).
	GS1—Identifies the carrier that contains unique device identifier information.

Symbol	Description
	GS1 Data Matrix—Two-dimensional code that encodes text or numeric data related to device identification (ISO 16022, Clause 6.3).
	Protective earth (ground) (ISO 60417-5019).
	Functional earth (ground) (ISO 60417-5017).
	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).
	Sterilizable up to the stated temperature (ISO 7000-1844).
	Steam sterilizable up to the stated temperature (ISO 7000-2868).
	Alternate Current VAC symbol (ISO 60417-5032). VAC/VDC symbol (ISO 60417-5033).
	VDC symbol (ISO 60417-5031). VAC/VDC symbol (ISO 60417-5033).
	Model Number (Catalog Number) (ISO 7000-2493).
	Serial number (ISO 7000-2498).
	Medical Device (ISO 15223-1, Clause 5.7.7).
	Model / Type
	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 (ISO 7000-3500).

Symbol	Description
	Do not re-use. e.g., CAUTION: Disposable HVE and saliva ejector tips are not sterilizable and should not be reused (ISO 7000-1051)..
	For indoor use only (ISO 60417-5957).
	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).
	Total weight of device (ISO 7000-1321).
	Two-person lift is recommended.
	Three-person lift is recommended.

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%.
Operating Pressure	700 to 1060 hPa (20.3 to 30.7 inHg).
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
Electrical Rating	48 V DC Max Current of the device: 1,1 A @ 48 V DC Max current with the Power Supply: 2.0 A @ 100 VAC
Types of Shock Protection	Class I equipment
Recommended fuses	N/A
Degree of Shock Protection	Type B applied part: none
Degree of Protection Against Water Ingress	IP X4
Mode of operation	Continuous operation
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).
IEC 62471 Classification	Class I equipment No labelling requirement
Lithium Battery Type for microprocessor only	Renata CR1225 Panasonic BR1225

WARNING To avoid risk of electrical shock, which could lead to serious injury or death, this equipment must only be connected to a supply main 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.

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.

WARNING In the event of interference with medical deliveries or medical devices, to avoid risk of serious injury or death:

- Turn off the device and reconfigure to power the devices from separate mains supplies.
- Remove interfering device from room.
- Plug interfering device into an isolated circuit.
- Increase separation between unit and interfering device.
- Contact your authorized A-dec dealer if interference persists.

CAUTION The use of accessory equipment (including cables and transducers) not complying with the equivalent electromagnetic compatibility (EMC) requirements may negatively affect electromagnetic performance. Considerations relating to the use of accessory equipment shall include evidence that EMC certification has been performed in accordance with the IEC 60601-1-2 standard along with any national deviations.

CAUTION The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment, could result in increased electromagnetic emissions, decreased electromagnetic immunity of the equipment, and improper operation.

CAUTION portable RF communications equipment, including antennas, can effect me equipment. These devices must be used to a distance no closer than 30 cm (12 inches) to any part of the S76, including cables specified by the manufacturer.

CAUTION Use of this equipment adjacent to or stacked with other equipment should be avoided because it could lead to improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Electromagnetic Emissions

	Environment -
RF Emissions CISPR 11	suitable for use in all locations.
Harmonic emissions IEC 61000-3-2	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	

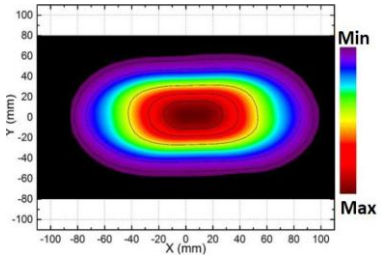
NOTE suitable for use in industrial areas and hospitals (CISPR 11 class A).
If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

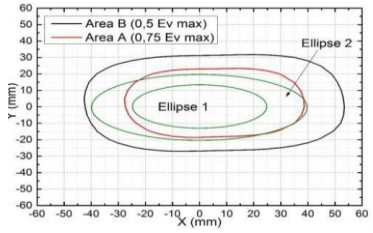
Electromagnetic Immunity

Immunity Test	Test Level	Environment Guidance
(ESD) IEC 61000-4-2	±2, 4, 8, 15 kV air	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	
Transient/Burst IEC 61000-4-4	lines ±1 kV for input/output lines	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.

Optical Specification for Dental Mode ISO 9680 (*)

	Dental Lamp Dental Lamp Head
Number of luminaries	2
IEC Classification 62471	Class 1 – Labelling Exempt
Maximum Illuminance	50.000 lux
Colour Rendering Index (*)	> 95
Correlated Colour Temperature CCT (*)	Tunable White: 4000 K – 5000 K – 5700 K Composave: 2700 K
Spot Dimension (*)	180 mm x 110 mm
Max Hard Shadow ISO 9680 (*)	10 mm x 5 mm
Nature of radiation	Non-ionising
Type of radiation	Visible light
Typical illuminance pattern ISO 9680 (*)	Typical illuminance pattern ISO 9680





(*) Typical values subjected to tolerances (10%)

Specification for Surgical Mode IEC 60601-2-41 (*)

illuminance	
a) central illuminance measured at reference distance	110.000 lx @ 1000 mm
b) maximum central illuminance	160.000 lx @ 760 mm
light field diameters at reference distance	
a) light field diameter D_10	218 mm
b) light field diameter D_50	145 mm
c) relationship between D_50 and D_10	66%
shadow dilution at reference distance	
a) remaining illuminance with one mask	3,32 %
b) remaining illuminance with two masks	39,67 %
c) remaining illuminance with simulated cavity	89,86 %
d) remaining illuminance with simulated cavity and one mask	3,37 %
e) remaining illuminance with simulated cavity and two masks	40,34 %
depth of illumination	610 mm
chromaticity at field center, reference distance, max irradiation setting	5000 K
colour rendering	
Ra	98
R9	98
Infrared radiation at the light field centre at maximum illuminance distance with the maximum irradiance setting	
IR irradiance 780 nm – 3000 nm	3,09W/m2
Ultraviolet radiation at the light field centre at maximum illuminance distance width the maximum irradiance setting	
UV hazard weighted irradiance 200 nm – 400 nm	6,53E-08 W/m2
UV-A irradiance 315 nm – 400 nm	1,63E-03 W/m2
Broadband radiation at the light field centre at maximum illuminance distance with the maximum irradiance setting	
total irradiance (200 nm – 3000 nm)	577,0 W/m2
relationship IRR to ILL	3,7 mW/m2/lx
blue light hazard IRR 300 nm – 700 nm	110,2 W/m2
retinal thermal hazard IRR 380 nm – 1400 nm	1,48E+03 W/m2
radiance with 11 mrad and 7 mm aperture stop	
blue light hazard RAD 300 nm – 700 nm	2,36 E+03 W/m2/sr
retinal thermal hazard RAD 380 nm – 1400 nm	3,13 E+04 W/m2/sr

(*) Typical values subjected to tolerances (10%)

Decommissioning and Disposal

Dental Light 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. 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

The Manufacturer device 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 The Manufacturer 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, the Manufacturer 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 CAS 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/Canada)

– +1.503.538.7478 (outside USA/Canada)

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

Product Documentation

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 this QR code, which points to: a-dec.com/resource-center.

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