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AlliedStar

AS 100

User Manual

Safety, Regulatory and Technical Specification



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Notice

The Safety, Regulatory and Technical Specifications User Guide includes information on the safety instructions, regulatory information, and the technical specifications of the devices. We recommend that you thoroughly familiarize yourself with this guide to make the most effective use of your system.
The information in this document is subject to change. Neither Alliedstar nor any of its subsidiaries shall be liable for errors contained herein or for incidental damages in conjunction with the furnishing, performance, or use of this material. No part of this publication may be reproduced without the permission of Alliedstar.

This document is originally written in English.

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The AS 100 is intended for professional use only.
U.S. Federal law restricts this device to sale by or on the order of a dentist.

If any serious incident occurs in relation to the device, the user must report it to Alliedstar and to the competent authority of its Member State in the European Union.

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1 Safety Information

Indication for Use

The AS 100 is a digital optical scanning device used to obtain digital impressions of hard and soft tissues such as teeth, gums and mucous membrane by means of oral scanning, for oral restoration and orthodontic treatment of malocclusion.
The AS 100 could be used for both adult and children in clinical practice.

Clinical Benefits and Performance Characteristics

Alliedstar's intraoral scanners benefit a dental practice by enabling practitioners to acquire digital impressions with the quality and accuracy required for digital CAD/CAM dental applications. The actual performance of the device is dependent on the user's training and operating execution. The user is solely responsible for the accuracy, completeness, and adequacy of the acquired data.

Conventions in This Guide

The following special messages emphasize information or indicate potential risks to personnel or equipment.



WARNING: Warns you to avoid injury to yourself or others by following the safety instructions precisely.



Note: Alerts you to a condition that might cause serious damage.

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Important: Alerts you to condition that might cause problems.



Tip: Provides extra information and hints.

Warnings and Safety Instructions



DANGER OF ELECTRIC SHOCK

This is an electrical unit. Do NOT expose it to water spray. Such action can cause an electric shock or a malfunction of the unit.



IMPORTANT: All known residual risks, contraindications, or undesirable side effects are listed in this guide. If any serious incident occurs in relation to the device, you must report it to Alliedstar and to the competent authority of your Member State in the European Union.



WARNINGS

AS 100:

- You MUST read and understand this safety information before using the scanner.
- This scanner shall only be used inside hospitals and other professional healthcare facilities and MUST NOT be used near high frequency surgical equipment and the RF shielded room of an ME System for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.
- Before using the scanner, check the outer surfaces of the unit and any accessories to ensure there are no rough surfaces, sharp edges, or protrusions which may cause a safety hazard.
- You are responsible for the operation and maintenance of the scanner. You MUST have training to use the scanner.
- DO NOT place objects within the field of operation of the unit.

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- When the unit is not in use, ensure that the scanner is turned OFF.
- DO NOT use the scanner in conjunction with oxygen-rich environments. This unit is not intended for use with flammable anesthetics or flammable agents.
- DO NOT pull or twist the cable.
- DO NOT drop the scanner or the accessories.
- DO NOT sterilize the scanner.
- DO NOT expose the scanner to water spray or submerge it in water or disinfectant.
- DO NOT expose the scanner to high vibrations.
- DO NOT expose the scanner to ultraviolet radiation directly. The scanner is not designed for ultraviolet disinfection.
- DO NOT stare at the LED emission window.
- DO NOT remove the cover of any scanner components. The scanner contains no user-serviceable parts. For any repairs, contact a qualified Alliedstar service technician.
- DO NOT replace the cables provided with the scanner with other cables. Doing so may damage the scanner and adversely affect the safety protection and EMC performance of the scanner.
- Any other equipment not complying with IEC-60601 shall be kept at least 1.5 meters away from the patient.
- If the equipment is faulty, turn it OFF, display an “Out of Service” notice, and contact a qualified Alliedstar service technician.
- Using components, accessories, cables and spare parts other than those specified or provided by the manufacturer of this equipment may impair the safety protection of the scanner and may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- No modification of this equipment is allowed.
- Additional multiple outlet strips or extension cords should not be connected to the system.
- The maximum temperature of the applied part may reach to 43 °C; to avoid overheating, do not use it for extended periods.
- To completely disconnect the device from the main power supply, unplug the USB connector from the USB port.
- DO NOT maintain or service this equipment while it is in use with the patient.
- Connection of the PEMS (Programmable Electrical Medical System) to an IT NETWORK that includes other equipment could result in risks to patients, operators, or third parties. The responsible organization should identify, analyze, evaluate, and control these risks.
- Patients with oral mucosal disease, mental illness, severe respiratory disease, asthma, Parkinson's disease, hyperactivity disease are forbidden.
- Patients with moderate or severe opening limitation should use it with caution.

Computer:

- Do NOT place any equipment which does not comply with IEC 60601-1 in the immediate vicinity of the patient. Leave at least 1.5 meters distance between the patient and the equipment.

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- The scanner is only intended to be connected to a computer that is at least IEC 60950 / IEC 62368, or equivalent standards certified. Connecting the scanner to other equipment may be hazardous.
- See the installation guide for your computer for information about the data processing system, computer, and screen. Leave a sufficient amount of clear space around the computer to ensure that it is properly ventilated.
- Position the screen to avoid light reflections from internal or external lighting for maximum image quality and visual comfort.

Disposal:



This equipment contains certain materials and chemical compounds incidental to the manufacture of electrical and electronic equipment, and improper “end-of-life” disposal of such equipment can result in environmental contamination. Therefore, this equipment should not be disposed of as ordinary household waste but should instead be delivered to a designated electrical and electronic waste disposal or recycling center. For further information on disposing of electrical and electronic waste, contact the cognizant authority within the local jurisdiction.

Dispose of the scanner tips according to standard operating procedures or local regulations for the disposal of contaminated medical waste. For additional scanner tips, contact your dealer.

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Cleaning, Disinfecting, Sterilizing

Perform the following maintenance activities on your scanner and accessories regularly.

To ensure maximum hygienic safety for the patient, carefully follow the instructions to prepare the scanner for use.

To ensure maximum hygienic safety for the patient and to minimize the risk of cross-contamination, carefully perform the following maintenance activities on your scanner and accessories.

After each patient:

- Clean and disinfect the scanner. See "Clean and Disinfect the Scanner".
- Reprocess the tip by applicable method:
  - Clean the tip, and then perform High Level Disinfection (See "Clean the Tip" and "Disinfect the Tip").
  - Clean the tip, and then perform Autoclave Sterilization (See "Clean the Tip" and "Sterilize the Tip").

  There are 3 models of tip as following, applicable to different reprocessing method:

Model	Size	DI	Manual Cleaning	Automatic Cleaning	High Level Disinfection	134°C Sterilization
TP101	Large	(01)06973993440020	√	√	√	×
TP102	Large	(01)06973993441010	√	√	×	√
TP103	Small	(01)06973993441027	√	√	×	√

Clean and Disinfect the Scanner

General Warnings

WARNINGS

- Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) for the disinfectant used to process the scanner.
- You must wear gloves while cleaning and disinfecting the scanner.
- The scanner must be disinfected with a recommended intermediate-level disinfectant solution with tuberculocidal activity between patients.
- DO NOT use a disinfectant containing phenolics or iodophors; doing so will damage the surface coating of the scanner.
- Never put the scanner in an autoclave device or immerse it in water or the disinfectant solution.

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- Excessive fluids can damage the scanner.
- Do not use cotton, cloth, or tissues soaked with disinfectant to disinfect the scanner.

Clean the Scanner

If the scanner is visibly contaminated with blood and/or body fluids, you must clean it before disinfecting it.

To clean the scanner, follow these steps:

1. Dampen (do not soak) a lint-free cloth with lukewarm water.
2. Remove the blood and/or body fluids with the dampened lint-free cloth.

Disinfect the Scanner

After each patient, the scanner must be thoroughly disinfected.

To adequately disinfect the scanner, follow the disinfectant manufacturer's instructions for the appropriate contact time.



Important: If the scanner is visibly soiled, it must be thoroughly cleaned prior to disinfecting. See "Clean the Scanner".

To disinfect the scanner, follow these steps:

1. Remove the reusable tip.
2. Remove all visible soil (see "Clean the Scanner").
3. Use a commercially prepared intermediate level disinfectant wipe. Follow the manufacturer's instructions for contact time.

Recommended disinfectant wipes: CaviWipes



WARNING: Using a disinfectant that has not been approved may cause damage to the scanner.

4. Thoroughly wipe all surfaces of the scanner. DO NOT allow liquid to enter through the gap, air outlet, or pin holes.

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WARNING: Do not rinse.

5. Allow to air dry.
6. After the scanner has dried, use a clean, lint-free cloth dampened with water to remove residual disinfectant from the surface of the scanner.

Clean and Sterilize the Tip



WARNINGS

- Wear gloves when handling a contaminated scanner tip.
- Read and follow the warnings and personal protection instructions provided in the manufacturer's SDS for the detergent used to clean the scanner tip.
- Do not soak the scanner tips in disinfectant for a long period.
- Dry the scanner tips thoroughly before mounting onto the scanner.
- Do not use an ultrasonic cleaning machine to clean the scanner tips.

Clean the tip by one of following ways:

Manually Clean the Tip

To manually cleaning the tip, follow these steps:

1. Rinse excess soil from the tip (2 minutes).
2. Using a soft brush, apply enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.
3. Rinse under clean, running water (2 minutes).
4. Inspect Tip. If the tip is not clean, repeat the steps 1-3.
5. Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

Clean the Tip in an Automatic Washer

To clean the tip in an automatic washer or disinfector, follow these steps:

1. Rinse excess soil from the tip (2 minutes).

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2. Using a soft brush, apply enzymatic detergent solution (e.g., Metrex EmPower) to all surfaces.
3. Load the Tips in to washer equipment.
4. Run the cycle per the equipment manufacturer's instructions (about 5 minutes). If the machine does not have an automatic rinse cycle, rinse thoroughly to remove detergent residues by immersing in clean water.
5. Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

Disinfect the Tip

To perform high level disinfection after cleaning the tip, follow these steps:

1. After cleaning the tip, check tip mirror to make sure the surface is free of stains or fog. Dry the mirror with a lens tissue or lint-free cloth.
2. Immerse AS 100 tips in to Johnson & Johnson® Cidex OPA disinfector for 5 minutes. Detailed disinfection method could be referred to instruction of Cidex OPA.
3. After immersing, clean the tips according to instruction of disinfector.
4. Use a lens tissue or lint-free cloth to remove any dust from the mirror in the tip.

Sterilize the Tip

Scanner tips received from the manufacturer are NOT sterilized. You must sterilize the tips before the first use.

Important: For TP102 and TP103, if you limit the exposure time at 134°C to not more than 6 minutes, you can autoclave the tip up to 60 cycles.

To sterilize the scanner tips, follow these steps:

1. Put the tip into a sealed steam sterilization pouch.
2. Place the tips in a steam autoclave for sterilization.

- For TP102 and TP103, exposure temperature should be set as 134°C, exposure time should exceed 3 minutes, while not exceed 6 minutes.

Important: For TP102 and TP103, exposure temperature should be set as 134°C.

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Important: For TP102 and TP103, exposure time should exceed 3 minutes.



Important: For TP102 and TP103, exposure time should not exceed 6 minutes.

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Precautions Before Use

Perform the following activities on your product and accessories before use.

Visually Inspecting the Scanner for Damage

Visually inspect the scanner for damage or signs of deterioration by doing the following:

- Inspect the scanner's lens window.
- Inspect around the scanner buttons and contact points.

If damage is noted, do not use the scanner and contact your representative.

Visually Inspecting the Scanner Tips

Visually inspect the scanner tips for signs of deterioration by doing the following:

- Verify that the tip is not damaged and its components are not detached.
- Verify that the tip mirror does not have any smudges or scratches on it.

If deterioration is noted, replace the tip.



WARNINGS

- **The lens window on the scanner is a delicate optical component. Mount the front protective cover to protect the lens window from damage and dirt when the scanner is not in use.**
- **The mirror in the tip is a delicate optical component. Its clean and undamaged surface is critical to scan quality.**

In the event that you see poor scan quality or an unclear video preview in the software, clean the tip mirror and the scanner's lens window using a microfiber cleaning swab, applying ethanol that is free of impurities.

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2 Regulatory Information

Marking and Labeling Symbols

	Type BF applied part symbol classification in accordance with IEC 60601 standards.
	In the European Union, this symbol indicates: DO NOT discard this product in a trash receptacle; use an appropriate recovery and recycling facility. Contact your local sales representative for additional information on the collection and recovery programs available for this product.
	Manufacturer
	Date of Manufacture
	Refer to instruction manual/booklet.
	Direct current.
	Sterilizable in a steam sterilizer (autoclave) at 134°C
	Model Number
	Serial number
	Class II equipment
	CE marks is a statement by medical equipment manufacturers that meet all the General Safety and Performance Requirements (GSPR) of all EU related medical instruments, and the CE mark is also a legal requirement for medical devices to list in the EU market.
	Name of the European authorized representative and address of the registered place of business.

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Regulatory Information

The AS 100 complies with the following regulations:

(EU) 2017/745 Medical Device Regulation (MDR), Cass I following the Rule 5.

FDA Center for Devices & Radiological Health CDRH - Title 21 CFR 872.3661 (USA).

Medical Devices Regulations (Canada).

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Compliance with European and International Standards

EN 60601-1 / IEC 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance

ANSI/AAMI ES 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

EN 60601-1-2 / IEC 60601-1-2: Medical Electrical Equipment, Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

EN 80601-2-60 / IEC 80601-2-60: Medical electrical equipment — Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

EN 62471 / IEC 62471: Photobiological safety of lamps and lamp systems: Equipment classification, requirements, and User's Guide

EN ISO 17664: Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices

EN ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

EN 60601-1-6 / IEC 60601-1-6: Medical Electrical Equipment, Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

EN 62366 / IEC 62366: Medical devices - Application of usability engineering to medical devices

EN 62304 / IEC 62304: Medical device software - Software life cycle Processes

EN ISO 10993: Biological evaluation of medical devices

EN ISO 14971: Medical devices - Application of risk management to medical devices

EN ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

EN ISO 20417:2021: Medical devices — Information to be supplied by the manufacturer

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ISO 9687: Dentistry - Graphical symbols for dental equipment

AAMI TIR 12: Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

AAMI TIR 30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

Classification in Accordance with EN/IEC 60601-1

Type of protection against electric shock: Class II
Degree of protection against electric shock: Type BF Applied Part
Mode of operation: Continuous operation
Flammable anesthetics: Not suitable for use in the presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide.

Conformity with EN/IEC 60601-1-2

IEC 60601-1-2 EMC requirements and tests, Medical Electrical Equipment including CISPR 11 Group 1, Class B.



Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in this documentation.
Other equipment can interfere with communications with the AS 100, even if the equipment complies with CISPR emissions requirements.
Warning: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AS 100, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declarations

Guidance and Manufacturer' s Declaration - Electromagnetic Emissions

The AS 100 is intended for use in the electromagnetic environment specified below. The customer or user of the AS 100 should assure that it is used in such an environment.

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Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1 Class B	The AS 100 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Guidance and Manufacturer' s Declaration – Electromagnetic Immunity for Equipment and Systems

The AS 100 is intended for use in the electromagnetic environment specified below. The customer or the user of the AS 100 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	3 V/m 80MHz – 2.7GHz	3 V/m 80MHz – 2.7GHz	Environment of a professional healthcare facility. WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AS 100 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

For the immunity to proximity fields from RF wireless communications equipment, the AS 100 is compliant with the test levels specified below, according to IEC 60601-1-2 standard. The customer or user of the AS 100 should assure that it is used in such an environment.

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels
385	380 – 390	Pulse modulation 18Hz, 27V/m
450	430 – 470	FM, ±5 kHz deviation, 1 kHz sine, 28V/m
710	704 – 787	Pulse modulation 217Hz, 9V/m

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745		
780		
810	800 – 960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700 – 1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400 – 2570	Pulse modulation 217Hz, 28V/m
5240	5100 – 5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Accessories

The use of cables or accessories other than those specified, with the exception of those sold by the manufacturer of the equipment, as replacement parts for internal components may result in increased emissions or decreased immunity of the medical equipment.

Other Equipment

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify normal operation.

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3 Technical Specification

Model

AS 100

AS 100 Technical Specifications

Components	Technical Specifications
Weight	Scanner (cable included) without tip: 260g Tip Large - High Level Disinfection (TP101): 12g Tip Large - Sterilization (TP102): 13g Tip Small - Sterilization (TP103): 12g
Color	3D full color
Connectivity	USB 3.0
Power Source	USB 3.0 5V, 900mA
Field of View	Tip Large - High Level Disinfection (TP101): 16mm x 14mm Tip Large - Sterilization (TP102): 16mm x 14mm Tip Small - Sterilization (TP103): 12mm x 12mm
Depth of Field	15mm
Configuration Requirement of Workstation	Processor: Intel® Core™ i7 9th Generation, base frequency 2.6 GHz (or better) Memory: 16 GB (or more) DDR4, frequency 2666 MHz (or better) Disk: 512G (or more) SSD Graphics card: NVIDIA® GeForce® GTX 1650 (or better) Display: 15.6" FHD (1920 x 1080) (or more) Others: USB 3.0 port Operating system: Windows 10 Pro Optional: Touch screen

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Important: It is MANDATORY to check that your system configuration is compatible with the computer system requirements for the AS 100 software.

AS 100 Environmental Requirements

Components	Environmental Requirements
Operating Temperature	15°C ~ 30°C
Transport and Storage Temperature	-10°C ~ 60°C
Operating Relative Humidity	10% ~ 65% RH
Transportation and Storage Relative Humidity	10% ~ 95% RH
Operating Atmospheric Pressure	70 ~ 106 KPa
Transportation and Storage Atmospheric Pressure	60 ~ 106 KPa

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4 Contact Information

Manufacturer

Alliedstar Medical Equipment Co., Ltd.

No.1-4, Floor 3, Unit 2, Building 3, No.222, West third section, Waihuan Road, Yanjiang District, Ziyang, 641300, Sichuan, P.R. China

E-mail: support@allied-star.com

Authorized Representatives

Authorized Representative in the European Community

EC REP

SUNGO Europe B.V

Olympisch Station 24 ,1076DE Amsterdam, Netherlands

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