S300W

Instructions

Trademarks

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Contact Information

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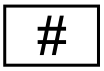
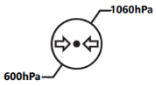
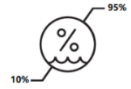
Lifetime: 6 years

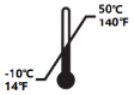
Contents

Labels & Symbols

CE	**EN** CE marking applicable for European Union **DE** CE-Kennzeichnung gilt für die Europäische Union **ES** Marca CE aplicable para la Unión Europea **FR** Marquage CE applicable à l'Union européenne **IT** Marchio CE applicabile all'Unione Europea
EC REP	**EN** Authorized Representative in the European Community **DE** Bevollmächtigter in der Europäischen Gemeinschaft **ES** Representante autorizado en la Comunidad Europea **FR** Mandataire Européen **IT** Rappresentante autorizzato per la Comunità Europea
CH REP	**EN** Authorized Representative in Switzerland **DE** Autorisierter Vertreter in der Schweiz **ES** Representante autorizado en Suiza **FR** Représentant autorisé en Suisse **IT** Rappresentante autorizzato in Svizzera
	**EN** Refer to the instruction manual/booklet **DE** Siehe Gebrauchsinformation **ES** Consultar el manual de instrucciones/manual **FR** Se reporter au manuel/notice d'utilisation **IT** Consultare le istruzioni del Manuale d'Uso
	**EN** Type BF applied part **DE** Anwendungsteil vom Typ BF **ES** Componente aplicado de tipo BF **FR** Partie appliquée de type BF **IT** Parte applicata di tipo BF
	**EN** Manufacturer **DE** Hersteller **ES** Fabricante **FR** Fabricant

	IT Fabbricante
	**EN** Date of Manufacture **DE** Herstellungsdatum **ES** Fecha de manufactura **FR** Date de fabrication **IT** Data di Produzione
	**EN** Model Number **DE** Modellnummerx **ES** Número de modelo **FR** Numéro de modèle **IT** Numero di modello
	**EN** Serial number **DE** Seriennummer **ES** Número de serie **FR** Numéro de série **IT** Numero di serie
	**EN** Direct current **DE** Gleichstrom **ES** Corriente continua **FR** Courant continu **IT** Corrente continua
	**EN** Sterilizable in a steam sterilizer (autoclave) at 134°C **DE** Sterilisierbar in einem Dampfsterilisator (Autoklav) bei 134°C **ES** Esterilizable en esterilizador de vapor (autoclave) a 134 °C **FR** Stérilisable dans un stérilisateur à vapeur (autoclave) à 134°C **IT** Sterilizzabile in uno sterilizzatore a vapore (autoclave) a 134°C
	**EN** Separate collection for waste electric and electronic equipment (WEEE) is required. **DE** Die getrennte Sammlung von Elektro- und Elektronikaltgeräten (WEEE) ist vorgeschrieben.

	ES Es necesario recoger por separado los residuos de aparatos eléctricos y electrónicos (RAEE). **FR** La collecte sélective des déchets d'équipements électriques et électroniques (DEEE) est obligatoire. **IT** È richiesta la raccolta differenziata dei rifiuti di apparecchiature elettriche ed elettroniche (RAEE).
MD	**EN** Medical Device **DE** Medizinisches Gerät **ES** Productos sanitarios **FR** Dispositif médical **IT** Dispositivo medico
	**EN** Atmospheric pressure limitation **DE** Atmosphärische Druckbegrenzung **ES** Limitación de la presión atmosférica **FR** Limitation de la pression atmosphérique **IT** Limitazione della pressione atmosferica
	**EN** Fragile, handle with care **DE** Zerbrechlich, mit Vorsicht zu behandeln **ES** Frágil, manipular con cuidado **FR** Fragile, à manipuler avec précaution **IT** Fragile, da maneggiare con cura
	**EN** Humidity limitation **DE** Begrenzung der Luftfeuchtigkeit **ES** Limitación de la humedad **FR** Limitation de l'humidité **IT** Limitazione dell'umidità
	**EN** Keep away from rain **DE** Vom Regen fernhalten **ES** Mantener alejado de la lluvia **FR** Tenir à l'écart de la pluie **IT** Tenere lontano dalla pioggia

	**EN** Stacking limit by number **DE** Stapelungsgrenze nach Anzahl **ES** Límite de apilamiento por número **FR** Limite d'empilage par nombre **IT** Limite di impilamento per numero
	**EN** Temperature limits **DE** Temperaturgrenzwerte **ES** Límites de temperatura **FR** Limites de température **IT** Limiti di temperatura
	**EN** This way up **DE** Dieser Weg nach oben **ES** Por aquí arriba **FR** Par ici **IT** Da qui in su
	**EN** Caution: US Federal law restricts this device to sale by or on the order of a licensed health-care practitioner. **DE** Achtung: US-Bundesgesetze beschränken den Verkauf dieses Geräts auf den Verkauf durch oder auf Anordnung eines lizenzierten Gesundheitsdienstleisters. **ES** Precaución: La ley federal de EE.UU. restringe la venta de este dispositivo a la venta por o bajo la orden de un profesional de la salud con licencia. **FR** Attention: La loi fédérale des États-Unis restreint la vente de cet appareil à la vente par ou sur ordre d'un professionnel de santé autorisé. **IT** Attenzione: La legge federale degli Stati Uniti limita la vendita di questo dispositivo alla vendita da parte o su ordine di un operatore sanitario autorizzato.
	**EN** Consult instructions for use. Follow the link to the eIFU: ifu.allied-star.com. **DE** Konsultieren Sie die Gebrauchsanweisung. Folgen Sie dem Link zur eIFU: ifu.allied-star.com. **ES** Consulte las instrucciones de uso. Siga el enlace al eIFU: ifu.allied-star.com. **FR** Consultez les instructions d'utilisation. Suivez le lien vers l'eIFU: ifu.allied-

	star.com. **IT** Consultare le istruzioni per l'uso. Seguire il link all'eIFU: ifu.allied-star.com.

Special Symbols

The following special symbols are used in this manual to emphasize information or to indicate the presence of potential hazards to personnel and devices.

WARNING

Avoids injury to yourself or others by following the safety instructions precisely.

CAUTION

Alerts to a condition that might cause serious damage or cause problems.

NOTE

Provides extra information and hints.

Precautions

This manual contains safety instructions, regulatory information, and technical specifications regarding this device.

It is recommended to familiarize yourself thoroughly with this manual to use the device efficiently.

S300W should only be used by professionals who have been trained in the system.

In the event of a serious accident while using this product, the user must report it to Alliedstar and the relevant authorities.

WARNING

- The Lens Window at the top of the Handpiece is a precision optical component. When the scanner is not in use, install the Lens Window Protective Cover to protect the Lens Window from damage or dust.
- The mirror inside the Scanner Tip is a delicate optical component. It is important for scanning quality to keep the mirror surface clean and undamaged.
- If a poor image quality is displayed by the software or the video preview is blurry, use a microfiber cleaning swab and unadulterated ethanol to clean the Scanner Tip Mirror and the Lens Window.

Safety Instructions

The safety instructions include the contents of the warning and safety instructions for scanners, computers, and disposal of discards. Before using this product, be sure to read the safety information and understand its meaning.

Warnings and Safety Instructions

WARNING ELECTRIC SHOCK

This device is an electrical device. Do not expose it to water spray as this may result in electric shock or device failure.

CAUTION

All known residual risks, contraindications, or undesirable side effects are listed in this document. 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.

WARNING

Scanner

- Before using the scanner, be sure to read the safety information and understand its meaning.
- The scanner should be used in hospitals and other specialized medical institutions and should not be used in places with high electromagnetic interference intensity, such as near high-frequency surgical device or in RF-shielded rooms of magnetic resonance imaging ME systems.
- The external surface of the device and all its accessories should be inspected first before using the scanner to ensure that there are no rough surfaces, sharp edges or protruding parts on the device to avoid danger.
- The user is responsible for the operation and maintenance of the scanner. The user must attend training on the use of the scanner.
- Maintenance of the scanner should only be performed by professionally trained personnel. Preventive inspections and periodic maintenance other than cleaning, disinfecting, and sanitizing of the scanner are generally not required by the user.

- Do not place objects in the operating area of the device.
- Make sure the scanner is turned off when the device is not in use.
- Do not use the scanner in an oxygen-enriched environment. Do not use this device with flammable anesthetics or combustible materials.
- Do not pull or twist the cables.
- Do not drop the scanner.
- Do not autoclave the scanner.
- Do not expose the scanner to water spray or submerge it in water or disinfectant.
- Do not subject the scanner to severe vibration.
- Do not expose the scanner to direct UV light. The scanner should not be sanitized with UV light.
- Do not stare directly at the LED emitting window.
- Once the Scanner Tip is removed, install the Lens Window Protective Cover to protect the Lens Window.
- Do not remove any scanner component covers. The scanner does not contain user-serviceable parts. Please contact Alliedstar technical personnel for any repairs.
- Do not use cables other than the ones provided with the scanner. Otherwise, it may damage the scanner and adversely affect its safety protection and EMC performance.
- Any other device that does not meet the requirements of IEC 60601-1 should be kept at least 1.5 meters away from the patient.
- If the device malfunctions, it should be turned off, marked as "out of service," and then contact the Alliedstar technical personnel.
- Using components, accessories, cables, and spare parts that are not specified or provided by the device manufacturer may weaken the safety protection of the scanner. It may also cause increased electromagnetic radiation or decreased electromagnetic compatibility, leading to improper operation.
- Do not modify the device without authorization.
- Do not connect additional power sockets or extension cables to the system.
- The maximum surface temperature of the Scanner Tip may reach 48°c. To avoid excessive temperature, do not prolong the usage time.
- If the device is completely separated from the main power source, please unplug the cable.
- Do not perform maintenance and servicing on the device while it is being used to treat patients.

- Connecting a Programmable Electronic Medical System (PEMS) to an IT network that includes other devices may pose risks to patients, operators, or third parties. Responsible parties should identify such risks and conduct analysis, evaluation, and control measures.
- Patients with oral mucosal diseases, mental illnesses, severe respiratory diseases, asthma, Parkinson's disease, attention deficit hyperactivity disorder (ADHD), and epilepsy are prohibited from using this product.
- Patients with moderate or severe limitation of mouth opening should use this product with caution.
- Do not position ME EQUIPMENT to make it difficult to operate the disconnection device.

Computer

- Do not place any device 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 device.
- 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.
- For information regarding data processing systems, computers, and related information, please see the installation guide provided with the computer's display. Leave enough clear space around the computer to ensure that it is properly ventilated.
- Position the screen appropriately to avoid glare caused by indoor or outdoor lighting, in order to achieve optimal image quality and visual comfort.

Disposal

- This device contains a rechargeable battery. Before disposing of this device, please remove the battery from the device. Before removing the battery, ensure that the battery is completely depleted of charge. Improper disposal of such devices after their service life may cause environmental pollution. Therefore, this device should not be treated as regular household waste but should be taken to designated electrical and electronic waste disposal or recycling centers. Please get in touch with your local environmental or waste management authorities for more information on electrical and electronic waste disposal.

- Dispose of the Scanner Tip according to the standard operating procedures or local regulations for the disposal of hazardous medical waste. For additional Scanner Tips, please contact the distributor.

1 Product Overview

S300W intraoral scanner (the "scanner") is a wireless intraoral scanner manufactured by Alliedstar.

The scanner can be used to capture 3D digital impressions of upper jaw, lower jaw, buccal bite registration, and intraoral soft tissues in conjunction with the scanning software, which can be used for data processing, data integration, data export, and data sending, as described in the scanning software instructions.

The scanner is used to acquire digital 3D models in the following modes:

- Upper Jaw
- Lower Jaw
- Buccal bite registration

1.1 Intended Use

The digital optical scanning device is used to obtain digital impressions of hard and soft tissues, such as teeth, gums, and mucous membranes, using oral scanning for oral restoration and orthodontic treatment of malocclusion.

The device could be used for both adults and children in clinical practice.

1.2 Contraindications

None

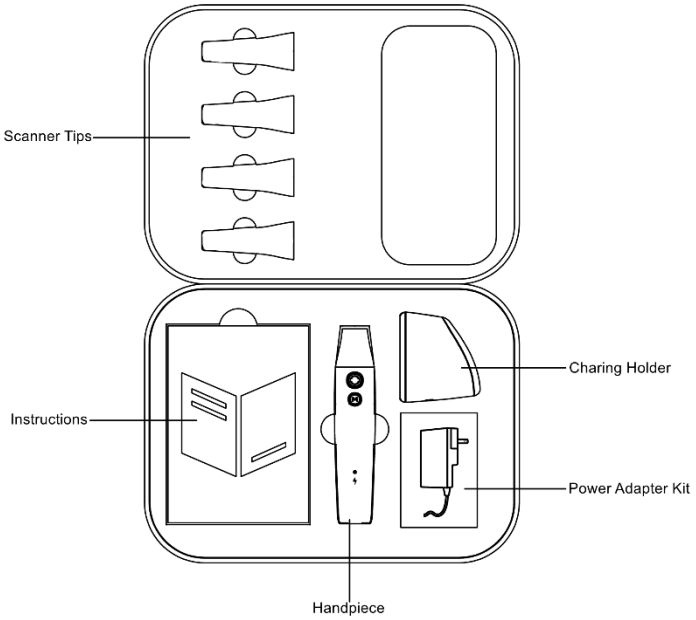
1.3 Clinical Benefits

S300W enables practitioners to capture digital impressions of the quality and accuracy required for computer-aided design and manufacturing (CAD/CAM) in dental applications that benefit dental practices.

The actual performance of this device is dependent on the degree to which the user implements the training and operational elements. The user is solely responsible for the accuracy, completeness and adequacy of the data acquired.

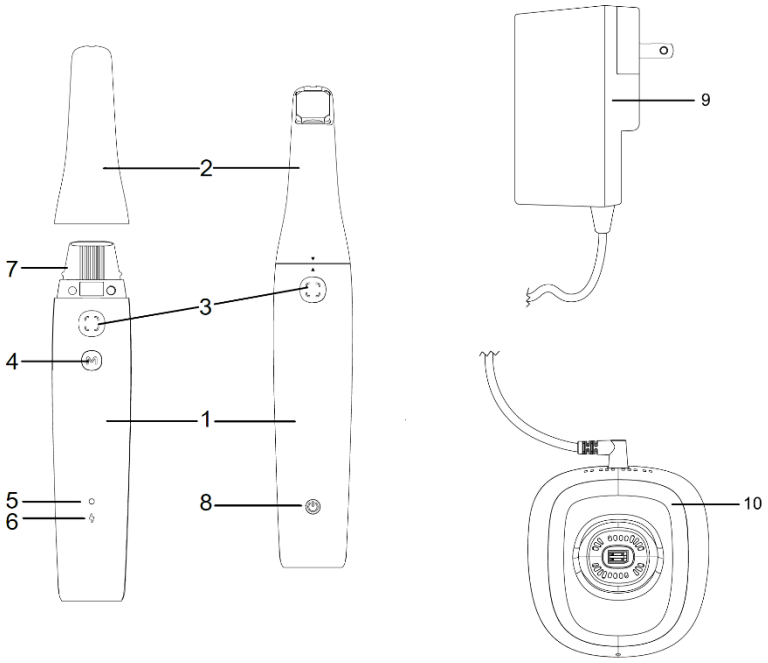
1.4 Unboxing Introduction

The unboxing part is shown in the below picture:

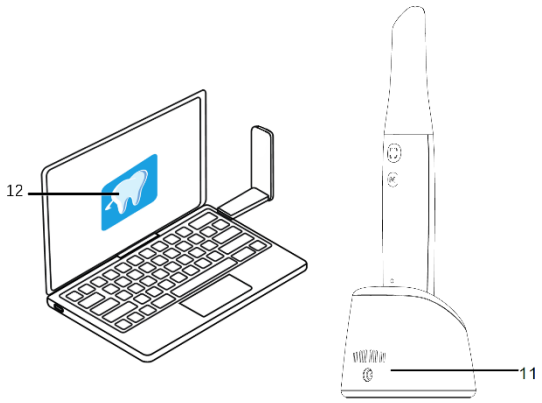


1.5 Component Structure

The main components of the product are shown in the following parts:



The scanner needs to be connected to a computer, and the user will need to provide their own computer and wireless adapter.



Component Descriptions

[1] Handpiece	Handheld part of the scanner.	
[2] Scanner Tip	Replaceable tip of scanner in contact with the patient's mouth.	
[3] Scan Button	Press the scan button to start scanning. Press the scan button again to end the scanning.	
[4] Mode Switch Button	Switch scanning modes.	
[5] Status Indicator	Green Light	Slowly flashing: Scanner is booting. Rapidly flashing: The Scanner is preparing the network. Breathing: Ready to be connected to the software. Solid on: Connected to the software and selected as an active scanner.
	Orange Light	Rapidly flashing: The Scanner has hardware failures. Solid on: The scanner is overheated.
[6] Battery Indicator	Green Light	Solid on: In use, the battery level is higher than 50%. In charging, the battery is fully charged. Breathing: In charging, the battery level is higher than 50%.
	Orange Light	Solid on: In use, the battery level is less than 50%. Slowly flashing: In use, the battery level is less than 20%. Breathing: In charging, the battery level is less than 50%.

		Rapidly flashing for 3 seconds then off: The scanner cannot be powered on.
[7] Lens Window	Avoid stains inside the scanner.	
[8] Power Button	• Activating from Power Off or Shipping Mode: Press the power button to transition the scanner to Standby Mode from either Sleep Mode or Shipping Mode. • Switching to Power Off Mode: While in Working Mode or Standby Mode, press and hold the power button for over 2 seconds to enter Power Off Mode.	
[9] Power Adapter	Convert alternating current (AC) to direct current (DC)	
[10] Charging Holder	Support the scanner on the desktop and charge the battery inside the scanner.	
[11] Charging Holder Indicator	When the charging holder is connected to the power source, it displays a solid green light.	
[12] Software	Scanning software for use with scanners.	

1.6 Computer Configuration Requirements

Refer to "8 Technical Specifications" for details on computer system configuration requirements.

WARNING

It must be verified that the computer system configuration meets the computer system requirements of the S300W software.

2 Setting Up the Scanner

The setting up of the scanner section includes a description of the scanner handpiece, power adapter, and holder installation.

2.1 Scanner Installation

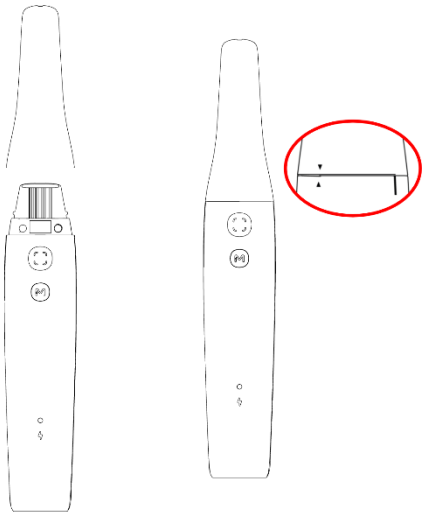
The scanner installation is described in the following three parts:

- Handpiece Installation
- Power Adapter Installation
- Place the Charging Holder

2.1.1 Handpiece Installation

1. Remove the Lens Window Protective Cover.

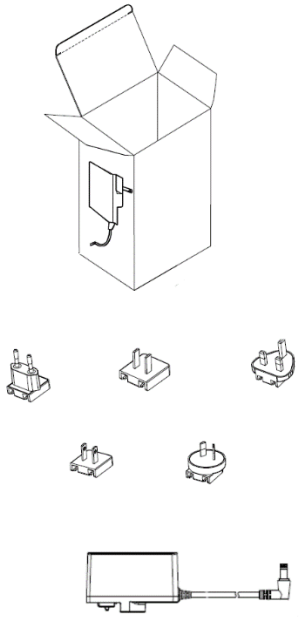
2. To install the scanner tip on the intraoral scanner handpiece, align the inverted triangle on the scanner tip with the upright triangle on the handpiece. Then, gently Insert the scanner tip into the handpiece.



2.1.2 Power Adapter Installation & Removal

- **Power Adapter Installation**

  Before You Start: Ensure you have the Power Adapter Kit for the scanner. Inside, you will find the Power Adapter and a set of interchangeable plugs designed to fit electrical outlets in different countries, including types for US/JP, EU, UK, AU, and CN.



1. Identify Your Components:

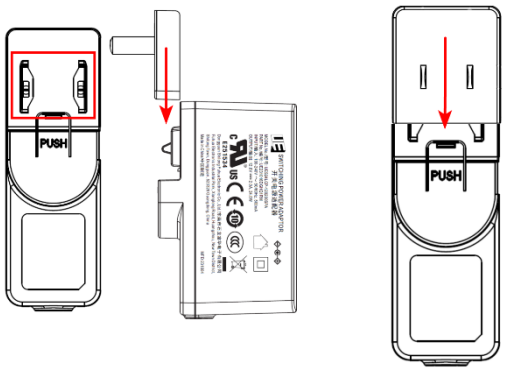
- Locate the Power Adapter.
- Select the Interchangeable Plug that corresponds to your country's electrical outlet standards.

2. Aligning the Plug:

- Take a closer look at the back of the Interchangeable Plug. You will notice a slot designed to accommodate a specific Power Adapter part.
- Similarly, examine the Power Adapter and identify the protruding part that matches the slot on the Interchangeable Plug.

3. Attaching the Plug:

- Align the slot on the back of the Interchangeable Plug with the protruding part on the Power Adapter.
- Gently slide the Interchangeable Plug into the Power Adapter, ensuring precise alignment.



4. Securing the Connection:

- Push the Interchangeable Plug into the Power Adapter until you hear a distinct "click" sound. This sound indicates the plug has been successfully installed and secured to the Power Adapter.
- Once the interchangeable plug is securely attached, please gently tug it to ensure it is firmly in place and will not detach easily.
- Your Power Adapter is now ready for use with your scanner.

CAUTION

Always ensure your hands are dry before handling electrical components.

Do not force the Interchangeable Plug if it does not seem to fit. Double-check the alignment and try again.

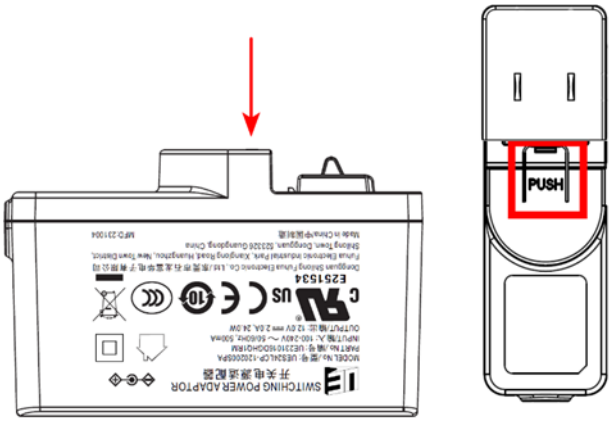
- **Remove the Interchangeable Plug from the Power Adapter**

Before You Start: Ensure the Power Adapter is disconnected from any power source before attempting to remove the Interchangeable Plug.

1. Locate the PUSH Label:

- Hold the Power Adapter in one hand, ensuring a firm grip.
- Look for a label or marking on the adapter that reads "PUSH." This label indicates the area you need to press to release the Interchangeable Plug.

2. Press Down on the PUSH Label:



- Apply pressure directly onto the PUSH label with your thumb or another finger.
- Press downwards firmly until you feel a release mechanism activates. This action disengages the lock that secures the interchangeable plug in place.

3. Slide Out the Interchangeable Plug:

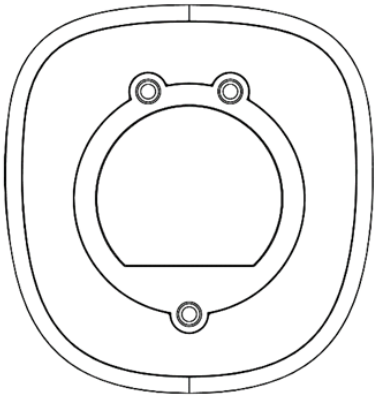
- While still applying pressure on the PUSH label, use your other hand to slide the interchangeable plug away from the adapter gently.
- Pull the plug out smoothly to avoid damaging the adapter or the plug.

4. After Removal:

- Once the Interchangeable Plug is removed, you can replace it with another plug suitable for your region or requirements.
- If the plug is being removed for storage or transportation, ensure it is kept in a safe place to avoid loss or damage.

2.1.3 Place the Charging Holder

Ensuring your scanner is always ready for use begins with proper placement and charging. The Charging Holder has been designed with added weight and non-slip pads at the bottom for stability and security. Follow these simple steps to place the Charging Holder on a table or desk correctly:



1. Selecting the Right Location:

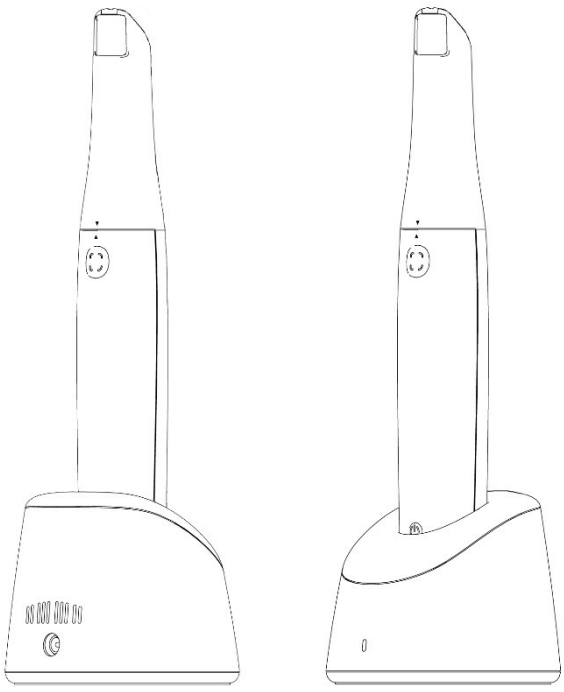
- Choose a clean, flat surface on a table or desk. This area should be away from any edges to prevent accidental falls and should not be exposed to direct sunlight, high temperatures, or moisture.
- Wipe the selected area with a dry or slightly damp cloth to remove dust or debris. This helps the non-slip pads on the bottom of the Charging Holder to adhere better to the surface, ensuring stability.

2. Placing the Charging Holder:

- Place the Charging Holder on the prepared surface. Make slight adjustments to the position of the Charging Holder to ensure it is perfectly flat and stable. The non-slip pads should make complete contact with the surface to prevent sliding.

3. Connecting to Power:

- Connect the Charging holder to a power source using the provided Power Adapter. Ensure the power outlet is easily accessible and the cable does not create a tripping hazard. Check for charging holder indicators to light to confirm that the device is properly charging.



4. Inserting the Scanner:

- Gently insert the intraoral scanner into the Charging Holder. Align it per the holder's design to ensure proper contact with the charging points.

WARNING

The provided Power Adapter is specifically designed for this scanner and is classified as a specialized medical device. Users mustn't attempt to use any third-party power adapters with this equipment.

2.2 Scanner Connection

To ensure seamless integration of the scanner with your dental practice's digital workflow, please follow the steps below to establish a connection between the scanner and your computer system. This process involves downloading the necessary software, preparing the hardware, and connecting the scanner via a wireless network.

2.2.1 Download and Install Scanner Software

Visit our support portal at https://support.allied-star.com/download to download the latest installation package specific to your scanner model. Ensure you select the correct version to avoid any compatibility issues.

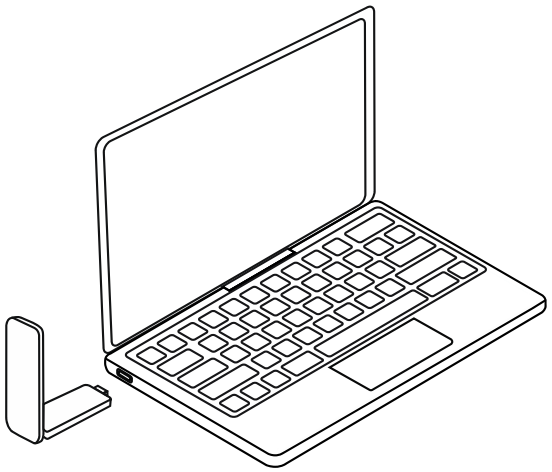
Refer to the scanning software documentation for comprehensive software installation guidelines.

Upon successful installation, remove the scanner from the charging holder. The scanner automatically switches from standby mode to working mode, with the Status Indicator flashing slowly. Shortly after, it will transition to breathing mode, signaling it is on standby and ready to establish a connection.

The Status Indicator will illuminate solid green once the scanner successfully connects with the software, indicating readiness for operation.

2.2.2 Wireless Connection

Before attempting to connect the scanner wirelessly, ensure a compatible wireless adapter is connected to the computer running the scanner software. This adapter facilitates the communication between the scanner and the computer.



NOTE

For optimal network signal strength, fully extend the wireless adapter. Compatibility and product model specifications for the wireless adapter can be found at https://www.allied-star.com/product/as-200e.

2.2.3 Scanner Selection and Connection

1. Within the scanner software, navigate to the "Scanner List" window at the bottom right corner.
2. Identify and select the desired scanner from the list. This icon  indicates a wireless scanner.
3. Click the "Connect" button to connect with the selected scanner.
4. Once the connection is established, the scanner is ready to be used.

3 Scanning Preparation

3.1 Charging the Scanner

Our intraoral scanner is designed with two charging modes to accommodate the varying needs of dental professionals: Fast Charging and Optimized Charging. The default setting for the scanner is the Optimized Charging Mode, which is ideal for rapid preparation between uses. The Optimized Charging Mode is an alternative option that prioritizes battery health and longevity and is suitable for overnight charging or periods when immediate use is unnecessary. You can switch mode through the scanner's software settings.

3.1.1 Fast Charging Mode

Designed to minimize downtime between uses, the Fast Charging Mode allows dental professionals to prepare the scanner for operation quickly. The scanner achieves up to 75% battery capacity in no more than 1 hour.

- **Quick Preparation:** Achieves 75% charge in less than one hour, drastically decreasing wait times.
- **Efficiency:** Facilitates swift preparation for dental procedures, significantly reducing interruptions to dental service continuity.

3.1.2 Optimized Charging Mode

The Optimized Charging Mode is specifically developed to maximize the battery's lifespan, ensuring your scanner remains efficient and reliable. When activated, this mode allows the scanner to achieve a full charge within 4 hours, making it perfect for charging overnight or during extended periods of inactivity. This mode is ideal for overnight charging or when the scanner is not needed for immediate use, ensuring it is ready for a full day of procedures without the risk of battery depletion.

- **Full Charge Time:** Approximately 4 hours to complete.
- **Battery Endurance:** Once fully charged, the scanner offers at least 3 hours of continuous use, accommodating extended dental procedures without interruption.
- **Shipping Mode Transition:** After two weeks of inactivity, the scanner automatically transitions to a shipping mode to conserve battery power. This feature ensures that the scanner remains ready for use whenever needed while minimizing the need for frequent charging. Press the Power Button and put the Handpiece into the Charging Holer to exit Shipping mode.

WARNING

Please be advised that removing the battery from the intraoral scanner is strictly prohibited for users. If your scanner requires battery replacement or any other battery-related assistance, immediately contact Alliedstar Technical Support: support@allied-

star.com.

NOTE

- Avoid depleting the battery entirely before charging to maintain battery health.
- Regularly monitor the battery level during use to plan charging accordingly, ensuring the scanner is always ready for dental procedures.

3.2 Software Interface

To access the software user interface, please follow these steps:

1. Double-click the software icon on the desktop.
2. The software will automatically pop up the login window.
3. If you don't have an account, click **Create an account** to register with the organization, and complete the email verification.
4. Type your account information in the username and password fields, click the **Log in** button.
5. The **Cases** page will be shown up.
6. Click the **New Case** button, then input patient name and click the **OK** button.
7. Click the **Scan** button.
8. If the scanner is not activated, the device activation dialog will be displayed. Follow the instructions on the screen to complete device activation.
9. Click the Option menu button and select **Preferences**.
10. Customize the configuration options.
11. You can now start acquiring 3D models.

3.3 Audio Prompts

3.3.1 Scanning Sounds

Continuous sound: When scanning sound is enabled, the computer will make a continuous sound when the scanner is scanning images normally.

Sound interruption: If the sound is interrupted, it indicates that the data cannot be scanned successfully, and the scanning is stopped.
To continue, return to the previously scanned area until the scanner resumes scanning, and the computer makes a continuous sound.
When the occlusion image is successfully scanned, the computer will also make a short sound.

3.3.2 Warning Sounds

A short warning sound is made if the cumulative scanning time for the current case exceeds the

recommended threshold, and the computer cannot maintain peak scanning performance or if the scanning process is exposed to bright light.

NOTE

To enable the scanning sound, the computer must be equipped with a loudspeaker.

3.3.3 Low Battery Alert

An audible alert will be triggered when the scanner's battery power falls below 20% and is in standby mode but not placed in its holder for charging. The buzzer will emit a series of five short beeps ("bee, bee, bee, bee, bee") every 30 seconds. This alert continues until the scanner enters sleep mode or is placed back into the holder for charging. This is to remind users to charge the scanner as soon as possible.

3.3.4 Charging Confirmation Alert

Upon placing the scanner into the charging holder, the buzzer will sound twice ("bee, bee") as a confirmation. This indicates that the scanner has successfully started charging.

3.4 Tooth Preparation

If there is a tooth preparation, shrink the gingiva around the prepared tooth so that the preparation is clearly highlighted.

Dry the teeth thoroughly before starting the scan.

Moderately re-dry the teeth during the scanning process.

3.5 Scanner Preparation

Pre-use Precautions: Before using the product and accessories, please follow the steps below:

- **Inspect the Scanner Visually**

  To visually inspect the scanner for damage or signs of deterioration, please follow the steps below:

  1. Inspect the handpiece Lens Window.

  2. Inspect the Scanner Buttons and contacts thoroughly.

  3. If damage is found, do not use the scanner and contact Alliedstar technical support personnel.

- **Inspect the Scanner Tip Visually**

  To visually inspect the Scanner Tip for damage or signs of deterioration, please follow these steps:

  1. Verify that the Scanner Tip is not damaged and that no components are detached.

2. Verify that the Scanner Tip Mirror is not smudged or scratched.

3. Replace the Scanner Tip if signs of deterioration are found.

WARNING

- The Lens Window on the handpiece is a delicate optical component. When the scanner is not in use, install the Lens Window Protective Cover to protect the Lens Window from damage or dust.
- The mirror inside the Scanner Tip is a delicate optical component. It is important for scanning quality that its surfaces are kept clean and undamaged.
- If the image quality displayed by the software is poor or the video preview is blurry, use a microfiber cleaning swab and unadulterated ethanol to clean the Scanner Tip Mirror and Lens Window.

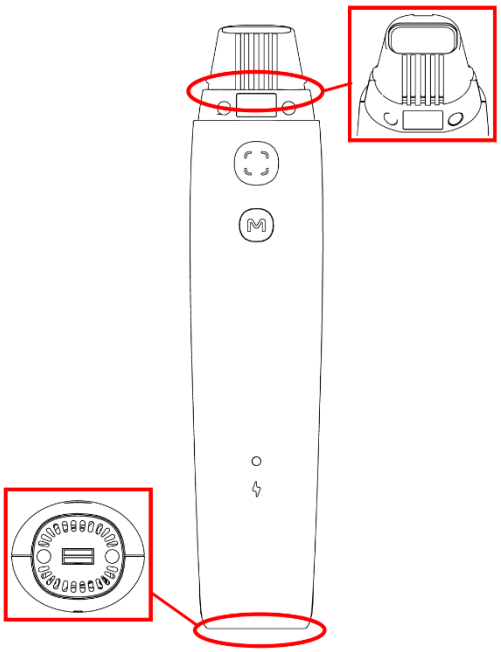
4. Disinfect the scanner and sterilize the Scanner Tip after each use.

CAUTION

- The Scanner Tip is not sterilized at the factory.
- Make sure to sterilize the Scanner Tip before using it for the first time.

CAUTION

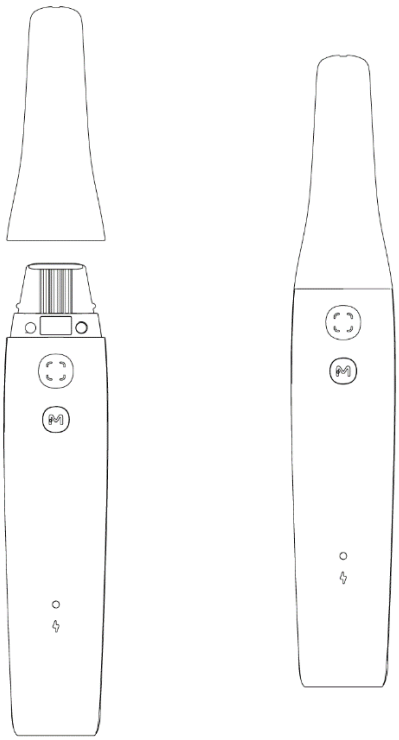
- Do not allow any liquid to penetrate the Air Outlet near the Lens Window or the Air Inlet at the rear of the scanner (see the following picture), as this may damage the scanner.
- Avoid liquid or any sharp objects that may cause damage to the Scanner Tip Detection Sensor.



To prepare the scanner, please follow these steps:

1. Make sure the scanner's Lens Window is clean by gently wiping it with a slightly damp, lint-free cloth or lens paper.

2. Assemble the Scanner Tip to the Tip Mount.



4 Scanning Starts

4.1 Scanning Method

4.1.1 Scanning Precautions

To ensure the highest quality and accuracy when using the scanner, please adhere to the following scanning precautions:

- **Initiating the Scan:** Gently position the scanner tip directly on the tooth's surface to begin scanning. This will help stabilize the scanner. Activate the scanning sequence by pressing the Scan Button and maintain this action until the 3D image is visibly rendered within the 3D model display area. Once the image appears, methodically and slowly guide the scanner across the tooth's surface and along the dental arch, ensuring comprehensive coverage.
- **Avoidance of Soft Tissues and Contaminants:** It is critical to steer the scanner away from soft tissues and foreign materials, such as saliva. Direct contact with these elements can distort the scan's accuracy and quality, leading to suboptimal outcomes.
- **Sensitivity to Gum Areas:** Exercise caution to prevent the scanner tip from contacting sensitive gum areas. Unnecessary contact can cause discomfort to the patient and potentially impact the scan's precision.
- **Bite Scanning Considerations:** It is essential to instruct the patient to bite down naturally, aiming for a centered bite whenever possible to capture an accurate representation of the occlusal surfaces. This position facilitates the capture of a symmetrical view of the occlusal area on both sides of the jaw. Adjust the scanner to ensure it evenly encompasses both the upper and lower teeth, avoiding missed areas that could compromise the scan's completeness.

NOTE

During the scanning process, adjust the surgical light so that the light is directed away from the patient's mouth to avoid interference with the imaging.

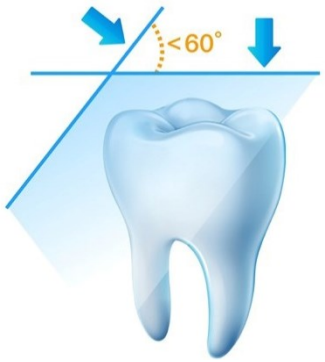
4.1.2 Recommended Scanning Sequence

Upper/Lower jaw - Lower/Upper jaw – Bites.

4.1.3 Recommended Scanning Approach

- **Recommended Scanning Angle**

  To ensure adequate surface overlap and successful alignment, the transformation of the scanning angle should be limited to 60°. This limitation is crucial as a smaller overlap area might result in alignment failure.



- **Recommended Scanning Path**

  The scanning path is divided into three main scans: occlusal, lingual, and buccal. These scans are designed to comprehensively capture the upper and lower jaw, providing a detailed reconstruction of all surfaces. Follow the steps below for an effective scanning process:

  1. Occlusal Scan

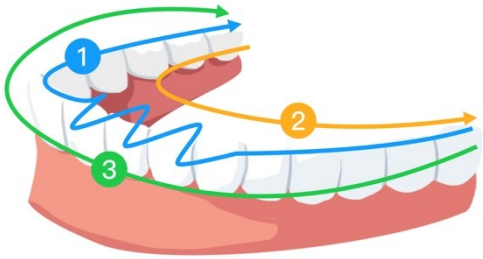
  Begin the scanning process with the occlusal surface of the first molars. This initial scan lays the foundation for the subsequent scans by capturing the biting surfaces of the teeth. Carefully move the scanner over the occlusal surfaces of the teeth, ensuring that all areas are adequately covered.

  2. Lingual Scan

  After completing the occlusal scan, proceed to the lingual surfaces. This scan captures the inner surfaces of the teeth. Adjust the scanner to capture these areas comprehensively depending on the jaw being scanned.

  3. Buccal Scan

  The final scan involves capturing the buccal (cheek-facing) surface. This scan should cover the opposite side of the second scan, ensuring that the outer surfaces of the teeth are thoroughly scanned.



  4. Supplementary Scanning

  Supplementary scans may be necessary to capture any areas missed in the initial scans or

improve the data quality of certain sections.

4.2 Operation Method

To scan the 3D model, the steps are generally as follows:

- Scan the upper jaw, lower jaw, bites
- Refine and check the 3D model
- Complete and save the 3D model

Starting steps:

1. Place the scanner's Scanner Tip on the tooth surface.
2. Wait for the scanner to stabilize and press the Scan Button.
3. Move slowly over the tooth and along the arch until a 3D image appears in the display area of the 3D model.

5 Maintenance

The scanner must be handled carefully in accordance with the instructions before use to ensure the highest level of hygiene and safety for each patient. Clean and sterilize the Scanner Tip after each patient.

To minimize the risk of cross-contamination, follow these steps after use for each patient:

- Clean and disinfect the Sanner (See "5.1 Scanner Cleaning and Disinfection ").
- Clean and sterilize the Scanner Tips (See "5.2 Scanner Tip Cleaning and Sterilization").

Product Model	UDI-DI	Manual Cleaning	134°C Sterilization
TP301	(01)06973993441669	Yes	Yes

CAUTION

This product is only suitable for the above Scanner Tip product models. If you use another Scanner Tip, situations such as failure to scan will be encountered.

5.1 Scanner Cleaning and Disinfection

WARNING

Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) for the sanitizer used to handle the scanner.
Gloves must be worn when cleaning and disinfecting the scanner.
The scanner must be disinfected with a recommended medium level disinfectant cloth (with tuberculocidal activity) after each patient.
Do not use a disinfectant containing phenol or iodine-based substances, as this may damage the surface coating of the scanner.
Do not place the scanner in a pressure steam sterilizer or immerse it in water or a disinfectant solution.

Excessive liquid may damage the scanner.

Do not use cotton balls, pieces of cloth or paper towels soaked in disinfectant to sanitize

the scanner.

5.1.1 Scanner Cleaning

If the scanner is visibly contaminated with blood or body fluids, it must be cleaned before it is sanitized.

To clean the scanner, please follow these steps:

1. Dampen a lint-free cloth with warm water (do not soak).

2. Use the dampened lint-free cloth to wipe away blood or body fluids.

5.1.2 Scanner Disinfection

The scanner must be thoroughly sanitized after use for each patient.

To adequately sanitize the scanner, determine the appropriate length of time to sanitize according to the sanitizer manufacturer's instructions.

CAUTION

If there are visible stains on the scanner, it must be thoroughly cleaned prior to disinfection, see "5.1 Scanner Cleaning and Disinfection ".

To sanitize the scanner, please follow these steps:

1. Remove the Scanner Tip.

2. Clean all visible stains （see "5.1 Scanner Cleaning and Disinfection "）.

3. Use a commercially available medium level sanitizing cloth. Determine the length of disinfection according to the manufacturer's instructions.

Recommended sanitizing cloths: CaviWipes

WARNING

Using a disinfectant that is not recommended may result in damage to the scanner.
Wipe all surfaces of the scanner thoroughly. Avoid liquid penetration into the scanner through crevices, Air Inlets, Outlets, etc.

WARNING

Do not rinse and allow it to dry naturally.

After the scanner has dried, wipe any residual disinfectant from the scanner surfaces with a clean, lint-free cloth dampened with water.

5.2 Scanner Tip Cleaning and Sterilization

The Scanner Tips supplied by the manufacturer were not cleaned. The Scanner Tip needs to be cleaned before the first use and after each use to clean off surface dirt.

WARNING

Wear gloves when handling contaminated Scanner Tips.

Read and follow the warnings and personal protection instructions provided in the Safety Data Sheet (SDS) of any cleaner or sanitizer used to handle the Scanner Tip.

Do not immerse the Scanner Tip in a disinfectant for an extended period of time.

Do not install the Scanner Tip on the scanner until thoroughly dry.

Do not use an ultrasonic cleaner to clean the Scanner Tip.

Do not soak the Scanner Tip in an alcohol-based sanitizer.

5.2.1 Scanner Tip Cleaning

To clean the Scanner Tip manually, please follow the steps below:

1. Rinse off excess dirt from the Scanner Tip with water (2 minutes).

2. Using a soft brush, apply an enzymatic cleaning solvent (e.g., Metrex EmPower) to all surfaces.

3. Rinse with clean tap water (2 minutes).

4. Inspect the Scanner Tip visually and repeat steps 1-3 if it is still not clean.

5. Dry the water on the Scanner Tip and reflector with lens paper or a lint-free cloth. Water entering the Handpiece will fog up.

5.2.2 Scanner Tip Sterilization

The Scanner Tip is not sterilized at the factory and must be sterilized before use.

CAUTION

For TP301, the Scanner Tip can be autoclaved up to 180 times if the holding time of 134°C is controlled within 6 minutes.

To autoclave the Scanner Tip, please follow these steps:

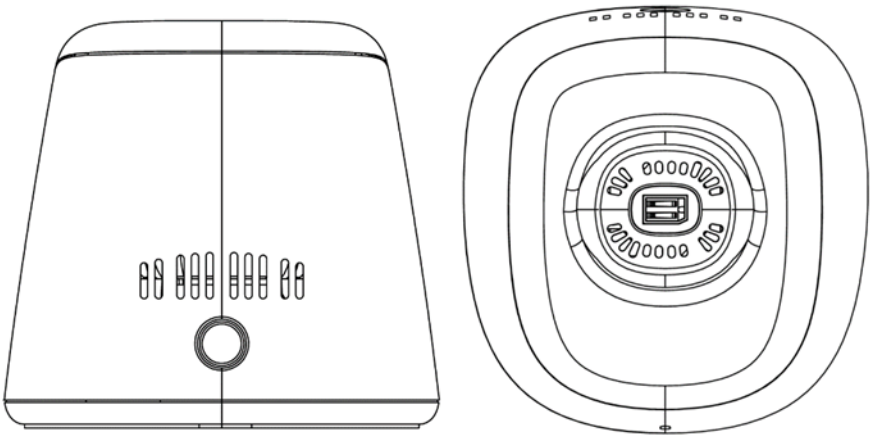
1. Place the Scanner Tip in a sealed steam sterilization bag.

2.Place the Scanner Tip in a steam autoclave for sterilization.

- Sterilization temperature should be set to 134°C.
- Duration should exceed 3 minutes.
- Duration should be no longer than 6 minutes.

5.3 Charging Holder Precautions

The Charging Holder features specifically engineered air vents located in the recess and on the back side of the holder. These air vents play a crucial role in maintaining the device's internal temperature by facilitating airflow, thus preventing overheating during charging and operation.



Caution must be exercised to prevent liquids from entering these air vents and charging contacts. Liquid exposure can significantly impair the Charging Holder's functionality, potentially leading to damage or failure of the intraoral scanner when docked for charging.

To ensure the integrity and performance of your Charging Holder, adhere to the following guidelines:

- **Avoid Spillage:** Ensure no liquids are present near the Charging Holder. Be vigilant during cleaning operations or when placing the holder in areas susceptible to spills.
- **Cleaning Procedure:** Before cleaning the Charging Holder, cut off the power and unplug the Power Adapter. Use a dry or slightly damp lint-free cloth, do not allow moisture to seep into the air vents. Wipe the exterior surfaces gently without applying excessive force that could push liquids into the vents.
- **Charging Contacts Precautions:** The Charging Holder contains charging contacts in metal springs. Not using disinfectants or wet liquids to wipe these contacts is crucial, as moisture can lead to corrosion and electrical failure. Keep these charging contacts dry and unobstructed at all times during charging.
- **Immediate Action for Liquid Contact:** If liquid accidentally enters the air vents or comes into contact with the charging contacts, stop using the Charging Holder immediately. Disconnect any power source and allow the holder to dry thoroughly in a well-ventilated area before using it again.
- **Regular Inspections:** Routinely inspect the air vents and charging contacts for any blockages or buildup of debris. Cut off the power and unplug the Power Adapter, then use a soft, dry brush to clear obstructions, ensuring unimpeded airflow through the vents and clean contact points for charging.

CAUTION

Use the Power Adapter included in the package or Incompatible Adapter may cause damage to the scanner.

6 FAQs

Description	Operation
Mismatches and overlaps are visible in the 3D image.	Use the **Cut** tool to remove mismatched data and excess tissue and rescan.
There is a gap or crossover in the occlusal capture.	Adjust the **Occlusal pressure level** in **Preferences**, then disable and enable **Occlusal pressure adjustment**. Delete the incorrect bite view and rescan.
A loss of accuracy or images that do not match well during scanning.	1. Ensure that the scanner's Lens Window is clean by gently wiping the Lens Window with a lightly dampened lint-free cloth or lens paper. 2. Use a slightly damp, lint-free cloth or lens paper to gently wipe any dust or water spots from the Scanner Tip Mirror. 3. Make sure the Scanner Tip is securely mounted and there are no black edges or black spots on the live video.
Difficulty in reconstructing metal preparation teeth.	1. Adjust the scanner position (e.g., distance or angle) and scan more areas. 2. Adjust the surgical light away from the patient to minimize light scatter. 3. Enable the **Shining Surface** function.
Scanner Tip installed but not detected. No live video is displayed, and the no Scanner Tip icon is displayed in the lower right of the software preview window.	1. Reinstall the Scanner Tip. 2. Ensure that the Scanner Tip is making firm contact with the scanner.
The inside surface of the Lens Window on the top of the handpiece appears to be fogged.	1. Install a completely dry Scanner Tip on the handpiece. 2. Place the scanner on a stand or a tabletop and wait for the fogging to disappear. 3. If the fogging does not completely disappear after the scanner has been sitting for 24 hours, contact the local service provider

	for assistance. NOTE: Make sure the Scanner Tip is completely dry before installation, and do not use a rag soaked in disinfectant to clean the scanner.
Scanner is not shown in the 'Scanner List' in the software while the Status Indicator keeps blinking in breathing mode.	Reset the network in the scanner after you confirm that the correct Wireless Adapter has been inserted. To do so, while the Status Indicator is in breathing mode, simultaneously press the Scan Button on both sides for two seconds and release. The Status Indictor should start blinking rapidly, then enter breathing mode. The device should then be shown in the 'Scanner List' in the software.

7 Regulatory Information

Regulatory Information

The device complies with the following regulations:

MDR: (EU) 2017/745 Medical Device Regulation, Class I following the Rule 5.
FDA Center for Devices & Radiological Health CDRH - Title 21 CFR 872.3661 (USA).
Medical Devices Regulations (Canada).
RoHS: Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, 2011/65/EU Annex II and its amendment Directive (EU) 2015/863
RED: Directive 2014/53/EU The Radio Equipment Directive
FCC: Part 15 of The Federal Communications Commission Rules
ISED: Innovation, Science and Economic Development Canada

Compliance with European and International Standards

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

EN / IEC 62471: Photobiological safety of lamps and lamp systems

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

EN / IEC 62366-1: Medical devices - Part 1: Application of usability engineering to medical devices

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

EN ISO 10993: Biological evaluation of medical devices

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: Medical devices — Information to be supplied by the manufacturer

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

EN / IEC 62133-2: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

EN 50566: Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body.

EN 301489-1: Electromagnetic compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU

EN 301489-17: Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonized Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

EN 301893: 5GHz RLAN; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Classification in Accordance with EN/IEC 60601-1

Type of protection against electric shock: Internally powered

Degree of protection against electric shock: Type BF Applied Part. Scanner tips is considered as 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 document.

Other equipment can interfere with communications with the device, 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 DEVICE, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could happen.

WiFi

The device operates with the 802.11a/n/ac protocol. Channel 38 or 46 is priority used for the handpiece. The channel bandwidth is 40MHz. The frequency range is 5150-5250MHz,5725-5850MHz (the actual frequencies are dependent on local regulations and the configuration of the product). The maximum output power is 17.88 dBm.

This device complies with part 15 of the FCC Rules and contains license exempt transmitter(s)/receiver(s) that comply with ISED's license-exempt RSS(s).

Operation is subject to the following two conditions:

- This device may not cause interference.
- This device must accept any interference, including interference that may cause undesired operation of the device.

NOTE

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

ISED Notice

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) this device may not cause interference, and

(2) this device must accept any interference, including interference that may cause undesired operation of the device.

This Class B digital apparatus complies with Canadian ICES-003.

IC: 29544-S300W

IC Radiation Exposure Statement

This EUT is in compliance with SAR for general population/uncontrolled exposure limits in IC RSS-102 and had been tested in accordance with the measurement methods and procedures specified in IEEE 1528 and IEC 62209. This equipment should be installed and operated with minimum distance of 0 cm between the radiator and your body. This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter.

Radio frequency (RF) energy

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the United States and Industry Canada.

During SAR testing, this device is set to transmit at its highest certified power level in all tested frequency bands, and placed in positions that simulate RF exposure in usage against the head with no separation, and near the body with the separation of 0 mm. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value. This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless base station antenna, the lower the power output.

The exposure standard for wireless devices employing a unit of measurement is known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg and 1.6 W/kg by Industry Canada.

This device is in compliance with SAR for general population /uncontrolled exposure limits in ANSI/IEEE C95.1-1992 and Canada RSS 102 and had been tested in accordance with the measurement methods and procedures specified in IEEE1528 and Canada RSS 102. This device has been tested and meets the FCC and IC RF exposure guidelines when tested with the device directly contacted to the body.

For this device, the highest reported SAR value for usage near the body is 0.219 W/kg.

While there may be differences between the SAR levels of various devices and at various positions, they all meet the government requirement.

SAR compliance for body-worn operation is based on a separation distance of 0 mm between the unit and the human body. Carry this device at least 0 mm away from your body to ensure RF exposure level compliant or lower to the reported level. To support body-worn operation, choose the belt clips or holsters that do not contain metallic components to maintain a separation of 0 mm between this device and your body.

RF exposure compliance with any body-worn accessory, which contains metal, was not tested and certified, and using such body-worn accessory should be avoided.

FCC Regulations

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

Remarque ISED

Cet appareil est conforme aux Normes RSS d'Industy Canada. Son utilisation est soumise à deux conditions:

(1) Ce dispositif ne peut pas provoquer d'interférences, et

(2) Ce dispositif doit accepter toutes les interférences reçues, y compris les interférences susceptibles de provoquer un fonctionnement non souhaité.

Cet appareil de classe B est conforme à la norme canadienne ICES-003.

IC : 29544-S300W

Déclaration d'exposition IC

Cet EUT est conforme aux valeurs SAR à la norme SAR pour le grand public ainsi qu'aux limites d'exposition non règlementée IC RSS-102 et a été testé selon les méthodes et procédures spécifiées par les Normes IEEE 1528 et IEC 62209. Cet appareil devrait être installé et utilisé en respectant une distance minimale de 1,0 cm avec votre corps. Cet appareil et son (ses) antenne (s) ne doivent pas être situés à proximité l'un de l'autre et ne doivent pas fonctionner en même temps qu'une autre antenne ou qu'un autre émetteur.

Énergie radioélectrique

Cet appareil est conçu et fabriqué de façon à ne pas dépasser les limites d'émission pour l'exposition à

l'énergie de radiofréquence (RF) fixées par la Federal Communications Commission des États-Unis et Industrie Canada.

Au cours des essais SAR, cet appareil est configuré pour transmettre des données à son niveau de puissance le plus élevé à toutes les bandes de fréquences testées et placées dans l'ensemble des positions simulant l'exposition aux radiofréquences contre la tête et près du corps, avec une séparation de 0 mm. Bien que le DAS soit déterminé par le niveau de puissance le plus élevé, le niveau SAR réel de l'appareil en fonctionnement peut être bien inférieur à la valeur maximale indiquée. Cela est dû au fait que l'appareil est conçu pour fonctionner à plusieurs niveaux d'alimentation, pour s'adapter aux capacités des différents réseaux électriques. De manière général, plus vous vous trouverez pès d'une station sans fil, plus la fréquence de transmission sera basse.

La norme d'exposition pour les dispositifs sans fil employant une unité de mesure est connue sous le nom de taux d'absorption spécifique (SAR). La limite SAR fixée par la FCC est de 1,6 W / kg et de 1,6 W / kg par Industry Canada.

Cet appareil est conforme à la norme SAR pour le grand public ainsi qu'aux limites d'exposition non règlementées ANSI / IEEE C95.1-1992 et Canada RSS 102, et a été testé conformément aux méthodes et procédures spécifiées par les Normes IEEE1528 et Canada RSS 102. Ce dispositif a été testé et respecte les directives FCC et IC sur l'exposition aux radiofréquences lorsqu'il est testé en contact direct avec le corps.

Pour cet appareil, la valeur SAR la plus élevée pour une utilisation près du corps est de

0.219 W/kg.

Bien qu'il puisse exister des différences entre les niveaux de SAR selon les dispositifs et les emplacements où ils sont utilisés, tous répondent aux exigences Gouvernementales.

La valeur SAR déclarée conforme est une distance de 0 mm entre l'unité et le corps humain. Eloignez cet appareil à une distance d'au moins 0 mm de votre corps pour vous assurer que le niveau d'exposition aux RF est conforme ou inférieur au niveau indiqué. Vous pouvez également opter pour un étui ne contenant aucun composant métallique, pour maintenir une séparation de 0 mm entre cet appareil et votre corps.

Pour tout appareil contenant du métal, la conformité de l'exposition aux radiofréquences n'a pas encore été testée / certifiée de manière précise.

Règlementations FCC

Cet appareil est conforme avec les règles FCC Partie 15. Son utilisation est soumise à deux conditions : (1) cet appareil ne doit pas provoquer d'interférence dangereuse et (2) il doit accepter toute interférence reçue, incluant une interférence qui peut provoquer un fonctionnement indésiré.

Ce matériel a été testé et jugé conforme aux normes de la classe B concernant les équipements numériques, selon l'article 15 de la réglementation de la FCC. Ces limitations sont conçues pour offrir une protection raisonnable contre les interférences dans une installation résidentielle. Cet équipement produit, utilise et peut émettre de l'énergie sous forme de radiofréquences ; s'il n'est pas utilisé conformément aux instructions, il peut produire des interférences nuisibles aux communications radio. Toutefois, rien ne garantit l'absence d'interférences dans une installation particulière. Si l'utilisateur constate des

interférences lors de la réception d'émissions de radio ou de télévision (pour le vérifier, il suffit d'allumer, puis d'éteindre l'appareil), pour les éliminer il devra prendre l'une ou plusieurs des mesures suivantes:

Réorienter ou déplacer l'antenne de réception.

Augmenter la distance entre l'équipement et le récepteur.

Connecter l'équipement à une prise située sur un circuit différent de celui du récepteur.

Demander de l'aide au revendeur ou à un technicien radio ou télévision expérimenté.

SAR Value for Handpiece:

0.798 W/Kg,10g for CE

0.219 W/Kg,1g for FCC

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Limited by local law regulations, the version for North America does not have a region selection option.

The device is for indoor use only and operates in the 5150-5250 MHz band to reduce the potential for harmful interference to co-channel mobile satellite systems.

NOTE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/ TV technician for help.

Restrictions in the 5 GHz band: According to Article 10 (10) of Directive 2014/53/EU, the packaging shows that this radio equipment will be subject to some restrictions when placed on the market in Belgium (BE), Bulgaria (BG), the Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE), Turkey (TR), Norway (NO), Switzerland (CH), Iceland (IS), and Liechtenstein (LI). The WLAN function for this device is

restricted to indoor use only when operating in the 5150 to 5250 MHz frequency range.

	AT, BE, BG, CH, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR

Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1 Class B	The S300W 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 devices and systems

The S300W is intended for use in the electromagnetic environment specified below. The customer or the user of the S300W should ensure 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 – 2.7GH	Environment of a professional healthcare facility.
NOTE: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an			

electromagnetic site survey should be considered. If the measured field strength in the location in which the DEVICE is used exceeds the applicable RF compliance level above, the DEVICE should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DEVICE.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity for Equipment and Systems (from RF Wireless Communication Equipment)

For the immunity to proximity fields from RF wireless communications device, the S300W is compliant with the test levels specified below, according to IEC 60601-1-2 standard. The customer or user of the S300W should be sure 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
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

Using cables or accessories other than those specified, except those sold by the device manufacturer, as replacement parts for internal components may result in increased emissions or decreased immunity of the medical device.

Other Devices

WARNING

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

8 Technical Specifications

Product Model

S300W

S300W Technical Specifications

Components	Technical Specifications		
Weight	Handpiece (including battery): 235g Tip – Sterilization (TP301): 15g		
Color	3D full color		
Charge port	AC Input		
Field of view	Tip – Sterilization (TP301): 16 mm × 14 mm		
Power Adapter model	UES24LCP-120200SPA		
Input voltage	100Vac-240Vac		
Battery model	Li-18650-3.6V 3400mAh -PCM-NTC		
Minimum computer system requirements		**Desktop**	**Laptop**
	CPU	• 10th Generation Intel® Core™ i5-10600 • AMD Ryzen™ 5 3600	• 11th Generation Intel® Core™ i5-11400H • AMD Ryzen™ 7 5700U
	Graphics	NVIDIA GeForce GTX 1660 Ti 6GB	NVIDIA GeForce GTX 2060 6GB
	RAM	16 GB	
	Disk	512 GB SSD	
	Display	15.6" FHD (1920x1080)	
	OS	Win 10 (build 18362+) / Win 11, 64 bit	
	Other	USB 3.0 port	
	WiFi Adapter	1300Mbps @ 5GHz	
	Optional	Touch screen	

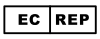
CAUTION

It is MANDATORY to verify that your system configuration is compatible with the computer system requirements of the S300W.

Environmental Requirements

Components	**Environmental Requirements**
Operating temperature	15°C ~ 30°C
Transport temperature	-10°C ~ 50°C
Storage temperature	-10°C ~ 50°C
Operating relative humidity	10% RH ~ 65% RH
Transportation relative humidity	10% RH ~ 95% RH
Storage relative humidity	10% RH ~ 85% RH
Operating atmospheric pressure	70 KPa ~ 106 KPa
Transportation atmospheric pressure	60 KPa ~ 106 KPa
Storage atmospheric pressure	70 KPa ~ 106 KPa

Contact Information

	**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
	**Etkon GmbH** Lochhamer Schlag 6, 82166 Gräfelfing, Germany

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