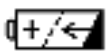
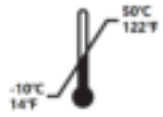
ST 200E

Instructions

Contents

Labels and Symbols

	**EN** Type BF applied part
	**EN** Separate collection for waste electric and electronic equipment (WEEE) is required.
	**EN** Manufacturer
	**EN** Date of Manufacture
	**EN** Refer to instruction manual/booklet
	**EN** Direct current
	**EN** Sterilizable in a steam sterilizer (autoclave) at 134°C
	**EN** Model Number
	**EN** Serial number
	**EN** Rechargeable battery
	**EN** Device fulfills the requirements of the European directives given on the EU Declaration of ConformityCE
	**EN** Authorized Representative in the European Community
	**EN** Authorized Representative in Switzerland

	**EN** Medical Device
	**EN** Atmospheric pressure limitation
	**EN** Fragile, handle with care
	**EN** Humidity limitation
	**EN** Keep box and contents dry
	**EN** Stacking limit by number
	**EN** Temperature limit
	**EN** This way up
	**EN** Caution: US Federal law restricts this device to sale by or on the order of a licensed health- care practitioner.

English

Notice

This document includes safety instructions, regulatory information, technical specifications and installation and operation instructions for the device. We recommend that you thoroughly familiarize yourself with this document to make the most effective use of your system.

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Conventions

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

	**WARNING**: Avoid injury to yourself or others by following the safety instructions precisely.
	**CAUTION**: Alerts you to a condition that might cause serious damage or problems.
	NOTE: Provides extra information and hints.

 **WARNING**: We recommend that you consult this document before using the device.

All trademarks and registered trademarks are the property of their respective holders.

The device is intended for professional use only.

U.S. Federal law restricts this device to sale to or on the order of a dentist.

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

Description

Intended use

The **ST 200E Intraoral Scanner** (herein after referred to as the "scanner") is a digital optical scanning device used to obtain digital impressions of hard and soft tissues such as teeth, gingiva, and mucous membranes by means of oral scanning, for the purpose of oral restoration and orthodontic treatment of malocclusion.

The scanner can be used on both adults and children in clinical practice.

Contraindications

None

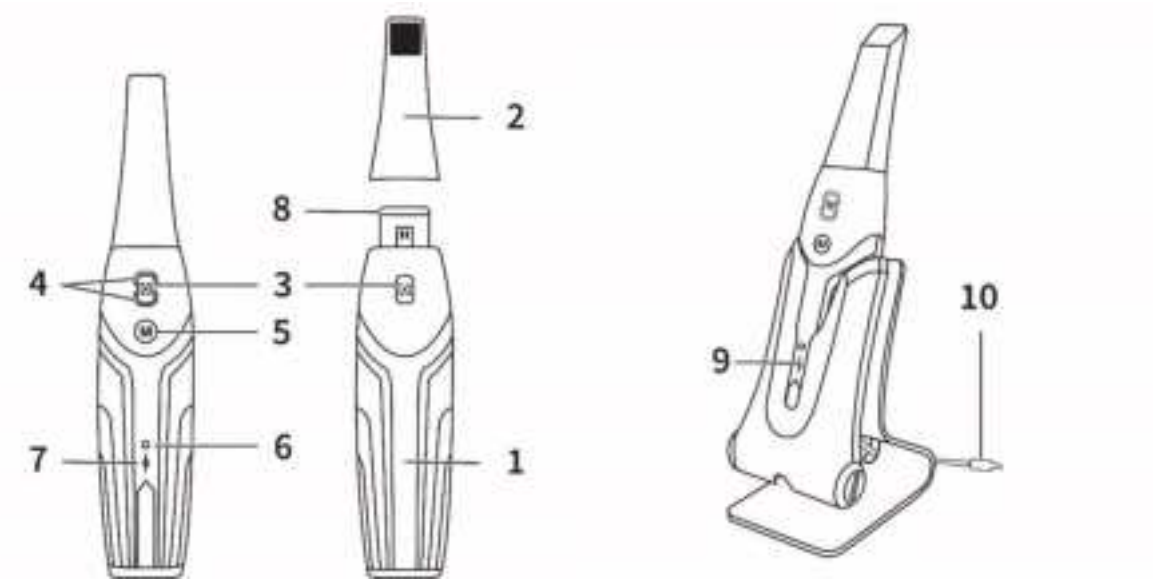
Clinical benefits and performance characteristics

The scanner benefits dental practices 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 upon the user's training and operation. The user is solely responsible for the accuracy, completeness, and adequacy of the acquired data.

The scanner is designed to acquire 3D models in the following:

- Upper jaw
- Lower jaw
- Buccal bite registration

Nomenclature



[1] Handpiece
[2] Scanner Tip
[3] Scan Button ● Press once to start scanning, press again to stop scanning
[4] Mode Indicator
Upper jaw scan mode
Lower jaw scan mode
Buccal bite registration mode
[5] Mode Switch Button ● Press this button to switch between different modes

[6] Status Indicator ● Slowly flashing: starting up ● Rapidly flashing: preparing network ● Breathing: ready to be connected to the software ● Solid on: connected to the software and selected as active scanner
[7] Battery Indicator In use: ● Solid green: battery level higher than 50% ● Solid yellow: battery level between 20% and 50% ● Flashing yellow: battery level lower than 20% In charger: ● Breathing green: battery level higher than 50% ● Breathing yellow: battery level lower than 50% ● Solid green: fully charged
[8] Lens Window
[9] Charging Holder
[10] USB Cable (1 m length)

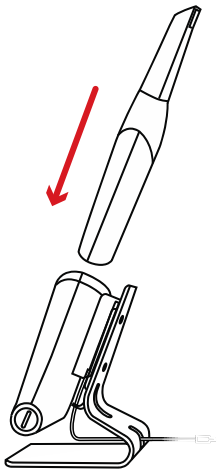
Computer system requirements

For the computer system requirements, refer to the *Technical Specifications* section.

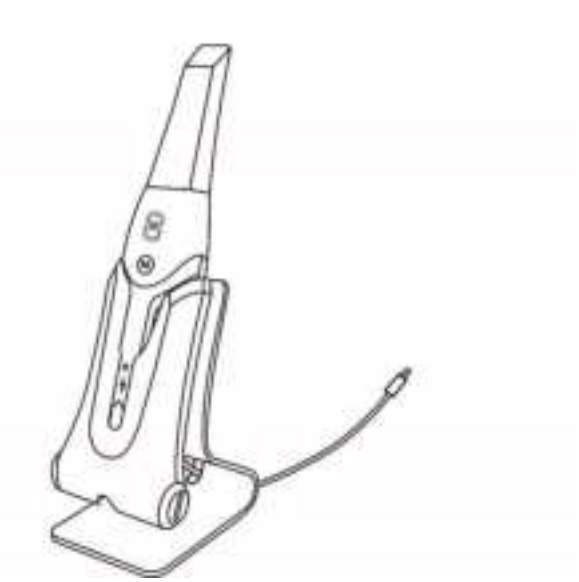
 **WARNING**: It is MANDATORY to check that your computer system configuration is compatible with the computer system requirements for the accompanying software.

Charging the battery

A fully charged battery can provide up to two hours of scan time. We recommend you keep the scanner in the powered Charging Holder when not in use. When the Battery Indicator flashes yellow the battery is low and needs to be charged immediately. To charge, insert the scanner into the Charging Holder.

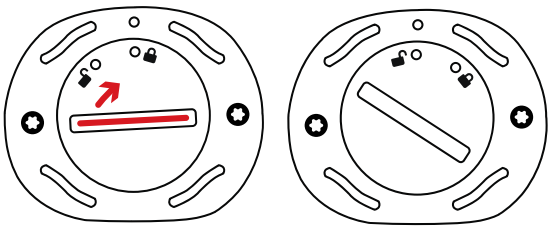


The Charging Holder must be connected to a USB Type-C power source to work.

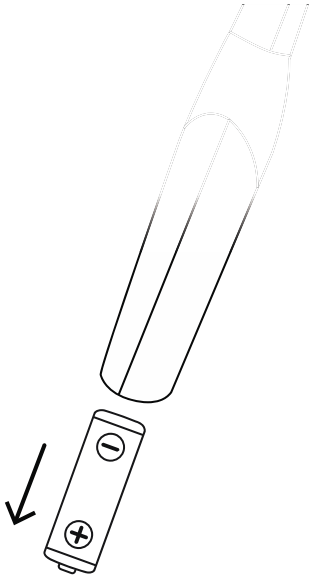


You can also continue to use the scanner by replacing the battery. Follow these steps to replace the battery:

- Turn the Scanner Battery Cover with the Battery Cover Turner (from the Wall Mounting Kit) or a coin to unlock.

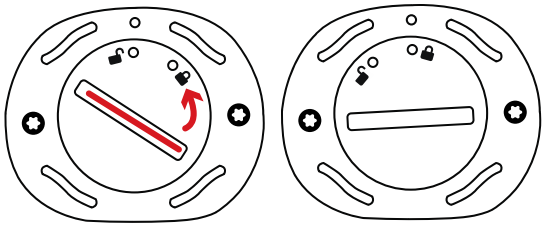


Take out the low battery and insert a charged one.

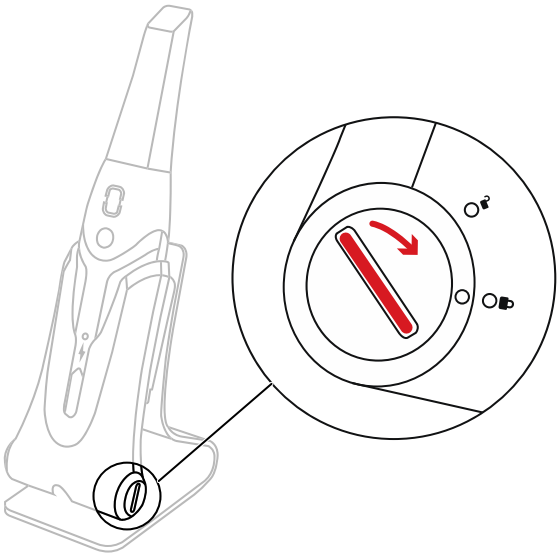


WARNING: Please use the battery specified by Alliedstar (Li-18650-3.6 V 3500 mAh-PCM-Cap)

- Close the Scanner Battery Cover by turning it to lock.



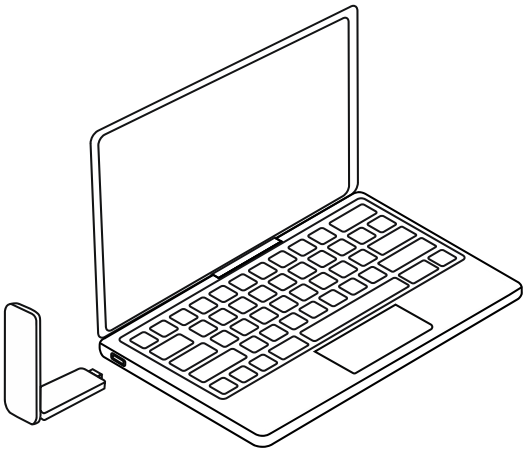
- The Charging Holder holds a spare battery. Open the Spare Battery Cover by turning it to unlock and remove the Spare Battery.
- **NOTE:** The spare batteries inside the Charging Holder are not charged when the scanner is in the Charging Holder (spare batteries only charge once the scanner is removed from the Charging Holder).



NOTE: Fully charge the battery before use.

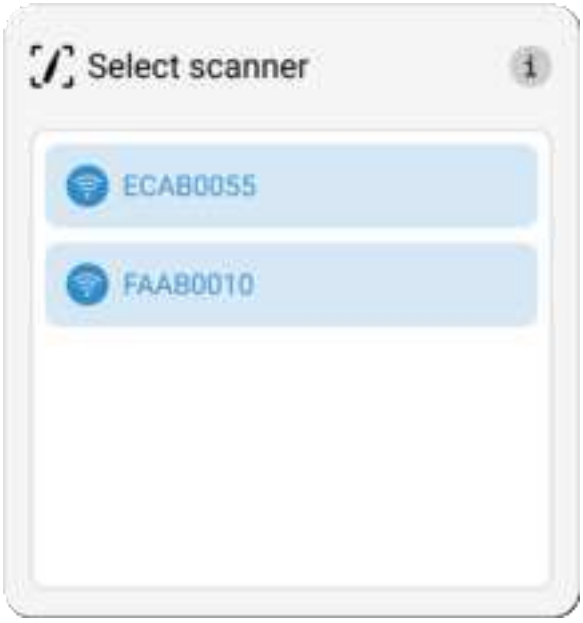
Wireless connection

The scanner communicates with the software through a wireless connection. Before using the scanner, a compatible wireless adapter must be connected to the computer running the software.



WARNING: Failure to detect the handpiece occurs if the wireless adapter is disconnected. Ensure the wireless adapter is connected correctly before use.

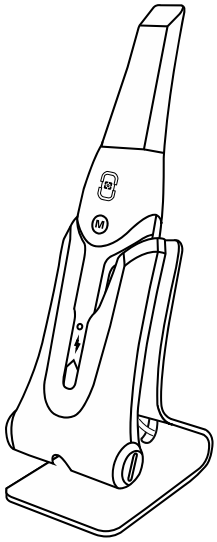
After the compatible wireless adapter is connected, select the scanner you want to connect from the *Select scanner* window and click **Connect**.



Indicates a wireless scanner	Indicates a wired scanner

Charging Holder overview

Place the scanner in the Charging Holder when not in use.



NOTE: The scanner automatically shuts down when it is idle for more than three minutes. To use it again, press

any button on the scanner, or take it out of the Charging Holder.

Setting up the scanner

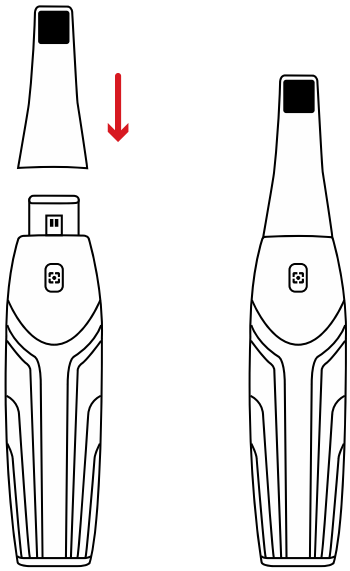
Setting up the scanner

When the scanner is activated for the first time, a wizard pops up to assist you with the basic settings:

- Creating an administrator account.
- Creating users.
- Setting credentials for the local network.
- Adjusting other scanner settings.

To prepare the device, follow these steps:

1. Remove the Lens Window Protective Cover from the Lens Window.
2. Firmly slide the Scanner Tip onto the end of the scanner.



3. Short press any button to start the scanner.
4. After the scanner is powered on, open the software and connect the scanner through the wireless network.

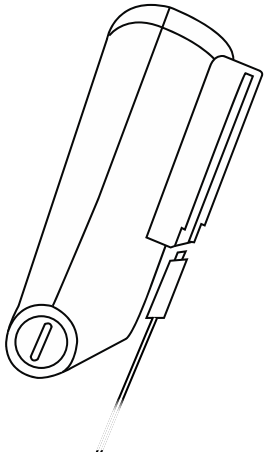
Using the scanner Charging Holder

The Charging Holder can sit on a desktop or be mounted on the wall for use.

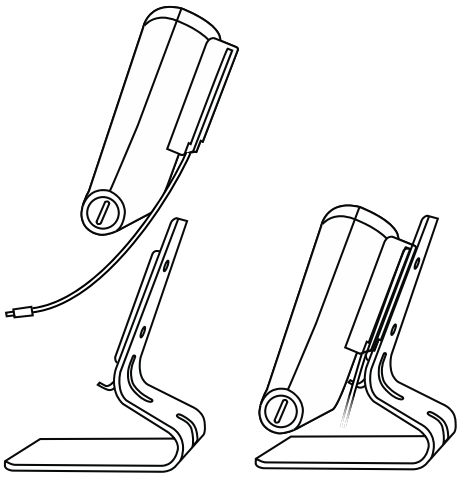
Installing the Desktop Charging Holder

To place the Charging Holder on a desktop, follow these steps:

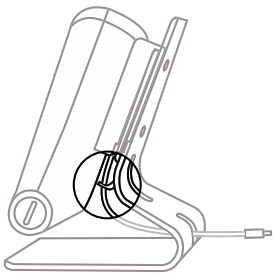
1. Select a clean surface area.
2. Insert one end of the USB cable into the bottom of the Charging Holder.



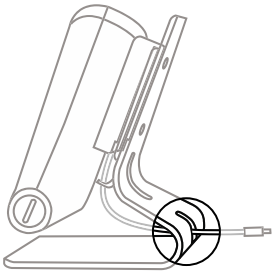
3. Insert the charger with the connected USB cable into the stand.



4. Insert the USB cable into the Cable Clips.



5. Pass the other end of the USB cable through the bottom hole on the stand.

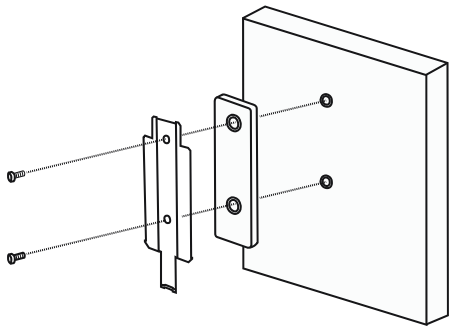


6. Place the scanner in the desktop Charging Holder.

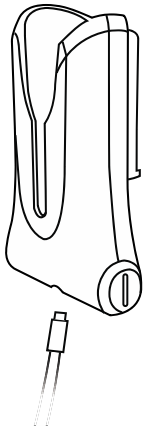
Installing the Wall Mount Charging Holder

To mount the Charging Holder on a wall, follow these steps:

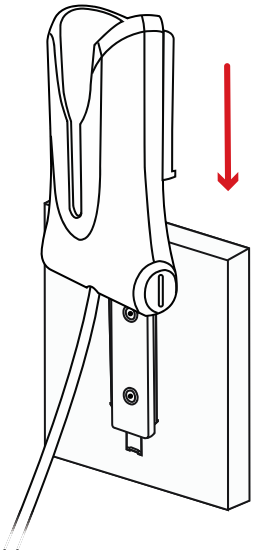
1. Select an area that you can access easily.



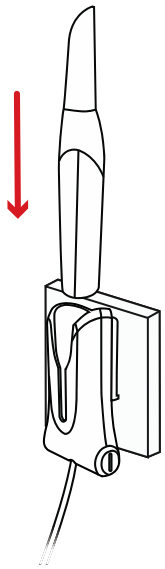
2. Insert the screws in the holes in the Holder Rail and Wall Mount Pad and screw it to a solid surface.
3. Insert one end of the USB cable in the bottom of the Charging Holder.



4. Slide the Charging Holder onto the Holder Rail.



5. Insert the scanner into the Wall Mount Charging Holder.



CAUTION: If the Wall Mount Charging Holder is not properly installed, there is a risk that the Charging Holder can fall off the wall and result in damage to the scanner.

Getting started

Using the software

To open the software, follow these steps:

1. Double-click the software icon on the desktop.
2. Select a user or a dentist.
3. Enter the security PIN.
4. Go to the Home Screen and click **New Case**.
5. Enter the case description including: tooth number, restoration type, material, and shade.
6. Set an **Appointment Date** for the preparation.
7. Set the **Due Date** as the target delivery date for the restoration at your clinic.
8. Specify if a **Pre-Preparation Scan** is desired.
9. **Create** or select a Patient.
10. Add notes and attach files as desired.
11. Click **Next** to proceed to the scanning phase.

CAUTION: Ensure the software version and name are correctly displayed upon startup or within the software settings. Lack of attention to these details may result in an incorrect software version, impacting operational efficiency and outcomes.

CAUTION: Always ensure a biunique relationship between patient, scan and treatment case.

WARNING: The user of this device is solely responsible for determining whether or not this device is suitable for a particular patient case and circumstances. The user is solely responsible for the correctness, completeness and adequacy of all data entered into this device and the software used. The user must check the correctness of the results and assess each individual case.

Preparing the teeth

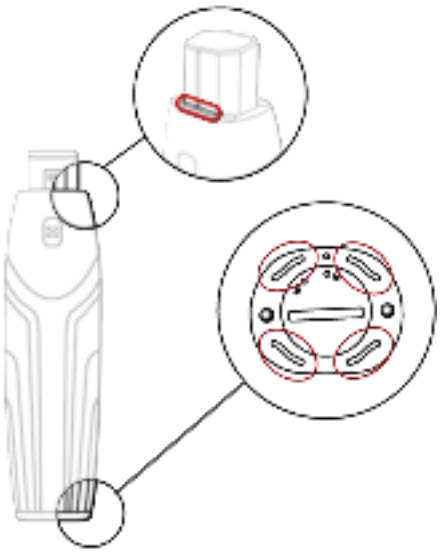
- If there is a preparation area, retract the gingiva using the gingival retraction cords. Extract the cords just before scanning the preparation.
- Dry the teeth thoroughly before starting the scan.
- Keep the teeth moderately dry during the scan.

Preparing the scanner

The Scanner Tip attached to the Handpiece acts as a sanitary shield for patients. Always disinfect the body of the scanner and sterilize the Scanner Tip after each use.

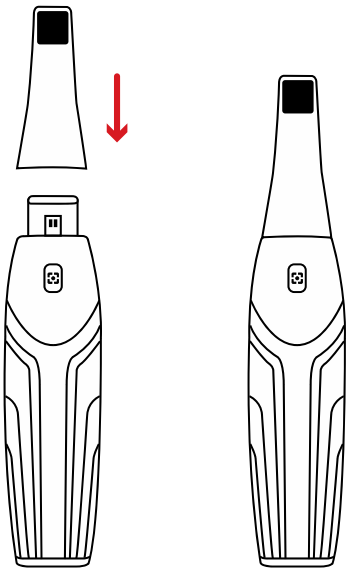
CAUTION: Scanner Tips are non-sterile when shipped. You must sterilize them before the first use.

CAUTION: Keep liquid from getting into the Air Outlet near the scanner Lens Window or the Air Inlet at the rear of the Handpiece or the Handpiece could be damaged.



To prepare the scanner, follow these steps:

- Make sure the Lens Window at the base of the scanner is clean by wiping it with a moist, lint-free cloth or lens tissue.
- Slide the Scanner Tip onto the scanner as shown below.



CAUTION: The scanner tip must be assembled to the handpiece before scanning. If it is not assembled correctly, the device won't scan properly.

Starting scanning

To start scanning, place the Scanner Tip on the surface of the tooth to stabilize the scanner and press the **Scan Button**. Wait until a 3D model appears on the 3D model display screen, and then slowly move it along the arch at 0-5mm from the teeth.

Scanning approach

The recommended scanning method is to start with a molar, as it has greater details for easier identification. Change the scanning angle to less than 60° during scanning to allow the surfaces to overlap, if the overlap is too small, the alignment may be lost.

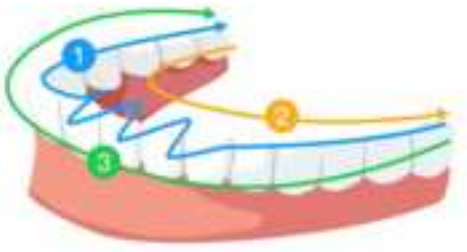
Scanning protocol

The recommended scanning protocol consists of three sweeps to ensure good data coverage of all surfaces:

- occlusal,
- lingual and
- buccal.

We recommend you start the first sweep from the occlusal surface, starting with the first molar.

In the second sweep you can scan both the lingual and buccal sides. In the third scan cover the opposite side of the second sweep.



Safety guide

Warnings and safety instructions

DANGER OF ELECTRIC SHOCK

This is an electrical unit. Do NOT expose it to water spray as that can cause an electric shock or unit malfunction.

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

 **WARNING**

Scanner

- 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.
- When the unit is not in use, ensure that the scanner is turned OFF.
- DO NOT use the scanner in 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 its 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 direct ultraviolet radiation. The scanner is not designed for ultraviolet disinfection.
- DO NOT stare at the LED emission window.
- When the Scanner Tip is removed, install the Lens Window Protective Cover to protect the Lens Window.
- DO NOT remove the cover of any scanner components. The scanner contains no user-serviceable parts. Contact a qualified Alliedstar service technician for any repairs.
- 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, power bars or extension cords should not be connected to the system.
- The maximum temperature of the applied part may reach 43°C. To avoid overheating, do not use it for extended periods. Ignoring overheating warnings may result in permanent damage to the device and loss of functionality.
- To isolate the Charging Holder from the power supply, unplug the USB connector from the USB port.
- DO NOT maintain or service this equipment while it is in use with a 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.
- Do not use the scanner on patients with oral mucosal disease, mental illness, severe respiratory disease, asthma, Parkinson's disease or ADHD.
- Use with caution on patients who have moderate or severe limitations opening their mouths.

Computer

- Do NOT place any equipment which does not comply with IEC 60601-1 in the immediate vicinity (1.5 meters) of the patient.

- The scanner is only intended to be connected to a computer that is at least IEC 60950 / IEC 62368 standard or equivalent 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 sufficient space clear around the computer to ensure that it is properly ventilated.
- Position the screen to avoid reflections from internal or external lighting for maximum image quality and visual comfort.
- Back up your data at regular intervals. It is the responsibility of the user to perform and maintain data backups in order to prevent data loss.
- Protection of the data entered into the software is a shared responsibility. The user is responsible for configuring the operating system of the Scanner, and integrating it in its network as applicable, as required by its IT Policy. This includes set up of automatic logoff, audit controls, authorizations, configuration of security features, emergency access, malware detection/protection, node authentication, personal authentication, physical locks, integration of the Scanner in the product life cycle roadmap, system and application hardening, and health data storage confidentiality.
- The user is responsible for ensuring health data de-identification, data backup and disaster recovery, and health data authenticity. Protect your data against loss, unauthorized access and unauthorized use.
  - Secure your computer system by installing a malware scanner or firewall.
  - Use a strong password to protect your computer system, storage media and presentation devices.
  - Use data encryption to secure data on your computer system and storage media.
  - Backup your data regularly to avoid loss of data.
  - Use the anonymization function to protect patient personal data if required.
- Certain functionalities and services require data transfer. Access to data, storage and transfer shall comply with national regulations on information security. Protect your data against loss, unauthorized access and unauthorized use.
- The scanner software requires a stable and sufficient power supply for optimal operation. Using the scanner with a laptop that lacks adequate power can result in decreased scanning accuracy and the potential for incomplete scans. Always connect your laptop to a direct power source before starting scanning operations. The scanner software has a feature to alert users if insufficient power is detected. It is crucial to respond to these warnings by securing an appropriate power source immediately. Ignoring these guidelines may compromise the scanner's performance, affecting the quality and reliability of scanning results.

Battery

- Do not dismantle, open, or shred secondary cells or batteries.
- Do not expose cells or batteries to heat or fire. Avoid storage in direct sunlight.

- Do not short-circuit a cell or a battery. Do not store cells or batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.
- Do not remove a cell or battery from its original packaging until required for use.
- Do not subject cells or batteries to mechanical shock.
- In the event of a cell leaking, do not allow the liquid to come into contact with skin or eyes. If contact has been made, rinse the affected area with plenty of water and seek medical advice.
- Do not use any charger other than that specifically provided for use with the equipment. Refer to the manufacturer's instructions for proper charging instructions.
- Do not use any cell or battery which is not designed for use with the equipment.
- Always purchase the battery recommended by the device manufacturer for the equipment.
- Keep cells and batteries clean and dry.
- Wipe the cell or battery terminals with a clean, dry cloth if they become dirty.
- Do not leave the battery charging for prolonged periods when not in use.
- After extended periods of storage, it may be necessary to charge and discharge the cells or batteries several times to obtain maximum performance.
- Keep the original product literature for future reference.
- Only use the cell or battery in the way in which it was intended.
- When possible, remove the battery from the equipment when not in use.
- Remove the battery using the specified tools. Do not remove the battery by hand.
- Dispose of the battery properly.

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 responsible authority in your 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.

Cleaning, disinfecting and sterilizing

To ensure maximum hygienic safety for the patient, carefully follow 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*).
- Clean the Scanner Tip, and then use autoclave sterilization (See *Clean and sterilize the Scanner Tip*).

There are 3 product models of Scanner Tip:

Product Model	Size	UDI-DI	Manual Cleaning	134°C Sterilization
TP202	Large	(01)06973993441034	Yes	Yes
TP203	Small	(01)06973993441041	Yes	Yes
TP204	Large	(01)06973993441386	Yes	Yes

Clean and disinfect the scanner

General Warnings

WARNING

- Read and follow the warnings and personal protection instructions provided in the *Safety Data Sheet (SDS)* for the disinfectant used to process the scanner.
- Wear gloves while cleaning and disinfecting the scanner.
- Between patients the scanner must be disinfected with a recommended intermediate-level disinfectant solution with tuberculocidal activity.
- 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, immerse it in water or immerse it in disinfectant solution.
- 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 or bodily 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 any blood or bodily fluids with the dampened lint-free cloth.

Disinfect the Scanner

The scanner must be thoroughly disinfected after each patient.

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

 **CAUTION**: If the scanner is visibly soiled, clean it thoroughly prior to disinfecting. See *Clean the scanner*.

Follow these steps to disinfect the scanner:

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

 **WARNING**:

- Do not rinse.
- Allow to air dry.
- 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 Scanner Tip

WARNING

- 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 Tip in disinfectant for a long period.
- Dry the Scanner Tip thoroughly before mounting onto the scanner.
- Do not use an ultrasonic cleaning machine to clean the Scanner Tip.
- Do not soak the Scanner Tip with alcohol-based disinfectants.

Clean the Scanner Tip

To manually clean the Scanner Tip, follow these steps:

1. Rinse excess soil from the Scanner Tip for two minutes.
2. Using a soft brush, apply enzymatic detergent solution (e.g. Metrex EmPower) to all surfaces.
3. Rinse under clean, running water for two minutes.
4. Inspect Scanner Tip. If the Scanner Tip is not clean, repeat the previous three steps.
5. Use a lens tissue or lint-free cloth to remove any dust from the mirror on the Scanner Tip.
6. Dry the scanner tip's mirror carefully with a lens tissue or lint-free cloth.

Sterilize the Scanner Tip

Scanner Tips are shipped non-sterile. You must sterilize them before use.

CAUTION: For TP202 and TP203, if you limit the exposure time at 134°C to not more than six (6) minutes, you can autoclave the Scanner Tip up to 60 cycles.

CAUTION: For TP204, if you limit the exposure time at 134°C to not more than six (6) minutes, you can autoclave the Scanner Tip up to 180 cycles.

To sterilize the Scanner Tip, follow these steps:

1. Put the Scanner Tip into a sealed steam sterilization pouch.

2. Place the Scanner Tip in a steam autoclave for sterilization.
    - Exposure temperature should be set to 134°C.
    - Exposure time should exceed three (3) minutes.
    - Exposure time should not exceed six (6) minutes.

Precautions before use

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

Visually inspect the scanner for damage

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

- Inspect the Lens Window.
- Inspect the buttons and contact points.

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

Visually inspect the Scanner Tip

Visually inspect the Scanner Tip for signs of deterioration by doing the following:

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

If deterioration is noted, replace the Scanner Tip.

 **WARNING**

- The Lens Window on the scanner is a delicate optical component. Mount the Lens Window Protective Cover to protect the Lens Window from damage and dirt when the scanner is not in use.
- The mirror in the Scanner Tip is a delicate optical component. A clean and undamaged mirror 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 Scanner Tip mirror and the Lens Window of the Handpiece using a microfiber cleaning swab, applying ethanol that is free of impurities.

Troubleshooting

Problem description	Action
There is mismatching and overlap on the 3D model.	Remove mismatched data and excessive tissue using the **Cut** tool and rescan.
After buccal bite registration, there is a gap or intersection between the upper jaw and the lower jaw.	Adjust the **Occlusal pressure level** in **Preferences**, then disable and enable **Occlusal pressure adjustment**. Delete the incorrect bite view and rescan.
Precision degradation is observed, or images are not well-stitched during acquisition.	Ensure that the Lens Window at the base of the scanner is clean by wiping it with a moist, lint-free cloth or lens tissue. Use a lens tissue or lint-free cloth to remove any dust or water stains. Make sure the Scanner Tip is firmly installed and there are no dark edges on the live video.
Reconstruction of metallic preparations is sometimes difficult.	Adjust the scanner position (for example: distance or angle) and scan more of the area. Move the surgical light away from the patient to decrease light scatter. Turn on the **Shine control** button.
The Scanner Tip is installed but not detected. No live video is displayed, and the Scanner Tip not detected icon is displayed at the bottom-right of the interface.	Reinstall the Scanner Tip, and make sure the Scanner Tip is in firm contact with the scanner.
Fogging appears on the inner surface of the Lens Window at the base of the scanner.	Mount a completely dry Scanner Tip on the scanner and place the scanner in the Charging Holder or set it on the desk and wait until the fogging fades. If the fogging does not disappear completely after 24 hours, contact your local service provider for assistance. Ensure that the Scanner Tip is thoroughly dry before mounting on the scanner, and do not use a cloth soaked in disinfectant to clean the scanner.
The scanner does not cast light, and a static preview image is displayed in the video preview screen.	Close the software, and then start the software again.
The scanner is not shown in the *Select scanner* window in the software while the Status Indicator keeps blinking in breathing mode.	Reset the network in the scanner: 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 Select scanner in the software.

Regulatory information

Regulatory information

The device complies with the following regulations:

MDR: (EU) 2017/745 Medical Device Regulation, Class I following 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

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 in) 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 the priority used for the handpiece. The channel bandwidth is 40 MHz. The frequency range is 5150-5250 MHz, 5725-5850 MHz (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.

SAR Value for Handpiece:

0.798 W/Kg, 10 g for CE

0.011 W/Kg, 1 g 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 different circuit 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 Declaration

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 DEVICE 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 (from Non-RF wireless communication equipment)

The DEVICE is intended for use in the electromagnetic environment specified below (IEC 60601-1-2 Table 4). The customer or the user of the DEVICE 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 80 MHz – 2.7 GHz	3 V/m 80 MHz – 2.7 GHz	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 equipment, the DEVICE is compliant with the test levels specified below, according to IEC60601-1-2 Table 9. The customer or user of the DEVICE should assure that it is used in such an environment.

Test Frequency (MHz)	Band (MHz)	Immunity Test Levels
385	380 – 390	Pulse modulation 18 Hz, 27 V/m
450	430 – 470	FM, ±5 kHz deviation, 1 kHz sine, 28 V/m
710	704 – 787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800 – 960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700 – 1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400 – 2570	Pulse modulation 217 Hz, 28 V/m
5240	5100 – 5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Accessories

The use of accessories other than those specified, except for 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.

Technical specifications

Product model

ST 200E

Technical specifications

Components	Technical Specifications
Weight	Scanner (including battery, without Scanner Tip): 245g Tip Large - Sterilization (TP202): 14 g Tip Small - Sterilization (TP203): 12 g Tip Large - Sterilization (TP204): 14 g
Color	3D Full Color
USB Wireless Card Port	USB 3.0
USB Charge Port	Type C Port
Field of View	Tip Large - Sterilization (TP202): 16 mm x 14 mm Tip Small - Sterilization (TP203): 12 mm x 12 mm Tip Large - Sterilization (TP204): 16 mm x 14 mm
Depth of Field	15mm
Minimum System Requirements of Laptop	**Processor**: 10th Generation Intel Core i7-10750H or AMD Ryzen 7 4700U **Memory**: 16 GB **Graphics Card**: NVIDIA GeForce GTX 1650 4 GB **Disk**: 512 GB SSD **Operating System**: Windows 10 (build 18362+) / Windows 11, 64 bit **Others**: USB 3.0 Port **Optional**: Touch Screen
Minimum System Requirements of Desktop	**Processor**: 9th Generation Intel Core i5-9600 or AMD Ryzen 5 2600 **Memory**: 16 GB **Graphics Card**: NVIDIA GeForce GTX 1650 4 GB **Disk**: 512 GB SSD **Operating System**: Windows 10 (build 18362+) / Windows 11, 64 bit **Others**: USB 3.0 Port **Optional**: Touch Screen

CAUTION: It is MANDATORY to check that your system configuration is compatible with the computer system requirements for the accompanying software. This is essential to prevent suboptimal performance or software failure due to incorrect specifications.

Environmental Requirements

Components	**Environmental Requirements**
Operating Temperature	15°C ~ 30°C
Transport and Storage Temperature	-10°C ~ 50°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

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

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