CORTEX®
The Future of Dental Implants

Instructions for Use

CORSCAN Digital Intraoral Scanner System

Model: S6500

CORSCAN

CE

(EN)

Table of contents

Manual Information

Part No.: PK-LF10
Version: V1.2
Date: 2025/08/10

These instructions for use are available electronically on our website:
https://www.cortex-dental.com

To the user

NOTE

The user of these accompanying documents is required to carefully read through and carefully consider the instructions, warnings and cautions contained therein before starting operation.
Even if you have already operated similar systems, changes in the design, production and functional routine of the system described here may have been made, which have a significant influence on the operation.
Assembly and service works on the system described here must be carried out by authorized and qualified personnel from CORTEX. Assembly personnel and other persons who are not employees of the technical service department of

CORTEX are requested to contact the local branch of CORTEX before assembly or service work is started.

NOTE

The use of the product with add-on or accessory parts not authorized by CORTEX or other unapproved components is not permitted.

NOTE

According to Regulation (EU) 2017/745 of medical devices, all serious incidents related to the device must be reported to the manufacturer and the responsible authority of the Member State where the user and/or the patient is established.

Refer to section 9 at this IFU

1 Device Description

1.1 Introduction

The instructions for use describe the performance characteristics and operation required for efficient and effective use of the CORSCAN digital intraoral scanner S6500.

Before you work with the CORSCAN digital intraoral scanner S6500, the complete instructions for use must be read, especially the Safety Instructions and the Chapter Handling.

1.2 Description

This product consists of a handpiece, scan tips, a holder, and its software.

The device is designed to acquire 3D still images in the following modes:

- Lower jaw
- Upper jaw
- Occlusion

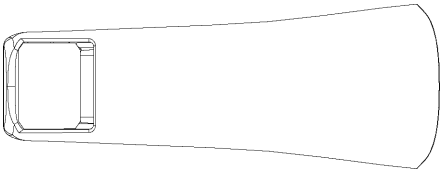
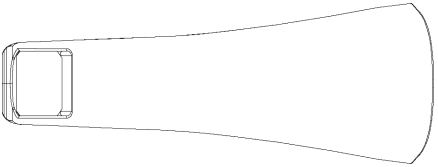
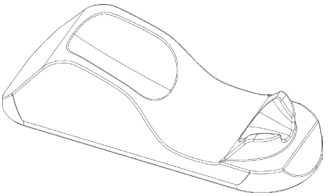
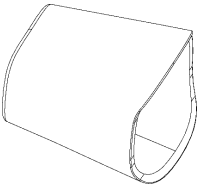
NOTE

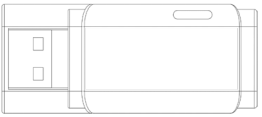
To avoid damage to the system, do not use the product in the following environment:

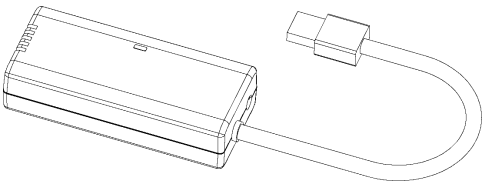
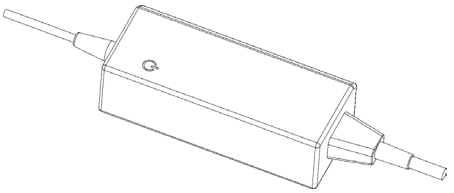
- Exposed to direct sunlight.
- Exposed to sharp temperature variation.
- Exposed to thick dust.
- Exposed to heat source.
- Exposed to high humidity.

1.2.1 Components

The CORSCAN digital intraoral scanner S6500 consists of the following main components:

Component	Picture	Quantity
Handpiece		1
Standard scan tip		3
Small scan tip		1
Scanner holder		1
Scan tip protector		1

Component	Picture	Quantity
USB Flash Drive		1
Instructions for Use		1
Software User Guide		1

Optional		
HUB		1
Adaptor		1

CORSCAN Digital Intraoral Scanner S6500 and its components can be purchased from your local dealer.

The USB Flash Drive includes the following:

- Digital intraoral scanner system software
- Instructions for Use in various languages

NOTE

If you order the components additionally, they are considered as accessories.

1.3 Intended Use

This product can be used in medical institutions to perform oral scanning, collect images of teeth and other tissues, and provide 3D digital model for computer-assisted design and manufacturing (CAD/CAM) denture design and processing, which can be used for tooth restoration, orthodontics, and implant.

1.4 Contraindications

Patients with oral mucosal disease, mental illness, severe respiratory disease, asthma, Parkinson's disease, Attention-Deficit / Hyperactivity Disorder (ADHD).

This product should be used with caution in patients with moderately or severely limited mouth opening.

1.5 Declaration of Conformity

CE

This product complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, including all applicable corrigendum.

2 Safety Instructions

NOTE xxx	**Contains information that must be observed during operation.**

CAUTION! **xxx**	**Contains information which, if not observed, can cause property damage.**

WARNING! **xxx**	**Contains information which, if not followed, can cause personal injury.**

Settings and calibrations that are not described in these instructions for use must be carried by CORTEX service department or a service company authorized by them.

NOTE

- All instructions supplied with the CORSCAN S6500 must be observed and the safety instructions contained therein must be carefully read and adhered to.
- The CORSCAN S6500 may only be commissioned if all safety measures for operator protection have been met and checked. These protective measures can include

door contact, designated area, dosimeter, protective clothing, etc.

- Equipment layout must not obstruct access to power plugs, switches, or emergency shutoff devices.

CAUTION!

The instructions for use contain all the information relevant to safety to generally put the CORSCAN S6500 into operation. The device may only be operated by appropriately trained and authorized personnel. In this context, operation is ensured by clear symbols on the control elements.

NOTE

All control elements are described again in detail in these operating instructions.

2.1 General Safety Instructions

2.1.1 Requirements for Operation

WARNING!

- **The CORSCAN S6500 is a protection class I device (according to IEC 60601-1).**
- **To avoid the risk of an electric shock, this device may only be connected to a supply network with a protective earthing conductor.**
- **For safe and effective use of the system, and to avoid system failure, users should first be familiar with operations in the Windows system, read this manual carefully and be familiar with the digital intraoral scanner system software and its operations. Users need to pay special attention to the following warnings and cautions during operation.**
- **Failure to operate the instrument and system in accordance with the safety instructions may endanger the operator. The manufacturer will take no liability for any injury resulting from improper operation.**
- **The system shall not be used for treatment.**
- **The system is to be used in a Professional Healthcare Environment.**
- **Diagnosis and examination with this system should be combined with clinic research on patients, and the diagnostic result should be used only for physician's reference.**

- **This system is furnished with no waterproof device and therefore shall not be used at any location exposed to humidity or water.**
- **Risk of electric shock - Do not handle the power supply component with wet hands. Be sure to touch the power cable with clean and dry hands.**
- **Be sure to operate any non-medical device (e.g. external printer) at least 1.5m/6ft away from the patient.**
- **Pay attention to and prevent any ESD and EMI of any other instrument.**
- **Using this instrument near any strong EMI source, such as surgical electrical equipment or MRI, may cause negative effects.**

Device Operation

In case of a malfunction, do not use the CORSCAN S6500 anymore and notify CORTEX service department or a service company authorized by them.

Scan tips received from the manufacturer are NOT disinfected. The scan tips must be disinfected before the first use. Please refer to section 6.3 Cleaning and Disinfection for details.

2.1.2 Operating Personnel

NOTE

- Only trained and authorized personnel are allowed to work on the CORSCAN S6500.
- The operating personnel must be familiar with all warning signs attached to the CORSCAN S6500. They are used for your own safety and that of others and ensure proper operation.

2.1.3 Crushing and Collision Hazard

WARNING!

It must be ensured that when operating the moving parts of CORSCAN S6500, no persons or objects are in the obvious danger area of the device. If not observed, it can result in personal injury or damage to the CORSCAN S6500 or other objects.

2.1.4 Explosion Protection

The CORSCAN S6500 is not designated for use within areas with explosive hazards.

3 Installation and Connection

CAUTION!

- **Before using this product, users must inspect the main unit and any accessory for any damage which may endanger the operator or impair the performance of the instrument. It is recommended to inspect the equipment weekly or more frequently. In case of any obvious damage, replace the damaged part before using this product.**
- **In case that the power cable is missing, damaged, or unavailable, select an alternative power cable that meets the original specifications and your local codes.**
- **Select a power cable with proper rating to minimize risk.**
- **In the process of installation, maintenance, and use, try to avoid the exposure of LED, do not look directly at the LED beam from the scanning window or aim the LED beam at others.**

NOTE

- The device should be installed on a firm desktop. Loosely coil the cable to avoid damaging the device.
- The main unit and monitor shall be placed at a dry location with good ventilation and not exposed to thick dust or humidity. The air duct cooling system shall be kept well-ventilated.

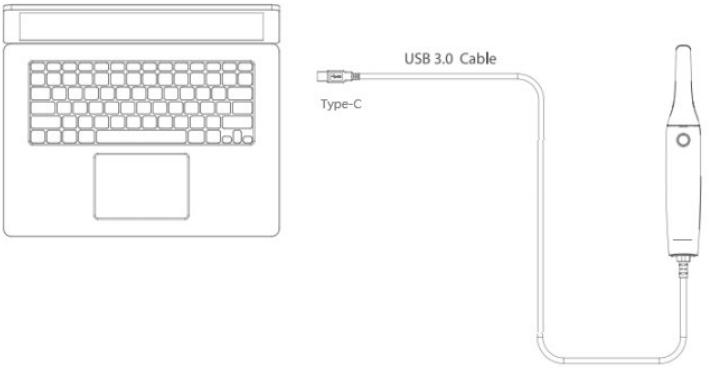
3.1 Installation of the Digital Intraoral Scanner System Software

Install Digital Intraoral Scanner System software on the computer. For details, please refer to the provided software user guide.

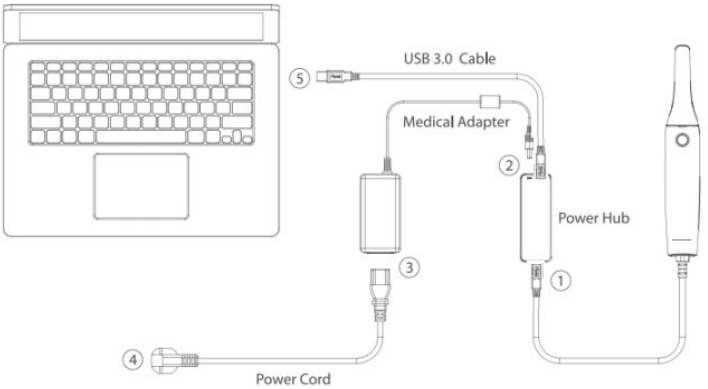
3.2 Installation of the Device

1. Place the scanner base on a flat and stable surface, place the CORSCAN S6500 handpiece securely in its base.
2. Connect the USB plug-in into USB3.0 port on computer.
3. After the device is connected with Computer the device power indicator LED blinks before the device is turned on.
4. Short Press the power/scan control button, it will lead to a short beep is heard from the handpiece. The power indicator LED stops blinking and displays stable blue light to indicate that the device is ready for scan.

5. Put the holder on a stable desktop and put the handpiece on the holder.



Optional:

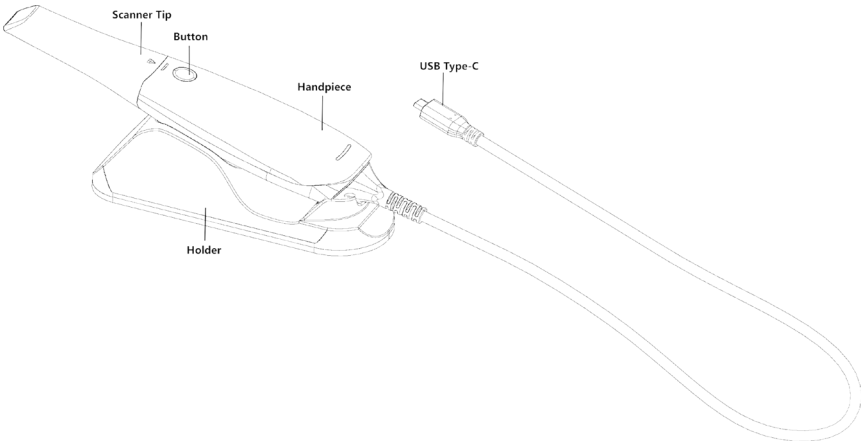


3.3 Computer

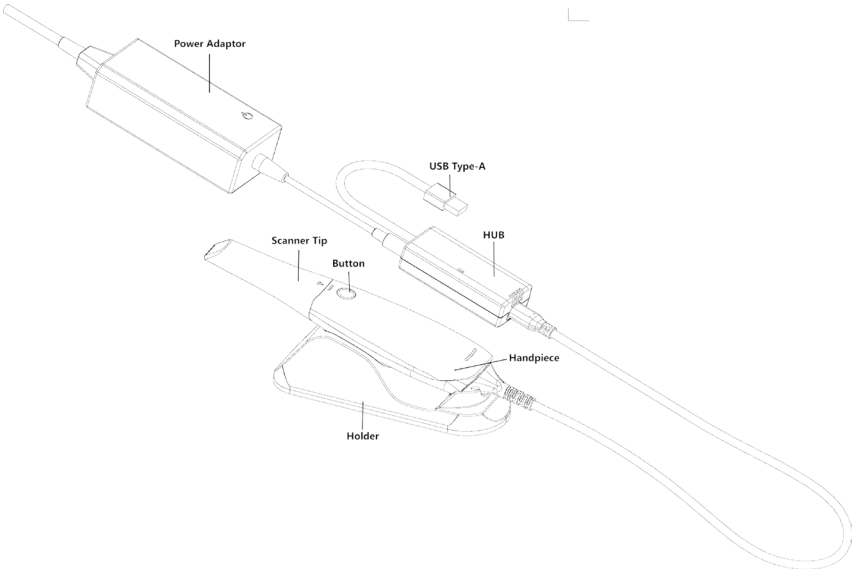
Place the computer and monitor close to the scanner to ensure that the operator can observe the monitor while scanning. Allowing patients to see the images simultaneously facilitates the communication between the operator and the patients.

4 Control Elements

- Scan Tip: It is reusable and needs to be cleaned and disinfected before use.
- Power/Scan Control Button:
    - Short press to turn on the scanner
    - Short press to Start/Pause scanning
    - Hold two second to switch workflow such as upper jaw/lower jaw
    - Double click to enter G-motion mode
    - Unplug power source directly to turn off the scanner
- Handpiece: The part of device which need to be held while scanning.
- Holder: Place it on a firm desktop. Place the device in the holder when it is not in use.


Scanner Tip
Button
Handpiece
USB Type-C
Holder

Optional:


Power Adaptor
USB Type-A
HUB
Scanner Tip
Button
Handpiece
Holder

5 Handling

NOTE

- To keep a clean environment and to protect the patient's safety, users should wear surgical gloves from starting to use the device until finishing the scan.
- Before scan, the tooth surface should be blow-dried and have moisture isolation treatment.
- When using the device, users should not stare at the scanner's light source for a long time or point the light at people's eyes, for strong light has a blinding effect.
- If the scanning quality decreases during scanning, replace the scan tip and try again.
- To avoid interruption from tongue, cheek and lips during scanning, use mouth mirror, swab, gloved fingers or mouth gag to assist in scanning.

5.1 Requirements before and during Operation

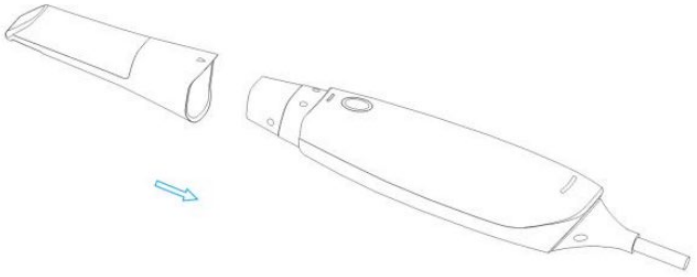
It must be ensured that the surfaces in contact with patients are disinfected before performing the scan of each patient.

5.2 Operation of the CORSCAN S6500

5.2.1 Installing and Heating a Scan Tip

1 Remove the scan tip protection cap and attach a clean and sterile tip to the scanner before scanning. The scan tip connection indicator LED blinks when the tip is correctly attached to the handpiece.

2 Press the power/scan button to turn on the device and tip heating system is automatically activated. Allow the CORSCAN S6500 to warm up for approximately 30 second before starting scanning to enable the anti-fog feature. The scan tip indicator LED stops blinking and displays solid blue light indicate the readiness for starting a scan.



5.2.2 Scan

NOTE

- The optimum distance between the tip and tooth is 3-5 mm. The scan tip shall not contact with the teeth during the scan.
- Steadily and slowly moving the tip and simultaneously check the scan results on the computer screen to ensure the quality of the acquired data.
    - Do not scan the lips, cheek, or tongue.
    - Leave spaces among teeth, lips, and cheek by inserting fingers or a mouth mirror.
    - Depart the lips and cheek by a lip buccal retractor.
- Do not scan fingers during scanning.
- If lips, cheeks, or tongue are scanned, please trim the corresponding data.

1 Hold the scanner steadily and place the scan tip into the patient's mouth. Ensure the scan tip window facing to the surface of the tooth to be scanned.

2 Press the scan control button on the device or click the scan icon through the software to start scanning. Follow the corresponding scanning path of unilateral scanning and bilateral scanning during scanning.

3

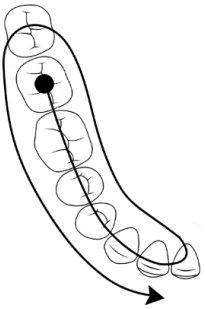
4 An acquired 3D image will be displayed on the computer screen as the scanning proceeds. Inspect the acquired images in 3D view to ensure the completeness and quality of the scan. For detailed analysis and operation, please refer to Software User Guide.

5.2.2.1 Unilateral Scan

5.2.2.1.1 Lower Jaw Scan

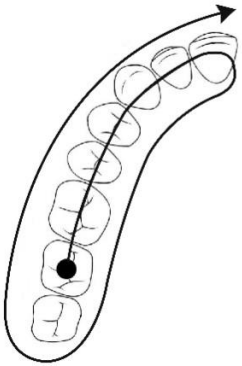
1 Scan from the third molar's occlusal surface to the top of an incisor.
2 Turn to the lingual side and scan back to the third molar. Try to mesh with the obtained occlusal data during scanning.
3 Turn to the buccal side and scan to the incisor.
4 Check if the scanned image is integrated and scan again for those disintegrated areas.

For the scan path, please see below the black lines with an arrow.



5.2.2.1.2 Upper Jaw Scan

1 Scan from the third molar's occlusal surface to the top of an incisor.
2 Turn to the lingual side and scan back to the third molar. Try to mesh with the obtained occlusal data during the scan.
3 Turn to the buccal side and scan to the incisor.
4 Check if the scanned image is integrated and scan again for those disintegrated areas.

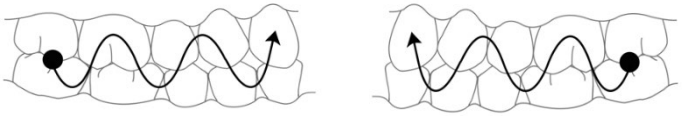


5.2.2.1.3 Occlusion Scan

NOTE

During occlusion scanning, the patient should bite the upper and lower jaws tightly. Let the scan tip window tip's mirror faces the teeth, and check if the occlusion is correct after scanning.

Scan in S-shaped path from the buccal side of the third molar to an incisor.



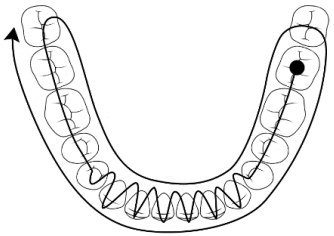
5.2.2.2 Full Arch Scan

5.2.2.2.1 Lower Jaw Scan

1 Scan from the third molar's occlusal surface of one side to the top of an incisor of the same side.
2 Scan the incisors from the tongue side, slowly wiggle the scanner when passing the centrals till the canine of the other side of arch, and then scan from the canine to the third molar's occlusal surface of the other side.
3 Turn to the lingual side, scan from the third molar of this side to that of the other side.
4 Turn to the buccal side, scan from the third molar of this side to that of the other side.

5 Check if the scanned image is integrated and scan again for those disintegrated areas.

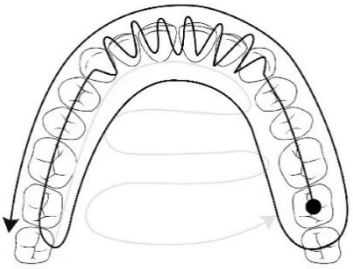
For the scan path, please see below the black line with an arrow.



5.2.2.2.2 Upper Jaw Scan

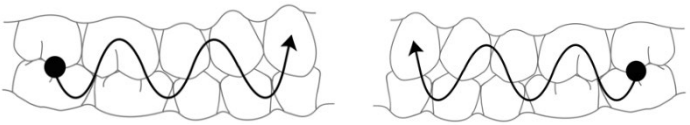
1 Scan from the third molar's occlusal surface of one side to the top of an incisor of the same side.
2 Scan the incisors from the tongue side, slowly wiggle the scanner when passing the centrals till the canine of the other side of arch, and then scan from the canine to the third molar's occlusal surface of the other side.
3 Turn to the lingual side, scan from the third molar of this side to that of the other side.
4 Turn to the buccal side, scan from the third molar of this side to that of the other side.
5 Scan the palate. Scan from the third molar to an incisor from the lingual side, then scan from hard palate to soft palate in S-shaped path.
6 Check if the scanned image is integrated and scan again for those disintegrated areas.

For the scan path, please see below the black line with an arrow.



5.2.2.2.3 Occlusion Scan

Occlusion scanning on bilateral contains two steps. Scan in S-shaped path from the buccal side of the third molar to an incisor on one side. Repeat the above-described operation on the other side to complete the scanning.



5.3 Trouble Shooting

This section lists common problems a user might encounter while using the CORSCAN S6500 device and the corresponding possible solutions.

Issue/Source of Problem	Possible Solution/Option
Power Source	Ensure that the scanner is properly connected to a power outlet or that the battery is charged to ensure it has enough power to function.
Calibration	Calibrating the scanner according to the manufacturer's instructions can help improve the accuracy of the images produced.
USB Connection	Verify that the USB connection between the scanner and the computer is secure. If there are connectivity issues, try using a different USB cable or port to establish a stable connection.
Obstructions	Check for any physical obstructions that could impede the movement of the scanner's components. Inspect cables, wires, and connectors for damage or blockages that may affect the scanner's functionality.

Issue/Source of Problem	Possible Solution/Option
Ambient Lighting	Pay attention to the lighting conditions in the scanning area. Excessive ambient light or shadows may affect the scanner's ability to capture accurate images. Ensure proper lighting for optimal scanning results.
Driver Installation	Install the necessary drivers for the scanner as instructed by the manufacturer. Outdated or incompatible drivers can cause connectivity or functionality problems.
Software Updates	Keeping the scanner's software up to date is essential for optimal performance. Check the manufacturer website regularly for any available software updates or patches.
Check System Requirements	Ensure that your computer meets the minimum system requirements specified by the scanner's manufacturer. Inadequate system specifications may lead to performance issues or compatibility problems.
Scanner Firmware Updates	Check for firmware updates specific to your scanner model. Firmware updates can address known issues, improve

Issue/Source of Problem	Possible Solution/Option
	performance, or introduce new features. Follow the manufacturer's instructions to update the scanner's firmware if applicable.
Storage Space	Verify that there is enough available storage space on both the scanner and the computer. Insufficient storage can impact the scanner's ability to save or transfer scans.
Cleaning and Maintenance	Regularly clean the scanning tip of the intraoral scanner and follow the manufacturer's guidelines for disinfection if necessary. Proper maintenance and cleanliness help ensure accurate and hygienic scans.
Error Messages	If the scanner displays any error messages, consult the user manual or contact the manufacturer's support for specific troubleshooting instructions and solutions related to the error message received.
Reboot	When facing temporary software or connectivity issues, try restarting both the scanner and the connected computer. This

Issue/Source of Problem	Possible Solution/Option
	simple step can often resolve minor glitches and restore normal functioning.
User Permissions	Ensure that you have the necessary user permissions to access and operate the scanner software. If you're using the scanner in a professional setting, consult with your IT department to ensure that there are no restrictions or limitations in place.
Network Security	If you're using a network-connected scanner, check your network security settings to ensure that they are not blocking the scanner's communication. Firewalls, antivirus software, or other security measures may interfere with the scanner's functionality.
Scan Technique	Review the proper scanning technique recommended by the scanner's manufacturer. Ensure that you are positioning the scanner correctly and following the suggested scanning motions or patterns. Incorrect scanning technique can result in distorted or inaccurate scans.

Issue/Source of Problem	Possible Solution/Option
Consult Peers or Online Communities	Reach out to colleagues or online communities for assistance. They may have encountered similar issues and can provide insights or solutions based on their own experiences.
Manufacturer Support	If the issue persists or if you encounter more complex problems, it is advisable to contact the manufacturer's support team. Provide them with detailed information about the problem, any error messages received, and the troubleshooting steps you have already taken. They can offer further assistance and guidance to resolve the issue.

NOTE

For more information, please contact Cortex Dental Implants Industries Ltd. (see section 9 at this IFU)

6 Safety and Maintenance

6.1 Introduction

In this chapter you will find information about safety and maintenance that are necessary to ensure the correct and reliable function of the device after installation.

6.2 Reusability

The CORSCAN S6500 handpiece can be reused without any special preparation procedures.
However, it must be ensured that the surfaces in contact with patients are disinfected before performing the scan of each patient (see also chapter 5.1).

The CORSCAN S6500 must no longer be used with patients if it shows signs of wear (e.g. wear of insulations) or dangerous technical defects (e.g. bent parts) or if the resulting image quality (e.g. artifacts in the image) is insufficient.

In this case, please contact CORTEX service department or a service company authorized by them immediately.

6.3 Cleaning and Disinfection

WARNING!

- **Make sure that no liquid enters the interior of the housing during cleaning and disinfection to prevent electrical short circuits and/or corrosion.**
- **Please obey applicable safety protection provisions.**
- **Please carefully read the material safety data list of each detergent.**
- **Prevent liquid from splashing on the device during cleaning.**

CAUTION!

Turn off the power before cleaning.

NOTE

- Clean the equipment according to demands before being used for the first time. See cleaning methods in this chapter.
- To prevent equipment damage, refer to data provided by the manufacturer in case of any question about detergent.

- Do not use organic, halogenated, or petroleum-based solvent, glass cleaner, acetone, or other irrational detergents.
- Do not use abrasive detergent (e.g. steel wool, silver polish, or detergent).
- Keep liquid away from electronic members.
- Prevent liquid from permeating into the equipment shell.
- The pH value of the detergent shall be within 7.0-10.5.
- Wear gloves to clean and disinfect the device.

6.3.1 Handpiece Disinfection Method

- Use disposable covers or sleeves to prevent cross-contamination.
- Clean the device's surface with a wet soft cloth, if necessary, clean with 75% medical alcohol.

6.3.2 Scan Tip Disinfection Method

6.3.2.1 Replace of Scan Tips

WARNING!

- **A scan tip must be disinfected before use.**
- **A scan tip could be sterilized through high temperature up to 100 times. After 100 times, the**

scan tip is recommended to be discarded if there is a sign of deterioration.

- **Please discard scan tips according to relevant local regulations or hospital's (or clinic's) waste treatment rules.**
- **When the scan tip is removed, DO NOT touch the heater.**

---

1 A sterilized scan tip should be installed before a new scan.
2 Hold the main part of the device to pull out the scan tip.
3 Install a sterilized scan tip on the device.

6.3.2.2 Disinfection Methods of Scan Tip

It is recommended to sterilize scan tips through high temperature or with o-benzaldehyde disinfectant (o-benzaldehyde content is 0.5%-0.6%).

6.3.2.2.1 High temperature Sterilization

- Manually clean the scan tip with clean water or soapy water. Check the scan mirror and make sure it has no stain. Repeat the cleaning process if any stains, smudges or milky hazes appear on the mirror. Dry the scan tip with air blow.
- Put the scan tip into a sterilizing pouch and then seal the sterilizing pouch.
- Sterilize the wrapped scan tip in an autoclave at 121°C for at least 15 minutes.

- After Sterilization, take the scan tips out from the sterilization pouch.

6.3.2.2.2 Ortho-Phthalaldehyde disinfectant

- Manually clean a scan tip with clean water or soapy water. Check its scan mirror and make sure it has no stain or milky mist. Repeat the cleaning process if any stains, smudges or milky hazes appear on the mirror. Dry the mirror with clean tissues.
- Use o-phthalaldehyde disinfectant to sterilize the scan tip for at least 5
  minutes. For details, please refer to the o-phthalaldehyde disinfectant's user manual.
- Take out the scan tip from the o-phthalaldehyde disinfectant and clean it with clean water. For details, please refer to the o-phthalaldehyde disinfectant's user manual.
- Dry the scan tip. Use a sterile and non-abrasive cloth or tissues to dry the scan tip.

6.4 Inspection and maintenance

WARNING!

No maintenance or repair work may be performed while the CORSCAN S6500 is being used with a patient!

CAUTION!

- **All maintenance and repair work may only be performed by personnel trained or authorized by CORTEX.**
- **In the process of installation, maintenance and use, try to avoid the exposure of LED, do not look directly at the LED beam from the scanning window or aim the LED beam at others.**

6.4.1 Daily Monitoring before and during the Examination Operation

Wear parts must be replaced with original components.
Prior to operation, the operator must ensure that all safety related mechanisms, indicators and/or
switches described within the user manual are fully functional and that the device is overall
operationally ready.

Check that the scan tip is attached correctly and the scan tip connection indicator LED displays solid blue light.

6.4.2 Regular Monitoring

Regularly inspect the scanner`s cables and connections for any signs of wear or damage. Wear parts must be replaced with original components. If any issues are found, contact the manufacturer for assistance or to arrange repairs.

6.4.3 Maintenance

Before using this system, users shall read this manual carefully and become familiar with all operations on the system.
Only simple maintenance is required in the operation of this equipment, while only proper operations on it can ensure its long-term stable operation. Therefore, you must fully comply with the manufacturer's instructions and recommendations.

- Clean the scanner regularly: Use a soft, non-abrasive cloth or disposable wipes to clean the scanner after each use. Avoid using harsh chemicals or excessive moisture to prevent damage.
- Store properly: When the scanner is not in use, store it in a clean, dry location at room temperature. Protect it from excessive heat, direct sunlight, and humidity.
- Handle with care: Avoid dropping or mishandling the scanner, as this may cause internal damage. When transporting the scanner, use a protective case or packaging recommended by the manufacturer.
- Protect the scanner from contamination: Use disposable covers or sleeves to prevent cross-contamination between patients. These covers should be changed regularly.
- Train and educate the users: Provide proper training to all users on the correct operation and handling of the intraoral scanner. This will help prevent accidental damage and ensure consistent and accurate results.

- Keep the scanner protected during travel: If you need to transport the scanner, use a secure and padded carrying case designed specifically for the device. This will help protect it from any accidental bumps or impact.

6.4.4 Computer Data Protection

The database must be backed up to any reusable high-capacity storage medium, such as mobile hard drive, flash drive, etc.

Store any copy of data at a safe location under the computer supplier's recommendation.

- Stay updated: Keep the scanner`s software and firmware up to date by installing any updates provided by the manufacturer. This helps ensure optimal performance and compatibility with other devices or software.
- Document usage and maintenance: Keep a record of the frequency of use, maintenance activities performed, and any issues encountered with the scanner. This documentation can be helpful for future reference, troubleshooting, or warranty claims.

6.4.5 Warranty

NOTE

CORTEX guarantees that all products supplied meet the specifications as labelled on them and contain no defect in the material or workmanship within the warranty period. The warranty period refers to 2 years after the products arrive at the dealer.

CORTEX guarantees that all products supplied meet the specifications as labelled on them and contain no defect in the material or workmanship within the warranty period. The warranty period refers to 2 years after the products arrive at the dealer.

The warranty will become invalid in any of the following cases:

- damage caused in shipping.
- damage caused by improper use or maintenance.
- damage caused by change or repair of any person other than authorized by CORTEX.
- accidental damage.
- the label indicating the serial number or manufacturer is replaced or removed.

6.4.6 Product Life Cycle

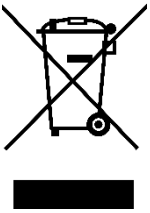
The CORSCAN S6500 is designed for a service life of 5 years when used in accordance with the specifications and regular maintenance by CORTEX service department or a service

company authorized by them. After the product has reached the end of its service life, further use is at your own risk.

6.4.7 Applied Parts and Parts Considered as Applied Parts

Part	**Definition** Applied part or part that is treated like an applied part but is not defined as an applied part.
Scan Tip	Applied part

6.4.8 Disposal Notes



The CORSCAN S6500 contains various plastics and metals. When disposing exchange and spare parts, or if necessary, the entire device, the valid rules and regulations must be observed. Please contact your contractual partner or service company or commission a company specialized in disposing the respective components.

7 Power Supply

Handpiece: 5V ⎓ 3A; optional: 12V ⎓ 6A

7.1 Guidelines and Manufacturer´s Declaration

7.1.1 Guidelines and Manufacturer´s Declaration - EMI

CORSCAN digital intraoral scanner S6500 is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment.

Measurement Interference	Compliance	Electromagnetic Environment
IEC 60601-1-2:2014 RF emission	Type B	CORSCAN's digital intraoral scanner uses RF energy exclusively for its internal function. As the result, its RF emission is very low, and it is unlikely that nearby electronic devices will be influence.
IEC 60601-1-2:2014 Conducted disturbance	Type B	
IEC/EN 61000-3-2:2014 Harmonic emissions	Type B	CORSCAN digital intraoral scanner is suitable for use in all facilities, including households and residential public low-voltage power supply networks directly connected to households
IEC/EN 61000-3-3:2013	compliant	

Measurement Interference	Compliance	Electromagnetic Environment
Voltage fluctuations and flicker emissions		The device is suitable for use in all facilities, including the residential areas and those that are directly connected to the public supply network, which also supplies buildings that are used for residential purposes, provided the following warning is observed:  **Warning:** This device is intended for use by medical professionals only.

7.1.2 Guidelines and Manufacturer´s Declaration - EMS

CORSCAN digital intraoral scanner is expected to be used in the electromagnetic environment specified below, and the purchaser or user should ensure that it is used in this electromagnetic environment.

EMS Test	**IEC60601 TEST VOLTAGE**	**COMPLIANCE VOLTAGE**	**Electromagnetic Environment**
ESD IEC 60601-1-2:2014	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	The floor should be wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30 %。
Electrical fast transient **IEC 60601-1-2:2014**	±2 kV to power line ±1 kV to in/out signal line	±2 kV to power line ±1 kV to in/out signal line	The network power supply should have the quality used in a typical commercial or hospital environment.

EMS Test	IEC60601 TEST VOLTAGE	COMPLIANCE VOLTAGE	Electromagnetic Environment
Surge **IEC 60601-1-2:2014**	±1 kV power line to line ±2 kV power line to earth	±1 kV power line to line ±2 kV power line to earth	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage dips and interruptions **IEC 60601-1-2:2014**	<5 % U_T,Duration 0.5 Period (%U_T>95 % dip and short interruptions) <5 % U_T,Duration 1 period (%U_T >95 % dip and short	<5 % U_T,Duration 0.5 Period (%U_T>95% dip and short interruptions) <5 % U_T,Duration 1 period (%U_T >95% dip and short interruptions)	The network power supply should have the quality used in a typical commercial or hospital environment. If users of CORSCAN Digital intraoral scanner need continuous operation during power

EMS Test	IEC60601 TEST VOLTAGE	COMPLIANCE VOLTAGE	Electromagnetic Environment
	interruptions) 70 % U_T, 25/30 period (%U_T 30 % dip and short interruption) <5 % U_T,250/300 (%U_T >95 % dip and short interruption)	70 % U_T, 25/30 period (%U_T 30% dip and short interruption) <5 % U_T,250/300 (%U_T >95% dip and short interruption)	interruption, it is recommended that CORSCAN Digital intraoral scanner use uninterrupted power supply or battery power supply.
Magnetic Field Immunity (50/60Hz) **IEC 60601-1-2:2014**	3A/m	3A/m/50Hz	The power frequency magnetic field should have the level characteristics of

EMS Test	IEC60601 TEST VOLTAGE	COMPLIANCE VOLTAGE	Electromagnetic Environment
			the power frequency magnetic field in a typical place in a typical commercial or hospital environment.

NOTE			
UT refers to the AC network voltage before the test voltage is applied.			
EMS Test	**IEC60601 TEST VOLTAGE**	**COMPLIANCE VOLTAGE**	**Electromagnetic Environment**
RF conduction **IEC 60601-1-2:2014** RF emission **IEC 60601-1-2:2014**	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communication equipment should not be used closer to any part of the CORSCAN Digital Dental Impression System than the recommended isolation distance, including cables. The distance should be calculated by the formula

			corresponding to the transmitter frequency. **Recommended isolation distance** d = 1.2 $\sqrt{P}$ d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz Above, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W), and d is the recommended isolation

			distance, in meters (m). The field strength of the fixed RF transmitter is determined by surveying the electromagnetic field a, and in each frequency range b should be lower than the compliance level. Interference may occur in the vicinity of equipment marked with the following symbols. 

NOTE

At 80 MHz and 800 MHz, the higher frequency band formula is used.

NOTE

These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and people.

a.) Strong fixed transmitting airports, such as: base stations of wireless (cellular/cordless) telephones and ground mobile radios, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasting and TV broadcasting, etc., the field strength is not theoretically accurate Foreknowledge. In order to assess the electromagnetic environment of a fixed RF transmitter, a survey of electromagnetic fields should be considered. If the measured field strength of the CORSCAN digital dental impression machine is higher than the RF compliance level of the above application, the CORSCAN digital dental impression machine should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or

position of the CORSCAN digital dental intraoral scanner.

b.) In the entire frequency range of 150KHz ~ 80MHz, the field strength should be lower than 3 V/m

Recommended isolation distance between portable and mobile radio frequency communication equipment and CORSCAN digital intraoral scanner					
CORSCAN digital intraoral scanner is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of the communication equipment, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the CORSCAN digital dental impression machine as recommended below.					
Maximum rated output power of the transmitter (W)	**Corresponding to the isolation distance of the transmitter at different frequencies /m**				
	IEC 60601-1-2:2007			**IEC 60601-1-2:2014**	
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{7}{E_1}]\sqrt{P}$	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.12	0.23	0.12	0.20
0.1	0.38	0.38	0.73	0.38	0.63
1	1.2	1.2	2.3	1.2	2.0

10	3.8	3.8	7.3	3.8	6.3
100	12	12	23	12	20

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d, in meters (m), can be determined by the formula in the corresponding transmitter frequency column, where P is the emission provided by the transmitter manufacturer The maximum rated output power of the machine, in watts (W).

NOTE

At 80MHz and 800MHz, the higher frequency band formula is used.

NOTE

These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and humans.

8 Technical Data

8.1 Product Specifications

Component		Parameter
Handpiece Dimension		247*43*35± 5%
Handpiece Wight		240 ± 20gram (without cable)
Light source		LED Light source: Red (617 nm), Green (520 nm), Blue (459 nm)
Anti-fogging technology		Actively heated tip
Scan mode		Video
Imaging color		True color
Accuracy (Single unit)		< 20 μm
Scanner tip	Dimensions	Standard tip: 95.3 x 22.5 x 16.6 mm, SD. ± 5%
		Small tip: 94.0 x 17.9 x 13.2 mm, SD. ± 5%
	Scan area	Standard tip: 16.0 x 13.0 mm, SD. ± 1mm
		Small tip: 12.0 x 9.0 mm, SD. ± 1mm
	Maintenance method	High temperature and pressure, immersion
	Autoclavable	Up to 100 times
Cable Length		2.0 m
Connection		USB 3.0 Type-A

Component	Parameter
Input	5V ⎓ 3A
Input (Optional)	100-240V~50/60Hz, 12 V ⎓ 6A
Output File Formats	STL, PLY, OBJ

8.1.1 Requirements on the computer system (including monitor)

The computer system (including the monitor) shall be equipped by the user according to the following listed configuration requirements:

Item	Recommended System Requirements
CPU	Intel i7 or above
RAM	32 GB or above
Hard Disk	1 TB SSD or above
Graphic	NVIDIA GeForce RTX 3060 6GB or above
Monitor resolution	1920x1080
Operating system	Windows 10 or Windows 11
USB port	USB 3.0 Type-A

8.1.2 Protection Type and Protection Class

The CORSCAN S6500 corresponds to protection class 1 and contains applied parts type BF (according to IEC 60601-1).

8.2 Environmental Conditions

8.2.1 Environmental Conditions during Operation

Ambient temperature	+5°C to +35°C
Relative humidity	<80% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa

8.2.2 Environmental Conditions for Shipping and Storage

Ambient Temperature	-20°C to +55°C
Relative humidity	<93% (non-condensing)
Atmospheric pressure	700 hPa to 1060 hPa

9 After-sales Service

CORTEX guarantees that all products supplied meet the specifications labeled on them and contain no defect in the material or workmanship within the warranty period.
The warranty will become invalid in any of the following cases.

- Damage caused in shipping.
- Damage caused by improper use or maintenance.
- Damage caused by change or repair of any person other than authorized by CORTEX.
- Accidental damage.
- The label indicating the serial number or manufacturer is replaced or removed.

Cortex declares that it uses Restriction of Hazardous Substances (EU RoHS Directive 2011/65/EU and its amendment (EU) 2015/863) compliant materials and components (based on information provided by its suppliers).

The device should be disposed of in accordance with local Waste Electrical and Electronics Equipment (WEEE) regulations. At the end of the device's useful life, contact your local distributor for disposal.

For any question on or problem in maintenance, technical specification, or equipment failure, contact your dealer or our after-sales service department.

Cortex Dental Implants Industries Ltd.
Manufacturer Address: Ya'ara Street 26, Shlomi 2283202, Israel **Tel:** +972-4-9873970
E-mail: info@cortex-dental.com
Website: https://www.cortex-dental.com

Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem,
The Netherlands
Phone: +31.70.345.8570
E-mail: EmergoEurope@ul.com

10 Description of Symbols, Labels and Abbreviations

10.1 Symbols

	**Warning**
	Caution
	Note
	Refer to the operation Instruction Manual
	Consult electronic Instructions For Use
	Recyclable
	Serial number
	Catalogue Number
	Model Number
	Unique Device Identification

	Date of manufacture
	Manufacturer information
	Authorized Representative in the European Community
	This Side Up
	Fragile Article
	Keep dry
	Keep away from sunlight
	Maximum Tiers of Stack
	Temperature Limits
	Relative humidity limit (no condensation)

	Atmospheric Pressure Limit
	Medical device
	Classification according to IEC 60601-1 (type BF applied part)
	Disposal instructions; WEEE (Waste of Electrical and Electronic Equipment)
	Class Ⅱ equipment
	CE
IPX0	Not protected from fluid ingress

10.2 Abbreviations

mm	Millimetres	SN	Serial Number
m	Meter	WAN	Wide Area Network
°C	Degree - lsius	LAN	Local Area Network
hPa	Hectopascal	CMOS	Complementary Metal Oxide Semiconductor
CE	CE marking	ESD	Electrostatic discharge
Hz	Hertz	EMI	Electromagnetic interference
V	Volt	CAD/CAM	Computer-assisted design & manufacturing
A	Ampere		