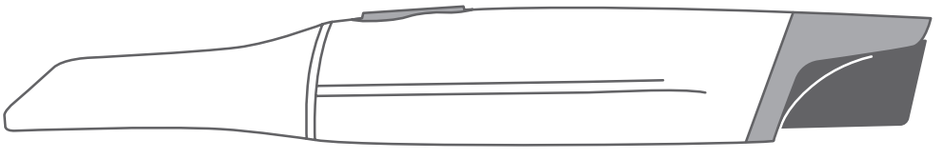
Safety and Setup Guide



3Shape TRIOS

TRIOS 6 # L1P-2

3shape

Table of Contents

1. Welcome Note 4

2. Conformity 4

3. About this Document – Hazard Symbols 4

3.1 General Information 4

3.2 Storage, Operating and Transport Conditions 4

3.3 Legend of Symbols 5

4. Description of TRIOS 6 system 5

4.1 Intended Use 5

4.2 Indications for use 5

4.3 Users of TRIOS System 5

4.4 Contraindications 5

4.5 Patient Target Group 5

4.6 System Description 5

4.7 Other System Elements Description 6

5. Setting up TRIOS 6

5.1 TRIOS Battery and TRIOS Battery Charger Description 6

5.2 Starting and Shutting Down the TRIOS System 6

5.3 Starting TRIOS Online Help 7

6. System Safety 7

6.1 Prerequisites 7

6.2 Potential Mechanical Damages 7

6.3 Explosion Hazards 8

6.4 Protection from Overheating 8

6.5 Electrical Safety 8

6.6 Eye Safety 8

6.7 Safety when Scanning 8

6.8 Epileptic Seizure 8

6.9 Hygiene 8

7. Cleaning, Disinfection, and Sterilization 9

7.1 TRIOS scanner Body and Mirror Housing: Cleaning and Disinfection 9

7.2 Pod: Cleaning and Disinfection 10

7.3 TRIOS scanner Tip: Cleaning and Sterilization 10

7.4 Cleaning of Batteries, Battery Charger and Other Parts of the System 11

8. Optical maintenance during scanning 11

9. Disposal 11

10. Technical Maintenance 11

11. Technical Specifications 11

12. Electromagnetic Compatibility 12

12.1 Electromagnetic Emissions 12

12.2 Electromagnetic Immunity 12

13. Consumable Accessories 12

14. Expected Service Life 13

15. Cybersecurity 13

16. Vigilance 13

1. Welcome Note

Dear Customer,
Thank you for purchasing your TRIOS system from 3Shape TRIOS A/S. The TRIOS system enables you to obtain oral scans of patient's teeth for use in dental CAD/CAM systems.

This TRIOS system Safety and Setup Guide describes safety precautions, warnings, and considerations related to your TRIOS system. For step-by-step instructions regarding the configuration and operation of the TRIOS system, please refer to the online help.

Before assembling or using your TRIOS system, please carefully read and follow the instructions in this Safety and Setup Guide and in the online help system. Please always keep this Safety and Setup Guide near the system.

Please follow all safety information and warnings to avoid personal injury, material damage or damage to your TRIOS system.

Thank you,
3Shape TRIOS A/S

2. Conformity

This guide is published by 3Shape TRIOS A/S, that reserves the right to improve and modify the content without prior notice. The modifications will, however, be published in future editions.

All rights reserved.

TRIOS is a trademark of 3Shape TRIOS A/S.

Manufacturer Information

3Shape Trios A/S located at Holmens Kanal 7, 1060 Copenhagen, Denmark is the legal manufacturer for the devices listed in this guide.

To learn more about 3Shape, our products and global office locations please visit our website: www.3shape.com

3. About this Document – Hazard Symbols

⚠	**WARNING** Warnings regarding situations where a medium risk or higher of injury to persons, property or environment exists if the information is not observed.
⚠	**CAUTION** Cautions regarding situations where a low risk of injury to persons, property or environment exists if the information is not observed or information which can affect system functionality if not observed.
📝	**IMPORTANT NOTICE** Important information that is not a warning/caution but must be strictly observed.

3.1 General Information

📝	**IMPORTANT NOTICE** **Be sure to observe all warnings!** Please observe all safety information and warnings to prevent personal injury, material damage or damage to your TRIOS system. Safety information and warnings are highlighted in this guide using the words **WARNING**, **CAUTION** or **IMPORTANT NOTICE**.
⚠	**CAUTION** Any person who assembles or modifies a medical electrical equipment or system complying with the standard IEC 60601-1 (safety requirements for medical electrical equipment) by combining it with other equipment is responsible for conducting appropriate inspection and testing to ensure continued safe use of the equipment and for ensuring that the requirements of this regulation are met to their full extent for the safety of the patients, the operators and the environment.

3.2 Storage, Operating and Transport Conditions

📝	**Operating Conditions** Ambient temperature range: +15 – +26 °C (+59 – +78.8 °F) Relative humidity: 10 – 85 % (non-condensing) Atmospheric pressure: 800 – 1100 hPa The TRIOS scanner should be used in an environment maintaining a consistent room temperature.
📝	**Storage Conditions** Ambient temperature range: -10 – +50 °C (+14 – +122 °F) Relative humidity: 10 – 85 % (non-condensing) Atmospheric pressure: 800 – 1100 hPa
📝	**Transport Conditions** Ambient temperature range: -10 – +50 °C (+14 – +122 °F) Relative humidity: 10 – 85 % (Non-condensing) Atmospheric pressure: 620 – 1200 hPa

3.3 Legend of Symbols

	Date of manufacture
	Manufacturer
	General warning
	Type BF applied part
	WEEE Product disposal
	Caution
CE	CE marking (applicable for accessories for European Union)
LOT	Lot number
SN	Serial Number
	Consult the electronic instructions for use
	Expiry Date
	Fragile, handle with care
	Refer to instruction manual / booklet. Follow instructions for use
	Electrical insulation Class II
MD	Medical Device
Rx Only	Prescription Only (applicable for the United States of America)
#	Model Number
UK CA	UKCA marking (applicable for accessories for Great Britain)
Li-ion	Disposal information: Li-ion battery recycling
	Device Quantity – indicates the number of pieces in the package
	Do not re-use
CC	Country of manufacture – "CC" denotes the country code
UDI	Unique Device Identifier
NON STERILE	Non- sterile
	Do not use if package is damaged
	Recycling material identification
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Keep dry
SGS c US	SGS certification mark

4. Description of TRIOS 6 system

4.1 Intended Use

L1P-2 is intended to obtain 3D digital images of the topographical characteristics of teeth, including bite, gingivae and palate directly from the patient's mouth or models of the teeth.

	CAUTION Unintended use of the TRIOS system can result in physical injury to patients, operators and damage to the TRIOS system.

4.2 Indications for use

The digital images from L1P-2 are indicated for use in:

- Restorations
- Orthodontics
- Implantology
- Assessment of dental status

4.3 Users of TRIOS System

The 3Shape TRIOS system is to be operated by legally qualified healthcare professionals in dental clinics.

Using the TRIOS system for any purpose other than outlined in the "intended use" may damage the TRIOS system and harm operators and patients. The proper use of the TRIOS system requires following the operation and maintenance instructions and observing warnings, cautions and important notices described in this user guide.

	IMPORTANT NOTICE The system is to be used in a Professional Healthcare Environment.

4.4 Contraindications

None.

4.5 Patient Target Group

The are no restrictions on patient population amongst the patient target group of the TRIOS system.

4.6 System Description

The TRIOS 6 system is available in these variants:

Regional variation can occur regarding the content of the system.

L1P-2	**TRIOS scanner, supplied with TRIOS scanner Tip, TRIOS Protection Tip, TRIOS Ready Tip, TRIOS Sleeve, TRIOS pod (holder), TRIOS Battery, and TRIOS Battery Charger.**

TRIOS 6 system consists of:

	TRIOS scanner (L1-3): Wireless handheld dental intraoral scanner for scanning a patient. Two main areas of the TRIOS scanner are referred to in this guide: mirror housing and scanner body.
	TRIOS scanner Tip (TST-11): Reusable scanner tip mounted to the TRIOS scanner to enable scanning. The TRIOS scanner Tip has a unique serial number located on the inside of each tip in the format "(21)YYXXXXXXX"

	TRIOS Ready Tip (TST-15): Single use tip mounted to the TRIOS scanner to enable scanning. For more information on TRIOS Ready Tip, refer to the TRIOS Ready Tip Instructions for Use
	TRIOS Protection Tip (TST-13): Protects the optical window of the TRIOS scanner from damage and dirt when the TRIOS scanner is not in use.

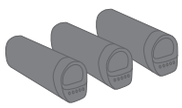
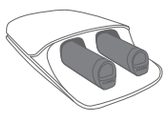
The TRIOS scanner has a built-in tip detection.

Please follow the steps below for attaching and detaching the TRIOS scanner Tip, TRIOS Ready Tip and TRIOS Protection Tip:

	1. To attach the tip, place the tip over the mirror housing facing downwards until it clicks. 2. To detach the tip, pull the tip away from the mirror housing.

	IMPORTANT NOTICE The TRIOS scanner Tip and TRIOS Ready Tip are the only applied parts of the TRIOS 6 system. The tips can only be mounted one way.
	IMPORTANT NOTICE The tips operating condition can reach up to 43 degrees Celsius.

	TRIOS Sleeve (TSL-01): Single use sleeve to cover the TRIOS scanner. For more information on TRIOS Sleeve, refer to the TRIOS Sleeve Instructions for Use.
	Pod (LP1-2): Holder for the scanner.

	**A set of batteries for the TRIOS scanner (TB-04):** Batteries for the TRIOS scanner with LED light to indicate battery status. Be aware that the batteries must be stored and operated under correct conditions, see section 3.2.
	**A battery charger (C2BP):** With two ports to charge TB-04 batteries. Be aware that the battery charger must be stored and operated under correct conditions, see section 3.2.

Power (mains) cable and plug:
The charger has a detachable cable (C8 connector) appropriate for your location, supplied in the packaging.

4.7 Other System Elements Description

	A USB wireless dongle for the PC. A USB license dongle - availability is region-dependent.

5. Setting up TRIOS

It is recommended that unpacking, assembling and connecting the TRIOS System should be performed by TRIOS authorized technical service personnel.

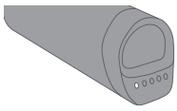
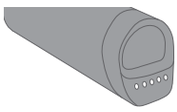
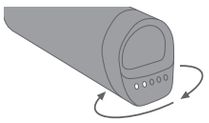
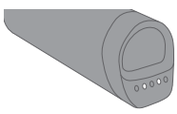
It is recommended to fully charge batteries for the TRIOS scanner before use.

	CAUTION Let the system adjust to room temperature before use.
	WARNING Examine all parts of the system. Look for physical damage, loose parts or signs of wear that could interfere with proper use and functionality. Contact your service provider if there is visible damage or malfunctioning.

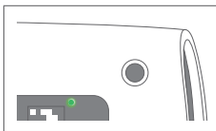
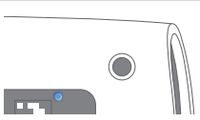
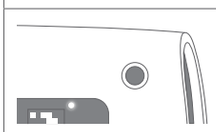
5.1 TRIOS Battery and TRIOS Battery Charger Description

Charging batteries:

Before you start: Place the TRIOS Battery Charger on a flat surface horizontally.
Step 1: Attach the power cord to the charger and plug it into mains power.
Step 2: Push the batteries one by one into the charger until they click into place. When charging, the 5 LEDs on the end of the battery will indicate the status:

	Each LED represents 20% of the battery capacity.
	Five constant LEDs means that the charging is complete.
	While charging is ongoing each LED will light up one at a time. The battery status will then be shown, with each LED representing 20% battery capacity.
	If any other charging pattern appears, a charging error has occurred. In this case, remove the batteries from the charger and reinsert them. If charging errors continue, please contact 3Shape support (support@3shape.com).

There is an LED under the TRIOS Battery Charger. The LED has the following indications:

	**Ready for use** A green light indicates the battery charger is on and working.
	**Unstable power source** A blue light indicates the power is unstable. Unplug and reinsert the power for the charger. If the LED continues to indicate a blue light please contact 3Shape support (support@3shape.com).
	**Incorrect insertion of the battery** A white light indicates the battery may have been inserted incorrectly. Try to insert the battery again. If the LED continues to indicate a white light, please contact 3Shape support (support@3shape.com).

Please follow the steps below for assembling the TRIOS system:

Before you start: Place the pod on a flat and horizontal surface optimally in relation to the patient chair and your work position. Attach the TRIOS Protection Tip to the TRIOS scanner if not already in place.	
Step 1: Insert a fully charged battery into the rear of the TRIOS scanner.	
Step 2: Place the TRIOS scanner in the pod.	
Step 3: Applicable only for TRIOS scanner Tip (TST-11). Prior to the use, clean and sterilize TRIOS scanner Tip. See section 6 for cleaning and sterilization instructions. TRIOS Ready Tip (TST-15) is a ready-to-use tip and doesn't require any prior preparation.	

5.2 Starting and Shutting Down the TRIOS System

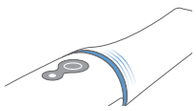
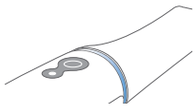
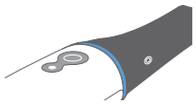
Please follow the steps below to start TRIOS System for the first time:

Before you start: Insert the USB wireless dongle and the USB license dongle, if delivered with the system, into the USB ports on your PC.
Step 1: Turn on the PC. Start the 3Shape software if it is not starting automatically.
Step 2: Follow the on-screen instructions to configure user settings.

Step 3: Follow the on-screen instructions for configuring TRIOS system settings, such as connecting the TRIOS scanner.

When using the TRIOS system, the user is guided by messages shown in the TRIOS software.

The TRIOS scanner has a LED ring which indicates the status of the scanner:

	**Searching for scanner software** Three blue blinks indicate that the TRIOS scanner is searching for a nearby scanner application to connect to.
	**Establishing connection** A rotating blue light indicates that the TRIOS scanner has located a scanner application and is establishing a connection to it.
	**Awaiting the tip to be mounted** A constant blue light indicates that the TRIOS scanner is connected to the system, but no tip is mounted.
	Heating up the tip A rotating green light indicates that the TRIOS scanner is heating the tip.
	Ready for use A constant green light indicates that the TRIOS scanner is ready to scan.
	Awaiting scan data A rotating white light indicates that the TRIOS scanner is waiting for scan data.
	Obtaining scanning data A constant white light indicates that the TRIOS scanner is scanning. The light intensity decreases if the TRIOS scanner loses scan focus.
	Battery Low Solid yellow indicates that the battery is low.

Scanner operation

The scanner has two buttons for operation; the button closest to the tip controls scanning operation, the button farthest from the tip controls navigation.

Power saving

The TRIOS scanner has integrated power control, and will go into sleep mode when not used, unless the software is on the Scan page.

5.3 Starting TRIOS Online Help

The TRIOS online help can be started from the TRIOS software by clicking on the Help button and choosing User Manual.

6. System Safety

6.1 Prerequisites

Training

CAUTION
Before you attempt to use the TRIOS system with patients:
- You must have read and understood all sections of this guide describing correct operation.
- You must be thoroughly familiar with the safe operation of the TRIOS system as described in this documentation.
- If the instructions for operating the TRIOS system as described in this guide are not observed and followed, the intended function and its safety for the user and patient may be impaired.

Preventive inspection before use of the system

WARNING
Please examine the TRIOS system for any mechanical damage on:
- All enclosures.
- All cables.

Safety can only be guaranteed if no damage to the TRIOS system is observed.

Modifications of the system

WARNING
Do not modify the TRIOS system without authorization from the manufacturer.

Approved software only

CAUTION
Install only 3Shape approved software – to prevent interference with TRIOS system performance.

Only connect specified items

CAUTION
Only connect items that have been specified as part of the TRIOS system or have been specified as being compatible with the TRIOS system.

In case of equipment failure

CAUTION
If at any time the TRIOS system malfunctions, or if you suspect that the TRIOS system is not working correctly:
- Remove the TRIOS scanner from patient contact immediately.
- Remove the battery and make sure it cannot be used before it is checked.
- Contact 3Shape support.
- Do not attempt to open any covers on the TRIOS system.

Radio performance

Connection	Type	Recommended use distances
Scanner – PC	Wireless	Distance between TRIOS scanner and wi-fi dongle/access point should be between 0.5 and 5m for best performance.

CAUTION
Other portable and mobile RF communication equipment could interfere with the wireless TRIOS scanner, even if the other equipment complies with emission requirements.

CAUTION
The wireless TRIOS scanner could interfere with other portable and mobile RF communication equipment.

IMPORTANT NOTICE
It is recommended to keep a line of sight between the wireless TRIOS scanner and the USB wireless dongle attached to the PC.

6.2 Potential Mechanical Damages

Inspect TRIOS scanner Tip and TRIOS Ready Tip before using

WARNING
Damaged tip may cause injuries to the patient. Inspect the tips before the use to ensure that there is no damage to the tips surface.

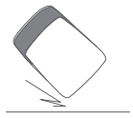
Dropped or damaged equipment

WARNING
Performance of the tip is compromised when dropped. If the tips are dropped on the floor, they must be discarded and not to be used for scanning. (see this guide's instructions in section 9. Disposal).

WARNING
The performance of the TRIOS scanner may be compromised when dropped. If the handheld scanner is dropped or bumped, it must be checked immediately before further use.
- Remove the battery, tip and sleeve from the scanner.
- Examine the TRIOS scanner for any mechanical damage or malfunction.
- If at any time the TRIOS system malfunctions, or if you suspect in any way that the TRIOS system is not working correctly contact your reseller or 3Shape support.

WARNING
The performance of the battery may be compromised when dropped. If a battery is dropped, it must be examined for any mechanical damage or malfunction. If a mechanical damage or malfunction is observed or suspected, the battery must be disposed of (see this guide's instructions on 9. Disposal).

WARNING
The performance of the battery charger may be compromised when dropped. If the battery charger is dropped, it must be checked immediately before further use:
- Unplug the battery charger and make sure it cannot be used before it is checked.
- Battery charger must be examined for any mechanical damages or malfunction.
- If mechanical damage or malfunction is observed, please contact 3Shape support (support@3shape.com).



CAUTION
To prevent overbalancing the system, always place the TRIOS system on a horizontal surface.

6.3 Explosion Hazards

Flammable liquids or gases

WARNING
The TRIOS system is not designed to be used in potentially explosive environments. Do not use the TRIOS system in close proximity to flammable liquids or gaseous flammable anaesthetic, or in oxygen-enriched atmospheres.

6.4 Protection from Overheating

CAUTION
The scanner may become uncomfortably warm and eventually shut down if the ventilation is obstructed.

To avoid the risk of the incresed surface temperature, the ventilation openings in the rear of the handheld scanner must never be blocked or obstructed.

6.5 Electrical Safety

Do not open the covers of the TRIOS system

WARNING
There is a risk of electrical shock if you attempt to access the inside of any part of the TRIOS system. Only authorized and qualified service personnel may access the inside of any part of the system.

Spilled liquids

WARNING
The electrical safety of the system may be compromised if it is exposed to any liquids. Do not bring liquids, such as beverages, near the TRIOS system. Do not spill liquids, such as cleaning agent, on the TRIOS system.

Condensation

CAUTION
Variations in temperature or humidity may cause water to condense inside the system, which can cause damage. Always let the system reach room temperature before you turn it on.

If you suspect that the system has been exposed to major temperature or humidity changes, wait at least 8 hours before turning it on.

Please see operating conditions for further information in section 3.2 Storage, Operating and Transport Conditions.

Disconnect the battery charger before cleaning

WARNING
The electrical safety of the system may be compromised if it is exposed to excessive amounts of cleaning liquids. Disconnect the battery charger from power before cleaning and allow to dry before reconnecting.

Disconnecting from mains

IMPORTANT NOTICE
There is no power ON/OFF switch on the battery charger; therefore, the only reliable means to disconnect the system from mains is to unplug the battery charger power cord. Do not position the system so that it is difficult to unplug the charger power cord.

PC connection options and requirements

IMPORTANT NOTICE
The PC should be located at least 1.5 m away from the patient. Do not scan the patient and touch the PC or any of its peripherals at the same time. You must not touch any peripherals connected with a cable to the PC while scanning a patient.

6.6 Eye Safety

CAUTION
The TRIOS scanner emits bright light from the scanner tip during the operation. Do not view directly into the light source as it might cause temporary vision distortion. The TRIOS scanner complies with IEC 62471 (Photobiological safety of lamps and lamp systems).

6.7 Safety when Scanning

CAUTION
The TRIOS scanner is a highly precise optical instrument and must be handled carefully. Do not drop, shake or bump the TRIOS scanner, as these actions could cause it to break or malfunction. Follow these guidelines:
- Always return the TRIOS scanner to its holder when not in use.
- Do not submerge the TRIOS scanner in any liquids.
- Do not place the TRIOS scanner on heated or wet surfaces.
- Grip the TRIOS scanner firmly during scanning and when removing or returning it to its holder.

IMPORTANT NOTICE
The TRIOS scanner will get warm during use. This is normal but not part of any patient treatment.

CAUTION
The TRIOS scanner Tip is fragile and contains a delicate window. To avoid damage to the tip and window, take care not to bump the tip onto the patient's teeth or restorations.

6.8 Epileptic Seizure

WARNING
There is a risk of injuries if the TRIOS scanner Tip is bitten. As a direct effect of an epileptic seizure, various degrees of involuntary biting can occur. Avoid any patient biting on the scanner tip or bumping the scanner tip into the teeth.

6.9 Hygiene

For instructions on cleaning and disinfection or sterilization go to section 7.

TRIOS Sleeve single use only

WARNING
TRIOS Sleeve must only be used once to avoid cross-contamination.

For instructions on how to mount the single use sleeve see the TRIOS Sleeve Instructions for Use.

TRIOS Ready Tip storage

WARNING
TRIOS Ready Tip must be stored in the original packaging before use.

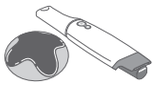
Always wear gloves

WARNING
To maintain a clean work environment and the safety of the patient, wear clean examination gloves when:
- Handling the TRIOS scanner Tip or TRIOS Ready Tip– changing the tip or handling the window.
- Handling the TRIOS Protection Tip.
- Applying the TRIOS scanner for scanning patients.
- Touching the TRIOS system.

Prepare the TRIOS scanner

WARNING
In order to avoid cross-contamination between patients before each use you must:
- apply a sterilized TRIOS scanner Tip or TRIOS Ready Tip to the TRIOS scanner.
- apply TRIOS Sleeve to cover the TRIOS scanner. See TRIOS Sleeve Instructions for use for more information.

Reprocess system after each patient

⚠	**WARNING** In order to avoid cross-contamination between patients you must before each use: • clean and disinfect or sterilize relevant parts of the TRIOS system. • clean and disinfect the TRIOS scanner before attaching the TRIOS Protection Tip. • change the TRIOS Sleeve.	

Clean and disinfect TRIOS scanner before mounting TRIOS Protection Tip

⚠	**WARNING** TRIOS Protection Tip must be mounted to the clean and disinfected TRIOS scanner. Do not allow patient contact with the TRIOS Protection Tip.

Scan only with TRIOS scanner Tip or TRIOS Ready Tip on

⚠	**WARNING** The tip must be mounted when the scanner is inserted into the patient's mouth or when the scanner comes in contact with the patient in any way in order to avoid cross-contamination. The tip prevents the patient from being exposed to a high temperature, ensures maximal electrical safety, and maintains the intended function of the scanner.
📋	**IMPORTANT NOTICE** Before each patient, make sure any PC connected to the system and its peripherals are disinfected. It is recommended to use medical-grade peripherals (e.g., keyboards and mice) that can be cleaned and disinfected easily.

7. Cleaning, Disinfection, and Sterilization

The following TRIOS system items shall be cleaned and disinfected or sterilized. Instructions are described in the following sections: 7.1, 7.2 and 7.3.

	TRIOS scanner body and mirror housing Cleaning and disinfection. See section 7.1
	Pod Cleaning and disinfection. See section 7.2
	TRIOS scanner Tip Cleaning and sterilization. See section 7.3

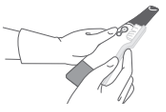
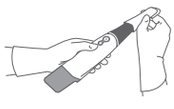
Accessories and materials: Cleaning and disinfection

The following accessories and materials are recommended to use for cleaning and disinfection.

	Examination gloves
	Cleaning/disinfectant wipes containing Isopropanol (17.2%) and ammonium chloride E.g. CaviWipes.
	Soft bristled brush E.g. Curaprox ultra soft toothbrush.
	A non-enzymatic pH neutral detergent E.g. Intercept.
	Non-woven swab E.g. Abena non-woven swabs.
	US FDA-cleared sterilization pouch

7.1 TRIOS scanner Body and Mirror Housing: Cleaning and Disinfection

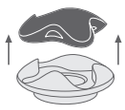
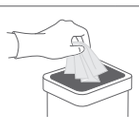
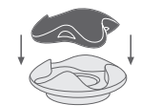
Clean and disinfect the TRIOS scanner body and mirror housing after each patient treatment (step 1-4). Also note that the scanner window is a delicate optical component and should be handled with extra care during cleaning and disinfection (see below).

Step 1: Remove gross contaminants	
	Wearing gloves, remove TRIOS Sleeve and TRIOS scanner Tip or TRIOS Ready Tip from TRIOS scanner body.
	Take a CaviWipe.
	Wipe the surface of the TRIOS scanner body and mirror housing with a CaviWipe to remove any gross contaminants.
	Dispose of the CaviWipe.
Step 2: Clean with brush	
	While still wet from the CaviWipe, use a dry soft bristled brush to clean around the gasket area (where the TRIOS scanner body and mirror housing connect).
	Use the brush to clean around the silicone button area.
Step 3: Wipe clean	
	Take another CaviWipe.
	Wipe the surface of the TRIOS scanner body and mirror housing with a CaviWipe.
	Dispose of the CaviWipe.
Step 4: Disinfect	
	Take a CaviWipe.
	Wet the surface of the TRIOS scanner body and mirror housing with the CaviWipe for a minimum of 120 seconds to disinfect. Allow to dry.
	Dispose of the CaviWipe.
	Place TRIOS protection Tip on TRIOS scanner.

⚠	**CAUTION** The TRIOS scanner's window is a delicate optical component. Its clean and undamaged surface is critical for the scan quality. The window should be handled with care. Make sure it is free from lint, stains, and other kinds of dirt.
⚠	**CAUTION** Never submerge the TRIOS scanner into any cleaning or disinfection solution.

7.2 Pod: Cleaning and Disinfection

Clean and disinfect the pod after each patient treatment. Disassemble the pod in order to thoroughly clean it. Follow the instructions below (step 1-6)

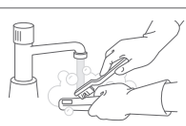
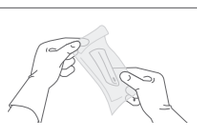
Step 1: Disassemble pod	
	Wearing gloves, remove the rubber insert from the pod (holder) by pressing down on the middle using a thumb and gripping the outer edge with the index finger.
Step 2: Remove gross contaminants from rubber insert	
	Take a CaviWipe.
	Wipe the surface of the top rubber insert to remove any gross contaminants.
	Dispose of the CaviWipe.
Step 3: Remove gross contaminants from metal holder	
	Take a CaviWipe.
	Wipe the surface of the metal holder to remove any gross contaminants.
	Dispose of the CaviWipe.
Step 4: Disinfect rubber insert	
	Take another CaviWipe.
	Wet the surface of the rubber insert for minimum 120 seconds to disinfect.
	Dispose of the CaviWipe.
Step 5: Disinfect metal holder	
	Take a CaviWipe.
	Wet the surface of the metal part for minimum 120 seconds to disinfect.
	Dispose of the CaviWipe.
Step 6: Assemble pod	
	Allow both parts to dry. Assemble the pod (holder).

7.3 TRIOS scanner Tip: Cleaning and Sterilization

TRIOS system is compatible with two sets of tips. A reusable TRIOS Scanner Tip (TST-11) and a single use TRIOS Ready Tip (TST-15). To ensure the proper usage and reprocessing, follow the instructions below:

⚠	**WARNING** TRIOS Scanner Tip (TST-11) must be cleaned and sterilized prior to its first use on patients. The TRIOS scanner Tip can be reprocessed up to 100 times and must be disposed afterwards as described in section 9. Disposal.

⚠	**WARNING** TRIOS Ready Tip (TST-15) must only be used once to avoid cross-contamination.

Step 1: Clean TRIOS scanner Tip	
	Wearing gloves, clean the TRIOS scanner Tip manually using detergent diluted according to manufacturer's instructions. Apply the detergent directly on a soft bristled brush. Wash the TRIOS scanner Tip under running lukewarm (30-40 °C) utility water.
	Inspect the window of the TRIOS scanner Tip after cleaning. If the window appears with stains, smudged or with a milky haze, repeat this step.
Step 2: Rinse and dry TRIOS scanner Tip	
	Rinse with lukewarm (30-40 °C) tap water to remove any residual detergent.
	Dry the TRIOS scanner Tip carefully with a non-woven swab.
Step 3: Sterilize TRIOS scanner Tip	
	Put the TRIOS scanner Tip in a sterilization pouch.
	Seal the pouch. Use either a self-adhesive or heat-sealed pouch.
	Sterilize the pouched TRIOS scanner Tip in a Dynamic-Air-Removal Steam Sterilizer (Class B autoclave) with one of the two programs depending on your region: In the US: Autoclave the TRIOS scanner Tip at 132 °C (269.6 °F) with a cycle of 4 minutes exposure time and 30 minutes dry time. In the EU: Autoclave the TRIOS scanner Tip at 134 °C (273.2 °F) with a cycle of 3 minutes exposure time and 30 minutes dry time.

⚠	**CAUTION** The window in the TRIOS scanner Tip is a delicate optical component. Its clean and undamaged surface is critical for the scan quality. The window should be handled with care. Do not scratch it. Be careful not to smudge it before scanning a patient.
⚠	**CAUTION** Never autoclave a TRIOS scanner Tip that is not placed in the sterilization pouch, since this will leave unremovable stains on the mirror. See the autoclave manual for more information.

📋	**IMPORTANT NOTICE** It is recommended to clean TRIOS scanner Tip immediately after use to ease the reprocessing.

7.4 Cleaning of Batteries, Battery Charger and Other Parts of the System

For cleaning of batteries, battery charger, and other parts of the system, please follow the instructions below:

	Cleaning of battery: Apply a mild detergent to a soft, damp cloth and wipe the surface of the battery.
	Cleaning of battery charger: Apply a mild detergent to a soft, damp cloth and wipe the surface of the battery charger.

For general cleaning, apply a mild detergent to a soft, damp cloth and wipe the surface of the area of the TRIOS system to be cleaned.

⚠	**WARNING** Do not spray directly onto any parts of the system, as the liquid solution can accumulate at the seals and leak into the TRIOS scanner, cords or pod.

8. Optical maintenance during scanning

In case of smudges or stains on the TRIOS scanner Tip window, TRIOS Ready Tip window, or the TRIOS scanner window, follow these steps for optimal scan quality:

Step 1: Take a damp non-woven swab and gently rub it on the inside and outside of the TRIOS scanner Tip window, TRIOS Ready Tip window as well as on the window on the mirror housing.
Step 2: Use a dry non-woven swab to dry the windows.

⚠	**CAUTION** Do not use acetone, Isopropyl Alcohol, or any oxidizing solutions to clean the TRIOS scanner Tip window or TRIOS Ready Tip window.

If the problem persists, please contact 3Shape support (support@3shape.com).

9. Disposal

Disposal of the TRIOS scanner, battery charger and batteries

Please dispose according to standard operating procedure or local regulations for the disposal of electronic waste.

⚠	**CAUTION** Dispose the TRIOS scanner and the battery charger as electronic waste.
⚠	**CAUTION** Batteries need to be removed and recycled or disposed of properly. TRIOS scanner batteries need to be disposed of as lithium-ion batteries. Lithium-ion batteries are recyclable and must not be treated as unsorted municipal waste, but must be collected separately.
🗑	Electronic waste must not be treated as unsorted municipal waste, but must be collected separately! Please contact 3Shape support (support@3shape.com) who can inform you about the local requirements for disposal of electronical, clinical waste. By disposing of the device in the proper manner, you help to avoid possible hazards for the environment and public health that could otherwise be caused by improper treatment of waste equipment.

Disposal of the TRIOS scanner Tip, TRIOS Ready Tip and TRIOS Sleeve

Please dispose according to standard operating procedures or local regulations for the disposal of clinical waste.

⚠	**CAUTION** Dispose the TRIOS scanner Tip, TRIOS Ready Tip and TRIOS Sleeve as clinical waste.

Disposal of the other parts of TRIOS System and packaging

Please dispose according to standard operating procedure or local regulations for the disposal of general waste.

For more information, contact 3Shape support (support@3shape.com).

10. Technical Maintenance

⚠	**CAUTION** All technical service and repair of the TRIOS system must be performed by 3Shape or 3Shape-authorized personnel only.

No regular maintenance of the TRIOS system is needed other than cleaning, disinfection and sterilization, as described here. Preventive and scheduled maintenance are not required.

11. Technical Specifications

Light source specifications	Do not view directly with optical instruments, such as spectacle microscopes. The product complies with IEC 62471 (Photobiological safety of lamps and lamp systems and UL-standard US code of federal regulations, 21 CRF 1040.10 and 1040.11.)	
	Type	**Light emission**
	Actinic UV	0 W/m²
	Near UV	0.052 W/m²
	Blue light	2853.67 W/(sr·m²)
	Retinal thermal	33192.49 W/(sr·m²)
	Retinal thermal, weak visual stimulus	60.57 W/(sr·m²)
	IR radiation, eye	0.02 W/m²
Sterilization	TRIOS scanner Tip (TST-11) - Sterilize by autoclave (see section 7.3 for the autoclave specification)	
Power input	C2BP: Battery charger Insulation class: Class II L1-3 scanner. Wireless, battery powered 3Shape TB-04 Battery: 3.6 V, 3300 mAh, 12 Wh	
Wireless	The TRIOS scanner contains an IECC 802.11 ac/a/b/g/n module	
Wireless Transmit Power	Maximum 100 mW (the actual transmit power is dependent on local regulations and the configuration of the product.)	
Wireless Frequency Band	Direct link (USB wireless dongle): Ch. 36 - 48, 5150-5250 MHz Ch. 149-161, 5725-5825 MHz Access point (TRIOS Share): Ch. 1-13 (11), 2400-2483.5 MHz (configuration) Ch. 36-48, 5150-5250 MHz Ch. 52-64, 5250-5350 MHz Ch. 100-144, 5470-5725 MHz Ch. 149-165, 5725-5850 MHz (the actual frequencies are dependent on local regulations and the configuration of the product.)	

Wireless Connection

The TRIOS scanner is intended to be used indoors or in commercial electromagnetic environment. The wireless connection is intended to relay image stream data and control data between the TRIOS scanner and the TRIOS software. The communication between TRIOS scanner and TRIOS software is handled by 3Shape communication services.

IT Network equipment

The TRIOS device can be connected to an IT Network for the purpose of Internet connection, data transmission between scanner and PC, and communication with other 3Shape products on an IT Network.

Network characteristics	IPv4 or IPv6 Static or dynamic address.
Network configuration	Firewall open for ports found on https://help.3shape.com/en-US/ under 3Shape Unite (Dental Desktop Network requirements and Connections). For further information on network configuration, contact 3Shape Support.
Security specification	It is recommended to use password protection on wireless network.
Connectivity specification	RJ45, IEEE 802.3 10/100 /1000BASE-T, Cat 5e All RJ45 sockets provide galvanic isolation between the device and IT Networks by a network isolator. IEEE 802.11 ac/a/b/g/n

IMPORTANT NOTICE
The device must be connected to an IT Network to transmit and receive data via the network. Integration of the device into an IT Network may lead to unknown IT security risks for users of the device or risk of compromising the stability or ability to use the device.

Network security is the responsibility of the customer's organization.

IMPORTANT NOTICE
If the TRIOS intraoral scanner system is connected to IT Network equipment, it is strongly recommended to apply network security measures and to analyze, evaluate, and control the IT network.

Analysis of IT Network security measures is recommended for:
- Changes to network configuration
- Addition of new devices
- Removal of devices
- Updates and Upgrades to devices

12. Electromagnetic Compatibility

The product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information.

The TRIOS system has been tested according to Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests, IEC 60601-1-2 ed. 4.0, and IEC 60601-1-2 ed. 4.1.

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

WARNING
Use of the TRIOS system adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the TRIOS system and the other equipment should be observed to ensure normal operation in the used configuration.

WARNING
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TRIOS system, including cables specified by the manufacturer. Otherwise degradation of the performance of system may occur.

IMPORTANT NOTICE
Portable and mobile RF communications equipment can affect medical electrical equipment.

12.1 Electromagnetic Emissions

The TRIOS system complies with the requirements IEC 60601-1-2 (Ed. 4.0 and Ed. 4.1) clause 7 (Emissions).

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

Emission measurement	Conformity	Electromagnetic environment – guidelines
Radiated RF CISPR 11	Group 1, Class B	The TRIOS system generates or uses RF energy only for its internal functioning. The TRIOS system is intended for use in Professional Healthcare Facility Environment including domestic establishments directly connected to the low voltage power supply network.

12.2 Electromagnetic Immunity

The TRIOS system complies with the requirements IEC 60601-1-2 (Ed. 4.0 and Ed. 4.1) clause 8 (Immunity). The test levels for immunity to RF electromagnetic fields are selected according to general test conditions for medical equipment.

The TRIOS system is intended for use in a Professional Healthcare Facility Environment with the electromagnetic environment specified below. The user of The TRIOS system should ensure that it is used in such an environment.

Immunity test	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m in the frequency range 80 MHz to 2.7 GHz	The TRIOS system is intended for use in Professional Healthcare Facility Environment.
Power frequency magnet field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic or hospital environment.
Proximity magnetic fields 9 kHz – 13.56 MHz IEC 61000-4-39	134.2 kHz: 65 A/m, 2.1 kHz pulse modulation 13.56 MHz: 7.5 A/m, 50 kHz pulse modulation	The TRIOS system is only intended for use in Professional Healthcare Facility Environment.
Note: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.		

A separation distance of 30 cm (12 inches) was utilized to determine compliance levels between the TRIOS system and any Portable RF communications equipment (transmitters), including peripherals such as antenna cables and external antennas. The TRIOS system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TRIOS system can help prevent electromagnetic interference by maintaining the 30 cm (12 inches) separation distance.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Band (MHz)	Service	Immunity test level (V/m)
380-390	TETRA 400	27
430-470	GMRS460, FRS 460	28
704-787	LTE Band 13, 17	9
800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	28
1700-1990	GSM 1800; CDMA 1900; GSM 1900; LTE Band 1,3,4, 25, UMTS	28
2400-2570	Bluetooth, WLAN, 802.11 ac/b/g/n, RFID 2450 LTE Band 7	28
5100-5800	WLAN 802.11 ac/a/n	9

13. Consumable Accessories

The consumable accessories to the TRIOS system are TRIOS scanner Tip, TRIOS Ready Tip, batteries and TRIOS Sleeve. New consumable accessories can be reordered by contacting 3Shape support or the reseller.

Replacements

TRIOS scanner Tip	Tips 3-pack TST-11-3
TRIOS Ready Tip	Single-use tip TST-15
TRIOS Sleeve	TRIOS Sleeve TSL-01
TRIOS Battery	Battery 3-pack TB-04-3

14. Expected Service Life

The expected service life of the TRIOS system is 5 years.

15. Cybersecurity

Cybersecurity controls and recommendations can be found in sections "Software Recommendations" in TRIOS Module User Manual.

The User Manuals can be accessed through the Help Center in the software or through www.3shape.com.

16. Vigilance

In case of any serious incident that has occurred in relation to the use of the device, please report the incident to 3Shape at email: support@3shape.com and please report it to the competent authority of the state in which the user and/or patient is established.

Notes

10037209A 2024-10 Copyright 3Shape TRIOS A/S

Let’s change dentistry together

More information at 3Shape.com

MD

3Shape TRIOS A/S
Holmens Kanal 7
1060 Copenhagen
Denmark