

# 3Shape TRIOS

Safety and Setup Guide



# S1P-2, S1P-4, S1A-10, S1A-12, S1A-22

04-2021

3shape 

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## 1. Dear Customer

Thank you for purchasing your TRIOS® intraoral scanner (IOS) system from 3Shape TRIOS A/S.

The TRIOS IOS system enables you to perform and digitally save oral scans of patient's teeth for use in dental CAD/CAM systems.

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

Before assembling or using TRIOS IOS 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 observe all safety information and warnings to prevent personal injury, material damage or damage to your TRIOS IOS system.

Thank you,  
3Shape TRIOS A/S

## 2. Conformity

This guide is published by 3Shape TRIOS A/S, who reserves the right to improve and modify the contents without prior notice. 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 legal manufacturer for devices listed in this guide.

To learn more about 3Shape, our products and global office locations please visit our website: [www.3shape.com](http://www.3shape.com)

If you would like to receive a free printed copy please contact 3Shape support via email, [support@3shape.com](mailto:support@3shape.com).

### Declaration of Conformity (EU):

3Shape TRIOS A/S hereby declares that the TRIOS observes the provisions of:

- Medical Device Regulation (EU) 2017/745 (MDR),
- Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU (RoHS),
- Waste Electrical and Electronic Equipment Directive 2012/19/EU (WEEE),
- Registration, Evaluation, Authorization and Restriction of Chemicals Regulation 1907/2006/EC (REACH)

and is in compliance with the following standards: EN (IEC) 60601-1, EN (IEC) 60601-1-2, EN (IEC) 60601-1-6, EN (IEC) 62471.

## 3. General Information

	<p><b>CAUTION</b> <b>Be sure to observe all warnings!</b></p> <p>Please observe all safety information and warnings to prevent personal injury, material damage or damage to your TRIOS IOS system. Safety information and warnings are highlighted in this guide using the words <b>WARNING</b>, <b>CAUTION</b> or <b>IMPORTANT NOTICE</b>.</p>
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### 3.1 About this Document – Symbols

The symbols used in this document imply the following:

	<p><b>WARNING</b></p> <p>Warnings regarding situations where a medium risk of injury to persons exists if the information is not observed. (Black on yellow)</p>
	<p><b>CAUTION</b></p> <p>Safety information where hazards such as slight risk of injury to persons, risk of property damage or damage to the system exist if the information is not observed.</p>
	<p><b>IMPORTANT NOTICE</b></p> <p>Important information that is not a warning/caution but must be strictly observed.</p>
	<p><b>TIPS</b></p> <p>Hints, tips, additional information to support optimal operation of the system.</p>

### 3.2 Legend of Labels and symbols

	Date of manufacture
	Manufacturer
	General warning sign– (black on yellow)

	Type BF applied part
	WEEE Product disposal symbol
	Caution
	CE marking
	Lot number
	Serial Number
	Consult instructions for use
	Alternating Current
	Protective Earth (ground)
	Warning – dangerous voltage (black on yellow)
	Expiry Date
	Standby
	Local area network, Ethernet connector (RJ45)
	Refer to instruction manual / booklet. Follow Instruction for Use (white on blue)
	Warning (black on yellow): Possibly hazardous optical radiation emitted from this product. Do not stare at operating lamp. May be harmful to the eyes. The present system is in risk group 2.
	The calibration patches must not be touched and must not be exposed to liquids (red on white).
	Mass of the TRIOS IOS system, incl. safe working load (in kilograms)
	Identifies the protection tip

	Identifies the calibration tip
	Medical Device
	Global Trade Item Number
	Prescription Only (applicable in the United States)
	Model Number

## 4. Description of TRIOS

### 4.1 Certification and Compliance Notes

#### CE Marking

This product bears CE marking in accordance with the provisions of Medical Device Regulation (EU) 2017/745, Registration, Evaluation, Authorization and Restriction of Chemicals Regulation 1907/2006/EC, Restriction of Hazardous Substances in Electrical and Electronic Equipment Directive 2011/65/EU, and Waste Electrical and Electronic Equipment Directive 2012/19/EU.

	<b>CAUTION – EU only</b> <b>CE marking for connected products</b> Further products which are connected to this unit must also bear CE marking.
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#### Electrical Safety

This system has been tested to conform with the EN (IEC) 60601-1 Safety Standard for medical electrical devices with Patient applied part (the standard title is: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), EN (IEC) 60601-1-2 Medical electrical equipment Part 1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, and EN (IEC) 62471 Photobiological safety of lamps.

The system has also been tested to conform with CAN/CSA-C22.2 No. 60601-1:14 and ANSI/AAMI ES60601-1 +C1(2009) + A1 (2012) + A2 (2010).

	<b>WARNING</b> Any person who assembles or modifies a medical electrical equipment or system complying with the standard EN (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.
	<b>WARNING</b> Use of the UNIT adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the UNIT and the other equipment should be observed to ensure normal operation in the used configuration.

	<p><b>WARNING</b></p> <p>The product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the TRIOS Technical Data.</p>
	<p><b>IMPORTANT NOTICE</b></p> <p>The system is to be used in a Professional Healthcare Environment.</p>

## 4.2 Intended Use

The 3Shape TRIOS 3 IOS system 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. See the online help for a list of supported indications.

	<p><b>CAUTION</b></p> <p>Unintended use of the TRIOS IOS system can result in physical injury to patients, operators and damage the system.</p>
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## 4.3 Users of TRIOS

The 3Shape TRIOS IOS system is to be operated by legally qualified healthcare professionals in dental clinics. Using the TRIOS IOS system for any purpose other than the "intended use" described above may damage the TRIOS IOS system and harm operators and patients. Proper use of the TRIOS IOS system includes following the operation and maintenance instructions, and observing warnings and caution descriptions in this user guide.

	<p><b>WARNING</b></p> <p><b>Carefully follow the instructions in this guide</b></p> <p>If the instructions for operating the TRIOS IOS system as described in this guide are <b>NOT</b> observed, the intended protection and safety of the user and patient may be impaired.</p>
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## 4.4 Contra-indications

None

## 4.5 Patient Target Group

No restrictions in patient population

## 4.6 System Description

**The system is available in these variants:**

Regional variation can occur regarding the contents of the systems.

<b>S1P-2</b>	<b>Pen grip scanner, supplied with a pod (holder) that is connected to an external PC via an Ethernet cable, and a cord.</b>
<b>S1P-4</b>	<b>Pen grip scanner (monochromatic variant), supplied with a pod (holder) that is connected to an external PC via an Ethernet cable, and a cord.</b>
<b>S1A-10</b>	<b>Pen grip scanner, supplied with a MOVE® cart with built-in PC.</b>
<b>S1A-12</b>	<b>Pen grip scanner (monochromatic variant), supplied with a MOVE cart with built-in PC.</b>
<b>S1A-22</b>	<b>Pen grip scanner, supplied with a MOVE®+ cart with built-in PC.</b>

You can find the figures in the final section of this guide. All system variants comprise (Figure 1)

- **Handheld TRIOS intraoral scanner, S1-2 or S1-4 (S1):** Wired handheld dental intraoral scanner for scanning the surface of the patient's teeth either in colour (S1-2) or monochrome (S1-4).
- **Scanner Tip (S-Tip) (S2):** Re-usable scanner tip attached to the handheld TRIOS scanner. The tip has a fixed window. When the tip is detached, the scanner's optical window (S4) is visible. A set of scanner tips is delivered with the scanner. The scanner tip must be cleaned and sterilized prior to first use on a patient and after each use on a patient. The scanner tip is the only applied part.
- **Protection Tip, (S-Ptip) (S3):** Protects the optical window of the scanner from damage and dirt when the scanner is not in use. When the tip is detached, the scanner's optical window (S4) is visible.

The scanner tip as well as the protection tip can be attached by the following procedure:

1. Place the tip over the front tube with the mirror facing upwards or downwards.
2. Mount the tip in a linear direction until a mechanical click is felt.
3. The tip is removed doing the opposite procedure:
4. Pull the tip away from the scanner body (S4).

- **Calibration Tip (S-Ctip) (S5):** Used for calibrating TRIOS scanners.
- **Color Calibration Kit, (S-Ckit) (S6):** Used for calibrating TRIOS scanners. The kit consists of the color calibration target (S7), the sleeve (S8), and the color calibration adaptor (S9).
- **TRIOS software:** Scan application/user interface for the scanner.
- **Power (mains) cable and plug:** The system is delivered with a cable appropriate for your location. In the USA and Canada, this is a Nema 5-15P Hospital Grade mains power cord with plug for the MOVE/MOVE+ cart.

### System with cart (S1A-10, S1A-12, S1A-22) furthermore comprises:

MOVE cart C 4.0 and MOVE+ cart C 4.1 (Figure 2, 3 & 4) for intraoral digital impression system. Following description applies to both MOVE and MOVE+ cart:

- Has an adjustable monitor (S10, S11, S12).
- Has a **scanner mount** (S13) for holding the scanner while not in use.
- Has **wheels** for mobility (and brakes (S14) if mobility is not desired).
- **Computer unit.** Attached to the cart for processing, storage and running the TRIOS software.
- **Touch screen:** Touch-enabled screen for real-time display of scanning results generated by the TRIOS software, and for interacting with the TRIOS software.
- The **system standby button** (S15) is on the back of the monitor.
- Under the low hinge on the back of the cart a scanner connection can be found (S16)
- In the bottom (S17), there is a power socket (S18), a network (LAN) connector (S19), and a fuse drawer (S20). In the top of the backpack (S21), the dongles are inserted, see description below.
- USB license dongle (access to 3Shape software)
- USB wifi dongle (for connecting cart to wifi network)
- **USB port (only MOVE+):** The MOVE+ cart has a USB port (Figure 3).

The friction of the arm of the MOVE/MOVE+ cart that holds the scanner and the display can be adjusted. The corresponding tool is provided with the system (Figure 4).

**Step 1:** Move the arm to the top-most position.

**Step 2:** Insert the tool into the hole on the bottom side of the arm, located approx. half way along the arm.

**Step 3:** Turn the tool clockwise to increase friction, anticlockwise to reduce friction.

**Step 4:** Adjust friction so that the monitor is steady (does not sink, does not go up) in the following scenarios:

- Scanner is positioned in scanner holder
- Scanner is not positioned in scanner holder



#### IMPORTANT NOTICE

Maximum current available for the USB port is 200 mA.

**Step 4:** Connect the scanner cable to the scanner connection socket on the MOVE/MOVE+ cart behind the screen below the hinge (S16).

- To connect - Push the plug into socket. There is a red orientation dot on the socket and plug that should match.
- To disconnect - Pull on the outer release sleeve.

**Step 5:** Connect the MOVE/MOVE+ cart end of the power cable to the socket at the bottom of the computer unit (S18).

**Step 6:** Connect the power cable to a grounded power outlet. Ensure that the MOVE/MOVE+ cart is placed so it does not block the switch on the mains socket-outlet. To isolate the MOVE/MOVE+ cart and thus the scanner from supply mains, unplug the flexible power cord from mains.

**Step 7:** Connect the LAN cable to the MOVE/MOVE+ cart's LAN connection at the bottom of the computer unit (S19).

### System with pod (SIP-2, SIP-4) furthermore comprises:

#### Pod with electronics, PS1-2 (Figure 5):

- A mount for the scanner
- Several connection sockets. On one side, there is a single socket for the scanner. On the other side, there are two connection sockets for the Ethernet cable to the PC and for the external medical power supply, respectively.
- A USB license dongle (access to 3Shape software)

## 4.7 Setting up TRIOS

It is recommended that unpacking, assembly and connection of the TRIOS IOS system shall be performed by TRIOS authorized technical service personnel.



#### CAUTION

If the system has just been delivered from a cold environment, let it adjust to room temperature to avoid internal condensation and to allow for proper calibration.



#### CAUTION

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.

### System S1A (MOVE/MOVE+ cart) only

#### Please follow the steps below for assembling TRIOS IOS system (Figure 1&2):

**Before you start:** Follow the instructions in the packaging to assemble the foot onto the the MOVE/MOVE+ cart. Tools are provided.

**Step 1:** Place the MOVE/MOVE+ cart optimally in relation to the patient chair and your work position.

**Step 2:** Attach the protection tip to the TRIOS scanner if not already in place. (S4)

**Step 3:** Place the scanner on its designated scanner mount on the MOVE/MOVE+ cart (S13).

### System SIP (pod) only

#### Please follow the steps below for assembling TRIOS IOS system (Figure 5 & 6):

**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 protection tip to the TRIOS scanner if not already in place. It is easiest not to place the scanner onto the pod at this time yet, because you may find it easier to lift the pod while connecting cables in the following.

**Step 1:** Connect the Ethernet cable to the pod. The cable goes into the left connection socket on the back side of the pod (the side that has two connection sockets). If you need to release the Ethernet cable, press on the small tab on the top of the connector.

**Step 2:** Connect the power supply to the pod. This cable goes into the connection socket next to the Ethernet cable described in the previous step.

- To connect - Push the plug into socket. There is a red orientation dot on the socket and plug that should match.
- To disconnect - Pull on the outer release sleeve.

The indicator light next to the scanner connection socket will light green.

**Step 3:** Connect the scanner cable to the scanner connection socket on the front side of the pod (the side that has only one connection socket).

- To connect - Push the plug into socket. There is a red orientation dot on the plug that should point upwards.
- To disconnect - Pull on the outer release sleeve.

Now all connections to the pod are established, and you can place the scanner onto the pod.

**Step 4:** Connect the other end of the Ethernet cable to the PC (if no Ethernet ports are available in the PC use an Ethernet to USB adapter)

**Step 5:** Connect the power (mains) cord to the power supply. The other end of the power (mains) cable goes into a grounded power outlet (not shown in the Figure). To isolate the pod and thus the scanner from supply mains, unplug the power cord from mains.

## 4.8 Starting and Shutting Down TRIOS IOS system

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

### Step 1: Turn the system ON.

S1P: Start the PC. If the PC has no TRIOS software installed, follow the instructions in the accompanying TRIOS online help. Then start the TRIOS software.

S1A: Press the standby button on the top of the backside of the display. The TRIOS software starts automatically.

### Step 2: Log on using a default TRIOS Operator.

### Step 3: Configure and use your TRIOS IOS system.

#### For models with pod: S1P-2, S1P-4

The wired scanner turns on automatically when the Laptop is turn on.

#### For models with cart: S1A-10, S1A-12, S1A-22

The wired scanner turns on automatically when the MOVE/MOVE+ cart is turned on.

When using the TRIOS IOS system, the user is guided by messages shown in the TRIOS software. This includes when calibration of the scanner is due. Other messages include a reminder to mount the calibration adaptor: "Please make sure the scanning tip is mounted on the scanner."

### Calibration

A calibration of the handheld TRIOS scanner is required before using TRIOS IOS system for the first time and every 8 days during regular use or when the scanner has been moved or sustained hits or strong temperature changes. The calibration is done by placing the Calibration Tip on the Scanner Tube, go to the Settings page in the TRIOS software, select Scan → 3D calibrate scanner, and then follow the on-screen instructions.

For a more detailed description of the 3D calibration, please refer to the TRIOS online help.

### Color Calibration

A color calibration of the handheld scanner is required before each scan in order to get optimal colors.

- Attach a cleaned and sterilized or high-level disinfected scanner tip on the scanner tube.
- Remove the sleeve from the color calibration target.
- Mount the color calibration target to the calibration adaptor with the color side, marked with the letter A, facing up.
- Attach the calibration adaptor to the cleaned and sterilized or high-level disinfected scanner tip.
- Go to the Settings page in the TRIOS software, select TRIOS → Scanner Management → Color calibrate scanner, and then follow the on-screen instructions, which will also include validation of the performed color calibration. Remember to save changes when prompted.

For a more detailed description of the color calibration, please refer to the TRIOS online help.

### Proper shutdown

Inside the TRIOS software, click on the Power button and select Shutdown or press the the standby button on the back of the monitor on the MOVE/MOVE+ cart.

System S1A (MOVE/MOVE+ cart) only: The light under the standby button turns off to confirm that the system is shut down.



### CAUTION

When switching off the system, allow enough time for it to shut down properly before disconnecting the mains cable.

### System S1A (MOVE/MOVE+ cart) only



### IMPORTANT NOTICE

The standby button can also be used to force TRIOS IOS system to shut down in case the screen stops responding. To force a shutdown, push and hold the standby button pressed for about 5 seconds. Then, restart the system.

## 4.9 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.

## 4.10 TRIOS IOS system Environment



### IMPORTANT NOTICE

#### Operating Conditions

Ambient temperature range: +15 – +30 °C  
Relative humidity: 10 – 85 % (non-condensing)  
Atmospheric pressure: 800 – 1100 hPa

The scanner should be used in an environment maintaining a consistent room temperature.



### IMPORTANT NOTICE

#### Storage Conditions

Ambient temperature range: -10 – +60 °C  
Relative humidity: 10 – 85 % (non-condensing)  
Atmospheric pressure: 800 – 1100 hPa



### IMPORTANT NOTICE

#### Transport Conditions

Ambient temperature range: -10 – +60 °C  
Relative humidity: 10 – 85 % (Non-condensing)  
Atmospheric pressure: 620 – 1200 hPa

## 4.11 Technical specifications

<b>Light source specifications</b>	Do not view directly with optical instruments, such as spectacle microscopes. The product complies with EN (IEC) 62471 Photobiological safety of lamps and lamp systems.
<b>Sterilization and high-level disinfection method</b>	Scanner tips can be autoclaved or high-level disinfected.
<b>Power input</b>	<p><b>C4.0/ C4.1 MOVE/MOVE+ cart (for S1A)</b> Power input: 100-240 VAC, 50/60 Hz, 180 VA max Insulation class: class I</p> <p><b>S1-2 scanner</b> External class I medical power supply rated 30W max, 1.0 A.</p>

## 5. Safety and Warnings

### 5.1 Prerequisites

	<p><b>CAUTION</b></p> <p>Read all instructions carefully, including all warnings and caution notices. You must comply with the warnings in this manual to prevent injury to persons and damage to equipment. Proper functionality and safety can only be guaranteed if the safety precautions in this safety guide and on the TRIOS IOS system are observed.</p>
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#### Preventive inspection before use of the system

	<p><b>CAUTION</b></p> <p>Please examine the TRIOS IOS system for any mechanical damage on:</p> <ul style="list-style-type: none"> <li>• all enclosures,</li> <li>• all cables.</li> </ul> <p>Safety can only be guaranteed if NO DAMAGE on the TRIOS IOS system is observed.</p>
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#### Modifications of the system

	<p><b>CAUTION</b></p> <p>Modifications of the system which may affect the safety of the operator, patients or third parties are prohibited by law!</p>
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#### Approved software only

	<p><b>CAUTION</b></p> <p>Install only approved software – to prevent interference with the runtime reliability of the system and programs within it.</p>
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#### Proper training

	<p><b>WARNING</b></p> <p>Before you attempt to use the TRIOS scanner equipment with patients:</p> <ul style="list-style-type: none"> <li>• You must be trained to use the TRIOS IOS system and have read and understood all sections of this guide describing correct operation.</li> <li>• You must also be thoroughly familiar with the safe operation of the TRIOS scanner equipment as described in this documentation.</li> </ul>
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#### In case of equipment failure

	<p><b>WARNING</b></p> <p>If at any time the TRIOS IOS system malfunctions, or if you suspect in any way that the TRIOS IOS system is not working correctly:</p> <ul style="list-style-type: none"> <li>• Remove the scanner from contact with the patient.</li> <li>• Unplug the system and make sure it cannot be used before it is checked.</li> <li>• Contact your reseller.</li> <li>• Do not attempt to open any covers on the TRIOS IOS system.</li> </ul>
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#### Portable RF communications equipment

	<p><b>WARNING</b></p> <p>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 MOVE/MOVE+ cart system, including cables specified by the manufacturer. Otherwise, the performance of this equipment may be impaired.</p>
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### 5.2 Mechanical Hazards

#### Fragile and movable parts

	<p><b>WARNING</b></p> <p>Be careful to avoid the following potential sources of injury:</p> <ul style="list-style-type: none"> <li>• Do not lean or sit on any part of the system.</li> <li>• Movable parts can pinch body parts.</li> </ul>
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#### Dropped or damaged equipment

	<p><b>WARNING</b></p> <p>If you drop a scanner tip on the floor, you MUST dispose of it immediately and NOT use the same tip again for scanning. There is risk that the mirror in the tip has become dislodged and can fall out.</p>
	<p><b>WARNING</b></p> <p>If the handheld scanner is dropped or bumped, it should immediately be calibrated before further use. If calibration fails, please contact your technical service provider. See this guide's instructions on calibrating the handheld scanner.</p>
	<p><b>WARNING</b></p> <p>If the handheld scanner is dropped, examine the TRIOS scanner for any mechanical damage. If a mechanical damage is observed or suspected, treat this as an equipment failure (see this guide's instructions on handling equipment failures).</p>

#### System S1A (MOVE/MOVE+ cart) only

	<p><b>WARNING</b></p> <ul style="list-style-type: none"> <li>• Keep both hands on the upper part of the MOVE/MOVE+ cart when moving it across the floor.</li> <li>• Do not attempt to lift the MOVE/MOVE+ cart alone. When moving the system over a door step or other unsmooth surface, get assistance from another person to ensure stability.</li> <li>• When moving the MOVE/MOVE+ cart across the floor, maintain all its wheels in contact with the floor and ensure that they are not locked.</li> <li>• Always place the scanner in its intended mount on the MOVE/MOVE+ cart when not in use and when moving the MOVE/MOVE+ cart.</li> <li>• Keep your feet clear of the MOVE/MOVE+ cart's base and wheels when moving the MOVE/MOVE+ cart.</li> <li>• Never drag the MOVE/MOVE+ cart across any of its cables.</li> <li>• Do not place the MOVE/MOVE+ cart on a slope greater than 10 degrees.</li> <li>• Keep sharp objects away from the touch screen.</li> </ul>
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## System SIP (pod) only

	<p><b>WARNING</b></p> <ul style="list-style-type: none"> <li>Always place the scanner in its intended mount on the pod when not in use.</li> <li>Do not place the pod on a slope greater than 5 degrees.</li> <li>Place all cables carefully so that patient and/or user do not get caught in them and accidentally pull any part of the system. Pulling cables may damage the system, interrupt the data connection, and/or drag the system off its supporting surface.</li> </ul>
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## 5.3 Explosion Hazards

### Environment

	<p><b>WARNING</b></p> <p>The TRIOS IOS system is not designed to be used in potentially explosive environments, such as in close proximity to flammable liquids or gases, or in oxygen-enriched atmospheres.</p>
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### Distance to the patient with anesthetic

	<p><b>WARNING</b></p> <p>There is a potential explosion hazard if the TRIOS IOS system is operated in the presence of flammable anesthetic.</p>
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## 5.4 Electrical Safety

### Ensure a grounded/earthed connection

	<p><b>WARNING</b></p> <p>To avoid the risk of electric shock, the MOVE/MOVE+ cart must only be connected to a supply mains with grounding/protective earth. The MOVE/MOVE+ cart is equipped with a three-pin (US: prongs) grounding/earth type plug. If you cannot insert the plug into your outlet, contact your electrician to replace the plug or outlet, to ensure a grounded power connection. Do not try to defeat or ignore the purpose of the grounding-type plug.</p>
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### Electrical shock

	<p><b>WARNING</b></p> <p>There is a risk of electrical shock if you attempt to access the inside of any part of the system. Only authorized and qualified service personnel may access the inside of any part of the system.</p>
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### Do not use a power strip

	<p><b>WARNING</b></p> <p>Do not connect the TRIOS IOS system to an ordinary power strip or extension cord, because these may not be secure in relation to grounding. If the ground connection fails, these can cause the following hazards and potential injury:</p> <ul style="list-style-type: none"> <li>The total leakage current for all the connected equipment can exceed the limits specified in EN (IEC) 60601-1.</li> <li>The impedance of the ground connection could exceed the limits specified in EN (IEC) 60601-1.</li> </ul>
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### Stress on cables

	<p><b>CAUTION</b></p> <p>All externally connected cables (the power cable, network cable, and the handheld scanner cable) must never be subjected to pulling stress.</p>
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### Spilled liquids

	<p><b>WARNING</b></p> <p>Do not bring liquids, such as beverages, near the TRIOS IOS system. Do not spill liquids on the TRIOS IOS system.</p>
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### Condensation

	<p><b>WARNING</b></p> <p>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 plug it into the power source.</p> <p>If the system has been subject to major temperature or humidity changes, wait till the system has reached room temperature before plugging it into the power source.</p> <p>If there is visible evidence of condensation, wait at least 8 hours before plugging it into the power source, to ensure that no internal condensation occurs.</p>
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### Disconnecting from mains

	<p><b>WARNING</b></p> <p>There is no power ON/OFF switch on the system; therefore, the only reliable means to disconnect the system from mains is to unplug the power cord. Do not position the system so that it is difficult to unplug the power cord. Please allow enough time for the system to shut down properly before disconnecting the power cord.</p> <p><b>System SIP (pod) only:</b> You must also disconnect the PC from mains.</p>
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### PC connection options and requirements

## System SIP (pod) only

	<p><b>WARNING</b></p> <p>The PC is a standard IT equipment certified to IEC 60950-1 and is located at least 1.5 m away from the patient. If you choose this setup, you must not scan the patient and touch the PC at the same time! You must not touch any peripherals connected with a cable to the PC while scanning a patient. See the PC's instructions for use for further details.</p>
	<p><b>WARNING</b></p> <p>Only use the power supply that is delivered as part of the system. OTHER POWER SUPPLIES MAY BE UNSAFE AND/OR MAY DAMAGE THE TRIOS IOS SYSTEM!</p>

**System S1A (MOVE+ cart) only**

	<p><b>WARNING</b></p> <p>Only connect bus-powered USB devices without external power supply.</p>
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**System S1P (pod) only**

	<p><b>WARNING</b></p> <p>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 disinfected easily.</p>
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5.5 Eye safety

	<p><b>WARNING</b></p> <p>The scanner emits bright light from its tip during operation. The scanner complies with EN (IEC) 62471 (Photobiological safety of lamps and lamp systems). However, we recommend caution when handling the scanner.</p> <p>A brief glimpse of the light into the eye is not dangerous, but do not stare into the beam or view directly with optical instruments, and do not aim the beam towards other people's eyes. In general, viewing bright light sources (e.g. headlights), which have a high secondary exposure potential due to their blinding effect, may cause temporary reduction in visual acuity and afterimages, leading to irritation, annoyance, visual impairment, and even accidents, depending on the situation.</p>
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5.7 Safety when scanning with TRIOS

	<p><b>CAUTION</b></p> <p>The handheld scanner is a highly precise optical instrument and must be handled carefully. Do not drop, shake or bump the handheld scanner, as these actions could cause it to break or malfunction. Follow these guidelines:</p> <ul style="list-style-type: none"> <li>• Always return the handheld scanner to its mount when not in use.</li> <li>• Do not submerge the handheld scanner in any liquids.</li> <li>• Do not place the handheld scanner on heated or wet surfaces.</li> <li>• Grip the handheld scanner firmly during scanning and when removing/returning it to its mount.</li> </ul>
	<p><b>IMPORTANT NOTICE</b></p> <p>The scanner will get warm during use. This is normal but not part of any patient treatment.</p>
	<p><b>CAUTION</b></p> <p>The handheld scanner tip is fragile and contains a delicate mirror. To avoid damage to the tip and mirror, take care not to bump the tip onto the patient's teeth or restorations.</p>
	<p><b>CAUTION</b></p> <p>When the TRIOS IOS system is used for pediatric patients, please pay extra attention while scanning the patient.</p>

5.6 Hygiene

	<p><b>WARNING</b></p> <p>To maintain a clean work environment and the safety of the patient, wear clean examination gloves when:</p> <ul style="list-style-type: none"> <li>• Handling the scanner tip – changing the tip, setting the tip for upper/lower scans or handling the mirror.</li> <li>• Handling the protection tip.</li> <li>• Handling the color calibration kit.</li> <li>• Applying TRIOS for scanning patients.</li> <li>• Touching the TRIOS IOS system.</li> </ul>
	<p><b>WARNING</b></p> <p>Always clean the scanner unit and it's optical window before attaching the protection tip. Do not allow patient contact with the protection tip.</p>
	<p><b>WARNING</b></p> <p>Always have the scanner tip mounted when you insert the scanner into the patient's mouth or when the scanner comes in contact with the patient in any way. Mounting of the scanner tip is always required for maximal electrical safety and due to the risk of contamination.</p>
	<p><b>WARNING</b></p> <p>Always have a cleaned and sterilized scanner tip mounted before attaching the color calibration adaptor. Do not allow patient contact with the color calibration kit.</p>
	<p><b>WARNING</b></p> <p>Before each patient, you must:</p> <ul style="list-style-type: none"> <li>• disinfect the system,</li> <li>• apply a new sterilized or high-level disinfected tip to the scanner.</li> </ul> <p>See the detailed instruction in the chapter 6.</p>

5.8 Protection from overheating

**System S1A (MOVE/MOVE+ cart) only**

	<p><b>WARNING</b></p> <p>Ventilation openings must never be blocked or obstructed. There are openings at the back of the MOVE/MOVE+ cart (behind the touch screen) and on the top and the bottom of the base of the MOVE/MOVE+ cart. If overheated, the system may stop functioning.</p>
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6. Cleaning, Disinfection, and Sterilization

6.1 Cleaning, high-level disinfecting, and sterilizing the scanner tip

The TRIOS scanner tip is the part of the scanner that is inserted into the patient's mouth during scanning. The tip can be reused a limited number of times, but it must be cleaned and sterilized between patients to avoid cross contamination.

The tip can be removed by pulling it away from the scanner body.

## Cleaning and sterilization procedure

<p><b>Step 1:</b> Clean the tip manually using soap water and a brush immediately after use. A mild dishwashing detergent is recommended. Inspect the mirror of the tip after cleaning. If the mirror appears with stains, smudged or with a milky haze, repeat cleaning using a soft dish-brush and soap water.</p> <p>Rinse with water.</p> <p>Dry the mirror carefully with a paper towel.</p>
<p><b>Step 2:</b> Put the tip in a paper sterilization pouch</p> <p>The pouch should be sealed airtight. Use either a self-adhesive pouch or heat-sealed pouch.</p>
<p><b>Step 3:</b> Sterilize the pouched tip in an autoclave with one of the two programs:</p> <p>At 134°C (273.2°F) for a minimum of 3 minutes.</p> <p>At 121°C (249.8°F) for a minimum of 15 minutes.</p> <p>Use an autoclave program that dries the pouched tip before opening the autoclave. A class B Vacuum autoclave according to EN13060 is required for sterilization of the scanner tip.</p>

## Cleaning and high-level disinfection procedure

<p><b>Step 1:</b> Clean the tip manually using soap water and a brush immediately after use. A mild dishwashing detergent is recommended. Inspect the mirror of the tip after cleaning. If the mirror appears with stains, smudged or with a milky haze, repeat cleaning using a soft dish-brush and soap water.</p> <p>Rinse with water.</p> <p>Dry the mirror carefully with a paper towel.</p>
<p><b>Step 2:</b> Immerse the tip completely in Wavicide-01 for 45 to 60 minutes.</p>
<p><b>Step 3:</b> Remove the tip from the Wavicide-01 solution and rinse it according to the Wavicide-01 Solution instructions for use.</p>
<p><b>Step 4:</b> Use a sterile and non-abrasive paper towel or cloth to gently remove remaining drops from the mirror and to dry the tip.</p>

	<p><b>CAUTION</b></p> <p>The mirror in the tip is a delicate optical component. Its clean and undamaged surface is critical for the scan quality. The mirror should be handled with care. Do not scratch it. Be careful not to smudge it before scanning a patient.</p>
	<p><b>CAUTION</b></p> <p>Always clean the tip immediately after use. If biological materials (bioburden) are allowed to dry on equipment, disinfection and sterilization processes may not be effective.</p>
	<p><b>CAUTION</b></p> <p>Never autoclave an unpouched tip, since this will leave unremovable stains on the mirror. See the autoclave manual for more information.</p>
	<p><b>CAUTION</b></p> <p>New tips must be cleaned and sterilized/high-level disinfected before using them for the first time.</p>

	<p><b>CAUTION</b></p> <p>A class B Vacuum autoclave according to EN 13060 is required for sterilization of the scanner tip.</p>
	<p><b>CAUTION</b></p> <p>The scanner tip can be re-sterilized up to 150 times and must be disposed afterwards as described in section Disposal.</p>
	<p><b>CAUTION</b></p> <p>The scanner tip can be high-level disinfected up to 150 times with Wavicide-01 Solution and must be disposed afterwards as described in section Disposal.</p>
	<p><b>CAUTION</b></p> <p>When high-level disinfecting the scanner tip using Wavicide-01 Solution, there may be a visual change to the tip after 70 disinfections. This change is only visual and does not pose a risk.</p>
	<p><b>IMPORTANT NOTICE</b></p> <p>High-level disinfection with Wavicide-01 Solution as an alternative to sterilization has been validated by 3Shape.</p> <p>The Wavicide-01 Solution is not allowed and/or recognized as a disinfectant of medical devices worldwide; always follow procedures that have been established for your clinic or institute, as well as any national guidelines.</p>
	<p><b>IMPORTANT NOTICE</b></p> <p>Always follow cleaning, disinfection and sterilization procedures that have been established for your clinic or institute, as well as national guidelines.</p>
	<p><b>IMPORTANT NOTICE</b></p> <p>If using Wavicide-01 for high-level disinfection, be sure to follow the Wavicide-01 Solution instructions for use.</p>

## 6.2 Cleaning, high-level disinfecting, and sterilizing the calibration kit

The color calibration adaptor must always be attached on a cleaned and sterilized scanner tip and must not have contact to patients. If these instructions are not followed the color calibration kit must be cleaned, disinfected and sterilized.

### Cleaning, high-level disinfection and sterilization procedure

<p><b>Step 1:</b> Disassemble the color calibration kit (remove the sleeve from the color calibration target and disassemble the color calibration target and the color calibration adaptor).</p>
<p><b>Step 2:</b> Clean the color calibration adaptor manually using soap water and a brush. Sterilize the cleaned color calibration adaptor in an autoclave using one of the programs listed for the scanner tip and using a paper sterilization pouch.</p>
<p><b>Step 3:</b> Clean the sleeve manually using soap water and a brush. Disinfect the sleeve using the recommended disinfection solution listed in section Cleaning and disinfecting other parts of the system.</p>
<p><b>Step 4:</b> The color calibration target must only be cleaned with air. The calibration patches must not be touched and must not be exposed to liquids. See the important notice below.</p>

**Step 5:** After cleaning, disinfection, and sterilization the color calibration kit must be reassembled before use. Ensure that all parts are dry before reassembly. If not used immediately place the color calibration target in the sleeve and leave the color calibration adaptor in the sterilization pouch.



#### IMPORTANT NOTICE

The calibration target is a delicate optical component. During disassembly and assembly of the calibration kit only the end-part to the calibration target (opposite of the calibration patches) must be touched, and the target must only be cleaned with air.

## 6.3 Cleaning and high-level disinfecting other parts of the system

After patient treatment, clean and disinfect all other surfaces of the system (except the scanner tip and color calibration kit, for which the previous sections apply). Also note that the optical window is a delicate optical component and should be handled with extra care during cleaning and disinfection (see below).

For general cleaning, a soft cloth and a mild detergent can be used.

#### Recommended disinfection solution:

Denatured alcohol (IPA – Isopropyl Alcohol or Ethanol) – typically 60-70% Vol.

#### To disinfect:

**Step 1:** Apply the disinfection solution to a soft, lint-free, non-abrasive cloth; the cloth must only be damp.

**Step 2:** Wipe the surfaces with the damp cloth.

**Step 3 (optical window on scanner only):** Dry the optical window with another clean, soft, lint-free, non-abrasive cloth.



#### CAUTION

The scanner's optical 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 the cleaning solution.



#### CAUTION

Do not use ammonia-based or chloride-based solutions, or acetone on any surface. Before returning the scanner to its holder, ensure both are dry.



#### CAUTION

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



#### IMPORTANT NOTICE

The scanner shell might get yellow-toned over a long period of use.



#### IMPORTANT NOTICE

All surfaces that the protection tip comes in contact with, particularly the scanner tube and its optical window, must always be cleaned and disinfected before attaching the protection tip.

## 6.4 Additional cleaning in case of poor scan quality

During scanning, the tip mirror may become unclean, resulting in a loss of scan quality. In this situation, you can clean the mirror following these steps:

**Step 1:** Remove the scanner tip.

**Step 2:** Apply alcohol to a clean cloth or cotton-tipped swab and wipe the tip mirror until it is clean. Use alcohol that is free of impurities, as those may stain the mirror. Ethanol or propanol (ethyl/propyl alcohol) can be used.

**Step 3:** Wipe the tip mirror dry with a dry, lint-free cloth to avoid leaving dust and fiber on the mirror.



#### CAUTION

Do not use acetone or any oxidizing solutions to clean the tip mirror.

If you still see problems, check the scanner's optical window for cleanliness, and apply the same procedure if necessary.

## 7. Disposal



Described devices follow the Waste Electrical and Electronic Equipment Directive. The Following symbol on the product, the accessories or packaging indicates that this device must not be treated as unsorted municipal waste, but must be collected separately! Please contact your 3Shape reseller, who can inform you about the local requirements for disposal of electrical, 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.

### 7.1 Disposal of the scanner tip

Sterilize the tip as described above. The scanner tip can then be disposed normally as other clinical waste.



#### CAUTION

Dispose the scanner tip as other clinical waste.



#### CAUTION

The scanner tip must be sterilized before disposal.

### 7.2 Disposal of the TRIOS IOS system

For disposal of the TRIOS IOS system, please contact your 3Shape reseller, who can inform you about the local requirements for disposal of electronic waste.

## 8. Technical Maintenance



### CAUTION

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

The user doesn't need to perform any regular maintenance other than calibration, cleaning, disinfection and sterilization, as described here. Preventive inspections and scheduled maintenance are not required.

### System S1A (MOVE/MOVE+ cart) only

#### Changing the fuses (Figure 2, S20):

Shut down the MOVE/MOVE+ cart by following the procedure described in Setting up & Starting TRIOS for the first time and disconnect the mains power cable from the MOVE/MOVE+ cart.



### CAUTION

The mains power cable must be disconnected before changing fuses.

Using a pair of tweezers or similar, push in the two tabs on each side of the fuse drawer simultaneously, as shown in the subfigure S20. The drawer will begin to emerge from its slot.

It is then possible to remove the drawer and replace the two fuses. Two spare fuses are provided with the system on delivery.



### WARNING

Only fuses with the correct rating and type (250 V, T 3.15 A H) must be used.

To replace the fuses, first mount them in the drawer, then insert the drawer back into the slot and push all the way in until the tabs click back into place and the drawer is no longer loose in the slot. Do not attempt to insert the fuses directly into the slot on the MOVE/MOVE+ cart.

The mains cable can now be reconnected, and the TRIOS IOS system started up.

#### Changing the dongle for the MOVE/MOVE+ cart (software license protection):

The USB wireless dongle, the USB license dongle and the USB wifi dongle, and the Bluetooth dongle are located behind the plastic lid on top of the backpack of the MOVE/MOVE+ cart. You can remove the lid by opening the screws holding the lid, as indicated by the arrows in figure S21.



### WARNING

The scanner must not be operated while the ventilation grid on the back side of the MOVE/MOVE+ cart is removed.

## 10. 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](mailto:support@3shape.com) and you can also report it to the competent authority of the state in which the user and/or patient is established.

## 9. Consumable Accessories

The consumable accessories to the TRIOS IOS system are the scanner tips and the calibration kit.

When the scanner tips are disposed, new tips can be ordered by contacting your 3Shape reseller. Also, a new calibration kit can be ordered from your 3Shape reseller.

Let's change dentistry **together**



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