



USER GUIDE

Modified for Cleaning and Disinfection

P200TE

P200TxE

Optos OCT Ophthalmoscope

*Page and part numbers throughout the guide reference Silverstone





Cleaning Guidelines

Chapter 3 - How to ...

3.4.8.3 Cleaning

Wear powder-free gloves at all times when cleaning the device including the scan head and main mirror. If the gloves become contaminated they must be replaced immediately.

In order to prevent any contamination always clean and disinfect parts of the equipment which will be in contact with the patient, see *Cleaning before each patient* on the facing page.

Adequate cleaning and disinfection is necessary to prevent disease transmission. Thoroughly clean and disinfect the equipment surfaces that contact the patient and all equipment surfaces likely to become soiled during use.

Improper cleaning methods or use of inappropriate cleaning and disinfecting agents can result in the following:

- · Damaged equipment
- · Poor imaging performance
- · Increased risk of electric shock



Always follow the cleaning and disinfecting agents' manufacturer's instructions and precautions; for storage, method of application, protective gloves, shelf life and disposal to help assure effective and safe use of the product.

Do not use lint cloths, tissues, or other materials that may create dust, on or near the scan head. Always allow cleaned areas to air-dry.

Do not use harsh detergent, abrasive cleaners or solvents that are not recommended by the manufacturer.

Do not expose equipment parts to steam or sterilizers as this will damage the device.

Do not allow liquids to get into the equipment.

If you believe cleaning sprays or liquids have got into the equipment, disconnect the power supply and have the equipment checked by Optos qualified service personnel.

Do not let the cleaning wipes come into contact with the inside of the instrument.

Do not use the equipment until you have confirmed it is safe to use.

3.4.8.3.1 General cleaning



Be careful not to damage the scan head covers when cleaning.

The equipment should be kept clean and dust free.

- . Logout, shut down and power off the device before cleaning the outer casing of the scan head.
- Use a soft, slightly damp cloth to clean the plastic surfaces.
- · Ensure debris does not fall inside the device.
- Use a glass-cleaning agent to clean the PC monitor and touch screen.

Cleaning Guidelines, cont'd

Cleaning materials

Wear powder-free gloves at all times when cleaning the device including the scan head and main mirror. If the gloves become contaminated they must be replaced immediately.

Do NOT use lint cloths, tissues, or other materials that may create dust, on or near the scan head. Always allow cleaned areas to air-dry.

Improper cleaning methods or use of inappropriate cleaning and disinfecting agents can result in the following:

- · Damaged equipment
- Poor imaging performance
- · Increased risk of electric shock



Always follow the cleaning and disinfecting agents' manufacturer's instructions and precautions; for storage, method of application, protective gloves, shelf life and disposal to help assure effective and safe use of the product.

Be careful NOT to damage the scan head covers when cleaning.

Do NOT use harsh detergent, abrasive cleaners or solvents that are NOT recommended by the manufacturer.

Do NOT expose equipment parts to steam or sterilizers as this will damage the device.

Do NOT allow liquids to get into the equipment.

If you believe cleaning sprays or liquids have got into the equipment, disconnect the power supply and have the equipment checked by Optos qualified service personnel.

Do NOT let the cleaning wipes come into contact with the inside of the instrument.

Do NOT use the equipment until you have confirmed it is safe to use.

Part Number: G102748/9GCA
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English

Cleaning Between Patients

Chapter 3 - How to ...

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3.4.8.3.2 Cleaning before each patient

The patient should not touch the touch screen. The patient should only be in contact with the forehead pad, chin pad and face pad.



Always follow the cleaning and disinfecting agents' manufacturer's instructions and precautions; for storage, method of application, protective gloves, shelf life and disposal to help assure effective and safe use of the product.

Do not attempt to wash or immerse the patient contact parts (for example, forehead pad, chin pad and face pad) in water or cleaning fluid.

Do not use lint cloths, tissues, or other materials that may create dust, on or near the scan head. Always allow cleaned areas to air-dry.

Do not let the cleaning wipes come into contact with the inside of the instrument.

The following cleaning procedures should be carried out before each session.

- 1. Clean the forehead pad, chin pad, face pad, dust cap, head and chin rest brackets with an individually sealed, 70% IPA (isopropyl alcohol) wipe.
- 2. Allow the cleaned areas to air-dry before imaging the next patient.

Note

The wipes should be checked periodically to ensure that they are within their marked expiration date.

How to remove the head and chin rests

The head rest and chin rest may be removed for periodic cleaning by following these steps:

- Stand in front of the device, hold both sides of the head or chin rest and pull towards you.
- 2. When the head or chin rest reaches the stops, gently lift the head or chin rest and pull to remove it from the casing.
- 3. After cleaning, slot the head or chin rest back into the casing and gently push back into position.

Part Number: G110230/1ENG

Cleaning the Main Mirror

Chapter 3 - How to ...

3.4.8.3.3 Cleaning the main mirror

The mirror can be damaged during cleaning. Preventing mirror contamination reduces the risk of damaging the mirror. It is not recommended to routinely clean the main mirror. Only clean the mirror if dust particles, smudges or spots have accumulated on its surface.

When cleaning the main mirror, do not rub the spots too hard, as this may cause damage.



Do not touch the edges of the main mirror. The edges of the main mirror are sharp.

Only clean visible areas of the main mirror. Do not put your hand or any cleaning material into parts of the device you cannot see.

Do not polish the mirror surfaces; clean only dust particles, smudges or spots.

Do not wear jewelry (for example rings, watches or bracelets) while cleaning the mirror surface as this may damage the mirror.

Dispose of the dirty cloth after each wipe to avoid transferring the dust back on to the mirror. You will have to use several wipes to clean the mirror.

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English

Depending on the operating environment dust may accumulate on the device that may affect image quality. To clean the main mirror follow the procedure below:

Note

Points to remember when cleaning the main mirror:

- To prevent contamination, take care not to touch the surface of the cloth that will be used to clean the mirror.
- Only hold the cloth by the corners.
- Capture a reference eye image.
- 2. Put on powder-free gloves.
- 3. Remove the face pad.
- 4. Inspect the surface of the mirror for visible dust. Take note of any smudges or spots.
- 5. Fold an Optos-approved cleaning cloth twice so that it has a number of layers.
- Use single downward strokes to gently wipe the mirror. Always start from the top of the visible area.
- Check the mirror again for any remaining dust, smudges or spots.
- 8. If the main mirror still shows smudges or spots, follow the sub-steps below, otherwise go to the next step.
 - a. Open an Optos-approved pre-moistened >99.5% IPA (isopropyl alcohol) wipe and fold twice.
 Mirror cleaning wipes are available from Optos.
 - b. Gently wipe individual smudges or spots; only wipe these areas and NOT the rest of the mirror.
 - c. Inspect the mirror surface and confirm all smudges or spots have been removed.
- 9. Refit the face pad.
- Take another image and compare it to the original reference eye image to determine if the image quality has been sufficiently improved.

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Disinfection

Chapter 3 - How to ...

3.4.8.3.4 Disinfection

Wear powder-free gloves at all times when cleaning the device including the scan head and main mirror. If the gloves become contaminated they must be replaced immediately.



Always follow the cleaning and disinfecting agents' manufacturer's instructions and precautions; for storage, method of application, protective gloves, shelf life and disposal to help assure effective and safe use of the product.

Be careful not to damage the scan head covers when cleaning.

Do not use lint cloths, tissues, or other materials that may create dust, on or near the scan head. Always allow cleaned areas to air-dry.

External surfaces must be cleaned of all visible contamination when they become dirty or soiled with bodily fluids. Follow your internal clinic or hospital decontamination procedures.

System Parts – Reference - *Monaco*

2.6.1 System parts

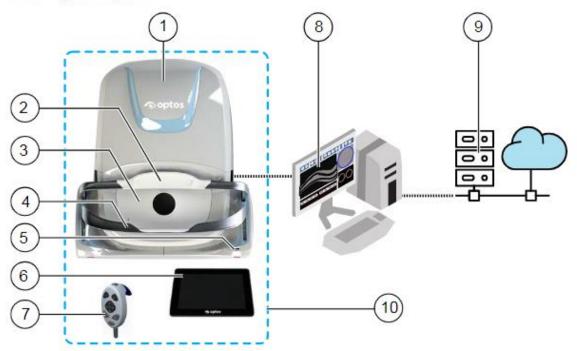


FIGURE 1: P200TE device connected to network

No.	Name of Part	Description
1	Scan head	The scan head comprises the light sources (lasers and SLD ¹) and electronics used to capture patient images.
2	Head rest	The head rest supports the patient's head when the patient is being imaged, see Using the chin rest and head rest on page 34.
3	Face pad	The face pad helps support the patient when the patient is being imaged.
4	Chin rest	The chin rest supports the patient's head when the patient is being imaged, see Using the chin rest and head rest on page 34.
5	Status indicator	The color changes to show the status of the device, see Status indicator on page 66.
6	Touch screen	The touch screen monitor is used to interact with the system. It displays alignment feedback and captured images.
7	Hand control	The hand control comprises buttons used to adjust the patient alignment and capture images.
8	Image server	Runs the OptosAdvance software and lets you manage the networked images. The image server will also let you review and analyze patient images.
9	Customer network	Switches, Firewalls, Internet access, Review clients, Virtual image server (if required)
10	Patient environment	The image server, switch and any browser-based review clients or monitors must be positioned outside the patient environment; more than 1.5 meters (5 ft) from the scan head.

System Parts – Reference - Silverstone

2.6.1 System parts

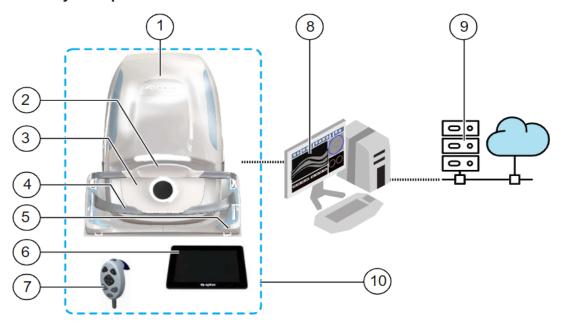


FIGURE 1: P200TxE device connected to network

No.	Name of Part	Description
1	Scan head	The scan head comprises the light sources (lasers and swept source) and electronics used to capture patient images.
2	Head rest	The head rest supports the patient's head when the patient is being imaged, see Using the chin rest and head rest on page 33.
3	Face pad	The face pad helps support the patient when the patient is being imaged.
4	Chin rest	The chin rest supports the patient's head when the patient is being imaged, see Using the chin rest and head rest on page 33.
5	Status indicator	The color changes to show the status of the device, see <i>Status indicator</i> on page 50.
6	Touch screen	The touch screen monitor is used to interact with the system. It displays alignment feedback and captured images.
7	Hand control	The hand control comprises buttons used to adjust the patient alignment and capture images.
8	Image server	Runs the OptosAdvance software and lets you manage the networked images. The image server will also let you review and analyze patient images.
9	Customer network	Switches, Firewalls, Internet access, Review clients, Virtual image server (if required)
10	Patient environment	The image server, switch and any browser-based review clients or monitors must be positioned outside the patient environment; more than 1.5 meters (5 ft) from the scan head.