CS 8100 and CS 8100 Access

User Guide

Notice

Congratulations on your purchase of the CS 8100 and CS 8100 Access. Thank you for your confidence in our products and we will do all in our power to ensure your complete satisfaction.

The User Guide for the CS 8100 and CS 8100 Access provides information on complete or segmented tomographic digital panoramic X-ray image features. We recommend that you thoroughly familiarize yourself with this Guide in order to make the most effective use of your system.



WARNING: We recommend that you consult the "Safety, Regulatory and the Technical Specification User Guide" before using the CS 8100 and CS 8100 Access.

The information contained in this Guide may be subject to modification without notice, justification or notification to the persons concerned.

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The US Federal law restricts this device to sale by or on the order of a physician.

This document is originally written in English.

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The CS 8100 and CS 8100 Access complies with Directive 93/42/EEC relating to medical equipment.



Manufacturer



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Conventions in This Guide

Conventions in this Guide

The following special messages emphasize information or indicate potential risk to personnel or equipment:



WARNING: Warns you to avoid injury to yourself or others by following the safety instructions precisely.



CAUTION: Alerts you to a condition that might cause serious damage.



Important: Alerts you to a condition that might cause problems.



Note: Emphasizes important information.



Tip: Provides extra information and hints.

2 cs 8100 Overview

The CS 8100 Family includes:

- CS 8100: complete modality
- CS 8100 Access: modality without the 2D+ feature

This document refers to both models as CS 8100 unless otherwise specified.

The following figures illustrate the general overview of the CS 8100.

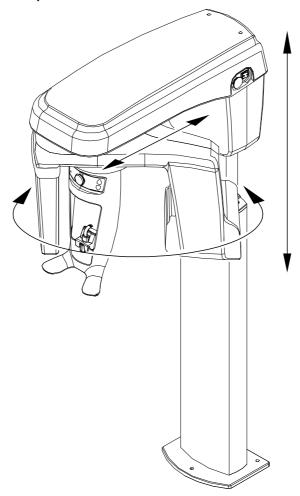
Mobile Components

Figure 1 illustrates the up and down movement of the unit mobile component and the rotation of the rotative arm.



Important: The patient can enter through either the left side or the right side of the unit.

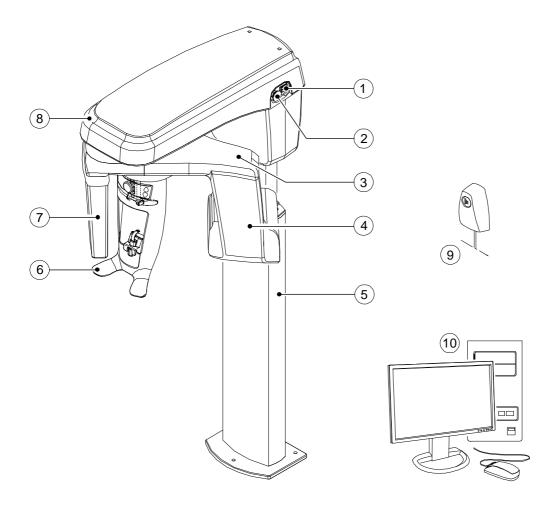
Figure 1 Unit Mobile Components



General Functional Components

Figure 2 illustrates the general functional components of the unit.

Figure 2 Unit Functional Components



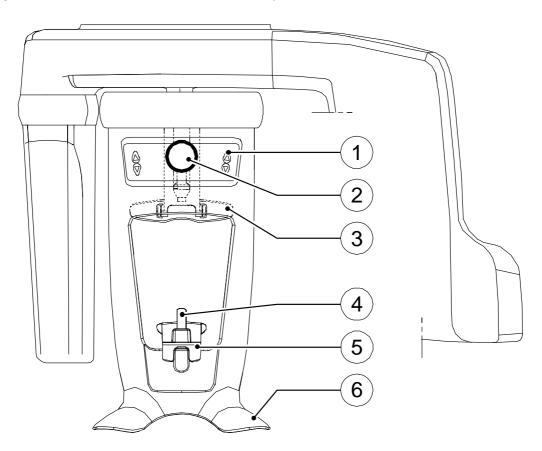
- 1 ON/OFF button
- 2 Emergency stop knob
- 3 Unit rotative arm
- 4 X-ray source assembly
- 5 Unit column
- 6 Head and chin rest
- 7 Digital sensor

- 8 Unit head
- 9 X-ray remote control
- 10 PC hosting the imaging and the acquisition software

Head and Chin Rest

Figure 3 illustrates the functional components of the head and chin rest.

Figure 3 Head and Chin Rest Functional Components



- 1 Positioning Panel
- 2 Frontal head rest adjustment knob
- 3 Head rest
- 4 Bite block
- 5 Chin rest
- 6 Hand grips

Positioning Accessories

The following accessories are used when positioning a patient. They are delivered with the CS 8100.

Table 1 lists the positioning accessories.

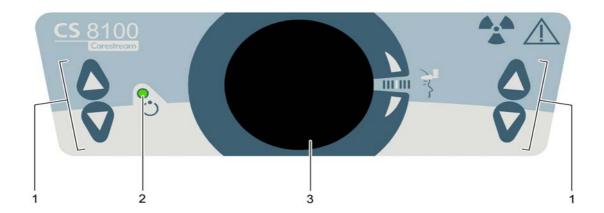
Table 1 Positioning Accessories

Accessory	Description
	Panoramic chin rest
	Sinus chin rest
	TMJ nose rest
	Standard bite block (x5)
	Bite block for edentulous patients (x2)
	Single use sheaths for bite block

Positioning Panel

The positioning panel is a console on the head and chin rest that enables you to correctly position and align a patient before you acquire an image.

Figure 4 Unit Positioning Panel

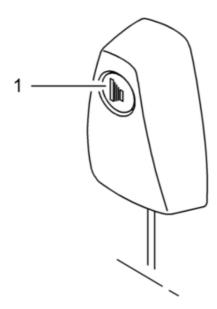


- 1 Height Adjustment button: Adjusts the height of the unit to the height of the patient.
- 2 Ready Indicator LED: Green indicates that the unit is ready for acquisition.
- **3** Frontal head rest adjustment knob: Positions the up or down inclination of the patient head by turning the knob.

X-Ray Remote Control Overview

The X-ray remote control enables you to launch a radiological image acquisition via the exposure button from outside the X-ray room. You must press and hold the exposure button until the end of acquisition. Premature release of the exposure button interrupts the acquisition.

Figure 5 X-Ray Remote Control



1 Exposure button: launches image acquisition.

3 Imaging Software Overview

Computer System Requirements

For the minimum computer system requirements and configuration for the Imaging Software, see the CS 8100 and CS 8100 Access Safety, Regulatory and Technical Specifications User Guide.



IMPORTANT

It is MANDATORY to check that the computer system configuration is compatible with the computer system requirements for the CS 8100 software. If necessary you MUST update your computer system configuration. The unit MUST be connected to the computer via a point-to-point Ethernet link and not via a LAN.

General Software Overview

The CS 8100 operates with the following software:

- Imaging software
- Acquisition interface

Imaging Software

The imaging software is a user-friendly working interface that was designed and developed specifically to support image diagnosis.

Acquisition Interface

The **Acquisition** interface is a user-friendly interface that was designed and developed specifically for the CS 8100.

Acquisition Interface

Acquisition Interface Overview

The **Acquisition** interface is the main interface of the CS 8100 that provides you with imaging acquisition functions.

Figure 6 Acquisition Interface



1 Information button:

- Show versions ...: Identifies Software and Firmware versions.
- Resetting Anatomy setting: Resets to the manufacturing parameter settings.
- Memorize Anatomy setting: Memorizes the user preference settings for each patient type (kV, mA and seconds).
- 2 Preview Screen: Displays the acquired image in real time.
- 3 Selected Parameter Display: Displays the current acquisition parameter settings.
- 4 System Status Screen: Displays various alert or warning messages originating from the unit.
- 5 Generator Cooling indicator: Indicates the automatic cooling time (mm:ss) required for the generator to reach 0 for a new acquisition.
- **Reset button:** Resets the unit to the starting position to enable you to position a patient in the unit.
- **Parallel position button:** Leaves more free space around the unit when it is not in use by placing the rotative arm in a parallel position to the unit head.
- 8 X-ray On/Off button: Enables or disables X-ray emission.

- 9 Ready Indicator LED
 - Green indicates the unit is ready to start acquisition.
 - Black indicates the unit is not ready to start acquisition.
- 10 Exit button: Closes the Acquisition interface.
- 11 X-ray Emission indicator: Yellow, indicates the X-ray emission status.
- 12 Selector Button: Selects different acquisition setting options.
 - Click **Program** to select examination type options.
 - Click Patient to select patient type parameters.
 - Click **Parameters** to select exposure parameter options.

Program Pane

The **Program pane** enables you to choose different radiological exams. The diagram in the **Program pane** represents a jaw, with the **R** side of the diagram corresponding to the right side of the patient.

Figure 7 Program Pane



Radiological exam options:

Segmented panoramic acquisition:

Click on the following areas of interest that you want to examine:

- Posterior
- Anterior

The selected area of interest will highlight. Example (anterior exam):



Maxillary Sinus acquisition:



TMJ acquisition:



Full panoramic acquisition:

Click on all the areas of interest. Example:



2D+ acquisition:

Click to examine a selected area of interest in 2D+ slices that can be moved in the buccal/lingual direction across a jaw.



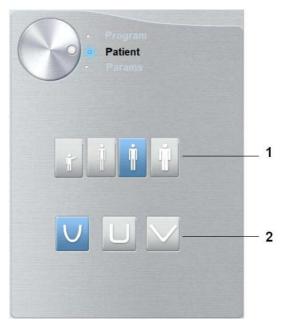
NOTE

The 2D+ feature is available for CS 8100. It is not available for CS 8100 Access.

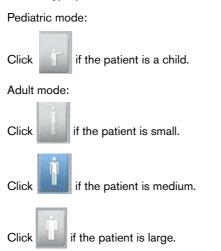
Patient Pane

The **Patient pane** enables you to choose different patient parameters. The selection of the patient parameters influences the quality of the image. The selected parameters must be based on the age and morphology of the patient.

Figure 8 Patient Pane



1 Patient type parameters:



2 Patient dental arch morphology:



Parameter Pane

The **Parameter Pane** enables you to choose exposure parameters for the radiological image acquisition. If the default parameter setting is not adapted to your patient type, you can manually adapt the parameter setting to the patient type and save this setting as the default setting.

To save a parameter setting, click and select Memorize Anatomy setting.

Figure 9 Parameter Pane



1 Exposure setting options:



2 Fine-tuning buttons:



4 Getting Started

Switching on the Unit

Before switching on the unit, check that:

- The installation of the unit is complete.
- The computer is switched on.



Important: You must switch on the computer and wait for it to be ready for the connection before switching on the unit.

To switch on the unit, follow these steps:

- 1. On the unit column, press the **ON** button.
- 2. You must wait for a minute for the connection between the unit and the computer to be established. If you start the imaging software before the connection is established an error message is displayed. Click **OK**, close the imaging software and wait for the connection to be established.
- 3. You can now proceed to start the imaging software.



Important: To increase the operating life of the X-ray tube, if the unit has not been used for a month, you must follow the following procedures before use.

- 1. In the Panoramic Acquisition Window, select the Parameter pane.
- 2. Select the following series of parameter settings:
 - 70 kV 6.3 mA
 - 80 kV 10 mA
 - 85 kV 10 mA
- 3. Leave the X-ray room and close the door. For each parameter setting, from the X-ray remote control, press and hold the button to launch the X-ray

The unit is now ready to be used for acquisition.

5 Acquiring Images

Acquiring a Panoramic, a TMJ x2, or a Sinus Image for the Adult and Pediatric Patient

Accessing the Acquisition Interface

To access the acquisition interface, follow these steps:

- Select the patient record.
 See the User Guide for your patient management software.
- 2 On your desktop, double-click or ... The Imaging Window is displayed.
- 3 In the **Imaging Window**, from the toolbar, click or to access the **Acquisition** interface.

Preparing the Unit and Setting the Acquisition Parameters

To set the acquisition parameters, follow these steps:

1 In the Acquisition interface, click the Program button to access the Program pane.



Click on one area of interest that you want to examine:

- Panoramic: for example,
- TMJ x2:
- Sinus:

2 Click the Patient button to access the Patient pane.



Select the patient:

- Type (1):
 - Child
 - Adult: Small, Medium, Large
- Dental arch morphology (2)
- 3 **(Optional)** If the default parameter setting is not adapted to your patient type, click the **Parameter** button:

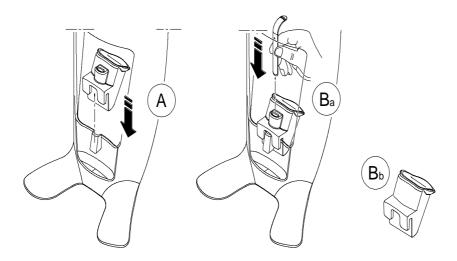


- Select the appropriate parameters.
- Click and select Memorize Anatomy setting to save the new parameter settings as the
 default settings.

4 Position and fix the panoramic chin rest (A). Fit the bite block to the panoramic chin rest (Ba). Make sure that you click it well into place. If needed, use the edentulous bite block.



Note: Use the panoramic chin rest (A) for a panoramic or TMJ x2 image acquisition. Use the sinus chin rest (Bb) for a sinus image acquisition.

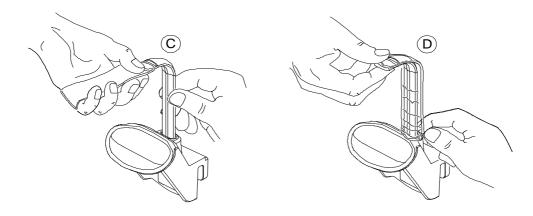


Insert a hygienic barrier over the bite block (C). Make sure that you cover the bite block completely with the hygienic barrier (D).



IMPORTANT

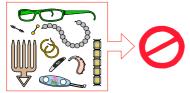
You must cover the bite block with FDA-cleared protective sheaths that are available from distributors.



Preparing and Positioning the Adult and Pediatric Patient

To prepare and position the patient, follow these steps:

1 Ask the patient to remove all metal objects.



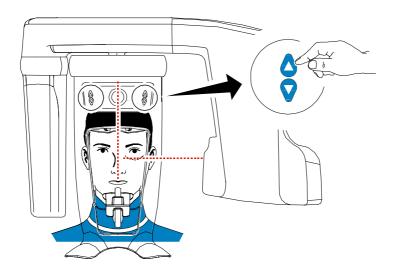
2 Ask the patient to wear a lead apron with a thyroid collar. Ensure that the apron lays flat across the patient's shoulders.



3 Ask the patient to enter the unit. On the **Positioning panel**, press and hold to raise the chin rest to the height of the patient.

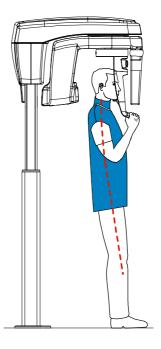


Note: If the patient is too tall, tell the patient to sit on a stool.



4 Ask the patient to:

- Stand up straight.
- Grip both the lower handles of the head and chin rest.
- Position the feet slightly forward.
- Relax and lower the shoulders for full motion of the unit rotative arm.





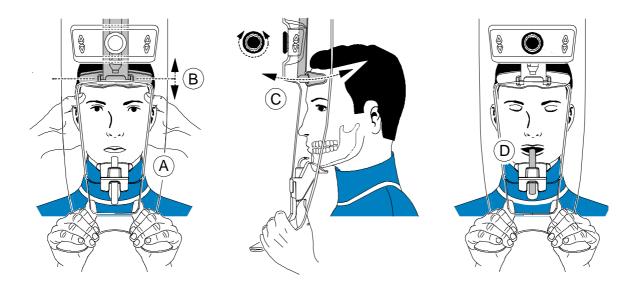
Note: By correctly positioning the patient, you can reduce the spinal column shadow that is transferred to the acquired image.

- 5 Ask the patient to place the chin on the chin rest support (A).
- Adjust the frontal head rest (B) to the forehead. Make sure that the forehead is firmly fixed on the frontal head rest. Using both hands, correctly align the horizontal and vertical position of the head.



Important: The spinal column and the nose of the patient must be aligned in a straight line.

- 7 Turn the frontal head adjustment knob (C) to adjust the up or down inclination of the patient head for a Frankfort plane alignment.
- 8 Ask the patient to:
 - Bite into the bite block (D).
 - Close the eyes.
 - Remain still.
 - Breathe through the nose.



Launching the X-ray

To launch the X-ray, follow these steps:

1 Leave the X-ray room and close the door. You must keep visual contact with the patient during acquisition.



Important: To stop the acquisition, if there is any problem, release the exposure button of the remote control or press the red emergency stop button.



2 Launch the X-ray with the remote control. Press and hold the exposure button until the end of the acquisition is indicated by the on-screen "Release Switch" message. The xurns yellow and a warning sound is heard, indicating X-ray emission. When the acquisition ends, the Acquisition interface disappears and the acquired image is automatically transferred to the Imaging Window.



- 3 Check the image quality.
- 4 Do the following when the acquisition is finished:
 - Release the patient.
 - Remove the hygiene barrier from the bite block.

Acquiring a 2D+ Image for the Adult and Pediatric Patient

Accessing the Acquisition Interface

To access the acquisition interface, follow these steps:

- Select the patient record.
 - See the User Guide for your patient management software.
- On your desktop, double-click or . The Imaging Window is displayed.
- In the Imaging Window, from the toolbar, click or to access the Acquisition interface.

Preparing the Unit and Setting the Acquisition Parameters

To set the acquisition parameters, follow these steps:

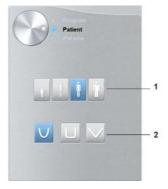
In the Acquisition interface, click the Program button to access the Program pane.



and click on the area of interest that you want to examine. Example:



Click the **Patient** button to access the **Patient pane**.



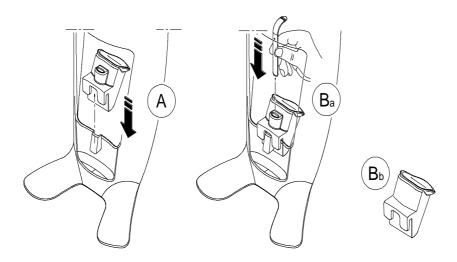
Select the patient:

- Type (1):
 - Child
 - Adult: Small, Medium, Large
- Dental arch morphology (2)

4 **(Optional)** If the default parameter setting is not adapted to your patient type, click the **Parameter** button:



- Select the appropriate parameters.
- Click and select Memorize Anatomy setting to save the new parameter settings as the
 default settings.
- Position and fix the panoramic chin rest (A). Fit the bite block to the panoramic chin rest (Ba). Make sure that you click it well into place. If needed, use the edentulous bite block.

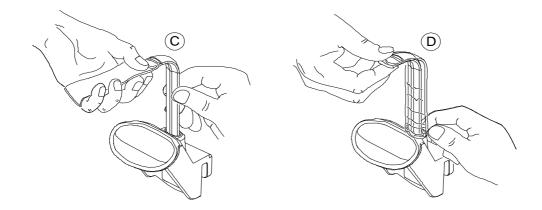


6 Insert a hygienic barrier over the bite block (C). Make sure that you cover the bite block completely with the hygienic barrier (D).



IMPORTANT

You must cover the bite block with FDA-cleared protective sheaths that are available from distributors.



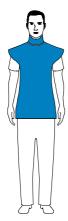
Preparing and Positioning the Adult and Pediatric Patient

To prepare and position the patient, follow these steps:

1 Ask the patient to remove all metal objects.



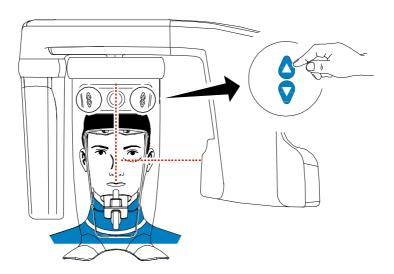
2 Ask the patient to wear a lead apron with a thyroid collar. Ensure that the apron lays flat across the patient's shoulders.



3 Ask the patient to enter the unit. On the **Positioning panel**, press and hold to raise the chin rest to the height of the patient.

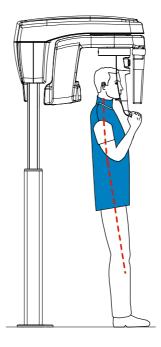


Note: If the patient is too tall, tell the patient to sit on a stool.



4 Ask the patient to:

- Stand up straight.
- Grip both the lower handles of the head and chin rest.
- Position the feet slightly forward.
- Relax and lower the shoulders for full motion of the unit rotative arm.





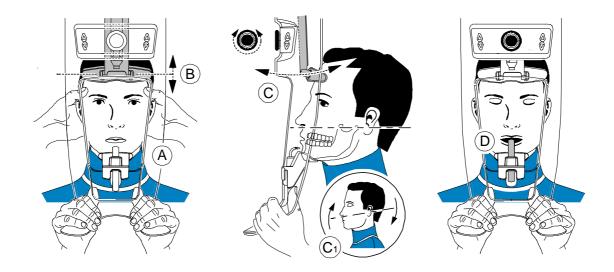
Note: By correctly positioning the patient, you can reduce the spinal column shadow that is transferred to the acquired image.

- 5 Ask the patient to place the chin on the chin rest support (A).
- Adjust the frontal head rest (B) to the forehead. Make sure that the forehead is firmly fixed on the frontal head rest. Using both hands, correctly align the horizontal and vertical position of the head.



Important: The spinal column and the nose of the patient must be aligned in a straight line.

- 7 Turn the frontal head adjustment knob (C) to adjust the patient head (C₁) for a Camper plane alignment.
- 8 Ask the patient to:
 - Bite into the bite block (D).
 - · Close the eyes.
 - Remain still.
 - Breathe through the nose.



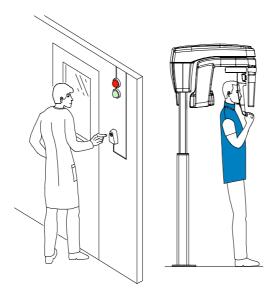
Launching the X-ray

To launch the X-ray, follow these steps:

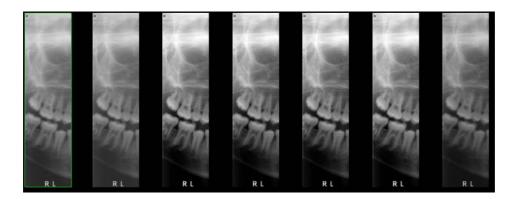
1 Leave the X-ray room and close the door. You must keep visual contact with the patient during acquisition.



Important: To stop the acquisition, if there is any problem, release the exposure button of the remote control or press the red emergency stop button.



2 Launch the X-ray with the remote control. Press and hold the exposure button until the end of the acquisition is indicated by the on-screen "Release Switch" message. The turns yellow and a warning sound is heard, indicating X-ray emission. When the acquisition ends, the Acquisition interface disappears and the acquired image is automatically transferred to the Imaging Window.



- 3 Check the image quality.
- 4 Do the following when the acquisition is finished:
 - Release the patient.
 - Remove the hygiene barrier from the bite block.

Acquiring a TMJ x4 Image for the Adult and Pediatric Patient

Accessing the Acquisition Interface

To access the acquisition interface, follow these steps:

Select the patient record.

See the User Guide for your patient management software.

- 2 On your desktop, double-click 🖊 or 💫 The Imaging Window is displayed.
- 3 In the **Imaging Window**, from the toolbar, click or to access the **Acquisition** interface.

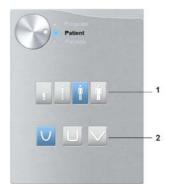
Preparing the Unit and Setting the Acquisition Parameters

To set the acquisition parameters, follow these steps:

1 In the Acquisition interface, click the Program button to access the Program pane.



- 2 Select and click 4.
- 3 Click the **Patient** button to access the **Patient pane**.



Select the patient:

- Type (1):
 - Child
 - Adult: Small, Medium, Large
- Dental arch morphology (2)

4 **(Optional)** If the default parameter setting is not adapted to your patient type, click the **Parameter** button:

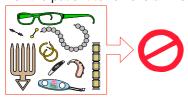


- Select the appropriate parameters.
- Click and select **Memorize Anatomy setting** to save the new parameter settings as the default settings.
- On the head and chin rest, remove or , place and cover it with a hygienic barrier.

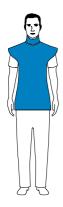
Preparing and Positioning the Adult and Pediatric Patient

To prepare and position the patient, follow these steps:

1 Ask the patient to remove all metal objects.



2 Ask the patient to wear a lead apron with a thyroid collar. Ensure that the apron lays flat across the patient's shoulders.

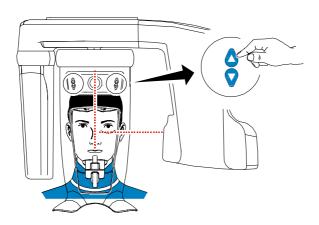


Ask the patient to enter the unit. On the **Positioning panel**, press and hold to raise the chin rest to the height of the patient.

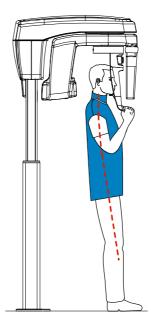




Note: If the patient is too tall, tell the patient to sit on a stool.



- Ask the patient to:
 - Stand up straight.
 - Grip both the lower handles of the head and chin rest.
 - Position the feet slightly forward.
 - Relax and lower the shoulders for full motion of the unit rotative arm.





Note: By correctly positioning the patient, you can reduce the spinal column shadow that is transferred to the acquired image.

Launching the X-ray

To launch the X-ray, follow these steps:

1 Tell the patient to remain still, eyes closed, and mouth closed. Leave the X-ray room and close the door. You must keep visual contact with the patient during acquisition.





Important: To stop the acquisition, if there is any problem, release the exposure button of the remote control or press the red emergency stop button.



2 Launch the X-ray with the remote control to acquire an image. Press and hold the exposure button until the end of the acquisition is indicated by the on-screen "Release Switch" message. The turns yellow and a warning sound is heard, indicating X-ray emission. When the acquisition ends, the Acquisition interface disappears and the acquired image is automatically transferred to the Imaging window.

Tell the patient to stay in the same position but with mouth opened. Repeat Step 2 to acquire another image with the mouth opened.



- 4 Check the quality of the images.
- 5 Do the following when the acquisition is finished:
 - · Release the patient.
 - Remove the hygiene barrier and the from the head and chin rest.

X-Ray Dose Emission Information

Compliance with EURATOM 97/43 Directive

You can right-click on each image to display the estimated emitted dose received by the patient. You can use this information to calculate the effective dose received by the patient for the image.

The radiation emission dose is expressed in mGy.cm². This dose is measured at the primary collimator outlet. The dose is accurate to +/-30%.

6 Maintenance

Perform the following maintenance activities on your CS 8100 and CS 8100 Access.

Daily

Cleaning the unit

To clean the unit, follow these steps:

- 1. Switch off the unit.
- Clean all accessible parts of the unit using low-level disinfectants that are U.S.
 Environmental Protection Agency (EPA)-registered or low-level disinfectants that are
 recognized by your Local Authority. An EPA-registered hospital disinfectant or any other
 low-level disinfectant must have clear label claims for intended use. You must follow the
 manufacturer instructions for use.



CAUTION

Avoid applying any cleaning liquid to the inside parts of the unit.

Cleaning and disinfecting the Accessories



CAUTION

You MUST cover the standard bite block and the bite block for edentulous patients with FDA-cleared protective sheaths that are available from distributors.

We recommend that you cover the TMJ nose rest with FDA-cleared protective sheaths that are available from distributors.

After you remove and discard the protective sheath, each accessory must be cleaned and disinfected between each patient use.

Cleaning and disinfecting the accessories that have contact with the mucous membranes

To ensure maximum hygienic safety for the patient, follow the following instructions carefully to prepare them for use:

The following accessories must be heat-sterilized or disinfected with high-level disinfectant between each patient use:

- TMJ nose rest
- Standard bite block
- Bite block for edentulous patient

To clean and disinfect the accessories, follow these steps:

1. Remove all visible soil by scrubbing with a surfactant, detergent, and water.

- 2. Rinse with water to remove chemical or detergent residue.
- 3. Autoclave up to 134 °C, or use a high-level disinfectant (for example, Glutaraldehyde, glutaraldehyde with phenol, hydrogen peroxide, hydrogen peroxide with peracetic acid, ortho-phthalaldehyde).



WARNING

To disinfect with heat, you must use a medical autoclaving equipment cleared by the FDA in the USA. You must always follow the operating parameters recommended by the manufacturer of the autoclaving equipment. You must always follow the manufacturer instructions for use of high-level disinfectants.

4. Use immediately or within a short period of time.

Cleaning and disinfecting the component and accessories that have skin contact

You must disinfect the following component and accessories with a low-level disinfectant between each patient use:

- Frontal head rest
- Panoramic/Sinus chin rest

To clean and disinfect the component and accessories, follow these steps:

- 1. Clean and remove all visible soil by scrubbing with a surfactant, detergent, and water.
- 2. Rinse with water to remove chemical or detergent residue.
- 3. Disinfect with an EPA-registered, hospital disinfectant for low-level activity (for example, quaternary ammonium compounds, some phenolics, and some iodophors). You must use the disinfectant according to the manufacturer instructions.



CAUTION

If there is a visible contamination with blood, you must clean the components and accessories with an EPA-registered intermediate-level hospital disinfectant that has a tuberculocidal claim. You must use the disinfectant according to the manufacturer instructions.

Monthly

Wipe the outer covers of the unit with a soft and dry cloth.

Annually

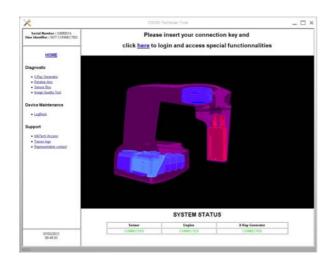
We recommend a general inspection of the unit carried out by an authorized service technician.

Controlling the Image Quality

To maintain optimum image quality, the image quality must be controlled regularly. To control the image quality, follow these steps:

1. On your desktop, double-click . The CS 8100 Technician Tools window is displayed.





2. In the left pane, double-click Image Quality Tool. The Image Quality Control window is displayed.



- 3. In the Image Quality Control window, to perform the test, you can either:
 - Select the desired device in the **List of detected acquisition devices** field. Or
 - Browse and import a file in the Import field. Click Next and follow the instructions.

4. Select the desired test and follow the on-screen instructions.

You have two test options:

• Constancy test: This test must be executed regularly by the user. The result of the tests must be compared to the Acceptance test. Select the desired test and follow the on-screen instructions.

Or

Acceptance test: This test is ONLY executed by the technician. It is a complete
image quality control test (make sure you have the required test tools). The result of
this test is used as reference for the Constancy test by the user.

Troubleshooting

Quick Troubleshooting

Occasionally, malfunctions can occur during use in the event of an incorrect action. An error message is displayed on the popup on the **Acquisition** interface **System Status Screen**.

The following table lists the information messages, their description and the action to take:



IMPORTANT

If an Error Code message is displayed, the malfunction persists or more serious conditions occur, contact a qualified technician. When you call the qualified technician have the following information ready:

Model Number: CS 8100Error Code Message

Table 2 Error Code Message

Error Code	Error Message	Description	Action
Err_S_8100_CJ848_GENERATOR_36865	released before the end of exposure.	released the exposure button	Relaunch the acquisition and hold the exposure button until the end of the acquisition cycle.

Table 3 Quick Troubleshooting

Message	Description	Action
X-ray tube cooling	Cooling in progress.	Wait until the Generator Cooling Indicator on the Acquisition interface reaches zero.
Thermal security	Cooling in progress.	Wait until the Generator Cooling Indicator on the Acquisition interface reaches zero.
Release handswitch	The acquisition has ended.	Release the exposure button of the x-ray remote control.
Start the acquisition	The acquisition has been launched.	Keep pressing and holding the exposure button.
Upgrade of the firmware	The system is being upgraded.	Wait for completion of the upgrade.