

# Respiratory Gating for Scanners Instructions for Use

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<b>Document Title</b>	<i>Respiratory Gating for Scanners Instructions for Use</i>
<b>Abstract</b>	<p>This document provides reference information and procedures for the following product:</p> <ul style="list-style-type: none"> <li>■ Respiratory Gating for Scanners 1.1</li> </ul> <p>This publication is the English-language original.</p>
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# Chapter 1 Introduction

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## About this Publication

This publication is primarily intended for physicists, radiation oncologists, and radiation therapists, who perform respiration-synchronized image acquisition and treatment delivery. It describes the most common procedures for using the Respiratory Gating for Scanners (RGSC) system in clinical use and provides supporting information.

The appendix has basic information about system configuration for system administrators.

## About Respiratory Gating for Scanners

Respiratory Gating for Scanners (RGSC) is an accessory system to diagnostic imaging devices. The system is used to observe and record the respiratory motion of a patient and to transfer this information to the imaging device and to radiation treatment planners. With integrated audio coaching and optional visual coaching, the system guides the patient in achieving a more regular and predictable breathing pattern during image acquisition or treatment delivery.

- Imaging devices use respiratory motion information to synchronize their operation with the respiratory motion of the patient. They either acquire images based on the trigger signal received from RGSC (*prospective* mode) or they use the respiratory motion information for 4D reconstruction after the scanning process (*retrospective* mode).
- Radiation treatment planners use respiration-synchronized images to ensure that the images used for planning and simulation correspond to a known breathing state that can be detected or reproduced before and during treatment, thereby enabling beam-on when and only when the patient is in that respiratory state.

## Intended Use

For image acquisition, Respiratory Gating for Scanners supports the following processes:

- Acquire respiratory traces by optically detecting the motion of a reflector block, typically positioned on the abdomen of the patient.
- Acquire respiration-synchronized images in connection with a diagnostic CT or PET scanner.

- Acquire respiration-synchronized 4D images (referred to as retrospectively gated images) in connection with a diagnostic CT or PET scanner.

To assist respiration-synchronized image acquisition and treatment delivery, Respiratory Gating for Scanners supports the following processes:

- Assess the amplitude and regularity of the external respiratory motion of the patient.
- Provide audio and visual coaching to the patient to achieve more regular respiration.
- Configure three different types of gating: phase gating, amplitude gating and breath-hold gating.

The system uses chest wall or abdominal motion as a surrogate for respiratory motion of the tumor and other organs and structures within the body. The adequacy of this surrogate indicator for application to the treatment of any specific patient condition or setup must be based upon clinical evaluation using CT imaging and other studies as deemed appropriate. These judgments are the sole responsibility of qualified medical personnel using the equipment.

## Clinical Workflow for Scan and Training Session

In addition to respiration-synchronized image acquisition (scan session), you can execute training sessions for the following purposes.

- Check whether a patient is able to breathe as needed for respiration-synchronized image acquisition or treatment delivery.
- Familiarize the patient with coaching techniques.
- Select appropriate options for respiration-synchronized image acquisition.

The training session workflow is a subset of the scan session workflow, according to which the chapters in this publication are structured.

**Table 1 Clinical Workflow**

Step	Task Description	Scan	Training
1	<a href="#">Chapter 4 Prepare the Equipment</a>	✓	✓
2	<a href="#">Chapter 5 Prepare the Session and the Patient</a>	✓	✓
3	<a href="#">Chapter 6 Acquire Respiration-Synchronized Images</a>	✓	-
4	<a href="#">Chapter 7 Finalize the Session</a>	✓	-

You can use a training session later to acquire respiration-synchronized images and finalize the session. If you do, the training session becomes a scan session.



# Visual Cues

This publication uses the following visual cues to help you find information:



**WARNING:** A warning describes actions or conditions that can result in serious injury or death.



**CAUTION:** A caution describes hazardous actions or conditions that can result in minor or moderate injury.



**NOTICE:** A notice describes actions or conditions that can result in damage to equipment or loss of data.



**Note:** A note describes information that may pertain to only some conditions, readers, or sites.



**Tip:** A tip describes useful but optional information such as a shortcut, reminder, or suggestion, to help get optimal performance from the equipment or software.

## Contact Varian Customer Support

Varian Customer Support is available on the internet, by e-mail, and by telephone. Support services are available without charge during the initial warranty period.

The MyVarian website provides contact information, product documentation, and other resources for all Varian products.

1. Go to [www.MyVarian.com](http://www.MyVarian.com).
2. Choose an option:
  - If you have an account, enter your User login information (email and password).
  - If you do not have an account, click **Create New Account** and follow the instructions. Establishing an account may take up to two working days.
3. Click **Contact Us** at the top of the window to display customer support and training options, and international e-mail addresses and telephone numbers.

4. From the Contact Us page, choose an option:

- Call Varian Medical Systems support using a phone support number for your geographic area.
- Complete the form corresponding to your request for use on a call with a live Varian representative; then follow the instructions to complete the remote connection.

You can order documents by phone, request product or applications support, and report product-related issues. Links on the MyVarian website navigate to other support resources for products, services, and education.

5. To find documents, click **Product Documentation**.

Online documents in PDF format include customer technical bulletins (CTBs), manuals, and customer release notes (CRNs).

# Chapter 2 Safety

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## Safety Overview

General safety precautions apply to the operation of Respiratory Gating for Scanners and all associated equipment. Procedures include warnings and cautions describing a particular hazard.

Where applicable, hardware and software are designed to meet current international technological and safety standards, for example, IEC for the protection of users and patients.

The hospital is responsible for establishing emergency and safety procedures to ensure safe operation and maintenance conditions. Hazards can be encountered, and risks cannot be ruled out completely. Thus operators must follow instructions and procedures in this manual to guarantee safety of patients and operators.

## Symbols Used on Equipment Labels

Symbols found on equipment labels have the following meanings:



Potential injury or damage to equipment: Observe safety precautions. Consult accompanying documents.



Laser radiation: Do not stare into beam; observe laser safety precautions.



Radio frequency radiation: Do not operate this equipment with the covers, output cable, or interlock cover removed. Radio frequency energy can cause injury or burns.



Hazardous voltage: Disconnect power before servicing. Contact may cause electric shock or burn.



Battery safety: Do not expose battery to fire.



Battery safety: Do not expose battery to water.



Battery safety: Do not charge battery that may be damaged.



Consult instructions for use. Follow operating instructions.



Type B applied part: This part complies with the specified requirements of EN 60601-1 to protect against electric shock, particularly regarding allowable leakage current.



Protective earth (ground): Identified terminals are intended for connection to earth (ground) for protection against electric shock.



EEE waste: The equipment has been designated as electrical and electronic equipment (EEE) that is not to be disposed of at the end of its life as unsorted municipal waste. EEE contains substances that may be hazardous to human health and to the environment. It must be recovered, reused, recycled, or otherwise treated and disposed of properly.



Recyclable material: This item can be recycled where correct facilities exist.



Equipment manufacturer: This symbol appears adjacent to the name and address of the equipment manufacturer.



Serial number: This symbol appears adjacent to the manufacturer's serial number.



Reference number: This symbol appears adjacent to the manufacturer's reference number (catalog number).



CE conformity: The equipment conforms to the official journal of the European Communities Council Directive 93/42/EEC.



ETL conformity: The equipment conforms to UL STD 60601-1. Certified to CAN/CSA STD C22.2 No 601.1-M90.



China RoHS conformity: The equipment conforms to People's Republic of China Electronic industry standard SJ/T11364-2006.

## Battery Safety

The battery for the optional Visual Coaching Device (VCD) is a lithium ion battery.

Improper battery use may result in fire, explosion, or other hazard. To avoid risk of injury, follow these instructions for using or storing the battery:

- Only use the battery with the VCD.
- Only use the battery with the dedicated charging station. Use of another charging station may present a risk of fire, explosion, leakage or other hazard.
- Do not disassemble or open, crush, bend or deform, puncture or shred the battery.
- Do not modify the battery or insert foreign objects into the battery.
- Do not immerse the battery in water or other liquids, or expose it to water, fire, explosion, or other hazard.
- Do not short-circuit the battery or allow metallic or conductive objects to contact the battery terminals.
- Replace the battery only with another VCD battery. Use of any other battery may risk fire, explosion, leakage, or other hazard.
- Promptly dispose of used batteries in accordance with local regulations.

## Maintaining System Integrity

Modifying or altering the products, or the software in the products, in any way constitutes willful infringement of Varian's intellectual property and may endanger patient safety. Any such modification or alteration will render the system adulterated under the United States Federal Food, Drug, and Cosmetic Act (or applicable law in the territory) and could subject the customer or the authorized users to action by the United States Food and Drug Administration, resulting in seizure, injunction, civil penalties, or criminal prosecution.



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**WARNING: Do not modify the hardware or software. Unauthorized modification or alteration of the hardware or software may endanger patients, operators, or service personnel.**

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### Unauthorized or Modified Software

Modifying any of the software provided with the system, or installation and use of any software other than that provided or validated by Varian, can seriously compromise the integrity of stored data and the performance of operational applications and can result in uncertain, unreliable, and potentially hazardous system operation.

By accepting Varian's Terms and Conditions of Sale, you authorize Varian to remove any unauthorized software that has been added to, or altered, the system computer, its operating systems, or the control applications.

To minimize system corruption that may result in serious damage to your system or in patient harm, follow these instructions:

- Do not modify the system software, including the operating system, control applications, and data files.
- Do not install software on the system.
- Do not alter the configuration of the system installed by Varian personnel, including printed circuit boards, control devices, and all settings.

## Unauthorized Hardware

Unapproved supplemental devices include the following:

- Any device interfaced to the system using an unauthorized interface.
- Any unapproved device interfaced to the system using authorized interfaces.

Be aware that installation of an unapproved supplemental device has these consequences:

- May modify or damage the calibration, performance, treatment, or safety measures installed.
- Will void the Varian warranty.
- Can result in the termination of applicable software licenses.
- Could lead to severe patient injury or death.

## Network Impact

The Varian Respiratory Gating for Scanners system is connected to your network, which may include other equipment. Varian has no control over how the network is used. It is possible that data traffic from the Varian RGSC system could impact the operation of other equipment and could result in previously unidentified risks to patients, operators, or third parties. The system owner is responsible for identifying, analyzing, evaluating, and controlling these risks.

## Third-Party Devices

Your site may use one or more non-Varian devices in the scanner room. Be sure to refer to the documentation that accompanies these devices.

## Authorized Maintenance and Service

Only service personnel who have received the appropriate maintenance training and are authorized by the owner are allowed to perform maintenance and service procedures.

Authorized service personnel must know and follow safety procedures established for local use by the owner during all service and maintenance procedures. They are also required to take all precautions necessary to protect themselves, patients, and other persons from injury, and to protect the equipment from damage.

## Preventive Maintenance

Preventive maintenance of the system is very basic and simple and if followed properly can eliminate potential defects and hazards. Preventive maintenance is conducted to keep the equipment working and extend the life of the equipment.

Elements of a good preventive maintenance program should include the following:

- Identification of components that may malfunction.
- Establishment of schedules and procedures for routine inspections.
- Periodic testing of equipment for sound functioning.
- Inventory of spare parts.

For more information about general maintenance, contact Varian service personnel.

## System Specifications and Requirements

Specifications and requirements include electromagnetic, electric, environmental, and other specifications.




**Note:** *Respiratory Gating for Scanners is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the published EMC test declarations and guidance provided.*

## Related Topics

[Electromagnetic Compatibility \(EMC\)](#) on page 71

## Electrical Specifications

Type	Specification
Mode of operation	The system is classified as being suitable for continuous connection to the supply mains in the Power Saver mode. This means that some elements of the system may be connected to main electrical power even when the system is powered off.
Type of protection against electric shock	Class I
Degree of protection against electric shock	Type B 
Operating voltage	100–240 V, 50/60 Hz



**WARNING: To avoid risk of electric shock, ensure that the equipment is connected to a supply mains with protective earth.**

## Environmental Specifications

Type	Specification
Humidity	15% to 75% relative, non-condensing humidity
Temperature	15° to 28° C (60° to 80° F)
Degree of safety of application in presence of a flammable anesthetic mixture	Unsuitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide
Degree of protection against ingress of water	IPX0 (Ingress Protection Rating) or not waterproof



## Environmental Specifications for Transport and Storage

Type	Specification
Humidity	0% to 50% relative, non-condensing humidity
Temperature	-20° to 60° C (-4° to 140° F)
Atmospheric pressure	≤ 15,000 feet elevation

## Backpointer Laser Specifications

Type	Specification
Laser class	II
Wavelength	650–660 nm
Pulse duration	Continuous
Power output	≤ 1 mW

# Chapter 3 System Overview

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## Client Application

The client application is divided into three main areas:



**New Scan / Open Scan** starts the main workflow for defining a new session and acquiring respiration-synchronized images or for reviewing an existing scan session.



**Verification / Calibration** starts the verification and calibration workflow for the camera. For ceiling-mounted or wall-mounted cameras, it guides you through the acquisition of the reflector block positions on the couch in order to calibrate the camera to the couch top.



**Configuration** is where administrators can view the configuration of application, export, scanner, VCD, database, archive, and camera.

In addition, you also find the following controls:



**Log Out / Log In** opens the user authentication prompt.



**Exit Application** closes the application.

## Related Topics

[Start up the System and Log in](#) on page 29  
[User Groups](#) on page 60

## Scan Workspaces

The application is designed to facilitate navigation along the clinical workflow. While it guides you from workspace to workspace, you can jump back or forth at any time.

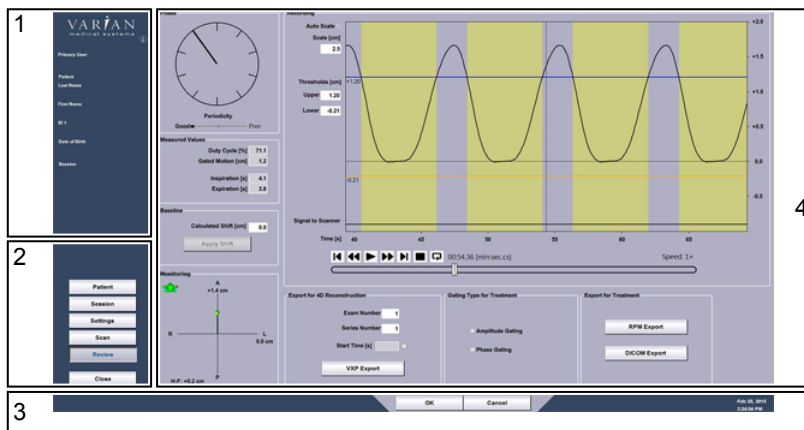
The typical workflow for respiration-synchronized image acquisition guides you through the workspaces as follows:

1. Initiate the workflow under **New Scan / Open Scan**.
2. Create or open a patient record under **Patient**.
3. Create or open a session under **Session**.

4. Specify scan settings under **Settings**.
  - Select a type of scan.
  - Specify gating and coaching options.
5. Acquire respiration-synchronized images under **Scan**.
  - Actively coach the patient: Start and stop coaching.
  - Adjust the gating thresholds.
  - Record the breathing.
  - Monitor the breathing.
  - Turn gating on and off.
6. Review a session under **Review**.
  - Review and apply the calculated baseline shift.
  - Review and export data for 4D reconstruction.
  - Review and export data for treatment delivery.
  - Close the session.

## User Interface

The user interface is divided into the following sections:

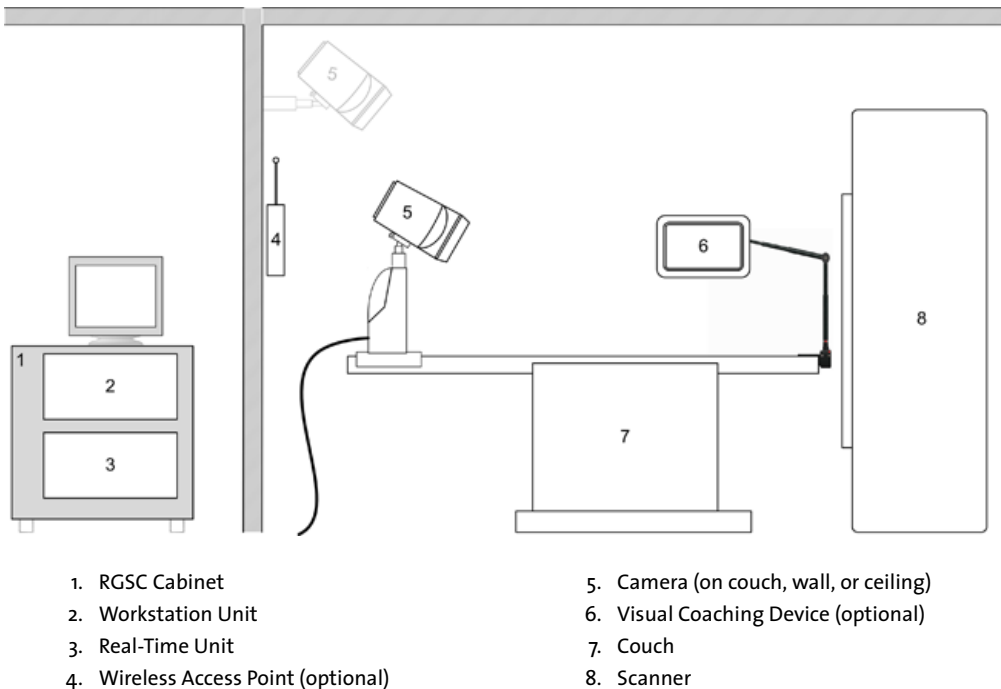


- |  |  |
|--|--|
| <ol style="list-style-type: none"> <li>1. Info Panel</li> <li>2. Workflow Panel</li> </ol> | <ol style="list-style-type: none"> <li>3. Control Bar</li> <li>4. Workspage Panel</li> </ol> |
|--|--|

**Figure 1 User Interface**

<b>Info panel</b>	<p>The info panel displays the name of the current user, the date of birth, first name, and last name of the patient, and the patient ID. After opening a session, the info panel also displays the name of the current session.</p> <p>The info button <i>i</i> under the Varian logo opens the <b>About RGSC</b> window. It provides information about the operating system and the application.</p> <p>If there are any pending alerts (RGSC Messages) for the system, an orange button appears. The button provides information about an alert or opens a dialog box.</p>
<b>Workflow panel</b>	<p>The workflow panel accommodates the buttons for navigating between workspaces. There is one button for each workspace. Workspace buttons are active according to user rights and workflow.</p>
<b>Workspace panel</b>	<p>Pressing a button in the workflow panel opens the corresponding workspace in the workspace panel. A workspace typically consists of one panel, but it can include tabs.</p>
<b>Control bar</b>	<p>The control bar accommodates confirmation and cancellation buttons. It also displays the current date and time, and workflow-specific messages.</p>

# Hardware Layout



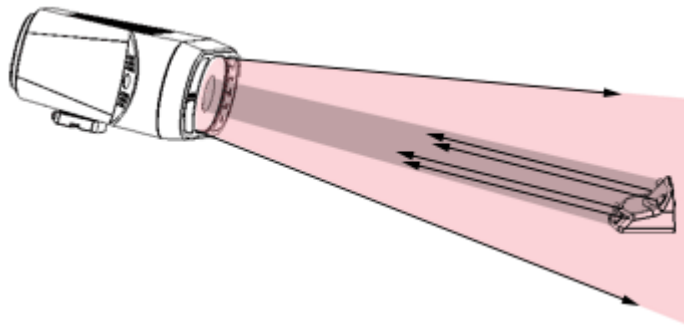
**Figure 2 Hardware Layout**

Hardware components are installed in two main areas: the control room and the scanner room. The illustration shows the location of the main hardware components.

The RGSC cabinet (including Workstation Unit and Real-Time Unit) and other computer peripherals are installed in the control room. The Real-Time Unit controls the interface to the scanner, camera and wireless access point in the scanner room.

The camera can be mounted in a fixed position on the wall or ceiling, or as a mobile version on the couch with a dedicated couch mount.

# Camera and Reflector Block



**Figure 3 Infrared Tracking Concept**

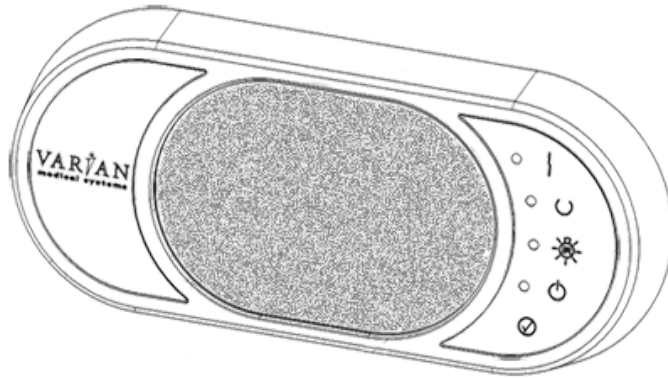
## Supported Tracking Distances

The camera delivers live video image data by tracking an infrared spectrum. It emits infrared light and detects the reflections from the passive markers of the reflector block. This allows identifying the exact position and orientation of the reflector block and tracking the respiratory motion. The camera is optimized to provide a high-contrast image of the reflector block markers.






Depending on the camera mount (couch, ceiling, or wall), one of the following camera lenses is in use:

Camera Mount	Lens	Distance
Wall or ceiling	25 mm	2500-5600 mm
Couch	12 mm	1000-2500 mm

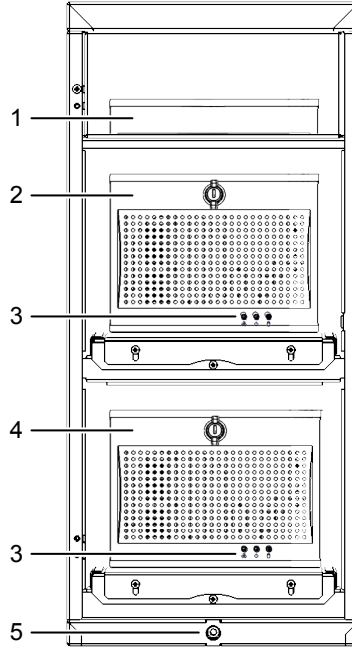
## Camera Controls



The following controls are available on the front of the camera.

-  **Connection Error** indicates that there is no Ethernet connection between camera and the Real-Time Unit.
-  **Tool Detected** indicates when reflector block is detected by the camera, the reported position is within the defined volume and acquisition is started.
-  **IR Illumination** indicates that infrared illumination is ON.
-  **Power** indicates that power is ON.
-  **Confirm** (button) confirms the calibration process and can be used as an alternative to the **OK** button in the calibration workspace.

# RGSC Cabinet






- |                                |   |
|--------------------------------|---|
| 1. Firewall and Network Switch | 4. Real-Time Unit                             |
| 2. Workstation Unit            | 5. Height Adjustment (extract/retract wheels) |
| 3. Status Indicators           |   |

**Figure 4 Cabinet**

The RGSC cabinet includes two processor units. The Workstation Unit runs the software application of Respiratory Gating for Scanners, the Real-Time Unit is responsible for real-time image data processing.

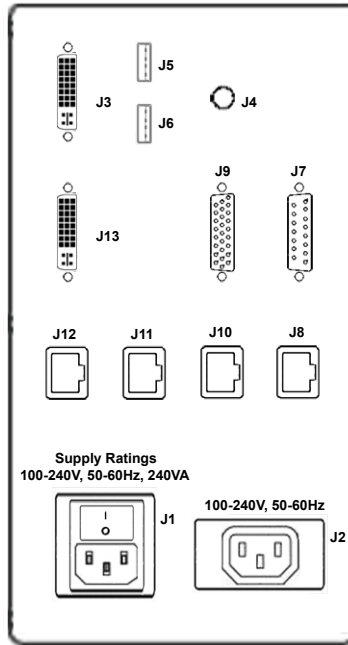
The Workstation Unit and the Real-Time Unit use the same three status indicators

-  On the Workstation Unit, red indicates a fan error is active.  
On the Real-Time Unit, the status indicator is not in use.
-  Blue indicates that power is on.
-  On the Workstation Unit, white indicates drive activity (SDD).  
On the Real-Time Unit, white indicates flash card activity.



## Patch Panel

All interfaces to the hardware are connected through the patch panel located at the back of the cabinet.



J3	DVI Monitor Output (primary)	J12	Service Port
J13	DVI Monitor Output (secondary)	J11	Hospital Network
J5	USB 1	J10	Wireless Access Point
J6	USB 2	J8	Camera Network
J4	Audio Output	J1	Main Power Inlet and Switch
J9	Scanner I/F	J2	Monitor Power Outlet
J7	Camera I/F		

**Figure 5 Patch Panel**



**Note:** Use the monitor power outlet only for the monitor provided with the system. Use the audio output to connect a speaker system and enable audio coaching.

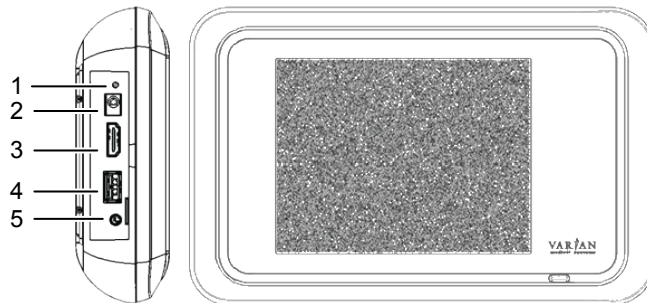
# Visual Coaching Device (VCD)

The Visual Coaching Device (VCD) is an optional accessory used in the scanner room to help the patient maintain a steady breathing pattern. Visual coaching gives visual feedback to the patient by displaying the current position and the targeted position of breathing. Visual coaching can increase the accuracy of the absolute position of the breathing process and the relative position within the breathing period.

The VCD operates in combination with following other components:

- RGSC application** The client application starts tracking on the Real-Time Unit, configures the coaching settings, and starts/stops the visual prompt on the VCD.
- Real-Time Unit** The Real-Time Unit processes image data from the camera to calculate the position and orientation of the reflector block. It then distributes the data to the VCD and the workstation unit.

The VCD includes various connectors, all located on the left side behind a cover.



- 1. Status LED (lit when booting or ready)
- 2. External DC Power Supply
- 3. Video Output
- 4. USB
- 5. Audio Output (no function)

**Figure 6 VCD Connectors**

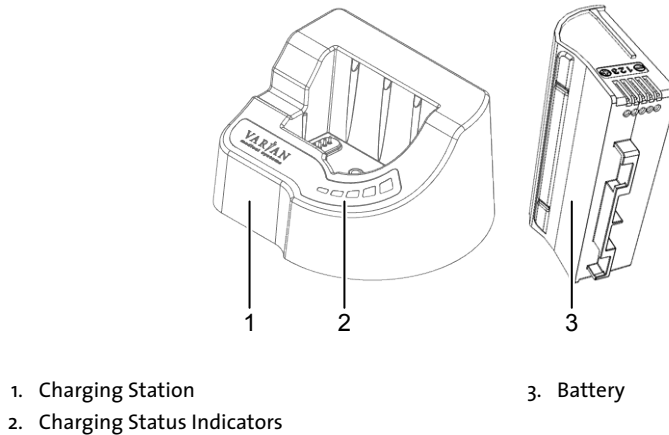
The external power supply used to power the charging station can also be connected to the VCD. This connection may be required when no battery is available or sufficiently charged.

The video output can be used to connect to an external monitor, projector or goggles.

The USB port can be used as power supply for external goggles (must be turned on and off in the VCD settings).

## VCD Battery and Charging Station

To ensure that one battery is always charged and available, the VCD comes with an additional battery and a charging station. The charging station indicates the status of charging.



**Figure 7 VCD Battery and Charging Station**

Different colors indicate the charging status:

- Red** An error occurred. The red indicator is always accompanied by a green indicator that identifies the type of error.
- If the first indicator from the left is green, the connection is faulty.
  - If the second indicator from the left is green, the temperature of the battery is too high or low ( $> 50^{\circ}\text{C}$  or  $< 10^{\circ}\text{C}$ ).
  - If the third indicator from the left is green, an undefined error occurred. To resolve the error, remove and reinsert the battery. If this does not resolve the error, replace the battery as it is likely damaged.
  - If the fourth indicator from the left is green, the power supply is faulty.
- Orange** No battery is in the charging station.
- Green** The battery is charging. The number of green indicators increases while the battery charges. The flashing indicator represents the current charging level. When the battery is charged, all indicators are lit (flashing stops).

### Related Topics

[Replace and Recharge the Battery of the VCD](#) on page 34

# Chapter 4 Prepare the Equipment

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## Prepare the Equipment (Overview)

This document describes use of Respiratory Gating for Scanners, but not its installation and configuration. Such tasks must be performed by trained Varian personnel only. For information about configuration settings, refer to the appendix.

1. Clean the reflector block.
2. Clean other equipment.
3. Start and log in to the application.
4. If the camera is couch-mounted, mount it.
5. If necessary, verify the calibration of the camera or calibrate it or both.
6. If available, mount and switch on the Visual Coaching Device (VCD).

Make sure the battery is loaded.

7. Review and resolve any remaining alerts (RGSC Messages).

Proceed to prepare the patient and the session.

## Clean the Reflector Block

Before each new patient, take special care to clean and inspect the reflector block.

1. Spray the reflector block with a 70% to 90% isopropyl alcohol solution.
2. Wipe with white sterile cloth.
3. Allow to dry according to the manufacturer's instructions.
4. Inspect for damage.

## Cleaning Other Equipment

Unlike the reflector block, which requires special care, clean any other equipment only when needed:

- Use only the following cleaning solutions and follow the instructions of the manufacturer:
  - Isotropy alcohol
  - CIDEX PLUS
  - Soap and Water (do not use to clean VCD couch mount)
  - Mild spray cleaner

- Diluted chlorine bleach
- Do not spray cleaning solutions. Pour solutions onto a cloth and wipe surfaces clean.
- Wipe off excess cleaning solution.

If you have questions about cleaning with chemical solutions, contact an authorized Varian representative.

## Start up the System and Log in

1. Switch on the workstation and log in to Windows.

After logging in to Windows, the application initiates automatically.

2. Log in to the application.



**Note:** Your credentials for Windows and Respiratory Gating for Scanners are not synchronized.

### Related Topics

[Client Application](#) on page 18

[User Groups](#) on page 60

## Mount the Camera on the Couch

The following instructions only apply if the system has a couch-mounted camera.

You can mount the camera before or after starting up the system. If the system is running, but the camera is not mounted, the application states `Camera not ready`.

1. Engage the camera stand with the docking unit on the couch top.



**CAUTION:** To avoid situations where the camera falls off the couch or on the patient, ensure that the locking mechanism is fully engaged.

2. If unplugged, plug the camera cable into the stand and secure the plug with the twist lock.



**CAUTION:** To avoid situations where the cable disconnects during couch movements or scanning, ensure that the locking mechanism of the cable connector is fully engaged (snapped in).

Up to a certain degree, the system is capable of detecting whether the camera is mounted correctly and will state `Camera misaligned` if a mismatch is detected. Nonetheless, an additional manual check is required.

## Calibrating the Camera

Calibration of the camera is critical to the acquisition of reference data. If the equipment is not calibrated correctly, a discrepancy can occur between actual positions and positions as determined by the system.

Access to the **Calibration** workspace requires that the system be connected and running properly, and that you have the necessary access rights.



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**WARNING: The camera must be calibrated after installation and after its position has changed. If the camera has been moved and the calibration is no longer correct, the acquired data will be incorrect. Ensure that the camera is calibrated after being moved. Verify periodically.**

---

### Calibrate the Camera (Couch-Mounted)

The following instructions only apply if the system has a couch-mounted camera.

Calibrate the camera periodically or when prompted by the system.

1. Open the **Calibration** workspace.
2. Place the reflector block in the field of view of the camera on the couch top, aligned with the couch axes.

Use the laser system of the scanner for orientation.

3. Click **OK**.

Successful calibration is confirmed with the calibration result `Calibration passed`.

## Verify the Camera is Calibrated (Wall- or Ceiling-Mounted)

The following instructions only apply if the system has a wall-mounted or ceiling-mounted camera.

Verify that the camera is calibrated under the following circumstances:

- Daily (recommended)
  - When prompted by the system
1. To access the verification wizard, choose **Verification / Calibration > Verification**.
  2. Place the reflector block in the isocenter of the scanner.  
Use the laser system of the scanner for orientation.
  3. Click **OK**.

The system automatically calculates reflector block positions. After completion, the result appears under **Progress**.

- If verification was successful, **Verification Results** states *Verification passed*.
- If verification was unsuccessful, **Verification Results** states *Verification failed*.

If verification failed, ensure that no reflective body interferes with the IR signal from the camera. To prevent reflections from the couch top, place the calibration board under the reflector block. Verify the correct alignment of the reflector block.

If verification fails several times, perform a new calibration procedure.

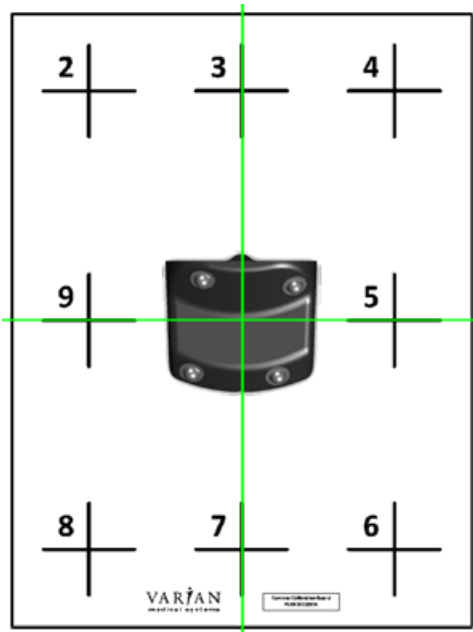
## Calibrate the Camera (Wall- or Ceiling-Mounted)

The following instructions only apply if the system has a wall-mounted or ceiling-mounted camera.

Calibrate the camera under the following circumstances:

- If calibration verification failed
  - After repositioning the camera
  - After updating the software
  - Periodically or when prompted by the system
1. To access the calibration wizard, choose **Verification / Calibration > Calibration**.
  2. Place the calibration board with position 1 in the isocenter of the scanner.

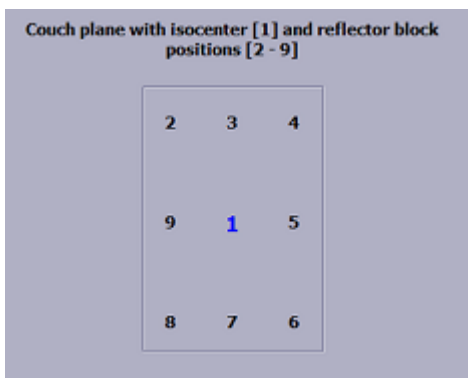
- Place the reflector block on position 1 on the calibration board.



**Note:** This position will be used for the verification process.

A correct alignment of the reflector block in the isocenter is essential for the entire calibration process.

- Press the **Confirm** button on the camera or click **OK** in the application.
- Move the reflector block on the calibration board, following the chart displayed at the bottom of the calibration display. After each position (2 to 9), press the **Confirm** button on the camera or click **OK** in the application.





The number of each step is highlighted successively through the positioning process.

During calibration, the position of the reflector block is displayed as follows:

- If the system was already calibrated, it shows coordinates relative to the calibrated isocenter position.
- If this is the first calibration of the system, no coordinates are displayed. Instead Valid or Not valid signals.

At the end of the calibration, the system calculates the plane values.

- If calibration is successful, **Progress** states Plane calculation is finished.
- If calibration is not successful, an alert pops up and states The calibration of the couch plane failed. Investigate and resolve possible causes, then repeat the calibration process. Possible causes can be the following:
  - Reflections from other objects than the reflector block (such as, couch top) interfere with the IR signal of the camera.
  - The distance between center position and any other position on the calibration board is too small (< 10 cm).
  - The orientation of the reflector block at center position of the calibration board is not valid.
  - The camera is not installed properly (wrong orientation, wrong angle to couch plane).
  - The surface on which the calibration is performed is not flat enough.

## Mount the Visual Coaching Device on the Couch

The following instructions only apply if the system has a couch-mounted Visual Coaching Device (VCD).

1. Attach the VCD couch mount base unit to the couch.
2. Attach the VCD on the telescope to the couch mount base unit.



**CAUTION: If the Visual Coaching Device is not properly mounted, it can fall on the patient causing injury. When using the Visual Coaching Device, always verify that the base part of the couch mount is correctly attached and locked to the scanner couch top and that the telescopic arm is correctly inserted and locked in the base part.**

3. Switch on the VCD.
4. Check the battery status and replace the battery if necessary.
5. Check the network connection.
6. If you are using video goggles, connect them to the video output terminal of the VCD.

## Replace and Recharge the Battery of the VCD

To avoid an unexpected shutdown of the VCD during image acquisition, check the battery status of the VCD before each use.



**Note:** *The Visual Coaching Device must be running properly during the entire scan to ensure that the patient is breathing periodically. Failure of coaching during acquisition can lead to irregular breathing. The scan may have to be repeated.*

1. Check the battery status on the VCD itself or in the desktop application
  - On the VCD, check the battery icon in the status bar. Alternatively, enter the maintenance mode (draw a capital **M** on the touchscreen), then choose the **Battery** tab.
  - In the desktop application, hover over the battery symbol in the coaching view. Alternatively, choose **Configuration > VCD**.

2. If necessary, replace the battery with a recharged one.

If you fail to replace the battery in time, the VCD shuts down without warning.

3. Connect the dedicated charging station to the power supply and insert the empty battery for recharging.



**CAUTION:** Incorrect voltage applied to the charging station can cause overheating or fire. Connect only the power supply provided by Varian (P/N B503887R01) to the Visual Coaching Device or to the charging station.

### Related Topics

[VCD Battery and Charging Station](#) on page 27

## Power On/Off of the VCD

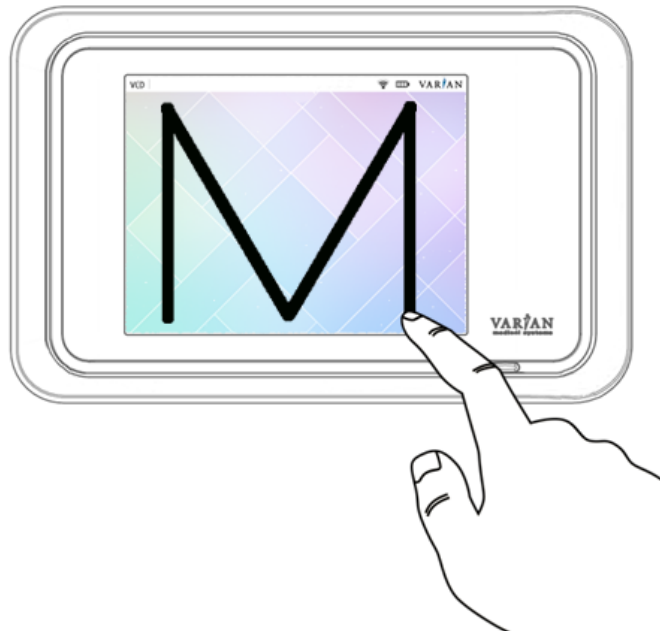
The power button of the VCD has the following functions:

- Press short: The VCD boots, goes to sleep, or wakes up.
- Press long: The VCD announces that it is shutting down (normal shutdown). If you keep the button pressed for more than 5 seconds, the VCD forces a hard shutdown.

## Using the VCD in Maintenance Mode

The VCD includes a maintenance mode to view the current state of the battery, to select or check the network, and to adjust display settings.

- To enter the maintenance mode from the home screen, draw a capital **M** on the touchscreen.
- To return to the home screen, touch the arrow symbol at the top left of the touchscreen.



**Figure 8** Enter Maintenance Mode of VCD

### Related Topics

[Using the VCD in Demo Mode](#) on page 44

## Resolve Alerts

If the system has any pending alerts (RGSC Messages), the info panel of the application displays an orange button labeled **Functionality limited**. Alerts can be error messages, warnings and informational messages.

1. To open the **RGSC Messages** dialog box, click **Functionality limited**.
2. Resolve the cause of the first alert (details and required actions are stated), then click it for confirmation.
3. Resolve the cause of the next alert, then click it for confirmation.
4. Repeat this step until all alerts are resolved and the **OK** button is active.
5. Click **OK**.

### Prepare the Session and the Patient (Overview)

The following instructions assume that you have prepared the equipment.

1. Open the patient record or create a new one.
2. Open a session or create a new one.
3. Select a type of scan (gating type), if applicable as prescribed.
  - To scan throughout the entire respiratory trace and reconstruct a 4D scan, choose **4D Scan**.
  - To scan only while the respiratory trace is within the phase gating window (1 scanner rotation per window), choose **Phase Gating**.
  - To scan only while the respiratory trace is within the amplitude gating window (1 scanner rotation per window), choose **Amplitude Gating**.
  - To scan only while the respiratory trace is held within the breath-hold gating window (x scanner rotations per window), choose **Breath-hold**.
4. If necessary, adjust the default settings of the selected type of scan.
  - To detect non-periodic breathing and prevent image acquisition if necessary, specify the breathing predictive filter.
  - For image acquisition with breath-hold gating, specify the delay with which to acquire scans after reaching the gating window.
  - For image acquisition with phase gating, specify the thresholds of the gating window in % relative to the inspiration peak (0% or 100%) and the expiration peak (50%).
  - For image acquisition with amplitude gating and breath-hold gating, specify the thresholds of the gating window in cm relative to the baseline determined during the learning process.
5. If necessary, enable visual patient motion monitoring.
6. Enable and configure coaching.
  - For audio coaching, select the language.
  - For visual coaching, select and configure a visual prompt style.

You can set the motion range and coaching speed manually or allow the system to determine them during the subsequent learning process.
7. Instruct the patient on how coaching works and on how to breathe with assistance of the VCD (demo mode).

8. Set up the patient on the couch.



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**WARNING: A mismatch between the patient on the couch and the patient data on display can lead to the storage of the wrong gating data for that patient. Check the patient details carefully against the patient on the couch to verify the correct patient is selected in the system.**

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**WARNING: RGSC supports only Head First Supine (HFS). If the patient orientation is not HFS, an inconsistency will result of the reference session with the delivery system treatment session. Ensure that only HFS is applied.**

---

9. Verify that the patient sees the VCD.
10. Verify that the reflector block is clean and undamaged.
11. Place the reflector block on the patient.
12. Instruct the patient to breathe regularly.
13. Start the learning process.

The system starts to track four cycles of the respiratory trace. Based on the learning process, the system determines the baseline (average expiration peaks). If enabled, the system also determines the motion range and coaching speed. Alternatively, both can be changed manually.

14. If necessary, restart the learning process.

The position of thresholds relative to their reference may change as a result.

15. If necessary, adjust the gating settings and coaching settings.

Depending on the purpose of the session, proceed as follows:

- If the session is intended for training only, help up the patient, and close the session.
- If the session is intended for image acquisition, proceed to prepare the scanner and acquire respiration-synchronized images.

## Patient and Session Data

Depending on the system configuration, the system saves and retrieves patient and session data either in database mode or file mode.

When you open the **Patient** workspace in file mode, it lists the patients that are in the system. In database mode, the list is empty.

## Open or Create a Patient Record

1. To clear any previous entries and start a new search, click **Clear**.
2. Enter search criteria in the available text boxes.

3. Depending on the local configuration, do one of the following:
  - Click **Find**.
  - Click **Filter**.
4. Do one of the following:
  - If the patient appears in the list, select it and click **Open**, or double-click it.
  - If the patient does not appear in the list, enter the mandatory data and click **Create**.

Mandatory entries are highlighted.

## Entering the Date of Birth

When you create a new patient record and go to **Date of Birth**, the current date appears. You can then adjust the date in different ways.

- Click the calendar symbol and select the correct date from the calendar.
- Adjust the date via keyboard.
  - To move between day, month, and year, use the division key (on the numeric keypad) or the left and right arrow keys.
  - To adjust day, month, and year, enter the numeric value or use the up and down arrow keys.

## Open or Create a Session

Before you can open or create a session, you must open a patient record.

The **Session** workspace lists the sessions (training and scan) that the patient has had in the past. You can create a new session from scratch or use an existing session of the same gating type as basis.

Depending on your approach, do one of the following:

- To create a new session from scratch, enter a unique session name and click **Create**.
- To create a new session based on a previous session, select an existing session and click **Open**, or double-click an existing session.

The session opens in the **Review** workspace. To create a new session, change to the **Scan** workspace, make adjustments as needed, and click **Record**. The system prompts you to give the session a new name.

## Choosing a Type of Scan

Before you can choose a type of scan, you must open or create a session.

## Retrospective Scan

**4D Scan** This type of gating is intended for continuous acquisition of motion data to reconstruct a 4D scan retrospectively. Depending on the scanner model on site, the gating system sends trigger signals at a predefined phase (0° by default). Once the scan is complete, the scanner synchronizes the respiratory trace with the acquired image data to generate the 4D image set.

## Prospective Scans

**Phase Gating** This type of gating is intended for phase-gated image acquisition of a free-breathing patient. With phase gating, you define the gating thresholds based on phase values. The gating system sends a trigger signal to the scanner when the respiratory trace enters the gating window. This allows acquiring a set of images at a specific couch position. Once acquisition at a couch position is complete, the scanner moves to the next position and waits for the next trigger signal.

**Amplitude Gating** This type of gating is intended for amplitude-gated image acquisition of a free-breathing patient. With amplitude gating, you define the gating thresholds based on amplitude values. The gating system sends a trigger signal to the scanner when the respiratory trace enters the gating window. This allows acquiring a set of images at a specific couch position. Once acquisition at a couch position is complete, the scanner moves to the next position and waits for the next trigger signal.

**Breath-hold Gating** This type of gating is intended for gated image acquisition of a patient able to hold breath. With breath-hold gating, you define the gating thresholds based on amplitude values. Depending on the scanner, the gating system sends one or several trigger signals to the scanner for as long as the respiratory trace is within the gating window. During that period, the scanner acquires sets of images, moving from couch position to couch position.

## Saving and Loading Default Settings

You can save and load specific gating settings as default for reuse on other scans.



**Save Gating Default Settings** saves the current settings as default settings for a particular type of gating.



Click the arrow to the right on the button to choose the applicable type.



**Load Gating Default Settings** loads the default settings for a particular type of gating. Once the site-specific default settings are saved, default settings are automatically loaded for each new scan with the same type of gating.

Click the arrow to the right on the button to choose the applicable type.

## Using the Breathing Predictive Filter

For image acquisition with amplitude gating, phase gating, or for 4D reconstruction, the breathing predictive filter monitors and predicts the breathing pattern of the patient to protect against misapplied radiation. The breathing predictive filter calculates a periodicity value by comparing phase and amplitude values of the latest breathing sample with the previous breathing pattern of the patient. If the periodicity values fall below the defined range, the system stops triggering scans. You can adjust the sensitivity of the filter to detect non-periodicity.

100% means maximum sensitivity. 0% means the filter is disabled. The following values are recommendations:

- For image acquisition with amplitude gating and phase gating, use 20%.
- For image acquisition for 4D reconstruction, use 5%.

For images acquired with breath-hold gating, the filter is disabled by default.

### Related Topics

[Periodicity Meter](#) on page 51

## Enabling Visual Monitoring of Patient Motion

Select **Enable Visual Patient Motion Monitoring** to continuously verify if the reflector block position is within the learned range. If the reflector block moves out of the learned range, the color of the ball (representing respiratory motion) changes. This monitoring is purely visual and has no effect on any other settings.

### Related Topics

[Monitoring of Patient Motion](#) on page 52

## Choosing a Coaching Mode

To access the coaching settings, open the **Coaching** tab. Based on patient requirements, you can choose either audio or visual coaching or both. If you use audio and visual coaching together, consider the audio coaching offset (defined in the application settings).

The goal of both coaching modes is to guide the patient toward a regular and reproducible breathing pattern and speed.

**Audio Coaching** Audio coaching supports two audio commands (*Inhale* and *Exhale*) in each of the offered languages.



**Note:** *Audio coaching requires that a speaker system be installed. It is not included in the scope of supply.*

**Visual Coaching** Visual coaching supports three visual prompt styles, which are displayed simultaneously on the Visual Coaching Device (VCD) and the desktop application if enabled. Communication to the VCD is first established by the application.

- For gating based on free breathing, choose **Curve** or **Dog** (or **Slider**).
- For gating based on breath-hold, only **Slider** is available.

You can set the motion range for visual coaching manually or let the system determine it during the learning process. **Motion Range** determines the vertical range of the visual prompt style.

**Coaching Speed** You can set the coaching speed (for audio and visual coaching) manually or let the system determine it during the learning process.

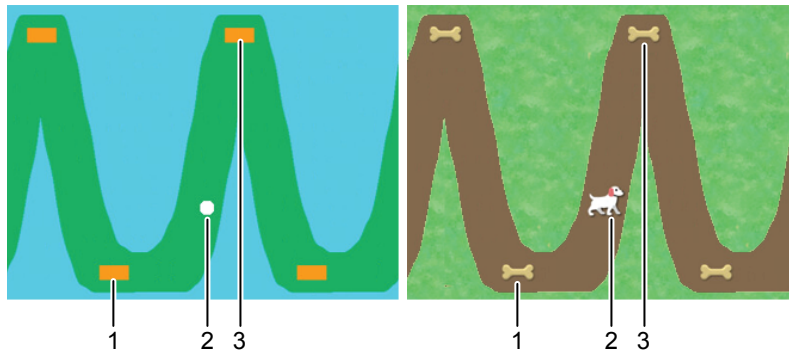
**Inspiration** determines the time provided for breathing in, **Expiration** the time provided for breathing out.

## Visual Prompt Styles

When visual coaching is enabled, a visual prompt appears on the VCD and under **Coaching** in the **Scan** workspace. The patient is required to follow the visual prompt and breathe accordingly. The following visual prompt styles are available:

- **Curve**
- **Dog**
- **Slider**

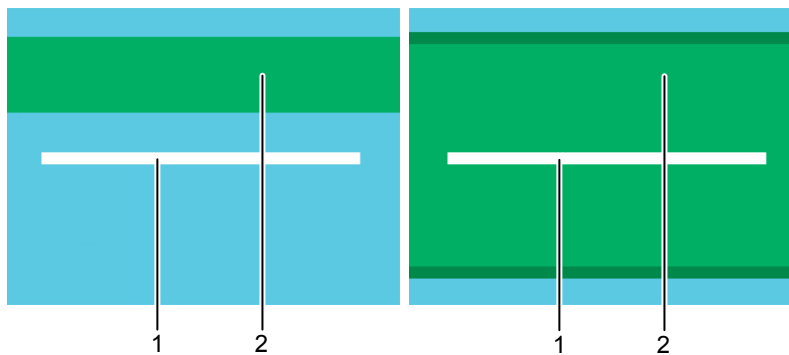
**Curve** and **Dog** visualize the targeted respiratory motion. These prompt styles are intended for free-breathing gating. The waveform shape is determined during the learning process and bases on the actual breathing pattern of the patient.



1. Expiration peak target (optional)
2. Current breathing position
3. Inspiration peak target (optional)

**Figure 9 Curve and Dog**

**Slider** visualizes the target area in which the patient is expected to hold breath. Even though this prompt style is primarily intended for breath-hold gating, it can also be used for the free-breathing gating types. In the latter case, the target area represents the gating window that the patient is expected to cover while breathing. Gating stops as soon as the white slider touches the blue area.



1. Current breathing position
2. Gating window (target area)

**Figure 10 Slider (breath-hold and free-breathing)**

## Using the VCD in Demo Mode

The VCD includes a demo mode to show the visual prompt styles to patients and instruct them on how to breathe with assistance of the VCD.

- To enter the demo mode from the home screen, draw a capital **D** on the touchscreen.
- To exit a prompt style animation, swipe from right to left on the touchscreen.
- To return to the home screen, touch the arrow symbol at the top left of the touchscreen.

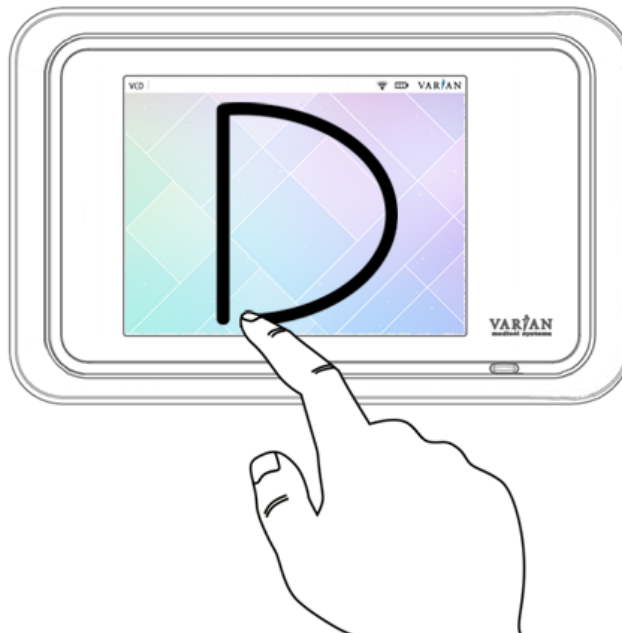


Figure 11 Enter Demo Mode of VCD

### Related Topics

[Using the VCD in Maintenance Mode](#) on page 35

## Place the Reflector Block

Before you place the reflector block on the patient, always verify that it is clean and undamaged.



**CAUTION:** Reuse of the reflector block can cause contamination to the patient. To avoid contamination ensure that the reflector block is cleaned prior to each use according to the cleaning instructions provided in this manual.

If a patient has open wounds, cuts, or other breaks in the skin, apply gauze or other protective barrier between the reflector block and the skin surface to prevent risk of infection or contamination.



**WARNING:** A wrong or damaged reflector block can cause an incorrect reflector block position to be measured. Do not use any other reflector block other than the one provided with the system (P/N B501928R02). Always visually inspect the reflector block prior to each use. Replace the reflector block if any damage is noticed.

After setting up the patient, place the reflector block as follows:

1. For the first session, place the reflector block with the reflectors facing the camera, where it is visible to the camera.
  - For the actual placement take into account the consistency of chest wall motion. Also, consult with the treatment planning team to establish the best position. To obtain optimum performance, place the reflector where vertical movement is at least 4 mm.
  - If no permanent or anatomical marks are used, mark the corners of the block on the skin and use hospital tape or other appropriate means to replicate the position as closely as possible from one session to the next. Advise the patient not to let the marks wash or rub off.
2. For consecutive sessions, place and attach the reflector block at the position marked during previous sessions and refresh marks if necessary.
3. Ensure that the camera has unobstructed view of the reflector block, and remove objects or clothing if necessary.

### Related Topics

[Clean the Reflector Block](#) on page 28

# Learning the Breathing Pattern

Before the system is able to display and record respiratory motion data, it has to adapt to the breathing pattern of the patient. The learning process runs for a minimum of four respiratory cycles. During the process, the system determines the minimal and maximal vertical position of the reflector block, the average inspiration and expiration time, and the baseline. The generated data provides the scale of the reflector block motion for display purposes and for setting the thresholds. At this point the periodicity filter checks that the respiratory trace (the reflector block position in relation to time) is regular. Once the stability of the minimal and maximal positions is verified and breathing is regular, the system can be placed in record mode.

Learning affects the motion range and coaching speed.

**Motion Range** If **Automatically set motion range to learned range** is enabled in the coaching settings, the learned motion range is used for coaching.

**Coaching Speed** If **Automatically set coaching speed to learned speed** is enabled in the coaching settings, the learned breathing speed is used for coaching.

For correct learning, the patient must exercise free breathing. If the system does not complete the learning process, check the following:

- The reflector block is visible to the camera for the entire respiratory cycle.
- Patient breathing is periodic (check the periodicity meter).
- The motion of the reflector block is at least 4 mm in vertical direction.
- The breathing frequency is within 6-20 respiratory cycles per minute.

You can restart the learning process at any time for the following purposes:

- Adapt to significant changes (range, speed and baseline) between the learning process and the actual acquisition.
- Repeat an attempt that failed due to irregular breathing.



**Note:** *If a couch-mounted camera is used on site and the camera gets disconnected while tracking the reflector block (during learning or else), reconnect the camera and restart learning.*

## Baseline

The reference point from which respiratory motion and thresholds are measured is the reflector block position at the expiration peak, when the patient is relaxed and breathing normally. Based on this position acquired during the learning process, the system defines the baseline as 0.0 amplitude.

## Adjusting the Gating Window

The system offers various ways of adjusting the thresholds of the gating window:

- In the **Settings** workspace, change the numeric value of the threshold.
- In the **Scan** workspace, you have the following options:
  - Drag the threshold lines (blue and orange) one by one, or both together.  
For amplitude and breath-hold gating, the threshold lines are located in the respiratory trace chart. For phase gating, they are located in the phase dial.  
To move the thresholds together (that is, the entire gating window), click somewhere between the threshold lines and drag the gating window.  
To move one threshold alone, click and drag the threshold line.
- Change the numeric value of the threshold, then press **TAB** to apply the change.

## Scaling

The respiratory trace chart visualizes two axes: time and motion. The default scale in the time axis is 5 seconds. The scale of the motion axis depends on the learned respiratory trace. **Auto Scale** is selected by default, but you can adjust the scale and view. As a consequence of some types of adjustments, auto-scaling is disabled.

- To change the scale of the time axis, press **Shift** and scroll.
- To change the scale of the motion axis, press **Ctrl** and scroll.
- To move the respiratory trace up and down (including baseline and thresholds) without changing the scale, press **Shift** and drag.
- To choose different views (Left-Right and Head-Feet) of the respiratory trace without changing the scale, right-click.

# Chapter 6 Acquire Respiration-Synchronized Images

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## Prepare the Scanner

The following instructions assume that you have prepared a session and set up the patient.

1. Open the patient record on the scanner.
2. Prepare the scan (that is, select a scan protocol, adjust scan parameters).
3. Verify that the patient sees the VCD, and that the VCD does not collide with the scanner gantry.



**CAUTION: A collision of the Visual Coaching Device with the scanner can cause damage to the scanner, VCD and other accessories. To avoid a collision with the scanner always verify that the clearance inside the scanner gantry is sufficient for the defined configuration of the Visual Coaching Device mount with regard to couch movements during the scanning process.**

4. Acquire a scout image (topogram).
5. Determine the scan range and reconstruction volume for final image acquisition.

Proceed to acquire respiration-synchronized images with prospective or retrospective gating.

## Acquire Images with Prospective Gating

The following instructions assume that you have prepared the scanner and a session, and set up the patient for one of the following types of gating:

- Phase gating
  - Amplitude gating
  - Breath-hold gating
1. Start audio or video coaching or both and instruct the patient to breathe accordingly.
  2. Start recording the respiratory trace.
  3. Start the gating signal.
  4. When the respiratory trace is regular, start the scanner.
  5. Monitor the respiratory trace for irregularities.
  6. When image acquisition is complete, stop recording the respiratory trace.



7. Instruct the patient to breathe regularly again.

Proceed to review and finalize the session.

## Acquire Images with Retrospective Gating

The following instructions assume that you have prepared the scanner and a session, and set up the patient for 4D scan gating.

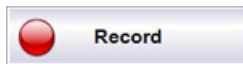
1. Start audio or video coaching or both.
2. Start recording the respiratory trace.
3. Start the gating signal.

For some scanners, you do not need to start gating for 4D scans.

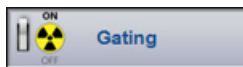
4. When the respiratory trace is regular, start the scanner.
5. Monitor the respiratory trace for irregularities.
6. When image acquisition is complete, stop recording the respiratory trace.
7. Instruct the patient to breathe regularly again.

Proceed to review and finalize the session.

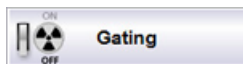
## Gating Buttons



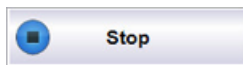
Starts recording of respiratory motion. Recording does not include sending trigger signals to the scanner. During recording, it is not possible to change the thresholds.



Starts and stops the sending of trigger signals to the scanner. ON means that trigger signals are sent to the scanner.



Starts and stops the sending of trigger signals to the scanner. OFF means that no trigger signals are sent to the scanner.



Stops recording of respiratory motion and disables the gating output.

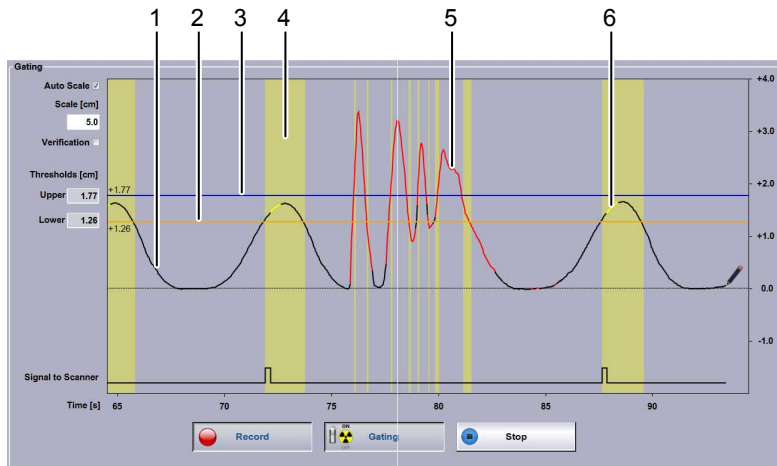
## Monitoring the Respiratory Trace

The system provides various features for monitoring the quality of the respiratory trace and the gating process.

Stop gating if the periodicity is continuously poor, or if the baseline drifts significantly (according to clinical policy).

## Colors Used in The Respiratory Trace Chart

Once you start recording, the respiratory trace and gating data is visualized in different colors.



1. Black trace: regular periodic breathing
2. Orange line: lower threshold
3. Blue line: upper threshold
4. Yellow column: breathing within gating window
5. Red trace: Irregular non-periodic breathing or reflector block not tracked correctly
6. Yellow trace: X-Ray On signal from scanner

**Figure 12 Respiratory Trace Chart Colors**

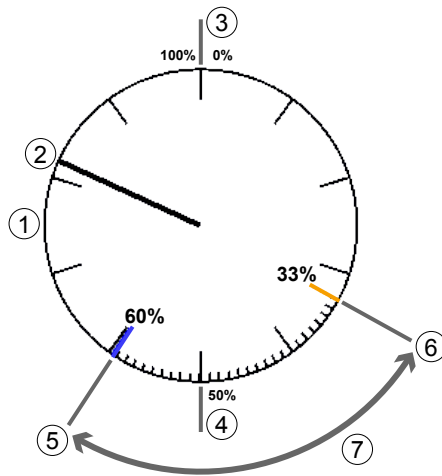
For comparison, you can select the **Verification** option, which adds a green verification trace behind the current trace. The verification trace is only available if a recording has been made or opened for the same session beforehand (for example, in a training session).



**Note:** If the scanner does not provide X-Ray On information, the respiratory trace does not turn yellow during image acquisition.

## Phase Dial

The phase dial shows the gating thresholds along a clockwise motion of the respiratory cycle. If breathing is irregular (poor periodicity), the needle jumps around.



1. Phase dial with indicators after each 10% (1% indicators appear in the gating window)
2. Needle indicating the current phase position in percent
3. Inspiration peak (approximate)
4. Expiration peak (approximate)
5. Upper gating threshold (blue)
6. Lower gating threshold (orange)
7. Gating window

**Figure 13 Phase Dial**

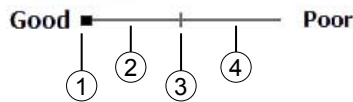
## Periodicity Meter

The system is capable of tracking respiratory rates ranging of 6-20 respiratory cycles per minute. An algorithm is used to calculate the similarity or difference of respiratory motion data over time. Assuming that the patient generally has a regular and steady breathing pattern, the goal of the calculation is to monitor any variance between the current and previous respiratory cycles.

The calculated value is referred to as the periodicity. The system recalculates the periodicity in real time.

The periodicity meter visualizes the regularity of breathing as a bar stretching along a horizontal line. This visual aid enables an estimate for the regularity and quality of the breathing pattern. A threshold (marked by a vertical line) is specified with the breathing predictive filter. As long as the periodicity is good, the bar is displayed in black.

As soon as the periodicity becomes poor, the bar stretches to the right, it turns red, and the system stops the trigger signals. The same applies when the system is unable to track the reflector block.



1. Current quality (turns red if poor)
2. Good quality
3. Threshold of breathing predictive filter (always in the middle of the range).
4. Poor quality

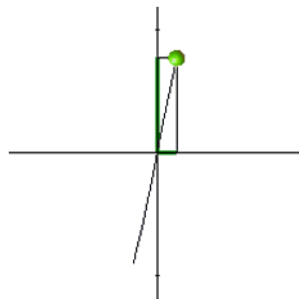
**Figure 14** Periodicity Meter

## Related Topics

[Using the Breathing Predictive Filter](#) on page 41

## Monitoring of Patient Motion

Monitoring of patient motion tracks in real time the position of the reflector block in vertical, lateral, and longitudinal dimensions. If visual monitoring is enabled and the reflector block moves out of the motion range identified during the learning process, the color of the ball (representing the reflector block) and of the affected axis changes. If visual monitoring is disabled, the position of the reflector block is tracked but deviations are not visualized.



**Figure 15** Monitoring of Patient Motion

The following visual aids are in use:

- Ball** The ball represents the current position of the reflector block in relation to the body axes.
- Green** Patient motion is within the motion range identified during the learning process.
- Yellow** Patient motion is out of the motion range identified during the learning process by 1% to 15%.
- Red** Patient motion is out of the motion range identified during the learning process by more than 15%.

In addition to the visual aids, the following reference information is available.

- Capital Letters** The capital letters designate the orientation of the body axes: A (anterior), P (posterior), R (right), L (left), H (head), F (feet).
- Numeric Values** The value at the top of the anterior-posterior axis indicates the current position of the reflector block in relation to the baseline.
- The value on the right of the left-right axis indicates the current position of the reflector block in relation to the average left-right position identified during the learning process.
- The value at the bottom left indicates the current position of the reflector block in relation to the average head-feet position identified during the learning process. Head-to-feet motion is not visualized but only indicated as numeric values.

## Related Topics

[Enabling Visual Monitoring of Patient Motion](#) on page 41

## About Phase Calculation in Real Time

Phase calculation is used both for phase gating and for determining the periodicity. The calculation converts the respiratory trace from a displacement signal as a function of time into values representing where the current sample falls along a sinus curve as a function of time. The phase is therefore an indicator of where the current time point falls within the interval of two consecutive end-inhale time points.

To obtain the phase, a peak-trough detection algorithm estimates the end-inhale and end-exhale time points and generates an estimate of the breathing period (time of a respiratory cycle) that is updated with every newly detected end-inhale and end-exhale time point. The breathing period is then used to select the points in the respiratory trace that are required for phase calculation.

The phase of each new sample of the respiratory trace is defined as the phase angle of the first harmonic complex Fourier coefficient calculated over a sliding time window, which is defined by the breathing period. The resulting value is shifted by  $\pi$  because the end-inhale is at signal minimum. In a sinus curve, phase calculation results in a value of 0% for the inspiration peak, 50% ( $\pi$ ) for the expiration peak, and 100% ( $2\pi$ ) for the consecutive inspiration peak.

## Challenges

The challenge in phase calculation is that the breathing period used to estimate the phase is a lagging value, representing the duration of the previous breathing period. The duration of the current breathing period is unknown until detection of the next end-inhale time point. As long as the breathing period does not change substantially from one respiratory cycle to the next (for example, by  $\leq 10\%$ ), the phase is a linear (saw tooth) plot as a function of time. If the breathing period changes significantly (for example, by  $\geq 10\%$ ) from one respiratory cycle to the next, the phase is not a linear function of time and the phase values of 0% and 100% do not represent the exact end-inhale time points.

If the breathing pattern of a patient is asymmetric (varying duration of inspiration versus expiration) or irregular (varying duration of breathing periods, or varying amplitude values), the system does not establish fixed phase values for inspiration and expiration peaks.

Audio and visual coaching can support the patient to breathe regularly with a constant breathing period. This will ensure a stable phase calculation. When using phase values for retrospective 4D reconstruction, use phase recalculation when reviewing the session.

## Related Topics

[Reviewing a Session](#) on page 55

# Chapter 7 Finalize the Session

---

## Finalize the Session (Overview)

The following instructions assume that you have just acquired respiration-synchronized images.

1. Review the recorded respiratory trace with special attention to the following:
  - Breathing phase (for 4D reconstruction)
  - Thresholds
  - Baseline drift
2. If necessary, change the gating type for treatment delivery.
3. If necessary, export the session (breathing data) to the file system, and import it from there to the scanner or the treatment delivery system.

In database mode with ARIA<sup>®</sup> OIS for Radiation Oncology 13.0 or higher, manual data export is not required.

4. Close the session.
5. Help up the patient.
6. If necessary, dismount the VCD and the camera from the couch.

## Reviewing a Session

### Retrospective Gating

For retrospective gating, you can recalculate the breathing phase, adjust thresholds, and add or delete peaks of the respiratory trace. Breathing phase values are indicated as a gray line that typically has a saw tooth shape.

Use **Auto Detect** to have the system recalculate the breathing phase of the recorded trace. Contrary to phase calculations during image acquisition, this considers the entire trace information and generally leads to higher image quality in 4D reconstructions. For phase recalculation, the system auto-detects the inspiration peaks of the respiratory trace and interpolates the phase linearly over time from 0% to 100% between two consecutive peaks. As a result you get consistent phase values even if breathing periods differ significantly from one respiratory cycle to the next. If automatic phase recalculation is enabled, the effect is the same as selecting **Auto Detect**.

Use the + and – buttons to add or remove inspiration peaks manually. Click the respective button again to disable the editing of the breathing phase. This switches back to editing of the gating thresholds if gating thresholds are defined.



**Note:** Various factors can lead to data being unusable for 4D reconstruction on the scanner system. Always review the recorded respiratory trace. If necessary, correct the inspiration peaks and execute a phase recalculation.

## Prospective Gating

For prospective gating, you can review and adjust thresholds.



**Note:** This task requires special user rights and user authentication.

If you adjust the thresholds, the yellow columns in the chart as well as the values for duty cycle and gated motion change accordingly. Adjustments to the thresholds are stored in the current session.

- To adjust amplitude thresholds, drag the respective line in the **Recording** chart to the wanted location or enter the corresponding values.
- To adjust phase thresholds, drag the respective line in the **Phase** dial to the wanted location or enter the corresponding values.

## All Types of Gating

<b>Recording</b>	Use the playback buttons and the position slider, to move along the recorded trace and view the parameters.
<b>Measured Values</b>	Review the values set for the recorded session.
<b>Baseline</b>	The baseline shift is calculated based on the average of all expiration peaks of the recorded respiratory trace compared with the learned baseline. If you apply a baseline shift, the trace shifts accordingly and amplitude thresholds are adapted.

## Shifting the Baseline

During recording, the expiration peaks can move away from the 0.0 reference position. This change is referred to as baseline drift.

A baseline drift occurs when the average of the expiration peaks calculated during the learning phase differs from the expiration peaks *after* starting the recording.



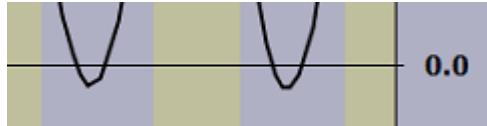


Figure 16 Baseline Drift

## Applying a Baseline Shift

In connection with treatment delivery, a baseline drift leads to incorrect thresholds for amplitude and breath-hold gating. Therefore, apply a baseline shift when it is apparent that the baseline has drifted. You can edit the calculated shift value if necessary.

Applying a shift means shifting the coordinate system. It leads to the recalculation of the respiratory trace and thresholds.



**Note:** This task requires special user rights and user authentication.

## Gating Type for Treatment

Except for images acquired with breath-hold gating, you can change type of gating for future treatment sessions. That is, you can acquire an image with a certain gating type, change it, adjust thresholds and store the new settings for treatment delivery.

The goal is typically to have comparable conditions for image acquisition and treatment delivery. Only change the gating type for treatment if compelling reasons exist (for example, if site policy mandates one gating type for image acquisition and the other for treatment delivery).

- To adjust amplitude thresholds, drag the respective line in the **Recording** chart to the wanted location or enter the corresponding values.
- To adjust phase thresholds, drag the respective line in the **Phase** dial to the wanted location or enter the corresponding values.



**Note:** This task requires special user rights and user authentication.

## Export for Treatment

Depending on the system configuration, one or both of the following features are available to export data for gated treatment delivery:

## Export to RPM

Use this feature for Clinac™ systems that support gating with an Real-time Position Management™ system (RPM). It exports gating data and patient data to the RPM database, and includes all settings (gating settings, coaching settings) of the gating session and the recorded trace.

## Export to DICOM

Use this feature to export data to TrueBeam™, VitalBeam™, or Edge™ systems with the following OIS:

- Third-party OIS
- ARIA® OIS for Radiation Oncology 11.0 or lower
- If in file mode, ARIA® OIS for Radiation Oncology 13.0 or higher



**Note:** *If in database mode, manual export is not required with ARIA® OIS for Radiation Oncology 13.0 or higher.*

## Export for 4D Reconstruction

Use the **Export to VXP** feature to export data from a recording session to a predetermined location and to use the data for 4D reconstruction on a scanner workstation.

To create an export file according to local file name convention, enter the requested information (depends on scanner).

Depending on the scanner on site, manual VXP export may not be required thanks to real-time data exchange via serial interface.

## Select a Start Time for VXP Export

When exporting data for 4D reconstruction, you can select a starting point from which to start the export. This can be useful when scout scan data is part of the recorded trace and you want to exclude that data from the export.

1. Under **Export for 4D Reconstruction** select **Start Time**.
2. Move the position slider in the recording control bar to the relevant time range.  
For scanners that provide X-Ray On signal on the RGSC interface, the scout scan and actual scan can be identified on the trace where it appears yellow (X-Ray On).
3. Move the cursor into the recording chart, to the beginning of the time range you want to export.  
A green vertical line appears and follows the cursor.

4. To set the start time, click into the recording chart.

## Close the Session

How you can close a session depends on the workspace. Closing the session saves all related data.

- In the **Review** workspace, click **OK** in the control bar or **Close** in the workflow panel.
- In any other workspace, click **Close** in the workflow panel.

## Shut Down the System

Shut down the system at the end of each working day.

1. On the application home screen, click **Exit Application**.
2. Shut down Windows.



**NOTICE: Do not turn off the Real Time Unit or main power switch. Switching off the Real Time Unit can result in damage to the scanner interface and to the flash card.**

# Appendix A System Configuration

---

## User Groups



**Note:** User administration is integrated into the Varian Oncology Systems Platform (OSP server or client) and independent from Windows.

The following user groups are available:

**Table 2 User Groups and Rights**

User Group Rights	Therapist	Oncologist	Physicist	Admin	Service
Perform a clinical workflow.	✓	✓	✓	✓	✓
Verify camera calibration.	✓	✓	✓	✓	✓
Change the gating mode for treatment.	-	✓	✓	-	-
Change thresholds in review.	-	✓	✓	-	-
Save scan settings as template.	-	-	✓	✓	✓
Calibrate the camera.	-	-	✓	✓	✓
Configure the system.	-	-	✓	✓	✓
Install the camera.	-	-	-	-	✓
Configure the camera.	-	-	-	-	✓
Configure the scanner.	-	-	-	-	✓
Upload software for VCD.	-	-	-	-	✓
Upload software for Real-Time Unit.	-	-	-	-	✓

## Application

To access the workspace, choose **Configuration > Application**.

## Coaching

Control	Description
Audio Coaching Offset [s]	Specify the offset according to the desired time lapse. Audio coaching starts with this offset before the inspiration or expiration peak is predicted.

## Verification

This setting is only enabled in connection with a wall-mounted or ceiling-mounted camera.

Control	Description
Verification Period [days]	Specify the number of days during which the camera verification is valid. If the verification is outdated, a new verification will be enforced.

## Calibration

This setting is only enabled in connection with a couch-mounted camera.

Control	Description
Calibration Period [days]	Specify the number of days during which the camera calibration is valid. If the calibration is outdated, a new calibration will be enforced.

## DICOM Import/Export

Control	Description
Specific Character Set	Select the applicable character set. The applicable character set depends on the DB daemon or, if applicable, on the TrueBeam system.

## Export

To access the workspace, choose **Configuration > Export**.

## VXP Export

Control	Description
Enable VXP file export	Select to enable the VXP export option in the <b>Review</b> workspace.
Directory	Specify the file path of the target database for export.
File Name Format	Specify the file name format according to the format that is expected by the 4D reconstruction software of the scanner.
Automatic phase recalculation	Select to enable automatic off-line phase processing when entering the <b>Review</b> workspace.
Prompt for VXP export in retrospectively gated cases	Select to activate an export prompt when you close the session after review.

## RPM Export

Control	Description
Enable RPM data export	Select to enable the RPM export option in the <b>Review</b> workspace.
RPM Database File	Specify the file name and path of the target database for export.
Automatic export after acquisition	Select to enable automatic export when you close the session after review.
Prompt for manual export after acquisition	Select to activate an export prompt when you close the session after review.
RPM System Frame Rate	Select the required frame rate.

## DICOM Export

Control	Description
Enable DICOM file export	Select to enable the DICOM export option in the <b>Review</b> workspace.
Directory	Specify the file path of the target database for export.
Patient-specific Folder Format	Specify the folder name format for patient data.
Automatic export after acquisition	Select to enable automatic export when you close the session after review.
Prompt for manual export after acquisition	Select to activate an export prompt when you close the session after review.

## Export File Structure and Format

The system supports the export of motion data files for post-processing. Motion data files are created in text format after data acquisition is finished or when a previously recorded session is retrieved.

A text file is used for the export parameters. Depending on the scanner, the file name must follow one of the following formats for 4D reconstruction.

- PatientID\_ExamNumber\_SeriesNumber.vxp
- PatientID\_SessionNumber.vxp

Data contained in the export file is organized into a header section and a data section. The <cr> symbol represents a carriage return.

### Header Section

Line	Data Format	Description
1	[Header]<cr>	Prefix of the header section
2	CRC=crcChecksum<cr>	CRC checksum
3	Version=versionNumber<cr>	The version number of the export file
4	Data_layout=field1[,field2...], fieldn<cr>	The layout of the data section; field1 through fieldn represent the names of the fields in the data section.
5	Patient_ID=patId<cr>	The Patient ID of the patient record created in RGSC system
6	Date=mm-dd-yyyy<cr>	The date the acquisition session was recorded
7	Total_study_time=studyTime<cr>	The actual recording length in seconds to a thousandth of a second
8	Samples_per_second=sampleRate <cr>	<ul style="list-style-type: none"><li>■ NTSC: 30 or 15</li><li>■ CCIR: 25 or 12.5</li></ul>
9	Scale_factor=scale<cr>	The scale factor for the signal data (in mm). For example, if the data field ValueOfRespiratoryWave is given in cm, the scale factor is 10.0.

### Data Section

At line 10, [Data]<cr> is used to demarcate the beginning of the data section, whose data fields are separated by comma.

The layout of the data section, is defined in line 4 of the header section. This version's format is described in the following table.

Field	Description
Value_of_respiratory_wave	Position in centimeters relative to reference
Phase_value	Phase value for the current sample
Time_Stamp	Time of the sample measurement in milliseconds
Valid_Flag	<ul style="list-style-type: none"> <li>■ <math>\geq 0</math>: a valid track and a periodic signal</li> <li>■ <math>&lt; 0</math>: either a lost track, a bad video signal, or a non-periodic signal</li> </ul>
TTL_In	Bit value indicating the status of a sensed x-ray on signal from scanner <ul style="list-style-type: none"> <li>■ 1: +5 VDC</li> <li>■ 0: 0 VDC</li> </ul>
Mark	Letter specifying the sample when the phase value is closest to 0 or pi <ul style="list-style-type: none"> <li>■ Z: 0 phase</li> <li>■ P: pi phase null string: no data</li> </ul>
TTL_Out	Bit value indicating the status of a gating signal to the scanner <ul style="list-style-type: none"> <li>■ 1: +5 VDC</li> <li>■ 0: 0 VDC</li> </ul>

## Example

The following is a fragment of a sample export file:

```
[Header]
CRC=53224
Version=1.6
Data_layout=amplitude,phase,timestamp,validflag,ttl,mark,ttlout
Patient_ID=990310B
Date=10-06-2012
Total_study_time=32.533
Samples_per_second=30
Scale_factor=10.0
[Data]
4.7171,1.4994,29441,0,1,,0
```



4.7189,1.5135,29464,0,1,,0

...

5.0888,2.3434,30384,0,1,,0

5.0998,2.3695,30401,0,1,,0

## Scanner

To access the workspace, choose **Configuration > Scanner**.

### Select Scanner

Control	Description
Manufacturer	Select the manufacturer of the scanner: <ul style="list-style-type: none"><li>■ User defined (all settings customizable)</li><li>■ Siemens</li><li>■ Toshiba</li><li>■ Philips</li><li>■ GE Healthcare</li></ul>
Product Name	Select the scanner/interface.
Description	Comment in the context of the setting.

### Scanner Interface

These settings define how data is transferred through the binary lines and through the serial interface.



**Note:** For a compatible scanner connection, the following settings need to be configured properly. These settings can only be changed when **User defined** is selected as manufacturer.

Control	Description
Trigger Signal Length [s]	Specify the length of the trigger signal. Default is 0.50.
Trigger Signal Polarity	Select the polarity of the binary output line. <ul style="list-style-type: none"><li>■ Positive Pulse (default)</li><li>■ Negative Pulse</li></ul>
X-Ray On Signal Polarity	Select the polarity of the binary input line. <ul style="list-style-type: none"><li>■ High signal means ON (default)</li><li>■ Low signal means ON</li></ul>

Control	Description
X-Ray On Signal Circuit	<ul style="list-style-type: none"> <li>■ Single-Ended (default)</li> <li>■ Differential</li> </ul>
Heartbeat Signal	Specify whether a heartbeat signal between scanner and RGSC exists. <ul style="list-style-type: none"> <li>■ Not supported (default)</li> <li>■ Supported</li> </ul>
Heartbeat Timeout [s]	Specify the length of the heartbeat timeout. Default is 0.5.

## Serial Data Interface

Control	Description
Baud Rate	<ul style="list-style-type: none"> <li>■ 34800 (default)</li> <li>■ 1152000</li> </ul>
Stop Bits	<ul style="list-style-type: none"> <li>■ 1 (default)</li> <li>■ 2</li> </ul>
Parity	<ul style="list-style-type: none"> <li>■ None (default)</li> <li>■ Even</li> <li>■ Odd</li> </ul>
Flow Control	<ul style="list-style-type: none"> <li>■ None (default)</li> <li>■ RTS/CTS</li> </ul>

## Output for 4D Scanning

Control	Description
Trigger at [°]	Specify the phase at triggers are to be sent for retrospective gating (4D reconstruction). Default is 0.

## Output for Breath Hold Scanning

Control	Description
Breath Hold Signal	<ul style="list-style-type: none"> <li>■ Continuous (default)</li> <li>■ Single Trigger</li> <li>■ Burst Triggers</li> </ul> Burst Trigger allows acquiring multiple slices per breath-hold cycle.

# VCD

To access the workspace, choose **Configuration > VCD**. The workspace is only available, if visual coaching is in use.



**Note:** *The VCD must be connected and turned on.*

## Software Version

Control	Description
Application Version	Current application version installed on the VCD
Operating System Version	Current operating system version installed on the VCD

## Battery Status

Control	Description
Charge Status [%]	Status of the battery
Remaining Capacity [mAh]	Remaining capacity of the battery
Voltage [V]	Current cell voltage
Low Battery Warning Level [%]	Specify when to issue an alert that the battery charge status is low. If the charge status is lower, do not start a new recording.
Power Supply	External or battery powered
Number of Charging Cycles	Accumulated number of charge and discharge cycles
Temperature [°C]	Temperature of the battery

## Software Update

Control	Description
Application	Download file
Operating System	Download file

# Database

To access the workspace, choose **Configuration > Database**.

## DICOM Stream Service Connection

Control	Description
DSS Host	Specify the host name of the DSS (DICOM Stream Service) workstation
DSS Port	Specify the port number to connect to the DSS.

## Daemon Connection

Control	Description
Enable Database Mode (with ARIA DB)	Enable the system to run in database mode. Only a Varian System database is supported.
Enable Patient Creation (Activate UI)	Enable the system to support local patient creation. If disabled, the patient must exist in the database.
Local Host	Specify the host name of the DSS workstation.
Local Port	Specify the port number of the connection from DB Daemon to DSS.
Local AE Title	Specify the entity name of the DSS application.
Remote Host	Specify the host name of the DB Daemon workstation.
Remote Port	Specify the port number of the connection from DSS to DB daemon.
Remote AE Title	Specify the entity name of the DB Daemon.

## File Mode

Control	Description
Enable File Mode	Enable the system to run in file mode. Data is stored as DICOM files.
Patient Data Path	Specify the location where the system creates a subfolder per patient and stores all sessions and DICOM files.
Patient Archive Path	Specify the location where the system archives patient data.

## Services

Control	Description
DICOM Stream Service	Status of the DSS
DB Daemon Service	Status of the DB Daemon Service (may not be applicable in file mode)

## Archive

To access the workspace, choose **Configuration > Archive**.

- To find a specific patient, enter search criteria in the available text boxes.
- To select consecutive files, click the first file, press and hold down **Shift**, and then click the last item.
- To select non-consecutive files, press and hold **Ctrl**, then click each file you want to select.

### Patient Data Content

Control	Description
Move Selection to Archive	Archive selected patient files.

### Patient Archive

Control	Description
Restore Selection from Archive	Restore selected patient files.



**Note:** *If you change from database mode to file mode or vice versa, the **Archive** only becomes available after exiting and re-entering the application.*

## Camera

To access the workspace, choose **Configuration > Camera**.

## Camera

Control	Description
Configuration	<p>Changing the camera settings is reserved to Varian Service personnel.</p> <p>Available configurations are the following:</p> <ul style="list-style-type: none"><li>■ Wall Mount (25 mm)</li><li>■ Ceiling Mount (Upside down, 25 mm)</li><li>■ Couch Mount (12 mm)</li></ul>
Camera Installation	<p>Changing the camera settings is reserved to Varian Service personnel.</p>

## Appendix B EMC Data and Guidance

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### Electromagnetic Compatibility (EMC)

Respiratory Gating for Scanners (RGSC) is EMC-tested in conformity with the requirements of IEC 60601-1-2:2007 and can be used in the vicinity of other EMC-tested devices that fulfill the requirements of the relevant IEC 60601-1-2 standard. Untested HF (high-frequency) sources, radio networks or the like can influence the operation of the device and may not be operated in combination with the system.

Use of accessories, transducers and cables other than those specified (or supplied with the system as replacement parts for internal components) may result in increased emissions or decreased immunity of the system.

The following table is pursuant to IEC 60601-1-2. The cables listed meet IEC60601-1-2 emissions requirements.

**Table 3 Cables and Maximum Lengths**

Part Number	Name	Maximum Length
B501272	Cable CTIF – Single Camera (W01)	35 m
B504863	Cable Ethernet Single Camera (W02)	35 m
B504867	Cable Ethernet AP6511 (W03)	35 m
B503295	Cable GND Cabinet – Cam Mount (W04)	35 m
B504864	Cable GND Camera – Cam Mount (W05)	15 cm
P1012814	Camera Cable (W06)	10 m

### Electromagnetic Interference (EMI)

To prevent damage or injury to electronic equipment resulting from EMI interference, follow these instructions:

- Avoid use of unnecessary electrical devices near the scanner and the system.
- Use only Varian accessories, transducers, and cables.
- Do not use or stack the equipment with other equipment than compatible scanners. If adjacent or stacked use is necessary, place the equipment in the configuration in which it will be used prior to clinical use and observe its behavior to verify normal operation.
- Allow only trained, qualified personnel to operate or maintain the system.

## Varian Test Declarations and Guidance



**Note:** *This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules and meets all requirements of the Canadian Interference-Causing Equipment Standard ICES-003 for digital apparatus. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:*

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Contact Varian Support services for help.*



**Note:** *You must verify the actual shielding effectiveness and filter attenuation of the shielded location to ensure that they meet the minimum specifications.*

### Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that system is used in such environment.



**Table 4 Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 1)**

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

**Table 5 Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 2)**


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV line(s) to earth	±1 kV differential mode ±2 kV line(s) to earth	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 seconds	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ (>95% dip in $U_T$ ) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	100 A/m	30 A/m	Power frequency magnetic fields should be at levels of a typical commercial or hospital environment.



**Note:**  $U_T$  is the a.c. mains voltage prior to application of the test level.

**Table 6 Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 4)**

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	10 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 0.35\sqrt{P}$ $d = 0.35\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 0.7\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p><math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.<sup>1</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following</p> <div style="text-align: center;">  </div> <p>symbol:</p>
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	10 V/m	



**Note:** At 80 MHz and 800 MHz, the higher frequency range applies.

<sup>1</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.



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

## Recommended separation distance between portable and mobile RF communications equipment and RGSC

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

**Table 7 Electromagnetic Compatibility (EMC, IEC 60601-1-2:2007, Table 6)**

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter [m]		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7\sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.21
100	3.50	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.



**Note:** *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*



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

## Visual Coaching Device WLAN Specifications

WLAN specifications for wireless communication between VCD and wireless access point are as follows:

Type	Specification
Frequency range	2400 MHz to 2485 MHz (802.11b/g)
Rated RF output	18 dBm
Modulation	DSSS

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