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Instructions for Use

RPM Respiratory Gating System 1.7

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Abstract

The RPM Respiratory Gating System 1.7 Instructions for Use (P/N 100025304-01) provides reference information and procedures for using the RPM Respiratory Gating System 1.7 application software.

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Notice

FDA 21 CFR 820 Quality System Regulations (CGMPs)

Varian Medical Systems, Oncology Systems products are designed and manufactured in accordance with the requirements specified within this federal regulation.

ISO 13485

Varian Medical Systems, Oncology Systems products are designed and manufactured in accordance with the requirements specified within ISO 13485 quality standards.

CE

Varian Medical Systems, Oncology Systems products meet the requirements of Council Directive MDD 93/42/EEC.

HIPAA

Varian's products and services are specifically designed to include features that help our customers comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The VARiS Vision system uses a secure login process, requiring a user name and password, that supports role-based access. Users are assigned to groups, each with certain access rights, which may include the ability to edit and add data or may limit access to data. When a user adds or modifies data within the database, a record is made that includes which data were changed, the user ID, and the date and time the changes were made. This establishes an audit trail that can be examined by authorized system administrators.

Trademarks

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Chapter 1 Introduction

This guide describes the Real-Time Position Management Respiratory Gating System 1.7. The system helps you decide upon and implement a tumor treatment plan that accounts for the patient's breath, targets the tumor more effectively, and reduces delivery of dose radiation to adjacent healthy tissue.

This guide is written for reference by the following personnel:

- The team planning a treatment
- Radiotherapists and other operators of the system
- Installers of the system

Guide Structure

The chapters of the guide pertain to task areas as follows:

- Learning the components of the system and the graphical user interface of the software
- Making initial planning decisions before recording data for breathing-synchronized simulation images acquired on CT or PET equipment—prospective gating—for a field
- Recording data for breathing-synchronized simulation image sequences acquired on 4D CT or PET equipment for a field, deferring planning decisions. The planning decisions take place in retrospect, based on the recorded data and acquired image sequences for the field.

Visual Conventions

This guide uses the following notational conventions to help you locate and identify information.

Italic text is used for emphasis, examples, new terminology, text that you type, and book titles.

Bold text identifies menu names and commands, items you can click or select on the screen, keyboard keys, and names of hardware controls.

A `monotype font` identifies file names, folder names, text file contents, and text that either appears on the screen or that you are required to type in.

View > Options indicates selecting a menu, then selecting a command from that menu. In this example, click the View menu, then click the Options command in that menu.

Notes, Cautions, and Warnings

Notes identify additional information about using the Real-Time Position Management (RPM) Respiratory Gating system that can help you obtain optimum performance from the hardware or software.

Note: Make sure to familiarize yourself with the information in "Safety Features and Procedures" on page 19.

Cautions identify important information about actions or conditions that can result in minor or moderate injury to personnel or can result in damage to hardware or data.

CAUTION: Turn off all equipment that is connected to any cables before connecting or removing the cables.

Warnings identify important information about actions or conditions that can result in serious injury.

WARNING: Bodily fluids, water, and cleaning agents that enter the RPM Respiratory Gating System components could cause a short circuit, which could damage the equipment and cause serious bodily injury.

Contacting Support

Support services are available without charge during the initial warranty period. If you seek information not included in this publication, call Varian Medical Systems support at the following locations:

- North America toll-free telephone support +1.888.827.4265
- Global telephone support +1.702.938.4807

- Global telephone support for treatment planning +1.702.938.4712

Ordering Additional Documents

To order additional documents, call the following:

- North America +1.800.535.5350 (Press 1 for parts)
- Global +1.702.938.4700

Communicating Via the World Wide Web

If you have access to the Internet, you will find Varian Medical System support at the following location:

Oncology Systems — http://www.varian.com/oncy/

Then click **Support** from the menu list along the left side of the window.

Sending E-Mail

Send your e-mails to the following locations for support:

- Information Management Systems

  onc.helpdesk@varian.com
- Digital Imaging Management Systems

  onc.helpdesk@varian.com
- Delivery Systems

  onc.helpdesk@varian.com
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  tps.support@us.varian.com
- Brachy Therapy Systems

  brachy.support@varian.com

Concept Overview

The RPM Respiratory Gating System 1.7 plays roles in treatment simulation, treatment planning, and treatment itself.

Two Kinds of Planning

An imaging study can indicate that delivery of the planned treatment volume should take into account the motion of a tumor with the patient's respiration. The technique of respiratory gating starts and stops a treatment beam—metaphorically speaking, opening and shutting a gate that holds in the radiation—according to a pattern of breathing. To simulate the respiratory gating treatment technique, the RPM Respiratory Gating System, working with many imaging systems under many configurations, synchronizes imaging acquisition data and breath motion data for two planning approaches:

- Synchronizing the RPM Respiratory Gating System with the imaging system at the time images are acquired, using the imaging device prospectively to plan treatment
- Synchronizing the RPM Respiratory Gating System with the imaging system after the images are acquired, using the acquired images retrospectively to plan treatment

Breathing-Synchronized Image Acquisition

When working with an imaging device, the RPM Respiratory Gating System 1.7 is used to correlate the time of the acquisition of an image with a breathing signal it detects. This process is also referred to as breathing-synchronized image acquisition. The reasons for this process have to do with modern treatment planning.

Modern treatment planning uses volumetric images produced by CT, MR and PET scanners. Breathing-synchronized acquisition of these images ensures that the image used for planning and simulation corresponds 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. It is therefore important that the respiratory gating system used for treatment be identical to the respiratory gating system used in image acquisition for planning and treatment simulation.

The next sections discuss how each of these types of images or sequences are acquired and what role the RPM Respiratory Gating System plays in capturing data about acquisition.

CAUTION: The RPM system uses chest wall or abdominal motion as a surrogate for the respiration-induced 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 or fluoroscopic imaging and other studies as deemed appropriate. These judgements are the sole responsibility of qualified medical personnel using the equipment.

CT or PET Scans

For these image scans, the image formation, acquisition, and storage processes are performed by an external third party vendor device; this is the case for third party diagnostic CT, PET and MR scanners.

Because the device is external to the RPM Respiratory Gating System, a means of synchronization is needed. Breathing synchronization is achieved by the exchange of synchronization pulses—in real time during image acquisition—between the external device and the RPM Respiratory Gating System.

The synchronization scheme for CT or PET scans is prospective in that the RPM Respiratory Gating System controls image acquisition. It issues a trigger signal. The imaging device responds to the trigger and starts or stops the image acquisition.

Since the external imaging device also performs image formation and storage, there needs to be a means to transfer to the device the breathing signal and any synchronization tags recorded by the RPM Respiratory Gating System. Transfer is achieved through a file that the RPM Respiratory Gating System exports to the computer's file system. The file is then read by the imaging device, typically over the facility's computer network; removable storage media can also be used.

Special Prospective Synchronizations

Data capture with the prospective approach can also include synchronization data that can be used retrospectively for verification of CT Scans. For example, the RPM Respiratory Gating System, in a customized mode, can trigger acquisition of a set of axial CT slices and simultaneously record the output pulses from the scanner that indicate—more accurately than the trigger—the actual onset of data acquisition on the CT scanner for each slice.

4D CT or 4D PET Sequences

For these image sequences, the image formation, acquisition, and storage processes are performed by an external third party vendor device; this is the case for third party diagnostic 4D CT, PET and MR scanners.

Because the device is external to the RPM Respiratory Gating System, a means of synchronization is needed. Breathing synchronization is achieved by the exchange of synchronization pulses—in real time during image acquisition—between the external device and the RPM Respiratory Gating System.

The synchronization scheme for 4D CT or 4D PET sequences is retrospective in that both systems can capture synchronization data that is reconstructed later. This data capture can take the form of the following examples:

- At the onset of each acquisition interval, the imaging device can output a pulse—for example, the X-ray-on signal that comes at the exact time of the start of image acquisition on a CT scanner. The RPM Respiratory Gating System can sense and record this pulse.
- The imaging device can tag the acquired raw image data with the synchronization pulse it receives from the RPM Respiratory Gating System.

Since the external imaging device also performs image formation and storage, there needs to be a means to transfer to the device the breathing signal and any synchronization tags recorded by the RPM Respiratory Gating System. Transfer is achieved through a file that the RPM Respiratory Gating System exports. The file is then read by the imaging device, typically over the facility's computer network; removable storage media can also be used.

The file contains a number of flags in addition to the respiration signal, estimated phase, and the time stamp. This data is later used by the CT reconstruction software, provided by the CT vendor, to rearrange the CT slices so that a sequence of volumetric data is created. Each 3D image corresponds to a phase bin of the breathing cycle.

After data capture and export, another system reads the data file and reconstructs and correlates the acquired images with the breathing data recorded by the RPM Respiratory Gating System.

Breath Motion Tracking

The patient is positioned on the imaging device's couch in the view of the RPM Respiratory Gating System's camera, a charge-coupled device (CCD) tracking camera which is sensitive to infrared light. A set of infrared light sources provides the light. The camera's lens fits through a ring on which the light sources are mounted. A small plastic block placed on the patient moves with the patient's breath. Circular reflective markers on the block, reflecting the infrared light, appear in the video signal that the camera sends to the RPM Respiratory Gating System. Figure 1 shows a frame in the video signal during a test.

Figure 1 Frame Sent to RPM Respiratory Gating System

CAUTION: Placement of the marker block varies based on the patient's physique, clinical condition, and treatment prescription. As a general rule of thumb, the block can be placed approximately midway between the xyphoid process (at the base of the sternum) and the umbilicus. Actual placement should take into account the consistency of chest wall motion, and you should consult with the treatment planning team to establish the desired position.

CAUTION: The RPM system is intended for use in the treatment of lesions or other anatomical structures directly affected by respiration motion, particularly in the thorax and upper abdomen. This includes, but is not limited to, regions in the lung, breast, esophagus, liver, and pancreas. This can also include regions in the lower abdomen or pelvis in cases where patients have significant diaphragm motion in their respiratory cycle (that is, "belly breathers"). This system is generally not intended for regions not affected by respiration motion, such as the head, extremities, or nonmoving bony structures. The appropriateness of the use of this respiration motion technique is at the discretion of qualified medical personnel using this equipment.

CAUTION: Use of the RPM system is not limited by patient factors such as sex, age, weight, and so on, except in those instances where the Clinac linear accelerator system is so limited (by patient weight, for example). The system might, however, be limited by a patient condition such as compromised lung function where there is little or no motion of the chest wall during respiration, or if the respiratory cycle is too irregular to adequately define a repeatable gated interval. The appropriateness of the use of this respiration motion technique is at the discretion of qualified medical personnel using this equipment.

Markers

The system uses the marker block to track breath motion. Blocks come with two or six markers. The original RPM Respiratory Gating System used a two-dot marker block used to track vertical motion. The RPM Respiratory Gating System 1.7 uses a six-marker block as the basis for more sophisticated calculations and finer tracking in three dimensions, although this version retains the capability to track a two-marker block as well.

When the six-marker block is used, the camera in the RPM Respiratory Gating System must be calibrated to establish the coordinate system needed for tracking in three dimensions. Typically, the calibration is performed during installation of the system. The system has a facility for checking the calibration as required—for example, at the beginning of the working day. If the camera is moved, it must be calibrated again.

The system cannot establish tracking if a dominating object—brighter than the marker and with a shape or size consistent with a marker—is located in the field of view. However, once the tracking is established,

the system maintains it if such an object enters the field of view—provided that the object does not enters the tracking boundary around each marker.

The Session

A session must be created or opened before the system can use the images sent by the camera.The session, associated with a specific treatment field, is the repository for data including the following:

- All motion data that the system calculates for a patient, based on the motion of the markers in the images sent by the camera
- Triggering data generated by the system and received from the imaging device

The system accounts for a patient's personal data—name and patient identification. After a patient is established in the system, the system can then link the patient to sessions created for a patient's field.

There can only be one *reference session* for a patient's treatment field. The system enforces this condition to make sure that treatment planning, which can result in many treatment sessions, has a consistent basis.

CAUTION: Keep in mind the following considerations:

- The RPM Respiratory Gating System is designed to cover a wide range of respiratory patterns. The system can measure down to submillimeter accuracy. However, placement of the marker block varies based on the patient's physique, clinical condition, and treatment prescription. Actual placement should take into account the consistency of chest wall motion, and you should consult with the treatment planning team to establish the desired position.
- In addition, the system is capable of tracking respiratory rates ranging from 6 to more than 25 respiration cycles per minute. If the system is unable to track the marker motion, the blue squares at the top left corner of the camera image displayed on the workstation monitor. Check the patient and marker position to establish a reliable signal.
- Use chest wall or marker motion of at least 4 mm to obtain optimum performance.

Chapter 2 System Description

This chapter provides a description the essential general functionality of the RPM Respiratory Gating System 1.7.

Starting the Software

This section describes the preliminary steps required to use the RPM Respiratory Gating System 1.7. Refer to the remaining chapters in the guide for complete details on providing specific types of simulation and treatment.

To start the RPM Respiratory Gating System 1.7 software:

1. Log in to the Windows XP or Windows 2000 operating system on the RPM workstation with your username and password.
2. Choose the following items beginning with the Windows **Start** menu: **Programs > Varian Respiratory Gating 1.7 > RPM Respiratory Gating System 1.7 1.7**.

   The RPM Respiratory Gating System 1.7 window opens, along with the Patient List dialog box.
3. Look at the file path in the title bar of the RPM Respiratory Gating System 1.7 window and verify that the path—for example, S:\PatientsData—is a folder with a database of clinical data and not research data.
   - If the database folder displayed is incorrect, do the following:

   a. Click **Close** to close the Patient List dialog box.

   b. On the **View** menu, click **System Configuration** to open the System Configuration dialog box to the General tab.

   c. Click the first **Browse** button to open the Database Location dialog box.

   d. Use this standard dialog box to select the correct database file and click **Open**.

   e. Click **OK** in the message box about exiting the system to make the change take effect.

   f. Click **OK** in the System Configuration dialog box.

g. On the **File** menu, click **Exit**.

The RPM Respiratory Gating System 1.7 software window closes.

Software Window Overview

The RPM Respiratory Gating System window contains a title bar, a menu bar, a toolbar, and a number of display areas. The title bar of the main window shows the current patient and treatment session.

Under the standard menu bar and toolbar appear session-specific areas:

- An image area displays video images from either the camera or the fluoroscope.
- A session panel area displays session information and buttons for session options or closing the session of the patient.
- A chart area shows the relative phase of the respiratory cycle in a dial chart and plots the motion data in a moving graph.

At certain times—for example, during recording—a Visual Prompt area appears in the upper right corner of the main window.

Note: In general, leave the window maximized. Resizing the window is of limited advantage because there is no scrolling.

Menu Bar

The menu bar contains the following menus and submenus:

- **File** enables you to set up patients and treatment sessions, and manage and save recorded data with the following commands:
  - **Select Patient** opens the Patient List dialog box, which allows you to select, create, edit, or delete a patient in the database the system uses to account for patients and sessions.

- **Select Session** opens the Treatment Fields and Sessions dialog box, which allows you to select, create, or delete a session in the system database for the currently selected patient.
- **Reload Current Session Data** reloads the current session from the database, discarding any data that has been recorded since the last time the session was saved.
- **Archive/Restore Database** launches a Wizard that guides you through archiving or restoring database records for specific patients.
- **Save** saves the most recently recorded data to the current session.
- **Save As** creates a new session with the most recently recorded data. The field for the new session is selected in the Save As dialog box.
- **Export** saves a respiratory data file from a recording session to a predetermined location.
- **Exit** closes the RPM Respiratory Gating system application. This command prompts you to save any unsaved recorded data, then closes the main window.

View allows you to set program parameters, display detected gating hardware, and hide or show the status bar.

- **Session Options** opens the Session Options dialog box which enables setting of parameters related to the specific session, including the basis for gating, the type of breathing, the threshold default value for predicting normal breathing, and options for audio and visual prompting.
- **Detected Hardware** displays a message listing all the gating hardware detected in the RPM Respiratory Gating system workstation.
- **Workstation Log** displays a list of times, users, and workstation events: starting and closing the application.
- **System Configuration** opens the System Configuration dialog box which enables setting of installation parameters, including the system type, video standard, CT interface, file export, chart, and tracking options. For the most part these parameters should not be changed.
- **Status Bar** makes a bar at the bottom of the screen visible. The bar presents suggestions and information.

- Tools contains two options needed by the system for working with a six-dot marker block
  - **Calibration Check** confirms, when the room uses a six-dot marker block, that the camera has not moved since the last camera calibration.
  - **Calibration** opens a tool for calibrating the camera.
- Help provides access to online help topics.
  - **Contents** provides direction about documentation.
  - **About RPM Respiratory Gating System** displays a box with version information.

Toolbar

Use the toolbar buttons to initiate the primary program functions. Each function applies to the patient session currently open.

Use the buttons of the toolbar in the following ways:

- Click **Camera** to display live video from the tracking camera in the Image window.
- Click **Fluoro** (enabled if the workstation is configured for fluoroscopic simulation) or **2nd Video Ch** (enabled if the workstation is configured for virtual simulation or treatment) to display video:
  - When you click **Fluoro**, the system displays live video from the fluoroscope during a fluoroscopic simulation.
  - When you click **2nd Video Ch**, the system displays live video from the tracking camera during a virtual simulation or treatment.

Note: There are two video inputs on the PC workstation: One is always connected to the tracking camera; the button for controlling this video channel is always labeled **Camera**. When the workstation is installed in a CT simulator or treatment room, the other video input is also connected to the tracking camera and the button controlling this second video channel is labeled **2nd Video Ch**. When the workstation is installed in a fluoroscopic simulator room, the second video input is connected to the fluoroscope and the button controlling the second video channel is labeled **Fluoro**.

- Click **Track** to begin video tracking and learning the limits of patient respiration motion.

- Click **Verify** to use on-board imaging as verification of the planned gating before treatment.
- Click **Treat** to start up a treatment session from a planning session.
- Click **Record** to start recording motion and video data. (If you have selected Auto start of session recording in the Gating tab of the Options dialog box: when you click Track or Treat, recording begins automatically after four and a half respiratory cycles.)
- Click **Stop** to stop recording, playback, or gated treatment.
- Click **Pause** to temporarily suspend recording, playback, or gated treatment.
- Click **Playback** to start a gated playback recording of motion and video data.
- Click **Save** to save the most recently recorded data to a file.
- Click **Stop Gating** to disable gating in treatment mode, or to disable triggering of the CT scan in virtual simulation data acquisition.
- Click **Enable Gating** to enable gated radiation treatment when the system is in treatment mode. In virtual simulation data acquisition, click to enable automatic triggering of the CT scanner.

Working with Patient Information

Creating Patient Information

To create information in the system database for a patient, click **New Patient** in the Patient List dialog box. The box opens right after the software is started, and, if no patient information exists in the database, the Patient Data dialog box opens for the patient's details as described below in step 3 The Patient List dialog box can also be opened from the File menu.

To open the New Patient dialog box and fill in patient data

1. On the **File** menu, click **Select Patient**.

   The Patient List dialog box opens.

2. Click **New Patient**.

   The Patient Data dialog box opens.

3. Type the following information:
   - A unique patient ID. You can use any unique string of up to 50 characters for the ID. The ID can include upper- and lowercase letters and numbers.
   - A last name, first name, and, optionally, a middle name or initial. Each part of the patient name can contain up to 50 characters. Names can include upper- and lowercase letters, spaces, apostrophes, hyphens, and periods.
4. Click **OK**.

   The software enters the new patient information into the database and adds it to the Patient List dialog box.

Selecting a Patient

To select a patient, scroll through the Patient List dialog box for the patient's name and double-click it; you can also click the name and click **Select**.

The Patient List dialog box opens in two ways:

- Right after the software is started

  If no patient information exists in the database, the Patient Data dialog box opens for the patient's details as described on page 16 in step 3.
- After choosing Select Patient from the File menu

To open the Patient List dialog box

1. On the **File** menu, click **Select Patient**.

   The Patient List dialog box opens.
2. If needed, click a heading of the list, **Last Name**, **First Name**, or **ID**, to sort it by that heading. To sort the list in the reverse order, click the heading again.
3. Scroll through the rows of patient details in the list to find the row with the patient's name or ID.

4. Double-click the row, or click the row and then click **Select**.

   RPM Respiratory Gating System 1.7 window title bar changes to add the patient's last name and first name. After that, the Treatment Fields and Sessions dialog box opens, displaying the reference and treatment review sessions available for the patient.

   If there are no sessions for the patient, the New Treatment Field dialog box opens; see "Adding a New Field" on page 17 for more details.

5. Use the Treatment Fields and Sessions dialog box by doing any of the following:
   - In the Show drop-down list, choose Reference sessions only or All sessions.
   - Scroll through the rows of sessions to find the row you want to review, and either double-click the row or click the row and then click **Select**. Refer to "The Session" on page 9 for further details.
   - Click **Add New Field**. See the next section for more details.

Adding a New Field

To add a treatment field for simulation, open the New Treatment Field dialog box and either select a field name from the list or type the name in the list.

The New Treatment Field dialog box opens in one of two ways:

- As described on page page 17 in step 4
- As described on page page 17 in step 5

To add a field, refer to the procedure "Selecting a Patient" on page 16 and continue the task here:

6. In the New Treatment Field dialog box field list, do one of the following:
   - Select an existing treatment field from the list
   - Click Breast Medial to highlight it and type the field's name over it

7. Click **OK**.

   If there is no reference session for the field, the Treatment Fields and Sessions dialog box closes, and the software opens a decision box for creating a reference session.

   If there is a reference session for the field, a message box opens to provide a list of options. Click **OK** to close the message box, and click **Cancel** to close the New Treatment Field dialog box.

8. Do one of the following:
   - Click **Yes** to create the reference session. Refer to "The Session" on page 9 for further details.
   - Click **No** to return to the New Treatment Field dialog box. Refer to step 6
   - Click **Cancel** to return to the Treatment Fields and Sessions dialog box. Refer to page 17, step 4

Exporting Session Data

To supplement imaging data on the machines that acquire or reconstruct it, a file of breath motion can be exported from the RPM Respiratory Gating System. The dialog box to do this can be opened after a session recording is stopped; use the option **Prompt to export a respiration data file after recording is finished** in the Export File tab of the System Configuration dialog box. This dialog box tab also displays the option

To export session data, do the following:

9. At the workstation, press Ctrl-P or click **File** in the menu bar and **Select Patient** in the menu to open the Patients List dialog box.
10. Click a patient's name and click **Select**.

    The Treatment Fields and Sessions dialog box opens.

11. Click the relevant reference session in the list and then click **Select**.

    The reference session opens in playback.

12. Click **Stop** in the taskbar.
13. Click **File** in the menu bar and **Export** in the menu.
14. Fill in the blanks with the identified numbers.

15. (Optional) Click **Review** to open the Phase Recalculation Review dialog box. Review the peak recalculations, and, as needed, add or delete peaks and click **Save Changes** and **Exit**.
16. Click **OK** to close the file export dialog box.

    If an export file of the same name exists, then the system prompts you for permission to delete the existing export file.

    The system displays a message about data being written with a progress bar. When finished, the system displays a message box with the patient ID, indicating that the file export is complete.

Shutting Down the System

At the end of the day, to shut down the RPM system:

1. In the **File** menu, click **Exit**.

   The RPM system shuts down and the main window closes.
2. In the Windows taskbar, click **Start** and then **Shut Down** or **Turn Off Computer**. If prompted, click the Turn Off icon.

   Windows shuts down and the RPM workstation turns off.
3. Turn off the camera and illuminator.

Safety Features and Procedures

It is possible that gating simulations have to be stopped for safety reasons. This section provides descriptions of safety features and procedures for these tasks.

Stopping Gating

If you need to stop an automatically triggered gated CT imaging sequence, follow the normal disable-scan procedure for the CT system you are using. You can also click **Stop** or **Stop Gating** on the toolbar. Both of these buttons immediately suspend triggering of subsequent CT slices, except that when using the **Stop Gating** button, data recording continues.

CAUTION: Pressing the **Stop** button on the toolbar does not stop retrospective CT X-rays or data collection. Failure to stop the CT scan may result in excessive diagnostic X-ray exposure to the patient.

Chapter 3 Recording CT or PET Simulation Data with Prospective Gating

In a reference session, the RPM Respiratory Gating System can record breath motion and other data when connected to a CT or PET imaging system. To simulate the respiratory-gated treatment session, the system can use a link to the CT or PET scanner and trigger imaging. After data is recorded, planning the treatment session involves adjusting the gated interval in the reference session to compensate for the delay between triggering and image acquisition.

Although the procedure below works with a patient's periodic and regular breathing pattern, the breath-hold technique can also be used as described on page 26.

Before You Begin

Confirm the following points:

- The CT or PET scanner is set for an axial scan with automatic external trigger.
- Any additional CT or PET system setup features have been activated.

As needed, click **View** in the menu bar and **Session Options** in the menu. Adjust settings in the **Gating**, **Audio**, and **Visual Prompt** tabs of the Session Options dialog box, and click **OK**.

CAUTION: Keep the following in mind:

- As a safety precaution, it is important to continuously refer to the RPM system screen while the system automatically triggers the CT scanner during recording. If you detect power loss to the RPM workstation, or the system stops responding, immediately stop CT scanning manually using the procedures for your CT scanner.
- If the RPM system circuit that issues the trigger signal should stick in the closed position after power loss to the system, the CT scanner may continue to perform unwanted scans at incorrect respiratory states, thus producing the wrong CT images for planning. Mistreatment could result if the wrong CT image is used for planning the therapy.

If you detect power loss to the RPM workstation, or the system stops responding, immediately stop CT scanning manually using the procedures for your CT scanner.

If patient respiration becomes unstable, the CT system may time-out before reestablishing periodicity. If so, refer to your department's procedures manual for restarting the scan sequence.

If the patient's movement changes the waveform substantially, the system stops issuing triggers altogether, even if periodicity is reestablished. This is because the patient or the marker block may have changed position.

1. Click **Stop** on the toolbar to stop recording, then check the patient and the marker block.
2. Once the patient has been checked, click **Track** to begin the scan sequence over again from the beginning.

   A dialog box appears asking if you want to save the motion data just recorded.
3. Click **No** and then start the recording and gated triggering process as before.

Procedure

To acquire prospectively-gated images and record breath and synchronization data, do the following:

1. Prepare the system.

   If necessary, turn on the workstation and start the RPM Respiratory Gating System.
2. Move the couch to the position of the first slice.
3. Set up the patient on the couch.
4. Place a marker block on the patient.
5. Prepare the imaging device.
6. As needed, perform a scout view or any tasks required by pilot studies.
7. At the workstation, press Ctrl-P or click **File** in the menu bar and **Select Patient** in the menu to open the Patients List dialog box.
8. Do one of the following:
   - Click a patient's name and click **Select**.
   - Click **New Patient**, fill in the details, and click **OK**.
9. Establish a session in one of these ways:
   - Select a field or type a field name in the New Treatment Field dialog box and click **OK**.
   - Click **Add New Field** in the Treatment Fields and Sessions dialog box, select a field or type a field name in the New Treatment Field dialog box, and click **OK**.
   - Click an existing session for a field in the Treatment Fields and Sessions dialog box, click **Delete Session** to delete it, click **Add New Field**, select a field or type a field name in the New Treatment Field dialog box, and click **OK**.
10. If tracking has not already started for a new treatment field, then click **Track**.

11. Allow the system to learn the extent of the patient's breathing motion. Observe the row of blue squares at the top left of the image area and the color of the Record button. A few blue squares and a black Record button mean that the breathing is regular enough for the system to record data.
12. Coach the patient about what is happening and what the patient needs to do—for example, following the speech and visual prompts to maintain a regular breathing pattern.
13. (Optional) Allow the system to begin recording automatically and continue at step 16
14. Click **Record**.
15. Allow the planning team to adjust the thresholds of the gated interval.
16. Click **Enable Gating**.
17. Wait for the breath motion to leave the exit target of the gated interval, and then press the scanner **Start** button.

    Use this approach to avoid starting a scan within the gated interval.
18. Allow the recording and scanning to continue according to the facility's protocol or instructions specific to the patient.
19. If any interruption to the regular breathing pattern results in the CT or PET system timing out or the marker block has changed its position on the patient, do the following:
    a. Click **Stop** on the toolbar to stop recording, then check the patient and the marker block.
    b. Once the patient has been checked, click **Track** to begin the treatment session over again.

       A dialog box appears asking if you want to save the motion data just recorded.
    c. Click **No** and then start the recording and gated treatment process again at step 11

20. When there have been a sufficient number of scans, wait for the breath motion to leave the exit target of the gated interval, and then click **Stop Gating**.

    Use this approach to avoid stopping a scan within the gated interval.

21. Click **Stop**.

22. (Optional) In the file export dialog box, type the information as prompted—for example, the exam and series numbers.

    (Optional) Click **Review** to open the Phase Recalculation Review dialog box. Review the peak recalculations, and, as needed, add or delete peaks and click **Save Changes** and **Exit**.

    Click **OK** to close the file export dialog box.

23. If the recording is unsatisfactory, it is possible to start the recording and scanning process again. To do this, click **Track**, click **Yes** to save the data as a new session, and continue at step 11

    Otherwise, continue to the next step.

24. Do one of the following as needed:
    - Press Ctrl-S.
    - Click **Save** in the toolbar.
    - Click **File** in the menu bar and **Save** in the menu.

    At this point, the session is now ready for planning.

25. As needed for file export, do the following:
    a. Do one of the following:
       - Press Ctrl-E
       - Click **File** in the menu bar and **Export** in the menu

    b. In the file export dialog box, type the information as prompted—for example, the exam and series numbers.

    c. (Optional) Click **Review** to open the Phase Recalculation Review dialog box. Review the peak recalculations, and, as needed, add or delete peaks and click **Save Changes** and **Exit**.

    d. Click **OK** to close the file export dialog box.

26. Click **Close Patient** in the session panel.

Using Breath-Hold in CT Prospective Simulation Sessions

When the RPM Respiratory Gating System is connection to a CT scanner with an automatic triggering feature, the breath-hold breathing type can be used. The some session options must be set before you begin the procedure.

Before You Begin

To prepare the system for using breath-hold breathing techniques, do the following:

1. Click **View** in the menu bar and **Session Options** in the menu.

   The Session Options dialog box opens to the Gating tab.

2. Examine the selection under Breathing Type, and if it is Periodic, click **Breath-hold**.

   If you have changed the selection from Periodic, a message box asks if you want to set session options to the defaults commonly used with the breath-hold breathing type.

3. Click **Yes** to have the Session Options dialog box set automatically.
4. Click **OK**.
5. Click **View** in the menu bar and **System Configuration** in the menu.

   The System Configuration dialog box opens to the General tab.

6. Click the File Export tab.
7. Examine the option Recalculate phase before respiration data export. If it is selected, click the check box to clear the check mark.
8. Click **OK**.

Procedure for Trial Run

The first recording is a practice run from the perspective of the patient. The planning team uses the first recording to set the thresholds for the breath-hold level that the patient can comfortably achieve and maintain.

To accustom the patient to the a breath-hold technique and set the threshold, do the following:

1. Prepare the system.

   If necessary, turn on the workstation, start the RPM Respiratory Gating System, and prepare it as described in “Before You Begin” on page 21.

2. Move the couch to the position of the first slice.
3. Set up the patient on the couch.
4. Place a marker block on the patient.
5. Prepare the imaging device.
6. As needed, perform a scout view or any tasks required by pilot studies.
7. At the workstation, press Ctrl-P or click **File** in the menu bar and **Select Patient** in the menu to open the Patients List dialog box.
8. Do one of the following:
   - Click a patient’s name and click **Select**.
   - Click **New Patient**, fill in the details, and click **OK**.
9. Establish a session in one of these ways:
   - Select a field or type a field name in the New Treatment Field dialog box and click **OK**.
   - Click **Add New Field** in the Treatment Fields and Sessions dialog box, select a field or type a field name in the New Treatment Field dialog box, and click **OK**.
   - Click an existing session for a field in the Treatment Fields and Sessions dialog box, click **Delete Session** to delete it, click **Add New Field**, select a field or type a field name in the New Treatment Field dialog box, and click **OK**.
10. If tracking has not already started for a new treatment field, then click **Track**.
11. Allow the patient to relax.

12. Ask the patient to take and hold a breath to a higher than normal level.

    The higher level establishes the limits for the vertical scale of motion when the patient holding the breath. The patient should not be able to reach the higher level when breathing normally.

13. Ask the patient to relax again and monitor the image area for a regular and periodic breathing pattern.

14. When the patient achieves normal and periodic breathing, click **Record** in the taskbar and start monitoring the waveform in the graph.

15. Give the patient a specific sequence of instructions designed to achieve a deep inhalation state:
    - Breathe out
    - Breathe in to the high level
    - Hold breath

16. Repeat step 15 a few times to practice the technique, asking the patient to relax and breath normally after a breath-hold is finished.

17. Click **Stop** in the taskbar.

18. Ask the patient to relax and breathe normally.

19. Review the graph and the traces for practice breath-holds, and decide on the breath-hold level for the patient.

20. Drag the two amplitude threshold lines to the levels just below and just above the selected breath-hold level while keeping them separated by the margin you choose to allow for movement during breath-hold: for example, 0.5 cm. Figure 2 and Figure 3 show an example.

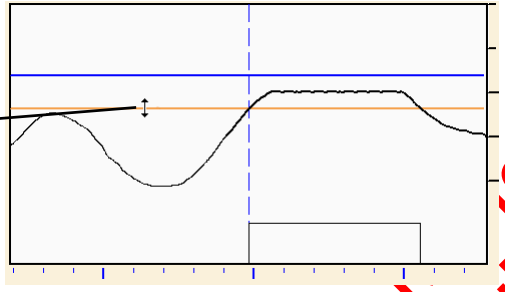

Figure 2 Selecting the Lower Threshold

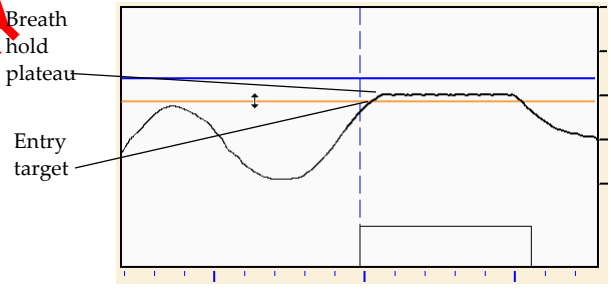

Figure 3 New Position for the Lower Threshold

21. Choose the length of time for the helical CT or PET scan based on the observed patient performance during the practice run, and program the scanner accordingly.
22. Examine the first seconds of each breath hold and determine if there is unstable motion—for example, a bounce—between the entry target and the start of the plateau. If there is sufficient unstable motion to justify delaying a scan during the unstable motion, do the following:
    a. Click **View** in the menu bar and **Session Options** in the menu.

       The Session Options dialog box opens to the Gating tab.
    b. Click the up and down arrowhead buttons under Breath-hold delay to set the duration of the unstable motion.
    c. Click **OK**.

Procedure for Simulation

After setting the thresholds for the breath-hold level maintained in the trial run, the system is ready for simulation.

To use a breath-hold technique while acquiring prospectively-gated images and record breath and synchronization data, do the following:

1. Click **Track** in the taskbar.
2. Click **Yes** to save changes to the thresholds.
3. With the patient relaxed and breathing normally, wait for the Record button to turn from grey to black. This is an indication that tracking has been established.

4. Ask the patient to repeat the breathing actions with the instructions you used in step 15 on page 28 to set the vertical scale and establish the motion reference:
   - Breathe out
   - Breathe in to the high level
   - Hold breath
5. In the taskbar, click **Record** and monitor the respiration signal in the graph.
6. Continue to instruct the patient as you did during the practice run, paying attention to the graph and issuing the "hold breath" command as soon as the breathing signal crosses into the region between the amplitude thresholds.

   The visual prompt to the patient is the yellow or green bar moving in and out of the dark blue region as shown in Figure 4.

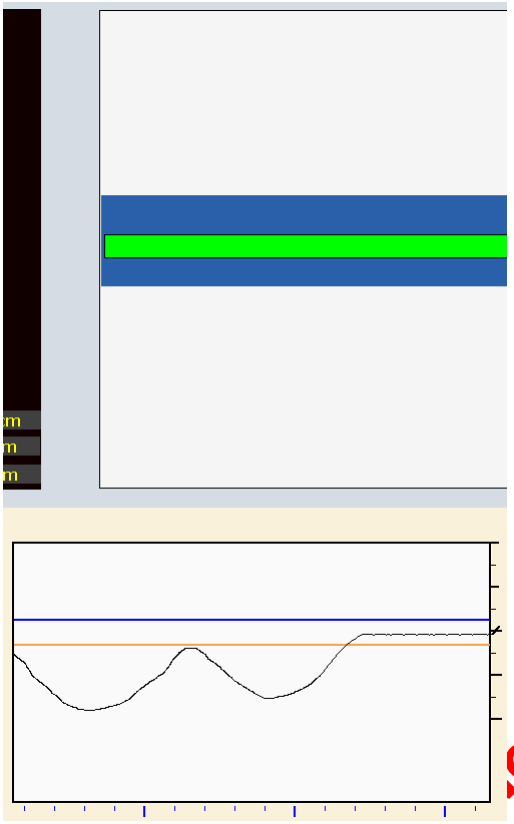

Figure 4 Visual Prompt and Chart During Breath Hold

7. Have the patient follow the moving bar in the visual prompt or the breathing signal in the graph to enable the patient to achieve the desired breath-hold level and maintain the breathing signal level in the area defined by the two thresholds. The bar should be yellow and under the dark blue band when the patient is relaxed and breathing normally.
8. Move the cursor to the Enable Gating button. Do not click.
9. Wait for the breathing waveform to fall below the threshold.
10. Perform the following sequence in a smooth succession of actions:
    a. Issue a breathe out command as you have done for the patient.
    b. Issue a breathe in high command as you have done for the patient.
    c. Click **Enable Gating**.
    d. Issue the voice command to hold breath as soon as the breathing signal crosses into the region between the amplitude thresholds.
11. While monitoring the breathing trace for the held breath in the graph, wait for the CT or PET scan to complete, and then ask the patient to relax and breathe normally.

    If, during the scan, the patient releases the breath-hold, stop the scan on the scanner.
12. Monitor the breath and at the next appropriate opportunity issue the breath out, breathe in high, and hold breath instructions as previously done.

    The waveform moves into the gated interval and the slider bar moves into the dark blue band. Because gating is enabled, a scan is triggered.
13. While monitoring the breathing trace for the held breath in the graph, wait for the CT or PET scan to complete, and then ask the patient to relax and breathe normally.

    If, during the scan, the patient releases the breath-hold, stop the scan on the scanner.
14. Repeat the above two steps until a sufficient number of scans have been acquired.

15. Click **Stop**.

    The session mode changes from Acquisition to Planning.

16. (Optional) In the file export dialog box, type the information as prompted—for example, the exam and series numbers.

    (Optional) Click **Review** to open the Phase Recalculation Review dialog box. Review the peak recalculations, and, as needed, add or delete peaks and click **Save Changes** and **Exit**.

    Click **OK** to close the file export dialog box.

17. If the recording is unsatisfactory, it is possible to start the recording and scanning process again. To do this, click **Track**, click **Yes** to save the data as a new session, and continue at step 3 on page 29.

    Otherwise, continue to the next step.

18. Do one of the following as needed:
    - Press Ctrl-S.
    - Click **Save** in the toolbar.
    - Click **File** in the menu bar and **Save** in the menu.

    At this point, the session is now ready for planning.

19. As needed for file export, do the following:
    a. Do one of the following:
       - Press Ctrl-E
       - Click **File** in the menu bar and **Export** in the menu

    b. In the file export dialog box, type the information as prompted—for example, the exam and series numbers.

    c. Click **OK** to close the file export dialog box.

20. Click **Close Patient** in the session panel.

Chapter 4 Recording 4D CT Simulation Data for Retrospective Gating

In a reference session, the RPM Respiratory Gating System can record breath motion and other data when connected to a CT or PET imaging system producing a 4D image sequence simulating a treatment session. The data, synchronized with the 4D image sequence on an image reconstruction workstation, is used to determine a phase-based gated interval in retrospect. This gated interval is applied to the reference session in the RPM Respiratory Gating System as a further step in planning.

Before You Begin

Because the gated interval determined on the image reconstruction workstation is typically phase-based, the gate option is set to Phase for the session in the procedure, and the procedure below includes a step to verify selection of this option.

Settings that regulate recording might need to be changed, depending on your facility's protocols or special instructions for the patient.

To check the settings, do the following:

1. Click **View** in the menu bar and click **Session Configuration** in the menu.
2. Click the **CT Triggering** tab.
3. (Optional) Click the up or down arrowhead buttons to set or adjust the numbers of seconds under the label **Stop recording if** for the following parameters:
   - No first pulse after
   - No new pulse after

   These settings ensure that recording is stopped if the imaging device does not start as anticipated or stops unexpectedly.
4. Click **OK**.

Confirm that the CT or PET scanner is set up for 4D CT or PET acquisition according to the manufacturer's protocol and that any additional CT or PET system setup features have been activated.

Procedure

To record data synchronized with 4D CT or PET imaging, do the following:

1. Prepare the system.

   If necessary, turn on the workstation and start the RPM Respiratory Gating System.

2. Set up the patient on the couch.
3. Place a marker block on the patient.
4. Prepare the imaging device.
5. As needed, perform a scout view or any tasks required by pilot studies.
6. At the workstation, press Ctrl-P or click **File** in the menu bar and **Select Patient** in the menu to open the Patients List dialog box.
7. Do one of the following:
   - Click a patient's name and click **Select**.
   - Click **New Patient**, fill in the details, and click **OK**.
8. Establish a session in one of these ways:
   - Select a field or type a field name in the New Treatment Field dialog box and click **OK**.
   - Click **Add New Field** in the Treatment Fields and Sessions dialog box, select a field or type a field name in the New Treatment Field dialog box, and click **OK**.
   - Click an existing session for a field in the Treatment Fields and Sessions dialog box, click **Delete Session** to delete it, click **Add New Field**, select a field or type a field name in the New Treatment Field dialog box, and click **OK**.
9. Click **Session Options**, verify or select the **Phase** setting of the Gate on Amplitude of Phase area in the Gating tab.

10. As needed, adjust settings in the Audio and Visual Prompt tabs of the Session Options dialog box.
11. Click **OK**.
12. Click **Track**.
13. Allow the system to learn the extent of the patient's breathing motion. Observe the row of blue squares at the top left of the image area and the color of the Record button. A few blue squares and a black Record button mean that the breathing is regular enough for the system to record data.
14. Coach the patient about what is happening and what the patient needs to do—for example, following the speech and visual prompts to maintain a regular breathing pattern.
15. (Optional) Allow the system to begin recording automatically and continue at step 17
16. Click **Record**.
17. Allow the recording and scanning to continue according to the facility's protocol or instructions specific to the patient.
18. When the recording is sufficiently long, click **Stop**.
19. (Optional) In the file export dialog box, type the information as prompted—for example, the exam and series numbers.

    (Optional) Click **Review** to open the Phase Recalculation Review dialog box. Review the peak recalculations, and, as needed, add or delete peaks and click **Save Changes** and **Exit**.

    Click **OK** to close the file export dialog box.
20. If the recording is unsatisfactory, it is possible to start the recording and scanning process again. To do this, click **Track**, click **Yes** to save the data as a new session, and continue at step 13

    Otherwise, continue to the next step.
21. Do one of the following as needed:
    - Press Ctrl-S.
    - Click **Save** in the toolbar.
    - Click **File** in the menu bar and **Save** in the menu.

    At this point, the session is now ready for planning.

22. As needed for file export, do the following:
    a. Do one of the following:
        - Press Ctrl-E.
        - Click **File** in the menu bar and **Export** in the menu.
    b. In the file export dialog box, type the information as prompted—for example, the exam and series numbers.
    c. (Optional) Click **Review** to open the Phase Recalculation Review dialog box. Review the peak recalculations, and, as needed, add or delete peaks and click **Save Changes** and **Exit**.
    d. Click **OK** to close the file export dialog box.
23. Click **Close Patient** in the session panel.