

VARISEED™

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Equipment Specifications

VariSeed: The Standard for Prostate Seed Implant Brachytherapy

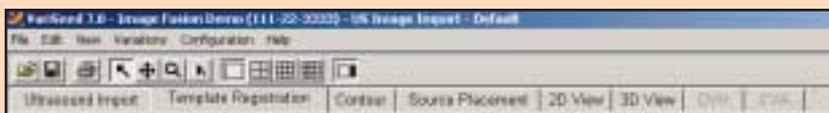
With more than ten years of excellent clinical results, transrectal ultrasound guided transperineal permanent seed implant brachytherapy of the prostate has become the treatment of choice for early stage prostate cancer.

Designed for ease of use, and configured to support all popular treatment protocols, VariSeed has evolved with the demands of practitioners to become the standard treatment planning system against which all others are measured. With more than 500 systems in use throughout the world, VariSeed is the prostate brachytherapy system you can trust to meet your needs, now and in the future.

The newest version of VariSeed is enriched with features designed to overcome the technical difficulties associated with the protocol. These enhancements address real time planning in the procedure room, and image guided therapy.

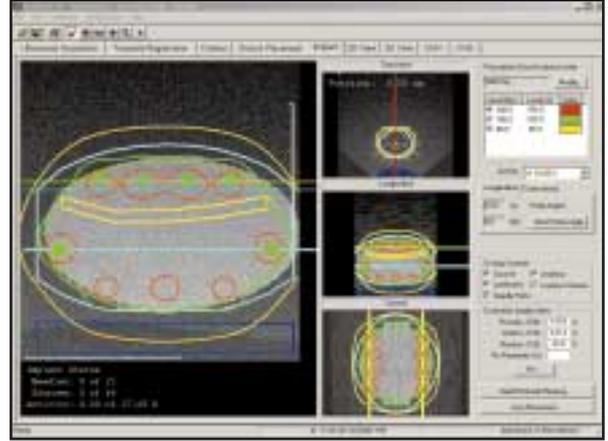
Optimized for Planning Efficiency

VariSeed has been optimized for the planning of permanent seed implants. By concentrating on serving the needs of one procedure, VariSeed is an efficient, focused tool that guides you through the planning process and anticipates your requirements. The user interface is built around the procedure workflow, using tabs that become enabled as they are logically needed.



The easy, tabbed workflow allows VariSeed to support your particular planning process.

VariSeed relies heavily on user-selected options, making the system configurable to your particular workflow, while retaining the flexibility to support your current and possible future needs.



Real time planning in Implant View gives you the complete dosimetry picture in the procedure room, while there is still time to do something with it!

True Real Time Planning

The holy grail of prostate planning is to use real time dosimetry during the implant process to help adapt to the individual implant. The latest version of VariSeed offers the option of real time planning, extending the 'all in one day' functionality of peri-operative planning presented by the earlier version, to true real time planning.

VariSeed: The Prostate Brachytherapy System

VariSeed offers features not found in other systems:

- SeedFinder™ feature automatically locates seeds in a CT data series, dramatically reducing the time needed to create post-plans.
- Rules-based dose optimization to create the ideal pre-plan, first time, every time.

New...

- Dynamic interpolation of contour entries for faster planning.
- Image fusion for targeted therapies or to compare pre-and post-plans.
- Instantly auto-trace solid line contours from ultrasound images.
- Modify pre-plan dosimetry as seeds are placed using the Implant View real-time dosimetry module.

Features

Patient Data Management

VariSeed incorporates a database which tracks patient names and patient images, contours, plan variations and doses. An Archive and Retrieve module supports off-line storage of patient data to avoid disk limitations.

Data Acquisition

VariSeed offers two main image acquisition methods: video frame capture, and DICOM 3 data interface. A digitizer option is also available for non-image based planning, and a film scanner can be used to acquire images from film.

- Video capture allows you to acquire data from the video output of an ultrasound unit, or from a Video Cassette Recorder output of pre-recorded ultrasound studies.
- The DICOM 3 interface allows you to acquire CT, MRI, SPECT, US or other data over a network, or from another DICOM 3-compatible source.

Imaging

Window/Level adjustments can be made on images to help improve visibility. Ultrasound images can be registered and scaled in two dimensions using the ultrasound template overlay. Multiple pre-stored templates may be used (more are added as required). You can assemble a set of evenly spaced transverse images to build a 3D volume image.

Fusion

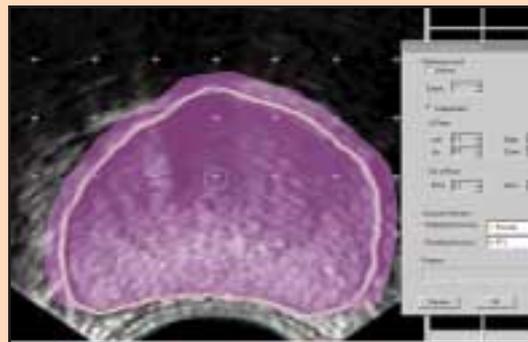
3D data sets may be co-registered using anatomical landmarks or manual methods. Contours and dose distributions created on one set of fused data may be viewed on the other. Image fusion can be used to register CT data to MR for more accurate target identification, or CT to ultrasound for pre- and post-plan comparisons, or DICOM-compatible SPECT or MR functional images to ultrasound images for targeting treatment to disease focal areas for image based pre-plans.

Contouring

VariSeed supports the entry of a group of contours in any image data set. Contours can have user-assigned default names, colors, and transparency. Dynamic contour interpolation allows you to enter as many contour slices as are necessary to define the outline. All contours on slices between entered slices are automatically interpolated, so you enter only as much



Fusion of two 3D data sets allows more precise target definition, and therapies that target disease hot spots.



Complete set of contouring tools includes Auto-Trace from Ultrasound, Dynamic Interpolation and Auto-Margining, to speed contouring operations.

data as necessary to adequately define the volume. Contours can be instantly extracted from solid line outlines on ultrasound images, and tools are provided for editing entered contours. In addition, you can easily make a new contour from an existing one, such as a target volume from a prostate volume, with the auto-margin tool, with the margin having a unique value on each major axis.

Pre-Planning Flexibility

With VariSeed, you have extremely flexible and efficient methods for planning the placement of seeds in a pre-plan. You can manually place loose seeds, or empty needles in which seeds can be loaded, or you can use one of our pre-defined geometric patterns to generate a seed and/or needle loading pattern.

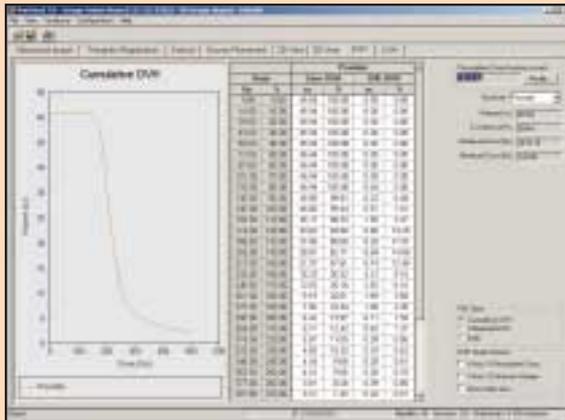
With the optional Dose Optimization/Inverse Planning feature, you may place minimum and maximum dose constraints on any structure. VariSeed will find the needle and seed loading pattern which most closely meets your criteria.

True Real Time Planning

With the real time planning features of the optional Implant View module, you can create a volume study, a proposed plan, and a completed post plan, all as part of the implant process itself.

Implant View provides three interactive views of the pre-operative plan and correlates the pre-operative plan to the live longitudinal or transverse ultrasound image. You may select the current needle, and VariSeed will snap to the longitudinal image through the selected needle. The pre-operative plan (structures, needles, seeds, and dose distribution) may then be overlaid onto the live ultrasound image.

You may adjust entire needles or seeds individually to account for differences between the pre-operative plan and the actual implant. The dose distribution may also be displayed as it is evolving on the live ultrasound view. The addition of an interface to a stepper with positional feedback allows VariSeed to accurately locate the seeds as they are implanted.



Dose Volume Histogram information is provided in multiple views for one or all structures identified.

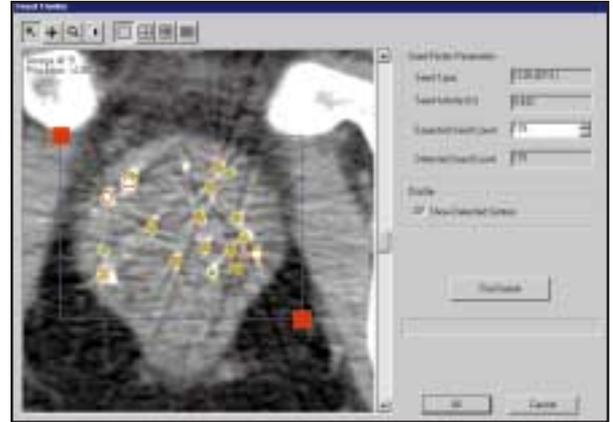
As seeds are located, the pre-plan dose distribution is updated to reflect the implanted source positions. User-defined or pre-set Dosimetric Quality Alerts notify you when the implant is deviating from the intended plan. This information can be used to adjust the remaining seeds in the pre-plan to get the best possible implant.

In addition to the optional Implant View feature, the base package includes a peri-operative capability, whereby needles may be relocated to their observed

transverse view location in a static displayed pre-plan image. In this mode, needles remain perpendicular to the template.

Efficient Post-Planning

The post-planning process has traditionally been a bottleneck for centers performing permanent seed implants. The incentive to perform the task, which is necessary to improve technique, is often not enough to overcome the volume of work required. With VariSeed, this is no longer a problem.



SeedFinder™ makes the production of post-plans almost effortless!

The SeedFinder function allows you to rapidly identify the seeds in a CT data study with incredible precision. Further tools help the manual process of identifying any unresolved overlapping seeds. Once the seeds have been located, the finished plan is just seconds away.

The Image Fusion tool can further aid this process by co-registering pre-plan data sets with those for the post-plan.

Plan Analysis

A rich suite of plan evaluation tools is provided as part of VariSeed:

- Examine Point dose, D90, D100... values.
- Review multiple interactive orthogonal 2D views of images and dose distributions, with or without seed locations marked.
- Review 3D distributions with dose clouds or painted surface dose.
- Perform numeric analysis with Dose Volume Histograms (cumulative or differential) and contiguous volume analysis.

System Configurations¹

Full Planning Systems

VariSeed planning systems are available with both standard and optional software features, so you can tailor the system to most closely match your individual needs. If you require added planning capability, additional planning stations are available at favorable pricing.

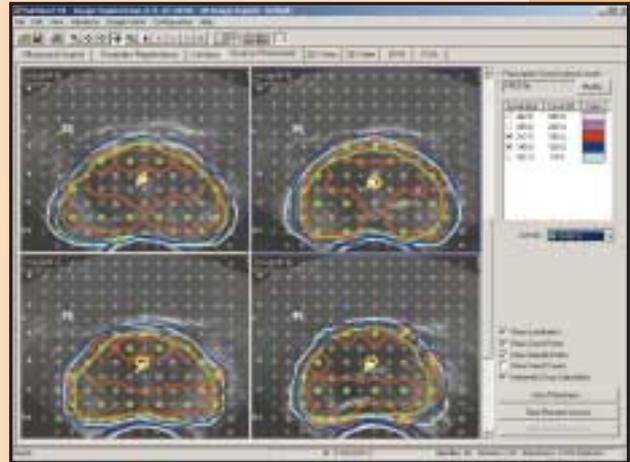
Standard Features

- Patient Database
- Plan variations
- Frame grabber for Ultrasound import
- Contouring with dynamic interpolation
- Image enhancement
- Needle guide templates
- Nomograms for automated seed placement
- Manual seed placement
- Place, manipulate and cut seeds in strands
- TG-43 / TG-56 compliant - Data for all published seeds
- User-defined defaults
- Real time dose calculation
- 2D orthogonal views
- Advanced 3D visualizations
- Dose Volume Histograms
- Contiguous Volume Analysis
- User selectable reports
- User-defined data export - including DICOM RT export

User-Defined Reports

A wide collection of printed reports and graphical outputs in clear and crisp formats are available, including reports for:

- Study summary
- Needle loading
- Strand cutting
- Seed positions
- Dose points
- Dose Volume Histograms
- Contiguous Volume Analysis
- Gray scale images (Transverse, Sagittal, Coronal views) with anatomy outlines and isodose levels
- 3D view of anatomy outlines
- Placed sources
- Isodose cloud



Multiple transverse section view with Isodose lines and seed arrangement is easily reviewed for dose coverage.

A Plan Export function provides for output in delimited tables for import into word processors or spreadsheets, DICOM 3 output to other planning systems such as BrachyVision™ or Eclipse™ from Varian Medical Systems, and needle loading outputs for automated needle loading devices.

Special Features

- Nomograms for some turnkey system providers.
- Easy placement and optimized cutting of seeds in strand.

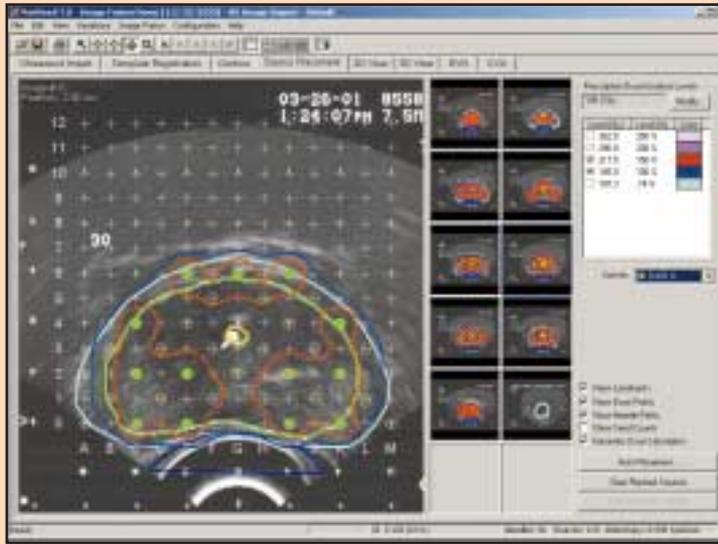
Optional Features

- DICOM 3 data interface for data import and export
- Dose Optimization and inverse planning
- SeedFinder™ for automated seed extraction module
- Image Fusion for co-registration of any two 3D data sets
- Implant View for real time planning

Acquisition Systems

If you intend to acquire data in multiple locations, and perform treatment planning at a central site, consider the Acquisition Station configuration. This product provides a reduced feature set for acquiring volume studies and contours, such as from a Urology practice, or a center for which you wish to provide treatment planning services. This feature set allows for transferring that data over a network, or by removable media, to a central VariSeed planning workstation for plan preparation and analysis.

¹ This product includes BrachyTherapy Software that is the property of Varian Medical Systems, Inc. (VMS). VMS has sole and exclusive ownership of all rights, title, interest in and to its BrachyTherapy Software, and all modifications and enhancements thereof (including ownership of all trade secrets and copyrights pertaining thereto), subject only to the rights and privileges expressly granted by VMS or granted to VMS by third parties.



VariSeed provides for both manual and automatic source placement. Adding and removing sources from a plan is just a simple click of the mouse. Dose contours are quickly and automatically updated. The Geometric Planning tools conform to many of the commonly used placement methods in practice today.

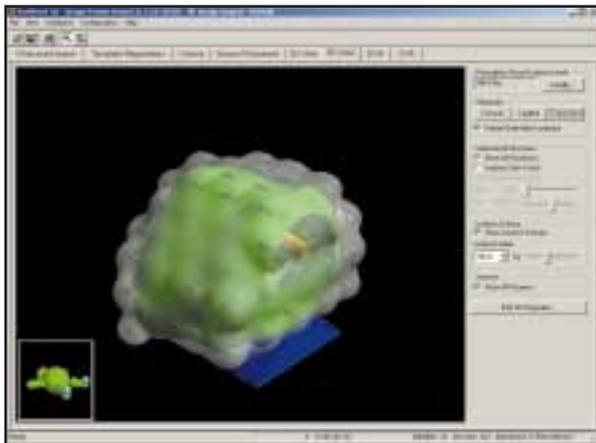
Hardware Specifications²

Tower Configuration

The computer hardware configuration will be as outlined below, or better.

For traditional pre/post plan environments:

- Tower PC: Pentium IV, 1.5 GHz
- 20 GB Hard Drive
- 128 MB RAM
- 40x CD ROM
- 32 MB Graphics Controller
- Video Frame Grabber
- Ethernet Card
- Microsoft Windows® Operating System
- 19-inch Monitor
- Color Printer



Plans may be reviewed in multiple interactive 2D planes, or, as shown in an interactive 3D view for rapid evaluation of dose coverage. A dose-surface view is also available.

Laptop Computer Configuration

The VariSeed laptop configuration is ideal for real time planning techniques.

- Laptop PC with PIII 1.13 GHz, certified for use in the Operating Room*
- 128 MB RAM
- 10 GB Hard Drive
- 8/4/24x CD-RW
- 16 MB Graphics Controller
- 15-inch Active Matrix Display
- Video Frame Grabber
- Ethernet Card
- Microsoft Windows Operating System
- Color Printer

* *Tested to Medical Safety Standard IEC 601-1 (EN 60601-1-1). The laptop is classified as Type B equipment and as non-medical information technology.*

Software Only

Software licenses are available for customers who have hardware that matches our specification.

Option

- Digitizer tablet for data entry from films

² *Hardware specifications change frequently. We expect that any changes will exceed the specifications shown here, but please check for the latest specification at time of purchase.*

Standard Service

Installation

Systems are shipped pre-configured so you can normally accomplish cable connections and power on without complications. Telephone support is available to help you establish interfaces to ultrasound scanners, tracked steppers, and image networks. If you elect on-site training, our applications specialist will also help you with any installation problems you might have.

Training

Application training is included with every system. At your selection, one day of on-site or two days of classroom training, including travel and accommodation, are available.

Further training support, such as attendance at first clinical application, and refresher classroom or on-site training, is also available at extra cost.

Support

Toll free access to our applications specialists to address your concerns is included with the warranty, and available in subsequent periods.

Three levels of support are available:

- **Silver:** Help Desk support and software updates for functionality originally purchased. This is available exclusively for Software-only customers.
- **Gold:** Includes Silver coverage plus loaner hardware to cover failed hardware components while they are being repaired. Repair costs, if not covered by manufacturer's warranty, are extra.
- **Platinum:** Total coverage, including Gold service features, plus full hardware repair/replacement service, training credits, and guaranteed PC hardware replacement on a three-year cycle.

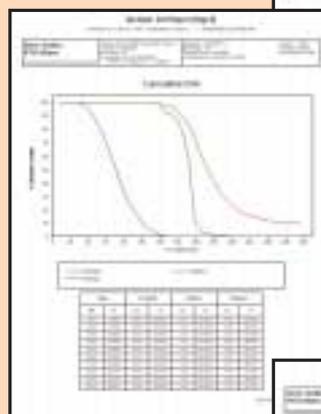
Note: In some international markets, Gold Service only is offered.

The screenshot shows a 'VariSeed Study Summary Report (Page 1)'. It includes fields for 'Patient Name', 'Study ID', 'Study Date', and 'Study Time'. Below this is a 'Data Information' section with a table listing 'Source' and 'Needle' details, including 'ID', 'Type', 'Status', 'Depth', 'Length', 'Dose', and 'Loading'.

The user-defined Study Summary Report provides a snapshot review of the plan.

The screenshot shows a 'VariSeed second verification sheet'. It features a large grid of colored geometric shapes (circles, squares, triangles) representing needles and sources. The grid is organized into columns and rows, with some cells containing text labels.

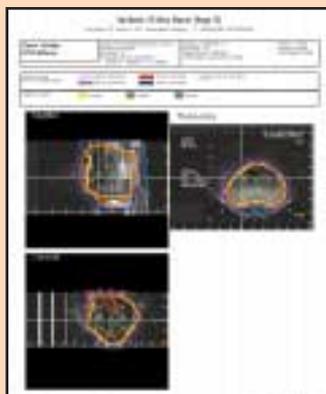
VariSeed provides a second verification sheet that graphically displays the needles, sources and loading.



The DVH report provides dose information for single or multiple structures.

The screenshot shows a 'VariSeed needle loading report'. It features a large grid of colored geometric shapes (circles, squares, triangles) representing needles and sources. The grid is organized into columns and rows, with some cells containing text labels.

Per RTOG recommendations, the needle loading report provides accurate and easily read documentation used for the day of the implant. Colored geometric shapes, plus the number of sources and needle number, provide a useful tool in following the implant procedure. Red dots indicate a non-uniform needle loading. This document also provides for signature approvals and needle and source purchasing.



VariSeed provides for the Visualization tools to be printed as well.

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